



Narrative review of esophageal motility changes after endoscopic therapy for gastroesophageal reflux disease

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Objective: This review is focused on the changes in esophageal motility after endoscopic therapy (injectable agents, mucosectomy, radiofrequency, endofundoplication) for gastroesophageal reflux disease (GERD).

Background: Endoscopic therapy is an alternative to treat GERD. The majority of available endoscopic techniques do not fix all natural antireflux mechanisms and does not contemplate full GERD pathophysiology. Most papers on these alternatives to laparoscopic antireflux surgery focuses on GERD control and morbidity but only few really analyzes the consequences on the esophageal motility that could shed light in the real usefulness of the method and the expectations for long-term outcomes.

Methods: The study is a narrative overview of the literature synthesizing the findings of literature retrieved. Data was retrieved from searching the computerized database PubMed for original and review papers on studies including manometry analysis of the esophageal motility after endoscopic therapy for GERD (injectable agents, mucosectomy, radiofrequency, endofundoplication). Additional hand searches were also performed.

Conclusions: Most studies evaluate subjective outcomes, rarely through esophageal function tests. Also, there are no studies with a significant number of individuals. There is scarce data on injectable agents and most were discontinued in the market due to complications. Mucosectomy and band ligation are new methods with few studies. Most data available comes from studies based on radiofrequency and endofundoplication. Although some techniques may increase lower esophageal sphincter basal pressure, GERD control is generally suboptimal. Current endoscopic therapy modalities did not reach same outcomes as provided by laparoscopic fundoplication.

Keywords: Esophageal motility; gastroesophageal reflux disease (GERD); surgical endoscopy; esophageal manometry

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Introduction

Gastroesophageal reflux disease (GERD) surgical treatment has survived 65 years—since Rudolph Nissen described his and the first fundoplication in 1956 (1)—despite several

downfalls along time (2). Surgery has been accused of being not durable (3), carrying a high risk of mortality (4) (0.05% according to the authors of this review!), being morbid (5) and now of making too many holes in the abdomen.

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Thus, endoscopic therapy for GERD flourished (6). Innumerable and ingenious devices and techniques were created to decrease the complacency of the esophagogastric junction (creating bulking effect by injecting polymers, hydrogel or microbeads or inducing fibrosis by radiofrequency or, mucosectomy) or recreate a valve with an endofundoplication.

Studies on these alternatives to laparoscopic antireflux surgery should analyze the consequences on the esophageal motility that could shed light in the real usefulness of the method and the expectations for long term outcomes not focus only on short-term GERD control and morbidity. We opted to compile the motility changes after these procedures as there are plenty of other reviews on the techniques per se, outcomes and complications. As far as we know there are no narrative reviews on the motility showing results based on GERD pathophysiology.

This review is focused on the changes in esophageal motility after endoscopic therapy for GERD.

We present the following article in accordance with the Narrative Review reporting checklist (available at <https://dx.doi.org/10.21037/dmr-21-54>).

Methods

The study is a narrative overview of the literature synthesizing the findings of literature retrieved. Data was retrieved from searching the computerized database PubMed for original and review papers on studies including manometry analysis of the esophageal motility after endoscopic therapy for GERD (injectable agents, mucosectomy, radiofrequency, endofundoplication). Additional hand searches were also performed.

Term used for search were “Gastric Acid Reflux,” or ‘Esophageal Acid reflux “Gastroesophageal Reflux Disease,” or “GERD” AND “Endoscopic treatment,” or “Gastrointestinal Endoscopy,” or “Surgical Procedures,” or “Gastrointestinal Surgeries” AND “manometry”, or “motility”.

Three independent authors searched for papers.

Pathophysiology of GERD and how an antireflux procedure should work

We need to understand GERD pathophysiology and what is expected from an antireflux procedure to be successful before analyzing changes in esophageal motility.

GERD pathophysiology is complex (7). Basically, a

transdiaphragmatic pressure gradient (negative thoracic pressure and positive abdominal pressure) must be counteracted by a valve mechanism represented by the natural antireflux structures: (I) intra-abdominal length of the esophagus, (II) diaphragmatic sphincter, (III) angle of His, (IV) Gubaroff valves, and (V) lower esophageal sphincter (LES) (8) (*Figure 1*). Failure of a single component of this valval complex may not be enough to cause GERD. Thus, a hypotonic LES does not translate necessary into GERD (9). In fact, most natural antireflux structures are flaw in the setting of hiatal hernia but, again, the presence of a hiatal hernia is not synonym to GERD (10).

A hiatoplasty and fundoplication, the procedure to which others should be compared, is able to restore all mentioned natural antireflux structures (*Figure 2*) (11). The intra-abdominal length of the esophagus is restored if a hiatal hernia was present, the diaphragmatic hiatus is reapproximated, the angle of His is hyperaccentuated, and the LES is reinforced by the synergistic contractions of the gastric fundus. Similarly, in the presence of GERD, the correction of a single mechanism may not guarantee GERD control (12). Historically, every attempt to restore a single mechanism failed (12). Thus, an ideal antireflux procedure should be able to restore all natural antireflux structures.

Endoscopic GERD therapy: procedures to decrease the complacency of the esophagogastric junction

Injectable agents

The idea of injecting bulking agents to provide augmentation of the LES pressure started in 1984 when O'Connor and colleagues used both biodegradable and non-degradable material in dogs (13).

Copolymers

An injectable non-resorbable solution of 8% ethylene vinyl alcohol copolymer dissolved in dimethyl sulfoxide was used to treat patients with GERD for the first time in 1999 after previous studies in porcine models (13).

The procedure is performed as an outpatient procedure (13). The non-viscous solution is injected through a sclerotherapy-type needle near the squamocolumnar junction (Z-line), and 1–2 mL implant solution is injected deep into the wall circumferentially with fluoroscopy guidance (14).

In a multicenter prospective trial (15), 80% of the patients presented improvement in symptom scores, and cessation of proton pump inhibitors (PPI) was achieved in 86% at 12-month follow-up. pH normalization was achieved in only 39% of patients, and esophageal

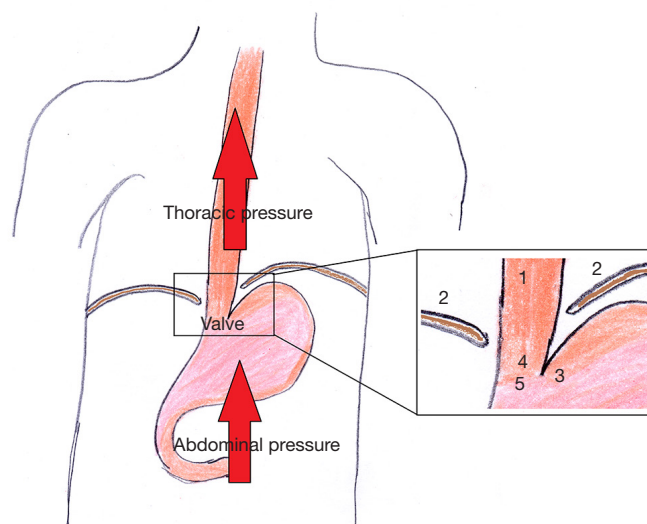


Figure 1 Gastroesophageal reflux disease pathophysiology represented by a transdiaphragmatic pressure gradient (negative thoracic pressure and positive abdominal pressure) with a valve mechanism interposed and represented by the natural antireflux structures: 1, intra-abdominal length of the esophagus; 2, diaphragmatic sphincter; 3, angle of His; 4, Gubaroff valves; and 5, lower esophageal sphincter.

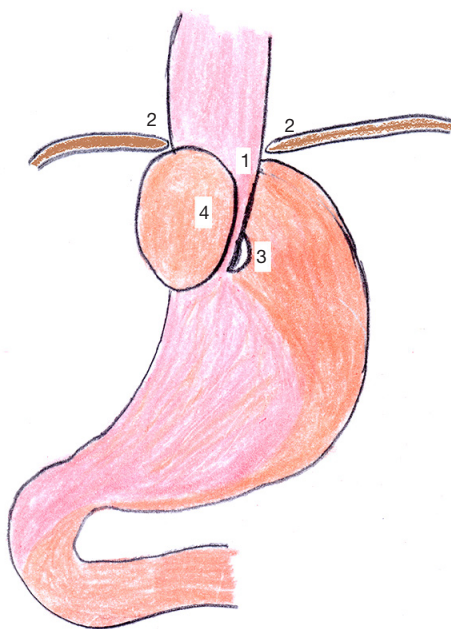


Figure 2 A hiatoplasty and fundoplication restores the natural antireflux structures: 1, intra-abdominal length of the esophagus is restored; 2, crura is reapproximated; 3, angle of His is hyperaccentuated; and 4, lower esophageal sphincter is reinforced by the gastric fundus.

manometry revealed no significant change in the LES pressure or length, residual LES pressure, or in peristaltic amplitude. The same group of authors of mentioned above expanded the follow-up and published the data after 24 months of the procedure (16). Symptom scores remained stable after implantation. There was a decrease in the rate of patients off PPI from 86% to 67%. And there was not changes on previously described results of pH monitoring or esophageal manometry.

There are some cases of serious complications related to the use of this product (17) forcing removal from market due to safety concerns and lack of long-term efficacy (18).

Graphites

Graphite was approved by Food and Drug Administration (FDA) in 1999 to be initially used for the treatment of stress urinary incontinence and later in some cases of fecal incontinence (18). It was tested in a pilot study of 10 patients with moderate GERD published in 2009 (6).

It is composed of coated graphite beads containing zirconium oxide, suspended in a water-based, absorbable polysaccharide carrier gel (6). It is prepackaged in syringes containing 1.0 mL of the substance with a 20-gauge needle sclerotherapy catheter. The application is quite similar to the agent mentioned before. The substance is injected into

the submucosal space in the region of the gastroesophageal junction (GEJ), at or within the z-line, in 4 quadrant injections (18).

In the pilot study mentioned before, all 10 patients were on daily PPI therapy and had a hiatal hernia (HH) <3 cm. Seven patients did not have erosive esophagitis and 3 patients had mild erosive esophagitis. In the follow-up of 12 months, there was an improvement of 90% in symptom scores; 70% of the patients were off all antacid medication and 90% reduced PPI use by greater than 50%. A manometric study of these patients was conducted before application but not described after the application and no other study showed changes in motility after this procedure.

This product is not currently FDA-approved for the treatment of GERD (6).

Hydrogel prosthesis

Hydrogel was initially tested in farm-pigs (19) and subsequently in patients with GERD for the first time at the end of 2000 (19,20).

The device is a 6-mm × 15-mm cylinder-shaped soft pliable cushion hydrogel prosthesis implanted into the submucosa of the GEJ (6). The hydrogel expands in 24 hours creating a mechanical anti-reflux barrier (20).

In a prospective randomized trial, 78 patients showed significant improvement in heartburn, regurgitation, and medication usage at 6 months. There was an improvement in the DeMeester score values, but without normalization in the follow-up. There was no statistically significant improvement in LES pressure compared with baseline (21). It was terminated early due to the lack of compelling efficacy data. In another European multicenter study (21,22), 79% of the patients had an improvement in symptom scores and 53% were off PPI use. At 6 months, 40% had a normal pH level. LES pressure went from 8.8 on baseline to 13.8 ($P<0.01$). This product was removed from the market because of poor long-term results (6,22).

Mucosectomy and band ligation

Anti-reflux mucosectomy (ARMS) was adopted as an alternative endoscopic method for GERD treatment after incidentally discovered in 2003 when a patient with Barrett's esophagus was submitted to endoscopic mucosal resection (EMR) and experienced improvement in GERD symptoms (23). As the mucosectomy area heals and scars, the tissue contracts to augment the natural antireflux valve.

It is considered one technique that does not require specialized equipment, and consists of a hemi-circumferential EMR of the gastric cardia around the

GEJ. With the scope in a retroflexed position, the mucosa is marked with the snare 240–270° around de gastroesophageal valve. Then the mucosa of the cardia is raised with solutions, and then the tissue is banded and transected with forced coagulation (6,23).

In the largest series of ARMS conducted by Yoo *et al.* and encompassing 33 patients, 63% of patients completely discontinued PPI, and there was a significant reduction in GERD health-related quality of life (HRQL) scores. There was an increase of the LES pressure from 16.3 to 20.7 at 6 months ($P=0.005$) (24).

With the same mechanism to augment the natural antireflux valve mentioned before, and as another alternative method, some authors perform the clip band ligation anti-reflux therapy. Using a multi-band device, two bands were ligated to the cardial mucosa and fixed with a single-use clip. Promoting the protrusion of the cardial tissue, the space is reduced by constricting the anterior and posterior walls of the cardia with two clips at the 6 and 12 o'clock positions (25). Using this technique, the DeMeester score decreased from 105.9 ± 74.8 to 41 ± 43.8 , HRQL showed a significant improvement 6 months later the procedure, and 43% of the patients discontinued PPIs. There was no significant improvement on LES pressure compared to baseline 6 and 12 months after (25,26).

Radiofrequency (RF)

RF energy may be applied to the distal esophagus, GEJ, and the cardia (6,27). The first series reported with the use of this method was published in 2000 in canine and porcine models (27). It is performed transorally initially with a conventional endoscopy, then the distance from the incisors to the z-line is measured, and the endoscope removed. A flexible RF energy catheter is passed transorally and positioned 2cm distal to the level of z-line. Low-power RF energy is delivered to the deeper muscular layers of the esophagus and stomach, leading to augmentation of the LES and increasing resistance to reflux during gastric distension.

In a multicenter prospective study with 118 patients treated with RF, there were improvements in symptoms with reduction of heartburn and GERD HRQL scores at 12 months. 61% of the patients discontinued PPI use or used over-the-counter. The DeMeester score improved from 40.0 to 26.3 (28). Only 18 of the patients were submitted to esophageal manometry that showed reduction in the number of transient LES relaxations, but without significant change in other esophageal motility parameters (29).

In a double-blind sham-controlled study from Belgium, patients submitted to radiofrequency treatment of the GEJ presented improvement in symptom scores, but no changes were observed in esophageal acid exposure and LES pressure. (30)

A systematic review and meta-analysis revealed an improvement of 65% in symptom scores, and 75–86% of patients were medication free at follow-up. This procedure was able to reduce but not to normalize esophageal acid exposure or DeMeester scores in pH monitoring results. There was not significant change in LES pressure after the radiofrequency procedure. The rate of failure of the radiofrequency delivery to GEJ was almost 60%, and these patients required an anti-reflux surgery 6 months after the endoscopic procedure for GERD treatment (31).

Endoscopic GERD therapy: endofundoplication

Also called transoral incisionless fundoplication (TIF), endofundoplication was first described in 1992 using an endoscopic transgastric approach in pigs (32). Currently, the procedure consists in creating a 3.0 cm in length and 200° to 300° circumference valve, through a full-thickness plication of distal esophagus and cardia using a single use device guided by endoscopic retroflexion view. TIF operates trying to rebuild the anatomy of gastric cardia and strengthening a valve mechanism. (33)

Summarizing the results of many studies, short term follow-up showed improvement in symptom scores; 40–90% of patients stopped using PPI at some stage of follow-up, and 40–80% had normalization of esophageal pH monitoring (34). In the opposite side, in a 6 years' follow-up, the rate of PPI-free patients reduced to about 30%. (35).

Regarding esophageal motility, Rinsma *et al.* (36) demonstrated in a follow-up of 6 months after TIF that there was a reduction in the number of postprandial transient LES relaxations (TLESRs), as well as in the TLESRs associated with reflux. Otherwise, Schwartz *et al.* (37) and Testoni *et al.* (35,38) showed no significant changes in LES basal pressure or distal esophageal amplitude (DEA) in a 12-month follow-up. Some papers propose that the improvement of the symptoms occurred due to the creation of greater length new valve more than the increasement of the valve pressure (35,38).

Bell *et al.* founded normalization of acid exposure and DeMeester score in 61% and 56% of the patients, respectively, in a 6-months follow-up (39). On the other hand, other studies demonstrated a reduction on acid

exposure but not reaching normal values of physiologic acid exposure (35,40,41).

When we analysis morphological assessment, Kalapala *et al.* demonstrated in a 12-months follow-up that new valve Hill grade I was presented in 77.8% of the patients (41). After 24 months, Testoni *et al.* showed that in 50% of the patients there is a recurrence of the hiatal hernia, and in patients with Hill grade of the gastroesophageal valve II or III before the TIF, the new valve Hill grade I was presented in 63.7% and 33.6% respectively (35,41).

Discussion

This review focused on the changes in esophageal motility after endoscopic therapy for GERD (injectable agents, mucosectomy, radiofrequency, endofundoplication). Several ingenious devices and techniques were created but, unfortunately, often ignoring lessons learned from the past (12). Previous experiences to treat GERD restoring a single antireflux mechanism failed. The consequences of a recurrent hiatal hernia after a fundoplication are well-known (42). Symptoms reappear even though the LES is reinforced with a fundoplication. Similarly, LES augmentation with a magnetic ring around the GEJ brings suboptimal GERD control since the angle of His is not hyperaccentuated (43). Available and past endoscopic techniques focused essentially on the augmentation of the LES. Some endoscopic techniques rely on devices implanted at the GEJ. Again, history showed that foreign body around a mobile viscus may be catastrophic leading to complications and a high rate of removal. This was true for the Angelchik prosthesis (44) and now to the magnetic ring (43). Not surprisingly, several devices were removed from market due to complications or poor outcomes.

Most studies that we reviewed evaluate subjective outcomes, rarely through esophageal function tests. Also, the methodology quality of the studies is not always ideal. There are few prospective studies, no studies with a significant number of individuals and, curiously, most papers dealing with a specific technique comes from the same groups. There is scarce data on injectable agents and most were discontinued in the market due to complications. Mucosectomy and band ligation are new methods with few studies yet. Most data available comes from studies based on radiofrequency and endofundoplication. Although some techniques may increase lower esophageal sphincter basal pressure, GERD control is generally suboptimal with decrease in acid exposure time but not normalization

Table 1 Estimated gastroesophageal reflux disease endoscopic treatment outcomes comparisons

Outcomes/technique	Copolymers	Graphites	Hydrogel prosthesis	Mucosectomy	Radiofrequency	Endofundoplication
Symptom scores improvement	80%	90%	80%	70%	65%	40%
Off PPI's	65%	70%	50%	60%	80%	65%
DeMeester normalization	No	No	No	No	No	No
pH normalization	40%	40%	40%	-	-	60%
LESP improvement	N/S	N/S	Yes	N/S	N/S	N/S
tLESr improvement	N/S	N/S	N/S	N/S	N/S	N/S

PPI, proton pump inhibitors; LESP, lower esophageal sphincter pressure; tLESr, transient lower esophageal sphincter relaxations; N/S, not studied.

to physiologic values (*Table 1*). Future technology must consider GERD pathophysiology. Endofundoplication seems to be the most promising endoscopic technique. The development of new images methods adapted to the endoscope may allow an endoscopic hiatal repair in the future. The current alternative of performing a laparoscopic hiatal repair combined to endofundoplication (45) seems like an illogic overindication of the endoscopic method.

Laparoscopic fundoplication and hiatoplasty brings excellent and durable symptomatic as well as manometric and pHmetric outcomes even after 15 years (44, 46). Any new technology or operation must be compared to these results. Current endoscopic therapy modalities certainly did not reach these outcomes yet.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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