The First Endoscopic Sleeve Gastroplasty and Transoral Outlet Reduction in Thailand: Case Report and Literature Review

Voraboot Taweerutchana, M.D.*,, Kotchakon Maipang, M.D.*, Nicha Srisuworanan, M.D.*,**, Parichat Tovikkai, M.D.***, Pichamol Jirapinyo, M.D., MPH****, Christopher C. Thompson, M.D., M.Sc.****, Nonthalee Pausawasdi, M.D.*,*****

**Siriraj GI Endoscopy Center, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand, **Minimally Invasive Surgery Unit, Division of General Surgery, Department of Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand, ***Department of Anesthesiology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand, ****Division of Gastroenterology, Hepatology, and Endoscopy, Department of Internal Medicine, Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts, USA, *****Division of Gastroenterology, Department of Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand.*

ABSTRACT

Obesity is becoming a universal healthcare problem. The role of endoscopic bariatric and metabolic therapies is emerging in the management of obesity and its related conditions. The endoscopic treatment can be used as a primary weight loss procedure and a revision procedure after bariatric surgery. While the prevalence of obesity has been rising over the past two decades in Thailand, the treatment options have been limited to diet and exercise, pharmacological treatment, and bariatric surgery until recently. In 2020, an endoscopic full-thickness suturing device was introduced to Thailand, leading to successful endoscopic bariatric therapy using a suturing device in Thai patients. This article intends to report the first successful endoscopic sleeve gastroplasty and transoral outlet reduction in Thailand with a mini-review focusing on these two procedures' outcomes.

Keywords: Endoscopic sleeve gastroplasty; transoral outlet reduction; bariatric endoscopy; bariatric surgery; obesity; endoscopy (Siriraj Med J 2021; 73: 282-288)

INTRODUCTION

Obesity is a significant health problem affecting over 700 million people globally, with an increased prevalence by nearly triple since 1975. In 2011, Thailand became the country with the second-highest prevalence of obesity in Southeast Asia (second to Malaysia).[1] The treatment options include lifestyle modification, medications, endoscopic bariatric therapy (EBT), and bariatric surgery. Lifestyle modification and medical treatment fail to attain long-term weight loss in a substantial proportion of the patients. Bariatric surgery is the most effective treatment for patients with morbid obesity. Still, under 2% of suitable patients undergo surgical treatment due to the risk of complications, the procedure's irreversible nature, limited budget, and access to surgery.[2,3] The EBT has gained more interest as a primary weight loss procedure (endoscopic sleeve gastroplasty, ESG) and revision procedures, including transoral outlet reduction (TORe) and endoscopic sleeve revision, as it offers a minimally invasive option to achieve weight loss. Despite

Corresponding author: Nonthalee Pausawasdi
E-mail: nonthaleep7@gmail.com
Received 15 February 2021 Revised 15 March 2021 Accepted 16 March 2021
ORCID ID: http://orcid.org/0000-0002-3737-8555
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the increasing incidence of obesity-related medical conditions in Thai people, the treatment options for obesity were limited to medical treatment and bariatric surgery until 2020, when the endoscopic suturing device (Apollo Endosurgery, Austin, TX) successfully obtained regulatory approval and became commercially available in Thailand.

Herein, we report first ESG and TORe cases in Thailand using the full-thickness endoscopic suturing system with a single-channel endoscope.

Case 1:

A 55-year-old woman with class I obesity, hypertension, dyslipidemia, and severe obstructive sleep apnea treated with AutoPAP ranging from 5-15 cmH_2O presented for the treatment of obesity. Her body weight (BW) was 85 kg, with a body mass index (BMI) of 34.9 kg/m^2. She was unable to achieve sustained clinically significant weight loss with lifestyle modification and medical treatment, including topiramate 100 mg daily, which was discontinued due to severe dizziness. After discussing the treatment options, she decided to undergo ESG. Pre-operative evaluation, including cardiac and pulmonary assessment, psychological evaluation, abdominal ultrasound, and duplex ultrasound for deep vein thrombosis (DVT) screening, were unremarkable. Her physical status was compatible with the American Society of Anesthesiologists (ASA) class II. She also underwent colonoscopy, pelvic examination, and mammography for cancer screening before the endoscopic procedure. Her pre-procedural BW was 78 kg, and her BMI was 32.05 kg/m^2.

The following items have been prepared; 1) The suturing device (OverStitch Sx™; Apollo Endosurgery Inc., Austin, Texas, U.S.) connected to a 9.8 mm diameter gastroscope (GIF-H180; Olympus, Tokyo, Japan). The endoscopic suturing device has an external catheter sheath, consisting of two separate working channels allowing the anchor exchange and the OverStitch Sx™ accessories to operate independently of the scope channel. The needle driver handle is attached to the control section of the endoscope, and the needle endcap is attached to the distal tip of the endoscope, 2) Intravenous prophylactic antibiotics with 2 grams of ceftriaxone and 500 mg of metronidazole, 3) Carbon dioxide for insufflation. The procedure was performed under general anesthesia with the patient placed in the left lateral position. Enhanced recovery after surgery (ERAS) principles were applied, including short-acting anesthetic drugs, short-acting opioid, thromboprophylaxis, postoperative nausea and vomiting (PONV) prophylaxis and ventilator setting with lung protective strategy. A thorough gastric examination was done during the upper endoscopy before performing gastroplasty.

After the suturing device was advanced into the stomach, suturing was started from the level of incisura angularis. A running suture pattern, composed of 5 full-thickness bites, was started from the anterior wall, greater curvature, and posterior wall. The helix was used to grasp the tissue and pull it into the suturing device's jaws to facilitate a full-thickness bite. Upon finishing the running suture pattern, the needle was released to function as a tissue anchor, followed by removal of the anchor exchange catheter. The cinching catheter was inserted over the suture, which was tightened by applying intermittent and incremental tension before cinching. The suture was secured and cut by deploying a cinch. The following sutures were made in a "U" suture pattern alternating with an interrupted reinforcement suture. Each "U" was made of 8-12 stitches starting from the anterior wall, greater curvature, and posterior wall and then reverse pattern from the posterior wall more proximally, greater curvature and anterior wall. This pattern was then repeated following interrupted reinforcement with the next suture placed within 1 cm proximal to the previous set. In total, seven sutures were placed along the greater curvature in the distal to proximal direction, producing a sleeve-shaped gastric tube (Fig 1). The gastric fundus was not sutured, so that the patient had a pouch and accommodation capability. The procedure was successfully performed with a total procedure time of 120 minutes without adverse events. The patient was discharged two days after the procedure. A 3-day course of antibiotics and a 1-month course of daily proton pump inhibitor were prescribed. She was kept on full liquid diet for two weeks, followed by four weeks of soft diet and subsequently regular diet. The patient did well and her weight went from 78 kg to 67.7 kg at a three-month follow-up, representing a 13.2% total weight loss (TWL).

DISCUSSION

ESG is a primary endoscopic bariatric procedure using a suturing system that allows placement of full-thickness stitches through a minimally invasive method. This procedure was performed for the first time in 2012 by Thompson and Hawes using the Apollo Overstitch™ endoscopic suturing system.[4] The application of OverStitch™ requires a dual-channel therapeutic endoscope, and thus compatible with the Olympus GIF-2TH180 and GIF-2T160 scopes. Since then, several studies have demonstrated the technical feasibility, safety, and efficacy of ESG for weight loss and co-morbidity improvement using this

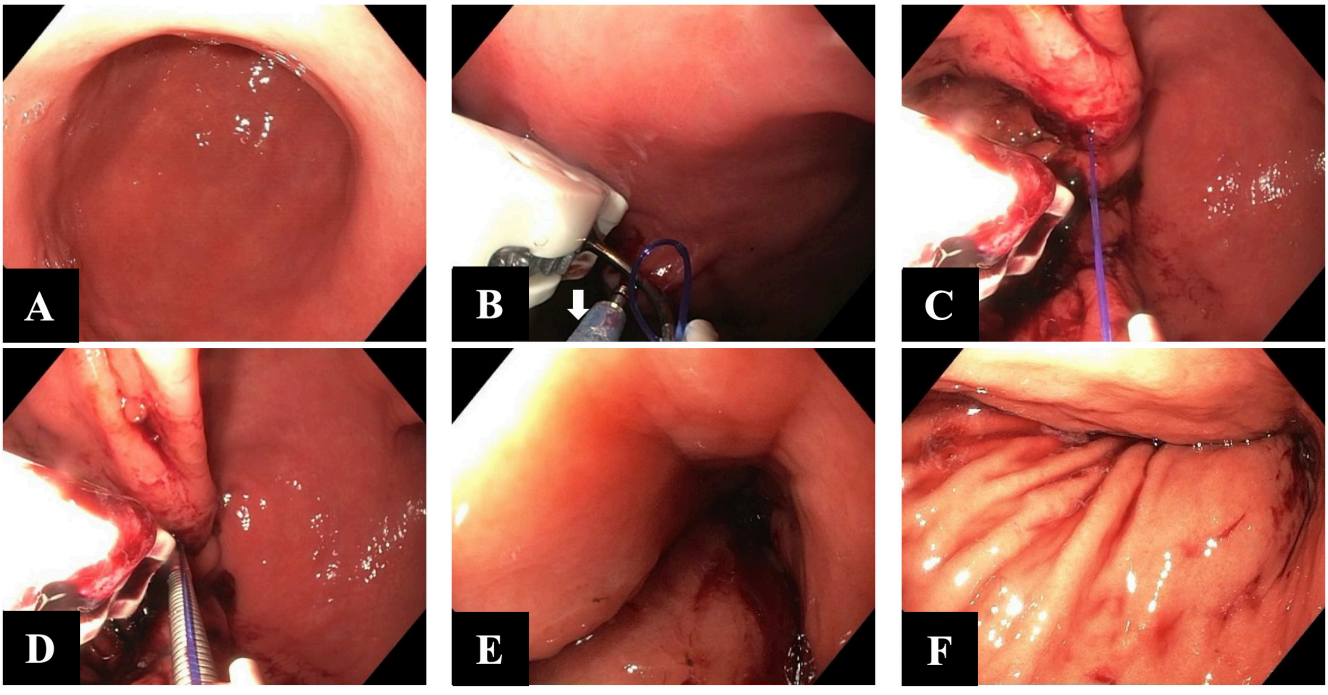

Fig 1. (A) Endoscopic image of the stomach. **(B)** The tissue helix (white arrow) is used to grasp tissue facilitating full-thickness bites. **(C)** The anchor is deployed, and the anchor exchanged device is removed after the last bite. **(D)** Cinching is performed to tighten the suture by applying intermittent and incremental pressure until adequate tissue approximation. **(E, F)** Endoscopic view demonstrating gastric sleeve on completion of the procedure.

device. Recently, Apollo Endosurgery released a newly developed suturing device, the OverStitch Sx™, which is compatible with single-channel flexible endoscopes. The OverStitch Sx™ keeps the needle (tissue anchor) and the needle driver in a secured cap on the end of the endoscope. The tissue helix can be inserted through a separate working channel.

Our first case of ESG was successfully performed using the OverStitch Sx™. The "U stitch" suture pattern with reinforcing stitches was used. The OverStitch Sx™ was capable of placing different suture patterns, including running and interrupted without difficulties. There were no adverse events during or after the procedure and no morbidity and mortality within the 90-day postoperative period. The percent of total weight loss (%TWL) and percent of excess weight loss (%EWL) was 13.2% and 38.1%, respectively, at the three-month follow-up. These results were similar to the outcomes of ESG reported in other studies.

Literature review

The principle of ESG is to create a restrictive gastric tube by placing transmural sutures along the greater curvature of the gastric body starting from the level of incisura angularis to the proximal body resulting in a gastric sleeve with an approximate 70% reduction in volume with likely delayed gastric emptying. A study has been conducted to compare gut hormone changes at six months after ESG vs. laparoscopic sleeve gastrectomy (LSG). The data demonstrated a significant decrease of the leptin level without significant changes of ghrelin, GLP-1, and PYY after ESG. In comparison, LSG resulted in a significant decline of ghrelin and a significant increase in GLP-1 and PYY level after six months. It is hypothesized that ESG does not affect the Ghrelin level because the fundus, where ghrelin is produced, is preserved after the procedure. In contrast, the fundus is excised, and the greater curvature is removed during LSG, which may decrease the ghrelin level. Therefore, the mechanism of weight loss after ESG is mainly related to early satiety by volume reduction and delayed gastric emptying.[5]

Different suture patterns and numbers of sutures have been reported, including "Z," "W", "U", and triangular or interrupted patterns.[6-10] Serial U suture patterns are performed starting on the anterior wall, the greater curvature, followed by the posterior wall, and moving proximally to the greater curvature concluding on the anterior wall proximal to the first bite. This procedure's primary focus is placing a running suture along the greater curvature, resulting in gastric shortening while concurrently narrowing the gastric lumen.[11] Another crucial point is the use of reinforcement sutures, which

may protect and help minimize U stitch tension.[12] To achieve efficiency in maneuvering the overstitch devices, at least 35 cases are required.[7,13]

The largest prospective study assessing the outcomes of ESG in 1000 patients showed that the mean %TWL at 6, 12, and 18 months was 13.7%, 15.0%, and 14.8%, respectively, and the mean %EWL at 6, 12, and 18 months was 64.3%, 67.5%, and 64.7%, respectively.[14] These outcomes were confirmed by three large meta-analyses, including over 1,500 patients in each study. The pooled analysis showed that the mean %TWL at 6, 12, and 24 months was 14.5%, 16%, and 17-20%, respectively. The pooled mean %EWL at 6, 12, and 24 months was approximately 53-57%, 60%, and 60%, respectively.[15-17] The weight loss following ESG appeared to plateau after 1 year, which is similar to that of bariatric surgery.[17] In terms of metabolic outcomes, a significant reduction in hemoglobin A1c, systolic blood pressure, waist circumference, alanine aminotransferase, and serum triglyceride has been reported at 12 months after ESG. The hypoglycemic agents were discontinued in 11% of the patients with pre-existing type 2 diabetes mellitus.[7] By far, ESG appeared to be an effective non-invasive method for weight reduction in those between a BMI of 30-40 kg/m^2.[18] Compared to intragastric balloon (IGB), ESG is superior in regards to %EWL and durability. A meta-analysis showed that ESG offered more %EWL at one year than IGB (60.51% vs. 29.65%). Also, weight loss after ESG is more durable than the IGB. The study showed that %EWL after IGB dropped from 34.83% at six months to 23.88% at 18 months, indicating weight regain after device removal. In contrast, %EWL after ESG remained above 50% at 18-24 months after the procedure.[19]

Nonetheless, ESG appears to have less effect in weight reduction than laparoscopic sleeve gastrectomy (LSG). A non-matched cohort study demonstrated that %TWL after ESG was significantly lower compared to LSG both at 6 months (14.4% vs. 23.5%, p <0.001) and 12 months (17.6% vs. 29.3%, p <0.001) after the procedures.[18] A case-matched retrospective study also showed that %TWL in the patients post ESG was lower than those with LSG (17.1% vs. 23.6%, p <0.01). However, a subgroup analysis demonstrated that %TWL of the patients receiving ESG was significantly lower than LSG in those with BMI >40 kg/m^2, but the difference was not statistically significant in those with BMI <40 kg/m^2. In contrast, the rate of adverse events after ESG was significantly lower compared to LSG (5.2% vs. 16.9%, P <0.5).[20] The pooled adverse event rate of ESG was approximately 2%, and no mortality has been reported. The most common severe adverse events were gastrointestinal bleeding and perigastric fluid collections, in which the incidence of each were <1%. Gastrointestinal bleeding in all cases can be managed conservatively, while the perigastric fluid collection was successfully managed by percutaneous drainage in most cases.[16] A study showed that 0.3% of the patients required reversal of ESG due to persistent symptoms of severe abdominal pain and vomiting, suggesting endoscopic reversibility of the procedure.[14] In patients with weight regain or inadequate weight loss after procedure, redo ESG or conversion to bariatric surgery (both laparoscopic sleeve gastrectomy and Roux-en-Y gastric bypass) remains an option.

In summary, this case report demonstrated the first successful application of the Overstitch Sx to perform ESG in Thailand. Our patient experienced clinically significant weight loss, defined as greater than 10% TWL, at 3 months, which was consistent with the reported data worldwide. Given a rising prevalence of obesity in Thailand, ESG may be considered an alternative treatment option in addition to pharmacotherapy and bariatric surgery.

Case 2:

A 45-year-old man presented with weight regain after Roux-en-Y gastric bypass (RYGB). His underlying medical comorbidities were hypertension, dyslipidemia, and non-alcoholic fatty liver diseases (NAFLD). He underwent RYGB in October 2015. He lost 58 kg after surgery; however, he regained 28 kg 2 years later. He developed a gastro-jejunal anastomotic (GJA) ulcer, proven by endoscopy, which was treated successfully with proton-pump inhibitors. The decision was made to proceed with transoral outlet reduction (TORe) after failing a 6-month trial of diet modification and exercise. Pre-operative evaluation, including cardiac and pulmonary assessment, psychological evaluation, abdominal ultrasound, and duplex ultrasound for DVT screening, were normal. His physical status was compatible with class II ASA.

He underwent TORe with a pre-procedural weight of 114.2 kg and a BMI of 35.2 kg/m^2. The procedure was performed with the patient in the left lateral decubitus position and under general anesthesia. ERAS principles, including short-acting anesthetic drugs, short-acting opioid, thromboprophylaxis, postoperative nausea and vomiting (PONV) prophylaxis and ventilator setting with lung protective strategy, were used. Upper endoscopy showed evidence of RYGB anatomy with a dilated GJA of 25 mm. The gastric pouch was 6 cm in length. Argon plasma coagulation (APC) was performed 1 cm circumferentially around the GJA to ablate the mucosa and facilitate submucosal-to-submucosal tissue apposition.

The APC settings were a power of 30 Watts and a flow rate of 0.8 L/min. The single-channel endoscopic suturing device was mounted on the GIF-H180 gastroscope and inserted into the gastric pouch. A simple two-stitch interrupted suture was placed at the 12 and 6 o'clock of the GJA to reduce its diameter, followed by cinching. Then, we reduced the pouch size starting with a simple interrupted pattern at the 12 and 6 o'clock on a greater curvature side of the distal pouch. Subsequently, the proximal pouch was reduced using a 6-stitch U-shape running suture pattern on the greater curvature side (Fig 2). The procedure was successfully performed with a total procedure time of 90 minutes without adverse events. The patient was discharged two days after the procedure. A 3-day course of antibiotics and a 1-month course of daily proton pump inhibitor were prescribed. He was placed on two weeks of full liquid diet, followed by four weeks of soft diet and subsequent regular diet. The patient did well and his weight decreased from 114.2 to 102 kg, representing a 10.7% TWL at a three-month follow-up.

DISCUSSION

Bariatric surgery is the most effective treatment with a durable long-term result for the treatment of obesity.[20] However, 10-20% of the patients who underwent RYGB, fail to achieve 50% EWL after one year of surgery.[22] Furthermore, a long term study revealed that most patients regained approximately a third of their lost weight, with a third of the patients regaining nearly all of their lost weight.[23] Weight regain can be caused by multiple reasons, including hormonal disturbances, patient behaviors, and anatomical factors. Anatomical characteristics, including gastro-gastric fistula and dilatation of GJA, are risk factors for weight regain.[24-26] Endoscopic therapy has become a treatment option for weight regain as it is effective and less invasive than revisional surgery. Our patient regained 48% of his lost weight two years after surgery, suggestive of failed primary bariatric operation requiring revisional procedure. Furthermore, the upper endoscopy showed a dilated GJA of 25 mm in diameter, making endoscopic therapy an attractive treatment option for outlet reduction. Therefore, we elected to perform our first case of TORe using the OverStitch Sx™ with interrupted suture pattern. The procedure was performed successfully without intra- or post-procedural adverse events. The GJA was sized to approximately 10 mm in diameter to avoid symptoms of outlet obstruction. At three-month follow-up, his %TWL was 10.7, and %EWL was 33.7%.

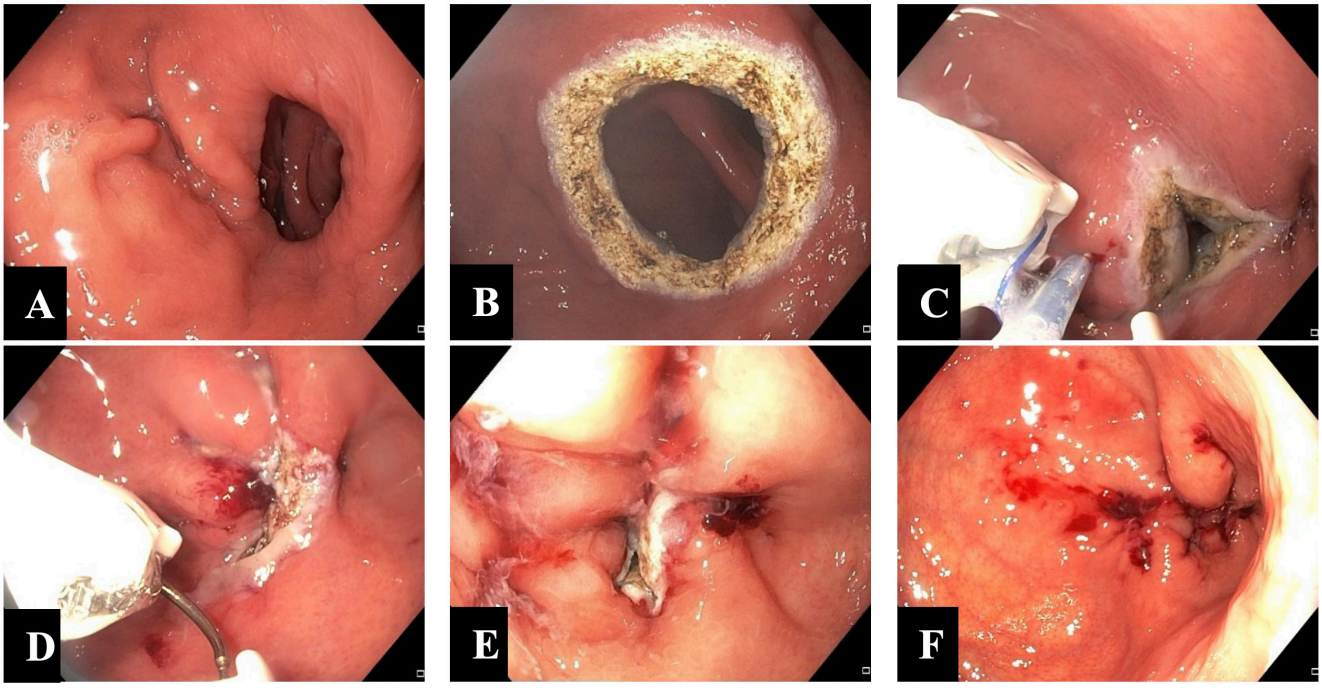

Fig 2. **(A)** Endoscopic view showing dilated gastro-jejunal anastomosis **(B)** Argon plasma coagulation was applied circumferentially around the edge of the outlet **(C)** The tissue helix was used to grasp the tissue at the gastrojejunal anastomosis **(D)** Gastro-jejunal anastomosis size reduction after first plication **(E, F)** Endoscopic view demonstrating gastrojejunal anastomosis revision and gastric pouch reduction.

Literature review

Endoscopic therapy has emerged as an alternative option for the treatment of weight regain. Various endoscopic techniques have been described, including sclerotherapy, ablation therapy, clipping, suturing and plication. TORe applies full-thickness suturing to reduce the size of the GJA. The %TWL at 1 year, 2 years, and 3 years was 9.5%, 8.1%, and 8.6%, respectively, in 150 patients post-RYGB.[27] A retrospective study of 342 patients with RYGB assessed the 5-year outcomes of TORe and demonstrated the safety and efficacy of the procedure, with a mean %TWL at 1 year, 3 years, and 5 years of 8.5%, 6.9%, and 8.8% respectively. In this series, a variety of suturing patterns were used: 76%, 17.5%, 4.4%, and 2.1% were performed using single purse-string, interrupted, double purse-string, and running suture patterns, respectively. Pouch reinforcement was performed in about 60% of the cases. About 40% required additional weight loss therapy, including medical treatment and repeat TORe (3.6%).[28] The suturing technique used for TORe can be interrupted, purse-string, running or figure-of-eight. For the interrupted suture pattern, a single suture is used to place two stitches across from each other at the GJA until the size was reduced. If the gastric pouch was dilated, interrupted stitches were placed in the distal pouch to reduce pouch volume and size. In the purse-string pattern, one suture is used to place multiple stitches around the GJA in a continuous circumferential fashion, typically requiring 8 to 12 stitches. A hydrostatic balloon was inflated to a diameter of 8 to 12 mm inside the anastomosis before cinching over the balloon. A study comparing purse-string to an interrupted suture pattern for TORe demonstrated a greater weight loss in the purse-string group (8.6% TWL vs. 6.4% TWL, p=0.02) at 12 months.[29]

Argon plasma coagulation (APC) is generally performed circumferentially around the GJA before suturing. This ablation step is believed to be vital because it ablates the mucosal layer to allow submucosal to submucosal tissue apposition during suturing steps.[30] A meta-analysis showed that the combination of APC and TORe resulted in greater weight loss compared to suturing alone.[31] A recently published novel technique for endoscopic outlet revision was a combined endoscopic submucosal resection (ESD), performed circumferentially at the GJA before suturing (ESD-TORe technique). A retrospective study comparing the outcomes of 19 patients with ESD-TORe matched with 57 patients receiving APC-TORe, demonstrated that the ESD-TORe group experienced greater %TWL than the APC-TORe group (12.1% vs. 7.5%, p=0.036) at 12 months.[30]

The safety profile has been assessed, and the pooled rate of overall adverse events was 11.4%, with abdominal pain being the most common adverse event. The pooled rate of severe adverse events was 0.57%, with the bleeding rate of 1.14%, and the perforation rate of 0.46%.[32] Therefore, TORe appears safe, effective and durable for the treatment of weight regain or inadequate weight loss after RYGB.

CONCLUSION

Bariatric endoscopy will play an essential role in treating obesity in Thailand in the future as the obesity prevalence is rising. We reported the first two cases of successful ESG and TORe performed in Thailand. The endoscopic bariatric therapy using the full-thickness suturing device is safe, feasible, and effective as primary and revisional procedures and is a good alternative treatment option for obesity. These procedures may offer a paradigm shift in obesity management as they fill the treatment gap between medical therapy and bariatric surgery.

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