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DYNAMIC MANUSCRIPT

Purse-string sutures using novel endoloops and repositionable clips for the closure of large iatrogenic duodenal perforations with single-channel endoscope: a multicenter study

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Abstract

Background Serious complications due to perforation restrict the development of duodenal endoscopic treatment. The key stage for remediation is the successful endoscopic closure to prevent peritonitis and the need for surgical intervention. This report aimed to present a new simple method for the closure of large iatrogenic duodenal perforations with purse-string sutures using the novel endoloops and repositionable clips through a single-channel endoscope.

Methods A total of 23 patients with iatrogenic duodenal perforations ≥ 1 cm were retrospectively studied who were presently treated by purse-string sutures using the novel endoloops and the repositionable hemostasis clips with the single-channel endoscope at four institutes. During and after the procedure, a 20-gauge needle was used to relieve the pneumoperitoneum or subcutaneous emphysema. Finally, a gastroduodenal decompression tube was placed.

Results The median maximum diameter of iatrogenic duodenal perforations was 1.65 cm (range 1.0–3.0 cm). Complete endoscopic closure of all 23 perforations was achieved. No patient had severe complications such as peritonitis. The wounds were healed and no obvious duodenal stricture was observed in all cases after 3 months.

Conclusion Purse-string sutures using the novel endoloops and repositionable endoclips through single-channel endoscope were feasible, effective and easy methods for the closure of large duodenal iatrogenic perforations.

Keywords Endoscopic purse-string suture · Duodenal perforation · Single-channel endoscope

Gastrointestinal endoscopy procedures, such as endoscopic mucosal resection (EMR), endoscopic submucosal dissection (ESD), endoscopic ultrasonography (EUS) and endoscopic retrograde cholangiopancreatography (ERCP), are widely used for the diagnosis or treatment of digestive diseases. Duodenal endoscopic treatment is the most difficult type in the gastrointestinal tract (GI) and is technically challenging because of anatomical specificities [1]. In addition to these technical difficulties, the duodenal procedures are associated with a significantly higher rate of complication than endoscopic treatment in other parts of the GI tract [1]. Perforation is one of the hazardous complications. Small perforations can be managed by metallic clips [2]. For the larger iatrogenic perforations, the over-the-scope clip (OTSC) system or the Overstitch endoscopic suturing device may be selected, but the high cost and difficult operation limits their application. Recently, the endoscopic purse-string suture (EPSS) method via a two-channel endoscopy is proved to be an effective and safe technique for the closure of large perforation [2–4]. However, compared with

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a single-channel endoscope, a dual-channel endoscope is not usually available and difficult to operate. Therefore, the treatment of large perforations may still require surgery [5–7]. The secure closure of iatrogenic perforation has been considered to be the major obstacle in duodenal endoscopic treatment. This report presents a new simple method for the successful closure of large iatrogenic duodenal perforations with purse-string sutures using the novel endoloops and repositionable clips through standard single-accessory-channel endoscope.

Methods

Patient information

From January 2016 to January 2018, a total of 23 patients with iatrogenic duodenal perforations ≥ 1 cm were retrospectively studied who were presently treated by purse-string sutures using the endoloops (LeCamp™ Loop-15, Loop-20 and Loop-30, Leo Medical Co., Ltd., Changzhou, China) and the repositionable hemostasis clips (SureClip™, Micro-Tech Co., Ltd., Nanjing, China) with the single-channel endoscope respectively at four institutes. The research was approved by the Ethics Committee of the First Affiliated Hospital of Nanjing Medical University (NJMU), the Second Affiliated Hospital of NJMU, General Hospital of XuZhou Mining Group and the People's Hospital of Lianshui in accordance with the Helsinki Declaration, and written informed consent was obtained from each patient. Detailed clinic data are listed in Table 1.

Procedure of purse-string suture with single-channel endoscope

Duodenal iatrogenic perforations (≥ 1 cm) were immediately closed with purse-string sutures using the endoloops and the repositionable hemostasis clips by means of single-channel endoscope. In the preparation stage, a carbon dioxide (CO_2) insufflator (UCR; Olympus, Tokyo, Japan) was applied, and a transparent cap (ND-201-11802; Olympus) was attached to the front of the single-channel therapeutic endoscope (GIF-260J, Olympus). As a first step of purse-string suture, a novel endoloop (Fig. 1) was inserted to the perforation site by forceps through the biopsy channel. After adjusting the location and angle of the endoloop, it was anchored onto the full thickness of the perforation's margin with a repositionable hemostasis clip, followed by insertion of several additional clips to symmetrically hold the endoloop at different sides of the margin. Before tightening the endoloop, the biopsy forcep was used to adjust the clips head to the duodenal lumen. Then the delivery system was inserted. The removable hook was connected with the ligation loop of the LeCamp™ device, which was tightened by slight pulling all the edges together. Subsequently the delivery system was removed from the endoloop and the perforation was closed. If any clip was not accurately positioned or the purse-string suture was not tight, the remedy was to clamp, pull and loosen the endoloop gently with the forceps, add the clips in the right place and repeat the steps of tightening the endoloop. An example of closure procedure is shown in Fig. 2 and Video 1. A 20-gauge needle was used to relieve the pneumoperitoneum or subcutaneous emphysema during and after the procedure. Finally, a gastroduodenal decompression tube was placed.

Postoperative care

After the operation, the white blood cell (WBC) count was evaluated daily until it was normal. The patients were asked to fast until the WBC count was normal without abdominal pain or tenderness. Proton pump inhibitors (PPIs) and antibiotics were used until the end of fasting. Then they were allowed to take fluids for 1 week, semifluids for 1 week and soft diets for 2 weeks.

Results

23 large iatrogenic duodenal perforations were identified in patients undergoing endoscopy (Table 1). The median age (13 men and 10 women) was 57 years (range 23–82 years). The 23 perforations included 9 located in the duodenal bulb, 7 located in the duodenal descending segment (non-duodenal papilla site) and 7 located in the junction of bulb and descending part, as shown in Table 1. Perforations occurred during EMR (including endoscopic piecemeal mucosal resection, EPMR, $n = 3$), ESD (including endoscopic full-thickness resection, EFTR, $n = 14$), ERCP ($n = 3$) and EUS ($n = 3$). The median maximum diameter of the defects was 1.65 cm (range 1.0–3.0 cm). Complete closure of all 23 duodenal perforations was achieved (success rate 100%). In these processes, eight titanium clips were used on average, and the mean suture time was 8 min.

During or after the procedure, no laparoscopic assistance or surgery was needed, and no severe complications such as massive bleeding, leak, or infection occurred. The postoperative WBC count was elevated in 11 patients. It dropped to a normal level after the use of antibiotics during the following 2–5 days. Three patients experienced low-grade fever after the procedure, and seven patients reported mild abdominal pain. All the patients were managed with conventional therapy.

The mean hospital stay after perforation closure was 6.4 days (range 3–14 days). All the wounds were healed and no obvious duodenal stricture was observed when the patients

Table 1 Characteristics of the cases of iatrogenic duodenal perforations closed by purse-string sutures with single-channel gastroscope

Patient no.	Sex	Age (years)	Procedure	Duodenal site	Size (cm)	Titanium clips (*n*)	Suture time (min)	Complications	Elevated WBC count
1	F	65	ESD of ectopic pancreas	Junction of bulb and descending part	1.0×1.5	8	10	No	Yes
2	M	67	ESD of lipoma	Junction of bulb and descending part	1.0×1.0	6	8	No	No
3	F	64	ESD of GIST	Descending part	1.7×2.0	10	14	Abdominal pain	Yes
4	M	62	EMR of adenomatous polyp	Bulb	1.0×1.5	5	5	No	No
5	M	51	EPMR of adenomatous polyp	Descending part	1.5×1.8	10	15	No	No
6	F	65	EUS	Bulb	2.0×2.0	8	10	Abdominal pain	No
7	M	80	ERCP	Descending part	2.0×2.5	12	20	Fever, abdominal pain	Yes
8	F	23	ESD of ectopic pancreas	Junction of bulb and descending part	1.5×2.0	8	8	Abdominal pain	Yes
9	M	42	ESD of NET	Bulb	1.0×1.0	4	5	No	No
10	F	49	ESD of HGIN	Bulb	1.8×2.0	8	12	No	Yes
11	F	53	ESD of ectopic pancreas	Bulb	1.0×1.5	6	6	No	No
12	M	72	ESD of cyst	Bulb	1.0×1.0	4	5	No	No
13	F	82	EUS	Bulb	1.0×1.0	4	5	No	No
14	F	49	ERCP	Descending part	1.5×2.0	10	15	Abdominal pain	Yes
15	M	44	ESD of GIST	Descending part	3.0×3.0	14	20	Fever, abdominal pain	Yes
16	M	59	ESD of GIST	Junction of bulb and descending part	1.0×1.5	5	8	Fever	Yes
17	F	76	EUS	Junction of bulb and descending part	1.0×1.0	4	6	No	No
18	M	65	ESD of GIST	Bulb	1.5×2.0	8	6	No	Yes
19	M	43	ESD of GIST	Descending part	1.7×2.0	10	14	Abdominal pain	Yes
20	M	46	ERCP	Descending part	1.5×1.8	10	12	No	No
21	M	52	EMR of adenomatous polyp	Bulb	1.0×1.5	8	8	No	No
22	F	48	ESD of cyst	Junction of bulb and descending part	1.0×1.0	6	7	No	No
23	M	57	ESD of lipoma	Junction of bulb and descending part	1.0×1.0	6	8	No	Yes

ESD endoscopic submucosal dissection, *EMR* endoscopic mucosal resection, *EPMR* endoscopic piecemeal mucosal resection, *EUS* endoscopic ultrasonography, *ERCP* endoscopic retrograde cholangiopancreatography, *GIST* gastrointestinal stromal tumor, *NET* neuroendocrine tumors, *HGIN* high-grade intraepithelial neoplasia

were followed up by gastroscopy after 3 months (follow-up of patient No. 3 was taken as an example, whose endoscopic examination of the site of perforation was shown in Fig. 3). In 3 cases, the clips remained in situ without any side effects at the third month of follow-up.

Discussion

The incidence of perforation in duodenum is much higher compared with in the esophagus, stomach and colon

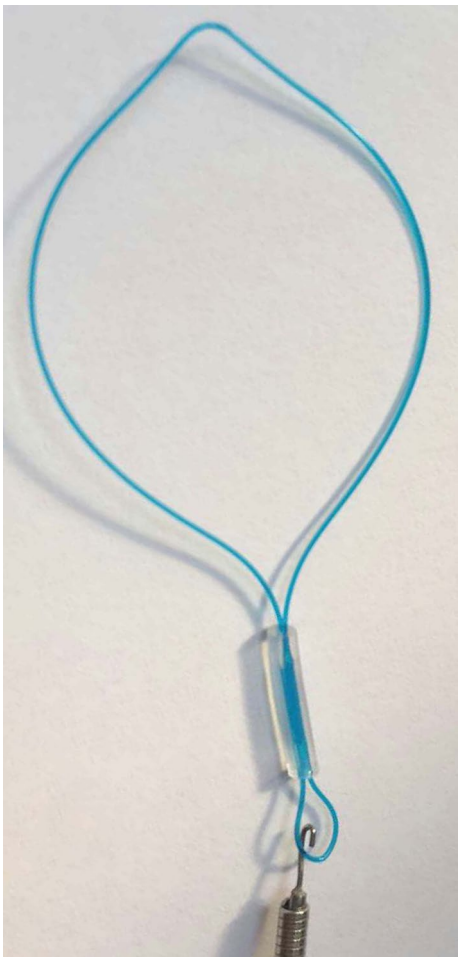

Fig. 1 The LeCamp™ endoloop and the delivery system

because duodenum is the most difficult and risky place in the GI to perform endoscopic treatment [8]. On the one hand, it is related to the anatomical specificity of the duodenum: (1) a thinner duodenal wall than in other organs of the digestive tract; (2) difficulty working the scope; (3) location in the retroperitoneum. On the other hand, iatrogenic duodenal perforations have been associated with the endoscopic techniques. It was reported that the incidence of immediate duodenal perforation during EMR ranges from 0% to 4.3% [1]. More perforation occurs during ESD, and duodenal ESD has a reported risk of immediate perforation of 6.3–75% [1]. The incidence of duodenal perforation during ERCP is reportedly approximately 1% [9]. In the present study, 60.9% (14/23) duodenal perforations occurred in the procedure of ESD, while 13.0% (3/23) perforations occurred during EMR (two in EMR and one in EPMR). The reasons for the higher incidence of duodenal perforation with ESD than with EMR may be as follows: (1) longer time of electrical cautery during ESD causes damage in the muscularis propria, with resulting necrosis [10]; and (2) the operation time is longer and the technical difficulties are higher than that of EMR. EPMR for large lesions might increase the risk of iatrogenic perforation. Not only that, but duodenal perforation is one of the most serious complications of ERCP and EUS, which are associated with the technical difficulties because neither the duodenal endoscope nor the ultrasound endoscope is the front-view scope. Six cases of perforations during ERCP and EUS in our study were caused by improper operation due to the unskillfulness of the physician.

Serious complications of peritoneal or retroperitoneal intestinal leakage due to perforation restrict the development of duodenal endoscopic treatment. The key stage for remediation is the successful endoscopic closure of the duodenal wall defect, to prevent peritonitis and the need for surgical intervention. A large variety of methods and devices for the endoscopic closure of gastrointestinal defects have been studied [5, 11–14]. Endoclips are still in common usage, which is yet limited to the perforations less than 1 cm in size and linear in shape [2]. The reason for this is that the open size and the grasping power of the conventional clips are insufficient to hold a large defect [15]. OTSCs are made of elastic, biocompatible nitinol and are capable of full thickness closure defects measuring 2 cm in diameter [12]. The Overstitch endoscopic suturing device is specifically designed for tissue approximation and allows the creation of either a continuous suturing line or separate stitches [13]. However, OTSCs and the Overstitch systems, as the new medical technologies, are costly and are not covered by national insurance in most countries. Therefore, there are many limitations to their use and most endoscopists have less experience in such technologies.

It has been reported previously that two-channel gastroscope could be applied to close the perforation using a nylon loop and metallic clips [16]. This closure method is based on clip closure plus endoloop ligature, which would tightly close both sides of the defect. However, the two separate channels of this kind of dual-channel gastroscope are parallel, and it is not easy for the instruments placed within the two different channels to work together, therefore making it difficult to clip the nylon loop around the edge of the perforation [17]. Moreover, dual-channel endoscope is not usually available in most Chinese endoscopy units. Furthermore, the most commonly used endoloops (MAJ339-340, Olympus) in the above closure method require installation in advance of insertion, which cannot be loosen and re-tightened even if purse-string suture is not tight or the closure operation fails. The endoloop which we used in this study is a novel endoscopic product using the purse-string suture idea with certain advantages. Its loop does not need to be preloaded prior to insertion and it can be applied easily using the single working channel of conventional endoscope. Because the part of ligation loop at the tail end of the novel endoloop is larger

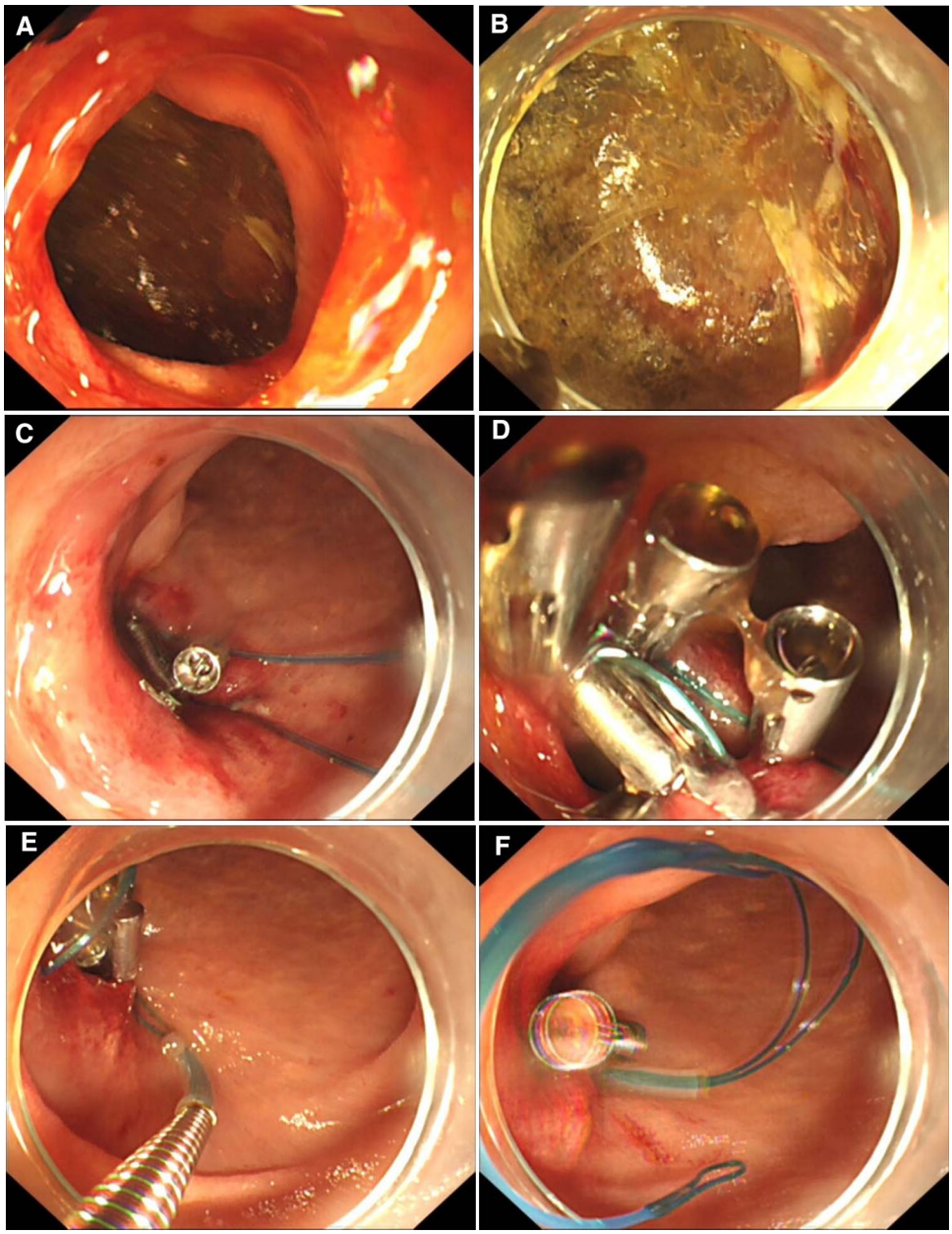

Fig. 2 Purse-string suture using the novel endoloop and repositionable clips for the closure of iatrogenic duodenal perforation with single-channel therapeutic endoscope. **A** and **B** Iatrogenic perforation due to EUS located at the interior wall of descending duodenum; **C** the repositionable clips were used to symmetrically hold the endoloop at different sides of the perforation's margin; **D** before tightening the endoloop, the biopsy forceps were used to adjust the clips head to the duodenal lumen; **E** the removable hook was connected with the endoloop; **F** successful closure of the perforation following tightening of the endoloop by slight pulling of all the edges together

than that of Olympus, it can be conveniently connected with or removed from the hook of the delivery system. If any clip was not accurately positioned or the purse-string suture was not tight, amends can be made by loosening the endoloop gently with the forceps, adding the clips in the right place and repeating the steps of tightening the endoloop. This design may also realize multi-loop operation at one time. In addition, the loop size ranging from 15 mm to 40 mm meets most of the endoscopic closure including larger defects. Instead of Olympus metallic clips, the hemostasis clips we used in the present study are rotatable and repositionable. By rotating, the clips can be easily placed to the suitable position with the right angle. Because of the advantage of reposition, the clips can be pre-clamped but not released, which helps to determine whether the placement is suitable. This kind of clip can also be not fully opened, which is more beneficial to the operation in the narrow space. These improvements reduce the difficulty of using the titanium clips. In addition, according to the sizes of the defects and the operating space, the clips with different open sizes can be selected. With regard to the strength of the closure, that the endoclips fixed to the full thickness of the defect's distal margin (from mucosa to outer membrane) could prevent the clips from tearing the mucous membrane and shedding. In the present study, we achieved complete closure of all cases using the endoloops and the repositionable clips with single-channel endoscope. Since it is more difficult to operate in the duodenal descending segment than in the duodenal bulb due

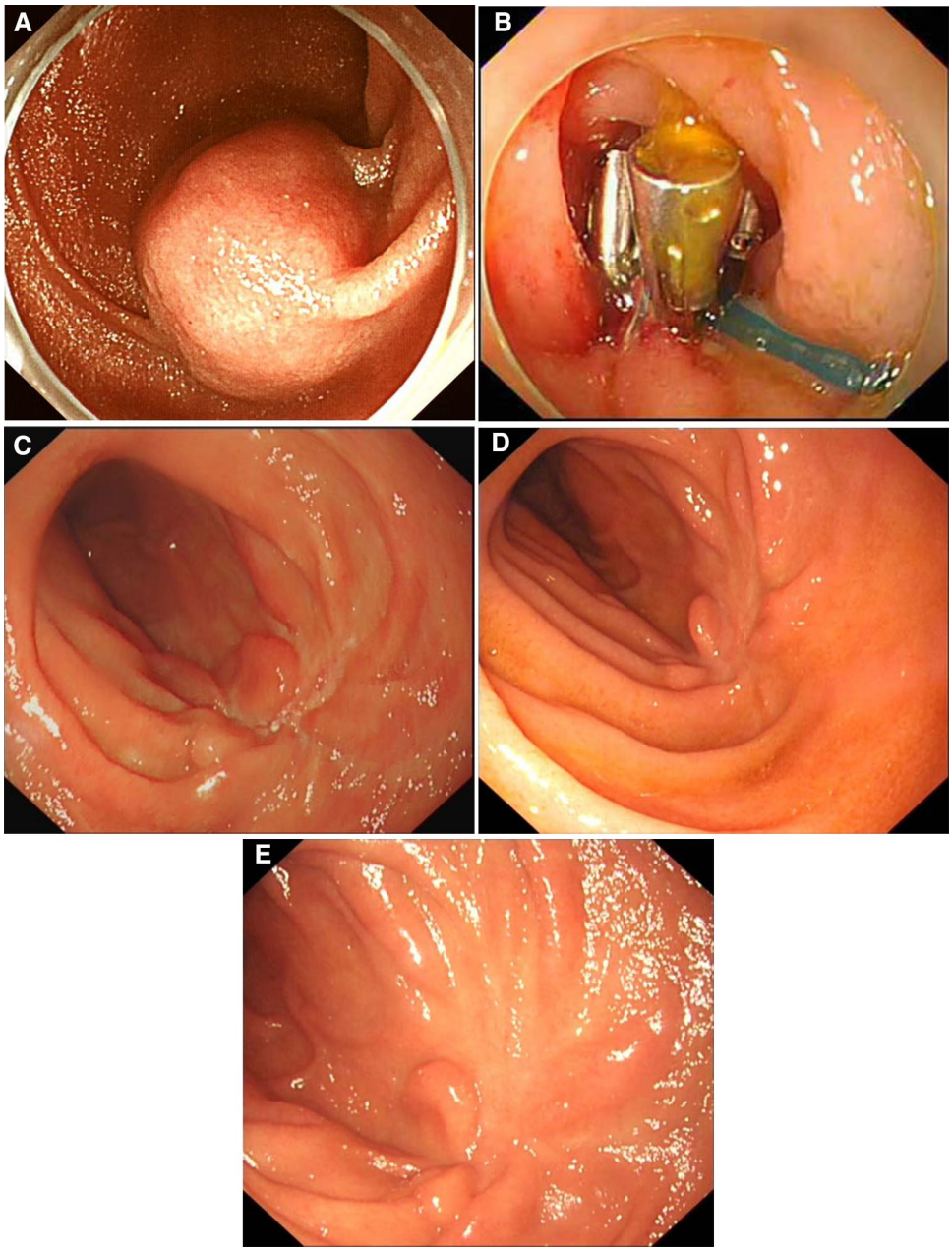

Fig. 3 Examination of the site of perforation by surveillance endoscopy indicated that the wound healed well. **A** The protruding submucous lesion of patient No. 3 was initially detected by endoscopy. **B** The perforation due to an EFTR was closed with purse-string suture. **C** Follow-up 3 months after operation. **D** Follow-up 12 months later. **E** Follow-up 29 months later

to the limitation of operating space and angle, our experience is that the advantage of using repositionable clips is more obvious at the duodenal descending part.

In this multi-center study, we first applied this method of purse-string suture in three hospitals (patient No. 1 to No. 20) and found that it was reliable and easy to operate. A large duodenal ulcer perforation after failed laparoscopic repair was even successfully closed by this method [18]. Whereafter, this technology was extended to another cooperative hospital (patient No. 21 to No. 23), where dual-channel endoscope is not yet equipped. Based on the effective suture of the duodenal iatrogenic perforation, the endoscopic treatments of the duodenum, such as ESD, have been promoted in our four hospitals. In addition, it avoids the conversion to operation, which is more acceptable to patients, and helps to reduce medical disputes.

In summary, purse-string sutures using the novel endoloops and repositionable endoclips through single-channel endoscope seem to be feasible, effective, and easy methods for the closure of large duodenal iatrogenic perforations. Although the series of 23 patients was small, we would like to share this method. In the further study, we will investigate the potential value of this technique in the treatment of perforation of duodenum and other GI tract, and a large-scale, randomized control study will be required.

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Compliance with ethical standards

Disclosures Sumin Zhu, Jie Lin, Fazhen Xu, Simin Guo, Shu Huang, and Min Wang have no conflict of interest or financial ties to disclose.

References

1. Fujihara S, Mori H, Kobara H et al (2016) Management of a large mucosal defect after duodenal endoscopic resection. World J Gastroenterol 22(29):6595–6609
2. Shi Q, Chen T, Zhong YS et al (2013) Complete closure of large gastric defects after endoscopic full-thickness resection, using endoloop and metallic clip interrupted suture. Endoscopy 45(5):329–334
3. Zhang Y, Wang X, Xiong G et al (2014) Complete defect closure of gastric submucosal tumors with purse-string sutures. Surg Endosc 28(6):1844–1851
4. Ye LP, Yu Z, Mao XL et al (2014) Endoscopic full-thickness resection with defect closure using clips and an endoloop for gastric subepithelial tumors arising from the muscularis propria. Surg Endosc 28(6):1978–1983
5. Paspatis GA, Dumonceau JM, Barthet M et al (2014) Diagnosis and management of iatrogenic endoscopic perforations: European Society of Gastrointestinal Endoscopy (ESGE) position statement. Endoscopy 46(8):693–711
6. Donatelli G, Vergeau BM, Dritsas S et al (2013) Closure with an over-thescope clip allows therapeutic ERCP to be safely performed after acute duodenal perforation during diagnostic endoscopic ultrasound. Endoscopy 45(Suppl 2):E392–E393
7. Merchea A, Cullinane DC, Sawyer MD et al (2010) Esophagogastroduodenoscopy-associated gastrointestinal perforations: a single-center experience. Surgery 148(4):876–880
8. Honda T, Yamamoto H, Osawa H et al (2009) Endoscopic submucosal dissection for superficial duodenal neoplasms. Dig Endosc 21(4):270–274
9. Prachayakul V, Aswakul P (2014) Endoscopic retrograde cholangiopancreatography-related perforation: management and prevention. World J Clin Cases 2(10):522–527
10. Hanaoka N, Uedo N, Ishihara R et al (2010) Clinical features and outcomes of delayed perforation after endoscopic submucosal dissection for early gastric cancer. Endoscopy 42(12):1112–1115
11. Raju GS (2014) Endoscopic clip closure of gastrointestinal perforations, fistulae, and leaks. Dig Endosc 26(Suppl 1):95–104
12. Ghossaini AI, Lucidarme N, Bulois D P (2014) Endoscopic treatment of iatrogenic gastrointestinal perforations: an overview. Dig Liver Dis 46(3):195–203
13. Kantsevoy SV, Bitner M, Mitrakov AA et al (2014) Endoscopic suturing closure of large mucosal defects after endoscopic submucosal dissection is technically feasible, fast, and eliminates the need for hospitalization (with videos). Gastrointest Endosc 79(3):503–507
14. Schmidt A, Damm M, Caca K (2014) Endoscopic full-thickness resection using a novel over-the-scope device. Gastroenterology 147(4):740–742
15. Mori H, Shintaro F, Kobara H et al (2013) Successful closing of duodenal ulcer after endoscopic submucosal dissection with over-the-scope clip to prevent delayed perforation. Dig Endosc 25(4):459–461
16. Nakagawa Y, Nagai T, Soma W et al (2010) Endoscopic closure of a large ERCP related duodenal perforation by using endoloops and endoclips. Gastrointest Endosc 72(1):216–217
17. Zeng CY, Li GH, Zhu Y et al (2015) Single-channel endoscopic closure of large endoscopy-related perforations. Endoscopy 47(8):735–738
18. Huang S, Zhu S (2017) Closure of duodenal ulcer perforation using a novel endoloop device with a single-channel gastroscope after failed laparoscopic repair. Endoscopy 49(S 01):E31–E32