

# Tubularization of the gastric pouch helps sustain weight loss after transoral outlet reduction for post-Roux-en-Y gastric bypass weight recurrence



## Authors

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## ABSTRACT

**Background and study aims** Traditional transoral outlet reduction (TORe) is a minimally invasive endoscopic approach focused on reducing the aperture of the gastrojejunal (GJ) anastomosis, while the tubular transoral outlet reduction (tTORe) consists of tubularization of the distal pouch utilizing an O-shape gastroplasty suturing pattern. The primary aim of this study was to compare short-term weight loss between TORe and tTORe.

**Patients and methods** Retrospective analysis of a prospectively maintained database was conducted at a tertiary care bariatric center of excellence. The study included patients with history of Roux-en-Y gastric bypass (RYGB) who had an endoscopic revision by TORe or tTORe and had follow-up data in their electronic medical record. The primary outcome was percent total body weight loss (%TBWL).

**Results** A total of 128 patients were included (tTORe = 85, TORe = 43). At 3 and 6 months, the tTORe and TORe cohorts presented similar %TBWL (3 months:  $8.5 \pm 4.9$  vs.  $7.3 \pm 6.0$ ,  $P=0.27$  and 6 months:  $8.1 \pm 7.4$  vs.  $6.8 \pm 5.6$ ,  $P=0.44$ ). At 9 months, there was a trend toward greater weight loss in the tTORe cohort ( $9.7 \pm 8.6\%$  vs.  $5.1 \pm 6.8\%$ ,  $P=0.053$ ). At 12 months, the %TBWL was significantly higher in the tubularization group compared to the standard group ( $8.2 \pm 10.8$  vs.  $2.3 \pm 7.3\%$ ,  $P=0.01$ ). Procedure time was significantly different between both groups (60.5 vs. 53.4 minutes,  $P=0.03$ ). The adverse events rate was similar between groups (8.2% vs. 7.0% for tTORe and TORe, respectively,  $P=0.61$ ).

**Conclusions** The tTORe enhances efficacy and durability of the standard procedure without adding significant procedure-related risks.

## Introduction

Roux-en-Y gastric bypass (RYGB) is one of the most commonly performed bariatric surgeries to treat morbid obesity [1]. RYGB promotes around 56.7% to 67% excess weight loss (%EWL) within 2 years of the procedure, significantly decreasing long-term obesity-related complications and mortality [2,3,4,5]. However, weight recurrence (WR) is not uncommon after RYGB. The reported onset of weight regain after RYGB varies between studies, but it positively correlates with the number of years after surgery [6]. Two years after the procedure, approximately 17% of patients regain more than 15% of their nadir weight [7]. In the longer term, one of every five patients will recover more than 40% of their maximum weight loss [8]. With that, recidivism of comorbidities and worsening quality of life typically ensue.

The etiology of WR after RYGB is multifactorial and includes psychological, behavioral, hormonal, and anatomical components [9,10]. Anatomically, the gastrojejunostomy (GJ) size has been listed as an independent risk factor [11]. In addition, the pouch length and volume inversely correlate with weight loss after the surgery [12].

While surgical revision is invasive and carries a significant risk of adverse events (AEs) [13,14], the transoral approach to the pouch and GJ is easy and safe. Consequently, several centers have successfully employed endoscopic suturing to reduce the stoma size and/or the pouch size to treat WR [15,16,17,18]. Currently, the most common technique involves mucosal ablation with argon plasma coagulation (APC) around the gastrojejunal anastomosis (Supplemental Fig.1) before applying running stitches [19].

In addition to reducing the stoma size, our institution has recently adopted a novel approach consisting of tubularization of the distal pouch with an O-shaped gastroplasty suturing pattern. Preliminary data have demonstrated that the tubular TORe (tTORe) carries better weight loss outcomes than the standard TORe [17]. This is the first study to describe the tTORe approach fully and to compare its safety and efficacy to the standard procedure.

## Patients and methods

This is a retrospective cohort study of a prospectively maintained database conducted at Mayo Clinic, Rochester, Minnesota, United States. Patients with a previous RYGB who underwent endoscopic revision by either TORe or tTORe between 2012 and 2020 were included. Patients with gastro-gastric fistulas and those with incomplete weight loss data at follow-up were excluded. Per institutional regulations, all patients have consented to chart reviews and de-identified data collection for research purposes.

### Procedures

All patients were under general anesthesia in a supine or left lateral decubitus position for the endoscopic revision of the gastric pouch. First, the operator performed a diagnostic esophagogastroduodenoscopy (EGD) to confirm eligibility. If no

exclusion criteria were found, the procedure started after administering prophylactic antibiotics (which were given due to the potentially nonsterile nature of the full-thickness suturing). Most patients received ablative procedures on the rim of the GJ before suturing at the endoscopist's discretion (APC). Then, the endoscopic suturing device (Overstitch, Apollo Endosurgery, Austin, Texas, United States) was mounted onto a double channel gastroscope (Olympus 2TH-180, Olympus America, Brooklyn Park, Minnesota, United States) and used to perform the running stitches at the GJ. Different stitching patterns were employed at the operator's discretion based on a tailored evaluation of the pouch's anatomy. For the tTORe group, additional O-shaped stitches were placed on the gastric pouch after finishing GJ revision. The decision of performing pouch revision was also made at the discretion of the endoscopist based on pouch anatomy, primarily the pouch diameter (large pouches, generally considered over 4cm, were selected to undergo tTORe).

### Data collection and definitions

Researchers collected data from patient electronic medical records. Baseline characteristics included age, gender, years after RYGB, time from RYGB to endoscopic revision, presurgical weight, nadir weight, concomitant use of weight loss medications at the endoscopic revision, preprocedural weight, and preprocedural stoma size and pouch diameter.

%EWL was defined as the percent of excess body weight compared to the ideal weight for a body mass index of 25 kg/m<sup>2</sup>. Percent total body weight loss (%TBWL) was defined as the percent body weight loss relative to the patient's weight before each procedure. Procedure characteristics included procedure time, number of sutures used, and final stoma diameter. Patients were followed over 1 year, and patient weight after the procedure was documented at 3, 6, 9, and 12 months. Information on the need for an additional endoscopic evaluation and AEs also was collected.

The primary outcome was the %TBWL after the endoscopic revision. Secondary outcomes entailed AEs, serious AEs (SAEs), and procedure time.

### Statistical analysis

Continuous variables were reported as means and standard deviations, and categorical ones as frequencies or percentages. Either chi-squared or Fisher's exact test was used to compare categorical variables and the Student's *t*-test to compare continuous ones. The analysis of variance for repeated measures (ANOVA test) was used to analyze and compare weight trends between cohorts. Within each cohort, we ran a separate analysis for patients on and off weight loss medications.

## Results

### Baseline characteristics

One hundred twenty-eight patients (85 tTORe, 43 TORe) fulfilled eligibility and were included in the study. The whole cohort had a mean age of 46.2 ± 12.0 with a predominance of female sex (86.7%). The average time from surgery to endoscopic revi-

► **Table 1** Baseline characteristics of the 128 patients undergoing endoscopic revision for WR after RYGB.

Variable	Overall n = 128 (mean ± SD)	Tubular TORe n = 85 (mean ± SD)	TORe n = 43 (mean ± SD)	P value
Age, years	46.2 ± 12.0	46.4 ± 11.6	45.7 ± 12.9	0.77
Sex, % female	86.7%	83.5%	93.0%	0.55
Nadir %EWL	84.0 ± 25.0	82.4 ± 25.1	87.0 ± 24.7	0.33
Nadir %TBWL	38.3 ± 11.5	37.7 ± 12.0	39.5 ± 10.7	0.41
Years from RYGB	11.4 ± 6.6	11.4 ± 6.7	11.3 ± 6.5	0.92
Pre-revision stoma size, mm	28.9 ± 7.0	28.8 ± 7.3	29.2 ± 6.4	0.77
Pre-revision pouch length, cm	5.7 ± 3.4	5.9 ± 2.1	5.2 ± 5.2	0.30
Stitching pattern, %				
▪ Zipper-like	8.6%	5 (5.9%)	6 (14.0%)	0.29
▪ Purse-string	28.9%	29 (34.1%)	8 (18.6%)	
▪ Figure of eight	22.7%	20 (23.5%)	9 (20.9%)	
▪ Interrupted	15.6%	7 (8.2%)	13 (30.2%)	
▪ Triangular	15.6%	18 (21.2%)	2 (4.7%)	
▪ Non-specified	11%	6 (7.1%)	5 (11.6%)	
APC performed, %	75.8%	69.4%	88.4%	0.02
Final stoma diameter, mm	8.2 ± 1.1	8.1 ± 1.2	8.2 ± 0.9	0.51

WR, weight recurrence; RYGB, Roux-en-Y gastric bypass; TORe, transoral reduction; tTORe tubular transoral reduction; EWL, excess weight loss; TBWL, total body weight loss; IQR, interquartile range; SD, standard deviation; APC, argon plasma coagulation.

► **Table 2** Weight loss data for tTORe and TORe groups.

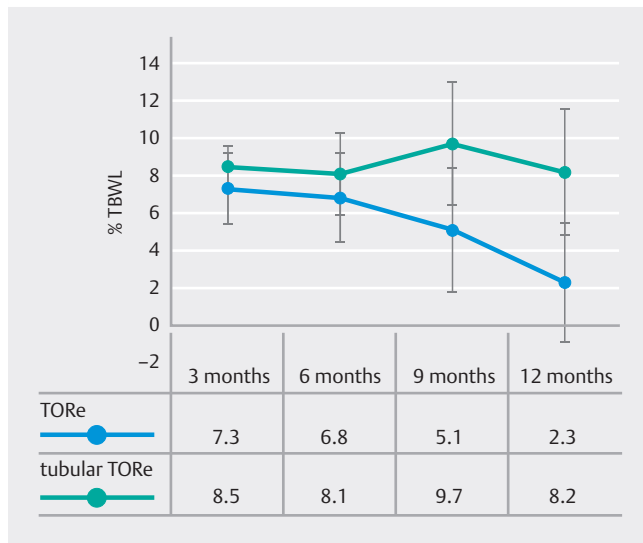
%TBWL	Overall (mean ± SD)	Tubular TORe (mean ± SD)	Sample (n = 85)	TORe (mean ± SD)	Sample (n = 43)	P value
<b>3 months</b>	8.0 ± 5.3	8.5 ± 4.9	73	7.3 ± 6.0	39	0.278
<b>6 months</b>	7.6 ± 6.8	8.1 ± 7.4	45	6.8 ± 5.6	24	0.445
<b>9 months</b>	7.9 ± 8.1	9.7 ± 8.6	29	5.1 ± 6.8	19	0.053
<b>12 months</b>	5.7 ± 10.0	8.2 ± 10.8	40	2.3 ± 7.3	23	0.013

sion was 11.4 ± 6.6 years. At the nadir weight, patients presented a mean %EWL of 83.9 ± 25% and a mean %TBWL of 38.3 ± 11.5%. At the time of the endoscopic revision, the mean stoma size and pouch were 28.9 ± 7.0 mm and 5.7 ± 3.4 cm, respectively. All baseline characteristics were similar between both groups (► **Table 1**). The tTORe procedure required more sutures than the standard TORe ( $P = 0.03$ ).

### Weight loss

At 3 and 6 months, the tTORe and TORe cohorts presented similar %TBWL (3 months: 8.5 ± 4.9 vs. 7.3 ± 6.0,  $P = 0.27$  and 6 months: 8.1 ± 7.4 vs. 6.8 ± 5.6,  $P = 0.44$ ). At 9 months, there was a trend toward greater weight loss in the tTORe cohort

(9.7 ± 8.6% vs. 5.1 ± 6.8%,  $P = 0.053$ ). Finally, at 12 months, the %TBWL was significantly higher in the tubularization group compared to the standard group (8.2 ± 10.8 vs. 2.3 ± 7.3%,  $P = 0.01$ ). %TBWL increased from 6 to 9 months in the tTORe cohort but decreased in the TORe group. Therefore, we found a significant difference in weight loss trend over time between groups ( $P = 0.03$ ). ► **Table 2** summarizes weight loss data for the whole cohort and both groups and ► **Fig. 1** depicts weight loss trends over the 12-month follow-up period. In a subanalysis whereby non-APC patients were removed, at 3 and 6 months, the tTORe and TORe cohorts presented similar %TBWL (3 months: 9.0 ± 4.9 vs. 7.8 ± 6.3,  $P = 0.32$  and 6 months: 9.0 ± 7.4 vs. 7.1 ± 5.7,  $P = 0.29$ ). However, at 9 and 12 months, the %TBWL was signifi-



► **Fig. 1** Comparison of % TBWL trend between tTORe and TORe over a 1-year period. At 12 months,  $P=0.01$ .  $P$  value was non-significant at 3, 6, and 9 months.

cantly higher in the tubularization group compared to the standard group (9 months:  $10.9 \pm 8.6$  vs.  $5.1 \pm 7.4\%$ ,  $P=0.03$ , 12 months:  $9.0 \pm 10.8$  vs.  $2.5 \pm 7.2$ ). Supplemental Table 1 summarizes weight loss data for both groups after removing non-APC patients, and Supplemental Fig. 2 depicts weight loss trends over the 12-month follow-up period in the APC-only cohort.

### Secondary outcomes

The overall mean procedure time, including the diagnostic EGD, was 58.1 minutes. There was a statistically significant difference between the tTORe and TORe groups (60.5 vs. 53.4 minutes,  $P=0.03$ ). Weight loss of patients under concomitant weight loss medications also did differ from that of those not receiving pharmacotherapy (► **Table 3**). However, at 12 months, there was trend toward a more significant loss in tTORe patients receiving medications at 12 months ( $13.8$

$\pm 12.0$  vs.  $6.6 \pm 10.1$  for tTORe + medications and tTORe alone, respectively,  $P=0.08$ ).

There was a 7.8% overall AE rate (10/128), which was similar between groups (8.2% vs. 7.0% for tTORe and TORe, respectively,  $P=0.61$ ). The AEs included refractory nausea and vomiting requiring endoscopic balloon dilation in three patients and hematemesis requiring endoscopic clipping in one patient. Ten patients presented to the Emergency Department (ED) within 30 days of the procedure with nausea/vomiting ( $n=5$ ) followed by abdominal pain ( $n=3$ ) as the main reasons. Three of these 10 patients were managed conservatively and discharged on the same day, while seven required hospitalization (7/128, 5.4%). There were no related deaths.

### Discussion

In our retrospective single-center study of 128 patients, we demonstrated that tubularization of the distal pouch enhanced the durability of weight loss compared to traditional TORe. While there was no difference within the first 9 months of follow-up, subjects undergoing tTORe experienced more significant weight loss than those receiving standard TORe at 1 year. Remarkably, weight loss trends are different between groups due to a dichotomization starting at the 6- to 9-month timeframe. That seems to be the most relevant effect of adding pouch tubularization to the TORe procedure in our cohort.

In 2016, Kumar et al. reported TORe outcomes in 150 patients with post-RYGB weight regain. Patients presenting with pouch dilation underwent concomitant pouch reduction with endoscopic suturing. However, there is no description of the pouch reduction technique, no sample distinction between TORe and tTORe samples, and no definition for pouch dilation. Therefore, their data lack clinical applicability and highlight the importance of the present study [20].

Interestingly, weight results in our TORe cohort seem worse than previously published data. For example, in 2018, Jirapinyo et al. reported a 9.6% TBWL at 6 months and 8.4% at 12 months following a purse-string TORe associated with APC or ESD [21]. In another retrospective study investigating TORe with adjunctive therapies, patients had a similar %TBWL (8.5%) at 1 year [22]. In contrast, the %TBWL of our TORe cohort was 6.8% and

► **Table 3** Weight loss data comparing outcomes of concomitant pharmacotherapy within groups.

	tTORe (n=85)		Mean difference (%TBWL)	P value	TORe (n=43)		Mean difference (%TBWL)	P value
	Pharmacotherapy				Pharmacotherapy			
	Yes	No			Yes	No		
<b>3 months</b>	10.0 $\pm$ 5.6	8.1 $\pm$ 4.7	1.9	0.20	7.4 $\pm$ 6.2	6.9 $\pm$ 5.6	0.5	0.86
<b>6 months</b>	8.4 $\pm$ 8.4	8.0 $\pm$ 7.1	0.4	0.86	9.5 $\pm$ 5.6	6.2 $\pm$ 5.5	3.3	0.29
<b>9 months</b>	13.0 $\pm$ 8.5	8.3 $\pm$ 8.4	4.7	0.18	3.9 $\pm$ 6.6	7.1 $\pm$ 7.2	3.2	0.33
<b>12 months</b>	13.8 $\pm$ 12.0	6.6 $\pm$ 10.1	7.2	0.08	1.6 $\pm$ 8.4	2.6 $\pm$ 7.2	1.0	0.80

tTORe, tubular transoral outlet reduction; TORe, transoral outlet reduction; %TBWL, percent total body weight loss.

2.3% at 6 and 12 months, respectively. In our center, highly specialized healthcare professionals recorded all documented weight values during clinic visits, thus the values were not self-reported. Our weighing protocol avoids self-enhancement bias and may have accounted for part of the difference between our data and data in the literature [23].

As secondary outcomes, we compared the mean procedure time, the impact of concomitant pharmacotherapy, and AEs. Because tTORe inherently involves adding a pouch tubularization to the standard TORe, increased procedure time is inevitable. However, only 7 minutes were added (60.5 vs. 53.4 minutes), which is probably cost-effective and logistically feasible.

Remarkably, adjunct pharmacotherapy did not positively correlate with weight loss. While this may initially seem illogical, it is consistent with a previous study that demonstrated a lower %TBWL in patients receiving adjunct pharmacotherapy [22]. Because this was a retrospective study with no standardized guidelines for introducing weight loss medications, selection bias may have played a central role. Those patients losing less weight were probably more frequently receiving weight loss medications. Possibly, a type 2 error may have also influenced our results. The difference in %TBWL between tTORe patients with and without adjunct pharmacotherapy is striking:  $13.8 \pm 12.0$  versus  $6.6 \pm 10.1$  for a mean difference of 7.2. Therefore, we probably failed to detect a real difference due to an underpowered sample.

Our overall AE rate (7.8%) compared to the literature is within the expected ranges. Dhindsa et al. recently published a systematic review showing a pooled AE rate of 11.4% for TORe, with abdominal pain being the most common (4.2%). Nonetheless, the SAE rate was as low as 0.57%, contrary to our 5.4% rate led by seven cases requiring hospitalization. Our center is a high-volume center with a low threshold for hospital admission for post-procedure ED visits because most of our patients come from other states or countries with no nearby household. In non-academic non-referral centers, some individuals would have probably been treated as outpatients, which could have led to a lower SAE rate.

Our study has some limitations. First, the study was retrospective and restricted to a single center of excellence, which may limit its generalizability. However, this resulted in an advantage as the weight reporting was consistent and performed at our institution by highly specialized healthcare professionals. Second, there was a heterogeneous distribution of adjunct APC to perform tTORe and TORe, with more APC cases in the later cohort. Sound evidence shows that APC enhances weight loss during stoma revision [19]. Ultimately, that fact highlights the tTORe results, as one would expect an even more significant difference in weight loss had the cohorts equally received APC. Finally, patients with larger pouches were the ones undergoing concomitant pouch reduction. In this sense, it remains unknown how the pooled weight loss would behave if tTORe were a routine rather than a tailored procedure.

## Conclusions

In conclusion, distal tubularization of the pouch seems an attractive adjunct to the standard TORe procedure. It may improve the durability of weight loss outcomes without adding significant procedure-related risks. However, controlled studies are warranted to confirm our findings.

## Conflict of Interest

BKA reports consultant roles with Endogenex, Endo-TAGSS, Metamodix, and BFKW; consultant and grant/research support from USGI, Cairn Diagnostics, Aspire Bariatrics, Boston Scientific; Speaker roles with Olympus, Johnson and Johnson; speaker and grant/research support from Medtronic, Endogastric solutions; and research support from Apollo Endosurgery, and Spatz Medical. ACS reports institutional research grants from Boston Scientific, Enterasense, Endogenex; consulting fees from Olympus; consulting fees and research grants from Endo-TAGSS, and Apollo Endosurgery; Participation in Data Safety Monitoring Board with GI Dynamics, and ERBE. VOB: Honoraria payment for lectures and testimonies from Erbe Elektromedizin GMHB. All other authors have no COI.

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