

Endoscopic treatment of gastroesophageal reflux disease

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Abstract

Gastroesophageal reflux disease (GERD) is a highly prevalent condition and one of the most frequent causes of medical consultation. Traditional treatments consist of life-style changes, pharmacologic and surgical treatments. In recent years, various endoscopic treatments for GERD have been described and studied, and some of them have emerged as safe and effective alternatives to conventional treatments. The most studied are radiofrequency application to the gastroesophageal junction, incisionless transoral fundoplication, endoscopic suturing of the esophagogastric junction, and other novel techniques such as endoscopic transmural plication, endoscopic mucosal ablation, and endoscopic mucosal resection. This article discusses the scientific evidence on the indications, outcomes, adverse events, and role of the various endoscopic treatments for GERD treatments.

Keywords: Gastroesophageal reflux disease. Endoscopic treatment. Incisionless transoral fundoplication. Endoscopic suturing. Radiofrequency ablation.

Tratamiento endoscópico de la enfermedad por reflujo gastroesofágico

Resumen

La enfermedad por reflujo gastroesofágico (ERGE) es altamente prevalente y ocupa los primeros lugares en la búsqueda de atención médica. Los tratamientos tradicionales para la ERGE consisten en cambios en el estilo de vida, tratamiento farmacológico y cirugía. En los últimos años se han descrito y estudiado diversos tratamientos endoscópicos para la ERGE y algunos de ellos han emergido como alternativas seguras y eficaces a los tratamientos convencionales. Los más estudiados son la aplicación de radiofrecuencia en la unión gastroesofágica, la funduplicatura transoral sin incisiones, la sutura endoscópica de la unión esofagogástrica y otras técnicas novedosas como la plicatura endoscópica transmural, la ablación y la resección endoscópica de la mucosa. En este artículo se discute la evidencia científica sobre las indicaciones, los desenlaces, los eventos adversos y el papel de los diversos tratamientos endoscópicos para la ERGE.

Palabras clave: Enfermedad por reflujo gastroesofágico. Tratamiento endoscópico. Funduplicatura transoral sin incisiones. Sutura endoscópica. Ablación por radiofrecuencia.

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Introduction

Gastroesophageal reflux disease (GERD) originates from the retrograde flow of gastric contents into the esophagus and is defined as a broad spectrum of symptoms and complications that interfere with the patient's quality of life¹. It is one of the main reasons for consultation for both primary care physicians and gastroenterologists, with a prevalence of approximately 20% of the general population¹.

Currently, various therapeutic tools are available to address GERD, which should be individualized according to the patient's characteristics. Among the available treatments, on one hand, there is medical treatment that includes lifestyle changes and medications, and on the other, interventional treatment with surgical and endoscopic options.

Endoscopic treatments for GERD (ET-GERD) have been available since the first decade of the 21st century and have been refined and studied in parallel with technological advances.

ET-GERD comprises various types of endoluminal procedures^{2,3} that are worth categorizing according to the techniques used: radiofrequency ablation, endoscopic fundoplication, transmural endoscopic suturing, and mucosal ablation/resection procedures. Each of these treatments has a role in the GERD spectrum and must be carefully selected, as discussed in this article.

To understand the various ET-GERD, it is first necessary to understand the anatomy of the esophagogastric junction (EGJ) and its role in the pathophysiology of GERD.

Anatomy of the esophagogastric junction

The antireflux barrier at the EGJ is composed of two structures connected by the phrenoesophageal ligament: the lower esophageal sphincter (LES) and the diaphragmatic crura. In turn, the LES is composed of circular smooth muscle fibers of the distal esophagus and muscle fibers of the proximal stomach that form a sling that, when contracted, accentuates the esophagogastric angle³. The presence of a hiatal hernia generates an anatomical disruption by separating the LES from the diaphragmatic crura³.

ET-GERD have a role in restoring LES competence, especially in patients without a hiatal hernia. These treatments hypothetically act by preventing LES shortening when the stomach distends, by improving LES resting pressure, and by reinforcing the sling fibers³.

The Hill classification (Table 1) is useful for evaluating hiatal morphology. Adequate assessment is considered essential for correctly selecting candidates for the various ET-GERD^{3,4}.

Radiofrequency ablation (Stretta®)

The Stretta® system is based on the application of radiofrequency to the LES muscle through a catheter-balloon with electrodes. Radiofrequency application modifies the neuromuscular functions of the distal esophagus with an increase in LES resting pressure, decreasing transient LES relaxations and reducing EGJ distensibility^{3,5}. This latter benefit does not appear to be due to tissue fibrosis, as it can be reversed with sildenafil⁵.

Indications

Stretta® can be used in patients with reflux but without anatomical disruption of the EGJ (closed sphincter and hiatal hernia < 2 cm).

Short- and long-term outcomes

In the short term, Stretta® has shown efficacy in symptom control. In two randomized clinical trials, it demonstrated improvement in GERD symptoms and quality of life^{5,6}.

These results appear to be maintained in the long term. In a 4-year follow-up, 75% of patients did not require continuation with proton pump inhibitors (PPIs)⁷. Along the same lines, a prospective study of patients (n = 217) with refractory GERD found sustained efficacy at 10 years in quality of life and decreased PPI use⁸. However, this latter effect has not been consistently reproduced, and the results are contradictory^{9,10}.

On the other hand, Stretta® also does not consistently reduce acid exposure time or the proportion of patients with erosive esophagitis^{5,6}. Therefore, it is thought that the benefits observed with Stretta® have more to do with modulation of reflux sensitivity than with a benefit on total acid exposure time⁵.

In general, there is a contradiction among published studies on Stretta®, as randomized clinical trials show non-significant results, with a high risk of bias, while cohort studies show favorable outcomes¹¹. When performing meta-analyses with published studies, the certainty of evidence is low, with risk of bias and high heterogeneity, without showing benefits in any of the important outcomes, such as PPI discontinuation,

Table 1. Hill Classification for endoscopic evaluation of hiatal morphology

Type	Description
1	Well-closed tissue fold that hugs the endoscope with a length of 3-4 cm toward the lesser curvature
2	The tissue fold does not completely hug the endoscope or hugs it variably during respiration, and is generally shorter than the normal length
3	The fold does not consistently compress the endoscope and the fold length is very shortened
4	There is a hiatal hernia; the endoscope is not compressed and the fold is not identified

reduction of acid exposure time, symptom resolution, or reduction of reflux and quality of life scale scores¹¹.

Adverse effects

In a meta-analysis, the rate of adverse effects was higher in patients treated with Stretta® (42%) than in those who received a PPI or placebo (11%) (relative risk [RR]: 3.06; 95% confidence interval [95% CI]: 1.09-8.6; $p < 0.01$)¹¹.

In general, most adverse effects can be managed with medical treatment. The most commonly reported complications with the use of Stretta® are ulcerative esophagitis and gastroparesis^{12,13}. Other minor adverse effects have also been reported, such as pain, low-grade fever, and dysphagia³. Infrequently, deaths from aspiration pneumonia have occurred. Other serious adverse effects, such as esophageal perforation, are rare and have been associated with errors in patient selection and procedure execution³.

In conclusion, Stretta® is not recommended as an alternative to medical or surgical treatment in national¹ and international^{11,14} guidelines, so its use should currently be limited to patients with hiatal hernias < 2 cm and Hill 1 or 2 hiatal anatomy, and when one of the standard treatments is not available or not feasible, either due to contraindication or patient preference¹⁴.

Transoral incisionless fundoplication

Transoral incisionless fundoplication (TIF) consists of creating a 3-cm, 270° gastroesophageal antireflux valve in an omega shape that resembles the geometry and symmetry of the normal LES².

The procedure is performed with the EsophyX® device, which has been approved by the Food and

Drug Administration (FDA) since 2007, and consists of folding the gastric fundus around the distal esophagus, reinforcing the sling fibers, accentuating the angle of His, and improving the valve mechanism³. The device has been refined for automation and standardization purposes, and its current version (TIF 2.0) incorporates a rotational mechanism of the cardia and gastric fundus around the distal esophagus².

From a physiological standpoint, TIF reduces transient LES relaxations, postprandial LES relaxations associated with reflux, esophageal acid exposure, the number of reflux events, and EGJ distensibility measured by endo-FLIP (Endoscopic Functional Imaging Luminal Imaging Probe)¹⁵.

Indications

TIF can be considered in patients with GERD with conclusive evidence of reflux by endoscopy (esophagitis B, C, or D), pH monitoring (acid exposure time $> 6\%$, > 80 reflux episodes, nocturnal baseline impedance > 1500 ohms) who have favorable anatomy for the procedure (hiatal hernia < 2 cm and hiatal morphology type 1 or 2) and who meet one of the following characteristics^{11,16}: chronic reflux (> 6 months), chronic PPI use (> 6 months), refractory GERD, GERD with predominant regurgitation, or preference to avoid chronic PPI use.

In patients with a hiatal hernia > 2 cm, TIF can be combined with hernia repair during the same anesthetic event. This indication is approved by the FDA and considered by guidelines, although with a lower level of evidence^{3,11}. In patients with refractory GERD (acid exposure time $> 4\%$ and > 80 reflux episodes, despite treatment), TIF does not replace surgical fundoplication, which is the most studied treatment¹⁷.

A critical step in selecting TIF candidates is a good evaluation of hiatal morphology using the Hill classification, as alterations in the diaphragmatic opening are commonly underestimated. In a retrospective study of five patients who did not improve with TIF, three had a hiatal hernia > 2 cm that had not been diagnosed³.

To avoid underestimation of the diaphragmatic opening, it is recommended to observe the hiatus in retroflexion for at least 60 seconds and under optimal insufflation³.

Patients with GERD after peroral endoscopic myotomy and those who will undergo a gastric sleeve procedure are also potential candidates for TIF use, but more published evidence is required³.

Short- and long-term outcomes

The TEMPO study was one of the first randomized clinical trials comparing TIF versus high-dose PPIs¹⁵. In this study, 63 patients with GERD with predominant regurgitation or extraesophageal symptoms were randomized to be treated with TIF (n = 40) or high-dose PPIs (n = 23). After 6 months, 97% of patients with TIF were free of regurgitation, in contrast to 50% of those who received PPIs (RR: 1.9; 95% CI: 1.2-3.11; p = 0.006). Acid exposure time was normalized in 54% of the TIF group and 52% of the PPI group (RR: 1.0; 95% CI: 0.6-1.7; p = 0.914). Ninety percent of TIF patients were able to discontinue PPIs and achieved a 100% erosive esophagitis cure rate¹⁵.

In a meta-analysis of three randomized clinical trials on TIF versus PPI or placebo (n = 233), TIF showed significant changes in terms of acid exposure time, lower PPI use, and better quality of life¹⁸.

In another meta-analysis, patients undergoing TIF, compared to placebo or chronic PPI use, had better PPI discontinuation rates, greater reduction in PPI use, greater symptom resolution, and lower acid exposure times, although not completely normalized¹¹.

TIF has been found to have lasting benefits¹⁹. In a meta-analysis that included eight studies of patients (n = 418) undergoing TIF with an average follow-up of 5.3 years (range: 3-10 years), patients with TIF had greater satisfaction than before the procedure. The rate of patients free of PPIs in those treated with TIF was 75.8% (95% CI: 67.6-82.6) and the rate of normalization of heartburn and regurgitation was 86% (95% CI: 75-91)¹⁹.

Adverse events

Adverse effects can be managed in their vast majority conservatively and include chest pain, nausea, vomiting, abdominal pain, hemorrhage, aspiration, fever, and dysphagia¹¹. Serious adverse effects, such as perforation, are rare^{11,20,21}.

One study analyzed adverse event reports to the FDA in patients undergoing TIF. Over a 10-year period, 95 serious adverse events and 131 patients with complications were reported²⁰. The most frequent adverse event was perforation (19.8%), followed by lacerations (17.6%), hemorrhage (9.2%), and pleural effusion (9.2%). In most cases, adverse events could be managed conservatively with endoscopy (clips (12.3%), esophageal stents (8.6%) or chest tube (12.3%), and only a small percentage required surgery (11.1%)²⁰.

In a meta-analysis that included 781 patients undergoing TIF, 19 serious adverse events were found,

representing an incidence of 2.4%²⁰. Serious adverse events reported were esophageal perforation (0.9%), post-TIF hemorrhage (0.65%), and pneumothorax (0.5%)²¹.

In a meta-analysis of four randomized clinical trials, adverse events were analyzed in 188 patients undergoing TIF and 105 patients who received PPI or placebo¹¹. The rate of adverse events was higher in patients with TIF compared to PPI or placebo (37.8% vs. 14.3%; RR: 2.56; 95% CI: 1.36-4.81; p < 0.01); however, when analyzing the rate of serious adverse events, there was no statistically significant difference (8% vs. 1.9%; RR: 2.94, 95% CI: 0.94-9.19; p < 0.01)¹¹.

In conclusion, TIF is a safe and effective procedure in the treatment of GERD. International guidelines establish that it can be considered as an alternative to medical treatment in carefully selected patients with hiatal hernia < 2 cm, Hill 1 or 2 hiatal morphology, and without severe erosive esophagitis^{11,14}. Mexican guidelines recognize the utility of TIF, but with the limitation that it is not available in Mexico¹.

Endoscopic suturing

Endoscopic suturing can be used to approximate tissues and improve the antireflux barrier. Several described techniques are generally performed in a frontal view, in contrast to TIF, which is performed in retroflexion³. These techniques use the OverStitch® device (Apollo Endosurgery, Austin, Texas, USA).

Described techniques include simple suturing with interrupted stitches at the cardia, the combination of suturing with mucosal ablation (MASE, mucosal ablation and suturing of the esophago-gastric junction), and the combination of suturing with mucosal resection (RAP, resection and plication)^{2,3}. All have the common goal of narrowing and elongating the EGJ.

Indications

Endoscopic suturing may have a role in patients with GERD who are not candidates for surgical or endoscopic fundoplication, such as those with anatomy altered by previous surgeries (esophagectomy, Billroth II, Roux-en-Y, or gastric sleeve).

Short- and long-term outcomes

In a prospective pilot study of patients with GERD (n = 10), endoscopic suturing was performed with a dual-channel endoscope using the Apollo OverStitch™

device. Sutures were placed with simple stitches from 12 to 3 o'clock and from 4 to 6 o'clock, in order to decrease the EGJ diameter. There was significant improvement in GERD and quality of life, but the duration of symptomatic improvement was only 1-month (range: 0.5-4 months)²².

MASE appears to improve results. In a prospective study, 27 patients with GERD underwent argon plasma ablation of the gastric mucosa below the EGJ followed by endoscopic suturing with an Apollo OverStitch™ device with interrupted stitches. After the procedure, in an average follow-up of 124 days (range: 34-338 days), 13 of 22 (59%) patients were able to discontinue PPIs, and 3 of 22 (14%) were able to reduce the dose²³. A notable aspect of this study is that 7 of 27 patients (26%) had anatomy altered by previous surgery: fundoplication (n = 4), Billroth II (n = 1), Roux-en-Y (n = 1), and gastric sleeve (n = 1).

A variant of the procedure is the RAP combination²⁴. In a pilot study of patients with GERD with typical symptoms, documented with objective tests and failure of PPI treatment, 10 patients underwent RAP. Mucosal resection (2 cm) was performed on the posterolateral axis aligned with the greater curvature, with standard endoscopic mucosal resection technique with snare or with band ligation resection using the Cook Duette® device. The chosen anatomical area is the zone with the greatest overlap of sling fibers. Endoscopic suturing was performed with an Apollo OverStitch™ device and was directed toward the exposed muscular fibers with a continuous suture technique in an indented pattern. In 100% of patients, Hill 1 hiatal morphology was achieved after the procedure. With a follow-up of 5-24 months (median: 9 months), all patients had significant improvement in GERD and quality of life scores, and 80% were able to reduce PPI doses²⁴.

In another pilot study, RAP was performed on 26 patients, and a 100% technical success was obtained. Of these, 18 (69%) had anatomy altered by previous surgeries, such as esophagectomy (n = 4), Roux-en-Y (n = 4), gastric sleeve (n = 2), failed Nissen fundoplication (n = 5), failed TIF (n = 2), and endoscopic sleeve gastropasty (n = 2). After an average follow-up of 6 months, significant improvement in reflux and quality of life was found, and 60% of patients were able to discontinue or reduce PPI dose²⁵.

Adverse events

None of the pilot studies discussed reported serious adverse events. In the simple suturing study, one patient

had nausea and vomiting after the procedure that improved after 2 days of antiemetic treatment²².

In the case of MASE, 22% of patients had epigastric pain, and one patient required hospital admission for analgesia. There were no immediate or late complications²³.

Finally, in the RAP pilot study, 1 of 10 patients had intermittent dysphagia after 1 month of the procedure that was treated with endoscopic dilation²⁴.

In conclusion, technical variants of endoscopic suturing are heterogeneous. Those that combine endoscopic suturing with ablation or mucosal resection appear to be more effective than simple suturing, without serious adverse effects reported.

At this time, the main role of endoscopic suturing appears to be for those patients with anatomy altered by surgery; however, most of the evidence comes from pilot studies, so randomized clinical trials are needed to make formal recommendations.

Other novel endoscopic treatments

Other ET-GERD have been described that use a variety techniques, such as mucosal resection/ablation, video-assisted endoluminal stapling devices such as MUSE™ (Medigus Ultrasonic Surgical Endostapler), or transmural plication devices such as GERDx™¹¹.

Of these ET-GERD, one of the most studied is endoscopic full-thickness plication (EFTP) using the GERDx™ device, which allows endoscopic transmural plications to be performed by suture application.

A randomized clinical trial with 70 patients with GERD compared the efficacy of EFTP (n = 35) versus placebo (n = 35). Patients undergoing EFTP had significant improvement in GERD and quality of life scores, with sustained efficacy at 6 and 12 months. Sixty-two percent of patients treated with EFTP were free of PPIs at 12 months, compared to 11.4% of the group that received placebo. No adverse effects were observed in either group. However, more studies are needed to support its use²⁶.

MUSE™ is a device similar to a video endoscope that contains a surgical staple cartridge and an ultrasound transducer. It is introduced through an overtube and the staples are applied by endoscopic retroflexion. The ultrasound transducer is used to evaluate the thickness of the tissue to which the staples will be applied. The objective is to mimic an anterior partial fundoplication. In a prospective study (n = 66), improvement was observed in 73% of patients treated with MUSE™, compared to 50% of those who received PPIs. A total of 64.6% of patients were able to discontinue PPIs. A decrease in acid exposure was also observed, and two serious

adverse events were reported²⁷. When analyzing the results of studies with MUSE™, clinical effectiveness is 69-92% in a follow-up of up to 4-5 years, but apparently with a higher rate of serious adverse events such as empyema, hemorrhage, and esophageal perforation (3.5-13.9%) compared to other safer techniques, such as TIF¹¹.

There are other ablative techniques, such as antireflux mucosectomy (ARMS) and antireflux mucosal ablation (ARMA), which are based on the principle of mucosal resection or ablation in order to generate submucosal fibrosis and scarring, and consequently, a reduction in the diameter and distensibility of the EGJ².

In a meta-analysis of 10 studies (8 prospective and 2 retrospective), patients undergoing ARMS achieved a technical success of 97% (95% CI: 64-99) and a clinical success of 80.1% (95% CI: 61.6-91) were found. The rate of adverse events was 17.2% (95% CI: 13.1-22.2), with the most common being dysphagia or esophageal stenosis (11.4%) and hemorrhage (5%)²⁸.

A meta-analysis of three studies explored the efficacy and safety of ARMA (n = 130). Eighty-one percent of patients were able to discontinue PPIs, with sustained efficacy at one year in 89% and at 3 years in 72.2%. The most frequent adverse effect was dysphagia; 10% (4-16%) of patients who had dysphagia required intervention²⁹.

In conclusion, there are several novel ET-GERD, but the level of evidence cannot be assessed by the GRADE methodology and is not currently considered robust enough to allow definitive conclusions. More prospective and comparative studies are needed to issue recommendations.

Conclusions

ET-GERD are heterogeneous and, with the exception of TIF, have a low to moderate level of evidence, so they cannot be universally recommended as an alternative to medical or surgical treatment.

As mentioned, of the ET-GERD, TIF is the only one with sufficient quality evidence to be used as an alternative to medical or surgical treatment in well-selected patients.

Regarding the rest of the treatments, experience and standardization of techniques and indications are lacking. High-quality studies are needed that compare ET-GERD and conventional surgical treatment, as well as studies that compare ET-GERD with each other to issue solid recommendations.

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Conflicts of interest

The author declares that he receives honoraria from Grupo Columbia for lectures.

Ethical considerations

Protection of people and animals. The author declares that no experiments were performed on human beings or animals for this research.

Confidentiality, informed consent, and ethical approval. The study does not involve personal patient data or require ethical approval. SAGER guidelines do not apply.

Declaration on the use of artificial intelligence. The author declares that no type of generative artificial intelligence was used in writing this manuscript.

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