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Application of a traction metal clip with a fishhook-like device in wound sutures after endoscopic resection

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Background/Aims: Endoscopic wound suturing is an important factor that affects the ability to remove large and full-thickness lesions during endoscopic resection. We aimed to evaluate the effect of a traction metal clip with a fishhook-like device on wound sutures after endoscopic resection.

Methods: From July 2020 to April 2021, patients who met the enrollment criteria were treated with a fishhook-like device during the operation to suture the postoperative wound (group A). Patients with similar conditions and similar size wounds who were treated with a "purse-string suture" to suture the wounds were retrospectively analyzed as the control group (group B). Difference in the suture rate, adverse events, time required for suturing, and number of metal clips were compared between the two groups.

Results: The time required for suturing was 7.72 ± 0.51 minutes in group A and 11.50 ± 0.91 minutes in group B. This difference was statistically significant (*F*=13.071, *p*=0.001). The number of metal clamps used in group A averaged 8.1 pieces/case, and the number of metal clamps used in group B averaged 7.3 pieces/case. This difference was not statistically significant (*F*=0.971, *p*=0.331).

Conclusions: The traction metal clip with the fishhook-like device is ingeniously designed and easy to operate. It has a good suture effect on the wound after endoscopic submucosal dissection and effectively prevents postoperative adverse events.

Keywords: Endoscopic resection; Fishhook traction clip; Purse-string suture; Suture techniques; Wound suture

INTRODUCTION

Gastrointestinal tumors, such as esophageal, stomach, and colon cancers, are among the top ten malignant tumors that threaten the health of the Chinese population. Advanced tumors are associated with a poor prognosis and high treatment

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new stitching techniques are used.^{4,6-8} However, these methods are technically difficult and expensive and require specialized equipment. Our team invented a traction metal clip with a fishhook-like device (patent number: ZL201921076676.3) for suturing large-area wounds after endoscopic resection. Therefore, we aimed to evaluate the effect of a traction metal clip with a fishhook-like device on wound sutures after endoscopic resection.

METHODS

Objectives

From July 2020 to April 2021, patients who were treated with endoscopic resection in our hospital due to gastrointestinal diseases were included in this study. The inclusion criteria were as follows: (1) digestive tract diseases (stomach and colon) that met endoscopic resection indications; (2) without endoscopic resection contraindications; (3) complete removal of the lesion; (4) the maximum diameter of the full-thickness lesion or wound area was more than or equal to 3 cm; (5) signed a preoperative informed consent form. The exclusion criteria were as follows: (1) lesions that could not be completely removed; (2) surgery was required due to adverse events, such as intraoperative bleeding, and (3) shock, intestinal obstruction, gastrointestinal perforation, severe heart or lung disease, and mental illness.

The following equipment was used: CV-260HDTV host (Olympus, Tokyo, Japan); PCF-Q260J therapeutic gastroscope (Olympus); PCF-Q260JI therapeutic colonoscopy (Olympus); dual knife (Olympus); IT knife (Olympus); self-designed traction metal clip with a fishhook-like device produced by Nanjing MicroPort (Nanjing, China; fishhook traction clip; patent number, ZL201921076676.3) (Fig. 1); metal clips (harmonious clip produced by Nanjing MicroPort); and hot biopsy forceps (Olympus). For gastric and colon lesions, the wound was assessed before surgery according to the size. After the lesion was removed, there was a large defect in the digestive tract (full-thickness resection), or the range was no less than 3 cm. Patients in whom suturing with metal clips was difficult were included in the fishhook traction clip suturing group (group A). Patients with similar conditions and wounds of similar size who had been treated with a purse-string suture to suture the wounds were retrospectively included as the control group (group B). When multiple patients met the control standard, the patient with the shortest operation time was used as the control.

Methods

1) Group A (fishhook traction clip suture group)

For large wounds after endoscopic resection that were difficult to suture with ordinary metal clips, after the hot biopsy forceps were fully processed, the fishhook traction clip was first inserted through the endoscopic forceps channel. The hook-traction clip was opened, and the proximal side of the middle of the wound was clamped. By changing the angle, the hook-like device was inserted into the clamped mucosa, and the mucosa was clamped and moved to the side of the wound surface. The clamped mucosa was fixed to the hook-traction clip to ensure that it would not fall off, thus forming a good pulling effect due to the existence of the hook device. The opened fishhook traction clip was clamped to the side mucosa of the wound to suture the mucous membranes on both sides. The entire wound surface was closed and reduced due to the suturing effect of the first fishhook traction clip, and then the wound was completely stitched through the ordinary harmony clip. If necessary, a second fishhook traction clip could be used, and finally, air injection could be used to assess the suturing effect, as shown in Figure 2 and Supplementary Video 1.

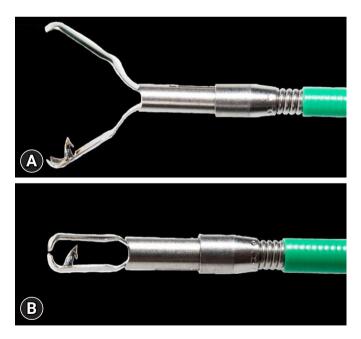


Fig. 1. Fishhook traction clip. (A) When the traction clip is opened, the fishhook-like structure can penetrate the mucosal surface. (B) When the traction clip is closed, the fishhook-like structure prevents the mucosa from falling.

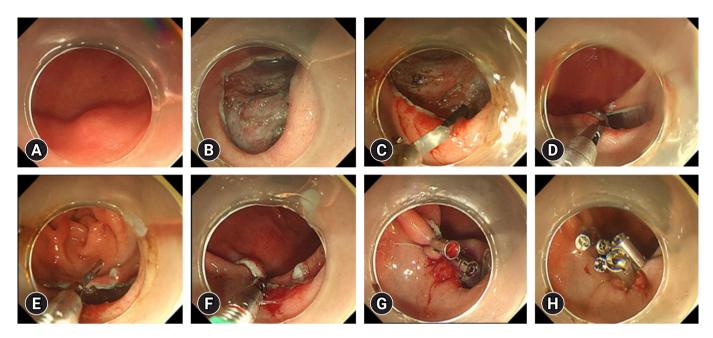


Fig. 2. The procedure of endoscopic submucosal dissection using fishhook traction clips to suture the wound. (A) A submucosal tumor on the greater curvature of the stomach, approximately 1.0×1.0 cm. (B) After removing the lesion, the wound area was approximately 2.0×3.0 cm. (C) A fishhook traction clip was used to clamp the mucosa on the side edge of the wound. (D) The mucosa was lifted so that the hook-like device penetrated the mucosa. (E) The fishhook traction clip was opened, and the mucosa was pushed from the oral side to the anal side. (F) The anal mucosa of the wound was clamped, and the wound orifice and anal side were seamed. (G) The reduced wound was sutured with ordinary metal clips. (H) The wound was sutured well.

2) Group B (purse-string suture group)

For large wounds after endoscopic resection that were difficult to suture with ordinary metal clips, after the hot biopsy forceps were fully processed, a nylon string was inserted through single-channel endoscopy or double-channel endoscopy, and a nylon string was placed around the wound. After determining the proper size, the nylon rope was fixed around the wound with a harmonious clip and tightened to suture the wound, and the suture effect was observed by air injection. If necessary, metal clips were used to reinforce the suture, or nylon ropes were placed to reinforce the suture; the operation process is shown in Figure 3.

Observation index

The main observation indicators of this study included the wound suture rate, adverse events, metal clip usage, and suture time.

Statistical analyses

IBM SPSS ver. 23.0 (IBM Corp., Armonk, NY, USA), was used to analyze the data. Measurement data between the two groups

were compared by analysis of variance, and count data between two groups were compared using the chi-square test or Fisher exact probability method. Statistical significance was set at p<0.05.

Ethical statements

This study was approved by Jiangyin Hospital Affiliated to Nantong University ethics committee (IRB No: 14). All patients included in this study signed informed consents.

RESULTS

In this study, 18 patients were enrolled in group A, and 18 patients were enrolled in group B; there were 17 male and 19 female patients. The average age of group A was 64.17 ± 2.10 years, and the average age of group B was 65.89 ± 1.94 years. This difference was not statistically significant (*F*=0.363, *p*=0.551) (Fig. 4A). Postoperative pathology revealed four cases of early gastric cancer and precancerous lesions, two cases of gastric leiomyoma, one case of gastric granular cell tumor, one case of gastric schwannoma, 18 cases of gastric stromal tumor,

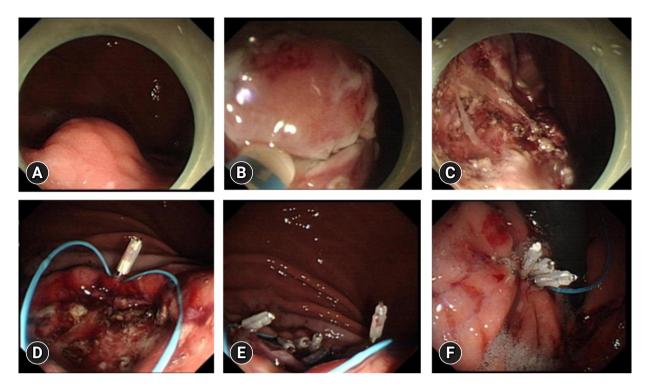


Fig. 3. The procedure of endoscopic submucosal dissection using purse-string suture. (A) A submucosal tumor about 1.8×1.5 cm in the posterior wall of the upper gastric body. (B) Make circular incision of the mucosa, expose the lesion, and peel off the tumor. (C) The wound after resection was about 2.5×3.0 cm, with 2 mm small perforations locally. (D) The first metal clip fixes the nylon rope on the distal side of the wound. (E) Use metal clips to fix the nylon rope around the wound several times. (F) Finally tighten the nylon rope to suture the wound.

two cases of gastric heterotopic pancreas, six cases of colorectal adenoma, and two cases of rectal neuroendocrine tumor. The average wound size of group A was 3.64 ± 0.17 cm, and average wound size of group B was 3.78 ± 0.21 cm. This difference was not statistically significant (*F*=0.268, *p*=0.608) (Fig. 4B).

Observation index comparison

All wounds in both groups were sutured successfully. There were four cases of group A and group B with perforation during the operation, and they were sutured successfully. There were no postoperative adverse events, such as delayed bleeding, perforation, or abdominal infection, in either group, and the suture effect was good. The average suture time for group A was 7.72±0.51 minutes, and the average suture time for group B was 11.50±0.91 minutes; this difference was statistically significant (*F*=13.071, *p*=0.001) (Fig. 4C). The metal clips used in group A averaged 7.3 pieces/case; this difference was not statistically significant (*F*=0.971, *p*=0.331) (Fig. 4D). In group A, three cases used two fishhook clips, and no case used more than two fish-

hook clips. The observation indices are listed in Table 1.

DISCUSSION

With the development of endoscopic resection technology, the mucosal layer and submucosal lesions of the digestive tract can be treated by endoscopic resection. Whether a wound can be sutured with high quality affects wound healing and the occurrence of adverse events such as bleeding and perforation after the operation.⁹ Akimoto et al.¹⁰ found that suturing a wound after ESD, resulting in mucosal closure, can help prevent delayed perforation and bleeding. In endoscopic surgery, gastrointestinal perforation or full-thickness resection of the gastrointestinal tract due to deep growth of the disease requires complete suturing of the wound to avoid serious adverse events such as peritonitis, abdominal infection, and fistula. Not all wounds need to be sutured after endoscopic resection, but when there is a perforation of the digestive tract, it is recommended to suture the wound with high quality to prevent complications such as infection. For wounds without perforations after ESD, further

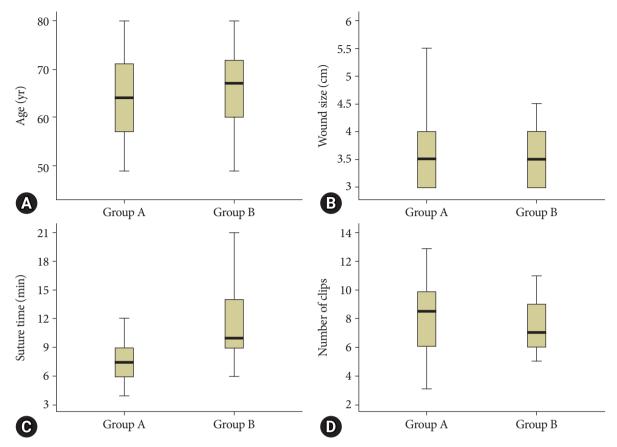


Fig. 4. Box plots of observation index comparison. These four groups of data can be statistically compared, and box plots are used to compare the data more intuitively. (A) Comparison of the age of the two groups. (B) Comparison of the wound size of the two groups. (C) Comparison of the suture time of the two groups. (D) Comparison of the number of clips of the two groups.

Table 1. The major observation indexes comparison between groups A and B
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Clinical characteristic	Group A	Group B	<i>p</i> -value
Sex			-
Male	9	8	
Female	9	10	
Age (yr)	64.17±2.10	65.89±1.94	0.551
Maximum diameter of wound area (cm)	3.64±0.17	3.78±0.21	0.608
Suture time (min)	7.72±0.51	11.50 ± 0.91	0.001
Number of metal clips	8.06±0.67	7.28±0.42	0.331
Postoperative adverse event	0	0	-
Postoperative pathology			-
Early gastric cancer and precancerous lesions	2	2	
Gastric leiomyoma	1	1	
Gastric granular cell tumor	0	1	
Gastric schwannoma	1	0	
Gastric stromal tumor	9	9	
Gastric heterotopic pancreas	1	1	
Colorectal adenoma	3	3	
Rectal neuroendocrine tumor	1	1	

Values are presented as case or mean±standard deviation.

Group A, patients who were treated with a fishhook clip to suture the postoperative wounds; group B, patients who were treated with a "purse-string suture" to suture the postoperative wounds. studies on the indications for sutures are needed.

At present, wound suturing after endoscopic resection mainly involves direct clamping with metal clips, purse-string suturing with metal clips combined with a nylon rope, OTSCs, and new types of suture devices.^{4,6-8,11,12} OTSCs suture wounds reliably and have good effects, but they are expensive. Some scholars have developed new types of suture devices that have shown good application prospects, but most of them are in the development stage and have not been widely used in clinical practice.^{12,13} In clinical practice, purse-string sutures with metal clips combined with nylon ropes and directly clamped metal clips are the most widely used. However, for large and high-tension wounds, metal clips often cannot be used for suturing because of their limited opening size. The purse-string suture method that involves metal clips combined with nylon ropes can also be used to suture large wounds well. This method is widely used in clinical practice, but its operation steps are relatively cumbersome and difficult to perform. For the wound surface of the perforation of the digestive tract, there is a possibility that the metal clip will turn towards the abdominal cavity. A double-port endoscope is required for purse-string suturing for a wound in the right colon, and many primary hospitals do not have a double-port endoscope, which limits its application.

The research team designed a fishhook-like device on the clamping arm of a metal clip to explore an endoscopic suture method with a simple operation, low price, and good suture effect. When the metal clamp with the fishhook device clamps the tissue, the fishhook-like device pierced the mucosa so that the clamped mucosa could be lifted and fixed like a harpoon stabbing a fish to prevent it from falling off. In this way, the mucosa and other parts pulled by the metal clip were sutured. As a result, the team invented a traction metal clip with a fishhook device, termed a fishhook traction clip, which was initially transformed and produced by Nanjing MicroPort.

In practical applications, this study showed that in group A (fishhook traction clip group), all wounds were sutured well, and there were no adverse events, such as delayed perforation or abdominal infection. The wound suture time was significantly shorter than that of the purse-string suture group, and this result is believed to be related to the easy use of the hook-traction clip, low operation difficulty, and good traction effect. A comparison of the metal clips used in the two groups suggested that the hook-traction clip method may require more metal clips, but there was no significant difference compared with the purse-string suture method. The sample size needs to be fur-

ther expanded for verification in later stages. The limitations of this study are that the number of patients was small, it was not a prospective study, and it was difficult to avoid subjective bias. As a new type of suture technology, this device shows good application effects in preliminary exploration. In future research, we will expand the research sample size, optimize its technical details, and improve the fishhook traction clip to achieve a better suture effect.

In conclusion, this study showed that the traction metal clip with a fishhook device is cleverly and ingeniously designed, easy to operate, has a good suture effect on a wound after endoscopic surgery, and has good clinical application prospects.

Supplementary Material

Supplementary Video 1. Using a fishhook clip to suture the wound after gastric endoscopic submucosal dissection (https://doi.org/10.5946/ce.2021.241.v001).

Supplementary materials related to this article can be found online at https://doi.org/10.5946/ce.2021.241.

Conflicts of Interest

The self-designed traction metal clip with a fishhook-like device was produced by Nanjing MicroPort and provided free of charge for the purpose of this study. Employees in the company were not involved in the clinical trial in any way, including the study design, statistical analysis, or manuscript writing. The authors have no potential conflicts of interest.

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Author Contributions

Conceptualization: WF, LX, LP; Data acquisition: LX, GY, SX, WW; Formal analysis: WF, LX; Resources: LH, LP; Writing-original draft: WF, LX; Writing-review & editing: all authors.

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