

Outcomes following 50 consecutive endoscopic gastrojejunal revisions for weight gain following Roux-en-Y gastric bypass: a comparison of endoscopic suturing techniques for stoma reduction

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Abstract

Background Approximately 20–30 % of morbidly obese patients undergoing Roux-en-Y gastric bypass (RYGB) will experience significant weight regain in the years following surgery. Endoscopic gastrojejunal revision (EGJR) has been shown to be a safe, effective and less invasive alternative to revisional surgery, with promising weight loss outcomes. However, minimal data exist regarding how to perform the procedure most effectively and what factors may predict good outcomes. We compared weight loss outcomes between patients undergoing endoscopic stoma revision by one of two full-thickness suturing techniques.

Methods A retrospective review of patients undergoing EGJR between 06/2012 and 09/2015 was performed. Included patients were adults 18–74 years of age who had experienced weight regain ≥ 2 years after initial RYGB with stoma dilation ≥ 15 mm in diameter. Revision was done with either an interrupted (IRT) or purse-string (PST) suture technique. A linear mixed effects model was constructed to predict postoperative weight loss.

Results Fifty revisions (IRT = 36, PST = 14) were performed in 47 patients (92 % female, mean age of 50.9 ± 10.9 years and body mass index of 41.4 ± 7.1 kg/m²). Technical success (stoma diameter ≤ 10 mm) was achieved in all cases. Final diameter was significantly smaller in the PST group, 6.6 ± 2.2 mm versus 4.8 ± 1.8 mm ($p < 0.01$),

resulting in a significantly greater % stoma reduction (76.8 ± 8.5 % vs. 84.2 ± 5.1 %, $p < 0.01$) versus the IRT group. PST resulted in greater % excess weight loss over time compared to IRT. Sixteen comorbid conditions resolved among 12 patients. No major complications occurred.

Conclusion Endoscopic revision of the gastric outlet results in meaningful weight loss and comorbidity resolution in select patients experiencing weight regain following RYGB. A PST revision likely results in higher and more sustainable weight loss when compared to IRT.

Keywords Endoluminal therapy · Weight regain · Gastric pouch and stoma dilation · Revisional bariatric surgery

Obesity continues to be a major growing health concern globally. In the USA alone, it is estimated that more than one-third of the adult population has a BMI > 30 kg/m² [1]. Overweight and obese patients also suffer from many weight-related comorbidities such as type II diabetes mellitus (T2DM), hypertension (HTN), hyperlipidemia, obstructive sleep apnea (OSA), and osteoarthritis (OA), among others [2, 3], all of which can contribute to further cardiovascular disease, stroke, and malignancy [4]. Bariatric surgery remains the most effective treatment for morbid obesity, resulting in significant and durable weight loss [5]. For many years, Roux-en-Y gastric bypass has been the most commonly performed bariatric operation worldwide and considered to be the gold standard among weight loss procedures [6]. The average bypass patient can expect to lose 70–80 % of their excess body weight (EBW) within 12–24 months, and many will experience significant improvement or complete resolution of obesity-related comorbidities, while ameliorating associated risk factors elevated at baseline [7, 8]. However, despite these impressive initial outcomes, 20–30 % of bypass patients will

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experience significant weight regain in the years following nadir weight loss, and up to 50 % of them will have regained some portion of their lost weight as early as 2–5 years after achieving their nadir [9–11].

Many factors may contribute to weight loss failure or weight regain following gastric bypass. Non-compliance with diet and exercise is a common problem [12], but anatomical and physiological changes that occur in the years following bypass may also play a role. Dilatation of the gastric pouch and stoma has both been implicated in weight re-gain [13, 14]. Management of weight re-gain poses a vexing challenge for both patients and bariatric surgeons. Surgical revision, with restrictive (i.e., band over bypass, pouch reduction, bypass revision) and/or malabsorptive components (duodenal switch, limb lengthening bypass revision, etc.), is technically more difficult and associated with not only the increased morbidity inherent to any redo operation, but also the increased risk of complications specific to morbidly obese patients that may require additional surgical management [15]. Furthermore, the weight loss outcomes following revisional surgery are not as robust as compared to the initial operation [16].

Endoscopic bariatric therapies (EBT) have been increasingly utilized as a less invasive option to revisional surgery. Initial attempts at endoluminal stoma reduction involved the use of partial thickness tissue plication devices that resulted in modest weight loss outcomes at 6 months [17]. With advancements in endoscopic suturing technology, increasing reports of more significant and sustainable weight loss following full-thickness plication have been shown to be feasible, safe and associated with less morbidity compared to surgical revision [18].

Experience from high-volume centers performing endoscopic suture revision shows that stoma size is critical to weight loss outcomes in these patients [14]. However, minimal data exist regarding how to perform the procedure most effectively and what factors may predict good outcomes. We compared clinical outcomes in patients with weight regain undergoing full-thickness endoscopic gastrojejunal revision (EGJR) two different endoscopic suturing techniques and analyzed several patient and procedural variables for their ability to predict one-year weight loss outcomes. To our knowledge, this is the first report comparing outcomes between different suturing techniques in this subset of patients.

Methods

Study design

An institutional review board-approved retrospective evaluation of all patients who underwent an EGJR

procedure at our institution between June 2012 and September 2015 was performed. Included patients were adults aged 18–74 years of age who had experienced weight regain ≥ 2 years after initial RYGB with achievement of ≥ 50 % excess weight loss, and determined to have gastrojejunal anastomotic (GJA) stoma dilation to greater than 15 mm in diameter by diagnostic upper endoscopy. All included patients additionally underwent a preoperative upper gastrointestinal contrast study to evaluate for gastrogastroic fistula or evidence of other pathology. Patients found to have marginal ulcers or those not meeting the above criteria were excluded. Figure 1 provides an overview of the study design and follow-up. Forty-seven patients meeting criteria were then required to undergo evaluation by both a registered dietician and psychologist. Dietary clearance was only granted to those patients who were engaged during regularly scheduled evaluations, compliant with taking vitamins, had given up carbonated beverages, and showed interest in making appropriate behavioral changes. Psychosocial criteria included being free from active or untreated mental health illness, addiction or addictive behavior, ability to demonstrate insight regarding their current situation, and display willingness and ability to make appropriate behavioral changes with adequate social support. The average time from initial consultation to revision was 4 months. If a patient was not cleared from a dietary or psychosocial standpoint, he or she was referred for supervised medical weight loss (SMWL) and could re-initiate the process after 1 month.

Data collection

Patient demographics, baseline weight characteristics (pre-EGJR weight data including highest weight pre-RYGB, weight at RGYB, post-RYGB nadir, highest weight post-RYGB, pre-EGJR evaluation weight and weight on day of EGJR), operative findings, and complications were recorded. The presence of obesity-related comorbidities, including obstructive sleep apnea (OSA) requiring Continuous Positive Airway Pressure (CPAP), gastroesophageal reflux disease (GERD), hypertension, diabetes mellitus, hyperlipidemia, and osteoarthritis or joint pain were documented during initial preoperative evaluation and at each postoperative clinic visit. Comorbidity resolution, defined as no longer requiring CPAP or medications for specific medical conditions or symptom improvement for others, was assessed at each time point. Preoperative diagnostic upper endoscopy was performed to assess the GJA, gastric pouch, and presence of gastrogastroic fistula or other pathology that would exclude patients as described above. Pre- and post-revision stoma diameter and pouch volume measurements were estimated following carbon dioxide (CO₂) insufflation and dilation, using the

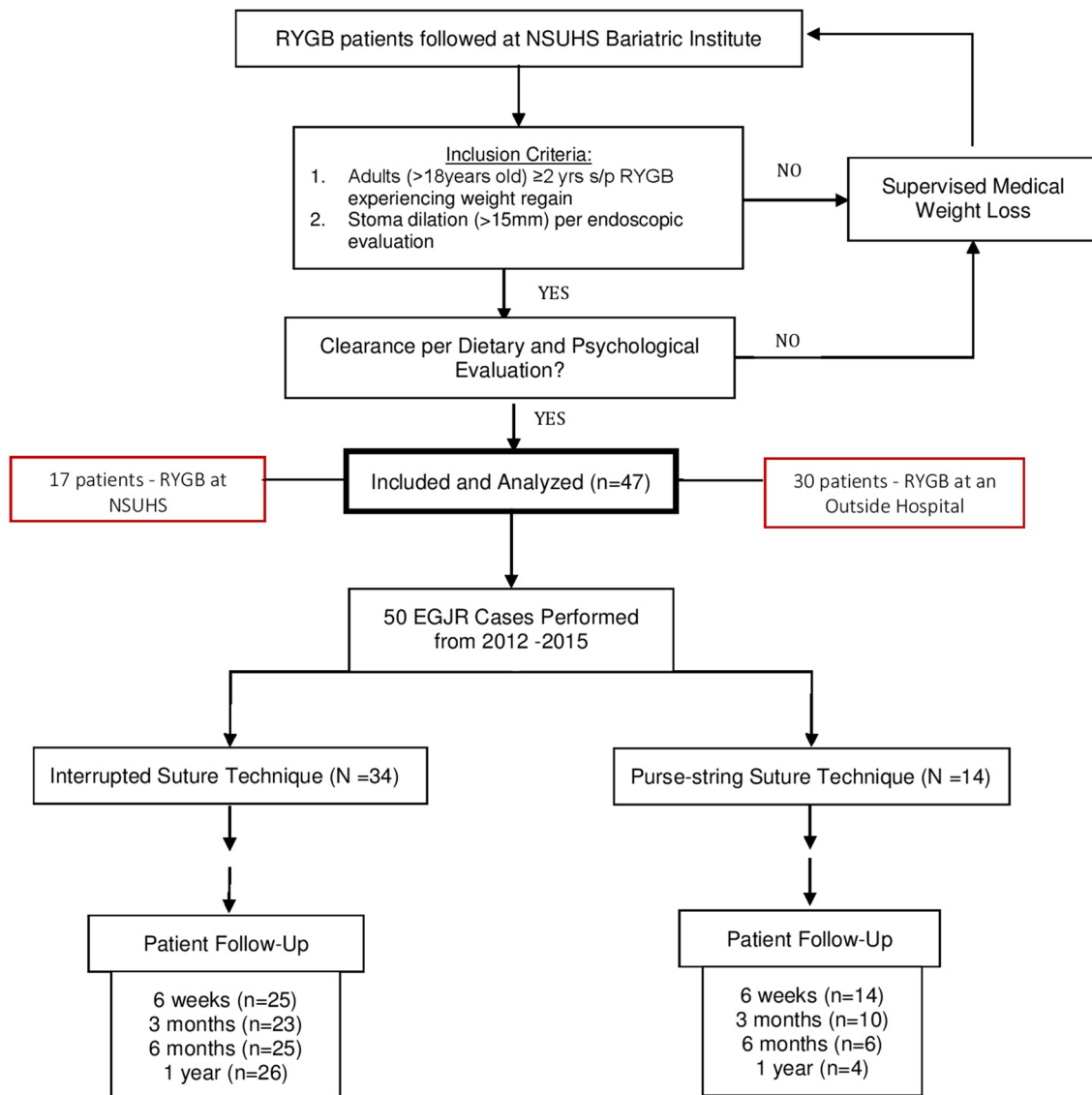


Fig. 1 Study design/follow-up flow diagram

predetermined 7 mm jaw width of an endoscopic biopsy forceps or an endoscopic snare with a deployed circumference that was then measured *ex vivo*. Additionally, the UGI swallow study provided radiologic estimates of pouch size in select cases. Follow-up data were collected at post-procedure clinic visits regularly scheduled at 2 weeks and 6 weeks, 3 months and 6 months, 1 year, and annually thereafter.

As part of our institution's bariatric protocol, all patients were scheduled for ongoing dietary evaluation postoperatively. The importance of dietary compliance and consistent follow-up to monitor nutritional status and potential complications were emphasized at each encounter. A bariatric coordinator was responsible for centralizing patient follow-up. Patients who failed to attend scheduled appointments were contacted over the phone to inquire about their status

and to reschedule missed appointments. Patient weights obtained via phone calls were not included in this study. A certified letter was sent to those patients who failed to be reached after three phone attempts. If a patient missed a bariatric appointment but had been seen by another department within our hospital system, recorded weight and comorbidity-related information documented in the clinician's note for that encounter were reviewed when available.

Procedure

Two bariatric surgeons within the NorthShore University HealthSystem performed all procedures at one of two locations, under general anesthesia, in either the operating room or outpatient endoscopy lab. Cases performed in the operating room were typically done so in conjunction with

another procedure. Following successful endotracheal intubation, the procedure began with a diagnostic upper endoscopy. An Olympus GIF Type H180 upper endoscope (Olympus, Center Valley, PA) was inserted into the oropharynx and the GE junction, followed by evaluation of the gastric pouch and stoma. Baseline stoma diameter and pouch volumes were re-assessed as previously described and measurements recorded. An Overtube device (Apollo Overtube) was then placed over the scope to protect the oropharynx and esophagus from potential iatrogenic mucosal injury. Next, taking care not to cause a full-thickness thermal injury, Argon Plasma Coagulation, with settings of 30 watts, effect 1, pulsed flow (0.8 L), was used to circumferentially cauterize the mucosa of the stoma in order to promote optimal fibrosis and scarring of the plication that followed. After ensuring that approximately 1-cm ring of mucosa was cauterized, the upper endoscope was withdrawn and exchanged for a therapeutic dual lumen scope with the endoscopic suturing device attached.

Full-thickness tissue plication was performed using the Overstitch™ Endoscopic Suturing System (Apollo Endosurgery, Austin, TX). The Overstitch system allows multiple sutures to be placed, in both interrupted and purse-string patterns, without necessitating device removal and thus minimizing potential iatrogenic injury associated with repeated exchanges. The suturing device was first loaded onto a dual-channel therapeutic upper endoscope and then re-inserted into the patient through the overtube (Fig. 2 provides an image of the endoscopic suturing device used for the procedure). The technical endpoint of the procedure was to achieve a final stoma diameter measuring between 5 and 10 mm. Figure 3 presents images from patients with purse-string and interrupted sutures. Monofilament non-absorbable sutures were placed in either an interrupted or purse-string pattern. In the interrupted group, simple interrupted sutures were placed to reduce stoma diameter to goal size. For the purse-string technique, running suture incorporated 0.5–1.0 cm of tissue circumferentially prior to being cinched in place. Additional interrupted sutures were then placed on either side of the repair, in an anterior–posterior orientation, acting as a buttress and further narrowing the diameter to within goal range. Final stoma diameter was then recorded, hemostasis confirmed, and the scope, suturing device, and overtube withdrawn prior to emergence and extubation. Following monitored recovery in the post-anesthesia care unit, patients were started on clear liquids and discharged home the same day with specified dietary restrictions—liquid diet for 2 weeks, progressed slowly to a pureed/soft diet by 4–5 weeks before returning to a general heart healthy diet by week 6 following the procedure.



Fig. 2 Endoscopic suturing device used for full-thickness plication—Overstitch™ (Apollo Endosurgery)

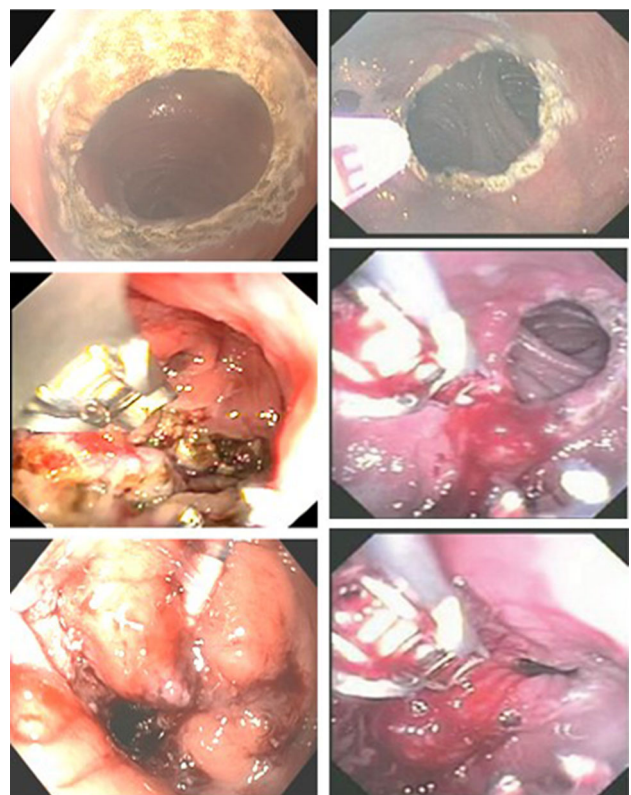


Fig. 3 Endoscopic images from patients with purse-string (*left*) versus interrupted revision (*right*)

Statistical analysis

Patient demographics, intraoperative characteristics, and postoperative outcomes were compared between groups. Primary outcomes were percent excess weight loss (%EWL) and comorbidity resolution. Secondary endpoints included length of procedure, final stoma diameter, percent stoma reduction, hospital stay, complications and re-operation. Categorical variables were compared using Chi-square test or Fisher's exact test (for small cell size), and continuous variables were compared using *t* test or Mann–

Whitney *U* test (nonparametric). Due to the limited follow-up after 1 year in the purse-string group, study data were included through 1 year only. Differences in weight outcomes from 6 weeks to 1-year post-EGJR were calculated using one-way repeated measures ANOVA.

Predictors of percent excess weight loss over the year were determined by linear mixed effects models. Univariate models were constructed for each candidate variable from Tables 1 and 2. Univariate predictors at $p < 0.20$ were included in a multivariable model with manual backwards selection. All possible interactions were assessed in the final multivariable

Table 1 Baseline patient characteristics by revision technique ($n = 50$)

Parameter	Interrupted ($n = 34$)	Purse-string ($n = 16$)	<i>p</i> value
Age ^a	48.6 ± 10.3	55.8 ± 10.8	0.03
Sex [n (%)]			0.58
Male	2 (5.9)	2 (12.5)	
Female	32 (94.1)	14 (87.5)	
Baseline weight (kg)	114.5 ± 20.5	110.2 ± 22.6	0.51
Baseline BMI, kg/m ²	41.7 ± 6.4	40.7 ± 8.7	0.63
Obesity severity [n (%)]			
BMI > 35 kg/m ²	29 (85.3)	12 (75.0)	0.44
BMI > 40 kg/m ²	19 (55.9)	6 (37.5)	0.23
BMI > 45 kg/m ²	9 (26.5)	4 (25.0)	0.99
GJ diameter (mm)	29.3 ± 6.8	30.2 ± 5.4	0.66
Years from RYGB to EGJR	9.6 ± 3.3	9.5 ± 3.5	0.92
Weight before RYGB (kg)	151.9 ± 31.7	143.7 ± 30.4	0.40
Max post-RYGB weight loss (kg)	62.8 ± 21.7	54.4 ± 17.9	0.18
Max %EWL after RYGB	79.3 ± 20.0	61.0 ± 17.5	<0.01
Weight gain, nadir to baseline (kg)	25.4 ± 12.9	20.8 ± 12.2	0.24
% Excess weight at baseline	38.7 ± 9.5	34.9 ± 11.8	0.24

^a Plus minus values are presented as mean ± SD

Table 2 Peri-operative outcomes by revision technique ($n = 50$)

Parameter	Interrupted (IST, $n = 34$)	Purse-string (PST, $n = 16$)	<i>p</i> value
OR procedure length (min)*	50.4 ± 25.3	42.9 ± 18.1	0.29
Successfully reduced GJ ≤ 10 mm, n (%)	34 (100.0)	16 (100.0)	–
GJ diameter start (mm)	29.3 ± 6.8	30.2 ± 5.4	0.66
GJ diameter end (mm)	6.6 ± 2.2	4.8 ± 1.8	<0.01
% GJ diameter reduction	76.8 ± 8.5	84.2 ± 5.1	<0.01
Sutures [median (range)]	3 (1–8)	3 (1–7)	0.72
Postoperative			
Nausea	4 (11.8)	3 (18.8)	0.51
Emesis	2 (5.9)	4 (25.0)	0.07
Abdominal pain	1 (2.9)	1 (6.3)	
30-day complications [n (%)]	1 (2.9)	0	–
Sensation of restriction at 1st follow-up	19 (55.9)	15 (93.7)	<0.01
Required redo revision [n (%)]	3 (8.8)	0	–
Time from initial revision (years)	2	–	–

* Plus minus values are presented as mean ± SD

Table 3 Overall weight loss outcomes in total cohort at week 6, month 3, month 6, and year 1

Postoperative clinic visit, median (q1, q3)	Week 6 (<i>n</i> = 39)	Month 3 (<i>n</i> = 33)	Month 6 (<i>n</i> = 31)	Year 1 (<i>n</i> = 30)
1. Absolute weight loss from baseline (kg)	5.4 (4.1, 10.0)	5.9 (4.1, 11.3)	5.0 (1.8, 11.3)	4.5 (−1.4, 12.2)
2. % Weight loss from baseline	5.7 (3.4, 8.8)	5.3 (3.2, 10.2)	4.2 (1.4, 8.8)	3.9 (−1.2, 10.1)
3. % Excess weight loss ^a	15.0 (9.0, 22.0)	19.0 (9.0, 27.0)	13.0 (5.0, 32.0)	10.0 (−3.2, 23.1)
4. % Weight regain lost ^b	25.0 (19.1, 42.9)	31.6 (20.7, 55.0)	31.3 (10.0, 76.0)	13.7 (−4.8, 42.2)
5. Weight stabilization/weight loss ^c [<i>n</i> (%)]	38 (97.4)	32 (97.0)	30 (96.8)	23 (76.7)
≥10 % EWL	28 (71.8)	23 (69.7)	18 (58.1)	15 (50.0)
≥15 % EWL	20 (51.3)	18 (54.6)	15 (48.4)	11 (36.7)
≥20 % EWL	15 (38.5)	14 (42.4)	12 (38.7)	9 (30.0)

^a %EWL is computed as follows: $([\text{weight at baseline} - \text{weight at assessment time period}]/[\text{weight at baseline} - \text{ideal weight at body mass index of 25}]) \times 100$

^b %Weight regain lost is computed as follows: $([\text{weight at baseline} - \text{weight at assessment time period}]/[\text{weight at baseline} - \text{nadir weight}])$

^c Weight stabilization defined as $\pm 2\%$ of weight at baseline

model. Statistical significance was established at an alpha level of 0.05. All statistical analyses were performed using SAS 9.3 statistical software (SAS Inc. Cary, NC).

Results

Patient characteristics

Forty-seven patients (92 % female and mean age of 50.9 ± 10.9) meeting criteria were included in the study. Seventeen patients had their initial gastric bypass within our hospital system, while thirty patients underwent bypass at an outside institution. Mean time from bypass to EGJR was 9.6 ± 3.4 years. A total of 50 EGJR procedures were performed during the study period. From June 2012 to August 2014, thirty-four consecutive cases were performed using the IRT. The purse-string technique was utilized from September 2014 to December 2015 for primary revision in 13 patients and redo revision in three patients who had failed an initial IRT attempt. Weight loss outcomes for those three patients were included as part of IRT follow-up until they were re-evaluated for redo revision at which point their preoperative and postoperative weights thereafter were included as part of the PST group only. Demographic and baseline weight characteristics by group are presented in Table 1. The PST group was significantly older than the IRT group (55.8 ± 10.8 vs. 48.6 ± 10.3 , $p = 0.03$). The maximum %EWL after RYGB was higher in the IRT group than the PST group (79.3 ± 20.0 vs. $61.0 \pm 17.5\%$, $p < 0.01$). There were no other baseline differences between groups.

Procedural outcomes

Technical success, defined as a final stoma diameter of 4–10 mm, was achieved in all 50 cases (100 %), with a

mean length of procedure similar between groups (IST = 50.4 ± 25.3 vs. PST = 42.9 ± 18.1 min, $p = 0.29$). A summary of operative details for both groups is shown in Table 2. Eight cases performed in the operating room were done so in conjunction with another operation, but time from scope-into scope-out for revision was the same. There were no intra-operative complications in either group, and most patients were discharged home the same day of the procedure. A total of 7 patients were admitted overnight for observation: 4 underwent concomitant incisional hernia repair, and 3 underwent EGJR alone and experienced ongoing nausea or abdominal pain. Six patients reported emesis within 24 h of the procedure, which may have been due to a gastrojejunal stoma diameter on the low end of the target range (Table 2). Postoperatively, one patient in the IRT group presented with an acute but mild UGI bleed 6 days following the procedure and required therapeutic endoscopy to control bleeding from a marginal ulcer. Nineteen (55.9 %) patients in the IRT group indicated sensation of restriction at their first follow-up as compared to 15 (93.7 %) in the PST group ($p < 0.01$). Three patients in IST group required re-operation (via PST) a mean of 2 years following the initial attempt.

Weight loss outcomes

For the 50 EGJR procedures performed, weight data were available for 37 at 2 weeks, 39 at 6 weeks, 33 at 3 months, 31 at 6 months, and 30 at 1 year. Compliance with regularly scheduled bariatric follow-up was 97.4 % at 2 weeks, 78.0 % at 6 weeks, 66.0 % at 3 months, 62.0 % at 6 months, and 73.2 % at 1 year. Overall weight loss outcomes at 6 weeks through 1-year post-EGJR are shown in Table 3. Median weight loss from baseline was 5.4 kg at 6 weeks, 5.9 kg at 3 months, 5.0 kg at 6 months, and

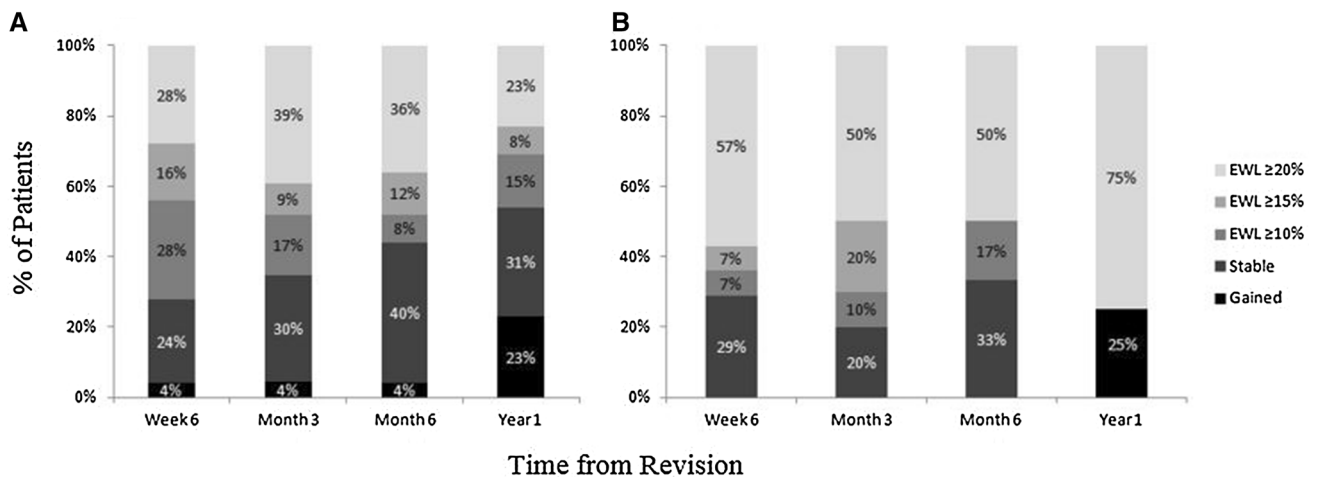


Fig. 4 Weight changes in **A** Interrupted and **B** purse-string patients at week 6, month 3, month 6, and year 1. EWL, excess weight loss; stable, $\pm 2\%$ of weight at baseline

4.5 kg at 1 year. All other measures of weight loss were high and similarly consistent from 6 weeks through 6 months, with a decrease at 1 year. At 6 weeks, 3 months, and 6 months, 97 % of patients achieved weight stabilization or weight loss. By 1 year, 77 % had weight stabilization or weight loss.

Figure 4 shows the degree of weight change experienced by patients in each group from 6 weeks through 1 year. Weight gain was experienced by a few patients at every time point in the IRT group, and by 1 year, 54 % of IRT patients had either gained weight or remained stable, while 46 % achieved EWL $\geq 10\%$. Comparatively, one patient (25 %) in the PST group had gained weight, while 75 % achieved EWL $\geq 10\%$ at 1 year. Additionally, an EWL $\geq 20\%$ was consistently achieved by at least 50 % of patients in the PST from 3 months to 1 year. There was a trend toward significantly greater weight loss in the PST group at 1 year ($p = 0.07$). Figure 5 presents the median % EWL by group over time. Groups start out similar at 2 weeks and slowly begin to diverge with the PST group showing greater improvement over time. Due to the limited sample size at 1 year in the PST group, group differences do not reach conventional statistical significance.

Independent predictors of %EWL over time are presented in Table 4. %EWL increases significantly over time from week 2 to 1-year post-EGJR (estimate (se) = 0.03 (0.01), $p = 0.03$). Greater or equal to 85 % stoma diameter reduction (0.10 (0.04), $p = 0.01$) and increasing years from RYGB to EGJR (0.01 (0.004), $p = 0.02$) were independent predictors of increasing % EWL. While there was not a significant difference found between purse-string and interrupted group, there was a significant interaction effect between group and time. This interaction can be visualized in Fig. 5, indicating that PST patients show a greater improvement in %EWL over time than IST patients.

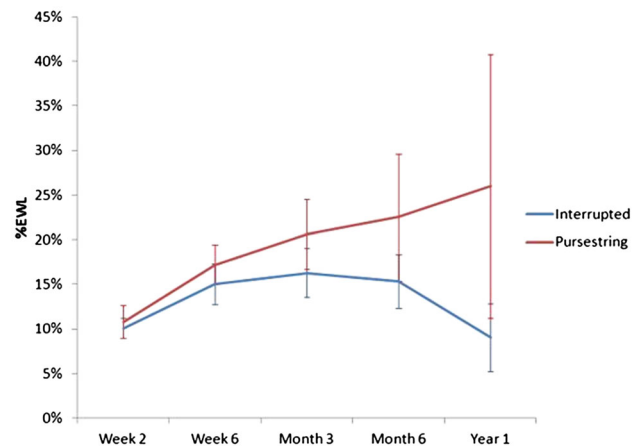


Fig. 5 Median percent excess weight loss (%EWL) over time per group. Vertical lines denote standard error patients maintain or increase %EWL until month 6, when we see a divergence in rate (%EWL/time) between groups. PST patients continue to increase %EWL, while IST patients show a decrease in %EWL

Table 4 Predictors of percent excess weight loss (%EWL) over time

Parameter	Estimate (SE)	p value
Time	0.03 (0.01)	0.03
Time ²	-0.02 (0.01)	0.03
Purse-string (vs. interrupted)	-0.07 (0.05)	0.11
Purse-string by time interaction	0.04 (0.01)	0.01
$\geq 85\%$ GJ diameter reduction	0.10 (0.04)	0.01
Interval: bypass—revision (years)	0.01 (0.004)	0.02

Postoperatively, 8 (57 %) PST patients attended at least one bariatric dietician visit compared to 14 (41 %) IRT patients ($p = 0.30$) (data not shown). Patients who attended dietary visits had significantly greater %EWL in

Table 5 Summary of comorbid conditions present at baseline and resolved at year 1 post-revision ($n = 50$)

Comorbidity	Interrupted ($n = 34$)	Purse-string ($n = 16$)	p value
Presence of any condition	23/34 (68.0)	11/16 (69.0)	0.94
Sleep Apnea, n/N (%)	2/10 (20.0)	2/5 (40.0)	0.56
Joint Pain	2/2 (100.0)	0/1 (0.0)	0.33
GERD	4/12 (33.3)	2/5 (40.0)	0.99
Hyperlipidemia	2/7 (28.6)	0/3 (0.0)	0.99
Hypertension	1/17 (5.9)	1/8 (12.5)	0.99
Diabetes	0/6 (0.0)	0/1 (0.0)	–
Resolution of any condition	11/23 (43.5)	5/11 (36.4)	0.99

N total number of patients with a condition at baseline; n number of patients with a resolved condition

univariate analysis (estimate (se) = 0.05 (0.02), $p = 0.02$); however, this did not remain a significant predictor after adjustment. Four (29 %) PST patients reported attending support groups postoperatively compared to 3 (9.4 %) patients in the IRT group ($p = 0.18$). Support group attendance did not predict %EWL.

Comorbidity resolution

Table 5 provides a summary of the comorbid conditions present in each group pre- and post-revision. Thirty-four patients had a comorbid condition preoperatively: 23 (68 %) in the IST group versus 11 (69 %) in the PST group. Sixteen conditions were resolved by 1 year among 14 patients.

Discussion

Recent data show that the numbers of primary and revisional bariatric procedures being performed in the USA have increased 26 and 32 %, respectively, from 2011 to 2014 [1]. Naturally, the number of patients experiencing weight re-gain in the years that follow can be expected to increase proportionally. Surgical revision for weight loss failure or weight regain following gastric bypass can be sought in a variety of ways in order to re-establish or enhance restriction and/or malabsorption in these patients. However, all surgical modalities are associated with increased risk of morbidity and reports have shown major complication rates to be as high as 30 % [19]. As such, the need for less invasive alternatives to revisional surgery, such as endoscopic therapies, continues to increase.

In a 2009 attempt to assess the expectations of revisional endoluminal procedures, the American Society for Metabolic and Bariatric Surgery (ASMBS) Emerging Technologies Committee surveyed 214 bariatric surgeons regarding the level of risk they would consider acceptable for such a procedure that could specifically achieve 10–20 % EWL outcomes at 1 year. Seventy-six percent of

respondents indicated that a level equivalent to a therapeutic endoscopy would be acceptable. However, the same survey showed varying beliefs among respondents as to an acceptable degree of %EWL following an endoscopic outlet reduction procedure: 25 % indicated 10–20 %EWL, while 37 and 23 % of respondents felt 20–30 % EWL and 30–40 % EWL, respectively, would be a considered a good outcome [20].

The primary goal of any bariatric procedure is to induce meaningful weight loss able to decrease metabolic comorbidities. Additionally, we must consider that BMI is only the best available surrogate for an estimate of tissue adiposity, the real determinant of obesity with clinical implications. As little as a 5 % reduction in excess weight can be enough to resolve type 2 diabetes and hypertension, and in turn, the risk of cardiovascular events for that patient, which may be potentially lifesaving in the long term [21].

While long-term data supporting the durability of outcomes for end luminal treatments are limited, our findings and those of other authors support EGJR as a less invasive, cost- and clinically effective alternative to revisional surgery. Our 6-month and 1-year outcomes demonstrated a median percent EWL of 13.0 and 10.0 %, respectively, with an overall complication rate of 2 % (1/50), similar to that of a therapeutic upper endoscopy. Collectively, 77 % of patients in our series experienced weight stabilization or some degree of weight loss (median weight loss of 4.5 kg) at 1 year following revision. When weight loss outcomes were compared between groups, patients in the PST were found to have better results across all times points; however, no statistical significance was ever reached. Patients in both groups of our study experienced improvement or resolution of comorbidities. Although weight loss outcomes were better in the purse-string group, there were no statistically significant differences in the number of patients with comorbidity resolution.

The premise behind stoma reduction, and to a lesser degree pouch volume reduction, is to re-establish neuro-hormonal signaling that induces early satiety. In our

previous report, a sense of restriction was not found to be a predictor of weight loss. However, in that cohort, only interrupted technique patients were analyzed [22]. We decided to change to purse-string technique in 2014. As full-thickness endoscopic suture revision was still a relatively novel approach when we started, we were simultaneously conducting a bench study comparing the mechanical strength of different suture patterns used to reduce stoma aperture in an *ex vivo* porcine model. Although our data have not been published, our preliminary findings suggested that a purse-string suture pattern could withstand a significantly greater burst pressure when compared to interrupted suture placement. In this study, a significantly greater number of purse-string patients experienced a sense of restriction at the time of their first follow-up appointment, at either 2 or 6 weeks post-revision, as compared to interrupted technique patients, but it was not a predictor of weight loss. In our current study, the purse-string technique leads to smaller stoma diameters and greater % stoma reduction when compared to the interrupted technique. We also found % stoma reduction to be a predictor of %EWL over time. The %EWL achieved by patients in our PST group is comparable to recently published long-term outcomes from a high-volume institution reported to use the PST. In their series of 150 patients with 3-year outcomes following endoscopic revision, the group from Brigham and Women's Hospital reported that %EWL was consistently >19–20 % at 1-, 2-, and 3-year follow-up [23]. The %EWL in our PST group was 25 % at 1 year which is comparable. The 25 % of patients in the PST group noted to have gained weight represented only 1 individual.

Literature has shown stoma diameter to play a key role in weight loss outcomes following bariatric procedures [14]. Although there is no consensus as to an absolute value for final stoma diameter, most authors choose an endpoint similar to that created during RYGB, 1.5 cm or less. For our group, the goal is to achieve a final stoma diameter between 4–10 mm. We found that the PST not only allowed for a significantly greater percent reduction in stoma diameter, but also lead to more sustainable %EWL over time, supporting PST's ability to achieve more durable weight loss outcomes. PST provides a full circumferential reinforcement of the dilated tissue comprising the stoma orifice. IST, on the other hand, only decreases stoma aperture in anterior/posterior orientation, leading to a “tear drop” shaped outlet comprised of dilated tissue that has not been reinforced, and thus more likely to continue to dilate. Theoretical benefits of a purse-string suture pattern over interrupted may include the ability to achieve a more uniform distribution of mechanical stress across the stoma aperture. In the IRT, sutures only approximate tissue in the anterior–posterior plane and hence may be at increased risk for mechanical failure over time.

Furthermore, we tend to buttress the PST with additional interrupted sutures placed on either side. This likely further decreases the mechanical load placed on the purse-string suture and is done so because a failure of the purse-string suture material at any point could potentially comprise the entire circumference of tissue incorporated. This reasoning may be supported by the fact that three patients in our IRT group had weight loss failure and after undergoing a redo revision with PST, they went on to have meaningful weight loss comparable to the others in that group.

Another factor that may explain the modest weight loss in the IRT group and could potentially affect future weight loss in the PST group is the time interval from bypass to revision. Patients in our study underwent revision an average of 9.2 years after their bypass surgery. Based on endoscopic evaluation of 205 RYGB patients undergoing a revisional bariatric operation or endoluminal procedure, Yimcharoen et al. [24] suggested that optimal weight loss outcomes can be achieved if revision is performed within 5 years of initial bypass. It would be interesting to see how the stoma diameter changes over time; however, we do not routinely perform surveillance endoscopy in these patients. Future studies with visual inspection and serial measurements obtained by upper endoscopy could prove useful.

The presence of gastro-gastric fistulae (GGF), an abnormal epithelialized communication between the functional gastric pouch and excluded stomach remnant, can complicate approximately 6 % of RYGB cases [25] and contributes to weight regain as these tracts allow for rapid emptying of the gastric pouch and thus dumping [26]. Typically, surgical revision has been the definitive treatment option for patients with a GGF accompanied by refractory symptoms (ulcers or pain) or weight gain [27]. More recently, a variety of endoscopic therapies have been utilized. Nine patients in our study were found to have concomitant GGF that were simultaneously repaired by endoscopic suturing. While simultaneous fistula repair may lead to greater % EWL, it is necessary in order to provide patients the best chance at experiencing optimal clinical and weight loss outcomes. Incidentally, the 9 patients who also underwent a gastrogastic fistula closure had 15.4 % EWL on average. The durability of endoscopic fistula closure is unknown and previously suggested to have a high failure rates if used for fistulae >10 mm [28]. However, there are only limited reports of full-thickness suture techniques being used and longer follow-up is necessary. It is our practice to wait a full year before radiographically confirming the presence or absence of a fistula.

Limitations

Our findings must be considered within the context of the study design and limitations in statistical power. Having

switched to the purse-string in September 2014, we have fewer patients in this group and even less with appropriate follow-up at 1 year, despite the efforts of a dedicated bariatric coordinator who contacts all patients at regular intervals. We also chose to exclude any patient reported weights in order to minimize bias. Alternatively, we could have performed an intention to treat analysis, but on-treatment analysis allows for more accurate reporting [22]. In addition, documentation of patient compliance and psychosocial well-being is challenging and likely incomplete, which can affect the durability of weight loss outcomes. In our study, participation in dietary evaluation postoperatively was associated with increased weight loss but it did not remain an independent predictor. Ultimately, patients will make their own decisions about attending, not only follow-up appointments, but support-groups and other life-style modification programs as well. Perhaps the implementation of more stringent perioperative dietary and psychological requirements could help alleviate this problem.

Furthermore, the current study does not include a control arm. Comparing weight loss outcomes in patients undergoing revision to those enrolled in aggressive nutritional counseling alone could provide more insight regarding the efficacy and durability of endoscopic revision. Patients not meeting inclusion criteria for revision at our institution, typically due to psychological or dietary reasons, but who do have anatomical dilation, are referred to Supervised Medical Weight Loss programs for several weeks and are then reconsidered for revision in almost all cases. We have seen that counseling alone can lead to *cessation of weight gain*, but it is minimally effective in terms of *actual weight loss*. Even those few patients that do manage to lose weight, the results are not sustained as many revert back to old habits, become non-compliant and continue to have an anatomical factor leading to further weight gain.

Another factor to consider is that patients in our study underwent their initial bypass, either open or laparoscopically, at several different institutions and operative details were not always available. Varying lengths of alimentary limb reconstruction could theoretically affect intestinal absorption and weight changes, as could the fact that some underwent concurrent cholecystectomy and some did not.

Endoscopic gastric outlet reduction for weight regain following RYGB can provide effective weight loss and comorbidity resolution in select patients. While our study was underpowered, our findings do seem to indicate that a purse-string suture reduction of the gastrojejunal stoma results in better and more sustainable outcomes when compared to interrupted suture revision. Our findings, in addition to the growing body of evidence demonstrating similar results with full-thickness suture plication, lend

support for EGJR being considered as first-line treatment for patients experiencing weight loss failure or weight regain following gastric bypass. The procedure can be accomplished on an outpatient basis with same-day discharge. The added benefits of a low-risk profile and cost-effectiveness make it more appealing to patients than having to undergo a revisional operation and do not preclude them from being able to have such operations in the future if indicated. However, further investigation is necessary in order to identify the type of patients for which this procedure would be most effective.

Compliance with ethical standards

Disclosures Drs. Lava Patel, Brittany Lapin, Craig S Brown, Tom Stringer, Matthew Gitelis, John Linn, Woody Denham, Liz Farwell, Stephen Haggerty, Michael Ujiki have no conflicts of interest or financial ties to disclose. Dr. Ujiki is a consultant for Apollo Endosurgery.

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