Exposed versus nonexposed endoscopic full-thickness resection for duodenal subepithelial lesions: a tertiary care center experience (with videos)

Zaheer Nabi, MD, DNB, Jahangeer Basha, MD, DM, Pradev Inavolu, MD, DM, Mahiboob Sayyed, MD, DNB, Mohan Ramchandani, MD, DM, Rajesh Goud, PhD, Santosh Darisetty, MD, Rama Kotla, MD, D. Nageshwar Reddy, MD, DM

Hyderabad, India

Background and Aims: Endoscopic full-thickness resection (EFTR) has been shown to be effective in selected lesions located in the stomach and colorectum. Data regarding the feasibility, safety, and efficacy of EFTR in the duodenum are limited. In this study, we aimed to evaluate the feasibility and safety of exposed and nonexposed EFTR in patients with large (≥10 mm) duodenal subepithelial lesions.

Methods: Data of all patients who underwent EFTR for duodenal subepithelial lesions with exposed and nonexposed (device-assisted) techniques were analyzed, retrospectively. The primary outcome of the study was technical success of EFTR in the duodenum. Secondary outcomes were adverse events, R0 resection, and recurrence at follow-up.

Results: Twenty patients with duodenal subepithelial lesions (mean size, 14.2 ± 3.6 mm) underwent EFTR during the study period. Exposed and nonexposed EFTRs were performed in 11 and 9 patients, respectively. The mean procedure duration was 70.3 ± 46.5 minutes. Technical success with exposed and nonexposed techniques was 100% and 75%, respectively. Histologically complete resection (R0) was achieved in 15 patients (75%). Moderate and severe adverse events were recorded in 3 patients, including a leak in 2 patients and partial obstruction of the lumen in 1 patient.

Conclusions: EFTR is feasible in large duodenal subepithelial lesions with a reasonable safety profile. EFTR enables complete resection in most duodenal subepithelial lesions. (iGIE 2023;2:154-60.)

Duodenal subepithelial lesions are a heterogenous group of lesions that include neuroendocrine tumors, cysts, GI stromal tumors, and ectopic pancreas. Endoscopic resection is recommended for the management of small (<10 mm) subepithelial lesions in the duodenum,[1] whereas surgery is recommended in larger lesions (>20 mm) and in those with infiltration beyond the submucosal layer. The management of intermediate-sized lesions (10-20 mm) is individualized based on the available expertise and characteristics of the lesion.

The anatomic peculiarities of the duodenum pose special challenges to endoscopic resection. The relatively thinner muscular layer, concavity of the duodenal bulb, and exposure of the postresection defect to biliopancreatic juices all render the management of larger lesions (≥10 mm) more complex with a high risk of immediate and delayed perforation.[2] With recent innovations in devices and closure techniques, endoscopic full-thickness resection (EFTR) is increasingly used for nonlifting and deep-seated lesions located in the stomach and colorectum.[3] However, data are limited in duodenal subepithelial lesions. In this study, we aimed to analyze the feasibility and safety of exposed and nonexposed EFTR in patients with large (≥10 mm) duodenal subepithelial lesions.

METHODS

In this study, the outcomes of consecutive patients who underwent EFTR for duodenal subepithelial lesions from December 2020 to March 2022 were analyzed retrospectively. Informed consent was obtained from all study participants, and the study was approved by the institutional ethics board review.

Inclusion criteria for EFTR were patient age >18 years, subepithelial lesions ≥10 mm, EFTR with or without the assistance of a device, and refusal for surgery. Exclusion criteria were mucosal lesions, nonduodenal location, local or distant metastases, large lesions occluding the lumen,

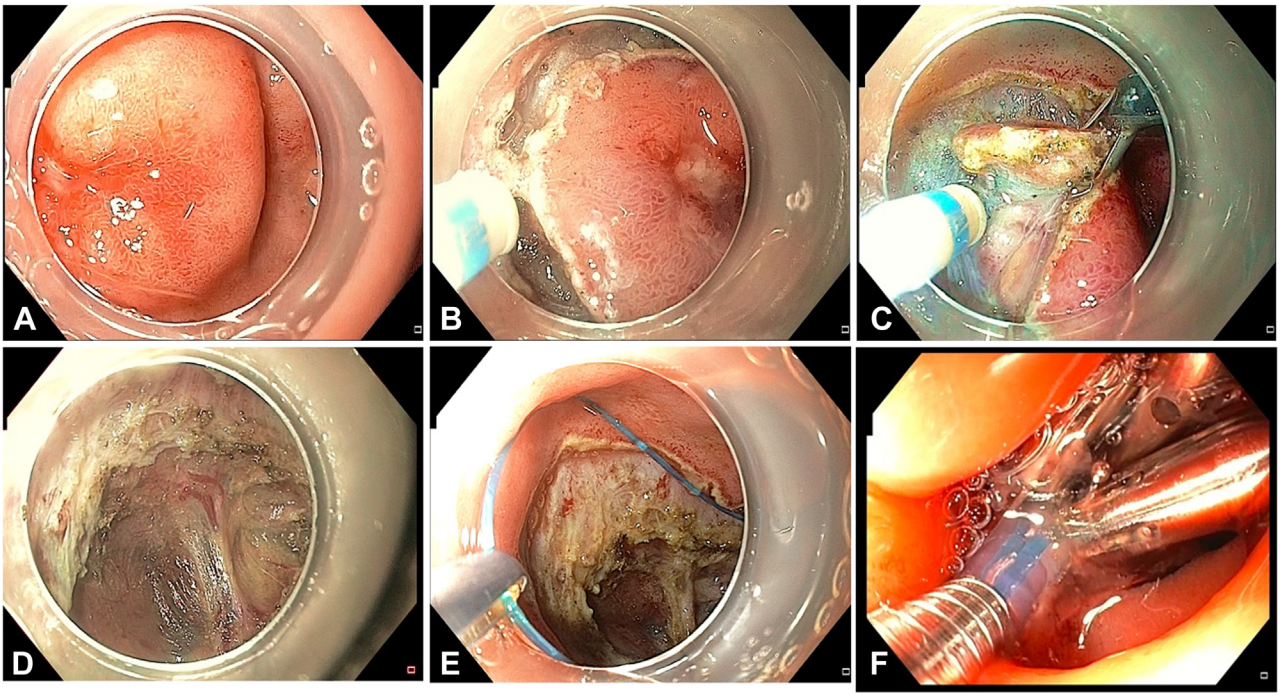

Figure 1. Technique of exposed or conventional endoscopic full-thickness resection. **A,** Large neuroendocrine tumor in the first part of the duodenum. **B,** Circumferential incision around the lesion. **C,** Endoscopic full-thickness resection after internal traction using a rubber band and 2 endoclips. **D,** Full-thickness defect after completion of full-thickness resection. **E,** Closure of the defect with loop and endoclips. **F,** Completion of the closure.

uncorrectable coagulopathy, and contraindication to general anesthesia.

Outcomes

The primary outcome of the study was to evaluate the technical success of EFTR in duodenal subepithelial lesions. Secondary outcome measures were adverse events, R0 resection, and recurrence on follow-up.

Preprocedural evaluation

All patients were evaluated using a standard battery of tests before the EFTR procedure. Upper GI endoscopy was performed to assess the size, location, and surface characteristics of the lesion. Biopsy sampling was performed in all patients before contemplating endoscopic resection. EUS was performed to determine the layer of origin, vascularity, and presence of regional lymph nodes, if any. ^{68}Ga-DOTANOC positron emission tomography CT was performed in patients with suspected neuroendocrine tumors to rule out distant metastases.

Technique

In this series, EFTR was performed either with (nonexposed EFTR) or without (exposed EFTR) the assistance of a dedicated device. Exposed EFTR was performed with patients under general anesthesia in all the cases. Nonexposed EFTR was performed with patients under general anesthesia in the initial 3 cases and propofol sedation in the subsequent 6 cases.

For exposed EFTR, resection was performed in a similar fashion to endoscopic submucosal dissection (ESD) (Fig. 1). The important difference was the plane of dissection was below the muscularis propria in contrast to the submucosal plane in ESD. Exposed EFTR was performed as follows. First, the lesion was marked using an electrosurgical knife (Dual knife J [soft coagulation, E4; 80 W]; Olympus, Tokyo, Japan). A circumferential mucosal incision was then created, and submucosal dissection was initiated. An intentional defect was created in the muscle layer at the point of infiltration, and subsequent dissection was performed in the serosal plane. In some cases, a rubber band was used for providing internal traction. After completing the resection, the sample was retrieved for histopathologic evaluation, and the full-thickness defect was closed using a loop and multiple endoclips (Video 1, available online at www.igiejournal.org).

For nonexposed (device-assisted) EFTR, a dedicated device was used. The gastroduodenal full-thickness resection device (FTRD; Ovesco Endoscopy, Tübingen, Germany) consists of an application cap with an outer diameter of 19.5 mm and a depth of 23 mm, a ready-to-use mounted FTRD clip, and an integrated snare (Fig. 2). An insertion balloon and guidewire are also available in the FTRD set to facilitate passage through the esophagus and pylorus. The gastroduodenal FTRD is compatible with endoscopes with diameters of 10.5 to 12.0 mm and a working channel diameter of at least 3.7 mm.

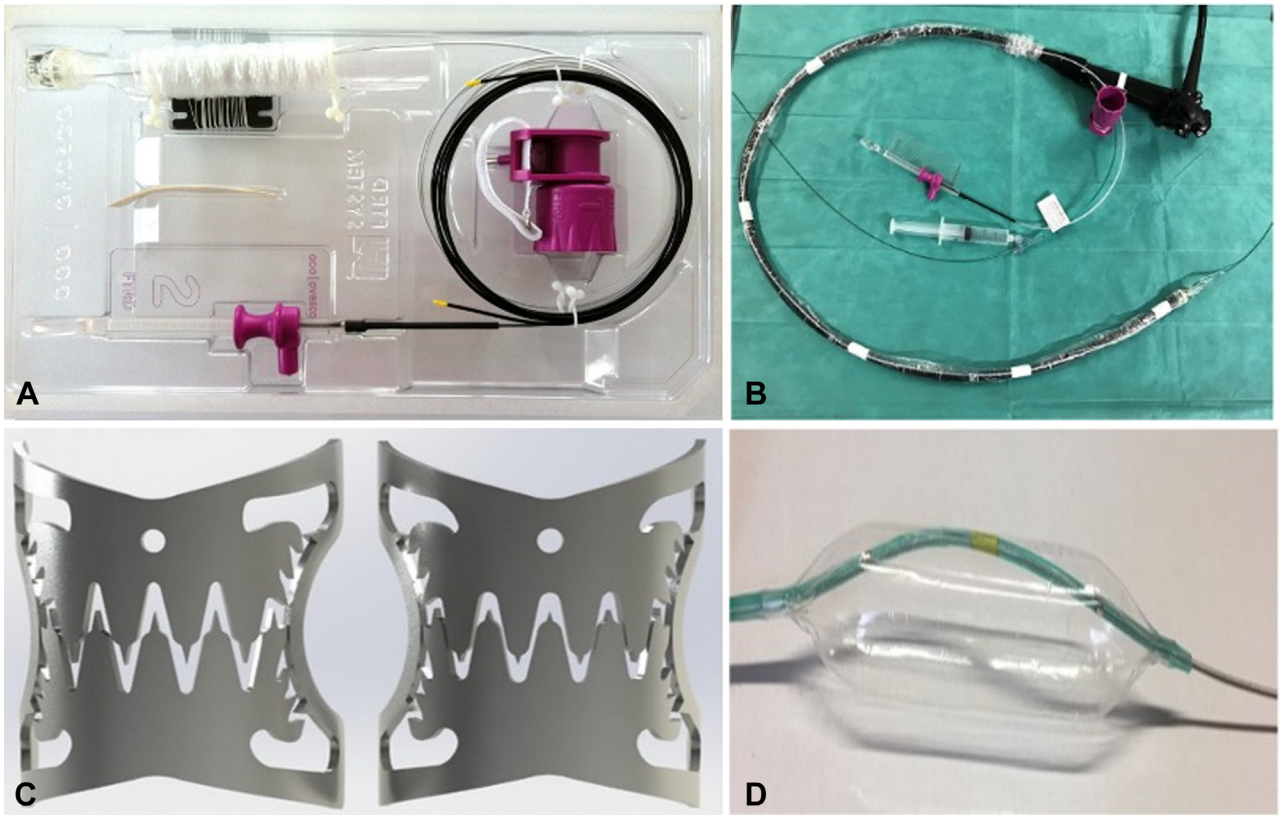

Figure 2. Upper GI full-thickness resection device (FTRD). **A,** Complete setup of the FTRD system. **B,** Mounting of the FTRD on the endoscope. **C,** Image of the over-the-scope clip with the FTRD system. **D,** Balloon available with the FTRD system for facilitating insertion across the cricopharynx.

The steps of nonexposed EFTR are as follows (Figs. 2 and 3). Initially, the lesion was marked circumferentially using the FTRD probe available with the device (forced coagulation, E1; 20 W). Subsequently, wire-guided balloon dilatation of the pyloric channel was performed (Fig. 3). The device was mounted over a therapeutic channel gastroscope. The FTRD was negotiated across the cricopharynx over the guidewire with or without assistance of the dilating balloon available with the device. In the balloon-assisted group, the balloon was inserted over the guidewire through the channel of the scope and positioned across the cricopharynx. The inflated balloon was pulled within the FTRD cap to the halfway mark so that the other half of the balloon was still across the cricopharynx. Finally, the device and balloon were gently negotiated across the cricopharynx as a single unit. After reaching the target site, the lesion was pulled with the FTRD cap with the help of grasping forceps and gentle suctioning. The clip was fired after ensuring the entry of the lesion inside the cap. The premounted snare was finally closed and electrocautery activated to cut the grasped tissue (high cut, 200W; effect 4) (Video 2 and Supplementary Fig. 1, available online at www.igiejournal.org).

Definitions

Exposed EFTR was the intentional full-thickness resection of the entire lesion using an electrosurgical knife followed by closure of the defect, whereas nonexposed or device-assisted EFTR was the resection of the lesion using a dedicated FTRD. Technical success was defined as complete endoscopic resection of the lesion (en bloc or piecemeal) with no endoscopically visible residual tumor. Complete pathologic or R0 resection was defined as the absence of vertical and lateral margin involvement in the histopathologic evaluation. Finally, adverse events were defined according to the American Society for Gastrointestinal Endoscopy lexicon for adverse events.[4]

Statistics

Data are presented as median (range) or mean ± standard deviation. The data were analyzed using MedCalc for Windows, version 12.2.1.0 (MedCalc Software, Ostend, Belgium).

RESULTS

Twenty patients (17 men; mean age, 55.9 ± 9.1 years) underwent EFTR for duodenal subepithelial lesions during the study period. Locations of the duodenal lesions were the first part of the duodenum in 16 patients (80%), the junction of the first and second parts of the duodenum in 2 patients (10.5%), and the third part of duodenum in

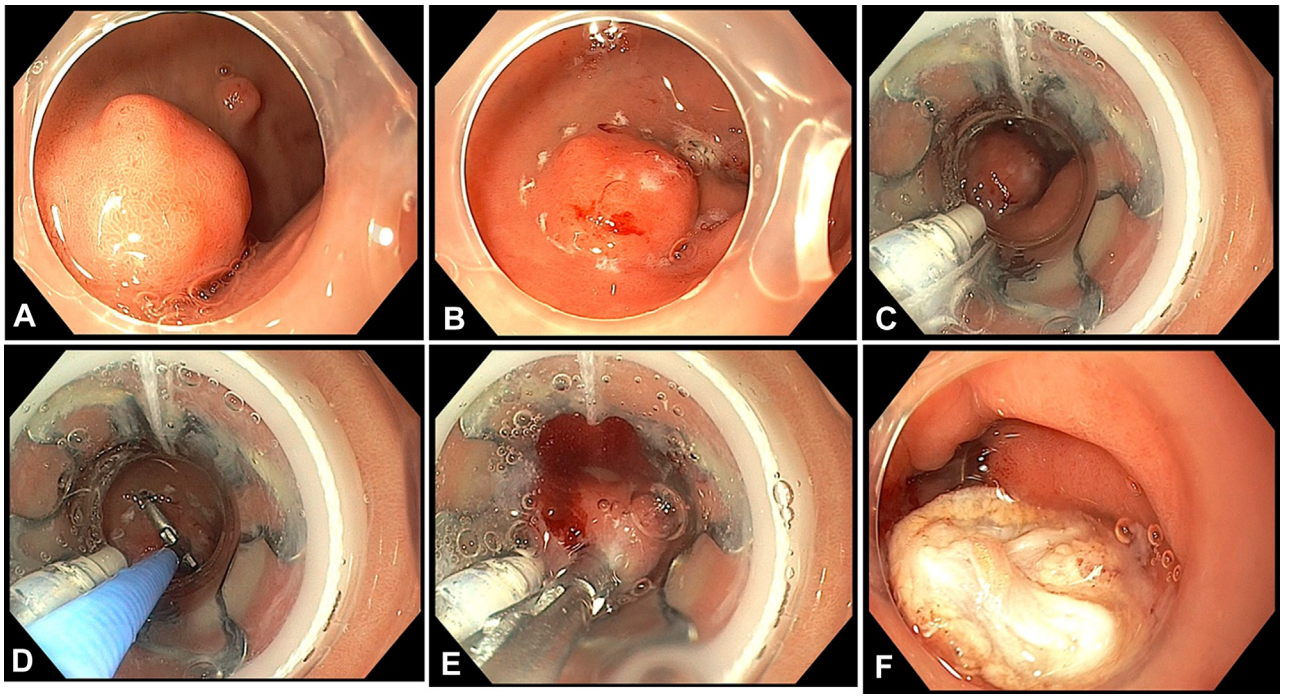

Figure 3. The technique of nonexposed (device-assisted) endoscopic full-thickness resection. **A,** Subepithelial lesion in the first part of the duodenum. **B,** Circumferential marking of the lesion. **C,** Focusing the lesion with the full-thickness resection device (FTRD) mounted over the endoscope. **D,** Grasping of the lesion with the grasper available with the FTRD. **E,** Pulling the lesion inside the FTRD cap. **F,** Complete resection of the lesion after deploying the clip (subserosal fat can be visualized).

2 patients (10.5%). The mean size of the lesions was 14.2 ± 3.6 mm (Table 1).

Technical outcomes

Exposed EFTR was performed in 11 patients (55%) with a mean lesion size of 14.6 ± 4.0 mm. The procedure was technically successful in all patients with a mean procedure duration of 92.3 ± 40.8 minutes (range, 50-180). Closure of the postresection defect was achieved by the purse-string closure technique (loop and clips) in 10 cases. In 1 patient, the defect was closed using a combination of an over-the-scope clip and through-the-scope endoclips (Table 2).

Nonexposed EFTR was performed in 9 patients (45%) with a mean lesion size of 13.8 ± 3.1 mm. Technical success was achieved in 7 patients (78%) with a mean procedure duration of 23.3 ± 8.8 minutes. The insertion of the device across the cricopharynx was facilitated by a balloon in 4 patients. In 2 patients, predilatation was performed using Savary-Gilliard dilators (Cook Medical, Billerica, Mass) (up to 20 mm). In the other 3 patients, no dilatation was required for the insertion of the device.

Technical failure occurred in 2 patients with lesion sizes of 15 and 20 mm, respectively. In 1 patient, the duodenal cap was deformed presumably because of a healed duodenal ulcer. The lesion was located close to pylorus along the anterior wall of the first part of the duodenum (size ~15 mm), and the lesion could not be satisfactorily pulled inside the FTRD cap with grasping forceps (Supplementary Fig. 2, available online at www.igiejournal.org). In another patient with technical failure, the lesion was located in third part of the duodenum (size ~20 mm) and could not be maneuvered satisfactorily within the FTRD cap because of its large size (Supplementary Fig. 2). In both patients, conventional EFTR was successfully performed in the same session (Table 2).

Clinical outcomes

Endoscopic complete resection was achieved in all patients. The final histopathologic diagnosis was duodenal neuroendocrine tumor in 18 patients (90%) and GI stromal tumor in 2 patients (10%). Overall, histologic complete resection (R0) was achieved in 15 patients (75%), including device-assisted EFTR in 6 (85.7%) and exposed EFTR in (10 (76.9%). In 1 patient undergoing exposed EFTR, the histologic margins could not be assessed because of piecemeal resection. At a mean follow-up of 12 months, no recurrence was seen in histologically complete or incomplete resection groups (Table 2).

Adverse events

There were 3 adverse events, 2 moderate and 1 severe. In 1 patient, partial obstruction of the lumen occurred in the third part of the duodenum after device-assisted EFTR. A guidewire was negotiated across the narrowing, and a nasojejunal feeding tube was initiated. The patient improved with conservative management, and subsequent endoscopy after 2 weeks revealed near-complete resolution of the stenosis. In the 2 patients who underwent exposed EFTR, a CT

TABLE 1. Baseline characteristics of patients duodenal subepithelial lesions (n = 20)

Characteristics	Values
Gender, male/female	18/2
Age, y	55.9 ± 9.1
Location	
D1	16
D1/D2	2
D3	2
Lesion size, mm	14.2 ± 3.6
Technique	
Exposed EFTR	11 (D1, 10; D1/D2, 1)
Nonexposed or device-assisted EFTR	9 (D1, 6; D1/D2, 1; D3, 2)

Values are n or mean ± standard deviation.
EFTR, Endoscopic full-thickness resection; *D1*, first part of the duodenum; *D1/D2*, junction of the first and second parts of the duodenum; *D3*, third part of the duodenum.

TABLE 2. Outcomes of endoscopic full-thickness resection

Characteristics	Values
Technical success (overall)	
Device-assisted EFTR	7 (78)
Exposed EFTR	11 (100)
Procedure time, min	70.3 ± 46.5
Endoscopic complete resection	20 (100)
R0 resection	15 (75)
Device-assisted EFTR	6 (85.7)
Exposed EFTR	10 (76.9)
Major adverse events	3 (15)
Nonexposed EFTR	1
Exposed EFTR	2
Histology	
Neuroendocrine tumor (grade I/II)	18
GI tumor	2
Follow-up, mo	11.9 ± 7.2
Recurrence	0

Values are n (%), n, or mean ± standard deviation.
EFTR, Endoscopic full-thickness resection.

with oral contrast revealed a small, contained leak. Both patients were managed conservatively (nothing by mouth and intravenous antibiotics) but required prolonged hospital stays (8 and 11 days). In 1 patient, percutaneous needle aspiration was performed for an infected periduodenal fluid collection.

DISCUSSION

In this study, EFTR was feasible and effective in the management of large (>10 mm) duodenal subepithelial lesions. Histologically complete resection could be achieved in most cases.

Several endoscopic resection techniques have been reported for the management of duodenal subepithelial lesions, including EMR and ESD.[5] Both techniques may not be feasible in large, deeply infiltrating, and nonlifting lesions. More recently, EFTR has emerged as a safe and effective alternative for resection of subepithelial and nonlifting lesions in the stomach and colon.[6-8] EFTR involves full-thickness resection of GI lesions by exposed or nonexposed techniques. The exposed technique of EFTR is similar to ESD except for the plane of dissection, which is deeper to the muscularis propria layer. The postresection defect after exposed EFTR is closed using different techniques. In contrast, the nonexposed technique of EFTR involves the use of a dedicated device that secures a suture or clip below the lesion before resection of the target lesion.[9] Data are limited regarding the utility of EFTR in the duodenum, especially duodenal subepithelial lesions (Table 3).[10-17]

In this study, we evaluated the outcomes of exposed and nonexposed EFTR in duodenal subepithelial lesions. Most lesions were duodenal neuroendocrine tumors and located in the first part of the duodenum. Technical success was achieved in all patients undergoing the exposed technique and in most patients (78%) undergoing the nonexposed technique (ie, device-assisted EFTR). There were 2 technical failures in the nonexposed group, mainly attributed to difficult location (juxtapyloric) and large size (20 mm) of the lesion, respectively (Supplementary Fig. 2). Therefore, careful selection of cases is paramount to minimize technical failures with nonexposed EFTR. Besides visual impression, the feasibility of resection can also be predicted in advance by the use of a special cap available with the device (gastroduodenal FTRD prOVE Cap; Ovesco.

Data regarding the utility of EFTR (exposed or nonexposed) in duodenal subepithelial lesions are limited (Table 3). Most published studies have reported the use of EFTR in the stomach or colon and either used a colonic EFTR device or resected the lesion after applying an over-the-scope clip. While the colonic EFTR device is not suitable for upper GI use because of the larger outer diameter (21 mm), resection may be incomplete if performed after application of an over-the-scope clip. In contrast to published studies, we used a dedicated gastroduodenal EFTR device with a smaller outer diameter (19.5 mm). In addition, the outcomes of exposed EFTR were also evaluated. Endoscopic complete resection was achieved in all patients, and histologic complete resection (R0) was observed in three-fourths of the patients.

Three adverse events occurred, including 2 incidences of leaks after exposed EFTR. We presumed that the exposure of the resection site to a copious volume of biliopancreatic juices may predispose to delayed leaks. Therefore, robust closure of the defect is paramount, especially in the second

TABLE 3. Studies reporting the outcomes of full-thickness resection in the duodenum

Study	No. of total/ duodenal lesions	Size* (mm)	Dedicated endoscopic full-thickness resection device	Technical success (%)	R0 resection (%)	Adverse events (%)	Mean/median follow-up (mo)
Sarker et al, 2014[17]	8/4	13.4 (9-20)	No (OTSC)	100	87.5	0	8
Schmidt et al, 2015[13]	4	10-30	No (colonic FTRD)	100	75	50 (mild bleeding)	2
Al-Bawardy et al, 2017[12]	9/4	8 ± 3	No (OTSC, Padlock clip [Steris, Mentor, Ohio])	100	100	0	169 days (range, 45-217)
Bauder et al, 2018[16]	20 (most adenomas)	17 (5-35)	No (colonic FTRD)	85	63.2	15.8 (minor bleeding)	12
Kappelle et al, 2018[19]	12/6	11 ± 4	No (Padlock clip)	85	100	Pain 1, bleeding 1, perforation 1, microperforation 3	6
Andrisani and Di Matteo 2020[14]	10	10-25	No (OTSC)	80	80	No major adverse event	6
Tashima et al, 2021[15]	13	6 (4-10)	No (OTSC)	100	92.9	14.3 (delayed bleeding)	12
Wei et al, 2021[10]	13	6-20	No (OTSC)	100	92.3	0	357 days
Hajifathalian et al, 2020[11]	56/8	14 (3-33)	No (colonic FTRD)	93	68	21	3
Nabi et al, 2022 (current study)	20	14.2 ± 3.6	Yes (upper GI FTRD)	100, exposed; 78, nonexposed	75	15.8	12

FTRD, Full-thickness resection device; *OTSC*, over-the-scope clip.
*Values are median (range), range, or mean ± standard deviation.

part of the duodenum. Our hypothesis is supported by the fact that delayed perforations after duodenal ESD can be effectively prevented by endoscopic drainage of biliary and pancreatic juices.[18] There were no instances of delayed perforation in the nonexposed or device-assisted EFTR groups.

Our study has several implications on clinical practice. First, endoscopic resection can be attempted for selected cases with duodenal neuroendocrine tumors >1 cm. Second, device-assisted EFTR using a novel gastroduodenal FTRD is a safe and effective technique in these cases. Appropriate case selection is paramount to avoid technical failures. In our experience, it may be difficult to perform device-assisted EFTR in juxtapyloric lesions, those situated close to the ampulla, and when the duodenal cap is deformed. Also, it may be difficult to grasp and pull flat subepithelial lesions (vs protruded) in the first part of the duodenum. In these cases, exposed EFTR may be preferred to device-assisted EFTR. However, robust closure techniques should be available, especially when contemplating exposed EFTR in the second part of the duodenum because of the risk of delayed leaks. Therefore, device-assisted EFTR should be preferred to exposed EFTR in the second part of the duodenum.

There are several strengths of our study. All procedures were performed with a curative intent after ruling out nodal and distant metastases. Both EFTR techniques were described including exposed EFTR with a novel device and nonexposed EFTR. We acknowledge some drawbacks of our study, including the small sample size, retrospective design, and short follow-up period. The selection of the EFTR technique was not random and was left to the discretion of the endoscopist. Expertise is required for closure of full-thickness defects after exposed EFTR, which should be taken into account before generalizing the results of our study.

In conclusion, EFTR is a feasible and effective treatment option in patients with duodenal subepithelial lesions. However, caution is advised while performing exposed EFTR because of the risk of delayed leaks.

DISCLOSURE

All authors disclosed no financial relationships.

Abbreviations: EFTR, endoscopic full-thickness resection; ESD, endoscopic submucosal dissection; FTRD, full-thickness resection device.

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Asian Institute of Gastroenterology, Hyderabad, India.

Reprint requests: Zaheer Nabi, MD, DNB, Associate Director Interventional Endoscopy, Department of Gastroenterology, 6-3-661, Asian Institute of Gastroenterology, Hyderabad 500082, India.

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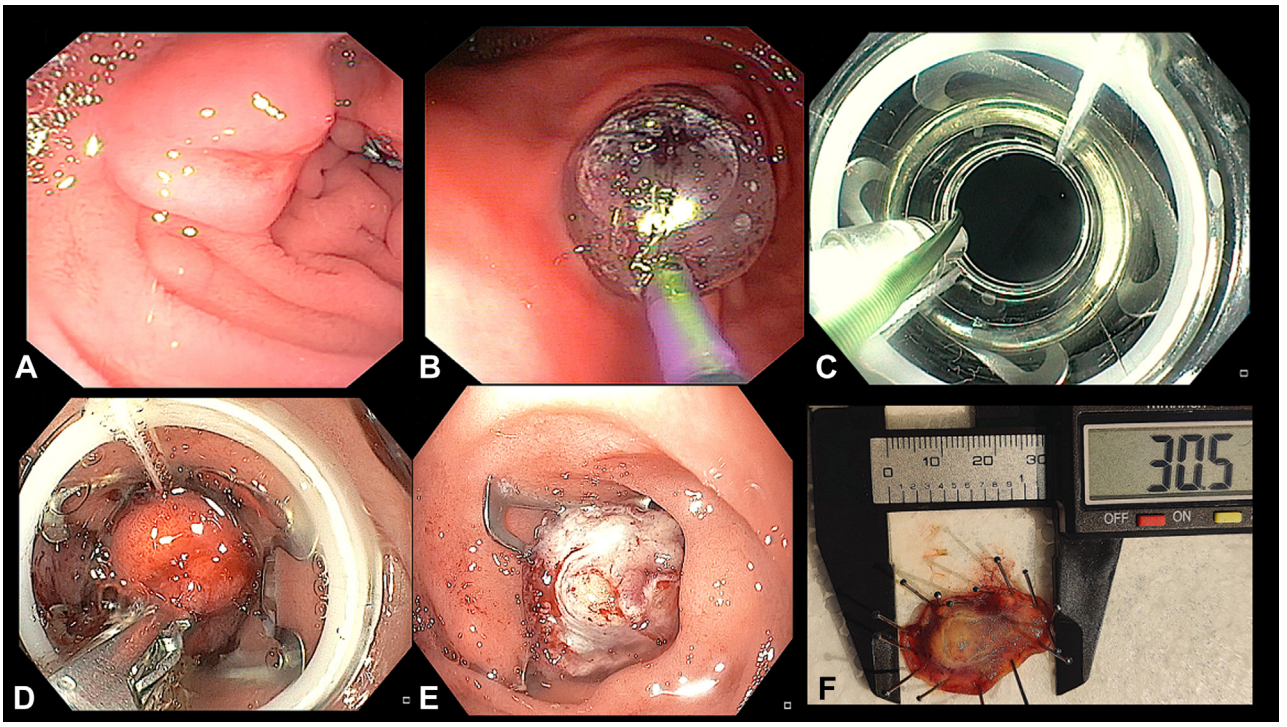
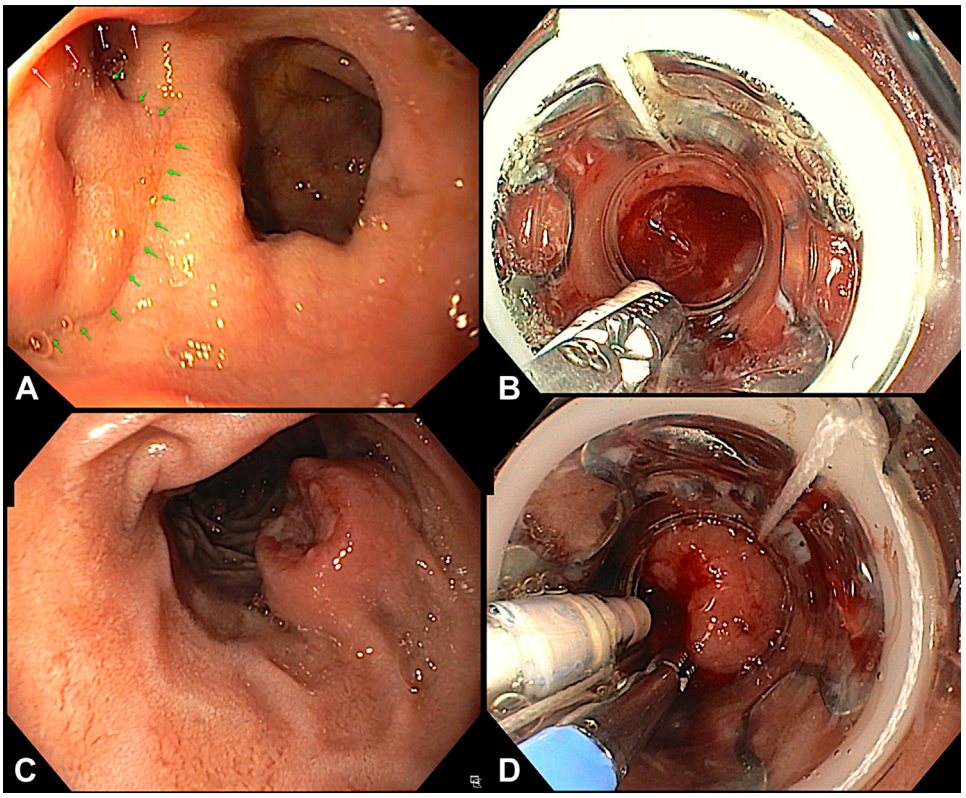


Supplementary Figure 1. Device-assisted endoscopic full-thickness resection in a patient with duodenal neuroendocrine tumor. **A,** A duodenal subepithelial lesion located at the junction of the first and second parts of the duodenum. **B,** Dilatation of the pylorus with a balloon. **C,** Mounting of the full-thickness resection device (FTRD) system over the endoscope. **D,** Pulling the lesion into the FTRD cap using grasping forceps. **E,** Complete resection of the lesion after deploying the over-the-scope clip. **F,** En-bloc resected specimen.



Supplementary Figure 2. Technical failures in 2 patients undergoing device-assisted full-thickness resection. **A,** Endoscopic image revealing a flat duodenal subepithelial lesion (*green arrows*) in close proximity to the pylorus (*white arrows*). **B,** Difficulty in grasping the lesion because of juxtapyloric location and bleeding. **C,** Endoscopic image revealing an ulcerated subepithelial lesion in the third part of the duodenum. **D,** The lesion could not be pulled inside the cap of the full-thickness resection device.