Minimally Invasive Therapy for GERD - An Update

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Introduction

Gastro-oesophageal reflux disease (GERD) is a condition characterized by symptoms caused by the reflux of gastric and/or duodenal contents into the distal oesophagus. The classical symptoms include retrosternal burning discomfort, belching and dyspepsia. GERD may also manifest with extra-intestinal symptoms such as chronic cough, asthma and chronic pharyngitis. Definitive diagnosis of this condition relies on upper GI endoscopy, oesophageal pH and motility studies. However characteristic symptoms are usually sufficient in most cases. The basic pathophysiology of GERD involves a combination of abnormal oesophageal motility, lower oesophageal sphincter (LES) mechanism and gastric emptying. Apart from having an undesirable impact on the quality of life, GERD may eventually result in adenocarcinoma of the oesophagus through a number of intermediate conditions including Barrett’s oesophagus. Potent gastric acid suppression with proton pump inhibitors (PPI) is the mainstay of treatment. Medical treatment is not only efficacious in achieving symptoms relief and healing of oesophagitis, it also carries no immediate safety concern and a low short term cost. However, despite its efficacy in symptoms relief, acid suppression by PPI may not prevent GERD complications as the reflux of gastric and duodenal contents may continue since the mechanisms leading to reflux are not corrected. Relapse rates as high as 80% after discontinuation of PPI has also been reported. Although relapse may be managed by longer term PPI, but the effect of prolonged gastric acid suppression by PPI is unknown. Concerns such as carcinogenesis from chronic hypergastrinaemia, bacterial overgrowth, etc remain to be settled. It is therefore not surprising that there are still keen interests in alternative treatment modalities for the treatment of GERD.

Minimally Invasive GERD Therapy

The main treatment modalities under this heading include the various types of laparoscopic anti-reflux surgery and endoscopic therapy.

Indications

Before considering minimally invasive therapy for GERD, it is recommended that patients undergo both an upper GI endoscopy with biopsy where appropriate and an oesophageal manometric evaluation. In selected patients, further assessment by 24-hour oesophageal pH monitoring and contrast swallow may be useful. There is no absolute indication for non-medical treatment for GERD per se, the relative indications include:

A. Failed medical therapy.
B. Patient’s choice despite successful medical management (due to life style considerations including age, time or expense of medications, etc.)
C. Complications such as Barrett’s oesophagus or severe oesophagitis.
D. Complications such as bleeding or dysphagia attributable to a large hiatal hernia.
E. Refractory atypical symptoms and reflux documented on 24-hour pH monitoring.

Laparoscopic Surgery

Surgery has hitherto been the only treatment that is able to correct the underlying abnormal mechanisms proposed to have led to GERD. Although surgery for oesophageal reflux and hiatal hernia has been around since the 1960s, it only gained popularity after the advent of laparoscopic surgery. The laparoscopic technique offers the advantages of rapid recovery, low morbidity, better cosmetic results, decreased pain and low overall cost. Laparoscopic fundoplication is now the ‘gold standard’ for the surgical management of GERD, excellent long-term results in 80-93% of surgically treated patients have been reported in recent literature. Popular surgical approaches include the Nissen fundoplication, which is a 360-degree wrap (Fig. 1). Other modifications such as the Lind, Dor or Toupet are partial wraps and they were found to have no significant difference at preventing reflux and a lower incidence of re-operation for failure as compared with the Nissen fundoplication. The Hill repair attempts to restore the gastroesophageal junction with posterior anchoring and reconstruction of the flap-valve mechanism, calibration of the cardia and intraoperative measurement of the lower oesophageal sphincter pressure. It is a ‘no wrap’ procedure that is technically very demanding.

Figure 1 Nissen Fundoplication

Three factors determine the outcome and success of antireflux surgery: good indication after a thorough preoperative assessment, correct choice of surgical procedure and the performance of a good quality operation. The last factor appears...
to be dependent on the level of experience of the surgeon\textsuperscript{10}. After 5 to 8 years follow-up, 96.5\% of patients who had a laparoscopic Nissen fundoplication were satisfied with the result\textsuperscript{11}. Fourteen percent of patients remained on continuous PPI but 79\% of them were prescribed for non-specific chest or abdominal symptoms unrelated to reflux. In one of the largest randomized trial comparing antireflux surgery with long-term omeprazole, surgery was found to be superior in improving symptoms and endoscopic oesophagitis\textsuperscript{12}. Quality of life was also found to be better in patients following laparoscopic fundoplication compared with medical therapy\textsuperscript{13}.

**Endoluminal therapy for GERD**

Endoluminal therapies for GERD have rapidly evolved over the past few years. These minimally invasive approaches have move from the laboratory to clinical trials with some being available for general clinical use. Most can be carried out by a skilled endoscopist using conscious sedation in an outpatient fashion. The basis for these procedures has focused on the LES region and attempts to reinforce the anti-reflux barrier. This has been accomplished in a number of ways including:

1. Placement of biocompatible substances/prosthesis into the LES, e.g.- Enteryx (Boston Scientific), Gatekeeper (Medtronic).
2. Radiofrequency energy delivery, e.g.: - Stretta (Curon Medical).
3. Endoscopic suture plication, e.g.: EndoCinch (Bard), NDO Plicator (NDO Surgical).

**Enteryx**

Enteryx is a radio-opaque non-resorbable biocompatible polymer composed of 8\% ethylene vinyl alcohol in DMSO. It is injected circumferentially within and along the muscle layer of the LES. This elicits an acute inflammatory reaction of the surrounding tissue. Over time, with resolution of the inflammation, fibrous encapsulation of Enteryx occurs. The altered compliance of the LES forms a more effective reflux barrier. No randomized trial has been published to date. A prospective multicentre trial involving 85 patients reported symptomatic relieve and correction of the lower oesophageal pH in over 80\% of patients at 12-month follow up\textsuperscript{14}. However there was no improvement in oesophagitis grades as assessed endoscopically. No major complication has been reported but transient retrosternal chest pain was experienced by 91.8\% of patients.

**Stretta**

The Stretta procedure uses a radiofrequency (RF) energy-emitting device which when placed across the lower oesophagus and gastric cardia would create minute thermal lesions of the adjacent muscle layer. The result is collagen contraction when these lesions heal, which decreases LES compliance, increases LES muscle mass and limits the inappropriate transient LES relaxation responsible for GERD in many patients. This may be repeated several times to produce the desirable effect. It has been shown to improve GERD symptoms, quality of life, reduce oesophageal acid exposure, and eliminate the need for PPI in the majority of patients at 12 months\textsuperscript{16}. So far, this is the only endoscopic anti-reflux procedure that has been shown to be effective in a sham-controlled trial\textsuperscript{17}.

**EndoCinch**

This is one of the first endoscopic suturing devices that was openly available to the market. A number of sutures are placed into the mucosal folds of the LES region after having been sucked into the device. This, in effect, mimics a gastroplasty and creates valve-like pleats, which prevent reflux. Significant improvement in symptoms, acid exposure, quality of life and reduced drug use at 12 months post procedure has been reported\textsuperscript{18}. However, there is no evidence that reflux-related complications could be prevented. As the sutures are not full-thickness, they may cut through and fail in the longer term. Comparison with laparoscopic fundoplication indicated that endoscopic gastroplasty is not as effective in reducing PPI use and maintaining patient satisfaction\textsuperscript{19}.

**Gatekeeper**

This system involves the implantation of a pin-like hydrogel prosthesis into the submucosa of the LES. Once implanted, the prostheses expand thus causing the LES mucosa to oppose. One of the advantages it has over endoscopic treatments currently being developed is its reversibility\textsuperscript{15}. Little data regarding this method are available.
NDO Plicator

Full-thickness serosa-to-serosa sutures are placed under direct endoscopic visualization with this device. The provision of a single pre-tied implant for each suture also avoids the tedious task of extra-coporeal knot tying as in the case of the EndoCinch. It has the theoretical advantage of a more permanent effect. A multicentre study involving 64 patients with 6 months follow up revealed improved symptom scores and discontinuation of reliance on daily PPI in over 70% of patients.

Conclusion

In conclusion, short and long term results following laparoscopic fundoplication for GERD are excellent in terms of symptoms control and avoidance of long-term use of medication. Nonetheless, there are benefits and risks to both medical and surgical treatments and longer-term issues for both therapies remain unresolved. As for the novel endoscopic anti-reflux procedures, most can achieve good symptomatic relieve. However large-scale risks to both medical and surgical treatments and longer-term issues for both therapies remain unresolved. As for the novel endoscopic anti-reflux procedures, most can achieve good symptomatic relieve. However large-scale studies and long term results are lacking. They also share the limitations that the hiatus is not repaired and the OGJ is not returned to the abdomen. For these reasons they have largely remain experimental while more advanced technology and good quality outcome data are pending.

References