

## Conference Report DGVS/DGAV

**74<sup>th</sup> annual conference of the German Society of Gastroenterology, and Digestive and Metabolic Diseases with Endoscopy Section (DGVS)**

**13<sup>th</sup> autumn conference of the German Society of General Surgery and Visceral Surgery (DGAV) together with the working groups of the DGAV**

**October 02-05, 2019, Wiesbaden**

**Congress president DGVS: Prof. Dr. med. Stefan Zeuzem, University Hospital Frankfurt**  
**President DGAV 2019/2020: Prof. Dr. med. Thomas Schiedeck, Hospital Ludwigsburg**  
**Chairman endoscopy section: Prof. Dr. med. Ralf Jakobs, Hospital Ludwigshafen**

Ovesco products were presented in talks, posters, meetings, video forums, workshops and hands-on training sessions.

### **Endoscopic full-thickness resection with the FTRD<sup>®</sup> System is highly cost-effective when compared to surgical and endoscopic alternatives.**

**Additional costs per R0 resection in relation to EFTR are +27,000 € for the surgical alternative and +4,800 € for EMR/ESD**

A. Kuellmer, University Hospital Freiburg, presented a cost-effectiveness study of the endoscopic full-thickness resection (EFTR) of difficult-to-remove lesions with the FTRD System in comparison to available alternative therapies. The data for analysis was drawn from the patients of the WALL-RESECT study and a hypothetically designed control group. The control group was generated by a systematic survey of the treating physicians of all participating centers of the study (University Hospital Freiburg, Hospital Ludwigsburg, Evangelical Hospital Duesseldorf, Elisabeth-Hospital Essen, University Hospital Ulm, University Hospital Wuerzburg, Hospital Augsburg, Hospital Dortmund, Hospital Krefeld, and Hospital Boeblingen-Sindelfingen) and comprised various alternative therapies (ESD, EMR, surgical resection). Costs and revenues were determined from the DRG-Report 2019. The defined effectiveness parameter was the primary endpoint of the WALL-RESECT study, the R0 resection. For the control group, the R0 resection rates published in current literature were used. ICER (Incremental Cost-Effectiveness Ratio) and ACER (Average Cost-Effectiveness Ratio) served as cost effectiveness criteria. Data was presented from the payers' point of view and from the care providers' point of view.

In the control group, 106 patients underwent surgical resection (59 %), 45 patients underwent EMR (25 %) and 29 patients underwent ESD (16 %). Case costs for the different procedures were 2,758 € for EFTR, 8,895 € for surgical resection, 1,712 € for endoscopic alternatives (EMR/ESD), and 5,828 € for the whole group of all alternative therapies ("casemix-alternative"). From the care providers' point of view, the ACER for EFTR is 3,582 €, for surgical resection 8,924 €, for EMR/ESD 2,985 € and for the casemix-alternative 7,195 €. The ICER in relation to EFTR, meaning the additional costs per R0 resection, are +27,066 € for the surgical alternative, +4,788 € for the endoscopic alternative and +76,748 € for the casemix alternative.

The authors concluded that endoscopic full-thickness resection with the FTRD System is highly cost-effective when compared to surgical and also endoscopic alternative therapies.

**Endoscopic full-thickness resection in the colorectum with the FTRD System – a cost-effectiveness analysis.**

**(Die endoskopische Vollwandresektion im Kolorektum mit dem FTRD System – eine**

**Kosteneffektivitätsanalyse.)** Kuellmer A, Behn J, Beyna T, Schumacher B, Meining A, Messmann H, Neuhaus H, Albers D, Birk M, Probst A, Faehndrich M, Frieling T, Goetz M, Caca K, Thimme R, Schmidt A. Freiburg, Ludwigsburg, Duesseldorf, Essen, Ulm, Wuerzburg, Augsburg, Dortmund, Krefeld, Boeblingen-Sindelfingen.

**Costs for EFTR are significantly lower by 5,094 € when compared to surgical segment resection**

M. Rathmayer, Inspiring-health GmbH, Munich, presented first results of a study, which compares the costs for open-surgical and laparoscopic procedures with EFTR. In addition, an analysis of cost-covering by the G-DRG System was performed. Performance numbers were queried at the German Federal Statistical Office (DeStatis). Healthcare costs will be represented by the respective DRG revenues of 2019. For calculation of the actual costs, cost data of hospitals shall be used, which participate in the cost calculation of the Institute for Remuneration System in Hospitals (Institut fuer Entgeltsystem im Krankenhaus - InEK). The proof of cost coverage shall be provided by the comparison of the actual costs of the hospitals with the standard deviation of the respective DRG as published by InEK.

2016, EFTR was performed in 166 hospitals 763 times (OPS 2016: 5-452.25; from 2017: 5-452.65); in 2017, the FTRD System was used in 234 hospitals 1,096 times. In comparison, in 2016 and 2017, 5,922 and 8,184 open surgical and laparoscopic segment resections of the colon with anastomosis were performed (OPS 2019: 5-455.01 and 5-455.02). EFTR is represented in the G-DRG System by DRG G47B. The average costs are 3,058 € and are remuneration with 3,069 €. Open-Surgical and laparoscopic segment resection has an average cost of 8,138 € and a remuneration of 8,164 € (DRG G18C).

In summary, the number of deployments of the FTRD System increased by 44 % from 2016 to 2017 to 1,096 cases in 2017. The costs for the health care system are significantly lower by 5,094 € when compared to surgical segment resection. A cost-cost comparison of cases in hospitals, which participate in the InEK-calculation, will show, whether this advantage can also be proved on case level. In addition, the cost coverage in the G-DRG-System 2019 in these hospitals will be evaluated and compared with the cost data from 2018.

**Economic analysis of the endoscopic full-thickness resection (Ökonomische Analyse der endoskopischen Vollwandresektion).** Rathmayer M, Schmidt A, Schepp W, Heinlein W, Albert JG, Gundling F. Munich, Freiburg, Stuttgart.

**Pooled analysis from 5 hospitals shows 77.9 % R0 resection rate and 1.3 % rate of major complications for EFTR of various lesions in the whole GI-tract**

B. Lewerenz, Hospital Bogenhausen, Munich, presented a study comprising data of 232 patients from 5 different hospitals in Southern Germany (focal care and maximum care hospitals), in whom an EFTR was performed between 11/2014 and 08/2019. Technical success rate, resection status, and procedural complications were retrospectively analysed.

EFTR was performed in 232 patients on the basis of the following indications: 69.4 % adenomas with negative lifting sign, thereof 22.8 % relapse adenomas, 28.0 % residual adenomas after uncomplete resection and 18.5 % native adenomas. In 21.1 % of cases, a proven colonic or gastric adenocarcinoma existed or was suspected to a high degree, in 0.9 % of cases there was a DALM (Dysplasia associated lesion or mass) and in 8.2 % a submucosal tumor or NET (neuro-endocrine tumor). In one case, biopsy was performed on suspicion of M. Hirschsprung.

Localisation of EFTR was in 25.4 % in the ascending colon, in 25.0 % in the rectum, 14.7 % in the sigmoidal colon, in 11.6 % in the transverse colon, in 8.2 % in the descending colon, in 8.2 % in the cecum, in 3.9 % at the appendiceal orifice, in 1.7 % at a colonic surgical anastomosis, in 0.9 % in the stomach and in 0.4 % in the duodenum. The median size of the resected lesions was 16.22 mm (range 3 – 50 mm). EFTR could not be performed in 8 cases (3.4 %) due to impossibility of endoscope advancement with FTRD cap and in 29 cases (12.5 %) resection was technically not successful (n=1 marking of the lesion not possible, n=7 tissue cannot be fixed, n=8 suction in FTRD cap not sufficient because of severe scarring, n=1 clip malfunction, n=3 tissue avulsion by grasper, n=9 macroscopically diagnosed residual adenoma after EFTR). Thus, the technical success-rate was 84.8 %, the R0 resection rate was 77.9 %. Post-interventionally, in 3 cases (1.3 %) major complications occurred (1 perforation, 2 acute appendicitis).

The authors concluded that EFTR as minimally invasive method is highly successful in the resection of various lesions in the whole gastrointestinal tract with an overall very low procedural complication rate.

**Technical success, resection status, and procedural complication rate of the endoscopic full thickness resection with the “full-Thickness Resection Device” (FTRD) – results of a pooled analysis from various hospitals.**

**(Technischer Erfolg, Resektionsstatus sowie prozedurale Komplikationsrate der endoskopischen Vollwandresektion mittels „Full-Thickness Resection Device“ (FTRD) – Ergebnisse einer gepoolten Analyse aus verschiedenen Kliniken).** Krutzenbichler I, Dollhopf M, Lewerenz B, Lilje T, Fuchs M, Herrmann S, Vitali F, Rath T, Kaiser C, Eigler A, Diepolder H, Schepp W, Gundling F. Munich, Kaufbeuren, Erlangen.

**The FTRD System is a safe and effective instrument for resection of adenomas with high-grade dysplasia and of small early-stage adenocarcinomas**

P. Stathopoulos, University Hospital Marburg, presented monocentric data supplying information on the deployment of the FTRD in the colon and rectum. Between 11/2016 and 08/2019, 50 patients (32 % female, median age 66 ± 13 years) were treated with the FTRD System. 23 lesion (60.5 %) were located in the colon and 15 lesions (29.5 %) in the rectum. Median size of the lesions was 18.9 mm (range 3-50 mm). Indication for EFTR was in 21 cases a relapse/residual adenoma, in 10 cases an adenoma with negative lifting-sign, in 12 cases an incompletely resected early-stage carcinoma or adenoma with high-grade dysplasia, in 6 cases a rectal NET, in 1 case a submucosal tumor, and in 1 case the suspicion of M. Hirschsprung. All lesions could be reached with FTRD cap. In 2 lesions, a hybrid technique was performed (EMR +EFTR) due to the big size of the lesions (lesion size 40 and 50 mm, respectively). The median procedural time was 50 min (10 – 110 min). Resection was technically successful in 94 % (47/50, in 2 cases insufficient suction into FTRD cap due to severe scarring, in one case cutting of the loop at the side of clip). The R0 resection rate was 76 % (38/50). In 11 patients, histological examination proved the existence of an adenocarcinoma (R0 in 6/11 cases, 55 %). 2 of the adenocarcinomas were diagnosed as sm2 stage, 8 of the adenocarcinomas as sm3 stage and one as T2 stage, 4 patients underwent oncological surgical revision. In 7 cases, complications occurred: 4 bleedings which could be managed conservatively, 2 perforations (1 treated surgically, 1 closed endoscopically with OTSC) and 1 Subileus (treated with balloon dilation and decompression tube). In 34 patients, follow-up data was available, in 2 cases a residual/relapse adenoma was found, both could be curatively resected by de novo EFTR.

The authors concluded that EFTR represents a safe and effective method, which usefully complements the present endoscopic set of instruments. According to the authors, EFTR plays a particular role in the resection of adenomas with high-grade dysplasia and of small early-stage adenocarcinomas.

**Endoscopic full-thickness resection (eFTR) of colorectal lesions – a retrospective analysis of 50 consecutive cases.**

**(Endoskopische Vollwandresektion („endoscopic full-thickness resection“, eFTR) für kolorektale Läsionen – eine retrospektive Analyse von 50 konsekutiven Fällen.)** *Stathopoulos P, Gallmeier E, Gress TM, Denkert C, Denzer U. Marburg.*

### **Medium risk of appendicitis after EFTR of adenomas near the appendiceal orifice**

S. Schmidbaur, University Hospital Ulm, reported on a study examining how high the risk for post-interventional appendicitis is after full-thickness resection at the appendiceal orifice. Data of patients of 3 centers (Hospital Ludwigsburg, Hospitals of the Neumarkt district, and University Hospital Ulm), in which an EFTR of adenomas near the appendiceal orifice had been performed between 2014 and 2018, was retrospectively evaluated. Patients which had undergone appendectomy prior to EFTR were excluded from the study. 50 patients (16 male, median age 65.8 years, range 46-83 years) fulfilled the inclusion criteria.

All patients received peri-interventional antibiotics for median 3.7 days. Intra-interventionally, no major complications occurred. During in-hospital and further follow-up (4 months), 7 patients developed signs of appendicitis (14 %). In 4 patients, the signs arose within 10 days after the intervention, in the remaining 3 patients about 1 month after intervention. In 4 cases, conservative therapy was possible, in 3 patients, surgical appendectomy was necessary. In summary, 57 % of patients with appendicitis could be treated conservatively. Development of mucocele was not observed in any patient.

The authors concluded that a medium risk of appendicitis must be presumed for EFTR of adenomas near the appendiceal orifice. Thus, it is necessary to sufficiently inform the patients about the risk and the eventual necessity for surgical appendectomy. Possibly, the risk can be minimized by longer-time post-interventional antibiotics. Further studies on this would be desirable.

**Moderately increased risk of appendicitis after eFTR of adenomas near the appendiceal orifice – a retrospective analysis. (Moderat erhöhtes Appendizitisrisiko nach eFTR von Adenomen nahe des Appendixabgangs – eine retrospektive Analyse.)** *Walter B, Schmidbaur S, Wannhoff A, Meier B, Meining A, Caca K. Ulm, Ludwigsburg, Wuerzburg.*

### **Application-oriented lectures at the conference underline the establishment of the instrument in everyday clinical practice**

Various other lectures, held e.g. by B. Schuhmacher, Elisabeth Hospital Essen, K. Caca, Hospital Ludwigsburg, and S. Hollerbach, AKH Celle, explained application-oriented and practically the deployment of the FTRD in everyday clinical practice. By means of clinical examples, photos, videos and illustrations, the correct deployment and avoidable mistakes were illustrated and appropriate indications were explained as well as therapy alternatives. Besides, data from actual studies evaluating the deployment of the FTRD in the upper GI tract was presented.

**Full-thickness resection in the colorectum. Why do we need endoscopic FTRD? (Vollwandresektion im Kolorektum. Warum brauchen wir die endoskopische FTRD?)** *Hollerbach S, Celle.*

**Endoscopic Full Thickness Resection (EFTR).** *Caca K, Ludwigsburg.*

**Endoscopic Full-Thickness Resection in the duodenum (Endoskopische Vollwandresektion im Duodenum).** *Caca K, Ludwigsburg.*

**Submucosal tumors in the upper gastrointestinal tract. Tunnel techniques and full-thickness resection – the solution for many clinical conditions? (Subepitheliale Tumoren im oberen Gastrointestinaltrakt. Tunneltechniken und Vollwandresektion – die Lösung für vieles?)** *Schumacher B, Essen.*

**Tumor resection by tunneling and by full-thickness resection in the upper GI-tract (Tumorresektion durch Tunnel und per Vollwandresektion im oberen GI Trakt).** *Caca K, Ludwigsburg.*

## **Deployment of an additional working channel leads to the development of new techniques from EMR and ESD, which show significant advantages regarding resectable lesion size, procedural time and complication rate**

### **ESD+ is in ex-vivo model related to significantly shorter procedural time (24.5 vs. 32.5 min) and causes significantly less muscular damage (1/32 vs. 6/32, p=0.04) than conventional ESD**

S. Kunsch, University Medicine Goettingen, presented a study at the ex-vivo model, which compares the new resection technique ESD + with the conventional ESD technique. The study was performed in the ex-vivo model of a porcine stomach in the EASIE-R-Simulator. Lesions of 3 cm and 4 cm were manually placed and afterwards resected by ESD or ESD+, respectively. Overall 64 interventions (32 ESD and 32 ESD+; each (n=16) 3 cm and (n=16) 4 cm lesions, thereof again half (n=8) antegrade and the other half retrograde) were performed. En-bloc resection was reached in all resections. Procedural time was significantly shorter with ESD+ than with conventional ESD (median 24.5 min vs. 32.5 min). Particularly in 3 cm and 4 cm lesions resected in retroflexion, this advantage could be seen. Perforations did not occur, however, in the ESD+ group, there was significantly less muscular damage than in the ESD group (1/32 vs. 6/32; 3.2 % vs. 18.7 %; p=0.04).

In conclusion, the authors rated ESD+ a promising new resection method, which shows significant advantages concerning procedural time and complication risk when compared to conventional ESD.

**Endoscopic submucosal dissection with an additional working channel (ESD plus) as new method improving the traditional ESD in the es vivo model. (Endoskopische Submukosadisektion mit einem zusätzlichen Arbeitskanal (ESD plus) als neue Methode zur Verbesserung der traditionellen ESD im Ex-vivo-Model.)** *Knoop RF, Wedi E, Ellenrieder V, Neesse A, Kunsch S, Goettingen.*

### **Lesions of 3 cm or 4 cm size can be resected en-bloc by EMR+ (86.36 % and 60 % en-bloc resection rate, respectively), this is insufficient up to not possible by conventional EMR (18.8 % and 0 % en-bloc resection rate, respectively)**

R.F. Knoop, University Medicine Goettingen, presented a study evaluating the EMR+ technique in the ex-vivo model. EMR+ in contrast to EMR is performed using an additional working channel (AWC), which enables the additional use of a grasping instrument. The study was performed prospectively in the ex-vivo model of a porcine stomach in the EASIE-R-Simulator. Lesions (overall n=152) of 1 cm, 2 cm, 3 cm, and 4 cm in size were manually placed by coagulation. In 1 cm-lesions, EMR and EMR+ achieved the same en-bloc resection rate of 100 %. In 2 cm-lesions, the en-bloc resection rate dropped to 54.55 % with EMR, while EMR+ still achieved 95.44 %. Conventional EMR did not achieve sufficient results in 3 cm and 4 cm lesions (18.8 %; 0 %). However, EMR+ still achieved an en-bloc resection rate of 86.36 % in 3 cm lesions and dropped to 60 % in 4 cm lesions.

In conclusion, the authors rated the EMR+ technique a promising new resection technique with the potential to improve the safe en-bloc resection rate of lesions  $\geq 2$  cm with reasonable technical and financial effort.

**EMR+: Presentation of a new endoscopic resection method in the ex-vivo model. (EMR+: Vorstellung einer neuen endoskopischen Resektionsmethode im Ex-vivo Model.)** *Knoop RF, Wedi E, Ellenrieder V, Neesse A, Kunsch S, Goettingen.*

## **The clinical application of the OTSC® System is trained in workshops and hands-on training sessions**

### **Hands-on training of hemostasis techniques in small groups attracted lively interest**

On Wednesday, hands-on trainings sessions of endoscopic-interventional techniques took place. Training on two different topics was offered: first hemostasis and clips, and second stent placement. In the beginning, a short lecture gave an overview over the respective topic, then hands-on training of the respective procedures was performed in small groups. Within this part, also possible complications of the hemostasis procedures were presented and acceptable therapeutic solutions worked out. The mainly practical instruction in small groups on the basis of examples from everyday endoscopic practice found widespread appeal among the very interested endoscopists.

### **DEGEA offers instruction on leakage closure and variceal bleeding at the training model**

The German Society for Endoscopy Professionals (Deutsche Gesellschaft für Endoskopiefachberufe – DEGEA) offered several workshops on Saturday, including one workshop with the topic: “What is when... difficult situations and prevention of complications”. In the theoretical part, S. Loeffler, ovesco Endoscopy AG, Tuebingen, spoke about perforation closure, foreign body removal and stent fixation. In the practical part, various techniques were trained under instruction by different tutors at the training model; besides others, the OTSC System and endoclips were employed for leakage closure and variceal bleeding. The program was well attended by experienced colleagues and beginners.

### **Endoscopic closure techniques are highly effective for the management of acute perforations**

A. Schmidt, University Hospital Freiburg, reported on perforation management in endoscopy. First, he defined the term perforation and differentiated it from leakage/insufficiency and fistula development on the basis of clinical characteristics. Then he explained that a paradigm change has taken place within the last years in the management of free abdominal air due to the introduction of highly effective endoscopic closure techniques. The presence of extraluminal air does not automatically imply the need for surgical therapy any more. Based on the recommendations of the ESGE Position Statement 2014, he explained general measures in case of acute perforation and criteria for decision making between endoscopic and surgical treatment. He emphasized, how important it is for therapeutical success, to keep the time between discovery of the perforation and start of therapy as short as possible. After that, he presented common endoscopic closure techniques. These included through-the-scope clips, OTSC clips, stents (SEPS, SEMS) and sponge/drainage for endoscopic vacuum therapy. Endoscopic suturing techniques were not part of the lecture. Depending on defect size, localization and local expertise, the different endoscopic closure techniques are employed for perforation management. Herein, interdisciplinary peri-interventional patient care is of great importance. In cases of late diagnosis or not certain/ not possible closure, or clinical worsening, surgical therapy is still the treatment of choice.

**Perforations in endoscopy – do I still need my surgeon? (Perforationen bei der Endoskopie – brauche ich meinen Chirurgen noch?)** *Schmidt A, Freiburg.*

*For questions and further information:*

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