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Endoscopic full-thickness resection (EFTR) without laparoscopic assistance for nonampullary duodenal subepithelial lesions: our clinical experience of 32 cases

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Abstract

Background Standard treatment for nonampullary duodenal tumors has not yet been established. In case of tumors originated from the muscularis propria (MP) layer and adherent to the serosa layer, the lesions can not be completely removed by ESD. However, with the development of the endoscopic suture technique, endoscopic full-thickness resection (EFTR) of duodenal subepithelial lesions has become possible.

Methods We retrospectively analyzed 32 patients with nonampullary duodenal subepithelial lesions who underwent EFTR between February 2012 and January 2017. The suturing method, complications that occurred during and after the operations, perioperative management, tumor characteristics, and pathological findings were analyzed in all patients.

Results The complete resection rate was 100%; all patients successfully received EFTR except for one patient who required conversion to open surgery. Severe abdominal pain was observed after the operation in one patient who then received laparoscopic exploration, and the possibility of delayed perforation was considered. Another patient showed a decline in blood oxygen saturation (SO_2) and was transferred to the intensive care unit (ICU) for further management. Delayed bleeding and fistula were not observed. All patients achieved complete remission.

Conclusion EFTR is a safe, minimally invasive treatment modality that ensures complete eradication of the duodenal subepithelial lesions.

Keywords Nonampullary duodenal subepithelial lesion · Endoscopic full-thickness resection · Complications

With the development of endoscopic technique, an increasing number of duodenal subepithelial lesions are being detected. Subepithelial lesions that can arise in the duodenum include lipomas, gastrointestinal stromal tumors, and neuroendocrine neoplasms [1]. According to the site of tumor growth, these lesions can be divided into ampullary duodenal tumors and nonampullary duodenal tumors.

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However, standard treatment for nonampullary duodenal tumors has not yet been established [2–5]. Surgical treatment for duodenal tumors is complex and carries a higher risk as compared to that for tumors at other sites of the gastrointestinal tract due to the special anatomy of the duodenum. To date, endoscopic submucosal dissection (ESD) has been widely used in clinics and it is feasible for the treatment of duodenal subepithelial lesions. ESD has the advantage of removing the lesion en bloc with negative lateral and deep margins by dissecting through the submucosal plane. However, tumors originating from the muscularis propria (MP) layer and adhering to the serosa layer cannot be completely removed by ESD. Submucosal tunneling endoscopic resection (STER) is derived from peroral endoscopic myotomy (POEM), which is used to treat achalasia. By establishing a submucosal ''tunnel,'' the tumor originating from the MP layer can be resected safely and completely. However, the STER [6] techniques for removing Gastrointestinal Stromal Tumors (GISTs) and other subepithelial tumors in the

esophagus or proximal stomach are not typically employed in the duodenum, due to the challenging anatomic and endoscopic features in duodenum [1].

Endoscopic full-thickness resection (EFTR) without laparoscopic assistance has been derived from ESD. It can resect the tumors originated from the MP layer and adherent to the serosa layer. EFTR avoids the possibility of involved margins and the potential for a local relapse [7]. However, treatment of duodenal subepithelial lesions using this technique is a challenge for the endoscopist. Traditionally, the duodenum has been considered a forbidden zone for EFTR due to its special anatomical features. However, with the improvement in metal clips and the extensive use of the endoloop and metal clip suture in recent years, many "forbidden zones" have been broken through, and the indications for EFTR have been expanded. From February 2012 to January 2017, 32 patients with nonampullary duodenal subepithelial lesions received EFTR at our center. Herein, the feasibility and the clinical efficacy of EFTR were evaluated in the treatment of nonampullary duodenal subepithelial lesions.

Patients and methods

Patient information

Between February 2012 and January 2017, 32 consecutive patients with nonampullary duodenal subepithelial lesions originating from the MP layer were treated in our center. There were 16 males and 16 females, and the median age was 52 years (range 31–81 years). Patients with lesions located within the ampullary area were excluded from our study. The size and origin of the lesions were confirmed by endoscopic ultrasonography (EUS) and computed tomography (CT). All patients underwent EFTR by experienced endoscopists. The clinicopathological characteristics of these patients are listed in Table 1. This study was approved by the Ethics Committee of Zhongshan Hospital affiliated to Fudan University, and it was performed in accordance with the Helsinki Declaration. Written informed consent was obtained from all patients.

Endoscopic equipment and accessories

Standard single-accessory-channel endoscope (GIT-H260, Olympus) and dual-channel endoscopy (GIF-2T240, Olympus) were used during the procedures. A transparent cap (D-201–11304; Olympus) attached to the front of the endoscope, a hybrid knife (I or T type) (ERBE, Tübingen, Germany) and an insulated-tip electrosurgical knife (KD-611L,

Table 1 Demographic data, clinical characteristics, and therapeutic outcomes of endoscopic full-thickness resection (EFTR) for nonampullary duodenal subepithelial lesions

Data	Patients ($n = 32$)
Median age [years (range)]	52 (31–81)
Gender (n)	
Male/female	16/16
Median tumor size [diameter, cm (range)]	1.2 (0.5–3.0)
Tumor location (n)	
Anterior wall of the bulb	21
Anterior wall of the bulb-descending junction	8
Descending part (opposite side of papillary)	2
Posterior wall of the bulb	1
Layer involved	
Muscularis propria	32
En bloc resection [n (%)]	32 (100%)
Repairing method	
Metallic clips	6
Endoloops and metallic clips suture	20
Endoloops and metallic clips suture plus fibrin glue	4
OverStitch™	1
Transferred to open surgery	1
Complications	
Delayed perforation	1
Delayed hemorrhage	0
SO_2 decline	1
Abdominal pain and/or fever	7
Additional therapy	
Transferred to open surgery	1
Laparoscopic exploration	1
Admitted to ICU	1
Pathological diagnosis (n)	
GIST	14
Neuroendocrine neoplasm	4
Heterotopic pancreas	11
Leiomyoma	2
Lipoma	1
Average hospital stay after procedure [days (range)]	6.2 (2–19)
Average follow-up period [months (range)]	38 (14–73)
Recurrence [n (%)]	0

Olympus) were used to dissect the submucosal layer and peel the tumor.

Other equipment included a high frequency generator (ICC-200, ERBE, Erbe Elektromedizin GmbH, Tübingen, Germany), injection needles (NM-4L-1, Olympus), grasping forceps (FG-8U-1, Olympus), snares (SD-230U-20, Olympus), hot biopsy forceps (FD-410LR, Olympus), clips (AG-51066, AGS Medtech, Hangzhou, China), endoloops

(MAJ-339, Olympus), and OverStitch™ system (Apollo Endosurgery).

EFTR procedure and postoperative management

Patients received treatment under endotracheal intubation and general anesthesia. Prophylactic antibiotic (ceftriaxone sodium 2.0 g) was administered intravenously during the anesthetic induction period. If the procedure time exceeded 2.5 h, the same dosage was used again during the operation. Then, several points were marked around the lesion, and a mixture solution (including 100 ml of normal saline, 1 ml of indigo carmine, and 1 ml of epinephrine) was injected into the submucosa. EFTR without laparoscopic assistance was performed as previously described [8]. In each patient, the tumor, including its surrounding MP layer and serosa layer, was removed safely and completely without disruption of the tumor capsule (defined as R0 resection) (Fig. 1, Video). The large post-resection defect was separately closed with metallic clips, endoloops and metallic clip suture and Over-Stitch™. A 20-gauge needle was used to relieve the pneumoperitoneum during and after the procedure. Then, a gastrointestinal decompression tube was placed near the wound for drainage and detection of any postoperative hemorrhage.

After the operation, all patients were fasted and they remained in a semirecumbent position, oxygen was administered, electrocardiograph (ECG) monitoring was performed, and antibiotics (ceftriaxone sodium plus ornidazole) and a PPI inhibitor were administered. On the third day after the operation, if the patient had passed gas, the gastrointestinal decompression tube was removed and a liquid diet was administered. After discharge, the patient was asked to remain on a liquid diet for 1 week and a semiliquid diet for another week (Fig. 2).

Follow-up

Patients received follow-up by endoscopy and/or EUS at 3, 6, and 12 months after the operation and once yearly thereafter to evaluate the wound healing and to check if there was any tumor recurrence.

Results

The completeness of resection

A total of 32 patients received EFTR at our center. All the subepithelial lesions were located in the deep MP layer and were close to the serosa layer, and some lesions showed
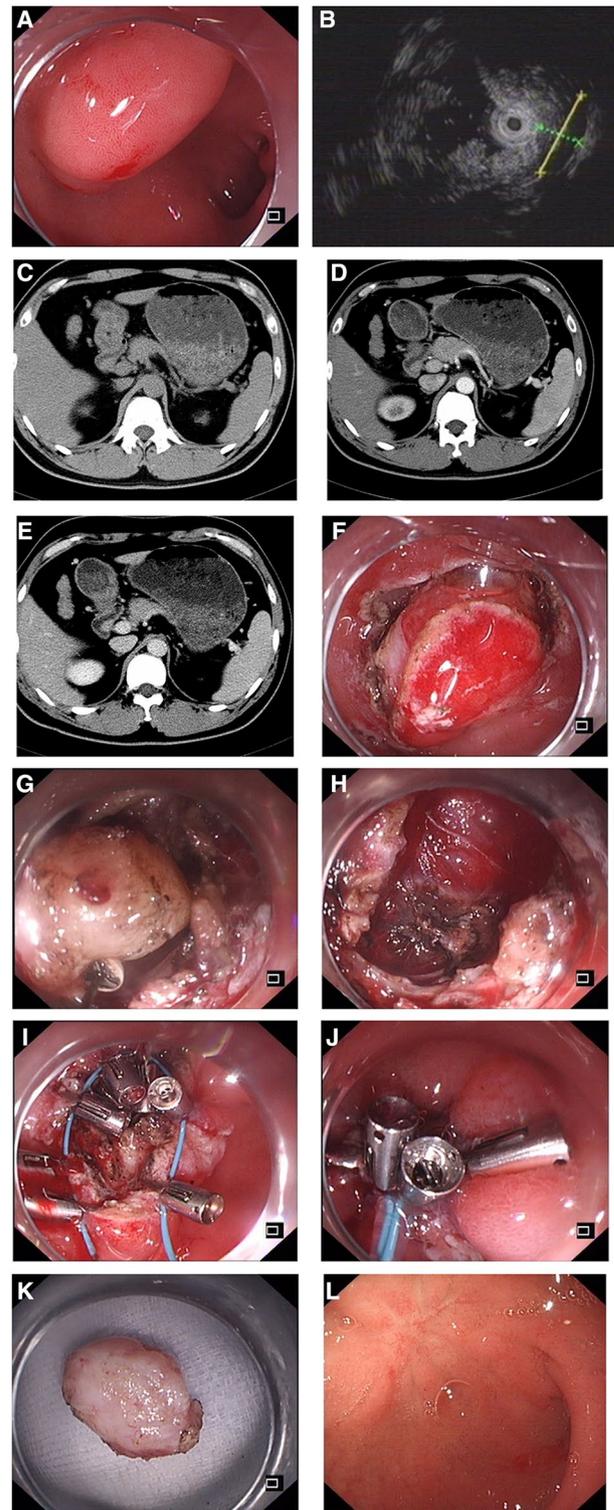
Fig. 1 Endoscopic full-thickness resection (EFTR) procedure for a subepithelial tumor (SET) in the anterior wall of the bulb. **A** An 1.2-cm SET in the anterior wall of the bulb. **B** EUS imaging of the tumor. **C–E.** CT imaging of the tumor. **C** Plain scan. **D** Arterial phase. **E** Portal phase. **F, G** The tumor was dissected under direct vision using the endoscopic full-thickness resection (EFTR) method. **H** The defect in the wall of the bulb after tumor resection. **I, J** The defect was occluded by using endoloops and metallic clips suture. **K** The resected tumor, and the pathologic examination showed GIST. **L** 3 months after the operation, the wound healed well

Fig. 2 A 51-year-old female patient. After resection of a 1.5-cm lesion in the anterior wall of the bulb, she developed low-grade fever and mild abdominal distension. CT showed free gas under the diaphragm and hydrothorax (left and right). After conservative treatment, she recovered smoothly
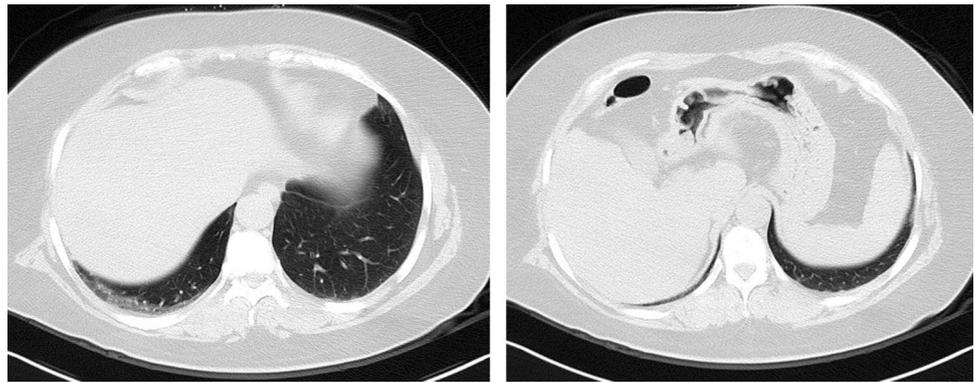
partial extraluminal growth. The complete resection rate was 100%. In these 32 cases, a lesion was found in the anterior wall of the bulb in 21 patients, in the anterior wall of the bulb-descending junction in eight patients, in the descending part (opposite side of the papillary region) in two patients, and in the posterior wall of the bulb in one patient. The median maximal diameter of these lesions was 1.2 cm (range 0.5–3.0 cm), and the average operation time was 68 min (range 17–186 min). All patients stayed in the hospital for observation after EFTR; the average hospital stay was 6.2 days (range 2–19 days).

Pathology

Pathological examination showed a GIST in 14 patients, a neuroendocrine neoplasm in four patients, a leiomyoma in two patients, a lipoma in one patient, and heterotopic pancreas in 11 patients (Table 1). After en bloc resection, both lateral and deep margins of all specimens were free of tumor on pathologic examination.

In the 14 cases of GISTs, the median diameter of the tumor was 1.5 cm (range 1.0–3.0 cm). Eleven GISTs had a very low risk of recurrence because not more than five mitoses were seen per 50 high-power field and three GISTs showed 7 or 8 mitoses per 50 high-power field, indicating an intermediate risk of recurrence. Further treatment was not given to these patients.

Complications

Intra-operative hemorrhage was treated successfully by using argon plasma coagulation, coagulating forceps, and metal clips.

Perforation that occurred in 31 patients during the procedure was managed successfully with use of metal clips, endoloops and metallic clip suture and OverStitch™ separately. Among these 31 patients, the perforation in four patients (including 1 patient with a lesion in the descending part) was

occluded with endoloops and metallic clips suture, and reinforced with fibrin glue. In a female patient aged 56 years, after resection of a lesion (2.0 cm in diameter) in the anterior wall of the bulb-descending junction, a 2.5-cm defect was left and it could not be occluded by endoscopy, and then, open surgery was performed. On the 19th day after the operation, she recovered smoothly and was discharged.

In a male patient aged 50 years, after EFTR for a 2.5-cm lesion in the anterior wall of the bulb-descending junction, a 3.0-cm defect was left and it was successfully occluded with endoloops and metallic clip suture. In the night after the operation, he developed severe abdominal pain with signs of peritonitis. Delayed perforation was suspected and a laparoscopic exploration was performed thereafter. However, perforation was not detected, and then, a drainage tube was placed near the wound. On the 6th day after the operation, he recovered smoothly and was discharged.

A male patient aged 81 years had a history of chronic obstructive pulmonary disease (COPD). During the procedure a 1.5-cm lesion in the anterior wall of the bulb was resected and the defect was managed successfully. In the night after the operation, he showed chest distress, shortness of breath, abdominal distension and a decline in blood SO_2. Then, he was transferred to the intensive care unit (ICU) for further treatment. On the 3rd day after the operation, the symptoms were alleviated. On the 10th day, he recovered smoothly and was discharged.

Subcutaneous and mediastinal emphysema was not observed in this cohort. Seven patients developed mild abdominal pain and distension, and imaging examination showed mild pneumoperitoneum and hydrothorax. They all recovered smoothly after conservative treatment.

Delayed bleeding and fistula were not occurred in this cohort.

Follow-up

All the patients received follow-up, and the wound healing was favorable in all cases. Local recurrence and distant metastasis were not found during the follow-up (average, 38 months, range 14–73 months) period.

Discussion

The incidence of duodenal subepithelial lesions is low and most of the lesions do not produce any typical symptoms. Some patients are accidentally diagnosed by gastroscopy. There is still controversy about whether resection should be performed. Many clinicians recommended regular follow-up for the lesions < 2 cm. However, some such tumors, especially mesenchymal neoplasms—including GI stromal tumors (GISTs)—originating from the MP layer, do have malignant potential [9]. Although most small GIST or micro-GIST show benign or indolent clinical course, there are still very few cases showing aggressive behavior, especially those tumors with high mitotic counts [10]. Besides, for some suspicious duodenal lesions, biopsy under endoscopy is not appropriate, and excision is the only option for establishing a definite diagnosis. However, it is difficult to perform traditional surgery for duodenal lesions due to the unique anatomical features of the duodenum as compared to other parts of the gastrointestinal tract. ESD is an endoscopic resection method that has been used to treat subepithelial lesions of the upper GI tract in recent years. It appears to be a safe, feasible, and effective procedure for providing accurate histopathologic evaluation, curative treatment, and improved quality of life for the patients. However, in case of a tumor originating from the MP layer and adhering to the serosa layer, it is very difficult to resect the tumor completely and there is a risk of residual. It appears that EFTR can be employed to resect these tumors completely.

However, it is difficult to perform an endoscopic operation in the duodenum because (1) the duodenal lumen is narrow; (2) a "C-loop" that makes maintaining endoscope position difficult; (3) Brunner's glands in the submucosal layer that stiffen the wall and make mucosal lifting difficult; (4) a thin deep muscle layer that results in a higher rate of perforation; and (5) difficult access if emergency or salvage surgery becomes necessary [11–13]. A more important point is that the bile duct and the pancreatic duct converge in the duodenum. Once perforation occurs, it will be more serious than those occurring at other sites of the gastrointestinal tract [14]. Besides, caution is required not only against intraprocedural perforation, but also against delayed perforation due to exposure to bile and pancreatic juice [11]. If delayed perforation occurs, the digestive juices and intestinal contents will flow into the retroperitoneum, resulting in retroperitoneal infection and abscess. Besides, EFTR of duodenum without laparoscopic observation may lead to suction of the adjacent tissue or an organs, such as the transverse colon, pancreas, or gallbladder, which may lead to serious complications [15]. Thus, the duodenum has been traditionally regarded as a forbidden zone for EFTR.

The key to the success of an endoscopic operation (including EFTR) of the duodenum is appropriate treatment of the wound. If the perforation can be successfully managed, the patient will recover quickly. Recently, many new types of clips that can open and close repeatedly have been developed and their use has significantly improved the success rate of wound suture. In this cohort, the clips could completely occlude the defects < 1 cm. However, it is difficult to close larger defects with these clips due to their smaller span. Even if a large defect is managed with these clips, the risk of delayed perforation and fistula is high due to the corrosive effects of the bile and pancreatic juice. The use of endoloops and metallic clips suture raises hope of solving this problem. Compared with the defects caused by laceration, the defects caused by EFTR are the "active" perforation which has a well-defined edge and mild edema. The metal clip can be firmly fixed on the wound edge. After tightening the nylon cord, the defect can be completely closed by applying high tension. The advantage of the endoloops and metallic clips suture is that larger defects can be closed by applying high tension with the use of several clips and the endoloop, which can resistant the corrosion caused by digestive juice. In this cohort, 24 patients with the defects larger than 1 cm were treated with this method, of which, the defects in four cases were reinforced with fibrin glue, and a favorable efficacy was achieved.

The OverStitch™ equipment is derived from the "Eagle Claw," and was developed by Apollo Endosurgery. Kantsevoy and Thuluvath [16] introduced the OverStitch technique into clinical practice for the first time, and they treated 12 patients, who had undergone ESD, with this technique and achieved favorable efficacy. In this cohort, a female patient aged 53 years developed a lesion located in the anterior wall of the bulb-descending junction. After resection of the lesion, a defect larger than 2 cm was left, and it was successfully sutured with OverStitch™. On the first day after the operation, her body temperature was 38 °C. Antibiotics (imipenem and cilastatin sodium) and a PPI inhibitor (pantoprazole) were administered intravenously. Somatostatin was also used to inhibit the secretion of digestive juices. After 5 days, her body temperature returned to normal. On the 9th day after the operation, the gastrointestinal decompression

tube was removed. On the 10th day, a liquid diet was given; and on the 12th day, she was discharged.

Subcutaneous emphysema and pneumoperitoneum did not occur in any of the cases in this cohort due to the use of CO_2 insufflation during the procedure.

There were two patients with lesions in the descending part (opposite side of the papillary region) of the duodenum. The defects were occluded by using the endoloops and metallic clip suture; the defect was reinforced with fibrin glue in one patient and an enteral feeding tube was placed in the other patient. Somatostatin was given to inhibit the secretion of digestive juices. Elevated serum amylase was not observed, and the wound healed well.

If severe abdominal pain, abdominal distension and fever are present and the pain radiates to the shoulder, delayed perforation should be suspected. The patient may show signs of peritonitis, and the white blood cells and neutrophils counts may increase. Then, a laparoscopic exploration should be conducted as soon as possible. In our cohort, a patient developed severe abdominal pain with the signs of peritonitis in the night of the operation. Although perforation was not found during laparoscopic exploration, this patient showed the symptom of peritonitis. As no other reason was identified, we consider that this was a case of delayed perforation, may be a micro-perforation, which had sealed spontaneously after an effective drainage.

The duodenum has an extensive vascular network supplied by the gastroduodenal artery that increases the risk of bleeding, which can be severe and potentially lifethreatening [1]. Based on our experience, the best way to treat bleeding is to prevent its occurrence. When the vessels are visible within the operation field, coagulation should be performed in advance with hemostatic forceps. After excision of the lesion, remnant vessels and the bleeding spot should be coagulated and occluded completely. Flushing equipment should be connected to the endoscope. Once bleeding occurs and the surgical field is blurred by the blood, the wound should be flushed sufficiently to locate the hemorrhagic site, followed by immediate coagulation with hemostatic forceps. Delayed bleeding often occurs within 24 h after the operation. Therefore, on the day of the operation and the 1st day after the operation, vital signs of the patients and the drainage fluid should be closely monitored. When a large amount of fresh blood is collected from the gastrointestinal decompression tube, the heart rate increases and the blood pressure drops, delayed hemorrhage should be suspected and gastroscopy should be performed immediately. If a large amount of blood clot and a hematocele are found in the stomach and duodenum, delayed bleeding is confirmed. The sludged blood should be removed and the hematocele should be cleaned by flushing and suction. Then, the ruptured vessels and the hemorrhagic spot should be identified. After washing the wound, the bleeding site should be located

and coagulated with hemostatic forceps as soon as possible. Metal clips can be used to close the bleeding site. After hemostasis, a gastrointestinal decompression tube should be placed again near the wound surface, and the drainage fluid should be monitored closely. If successful hemostasis can not be achieved by endoscopy, the patient should be immediately converted to surgery.

Laparoscopic and endoscopic cooperative surgery (LECS) provides all the advantages of endoscopy and laparoscopy, and it is also minimally invasive and can resect the lesion completely. The patient may make a quick recovery after the operation. However, the holes should be drilled in the abdominal wall and a pneumoperitoneum should be established during LECS. Besides, it is difficult to access the lesion site under the laparoscopic guidance. To uncover the lesion, the lateral wall of the peritoneum should be opened and the duodenum should be freed. All these procedures may cause injure to the surrounding organs and vessels. With the application of endoloops and metallic clip suture and the OverStitch™ system, the efficacy of suturing under endoscopic guidance is not inferior to that under laparoscopic guidance.

It is important to perform preoperative evaluation before EFTR for duodenal subepithelial lesions. For duodenal lesions, the obvious critical factors include size, macroscopic morphology, location (particularly in relationship to the major and minor papillae), and mucosally based or subepithelial layer of origin. A duodenoscope will often be required to definitively determine a lesion's exact relationship to the major and minor papillae, which can dramatically change the subsequent approach to endoscopic resection [1]. Endoscopic ultrasonography is a widely available and effective imaging modality that enables real-time assessment of a lesion's depth of invasion (T-stage) and nodal status (N-stage). When considering duodenal lesions, EUS has a clear role in the evaluation and differentiation of subepithelial lesions [1]. Abdominal CT is essential for determining the relationship between the lesion and the adjacent organs and large vessels, and it is also helpful for detecting whether the lesion shows extraluminal growth and whether lymphatic metastasis has occurred. If the lesion is > 3 cm, or most part of the lesion grows outward, laparoscopy or LECS is recommended. If advanced cancer with lymph node metastasis is diagnosed, the surgical operation should be carried out.

On the basis of our experience, we speculate that the EFTR is appropriate for the treatment of lesions located in the anterior wall of the bulb and on great curvature side of the descending part of the duodenum. If the target lesion involves the papilla or its vicinity, EFTR is difficult to perform because the pancreas is located posteriorly [17]. Although EFTR was performed in a patient who had a lesion located in the posterior wall of the bulb, we speculate that EFTR is not appropriate for this lesion because

the posterior wall of the bulb is at the beginning of the "C-loop" and it is very difficult to maintain the endoscope in this position. Thus, for the lesions located in the posterior wall of the bulb and on the lesser curvature side of the descending part involving the papilla or its vicinity, endoscopic mucosal resection (EMR) or endoscopic piecemeal mucosal resection (EPMR) is preferred.

Because of the difficulty and challenge of this procedure, more than ten simulated operations were performed in experimental pigs at our center prior to performing duodenal EFTR. We have also conducted EMR and ESD procedures for duodenal lesions in more than 200 cases, and we have accumulated rich experience in handling the complications during and after endoscopic surgery for duodenal lesions. The senior endoscopist who was considered qualified to perform the duodenal EFTR operation has more than 10 years of working experience as an endoscopist and performs gastrointestinal ESD in more than 100 cases every year. Besides, familiarity or skill with endoscopic retrograde cholangiopancreatography (ERCP) can be very helpful when assessing and resecting these duodenal lesions [1]. In our center, the endoscopist who has successfully performed ERCP in more than 200 cases is considered qualified to conduct this procedure.

Although EFTR was performed in 32 cases with the duodenal subepithelial lesions at our center and the results showed that EFTR is a safe, minimally invasive treatment modality that ensures complete eradication of these lesions as compared to traditional surgery, there are still some issues, especially regarding selection of indications. Most of the lesions found in our center were < 1 cm, the patients had no symptoms, and treatment was not needed. In most of the cases, we just performed a follow-up. According to the ESMO guideline (2014) [18] combined with our experience, we suggest that the indication of the procedure for duodenal subepithelial lesions is as follows: The lesion is larger than 1.5 cm, or the ultrasound shows blurred boundaries, ulcers, strong or uneven echo, or the patient has fear and anxiety about his disease and strongly demands surgical removal. However, how to grasp the indications strictly and to balance between the risk of this procedure and the clinical benefit more carefully? Additional studies and experience with more number of cases are necessary to weigh the pros and cons of this procedure and to confirm the clinical efficacy and safety of EFTR for the treatment of duodenal subepithelial lesions.

Compliance with ethical standards

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