Curr Gastroenterol Rep (2016) 18: 26
DOI 10.1007/s11894-016-0501-5

Endoscopic Bariatric Therapies

Deepinder Goyal[1] · **Rabindra R. Watson**[1]

Published online: 20 April 2016

Abstract Obesity and its associated cardio-metabolic comorbidities have emerged as a global pandemic. The efficacy of various hypo-caloric diets and prescription drugs has been poor with respect to sustained weight loss. Recent advancements in endoscopic technology and techniques have opened a new field of minimally invasive endoscopic treatment options for combatting obesity both as a first line and adjunctive therapy. Presently, two endoscopic space-occupying devices in the form of intragastric balloons have received FDA approval for 6-month implantation in patients within a BMI range of 30–40 kg/m^2. Furthermore, full-thickness suturing has led to the development of primary endoscopic sleeve gastroplasty and Roux-en-Y gastric bypass revision as viable endoscopic alternatives to surgical approaches. These techniques have the potential to reduce adverse events, cost, and recovery times. Looking forward, a variety of promising and novel medical devices and endoscopic platforms that target obesity and diabetes are in various phases of development and investigation. The present review aims to discuss the current and forthcoming endoscopic bariatric therapies with emphasis on relevant procedural technique and review of available evidence.

Keywords Bariatric endoscopy · Obesity · Bariatric surgery · Gastric bypass revision · Intragastric balloon

This article is part of the Topical Collection on *Stomach and Duodenum*

✉ Rabindra R. Watson
rwatson@mednet.ucla.edu

[1] Center for Obesity and Metabolic Health (COMET), Division of Digestive Diseases, David Geffen School of Medicine at UCLA, UCLA Medical Center, 200 UCLA Medical Plaza, Suite 330-33, Los Angeles, CA 90095, USA

Introduction

According to the National Health and Nutrition Examination Survey, about 68.8 % adults are overweight and 35.7 % of adults are estimated to be obese in the USA [1]. A steady rise in the overall prevalence of obesity has been demonstrated over the past 20 years [1]. Obesity poses a major public health challenge and a significant burden on healthcare resources both in terms of direct and in-direct costs [2]. The risk of type 2 diabetes increases linearly with increasing BMI and affects approximately 8.3 % of the American population [1, 2]. Obesity also increases the risk of development of other significant co-morbidities such as hypertension, obstructive sleep apnea and arthritis [3, 4].

Efficacy of Non-Endoscopic Therapies

Physical activity and various hypocaloric diets have demonstrated an overall poor efficacy both in terms of clinically meaningful weight loss achieved and durability. One of the largest reported randomized controlled trials on dietary interventions involving 811 overweight adults demonstrated 7 % total body weight loss at 6 months with reduced-calorie diets, regardless of the macronutrient distribution. However, a trend towards weight regain was seen at 12 months [5]. A recent meta-analysis showed only modest weight loss with various commercial and popular proprietary weight-loss programs at 12 months as compared to control and education: 2.6 % with Weight Watchers, 4.9 % with Jenny Craig, 3.8 % with Nutrisystem, 4 % very-low-calorie programs such as Health Management Resources, Medifast, and Optifast, and 0.1–2.9 % with Atkins diet [6].

Five pharmacotherapy agents have been approved so far by the Food and Drug Administration (FDA) for long-term

weight management. These include orlistat, lorcaserin, phentermine/topiramate, naltrexone/bupropion, and liraglutide. Weight loss is limited to about 5 to 10 % of total body weight in various phase III clinical trials [7]. Furthermore, data on long-term weight loss maintenance for most of these drugs is not yet available, and side effects are of concern.

Surgical weight loss is efficacious but highly invasive. At present, Roux-en-Y Gastric bypass (RYGB) and laparoscopic sleeve gastrectomy constitute the majority of the weight loss procedures performed in the USA. Both surgical procedures have demonstrated good efficacy in terms of weight loss (50–70 % excess weight loss at 1 year) and improvement in comorbidities such as diabetes (~80–90 %) [8]. However, such operations remain highly invasive and carry a significant postoperative mortality rate of 0.31 %, adverse event rate of 10–17 %, failure rate of 10–20 %, with weight regain reported in 20–30 % of the patient population [9]. Furthermore, only approximately 1 % of eligible patients consider surgical methods of weight loss, due in part to its invasiveness, cost, and availability [10].

Rationale for Endoscopic Bariatric Therapies

There is a huge unmet need for minimally invasive, safe and effective therapies for obesity. The endoscopic bariatric therapy (EBT) may fill this therapeutic gap between pharmacotherapy and bariatric surgery. Recent advancements made in the field of endoscopic devices and techniques have provided an increased array of minimally invasive non-surgical options which are efficacious for encountering obesity (Table 1). EBT has a potential major future role in the comprehensive management of obesity both as a first line and adjunctive therapy to medical and surgical treatments. The present review aims to discuss the current and promising endoscopy based obesity management strategies.

Endoscopic Strategies Currently Approved for Use in the USA

1. *Intra-Gastric Balloons*: Space occupying devices that may induce gastric distension, delay gastric emptying, and potentially alter gastro-intestinal orexigenic and anorexigenic hormones thereby inducing satiety have been developed and studied for the last several decades. The Garren Edwards Bubble was the first intra-gastric balloon to be approved in the USA in 1980s but was soon withdrawn from the market due to poor efficacy and significant adverse events [11]. Since then, intra-gastric space occupying devices with a better design, efficacy and safety have been built and studied in Europe and the USA [12••].

   A. *The Orbera™ (Formerly Known as BioEnterics®) Intra-gastric Balloon (IGB)* (Apollo Endosurgery, Austin, TX) is a saline-filled, spherical silicone elastomer balloon with a volume of 400–700 mL that is placed in the stomach endoscopically under sedation. The filled balloon is designed to act as an artificial

Table 1 Endoscopic Bariatric Therapies

	Total body weight loss	Advantages	Disadvantages
Approved therapies			
Orbera intra-gastric balloon	10–12 %	Minimally invasive, overall good safety track record, requires no permanent alteration of GI tract, potential for bridge therapy	Approved for only 6 months, concern for long-term maintenance of weight loss post retrieval, not approved for severe obesity (BMI >40 kg/m^2)
Reshape duo balloon	8–15 %	Reduced risk of migration	Relatively newer device with shorter clinical track record on efficacy and safety compared to Orbera balloon
Endoscopic sleeve gastroplasty	18–20 %	Robust weight loss, incisionless	Long-term outcomes unknown; concern for potential challenges if bariatric surgery needed in future
RYGB revision with TORe-G	10–15 %	Majority of the regained weight lost, minimally invasive, safe, short recovery time	Long-term outcomes (beyond 3 years) unclear
Promising therapies under FDA review			
POSE procedure	15 %	Robust weight loss, incisionless	Long-term outcomes unknown, requires additional procedure and device-specific training
Aspiration therapy	18 %	Minimally invasive, reversible procedure, requires minimal additional training for GI providers	Aspiration related inconvenience, low societal acceptance, concern for bulimia, potential for fistula formation post removal

bezoar and move freely within the stomach while inducing weight loss via gastric distension, reducing gastric emptying and increasing baroreceptor stimulation thereby inducing satiety [12••].

Procedure Description: The Orbera™ intragastric balloon comes pre-loaded within a placement catheter assembly which consists of a 6.5-mm external-diameter silicone catheter, one end of which is connected to a sheath in which the collapsed balloon resides. The opposite end is connected to a Luer lock connector for attachment to a filling system. A self-sealing valve permits detachment from the external catheter. After sedating the patient, an upper endoscopy with a flexible standard gastroscope is performed to visually inspect the esophagus and stomach and rule out any contraindications such as large hiatal hernia, erosive esophagitis, active peptic ulcer disease or gastropathy. The endoscope is then removed. The Orbera® system placement sheath is lubricated with gel and passed gently through the mouth in to the stomach. The endoscope is then re-inserted in the stomach while the balloon is in situ (below the GE junction) to observe the filling steps. The guidewire from the fill tube is removed and a three-way stopcock along with a 50-cc syringe is attached to the Luer-Lock. The balloon is slowly filled with sterile saline in 50-cc increments to a goal volume of 500–700 mL. After filling the balloon, the tube is gently pulled out and integrity of the valve checked for any leakage.

Post-Procedure Care: All patients who undergo IGB implantation are recommended to remain on proton pump inhibitors (PPI) throughout the implant period to prevent gastro-esophageal reflux and gastric ulcerations. Activation of stretch receptors may cause vigorous nausea, abdomen pain and vomiting until gastric accommodation develops in 1–2 weeks. Hence anti-cholinergic agents such as sublingual hyoscyamine and a scopolamine patch may be used in the immediate post-implantation period. Furthermore, patients commonly require narcotic analgesia, anti-emetic agents such as Ondansetron, pro-kinetic drugs such as metoclopramide or anti-anxiety medications such as Diazepam on an as needed basis in the immediate post implantation period. In the rare event of severe vomiting leading to dehydration, urgent intravenous rehydration may be necessary.

Balloon Retrieval: The Orbera® balloon is approved for a maximum duration of 6 months. The removal procedure is performed under sedation in an endoscopy suite. The balloon is deflated using a proprietary through the scope needle and then grasped at the opposite end of the valve with rat-tooth forceps passed through working channel of the endoscope. After securing firm grasp of the balloon, it is then extracted from the mouth together with the endoscope.

Efficacy and Safety: The Orbera balloon has been extensively studied outside the USA during the last two decades [13, 14]. A meta-analysis of 15 studies including 3,608 patients demonstrated an average total body weight loss of 12.2 %, excess weight loss (EWL) of 32.1 % and reduction in BMI of 5.7 kg/m^2 at balloon removal after 6 months. Reported adverse events included nausea and vomiting (8.6 %), abdominal pain (5 %), deflation and displacement (2.5 %), gastro-esophageal reflux (1.8 %), dehydration (1.6 %), bowel obstruction (0.8 %), gastric ulcer (0.4 %), and gastric perforation (0.1 %). Early device removal was required in 4.2 % of all the implanted patients [15]. The largest study included in the meta-analysis involving 2,515 patients showed an average reduction in BMI of 9 kg/m^2 at 6 months [14]. The Orbera balloon gained FDA approval in 2015 for insertion for up to 6 months in obese patients with BMI between 30 and 40 after a recently concluded multicenter US pivotal trial involving 215 patients. An average of 10 % total body weight loss was seen at the time of balloon removal, as compared to 4 % in the control group at 6 months. The reported EWL was approximately 40 vs. 13 % respectively. Three months after device removal, the mean EWL was 26.5 % in the balloon group. Approximately 45 % of the IGB group patients had an excess weight loss at least 15 % higher than patients in the control group [16].

Effects on Metabolic Syndrome: Orbera balloon therapy has been reported to improve several metabolic parameters. An Italian prospective study involving 130 obese patients showed significant improvement in glycemia, insulin resistance, triglyceridemia, and liver steatosis in addition to significant weight loss in 91 responders to the intra-gastric balloon [17].

Long-Term Weight Loss: Maintenance of weight loss 5 years after balloon removal was evaluated in a group of 474 patients. A threshold of at least 20 % EWL was reported in 83 % of patients at the time of removal and in 53, 27, and 23 % at 12, 24, and 60 months follow-up, respectively. In general, those who lost 80 % of the total weight lost during the first 3 months of balloon treatment succeeded in maintaining long-term weight loss after its removal [18].

Role of Concurrent a Behavior Modification Program: Long-term weight loss with Orbera balloon therapy requires a comprehensive weight management strategy involving dietary and lifestyle changes. In a small study involving 28 patients, of those achieving at least 20 % EWL, 85 % attended half of their dietician appointments, whereas of those who failed to reach the above target weight loss threshold, 75 % missed at least half of the dietician appointments [19].

Bridge Therapy: The Orbera balloon has also been studied as a bridge therapy before gastric bypass surgery in

super obese patients. In a study of 60 patients with an average BMI of 66 kg/m^2, the 23 patients who received an intra-gastric balloon prior to surgery experienced shorter operative time, ICU stay, total hospital stay, and fewer adverse events than the 37 patients who underwent surgery directly [20]. The intra-gastric balloon was also utilized pre-operatively in a small cohort of 10 obese patients awaiting abdominal hernia repair in Europe. Although investigators reported significant pre-operative weight loss, surgical outcomes were not reported [21].

B. *The ReShape Duo® Integrated Dual Balloon System* (ReShape Medical, Inc., San Clemente, CA) is a dual-balloon implant that is endoscopically placed and retrieved following 6 months of treatment. This is the second endoscopically implanted space occupying device to be recently approved by the FDA. The dual balloon design provides enhanced gastric space filling while potentially reducing the risk of intestinal migration [22•]. However, as compared to the Orbera balloon, The ReShape Duo is a relatively new device with significantly less published clinical data regarding efficacy and safety.

   In a prospective sham controlled US pivotal trial, it resulted in significantly greater %EWL [25.1 % intent-to-treat (ITT), 27.9 % completed cases (CC, $n=167$)] as compared to patients managed with diet and exercise alone (11.3 % ITT, $P=0.004$, 12.3 % CC, $n=126$) at 24 weeks. There were no deaths, intestinal obstructions, gastric perforations, or device migrations. Seventy-five percent of the device-related serious adverse events were visits to the emergency room for medical management of accommodative symptoms. Balloon deflation without migration occurred in 6 %, and early retrieval for non-ulcer intolerance was required in 9.1 %. Gastric ulceration at the incisura was observed in 39 % but was significantly reduced to 10 % after a minor device change [22•].

   In a smaller single-center European study including 60 patients, the reported decrease in BMI, mean TBWL, %TBWL, and %EWL was 6.1 units, 16.6 kg, 15.4 %, and 47.1 %, respectively. In this study, there was only one case each of early removal for intolerance, early deflation without migration, and gastric perforation. Furthermore, 14 patients had small, clinically insignificant ulcers or erosions noted at the time of removal [23].

2. *Primary Endoscopic Sleeve Gastroplasty (ESG)*: Gastric volume reduction to emulate the anatomy of a surgical sleeve gastrectomy can be achieved trans-orally using recently developed endoscopic suturing devices. It potentially allows for an incisionless procedure with lower costs and shorter recovery times compared with surgery. This also has the potential to reduce the complications associated with current surgical approaches while effecting the desired gastric restriction.

   Using a suction-based superficial-thickness endoscopic suturing device, the EndoCinch™, the safety and efficacy of endo-luminal vertical gastroplasty was first reported in a cohort of 64 obese patients by Fogel et al. in 2008. The reported %EWL at 12 months was 58.1 %, with 97 % of patients attaining a 30 % or greater excess weight loss [24]. More recently, a non-suction-based endoscopic suturing device designed place full-thickness stitches in a variety of interrupted or running patterns has been approved by the FDA (Apollo OverStitch™ by Apollo Endosurgery, Austin, TX) and used for ESG creation.

   Procedure Description: Following induction of anesthesia, a dual channel therapeutic flexible upper endoscope is inserted to examine esophageal and gastric anatomy and evaluate for any anatomical contraindications to the procedure. CO_2 insufflation is used to minimize post-procedure discomfort. Argon plasma coagulation is used to ablate the mucosa of the stomach to expose the substrate collagen required for durable tissue apposition. This technique also serves to map the predicted gastric plication sites. The endoscope is then withdrawn and loaded with the endoscopic suturing device. Interrupted plications using 2-0 prolene suture are then placed in a triangular stitch pattern running from the anterior gastric wall to greater curvature to the posterior gastric wall in a distal to proximal fashion from proximal antrum at the incisura to the gastric fundus immediately below the gastro-esophageal (GE) junction resulting in a tube-like passage less than 1.5 cm in diameter. It is important to note that comparative studies of stitch patterns are lacking.

   Post-Procedure Care: Patients are recovered in the post anesthesia care unit, furnished with analgesia and anti-emetics as needed and are typically discharged in less than 24 h. Post-operatively, patients will remain NPO on the day of procedure, followed by a clear liquid diet for two days, full liquid diet for 2 days, mechanical soft diet for 2 days, and advancement as tolerated thereafter.

   Efficacy and Safety: Using the OverStitch device, preliminary studies using different stitching techniques have demonstrated encouraging safety and efficacy results [25, 26]. Lopez-Nava and colleagues demonstrated a robust 17.8 % total body weight loss (TBWL) at 6 months in a 20 patient study with mean baseline BMI of 38.5 (range, 30.2–47.0) kg/m^2. No major adverse events were reported except intra-procedural bleeding requiring injection therapy in 2 patients [27]. The investigators further reported their experience in a larger cohort of 50 patients with 13 having reached 1-year

follow-up [28]. The procedure duration averaged 66 min during which an average of six to eight sutures were placed. All patients were discharged in less than 24 h and there were no major intra-procedural, early, or delayed adverse events. Mean %TBWL was 19.0 ± 10.8 and BMI reduced from 37.7 ± 4.6 to 30.9 ± 5.1 kg/m^2 at 1 year. Oral contrast studies and endoscopy revealed a preserved sleeve gastroplasty configuration at 1 year of follow-up [28].

A US group performed the same procedure in 10 obese patients with higher baseline BMI of 45.2 kg/m^2. They demonstrated an average weight loss of 14.1 kg, with 30 % EWL and a 5.5-kg/m^2 drop in BMI at 6 months [29]. The median procedure time was 157 min (range 118–360 min) and no major intra-operative adverse events were reported. Mild post-procedure adverse events included abdominal pain and nausea in eight patients and chest pain in two patients [29]. Although trans-oral suturing is safe and efficacious, the long-term durability of weight loss achieved with this procedure is still unknown.

3. *Gastric-Bypass Revision*: Weight regain is an increasingly common referral indication for revision operations. More than 20 % of patients experience significant post-operative weight regain and risk recurrence or worsening of comorbid conditions such as diabetes, hypertension, and obstructive sleep apnea. Enlargement of the remnant gastric pouch or gastro-jejunal (GJ) stoma post-RYGB has been demonstrated to be an independent predictor of weight regain in multiple studies [30, 31]. 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 [32, 33, 34•]. The largest case series reported 20 % EWL at 6 months in 59 patients with GJ outlet revision using the Overstitch device [35]. More recently, we have recently demonstrated greater efficacy of a combined approach using endoscopic trans-oral outlet reduction (TORe) in combination with gastroplasty of the entire gastric pouch from the gastro-esophageal (GE) junction to the GJ stoma (TORe-G). TORe-G resulted in robust weight loss in a cohort of 20 obese patients with median %EWL seen at 3 and 6 of 39.35 and 52.8 %, respectively, without any increase in significant adverse events as compared to historical controls [36].

Promising Endoscopic Strategies Currently Under Investigation and Review

1. *Primary Obesity Surgery Endolumenal (POSE™) Procedure*: The POSE procedure involves the use of the Incisionless Operating platform (IOP) (USGI Medical, San Clemente, CA) to apply suture-anchor plications in the gastric fundus to limit gastric fundal accommodation, and distal body near the proximal antral inlet to delay gastric emptying. The IOP consists of the TransPort, a flexible, steerable, multilumen access device that is passed transorally under general anesthesia. The g-Cath suture anchor delivery catheter, g-Prox endoscopic grasper and g-Lix tissue grasper, are passed through the device along with a gastroscope in order to place nitinol Snowshoe tissue anchors for full-thickness tissue approximation. The anchors are designed to distribute the compression force of tissue approximation along the larger surface area of the anchor mesh which theoretically results in superior durability compared with sutured approximation.

Initial experience with the POSE procedure was reported by Espinos et al. in 45 patients with a baseline mean BMI of 36.7 ± 3.8. Mean operative time was 69.2 ± 26.6 min and a mean of 8.2 suture–anchor plications were placed in the fundus and 3 anchors along the distal body wall. BMI loss was 5.8 kg/m^2, % EWL was 49.4 %; and %TBWL was 15.5 % at 6 months. No mortality or operative morbidity was observed [37]. Lopez-Nava and colleagues recently published the largest case series to date of POSE procedure involving 147 obese patients with baseline BMI of 38.0 ± 4.8 kg/m^2. Follow-up at 1 year was obtained in 79 % of patients who achieved a mean TBWL of 16.6 ± 9.7 kg, %TWL of 15.1 ± 7.8, and %EWL of 44.9 ± 24.4. No serious short-term or long-term adverse events were reported [38]. The enrollment for the US multicenter ESSENTIAL trial has ended and the results are awaited.

2. *Aspiration Therapy*: Aspiration therapy involves the endoscopic placement of the AspireAssist Device (Aspire Bariatrics, King of Prussia, Pennsylvania, USA) consisting of a 30 Fr gastrostomy tube (A-Tube). Patients attach an AspireAssist siphon assembly to aspirate gastric contents 20 min after meal consumption. Though concerns are naturally raised regarding the palatability and ethics of this approach, the procedure has nonetheless been shown to be effective in early trials.

In a US pilot comparative study involving 18 patients, the aspiration therapy group lost 18.6 % ± 2.3 % of their body weight (49.0 % ± 7.7 % EWL) compared to 5.9 % ± 5.0 % (14.9 % ± 12.2 % of EWL) in the lifestyle therapy group at 1 year of therapy. Seven of the 10 subjects in the aspiration therapy group completed an additional year of therapy and maintained a 20.1 % ± 3.5 % body weight loss (54.6 % ± 12.0 % of EWL). No compensation for aspirated calories with increased food intake or binge eating was observed [39]. In a European prospective study with 22 subjects, the mean 6-month weight loss after aspiration therapy was 16.5 ± 7.8 kg and the mean %EWL was 40.8 ± 19.8 % (P = 0.001). Two subjects required hospitalized for complications: pain (1) and aseptic

intra-abdominal fluid collection after gastrostomy tube placement (1) [40]. The US prospective multicenter PATHWAY trial completed enrollment in 2014 and outcomes data have been submitted to the FDA for approval.

Endoscopic Devices in Early Phases of Development

Several endoscopic bariatric strategies are in various stages of development ranging from proof of concept to feasibility and safety studies and design modifications. Duodenal Mucosal Resurfacing (DMR) (Fractyl Laboratories, Cambridge, Massachusetts, USA) involves superficial mucosal thermal ablation using recirculating hot water within a balloon catheter to treat diabetes. Neto and colleagues found a two-point HbA1c reduction in a single-center small unpublished case series in Chile and currently a definitive multi-center prospective double-blind sham-controlled trial is underway in Europe and South America [41••]. A second innovative approach includes endoscopic deployment of self-assembling magnets to create incision-less magnetic compression gastro-jejunostomy (GI Windows Inc., Bridgewater, MA). Ryou et al. recently demonstrated successful creation of large-caliber, leak-free, foreign body-free endoscopic intestinal bypass by using the incisionless anastomosis system (IAS) in a porcine model (5 out of 5) [42].

Several new designs of endoscopically placed space occupying devices are also under development and investigation. The transpyloric Shuttle (Baronova Inc., Goleta, California, USA) consists of a large spherical bulb connected by a flexible catheter to a smaller cylindrical bulb. It is designed to cause intermittent gastric obstruction leading to early and prolonged satiety. An initial multicenter U.S. trial is currently being planned. The Spatz Adjustable Balloon System (Spatz FGIA, Jericho, NY, USA) uses an extractable inflation tube for volume adjustment, while the IGB remains in situ in the stomach [41••]. It should be noted that these approaches and devices are still in their infancy and their ultimate efficacy, safety and applicability have yet to be determined.

The Endobarrier or duodeno-jejunal bypass sleeve (GI dynamics, Lexington, Massachusetts, USA), is a 60-cm fluoropolymer liner designed to create a mechanical barrier between food and the proximal small bowel. While it has demonstrated promising results with respect to weight loss and improvement of diabetes, a multi-center US pivotal trial was recently stopped prematurely due to safety concerns over reports of infectious complications including liver abscesses associated with device.

Future Directions

In response to the rapid development of novel endoscopic therapies for primary management of obesity, the FDA has developed an objective tiered model to review such device applications [38]. During review, the FDA evaluates the probable benefit to health from the use of the device against any probable risk of injury or illness using the submitted preclinical and clinical scientific data. The relevant factors taken in to account include the probability, type, magnitude, and duration of benefit versus rate, severity, and type of harmful events associated with use of the device or the endoscopic procedure. Importantly, the FDA recommends using percent total body-weight loss (%TBL) as the primary end point for endoscopic bariatric devices. The percent excess weight loss (%EWL) is accepted only as a secondary end point of any device related clinical trial in order to allow comparison with previously approved devices that used %EWL as their primary outcome. In general, the devices with higher risk are expected to yield correspondingly greater benefit [43]. Finally, medical providers who plan to offer endoscopic bariatric therapies in their clinical practice need appropriate training in both medical and endoscopic management of obesity and its associated comorbidities. It is anticipated that national GI societies will provide such training in a structured environment and standardize objective benchmarks for competency in the near future. Additionally, all patients should be managed by a multidisciplinary team encompassing nutritional, psychological, medical and social support [44••].

Conclusions

Endoscopic bariatric therapies have ushered in a new paradigm in the management of obesity. Several technologies are now available and FDA approved in the U.S., including two intragastric balloon devices approved for 6-month placement in patients suffering from mild to moderate obesity. In addition, full-thickness endoscopic suturing has led to the development of techniques that may be utilized as a primary treatment in the form of an endoscopic sleeve gastroplasty and revision procedure via TORe-G. Several other innovative technologies are currently under investigation, though pivotal trial data and regulatory approval are still awaited. As the field of endoscopic bariatric therapies continues to develop, rigorous evaluation of new technology by regulatory agencies and proactive engagement by GI societies is paramount to ensure safe and efficient integration of this technology into the multidisciplinary management of obesity.

Compliance with Ethical Standards

Conflicts of Interest DG declares that he has no conflicts of interest. RRW reports that he is a consultant for Apollo Endosurgery, outside the submitted work.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

References

Papers of particular interest, published recently, have been highlighted as:
- • Of importance
- •• Of major importance

1. Flegal KM, Carroll MD, Ogden CL, Curtin LR. Prevalence and trends in obesity among US adults, 1999–2008. JAMA. 2010;303:235–41.
2. Must A, Spadano J, Coakley EH, Field AE, Colditz G, Dietz WH. The disease burden associated with overweight and obesity. JAMA. 1999;282(16):1523–9.
3. Frohlich ED. Clinical management of the obese hypertensive patient. Cardiol Rev. 2002;10(3):127–38.
4. Hall JE. Pathophysiology of obesity hypertension. Curr Hypertens Rep. 2000;2(2):139–47.
5. Sacks FM, Bray GA, Carey VJ, Smith SR, Ryan DH, Anton SD, et al. Comparison of weight-loss diets with different compositions of fat, protein, and carbohydrates. N Engl J Med. 2009;360(9):859–73.
6. Gudzune KA, Doshi RS, Mehta AK, Chaudhry ZW, Jacobs DK, Vakil RM, et al. Efficacy of commercial weight-loss programs: an updated systematic review. Ann Intern Med. 2015;162(7):501–12.
7. Kumar RB, Aronne LJ. Efficacy comparison of medications approved for chronic weight management. Obesity (Silver Spring). 2015;23 Suppl 1:S4–7.
8. Buchwald H, Estok R, Fahrbach K, Banel D, Jensen MD, Pories WJ, et al. Weight and type 2 diabetes after bariatric surgery: systematic review and meta-analysis. Am J Med. 2009;122(3):248–56.
9. Adams TD, Gress RE, Smith SC, Halverson RC, Simper SC, Rosamon WD, et al. Long-term mortality after gastric bypass surgery. N Engl J Med. 2007;357(8):753.
10. Avidor Y, Still C, Brunner M, Buchwald JN, Buchwald H. Primary care and subspecialty management of morbid obesity: referral patterns for bariatric surgery. Surg Obes Relat Dis. 2007;3:392–407.
11. Kramer FM, Stunkard AJ, Spiegel TA, Deren JJ, Velchik MG, Wadden TA, et al. Limited weight losses with a gastric balloon. Arch Intern Med. 1989;149(2):411–3.
12. •• ASGE Bariatric Endoscopy Task Force and ASGE Technology Committee, Abu Dayyeh BK, Kumar N, Edmundowicz SA, Jonnalagadda S, Larsen M, et al. ASGE Bariatric Endoscopy Task Force systematic review and meta-analysis assessing the ASGE PIVI thresholds for adopting endoscopic bariatric therapies. Gastrointest Endosc. 2015;82(3):425–438.e5. **Summary of data on current EBTs**.
13. Lopez-Nava G, Rubio MA, Prados S, Pastor G, Cruz MR, Companioni E, et al. BioEnterics® intragastric balloon (BIB®). Single ambulatory center Spanish experience with 714 consecutive patients treated with one or two consecutive balloons. Obes Surg. 2011;21(1):5–9.
14. Genco A, Bruni T, Doldi SB, Forestieri P, Marino M, Busetto L, et al. BioEnterics intragastric balloon: the Italian experience with 2, 515 patients. Obes Surg. 2005;15(8):1161–4.
15. Imaz I, Martínez-Cervell C, García-Alvarez EE, Sendra-Gutiérrez JM, González-Enríquez J. Safety and effectiveness of the intragastric balloon for obesity. A meta-analysis. Obes Surg. 2008;18(7):841–6.
16. Barham K. Abu Dayyeh, Laura L. Eaton, George Woodman, Mark Fusco, Vafa Shayani, Helmuth T. Billy, Anita Courcoulas, Daniel J. Pambianco, Christopher J. Gostout. A randomized, multi-center study to evaluate the safety and effectiveness of an intragastric balloon as an adjunct to a behavioral modification program, in comparison with a behavioral modification program alone in the weight management of obese subjects. Abstract 444. Digestive Disease Week 2015, Washington, DC.
17. Forlano R, Ippolito AM, Iacobellis A, Merla A, Valvano MR, Niro G, et al. Effect of the BioEnterics intragastric balloon on weight, insulin resistance, and liver steatosis in obese patients. Gastrointest Endosc. 2010;71(6):927–33.
18. Kotzampassi K, Grosomanidis V, Papakostas P, Penna S, Eleftheriadis E. 500 intragastric balloons: what happens 5 years thereafter? Obes Surg. 2012;22(6):896–903.
19. Tai CM, Lin HY, Yen YC, Huang CK, Hsu WL, Huang YW, et al. Effectiveness of intragastric balloon treatment for obese patients: one-year follow-up after balloon removal. Obes Surg. 2013;23(12):2068–74.
20. Zerrweck C, Maunoury V, Caiazzo R, Branche J, Dezfoulian G, Bulois P, et al. Preoperative weight loss with intragastric balloon decreases the risk of significant adverse outcomes of laparoscopic gastric bypass in super-super obese patients. Obes Surg. 2012;22(5):777–82.
21. Dąbrowiecki S, Szczęsny W, Popławski C, Sosnowski D. Intragastric Balloon (BIB system) in the treatment of obesity and preparation of patients for surgery - own experience and literature review. Pol Przegl Chir. 2011;83(4):181–7.
22. • Ponce J, Woodman G, Swain J, Wilson E, English W, Ikramuddin S, et al. The REDUCE pivotal trial: a prospective, randomized controlled pivotal trial of a dual intragastric balloon for the treatment of obesity. Surg Obes Relat Dis. 2015;11(4):874–81. **Pivotal FDA trial for intragastric balloon**.
23. Lopez-Nava G, Bautista-Castano I, Jimenez-Banos A, de Grado Manchado T, Fernandez-Corbelle J. A prospective evaluation of a new dual intragastric balloon. Obes Surg. 2014;24:1131.
24. Fogel R, De Fogel J, Bonilla Y, De La Fuente R. Clinical experience of transoral suturing for an endoluminal vertical gastroplasty: 1-year follow-up in 64 patients. Gastrointest Endosc. 2008;68(1):51–8.
25. Abu Dayyeh BK, Rajan E, Gostout CJ. Endoscopic sleeve gastroplasty: a potential endoscopic alternative to surgical sleeve gastrectomy for treatment of obesity. Gastrointest Endosc. 2013;78(3):530–5.
26. Kumar N, Sahdala HN, Shaikh S, Wilson E, Manoel GN, Zundel N, et al. Endoscopic sleeve gastroplasty for primary therapy of obesity: initial human cases. Gastroenterology. 2014;Mo1155:S-571–2.
27. Lopez-Nava G, Galvão MP, da Bautista-Castaño I, Jimenez A, De Grado T, Fernandez-Corbelle JP. Endoscopic sleeve gastroplasty for the treatment of obesity. Endoscopy. 2015;47(5):449–52.
28. Lopez-Nava G, Galvão MP, Bautista-Castaño I, Jimenez-Baños A, Fernandez-Corbelle JP. Endoscopic sleeve gastroplasty: how I do it? Obes Surg. 2015;25(8):1534–8.
29. Sharaiha RZ, Kedia P, Kumta N, DeFilippis EM, Gaidhane M, Shukla A, et al. Initial experience with endoscopic sleeve gastroplasty: technical success and reproducibility in the bariatric population. Endoscopy. 2015;47(2):164–6.
30. Abu Dayyeh BK, Lautz DB, Thompson CC. Gastrojejunal stoma diameter predicts weight regain after Roux-en-Y gastric bypass. Clin Gastroenterol Hepatol. 2011;9(3):228–33.
31. Heneghan HM, Yimcharoen P, Brethauer SA, et al. Influence of pouch and stoma size on weight loss after gastric bypass. Surg Obes Relat Dis. 2012;8:408–15.
32. Hallowell PT, Stellato TA, Yao DA, Robinson A, Schuster MM, Graf KN. Should bariatric revisional surgery be avoided secondary to increased morbidity and mortality? Am J Surg. 2009;197(3):391–6.
33. Dakin GF, Eid G, Mikami D, Pryor A, Chand B. Endoluminal revision of gastric bypass for weight regain – a systemic review. Surg Obes Rel Dis. 2013;9:335–43.
34. • Thompson CC, Chand B, Chen YK, DeMarco DC, Miller L, Schweitzer M, et al. Endoscopic suturing for transoral outlet reduction increases weight loss following Roux-en-Y gastric bypass

surgery. Gastroenterology. 2013;145(1):129–37. **Randomized trial of TORe**.

35. Kumar N, Thompson CC. Comparison of a superficial suturing device with a full-thickness suturing device for transoral outlet reduction (with videos). Gastrointest Endosc. 2014;79(6):984–9.
36. Deepinder Goyal, Stephen Kim, Eric Dutson, Yijun Chen, Joseph Pisegna, Rabindra Watson. Endoscopic trans-oral outlet reduction in combination with gastroplasty (TORe-G) is a novel technique that is highly efficacious and safe for weight loss in patients with failed Roux-en-Y gastric bypass. American College of Gastroenterology Annual Meeting Oct 18, 2015. Honolulu, USA; Poster 186.
37. Espinos JC, Turro R, Mata A, et al. Early experience with the incisionless operating platform. Obes Surg. 2013;23:1375–83.
38. López-Nava G, Bautista-Castaño I, Jimenez A, de Grado T, Fernandez-Corbelle JP. The primary obesity surgery endolumenal (POSE) procedure: one-year patient weight loss and safety outcomes. Surg Obes Relat Dis. 2015;11(4):861–5.
39. Sullivan S, Stein R, Jonnalagadda S, Mullady D, Edmundowicz S. Aspiration therapy leads to weight loss in obese subjects: a pilot study. Gastroenterology. 2013;145(6):1245-52.e1-5.
40. Forssell H, Norén E. A novel endoscopic weight loss therapy using gastric aspiration: results after 6 months. Endoscopy. 2015;47(1):68–71.
41.•• ASGE Bariatric Endoscopy Task Force; ASGE Technology Committee, Abu Dayyeh BK, Edmundowicz SA, Jonnalagadda S, Kumar N, Larsen M, et al. Endoscopic bariatric therapies. Gastrointest Endosc. 2015;81(5):1073–86. **Concise summary of current endoscopic bariatric therapies**.
42. Ryou M, Agoston AT, Thompson CC. Endoscopic intestinal bypass creation by using self-assembling magnets in a porcine model. Gastrointest Endosc. 2015. Epub.
43. Lerner H, Whang J, Nipper R. Benefit-risk paradigm for clinical trial design of obesity devices: FDA proposal. Surg Endosc. 2013;27(3):702–7.
44.•• ASGE Bariatric Endoscopy Task Force, Sullivan S, Kumar N, Edmundowicz SA, Abu Dayyeh BK, Jonnalagadda SS, et al. ASGE position statement on endoscopic bariatric therapies in clinical practice. Gastrointest Endosc. 2015;82(5):767–72. **Detailed report on proper implementation of EBT**.