2021 NCSCG 18TH ANNUAL GI SYMPOSIUM HYBRID

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Advanced Endoscopy Showcase

ANDREW NETT, MD

DIRECTOR OF ADVANCED FOREGUT ENDOSCOPY, INTERVENTIONAL ENDOSCOPY SERVICES, CPMC

ASSISTANT CLINICAL PROFESSOR, UCSF, SFVAMC

Outline

- Updated/Consolidating Evidence
  - EUS-GJ
  - GB Drainage
  - Glue-coil embolization as primary prophylaxis
  - Anti-Reflux Therapy - cTIF
  - Post-ERCP Pancreatitis
- Innovations in Interventional Endoscopy
  - POEM Applications
    - C-POEM
    - Underwater Z-POEM
    - Post-POEM GERD
    - POEF
  - Subserosal dissection

Consolidating Evidence
EUS-guided gastroenterostomy

- Technique - oroenteric catheter-assisted, wire-free puncture
- Retrospective analysis, n=42 (37 benign, 5 malignant)
- 98% technical success
- Mean procedure time 36 min (SEM 3 min)
- No serious adverse events
- 93% clinical success (non-liquid diet) @ 5.7 mo f/u (SEM 2.6 mo)

VIDEO 1

Nguyen et al. Endoscopy. 2021.

EUS-guided gastroenterostomy

- Comparison of EUS-GE and open surgical gastrojejunostomy (2021)
  - Retrospective, clinical outcomes and cost-effective analysis
  - N=66, benign and malignant etiologies of GOO
  - 60% EUS-GE, 40% OGJ

Kouanda et al. Surg Endosc. 2021.

EUS-GE versus OGJ Outcomes

Outcome	EUS-GE	OGJ	P-value
Technical Success	92.5%	100%	0.15
Clinical Success	85%	84%	0.97
Time to PO intake (days)	1.3 +/- 0.95	4.7 +/- 2.7	<0.001
Solid diet tolerated	50%	81.85%	0.02
LOS (days)	5	14.5	<0.001
Chemo resumption (days)	17.7+/-11.8	31.3 +/- 11.2	0.033
Procedure time (mean, min)	57	227.5	P<0.001

Kouanda et al. Surg Endosc. 2021.

EUS-GE versus OGJ

- Lower adverse events with EUS-GE
  - Infection
  - Post-procedure ileus
  - AKI
- No difference:
  - Symptom recurrence
  - Reintervention
  - Death within 30 days
  - 30 day readmission

Kouanda et al. Surg Endosc. 2021.

EUS-GE versus OGJ

- Cost Analysis
  - Total costs
    - OGJ - $124,192
    - EUS-GE - $49,387 (p<.0001)
  - Mean inpatient costs
    - OGJ - $42,716
    - EUS-GE - $19,785 (p,<0.001)

Kouanda et al. Surg Endosc. 2021.

EUS-GE versus Enteral Stent versus Surgical GJ

- EUS-GE versus duodenal stent placement and surgical GJ for palliation of malignant GOO
- 2021 systematic review/meta-analysis
- 7 studies, n=513

Boghossian et al. Langenbecks Arch Surg. 2021.

EUS-GE v SGJ for Malignant GOO

- Lower technical success (91.41% v 100%, $p < 0.01$)
- Equivalent clinical success (86.71% v 90.21%, p – 0.48)
- Decreased LOS – mean difference of 5.11 days, $p < 0.01$
- Comparable reintervention, 30 day mortality, severe adverse events

Boghossian et al. Langenbecks Arch Surg. 2021.

EUS-GE v Enteral Stent for Malignant GOO

- Comparable Technical Success (93.33% v 98.35%, p=0.68)
- Higher Clinical Success (88.3% v 78.02%, p – 0.01)
- Fewer SAEs (11.66% v 31.32%, p – 0.002)
- Decreased stent obstruction (3.33% v 24.17%, p <0.02)
- Decreased tumor ingrowth (1.66% v 16.48%, p < 0.01)
- Decreased need for reintervention (6.67% v 28.57%, p < 0.01)

Boghossian et al. Langenbecks Arch Surg. 2021.

EUS-guided gallbladder drainage versus percutaneous cholecystostomy

- Percutaneous cholecystostomy versus EUS-guided GB drainage for acute cholecystitis in very high-risk surgical patients
- 2020. Teoh et al – multicenter, international, superiority RCT
- Very high risk
  - Age >/= 80 yo
  - American Society of Anesthesiology grade 3 or above
  - Age=adjusted Charlson Comorbidity Index > 5 and/or Karnofsky score <50
  - Elderly pateints refusing cholecystectomy
- No subsequent cholecystectomy

Teoh et al. Gut 2020.

EUS-GBD v Percutaneous Cholecystostomy

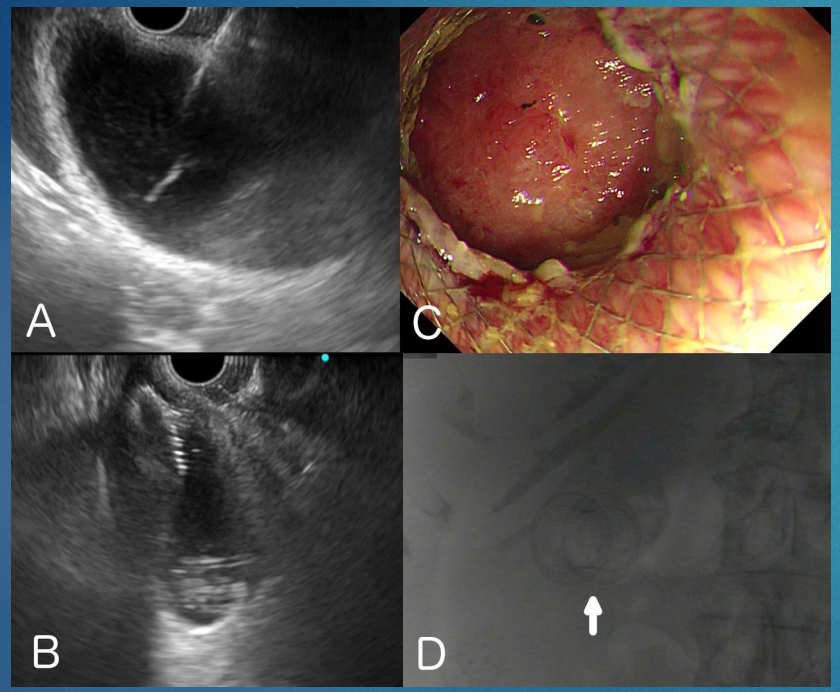
- Procedure Protocol
  - EUS-GBD - 10mm x 10 mm or 15mm x 10 mm LAMS depending on size of largest gallstone (</> 10mm)
  - Additional DPS placed through LAMS at endoscopist discretion
  - EUS-GBD – f/u peroral cholecystoscopy 1 mo to assess for stone clearance
    - If cleared → LAMS exchanged for permanent 7Fr DPS,
    - If not cleared → q 1 mo cholecystoscopy until stones and LAMS removed
    - If too old or frail for additional endoscopies → GB stents (LAMS +/- DPS) left permanently
  - PT-GBD – tube cholecystogram 1 mo post-procedure
    - If cystic duct patent, cholecystostomy capped and left in-situ or removed
    - If cystic duct obstructed, long-term cholecystostomy drainage

Teoh et al. Gut 2020.

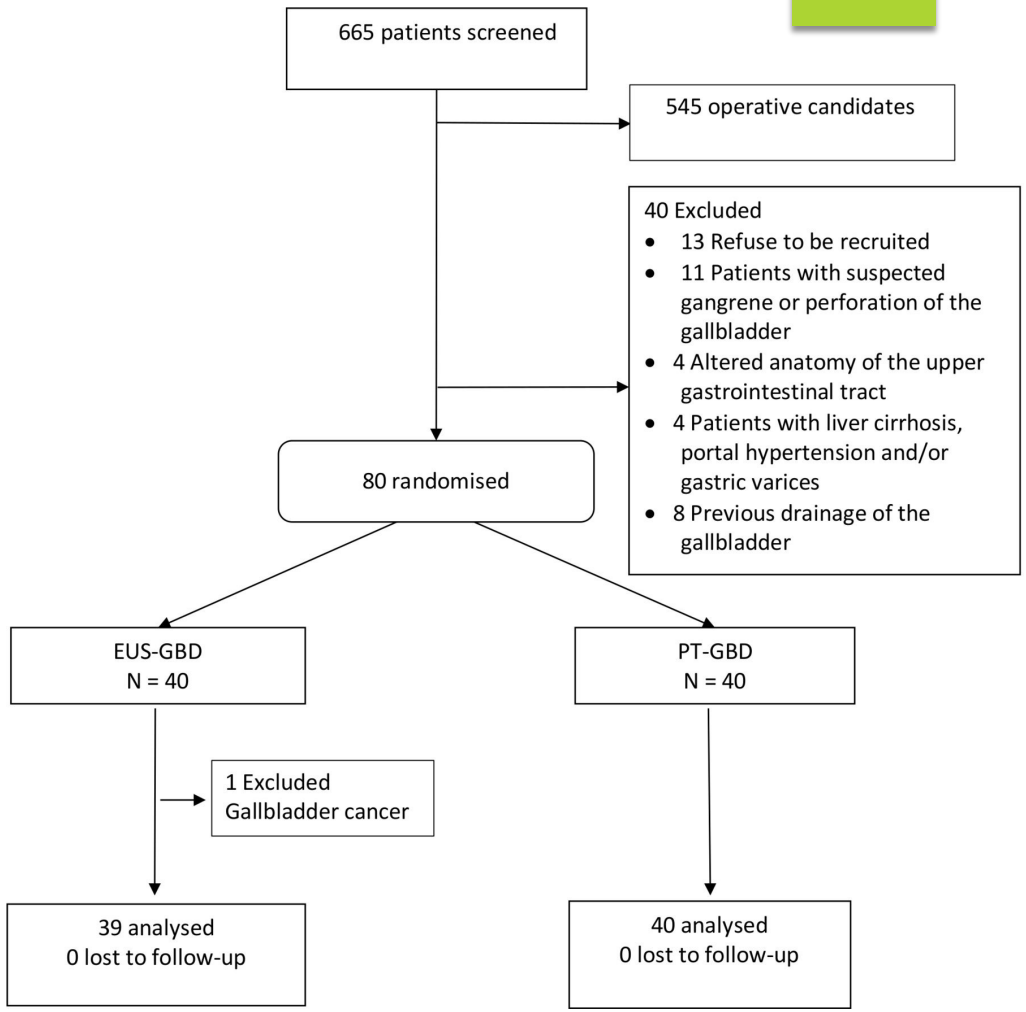
EUS-GBD v Percutaneous Cholecystostomy

- Video 2

EUS-GBD v PT-GBD



- Teoh et al. Gut 2020.



EUS-GBD v PT-GBD

- No difference in technical success
  - EUS-GBD 38/39 (97.4%) v 40/40 (100%), p=0.494
- No difference in clinical success
  - EUS-GBD 36/39 (92.3%) v 37/40 (92.5%), p=1
- Significantly less recurrent acute cholecystitis at 1 year in EUS-GBD group (2.6% v 20%, p=0.029)
- EUS-GBD → Lower reinterventions for acute cholecystis after 30 days, lower number of unplanned admissions

Table 2

Comparison of the clinical outcomes between the two groups

	EUS-GBD n=39	PT-GBD n=40	P value
1-year adverse events (%)	10 (25.6)	31 (77.5)	<0.001
Grading 1/2/3/4/5	1/1/6/0/2	13/6/8/0/4	
Recurrent acute cholecystitis (%)	1 (2.6)	8 (20)	0.029
Reinterventions after 30 days (%)	1 (2.6)	12 (30)	0.001
Reinsertion of PT-GBD	0	12	
Clearing blocked stent	1	0	
Unplanned admissions (%)	6 (15.4)	20 (50)	0.002
30-day adverse events (%)	5 (12.8)	19 (47.5)	0.001
Grading 1/2/3/4/5	0/1/2/0/2	6/4/5/0/4	
30-day mortality (%)	3 (7.7)	4 (10)	1
Technical success (%)	38 (97.4)	40 (100)	0.494
Clinical success (%)	36 (92.3)	37 (92.5)	1
Procedure time (minutes)	22.7 (13.0)	27.4 (12.0)	0.108
Analgesic requirements (total paracetamol in mg)	3345 (5663)	5165 (5068)	0.034
Hospital stay (days)*	8 (4–13)	9 (7–14)	0.181

Teoh et al. Gut 2020.

EUS-GBD v PT-GBD

- EUS-GBD → reduced 30 day adverse events (12.8% v 47.5%, p = 0.01)
- EUS-GBD → reduced 1 year adverse events (25.6% v 77.5%, p<0.001)
- Most adverse events in PT-GBD group due to tube dislodgements, 8 were recurrent acute cholecystitis

Table 3

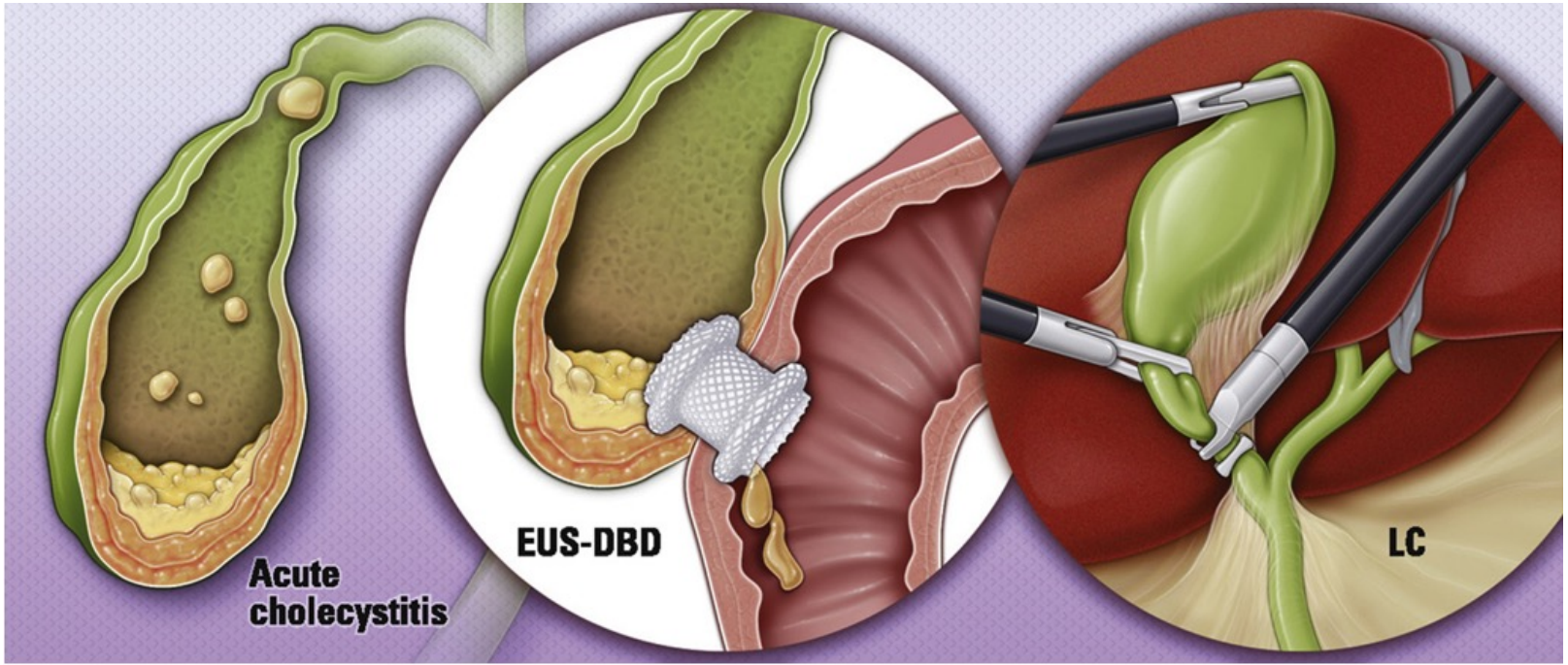
The 30-day and 1-year adverse events in both groups

	EUS-GBD n=39	PT-GBD n=40	P value
30-day adverse events (%)	5 (12.8)	19 (47.5)	0.010
Tube dislodgement	0	15 (0/3/12/0/0)	
Blocked stent	2 (0/1/1/0/0)	0	
Perforation	1 (0/0/1/0/0)	0	
Multiorgan failure	0	3 (0/0/0/0/3)	
Pericholecystic collection	0	1 (0/0/1/0/0)	
Acute myocardial infarction	0	1 (0/1/0/0/0)	
Atrial fibrillation	1 (0/1/0/0/0)	1 (0/1/0/0/0)	
Pneumonia	3 (0/1/0/0/2)	1 (0/1/0/0/0)	
Bleeding	0	1 (0/1/0/0/0)	
Decompensated liver cirrhosis	0	1 (0/0/0/0/1)	
Urinary tract infection	0	1 (0/2/0/0/0)	
1-year adverse events (%)	10 (25.6)	31 (77.5)	<0.001
30-day adverse events*	5	19	
Recurrent acute cholecystitis	1 (0/0/1/0/0)	8 (0/5/3/0/0)	
Tube dislodgement	0	18 (4/5/9/0/0)	
Blocked stent / tube	1 (0/0/1/0/0)	2 (0/2/0/0/0)	
Common bile duct stones requiring ERCP	3 (0/0/3/0/0)	1 (0/0/1/0/0)	

Teoh et al. Gut 2020.

EUS-GB vs Lap Cholecystectomy for Acute Cholecystitis

- Propensity score matching → compare very high risk patients undergoing EUS-GBD and surgical candidates undergoing LC during study period
- Covariates age, sex, age-adjusted Charlson score, matched 1:1 basis



Teoh et al. GIE 2021.

EUS-GB vs Lap Cholecystectomy for Acute Cholecystitis

- 1 year f/u

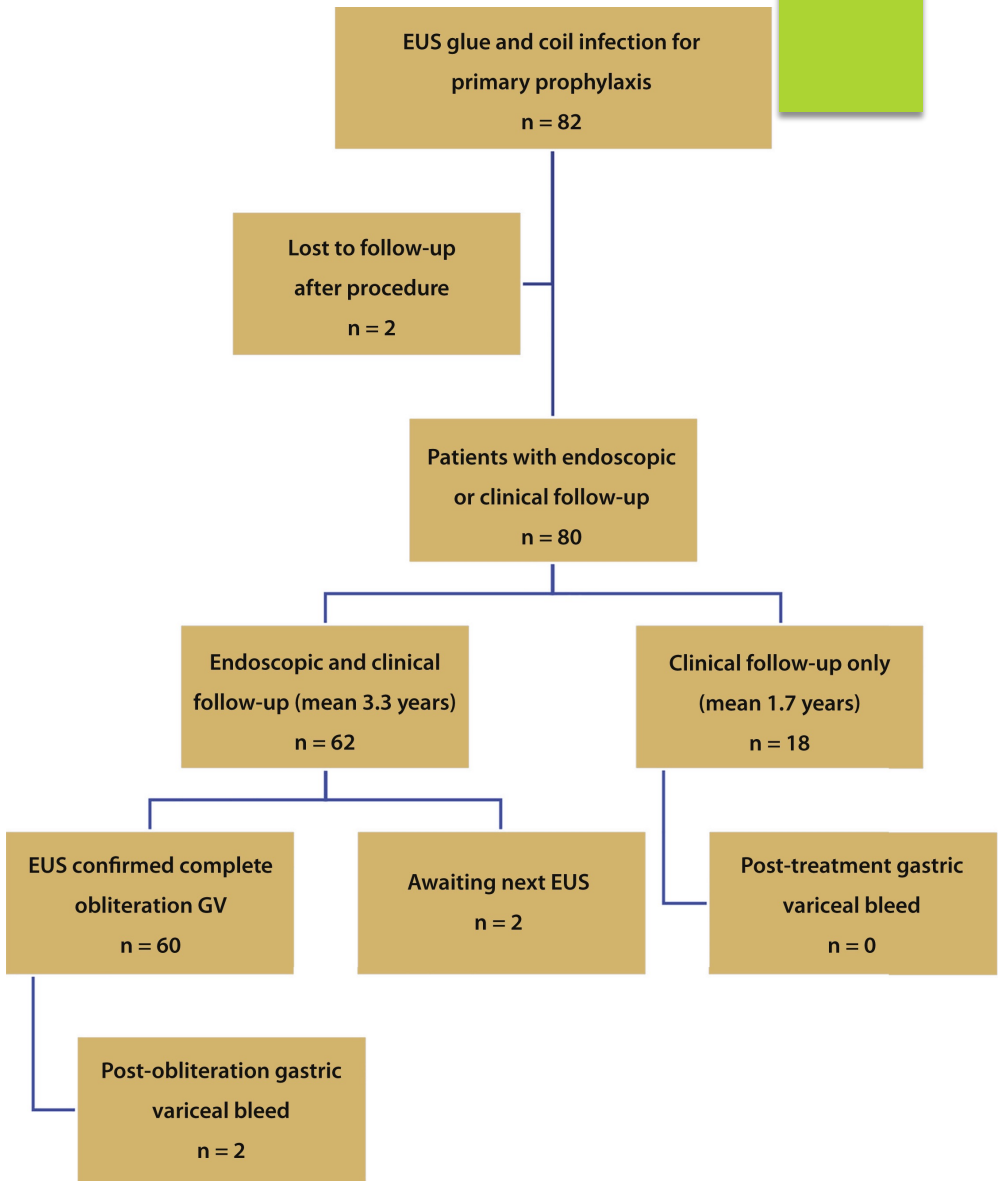
Comparison on clinical outcomes of the two procedures

	EUS-GBD n = 30	LC n = 30	*P* value
Technical success (%)	30 (100)	30 (100)	-
Clinical success (%)	28 (93.3)	30 (100)	1
Length of hospital stay (days)	6.8 (8.1)	5.5 (2.7)	1
30-day adverse events (%)	4 (13.3)	4 (13.3)	1
30-day mortality (%)	2 (6.7)	0 (0.0)	1
Recurrent cholecystitis (%)	1 (3.3)	0 (0.0)	0.168
Recurrent biliary events (%)	3 (10.0)	3 (10.0)	0.784
Re-interventions (%)	4 (13.3)	3 (10.0)	1
Unplanned readmissions (%)	3 (10.0)	3 (10.0)	0.784

Teoh et al. GIE 2021.

EUS-guided glue coil embolization for gastric variceal bleed primary prophylaxis

- Single center, retrospective study
- n-=82
- 88.7% cirrhosis (mean MELD12.3 +/- 3.7), 11.3% non-cirrhotic portal HTN
- NSBB use 51.3%



Kouanda et al. GIE 2021.

EUS-GC for GV primary prophylaxis

- Mean variceal size 22.5 +/- 9.4 mm
- 86.3% IGV1 (IGV1 bleed rate of 78% per Sarin et al. Hepatology. 1992)
- Mean length f/u – 3 +/- 2.4 yrs
- Mean 1.5 coils (1-3), 2mL glue (0.5-5)
- Technical success 100%
- 96.7% EUS confirmed GV obliteration
- Overall highly effective with low adverse event rate

Kouanda et al. GIE 2021.

EUS-GC for GV primary prophylaxis

Endoscopic and clinical follow-up	62 (77.5)
EUS-confirmed obliteration	60/62 (96.7)
EUS glue-coil encounters to obliteration	
1	43
2	14
3	0
4	2
5	1
Clinical follow-up only	18 (22.5)

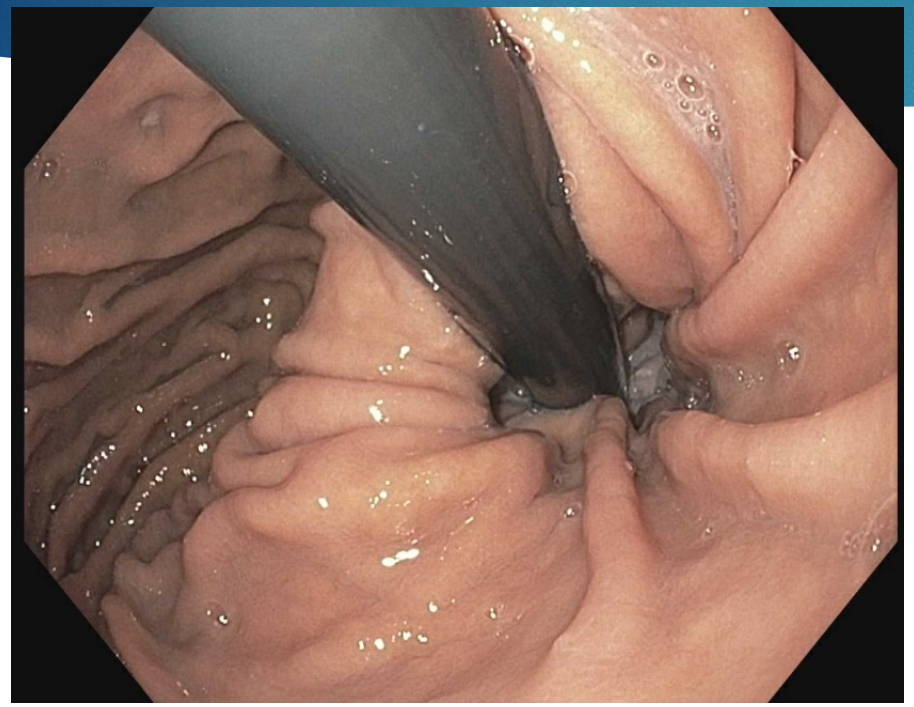
Kouanda et al. GIE 2021.

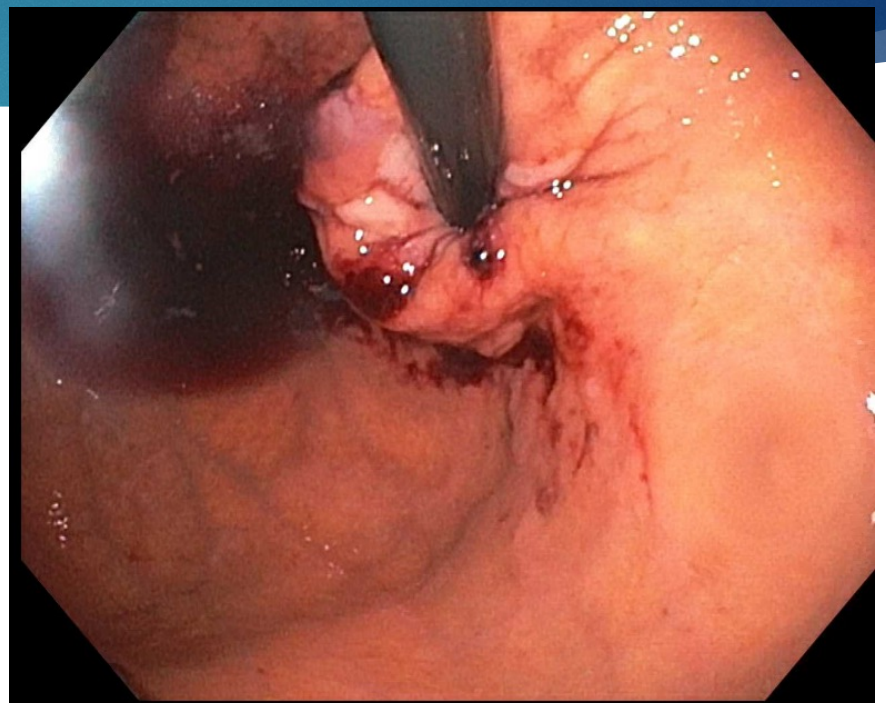
EUS-GC for GV primary prophylaxis

- Adverse events, n-4 (4.9%)
- Two – self-limited postprocedural abdominal pain with 1d hospital admission
- 6 patients – GI bleed (7.5%)
  - 2 (2.5%) – GVB after prior confirmation of obliteration (1.1 and 5.3 yrs later), treated successfully with EUS-glue/coil, no TIPS, no death
  - Others were esophageal varices, n-3, 3.7%, gastric ulcer, n-1, 1.3%
- 2 PE within 2 wks of treatment
  - One attributed to glue embolization
  - One attributed to DVT
  - Medically managed all on NSBB

Kouanda et al. GIE 2021.

Lap HHR + TIF (c-TIF)





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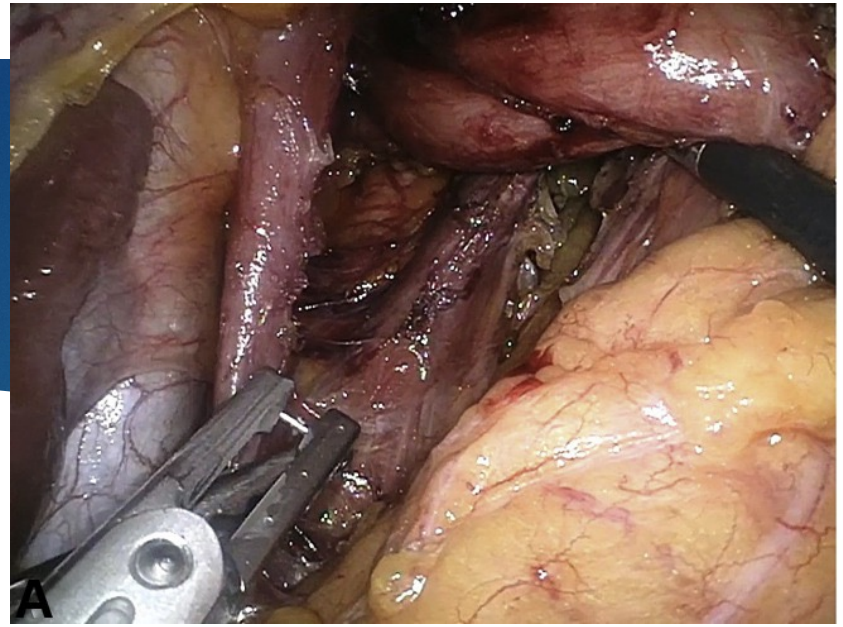
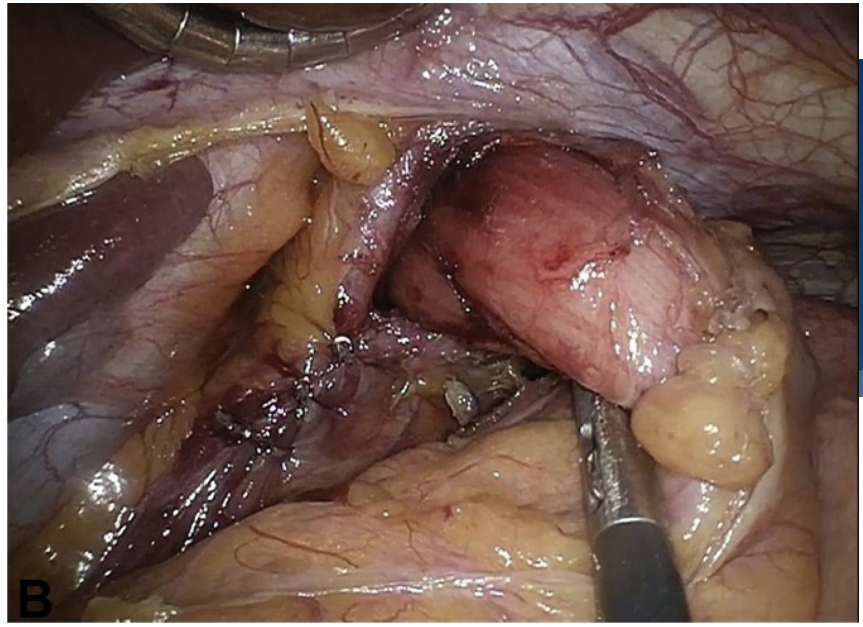
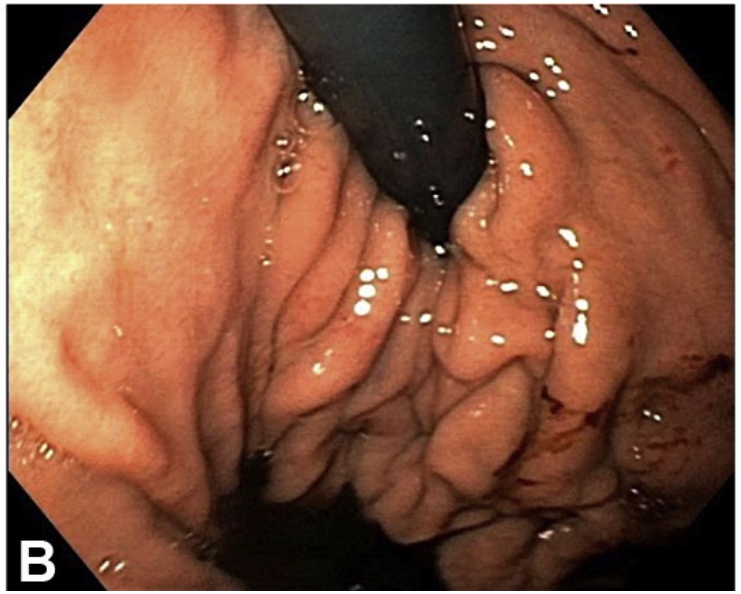
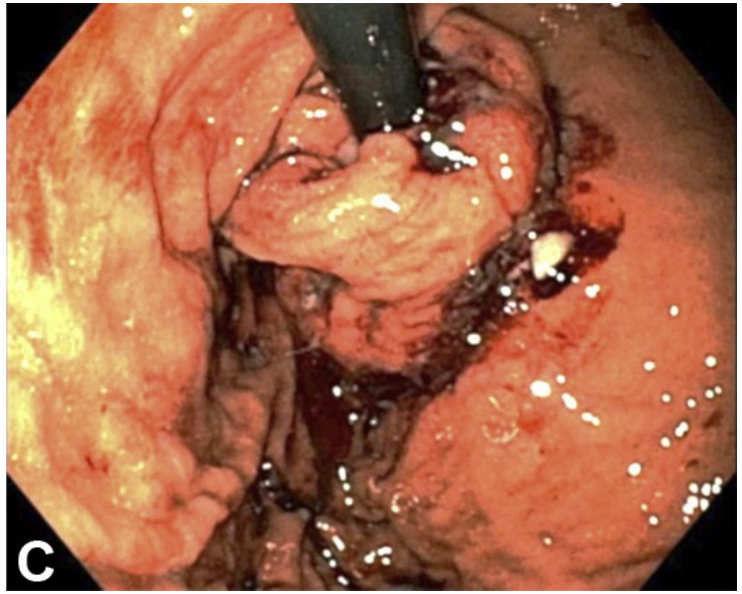








Choi et al. J Am Coll Surg. 2021.

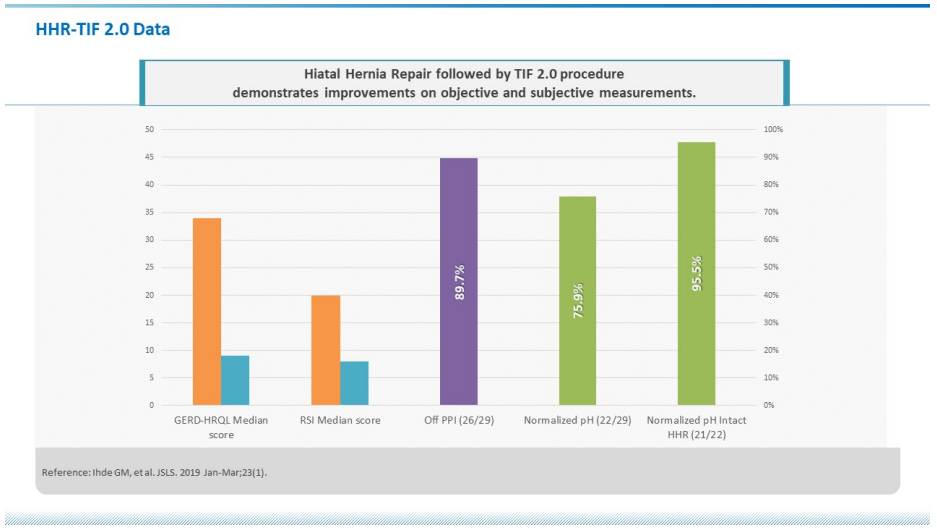
c-TIF → Janu et al. 2019.

- **N=99**
- **PPI usage**
  - **At baseline – 63.6% daily PPI, 29.3% twice daily PPI**
  - **6 months – 70% never PPI (11.4% daily, 3% twice daily)**
  - **12 months – 74.1% never PPI**
- **No laparoscopic or endoscopic complications**
- **No increased rates of gas-bloat, inability to eructate or vomit**

Janu P et al. Surg Innov. 2019 Dec; 26(6): 675-686.

c-TIF → Ihde et al. 2019.

- **N=55, mean f/u = 296 days**
- **Significant ↓ mean GERD HRQL, RSI scores**
- **pH score improved significantly**
- **95% normalized pH (EAE) when HHR/TIF remained intact (75.9% overall)**



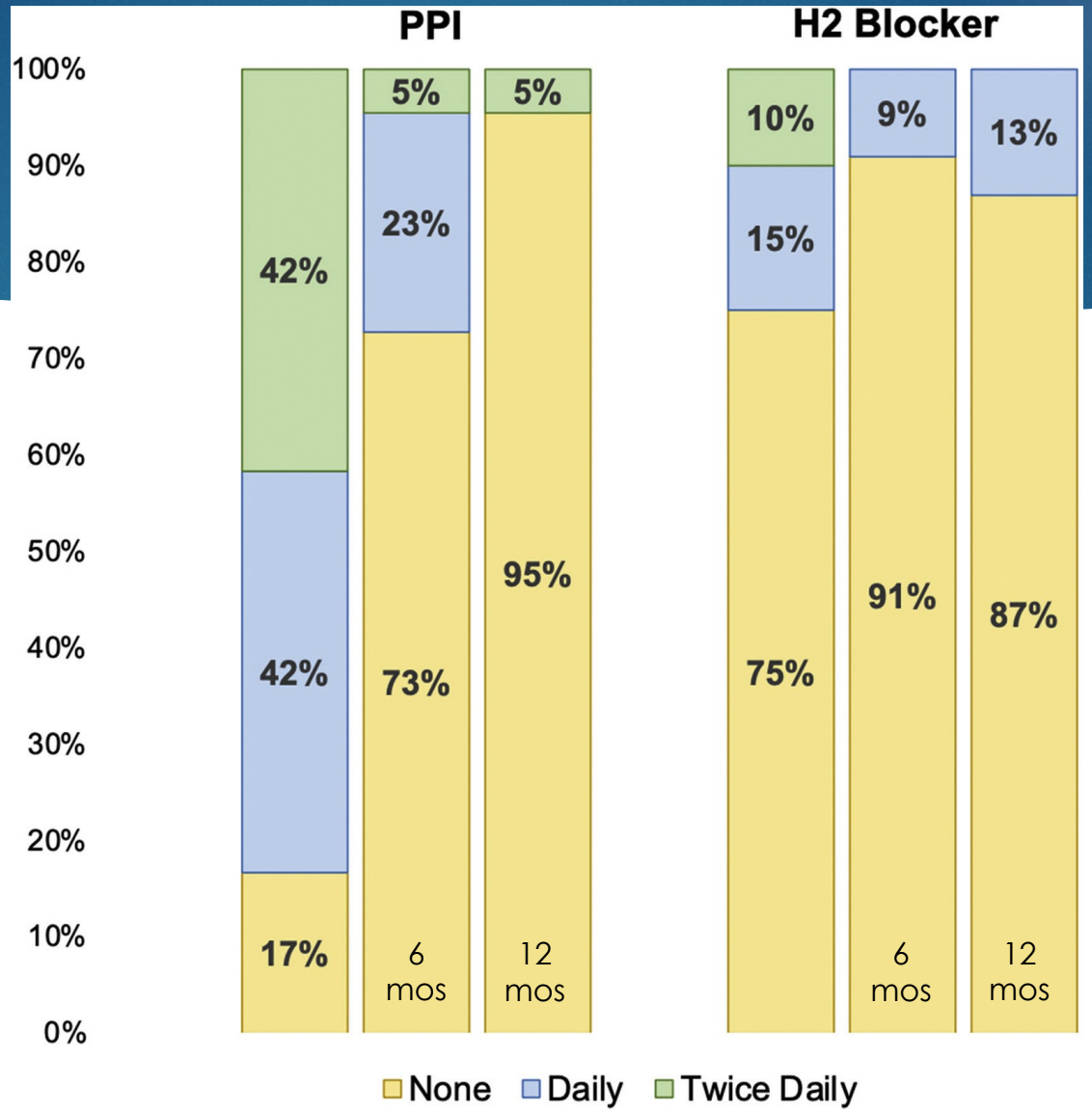
Ihde GM et al. JSLS. 2019 Jan-Mar; 23(1).

c-TIF → Choi et al

- N = 60,
  - clinically significant GERD (DeMeester>14.7, BE, LA C or D esophagitis)
  - HH > 2 cm or Hill Grade >2
- Mean HH 2.9 +/1.5 cm
- 100% technical success
- GERD HRQL, RDQ, RSI scores improved significantly
- Mean DeMeester 43.7 to 4.9, EAE 12.7 to 1.28%, p= 0.06

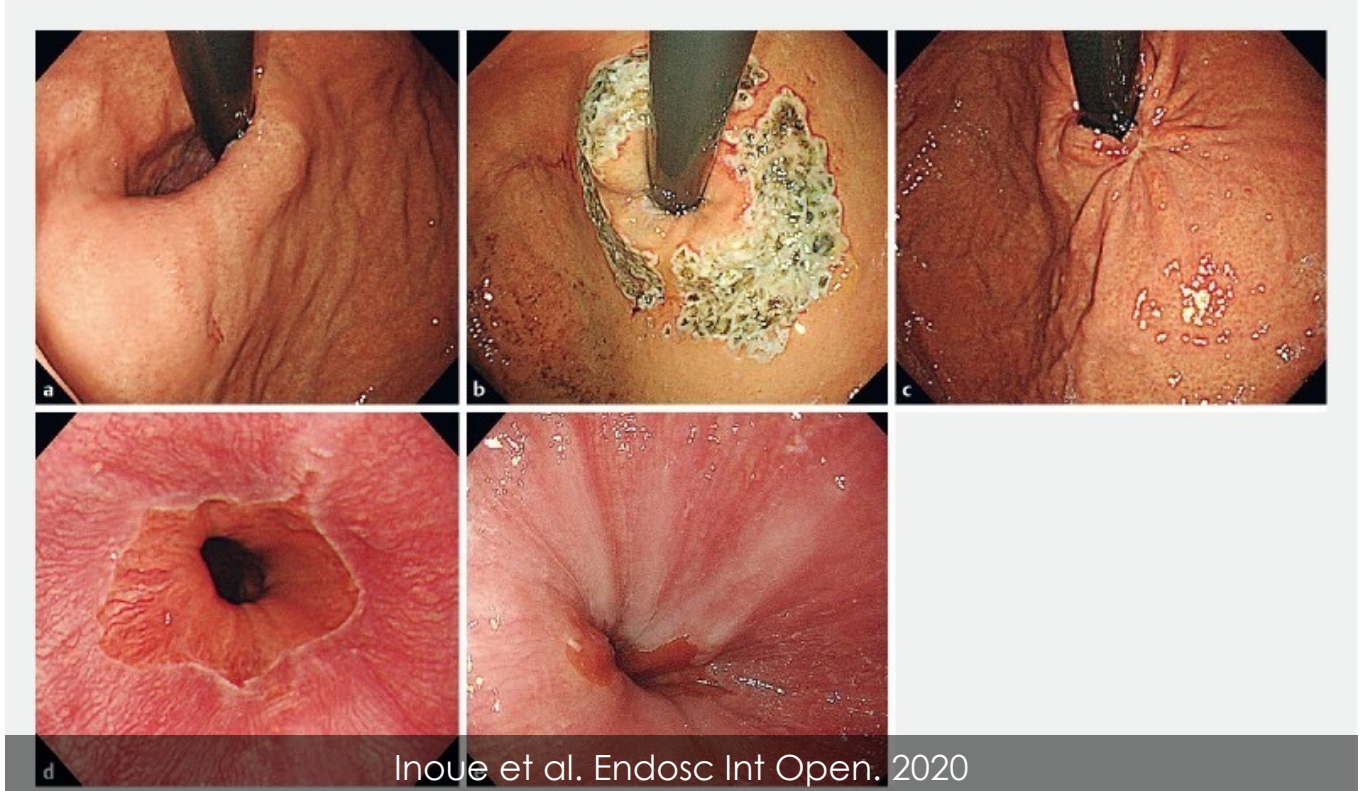
Choi et al. J Am Coll Surg. 2021.

C-TIF



Choi et al. J Am Coll Surg. 2021.

Anti-Reflux Ablation

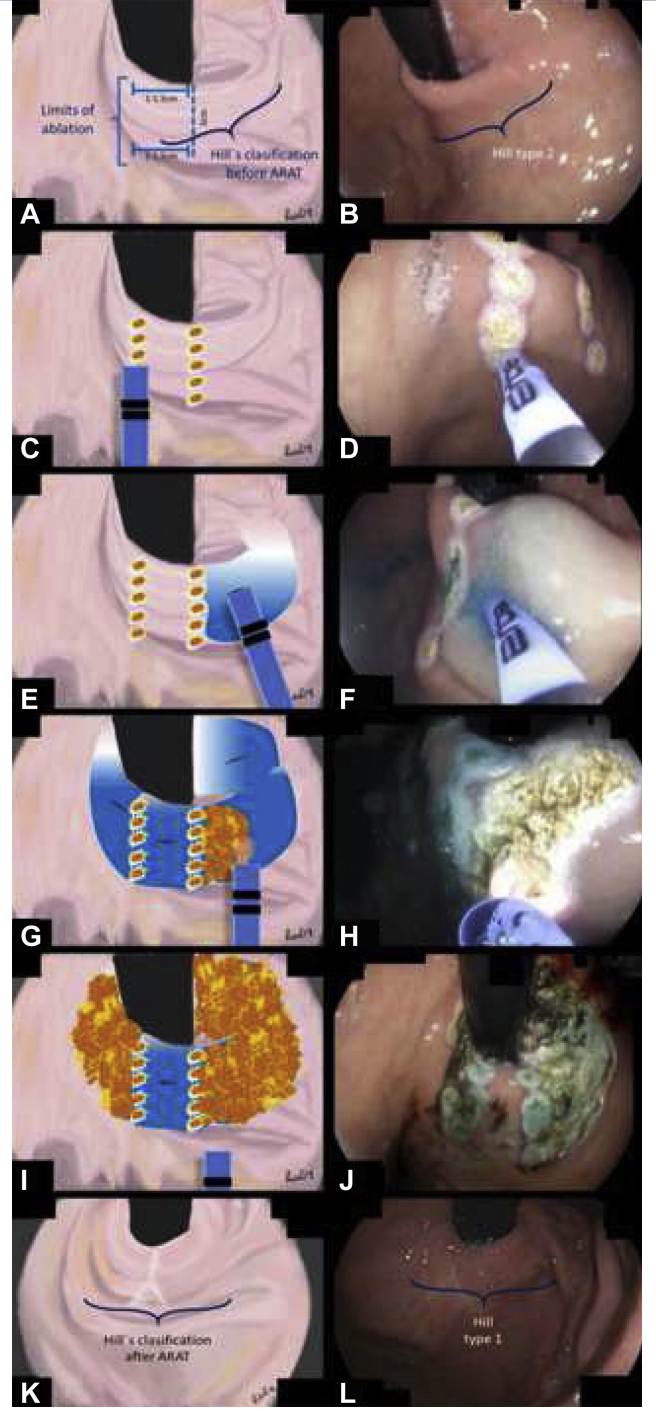


Inoue et al. Endosc Int Open. 2020

- N=12, f/u 9 mos
  - Refractory GERD Sx despite bid PPI x 6 mos
  - Abnl acid (DeMeester or EAE)
  - 92% Hill Grade III
- Submucosal injection + 50W spray coag
- @2 mo, improved GERD-HRQL, FSSG, DeMeester score
- 8.3% (n=1) – esoph stenosis with dysphagia, dilated over 2 sessions

Anti-Reflux Ablation

- Hill Grade II or III without hiatal hernia
- Persistent GERD despite bid PPI >12 wks, DeMeester > 14.7 or EAE > 6%, erosive esophagitis, and abnl GERD-HRQL
- Hybrid APC, Effect 2, 40W
- N-180
- 12.9% developed stenosis responsive to balloon dilation (<5 sessions), 19.4% had dysphagia to some solid food
- At 3 mos, significant decrease in DeMeester, EAE, GERD-HRQL
- Clinical success (EAE <4%) = 89% at 3 mos, 72.2% at 36 mos



Hernandez Mongragan. GIE. 2020

Post-ERCP Pancreatitis Prophylaxis – Role for IV hydration?

- Survey of endoscopists involved in advanced endoscopy fellowships - 83% of responders report use of IVF to prevent PEP[1]
  - Is there benefit?
- Multicenter, open-label, RCT[2]
  - N=826, moderate to high risk of PEP
  - Aggressive hydration = 20mL/kg LR within 60 min + 3ml/kg/h for 8 hours
  - Rectal NSAID = 100mg diclofenac or indomethacin

1. Avila et al. GIE. 2020.
2. Weiland et al. Lancet Gastroenterol Hepatol. 2021

PEP Prophylaxis – Role for IV Hydration?

- Excluded low PEP risk patients
  - chronic calcific pancreatitis, prior sphincterotomy, pancreatic head mass, routine biliary stent exchange
- Excluded patients with active acute pancreatitis, contraindications to aggressive hydration or rectal NSAIDs
- PEP Definition
  - new onset of upper abd pain
  - extension of hospitalization for 2 nights
  - elevation of lipase/amylase > 3 x ULN 24 h after ERCP
- PD stent placement 6% in both study groups

Weiland et al. Lancet Gastroenterol Hepatol. 2021

PEP Prophylaxis – Role for IV hydration?

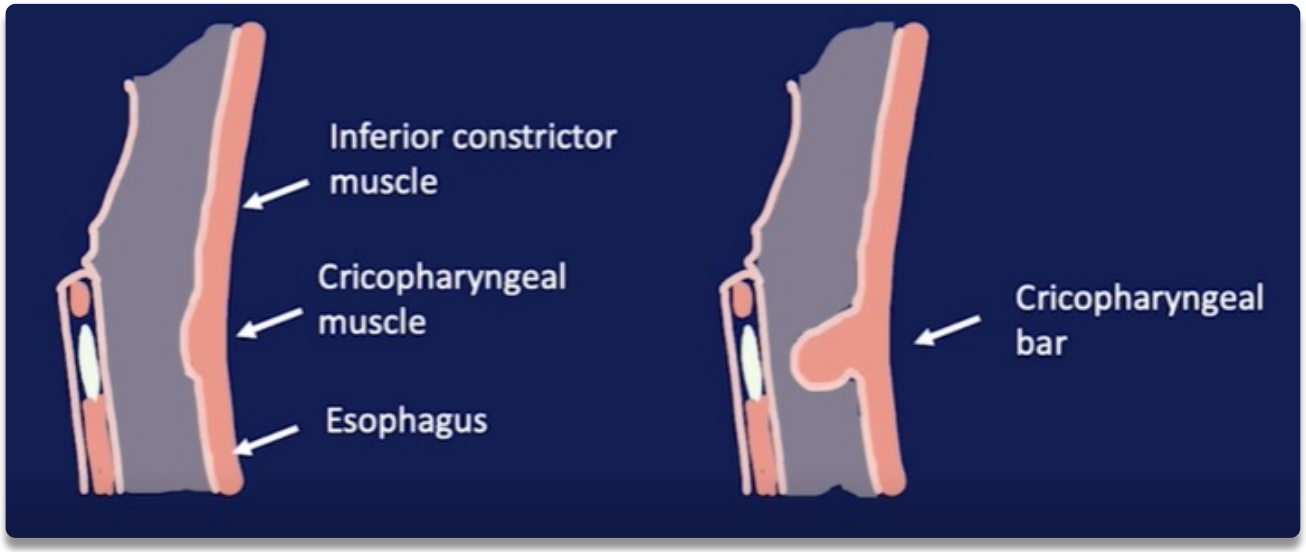
- No difference in PEP
  - 8% in aggressive hydration + rectal NSAID group
  - 9% in rectal NSAID alone group (p=0.53)
- No difference in SAE
- No difference in hydration-related complications, ERCP-related complications, ICU admission, 30 day mortality

Weiland et al. Lancet Gastroenterol Hepatol. 2021

POEM Innovations – CP-POEM

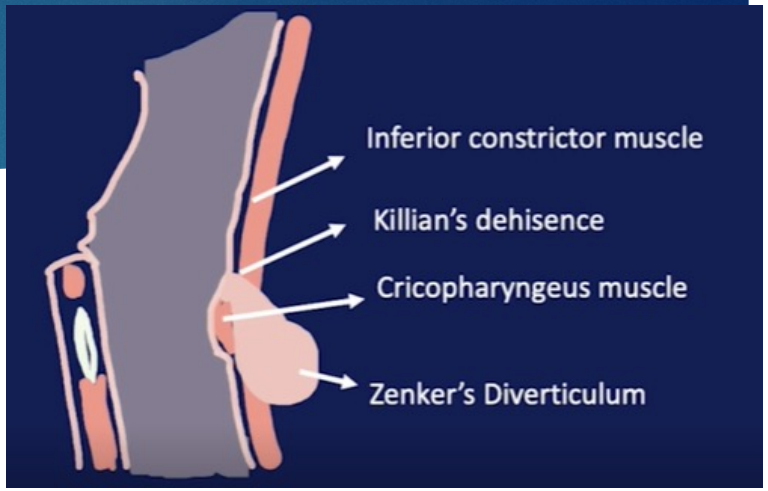
- CP-POEM
  - Al Ghamdi SS et al. DDW 2021. Multicenter study, n=27 (05/15-12/20)
  - Technical success: 100%
  - AE:7.4% (n=2 – mucosotomy, leak)
  - Symptom recurrence: 1 patient (median f/u 3.5 years)
  - Clinical success 100% (decrease in dysphagia score >2)

VIDEO 3

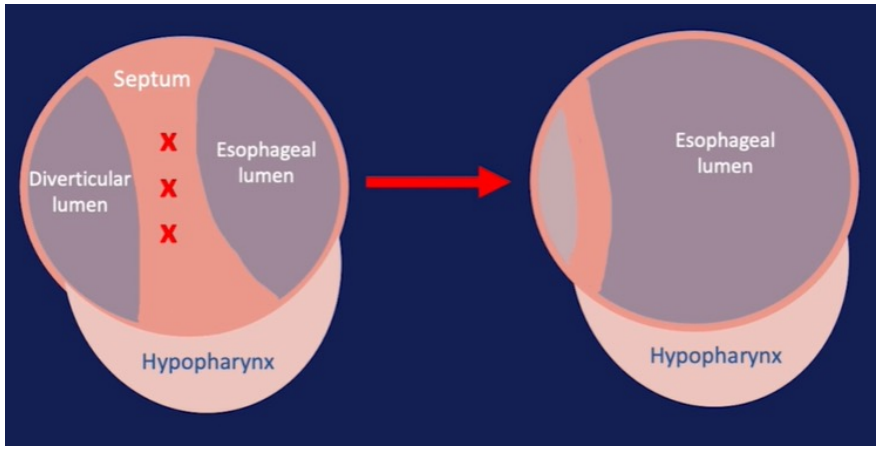


AlGhamdi et al. Video GIE 2021. DDW 2021.

Z-POEM Variations



- Multicenter comparison Z-POEM (n=52) versus endoscopic septotomy (n=42)[1]
  - Z-POEM → significantly fewer adverse events (p=0.017)
- Traditional ZPOEM tunnel starts in hypopharynx proximal to esophagus/septum
- POES (Peroral endosopic septotomy) – tunnel entry overlying the septum
  - Easier tunnel closure, decreased procedure duration, decreased foreign body sensation
  - Repici et al.[2] n=20 → Clinical success 95%, no adverse events, Mean procedure time 13.8, 16 patients discharged same day, no recurrence (f/u mean12 mos)
- Multicenter Retrospective comparison of standard Z-POEM v POES (n=174)[3]
  - Similar clinical success - 93.5 versus 94.1%
  - POES (Septal mucosotomy) – shorter procedure time
  - No difference in adverse events, LOS, symptom recurrence



1. Kahaleh et al. DDW 2021
2. Repici et al. Endoscopy 2020
3. Al Ghamdi et al. DDW 2021.

Underwater Z-POEM

VIDEO 4

- Binmoeller KF et al. DDW 2021
  - n-=31, 29% prior treatment
  - Procedure time 40 +/- 17 min
  - Tech success 100%, No immediate adverse events
  - 3% delayed adverse event (contained leak)
  - Median f/u 21 pts (41 wks) – Eckardt score = 0 at final f/u
  - 1 patient with stricture treated with dilation

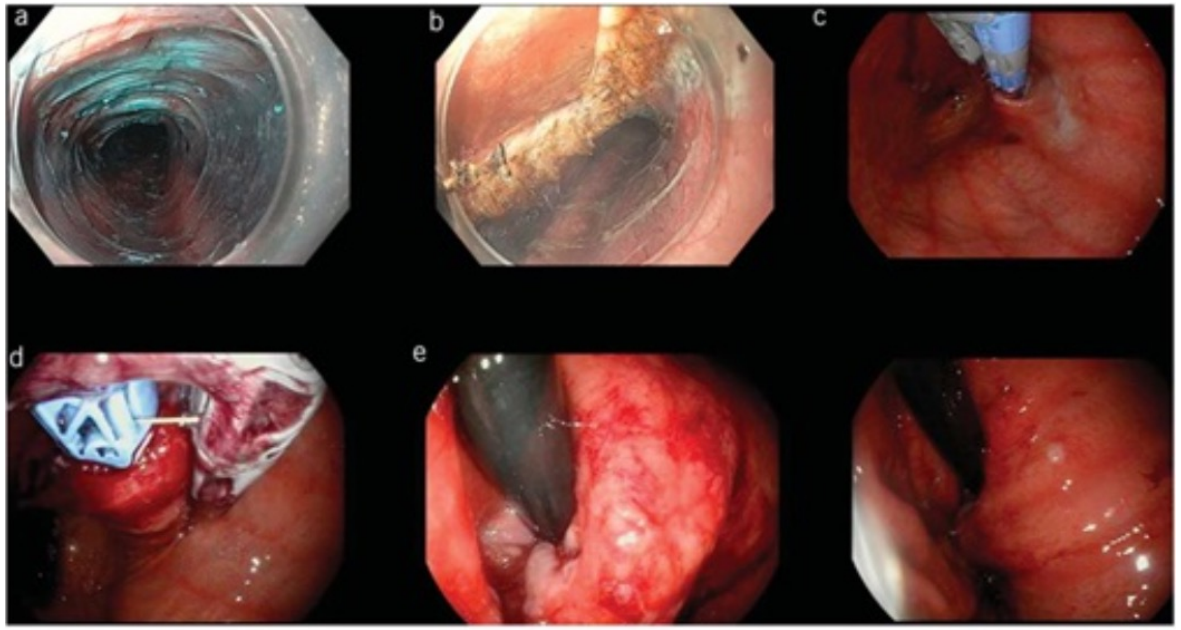
GERD after POEM

- Stavropolous et al. DDW 2021, n=704

GERD Sx Frequency	Rate (at 38 mo f/u)
Never	51.8%
</= 1time/week	32.3%
2-4 times/week	8.7%
>4 times /week	7.2%

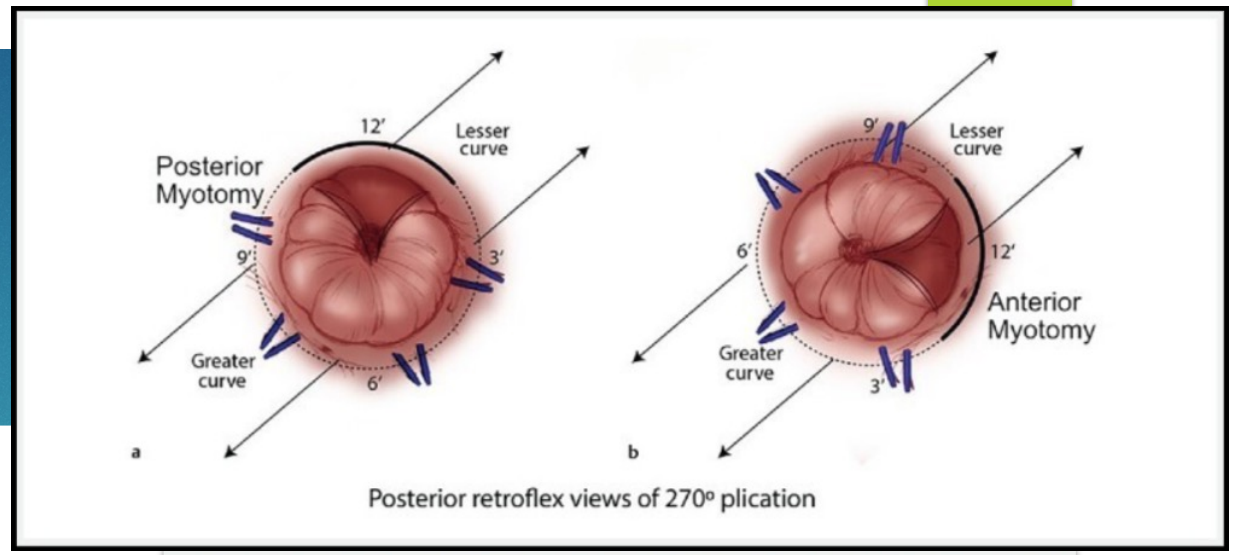
TIF after POEM

- TIF after POEM, n=12 pts
  - 75% daily GERD sx, 91.7% on bid PPI
  - 100% technical success
  - 2/12 adverse events
  - Significant decreases:
    - Bid PPI (p=0.03)
    - Daily Sx frequency, RSI, GERD-HRQL p=0.03
    - Mean DeMeester (p=0.05)
    - Mean % acid exposure time (p=0.04)

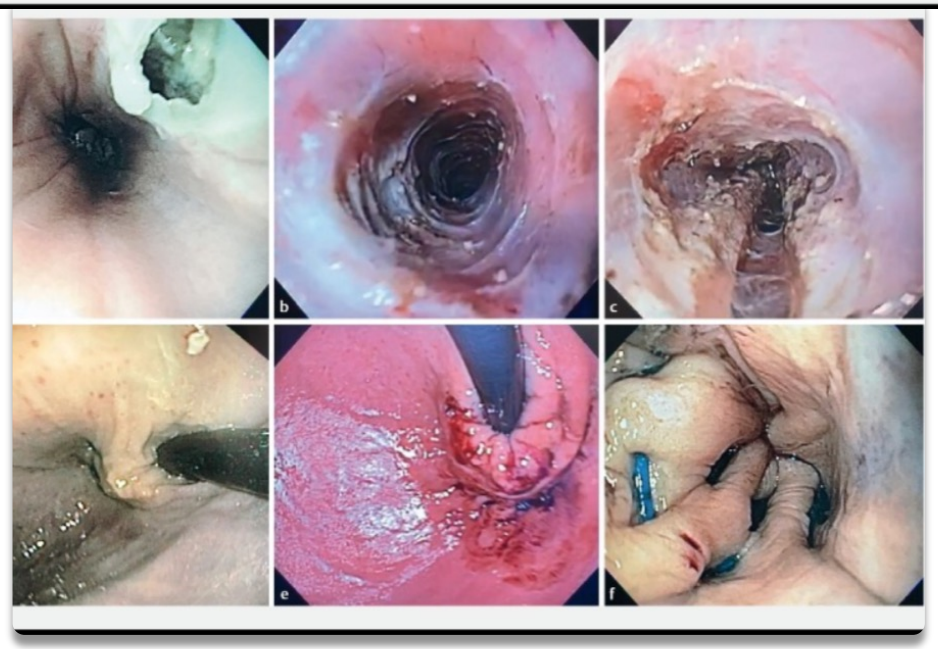


Gutierrez et al. Endoscopy 2021.

POEM + TIF



- Single session POEM + TIF safe and feasible
- Initial animal series – canine model
  - 3 anterior myotomy, 3 posterior
- Next performed in 5 patients
- No intraprocedural or delayed complications including mucosal injury or leak, 38 min added for TIF
- Normal DeMeester (<14.72) in 4/5 patients at 6 months
- 1/5 – esophagitis
- Added benefit to lengthening/straightening the esophagus in achalasia patients with improved esophageal clearance?

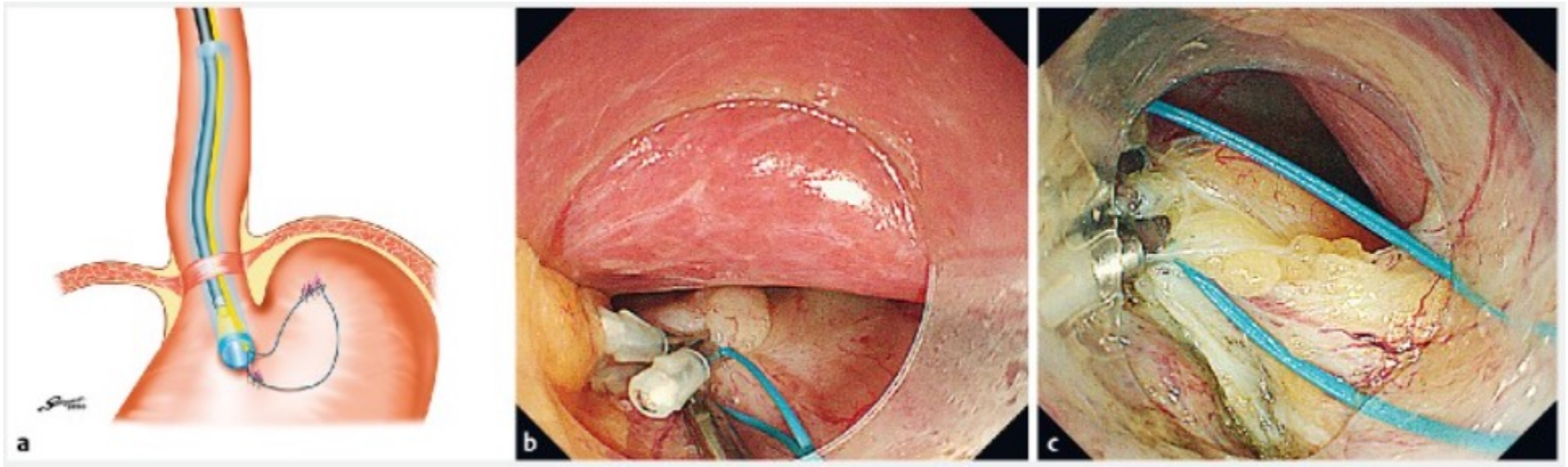


Benias et al. Endosc Int Open. 2021.

POEM + F

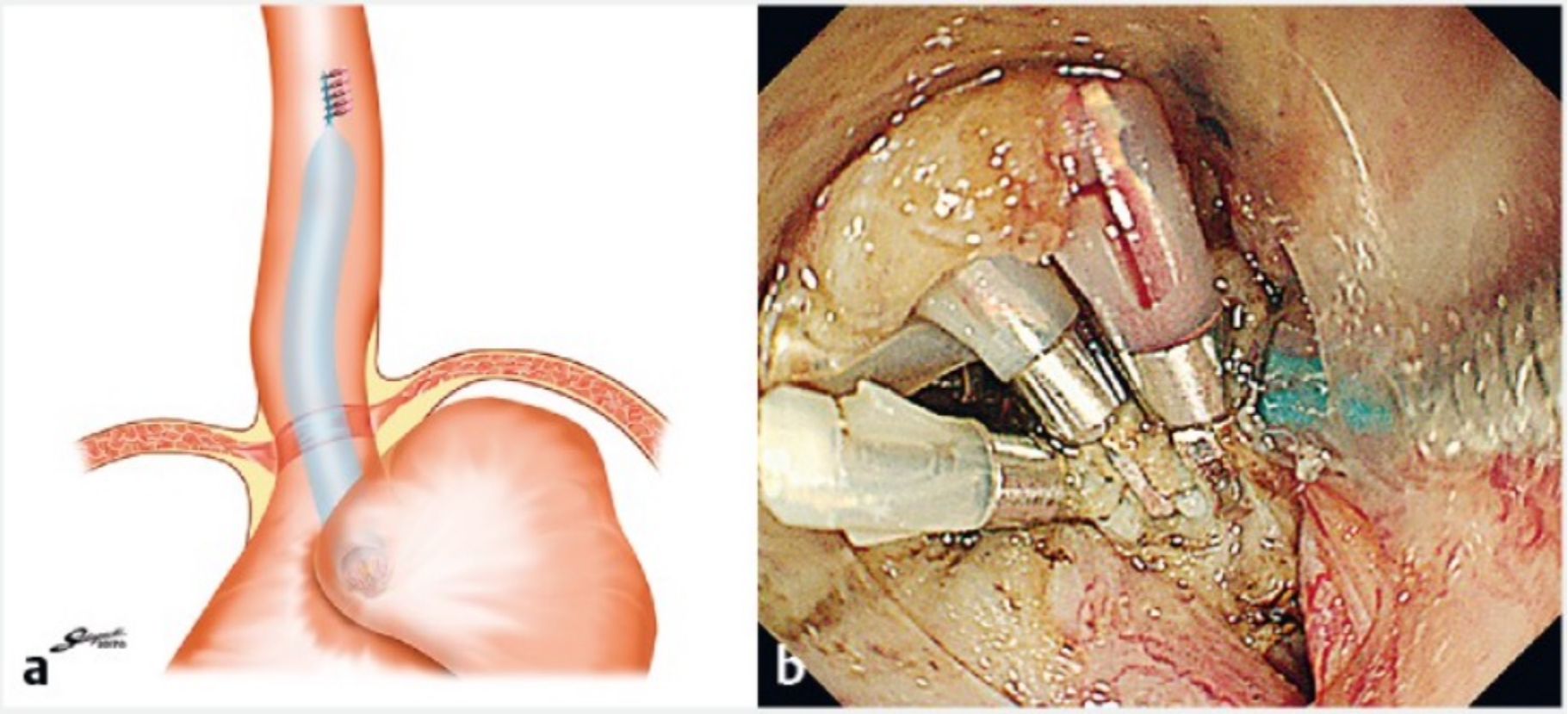
Inoue et al. Endoscopy. 2019.

POEM + F



Inoue et al. Endoscopy. 2019.

POEM + F



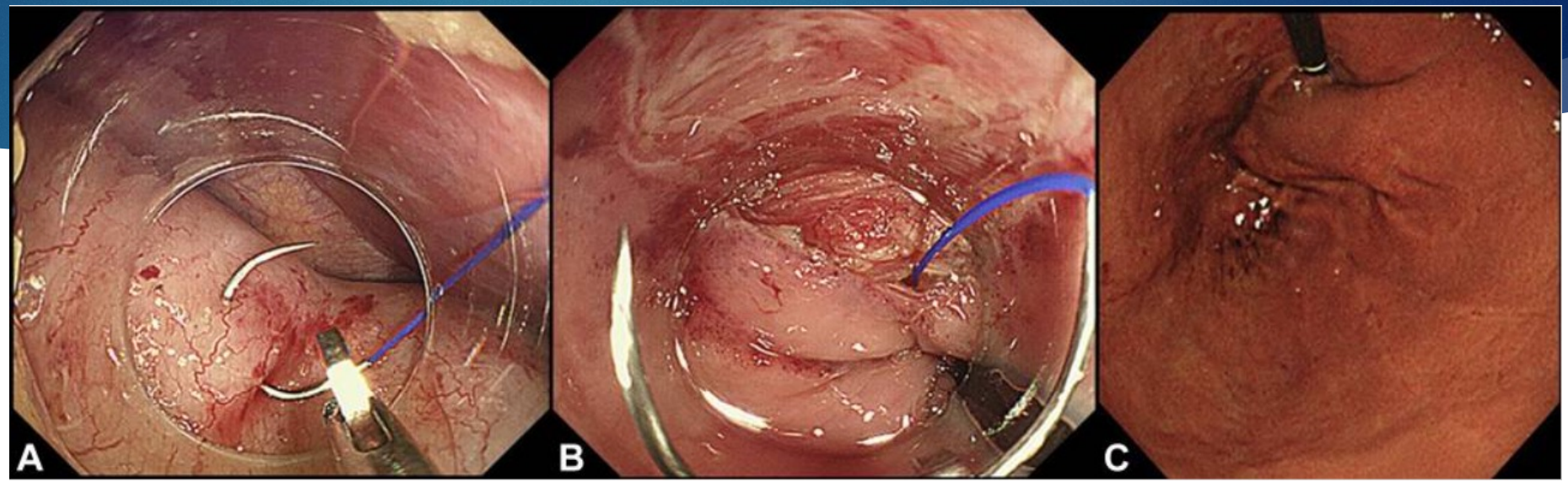
Inoue et al. Endoscopy. 2019.

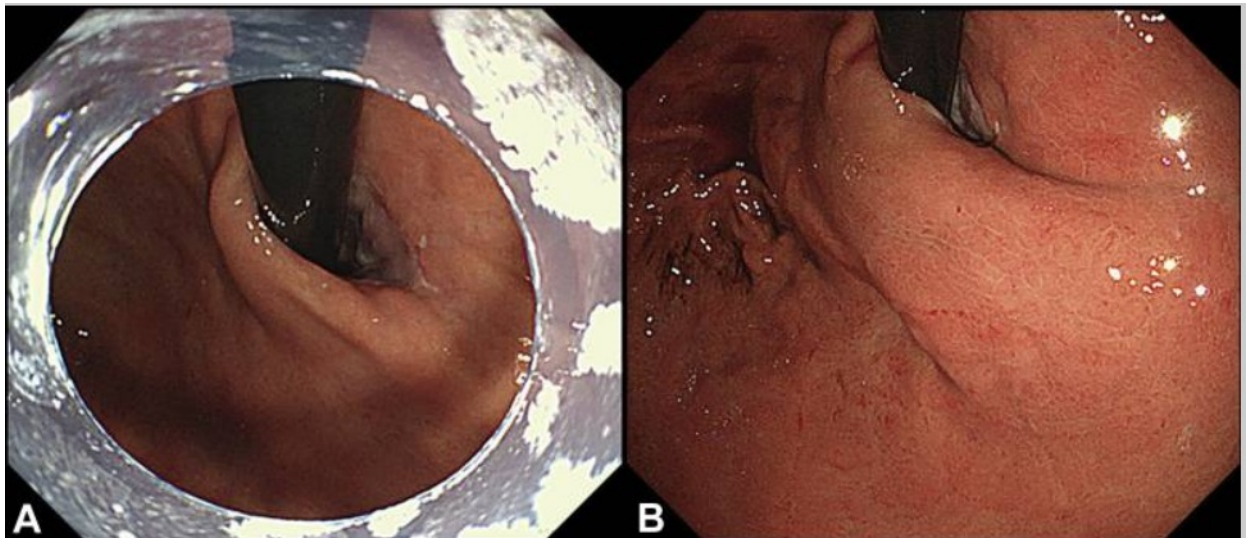
POEM + F

- Inoue et al. Endoscopy 2019. N=21
  - 100% Technical Success
  - Mean total procedure time 118.9 min
  - Mean fundoplication time 51.3 min
  - 0 adverse events
  - 95.2% retained wrap structure at 2 mo f/u EGD

VIDEO 5

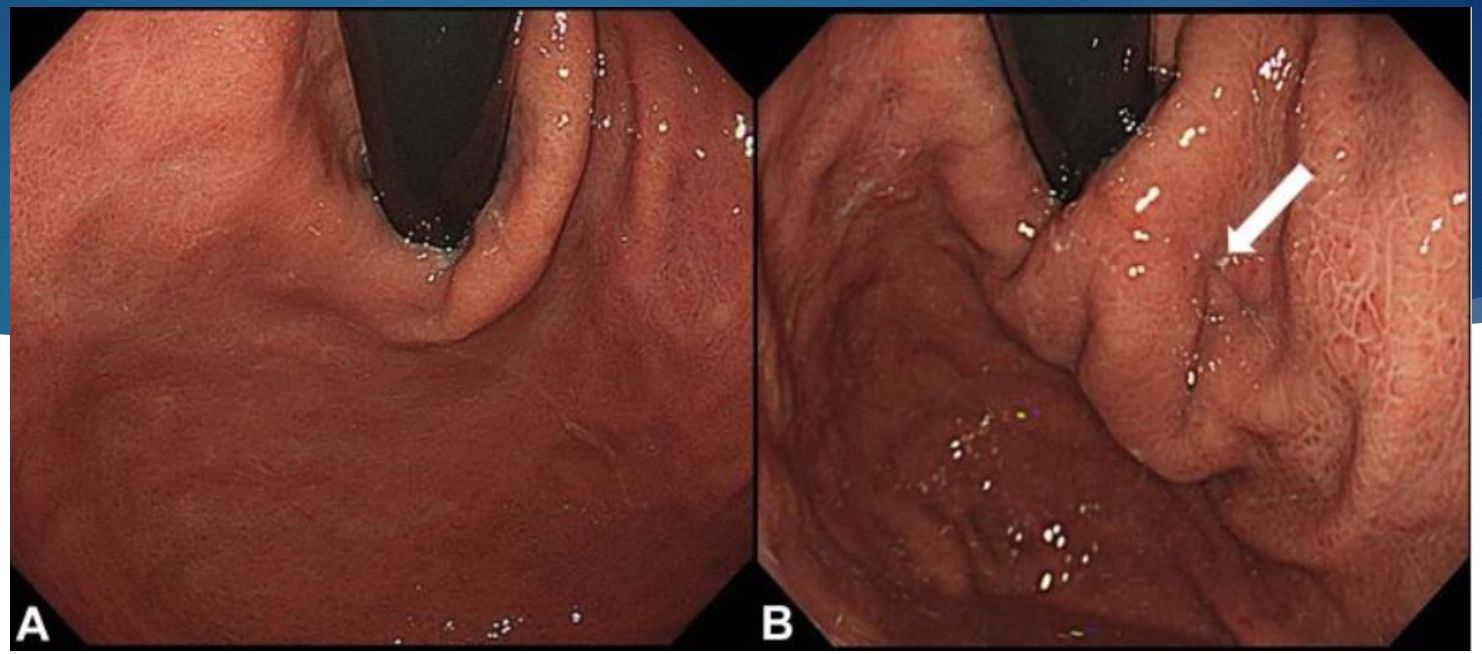
POEF

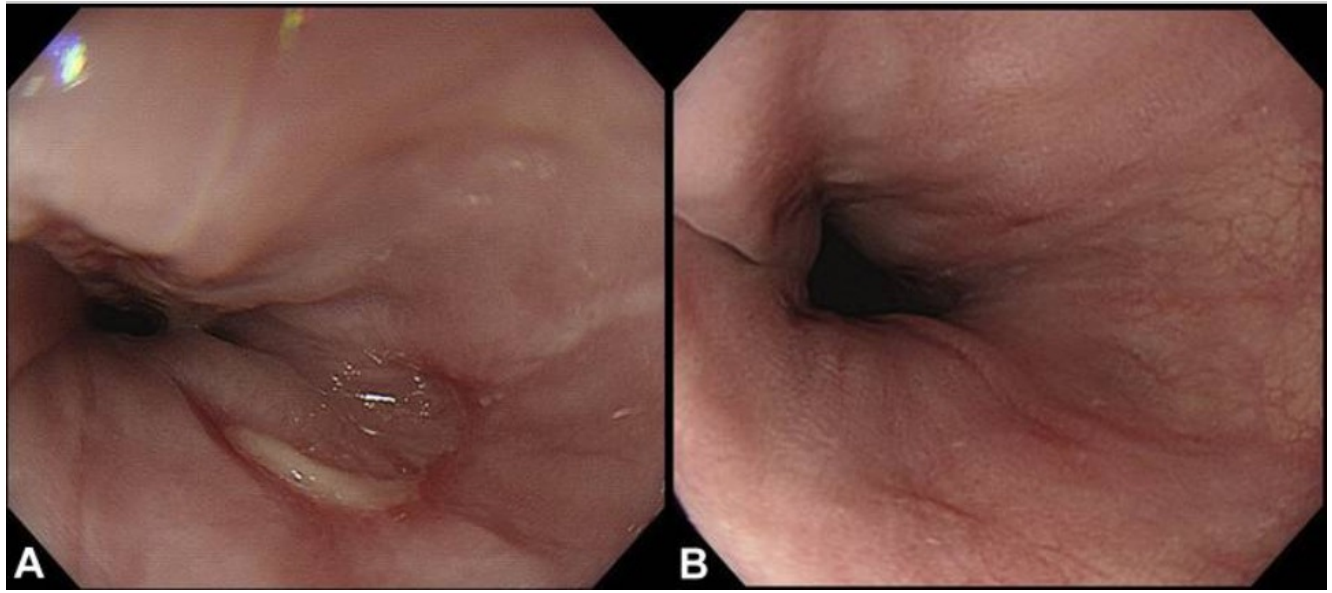




Toshimori. Video GIE. 2020.

POEF





Toshimori. Video GIE. 2020.

POEF

VIDEO 6

Toshimori. Video GIE. 2020.