

The surgical management and prevention of laparoscopic cholecystectomy associated bile duct injuries

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ABSTRACT

Laparoscopic cholecystectomy (LC) is considered the gold standard in the surgical management of gallstone disease and is one of the most commonly performed general surgery operations worldwide. Bile duct injury (BDI) in LC remains a feared complication as it is associated with significant morbidity, prolonged hospital stay, increased costs, and reduced quality of life for patients, as well as the risk of litigation for the injuring surgeon. The initial incidence of BDI after the introduction of LC was reported to be between 0.4 and 0.8%, which was higher than the estimated 0.2% reported during the open cholecystectomy era. However, recent reports from the United States and Europe suggest a return to open cholecystectomy rates. Despite being a frequently performed operation in both the private and public health sectors in South Africa, there is a paucity of data on the incidence of BDI. In the only study to date reporting the frequency of BDI in South Africa, a single centre incidence of 1.2% was documented over an 18-month period, which is significantly higher than previous reports.

No data have been published on the implications of BDI for patients treated within the South African healthcare system. This thesis describes the surgical management of BDI at an academic referral centre over a thirty-year period. Potential factors influencing treatment and patient outcome after BDI are investigated. These include the influence of geographic distance from referral centre on the timing of referral and repair, and subsequent long-term patient outcomes. The influence of dual healthcare sectors (public vs. private) on access to diagnostic and interventional modalities, and eventual outcome is also investigated, and the evolution in the management of BDIs over the three studied decades is documented. Factors associated with loss of patency following surgical repair of LC-BDIs are also determined. Based on the findings of this detailed review of the management and outcomes of LC-BDIs, a treatment algorithm for management in resource-constrained environments is proposed.

Establishing the optimal management of LC-BDIs in the South African healthcare setting is important but does not address the source of the problem. In an effort to make LC-BDI a near-never event, a standardized method of performing, documenting and monitoring the quality of LC was developed and implemented for all LCs performed in the Cape Metro West Health District. Prospective data collection is scheduled to continue to the end of 2020; however, an interim analysis is presented. A previously published scoring system for

assessing quality of the critical view of safety achieved during LC, a critical component of a safe LC, is applied and validated in a large cohort of LC patients. A prospective database was created for data capture along with a Standard Operating Procedure, both designed with the goal of expanding the intervention and database nationally.

The studies reported in this thesis make a substantial contribution to the literature and will have a beneficial impact on patient care in two important ways. Firstly, the management of BDI in South Africa is described and a treatment algorithm for resource-constrained environments is proposed, based on local experience. Secondly, a change of practice was implemented and a LC database was established with the possibility of expanding the effort to the national level. Locally, the change in practice has thus far resulted in identification of areas of improvement to limit BDI and increased knowledge about the appropriate steps to take to avoid causing a LC-BDI.

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DEDICATION

I dedicate this thesis to my father and mother, Dennis and Daphne Lindemann, who have spent the last thirty years working to ensure their daughters had every opportunity to be anything they want to be. May this be your reward.

To my sisters, Alexis and Olivia, your unfailing love and friendship is a constant in my life from which I draw great strength, no matter where in the world we find ourselves.

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ABBREVIATIONS

ALP – alkaline phosphatase
ALT – alanine aminotransferase
AMC – Amsterdam Medical Centre
ASA – American Society of Anesthesiologists
AST – aspartate aminotransferase
ATOM – anatomic, time of, mechanism
BDI – bile duct injury
BMI – body mass index
CD – choledochoduodenostomy
CE-CT – contrast-enhanced computed tomography
CHMC – City of Hope Medical Center
CUHK – Chinese University Hong Kong
CVS – critical view of safety
ERC – endoscopic retrograde cholangiography
GDI – gender development index
GII – gender inequality index
GiQLi – gastrointestinal quality of life Index
GNI – gross national income
GORD – gastro-oesophageal reflux disease
GSH – Groote Schuur Hospital
GGT – gamma glutamyl transferase
HC-HJ – Hepp–Couinaud hepaticojejunostomy
HD – hepaticoduodenostomy
HDI – human development index
HIC – high-income country
HIV – human immunodeficiency virus
HJ - hepaticojejunostomy
HPB – hepato-pancreato-biliary
HREC – Human Research Ethics Committee
HRQoL – health-related quality of life
ICC – intraclass correlation coefficient
ICU – intensive care unit

IHDI – inequality-adjusted human development index
INR – international normalized ratio
IOC – intraoperative cholangiogram
IQR – interquartile range
LC – laparoscopic cholecystectomy
LMIC low- and middle-income country
MAGS – Modified Accordion Grading System
MBD – main biliary duct
MCS – mental composite score
MIC – middle-income country
MRCP – magnetic resonance cholangiopancreatography
MRI – magnetic resonance imaging
MPI – multi-dimensional poverty index
NHLS – National Health Laboratory Service
OC – open cholecystectomy
PAIS – psychosocial adjustment to illness scale
PCS – physical composite score
PTBC – percutaneous transhepatic biliary catheter
PTC – percutaneous transhepatic cholangiogram
REDCap – Research Electronic Data Capture
SAGES – Society of American Gastrointestinal and Endoscopic Surgeons
SD – standard deviation
SDRC – Surgery Department Research Committee
SEMS – self-expanding metal stent
SF – short form
SOP – standard operating procedure
TB – total bilirubin
UCT – University of Cape Town
VBI – vasculobiliary injury
WCC – white cell count
WLQ – work limitation questionnaire

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Introduction

1.1 Laparoscopic cholecystectomy: From a novel operation to the standard of care

The first open cholecystectomy (OC) was performed in 1883 by the German surgeon Carl Langebuch.¹ More than 100 years passed before the first laparoscopic cholecystectomy (LC) was performed in 1985 by another German surgeon, Erich Mühe.² Despite having successfully completed 94 LCs, Mühe's achievement was met with significant criticism and was largely ignored by the German Surgical Society at the time.² It was not until French surgeons, first Philippe Mouret in 1987, then Francois Dubois in 1988 and finally, Jacques Perissat in 1989, began performing the operation that the procedure started to generate interest from surgeons around the world.¹ The 1989 Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) meeting, where in an isolated corner of the exhibition area Perissat presented the LC technique using a videotaped recording, marked the beginning of what would quickly become a worldwide revolution in laparoscopic surgery.^{1,3} Within a few years following Perissat's well received presentation, LC had become integrated into the field of general surgery.^{1,3} Despite the initial learning curve, marked by a higher incidence of bile duct injury (BDI) compared to the OC era, the procedure was soon accepted as the standard of care for gallstone disease, recommended as such by a National Institute of Health consensus statement published in 1993.⁴ The recommendation was undoubtedly facilitated by the numerous benefits of LC compared to OC, namely decreased postoperative pain, wound infections, and length of hospital stay, as well as earlier return to normal activities and improved cosmetic results.⁵⁻⁸

1.2 Establishing the incidence of laparoscopic cholecystectomy bile duct injuries

The rapid adoption of LC into general practice was not without challenges. Several early reports demonstrated an incidence of BDIs ranging from 0.50% to 0.66%,⁹⁻¹¹ significantly higher than the generally accepted incidence of 0.2% in the OC era.¹² Similar findings of increased incidence of BDIs in LC were reported from Australia, Canada, and several countries in Europe throughout the late 1990's, with the incidence of BDIs remaining between 0.3% and 0.9%.¹³⁻¹⁷ This increased rate was attributed to the "learning curve" of LC, supported by studies demonstrating a decreased incidence of BDIs as the number of LCs performed per surgeon increased.^{9,18-20} However, other studies found a persistently elevated incidence even among experienced surgeons.²¹⁻²³ Until recently, the reported rates of LC-

BDIs remained constant at approximately 0.3% to 0.4%.²⁴⁻²⁸ Although there were reports of an incidence of LC-BDI between 0.1% and 0.2% in large database studies in the early 2010s,²⁹⁻³¹ only in the last five years have results from large, population-based studies consistently suggested that the rate of BDI in LC is comparable to the OC injury rate.³²⁻³⁵ Population-level data for LC-BDIs from low- and middle-income countries (LMICs) are lacking. In a large study of 13,500 cholecystectomies performed at a single centre in India, a BDI incidence of 0.39% was reported.²⁵ An early study from a teaching hospital in Mexico included 1,126 LCs and reported a LC-BDI incidence of 0.36%.³⁶ Interestingly, in a series of 10,000 LCs performed at a single centre in China, no bile duct injuries occurred with a bile leak (liver bed or cystic stump) rate of 0.16%.³⁷ In a study on postoperative complications after LC in a South African patient cohort published in 2016, a single centre series of 147 LCs over an 18-month period reported a BDI rate of 1.2% and a bile leak rate of 1.5%.³⁸ To date, there are no available population-level data on the incidence of BDI in LC for South Africa.

Interpreting the reported incidence of BDIs in LC and understanding how the incidence has changed over time is problematic for two important reasons. The first is the large numbers required to accurately estimate the incidence of a relatively uncommon event. This necessitates access to large, multicentre or national databases which, particularly in the early years after the adoption of LC into general practice, were not available. The majority of the estimates for the incidence of LC-BDIs come from retrospective review of single centre experiences or from societal or national surveys, all with associated selection and recall biases. The second reason is the wide variation in the definition of BDI used in reporting. In some studies, BDI includes the entire spectrum of biliary complications, from a cystic stump leak to a complete transection, while others make a distinction between “major” and “minor” BDIs, the definitions of which also vary depending on the BDI classification system used. These factors limit our ability to use systematic reviews and meta-analyses to determine a pooled estimate of LC-BDIs from the literature, as they result in significant individual study bias and heterogeneity among included studies. While the true incidence of LC-BDIs is unlikely to ever be precisely reported, national databases represent the most accurate method for estimation. The current evidence suggests that for high-income countries (HICs), LC-BDI rates are comparable to OC-BDI rates. Population-based data from LMICs are lacking, but single-centre studies suggest the incidence of LC-BDIs is higher than the 0.2% rate reported in the OC era.

1.3 Risk factors and direct causes of laparoscopic cholecystectomy bile duct injuries

There are several risk factors reported in the literature that are associated with BDI in LC. These include age,^{13,39} male sex,^{13,39} severe acute inflammation,^{5,40} chronic inflammation with fibrosis,^{40,41} aberrant anatomy, particularly an aberrant right posterior sectoral duct^{5,42,43} and intraoperative bleeding.^{5,44} The timing of cholecystectomy for acute cholecystitis and the influence of timing on the rate of BDIs has long been debated. The most recent Cochrane review assessing this important question concluded that there were no significant differences in measured outcomes, including rate of BDIs, between an early (within 7 days of presentation) or a delayed (more than six weeks after admission) LC for acute cholecystitis.⁴⁵ Importantly, the authors acknowledged the wide confidence intervals related to the relative rarity of events for the measured outcomes in the study and note that a single randomized controlled trial is unlikely to be adequately powered to answer the question, but future meta-analyses of smaller trials may provide a definitive answer.⁴⁵ The internationally recognized Tokyo Guidelines from 2018 suggest early LC for mild, moderate and severe acute cholecystitis after consideration of the patient's overall condition.⁴⁶

Aberrant biliary anatomy is common and may contribute to LC-BDI. "Normal" anatomy at the hepatic confluence formed by the union between the right and left hepatic ducts, where the right hepatic duct is formed as the right anterior and right posterior sectoral ducts join, is present in only 57% of the general population.⁴⁷ Anatomic configurations particularly relevant to LC and incidentally, most common of all variations, include those with low insertion of the right posterior sectoral duct into the common hepatic duct, cystic duct or directly into the gallbladder.⁴⁷ These configurations of aberrancy put the right posterior sectoral duct at increased risk of injury during LC dissection.^{42,48} Ectopic drainage of the gallbladder with the cystic duct draining into the left hepatic duct, the hepatic confluence, the right posterior sectoral duct, or a segment VI duct as well as variation in the relationship between the cystic duct and common bile duct (angular, parallel or spiral union) may make identification of the relevant anatomy at LC challenging.⁴⁷ The presence of hepatocystic (accessory biliary drainage from the liver directly to the gallbladder) and subvesical ducts (accessory biliary drainage that does not communicate with the gallbladder) may result in postoperative bile leaks from the gallbladder bed if injured during dissection.^{49,50} The eponym "ducts of Luschka" is often incorrectly used to refer to both hepatocystic and subvesical ducts. The term was originally used in 1863 by the German anatomist Hubert von Luschka to describe microscopic glands he observed in the gallbladder wall, likely

representing intramural glands and lymphatics, and therefore should not be used to describe injured ducts resulting in bile leaks originating from the liver bed.⁵¹ Laparoscopic surgeons should have an appreciation of the relevant anatomic biliary variations commonly present in the general population, particularly those which increase the risk of BDI.^{48,52}

The direct causes of LC-BDIs can be divided into two categories: technical errors and misidentification of the anatomy.⁴⁸ Technical errors related to surgical skill and intraoperative decision making include misuse of electrocautery,^{43,48,53} use of sharp dissection in the triangle of Calot,⁵⁴ dissection in too deep a plane during removal of the gallbladder,^{43,48} and injudicious use of clips to control bleeding.⁵⁵ However, technical errors are generally uncommon causes of LC-BDI, whereas misidentification of relevant anatomy is by far the most common direct cause of LC-BDI reported in the literature.^{43,48,55,56} In a detailed review of intraoperative videos and operative notes, technical errors were responsible for only 3% of LC-BDIs.⁵⁵ Misidentification occurs when the surgeon, based on visual cues and stored knowledge of biliary anatomy, perceives the anatomy differently from what is actually present.^{43,55,56} This can happen, for example, when the cystic duct is shortened or “hidden” in the infundibulum of the gallbladder as a result of inflammation.⁴⁰ In this case, the surgeon interprets the classic flare or funnel shape as the cystic duct entering the gallbladder, when in fact the flare is formed by the edges of the common bile duct, the gallbladder and the common hepatic duct.⁴⁰ The visual cue can be very convincing and the surgeon proceeds with clipping, dividing and excising a portion of the common hepatic duct, resulting in a BDI.⁴⁰ As is often the case, the intraoperative view is incomplete due to connective tissue, fibrosis, inflammation and/or blood obscuring the anatomy. In this instance, the brain subconsciously fills in the missing information based on memory of biliary anatomy.⁵⁵ This automatic processing of visual cues is outside the control of the surgeon.⁵⁵ It has been hypothesized that visual misperception leads to a greater number of BDIs in LC because of the loss of haptic feedback, or ability to palpate the surrounding anatomy in laparoscopic surgery, thus accounting for the slightly higher rate of LC-BDIs observed even beyond the learning curve.^{55,56}

1.4 Classification of bile duct injuries

Several classification systems for BDIs have been proposed in an effort to guide treatment, standardize reporting and compare outcomes. The advantages and disadvantages of commonly used classification systems are summarized in Table 1.1. There is no single

universally accepted classification system, but the Strasberg classification is by far the most commonly used and is based on a proposed classification of postoperative strictures of the bile duct by Bismuth in 1982.^{43,57} The Bismuth classification includes five types of biliary strictures, subdivided based on location within the extrahepatic biliary tree with the intention of guiding surgical intervention.⁵⁷ A Bismuth type 1 injury is a common hepatic duct stricture located > 2 cm from the hepatic confluence, whereas type 2 is a stricture < 2 cm from the hepatic confluence.⁵⁷ Types 3 and 4 involve the confluence with communication between the left and right hepatic ducts preserved in type 3 and lost in type 4.⁵⁷ A type 5 BDI involves an aberrant right sectoral hepatic duct with a concomitant stricture of the common hepatic duct.⁵⁷ The Bismuth classification was proposed in the era before LC and as such a major limitation of the classification is its inability to classify the spectrum of BDIs observed in LC. The Strasberg classification, proposed in 1995, expanded on the Bismuth classification to include cystic duct and liver bed leaks (type A), occlusion (type B) or transection (type C) of a part of the biliary tree, which is almost always an aberrant right hepatic duct, and lateral injury to the extrahepatic bile ducts (type D) (Figure 1.1).⁴³ Type E injuries are subdivided as per the Bismuth classification.^{43,57} Similar to the Bismuth classification, the Strasberg classification also offers treatment guidance based on injury type.

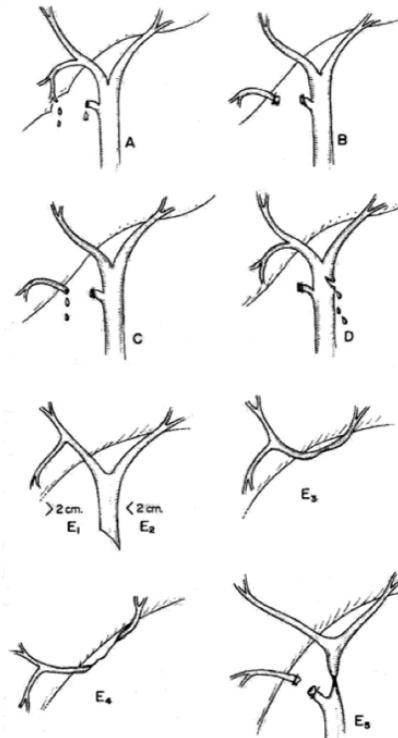


Figure 1.1. Strasberg classification of bile duct injuries.

Original Source: Strasberg SM, Hertl M, Soper NJ. An analysis of the problem of biliary injury during laparoscopic cholecystectomy. J Am Coll Surg. 1995;180(1):101-25 and reprinted with permission from the Journal of the American College of Surgeons, formerly Surgery Gynecology & Obstetrics

Before Strasberg proposed additions to the Bismuth classification, Siewert et al. in 1994 published an article describing a classification including four types of injuries.⁵⁸ Type I BDIs cause immediate biliary fistulae and are usually from the cystic duct or liver bed.⁵⁸ Strictures that present late without obvious intraoperative duct trauma are considered type II.⁵⁸ For types III, tangential lesions without structural loss of the duct, and IV, lesions with structural defects, “a” and “b” were added to indicate the presence (a) or absence (b) of a concomitant vascular injury.⁵⁸ Inclusion of vascular injury in the Siewert classification was an advantage over the Bismuth and Strasberg classifications. Also published in 1995, McMahon et al. suggested a distinction between major and minor BDIs for bile duct lacerations, transections (or excisions) and strictures to be used along with the Bismuth classification.⁵⁹ Minor injuries were defined as lacerations of the common bile duct involving less than 25% of the circumference or injury at the cystic-common bile duct junction.⁵⁹ These injuries usually only require simple suture repair and/or insertion of a T-tube.⁵⁹ Major injuries usually require hepaticojejunostomy (HJ) repair as they include at least one of the follow criteria: laceration greater than 25% of the bile duct circumference, transection of the common hepatic or bile duct, and/or development of postoperative stricture.⁵⁹ The terms “major” and “minor” bile

duct injuries are still commonly used today, however they are used more broadly than originally defined by McMahon.

In 1996, the Amsterdam Medical Centre group proposed a simple set of criteria for classifying BDIs that includes four types namely, minor bile leaks (type A), major bile leaks (type B), bile duct strictures (type C) and complete transections (type D).⁶⁰ Although this classification system is straightforward in its application, it does not include location of injury in the biliary tree and therefore, does not provide the advantage of guiding treatment based on injury type. Csendes et al. in 2001 published a BDI classification system also including four types of injury, but with subdivisions based on mechanism rather than injury pattern.⁶¹ Type I includes a small tear of the common or right hepatic duct due to dissection with hook or scissors.⁶¹ Type II comprises lesions at the junction of the cystic and common bile ducts due to excessive traction, use of a Dormia basket catheter, division of the cystic duct close to the junction, or thermal injury of the junction using cautery.⁶¹ Types III and IV are partial or complete division of the common bile duct and division with resection of more than 10 mm of the common bile duct, respectively.⁶¹ The authors suggest that the Csendes classification is advantageous because the types of injury can guide treatment. However, there is incomplete description of the location of the injury within the biliary tree and there is no provision for an injury type that can be used to classify biliary strictures, limiting the usefulness of this classification.

Following Csendes, the Stewart-Way classification was used in a 2003 analysis of human factors related to LC-BDIs in more than 250 cases.⁵⁵ The classification system is based on a combination of mechanism and location of injury and includes four classes.⁵⁵ A class I injury involves an incision in the common bile duct with no loss of duct substance, which results from mistaking the cystic duct for the common bile duct, where the error is recognized before complete transection.⁵⁵ This injury typically occurs when an intraoperative cholangiogram (IOC) is performed with placement of the catheter in the common bile duct. Lateral damage to the common hepatic duct resulting in a stricture and/or fistula after placement of clips on the duct or excessive cautery in an attempt to control bleeding or due to poor exposure is considered a class II injury.⁵⁵ In a class III injury, the common bile duct is mistaken for the cystic duct and transected.⁵⁵ This class is subdivided into classes IIIa through IIIc, based on the proximal extent of the injury.⁵⁵ Class IV injuries involve transection or injury to the right hepatic or a right sectoral duct and is often associated with transection of the right hepatic

artery after misinterpretation of the anatomy.⁵⁵ The major limitation of the Stewart-Way classification is the absence of a class for presentation of late strictures. The classification of injuries using both mechanism and injury pattern is useful for investigating causes of BDI, but the classification system lacks the anatomic biliary detail of the Strasberg classification.

The Neuhaus classification is based on injury patterns and was first proposed in 2000 by Neuhaus et al.⁶² The classification system distinguishes between the type A Strasberg bile leaks by subdividing type A into A1 (cystic duct leak) and A2 (gallbladder bed leak).⁶² Type B (occlusions), type C (lateral injuries), type D (complete transections) and type E (late strictures) are also included with subtypes for extent and location of injury, resulting in a detailed classification of BDIs, although there is no inclusion of concomitant vascular injury.⁶² The Hannover classification system was first proposed by Bektas et al. in 2007 and is modelled after the Neuhaus classification.⁶³ In the Hannover classification, types C and D were expanded to include location of the injury in relation to the confluence.⁶³ The main advantage of the Hannover classification system over Neuhaus and others is the addition of a system to classify vascular injuries. However, it is a complicated classification system which is difficult to apply in clinical practice.

Using a retrospective cohort of 74 patients, the Hannover, Neuhaus, Stewart-Way, Strasberg and Siewert classification systems were compared to determine the correlation of each classification system's ability to discriminate between injury pattern and 1) type of surgical intervention required, 2) need for liver resection, 3) resection of the hepatic bifurcation, 4) performance of a peripheral HJ without resection of the bifurcation, and 5) long-term recurrent cholangitis.⁶³ All but the Stewart-Way classification had a statistically significant correlation between injury pattern, resection of the bifurcation and need for peripheral HJ without resection of the bifurcation.⁶³ Not surprisingly, the two classification systems that do not include extent of vascular injuries (Strasberg and Neuhaus) did not have a significant correlation between injury pattern and need for liver resection.⁶³ The only classification system with a significant correlation between injury pattern and long-term recurrent cholangitis was the Neuhaus classification.⁶³ Importantly, all five classification systems had a statistically significant correlation between injury pattern and choice of surgical intervention and for the Hannover classification specifically, there was no significant correlation between the exact determination of vascular injury and the choice of surgical therapy.⁶³

Based on an assessment of seven classification systems, the Chinese University of Hong Kong (CUHK) classification was proposed in 2007 to address some of the problems associated with the currently used classifications.⁶⁴ However, the CUHK classification is not well known or widely used and lacks complete biliary anatomy detail which makes interpretation of BDI type difficult. Similarly, in 2011 Cannon et al. proposed a three-tiered grading system for BDIs which was successful in achieving the authors' primary outcome of assessing the financial impact of BDI, but the absence of detailed biliary anatomy in the classification system makes the assignment of grades I–III impractical for guiding treatment.⁶⁵ The Anatomic, Time Of detection and Mechanism (ATOM) classification is a recent, detailed classification system that includes the anatomic location, mechanism of injury and timing of diagnosis.⁶⁶ Proposed in 2013 and based on a review of 15 different classification systems, the anatomic classification of the level of injury includes six subtypes, similar but not identical to the Strasberg and Bismuth types E1-E5, as well as injured vascular structures.⁶⁶ The time of detection is classified as either early or late, with further subdivision of early into early intraoperative or immediate postoperative detection.⁶⁶ Mechanism of injury is divided into mechanical or energy driven.⁶⁶ The ATOM classification has the advantage of including the timing of diagnosis, which no other classification system to date has incorporated. The major disadvantage of this classification is its extensive detail which, while useful for research purposes, is not easily incorporated into clinical practice.

The ideal BDI classification system should offer enough information about the injury to facilitate meaningful research but remain simple enough to remember for use in every day clinical practice and provide guidance for treatment. Based on the findings from the Bektas et al. analysis and the detailed review of the more recent classification systems, the Hannover, Neuhaus, Stewart-Way, Strasberg, Siewert and ATOM classifications all provide enough detail for research while offering treatment guidance. However, of all the classification systems, the Strasberg classification offers the most ideal balance between the level of detail of the BDI, treatment guidance and ease of use in routine patient care, as underscored by its widespread application in the literature.

Table 1.1. Summary of advantages and disadvantages of bile duct injury classifications.

Classification	Year	Based on	Advantage	Disadvantage
Bismuth ⁵⁷	1982	Anatomic location	Location of injury; guides treatment	OC injuries + strictures only
Siewert ⁵⁸	1994	Injury pattern	Vascular injuries included	Minimal biliary anatomy detail
Strasberg ⁴³	1995	Anatomic location	Covers spectrum of LC-BDIs	Vascular injury not included
McMahon ⁵⁹	1995	Extent of injury	Related to outcome	Incomplete classification
AMC Criteria ⁶⁰	1996	Injury pattern	Simple, easy to use	Minimal biliary anatomy detail
Neuhaus ⁶²	2000	Injury pattern + mechanism of injury	Subtypes for extent and location	Vascular injury not included
Csendes ⁶¹	2001	Mechanism of injury	Simple, easy to use	No stricture type + incomplete detail of injury location
Stewart-Way ⁵⁵	2003	Injury pattern + mechanism of injury	Includes complex BDIs + vascular injuries	No class for strictures
Hannover ⁶³	2007	Injury pattern + mechanism of injury	Vascular injuries included	Complicated for clinical use
CUHK ⁶⁴	2007	Mechanism of injury	Injury + prevention + treatment	Minimal biliary anatomy detail
Cannon ⁶⁵	2011	Injury severity	Simple, easy to use	Created for cost analysis
ATOM ⁶⁶	2013	Anatomic location + mechanism of injury + timing of diagnosis	Location + vascular injury + mechanism	Complicated for clinical use

AMC – Amsterdam Medical Centre, ATOM – anatomic, time of, mechanism, BDI – bile duct injury, CUHK – Chinese University Hong Kong, LC – laparoscopic cholecystectomy, OC – open cholecystectomy

Although there are several classification systems for BDIs reported and used in the literature, there is one pattern of injury in particular that was recognized early after the introduction of LC into general practice and is still universally known as the “classic” LC-BDI today.⁶⁷⁻⁷⁰ First described by Davidoff et al. in 1992, the injury involves misidentification of the common bile duct as the cystic duct which is then clipped and divided.⁷¹ The dissection continues upward along the left border of the common hepatic duct, which is interpreted as dissection of the underside of the gallbladder.⁷⁰ The common hepatic duct is then divided as the surgeon proceeds to remove the gallbladder from the liver bed.⁷⁰ If recognized as a bile duct, it is assumed to be an accessory or second cystic duct.⁷⁰ The position of the right hepatic artery immediately posterior to the common hepatic duct makes it particularly vulnerable to injury in this scenario.^{70,71} The “classic” injury results in an en bloc excision of a portion of the common bile duct, the cystic duct and gallbladder, and a variable length of the common hepatic duct, often with a concomitant right hepatic artery injury (Figure 1.2).^{70,71}

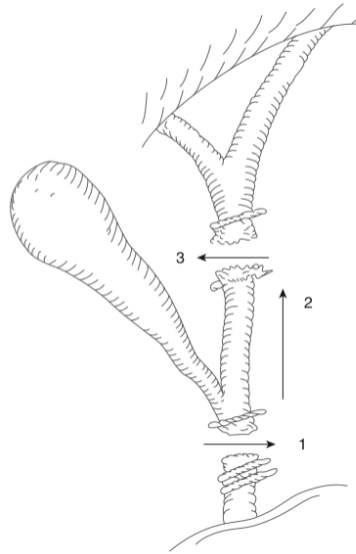


Figure 1.2. Pathogenesis of the “classic” laparoscopic cholecystectomy bile duct injury. In step 1, the common bile duct is mistaken as the cystic duct and is clipped and divided. In step 2 dissection continues upward along the left border of the common hepatic duct. In step 3 the common hepatic duct is divided with complete excision of a portion of the extrahepatic biliary tree together with the cystic duct and gallbladder.

Original Source: Strasberg SM, Helton WS. An analytical review of vasculobiliary injury in laparoscopic and open cholecystectomy. HPB (Oxford). 2011;13(1):1-14, reproduced with permission from Elsevier.

1.5 Management of laparoscopic cholecystectomy associated bile duct injuries

There is little debate that patients with LC-BDIs should be referred early to specialized hepato-pancreato-biliary (HPB) units and are best managed by a collaborative, multidisciplinary team who can provide the necessary radiologic, endoscopic and surgical interventions.⁷²⁻⁷⁵ When surgical repair is required, it should be performed by an experienced HPB surgeon.⁷⁶⁻⁷⁸ There are four essential principles of surgical repair including: (1) a tension-free, (2) widely-patent mucosa-to-mucosa anastomosis, (3) using well-vascularized bile ducts, (4) to provide drainage of the entire liver.⁷⁹ Surgical repair should be delayed until sepsis has been resolved.^{76,80} “Minor” injuries, such as Strasberg type A and even most type D injuries, can be managed endoscopically.^{43,81} For “major” injuries, those with either complete transection or stricture of the common bile or common hepatic ducts (Strasberg types E1 to E5), and for type D injuries which fail endoscopic management, surgical repair is required.^{43,81,82} The surgical technique with the best reported long-term outcomes in the literature is HJ.^{80,82,83} An end-to-end biliary repair with or without placement of a T-tube is associated with unacceptably high postoperative stricture rates.^{43,76,84} For example, in a series of 56 patients treated with an end-to-end anastomosis, all patients required some form of

percutaneous, endoscopic or surgical re-intervention for postoperative anastomotic stricture.⁸⁵ Choledochoduodenostomy is not advised as an anastomotic leak results in a duodenal fistula and there is a documented higher risk of recurrent cholangitis compared to HJ.^{82,86}

In cases where the injury involves but does not disrupt the confluence (Strasberg type E3) or where a concomitant vascular injury is present, a Hepp–Couinaud anastomosis is recommended to minimize the likelihood of postoperative stricture.⁸⁷⁻⁹⁰ The Hepp–Couinaud technique involves lowering of the hilar plate, identification of the extrahepatic portion of the left hepatic duct and a longitudinal incision made in the duct to facilitate a wide, side-to-side HJ. This approach does not damage the collateral blood supply of the hepatic confluence via the hilar shunt.⁷⁰ When possible, the incision is extended onto the right hepatic duct. This approach may be used with modifications to reconstruct more complex injuries with disruption of the confluence or with sectoral and/or segmental duct involvement (Strasberg types E4 and E5) as a “sideways” repair.⁷⁹ Successful management of strictures using an endoscopic approach has been reported,⁸¹ however, the role of endoscopy in the management of complete transections was only recently realized.^{91,92} In a study from the Netherlands that included 47 patients with complex LC-BDIs, 66% of whom had a Strasberg type E1 to E5 injury, a long-term success rate of 55% was reported after treatment using a combination of endoscopic and percutaneous therapies only.⁹¹ A second study of 22 patients with complete transection of the bile duct after LC reported a 100% initial success rate using a combined percutaneous and endoscopic rendezvous procedure, with 16 of the 22 patients remaining asymptomatic at a median follow-up of 4 years.⁹² However, long-term outcome data for this approach are limited.

Management of sectoral and/or segmental duct injuries (Strasberg types B and C) can be challenging and there is little evidence in the literature to support a standard approach. For type C injuries, treatment strategies vary based on when the BDI is diagnosed, with some studies reporting a preference for immediate reconstruction with HJ to the isolated segments if the injury is diagnosed at the time of LC and the duct is greater than 2-3 mm in size, or ligation of smaller ducts that have not been instrumented and are therefore not contaminated.^{42,93} For patients presenting with a bile leak from a sectoral or segmental duct, some advocate conservative management of the biliary fistula with percutaneous transhepatic biliary catheter (PTBC) placement into the disconnected segment, adequate intraperitoneal drainage and observation for 6-8 weeks allowing the fistula time to close without surgery.⁹⁴⁻⁹⁶

If the fistula persists, reconstruction with a HJ to the disconnected segmental or sectoral duct is then recommended.^{95,96} For patients with isolated right hepatic or left hepatic duct transections, surgical repair with a HJ is often pursued. Most advocate using partial hepatectomy as a last resort, either in the case of delayed presentation with ongoing recurrent cholangitis that does not respond to percutaneous treatment or for ducts that are too small for reconstruction.^{96,97} Importantly, there is evidence to suggest that a HJ to a segmental or sectoral duct has a greater risk of anastomotic stricture than is observed in patients who undergo HJ for complete transection of a common bile or common hepatic duct.^{96,98} In Strasberg type B injuries, patients usually remain asymptomatic and the injury is only discovered as an incidental finding of segmental hepatic atrophy on subsequent imaging.⁹⁷ This injury is likely under-reported in the literature because of its indolent natural history.⁴² Some patients, however, have a delayed presentation of right upper quadrant pain and fever, or recurrent episodes of cholangitis and may require percutaneous or surgical intervention.⁸⁶

The focus of this thesis will be on the management and prevention of major BDIs, defined as Strasberg type B, C and E1 to E5 injuries requiring surgical HJ repair. There is much debate in the literature over the timing of surgical repair of BDI. This is in part due to the complexity of decision making that must take into account multiple factors, including many that are outside of the surgeon's control. When present, sepsis and biliary peritonitis require immediate intervention with percutaneous drainage, or laparoscopy or laparotomy and drainage for source control, followed by a delayed surgical repair.⁹⁹ The presence of a concomitant vascular injury also influences the decision of when to operate.¹⁰⁰ Although definitive evidence is lacking, consideration of a delayed repair when vascular injury is present has been recommended to allow for complete demarcation of the resulting biliary ischaemia prior to repair.^{70,101} If a BDI is recognized at the time of LC, an immediate HJ repair is sometimes pursued, with lower morbidity, mortality and cost, and shorter hospital stay reported.¹⁰² Conversely, a national French survey on LC-BDIs, 640 patients who underwent immediate (at LC, n = 194), early (within 45 days, n = 216) and late (after 45 days, n= 133) HJ repairs found that the rate of postoperative re-intervention was significantly less in patients who underwent a late repair (7%) compared to immediate (57%) and early (41%) repairs ($p < 0.001$).¹⁰³ However, there are reports of "immediate" repairs, performed within 48-72 hours of injury with good patient outcome.¹⁰⁴ Yet other studies report equivalent outcomes between early and delayed repairs when patients are managed at HPB centres.^{105,106} In a multi-centre study spanning Europe and Africa including 913 patients, no association

was found between the timing of HJ repair and postoperative complications, 90-day re-interventions or liver-related mortality.¹⁰⁷ An internationally accepted definition of timing of repair is lacking and without this, it is difficult to compare outcomes of patients across studies, limiting our ability to understand how the timing of surgery influences patient outcome.¹⁰⁸

1.6 Postoperative outcomes after surgical repair of bile duct injury

The concept of restoration of biliary-enteric continuity with no resultant postoperative symptoms during follow-up or the need for re-intervention, or indwelling stents or catheters, was recently termed primary patency and is the main objective of surgical repair.¹⁰⁹ The morbidity associated with operative repair of LC-BDIs is not insignificant, with overall complication rates ranging from 24% to 33% reported in recent literature.^{108,110-112} Common early postoperative complications include anastomotic leak, cholangitis, intra-abdominal collections or infection, and liver abscess.¹¹³ Later complications include anastomotic strictures resulting in recurrent cholangitis, that can eventually cause secondary biliary cirrhosis, portal hypertension, liver failure and even death.¹¹³⁻¹¹⁵ Contemporary studies report anastomotic stricture rates of between 3% and 30%.^{108,116-120} Some patients may go on to require a surgical revision of the HJ, others can be managed with endoscopic or radiologic interventions.¹¹⁴ In extreme cases, liver transplant may be required.¹¹³

Patients with vasculobiliary injuries (VBI) have been documented to have a higher associated morbidity after LC-BDI due to the consequences of ischaemia and necrosis.¹²¹ Some studies report hepatic necrosis after right hepatic arterial injury resulting in the need for percutaneous and even surgical intervention.^{122,123} There is conflicting evidence whether vascular injury results in increased anastomotic stricture after HJ repair, with no definitive conclusion.^{70,100,121-124} Several studies have shown a significant mortality risk associated with BDI.^{32,115,125} In a large study including 1584 BDI patients from a state-wide Californian database, patients with a BDI were more likely to have died at 1 and 5 years follow-up after repair compared to propensity-matched controls (7.2% vs 1.3% at 1 year and 14.5% vs 4.8% at 5 years, $p < 0.001$), a difference which persisted in multivariate analysis (OR 2.0, 95% CI 1.6–2.6, $p < 0.001$).³² Similarly, Halbert et al. reported a 20% long-term mortality for surgically repaired BDIs, 8.8% higher than the expected age-adjusted mortality rate.¹²⁵

Depending on the timing of repair and postoperative complications, the management of BDI may result in a prolonged course. Several studies have investigated the effect of BDI on health-related quality of life (HRQoL), with mixed results. Some have found no significant effect on HRQoL after BDI.¹²⁶⁻¹²⁸ However, in a meta-analysis of 6 studies on the long-term effects of BDI on HRQoL, patients were 38 times more likely to have a lower scores in the mental domain of HRQoL compared to a control group of patients who underwent uncomplicated LC.¹²⁹ Interestingly, scores in the physical domain of HRQoL were similar between the two groups. Other studies not included in the meta-analysis report a statistically significant decrease in multiple domains of HRQoL in BDI patients.¹³⁰ Factors associated with poorer HRQoL include a delay in diagnosis of the injury¹³¹ and involvement in a malpractice claim.^{126,132,133} A protracted treatment course, multiple re-interventions and the associated costs have been hypothesized as additional contributing factors.¹²⁹

Although it is generally accepted that there are significantly increased costs associated with LC-BDIs, quantification of the cost is difficult and few studies have been published on the issue.^{65,134-136} This is largely due to the number of factors contributing to costs including prolonged hospitalization, multiple investigations, major reconstructive surgery, postoperative rehabilitation, loss of income and litigation.¹³⁴ In a recent study in patients with BDI undergoing surgical repair in the private healthcare sector in South Africa, the average cost was ZAR 215000, six times the cost of a LC.¹³⁴ Costs were as high as ZAR 980000 in patients with prolonged hospitalization.¹³⁴ A limitation in many of the cost studies is the exclusion of costs associated with days lost from work, decreased productivity and HRQoL, litigation, and hospital costs prior to referral. For the surgeon, medicolegal consequences after a LC-BDI can be severe, with up to a third of cases resulting in litigation claims in Europe.¹³⁷ Recent trends suggest that pay-outs are increasing,¹¹⁵ with compensation ranging from \$628138 to \$2891421 in the United States, £2500 to £216000 in the UK and €9826 to €55,301 in the Netherlands according to a recent review of the literature by Harihana et al.¹³⁸

1.7 Prevention of laparoscopic cholecystectomy associated bile duct injuries

The most effective way to minimize the morbidity, mortality and cost associated with LC-BDI is through prevention. The Critical View of Safety (CVS), first published in 1995 by Strasberg et al., is widely accepted as the best method for avoiding BDI in LC.^{43,52,139-141} To achieve the CVS, three elements must be present:⁴³

1. The hepatocystic triangle, defined by the cystic duct, common hepatic duct and inferior edge of the liver, should be free of fat and fibrous tissue.
2. The lower portion of the gallbladder should be dissected free of the liver to expose the lower 1/3 of the cystic plate.
3. Two and only two structures should be seen entering the gallbladder.

Although there are no head-to-head comparisons in randomized controlled trials of the CVS method versus a fundus-first or infundibular approach for LC, there is a large body of evidence to support its use over other methods.^{40,139,141-145} Several case series and large cohort studies have reported very low and even no LC-BDIs when the CVS is routinely used.^{139,142-145} Perhaps most convincing are studies which report on intraoperative video findings, as operative notes rarely reflect the intraoperative findings at LC.^{145,146} In a study by Nijssen et al., 65 intraoperative videos were reviewed and in only 11% was the CVS achieved, despite having been documented as achieved in 80% of the corresponding operative notes.¹⁴⁵ Furthermore, the CVS was not achieved in any patient in the study who suffered a LC-BDI.¹⁴⁵

The role of IOC in the prevention of LC-BDIs has been extensively debated. There is conflicting evidence around the utility of IOC in the reduction of LC-BDIs, with several large non-randomized studies suggesting a benefit,¹⁴⁷⁻¹⁵¹ while others demonstrate no benefit.^{152,153} Critics argue IOC is time consuming, cumbersome and the findings can be interpreted incorrectly.^{52,153,154} Some advocate routine use^{155,156} and others for selective use in difficult cases.^{157,158} In a systematic review by Ford et al. including eight randomized controlled trials, it was determined that a lack of adequate evidence precluded recommendation for or against the use of IOC.¹⁵⁹ The authors noted that the quality of the available Level 1 evidence was poor to moderate and none of the trials, individually or in combination, were adequately powered to demonstrate a reduction in LC-BDIs with IOC.¹⁵⁹ Similar conclusions were made in a recent systematic review by van De Graaf et al.¹⁶⁰ In a study including 51,404 cholecystectomies from the GallRiks database, IOC was only shown to reduce the incidence of BDIs for patients with acute cholecystitis or a history of acute cholecystitis.¹⁴⁸ Based on the available evidence, SAGES recommends liberal use of biliary tree imaging modalities, especially IOC, while acknowledging the controversies around its use.¹⁶¹ Additionally, a multi-society international consensus meeting on LC-BDIs held in Boston, Massachusetts, United States in 2018 recommended the use of IOC in patients with unclear anatomy or if

there is a suspicion of a BDI.¹⁶² They also suggested liberal use of IOC in patients with acute cholecystitis or a history of acute cholecystitis to reduce the risk of BDI.¹⁶²

Additional modalities for intraoperative imaging of the biliary tree that may result in decreased BDIs include intraoperative ultrasound and fluorescent cholangiography. For surgeons with access to intraoperative ultrasound and appropriate training, this may be a useful, time efficient alternative to IOC without the associated radiation exposure.^{163,164} However, the technique is highly operator dependent and insufficient data exist to assess its utility on preventing LC-BDIs.⁵² Indocyanine green with near-infrared fluorescent cholangiography is a relatively new imaging modality that is technically easy to perform, but requires a dedicated laparoscopic fluorescence imaging system. There is a lack of data on how it performs in higher risk patients, such as those with obesity or acute cholecystitis.⁵² Similarly to intraoperative ultrasound, there are insufficient data to determine whether fluorescent cholangiography reduces the incidence of LC-BDIs.¹⁴¹ A recently published multi-centre randomized controlled trial comparing near-infrared fluorescent cholangiography to white light alone found that fluorescent cholangiography was superior to white light for visualization of the biliary anatomy.¹⁶⁵ There were two BDIs reported, both in the white light arm, however, the study was not powered to detect a difference in rate of BDIs between the two study arms.¹⁶⁵ The FALCON trial (NCT02558556), in which patients are randomized to near-infrared fluorescence cholangiography assisted LC and conventional LC is scheduled to complete enrolment in July of 2020 and may provide further evidence on the role of fluorescent cholangiography in reducing LC-BDIs.

When the CVS cannot safely be achieved, there are several bailout procedures that may prevent BDI, including calling for help from a more experienced surgeon, subtotal cholecystectomy, conversion to OC, cholecystostomy tube drainage, and aborting the operation and transferring to a tertiary centre.^{52,166,167} Surgeons should have a low threshold for calling for help from another surgeon when operative conditions are difficult.⁵² However, when help is not available, other bailout procedures should be considered. Subtotal cholecystectomy, although associated with a higher risk of postoperative bile leaks, was in a recent systematic review and meta-analysis shown to have an overall morbidity comparable to LC, while minimizing the risk of BDI.¹⁶⁸ Similarly, in a systematic review investigating methods for prevention of BDI, the rate of LC-BDI was found to be significantly decreased with the use of subtotal cholecystectomy.¹⁶⁰ Subtotal cholecystectomy can be performed

laparoscopically or open, although laparoscopic is the preferred method if the surgeon's skill allows, as it results in lower postoperative morbidity compared to an open approach.¹⁶⁸ The key principle of a subtotal cholecystectomy is that dissection of the gallbladder stops at the neck, eliminating the need to continue dissection in proximity to the critical portal structures and minimizing the risk of causing a BDI.

Two different types of subtotal cholecystectomy have been described, namely fenestrating and reconstituting.¹⁶⁹ In a fenestrating subtotal cholecystectomy, the remaining gallbladder is left open to the peritoneum, while in a reconstituting subtotal cholecystectomy the gallbladder is closed, forming a small remnant gallbladder.¹⁶⁹ The reconstituting type is associated with a lower rate of postoperative bile leaks (16% vs 42% for fenestrating)¹⁶⁸, however the remnant gallbladder may become symptomatic in the future, requiring a second operation.¹⁶⁹ If subtotal cholecystectomy is not technically feasible, intraoperative placement of a cholecystostomy tube is an additional bailout option. One suggested method is placement of a balloon catheter, usually a Foley catheter, into the fundus of the gallbladder securing it in place with a purse-string suture.⁵² The appropriate bailout procedure will differ by patient and according to intraoperative findings. As with all surgical decision making, the surgeon should choose the safest course of action, considering his or her own skill and available resources in addition to patient factors.

1.8 The South African context

According to the World Bank classification by gross national income (GNI), South Africa is an upper middle-income country, similar to Mexico and China.¹⁷⁰ The United Nations Human Development Index (HDI), which includes multiple factors that determine a country's level of health, equality and education in addition to GNI, classifies South Africa as a medium human development country on a low, medium, high and very high human development scale.¹⁷¹ The greatest differences between South Africa and the world averages are in the inequality-adjusted HDI and the multi-dimensional poverty index, emphasizing the large gap between the wealthy and the underprivileged in South Africa (Figure 1.3). South Africa is the second most unequal country in the world in terms of equality of distribution of income according to the 2020 Gini scores from The World Bank data.¹⁷² The wealthiest 10% of the population possess more than 70% of South Africa's wealth, while the poorest 60% account for only 7% of the country's wealth.¹⁷² An estimated 55.5% of the population live in poverty with an income of just \$83 per month.¹⁷²

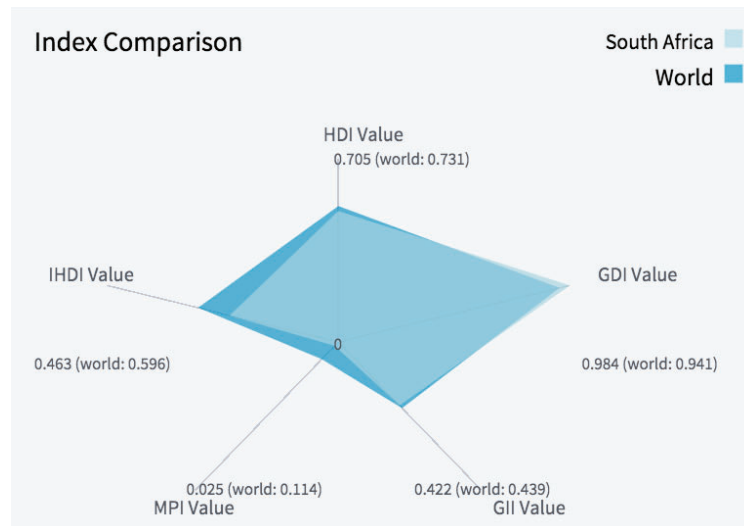


Figure 1.3. Comparison between South Africa and world averages according to the 2019 United Nations Human Development Report.

HDI – human development index, IHD – inequality-adjusted human development index, GDI – gender development index, MPI – multi-dimensional poverty index, GII – gender inequality index

Image from: United Nations Development Programme: Human Development Report 2019. Accessed 12 February 2020 at: <http://hdr.undp.org/en/countries/profiles/ZAF>.

Despite being an upper middle-income country, a significant portion of the population live in conditions similar to a low-income country, making access to healthcare for many patients difficult and limited. The challenges specific to this environment include delays in seeking care, long geographic distances to reach care, over-burdened and inadequately funded health systems that result in delays in provision of care which translate into delayed diagnosis and referral to specialists.¹⁷³ The prevalence of chronic infectious diseases such as human immunodeficiency virus (HIV) and tuberculosis, as well as poor nutrition also contribute to the complexity of the general management of patients.¹⁷⁴ Unfortunately, the underprivileged bear the greater burden of these challenges as they are more likely to access the resource constrained public healthcare sector.¹⁷³ The better resourced private healthcare sector accounts for half of the healthcare expenditure in South Africa and provides increased access to investigations, interventions and specialists, but is only accessible to approximately 16% of the population.¹⁷⁵ The poorly funded public sector, while receiving half of the country’s healthcare expenditure, serves 84% of the population, of whom a disproportionate number live in poverty.¹⁷⁵

1.9 The South African patient population

There are very few publications that examine the characteristics of the South African population undergoing LC, nearly all of which are from the twentieth century.¹⁷⁶⁻¹⁷⁸ In the 1940's, Lopis reported an incidence of gallstone disease of 4% in a black South African cohort, compared to 15% in South Africans of European descent.¹⁷⁶ He noted that nutritional and dietary factors and way of life contribute to the burden of cholelithiasis in a population. All of the patients included in his study lived in Johannesburg and its surrounding districts and would to some degree have been influenced by the European way of life.¹⁷⁶ A publication in 1976 on the worldwide incidence of gallstones estimated an incidence of 9.7% in the general South African population.¹⁷⁷ More recently, in a 2003 single centre comparison study of the rate of cholecystectomy in a predominantly black African population before and after the introduction of LC, the incidence of symptomatic gallstone disease requiring an operation in the black African population was rising.¹⁷⁹ This was in contrast to what had been previously published. Historically, from autopsy and hospital prevalence studies, black African populations had the lowest incidence of gallstone disease, attributed largely to diet and lifestyle.^{176,178} One of the reasons suggested for the increasing incidence of gallstone disease was an increase in urbanization of the population in addition to a growing acceptance that Western medicine can successfully treat medical problems.¹⁷⁹

The increase in urbanization in South Africa is shown in Figure 1.4. The proportion of people living in urban areas in South Africa surpassed the proportion living in rural areas in the late 1980's, continuing to increase to over 65% today, and the trend is predicted to continue according to the most recent estimations by the United Nations (Figure 1.4).¹⁸⁰ In South Africa, urbanization has resulted in westernization of the diet through an increase in fat and a decrease in fibre intake as well as an increase in obesity rates,¹⁸¹ factors which all have been linked to increasing the burden of cholelithiasis.¹⁸² Although the national trend in annual cholecystectomies performed in South Africa from before and after the introduction of LC is unknown, it is likely that urbanization has resulted in an increase of cholecystectomies performed in the country. In a study examining gallbladder specimens submitted to the national public healthcare sector pathology lab, an absolute increase of 92% in the number of cholecystectomies performed in 2004 compared to 2014 was reported, evidence supporting cholecystectomy as an increasingly common operation in South Africa.¹⁸³

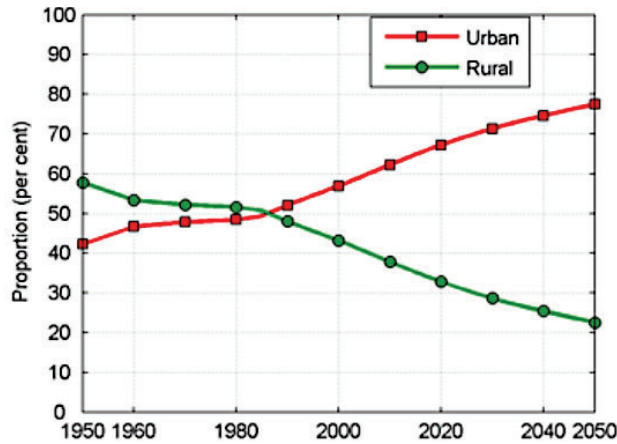


Figure 1.4. Proportion of urban and rural population in South Africa from 1950 to 2050. Years after 2014 are projected based on historical data.

Image from: United Nations, Department of Economic and Social Affairs, Population Division (2014): World Urbanization Prospects: The 2014 Revision. Accessed on 17 April 2018 at: <https://esa.un.org/unpd/wup/Country-Profiles/>.

1.10 Research aims

The purpose of this research was twofold, first to describe in detail the problem of LC-BDIs in the South African context and second to develop and implement an intervention aimed at reducing the burden of disease associated with the problem of LC-BDI. This research describes the incidence, management and outcomes of patients with LC-BDIs treated at a tertiary referral centre in Cape Town, South Africa, outlines the elements of an intervention implemented across the Cape Metro West Health District to limit LC-BDI and presents preliminary data after implementation. The specific aims of this research were to:

1. Estimate the number of overall cholecystectomies and LCs performed locally and nationally, and estimate the local incidence of LC-BDIs
2. Document the evolution in the management of LC-BDIs over a thirty-year period at a tertiary referral centre
3. Investigate the influence of geographic distance from referral centre on the timing of referral, repair and subsequent patient outcome
4. Determine the effect of treatment within the public compared to the private healthcare sector on patient outcome
5. Assess the relationship between the type of LC-BDI and patient outcome after surgical repair
6. Analyse factors potentially contributing to loss of patency after surgical repair

7. Evaluate the potential causes of LC-BDIs through detailed review of operative notes
8. Develop and implement an intervention to make LC-BDI a near-never event

1.11 Importance of the study

No data have been published on the implications of LC-BDI for patients treated in South Africa. As a common operation associated with potentially severe morbidity and cost for the patient, the surgeon and the healthcare system, a detailed analysis of the management and outcomes of LC-BDIs in a South African context is necessary. Although understanding the current problem of LC-BDI and establishing the optimal management of LC-BDIs in a middle-income country (MIC) healthcare setting is important, it does not address the source of the problem. In an effort to make LC-BDI a near-never event, a standardized method of performing, documenting and monitoring the quality of LC using the CVS was developed and implemented, and a prospective database was created for data capture along with a standard operating procedure, both designed with the goal to expand the intervention and database nationally. The studies reported in this thesis make a substantial contribution to the literature and will have a beneficial impact on patient care in two important ways. Firstly, the management of BDI in South Africa is described and a treatment algorithm for the management of BDIs in resource-constrained environments based on local experience is proposed. Secondly, a change of practice was implemented, and a LC database was established with the possibility of expanding the effort to a national level. Locally, the change in practice has thus far resulted in identification of areas of improvement to limit BDIs and increased knowledge about the appropriate steps to take to avoid causing a LC-BDI.

2.1 The Hepato-Pancreato-Biliary unit

The HPB service at Groote Schuur Hospital (GSH), a tertiary level public hospital affiliated with the University of Cape Town (UCT), is part of the Surgical Gastroenterology Unit that was established in 1983 under the leadership of Professors John Terblanche and Phillip Bornman.¹⁸⁴ The unit has a long history of excellence with several publications representing seminal contributions and innovative techniques in the field of HPB surgery, and has become a major referral centre for complex HPB problems.¹⁸⁴⁻¹⁸⁶ The establishment of the Biliary Clinic within the HPB unit in 1988 by Professor Jake Krige facilitated the referral and management of patients with BDIs from the onset of the LC era. The Digestive Diseases Centre at the UCT Private Academic Hospital is a multidisciplinary service which allows patients with private health insurance access to the clinical services rendered by university-associated clinicians. The same HPB surgeons, endoscopists and interventional radiologists work in both the HPB unit at GSH in the public healthcare sector and in the Digestive Diseases Centre in the private healthcare sector, ensuring consistency in management, including the management of BDI patients, with equally high standards of care. This has been the case for much of the last 30 years. As such, from this point forward, the combined public and private HPB services will be referred to as the HPB unit.

2.2 The bile duct injury database

The prospectively managed BDI database was established in 1991 and includes all patients referred with major cholecystectomy associated BDIs to the HPB unit. Data were initially captured using Microsoft Access¹⁸⁷ but from 2017 were recorded in the Research Electronic Data Capture (REDCap) tool hosted on the firewall-protected platform of UCT.^{188,189} REDCap is a secure, web-based software solution designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources.

The database consists of 670 data entry fields across 19 data collection instruments which include basic demographic information, details of the cholecystectomy operation, admission to the HPB unit, BDI characteristics, reconstructive surgery, postoperative complications, follow-up and re-admissions. Details of revision operations and any re-interventions following index repair of the BDI are also recorded. BDIs are classified in the database using the Bismuth, Strasberg and ATOM classification systems.^{43,57,66} Postoperative complications are classified using the Modified Accordion Grading System (MAGS).^{190,191}

The MAGS has a contracted format, which includes mild, moderate, severe and death categories for postoperative complications as well as an expanded format which ranges in severity from one to six, with one being a mild complication, two a moderate complication, three to five severe complications and six classified as a mortality.^{190,191} The three categories of severe (three, four and five) are differentiated by increasingly invasive interventions required for management where three is endoscopic, interventional radiology or surgical re-intervention without general anaesthesia, four is re-intervention with general anaesthesia or single organ failure and five is re-intervention with general anaesthesia and single organ failure.¹⁹⁰ The detailed definition of each category of complication severity within the MAGS is summarized in Table 2.1.

Table 2.1. The expanded and contracted definitions for the Modified Accordion Grading System.^{190,191}

Modified Accordion Grading System		
<i>Contracted Definitions</i>	<i>Expanded Definitions</i>	
Mild	1	Minor invasive procedures that can be done at the bedside such as physical therapy or insertion of IV lines, urinary catheters, and nasogastric tubes, drainage of wound infections or use of drugs including antiemetics, anti-pyretics, analgesics, diuretics, and electrolytes are permitted
Moderate	2	Pharmacologic treatment with drugs other than such allowed for minor complications. Includes antibiotics, blood transfusions and total parenteral nutrition
Severe	3	Invasive procedure without general anaesthesia (endoscopic or interventional procedure, or re-operation without general anaesthesia)
	4	Invasive procedure under general anaesthesia (endoscopic, interventional or surgical) or single organ failure
	5	Invasive procedure under general anaesthesia and single organ failure, or multisystem organ failure (≥ 2 organ systems)
Death	6	Postoperative death

2.3 Patients

Consecutive patients referred to the HPB unit for a BDI requiring surgical repair are prospectively collected in the BDI database. The first referral for a LC-BDI was received in 1991, however, prospective collection of all referrals for laparoscopic as well as OC associated BDIs are captured in the database. Referrals include patients from the public and private healthcare sectors, with some patients referred from as far as 2,000 km from the HPB unit, as well as international referrals from Namibia.

2.4 Standard preoperative evaluation¹

Patients referred to the HPB unit undergo a standard evaluation prior to surgical repair in order to fully characterize the extent of the injury, delineate the relevant vascular anatomy and identify any undrained intra-abdominal fluid collections. The first investigation performed is a contrast-enhanced computed tomography (CE-CT). In the absence of undrained intra-abdominal fluid collections which could obscure the findings, this is followed by a magnetic resonance imaging (MRI) with magnetic resonance cholangiopancreatography (MRCP). Although used infrequently, but when indicated, endoscopic retrograde cholangiography (ERC) is used. Whenever possible, percutaneous transhepatic cholangiography (PTC) is performed with placement of PTBC. This facilitates drainage of an obstructed biliary system, addresses undrained subhepatic collections resulting from transected non-occluded bile ducts, and assists in identification of the bile ducts at the time of repair. Bilateral PTBC are placed when the right and left ducts are separated due to the injury. Abdominal collections are drained percutaneously. Importantly, surgical reconstruction is delayed until the general condition of the patient is optimized with resolution of sepsis and restoration of organ function.

In patients who are referred for a failed index repair performed elsewhere, details of the reconstruction are obtained from referral letters and from the referring surgeon directly. Patients referred for a revision of a previous repair undergo the same preoperative evaluation as for primary referrals with particular attention given to defining the biliary anatomy, extent

¹Lindemann J, Krige JEJ, Kotze U, Jonas E. Factors leading to loss of patency after biliary reconstruction of major laparoscopic cholecystectomy bile duct injuries: an observational study with long-term outcomes. HPB (Oxford). 2020 Mar 20. [Epub ahead of print] DOI: 10.1016/j.hpb.2020.02.010. PMID: 32201053.

of the anastomotic stricture and whether hepatic atrophy is present which might influence the surgical approach.

2.5 Operative repair technique

In patients undergoing index BDI repair, a standard operative technique for HJ is used, the full technical details of which have been published previously.⁸⁸ Briefly, after identifying the site of the injury in the hepatoduodenal ligament, any fibrotic and/or necrotic tissue is resected until healthy, well-vascularized ductal mucosa is identified. When necessary, the hilar plate at the base of the quadrate lobe is incised and the extrahepatic left hepatic duct and the hepatic duct confluence is exposed and lowered. To ensure a sufficient biliary lumen an anterior longitudinal incision is made in the extrahepatic component of the left hepatic duct using the Hepp-Couinaud approach.⁸⁷ Where indicated and technically feasible, intraoperative choledochoscopy is performed to identify the right and left intrahepatic segmental ducts and ensure the absence of intrahepatic stones. The operative findings are reconciled with the preoperative imaging to ensure identification of all ducts. A jejunal Roux-en-Y loop is used and a side-to-side HJ anastomosis is constructed using preplaced 5/0 absorbable monofilament sutures. A PTBC is used to stent across the HJ anastomosis if one has been previously placed.

In the situation where there is complete separation of the hepatic duct bifurcation, the left and right hepatic ducts are mobilized and the back walls approximated and sutured together to enable the construction of a single HJ anastomosis. When insufficient length is present to allow a tension-free union between right and left hepatic ducts, two separate HJ anastomoses are created. For patients undergoing a revision of a previous surgical repair, a similar surgical approach is followed. The existing jejunal Roux-en-Y loop is used if of sufficient length and quality and a HJ anastomosis is constructed in the same fashion using preplaced 5/0 absorbable monofilament sutures.

2.6 Definitions of geographic distance and timing of repair

Geographic distance from referring hospital was classified into three distinct groups: < 100 km, 100-500 km and > 500 km from the HPB unit. Timing of index reconstruction was

defined as immediate (during the same anaesthesia as LC), urgent (within 72 hours of LC), early (> 72 hours, but ≤ 14 days), intermediate (>14, but ≤ 90 days) and late (> 90 days) repairs. The timing of BDI repair has been extensively discussed, but an internationally recognized classification system has not materialized. A five category classification system is utilized in this research to account for the differences in patients who undergo reconstruction at the time of LC, those who have an expedited referral and evaluation, and those who are referred “early” but for multiple reasons wait up to two weeks before undergoing reconstruction. The urgent repair (≤ 72 hours after LC) category is used to identify those patients who were treated with the intention of an immediate repair, but in whom delays in transfer, the necessity of a thorough preoperative evaluation and delays in operating theatre availability precluded repair under the same anaesthetic as the LC.

2.7 Postoperative care and follow-up

One week postoperatively, PTC is performed via the PTBC to confirm an intact biliary-enteric anastomosis. The PTBC are removed between 10 and 14 days postoperatively, usually at the first postoperative outpatient visit. Patients who live locally are followed in the HPB unit with an outpatient visit and liver function tests every three months for the first year, six monthly for the second year and then annually, unless more frequent visits are clinically indicated. Patients referred from geographically distant hospitals are discharged with a letter to the referring surgeon detailing the patient’s hospital course and instructions for follow-up according to our standard practice. Duration of follow-up is calculated from postoperative day one until the patient’s last contact with the healthcare system. Outpatient visits, repeat admissions, and letters or emails from referring surgeons of clinical patient updates with laboratory values are used to determine days of follow-up.

2.8 Classification of postoperative outcomes

Thirty-day postoperative complications are recorded and graded using the previously described MAGS (Table 2.1).¹⁹⁰ Long-term outcomes after surgical repair of BDI are reported using the recently proposed standardized method of reporting by Cho et al.¹⁰⁹ Briefly, a set of definitions and a method for standardized reporting of outcomes after repair of BDI are outlined in the proposal. The central premise for the reporting of outcomes is focused on the concept of patency, which is defined as an open, functional biliary tree free

from stents, catheters and the need for invasive interventions with no episodes of cholangitis, liver abscess, jaundice or biliary fistula.¹⁰⁹ A patient achieves primary patency if they meet the designated criteria within 90 days of surgical repair.¹⁰⁹ When a patient fails to achieve primary patency or primary patency is lost, secondary patency is achieved only after restoration of biliary-enteric continuity and resolution of symptoms.¹⁰⁹ Outcome is graded based on an A through D scale, with A representing an ideal outcome and D a poor outcome.¹⁰⁹ A summary of the definitions and grading for surgical outcomes can be found in Table 2.2.

Table 2.2. A summary of the standardized definitions for patency, treatment period and patency grading as proposed by Cho et al.¹⁰⁹

Patency: Open functional biliary tree free of stents and the need for invasive interventions, in a patient who following completion of treatment, has no episodes of cholangitis, liver abscess, jaundice or external biliary fistula.						
Primary Patency	Achieved if the definition of patency is fulfilled by the end of the index surgical treatment period (90 days from surgical repair).					
Secondary Patency	For patients who failed to attain or who lost primary patency, achieved when the definition of patency has been fulfilled and/or restored. Can be attained and lost multiple times.					
Patency Grading						
	Stents/other devices	Endoscopic/ IR treatment	Cholangitis^a	Liver abscess	Biliary fistula	Surgical re-intervention
Grade A	Primary patency, as defined above.					
Grade B^b	Retained ≤ 18 months	Required after 90 days, completed ≤ 1 year	1-2 episodes, successfully treated	1 episode, successfully treated	Occurred and healed ≤ 1 year after onset	None
Grade C[^]	Retained > 18, but ≤ 24 months	Required after 90 days, completed > 1 year	≥ 3 episodes	> 1 occurrence, each at least 3 months apart	Occurred and healed ≤ 2 years after onset	2nd bile duct repair
Grade D	Retained > 24 months	-	Development of cirrhosis	-	Present for > 2 years	Liver resection, transplant or a 3rd repair

^aCholangitis defined according to the 2013 Tokyo Guidelines¹⁹²

^bPrimary patency was either not achieved or was lost; secondary patency was achieved and maintained by the specified criteria for each grade

IR – interventional radiology

2.9 The laparoscopic cholecystectomy database

The LC database was established in 2019 for the purpose of capturing data following an intervention at GSH using a LC checklist, standardized operative note and mandatory photo or video documentation of the CVS. Similar to the BDI database, the LC database is

prospectively maintained using the REDCap tool hosted at the UCT.^{188,189} The database consists of 146 data entry fields across 7 data collection instruments which include capture of patient demographic information, a standardized operative note, CVS photos, four blinded reviewers scores for assessing CVS quality, and postoperative complications and re-admissions at 30 days after LC. Patient characteristics include indication for LC, duration of symptoms, timing of LC (elective vs same admission) and patient comorbidities. The CVS photos are scored using a previously described method by independent, blinded reviewers who have REDCap access limited only to the CVS photos.¹⁹³ Postoperative complications are classified using the MAGS.¹⁹⁰ Data capture was subsequently expanded to include data of all LCs performed in the Cape Metro West Health District public hospitals which includes Victoria Hospital, Somerset Hospital and Mitchells Plain Hospital.

2.10 Statistical analysis

Normally distributed continuous variables are presented using mean and standard deviation (SD) and non-parametric continuous variables are reported as median with range and interquartile range (IQR). Categorical variables are presented as number and percent. The two-tailed *t*-test for normally distributed continuous variables was used. The Mann–Whitney U and Kruskal–Wallis tests were used to compare two and greater than two non-parametric continuous variables, respectively. The median test was used when comparison of medians across samples with unequal variance was required. Fisher’s exact was used to compare categorical variables. The Spearman rank-order correlation coefficient (r_s) for nonparametric data was used to test for monotonic relationships between variables. The intra-class correlation coefficient (ICC) with a two-way mixed effects model and absolute agreement was used to assess reliability of the previously published method for scoring the quality of the CVS.¹⁹³ The Kaplan-Meier method was used to determine primary and secondary patency rates and the life table (actuarial) method was used to determine actuarial patency rates after surgical repair of BDIs. Patency outcomes are presented according to recently published methods.¹⁰⁹ A p-value < 0.05 was considered statistically significant. All statistical analyses were performed using SPSS version 25 (IBM SPSS Statistics, IBM Corporation, Armonk, NY).

2.11 Ethical considerations

Research for the purpose of this degree was performed in compliance with the ethical guidelines of the “World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects” adopted by the 18th WMA General Assembly in Helsinki, Finland (1964) and most recently revised in October 2013 at the 64th WMA General Assembly, Fortaleza, Brazil, as well as the Declaration and the Department of Health: Ethics in Health Research: Principles, Processes and Structures.^{194,195}

2.11.1 Risks and benefits

There was minimal risk to the patients included in this research. While there was minimal risk to participating patients, there was also minimal benefit. The findings of this research did not influence or change their clinical course. However, it is possible that the findings, conclusions and resulting prospective intervention may benefit future patients.

2.11.2 Informed consent, privacy and confidentiality

Patients were included in the BDI database according to the previously determined Human Research Ethics Committee (HREC) requirements for consent, which includes consent regarding the possibility of using data from databases in future studies. Therefore, a separate informed consent for the retrospective components of the research was not obtained.

Similarly, patients completed an HREC-approved informed consent form for entry into the LC database. The REDCap databases are secure with password protection and any activity is automatically logged. All data exported for analysis is done without patient identifiers for the purpose of analysis to ensure that patient confidentiality was maintained. Exported data is stored electronically on a password protected computer. When hard copies of data are required, they are kept in a locked file cabinet in the Surgical Gastroenterology and HPB Unit. Only supervisors and other co-authors have access to the REDCap database and electronic and hard copy forms of extracted data.

2.11.3 Ethics approval

Surgery Department Research Committee (SDRC) and HREC approval was obtained for the BDI and LC databases, the degree proposal and all studies completed in relation to this

research. A summary of SDRC and HREC approvals for included studies can be found in Table 2.3. Additional permission was obtained from the Chief Operational Officer of GSH to review historical theatre registers (Appendix A) and for capture of patient data at hospitals outside GSH within the Cape Metro West Health District (Appendix B.5.2).

Table 2.3. Surgery Department Research Committee and Human Research Ethics Committee reference numbers for included studies.

Study Question	SDRC Reference	HREC Reference	Chapter Number
BDI database	n/a	R023/2014	n/a
LC database	n/a	R040/2019	n/a
Degree Protocol ^a	2018/031	348/2018	n/a
What is the frequency of cholecystectomies and LCs performed in locally and nationally and what is the incidence of LC-BDIs? ^a	2018/031	348/2018	3
How has the management of LC-BDIs evolved at a major tertiary referral centre over the last three decades?	2018/135	721/2018	4
How does geographic distance from referral centre influence time to referral, repair and outcome after surgical repair of LC-BDIs?	2018/132	720/2018	5
How do management and outcomes after LC-BDI compare in the public vs private healthcare sectors?	2018/133	731/2018	6
Is an endoscopic-percutaneous rendezvous approach to management of major LC-BDIs feasible?	2018/068	414/2018	8
What is the correlation between type of BDI and postoperative complications?	2018/034	248/2018	7
What factors predict loss of patency after surgical repair of LC-BDIs?	2018/134	719/2018	9
What are the potential causes of LC-BDI in patients referred to a tertiary centre in South Africa?	2020/030	173/2020	11
What is the quality of the CVS achieved in LCs performed at GSH and is the CVS scoring method reliable?	2020/017	100/2020	12
What is the quality of the CVS in LCs performed across Cape Metro West Health District public hospitals and what is the associated morbidity?	2020/039	199/2020	13, 14

^aSDRC and HREC approval for the degree protocol included data collection and analysis for determination of the frequency of LCs and incidence of LC-BDIs therefore SDRC and HREC references are the same.

BDI – bile duct injury, CVS – critical view of safety, HREC – Human Research Ethics Committee, LC – laparoscopic cholecystectomy, n/a – not applicable, SDRC – Surgery Department Research Committee

An Estimation of the Problem

3.1 Rationale

Early after the introduction of LC into general practice, the incidence of BDIs was reported to be several times that of the 0.2% reported during the OC era, ranging from 0.3% to 0.82%.^{24,147,196} Recently, population-based estimates have been reported to be between 0.08% and 0.4%.^{27,32,33} For South Africa, little data exist on the incidence of BDIs. In a single centre analysis of the early LC experience in South Africa, 144 patients who underwent OC from January 1990 to December 1992 were compared to a cohort of 156 patients who underwent LC from February 1992 to December 1994.¹⁷⁹ There were two major BDIs (1.4%) and one mortality (0.7%) in the OC group compared to one cystic duct leak (0.6%), no mortalities and an 18% conversion rate in the LC group.¹⁷⁹ While encouraging, the absence of major BDIs in the LC cohort of this small, single centre study is unlikely to be representative of the incidence of BDIs locally or nationally. In a series of 167 South African patients who underwent LC from January 2010 to June 2011, a BDI rate of 1.2%, a mortality rate of 0.6% and a conversion rate of 5.4% were reported.³⁸ There are no further published data on the incidence of LC-BDIs for South Africa.

Determination of an accurate estimate of the incidence of BDIs in South Africa is challenging due to separate public and private healthcare sectors, a lack of electronic theatre logs and electronic medical record keeping, and no established national database for LCs. However, an estimate of the annual number of cholecystectomies (LC and OC) performed in the public sector utilizing data from the National Health Laboratory Service (NHLS), has been reported.¹⁸³ The NHLS provides laboratory services to the entire public sector, serving approximately 80% of the population, and represents the largest pathology laboratory organization in South Africa. In the previously published report by Khan, a review of 10 years of cholecystectomy specimens was performed.¹⁸³ During the study period, the overall rate of cholecystectomies increased by 65% from 8.4 per 100,000 population in 2004 to 13.8 per 100,000 population in 2013.¹⁸³ This estimate includes all cholecystectomies (LC and OC) performed in the public healthcare sector with gallbladder specimens submitted to pathology. Although the data are now seven years old and there are limitations regarding accuracy, the study represents the best available epidemiological data on cholecystectomy rates in the public sector for South Africa to date.

The purpose of this chapter is to demonstrate how the number of LCs performed annually has changed over the last 10 years at GSH, a tertiary academic teaching hospital in Cape Town, South Africa, and to provide an estimate of the incidence of BDIs for the institution. Using previously published data on the prevalence of cholecystectomies performed in South Africa, population data reported by the South African government and recent local trends in the prevalence of LCs performed, an estimation of the number of LCs performed in the Cape Metro West Health District and an estimation of the number of all cholecystectomies performed nationally are determined to provide context to the problem of BDIs in South Africa.

3.2 Methods

3.2.1 Estimation of the annual number of cholecystectomies

Previously published cholecystectomy prevalence data, and population and medical insurance coverage data from Stats South Africa for the year 2018 were used to estimate the number of cholecystectomies performed nationally.^{183,197} Similarly, for the Cape Metro West Health District, population and medical insurance coverage data from the Western Cape Government were used to estimate the number of cholecystectomies performed for the year 2018.¹⁹⁸ To make these calculations, three important assumptions were made:

1. The annual rate of increase was constant over the 10 years of the study (2004–2013).
2. The previously published trend of increasing cholecystectomies performed in the public sector across South Africa has continued on the same trajectory for the last five years (2014–2018).
3. A similar trend in the increase in cholecystectomies performed nationally occurred locally within the Cape Metro West Health District.

To account for the 83.6% of patients without medical insurance accessing the public healthcare sector nationwide in 2018, the reported national population was adjusted by removing the proportion of the population (16.4%) with medical insurance for the private healthcare sector. A similar calculation was performed for the Cape Metro West region, where 76.8% of the population is uninsured. The year 2018 was chosen as it represents the most recent year with complete population and medical insurance coverage data. Calculation of the annual number of LCs for the public sector in South Africa was not possible using the available evidence. However, the annual number of LCs performed in the Cape Metro West

Health District for the year 2020 was calculated using the first three months of data collected in 2020 following a LC intervention implemented across the public sector Cape Metro West hospitals.

3.2.2 Annual number of laparoscopic cholecystectomies and the estimated incidence of bile duct injuries at Groote Schuur Hospital

A retrospective review of theatre registers from GSH over a 10-year period, from January 2010 through December 2019, was performed. For patients who underwent a LC, medical ID, name, date and final procedure performed were recorded. An electronic medical record has been used by the Acute Care Surgery Unit at GSH from July of 2017. Operative notes retrieved from the electronic medical record from its inception through December 2019 were reconciled with data extracted from the theatre registers. Complete data were available for the years 2011, 2012, 2018 and 2019. Patient data including demographic characteristics, LC indication, timing of BDI diagnosis, and details of BDI management for the years with complete data were retrieved from the prospectively maintained BDI database. For the purpose of this analysis, a BDI was defined as an injury requiring surgical repair. To calculate the incidence of LC-BDIs at GSH, the number of LCs performed was used as the denominator and the number of BDIs requiring surgical repair was used as the numerator, for the years with complete data (2011, 2012, 2018 and 2019). BDI incidence estimates for GSH are presented overall and by year. The available data did not allow estimation of the incidence of LC-BDIs beyond GSH.

3.3 Results

3.3.1 Estimation of the national number of cholecystectomies performed in the public sector in 2018

To estimate the number of cholecystectomies performed in the public sector for the year 2018, previously published data from 2004 to 2013 were used.¹⁸³ The number of cholecystectomies performed in 2004 was 8.36 per 100,000 population compared to 13.81 per 100,000 population in 2013, representing an annual increase in cholecystectomies of approximately 0.545 per 100,000 population over the 10-year period.¹⁸³ The estimated annual number of cholecystectomies for 2014 to 2018 are shown in Table 3.1. Assuming a constant annual increase, the estimated number of cholecystectomies performed in the public healthcare sector in South Africa for the year 2018 was 16.54 per 100,000 population.

Table 3.1. Calculation of the annual cholecystectomy rates for South Africa using previously published data.¹⁸³

Year	Cholecystectomies per 100,000 population ^a
2004	8.36 ¹⁸³
2013	13.81 ¹⁸³
2014	14.36
2015	14.90
2016	15.45
2017	16.0
2018	16.54

^aYears beyond 2013 calculated assuming: $13.81 - 8.36 = 5.54 / 10 \text{ years} = \text{annual increase of } 0.545 \text{ per } 100,000 \text{ population}$

To determine the annual number of cholecystectomies performed nationally, population data from Statistics South Africa were used.¹⁹⁷ The estimated population of South Africa in 2018 was 57,458,000 with 16.4% of the population having medical insurance coverage to access healthcare in the private sector.¹⁹⁷ The portion of the national population accessing care in the public sector (74.6%) was estimated to be 48,034,888. Using the previously calculated rate of 16.54 cholecystectomies per 100,000 population, the annual number of cholecystectomies performed in the public healthcare sector for South Africa was estimated to be 7,945 for 2018.

3.3.2 Estimation of the annual number of cholecystectomies (2018) and laparoscopic cholecystectomies (2020) for the Cape Metro West Health District

Population and medical insurance coverage data from the Western Cape Government were used to estimate the number of cholecystectomies performed using the previously published data and estimates from Table 3.1.^{183,198} In 2018, the Cape Metro West Health District had an estimated population of 2,036,815 and 23.2% of the population was documented as having health insurance to access the private healthcare sector.¹⁹⁸ Adjusting for the portion of the population with medical insurance, the estimated population of the Cape Metro West Health District accessing the public healthcare sector (76.8%) was 1,564,274 people. Using the estimates from Table 3.1, the annual number of cholecystectomies performed in the public sector was estimated to be 259 cholecystectomies for the year 2018.

For comparison, the number of LCs performed in 2020 for the Cape Metro West Health District was estimated. For the first three months of 2020, 97 LCs were performed across all

public sector hospitals in the Cape Metro West Health District, according to data collected in the LC database as part of a study to evaluate implementation of a change in practice for LCs. Regular data quality checks of the database revealed an additional 22 LCs that were not recorded over the same time period, resulting in a total of 119 LCs performed in the Cape Metro West Health District for the first quarter of 2020. Extrapolating from the first three months of data, an estimated 476 LCs may be performed for the year 2020. During the first three months of data collection, no major BDIs requiring surgical repair occurred.

3.3.3 Annual number of laparoscopic cholecystectomies for Groote Schuur Hospital

The annual number of completed LCs, subtotal LCs and LCs converted to OCs for the years with complete data are shown in Figure 3.1. There were 131 LCs attempted in 2011, with 124 (95%) completed as a LC and 7 (5%) converted to OC. No subtotal LCs were performed and 6 (5%) patients underwent IOC. In 2012, there were 138 attempted LC operations, 123 (89%) of which were completed as a LC with conversion to an open procedure in 14 (10%). There was one (0.7%) subtotal LC and 17 (12%) IOCs performed. For the year 2018, 176 LCs were attempted with 156 (89%) completed as a LC, conversion to OC in 13 (7%) and subtotal LC performed in 7 (4%). Twenty-two (13%) patients underwent IOC at the time of LC. There was a total of 177 LCs attempted in 2019, 163 (92%) of which were completed as a LC with 2 (1%) conversions to OC and 12 (7%) subtotal LCs performed. Fifteen (8%) patients underwent IOC. Overall, there was a 35% absolute increase in the number of LCs attempted in 2011 (n = 131) compared to 2019 (n = 177).

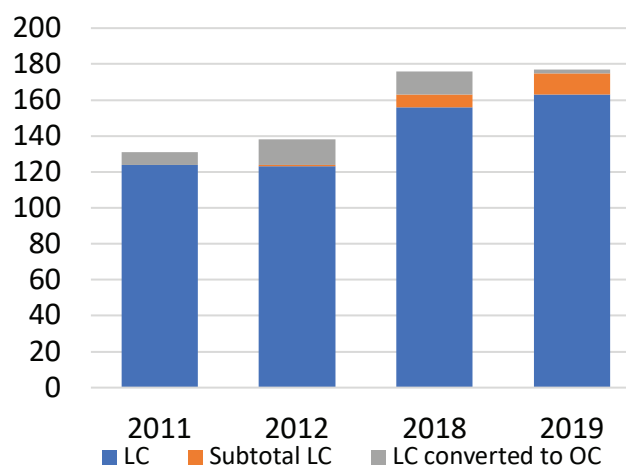


Figure 3.1. Annual number of cholecystectomies performed in 2011, 2012, 2018 and 2019 at Groote Schuur Hospital.

LC – laparoscopic cholecystectomy, OC – open cholecystectomy

3.3.4 Estimation of the incidence of laparoscopic cholecystectomy associated bile duct injury at Groote Schuur Hospital

Two major BDIs occurred at GSH during the four years with complete data, one in 2012 and one in 2018. This translated into an annual LC-BDI incidence of 0.7%, 0%, 0% and 0.6% for 2012, 2013, 2017 and 2018 respectively, and a LC-BDI incidence of 0.3% for the four year study period. The annual incidence of LC-BDIs for 2012 was 0.7% and for 2018 was 0.6%. The first patient in 2010 was a healthy 42-year-old female who underwent an uneventful LC for acute cholecystitis. On postoperative day 5 she was noted to have a bile leak. Cross sectional imaging demonstrated an intra-abdominal fluid collection, complete transection of the common bile duct and a right hepatic artery injury. She underwent placement of a right sided PTBC to control the biliary fistula and was discharged with the intention of performing a delayed repair. Two months later she was readmitted for a HJ repair of the Strasberg type E2 injury. She recovered well and remains asymptomatic at last follow-up seven years post-repair. The second patient who presented in 2018 was an otherwise healthy 59-year-old female who underwent LC after developing acute cholecystitis in a remnant gallbladder following a subtotal LC in 2015. At the time of completion LC, dense adhesions and a difficult dissection were noted. The BDI was diagnosed intraoperatively and confirmed as a complete transection of the common bile duct on IOC. The operation was converted to open and an HPB surgeon was consulted for an immediate HJ repair of the Strasberg type E3 injury. The patient is alive and well at last follow-up 18 months post-repair.

3.4 Discussion

This study aimed to provide context to the problem of LC-BDI in South Africa using all available evidence from the public healthcare sector at the local, regional and national level. There was a 35% increase in the number of LCs performed at GSH from 2011 to 2018, with a concurrent decrease in the conversion to open rate, an increase in the number of subtotal LCs and a relatively constant rate of IOCs performed. The incidence of BDIs for the years with complete data was estimated to be 0.3%, with annual rates of 0.7% (2012) and 0.6% (2018) for the individual years during which the BDIs occurred. Establishing an accurate estimate of the incidence of LC-BDIs for a region is problematic due to several factors including a lack of national databases, the relative rarity of LC-BDI requiring large numbers to measure events and under reporting of events. The barriers to making accurate estimates of the incidence of LC-BDIs are significantly greater in South Africa, where there is a distinct divide between the public and private healthcare sectors, theatre registers that are maintained

in handwritten books which are often incomplete or missing, the absence of an electronic medical record and limited capacity to create national databases.

A recent systematic review aimed to determine the incidence of LC-BDIs as well as quantify the morbidity and mortality associated with LC from studies published in developed and developing countries from 1994 to 2015.¹⁹⁹ There were 151 studies included, representing 505,292 patients, with a reported LC-BDI incidence of between 0.32% to 0.52%.¹⁹⁹ However, the authors note limitations of the pooled estimate including differences in classifications systems used to report BDIs, the high likelihood of a large volume of unpublished LCs, significant heterogeneity with poor study quality limiting the ability to perform a meta-analysis and significant publication bias.¹⁹⁹ The reported incidence of LC-BDIs from countries with national databases represent the most accurate estimates, of which the recently published 0.3% BDI incidence from the Swedish Gallriks registry is considered the standard due to its long history of near-complete coverage of the entire population of Sweden.²⁷ El-Dhuwaib et al. reported a LC-BDI incidence of 0.09% for England over a 12-year period using data from the National Health Service Information Centre over a 12-year period.²⁰⁰ A recent study using a state-wide database for California in the United States reported a BDI incidence of 0.22% in 711,454 cholecystectomies performed over a 10-year period.³² A LC-BDI incidence of 0.3% for the four years with complete data at GSH is comparable to previously published population-based rates.^{27,32,200}

The observed trends in decreasing conversion rates and increasing use of laparoscopic subtotal cholecystectomy suggest a growing success using bailout procedures, which is in line with the current consensus recommendations from the 2018 State-of-the-Art Consensus Conference on Prevention of Bile Injury During Cholecystectomy, jointly hosted and endorsed by several American, European and international surgical societies.¹⁶² Interestingly, the previously mentioned systematic review found that for developing countries, the conversion rate from LC to OC was lower compared to developed countries in meta-regression analysis (mean 3.4 % vs 4.7%, $p = 0.026$).¹⁹⁹ The use of IOC during the years of the current study was between 5-15%, slightly lower than previously reported rates. In a systematic review of BDI prevention, 4 studies reported selectively using IOC with a median IOC use of 29% (IQR 11.8%–34.6%) for all LCs performed.^{157,160,201-203} Routine use of IOC was also investigated and after review of the literature, the authors conclude that no recommendations can be made regarding selective or routine use of IOC given the low level

of available evidence.¹⁶⁰ This conclusion was similar to a systematic review on the use of IOC in cholecystectomy, published six years previously.¹⁵⁹

Extrapolating from previously published data, the estimated number of cholecystectomies performed nationally in the public healthcare sector for 2018 was approximately 8,000 while the estimated number performed in the Cape Metro West Health District was 259 for the same year. For the year 2020, the number of estimated LCs performed for the Cape Metro West Health District was 476 LCs. The results of the annual number of cholecystectomies presented here represent a first attempt at estimating the local, regional and national numbers for South Africa. Understanding the scope of the problem of LC-BDIs requires context for the number of LCs performed across the country. The estimate from this study suggests approximately 8,000 cholecystectomies were performed in the public sector in 2018. This number includes both LCs and OCs and is very likely to be an underestimate, as it is based on gallbladder specimens submitted to pathology, which is not routine at all hospitals. This is supported by the nearly doubled and more accurate estimate of 476 LCs in 2020 for the Cape Metro West Health District compared to the estimated 259 cholecystectomies (LCs and OCs combined) for 2018.

The limitations of the estimates in this study cannot be overstated. Several assumptions were made about local and national trends in cholecystectomies performed and about access to the public healthcare sector, which cannot be confirmed given the available evidence. There were no data available that allowed for an estimation of the proportion of cholecystectomies performed laparoscopically in the public healthcare sector in South Africa. Similarly, there were no data available to estimate the number of LC-BDIs. The estimates presented here do not account for any cholecystectomies performed in the private sector, as no central database exists and data from private medical insurance companies are not made publicly available. However, cholecystectomies performed in the private sector could represent a substantial proportion of the total number of cholecystectomies performed in South Africa. For example, at GSH, 50% of referrals for BDIs come from the private sector, despite the private sector serving only approximately 20% of the population.²⁰⁴ Simply extrapolating the numbers and trends observed in the public sector and applying them to the private sector is unlikely to give an accurate estimate for a number of reasons. The proportions of the different population groups in South Africa are not equally represented in the group with healthcare insurance. Seventy-two percent of white South Africans are covered by medical aid, compared to 49%

of the population classified as Indian/Asian, 20% classified as Coloured and 10% classified as Black South Africans.¹⁹⁷ Furthermore, there are well documented differences in the prevalence of gallstones in different population groups.¹⁷⁷ Access to healthcare has also been shown to influence the numbers of patients who undergo elective operation for chronic gallstone-related symptoms.²⁰⁵

In conclusion, the 0.3% estimated incidence of LC-BDIs for GSH is comparable to population-based estimates, however, it must be interpreted with caution as the estimate is based on selected years, limited by the availability of complete data. Establishing the prevalence of LCs performed in South Africa, a necessary step to accurately determine the incidence of LC-BDIs, is problematic due to several barriers related to accessing accurate and complete data. A likely underestimated number of 8,000 cholecystectomies performed nationally within the public healthcare sector for 2018 was proposed, however several assumptions were made that cannot be validated with the available evidence. No data were available to allow for an estimation of the national prevalence of LC or incidence of BDI. LC is considered a commonly performed operation in South Africa and is associated with potentially severe morbidity when BDI occurs. The lack of available data for LC in South Africa precludes establishing the baseline morbidity associated with LC and limits the possibility of performing quality improvement interventions for this common procedure. Future efforts to establish a national database as a means to document the prevalence of LC and monitor the incidence of LC-BDI for South Africa are warranted.

Evolution in the Management of Bile Duct Injuries²

4.1 Rationale

There is consensus that patients with BDIs should be referred early to centres with specialized HPB surgeons for management to minimize the associated morbidity and mortality.^{74,206} While the management and outcomes of surgical repair of BDI have been well documented in seminal articles and guidelines, few studies have specifically evaluated the evolution of treatment strategies for BDI over time.^{40,43,48,55,207} An uncommon event such as BDI requires decades to accumulate enough events for a meaningful analysis. A detailed evaluation of how management has evolved over time is important for the interpretation of surgical outcome results.

In addition, there is a paucity of data from LMICs regarding the presentation and management of LC-BDIs. Nearly 90% of the world population live in low, lower-middle- or high-middle-income countries, so it is likely that a significant number of cholecystectomies are performed in these countries.¹² In these situations, the desired and recommended treatment algorithms for BDIs may not be applicable or achievable. LMICs face unique challenges such as limited access to healthcare, and in particular, tertiary surgical care. This chapter provides important insight into the realities healthcare providers face when treating BDIs in a MIC setting. Referral patterns, management and postoperative short- and long-term outcomes after surgical repair of BDI are assessed with regard to how these have evolved during two time periods over the last three decades.

4.2 Methods

4.2.1 Study design

A retrospective review was performed of the prospectively maintained BDI database for all patients who underwent HJ repair of a LC-BDI from January 1991 through December 2017. The preoperative evaluation and surgical repair technique were described in Chapter 2: Methods. Using the year in which the HJ was done, patients were divided into two groups, 1991 to 2004 and 2005 to 2017 to allow for comparison of LCs before and after the

²Lindemann J, Jonas E, Kotze U, Krige JEJ. Evolution of bile duct repair in a low and middle-income country (LMIC): A comparison of diagnosis, referral, management and outcomes in repair of bile duct injury after laparoscopic cholecystectomy from 1991 to 2004 and 2005-2017. *HPB (Oxford)*. 2020;22(3):391-397.

dissemination of LC to peripheral hospitals across South Africa. Follow-up data were retrieved through June 2018 to allow for a minimum follow-up period of 6 months follow BDI repair.

4.2.2 Patient characteristics and study definitions

Demographic and clinical characteristics including age, gender, Strasberg classification of the BDI and presence of a concomitant vascular injury were retrieved and documented.⁴³ The timing of BDI diagnosis, days from diagnosis to referral, and days from referral to repair were recorded. Preoperative radiologic imaging and interventions were retrieved for comparison. Imaging and interventions that occurred at the referring hospital were also included in the analysis. Geographic location and distance from the referring hospital were recorded to track changes in referral pattern over time. Geographic distance and timing of surgical repair categories were used as previously described (Chapter 2: Methods). Thirty-day postoperative complications were according to the MAGS.¹⁹⁰ Long-term outcome was defined using the recently proposed definition of patency after surgical repair of BDI.¹⁰⁹ Length of follow-up was calculated as the time from surgical repair to last patient contact with the healthcare system. Follow-up at locations other than the HPB unit was included for patients referred from geographically distant hospitals.

4.2.3 Statistical analysis

All continuous variables were non-parametric in distribution and are presented as median, range and IQR. Categorical data are given as number and percent. The Mann–Whitney U test was used for continuous variables and Fisher’s exact test for categorical variables. A p-value < 0.05 was considered significant. Data analysis was performed in SPSS Statistics for MacIntosh, Version 25.0 (IBM SPSS Statistics, IBM Corporation, Armonk, NY).

4.3 Results

4.3.1 Patient characteristics, the classification of bile duct injury and preoperative interventions

Of a total of 200 patients referred to our centre from 1991 to 2017, 125 patients who underwent HJ repair for BDI were assessed (Figure 4.1). Thirty-two patients underwent repair in the earlier half of the study and 93 in the latter half. Results of a comparison of patient characteristics, classification of BDI and preoperative interventions between patients in the two time periods are shown in Table 4.1. In both time periods the majority of patients

were female with a median age of 46 (range 22-73) years in the earlier group and 45 (range 18-80) years in the latter study group. There was no difference in the type of BDI by the Strasberg classification or in the prevalence of concomitant vascular injury ($p = 0.615$, $p = 0.114$). There was a statistically significant increase in the use of preoperative PTBCs as well as CE-CT, MRI/MRCP and ultrasound during the second time period.

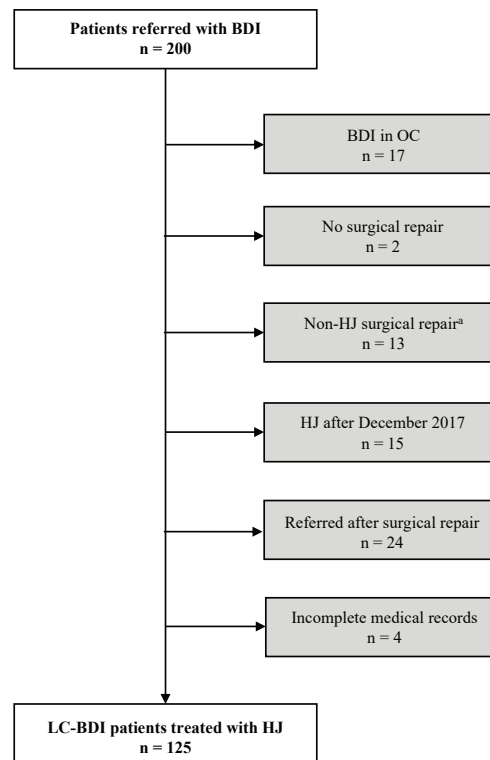


Figure 4.1. Flow diagram of all patients referred to the HPB unit for management of a bile duct injury from 1991 to 2017. Patients were included in the study only if they had a LC-BDI and underwent the index HJ in the HPB unit.

^aNon-HJ surgical repairs included direct suture repair of the bile duct or a direct bile duct repair over a t-tube

BDI – bile duct injury, HJ – hepaticojejunostomy, LC – laparoscopic cholecystectomy, OC – open cholecystectomy

Original source: Lindemann J, Jonas E, Kotze U, Krige JEJ. Evolution of bile duct repair in a low and middle-income country (LMIC): A comparison of diagnosis, referral, management and outcomes in repair of bile duct injury after laparoscopic cholecystectomy from 1991 to 2004 and 2005-2017. HPB (Oxford). 2020;22(3):391-397. DOI: <https://doi.org/10.1016/j.hpb.2019.07.009> and reproduced according to the CC-BY-NC-ND license.

Table 4.1. Patient and clinical characteristics for patients who underwent surgical repair of bile duct injury from 1991 to 2004 compared to 2005 to 2017.

Characteristic	1991-2004 n = 32 (%) or median (range); (IQR)	2005-2017 n = 93 (%) or median (range); (IQR)	p-value
Age, years	46 (22-73); (38.5-53.5) ^a	45 (18-80); (36.0-56.0)	0.817
Sex, female	24 (75.0)	80 (86.0)	0.174
Strasberg classification			
E1	5 (15.6)	9 (9.7)	0.347
E2	18 (56.3)	48 (51.6)	0.686
E3	4 (12.5)	22 (23.7)	0.215
E4	3 (9.4)	10 (10.8)	1.000
E5	2 (6.3)	4 (4.3)	0.645
Vascular injury	1 (3.1)	13 (14.0)	0.114
Preoperative investigations and interventions			
ERC	20 (62.5)	45 (48.4)	0.219
PTBC	17 (53.1)	78 (83.9)	0.001
Percutaneous Drain	7 (21.9)	17 (18.3)	0.795
Laparotomy	7 (21.9)	32 (34.4)	0.269
Laparoscopy	2 (6.3)	4 (4.3)	0.645
MRI/MRCP	7 (21.9)	46 (49.5)	0.007
CE-CT	3 (9.4)	43 (46.2)	<0.001
Ultrasound	7 (21.9)	23 (24.7)	0.004

^aOne patient with unknown age

CE-CT – contrast-enhanced computed tomography, IQR – interquartile range, ERC – endoscopic retrograde cholangiography, MRI/MRCP – magnetic resonance imaging/magnetic resonance cholangiopancreatography, PTBC – percutaneous transhepatic biliary catheter

4.3.2 Referral pattern from 1991 to 2004 and 2005 to 2017

The distribution of referrals from 1991 to 2004 and from 2005 to 2017 is demonstrated in Figure 4.2. In the earlier time period, 28.1% of patients were referred from hospitals located further than 500 km away from the tertiary referral centre compared to 40.9% of patients in the later time period. The 46.5% increase in geographically distant referrals was not statistically significant ($p = 0.214$), nor was the distribution of referrals across the four geographic distance categories ($p = 0.632$). The greatest increase in referrals during the 2005 to 2017 time period came from the Eastern Cape Province. Although the total number of referrals from within 100 km of the tertiary referral centre increased, the proportion of local

referrals decreased from 56.3% in the 1991 to 2004 time period to 43.0% in the latter time period.

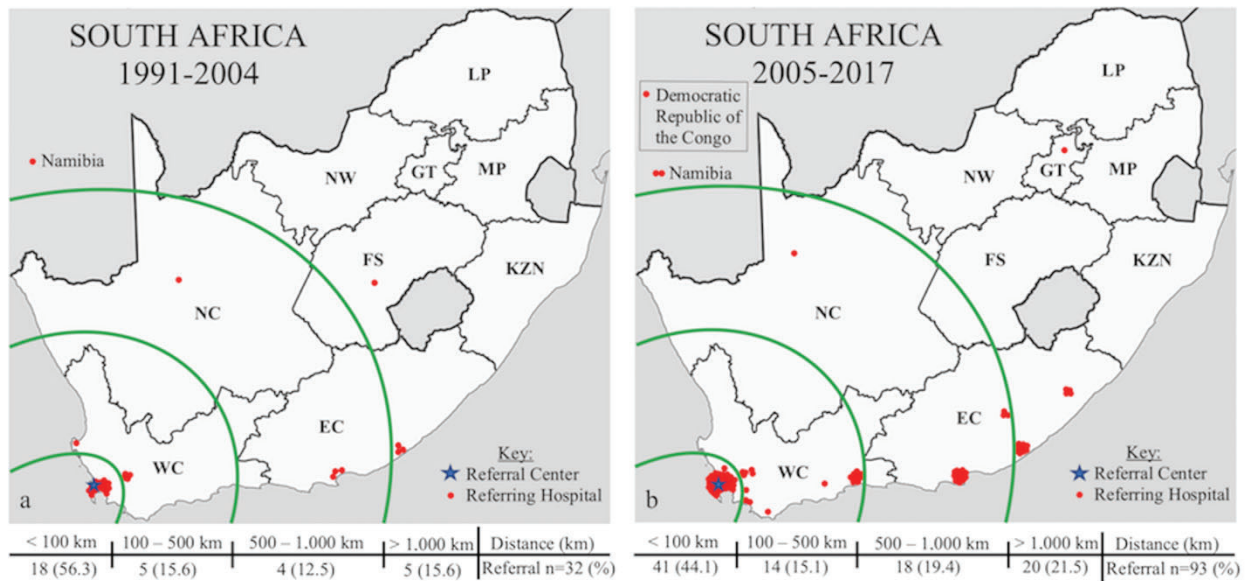


Figure 4.2. Referral pattern for surgical repair of bile duct injury from 1991 to 2004 compared to 2005 to 2017. Each dot represents a single patient and is placed at the approximate location of the referring hospital. **Figure 4.2a** shows the distribution of referrals for the earlier half of the study (1991 to 2004). Nine (28.1%) patients were referred from a distance greater than 500 km from the tertiary referral centre. **Figure 4.2b** shows the distribution of referrals for the latter half of the study (2005 to 2017). Thirty-eight (40.9%) patients were referred from a distance greater than 500 km from the tertiary referral centre, a 45.6% increase over geographically distant referrals in the first half of the study.

EC – Eastern Cape Province, FS – Free State Province, GT - Gauteng Province, KZN – KwaZulu-Natal Province, LP – Limpopo Province, MP – Mpumalanga Province, NC – Northern Cape Province, NW – Northwest Province, WC – Western Cape Province

The maps in this figure were originally created by Adrian Frith (2010) and were used with modifications under the Creative Commons License (CC-BY-SA) in the publication: Lindemann J, Jonas E, Kotze U, Krige JEJ. Evolution of bile duct repair in a low and middle-income country (LMIC): A comparison of diagnosis, referral, management and outcomes in repair of bile duct injury after laparoscopic cholecystectomy from 1991 to 2004 and 2005-2017. HPB (Oxford). 2020;22(3):391-397. DOI: <https://doi.org/10.1016/j.hpb.2019.07.009> and reproduced here according to the CC-BY-NC-ND license.

4.3.3 Comparison of days to diagnosis, referral and repair

The number of days from LC to time of diagnosis of BDI, referral and repair for patients treated during the two time periods are shown in Figure 4.3. While there was no difference in the time from LC to diagnosis between the two time periods (median 5 (0-91) vs 3 (0-156) days for early and late, respectively), there was a statistically significant increase in the time from diagnosis to referral (median 1.5 (0-174) vs 6 (0-258 days) and from referral to repair

(2.5 (0-76) vs 8 (0-583) days) in the second time period. When the timing of repair was compared, there was no difference in the distribution of patients across the five timing of repair groups between the earlier and the later time periods (Figure 4.4, $p = 0.207$). There were more early repairs of geographically distant referrals in the latter half of the study (0% vs 26.1%) and although not statistically significant, the proportion of intermediate and late repairs for geographically distant referrals decreased in the latter half of the study.

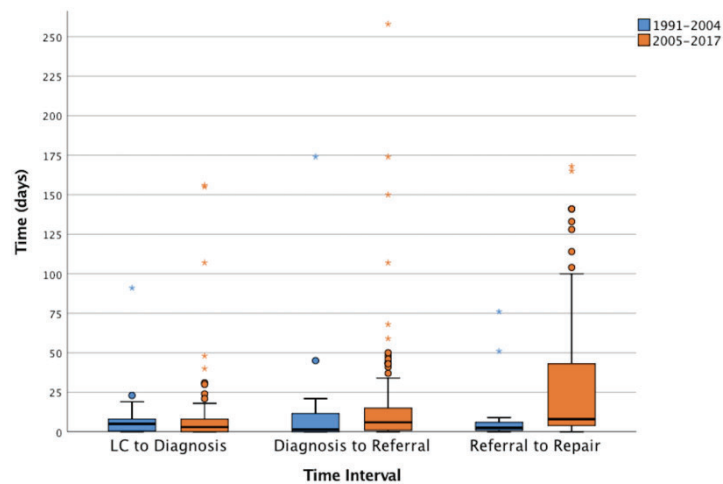


Figure 4.3. Days from laparoscopic cholecystectomy to diagnosis, diagnosis to referral and referral to repair for patients who underwent surgical repair of a major bile duct injury in the HPB unit from 1991 to 2004 compared to 2005 to 2017. A circle represents days to diagnosis, referral or repair that are greater than 1.5 times outside the third quartile. An asterisk represents days to diagnosis, referral or repair that are greater than 3 times outside the third quartile. The Mann–Whitney U test was performed to compare differences in distribution of days from LC to diagnosis ($p = 0.443$), diagnosis to referral ($p = 0.031$) and referral to repair ($p < 0.001$) between the earlier and later time periods. Two outliers are not represented, one 454 and one 583 days from referral to repair.

LC – laparoscopic cholecystectomy

Original source: Lindemann J, Jonas E, Kotze U, Krige JEJ. Evolution of bile duct repair in a low and middle-income country (LMIC): A comparison of diagnosis, referral, management and outcomes in repair of bile duct injury after laparoscopic cholecystectomy from 1991 to 2004 and 2005-2017. HPB (Oxford). 2020;22(3):391-397. DOI: <https://doi.org/10.1016/j.hpb.2019.07.009> and reproduced according to the CC-BY-NC-ND license.

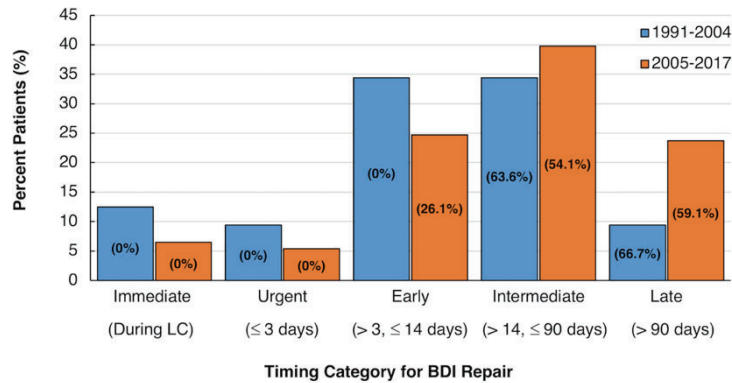


Figure 4.4. Comparison of the distribution of patients across the five timing of repair categories between the earlier (1991 to 2004) and later (2005 to 2017) time periods. The value in parentheses within the bars indicates the proportion of patients in each timing of repair category who were referred from a distance greater than 500 km from the referral centre. There was no statistically significant difference between the two time periods in distribution of patients across the five timing of repair categories ($p = 0.207$) or in the proportion of patients referred from greater than 500 km in the intermediate and late repair groups ($p = 0.514$ and $p = 1.000$, respectively).

BDI – bile duct injury, LC – laparoscopic cholecystectomy

Original source: Lindemann J, Jonas E, Kotze U, Krige JEJ. Evolution of bile duct repair in a low and middle-income country (LMIC): A comparison of diagnosis, referral, management and outcomes in repair of bile duct injury after laparoscopic cholecystectomy from 1991 to 2004 and 2005-2017. HPB (Oxford). 2020;22(3):391-397. DOI: <https://doi.org/10.1016/j.hpb.2019.07.009> and reproduced according to the CC-BY-NC-ND license.

4.3.4 Follow-up, postoperative short- and long-term complications

Results of a comparison of follow-up, 30-day postoperative complications and long-term outcomes between the earlier and later time periods are shown in Table 4.2. The median length of follow-up was similar between the two time periods. There was a statistically significant difference in the prevalence of 30-day postoperative complications ($p = 0.041$) with a significant decrease in severe complications among patients with BDIs repaired in the latter half of the study ($p=0.022$). The need for postoperative percutaneous and surgical re-interventions were similar between the two groups ($p = 0.645$, $p = 0.602$) resulting in comparable primary and secondary patency rates ($p = 0.094$, $p = 0.202$).

Table 4.2. Comparison of the distribution of 30-day complications and long-term outcomes after surgical repair between the earlier (1991 to 2004) and later (2005 to 2017) time periods.

Variable	1991-2004 n = 32 (%) or median (range); (IQR)	2005-2017 n = 93 (%) or median (range); (IQR)	p-value
MAGS			
Mild	5 (15.6)	7 (7.5)	0.183
Moderate	6 (18.8)	36 (38.7)	0.130
Severe	7 (21.9)	8 (8.6)	0.022
Death ^a	0	0	-
Long-term outcome			
Percutaneous Re-intervention	2 (6.3)	4 (4.3)	0.645
Surgical Re-intervention	2 (6.3)	3 (3.2)	0.602
	n = 32	n = 93	
Primary Patency	26 (81.3)	86 (92.5)	0.094
	n = 4	n = 7	
Secondary Patency	4 (100.0) ^b	4 (57.1)	0.202
Median follow-up, months	17.3 (0.2-225.6); (1.2-144)	13.9 (0.2-146.5); (3.7-36.9)	0.348

^aThirty-day mortality was zero with two mortalities at 90 days, both occurred in the 1991 to 2004 time period

^bTwo patients that died before 90 days were not included in secondary patency calculation

IQR – interquartile range, MAGS – Modified Accordion Grading System

4.4 Discussion

This analysis investigated the change in referral pattern, management and postoperative outcomes after surgical repair of major BDIs in patients treated over a 27 year period in the HPB unit at a tertiary referral centre in South Africa. The number of referrals for management of major BDI nearly tripled in the latter half of the study compared to the earlier time period. Several important changes regarding LC occurred in the early 2000's which underpin the rationale for dividing the cohort of patients into two time periods from 1991 to 2004 and from 2005 to 2017.

Population-based studies from Europe, the USA and Australia have shown that the proportion of LCs performed annually increased dramatically in the first 10 years after it was introduced.^{32,39,208,209} Interestingly, in these studies the number of LCs continued to rise, significantly increasing the total number of cholecystectomies performed annually beyond OC rates in the pre-LC era.²⁰⁸ While this trend occurred in South Africa as well, it lagged

behind Europe and the USA as it was only in the early 2000's that endoscopic treatment, including LC, was disseminated to peripheral hospitals, a phenomenon that likely occurred in most LMICs. This may have contributed to the substantial increase in referrals observed in the latter half of the study.

There has also been a shift from only experienced senior surgeons performing LC to trainees performing the procedure early in their training, a trend that occurred in South Africa as well.²¹⁰ However, LMICs are unique in the way laparoscopic technology was introduced. Unlike the USA and Europe, where access became universally available relatively quickly, in South Africa there are isolated and under-resourced areas that lagged in obtaining laparoscopic equipment and providing surgeons with laparoscopic skills. These trends add to the complexity of understanding the evolution of BDIs in South Africa, a consideration that may be applicable to other LMICs.

The HPB unit is located in a large metropole and serves as a major referral centre for BDIs, not only for the immediate area, but also for hospitals as far away as 2,000 km. Distances in South Africa are vast with sparse populations in rural areas and often without local surgical expertise. In this study, the number of geographically distant referrals has increased in the last 15 years, contributing to the rise in BDIs treated in the HPB unit. This pattern of referral is consistent with the realization that BDIs have better outcomes when treated at high volume centres which offer multidisciplinary care that includes specialized HPB surgeons, interventional radiologists and endoscopists.⁸³

In this analysis the marked increase in the number of delayed geographically distant referrals required a change in treatment practice in the second half of the study that resulted in an increase in intermediate and late repairs which is contrary to international trends.¹⁰⁸ Additionally, it was local policy to travel to the referring hospital for intraoperative consultations, whenever it was logistically and geographically feasible. However, this practice was stopped in the latter time period as the operative situation was often found to be suboptimal for performing a repair. This change explains, in part, the decrease in the number of immediate repairs performed in the latter half of the study.

Despite more patients being referred from geographically distant locations and a statistically significant increase in time to referral and repair, there was a statistically significant decrease

in severe complications during the latter half of the study. Although there are likely other unmeasured influencing factors, these findings support the general approach in the HPB unit to make every effort to achieve a repair as early as is feasible, accepting that preoperative optimization of these often severely ill patients may delay repair. The financial implications of a LC-BDI have been highlighted in previous studies and make a further compelling argument for avoiding unnecessary delay and performing repair as early as possible and appropriate.^{134,135} This is particularly important in LMICs, where the financial burdens associated with a BDI are exacerbated by high unemployment and a lack of social security networks, especially when a single breadwinner for an extended family is involved.

This analysis has several limitations that should be considered. The data presented are from a tertiary referral centre and are not population-based with a defined denominator. In addition, there are no previous reports on the annual frequency of LC or incidence of BDI for South Africa to provide context for the increase in BDI referrals during the study period. Patients were included in the analysis only if they had undergone a HJ repair of a LC-BDI. This resulted in a more homogenous cohort of patients at the cost of excluding patients referred and treated by endoscopic methods only. Comparison data for BDI repair at local hospitals is not available, however, the findings of this study suggest that patients cared for at a tertiary referral centre with a specialized HPB unit have good outcomes regardless of the multifactorial influences causing delays in referral and repair. The strengths of this analysis are the prospective design, the large cohort of patients and the standardized surgical repair used in an exclusively LC-BDI patient cohort from a MIC.

In conclusion, there is a paucity of literature on the management of LC-BDIs from LMICs, where nearly 90% of the world's population live. Importantly, this analysis shows that the number of geographically distant referrals have increased in a country where most patients face significant socioeconomic challenges and difficulties accessing healthcare. The study also highlights interesting and unique trends over time in presentation and management of patients with LC-BDIs, that are the result of changing referral patterns that necessitated adjustments in management over the study period. The findings reported in this analysis provide context for future studies regarding the way management of LC-BDIs has evolved over time.

5.1 Rationale

In the previous chapter, the evolution of the management of BDIs over time for an HPB unit in a MIC was presented. The following chapters will examine in detail specific factors that may influence patient outcome after LC-BDI in the South African healthcare system context. The current chapter focuses on the effect geographic distance from the referral centre has on the timing of repair and patient outcome after LC-BDI.

There is considerable debate in the literature on the optimal timing of surgical repair of a BDI. This is in part due to the complexity of decision making that must take into account multiple factors. Generally, sepsis and biliary peritonitis require immediate intervention with percutaneous drainage, and laparoscopy or laparotomy and drainage for source control, followed by a delayed surgical repair.^{82,99,211} Factors such as the timing of the diagnosis of BDI as well as the presence of a concurrent vascular injury also influence the decision of when to operate.^{70,100} If recognized at the time of LC, immediate HJ is often pursued.¹⁰² However, previous studies reported better outcomes for a repair performed later than six weeks after BDI^{106,116} Others have shown that early repair of BDI results in similar postoperative outcomes with the benefit of decreased healthcare costs and improved quality of life.^{77,136} Additional evidence suggests that a repair in the intermediate period results in worse outcomes.^{104,108,120}

LMICs face unique challenges including delays in seeking care, long geographic distances to reach care, and over-burdened and inadequately funded healthcare systems. This often results in delays in provision of care and subsequently delays diagnosis and referral, which could have a significant effect on patient outcome after surgical repair of BDIs. In a previously published study on outcomes after LC in South Africa, 167 patients underwent LC at a public sector secondary level hospital over an 18-month period with a BDI rate of 1.5%.³⁸

Importantly, compared to higher income countries, patients in the study were much more likely to undergo a delayed cholecystectomy for acute cholecystitis due to late presentation to the hospital and limitations within the healthcare system including limited operating time, delays in obtaining preoperative investigations, a lack of access to IOC and no on-site ERC

capabilities.³⁸ The limitations in access to diagnostic tests, interventional procedures and surgery are similarly experienced by LC-BDI patients.

Although LC is widely available in South Africa, the effects of limited resources and geographic distance from referral centre on surgical management and patient outcome after BDI are unknown. As a regional referral centre for patients with BDI after LC with a catchment area of over 2,000 kilometres, the HPB Unit at GSH is an ideal location for investigating the relationship between the geographic distance from the referral centre, delays in referral, and patient outcome after surgical repair of BDI in a MIC healthcare system context. The aim of this analysis is to assess the influence of geographic distance from referral centre on the time to diagnosis, referral and surgical repair, and determine how time delays may affect outcomes after surgical repair of LC-BDIs.

5.2 Methods

5.2.1 Study design and patient characteristics

All patients in the prospectively maintained BDI database who received a HJ repair for a LC-BDI from January 1991 through December 2019 were included. Follow-up data were retrieved through 31 March 2020 to allow for a complete 90-day follow-up post-repair. Patient characteristics, including age, sex, comorbidities and Strasberg type of BDI were analysed. The date of LC, BDI diagnosis, admission to referral centre and surgical repair were recorded. All surgical and nonsurgical complications, re-admissions and mortality up to 90 days were also extracted from the database for analysis.

5.2.2 Study definitions

The geographic distance from referral centre was estimated as the fastest route by car using Google Maps²¹² between the referral hospital and GSH. Distances were rounded to the nearest km and the geographic distance from referral centre categories were used according to the definitions in Chapter 2: Methods. The timing of repair was divided into immediate, urgent, early, intermediate and late as described in Chapter 2: Methods. The contribution of time to diagnosis, referral and repair were assessed separately for each timing of repair category. Morbidity at 90 days was recorded using the MAGS classification system (see Chapter 2: Methods).

5.2.3 Statistical analysis

All continuous variables were non-parametric in distribution and are presented as median, IQR and range. Categorical data are given as number and percent. The Mann–Whitney U test was used for continuous variables and Fisher’s exact test was used for categorical variables. The chi squared (X^2) test and the linear-by-linear statistic were used to determine whether there was an association between geographic distance from referral centre and timing of referral and BDI repair. A p-value < 0.05 was considered significant. Data analysis was performed in SPSS Statistics for MacIntosh, Version 25.0 (IBM SPSS Statistics, IBM Corporation, Armonk, NY).

5.3 Results

5.3.1 Patient characteristics

A summary of the characteristics of the 142 patients who underwent surgical repair for a LC-BDI from 1991 to 2019 is shown in Table 5.1. The median age was 45 (17–80) years and 81% of patients were female. The most commonly reported comorbidity was hypertension (24%) followed by diabetes mellitus (12%), while 68 patients (48%) had no comorbidities. For the 71 patients with a body mass index (BMI) recorded, BMI ranged from 19.1 to 52.7 with a median BMI of 30.1. Most patients presented with a Strasberg type E2 injury (53%), followed by type E3 (20%). There was one patient with a type C injury to the right posterior sectoral duct who required a HJ repair. The most common symptom at the time of referral was a bile leak (68%) and more than three-quarters of patients presented with liver function abnormalities (n = 110, 78%). There were 11 immediate (8%), 12 urgent (9%), 37 early (26%), 56 intermediate (39%) and 26 late (18%) repairs. Just under half of all patients were referred from a hospital located less than 100 km away (n = 70, 49%), while 40% of patients were referred from hospitals greater than 500 km from the referral centre.

Table 5.1. Characteristics of patients who underwent hepaticojejunostomy repair for laparoscopic cholecystectomy bile duct injury.

Variable	Patients, n = 142 (%) or median (range); (IQR)
Age, years ^a	45 (17–80); (36–56)
Sex, female	115 (81.0)
Comorbidities^b	
None	68 (47.9)
Diabetes mellitus	17 (12.0)
Hypertension	34 (23.9)
COPD/Asthma	11 (7.7)
Ischaemic heart disease	13 (9.2)
Smoking history	14 (9.9)
GORD	3 (2.1)
HIV	2 (1.4)
Depression	2 (1.4)
History of cancer	3 (2.1)
Other ^c	13 (9.2)
BMI ^d	30.1 (19.1–52.7); (26.9–34.8)
Strasberg Level of BDI	
C	1 (0.7)
E1	16 (11.3)
E2	75 (52.8)
E3	29 (20.4)
E4	20 (14.1)
E5	1 (0.7)
Signs and Symptoms at referral^e	
Bile leak	96 (67.6)
Cholangitis/sepsis	17 (12.0)
Jaundice	52 (36.6)
Pruritus	6 (4.2)
Liver function derangement	110 (77.5)
Concurrent vascular injury	3 (2.1)
Abdominal Pain	44 (31.0)
Other ^c	6 (4.2)
Timing of Repair Categories	
Immediate (at LC)	11 (7.7)
Urgent (\leq 72 hrs)	12 (8.5)
Early ($>$ 72 hrs, \leq 14 days)	37 (26.1)
Intermediate ($>$ 14, \leq 90 days)	56 (39.4)
Late ($>$ 90 days)	26 (18.3)
Geographic Distance Categories	
$<$ 100 km	70 (49.3)
\geq 100, $<$ 500 km	21 (14.8)
\geq 500 km	51 (39.5)

^aOne patient with missing age

^bPatients may have reported multiple comorbidities or had multiple signs and symptoms

^cHyperlipidaemia, migraine headache, eczema, congenital adrenal hyperplasia, vascular disease, hypothyroidism, atrial fibrillation, sarcoidosis, polycystic ovarian syndrome, Madelung's deformity and endometriosis (n = 1), and osteoarthritis (n = 2)

^d71 patients with BMI reported

^eBile peritonitis, intra-abdominal bleeding, loss of weight, loss of appetite and emesis (n = 1)

BMI – body mass index, COPD – chronic obstructive pulmonary disease, GORD – gastro-oesophageal reflux disease, HIV – human immunodeficiency virus, IQR – interquartile range, LC – laparoscopic cholecystectomy

5.3.2 Days to diagnosis, referral and repair

The number of days from injury to diagnosis, diagnosis to referral, referral to repair and total days from injury to repair are shown in the box and whisker plot in Figure 5.1. For the immediate repair category, per definition, the BDI diagnosis, referral and repair all occurred on the same day as the LC. Each of the three time periods including the time from injury to diagnosis, time from diagnosis to referral and time from referral to repair, progressively increased in duration for the urgent through the late timing of repair categories. This lengthening of time intervals occurred in a stepwise fashion with the exception of the time from injury to diagnosis for the early repair category and the diagnosis to referral in the intermediate repair category. In the early timing of repair category, the median time from the injury to the diagnosis was longer than the median time from the diagnosis to referral. Similarly, for the intermediate time of repair category, the median time from diagnosis to referral was longer than the median time from referral to repair.

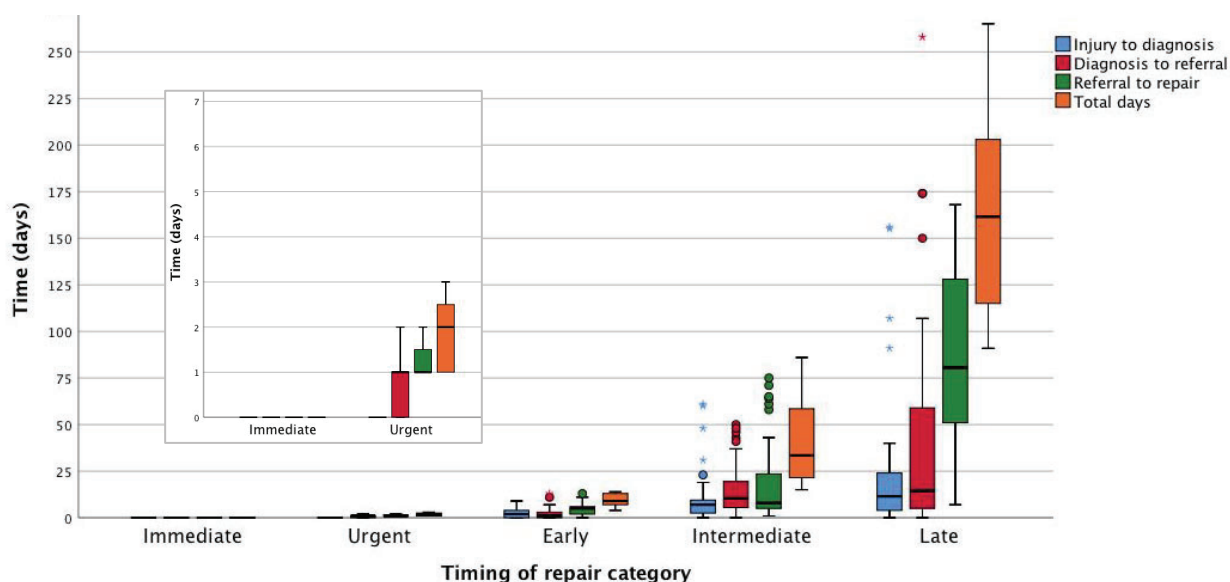


Figure 5.1. Box and whisker plot for time in days from injury to diagnosis, diagnosis to referral, referral to repair and the total time from laparoscopic cholecystectomy to repair for immediate, urgent, early, intermediate and late timing repair groups. A more detailed view of the first seven days for the immediate and urgent timing of repair categories is shown as an inset in the bottom left of the figure to better display the data. A circle represents days to diagnosis, referral or repair that are greater than 1.5 times outside the third quartile. An asterisk represents days to diagnosis, referral or repair that are greater than 3 times outside the third quartile. There are two patients with data not shown, one with 454 days from referral to repair and 457 total days from LC to repair, and another patient with 583 days from referral to repair and 486 total days from LC to repair.

5.3.3 Association between geographic distance and timing of repair

The correlation between geographic distance from referral centre in km and time to diagnosis, referral and repair in days, are displayed as dot plots in Figure 5.2. For all three time periods, there was poor linear correlation between geographic distance and timing of repair with R^2 values below 0.5, therefore correlation statistics were not performed. The proportion of patients in each timing of repair category who were referred from < 100 km, 100-500 km and > 500 km from the referral centre is shown in the bubble chart in Figure 5.3. The relative proportion of patients referred from nearby geographic locations (< 100 km) decreased as the time from injury to repair increased, with the greatest proportion of local referrals occurring in the immediate repair category and the greatest proportion of geographically distant referrals occurring in the late repair category. There was a statistically significant association between the timing of repair and geographic distance from the referral centre ($p < 0.001$) as well as a statistically significant linear-by-linear association ($p < 0.001$) indicating that as geographic distance from referral centre increased, the time to repair also increased.

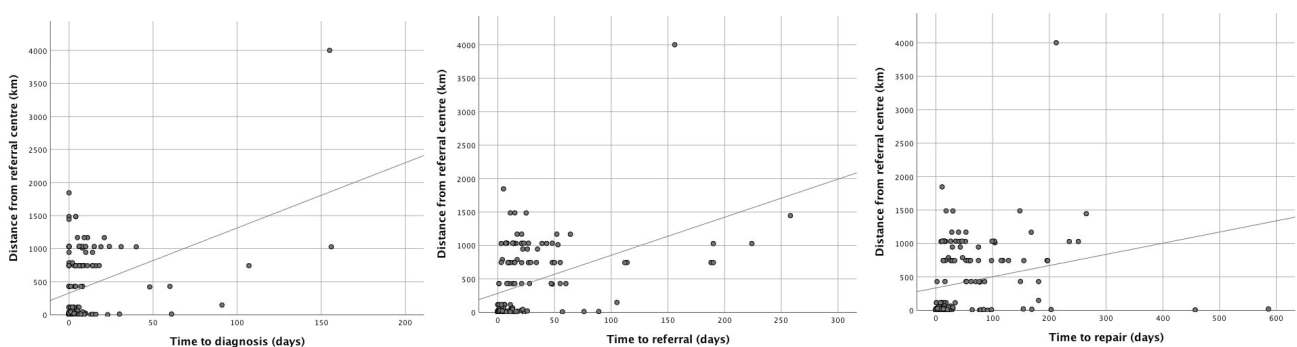


Figure 5.2. Correlation between geographic distance from referral centre (km) and days to diagnosis (left), referral (middle) and repair (right). For all three time periods, there was an insufficient linear relationship to proceed with linear correlation statistics with R^2 values of 0.166, 0.201 and 0.061 for time to diagnosis, referral and repair, respectively.

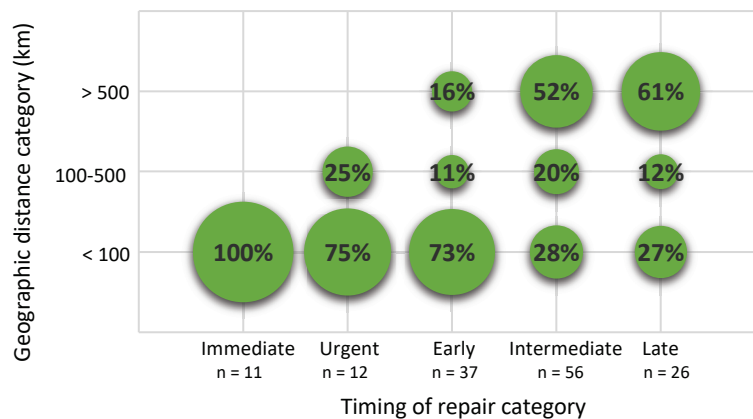


Figure 5.3. Proportion of patients referred from < 100 km, 100–500 km and > 500 km from the referral centre for the five timing of repair categories. The association between the geographic distance and the timing of repair variables was statistically significant using the X^2 test ($p < 0.001$). There was also a statistically significant linear-by-linear association ($p < 0.001$).

5.3.4 Ninety-day postoperative outcomes

The 90-day postoperative outcomes according to the MAGS are shown in Table 5.2. Seventy-five (53%) patients had at least one complication, most of which were mild to moderate in severity. The immediate repair category had the greatest proportion of patients with complications, while the intermediate repair category had the lowest proportion among the five timing of repair categories. Both mortalities occurred in patients who were repaired within 72 hours of the injury. The first was a 73-year-old male with multiple comorbidities who had a portal vein injury during LC, which resulted in conversion to laparotomy for control of bleeding. After an urgent transfer to the HPB unit he underwent HJ repair on the day following the injury during which a right hepatic artery injury was identified. A relook laparotomy was performed on day 6 for a bile collection. He developed intractable sepsis and died 65 days after HJ repair of multi-organ failure. The second patient was a 50-year-old male who underwent immediate HJ repair at the time of LC and was discharged on postoperative day 5 with no complications. He presented on postoperative day 48 with septic shock. At emergency laparotomy the anastomosis was intact and patent, but a large liver abscess was found and drained. Postoperatively he remained unstable and died 24 hours later from overwhelming sepsis.

Table 5.2. Ninety-day postoperative outcomes using the expanded and contracted forms of the Modified Accordion Grading System for patients with bile duct injury requiring surgical repair.

Timing of repair category	Modified Accordion Grading System, n = 142 (%)						Total
	Mild (1)	Moderate (2)	Severe			Death (6)	
			(3)	(4)	(5)		
Immediate n = 11 (7.7)	1 (9.1)	2 (18.2)	1 (9.1)	2 (18.2)	-	1 (9.1)	7 (63.6)
Urgent n = 12 (8.5)	2 (16.7)	3 (25.0)	-	1 (8.3)	-	1 (8.3)	7 (58.3)
Early n = 37 (26.1)	4 (10.8)	14 (37.8)	-	2 (5.4)	-	-	20 (54.1)
Intermediate n = 56 (39.4)	2 (3.6)	19 (33.9)	6 (10.7)	-	1 (1.8)	-	27 (48.2)
Late n = 26 (18.3)	1 (3.8)	9 (34.6)	4 (15.4)	-	-	-	14 (53.8)
Entire cohort n = 142	10 (7.0)	47 (33.1)	11 (7.7)	4 (2.8)	1 (0.7)	2 (1.4)	75 (52.8)

5.4 Discussion

The patients in this analysis encompassed all patients included in the previous chapter in addition to the two most recent years of LC-BDI referrals (2018 to 2019). This study identified a statistically significant association between the geographic distance from referral centre and the timing of surgical repair after LC-BDI, although a linear correlation was not demonstrated. A stepwise increase in the lengths of time from injury to diagnosis, diagnosis to referral and referral to repair was shown across the five timing of repair categories. There was also a trend toward less severe complications for a later repair, with increased complications and mortality for repairs performed within 72 hours of the injury. Whereas in the previous chapter changing trends in management over two time periods were assessed in the context of shifting referral patterns, this chapter considered all patients over a single study period, with an emphasis on the geographic distance from the referral centre. The focus was specifically on the relationship between the geographic distance from the referral centre and the timing of diagnosis, referral, and repair, and whether timing of repair influenced patient outcomes.

The category of geographic distance from referral centre was strongly associated with the timing of repair category. This statistically significant finding suggests that as geographic distance from referral centre increases, the time to repair also increases. When the individual time periods of time from injury to diagnosis, diagnosis to referral and referral to repair were examined across the five timing of repair categories, a stepwise lengthening of the time periods was observed. This suggests that a delay in diagnosis results in a greater delay in

referral which translates into an even longer delay in the time from referral to repair. Disparity in delays to referral were identified in a recently published study comparing outcomes of patients with BDIs treated in a HIC versus a MIC.²¹³ More than half (52%) of patients treated in a HIC were referred to an HPB specialist within 72 hours of the injury, while less than 1% of patients treated in MICs were referred within the same time period.²¹³ Furthermore, 53% of patients in MICs were referred at least 6 weeks after the injury compared to only 9% of patients treated in a HIC.²¹³ The results of the current study are comparable to the reported MIC findings.

The stepwise increase in time to diagnosis, referral and repair is likely the result of a variety of contributing factors that are not possible to elucidate with the currently available data. However, the study published by Mbatha et al. highlights factors within the South African healthcare system context that potentially may have contributed to the delays observed in this study, including late presentation to hospital, limited access to diagnostic tests and interventional procedures and limited theatre time.³⁸ Additional contributing factors may include limited access to specialist HPB surgeons, which often requires transport across vast distances. Arranging transport is logistically challenging and can also contribute to delays. The pattern of increasing length of time across all three time intervals supports the conclusion of multifactorial contributions to delays. For example, the data in this study do not suggest that a late repair is due solely to surgeon decision making, as lengthy delays in diagnosis and referral also substantially contributed to a repair beyond 90 days.

Importantly, there were less severe complications in the late timing of repair category and the intermediate repair category had the lowest proportion of complications overall. The only mortalities in this series occurred in patients who were repaired within 72 hours of injury and the immediate and urgent timing of repair categories had the largest and second largest proportion of complications, respectively. This suggests that perhaps some of the negative effects of a delayed diagnosis and referral may be overcome by performing a later repair in the context of limitations inherent to LMIC healthcare systems. The 53% complication rate in this series is higher than previously reported overall complication rates from other LMICs.¹⁰⁴ However, in the study by Rueda-de-Leone et al. published in 2020, the complication rate for patients treated in a MIC was 56%, comparable with the current study.²¹³ The variation in reported complication rates may be due to a lack of standardized reporting. Both the Rueda-

de-Leone and the current study used the MAGS to systematically report all complications of patients undergoing surgical repair for BDI.

In conclusion, geographic distance from the referral centre was significantly associated with the timing of LC-BDI repair. The delays in referral observed in this study were similar to those recently reported in another MIC. Delays in diagnosis, referral and repair increased in a stepwise manner, implying that the timing of bile duct repair is influenced by many factors beyond the control of the surgeon. A later repair resulted in less severe complications and a lower overall rate of complications in a MIC healthcare system context.

6.1 Rationale

In South Africa, patients access the healthcare system via two financially disproportionate sectors. The public sector serves 84% of the population and receives less than half of the country's total health spending, while the private sector serves only 16% of the population, but comprises more than 50% of the country's total health spending.^{204,214} To receive treatment in the private healthcare sector, a patient either needs to have private medical insurance or have the means to pay out of pocket for the care received. This results in two different patient populations treated in the public compared to the private healthcare sector. In general, patients with a lower socioeconomic status utilize the public sector while patients with a higher socioeconomic status receive treatment in the private sector. Although difficult to definitively establish a causal relationship, socioeconomic status has been shown to be significantly associated with overall health, access to healthcare and life expectancy.²¹⁵⁻²²² In addition to limited access to healthcare due to high costs and a lack of insurance coverage,²²² patients with lower socioeconomic status have more chronic comorbidities,²¹⁸⁻²²¹ shorter life expectancy²¹⁷ and worse self-reported health^{215,216} compared to patients with a higher socioeconomic status. In South Africa in particular, patients with a lower socioeconomic status carry a higher burden of chronic infectious diseases such as HIV and tuberculosis.^{223,224}

LC is a commonly performed operation in both healthcare sectors in South Africa. The HPB service in the Surgical Gastroenterology Unit at GSH and the Digestive Diseases Centre, UCT Private Academic Hospital function as a single HPB unit, serving both the public and private sectors. Patients treated in the HPB unit for BDI in either healthcare sector are managed by the same multi-disciplinary team of HPB surgeons, endoscopists and interventional radiologists. This organizational structure provides the unique opportunity to objectively study how disparities in access to healthcare resources and different patient populations may influence the management and outcomes of patients with BDIs. This chapter specifically assesses the implications of diagnostic and referral delay and postoperative outcome in two cohorts of patients with LC-BDIs who were initially treated and then referred

³Lindemann J, Krige JEJ, Kotze U, Jonas E. Complex bile duct injuries after laparoscopic cholecystectomy: a comparative outcomes analysis of patients treated in tertiary private and public health facilities in Cape Town, South Africa. *S Afr J Surg.* 2019;57(3):24-29.

from either private or public healthcare facilities.

6.2 Methods

6.2.1 Study design

A retrospective review was performed of the prospectively maintained BDI database. Only patients who underwent a HJ repair of a major BDI after LC from January 1991 to 2017 were included. Relevant patient characteristics, preoperative investigations, type of injury defined according to the Strasberg classification, timing of diagnosis, referral and repair, geographic distance from referral centre and postoperative complications classified using the MAGS were retrieved.^{43,190} The timing of surgical repair was defined using the five timing of repair categories detailed in Chapter 2: Methods. Primary and secondary patency after BDI repair were applied using the recently proposed definitions (see Chapter 2: Methods).¹⁰⁹ Preoperative interventions and patient outcome were compared for patients referred from the public versus the private healthcare sectors.

6.2.2 Patient management

All preoperative investigations and interventions were recorded, including those performed at the referring hospitals prior to patient arrival at the referral centre. After arrival, patients completed a standard evaluation to fully assess the extent of the injury, as described in Chapter 2: Methods. A standard operative technique was used for bile duct reconstruction, the technical details of which were described in Chapter 2: Methods and have been published previously.⁸⁸

6.2.3 Statistical analysis

Non-parametric continuous data is presented as medians with ranges. Categorical data is given as numbers and percent. The Mann–Whitney U test was used for non-parametric continuous variables and Fisher’s exact test was used for categorical variables. A p-value < 0.05 was considered significant. Data analysis was performed in SPSS Statistics for MacIntosh, Version 25.0 (IBM SPSS Statistics, IBM Corporation, Armonk, NY).

6.3 Results

6.3.1 Patient demographic and clinical characteristics

Patient demographic and clinical characteristics are summarized in Table 6.1 and preoperative interventions are summarized in Table 6.2. There was a total of 125 patients

included in the study, 58 of which were referred from the public sector and 67 from the private sector. Nearly half of patients referred from the private sector came from a geographic distance greater than 500 km from the referral centre (n = 30, 44.1%) compared to 29.3% (n = 17) of patients referred from the public sector (p = 0.096). Nine patients migrated to the public sector because of financial constraints and four patients chose to transfer to the private sector for further management, resulting in 63 surgical repairs performed in the public sector and 62 in the private sector. There were nine patients in the public sector with a BDI after LC performed at GSH that were subsequently referred to the HPB unit for management. For all measured variables of patient and clinical characteristics, there were no differences between patients referred from the public versus the private healthcare sector (all p > 0.05). Patients referred to the HPB unit from the private sector were more likely to undergo PTBC placement prior to referral (11.9% vs 1.7%, p = 0.037). However, after admission to the HPB unit, patients referred from the public sector were more likely to undergo a CE-CT and ERC prior to repair (p = 0.044 and p = 0.038, respectively). When total preoperative investigations and interventions were compared between public and private referrals, CE-CT prior to repair was more common in public sector referrals (48.3% vs 29.9%, p = 0.043).

Table 6.1. Comparison of patient demographic and clinical characteristics between patients referred from the public versus the private healthcare sector.

Characteristic	Public referral n = 58 (%) or median (range); (IQR)	Private referral n = 67 (%) or median (range); (IQR)	p-value
Median age, years	43.5 (22-80); (33.8-56)	47 (18-78); (38.3-54) ^a	0.762
Sex, female	51 (87.9)	51 (76.1)	0.108
> 500 km from referral centre	17 (29.3)	30 (44.1)	0.096
Strasberg classification			
E1	8 (13.8)	6 (9.0)	0.411
E2	29 (50.0)	37 (55.2)	0.593
E3	13 (22.4)	13 (19.4)	0.826
E4	5 (8.6)	8 (11.9)	0.574
E5	3 (5.2)	3 (4.5)	1.000
Converted to OC	14 (24.1)	17 (25.4)	1.000

^aOne patient with unknown age

HPB – hepato-pancreato-biliary, IQR – interquartile range, OC – open cholecystectomy

Table 6.2. Preoperative investigations and interventions performed before and after referral from the public versus private sector.

Investigation or intervention	Before referral			After referral			Total		
	Public n = 58 (%)	Private n = 67 (%)	p-value	Public n = 58 (%)	Private n = 67 (%)	p-value	Public n = 58 (%)	Private n = 67 (%)	p-value
US	10 (17.2)	8 (11.9)	0.451	11 (19.0)	12 (17.9)	1.000	21 (36.2)	20 (29.9)	0.567
CE-CT	7 (12.1)	7 (10.4)	0.784	21 (36.2)	13 (19.4)	0.044	28 (48.3)	20 (29.9)	0.043
MRI/MRCP	4 (6.9)	11 (16.4)	0.166	20 (34.5)	20 (29.9)	0.701	24 (41.4)	31 (46.3)	0.594
ERC	16 (27.6)	18 (26.9)	1.000	19 (32.8)	11 (16.4)	0.038	35 (60.3)	29 (43.3)	0.073
PTC	1 (1.7)	8 (11.9)	0.037	40 (69.0)	46 (68.7)	1.000	41 (70.7)	54 (80.6)	0.214
Percutaneous drain	4 (6.9)	2 (3.0)	0.415	9 (15.5)	9 (13.4)	0.802	13 (22.4)	11 (16.4)	0.496
Laparoscopy	2 (3.4)	5 (7.5)	0.449	1 (1.7)	-	0.464	3 (5.2)	5 (7.5)	0.724
Laparotomy ^a	17 (29.3)	21 (31.3)	0.847	1 (1.7)	1 (1.5)	1.000	18 (31.0)	22 (32.8)	0.850

^aLaparotomy includes exploratory laparotomy for bile peritonitis or intra-abdominal sepsis only and does not include laparotomy for laparoscopic converted to open cholecystectomies.

CE-CT – contrast-enhanced computed tomography, ERC – endoscopic retrograde cholangiography, MRI/MRCP – magnetic resonance imaging/magnetic resonance cholangiopancreatography, PTC – percutaneous transhepatic cholangiogram, US – ultrasound,

6.3.2 Comparison of the timing of repair

When the days from LC to diagnosis, diagnosis to referral and referral to repair were compared between the two referral groups, there was no statistically significant difference in median days for any of the time periods (Figure 6.1). There was a median difference of 11 days in total time from LC to repair between the public and private referral groups, but this was not significant.

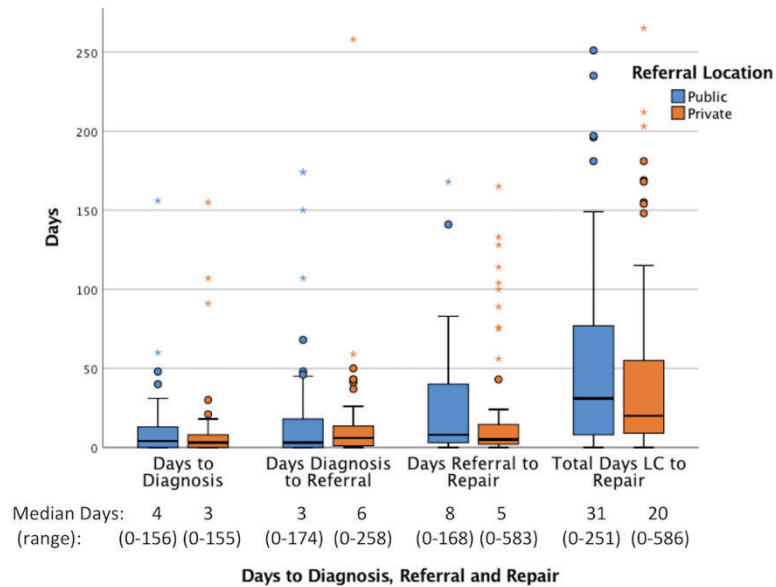


Figure 6.1. Comparison of median days to diagnosis, referral and repair for patients referred from the public versus the private healthcare sectors. A solid coloured circle represents days to diagnosis, referral or repair that are greater than 1.5 times the value of the third quartile. A coloured asterisk represents days to diagnosis, referral or repair that are greater than 3 times the value of the third quartile. There were no statistically significant differences in distribution of days from LC to diagnosis ($p = 0.262$), diagnosis to referral ($p = 0.301$), referral to repair ($p = 0.188$) and total days LC to repair ($p = 0.612$) between the public and private sector referral groups.

LC – laparoscopic cholecystectomy

Original source: Lindemann J, Krige J, Kotze U, Jonas E. Complex bile duct injuries after laparoscopic cholecystectomy: a comparative outcomes analysis of patients treated in tertiary private and public health facilities in Cape Town, South Africa. S Afr J Surg. 2019;57(3):24-29. Retrieved from: <http://sajs.redbricklibrary.com/index.php/sajs/article/view/3026> and reproduced according to the Creative Commons Attribution Non-commercial Works 4.0 South Africa license.

6.3.3 Short- and long-term postoperative outcomes

There was no statistically significant difference in 30-day postoperative complications between the public versus private healthcare sector referral groups (Table 6.3). Long-term outcome was assessed using primary and secondary patency rates, which were similar between public and private referrals (Table 6.4). Although secondary patency rates were lower in the group of patients referred from the private sector, this difference was not statistically significant ($p = 0.567$). There were no differences in need for postoperative percutaneous re-intervention or surgical revision between the two referral groups ($p = 0.724$ and $p = 1.000$, respectively, Table 6.4).

Table 6.3. Thirty-day postoperative complications using the Modified Accordion Grading System for patients referred from the public versus private sector.

Modified Accordion Grade	Public referral n = 58 (%)	Private referral n = 67 (%)	p-value
Mild	4 (6.9)	8 (11.9)	0.380
Moderate	20 (34.5)	21 (31.3)	0.849
Severe (3)	5 (8.6)	3 (4.5)	0.470
Severe (4)	3 (5.2)	2 (3.0)	0.662
Severe (5)	-	2 (3.0)	-
Total complications^a	32 (55.2)	36 (53.7)	0.205

^aNo deaths at 30 days, two mortalities at 90 days

Table 6.4. Comparison of long-term outcomes after surgical repair of major bile duct injury between patients referred from the public versus the private healthcare sector.

Postoperative interventions	Public referral n = 58 (%)	Private referral n = 67 (%)	p-value
Percutaneous intervention	3 (5.2)	5 (7.5)	0.724
Surgical revision	2 (3.4)	3 (4.5)	1.000
Primary patency	52 (89.7)	59 (88.1)	1.000
	n = 5 (%)	n = 7 (%)	-
Secondary patency^a	4 (80.0)	4 (57.1)	0.567

^aTwo patients died before secondary patency could be achieved, one in the public referral cohort and one in the private referral cohort, and were not included in the secondary patency analysis

6.4 Discussion

This study investigated the difference between management and outcomes of major LC-BDIs in patients referred from and treated at public and private healthcare facilities at a single HPB unit in South Africa. Although there were differences between the two sectors in preoperative investigations, this did not translate into a statistically significant difference in short- or long-term outcomes. Additionally, there were no unequal delays in time to diagnosis or in time to receiving care after diagnosis between the two healthcare sectors despite a large proportion of patients who were referred from a geographic distance greater than 500 km from our referral centre.

The UCT-affiliated Surgical Gastroenterology Unit at GSH and the Digestive Diseases Centre, UCT Private Academic Hospital function as a single HPB unit serving both sectors. In general, there are major discrepancies in the availability and access to diagnostic, interventional and surgical facilities between public and private healthcare services. However, the UCT-affiliated services offer a largely comparable level and access to facilities

and are served by the same HPB multidisciplinary team. The more frequent use of PTBCs prior to referral in the private sector is likely a result of better resources and easier access to interventional radiologists compared to the public sector, especially in smaller hospitals.

The discrepancies in availability and access to high end diagnostic and interventional investigations are often discussed and highlighted as an obstacle to optimal management of patients in the public sector. However, the data presented here show that patients in the public sector underwent preoperative evaluation with cross sectional imaging more often compared to the private sector. ERC was available and performed with similar frequencies in both groups. The only discernible difference was the availability of sophisticated interventional radiology including PTC with PTBC placement in the private sector. This however, had no influence on ultimate outcome, because this intervention was subsequently provided at the tertiary level in the HPB unit prior to reconstruction. Achieving the above was facilitated by a common rapid, standardized evaluation and treatment algorithm that is applied to all patients regardless of the treatment facility, i.e. public or private.

Despite a poorly resourced and overburdened public sector, there was no statistically significant increase in delays in diagnosis, referral or repair for patients referred from the public sector compared to the private sector. Although not statistically significant, total median days from LC to repair was eleven days longer for the public sector referral cohort, which could arguably be considered a clinically relevant difference. Longer time to repair means higher costs to the patient and healthcare system as well as increased personal costs to the patient in terms of time lost at work, time away from family and overall quality of life.^{129,225} Interestingly, the greater proportion of patients in the private sector who were referred from a geographic distance farther than 500 km away did not seem to influence time to referral or repair.

Importantly, despite the statistically significant differences in preoperative investigations and interventions as well as the non-significant, but perhaps clinically relevant differences in time to repair, there were no statistically significant differences in long-term outcomes between the two sectors. Although not statistically significant, there was a difference in secondary patency rates between the two sectors. This difference is largely due to patient choice. There were two patients referred from the private sector who requested no further surgical

intervention and opted for PTBC management of biliary anastomotic strictures after initial surgical repair, preventing them from achieving secondary patency.¹⁰⁹

In conclusion, despite known differences in public and private healthcare system resources, in this study patients were referred appropriately and had similar postoperative outcomes when treated by an HPB multidisciplinary team, regardless from which healthcare sector they were initially referred.

Management: Influence of Injury Level and Extent on Patient Outcome⁴

7.1 Rationale

In Chapter 4, the evolution in the management of LC-BDIs over time was explored. This was followed by detailed analyses investigating factors that may potentially influence patient outcome after surgical repair of LC-BDI including the geographic distance from the referral centre and delays in diagnosis, referral and repair (Chapter 5) as well as the healthcare sector within which patients received treatment (Chapter 6). This chapter will focus on another potentially relevant factor that may influence patient outcome, namely, the level and extent of the LC-BDI.

A number of BDI classification systems have been proposed, the details, strengths and weaknesses of which were described in Chapter 1: Introduction. Briefly, Strasberg et al. adapted the Bismuth classification, which is now widely used for injuries occurring in LC.^{43,57,64} However, the Strasberg classification does not include concomitant vascular injury, suggested to be a predictor of poor postoperative outcome.¹¹⁹ The most detailed classification system is the ATOM classification which includes information on the anatomic level and extent of the injury, associated vascular injury, timing of detection and mechanism of injury.⁶⁶ For anatomic classification of the level of injury, six subtypes are defined.⁶⁶ Time of detection is classified as either early or late, with further subdivision into early intraoperative or immediate postoperative.⁶⁶ The mechanism of injury is divided into mechanical or energy driven.⁶⁶

Using different classification systems, several studies have investigated the relationship between the level and extent of injury and postoperative outcomes with conflicting results. In some, an injury above the hepatic duct bifurcation was a predictor of poor outcome.^{114,226} In others, no correlation between severity of injury and long-term outcome was found.^{108,227} In this analysis, the correlation between the level and extent of injury according to the ATOM classification and the risk of postoperative complications as classified by the MAGS was assessed for patients who underwent surgical repair of a LC-BDI by the HPB unit.^{66,190}

⁴Lindemann J, Jonas E, Kotze U, Krige JEJ. An analysis of early postoperative complications following biliary reconstruction of major bile duct injuries using the modified accordion and anatomic, timing of and mechanism classifications. *Surg Open Sci.* 2019;1(1):2-6.

7.2 Methods

7.2.1 Study design and patient management

A retrospective review of the prospectively maintained BDI database was performed and patients who underwent surgical repair of a LC-BDI from January 1991 to January 2018 were reviewed. The primary outcome was the correlation between the level and extent of BDI as per the ATOM classification and severity of postoperative complications according to the MAGS.^{66,190} Patient characteristics, preoperative data, operative details and postoperative outcomes were retrieved from the database. Patients who had undergone an attempted repair prior to referral were excluded. The geographic distances from referral hospital to treatment facility and timing of repair categories were defined as previously described in Chapter 2: Methods. Patients underwent a standard evaluation and operative repair (see Chapter 2: Methods).

7.2.2 Statistical analysis

Baseline characteristics are presented using median, range and IQR for continuous variables. Categorical variables are expressed as total number and percent. The Spearman rank-order correlation coefficient (r_s) for nonparametric data was used to assess the association between the level and extent of the BDI and postoperative complications. P-values < 0.05 were considered significant. SPSS Statistics for MacIntosh, Version 25.0 (IBM SPSS Statistics, IBM Corporation, Armonk, NY) was used for statistical analysis.

7.3 Results

7.3.1 Patient characteristics and preoperative investigations

The demographic and clinical characteristics of the 128 included patients are summarized in Table 7.1. The median age of the cohort was 45 (18-80) years. Most patients were female (82%). Nine patients underwent LC at GSH, with the remaining 119 referred from other hospitals. Median time from LC to diagnosis was 4 (0-156) days and median time to referral was 11 (range 0-258) days. Sixty-eight patients (53.1%) underwent LC at a geographically distant (> 100 km) centre. The most common presenting feature after BDI was a bile leak, followed by jaundice, sepsis, and cholangitis. Preoperative investigations are also summarized in Table 7.1. Seventy-six percent of patients received a PTC with PTBC placement. Sixty-eight (53.1%) patients underwent ERC, most of which were performed in the pre-MRCP era and mostly in patients undergoing an intermediate or delayed repair.

Cross-sectional imaging included CE-CT in 48 (37.5%) patients and MRI/MRCP in 55 (43.0%) patients.

Table 7.1. Demographic characteristics, clinical presentation and preoperative investigations.

Characteristics	Patients, n = 128 (%) or median (range); (IQR)
Demographics	
Age, years	45 (18-80); (36-55)
Sex, female	105 (82.0)
LC at referring hospital	119 (93.0)
LC at GSH	9 (7.0)
LC hospital location	
< 100 km from referral centre	60 (46.9)
100-500 km from referral centre	20 (15.6)
> 500 km from referral centre	48 (37.5)
Clinical presentation	
Days to diagnosis	4 (0-156); (0-8.3)
Days to referral	11 (0-258); (2.8-26)
Bile leak	87 (68.0)
Jaundice	48 (37.5)
Cholangitis	10 (7.8)
Sepsis	14 (10.9)
Abnormal liver function tests	99 (77.3)
Preoperative investigations	
Ultrasound	24 (18.8)
CE-CT	48 (37.5)
MRI/MRCP	55 (43.0)
ERC	68 (53.1)
PTC/PTBC	98 (76.6)

CE-CT – contrast-enhanced computed tomography, ERC – endoscopic retrograde cholangiography, GSH – Groote Schuur Hospital, LC – laparoscopic cholecystectomy, MRI/MRCP – magnetic resonance imaging/magnetic resonance cholangiopancreatography, PTC/PTBC – percutaneous transhepatic cholangiogram/percutaneous transhepatic biliary catheter

7.3.2 Assessment of injuries and surgical repair

The BDIs classified according to the ATOM classification are summarized in Table 7.2. Most patients presented with main biliary duct (MBD) level 2 (54.7%) or level 3 injuries (18.8%). Sixty-two patients (48.4%) had complete occlusions, 26 (20.3%) partial occlusions and 97 (75.8%) had a complete division of the MBD, 82 of which (64.1%) included excision of

variable lengths of duct. Fourteen patients (10.9%) had a VBI, the majority of which involved the right hepatic artery. The injury was detected intraoperatively in only 36 patients (28.1%). In 46 patients (35.9%) the BDI was identified within seven days, and in the remaining 46, more than 7 days postoperatively. Mechanical injury was the most common mechanism of BDI (n=106, 82.8%). The median time from injury to repair was 22 (0-586) days. In 8 patients (6.3%) the BDI repair was undertaken immediately, in 11 (8.6%) urgently, in 34 (26.6%) early, in 50 (39.1%) during the intermediate period and 25 (19.5%) were repaired late (Table 7.3). Five of the eight immediate repairs were performed by an HPB surgeon who travelled to the local hospital where the LC was being performed. The remaining three immediate repairs were in patients with intraoperative recognition of the BDI at GSH, followed by intraoperative consultation for repair by an HPB surgeon. Of the patients who had a VBI, three had primary repairs of the injured artery (one right hepatic and two common hepatic arteries) (Table 7.2).

Table 7.2. Anatomic, Time Of detection and Mechanism Classification for laparoscopic cholecystectomy bile duct injuries of referred patients.

ATOM classification	Patients, n = 128 (%)
MBD 1	14 (10.9)
MBD 2	70 (54.7)
MBD 3	24 (18.8)
MBD 4	14 (10.9)
MBD 5	6 (4.7)
Anatomic characteristics	
Complete occlusion	62 (48.4)
Partial occlusion	26 (20.3)
Complete division	97 (75.8)
Partial division	8 (6.3)
Loss of substance	82 (64.1)
VBI present	14 (10.9) ^a
Right hepatic artery	11 (8.6) ^b
Left hepatic artery	1 (0.8)
Common hepatic artery	2 (1.6) ^b
Time of detection	
Early, intraoperative	36 (28.1)
Early postoperative (≤ 7 days)	46 (35.9)
Late postoperative (> 7 days)	46 (35.9)
Mechanism of injury	
Mechanical	106 (82.8)
Energy device	1 (0.8)
Unknown	21 (16.4)

^aNo VBIs identified between 1993 and 2008

^bOne patient with a right hepatic artery and two patients with common hepatic artery injuries had primary repairs of the injured artery

ATOM – anatomic, time of detection, mechanism; MBD – main biliary duct; VBI – vasculobiliary injury.

Table 7.3. Timing of hepaticojejunostomy repair for laparoscopic cholecystectomy bile duct injuries of referred patients.

Timing of HJ repair	Patients, n = 128 (%) or median (range); (IQR)
Days injury to repair	22 (0-586); (8.8-75)
Timing Category	
Immediate (same anaesthesia as LC)	8 (6.3)
Urgent (≤ 72 hours)	11 (8.6)
Early (>72 hours, ≤ 14 days)	34 (26.6)
Intermediate (>14 days, ≤ 90 days)	50 (39.1)
Late (> 90 days)	25 (19.5)

HJ – hepaticojejunostomy, IQR – interquartile range, LC – laparoscopic cholecystectomy

7.3.3 Complications

Median length of follow-up was 12.9 (0.2-226) months. Postoperative complications are listed by the MAGS in Table 7.4. Sixty-five patients (50.8%) had at least one complication following HJ, most of which were moderate (Grade 2), with wound infection occurring in 28 (21.9%) patients. Bile leaks were mostly mild (Grade 1), but severe in two patients, one requiring a PTBC (Grade 3) and the other re-laparotomy (Grade 4). Of the patients who developed a bile leak, four had preoperatively placed PTBC used in the HJ reconstruction. The other severe complications included three patients with intra-abdominal infections and one patient with an enterocutaneous fistula, managed successfully with percutaneous drainage (Grade 3), one patient with bowel obstruction requiring re-laparotomy (Grade 4) and two with systemic sepsis associated with single organ failure (Grade 4), one patient developed an upper gastrointestinal bleed requiring gastroscopy (Grade 3) and two patients had prolonged intensive care unit (ICU) stays for multi-organ failure (Grade 5). Two patients developed intrahepatic abscesses that were successfully managed with percutaneous drainage (Grade 3). The delay in referral from geographically distant hospitals did not translate into a statistically significant difference in complication rate ($p=0.412$). There were two deaths at 90 days in this series (1.6%), the details of which are described in Chapter 5: Geographic Distance and Timing of Repair.

Table 7.4. Postoperative complications by the Modified Accordion Grading System in patients who underwent hepaticojejunostomy repair.

Complications	Modified Accordion Grading System, n = 128 (%)				
	Mild	Moderate	Severe		
	1	2	3	4	5
Surgical complications					
Biliary					
Bile leak	5 (3.9)	-	1 (0.8)	1 (0.8)	-
Liver abscess	-	-	2 (1.6)	-	-
Intra-abdominal infection	-	1 (0.8)	3 (2.3)	-	-
Small bowel obstruction	-	-	-	1 (0.8)	-
Postoperative ileus	-	1 (0.8)	-	-	-
Entero-cutaneous fistula	-	-	1 (0.8)	-	-
Wound					
Dehiscence	1 (0.8)	-	-	-	-
Seroma	1 (0.8)	-	-	-	-
Infection	3 (2.3)	28 (21.9)	-	-	-
Nonsurgical complications					
Acute kidney injury	-	1 (0.8)	-	-	-
Upper gastrointestinal bleed	-	-	1 (0.8)	-	-
Delirium	-	2 (1.6)	-	-	-
Nonsurgical infection	-	7 (5.5)	-	-	-
Systemic sepsis	-	1 (0.8)	-	2 (1.6)	-
Multi-organ failure	-	-	-	-	2 (1.6)
Total	10 (7.8)	41 (32.0)	8 (6.3)	4 (3.1)	2 (1.6)
90-day Mortality	2 (1.6)				

7.3.4 Correlation between level and extent of injury and severity of postoperative complications

The association between level and extent of BDI and severity of postoperative complications is shown in Figure 7.1. Most patients with postoperative complications had MBD 2 injuries, and the greatest proportion of complications occurred in the moderate category (MAGS Grade 2). However, when the number of patients in each ATOM injury level were correlated to the number and severity of MAGS complications there was no statistically significant relationship ($r_s(128) = -0.113$, $p = 0.203$).

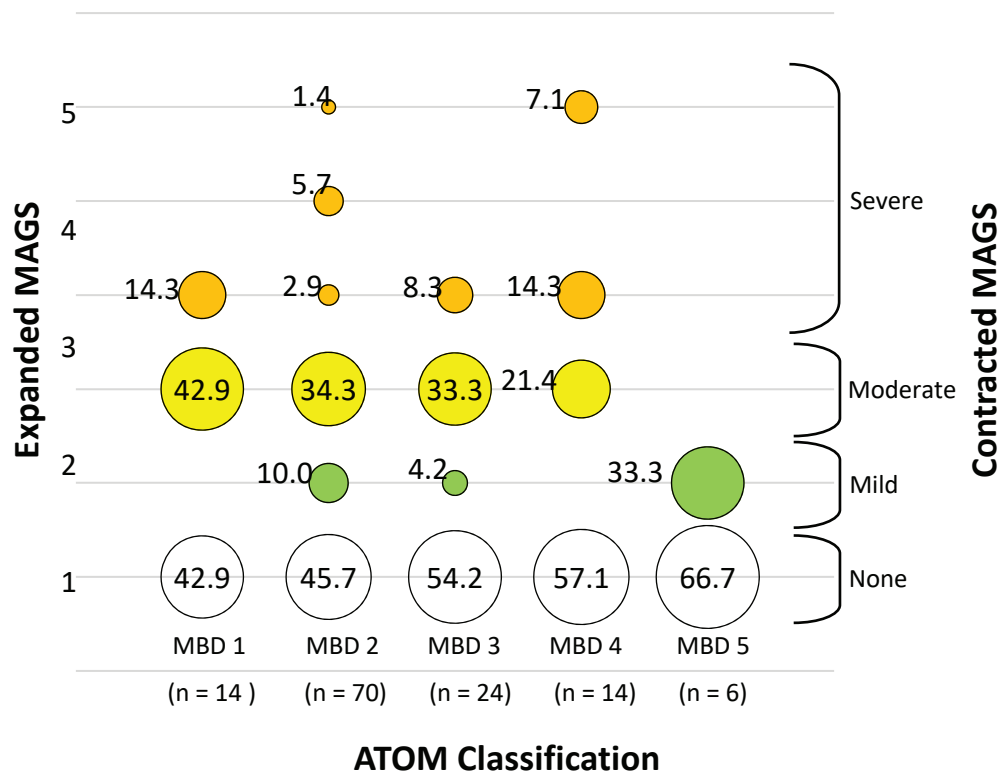


Figure 7.1. Postoperative complications defined using the Modified Accordion Grading System stratified by Anatomic, Time Of detection and Mechanism classification grouping, expressed as proportions. The postoperative complications are defined using the expanded¹⁹⁰ (left) and contracted¹⁹¹ (right) MAGS definitions. The size of each bubble represents the proportion of patients in each category. There was no significant correlation between level of injury and severity of postoperative complication using the Spearman rank-order correlation coefficient ($r_s(128) = -0.113, p = 0.203$).

ATOM – anatomic, time of detection, mechanism, MAGS – Modified Accordion Grading System, MBD – main biliary duct

Original Source: Lindemann J, Jonas E, Kotze U, Krige JEJ. An analysis of early postoperative complications following biliary reconstruction of major bile duct injuries using the modified accordion and anatomic, timing of and mechanism classifications. Surg Open Sci. 2019;1(1):2-6. DOI: <https://doi.org/10.1016/j.sopen.2019.01.001> [open access] and reproduced according to the CC BY-NC-ND 4.0 license.

7.4 Discussion

This analysis investigated the relationship between the severity of postoperative complications following bile duct reconstruction for LC-BDI according to the MAGS and the level and extent of BDI as assessed by the ATOM classification. Interestingly, there was no significant correlation between the level and extent of injury and the severity of postoperative complications. Approximately half of the patients undergoing a HJ repair of LC-BDI had one or more complications, most of which were mild to moderate in severity.

From its inception, the database included detailed documentation of complications that allowed accurate assignment of events to the MAGS grades. This may explain the higher rate of complications in this study compared to other published series, including studies from other MICs, which have reported complication rates between 18% and 43%.^{78,99,104,112,120} However, the distribution of the severity of complications in this study is comparable to those previously published.^{99,114,120} The majority of patients were referred from geographically distant centres, which is associated with referral delays and may have potentially influenced the complication rate. However, it was previously shown in Chapter 5: Geographic Distance and Timing of Repair, that later repairs resulted in less severe complications within the study population.

The use of PTC with PTBC placement has been reported to increase the risk of postoperative complications, particularly wound infections.²²⁸ Preoperative PTBCs in this study were more frequently used than in previous reports, which may have contributed to the higher rate of observed complications.¹⁰⁴ Although there is ongoing debate as to whether VBI influences outcome, a number of studies have documented the negative impact of VBI on the postoperative course.^{229,230} In this study, the prevalence of VBI was similar to previously published studies.^{116,227} Notably however, no VBIs were identified preoperatively in patients treated before 2008, during a period of time when there was less routine utilisation and poorer quality of cross sectional imaging. It is therefore possible that the incidence of VBI in this analysis is under-reported.

In this analysis, the level of injury had no influence on the severity of postoperative complications. There is a paucity of reports in the literature where a systematic and validated classification system was used to assess postoperative complications following BDI. In a recent analysis including open and laparoscopic injuries, the MAGS was used and the level of injury as assessed by the Strasberg classification was not found to be an independent predictor of postoperative complications.¹²⁰ Similarly, Booij et al. using the Clavien–Dindo classification found that for complications greater than grade 3, level of injury was not independently associated with postoperative outcome.¹⁰⁸ In both studies, the distribution of injury types was similar to the distribution in this study. Conversely, in a series of 138 patients from India, injury at or above the bifurcation was a significant predictor of

postoperative complications.¹¹⁹ However, postoperative complications were not recorded using a validated classification system and most BDIs occurred during OCs.¹¹⁹

In conclusion, although the overall short-term complication rate in this study was higher than previously reported, the distribution of the severity of complications and injury characteristics were similar to previously published studies and no correlation was found between level and extent of injury and severity of postoperative complications.

8.1 Rationale

The standard approach to a LC-BDI involving complete transection of the common bile or common hepatic duct is a HJ repair.⁸² However, surgical repair may result in significant morbidity and in some cases, mortality.²²⁵ For patients with LC-BDI, reconstruction is usually deferred for uncontrolled sepsis and when necessary, to optimize the patient for surgery.¹⁰³ In this interval, the biliary fistula is often controlled with percutaneous drainage resulting in external loss of bile and possible fluid and electrolyte imbalances.⁹¹ Maintaining or improving nutritional status during this period can be difficult because of the luminal absence of bile.²³¹ Due to complete transection of the extrahepatic biliary tree, it can be technically challenging to internalize the drainage of bile using a percutaneous or endoscopic approach alone. This is especially true if there is an excised portion of the bile duct or a large subhepatic collection. Several case reports and small case series have suggested using combined percutaneous transhepatic and endoscopic access in a rendezvous procedure for establishing biliary continuity in patients with a complete transection.^{92,232,233} This approach facilitates both control of the bile leak and internalization of bile drainage. However, data on long-term outcomes of this technique as a definitive therapy and a bridge to surgery, are lacking.

The rendezvous intervention can be performed in several different configurations including intraluminal (within the duodenum or biliary tree) or extraluminal (in the peritoneal space), with a unilateral or bilateral percutaneous approach and with antegrade or retrograde placement of stents.⁹¹ The procedure is performed with coordination between the endoscopist and interventional radiologist, and the location of the rendezvous is dependent on the access achieved. In brief, two separate biliary cannulations are obtained, one percutaneous through the liver during a PTC and a second endoscopic via ERC. From one access point a guidewire is inserted into the gap at the site of bile duct disruption and either a basket or snare is used from the other access point to retrieve the wire, bridging the gap. Once a percutaneously placed guidewire is internalized or an endoscopically placed guidewire is exteriorized, standard techniques for endoscopic or percutaneous stenting can be used.

The focus of this chapter will be on the use of an extraluminal rendezvous technique using combined PTC and ERC in patients who were referred to our centre with complete transection and significant bile duct tissue loss after LC. The indications for rendezvous over a surgical approach to management are discussed. The minimally invasive technique demonstrated can be used as a bridge to surgery or as definitive treatment in selected patients managed in a resource-limited healthcare system. A detailed description of the procedure, including the novel use of a fully covered self-expanding metal stent (SEMS) placed at the time of extraluminal rendezvous and outcomes post-rendezvous procedure are presented.

8.2 Methods

8.2.1 Study design

Three patients referred to the HPB unit with LC-BDIs and substantial bile duct tissue loss were included in this case series. Patient characteristics, diagnostic interventions, Strasberg type of injury, complications and follow-up were retrieved from the prospective BDI database and additional information was collected from patient records. The most recent laboratory results immediately prior to the extraluminal rendezvous intervention and at three months after the procedure are reported.

8.2.2 Interventional technique

The steps of the extraluminal rendezvous intervention are shown in Figure 8.1. After establishing the extent of the injury on cross-sectional imaging, a PTC was performed to confirm the imaging findings, specifically assessing the integrity of the biliary confluence and if the length of remaining proximal common hepatic duct would make placement of a fully covered SEMS technically feasible. At PTC, a PTBC was passed through the severed bile duct into the subhepatic space for drainage of collections. Step 1 of the rendezvous intervention was performing an ERC with a distal cholangiogram (Endoscope, Olympus Exera III). Matching the PTC and ERC images, the extent of bile duct tissue loss was determined. In Step 2, a stone retrieval basket was passed endoscopically through the distal end of the bile duct and opened in the subhepatic space. In Step 3, a standard 420 cm ERC guidewire was passed transhepatic via the PTBC into the subhepatic space. In Step 4, the wire was caught in the basket under fluoroscopic guidance and pulled through the working channel of the duodenoscope out of the oral cavity, after which the PTBC was removed. In Step 5, a fully covered SEMS (10 cm x 8 Fr; Boston Scientific, Boston MA) was deployed endoscopically, bridging the defect. Care was taken to have the proximal stent border distal to

the biliary confluence, ensuring bilateral biliary drainage. In Step 6, using the guidewire already in place, a new antegrade placed PTBC was deployed through the stent to prevent bile leak from the puncture on the liver surface, maintain percutaneous access for further intervention if needed and catch a migrating stent, should it occur.

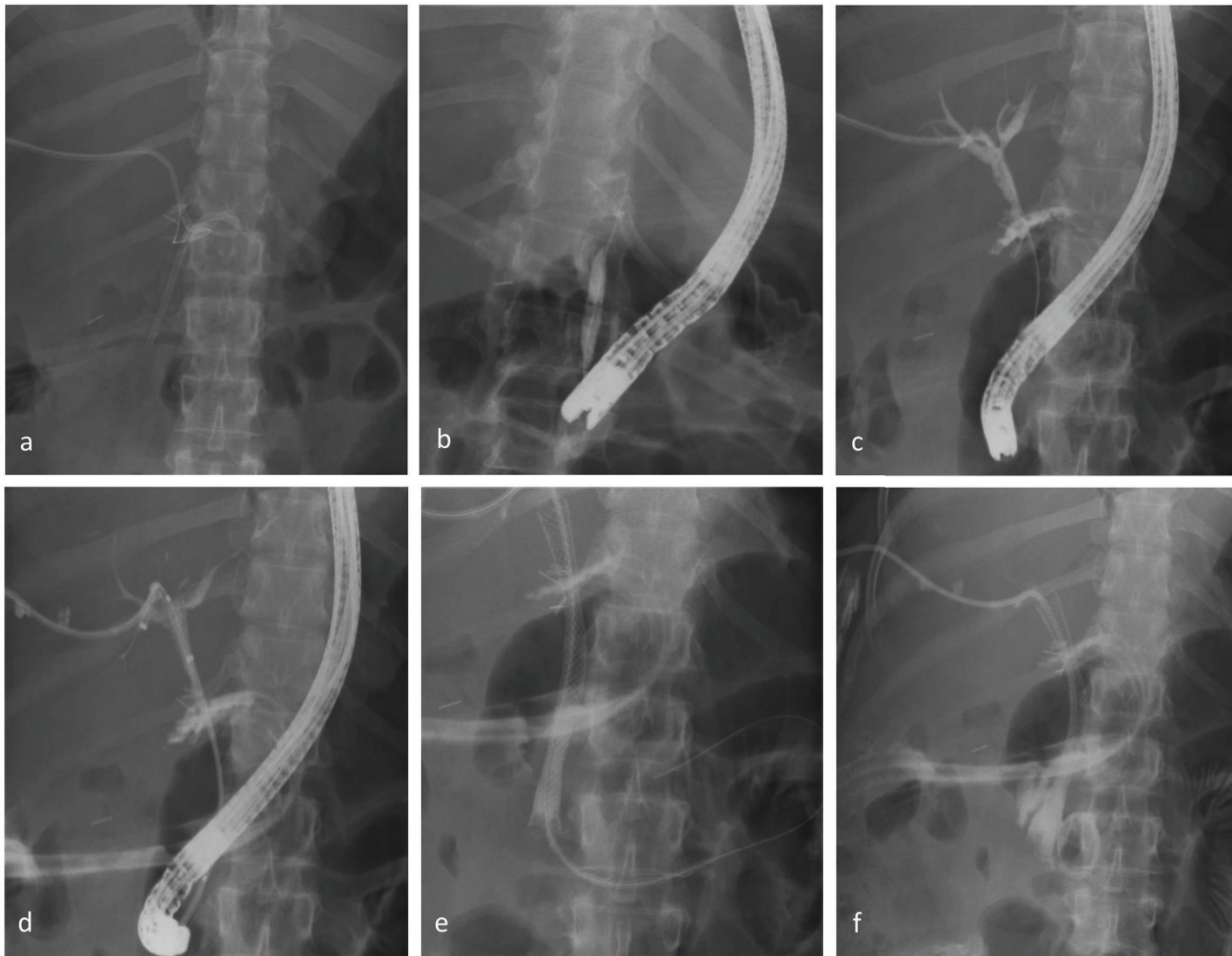


Figure 8.1. Extraluminal rendezvous with simultaneous self-expanding metal stent placement. **Figure 8.1a** shows the PTBC in place prior to performing the extraluminal rendezvous intervention. **Figure 8.1b** demonstrates the initial cholangiogram at ERC (Step 1) as the endoscopist prepares to position and deploy the stone extraction basket in the subhepatic space (Step 2). In **Figure 8.1c** the guidewire has been passed transhepatic through the PTBC access (Step 3) and caught in the stone retrieval basket (Step 4). **Figure 8.1d** shows the fully covered SEMS in place, but not yet expanded, bridging the gap (Step 5). **Figure 8.1e** shows the fully expanded stent with the transhepatic wire in place as a new PTBC is placed (Step 6). **Figure 8.1f** demonstrates the final result of the extraluminal rendezvous with the right-sided PTBC internalized through a SEMS.

ERC – endoscopic retrograde cholangiography, PTBC – percutaneous transhepatic biliary catheter, SEMS – self-expanding metal stent

Original source: Lindemann J, Kloppers C, Burmeister S, Bernon M, Jonas E. Mind the gap! Extraluminal percutaneous-endoscopic rendezvous with a self-expanding metal stent for restoring continuity in major bile duct injury: A case series. Int J Surg Case Rep. 2019;60:340-344. DOI: <https://doi.org/10.1016/j.ijscr.2019.06.059> [open access] and reproduced according to the CC BY 4.0 license.

8.2.3 Patient 1

A 33-year-old morbidly obese female (BMI 44.7) underwent an elective LC for symptomatic cholelithiasis and was discharged home. She subsequently developed jaundice and a bile leak and was diagnosed with an iatrogenic BDI on postoperative day 22. She was taken for an exploratory laparotomy, washout and drainage and then referred to our unit for further management five days later. Cross-sectional imaging confirmed a complete transection of the extrahepatic bile duct with 10 mm of tissue loss. Due to uncontrolled sepsis the decision was made to defer definitive treatment. An ERC was performed that showed extravasation of contrast into the subhepatic space and no filling of the proximal bile ducts. After placement of a transhepatic drain an extraluminal rendezvous procedure was performed and a 10 x 80 mm fully covered SEMS (Boston Scientific, Boston MA) was placed, bridging the defect (Figure 8.1).

8.2.4 Patient 2

A 42-year-old HIV positive morbidly obese female (BMI 41.2) underwent an elective LC for symptomatic cholelithiasis and was diagnosed with a BDI on postoperative day seven. She subsequently required a laparoscopic washout and drainage on postoperative day 10, where a leak from the gallbladder bed was noted. The bile leak did not improve and on postoperative day 22 she required an exploratory laparotomy for bile peritonitis at which time 3.5 L of bile was drained. She was referred to our unit for further management four days later with an ongoing bile leak and acute kidney injury. Forty-eight hours after presentation to the HPB unit, the patient developed acute respiratory failure requiring intubation and admission to the intensive care unit. She improved after antibiotic therapy and intercostal drain placement for a large pleural effusion and was extubated the following day. Cross-sectional imaging demonstrated complete transection of the common hepatic duct and a right hepatic artery injury. Due to her already prolonged course and recent ICU admission, it was decided to proceed with an extraluminal rendezvous as a bridge to surgery. A PTC was performed which showed contrast extravasation from the proximal common hepatic duct and PTBC with the tip in the subhepatic space was placed. An extraluminal rendezvous procedure was subsequently successfully performed with placement of a 10 x 80 mm fully covered SEMS (Boston Scientific, Boston MA) to bridge the defect.

8.2.5 Patient 3

A 57-year-old obese (BMI 30.8) female with diabetes mellitus underwent an elective LC for a previous episode of acute cholecystitis. A fibrous, thick-walled gallbladder with a large stone and a difficult dissection were noted at the time of the operation. She subsequently developed abdominal pain and jaundice and was diagnosed with a BDI on postoperative day five. The patient was referred to the HPB unit two days later and underwent a laparoscopic washout and drainage for a large intra-abdominal bile collection. Cross-sectional imaging showed a complete transection of the common hepatic duct just distal to the hepatic confluence with significant loss of bile duct length. Given her recent relook operation with evidence of severe inflammation and favourable biliary anatomy on cross-sectional imaging, the decision was made to perform an extraluminal rendezvous as a bridge to surgery. She subsequently underwent a right-sided PTC with placement of an external PTBC. The extraluminal rendezvous was successfully performed and the PTBC was internalized. No stent was placed as the remaining cuff of common hepatic duct was of insufficient length.

8.2.6 Follow-up

Patients were followed every three months with endoscopic SEMS stent exchange and laboratory tests. PTBCs were left in place until after the first stent exchange in the event they were needed to assist with stent migration or failure of the intervention. Removal was also delayed until a final decision regarding surgical repair was made, in line with the preference of the HPB unit to utilize PTBCs in BDI repairs. Cholangiogram at the time of stent exchange was used to evaluate the stricture and guide duration of endoscopic therapy in the absence of evidence-based guidelines.

8.3 Results

A detailed summary of the results from diagnostic interventions performed is presented in Table 8.1. There were no immediate complications following the extraluminal rendezvous procedure. Pre- and post-rendezvous blood tests are shown in Table 8.2. Patients 1 and 3 were discharged within four days of the procedure. Patient 2 was discharged 15 days post procedure due to difficulty arranging transport. None of the patients required re-admission or re-intervention for procedure-related complications. Notably, total bilirubin and albumin normalized within 3 months in all patients.

Table 8.1. Demographics and clinical information for patients with bile duct injury and substantial loss of bile duct length who were successfully treated with extraluminal rendezvous.

Pre-rendezvous imaging	Patient 1	Patient 2	Patient 3
CE-CT	Free fluid	Free fluid	Free fluid, RHA injury
MRI/MRCP	Complete transection of common hepatic duct	Complete transection of common hepatic duct	Complete transection of common hepatic duct
ERC	Complete transection of common bile duct	-	Complete transection of common bile duct, bile leak
PTC drainage	Via seg 8 duct, 8 Fr pigtail	Via seg 6 duct, 8 Fr pigtail	Via seg 8 duct, 8 Fr pigtail
Characteristics of injury			
Strasberg type	E2	E2	E2
Distance from confluence	10 mm	10 mm	5 mm
Length of substance loss	10 mm	25 mm	12 mm
Diameter of collection	95 x 90 mm	18 x 20 mm	52 x 32 mm

CE-CT – contrast-enhanced computed tomography, ERC – endoscopic retrograde cholangiography, Fr – French, MRI/MRCP – magnetic resonance imaging/magnetic resonance cholangiopancreatography, PTC – percutaneous transhepatic cholangiogram

8.3.1 Patient 1

For Patient 1, the PTBC was removed at 4 months post-rendezvous after multidisciplinary consultation and discussion with the patient to proceed with definitive endoscopic management. In March of 2020 she completed 24 months of endoscopic therapy. At the final ERC, the cholangiogram revealed a slight narrowing of the common hepatic duct at the site of the BDI with no intrahepatic bile duct dilatation. Based on the imaging findings, the decision was made not to replace the metal stent. The patient was initially referred from a hospital located more than 1000 km from our centre and for that reason she was discharged with instructions to follow-up locally and to return if she develops biliary obstruction symptoms. Throughout the duration of her 24 months follow-up, she did not develop any complications related to the extraluminal rendezvous procedure or the in situ SEMs.

8.3.2 Patient 2

The PTBC was removed after 2 months, when it was decided after multidisciplinary discussion and in consultation with the patient that a definitive endoscopic approach would be followed. An ERC performed in March of 2020 at 15 months post-rendezvous demonstrated a residual common hepatic duct stricture and a new SEMs was placed. The patient remains asymptomatic with no long-term complications. She will continue to be followed with regular laboratory tests and three-monthly stent exchanges for a total of 24

months, at which time the stricture will be evaluated and consideration given to stent removal.

8.3.3 Patient 3

The PTBC remained in situ for Patient 3 who, due to personal preference, underwent a definitive HJ surgical repair 3 months after the rendezvous procedure. The surgical repair was uneventful and well tolerated. The patient's postoperative course was complicated by a superficial wound infection that was managed with antibiotics and local wound care. Postoperative cholangiogram demonstrated an intact HJ anastomosis with no bile leak and she was discharged on postoperative day seven. The PTBC was removed at the first postoperative follow-up appointment. At one year follow-up in February of 2020 she was asymptomatic with normal liver function tests. Follow-up will continue six monthly for the next year and then annually.

Table 8.2. Pre- and three months post-extraluminal rendezvous blood results.

Laboratory result	Patient 1		Patient 2		Patient 3	
	Before	After	Before	After	Before	After
TB (umol/L)	19	8	20	3	26	9
ALT (IU/L)	16	14	48	25	29	91
AST (IU/L)	23	16	53	-	28	106
GGT (IU/L)	69	33	464	105	172	1584
ALP (IU/L)	166	86	342	98	218	816
Albumin (g/L)	24	39	26	40	27	45
Sodium (mmol/L)	137	138	152	139	136	139
Potassium (mmol/L)	3.9	4.3	2.7	-	4.9	4.8
Urea (mmol/L)	1.8	3.1	13.6	6.6	3.9	3.1
Creatinine (umol/L)	46	38	117	60	53	5.2
WCC (x10 ⁹ /L)	12.50	7.17	7.28	4.66	12.66	7.83
Haemoglobin (g/L)	84	123	90	121	110	132
Platelets (x10 ⁹ /L)	539	344	216	246	457	455
INR	1.56	1.27	0.88	1.00	1.57	-

ALP – alkaline phosphatase, ALT – alanine transaminase, AST – aspartate transaminase, GGT – gamma glutamyl transferase, INR – international normalized ratio, TB – total bilirubin, WCC – white cell count

8.4 Discussion

The extraluminal rendezvous technique described in this chapter may serve as a useful bridge to surgery strategy for patients where surgical management for LC-BDI is deferred. As

demonstrated by Patient 1, the procedure can also be used as definitive treatment for LC-BDI, even in the case of significant bile duct tissue loss. An important advantage of the internalization of bile in this approach is the prevention of external bile fluid loss, which optimizes nutritional status, and prevents electrolyte abnormalities and dehydration.⁹¹ In previously published series, the extraluminal rendezvous was found to be particularly useful for patients who have previously failed ERC and/or PTC alone and in whom immediate surgical repair is not an option.^{91,92} For the three patients presented here, the rendezvous intervention allowed significant bile leaks to be internalized in a physiologically favourable manner and improvement in the overall condition of the patients.

The patients who underwent an extraluminal rendezvous in this series required at least one re-look operation for large bile collections and/or bile peritonitis and were referred to the HPB unit between one and four weeks after LC. In this situation, a surgical repair is not desirable because there is likely to be significant inflammation, precluding an optimal repair.^{234,235} All three patients were also obese, with Patients 1 and 2 having BMIs over 40, putting them at increased risk for postoperative complications.^{236,237} The extraluminal rendezvous was determined to be the best course of treatment as it would immediately restore biliary continuity, provide an opportunity for the patients to improve their nutrition at home, and offer at least a bridge to surgery, if not allow them to avoid surgery all together.

In addition to indication, there are important anatomic considerations for the extraluminal rendezvous procedure. In order to successfully bridge the gap in the biliary tree with a fully covered SEMS, there must be adequate length of common hepatic duct distal to the confluence to avoid obstruction or exclusion of the left or right hepatic duct when the SEMS expands. In this series, 10 mm of duct was sufficient. The length of the biliary defect may also limit the success of an endoscopic only management approach. In this series, Patient 2 had a 25 mm defect and at 15 months post-rendezvous had a persistent but improving stricture. There are very little data on the success of endoscopic management in patients with defects greater than 10 mm. In the largest series of endoscopic management after rendezvous for LC-BDI patients, the authors suggest that an endoscopic approach for defects greater than 10 mm is unlikely to be successful, but also acknowledge their hypothesis is not supported by data from their retrospective study.⁹¹ Additionally, the study also reported a trend toward failure of endoscopic management in the presence of a concomitant vascular injury due to increased ischemia of the bile duct.⁹¹ Patient 3 in this series sustained a VBI with transection

of the right hepatic artery, which was considered in the decision to proceed with a definitive surgical repair.

The technique of extraluminal rendezvous for LC-BDI has been described previously. Odemis et al. performed an intraperitoneal rendezvous procedure with placement of a single plastic stent into the right biliary system at the time of rendezvous in a patient with a complex BDI.²³² Over the next year, multiple additional plastic stents were placed with resolution of the stricture. However, evidence of long-term success using a definitive stent strategy in these patients is lacking, especially long-term results after SEMS placement. In a series of 22 patients with complete bile duct transection after LC managed with extraluminal rendezvous, 18 patients were asymptomatic and 4 underwent surgical repair after a mean follow-up period of 5 years.⁹² Schreuder et al. found a long-term success rate of 55% in 47 patients after a median follow-up of 40 months.⁹¹ Notably, only 31 of the 47 patients had a complete transection of the bile duct and in both of the previously mentioned studies, plastic stents were exclusively used.^{91,92} The use of SEMS for major BDIs in the acute setting has to our knowledge not been described previously. Although long-term results need to be confirmed, the creation of a lumen substantially larger than plastic stents with a stent less prone to blockage may contribute to better long-term results in these patients.

In conclusion, the extraluminal rendezvous procedure was feasible and safely performed in three patients with complete transection and substantial bile duct tissue loss after LC. Placement of a SEMS at the time of extraluminal rendezvous effectively bridged the gap and allowed for internalization of bile flow and optimization of patients with no procedure-related complications. This approach, including the regular follow-up for endoscopic only management, was successful despite logistic challenges with patients being referred from further than 1000 km from our centre. In selected patients, the extraluminal rendezvous technique can result in favourable outcomes in a resource limited healthcare setting and represents an alternative approach to the management of LC-BDIs.

Management: Factors Influencing Loss of Patency⁵

9.1 Rationale

A substantial body of literature has addressed the management and outcomes of LC-BDI. However, the small number of patients who require revisionary surgery has limited the investigation of factors contributing to loss of patency of the initial biliary reconstruction and long-term outcome after revision. Previously reported factors that may contribute to anastomotic failure include concomitant vascular injury,¹⁰⁰ thermal injury, the extent of which is not visible during early reconstruction,²³⁸ and preoperative cholangitis.²³⁹ In addition, several proposed modifiable contributing factors have been identified including incomplete imaging of the biliary tree before index reconstruction,^{239,240} choice of surgical technique,^{124,241} initial reconstruction by a non-specialized HPB surgeon,²⁴² early index reconstruction^{239,242} and late referral to an HPB specialist.^{242,243}

Very few studies have evaluated BDI patients who require a revision of the initial reconstruction as the primary study population.^{74,124,239,241,244,245} These studies consist of small case series and the conclusions are not consistent across reports. In addition to small sample sizes, studies are composed of heterogeneous groups of patients including both LC and OC BDIs, different types of injuries and various techniques used for the index reconstruction. Furthermore, as is the case in many surgical observational studies, a standardized method of reporting and analysing data has not been applied. Without a universally accepted system for data reporting, the synthesis of data from multiple studies, a potential solution for small sample sizes, is problematic. The recently proposed standardized method for reporting outcomes after treatment of BDI, as described in Chapter 2: Methods, offers a solution to the problem of heterogeneous reporting.¹⁰⁹

The current study had two major objectives. First, factors contributing to loss of patency following index biliary-enteric reconstruction of LC-BDIs were evaluated by comparing patients who underwent revision of the index reconstruction to patients with successful initial

⁵Lindemann J, Krige JEJ, Kotze U, Jonas E. Factors leading to loss of patency after biliary reconstruction of major laparoscopic cholecystectomy bile duct injuries: An observational study with long-term outcomes. *HPB (Oxford)*. 2020 [in press]. DOI: <https://doi.org/10.1016/j.hpb.2020.02.010>

reconstruction using the proposed standardized reporting method. Second, postoperative outcomes for the two cohorts were compared.

9.2 Methods

9.2.1 Study design and definitions

A retrospective review was performed of the prospectively maintained BDI database for patients who required a surgical intervention for LC-BDI from January 1991 to June 2018. The study population consisted of patients who were referred for HJ revision due to loss of patency after an index reconstruction elsewhere as well as patients primarily treated in the HPB unit who subsequently required re-repair. The comparison group consisted of patients who had undergone a successful index reconstruction in the HPB unit defined as maintenance of primary patency after a minimum 3-year follow-up.

Patient characteristics, indication for LC, time to BDI diagnosis, time to referral to the HPB unit, time to index reconstruction and if required, time to any subsequent reconstructions, Strasberg classification of the initial BDI as well as the anastomotic stricture,⁴³ postoperative complications as classified by the contracted version of the MAGS¹⁹⁰ and long-term outcomes, defined as status at last known follow-up, were assessed. Any surgery related complications after the immediate postoperative period were recorded and included in the analysis of long-term outcomes. Geographic distance from referring hospital to the HPB unit was also analysed as this may influence timing of referral and repair in our patient population (see Chapter 5: Geographic Distance and Timing of Repair). The geographic distance groups, timing of repair categories, standard preoperative evaluation, surgical repair and follow-up were used as described in Chapter 2: Methods.

9.2.2 Statistical analysis

The Mann–Whitney U test was used to compare medians of non-parametric data and Fisher’s exact test for categorical variables were used. The Kaplan–Meier method was used to determine primary and secondary patency rates and the life table (actuarial) method was used to determine actuarial patency rates. Patency outcomes were presented according to recently published methods.¹⁰⁹ A p-value < 0.05 was considered statistically significant. Statistical analysis was performed using SPSS version 25 (IBM SPSS Statistics, IBM Corporation, Armonk, NY).

9.3 Results

9.3.1 Study population

Of the 190 BDI patients logged in the prospective database as of June 2018, 131 underwent a biliary-enteric reconstruction for LC-BDI. There were 108 patients who underwent index HJ reconstruction in the HPB unit. Twenty-eight patients required a revision of the initial reconstruction, 23 of whom had undergone index reconstruction by the referring surgeon and five of whom were had undergone index HJ repair in the HPB unit (Figure 9.1).

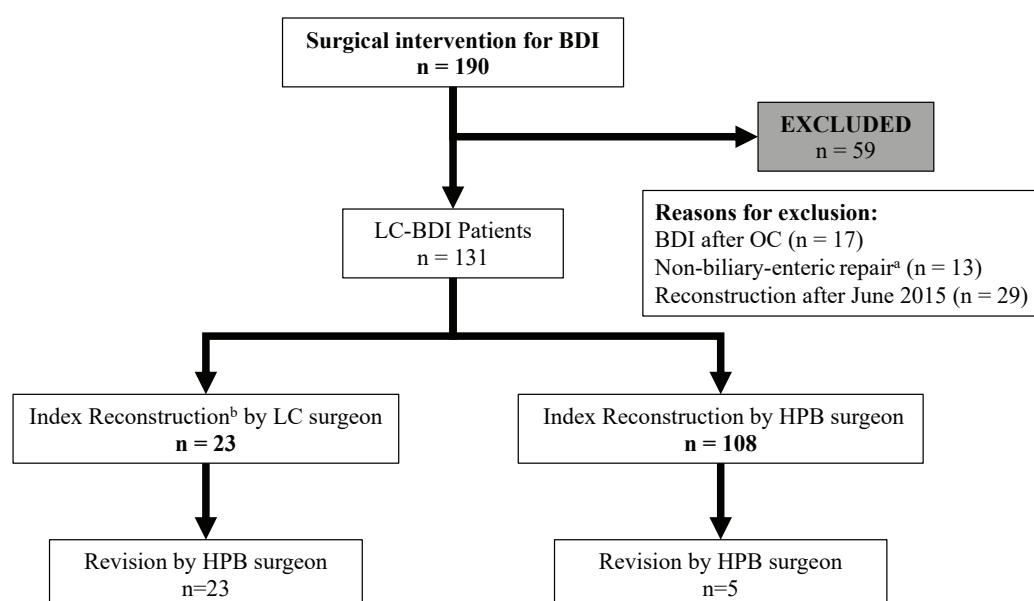


Figure 9.1. Flow diagram of included and excluded bile duct injury patients.

Distribution of patients from the prospective BDI database. Patients were excluded if they had a BDI after an OC, underwent an initial non-biliary-enteric repair, or had a biliary-enteric reconstruction of a BDI within the last 3 years.

^aNon-biliary-enteric repair includes direct suture repair of the duct and an end-to-end biliary anastomosis

^bReconstruction by referring surgeon included choledochoduodenostomy (CD), hepaticoduodenostomy (HD) and HJ. HJ was the only method of reconstruction used by the HPB unit for BDI repair over the duration of the study

BDI – bile duct injury, CD – choledochoduodenostomy, HD – hepaticoduodenostomy, HJ – hepaticojejunostomy, HPB – hepato-pancreato-biliary, LC – laparoscopic cholecystectomy, OC – open cholecystectomy

Original source: Lindemann J, Krige JEJ, Kotze U, Jonas E. Factors leading to loss of patency after biliary reconstruction of major laparoscopic cholecystectomy bile duct injuries: An observational study with long-term outcomes. HPB (Oxford). 2020 [in press]. DOI: <https://doi.org/10.1016/j.hpb.2020.02.010> and reproduced according to the CC-BY-NC-ND license.

9.3.2 Patients requiring revision of initial reconstruction

Patient and clinical characteristics for patients who underwent revision of the index reconstruction are shown in Table 9.1. Median age was 50.5 (29-73) years and the majority of patients were female (n = 23, 82.1%). In 10 of the 28 patients the BDI was detected during the LC. In the remainder, the median time to BDI diagnosis was 4 (1-61) days. Nineteen patients underwent index reconstruction within two weeks of LC-BDI. All but three patients had a single end-to-side HJ as the index reconstruction operation. Two had a choledochoduodenostomy (CD) and the third had a hepaticoduodenostomy (HD).

Nine patients were referred from a distance < 100 km from the HPB unit, five of whom were referred from GSH where the HPB unit is located. The median time to referral from LC-BDI was 17.4 (0.1-109.6) months. Most patients (50%, n = 14) had Strasberg type E3 anastomotic strictures following index reconstruction. Median time from index reconstruction to revision was 20.4 (0.6-121.0) months. One patient with an E2 stricture after index reconstruction had an end-to-side HJ revisionary reconstruction. Four of the five E4 strictures were reconstructed with a single Hepp-Couinaud-HJ (HC-HJ) anastomosis, one of whom also underwent a left-sided hemi-hepatectomy and another a simultaneous duodenal fistula repair. The remaining patient required an additional separate anastomosis for a segment VI ductal stricture.

Table 9.1. Detailed description of clinical characteristics for patients requiring re-repair after index reconstruction for laparoscopic cholecystectomy bile duct injury.

ID	Age	Sex	Days to index repair	Strasberg BDI	Repair type	Days to revision surgery	Strasberg stricture type	Revision surgery type	Modified Accordion Grade	Total days follow-up ^a	Clinical outcome at last follow-up
1	71	M	0	E3	HJ	162	E3	HC-HJ	2	133	Well
2	39	F	53	E3	HJ	638	E3	HC-HJ	2	29	Well
3	71	F	61	E2	CD	124	E3	HC-HJ	2	366	Well
4	57	F	0	E4	HJ	2143	E4	HJ	0	11	Well
5	73	F	7	E1	CD	467	E2	HC-HJ	0	36	Well
6	36	F	7	E2	HJ	162	E4	HC-HJ	2	15	Well
7	53	F	0	E4	HJ	372	E4	L HJ	3	467	Well
8	63	M	2	E3	HD	2283	E3	HC-HJ	0	281	Well
9	71	F	6	E1	HJ	1811	E2	L HJ	0	2961	Well
10	36	F	3	E3	HJ	1442	E3	HC-HJ	0	8	Well
11	69	M	0	E3	HJ	2106	E3	HC-HJ	1	573	Secondary biliary cirrhosis of right liver
12	56	F	76	E2	HJ	217	E2	HC-HJ	2	1371	Well
13	42	F	7	E1	HJ	3356	E2	HJ	0	36	Well
14	65	F	3	E2	HJ	1954	E3	HC-HJ	0	4318	Well
15	64	M	2	E2	HJ	238	E3	HC-HJ	0	2244	Well
16	58	F	34	E5	HJ	263	E5	HC-HJ	0	617	Well
17	52	F	0	E2	HJ	3054	E3	HC-HJ	2	3395	Well
18	48	F	0	E2	HJ	1310	E3	HC-HJ	0	39	Well
19	49	F	0	E3	HJ	603	E3	HC-HJ	0	147	Well
20	36	F	0	E1	HJ	19	E2	HC-HJ	0	288	Well
21	36	F	45	E2	HJ	2276	E3	HC-HJ	2	49	Well
22	39	F	19	E2	HJ	717	E2	HC-HJ	0	11	Well
23	31	F	0	E3	HJ	596	E3	HC-HJ	0	1013	Well
24	46	F	169	E3	HJ	2297	E3	HC-HJ	0	1110	Incisional hernia, otherwise well
25	29	F	14	E2	HJ	513	E2	HC-HJ	0	43	Well
26	51	F	29	E3	HJ	3680	E4	HC-HJ ^b	1	800	Well
27	48	F	79	E4	HJ	397	E4	HC-HJ	0	3304	Well
28	50	M	0	E2	HJ	145	E4	HC-HJ	2	37	Well

^aTotal days follow-up begins on post-revision repair day 1 and ends at the last known contact with the healthcare system.

^bThis patient also required a separate HJ anastomosis to an isolated segment VI duct that could not be incorporated into the HC-HJ

BDI – bile duct injury, CD – choledochoduodenostomy, F – female, HC-HJ – Hepp-Couinaud hepaticojejunostomy, HD – hepatoduodenostomy, HJ – hepaticojejunostomy, M – male

9.3.3 Bivariate comparison of successful and failed index reconstruction groups

Demographic and clinical characteristics of patients with a successful index reconstruction and patients with a failed index reconstruction are compared in Table 9.2. Age, gender and intraoperative diagnosis of BDI were similar between the two groups (all $p > 0.05$). Patients requiring a revision underwent index reconstruction much earlier, at a median of 4.5 (0-169) days after injury compared to a median of 22 (0-586) days for the successful index reconstruction group ($p = 0.001$). Patients with a failed index reconstruction were more likely to have had incomplete depiction of the biliary tree prior to index reconstruction ($p < 0.001$). The distribution of patients within the successful index reconstruction and the failed index reconstruction groups was similar in terms of geographic distance from referral centre, level of initial injury in relation to the confluence and number of patients with concomitant vascular injury.

Table 9.2. Demographic and clinical characteristics of patients with a successful index reconstruction compared to patients with loss of patency after repair for laparoscopic cholecystectomy bile duct injury.

Variable	Successful index reconstruction n = 103 (%) or median (range); (IQR)	Failed index reconstruction n = 28 (%) or median (range); (IQR)	p-value
Age, years	45.0 (18-78); (36-56)	50.5 (29-73); (39-63.3)	0.089 [^]
Sex, female	79 (76.7)	23 (82.1)	0.617
Intraoperative diagnosis	29 (28.2)	10 (35.7)	0.487
Complete depiction of biliary tree	91 (88.3)	5 (17.9)	< 0.001
Days to referral	11 (0-285); (3-24)	528 (4-3335); (135-1851.3)	<0.001 [^]
Days to index reconstruction	22 (0-586); (8.5-76)	4.5 (0-169); (0-32.3)	0.001 [^]
Index reconstruction timing groups			
Immediate	8 (7.8)	10 (35.7)	0.001
Urgent	6 (5.8)	4 (14.3)	
Early	28 (27.2)	5 (17.9)	
Intermediate	37 (35.9)	8 (28.6)	
Late	24 (23.3)	1 (3.6)	
Geographic distance from referral centre			
< 100 km	51 (49.5)	9 (32.1)	0.249
100 – 500 km	16 (15.5)	6 (21.4)	
> 500 km	36 (35.0)	13 (46.4)	
Strasberg classification *			
E1	13 (12.6)	4 (14.3)	0.504
E2	56 (54.4)	11 (39.3)	
E3	22 (21.4)	10 (35.7)	
E4	11 (10.7)	3 (10.7)	
E5	1 (1.0)	0	
Below bifurcation (E1-E2)	69 (67.0)	15 (53.6)	0.266
At or above bifurcation (E3-E5)	34 (33.0)	13 (22.4)	
Vascular injury	11 (10.6)	1 (3.6)	0.460

IQR – interquartile range

9.3.4 Multivariate analysis of factors influencing loss of patency

In the multivariate analysis, the only statistically significant independent predictor of a failed index reconstruction requiring revision was incomplete depiction of the biliary tree prior to the index reconstruction which resulted in a 10-fold increase in the odds of needing a revision (OR 10.131, CI 1.180-86.978, p = 0.035) (Table 9.3).

Table 9.3. Multivariate logistic regression analysis of potential factors influencing loss of patency after index reconstruction of a laparoscopic cholecystectomy bile duct injury.

Variable	Odds Ratio	95% CI	p-value
Age	1.02	0.96 - 1.09	0.556
Sex, female	2.84	0.33 - 24.24	0.339
Incomplete depiction of biliary tree	10.13	1.18 - 86.98	0.035
Days to referral	1.01	1.00 - 1.03	0.070
Days to index reconstruction	0.99	0.97 - 1.01	0.362
HJ for index reconstruction	2.93	0.27 - 31.85	0.378
Injury below hepatic confluence	0.46	0.08 - 2.55	0.370
Vasculobiliary injury	1.23	0.11 - 14.03	0.870

HJ – hepaticojejunostomy

9.3.5 Comparison of postoperative outcomes between successful and failed index reconstruction groups

There was proximal migration of the level of the stricture compared to the initial injury with a greater proportion of patients having E3 and E4 type strictures in the failed index reconstruction group ($p = 0.001$, Table 9.4). No difference in 30-day postoperative MAGS complications or long-term biliary and non-biliary complications between the two groups ($p > 0.05$) was observed. This was also true for total short and long-term complications. Median alkaline phosphatase (ALP) and total bilirubin (TB) values at last follow-up for the successful index repair group were 90 (IQR 72.8-132) U/L and 8 (IQR 6-11) $\mu\text{mol/L}$ (0.47, IQR 0.35-0.64 mg/dL), respectively. Similarly, median ALP and TB values after a second reconstruction for loss of patency were 122.5 (IQR 87.8-244.5) U/L and 9 (IQR 6-14) $\mu\text{mol/L}$ (0.53, IQR 0.35-0.82 mg/dL). Median ALP between the two groups was significantly different ($p = 0.025$). There were no statistically significant differences between the two groups for median TB value ($p = 0.543$) or length of follow-up ($p = 0.275$).

Table 9.4. Short- and long-term postoperative complications for the successful index reconstruction group compared to the group of patients with loss of patency.

Variable	Successful index reconstruction n = 103 (%) or median (range); (IQR)	Failed index reconstruction n = 28 (%) or median (range); (IQR)	p-value
Strasberg classification^a			0.001^b
E1	13 (12.6)	0	-
E2	56 (54.4)	7 (25.0)	0.005
E3	22 (21.4)	14 (50.0)	0.004
E4	11 (10.7)	6 (21.4)	0.200
E5	1 (1.0)	1 (3.6)	0.383
Modified Accordion Grade			
Mild	8 (7.8)	2 (7.1)	0.609
Moderate	30 (29.1)	8 (28.6)	
Severe	13 (12.6)	1 (3.6)	
Death	0	0	
Total Complications	51 (49.5)	11 (39.0)	0.396
Long-term complications: non-biliary			
Incisional hernia	3 (2.9)	1 (3.7)	1.000
Small bowel obstruction	1 (1.0)	0	-
Long-term complications: biliary			
Cholangitis, managed conservatively	3 (2.9)	0	-
Stricture, PTC + balloon dilatation	2 (1.9)	1 (3.6)	0.517
Chronic PTBC	1 (1.0)	1 (3.6)	0.383
Re-exploration	1 (1.0)	0	-
Secondary sclerosing cholangitis	1 (1.0)	0	-
Secondary biliary cirrhosis	0	1 (3.6)	-
Mortality	2 (1.9)	0	-
Total long-term complications	14 (13.6)	4 (14.3)	1.000
Length of follow-up, months	15.7 (0-228); (2.1-56.3) ^c	9.2 (0.3-142.0); (1.2-34.1)	0.275 ^d

^aStrasberg classification for level of injury in the successful index repair group compared to the level of stricture in patients requiring re-repair

^bSignificant p-value, therefore direct comparisons between the two groups from each injury type performed

^cTwo patients died in hospital and therefore have “0” days follow-up

^dMann–Whitney U test used for analysis

IQR – interquartile range, PTC – percutaneous transhepatic cholangiogram, PTBC – percutaneous transhepatic biliary catheter

9.3.6 Primary and secondary patency

For the 108 patients undergoing index reconstruction in the HPB unite, 100 (92.6%) achieved primary patency (Grade A result) with an actuarial primary patency rate of 81.5% at 10 years (Figure 9.2). Two patients died within 90 days of index reconstruction and thus failed to achieve primary patency. One patient developed secondary sclerosing cholangitis managed with repeated PTBCs (Grade D result). Another patient was referred after three exploratory laparotomies elsewhere for attempted reconstruction during which the bile ducts could not be

identified. A successful reconstruction was performed at our centre, with a single anastomosis to separated left, right and an anomalous segment VII duct. This patient has required indwelling PTBCs since reconstruction and remains clinically well but has declined further operations for domestic reasons (Grade D result). Four patients developed anastomotic strictures requiring revision, one of whom developed secondary biliary cirrhosis of segments VI and VII before re-repair. The fifth patient who required revision developed an anastomotic stricture more than 10 years after index reconstruction and is not represented in the 10-year primary patency results.

Ninety-two percent of patients undergoing revision achieved secondary patency, with an actuarial patency rate of 89.7% at 1, 3, 5 and 10 years. A total of 26 patients achieved and maintained secondary patency following revision (Grade C result). Two patients had loss of secondary patency, one of whom required PTC with balloon dilatation one year after the second reconstruction with resolution of symptoms and restoration of secondary patency (Grade C result). The second patient developed an anastomotic stricture after the second reconstruction that was successfully managed with regular PTCs and balloon dilatations after declining further surgical intervention (Grade D result).

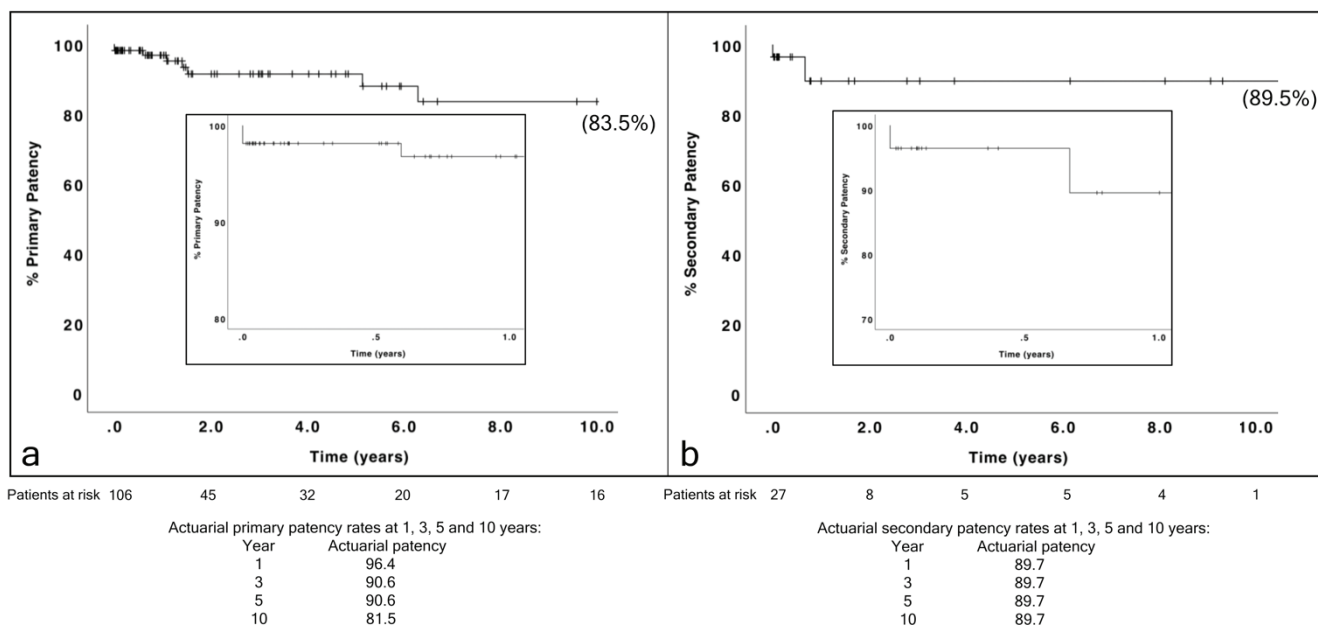


Figure 9.2. Kaplan–Meier primary and secondary patency curves demonstrating patency rates after index reconstruction and revision of index reconstruction for laparoscopic cholecystectomy bile duct injury. Primary patency curve (9.2a): One hundred and eight patients had a surgical bile duct reconstruction by the HPB unit, two of which did not achieve primary patency within the treatment period. The initial proportion of patients who achieved primary patency was therefore 98.1%. Six additional patients lost primary patency over the duration of the study. The primary patency probability at 10 years is shown on the curve and actuarial primary patency rates at 1, 3, 5, and 10 years are shown below. First year data is enlarged in the inset. **Secondary patency curve (9.2b):** Twenty-eight patients required revision of an index reconstruction by the HPB unit, one of whom failed to achieve secondary patency within the treatment period resulting in a secondary patency rate of 96.4%. Two patients lost secondary patency, both within the first year after revision. The secondary patency probability at 10 years is shown on the curve and actuarial secondary patency rates at 1, 3, 5, and 10 years are shown below. First year data is enlarged in the inset.

Original source: Lindemann J, Krige JEJ, Kotze U, Jonas E. Factors leading to loss of patency after biliary reconstruction of major laparoscopic cholecystectomy bile duct injuries: An observational study with long-term outcomes. HPB (Oxford). 2020 [in press]. DOI: <https://doi.org/10.1016/j.hpb.2020.02.010> and reproduced according to the CC-BY-NC-ND license.

9.4 Discussion

This analysis evaluated factors potentially contributing to loss of patency requiring subsequent reconstructions after index repair of LC-BDI. The only independent predictor of loss of patency was incomplete depiction of the biliary tree before the initial reconstruction. Postoperative complications at 30-days were similar, and primary and secondary patency rates comparable in patients after successful index reconstruction and after a second repair in patients where the first reconstruction failed. There was a more than 10-fold increase in the

odds of loss of patency requiring revision in patients with incomplete depiction of the biliary tree, emphasizing that incomplete assessment of the extent of the biliary injury prior to index reconstruction may underestimate the severity of the injury, which can compromise the success of the surgical repair.²⁴² The possibility remains that incomplete depiction of the biliary tree is a surrogate marker for immediate repairs performed by the injuring surgeon, as it is unlikely that biliary imaging is obtained in that scenario. However, this question could not be answered by this analysis because a non-consecutive group of patients requiring revision of the index repair were used, resulting in a heavily biased sample.

In patients where patency was lost, there was a proximal migration of the level of biliary strictures, with extension into the bile duct above the anastomosis. This is most likely due to associated iatrogenic injury to the hepatic artery, marginal arteries or epicholedochal plexus during extensive dissection or thermal injury, the extent of which is not fully manifest at the time of index reconstruction.^{70,185} Proximal migration increases the complexity of a revision, which has been reported to negatively impact the long-term success of the subsequent reconstruction.^{239,245,246} Similar to previously reported data, the majority of patients did not have normal liver function tests after reconstruction.²⁴⁶ The median ALP at last follow-up was higher after the second reconstruction in the failed index reconstruction group, however the difference is unlikely to be clinically significant, particularly when compared to levels previously reported, as values in this study are in keeping with previously reported ranges.²⁴⁷ Despite the reported complexity of multiple reconstructions, the data reported here show that similar favourable outcomes can be achieved when subsequent reconstructions are performed by an experienced multidisciplinary HPB team, a finding supported by several other studies.^{76,77,239,240,244} Large hepatic ducts that have dilated as a result of stricture formation, elective surgery with the use of PTBCs and the Hepp-Couinaud approach all likely contributed to these favourable results.

This study presented outcomes after LC-BDI repair using the recently proposed standardized method for reporting by Cho et al.¹⁰⁹ Compared to the Cho study, the reported percentage of patients who achieved primary patency after undergoing index reconstruction at our institution was similar.¹⁰⁹ The actuarial primary patency rate at 5 and 10 years in their report was higher than in our study (91.8% vs. 90.6% and 81.5%), which could be explained by the increased number of events observed 1 year after index reconstruction in the current patient cohort. There are no previous reports of outcomes after repeat reconstruction for failed initial

repairs using the standardized reporting method. A higher secondary patency probability at 10 years for patients who underwent a second reconstruction after loss of patency was observed compared to the successful index reconstruction group. Further studies using this standardized method of reporting are needed to facilitate comparisons and benchmark outcomes after surgical reconstruction for BDIs.

There is significant heterogeneity in the literature regarding factors contributing to loss of patency after index reconstruction of LC-BDIs. Even though this study is one of the largest reporting on reconstruction after loss of patency, the number of patients assessed is still relatively small. Previous studies have, apart from small sample sizes, also been hampered by a lack of standardized reporting of outcomes. Age, gender, concomitant vascular injury, surgical technique and timing of index reconstruction have both been supported and refuted as contributors to loss of patency.^{16,79,100,108,124,241} Although concomitant vascular injury is considered a major contributing factor to failed reconstruction, this was not associated with higher rates of anastomotic stricture in a comparison study of 22 patients undergoing revision and 24 patients undergoing index reconstruction.²⁴¹ However, in a retrospective review of 18 patients with a failed surgical reconstruction after BDI, 11 (61%) had a concomitant vascular injury, which was the presumed contributing factor to loss of patency.¹²⁴ Conversely, in a large study from the Netherlands which included 281 patients, the only independent predictor of anastomotic stricture after index surgical reconstruction on multivariate analysis was male gender.¹⁰⁸

The limitations of this study include the retrospective analysis, although data were sourced from a prospectively maintained database. Secondly, as in previous studies, numbers are small due to the rarity of events. The relatively small sample size resulted in a wide 95% CI for our primary outcome. However, without use of a national database or multi-institutional collaboration, larger sample sizes and therefore narrower 95% CIs, are unlikely to be achieved. Thirdly, the study period was prolonged which was required to accumulate a sufficient number of patients for the analysis. In Chapter 4 a detailed analysis of the evolution of BDI management on the same patient cohort showed a statistically significant increased use of preoperative PTBC, CE-CT and MRI/MRCP, with a decrease in severe complications. This highlights the importance of preoperative biliary imaging, but also may represent a potential confounder in our analysis. In addition, obtaining complete follow-up was challenging, particularly due to the large number of geographically distant referrals received.

The wide variation in available follow-up data does somewhat limit the strength of the findings presented here. However, the standard methodology, continuity of treatment by a dedicated multidisciplinary HPB team and detailed patient documentation help to minimize confounders and increase the validity of the data allowing for a robust analysis.

In conclusion, the only independent predictor of loss of patency after index reconstruction for LC-BDIs was incomplete preoperative depiction of the biliary tree, which resulted in a 10-fold increase in the odds of requiring a revision. Patients who undergo a second reconstruction for loss of patency can expect to have a similar postoperative outcome and patency rate when compared to patients who undergo index reconstruction when both operations are performed in an HPB specialized unit. Further studies using the standardized method of reporting and multi-institutional collaboration are required to minimize observational study bias and achieve sufficient statistical power to definitively determine which factors influence loss of patency.

10.1 Rationale

In the preceding six chapters various factors potentially related to patient outcome after surgical repair of LC-BDI were investigated. These included an analysis of how management has evolved over time (Chapter 4), the influence of geographic distance from referral centre on timing of referral, repair and outcome (Chapter 5), differences in treatment and outcome between the public and private healthcare sectors (Chapter 6), the relationship between level and extent of BDI and the severity of postoperative complications (Chapter 7), potential endoscopic alternatives to management (Chapter 8) and what factors may increase the likelihood of loss of patency and failure of the index repair (Chapter 9). The findings represent conclusions from data that span three decades of experience in managing LC-BDIs in a MIC and address a significant gap in the literature. The purpose of this chapter is to present an evidence-based treatment algorithm for managing LC-BDIs in a LMIC setting, designed after consideration of the findings presented in Chapters 4 through 9 and the previously published literature. The algorithm is accompanied by checklists for the referring hospital and the referral centre to facilitate its application.

10.2 Proposed algorithm

The proposed algorithm for management of LC-BDI is shown in Figure 10.1 with the accompanying checklists shown in Tables 10.1 and 10.2. Management begins with consideration of the timing of diagnosis of the BDI and what sequelae of the injury are present. If diagnosed at the time of LC, the operation should not proceed, a drain should be left, and the patient should be transported immediately to a tertiary hospital that offers specialized HPB services. When the BDI is diagnosed in the early postoperative period, either as a result of a bile leak or bile peritonitis, the patient should be evaluated for immediate transportation to a referral centre. Important considerations for transport include the distance and duration as well as the overall patient condition, all of which influence whether immediate transport is feasible. In the case of bile peritonitis in particular, the need for urgent laparoscopy or laparotomy and drainage should be assessed. If the patient is unable

⁶Lindemann J, Jonas E, Kotze U, Krige JEJ. Evolution of bile duct repair in a low and middle-income country (LMIC): A comparison of diagnosis, referral, management and outcomes in repair of bile duct injury after laparoscopic cholecystectomy from 1991 to 2004 and 2005 to 2017. *HPB (Oxford)*. 2020;22(3):391-397.

to tolerate transport, then the condition should be optimized according to the referring centre checklist (Table 10.1). When a BDI is diagnosed late in the postoperative course after presenting with chronic sequelae of the injury including obstructive jaundice or cholangitis, again duration, distance and patient condition should be considered and if possible, immediate transportation to a specialized HPB unit should occur. When it is determined transportation will not be tolerated, the patient should be optimized at the referring centre according to the checklist (Table 10.1).

Once the patient arrives at the referral centre a standardized and timely evaluation should follow while any necessary interventions to optimize the patient for major abdominal surgery are simultaneously performed (Table 10.2). A detailed description of a standardized evaluation has been presented in Chapter 2: Methods. Briefly, cross-sectional imaging should be obtained either as CE-CT, MRI/MRCP or both to evaluate the presence of a concomitant vascular injury and, in the case of MRCP, the biliary anatomy. Control of the biliary fistula or drainage of an obstructed biliary system should occur early in the treatment course, preferably with PTC and PTBC placement if the service is available. Biliary anatomy can also be assessed at the time of PTC. When indicated, ERC can be a useful diagnostic and therapeutic intervention, for example in the case of a suspected cystic stump leak related to a retained common bile duct stone. Finally, a sinogram through surgical or percutaneously placed drains can be useful in identifying the extent of the injury. Optimal nutritional status is critical to ensuring a successful HJ repair and an uneventful postoperative course and nutritional supplementation is recommended.

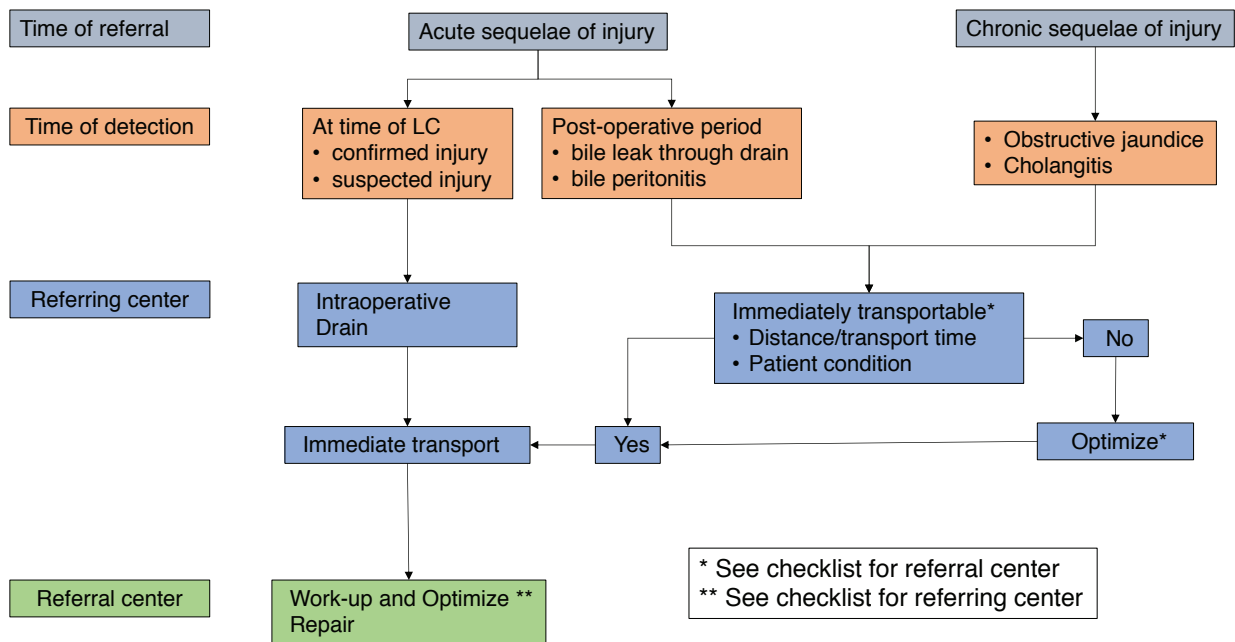


Figure 10.1. Proposed algorithm for management of laparoscopic cholecystectomy bile duct injuries in low- and middle-income countries.

LC – laparoscopic cholecystectomy

Original source: Lindemann J, Jonas E, Kotze U, Krige JEJ. Evolution of bile duct repair in a low and middle-income country (LMIC): A comparison of diagnosis, referral, management and outcomes in repair of bile duct injury after laparoscopic cholecystectomy from 1991 to 2004 and 2005 to 2017. *HPB (Oxford)*. 2020;22(3):391-397. DOI: <https://doi.org/10.1016/j.hpb.2019.07.009> and reproduced according to the CC-BY-NC-ND license.

Table 10.1. Checklist for referring centre.

Information needed to make transport decision	Yes	No
Is the patient transportable (consider patient condition as well as mode and duration of transport)		
If no, optimize according to the patient’s condition:		
(1) Antibiotics; must cover gram negative and anaerobic organisms		
(2) Percutaneous US-guided drainage for localized bile collection		
(3) Laparoscopy or laparotomy with washout and placement of drains for generalized bile peritonitis (do not attempt to identify the injury)		
Transfer immediately to referral centre as soon as patient is able to tolerate the transport		

US – ultrasound

Table 10.2. Checklist for referral centre.

Anatomical mapping (biliary and vascular)	Yes	No
Has the extent of the injury been confirmed?		
If no, consider: MRCP PTC ERC Cholangiogram through percutaneous or surgically placed external drain		
Has a vascular injury been excluded?		
If no, consider CE-CT with both arterial and venous phases		
Sepsis		
Has abdominal sepsis been treated sufficiently?		
If not, consider: PTC drainage for cholangitis of biliary tree Percutaneous drainage of intra-abdominal collections Laparoscopy or laparotomy with washout and placement of additional drains		
Nutritional status		
Is the patient's nutritional status optimal for a surgical procedure?		
If not, consider: Enteral supplementation (via nasogastric or nasojejunal feeding tube if necessary) If enteral nutrition not possible or sufficient, then TPN		

CE-CT – contrast-enhanced computed tomography, ERC – endoscopic retrograde cholangiography, MRCP – magnetic resonance imaging cholangiopancreatography, PTC – percutaneous transhepatic cholangiogram, TPN – total parenteral nutrition

10.3 Discussion

The current chapter presents an evidence-based treatment algorithm that aims to provide guidance and advise appropriate actions at critical time points in the management of patients with LC-BDIs. This includes time from the detection of the injury at the referring unit to the management and definitive surgery at the tertiary facility. The algorithm was created to be used with two checklists, one for the referring centre and one for the referral centre.

Importantly, the proposed algorithm is based on results from a series of six studies (Chapters 4 to 9) investigating potential factors that may influence patient outcome after LC-BDI in a MIC healthcare system setting. Although also based on previously published literature, the algorithm has been adapted to function within the realities of a resource-constrained, low socio-economic status environment.

Geographic distances in LMICs like South Africa can be vast and many patients do not own or have access to private vehicles. This can result in substantial delays in diagnosis, due to late presentation to hospital and in referral, due to logistical challenges arranging transport (Chapter 5). This is especially true for lower socio-economic status patients receiving treatment in the public sector. Although not statistically significant, a clinically significant difference of 11 days from LC to repair was identified in patients treated in the public compared to the private healthcare sector (Chapter 6). Placing a PTBC and discharging a patient to wait at home for a delayed repair is not always feasible. If a patient develops a complication related to the PTBC or the BDI, transport to the tertiary centre with access to interventional radiology is required. Due to financial constraints, patients may not be able to return to the hospital for the surgery date, further delaying their care. However, as was demonstrated in Chapter 8, two patients referred from more than 1,000 km from the HPB unit underwent successful endoscopic management of LC-BDIs, requiring multiple admissions for stent exchange over a two-year period. This demonstrates an important point that algorithms should not be static, rigid and prescriptive, but rather flexible and adapted to specific logistic and evolving clinical situations such as occur in LMICs.

As a result of the geographic and logistic constraints and an increase in geographically distant referrals, more intermediate and late repairs were performed in the HPB unit in recent years, contrary to the recent trend of early repair (Chapter 4).^{77,136} In a LMIC setting repair should be undertaken when the patient has been optimized for the procedure, rather than performing an obligatory early or late repair. The approach of the HPB unit has consistently been to optimize patients to undertake a repair as early as possible during their initial admission even if that requires an intermediate repair, minimizing hospital stay and duration of treatment. As a consequence, the algorithm for BDI repairs presented here is different from that used in HICs, where intermediate repairs are avoided due to worse outcomes.^{104,108,120}

The level and extent of BDI did not influence the severity of postoperative complications when patients were treated in a specialized HPB unit (Chapter 7). Similarly, patients requiring revision of a biliary-enteric repair performed by the injuring surgeon had comparable short and long-term outcomes to patients undergoing an index HJ repair when patients were treated in the HPB unit (Chapter 9). Incomplete imaging of the biliary tree, a likely scenario when BDI repairs are performed by the injuring surgeon who may not have access or the technical skills to utilise advanced imaging modalities, resulted in a more than

10-fold increase in the odds of loss of patency and failure of the index repair (Chapter 9). Both of these studies provide evidence to support immediate referral to a specialized HPB unit whenever a BDI is suspected.

In conclusion, the proposed algorithm represents guidance for the management of LC-BDIs in a limited-resource setting and is based on thirty years of experience from an HPB unit in South Africa. The algorithm varies slightly from current trends in timing of repair due to the geographic, logistic and socio-economic constraints associated with providing healthcare in a LMIC country.

The Tangible Consequences and Intangible Implications of Bile Duct Injury⁷

11.1 Introduction

The tangible consequences of a BDI are well described and easily measured. Prolonged hospital stay, ICU admission, multiple invasive investigations and interventions, additional operations, and postoperative complications can be calculated, tabulated and reported. Suboptimal surgical intervention and bile duct reconstruction may lead to recurrent ascending cholangitis, secondary biliary cirrhosis and portal hypertension.²⁴⁸ The long-term consequences are emphasized by data from a large, national database study which reported that patients who undergo BDI repair have a substantially decreased survival rate with a four-fold increased long-term risk of dying prematurely from liver disease compared to the general population.²²⁵ Equally important, but more difficult to measure, are the intangible implications of a BDI. The anxiety of undergoing major reconstructive surgery, loss of income compounded by the worry of ever increasing medical bills, protracted recovery and in some cases prolonged and unpleasant litigation are some of the complexities patients with a BDI may face, all of which may result in a significant decrease in HRQoL.^{249,250} Finally, often ignored and seldom reported are the injuring surgeon's emotions of guilt and worry, often aggregated by the prospect of litigation. In total, a BDI is a grievous experience, often resulting in significant personal, financial and medicolegal burdens, the extent of which is difficult to quantify.^{251,252}

11.2 Intangible aspects of bile duct injury

11.2.1 Medicolegal aspects

The threat of litigation looms large in complications following laparoscopic surgery. In no other surgical field has the growth of litigation been as rapid as in laparoscopic surgery, which represents one-third of general surgery indemnity (money paid out by insurers).¹⁴⁹ The vulnerability of BDIs to civil litigation is well known to plaintiffs and more so to the medical malpractice litigation fraternity who view BDIs as low-hanging fruit. Biliary injury ranks first on the list of negligence claims worthy of pursuance. Four studies from the United States by Kern, Chandler, McLean and Carroll have examined litigation following LC.²⁵³⁻²⁵⁶ In the

⁷Lindemann J, Krige JEJ, Jonas E. The tangible consequences and intangible implications of laparoscopic cholecystectomy-associated bile duct injuries. *S Afr J Surg.* 2020;58(01); 4-6.

most recent among these, McLean in 2006 reported an average payment of US \$508,341 in 104 patients where complications followed LC.²⁵⁵ Data from the National Health Service Litigation Authority on clinical negligence claims following LC in the UK showed that 418 claims were made in 2006, of which 303 were settled, two-thirds in the claimant's favour.²⁵⁷ The average pay-out for a successful claim was £102,827.²⁵⁷ However, the application and outcome of medical malpractice litigation vary considerably world-wide. In many European countries, as opposed to the litigation and tort system used in the US, malpractice litigation is conducted through an arbitration system and large settlements are uncommon. In a Dutch study the mean financial settlement for BDI reported in 2008 was €12,795.¹³² In addition to the measurable tangible consequences above, the associated *mea culpa* concerns and moral liability as well as the consequences of litigation may have a detrimental effect on the injuring surgeon's life and psyche. Concerns regarding possible reputational damage to the surgeon's practice may be further compounded by angst, loss of confidence, uncomplimentary media coverage and protracted litigation. Ultimately, both parties, the patient and the surgeon, may become victims as two opposing legal teams quibble, spar and joust for pecuniary advantage and a favourable verdict.

11.2.2 Financial aspects

While the medicolegal issues are often reported and frequently sensationalized in the media, there has been less focus on the socioeconomic impact, in particular from the patient's perspective. In the worst-case scenario, a patient may face financial ruin with severe repercussions, especially where he or she is the (sole) breadwinner for an extended family. The financial consequences can be substantial for the healthcare provider, the injuring surgeon, malpractice insurance companies and, not least, the patient. An analysis of the available information on cost, including studies from the USA, Belgium and India, emphasizes that the total cost of BDI repair is considerably greater than an uncomplicated LC and the quantum increases with delayed diagnosis of the injury and with an inadequate repair, which is often the case when the repair is performed by the injuring surgeon.²⁵⁸ Savader et al. in 1997 reported that the mean cost of a definitive bile duct reconstruction was \$51,411 and ranged from 4.5 to 26 times the cost of an uncomplicated LC.¹⁰² South African data on the cost implications of a LC-BDI are limited. In a Cape Town study from 2015, total mean cost with adjustment for inflation in a cohort of 44 patients with a major BDI repaired HJ, was R 215,711 which is 6.4 times the cost of an uncomplicated LC and the most expensive repair amounted to R 980,830 after an 86-day hospital stay.¹³⁴ Accumulated costs before referral

may also be substantial, including imaging, intervention for complications and an unsuccessful initial attempt at a definitive repair of the injury. Importantly, no studies have accounted for costs of management before referral.^{102,134}

Whereas there are data on the costs incurred for the healthcare provider and the magnitude of financial settlements by the injuring surgeon and/or insurance companies as has been shown, there is little in-depth information from the patients' perspective. An aspect frequently overlooked is the paucity of data on the indirect and personal costs incurred by the patient after a BDI. These include diverse costs such as loss of income due to time off from work, travel expenses, medical fees, rehabilitation and litigation. Loss of income may also extend to a partner or spouse involved in a supportive capacity who may need to travel long distances between home and healthcare facilities.¹³⁴ In a worst-case scenario inability to return to his or her profession may result in permanent loss of income.

11.2.3 Health-related quality of life

HRQoL, a cumulative consequence of the above factors, has also received considerably less attention. While there are numerous publications on BDIs, only 12 have investigated HRQoL after BDI, the findings of which are summarized in Table 11.1.^{118,126-128,130,131,133,249,259-262}

Assessing HRQoL is important and relevant as this quantifies the impact and consequences of a BDI from the patient's perspective, reflects self-perception of well-being and considers functionality, relief of a particular symptom, emotional status, social role, and mental health.²⁶³ Previous studies on HRQoL outcome after BDI have reported discordant results, with some showing no difference between patients with LC-BDI and those who had an uneventful LC, while others report significant long-term reductions in both physical and mental HRQoL.¹²⁹ This discordance may be due to underpowered designs, patient selection, selection bias and inclusion of heterogeneous populations treated with either endoscopy, interventional radiology or surgery.²⁶⁴ In the first detailed analysis of the impact of LC-BDI on HRQoL, the Amsterdam group used the Short Form 36 Health Survey® (SF-36) and reported worse physical and mental HRQoL compared to a cohort of patients with uncomplicated LC and average general population values.¹³⁰ These findings were later replicated in an expanded sample by the same group and were similar to a report from Moore et al., showing worse short form (SF)-36 physical and mental HRQoL in patients with BDI compared to patients with uncomplicated LCs.^{126,249} In a study that used the modified City of Hope HRQoL assessment tool, Melton et al. however, reported worse mental HRQoL in

patients with BDI but similar physical and social HRQoL when compared with a healthy cohort.¹³³ This is in contrast to a report by Sarmiento et al. which reported no difference in HRQoL after a minimum of 5 years follow-up between patients who underwent BDI repair and those who underwent an uncomplicated LC.¹²⁷ Similarly, Hogan et al. concluded that the HRQoL of patients after BDI repair compares favourably with that of patients who underwent an uncomplicated LC.^{127,128}

Two systematic reviews, one published in 2013 by Landman et al. and another currently in press by Halle-Smith et al. concluded that given the current available evidence, it is difficult to make any conclusions about the influence of BDI on HRQoL.^{129,264} The Landman paper, after controlling for length of follow-up, found there was no difference between matched BDI and uneventful LC patients in the physical composite HRQoL score.¹²⁹ However, patients with BDI were 38 times more likely to have a decreased mental composite score and this reduced score did not seem to improve over time. Halle-Smith et.al. concluded that the effect of BDI on HRQoL remains unclear, but that it is possibly related to the severity of the injury and whether a surgical repair was performed, a conclusion that seems plausible despite several studies that conclude the contrary.²⁶⁴

A number of additional factors preclude comprehensive investigation of this important and relevant topic. No disease-specific HRQoL survey tool for patients with BDI exists, and although the SF-36 and Gastrointestinal QoL (GiQLi) surveys are the most commonly used, there remains a significant degree of variability in HRQoL surveys between studies. In addition to defining a suitable reference group, the timing of survey administration could influence HRQoL scores and should be considered in the interpretation of results. Finally, patients with all types of BDIs are often included in HRQoL studies which results in comparison of HRQoL in a wide range of patients from those with minor bile leaks that resolve with conservative management to patients with major BDIs requiring surgical repair.

The relationship between litigation and HRQoL after BDI is also important to consider. In two HRQoL studies that included litigation as a potentially influential factor, litigation was found to have a negative impact on HRQoL scores compared to patients with BDI who did not pursue litigation, patients with uneventful LCs and healthy population controls.^{126,133} Melton et al. have shown that patients with a BDI who are involved in legal proceedings have a poorer HRQoL.¹³³ In the largest study to date, including 800 BDI patients, the Amsterdam

group reported a significant reduction in HRQoL in patients involved in malpractice litigation, but interestingly, significantly better HRQoL when the verdict of the malpractice claim was in the patient's favour compared to when it was not.²⁴⁹

11.3 Discussion

The tangible consequences and intangible implications of BDI can be minimized by early recognition of the injury and referral to a surgeon with experience in management of the complication in a facility with the necessary multidisciplinary support.²⁶⁵ The findings in the Cape Town study, where the BDIs in more than half of referred patients were only recognized after five days and in three quarters of patients were associated with sepsis due to cholangitis or biliary peritonitis, reinforce the maxim that all LC patients who have any deviation from the expected postoperative course, notably postoperative abdominal symptoms, require thorough assessment and investigation to exclude an iatrogenic BDI.¹³⁴ Analysis shows that socio-economic and litigation implications of a major BDI incurred during LC remain a serious concern for patients, surgeons, healthcare providers and employers and is associated with long-term HRQoL impairment as well as increased costs with repercussions lasting years after repair. The ensuing consequences may lead to litigation which results in a substantial financial drain on healthcare and insurance systems. In order to minimize these unfortunate and wholly preventable consequences in the future, it behoves surgeons to make a BDI after LC a rare event.

Table 11.1. Summary of study characteristics and findings for HRQoL after bile duct injury.

Author (year)	Study Design	Operation (n)	BDI type (n)	Management (n)	HRQoL Tool	Response Rate	Primary outcome for BDI cohort (IQR)	Follow-up, months (range); [IQR]	Additional Findings
AbdelRafee (2015) ¹¹⁸	retrospective cohort	OC (109) LC (7) LC to OC (4)	“major” BDI	surgical (120)	SF-8	NR	PCS: 41.0 ± 8.9 MCS: 48.4 ± 7.3	149 (7-246)	Complicated HJ PCS: 35.54 Uncomplicated HJ PCS: 42.15
Boerma (2001) ^{259,a}	prospective cohort	LC (89)	AMC type: A (36) B (24) C (15) D (31)	endoscopic (69) surgical (31)	SF-36	92%	PCS: 38.4 MCS: 40.5	70 (37-110)	Control PCS: 51.5 Control MCS: 54.9 (all p < 0.05)
Booij (2018) ^{249,a}	case-control	OC (79) LC (477) LC to OC (244)	Strasberg: A (216) B (15) C (36) D (130) E (403)	endoscopic (398) radiologic (96) surgical (272) other (34)	SF-36 GiQLi WLQ	BDI: 63% control: 54%	PCS: 46.3 (IQR 36.3-54.7) MCS: 52.1 (IQR 42.8-56.2) GiQLi: 116 (IQR 96-127) WLQ: all p < 0.05	BDI: 4.3 [1.3-10.3] yrs Control: 10.0 [9.1-10.8] yrs	Control PCS: 53.9 (IQR 44.3 – 57.6) Control MCS: 53.0 (IQR 48.2-56.3) Control GiQLi: 127.0 (IQR 115.0 – 139.0) (p < 0.05 for PCS, GiQLi)
de Reuver (2008) ^{130,a}	case-control	OC (24) LC (254)	AMC type: A (69) B (48) C (30) D (131)	endoscopic (130) radiologic (45) surgical (103)	SF-36 GiQLi	BDI: 69% control: 70%	PCS: 44 ± 12 MCS: 47 ± 11	5.9 ± 3.8 yrs	Higher MCS for LC control, higher PCS and MCS for general population control; higher GiQLi score in LC-control (all p < 0.05)
Dominguez-Rosado (2014) ²⁶⁰	case-control	NR	Strasberg: E (88)	surgical (88)	SF-36	group 1: 31% group 2: 57%	Higher scores, all domains preoperatively vs 1, 5, 10 yrs follow-up (all p < 0.05)	NR	Patients with BDI did not reach population norms on the SF-36 even after 10 yrs follow-up
Ejaz (2014) ²⁶¹	self-controlled case series	LC (40) LC to OC (21)	Bismuth: I (6) II (21) III (11) IV (8) V (12)	surgical (62)	SF-36 GiQLi	37%	Improved mood and energy levels after repair at median 14 yrs follow-up (all p < 0.05)	169 [125-222]	72% uninformed about BDI risk 67% biliary tubes interfered with daily life 44% suffered financial hardship

Flores-Rangel (2018) ²⁶²	case-control	NR	“major” BDI	surgical (49)	SF-12	BDI: 94% control: 76%	Worse general health, physical functioning, limitations due to physical problems, social functioning (all p < 0.05)	BDI: 49.5 (12-162) Control: 57.6 (14-240)	BDI patients felt their HRQoL was significantly worse after BDI
Hogan (2009) ¹²⁸	case-control	OC (21) LC (57)	Bismuth: I (12) II (40) III (13) IV (12) V (1)	endoscopic (1) radiologic (4) surgical (73)	SF-36	BDI: 79.5% control: 100%	No statistically significant difference in PCS or MCS between two groups	BDI: 0.7 (0.2-20) yrs LC: 2.3 (2-2.8) yrs	No difference in HRQoL scores on subgroup analysis by method of intervention; borderline worse mean emotional scores (p = 0.045)
Melton (2002) ¹³³	case-control	LC (89)	“major” BDI	surgical (89)	CHMC QoL	BDI: 61% LC: 50% control: 45%	Psychological domain BDI: 77% LC: 85% control: 84% (all p < 0.05)	BDI: 59 ±33 LC: 43 ±14	No significant differences found on subgroup analysis of clinical and management factors; filing a lawsuit negatively impacted all 3 domains
Moore (2004) ¹²⁶	retrospective cohort, case-control	LC (86)	Bismuth: I/II (20) III/IV/V (30)	endoscopic/ radiologic (13) surgical (37)	SF-36 PAIS	BDI: 58% control: NR	Lower score across SF-36 domains, PCS and MCS (p < 0.05) Similar global score, lowers healthcare orientation, domestic environment (p < 0.05)	BDI: 62 ±6 LC: 47 ± 3	Karnofsky PS: worse for BDI (p < 0.001) statistically significant difference in PCS/MCS for patients who did and did not file lawsuits
Rystedt (2016) ¹³¹	matched case-control	LC (106)	Hannover Grade A excluded	endoscopic (7) surgical (99)	SF-36	BDI: 64% control: 59%	Similar scores in all domains, MCS, PCS	BDI: 4.3 (2-6.9) yrs	Later repair/referral resulted in worse PCS (p=0.002), similar MCS
Sarmiento (2004) ¹²⁷	case-control	LC (59)	Strasberg: B (2) C (1) D (2) E (54)	surgical (59)	SF-36	BDI: 82% control: 80%	Similar scores in all domains	BDI: 8.4 (5.2-11.4) yrs control: 9.1 (6-11.8) yrs	No significant clinical characteristics affected PCS or MCS values for BDI patients in subgroup analysis

^aCohorts of patients from Boerma²⁵⁹, Booij²⁴⁹ and de Reuver¹³⁰ studies may represent duplications

AMC – Amsterdam Medical Center, BDI – bile duct injury, CHMC QoL – City of Hope Medical Center quality of life, GiQLi – gastrointestinal quality of life index, LC – laparoscopic cholecystectomy, LC to OC – laparoscopic converted to open cholecystectomy, MCS – mental composite score (reference to general population = 50), OC – open cholecystectomy, PAIS - psychosocial adjustment to illness scale, PCS – physical composite score (reference to general population = 50), SF – short form, WLQ - work limitation questionnaire

The Role of Visual Misperception in Laparoscopic Cholecystectomy Bile Duct Injury

12.1 Rationale

Despite three decades of experience and extensive research on the topic, the explanation for the increased rate of BDIs in LC remains elusive. Initially, the “learning curve” of LC was thought to be the main contributor, but after several years of experience beyond the curve, the incidence of BDIs in LC remained higher than what had been previously reported for OC.^{24,28,196} Attention then turned to the concept of intraoperative visual misperception where the common bile duct is mistaken for the cystic duct and divided.^{40,55,266} Finally, researchers asked the question of whether the inexperience of surgical trainees at academic centres might be contributing to the increased incidence.²⁶⁷⁻²⁶⁹ This proved not to be the case and visual misperception was left as an important contributor to the higher BDI incidence in LC.

The phenomenon of subconscious, automatic processing of perceived visual images in the brain in the setting of LC-BDI was ingeniously described by Way et al. in 2003.⁵⁵ Briefly, the surgeon has stored in his or her long-term memory a mental model of the biliary tree.⁵⁵ Intraoperatively, as the surgeon examines the gallbladder and surrounding anatomy to identify the cystic duct, the subconscious brain matches the perceived intraoperative images with the stored biliary tree model.⁵⁵ However, the intraoperative view is often incomplete, with connective tissue, fibrosis, inflammation and/or blood obscuring the anatomy.⁵⁵ The brain subconsciously fills in the missing pieces based on the stored mental image of the biliary tree and a decision about anatomy is made.⁵⁵ This interpretation of anatomy occurs at a subconscious level, which means there is no opportunity for introspective or objective analysis, unless intraoperative findings that contradict the conclusion that the identified structure as the cystic duct are made and acted upon before the BDI occurs.⁵⁵ Alternatively, as has been advocated by, among others, the SAGES Safe Laparoscopic Cholecystectomy Program, the assistant or other members in theatre should state that they either agree or disagree with the CVS during an intraoperative “time out” prior to clipping the duct.^{161,270,271} This provides an opportunity for correction of the visual misperception, assuming the observers have not also made the same error in interpretation of the biliary anatomy.

Automatic processing by the brain has its advantages, namely efficiency and predictability. The downside, however, was well stated by Reason in his 1990 book on human error, “The

price we pay for this largely automatic processing of information is that perceptions, memories, thoughts and actions have a tendency to err in the direction of the familiar and the expected.”²⁷² In the case of LC, this can be particularly dangerous given the frequency of distorted or anomalous anatomy due to acute and/or chronic inflammation, fibrosis and aberrant biliary and vascular anatomy, the latter of which are almost as common as the “classic” anatomy most general surgeons have stored in their long-term memory. To investigate the potential effect of intraoperative visual misperception in LC-BDIs referred to a specialized HPB unit, a detailed review of all available LC operative notes of LC-BDIs from 1991 to 2020 was performed.

12.2 Methods

A retrospective review of referral documentation for patients treated in the HPB unit from 1991 to 2020 was performed. The final cohort consisted of patients with LC operative notes included in the original referral documents. General patient characteristics including age, gender, indication for LC, timing of BDI diagnosis and Strasberg type of injury were retrieved from the BDI database. Operative notes were classified as “informative” or “uninformative” based on whether intraoperative conditions resulting in difficulty identifying anatomy and the anatomical rationale for how the cystic duct was identified were included, similar to a previously described method.⁴⁰ Operative note length presented as median number of words up to the end of the description of division of the cystic duct and artery for informative and uninformative notes was determined. Patient and operative factors that might have contributed to the BDI were recorded and included the presence of severe acute and/or chronic inflammation, fibrosis, adhesions, gallbladder wall thickening, tense or distended gallbladder, stone impaction, aberrant anatomy, significant bleeding, whether the CVS method^{40,271} or the infundibular technique⁴⁰ was used and the anatomic rationale for determining which structure was in fact, the cystic duct.

12.3 Results

Twenty-two LC-BDI operative notes were available for review. Of the included patients, 17 (77%) were female and the median age was 42 (26-59) years. The majority (n = 19) of the LC operations were scheduled as elective. The most common indication for LC was acute cholecystitis (n = 8) followed by biliary colic (n = 7), chronic cholecystitis (n = 3), choledocholithiasis (n = 2) and gallstone pancreatitis (n = 2). Of the three LCs performed during the same admission, one was for acute cholecystitis, one for gallstone pancreatitis and

another for biliary colic. Fifteen of the LC-BDIs were diagnosed intraoperatively and the remainder were diagnosed at a median of 3 (1-7) days postoperatively. There were two Strasberg type A, one type C and one type D injuries with six type E1, eight type E2, two type E3, and two type E4 injuries.

Three (14%) of the 22 LC-BDI operative notes were considered informative, and in all three the infundibular technique for identifying the cystic duct was described. In the remainder of the operative notes, insufficient information precluded conclusions about how the cystic duct was identified. The median number of words up to the end of the of division of both the cystic duct and artery was 59.5 (9-293; IQR 19.5-71)) words for all 22 operative notes, 121 (68-293; IQR 94.5-207)) words for the 3 informative operative notes and 46 (9-131, IQR 17-68) words for the 19 uninformative operative notes. Eighteen notes included a description of at least one intraoperative factor that led to difficulty, the findings of which are summarized in Figure 12.1. The most commonly reported difficulty was extensive adhesions followed by severe inflammation and stone impaction, all of which were often reported in combination. Some form of change in the gallbladder, including wall thickening, distention or a shrunken gallbladder were reported in eight notes. Aberrant anatomy and a shrunken gallbladder did not appear to be associated with the more commonly reported intraoperative difficulties.

	Adhesions	Severe Inflammation	Stone impaction	Fibrosis	Bleeding	GB wall thickening	Distended GB	Shrunken GB	Aberrant anatomy
1	x	x					x		
2	x		x	x	x	x			x
3	x								
4	x								
5	x	x	x		x		x		
6	x	x	x						x
7	x	x							
8	x		x	x		x			
9	x		x	x					
10		x	x		x			x	x
11		x	x			x			
12		x							
13			x						
14			x						
15				x		x			x
16					x				
17								x	x
18									x

Figure 12.1. Summary of reported intraoperative difficulties from 18 laparoscopic cholecystectomy bile duct injury operative notes. Each horizontal line numbered 1-18 represents a LC operative note. An “x” indicates the intraoperative difficulty was reported.

GB – gallbladder

12.4 Discussion

The HPB unit has received over 200 referrals for LC-BDIs over the last 30 years. The majority of patients referred for further management of suspected LC-BDIs arrived with a referral letter, but no operative note. As evident in this analysis, when operative notes are sent with the patient, they are often uninformative, without an adequate description of the operative technique and anatomical reason for determining which structure is the cystic duct. For those few notes which provided sufficient detail, the infundibular method to identify the cystic duct was used in all three.

In the infundibular technique, the cystic duct is isolated through dissection of the triangle of Calot and then traced back to the point at which it joins the gallbladder.⁴⁰ Confirmation that the structure is indeed the cystic duct relies on the recognition of the characteristic funnel shape as the cystic duct widens to become the gallbladder infundibulum.⁴⁰ There is no requirement to identify the cystic artery and confirm two and only two structures entering the gallbladder prior to clipping and dividing the cystic duct, unlike in the CVS method. The problem with the infundibular method is that it is unreliable, particularly when the cystic duct is obscured by severe gallbladder inflammation or scarring.⁴⁰ This “hidden cystic duct” syndrome, as described by Strasberg et al., makes use of the infundibular technique during LC dangerous, particularly in an age where LC for cholecystitis is increasingly being performed in the acute setting.⁴⁰

The phenomenon that results in visual misidentification of the cystic duct is a direct result of automatic processing. In the case of inflammation or fibrosis, the cystic duct can contract and the funnel shape created by the natural division of the common bile duct into the cystic and common hepatic ducts can have a similar appearance to the cystic duct joining the infundibulum. The surgeon recognizes the characteristic flare of the duct as it appears to be entering the gallbladder. Convinced that the cystic duct has been positively identified, a BDI is a *fait accompli* as the erroneously perceived cystic duct is clipped and divided. While the surgeon perceives the dissection is taking place at the edge of the gallbladder based on visual cues and past experience, dissection is actually occurring on the common bile duct at the edge of an inflammatory mass, within which the cystic duct is located.⁴⁰ In one of the three informative operative notes reviewed in this study, a surgeon manifestly describes this visual misperception:

“It would appear that in reconstructing the cause of the mishap that an exceptionally short cystic duct was present. This was drawn up into Calot’s triangle by the fibrosis and lay posterior to Hartmann’s pouch – thus erroneously giving the impression that the common bile duct actually inserted directly into the fundus of the gallbladder. A clear infundibulum had been seen – obviously in error.”

In addition to severe inflammation, other factors previously identified as risk factors for BDI using the infundibular technique include adhesions, difficulty grasping the gallbladder to retract and expose the triangle of Calot, large impacted stones and Mirizzi syndrome.⁴⁰ Although 19 of the operative notes did not include adequate detail to determine the operative technique used to identify the cystic duct, 18 did report at least one of the previously mentioned contributing factors.

The CVS method, first proposed by Strasberg et al. in 1995,⁴³ was recommended as the gold standard method for performing a LC in a literature review published 15 years after the method was first described.¹⁴¹ In the review, four studies including over 4,500 patients reported a BDI incidence of between 0% and 0.03%, much lower than even that reported during the era of OC.^{12,141} In the absence of the highest level of evidence from randomized controlled trials, the CVS method remains the gold standard for identifying the cystic duct in LC.¹⁴⁰ Out of the 22 available operative notes reviewed in this study for LC-BDIs, not one included a description of achieving all three elements of CVS.

The findings of this detailed review of 22 LC-BDI operative notes demonstrate the potential peril of not following best practices for performing LC, especially in circumstances of severe inflammation. The CVS method, while not supported by level I evidence, has nonetheless been shown to be a safe and reliable method for minimizing BDI in LC. Accordingly, an intervention that standardizes the way LC is performed in an effort to make best practice a habit, is likely to have the desired effect of making an LC-BDI a near-never event in the future.

13.1 Rationale

“To Err is Human” highlighted deaths in US hospitals from avoidable medical errors and generated a global surgical interest in improving patient safety given the increasing complexity of surgical care delivery and the associated risk of adverse events.²⁷³ Based on the established efficacy for safety in the airline industry, checklists were introduced into surgical practice. The World Health Organization Surgical Safety Checklist, perhaps the most widely used surgical checklist, was specifically designed to decrease errors, reduce adverse events and improve communication and teamwork in the operating theatre, and has resulted in a significant improvement in surgical morbidity and mortality.²⁷⁴

LC is one of the most common laparoscopic procedures performed by general surgeons in South Africa, but the national annual number of LCs is unknown. At GSH, where between 170 and 180 LCs are performed annually, the BDI incidence for 2018 was 0.6%, higher than recently reported rates (Chapter 3).^{27,32} As a common general surgery operation with potential for significant morbidity, LC is an ideal operation for checklist design and implementation. Achieving the CVS in LC has been shown to prevent BDIs in large patient cohorts.^{139,142,275} Therefore, the three key anatomical elements of the CVS namely, a hepatocystic triangle free of fibrous and fatty tissue, two and only two structures entering the gallbladder and a visible distal 1/3 of the cystic plate, should be included in a procedure-specific intraoperative checklist.⁴³

However, the literature suggests that a lack of technical skills and experience alone do not explain the number of BDIs occurring annually.⁵⁵ Non-technical skills in surgery, including situational awareness, decision making, communication and team work, and leadership, have been identified as essential to a successful outcome in surgery.²⁷⁶ Detailed retrospective analysis of video and operative notes from LCs during which the bile ducts were injured show that BDIs often occur due to a misperception of the biliary anatomy.⁵⁵ Evidence to support this conclusion was presented in Chapter 12 after review of LC operative notes included in BDI referrals to the HPB unit. The anatomical details of so-called “error traps” in intraoperative visual misperception were more fully defined by Strasberg and provide further evidence supporting the value of using the CVS technique.^{43,266}

A recently proposed checklist by Connor et al. addresses both the technical and non-technical skills required to perform a safe LC.²⁷⁰ The checklist includes a pre-incision component, composed of an intraoperative verbal statement of relevant radiological findings, liver function blood results and acknowledgement of whether the case is expected to be difficult.²⁷⁰ Before dissection of the hepatocystic triangle, there are five important surgical steps that should be performed to ensure the dissection begins in a standardized fashion and at a safe level.²⁷⁰ Before clipping the cystic duct, the three elements of the CVS need to be achieved.²⁷⁰ The five dissection steps and the three elements of the CVS must be confirmed with the assistant before proceeding.²⁷⁰ The checklist facilitates communication between the surgery and anaesthesia teams and theatre staff, addressing the non-technical skills of communication, teamwork and leadership while also providing a series of technical surgical steps aimed at overcoming the visual misperception implicated in BDIs.

An important study by Wauben et al. found that operative notes rarely reflect what actually occurred during LCs.¹⁴⁶ Similar findings were shown in the detailed analysis of LC-BDI operative notes from patients referred to the HPB unit (Chapter 12). The Dutch have led the way in advocating for intraoperative video documentation of the CVS to be a part of the operative record. However, storage and regular review of intraoperative videos is time and resource intensive. An alternative method of capturing the CVS using intraoperative photos has been shown to allow for accurate recording of the CVS.¹⁹³ The advantages of this method over intraoperative video recordings are the clearly defined steps to taking optimal intraoperative photos, the accompanying primer for teaching the “doublet” photography method and the simple, easy to use scoring method to assess the quality of the CVS.¹⁹³

In the doublet photography method, after the surgeon confirms with the assistant that the CVS has been achieved, he or she takes a photo of the anterior and posterior view of the hepatocystic triangle to capture the three elements of the CVS.¹⁹³ These photos then become a part of the medical record to improve representation of intraoperative conditions as described in the operative note.¹⁹³ The study also proposes a simple six-point scale scoring system for assessing the quality of the images, where the three elements of the CVS can receive up to a total of two points each for a maximum overall score of six.¹⁹³ A high degree of agreement (96.4%) between reviewers using the CVS scoring method has been shown, however formal validation using reliability statistics was not performed.¹⁹³

An intraoperative checklist adapted from the one proposed by Connor et al., a standardized operative note and mandatory intraoperative photo documentation of the CVS were implemented at our centre in September 2019. A database was created to capture patient characteristics, operative data and 30-day postoperative complications and re-admissions for all LCs performed. The purpose of the intervention was to ensure a minimum quality of performance for a routinely performed general surgery operation. The LC database served as a means for regular audits to assess adherence and quality. Through this change of practice, the goal was to create a culture of safety for LCs and make BDIs a near-never event by overcoming visual misperceptions, guiding intraoperative decision making, and encouraging teamwork and communication.

Measuring the quality of an operation is challenging and often only achievable indirectly through analysis of the postoperative course including length of stay and complications. For LC-BDI in particular, it is especially difficult to measure a decrease in BDI rate without several years of data as it is an uncommon event. The purpose of this study was to perform an audit of the first four months after the change in practice was implemented using data collected in the LC database. The primary aim was to determine initial scores of the CVS photos and explore any potential for quality improvement. Secondary aims included adherence to the checklist and analysis of 30-day postoperative complications and re-admissions.

13.2 Methods

13.2.1 Development of the checklist

The previously published checklist by Connor et al. was adapted for local use after discussion in a forum including the researcher and all general and HPB surgeons at GSH, a tertiary academic hospital in Cape Town, South Africa.²⁷⁰ The resulting modifications included minor changes in terminology to match what is locally used, the addition of common reasons for a difficult cholecystectomy, simplification of important findings on IOC, the addition of mandatory capture of intraoperative CVS photos, and new sections on informed consent, bailout techniques and what to do if a BDI is recognized intraoperatively. With group consensus, the modified checklist was finalized prior to the start of the study and the final version can be found in Appendix B.3.2

13.2.2 Development of the standardized operative note

A standard LC operative note was created by the same forum of general and HPB surgeons. In addition to ensuring complete documentation of the surgical procedure, the operative note was also created for use as a data collection sheet. Basic demographic information and important clinical information such as indication, duration of symptoms, timing of the operation and patient comorbidity were included. To maximize the effectiveness of the checklist, the intraoperative elements were built into the standard operative note which encouraged repetition, in an effort to make best practice a habit. During the study, biweekly meetings were held to review captured data and to refine the standardized operative note until data capture was optimized. The final version of the operative note can be found in Appendix B.3.3.

13.2.3 Collection and scoring of “doublet” photos of the critical view of safety

Visual documentation of the CVS was implemented using the method previously published by Sanford and Strasberg.¹⁹³ Briefly, following dissection of the CVS and prior to placing clips on the cystic duct and artery, the neck of the gallbladder should be swung left and right by the surgeon to confirm the CVS can be visualized from the front and behind.¹⁹³ Anterior and posterior photos of the CVS are taken.¹⁹³ To enable a reviewer to have adequate perspective of the operative field, the entire hepatocystic triangle and lower one-third of the cystic plate should be included in both photos.¹⁹³ The two photos, along with a photo of the standardized operative note were then sent using WhatsApp to the LC database group maintained by the researcher. Surgeons were given the option to take intraoperative videos rather than photos of the anterior and posterior CVS. To minimize risk of exposure of patient-sensitive information, intraoperative photos and/or video on the WhatsApp group were deleted on a weekly basis after being uploaded to the LC database.

The CVS photos and/or videos were scored by four blinded reviewers, two general surgeons and two HPB surgeons, using the scoring system described by Sanford and Strasberg.¹⁹³ Prior to scoring, each of the blinded reviewers were asked to read the manuscript and supplemental PowerPoint presentation by Sanford and Strasberg.¹⁹³ The presentation included an anatomy review and detailed description of the scoring system with several examples of annotated photos of the CVS for practice scoring. In summary, each doublet photo could earn a total of six points, two points for each of the three elements of the CVS.¹⁹³ Two points were awarded if the criterion was immediately and clearly recognized in the photo.¹⁹³ A single point was

given if detailed assessment was required to identify the criterion due to instrument overlap, poor image quality, or partial visualization.¹⁹³ If the criterion was not visible, no points were awarded.¹⁹³ A score of at least five was considered satisfactory.¹⁹³

13.2.4 Patient follow-up

All patients who underwent LC over the duration of the study were followed to 30-days postoperatively. Length of hospital stay, surgical and non-surgical 30-day complications and re-interventions, as well as re-admissions were captured. Re-interventions also included post-LC ERC for stones noted on IOC. Each patient's medical record was reviewed at 30-days post-LC to confirm complications, re-interventions and re-admissions, and prevent inaccurate or missing data due to loss of follow-up.

13.2.5 Implementation

The intervention, including a detailed presentation on anatomy, photo capture and scoring of the CVS, was presented to all consultants and registrars performing LCs prior to initiation of data collection. The presentation was repeated when new registrars rotated through the surgical team. LC packets were created that included a standard procedure consent form, the study consent form, the LC checklist and the standardized operative note. Each ward where patients were admitted preoperatively received a clearly labelled folder with prepared LC packets. Before the patient was taken from the ward to theatre, the necessary consent forms and preoperative portions of the checklist needed to be completed. Intraoperatively, the CVS photos and/or video were taken on the cell phone of a member of the surgical team. Postoperatively, the standard operative note was completed and a photo was taken. Photos of the signed study consent form, operative note and CVS were then sent to the LC WhatsApp group.

13.2.6 Data capture

The data from WhatsApp were entered into the REDCap LC database described in Chapter 1. The database fields were identical to the standardized operative note form. The intraoperative CVS photos and videos were uploaded on a separate instrument in REDCap to allow blinding of the four reviewers. Thirty-day follow-up was entered on a third instrument and included fields for date of discharge, surgical and non-surgical complications, type (endoscopic, radiologic, surgical) and findings of any re-interventions, and re-admissions. For the four blinded reviewers, REDCap access was limited to only the CVS photo and/or video upload

and their own blinded reviewer data collection instruments. Reviewers were reminded monthly via email to score all new database entries, with additional reminder emails when required.

13.2.7 Ethics approval and patient consent

The HREC approved the LC database and the retrospective audit (see Chapter 1). Patient consent included agreement to collect clinical data and the transfer of patient health information using the cell phone application WhatsApp. The HREC-approved consent form can be viewed in Appendix B.3.1.

13.2.8 Data analysis

Continuous variables are presented as mean with standard deviation. Non-parametric continuous variables are presented as median with range and interquartile range, and categorical variables are shown as number and percent. Compliance was reported as the proportion (%) of operative notes with the specified variable documented and overall compliance was reported as the proportion (%) of operative notes with all of the required variables documented. For bivariate analysis, the Mann–Whitney U test for non-parametric continuous variables and Fisher’s exact for categorical variables were used. A p-value of < 0.05 was considered significant. All statistical analysis was performed using SPSS version 25 (IBM SPSS Statistics, IBM Corporation, Armonk, NY).

13.3 Results

13.3.1 Study patient characteristics

Clinical characteristics of the patients included in this study are presented in Table 13.1. There were 58 LCs performed in the four months following the intervention. The median age of included patients was 42.5 (17-77) years and 82.8% (n = 48) were female with a median BMI of 33.05 (20.8-53.3). Most (n = 49, 84.5%) of the LCs were scheduled as elective cases and the median length of time from treatment decision to the day of surgery was 35 (0-318) days. Biliary colic (58.6%) and acute cholecystitis (25.9%) were the two most common indications and accounted for 49 (84.5%) of the LCs performed. Over half (58.6%) of patients were reported as having at least one comorbidity. In 51 patients a standard LC was performed and in 7 a subtotal LC was performed as a bailout procedure.

Table 13.1. Clinical characteristics of the patients who underwent laparoscopic cholecystectomy after checklist implementation.

Clinical characteristic	Patients, n = 58 (%) or median (range); (IQR)
Age, years	42.5 (17-77); (32.35-56.75)
Sex, female	48 (82.8)
Timing of operation	
Elective	49 (84.5)
Same admission	9 (15.5)
Days from booking to operation	35 (0-318); (5-196)
Indication	
Biliary colic	34 (58.6)
Acute cholecystitis	15 (25.9)
Gallstone pancreatitis	4 (6.9)
Cholangitis	1 (1.7)
Duration of symptoms, days	120 (2-370); (45-240)
Comorbidities	
None	24 (41.4)
Cardiovascular	14 (24.1)
Respiratory	6 (10.3)
Diabetes mellitus	5 (8.6)
Hypothyroid	3 (5.2)
Chronic kidney disease	1 (1.7)
Other ^a	6 (10.3)
HIV Status	
Positive	4 (6.9)
Negative	37 (63.8)
Unknown	17 (29.3)
BMI	33.05 (20.8-53.3); (29.13-37.1)
ASA Status	
ASA I	18 (31.0)
ASA II	27 (46.6)
ASA III	7 (12.1)
Final procedure	
LC	51 (87.9)
Subtotal fenestrating cholecystectomy	6 (10.3)
Subtotal reconstituting cholecystectomy	1 (1.7)

^aOther comorbidities included: breast cancer, gastritis, multiple sclerosis, polycystic ovarian syndrome, right renal angiomyolipoma, systemic lupus erythematosus (all n = 1)

ASA – American Society of Anesthesiologists, BMI – body mass index, HIV – human immunodeficiency virus, IQR – interquartile range, LC – laparoscopic cholecystectomy

13.3.2 Intraoperative findings

The intraoperative findings of the 58 LCs performed during this study are included in Table 13.2. Thirty-two patients had the gallbladder removed intact and all instances of bile leakage (n = 22) were a result of perforating the gallbladder during dissection. Stone spillage was present in 14 operations, with full retrieval reported in 12 (85.7%). The most commonly reported intraoperative difficulty was problems grasping the gallbladder (n = 12, 20.7%) followed by bleeding (n = 7, 12.1%). Median operative time was 90 (40-170) minutes.

Table 13.2. Intraoperative details of patients who underwent laparoscopic cholecystectomy after checklist implementation.

Intraoperative variable	Patients, n = 58 (%) or median (range); (IQR)
Gallbladder removed intact	32 (55.2)
Stone spillage	14 (24.1)
Full retrieval of spilled stones ^a	12 (85.7)
Bile leak noted intraoperatively	22 (37.9)
Location of bile leak	
Gallbladder	22 (100)
Liver bed	-
Bile duct	-
Intraoperative difficulty ^b	
Bleeding	7 (12.1)
Aberrant biliary anatomy	1 (1.7)
Aberrant arterial anatomy	3 (5.2)
Equipment problems	1 (1.7)
No progress	1 (1.7)
Difficult grasping the gallbladder	12 (20.7)
Contracted gallbladder	3 (5.2)
Severe inflammation	2 (3.4)
Extensive adhesions	3 (5.2)
Avulsion of cystic artery	3 (5.2)
Stone in Hartmann's pouch	2 (3.4)
Other ^c	5 (8.6)
Operative time, minutes	90 (40-170); (75-112.5)
Estimated blood loss	
Minimal	44 (75.9)
Moderate	12 (20.7)
Severe	-
Drain left	15 (25.9)

^aOne operative note did not document stone retrieval

^bA single operation may have multiple intraoperative difficulties

^cOther difficulties included: hepatomegaly, fatty liver, intrahepatic gallbladder, empyema/gallbladder perforation, angiomyolipoma of right kidney (all n = 1)

IQR – interquartile range

13.3.3 Checklist and standardized operative note compliance

Adherence to the LC checklist and standardized operative note is shown in Table 13.3.

Overall compliance was greatest for the pre-incision portion of the checklist and operative note (96.6%) and lowest for the CVS portion (63.8%). Documentation of whether the assistant agreed or disagreed that the three elements of the CVS were achieved was documented in only 37 (63.8%) of the 58 operative notes. The most common reason for difficulty obtaining the CVS was trouble grasping the gallbladder (n = 5) followed by bleeding (n = 3), although in four cases there was no reported difficulty. Six IOCs were performed with complete documentation of the required elements of the IOC in all cases. There were eight LCs included in the analysis of checklist compliance that did not report

achieving a CVS on the operative note. In five, the cystic artery was either avulsed or there was aberrant arterial anatomy that prevented the surgeon from achieving two and only two structures entering the gallbladder. Two LCs had standardized operative notes that documented not achieving a visible lower 1/3 of the cystic plate, but also documented that the assistant agreed all three of the elements of the CVS were achieved.

Table 13.3. Reported adherence to the intraoperative portions of the checklist for patients scheduled for laparoscopic cholecystectomy after checklist implementation.

Checklist criteria	Patients n = 58 (%)
Pre-incision review	
Imaging	56 (96.6)
Liver function tests	57 (98.3)
Expected difficulties	56 (96.6)
Pre-incision overall compliance	96.6%
Pre-dissection steps completed	
Fundus retracted to 10 o'clock	54 (93.1)
Hartmann's pouch lifted toward segment IV	51 (87.9)
Line between Rouviere's sulcus and falciform identified	46 (79.3)
Safe level of dissection identified	51 (87.9)
Posterior leaf of peritoneum released	51 (87.9)
Did the assistant agree all five steps were completed?	51 (87.9)
Pre-dissection overall compliance	79.3%
CVS elements achieved	
Hepatocystic triangle free of fibrous and fatty tissue	49 (84.5)
Two and only two structures entering gallbladder	46 (79.3)
Distal 1/3 of the cystic plate visible	47 (81.0)
CVS achieved	43 (74.1)
Did the assistant agree all 3 elements were achieved?	37 (63.8)
CVS overall compliance	63.8%
Reasons for not obtaining the CVS^a	
Bleeding	3 (5.2)
Aberrant arterial anatomy	2 (3.4)
Aberrant biliary anatomy	1 (1.7)
Difficulty grasping gallbladder	5 (8.6)
Contracted gallbladder	2 (3.4)
Intrahepatic gallbladder	1 (1.7)
Extensive adhesions	1 (1.7)
Severe inflammation	1 (1.7)
No progress	1 (1.7)
Avulsion of cystic artery	2 (3.4)
Fatty liver	1 (1.7)
Short cystic duct	1 (1.7)
Unreported	4 (6.9)
IOC performed	6 (10.3)
Findings	
Flow into duodenum	6 (10.3)
3 proximal hepatic ducts visualized	6 (10.3)
Spiral valves in cystic duct	3 (5.2)
Bile duct filling defects	3 (5.2)
IOC overall compliance	100%

^aMultiple reasons for not obtaining the CVS may have been reported

CVS – critical view of safety, IOC – intraoperative cholangiogram

13.3.4 Critical view of safety scores

Average scores for the three elements of the CVS and total CVS score by the four blinded reviewers are displayed in Figure 13.1. The averages represent scores photos from completed

LCs (n = 51) and exclude operations where a subtotal LC was performed. There were no intraoperative videos scored in the LC database. HPB Surgery Reviewer 1 was the only reviewer to report overall CVS scores that on average met the threshold of 5 for an acceptable critical view. General Surgery Reviewer 1 consistently reported lower average scores compared to the other blinded reviewers. The overall average of the CVS score was 4.50 (SD \pm 1.70) and reviewers judged images to be of inadequate quality for scoring 34 times (16.7%) out of the 204 scores submitted.

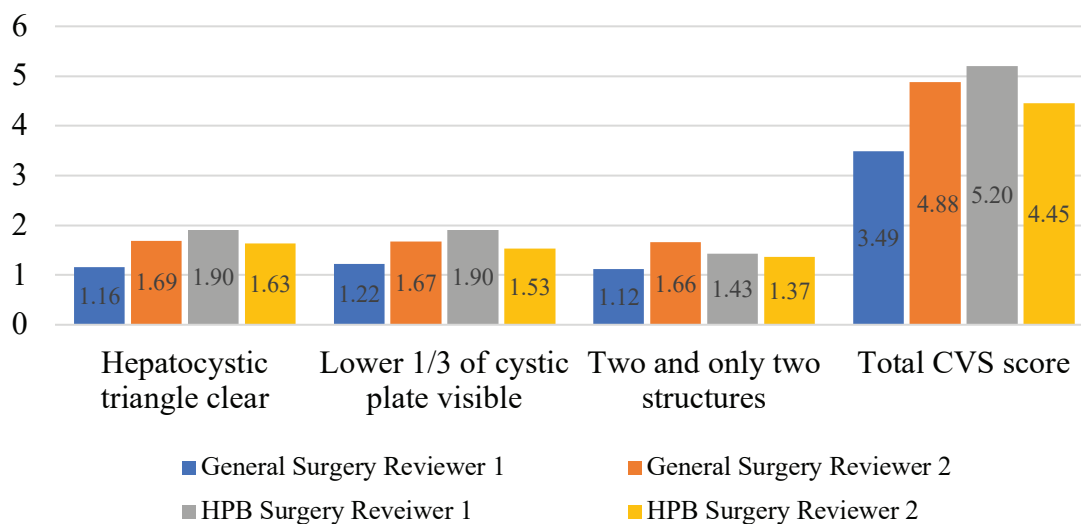


Figure 13.1. Average scores for the three elements and the total critical view of safety score by reviewer. The overall average CVS score across all 4 blinded reviewers was 4.50 with a SD of \pm 1.70. Blinded reviewers reported inadequate photos for analysis in 34 (16.7%) instances.

CVS – critical view of safety, HPB – hepato-pancreato-biliary, SD – standard deviation

13.3.5 Bivariate analysis comparing operations that did and did report achieving the critical view of safety

Results of a comparison between the 43 patients with an operative note reporting the CVS was achieved and the 15 patients where the CVS was documented as not achieved are displayed in Table 13.4. The patients for which the CVS was reported as not achieved had a statistically significant longer operative time ($p = 0.004$), were more likely to have acute cholecystitis as an indication for LC ($p = 0.045$) and were more likely to have a drain left at the end of the operation ($p = 0.003$). There was a non-significant trend toward older patients ($p = 0.057$) and expected difficulty preoperatively ($p = 0.056$) for not achieving the CVS. Sex, BMI, duration of symptoms, timing of LC and intraoperative blood loss were similar between the two groups.

Table 13.4. Bivariate analysis of operations during which the critical view of safety was and was not achieved.

Clinical variable	CVS achieved n = 43 (%) or median (range); (IQR)	CVS not achieved n = 15 (%) or median (range); (IQR)	p-value
Age, years	40 (17-73); (31.5-54.5)	54 (30-77); (38-59)	0.057
Sex, female	37 (86.0)	11 (73.3)	0.265
BMI	33.6 (20.8-52.1); (28.6-37.1)	31.8 (23-53.3); (29.35-38)	0.831
Indication for LC			
Biliary Colic	27 (62.8)	7 (46.7)	0.364
Acute Cholecystitis	8 (18.6)	7 (46.7)	0.045
Choledocholithiasis	3 (7.0)	1 (6.7)	1.000
Gallstone pancreatitis	4 (9.3)	-	-
Cholangitis	1 (2.3)	-	-
Duration of symptoms, days	145 (2-365); (60-247.5)	90 (3-370); (18.5-210)	0.633
Timing of LC			
Elective	36 (83.7)	13 (86.7)	1.000
Same admission	7 (16.3)	2 (13.3)	
Expected difficulty	23 (53.5)	11 (73.3)	0.056
Operative time, minutes	85 (40-170); (67.5-100)	115 (75-140); (101.3-122.5)	0.004
Estimated blood loss			
Minimal	34 (79.1)	10 (66.7)	0.312
Moderate	7 (16.3)	5 (33.3)	
Severe	-	-	
Drain left	6 (14.0)	9 (60.0)	0.003

BMI – body mass index, CVS – critical view of safety, IQR – interquartile range, LC – laparoscopic cholecystectomy

13.3.6 Thirty-day post-laparoscopic cholecystectomy complications, admissions and interventions

Postoperative complications, admissions and interventions at 30-days post-LC are presented in Tables 13.5 and 13.6. In total, there were 11 (19%) complications in 7 (12.1%) patients. Two patients developed a bile leak after a subtotal LC, one of whom presented with bile peritonitis. Both patients underwent laparoscopic washout and drainage. One patient was also treated with antibiotics for a wound infection. A third patient was readmitted with a bile leak and jaundice. The bile leak was managed with a percutaneous drain and no cause of the jaundice or location of the bile leak was identified at ERC. The bile leak resolved with conservative management and the jaundice spontaneously improved. This patient also developed pancreatitis prior to ERC and after extensive work-up was eventually presumed to have antiretroviral medication-related pancreatitis. One patient was readmitted with a wound infection and underwent incision and drainage and a course of antibiotic therapy. Another patient had a prolonged hospital stay due to postoperative ileus, which resolved with

conservative management. The two patients with common bile duct stones noted at IOC underwent successful ERC with stone extraction.

There were two (3.4%) mortalities in this series. The first was a 47-year-old male with severe cor pulmonale and chronic kidney disease who developed a persistently distended abdomen on post-LC day one. A CT scan was obtained, which was unremarkable. He subsequently developed acutely worsening renal function with poor respiratory function. He was deemed not to be a candidate for renal support or ICU care and subsequently demised as a result of acute complications of his chronic comorbidities. The second patient was a 27-year-old morbidly obese male who became diaphoretic and short of breath on post-LC day two. He rapidly decompensated to a cardiac arrest. Cardiopulmonary resuscitation was initiated with return of spontaneous circulation initially, however he died shortly after.

Table 13.5. Thirty-day postoperative complications for patients who underwent laparoscopic cholecystectomy after checklist implementation.

Variable	Modified Accordion Grade					
	Mild	Moderate	Severe			Death
	1	2	3	4	5	6
Surgical Complications^a						
Bile leak	-	-	1 (1.7)	1 (1.7)	-	-
Bile peritonitis	-	-		1 (1.7)	-	-
Jaundice	-	-	1 (1.7)	-	-	-
Wound infection	-	2 (3.4)	-	-	-	-
Ileus	1 (1.7)	-	-	-	-	-
Retained stones	-	-	2 (3.4)	-	-	-
Total	1 (1.7)	2 (3.4)	4 (6.9)	2 (3.4)	-	-
Non-surgical Complications*						
Pancreatitis	-	-	1 (1.7)	-	-	-
Cardiovascular event	-	-	-	-	-	1 (1.7)
Renal failure	-	-	-	-	-	1 (1.7)
Total	-	-	1 (1.7)	-	-	2 (3.4)
Total overall	1 (1.7)	2 (3.4)	6 (10.3)	2 (3.4)	-	2 (3.4)

^aA single patient may have multiple complications recorded

Table 13.6. Thirty-day post-laparoscopic cholecystectomy admissions and post-laparoscopic cholecystectomy interventions for patients who underwent laparoscopic cholecystectomy after checklist implementation.

Variable	Patients n = 58 (%)
30-day post-LC admissions	2 (3.4)
30-day post-LC interventions	
Laparoscopic washout and drainage	2 (3.4)
Percutaneous drain	1 (1.7)
ERC	4 (6.9)
Incision and drainage of wound	1 (1.7)
Total	8 (13.8)

ERC – endoscopic retrograde cholangiography; LC – laparoscopic cholecystectomy

13.4. Discussion

As called for in a 2016 South African Journal of Surgery editorial, “Instilling a culture of safety for laparoscopic cholecystectomy”, a LC checklist was adapted from the proposed checklist by Connor et al. and implemented at an academic hospital in Cape Town, South Africa.^{265,270} To accompany the checklist, a standardized operative note incorporating critical elements of the checklist was created, and anterior and posterior intraoperative photos or videos of the CVS were made mandatory. This intervention was in an effort to establish a minimum quality of performance for a common general surgery operation and to provide a means for regular quality assessment. Results of the first four months of the intervention are reviewed in this analysis. The patient population undergoing LCs at GSH is representative of the typical population of LC patients.²⁷⁷ There were no conversions from LC to OC in this series, likely due to the small sample size as conversion rates have been reported as stable and relatively low over the last two decades.¹⁹⁹ Not surprisingly, acute cholecystitis and longer operative times more often resulted in failure to achieve the CVS.

CVS scores were used as a surrogate marker for LC quality because, as an infrequent event, the incidence of BDI is an impractical measure. The overall average CVS score was 4.50 (SD \pm 1.70), below that of the previously suggested target score of 5 for an acceptable critical view.¹⁹³ One explanation for the lower CVS score is the 16.7% rate of inadequate images for scoring reported by the blinded reviewers. This may be due to the CVS not being achieved, but a suboptimal technique of image capture or low quality photos may also have contributed. The poor quality of CVS images could be addressed by providing a review of the image

capture technique and utilization of electronic capturing, rather than mobile phone photography of a screen.

The purpose of the checklist intervention was to standardize the performance of a common procedure in an effort to make best practice a habit. Particular attention was paid to presentation of the anatomy for the pre-dissection and CVS portions of the checklist during implementation. Even so, blinded reviewer scores for LCs with operative notes that documented the CVS was achieved were lower than the previously proposed target, suggesting further education of the anatomy of the CVS and image capture technique may be beneficial.¹⁹³ Additionally, there was variation among the reviewer's scores with one reviewer scoring on average above 5, two between 4 and 5 and the other scoring less than 4 on average. Assessment of inter-rater reliability for this scoring system is needed to more accurately interpret the CVS scores reported in this study.

The reported average CVS scores were calculated using only photos from operative notes that documented the operation was completed as a LC (n = 51). Seven patients were excluded because they received subtotal LCs. There were eight LCs included in the analysis of CVS scores that did not report achieving a CVS on the operative note. The scores for each of these patients ranged from 0 to 4 points for the first and from 3 to 5 points for the second. Notably, half of the reviewers felt the images were inadequate for scoring in both cases. The remaining LC was performed without using the standardized operative note. The elements of the CVS were not mentioned in the non-standardized operative note and therefore it is unknown if the CVS was perceived to be achieved by the surgical team.

The eight LC cases that did not report achieving the CVS and the subtotal LCs highlight three important limitations. First, the CVS scoring system is only useful in completed LCs and has no role in evaluating the quality and safety of subtotal cholecystectomy. However, subtotal cholecystectomy is considered a bailout procedure on the LC checklist intervention and is an operation surgeons were encouraged to consider performing when the CVS could not be safely achieved. Consequently, a subtotal cholecystectomy as a bailout procedure for a difficult LC after checklist implementation is considered a successful operation that minimizes the risk of BDIs. Second, there are intraoperative situations when the cystic artery is divided early before the CVS photos are taken or there is aberrant arterial anatomy, but an otherwise satisfactory CVS is achieved and the LC is safely completed. Under these

circumstances the CVS score can only be a maximum of four, lower than the target score of five, despite a safe operation. Capture and review of the standardized operative notes allows for detailed analysis of individual LC operations to address this limitation. Finally, human error in reporting on operative notes is unavoidable and will result in some degree of inaccuracy in the analysis. The operative note is designed for efficiency by minimizing the number of fields where written descriptions are required and providing options to choose from instead. This can result in inaccuracies in recording as the surgeon quickly circles options without adequate attention to the legends. In the conflicting answers for the two LCs completed without achieving the CVS described above, this was likely the case.

Compliance related to following the checklist and completeness of the standardized operative note were used as secondary measures to assess LC quality. The high rate of compliance for the pre-incision portion of the checklist suggests that review of imaging, laboratory results and consideration of LC difficulty were a part of routine practice prior to checklist implementation. Identification of the line between Rouviere's sulcus and the falciform compromised pre-dissection compliance. This may be because Rouviere's sulcus is only present in approximately 80% of normal livers²⁷⁰ or due to unfamiliarity with the anatomic landmark. Out of the four intraoperative portions of the LC checklist, the CVS section had the lowest overall compliance. Complete adherence was not expected as 7 of the 58 cholecystectomies included in the analysis were completed as subtotal LCs. After review of the LC operative notes, the lowest compliance associated with the two and only two structures criterion can be explained by LCs in which the cystic artery was divided either close to the gallbladder or, due to aberrant anatomy, the CVS was not possible. However, the question regarding whether the assistant agreed the CVS was achieved limited the overall compliance for this portion of the checklist to 63.8%. In all cases, the non-compliance was a result of not completing that specific question on the operative note, and not a result of a negative ("no") answer. A conclusion cannot be made based on the available data about whether the low compliance was due to not asking the assistant for confirmation or if the field was simply overlooked when filling out the operative note. However, the role the traditional hierarchy in surgery plays for compliance to this question in particular should be considered.

Thirty-day complications and admissions following LC were assessed as surrogate markers for LC quality. The rate of complications after LC in this small series was higher than the

recent pooled estimates of 1.6-5.3%.¹⁹⁹ However, of the seven patients who experienced postoperative complications, two had undergone subtotal LCs. Another two patients had suspected common bile duct stones on IOC and went on to have post-LC ERCs, which is standard of practice at our hospital. The mortality rate in this series was also higher than that reported in the literature.¹⁹⁹ Although both were postoperative deaths, the patients died as a result of acute complications of chronic comorbidities and not as a direct result of a surgical complication. This suggests criteria for patient selection for LC should be reviewed with careful consideration of comorbid conditions and fitness for surgery.

In the absence of an integrated electronic patient record system in our facilities, we had to resort to alternatives for collection and storage patient data. We used REDCap, a secure, web-based software solution for data capturing. For transfer of operation notes and intraoperative images, WhatsApp Messenger, a reliable, affordable, efficient and user-friendly tool, was used. WhatsApp has become ubiquitous in clinical practice in South Africa.²⁷⁸ However, the Health Professions Council of South Africa does not have guidelines for good ethical practice in the use of social media and to date, no legal precedent in South Africa has been set regarding the use of WhatsApp in clinical practice.²⁷⁹ Opperman and van Vuuren advocated for patient consent if personal health information will be sent using WhatsApp, and in the event consent is not obtained, the sharing of patient information must be, “justifiable in the eyes of the law, in the patient’s best interest and able to withstand moral judgment if questioned on professional boards”.²⁷⁸ To address this ethical problem, written informed consent using an ethics committee-approved consent form was obtained for all LC patients entered into the database. Acknowledgement of the risk of a breach of patient privacy when using WhatsApp and the measures taken to minimize that risk were also stated. The measures included the end-to-end encryption of WhatsApp conversations, double password protection (phone and WhatsApp lock), deletion of photos and patient information within 7 days of being sent to the group and limiting the number of clinicians who have access to the WhatsApp group to an absolute minimum.²⁸⁰

In conclusion, implementation of the LC checklist, standardized operative note, mandatory intraoperative CVS photos and creation of the LC database allowed for quality assessment of a commonly performed operation. Initial results indicate that review of the anatomy of the CVS and methods for taking adequate intraoperative photos for blinded review, and a subsequent reassessment of CVS scores is required. The use of the CVS scoring system

should be evaluated for inter-rater reliability so that we can have confidence that the CVS scoring method is an accurate quality measure. Finally, taking into consideration the findings and areas for improvement, expansion of the intervention to the broader Cape Metro West Health District is warranted to continue to assess the quality of a commonly performed operation.

Laparoscopic Cholecystectomy Intervention Expanded to the Cape Metro West Region

14.1 Rationale

The pilot study presented in Chapter 13, which examined implementation of a LC intervention, resulted in optimized versions of the checklist and standardized operative note for use in the South African healthcare system. Pursuing the goal of making BDI in LC a near-never event, the intervention was expanded to include all hospitals with general surgery units in the Cape Metro West Health District. The hospitals included Mitchells Plain and Victoria Hospitals, both medium-sized (between 150 and 300 beds) district or level 1 hospitals and New Somerset, a regional or level 2 hospital.²⁸¹ The primary differences between a district (level 1) and a regional (level 2) hospital are that a regional hospital is larger with between 400 and 800 beds and offers access to specialists and ICU care.²⁸¹ Both Mitchells Plain and Victoria hospitals have specialized general surgeons on staff, despite being district level hospitals. Mitchells Plain Hospital has four theatres which are used by two general surgeons and six non-specialized doctors (medical officers), while Victoria Hospital has three theatres used by one general surgeon and three medical officers.²⁸¹ New Somerset Hospital has four theatres used by three general surgeons and four medical officers.²⁸¹ Together with the tertiary (level 3) GSH Acute Care Surgery unit, the hospitals serve a population of more than 2 million people.¹⁹⁸

The aim of broadening the implementation of the LC intervention remained the same, with the primary goal of ensuring a minimum quality of performance of a routine general surgery operation. Through expansion of the LC intervention to the general surgery units in the Cape Metro West Health District using the checklist, standardized operative note and CVS photo documentation and scoring, we hoped to create a culture of safety for LCs, to address intraoperative visual misperceptions, to guide intraoperative decision making, to encourage teamwork and communication and to improve trainee education. To measure the quality of LCs performed, a reliable CVS scoring method (Chapter 15) is used to score intraoperative doublet photos taken by the surgeon of the CVS. Compliance to the evidence-based LC checklist is also measured. Additionally, 30-day postoperative complications, re-admissions and re-interventions are recorded. Data collection is scheduled to run for 12 months from January through December 2020. The primary aim of this study was to demonstrate comparable compliance after expansion to district and regional hospitals and to establish a

baseline for post-operative outcomes to be used in future comparisons. The results presented in this analysis represent data from the first three months of the study following implementation in hospitals with general surgery units in the Cape Metro West Health District.

14.2 Methods

14.2.1 Intervention elements

Similar to the pilot study, the elements of the intervention included the ethics approved consent form, the checklist adapted from Connor et al.,²⁷⁰ the standardized operative note and the capture of intraoperative photos of the CVS, which were scored by blinded reviewers using the same, previously published method.¹⁹³ The checklist and standard operative note can be viewed in Appendix B.3.2 and B.3.3. As a reference in theatre, a poster was created that included an example of an ideal anterior and posterior photo of the CVS with the elements of the CVS annotated and a table with the detailed version of the scoring system as published by Sanford et al.¹⁹³ The study sites were asked to display the poster in theatres where LCs were performed. The poster can be viewed in Appendix B.3.4

14.2.2 Implementation

In the two months prior to initiation of the LC intervention, meetings were held with the heads of the general surgery units at Mitchells Plain Hospital, New Somerset Hospital and Victoria Hospital. The purposes of the meetings were to briefly explain the intervention, the motivation for the project and to address any concerns or barriers to implementation. The month before implementation a joint meeting was held with the heads of each of the general surgery units where a detailed presentation of elements of the intervention and the process of implementation and data collection were explained. The checklist, operative note and consent form were distributed at that time. During the week of implementation, the researcher travelled to each of the participating hospitals and gave the same presentation to the consultants, junior consultants, registrars and medical officers who would be performing LCs during the study period. The annotated presentation can be viewed in Appendix C. The fourth surgery unit to participate in this study was from GSH where the pilot study was performed. For this general surgery unit, a brief reminder of the elements of the intervention and its implementation was given to all staff and trainees performing LCs, emphasizing the changes made to improve checklist compliance and the quality of intraoperative CVS photos.

14.2.3 Data collection

Data collection proceeded similar to the pilot study (Chapter 13). Photos of the signed informed consent and the standardized operative note were sent via WhatsApp along with the intraoperative photos taken using a cell phone to the LC database group. Data from the operative note and the intraoperative images were then uploaded to the LC database. Scoring of the CVS images was performed by one HPB and one general surgeon using the same previously published method.¹⁹³ There were a total of four blinded reviewers (two HPB and two general surgeons) who were the same reviewers from the pilot study and remained consistent throughout the current study duration. To ensure accuracy and completeness of 30-day follow-up data, monthly emails were sent to the heads of the general surgery units confirming the number of patients who received LCs and reminding them about the completion of discharge dates, complications and any re-admissions. Where data were incomplete, a search was performed in the NHLS and when necessary, patient folders were requested.

14.2.4 Data analysis and distribution

Interim analyses are scheduled to be performed quarterly. The four participating hospitals receive the quarterly reports including a summary of LCs performed, patient population characteristics, average length of stay, 30-day morbidity and CVS scores in total for the study and also by hospital. The data included in this chapter represent the first quarter interim analysis. Non-parametric continuous data are presented as a median with range and interquartile range. Categorical data are presented as numbers and percent. The Mann–Whitney U test was used for continuous variables and Fisher’s exact test was used for categorical variables. A p-value < 0.05 was considered significant. Data analysis was performed in SPSS Statistics for MacIntosh, Version 25.0 (IBM SPSS Statistics, IBM Corporation, Armonk, NY).

14.3 Results

14.3.1 Patient characteristics

Patient characteristics are summarized in Table 14.1. There were 88 LCs performed during the three-month study period from January through March 2020. Patient median age was 42.5 (25-85) years and 88% were female (n = 77), with most patients undergoing elective operations (92%, n = 81). The median BMI was 32.5 (17.1-54.8). Mitchells Plain Hospital performed the largest number of LCs during the study period, followed by GSH, while

Victoria Hospital performed the smallest number. Patients waited a median of 67 (0-380) days for their LC operation. The most common indication for LC was biliary colic (40%), followed by acute cholecystitis (33%) and choledocholithiasis (11%). Symptom duration ranged from 2 to 1500 days, with a median symptom duration prior to surgery of 140 days. Two-thirds of patients were reported to have at least one comorbidity, the most common of which was cardiovascular in nature. Of the 28 patients with a cardiovascular comorbidity, one patient had a diagnosis of peripheral vascular disease, one had a mitral valve replacement and the remainder were being treated for hypertension. Forty-two percent of patients were American Society of Anesthesiologists (ASA) II (n = 37). There were six HIV positive patients (6.8%) while 50% of patients (n = 44) had an unknown HIV status. Nearly all patients (96%) underwent a LC (n = 84). There were four subtotal LCs performed (4%), two using the fenestrating method and two using the reconstituting method.

Table 14.1. Patient characteristics after implementation across the Cape Metro West Health District.

Clinical Characteristics	Patients n = 88 (%) or median (range); (IQR)
Age, years	42.5 (25-85); (34.8-58.3)
Sex, female	88 (87.5)
Timing of operation	
Elective	81 (92.0)
Same admission	7 (8.0)
Hospital	
Groote Schuur	23 (26.1)
Mitchells Plain	34 (38.6)
New Somerset	20 (22.7)
Victoria	11 (12.5)
Days from booking to operation	67 (0-380); (17.5-112.5)
Indication	
Biliary colic	35 (39.8)
Acute cholecystitis	29 (33.0)
Choledocholithiasis	10 (11.4)
Gallstone pancreatitis	8 (9.1)
Gallbladder polyp	3 (3.4)
Gallbladder empyema + percutaneous drainage	2 (2.3)
Cholangitis	1 (1.1)
Duration of symptoms, days	140 (2-1500); (37.5-240)
Comorbidities	
None	29 (33.0)
Cardiovascular	28 (31.8)
Respiratory	8 (9.1)
Diabetes mellitus	4 (4.5)
GORD	4 (4.5)
Arthritis	3 (3.4)
Smoker	2 (2.3)
Dementia	2 (2.3)
Hyperlipidaemia	2 (2.3)
Myasthenia gravis	1 (1.1)
Chronic kidney disease	1 (1.1)
Not reported	16 (18.2)
HIV Status	
Positive	6 (6.8)
Negative	38 (43.2)
Unknown	44 (50.0)
BMI	32.5 (17.1-54.8); (27.1-37.8)
ASA Status	
ASA I	23 (26.1)
ASA II	37 (42.0)
ASA III	4 (4.5)
Not reported	24 (27.3)
Final procedure	
LC	84 (95.5)
Subtotal fenestrating LC	2 (2.3)
Subtotal reconstituting LC	2 (2.3)

ASA – American Society of Anesthesiologists, BMI – body mass index, GORD – gastro-oesophageal reflux disease, HIV – human immunodeficiency virus, IQR – interquartile range, LC – laparoscopic cholecystectomy

14.3.2 Intraoperative findings

Intraoperative details of patients who underwent attempted LC are summarized in Table 14.2. Median operating time was 80 (20-180) minutes. In 42% (n = 37) of LCs a bile leak was reported, almost exclusively from the gallbladder (n = 34), although there was one bile leak from the cystic duct noted intraoperatively. The gallbladder was removed intact in 55 LCs with stone spillage reported in 17 (19%) and complete retrieval of stones reported in 15 of the 17 operations. The most commonly reported intraoperative difficulty was trouble grasping the gallbladder (34%, n = 30), followed by severe inflammation and/or empyema and extensive adhesions (both 12.5%, n = 11). Estimated blood loss was most often minimal (74%, n = 65) and a drain was left in 18 of the 88 (21%) LCs performed.

Table 14.2. Intraoperative details of patients who underwent laparoscopic cholecystectomy after implementation across the Cape Metro West Health District.

Intraoperative variables	Patients, n = 88 (%) or median (range); (IQR)
Gallbladder removed intact	55 (62.5)
Not reported	5 (5.7)
Stone spillage	17 (19.3)
Full retrieval of spilled stones	15 (17.0)
Bile leak noted intraoperatively	37 (42.0)
Not reported	7 (8.0)
Location of bile leak	
Gallbladder	34 (38.6)
Cystic duct	1 (1.1)
Not reported	2 (2.3)
Intraoperative difficulty ^a	
Bleeding	9 (10.2)
Aberrant arterial anatomy	10 (11.4)
Equipment problems	4 (4.5)
Hepatomegaly	2 (2.3)
Fatty liver	2 (2.3)
Difficulty grasping the gallbladder	30 (34.1)
Contracted gallbladder	6 (6.8)
Intrahepatic gallbladder	8 (9.1)
Severe inflammation/empyema	11 (12.5)
Extensive adhesions	11 (12.5)
Operative time, minutes	80 (20-180); (60-103.5)
Estimated blood loss	
Minimal	65 (73.9)
Moderate	9 (10.2)
Not reported	14 (15.9)
Drain left	18 (20.5)
Not reported	3 (3.4)

^aA single operation may have multiple intraoperative difficulties

IQR – interquartile range

14.3.3 Checklist compliance

Compliance to the LC checklist is summarized in Table 14.3. Compliance was 97% for the pre-incision portion of the checklist, which requires review of relevant imaging, recent liver function tests and consideration of any expected intraoperative difficulties. The pre-dissection portion of the checklist was adhered to 85% of the time. Identification of the imaginary line between Rouviere's sulcus and the falciform ligament was followed the least often out of the five pre-dissection steps. The CVS was documented as achieved for 88% of the LC operations. Each of the elements were achieved at a slightly higher rate of 93% for a hepatocystic triangle free of fibrous and fatty tissue and for a visible distal 1/3 of the cystic plate. Two and only two structures entering the gallbladder was achieved in 90% of operations. Overall compliance for the CVS portion of the checklist was the lowest at 66%. The most common reason reported for not achieving the CVS was extensive adhesions (n = 6). Two IOCs were performed with 100% compliance to documentation requirements. One IOC showed common bile duct filling defects, while the other was documented as normal. Neither IOC demonstrated spiral valves in the cystic duct. From the regular monthly follow-up emails, there were a total of 22 LC operations in the Cape Metro West Health District that were not captured in the LC database, representing 20% of all LCs performed during the study period. One LC from New Somerset Hospital, 3 LCs from GSH and 18 LCs from Victoria Hospital were not captured.

Table 14.3. Reported adherence to the intraoperative portions of the checklist after implementation across the Cape Metro West Health District.

Checklist criteria	Patients n = 88 (%)
Pre-incision review of	
Imaging	85 (96.6)
Liver function tests	85 (96.6)
Expected difficulties	86 (97.7)
Pre-incision overall compliance	96.6%
Pre-dissection steps completed	
Fundus retracted to 10 o'clock	86 (97.7)
Hartmann's pouch lifted toward segment IV	80 (90.9)
Line between Rouviere's sulcus and falciform identified	75 (85.2)
Safe level of dissection identified	83 (94.3)
Posterior leaf of peritoneum released	83 (94.3)
Pre-dissection overall compliance	85.2%
CVS elements achieved	
Hepatocystic triangle free of fibrous and fatty tissue	82 (93.2)
Two and only two structures entering gallbladder	79 (89.8)
Distal 1/3 of the cystic plate visible	82 (93.2)
CVS achieved	77 (87.5)
Did the assistant agree all 3 elements were achieved?	49 (55.7)
Did not agree	9 (10.2)
Not reported	30 (34.1)
CVS overall compliance	65.9%
Reasons for not obtaining the critical view^a	
Bleeding	2 (2.3)
Aberrant arterial anatomy	1 (1.1)
Fatty liver	1 (1.1)
Difficult grasping the gallbladder	5 (5.7)
Contracted gallbladder	1 (1.1)
Intrahepatic gallbladder	1 (1.1)
Severe inflammation/empyema	3 (3.4)
Extensive adhesions	6 (6.8)
None reported	2 (2.3)
IOC performed ^b	2 (2.3)
Findings	
Flow into duodenum	1 (1.1)
3 proximal hepatic ducts visualized	2 (2.3)
Spiral valves in cystic duct	0 (0)
Common bile duct filling defects	1 (1.1)
IOC overall compliance	100%

^aA single operation note may have reported multiple reasons for not obtaining the critical view of safety

^bOnly two IOCs were performed, all elements documented (100% compliance), although spiral valves in the cystic duct were not observed

CVS – critical view of safety, IOC – intraoperative cholangiogram

14.3.4 Average critical view of safety scores

The average scores for each of the three elements of the CVS and in total are shown in Figure 14.1. The maximum score per element is two for a maximum overall score of six. The

average total CVS score was 4.90 (SD \pm 1.50) and the highest scoring element of the CVS was a visible lower 1/3 of the cystic plate (1.72 \pm 0.53). The lowest scoring element was two and only two structures entering the gallbladder, with an average score of 1.58 (SD \pm 0.69). The hepatocystic triangle free of fat and fibrous tissue received an average score of 1.60 (SD \pm 0.58). Blinded reviewers reported inadequate photos for analysis in 9 (5.4%) instances. In all cases of reported inadequate photos, a CVS score was provided by the reviewers.

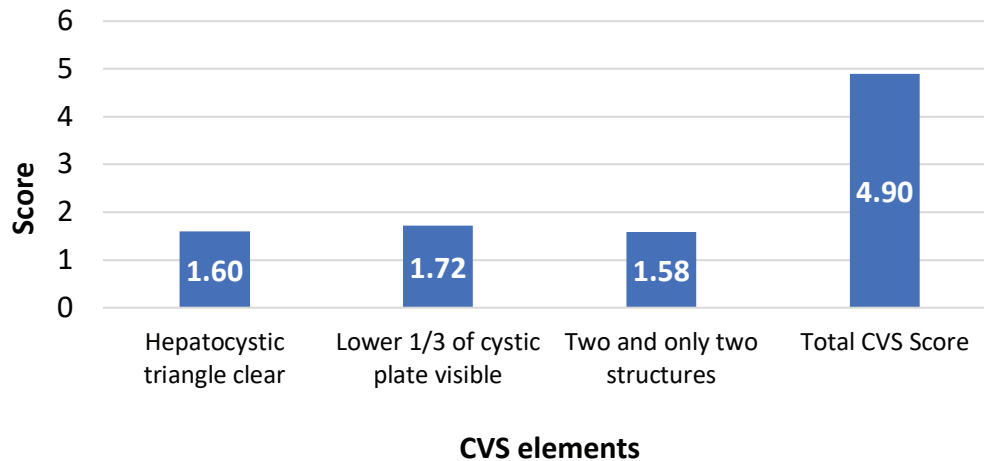


Figure 14.1. Average scores for the three elements and the total critical view of safety score. Average scores were calculated using the 84 patients with completed LCs, subtotal LCs were excluded. Each doublet CVS photo set received a score from two blinded reviewers, one HPB and one general surgeon. The overall average CVS score was 4.90 with a SD of \pm 1.50.

CVS – critical view of safety

14.3.5 Comparison of laparoscopic cholecystectomies where the critical view of safety was and was not achieved

A bivariate analysis of LCs where the CVS was and was not achieved is presented in Table 14.4. The CVS was documented as achieved in 76 (86%) of the 88 LCs performed. Of the 12 operations where a CVS was not achieved, 4 resulted in subtotal LCs. In bivariate analysis, patients in whom a CVS was achieved were younger, more likely to require a LC for biliary colic and were less likely to require a LC for choledocholithiasis and have a drain left at the end of the operation. Patients in whom a CVS was not achieved were more likely to be considered a difficult case prior to incision. There was a trend toward a longer operative time and length of stay for patients in whom a CVS was not achieved, however these were not statistically significant. Sex, BMI, duration of symptoms, timing of operation, hospital where

operation was performed and estimated blood loss were similar between the two groups (all $p > 0.05$).

Table 14.4. Bivariate analysis of laparoscopic cholecystectomies during which the critical view of safety was and was not achieved.

Clinical variable	CVS achieved n = 76 (%) or median (range); (IQR)	CVS not achieved n = 12 (%) or median (range); (IQR)	p-value
Age, years	40.5 (25-73); (34-55)	59 (25-85); (53.5-64.3)	0.008
Sex, female	67 (88.2)	10 (83.3)	0.642
BMI	32.5 (19.5-54.8); (28.2-37.5)	36.2 (17.1-46.7); (24.3-41.5)	0.883
Indication for LC			
Biliary colic	34 (44.7)	1 (8.3)	0.024
Acute cholecystitis	23 (30.2)	6 (50.0)	0.520
Choledocholithiasis	7 (9.2)	4 (33.3)	0.040
Gallstone pancreatitis	7 (9.2)	1 (8.3)	1.000
Gallbladder polyp	3 (3.9)	-	-
Gallbladder empyema	2 (2.6)	-	-
Duration of symptoms, days	125 (2-1500); (26.3-285)	150 (42-330); (107.5-195)	0.825
Timing of LC			
Elective	69 (90.8)	12 (100.0)	0.567
Same admission	7 (9.2)	-	
Hospital			
Groote Schuur	24 (31.6)	3 (25.0)	0.532
Mitchells Plain	27 (35.5)	3 (25.0)	
New Somerset	17 (22.4)	3 (25.0)	
Victoria	8 (10.5)	3 (25.0)	
Expected difficulty	34 (44.7)	10 (83.3)	0.027
Operative time, minutes	76.5 (20-180); (60-100)	90 (50-165); (87-150)	0.066
Estimated blood loss			
Minimal	59 (77.6)	6 (50.0)	0.249
Moderate	7 (9.2)	2 (16.7)	
Not reported	10 (13.2)	4 (33.3)	
Drain left	11 (14.5)	7 (58.3)	0.003
Length of stay, days	1 (1-4); (1-1)	1 (1-6); (1-2)	0.088

BMI – body mass index, CVS – critical view of safety, IQR – interquartile range, LC – laparoscopic cholecystectomy

14.3.6 Thirty-day postoperative complications, re-interventions and re-admissions

Thirty-day postoperative complications are shown in Table 14.5 and re-admissions and re-interventions are shown in Table 14.6. Three patients required re-admission, one for severe postoperative pain, one for suspected retained common bile duct stones that subsequently passed spontaneously and one for a bile leak. The patient with postoperative pain had normal laboratory results with no concerning findings on CT scan and was discharged with pain well controlled on oral analgesia (grade 2). The patient admitted for retained stones presented with pain, nausea, vomiting and an elevated serum bilirubin and ductal enzymes on postoperative

day 5. MRCP did not identify any retained stones in the bile duct and her bilirubin and ductal enzymes resolved without intervention, so it was assumed she had spontaneously passed a stone (grade 2). She was readmitted on postoperative day 40 with gallstone pancreatitis, which resolved after ERC and removal of bile duct stones and otherwise conservative management. This re-admission and re-intervention were not recorded per protocol, as they occurred beyond 30-days after LC. The third patient was a 76-year-old female who was readmitted with abdominal pain, right upper quadrant cellulitis and findings on CT scan concerning for a bile leak (grade 4). She was promptly transferred to the HPB unit at a tertiary care hospital for further management. A percutaneous drainage was performed to address the intra-abdominal fluid collection. ERC was unsuccessful due to failure to cannulate the common bile duct. Therefore, a PTC was performed which demonstrated a leak from the liver bed and a distal, benign common bile duct stricture. An external PTBC was placed. A second PTC procedure was performed to internalize the biliary catheter, which was subsequently upsized. The patient required intravenous antibiotics for intra-abdominal sepsis and cholangitis, which eventually resolved. She also required a prolonged period of physiotherapy and rehabilitation prior to discharge.

One patient developed a bile leak after a subtotal cholecystectomy which resolved with conservative management without requiring further intervention (grade 1). Another patient developed urinary retention on postoperative day one, which resolved after repeat catheterization (grade 1). A third patient had a superficial wound infection at follow-up which was successfully treated with a course of oral antibiotics (grade 2). One of the patients who underwent IOC at the time of LC was noted to have common bile duct stones which were managed successfully with a postoperative ERC and stone extraction (grade 3). Overall, follow-up was complete for 83 (94.3%) of patients. There was a complication rate of 10.2% (n = 9) with a 3.4% re-admission rate (n = 3). There were no re-operations performed, nor where there any 30-day mortalities during the study period.

Table 14.5. Thirty-day postoperative complications of patients who underwent laparoscopic cholecystectomy after implementation across the Cape Metro West Health District.

Variable	Modified Accordion Grading System, n = 88 (%)					
	Mild	Moderate	Severe			Death
	1	2	3	4	5	6
Surgical complications^a						
Bile leak	1 (1.1)	-	-	1 (1.1)	-	-
Wound infection	-	1 (1.1)	-	-	-	-
Retained stones	-	1 (1.1)	1 (1.1)	-	-	-
Total	1 (1.1)	2 (2.3)	1 (1.1)	1 (1.1)	-	-
Non-surgical complications^a						
Postoperative pain	-	1 (1.1)	-	-	-	-
Urinary retention	1 (1.1)	-	-	-	-	-
Total	1 (1.1)	1 (1.1)	-	-	-	-
Total overall	3 (3.4)	4 (4.5)	1 (1.1)	1 (1.1)	-	-

^aA single patient may have multiple complications recorded.

Table 14.6. Thirty-day re-admissions and re-interventions of patients who underwent laparoscopic cholecystectomy after implementation across the Cape Metro West Health District.

Variable	Patients, n = 88 (%)
Re-admissions	3 (3.4)
Re-interventions	
Percutaneous drain	1 (1.1)
ERC	2 (2.3)
PTC	1 (1.1)

ERC – endoscopic retrograde cholangiography, PTC – percutaneous transhepatic cholangiogram

14.4 Discussion

The results of an analysis of the first three months of data following implementation of a change in practice for LC across the Cape Metro West Health District are presented in this chapter. Eighty-eight LCs were recorded during the study period, representing 80% of all LCs performed in the Cape Metro West Health District. The average total CVS score of 4.90 approached the previously published benchmark of at least 5 for an adequate critical view.¹⁹³ Adherence to the checklist was higher than reported in the pilot study and there were no recorded BDIs, re-operations or mortalities during the current study period. The first three months of data demonstrate successful implementation of the intervention in multiple hospitals and provide a baseline for assessing the quality of LCs performed in the Cape Metro

West Health District. The results also allowed for identification of areas for improvement in the future.

During the pilot phase of implementation (Chapter 13), the average total CVS score for 51 LCs performed over a four month period was 4.50 (SD \pm 1.70), compared to an average total CVS score of 4.90 (SD \pm 1.50) for 84 LCs performed over the first three months of implementation across Cape Metro West Health District hospitals. In addition to a higher overall score, the standard deviation decreased, suggesting values for individual CVS scores were closer to the mean in the current study, compared to the pilot study. The improvement in the total CVS score followed an effort to focus on the elements of the intervention that were poorly adhered to during the pilot study (Chapter 13). This involved emphasizing the anatomical and technical aspects of achieving the CVS and of intraoperative photo capture during a presentation of the implementation to consultants, junior consultants, registrars and medical officers at the participating hospitals. The success of the change following the presentation is reflected in the 5.4% reported rate of inadequate photos for scoring in the current study compared to the 16.7% reported rate of inadequate photos for scoring in the pilot study.

Of the 12 patients in whom the CVS was not achieved 4 underwent subtotal LCs as bailout procedures. For the remaining 8 patients, two and only two structures entering the gallbladder was the most common element of the CVS that was not achieved ($n = 5$). In one patient, there was an aberrant artery resulting in three structures in the hepatocystic triangle. Severe inflammation and bleeding prevented two and only two structures from being achieved in three patients and in another patient, the cystic artery was divided by cautery before all of the elements of the CVS were completed. In the remaining three patients, the lower 1/3 of the cystic plate was not able to be visualized due to gallbladder empyema and severe inflammation. Patients in whom the CVS was not achieved were more likely to be older and have choledocholithiasis as their indication for LC, both previously reported risk factors for conversion to OC.²⁸²⁻²⁸⁵

Similar to improved CVS scores, compliance to the checklist also increased during the current study period. The five critical steps to ensure dissection is initiated at a safe level were documented as being followed 85% of the time compared to 79% adherence in the pilot study. There was a modest increase in overall compliance for the CVS, increasing from 64%

to 66% in the current study and adherence to the pre-incision and IOC portions of the checklist remained high. The increased emphasis on the elements of the checklist during implementation of the LC intervention likely contributed to the higher rates of compliance in the current study. However, there is still room for improvement, particularly with compliance to the CVS portions of the checklist. In 6 of the 12 LCs where the CVS was not achieved, the surgeon proceeded with an LC despite not reaching the CVS. The current recommendation in the LC intervention, based on the available evidence, is that if the CVS cannot be achieved, a bailout procedure starting with calling for help of a colleague and an attempt at subtotal cholecystectomy should be the next steps.^{166,169} This point was addressed in the quarterly report to each of the participating hospitals. The report can be found in Appendix D. There were fewer IOCs performed in the current study (n = 2, 2.3%) compared to the pilot study (n = 6, 10.3%). This difference could be a result of relatively small sample sizes but is more likely related to resource availability at secondary level hospitals.

The overall complication rate of 10% in the current study is comparable to a contemporary study using a large database including over 300,000 patients.³⁴ However, in a systematic review with pooled analyses, postoperative morbidity following LC ranged from 1.6% to 5.3%.¹⁹⁹ Notably, there were no BDIs in this analysis and most of the complications were mild to moderate in severity. There were only two severe complications, none of which were severe grade 5 complications and no mortalities within 30-days, compared to two mortalities reported in the pilot study (Chapter 13). Without historical data from Cape Metro West hospitals to compare the current findings to, it is not possible to assess whether there was a reduction or increase in morbidity and/or mortality following implementation of the LC intervention. The current data do provide a baseline and allow for identification of opportunities for improvement with the benefit of ongoing routine data collection to measure any changes in morbidity and mortality as the study continues.

Broadening the implementation of the LC intervention to include all hospitals with a general surgery unit within the Cape Metro West Health District was successful. Approximately 80% of all LCs performed within the region were captured with an increase in compliance to the checklist and the CVS scores, and a decrease in mortality compared to the pilot study. Strict adherence to the CVS method should be emphasized in the quarterly hospital reports to address the lower levels of compliance to the CVS portion of the checklist and to ensure safe LCs continue to be performed. Assessment of compliance and evaluation of the morbidity

and mortality benefit from increased compliance is possible through the continued capture of LCs performed using the established LC database.

Establishing the Inter-rater Reliability of the Critical View of Safety Scoring Method

15.1 Rationale

The CVS method has been shown to dramatically reduce BDIs in LC and is considered the gold standard approach to intraoperative identification of the biliary anatomy.¹⁴¹ However, operative notes rarely reflect the intraoperative conditions during cholecystectomy.¹⁴⁶ Sanford and Strasberg published a “doublet” photography method for capturing the CVS in which intraoperative photos of the anterior and posterior critical view are taken.¹⁹³ The authors proposed including the photos as part of the operative note, serving as documentation of the CVS in the permanent medical record.¹⁹³ In the same study, criteria for scoring the quality of the CVS were also proposed and applied to 28 patients who underwent LC.¹⁹³ Agreement among reviewers was high, with either complete agreement or scores within one point of agreement in 96% of CVS photos evaluated.¹⁹³

This method of scoring the CVS was recently applied in two different study designs. The first study utilized crowd workers (anonymous individuals used to perform a human intelligence task) and faculty experts from SAGES to score the elements of the CVS from 160 videos of LCs published on the internet from sources such as YouTube, the SAGES video library and Vimeo.²⁸⁶ Inter-rater reliability among faculty experts using the CVS scoring method as measured by the ICC was 0.72, a “good” reliability according to thresholds typically used for Cronbach’s alpha statistic.^{286,287} The scoring method was subsequently used in a recently published proof-of-concept study that evaluated the feasibility of providing real time intraoperative feedback of the quality of the CVS prior to clipping and dividing of the cystic duct.²⁸⁸ Percentages were used to measure agreement between reviewers and were 85% for anterior and 82% for posterior view CVS photos.

In Chapter 13, a change in practice for LCs performed at GSH was described. The intervention included a LC checklist modified from the checklist proposed by Connor et al.,²⁷⁰ a standardized operative note, mandatory intraoperative doublet photos of the CVS and scoring of the photos by blinded reviewers using the previously mentioned scoring method.¹⁹³ Results of the first three months following implementation at GSH were presented. The LC implementation was then expanded to include hospitals with general surgery units within the Cape Metro West Health District and data from the first three months following

implementation are presented in Chapter 14. Over the six months following implementation, first at GSH and then throughout the Cape Metro West, more than 100 LCs with intraoperative doublet CVS photos were performed. This study aimed to assess inter-rater reliability of the previously published CVS scoring method using intraoperative photos from the first consecutive 100 LCs performed after implementation of the LC intervention.

15.2 Methods

15.2.1 Study design

The first 100 doublet photos of LCs collected and entered into the LC database were used. Operations that ended in a subtotal LC were excluded. Four local surgeons from GSH scored the photos as part of the ongoing quality assessment project following the LC intervention. Two international experts were invited to participate in the study after development of the intervention, implementation and data collection following implementation were completed. All reviewers used the previously described CVS scoring system.¹⁹³ Briefly, each doublet photo may earn a total of six points, two points for each of the three elements of the CVS. Two points were awarded if the criterion was immediately and clearly recognized in the photo. A single point was given if detailed study was required to identify the criterion due to instrument overlap, poor image quality, or partial visualisation. If the criterion was not visible, no points were awarded. A score of at least five was considered satisfactory, as previously proposed. Prior to scoring, reviewers received a presentation on the scoring method and were subsequently provided with copies of the previously published manuscript and supplemental presentation. Reviewers were asked to refer to the specified CVS criteria during the scoring process. The presentation included an anatomy review and detailed description of the scoring system with several examples of annotated intraoperative photos of the CVS for practice scoring.

15.2.2 Statistical analysis

The ICC with a two-way mixed effects model and absolute agreement was used to determine consistency among blinded reviewers' scores for each of the CVS elements and overall for the total CVS score.²⁸⁹ ICCs for average measures with 95% CIs are reported. Agreement was considered poor for ICCs < 0.40, fair for ICCs 0.4 to 0.59, good for ICCs 0.60 to 0.74 and excellent for ICCs > 0.75, as previously suggested.²⁹⁰ Cronbach's alpha is reported only for the purpose of exploration of individual reviewer contributions and not for evaluation of reliability, as it is known to be an inaccurate measure of reliability when the reviewer

variance is anything other than zero. All statistical analyses were performed using SPSS version 25 (IBM SPSS Statistics, IBM Corporation, Armonk, NY).

15.3 Results

15.3.1 Blinded reviewers and average critical view of safety scores

A total of six reviewers were invited to participate in the validation study, two international experts, both of whom were specialized HPB surgeons, and four local reviewers, of whom two were practising general surgeons and two were specialized HPB surgeons. One local reviewer, an HPB surgeon, was excluded from the analysis for incomplete data. The following results represent CVS scores from two general surgeons (reviewers 1 and 2) and three HPB surgeons (reviewers 3, 4 and 5). Average CVS scores are presented in Table 15.1. The criterion with the highest mean score was the hepatocystic triangle free of fibrous and fatty tissue (1.64 ± 0.62), while the lowest mean score was for two and only two structures entering the gallbladder (1.39 ± 0.81). The mean overall CVS score was 4.53 (± 1.71), below the threshold score of 5 for an adequate CVS.¹⁹³ Average scores for the three elements of the CVS varied by less than 0.5 points and average total CVS scores varied by less than 1 point between the five reviewers (Figure 15.1).

Table 15.1 Average critical view of safety scores.

CVS criteria	Mean score (\pm SD)
Hepatocystic triangle clear	1.64 \pm 0.62
Two and only two structures entering the gallbladder	1.39 \pm 0.81
Lower 1/3 of the cystic plate visible	1.51 \pm 0.64
Total CVS score	4.53 \pm 1.71

CVS – critical view of safety

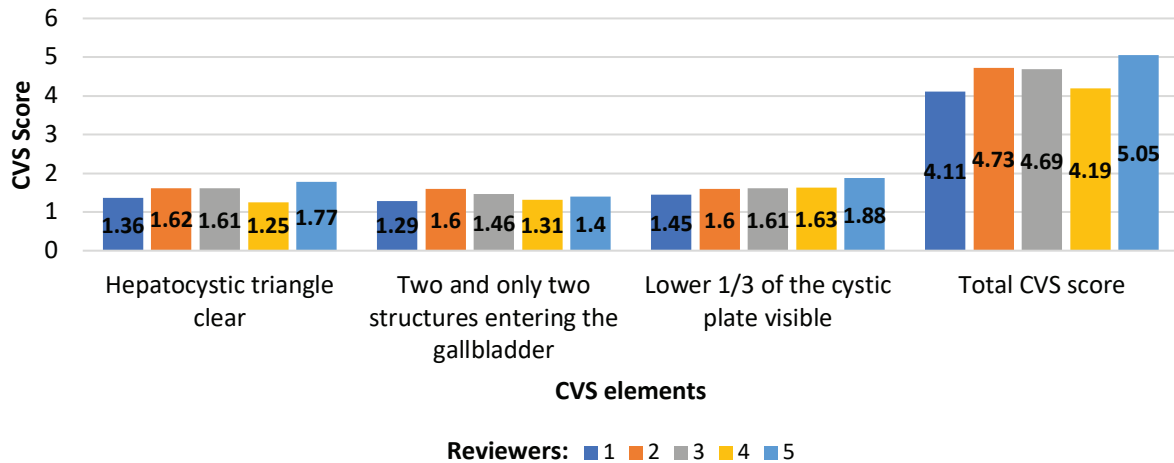


Figure 15.1 Average scores from each of the five reviewers for the three elements and the total critical view of safety score.

CVS – critical view of safety

15.3.2 Intra-class correlation coefficients and reliability categories

The ICCs with 95% CI and the corresponding reliability category are shown in Table 15.2. The ICCs for the hepatocystic triangle free of fibrous and fatty tissue and for the visible lower 1/3 of the cystic plate criteria were similar, 0.73 (95% CI 0.57-0.84) and 0.74 (95% CI 0.58-0.84), respectively, and were at the upper limit of the “good” reliability category. The two and only two structures entering the gallbladder criterion had the largest ICC and at 0.88 (95% CI 0.81-0.93) is within the “excellent” reliability category. The ICC for the total CVS score was 0.85 (95% CI 0.75-0.92), also within the “excellent” reliability category.

Table 15.2. Intraclass correlation coefficients, 95% CI and reliability category for each of the three elements and overall critical view of safety scores.

CVS element	ICC	95% CI	Reliability
Hepatocystic triangle clear	0.73	0.57-0.84	good
Two and only two structures entering gallbladder	0.88	0.81-0.93	excellent
Lower 1/3 of the cystic plate visible	0.74	0.58-0.84	good
Overall CVS score	0.85	0.75-0.92	excellent

CVS – critical view of safety, ICC – intra-class correlation coefficient

15.3.3 Visualization of agreement between reviewers for the critical view of safety scores

Dot plots demonstrating individual patient CVS scores from the five blinded reviewers are shown in Figure 15.2a-d. The greatest amount of agreement between reviewers occurred for scoring of the two and only two structures entering the gallbladder criterion of the CVS as

indicated by the fewest gaps in the rows of dots along the z axis which is supported by the ICC of 0.88 (Figure 15.1c and Table 15.2). A hepatocystic triangle free of fibrous and fatty tissue received the highest mean score of the three elements (1.64, Table 15.1) as is demonstrated by the greatest concentration of dots with a score of two on the y axis in Figure 15.1a. The two and only two structures entering the gallbladder criterion had the greatest number of zero points scores given by the reviewers, demonstrated by the greatest concentration of dots with a score of zero on the y axis (Figure 15.1b). Although all included patients had an operative note that documented the three elements of the CVS were achieved (n = 100), only 52% of scores met the five points or greater criteria for an adequate critical view (Figure 2d).

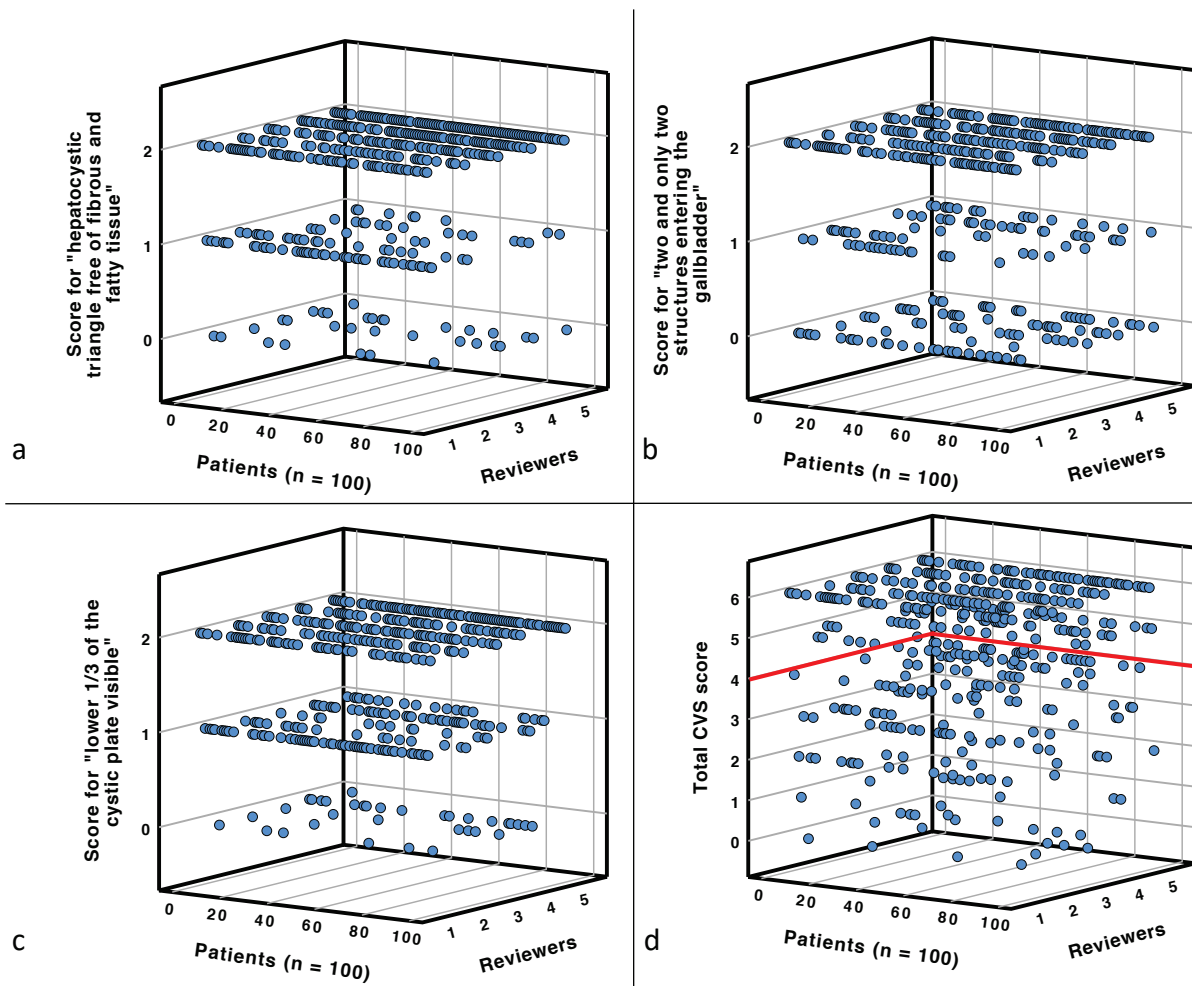


Figure 15.2a-d. Dot plots demonstrating critical view of safety scores for each of the three elements of the critical view and the total overall score. Each patient (n = 100) is represented by a number along the x-axis and the score from each blinded reviewer is represented as a blue dot on the y-axis. Blinded reviewers are listed along the z axis. Perfect agreement between the five reviewers results in a line of five dots along the z axis. Where there is disagreement, there are gaps in the line with the incongruous score(s) plotted as a blue dot either above or below. Scores for a hepatocystic triangle free of fibrous and fatty tissue are shown in (a), scores for two and only two structures are shown in (b), scores for the lower third of the cystic plate visible are shown in (c) and overall total CVS scores are shown in (d). In figure 15.2d, the red horizontal line indicates the target total minimum score of five (all blue dots above four represent a score of five or greater).

CVS – critical view of safety

15.3.4 Exploratory analyses for the total critical view of safety score

The inter-item correlation matrix for the total CVS score is presented in Table 15.3 and demonstrates the correlation of total CVS scores between pairs of reviewers for all possible comparisons. The lowest correlation for total CVS score was between reviewers 1 and 2 (0.44) followed by reviewers 2 and 4 (0.48) and then reviewers 2 and 3 (0.49). All but four pairwise comparisons resulted in correlations greater than 0.70, which corresponds to a high

degree of agreement. Cronbach’s alpha for the total CVS scores across all reviewers was 0.90 (Table 15.4). The adjusted Cronbach’s alpha after stepwise removal of each reviewer in turn is presented in Table 15.4. Notably, removal of any of the five reviewers would result in a small change in Cronbach’s alpha. The largest change (– 0.05) occurred when scores from reviewer 3 or 4 were removed from the analysis, with a decrease from 0.90 to 0.85. Removal of scores from reviewer 2 resulted in a small increase in Cronbach’s alpha, from 0.90 to 0.91, and was the only reviewer that resulted in an increase in Cronbach’s alpha after removal.

Table 15.3 Inter-item correlation matrix total critical view of safety score.

	Reviewer 1	Reviewer 2	Reviewer 3	Reviewer 4	Reviewer 5
Reviewer 1	1.00	0.44	0.71	0.72	0.71
Reviewer 2	0.44	1.00	0.49	0.48	0.53
Reviewer 3	0.71	0.49	1.00	0.80	0.78
Reviewer 4	0.72	0.48	0.80	1.00	0.83
Reviewer 5	0.71	0.53	0.78	0.83	1.00

Table 15.4 Cronbach’s alpha for total critical view of safety scores, adjusted for stepwise removal of individual reviewers.

Cronbach’s alpha = 0.90	
Reviewer number	Cronbach’s alpha if deleted
Reviewer 1	0.87
Reviewer 2	0.91
Reviewer 3	0.85
Reviewer 4	0.85
Reviewer 5	0.87

15.4 Discussion

This study aimed to determine the inter-rater reliability of the previously described CVS scoring method using the ICC and the originally proposed values by Cicchetti for “poor”, “fair”, “good” and “excellent” reliability.^{193,289,290} The total CVS score was found to have an excellent reliability, indicating that when reviewers were instructed on how to apply the CVS scoring method, there was a high degree of agreement and the CVS was rated similarly by reviewers. The high ICC suggests that a minimal amount of measurement error was introduced by the independent reviewers, therefore the CVS scoring method is highly likely to result in consistent scores when appropriately applied by other reviewers. Similarly, the scores for each of the three elements of the CVS resulted in excellent reliability for the two and only two structures, and good reliability for the hepatocystic triangle free of fibrous and

fatty tissue and the visible lower 1/3 of the cystic plate criteria. Exploratory analyses for the total CVS score supported the high degree of consistency among scores, with minute changes to Cronbach's alpha when reviewers were removed in a stepwise fashion. Finally, although there was excellent inter-rater reliability for the CVS scoring method, the overall mean total CVS score was only 4.53, below the required score of 5 for an adequate critical view. Potential contributing factors, future interventions and the limitations of this finding are addressed in Chapters 13 and 14.

ICC observed in this study for total CVS score were comparable to the only other previously reported ICCs for this method (0.85 vs 0.72).²⁸⁶ Even though two of the elements of the CVS, the hepatocystic triangle and the lower 1/3 of the cystic plate, had ICCs in the "good" reliability range, they were both at the upper limit (0.73 and 0.74, respectively) for the "good" category. Additionally, the 95% CI for the two elements reached just below the upper limit of the "fair" reliability category but extended well into the "excellent" category. For the total CVS score, the 95% CI were within the "excellent" reliability category, supporting the reproducibility of the CVS scoring method. This was further supported in the exploratory analyses.

The availability of an easy to use, validated and reliable method for assessing the quality of the CVS in LC is beneficial for several reasons. First, the CVS is considered the gold standard for the intraoperative identification of anatomy.¹⁴¹ A method for scoring the quality of the CVS may provide a means for regular or even real-time feedback to prevent BDIs from occurring. Second, a standardized, reliable and validated scoring system is necessary for research and facilitates comparison across studies.^{291,292} Finally, tracking scores of the CVS over time is a potential means for measuring the success of an intervention aimed at improving the quality of LC. A reliable scoring method is particularly relevant to the ongoing LC intervention and quality assessment in the Cape Metro West Health District hospitals, presented in Chapters 13 and 14.

For a score or a test to be considered useful, evidence to support its reliability *and* validity must be available.²⁹¹ The results of the reliability assessment of the CVS scoring method presented here, in addition to those reported by Deal et al., add to the confidence in its ability to generate reproducible scores.²⁸⁶ While reliability tells us how trustworthy results from a scoring system are, validity assesses whether the score is appropriate for a given situation.¹⁰

In other words, validity answers the question whether the CVS score correlates with surgeon performance or a reduction in BDIs. Measuring a reduction in the incidence of BDIs is not a feasible endpoint as the occurrence of BDI is a relatively uncommon event and substantial numbers are required to measure a change in incidence. However, a statistically significant correlation between an instrument used to assess skills in laparoscopic surgery and the CVS score was demonstrated when LC videos were scored by crowd workers and faculty experts (Spearman correlation coefficient 0.77 and 0.71, respectively, $p < 0.0001$).²⁸⁶ Although the authors present limitations to these findings, including overall low GOALS and CVS scores, their report provides evidence to support the validity of the CVS scoring method.

There are several limitations to this study that need to be mentioned. The reviewers included only general and HPB surgeons, therefore the high degree of inter-rater reliability can only be generalized to use of the CVS scoring method by other surgeons of the same specialties. Deal et al. found that CVS scores of crowd workers were non-inferior to those of faculty experts, but note that due to the low number of adequate critical views, crowd workers were rather found to be non-inferior to experts at identifying an unsatisfactory CVS.²⁸⁶ Further work should be done to assess the reliability of scores by non-experts to make routine audits of intraoperative critical views feasible and affordable. Instructing reviewers on how to use the CVS score requires careful attention and time. In future studies and for general use, education about the CVS score is required and necessary for consistently reliable scores. Finally, this analysis is not a complete validation study, as only reliability was assessed. Some work to assess the validity of the CVS scoring method has already been done²⁸⁶ and future work to establish validity should continue.

In conclusion, the CVS scoring method using intraoperative doublet photography is a simple and highly reliable method for assessing the quality of the CVS when reviewers are appropriately instructed on how to apply the scoring criteria. Assessment of the validity of the scoring method is incomplete and should be pursued so that it can be confidently used as a measure of the quality of the CVS in LC. As there are no other reliable scores for assessing the CVS, the currently assessed method should continue to be used to evaluate the quality of the critical view for the ongoing LC intervention within the Cape Metro West Health District hospitals.

Development of a Standard Operating Procedure, Binder and eBinder

16.1 Rationale

In an effort to promote a culture of safety in LC, a checklist, adapted from the checklist proposed by Connor et al.,²⁷⁰ a standardized operative note and mandatory intraoperative photo documentation of the CVS¹⁹³ were implemented across four hospitals in the Cape Metro West Health District in Cape Town, South Africa. The intervention was in an effort to establish a minimum quality of performance for LC and to provide a means for regular quality assessment through CVS scores, review of operative notes and analysis of LC-associated morbidity and mortality. The LC database, maintained at UCT, was created to capture data generated after this change of practice was implemented. Data collection is scheduled to proceed for one year following implementation after which the aim is to expand the intervention across the Western Cape and beyond. From the beginning, the vision of the team involved in implementation and maintenance of LC database was to ensure that the project's success was not dependent on a single individual. As such, a Standard Operating Procedure (SOP) and a LC database Binder and eBinder were created.

16.2 Methods

16.2.1 The standard operating procedure

The LC database SOP was created to promote continuity of research related to the LC intervention. The document articulates the primary aim and objectives of the research and includes a list of relevant abbreviations, terms and definitions. Importantly, the ethics requirements for maintenance of the database including procedures for ethics renewal and a method for tracking ethics applications and approvals are described. User rights for researchers involved in data entry, minimum requirements for use of the data, and authorship of publications and presentations originating from studies using the database are addressed. Methods that should be employed to ensure the data are complete, accurate and up to date are described. Steps that should be taken to maintain confidentiality and informed consent requirements are included. Finally, the procedure for regular audits of the database to ensure quality of the data are specified. The SOP should be reviewed annually by the research team and any changes made and documented accordingly. The complete SOP for the LC database is included in Appendix B.1.

16.2.2 The laparoscopic cholecystectomy database binder and eBinder

The LC database binder was created to accompany the SOP. The binder consists of six tabs including, “Letters”, “Intervention”, “Code Book”, “Forms and Templates”, “Relevant Literature” and “LC Database Study Protocols”. The SOP is located at the front of the binder. All HREC and GSH approval letters for the database and data collection across the Cape Metro West hospitals are found under the Letters tab. The Intervention section includes the most recent version of the LC checklist, standardized operative note, informed consent form, a template for a poster of an example of the ideal anterior and posterior CVS photos and a draft of a patient information sheet. The patient information sheet is not yet used but is currently being considered as an addition to the change of practice intervention. Under the Code Book tab is a copy of the REDCap LC database code book. All required forms for ethics renewal and application for user access to non-UCT researchers as well as templates for the monthly emails sent to participating hospitals can be found under the Forms and Templates tab. The Relevant Literature section includes the literature on which the intervention is based. Finally, a copy of all HREC approved study protocols, and SDRC and HREC approval letters for studies using data extracted from the LC database are located under the LC database Study Protocols section. The paper version of this binder is kept in the Surgical Gastroenterology Unit with the unit’s research manager. An electronic version of the LC database Binder (eBinder) was created to facilitate easy use of forms, templates and intervention materials. The eBinder is shared via Dropbox with the principal investigators and any researchers identified as data managers. Both versions of the binder are maintained by the researcher designated by the research team as the person responsible. An outline of the binder and reference to the included documents can be found below, the complete binder is located in Appendix B.

Laparoscopic cholecystectomy database binder (and eBinder) contents

1. Standard operating procedure
2. Letters
 - HREC approval letter
 - Chief Operational Officer approval letter
3. Intervention
 - LC checklist
 - Standardized operative note
 - Informed consent form

CVS anterior and posterior photo example poster

LC patient information page

4. Code book

REDCap code book for the LC database

5. Forms and templates

FHS017 form for HREC renewal of the LC database

Annexure 2 form for Chief Operational Officer approval

BAS03 form for T-number to grant access to REDCap for non-UCT researchers

Monthly email template

6. Relevant literature

Connor SJ, Perry W, Nathanson L, Hugh TB, Hugh TJ. Using a standardized method for laparoscopic cholecystectomy to create a concept operation-specific checklist. *HPB (Oxford)*. 2014;16(5):422-429.

Sanford DE, Strasberg SM. A simple effective method for generation of a permanent record of the Critical View of Safety during laparoscopic cholecystectomy by intraoperative "doublet" photography. *J Am Coll Surg*. 2014;218(2):170-178. (supplemental material in the form of PowerPoint presentation included)

Strasberg SM, Hertl M, Soper NJ. An analysis of the problem of biliary injury during laparoscopic cholecystectomy. *J Am Coll Surg*. 1995;180(1):101-25.

Strasberg SM, Pucci MJ, Brunt LM, Deziel DJ. Subtotal cholecystectomy-"fenestrating" vs "reconstituting" subtypes and the prevention of bile duct injury: Definition of the optimal procedure in difficult operative conditions. *J Am Coll Surg*. 2016;222(1):89-96.

Kubheka B. Ethical and legal perspectives on use of social media by health professionals in South Africa. *S Afr Med J*. 2017;107(5):386-369.

Mars M, Scott R. WhatsApp in clinical practice: A literature review. *Stud Health Technol Inform*. 2016:231:82-90.

Opperman CJ, Janse van Vuuren M. WhatsApp in a clinical setting: The good, the bad and the law. *S Afr J Bioethi Law*. 2018;11(2):102-103.

7. LC Database study protocols

“An assessment of the quality of the critical view of safety achieved in laparoscopic cholecystectomy”

PI: Professor Eduard Jonas; Student: Dr. Jessica Lindemann

Attachments:

HREC application

HREC protocol
Data collection sheet
SDRC approval Letter
HREC approval letter

“Interim analysis of the LC database: January – March 2020”

PI: Professor Eduard Jonas; Student: Dr. Jessica Lindemann

Attachments:

HREC application
HREC protocol
Data collection sheet
SDRC approval letter
HREC approval letter

16.3 Discussion

Simply stated, the purpose of an SOP is to define “who does what when”.³ SOPs are used in multiple contexts and across many disciplines, including medicine and medical research, to promote efficiency, consistency, and safety, and to ensure compliance with institutional, industry and governmental standards.^{293,294} Importantly, SOPs are not “one size fits all” documents, but rather are created in a variety of forms, adapted to fit the environment within which they will be used.²⁹⁴ The development of the LC database SOP was guided by principles and requirements outlined by the Clinical Research Centre at UCT. The purpose of the LC database SOP is to provide guidelines for the management of the database, supporting data collection for the ongoing change of practice implementation. The document is intended to be a living document, used daily and reviewed at regular intervals with appropriate updates and changes as necessary.

17.1 Summary of findings

Although population level data are lacking, large single-centre studies suggest that the incidence of LC-BDIs is higher in LMIC compared to HICs.^{25,36,38} The morbidity associated with a major LC-BDI can be significant with a prolonged hospital stay, the need for multiple invasive investigations and interventions, major reconstructive surgery, a lengthy recovery period and loss of income.²⁵¹ The burden of disease related to LC-BDI for the patient, their family and the healthcare system is amplified in LMICs with resource-constrained healthcare systems and widespread economic hardship. In LMICs, the financial burdens associated with a BDI are exacerbated by high unemployment and a lack of social security networks, especially when a single breadwinner for an extended family is involved.²⁹⁵ There are little data available on the scope of the problem of LC-BDIs and minimal evidence on management and outcomes after surgical repair for South Africa. This research aimed to address this knowledge gap in the literature, to provide context for future studies and to inform changes in management moving forward.

In Chapter 3, the estimated incidence of LC-BDIs at a tertiary academic teaching hospital in Cape Town, South Africa was 0.3% for years with complete data, a finding consistent with the recently published literature.^{27,32} Several limitations prevented extrapolation of the local incidence of BDIs to determine regional and national LC-BDI rates. Perhaps more important than the local LC-BDI incidence, were the deficiencies in available data highlighted by this chapter. There is no multi-institutional registry or database, insurance company, pathology laboratory or independent regulatory body from which a cross-sectional sample of national data can be extracted. This, in addition to the current organization of the healthcare system, make generating a reasonably accurate estimate of the annual number of LCs performed in South Africa incredibly challenging and estimating the incidence of LC-BDIs essentially impossible. This deficiency in data availability must be addressed to fully understand the problem of LC-BDI and to facilitate quality improvement of a commonly performed operation that has the potential for severe complications.

Chapters 4 through 10 focused on different aspects of the management of LC-BDIs that may influence patient outcome after surgical repair. As the analyses for each chapter utilized data from a BDI database spanning 30 years, Chapter 4 began by investigating the evolution in the management of LC-BDIs over time. Between the two study time periods (1991 to 2004 and 2004 to 2017), the number of referrals for LC-BDI nearly tripled, and the number of geographically distant referrals nearly doubled. This resulted in an increase in the number of intermediate and late repairs. Not surprisingly, there was increased access to cross-sectional imaging and PTBCs prior to repair in the more recent time period. Chapter 5 investigated the relationship between the geographic distance from the referral centre and the timing of repair. A significant association between the two was demonstrated with a trend toward less severe complications for later repairs. In Chapter 6, the influence of healthcare sector on management and outcomes was explored. Although there was an observed increase in access to some preoperative investigations in the private healthcare sector, there were no unequal delays in receiving care and the difference in access to investigations did not result in statistically significant differences in short- or long-term outcomes among patients treated in the private compared to the public healthcare sector.

In an analysis of the correlation between the type of injury and severity of postoperative complications in Chapter 7, no statistically significant relationship was identified. Evidence in the literature on this finding is conflicted.^{108,114} A definitive conclusion regarding level of injury and postoperative outcomes is unlikely to come from single centre studies due to the large sample size required to allow for consideration of multiple contributing factors in the analysis. A minimally invasive treatment alternative for the management of LC-BDI was explored in three cases presented in Chapter 8. The feasibility of long-term endoscopic stent exchanges for selected patients with LC-BDI who underwent definitive treatment with the extraluminal rendezvous procedure and who live farther than 1000 km from the referral centre was demonstrated. In Chapter 9 potential factors influencing loss of patency after surgical repair were analysed using multivariate logistic regression analysis and a recently proposed standardized method of reporting. The only independent predictor of loss of patency was incomplete preoperative depiction of the biliary tree, resulting in a more than 10-fold increase in the odds of requiring revision of the HJ repair. Further studies are required to investigate whether incomplete biliary imaging prior to repair results in loss of patency due to an under appreciation of the severity of the injury or if it serves as a surrogate marker of the repair by a non-HPB specialized surgeon, or perhaps both. Encouragingly, patients who

required a second HJ reconstruction for loss of patency had similar postoperative outcomes compared to patients undergoing an initial HJ repair when repairs were performed in a specialized HPB unit. Finally, in Chapter 10 a treatment algorithm for the management of LC-BDIs in LMICs was proposed.

Chapter 11 addressed the tangible consequences and intangible costs of LC-BDI, highlighting the difficulties in measuring costs such as the anxiety of undergoing a major operation, the worry over accumulating medical costs amplified by loss of income from time spent away from work, the frustration of a lengthy recovery period and potentially, unpleasant and prolonged litigation. Importantly, the often-ignored aspects of LC-BDI including the surgeon's emotions of guilt and worry, worsened by the prospect of litigation were also discussed.

A better understanding of the management and outcomes after LC-BDI in the South African healthcare setting was achieved in the first portion of this research, but the source of the problem was not addressed, namely the prevention of BDI. The focus of the remaining chapters in this thesis was on the development and implementation of an intervention aimed at making LC-BDI a near-never event. In Chapter 12, to understand factors contributing to the occurrence of LC-BDIs in South Africa, a detailed analysis of 22 LC operative notes from BDI referrals was performed. The findings revealed a failure to follow the CVS method in every case, despite it being the widely accepted gold standard technique for performing a safe LC. This finding is not surprising as a BDI when using the CVS method is exceedingly rare,^{139,142,145} but it does emphasize the need for further education in the elements of the CVS and which bailout procedures are applicable if the CVS cannot safely be achieved. This analysis in addition to the seminal work of Strasberg, Way, Connor and others, prompted the LC intervention outlined in the following chapters.^{43,55,270}

In Chapter 13 a description of the LC intervention including the LC checklist, standardized operative note and intraoperative photo documentation of the CVS, and the results of a three-month pilot study are described. Compliance with use of the LC checklist was high after initial implementation at our tertiary academic hospital, with the exception of achieving the CVS which was limited by the number of subtotal LCs performed. The overall average CVS score was 4.50 (SD \pm 1.70), slightly below that of the previously suggested acceptable target score of 5.¹⁹³ Improvement in the quality of intraoperative photos taken as well as changes to

the operative note to limit the likelihood that questions go unanswered were two areas where opportunities for improvement were identified. Additionally, the need for validation of the CVS scoring method was also recognized. In Chapter 14, the results of expanded implementation of the LC intervention to include the hospitals in the Cape Metro West Health District were presented. Adherence to the LC checklist improved or remained greater than 96% compared to compliance in the pilot study. Although compliance for the CVS section remained below 70%, the average of total CVS scores increased to 4.90 (SD \pm 1.50). Overall, the first quarter of data collection and analysis demonstrated successful implementation of an evidence-based change in practice for LCs across the Cape Metro West, provided a baseline for assessing the quality of LCs performed and allowed for identification of opportunities for further development as part of an ongoing quality improvement process.

The reliability assessment for the CVS scoring method was presented in Chapter 15. The scoring method was found to be highly reliable when used by HPB and general surgeons after being instructed on how to apply the scoring criteria. Chapter 16 addressed the steps taken to ensure that the LC database continues to produce high quality data suitable for research and quality improvement, to support adherence to ethical standards in research and to promote continuity of research related to the LC intervention. An SOP, binder and eBinder were developed for the LC database to achieve these goals and to facilitate the process of broadening the LC intervention and data collection to the provincial and eventually national level.

17.2 Limitations

There are several limitations of this research that should be acknowledged. According to the US (prevalence of <200,000 people each year) and the European Union (<50 per 100,000 people) definitions, LC-BDI is considered an uncommon event.^{296,297} There are several challenges related to studying uncommon events which include concern of whether the study sample is representative, the risk of significant confounding within the study population and acknowledgement that p-values are particularly vulnerable to small changes in the data when the sample size is small.^{298,299} Each of these represent limitations of the research presented here, with the additional problem of non-standardized reporting of LC-BDIs in the previously published literature. There are several techniques that have been suggested to overcome these limitations including case-control study designs, propensity score matching and modelling to address potential confounders. However, these interventions can only adjust for measured

variables and do not address unmeasured sources of confounding within the study population. Another study design method used to overcome some of the limitations related to studying uncommon events is systematic review and meta-analysis. Due to a lack of standardized reporting, generating pooled estimates through a meta-analytical methodology is not possible for LC-BDIs. Differences in terminology used to classify BDIs, the observational and often retrospective study design and the wide variation in the presentation of outcomes after treatment of BDI result in significant individual study bias and heterogeneity between studies, which prohibit summarizing the data using statistical methods.

Although database research allows for larger sample sizes and is particularly useful in studying uncommon events such as LC-BDI, there are limitations in the extracted data. Incomplete coverage and partial individual patient entries will compromise data quality and decrease accuracy of results. Inaccuracies in data entry are unavoidable as a result of human error in the entry process and missing data are inevitable in the medical record. Traditionally, national, multinational or administrative databases allow for large patient numbers with relatively few data points per patient, limiting the type of questions that can be investigated. The BDI database used for this research is an exception, including 671 data fields for every patient entered. However, there was incomplete data, particularly follow-up data, as patients are often referred from several hundred kilometres away and follow-up in many cases occurs at referring centres. Although email correspondence was available for some patients, without a national electronic medical record system, obtaining complete follow-up data is challenging. Additionally, in a healthcare system that is over-burdened and treating patients who may not have the financial means for transport and to take time off from work for follow-up visits, routine follow-up for the asymptomatic patient is often neglected.

The primary aim of the LC intervention was to make LC-BDI a near-never event. However, measuring a change in the incidence of LC-BDIs requires a significant sample size, one that is likely not feasible even when all LCs performed across a geographic area the size of the Cape Metro West Health District are included. For example, to test an intervention aimed at limiting LC-BDIs, each study arm would need 16,989 patients for a total of almost 34,000 patients to measure a 50% difference in the incidence of BDIs with a known local incidence of approximately 0.3%, assuming an alpha of 0.05 and 80% power.¹⁹⁹ Instead, outcome measures for a safe LC were used, including length of hospital stay, 30-day complications, mortality and re-interventions. However, in the absence of an adequate sample size, accurate

determination of whether the intervention resulted in a decrease in LC-BDIs remains problematic. Importantly, the reliability of a method for scoring the CVS was investigated and shown to be a reliable and reproducible method for scoring the CVS in LC. However, the CVS score represents another surrogate marker for LC-BDI and although widely accepted as the gold standard for performing a safe LC, level I evidence to support the CVS method is lacking. Perhaps the greatest limiting factor in assessing the effectiveness of the LC intervention is the paucity of data available to define the baseline incidence of LC-BDIs and establish the morbidity, mortality and CVS scores before the LC intervention was implemented. As described in Chapter 3, in South Africa the non-existence of a national database, the distinct divide between the public and private healthcare sectors and the absence of an electronic medical record significantly limited data collection on prevalence of LC, incidence of BDIs and associated morbidity and mortality prior to the LC intervention and database creation.

17.3 Recommendations

According to the findings reported in this research, the following recommendations regarding the prevention and management of LC-BDIs are made:

Recommendation 1. Continue surgeon education on best practices for performing a safe LC
This should include ongoing education for specialized general surgeons in the form of online educational material, skills workshops and LC-specific sessions at local, regional and national conferences. Surgeons should be able to earn continued profession development points for educational activities related to LC. For surgical trainees, mastery of the LC procedure and the CVS method for performing LC should be mandatory. Experience in using bailout procedures such as subtotal LC and conversion to OC and adjuncts to LC such as IOC should be provided. An excellent, evidence-based resource for specialized surgeons and trainees is The Safe Laparoscopic Cholecystectomy Program on the SAGES website. The program includes 12 didactic modules with intraoperative photo and video and quizzes to assess comprehension and is free of charge. The program can be accessed at: <http://fesdidactic.org/> and should be considered as a potential requirement for trainees prior to completion of their training.

Recommendation 2. Continue to advocate early referral to an HPB specialized unit for management of LC-BDIs

As demonstrated in Chapter 4, an increasing number of referrals to a specialized HPB unit was in line with the widespread practice of referring patients for management of LC-BDIs. However, timing of referral varied with some patients referred weeks to months after the injury. The message of early referral to a specialized HPB unit should continue to be promoted at educational meetings and professional society conferences using the proposed algorithm for management of LC-BDIs in resource-constrained environments. The outcome of patients managed in a specialist unit in South Africa is comparable to results reported from the rest of the world, but the outcomes of patients treated locally were not evaluated in this research. The literature suggests early referral to an HPB specialized unit results in the best long-term outcome for the patient with a LC-BDI.

Recommendation 3. Universal adoption of a standardized approach to BDI classification and reporting of outcomes for LC-BDI

One of the most significant limitations in studying LC-BDI is the lack of standardization in the classification system and reporting method used within the expansive body of literature on the topic. A single classification system should be used to allow for comparison of injury types across studies. The most widely accepted classification system is the Strasberg classification.⁴³ To facilitate comparisons, future studies should include the Strasberg classification of LC-BDIs, even if other classifications are also used. Although retrospective re-classification is possible in some cases, many classification systems do not include sufficient information to accurately re-assign a Strasberg classification retrospectively. Reporting of outcomes is similarly varied, limiting the possibility of comparing outcomes across studies. A recently proposed method for standardized reporting of outcomes after endoscopic and surgical management of BDI, which incorporates the Strasberg classification, was recently proposed and applied in this research.¹⁰⁹ Consideration should be given to submitting the proposed method of reporting to the Equator Network and requiring relevant speciality-specific journals to adopt the standardized reporting requirements.

Recommendation 4. Establish a national database for LC

As part of the LC intervention, a database was created to routinely capture standardized, routine data for every LC performed with the aim of scaling up data collection to the provincial and eventually national level. The absence of a national database significantly

limits the possibility of quantifying the number of LCs performed, the incidence of BDIs and the morbidity and mortality associated with LCs in South Africa. Understanding the baseline burden of disease associated with LCs is essential to future studies aimed at reducing morbidity and cost associated with this commonly performed operation.

Recommendation 5. Create a mechanism for regular audits of quality and safety of LC at the surgeon, institutional, regional, healthcare sector and national level

Ongoing quality assurance and patient safety assessment in the provision of healthcare are necessary to ensure patients receive the best possible care and are routinely performed in many HICs.³⁰⁰ Currently, there is no system in place to assess important patient-related outcomes, quality of care or patient safety for surgery in South Africa. The LC database provides a mechanism for regular audits of quality of LC at the individual surgeon, institutional and regional levels and can be expanded to the national level. Quarterly analyses of the LC database should be continued with results presented to the participating hospitals in a similar format to that used in this research, as detailed in Chapter 14. The presentation should facilitate a conversation around potential areas of improvement. Changes in practice based on the quarterly analysis should be documented and the effect on patient outcome investigated. Careful consideration should be given regarding how quality assurance is performed to ensure the process results in professional advice and support rather than punitive action for surgeons.

17.4 Conclusion

LC continues to be a commonly performed operation worldwide. BDI in LC is an uncommon but feared complication with significant associated morbidity and mortality. There is insufficient data available to estimate the frequency of LC and the incidence of LC-BDIs for South Africa. The surgical management and outcomes after LC-BDI for the country was previously unknown. This research aimed to fill the gap in the literature by performing a detailed analysis of the management of LC-BDI at a tertiary referral centre in Cape Town, South Africa with a catchment radius of more than 1,000 km. A treatment algorithm for management of LC-BDI in resource-constrained environments was proposed based on local experience. To address the problem of LC-BDI a change of practice for LC was implemented, aimed at making BDI a near-never event. A LC database for the Cape Metro West Health District was also created to provide a mechanism for local and regional quality assurance and patient safety analysis, with the possibility of expanding the effort to the

national level. Finally, five recommendations were made regarding the future management and prevention of LC-BDIs in South Africa based on to the results presented in the studies on which this thesis is based.

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Appendix A: Chief Operational Officer letter of approval



GROOTE SCHUUR HOSPITAL

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Professor Eduard Jonas
SURGICAL GASTROENTEROLOGY

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Dear Professor Jonas,

RESEARCH PROJECT: Factors Influencing Patient Outcomes In The Surgical Management Of Bile Duct Injuries In Laparoscopic Cholecystectomy

Your recent letter to the hospital refers.

You are granted permission to proceed with your research, which is valid until **30 June 2020**.

Please note the following:

- a) Your research may not interfere with normal patient care.
- b) Hospital staff may not be asked to assist with the research.
- c) No additional costs to the hospital should be incurred i.e. Lab, consumables or stationary. **If access to TRACK Care/NHLS is required, kindly attach our letter of approval to the application form.**
- d) **No patient folders may be removed from the premises or be inaccessible.**
- e) Please provide the research assistant/field worker with a copy of this letter as verification of approval.
- f) Confidentiality must always be maintained .
- g) **Should you at any time require photographs of your subjects, please obtain the necessary indemnity forms from our Public Relations Office (E45 OMB or ext. 2187/2188).**
- h) Should you require additional research time beyond the stipulated expiry date, please apply for an extension.
- i) Please discuss the study with the HOD before commencing.
- j) Please introduce yourself to the person in charge of an area before commencing.
- k) On completion of your research, please forward any recommendations/findings that can be beneficial to use to take further action that may inform redevelopment of future policy / review guidelines.
- l) **Kindly submit a copy of the publication or report to this office on completion of the research.**
- m) **At no time should any posters encouraging patients to partake in research, be displayed within a clinical area.**

I would like to wish you every success with the project.

Yours sincerely

A handwritten signature in black ink, appearing to read 'B Eick'.

DR BERNADETTE EICK
CHIEF OPERATIONAL OFFICER

Date: 12 September 2019

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Appendix B: Laparoscopic cholecystectomy database binder

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B.6.1 Reference list of relevant literature

B.7 Letters of approval for study protocols related to the LC database

Note: full protocols of approved studies are included in the print and electronic versions of the LC database binder.

Appendix B.1 – Standard operating procedure

 University of Cape Town		Standard Operating Procedure
Title	Laparoscopic Cholecystectomy Database	
Number	01	
Version	1	

	Name	Title	Signature	Date
Reviewer	Jessica Lindemann	Doctor		16/06/2020
Authoriser	Eduard Jonas	Professor		19/06/2020
			Effective date	19/06/2020
			Review date	01/06/2021

Document History

Version	Date	Reviewer	Details of changes
1.0	16/06/2020	Jessica Lindemann	creation of version 1.0

1. Introduction

A carefully constructed standard operating procedure (SOP) is the optimal methodology for promoting supportive environments for and ensuring continuity of research. The purpose of this SOP is to provide an outline for the management of the laparoscopic cholecystectomy (LC) database. Compliance with the standards outlined in this SOP will assure that the rights, safety and well-being of both researchers and research participants are protected and that the data produced are credible.

2. Laparoscopic Cholecystectomy Database

The LC database was established in 2019 and is housed in the Surgical Gastroenterology Unit of the Department of Surgery in the Faculty of Health Sciences at the University of Cape Town (UCT). The database for which this SOP is written is considered a health service registry (database) as it consists of patients who have had a common procedure, clinical encounter, and/or hospitalization. LC is one of the most common laparoscopic operations performed by general surgeons in South Africa. Bile duct injury (BDI) is one of the most feared LC complications as it is associated with significant morbidity, prolonged hospital stays, increased costs and reduced quality of life for patients, as well as the risk of litigation for the injuring surgeon. The objective of the LC database is to facilitate quality improvement and collaborative research across the Cape Metro West region, and in the future, throughout South Africa. Use of the LC database provides an opportunity to monitor the frequency and quality of a commonly performed operation.

3. Aims and Objectives

The primary aim of the LC database is to make BDI a near-never event.

The specific objectives to achieve that aim include:

- 1) Standardization of a commonly performed operation (make best practice habit)
- 2) Establishment of a minimum requirement for documentation of the operation
- 3) Evaluation of the quality of the intraoperative critical view of safety (CVS)
- 4) Assessment of the 30-day morbidity and mortality associated with LCs
- 5) Documentation of the number of LCs in the Cape Metro West region
- 6) Determination of the incidence of LC-BDIs in the Cape Metro West region
- 7) Routine performance of quality assessment and improvement

4. About this SOP

This SOP is intended to support the ongoing implementation, data collection and management of the LC database created to record and monitor the quality of LC operations and increase understanding of patient outcomes post-LC. The purpose of this document is to provide guidelines and requirements for maintenance of the LC database.

5. Abbreviations & Definitions

BDI – *Bile duct injury*: damage to the biliary tree during LC

CVS – *Critical View of Safety*: a method used to ensure safety and minimize BDIs in LC

GSH – *Groote Schuur Hospital*: academic hospital affiliated with UCT

HREC – *Human Research Ethics Committee*: title of the ethics committee at UCT

ICMJE – *International Committee of Medical Journal Editors*: small working group of general medical journal editors who meet annually to create recommendations for the conduct, reporting, editing and publication of scholarly work in medical journals

LC – *Laparoscopic cholecystectomy*: the gold standard operation for symptomatic gallstone disease

SDRC – *Surgery Departmental Research Committee*: responsible for a formal scientific review process that evaluates the scientific merit and potential risks of each protocol before that protocol is submitted to the HREC

SOP – *Standard Operating Procedure*: detailed written instructions to achieve uniformity of the performance of a specific function

REDCap – *Research Electronic Data Capture*: a secure web application for building and managing online surveys and databases, specifically geared to support online or offline data capture for research studies and operations

UCT – *University of Cape Town*: university where the LC database is maintained

CRF – *Case Report/Record Form*: the form used to record patient data for entry into the database. The standardized operative note (see Intervention tab in the LC binder) is the CRF used for the LC database

PI – *Principal Investigator*: the lead investigator on a study

6. Ethics

Ethics approval is mandated by Section 72 of the National Health Act 61 of 2003. The National Health Research Ethics Council is mandated to regulate research ethics committees in South Africa. The main responsibility of each ethics committee is to conduct rigorous ethics review of research proposals to ensure that the welfare and interest of participants is protected and that the research will be conducted in accordance with required ethical norms and standards. All research team members are expected to adhere to the ethics guidelines which underscore responsible and ethical research conduct. In order for the LC database to continue to meet these guidelines, the research team responsible for the database must ensure that:

1. The UCT, Faculty of Health Sciences, Human Research Ethics Committee (HREC) approval for the database is renewed every three years. The required form for renewal is the FHS017, which can be downloaded from the HREC website: <http://www.health.uct.ac.za/fhs/research/humanethics/about>. This form should be submitted in person to the HREC Office, Room E45, Old Main Building, Groote Schuur Hospital.

2. Approval from the Chief Operations Office (Dr. Bernadette Eick) at Groote Schuur Hospital (GSH) to enter patients into the LC database from all hospitals in the Cape Metro West Region is renewed every three years, following approval by the HREC. This requires electronic submission of the Annexure 2 form in addition to the FHS017 renewal application, database consent form, data collection sheet and the HREC renewal approval letter to: Veronica.Sasman@westerncape.gov.za.

3. The record of ethics submissions to the HREC and GSH should be maintained in the table below and a copy of the HREC and GSH approval letters should be kept under the “Letters” tab of the LC database binder:

Application	Date submitted	Submitted by	Reference	Renew by
HREC	01/10/2019	Jessica Lindemann	HREC: R040/2019	30/11/2022
GSH	28/11/2019	Jessica Lindemann	n/a	30/11/2022
HREC			HREC:	
GSH			n/a	

4. A record of all signed informed consent forms for patients included in the database should continue to be maintained electronically on a password protected/encrypted device.

Copies of all required forms can be found under the “Forms” tab in the LC database binder.

In addition, any research projects utilizing data from the LC database must be approved by the HREC and linked as a sub-study to the LC database. Preference for use of the data should be given to researchers who have contributed to the LC database by either personally contributing with patients or assisting with data entry and/or completing follow-up data. The following guidelines should be followed for any research project utilizing data from the LC database:

1. A proposal to conduct the research must undergo ethics review and receive approval by the HREC before the research begins.
2. The proposed research must promote health and contribute to the prevention of disease or disability, or result in cure or alleviation of suffering.
3. The research proposal must stand up to scientific and ethical scrutiny appropriate to the discipline.
4. Harm to the research participants must be prevented or at least minimized and balanced against the likelihood of benefit.
5. The safety and welfare of research participants must be promoted.
6. Researchers must be accountable for their research activities.
7. Social and ethical values must be promoted.

The record of linked sub-studies to the LC database should be maintained in the table below and a copy of the Surgery Department Research Committee (SDRC) and HREC approval letters should be kept under the “Letters” tab in the LC database binder:

Project title (short)	PI	Student (if applicable)	SDRC Ref	HREC Ref	Renew by
Inter-rater reliability of CVS score	Prof Jonas	Jessica Lindemann	2020/017	100/2020	30/03/2021
Interim analysis: 1 st 3 months	Prof Jonas	Jessica Lindemann	2020/039	199/2020	30/06/2021

Every patient entered into the LC database must have a signed informed consent form (refer to the “Intervention” tab in the LC database binder) confirming the patient understands how their data will be shared, the associated risks and the measures taken to minimize those risks.

7. Set-up of User Rights & Data Access Groups

To provide instruction to the data management team members with the delegated responsibility for assigning user rights to research staff and collaborators.

7.1 Responsibilities & Procedures

1. The PI will delegate responsibility for assigning user rights to research staff and collaborators of the project to an appropriately experienced data manager or any dedicated staff member who has been trained on REDCap.
2. The data manager will create appropriate user roles that specify the level of permissions for the project including setup, data exports, creating, renaming, and/or deleting records, locking and unlocking records, and data collection instruments.
3. The data manager will also create data access groups when required, to represent each hospital site included in the database and use consistent language across all projects.
4. All users should be actively involved in the project and their contact and personal information should be kept by the data manager and the PI.

The data manager(s) responsible for maintaining the database have full user rights and should observe the following guidelines when assigning access and user rights:

1. Restricted user access may be given to anyone accepting responsibility for data entry at any of the hospital sites contributing to the LC database. Access in REDCap should be limited to the ability to: create records, access to REDCap using the mobile application, and access to the calendar. The ability to view and edit the “Cholecystectomy Operation Note”, “CVS Photo/Video Upload”, and “Follow-up” data instruments should also be granted. No access should be given to the CVS blinded reviewer scores data instruments.
2. Restricted user access may also be given to anyone accepting the research team’s invitation to be a blinded reviewer of the CVS photos. Access in REDCap should be limited to the ability to: create records and access to REDCap using the mobile application. The ability to view and edit only the designated CVS blinded reviewer data

instrument that corresponds to their assigned status (i.e. General Surgery Blinded Reviewer 1) should also be given. No access should be given to the other data collection instruments to ensure blinding of the CVS reviewers.

REDCap access is not required for researchers who would like to utilize data from the LC database. For further information, see section 11, Access to Data, below.

Access to the LC database WhatsApp group should only be given to those researchers who are involved in providing data to be entered into the database or who are directly responsible for data entry. The data manager and each research site representative is granted “Admin” rights to the LC database WhatsApp group, and may add and remove researchers as required.

7.2 Username & Password Management

Username are assigned either as an individual’s UCT staff or student number, or after successful application for a T-number (“temporary” number) if the researcher does not have one of the previously mentioned UCT numbers. The T-number application should be completed by the researcher with the assistance of the data manager. The required form is the BAS03 and it should be emailed to: warda.brown@uct.ac.za for processing. The form can be found under the “Forms” tab in the LC database binder. Each user’s username and password combination must be unique and stands in the place of their handwritten signature. Therefore:

1. Usernames must never be used by more than one person i.e. users must not share their username and password.
2. Passwords must not be revealed to any other persons. Users must never write down their username and password in an unsecure place. Users must never save their passwords to the internet browsers of unsecured computers, i.e. computers that do not require a unique login on start-up.
3. If a user suspects that their password has been compromised in anyway, they must immediately reset their password.
4. If a user forgets their password, they must immediately reset their password.
5. Users must log out whenever they have finished their session.
6. Passwords should be strong (alphanumeric), but easy to remember.

8. Data Recording, Definitions and Selection of Data Variables

Data entry is the responsibility of the data manager(s) and any assistants designated by the PI and data manager(s). The procedure for data entry is as follows:

1. The data manager(s) and/or assistant(s) transfer data from the standardized operative note (CRF) to the REDCap database within 24 hours of the data being posted on the WhatsApp LC database group
2. The data manager(s) and/or assistant(s) save an electronic copy of the intraoperative CVS photos using the following format: foldernumber_anterior or foldernumber_posterior (as appropriate).

3. The CVS photos, named using the format above, are then uploaded to the CVS photo upload data collection instrument.
4. Any follow-up data (i.e. discharge date) that is posted on the LC database WhatsApp group is uploaded on the follow-up data collection instrument.
5. To ensure the data is complete, accurate and up to date, the data manager(s) send monthly emails to the lead researchers at each of the participating hospitals that include:
 - a. A list of all LCs recorded from their hospital in the last 30 days
 - b. Date of discharge for each LC case logged (when known)
 - c. Any known follow-up information logged in the database
 - d. A request for completion of the missing data

A template of the email can be found under the “Templates” tab in the LC database binder. In the event there is still data missing, follow-up emails should be sent to the lead researcher(s).

Blinded reviewers are assigned LC CVS photos to review on a monthly basis. Emails are sent at the beginning of each month with a list of folder numbers for each reviewer. All LC cases entered should have at least two blinded reviewers scores logged in the database. Every attempt should be made to assign LC cases to reviewers who were not involved in the operation. A template for the monthly emails can be found under the “Templates” tab in the LC database binder. Follow-up emails should be sent to those reviewers who do not complete their assigned cases.

The data variables for the LC database were finalized after a pilot study during which changes were made to the initially chosen variables based on how data were reported and the format of extracted data from REDCap. The data dictionary for the LC database, which includes all records, instruments, fields, and project attributes for the database, can be found in under the “Data Dictionary” tab in the LC database binder.

9. Sources of Information

The sources of information used in collection of data for the LC database primarily include:

1. The standard operative note (CRF) uploaded to the WhatsApp group
2. CVS photos (or videos) uploaded to the WhatsApp group

When further clinical data is required, additional sources of information may include:

1. Patient folders
2. Pathology laboratory reports via the National Health Laboratory Service website
3. Electronic medical records via the worcesterhospital.org website
4. iSite radiology platform – picture archiving and communication system (PACS)

10. Confidentiality

The LC database aims to maintain the confidentiality of all patient information collected for the following reasons:

1. To protect the privacy of included patients
2. To protect the privacy of the healthcare facilities reporting the LC case

3. To protect the privacy of the healthcare providers
4. To protect from abuse and misuse of the data

To promote confidentiality the data is registered in the secure, web-based REDCap application with access limited to researchers involved in data entry. The ability to export data is only assigned to the data manager(s) and data is exported in its de-identified form. Additionally, to limit the risk of exposure of confidential patient information, members of the WhatsApp LC database group should be reviewed quarterly (every 3 months) and if no longer contributing, deleted from the group. Further information regarding patient privacy and the use of WhatsApp can be found under the “Literature” tab of the LC database binder.

11. Access and Storage of data

To maintain confidentiality, strict security measures are exercised including:

1. Limiting access to the REDCap LC database and the LC database WhatsApp group to authorized persons only
2. Any paper database records are stored in a locked cabinet in a room which can also be locked. Access is limited only to authorized persons.
3. Devices that access the electronic records are all password protected

Data access groups have not been created for the LC database, but could serve as a useful tool for participating hospitals to access de-identified data of patients they have contributed. Use of data access groups in the future should be considered.

11.1 Use and Release of Data

Confidential data may be provided to external researchers only upon written request, including the exact purpose for which the data will be used, the information required, the name(s) of the person(s) responsible for keeping the confidential information and the time period for which the data are needed. Proof of HREC approval of the study protocol is also required. The PI and data manager(s) should ensure that those receiving the data:

1. Are bound by the same rules of confidentiality observed by the team of researchers responsible for the LC database.
2. Will use the data only for the purpose agreed upon at the time of provision and will not make them accessible to other parties.
3. Will destroy the data when they are no longer needed for the said purposes.

For researchers with an HREC approved study protocol who are not directly involved in data entry, de-identified data will be extracted by the data manager(s) and then given to the researcher(s) for analysis. No patient information will be provided to insurance companies, medical funds pension schemes employers, the police or at the request of a physician caring for the patient.

11.2 Authorship

All researchers contributing to the database, either through provision of his or her own patients or assistance with data entry, will be invited as an author on publications using data extracted from the LC database. However, co-authors must comply with

International Committee of Medical Journal Editors (ICJME) criteria for authorship. This set of requirements are routinely used by peer-reviewed journals and are considered the international standard. The ICMJE recommends that authorship be based on the following 4 criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

In addition to being accountable for the parts of the work he or she has done, an author should be able to identify which co-authors are responsible for specific other parts of the work. Authors should also have confidence in the integrity of the contributions of their co-authors.

12. Quality Assurance

Reports will be generated quarterly using the “create a new report” function in REDCap to monitor how the database is operating and to assess the quality of the included data. Deficiencies should be promptly addressed.

To minimize missing data, the calendar feature in REDCap is used to track when 30-day follow-up data is required for each LC case entered. A patient is added to the calendar at the time of initial entry into the database on the date 30 days after the LC operation. Researchers responsible for data entry are trained in how to use the calendar feature prior to starting data entry.

One of the aims of the LC database is to monitor, and whenever possible, improve the quality of a commonly performed operation. To that end, regular audits of the database to assess case numbers, associated morbidity, and CVS scores is strongly encouraged.

Appendix B.2 – Database code book

1/17/2020

Laparoscopic Cholecystectomy | REDCap

Laparoscopic Cholecystectomy

Codebook ▾

Data Dictionary Codebook

17/01/2020 21:11

[^ Collapse all instruments](#)

#	Variable / Field Name	Field Label <i>Field Note</i>	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)										
Instrument: Cholecystectomy Operation Note (cholecystectomy_operation_note) ^ Collapse													
1	folder_number	Patient Folder Number	text (number)										
2	dob	Date of birth	text (date_dmy)										
3	age	Patient age	calc Calculation: round(datediff([dob], [op_date], "y", "dmy", true), 0)										
4	gender	Patient gender	radio <table border="1"> <tr><td>1</td><td>Male</td></tr> <tr><td>2</td><td>Female</td></tr> </table>	1	Male	2	Female						
1	Male												
2	Female												
5	procedure_type	Intended procedure	radio <table border="1"> <tr><td>1</td><td>Laparoscopic cholecystectomy</td></tr> <tr><td>2</td><td>Open cholecystectomy</td></tr> <tr><td>3</td><td>Subtotal cholecystectomy</td></tr> <tr><td>4</td><td>Cholecystostomy</td></tr> </table>	1	Laparoscopic cholecystectomy	2	Open cholecystectomy	3	Subtotal cholecystectomy	4	Cholecystostomy		
1	Laparoscopic cholecystectomy												
2	Open cholecystectomy												
3	Subtotal cholecystectomy												
4	Cholecystostomy												
6	op_date	Date of operation	text (date_dmy)										
7	date_booked	Date when surgery was booked	text (date_dmy)										
8	procedure_timing	Procedure timing	radio <table border="1"> <tr><td>1</td><td>Elective</td></tr> <tr><td>2</td><td>Within 72 hours from admission</td></tr> <tr><td>3</td><td>> 72, within 7 days from admission</td></tr> <tr><td>4</td><td>> 7 days from admission</td></tr> </table>	1	Elective	2	Within 72 hours from admission	3	> 72, within 7 days from admission	4	> 7 days from admission		
1	Elective												
2	Within 72 hours from admission												
3	> 72, within 7 days from admission												
4	> 7 days from admission												
9	surgeon	Surgeon:	text										
10	assistant	Assistant:	text										
11	assistant_2	Second Assistant:	text										
12	hospital	Hospital	radio <table border="1"> <tr><td>1</td><td>GSH</td></tr> <tr><td>2</td><td>MPH</td></tr> <tr><td>3</td><td>NSH</td></tr> <tr><td>4</td><td>VH</td></tr> <tr><td>5</td><td>UCTPAH</td></tr> </table>	1	GSH	2	MPH	3	NSH	4	VH	5	UCTPAH
1	GSH												
2	MPH												
3	NSH												
4	VH												
5	UCTPAH												
13	indication	Indication	dropdown <table border="1"> <tr><td>1</td><td>Biliary colic</td></tr> <tr><td>2</td><td>Acute cholecystitis</td></tr> <tr><td>3</td><td>Choledocholithiasis</td></tr> <tr><td>4</td><td>Gallstone pancreatitis</td></tr> <tr><td>5</td><td>Other</td></tr> </table>	1	Biliary colic	2	Acute cholecystitis	3	Choledocholithiasis	4	Gallstone pancreatitis	5	Other
1	Biliary colic												
2	Acute cholecystitis												
3	Choledocholithiasis												
4	Gallstone pancreatitis												
5	Other												
14	other_indication Show the field ONLY if: [indication] = '5'	If other, describe	text										
15	symp_duration	Duration of symptoms prior to operation (in days)	text										

16	pt_comorb	Patient co-morbidity	checkbox <table border="1"> <tr><td>1</td><td>pt_comorb__1</td><td>None</td></tr> <tr><td>2</td><td>pt_comorb__2</td><td>CVS</td></tr> <tr><td>3</td><td>pt_comorb__3</td><td>Respiratory</td></tr> <tr><td>4</td><td>pt_comorb__4</td><td>Liver</td></tr> <tr><td>5</td><td>pt_comorb__5</td><td>DM</td></tr> <tr><td>6</td><td>pt_comorb__6</td><td>Other</td></tr> </table>	1	pt_comorb__1	None	2	pt_comorb__2	CVS	3	pt_comorb__3	Respiratory	4	pt_comorb__4	Liver	5	pt_comorb__5	DM	6	pt_comorb__6	Other
1	pt_comorb__1	None																			
2	pt_comorb__2	CVS																			
3	pt_comorb__3	Respiratory																			
4	pt_comorb__4	Liver																			
5	pt_comorb__5	DM																			
6	pt_comorb__6	Other																			
17	pt_comorb_other Show the field ONLY if: [pt_comorb(6)] = '1'	If other, describe	text																		
18	hiv_status	HIV Status	radio <table border="1"> <tr><td>1</td><td>Negative</td></tr> <tr><td>2</td><td>Positive</td></tr> <tr><td>3</td><td>Unknown</td></tr> </table>	1	Negative	2	Positive	3	Unknown												
1	Negative																				
2	Positive																				
3	Unknown																				
19	height	Height (m)	text (number)																		
20	weight	Weight (kg)	text (number)																		
21	bmi	BMI	calc Calculation: round([weight]/([height]*[height]),1)																		
22	asa_status	ASA Status	radio <table border="1"> <tr><td>1</td><td>ASA I</td></tr> <tr><td>2</td><td>ASA II</td></tr> <tr><td>3</td><td>ASA III</td></tr> <tr><td>4</td><td>ASA IV</td></tr> </table>	1	ASA I	2	ASA II	3	ASA III	4	ASA IV										
1	ASA I																				
2	ASA II																				
3	ASA III																				
4	ASA IV																				
23	imaging_rev	Section Header: <i>PREOP CHECKLIST: SURGEON TO CONFIRM WITH ASSISTANT</i> Imaging reviewed?	yesno <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>0</td><td>No</td></tr> </table>	1	Yes	0	No														
1	Yes																				
0	No																				
24	lft_rev	Liver function tests reviewed?	yesno <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>0</td><td>No</td></tr> </table>	1	Yes	0	No														
1	Yes																				
0	No																				
25	difficult_gb	Expected difficult gallbladder?	yesno <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>0</td><td>No</td></tr> </table>	1	Yes	0	No														
1	Yes																				
0	No																				
26	risk_factors Show the field ONLY if: [difficult_gb] = '1'	Reasons for expected difficulty	checkbox <table border="1"> <tr><td>1</td><td>risk_factors__1</td><td>BMI > 35</td></tr> <tr><td>2</td><td>risk_factors__2</td><td>Previous upper abdominal surgery</td></tr> <tr><td>3</td><td>risk_factors__3</td><td>Liver disease</td></tr> <tr><td>4</td><td>risk_factors__4</td><td>Previous percutaneous drain</td></tr> <tr><td>5</td><td>risk_factors__5</td><td>Previous ERCP</td></tr> <tr><td>6</td><td>risk_factors__6</td><td>Other</td></tr> </table>	1	risk_factors__1	BMI > 35	2	risk_factors__2	Previous upper abdominal surgery	3	risk_factors__3	Liver disease	4	risk_factors__4	Previous percutaneous drain	5	risk_factors__5	Previous ERCP	6	risk_factors__6	Other
1	risk_factors__1	BMI > 35																			
2	risk_factors__2	Previous upper abdominal surgery																			
3	risk_factors__3	Liver disease																			
4	risk_factors__4	Previous percutaneous drain																			
5	risk_factors__5	Previous ERCP																			
6	risk_factors__6	Other																			
27	other_risks Show the field ONLY if: [risk_factors(6)] = '1'	If other, describe	text																		
28	access	Section Header: <i>ACCESS</i> Access to the abdomen obtained via	radio <table border="1"> <tr><td>1</td><td>Hasson (open)</td></tr> <tr><td>2</td><td>Veress needle</td></tr> <tr><td>3</td><td>Other</td></tr> </table>	1	Hasson (open)	2	Veress needle	3	Other												
1	Hasson (open)																				
2	Veress needle																				
3	Other																				
29	other_access Show the field ONLY if: [access] = '3'	If other, describe	text																		
30	ports	Number of ports used	text (number)																		
31	access_difficulty	Access to the abdomen was	checkbox <table border="1"> <tr><td>1</td><td>access_difficulty__1</td><td>Uneventful</td></tr> <tr><td>2</td><td>access_difficulty__2</td><td>Difficult</td></tr> </table>	1	access_difficulty__1	Uneventful	2	access_difficulty__2	Difficult												
1	access_difficulty__1	Uneventful																			
2	access_difficulty__2	Difficult																			

32	difficult_description Show the field ONLY if: [access_difficulty(2)] = '1'	If difficult, describe	text																																													
33	dissection_check_list	Section Header: <i>PRE-DISSECTION CHECKLIST: SURGEON TO CONFIRM WITH ASSISTANT</i> Tick all that apply	checkbox <table border="1"> <tr> <td>1</td> <td>dissection_check_list__1</td> <td>Fundus retracted to 10 o'clock</td> </tr> <tr> <td>2</td> <td>dissection_check_list__2</td> <td>Hartmann's pouch lifted up, across to origin of segment IV pedicle</td> </tr> <tr> <td>3</td> <td>dissection_check_list__3</td> <td>Line between Rouviere's sulcus and base of segment IV identified</td> </tr> <tr> <td>4</td> <td>dissection_check_list__4</td> <td>Safe level of dissection identified</td> </tr> <tr> <td>5</td> <td>dissection_check_list__5</td> <td>Posterior leaf of peritoneum over hepatobiliary triangle released</td> </tr> </table>	1	dissection_check_list__1	Fundus retracted to 10 o'clock	2	dissection_check_list__2	Hartmann's pouch lifted up, across to origin of segment IV pedicle	3	dissection_check_list__3	Line between Rouviere's sulcus and base of segment IV identified	4	dissection_check_list__4	Safe level of dissection identified	5	dissection_check_list__5	Posterior leaf of peritoneum over hepatobiliary triangle released																														
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34	cvs_elements	Section Header: <i>PRIOR TO CLIPPING THE CYSTIC DUCT: SURGEON TO CONFIRM WITH ASSISTANT</i> Tick all that apply	checkbox <table border="1"> <tr> <td>1</td> <td>cvs_elements__1</td> <td>(1) Hepatocystic triangle free of fibrous and fatty tissue</td> </tr> <tr> <td>2</td> <td>cvs_elements__2</td> <td>(2) Two and only two structures entering the gallbladder</td> </tr> <tr> <td>3</td> <td>cvs_elements__3</td> <td>(3) Distal 1/3 of the cystic plate cleared</td> </tr> </table>	1	cvs_elements__1	(1) Hepatocystic triangle free of fibrous and fatty tissue	2	cvs_elements__2	(2) Two and only two structures entering the gallbladder	3	cvs_elements__3	(3) Distal 1/3 of the cystic plate cleared																																				
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3	cvs_elements__3	(3) Distal 1/3 of the cystic plate cleared																																														
35	cvs_achieved	CVS achieved	yesno <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>0</td> <td>No</td> </tr> </table>	1	Yes	0	No																																									
1	Yes																																															
0	No																																															
36	cvs_assistant	Did the assistant agree all 3 components of the CVS were achieved?	yesno <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>0</td> <td>No</td> </tr> </table>	1	Yes	0	No																																									
1	Yes																																															
0	No																																															
37	cvs_difficulty	Reason(s) for not obtaining CVS or noted intra-operative difficulties	checkbox <table border="1"> <tr> <td>1</td> <td>cvs_difficulty__1</td> <td>Bleeding</td> </tr> <tr> <td>2</td> <td>cvs_difficulty__2</td> <td>Aberrant biliary anatomy</td> </tr> <tr> <td>3</td> <td>cvs_difficulty__3</td> <td>Aberrant arterial anatomy</td> </tr> <tr> <td>4</td> <td>cvs_difficulty__4</td> <td>Equipment problems</td> </tr> <tr> <td>5</td> <td>cvs_difficulty__5</td> <td>No progress</td> </tr> <tr> <td>6</td> <td>cvs_difficulty__6</td> <td>Hepatomegaly</td> </tr> <tr> <td>7</td> <td>cvs_difficulty__7</td> <td>Fatty liver</td> </tr> <tr> <td>8</td> <td>cvs_difficulty__8</td> <td>Difficulty grasping GB</td> </tr> <tr> <td>9</td> <td>cvs_difficulty__9</td> <td>Contracted GB</td> </tr> <tr> <td>10</td> <td>cvs_difficulty__10</td> <td>Intrahepatic GB</td> </tr> <tr> <td>11</td> <td>cvs_difficulty__11</td> <td>Severe inflammation</td> </tr> <tr> <td>12</td> <td>cvs_difficulty__12</td> <td>GB empyema</td> </tr> <tr> <td>13</td> <td>cvs_difficulty__13</td> <td>Extensive adhesions</td> </tr> <tr> <td>14</td> <td>cvs_difficulty__14</td> <td>Other</td> </tr> <tr> <td>15</td> <td>cvs_difficulty__15</td> <td>None</td> </tr> </table>	1	cvs_difficulty__1	Bleeding	2	cvs_difficulty__2	Aberrant biliary anatomy	3	cvs_difficulty__3	Aberrant arterial anatomy	4	cvs_difficulty__4	Equipment problems	5	cvs_difficulty__5	No progress	6	cvs_difficulty__6	Hepatomegaly	7	cvs_difficulty__7	Fatty liver	8	cvs_difficulty__8	Difficulty grasping GB	9	cvs_difficulty__9	Contracted GB	10	cvs_difficulty__10	Intrahepatic GB	11	cvs_difficulty__11	Severe inflammation	12	cvs_difficulty__12	GB empyema	13	cvs_difficulty__13	Extensive adhesions	14	cvs_difficulty__14	Other	15	cvs_difficulty__15	None
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14	cvs_difficulty__14	Other																																														
15	cvs_difficulty__15	None																																														
38	other_difficulty Show the field ONLY if: [cvs_difficulty(14)] = '1'	If other, describe	text																																													
39	cvs_image	Were images of the CVS taken?	yesno <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>0</td> <td>No</td> </tr> </table>	1	Yes	0	No																																									
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40	ioc	Was an intra-operative cholangiogram performed?	yesno 1 Yes 0 No
41	ioc_findings Show the field ONLY if: [ioc] = '1'	IOC findings, tick all that apply	checkbox 1 ioc_findings__1 Flow into duodenum 2 ioc_findings__2 3 Proximal hepatic ducts visualized 3 ioc_findings__3 CBD filling defects 4 ioc_findings__4 Spiral valves in cystic duct 5 ioc_findings__5 Other
42	ioc_findings_other Show the field ONLY if: [ioc_findings(5)] = '1'	If other, describe	text
43	procedure_performed	Section Header: <i>PROCEDURE</i> : Final procedure performed	radio 1 Laparoscopic cholecystectomy 2 Laparoscopic converted to open cholecystectomy 3 Open cholecystectomy 4 Subtotal cholecystectomy 5 Cholecystostomy 6 Gallbladder left in situ 7 Other
44	procedure_type_other Show the field ONLY if: [procedure_performed] = '7'	If other, describe	text
45	gb_intact Show the field ONLY if: [procedure_performed] = '1' or [procedure_performed] = '2' or [procedure_performed] = '3'	Was the gallbladder removed intact?	yesno 1 Yes 0 No
46	cd_secured Show the field ONLY if: [procedure_performed] = '1'	The cystic duct was secured with	radio 1 LIGA clips 2 Hem-o-lock 3 Suture ligation 4 Other
47	clips_number Show the field ONLY if: [cd_secured] = '1'	Number of clips on "stay" side	text (number)
48	cd_clip_other Show the field ONLY if: [cd_secured] = '4'	If other, describe	text
49	ca_secured Show the field ONLY if: [procedure_performed] = '1'	The cystic artery was secured with	radio 1 LIGA clips 2 Hem-o-lock 3 Suture ligation 4 Other
50	ca_clips_number Show the field ONLY if: [ca_secured] = '1'	Number of clips on "stay" side	text (number)
51	ca_secured_other Show the field ONLY if: [ca_secured] = '4'	If other, describe	text
52	conversion_time Show the field ONLY if: [procedure_performed] = '2'	Time from start of operation to conversion (in minutes)	text (number)

53	subtotal_cck Show the field ONLY if: [procedure_performed] = '4'	Type of subtotal cholecystectomy	radio 1 Reconstituting 2 Fenestrating
54	stone_spill Show the field ONLY if: [procedure_performed] = '1'	Stone spillage?	yesno 1 Yes 0 No
55	stones_spill_retrieve Show the field ONLY if: [stone_spill] = '1'	Were all spilled stones retrieved?	yesno 1 Yes 0 No
56	bile_leak Show the field ONLY if: [procedure_performed] = '1'	Was a bile leak identified?	yesno 1 Yes 0 No
57	bile_leak_location Show the field ONLY if: [bile_leak] = '1'	Location	dropdown 1 gallbladder 2 liver bed 3 bile duct 4 other
58	bile_leak_other Show the field ONLY if: [bile_leak_location] = '4'	If other, describe	text
59	op_time	Section Header: <i>FINAL COMMENTS:</i> Operating time (min)	text
60	ebl	Estimated blood loss	dropdown 1 minimal 2 moderate 3 severe
61	drain	Was a drain left?	yesno 1 Yes 0 No
62	specimen_lab	Specimen sent to histology lab?	yesno 1 Yes 0 No
63	lc_checklist	Was the laparoscopic cholecystectomy checklist used?	yesno 1 Yes 0 No
64	other_observations	Other observations:	notes
65	cholecystectomy_operation_note_complete	Section Header: <i>Form Status</i> Complete?	dropdown 0 incomplete 1 Unverified 2 Complete
Instrument: CVS Photo/Video Upload (cvs_photovideo_upload)			^ Collapse
66	ant_photo	Please upload your anterior photo or video documentation of the critical view of safety	file
67	post_photo_2	Please upload your posterior photo documentation of the critical view of safety	file
68	cvs_scoring_guide_2	Section Header: <i>Please score the critical view of safety photo/video documentation using the scale below</i> Refer to the scoring system below to complete your assessment of the documented CVS	descriptive
69	structures_surgeon	Two structures entering the gallbladder	radio 1 2 points 2 1 point 3 0 points

70	cystic_plate_surgeon	Cystic plate	radio <table border="1"> <tr><td>1</td><td>2 points</td></tr> <tr><td>2</td><td>1 point</td></tr> <tr><td>3</td><td>0 points</td></tr> </table>	1	2 points	2	1 point	3	0 points																					
1	2 points																													
2	1 point																													
3	0 points																													
71	cystohepatic_triangle_surgeon	Clearance of the cystohepatic triangle	radio <table border="1"> <tr><td>1</td><td>2 points</td></tr> <tr><td>2</td><td>1 point</td></tr> <tr><td>3</td><td>0 points</td></tr> </table>	1	2 points	2	1 point	3	0 points																					
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72	cv_s_photovideo_upload_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr><td>0</td><td>Incomplete</td></tr> <tr><td>1</td><td>Unverified</td></tr> <tr><td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete																					
0	Incomplete																													
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Instrument: Follow-up (followup)			^ Collapse																											
73	date_dch	Date of discharge	text (date_dmy)																											
74	los	Length of stay	calc Calculation: datediff([op_date], [date_dch], "d", "dmy", true)																											
75	surg_comp	Did the patient develop any surgical complications? <i>Tick all that apply</i>	checkbox <table border="1"> <tr><td>1</td><td>surg_comp__1</td><td>Bile leak</td></tr> <tr><td>2</td><td>surg_comp__2</td><td>Bile duct injury</td></tr> <tr><td>3</td><td>surg_comp__3</td><td>Jaundice</td></tr> <tr><td>4</td><td>surg_comp__4</td><td>Intra-abdominal collection</td></tr> <tr><td>5</td><td>surg_comp__5</td><td>Intra-abdominal bleeding</td></tr> <tr><td>6</td><td>surg_comp__6</td><td>Wound infection</td></tr> <tr><td>7</td><td>surg_comp__7</td><td>Liver abscess</td></tr> <tr><td>8</td><td>surg_comp__8</td><td>Bowel injury</td></tr> <tr><td>9</td><td>surg_comp__9</td><td>Other</td></tr> </table>	1	surg_comp__1	Bile leak	2	surg_comp__2	Bile duct injury	3	surg_comp__3	Jaundice	4	surg_comp__4	Intra-abdominal collection	5	surg_comp__5	Intra-abdominal bleeding	6	surg_comp__6	Wound infection	7	surg_comp__7	Liver abscess	8	surg_comp__8	Bowel injury	9	surg_comp__9	Other
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76	surg_comp_other Show the field ONLY if: [surg_comp(9)] = '1'	If other, describe	text																											
77	surg_comp_int Show the field ONLY if: [surg_comp(1)] = '1' or [surg_comp(2)] = '1' or [surg_comp(3)] = '1' or [surg_comp(4)] = '1' or [surg_comp(5)] = '1' or [surg_comp(6)] = '1' or [surg_comp(7)] = '1' or [surg_comp(8)] = '1' or [surg_comp(9)] = '1'	Did the surgical complication require any intervention?	yesno <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>0</td><td>No</td></tr> </table>	1	Yes	0	No																							
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78	surg_comp_int_type Show the field ONLY if: [surg_comp_int] = '1'	Specify	checkbox <table border="1"> <tr><td>1</td><td>surg_comp_int_type__1</td><td>Re-operation</td></tr> <tr><td>2</td><td>surg_comp_int_type__2</td><td>Percutaneous drainage</td></tr> <tr><td>3</td><td>surg_comp_int_type__3</td><td>PTC</td></tr> <tr><td>4</td><td>surg_comp_int_type__4</td><td>ERCP</td></tr> <tr><td>5</td><td>surg_comp_int_type__5</td><td>Other</td></tr> </table>	1	surg_comp_int_type__1	Re-operation	2	surg_comp_int_type__2	Percutaneous drainage	3	surg_comp_int_type__3	PTC	4	surg_comp_int_type__4	ERCP	5	surg_comp_int_type__5	Other												
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79	reop_int_date Show the field ONLY if: [surg_comp_int_type(1)] = '1'	Date of re-operation	text (date_dmy)																											
80	reop_description Show the field ONLY if: [surg_comp_int_type(1)] = '1'	Brief description of re-operation	text																											
81	perc_drain_date Show the field ONLY if: [surg_comp_int_type(2)] = '1'	Date of percutaneous drainage	text (date_dmy)																											

82	percdrain_description Show the field ONLY if: [surg_comp_int_type(2)] = '1'	Brief description of percutaneous drainage	text																		
83	ptc_date Show the field ONLY if: [surg_comp_int_type(3)] = '1'	Date of PTC	text (date_dmy)																		
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85	ercp_int_date Show the field ONLY if: [surg_comp_int_type(4)] = '1'	Date of ERCP	text (date_dmy)																		
86	ercp_description_3 Show the field ONLY if: [surg_comp_int_type(4)] = '1'	Brief description of ERCP findings	text																		
87	other_int_date Show the field ONLY if: [surg_comp_int_type(5)] = '1'	Date of "other" intervention	text (date_dmy)																		
88	other_description Show the field ONLY if: [surg_comp_int_type(5)] = '1'	Brief description of "other" intervention	text																		
89	ns_comp	Did the patient develop and non-surgical complications? <i>Tick all that apply</i>	checkbox <table border="1"> <tr><td>1</td><td>ns_comp__1</td><td>Non-surgical infection</td></tr> <tr><td>2</td><td>ns_comp__2</td><td>DVT</td></tr> <tr><td>3</td><td>ns_comp__3</td><td>Pulmonary embolism</td></tr> <tr><td>4</td><td>ns_comp__4</td><td>Cardio-vascular complications</td></tr> <tr><td>5</td><td>ns_comp__5</td><td>Renal complications</td></tr> <tr><td>6</td><td>ns_comp__6</td><td>Other</td></tr> </table>	1	ns_comp__1	Non-surgical infection	2	ns_comp__2	DVT	3	ns_comp__3	Pulmonary embolism	4	ns_comp__4	Cardio-vascular complications	5	ns_comp__5	Renal complications	6	ns_comp__6	Other
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90	ns_comp_other Show the field ONLY if: [ns_comp(6)] = '1'	If other, describe	text																		
91	clavien_dindo_descript Show the field ONLY if: [surg_comp(1)] = '1' or [surg_comp(2)] = '1' or [surg_comp(3)] = '1' or [surg_comp(4)] = '1' or [surg_comp(5)] = '1' or [surg_comp(6)] = '1' or [surg_comp(7)] = '1' or [surg_comp(8)] = '1' or [surg_comp(9)] = '1' or [ns_comp(1)] = '1' or [ns_comp(2)] = '1' or [ns_comp(3)] = '1' or [ns_comp(4)] = '1' or [ns_comp(5)] = '1' or [ns_comp(6)] = '1'	Clavien-Dindo Classification	descriptive																		
92	clavien_dindo_class Show the field ONLY if: [surg_comp(1)] = '1' or [surg_comp(2)] = '1' or [surg_comp(3)] = '1' or [surg_comp(4)] = '1' or [surg_comp(5)] = '1' or [surg_comp(6)] = '1' or [surg_comp(7)] = '1' or [surg_comp(8)] = '1' or [surg_comp(9)] = '1' or [ns_comp(1)] = '1' or [ns_comp(2)] = '1' or [ns_comp(3)] = '1' or [ns_comp(4)] = '1' or [ns_comp(5)] = '1' or [ns_comp(6)] = '1'	Please score the complication using the Clavien-Dindo Classification as specified above <i>Only record score of most severe complication</i>	radio <table border="1"> <tr><td>1</td><td>Grade I</td></tr> <tr><td>2</td><td>Grade II</td></tr> <tr><td>3</td><td>Grade IIIa</td></tr> <tr><td>4</td><td>Grade IIIb</td></tr> <tr><td>5</td><td>Grade IVa</td></tr> <tr><td>6</td><td>Grade IVb</td></tr> <tr><td>7</td><td>Grade V</td></tr> </table>	1	Grade I	2	Grade II	3	Grade IIIa	4	Grade IIIb	5	Grade IVa	6	Grade IVb	7	Grade V				
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93	<p>clavien_dindo_d_class</p> <p>Show the field ONLY if: [surg_comp(1)] = '1' or [surg_comp(2)] = '1' or [surg_comp(3)] = '1' or [surg_comp(4)] = '1' or [surg_comp(5)] = '1' or [surg_comp(6)] = '1' or [surg_comp(7)] = '1' or [surg_comp(8)] = '1' or [surg_comp(9)] = '1' or [ns_comp(1)] = '1' or [ns_comp(2)] = '1' or [ns_comp(3)] = '1' or [ns_comp(4)] = '1' or [ns_comp(5)] = '1' or [ns_comp(6)] = '1'</p>	Was the complication still ongoing at discharge (requires Clavien-Dindo "d" designation as above)?	<p>yesno</p> <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>0</td><td>No</td></tr> </table>	1	Yes	0	No																							
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94	readmit_yes	Re-admission within 30 days?	<p>yesno</p> <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>0</td><td>No</td></tr> </table>	1	Yes	0	No																							
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95	readmit_date	Date of readmission	text (date_dmy)																											
96	<p>surg_comp_2</p> <p>Show the field ONLY if: [readmit_yes] = '1'</p>	<p>Please indicate if the patient was admitted for any of the following surgical complications</p> <p><i>Tick all that apply</i></p>	<p>checkbox</p> <table border="1"> <tr><td>1</td><td>surg_comp_2__1</td><td>Bile leak</td></tr> <tr><td>2</td><td>surg_comp_2__2</td><td>Bile duct injury</td></tr> <tr><td>3</td><td>surg_comp_2__3</td><td>Jaundice</td></tr> <tr><td>4</td><td>surg_comp_2__4</td><td>Intra-abdominal collection</td></tr> <tr><td>5</td><td>surg_comp_2__5</td><td>Intra-abdominal bleeding</td></tr> <tr><td>6</td><td>surg_comp_2__6</td><td>Wound infection</td></tr> <tr><td>7</td><td>surg_comp_2__7</td><td>Liver abscess</td></tr> <tr><td>8</td><td>surg_comp_2__8</td><td>Bowel injury</td></tr> <tr><td>9</td><td>surg_comp_2__9</td><td>Other</td></tr> </table>	1	surg_comp_2__1	Bile leak	2	surg_comp_2__2	Bile duct injury	3	surg_comp_2__3	Jaundice	4	surg_comp_2__4	Intra-abdominal collection	5	surg_comp_2__5	Intra-abdominal bleeding	6	surg_comp_2__6	Wound infection	7	surg_comp_2__7	Liver abscess	8	surg_comp_2__8	Bowel injury	9	surg_comp_2__9	Other
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5	surg_comp_2__5	Intra-abdominal bleeding																												
6	surg_comp_2__6	Wound infection																												
7	surg_comp_2__7	Liver abscess																												
8	surg_comp_2__8	Bowel injury																												
9	surg_comp_2__9	Other																												
97	<p>surg_comp_other_2</p> <p>Show the field ONLY if: [surg_comp_2(9)] = '1'</p>	If other, describe	text																											
98	<p>surg_comp_int_2</p> <p>Show the field ONLY if: [surg_comp_2(1)] = '1' or [surg_comp_2(2)] = '1' or [surg_comp_2(3)] = '1' or [surg_comp_2(4)] = '1' or [surg_comp_2(5)] = '1' or [surg_comp_2(6)] = '1' or [surg_comp_2(7)] = '1' or [surg_comp_2(8)] = '1' or [surg_comp_2(9)] = '1'</p>	Did the surgical complication require any intervention?	<p>yesno</p> <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>0</td><td>No</td></tr> </table>	1	Yes	0	No																							
1	Yes																													
0	No																													
99	<p>surg_comp_int_type_2</p> <p>Show the field ONLY if: [surg_comp_int_2] = '1'</p>	Specify	<p>checkbox</p> <table border="1"> <tr><td>1</td><td>surg_comp_int_type_2__1</td><td>Re-operation</td></tr> <tr><td>2</td><td>surg_comp_int_type_2__2</td><td>Percutaneous drainage</td></tr> <tr><td>3</td><td>surg_comp_int_type_2__3</td><td>PTC</td></tr> <tr><td>4</td><td>surg_comp_int_type_2__4</td><td>ERCP</td></tr> <tr><td>5</td><td>surg_comp_int_type_2__5</td><td>Other</td></tr> </table>	1	surg_comp_int_type_2__1	Re-operation	2	surg_comp_int_type_2__2	Percutaneous drainage	3	surg_comp_int_type_2__3	PTC	4	surg_comp_int_type_2__4	ERCP	5	surg_comp_int_type_2__5	Other												
1	surg_comp_int_type_2__1	Re-operation																												
2	surg_comp_int_type_2__2	Percutaneous drainage																												
3	surg_comp_int_type_2__3	PTC																												
4	surg_comp_int_type_2__4	ERCP																												
5	surg_comp_int_type_2__5	Other																												
100	<p>reop_int_date_2</p> <p>Show the field ONLY if: [surg_comp_int_type_2(1)] = '1'</p>	Date of re-operation	text (date_dmy)																											
101	<p>reop_description_2</p> <p>Show the field ONLY if: [surg_comp_int_type_2(1)] = '1'</p>	Brief description of re-operation	text																											
102	<p>percdrain_int_date_2</p> <p>Show the field ONLY if: [surg_comp_int_type_2(2)] = '1'</p>	Date of percutaneous drainage	text (date_dmy)																											

103	percdrain_description_2 Show the field ONLY if: [surg_comp_int_type_2(2)] = '1'	Brief description of percutaneous drainage	text																		
104	ptc_int_date_2 Show the field ONLY if: [surg_comp_int_type_2(3)] = '1'	Date of PTC	text (date_dmy)																		
105	ptc_description_2 Show the field ONLY if: [surg_comp_int_type_2(3)] = '1'	Brief description of PTC findings	text																		
106	ercp_int_date_2 Show the field ONLY if: [surg_comp_int_type_2(4)] = '1'	Date of ERCP	text (date_dmy)																		
107	ercp_description_2 Show the field ONLY if: [surg_comp_int_type_2(4)] = '1'	Brief description of ERCP findings	text																		
108	other_int_date_2 Show the field ONLY if: [surg_comp_int_type_2(5)] = '1'	Date of "other" intervention	text (date_dmy)																		
109	other_description_2 Show the field ONLY if: [surg_comp_int_type_2(5)] = '1'	Brief description of "other" intervention	text																		
110	ns_comp_2 Show the field ONLY if: [readmit_yes] = '1'	Please indicate if the patient was admitted for any of the following non-surgical complications <i>Tick all that apply</i>	checkbox <table border="1"> <tr> <td>1</td> <td>ns_comp_2__1</td> <td>Non-surgical infection</td> </tr> <tr> <td>2</td> <td>ns_comp_2__2</td> <td>DVT</td> </tr> <tr> <td>3</td> <td>ns_comp_2__3</td> <td>Pulmonary embolism</td> </tr> <tr> <td>4</td> <td>ns_comp_2__4</td> <td>Cardio-vascular complications</td> </tr> <tr> <td>5</td> <td>ns_comp_2__5</td> <td>Renal complications</td> </tr> <tr> <td>6</td> <td>ns_comp_2__6</td> <td>Other</td> </tr> </table>	1	ns_comp_2__1	Non-surgical infection	2	ns_comp_2__2	DVT	3	ns_comp_2__3	Pulmonary embolism	4	ns_comp_2__4	Cardio-vascular complications	5	ns_comp_2__5	Renal complications	6	ns_comp_2__6	Other
1	ns_comp_2__1	Non-surgical infection																			
2	ns_comp_2__2	DVT																			
3	ns_comp_2__3	Pulmonary embolism																			
4	ns_comp_2__4	Cardio-vascular complications																			
5	ns_comp_2__5	Renal complications																			
6	ns_comp_2__6	Other																			
111	ns_comp_other_2 Show the field ONLY if: [ns_comp_2(6)] = '1'	If other, describe	text																		
112	clavien_dindo_2 Show the field ONLY if: [surg_comp_2(1)] = '1' or [surg_comp_2(2)] = '1' or [surg_comp_2(3)] = '1' or [surg_comp_2(4)] = '1' or [surg_comp_2(5)] = '1' or [surg_comp_2(6)] = '1' or [surg_comp_2(7)] = '1' or [surg_comp_2(8)] = '1' or [surg_comp_2(9)] = '1' or [surg_comp_2(9)] = '1' or [ns_comp_2(1)] = '1' or [ns_comp_2(2)] = '1' or [ns_comp_2(3)] = '1' or [ns_comp_2(4)] = '1' or [ns_comp_2(5)] = '1' or [ns_comp_2(6)] = '1'	Clavien-Dindo Classification	descriptive																		

113	clavien_dindo_class_2 Show the field ONLY if: [surg_comp_2(1)] = '1' or [surg_comp_2(2)] = '1' or [surg_comp_2(3)] = '1' or [surg_comp_2(4)] = '1' or [surg_comp_2(5)] = '1' or [surg_comp_2(6)] = '1' or [surg_comp_2(7)] = '1' or [surg_comp_2(8)] = '1' or [surg_comp_2(9)] = '1' or [ns_comp_2(1)] = '1' or [ns_comp_2(2)] = '1' or [ns_comp_2(3)] = '1' or [ns_comp_2(4)] = '1' or [ns_comp_2(5)] = '1' or [ns_comp_2(6)] = '1'	Please score the complication using the Clavien-Dindo Classification as specified above <i>Only record score of most severe complication</i>	radio <table border="1"> <tr><td>1</td><td>Grade I</td></tr> <tr><td>2</td><td>Grade II</td></tr> <tr><td>3</td><td>Grade IIIa</td></tr> <tr><td>4</td><td>Grade IIIb</td></tr> <tr><td>5</td><td>Grade IVa</td></tr> <tr><td>6</td><td>Grade IVb</td></tr> <tr><td>7</td><td>Grade V</td></tr> </table>	1	Grade I	2	Grade II	3	Grade IIIa	4	Grade IIIb	5	Grade IVa	6	Grade IVb	7	Grade V
1	Grade I																
2	Grade II																
3	Grade IIIa																
4	Grade IIIb																
5	Grade IVa																
6	Grade IVb																
7	Grade V																
114	clavien_dindo_d_class_2 Show the field ONLY if: [surg_comp_2(1)] = '1' or [surg_comp_2(2)] = '1' or [surg_comp_2(3)] = '1' or [surg_comp_2(4)] = '1' or [surg_comp_2(5)] = '1' or [surg_comp_2(6)] = '1' or [surg_comp_2(7)] = '1' or [surg_comp_2(8)] = '1' or [surg_comp_2(9)] = '1' or [ns_comp_2(1)] = '1' or [ns_comp_2(2)] = '1' or [ns_comp_2(3)] = '1' or [ns_comp_2(4)] = '1' or [ns_comp_2(5)] = '1' or [ns_comp_2(6)] = '1'	Was the complication still ongoing at discharge (requires Clavien-Dindo "d" designation as above)?	yesno <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>0</td><td>No</td></tr> </table>	1	Yes	0	No										
1	Yes																
0	No																
115	notes	Notes	notes														
116	followup_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr><td>0</td><td>Incomplete</td></tr> <tr><td>1</td><td>Unverified</td></tr> <tr><td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete								
0	Incomplete																
1	Unverified																
2	Complete																
Instrument: Critical View of Safety - General Surgeon Blinded Reviewer 1 (critical_view_of_safety_general_surgeon_blinded_re) ^ Collapse																	
117	cvs_scoring_guide_v2	Refer to the scoring system below to complete your assessment of the documented CVS	descriptive														
118	structures_v2	Two structures entering the gallbladder	radio <table border="1"> <tr><td>1</td><td>2 points</td></tr> <tr><td>2</td><td>1 point</td></tr> <tr><td>3</td><td>0 points</td></tr> </table>	1	2 points	2	1 point	3	0 points								
1	2 points																
2	1 point																
3	0 points																
119	cystic_plate_v2	Cystic plate	radio <table border="1"> <tr><td>1</td><td>2 points</td></tr> <tr><td>2</td><td>1 point</td></tr> <tr><td>3</td><td>0 points</td></tr> </table>	1	2 points	2	1 point	3	0 points								
1	2 points																
2	1 point																
3	0 points																
120	cystohepatic_triangle_v2	Clearance of the cystohepatic triangle	radio <table border="1"> <tr><td>1</td><td>2 points</td></tr> <tr><td>2</td><td>1 point</td></tr> <tr><td>3</td><td>0 points</td></tr> </table>	1	2 points	2	1 point	3	0 points								
1	2 points																
2	1 point																
3	0 points																
121	image_quality	Were the images/video of sufficient quality for evaluation?	yesno <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>0</td><td>No</td></tr> </table>	1	Yes	0	No										
1	Yes																
0	No																
122	image_quality_reason	If no, please comment	yesno <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>0</td><td>No</td></tr> </table>	1	Yes	0	No										
1	Yes																
0	No																
123	reviewer_v2	Reviewer	dropdown <table border="1"> <tr><td>1</td><td>Prof Panieri</td></tr> <tr><td>2</td><td>Shreya Rayamajhi</td></tr> </table>	1	Prof Panieri	2	Shreya Rayamajhi										
1	Prof Panieri																
2	Shreya Rayamajhi																

124	critical_view_of_safety_general_surgeon_blinded_reviewer_complete	Section Header: <i>Form Status</i> Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: Critical View of Safety - HPB Blinded Reviewer 1 (critical_view_of_safety_hpb_blinded_reviewer_1)			^ Collapse
125	cvs_scoring_guide	Refer to the scoring system below to complete your assessment of the documented CVS	descriptive
126	structures	Two structures entering the gallbladder	radio 1 2 points 2 1 point 3 0 points
127	cystic_plate	Cystic plate	radio 1 2 points 2 1 point 3 0 points
128	cystohepatic_triangle	Clearance of the cystohepatic triangle	radio 1 2 points 2 1 point 3 0 points
129	image_quality_2	Were the images/video of sufficient quality for evaluation?	yesno 1 Yes 0 No
130	image_quality_reason_2	If no, please comment	notes
131	reviewer	Reviewer	dropdown 1 Marc Bernon 2 Christo Kloppers
132	critical_view_of_safety_hpb_blinded_reviewer_1_complete	Section Header: <i>Form Status</i> Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: Critical View of Safety - General Surgeon Blinded Reviewer 2 (critical_view_of_safety_general_surgeon_blind_0718)			^ Collapse
133	cvs_scoring_guide_v2_v2	Refer to the scoring system below to complete your assessment of the documented CVS	descriptive
134	structures_v2_v2	Two structures entering the gallbladder	radio 1 2 points 2 1 point 3 0 points
135	cystic_plate_v2_v2	Cystic plate	radio 1 2 points 2 1 point 3 0 points
136	cystohepatic_triangle_v2_v2	Clearance of the cystohepatic triangle	radio 1 2 points 2 1 point 3 0 points
137	image_quality_v2	Were the images/video of sufficient quality for evaluation?	yesno 1 Yes 0 No
138	image_quality_reason_v2	If no, please comment	yesno 1 Yes 0 No

139	reviewer_v2_v2	Reviewer	dropdown 1 Prof Panieri 2 Shreya Rayamajhi
140	critical_view_of_safety_general_surgeon_blind_0718_complete	Section Header: <i>Form Status</i> Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: Critical View of Safety - HPB Blinded Reviewer 2 (critical_view_of_safety_hpb_blinded_reviewer_2)			^ Collapse
141	cvs_scoring_guide_v2_caa716	Refer to the scoring system below to complete your assessment of the documented CVS	descriptive
142	structures_v2_77371d	Two structures entering the gallbladder	radio 1 2 points 2 1 point 3 0 points
143	cystic_plate_v2_ad54b7	Cystic plate	radio 1 2 points 2 1 point 3 0 points
144	cystohepatic_triangle_v2_5b084b	Clearance of the cystohepatic triangle	radio 1 2 points 2 1 point 3 0 points
145	image_quality_2_v2	Were the images/video of sufficient quality for evaluation?	yesno 1 Yes 0 No
146	image_quality_reason_2_v2	If no, please comment	notes
147	reviewer_v2_7567b1	Reviewer	dropdown 1 Marc Bernon 2 Christo Kloppers
148	critical_view_of_safety_hpb_blinded_reviewer_2_complete	Section Header: <i>Form Status</i> Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete

Appendix B.3.1 –Informed consent form

CONSENT TO LAPAROSCOPIC CHOLECYSTECTOMY DATA COLLECTION

Laparoscopic cholecystectomy is a common surgery. To make sure we continue to perform a high quality operation, we keep a registry where we collect and store medical data that may be used for research. This data may include intraoperative photographs or videos. It will not be possible to identify who you are from the photos or videos used in our registry. The images will be shared via the Whatsapp application, which uses end-to-end encryption to protect your personal information during sending. To minimize the risk of sharing personal information, images will be transmitted using password protected phones with a second password required to access the Whatsapp application. Images will be permanently deleted from the application within 24 hours of sending. The only people with access to the photos will be a small group of doctors involved in maintaining the database.

In order to use your medical data for research and future publications, we require your permission. This is voluntary. It will not influence your treatment in any way if you decide that we cannot store your data. We will continue to give you the best possible care. If you allow us to collect your data, we will ask you to sign the consent below. You can withdraw from the registry at any time. Access to the registry is restricted. Your confidentiality is protected because any information that may identify you is removed when it is used for research or studies. Our registries are approved by the University of Cape Town Human Research Ethics Committee (HREC). Their contact details are: Room E53-46, Old Main Building, Groote Schuur Hospital, Tel: 021-406 6492. Your data will only be used for research, once the HREC give their approval.

Principal Investigator: Professor Eduard Jonas
Contact details: Department of Surgery, Floor J45, Old Main Building, Groote Schuur Hospital
Tel: 021 4043156

PATIENT CONSENT

I understand that adding my data to the registry is voluntary, and that I can withdraw consent at any stage without giving a reason, and that it will not affect my medical care.

Name _____

Signature _____ Date _____

CERTIFICATION OF CONSENT

I certify that I explained the purpose of data collection for the Surgical Gastroenterology registries to the above-named individual.

Name _____

Signature _____ Date _____

Patient Sticker

Laparoscopic Cholecystectomy Checklist

Informed Consent	
	Describe the operation in common language
	Review risks: 5% chance of conversion to open operation <ul style="list-style-type: none"> • Infection: wound/intra-abdo treated with abx, may require re-intervention • Bile leak: often resolves with conservative treatment, may require endoscopic or surgical reintervention • Injury to nearby structures: rare (< 1 in 100 operations), bile duct or bowel, usually requires repeat operation • Bleeding: very rare, injury to liver or blood vessels, may require blood transfusion or additional procedures
	Review benefits: likely to resolve symptoms Compared to open surgery: <ul style="list-style-type: none"> • Shorter hospital stay • Earlier return to normal activities • Lower risk of wound infection • Smaller, less visible scars
Pre-operative/Pre-incision	
	Review imaging
	Review liver function tests
	Is this likely to be a difficult cholecystectomy <ul style="list-style-type: none"> • Is the gallbladder likely to be contracted • Appropriated indication (e.g. cholecystitis) • Previous upper abdominal surgery
Pre-dissection	
	Fundus retracted to 10 o'clock
	Hartmann's pouch lifted up and across to origin of segment 4 pedicle
	Line between Rouviere's Sulcus and falciform ligament identified
	Safe level of dissection identified
	Posterior leaf of peritoneum covering hepatocystic triangle can be released
Prior to Clipping the Cystic Duct	
	Surgeon confirmed critical view with the assistant <ul style="list-style-type: none"> • Hepatocystic triangle cleared of tissue • Only two structures entering the gallbladder • Distal 1/3 of the cystic plate cleared • Anterior and posterior photographs taken
	Surgeon to consider performing and Intraoperative cholangiogram (IOC) and confirm with assistant: <ul style="list-style-type: none"> • Flow into the duodenum • Three hepatic ducts are seen proximally, including right posterior sectoral duct • No filling defects within the common bile duct • Presence of spiral valves within cystic duct
Bailout Techniques/Intraoperative Recognition of BDI	
	If the CVS cannot safely be obtained, DO NOT proceed, instead consider: <ul style="list-style-type: none"> • Calling for help from an experienced colleague • Subtotal "fenestrating" or "reconstituting" cholecystectomy • Cholecystostomy tube placement
	If a bile duct injury is suspected intraoperatively: <ul style="list-style-type: none"> • DO NOT attempt repair, rather stop dissection and leave a drain • Immediate referral to an HPB surgeon

Appendix B.3.3 – Standardized operative note

LAPAROSCOPIC CHOLECYSTECTOMY OPERATION NOTE

PATIENT STICKER

Medical aid: _____

Date of operation: _____

Date booked: _____

Timing: elective/ same admission

Surgeon: _____ Assistant(s): _____ Hospital: GSH/ MPH/ NSH/ VWH/ UCT-PAH

INDICATION: Biliary colic/ acute cholecystitis/ choledocholithiasis/ gallstone pancreatitis/ other: _____
Duration of symptoms (days): _____

PATIENT CO-MORBIDITY CVS/ Resp/ Liver/ DM/ other _____ HIV: NEG/POS/UNK Ht(m) _____ Wt(kg) _____ ASA _____

PREOP CHECK LIST: SURGEON TO CONFIRM WITH TEAM: Y/N

IMAGING REVIEW: Y/N	LIVER FUNCTION REVIEW: Y/N	WILL THIS BE A DIFFICULT GALL BLADDER REVIEW: Y/N
Reason for expected difficulty:	BMI >35: Y/N Previous surgery: Y/N Liver disease: Y/N Previous perc drain: Y/N Previous ERCP: Y/N Previous pancreatitis: Y/N Other: _____	

ACCESS: Hasson / Veress/other: _____ Ports used: _____ Any difficulty: _____

PRE-DISSECTION CHECKLIST: SURGEON CONFIRMED WITH ASSISTANT: Y/N

Fundus retracted to 10 o'clock: Y/N	Hartmann's pouch lifted up, across to origin of segment IV pedicle: Y/N	Line between Rouviere's sulcus and base of segment IV identified: Y/N
Safe level of dissection identified: Y/N	Posterior leaf of peritoneum over hepatobiliary triangle released: Y/N	

PRIOR TO CLIPPING CYSTIC DUCT: SURGEON CONFIRMED WITH ASSISTANT: Y/N

Hepatocystic triangle clear: Y/N	If any no, indicate why CVS was not achieved: Bleeding Aberrant biliary anatomy Aberrant arterial anatomy Equipment problems No progress Hepatomegaly Fatty liver	Difficulty grasping GB Contracted GB Intrahepatic GB Severe inflammation GB empyema Extensive adhesions Other: _____	Images or video of CVS taken with camera (anterior/posterior): Y/N
Only 2 structures: Y/N			
Lower 1/3 cystic plate clear: Y/N			
Intraoperative cholangiogram: Y/N If YES confirm findings below: Flow into duodenum: Y/N 3 proximal hepatic ducts visualized: Y/N CBD filling defects: Y/N Spiral valves in cystic duct: Y/N Other observations:			

PROCEDURE: Cholecystectomy completed laparoscopically: Y/N GB removed intact: Y/N

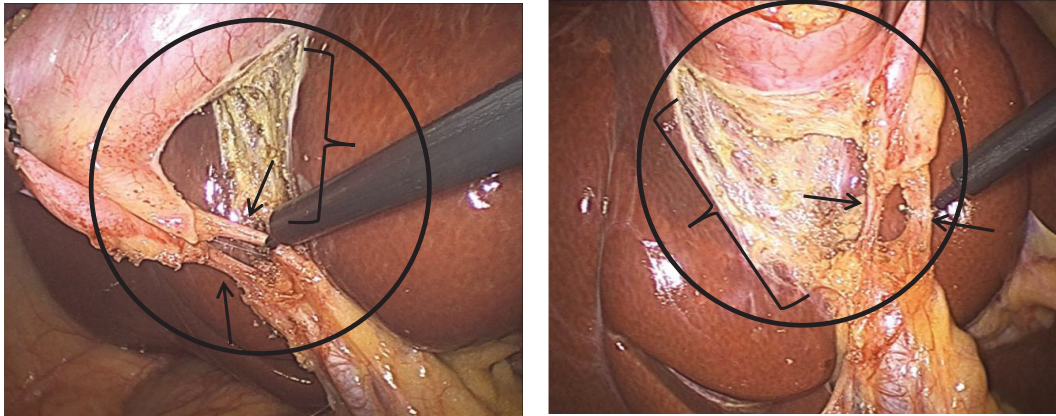
Subtotal Y/N	LC converted to open Y/N	Cholecystostomy Y/N	GB left in situ Y/N
If subtotal: fenestrating / reconstituting		If converted, time to conversion (minutes): _____	
Cystic duct control: LIGA clip _____ other _____		Cystic artery control: LIGA clip _____ other _____	
Number clips on "stay" side: _____		Number clips on "stay" side: _____	
Stone spillage: Y/N	Fully retrieved: Y/N	Bile leakage: Y/N From: GB/ liver bed/ bile duct/ other _____	

FINAL COMMENTS: Operation time(minutes): _____ Estimated blood loss: minimal/ moderate/ severe

Port closure:	Skin closure:	CVS Images uploaded: Y/N
Drain:	Specimen to histology lab:	Operation note uploaded: Y/N
Other observations:		
Signature: _____		

Appendix B.3.4 – Critical view of safety theatre poster

Ideal anterior and posterior photos of the critical view of safety



- 1) Two and only two structures entering the gallbladder
- 2) Lower 1/3 of cystic plate dissected free
- 3) Hepatocystic triangle free of fibrous and fatty tissue

Detailed scoring criteria for critical view of safety photos

Table 2. Criteria for Judging Still Photographs of the Critical View of Safety

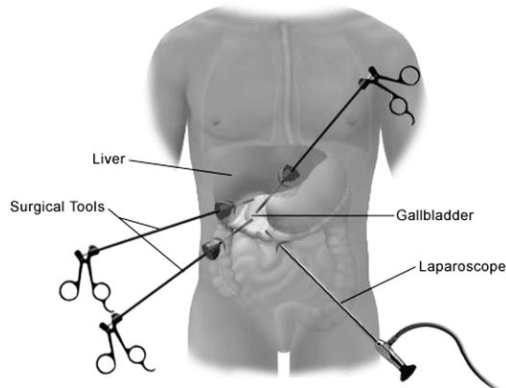
Two structures connected to the gallbladder	
2 points	Two structures can immediately and clearly be seen connecting to the gallbladder.
1 point	Two structures can be seen connecting to the gallbladder, but there is some overlap of duct and artery or a technical feature, such as poor lighting or lack of color contrast, that interferes with clarity of determination. Photograph requires study to make assessment.
0 points	Due to overlap or technical issues 2 separated cystic structures cannot be seen.
Cystic plate	
2 points	Cystic plate is immediately clearly visible to approximately its bottom one third.
1 point	Cystic plate is visible but overlapped by other structures so that it is not optimally seen or an insufficient amount of the plate is shown. Photograph requires study to make assessment.
0 points	Cystic plate not visible due to positioning, light, obstruction of view by instruments, or coverage with clot.
Clearance of hepatocystic triangle	
2 points	Hepatocystic triangle is cleared of tissue so that visibility of cystic structures and plate are completely unimpeded, but also so that viewer can be immediately certain than no other structures are in the triangle.
1 point	Somewhat less than the whole triangle can be clearly seen or technical issues reduce ability to see optimally. Photograph requires study to make assessment.
0 points	Tissue in triangle obscures view of cystic structures cystic plate and does not allow conclusion that that there are no other structures in triangle. Or technical issues prevent determination of how well cleared the triangle is.

Sanford DE, Strasberg SM. *J Am Coll Surg.* 2014;218(2):170-8.

Original Source: Sanford DE, Strasberg SM. A simple effective method for generation of a permanent record of the Critical View of Safety during laparoscopic cholecystectomy by intraoperative "doublet" photography. J Am Coll Surg. 2014;218(2):170-179, reproduced with permission from Elsevier.

Appendix B.3.5 Patient information sheet

Laparoscopic Cholecystectomy *Surgical Removal of the Gallbladder*



Details of the Operation:

- Four small incisions are made in the abdomen
- Ports are inserted into the openings
- Surgical tools and a lighted camera are placed into the ports
- The abdomen is inflated with carbon dioxide gas to make it easier to see the internal organs
- The gallbladder is removed, and the port openings are closed with sutures, clips or glue
- The procedure takes about 1 to 2 hours
- There is a 5% chance of conversion to an open operation for gallbladder removal

Risks of a Laparoscopic Cholecystectomy:

- Infection: wound or in the abdomen, treated with antibiotics, may require re-intervention
- Bile leak: often improves with conservative treatment, may require endoscopic or surgical re-intervention
- Injury to nearby structures: bile duct or bowel rare (< 1 in 100 operations), usually requires re-operation
- Bleeding: very rare, injury to liver or blood vessels, may require blood transfusion or additional procedures

Benefits of a Laparoscopic Cholecystectomy:

- After the operation, your symptoms are likely to resolve
- Shorter hospital stay
- Less pain after surgery
- Lower risk of wound infection
- Earlier return to normal activities
- Smaller, less visible scars

Recovery:

- After general anesthesia and when using narcotic pain medication, you may feel different for 2-3 days, have difficulty with memory or feel more tired
- You should not drive, drink alcohol, or make any big decisions for at least 2 days after your operation
- You may return to your normal diet
- It is important that you stay hydrated and eat a high-fibre diet to keep your bowel movements soft while your incisions heal
- Slowly increase your activity. Be sure to get up and walk every hour to prevent blood clot formation
- Patients usually take 1-3 weeks to return comfortably to normal activity
- You may usually return to work 1 week after laparoscopic or open repair, as long as you do not do any heavy lifting
- Do not lift anything heavier than 5 kg or participate in strenuous activity for at least 4-6 weeks

Adopted from the American College of Surgeons “Cholecystectomy” patient information bulletin. Access at: <https://www.facs.org/~media/files/education/patient%20ed/cholesys.ashx>

Laparoscopic Cholecystectomy

Surgical Removal of the Gallbladder

Wound Care:

- Always wash your hands before and after touching near your incisions
- Do not soak in bathtub until your stitches, glue or staples are removed (2 weeks)
- A small amount of drainage from the wound is normal
- Avoid wearing tight or rough clothing. It may rub your incisions and make it harder for them to heal
- Your scars will heal in about 4-6 weeks and will be softer and continue to fade over the next year

When to return to hospital:

- Pain that will not go away
- Pain that gets worse
- A fever of more than 38.3 C
- Continuous vomiting
- Swelling, redness, bleeding or bad-smelling drainage from your wound site(s)
- Strong or continuous abdominal pain or swelling of your abdomen



If you develop any of the symptoms above, return to the hospital immediately for further evaluation





FHS017: Annual Progress Report / Renewal

Record Reviews/Audits/Collection of Biological Specimens/Repositories/Databases/Registries

HREC office use only (FWA00001637; IRB00001938)			
This serves as notification of annual approval, including any documentation described below.			
<input type="checkbox"/> Approved	Annual progress report	Approved until/next renewal date	
<input type="checkbox"/> Not approved	See attached comments		
Signature Chairperson of the HREC		Date Signed	

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)			
HREC REF Number		Current Ethics Approval was granted until	
Protocol title			
Principal Investigator			
Department / Office Internal Mail Address			
1.1 Does this protocol receive US Federal funding?			<input type="checkbox"/> Yes <input type="checkbox"/> No

2. Protocol status (tick ✓)

<input type="checkbox"/>	Research-related activities are ongoing
<input type="checkbox"/>	Data collection is complete, data analysis only
Please indicate (in the block below) the titles and HREC reference numbers of any projects currently making use of the Database/registry/repository.	

3. Protocol summary

Total number of records or specimens collected, reviewed or stored since the original approval	
Total number of records or specimens collected, reviewed or stored since last progress report	
Have any research-related outputs (e.g. publications, abstracts, conference presentations) resulted from this research? If yes, please list and attach with this report.	<input type="checkbox"/> Yes <input type="checkbox"/> No

4. Signature

Signature of PI		Date	
-----------------	--	------	--

Appendix B.4.2 – Annexure 2 form



**RESEARCH ANNEXURE 2
PROPOSAL SUMMARY**

For Official Use:
Research Proposal Number

ANNEXURE 2 PROPOSAL SUMMARY	
Name of Institution/organisation conducting research	
Name of Investigators	
Postal Address	
Telephone Number	
Fax number	
Mobile Number	
Email Address	
Institution which gave ethical approval	
Date of Ethical approval	
Date research expected to commence	
Proposed data collection dates at requested facilities	
Date research expected to end	
Date research reports should be expected	
Western Cape Districts where research will be done: (Please mark with an X)	Metro Westcoast Cape Winelands Overberg Central Karoo Eden
WC DOH Facilities where research will be done: (Please list the name of the facility under appropriate category)	Tertiary Hospitals: District Hospitals: Community Health Centres: Clinics:
Other facilities in the WC DOH where research will be done (Please specify)	Psychiatric Hospitals: TB Hospitals Other: Databases :
Research title	
Research aim	
Research objectives	
Key Words	

Appendix B.4.3 – BAS06 form



BAS06 – New Third Party System user application

A. INSTRUCTIONS

<ul style="list-style-type: none"> For new users, ensure ALL fields are completed and ALL relevant signatories have signed this form. Please send this form to Systems Access via email to icts-systemsaccess@uct.ac.za or via internal mail to Room 201A, ICTS-on-Main, 7 Main Road, Mowbray. <p>Note: In the case where a department needs to add a third party, BAS03 must be accompanied with BAS06 and sent to Access Control at Properties and Services Maintenance Building, Room No.2.01, Upper Campus, Rondebosch Phone (021) 650 1199</p> <ul style="list-style-type: none"> Once the form has been received, you will be contacted regarding booking on Third Party System training. Upon your successful completion of the Third Party System course, the Third Party System trainer will send Systems Access an e-mail confirming your attendance. This will be attached to your form and Systems Access will proceed with the creation of your Third Party System user account. If your department has thirty or more third parties, it is recommended that the department has two Third Party System users. <p>Note: Access Control will only renew or edit third parties on presentation of a copy of a submitted BAS06 form and in an emergency.</p>

B. PERSONAL DETAILS

First name and surname	
Staff number	
Third party (T) number	
Contact telephone number	
E-mail address	
Organisational unit(s)	
Department	

C. MANAGEMENT AGREEMENT

<p>Please Note: Your signature indicates that:</p> <ol style="list-style-type: none"> The person named on this form has a legitimate requirement to use the Third Party System and the access requested is in accordance with his/her departmental responsibilities. You agree to make this person available to receive Third Party System training in accordance with his/her responsibilities. 					
HOD/Section head name		Signature		Date	

D. PROCESSING (For office use only)

User has successfully completed training	Trained by (Signature)		Date	
User name created / edited and communicated	Authorised by (Signature)		Date	

Appendix B.4.4 – Monthly email template

Dear [designated representative],

Thanks very much for your participation and commitment to the LC project. This serves as the monthly email with the list of the [insert hospital] patients we've entered over the last 30 days. I've cc'ed Mariska Calitz who is helping us with data collection and maintaining the database.

Thanks to everyone's efforts, we've logged [insert number] LC's since the project started, [insert number] of which have been entered from January 2020.

Below is the list of [insert number] patients we have in the database since the start of the project – the patients in bold are the new additions over the last 30 days. We're missing [summarize missing data]. Many of the patients have not reached the 30-days postoperative mark, but if you are aware of any re-admissions/complications please let us know and we can update the database.

Folder Number	LC Date	Discharge Date	Re-admissions/Complications
[insert]	[insert]	[insert if known]	[insert if known]
[insert]	[insert]	[insert if known]	[insert if known]
[insert]	[insert]	[insert if known]	[insert if known]
[insert]	[insert]	[insert if known]	[insert if known]

According to your records, are there any patients not added that should have been, or were there any LC's performed where CVS photos weren't taken? Every once in a while, a patient gets missed. We'd just like to keep track, so we have an idea of how often we're excluding patients from the database.

Thanks very much! Your feedback is always welcome, and please let me know if there are any problems I can help with.

Kind Regards,

Appendix B.5.1 – Human Research Ethics Committee letter of approval



UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee



Room G50-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: Sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

23 November 2019

HREC/REF: R040/2019

Prof E Jonas
Department of General Surgery
Division of Gastroenterology
E23 Room 19, GI-Clinic,
NGSH

Dear Prof Jonas

Project Title: Laparoscopic Cholecystectomy Registry

Thank you for response letter dated 24 October 2019, addressing the issues raised by the Human Research Ethics Committee.

The HREC has **approved** the registration of your registry.

The registration of this registry is valid until 30 November 2022.

Please provide the HREC with an update if the registry continues beyond this period.
Please Note: All research, including that undertaken for a master's or doctoral degree, using registered databases, registries and repositories, requires submission as a new study. It requires an application form (FHS013) and a protocol which has undergone departmental review. The study will receive its own HREC REF number which will be linked to the main database or repository.

Please note that any studies using the collected data require separate ethics approval.

Please quote the HREC REF in all your correspondence.

Yours sincerely

PROFESSOR MARC BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

HREC/ref:R040/2019

B.5.2 – Chief Operational Officer letter of approval



GROOTE SCHUUR HOSPITAL

Enquiries: Dr Bernadette Eick
e-mail: Bernadette.Eick@westerncape.gov.za

Professor Eduard Jonas
GENERAL SURGERY - GASTROENTEROLOGY

E-mail: eduard.jonas@uct.ac.za / lidemann.jessica@gmail.com

Dear Professor Jonas,

RESEARCH PROJECT: Laparoscopic Cholecystectomy Registry

Your recent letter to the hospital refers.

You are granted permission to proceed with your research, which is valid until **30 November 2022**.

Please note the following:

- a) Your research may not interfere with normal patient care.
- b) Hospital staff may not be asked to assist with the research.
- c) No additional costs to the hospital should be incurred i.e. Lab, consumables or stationary. **If access to TRACK Care/NHLS is required, kindly attach our letter of approval to the application form.**
- d) **No patient folders may be removed from the premises or be inaccessible.**
- e) Please provide the research assistant/field worker with a copy of this letter as verification of approval.
- f) Confidentiality must always be maintained .
- g) **Should you at any time require photographs of your subjects, please obtain the necessary indemnity forms from our Public Relations Office (E45 OMB or ext. 2187/2188).**
- h) Should you require additional research time beyond the stipulated expiry date, please apply for an extension.
- i) Please discuss the study with the HOD before commencing.
- j) Please introduce yourself to the person in charge of an area before commencing.
- k) On completion of your research, please forward any recommendations/findings that can be beneficial to use to take further action that may inform redevelopment of future policy / review guidelines.
- l) **Kindly submit a copy of the publication or report to this office on completion of the research.**
- m) **At no time should any posters encouraging patients to partake in research, be displayed within a clinical area.**

I would like to wish you every success with the project.

Yours sincerely

A handwritten signature in black ink, appearing to read 'B Eick'.

DR BERNADETTE EICK
CHIEF OPERATIONAL OFFICER
Date: 11 December 2019

C.C. Mr. L. Naidoo
Dr B. Jacobs
Professor E. Muller

G46 Management Suite, Old Main Building,
Observatory 7925
Tel: +27 21 404 6288 fax: +27 21 404 6125

Private Bag X,
Observatory, 7935
www.westerncape.gov.za/health

Appendix B.6 – Literature

Connor SJ, Perry W, Nathanson L, Hugh TB, Hugh TJ. Using a standardized method for laparoscopic cholecystectomy to create a concept operation-specific checklist. *HPB (Oxford)*. 2014;16(5):422-429.

Sanford DE, Strasberg SM. A simple effective method for generation of a permanent record of the Critical View of Safety during laparoscopic cholecystectomy by intraoperative "doublet" photography. *J Am Coll Surg*. 2014;218(2):170-178. (supplemental material in the form of PowerPoint presentation included)

Strasberg SM, Hertl M, Soper NJ. An analysis of the problem of biliary injury during laparoscopic cholecystectomy. *J Am Coll Surg*. 1995;180(1):101-125.

Strasberg SM, Pucci MJ, Brunt LM, Deziel DJ. Subtotal cholecystectomy-"fenestrating" vs "reconstituting" subtypes and the prevention of bile duct injury: Definition of the optimal procedure in difficult operative conditions. *J Am Coll Surg*. 2016;222(1):89-96.

Kubheka B. Ethical and legal perspectives on use of social media by health professionals in South Africa. *S Afr Med. J* 2017;107(5):386-389.

Mars M, Scott R. WhatsApp in clinical practice: A literature review. *Stud Health Technol Inform*. 2016;231:82–90.

Opperman CJ, Janse van Vuuren M. WhatsApp in a clinical setting: The good, the bad and the law. *S Afr J Bioeth Law*. 2018;11(2):102-103.

Appendix B.7 – Study protocol approval letters



UNIVERSITY OF CAPE TOWN



Department of Surgery
Departmental Research Committee
Dr Timothy Pennel
D24 Office, Grootte Schuur Hospital
Observatory 7925
South Africa
Tel (021) 404 3430
Email: tim.pennel@uct.ac.za

3 Feb 2020

Dr J Lindemann
Department of Surgery
University of Cape Town

Dear Dr Lindemann
RE: Project 2020/017

PROJECT TITLE: An Assessment Of The Quality Of The Critical View Of Safety Achieved In Laparoscopic Cholecystectomy

The above protocol has been reviewed by the Department of Surgery Research Committee. I am pleased to inform you that the committee approved the scientific merit of the study, and endorse the protocol for submission to the relevant ethics committee.

Although this letter serves as confirmation that the above protocol has successfully passed through the surgical DRC, respective ethics committees still require DRC chair signature before submission.

Please use the above project number in all future correspondence,

Yours sincerely

Signature removed to avoid exposure online

Signature removed

DR TIMOTHY PENNEL
CHAIR: SURGICAL DRC

DR MARITZ LOUBSCHER
CHAIR: PROTOCOL REVIEW COMMITTEE

"OUR MISSION is to be an outstanding teaching and research university, educating for life and addressing the challenges facing our society."



UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee



Room G50- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-enquiries@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

03 March 2020

HREC REF:100/2020

Prof E Jonas
Surgical Gastroenterology and Hepatobiliary Unit
J-45, OMB

Dear Prof Jonas

PROJECT TITLE: AN ASSESSMENT OF THE QUALITY OF THE CRITICAL VIEW OF SAFETY ACHIEVED IN LAPAROSCOPIC CHOLECYSTECTOMY (PhD -DR J. LINDEMANN) sub-study - R040/2019

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 March 2021.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

The HREC acknowledge that the student: Dr Jessica Lindemann will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

Signature removed to avoid exposure online

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

HREC 100/2020sa



**Department of Surgery
Departmental Research Committee**

Dr Timothy Pennel

D24 Office, Groote Schuur Hospital
Observatory 7925
South Africa

Tel (021) 404 3430

Email: tim.pennel@uct.ac.za

25 Mar 2020

Doctor J Lindemann

Department of Surgery
University of Cape Town

Dear Doctor Lindemann

RE: Project 2020/039

PROJECT TITLE: Interim Analysis Of The Laparoscopic Cholecystectomy Database: January – March 2020

The above protocol has been reviewed by the Department of Surgery Research Committee. I am pleased to inform you that the committee approved the scientific merit of the study, and endorse the protocol for submission to the relevant ethics committee.

Although this letter serves as confirmation that the above protocol has successfully passed through the surgical DRC, respective ethics committees still require DRC chair signature before submission.

Yours sincerely

Signature removed to avoid exposure online

Signature removed

DR TIMOTHY PENNEL
CHAIR: SURGICAL DRC

DR MARITZ LAUBSCHER
CHAIR: PROTOCOL REVIEW COMMITTEE

"OUR MISSION is to be an outstanding teaching and research university, educating for life and addressing the challenges facing our society."



UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee



Room G50- Old Main Building
Groote Schuur Hospital
Observatory 7925

Telephone [021] 406 6492

Email: hrec-enquiries@uct.ac.za

Website: www.health.uct.ac.za/fhs/research/humanethics/forms

19 June 2020

HREC REF: 199/2020

Prof Eduard Jonas

Department of Surgery
Health Science Faculty
Anzio Road
Observatory
7925

Email: Eduard.jonas@uct.ac.za

Student: lindemann.jessica@gmail.com

Dear Prof Jonas

**PROJECT TITLE: INTERIM ANALYSIS OF THE LAPAROSCOPIC CHOLECYSTECTOMY
DATABASE: JANUARY – MARCH 2020 (PHD DR JESSICA LINDEMANN)**

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, dated 17 March 2020.

Approval is granted for one year until the 30 June 2021.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the student: Dr Jessica Lindemann will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

HREC 199/2020 le

Yours sincerely

Signature removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

HREC 199/2020 le

Quality Improvement for Laparoscopic Cholecystectomies

Making bile duct injuries a near-never event

Jessica Lindemann, MD



Surgical Gastroenterology Unit
Division of General Surgery
University of Cape Town
Groote Schuur & UCT Private Academic
Hospital



Motivation

- LC is a commonly performed general surgery operation
 - Important laparoscopic operation for surgical trainees to learn
- The annual number of LCs performed is unknown
- The national incidence of BDIs is unknown
 - Higher than previously reported studies at a tertiary academic center

Components

- Registry consent form
- Checklist
- Standardized operative note
- Photo (video) documentation of the critical view of safety (CVS)
- 30-day complications and readmissions

The intervention has five components. The central element is the LC checklist. There is also a standardized operative note, mandatory photo or video documentation of the CVS, collection of 30-day complications and readmissions, and importantly a database consent form.

Registry Consent Form

- Required for prospective capture of patient data into an HREC-approved database
- Includes information on the transfer of patient information using WhatsApp
- A record of signed forms for all included patients needs to be maintained

HREC has approved the database and the consent form. It is necessary that we get a patient's permission to collect their data in the LC database, especially because we will be sending their personal information via WhatsApp. The measures that we will take to protect their information are listed on the consent form. Once its signed, take a photo and upload to the WhatsApp group.

Checklist: Consent for LC

- Informed consent
 - Describe the procedure in plain language
 - Review risks
 - Review benefits
 - Review alternatives
 - Answer any questions

The top portion of the LC checklist is about obtaining informed consent for the operation. What is included in the checklist is meant to be a guide or a reference.

Checklist: Pre-incision

- Review imaging
 - Appropriate indication; concerning findings
- Review liver function tests
 - Concern for choledocholithiasis
- Is it likely to be a difficult cholecystectomy?
 - Contracted gallbladder, acute cholecystitis, BMI, previous upper abdominal surgery, liver disease

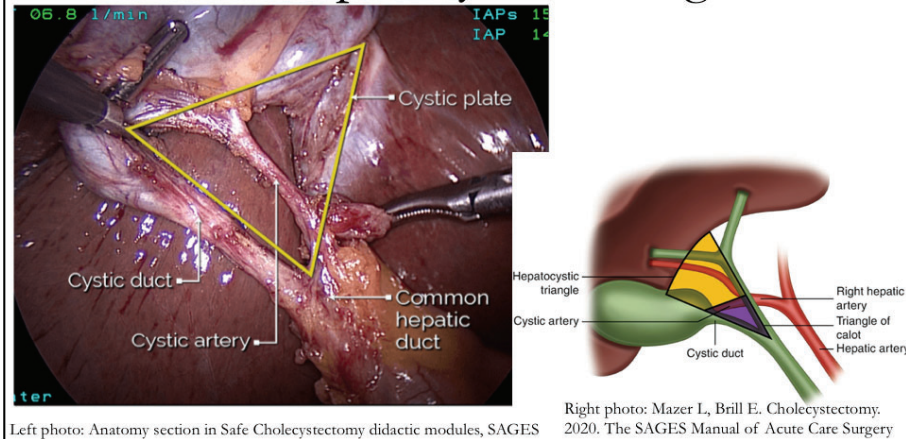
The next portion of the check list is the pre-incision section. This is meant to be performed right after the WHO surgical checklist and includes a review of the imaging, is the indication appropriate, are there any concerning findings that might change our operative approach or influence our intraoperative decision making, a review of the liver function tests (LFTs), then consideration of whether this might be a difficult operation and why. For example, the surgeon might say we're doing a LC for symptomatic gallstones, there was concern for a stone in the duct on imaging with abnormal LFTs so we're likely to perform an IOC, but we don't expect a difficult operation.

Checklist: Pre-dissection

- 1) Fundus retracted to 10 o'clock position
- 2) Hartmann's pouch lifted up and across to segment 4
- 3) Line between Rouviere's Sulcus and falciform ligament identified
- 4) Safe level of dissection identified
- 5) Posterior leaf of peritoneum covering hepatocystic triangle can be released

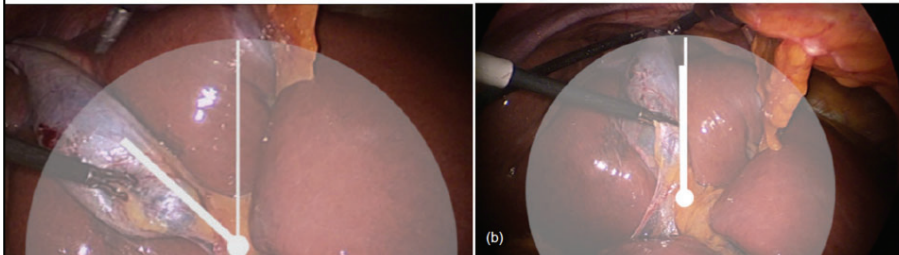
There are 5 important operative steps to perform to make sure that dissection of the hepatocystic triangle starts at a safe level, above the major portal structures. As you perform each of these steps, it's important to engage your assistant and confirm with them that each of the five steps have been performed. For less experienced assistants, use it as a teaching opportunity.

The Hepatocystic Triangle



The hepatocystic triangle is defined as the area between the gallbladder, liver, cystic duct and common hepatic duct. The cystic artery can be found within the hepatocystic triangle. The hepatocystic triangle is the focus of the dissection to achieve the CVS. The Triangle of Calot is not the same – it is the smaller triangle *within* the hepatocystic triangle with boundaries defined by the cystic duct, cystic artery and common hepatic duct (rhomboid shape due to retraction of the gallbladder in the image above).

1) Retract GB to the 10 o'clock position (toward the patient's right shoulder)



10 o'clock

Aids in opening the
hepatocystic triangle

12 o'clock

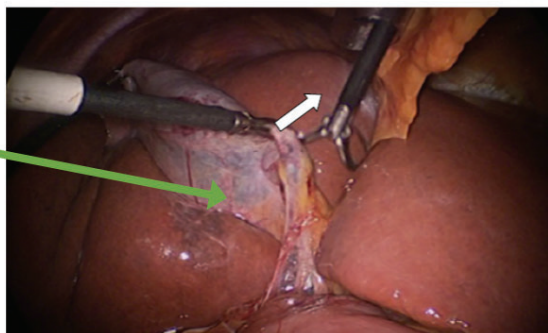
Closes the hepatocystic
triangle and risks injuring the
common hepatic duct

Connor et al. HPB. 2014;16(5):422-9

- (a) Retracting the gallbladder (GB) to the 10 O'clock position assists in the eventual exposure of the posterior peritoneum covering the hepatocystic triangle. This position "opens" the triangle.
- (b) If the gallbladder is retracted cephalad and medially (12 o'clock), the surgeon is obliged to dissect the cystic duct front on. This position "closes" the triangle and risks injuring the common hepatic duct located posteriorly.

2) Lift Hartmann's pouch up and across toward segment IV

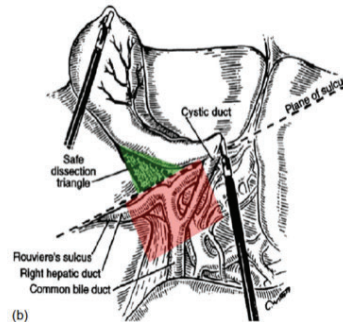
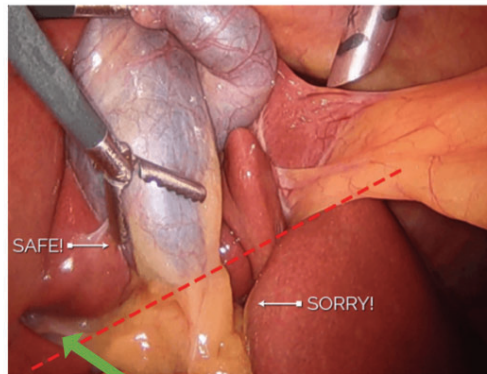
Maximizes exposure to posterior peritoneum



Connor et al. HPB. 2014;16(5):422-9

Hartmann's pouch should be lifted up and across toward the segment IV pedicle to maximize the exposure of the posterior peritoneum of the hepatocystic triangle to the operating surgeon.

3) Identify the line between Rouviere's sulcus and segment IV of the liver



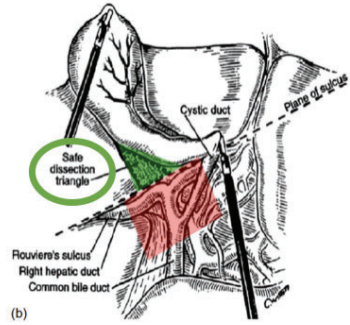
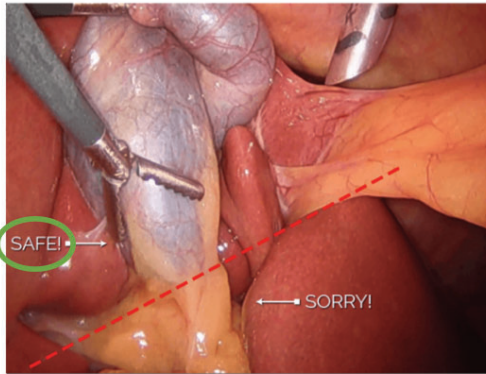
Connor et al. HPB. 2014;16(5):422-9

ROUVIERE'S SULCUS

Photo from: Anatomy section in Safe Cholecystectomy didactic modules, SAGES

Rouviere's sulcus marks the site where the right portal pedicle enters the liver and is present in about 80% of normal livers. When present, Rouviere's sulcus is an important landmark during LC because the common hepatic duct lies below, while the cystic duct and artery are above. Dissection above Rouviere's sulcus occurs in a safe plane, while dissection below is dangerous and risks injuring the common hepatic duct and other portal structures.

4) Identify the safe level of dissection ABOVE

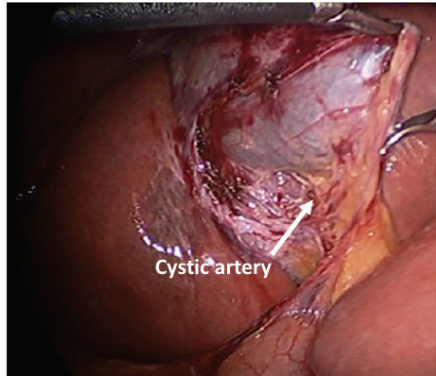


Critical structures located BELOW

Photo from: Anatomy section in Safe Cholecystectomy didactic modules, SAGES

Connor et al. HPB. 2014;16(5):422-9

5) Safe to proceed with releasing the posterior peritoneum



Once free, proceed to releasing the anterior peritoneum and achieving the critical view of safety

Connor et al. HPB. 2014;16(5):422-9

The posterior peritoneum of the hepatocystic triangle should be released and dissection continued until the posterior surface of the cystic artery can be seen.

Checklist: Prior to Clipping the Cystic Duct

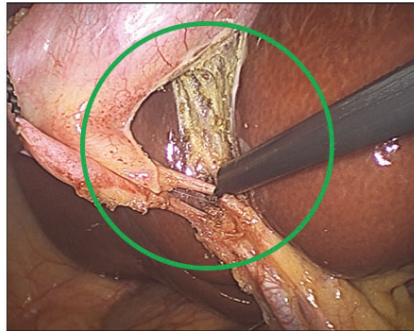
Surgeon to confirm with assistant:

- 1) Hepatocystic triangle is free of fibrous and fatty tissue
- 2) Two and only two structures are entering the gallbladder
- 3) Distal 1/3 of the cystic plate is dissected free

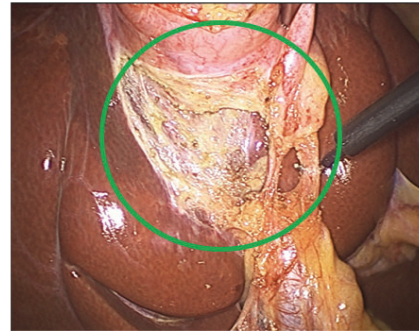
Capture anterior and posterior CVS photos (or videos)

Photos get uploaded along with the consent form to the WhatsApp group

1) Hepatocystic triangle clear of fat and fibrous tissue in both views



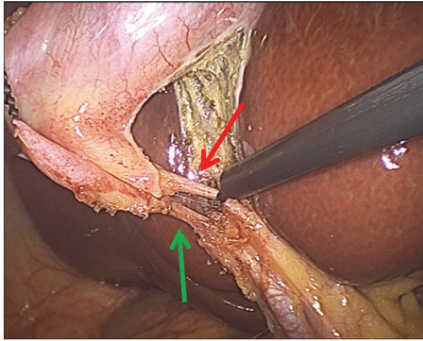
Anterior



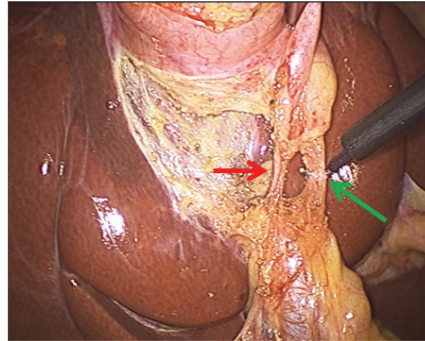
Posterior

Sanford DE, Strasberg SM. J Am Coll Surg. 2014;218(2):170-8.

2) Two and only two structures are connected to the gallbladder



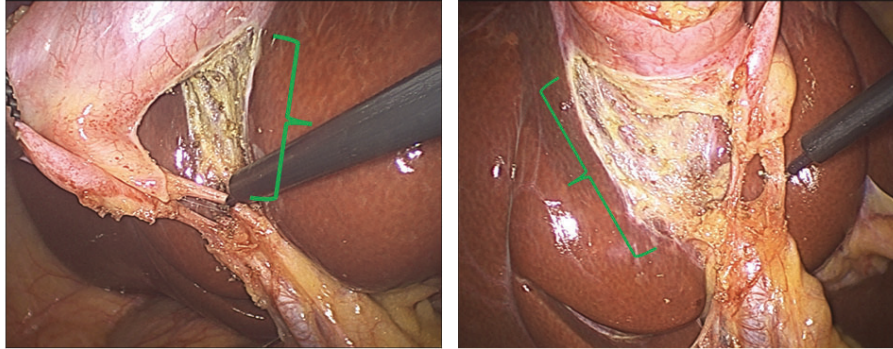
Anterior



Posterior

Sanford DE, Strasberg SM. J Am Coll Surg. 2014;218(2):170-8.

3) The lower one-third of the cystic plate is visible



Anterior

Posterior

Sanford DE, Strasberg SM. J Am Coll Surg. 2014;218(2):170-8.

CVS Scoring

- 1) Hepatocystic triangle free of fibrous and fatty tissue
- 2) Two and only two structures are entering the gallbladder
- 3) The lower 1/3 of the cystic plate is clearly visible

Yes = 2 points

Maybe = 1 point

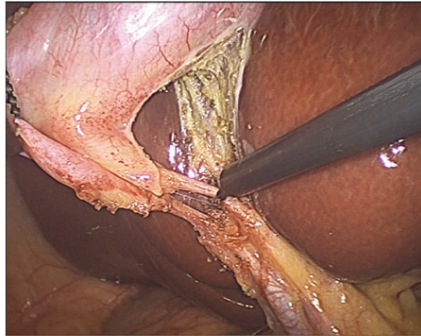
No = 0 points

Goal: score 5-6 points on every CVS

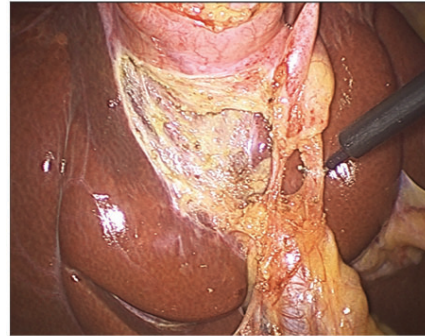
Sanford DE, Strasberg SM. J Am Coll Surg. 2014;218(2):170-8.

Photos should be sent on the WhatsApp group and from there will get uploaded onto the REDCap LC database where blinded reviewers will score the images using a previously published scoring system. Each of the three elements can receive up to 2 points, for a total of 6 points.

Ideal Photos



Anterior



Posterior

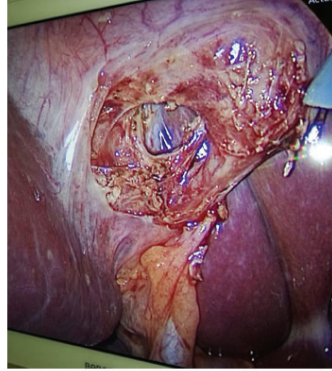
Sanford DE, Strasberg SM. J Am Coll Surg. 2014;218(2):170-8.

All three elements of the CVS are immediately recognizable. The images are in focus, appropriately white-balanced with the correct angle and zoom to give perspective to a reviewer. The surgical field is free from blood and the surgical instrument is assisting in demonstrating the CVS rather than blocking the critical structures. The photos can be taken by a cell phone or the screen in theatre.

Not so bad...

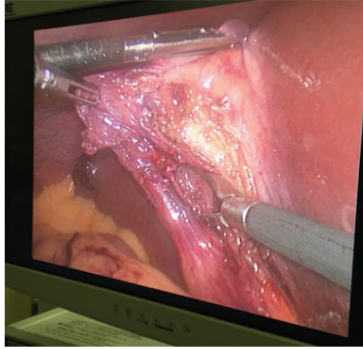


Anterior

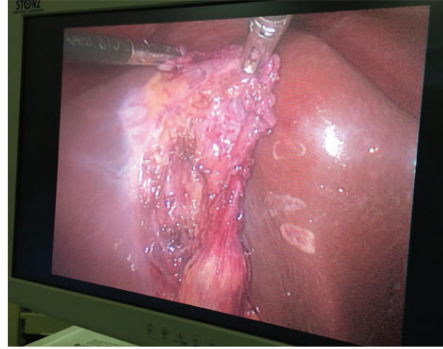


Posterior

Room for improvement

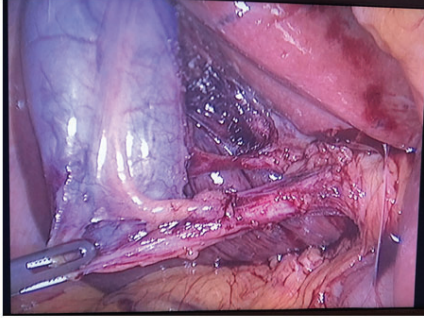


Anterior

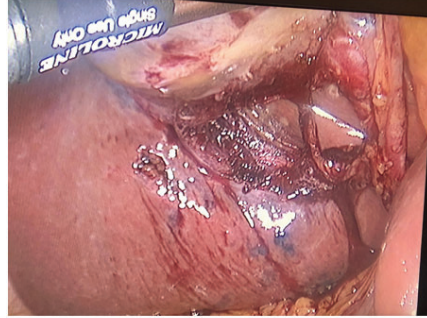


Posterior

Not so bad...

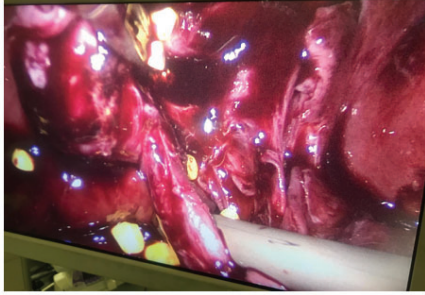


Anterior

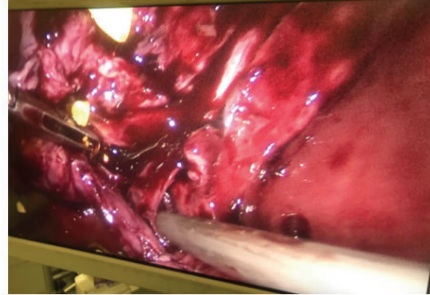


Posterior

Room for improvement

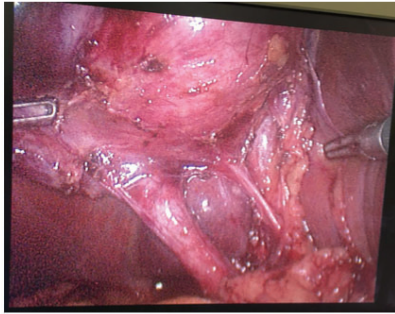


Anterior

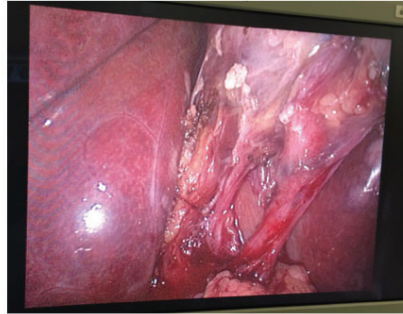


Posterior

Not so bad...

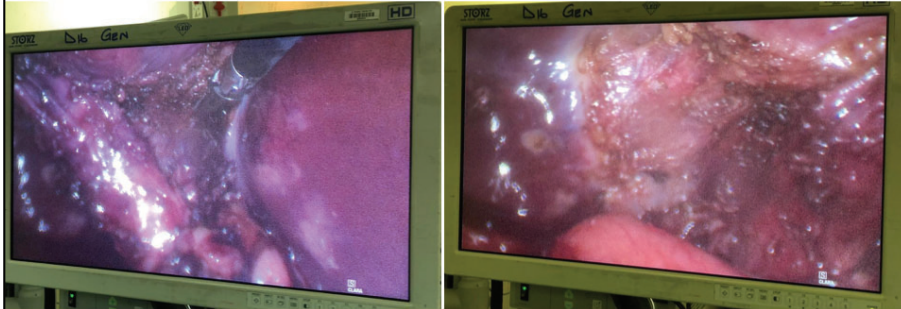


Anterior



Posterior

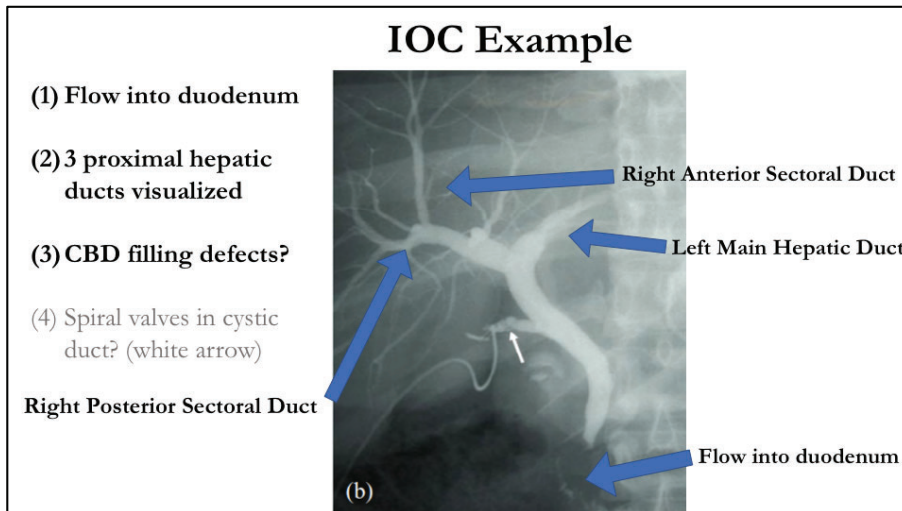
Room for improvement



Anterior

Posterior

Critical Elements of the Intraoperative
Cholangiogram



There are three critical findings to demonstrate in an IOC, namely flow into the duodenum, identification of the three proximal hepatic ducts (right posterior and anterior sectors, left main hepatic duct as shown above) and no filling defects in the common bile duct (CBD). It is critical to demonstrate THREE proximal hepatic ducts, as an aberrant right posterior sectoral duct with a low insertion is one of the most common biliary anomalies and is at high risk of transection during LC. If filling defects are identified, this should be noted in the operative report. If the skills and tools required for intraoperative stone extraction are available, then proceed, otherwise plan for post-LC ERC for stone extraction. Spiral valves in the cystic duct are not always visualized, but if present can confirm the correct duct was cannulated.

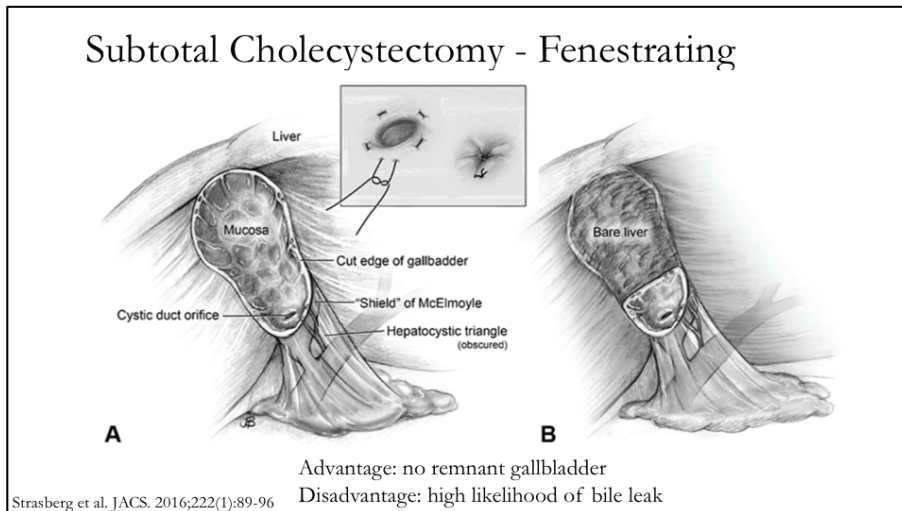
Checklist: Bailout Techniques

If the CVS cannot be safely obtained DO NOT proceed, rather:

- Call for help from a colleague
- Perform a subtotal cholecystectomy
- Cholecystostomy tube placement
- Leave gallbladder in situ and leave a drain

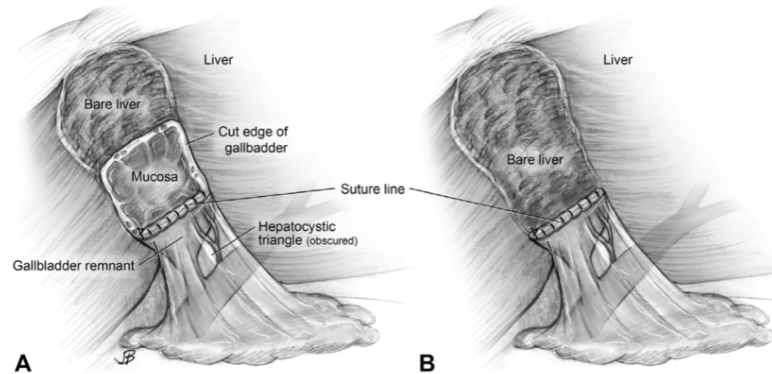
Types of Subtotal Cholecystectomies
(laparoscopic or open)

Subtotal Cholecystectomy - Fenestrating



The gallbladder is opened along its long axis, all of the stones are removed anterior wall is resected. The posterior wall on the liver side can either be left in situ and ablated or removed. Any gangrenous tissue should be removed. The cystic duct can be sutured from the inside, but it is not required and often is not possible. Leave a well-placed drain. These patients often develop bile leaks post-op, but they usually resolve spontaneously with conservative management.

Subtotal Cholecystectomy - Reconstituting



Advantage: lower likelihood of bile leak

Disadvantage: remnant gallbladder

Strasberg et al. JACS. 2016;222(1):89-96

In a reconstituting cholecystectomy, often its easiest to use the fundus first approach and then staple across the gallbladder distally. Surgical clips, endoloop, suture ligation, purse string suture or intracorporeal sutures are other options. The difference is in some fashion, the remaining gallbladder is closed or “reconstituted” to form a remnant gallbladder. Because of that, there is a lower likelihood of bile leak, but a possibility that the remnant gallbladder will become symptomatic and require additional procedures in the future.

Checklist: Intraoperative recognition of BDI

- Do not attempt repair
- Stop dissection
- Leave adequate drainage
- Immediate referral to an HPB surgeon

If recognized during the laparoscopic portion, no need to open.

Standardized Operative Note

- Follows the checklist
- Complete and take a photo, note stays in patient's folder
- Important to fill out every field for data collection

Data Capture

- Photos submitted on Cholecystectomy Op Notes WhatsApp group

- Send photos of:
 - 1) Signed registry consent form
 - 2) Operative note
 - 3) Anterior CVS photo (or video)
 - 4) Posterior CVS photo (or video)

Follow-up

- Date of discharge
- Complications during hospital stay (surgical or non-surgical)
 - Re-interventions, if required
- 30-day readmissions
 - Complications (or reason for readmission)
 - Re-interventions, if required

For most patients, it will just be a date of discharge.

Data Capture - REDCap

Patient Folder Number	Cholecystectomy Operation Note	CVS Photo/Video Upload	Follow-up	Critical View of Safety - General Surgeon Blinded Reviewer 1	Critical View of Safety - HPB Blinded Reviewer 1	Critical View of Safety - General Surgeon Blinded Reviewer 2	Critical View of Safety - HPB Blinded Reviewer 2
16269573	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16369878	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
16422412	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
17417353	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17831231	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18014126	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23992308	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28041946	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
29629805	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

The operative note and CVS photos get uploaded, 30-day follow-up data gets recorded. We have 4 reviewers, two general and two HPB surgeons who will review and score the two CVS photos for each patient. They are blinded to the operative note and follow-up pages, so they do not have access to any of that data. All they can view are the CVS images.

References

Connor SJ, Perry W, Nathanson L, Hugh TB, Hugh TJ. Using a standardized method for laparoscopic cholecystectomy to create a concept operation-specific checklist. *HPB (Oxford)*. 2014;16(5):422-9.

Sanford DE, Strasberg SM. A simple effective method for generation of a permanent record of the Critical View of Safety during laparoscopic cholecystectomy by intraoperative "doublet" photography. *J Am Coll Surg*. 2014;218(2):170-8.

Strasberg SM, Pucci MJ, Brunt LM, Deziel DJ. Subtotal cholecystectomy – “Fenestrating” vs “Reconstituting” subtypes and the prevention of bile duct injury: definition of the optimal procedure in difficult operative conditions. *J Am Coll Surg*. 2016;222(1):89-96.

For further information on performing a safe laparoscopic cholecystectomy, access the Safe Laparoscopic Cholecystectomy Program didactic modules created by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) free of charge at: <https://www.fesdidactic.org/>

LC Database: Interim Analysis

January – April 2020

Jessica Lindemann



Department of Surgery, University of Cape Town
Health Sciences Faculty, Surgical Gastroenterology
Unit, Groote Schuur Hospital, Cape Town, South Africa



Overview

Cape Metro West

- 13 January 2020 – 30 April 2020
- 109 LCs
 - 6 subtotal LCs (5.5%)
 - 1 GB left in situ (0.9%)
 - 12 IOCs (11.0%)
 - 84 (77.1%) elective
 - 25 (22.9%) same admission
 - No conversions to open

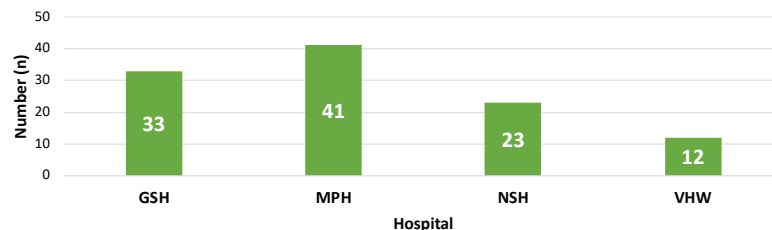


Figure 1. Number of LC operations by hospital. The number of LCs performed at each hospital are shown within the green bars.

GB – gallbladder, IOC – intraoperative cholangiogram, LC – laparoscopic cholecystectomy

Patients & Indications

Patient Characteristics	Patients, n = 109 (%) or median (range); (IQR)
Age, years	43 (19-85); (34-57)
Sex, male	18 (19.4)
Time booking to LC, days	46 (0-380); (3-98.8)
Duration of symptoms, days	90 (2-1500); (10-180)
BMI	32.4 (17.1-54.8); (27.1-36.7)
ASA status	
ASA I	36 (33.0)
ASA II	43 (39.4)
ASA III	4 (3.7)
Unknown	26 (23.9)
HIV status	
Positive	8 (7.3)
Negative	49 (45.0)
Unknown	52 (47.7)

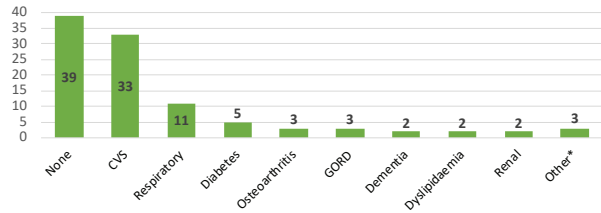


Figure 2. Patient comorbidities. Patients may have multiple reported comorbidities. *Includes: hiatal hernia, myasthenia gravis, pregnancy (all n = 1)

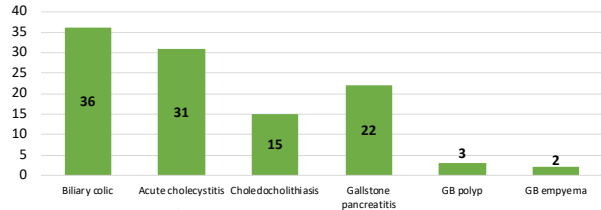


Figure 3. Indications for LC.

ASA – American Society of Anesthesiology, BMI – body mass index, GB – gallbladder, CVS – cardiovascular system, GORD – gastro-oesophageal reflux disease, HIV – human immunodeficiency virus, IQR – interquartile range, LC – laparoscopic cholecystectomy

Intraoperative Findings

Intraoperative variables	n = 109 (%) or median (range); (IQR)
Gallbladder removed intact	64 (58.7)
Not reported	9 (8.3)
Stone spillage	20 (18.3)
Full retrieval of spilled stones	18 (90.0)
Bile leak noted intraoperatively	46 (42.4)
Not reported	12 (11.0)
Location of bile leak	
Gallbladder	43 (94.5)
Cystic duct	1 (2.3)
Not reported	2 (4.7)
Intraoperative difficulty*	
Bleeding	9 (8.3)
Aberrant arterial anatomy	5 (4.6)
Equipment problems	2 (1.8)
Difficult grasping the gallbladder	16 (14.7)
Contracted gallbladder	5 (4.6)
Intrahepatic gallbladder	5 (4.6)
Severe inflammation	12 (11.0)
Extensive adhesions	17 (15.6)
Gallbladder empyema	5 (4.6)
Other^	3 (2.8)

Intraoperative variables	n = 109 (%) or median (range); (IQR)
Final procedure	
LC	102 (93.6)
Subtotal fenestrating LC	3 (2.8)
Subtotal reconstituting LC	3 (2.8)
Operative time, minutes	87 (20-180); (60.5-107)
Estimated blood loss	
Minimal	81 (74.3)
Moderate	9 (8.3)
Not reported	19 (17.4)
Drain left	21 (19.3)
Not reported	3 (2.8)

*A single operation may have multiple intraoperative difficulties

^Includes: hepatomegaly, fatty liver, shortened cystic duct (all n = 1)

Checklist Compliance

Checklist criteria	n (%), n = 109
Pre-incision review	
Imaging	107 (98.2)
Liver function tests	106 (97.2)
Expected difficulties	105 (96.3)
Pre-incision overall compliance	96.3%
Pre-dissection steps completed	
Fundus retracted to 10 o'clock	104 (95.4)
Hartmann's pouch lifted toward segment IV	97 (89.0)
Line between Rouviere's sulcus and falciform	93 (85.3)
Safe level of dissection	101 (92.7)
Posterior leaf of peritoneum released	100 (91.7)
Pre-dissection overall compliance	85.3%
CVS elements achieved	
Hepatocystic triangle free of fibrous and fatty tissue	97 (89.0)
Two and only two structures entering gallbladder	94 (86.2)
Distal 1/3 of the cystic plate visible	99 (90.8)
CVS achieved	91 (83.5)
Did the assistant agree all 3 elements were achieved?	
Did not agree*	6 (5.5)
Not reported	41 (37.6)
CVS overall compliance	62.4%

Checklist criteria - IOC	n = 12 (%)
Findings	
Flow into duodenum	11 (91.7)
3 proximal hepatic ducts visualized	12 (100)
Spiral valves in cystic duct	7 (58.3)
CBD filling defects	5 (41.7)
IOC overall compliance*	100%

*Documentation was complete, although not all criteria were present in every IOC
 CBD – common bile duct, IOC – intraoperative cholangiogram

*CVS was documented as not achieved in all cases
 CVS – critical view of safety

Average CVS Scores

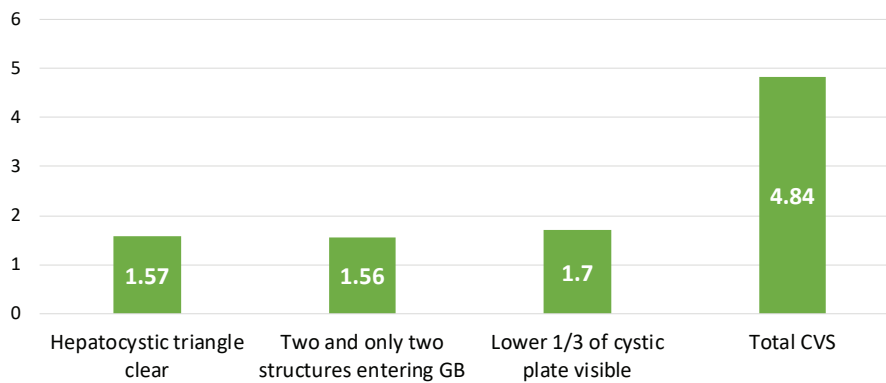


Figure 4. Average CVS scores for all LCs performed from Jan – April 2020 (n = 109). All LCs included even if CVS was documented as not achieved. Average score for hepatocystic triangle clear was 1.57 (+/- 0.61), for two and only two structures was 1.56 (+/- 0.71) and for lower 1/3 of the cystic plate visible was 1.70 (+/- 0.55). The average total CVS score was 4.84 (+/- 1.61).

30-day Complications

Variable	Modified Accordion Grading System, n = 109 (%)					
	Mild	Moderate	Severe			Death
	1	2	3	4	5	6
Surgical complications*						
Bile leak	1 (0.9)	-	-	2 (1.8)	-	-
Intra-abdominal bleeding	-	-	-	-	1 (0.9)	-
Wound infection	-	2 (1.8)	-	-	-	-
CBD stones	-	-	1 (0.9)	-	-	-
Postoperative pain	1 (0.9)	-	-	-	-	-
Total	2 (1.8)	2(1.8)	1 (0.9)	2 (1.8)	1 (0.9)	-
Non-surgical complications*						
Urinary retention	1 (0.9)	-	-	-	-	-
Total	-	-	-	-	-	-
Total overall	3 (2.8)	2 (1.8)	1 (0.9)	2 (1.8)	1 (0.9)	-

CBD – common bile duct

NOTE – no major BDIs recorded

Modified Accordion Grade Criteria

Modified Accordion Grading System ¹		
Contracted Definitions		Expanded Definitions
Mild	1	Minor invasive procedures that can be done at the bedside such as physical therapy or insertion of IV lines, nasogastric tubes and urinary catheters, drainage of wound infections or use of drugs including antiemetics, antipyretics, analgesics, and electrolytes.
Moderate	2	Pharmacologic treatment with drugs other than those for minor complications including antibiotics, blood transfusions and total parenteral nutrition
Severe	3	Invasive procedure without general anaesthesia (endoscopic, interventional, surgical)
	4	Invasive procedure under general anaesthesia (endoscopic, interventional, surgical) or single organ failure
	5	Invasive procedure under general anaesthesia and single organ system failure, or multisystem organ failure (> 2 organ systems)
Death	6	Post-operative death

- Hall B, Hirbe M, Strasberg S. Quantitative Weighting of Postoperative Complications Based on the Accordion Severity Grading System: Demonstration of Potential Impact Using the American College of Surgeons National Surgical Quality Improvement Program. J Am Coll Surg. 2010;210:286-98. 10.1016/j.jamcollsurg.2009.12.004.

Detailed Review - Severe Complications

- Modified Accordion Grade 3, CBD stones
 - **Nature of disease;** required ERC under sedation
- Modified Accordion Grade 4, Bile Leak
 - **Device failure; error in technique;** on-table ERC for ? CBD stones on IOC, bile leak at cystic duct stump noted, re-laparoscopy performed, no clips on cystic duct, clips replaced, subsequent abdominal wall hematoma at umbilical incision required wound exploration and hematoma evacuation under general anaesthesia
- Modified Accordion Grade 4, Bile Leak
 - **Possible error in judgement, nature of disease;** known benign distal CBD stricture, bile leak from liver bed post-operatively, required ERC (failed), multiple PTCs, percutaneous drainage, prolonged hospital course due to poor general condition and intra-abdominal sepsis
- Modified Accordion Grade 5, Intra-abdominal bleeding
 - **Error in technique, error in judgement;** required 2 units PRBCs post-op, exploratory laparotomy under general anaesthesia day 5 after subtotal cholecystectomy, no source of bleeding identified, single organ failure, ICU admission

30-day Re-interventions & Re-admissions

- Median length of stay: 1 (range 1-13); (IQR 1-2) days
- Re-admission rate: 2.8% (n = 3)

Re-interventions	n = 9 (%)
ERC	3 (33.3)
PTC	2 (22.2)
Percutaneous drainage	1 (11.1)
Re-laparoscopy	1 (11.1)
Re-laparotomy	2 (22.2)

- Rate of missing follow-up data: 9.2% (n = 10)
- Rate of missing LCs: 20% (approximately, n = 28)

Overview

- 13 January 2020 – 30 April 2020
- 12 LCs
 - 2 subtotal LCs (16.7%)
 - 0 GB left in situ (0%)
 - 0 IOCs (0%)
 - 11 (91.7%) elective
 - 1 (8.3%) same admission
 - No conversions to open

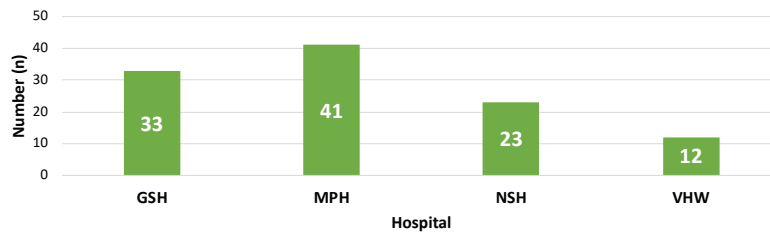


Figure 1. Number of LC operations by hospital. The number of LCs performed at each hospital are shown within the green bars.

GB – gallbladder, IOC – intraoperative cholangiogram, LC – laparoscopic cholecystectomy

Patients & Indications

Patient Characteristics	Patients, n = 12 (%) or median (range); (IQR)
Age, years	41.5 (25-76); (33.5-55)
Sex, male	3 (25.0)
Time booking to LC, days	125.5 (3-140); (69.5-131.3)
Duration of symptoms, days	120 (5-365); (7.5-140)
BMI	34.95 (23-43.8); (28.1-37.7)
ASA status	
ASA I	4 (33.0)
ASA II	3 (25.0)
ASA III	-
Unknown	5 (41.7)
HIV status	
Positive	-
Negative	4 (33.3)
Unknown	8 (66.7)

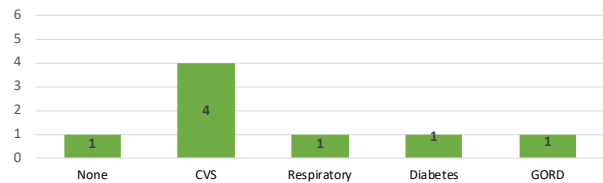


Figure 2. Patient comorbidities. Patients may have multiple reported comorbidities.

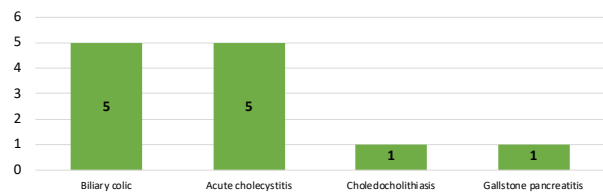


Figure 3. Indications for LC.

ASA – American Society of Anesthesiology, BMI – body mass index, CVS – cardiovascular system, GORD – gastro-oesophageal reflux disease, HIV – human immunodeficiency virus, IQR – interquartile range, LC – laparoscopic cholecystectomy

Intraoperative Findings

Intraoperative variables	n = 12 (%) or median (range); (IQR)
Gallbladder removed intact	7 (58.3)
Not reported	3 (25.0)
Stone spillage	1 (8.3)
Full retrieval of spilled stones	1 (8.3)
Bile leak noted intraoperatively	4 (33.3)
Not reported	3 (25.0)
Location of bile leak	
Gallbladder	4 (100)
Cystic duct	-
Not reported	-
Intraoperative difficulty*	
Bleeding	2 (16.7)
Aberrant arterial anatomy	1 (8.3)
Equipment problems	-
Difficult grasping the gallbladder	2 (16.7)
Contracted gallbladder	1 (8.3)
Intrahepatic gallbladder	2 (16.7)
Severe inflammation	3 (25.0)
Extensive adhesions	5 (41.7)
Gallbladder empyema	-
Other^	1 (8.3)

Intraoperative variables	n = 12 (%) or median (range); (IQR)
Final procedure	
LC	10 (83.3)
Subtotal fenestrating LC	2 (16.7)
Subtotal reconstituting LC	-
Operative time, minutes	100 (60-150); (90-127.5)
Estimated blood loss	
Minimal	11 (91.7)
Moderate	1 (8.3)
Not reported	-
Drain left	3 (25.0)
Not reported	1 (8.3)

*A single operation may have multiple intraoperative difficulties

^Includes: fatty liver (n = 1)

Checklist Compliance

Checklist criteria	n (%), n = 12
Pre-incision review	
Imaging	12 (100)
Liver function tests	12 (100)
Expected difficulties	12 (100)
Pre-incision overall compliance	100%
Pre-dissection steps completed	
Fundus retracted to 10 o'clock	12 (100)
Hartmann's pouch lifted toward segment IV	11 (91.7)
Line between Rouviere's sulcus and falciform	11 (91.7)
Safe level of dissection	11 (91.7)
Posterior leaf of peritoneum released	11 (91.7)
Pre-dissection overall compliance	91.7%
CVS elements achieved	
Hepatocystic triangle free of fibrous and fatty tissue	10 (83.3)
Two and only two structures entering gallbladder	9 (75.0)
Distal 1/3 of the cystic plate visible	10 (83.3)
CVS achieved	9 (75.5)
Did the assistant agree all 3 elements were achieved?	
Did not agree*	1 (8.3)
Not reported	4 (33.3)
CVS overall compliance	66.7%

*CVS was documented as not achieved in all cases
CVS – critical view of safety

Average CVS Scores

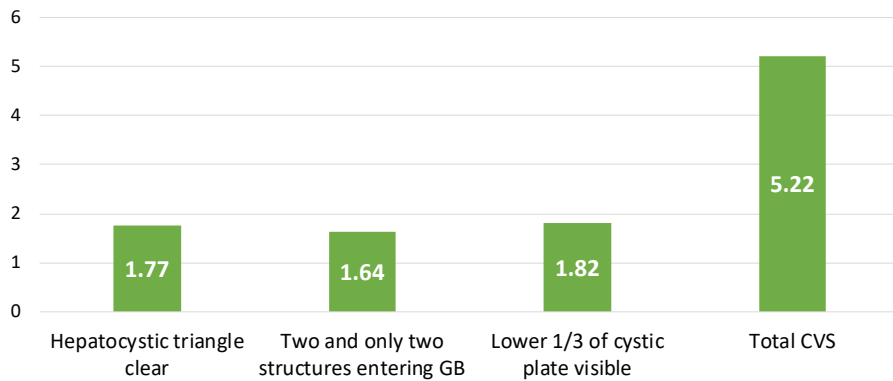


Figure 4. Average CVS scores for all LCs performed from Jan – April 2020 (n = 12). All LCs included even if CVS was documented as not achieved. Average score for hepatocystic triangle clear was 1.77 (+/- 0.62), for two and only two structures was 1.64 (+/- 0.74) and for lower 1/3 of the cystic plate visible was 1.81 (+/- 0.60). The average total CVS score was 5.22 (+/- 1.86).

CVS Feedback

- Rate of adequate photos for scoring: 95.5%
- Representative selection of reviewer comments:
 - “Excellent anterior image, poor posterior image”
 - “Two structures not clear”
 - “Only one structure, quite large duct. Not clear CVS”
- Note – the CVS score is a composite of the two photos, an excellent anterior photo with all 3 elements of the CVS present and a poor posterior photo will still score a 6

30-day Complications

Variable	Modified Accordion Grading System, n = 12 (%)					
	Mild	Moderate	Severe			Death
	1	2	3	4	5	6
Surgical complications*						
Bile leak	1 (8.3)	-	-	-	-	-
Intra-abdominal bleeding	-	-	-	-	-	-
Wound infection	-	1 (8.3)	-	-	-	-
CBD stones	-	-	-	-	-	-
Postoperative pain	-	-	-	-	-	-
Total	1 (8.3)	1(8.3)	-	-	-	-
Non-surgical complications*						
Urinary retention	-	-	-	-	-	-
Total	-	-	-	-	-	-
Total overall	1 (8.3)	1 (8.3)	-	-	-	-

CBD – common bile duct

30-day Re-interventions & Re-admissions

- Median length of stay: 1 (range 1-6); (IQR 1-2) days
- Re-admission rate: 0% (n = 0)

Re-interventions	n = 0 (%)
ERC	-
PTC	-
Percutaneous drainage	-
Re-laparoscopy	-
Re-laparotomy	-

- Rate of missing follow-up data: 25% (n = 3, d/c dates only)
- Rate of missing LCs: 66.7% (estimated missing 1-2 LCs per week, n = 24)

Overview

- 13 January 2020 – 30 April 2020
- 23 LCs
 - 1 subtotal LCs (4.3%)
 - 1 GB left in situ (4.3%)
 - 0 IOCs (0%)
 - 18 (78.3%) elective
 - 5 (21.7%) same admission
 - No conversions to open

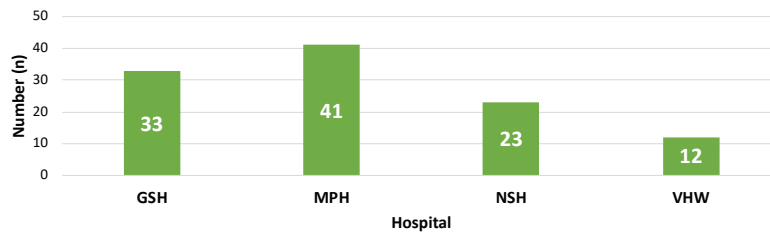


Figure 1. Number of LC operations by hospital. The number of LCs performed at each hospital are shown within the green bars.

GB – gallbladder, IOC – intraoperative cholangiogram, LC – laparoscopic cholecystectomy

Patients & Indications

Patient Characteristics	Patients, n = 23 (%) or median (range); (IQR)
Age, years	44 (27-69); (37.5-49.5)
Sex, male	3 (13.0)
Time booking to LC, days	63 (0-242); (33.3-99)
Duration of symptoms, days	120 (4-1500); (60-180)
BMI	32.5 (21.3-54.8); (27.1-36.2)
ASA status	
ASA I	7 (30.4)
ASA II	9 (39.1)
ASA III	1 (4.3)
Unknown	6 (26.0)
HIV status	
Positive	2 (8.7)
Negative	14 (60.9)
Unknown	7 (30.4)

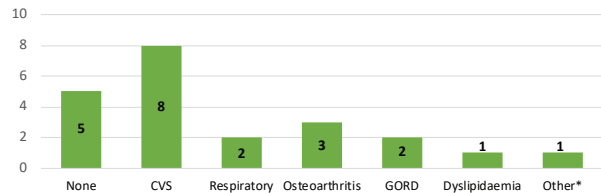


Figure 2. Patient comorbidities. Patients may have multiple reported comorbidities. *Includes: pregnancy (all n = 1)

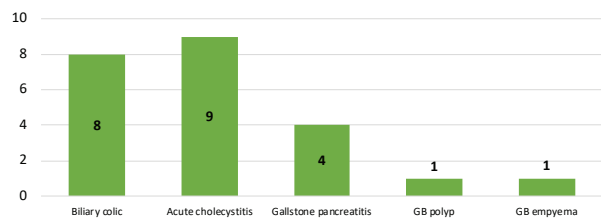


Figure 3. Indications for LC.

ASA – American Society of Anesthesiology, BMI – body mass index, GB – gallbladder, CVS – cardiovascular system, GORD – gastro-oesophageal reflux disease, HIV – human immunodeficiency virus, IQR – interquartile range, LC – laparoscopic cholecystectomy

Intraoperative Findings

Intraoperative variables	n = 23 (%) or median (range); (IQR)
Gallbladder removed intact	12
Not reported	2 (8.7)
Stone spillage	4 (17.4)
Full retrieval of spilled stones	3 (75.0)
Bile leak noted intraoperatively	8 (34.5)
Not reported	2 (8.7)
Location of bile leak	
Gallbladder	8 (100)
Cystic duct	-
Not reported	-
Intraoperative difficulty*	
Bleeding	1 (4.3)
Aberrant arterial anatomy	2 (8.7)
Equipment problems	-
Difficult grasping the gallbladder	5 (21.7)
Contracted gallbladder	1 (4.3)
Intrahepatic gallbladder	-
Severe inflammation	4 (17.4)
Extensive adhesions	2 (8.7)
Gallbladder empyema	2 (8.7)
Other	-

Intraoperative variables	n = 23 (%) or median (range); (IQR)
Final procedure	
LC	21 (91.3)
Subtotal fenestrating LC	-
Subtotal reconstituting LC	1 (4.3)
Operative time, minutes	74 (25-152); (51.3-90)
Estimated blood loss	
Minimal	16 (69.6)
Moderate	2 (8.7)
Not reported	5 (21.7)
Drain left	5 (21.7)
Not reported	1 (4.3)

*A single operation may have multiple intraoperative difficulties

Checklist Compliance

Checklist criteria	n (%), n = 23
Pre-incision review	
Imaging	22 (95.6)
Liver function tests	21 (91.3)
Expected difficulties	22 (95.6)
Pre-incision overall compliance	91.3%
Pre-dissection steps completed	
Fundus retracted to 10 o'clock	22 (95.6)
Hartmann's pouch lifted toward segment IV	21 (91.3)
Line between Rouviere's sulcus and falciform	17 (73.9)
Safe level of dissection	22 (95.6)
Posterior leaf of peritoneum released	21 (91.3)
Pre-dissection overall compliance	73.9%
CVS elements achieved	
Hepatocystic triangle free of fibrous and fatty tissue	21 (91.3)
Two and only two structures entering gallbladder	20 (87.0)
Distal 1/3 of the cystic plate visible	21 (91.3)
CVS achieved	19 (82.6)
Did the assistant agree all 3 elements were achieved?	
Did not agree*	2 (8.7)
Not reported	13 (56.5)
CVS overall compliance	43.5%

*CVS was documented as not achieved in all cases

CVS – critical view of safety

Average CVS Scores



Figure 4. Average CVS scores for all LCs performed from Jan – April 2020 (n = 23). All LCs included even if CVS was documented as not achieved. Average score for hepatocystic triangle clear was 1.46 (+/- 0.60), for two and only two structures was 1.56 (+/- 0.72) and for lower 1/3 of the cystic plate visible was 1.67 (+/- 0.53). The average total CVS score was 4.69 (+/- 1.62).

CVS Feedback

- Rate of adequate photos for scoring: 87.2%
- Representative selection of reviewer comments:
 - “Too far from the screen”
 - “Good. Anterior better than posterior”
- Note – the CVS score is a composite of the two photos, an excellent anterior photo with all 3 elements of the CVS present and a poor posterior photo will still score a 6

30-day Complications

Variable	Modified Accordion Grading System, n = 23 (%)					
	Mild	Moderate	Severe			Death
	1	2	3	4	5	6
Surgical complications*						
Bile leak	-	-	-	-	-	-
Intra-abdominal bleeding	-	-	-	-	-	-
Wound infection	-	-	-	-	-	-
CBD stones	-	-	-	-	-	-
Postoperative pain	1 (4.3)	-	-	-	-	-
Total	1 (4.3)	-	-	-	-	-
Non-surgical complications*						
Urinary retention	-	-	-	-	-	-
Total	-	-	-	-	-	-
Total overall	1 (4.3)	-	-	-	-	-

CBD – common bile duct

30-day Re-interventions & Re-admissions

- Median length of stay: 1 (range 1-3); (IQR 1-2) days
- Re-admission rate: 4.3% (n = 1)

Re-interventions	n = 0 (%)
ERC	-
PTC	-
Percutaneous drainage	-
Re-laparoscopy	-
Re-laparotomy	-

- Rate of missing follow-up data: 17.4% (3 d/c dates, 1 follow-up at 30 days)
- Rate of missing LCs: 4.3% (n = 1)

Overview

- 13 January 2020 – 30 April 2020
- 41 LCs
 - 1 subtotal LCs (2.4%)
 - 0 GB left in situ (0%)
 - 6 IOCs (14.6%)
 - 33 (80.5%) elective
 - 8 (19.5%) same admission
 - No conversions to open

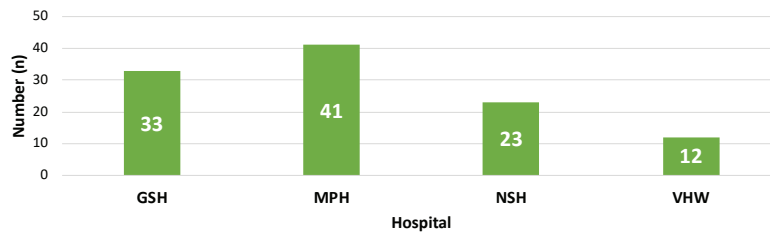


Figure 1. Number of LC operations by hospital. The number of LCs performed at each hospital are shown within the green bars.

GB – gallbladder, IOC – intraoperative cholangiogram, LC – laparoscopic cholecystectomy

Patients & Indications

Patient Characteristics	Patients, n = 41 (%) or median (range); (IQR)
Age, years	36 (25-73); (33-56)
Sex, male	4 (9.8)
Time booking to LC, days	33 (0-231); (4-78)
Duration of symptoms, days	60 (4-730); (7-270)
BMI	34 (21.9-52.4); (29.6-37)
ASA status	
ASA I	12 (29.3)
ASA II	20 (48.8)
ASA III	2 (4.9)
Unknown	7 (17.1)
HIV status	
Positive	4 (9.8)
Negative	11 (26.8)
Unknown	26 (56.1)

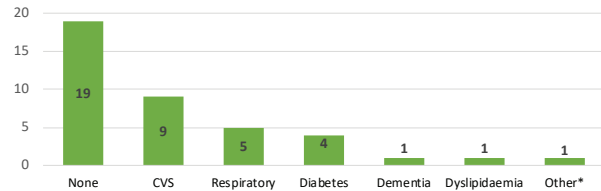


Figure 2. Patient comorbidities. Patients may have multiple reported comorbidities. *Includes: hiatal hernia (n = 1)

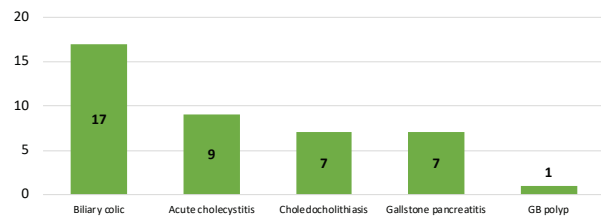


Figure 3. Indications for LC.

ASA – American Society of Anesthesiology, BMI – body mass index, GB – gallbladder, CVS – cardiovascular system, GORD – gastro-oesophageal reflux disease, HIV – human immunodeficiency virus, IQR – interquartile range, LC – laparoscopic cholecystectomy

Intraoperative Findings

Intraoperative variables	n = 41 (%) or median (range); (IQR)
Gallbladder removed intact	26 (63.4)
Not reported	2 (4.9)
Stone spillage	6 (14.6)
Full retrieval of spilled stones	5 (12.2)
Bile leak noted intraoperatively	15 (36.6)
Not reported	4 (9.8)
Location of bile leak	
Gallbladder	13 (31.7)
Cystic duct	1 (2.4)
Not reported	1 (2.4)
Intraoperative difficulty*	
Bleeding	3 (7.3)
Aberrant arterial anatomy	-
Equipment problems	1 (2.4)
Difficult grasping the gallbladder	5 (12.2)
Contracted gallbladder	2 (4.9)
Intrahepatic gallbladder	2 (4.9)
Severe inflammation	3 (7.3)
Extensive adhesions	2 (4.9)
Gallbladder empyema	2 (4.9)
Other [^]	1 (2.4)

Intraoperative variables	n = 41 (%) or median (range); (IQR)
Final procedure	
LC	40 (97.6)
Subtotal fenestrating LC	1 (2.4)
Subtotal reconstituting LC	-
Operative time, minutes	80.5 (28-180); (60-103.5)
Estimated blood loss	
Minimal	41 (75.6)
Moderate	4 (9.8)
Not reported	6 (14.6)
Drain left	7 (17.1)
Not reported	1 (2.4)

*A single operation may have multiple intraoperative difficulties
[^]Includes: shortened cystic duct (n = 1)

Checklist Compliance

Checklist criteria	n (%), n = 41
Pre-incision review	
Imaging	40 (97.6)
Liver function tests	40 (97.6)
Expected difficulties	38 (92.7)
Pre-incision overall compliance	92.7%
Pre-dissection steps completed	
Fundus retracted to 10 o'clock	39 (95.1)
Hartmann's pouch lifted toward segment IV	35 (85.4)
Line between Rouviere's sulcus and falciform	38 (92.7)
Safe level of dissection	38 (92.7)
Posterior leaf of peritoneum released	37 (90.2)
Pre-dissection overall compliance	85.4%
CVS elements achieved	
Hepatocystic triangle free of fibrous and fatty tissue	37 (90.2)
Two and only two structures entering gallbladder	37 (90.2)
Distal 1/3 of the cystic plate visible	38 (92.7)
CVS achieved	36 (87.8)
Did the assistant agree all 3 elements were achieved?	
Did not agree [*]	1 (2.4)
Not reported	18 (43.9)
CVS overall compliance	56.1%

Checklist criteria - IOC	n = 6 (%)
Findings	
Flow into duodenum	6 (100)
3 proximal hepatic ducts visualized	6 (100)
Spiral valves in cystic duct	3 (50.0)
CBD filling defects	4 (66.7)
IOC overall compliance[^]	100%

*Documentation was complete, although not all criteria were present in every IOC
 CBD – common bile duct, IOC – intraoperative cholangiogram

*CVS was documented as not achieved in all cases
 CVS – critical view of safety

Average CVS Scores



Figure 4. Average CVS scores for all LCs performed from Jan – April 2020 (n = 41). All LCs included even if CVS was documented as not achieved. Average score for hepatocystic triangle clear was 1.46 (+/- 0.70), for two and only two structures was 1.44 (+/- 0.75) and for lower 1/3 of the cystic plate visible was 1.61 (+/- 0.67). The average total CVS score was 4.51 (+/- 1.83).

CVS Feedback

- Rate of adequate photos for scoring: 88.6%
- Representative selection of reviewer comments:
 - “Poor image especially the anterior image”
 - “The extent of dissection in the triangle and of the cystic plate is not clear ”
 - “A bit blurred”
- Note – comments reflect *image* quality, not quality of the CVS

30-day Complications

Variable	Modified Accordion Grading System, n = 41 (%)					
	Mild	Moderate	Severe			Death
	1	2	3	4	5	6
Surgical complications*						
Bile leak	-	-	-	1 (2.4)	-	-
Intra-abdominal bleeding	-	-	-	-	1 (2.4)	-
Wound infection	-	-	-	-	-	-
CBD stones	-	-	-	-	-	-
Postoperative pain	-	-	-	-	-	-
Total	-	-	-	1 (2.4)	1 (2.4)	-
Non-surgical complications*						
Urinary retention	-	-	-	-	-	-
Total	-	-	-	-	-	-
Total overall	-	-	-	1 (2.4)	1 (2.4)	-

CBD – common bile duct

Detailed Review - Severe Complications

- Modified Accordion Grade 4, Bile Leak
 - **Possible error in judgement vs nature of disease;** known benign distal CBD stricture, bile leak from liver bed postoperatively, required ERC (failed), multiple PTCs, percutaneous drainage, prolonged hospital course due to poor general condition and intra-abdominal sepsis
 - **Op note:** no intraoperative difficulties noted, three elements of CVS achieved
 - **Photo scores:** reviewer one – 3; reviewer two – 2 (no comments from reviewers)
- Modified Accordion Grade 5, Intra-abdominal bleeding
 - **Error in technique, error in judgement;** required 2 units PRBCs post-op, exploratory laparotomy under general anaesthesia day 5 after subtotal cholecystectomy, no source of bleeding identified, single organ failure, ICU admission
 - **Op note:** very difficult dissection, colon and duodenum stuck to GB, gallbladder empyema, contracted and intrahepatic, difficulty grasping, entered fundus - stones and pus, type 3 Mirizzi on IOC.
 - **Photo scores:** none submitted (subtotal cholecystectomy)

30-day Re-interventions & Re-admissions

- Median length of stay: 1 (range 1-13); (IQR 1-1) days
- Re-admission rate: 2.4% (n = 1)

Re-interventions	n = 5 (%)
ERC	-
PTC	2 (40.0)
Percutaneous drainage	1 (20.0)
Re-laparoscopy	-
Re-laparotomy	1 (20.0)

- Rate of missing follow-up data: 4.9% (n = 2)
- Rate of missing LCs: 0% (no record of missed LCs)

Overview

- 13 January 2020 – 30 April 2020, both ACS and HPB units
- 33 LCs
 - 2 subtotal LCs (6.1%)
 - 0 GB left in situ (0%)
 - 6 IOCs (18.2%)
 - 22 (66.7%) elective
 - 11 (33.3%) same admission
 - No conversions to open

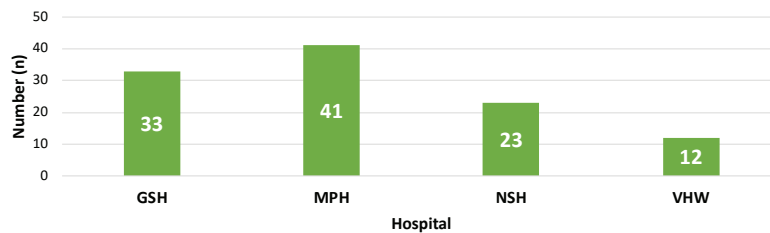


Figure 1. Number of LC operations by hospital. The number of LCs performed at each hospital are shown within the green bars.

GB – gallbladder, IOC – intraoperative cholangiogram, LC – laparoscopic cholecystectomy

Patients & Indications

Patient Characteristics	Patients, n = 33 (%) or median (range); (IQR)
Age, years	51 (26-85); (36-64)
Sex, male	8 (24.2)
Time booking to LC, days	11 (0-380); (1-106)
Duration of symptoms, days	66 (2-730); (10-233)
BMI	29.5 (17.1-46.7); (24.9-33.8)
ASA status	
ASA I	13 (39.4)
ASA II	11 (33.3)
ASA III	1 (3.0)
Unknown	8 (24.2)
HIV status	
Positive	2 (6.1)
Negative	20 (60.6)
Unknown	11 (33.3)

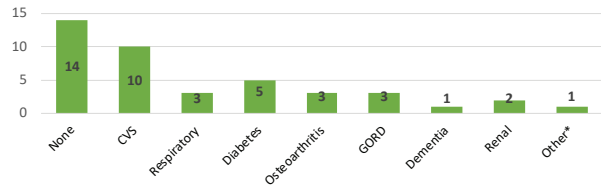


Figure 2. Patient comorbidities. Patients may have multiple reported comorbidities. *Includes: myasthenia gravis (n = 1)

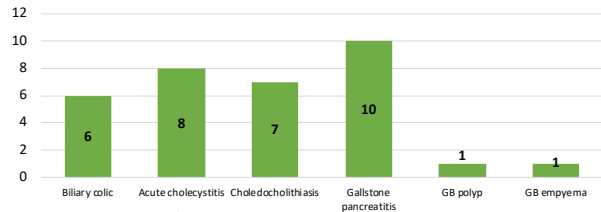


Figure 3. Indications for LC.

ASA – American Society of Anesthesiology, BMI – body mass index, GB – gallbladder, CVS – cardiovascular system, GORD – gastro-oesophageal reflux disease, HIV – human immunodeficiency virus, IQR – interquartile range, LC – laparoscopic cholecystectomy

Intraoperative Findings

Intraoperative variables	n = 33 (%) or median (range); (IQR)
Gallbladder removed intact	19 (57.6)
Not reported	2 (6.1)
Stone spillage	9 (29.0)
Full retrieval of spilled stones	8 (88.9)
Bile leak noted intraoperatively	19 (57.6)
Not reported	2 (6.1)
Location of bile leak	
Gallbladder	16 (48.5)
Cystic duct	1 (3.0)
Not reported	2 (6.1)
Intraoperative difficulty*	
Bleeding	4 (12.1)
Aberrant arterial anatomy	2 (6.1)
Equipment problems	1 (3.0)
Difficult grasping the gallbladder	4 (12.1)
Contracted gallbladder	1 (3.0)
Intrahepatic gallbladder	1 (3.0)
Severe inflammation	2 (6.1)
Extensive adhesions	7 (21.2)
Gallbladder empyema	1 (3.0)
Other^	1 (3.0)

Intraoperative variables	n = 33 (%) or median (range); (IQR)
Final procedure	
LC	31 (93.9)
Subtotal fenestrating LC	-
Subtotal reconstituting LC	2 (6.1)
Operative time, minutes	90 (20-165); (66.5-107.5)
Estimated blood loss	
Minimal	23 (69.7)
Moderate	2 (6.1)
Not reported	8 (24.2)
Drain left	6 (18.2)
Not reported	-

*A single operation may have multiple intraoperative difficulties
^Includes: hepatomegaly (n = 1)

Checklist Compliance

Checklist criteria	n (%), n = 33
Pre-incision review	
Imaging	32 (97.0)
Liver function tests	33 (100)
Expected difficulties	33 (100)
Pre-incision overall compliance	97.0%
Pre-dissection steps completed	
Fundus retracted to 10 o'clock	32 (97.0)
Hartmann's pouch lifted toward segment IV	31 (93.9)
Line between Rouviere's sulcus and falciform	27 (81.8)
Safe level of dissection	30 (90.9)
Posterior leaf of peritoneum released	31 (93.9)
Pre-dissection overall compliance	81.8%
CVS elements achieved	
Hepatocystic triangle free of fibrous and fatty tissue	29 (87.9)
Two and only two structures entering gallbladder	28 (84.8)
Distal 1/3 of the cystic plate visible	30 (90.9)
CVS achieved	27 (81.8)
Did the assistant agree all 3 elements were achieved?	
Did not agree*	4 (12.1)
Not reported	6 (18.2)
CVS overall compliance	81.8%

Checklist criteria - IOC	n = 6 (%)
Findings	
Flow into duodenum	5 (83.3)
3 proximal hepatic ducts visualized	6 (100)
Spiral valves in cystic duct	2 (33.3)
CBD filling defects	3 (50.0)
IOC overall compliance*	100%

*Documentation was complete, although not all criteria were present in every IOC
 CBD – common bile duct, IOC – intraoperative cholangiogram

*CVS was documented as not achieved in all cases
 CVS – critical view of safety

Average CVS Scores

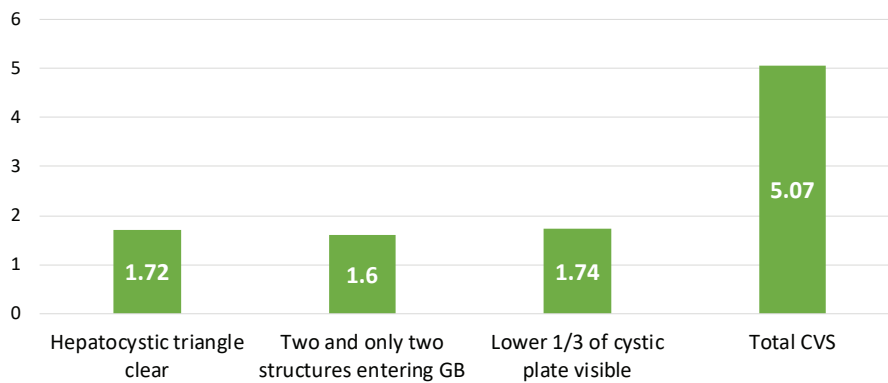


Figure 4. Average CVS scores for all LCs performed from Jan – April 2020 (n = 109). All LCs included even if CVS was documented as not achieved. Average score for hepatocystic triangle clear was 1.72 (+/- 0.45), for two and only two structures was 1.60 (+/- 0.73) and for lower 1/3 of the cystic plate visible was 1.74 (+/- 0.44). The average total CVS score was 5.07 (+/- 1.42).

CVS Feedback

- Rate of adequate photos for scoring: 97.7%
- Representative selection of reviewer comments:
 - “Cystic plate dissection better seen on posterior picture, could have been dissected further”
 - “Excellent 10/10 - best so far”
- Note – the CVS score is a composite of the two photos, an excellent anterior photo with all 3 elements of the CVS present and a poor posterior photo will still score a 6

30-day Complications

Variable	Modified Accordion Grading System, n = 33 (%)					
	Mild	Moderate	Severe			Death
	1	2	3	4	5	6
Surgical complications*						
Bile leak	-	-	-	1 (3.0)	-	-
Intra-abdominal bleeding	-	-	-	-	-	-
Wound infection	-	1 (3.0)	-	-	-	-
CBD stones	-	-	-	1 (3.0)	-	-
Postoperative pain	-	-	-	-	-	-
Total	-	1 (3.0)	-	2 (6.1)	-	-
Non-surgical complications*						
Urinary retention	1 (3.0)	-	-	-	-	-
Total	-	-	-	-	-	-
Total overall	1 (3.0)	1 (3.0)	-	2 (6.1)	-	-

CBD – common bile duct

Detailed Review - Severe Complications

- Modified Accordion Grade 3, CBD stones
 - **Nature of disease**; required ERCP under sedation
- Modified Accordion Grade 4, Bile Leak
 - **Device failure; error in technique**; on-table ERC for ? CBD stones on IOC, bile leak at cystic duct stump noted, re-laparoscopy performed, no clips on cystic duct, clips replaced, subsequent abdominal wall hematoma at umbilical incision required wound exploration and hematoma evacuation under general anaesthesia
 - **Op Note**: uneventful, no difficulties, all elements of CVS achieved, bile leak from cystic duct diagnosed during on-table ERC for CBD stones on IOC, re-laparoscopy was immediately performed
 - **Photo scores**: reviewer one – 6 (only one score available)

30-day Re-interventions & Re-admissions

- Median length of stay: 1 (range 1-10); (IQR 1-2) days
- Re-admission rate: 3.0% (n = 1)

Re-interventions	n = 4 (%)
ERC	2 (50.0)
PTC	-
Percutaneous drainage	-
Re-laparoscopy	1 (25.0)
Re-laparotomy	1 (25.0)

- Rate of missing follow-up data: 3.0% (n = 1)
- Rate of missing LCs: 9.1% (n = 3)