Symptoms and Intraoperative Findings in Patients Undergoing Revision Fundoplication.

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DECLARATION

I, Mohamed Etalleb, 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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Abstract

Background: Approximately 20% of patients who undergo anti-reflux surgery will report a recurrence of reflux symptoms or develop new symptoms, with 5% ultimately requiring revision fundoplication. The aim of this study is to document symptoms at representation, pre-operative work-up and intraoperative findings of patients presenting for revision fundoplication (RF).

Methods: This is a single center descriptive retrospective review of 37 patients who required revision of a previous fundoplication for significant recurrent symptoms between January 2015 and December 2017 at Groote Schuur Hospital and UCT Private Academic Hospital. Patient data included demographics, body mass index (BMI), patient reported symptoms prompting initial fundoplication, interval to symptom recurrence and RF, technique of the first and subsequent revision surgery and perioperative morbidity. Recurrent symptoms at representation, results of pre-operative investigations and actual intraoperative assessment during RF were reviewed.

Results: During the two-year study period 37 patients underwent RF. The mean age was 52.9 years (range 22 – 77 years, SD =13.3), with 25 (67.6%) females and 12 (32.4%) males included in the cohort. The most frequent patient-reported indication for index fundoplication was gastro-oesophageal reflux (GOR) (65%). Symptoms at representation prior to RF included dysphagia (51.4%) and heartburn (51.4%) equally, epigastric pain (48.6%), volume reflux (43.2%), atypical chest pain (24.3%), bloating (16.2%), nausea (13.5%) and early satiety (10.8%). The most observed endoscopic finding (available in 35 patients) was a recurrent sliding hiatus hernia

(42.9%). All had a contrast swallow with evidence of delayed transit into the stomach present in 45.9%, recurrent sliding hernia and dilated distal oesophagus in 35.1% equally.

The RF was performed at a median of 24 months (IQR 2.5 - 66 months) following prior fundoplication. Technique of RF included 17 (45.9%) conversions from full Nissen to partial anterior fundoplication (Dor), 10 (27.0%) re-do Nissen's, two (5.4%) conversions from full Nissen to partial posterior fundoplication's (Toupet), three (8.1%) complete reversal of fundoplication with oesophagogastric junction adhesiolysis, two (5.4%) Heller's myotomies with anterior fundoplication, two (5.4%) crural repairs only (intact wraps) and one (2.7%) opening of tight crura closure. The majority (83.8%) of revisions were completed laparoscopically. The most frequent intraoperative findings included significant oesophagogastric adhesions with wrap distortion (75.7%), recurrent crural defect (51.4%), slipped wrap (45.9%), distal oesophageal/crural fibrosis (37.8%), recurrent sliding hernia (35.1%), a tight crural inlet (24.3%), mixed herniation (10.8%) and three (8.1%) para-oesophageal hernias.

Conclusion: This single-center review on revision fundoplication conforms with much of what is written in other studies. Dysphagia is the predominant symptom prompting repeat surgery and most patients present two years after their initial operation. Despite revision anti-reflux surgery remaining technically challenging, the vast majority of operations were completed laparoscopically with low associated morbidity. Larger, multi-center studies would allow for a bigger picture of revision anti-reflux surgery in the greater South African context.

Introduction

Anti-reflux surgery is an effective treatment option for managing gastro-oesophageal reflux disease (GORD) specifically for patients with confirmed volume reflux.[1,2] While Nissen's fundoplication has been considered the gold standard for surgical treatment of GOR with success rates of the index surgery reported between 80% to 90%[3-5], traditional anti-reflux surgery has been gradually decreasing in popularity. While many studies report good outcomes, complications occur in about 5% of patients who present with functional and clinical outcomes that may warrant further revision surgery.[6] Poor functional outcomes of fundoplication include oesophageal dysmotility, gas-bloat syndrome (abdominal bloating, inability to burp, postprandial fullness, nausea, flatulence, inability to vomit and abdominal pain), atypical chest pain and diarrhoea.[7] Patients with poor clinical outcomes present with new complaints or recurrence of previous GOR symptoms such as heartburn, regurgitation and erosive oesophageal disease.[7] Patients who have undergone fundoplication may also present with subsequent dysphagia related to crural fibrosis without recurrent herniation, or due to anatomical distortions associated with the actual wrap.[7]

Revision of a prior fundoplication is considered potentially complex surgery due to adhesions, distorted anatomy and occasionally the presence of mesh from previous surgery.[8] The success rates decline with each subsequent procedure while complication rates increase.[9,10] Fundoplication revision has a mortality rate of 1% with increased risk of perforation, postoperative leak, vagal nerve injury and treatment failure with each subsequent surgery.[8] A systematic review of failed laparoscopic anti-reflux surgery spanning 20 years, reported a complication rate of 14% with 5% of patients progressing to require RF.[11] Recurrent reflux or heartburn were the most common symptoms reported in this study (61%) followed by dysphagia which was observed in 31% of the

patients.[11] A further analysis of 9 462 patients post-fundoplication similarly determined that 4.5% required RF.[12]

While the risk of complication is higher after revisions, symptom remission with good patient satisfaction after revision surgery is reported. For example, a review of 307 patients by Smith *et al* (2005), found that 89% reported symptomatic remission while 70% reported satisfaction after re-operation.[13] The factors associated with increased complications in RFs are high BMI, younger age, female sex and the presence of cardiopulmonary disease.[12] Given the high percentage and variation of recurrent symptoms it is crucial to appreciate the clinical characteristics of patients that required RF. The aim of this study was to describe the presenting symptoms, pre-operative investigations and intraoperative findings in patients presenting for laparoscopic revision fundoplication after failed index anti-reflux surgery.

Methods

Study design and data collection

This was a single center retrospective descriptive review of patients who were referred to the Upper Gastrointestinal Surgery Unit at Groote Schuur Hospital and UCT Private Academic Hospital for consideration for RF. All patients presenting with symptoms and pre-operative findings significant enough to be referred for consideration for RF between 1st January 2015 and 31st December 2017 were evaluated for possible inclusion. Inclusion required progression to RF following significant findings on either or both gastroscopy and contrast swallow. The need for high resolution oesophageal manometry (HRM) and 24-hour pH study was individualized and not a routine investigation prior to RF. Patients deemed not to require revision fundoplication after clinical

evaluation and review of investigations or declining surgery were excluded from this study.

The main variables of interest were the range of new or recurrent symptoms following prior fundoplication surgery that were significant enough to warrant referral for possible revision; the interval to RF following prior fundoplication, pre-revision surgery investigation results and subsequent intraoperative findings at RF. The findings of the pre-RF gastroscopy were documented as reported by the performing endoscopist, who was not always someone from the operative team. The findings of the pre-RF contrast swallow were documented as outlined by the reporting radiologist on the day. The contrast swallows performed were standard barium swallows, not timed barium swallows. In addition, patient demographics (age, gender, co-morbidities, BMI) and index surgery details (as reported by the patient or referral physician) were noted. These included indication (as reported by the patient or referring physician) for the index fundoplication and the type of fundoplication performed at index surgery. However, the appropriateness of any pre-operative assessments and decisions prior to the index fundoplication were not evaluated, as for the majority these were performed elsewhere and as such did not fall within the scope of this study.

The intra-operative findings at RF were reported as documented in the operative notes, with the RF performed by the same team of two consultant surgeons for all 37 patients. It is standard practice in our unit to routinely perform a day 1 post-operative contrast swallow for all fundoplications (index or revision surgery) to exclude early a tight/loose wrap, recurrent herniation or iatrogenic leak before commencing oral intake. Success of the RF was determined by subjective patient reported improvements in the severity of the current symptoms that were the reason for revision surgery referral (not the symptoms present prior to index fundoplication). This was ascertained at review two weeks post-surgery and then again after 30 days.

Data exploration and analysis were done using Microsoft Excel and IBM SPSS Statistics (version 28.0.1.1). Patient demographics, surgical history, recurrent symptoms, gastroscopy and contrast swallow findings and complication rates were described using simple descriptive statistics. Parametric data were described using mean with standard deviation and non-parametric data were described using median with inter-quartile range. Ethical approval for the registry (Upper Gastrointestinal Surgery Registry, HREC R031/2015) and this sub-study (HREC 517/2018) were obtained from the Human Research Ethics Committee of the University of Cape Town.

Results

Description of the cohort referred with new or recurrent symptoms post prior fundoplication

There were 37 patients included that underwent revision surgery during the study period of two years. The mean age of the cohort was 52.9 years (range 22 – 77 years, SD = 13.3) at presentation for RF. Twenty-five (67.6%) females and 12 (32.4%) males were included. The mean BMI was 27.1 kg/m^2 (range 22 – 32.4, SD = 5.0). Referring physicians or patients reported the indication for the index or prior fundoplication being GOR (65%), a combination of GOR and another symptom (10.8%), atypical chest pain of non-cardiac origin (8.1%), dyspnoea (5.4%), dysphagia (2.7%) and epigastric pain (2.7%) (*Table 1*). Twenty-nine (78.4%) patients had one prior fundoplication, six (16.2%) had two previous fundoplications and two patients (5.4%) had three prior fundoplications before re-presenting during the study period with symptoms significant enough to warrant repeat investigations.

Table 1: Patient reported symptoms prior to index and revision fundoplication (n=37)

Symptoms prior to index fundoplication:	**Frequency**	**Percentage**
GOR* as dominant symptom	24	64.9%
GOR* plus other symptoms	4	10.8%
Atypical chest pain of non-cardiac origin	3	8.1%
Dyspnoea	2	5.4%
Chronic cough	2	5.4%
Dysphagia	1	2.7%
Epigastric pain	1	2.7%
Patient could not recall	3	8.1%
Symptoms prior to revision fundoplication:		
Dysphagia	19	51.4%
Heartburn	19	51.4%
Epigastric pain	18	48.6%
Volume reflux	16	43.2%
Atypical chest pain of non-cardiac origin	9	24.3%
Bloating	6	16.2%
Nausea	5	13.5%
Early satiety	4	10.8%
Other	6	16.2%

**GOR gastro-oesophageal reflux*

Symptoms prior to revision fundoplication

The most frequently reported symptoms included dysphagia, heartburn, epigastric pain and volume reflux followed by atypical chest pain, bloating, nausea and early satiety (*Table 1*). Other symptoms that were reported included odynophagia, globus sensation and vomiting. The median time in months between the previous fundoplication and referral for RF was 24 months (IQR 2.5 - 66 months).

Endoscopic and contrast swallow findings

Endoscopic findings were available for 35 of the 37 patients who had revision fundoplication (*Table 2*). The most frequent endoscopic finding was a recurrent sliding hiatal hernia which was observed in 42.9% of patients. A slipped wrap was observed in 25.7% and a tight oesophagogastric junction (OGJ) was appreciable in 25.7%. Mixed herniation, paraoesophageal hernia and erosive oesophagitis were less frequent, occurring in 8.6% equally. Additional endoscopic findings included OGJ distortion, gastritis, stasis of distal oesophageal food, eroded pledgets and prepyloric ulceration.

A standard barium contrast swallow was performed for all 37 patients during pre-operative assessment for RF *(Table 2).* The most frequent finding observed in 45.9% of patients was a contrast transit delay across the OGJ into the stomach. A recurrent sliding hiatal hernia (35.1%) and dilated distal oesophagus (35.1%) were observed equally frequently. Reflux was reported occurring during the contrast study in 29.7% of patients. A slipped wrap was noted in 27.0% of patients and in 27.0% mention was made of the presence of tertiary contractions occurring during the radiological study. Para-oesophageal and mixed hernias were observed less frequently, in 10.8% of patients equally. Two patients were referred additionally for high resolution manometry due to concerns for a possible dysmotility of the oesophagus. Both presented with dysphagia for solids and liquids, regurgitation of oral intake, chest discomfort plus evidence of oesophageal dilatation and OGJ hold-up on both endoscopic and radiological investigations. Manometry confirmed complete oesophageal aperistalsis with increased lower oesophageal sphincter pressures and integrated relaxation pressures in keeping with type I achalasia (as per the Chicago Classification of oesophageal motility disorders version 3.0). As both patients developed their

dysphagia some years after their fundoplication surgery, it is not possible to confidently say whether this was an incorrect diagnosis of GOR at the onset, with a missed motility disorder of the oesophagus, or if this was due to oesophageal "burn-out" due to a tight wrap.

Table 2: Endoscopic and contrast swallow findings of 37 patients presenting with recurrent symptoms following prior fundoplication

Endoscopy Findings	**Frequency (%)**	**Contrast swallow finding**	**Frequency (%)**
Recurrent sliding HH*	15 (42.9%)	Contrast transit delay across OGJ[2] into stomach	17 (45.9%)
Slipped wrap	9 (25.7%)	Recurrent sliding HH[1]	13 (35.1%)
Tight oesophageal junction	9 (25.7%)	Dilated distal oesophagus	13 (35.1%)
Mixed hernia	3 (8.6%)	Contrast reflux	11 (29.7%)
Para-oesophageal hernia	3 (8.6%)	Slipped wrap	10 (27.0%)
Erosive oesophagitis	3 (8.6%)	Tertiary contractions	10 (27.0%)
Other	11 (31.4%)	Para-oesophageal hernia	4 (10.8%)
		Mixed hernia	4 (10.8%)
		Other	3 (8.1%)

[1]HH hiatal hernia; [2]OGJ oesophagogastric junction

Intraoperative findings

The most frequent intraoperative finding was significant adhesions with distortion (75.7%) between the distal oesophagus, wrap and crura. Other findings included a recurrent crural defect (51.4%), slipped wrap (45.9%), dense fibrosis between the distal oesophagus and crural inlet (37.8%), OGJ positioned above the diaphragm (35.1%), recurrent sliding hiatal hernia (32.4%),

crural narrowing (24.3%), mixed herniation (10.8%) and para-oesophageal hiatal hernia (8.1%) (*Table 3*). One patient had crural pledgets placed at index surgery eroding through into the oesophageal lumen at the level of the OGJ with significant distal oesophageal stricturing and surrounding fibrosis.

Table 3 Intraoperative findings at revision fundoplication

Intraoperative findings	**Frequency (%)**
Significant adhesions and distortion between distal oesophagus, wrap and crura	28 (75.7%)
Crural defect	19 (51.4%)
Slipped wrap	17 (45.9%)
Distal oesophageal fibrosis	14 (37.8%)
OGJ* above diaphragm	13 (35.1%)
Recurrent sliding hiatal hernia	12 (32.4%)
Crural narrowing	9 (24.3%)
Mixed hernia	4 (10.8%)
Para-oesophageal hiatal hernia	3 (8.1%)

**OGJ oesophagogastric junction*

Revision Fundoplication and Surgical outcomes

The technique of RF included 17 (45.9%) conversions from full Nissen to partial anterior fundoplication (Dor), 10 (27.0%) re-do Nissen's, two (5.4%) conversions from full Nissen to partial posterior fundoplication (Toupet), three (8.1%) complete reversal of fundoplication with oesophagogastric junction adhesiolysis, two (5.4%) crural repairs only (intact wraps) and one (2.7%) opening of a tight crural closure. Two patients (5.4%) presenting with high grade dysphagia, increased integrated relaxation pressures and complete oesophageal aperistalsis on

HRM in keeping with type I achalasia, had their previous Nissen's fundoplications taken down with a subsequent Heller's myotomy and partial anterior wrap performed.

The majority of RF were completed laparoscopically (31; 83.8%). There were five planned open revisions of these, three were performed by thoracoabdominal and two upper midline incisions. Only one conversion occurred; a patient on their fourth revision with dense adhesions required conversion to open surgery. Only four early complications occurred (10.8%). Two patients had urine retention requiring catheterization, one patient developed a urinary tract infection and one had symptomatic basal atelectasis requiring chest physiotherapy. Most patients (34; 91.9%) reported improvements in symptoms at two weeks follow up while three patients reported no improvements. Late symptom recurrence (>30 days post-surgery) occurred in 13 (35%) patients of which the most frequent was persistence of pre-operative symptoms (*Table 4*). None of the patients who were on their second (n=7) and third revisions (n=2) reported complications.

Table 4 presents a summary of late symptom recurrence

Late Symptom recurrence >30 days post-surgery	**Frequency (%)**
Yes	13 (35.1%)
No	24 (64.9%)
Late Symptoms Specified (*n* = 13)	
Persistent symptoms, as before	4 (10.8%)
New dysphagia	3 (8.1%)
Persistent symptoms, but improved	3 (8.1%)
New GOR*/Reflux	2 (5.4%)
Port-site Hernia	1 (2.7%)

**GOR gastro-oesophageal reflux*

Discussion

The popularity of laparoscopic fundoplication surgery peaked around 2000 internationally, with the subsequent realization of the significant long-term recurrence rates, recurrent symptoms, effectivity of proton pump inhibitor therapy and the development of alternative techniques resulting in a subsequent steady decline.[14-16] In patients investigated appropriately and with confirmation of volume reflux, surgical fundoplication remains a good treatment option. However, patients should be made aware of the approximately 5% that may develop late symptoms to a degree that revision surgery is required.[7] While we cannot comment on decisions around the index fundoplication indications and decisions in this cohort, no doubt the considerable number of new and recurrent long-term complications following this type of surgery are discouraging both patients and surgeons alike locally too. As a consequence, in our unit, revision fundoplication surgery is now more frequently performed than new primary anti-reflux procedures. Our time frame between index surgery and RF was similar to the report by Celasin et al; a retrospective study of 43 patients in which the mean time from first operation to the redo operation was 26.3 months.[17] However, a larger prospective cohort of 130 patients documented a mean of 70 months between index surgery and revision.[18] These differences may be due to the fact that the prospective cohort had a larger sample size over a longer period of time.

As our patients were referred specifically for revision surgery, there is no conformity as to their pre-operative assessments for their primary fundoplication. Prior to consideration for revision fundoplication, it is our practice to routinely investigate by repeat gastroscopy and contrast swallow. The need for HRM is individualized and requested if dysphagia dominates with evidence of OGJ hold-up where difficulties differentiating between outflow obstruction from the previous

wrap and possible oesophageal dysmotility disorders exist. The presenting symptoms observed in this cohort prior to revision are congruent with indications reported by other studies on laparoscopic revision fundoplication. Dysphagia, heartburn and epigastric pain predominated. Similarly, Celasin et al (2017) reported 65% of 43 patients representing with heartburn, heartburn and dysphagia, nausea and epigastric pain.[17] A prospective follow-up of 130 patients identified recurrent reflux in 65.3% of the patients who needed reoperation and dysphagia in 34.7%.[18] When comparing the prevalence of symptoms before index surgery to symptoms prior to revision, heartburn is a more common symptom for the index operation while dysphagia is a more common indicator for subsequent revisions.[8] Similar observations were made in this current study, with dysphagia an indication for revision surgery in over half of our patients, while others have reported less dysphagia incidence (20-30%).[19,20]

By nature of the surgery, Nissen fundoplication requires a complete take-down of the natural antireflux barriers around the OGJ; it therefore comes as no surprise that recurrent herniation is so common. Dallemagne et al. reviewed 129 patients who had laparoscopic reinterventions and confirmed herniation (either recurrent sliding hiatal hernia, migration of the wrap above the diaphragm with or without symptoms or para-oesophageal herniation) and wrap slippage to be the most frequent causes of failure.[21] Similar observations have been made by other authors, with the most frequent indication for revision to be either a complete or partial disruption of the wrap, cephalad slippage of the OGJ followed by wrap migration into the chest or the presence of a paraoesophageal hernia.[13,18]

Our most prominent intraoperative findings included dense adhesions with distortion of the OGJ and previous wrap, followed by recurrent crural defects, slipped wrap and herniation. The presence of dense symptomatic adhesions was mentioned by Bell et al, (2015) who reported this in 14% of their cohort that underwent revision fundoplication.[22] A further study of 68 patients who underwent revision, found slippage of the wrap (with or without hiatal hernia) and malpositioned wraps (with or without hiatal hernia) to be the most common findings.[23] Interestingly, dense adhesions were not observed in this study. Perhaps the high incidence of dysphagia in our cohort is in keeping with the high incidence of adhesions encountered locally compared to other reviews.

The most prevalent surgical approach locally was conversion to partial fundoplication, followed by a revision Nissen fundoplication. It is our practice to routinely convert anyone presenting with significant dysphagia to a partial wrap at revision. Two patients presenting with high grade dysphagia and subsequent achalasia diagnosed on HRM had their Nissen's taken down with a subsequent Heller's myotomy and partial anterior wrap performed. It is unclear whether the aperistalsis was due to oesophageal "burn-out" due to a longstanding outflow obstruction related to the previous fundoplication or indeed due to the presence of primary achalasia missed on initial assessment. This highlights the need for adequate pre-operative oesophageal motility evaluation at primary presentation for fundoplication, and as such it is our practice to offer all patients presenting for primary fundoplication an oesophageal manometry. While HRM is not freely available to most clinicians in South Africa (unless based in the major centers), contrast swallows are. Performing these routinely pre-fundoplication will usually raise concerns as to the possibility of an associated oesophageal dysmotility requiring referral for motility studies.

Pneumothorax, pneumonia, and oesophageal leak have been reported as the most common early postoperative complications occurring during revision fundoplication surgery.[11] Our RF procedures had an early success rate of 91.1 %, with most patients reporting improvements of symptoms in the first month. These early success rates were comparable to success rates (70-93%) reported in the literature.[11,17,18] The most common late complications are reported as persistent symptoms, new onset dysphagia and GOR.[11,13,24] This is in keeping with our findings where persistent symptoms recurred in four patients and new onset dysphagia was the most frequent complaint after 30 days. While this specific cohort did not have a long follow-up period, the decrease in severity of both new and recurrent symptoms has been well documented to fortunately improve as the time interval increases from the fundoplication procedure.[24]

While only a very small proportion (0.4%) of revision fundoplications have been reported necessary within the first three months following fundoplication,[25] we are unable to report on accurate local revision rates as most patients are referred following their primary surgery elsewhere. As this is a single-center retrospective study, the findings therefore cannot be generalized to the South African context. In addition, due to the small sample size, associations between patient characteristics and outcomes could not be made. Dysphagia did however seem to dominate strongly compared to other reports as an indication for RF locally. Prospective, multi-center longitudinal studies are necessary to get a more comprehensive picture of fundoplication outcomes and revisions being performed in South Africa. Despite these limitations, this study provides valuable insights into laparoscopic revision fundoplication outcomes, confirming low morbidity and conversion rates in what is often challenging surgery. It is our opinion that specifically dysphagia and significant volume reflux require active re-investigation following a

previous fundoplication, but that all more functional symptoms should be managed conservatively as far as is possible.

Conclusion

This single-center review on revision fundoplication conforms with much of what is written in other studies. Dysphagia is the predominant symptom prompting revision surgery with most patients presenting two years after their initial operation. Despite revision anti-reflux surgery remaining technically challenging, the vast majority of operations were completed laparoscopically with low associated morbidity. Larger, multi-center studies would allow for more clarity as regards revision fundoplication surgery outcomes in the greater South African context.

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