Comparison of a superficial suturing device with a full-thickness suturing device for transoral outlet reduction (with videos)

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Background: Larger gastrojejunal (GJ) anastomosis aperture is one independent predictor for weight regain after Roux-en-Y gastric bypass. Transoral outlet reduction (TORe) has proven safe and effective for treatment of weight regain by using a superficial-thickness (ST) suturing device. Full-thickness (FT) suturing devices are now available, potentially providing more effective results.

Objective: To compare effectiveness of superficial-thickness with full-thickness TORe.

Design: Matched cohort study: patients were matched sequentially by GJ anastomosis aperture, body mass index, and age.

Setting: Tertiary-care center.

Patients: A total of 59 consecutive patients undergoing full-thickness TORe were matched with 59 patients undergoing superficial-thickness TORe. All had GJ anastomosis apertures >20 mm.

Intervention: Transoral outlet reduction.

Main Outcome Measurements: Weight loss and rate of adverse events.

Results: Post-TORe GJ anastomosis apertures were similar between groups (ST 6.9 $\pm$ 0.2 mm vs FT 7.1 $\pm$ 0.3 mm). Weight loss was greater at 6 months in the FT group (10.6 $\pm$ 1.8 kg in FT vs 4.4 $\pm$ 0.8 kg in ST; $P < .01$) and at 1 year (8.6 $\pm$ 2.5 kg in FT vs 2.9 $\pm$ 1.0 kg in ST; $P < .01$). Excess weight loss was greater in the FT group at 6 months (20.4 $\pm$ 3.3% in FT vs 8.1 $\pm$ 2.5% in ST; $P < .01$) and at 1 year (18.9 $\pm$ 5.4% in FT vs 9.1 $\pm$ 2.3% in ST; $P = .03$).

Limitations: This was a single-center, retrospective, cohort study.

Conclusion: There is level 1b evidence for effectiveness of TORe by using a superficial mucosal suturing device. This matched cohort study compared TORe by using the same ST suturing device with TORe by using a newer, FT suturing device and the same operative methods. FT TORe resulted in significantly more weight loss than ST TORe at 6 months and at 1 year. Full-thickness TORe is a significant improvement over ST TORe for endoscopic therapy of weight regain in patients with dilated GJ anastomosis.

Abbreviations: BMI, body mass index; EWL, excess weight loss; FT, full thickness; GJ, gastrojejunal; RYGB, Roux-en-Y gastric bypass; ST, superficial thickness; TORe, transoral outlet reduction.

DISCLOSURE: *C. Thompson is a consultant for Apollo Endosurgery and CR Bard. All other authors disclosed no financial relationships relevant to this publication.*

This video can be viewed directly from the GIE website or by using the QR code and your mobile device. Download a free QR code scanner by searching "QR Scanner" in your mobile device's app store.

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As the population of bariatric surgery patients increases, postoperative weight regain is a growing concern. Reversal of weight loss reintroduces comorbidities and decreases quality of life.[1] After dramatic initial postoperative weight loss, many bariatric surgery patients reach a weight plateau in 1 to 2 years.[2] Approximately 20% of patients do not reach 1-year weight loss goals, and 30% of patients begin to regain weight within 2 years. Nearly two-thirds of patients regain substantial weight within 4 years.[3-5]

Larger gastrojejunal (GJ) anastomosis aperture is one independent predictor for postoperative weight regain.[6-7] Surgical revision is problematic. Adverse event rates are prohibitively high, reaching over 15%, and procedures entail longer intraoperative time and greater blood loss.[8-10]

Transoral outlet reduction (TORe) offers a less-invasive alternative (Fig. 1). Revision of bariatric surgery by using endoluminal suturing was first reported in 2004.[11-12] Since then, a number of devices have been studied for revision, including the Incisionless Operating Platform (USGI Medical, San Clemente, CA) and StomaphyX (EndoGastric Solutions, Redmond, WA).[13-16] Recently, a randomized, double-blinded, sham-controlled trial that used the EndoCinch (CR Bard, Murray Hill, NJ), a suction-based superficial suturing device, provided level 1b evidence for effectiveness of TORe.[17] More recently, the OverStitch (Apollo Endosurgery, Austin, Tex) has demonstrated safety and effectiveness for TORe.[18] Unlike the prior EndoCinch device, the OverStitch uses a curved needle for tissue purchase and allows placement of full-thickness (FT) sutures.

The aim of this study was to compare the relative effectiveness of a suction-based, superficial-thickness (ST) suturing device versus an FT endoscopic suturing device for TORe in patients who are status post Roux-en-Y gastric bypass (RYGB) with weight regain.

Take-home Message

- Full-thickness transoral outlet reduction (TORe) is a significant improvement over superficial-thickness TORe for endoscopic therapy of weight regain in patients with dilated gastrojejunal anastomoses.

METHODS

Patients

All consecutive patients undergoing full-thickness TORe between 2010 and 2012 were included. To be eligible for TORe, patients had GJ anastomosis dilated to apertures >20 mm. Procedures in the ST cohort were performed between 2004 and 2008, after which the device was withdrawn. The device for FT TORe became available in 2010; hence, there was no temporal overlap regarding patient allocation to a particular procedure. All consecutive patients undergoing FT TORe were matched; each patient undergoing FT TORe was matched 1:1 with a patient from the ST group. Matching factors were applied sequentially: GJ anastomosis aperture at time of TORe, body mass index (BMI) at time of TORe, and age.

Procedure

In the FT group, TORe was performed by using the Overstitch Endoscopic Suturing System (Fig. 2). The Overstitch attaches to a double-channel endoscope (GIF-2T160; Olympus America, Center Valley, Pa). It comprises a curved suture arm attached to the endoscope tip and an anchor exchange deployed through one channel. When the handle is activated, the suture arm pushes the needle through the tissue and passes the needle to the anchor exchange. The handle is then opened, releasing the tissue. The anchor then can be passed back to the suture arm for additional stitch placement (Video 1, available online at www.giejournal.org).

In the ST group, TORe was performed by using the most recent iteration of EndoCinch (Fig. 3). Patients included in other trials were not included in the present study, because they underwent specific and varied trial protocols. Furthermore, procedures performed with previous iterations of EndoCinch and other devices were not included in the present study. Tissue at the rim of the GJ anastomosis is suctioned into the device, and the handle is activated to place a stitch. The device is then removed and reloaded. The device must be reinserted to place the next stitch. The sutures are tightened and secured to form a tissue plication or left to be secured at the end of the procedure (Video 2, available online at www.giejournal.org).

All procedures in both arms were performed by using the same method. General anesthesia with endotracheal intubation was used. Upper endoscopy was performed to record GJ anastomosis aperture and pouch length, and an overtube was inserted. A 5 to 10–mm area around the margin of the GJ anastomosis was ablated by using end-firing forced argon plasma coagulation at 30 W. Interrupted stitches were placed sequentially from the lower left to the upper right of the GJ anastomosis until the aperture was reduced to 12 mm or less. If the gastric pouch was dilated, interrupted stitches were placed in the distal pouch to reduce pouch volume.

Patients were given nothing by mouth on the evening after the procedure. They proceeded to a clear liquid diet for 1 day, followed by full liquids for 6 weeks and soft solids for 2 weeks. Follow-up clinical examinations were scheduled at 3, 6, and 12 months and entailed weight recording and interview regarding postprocedure symptoms, dietary and exercise habits, and satiety.

RESULTS

All 59 patients who underwent FT TORe and 59 of 129 patients who underwent ST TORe were included.