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Transoral gastric volume reduction for weight management: technique and feasibility in 18 patients

Stacy A. Brethauer, M.D.[a,*], Bipan Chand, M.D.[a], Philip R. Schauer, M.D.[a], Christopher C. Thompson, M.D.[b]

[a]*Bariatric and Metabolic Institute, Cleveland Clinic, Cleveland, Ohio*
[b]*Department of Gastroenterology, Brigham and Women's Hospital, Boston, Massachusetts*

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Abstract

Background: Endoluminal suturing to reduce the gastric volume might provide an additional option for the treatment of obesity. Potential advantages of a nonoperative endoluminal intervention include less pain, the ability to perform it as an outpatient procedure, and a high level of patient acceptance. The purpose of the present pilot study was to demonstrate the feasibility and procedural safety of transoral gastric volume reduction (TRIM procedure) using the Restore Suturing System in patients with a body mass index of 30–45 kg/m^2. Successful completion of the procedure and adverse events were evaluated at academic/university hospitals.

Methods: This was a nonrandomized feasibility study performed at 2 institutions. After institutional review board approval, the patients underwent the TRIM endoluminal gastric plication procedure with the Restore Suturing System (Restore device). Gastric plications were completed to approximate the anterior and posterior gastric walls to achieve restriction of the upper stomach. The number and location of successful plications were recorded, and patients were monitored for complications. The present report described the short-term procedural results (≤24 hours after the procedure) of the studied cohort.

Results: A total of 18 patients were enrolled in the present study. The TRIM procedure was successfully completed in all patients, with placement of 4–8 plications (average 6 per patient). The average procedure time was 125 ± 23 minutes, and no serious or significant procedure-related complications occurred. After the procedure, common patient complaints were nausea, vomiting, and abdominal discomfort. The first 10 patients enrolled were kept overnight according to the study protocol, and the remaining 8 patients were discharged on the day of the procedure.

Conclusion: Endoluminal suturing using the TRIM procedure and the Restore device was technically feasible, and no serious or significant procedure-related complications were reported. Weight loss, co-morbidity improvement, and durability are under assessment. (Surg Obes Relat Dis 2010; 6:689–694.)

Keywords: Endoluminal; Gastroplasty; Bariatric

Primary endoluminal therapies for the treatment of obesity hold promise as low-risk, outpatient procedures. These procedures could involve gastric partitioning with sutures, staples, implanted devices, or endoluminal barriers to prevent nutrient absorption. In addition to the potential for significant weight loss and co-morbidity reduction, these therapies might result in acceptance greater than that for surgery for patients and referring physicians. This field, however, is early in its development, and endoluminal procedures intended as primary therapy for obesity will need to be rigorously evaluated for safety, efficacy, patient tolerance, durability, and acceptable weight loss outcomes [1].

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*Correspondence: Stacy A. Brethauer, M.D., Bariatric and Metabolic Institute, 9500 Euclid Avenue, M61, Cleveland, OH 44195.

E-mail: brethas@ccf.org

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Fig. 1. Restore Suturing System uses a suction capsule placed on the end of a standard endoscope. Suction is applied to capsule using tubing attached to outside of endoscope. Suturing system and suture fastening system are operated through working channel of the endoscope. Multiple gastric plications can be completed with single esophageal intubation and no overtube.

Several devices have undergone feasibility studies or are currently being evaluated in multicenter pivotal trials [2–5].

The use of endoscopic gastric plications to achieve weight loss has been previously reported. A study by Fogel et al. [6] reported endoluminal suturing as a primary weight loss procedure in 64 patients with a baseline body mass index (BMI) of 39.9 ± 5.1 (range 28.0–60.2). In that study, the investigators used the Bard Endocinch device and a continuous suture pattern to achieve proximal gastric restriction. They reported a decrease in BMI from 39.9 to 30.1 kg/m^2 and 58% excess weight loss at 1 year after the procedure. However, some of the follow-up weights were obtained by telephone interview. No serious procedure-related adverse events were reported [6].

Endoluminal gastric partitioning has also been accomplished using other devices. Two feasibility trials using the TOGA gastric stapling system (Satiety, Palo Alto, CA) have reported excess weight loss ranging from 24% to 42% and improved quality of life at 6 months after the procedure. No adverse events were reported in these feasibility trials [2,5].

The purpose of the present pilot study was to demonstrate the feasibility and initial safety of the TRIM procedure using the Restore Suturing System (Bard-Davol, Warwick, RI) in patients with a BMI of 30–45 kg/m^2. In the present report, we have described the short-term procedural results (≤24 hours after the procedure), including the patient evaluation, procedural technique, and intraoperative results in achieving endoluminal gastric volume reduction with this investigational device. Longer term follow-up is ongoing.

Methods

Device

The Restore Suturing System is a single-intubation, multistitch, endoscopic suturing system designed to place sutures through the muscular wall of the stomach and approximate gastric tissue. The device capsule is placed at the end of a standard endoscope, and the suturing system and suture fastening systems are placed through the working channel of the endoscope (Fig. 1). An overtube is not used with this device. The capsule is placed in the desired position on the gastric wall, and suction is applied. The suturing system is activated by depressing a plunger on the top of the device. When activated, the system deploys a 3-0 polypropylene suture through the tissue in the suction chamber and deposits the suture tag in the end of the capsule (Fig. 2). According to the device manufacturer's independent testing results, when stitching ex vivo porcine gastric tissue, the Restore device penetrated the submucosal layer or deeper not <75% of the time, with 95% confidence (unpublished data on file at the device manufacturer). The suture can then be re-

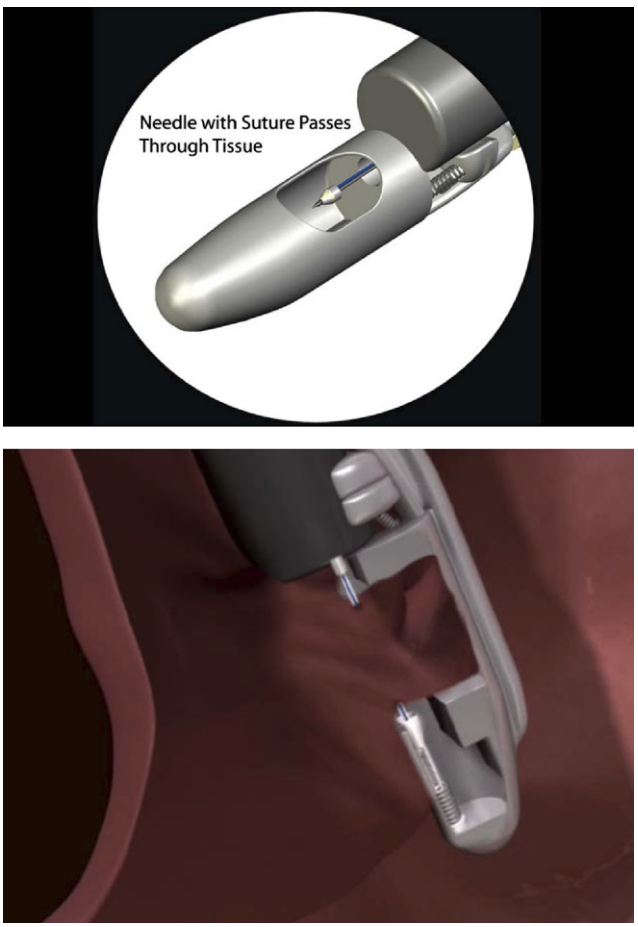

Fig. 2. Capsule applied to tissue, and suction applied. Needle drives suture and suture tag through muscular wall of stomach and deposits tag in end of capsule.

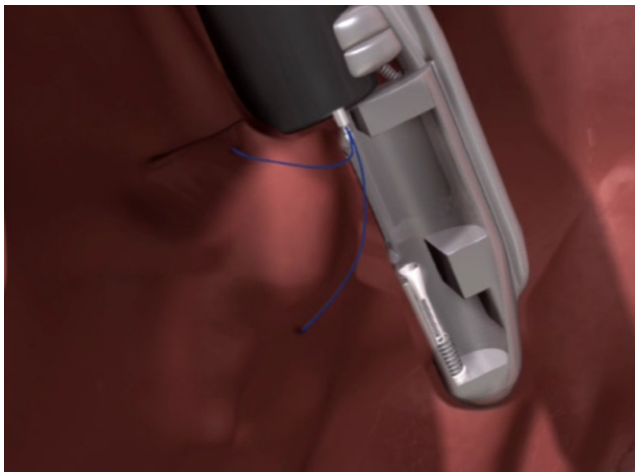

Fig. 3. Tag and suture are retrieved from end of capsule by activating plunger on device. Capsule is then positioned for next suture placement.

trieved by activating the device again (Fig. 3). The device is then repositioned, and subsequent bites are taken without removing the endoscope from the gastric lumen (Fig. 4).

When the desired number of bites has been taken, the suture delivery device is removed over the sutures. The suture fastening system is placed over the free ends of the sutures outside the endoscope, passed over the suture through the working channel, and locked into place. The suture is then tightened to pull the tissue plication together under direct vision, and the fastening system is deployed (Fig. 5). These steps are repeated until the desired number of plications has been achieved.

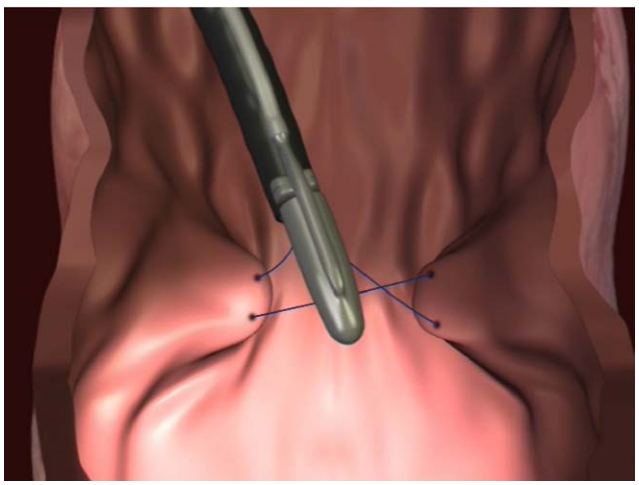

Fig. 4. After the desired number of bites have been taken, the suturing device is removed from the working channel over the sutures, and the suture fastening device is passed down the working channel over the sutures. The tissue is approximated by pulling the free ends of the sutures outside the endoscope.

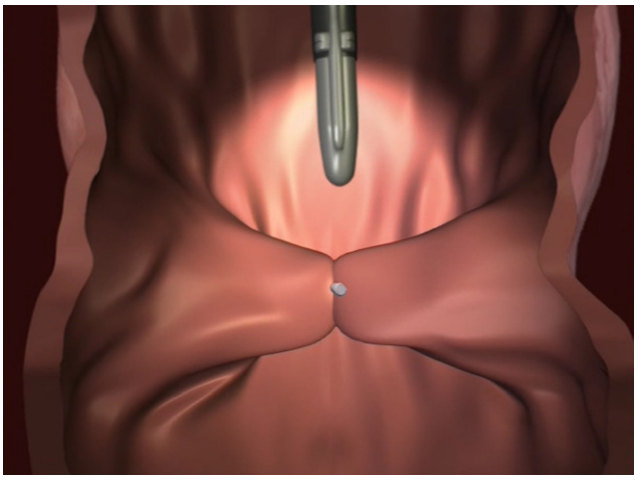

Fig. 5. Once the plication has been approximated, the fastener is deployed, and the suture cut with activation of the fastening device. Another suturing device is then placed down the working channel, and the steps are repeated.

Patients

The inclusion criteria for the present study included age ≥18 but ≤60 years and a BMI of 30–39 kg/m^2 with ≥1 co-morbidity or a BMI of 40–45 kg/m^2 with or without co-morbidities; a history of obesity for ≥5 years with unsuccessful attempts at conservative weight loss therapy; stable weight (no change of ≥5% within 2 months before enrollment). The exclusion criteria included uncontrolled endocrine disorders, previous bariatric or gastric surgery, diabetic gastroparesis, or a diagnosis of diabetes for >10 years, the presence of a hiatal hernia >2 cm, active *Helicobacter pylori* infection, a history of eating disorders such as bulimia, medical therapy for weight loss within the previous 3 months, or any other medical or psychological condition that, in the opinion of the investigators, would limit patient adherence to the study protocol or pose a significant risk for undergoing the procedure.

The patients were evaluated by a psychologist and nutritionist and were medically cleared for a general anesthetic before undergoing the procedure. Additional preprocedure screening included upper endoscopy and an upper gastrointestinal contrast study. Patients also underwent a upper gastrointestinal contrast study 1 month after the procedure.

Procedure

The institutional review board of both participating institutions approved the present study, and all patients provided consent to undergo this investigational procedure. During the TRIM trial, the suture plication pattern shown in Figure 6 was used to achieve an anterior to posterior gastric plication with the intention of achieving gastric volume reduction. This pattern was developed during preclinical laboratory testing to achieve the greatest amount of proximal gastric volume reduction with a limited number of plications.

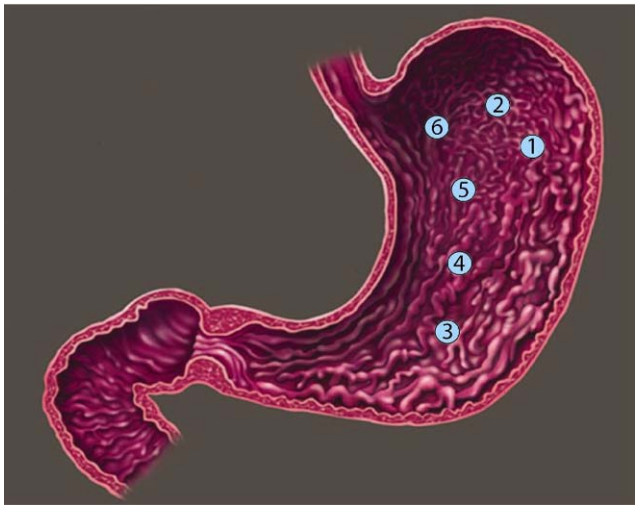

Fig. 6. Location of plications placed for TRIM trial.

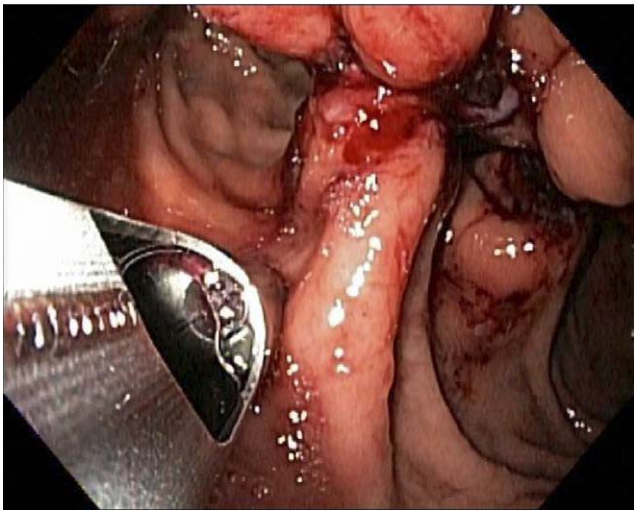

Fig. 8. Plications continued from distal to proximal toward angle of His.

All procedures were performed with the patient under general endotracheal anesthesia. Once the patients were intubated, an initial endoscopy was performed to assess the stomach for any abnormalities and to determine the preprocedure gastric shape and volume and to plan the location of the plications. The first suture plication was placed high along the greater curvature to reduce the fundic volume. A second plication was then placed higher in the fundus. We then performed a series of 3 bite plications starting approximately 10 cm distal to the gastroesophageal junction. The first bite was taken anteriorly, the second was taken more distally on the anterior wall, and the third bite was taken on the posterior wall. Once all 3 bites have been taken, the plication was secured (Fig. 7). Two bite plications could be placed at the discretion of the endoscopist, and this was determined on device limitations during the case. Subsequent plications were placed moving proximally along the lesser curve (Fig. 8). The final 2 plications were continued proximally toward the angle of His. The protocol called for 4–8 plications per patient. The number of plications placed during each procedure was determined by the patient's anatomy and the discretion of the investigator.

A final inspection of the procedure was made to ensure hemostasis and adequate volume reduction (Fig. 9). No quantitative gastric volume measurements were taken during the trial. However, qualitative endoscopic visualization was performed before and after the procedure by the investigator to assess for changes in gastric volume and distensibility with endoscopic insufflation.

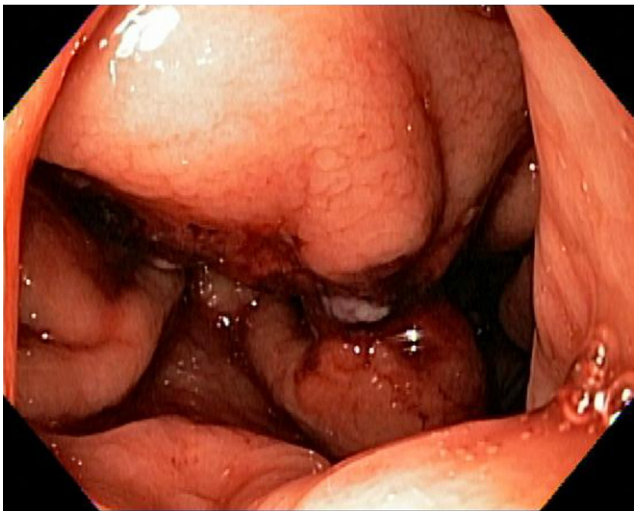

Fig. 7. Three-bite plication approximated before firing fastening device.

Fig. 9. Gastric volume reduction achieved after completion of plications.

Results

In the present pilot study, 94% of the patients were women. The mean age was 40.4 years (range 21–52), the mean preprocedure weight was 105.6 ± 13.7 kg, and the mean BMI was 38.6 ± 4.2 kg/m^2 (range 31.4–44.3). Nine procedures were completed at each participating institution (1 gastroenterologist at Brigham and Women's Hospital, Boston, MA; 3 surgeons at Cleveland Clinic, Cleveland, OH).

The device limitations from this "first human-use" experience included increased resistance encountered when attempting to generate a slack in the suture or exchange the suturing device with the fastening device, which resulted in increased procedure times. The 3 bite plications were more commonly achieved, when less angulation of the endoscope (plications 3–6) was present and thus less resistance on the suture as it passed through the tissue.

A consensus was reached among the investigators that the maximal number of plications (≤8) should be placed during each case. In those cases in which fewer were placed, the investigator determined that additional volume reduction was not necessary or was not possible owing to the limited working space.

Gastric volume reduction was achieved in all 18 subjects as determined by qualitative assessments by the investigator. A total of 4–8 plications were placed, with an average of 6 per patient. The average procedure time was 125 ± 23 minutes, and no serious or significant procedure-related complications occurred. During recovery, before discharge, the common patient complaints were nausea, vomiting, and abdominal discomfort. No patients required readmission to the hospital for these symptoms. The first 10 patients enrolled were kept overnight according to the study protocol, and the remaining 8 patients were discharged on the day of the procedure.

Discussion

Many different types of gastric restrictive procedures have been used in the past 4 decades to achieve weight loss. These have ranged from open vertical and horizontal gastroplasties to nonadjustable gastric banding in the 1970s to laparoscopic adjustable gastric banding and sleeve gastrectomy used today. The initial gastroplasty procedures were not successful in the long term because of outlet stenosis or weight regain secondary to staple line failure. The laparoscopic adjustable band has proved to be a safe procedure to perform; however, placement of a permanent device, the long-term risk of prolapse, and the need for adjustments have not appealed to many patients. Sleeve gastrectomy results in rapid weight loss but has well-described, short-term complications and limited of long-term weight loss data. Also, the irreversibility of this operation has been a concern for some patients. All these surgical procedures have been associated with risk/benefit ratios that could appeal to some surgeons and patients. The level of invasiveness, reversibility, adjustability, and complication rates are important factors for patients considering bariatric procedures and must be evaluated in the context of the efficacy, durability, and cost. Although the efficacy and durability of endoscopic weight loss procedures has not been proved, this low-risk nonoperative approach is likely to appeal to many patients and referring physicians, even if the weight loss and durability are less than those with the current surgical procedures [1]. Whether patients would be willing to undergo repeated endoscopic procedures to maintain their weight loss not yet clear. Nevertheless, the endoscopic procedures currently being developed are likely to play some role in the future of obesity management. Another appeal of this procedure is that it has the potential to be performed using conscious sedation. Because this was a first-time use trial for this device, we elected to use a general anesthetic rather than conscious sedation. We recognize that a risk is associated with the use of general anesthesia, particularly in morbidly obese patients. For the present study, patients were carefully screened and selected to minimize the risk of procedural anesthetic complications.

One of the criticisms of this type of procedure is that it is an attempt to re-create a procedure such as vertical banded gastroplasty that has been proved ineffective. Although the efficacy of the procedure described in the present study will not be known until the study follow-up period is complete, it was not intended to replicate an endoscopic version of the vertical banded gastroplasty or to create a watertight channel in the upper stomach. Rather, the concept of the procedure is to decrease gastric compliance and achieve gastric distension (and satiety) early during a meal using a series of anterior to posterior plications rather than a proximal pouch. Additionally, this endoscopic procedure does not involve the short- or long-term risk of a surgical procedure such as vertical banded gastroplasty. We recognize that this procedure will not be a substitute for accepted surgical procedures; however, it might appeal to, and have a role for, specific patient groups, given its low risk.

The potential weaknesses of this procedure include the tension on the sutures and tissue when the suturing device is exchanged for the fastening device and that the plications are not full-thickness stitches. Additional modifications of the device and suture material are ongoing to decrease the amount of tension on the plicated tissue during the procedure.

Conclusion

In the present study, we have reported our technique using an investigational endoluminal suturing device to achieve gastric volume reduction. The Restore device can be used with a standard endoscope and can achieve multiple gastric plications with a single esophageal intubation and no overtube. This procedure is technically feasible, and no serious or significant procedure-related complications were reported in this limited series. We were able to achieve

gastric restriction as determined by our endoscopic assessment in all cases. Although the ease of use and initial safety of this new device have been demonstrated in the present pilot study, the 1-year follow-up is ongoing to investigate the efficacy and durability of the procedure. Additionally, the investigators were experienced endoscopists and the use of this device should be studied with providers who have a broad range of endoscopic skills. A prospective multicenter trial using this device is being planned.

Disclosures

All authors of the present report are consultants for, and have received research grants from, C. R. Bard, Inc.

Appendix

Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.soard.2010.07.012.

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