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NEW CONCEPT

Efficacy and Safety of Novel, Disposable Endoscopic Scissors in Patients with Roux-en-Y Gastric Bypass: a Single-Center Feasibility Study

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Abstract

Background Retained suture material from primary Roux-en-Y gastric bypass or revisions may result in local inflammation, ulcer formation, and abdominal pain. The primary aim of this study was to evaluate the feasibility, efficacy, and safety of novel, disposable endoscopic scissors for suture removal.

Methods This was a single-center, retrospective analysis of prospectively collected data from December 2016 to January 2019. Patients with history of Roux-en-Y gastric bypass and upper endoscopy utilizing this novel, disposable endoscopic scissors device were reviewed. Measured outcomes included endoscopy indication, technical success (as determined by ability to achieve adequate cut and suture removal), improvement in abdominal pain if present prior to procedure, and adverse events.

Results Sixty-two patients were included in this analysis. Mean age was 54.69 ± 9.40 years. Eighty-eight percent of patients were female. Roux-en-Y gastric bypass occurred on average 142.43 ± 62.33 months prior to suture removal. Primary indications for endoscopy were evaluation of gastric pouch and gastrojejunal anastomosis for weight regain (37.10%) and abdominal pain (30.65%). Overall, technical success of these novel endoscopic scissors was 100% with a mean procedure duration of 23.00 ± 9.50 min. Symptom improvement post-suture removal occurred in approximately half of the patients (48.65%). Post-procedure bleeding was self-limited and occurred in 2 patients (3.23%). Two patients developed transient post-procedure abdominal pain.

Conclusions Novel, disposable endoscopic scissors appear to be highly effective and safe for removal of suture material with high technical success and minimal adverse events.

Keywords Obesity · Roux-en-Y gastric bypass · Endoscopy · Endoscopic scissors

Introduction

The prevalence of obesity has nearly tripled over the past four decades, approaching approximately 40% among US adults [1, 2]. Although bariatric surgery has reached a plateau over the last 2 decades, the mainstay of weight loss surgery revolves around sleeve gastrectomy and the more traditionally utilized Roux-en-Y gastric bypass procedure [3–6]. Despite its efficacy in achieving weight loss, Roux-en-Y gastric bypass can be associated with a host of potential short- and long-term complications [7–9]. While early complications may include leak, ileus, and post-operative hemorrhage, late complications can involve weight regain, anastomotic ulcers or strictures, dumping syndrome, gastro-gastric fistula, hernias, bowel obstruction, nutritional deficiencies, and abdominal pain [9]. Although evaluation of abdominal pain in patients with Roux-en-Y gastric bypass can be challenging, often necessitating esophgogastroduodenoscopy, the cause in many cases may not be easily elucidated [10, 11].

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While the erosion of non-absorbable foreign material into the gastric pouch after bariatric surgery (usually seen in classic two-layered gastrojejunostomy) is commonly regarded as a normal or unremarkable post-operative finding, retained sutures in patients with Roux-en-Y gastric bypass have recently emerged as a potential cause for unexplained abdominal pain [12, 13]. Furthermore, additional data suggests that exposed suture may result in marginal ulcer formation with improvement illustrated post-suture removal [13]. Based upon previous literature, it is now believed that retained suture material from primary Roux-en-Y gastric bypass or revisions may result in local inflammation, ulcer formation, abdominal pain, and also promote bezoar formation [13–15].

With retained suture identified as possible sources of previously unexplained abdominal pain, there remains a paucity of data regarding optimal methods for suture removal through endoscopic means. Although conventional endoscopic scissors and loop cutters are reusable, they have been associated with varying technical success and may incur large costs given the need for sterilization and treatment. Recently, a novel, disposable endoscopic scissor (Ensizor, Slater Endoscopy, Miami Lakes, Florida) has been developed. Despite increasing use for various indications, limited data exists to assess this device's effectiveness, safety profile, and impact on patient symptoms.

The primary aim of this study was to evaluate the feasibility, efficacy, and safety of a novel, disposable endoscopic scissors device to assist in the removal of retained sutures among patients with Roux-en-Y gastric bypass.

Methods

Study Design and Patient Selection

This was a single-center, retrospective analysis of prospectively collected data from December 2016 to January 2019. Patients were identified from our tertiary care practice that sees more than 850 bariatric patients annually with a dedicated bariatric endoscopy program performing more than 700 bariatric endoscopy cases yearly. Data on endoscopic scissor use was obtained from multiple gastroenterologists with varying years of experience. Institutional Review Board approval was obtained for retrospective data collection from a prospective registry. Eligible patients for inclusion were those patients with a history of prior Roux-en-Y gastric bypass surgery with or without previous endoscopic revision. All included patients in this study underwent use of this novel, disposable endoscopic scissors device. This data was obtained using endoscopic billing codes.

Endoscopy Protocol

Included patients underwent procedural sedation with fentanyl and midazolam, which is the standard moderate sedation protocol at our institution. In rare instances, and when deemed appropriate by anesthesia, patients underwent deep sedation using propofol, particularly in patients with multiple comorbidities, ASA grade > 2 or history of not tolerating moderate sedation. In no cases was the sedation plan altered for the use of this endoscopic scissors device. All patients were consented for standard esophagogastroduodenoscopy with the potential for endoscopic suture removal if retained sutures were encountered. A standard upper endoscope (Olympus GIF-HQ190, Olympus America, Center Valley, PA) was used for all procedures. The gastric pouch was examined for evidence of ulceration or fistula. The gastrojejunal anastomosis was also examined for ulcers, erosions, or retained suture material.

Endoscopic Scissors and Suture Removal Technique

Once suture material was identified, attempts were made to remove any submucosal suture using biopsy forceps. Next, once fully exposed, the suture material was cut using the flexible endoscopic scissors device (26 mm × 235 cm) (Ensizor, Slater Endoscopy, Miami Lakes, Florida). These disposable endoscopic scissors allow for the ability to cut through tissue, sutures, and many other non-metal materials using lateral forces with reinforced blades to prevent malleation, deviation, or bending. With this device, each blade is two components assembled together which may provide more consistent results for suture cutting (Figs. 1 and 2). All suture material was specifically removed with these novel endoscopic scissors as a first-line step (attempts with other devices such as loop cutters was not performed). In certain instances, grasping forceps were used to pull suture material to allow more exposure at the site of mucosa attachment—thus allowing more suture to be cut with the endoscopic scissors device. Suture material was detached from the mucosa post-incision, cut, and then retrieved with the assistance of endoscopic grasping forceps (Fig. 3).

Outcome Measures

Primary measured outcomes of this study included technical success as determined by ability to achieve adequate cut and suture removal as well as adverse events. Secondary outcomes included date of Roux-en-Y gastric bypass surgery, indication for esophagogastroduodenoscopy, record of specific gastroenterology proceduralist, and assessment for improvement in abdominal pain if present prior to procedure at follow-up. Duration of procedure (in minutes), characterized by start time of sedation to removal of gastroscope, and type of sedation were also documented.

Statistical Analysis

Statistical analysis was performed using the Stata 15.0 software package (Stata Corp LP, College Station, TX).

Fig. 1 Gross appearance of novel, disposable endoscopic scissors

Continuous variables were expressed as means and categorical data as numbers and percentages.

Results

Patient Demographics and Procedure Characteristics

A total of 62 patients were enrolled in this study. The mean age of included patients was 54.69 ± 9.40 years with an overwhelming percentage of females represented ($n = 59$; 88.71%). A majority of endoscopic procedures involving suture removal were among outpatients (77.42%). The remaining cases occurred among patients admitted to the hospital. A total of 38 patients (61.29%) underwent moderate sedation for esophagogastroduodenoscopy with the remaining patients requiring deep sedation per standard protocol. The mean procedure duration was 23.00 ± 9.50 min. Bariatric surgery with Roux-en-Y gastric bypass procedure occurred on average 142.43 ± 62.33 months prior to suture removal. A summary table of patient characteristics is highlighted in Table 1.

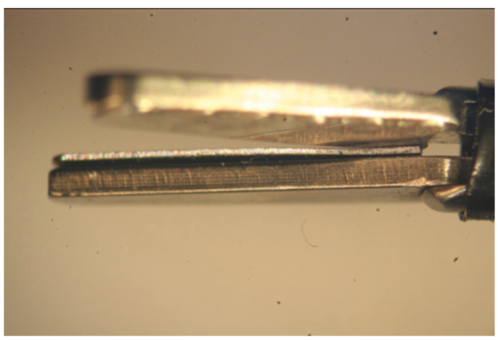

Fig. 2 Unique blade design of novel, disposable endoscopic scissors

A total of 8 different attending gastroenterologists utilized the flexible endoscopic scissors device; however, a majority of cases were performed by one provider ($n = 50$; 80.65%). The most common primary indications for upper endoscopy were for evaluation of gastric pouch and gastrojejunal anastomosis for weight regain ($n = 23$; 37.10%), abdominal pain ($n = 19$; 30.65%), and nausea or vomiting ($n = 9$; 14.52%). Other indications included gastrojejunal anastomotic stenosis or stent exchange ($n = 4$; 6.45%), dysphagia ($n = 3$; 4.84%), follow-up of marginal ulceration ($n = 3$; 4.84%), and percutaneous endoscopic gastrostomy exchange ($n = 1$; 1.61%). Some patients had more than one indication though the primary indication was derived from direct chart review. Among patients with sutures identified on esophagogastroduodenoscopy though without reported symptoms, sutures were removed due to appearance suggesting a higher risk of future complications including sutures that cross the anastomosis and long redundant sutures.

Efficacy and Safety of Endoscopic Scissors Device

Surgical suture material was visualized in all included procedures with endoscopic cinches and tissue anchors noted in 4 cases. Suture-associated ulceration was visualized in 29.03% of cases. Overall, the endoscopic scissors device was able to successfully cut the suture material in 100% of patients. Technical success of the device was 100%. Removal of cut suture material was easily accomplished with the aid of rat-tooth forceps when required.

Symptom improvement post-suture removal occurred in approximately half of the patients (18 of 37 patients; 48.65%). Among the 22 patients with abdominal pain prior to procedure, 13 patients (59.09%) had resolution after suture removal. Post-procedure bleeding occurred in only 2 patients (3.23%). These episodes of bleeding were self-limited and did not require blood transfusion or further interventions. Two patients developed transient post-procedure abdominal pain with nausea and vomiting requiring admission to the hospital. Both patients improved with conservative management and were discharged a few days later.

Discussion

This single-center, retrospective study of a novel, disposable endoscopic scissors device demonstrated an impressive

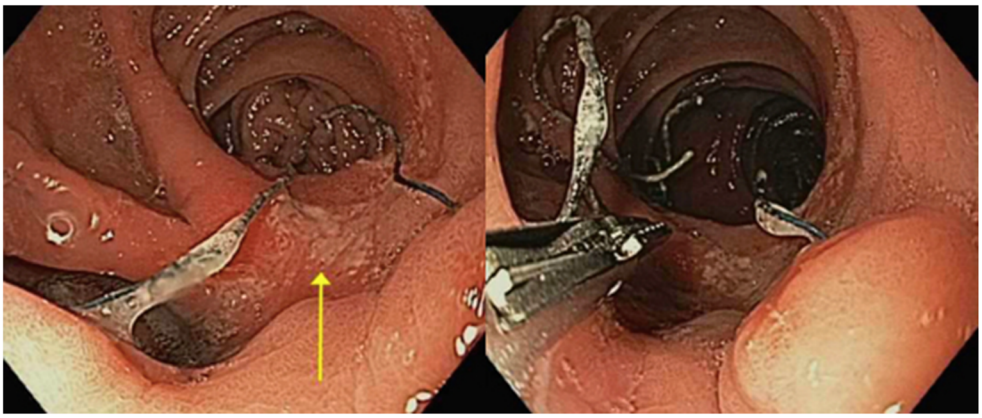

Fig. 3 Esophgogastroduodenoscopy of patient with Roux-en-Y gastric bypass visualizing long suture material-associated ulceration (yellow arrow) and successful removal with endoscopic scissors

technical success rate of 100%, ensuring safe and effective removal of suture material via endoscopic means with low rates of adverse events. There were no cases of unsuccessful endoscopic scissor use. Given symptomatic improvement post-suture removal, this study also validates previous literature that foreign bodies eroding into the gastric pouch may cause chronic abdominal pain in among patients who have undergone Roux-en-Y gastric bypass [13]. To these authors knowledge, this study is the first of its kind in evaluating the feasibility of these novel endoscopic scissors among patients with Roux-en-Y gastric bypass.

Table 1 Summary study characteristics of Roux-en-Y patients with suture removal

Number of patients	62
Mean age (years)	54.69 ± 9.40
Number of females (%)	59 (88.71%)
Time since Roux-en-Y (months)	142.43 ± 62.33
Moderate sedation (%)	38 (61.29%)
Mean procedure time (minutes)	23.00 ± 9.50
Suture appearance	
Long or redundant	27 (43.55%)
Crossing anastomosis	16 (25.81%)
Associated with ulcer	18 (29.03%)
Primary indications for EGD	
Weight regain	23 (37.10%)
Abdominal pain	19 (30.65%)
Nausea and vomiting	9 (14.52%)
Gastrojejunal stenosis	4 (6.45%)
Dysphagia	3 (4.84%)
Follow-up of marginal ulcer	3 (4.84%)
PEG exchange	1 (1.61%)

EGD esophgogastroduodenoscopy, *PEG* percutaneous endoscopic gastrostomy exchange

Retained sutures have been associated with marginal ulcerations or erosions when present at the gastrojejunal anastomosis and may cause unexplained abdominal pain in some patients. This concept of eroding foreign materials and exposed suture material causing local inflammation, ulcer formation, abdominal pain, and also bezoar formation has been demonstrated in previous literate to date [13–15]. Ryou et al. evaluated 21 patients with chronic abdominal pain for which the cause was believed due to exposed sutures, of which 5 patients were noted to have marginal ulcers [13]. All patients had suture material removed with a variety of instruments including grasping forceps, loop cutters, and rat-tooth forceps. Seventy-one percent of patients in this previous study reported immediate improvement of symptoms at follow-up.

Current approaches to retained sutures or foreign body material entail conventional, through-the-scope grasping forceps. This traditionally involves grasping the end of the suture and applying force by pulling the forceps back until the suture separates from the mucosa. This may often result in bleeding and potential worsening of pain. Although this has been postulated to potentially aid in confirming the etiology through endoscopic tugging to assess reproducibility of symptoms, and identify potential individuals that would derive clinical benefit, this has not been validated in previous clinical studies [13]. Alternatively, endoscopic through-the-scope loop cutters (Olympus America, Center Valley, PA) can be utilized to remove foreign material. However, it is important to note that this device is not disposable, can be costly, and may carry risk of infections if not cleaned and disinfected per standard distributor recommendations.

While multiple prior studies have assessed various through-the-scope scissor-like devices, many of these have been premised on tissue resection, such as those utilized to assist in endoscopic submucosal resection using an SB knife (SB Knife Jr.; Olympus America, Center Valley, PA, USA) or for the sole purpose of removing eroded prosthesis like vertical gastric bands [16–21]. To our knowledge, this is the largest

study to date assessing use of an endoscopic scissors device for successful resection and removal of retained sutures among patients with bariatric surgery.

In our study, we highlight that the technical success of 100% was achieved despite the device being utilized by 8 different endoscopists with varying years of expertise; thus confirming its feasibility and ease of use. No appreciable learning curve was needed. The high success rate associated with these scissors may be attributed to a unique design. When compared with conventional scissors that rely upon longitudinal forces which may diminish cutting quality, this device creates a lateral force to affect cutting. This may effectively allow for improved efficacy although head to head comparator studies are lacking. This study is also unique in that we addressed sutures among symptomatic and asymptomatic patients. In patients with sutures not associated with symptoms, sutures were removed due to appearance suggesting a higher risk of future complications. This included sutures that crossed the anastomosis that may lead to anastomosis obstruction and long redundant sutures that can cause ulcerations.

We acknowledge a few limitations to this study including its single-center and retrospective design. Although this study adds to available literature that suture removal can assist with pain and ulcer resolution as symptom improvement was noted in almost half of the patients, many of these patients were also placed on proton pump inhibitors and sucralfate which may have confounded these results. Additionally, there remains a lack of comparator studies to assess these novel, disposable scissors compared with other available products on the market. Finally, while we believe the disposable scissors do incur less costs, a cost-utility analysis would be of benefit to compare this device with other standard methods for suture and foreign body removal.

Overall, this study reveals that novel, disposable endoscopic scissors appear to be a highly effective and safe device. The observed high technical success rate and minimal adverse events suggest these scissors may aid in removal of foreign material within the gastrointestinal tract. This notion should have special relevance to an increasing number of gastroenterologists encountering bariatric surgery patients in clinical practice [13]. Larger studies are needed to reproduce this data and compare clinical outcomes as well as costs to non-disposable devices. Additionally, further studies should assess the feasibility of this device for removal of other foreign material.

Compliance with Ethical Standards

Conflict of Interest Christopher C. Thompson is a consultant for Boston Scientific, Olympus America, and Apollo Endosurgery. The other authors declare that they have no conflict of interest.

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