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Pilot study of metallic clip-assisted through-the-scope twin clip technique for defect closure after endoscopic full-thickness resection of small gastric subepithelial tumors

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Abstract

Background This pilot study aimed to evaluate the feasibility and efficacy of metallic clips assisted by through-the-scope twin clips (TTS-TC) for closing gastric wall defects following endoscopic full-thickness resection (EFR) for small gastric submucosal tumors (SMTs).

Methods Nineteen patients with gastric SMTs originated from the muscularis propria were treated by EFR between May 2022 and July 2024. Twelve patients underwent endoscopic closure of the gastric wall defects after EFR with metallic clips and seven patients with TTS-TC and metallic clips.

Results No significant differences existed between the two groups in terms of demographics, clinical characteristics, and the size of the gastric wall defects. The average time to close gastric wall defects was shorter in the TTS-TC group (6.3 ± 0.8 min) compared to the metallic clip group (9.9 ± 2.9 min). Closure costs were higher for the TTS-TC group than for the metallic clip group. The hospitalization time of the two groups had no statistical significance. No single case had surgical intervention or complications, such as gastric bleeding, perforation, peritonitis, or abdominal abscess. A follow-up EGD at the second month after surgery indicated that no postoperative complications occurred.

Conclusion The metallic clips assisted with or without TTS-TC are safe and effective techniques for gastric defect closure after EFR for gastric SMTs. Because of the "kissing close," the TTS-TC more suitable for the lesions located at the gastric fundus, the greater curvature or anterior wall of the gastric body.

Keywords Through-the-scope twin clip · Endoscopic full-thickness resection · Gastric submucosal tumor · Perforation

Endoscopic full-thickness resection (EFR), an endoscopic technique developed on the basis of traditional endoscopic submucosal dissection (ESD), is currently mainly used in treatment of submucosal tumors (SMTs) [1]. During the procedure, we first perform "active perforation" to remove the tumor and then we seal the perforation. Safely and effectively sealing the perforation is crucial to preventing postoperative peritonitis and the need for further surgical intervention [2]. The through-the-scope twin clip (TTS-TC) is a novel sealing device (Fig. 1) [3–5]. This study was designed to evaluate the feasibility and efficacy of metallic clips assisted with TTS-TC closing the gastric wall defect after EFR for SMTs. Our preliminary experience is retrospectively reviewed in this study.

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Materials and methods

Patients

From May 2022 to July 2024, 19 patients (5 males and 14 females, aged 24–68 years, mean age 57.8 ± 10.6 years) with SMTs originating from the muscularis propria underwent EFR treatment at Xi'an People's Hospital. Their defects were closed using metallic clips, with or without TTS-TC. Among the 19 cases, 8 tumors were located at the gastric fundus, 5 tumors were located at the anterior wall of the gastric body, 2 tumors were located at the posterior wall of

Fig. 1 The structure of novel through-the scope twin clip (TTS-TC)

the gastric body, 2 tumors were located at the greater curvature of the gastric body, 1 tumor was located at the minor curvature of the gastric body, and 1 tumor was located at the gastric antrum. No metastasis was identified in any of the patients during the computed tomography (CT) examination. Informed consent was obtained from all patients to take part in this study.

Instruments

The following instruments were used: single-channel endoscopy (GIF-Q260 J, Olympus), transparent cap (D-201–11804, Olympus), Dual knife (KD- 650L, Olympus), water-injected knife (MK-T- 2–195, Micro-Tech), IT knife nano (KD- 612L, Olympus), injection needles (NM- 400L-0425, Olympus), through-the-scope twin clip (STA00002, Micro-Tech), and metallic clip (ROCC-D- 26–195, Micro-Tech). Technical parameters of the through-the-scope twin clip: maximum outer diameter of the insertion portion: 2.9 mm; maximum single-sided opening angle: 60°; single-sided opening dimension: 1.0 cm. Technical parameters of the metallic clip: opening dimension: 1.2 cm.

Endoscopic operation

The standard endoscopic full-thickness repair (EFR) technique has been detailed in previous studies [6]. All procedures were performed by one endoscopist. The gastric wall defects were closed by metallic clips or metallic clips combined with TTS-TC, without the assistance of an endoloop. In metallic clip group, the perforation was closed using varying numbers of metallic clips. In TTS-TC group, the perforation was closed by TTS-TC and metallic clips. First step, we inserted a TTS-TC through the biopsy channel of the endoscope. We first clamped one side of the gastric wall layer near the perforation. After positioning the other side, we released the TTS-TC, a technique we call "kissing close." After the TTS-TC was released, we observed that the perforation was almost closed. Second step, we used metallic clips to complete sealing of the perforation along both sides. (Fig. 2, 3).

Post-endoscopic therapy management

The gastrointestinal decompression tube was placed and prophylactic antibiotics was administered for preventing secondary peritonitis after endoscopic procedure. The conventional treatment involved fasting and fluid replacement. The patient experienced no postoperative complications, such as abdominal pain or fever. Abdominal pain, abdominal distention, and any sign of peritonitis should be under exactitude observation, as information for any complications, such as delayed hemorrhage or perforation. Patients were advised to undergo a follow-up gastroscopy two months after the endoscopic procedure to evaluate the wound healing.

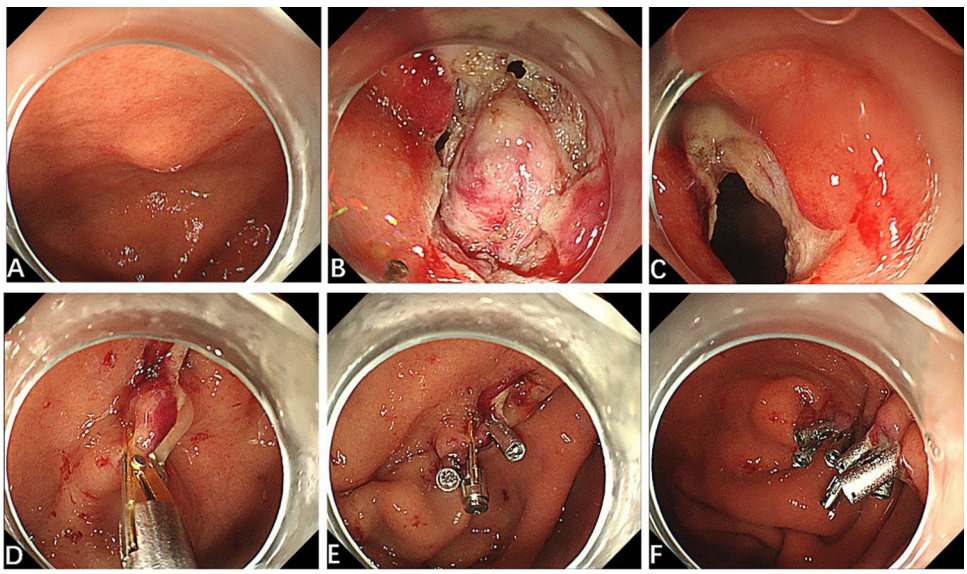

Fig. 2 The lesion in the great curvature of stomach fundus, with an estimated size of 1.0 × 0.6 cm (**A**); EFTR was performed to remove the lesion successfully (**B**); a 12-mm perforation was observed after the lesion was removed (**C**); "Kissing close" was performed using TTS-TC (**D**); conventional clips were used to complete seal the perforation along both sides of TTS-TC (**E**, **F**)

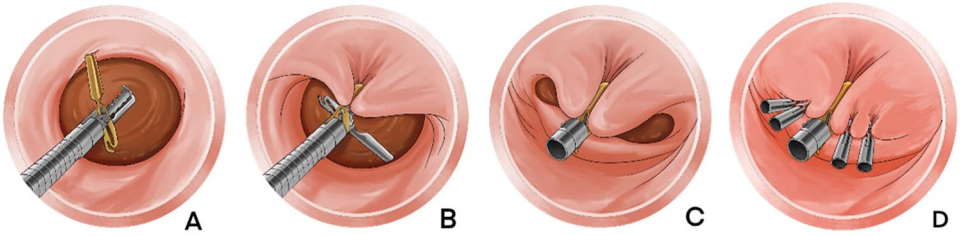

Fig. 3 Perforation sealing process: inserting a TTS-TC through the biopsy channel of the endoscope (**A**); accurately clamped one side of the entire gastric wall layer near the perforation (**B**); positioned the other side of perforation, and then released the TTS-TC, which was called "kissing close" (**C**); and complete sealing combined with conventional clips along both sides of TTS-TC (**D**)

Statistical analysis

For evaluation of the results, a descriptive statistic of the biometric data using mean ± SD was employed. All the data of the two groups were analyzed by *t* test or chi-square test using SPSS version 22.0 (SPSS, Chicago, IL, USA). A P value lower than 0.05 was considered statistically significant.

Results

All the 19 patients successfully completed EFR. Twelve patients underwent endoscopic closure of the gastric wall defects after endoscopic resection with metallic clips, and seven patients with metallic clips and TTS-TC. The localization of the SMTs of the two groups is presented in Table 1. The pathologic diagnoses included gastrointestinal stromal tumors (n = 13), leiomyomas (n = 5) and Schwannoma (n = 1). Mean size (the maximum diameter) of the defects in the metallic clip group was 1.1 ± 0.2 cm, while mean size of the gastric wall defects in the TTS-TC group was 1.3 ± 0.3

Table 1 Clinicopathological characteristics and outcomes of two groups

	Metallic clip group (n = 12)	TTS-TC group (n = 7)	P value
Sex (F/M)	9/3	5/2	0.634
Age (y)	56.5 ± 12.7	60.2 ± 5.2	0.519
Location of the SMTs			-
Gastric fundus	4	4	
Anterior wall of the gastric body	3	2	
Posterior wall of the gastric body	2	0	
Greater curvature of gastric body	1	1	
Minor curvature of gastric body	1	0	
Gastric antrum	1	0	
Size of the gastric wall defects (cm)	1.1 ± 0.2	1.3 ± 0.3	0.238
Time spent in defect closure (min)	9.9 ± 2.9	6.3 ± 0.8	0.017
Expense of defect closure (RMB)	1355.2 ± 472.2	2259.8 ± 342.7	0.001
Complications			-
Gastric bleeding	0	0	
Perforation	0	0	
Peritonitis	0	0	
Surgical intervention	0	0	-
Pathology			0.734
Gastrointestinal stromal tumor	8	5	
Leiomyoma	3	2	
Schwannoma	1	0	
Hospital stay (Days)	5.6 ± 1.4	6.7 ± 1.0	0.128

cm (Table 2). No significant differences existed between the two groups in terms of demographics, clinical characteristics, and the size of the defects. The average time spent in closing the gastric wall defects of the TTS-TC group were shorter than metallic clip group (6.3 ± 0.8 min vs 9.9 ± 2.9 min, P = 0.017) (Table 2). The expense of defect closure of TTS-TC group was significantly higher than metallic clip group (2259.8 ± 342.7 RMB vs 1355.2 ± 472.2 RMB, P = 0.001). The average hospitalization time of the two groups had no statistical significance. No single case had surgical intervention or complications, such as gastric bleeding, perforation, and peritonitis (Table 1). The gastrointestinal decompression tube was placed to drain the gastric fluid and blood. Prophylactic antibiotics was administered for preventing secondary peritonitis after endoscopic procedure. All the patients fasted no more than 48 h after EFR, and the gastrointestinal decompression tube were removed since there were no signs of gastric bleeding or perforation. The average time to resume oral diet after the procedure was 2 days. Follow-up gastroscope is performed in the second month after EFR. The metallic clips and TTS-TC at the lesion site were desquamated or partially desquamated, and the wounds were healing. All cases had negative pathologic margins, confirming complete resection of the tumors. No recurrence or metastasis was found. No recurrence was observed during the 2-month follow-up endoscopy and both groups were followed up for a total of 6 months, during which no recurrence or metastasis was found as shown in Table 2.

Discussion

EFR has achieved an effective treatment for SMT, which involves performing "active perforation" to remove the tumor. Since perforation is unavoidable during the procedure, ensuring secure closure of the incision is crucial. Therefore, it is valuable to explore a convenient and effective method for securely closing the defect to complete endoscopic therapy.

To the best of our knowledge, current sealing instruments include conventional metallic clips with or without nylon purse-string sutures, over-the-scope clips (OTSC), and high-end suture devices [7–13]. Although the above techniques seem to be safe and effective alternative to surgical intervention to perform defect closure after EFR, however, these are time-consuming, high-cost, and difficult to use. Conventional metallic clips can close part of gastrointestinal perforations. Nevertheless, closing large gastric perforations with clips alone is more difficult [14]. The thick and irregular gastric folds at the edge of the perforation make it easy for conventional clips to slip when released. This leads to longer sealing times and a lower success rate.

Table 2 Details of all the patients

	Location of the SMTs	Size of the gastric wall defects (cm)	Time spent in defect closure (min)	Numbers of clips		Pathology
				Metallic clip	TTS-TC	
patient1	Anterior wall of the gastric body	1.3	8.3	4	0	Gastrointestinal stromal tumor
patient2	Posterior wall of the gastric body	1.2	6.5	5	0	Gastrointestinal stromal tumor
patient3	Gastric antrum	1.4	9.2	7	0	Schwannoma
patient4	Greater curvature of gastric body	1	7.4	6	0	Gastrointestinal stromal tumor
patient5	Gastric fundus	1	11.4	7	0	Gastrointestinal stromal tumor
patient6	Anterior wall of the gastric body	0.9	10.2	7	0	Gastrointestinal stromal tumor
patient7	Minor curvature of gastric body	1.1	8.6	6	0	Gastrointestinal stromal tumor
patient8	Gastric fundus	0.8	7.7	5	0	Leiomyoma
patient9	Posterior wall of the gastric body	1.5	10.2	9	0	Gastrointestinal stromal tumor
patient10	Greater curvature of gastric body	1.2	17.4	12	0	Leiomyoma
patient11	Gastric fundus	1.1	9.4	8	0	Gastrointestinal stromal tumor
patient12	Gastric fundus	1.1	9.9	7	0	Leiomyoma
patient13	Gastric fundus	1	5.1	4	1	Gastrointestinal stromal tumor
patient14	Gastric fundus	1.5	6.6	7	1	Leiomyoma
patient15	Gastric fundus	1.3	7	8	1	Gastrointestinal stromal tumor
patient16	Gastric fundus	1.6	7.4	9	1	Gastrointestinal stromal tumor
patient17	Anterior wall of the gastric body	1.4	6.3	7	1	Gastrointestinal stromal tumor
patient18	Anterior wall of the gastric body	0.9	5.7	6	1	Leiomyoma
patient19	Greater curvature of gastric body	1.3	6.3	7	1	Gastrointestinal stromal tumor

In the past two years, a new sealing instrument called TTS twin clip (TTS-TC, which is expected to achieve efficient closure of large perforations at difficult locations has been used in China [15]. Using the characteristics of the TTS-TC, the two sides of the mucous are first closed at the widest part of the perforation, which then significantly narrows down the perforation and made it easier to continue to complete the sealing with conventional metallic clips. The procedure for using the TTS-TC is as follows: (1) insert the TTS-TC through the biopsy channel of the endoscope, clamp one side of the gastric wall near the perforation, position the other side, and release the TTS-TC, a technique known as "kissing closure" and (2) insert metallic clips to seal the perforation along both sides of the TTS-TC. Our study demonstrates that the TTS-TC is a safe and effective tool for closing gastric defects following endoscopic full-thickness resection (EFR) for gastric submucosal tumors (SMTs). Use of this instrument can shorten the operation time. On account of the "kissing close," the TTS-TC is more suitable for the lesions located at the gastric fundus, the greater curvature, or anterior wall of the gastric body. This method can be done using only a single-channel endoscopy, has the advantage of being a simple procedure and does not require complex or specialized equipment, and save the average time spent in closing the gastric wall defects. In addition, no single case had severe complications, such as gastric bleeding, perforation, peritonitis, or surgical intervention.

One of the notable advantages of the TTS-TC is its potential applicability in closing larger perforations, particularly those exceeding 1 cm in diameter. Traditional metallic clips often struggle to effectively close larger defects due to the limitations in their grasping capacity and the tendency to slip on thicker gastric folds. The TTS-TC, with its unique "kissing close" mechanism, can initially approximate the edges of larger perforations, significantly reducing the defect size and making subsequent closure with metallic clips more manageable. This feature suggests that TTS-TC could be particularly beneficial in cases where large perforations are encountered, such as in more extensive EFR procedures or in cases of accidental perforations during complex endoscopic interventions. However, further studies are needed to validate the efficacy and safety of TTS-TC in larger perforations, as our current study primarily focused on defects within a specific size range. Future research should explore the upper limits of defect size that can be effectively managed with TTS-TC and compare its performance with other closure techniques in larger perforations.

Despite the promising results, this study has several limitations that should be acknowledged. Firstly, the sample size was relatively small, with only 19 patients included in the analysis. This limits the statistical power of the study and may affect the generalizability of the findings. Secondly, the study was conducted at a single center, which may introduce bias related to the specific patient population, endoscopic techniques, and postoperative management protocols used at that institution. Thirdly, the study design was retrospective, which inherently carries the risk of selection bias and limits the ability to establish causal relationships. Prospective, multicenter studies with larger sample sizes are needed to confirm the efficacy and safety of TTS-TC in a broader patient population. Additionally, the follow-up period, although extended to 6 months, may still be insufficient to fully assess long-term outcomes, such as recurrence rates or delayed complications. These limitations highlight the need for further research to validate the findings and explore the broader applicability of TTS-TC in different clinical settings.

During the application, two major issues were identified: first, the angle of the TTS-TC device cannot be adjusted freely after entering the endoscope's biopsy channel, requiring the endoscope to be rotated for adjustments. Second, although TTS-TC can decrease reliance on metallic clips, its high cost leads to total expenses that surpass those of using metallic clips alone.

Conclusion

According to the findings, the metallic clips or metallic clips combined with TTS-TC are safe and effective techniques for gastric defect closure after EFR for SMTs. Although the overall cost is higher, but using TTS-TC can reduce operative time. If sealing the perforation with a metallic clip is challenging during the endoscopic procedure, TTS-TC can be employed as a supportive option.

Declarations

Disclosure Gaofei Shen, Zhenzhen Liu, Fei Zhu, Junyi Zheng, Jinpeng Li, Baozhen Guo, and Rui Huang have no conflicts of interest or financial ties to disclose.

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