

## Transoral outlet reduction for weight regain after gastric bypass: long-term follow-up

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**Background and Aims:** Dilated gastrojejunal anastomosis aperture is associated with weight regain after Roux-en-Y gastric bypass (RYGB). Transoral outlet reduction (TORe) has proved safe and effective for the treatment of weight regain. The objective of this study was to determine the long-term weight trend and number needed to treat for TORe.

**Methods:** This prospective series included consecutive post-RYGB patients with weight regain and a gastrojejunal anastomosis aperture greater than 15 mm. TORe was performed with a full-thickness endoscopic suturing device.

**Results:** A total of 150 patients who had regained  $49.9\% \pm 3.6\%$  of the weight lost after gastric bypass ( $4.1 \pm 0.3$  kg/y after nadir) before TORe. At TORe, body mass index was  $40.2 \pm 0.8$  kg/m<sup>2</sup> and weight was  $110.7 \pm 2.2$  kg. At 1 year, weight loss was  $10.5 \pm 1.2$  kg or  $24.9 \pm 2.6\%$  excess weight loss (EWL); at 2 years, weight loss was  $9.0 \pm 1.7$  kg or  $20.0\% \pm 6.4\%$  EWL; at 3 years, weight loss was  $9.5 \pm 2.1$  kg or  $19.2\% \pm 4.6\%$  EWL. The number needed to treat for arrest of weight regain was 1.0 at 6 months, 1.1 at 1 year, and 1.2 at 2 and 3 years. The number needed to treat to maintain weight loss of  $\geq 5$  kg from TORe was 1.2 at 6 months, 1.5 at 1 year, 1.9 at 2 years, and 2.0 at 3 years.

**Conclusion:** TORe safely and effectively arrested weight regain and provided durable weight loss with a low number needed to treat. Patients with weight regain after RYGB should be evaluated for dilation of the gastrojejunal anastomosis, as TORe can be part of a multidisciplinary strategy to address post-RYGB weight regain. (Gastrointest Endosc 2015; ■:1-4.)

Obesity and its comorbidities are a growing worldwide epidemic.<sup>1</sup> Bariatric surgery has proved effective, resulting in durable weight loss and improvement in or reversal of comorbidities.<sup>2</sup> Roux-en-Y gastric bypass (RYGB) has demonstrated an average excess weight loss (EWL) of

*Abbreviations:* BMI, body mass index; EWL, excess weight loss; NNT, number needed to treat; RYGB, Roux-en-Y gastric bypass; TORe, transoral outlet reduction; TWL, total weight loss.

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62% after 1 year and has been the most commonly performed bariatric surgery in recent years.

With the cumulative increase in RYGB patients, weight regain and recurrence of comorbidities are a growing concern. A majority of patients regain 30% of lost weight, and a significant fraction regain substantial weight.<sup>3,4</sup> This can affect quality of life and health care costs. Dietary and lifestyle factors affect weight regain. Anatomic factors also play a role: a larger gastrojejunal anastomosis aperture is 1 significant and independent predictor of weight regain after RYGB and is associated with weight regain in a linear fashion.<sup>5,6</sup> There are a number of options for surgical revision, but reoperation can be technically challenging in the setting of altered anatomy, adhesions, and scar tissue. Surgical revision is associated with higher adverse event, morbidity, and mortality rates.<sup>7,8</sup>

Transoral outlet reduction (TORe) is a less-invasive alternative. TORe by using various devices has proved safe and effective for post-RYGB weight regain in a randomized, sham-controlled trial, as well as multiple series.<sup>9-11</sup> This procedure can be used to place sutures, superficial or more recently full thickness, to reduce the

TABLE 1. Weight results

|                             | 3 months   | 6 months   | 12 months  | 24 months  | 36 months  |
|-----------------------------|------------|------------|------------|------------|------------|
| No. (no. lost to follow-up) | 146 (4)    | 144 (2)    | 109 (2)    | 63 (1)     | 40 (3)     |
| Weight loss, kg             | 9.6 ± 0.6  | 10.6 ± 0.7 | 10.5 ± 1.2 | 9.0 ± 1.7  | 9.5 ± 2.1  |
| BMI loss, kg/m <sup>2</sup> | 3.5 ± 0.2  | 3.8 ± 0.2  | 3.8 ± 0.4  | 3.3 ± 0.6  | 3.4 ± 0.8  |
| EWL, %                      | 25.0 ± 1.9 | 28.8 ± 2.7 | 24.9 ± 2.6 | 20.0 ± 6.4 | 19.2 ± 4.6 |
| TWL, %                      | 8.7 ± 0.5  | 9.6 ± 0.6  | 9.5 ± 0.9  | 8.1 ± 1.4  | 8.6 ± 1.5  |

BMI, Body mass index; EWL, excess weight loss; TWL, total weight loss.

aperture of the gastrojejunal anastomosis. Gastric pouch volume can be reduced concurrently.

The aim of this study was to determine long-term weight trends and the number needed to treat (NNT) for TORe in patients with weight regain after RYGB.

## METHODS

This prospective series included all consecutive full-thickness TORe procedures performed at a tertiary referral center. The study was approved by the Brigham and Women's Hospital institutional review board. Patients were assessed to determine the necessity of revision. Evaluation in the clinic included assessment of pre- and post-RYGB history, current weight management measures, and diet and exercise history. Endoscopic assessment was also performed, and patients with a gastrojejunal anastomosis aperture of 15 mm or larger were scheduled for TORe.

Procedures were performed with the patients under general anesthesia, with endotracheal intubation and carbon dioxide insufflation. Upper endoscopy was performed to ablate 5 to 10 mm of tissue around the entire margin of the gastrojejunal anastomosis by using end-firing forced argon plasma coagulation at 30 W and to place an overtube. Anastomotic reduction was performed by using the Apollo OverStitch Endoscopic Suturing System (Apollo Endosurgery, Austin, Tex) with double-channel endoscope (GIF-2T160; Olympus America, Central Valley, Pa). In patients with a dilated gastric pouch, stitches were placed in the distal pouch to reduce pouch volume. The device was exchanged for an upper endoscope, which was used to examine the gastric pouch and the esophagus after overtube removal. Patients were discharged home after extended postprocedure observation on the day of the procedure. They took nothing by mouth on the evening after the procedure, other than necessary medications, and then proceeded to a clear liquid diet for 1 day, full liquids for 6 weeks, and soft solids for 2 weeks. Patients were followed in the clinic every 3 months for the first year and then every 6 to 12 months afterward. Follow-up included a brief discussion regarding dietary and lifestyle measures.

Follow-up weight change, body mass index (BMI) change, percentage of EWL, and percentage of total weight loss (TWL) were measured or determined. The NNT was calculated by using the difference between the weight

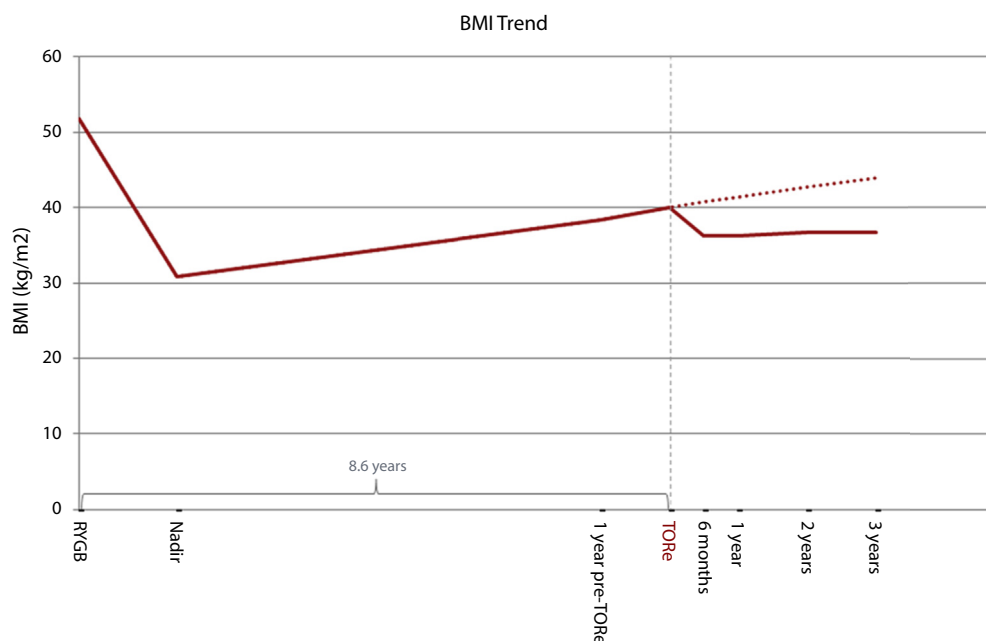
at the time of TORe and the weight at each time point (6 months and 1, 2, and 3 years). The NNT was calculated for 3 targets at each time point: maintenance of weight at the time of TORe, maintenance of ≥5 kg loss, and maintenance of ≥10 kg loss. Means were compared by using the Student *t* test, and proportions were compared by using the Fisher exact test. All statistics are reported as mean ± standard error of the mean.

## RESULTS

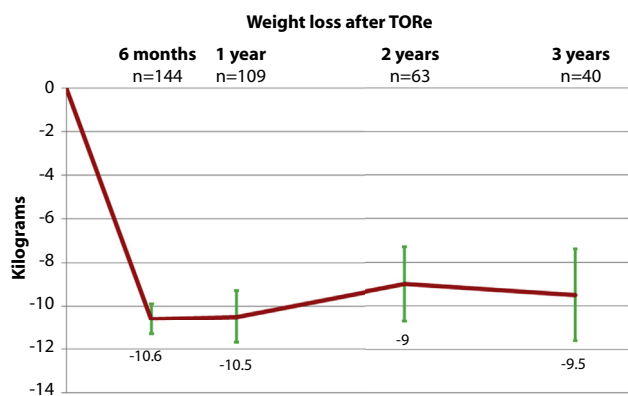
A total of 150 patients (mean age, 51.2 ± 0.8 years; 27 male/123 female) were included. At the time of the gastric bypass, BMI was 51.7 ± 0.8 kg/m<sup>2</sup>. Postoperative nadir BMI was 30.9 ± 0.6 kg/m<sup>2</sup>, reached 16.7 ± 0.6 months after the gastric bypass. The average time to TORe was 8.6 ± 0.3 years after the gastric bypass. The average weight gain rate from nadir to TORe was 4.1 ± 0.3 kg/year. Patients regained an average 49.7 ± 4.3% of lost weight before undergoing TORe. The average BMI at the time of TORe was 40.1 ± 0.7 kg/m<sup>2</sup>, and the average weight was 110.7 ± 2.2 kg.

Before TORe, the average gastrojejunal anastomosis aperture was 24.1 ± 0.6 mm. TORe reduced the average aperture to 9.0 ± 0.2 mm. Procedural adverse events requiring emergency evaluation or admission for observation included abdominal pain in 6 patients (4.0%), bleeding (hematemesis or melena) in 5 patients (3.3%), and nausea in 3 patients (2.0%).

Weight results are reported in Table 1. Cumulatively, loss to follow-up occurred in 11 patients (7.3%). The overall weight trend, including imputed baseline weight gain rate and actual weight loss after TORe, is shown in Figure 1. Weight loss remained between 9 and 11 kg throughout the follow-up period (Fig. 2). BMI loss remained greater than 3 kg/m<sup>2</sup> throughout follow-up. EWL was 24.9% at 1 year, 20.0% at 2 years, and 19.2% at 3 years. Comparison between weight change during the 12 months immediately before TORe (gain of 3.5 ± 0.7 kg) and the 12 months after (loss of 10.5 ± 1.2 kg) yielded *P* value of <.0001 by using the paired *t* test. The effect of pouch reduction was investigated by comparing TWL in patients who had pouch reduction with those who did not (Table 2). There was no difference in TWL between groups at 12-, 24-, and 36-month follow-up.



**Figure 1.** Body mass index (BMI) trend. RYGB, Roux-en-Y gastric bypass; TORe, transoral outlet reduction.



**Figure 2.** Weight loss trend. TORe, transoral outlet reduction.

The NNT to achieve arrest of weight regain was 1.0 at 6 months, 1.1 at 1 year, and 1.2 at 2 and 3 years. The NNT to maintain a weight loss of  $\geq 5$  kg from weight at the time of TORe was 1.2 at 6 months, 1.5 at 1 year, 1.9 at 2 years, and 2.0 at 3 years. The NNT to maintain a weight loss of  $\geq 10$  kg after TORe was 2.0 at 6 months, 2.3 at 1 year, 2.9 at 2 years, and 2.4 at 3 years.

## DISCUSSION

This prospective series demonstrated the safety, efficacy, and durability of TORe in patients with weight regain after a gastric bypass. TORe was effective in arresting weight regain in nearly all patients, and patients

**TABLE 2.** Total weight loss with and without pouch reduction

|       | No pouch reduction | Pouch reduction | P value |
|-------|--------------------|-----------------|---------|
| 12 mo | 6.7 $\pm$ 1.5      | 9.9 $\pm$ 1.2   | .10     |
| 24 mo | 9.6 $\pm$ 2.4      | 6.5 $\pm$ 1.7   | .28     |
| 36 mo | 7.5 $\pm$ 2.3      | 7.2 $\pm$ 2.1   | .94     |

additionally had a high probability of achieving and maintaining weight loss. The average BMI loss remained clinically significant during all follow-up periods.

The safety and short-term efficacy of TORe by using a superficial-thickness suturing device is supported by Level I evidence.<sup>9</sup> In the Randomized Evaluation of Endoscopic Suturing Transorally For Anastomotic Outlet Reduction (RESTORE) trial, 96% of revised patients had weight loss or stabilization in the 6 months after the procedure. It has been shown that greater anastomotic reduction results in greater postprocedure weight loss.<sup>12</sup> Subsequently, full-thickness TORe proved more effective than superficial-thickness TORe in a matched cohort study.<sup>11</sup> Additionally, retrospective series of full-thickness TORe have demonstrated safety as well as efficacy for up to 1 year.<sup>10,11</sup> This series is the largest series of TORe to date and includes long-term follow-up of full-thickness TORe.

The etiology of weight loss after gastric bypass and of subsequent weight regain is likely multifactorial, including behavioral, physiologic, neurohormonal, and anatomic factors. Although the mechanism by which TORe induces weight loss has not been fully elucidated, surgical procedures to augment the restrictive component of gastric

bypass have proved effective.<sup>13-15</sup> Given the lower cost, less invasiveness, and lower morbidity, TORe presents an appealing alternative to these procedures. TORe appeared durable in this study, but repeatability as necessary should be investigated as another potential advantage compared with surgical revision.

This study has some limitations. It was performed at a single center. Additionally, endoscopic follow-up was rarely performed due to lack of clinical indication and insurance approval.

In summary, weight regain after RYGB is a serious and growing issue. In this prospective series, TORe effectively arrested weight regain and provided durable weight loss with a low NNT. TORe is a safe and effective component of a multidisciplinary strategy, including dietary and lifestyle changes, to address weight regain after RYGB. Patients with weight regain after RYGB should be evaluated for dilation of gastrojejunal anastomosis.

Furthermore, the durable efficacy of TORe ultimately enhances RYGB, making it a more effective long-term therapy for morbid obesity.

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