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A new endoscopic treatment for gastric fundal subepithelial lesions using loop-assisted inversion and double suture technique

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The loop-assisted inversion and double suture technique has been used as an endoscopic treatment for gastric fundal subepithelial lesions. This study aimed to analyse the efficacy and safety of the loop-assisted inversion and double suture technique for the treatment of gastric fundal subepithelial lesions. Consecutive patients with gastric fundal tumours who underwent the loop-assisted inversion and double suture technique at our centre between January 2023 and January 2024 were retrospectively assessed. The primary outcome was surgical success. Twelve patients with 14 gastric fundal subepithelial lesions underwent the loop-assisted inversion and double suture technique during the study period. Two patients had double lesions. Pathology confirmed that out of 14 lesions, 12 were gastrointestinal stromal tumors and 2 were leiomyomas.All the gastrointestinal stromal tumors were of low-risk G1. Operative success was achieved in 14 lesions with complete resection, with no intraoperative transfer to surgery; no adverse effects, including postoperative perforation and bleeding; and no postoperative antibiotic use. During the follow-up period, all 14 lesions showed no recurrence. The loop-assisted inversion and double suture technique is a safe, effective, and time-saving endoscopic treatment for gastric fundal subepithelial lesions. However, prospective large-scale multicentre studies are required.

Keywords Loop-assisted inversion and double suture technique, Gastric fundal subepithelial lesions, Surgical success, Procedure time, Postoperative adverse events

Gastric subepithelial lesions (SELs) are tumours that originate from the muscularis mucosa, submucosa, or muscularis propria[1]. SELs are frequently observed owing to the increasing number of patients undergoing endoscopy[2]. Some of these tumours, such as gastrointestinal stromal tumours (GISTs), have malignant potential. Despite recent revolutionary breakthroughs in the treatment of GISTs by the introduction of targeted tyrosine kinase inhibitors (TKIs), complete resection of the tumour remains the preferred treatment for patients with GISTs. Endoscopic resections, such as endoscopic mucosal dissection (ESD) and endoscopic full-thickness resection (EFTR), are the standard endoscopic treatment methods for gastric SELs[3].

SELs located in the gastric fundus have a 50% rate of perforation under ESD or EFTR, which is higher than those in other gastric locations, such as the gastric body and cardia[4]. Although endoscopic suture techniques have improved, switching to surgical resection, post-bleeding, and infection are inevitable problems for gastric fundus SELs using ESD or EFTR[5].

We reported the first case of a loop-assisted inversion and double suture technique (LAIDST) to successfully treat gastric fundal SELs without postoperative bleeding, perforation, or infection[6].

The LAIDST can convert an inaccessible gastric fundal tumour into an inverted tumour-like polyp, which is easy to access, time-saving, and unable to present intraoperative massive haemorrhage, post-bleeding, and infection because of the preligation method. However, the efficacy and safety of the LAIDST for the treatment of gastric subepithelial lesions have not yet been clarified.

In this study, we aimed to assess the effectiveness and safety of the LAIDST for gastric LELs by retrospectively analysing 12 patients with 14 gastric fundal LELs treated by the LAIDST.

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Materials and methods

Study design

We conducted a retrospective case series study in a tertiary hospital (Nanchong Central Hospital, Second Clinical Medical College, North Sichuan Medical College, Nanjing, China). This study was approved by the Ethics Committee of Nanchong Central Hospital, The Second Clinical Medical College, North Sichuan Medical College. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki (6th revision, 2008).

Patients

We collected data from consecutive patients with fundic tumors who underwent LAIDST at our center between January 1, 2023, and January 1, 2024. We accessed the data retrospectively on May 1, 2024. We had access to information that could identify individual participants during data collection. All patients underwent endoscopic ultrasonography (EUS) and abdominal computed tomography (CT) scans to identify whether the gastric fundal lesions were tumours or external pressure from normal organs, such as the spleen or artery. Patients with tumours > 3 cm in size or suspected tumour metastasis, such as hepatic metastasis under abdominal CT scan, were excluded from this study. All included patients underwent a preoperative conversation with a detailed explanation of the advantages and disadvantages of the different operations involving EFTR, surgery, and the LAIDST. All patients signed the informed consent to undergo the LAIDST. Patients are recommended to undergo endoscopic follow-up at our hospital at 1 month, 3 months, 6 months, and 12 months postoperatively. We collected data on patients' age, sex, location of gastric fundal lesions (anterior wall of the gastric fundus, posterior wall of the gastric fundus, and gastric fundus fornix), size range of the lesions, histopathological results, operation time, fasting times, postoperative complications (delayed postoperative bleeding or perforation), postoperative infections (intra-abdominal abscess, pulmonary or urinary tract infection), postoperative antibiotic use, postoperative hospital stay duration, and hospital cost.

Procedures

All LAIDST procedures were performed by a skilled endoscopist, who had performed ≥ 300 EFTR for gastric fundal tumours before this study. All patients fasted for > 12 h and underwent general anaesthesia induction with intubation. All LAIDST procedures were performed using SonoScape endoscopes (Kai Li, Beijing, China) and routine EFTR instruments: loop instrument, metal clips, IT knife, electric knife, and 11-mm-diameter white cap.

The following steps were performed in the LAIDST procedure (see Supplementary Video S1) (Fig. 1): (1) circumferentially incising the mucous and submucosal layers 0.5 cm away from the label point using gold and IT knives after submucosally injecting methylene saline following the circumferential labelling of the tumour lesion border using an electric knife with a forced coagulation ERBE mode, (2) fastening the loop with metal clip 1 cm away from the circumferential incision, (3) pre-tightening the loop after pulling the tumour into the gastric cavity using the snare that trapped the incised circumferential mucosa, (4) exposing the tumour root by IT knife incision, (5) completely electrically cutting the tumour using a snare, (6) suturing the inverted wound surface using metal clips, and (7) double suturing the wound by releasing the tightened loop. The patients fasted for 3 days after the procedure without intravenous or oral antibiotic use. Patients were treated with a 3-day course of PPIs.

Outcomes and definitions

The primary endpoint of this study was successful LAIDST. The secondary endpoints were procedure time, postoperative adverse events, postoperative antibiotic use, postoperative hospitalisation days, and recurrence. Surgical success was defined as complete tumour resection without transfer to surgery because of unmanageable bleeding or perforation. Postoperative adverse events were defined as delayed postoperative bleeding or

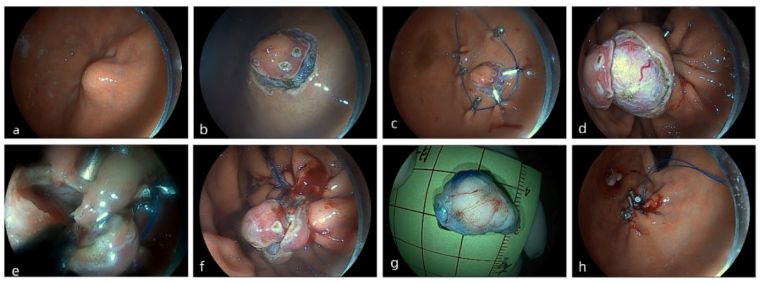

Fig. 1. Procedure images of the loop-assisted inversion and double suture technique. (**a**) A gastric fundal tumour; (**b**) circumferential incision mucous and submucosal layers 0.5 cm away from the label point; (**c**) fastening the loop using a metal clip 1 cm away from the circumferential incision; (**d**) pre-tightening of the loop after pulling the tumour into the gastric cavity using the snare that trapped the incised circumferential mucosa; (**e**) exposing the tumour root using an IT knife; (**f**) completely electrically cutting the tumour using a snare; (**g**) the excised tumour; (**h**) double suturing the wound by suturing the inverted wound surface using metal clips and releasing the tightened loop.

perforation[7]. Postoperative antibiotic use was defined as passive antibiotic use owing to postoperative infection. Postoperative infection was defined as a postoperative intraperitoneal abscess or pulmonary or urinary tract infection, which relied on symptoms and signs of respiratory infection, elevated white blood cell and neutrophil counts in complete blood analyses, and positive chest radiography and CT findings[8]. Urinary tract infection was diagnosed with a positive urine culture showing bacterial counts of ≥100,000/mL, a neutrophil count in the urine of ≥10/mL, and corresponding clinical manifestations[9]. The diagnosis of postoperative intraperitoneal abscess was based on postoperative CT imaging[10]. Recurrence was defined as the presence of a tumour at the same gastric fundal site. All patients were followed up for recurrence through January 2024. The patients were notified by telephone postoperatively to arrange for a standard upper gastrointestinal endoscopy in the outpatient clinic, and histopathological assessments were performed, as necessary.The pathological assessment of resection margins involved: (1) Determining whether the tumor capsule was intact. (2) Using immunohistochemistry to evaluate the presence of positive markers at the outer margin of the tumor, including gastrointestinal stromal tumor (GIST) markers (CD117, DOG1, CD34) and leiomyoma markers (SMA, Desmin, h-caldesmon).

Statistical analyses

Statistical analyses were performed using the SPSS version 28.0.1.1 statistical software (SPSS Inc., Chicago, Illinois, USA). Count numbers and percentages were used as categorical variables. For continuous variables, medians and ranges were used.

Results

Twelve patients with 14 SELs in the gastric fundus underwent the LAIDST. Two patients had double lesions in the gastric fundus. The characteristics and outcomes of the 14 lesions are presented in Table 1. The median age of the patients was 61 (range, 45–76) years. There were nine females and three males. Four lesions were located in the gastric fundus fornix, two in the posterior wall of the gastric fundus, two in the anterior wall of the gastric fundus, and six in the gastric fundus fornix (Fig. 2). Lesion sizes ranged from 8 to 22 mm, with a median size of 12 mm.Resection Margin Status: 1.All tumors showed negative margins after local excision, with no residual tumor. 2.Immunohistochemical Characteristics: 12 cases were diagnosed as gastrointestinal stromal tumors, and 2 cases were diagnosed as leiomyomas.All the gastrointestinal stromal tumors were of low-risk G1.

Twelve patients with 14 gastric fundal SELs underwent successful surgery. The median procedure time was 20 (range, 12–40) min. None of the 12 patients underwent intraoperative transfer to surgery because of extraluminal bleeding, which was difficult to control, or because of perforation. Moreover, no postoperative antibiotics were administered in any of the 12 patients without postoperative adverse events involving delayed bleeding and perforation. Gastric tubes were implanted in 12 patients after endoscopic surgery. The fasting time

Age, median (range), years	61 (45,76)
Genda, n(%)	
Male	3 (25)
Female	9 (75)
Lesion site, n (%)	14 (100)
Greater curvature of gastric fundus	4
Posterior wall of gastric fundus	2
Anterior wall of gastric fundus	2
Gastric fundus fornix	6
Lesion size, median (range), mm[1]	12 (8, 22)
Procedure time, median (range), minutes	20 (12, 40)
Operation success, n(%)	14 (100)
Intraoperative transferring to surgery, n	0
Postoperative adverse events, n	0
Postoperative delayed bleeding, n	0
Postoperative delayed perforation, n	0
Postoperative antibiotics use, n	0
Postoperative gastric tube implantation, n(%)	12 (100)
Histological type, n(%)	
Stromal tumor, G1	12 (86)
Leiomyomas	2 (14)
Fasting time, days	3
Postoperative hospital stays, days	3
Hospital cost, median(range), yuan	22,133 (15873, 27801)
Follow-up time, median (range), months	6 (1,12)
Recurrence, n(%)	0 (100)

Table 1. Characteristics and outcomes of all 12 patients with 14 lesions. [1]mm means millimeter.

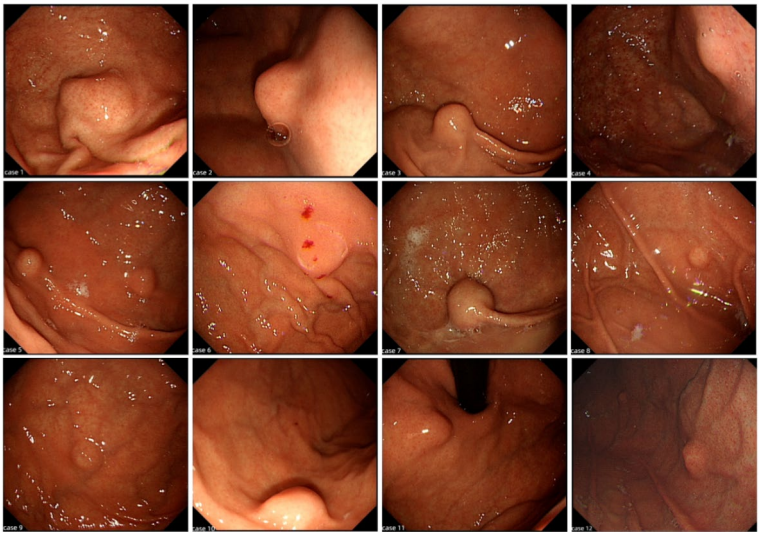

Fig. 2. Images of 12 patients with 14 gastric fundal subepithelial lesions. The image of patient 1 has been published previously[6]. Both patients 5 and 12 had double gastric fundal subepithelial tumours.

and postoperative hospital stay were 3 days. The median hospital cost was 22,133 (range, 15873–27801) yuan. No recurrence occurred during the median follow-up period of 6 (range, 1–12) months.

Discussion

Gastric subepithelial lesions (SELs) include gastrointestinal stromal tumors and gastric leiomyomas, among others. With the escalating identification of patients having gastric SELs via endoscopic examination, most asymptomatic SELs are characterised by small lesions devoid of depression, slight elevation, and coverage by intact normal mucosa, leading to a classification of these lesions as slow-growing and generally clinically irrelevant. Nevertheless, within this category, certain types of tumours, such as GISTs, are recognised for their potential malignancy. Specifically, high-risk GISTs can rapidly increase in size, undergo metastasis, and pose a significant threat to the lives of individuals[11].

GISTs are the most common mesenchymal tumours of the gastrointestinal tract and are currently treated with pharmacotherapy, surgical excision, and endoscopic resection. A revolutionary breakthrough in the pharmacological treatment of GISTs has been achieved recently with the introduction of targeted TKIs, and the elucidation of the molecular pathogenesis of GISTs has allowed the rational translation of basic science into clinical therapies targeting the root cause of the disease, usually proto-oncogene, receptor tyrosine kinase (KIT) or platelet-derived growth factor receptor alpha (PDGFRA) mutations. PDGFRA encodes PDGFRa, which, similar to KIT, belongs to the family of type III receptor tyrosine kinases. Constitutively activating mutations of KIT are often present in GISTs and result in increased cell proliferation and enhanced survival. Mutations occur most commonly in the juxtamembrane exon 11 of the gene (in 65% of all GISTs), whereas 10% of GISTs have KIT exon 9 mutations and 2% exon 13 or exon 17 mutations. Among them, the response to imatinib is the greatest in terms of the juxtamembrane exon. The molecular biology of wild-type GISTs with respect to KIT and PDGFRA is incompletely understood, but the KIT tyrosine kinase appears to be activated in many of these tumours, despite the lack of detectable KIT mutation[12]. The inhibition of these driver mutations has improved disease control, leading to increased survival of patients with GISTs[13]. In patients with metastatic GISTs, the application of TKIs has extended the median survival from 1 year to 57 months, thereby significantly altering the prognosis for patients with metastatic GISTs[14,15]. TKIs can also be utilised in an adjuvant setting, where postoperative use aids in preventing disease recurrence and improving overall survival[16,17]. Despite the remarkable effects of TKI treatment on GISTS, recurrence and metastasis remain common, and resistance to these inhibitors remains a challenge. Several studies have demonstrated the safety and prognosis-improving benefits of surgery, even in metastatic scenarios, and have updated original operative techniques[18]. Complete surgical resection is the standard treatment approach[19].

EUS and CT are the diagnostic techniques for SELs[11]. In the present study, all 14 lesions were found to originate from the muscularis propria on EUS and CT. SELs at the gastric fundus originating from the muscularis propria under EUS localisation have a high probability of being GISTs[20]. The clinical manifestations of GISTs are diverse, ranging from benign to fully malignant, making their prognosis unpredictable. Apart from evident metastases at the time of surgery, predicting the malignant potential of GISTs based solely on their clinical manifestations is challenging. The histological grading of most GISTs is relatively low, further complicating the histological distinction between benign and malignant GISTs[21]. Even small GISTs have malignant potential[11,22]. Therefore, resection of gastric GISTs > 20 mm in size is also considered[1]. Leiomyomas are benign, and asymptomatic cases generally do not require surveillance or resection. Patients with disease-specific symptoms, such as gastrointestinal bleeding, or those with size increments are recommended to undergo endoscopic resection and

surgery. Asymptomatic patients without evidence of size increment are advised to undergo endoscopic resection and surgery only when lesions exhibit malignant features[23,24].

Compared with surgical resection, endoscopic resection offers similar safety and efficacy and advantages, such as minimal invasiveness, better preservation of organ structure and functionality, and a more accurate incision line for intraluminal lesions[25]. Consequently, ESD and EFTR are recommended as the standard endoscopic treatment modalities for gastric SELs[1,3].

However, for SELs located at the gastric fundus, both ESD and EFTR present challenges in accessing the gastric fundus and exhibit a perforation rate of 50% at this location, which is higher than that observed in SELs of other gastric regions, such as the gastric body and gastroesophageal junction[4]. Endoscopic therapy for gastric GISTs with a nonintraluminal growth pattern, gastric fundus, and large tumour size are independent risk factors for perforation[26]. Although endoscopic suture techniques have improved[27], perforation leading to possible abdominal infection, abdominal cavity planting increasing the risk of GIST, switching to surgical resection, post-bleeding, and infection are inevitable problems for gastric fundal SELs using ESD or EFTR[5].

This study revealed that among the 14 SELs in 12 patients, 12 SELs were pathologically confirmed as gastrointestinal stromal tumors, and 2 SELs were confirmed as leiomyomas. All SELs were successfully resected using the LAIDST with short procedure times, no intraoperative transfer to surgery, no postoperative delayed bleeding and perforation, no postoperative antibiotic use, and no recurrence, confirming that the LAIDST is a safe, effective, and time-saving method for treating gastric fundal SELs.

The LAIDST can enable an inaccessible gastric fundal tumour to enter an inverted tumour-like polyp, which is easy to access and time-saving and does not present intraoperative massive haemorrhage, post-bleeding, and infection. The LAIDST includes three key techniques: inversion technique, preligation technique, and double suturing.

Endoscopic resection of SELs at the gastric fundus showed high perforation and bleeding rates because of the inaccessibility and thin muscularis propria. However, the inversion technique uses a snare to pull the SELs into the gastric cavity similar to a polyp, making it easy to approach and display tumour margins during the resection procedure. The gastric fundus, where the muscle layer is relatively thin, provides a fundamental condition for capturing the entire tumor with an endoloop and pulling it into the gastric cavity.Traction is applied to the mucosal and submucosal layers. After sufficient upward traction, preligation was performed. This preligation was not fully secured, allowing exposure of the tumour margins during resection. This step enabled the observation and confirmation of complete tumour capture. The preligation technique had two advantages: the first was it prevented gastric fluid from entering the abdominal cavity, abdominal cavity vessel massive haemorrhage, and tumour seeding because of preligating the tumour base by endoloop, and the second was that the preligation loop was the external suture layer after releasing the loop, which was one of the double sutures. The double suture technique included an internal metal clip suture and a tumour base endoloop suture, which were sufficiently safe to prevent postoperative delayed perforations. Additionally, the insertion of a nasogastric tube and fasting can reduce intragastric pressure, thereby promoting adequate wound healing. This approach reduces the risk of delayed postoperative bleeding and perforation. The three key techniques ensured that there were no intraoperative or postoperative adverse events in any of the 14 gastric fundal SELs. Twelve patients experienced no recurrence during the follow-up period.Moreover, this technique is theoretically suitable for colorectal tumors with a thinner muscular layer. The following steps are taken to make sure that the tumor is completely removed. The entire tumor is pulled into the gastric cavity, and after adequate traction, pre-ligation of the tumor base is performed to clearly expose the tumor margins. The tumor is then excised along its edges, and dissection is carried out along the tumor base. Observing that the serosal layer of the tumor's capsule remains intact indicates that the tumor has been completely removed. Following excision, the surgical site is inspected for any residual tissue, further confirming the complete removal of the gastric SEL. Pathological evaluation is used to assess the integrity of the tumor capsule. If the capsule is intact, it confirms the tumor has been fully resected. If pathology is unable to fully assess the integrity of the capsule, we will re-evaluate it during regular follow-up visits using endoscopy and enhanced CT.

In short, this technique is primarily used for tumors located in the gastric fundus, where the muscle layer is relatively thin, thus facilitating the endoscopic capture of the entire tumor. This method is suitable for tumors smaller than 3 cm; we have not yet applied this technique to larger tumors. Given that tumors ≥ 3 cm have a higher likelihood of malignancy, surgical resection is considered more appropriate. All tumors ≥ 3 cm encountered in our study met the criteria for surgical intervention and were treated surgically. There is no significant limitation regarding tumor depth, as this technique primarily targets the gastric fundus, where the muscle layer is relatively thin, making it easy to manipulate the tumor with a snare.LAIDST can convert otherwise unreachable gastric fundus tumors into inverted tumor-like polyps, making the lesions more accessible and the procedure more time-efficient. It also employs pre-ligation and double suturing techniques, which reduce the risks of bleeding, infection, and perforation. In contrast, for gastric fundus SELs, both ESD and EFTR face challenges due to the difficulty in accessing the gastric fundus. The perforation rate for ESD and EFTR in gastric fundus SELs can be as high as 50%, and complications such as large bleeding leading to conversion to surgical resection, abdominal implantation of GIST, and bleeding and infection are unavoidable risks with ESD or EFTR in treating gastric fundus SELs. However, tumors located in the thicker muscle layers of the gastric body and antrum are more difficult to manipulate into a nylon loop, which makes ESD or EFTR more suitable for tumors located in these areas. ESD is more appropriate for tumors confined to the gastric cavity, while EFTR is better suited for tumors with both intra- and extra-gastric components, or those mostly located outside the gastric cavity. Nevertheless, ESD or EFTR still carry risks of perforation, conversion to surgical resection due to major bleeding, and abdominal implantation of GIST.

This study has some limitations. First, this was a retrospective case series conducted at one centre. Although consecutive patients who underwent the LAIDST were collected and the patients had different tumour sizes

and locations, selection bias cannot be ruled out. Second, the sample size was small. Although the gastric fundal SELs were not large, the 14 lesions did not involve all possible gastric fundal SELs. Due to the short follow-up period of only 1 to 12 months, we were unable to fully assess the long-term recurrence and treatment outcomes. This is one of the major limitations of the study. Future research should consider longer follow-up periods to comprehensively evaluate the long-term efficacy and recurrence risk of this treatment. Finally, this was a single-arm study. However, whether the LAIDST is safer and more effective than EFTR or ESD requires further investigation.

In conclusion, the LAIDST is a safe and effective treatment for gastric fundal SELs. However, prospective, large-scale, multicentre comparative studies are required.

Data availability

The endoscopic findings of lesions, treatment informations, and surgical procedures of patients generated or analyzed during this study are included in this published article (and its supplementary information files). The remaining datasets generated and/or analyzed during the study are available from the corresponding author on reasonable request.

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Author contributions

Zhang Tao conceived the study design. Zhang Tao and Qing-Yu Zeng wrote the main manuscript text. Lan Chao, Bin-Bo He and Long Chen prepared Figs. 1 and 2. Qing-Yu Zeng, Liu Jie and Kong Tao performed data compilation and analysis.Lan Chao and Xu Shan supervised the experiments. All authors reviewed the manuscript.

Declarations

Competing interests
The authors declare no competing interests.

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