

# Re-operations for failed anti-reflux surgery. Lessons from the Past and Prospects for the Future



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## Re-operations for failed anti-reflux surgery. Lessons from the Past and Prospects for the Future

**OBJECTIVE:** *The total number of re-operations for failed antireflux surgery is increasing dramatically worldwide. We reviewed our experience of re-operations for failed anti-reflux surgery to identify the factors contributing to unsuccessful re-operation which can be used in the era of laparoscopic surgery.*

**METHOD:** *One hundred twentyone patients were re-operated. Only patients whose information responded to 16 variables were included. Those patients who underwent only 1 re-operation, formed group A, and those who had more than 1 re-operation were included in group B.*

**RESULTS:** *Seventy-seven patients entered the study. Fifty-eight patients were included in Group A and 19 in Group B. Thirty-five patients of Group A were male, whilst 12 of Group B were female. Dysphagia was the leading symptom in the 1st and subsequent re-operation. After the initial operation, 21 patients developed a symptom different from the main preoperative one. Nine of these (15%) were in group A, whilst 12 (63%) were in group B ( $p=0.001$ ). Intra-operative peri-esophageal fibrosis during the first re-operation was present in 18% of patients of group A, and 47% of group B ( $p=0.01$ ). The presence of an anatomical defect was most common in patients of group A ( $p=0.02$ ). Mean follow-up was 10.4 years with excellent/good results in 90% of the patients.*

**CONCLUSION:** *These findings will help in informing surgeons about the factors influencing the outcome of re-doing operations for failed anti-reflux surgery. Meticulous diagnosis and operative techniques may permit excellent/good results in this difficult group of patients.*

**KEY WORDS:** Complications, Gastroesophageal reflux, Reoperation, Surgery reoperation.

### Introduction

Although 50 years have lapsed since the introduction of the surgical basis to treat the gastro-oesophageal reflux disease (GERD) <sup>1</sup>, and despite the variety of surgical operations and strategies employed, the common denominator for unsuccessful results is almost constant at approximately 5 - 7% at 5 years, rising to 11 - 14% at 10 years <sup>2-6</sup>. Almost 4 - 6% of dissatisfied patients require a re-operation and the results are unpredictable and inde-

pendent of the experience possessed by the surgeon and the type of re-fundoplication <sup>7</sup>.

In the last few years we have witnessed an evident rise in the rate of published papers on failure and/or complications after antireflux surgery <sup>8-15</sup>. The reason for this is found in the introduction of laparoscopic Nissen fundoplication which has resulted in an 8-fold increase in the rate of failed anti-reflux surgery. The finding that after a refundoplication there is a 6 times higher conversion rate and a 10 times higher mortality rate than for primary antireflux surgery <sup>15</sup> is a matter of great concern. Hence, the importance to know what led to failure to "get the operation right, on at least the second time" is mandatory for patients and surgeons.

With this in mind, this study has been undertaken to elucidate the factors contributing to unsuccessful re-operation following GERD surgery.

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## Material and methods

The discharge summaries of all patients who entered the Department of Thoracic Surgery at Frenchay Hospital in Bristol, England, (1985-1998) and The Department of Surgery, Section of General Thoracic Surgery and General Surgery of the University of Catania (1990-2003), Italy, for symptoms following GERD surgery were reviewed. We identified 255 patients with unsuccessful surgery; of those 121 patients (47.5%) were re-operated on for a total of 141 procedures. The notes of all patients have been carefully reviewed; some of them were only available in microfilms. Barium meal, endoscopy were always performed and functional studies such as manometry and pHmetry have also been examined. All operative notes of the first operation, first re-operation or subsequent operation have been carefully reviewed.

## Criteria of inclusion and exclusion

Criteria to enter the study were to include only patients who have been re-operated, and whose information responded to 16 variables which were tracked (Table I). Intra-operative variables studied were: presence of anatomical defect, presence of fibrosis around the oesophagus, type of wrap (partial or total) and evident technical errors. Patients who underwent only 1 re-operation were included in group A and those who had more than 1 re-operation formed group B. Exclusion criteria were the presence of confirmed primary motility disorders such as achalasia, diffuse oesophageal spasm and oesophageal diverticula at the time of the initial operation.

TABLE I - Variables Studied

Age at 1st operation
Sex
Age at 1st re-operation
Time interval between 1st operation and 1st re - operation
1st operation performed in another hospital
Type of Fundoplication at the time of first operation
Partial
Total
Pre and post-operative symptoms
Intra-operative findings
Fibrosis
Anatomical failure
Nill-Functional disorder
Type of re-operations or fundoplication
Partial
Total
Gastroplasty
Other
Mortality

## Indications for Surgery

All patients underwent therapy with a variety of medications (proton pump inhibitors, H2 receptor antagonist, prokinetic agents). Operation was advised after the persistence of severe clinical symptoms which led to a poor quality of life.

The surgical approach was decided following the patient's anatomic and functional assessment <sup>7</sup>.

### PRE-OPERATIVE STUDIES

Upper gastro-intestinal tract series were performed to identify recurrence of Hiatal Hernia (HH), stenosis, oesophageal shortening and massive GER. Recording of video fluoroscopy was used in difficult cases.

Flexible endoscopy of the oesophagus and stomach was performed in all patients under sedation. The procedure was used in order to discover the size of HH, the presence of esophagitis, Barretts oesophagus, stricture or cancer, and the presence of retained food in the stomach. The position, tightness or disruption of the fundoplication was also evaluated with the retroflexed endoscope. On a subsequent admission manometric study was performed after an overnight fast. The slow and stationary pull-through techniques were used to study the entire oesophagus and upper and lower oesophageal sphincters. Relaxation of the sphincters and the presence of repetitive contractions were noted.

Twenty-four hour pH monitoring was performed selectively to identify any pathological GER. The standard probe was positioned 5 cms above the lower oesophageal sphincter. Anti-acid medications were suspended at least 48 hours before the test.

### DEFINITIONS

The term failure was used when the symptom, which led the patient to undergo surgery in the first instance was still present with the same intensity after the operation.

The term complication was used when the symptom before the 1<sup>st</sup> operation appeared again with greater intensity or if a new, more severe symptom appeared. Intra-operative fibrosis was confirmed by the loss of a surgical plane between the muscular wall of the oesophagus and the mediastinal pleura. Nevertheless, this was only accepted in those patients with a confirmed biopsy of the tissues.

Shortening of the oesophagus was defined when 2.5 cm of intra-abdominal oesophagus was not present after extensive mediastinal dissection and using minimal traction. Anatomical failure was used to include all cases, in which there was a recurrence of HH, the appearance of a para-oesophageal hernia, rupture of the fundoplication or hiatoplasty.

Total fundoplication was synonymous with a Nissen type fundoplication. The term partial fundoplication included Belsey, Toupet or Dor wraps.

The functional results of the operation were classified as excellent if the patient was eating well without medication; good, if the patient had minimal symptoms and occasionally took medication; fair, when the patient required daily medication; and poor, if the symptoms were severe, requiring a re-operation.

#### FOLLOW-UP

The patient was seen at 3, 6, and 12 months after the operation, and then regularly every one or two years to ascertain the long-term results. As usual, the patients were asked about the following clinical symptoms: heart-burn, dysphagia, chest pain, epigastric pain, weight loss, gas bloat and regurgitation. Barium meals were performed prior to discharge from hospital, and at 1 year following the operation. Other tests, such as endoscopy, manometry or 24 hour pHmetry, were performed only when necessary. Interviewers were independent junior staff or consultant.

#### STATISTICAL ANALYSIS

Data relating to patients' demographics were expressed as the mean and range. Between groups, comparisons were performed using t-tests for continuous variables and Fisher's exact test for categorical variables. Significance was taken as a P-value less than 0.05 in each analysis. Statistical analyses were performed using Statistical Package for the Social Sciences (SPSS) Version 14 (Chicago, Illinois, USA).

## Results

Seventy-seven patients entered the study. There were 36 males and 41 females, with a mean age of 54 years. Fifty-eight patients were included in Group A and 19 in Group B. Fifty-one patients were operated on in Bristol, UK, and 16 in Catania, Italy. Eighteen patients of the group B have been operated in Bristol. A total of 101 re-operations have been performed.

## Surgical approaches

Twenty-one patients had the first operation performed in another hospital and the operations were performed by a variety of general and thoracic surgeons. Forty were partial and 37 total fundoplication. Eleven patients had already had more than one operation for GER, when they arrived with us. Preoperative sessions of oesophageal dilatation were performed in 16 patients with stricture. Laparoscopic approach was used at the first operation in 5 out of 47 patients who underwent an abdominal approach. Thirty patients had a transthoracic approach to treat complicated HH and/or GERD.

Laparoscopic attempt to perform a re-operation was made in 1 patient, but we converted to an open procedure. Gastroplasty was performed in 13 patients as previously described<sup>16</sup>. The comparison of factors predictive of outcome between groups A and B is shown in Table II.

TABLE II - Comparison between groups A and B.

	Group A 58 pts.	Group B 19 pts	Significance
Age at 1st operation	56.0	48.5	P=0.06
Sex	35 males 23 females	7 males 12 females	NS
Age at 1st re-operation	57.7	50.8	NS
Interval between 1st op. and 1st re-operation (years)	5.1	2.7	P=0.03
1st op. performed in another hospital	12 (20%)	9 (47%)	P=0.02
Fundoplication at the time of the first operation –			
partial	29	11	NS
total	30	7	NS
Different symptoms than pre-op	9	12	P=0.001
Intra-operative findings at the time of first re-operation			
Fibrosis	11 (18%)	9 (47%)	P= 0.01
Anatomical failure	38 (65%)	9 (47%)	NS
Nill-Functional disorder	9	1	NS
Fundoplication at first re-operation			
Partial	22	10	NS
Total	24	2	NS
Gastroplasty	12	1	NS
Other	–	6	NS
Mortality	0	1	NS

TABLE III - Leading symptoms prior to and after the initial operation (IO) for GER. Some patients presented more than 1 symptom.

Symptom	Patients before IO	Patients after IO
Heartburn	44	22
Dysphagia	15	32
POD	0	5
Epigastric pain	8	1
Gas bloat	-	4
Chest pain	3	5
Shortness of breath	2	2
Vomit	1	5
Regurgitation	2	3
Weight loss	-	5

(Associated)

Other procedures were Roux en Y biliary diversion in 3 patients, pyloroplasty in 2 patients, cholecystectomy in 1 patient. One patient with a right pneumonectomy underwent 2 transthoracic re-operation procedures.

#### SUBJECTIVE RESULTS

Symptoms, before and after the first operation, are summarized in Table III. Between them, heartburn was the most common symptom before the first operation, while dysphagia was the leading symptom to the 1st and subsequent re-operation. After a total fundoplication, 5 patients developed high dysphagia associated with weight loss. After the first operation, 21 patients developed a symptom different from the preoperative one. Of these 9 were in group A whilst 12 were in group B ( $p=0.001$ ).

#### OBJECTIVE STUDIES

Barium meal showed a recurrence of HH in 24 patients, a para-oesophageal hernia in 6, an oesophageal stenosis in 16 patients (3 achalasia and 13 oesophageal stricture), oesophageal shortening in 2 patients and massive GER in 9 patients. Oesophagitis grade III was present in 7 patients. Motility studies, performed in 56 patients, showed a wide range of motility abnormalities, ranging from hypotonic peristaltic contraction to non specific motility disorders and hypertensive lower oesophageal sphincter. All patients with tight fundoplication had a high pressure response to a bolus of water. One patient had scleroderma. Twenty-four hour pHmetry was performed in 35 patients, and pathological GER was diagnosed in 27 patients.

Fibrosis was diagnosed in all 6 patients who had intra-operative biopsy of the tissue around the distal oesophagus.

#### FOLLOW-UP

Follow up is complete, ranging from 2-18 years with an average of 10.4 years.

The long-term clinical results following re-operations were excellent-good in 71 patients (91%). After the first

re-operation, good to excellent results were achieved in 58 out of 77 patients (75%). Nineteen patients had a second or third re-operation, and 13 (62.4%) of them had good results.

The overall mortality was 1.3% (1 out of 77). Mortality was 0% in group A and 5.2% in group B. This patient died due to a leak from an intra-thoracic oesophageal anastomosis after a third re-operation for a complex esophago-gastric problem. One patient developed Barrett oesophagus, 5 years after the re-operation. Two patients died during the follow-up; the first due to a bronchoalveolar carcinoma of the left upper lobe, and the second because of a stroke.

#### Discussion

Unsuccessful results of surgery for GER, is a frustrating event for the surgeon, but far more so for the patient because of the well-known poor quality of life. Crural tightening, recurrent HH, and disrupted malformation of the wrap are the main reported causes of failure of anti-reflux procedures<sup>13,14</sup>. It is also well known that the need for a full pre-operative diagnostic evaluation, including tests such as manometry and 24 hour pHmetry, is mandatory to try and understand the underlying reason which led the operation to fail<sup>7,13,18</sup>.

Age at the time of initial operation seems important. Patients, who had the initial operation performed when they were younger than 50 years old, have shown a risk of having more than 1 re-operation.

Why is a longer interval between the first operation and the first re-operation found more commonly in patients who underwent only 1 re-operation? The answer probably lies in the quality of life (QoL)<sup>18</sup>: patients with a satisfactory QoL prefer to wait. On the contrary, patients with poor QoL generally need and accept the operation earlier.

Our experience shows that when a re-operation is performed for symptoms different from preoperative ones the outcome of the re-operation is unsatisfactory, and the patient needs a second re-operation. Dysphagia is, in the present experience, the most common symptom following unsuccessful GER surgery: it generally suggests the presence of a tight or long fundoplication<sup>19</sup> or tight hiatus. In our experience the presence of dysphagia following primary repair is associated with negative outcome of the re-operation, requiring often a second re-operation. The finding that the most challenging patients are those with post-operative dysphagia has also been reported by Smith et al<sup>11</sup>. Furthermore 5 of our patients presented high dysphagia as primary symptom. Postoperative high dysphagia should not be underestimated as it can be an indicator of a tight fundoplication<sup>20</sup>.

#### FACTORS CONTRIBUTING TO FAILURE

Surgeons performing re-operation for failed GERD



surgery know that there is often fibrosis involving the distal oesophagus and gastro oesophageal junction<sup>12, 21, 22</sup>. Our study shows that the presence of perioesophageal fibrosis during the re-operation is associated with failure of the re-operation. The common belief that fibrosis is more common in open surgery than laparoscopic surgery has not been demonstrated to be true; in fact fibrosis has also been described after laparoscopic surgery for GERD<sup>23-26</sup>. The reason why fibrosis is found after laparoscopic surgery for GERD is probably due to the excessive mediastinal dissection during isolation of the distal oesophagus or from the use of cautery. Fibrosis causes more difficulties during re-operation, and it can be very difficult to distinguish the longitudinal muscle of the oesophagus. During the dissection the possibility of intra-operative vagal nerve injury or oesophageal wall damage is not uncommon; therefore it can be possible to transform an anatomical fundoplication failure into a more complex esophago-gastric functional disorder.

Dense mediastinal adhesion is one of the reasons which obliged some authors to transform a laparoscopic approach into a thoracotomy<sup>8</sup>. The presence of mediastinal adhesions should therefore not be underestimated when planning the re-operation.

Although today, it seems logical to offer the minimally invasive approach to patients with failure or complication after anti-reflux surgery, the appropriate surgical approach for a re-operation is still unclear: in fact open abdominal, laparoscopic<sup>9,19,27</sup>, trans-thoracic<sup>7,13,21,22</sup> or thoracoabdominal<sup>28</sup> approaches are used by surgeons on the basis of their own experience, and only few surgeons tailor the operation according to the patient's need<sup>29</sup>. Although Luketich demonstrated that laparoscopic re-operations for GERD can be performed safely with complication and success rate similar to open operations, in a centre with an extensive laparoscopic experience<sup>27</sup>, the length of the follow-up is too short (18 months) before definitive conclusion can be accepted by the surgical community. Nevertheless Soper and Dunnegan converted 1 out of six patients to thoracotomy during a laparoscopic re-operation, because of dense mediastinal adhesions<sup>8</sup>, Floch reported good results of laparoscopic re-operation, despite the technical difficulty of the procedure<sup>19</sup> and Collard found tight adhesions, even following laparoscopic anti-reflux surgery<sup>30</sup>.

The trans-thoracic approach is criticised because of inexperience, lack of thoracic surgery in the hospital and the risk of pulmonary complications<sup>12</sup>. Based on our experience we still think that, in the era of minimally invasive surgery, the transthoracic approach should always be taken in consideration in the case of long lasting recurrent para-oesophageal HH, true shortening of the oesophagus or if a dense peri-oesophageal fibrosis is suspected. The transthoracic approach allows full mobilisation of the oesophagus and complete visualization of the cardia, upper stomach and fundoplication<sup>7,13,21,28,29</sup>. Our experience shows that the kind of total or partial

wrap used during the first re-operation does not correlate with the outcome. Recently, some authors advocate inserting a mesh to reinforce sutured cruroplasty in all patients with recurrent herniation of the stomach<sup>14</sup> but we have never used one in our patients.

In group A, several patients underwent gastroplasty with good results demonstrating the efficacy of the technique for complex oesophageal problem.

It should be noted that, in group B, a number of different procedures have been performed ranging from a Roux en Y reconstruction to an esophagectomy with gastric or colon reconstruction<sup>32,33</sup>. The reason why several procedures are included in group B can be explained by the fact that, at this stage, the oesophageal wall and vagal nerves are often damaged or devascularised by previous operations. We can speculate that, if the first re-operation fails, the patient has a good chance to develop a complex functional disorder, because of muscular wall devascularisation and vagal nerve damage secondary to surgical manipulation.

Skinner demonstrated that after the second and subsequent re-operation, good results can be achieved only in 33-50% of patients, and mortality is higher<sup>22</sup>; therefore an early esophagectomy can be suggested to treat patients with previous anti-reflux procedures. Gadenstatter et al. demonstrated that in case of total loss of oesophageal motility and in cases of undeletable stricture, an esophagectomy can be safely performed with no mortality and a success rate of almost 100%<sup>33</sup>.

#### OUTCOME OF THE RE-OPERATION

Our experience shows overall excellent-good results in 90% of patients. The presence of an anatomical defect as cause of failure of GER surgery, is associated with excellent or good results in almost 100% of patients, and this has been reported by others too<sup>5, 17</sup>. It is well demonstrated in our experience that the percentage of failure increases with each re-operation going from 75% after the first re-operation to 64.5% after 2 or 3 re-operations. The mortality after the first re-operation was zero. Five per cent mortality after 2 or 3 operations has been found by other surgeons with similar experience.

#### POTENTIAL LIMITATIONS

There are some limitations to this study. The primary limitation is that it is a retrospective study. Most of our patients have been operated by a non-laparoscopic technique, and the fact that we attempted only one laparoscopic procedure can be criticised by laparoscopic surgeons. Another limitation is the small number of patients with the potential risk of type II errors. The extent to which non diagnosed motility disorders known to be pre-existing, or caused by damage to the oesophageal wall, by repeated operations, contributed to failure could not be accurately estimated.

#### PROSPECTS FOR THE FUTURE

Looking forward to the next 20 years, we believe that efforts should be made mainly in the area of prevention; in fact, we believe that the most powerful tools to decrease the number of failed antireflux surgery are the proper selection of patients and meticulous surgical technique at the time of initial operation. To achieve this challenging goal, the surgeon operating on patients with GERD needs not only practical skills but also he/she must have competence in oesophageal pathophysiology. The evolving technology such as EUS of the fundoplication and hiatal region will provide more detailed information regarding the integrity and the position of the fundoplication<sup>34</sup>. More physiologic tests further permit a precise functional diagnosis in those difficult groups of patients without an anatomical or technical complication after surgery. Surgeons will operate on fewer patients because of the introduction of more sophisticated diagnostic tools and drugs. Surgeons will prefer to re-operate earlier to avoid the late complications of periesophageal fibrosis.

Controversies regarding the most appropriate surgical approaches hinder progress. We feel in fact that real improvement will be obtained when the surgeon will choose the operative strategy on the basis of pre-operative functional and objective tests. Then surgery will be transabdominal (open or laparoscopic) or transthoracic according to the patient's need, and not to the surgeon's preference.

As with the experience of cancer centers, the centralisation of patients in a single specialist unit seems also necessary to improve re-operation outcomes.

#### Conclusion

These findings will help to inform surgeons about the factors influencing the outcome of re-doing operations for failed anti-reflux surgery. Re-operations for failed or complicated antireflux surgery can achieve excellent/good long term results in 90 % of patients. The selection of patients and a meticulous tailored surgical technique are the key to successful management of failed antireflux surgery.

#### Riassunto

SCOPO DEL LAVORO: Il numero degli interventi per insuccesso della terapia chirurgica del reflusso gastroesofageo sta incrementando drammaticamente in tutto il mondo. Abbiamo rivisto la nostra esperienza sugli interventi per insuccesso della terapia chirurgica del reflusso gastroesofageo con l'obiettivo di identificare i fattori che contribuiscono all'insuccesso del re intervento che possono essere usati nell'era della chirurgia laparoscopica.

METODO: 121 pazienti sono stati sottoposti a re-inter-

vento. Solo i pazienti le cui informazioni erano complete per rispondere a 16 quesiti sarebbero stati inclusi. I pazienti che sono stati sottoposti ad un solo reintervento hanno formato il gruppo A mentre coloro che erano stati sottoposti a più di un reintervento formavano il gruppo B.

RISULTATI: 77 pazienti sono stati inclusi nello studio. 58 pazienti formavano il gruppo A e 19 il gruppo B. 35 pazienti del gruppo A erano maschi mentre 12 del gruppo B erano femmine. La disfagia era il sintomo più presente nei pazienti sottoposti a re intervento. Dopo il primo intervento, 21 pazienti hanno sviluppato un sintomo differente del preoperatorio. Nove di questi pazienti (15%) appartenevano al gruppo A, mentre 12 (63%) al gruppo B (p=0.001). La fibrosi periesofagea era presente nel 18% dei pazienti del gruppo A e nel 47% dei pazienti del gruppo B (p=0.01). La presenza di un difetto anatomico era più comune in pazienti del gruppo A (p=0.02). Il follow up medio è di 10,4 anni con risultati buoni/eccellenti nel 90% dei pazienti.

CONCLUSIONI: Questo studio permette di informare i chirurghi sui fattori che influenzano i risultati del trattamento chirurgico dei re-interventi in caso di insuccesso della terapia chirurgica del reflusso gastro-esofageo. L'accurata diagnosi e quindi una precisa indicazione chirurgica associata a una appropriata tecnica operatoria permettono il conseguimento di risultati buoni/eccellenti nel 90 % dei pazienti.

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