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REVIEW

Endoscopic management of weight regain following Roux-en-Y gastric bypass

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ABSTRACT

Introduction: With the cumulative increase in the number of patients undergoing bariatric surgery, postoperative weight regain has become a considerable challenge. Mechanisms for weight regain are not fully understood and the process is likely multifactorial in many cases. Endoluminal revisions that reduce gastric pouch size and diameter of the gastrojejunal anastomosis may offer an effective and less invasive management strategy for this population.

Areas covered: We critically review data from case series, retrospective and prospective studies, and meta-analyses pertaining to weight regain after gastric bypass. A variety of endoscopic revision approaches are reviewed, including technique details, procedural safety and efficacy, and post-procedure care.

Expert commentary: Given the proliferation of endoluminal therapies with evidence showing safety and efficacy in the treatment of weight regain, it is likely that endoscopic revision will be the gold standard to treat weight regain in patients with gastric bypass.

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Bariatric; endoscopy; surgery; obesity; weight regain; sclerotherapy; endoscopic; gastric plication; transoral; endoluminal

1. Introduction

Obesity is a pandemic with an estimated worldwide incidence of more than 700 million, and an additional 2 billion overweight. Obesity is associated with metabolic conditions, such as type 2 diabetes, hypertension, cardiovascular diseases, and others [1,2]. Non-invasive methods of weight reduction appear to offer limited potential for consequential and sustained weight loss. Lifestyle changes and pharmaceuticals demonstrated disappointing effective excess weight loss (EWL) of less than 5% at 12 months [3–5]. Gastrointestinal weight loss surgery, in contrast, has been shown to be effective and is finding increased use [3,6–9]. In this review, we will briefly discuss Roux-en-Y gastric bypass (RYGB) and the general mechanism of weight regain after bariatric surgery. Then, we will focus on the potential anatomic causes of weight regain and the endoscopic approaches for the treatment of this condition.

1.1. Gastric bypass

Laparoscopic or open Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy, adjustable gastric band, and duodenal switch comprise the vast majority of bariatric surgeries [10,11]. A meta-analysis including 22,094 subjects found that RYGB is the most prevalent and revealed that RYGB resulted in average EWL of 56.7% to 66.5% over 24 months post-surgery [4]. There was the resolution of diabetes and obstructive sleeve apnea in more than 80%, hypertension in 68%, and improvement in hyperlipidemia in 97%; improving the survival benefits [12–16]. However, around 20% of patients fail to reach postoperative success, defined as >50% EWL within 1 year of surgery [17–20].

The success of RYGB may be partially credited to restriction produced by the small gastric pouch and stoma, resulting in reduced caloric intake, as well as a bypass of the digestive and absorptive regions of the GI tract, but the mechanisms by which gastric bypass leads to weight loss are not completely understood [3,21,22].

1.2. Postoperative weight regain

There are a variety of definitions for weight regain after bariatric surgery, including an increase of more than 15% of weight from nadir, increase of 10 kg from nadir, increase of more than 25% EWL from nadir, an increase in BMI of 5 kg/m2, any weight regain after T2DM remission, weight regain to a BMI> 35 kg/m2 after successful loss, and any weight regain [17–20,23–25]. After losing weight for 12 to 18 months postoperatively, the patient reaches a balance between energy intake and expenditure and a stable body weight is typically acheived [17,18]. Maintenance of body weight is regulated by the interaction of several processes, encompassing homeostatic, environmental and behavioral factors [19].

Between 18 and 24 months after surgery, 30% of patients experience weight regain [19,20,26–32]. Magro et al. [33], in a retrospective study with 5-year follow-up, reported that approximately half of the patients had weight regain during the first two years (46% within 24 months and 63.6% within 48 months). Others reported a long-term failure rate of approximately 35%, with the inability to achieve a body mass index (BMI) of <35 kg/m^2 in 60% of superobese (>50 kg/m^2) patients [29,34].

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The impact of weight regain on quality of life, mental health, and recurrence of obesity-associated diseases presents a significant challenge [29,35].

1.3. Mechanism of weight regain

Mechanisms for weight regain are not fully understood and the process is likely multifactorial in many cases. An extensive review of the medical causes for weight regain is beyond the scope of this review, however, we will briefly address this topic and instead focus on the potential anatomic causes for weight regain. Preoperative predictors of weight regain includes higher preoperative BMI and psychiatric disorders. Postoperative conditions that favor weight regain include the type of surgery, physical activity, psychiatric comorbidities, and patient dietary adherence [36,37]. Some medications may be related to weight gain including tricyclic antidepressants such as amitriptyline and nortriptyline, and mood stabilizers such as valproic acid and lithium that causes increased appetite [38,39]. Antihistamines such as cetirizine or fexofenadine and antihypertensives as beta-blockers, such as atenolol and metoprolol increases the sensation of fatigue, contributing to physical inactivity and reduced energy expenditure [40,41]. High dose contraceptives are associated with fluid retention. Corticosteroids increase fluid retention and insulin resistance and stimulate appetite. Diabetes control medications such as the sulfonylurea class: glibenclamide, gliclazide, and glimepiride increase blood insulin levels, leading to increased appetite and fat accumulation. Drugs of the class of thiazolidinedione, such as pioglitazone and rosiglitazone promote fluid retention and also should be prescribed with caution in patients with heart failures [42,43]. Antipsychotic agents have been strongly associated with weight gain [44]. According to a recent study [45], 78.8% of patients receiving antipsychotic agents increased their baseline weight by more than 7%. Clozapine and olanzapine produce the highest weight gain, while quetiapine and risperidone produce intermediate weight gain, and ziprasidone and aripiprazole produce the lowest weight gain [44,45]. Neuroendocrine-metabolic dysregulation in the form of a starvation response may also increase appetite and promote energy conservation [46].

Additionally, decreased satiety and increased food intake may be secondary to loss of restriction [47]. Consistent with this, larger pouch size and the larger diameter of the gastrojejunal anastomosis (GJA) have been shown to correlate with increased postoperative weight gain [48–51].

2. Methods

This is an expert review on endoscopic therapies for weight regain after RYGB based on the experience of the authors and the available published data, including clinical trials, observational studies, case series, and case reports.

The literature screening was independently performed by two authors after searching Medline, EMBASE, Cochrane, Lilacs, Scopus, and CINAHL databases with the following strategy: (Bariatric* OR Gastric Bypass OR Gastroileal Bypass OR Gastrojejunostomy OR Gastrojejunostomies) AND (Endoscopy OR Endoscopic OR Endolum* OR Transoral*). Additionally, references of related manuscripts were screened until 01/10/2019.

3. Intervention for weight regain

Since weight regain can accompany re-emergence of obesity-related comorbidities, early intervention is important. The initial step in the management of weight regain is a comprehensive evaluation of contributing factors, as detailed above. While lifestyle therapy including diet, exercise, and behavior modification are fundamental, they have limited efficacy which can be enhanced by medications and/or gastric bypass revision. Assessment of surgical anatomy for potential endoscopic intervention is an important part of this evaluation [36,52–55]. With continued growth in the number of bariatric surgeries performed and increase in duration of follow-up, a huge number of patients will require intervention for post-operative adverse events and weight regain [52,53,56–58].

Surgical options to address weight regain include recreating the gastrojejunostomy, revision of the pouch, placement of an adjustable gastric band, taking down of the Roux limb, and distal gastric bypass [35,49–51]. Though effective, traditional surgical revision is used in 3–13% of patients, with complication rates of between 15% and 50%, mortality rates of more than double the original procedure, and high medical costs that may not be covered by insurance [52,59–62]. Surgical revision procedures also involve longer operative time and higher intraoperative blood loss [63,64].

Due to the high risk of surgical revisional procedures, an endoscopic revision of a dilated GJA was first reported in 2004, and the use of this technique has been increasing since that time [65]. Weight loss with endoscopic revision appears substantial and durable, and vastly safer and less expensive than surgical revision [66].

A recent review [36] about predictors and management of weight regain discussed factors including behavioral and psychotherapeutic interventions and pharmacotherapy. However, this review did not discuss endoscopic revision. A recent published study [67], including 55 patients and 2-year follow-up demonstrated that the revision group had an overall improvement in comorbidities compared to medical management group (surgeon, dietician, and psychologist).

Less invasive endoluminal revisions that reduce gastric pouch size and GJA diameter appear to effective and safe, offering a more favorable risk profile in this population. A variety of techniques are now available including sclerotherapy, argon plasma coagulation, endoluminal suturing, and tissue plication, and several emerging technologies are on the horizon. These will be the focus of this review.

4. Pouch and gastrojejunal anastomosis measuring

The gastric pouch is measured using endoscope markings. For the gastrojejunal anastomosis (GJA) maximal diameter there are some techniques including a reusable flexible measuring device (Olympus, Center Valley, PA, USA) (Figure 1(a)) which is no longer commercialized. The other techniques including any grasping forceps (Rat Tooth or Alligator) (Figure 1(b)) based on the size of the opening and conventional guidewire (Figure 1(c)) or devices such as endovascular laser catheter (Figure 1(d)) with markings [68–70]. It is important to notice that after endoscopic procedures the diameter of the GJA is initially

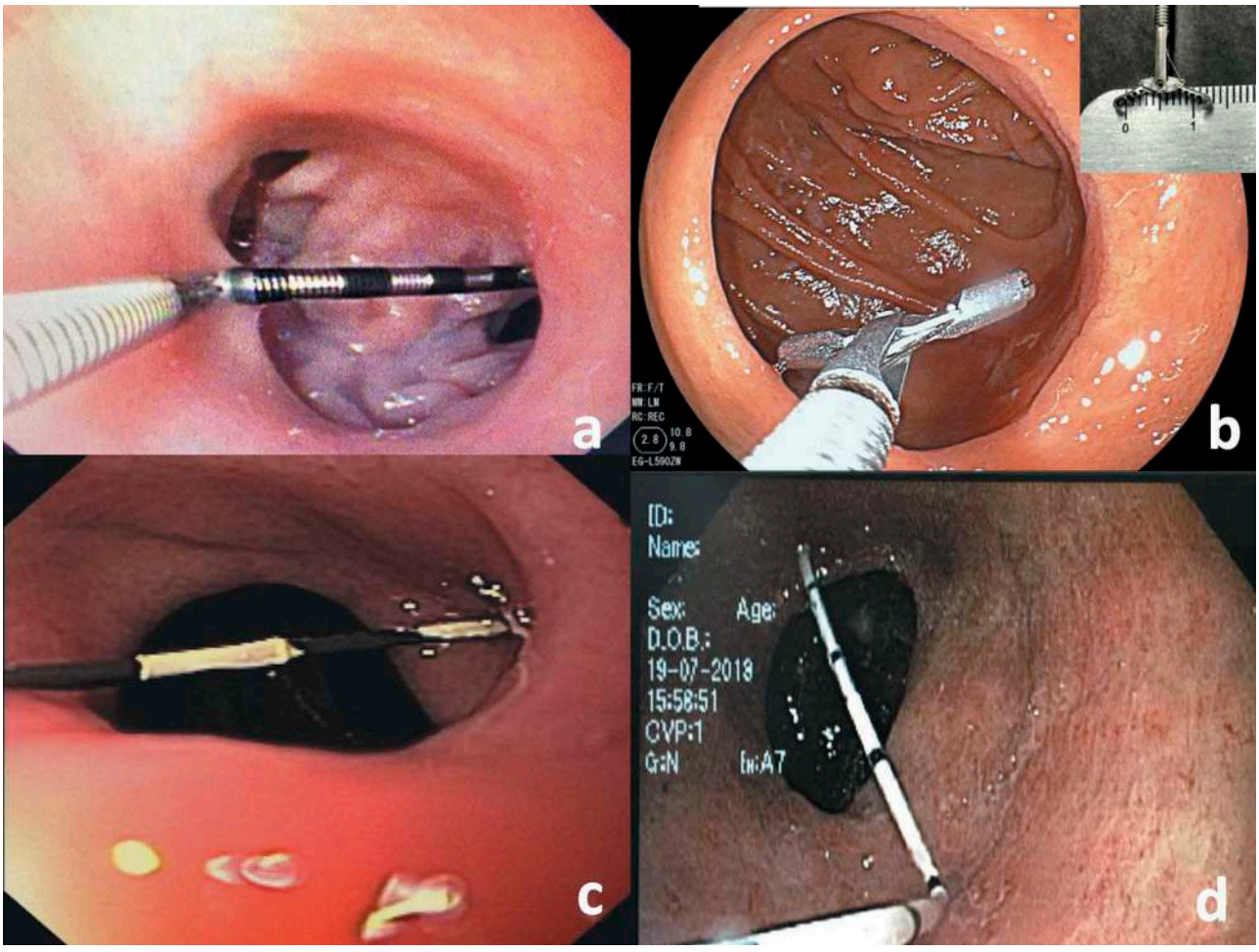

Figure 1. Gastrojejunal anastomosis measuring devices. (a). Olympus measuring device (Olympus, Center Valley, PA, USA) (b). Grasping forceps (c). Conventional guidewire with markings (d). Endovascular laser catheter with markings.

reduced by edema and because of that post-procedure measurements are not obtained until the next scheduled endoscopy[71].

5. Endoscopic techniques for weight regain

5.1. Sclerotherapy

Sclerotherapy entails injection of sodium morrhuate around the GJA using an endoscopic needle with the goal of reducing GJA aperture and tissue compliance (Figure 2). The procedure takes about 20 min and is easily performed with standard endoscopic instruments and under conscious sedation. A sodium morrhuate solution is injected in 2 mL aliquots. A total of 10 to 30 mL is injected along the rim of the GJA. Care is taken to avoid over-injection, which can result in bleeding or late perforation. Dark red or black discoloration may be a warning. On repeat procedures, tissue sclerosis may make injection difficult. Further sessions are scheduled every three months until adequate weight loss is achieved or the GJA measures less than 12 mm in diameter. Most patients require two or three sessions [68,71–73].

The first published report in patients with dilated GJA and weight regain reported weight loss in 75% of the patients at two months [72]. Another study including 32 patients demonstrated

Figure 2. Medical illustration showing the sclerotherapy technique.

weight loss or stabilization in 91.6% of patients after 1 year of follow-up [71].

The largest series included 231 consecutive patients undergoing 575 sclerotherapy procedures for weight regain, receiving single or multiple sessions of sodium morrhuate injections at the rim of the GJA. At 6 and 12 months from last sclerotherapy, procedure weight regain stabilized in 92% and 78% of patients, respectively. Those who underwent 2 or 3 sclerotherapy sessions had significantly higher rates weight stabilization than those who underwent a single session (90% vs. 60% at 12 months). The average weight loss at 6 months was 18% of the weight regained after RYGB. The authors described some predictors of favorable outcome including a higher magnitude of weight regain and number of sclerotherapy procedures. Bleeding was reported in 2.4% of procedures and transient diastolic blood pressure elevations in 15%, without adverse health outcomes. No gastrointestinal perforations were reported [74].

5.2. Argon plasma coagulation

In 2008, Ali *et al.* [75]. reported the first use of argon plasma coagulation (APC) by flexible endoscopy to reduce the stomal size, improve restriction, and avoid revisional surgery. The treatment consists of applications of concentric rings of APC at the margin of the GJA (Figure 3). Settings vary widely depending on processor type and technique employed. In our experience, a non-contact technique with settings of 1.0 L/min and 50 to 80 Watts are most effective. Patients typically undergo repeat procedures every 8–12 weeks as needed until they reach an optimal GJA size of 8–10 mm and effective weight loss [69,76].

A single center prospective study in the U.S. including 53 patients with a mean BMI of 35 ± 1.1 kg/m2 and a mean GJ diameter of 16 ± 0.5 mm patients were treated with an average of 1.3 ± 0.1 sessions of APC and evaluated at 3 and 6 months post-procedure. Post-procedure BMI significantly decreased to 32 ± 1.0 kg/m2 at 3 months and maintained at 6 months. Patients lost on average 4.8 ± 0.72 kg at 3 months and 5.3 ± 1.7 kg at 6 months. The excess weight loss was 14 ± 2.4% at 3 months and 16 ± 4.7% at 6 months. This result represents a loss of 37 ± 10% and 56 ± 17% of their regained weight at 3 months and 6 months, respectively. Three patients had adverse events, including melena or hematemesis post procedure; however, no intervention was necessary. One patient presented with stenosis of the GJ anastomosis and was successfully treated by dilation [76].

Another prospective study [69], including 30 patients, demonstrates a reduction of 66.89% in anastomotic diameter from the initial size after 1–3 session of APC. This study reported a loss of 15.48 kg of regained weight after APC treatment (Figure 4).

A recent large multicenter retrospective series, including 558 patients who underwent APC on patients who regained weight after RYGB procedure reported a mean weight loss of 6.5, 7.7, and 8.3 kg at 6, 12, and 24 months, respectively, and the change in weight over time was statistically significant. This study showed the lower BMI group (BMI < 30 kg/m2) to have greater TWL than the higher BMI group. In the 333 patients who provided adverse event information: stenosis (n = 9), GJA ulcer (n = 3), vomiting (n = 3), GJA leakage (n = 2), and melena (n = 1) were reported [77].

These results indicate that the use of APC to treat weight regain after RYGB is safe and effective in promoting a reduction of GJA diameter, body weight, and BMI, with a low rate of adverse events. However, randomized trials would be needed to validate these findings.

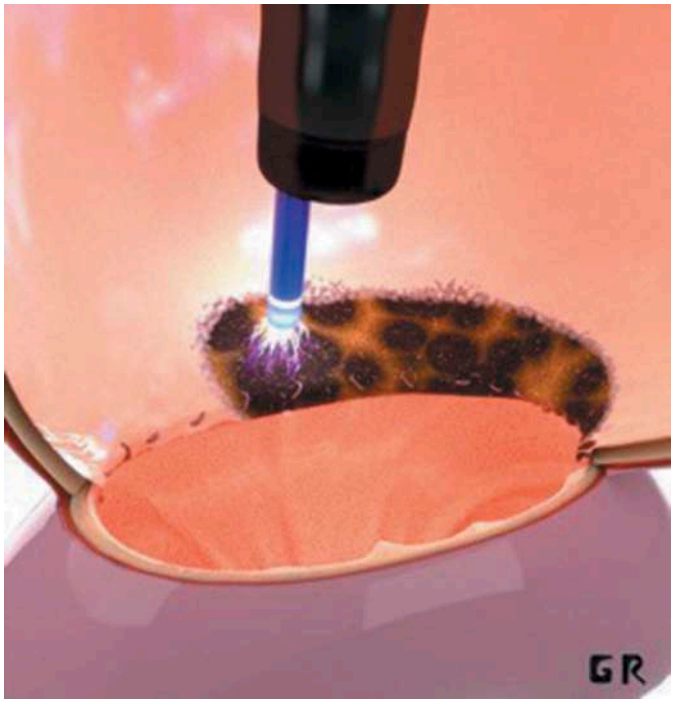

Figure 3. Medical illustration showing the Argon Plasma Coagulation Technique.

5.3. Suturing

Endoluminal suturing platforms have been studied for revision of dilated GJA and gastric pouches. There are two types of endoluminal suturing platforms, superficial suturing and full-thickness suturing devices. The devices are discussed below.

5.3.1. Superficial suturing

5.3.1.1. Endocinch suturing system. The Bard EndoCinch Suturing System (C.R. Bard, Inc., Murray Hill, NJ) (Figure 5) is a versatile platform for endoscopic surgery [78]. For revision of dilated GJA, the device is used to place interrupted stitches around the GJA after its rim is pretreated with APC. The mucosa to be sutured is suctioned into a hollow capsule placed on the endoscope tip and a hollow needle passes a suture through the trapped tissue.

In the first study for revision of dilated GJA [78], 8 patients with average weight regain of 24 kg from nadir were included; average GJA diameter was 25 mm. An average of two interrupted stitches were placed at the rim of the GJA; average post-procedure stoma diameter was 10 mm. Six of eight patients had a mean weight loss of 10 kg at 4 months. Three patients had a repeat procedure; two of them had a weight loss of 19 kg and 20 kg at 5 months. Average BMI fell from

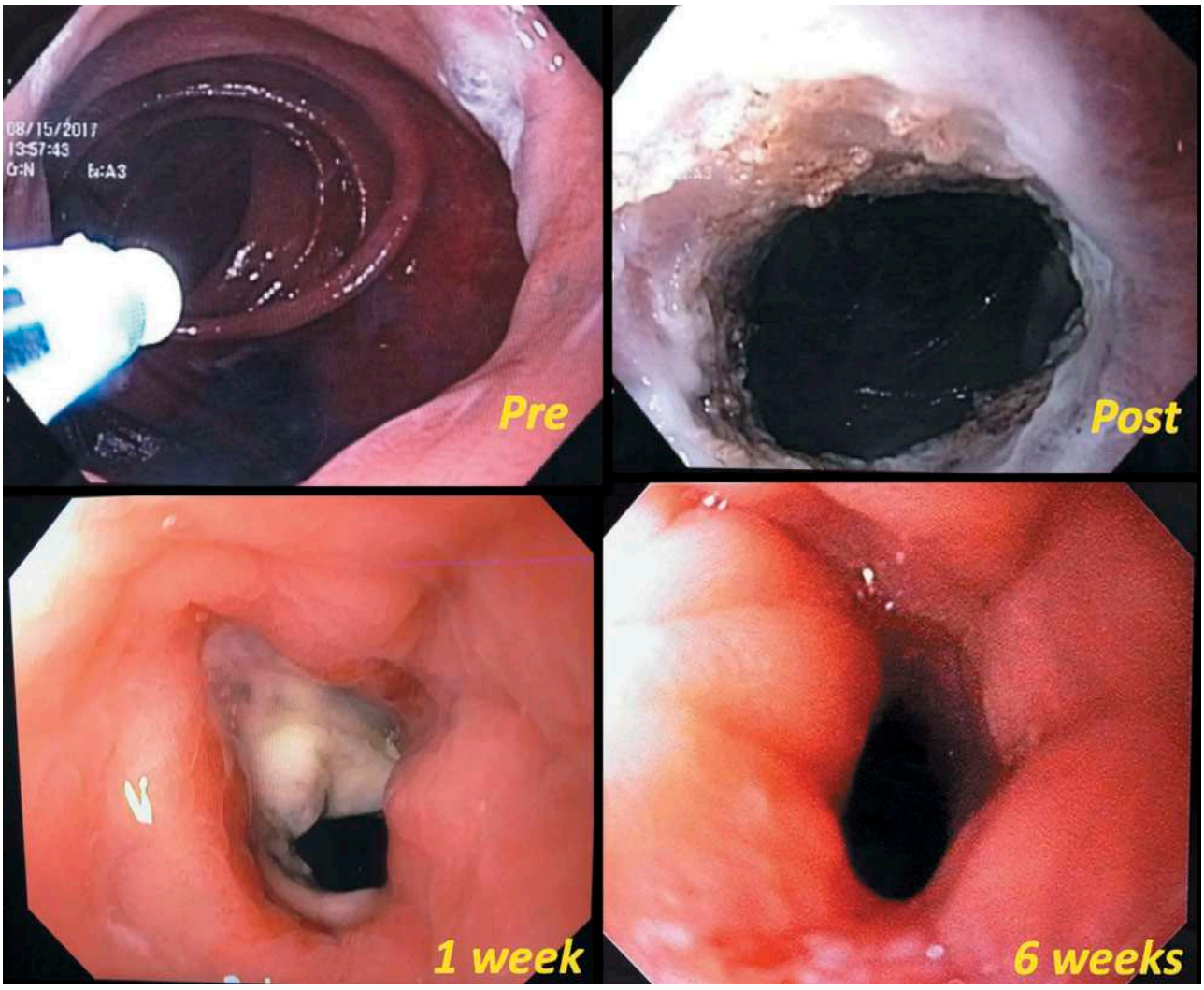

Figure 4. Argon plasma coagulation of the GJA showing the technique and the follow-up.

40.5 kg/m^2 to 37.7 kg/m^2 and % EWL was 23.4%. No significant adverse events occurred during the study.

In a randomized multicenter trial [79], including 77 patients with mean BMI of 47.6 kg/m^2 and GJA diameter >20 mm, comparing transoral revision of dilated GJA with sham procedure, a reduction of GJA to <10 mm was achieved in 89% of the revised group. There were no significant complications, and the adverse event rate was similar between the two groups. In the 6-month follow-up, 96% of the revised patients achieved weight loss or stabilization. In a per-protocol analysis, the revised group had a mean weight loss of 4.7 ± 5.7% versus 1.9 ± 5.2% in the sham group (p = 0.041).

Due to the evolution of other suturing systems, including the full-thickness suturing devices, this system is no longer commercialized.

5.3.2. Full-thickness suturing and plication

5.3.2.1. Incisionless operating platform & ROSE procedure.

The Incisionless Operating Platform (*USGI Medical, San Clemente, CA)* (Figure 6) is a multichannel instrument that can create full-thickness plications for the treatment of dilated gastric pouch and GJA [80]. Endoscopic visualization is via 4.9mm endoscope (GIFN180; Olympus, Center Valley, PA, USA) through one of the four accessory channels. Another channel is used for a tissue grasper. A tissue approximator, g-Prox, is placed through a third channel. Tissue to be plicated is pulled by the grasper into the g-Prox, and the tissue approximator is closed. This allows the needle to deploy a self-expanding tissue anchor on both sides of the tissue fold. The anchors are connected by a suture that runs through the tissue fold. The connecting suture is tightened, which approximates the tissue anchors and the plicated tissue is released. These anchors spread the force load across the wound, supporting tissue remodeling and healing [81].

Endoluminal revision using the platform, or Revision Obesity Surgery Endoscopic (ROSE), has been studied in a prospective study, including 20 weight regain patients with dilated gastric pouch and GJA. The procedure was technically successful in 85% of cases, with an average reduction in pouch length of 2.5 cm (36% reduction) and a post-procedure stoma diameter of 16 mm (65% smaller). Mean weight loss was 8.8 kg at 3 months [80]. Other study, using a second-generation device capable of working in smaller pouches, had technical success in 100% of patients and similar mean weight loss at the same period [82].

Figure 5. Medical illustration of the Bard EndoCinch Suturing System (superficial suturing).

A large prospective multicenter included 116 patients with success after RYGB (>50% EWL) and subsequent regain in the setting of pouch and GJA dilation [83]. The technically success rate was 97%, with a 44% reduction in pouch length and 50% reduction in GJA diameter. At six months, 32% of the regained weight was lost. A subset of these patients with GJA >12 mm who had post-repair GJA diameter <10 mm experienced significantly more post-procedure weight loss: 24% EWL versus 10% for the rest of the cohort. There were no significant adverse event [84].

5.3.2.2. Stomaphyx. The StomaphyX suturing system (*EndoGastric Solutions, Inc., Redmond, WA)* is a fastener delivery device that can address dilation of the pouch or GJA [85]. It uses 7 mm polypropylene H-fasteners to create tissue plications, which can be applied in a circumferential manner in the gastric pouch or at the GJA. The device is attached around the endoscope and they are positioned so that the StomaphyX passes through the GJA. Tissue 1 cm proximal to the GJA is suctioned into the device, and approximately 20 H-fasteners are used to form a tight circular pleat of tissue.

In a studied including 39 patients with an average BMI of 39.8 kg/m^2 and an average weight of 108 kg this device was used [85]. Average % EWL was 10.6% at 1 month, 13.1% at 3 months, and 19.5% at 1 year. Another study of 64 patients found an average weight loss of 7.6 kg at a mean follow-up of 5.8 months[86].

5.3.2.3. Apollo overstitch endoscopic suturing system. The OverStitch (Apollo Endosurgery, Austin, TX) is an endoscopic suturing platform that uses a catheter-based actuating needle to place full-thickness (FT) stitches under direct visualization (Figure 7). Use of a double-channel endoscope permits installation of a tissue retractor, which allows for accurate suture placement. Sutures can be reloaded without removal of the endoscope [87]. Because the FT device can target suture placement precisely by using a curved needle rather than tissue acquisition that uses suction, suture placement is more accurate and more durable than superficial mucosa apposition [88].

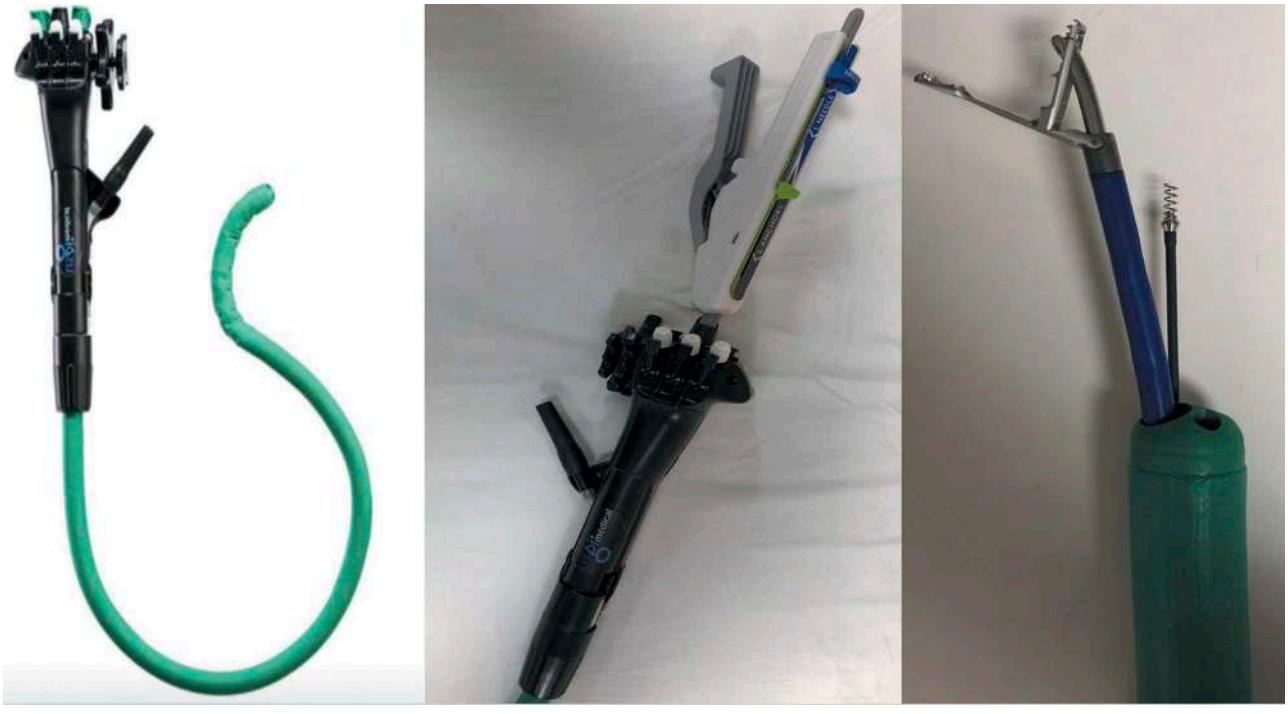

Figure 6. A. The Incisionless Operating Platform™ (USGI Medical, San Clemente, CA) consists in a g-Cath™ EZ Delivery Catheter with Snowshoe® suture anchors, g-Prox® EZ, g-Lix™ and Transport®.

Figure 7. Medical illustration of the Full-thickness suturing technique (OverStitch, Apollo Endosurgery, Austin, TX).

A prospective series including 150 consecutive post-RYGB patients with weight regain and a GJ anastomosis aperture greater than 15 mm underwent TORe with FT endoscopic suturing which proved to be safe and effective at arresting weight regain and provided durable weight loss. This study reported a 1-year total body weight loss (AWL) of 10.5 ± 1.2 kg and 24.9 ± 2.6% EWL; at 2 years, AWL was 9.0 ± 1.7 kg with 20.0% ± 6.4% EWL; and at 3 years, AWL was 9.5 ± 2.1 kg with 19.2% ±4.6% EWL. The number needed to treat for arrest of weight regain was 1.0 at 6 months, 1.1 at 1 year, and 1.2 at 2 and 3 years. The number needed to treat to maintain weight loss of 5 kg from TORe was 1.2 at 6 months, 1.5 at 1 year, 1.9 at 2 years, and 2.0 at 3 years[89].

There are two techniques of TORe with FT suturing device, the interrupted and the purse-string techniques (Figures 8 and 9) [90,91]. In the interrupted pattern, sutures are secured and cut after one pair of interrupted stitch placements or a short running pattern is performed. In the purse-string technique, the running suturing is started at between the 2 o'clock and 5 o'clock positions and is typically continued in a counter-clockwise fashion. Care must be taken to not cross or knot sutures as this will increase tension and lead to early suture loss. After the starting point is again reached and the full purse-string is accomplished, a dilation balloon is deployed through the second endoscope channel and is inflated to a diameter of 8 mm inside the anastomosis. The purse-string suture is then tightened around the balloon and cinched. There is also a third technique, called double purse-string technique, which may offer additional reinforcement. In this procedure, a purse-string is created but not cinched. Then, a second purse-string is placed and cinched around a dilation balloon. Subsequently, the initial purse-string is then cinched. Thus, far there are only case reports of this method [91].

A multicenter study, including 130 consecutive patients across three centers who underwent FT TORe with interrupted suturing, had experienced a loss of 24.6% weight regain from nadir weight after RYGB. Average weight loss at 6, 12 and 18 months were 9.31 ± 6.7 kg, 7.75 ± 8.4 kg, 8 ± 8.8 kg, with statically significate for all three-time points, respectively [92]. Another study including patients with GJA > 15 mm underwent a TORe procedure, with interrupted sutures and demonstrate a reduction of the anastomosis diameter from 36 mm (20–45 mm) to 9 mm (5–12 mm) (reduction of 75%), with a mean of 2.5 sutures and the pouch size from 7.2 cm (2–10 cm) to 4.7 cm (4–5 cm), with a mean of 2.7 sutures. The AWL and the % EWL at 6 months were 12.29 kg and 56.85%, with no adverse events [93].

Compared with an interrupted suture pattern, a purse-string suture pattern provides some advantages. First, it allows clear visibility of the GJA rim throughout the procedure until suturing is completed. Additionally, the final GJA aperture can be more accurately sized using a hydrostatic balloon. During this procedure, reinforcing stitches are also placed proximal to the GJA in order to protect this area while it is healing. Lastly, fewer sutures and cinches are required, which may lead to the procedure being more cost effective[94].

A prospective study including 241 patients compared the purse-string suture and interrupted suturing patterns. At 3 months, there was no statistic difference between the methods. However, on the 12-month analysis, the purse-string achieved statistically significant improvement in %TWL, % EWL and AWL [90]. Another study comparing these techniques demonstrated 100% technical success in all cases, and no adverse events were reported. Final diameter was significantly smaller in the purse-string group, 6.6 ± 2.2 mm versus 4.8 ± 1.8 mm, resulting in a significantly greater % stoma reduction (76.8 ± 8.5% vs. 84.2 ± 5.1%) versus the interrupted pattern, and then resulting in a greater % EWL over time [95].

The largest prospective series including 252 patients underwent purse-string TORe achieved 100% technical success rate, and %TBWL at 6 and 12 months were 9.6 ± 6.3 and 8.4 ± 8.2, with just two adverse events (0.8%). The study also demonstrated blood pressure, hemoglobin A1c, and ALT improvement at 12 months [94].

Nevertheless, the purse-string technique is more technically challenging because of the increased precision required for stitch placement, tissue drag caused by the suture going through multiple bites, and possible entanglement of the long suture. Studies to assess the learning curve of different suturing techniques may be useful. Also, a RCT comparing the efficacy and durability of different suturing patterns is needed to confirm the superior of purse-string, before any recommendation regarding the optimal TORe technique can be made [94].

Additionally, this system can be used to perform endoscopic sleeve gastroplasty as a primary procedure for obesity [96]. This technique has been used to treat weight regain in patients with gastro-gastric fistula by performing an endoscopic sleeve

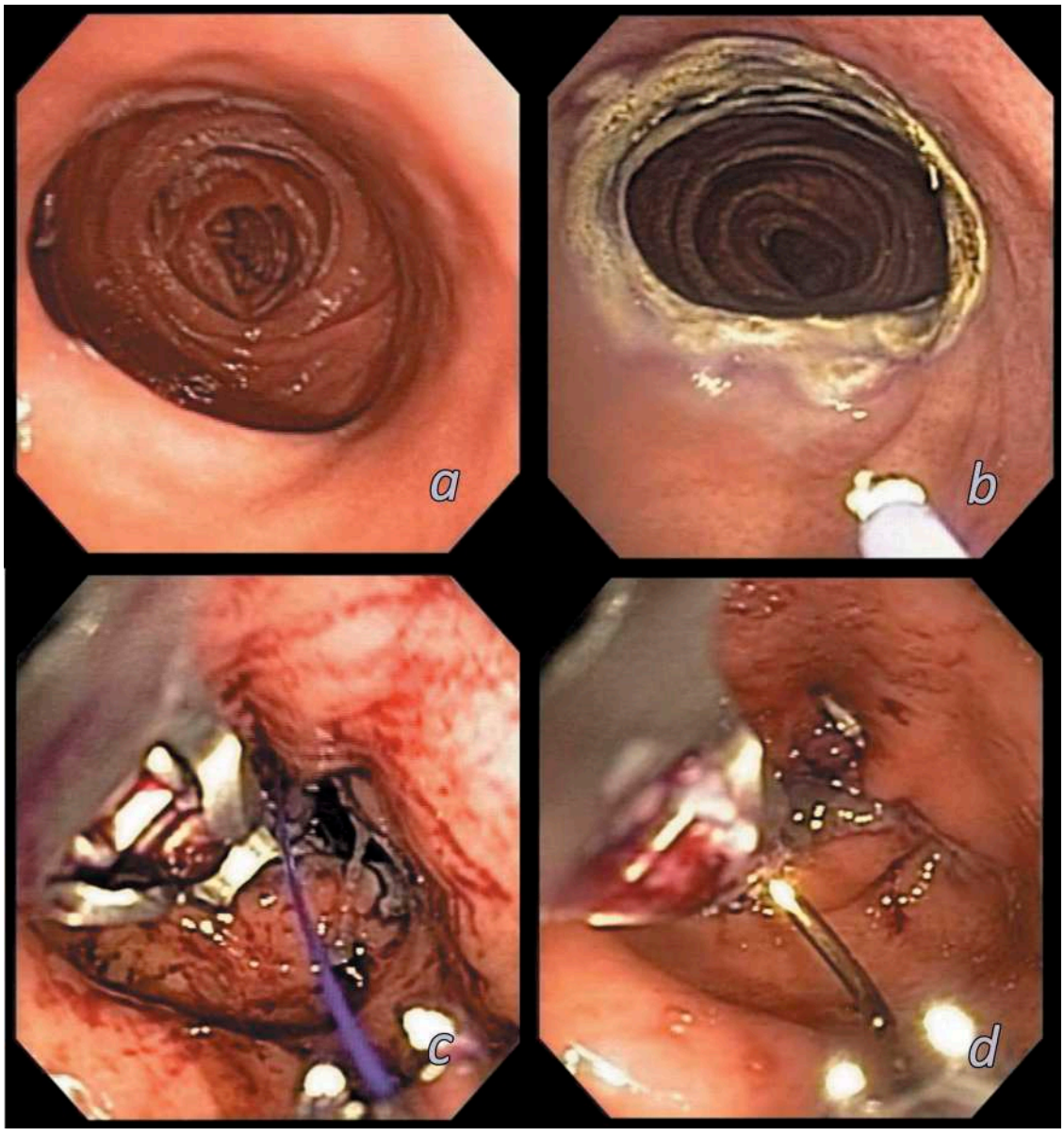

Figure 8. Interrupt suturing of a GJA. (a). Dilated GJA. (b). 5-to10-mm ring ablation with APC of the anastomotic margin. (c). Interrupt suturing of a GJA with the endoscopic suturing device. (d). Final appearance of the interrupt suturing of a GJA.

gastroplasty in the remnant stomach [97]. Also, this technique has been used to treat weight regain after sleeve gastrectomy, however, there is no data available regarding this technique at the present time.

5.3.2.4. OTSC. The over-the-scope clip (OTSC) (Ovesco Endoscopy AG; Tubingen, Germany) is a Nitinol clip attached to an applicator placed on the endoscope tip (Figure 10) [98]. It has been used for gastrotomy, perforation, and fistula closure, as well as successful reduction of dilated GJA. A study of 94 post-RYGB patients with a starting mean BMI of 32.8 ± 1.9 kg/m^2 had mean BMI of 29.7 ± 1.8 kg/m^2 at 3 months and 27.4 ± 3.8 kg/m^2 at 1 year. The procedure was most efficacious when clips were placed at opposite sites, reducing GJA diameter by >80%. A limitation of this technique is that OTSC removal is a technique challenge and can preclude subsequent endoscopic therapy. OTSC has been used as salvage therapy after failed TORe, which may be the preferred indication [99].

6. Studies comparing endoscopic approach

6.1. Sclerotherapy vs suturing

One study that compared patients who underwent sclerotherapy (median of 2 sessions) and FT suturing showed that patients that underwent endoscopic suturing lost a greater amount of weight, with greater improvement in eating behavior (cognitive restraint domain) and smaller anastomotic size at 3-month follow-up [73].

6.2. Superficial vs full-thickness

Full-thickness suturing is more durable than superficial (ST) mucosa apposition because the FT device can target suture placement precisely by using a curved needle rather than

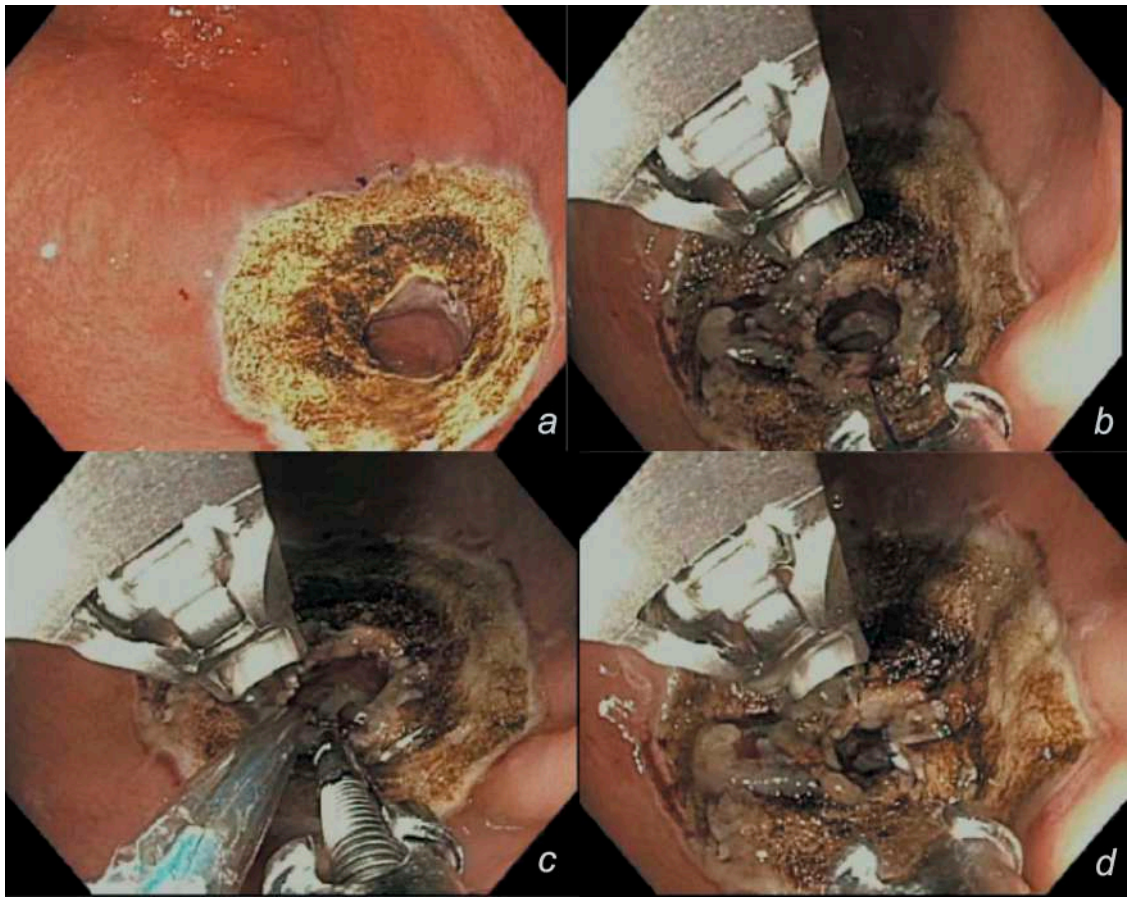

Figure 9. Purse-string suturing of a GJA. (a). Dilated GJA. (b). 5-to10-mm ring ablation with APC of the anastomotic margin. (c). Purse-string suturing of a GJA with the endoscopic suturing device. (d). Final appearance of the purse-string suturing of a GJA.

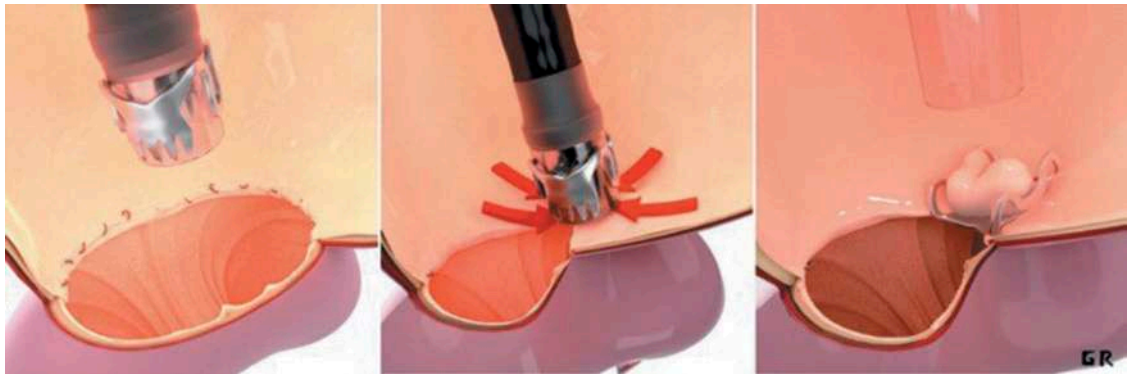

Figure 10. The over-the-scope clip (OTSC) (Ovesco Endoscopy AG; Tubingen, Germany) reducing the GJA size.

tissue acquisition that uses suction, suture placement is more accurate. Also, the suction-based tissue acquisition used by ST devices may result in more collateral tissue trauma and inflammation, resulting in a higher rate of suture loss. This theory was proved in a prospective study, level 1b evidence, comparing the ST versus FT TORe which demonstrates in similar GJ anastomosis apertures a more significant weight loss and excess weight loss at six months and one-year follow-up in the FT group [88].

6.3. Systematic review and metanalysis comparing endoscopic techniques in weight regain after RYGB

A systematic review and metanalysis [100] studied endoscopic suturing and APC technique in patients with weight regain after RYGB. This metanalysis was divided into three categories based on the follow-up time:

(1) Short-Term Efficacy (0–3 months): 320 patients underwent FT with an average follow-up of 2.8 ± 0.7 months were

Table 1. Summary of the results of a systematic review and meta-analysis comparing endoscopic techniques in weight regain after RYGB [101].

Endoscopic technique	Short-Term Efficacy (0–3 months)	Mid-term Efficacy (3 < 12 months)	Long-Term Efficacy (> 12 Months)	*p* value
FT	AWL: 6.61 kg ± 2.41	AWL: 7.16 kg ± 3.58	AWL: 5.66 kg ± 2.96	$p < 0.0001$
	EWL: 17.95% ± 7.38	EWL: 19.50% ± 9.95	EWL: 11.30% ± 5.86%	$p < 0.0001$
FT-APC	AWL: 9.88 kg ± 3.27	AWL: 10.85 kg ± 2.81	AWL: 5.66 kg ± 2.96	$p < 0.0001$
	EWL: 25.11% ± 12	EWL: 28.58% ± 12.12	EWL: 25.05% ± 14.43	$p < 0.0001$
Total	AWL: 8.56 kg ± 2.95	AWL: 8.60 kg ± 3.56	AWL: 7.63 kg ± 4.37	$p < 0.0001$
	EWL: 21.65% ± 9.34	EWL: 23.74% ± 12.39	EWL: 16.97% ± 11.19	$p < 0.0001$

included in this analysis. The AWL was 8.9 ± 0.71 kg with a %EWL of 24.7 ± 2.5%. Of these, 221 patients underwent FT-APC with a AWL of 9.0 ± 0.59 kg and a %EWL of 25.0 ± 1.99%; and 99 patients underwent FT-alone (without APC) with a AWL of 5.5 ± 3.96 kg and a %EWL of 15.3 ± 9.88%

(2) Mid-term Efficacy (3 ≤ 12 months): 619 patients underwent FT with an average follow-up of 5.9 ± 0.35 months were included in this analysis: The AWL was 10.3 ± 1.2 kg with a %EWL of 26.6 ± 4.15%. Of these, 214 patients underwent FT-APC with a AWL of 10.6 ± 0.83 and a % EWL of 27.0 ± 2.91; and 405 patients underwent FT alone with a AWL of 9.4 ± 2.0 kg and a %EWL of 17.8 ± 15.3%.

(3) Long-Term Efficacy (12 Months or Greater): 455 patients underwent FT with an average follow-up of 15.3 ± 9.1 months were included in this analysis. The AWL was 9.8 ± 1.92 kg with a %EWL of 24.0 ± 4.38% Of these, 173 patients underwent FT-APC with an AWL of 10.3 ± 1.42 Kg and a % EWL of 24.2 ± 0.84%; and 282 patients underwent FT alone with a AWL of 8.5 ± 2.98 kg and a %EWL of 11.7 ± 21.6%.

This systematic review and metanalysis demonstrate that FT to reduce the GJ anastomotic size is effective at treating weight regain after RYGB. Performing APC prior to suturing results in greater weight loss compared to suturing alone [100]. Table 1 summarize these results.

A metanalysis including 330 unique TORe cases using the Overstitch device demonstrates an absolute weight loss at 6, 12, and 18–24 months of 9.5 kg (95% CI 7.9–11.1), 8.4 kg (95% CI 6.5–10.3), 8.4 kg (95% CI 5.9–10.9), respectively [92].

Another systematic review [101] including 59 patients, who underwent TORe with either PTS and FTS after weight regain, with a mean time of 5.75 years post RYGB, demonstrates a reduction in anastomotic diameter (pre: 24.8 mm; post: 8 mm) with an AWL of 10.1 kg in 3 to 4 months. The mean time of the procedure was 74 min and the combined technical and clinical success rate was 94.9%.

7. Post-procedure care

The literature diverges regarding post-procedure diet. In general, patients are kept NPO for the night post-procedure and then advance to clear liquid diet for 1–3 days. This is then advanced to 2–6 weeks full liquids, followed by 2 weeks of soft diet. Subsequently, the patient may return to a regular post-gastric bypass diet. Proton pump inhibitor should be prescribed for at least 30-days after the procedure and liquid sucralfate may be prescribed for 3 days to 4 weeks. Pain medications can also be prescribed for three days after the procedure, however, this is rarely required [69,71–73,76,77,88,93,95].

8. Adverse events

The adverse events varies from each technique. However, in general, all of these procedures are related to a low rate of adverse events, without related death. The post-procedure adverse events includes: melena or hematemesis, nauseas or vomits, pain, GJA ulcer, vomiting, leakage, and stenosis of the GJ anastomosis. Stenosis is the most frequent adverse event and can be treated by endoscopic dilation or endoscopic stenting [69,71–73,76,77,88,93,94,102,103].

9. Training to perform endoluminal therapies for weight regain

Endoscopic revisional procedures should be performed by gastroenterologists or surgeons with experience in advanced endoscopic procedures. Before training, it is important for the trainee to understand that a multi-disciplinary team is essential to the success of any endoscopic revisional procedure. First, the trainee needs to familiarize themselves with the devices and techniques. Then, practicing with a simulator and ex-vivo models are suggested prior to initial human cases. These initial cases should be performed under supervision. Currently, there are no objective assessment tools to determine competency in bariatric endoscopy. A previous questionnaire study surveying including experts in the field revealed that a minimum of 15 revisional endoscopic procedures are required for the trainee to become independent [104–106].

10. Conclusion

With cumulative increase in the number of patient status post-bariatric surgery, postoperative weight regain has become a considerable challenge. Endoluminal therapies are safe, reproducible, and effective in the treatment of weight regain and may be utilized as a first line approach to manage this condition. Purse-string FTS associated with APC seems to be the most effect method. Additionally, a RCT would be helpful to better understand the cost-benefit ratio of these various technique and would provide further insight into the optimal care for this challenging patient population.

11. Expert commentary

Obesity is a pandemic with an estimated worldwide incidence of more than 700 million, and an additional 2 billion overweight.

With the cumulative increase in the number of patients undergoing bariatric surgery, postoperative weight regain has become a considerable challenge.

Maintenance of body weight is regulated by a number of processes including homeostatic, behavioral, environmental, and genetic elements. The hypothalamus plays an important role in the integration of signals regarding body weight, caloric intake, and energy balance. Environment and behavioral influences effect the amount and type of food consumed and the level of physical activity. Other environmental factors, including sleep deficiency, genetically modified and processed foods, and iatrogenic effects of medications are also thought to have an impact. Genetic predisposition and epigenetic phenomena are also thought to play an important role in body weight regulation and weight gain. Unfortunately, the physiological response to weight loss tends to favor weight regain.

Weigh regain is often multifactorial and the initial step in the management of this condition is a comprehensive evaluation of contributing factors. A multidisciplinary evaluation, including dietary and lifestyle factors, and a general medical history and examination are essential. Any potential causes of weight regain, such as hypothyroidism, a medication that cause weight gain, and dietary noncompliance should be addressed. The next step is an anatomic evaluation. Several groups have shown that dilation of the gastrojejunal anastomosis is directly correlated with the amount of weight regain following gastric bypass. As such, evaluation of postsurgical anatomy is an important part of the evaluation. While lifestyle therapy including diet, exercise, and behavior modification are fundamental to the treatment of this condition they typically have limited efficacy in this population.

There are several available endoluminal therapies to help manage weight regain after RYGB. Argon plasma coagulation, suturing, and plication are safe, reproducible, and effective in the treatment of weight regain. There have been sham-controlled randomized trials and meta-analysis providing strong evidence to support their use. There are also long-term studies, up to 5 years [107], supporting durability of suturing. The optimal technique is yet to be determined and likely will vary depending on patient characteristics, however, the authors prefer a purse-string suture pattern, or gastric plication, with concomitant APC as these provide the greatest amount of durable weight loss in our experience. Current studies are evaluating optimal suture patterns and patient selection to enhance clinical outcomes. Additionally, combination therapy with medications is being explored and is likely to improve weight loss and durability. Studies focusing on comorbidity resolution, predictors of response, and personalized approaches to therapy are now needed to improve outcomes for this population.

There have also been reports of endoscopic revision for weight regain following sleeve gastrectomy. However, the literature is scant on this topic and surgical revision or conversion to RYGB or occasionally DS is most commonly performed in this situation.

We believe that endoscopic revision will be of increased importance in bariatric care moving forward. However, challenges remain in improving the availability of these procedures for patients who would benefit from them. Bariatric specialists should be educated in the value of these alternative approaches to better direct early patient referral. Additionally, we must work to broaden the adoption of these techniques by addressing the training of fellows and practicing clinicians, as well as improving insurance reimbursement moving forward.

12. 5-year view

In 5 years we will begin to see improved insurance reimbursement and broader adoption of these methods. Additionally, early referral for weight regain or inadequate weight loss will start to have an impact on clinical outcomes, further enhancing the already excellent results of bariatric surgery.

Key issues

- Although bariatric surgery is the most effective and durable treatment for obesity, weight regain is common and has become a considerable challenge.
- Nutritional non-compliance, hormonal/metabolic imbalance, physical inactivity, psychiatric comorbidities, larger pouch size, and larger diameter GJA are predictors of weight regain.
- The initial step in treating weight regain is a comprehensive assessment of the patient by a multi-disciplinary team.
- Endoluminal therapies are safe, reproducible, and effective in the treatment of weight regain and should be utilized as a first line approach to manage this condition.
- Purse-string FTS associated with APC appears to be the most effective method.

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