

Endoscopic Full-thickness Resection with the Full-Thickness Resection Device (FTRD) for “difficult to resect” colonic lesions.



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A single-center experience

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Endoscopic Full-thickness Resection with the Full-Thickness Resection Device (FTRD) for “difficult to resect” colonic lesions. A single-center experience

INTRODUCTION: Aim of our observational and retrospective study is to compare efficacy and indications of endoscopic full-thickness resection device (FTRD) with the over-the-scope (OVESCO) clip closure for en bloc resection of colorectal lesions (including adenomas, early carcinomas, inflammatory polyps and neuroendocrine tumors).

MATERIAL AND METHODS: This article collected 36 cases of colorectal neoplasms from a single Italian referral center per colorectal disease treatment. Primary endpoints included en bloc resection, R0 resection and an early discharge of the patient. Secondary endpoints included procedure-related adverse events. Results: Mean procedure time \pm standard deviation (SD) was 19.6 \pm 22.1 minutes and mean hospital stay (\pm SD) was 2.2 \pm 1.1 days. Overall, an en bloc resection was achieved in 34 cases (94.4%), with an R0 resection rate of 91.6%. Among the three not R0 patients, further additional treatments were needed. Discussion: Along the same line of other already published articles, the main current indications of EFTR by FTRD-OVESCO are limited to superficial or low-risk malignancy lesions (eg, adenomas, early cancers or subepithelial tumors), not suitable to conventional endoscopic resection or in patients with a severe surgical risk. Both en bloc resection rate and complication rate are aligned with other authors' data.

CONCLUSIONS: EFTR by FTRD system represents an effective and safe options whenever a recurrent lesion in a challenging environment occurs (eg, recent scar, low rectum or beyond a large colonic bend). Procedure-related adverse events are potentially severe, so that this novel technique should be performed by “expert hands”.

KEY WORDS: Difficult polypectomies, Early carcinomas, Endoscopic Full-Thickness Resection (EFTR), Full-Thickness Resection Device (FTRD) by Over-The-Scope (OVESCO) clip closure, Literature overview, Single center experience

Introduction

Colorectal cancer is the third most common neoplasm in males and the second in females, respectively ¹. In contrast to incidence trends, colorectal cancer screening

is worldwide leading to a decreasing of its mortality rate ^{1,2}. In particular, several kinds of epithelial and subepithelial tumors (eg, adenomas, pedunculated lesions, gastrointestinal stromal tumors, early colorectal cancers, invasive cancers, neuroendocrine tumors) can be detected thanks to colonoscopy ^{3,4}.

Considering the crucial role of flexible endoscopy both as a diagnostic and as a therapeutic procedure, in 2015 Conway et al. gave it the definition of “truly the queen of minimally invasive interventions, being less morbid than surgery and without the radiation exposure of interventional radiological interventions” ⁵. Thanks to a continuous and increasing interest in this field, several inno-

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vative tools have been introduced in clinical practice to resect challenging lesions, sometimes called "difficult polyps"⁴. Even if no univocal definition still exists, in more objective way, polyps larger than 1.5-2 cm, flat or laterally spreading, located in right colon or cecum, located around haustral folds (therefore difficult to access) should always be considered "difficult".⁴

Multiple techniques are available to interventional endoscopists to remove these lesions limited to the superficial layers of the wall: conventional cold-snare polypectomy, endoscopic mucosal resection (EMR), cap-assisted EMR (EMR-C or aspiration lumpectomy), endoscopic submucosal dissection (ESD) and various systems of endoscopic full-thickness resection (EFTR)⁶⁻⁸.

TECHNIQUES DESCRIPTION

EFTR is an expression referring to a series of different devices offering the possibility of "one-shot" resection of a lesion together with secure defect closure⁹. For several years, the lack of safe and standardized devices has not allowed the introduction of such tools in the clinical practice. In 2015, Schurr MO et al. proposed an innovative EFTR system, named "full-thickness resection device" (FTRD[®], Ovesco Endoscopy, Tübingen, Germany), designed for one-step colonic EFTR after over-the-scope (OVESCO[®]) application¹⁰.

Such as OTSC system, the FTRD combines a modified OTSC mounted on the distal tip of a standard endoscope (either a colonoscope or an operative gastroscope) and consists of a plastic cap (21 mm × 23 mm) loaded with an FTRD clip. The system has a preloaded 14 mm polyfilament polypectomy snare inside the cap, a tissue grasper, and a high frequency marking device.

Once premarked the target lesion with the apposite probe, the endoscope is withdrawn, so that the FTRD system can be loaded on the scope.

As soon as reached the lesion by the FTRD system, the whole colonic wall is pulled into the cap through a spe-

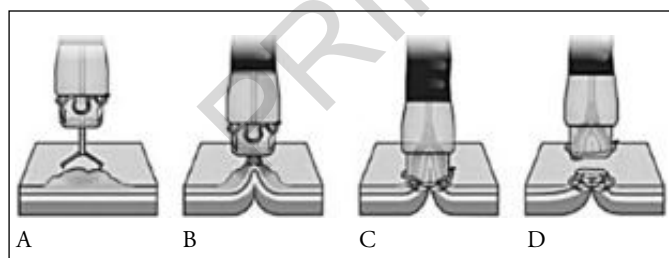


Fig. 1: Subsequent steps of EFTR with FTRD tools. A) The pre-marked lesion is reached by the FTRD system and the grasping forceps is advanced outside the working channel; B) The polyp is grasped with the apposite forceps and a mild aspiration of the instrument is applied; C) One obtained a good duplication of the wall, the lesion is pulled into the cap; D) Final result, showing the rectal wall closed by the OTSC system, with the lesion inside the cap.

TABLE I - FTRD system-related indications.

Recurrent non-lifting adenoma after previous polypectomy
Non-lifting adenoma without previous polypectomy
Full-thickness biopsy (if a malignancy is suspected)
Adenoma near-sited to the appendiceal orifice
Adenoma near-sited to a diverticulum
Primary EFTR of polyps suspected for malignancy
Primary EFTR of submucosal lesions (included neuroendocrine tumors)
Hirschsprung disease primary workup

cific grasping forceps, together with a mild aspiration, thereby allowing a full-thickness duplication of the colonic wall¹¹⁻¹³.

As soon as the clip has been deployed, the electrocautery snare is activated using a monopolar current (VIO 200, Endocut Q), excising the full-thickness tissue captured by the clip. The specimen is then retrieved, leaving the colonic wall closed by the OTSC.

Reintroduction of the endoscope is usually suggested, in order to control the right clip positioning and the correct closure of the hole. Subsequent steps of FTRD system are described in Video 1 and Fig. 1.

To date, main indications of the system are summarized in Table I.

The clinical use of the system is critically related to the maximum size of the lesion to resect^{6,14,15}. In Schmidt et al. article, a median diameter of 24 mm (range 12-40 mm) is reported, whereas a diameter of specimen up to 54 mm has been reported in porcine models⁶⁻¹⁶.

Another limit of this tool is represented by the long plastic cap, often reducing the flexibility of the endoscope tip, so that advancement of the scope across the sigmoid colon or beyond the colonic flexures can be very challenging; for this reason, sometimes, a preliminary colonoscopy with a prove-cap is performed (especially if a diverticular disease is suspected) to check the feasibility of the procedure⁹⁻¹¹. The OTSC clip-based FTRD system represents a true change in the clinical management of colorectal non-lifting lesions, avoiding the need of a surgical therapy in selected patients (Figs. 2, 3).

Materials and Methods

We conducted a retrospective and observational study, collecting data from a single hospital institution (Azienda Ospedaliero Universitaria Careggi, Florence, Italy) within December 2015 and January 2020. All the patients underwent a preliminary complete colonoscopy, documenting the lesion.

A written informed consent was obtained from all the patients. The study was carried out in accordance with the Declaration of Helsinki adopted in 1964 incorporating all later amendments.

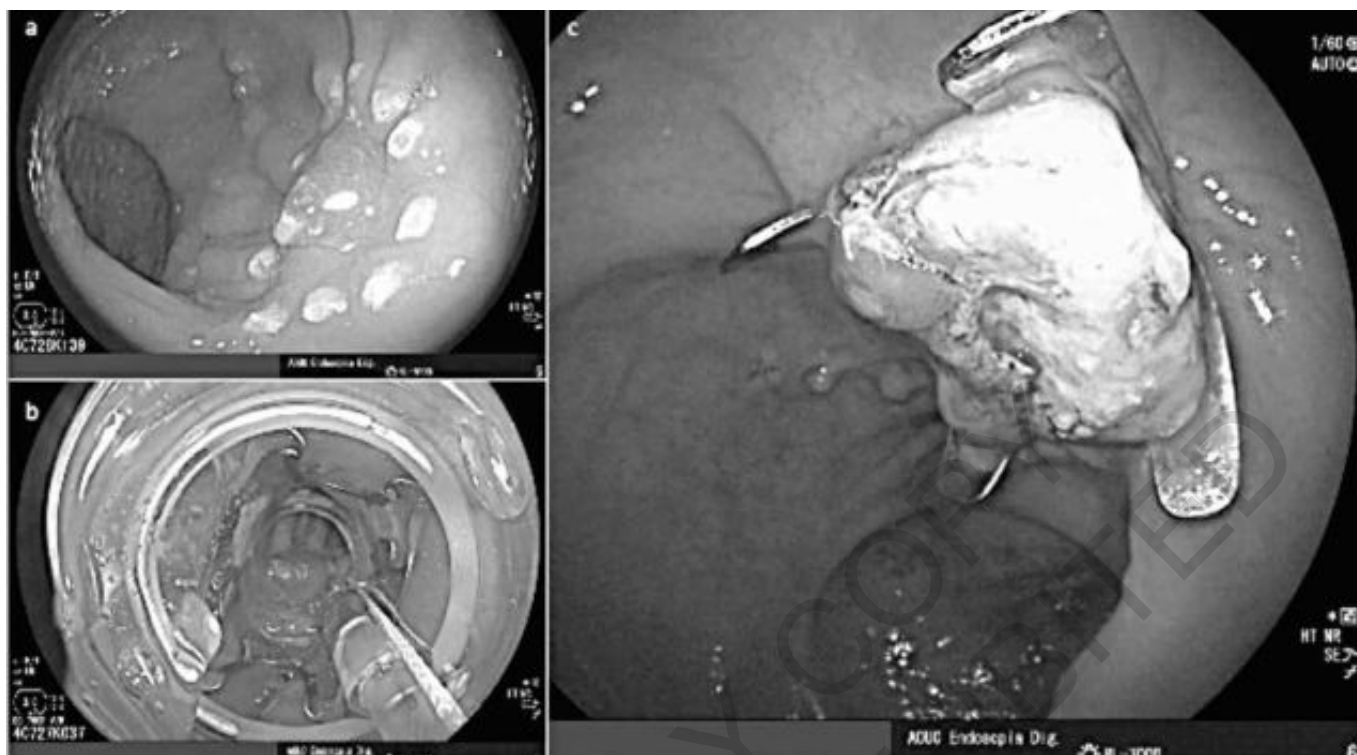


Fig. 2: A) Recurrent adenoma of the middle rectum premarked circumferentially through the apposite probe; B) The colonic wall is pulled into the cap through the specific grasping forceps together with a mild aspiration, thus allowing a good duplication of the tissue; C) Final result, showing rectal wall closed by the OTSC system, without any sign of residual adenomatous tissue.

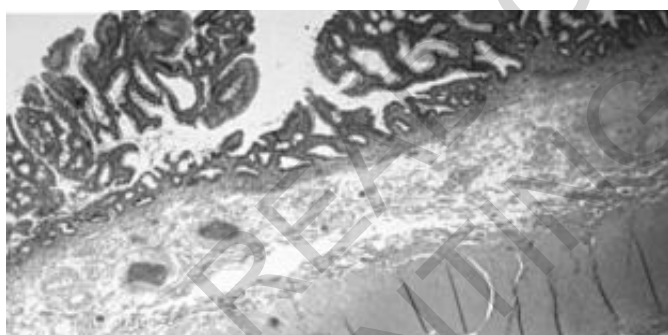


Fig. 3: Histological appearance of the final resected specimen, showing all the layers of colonic wall.

Indications for the procedure were recurrent lesions after EMR, non lifting superficial neoplasms, full-thickness biopsies or resections, removal of submucosal lesions. EFTR by FTRD method was performed by expert endoscopists, each one with over 15 years of experience; these procedures were equally distributed among them. Before the procedure, complete blood exams and an electrocardiogram were obtained, in order to establish the feasibility of the procedure. A specific antibiotic-therapy was performed only in selected patients (eg, previous cardiac valve implant, severe immunodepression, high risk of post-procedural infection).

EFTRs were carried out using high-definition endoscopes with CO₂ insufflation in an inpatients setting. All the patients were left side positioned. We excluded from the study all the cases in which, either for technical reasons or because of inflammatory conditions (ie, diverticulitis), the target lesions wasn't reached by the FTRD tool. The EFTR was achieved following the procedure described in the introductory section and shown in the *Video 1*.

Procedural time was measured by another physician from the FTRD introduction until complete resection was achieved.

The sample retrieved was put into formalin and sent for histopathological evaluation to the pathologists of the same hospital. If no adverse event occurred, the patients received regular diet the next day and were discharged a few days after the procedure.

Patients underwent the first follow-up endoscopy within three months after EFTR, whereas the further endoscopic controls were scheduled according to international guidelines and basing upon the final histology of the resected specimen.

If still in place after three months, the apposite bipolar cutting device (remOVE® System, OVESCO Endoscopy) was used for FTRD clip removal.

Procedure-related adverse events were recorded as follow explained.

Hemorrhage was defined as a reduction of hemoglobin concentration of at least 3 g/dL (within 24-48 hours after the procedure) or a clinical evidence of bleeding. Perforation was defined as a clinical condition of severe abdominal pain, confirmed by radiological exams. Post-polypectomy syndrome was defined as a clinical condition consisting of abdominal pain, fever (at least 38°C) and leukocytosis (more than 11000 white blood cells/microL).

GENERAL ASSESSMENTS

En bloc resection and R0 resection were defined as a complete removal of the specimen in one piece and the negative margins at the pathological examination, respectively.

Technical success was considered as both a complete en bloc resection (without any fragmentation of the sample) and no evidence of any intra-procedural adverse event. Clinical success was considered as an early discharge of the patient (within 5 days) and no evidence of tumoral recurrence at the endoscopic surveillance.

STATISTICAL ANALYSIS

Statistical analysis of data collected was performed using the SAS system software, version 9.2. Distributions of all patients were reported with respect to their demographic and clinical characteristics and were summarized as frequencies and percentage. Continuous variables were reported as mean, standard deviation and range of variation. The presence of association between patients characteristics and clinical outcomes was evaluated by χ^2 and Fisher exact tests, when appropriate. Comparisons between means were performed using the unpaired Student's t-test. Estimates of odds ratios and their 95% confidence interval were calculated with the logistic regression model. A two-sided $P \leq 0.05$ was considered significant.

Results

STUDY POPULATION AND PROCEDURAL DATA

From December 2015 to January 2020, we collected 36 cases of colonic and rectal lesions treated with the FTRD system based on the OVESCO closure clip. Patient and tumor features are summarized in Table II. All the procedures were performed electively. We included 36 patients at the first time EFTR by FTRD system; most of them were referred to FTRD due to a recurrent lesion after EMR (52.8%). Over 80 % of collected cases presented a rectal polyp. Mean tumor diameter size was 19.8 ± 9.6 mm (range 0.3-

TABLE II - Data analysis.

Gender (male/female), n (%)	23(64)/ 13(36)
Age (years), mean \pm SD	69.6 \pm 11.8
Tumor size (mm), mean \pm SD	19.8 (9.6)
Tumor localization, n (%)	
- Rectum	29 (80.5)
- Sigmoid colon	0 (0)
- Descending colon	0 (0)
- Transverse colon	3 (8.3)
- Ascending colon	2 (5.5)
- Cecum	2 (5.5)
Indications, n (%)	
- Recurrent lesions after EMR	19 (52.8)
- Non lifting lesions	10 (27.8)
- Full-thickness biopsies/resections	6 (16.7)
- Submucosal lesions	1 (2.8)
Final histology of the resected specimens, n (%)	
- Adenoma with low-grade dysplasia	10 (27.8)
- Adenoma with high-grade dysplasia	11 (30.5)
- Intramucosal or sm1-adenocarcinoma	1 (2.8)
- Sm2 or Sm3-adenocarcinoma	5 (13.8)
- Other histologies	
(hyperplastic polyps, inflammatory polyps)	6 (16.7)
- Neuroendocrine tumors	3 (8.3)
Procedure time (minutes), mean \pm SD	19.6 (22.1)
Hospital stay (days), mean \pm SD	2.2 (1.1)
En bloc resection, n (%)	34 (94.4)
R0 resection, n (%)	33 (91.6)
Recurrence, n (%)	4 (11.1)
Bleeding, n (%)	4 (11.1)
Perforation, n (%)	3 (8.3)
Post polypectomy syndrome, n (%)	3 (16.7)

4.5 mm); localization along the colon-rectum are summarized in Table II.

21 were adenoma-patients, 6 adenocarcinoma-patients, 6 persons presented other histologies (including squamocellular carcinoma, flogistic tissue) and 3 lesions resulted as neuroendocrine tumors at the final histology.

FTRD - RELATED TECHNICAL AND CLINICAL RESULTS.

Mean procedure time was 19.6 ± 22.1 minutes and mean hospital stay was 2.2 ± 1.1 days.

An en bloc resection was achieved in 34 cases (94.4%), with an R0 resection rate of 91.6%.

Among the three not R0 patients, further additional treatments were addressed by a multidisciplinary team meeting. The two sm-2 invasive adenocarcinoma cases underwent a radical surgical resection (rectal anterior resection), but unfortunately one of them died due to a cardiac arrhythmia in the post-operative setting. The high grade adenoma patient, considering the young age, was referred to subsequent EFTRs (till an adequate R0 resection was achieved).

Among the two not en bloc patients, the one resulting high grade adenoma at the final histology was referred to a further treatment by the FTRD method, whereas the one resulting sm-2 adenocarcinoma experienced a

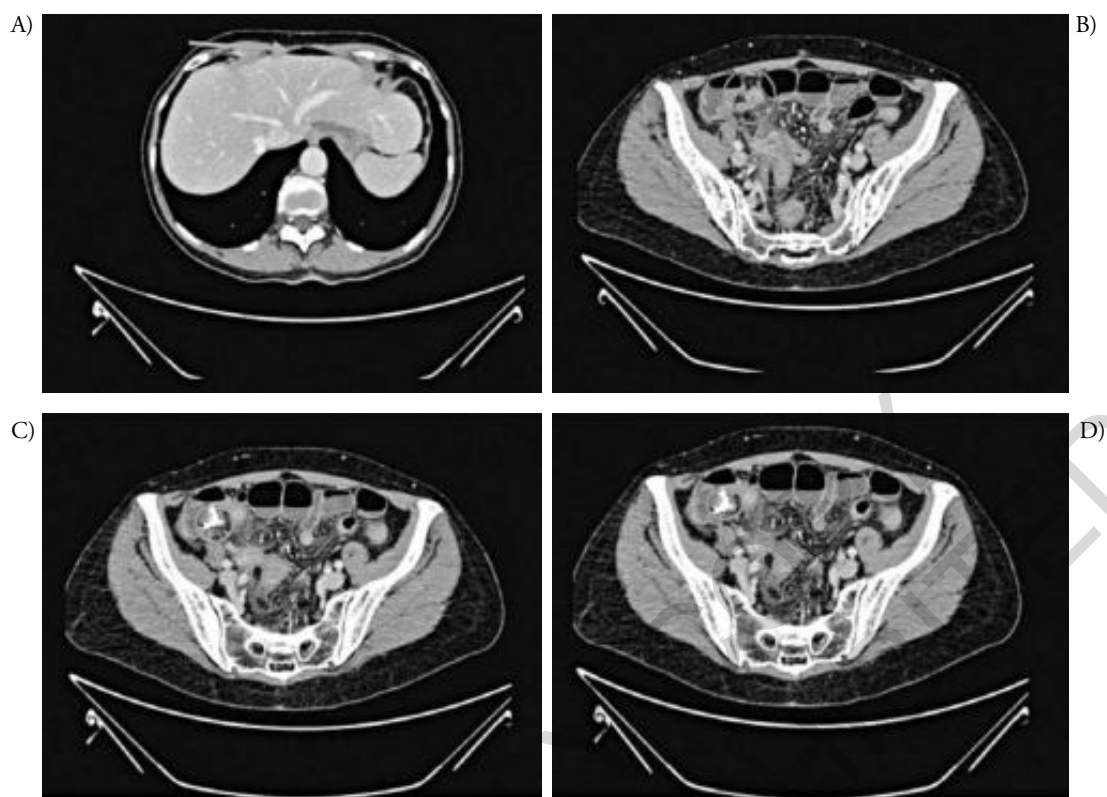


Fig. 4: A) CT-scan image showing signs of pneumoperitoneum (red arrow); B) Acute inflammation with edema of the appendicular walls (red circle), due to the closure of its orifice by the OTSC; C-D) OTCS clip closed to the appendicular orifice (red circles), with signs of appendicitis.

right colectomy (as the lesion was located in the ascending colon): both of them didn't show any sign of recurrence at the surveillance controls.

At univariable analysis, no statistically significant association between tumor size and R0 resection rate emerged ($p=1.0$; OR= 0.47, 95% CI= 0.39-5.71); thus showing that lesions smaller than the mean value (19.8 ± 9.6 mm) are not mostly related to a higher R0 resection rate.

Overall, 4 recurrences (11.1%) were observed after the first treatment. All the cases belonged to the adenoma-group and, after a multidisciplinary team meeting, the patients were referred to further subsequent EFTR by FTRD system. Concerning the relationship between disease-free survival and mean age, no statistically significant association emerged at univariable analysis ($p=0.46$); similarly, no statistical correlation was found out between disease-free survival and final histology ($p=0.17$).

4 OTCS clips were removed with the remOVE[®] System after 3 months: 2 were located in the rectum and one the transverse colon.

FTRD - RELATED COMPLICATIONS.

Overall, bleeding occurred in 4 patients (9%), 3 during the procedure and one in the recovery setting. All these episodes were effectively stopped through injection of either epinephrine or cyanoacrylate.

Perforation was found out in 3 patients (8.3%). Two cases occurred due to a malfunction of the device, leading to a missed release of the OVESCO clip: in both cases, the resulting large discontinuity of the wall was effectively closed by applying 4 hemostatic clips. Both patients experienced a post polypectomy syndrome in the post operative setting, effectively treated with an antibiotic therapy.

The remaining case of perforation was related to a resection of a large adenoma (about 22 mm in diameter size) critically closed to the appendicular orifice. During the second post operative day the patient presented high fever (over 39°C) and severe abdominal pain; since blood exams showed leukocytosis (18000 white blood cells/ mm^3), an emergency contrast enhancement-computed tomography (CT) was performed. A pneumoperitoneum and an acute inflammation of the appendix (due to a partial closure of its orifice) were found out, thus supporting the clinical hypothesis of a perforated appendicitis (Fig. 4). After obtaining an informed consent, the woman underwent a laparotomic surgical operation. A severe perforated appendicitis was found, due to OTCS clip closure of the internal orifice. At the light of these findings, a right colectomy was carried out, with resection of about 20 cm of the ileum and a side-to-side anastomosis was accomplished. At the opening of the resected specimen, the macroscopic appearance confirmed the clinical hypothesis of an iatrogenic appendicitis. A

careful control of haemostasis was done and a tube drainage (Blake® type) was placed into the pelvis. On the second post-operative day, she tolerated a soft diet, and on the sixth post-operative day, the drainage was removed. The hospital stay was uneventful, and she was discharged on the seventh post-operative day.

Last noteworthy adverse event was a missed opening of the FTRD-associated snare; therefore, once withdrawn the endoscope and removed the device from the tip of the colonoscope, a disposable 15 mm size snare was accomplished in order to perform the polypectomy just above the OVESCO clip.

At univariable analysis, no statistically significant association between tumor size and complication rate emerged ($p=0.46$; $OR= 1.75$, $95\% CI= 0.39-7.69$); thus showing definitely that lesions smaller than the mean value are not mostly related to a higher complication rate.

Discussion and Comments

Since the first article dealing with this innovative tool was published in 2015 by Schurr MO et al, clinical approach to “difficult colonic polyps” has considerably changed¹⁰⁻¹⁷.

Compared to the other techniques available for polypectomy, FTRD based on the OVESCO system brings several advantages^{11,17}. First, as underlined by multiple articles, this system is less time consuming as compared to ESD or EMR, therefore reducing anesthesiological time; in our study, the overall mean time was 19.6 ± 22.1 minutes, that's significantly shorter as compared to ESD-related procedural time reported in Arezzo A et al. review (mean time 96 minutes)^{11,17}. Second, it ensures a full-thickness closure of the colonic wall defect, thus reducing considerably the risk of bleeding and perforation. In 2010 Saito Y et al. published a relevant study on *Gastrointestinal Endoscopy*, reporting an overall mean procedure time \pm standard deviation (SD) of 116 ± 88 minutes with a mean tumor size of 35 ± 18 mm; perforation rate was 4.9%; comparing these data to ours, important differences emerge both in terms of time saving and regarding the perforation rate¹⁵. This fact shows clearly how, also in expert hands, ESD is a challenging and difficult to perform technique^{11,15}. In a recently published review, EFTR with the FTRD-OVESCO is described as a powerful option for en bloc resection in case of recurrent lesions after endoscopic resection, providing a good alternative to ESD^{11,15,17}.

Third, it has a significantly shorter learning curve as compared to ESD, enabling also less experienced endoscopists to remove challenging sessile lesion^{11, 18, 19}.

On the other side, a few inherent limits of this device have to be highlighted.

First, the main inherent limitation is related to the tumor size, as lesions larger than 40 mm are not feasible to be resected with this method; on the other hand, it has no

lesion-site limits, since it could be theoretically feasible from the anal verge to the cecum^{15, 17-19}.

As explained by several authors, this technique doesn't represent an adequate strategy for low-risk T1 carcinomas (with more than 30 mm in diameter size), since it would lead to an incomplete resection (due to the dimensional size-limits of cap); these cases should be preferentially referred to an ESD^{15,17-19}.

Our study, even if designed as retrospective and observational, shows interesting noteworthy results aligned with the ones already published in literature.

Along the same line of the papers published by Andrisani G et al. and Schmidt A et al, EFTR by FTRD finds its best application in case of recurrent rectal adenomas after EMR. In fact, in our analysis, most of the patients experienced an EFTR for recurrent rectal benign lesions following a mucosectomy^{9,11}.

Overall, a relapse rate of 11.1% was calculated, similar to the ones reported by other studies (ranging from 6% to 15.3%)^{9,11-14}. Statistical analysis performed on our data didn't reveal any significant relationship among the collected parameters; this fact, not so relevant, may be due to both the low number of cases and the very low recurrent rate after FTRD.

Comparing our data to Schmidt A et al.' article (one of the largest multicenter study concerning the efficacy and indications of the FTRD system), en bloc and R0 resection rates are 94.4% vs 89.5% and 91.6% vs 76.9%, respectively^{9,11,20}. Once again, this comparison confirms our noteworthy results, with a statistical relevance. Also taking into consideration the procedure-related complications, our overall rate (19.4%) is slightly higher to Van der Spek B et al.' one (13%)^{21,22}. As well as already reported by Schmidt A and Andrisani G et al, also in our single center experience a case of iatrogenic FTRD-related appendicitis was observed; unfortunately, in our case, the patient experienced a right colectomy^{9,11,20}.

Conclusions

To date, considering the literature available, this is one of the largest Italian single center experience for FTRD-OVESCO. Along the same line of the current literature, EFTR by FTRD system represents an effective and safe options whenever a recurrent lesion in a challenging environment occurs (eg, recent scar, low rectum or beyond a large colonic bend)^{9,11,20-21}. Main current indications are limited to superficial or low-risk malignancy lesions (eg, adenomas, early cancers or subepithelial tumors) not suitable to conventional endoscopic resection or in patients with a severe surgical risk. Nevertheless, considering the procedure-related complications (particularly bleeding and perforation), we think that, despite no specific skill-level competence is required, this device should be reserved only to selected patients.

Riassunto

La resezione di lesioni sessili del colon-retto, specialmente in siti considerati complessi (per esempio retto inferiore, a livello di austre coliche o su cicatrici di pregresse mucosectomie) costituisce un sfida per ciascun endoscopista. Considerando il costante incremento di incidenza delle neoplasie del colon retto nell'ultimo decennio, nuove metodiche di polipectomia sono state frutto della continua ricerca medica, fra cui, a partire dal 2015, la tecnica di Full-Thickness Resection Device (FTRD) basata sulla clip Over-The-Scope (OVESCO), nata da una brillante idea di Schurr MO^{1,2,9,10}. Peculiarità di questo sistema innovativo è la capacità di realizzare, in un unico tempo (ossia "one-shot") sia la resezione a tutto spessore della lesione target (garantendo pertanto un'alta percentuale di pazienti R0) sia la chiusura a tutto spessore della parete colica (o rettale)^{9,11,15,17}. Il kit FTRD consiste della specifica clip OVESCO modificata (al fine di poter afferrare a tutto spessore la parete colica o rettale), di una pinza con la funzione di sollevare la lesione target all'interno del cappuccio e, infine, di un'ansa annessa al sistema (che decorre esternamente lungo il tubo dell'endoscopio, avvolta da una guaina). Una volta che la lesione è stata marcata circonferenzialmente e raggiunta con il sistema FTRD, la pinza viene fatta avanzare attraverso il canale operativo per poter afferrare le lesione e, congiuntamente ad una modesta aspirazione dell'endoscopio, includerla all'interno del cappuccio apposito (con dimensioni di 21 mm × 23 mm). Una volta ottenuta una valida duplicazione della parete colica (o rettale) la clip viene rilasciata mediante l'apposito mulinello (analogo a quella della OVESCO classica); immediatamente dopo, l'assistente provvede a chiudere l'ansa, così da poter resecare la lesione mediante un sistema di corrente monopolare (Video 1, Figs. 1, 2)^{9,11}. La casistica del nostro centro comprende 36 casi di lesioni coloretali, raccolte in 5 anni. La maggior parte delle lesioni sono adenomi rettali recidivi (dopo mucosectomie endoscopiche). I risultati ottenuti, in termini di resezione en bloc e di R0, sono molto incoraggianti, peraltro in perfetta linea e coerenza con quelli dei più importanti lavori europei pubblicati sinora su questo tema. L'analisi statistica dei dati raccolti ha fatto emergere percentuali di resezione en bloc ed R0 del 94.4% e 91.6%, rispettivamente, confermando l'efficacia e sicurezza di questa innovativa tecnica per la resezione di lesioni complesse ("challenging") del colon-retto, specie in pazienti ad alto rischio chirurgico. Anche le percentuali relative alle complicanze post procedurali sono confortanti, in linea, ancora una volta, con le maggiori pubblicazioni. In conclusione, alla luce del confronto fra la nostra casistica e la letteratura attuale, la resezione full-thickness basata sul sistema OVESCO, costituisce un'ottima alternativa alla resezione chirurgica di lesioni polipoidi "difficili", ovviamente se affidata a mani esperte. Dall'analisi della casistica, sottoposta a studio statistico con analisi univariata,

non è emerso alcun valore di *p* con rilevanza statistica: questo dato, che potrebbe presentare varie chiavi di lettura, riteniamo sia fondamentalmente dovuto al numero piuttosto ristretto di casi ed al bassissimo numero di recidive (indice comunque dell'efficacia anche a lungo termine del trattamento con sistema FTRD).

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