



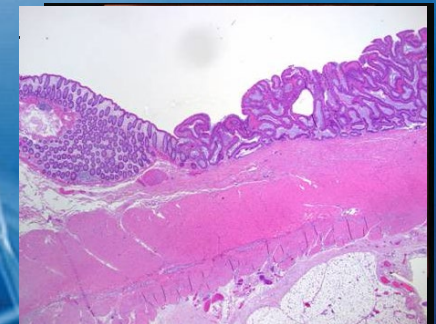
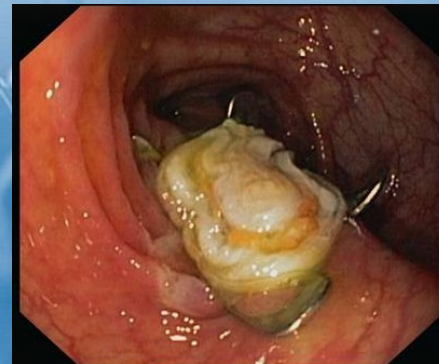
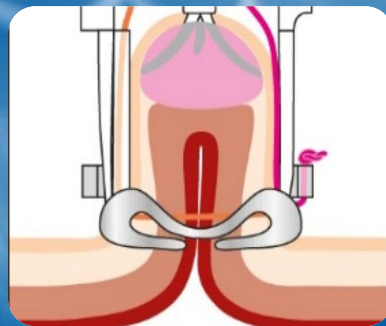
A Decade of FTRD

State-of-the Art



Karel Caca

Medizinische Klinik I, Klinikum Ludwigsburg, Germany



OTSC



just another clip?



- **endoscopic hemostasis (OTSC)**
- **perforation closure (OTSC)**
- **fistula closure (OTSC)**
- **stent clip fixation (Stentfix)**
- **bariatric reduction system (BARS)**
- **full thickness resection (FTRD)**

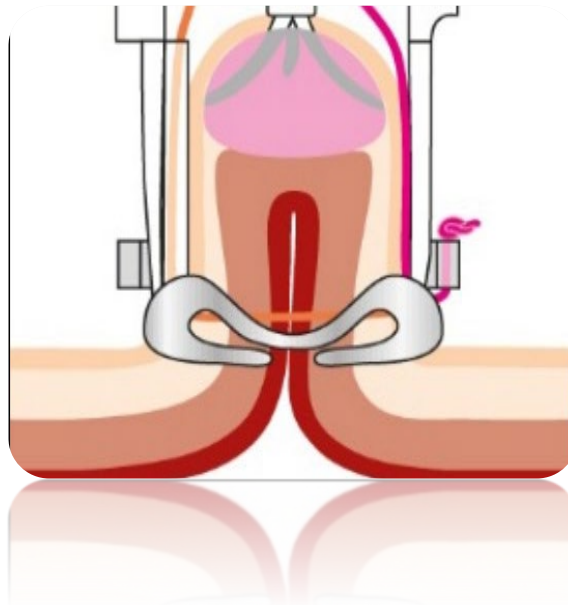


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Neo-EFTR

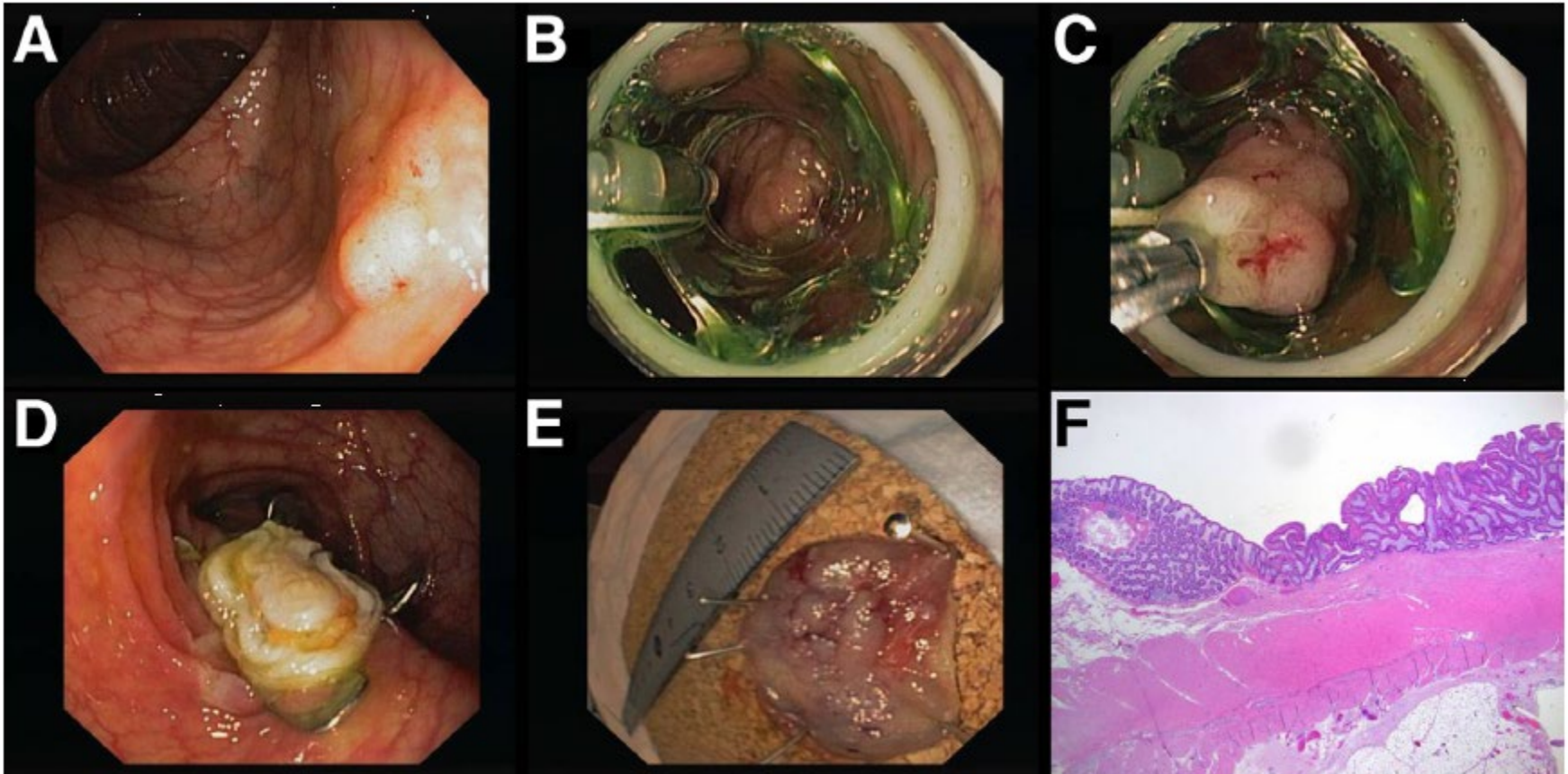
Non-Exposure Endoscopic Full Thickness Resection

- Concept:
- defect closure **before** resection
 - wall-duplication
 - „clip first – cut later“



FTRD – EFTR - Resection Technique

recurrent adenoma in the sigmoid after 2 x EMR



EFTR with FTRD in the lower GI

EFTR using FTRD™ – lower GI

- 1 prospective multi-center study (Wallresect; Schmidt A, Gut 2018)
- 2 national registries (Meier B, AJG 2020; Zwager LW 2020)

	No.	Technical success	R0	SAE (surgery)	Mortality
Wallresect 2018 02/15 – 04/16	181	90%	77%	10 (2,2%)	0
German registry 2020 09/15 – 10/19	1178	88%	80%	23 (2,0%)	0
Dutch registry 2020 07/15 – 10/18	367	84%	82%	10 (2,7%)	0

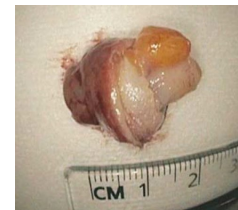
Endoscopic Full Thickness Resection (EFTR) in the Lower GI-Tract using the Full Thickness Resection Device (WALL RESECT STUDY, NCT02362126)

Inclusion criteria

- Adenoma with negative lifting sign (recurrent or untreated) **57%**
- Adenoma at difficult anatomic location (appendiceal orifice) **19%**
- T1-carcinoma with indication for endoscopic (re-) resection **8%**
- Subepithelial tumors (rectal NET's) **13%**

Study results

- location right-sided colon **50%**
- lesions reached **100%**
- Technical success rate **90%**
- R0 resection rate **77% (58% if size > 2cm)**
- SAE's **2,2%**
- Appendicitis (in appendical FTRD) **14% (7% surgery needed)** →



Dutch FTRD Registry T1 Cancer

	Overall	T1 CRCs	Difficult polyps	Subepithelial tumors
Initiated eFTR procedures, n	367	221	133	13
Technical success, n (%)	308 (83.9)	191 (86.4)	105 (78.9)	12 (92.3)
Procedures amenable to eFTR, n ¹	346	211	122	13
Resection, n (%)				
▪ R0	285 (82.4)	186 (88.2)	86 (70.5)	13 (100)
▪ Full-thickness	288 (83.2)	176 (83.4)	100 (82.0)	12 (92.3)

	n/N	%	95%CI
Overall curative resection rate PP¹	193/320	60.3	54.7–65.7
▪ Overall curative resection rate ITT	193/330	58.5	52.9–63.8
▪ Only lesions with T1 CRC at histology	23/112	20.5	13.7–29.4
▪ When excluding sm2–3 as risk factor ²	67/112	59.8	50.1–68.8
Curative resection for primary treatment PP	41/128	32.0	24.2–40.9
▪ Curative resection for primary treatment ITT	41/132	31.1	23.5–39.8
▪ Primary treatment (only T1 CRC at histology)	23/97	23.7	15.9–33.6
▪ Primary treatment (excluding sm2–3 as risk factor)	59/97	60.8	50.4–70.4
Curative resection for secondary treatment PP	152/192	79.2	72.5–84.5
▪ Curative resection for secondary treatment ITT	152/198	76.8	70.1–82.3
▪ Secondary treatment (only T1 CRC at histology)	0/15	0	0–5.3
▪ Secondary treatment (excluding sm2–3 as risk factor)	8/15	53.3	27.4–77.7

CI, confidence interval; PP, per protocol; ITT, intention-to-treat; CRC, colorectal cancer; sm2–3: deep submucosal invasion.

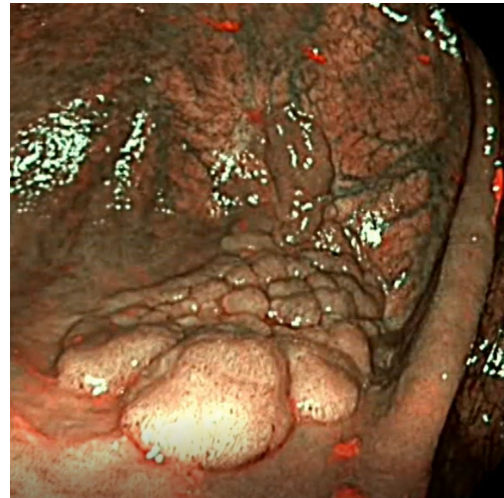
¹ A curative resection is defined as a histological R0 resection and, in case of residual cancer, without high-risk features for lymph node metastasis (LNM).

² Deep submucosal invasion (sm2-3) excluded as a risk factor for LNM.

Too big to FTRD-embloc + (partially) non-EMRable?

Too big to FTRD-embloc

> (2)-3 cm



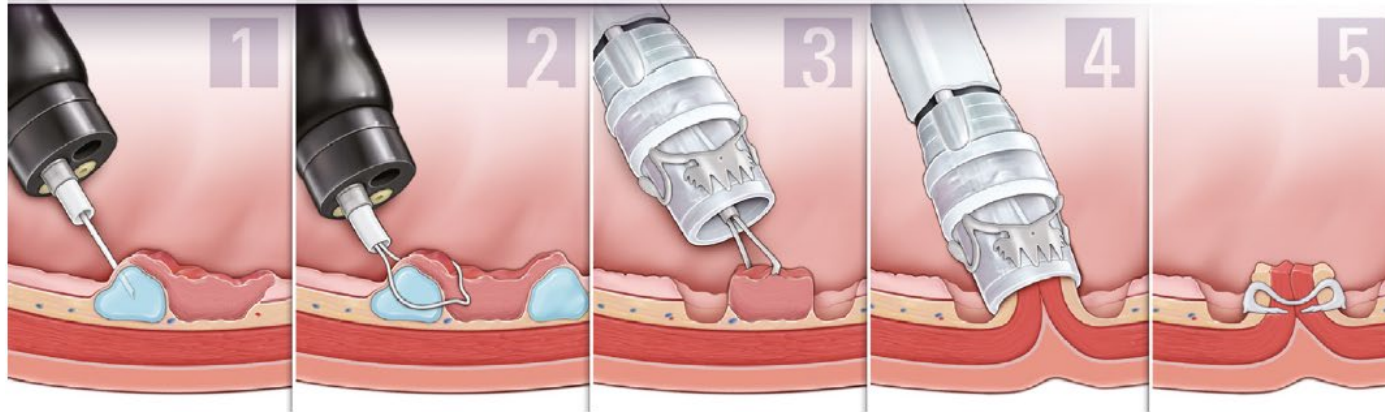
Non-EMRable complete

- negative lifting sign
- difficult location (e.g. appendix)



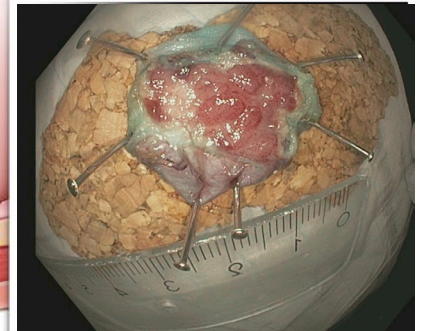
Hybrid EMR-EFTR (using FTRD)

Hybrid-Endoscopic Full-Thickness Resection



• Number of patients: 75

• Mean lesion size: 36.5 mm
(range 25-60 mm)



- **Procedure time: 84 min.**
- **Technical success rate: 100% (97% macroscopic complete resection)**
- **AE's: 6,7% SAE: 1,3% (appendectomy)**
- **T1 carcinoma: 16% (5% low-risk, 11% high-risk)**
- **FU (1 year): recurrent/residual adenom: 11%**
 - redo FTRD: 10%
 - redo EMR: 1%

FTRD – rectal NET's

Mean Procedure Time, min (range)	Macroscopic Complete Resection, n (%)	R0-Resection, n (%)	Full-Thickness-Resection, n (%)	Histology, n (%)
23.25 (7-60)	40/40 (100)	40/40 (100)	38/40 (95)	<u>NET, G1, pT1a, L0, V0</u> 28/40 (70) <u>Scar/Granulation Tissue</u> 12/40 (30)

Adverse Events, n (%)

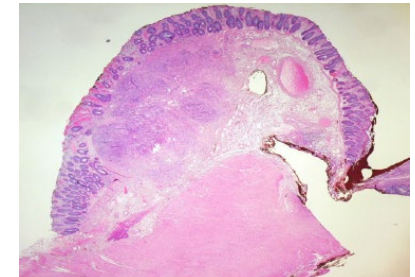
5/40 (12.5)

Periinterventional bleeding*, 4/40 (10)

Technical problem, 1/40 (2.5)

- rupture of the FTRD snare
- resection with conventional snare

* Minor bleeding, management endoscopically by injection and/or coagulation, no bleeding signs in endoscopic control one day later, no re-bleeding, no transfusion



Meier B et al., Endoscopy 2020

Conclusions

- Nearly 100% benign colorectal lesions can be resected endoscopically
= 3 x Hurra
- Aim for complete resection (≠ enbloc resection)
- FTRD-EFTR closed a major therapeutic gap
- Hybrid-EMR-FTRD is closing a small but important therapeutic gap
= logic next step when „in trouble“
- Sometimes EFTR is only a large biopsy = diagnostic ≠ therapeutic

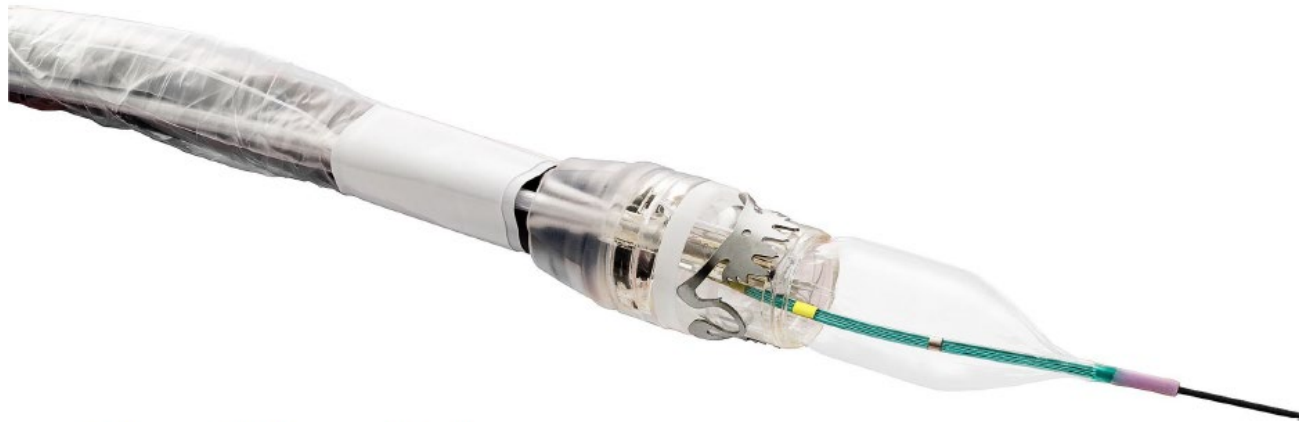
When in doubt

Take it out

Take it out endoscopically!

EFTR with FTRD in the upper GI

Gastroduodenal FTRD[®] (Ovesco, Tübingen)



Zulassung für Magen und Duodenum

Außendurchmesser 19.5 mm
Kappe 23 mm lang

Ballon 20 mm als Einführhilfe

Stomach

Subepithelial lesions

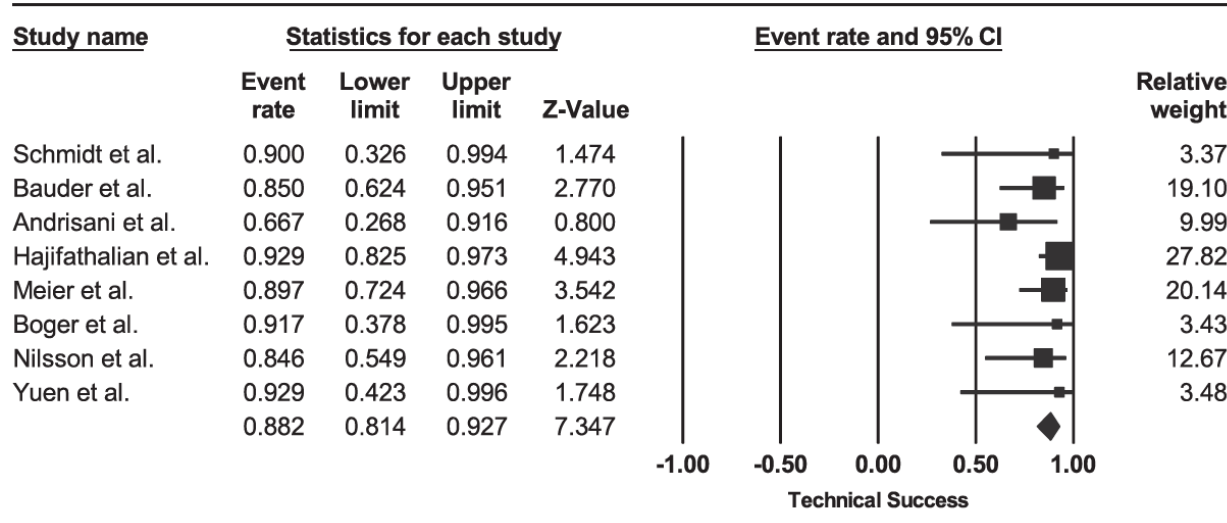
Duodenum

- **Subepithelial lesions**
- **non-lifting adenomas**
- **First-line?**

Meta-Analysis FTRD upper GI

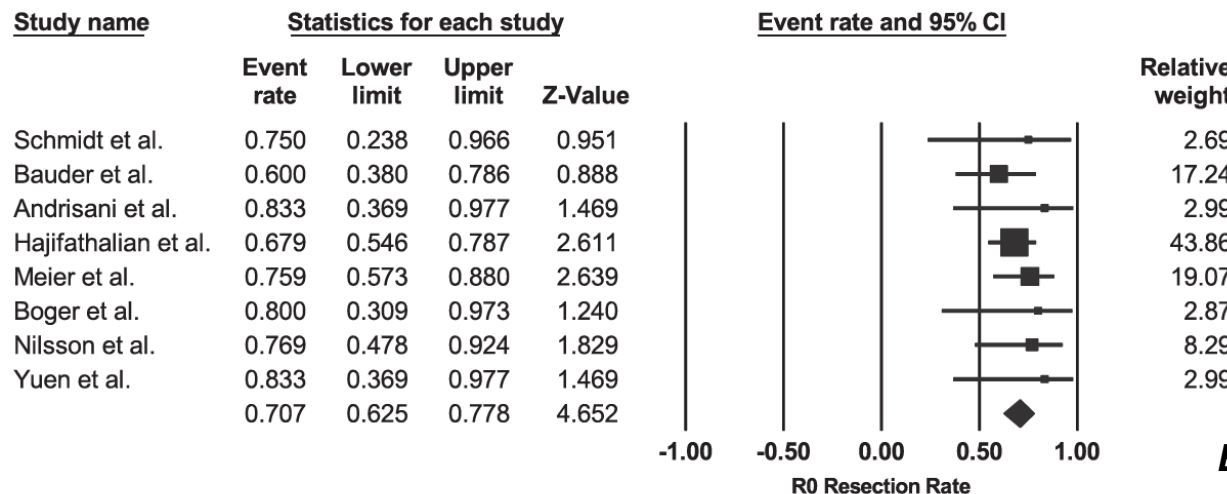
Technical success

88,2 %



R0

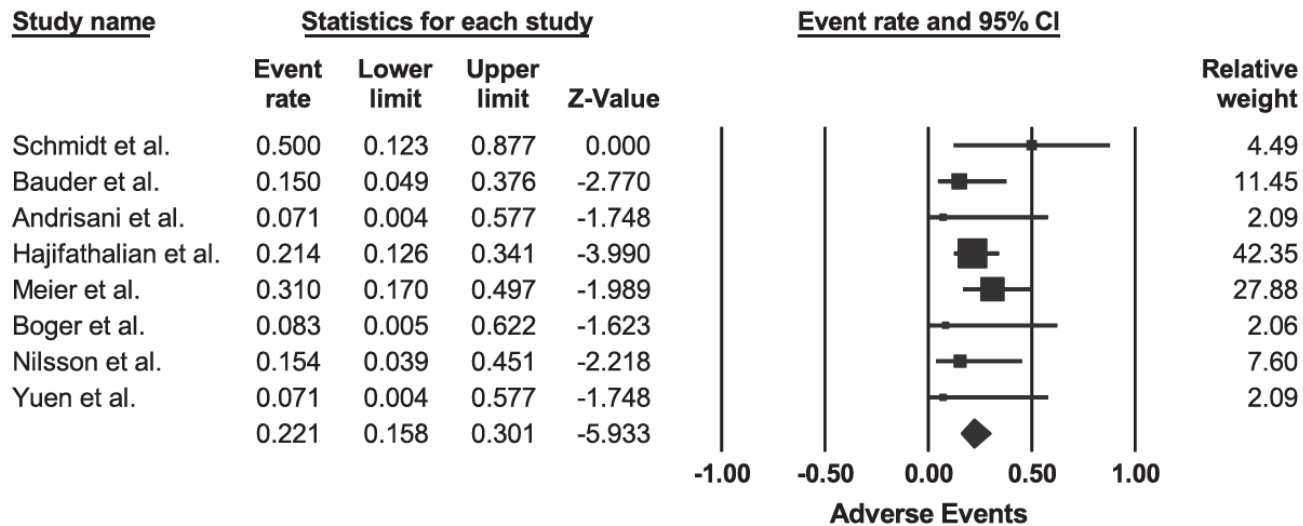
70,7 %



Meta-Analysis FTRD upper GI

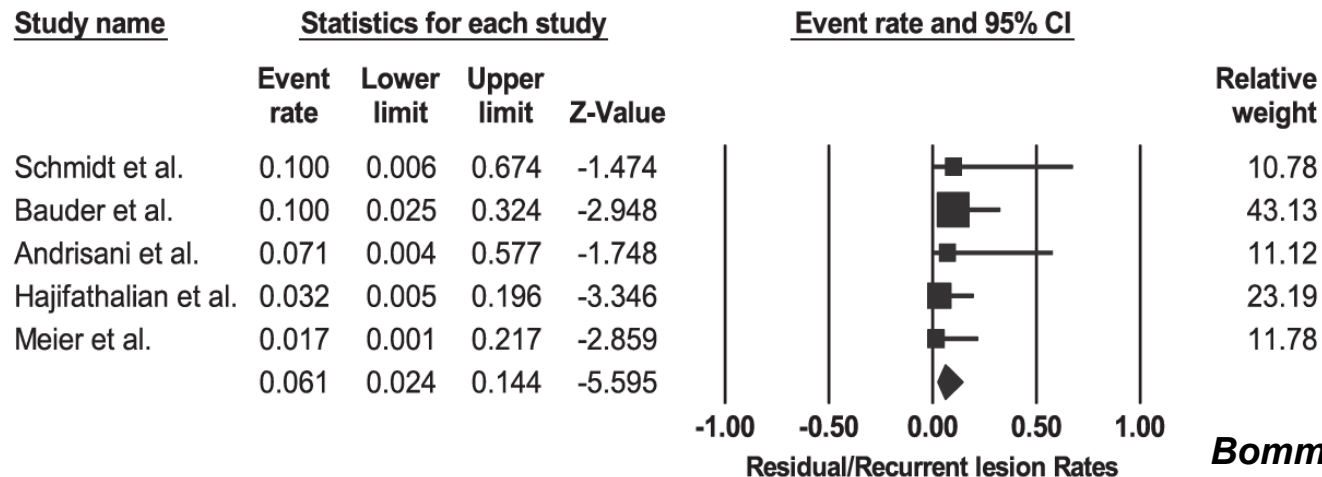
Adverse events

22,1 % (18,6% minor, no SAE)

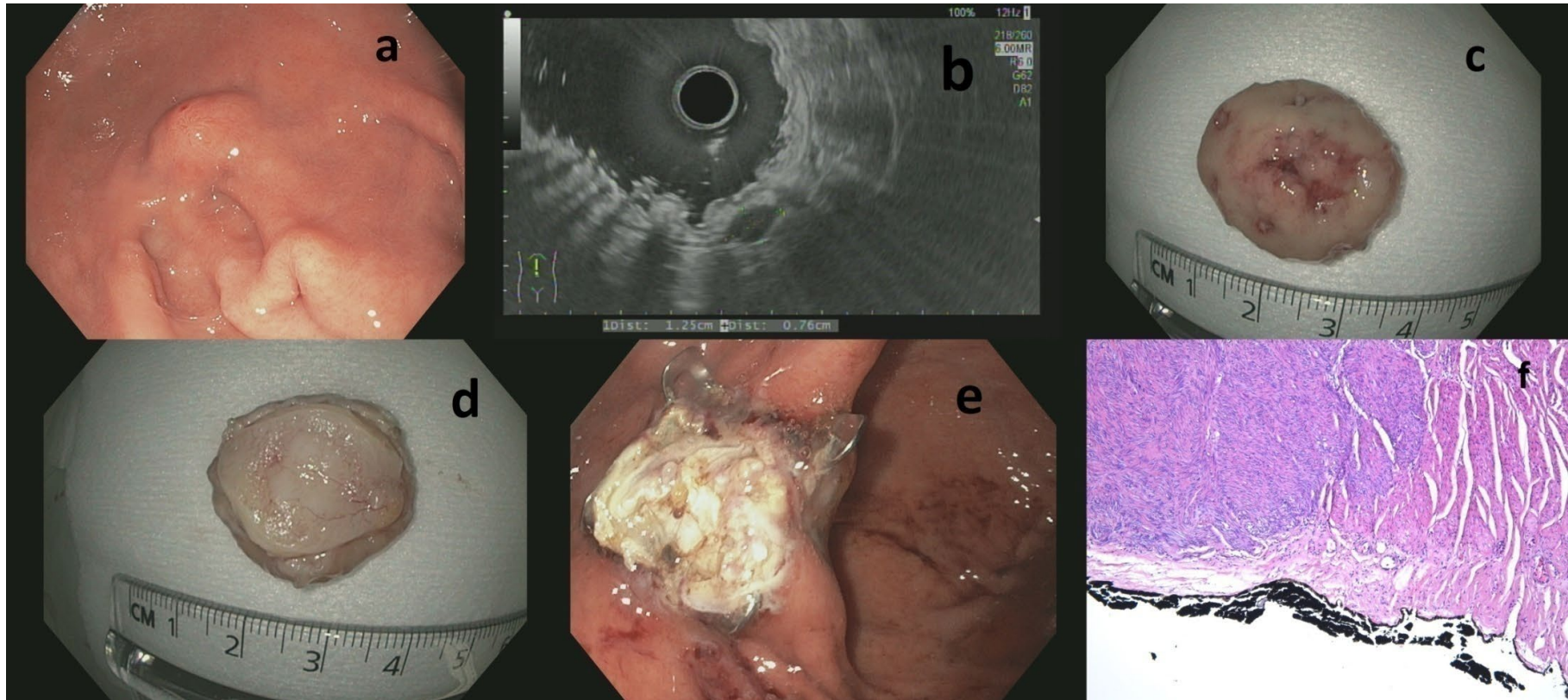


Residual/Recurrent lesions

6,1 %



Gastric EFTR (gdFTRD™) – gastric GIST



Gastric FTRD – Results

Technical Results	
Target lesion reached with gFTRD, n (%)	29 (100)
Balloon used, n (%)	7 (24)
Procedure time (min), median/SD (range)	36.3/14.4 (24-90)
Technical success, n (%)	26 (89.7)
R0 resection, n (%)	22 (76)
Full-thickness-resection, n (%)	19 (65.5)
Procedure-related adverse events, n (%)	9 (31)
minor adverse events (all minor periprocedural bleedings)	9 (31)
major adverse events	0 (0)

Gastric FTRD – Results

Histology after EFTR, n / %	
Ectopic Pancreas	1 (3.35)
Adipose Tissue	1 (3.35)

RECOMMENDATION
ESGE suggests considering removal of histologically proven gastric GISTs smaller than 20 mm as an alternative to surveillance. The decision to resect should be discussed in a multidisciplinary meeting. The choice of technique should depend on size, location, and local expertise. Weak recommendation, very low quality evidence.

→ Diagnosis in 29/29 (100 %)

* Low risk: < 20 mm, low mitotic index (<5/50 Hpf)

** Well Differentiated (low-grade, G1): Ki67 < 2%, low mitotic index (<2/50 Hpf)

dNET Study

RECOMMENDATION

ESGE suggests that for duodenal and colorectal SELs, all attempts should be made to establish a definite diagnosis to guide further decisions, since there is no evidence that surveillance is a safe option.

Weak recommendation, very low quality evidence.

Retrospective study of FTRD-resected duodenal neuroendocrine tumors

Multicenter, international:

Germany: Ludwigsburg, Deggendorf, Mannheim, Freiburg, Würzburg, Düsseldorf, Kassel, Marburg, Augsburg, Leipzig

France: Lyon, Paris

Italy: Milano, Modena

Belgien: Lüttich, Brussels

Netherlands: Amsterdam, Utrecht

England: Southampton, 2x London,

Greece: Heraklion, Athens

Poland: Warszaw

Switzerland: Luzern, Basel

USA: Seattle, Oklahoma, New York, Fort Wayne, Loma Linda, Minneapolis, Houston

India: Kochi Kerala, Chennai, Hyderabad

Endpoints: technical success rate, R0 resection rate, follow-up, adverse events

170 cases included

„NET-characteristics“:

Size: 10 mm (0 – 25)

Location: 143 (84.1%) in 1st part of duodenum (bulbus duodeni)

-> thereof 61 (35.9%) in the proximal part (close to pylorus)

Technical success: 163 (96%)

R0 Resection

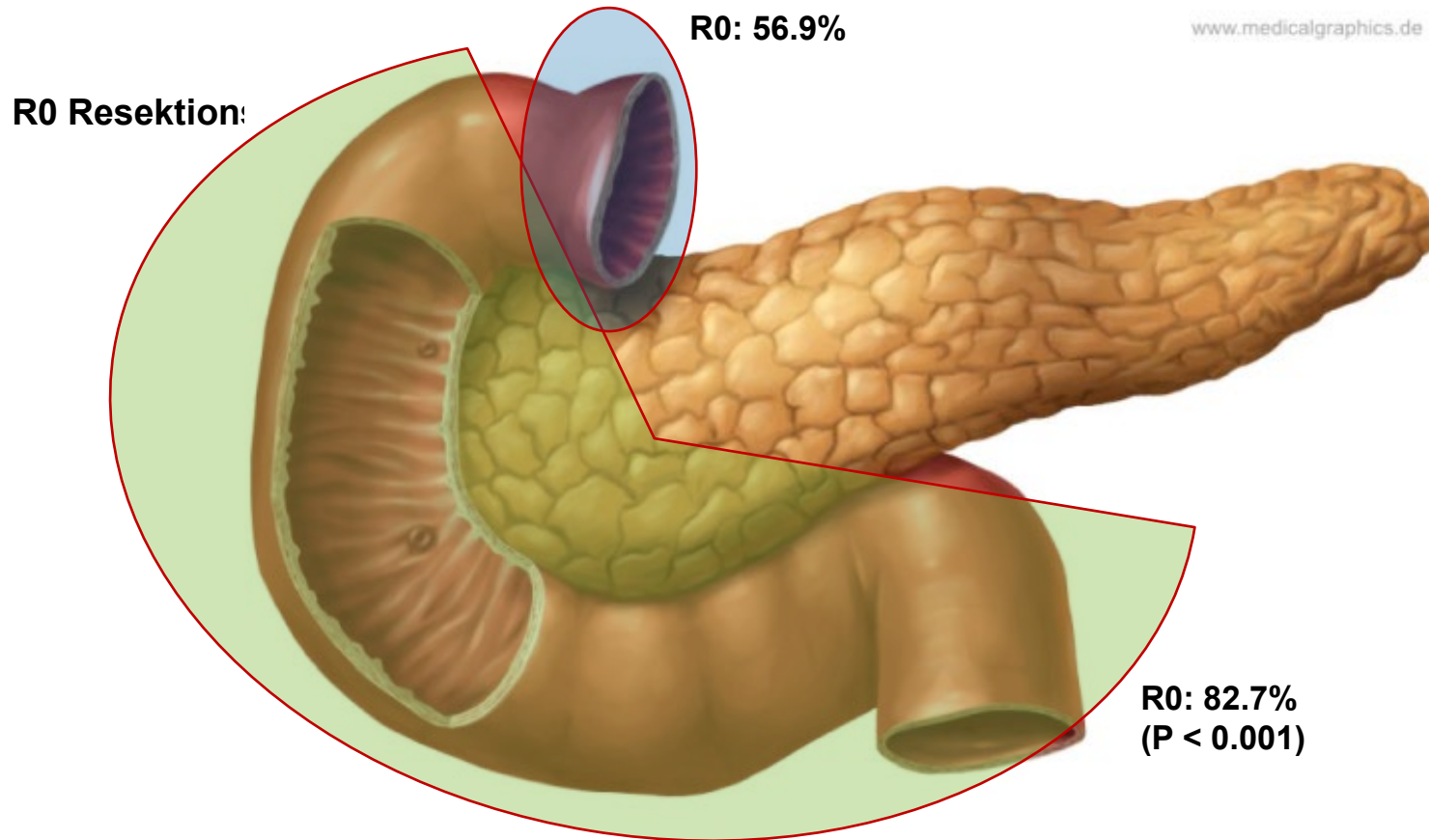
	Univariate HR (95% CI)	P	Multivariate HR (95 CI)	P
Age, years	.99 (.96 – 1.02)	.409		
Sex, female	1.82 (.85 – 3.90)	.122	1.31 (.56 – 3.03)	.532
Size, mm	1.05 (.95 – 1.15)	.343		
Location, distal ¹	3.61 (1.73 – 7.54)	< .001	3.73 (1.68 – 8.25)	.001
Depth of infiltration, <u>mucosa</u> or submucosa	.65 (.18 – 2.44)	.527		
Previous treatment, no	.85 (.34 – 2.16)	.736		
Type of FTRD, gastroduodenal	2.97 (.41 – 21.82)	.284		
Cases per center ²				
1-4 cases	.79 (.37 – 1.69)	.544		
5-9 cases	1.25 (.41 – 3.77)	.697		
Time period, 2021 onwards	2.37 (1.12 – 5.01)	.024	2.49 (1.08 – 5.74)	.032
Technique used to mobilize lesion into the cap, pulling ³	.26 (.07 – .89)	.033	.33 (.09 – 1.24)	.100

¹: distal of duodenal bulb's proximal third

²: compared to high-volume centers (i.e. those with ≥ 10 cases contributed)

³: pulling with grasping forceps or anchor device, compared to suction only

R0 Resection



AEs

±

	N (%)
Cases with AEs, n	33 (19.4)
AEs, n	35
Intraprocedural AEs	
Bleeding, n	5 (2.9)
Perforation, n	4 (2.4)
Allergic reaction, n	1 (.6)
Postprocedural AEs	
Bleeding, n	12 (7.1)
Pulmonary, n	2 (1.2)
Pain, n	3 (1.8)
Duodenal obstruction, n	5 (2.9)
Other, n	2 (1.2)
Late AEs (=> day 14)	
Infection, n	1 (.6)
Severity	
Mild, n	17 (10.0)
Moderate, n	15 (8.8)
Severe, n	3 (1.8)
Treatment	
Conservative, n	11 (6.5)
Endoscopy, n	21 (12.4)
Interventional, n	1 (.6)
Surgery, n	2 (1.2)

DUO-RESECT Study: RCT dFTRD vs. EMR

EFTR vs. EMR of extrapapillary duodenal adenomas < 25 mm using duodenal FTRD-system

Design

investigator initiated trial (K. Caca, Ludwigsburg)

randomized, prospective, multicenter

14 centers in Germany

Aim: lower complication rate of endoscopic resections in the duodenum

Primary Endpoint

combined endpoint: relevant reduction of significant bleeding and/or perforation

→ relevant: transfusion or need for endoscopic or surgical reintervention

Secondary Endpoints

enbloc resection, macroscopic complete resection

R0 resection rate as confirmed by histology

procedure time

residual/recurrent adenoma rate

Conclusions – non-exposure EFTR in the GI-Tract

- reality (main street) = major step forward in interventional endoscopy
- non-exposure EFTR „effective and safe“ = the **Western Way**
- resections in the complete GI-tract except esophagus achievable
- „killer“-indications: - non-lifting neoplasias
- subepithelial tumors
- expertise & close cooperation with surgeons

- **limitations** → lesion size (< 4 cm)
→ location