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## **Endoscopic full-thickness resection (eFTR) of colorectal lesions: results from the Dutch colorectal eFTR registry**

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# Endoscopic full-thickness resection in the colorectum: ready for prime time?

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Because of the lack of adequate closure techniques, endoscopic resection of gastrointestinal neoplasms has traditionally been limited to the mucosa and submucosa. Research on NOTES (natural orifice transluminal endoscopic surgery) and the introduction of the over-the-scope clip opened the door for transmural endoscopic interventions [1]. In 2014, two groups reported the first clinical cases of endoscopic full-thickness resection (eFTR) using a novel over-the-scope device [2, 3]. Since approval of the full-thickness resection device (FTRD; Ovesco Endoscopy, Tübingen, Germany) in 2014, multiple – mainly retrospective – studies on colorectal eFTR have been published.

In this issue of *Endoscopy*, Zwager and colleagues present the results of the Dutch colorectal eFTR registry [4]. Data were prospectively collected from 20 hospitals and a total of 367 procedures were included. As with other studies, the registry included various indications, with most of them classified as “difficult polyps.” Technical success was achieved in 83.9% of cases and the R0 resection rate was 82.4%. Adverse events were reported in 9.3% of cases, with 10 patients (2.7%) requiring emergency surgery. The median follow-up was 4 months, but was available in only 63.4% of cases. The total rate of residual or recurrent lesions was 6.4%.

At first glance, these results are very similar to those reported by many other studies on colorectal eFTR with the FTRD [5]. So why is this paper still important and what does it add to our current knowledge?

As we are still awaiting the final results of the German FTRD registry, the current paper is to date the largest published study on colorectal eFTR. In contrast to most other reports, data were collected prospectively from multiple centers. In the WALL RESECT study, we also prospectively reported on 181 patients [6]. Data were obtained from nine tertiary referral centers with extensive expertise in advanced endoscopic resection [6]. In contrast, the Dutch registry included 20 centers, 15 of them being non-academic hospitals. The procedures were performed by gastroenterologists who had attended a 1-day theoretical and hands-on training course on eFTR. The results regarding resection success and rate of adverse events were very similar to those reported in the WALL RESECT study. This indicates that the procedure can be performed with high quality, not only by experts but also by experienced endoscopists after limited (but still mandatory) training.

***“eFTR for T1 carcinoma in my view should primarily be considered as a diagnostic tool for risk stratification. However, the high proportion of patients with high risk features indicates that the selection criteria for “primary” eFTR need further evaluation.”***

The R0 resection rate in the total cohort was favorable and even better than in some other larger studies. This may be in part due to the relatively small lesions included (median 12 mm; range 8–17 mm). The upper limit of lesion size for eFTR with the FTRD has not yet been clearly determined. In the WALL RESECT study, we found that the R0 resection rate was significantly higher for lesions  $\leq 20$  mm than for those  $> 20$  mm (81.2% vs. 58.1%;  $P=0.004$ ) [2]. However, the present and other studies (Meier et al., manuscript submitted) have not consistently confirmed this difference. In our experience, apart from the degree of scarring, lesion size is still an important factor for complete resection. We therefore currently use a hybrid endoscopic mucosal resection (EMR) – eFTR approach for non-malignant lesions of borderline size (20–30 mm) or larger ( $> 30$  mm) [7]. Data for this approach are scarce but future studies may further address this technique.

Interestingly, the Dutch registry comprises quite a large subgroup of patients undergoing eFTR for T1 carcinoma ( $n=221$ ). This cohort has traditionally been under-represented in other publications, including the WALL RESECT trial. Apart from complete resection, thorough histological work-up of the resection specimen is mandatory for T1 tumors to determine the risk for lymph node metastasis. As discussed by the authors, full-thickness resection may therefore be preferable to mucosal resection for this indication. A recent retrospective study from our group demonstrated a high diagnostic value of eFTR for T1 carcinomas in facilitating the assignment of patients to the optimal treatment strategy [8].

The Dutch registry included 150 patients undergoing “secondary” eFTR after incomplete resection of malignant polyps. In line with the study by Kuellmer et al. [8], the vast majority of these patients were classified as “low risk” after eFTR and surgery was therefore not deemed necessary. According to both studies, it seems very clear that eFTR of post-polypectomy scars is a very good option in these cases.

The situation is more complex for untreated lesions suspicious for, or with proven, carcinoma. In the Dutch registry, oncologically “curative” resection was achieved in only 35.3% of cases. In the study by Kuellmer et al., as many as 83.7% of patients were at high risk for lymph node metastasis. In my view, eFTR for T1 carcinoma should primarily be considered as a diagnostic tool for risk stratification. However, the high proportion of patients with high risk features indicates that the selection criteria for “primary” eFTR need further evaluation. Moreover, future studies should evaluate the oncological long-term outcome for both primary and secondary eFTR.

As discussed by the authors, the present study has several limitations, which are mainly due to its design as a registry study. Nevertheless, owing to the reasons listed above, the data obtained from the study are important. Similarly to the German registry, it indicates that eFTR has gained broad acceptance and is already part of the clinical routine in many centers. So, is eFTR ready for prime time? Probably. To date, there are a

substantial number of studies showing the efficacy and safety of the FTRD device. The results for success and adverse event rates are consistent throughout almost all larger studies and the number of patients treated with eFTR since the introduction of the device is quite impressive.

We should not however be satisfied yet with the currently available data. Retrospective studies and registries, like the one currently reported, are important for initial evaluation of novel techniques. Although much more difficult to conduct, we must aim for prospective randomized controlled trials (RCTs) to compare, for instance, eFTR with other endoscopic methods. We also need to further investigate rare indications (such as appendiceal lesions and T1 carcinomas) and gather long-term follow-up data on recurrence rates and clinical outcomes. Such large-scale studies always require collaborative efforts. As demonstrated by the Dutch Registry, the broad dissemination of eFTR provides an excellent basis for prospective multicenter projects. If data from these future trials are also favorable, colorectal eFTR will continue its triumphal march through our endoscopy units.

## Competing interests

The author has received lecture fees and research grants from Ovesco Endoscopy.

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