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*Observational Study***Double-nylon purse-string suture in closing postoperative wounds following endoscopic resection of large (≥ 3 cm) gastric submucosal tumors**

Wang SS *et al.* New suture of EFTR

Shan-Shan Wang, Meng-Yao Ji, Xu Huang, Yan-Xia Li, Shi-Jie Yu, Yu Zhao, Lei Shen

Abstract**BACKGROUND**

Endoscopic full-thickness resection (EFTR) for gastric submucosal tumors (SMTs) have been shown to be safe and effective, but postoperative wound management is equally important. Published data on suturing following EFTR of SMTs for large (≥ 3 cm) are scarce and limited.

AIM

To evaluate the efficacy and clinical value of double-nylon purse-string suture in closing postoperative wounds following EFTR of large (≥ 3 cm) SMTs.

METHODS

We retrospectively analyzed the data of 85 patients with gastric SMTs in the fundus of the stomach or in the lesser curvature of the gastric body, whose wounds were treated with double-nylon purse-string suture after successful tumor resection at the endoscopy center of Renmin Hospital of Wuhan University. The patients' operative, postoperative, and follow-up conditions were evaluated.

RESULTS

All tumors were completely resected under EFTR. 36 (42.35%) cases were located in the fundus of the stomach and 49 (57.65%) cases were located in the body of the stomach. All patients were sutured with double-nylon after EFTR without laparoscopic assistance or further surgical treatment. Postoperative fever and stomach pain were also reported in 13 (15.29%) and 14 (16.47%) individuals, respectively. There were no serious adverse events in intraoperative and postoperative period. Postoperative review of all patients did not reveal any residual or recurrent lesions.

CONCLUSION

Double nylon purse-string sutures can successfully close wounds that cannot be completely closed with a single nylon suture, especially in large (≥ 3 cm) EFTR wounds in SMT.

Key Words: Endoscopic full-thickness resection; Purse-string suture; Postoperative wounds; Submucosal tumors

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Core Tip: This study aimed to evaluate the clinical value of double-nylon purse-string sutures in closing gastric defects following submucosal tumor treatment with endoscopic full-thickness resection. Findings revealed that gastric wall defects were successfully closed using double-nylon purse-string sutures in patients with a tumor (≥ 3 cm), without laparoscopic assistance or need for further surgical treatment. There was also no recurrence or residue of lesions in all participants. We believe that our study

makes a significant contribution to the literature because it evaluates the safety and short-term efficacy of a novel closure method in gastrointestinal endoscopy.

INTRODUCTION

Submucosal neoplasms (SMT) are tumors occurring in the lower layer of the gastrointestinal mucosa^[1]. Endoscopic full-thickness resection (EFTR) is becoming increasingly used in patients with deep lesions such as SMT because it results in minimal trauma and retention of the original anatomy and function of the stomach^[2,3]. EFTR can be regarded as the “last resort” of endoscopic treatment, similar to surgical resection, which can treat deeper lesions and make histological assessment more complete^[4]. However, when treating SMT with EFTR, the lesion is completely removed through “active perforation”^[5]. Consequently, it's essential to suture the wound's surface after tumor removal. After tumor resection with EFTR, the most critical issue is how to completely close the gastric wall defect, which is also the primary safety consideration for the clinical implementation of EFTR. Incomplete closure may lead to a higher rate of late perforation and even further surgical repair.

In recent years, various closure techniques have been used to suture gastric wall defects after EFTR, including wound clipping, endoscopic stapling, endoscopic full-layer folding system, over-the-scope-clip system, the Overstitch™ endoscopic suturing system, and bioabsorbable fillers^[6-9]. Some of these closure methods are simple to operate but can hardly achieve complete closure of large gastric wall perforation. However, some other endoscopic devices are relatively expensive and challenging to operate, which prevents them from being widely used in medical institutions.

In the absence of special devices or equipment, endoscopists in our endoscopy center practiced using double-nylon rope for purse-string sutures based on the single-nylon rope purse-string suture technique for large (≥ 3 cm) SMTs. This study aimed to analyze the safety and short-term efficacy of this novel closure method.

MATERIALS AND METHODS

Study design

This study was a retrospective single-arm clinical trial. Case inclusion criteria were as follows: (1) tumor located in the stomach and confirmed to originate from the muscularis propria on endoscopic ultrasonography; (2) tumor diameter ≥ 3 cm, no adhesion between the tumor and peritoneal tissues and organs, confirmed on ultrasonic endoscopy and computed tomography; (3) tumor showed no characteristics of malignancy under endoscopic ultrasonography, such as irregular boundary, numerous blood vessels, ulcers on the surface, strong echo focal area, or uneven echo under endoscopic ultrasonography; and (4) The patient was able to tolerate tracheal intubation anesthesia, and no coagulation dysfunction or anticoagulant drugs had been stopped before EFTR.

One of the authors of this study (Wang SS) independently analyzed patients' medical records from our hospital's endoscopy database as part of a quality assurance program. Between June 2019 and June 2022, 128 patients with large (≥ 3 cm) upper gastrointestinal SMTs were resected by the same endoscopist and closed with double-nylon purse-string suture in our endoscopy center. Based on the tumour site, we included 36 patients with gastric fundus SMTs and 49 patients with gastric body lesser curvature SMTs in this study.

All included patients provided informed consent after spoken and written detailed explanations regarding the endoscopic resection procedure and other possible treatment options. Furthermore, all patients were informed that surgery might be required if the tumor could not be removed en bloc endoscopically or that severe complications might not be managed by conservative treatment and/or endoscopic methods. The main outcome measures for this study were: (1) complete resection; (2) Complete wound closure; and (3) postoperative complications.

Devices

Gastroscope (GIF-Q260J, Olympus, Japan), electronic endoscopy system (Olympus-LUCERA CV-290), high-frequency electric coagulation and electrocution device (ERBE

VIO-200D), disposable high-frequency therapeutic forceps (FD-410 LR), hooking knife (Olympus), IT knife, dual knife, titanium clip release device (Olympus), snares, nylon ropes (MAJ340, MAJ254, Olympus), and CO₂ air pump were used. A transparent cap (D-201 series) was joined at the end of the endoscope during the treatment.

Surgical procedure

Within this study, the selection of employing double-nylon to strengthen the purse suture was determined by the wound condition after the single-nylon purse-string suture. Factors taken into consideration encompassed intraoperative sutures, creases, tension, and other pertinent variables.

The whole endoscopic procedure consisted of six main steps: (1) The location of the tumor was confirmed under endoscopic guidance, and the mucosa was incised to reveal the lesion; (2) Complete resection of the tumor through EFTR; (3) Wound treatment, observation, and evaluation of the gastric wall defect; (4) The gastric wall defect was closed with a single-nylon rope “purse-string suture;” (5) A second nylon rope was inserted to reinforce and close the treated wound again; (6) The endoscope was removed after confirming satisfactory closure, and the surgery was completed.

The process of executing double-nylon purse-string sutures was as follows (Figures 1-2): (1) The nylon rope was clamped using foreign body forceps inserted in the stomach cavity along with the endoscope and placed at the wound. The foreign body clamp was removed, and the titanium clamp was pushed through the biopsy channel. A titanium clip was used to clamp the distal end of the nylon rope on the normal mucosal tissue around the wound. The titanium clips were continued to be fixed around the wound in an annular shape at equal distances. The nylon-string outer casing was pushed forward, keeping the titanium clips vertical. The nylon rope was tightened to close the wound's distal and proximal gastric wall. The procedure of single-nylon purse-string sutures can be seen in our previous study^[10]; (2) The second nylon rope was advanced through the biopsy channel into the stomach cavity. Care was taken that the second nylon rope could wrap around the wound closure and all titanium clips; (3) The nylon loop was

pushed down to tighten the nylon rope. Whenever it was found that the nylon rope might slip from the holding place of the titanium clip, the position of the titanium clip was adjusted using the foreign body forceps to help the nylon rope reach the base of the wound; and (4) When the position of the second nylon rope was correct and not easy to move, the nylon rope was tightened to complete the secondary closure of the wound. Finally, the stomach was injected with CO₂ to observe whether the stomach cavity was inflated and filled to evaluate the success of the perforation closure. This closure process can be summarized as two main steps: (1) the initial closure of the wound surface using the single-nylon rope and the titanium clip; and (2) the reinforcement and closure of the second nylon rope.

Outcomes and follow-up

The operation time, closure time, and patient conditions during follow-up were observed. Operation time refers to the time of the entirety tumor extraction process. The closure time is defined as the interval between the commencement of nylon rope and titanium clip insertion and the culmination of the tightening of the second nylon rope.

After fixation, the excised lesions were delivered to the pathology department to study the pathological nature and immunohistochemical examinations. The patients were asked to avoid eating or drinking within 72 h postoperatively. The patients' vital signs were closely monitored along with symptoms such as fever, abdominal pain, melena, and peritonitis. Concurrently, standard measures were implemented, including gastrointestinal decompression, conventional fluid infusion, administration of proton pump inhibitors, hemostatics, antibiotics, and gastric mucosal protective drugs in oral form. Gastroscopy was scheduled at 3, 6, and 12 months postoperatively, followed by annual examinations thereafter.

End points and subgroup analyses

The primary outcome was the success rate of purse suture using nylon ropes and titanium clips in all patients, and whether all tumors were resected and taken out.

Secondary outcomes were total operation time and treatment outcomes (fever, abdominal pain, delayed perforation, and mean length of hospital stay) for EFTR. These endpoints were also compared between the two groups and subgroups. We selected lesion location and diameter for further subgroup analysis.

7 Statistical analysis

The data obtained from the experiments described above were analyzed using SPSS 23.0 software (IBM SPSS Inc., Armonk, NY, United States). Statistical data were expressed as rate (%), and χ^2 test was used for comparison between groups. Measurement data were expressed as mean \pm SD, and comparison between groups was performed by T test. P values < 0.05 were considered to be statistically significant.

RESULTS

Endoscopic treatment

The maximum diameter of lesions in this group was 5.0 cm (3.63 ± 0.54 cm). The tumors in all 85 cases were completely resected using EFTR. The gastric wall defect was successfully closed using the double-nylon purse-string suture (Figure 2). All procedures were completed under endoscopic guidance without laparoscopic assistance or transferred to surgery for further treatment. The mean operation time was 69.63 ± 21.09 min, the mean single nylon rope closure time 26.73 ± 6.89 min, and second nylon rope reinforcement time 5.98 ± 1.67 min. 6 titanium clips were used in 41 (41/85, 48.24%) patients, 7 titanium clips were used in 31 (31/85, 37.65%) patients; 8 titanium clips were used in 10 (10/85, 11.76%) patients; and 9 titanium clips were used in 2 (2/85, 2.35%) patients. The pathological results of all cases showed complete resection of the tumor and no obvious disruption of the tumor capsule. There were 59 cases of gastrointestinal stromal tumor (52 cases of fusiform cell type, 7 cases of mixed type), 23 cases were of leiomyoma, and 3 cases were of schwannoma. No serious adverse events occurred intra- and postoperatively. Patients were discharged after an average of 6.6 ± 0.74 d postoperatively (Table 1).

Adverse events

The main intraoperative adverse event of EFTR was bleeding. Bleeding was noticed in all patients intraoperatively, and hemostasis was performed successfully. No postoperative bleeding was observed in any case. Postoperative abdominal pain and fever were defined as mild complications in this study; none of the patients had serious complications. Postoperatively, 13 patients developed a low fever. Antibiotic treatment and gastrointestinal decompression were administered, and the patients were strictly confined to bedrest. The body temperature returned to normal on the second day postoperatively. Postoperatively, 14 patients had mild pain in the upper abdomen. Whenever necessary, abdominal ultrasound B was performed to determine whether the patients had exudation in the abdominal cavity. Through timely blood analysis and monitoring of vital signs, it was observed that the symptoms of abdominal pain resolved on their own.

We selected lesion location for further subgroup analysis (Table 2). Notably, no statistically significant disparities were observed between the subgroup focusing on the fundus of the stomach and the subgroup centered on the body of the stomach, concerning postoperative complications, operative time, closure time, the number of metal titanium clips, and postoperative hospital stays ($P > 0.05$). We also performed subgroup analysis based on diameter, which were divided into two subgroups: the < 4 cm subgroup and the ≥ 4 cm subgroup (Table 3). In the diameter subgroup, noteworthy statistical differences in postoperative abdominal pain ($P = 0.011$), low fever ($P = 0.005$), operation time ($P = 0.000$), the number of metal titanium clips ($P = 0.000$), and postoperative hospital stays ($P = 0.019$). Conversely, no statistically significant discrepancies were observed between the diameter subgroups in terms of single-nylon rope purse-string suture and second nylon rope reinforcement time ($P > 0.05$).

Follow-up

All patients were required to receive gastroscopy reexamination 3, 6, and 12 months postoperatively ¹ to check the healing situation of the postoperative wound surface. Meanwhile, ultrasonic gastroscopy could be used to detect recurrence and residues. All 85 patients underwent gastroscopy 3 months postoperatively, and all perforations were closed, among whom 28 (28/85, 32.94%) patients still had titanium clips and nylon rope residue on the wound (Figure 3). 6 months postoperatively, 13 (13/85, 15.29%) patients still had titanium clips and nylon rope residue. 12 months postoperatively, 4 (4/85, 4.71%) patients had titanium clips and nylon rope residue. All wounds had healed completely (Figure 3). No lesion residue or recurrence was observed on gastroscopy in any patient.

DISCUSSION

With the progress of endoscopic technology and the continuous update of endoscopic-assisted therapy instruments, most gastrointestinal submucosal tumors can be completely resected^[11]. ² However, in daily clinical practice, some patients with large (≥ 3 cm) upper gastrointestinal SMTs are unwilling to risk surgical complications and prefer endoscopic resection to surgical resection. In addition to ensuring R0 resection of the tumor, the successful repair of wound defects after EFTR is the pivotal step for achieving favorable outcomes in endoscopic treatment^[12]. It is also a difficult part of endoscopic treatment of gastrointestinal SMTs and an important step in minimizing complications and obviating the need for subsequent surgical interventions.

The technique of wound defect closure under endoscopy is more and more safe and effective. From pure titanium clips closure to the joint suture of titanium clip and nylon rope, from double forceps endoscopy to single forceps endoscopy and the emergence of various new sealing instruments (such as OTSC, *etc.*)^[13,14]. This study introduced a simple and innovative approach to endoscopic closure treatment, which can effectively and safely close the gastric wall wound. Double-nylon purse-string sutures can achieve a more reliable and secure closure that is all for large gastric wall defects compared titanium clip closures. This is particularly beneficial for SMTs larger than 3 cm, as it

enhances the stability of wound closure compared to single-nylon purse-string sutures. Additionally, this technique possesses economic advantages and is more readily conducive to widespread adoption compared to devices such as OTSC.

All patients in this study had lesions ⁵ located in the fundus of the stomach or in the lesser curvature of the gastric body, which were deliberately selected as these are common sites for gastric SMTs^[15,16]. These specific locations are characterized by higher gastric wall tension, or the mucosal muscularis layer is more pliable. In some cases in this study, even after the successful completion of a single-nylon rope purse-string suture, gaps on the wound surface were still observed (Figure 4). The addition of a second nylon rope for fixation allowed for complete closure of these wound surfaces. Therefore, for SMTs larger than 3 cm resected through EFTR, the use of a double-nylon rope purse-string suture proved to be safer and more effective than a single nylon rope suture.

The study conducted a further analysis in subgroups. The results showed that when lesions were located in different locations, there were no significant differences observed in operation time, closure time, number of metal titanium clips used, postoperative hospital stays, complications, and residual apparatus after the operation. However, when subgroup analyses were performed based on lesion size, significant between-group differences were found in operation time, number of metal titanium clips used, complications, and postoperative hospital stays. This can be attributed to the fact that larger lesions require resection over a larger area, resulting in increased operation time and the use of more metal titanium clips. The increased resection time is also associated with a higher likelihood of minor postoperative complications. However, no differences were observed in the comparison of closure time and postoperative instrument residue. From these findings, we can conclude that even if the diameter of the lesion is large, there is no significant increase in the technical difficulty of suturing, and better suture results can be achieved.

One patient in the study had throat discomfort and hoarseness after surgery. We're considering dislocating the cricoarytenoid joint by removing the tumor. It returned to

normal after manual reduction. We did not take part in the analysis since we did not think this was a problem during excision and suture.

In the purse-string suture technique, endoscopists can easily clamp the mucosal edges of the gastric wall incision using titanium clips when securing the nylon ropes. However, when dealing with larger wounds, instrument-assisted closure can increase the tension on the gastric wall, which may exceed the strength of endoscopic-assisted instruments. To address this, a second nylon rope is used for reinforcement and tightening to gradually close the defect in the gastric wall. The addition of the second nylon rope was prompted by the observation that after EFTR of lesions with relatively large diameters, there were still gaps present on the wound surface following a single-nylon rope purse-string suture. When a large number of titanium clips are required for fixation, the volume of the instrument can cause cracks when tightening the clips, and these gaps cannot be eliminated by tension from the nylon rope. Reducing the number of titanium clips used would result in larger mucosal gaps between the clips, and the folds formed by the mucosa during tightening would create additional gaps. To address this issue, a second nylon rope is employed for secondary ligation either at the root of the titanium clip or at the base of the mucosa. This further increases the pressure, helps gather the mucosa around the wound, and effectively prevents the occurrence of these gaps. On the lesser curvature of the stomach body, there are more and deeper gastric wall folds, making post-closure gaps more likely to occur during the tightening process of the nylon rope. The use of a second nylon rope for secondary fixation can help avoid such post-closure gaps and ensure a more secure closure.

Furthermore, during EFTR, repeated electrocoagulation of the mucosa is necessary to ensure a smooth and safe operation. To address this issue, the use of a secondary nylon rope for fixation helps reduce tension and ensures that the position of the titanium clips is not easily displaced or lost. In cases where the lesions are located in the lesser curvature of the gastric body, which has numerous folds and can result in a poor visual field, there may be uncertainties in clamping the titanium clips. In such situations, the complete sealing of the wound surface can be achieved through the secondary fixation

of a nylon rope. This further stabilizes the suture effect of the titanium clips and the first nylon rope, preventing premature detachment of the suture material and reducing the risk of postoperative complications. Overall, the use of a secondary nylon rope for reinforcement and stabilization is beneficial in cases where there is mucus hyperemia and edema, as well as in situations with poor visualization and uncertain clamping of titanium clips. It helps ensure a secure closure, prevents complications, and enhances the overall success of the procedure.

The success of the purse-string suture depends on correct wound size evaluation¹⁴ and appropriate titanium clip and nylon rope selection. When placing the second nylon rope over the wound after the initial purse sutures, care should be taken to maintain the nylon rope on the outside of all titanium clips. This ensures that the second nylon rope can completely wrap around the base when tightened, closing any gaps after the initial closure. Double-nylon rope purse-string suture greatly broadens the indication range of traditional purse suture, and enables more SMTs to be treated with minimally invasive endoscopic resection.

In this study, the focus was on studying large lesions with a diameter of 3 cm or greater. The double-nylon rope purse-string suture technique demonstrated a 100% success rate in achieving wound closure. No severe adverse events were observed in the postoperative period, and there were no cases of gastrointestinal leakage or sinus tract formation. All wounds healed completely with scars during the follow-up period.

Based on these results, it can be concluded that the double-nylon rope purse-string suture method is safe and effective, particularly for lesions with a diameter of 3 cm or larger ⁵ located in the fundus of the stomach or the lesser curvature of the gastric body. Our study was a retrospective, non-randomized, single center study and the sample size in the study was small, it has many limitations. It is important to note that the study did not explore the application of this closure technique for wound defects in other parts of the stomach or digestive tract. To further validate and expand the application of this technique, it is necessary to increase operational experience and conduct additional clinical operations. Continued research and clinical validation will

contribute to a better understanding and broader implementation of this closing technique.

CONCLUSION

In summary, the double-nylon rope purse-string suture technique is a viable, ³ effective, and safe method for closing gastric wall defects following EFTR for gastric SMTs. It offers several advantages over traditional and previously reported methods, including ease of operation, cost-effectiveness, and favorable prognostic outcomes. It is hoped that additional studies will be conducted to enhance the scientific understanding of this closure method and ultimately benefit a larger number of patients.

ARTICLE HIGHLIGHTS

Research background

Endoscopic full-thickness resection (EFTR) is increasingly employed in patients with deep lesions, such as submucosal tumors (SMTs), due to its minimal invasiveness and preservation of stomach anatomy and function. EFTR is considered a last-resort endoscopic treatment, like surgical resection, as it allows for the removal of deeper lesions and enables more comprehensive histological assessment. However, during SMT treatment with EFTR, the lesion is completely removed through intentional perforation, necessitating the closure of the resulting wound. Effective closure of the gastric wall defect is crucial for patient safety and the successful implementation of EFTR. Inadequate closure may lead to a higher risk of delayed perforation, requiring subsequent surgical intervention. In recent years, a variety of closure techniques have been utilized to suture gastric wall defects following EFTR. These methods include wound clipping, endoscopic stapling, the endoscopic full-layer folding system, the over-the-scope-clip system, the Overstitch™ endoscopic suturing system, and bioabsorbable fillers. While some of these techniques are straightforward to execute, they may not achieve complete closure for larger perforations of the gastric wall. On the

other hand, certain advanced endoscopic devices are relatively expensive and demand a higher level of expertise, limiting their widespread adoption in medical institutions.

Research motivation

To find a more economical, practical and convenient wound closure method for large wound after EFTR.

Research objectives

The double-nylon rope purse-string suture technique is a viable, ³ effective, and safe method for closing gastric wall defects following EFTR for gastric SMTs. It offers several advantages over traditional and previously reported methods, including ease of operation, cost-effectiveness, and favorable prognostic outcomes. It is hoped that additional studies will be conducted to enhance the scientific understanding of this closure method and ultimately benefit a larger number of patients.

Research methods

This study was a retrospective single-arm clinical trial.

Research results

The double-nylon rope purse-string suture technique is a viable, ³ effective, and safe method for closing gastric wall defects following EFTR for gastric SMTs.

Research conclusions

The double-nylon rope purse-string suture method is safe and effective, particularly for lesions with a diameter of 3 cm or larger ⁵ located in the fundus of the stomach or the lesser curvature of the gastric body.

Research perspectives

Wound closure of large wound after EFTR.

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