New Flat Adenoma Resection Instruments for More Specimen Quality and Less Residual Adenoma and Less Perforation Risk

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Received: November 25, 2018; Published: January 31, 2019

Abstract

Background: Despite EMR and ESD, being considered as preferred methods for removal of big and complex lesions in the gastrointestinal tract, some disadvantages - especially for ESD - are obvious: long and flat learning curve, long lasting and complex procedure, relatively high rate of complications (bleeding and especially perforations), uneven plane of resection, confined to expert endoscopists. Thus, a new method, called “Endoscopic Submucosal Resection (ESR)” inclusive innovative instruments, called “Flat Adenoma Resection Instruments (FARIn)”, have been developed to overcome these drawbacks. ESR consists like ESD of different steps. First a primary circumferential incision, but then followed by application of and resection with an innovative snare-like resection effector of a FARIn allowing vertically deep even plan RF-surgical cutting close the muscularis propria without danger of perforation.

Materials and Methods: First systematic clinical study in 22 patients with 15 big lesions in the rectum, 6 in the colon and one in the stomach. The lesions were bigger than 2 cm or had a risk of perforation (e.g. submucosal lesion, because of location). In order to evaluate safety and efficacy of ESR with FARIn especially the intended pressing of the instrument against the organ wall during RF-application to remove the specimen close at the muscularis propria, in a step-up approach these first patients have been treated without circumferential incision.

Results: In all 22 patients the lesions were removed successfully without relevant complications and without perforation. The rate of en-bloc resection or resection of one large piece with few small pieces was 15 of 22. Optimal cutting quality, no delay of cutting even in very big lesions, a completely even cutting plane close to the muscularis propria and very low thermal artifacts allowed a representative, high quality histopathology. A pure resection time less than 30 seconds could be achieved in all cases. The new method of ESR using FARIn proved to be promising, especially the possibility of vertically deep resection without risk of perforation, the high quality of cutting and specimen showed clear advantages compared to conventional snare-resection or to ESD. These findings and a short learning curve due to high ergonomics of the new instruments justify further studies including circumferential incision of the lesion as a first step before application of the snare-like effector of a FARIn to evaluate, if ESR may become a superior alternative to EMR and ESD in therefore suitable cases.

Conclusion: These promising results are a solid basis for further clinical studies, then exhausting the full capacities of ESR with FARIn, i.e. combining safe and fast circumferential incision with easy, quick and safe effective removal of lesions up to 4,5 cm en bloc with the new resection instruments, and this with a very low risk of perforations and nearly without thermal artifacts on the resected specimen.

Keywords: Endoscopic Submucosal Resection (ESR); Flat Adenoma Resection Instruments (FARIn); Resection of Big Lesions in the Gastrointestinal Tract; Innovative Method; Quality of ESR Specimen; Prevention of Perforation

Abbreviations

DST: Distance; EMR: Endoscopic Mucosal Resection; EPE: Endoscopic Polypectomy; ESD: Endoscopic Submucosal Dissection; ESR: Endoscopic Submucosal Resection; FARIn: Flat Adenoma Resection Instruments; GIT: Gastrointestinal Tract; MTE: MICRO-TECH Europe; RF: Radio Frequency

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Introduction

Endoscopic resection of hyperplastic and especially of neoplastic lesions of the mucosa of the gastrointestinal tract, should be performed horizontally in sano in order to avoid residual recurrences and vertically as deep as possible (in the colorectum > 1000 µm) below the muscularis mucosae, as close as possible to the muscularis propria, without damaging or even perforating the organ wall, in order to facilitate pT1 staging. This is problematic in so far as the submucosa in which the RF-surgery cutting takes place is < 1000 µm thin below flat (Paris type II) lesions, e.g. in the colorectum (Figure 1) and swells to only approximately 5 mm as a result of submucosal injection.

In order to confirm the horizontal in sano resection histopathologically, lesions should be resected en bloc. This is only possible with EPE and EMR for lesions < 2 cm, with ESD also for lesions >> 2cm. However, ESD is known to be technically difficult [1].

In order to avoid perforations, in EPE, EMR and ESD the RF-cutting is distanced as far as possible from the muscularis propria (cutting direction B in figure 2). This can be possible in Paris type I lesions on sufficiently thick submucosa without or after submucosal injection. But in flat lesions, especially with cancer penetration through the muscularis mucosae, it can be a serious problem. In flat lesions on < 1 mm submucosa or < 5 mm after submucosal injection RF-cutting is practiced close the muscularis mucosae. Consequently, pT1 staging at EMR and especially at ESD resectates is problematic or not possible at all.

Since 2014, novel RF-surgical resection instruments have been available with which lesions of the mucosa up to approximately 4 cm can be resected en bloc and especially neoplastic or T1 suspect lesions can be removed near the muscularis propria (cutting direction A in figure 2) and theoretically without the risk of perforation [2-9].

Following successful *in vitro* tests on pig stomachs, we used these instruments, which have been approved for clinical use, since 2014 in currently 27 selected and informed patients.

**Materials and Methods**

The novel “Flat Adenoma Resection Instruments (FARIn)” (Figure 3 and 4) (MTE, Düsseldorf, Germany) each consists of a special symmetrical or asymmetrical RF-surgical resection effector (2) at the distal end and an ergonomically optimized manipulation handle (3, 4) at the proximal end of a flexible catheter (1) for manipulating the effector and precise controlling the resection speed.

The symmetrical resection effector (Figure 4) of the FARIn used by us is electrically insulated in its proximal section (2, 4) and equipped distally with a sliding runner (5) made of electrically non-conductive ceramic. The actual RF-surgical cutting wire (3) is standardized 1.5 cm short for all RF-effectors. This RF-effector only cuts horizontally in its closing direction and may therefore be pressed against the organ wall during the RF-surgical cutting and, if the lesion has previously been circumferential incised as close as possible to the muscularis propria, also against it.

In the first 22 applications of the FARIn with symmetrical effector, we refrained from circumferential incision the lesion to be on the safe side and after pressing the RF-effector against the organ wall during the RF-cutting did not cause any perforation, in 5 further applications the lesions were circumferential incised laterally in sano after primary injection with a novel incision instrument FARIn U (Figure 5).

This instrument has a 1 mm or 1.5 mm short cutting needle (3) on an electrically insulated sliding runner (2) that can and may be pressed against the mucosa during RF-incision and cutting, automatically aligning the cutting needle against the mucosa before and during incision and cutting. The maximum cutting depth per cut corresponds to the needle length. After the primary circumferential incision, a secondary injection under the lesion was performed, whereby the lesion protruded more or less equidistantly from the submucosa under the lesion depending on the normal layer thickness of the submucosa. Bleeding during circumferential incision could be stopped by coagulation with this instrument.

_Citation:_ Klaus Metter, _et al._ "New Flat Adenoma Resection Instruments for More Specimen Quality and Less Residual Adenoma and Less Perforation Risk_. *EC Gastroenterology and Digestive System* 6.2 (2019): 114-123.
We have also tested the FARIn U before clinical use on pig’s stomachs.

In the 5 later applications the symmetrical RF-effector was applied deep at the ground of the circumferential incision. The RF-cutting quality depends on an intended cut-synchronous vessel occlusion (as slow as possible) or on avoiding a wide cutting gap and deep coagulation (as fast as possible).

Post resection hemostasis was endoscopically controllable despite large areas of resection close to the muscularis propria.

Results and Discussion

The results of the first 22 + 5 clinical applications of the FARIn with the resection effector shown in figure 4 and also with FARInU in figure 5 are:

- Mucosal lesions up to 4 cm can be resected en bloc without cut-delay.
- Mucosal lesions up to 4 cm can be resected en bloc without perforation.
- Pressing the RF-effector against the organ wall during the RF-cutting did not cause any perforation.
- Mucosal lesions can be resected without mechanical or thermal artifacts (Figure 7).
- RF-surgical cutting quality is well controllable with the novel manipulation handle.
- The standardized and constant 1.5 cm length of the cutting wire is a prerequisite of reproducible cutting quality (Figure 7).
- Submucosa > 1000 µm without mechanical and/or thermal artifacts on the resected specimen can be available for histopathological pT1 staging (Figure 8a and 8b).
- Effective RF-cutting time per specimen up to 4 cm takes < 30 seconds.

The interest of our clinic - a teaching hospital with 657 beds and an endoscopy department with a high number of examinations - in the new ESR method is based above all on the fact that many patients with complex and large lesions in the gastrointestinal tract would have to be referred to other centres for ESD because we have not performed ESD so far. In our opinion, ESR is a good alternative to ESD, especially for lesions larger than 2 cm in the GIT that are anatomically well accessible, not only of the medical and technical advantages mentioned above, but also in terms of procedure duration and staff retention. Very large and anatomical extremely complex lesions are still surgical presented and referred.

Figure 7: Smooth resection surface without thermal artifacts on the resectate.

Figure 8a

ESR and ESD as endoscopic resection procedures are similar in many steps, but differ significantly in some points. The different steps are:

1. Submucosal injection for the purpose of
   a. Visualization of the lesion’s planar extent.
   b. Checking the so-called lifting sign.
2. Marking of the horizontal resection limit in sano.
3. Circumferential incision at least up to the submucosa, for ESR as close as possible to muscularis propria.
4. Secondary injection only for ESR, not for ESD.
5. Application of the effector in the ditch as near as possible to the muscularis propria, only for ESR, not for ESD.
6. RF-surgical resection by effector of a FARIn, only for ESR, not for ESD.
7. General haemostasis, only for ESR, not for ESD (for ESD vascular occlusion and haemostasis already during dissection).

Some steps in ESR will be carried out as mentioned in ESD but for other purposes:

- The injection in the context of ESD is intended to increase the RF-cutting distance to the muscularis propria, in the context of ESR the injection is used to allow the distance to the muscularis mucosae to increase. In ESD there is only one primary injection. The additional injections during ESD serve only to maintain the primary injection. In ESR, the secondary injection is intended to lift the entire lesion out of the surrounding mucosa level like a table mountain.
- The histopathological weak point of ESD is the cutting close to the muscularis mucosae instead of cutting close to the muscularis propria.
- Actually, ESR is a further development of the so-called “hybrid EMR”.
- “Hybrid EMR” refers to an EMR in which the lesion is injected, then completely circumferential incised in sano, and then a conventional polypectomy snare is applied into the cutting trench and the lesion is endoscopically resected with it [10-12].
Advantages of ESR compared to conventional EMR:

- En-bloc resections up to approximately 4 cm.
- Avoidance of residual adenomas.
- Those who can EMR can also hybrid EMR.

Problems of “hybrid EMR”:

- Cutting away from the organ wall as with EPE and EMR
- Perforation risk if conventional polypectomy snares are used
- Risk of dangerous cut delay if the lesion is > 2cm

Why did “hybrid EMR” fail? As with EPE and EMR, the resection is made away from the organ wall.

In context of ESR with FARIn the effector may be pressed against the organ wall and do not cause any perforation. A deep resection near the muscularis propria is possible.

Conclusion

The innovative method ESR with FARIn for more specimen quality, less residual adenoma and less perforation risk could lead to a paradigm shift in the resection of big and complex lesions in the GIT. Further studies with a larger number of cases and dedicated evaluation of histopathological specimens are necessary and planned.

Conflict of Interest

No financial interest or any conflict of interest exists.

Bibliography

