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ORIGINAL CONTRIBUTIONS

A Real-World, Insurance-Based Algorithm Using the Two-Fold Running Suture Technique for Transoral Outlet Reduction for Weight Regain and Dumping Syndrome After Roux-En-Y Gastric Bypass

Lea Fayad[1] · Michael Schweitzer[1] · Micheal Raad[1] · Cem Simsek[1] · Roberto Oleas[1] · Margo K. Dunlap[1] · Tazkia Shah[1] · Jay Doshi[1] · Margueritta El Asmar[1] · Andreas Oberbach[2] · Vikesh K. Singh[1] · Kimberly Steele[1] · Thomas Magnussen[1] · Anthony N. Kalloo[1] · Mouen A. Khashab[1] · Vivek Kumbhari[1]

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Abstract

Background and Aims Transoral outlet reduction (TORe) by devitalization and/or endoscopic suturing (ES) has been implemented in the management of weight regain post-RYGB. This study aims to assess the efficacy and safety of TORe following an insurance-based algorithm.

Methods A prospectively maintained database of patients who underwent TORe between September 2015 and January 2018 at a single academic center was reviewed. An algorithm was followed whereby management was based on insurance coverage. As part of the algorithm, all patients presented for a repeat endoscopy at 8 weeks. Patients did not receive any diet, lifestyle intervention, or pharmacotherapy.

Results In total, 55 patients were included (median age 48 years), out of which 50 were females (90.9%). Patients presented for evaluation at a mean of 8.7 years post-RYGB. The main presenting symptom was combined dumping syndrome (DS) and weight regain (49.1%), followed by weight regain alone (45.5%). Twenty-nine patients required treatment at their second procedure, and 11 required treatment at their third procedure. Average percent total body weight loss (%TBWL) after TORe observed at 3-, 6-, 9-, and 12-month follow-up was 8.2, 9.3, 8.4, and 5.5%, respectively. The mean DS Severity Score was significantly reduced from 23.3 ± 12.4 before TORe to 16.3 ± 6.51 after TORe ($p < 0.01$). The adverse event rate from TORe was 14.5%.

Conclusion TORe is effective in halting ongoing weight regain and achieving moderate short-term weight loss as well as improving DS in post-RYGB patients. Durability at 1 year remains questionable due to weight recidivism.

Keywords Roux-en-Y gastric bypass (RYGB) · Transoral outlet reduction (TORe) · Endoscopic suturing · Weight regain · Dumping syndrome

Introduction

Roux-en-Y gastric bypass (RYGB) is a well-established bariatric surgery with marked success in the treatment of obesity and obesity-related comorbidities [1]. Unfortunately, a major limitation to the long-term success of RYGB is the development of both weight regain and dumping syndrome (DS) in post-surgical patients [2–5]. Studies that have followed RYGB patients for more than 5 years found that weight regain occurred in a significant proportion of patients [3–5]. Dumping syndrome is another long-term complication of RYGB that significantly affects the health-related quality of life of these patients [2]. Between 2011 and 2015, RYGB constituted a substantial proportion of bariatric surgeries performed, ranging between 23.1 and 37.5% in the USA. Because mean time to presentation for weight regain can range between 2 to 10 years, there is a resultant increase in the need for revision surgery today. In 2016, 18.7% of all bariatric surgeries remain RYGB, with a rising overall number of bariatric surgeries performed, according to the American Society for

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✉ Vivek Kumbhari
vkumbhari@gmail.com

[1] Johns Hopkins Medical Institutions, Baltimore, MD, USA

[2] Department of Diagnostics, Fraunhofer Institute for Cell Therapy and Immunology, Leipzig, Germany

Metabolic and Bariatric Surgery (ASMBS) [6]. Surgical revision may include conversion to distal RYGB, revision of the pouch and outlet, use of a gastric band, and revision to biliopancreatic diversion/duodenal switch. Literature on the use of revisional surgery for weight regain after RYGB has shown a high rate of morbidity and limited effectiveness. In particular, surgical revisions of the pouch and outlet did not result in sustainable weight loss and were associated with complication rates up to 30% [7].

With the growth of the obese population and the increasing adoption of bariatric surgery, there will be an increased number of post-RYGB patients who require revision for indications such as weight regain and DS.

Weight loss from RYGB is caused by alterations in both anatomy and physiology that include changes in bile acids, gut microbiota, and gut-brain and brain-endocrine axes, in addition to gut hormonal changes and changes in distensibility of the roux limb that influence meal size and appetite [8–10]. The etiology of weight regain post-RYGB is multifactorial [11], but one component that has been implicated is the size of the gastrojejunal anastomosis (GJA), which was found in one study to be significantly and independently associated with regained weight [12]. The size of the GJA has also been implicated in the development of DS symptoms [13]. Therapies to target the GJA have been developed and include the endoscopic reduction of the GJA termed transoral outlet reduction (TORe). These have been successful in halting weight gain and achieving weight loss, which may be marginal, but is worthwhile in view of the reported safety of these procedures [14–17].

TORe with endoscopic suturing (ES) has been used safely and effectively to induce weight loss in post-RYGB patients [14, 17–21]. The landmark RESTORE trial, a randomized, sham-controlled trial, demonstrated that 96% of patients who underwent TORe by ES with Argon Plasma Coagulation (ES-APC) subsequently had weight loss or stabilization. TORe was also associated with high levels of patient satisfaction, with 83% of patients stating that they would undergo the procedure again. In this trial, a superficial thickness suction-based suturing device was studied and the authors postulated that use of a full-thickness suturing device may confer even better outcomes [21].

In a later matched cohort retrospective study, Kumar and Thompson confirmed that using full-thickness endoscopic suturing with argon plasma coagulation (APC) was more effective in achieving weight loss at 6 months and 1 year when compared with superficial thickness devices with APC. They hypothesized that superiority of full-thickness devices may be due to more durable plications, lesser resultant tissue compliance, more precise suture placement with a curved needle, and less tissue trauma and subsequent suture loss [20].

Previously described suturing techniques using a full-thickness device include the interrupted suture technique and the purse-string technique. This study is the first to assess the use of the twofold running suture technique, which has been previously described in a video case report [22]. The twofold running suture technique uses a full-thickness endoscopic suturing device (Overstitch, Apollo Endosurgery, Austin, TX) to place two consecutive circumferential sutures at the GJA in an effort to achieve greater durability.

Unfortunately, despite its success, ES is often not covered by insurance. In these cases, APC alone can be performed. Baretta et al. demonstrated that serial sessions of APC alone can achieve loss of regained weight comparable to TORe with ES. This is particularly significant because APC does not confer additional cost or need for further training for endoscopists and is traditionally associated with a low rate of complications [23]. Our study was a retrospective, single-center, cohort study which aimed to assess the weight loss and DS symptoms of TORe using a predetermined algorithm which assigned patients to treatment based on insurance coverage. We hypothesized that TORe would be successful in achieving weight loss or halting weight gain in addition to improving DS in post-RYGB patients.

Methods

Patient Population

A prospectively maintained database of patients from September 2015 to January 2018 at a single academic center (Johns Hopkins Medical Institutions) was reviewed. Consecutive post-RYGB patients were included if they underwent TORe for weight regain and/or DS and had a dilated GJA. A dilated GJA was defined as a GJA diameter ≥ 20 mm. Weight regain was defined as > 10% regain of maximum weight lost at nadir after RYGB. DS was diagnosed using the clinical judgment of the diagnosing physician and recorded on the patient chart as the chief complaint.

An initial screening endoscopy was performed on all patients with pouch and GJA measurements to determine eligibility for TORe. Patients were eligible if they had a GJA diameter ≥ 20 mm as assessed visually by the endoscopist. Patients were excluded if they had a dilated pouch (defined as pouch length > 6 cm or width > 5 cm). Once determined to be eligible, patients applied to insurance for TORe using ES-APC. If accepted, ES-APC was performed. If denied, patients underwent APC only. All patients then had a follow-up EGD at 8 weeks. If GJA remained dilated (diameter > 12 mm), APC was performed and patients had another follow-up EGD scheduled. Similarly, at this follow-up, patients who still had a dilated GJA (diameter > 12 mm) underwent APC again. Patients who had GJA stenosis, defined as symptomatic GJA obstruction at follow-up, underwent balloon dilation to dilate the GJA. No intervention was performed on the pouch, as a previous study had shown no significant difference in

long-term weight loss outcomes when pouch reduction was performed in addition to outlet reduction [14]. All patients were offered referral to diet and lifestyle therapy and encouraged to follow-up. However, no patient chose to undergo this adjunct management during the follow-up period, as all patients had previously failed diet and lifestyle therapy.

Peri-procedure Care

Patients were placed on a full liquid diet the day before the procedure and asked to drink 20 oz. electrolyte water the night before the procedure. Post-procedure, patients were placed on a clear liquid diet for 1 week, a full liquid diet for 1 week, then advanced to a pureed diet for 1 week, then soft foods for 1 week, if tolerated. At discharge, patients were given ondansetron 4 mg Q6 hours as needed for nausea and hyoscyamine 0.125 mg Q6 hours as needed for cramps, in addition to a whole capsule proton pump inhibitor (PPI) 40 mg daily for 4 weeks.

TORe Procedure

All procedures were outpatient procedures. ES-APC was performed under general anesthesia, and APC was only performed under monitored anesthesia care. APC (50 W, pulsed, effect 2, flow 1 L/min) was used to devitalize the tissue around the GJA, using straight fire to create a 1-cm rim of devitalized gastric mucosa. In patients who underwent ES-APC, APC was performed prior to ES in an identical fashion to that in the APC group. ES was then performed using the twofold running suture technique as described by Barola et al. [22]. Successive full-thickness equidistant bites were taken circumferentially around the anastomosis with the first bite directed from the jejunal to the gastric side (Video 1). Then, without cinching the suture, the T-tag was dropped. Another suture was placed with a pattern of bites identical to the first, dropping the T-tag again without cinching. Both sutures were then consecutively cinched over an 8-mm dilation balloon placed through the GJA. The overarching goal was to achieve a GJA size < 12 mm at the follow-up (second) EGD. The GJA size was measured visually by the endoscopist.

Outcomes

Baseline patient characteristics were collected and included initial weight and BMI and comorbidities including diabetes, obstructive sleep apnea, and hypertension. Time since RYGB, weight before RYGB, weight nadir after RYGB, and weight regain since RYGB were also collected. Percent weight regain was calculated as a percent of the maximum weight lost between RYGB and nadir [24]. In the APC group, technical success was defined as successful circumferential APC. In the ES-APC group, technical success was defined as successful circumferential APC plus successful reduction in the size of the outlet to < 12 mm. Weight was followed at 3, 6, 9, and 12 months. DS symptoms before and after TORe were assessed by the clinical nurse using items from the Dumping Symptom Rating Scale (DSRS) [25]. Symptoms were assessed on a scale of 1–7 based on severity, with 1 meaning "no trouble at all" and 7 meaning "very severe problems". Since this was a retrospective study with clinical follow-up, the total index DSRS, which includes both severity and frequency scores, was not calculated. Items from the DSRS were only assessed for severity; thus, only the summary severity scale was completed. The scores on this scale were used only for follow-up in the patients who had presented with a chief complaint of dumping syndrome, and were not used for diagnostic purposes. Finally, patient charts were reviewed for adverse events for the duration of their procedure and up to 6 months after their last TORe procedure.

Statistical Analysis

Descriptive statistics for continuous and categorical variables were reported as mean ± standard deviation and proportions respectively. Tests of hypothesis for categorical variables were carried out using χ^2 test and Fisher's exact test whereas those for continuous variables were carried out using Student's t test for dependent and independent samples as appropriate. Correlations between continuous variables were assessed using linear regression analysis and reported as a beta coefficient, 95% confidence interval, and p value. All statistical analysis was conducted using STATA 14.0 (StataCorp LP, College Station, TX). A p value of < 0.05 was considered significant.

Results

In total, 55 patients were included (mean age 48.1 ± 9.5 years); 50 were female (90.9%). Patients presented for evaluation at a mean of 8.7 ± 4.6 years after RYGB. The main presenting symptom was combined weight regain and DS (49.1%), followed by weight regain alone (45.5%) and dumping syndrome alone (5.5%). On average, patients had regained 56 ± 26.7 lbs. from nadir after bariatric surgery, with an average percent weight regained of 45.8 ± 24.8%. Comorbidities in this cohort included diabetes mellitus (14.6%), obstructive sleep apnea (12.7%), and hypertension (36.4%).

Forty-four of 55 patients underwent ES-APC as their first procedure. Technical success was 98.2%. One patient in the ES-APC group had technical failure GJA size of 15 mm on completion. The sutures were presumed to have crossed, limiting the ability to cinch tightly around the controlled radial expansion (CRE) balloon (Boston Scientific, Natick, MA). Overall, out of 55 patients, 29 (52.7%) patients required

treatment at their second endoscopic procedure, and 11 (20%) required treatment at their third endoscopic procedure. Figure 1 shows the number of patients who were treated at each endoscopic procedure.

Compared to mean GJA size at first EGD (27.6 ± 6.9 mm), mean GJA size was significantly smaller at second EGD (15.3 ± 5.4 mm, $p < 0.001$) and at third EGD (13 ± 4.5 mm, $p < 0.001$) in our cohort. Average weight lost at 3-, 6-, 9-, and 12-month follow-up was 20.1, 24.3, 16.3, and 10.4 lbs., respectively. Figure 2 shows the %TBWL in patients during follow-up. At 3 and 6 months, 100% of patients had weight loss. At 9 months, 1 patient had returned to weight before TORe and 2 patients had weight gain of 1 and 13 lbs. from weight before TORe. At 12 months, these patients had weight gain of 5, 6, and 13 lbs. from their TORe procedure, respectively. All other patients had weight loss at 9 and 12 months. The size of the GJA at the end of the first TORe procedure was not significantly correlated with weight lost at 3 months (coef. 0.22, CI [− 1.43, 1.87] $p = 0.78$), 6 months (coef. − 0.44 CI [− 4.59, 3.70] $p = 0.82$) 9 months (coef. 1.51, CI [− 2.82, 5.85] $p = 0.43$), or 12 months (coef. 4.94, CI [− 1.19, 11.07] $p = 0.1$). The reduction in the size of the GJA during the first TORe procedure was not significantly correlated with weight lost at 3 months (coef. − .02, CI [− .4, .4] $p = 0.91$), 6 months (coef. − .16, CI [− .84, .51] $p = 0.61$), 9 months (coef. − .16, CI [− 1.06, .73] $p = 0.66$), or 12 months (coef. − .17, CI [− 1.21, .86] $p = 0.69$). Video 2 shows a GJA at follow-up EGD after ES-APC. Video 3 shows APC applied at follow-up. Two patients returned > 1 year after initial TORe with weight regain requiring repeat TORe with ES-APC (Fig. 3a–e). One patient had initial success using ES-APC in reducing the GJA from 35 mm on first EGD to 9 mm on second EGD. However, the patient returned 1 year later with weight regain and her GJA was dilated to 20 mm. This patient underwent repeat ES-APC. Another patient also had initial success in reducing the GJA using ES-APC from 30 to 12 mm on second EGD. However, this patient returned 1 year later with a GJA dilated to 30 mm requiring repeat ES-APC.

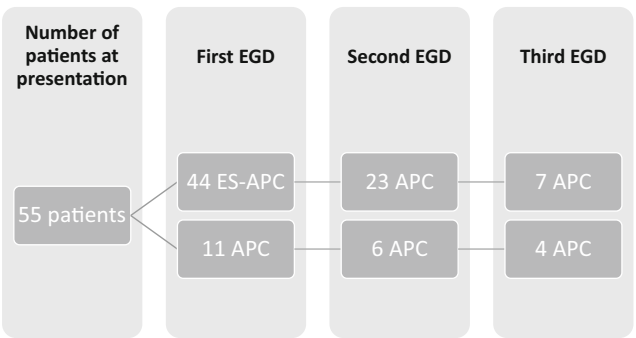

Figure 1 Flowchart of endoscopic procedures performed for TORe patients

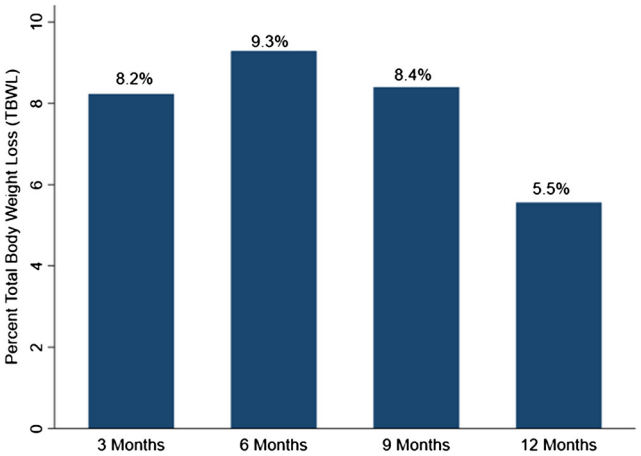

Fig. 2 Percent total body weight loss (%TBWL) in patients after TORe at 3, 6, 9, and 12 months

Thirty patients had presented with DS symptoms before TORe. In this subpopulation, the mean DS summary severity scale score was significantly reduced from 23.3 ± 12.4 before TORe to 16.3 ± 6.51 after TORe ($p < 0.01$). Table 1 demonstrates the DS symptom severity scores for individual symptoms before and after TORe procedure. Individual items that showed statistically significant improvement included fatigue (from 4.1 ± 2.3 to 2.7 ± 1.6, $p < 0.01$), sweating/flushing (from 3.2 ± 2.4 to 1.7 ± 1.2, $p < 0.01$), and diarrhea (from 3.5 ± 2.6 to 1.7 ± 1.1, $p < 0.01$).

The adverse event rate from this procedure was 14.5%. One patient required admission for symptomatic management of nausea, vomiting, and abdominal pain for 1 day post-procedure. Four patients developed GJA stenosis requiring balloon dilation (Fig. 4a–c). Three out of 4 of those patients had ES-APC as their index procedure. These patients presented with food intolerance, nausea, and vomiting of varying severity with 2 patients requiring emergency room visits. The GJA diameters ranged between 3 and 6 mm with a median of 4 mm. One patient had visible intact sutures, which were removed endoscopically using a regular biopsy forceps. In all 4 patients, CRE balloons were used for initial dilation. Initial dilation was performed to 12 mm in all cases. Two cases required a subsequent second dilation 2 weeks later to 15 mm. All procedures were successful in achieving a diameter of > 12 mm, with resolution of symptoms in all 4 cases.

In addition, 3 patients developed ulcers on the gastric side of the gastrojejunal anastomosis (Fig. 5). Among these, only 1 patient presented to emergency department 5 days post-procedure with abdominal pain while the others were asymptomatic and found incidentally upon follow-up EGD at 8 weeks. The long axis of the ulcers ranged between 5 to 20 mm and all the ulcerations had a clean base. In these patients, the gastric outlet diameter ranged between 5 and 12 mm. Intact sutures were seen in two of the patients and were removed. One of the asymptomatic patients with the widest 12-mm outlet was found to have a 14-mm gastro-gastric fistula opening to the gastric remnant. This

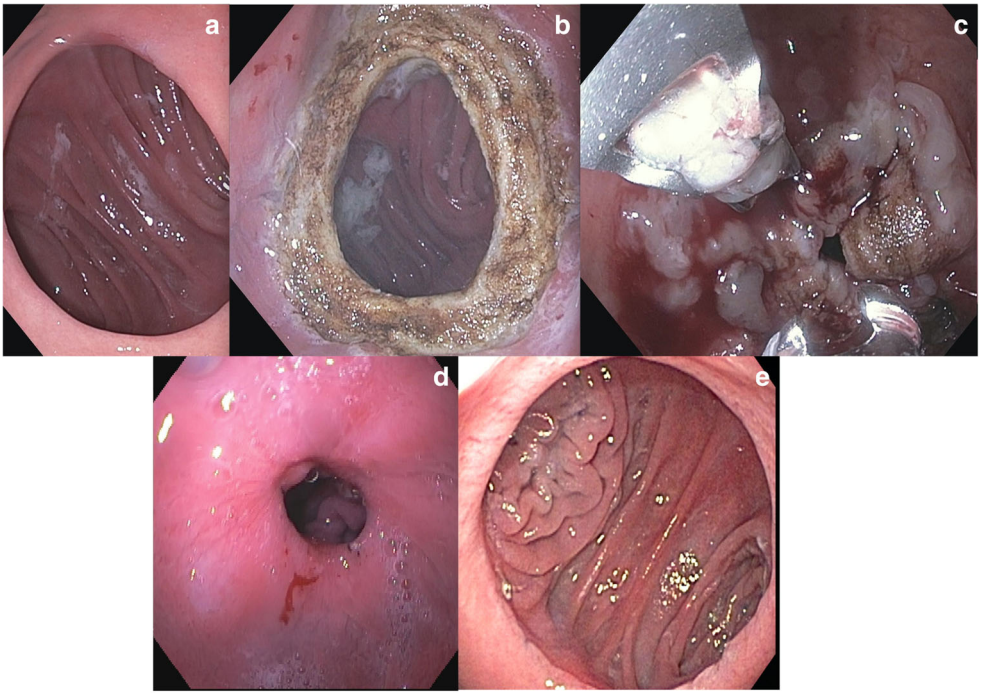

Fig. 3 **a** Endoscopic view showing dilated GJA. **b** Endoscopic view after devitalizing the tissue around gastric GJA. **c** Endoscopic view immediately after completion of TORe with endoscopic suturing. **d** Endoscopic view 8 weeks after procedure. **e** Endoscopic view at 1-year follow-up showing a dilated GJA requiring re-intervention

patient was referred to surgery for repair of his fistula. The other 2 patients were discharged on open capsule high-dose PPI. Finally, 1 patient presented with hematemesis and was found to have a visible vessel at the gastric ulcer at the GJA treated with a hemoclip and epinephrine.

Discussion

With the growing population of post-RYGB patients comes a need for minimally invasive means to manage long-term weight regain and DS associated with the procedure. TORe, in its various forms, has been successful in achieving weight loss in these patients [14, 15, 17, 19–21]. This study described a novel technique for performing TORe using the twofold running suture technique for endoscopic suturing [22]. Using a predetermined algorithm based on insurance coverage, we found significant short-term success in halting ongoing weight gain, achieving moderate weight loss, and a reduction in DS symptoms. However, there was weight recidivism at 1 year with some patients requiring re-intervention.

Table 1 Dumping syndrome symptoms in patients before and after TORe

Dumping syndrome symptom	Before	After	*p* value
Fatigue	4.1 ± 2.3	2.7 ± 1.6	*< 0.01*
Palpitations	1.5 ± 1.1	1.3 ± 1.1	0.58
Sweating/flushing	3.15 ± 2.4	1.7 ± 1.2	*< 0.01*
Cold sweats/paleness	2 ± 1.9	1.3 ± 0.8	0.08
Need to lie down after meals	2.6 ± 2.3	2.05 ± 1.8	*0.31*
Diarrhea	3.5 ± 2.6	1.7 ± 1.1	*< 0.01*
Nausea	2.9 ± 2.2	2.9 ± 2.0	0.93
"Cramp" in the stomach	2.4 ± 2.0	1.7 ± 1.3	0.1
Fainting esteem and/or shaky	1.4 ± 1.3	1 ± 0	0.26

p value < 0.05 was considered statistically significant

The efficacy of TORe using full-thickness endoscopic suturing has been demonstrated in multiple retrospective studies [17, 19, 20] and a prospective study which showed durable outcomes at 3 years [14]. There are multiple techniques for full-thickness endoscopic suturing, including the interrupted suture technique and more recently, the purse-string suture technique. The purse-string suture technique has shown to be technically feasible, safe, and effective [15, 26]. In a retrospective comparative study by Patel et al. (2016), the purse-string technique resulted in superior weight loss outcomes than the interrupted suture technique, but did not achieve statistical significance [15]. This was the first study to use a novel twofold running suture technique.

In this study, the technical success rate was 98.2%. Prior studies have reported technical success rates of 100% with TORe using the Overstitch suturing device [15, 26]. However, different suturing techniques have varying degrees of technical difficulty. Jirapinyo et al. cautioned that the purse-string technique was more technically difficult than the interrupted suture technique, despite its advantages [26]. The twofold running suture technique is arguably of greater difficulty than the previously described purse-string technique. It builds on the purse-string technique by performing a similar technique but uses two sutures running simultaneously

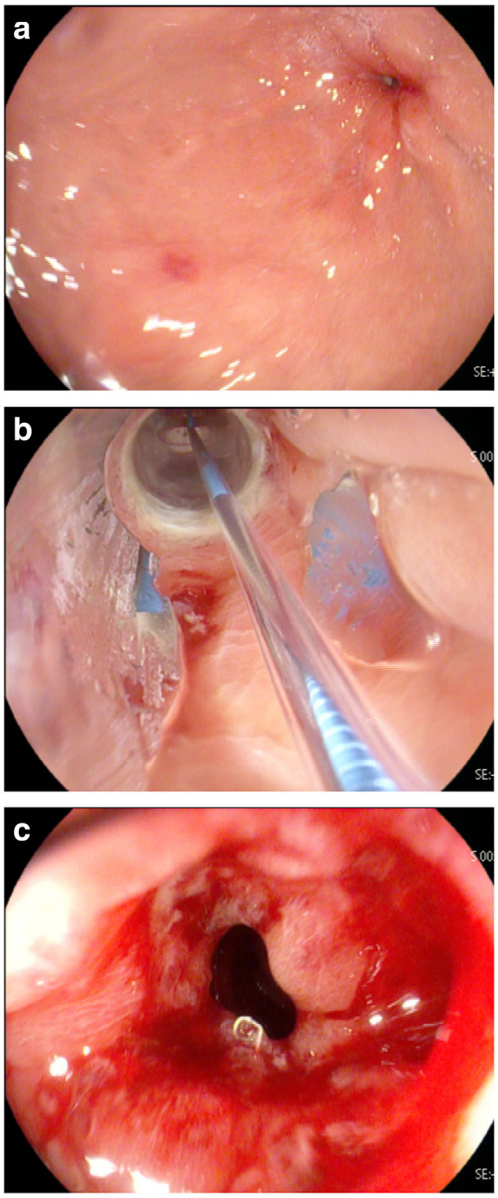

Fig. 4 **a** Endoscopic image showing GJA stenosis to 3-mm post-TORe, **b** endoscopic image showing balloon dilation for an GJA stenosis post-TORe using a 15-mm CRE balloon, **c** endoscopic image showing a GJA post-balloon dilation to 15 mm for GJA stenosis after TORe

through the working channel of the endoscope as opposed to one. Both sutures are cinched at the end of the procedure. The rationale behind using two sutures is to increase durability and result in a smaller GJA size. It may be worthwhile to compare these two methods of endoscopic suturing in their learning curve and clinical effectiveness.

One strength of this study is that the performance of multiple consecutive EGDs permitted an endoscopic follow-up of outcomes in addition to clinical follow-up. This allowed us to record the size of the GJA at each intervention, confirming a statistically significant decrease in size with multiple interventions. Interestingly, however, the size of the GJA achieved at third EGD was not significantly smaller than that achieved at second

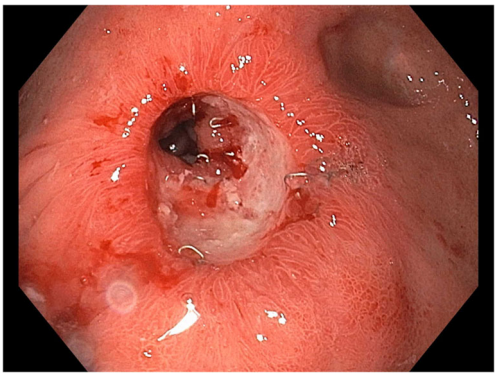

Fig. 5 Endoscopic view of an ulcer seen at follow-up EGD in a patient post-TORe

EGD. It is possible that some patients who require a second intervention may simply be recalcitrant to the treatment. It may also be that tissue which is already fibrosed from initial intervention is less responsive to subsequent attempts at inducing scarring with the use of APC. Another pertinent finding is that technical success did not translate to clinical success. Size of GJA measured at the end of the first procedure did not correlate with weight loss at 3, 6, 9 or 12 months. This is likely due to the multifactorial nature of the weight loss.

In our study we found a %TBWL of 8.2, 9.3, 8.4, and 5.5 at 3, 6, 9, and 12 months, respectively. Weight outcomes in our study were maintained over a 9-month period; however, weight recidivism was seen at 1 year. In a recently published retrospective study, Jiropinyo et al. [26] reported %TBWL of 8.7 at 3 months, 9.6 at 6 months, and 8.4 at 12 months with sutured TORe technique. A prospective study that assessed sutured TORe by Kumar et al. reported %TBWL of 8.7, 9.6, and 9.5 at 3, 6, and 12 months [14]. Our 3- and 6-month weight loss outcomes are comparable to previously reported outcomes, but the 12-month weight recidivism seen in our study has not been previously reported. The weight recidivism is surprising considering the technique used was very similar to the purse-string technique, but done in a twofold manner with the goal of improving durability and strength. The technique was thus arguably more aggressive and robust, a fact evident in the development of stenosis in some patients. In addition, the weight recidivism is difficult to interpret due to the small number of patients at 12-month follow-up. One explanation may be that our cohort did not undergo any diet or lifestyle therapy. Patients in this study were offered referral to diet and lifestyle therapy with a third party provider and strongly encouraged to follow-up. However, all patients decided against this as they had experienced failure with those therapies. Previous studies have successfully included patients in a weight management program post-procedure [21, 23]. Thus, there seems to be additional benefit from the inclusion of patients in such a program, particularly with regard to long-term outcomes and weight recidivism. Nevertheless, this procedure has been successful even in the absence of diet or

lifestyle changes. Importantly, all patients in this cohort were experiencing weight gain until the procedures were performed. This procedure successfully halted weight gain for all but 3 patients at 12-month follow-up.

Two patients returned at 1 year with weight recidivism and were found to have dilated GJAs requiring re-intervention. Fortunately, insurance approval allowed us to perform repeat endoscopic suturing. However, this may not be practicable or cost-effective in all cases. It is important to note that primary responders may experience weight regain and GJA dilation within a short timespan despite initial success. Maintenance of weight lost after TORe may necessitate adjunct pharmacological or diet and lifestyle interventions. Based on these findings, there may be an argument for annual EGD with endoscopic intervention.

DS has been well-described in the population post-RYGB [2, 13]. Our study demonstrated that the overall DS severity score improved with TORe, and all individual symptoms either improved or remained unchanged. None of the symptoms worsened, however. Thus, TORe was beneficial for the treatment of DS, and further research may seek to assess the effect of TORe on DS health-related quality of life. Further subjective and objective testing would be contributory.

In our cohort, TORe resulted in the development of GJA stenosis in 7.3% of patients. This is the first study to report this adverse event post-TORe, and it may be due to the more aggressive method of suturing. The patients in this study responded well to balloon dilation; however, 2/4 patients required two consecutive balloon dilation sessions in order to achieve the desired GJA size. Additionally, gastric ulceration was a significant concern in this cohort. Open capsule proton pump inhibitors for 4 weeks post procedure may be an appropriate prophylactic measure to avoid the development of such ulcers.

Some advantages of TORe include its short procedure time and repeatability which allows it to be tailored to individual patients depending on their responsiveness to treatment as assessed by symptom resolution, degree of satiety, and amount of weight loss. Currently, the treatment algorithm is dependent on GJA size at follow-up endoscopy. Conceivably, future algorithms may seek to incorporate symptom scores and weight loss into the decision-making model for further intervention. Importantly, we must remain aware that this procedure is not a single-session therapy, but will likely require a series of consecutive procedures with close follow-up. In our study, 40/55 patients required ≥ 2 follow-up treatment sessions. There also remains a need for evidence to guide the stratification of patients into surgical revision, endoscopic revision, or medical intervention. For instance, we suspect that patients who have a very large pouch (> 6 cm in length) or a gastrogastric fistula would benefit from surgical intervention. In such patients, in the absence of features of small bowel micronutrient deficiency, revisional surgery with a malabsorptive component could be considered as it can confer the additional benefit of malabsorption in addition to the restriction that can be provided by endoscopic methods. Future prospective studies should aim to compare surgical and endoscopic interventions, but will likely be limited by ethical concerns.

This study has all the limitations inherent to a retrospective design, including loss to follow-up. Follow-up at 12 months included only 15/55 patients. Another limitation is that sizing of the GJA was subjective and dependent on the judgment of the endoscopist. However, all procedures were performed by one endoscopist, limiting this bias. There was also no comparison group or control group. The patients were stratified into their respective groups based on insurance coverage, which may have reflected a selection bias. However, in the absence of published data at the time proving the superiority of endoscopic suturing over APC alone, this was not considered an ethical bias and was considered an accurate representation of the real-world outcomes. Finally, this study was performed at an academic center by an endoscopist who was experienced in endoscopic suturing, thus limiting generalizability.

Our study thereby demonstrates the technical feasibility and short-term efficacy of TORe using a novel twofold running suture technique. Moreover, it conveys the real-world applicability of a treatment algorithm using both APC and ES-APC depending on insurance coverage. However, durability remains questionable in the absence of diet and lifestyle intervention. There remains a need for a prospective randomized study using this novel technique.

Author Contributions Study conception and design: Schweitzer, Michael; Oberbach, Andreas; Kumbhari, Vivek; Fayad, Lea
Acquisition of data: Dunlap, Margo K.; Shah, Tazkia; Fayad, Lea
Analysis and interpretation of data: Raad, Micheal; Doshi, Jay; Oleas, Roberto; El Asmar, Margueritta, Fayad, Lea
Drafting of manuscript: Kumbhari, Vivek
Critical revision: Kalloo, Anthony N.; Khashab, Mouen A.; Steele, Kimberly; Magnussen, Thomas

Compliance with Ethical Standards

Ethical Approval For this type of study formal consent is not required.

Informed Consent Informed consent does not apply.

Conflict of Interest Mouen A Khashab is on the medical advisory board for Boston scientific and Olympus America and is a consultant for Boston scientific, Olympus America, and Medtronic.

Anthony N Kalloo is a founding member, equity Holder, and consultant for Apollo Endosurgery.

Vivek Kumbhari is a consultant for Medtronic, Reshape Lifesciences, Boston Scientific, and Apollo Endosurgery. He also receives research support from ERBE USA and Apollo Endosurgery.

All other authors declare that they have no conflict of interest.

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