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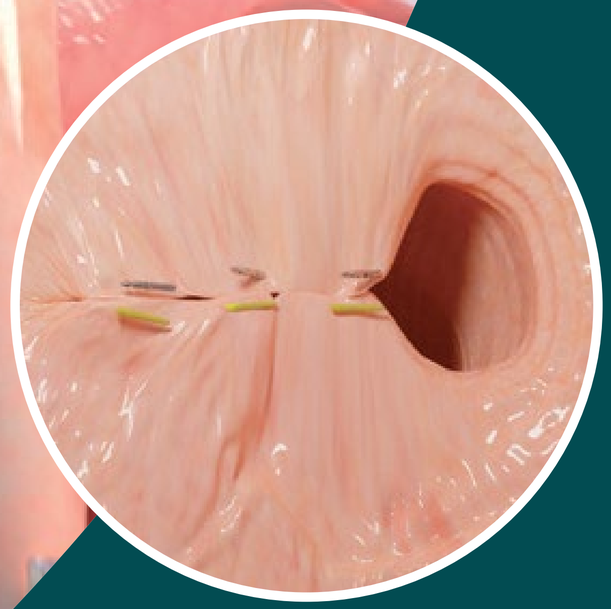
Clinical Evidence in Endobariatric Revisional Procedures

Start



Transoral Outlet Reduction (TORe) is one of the procedures that is part of Endura Weight Loss Solutions from Boston Scientific.

endura
Weight Loss Solutions

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Endoscopic Revision and Complication Management of Primary Bariatric Surgery

The below studies in the table show that using endoscopic techniques, along with lifestyle changes, behavior therapy, and medications, can help manage weight regain after initial bariatric surgeries like Laparoscopic Sleeve Gastrectomy (LSG) and Roux-en-Y gastric Bypass (RYGBP).

TORe efficacy and safety in Systematic Literature Review (SLR) and META-ANALYSIS:

Publication	Scope	Period	%TBWL		Adverse events	
			%	IC 95%	Type, %	±SD (CI95%)
Franken 2023 [133]	N studies: 39 TORe meta-analysis: 4 studies (269 patients) TORe + APC meta-analysis: 9 studies (1,226 patients)	TORe + APC 12 months:	4.96	(2.7–7.2)	Any complication 4.7%	-
			8.4	(6.7–10.1)	Gastro-intestinal stenosis 1.5%	-
		TORe + APC 24 months:	6.8	(3.7–9.9)		
		TORe + APC 36 months:	6.7	(3.4–10.1)	Bleeding 1.2	-
		TORe + APC 48 months:	1.8	(1.8 –5.4)		
		TORe + APC 60 months:	7.3	(-22.7–37.3)	Re-operation 0.3%	-

Expanding the clinical toolbox

Publication	Scope	Period	%TBWL		Adverse events	
			%	IC 95%	Type, %	±SD (CI95%)
Dhindsa 2020 [261]	N studies: 30 (850 patients)	3 months:	6.69	(3.82-9.55)	Overall 11.4	(±10.11)
			8.0	(6.3-9.7)	Mild 4.56	(±5.45)
		6 months:	11.34	(8.07-14.61)	Moderate 1.6	(±1.65)
		12 months:	8.55	(8.07-14.61)	Severe 0.57	(±1.35)
Jaruvongvanich 2020 [260]	N studies: 16 ft-TORe: 9 studies (737 unique patients) APMC-TORe: 7 studies (888 unique patients)	3 months:	9.0	(4.1-13.9)	9.3	8.0-17.8
			10.2	(8.4-12.1)	Overall 6.4	1.9-10.9
		6 months:	9.5	(8.1-11.0)	Stricture rate 3.3	1.4-5.3
		12 months:	9.5	(5.7-13.2)	Stricture rate 4.8	2.3-7.2
Vargas 2018 [169]	Systematic review: 130 patients Meta-analysis: 3 studies (330 patients)	6 months:	9.5	(7.9-11.1)		
		12 months:	8.4	(6.5-10.3)		
		24 months:	8.4	(5.9-10.9)		

Transoral Outlet Reduction (TORe)

LARGE RETROSPECTIVE STUDY AT 5YR

Five-year outcomes of transoral outlet reduction for the treatment of weight regain after roux-en-y gastric bypass

Jirapinyo P, et al. Gastrointest Endosc. 2020 May;91(5):1067-1073.

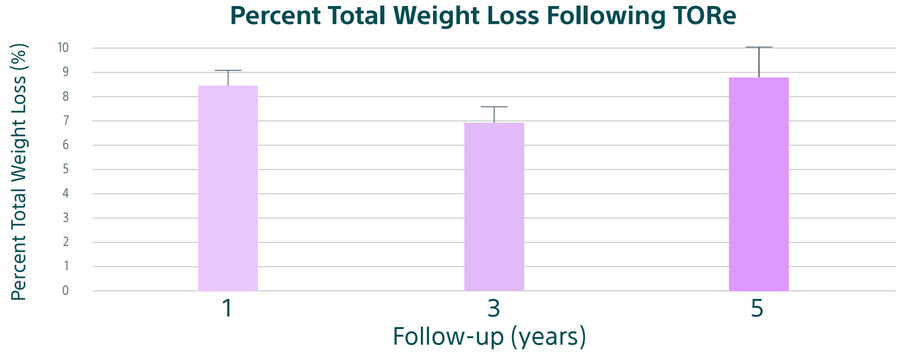
Background and Aims: Transoral outlet reduction (TORe) is a common endoscopic treatment for patients with weight regain after Roux-en-Y gastric bypass (RYGB) with a dilated gastrojejunal anastomosis (GJA). This study aims to assess long-term efficacy of TORe.

Methods: This was a retrospective review of prospectively collected data on RYGB patients who underwent TORe for weight regain or inadequate weight loss. The primary outcome was efficacy of TORe at 1, 3, and 5 years. Secondary outcomes were procedure details, safety profile, and predictors of long-term weight loss after TORe.

Results: A total of 331 RYGB patients underwent 342 TORe procedures and met inclusion criteria. Of these, 331, 258, and 123 patients were eligible for 1-, 3- and 5-year follow-ups, respectively. Mean body mass index (BMI) was 40 ± 9 kg/m2. Pre-TORe GJA size was 23.4 ± 6.0 mm, which decreased to 8.4 ± 1.6 mm after TORe. Patients experienced 8.5 ± 8.5%, 6.9 ± 10.1%, and 8.8 ± 12.5% total weight loss (TWL) at 1, 3, and 5 years with follow-up rates of 83.3%, 81.8%, and 82.9%, respectively. Of 342 TORe procedures, 76%, 17.5%, 4.4%, and 2.1% were performed using single pursestring, interrupted, double-pursestring, and running suture patterns, respectively, with an average of 9 ± 4 stitches per GJA. Pouch reinforcement suturing was performed in 57.3%, with an average of 3 ± 2 stitches per pouch. There were no severe adverse events. A total of 39.3% had additional weight loss therapy (pharmacotherapy or procedure), with 3.6% getting repeat TORe. Amount of weight loss at 1 year (β=0.43, p=0.01) and an additional endoscopic weight loss procedure (β=8.52, p=0.01) were predictors of %TWL at 5 years.

Conclusions: TORe appears to be safe, effective, and durable at treating weight regain after RYGB.

KEY HIGHLIGHTS



- At 5 years, TORe was successful at preventing weight gain in 77% of the patient cohort. (N=331)
- On average, patients lost 10.3±14.6 kg, which corresponded to 8.8±12.5% TWL (p<0.0001).

In addition to durability and efficacy, this study also demonstrates **repeatability of endoscopic bariatric procedures:** it is technically feasible and safe to perform other available endoscopic procedures for weight regain after the initial TORe.

- The SAE* rate of TORe at 5 years was 3.9%**

In summary, TORe appears to be safe, effective, and durable at treating weight regain after RYGB.

At 5 years after TORe, nearly all patients have cessation of weight gain with the majority experiencing clinically significant weight loss.

* Severe Adverse Event
** AEs as graded by the American Society for Gastrointestinal Endoscopy lexicon

Transoral Outlet Reduction (TORe)

PROSPECTIVE MULTICENTRE STUDY

Endoscopic management of dumping syndrome after Roux-en-Y gastric bypass: a large international series and proposed management strategy

Vargas E.J, et al. Gastrointest Endosc. 2020 Jul;92(1):91-96.

Background and Aims: Roux-en-Y gastric bypass (RYGB) is refractory to lifestyle and pharmacotherapy measures, requiring reversal of the patient's bariatric surgery. Reversal can lead to weight regain and recrudescence of their comorbidities. Our aim was to report a multicentre experience on the endoscopic management of refractory dumping syndrome with endoscopic transoral outlet reduction (TORe).

Methods: A multicentre international series of consecutive patients who underwent TORe with a full-thickness endoscopic suturing device was analyzed for technical success, improvement in Sigstad scores, and weight trajectories after the procedure. Failure was defined as needing an enteral feeding tube, surgical reversal, or repeat TORe.

Results: 115 patients across 2 large academic centres in Germany and the United States underwent TORe for dumping syndrome. Patient age was mean 8.9 ± 1.1 years from their initial RYGB with an average percent total body weight loss of 31% ± 10.6% at the time of endoscopy. Three months postprocedure, the Sigstad score improved from a mean of 17 ± 6.1 to 2.6 ± 1.9 (paired t test P = .0001) with only 2% of patients (n = 2) experiencing weight gain. Mean weight loss and percentage of total body weight loss 3 months post-TORe were 9.47 ± 3.6 kg and 9.47% ± 2.5%, respectively. Six patients (5%) failed initial endoscopic therapy, with 50% (n = 3) successfully treated with a repeat TORe. Three patients underwent surgical reversal, indicating an overall 97% endoscopic success rate.

Conclusions: TORe as an adjunct to lifestyle and pharmacologic therapy for refractory dumping syndrome is safe and effective at improving dumping syndrome and reducing rates of surgical revision.

KEY HIGHLIGHTS

Technical success was defined by improvement in Sigstad scores, weight trajectories and rates of medication discontinuation.

- All cases were technically successful.

CLINICAL SUCCESS:

- **100%** of patients reported discontinuation of their medication for dumping syndrome (at 3 months).
- **97%** (n=109) of cases were clinically successfully (at 3 months).
- 6 patients were considered a clinical failure, 50% had repeat TORe & 50% had G-Tube placement for enteral feeding.

EFFICACY:

- 3 months average TBWL 9.3% ±2.84%.

TABLE 3. Postintervention results

Variable	At 3 months	Mean difference	*P* value
Sigstad score	2.55 ± 1.87	–14.5 ± 5.5	<.0001
Weight, kg	89.4 ± 1.96	–9.3 ± 3.8	<.0001

Values are mean ± standard deviation.

TORe as an adjunct to lifestyle and pharmacologic therapy for refractory dumping syndrome **is safe and effective at improving dumping syndrome and reducing rates of surgical revision.**

Transoral Outlet Reduction (TORe)

RETROSPECTIVE COHORT STUDY 5yr

Endoscopic versus surgical gastrojejunal revision for weight regain in Roux-en-Y gastric bypass patients: 5-year safety and efficacy comparison

Dolan R. D, et al. Gastrointest Endosc. 2021 Nov;94(5):945-950.

Background and Aims: An enlarged gastrojejunal anastomosis (GJA) is associated with weight regain after Roux-en-Y gastric bypass (RYGB) and can be corrected with endoscopic or surgical revision; however, there has been no direct comparison between techniques. This study aims to compare serious adverse event (AE) rates and weight loss profiles between endoscopic and surgical revisional techniques over a 5-year period.

Methods: This is a retrospective matched cohort study of RYGB patients who underwent endoscopic or surgical revision for weight regain with an enlarged GJA (>12 mm). Patients who underwent endoscopic revision (ENDO group) were matched 1:1 to those undergoing surgical revision (SURG group) based on completion of 5-year follow-up, age, sex, body mass index, initial weight loss, and weight regain. Demographics, GJA size, serious AEs, and weight profiles were collected. The primary outcome was comparison of serious AE rates between groups. Secondary outcomes included weight loss comparisons. A Fisher exact test was used to compare the serious AE rate, and a Student t test was used for weight comparisons.

Results: Sixty-two RYGB patients with weight regain and an enlarged GJA (31 ENDO, 31 matched SURG) were included. Baseline characteristics were similar between groups. The AE rate in the ENDO group (6.5%) was lower than the SURG group (29.0%, P Z .043). Zero and 6 (19.4%) serious (severe) AEs occurred in the ENDO and SURG groups, respectively (P Z .02). There was no significant difference in weight loss at 1, 3, and 5 years.

Conclusions: Endoscopic revision of the GJA is associated with significantly fewer total and serious AEs and similar long-term weight loss when compared with surgical revision.

KEY HIGHLIGHTS

SAFETY:

- The AE rate in the ENDO group (6.5%) was lower than the SURG group (29.0%).
- 0 (0%) and 6 (19.4%) serious (severe) AEs occurred in the ENDO and SURG groups, respectively.*

TABLE 2. Adverse event rate comparison

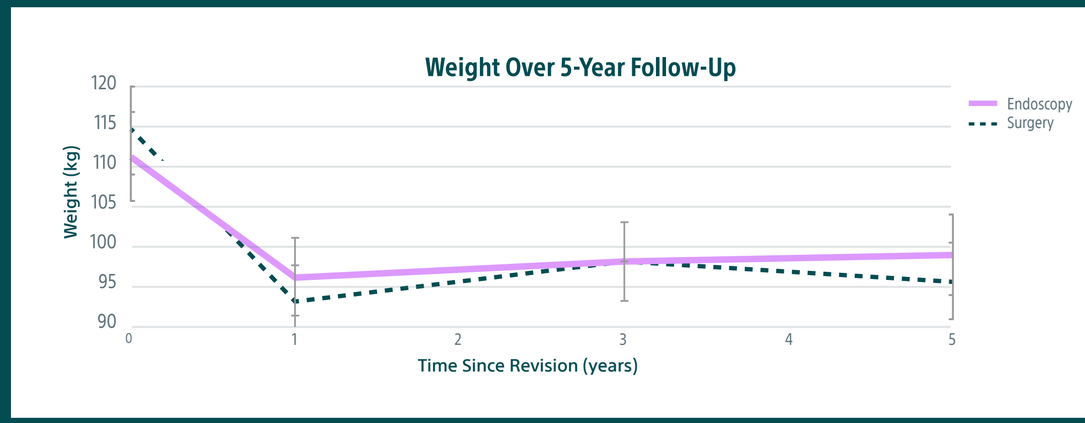
Outcome	Endoscopy (n = 31)	Surgical (n = 31)	*P* value
Adverse event	2 (6.5)	9 (29)	.043
GI leak/perforation	0	3 (9.7)	
Ulcer	0	1 (3.2)	
Gastrojejunal anastomosis stenosis	1 (3.2)	2 (6.5)	
GI bleeding	1 (3.2)	1 (3.2)	
Small-bowel obstruction	0	1 (3.2)	
Incarcerated incisional hernia	0	1 (3.2)	
Serious adverse events	0	6 (19.4)	.024
Early adverse events	1 (3.2)	7 (22.3)	.53

Values are n (%). Adverse event rate comparison between endoscopic and surgical gastrojejunal anastomosis revision. Serious adverse events were determined in reference to the American Society for Gastrointestinal Endoscopy lexicon for reporting endoscopic adverse events[1] and the National Surgical Quality Improvement Program.[2] Early events defined as those occurring within 30 days of revision.

1. Cotton PB, Eisen GM, Aabakken L, et al. A lexicon for endoscopic adverse events: report of an ASGE workshop. Gastrointest Endosc 2010;71:446-54.
2. 25. Ko CY, Hall BL, Hart AJ, et al. The American College of Surgeons National Surgical Quality Improvement Program: achieving better and safer surgery. Jt Comm J Qual Patient Saf 2015;41:199-204.

EFFICACY:

- Endoscopic Revision showed similar long-term weight loss when compared with surgical revision.



* SAE American Society for Gastrointestinal Endoscopy (ASGE) lexicon.

Transoral Outlet Reduction (TORe)

RETROSPECTIVE STUDY at 6, 12, and 24 months

Long-term outcomes oftransoral outlet reduction (TORe) for dumping syndrome and weight regain after Roux-en-Y gastric bypass

Pontecorvi V, et al. Obes Surg. 2023 Apr;33(4):1032-1039.

Background: Both weight regain and dumping syndrome (DS) after Roux-en-Y gastric bypass (RYGB) have been related to the dilation of gastro-jejunal anastomosis. The aim of this study is to assess the safety and long-term efficacy of endoscopic transoral outlet reduction (TORe) for DS and/or weight regain after RYBG.

Materials and methods: A retrospective analysis was performed on a prospective database. Sigstad's score, early and late Arts Dumping Score (ADS) questionnaires, absolute weight loss (AWL), percentage of total body weight loss (%TBWL), and percentage of excess weight loss (%EWL) were assessed at baseline and at 6, 12, and 24 months after TORe.

Results: Eighty-seven patients (median age 46 years, 79% female) underwent TORe. The median baseline BMI was 36.2 kg/m2. Out of 87 patients, 58 were classified as "dumpers" due to Sigstad's score ≥ 7. The resolution rate of DS (Sigstad's score < 7) was 68.9%, 66.7%, and 57.2% at 6, 12, and 24 months after TORe, respectively. A significant decrease in Sigstad's score as well as in early and late ADS questionnaires was observed (p < 0.001). The median Sigstad's score dropped from 15 (11–8.5) pre-operatively to 2 (0–12) at 24 months. The %TBWL was 10.5%, 9.9%, and 8.1% at 6, 12, and 24 months, respectively. Further, "dumpers" with resolution of DS showed better weight loss results compared with those with persistent DS (p < 0.001). The only adverse event observed was a perigastric fluid collection successfully managed conservatively.

Conclusion: TORe is a minimally invasive treatment for DS and/or weight regain after RYGB, with evidence of long-term efficacy.

KEY HIGHLIGHTS

Given the good outcomes and the excellent safety profile, TORe may play a key role in the multidisciplinary approach to weight regain and/or DS after RYGB when conservative therapy fails and before surgical revision.

EFFICACY:

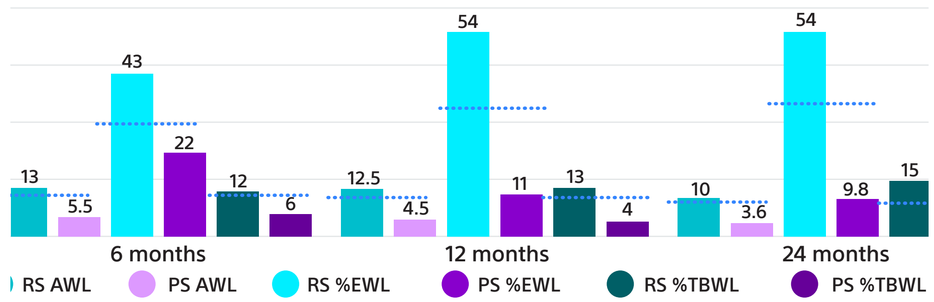
- 61% of patients showed %TBWL > 5% at 24 months. (N=87)

TABLE 5. Overall weight loss outcomes (n = 56)

	6 months	12 months	24 months	*p#*
AWL (kg)	11 (4–14)	10 (1–15)	8 (3–14)	< 0.001
EWL (%)	30.2 (14–44.8)	33.7 (3.8–48.7)	34.2 (9.9–57.8)	< 0.001
TBWL (%)	10.5 (4.1–13.7)	9.9 (1.1–14.3)	8.1 (3.1–13.3)	< 0.001

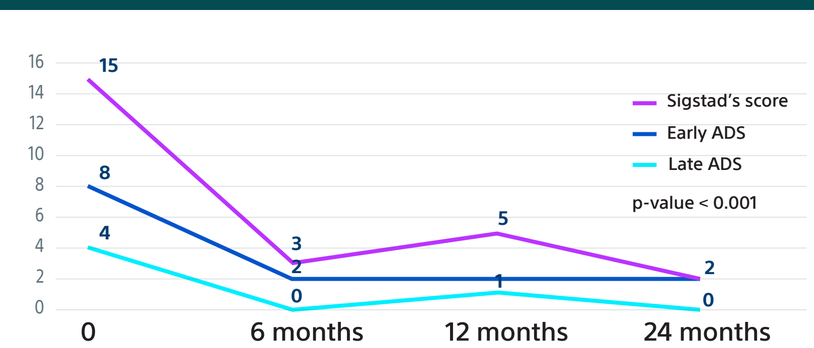
AWL, absolute weight loss; EWL, excess weight loss; TBWL, total body weight loss. #Friedman's test.

- Patients with resolution of DS had better **results on weight loss** compared with patients with persistent DS.



RS: resolution of symptoms; PS: persistence of symptoms; AWL: absolute weight loss; %EWL: percentage of excess weight loss; %TBWL: percentage of total body weight loss. In blue dotted line: the overall results of weight loss.

- **A decrease in all symptom based scores for DS** was observed which was statistically significant.



40 of 58 patients (68.9%), 34 of 51 patients (66.7%), and 20 of 35 patients (57.2%) showed resolution of symptoms (Sigstad's score) < 7 at 6, 12, and 24 months, respectively

LSG Endoscopic Revision

FIRST MULTICENTRE STUDY AT 1YR

Endoscopic Sleeve Gastroplasty in the management of weight regain after sleeve gastrectomy

de Moura DTH, et al. Endoscopy. 2020 Mar;52(3):202-210.

Background: Sleeve gastrectomy is a well-standardised surgical treatment for obesity. However, rates of weight regain after sleeve gastrectomy in long-term follow-up are relatively high. This multicentre study is the first to evaluate the use of an endoscopic sleeve gastroplasty (ESG) technique for the management of this population.

Methods: This was a multicentre retrospective study, including patients with weight regain following sleeve gastrectomy who underwent ESG for weight loss. Primary outcomes included absolute weight loss, percent total weight loss (%TWL), change in body mass index (BMI), percent excess weight loss (%EWL) at 6 and 12 months, and safety profile. Clinical success was defined as achieving ≥25% EWL at 1 year, ≤5% serious adverse event (SAE) rate following society-recommended thresholds, and %TWL ≥10%.

Results: 34 patients underwent ESG after sleeve gastrectomy. Technical success was 100%. At 1 year, 82.4% and 100% of patients achieved ≥10%TWL and ≥25% EWL, respectively. Mean (SD) %TWL was 13.2% (3.9) and 18.3% (5.5), and %EWL was 51.9% (19.1) and 69.9% (29.9) at 6 months and 1 year, respectively. Mean (SD) %TWL was 14.2% (12.5), 19.3% (5.3), 17.5% (5.2), and 20.4% (3.3), and %EWL was 88.5% (52.8), 84.4% (22.4), 55.4% (14.8), and 47.8% (11.2) for BMI categories of overweight and obesity class I, II, and III, respectively, at 1 year. No predictors of success were identified in the multivariable regression analysis. No SAEs were reported.

Conclusion: ESG appears to be safe and effective in the management of weight regain following sleeve gastrectomy.

KEY HIGHLIGHTS

Endoscopic therapies are appealing as they are more effective than lifestyle modification/ pharmacology and are associated with lower adverse event rates compared with revisional bariatric surgery.

SAFETY:

- No SAEs were reported.*

EFFICACY:

- BMI decreased from 34.8 kg/m2 to 28,9 kg/m2 at 1 year.
- At 1yr: 84,2% and 100% of patients achieved >10% TWL and >25% EWL.
- At 1 yr: %TWL is 18.3% (SD 5.5).

Table 2. Mean weight loss in all body mass index groups after endoscopic sleeve gastroplasty.[1]

Variables	Baseline (pre-ESG) (n = 32)	6 months (n = 32)	1 year (n = 17)	P value[2]
Absolute weight	99.6 (15.1)	86.2 (12.1)	83.6 (10.3)	< 0.05
Overweight	92.3 (12.9)	83.4 (9.9)	77.5 (5.5)	> 0.05
Obesity class I	94.6 (10.9)	81.2 (9.1)	79.8 (9.8)	< 0.05
Obesity class II	99.9 (4.9)	87.9 (5.8)	83.9 (8.7)	< 0.05
Obesity class III	127 (14.3)	107.9 (8.7)	95.8 (5.1)	< 0.05
%TWL	–	13.2 (3.9)	18.3 (5.5)	–
Overweight	–	9.3 (2.6)	14.2 (12.5)	–
Obesity class I	–	14.1 (4.2)	19.3 (5.3)	–
Obesity class II	–	12.1 (2.4)	17.5 (5.2)	–
Obesity class III	–	14.6 (4.5)	20.4 (3.3)	–
BMI	34.8 (4.4)	30.2 (4.1)	28.9 (4.4)	< 0.05
Overweight	29.4 (0.3)	26.7 (0.5)	25.4 (2.4)	> 0.05
Obesity class I	32.9 (1.2)	28.4 (1.7)	26.2 (1.5)	< 0.05
Obesity class II	36.7 (1.3)	32.2 (1.8)	30.2 (1.7)	< 0.05
Obesity class III	43.9 (4.4)	37.7 (5.4)	35.8 (4.5)	< 0.05

SD, standard deviation; ESG, endoscopic sleeve gastroplasty; TWL, percent total weight loss; BMI, body mass index; %EWL, percent excess weight loss.

1. All data are mean (SD) in kg.
2. Friedman test.

* SAE defined as per the ASGE guidelines

LSG Endoscopic Revision

PROSPECTIVE MULTICENTRE STUDY AT 1 YR

Revisional endoscopic sleeve gastroplasty of laparoscopic sleeve gastrectomy: an international, multicentre study

Maselli D. B, et al. Gastrointest Endosc. 2021 Jan;93(1):122-130.

Background and Aims: Laparoscopic sleeve gastrectomy (LSG) facilitates significant and durable weight loss; however, weight recidivism and need for revisional surgery occur in a subset of patients. Reduction of a dilated LSG using the revisional endoscopic sleeve gastroplasty (R-ESG) approach is an appealing and minimally invasive alternative to surgical revision that is congruent with obesity as a chronic relapsing disease model. In this study, we examine the safety and efficacy of the technique in a large multicentre international cohort.

Methods: Prospectively collected data from 9 centres for 82 consecutive adults who underwent R-ESG for weight regain after LSG using the OverstitchTM device (Apollo Endosurgery, Austin, Tex, USA) from March 2014 to November 2019 were reviewed. Total body weight loss (TBWL) and adverse events were reported up to 12 months. Univariable logistic regression was used to identify predictors of response at 12 months.

Results: Eighty-two adults (92.7% female) experienced 27.9 ± 20.7 kg weight regain from post-LSG nadir weight, prompting R-ESG (mean age, 42.8 ± 10.4 years) at a mean weight of 128.2 ± 57.5 kg.
Mean R-ESG procedure duration was 48.3 ± 20.5 minutes, and the median number of sutures used was 4 (interquartile range, 3-4). After R-ESG, TBWL (follow-up %) was 6.6% ± 3.2% at 1 month (81.7%), 10.6% ± 4.4% at 3 months (74.4%), 13.2% ± 10.1% at 6 months (63.4%), and 15.7% ± 7.6% at 12 months (51.2%). In a per-protocol analysis, ≥10% TBWL was achieved by 37 of 51 patients (72.5%) at 6 months and 34 of 42 patients (81.0%) at 12 months; ≥15% TBWL was achieved by 20 of 46 patients (43.5%) at 6 months and 22 of 42 patients (52.4%) at 12 months. Only 1 moderate adverse event occurred in the form of a narrowed gastroesophageal junction, which resolved after a single endoscopic dilation.

Conclusions: R-ESG is a safe and effective means of facilitating weight loss for weight recidivism after LSG, with sustained results at 1 year. R-ESG should be considered before pursuing more-invasive surgical revisional options.

KEY HIGHLIGHTS

Endoscopic volume reduction of a surgically created gastric sleeve is safe, feasible, and consistently effective for inducing sustained weight loss.

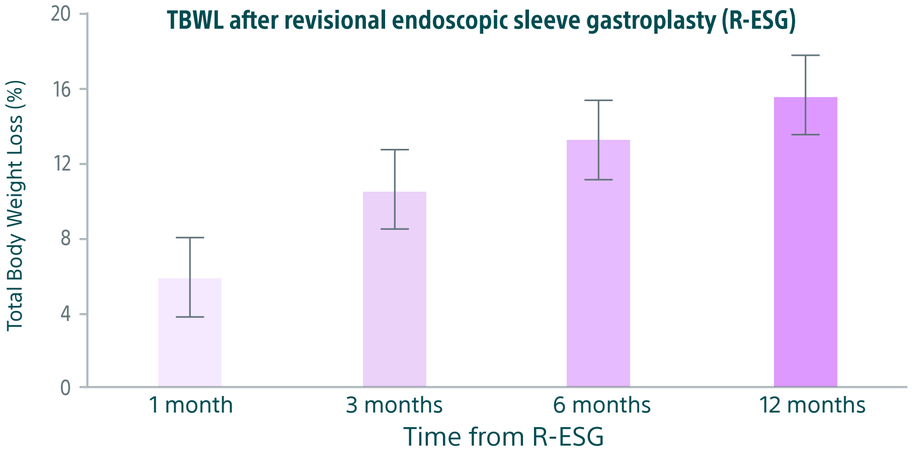
This transoral **anatomy-preserving procedure** should be considered before more invasive, morbid surgical revisions are pursued.

SAFETY:

- No serious adverse events were reported in any of the 82 patients during the 12-month study period.*
- Mild adverse events from R-ESG included 4 instances (4.9%) of dehydration requiring intravenous fluids but not requiring hospitalization or a repeat endoscopic procedure.*

EFFICACY:

- TBWL (follow-up %) is 15.7% ± 7.6% at 12 months (51.2%).



* SAE graded using the American Society for Gastrointestinal Endoscopy lexicon for endoscopic adverse events

Endoscopic Vacuum Therapy (EVT)

RETROSPECTIVE MULTICENTRE EVT HEALING RATE 90% AT 17 DAYS

Endoscopic vacuum therapy in salvage and standalone treatment of gastric leaks after bariatric surgery

Markus A., et al. Langenbecks Arch Surg. 2022 May;407(3):1039-1046.

Background: Gastric leaks constitute some of the most severe complications after obesity surgery. Resulting peritonitis can lead to inflammatory changes of the stomach wall and might necessitate drainage. The inflammatory changes make gastric leak treatment difficult. A common endoscopic approach of using stents causes the problem of inadequate leak sealing and the need for an external drainage. Based on promising results using endoscopic vacuum therapy (EVT) for esophageal leaks, we implemented this concept for gastric leak treatment after bariatric surgery (Ahrens et al., Endoscopy 42(9):693–698, 2010; Schniewind et al., Surg Endosc 27(10):3883–3890, 2013)

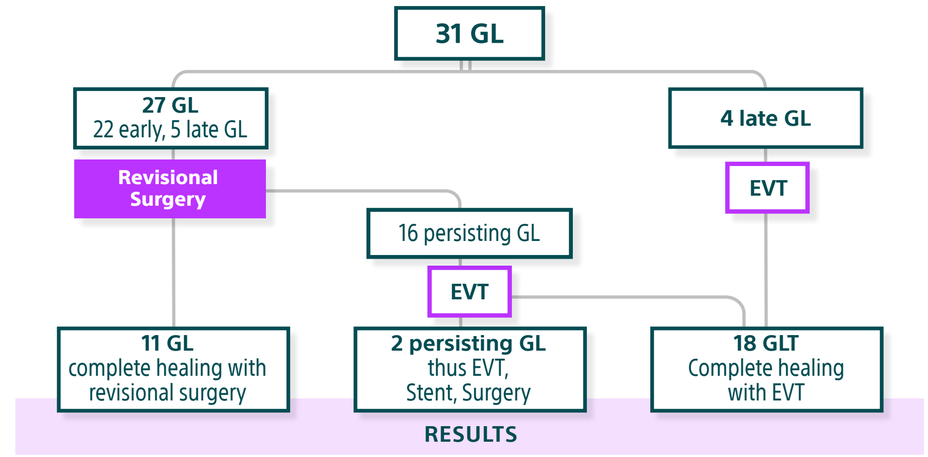
Methods: We retrospectively analyzed data of 31 gastric leaks after bariatric surgery. For leak therapy management, we used revisional laparoscopy with suturing and drainage. EVT was added for persistent leaks in sixteen cases and was used in four cases as standalone therapy.

Results: Twenty-one gastric leaks occurred in 521 sleeve gastrectomies (leakage rate 4.0%), 9 in 441 Roux-en-Y gastric bypasses (leakage rate 2.3%), and 1 in 12 mini-bypasses. Eleven of these gastric leaks were detected within 2 days after bariatric surgery and successfully treated by revision surgery. Sixteen gastric leaks, re-operated later than 2 days, remained after revision surgery, and EVT was added. Without revision surgery, we performed EVT as standalone therapy in 4 patients with late gastric leaks. The EVT healing rate was 90% (18 of 20). In 2 patients with a late gastric leak in sleeve gastrectomy, neither revisional surgery, EVT, nor stent therapy was successful. EVT patients showed no complications related to EVT during follow-up.

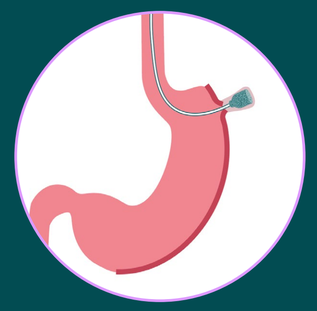
Conclusion: EVT is highly beneficial in cases of gastric leaks in obesity surgery where local peritonitis is present. Revisional surgery was unsuccessful later than 2 days after primary surgery (16 of 16 cases). EVT shows a similar healing rate to stent therapy (80–100%) but a shorter duration of treatment. The advantages of EVT are endoscopic access, internal drainage, rapid granulation, and direct therapy control. In compartmentalised gastric leaks, EVT was successful as a standalone therapy without external drainage.

KEY HIGHLIGHTS

Leakage rate after Bariatric surgery:
The overall leakage rate was 4% after SG and 2% after RYGB.



The overall healing rate with EVT was 90%.
The mean treatment time of EVT was 17 days.
For the 4 cases with late leaks were standalone.
EVT was applied, the mean EVT timespan was 12 days.



- There were no EVT-related complications such as dysphagia or chronic gastric fistulas.

"For patients showing signs of GL beyond 2 days of primary surgery, revisional surgery was insufficient in all cases due to local peritonitis."

For these patients, EVT resulted in a 90% healing rate normal weight loss, and no complications.

- EVT as standalone therapy in late leaks with good compartmentalization was as successful in all patients.

Endoluminal Suturing Post Bariatric Complications

RETROSPECTIVE SINGLE CENTRE 80% CLINICAL SUCCESS WITH ENDOLUMINAL SUTURING (ES) IN WALL DEFECTS

Endoscopic management of post-surgical GI wall defects with the Overstitch™ endosuturing system: a single-centre experience

Granata A., et al. Surg Endosc. 2020 Sep;34(9):3805-3817.

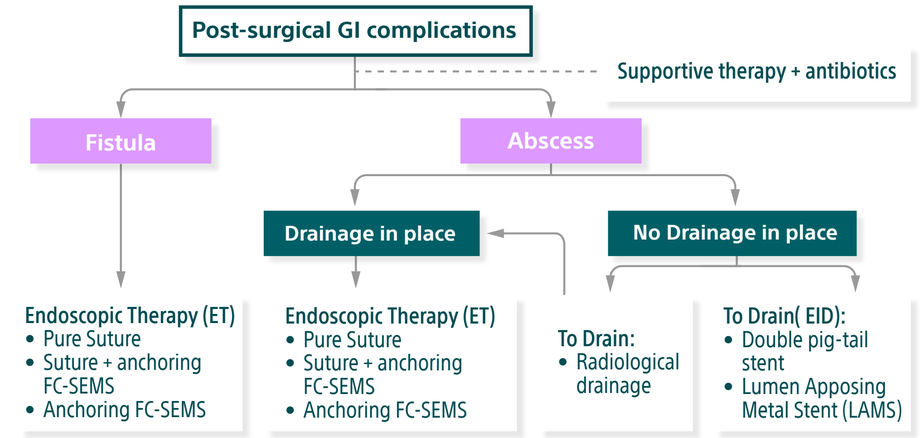
Background and aims: Post-GI surgical wall defects are frequent and life-threatening complications, with limited literature regarding current treatment. This case series aims to assess the safety, feasibility, and outcomes of endoluminal therapy with the Overstitch endoscopic suturing system (Apollo Endosurgery Inc, Austin).

Materials and methods: All patients who underwent endoscopic suturing for post-surgical wall defect management at IRCCS-ISMETT Palermo from October 2017 until January 2019 were retrospectively enrolled. Stratification therapy was applied according to the clinical scenario, time from surgery to endoscopic intervention, and structural condition of the wall defect layers (tissue status and suture feasibility). The therapeutic endoscopic strategy was divided into three groups (A: pure endoscopic direct suture; B: combined therapy with endoscopic direct suture + FC-SEMS placement + anchoring; C: FC-SEMS placement + anchoring). Success was considered the resolution of symptoms and the presence of a regular intestinal transit after a period of 4-6 weeks.

Results: Twenty (20) patients (male/female 7/13; mean age 54 ± 13.43 years) were included in the study (group A: 9 patients, group B: 7 patients, group C: 4 patients). The types of operative procedures were bariatric (9/20), post-tracheostomy (3/20), post-operative GI surgery (8/20). The post-surgical defects were predominantly intermediate and chronic (24-72 h: 1/20; 3-30 days: 13/20; > 30 days: 6/20). The overall clinical success was 80% (17/20 patients), with a success of 94% (16/17 patients) when excluding the three cases of tracheo-esophageal fistula. No evidence of migration was detected. The only complication was short stenosis of the distal esophagus, present in 4 patients (19%) and successfully treated with a novel lumen-apposing metal stent.

Conclusion: In our experience, considering the absence of clear guidelines, the endoluminal approach with the Overstitch™ endoscopic suturing system is a valid alternative to conventional therapy, offering mini-invasiveness, and presenting promising opportunities in terms of technical feasibility and clinical efficacy.

KEY HIGHLIGHTS



"In the bariatric surgery population, **fistula development is one of the most serious complications**, with incidences ranging from 1 to 8.3% after laparoscopic Roux-en-Y gastric bypass (LRYGB) and from 0 to 7% after laparoscopic sleeve gastrectomy (LSG)."

"With the increasing number of bariatric surgery procedures performed, **it has been noted that the incidence of post bariatric surgery complications is rising** despite the technical evolution in the surgical field."

The Overstitch™ endoscopic suturing system has been shown to be effective in leak management by placement of full-thickness sutures.

Limitations can also arise, such as the anatomic conditions of the narrow lumen. In fact, sufficient space in the lumen is essential because the Overstitch™ device is mounted onto the endoscope tip.

In particular, in group A, (post bariatric complications) the clinical success was **77%** (N=9), with the two failures in the treatment of tracheo-esophageal fistula (TEF).

The principal advantage of endoscopic suturing is its less invasive character, which prevents a reopening of recently operated tissues.

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