Damage Control Laparotomy for Abdominal Gunshot Wounds: Indications, Mortality, and Long-Term Outcome

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Declaration

I, Khaled Twier, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Dr. Khaled Twier

List of Abbreviation

ATLS: advanced trauma life support
ATC: Acute trauma coagulopathy
CI: Confident interval
CXR: Chest x ray
DCL: Damage control laparotomy
DSTC: definitive surgical trauma care
DIC: Intravascular coagulopathy
GCS: Glasgow coma scale
GSH: Groote Schuur hospital
GSW: Gunshot wound
Hb: Haemoglobin
HREC: Human research ethics committee
ICU: Intensive care unit
INR: International normalised ratio
INTRA-OP: Intraoperative
IQRs: Interquartile ranges
ISS: injury severity score
LIF: Left iliac fossa
LOS: Length of stay
LUQ: Left upper quadrant
OR: Odds ratio
OR: Operating Theatre
PRE-OP: Pre-operative
PATI: Penetrating abdominal trauma index
PT: prothrombin time
PTT: partial thromboplastin time
RIF: Right iliac fossa
RUQ: Right upper quadrant
SDs: Standard deviation
TRISS: Trauma related injury severity score

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ABSTRACT

Background: Outcomes of patients subjected to damage control laparotomy (DCL) for abdominal gunshot wounds (GSWs) remains relatively unknown. There is limited evidence as to which variables may reliably predict morbidity and mortality. The aim of this study was to evaluate the impact of DCL on long term morbidity and survival, to determine clinical characteristics associated with increased mortality, and to evaluate the indications for DCL in patients with abdominal GSWs.

Methods: A retrospective study of patients who underwent a damage control laparotomy for abdominal GSWs at Groote Schuur Hospital (GSH) was conducted. Data was collected on 50 consecutive trauma patients over a 4.5 years period between August 1st, 2004 and September 30th, 2009. Patients were stratified by, age, preoperative and intraoperative physiological parameters, trauma indices, numbers and locations of abdominal GSWs, extra abdominal involvement, intensive care unit and hospital length of stay, morbidity and mortality. Unadjusted and adjusted estimates of the association between these factors and the odds of survival were computed with univariate and multivariate logistic regression.

Results: Most of the patients were male (96%) with a mean age 29.7 year. Most patients had a single abdominal gunshot wound (60%). Liver injuries were the most common injury (58%) followed by small bowel (44%), 20 majors venous (40%), and colonic injury (38%) injuries. The overall mortality was 54%. The mean of length stay in the intensive care unit in

initial survivors was 7 days with overall mean hospital length of stay of 13 days. Factor an associated with a decreased odd of survival included PATI >25, pre-operative infusion of less than two litres of crystalloids, intra-operative blood lactate level >8mmol/L, massive transfusion >10 units PRBCs.

Conclusion: The overall mortality of patients requiring DCL for abdominal GSWs was 54%. In this limited study, there is significant evidence that after controlling for confounding PATI score of >25 is associated with a decreased odds of survival (OR:0.20, p-value 0.04).

Chapter 1

Literature Review

Damage Control Laparotomy

1.1 Introduction

The term "Damage Control" originates from the U.S. Navy and encompasses all the methods that can be employed to safely bring a damaged naval vessel to port.[1] The Navy stresses that adequate personnel training and preparation are paramount to successfully achieve damage control.[1] The concept of Damage Control can be applied to a patient with severe abdominal trauma; whereby steps are taken to restore, as much as possible, normal physiological function and promote survival in the immediate term. The concept of "abbreviated laparotomy" was first coined by *Stone et al*.[2] *Rotondo et al*.[3] first used the term "damage control" laparotomy (DCL), and showed survival benefit in patients with severe penetrating vascular and visceral injuries who had DCL when compared to patients who underwent attempted definitive surgery. More than two decades later, DCL, or Abbreviated Laparotomy, has now become essential in the management of the patient with severe abdominal trauma.[4,5]

Damage Control has evolved into an entity on its own and is primarily concerned with restoration of the patient's physiological function rather than addressing specific anatomical injuries.[5] Courses such as the Advanced Trauma Life Support (ATLS®) and the Definitive Surgical Trauma Care (DSTC®) provide the trauma surgeon with the essential framework to implement this life-saving measure.[6,7]

1.2 Physiological Basis for DCL - The Lethal Triad of Trauma

The lethal triad of trauma encompasses hypothermia, acidosis and coagulopathy (Fig1.1). In the trauma patient, haemorrhage from injured organs reduces the circulating blood volume and this leads to a drop-in temperature, as well as a reduction of oxygen supply to tissues. The latter promotes anaerobic respiration, which limits heat production and leads to increased lactic acid production, resulting in metabolic acidosis. This combination impairs the body's clotting ability (coagulopathy), which in turn leads to further haemorrhage. The net result is a vicious cycle of worsening hypothermia and acidosis leading to increased mortality.[8,9]

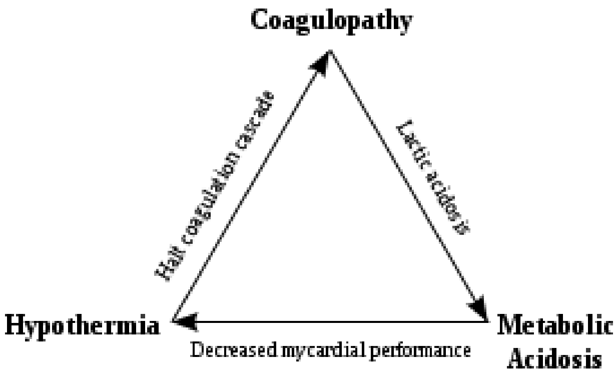

Figure 1.1 Triad Death(*https://en.wikipedia.org/wiki/Trauma_triad_of_death)*

1.2.1 Hypothermia

Trauma patients are at a disadvantage, because they can lose heat through exposure to the cold environment, haemorrhage, administration of cold resuscitation fluids and removal of clothing.[10] Hypothermia is defined as a core body temperature of less than 35 degrees Celsius. In a trauma patient with ongoing haemorrhage, the excessive loss of blood is associated with peripheral vasoconstriction in favour of blood flow to the heart and brain. This decrease in circulation, along with the decrease in the heat producing ability of skeletal muscles, can profoundly impact the core body temperature. Hypothermia is associated with impaired oxygen delivery and cardiac arrhythmias.[11] Furthermore, a decrease in core body temperature has been associated with a significant increase of both the prothrombin time (PT) and partial thromboplastin time (PTT). The resultant coagulopathy dramatically increases bleeding. In fact, a study by *Jurkovich et al*.[12] has shown that a core body temperature of less than 32 degrees in trauma patients, is associated with 100% mortality.[12] Rapid rewarming is essential in secondary hypothermia and techniques must be directed toward core rather than peripheral warming techniques.

1.2.2 Acidosis

In trauma patients, inadequate tissue perfusion leads to an increase in anaerobic respiration which in turn leads to increased levels of lactic acid in the circulating blood volume.[8] The net result is a metabolic acidosis, which has profound effects on several functions of the body, including decreased cardiac contractility, arrhythmias, vasodilatation and decreased renal and hepatic blood flow.[13] Moreover, acidosis also causes an impairment in the coagulation cascade, in fact, activated clotting factors are unable to function normally when pH levels drop below 7.3 and, pro-coagulant drugs cannot function in an acidic medium.[14,15]

1.2.3 Coagulopathy

Coagulopathy is defined as an International Normalised Ratio (INR) of more than 1.5 times normal.[16] In addition to acidosis, which inherently impairs coagulation, damaged tissues activate the clotting cascade in an abnormal way that causes fibrinolysis that is out of proportion to the injury. This consumption of clotting factors is termed disseminated intravascular coagulopathy (DIC) and exacerbates haemorrhage in a trauma patient.[17] Moreover, if the bleeding trauma patient is resuscitated with fluids that do not contain clotting factors, the latter gets diluted, leading to "dilutional coagulopathy".[8]

Furthermore, the mechanism and clinical importance of coagulopathy in trauma changed significantly with the understanding of trauma induced coagulopathy which consists of:

- Trauma itself and/or traumatic shock induced endogenous ATC

  Presents immediately after injury and continue during resuscitation phase and it is related to shock and tissue hypo-perfusion before the effects of acidosis, hypothermia and haemodilution.

- Resuscitation – associated coagulopathy, which encompasses dilutional coagulopathy, acidosis and hypothermia. (Fig 1.2)

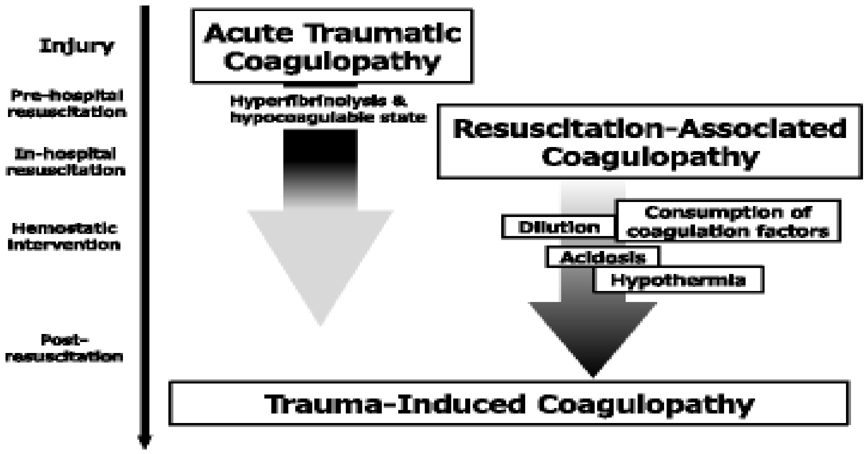

Figure 1.2 Two components of trauma-induced coagulopathy *(Journal of Intensive Care 2017 5:6).*[59]

1.3 Stages of DCL: Indications, Patient Selection and Management

A single-stage, or standard, trauma laparotomy involves the rapid evacuation of blood, four-quadrant packing, complete abdominal exploration and definitive repair of all injuries.[18] This approach, is however, not effective in severely injured patients: prolonged or extensive operation is associated with decreases in body temperature and arterial pH. Furthermore, administration of large amounts of fluid during single-stage laparotomy also promotes or worsens coagulopathy. Therefore, single-stage laparotomy leads to high mortality where trauma patients succumb to the lethal triad of death.[18-20] Patient selection for DCL is therefore essential in the trauma unit.

Since it was first described, DCL has brought about a paradigm shift in the management of trauma patient, but there exists no study to date that has compared the advantages of DCL to single-stage laparotomy.[21] Instead, focus has shifted on defining the stages of DCL as well as their respective effectiveness.[22] It is accepted that damage control involves a specific number of steps from patient selection and indications for DCL, to definitive management.[22-24] The staged approaches to damage control can either be :

- Three -staged approach
- Five-staged approach

The five-staged approach algorithm is simply achieved by subdividing stages 1 and 3 of the three-stage approach (Table 1.1). Regardless of preference there remains one pivotal point and that is to identify the patient who would benefit most from this approach.

Table 1.1 Staged approach to damage control surgery

Three staged approach		Five staged approach	
Stage1	Patient selection and damage control surgery	Stage 1	Patient selection
		Stage 2	Damage control surgery
Stage2	Restoration of physiology in ICU	Stage 3	Restoration of physiology in ICU
Stage3	Definitive operation with abdominal closure	Stage 4	Definitive surgery
		Stage 5	Abdominal closure

This five-staged approach will be further discussed below.

1.3.1 Stage 1: Patient Selection

In this pre-operative phase, also known as Damage Control 0 (or Damage Control ground zero), the potential need for damage control surgery is identified, and principles include rapid hospital transfer and damage control resuscitation in the emergency unit.[8,23,25] The clinical and laboratory indications, which favour the implementation of damage control surgery are:

- Penetrating trauma or complex/major vascular injuries
- Haemodynamic instability
  - Systolic blood pressure < 70mmHg
  - Tachycardia, dysrhythmias
  - Weak or non-palpable central pulse
- Complex anatomical presentation
  - Multivisceral injury
  - Multicavity and concomitant visceral injury
  - Multiregional injury
- Compromised ventilation

- Coagulopathy (PT >19s, aPTT >60s, INR >1.5 times normal)
- Hypothermia <34 C
- Acidosis: pH <7.2
- Inability to control bleeding or transfusion > 10 units of red blood cells
- Operative time >90 min
- Associated life-threatening extra-abdominal injury

Roberts et al.[26] conducted a cross-sectional international study to identify the appropriateness of guidelines for damage control, and, while they agree with the above indications, they also identified further injury patterns found during surgery, which indicate that DCL must be performed. These include an expanding pelvic haematoma, a juxta hepatic venous injury, an abdominal vascular injury and at least one major associated abdominal solid or hollow organ injury, a proximal superior mesenteric artery, devascularisation or destruction of the pancreas, duodenum, or pancreaticoduodenal complex with involvement of the ampulla, multiple blunt or penetrating injuries spanning across more than one anatomic region or body cavity that each require surgery, with or without angioembolization.

Therefore, the management of the trauma patient must be dynamic and proactive. The patient's physiology may evolve over the course of time, and the extent of injuries found intra-operatively may alter management plans. The operating surgeon must constantly have the patient's physiology in mind and tailor treatment accordingly: if the patient becomes coagulopathic, or hemodynamically unstable during an operation, or if the extent of injuries found during surgery would mean prolonged surgery, the decision must be made to undergo damage control rather than single-stage trauma laparotomy.

1.3.2 Stage 2: Initial Operation - DCL

The abbreviated laparotomy, termed Damage Control 1, is aimed at rapid assessment of injures, control of haemorrhage and contamination.[23,24,26] It consists of a midline incision from the xiphisternum to the pubic symphysis. The first step after entering the abdominal cavity is four quadrants packing of the abdomen. Further haemostasis is achieved by ligation, cross-clamping, shunting, or balloon catheter tamponade.[27,28] Haemorrhage from solid organs such as the spleen or kidney should be dealt with excision. There is no place for conservative management even if the injury is not devastating. Secondly, the intestine is inspected from the ligament of Treitz to the rectum and all contamination contained. Devitalised segments can be resected with staplers, or simply ligated.[23,24] Ureteric injuries also can be shunted.[29] The initial packs are then removed, and the abdomen inspected for further injuries before temporary closure. The abdominal packs may be left within the abdomen if there is ongoing bleeding from raw renal and splenic bed spaces, liver hemorrhage and exposed retroperitoneal surfaces. It is important to note that at this stage, once haemorrhage and contamination control are achieved, there should be no attempt at restoring gastrointestinal continuity and the abdomen left open with temporary wound closure.[23]

Temporary closure of the abdominal laparotomy wound after damage control surgery has five key objectives:

- Containment of viscera
- Control of abdominal secretions
- Maintenance of pressure on tamponaded areas
- Optimization of the likelihood of eventual closure
- Prevention of abdominal compartment syndrome

There are many different techniques for temporary closure which include, running nylon skin suture, towel clip closure, Bogota bag, Opsite-sandwich technique and vacuum assisted closure (Fig 1.3). This stage is performed in conjunction with ongoing anaesthetic resuscitation.

Figure 1.3: Temporary abdominal closure techniques (*IJAM 2016 | Volume: 2: 51-61)*

1.3.3 Stage 3: Intensive Care Unit Resuscitation

Following DCL, the trauma patient is transferred to the Intensive Care Unit (ICU) for resuscitation and restoration of his physiology. This includes active rewarming, reversal of acidosis, blood volume restoration and correction of coagulopathy.[30] Resuscitation endpoints include a systemic lactate concentration of <2.5 mmol/L, base deficit greater than -4mmol/L, core temperature > 35°C, haemoglobin level >10g/dL and haematocrit >30%.[31]

To obtain the physiological goals mentioned above, inotropes or vasopressor support should be considered. The addition of vasopressors should be started cautiously but should not be deferred until full intravascular volume loading has occurred.

1.3.4 Stage 4: Definitive Surgical Management

Timing of relook surgery is best decided by consensus among surgeon, anaesthetist and intensivist, usually 24-48 hours after the initial surgery, but can be as early as 8 hours or as late as 10 days once the patient has been fully resuscitated.[32] Early consideration should be given to patients with vascular injuries that were stented, those with multiple ligated bowel loops, or suspicion of gut ischemia.

The goal of the operating team conducts a thorough full abdominal exploration with injury reassessment, search for missed injuries and attempts to repair all the injuries that were initially found, packing removal with attempted abdominal closure.[23,25]

1.3.5 Stage 5: Abdominal closure

Permanent abdominal closure is performed after hypovolaemia, hypothermia, coagulopathy, and acidosis have been corrected and definitive surgery completed. Several methods of abdominal closure have been described. Primary closure of the fascia may be performed or a skin graft may be placed with a planned ventral hernia followed by delayed abdominal wall reconstruction which may be performed six to twelve months later, although definitive closure is recommended as soon as possible.[23,25]

Various methods of reconstruction have been described, including bilateral medial advancement of the rectus abdomens muscle and its fascia with or without skin-relaxation incisions, subcutaneous tissue expanders followed by bilateral myocutenous advancement flap have also been used. Midline abdominal defects may require flap reconstruction or reconstruction with non-absorbable mesh.

1.4 Complications of Damage Control Surgery

1.4.1 Abdominal Compartment Syndrome

This syndrome is defined as increased pressure within the abdominal cavity.[23] The incidence of abdominal compartment syndrome (ACS) is 6%-14% in patients with severe abdominal and/or pelvic trauma.[33-35] Patients managed by DCL are at high risk of intra-abdominal hypertension and ACS.[36] The exact pathogenesis of disease is still unknown,[33] but some predisposing factors are recognised such as the following list:[37]

- Severe abdominal injuries, spillage of intestinal content
- Primary fascial closure under tension
- Intra-abdominal packing for coagulation
- Massive transfusion with bowel oedema and distension
- Failure to control bleeding resulting in increased acidosis and coagulopathy

Clinically, ACS can be diagnosed by the presence of a tense, distended abdomen, with hypoxia, elevated peak airway pressures, inadequate ventilation, and oliguria or anuria. Measurement of abdominal pressure through either a Ryle's tube in the stomach or a 3-way Foley catheter in the bladder attached to a water manometer. While normal abdominal pressure is a zero cm of water, a pressure of over 28cm of water (20mmHg) is diagnostic of ACS.[38] Without decompression, most patients progress towards multi-organ failure.[39] Intra-abdominal pressures of 15-20mmHg are associated with oliguria, while anuria occurs at pressures of above 30mmHg. Moreover, respiratory compliance is affected because of diaphragmatic splinting, with respiratory failure ensuing at abdominal pressures of above

35mmHg.[34] ACS is treated with immediate decompression. However, the latter may also lead to ischemia-reperfusion syndrome, which may be fatal.[32]

1.4.2 Open Abdomen-related Complications

The management of the open abdomen is very challenging and resource consuming. There exist several methods to contain the abdominal viscera: towel clip closure, Bogota bag, vacuum-assisted closure, placement of mesh, sandwich techniques, and strategies using the patient's tissue.[40,41] Early abdominal closure within 3-4 days is associated with a low complication rate, but patients closed after 8 days have been noted to have a relatively higher complication rate, with increased incidence of abdominal wall infections, necrosis, abdominal sepsis and fistula formation.[35]

Between 8-11.5% of trauma patients with an open abdomen will develop intestinal fistulae.[35,42,43] The latter seem to develop when fascia is closed under tension: in fact, a study by *Barker et al*.[44] showed a comparatively low fistula rate (5.5%) when a vacuum assisted closure was used. Other risk factors for fistula formation are bowel injury and pancreatic injury.[24]

1.5 Mortality after Damage Control Surgery

The survival of severely injured trauma patients has improved steadily as proficiency in damage control principles increases: in fact, *Rotondo et al*.[3] reported a 58% survival rate in 1993, but *Brenner et al*.[45] had a 72% survival rate in 2011, with a four times larger cohort (24 versus 88 patients). However, each damage control exercise can require significant mobilisation of hospital resources, including blood products, ICU beds, operating time and surgical and nursing staff.[46] This has led to some studies that have considered the possibility of predicting the outcome for these severely injured patients.[5,47-49]

In fact, *Timmermans et al.*[48] retrospectively demonstrated that preoperatively, increasing age, large base deficit, low pH and hypothermia predict a negative outcome, while post operatively, coagulopathy, massive transfusion and blood product administration correlated with mortality in trauma patients. In the same centre, *Kairinos et al.*[49] validated a formula incorporating the same preoperative parameters to predict mortality in a severely injured trauma patient, which could be used in a resource-strapped setting such as South Africa or in massive casualty situations.

Once the trauma patient has survived the damage control procedure in its entirety, there is a good chance of long-term survival. *Brenner et al.*[45] reported an overall 72% survival rate following DCL, and, despite invariable morbidity-related readmission, all the survivors were still alive after seven years. However, it should be mentioned that the study was conducted in a first world setting, with good allied health care support.

1.5.1 Mortality Associated with Abdominal Gunshot Wounds

Abdominal gunshot wounds add another dimension to the damage control picture: often, the patients present with several injuries, which put them at a physiological disadvantage and therefore more susceptible to morbidity and mortality. In both military and civilian settings, the mortality rate rises with the number of intra-abdominal organs injured.[50,51] The presence of hypotensive shock on admission, increasing age as well as delay in surgical intervention are also correlated with high mortality in these patients.[50] Furthermore, the presence of colonic injuries is another predictor of poor outcome in victims of abdominal gunshot wounds.[52] The principles of damage control are therefore salient in the immediate management of the latter. When the patients reach hospital, mortality rates are 10-15%, and 3% in the absence of intra-abdominal vascular injuries.[53]

1.6 Civilian Abdominal Gunshot Injuries

The management of abdominal gunshot wounds in the United States dates as far back as the late 19th Century. The Second Amendment of the United States Constitution guarantees the “right of the people to keep and bear arms”, which means that firearm purchase is unrestricted. As such, there has been a constant increase in the incidence of abdominal gunshot wounds.[53] *Vassar et al.*[54] reported a rate of 32 discharges of firearm-injured persons per 100,000 in California in 1991, the large proportion of which were males aged 15-24 years old. It is estimated that about 127,000 individuals are treated in South African government/state hospitals each for non-lethal gunshot wounds, with each bullet having cost taxpayers the equivalent of USD 1467(ZAR 9240) in 2005.[55,56] In Cape Town, there are currently no formal trauma systems or data capturing methods, but a surveillance study conducted by *Nicol et al*.[57] identified firearm injuries as the 6th most common mechanism of injury in 9236 patients, with 4.8% of admissions in 2010. Moreover, most of the firearm injuries involved male patients, which shows a similar pattern to the United States.[57] A further study by *Chamisa* on civilian abdominal gunshot wounds in Durban showed that most patients were male with a median age of 25.[58]

Summary

Over the last two decades, the introduction of DCL has caused a paradigm shift in the management of selected trauma patients. Despite improvements in the survival rates of patients who undergo DCL, little is known about what factors could be used to predict patient outcomes. It is hypothesized that the lethal triad (hypothermia, acidosis and coagulopathy) contributes to the high mortality amongst these patients and could thus be used to predict patient outcome. This would-be of value in low income settings, as DCL requires significant hospital and human resources.

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Chapter 2

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Damage Control Laparotomy for Abdominal Gunshot Wounds: Indications, Mortality, and Long-Term Outcome

Damage Control Laparotomy for Abdominal Gunshot Wounds: Indications, Mortality, and Long-Term Outcomes

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ABSTRACT

Background: Outcomes of patients subjected to damage control laparotomy (DCL) for abdominal gunshot wounds (GSWs) remains relatively unknown. There is limited evidence as to which variables may reliably predict morbidity and mortality. The aim of this study was to evaluate the impact of DCL on long term morbidity and survival, to determine clinical characteristics associated with increased mortality, and to evaluate the indications for DCL in patients with abdominal GSWs.

Methods: A retrospective study of patients who underwent a damage control laparotomy for abdominal GSWs at Groote Schuur Hospital (GSH) was conducted. Data was collected on 50 consecutive trauma patients over a 4.5 years period between August 1st, 2004 and September 30th, 2009. Patients were stratified by, age, preoperative and intraoperative physiological parameters, trauma indices, numbers and locations of abdominal GSWs, extra abdominal involvement, intensive care unit and hospital length of stay, morbidity and mortality. Unadjusted and adjusted estimates of the association between these factors and the odds of survival were computed with univariate and multivariate logistic regression.

Results: Most of the patients were male (96%) with a mean age 29.7 year. Most patients had a single abdominal gunshot wound (60%). Liver injuries were the most common injury (58%) followed by small bowel (44%), 20 majors venous (40%), and colonic injury (38%) injuries. The overall mortality was 54%. The mean of length stay in the intensive care unit was 7 days with overall mean hospital length of stay of 13 days. Factor an associated with a decreased odd of survival included Penetrating abdominal trauma index(PATI) >25, pre-operative

infusion of less than two litres of crystalloids, intra-operative blood lactate level >8mmol/L, massive transfusion >10 units PRBCs.

Conclusion: The overall mortality of patients requiring DCL for abdominal GSWs was 54%. In this limited study, there is significant evidence that after controlling for confounding PATI score of >25 is associated with a decreased odds of survival (OR:0.20, p-value 0.04).

Introduction

Abdominal gunshot wounds (GSWs) and other types of firearm injuries are common in South Africa and associated with significant morbidity and mortality.[1-8] In 2010/2011, firearm injuries represented the sixth leading mechanism of injury managed by the Cape Town trauma system.[1] Even though outcomes have improved with time, the mortality associated with abdominal GSWs remains high, with many deaths occurring as a result of exsanguination, irreversible shock, and physiologic exhaustion/traumatic coagulopathy.[9-12]

Since the original description of the procedure by *Stone et al*.[13] damage control laparotomy has increasingly been utilized for management of severely injured patients with abdominal injuries.[14, 15] In contrast to definitive laparotomy (in which all injuries are repaired and the abdomen formally closed at the index operation), this procedure is characterized by an abbreviated initial operation that aims to rapidly and effectively control intra-abdominal haemorrhage and contamination using one or more abbreviated (or damage control) interventions.[13,16-18] When appropriately indicated, damage control laparotomy has been reported to be associated with improved mortality at the expense of increased morbidity among patients with severe abdominal injuries.[13, 17, 18]

Although damage control laparotomy is likely now commonly utilized for major trauma patients with abdominal GSWs, there exists considerable uncertainty regarding several aspects of the procedure. As a result of improvements in understanding of complications of damage control laparotomy (and how to potentially avoid them), and, pre-hospital and surgical care, resuscitation strategies, adjunctive pharmacotherapy, and other aspects of injury care in recent years,[19-22] the modern day outcomes of patients subjected to damage control laparotomy for abdominal GSWs remains relatively unknown.[12, 23-26] There is currently little evidence as to which variables may reliably predict morbidity and mortality in patients managed with damage control laparotomy for abdominal GSWs.[27-31] This is especially true as many previous studies enrolled patients injured by a variety of mechanisms in addition to abdominal GSWs, several of which have been reported to be associated with different outcomes.[27-31] Finally, at present it remains largely unknown which of the proposed indications for trauma damage control laparotomy may be valid and appropriate for use in patients with abdominal GSWs and other types of severe abdominal injuries.[16]

Objectives

The objectives of the present study are to:

1. Evaluate the clinical characteristics and short and long-term outcomes of patients managed with damage control laparotomy for abdominal GSWs at the Groote Schuur Hospital (GSH) in Cape Town, South Africa.
2. To determine which clinical characteristics are associated with increased morbidity and mortality among patients who underwent DCL for abdominal GSWs.
3. To evaluate which indications for DCL are used for patients with abdominal GSWs at an experienced, high volume trauma center.

Methods

Study design

A retrospective study of patients who underwent a damage control laparotomy for abdominal GSWs between August 1st, 2004 and September 30th, 2009 was conducted.

Setting

The study was conducted at Groote Schuur Hospital (GSH). The GSH is an academic, level 1, tertiary care trauma center that evaluates approximately 12,000 injured patients per year, many of which present for management of abdominal GSWs.[1]

Study Size

No formal *a priori* sample size calculation was conducted. The number of eligible patients during the study period determined the sample size.

Participants

Patients who underwent damage control laparotomy for an abdominal GSW were identified. These patients were screened for eligibility and excluded if:

- They did not undergo a damage control laparotomy
- Their full records were missing
- The underwent a damage control laparotomy for indications other than abdominal GSWs

One investigator reviewed the hospital records of eligible patients to extract the required data after ethical approval was obtained (HREC reference 455/2016) (Appendix 2).

Data collection

Damage control laparotomy was defined as an abbreviated laparotomy that aimed to rapidly and effectively control haemorrhage and/or contamination and which ended with temporary closure of the laparotomy wound.[16] In contrast, a definitive laparotomy was defined as the completion of repairs of all abdominal injuries followed by formal fascial closure of the abdomen during the index operation.

Variables of interest were collected from the charts of eligible patients using a standardized data extraction form in Microsoft excel spreadsheet. The following data was collected: age; sex; vital signs; Glasgow Coma Scale scores; numbers and locations of abdominal gunshot wound(s); whether more than one anatomical region or cavity was injured; pre- and intraoperative diagnostic imaging and arterial blood gas/laboratory test results; core body temperatures of patients in the trauma bay and operating theatre (OT) settings; whether patients were reported to have a clinically-observed coagulopathy in the OT; the volume or units of crystalloids, packed red blood cells (PRBCs), fresh frozen plasma (FFP), platelets, and cryoprecipitate administered across the trauma bay and OT settings; whether tranexamic acid was given or a thoracotomy was required, the time interval between patient arrival in the trauma bay and initiation of the operative procedure; the exact injury pattern identified during; the operative procedures conducted; the number of abdominal operations performed; and the length of time from laparotomy to closure of the abdominal wound. Where possible, data on the indications for damage control laparotomy that were reportedly utilized was collected, Injury Severity Scale (ISS), Revised trauma score (RTS), trauma related injury severity score (TRISS) and penetrating abdominal index score (PATI) scores were calculated for each patient.

Outcomes of interest will include the risk of mortality (in the OT and within 6- or 24-hours and 30-days of operation). Morbidity was evaluated by collecting data on complications including open abdomen, intra-abdominal abscesses/intra-abdominal sepsis, and enteroatmospheric fistulae. An enteroatmospheric fistula was defined as a communication between the gastrointestinal tract and the atmosphere in a patient with an open abdominal wound. Finally, data was collected on lengths of hospital and intensive care unit (ICU) stay and the long-term risk of mortality, small bowel obstruction, and ventral hernia.

Quantitative variables

Continuous variables were grouped to form new categorical variables, based on previous studies and clinical relevance.

Statistical Methods

The clinical characteristics and outcomes of patients who underwent damage control laparotomy for abdominal GSWs will be summarized using proportions, means [with standard deviations (SDs)], and medians [with interquartile ranges (IQRs)] as appropriate.

Initial data exploration was conducted using cross tabulation and the Mantel-Haenszel test. Following this, logistic regression was used to compute the unadjusted estimates (and 95% confidence intervals) for the association between each of the variables and the odds of survival after DCL for abdominal GSWs.

Variables selected for inclusion in the multivariate logistic regression were selected based on previous literature and clinical grounds. These included proxies for the "Lethal Triad" that were found to be associated with the outcome on univariate analysis, i.e.: hypothermia (temperature dichotomized at 32 degrees Celsius), acidosis (lactate dichotomized at 8mmol/L intraoperative) and coagulopathy (massive transfusion of greater than 10 units PRBCs). The trauma scoring system with the strongest association with mortality(PATI) was included. Age was included as an *a priori* confounder. The analysis was conducted in Stata MP version 13.1 (Stata Corp., College Station, TX, U.S.A). Proportions, odds ratios, 95% confidence intervals and p-values are reported to the second decimal point. All p-values in the logistic regression models were derived from the Likelihood Ratio Test.

Results

Participants

A query of the GSH database prior to submission of the study protocol for ethics review revealed 82 potentially eligible patients. Of these, 32 were excluded for the following reasons:

- 12 patients died in the emergency room prior to being taken to theatre
- 10 patients did not undergo a damage control laparotomy (as defined in the Methods)
- 4 patients underwent damage control laparotomy for injuries other than GSWs to the abdomen
- 2 patient records were missing
- 4 patient folder numbers were erroneously duplicated

Demographic and Descriptive Characteristic Data

Fifty patients who underwent DCL for abdominal gunshot wounds were included. There were 48 (96%) men and two (4%) women, with an age range of 17-62 years (mean age 29.7 years). Thirty (60%) and twenty patients (40%) had single and multiple gunshot wounds to the abdomen, respectively. The mean preoperative systolic blood pressure was 90.4 mmHg, mean heart rate 112 beats per minute, mean respiratory rate 19 breaths per minute, mean temperature 35.6 degrees Celsius and mean Glasgow Coma Scale score of 12 with an IQR of 13 to 15. Pre-operative blood investigations revealed a mean haemoglobin concentration of 8.35g/dl, mean pH 7.21, mean base deficit -9.71 mEq/L and a mean lactate of 5.25 mmol/L.

Four trauma indices were computed for this study. The mean ISS was 27.12, mean RTS 6.65, mean TRISS was 82.36% and mean PATI was 34.5. Intra-operatively the mean temperature was 35 degrees Celsius, mean pH 7.07, mean base deficit -14.41 mEq/L and mean lactate 7.95 mmol/L (Table 2.1).

Table 2.1 Descriptive statistics of fifty patients who underwent DCL at GSH between August 1st, 2004 and September 30th, 2009

Variable	
Sex	**N (%)**
Male	48 (96)
Female	2 (4)
Age in years (mean)	29.7
No. of GSWs	**N (%)**
Single	30 (60)
Multiple	20 (40)
Pre-operative vital signs	**Mean (SD)**
Systolic BP	90.04 (35.84)
Heart rate	111.92 (18.71)
Respiratory rate	18.98 (18.98)
Preoperative temperature	35.56 (1.11)
Glasgow Coma Scale	**Mean (IQR)**
	12.4 (13 - 15)
Blood investigations	**Mean (SD)**
Pre-operative Hb	8.35 (2.70)
Pre-operative pH	7.21 (0.11)
Pre-operative base deficit	-9.71 (4.91)
Pre-operative lactate	5.25 (2.45)
Trauma Indices	Mean (SD)
ISS	27.12 (15.26)
RTS	6.65 (1.75)
TRISS	82.36 (25.58)
PATI	34.5 (2.02)
Intraoperative parameters	**Mean (SD)**
Temperature	35.0 (1.19)
pH	7.07 (0.15)
Base deficit	-14.41 (5.01)
Lactate	7.95 (2.54)

The index procedure was terminated because of the following reasons: metabolic acidosis in 46 of 50 patients, increasing ionotropic support in 39 patients, rising lactate in 34 patients and diffuse haemorrhage in 28 patients. Hypothermia was noted as a reason for termination of the index procedure in 16 patients, and disseminated intravascular coagulopathy in 16 patients.

Most patients received either two (42% of patients) or three (38% of patients) litres of crystalloids and one (34% of patients) to two (40% of patients) units of packed red cells pre-operatively. Intra-operatively most patients received between one and six litres of crystalloids (39% of patients), four to ten units of packed red cells (30% of patients), between two and six units of fresh frozen plasma (29% of patients) and one unit of platelets (26% of patients) (Table 2.2).

Table 2.2 Pre- and intra-operative fluid resuscitation

Preoperative	**N (%)**
Units of packed red cells:	
0	5 (10)
1	17 (34)
2	20 (40)
3	5 (10)
4	2 (4)
5	1 (2)
Intra-operative	**N (%)**
Units of crystalloids:	
0-1	1 (2)
1.1-4	20 (40)
4.1-6	19 (38)
6.1-8	4 (8)
8.1-10	3 (6)
Units of packed red cells:	
0-4	6 (12)
4.1-10	30 (60)
10.1-15	10 (20)
15.1-20	4 (8)
Units of fresh frozen plasma	
0-2	9 (18)
2.1-4	15 (30)
4.1-6	14 (28)
6.1-8	9 (18)
8.1-10	3 (6)
Units of platelets	
0	5 (10)
1	26 (32)
2	11 (22)
3	1 (2)
4	4 (8)
5	0
6	3 (6)
Units of crystalloids:	
1	1 (2)
2	21 (42)
3	19 (38)
4	7 (14)
5	2 (4)

Forty (80%) patients had extra-abdominal gunshot wounds. The gunshot wounds to the abdomen were located on the patient's posterior torso in 24 (48%), in the epigastrium in 12 (24%), right iliac fossa in 12 (24%), left iliac fossa in 8 (16%), right upper quadrant 6 (12%), left upper quadrant in 5 (10%). Five of the fifty patients underwent thoracotomy in the operating room at the time of the time of laparotomy. The most common injuries noted at laparotomy were: liver (58%), small bowel (44%), major venous injuries (40%), colon (38%), major arterial injuries (22%) and pancreas (20%) (Table 2.3).

Table 2.3 Description of injuries found at DCL

Variable	**N (%)**
GSW site	
Epigastric	12 (24)
RUQ	6 (12)
RIF	12 (24)
LIF	8 (16)
LUQ	5 (10)
Suprapubic	0 (0)
Back	24 (48)
Extraabdominal	40 (80)
Thoracotomy	
No	45 (90)
Yes	5 (10)
Organ injuries noted	
Pericardium	1 (2)
Lung	1 (2)
Diaphragm	6 (12)
Oesophagus	1 (2)
Liver	29 (28)
Spleen	4 (8)
Pancreas	10 (20)
Bladder	4 (8)
Kidney	8 (16)
Stomach	9 (18)
Small Bowel	22 (44)
Colon	19 (38)
Rectum	5 (10)
Retroperitoneal	5 (10)
Venous	20 (40)
Arterial	11 (22)
Mesentery	3 (6)
Neurological	1 (2)

The mean time to operation was 2 hours 21 minutes (SD 80,3 minutes). The mean duration of surgery was two hours 21 minutes (SD 59,8 minutes) (Table 2.4).

Table 2.4 Time to and duration of surgery

Time frame	Mean (SD)	Median (IQR)
Time (in minutes) to operating room	141.1 (80.39)	120 (90)
Duration of surgery (minutes)	141.14 (59.86)	120 (90)

Participates Outcome Data

Twenty-seven (54%) of the fifty patients died. Of these, 14 patients died in the first six hours, six died between six and 24 hours, three died between 24 hours and seven days and four died between seven to 30 days (Table 2.5).

Table 2.5 Description of outcome of interest

Mortality data	
Number of deaths in given time-frame	**N (%)**
6 hours	14 (28)
6 to 24 hours	6 (12)
24 hours to 7 days	3 (6)
7 days to 30 days	4 (8)
Total number of deaths	**27 (54)**

Ten of the 27 deaths occurred in the operating room, 16 occurred post-operatively in ICU and one death occurred in the ward after discharge from ICU (Table 2.6).

Table 2.6 Description of location of deaths

Place of death	N (%)
Operating room	**10 (20)**
ICU	**16 (24)**
Ward	**1 (2)**

The mean length of stay in ICU amongst the patients who survived the index procedure was 7.64 days, median 4 days. Amongst those patients who survived ICU, the mean stay was 12.38 days, median 8 days. The mean total length of hospital stays amongst those patients who survived the index procedure was 16.64 days, median 13 days (Table 2.7).

Table 2.7 Duration of stay

Length of stay (in days)	Mean (SD)	Median (IQR)
In ICU in initial survivors	7.64 (7.90)	4 (6)
In ward stay in those who survived ICU	12.38 (10.22)	8 (6)
Total length of stay for those who survived index procedure	16.64 (15.33)	13 (10)

The most common short-term complications documented in ICU were acute renal failure (N=10), multi-organ failure (N=10), DIC (N=7) and abdominal compartment syndrome (N=7). Other complications included prolonged intubation requiring tracheostomy, ventilator associated pneumonia, superficial wound sepsis, intra-abdominal collection, anastomotic leak, deep vein thrombosis, limb ischemia, hypoglycaemia and gastro-intestinal bleeding.

Amongst those patients who survived ICU, the most common complications noted in the ward were superficial wound sepsis (N=5), open abdomen (N=5), paralytic ileus (N=4) and wound dehiscence (N=4). Other complications included atelectasis, pleural effusion, acute kidney injury, pancreatic fistula and a high output ileostomy.

The Clavien-Dindo Classification of all complications mentioned above is provided in (Table 2.8).

Table 2.8 Number and frequency of complications after DCL categorised by Clavien-Dindo classification

Clavien-Dindo Grade	Description	N (%)	Observed complications
I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgesics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.	5 (10)	atelectasis (1) hypoglycemia (1) paralytic ileus (3)
II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.	6 (12)	prolonged ileus requires TPN (1) pulmonary oedema (1) small-intrabdominal collection (1) pneumonia (1) ventilated associated pneumonia (1) high output ileostomy (1)
IIIa	Requiring surgical, endoscopic or radiological intervention (not under general anaesthesia)	1 (2)	wound dehiscence repaired by secondary closure (1)
IIIb	Requiring surgical, endoscopic or radiological intervention (under general anaesthesia	5 (10)	open abdomen requires skin graft (4) intraabdominal collection (1)
IVa	Life-threatening complication (including CNS complications) requiring ICU-management. single organ dysfunction (including dialysis)	2 (6)	acute kidney injury requires dialysis (2)
IVb	Life-threatening complication (including CNS complications) requiring ICU-management. Multi organ dysfunction.	1 (2)	acute compartment syndrome (1)
V	Death of patient	27(54)	

Long-term complications were noted in seven patients. Three patients presented with adhesive small bowel obstruction at 3 months, 1 year and seven years, respectively, after the index operation. A further three patients presented for elective ventral hernia repair at 9 months, 1 year and 6 years after the index operation. One patient known with a ventral hernia has been lost follow up.

Regression analysis

Univariate analysis of the association between the variables listed in (Table 2.9 and 2.10) and mortality revealed strong evidence that the following factors increase the odds of survival: PATI of less than 25, pre-operative infusion of greater than 2 litres of crystalloids, intra-operative lactate level of less than 8mmol/L and intra-operative transfusion of less than 10 units of PRBCs.

In this sample, there is significant evidence (p=0.01) that the odds of survival are 81% lower in patients with a PATI of more than 25 compared to those with a PATI of less than 25, OR 0.19 (95% CI: 0.05-0.72). There is significant evidence (p=0.02) that patients who received more than two litres of crystalloids pre-operatively were four times more likely to survive compared to those who received less than two litres of crystalloids, OR 4.12 (95% CI: 1.23-13.77).

On univariate analysis, there is significant evidence (p=0.01) that patients with an intraoperative lactate level of greater than 8 were 82% less likely to survive, OR 0.18 (95% CI: 0.05-0.6) and that patients who had massive transfusion (>10 units) of PRBCs intra-operatively, were 78% less likely to survive, OR 0.22 (95% CI: 0.05-0.92).

On multivariate analysis, there is significant evidence (p=0.04) that after considering the confounding effect of age and all other variables in the regression model, a PATI of greater than 25 was associated with an 80% lower odd of survival after DCL (OR 0.20, CI 0.04-1.00), however, there is considerable uncertainty around this estimate owing to the small sample size.

Table 2.9 Univariate and multivariate association between pre-operative patient factors and the odds of survival after DCL for abdominal GSWs

Variable	Died N (%)	Survivors N (%)	Unadjusted OR (95% CI)	P-value (LRT)	Adjusted OR (95% CI)	P-value (LRT)
Age (years):						**0.19**
<40	22 (44)	20 (40)	1	0.60	1	
>40	5 (10)	3 (6)	0.66 (0.143.12)		0.30 (0.04-2.00)	
Sex:						
Male	26 (54)	22 (44)	1	0.90		
Female	1 (2)	1 (2)	1.18 (0.0720.01)			
Pre-op systolic BP(mmHg):						
<90	12 (24)	12 (24)	1	0.59		
>90	15 (30)	11 (22)	0.73 (0.242.23)			
Pre-op HR (beats/min):						
<100	4 (8)	7 (14)	1	0.37		
≥100	23 (46)	16 (32)	0.40 (0.10-1.59)			
Pre-op RR (breaths/min):						
<20	14 (28)	13 (26)	1	0.74		
≥20	13 (26)	10 (20)	0.83 (0.27-2.53)			
GCS:						
<8	7 (14)	3 (6)	1	0.25		
≥8	20 (40)	20 (40)	2.33 (0.53-10.33)			
ISS:						
0-24	10 (20)	14 (28)	1	0.24		
25-74	13 (26)	9 (18)	0.49 (0.15-1.60)			
75	4 (8)	0				
RTS:						
<4	4 (8)	1 (2)	1	0.20		
≥4	23 (46)	22 (44)	3.82 (0.40-36.96)			
TRISS:						
<50	5 (10)	2 (4)	1	0.31		
≥50	22 (44)	21 (42)	2.39 (0.42-13.67)			
PATI:						**0.04***
<25	4 (8)	11 (22)	1	**0.01***	1	
≥25	23 (46)	12 (24)	0.19 (0.05-0.72)		0.20 (0.04-1.00)	
Pre-op haemoglobin (g/dL):						
<8	14 (28)	9 (18)	1	0.37		
≥8	13 (26)	14 (28)	1.68 (0.54-5.17)			
Pre-op RBCs:						
<3	21 (42)	21 (42)	1	0.18		
≥3	6 (12)	2 (4)	0.33 (0.60-1.84)			
Pre-op pH:						
<7.2	14 (28)	7 (14)	1	0.12		
≥7.2	13 (26)	16 (32)	2.46 (0.77-7.90)			
Pre-op base deficit (mEq/L):						
< -8	18 (36)	10 (20)	1	0.10		
≥ -8	9 (18)	13 (26)	2.6 (0.82-8.2)			
Pre-op crystalloids (litres):						
<3	16 (32)	6 (12)	1	**0.02***		
≥3	11 (22)	17 (34)	4.12 (1.23-13.77)			
Pre-op lactate (mmol/L):						
< 2.5	2 (4)	4 (8)	1	0.28		
≥ 2.5	25 (50)	19 (38)	0.38 (0.06-2.29)			

Table 2.10 Univariate and multivariate association between intra-operative patient factors and the odds of survival after DCL for abdominal GSWs

Variable	Died N (%)	Survivors N (%)	Unadjusted OR (95% CI)	P-value (LRT)	Adjusted OR (95% CI)	P-value (LRT)
Intra-op pH:						
<7.2	24 (48)	18 (36)	1	0.31		
≥7.2	3 (6)	5 (10)	2.22 (0.47-10.54)			
Intra-op lactate (mmol/L):						
< 8	9 (18)	17 (34)	1	**0.01***	1	**0.09**
≥ 8	18 (36)	6 (12)	0.18 (0.05-0.6)		0.29 (0.07-1.24)	
Intra-op temp (°C):						
<32	7 (14)	2 (4)	1	0.10	1	**0.42**
≥32	20 (40)	21 (42)	3.66 (0.68-19.84)		2.21 (0.31-15.76)	
Intra-op crystalloids:						
<3	22 (44)	21 (42)	1	0.31		
≥3	5 (10)	2 (4)	0.42 (0.07-2.40)			
Intra-op RBCs:						
<10	16 (32)	20 (40)	1	**0.03***	1	**0.61**
≥10	11 (22)	3 (6)	0.22 (0.05-0.92)		0.33 (0.07-1.62)	
Intra-op FFPs:						
<4	20 (40)	17 (34)	1	0.99		
≥4	7 (14)	6 (12)	1.01 (0.28-3.58)			
Thoracotomy:						
No	23 (46)	22 (44)	1	0.20		
Yes	4 (8)	1 (2)	0.26 (0.27-2.52)			
Time to surgery (minutes):						
<60	5 (10)	1 (2)	1	0.12		
≥60	22 (44)	22 (44)	5.68 (0.54-46.35)			
Operation time (minutes):						
<120	12(24)	7 (14)	1	0.31		
≥120	15(30)	16 (32)	1.83 (0.57-5.88)			

*All p-values are by the Likelihood Ratio Test. P-values <0.05 are denoted with *.*

Discussion

Summary of key results

This research aimed to describe the clinical characteristics of patients managed with DCL for abdominal GSWs at GSH. The indications and the long-term outcomes of patients undergoing DCL were examined. The overall mortality after DCL was 54%.

Univariate analysis revealed that the following factors were associated with an increase in the odds of survival after DCL: PATI of less than 25, pre-operative infusion of greater than 2 litres of crystalloids, intra-operative lactate level of less than 8mmol/L and intra-operative transfusion of less than 10 units of PRBCs.

Multivariate analysis revealed significant evidence (p=0.04) that a PATI score of greater than 25 is associated with an 80% decrease in the odds of survival (OR 0.20, 95% CI: 0.04-1.00). After considering the confounding effect of age and all other variables in the model, there was no evidence of an association between intra-operative lactate, temperature or massive transfusion with the odds of survival after DCL.

Limitations

The results summarised above should be interpreted with caution given the substantial uncertainty around the estimates (demonstrated by wide confidence intervals for most of the odds ratios in the univariate analysis, especially for pre-operative crystalloid infusion). This is most likely a result of the relatively small sample size.

Whilst the multivariate regression model controls for the confounding effect of the other variables in the model, the observed association between a high PATI score and a decrease in the odds of survival should not be interpreted as a causal relationship as the results may still be subject to random sampling error, selection bias, information bias or residual confounding after analysis.

Interpretation

The mortality rate after DCL for abdominal GSWs was notably higher in this sample than in previously published literature (54% compared to 42% reported by *Rotondo et al*[18] and 28% reported by *Brennar et al.*[32]). Factors contributing to this could anecdotally, include the delay to operation and long operation time, as well as other resource based constraints such as level of training of healthcare workers, access to operating theatre and intensive care and availability of allied healthcare support. Not captured in the data presented here is the additional delay between injury and arrival at GSH, owing to ambulance and emergency service shortages.

The results of the univariate analyses are supports the hypothesis that the "Lethal Triad" contributes significantly to patient mortality following major trauma. In this study sample, high lactate levels and massive transfusion were associated with a negative outcome. *Frischknecht et al.*[30] identified several risk factors for early mortality including severe head injury and the lethal triad (coagulopathy, acidosis and hypothermia) in patients undergoing damage control procedures. Similarly, *Timmermans et al.*[27] demonstrated that a large base deficit, low pH, hypothermia, coagulopathy and massive transfusion correlated with mortality in trauma patients.

The incidental finding of an association between high volumes of crystalloids administered pre-operatively and an increased odd of survival should be interpreted with caution, given the wide confidence interval of the estimate likely because of the small sample size. There is no published evidence to suggest a mechanism for this observed association.

Due to the lack of corroborative evidence, and given that the analysis is based on relatively small numbers, we would not recommend any change in fluid prescribing practice on the strength of these results. Of more value in future research, would be to examine the effect of the ratio of crystalloids to blood products on the odds of survival after DCL, as it is hypothesized that initial permissive hypotension followed by definitive control of haemorrhage and blood product based resuscitation is associated with positive outcomes.

The multivariate analysis demonstrated significant evidence that, after controlling for age and intraoperative factors, a high PATI score is associated with increased mortality. This finding is consistent with the results of a similar analysis by Adesanya *et al* who demonstrated that a PATI score > 15 was associated with a twenty-fold increased incidence of death (P<0.0001).[33]

Generalisability

There are many factors that may impact the external validity of the observed results. Notably, data on the socio-economic status, immune profile and comorbid conditions was not collected or analysed. These factors may have a significant impact on patients' recovery after major trauma, Thus, the observed results may not be applicable to high-income countries with different patient demographics.

Conclusion

The overall mortality of patients that required DCL for abdominal GSWs was 54%. In this limited study, there is significant evidence that after controlling for confounding PATI score of >25, is associated with a decreased odds of survival (OR:0.20, p-value 0.04).

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Appendix 1 Ethics Approval Letter

UNIVERSITY OF CAPE TOWN

Department of Surgery

Departmental Research Committee
Professor Anwar Suleman Mall
J-45 Room Old Main Building, Groote Schuur Hospital,
Observatory 7925, South Africa
Tel (021) 406 6168/6232/6227 Fax (021) 448 6461
Email: Anwar.Mall@uct.ac.za

27th October 2014

Prof P Navsaria
Department of Surgery
Division of General Surgery
Groote Schuur Hospital
University of Cape Town

Dear Prof P Navsaria,

RE: PROJECT 2014/104

PROJECT TITLE: **Damage control laparotomy for abdominal gunshot wounds: Indications and short and long-term outcomes**

The above proposal was reviewed by the Department of Surgery Research Committee and I am pleased to inform you that the committee approved the study.

Please use the above project number in all future correspondence.

Yours sincerely

PROFESSOR ANWAR S MALL
CHAIRMAN: RESEARCH COMMITTEE

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

Appendix 2 Human Research Ethics Committee Approval

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

Room E52-46 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

20 June 2016

HREC REF: 455/2016

Prof P Navsaria
Department of General Surgery
J-Floor
OMB

Dear Prof Navsaria

PROJECT TITLE: DAMAGE CONTROL LAPAROTOMY FOR ABDOMINAL GUNSHOT WOUND: INDICATION, MORTALITY, AND LONG TERM OUTCOME (MMeD-candidate-K Twier)

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 June 2017.

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)

Please quote the HREC REF in all your correspondence.

We acknowledge that the student, Dr Khaled Twier will also be involved in this study.

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 before the research may occur.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

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

HREC 455/2016

Appendix 3 Ethics Approval Renewal

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

30 JUN 2017
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938) This serves as notification of annual approval, including any documentation described below.			
☒ Approved	Annual progress report	Approved until/next renewal date	30. 7. 2018
☐ Not approved	See attached comments		
Signature Chairperson of the HREC		Date Signed	1/7/2017

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	**29/06/2017**		
HREC REF Number	**455/2016**	Current Ethics Approval was granted until	30/06/2017
Protocol title	**Damage control laparotomy for abdominal gunshot wound : Indication,mortality,and long term outcome**		
Protocol number (if applicable)			
Are there any sub-studies linked to this study?	☐ Yes ☒ No		
If yes, could you please provide the HREC Ref's for all sub-studies? Note: A separate FHS016 must be submitted for each sub-study.			
Principal Investigator	**Khaled Twier**		
Department / Office Internal Mail Address	**General surgery**		

1.1 Does this protocol receive US Federal funding?	☐ Yes	☒ No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval?	☐ Yes	☒ No
1.3 Has sponsorship of this study changed? If yes, please attach a revised summary of the budget.	☐ Yes	☒ No

23 July 2014 Page 1 of 5 FHS016

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)