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Colo-rectal endoscopic full-thickness resection (EFTR) with the over-the-scope device (FTRD®): A multicenter Italian experience

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ABSTRACT

Background and aim: Endoscopic full-thickness resection(EFTR) with FTRD® in colo-rectum may be useful for several indications.The aim was to assess its efficacy and safety.
Material and methods: In this retrospective multicenter study 114 patients were screened; 110 (61M/49F, mean age 68 ± 11 years, range 20–90) underwent EFTR using FTRD®. Indications were:residual/recurrent adenoma (39), incomplete resection at histology (R1 resection) (26), non-lifting lesion (12), adenoma involving the appendix (2) or diverticulum (2), subepithelial lesions(10), suspected T1 carcinoma (16), diagnostic resection (3).Technical success (TS: lesion reached and resected), R0 resection (negative lateral and deep margins),EFTR rate(all layers documented in the specimen) and safety have been evaluated.
Results: TS was achieved in 94.4% of cases. EFTR was achieved in 91% with lateral and deep R0 resection in 90% and 92%. Mean size of specimens was 20 mm (range 6–42). In residual/recurrent adenomas, final analysis revealed: low-risk T1 (11), adenoma with low-grade dysplasia (LGD) (24) and high-grade dysplasia (HGD) (3), scar tissue (1). Histology reports of R1 resections were: adenoma with LGD (6), with HGD (1), low-risk (6) and high-risk (1) T1, scar tissue (12). Non-lifting lesions were diagnosed as: adenoma with HGD (3), low-risk (7) and high risk (2) T1. Adverse clinical events occurred in 12 patients (11%),while adverse technical events in11%. Three-months follow-up was available in 100 cases and residual disease was evident in only seven patients.
Conclusions: EFTR using FTRD® seems to be a feasible, effective and safe technique for treating selected colo-rectal lesions. Comparative prospective studies are needed to confirm these promising results.

1. Introduction

Endoscopic full-thickness resection (EFTR) is a field of increasing interest for the treatment of specific colo-rectal lesions as an alternative to conventional minimally invasive approaches, including endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD) [1–5]. These well-established techniques are considered challenging in cases of non-lifting adenoma, resid-

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Table 1
Characteristics of patients and lesions.

Total number of patients, (n)	114
Total number of EFTR performed, n (%)	110 (96%)
Sex, n (%)	
Male	61 (55.4)
Female	48 (44.6)
Age,median (range)	68 (20–90)
Indication for EFTR, n(%)	
Endoscopic residual/recurrent adenoma after ER	39 (35.4)
Histological R1 resection (deep positive margin at histology)	26 (23.6)
Non-lifting sign adenoma	12 (11)
Para-diverticular and para-appendicular adenoma	4 (3.6)
Submucosal lesion	10 (9)
Suspected T1 carcinoma	16(14.6)
Diagnostic resection of colo-rectal wall	3(2.8)
Location of lesion, n (%)	
Coecum	7 (6.3)
Ascending colon	11 (10)
Transverse colon	17 (15.5)
Descending Colon	6 (5.5)
Sigmoid	10(9)
Rectum	59 (53,7)
Diameter of lesion, mean, mm (range)	17.83 (5–40)
Sedation n (%)	
deep	63(57.4)
conscious	37(33.6)
no	10(9)
Antibiotic prophylaxis n (%)	
yes	27(24.6)
no	83(75.4)

ual/recurrent adenoma, subepithelial lesions or, in the case of a lesion, located in a difficult anatomic site (e.g., para-diverticular or para-appendicular) due to higher perforation risk or an incomplete resection rate [6–12]. In the last several years, several devices have been produced to simultaneously allow EFTR and complete closure of wall defects. The FTRD® (Full Thickness Resection Device; Ovesco Endoscopy, Tübingen, Germany) is the only commercially available over-the-scope device designed for EFTR with a one-step clip-and-cut technique. This device consists of a modified 14 mm over-the-scope-clip (OTSC) mounted on a longer than standard cap OTSC (23 mm vs 6 mm), accommodating a larger amount of tissue with a preloaded 13 mm monofilament snare. The device has been approved in Europe (CE mark) for colo-rectal resection since September 2014 and has been investigated in preclinical and clinical trials [1–5,13–18].

In this report, we present the first Italian multicenter experience with the FTRD® for resection of selected colo-rectal lesions.

2. Patients and methods

This observational, retrospective study was conducted at 12 referral centres in Italy from January 2015 to March 2018. The study was not funded and was approved by the Ethics Committee of the coordinating centre.

The inclusion criteria were the following: endoscopic residual adenoma after endoscopic resection (ER), histological R1 resection (deep and lateral positive margins at histology), non-lifting sign adenoma, para-diverticular and para-appendicular adenoma, subepithelial lesion, suspected T1 carcinoma, and diagnostic resection of the colo-rectal wall.

Patient and lesion characteristics are shown in Table 1.

Outcome measures were the following:

1) Technical success rate: lesion reached and resected;

2) R0 resection: negative lateral and deep margins at histological examination;

3) EFTR rate: proportion of patients with histologically confirmed full-thickness resection (mucosal, submucosal and muscle layers);

4) Adverse events

– Technical: incomplete OTSC deployment, snare malfunction;

– Clinical: stenosis, appendicitis, bleeding, tenesmus, colorectal wall trauma, perforation/leak, and post-polypectomy syndrome;

5) Follow-up at 3 months: evaluation of residual/recurrent lesion and treatment.

Written informed consent was obtained from all patients, and data were treated according to privacy restriction laws.

In the case of an endoscopically suspected malignant lesion, the patient underwent staging endoscopic ultrasound (EUS) and/or magnetic resonance imaging (MRI) for rectal lesions and an abdominal computed tomography (CT) scan for colonic lesions.

Patients were scheduled for a follow-up colonoscopy 3 months after EFTR.

2.1. EFTR technique

The majority of procedures (57.4%, 63/110) were performed under deep sedation with propofol ± midazolam; 33.6% (37/110) were performed under conscious sedation with midazolam/pethidine, and only 9% (10/110) had no sedation (Table 1). Procedures were performed using carbon dioxide insufflation. Antibiotic prophylaxis was provided for only 24.54% (27/110). These data are lower than those reported in the literature [4,5]. However, to date, the administration of antibiotics is not recommended probably because it is a clip and cut technique. Patients on acetylsalicylic acid were advised to continue the medication and all other anti-platelet and/or anticoagulants (i.e., clopidogrel, low-molecular-weight heparin, warfarin or direct oral anticoagulants) were discontinued according to the international guidelines [19].

A preliminary colonoscopy was performed to reach the lesion and to mark its lateral margins with a FTRD marking probe (Ovesco Endoscopy, Tübingen, Germany) or Argon Plasma Coagulation (APC) (Erbe APC 300, 25 W). For colonic lesions, prOVE CAP (Ovesco Endoscopy, Tübingen, Germany), a cap similar in size to the FTRD cap, was mounted on the instrument tip to evaluate accessibility to the target lesion. The second colonoscopy was performed using another endoscope with the device mounted. Once the endoscope reached the target lesion, it was gently pulled into the cap using the FTRD grasper (Ovesco Endoscopy) until all of the lateral markers were visible inside. After OTSC deployment, the lesion was resected with the preloaded snare (Fig. 1), and the specimen placed in the cap was extracted simultaneously with the endoscope.

The last colonoscopy was performed to check the resection site.

The total procedure time was measured from the first introduction of the scope until its extraction after the post-procedural check. The time needed to reach the lesion with the device mounted on the tip of the scope was also measured. The time for resection was measured from reaching the lesion with the device until complete resection was achieved.

The majority of patients (82.7%, 91/110) were hospitalized for at least one night, remaining fasting after the procedure and resuming a normal diet at 24 h. Only 19/110 (17.3%) underwent outpatient procedures, resuming a normal diet after 12 h.

2.2. Histological evaluation

Histopathological evaluation was performed by a local pathologist in each centre. The histological classification was performed according to the Vienna staging system for epithelial neoplasms of

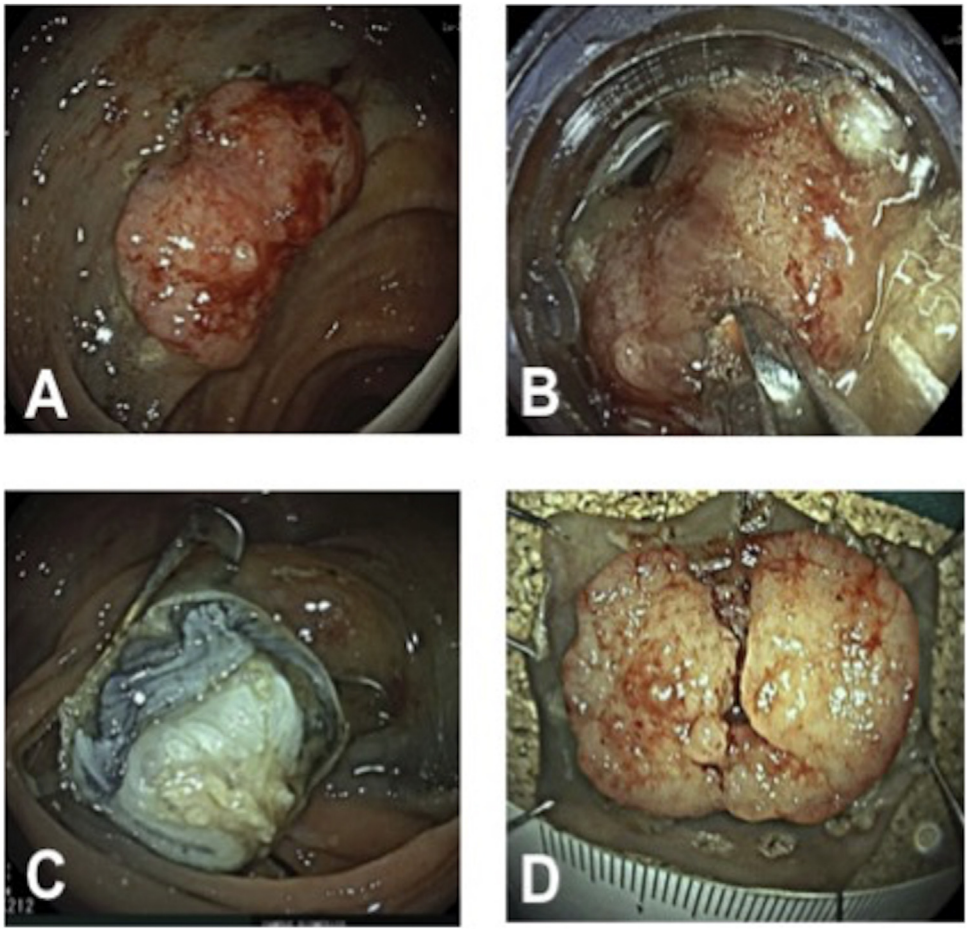

Fig. 1. FTRD System illustration. A: lesion marked with Argon Plasma Coagulation (APC); B: the target lesion is grasped and pulled into cap with grasping forceps; C: over-the-scope clips (OTSC) completely closing the full-thickness resection site; D: full-wall resection specimen.

the gastrointestinal tract [20], information regarding size, margins and specific criteria for a malignant polyp were provided [21].

2.3. Follow-up

Patients were scheduled for follow-up endoscopy 3 months after the procedure. In the presence of a residual/recurrent lesion on the EFTR scar, a new treatment was performed (polypectomy, EFTR, surgery).

The FTRD clip that was still in place at the endoscopic follow-up was removed only in patients with R1 or Rx (unknown resection) histology to perform a new resection. For removal, the clip was cut with a bipolar cutting device (Remove System, Ovesco Endoscopy, Tübingen, Germany), and the fragments were extracted.

3. Results

From January 2015 to March 2018, 114 patients were screened for eligibility in 12 Italian centres. Four patients were not included due to inaccessibility to the target lesion at the prOVE CAP test (e.g., subtenosis, diverticulitis). Therefore, 110 patients underwent EFTR (61 men/49 women; mean age 68, with a range 20–90 years). Patient and lesion characteristics are shown in Table 1. The resection sites were the following: rectum (59), transverse colon (17), ascending colon (11), sigmoid colon (10), descending colon (6), caecum (5), and caecal appendix (2). A full-thickness resection was achieved in 91% with lateral and deep R0 resections on histological examination in 90% and 92%, respectively (Table 2). A subgroup analysis showed no differences in the rate of EFTR (rectum 91% vs other 90%) between lesions located in the rectum and lesions located in other segments. The mean size of the target lesions and resected specimens were 17.83 mm (range 5–40) and 20 mm (range 6–42), respectively.

Table 2
Resections and follow-up.

Target lesion reached with FTRD, n (%)	110 (96)
Technical success, n (%)	103 (94.34)
R0 resection, n (%)	99 (90)
EFTR resection, n (%)	100 (91)
Diameter of resected specimen, mean (range), mm	20 (6–42)
Adverse events, n (%)	11 (10)
Traumatic wall lesions	4 (3.6)
Stenosis after the deployment of the clip	1 (0.9)
Appendicitis	1 (0.9)
Perforation/leak	1 (0.9)
Post polipectomy syndrome	1 (0.9)
tenesmus and perineal pain	2 (1,8)
Major bleeding (Hb drop > 2 g/l)	1 (0.9)
Snare malfunction	12 (11)
Fate of OTSC, n (%)	
Spontaneously fallen off	100 (91)
In place	10 (9)
Removed endoscopically	2 (1.8)

3.1. Residual/recurrent adenoma

Thirty-nine patients underwent EFTR for residual/recurrent adenoma after ER (piecemeal mucosectomy, polipectomy, ESD)

or surgical local excision with transanal endoscopic microsurgery (TEM). Resection sites were the following: rectum (19), transverse colon (5), ascending colon (6), sigmoid colon (5), descending colon (2), and caecum (2). The median lesion size was 16.6 mm (range 5–35) and the median specimen size was 19 mm (range 6–33). Full-thickness resection was histologically confirmed in 88.9% of cases. Complete resection (R0 resection) was achieved in 94.4%. Final histology revealed low-risk T1 carcinoma (11), adenoma with low-grade dysplasia (LGD) (24), adenoma with high-grade dysplasia (HGD) (3) and scar tissue (1).

3.2. R1 resection

Twenty-six patients had a R1 resection. The majority of lesions were located in the rectum (20), and others in the transverse colon (1), ascending colon (2), sigmoid colon (1), descending colon (1), and caecum (1). The median lesion size was 17.48 mm (range 6–35) and the median specimen size was 25.5 mm (range 6–42). The largest EFTR specimen was achieved in the caecum (42 mm). EFTR was histologically confirmed in 86.36% of cases. An R0 resection was achieved in 86.36%. Final histology revealed adenoma with LGD (6), adenoma with HGD (1), low-risk T1 carcinoma (6), high-risk T1 carcinoma (1) and scar tissue (12).

3.3. Suspected T1 carcinoma

The subgroup of patients with an endoscopically suspected T1 carcinoma according to Kudo classification [22] included 16 cases. Lesions were located in the rectum (7), transverse colon (1), ascending colon (2), sigmoid colon (2), and descending colon (3), and caecum (1). The median lesion size was 22.82 mm (range 10–40) and the median specimen size was 24.9 mm (range 13–40). The EFTR was achieved in all patients (100%). The R0 resection rate was 93.3%. Final histological examination showed: adenoma with LGD (8), adenoma with HGD (2), and low-risk T1 carcinoma (6).

3.4. Non-lifting lesions

In 12 patients with non-lifting lesions, histological analysis revealed: adenoma with HGD (3), low-risk T1 carcinoma (7), and high-risk T1 carcinoma (2); these last patients were scheduled for surgical resection. The median lesion size was 18.1 mm (range 10–25) and the median specimen size was 22.6 mm (range 15–33). The deep and lateral R0 resection rate for this subgroup was 90% and 80%, respectively, while the EFTR rate was 90.9%. Lesions were located in the rectum (3), transverse colon (8), and sigmoid colon (1).

4. Subepithelial lesions

In the 10 patients with subepithelial lesions, deep and lateral R0 resections were 85.7% and 100%, respectively. The EFRT rate was obtained in 9 cases. The median lesion size was 14.7 mm (range 8–30) and the median specimen size was 18.4 mm (range 8–32). The anatomic resection sites were: rectum (7), transverse colon (1), ascending colon (1), and sigmoid colon (1). Final histological examination showed a neuroendocrine tumour (6), gastrointestinal stromal tumour (GIST) (2) and fibroma (2).

5. Others

Our cohort also included adenoma involving the appendix (2), intradiverticular adenoma (2) and diagnostic resection of the colorectal wall (3). In this subgroup of patients, the R0 resection rate and EFTR rate were obtained in all patients. Final histology of the diagnostic resections showed 3 neurogenic GI diseases. The other 4 histological evaluations revealed adenoma with LGD (3) and low risk T1 carcinoma (1).

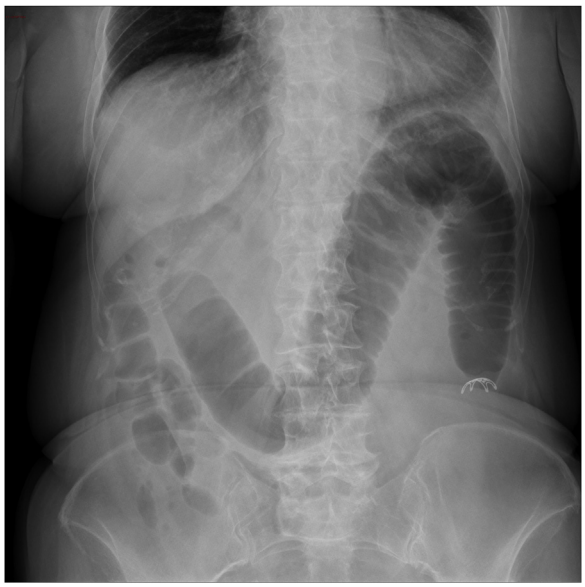

Fig. 2. Stenosis after the deployment of the OTSC clip in patient with non-lifting lesion of sigmoid.

6. Adverse events and technical issues

Adverse clinical events occurred in 12 patients (11%); only 2 of them required further surgical treatment.

Traumatic wall lesions due to progression of the endoscope with FTRD® occurred in 4 patients and did not require any treatment.

One patient developed post-polypectomy syndrome that was resolved with conservative therapy.

One patient delayed bleeding that occurred 24 h after resection and was treated with APC. Stenosis after deployment of the clip occurred in a patient with a non-lifting lesion of the sigmoid colon (Fig. 2); the patient was finally treated surgically after post-dilation perforation. One of 2 patients with adenoma involving the Appendix developed acute appendicitis and underwent surgery. Two patients with distal rectum lesions developed tenesmus and perineal pain, which healed after OTSC removal at 10 and 30 days. In one patient, with non-lifting adenoma of the transverse colon, a mucosal leak due to incomplete closure of the OTSC was successfully treated using standard OTSC (sharp teeth; cap size/depth: 14/6 mm), with no need for surgery.

Malfunction of the resection snare occurred in 12 (11%) cases. The device was extracted after clip deployment and resection was completed with a conventional snare in all patients (Fig. 3).

In 5 (4.6%) patients, an incomplete deployment of the OTSC was observed, but there was no secondary perforation or need for surgery.

7. Follow-up

Three-month follow-up was available in all patients, and residual/recurrence disease was evident in only 7 patients (6.4%). For these, the indications to the EFTR were R1 resection (1), subepithelial lesion (1), non-lifting lesion (2), suspected T1 carcinoma (2) and residual/recurrent adenoma (1). The lesions were treated with polypectomy (2), EFTR (4) and surgery (1). In 10 patients, the OTSC was still in place and in 2 cases was removed endoscopically.

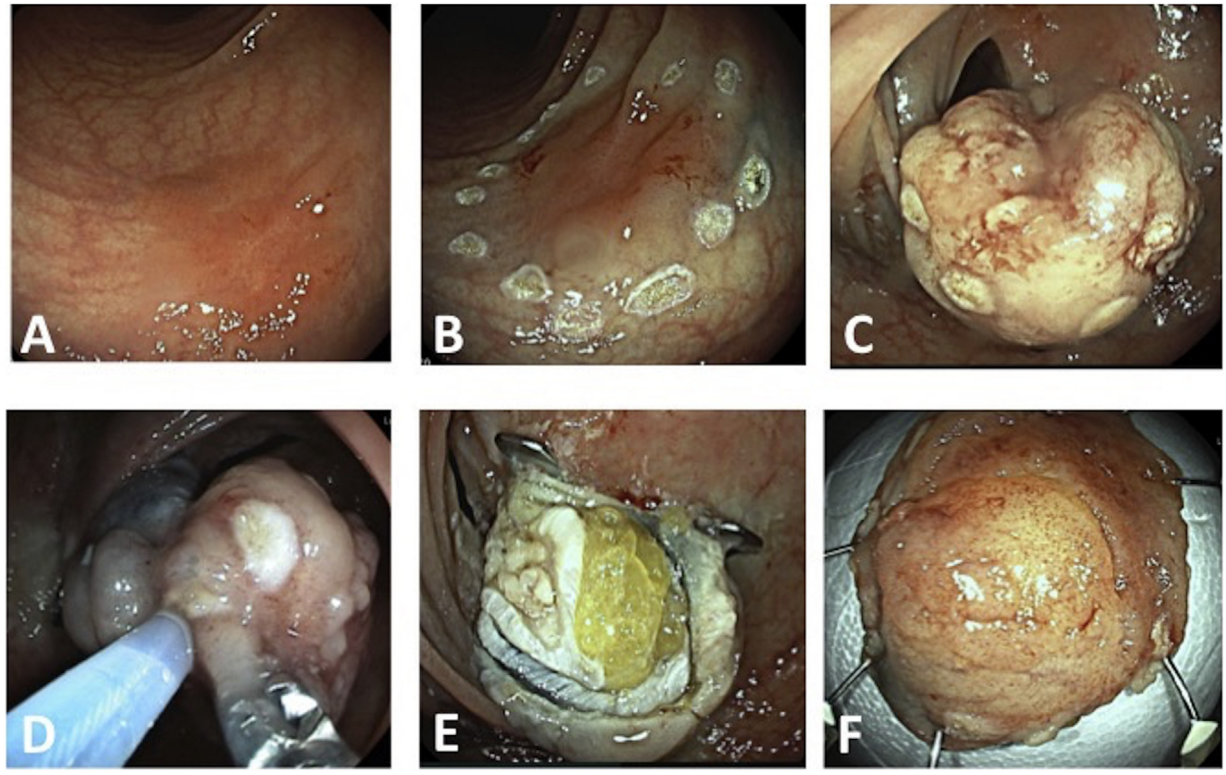

Fig. 3. A: adenoma non lifting sign; B: lesion marked with Argon Plasma Coagulation (APC); C: over-the-scope clips (OTSC) completely closing with the target lesion not resected; D: lesion resected with snare; E: resection site;F: full-wall resection specimen.

8. Discussion

This study shows the Italian experience on EFTR in the colorectum using FTRD®. The EFTR compared to common endoscopic resection techniques has the considerable advantage of guaranteeing a better histological evaluation of a particular setting of lesions at high risk of fragmentary or incomplete resection [2–5]. To date, the only endoscopic device that allows achievement of an EFTR using a clip-and-cut technique is FTRD®. The innovation of FTRD® is to perform EFTR after the release of a modified OTSC in order to avoid free perforation of the colon. The most frequent EFTR indication in this cohort of patients was residual/recurrent adenoma. Before the availability of FTRD®, these lesions were exclusively treated with polypectomy, ablation, and mucosectomy only in reference centres with ESD. The latter technique has a long learning curve, is time-consuming and requires careful patient scheduling and planning. Moreover, several studies have demonstrated that the perforation risk and the incomplete resection rate of EMR and ESD increase in the presence of fibrosis or scar/local recurrence, even in expert hands [23–25]. In our experience, the R0 resection rate in this subgroup was 94.4% compared to the 77.7% reported in the literature [5]. This promising result permits consideration of EFTR with FTRD® as a feasible and effective therapeutic option for the treatment of residual/recurrent adenoma.

In this cohort, the second most frequent indication was scars of previous ERs with positive deep or lateral resection defined as the presence of *foci* of pathological cells located within 1 mm of the deep or lateral resection margins (R1 resection) [20]. Currently, the surgical approach is undoubtedly the preferred treatment because it determines the radical and curative resection both of the colonic segment and of lymph nodes, even though laparoscopic (or occasionally open) surgery is burdened by a high rate of morbidity [26,27]. In the subgroup of patients with R1 resection lesions, histology showed 7 T1 carcinoma (1 high-risk referred to surgery), while 12 were histologically negative. Future comparative and costs-analysis studies are necessary in order to demonstrate the most adequate treatment.

Since the FTRD® allows resection only after release of the clip, reducing the theoretical risk of intra-abdominal tumour cell seeding upon resection of malignant lesions has been used to resect suspected T1 carcinoma. Better histological evaluation (deep invasion, well-differentiated tumour and submucosal infiltration\thousand microns), budding and lymphovascular invasion) was provided to obtain curative resection in all patients according to Japanese guidelines [21,28–29]. In this cohort, 7 lesions were localized in the rectum. Rectal lesions can be treated with either a surgical or endoscopic approach.

Compared to established surgical curative treatments for rectal cancer (i.e., a lower anterior resection with total mesorectal excision and abdominoperineal resection), less invasive trans-anal full-thickness excision techniques (e. g., conventional trans-anal excision, TEM, or trans-anal minimally invasive surgery (TAMIS)) have comparable 5- and 10-year survival rates, but clear advantages in limiting either surgery-related mortality or morbidity, and the need for a permanent stoma. However, by reducing both the resected specimens and the mesorectal lymph node assessment, these treatments hamper the exact disease staging, thereby implying an increased risk of local recurrence and missed micrometastases. In addition, following either TEM or TAMIS, major complications have been reported in 1.5– 7 % of patients and conversion to laparotomy with or without total mesorectal excision or temporary stoma is sometimes necessary. Therefore, EFTR with FTRD can be considered as a valid alternative to trans-anal full-thickness excision surgical techniques for selected lesions <20 mm, resulting in low comorbidity, a fast operating time and anaesthesiology-free procedures.

Compared to ESD or EMR, EFTR has the potential to allow for en bloc curative resection, with reduced risk of bleeding, perforation, and post-polypectomy syndrome, which appear considerable even in referral ESD centres. Furthermore, ESD is technically difficult, especially in fibrotic tissue due to previous excisions. It is time-consuming and requires a prolonged learning curve for inexperienced endoscopists. In fact, ESD outcomes from Western studies are substantially worse compared with Eastern studies, thereby limiting the generalizability of the results [21]. However, ESD represents the only reasonable endoscopic approach for low-risk T1 carcinoma >30 mm, since the use of the FTRD® would not be feasible for technical reasons (cap diameter/length 13 /23 mm), while EMR often leads to piecemeal resection, challenging histopathological assessment of R0 resections and increased risk of an incomplete excision [29–35].

Subepithelial lesions are another indication for the EFTR since the technique helps to prevent major surgery for these patients. EFTR could become the standard approach for these kinds of lesions, even arising from *muscolaris propria*.

Before the introduction of the FTRD®, the best way to obtain a diagnosis of gastrointestinal neuromuscular disorders was by laparoscopic or less frequently laparotomic full-thickness biopsies [36]. In this rare condition, FTRD® allows accurate histopathological evaluation based on a full-thickness sample, avoiding surgery and reducing costs.

In our cohort, 4 adenomas (2 at the appendiceal orifice and 2 at a diverticulum), usually treated with a surgical approach, were resected using FTRD®. The EFTR and RO resection rates were obtained in all patients. Acute appendicitis occurred in one patient who had undergone resection of an adenoma involving the appendiceal orifice and underwent surgery. Until now, approximately 10% of patients with adenoma involving the Appendix who underwent EFTR developed acute appendicitis with a subsequent rate of surgery of 2.9% [4,5]. Therefore, we agree with Schmidt and colleagues [5] in recommending EFTR only after providing thorough patient information, interdisciplinary discussion and that it is done within clinical studies.

Concerning technical aspects, the over-all mean time of the procedure was 45 min (range 8–68), while the insertion of a device until reaching the lesion was 10 min (range 1–50). These data were different from what was reported in the literature, because in our cohort, 63% of the lesions were located in the rectum-sigmoid, which was easier to reach with the device. In fact, the time of introduction of the FTRD® increases reaching the lesions in other colonic segments due to the size of the cap (23 mm × 13 mm), which limits vision. Moreover, the FTRD® increases the stiffness of the endoscope, making passing the sigmoid colon and flexures more difficult. Unlike in previous studies [1–5,14,15], we reported the R0 resection rate as 90% of patients, the technical success rate as 94.34% and a full-thickness resection rate with FTRD® as 91%. Even if the recommended resection size cut-off is 30 mm [2], it has been recently demonstrated that the R0 resection rate decreased up to 58.1% for lesions >2 cm versus 81.2% for lesions <2 cm ($p = 0.0038$) [5]. In our opinion, the performance of this tool increases for smaller lesions because it improves gripping the lesion into the cap, with subsequently more successful en bloc curative resections.

The mean diameter of the resected specimen was 20 mm (range 6–42). These data were lower than that reported in other studies [1–5] and probably depends on the greater number of lesions (53.7%) located in the rectum. In fact, analysis of the diameter of lesions not localized in the rectum showed the mean diameter was 25 mm (range 9–42).

Therefore, we agree with the common thought that the anatomy of the rectum and the greater fixation of its wall reduce the traction of the lesion in the cap and, consequently, the diameter of the resected specimen. In fact, a maximum diameter of 42 mm was obtained for lesions located in the caecum.

We strongly recommend using the prove-CAP to evaluate the accessibility of the lesions not localized in the rectum to avoid device wasting and possible complications. It is also necessary to evaluate the colo-rectal wall mobility through a gentle aspiration of the lesion into the cap and using the FTRD grasper; in fact wall mobility represents the fundamental requirement for a complete FTR.

In our experience, as already reported in the literature [4,5], we recorded 12 cases of snare dysfunction with rupture in 5 cases. The rupture seemed to be related to fibrosis of the wall, due to the presence of scars of previous ERs, especially for lesions located in the rectum. In these specific cases, we recommend a gentle snare closure to allow the snare to better comply with the target lesion during the cutting phase. The overall clinical adverse event rate in our cohort was 11% (12/110). However, only 2 cases required further surgical treatment (i.e., the closure of the sigmoid lumen following the release of the modified OTSC and acute appendicitis after removal of an adenoma involving the appendix), while the others were treated conservatively or with endoscopic treatment.

Considering the experience of all the centres in treating leakages and wall perforations with OTSC, we believe that the lumen closure could be due to excessive suction applied during the traction phase. In this phase, we recommend using mainly traction with a FTRD grasper to selectively include the lesion into the cap and to apply gentle aspiration only after seeing all the markers. Surely, in the case of lesions with marked fibrosis, with poor or absent mobility of the colo-rectal wall that would not permit complete inclusion into the cap, it is advisable not to perform the FTRD and, instead, to consider surgical treatment. EFTR with FTRD® is an invasive technique and therefore we strongly suggest it be performed by expert endoscopists, able to treat any complications or any eventual adverse events [4], such as: (i) gut injury, ranging from mucosal laceration to perforation and bleeding, caused by the device; (ii) tissue damage, burns, bleeding, and colonic gas explosion caused by the resection snare; (iii) insufficiency of OTSC closure; (iv) obstruction of the gut lumen; and (v) injury or resection of the surrounding tissues or organs.

During the 3 months follow up, only 7 patients showed residual/recurrence adenoma, OTSC was no longer *in situ* in 100/110 (9%) with no *sequelae* and in 2 patients the clip was removed with a clip cutter device.

There are few data supporting the OTSC removal timing. Schmidt et al. noted that the clip should not be removed until 8 weeks after EFTR [2].

Our experience demonstrates the feasibility and efficacy of EFTR with FTRD®. This device, using a clip-and-cut technique, permits obtaining a complete resection of a colo-rectal lesion at high risk of perforation and piecemeal resection, or with mainly surgical indications. Surely, the size of the cap and the presence of the cover can make achievement of lesions not localized in the rectum difficult, so this procedure must be carried out by a highly skilled endoscopist. The cut-off size of the lesion represents a limit to the possibility of using FTRD®, even if lesions localized in the transverse colon and in the ascending colon seem to decrease this dimensional drawback due to greater wall mobility. The limitations of this study include the retrospective design, the selection of patients and the short term follow up.

Randomized comparative and cost-analysis studies with current endoscopic and surgical resection techniques are needed to better define indications and outcomes.

Conflicts of interest
None declared.

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