Original Article

New endoscopic procedures for diabetes mellitus type 2 and obesity treatment

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Background: Obesity continues to be a growing epidemic worldwide. Obese patients have severe comorbidities that make risky and technically demanding the execution of bariatric surgery from both surgical and anesthetic point of view; therefore, the focus of bariatric surgeons is increasingly moving towards minimally invasive, endoscopic techniques.

Methods: The present review presents and discusses recent endoscopic techniques employed in obesity treatment, their features and results.

Results: Endoscopic treatment can be primary or revisional; we can mainly divide the endoscopic devices into five categories: space-occupying devices, restrictive procedures, bypass liner, aspiration therapy and endoscopic revision of gastric bypass for dilated gastric pouch.

Conclusions: Endoscopic treatments for obesity are promising techniques for selected patients but each procedure should be tailored on the patient in a multimodal approach.

Keywords: Endoscopy; obesity; bariatric surgery; weight loss

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Introduction

Obesity, defined as body mass index (BMI) equal to or greater than 30 kg/m^2, is a rising, epidemic disease worldwide. Dietary and lifestyle modifications and pharmacologic therapy revealed ineffective results as mid- and long-term weight loss. Presently bariatric surgery is the gold standard in severe obesity treatment (1). Since 1980, the prevalence of obesity has doubled, and almost two billion of adults are overweight and more than a quarter of these are obese (2). More and more obese patients have severe metabolic, cardiovascular or respiratory comorbidities, that make risky and technically demanding the execution of bariatric surgery from both surgical and anesthetic point of view. Increasing severity of obesity is associated with higher surgical morbidity and mortality, longer hospitalization, increasing rate of readmission (3) and costs for the treatment of a single patient. In addition, the last long term follow-up studies demonstrated the concerning issue of weight regain after primary bariatric surgery. More than 20% of patients, in fact, experience a significant post-operative weight regain after sleeve

gastrectomy or gastric bypass. This weight regain after a primary surgical treatment is a condition associated with a strong risk recurrence of comorbid conditions such as diabetes, hypertension, and obstructive sleep apnea (4). Revisional surgery is associated with higher morbidity compared to the primary treatment, and results in term of weight loss have been inconsistent (5).

For these reasons, even if bariatric surgery is nowadays the best-known treatment for obesity (6), the focus of bariatric specialists is increasingly moving towards minimally invasive, endoscopic techniques.

Emerging endoscopic bariatric therapies represent a sort of bridge between medical therapy and weight loss surgery, being more effective and durable than lifestyle intervention or drugs, but at the same time less invasive and risky; moreover, endoscopic techniques are easily performed and less expensive than surgical procedures (7).

Methods

The present review aims to discuss all the relevant current and the under study endoscopic procedures employed in obesity treatment. All the endoscopic procedures used for control of endoluminal bleeding and treatment of leaks in sleeve gastrectomy and gastric bypass were excluded from the review.

Results

Along as bariatric surgery, endoscopic treatment can be primary or revisional. As stated by the ASGE task force (7) endoscopic bariatric therapies should follow these thresholds:

- endoscopic bariatric treatment should be proposed to class II/III obese patients with a mean minimum 25% EWL at 12 months;
- the risk associated with endoscopic procedures should be ≤5% incidence of serious adverse events;
- similar to bariatric surgery, the function of endoscopic treatments is to reduce the weight altering gastrointestinal anatomy and physiology.

Endoscopic bariatric procedures can be divided in space-occupying devices, restrictive procedures, bypass liner, aspiration therapy and endoscopic revision of gastric bypass for dilated gastric pouch.

Space-occupying devices

Intragastric balloons are silicone devices, endoscopically placed in the stomach in order to occupy space, that can be filled by air, helium, (Heliosphere™), or fluid. Initially this type of devices has a leading role as bridge to bariatric surgery in high-risk patient for anesthesia or in very obese patient, whereas in the last years, balloons became a real therapeutic instrument: in fact, it may induce gastric distension, delay gastric emptying and alter the gastro-intestinal related hormones metabolism, inducing satiety (8). Generally, this type of device requires to be removed in 6 months from the implantation in order to avoid the balloon deflation which can lead to complications as device migration and consequent bowel obstruction (3,9). The majority of intragastric balloons consists of a single spherical shape, typically 500–750 mL in size, (Orbera™) or two connected spheres, independently filled (each 450 mL in size) (ReShape Duo™): the aim of the dual design is to potentially prevent migration in case of deflates of one sphere. Most of those devices are endoscopically placed under a light sedation, but some balloons are swallowed, along with an attached catheter, as a pill (Obalon™, Elipse™, Ullorex™) (7,10). Contraindications for balloon placement are erosive esophagitis, peptic ulcer disease, gastropathy or large hiatal hernia, so a preventive gastroscopy must be performed in order to evaluate the feasibility of the procedure. Many studies (3,6,8) demonstrated the well-tolerance and efficacy of intragastric balloons. Typical complications include nausea, vomiting and stomach pain. Other complications of intragastric balloon include esophagitis, gastric perforation, gastric outlet obstruction, gastric ulcer and balloon rupture. The rupture of the device can lead to more serious adverse event including balloon migration and bowel perforation, which can be life-threatening; in some cases, for this reason, the devices is filled during endoscopic visualization using about 600 mL saline and 10 mL methylene blue, a dye which alters urine colors in case of balloon perforation. Rare reported complications are esophageal perforation and small-bowel obstruction requiring surgery (10). In most of the studies that consider space-occupying devices, percent excess weight loss at the removal time is significant (6). In a meta-analysis (n=3,608 patients) the median percent excess weight loss (% EWL) upon removal of the device after 6 months of treatment was 32.1±5.3 and the median percent total weight loss (% TWL) was 12.2±2.2 (11). The main concern about this type of procedure in the few studies with long term follow-up is weight regain after balloon removal. One study, examining the long-terms effect in 122 patients presented 58%±19% EWL at the removal but only 17±8

after 5 years after balloon removal, with a sensible weight regain (12).

A meta-analysis also studied the benefits of the weight loss for the diabetes: significant decrease or normalization of hemoglobin A1c value was reported in 87.2% of the 488 diabetic patients in the study (13). A prospective trial including 130 patients studied the metabolic effect of Orbera™ balloon associated with 1,000–1,200 daily kilocalories diet; the average weight loss was 13.1 kg after 6 months and decreasing of hyperglycemia was from 50% to 12% of patients; weight regain occurred in 50% of patients during the follow-up period, with a median of 22 months after balloon removal (14).

Other space-occupating devices are in developing phase, and they have not the FDA approving yet: Transpiloric Shuttle™ is an endoluminally delivered, silicone-bulb device whit a large sphere connected by a flexible catheter to a small cylindrical sphere; it enters the duodenal bulb by peristalsis and pulls the larger sphere to the pylorus, intermittently obstructing it, leading to deferred gastric empting resulting in protracted satiety. Full Sense™ device is an enclosed, metal stent that is endoscopically placed across the gastro-esophageal junction to induce satiety and fullness by placing pressure on the distal esophagus and gastric cardia. SatiSphere™ is a line running through several spheres of mesh; it sits in the distal stomach or duodenum, slowing the food transit. No study with a large number of patient for precise and long-term results are been made using this new intragastric devices and balloons.

Restrictive procedures and devices

This group includes procedures and devices that remodel the stomach, suturing, stapling or tissue anchor placing trans-orally, in order to physically reduce gastric volume, emulating the anatomy of a surgical sleeve gastrectomy.

Endoscopic sleeve gastroplasty (OverStich™, Incisionless Operating Platform™, EndoCinch™, TransOral Gastroplasty™, ACE stapler™, Transoral Endoscopic Restrictive Implant System™) are devices that place full-thickness stiches endoscopically. The rational of this endoscopic procedure is miming a sleeve gastrectomy, from the prepyloric antrum to the gastroesophageal junction (15). Most of those instruments (1,6) are vacuum-based, full- or superficial-thickness suturing systems that create a staple line (one or two parallels rows of interrupted plications) along the lesser gastric curvature to perform a vertical sleeve gastroplasty. Other devices, non-vacuum-based, may require a preventive argon coagulation of the superficial mucosal layer in order to expose the submucosal collagen rich substrate that guarantees a more durable plication. In all cases, eight to ten plications are required at the level of the fundus to reduce volume and sometimes two plications are posed in the antrum to delay gastric emptying (16). This type of incisionless procedures is feasible and less expensive compared with surgery. Moreover, in literature are described few complications. A current large, randomized sham-controlled trial (ESSENTIAL) in U.S. studying the endoscopic suturing devices for primary weight loss reported nausea, pain, vomiting and temporary dysphagia as minor adverse events. Although the hopeful prospective of this technique is encouraging, there were no issues of plication durability and weight regain in the long period; in some studies, in fact, endoscopic follow-up performed 12 months after the procedure revealed 75% plication's remaining, as well as durability of gastric volume reduction (1). A 20 patients study underwent to primary endoscopic sleeve gastroplasty using OverStich™ devices reported a 6-month % EWL of 53.9±26.3 and % TWL of 17.8±7.5 with very few complications (17). A larger study, which regarded Incisionless Operating Platform™ device in 147 patients, reported a 1 year % EWL of 44.9±24.4 and % TWL of 15.1±7.8 (18). The promising results incentivized the development of other similar endoscopic device: studies based on different device, demonstrated a 1-year % EWL range from 27.7±21.9 to 58.1±19.9 (19-21), confirming that restrictive procedures are the most effective in terms of weight loss. Regarding metabolic effects and diabetes control, those studies also reported significant improvements in hemoglobin A1c, declining from 7.0% to 5.7% (22). Although comforting results in weight reduction and diabetes control associated with very few described adverse events, endoscopic controls at 1 year demonstrated only a partial sleeve maintained, with a partial or complete release of plication up to 72% of patients (20).

Bypass liners

Duodenal-jejunal bypass liner (EndoBarrier™) consist of the endoscopic implantation of a 60-cm Teflon sleeve in the duodenal bulb for a mean period of 6 months. The anchor is fixed to the intestinal wall within the duodenal bulb by small tips grasping the intestinal mucosa (23,24). This tube extends from the duodenum into the small bowel, allowing food to bypass the entire duodenum and proximal jejunum and not to shuffle with digestive fluid. In fact, pancreatic and

biliary secretions move along the outside of the device to the jejunum (6). Additionally, and equally important for the weight loss, it allows food to reach the mid-jejunum earlier.

Gastroduodenojejunal bypass sleeve (ValenTx™) is a 120-cm tube fixed at the level of gastroesophageal junction, and requires both endoscopic implantation and laparoscopic combined approach to dissect the GE junction and than to fasten the proximal end of the sleeve. This device mimes the surgical bypass and compartmentalization of the stomach. Several studies demonstrated duodenojejunal bypass sleeve leading to relevant weight loss, and in some cases even upgrading in diabetes (1). In some patients, however, is not possible to implant the device because of the smallness of the duodenal bulb. Among adverse reaction reported, migration, obstruction, pain, bleeding or anchor dislocation are the most frequent (25). Few case reports described cholecystitis and duodenal fistula or perforation as endoscopic bypass sleeve-associated complications (26). In high-volume laparoscopic center, those complications can be minimally invasive treated. In one case was described a sleeve invagination that required premature removal of the device. The device has the advantage of being fully reversible: the tube can be easily removed using an endoscope. Actually, the device is approved for a no longer than 12-month period. A multicentric, randomized controlled trial enrolling 77 patients demonstrated a (32.0±14.7)% EWL and 10±3.2 upon removal of device, reduced at (19.8±9.2)% EWL and (5.8±3)% TWL 6 months after device removal. Despite the good initial results, a high incidence of hepatic abscess leads to prematurely interrupt the study (27). The diabetes was also well controlled: a study of 25 patients demonstrated an improvement of A1c, from 7.2±1.22 to 6.0±0.43 in 19 patients (24). Other studies demonstrated the reduction of A1c levels after 6 months of implant of duodenojejunal bypass sleeve (–1.5%±0.4%). The EndoBarrier™ may be applicable as therapeutic device for the management of type II diabetes even in absence of obesity: this endoscopic bypass liner has been shown to improve A1c hemoglobin levels in non-obese patient, with a significant decrease of HbA1c, cholesterol and % EWL compared to medical treatment in a 12-month study (28).

Aspiration therapy

Consists in the insertion of a 30Ch gastrostomic tube (Aspire Assist™) into the stomach, attached to a skin port with a connector and valve. The patient uses this tube to evacuate up to 30% (600 mL reservoir) of each meal about 20 min after the consumption of a meal greater than 200 Kcal. In a prospective multicentric clinical trial, persistent gastrocutaneous fistula and infections are identified as complications of this procedure. Many study in literature described no evidence of increased food intake to compensate the aspirate food. A study of 22 patients reported a mean % EWL 40.8±19.8 and a % TWL of 14.8±6.3 after 6 months of usage (29). Now there are no available data regarding the diabetes control, but a prospective, multicentric clinical trial is ongoing.

Endoscopic revision of gastric bypass

Roux-en-Y gastric bypass (RYGB) is the most commonly performed and successful bariatric procedure in US at present; however, a portion of patients experience suboptimal weight loss in the postoperative period, and approximately 20% regain a significant proportion of their lost weight with longer term follow-up because of dilatation of gastric pouch (30). Due to the complexity and risks associated with surgical revision, endoscopic suturing has been explored as a minimally invasive and safe option for stomal revisions (8). Sclerotherapy endeavors to increase restriction by injecting a sclerosant in perianastomotic tissue. This procedure is generally straightforward with few complications and can be repeated with significant benefit. Several studies, analyzing a total of over 360 patients, demonstrated a high loss of weight, up to 75% of regained weight in a large number of patient (64% to 91.6% in 1 year). Although arresting weight regain, the subsequent weight loss after sclerotherapy is not significant (31-35).

In other case, a device for restrictive endoscopic procedure can be used (Incisionless Operating Platform™, EndoCinch™, OverStitch™) or apposite tissue approximation device (Stomaphy X™, OTSC-Clip™) with H-fasteners and can create full-thickness, serosa-to-serosa, endoluminal plications (36). Endoscopic plication is the less invasive option for weight regain after bariatric surgery with encouraging initial results. The loss of weight regains in this cases is described about 32%, with a 19.5% EWL after 1 year (28,37,38). Even if in literature there are comforting data for the secondary weight loss using endoscopic technologies, there are no clear result for diabetes control in these patients.

Other therapies

Electrical stimulation, magnetic compression anastomoses,

duodenal mucosal resurfacing and intragastric botulinum toxin injections represents other developing possible endoscopic treatment for obesity.

Discussion

Recent advances in technology and devices industry provided emerging and promising new endoscopic approaches to obesity and type 2 diabetes treatment. Currently some devices have been just approved as intragastric balloons and others are under investigation. Because of the increasing burden of obesity-related comorbidities and increasing age of bariatric patients there is a need for less-invasive weight loss procedures. Ideally, this type of treatment should reproduce the restrictive and/or malabsorptive effects of bariatric surgery avoiding the complications of surgical treatment.

The major concern about endoscopic bariatric therapies is durability of their metabolic and weight-loss effects. Intragastric balloons and duodenojejunal bypass liners need to be removed after 6 and 12 months respectively. Poor tolerance may affect patients submitted to intragastric balloon and bypass liners conditioning early retrieval of the device. Regarding safety each endoscopic procedure presents a limited but not null risk of complication such as bleeding, migration of the device, deflation of the balloon, erosion, bowel obstruction, visceral perforation. These devices provided at short-term follow-up encouraging weight-loss results as EWL 25–40% at 6–12 months but long-term data still lack.

Conclusions

Endoscopic treatments for obesity are promising techniques for selected patients, and can potentially change the approach to the bariatric disease, but are still in early stage of development. In fact, in order to achieve long-term follow-up results and to identify the adequate procedure for specific patient, further studies are required, considering the variability and the large number of different techniques available. Moreover, the need of rigorous evaluation of all these procedures, reproducibility and standardization of these treatments is very important to regularize their clinical applications.

Each procedure should be tailored on the anthropometric and clinical features of each patient, as bridge therapy or transient therapy, integrated in a multimodal approach because the transient loss of weight described in literature indicate not to use this emerging endoscopic devices as a standalone, definitive therapy for obesity.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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