

Lunch Symposium on the FTRD® System at the Conference of the DGE-BV 2019

During the 49th conference of the German Society for Endoscopy and Imaging Procedures (DGE-BV), which took place on March 28th – 30th, 2019 in Stuttgart, experts evaluated and discussed in a lunch symposium the current status of the clinical application of the FTRD System.

From the point of its introduction into clinical use until now, the FTRD System has become a well-established instrument for colonic full-thickness resection and can be used safely and effectively in hospitals of all levels of care

Prof. Dr. Karel Caca, Ludwigsburg: EFTR with the FTRD System is considered the standard procedure for resection of colonic lesions, which are not resectable or not safely resectable using conventional techniques

K. Caca, Ludwigsburg hospital, Germany, presented several recent studies on FTRD application. Especially in German-speaking countries the FTRD System is already in wide clinical use and has established as an efficacious and safe procedure. For resection of colorectal lesions, which are not resectable (i.e. non-lifting adenomas) or not safely resectable (i.e. lesions at diverticula) using conventional methods, EFTR with the FTRD System nowadays is considered the method of choice. For large, partly non-lifting lesions, hybrid-techniques in combination with EMR or ESD are used.

The FTRD is also increasingly used in the upper gastrointestinal tract. Here, it is currently preferably used for resection of relapse duodenal adenomas with non-lifting sign and for resection of submucosal tumors. Furthermore, full-thickness resection with the FTRD allows for definite diagnosis of gastric and duodenal lesions.

In conclusion, Caca stated that endoscopic full-thickness resection with the FTRD System has developed into a standard procedure in interventional endoscopy. Limitations of FTRD application are size and localization of the lesion, as well as availability of endoscopic equipment and expertise. Caca emphasized the importance of expertise and close cooperation with surgical colleagues.

**Is the FTRD nowadays a standard in endoscopic resection procedures? A positioning statement
(Ist das FTRD heute ein Standard bei endoskopischen Resektionsverfahren? Eine Positionsbestimmung)**

K. Caca¹

¹Ludwigsburg

PD Dr. Arthur Schmidt, Freiburg: prospective data of the German colonic FTRD registry confirm efficacy and safety of the colonic FTRD in broad clinical application

A. Schmidt, University Hospital Freiburg, Germany, presented the final evaluation of the German colonic FTRD registry. Between 09/2015 and 12/2018, prospective data from 64 endoscopic centers in Germany have been collected in the registry in order to assess safety and efficacy of the colonic FTRD in routine clinical use in hospitals of all levels of care. Data from overall 1176 patients (median age 69 years, range 11 – 93 years, 39.7 % female) have been evaluated. Primary endpoints were technical success (successful clip application and resection with the FTRD System) and R0 resection rate. Secondary endpoints were rate of full-thickness resection, procedural

time, complications, and follow-up findings. Indications for FTRD application were: non-lifting relapse adenomas (n=454), native non-lifting adenomas (n=223), adenoma at diverticula (n=10), adenoma at appendiceal orifice (n=87), follow-up resection of malignant polyp (n=171), early carcinoma (n=64), submucosal tumor (n=74), diagnostic FTRD without lesion (n=20) and others (n=73). Location of lesion and intervention was in 52.1 % rectal, in 14.2 % sigmoidal, in 5.3 % in the descendent colon, in 12.8 % in the transverse colon, in 18.3 % in the ascendant colon, in 19.2 % coecal, and in 5.2 % in other locations (right flexure, appendix, terminal ileum, recto-sigmoidal transition, left flexure, coecal pole). Average lesion size was 15 mm (range 2 – 56 mm, lesions with very large diameter were resected by hybrid-technique. Median procedure time was 35 min (range 2 – 203 min), technical success rate was 89.5 %, the rate of full-thickness resection was 87.3 % and of R0 resection 77.3 %. Minor or moderate complications (no need for surgery) occurred in 14.5 % of cases, major complications (need for surgery) in 1.8 %. Follow-up data after median 4.8 months was available for 595 patients. Rx/R1 situation was diagnosed in 43 patients (7.2 %), suspected local recurrence of initially diagnosed R0 resected lesion in 38 patients (6.4 %). Most of these patients underwent EFTR once more (33.3 %) or EMR/ESD (30.8 %).

(note: the listed data is preliminary, outstanding information on interventions is still delivered by users. Therefore, some values might still change. Final data can be extracted from the following publication)

For summary, Schmidt presented a pooled-proportion analysis of the registry data in comparison with recent meta-analysis data of EMR/ESD of large adenomas (>2 cm). With regard to technical success rate and R0 resection rate, the EFTR is in the range of the ESD, significantly higher than the success rates of the EMR. In regard to complication rates the following applies: the EFTR corresponds in peri-interventional bleeding rates to the conventional techniques, the perforation rate of EFTR is about as high as with EMR, which is significantly lower than with ESD. The need for surgery because of complications is with EFTR technique approximately as high as with the conventional resection techniques, however, this is frequently owed to a wrong sequence of the interventional steps.

Schmidt concluded, that the German colonic FTRD registry confirms that the colonic FTRD is safe and efficacious; results of the registry equal those of clinical studies, for example of the WALL RESECT study, a prospective multicenter study. Hence, the colonic FTRD has found broad-based appliance with comparable quality to large centers.

German colonic FTRD registry – final evaluation of 1176 cases (Deutsches colonic FTRD Register – Abschlussauswertung über 1176 Fälle)

A. Schmidt¹
¹Freiburg

Prof. Dr. Peter Bauerfeind, Zuerich: FTRD application in the upper gastrointestinal tract requires more experience, but is feasible, effective and safe

P. Bauerfeind, city hospital Triemli, Zuerich, Switzerland, presented on the basis of exemplary clinical cases the application of the FTRD in the upper gastrointestinal tract. In three cases, the FTRD was used in the duodenum, in one case in the distal esophagus and in another case in the stomach. Histological examination of the full-thickness resectate of patient 1 showed a well differentiated neuroendocrine tumor (NET G1) with infiltration of the muscular layer (ca. 4 mm DM), the resection margins were tumor-free. Patient 2 had a tubulovillous adenoma with focal high-grade dysplasia at the duodeno-jejunal transition, full-thickness resection was successful, no complications occurred, histological examination showed adenoma-free and dysplasia-free lateral and basal margins. In patient 3, a duodenal relapse adenoma with non-lifting sign was found, also in this case full-thickness resection with the FTRD was successful. Due to the lack of time, Bauerfeind then directly mentioned patient 5, this patient presented with a GIST at the gastral basis with Rx/R0 situation. Follow-up resection with FTRD was effective and without complications.

FTRD application in the upper intestinal tract is in some points technically more challenging than application in the lower GI-tract: for one thing, the pylorus represents a difficult-to-pass narrow and has to be dilated, on the other hand the mucosal layer of the stomach is very motile, which can cause difficulty especially in submucosal and small lesions in identifying whether the target tissue is sucked in correctly into the cap of the endoscope. Before application of the FTRD in the duodenum, the papilla should be reliably identified. The risk of post-intervention hemorrhage is increased in the upper gastrointestinal tract when compared to the lower GI-tract, it occurs in about 10 % of cases. This should be addressed in the informed consent discussion. Visible vessel endings should always be obliterated after FTRD application. Close monitoring of the patient after the intervention allows timely endoscopic re-intervention in case of hemorrhage.

Despite these technical specialties, also for the upper gastrointestinal tract the FTRD is a very promising instrument, first clinical applications show very good results. Indications for FTRD application are in a particular way submucosal tumors (NET, GIST...) up to 1.5 cm, adenomas and relapse adenomas with or without non-lifting sign and adenomas in patients at high surgical risk. Besides, the FTRD is very well suitable for follow-up resections of endoscopically pre-treated lesions with R1-finding.

**FTRD in the upper gastrointestinal tract: duodenum and stomach
(FTRD im oberen Verdauungstrakt: Duodenum und Magen)**

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