Digestive and Liver Disease xxx (2017) xxx–xxx

Contents lists available at ScienceDirect

Digestive and Liver Disease

journal homepage: www.elsevier.com/locate/dld

Digestive Endoscopy

Endoscopic full-thickness resection of superficial colorectal neoplasms using a new over-the-scope clip system: A single-centre study

Gianluca Andrisani[a,*], Margherita Pizzicannella[a], Margareth Martino[a], Roberta Rea[a], Monica Pandolfi[a], Chiara Taffon[b], Marco Caricato[c], Roberto Coppola[c], Anna Crescenzi[b], Guido Costamagna[d], Francesco Maria Di Matteo[a]

[a] Digestive Endoscopy Unit, University Campus Bio-Medico, Rome, Italy
[b] Department of Pathology, University Campus Bio-Medico, Rome, Italy
[c] Department of General Surgery, University Campus Bio-Medico, Rome, Italy
[d] Digestive Endoscopy Unit, Catholic University, Rome, Italy

ARTICLE INFO

Article history:
Received 9 January 2017
Received in revised form 18 April 2017
Accepted 24 April 2017
Available online xxx

Keywords:
Adenoma relapse
Colorectal cancer
Full thickness resection
No lift lesion
Scar of previous endoscopic resection

ABSTRACT

Background and aim: Endoscopic full-thickness resection (EFTR) provides complete en-bloc resection with a histopathological evaluation of submucosal, muscular, and serosal layers. The aim of this study was to investigate the efficacy and safety of a novel over-the-scope device for colorectal EFTR.
Material and methods: In this retrospective, observational, open-label case study, a total of 20 patients with superficial colorectal neoplasms, underwent EFTR using a new endoscopic full-thickness resection device (FTRD; Ovesco Endoscopy, Tübingen, Germany). Endoscopic treatment outcomes (technical success, rate of EFTR, adverse events) and early follow-up at three months, were analyzed.
Results: We reported a 100% of technical success, defined as full-thickness resection. Among the R1 resections, histology was negative for neoplasm. Non-lifting adenomas had histology positive for adenocarcinoma: seven T1/G1/sm1; one T1/G1/sm2; one, who underwent a surgical resection, T1/G1/sm3. Mean size of the resected lesions was 26 mm, ranging from 10 to 42 mm. One (5%) patient developed abdominal pain, fever and leukocytosis and was treated conservatively with medical therapy. In all specimens, histological complete resection was confirmed.
Conclusions: EFTR is a feasible and effective technique that could become a valid alternative to EMR and ESD in the management of recurrent adenomas, no-lifting lesions and scars of R1 resections. However, prospective studies are needed to further evaluate the device and technique.

1. Introduction

The majority of the superficial neoplasms of the colon can be treated by endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD) [1–5]. However, endoscopic resection of recurrent adenomas, no-lifting lesions (defined as the failure of a lesion to elevate above the surrounding mucosa after submucosal injection underneath the lesion), and T1-carcinomas currently represent a major challenge, at least for Western endoscopists. In the last few years, several studies have been carried out with the aim of creating specific devices for endoscopic full-thickness resection (EFTR) of colorectal lesions [6–9]. The advantage of EFTR is the possibility of obtaining a better histological evaluation with a concomitant closure of the colon wall defect, avoiding abdominal contamination.

A new over-the-scope device, the full thickness resection device (FTRD, Ovesco Endoscopy, Tübingen, Germany), was introduced in 2011 and has been evaluated in several experimental studies [10–13]. It was recently used for EFTR of colorectal lesions in small cohorts of subjects [14–17].

Aim of our retrospective study was to describe, in a population of consecutive patients with colorectal lesion with no-lifting sign or post endoscopic resection recurrences/residuals, the efficacy and

* Corresponding author at: Digestive Endoscopy Unit, Campus Bio–Medico, University of Rome, via Alvaro del Portillo 200, 00128 Roma, Italy.
E-mail address: gianluca.andrisani@gmail.com (G. Andrisani).

http://dx.doi.org/10.1016/j.dld.2017.04.015
1590-8658/

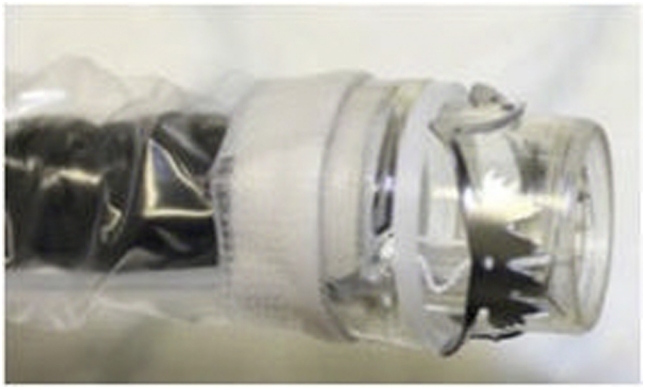

Fig. 1. The full-thickness resection device (FTRD; Ovesco Endoscopy, Tübingen, Germany): over-the-scope clip is mounted onto a long transparent cap.

safety of EFTR with FTRD by assessing the completeness of the full-thickness resection in the post-EFTR pathological specimen.

2. Patients and methods

An observational, retrospective, single centre study was conducted to analyse the endoscopic treatment outcomes and early follow-up in consecutive patients who underwent EFTR using the FTRD at a European tertiary referral centre from January to September 2016.

2.1. Inclusion criteria

Inclusion criteria were no-lifting lesions, adenoma recurrence/relapse of previous endoscopic resections with a negative lifting sign, and scars from incomplete endoscopic resection with a positive deep margin (R1 resection).

2.2. Exclusion criteria

Patients <18 years of age, pregnant, without a signed informed consent form, or with coagulopathy (international normalized ratio > 1.5 and/or platelet count <100,000/cu mm), as well as lesions with endoscopic features of deep invasion were excluded from the study.

Written informed consent was obtained from all patients, and the data were treated according to the privacy restriction laws. The study was not funded and was approved by the Ethics Committee of University Campus Bio-Medico (Prot: 49/16 OSS ComEt CBM). Demographics of the study sample, indications and main characteristics of the colonoscopy are shown in Table 1.

All cases were treated with the FTRD-System (Fig. 1). This tool consists of an over-the-scope (OTSC) system cap with a 14-mm distally-integrated monofilament polypectomy snare. The cap has an inner diameter of 13 mm and a length of 23 mm (measured from the tip of the endoscope). The snare handle runs along the outer surface of the colonoscope, under a plastic sheath that is fixed to the instrument. For the resection, after marking the lesion with either the FTRD marking probe or Argon plasma coagulation (APC), a forceps (FTRD grasper) is used via the operating channel to grasp and traction the lesion inside the cap. Immediately afterwards, the clip is released, and the overlying tissue is removed by the snare (Fig. 2).

2.3. Pre-EFTR staging

Before undergoing an EFTR, patients underwent staging EUS and/or MRI for rectal lesions, as well as abdominal CT scan was performed for lesions localized in other colonic segments.

2.4. Endoscopic outcomes of EFTR

The following outcomes were assessed for the efficacy and safety of the EFTR:

- Technical success, as en bloc transmural resection;
- Endoscopic features after EFTR, such as adenomatous residual or free transmural perforations;
- The resection rate R0, which was defined as the percentage of patients with histologically-negative lateral and deep margins;
- The rate of full-thickness resection, as confirmed histologically;
- The adverse events;

These outcomes were evaluated both at the time of the index examination and after 3 months (Early Follow Up).

2.5. EFTR technique

All procedures were performed with CO_2 insufflation and under deep sedation (midazolam bolus and continuous propofol infusion). No antibiotic treatment was provided. Each patient first underwent a colonoscopy (CF-Q-180 AL, Olympus Medical System, Tokyo, Japan) in order to identify the lesion and to mark its lateral margins with APC (Erbe APC 300, 25 W). For lesions that were not localized in the rectum, colonoscopy was performed by mounting a cap similar in size to the FTRD cap on the instrument tip (FTRD prOVE CAP, Ovesco Endoscopy, Tübingen, Germany) to evaluate their accessibility. The EFTR was then performed. After the resection, the sample was retrieved, and another colonoscopy without the FTRD system was performed in order to verify the correct positioning of the clip as well as potential complications that may have occurred. All the subjects were hospitalized for two nights and remained fasting after the procedure; their vital parameters and signs of bleeding or perforations were also monitored. Twenty-four hours after the procedure, they followed a semiliquid diet for three days.

2.5.1. Histological evaluation

The resected sample was fixed on a cork, assuring that the cutting edge was fixed directly in contact with the cork surface and was subsequently immersed in 4% buffered formalin. The pathologist systematically evaluated the dimensions of the lesion and the resection margins. The histological classification was carried out according to the Vienna staging system for the epithelial neoplasms of the gastrointestinal tract [18].

2.5.2. Follow-up

Patients were scheduled for a first follow-up colonoscopy 3 months after the procedure. We performed biopsies of the EFTR scar in each patient, even in the absence of visible adenomatous recurrence (at white light/chromoendoscopy). A post-EFTR surgical treatment was considered in all subjects with “high risk” T1 cancer. T1 colon cancers were defined as “high risk” following the NCCN guidelines: sessile polyps, fragmented specimens, grading 3–4, positive margins, angiolymphatic invasion and depth of submucosal invasion (sm2–3) [19].

Please cite this article in press as: Andrisani G, et al. Endoscopic full-thickness resection of superficial colorectal neoplasms using a new over-the-scope clip system: A single-centre study. Dig Liver Dis (2017), http://dx.doi.org/10.1016/j.dld.2017.04.015