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Internal traction in endoscopic full-thickness resection for gastric subepithelial lesions arising from the muscularis propria: a comparative study

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Abstract:
Background: Effective tissue traction is crucial for gastric endoscopic full-thickness resection (EFTR) to ensure a clear visual field for the dissection site. We aim to evaluate the effectiveness of internal traction using a novel clip-with-spring device in assisting gastric EFTR.
Patients: A total of 26 patients with gastric subepithelial lesions from the muscularis propria were enrolled for internal traction-assisted EFTR (IT-EFTR) and other 26 patients for non-assisted EFTR (NA-EFTR) were enrolled as controls.
Results: The average tumor size was 1.5 ± 0.4 cm. All EFTRs were completed successfully with an average total procedure time of 62.4 ± 43.0 min and perforation time of 37.2 ± 29.9 min. En bloc resection was achieved in 50 patients (96.2%). IT-EFTR significantly improved the serosa exposure score (3.4 ± 0.9 vs. 1.9 ± 0.7, P < 0.001) and shortened the total procedure time (33.0 ± 21.8 vs. 91.8 ± 38.6 min, P < 0.001) and the perforation time (19.0 ± 18.8 vs. 55.5 ± 27.8 min, P < 0.001), when compared with NA-EFTR; The complication rates had no significant difference between the two groups. However, the visual analogue score after operation was significantly lower (4.2 ± 1.0 vs. 4.7 ± 0.7, P = 0.037) and the postoperative hospital stay (3.7 ± 2.1 vs. 4.8 ± 1.3, P = 0.038) was significantly shorter in patients of IT-ERTR group than that of NA-EFTR group.
Conclusions: Internal traction using the novel clip-with-spring device could significantly improve the safety and efficacy of gastric EFTR in the distal stomach.

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Introduction

Endoscopic full-thickness resection (EFTR) is an advanced endoscopic technique that, after more than two decades of development, is now widely applied in the resection of gastric subepithelial lesions (SELs) originating from the muscularis propria (MP) [1]. The operation of EFTR is challenging and requires a high level of endoscopic skills and experiences. Effective tissue traction to ensure a clear visual field for the dissection site is crucial during EFTR. In the past few years, many studies have reported on the use of external traction by clip-with-thread or clip-with-snare device in assisting EFTR [2-4]. These techniques were effective for the resection of lesions especially in the gastric fundus [5-7]. However, the traction effects were less satisfactory for lesions at the distal stomach. What's more, external traction techniques require withdrawal of the endoscope and are relatively complex to prepare. In the present study, we introduced an internal traction strategy by using a novel clip-with-spring device to assist EFTR for the resection of MP-SELs at the distal stomach. We aim to evaluate the effectiveness and safety of this technique and provide vital evidence to guide future clinical practice.

MATERIALS AND METHODS

Study design and patient enrollment

This was a single-center, retrospective, cohort study. A total of 26 consecutive patients with MP-SELs at the distal stomach were enrolled for internal traction-assisted EFTR (IT-EFTR group) from January to September 2023 in Shanghai Tenth People's Hospital. Another 26 patients with MP-SELs at the distal stomach who had underwent non-assisted EFTR (NA-EFTR group) from January to December 2022 in our hospital were involved as controls. For all patients, the inclusion criteria were: age 35~80 years old; proven diagnosis of MP-SELs by common gastroscopy, endoscopic ultrasonography (EUS), and contrast-enhanced computed tomography (CT); location at the lower 2/3 of the corpus or the antrum; no regional lymph node or distant metastasis demonstrated by CT or MRI. Exclusion criteria were: lesions with absolutely extraluminal growth pattern or high-risk features of malignancy that were not amenable to endoscopic treatment; location at the fundus or the upper 1/3 of the corpus that could be applied the clip-with-thread technique; anticoagulant/antiplatelet agents that could not be suspended, and severe comorbidities or poor conditions that cannot tolerate the operation. The study was approved by the ethics committee of Shanghai Tenth People's Hospital and written informed consents were obtained from all patients.

EFTR procedure

All patients underwent EFTR under general anesthesia with intubation in a left lateral position under carbon dioxide insufflation. For IT-EFTR, the procedures were performed as follows: (1) Identification of the lesion and submucosal injection using sterile normal saline premixed with 1% indigo carmine; (2) Incision of the mucosa at the oral side of the lesion margin and initial submucosal dissection to reveal the tumor; (3) Submucosal excavation as deep as the seromuscular layer around the tumor body; (4) When we suffered difficulties in exposing the dissection site between the tumor and the seromuscular layer, attempts by NA-EFTR were allowed for no longer than 10 min, or the IT-EFTR would be conducted. (5) The clip-with-spring device have been reported in our previous studies [8,9]. This device consists of a metal clip and a 5-mm long spring with one end fixed between the two claws and the other end shaped as a ring (Figure 1).

When in use, it was inserted through the biopsy channel and anchored on the proximal edge of the resected mucosa above the lesion. Another metal clip was used to grasp the ring of the spring, pull it to the opposite gastric wall and anchor on the mucosa. The traction direction could be adjusted by changing the anchoring site on the opposite gastric mucosa [9]. After the traction was applied, the seromuscular layer under the tumor could be clearly visualized; (6) Full-thickness resection of the tumor and the surrounding MP layer and serosa; (7) Closure of gastric wall defects by using metal clips; (8) After resection, the specimen together with the clip-with-spring device were retrieved using grasping forceps. The procedures of IT-EFTR were shown in Figure 2 and Video 1.

Post-EFTR management

All patients were kept fasted for at least 48 hours after the procedure with given intravenous fluids, proton pump inhibitors and preventive antibiotics. If no signs of bleeding or perforation occurred after 48 hours, clear fluids and subsequent soft diets were introduced gradually. Patients' abdominal pain was evaluated using the visual analogue score (VAS) ranged from 0 (no pain) to 10 (severe pain) after operation and daily thereafter. If the VAS score was above 5 and symptoms such as abdominal distension or signs of peritonitis developed, a thoracoabdominal CT would be performed to rule out perforation. Endoscopy examination would be repeated in cases of hematemesis or melena and endoscopic hemostasis would be carried out if necessary. Oral proton pump inhibitors were prescribed routinely for two months after discharge. The criteria for discharge were as follows: completely normal for infection indicators including normal blood test, C-reactive protein and procalcitonin; stable hemoglobin; normal temperature (<37.2℃); no obvious symptoms such as stomachache (VAS score ≤2), hematemesis or melena emerged after soft diets; no significant signs of any other serious discomforts irrelevant to EFTR.

Definitions

The procedure time was defined as the time between submucosal injection of the first dot and the last withdraw of the endoscope. The perforation time was defined as the time between the initial creation of the iatrogenic perforation and complete closure of defect. *En bloc* resection was defined as an intact excision of the tumor in one piece without fragmentation. Intra-operative bleeding was defined as oozing or pulsating bleeding, necessitating the use of hemostatic forceps during the procedure. Delayed bleeding was defined as haematemesis or melena with decrease in hemoglobin level > 2 g/dL after EFTR. Serosa exposure score was classified as 1, 2, 3 and 4 when no serosa, <1/2 serosa of the tumor body, > 1/2 but not entire serosa of the tumor body and entire serosa area of the tumor body with adjacent serosa, respectively, could be seen during EFTR procedure (Figure 3).

Statistical analysis

The statistical analyses were performed using SPSS 23.0 software (SPSS Inc., Chicago, IL, USA). Continuous variables were presented as mean ± s.d. and were compared using unpaired Student's t test. Comparison of categorical variables was performed using χ^2 tests or Fisher's exact test. A two-sided $P \leq 0.05$ was considered statistically significant.

RESULTS

Main features of the whole study population

The study involved 18 males (34.6%) and 34 females (65.4%), with a mean age of 59.6 ± 8.9 years (range 38–78 years). The average tumor size was 1.5 ± 0.4 cm (range 0.9–2.5 cm). 48 tumors (92.3%) were located in the corpus and 4 (7.7%) in the antrum. 20 tumors (38.5%) presented partly extra-luminal growth pattern, while 32 tumors (61.5%) showed predominantly intra-luminal growth pattern. All EFTR procedures were completed successfully with an average total procedure time of 62.4 ± 43.0 min and perforation time of 37.2 ± 29.9 min. All specimens were retrieved orally and histopathological evaluation revealed that 40 tumors were gastrointestinal stromal tumors (GISTs) (76.9%) and 12 tumors were leiomyomas (23.1%). All GISTs were at low- or very low-risk according to the National Comprehensive Cancer Network Guidelines [10]. *En bloc* resection was achieved in 50 patients (96.2%).

Comparisons of clinical characteristics and therapeutic outcomes

The comparisons of clinical characteristics and therapeutic outcomes were listed in Table 1. Patients of the two groups had no significant difference in terms of sex, age, tumor diameter, tumor location, tumor growth pattern, the *en bloc* resection rate and histopathology.

IT-EFTR significantly improved the serosa exposure score during the procedure when compared with NA-EFTR (3.4 ± 0.9 vs. 1.9 ± 0.7, $P < 0.001$). The percentage of patients with a serosa exposure score of 3 or 4 in the IT-EFTR group was significantly higher than that in the NA-EFTR group (76.9% vs 15.4%, $P < 0.001$). The total procedure time was significantly shorter in the IT-EFTR group than that in the NA-EFTR group (33.0 ± 21.8 vs. 91.8 ± 38.6 min, $P < 0.001$). IT-EFTR also significantly shortened the perforation time when compared with NA-EFTR (19.0 ± 18.8 vs. 55.5 ± 27.8 min, $P < 0.001$) (Table 1).

Complications

A total of 10 (19.2%) patients suffered intra-operative bleeding and 3 (5.8%) patients suffered delayed bleeding. They were all successfully managed by endoscopic hemostasis. 5 (9.6%) patients had a transient fever above 38 °C after EFTR and were managed by upgraded intravenous anti-biotic. The rates of these complications all had no significant difference between the two groups (Table 1). However, the VAS score after operation was significantly lower in patients of IT-ERTR group than that of NA-EFTR group (4.2 ± 1.0 vs. 4.7 ± 0.7, P = 0.037). No patient presented delayed perforation, massive bleeding or any other serious complications. All patients were discharged with no severe complication after a mean postoperative hospital stay of 4.3 ± 1.8 days. The postoperative hospital stay was significantly shorter in the IT-EFTR group than the NA-EFTR group (3.7 ± 2.1 vs. 4.8 ± 1.3, P = 0.038).

Follow-ups

All patients underwent surveillance endoscopy within six months. The wound healing was satisfactory in all cases with no residual or recurrent tumors observed.

DISCUSSION

EFTR is a more challenging endoscopic technique compared with other endoscopic techniques such as ESD. After full-thickness incision, it is difficult to maintain the intraluminal gas in the digestive tract, resulting in poor exposure of the dissection field and an inability to clearly observe the blood vessels, particularly on the serosa side; What's more, the lesion is more likely to prolapse into the abdominal side due to the effect of gravity on the detached lesion and the pressure difference between the inside and outside of the digestive tract, which makes the procedure difficult to continue. Various auxiliary traction techniques are expected to reduce the difficulty and risk of EFTR and increase the effectiveness. Traction could help to pull the lesion into the gastric cavity, expose the lesion and make the dissection site clear, which could facilitate the process. In addition, traction could help to quickly identify bleeding point during EFTR to allow prompt hemostasis and this method could prevent accidental injury of extraluminal vessels. What's more, traction could help to prevent the specimens from dropping into the abdominal cavity. Although various traction methods using adjunctive devices have been developed in the past few years, comparative studies concerning the usefulness and efficacy of traction devices in assisting EFTR remain far from sufficient.

In the present study, we for the first time reported an internal traction strategy using a novel clip-with-spring device in assisting EFTR for gastric MP-SELs. The results showed that this technique significantly improved the dissection vision, represented by the serosa exposure sore, and consequently significantly shortened the total procedure time and the perforation time. Although complication rates showed no significance between the two groups, this technique significantly reduced the patients' discomforts after the operation. This may be explained by the shorter perforation time, which meant less leakage of the gas and gastric fluids into abdominal cavity. The less time for postoperative in-hospital observation also contributed to a significantly shorter postoperative hospital stay in the traction group than the non-traction group. Our study demonstrated great usefulness and efficacy of this technique in assisting EFTR.

Compared to other previously reported techniques, this technique has many advantages. Firstly, it is sterilized and ready-to-use without special preparation and endoscope withdrawal, making it safer and more convenient when compared with thread, rubber-band or snare-based traction method [2-7]. Secondly, the traction force could be displayed in any direction by using the clip-with-spring device. In contrast, the direction of the clip-with-thread technique is limited in which the line is pulled [5-7]. Thirdly, the traction direction of our clip-with-spring technique could be easily adjusted during the procedure, if necessary, without changing the patient's position [9]. If towing is in the wrong direction, the ring of the clip-with-spring device could be removed from the first anchoring site using a forceps and re-anchored to a second site using another clip. The traction force could be controlled by suction or inflation of the intraluminal gas. In comparison, the gravity or magnetic-based traction strategy usually involve position change and/or relatively fixed traction force [11]. Finally, this technique is more cost-effective when compared with some expensive dedicated device such as OTSC [12], FTRD [13,14], or robotics [15,16].

Concerning the clip-with-spring device, Sakamoto *et al* has previously reported a similar device named the S–O clip, which is a clip with a 5-mm spring plus a 4-mm nylon loop at one of the clip claws [17]. This device is convenient to use and could provide internal traction in any direction. However, it is only reported in assisting ESD for gastrointestinal superficial lesions [18-20]. No comparison study has been reported to prove the efficacy of this device in EFTR for gastric SELs. Whether the internal traction strategy using such clip-with-spring device could improve the safety and efficacy of gastric EFTR remains unclassified before our study. In addition, our novel clip-with-spring device present some modifications. The spring of our device is shorter in length, when compared with the S-O clip, enabling a continuous tension throughout the EFTR process. The metal ring at the top of the spring is more convenient to be grasped by another clip, when compared with the nylon loop of the S-O clip which is prone to deformation due to lack of rigidity.

Our study had several limitations. First, all EFTR procedures were performed by a single highly experienced endoscopist (Feng Liu) in a single center, which may impact the generalizability of the results. Since the timing of EFTR differs between the IT-EFTR and NA-EFTR groups, this may have impacted the technical maturity of the endoscopist. Second, we involved a relatively small sample of participants. The procedures of gastric EFTR could be affected by various factors. Some EFTRs for patients with specialized lesion location, gastric cavity configuration, and vascular malformation may cause inevitable variation in the procedure time and complication risks among the participants. Third, we did not include patients with MP-SELs at the proximal stomach due to well-established application of the clip-with-thread technique in treating such lesions. Comparisons between the clip-with-thread and clip-with-spring method were unable to be conducted. Finally, it was unable to perform double-blinding.

However, given the diversified lesions and equivalent baseline characteristics between the IT-EFTR and NA-EFTR groups, our results were inspiring to preliminarily show the great prospects of IT-EFTR using the novel clip-with-spring device. Large-scale, randomized, controlled studies were warranted for further investigation.

In summary, the internal traction using the novel clip-with-spring device could significantly improve the safety and efficacy of EFTR for MP-SELs in the distal stomach.

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Figure legends

Figure 1. The novel clip-with-spring device consists of a metal clip and a 5-mm spring fixed between the two claws of the clip.

Figure 2. Procedures of internal traction-assisted EFTR using the clip-with-spring device. a. Endoscopic view of the gastric SEL; b. mucosa incision and submucosal dissection to expose the tumor body; c. full-thickness resection with poor visualization of the dissection site; d, the internal traction using the clip-with-spring device was applied; e&f. resection became easy under countertraction; g. after resection of the lesion, the mucosal defect was closed by metal clips; h. the gross specimens.

Figure 3. Different serosa exposure score during EFTR. a. 1, no serosa could be seen, b. 2, <1/2 serosa of the tumor body could be seen; c. 3, > 1/2 but not entire serosa of the tumor body could be seen; d. 4, entire serosa area of the tumor body with adjacent serosa could be seen.

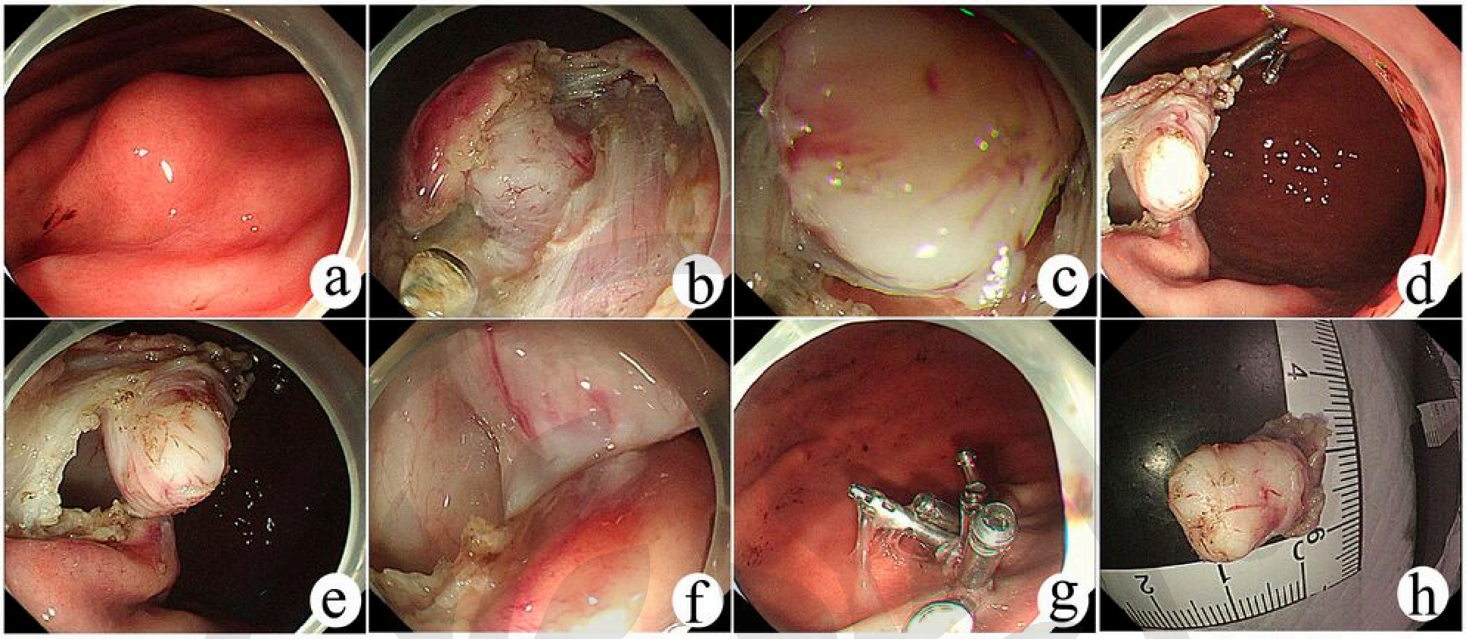
Video_image. Internal traction-assisted EFTR using the clip-with-spring device.

Table 1. Comparisons of clinical characteristics and therapeutic outcomes between patients of the two groups

Variables	IT-EFTR group (*n* = 26)	NA-EFTR group (*n* = 26)	*P* value
Sex (M/F)	10/16	8/18	0.560
Age, mean ± s.d., years	60.9 ± 10.0	58.4 ± 7.7	0.316
Maximum tumor diameter, mean ± s.d., cm	1.5 ± 0.4	1.6 ± 0.4	0.207
Tumor location (corpus/antrum)	24/2	24/2	1.000
Intra-luminal growth pattern (predominantly/partly)	15/11	17/9	0.569
En bloc resection, *n* (%)	26 (100)	24 (92.3%)	0.490
Procedure time, mean ± s.d., min	33.0 ± 21.8	91.8 ± 38.6	**<0.001**
Perforation time, mean ± s.d., min	19.0 ± 18.8	55.5 ± 27.8	**<0.001**
Serosa exposure score,			
mean ± s.d.	3.4 ± 0.9	1.9 ± 0.7	**<0.001**
<3/≥3	6/20	22/4	**<0.001**
VAS score after operation, mean ± SD	4.2 ± 1.0	4.7 ± 0.7	**0.037**
Histopathological type (leiomyoma/GIST)	7/19	5/21	0.510
Postoperative hospital stay, mean ± s.d., d	3.7 ± 2.1	4.8 ± 1.3	**0.038**
Complications, *n* (%)			

Intra-operative bleeding, *n* (%)	5 (19.2)	5 (19.2)	1.000
Delayed bleeding, *n* (%)	1 (3.8)	2 (7.7)	1.000
Fever (>38℃), *n* (%)	2 (7.7)	3 (11.5)	0.638

Abbreviations: EFTR, endoscopic full-thickness resection; IT, internal traction; NA, non-assisted; M, male; F, female; s.d., standard deviation; cm, centimeter; min, minute; d, day.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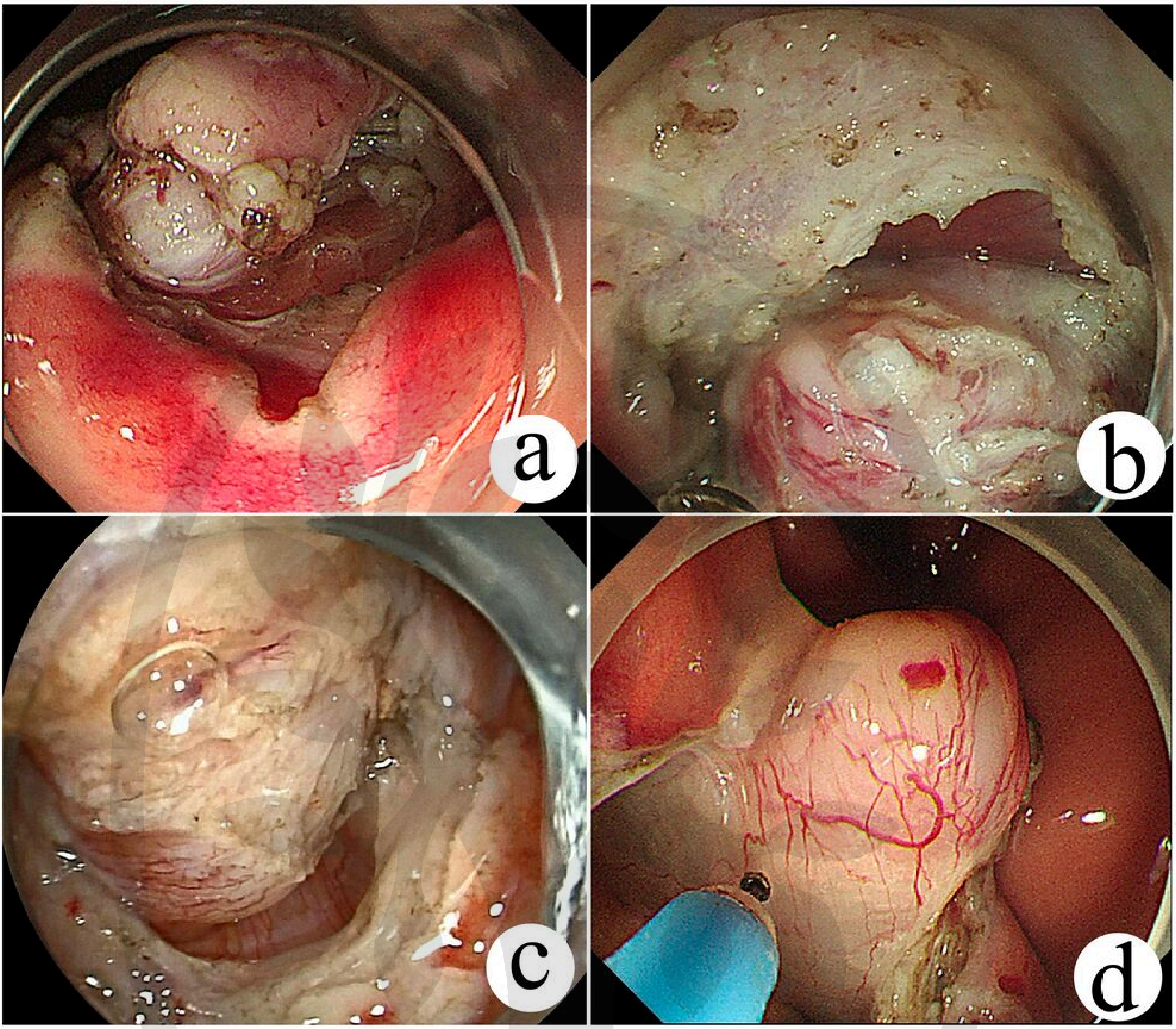
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