Best of DDW: EUS

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Disclosures

- None

Pancreatic Walled-Off Necrosis (WON)

1. Plastic Pigtail vs LAMS in EUS-guided Drainage of WON: A Multicenter Randomized Trial (Prometheus Study) – Julio Guillermo Velasquez-Rodriguez at el

- Prospective RCT, 9 tertiary care centers in Spain, 6/2017-10/2020
- Assess whether LAMS is superior to DPPS in the endoscopic management of WON
- N=61 pts with WON randomized to LAMS group (n=30) and DPPS group (n=31), followed for >12months

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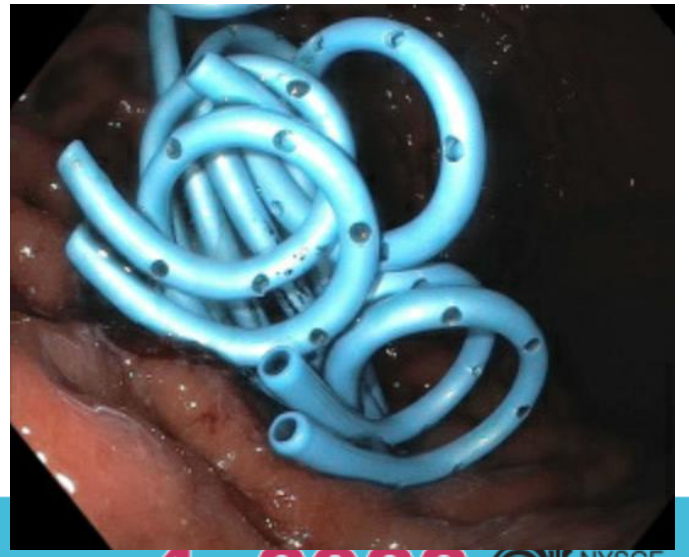


Prometheus Study Endpoints

- Primary endpoint:
  - Short-term clinical success (4 weeks) by reduction of pancreatic collection (<50% or <5cm)
- Secondary endpoints:
  - Long-term clinical success (at 4 months)
  - # of procedures
  - LOS
  - Procedure duration
  - Adverse events

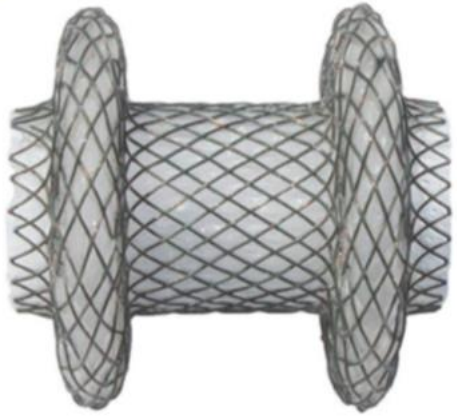
Prometheus Study: LAMS vs DPPS for Pancreatic WON

	LAMS	DPPS	P-value
Short-term Clinical Success (at 4wks)	63.6%	45.1%	p=0.218
Long-term Clinical Success (at 4m)	88%	73.1%	p=0.291
Stent-related Adverse Events	39%	45%	p<0.641
Procedure Duration	38min	53min	P=0.003
LOS (<1week)	58% Median 5 days	29% Median 15 days	p=0.04

- Fewer # of rescue procedures (i.e. cross-over, DEN, nasocystic drain) in LAMS
- *Similar short-term and long-term clinical success rates and AE but LAMS had shorter procedure duration, LOS, and fewer # of rescue procedures*

2. LAMS with or without Coaxial Plastic Stent for Treatment of Pancreatic WON: A Prospective Bicentric Randomized Controlled Trial – Petre Vanek et al

- Does placing double-pigtail plastic stents (DPPS) within LAMS prevent LAMS-related adverse events?
- N=67 consecutive patients with WON → LAMS with DPPS (n=34) vs LAMS without DPPS (n=34)
- All LAMS extracted 3 weeks after the index procedure



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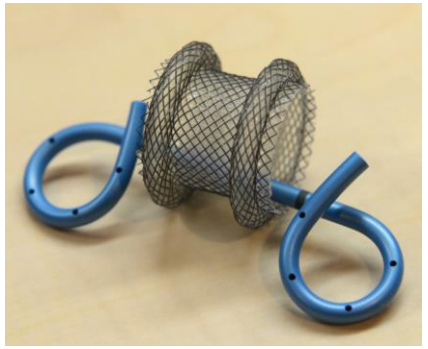


LAMS with or without Coaxial Plastic Stent for Treatment of Pancreatic WON: A Prospective Bicentric Randomized Controlled Trial

- Technical success rates: 100% in both groups
- No difference in need for re-intervention (i.e. endoscopy, perc drainage, or surgery)
  - Need for DEN 35% vs 48.5%, p=0.274
- Significantly lower AE in LAMS+DPPS (20.7% vs 51.5%, p=0.008)
  - Stent obstruction (14.7% vs 36.3%, p=0.042)
  - Bleeding (5.9% vs 12.1%, p=0.427)
  - Stent migration (0% vs 6.1%, p=0.239)
- No difference in mortality rate (2.9% vs 12.1%), p=0.197

EUS-Guided Gallbladder Drainage

1. EUS-Guided GB Drainage Using a Lumen-Apposing Metal Stent: A Multicenter Prospective Trial – Shayan Irani et el

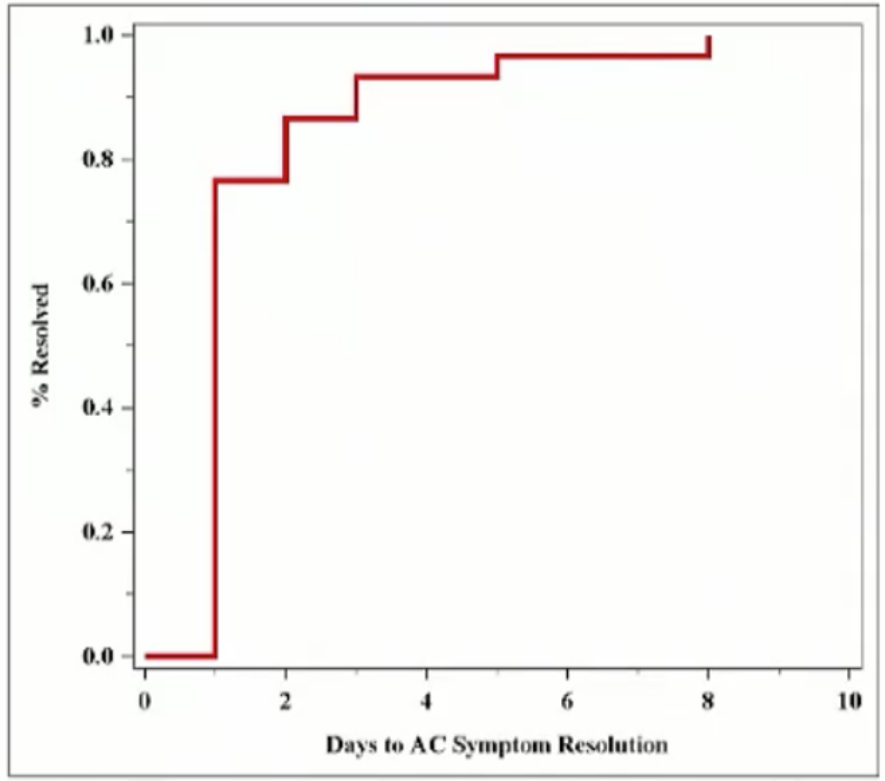
- Patients with acute cholecystitis (AC) unfit for cholecystectomy:
  - Assess safety and effectiveness of EUS-guided LAMS for GB drainage
- Consecutive patients with mild or moderate AC at 6 centers in the U.S.
  - Surgery/IR consulted on all patients
  - Exclusion criteria: ascites, contracted GB
  - LAMS size dependent on stone size/#
  - LAMS removed after 30-60 days (unless not medically recommended)
  - F/u at 30 days after LAMS removal or 90 days after LAMS placement (whichever came first)
- Endpoints:
  - Days until resolution of acute cholecystitis
  - Reintervention and recurrence rate
  - Adverse events

Results—Technical Success

- 30 patients underwent EUS-GB drainage
  - Transduodenal in 71.4% (20/28)
  - Transgastric in 28.6% (8/28)
- Technical success of LAMS placement: 93.3% (28/30)
  - 1 LAMS placement aborted due to intervening vessel
    - AC resolved with antibiotics
  - 1 LAMS misdeployed during transduodenal placement
    - managed with clip closure, AC resolved with perc chole
- Technical success of LAMS removal: 100%

Results—Clinical Success

- Clinical resolution of AC in 100%
  - Mean time to AC resolution: 1.4 ± 0.9 days for 28 patients who received LAMS



Results—Recurrence and Re-intervention

- Recurrence of AC: 10% (3/30) over mean f/u of 67.1 ± 22.6 days
- Re-intervention rate 16.7% (5/30)
  - 1 ERCP for biliary stent placement
  - 1 placement of double pigtail plastic stents to maintain patency of fistulous tract after removal of inwardly migrated LAMS + stone removal
  - 1 balloon dilation of transduodenal cholecystoduodenostomy +3 PS at LAMS removal
  - 2 ccy

Results—Adverse Events 36% (11/30)

Reported if unlikely, possible or probable relationship to LAMS and/or study procedure

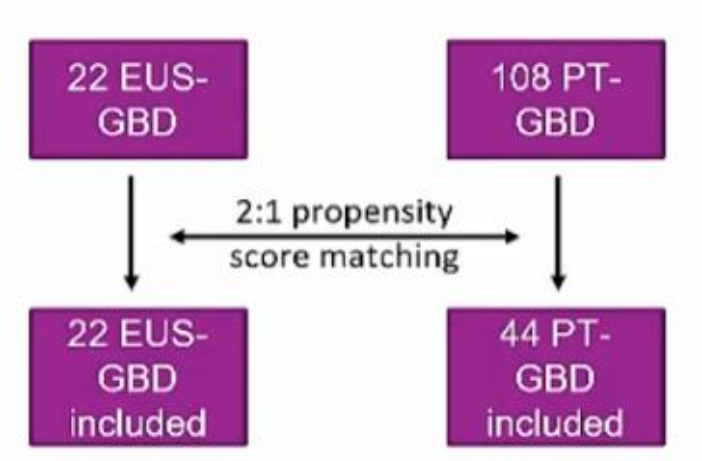
- 1 with sepsis 20 days after LAMS placement with residual GB wall thickening –resolved w abx
- 1 mild pleural effusion (hx of CHF and renal failure)
- 1 RUQ pain 56 days after LAMS placement, unlikely related to LAMS, resolved in 4 days
- 2 with self-limiting bleeding not requiring transfusion at LAMS removal after 1 month
- 1 death (hx of afib, CHF, CKD)
  - Day 3 AC resolved and LAMS removed on day 28. Stone/food debris also removed, GB polyp biopsied, two DDPS placed
  - Day 49: RUQ pain, cholecystitis, DPPS not visible → shock
  - Day 50: cardiac arrest, presumed septic shock possibly from recurrent AC

EUS-Guided GB Drainage Using a Lumen-Apposing Metal Stent: A Multicenter Prospective Trial

- Conclusion:
  - EUS-guided GB drainage with LAMS for patients with AC at high risk for ccy had high technical (93%) and clinical success (100%) with low recurrence rate of AC (10%) and moderate AE rate (36%).
  - Studies with long-term f/u are warranted
  - Studies on conversion to ccy after LAMS treatment are warranted

2.EUS-GBD vs Percutaneous GBD in Acute Cholecystitis: A Propensity Matched Analysis –Nicholas Koutlas

- Retrospective single-center study, 7/2019-10/2021
- Consecutive patients with AC, propensity score matched used to obtain a 2:1 ratio of P-GBD:EUS-GBD
  - Matched according to age, gender, and Charlson Comorbidity Index



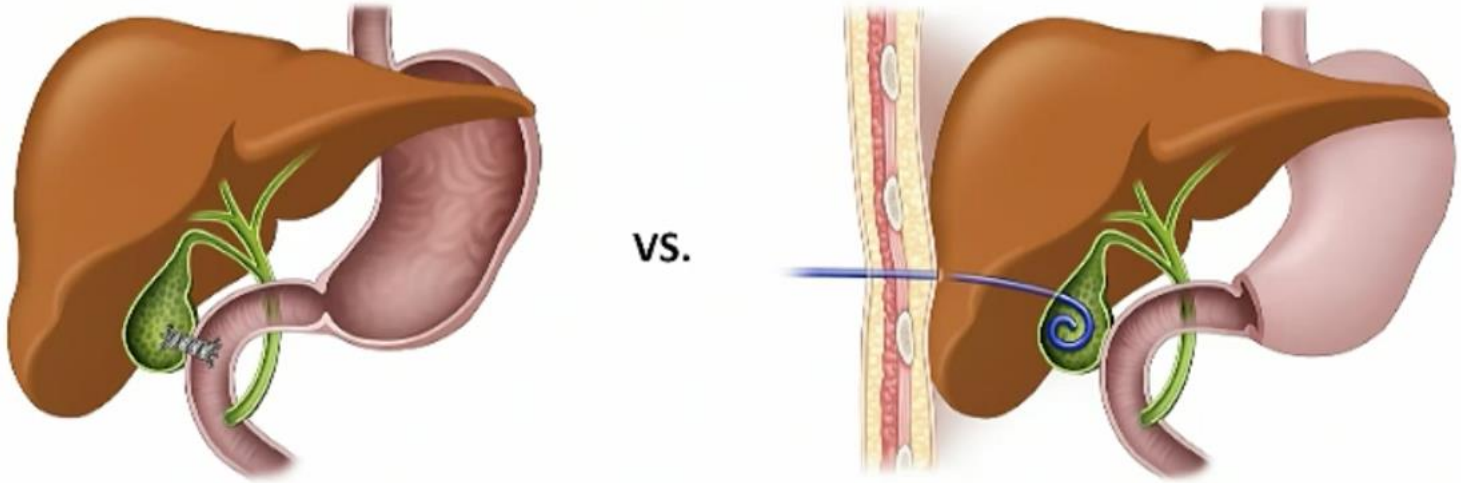
	EUS-GBD (n=22)	PT-GBD (n=44)	p value
Gender			0.77
Male	17 (77%)	31 (70%)	
Female	5 (23%)	13 (30%)	
Age Range			0.73
<50	0 (0%)	2 (5%)	
50-59	3 (14%)	3 (7%)	
60-69	4 (18%)	9 (20%)	
≥70 years	15 (68%)	30 (68%)	
Mean Charlson Comorbidity Index (SD)	7.7 (2.4)	7.7 (2.3)	0.94
Procedure Indication			0.10
Calculous cholecystitis	15 (68%)	39 (89%)	
Malignant cholecystitis	5 (23%)	4 (9%)	
Acalculous cholecystitis	2 (9%)	1 (2%)	

	EUS-GBD	PT-GBD	p value
Technical success	20/22 (91%)	44/44 (100%)	0.11
Clinical success	19/20 (95%)	40/44 (91%)	>0.99
Mean procedure time in minutes (SD)	38.9 (21.3)	27.8 (19.0)	0.028*
Mean number of procedures per patient (SD)	1.9 (0.6)	3.8 (2.9)	0.0003*
Adverse event rate	4/22 (18%)	26/44 (59%)	0.0006*
Mean post-procedure length of stay in days (SD)	5.6 (7.9)	6.1 (6.1)	0.77

- Similar technical/clinical success and LOS
  - Tech failure for EUG-GBD: 1 stent misdeployment and 1 lack of safe window
- Lower # of procedures and AE for EUS-GBD group
  - EUS-GBD: 2 stent migration, 1 abd pain, 1 stent misdeployment
  - P-GBD: 27 drain dislodgement, 3 abd pain, 3 drain occlusion, 1 cellulitis, 1 high drain output causing AKI, 1 bleeding, 1 encephalopathy, 1 bacteremia

3. Long-term Outcomes of EUS-guided GB drainage vs Percutaneous GB Drainage in Patients Are Unfit for Cholecystectomy: A Real-World Single-Center Experience –Sung Cho

- Aim: study long-term outcomes of EUS-GBD vs P-GBD in high surgical risk patients with acute cholecystitis (AC)
- Retrospective study, single-center, 2/2010-11/2015
- consecutive patients with AC by Tokyo guidelines
  - No improvement of AC after 24 hours of medical management
  - Excluded age <20, pregnant
- N=182, EUS-GBD (n=75) vs P-GBD (n=107)



ASAN Medical Center

Results

	EUS-GBD (n = 75)	P-GBD (n = 107)	*P*-value
Median age, years (IQR)	73 (65–79)	71 (59–79)	0.155
Sex, M:F, n (%)	35(47):40(53)	66(62):41(38%)	0.045
Indication of procedure, n (%)			0.964
ASA III or IV	39 (52%)	56 (52%)	
Advanced malignancy	36 (48%)	51 (48%)	
Cholecystitis type, n (%)			0.067
Calculous	36 (48%)	55(51%)	
Acalculous	10 (13%)	21 (20%)	
Malignant obstruction of cystic duct	29(39%)	31 (29%)	

Baseline characteristics: no differences except for gender distribution

ASAN Medical Center

Results

	EUS-GBD (n = 75)	P-GBD (n = 107)	*P*-value
Technical success	74/75 (98.6%)	106/107 (99.1%)	0.999
Clinical success			
Intention-to-treat analysis	74/75 (98.6%)	103/107 (96.3%)	0.292
Per-protocol analysis	74/74 (100%)	103/106 (97.1%)	0.270
Early adverse events	6/75 (8.0%)	15/107 (14.0%)	0.046
Bleeding		3	
Migration	1	6	
Leakage	2	3	
Pneumoperitoneum	3		
Occlusion		3	

Conservative management

Technical/clinical success: EUS-GBD ≒ P-GBD

Early adverse events: EUS-GBD < P-GBD

Cholecystogram

- Patent cystic duct → P-GBD tube removed (“ex-situ”) 81 patients
- Cystic duct not patent → P-GBD tube was maintained (“in-situ”) 18 patients

Conclusions:

- Comparable tech and clinic success rates with similar recurrence rate for ex-situ
- EUS-GBD with lower recurrence rate than in-situ
- Consider conversion to EUS-GBD for patients who cannot remove P-GBD to minimize AC recurrence

	EUS-GBD	P-GBD in-situ	p-value
Recurrence of cholecystitis	4.4%	38.9%	p<0.001
Cumulative recurrence during f/u			p<0.001
At 1month	1.5%	16.7%	
At 6 months	3.3%	34.20%	
At 1 year	3.3%	34.20%	
At 2 years	3.3%	67.10%	

	EUS-GBD	P-GBD ex-situ	p-value
Recurrence of cholecystitis	4.4%	7.4%	P=0.048
Cumulative recurrence during f/u			p<0.001
At 1month	1.5%	1.2%	
At 6 months	3.3%	3.7%	
At 1 year	3.3%	6.1%	
At 2 years	3.3%	6.1%	

4. EUS-Guided GB Drainage vs Percutaneous Drainage in Patients with Acute Cholecystitis Undergoing Elective Cholecystectomy –Amy Tyberg et al

- Multicenter international retrospective study
- Aim: compare outcomes of patients who undergo elective CCY after EUS-GBD vs P-GBD
- N=139 (EUS-GBD n=46, P-GBD n=93)
  - Similar tech/clin success and AE
  - EUS-GBD
    - shorter time to sx resolution
    - shorter LOS from procedure to discharge
    - lower re-admission rate

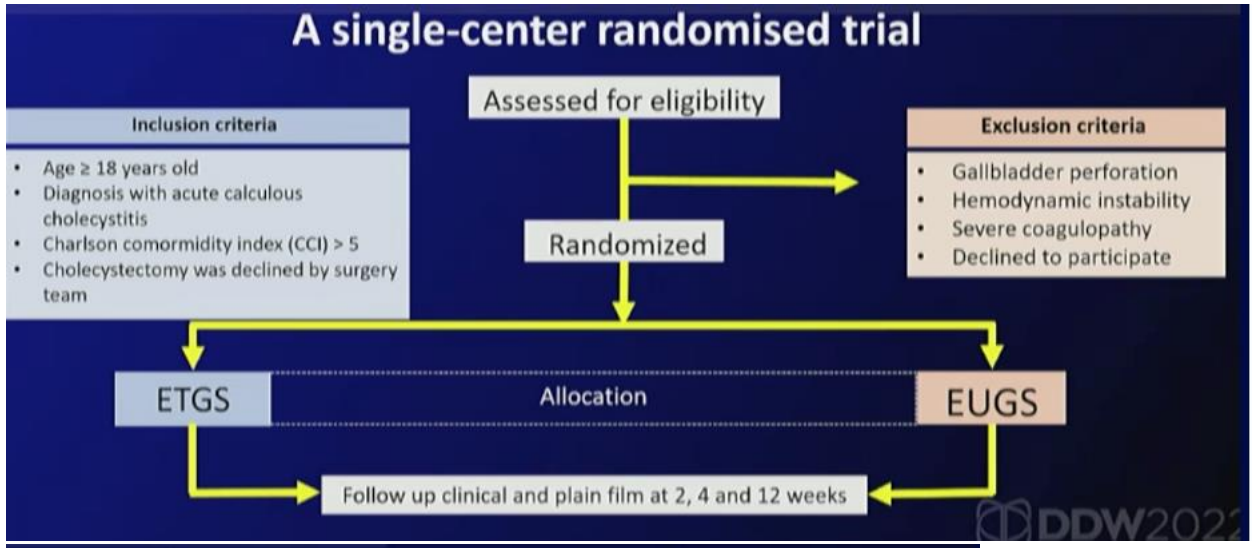
N=139	EUS-GBD N=46	PC-GBD N=93	
Gender (M/F)	27 Males	50 Males	
Age	Mean 73.7 years	Mean 71.7 years	
Etiology of Cholecystitis (Gallstones, Acalculous, Malignancy, Other = Please list)	Gallstones=36, Acalculous=8, Malignancy=2	Gallstones=75, Acalculous=13, Malignancy=5	
Charlson Co-Morbidity Index	Mean 3.9	Mean 4.3	
Length of Procedure (min)	Mean 39.6 mins	Mean 31 mins	
EUS puncture site (duodenum, stomach, jejunum)	Stomach= 37, Duodenum=9	NA	
Type of Stent: Plastic or Metal	Metal=46, Plastic=4	NA	
Technical Success (Y/N)	45/46	93/93	
Drainage Procedure Adverse Events	Bleeding=3, Stent Misplacement=3, Peritonitis=1, Pain=3, Ulcer in Stomach=2, Nausea /Vomiting = 1 (n=13, 28%)	Free air=1, Bleeding=4, sepsis=1, hypotension=2, Dislodged catheter/clogged=20, skin infection=4, acute cholecystits=2 (n=34, 36.6%)	
Clinical Resolution of Cholecystitis Symptoms (Y/N)	42/46 (91%)	80/93 (86%)	
Time to Resolution of Symptoms Post-Procedure (days)	Mean 1.5 days	Mean 2.4 days	p=0.0006
Hospital Re-admission for Cholecystitis or Procedure-Related Reason (Y/N)	Yes=4	Yes=35 (mostly due to clogged drain)	p=0.0003
Total Length of Hospital Stay from EUS-GBD to Discharge (days)	Mean 2.4 days	Mean 11.6 days	p=<.00001
How long after EUS-GBD/PC-GBD procedure was ccy performed (days)?	Mean 38 days	Mean 69.6 days	p=0.007

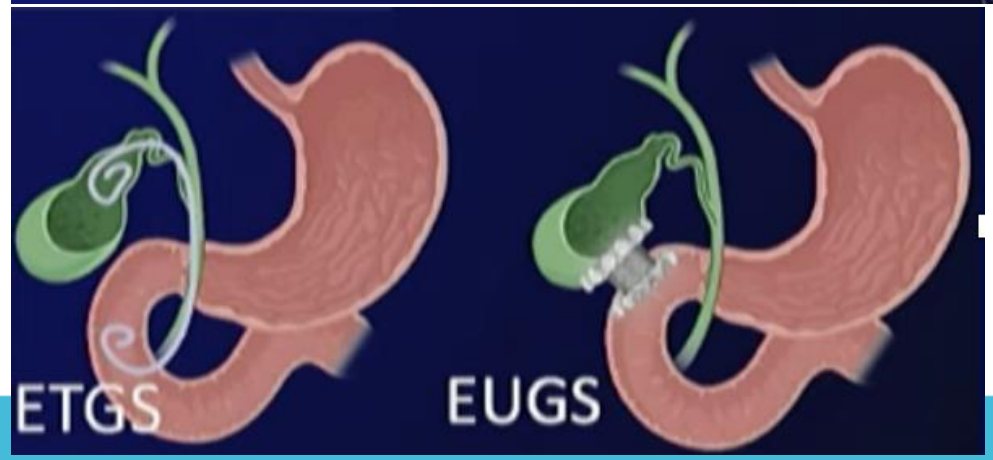
Surgical Outcome

- Surgical tech success rate >95%
- Rate of conversion to open ccy similar
- Similar post-op AE
- EUS-GBD: Shorter interval between GBD and surgery (38 vs 7 days, p=0.007), shorter surgery time, and LOS
- EUS-GBD should not be considered a contraindication for future ccy

Surgical Outcomes	EUS-GBD	PC-GBD	
Type of Cholecystectomy (lap, open, lap to open)	Lap=30, Lap to Open=5, Open=11	Lap=66, Lap to open=18, open=8	p=0.19
Technical Success (Y/N)	44/46	90/92	
Procedure Time (min)	Mean 84.2 mins	Mean 165.4 mins	p<0.00001
Surgery Procedure Adverse Events	Bleeding=2, Septic shock=1, bile leak=3, skin infection=3 (n=9, 19.5%)	Leak=4, bleeding =4, cystic duct injury=2, peritonitis=1, afib=3, skin infection-4, cholestasis=3, hypoxia=1 (n=22, 23.6%)	p=0.058
Clinical Resolution of Cholecystitis Symptoms (Y/N)	44/46 (95.6%)	88/92 (95.6%)	
Time to Resolution of Symptoms Post-Procedure (days)	Mean 4.2 days	Mean 6.3 days	p=0.005
Hospital Re-admission for Cholecystitis or Procedure-Related Reason (Y/N)	Yes = 8	Yes=15	
Number of Hospital Readmissions	Mean 0.75	Mean 1.4	
Total Length of hospital stay from CCY to Discharge (days)	Mean 5.4 days	Mean 12.3	p=0.001
Longest Follow-up Time (weeks)	Mean 20.7 weeks	Mean 39 weeks	

5. Endoscopic Transpapillary Stenting vs EUS-Guided Transmural GB Drainage in High Surgical-Risk Patients with Acute Calculous Cholecystitis: A Randomized Trial – Natee Faknak et al





- N=30, (ETGS 16, EUGS 14)
- Aim: compare the rate of recurrent cholecystitis after endoscopic GB drainage between ETGS and EUGS in high-surgical risk patients
  - Technical & Clinical success rate
  - Adverse events

Endoscopic transpapillary GB stenting (ETGS) using 7Fr x15cm double pigtail stent
EUS guided GB stenting (EUGS) using 6cm fully-covered w 7Fr x 5cm double pigtail stent or 15mm LAMS

Baseline characteristics	Group A: ETGS (n = 16)	Group B: EUGS (n = 14)	P value
Age (years), mean (SD)	83.6 (6.2)	81.7 (7.0)	0.45
Male, n (%)	7 (43.8)	7 (50)	0.73
Charlson comordity index, median (range)	6 (6-11)	6 (6-10)	0.21

- Comparable tech/clin success rates, AE, and recurrence rate
- ERCP for pts with concurrent choledocholithiasis or surgical candidates

	ETGS (n=16)	EUGS (n=14)	p-value
Technical success	81.3% (13/16) (2 cystic duct stone, 1 acute angle of cystic duct)	100% (14/14) (8 FCSEMS w DPS) (6 LAMS)	0.23
Clinical Success	100% (13/13)	100% (14/14)	1.00
Recurrent cholecystitis At median f/u of 215 days	0% (0/16)	7.1% (1/14) (due to stent migration)	0.47
Adverse events	12.5% (2/14) * 2 mild pancreatitis	21.4% (3/14) *3 abd pain *1 FCSEMS migration	0.64
LOS (median days)	6 (3-25)	7 (5-23)	0.87

6. Debate: EUS vs ERCP for GB Drainage

--Petros Benias and Todd Baron

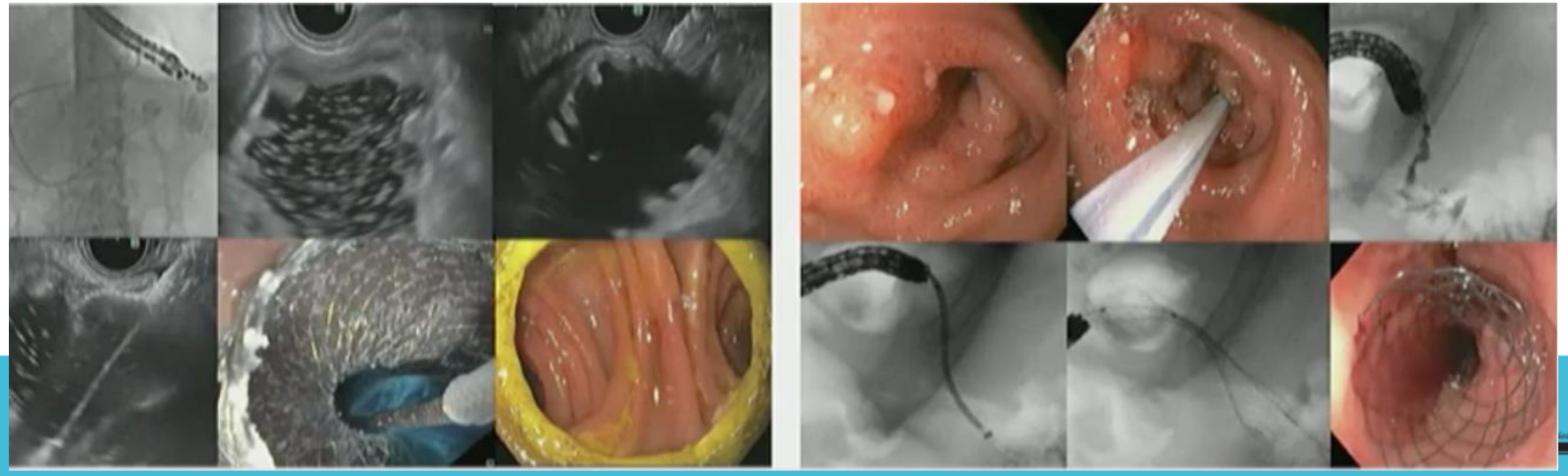
EUS-GBD	ERCP Transpapillary GBD

• Less/no fluoro
• Shorter procedure time
• Wider stent diameter
  • Stent patency
  • Allows GB stone extraction
• Similar clinical success rates and AE but no risk of PEP
• Not FDA approved
• When AE occurs it can be severe
	• Can remove CBD stone
	• Can be performed w/o sphincterotomy for pts with coagulopathy
	• When EUS approach is not ideal (large ascites, contracted GB, necrotizing AC)
	• Selective cystic duct cannulation can be challenging
	• Smaller stent diameters, tortuous cystic duct

EUS-Guided Gastrojejunostomy

1. EUS-Guided Gastrojejunostomy Shows Higher Clinical Success and Lower Dysfunction Rate in Comparison with Duodenal Stents in Malignant Gastric Outlet Obstruction: An International Multicenter Propensity Score Matched Comparison --- Rogier Voermans et al

- Multicenter retrospective study 2015-2021 in 3 European centers
- 224 consecutive pts undergoing duodenal SEMS placement (n=107) or EUS-GJ (n=107) for malignant GOO, min f/u 30 days
- Primary outcome:
  - clinical success (GOOSS ≥2) and stent dysfunction (GOOSS ≤ 1 after initial clinical success)



GOO Scoring System

- 0 = no oral intake
- 1 = liquids only
- 2 = soft solids
- 3 = almost complete diet
- 4 = full diet

EUS-GJ vs Duodenal Stent for Malignant GOO

- EUG-GJ had higher clinical success and lower stent dysfunction rate with similar AE rates
- EUS-GJ preferrable over duodenal stenting when adequate expertise is available

	EUS-GJ	Duodenal stent	
Technical Success	94.3%	97.7%	P=0.44
Clinical Success (GOOSS ≥2)	90.9%	75%	P=0.008
Stent Dysfunction (GOOSS ≤ 1)	1.3%	25.8%	P<0.001
Overall Adverse Events	10.2%	20.5%	P=0.093

GOO Scoring System

- 0 = no oral intake
- 1 = liquids only
- 2 = soft solids
- 3 = almost complete diet
- 4 = full diet

2. Outcomes of EUS-guided Gastroenterostomy vs Surgical gastroenterostomy and Enteral Stenting for GOO: A Large Two-Center International Study –Veeravich Jaruvongvanich

- Consecutive patients presenting with GOO
- N= 463 (EUS-GE n=241, ES n=142, surgical-GE n=80)
  - 81% malignant GOO, 6.5% altered anatomy
  - Followed for median 184 days
- Primary endpoint:
  - need for re-intervention
- Secondary endpoints:
  - Technical success
  - Clinical success (ability to tolerate at least a full liq diet within 5 days)
  - LOS
  - AE

Table 2 Treatment outcomes and adverse events

	EUS-GE (n=241)	ES (n=142)	Surgical-GE (n=80)	Overall P-value	P-value EUS-GE vs. ES ¶	P-value EUS-GE vs. surgical-GE ¶
Technical success (N, %)	237 (98.3)	141 (98.9)	80 (100.0)	0.58		
Clinical success (N, %)	235 (97.5)	128 (90.1)	68 (85.0)	<0.0001	0.002*	<0.0001*
Length of hospital stay (days, median [IQR])	2 (1-3)	4 (1-10)	5 (3-9.75)	<0.0001	<0.0001*	<0.0001*
Rate of re-intervention (N, %)	4 (1.7)	20 (14.1)	12 (15.0)	<0.0001	<0.0001*	<0.0001*
AEs, N (%)	22 (9.1)	55 (39.3)	23 (28.7)	<0.0001	<0.0001*	<0.0001*
Abdominal pain	2 (0.8)	1 (0.7)	3 (3.8)			
Stent misdeployment	5 (2.1)	0	0			
Ileus/gastroparesis	0	1 (0.7)	8 (10)			
Infection	9 (3.7)	10 (7.0)	6 (7.5)			
Anastomotic leak	1 (0.4)	0	4 (5.0)			
Perforation	0	3 (2.1)	1 (1.3)			
Bleeding	4 (1.6)	5 (3.5)	2 (2.6)			
Stent migration	1 (0.4)	8 (5.6)	0			
Stent tumor ingrowth	0	10 (7.0)	0			
Stent obstruction	1 (0.4)	13 (9.2)	0			
Stent inadequate expansion	1 (0.4)	0	0			
Biliary obstruction	0	2 (1.4)	1 (1.3)			
Others	4 (1.6)	13 (9.2)	7 (8.8)			

¶ P-value of less than 0.0167 indicates statistical significance based on a Bonferroni correction and * indicates statistical significant

Abbreviation: AE: adverse event; ES: enteral stenting; EUS-GE: endoscopic ultrasound-guided gastroenterostomy; surgical-GE: surgical gastroenterostomy

- Similar technical and clinical success.
- EUS-GE group had:
  - lower reintervention rate
  - shorter median LOS
  - Lower AE
- Multivariable logistic regression analysis adjusting for baseline differences showed that EUS-GE was a negative predictor for re-intervention relative to ES (OR 0.16, CI 0.30-0.87, p=0.03)

EUS-Guided Bile Duct Cannulation and Drainage

1. EUS-guided Rendezvous Technique vs Precut Papillotomy as Salvage Technique in Patients of Benign Biliary Disease with Difficult Biliary Cannulation: A Randomized Controlled Trial – Arup Choudhury et al

- Prospective RCT of patients with benign biliary disease who underwent ERCP and had difficult cannulation between 7/2020 – 5/2021
  - Excluded malignant etiology, hilar obstruction, prior sphincterotomy
- N=100, 50 pts randomized to EUS-guided rendezvous (EUS-RV) and 50 pts to pre-cut papillotomy (PcP)
- Primary outcomes: Technical success, procedure time, AE

EUS-guided hybrid rendezvous technique as salvage for standard rendezvous with intra-hepatic bile duct approach

Takuji Iwashita, Shinya Uemura, Kensaku Yoshida, Naoki Mita, Ryuichi Tezuka, Ichiro Yasuda, Masahito Shimizu

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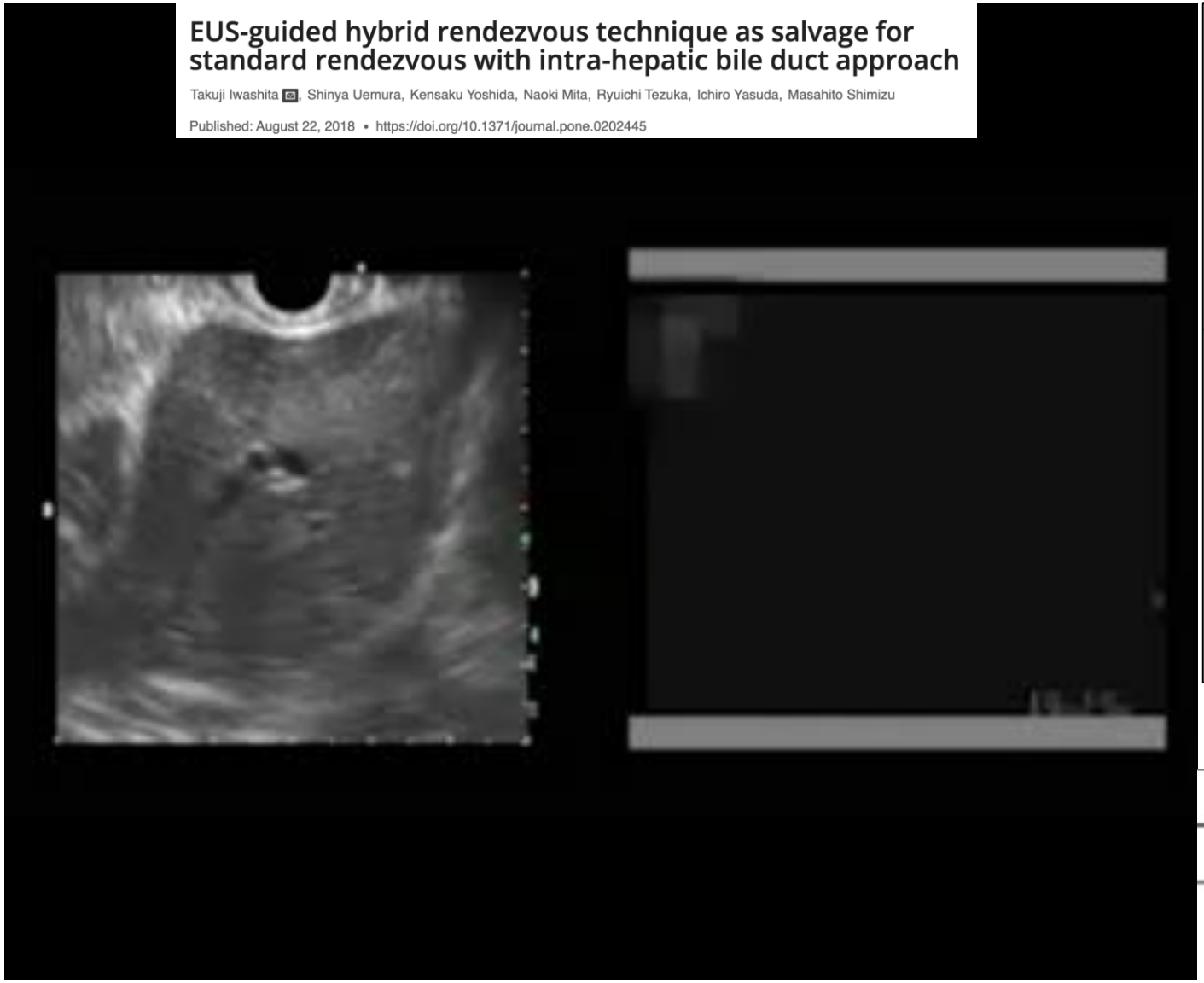
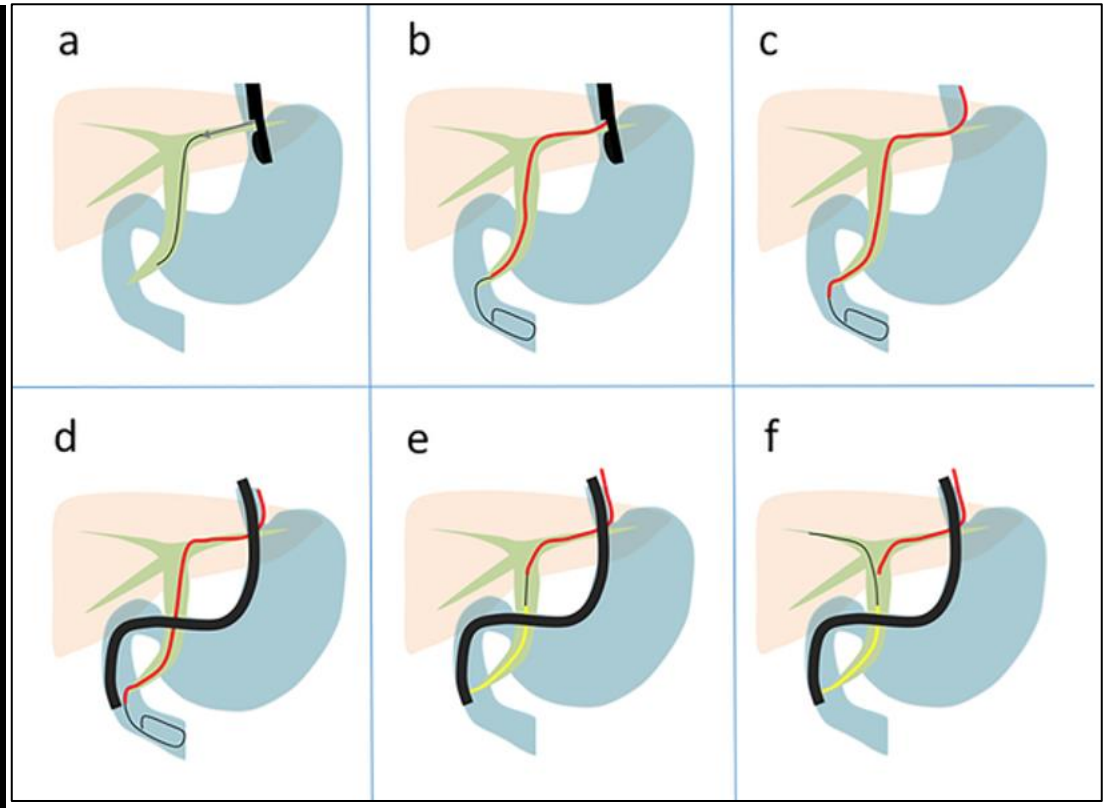
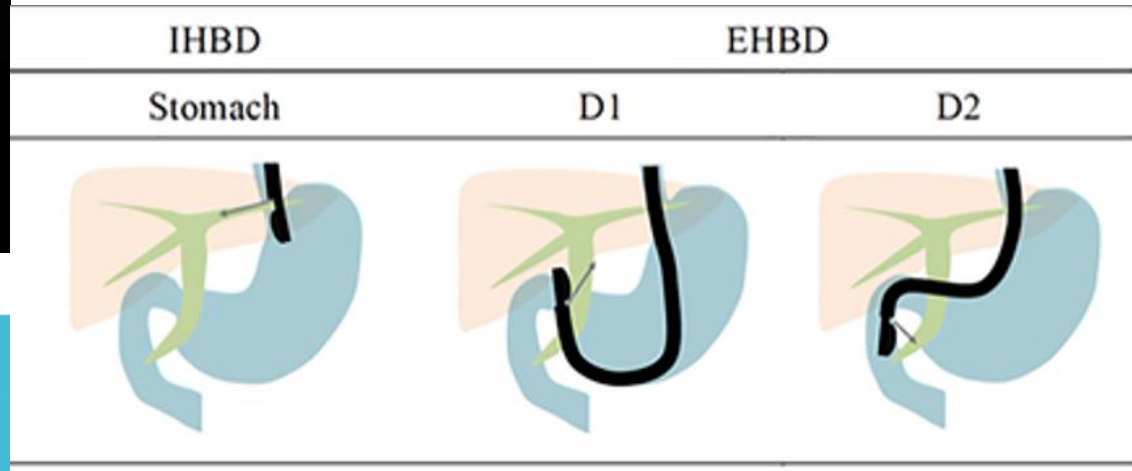






Iwashita et al. PLoS One. 2018 Aug 22;13(8)

June

Table 1: Comparison of technical success between EUS-RV vs PcP.

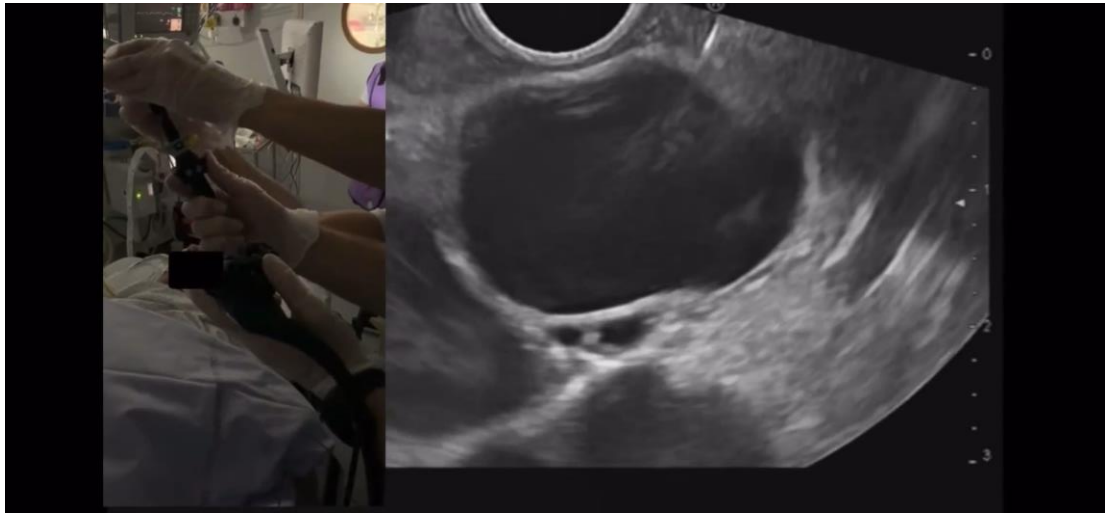
		EUS- guided rendezvous technique (n=50)	Precut papillotomy (n=50)	P value
Age (mean ± SD) years		52.98 ± 12.82	50.5 ± 15.65	
Sex (male) No (%)		9 (18%)	19 (38%)	
Cholangitis (yes) no (%)		9 (18%)	10 (20%)	
Etiology no (%)	Stone	43 (86%)	36 (72%)	0.155
	Stricture	5 (10%)	7 (14%)	
	Biliary injury	2 (4%)	7 (14%)	
Technical success in achieving of deep biliary cannulation no (%)		46 (92%)	45 (90%)	1.000
Overall time (total time) of the procedure (min.) (Median, IQR, min-max)		10.1,16.8,1.5-45.25	9.75,7.79,1.75-34	0.315
Requirement of rescue therapy n (%)		4 (8%)	5 (10%)	1.000

- Similar technical success rate (92% vs 90%) and median procedure time (10.1 vs 9.75 min) between EUS-RV and PcP
- Similar AE (12% vs 10%, p=0.749) including PEP rates
  - Inadvertent PD cannulation during primary cannulation attempt was a risk factor for PEP ($p<0.001$)
  - In a subgroup without inadvertent PD cannulation, EUS-RV group showed lower trend for PEP (0% vs 5.6%, p=0.49)

2. Short and Long-Term Efficiency of EUS-Guided Biliary Drainage Using Electrocautery-Enhanced LAMS In Case of Failed ERCP, A Large Prospective Study of 118 Cases –Jermie Albouys et al

- ERCP transpapillary stenting is the gold standard for distal malignant bile duct obstruction but is associated with 10-30% failure rate
- Aim: evaluate efficacy and safety of LAMS for biliary drainage for malignant obstruction
- Prospective, observational, single-center study (France), 8/2017-9/2021
- N=118
  - median bili 16.2mg/dL
  - median bile duct dilation 18mm
  - 77% with pancreatic adenocarcinoma

Result

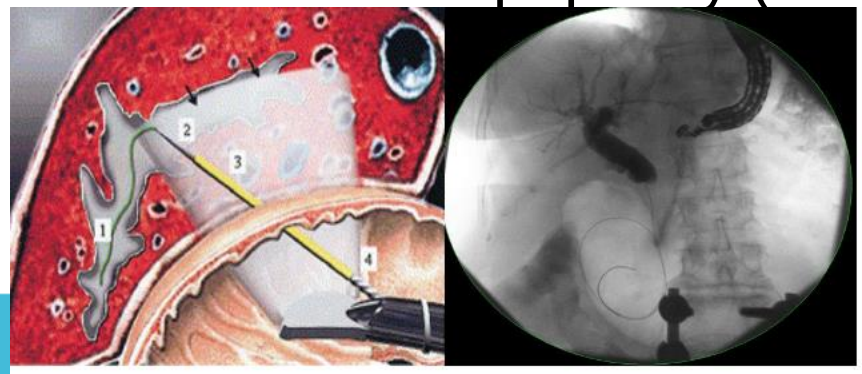


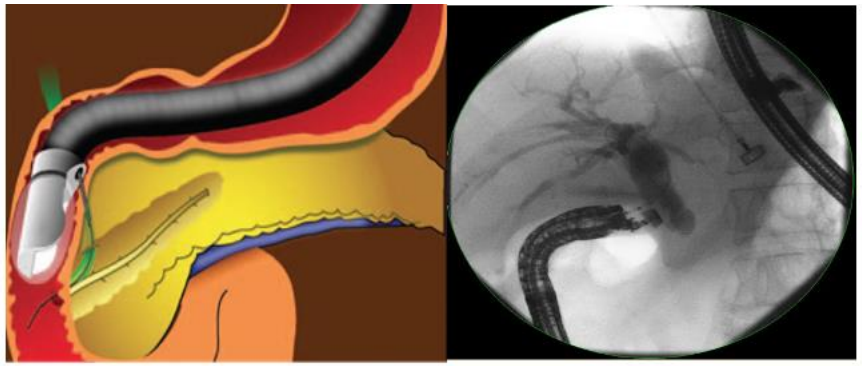
Jacques et al. Gastrointest Endosc. 2020 Jul

- Technical success 97.43%
- Clinical success 95.72%
- Stent dysfunction 16.10%
  - Increased risk in cholangiocarcinoma (p=0.011), duodenal stent (p=0.002), CBD diameter <14mm preprocedure (OR 4.395, CI 1.27-15.16, p=0.019)
- AE 0.8%
  - Stent misdeployement (distal flange in retroperitoneum, clip closed)
- Conclusion: overall durable stent function with minimal AE

3. EUS-Guided Biliary Drainage vs ERCP In Malignant Biliary Obstruction Prior to Hepatobiliary Surgery: An International Multicenter Comparative Study –Amy Tyberg et al

- Multicenter international retrospective study of patients who underwent hepatobiliary surgery after having EUS-BD or ERCP
- Outcome after hepatobiliary surgery after EUS-BD vs ERCP
- N=145, (EUS-BD n=58, ERCP n=87)
  - Pancreatic ca>CCA>other
  - EUS-BD: 29 hepaticogastrostomy (50%), 24 choledochoduodenostomy (41%), 5 EUS-rendezvous transpapillary (9%)





- Biliary Access: Intrahepatic vs Extrahepatic

Burmester E: Gastrointest Endos 2003
Gupta K. Rev Gastroenterol Disord 2007

Endoscopic Outcomes

- High technical and clinical success in both groups.
- Similar AE and LOS
- EUS-BD had lower
  - Reintervention prior to surgery (9% vs 38%, p=0.0001)
  - Time between endoscopy to surgery (37 days vs 64 days, p=0.0205)

n=145	EUS-BD, n=58	ERCP, n=87	
Age	Mean 66 years	Mean 68 years	
Gender	26 Males	46 Males	
Underlying diagnosis	Malignant=58	Malignant =87	
Diagnosis	CCA=12, PanCa=41, Other Malignancy=1, Other=4	PanCa=58, CCA=22, Gallbladder cancer=2, Other=5	
Failed conventional ERCP?	Yes, n=56	NA	
Abnormal anatomy?	Yes, n=2	Yes, n=4	
Stent location	Hepaticogastrostomy=29, Choledochoduodenostomy=24, Transpapillary via RDV=5	NA	
Type of stent placed	Plastic = 9, Metal =51	Plastic=65, Metal=13	
Endoscopy technical success (stent deployment)	n=58, 100%	n=83, 95%	
Endoscopy clinical success: resolution of obstruction post-procedure	Yes, n=57 (98%)	Yes, n=82 (94%)	
Endoscopy adverse events	Biloma=3, Bleeding = 4, Infection =1, Stent Dislodgement=2 (n=10, 17%)	Infection=2, Bleeding=7, Post-ERCP Pancreatitis=10, Cholangitis=4 (n=23, 26%)	p value 0.2288
Total length of hospital stay from endoscopy to discharge	Mean 6.7 days	Mean 9.25 days	p-value 0.3844
Additional intervention required	Yes, n=5 (9%)	Yes, n=33 (38%)	p- value 0.0001

Surgical Outcomes:

- Higher surgery technical/clinical success in EUS-BD group
- Total LOS from surgery to discharge was lower in the EUS-BD group

	EUS-BD, n=58	ERCP, n=87	
Type of surgery performed	Whipple=41, Diagnostic Lap=2, BD deviation=5, CCY=2, Partial hepatectomy=7, Gastroenterostomy=1	Whipple=56, Diagnostic Lap=4, CCY=2, Partial hepatectomy=14, Aborted Surgery=11	
Time between intial procedure and surgery	Mean 37 days	Mean 64 days	p-value 0.0205
Surgery technical success	Yes, n=56 (97%)	Yes, n=72 (83%)	p-value 0.009
Surgery clinical success (tumor resection, relief of obstruction, etc)	Yes, n=56 (97%)	Yes, n=65 (75%)	p-value 0.0004
Surgery adverse events	Leak=1, Bleeding=2, Abscess=2, Stricture=1 (n=6, 10%)	Sepsis=2, Skin infection=3, Post surgical collection=6, Leak=2, other=5 (n=18, 21%)	p-value 0.1152
Re-stenting after surgery	Yes, n=3 (5%)	Yes, n= 13 (15%)	
Total length of hospital stay from Surgery to Discharge (days)	Mean 10 days	Mean 19 days	p-value 0.0081
Total follow-up from initial intervention	Mean 12.8 months	Mean 6.9 months	
Alive	Yes, n=36 (62%)	Yes, n= 58 (67%)	

Conclusion

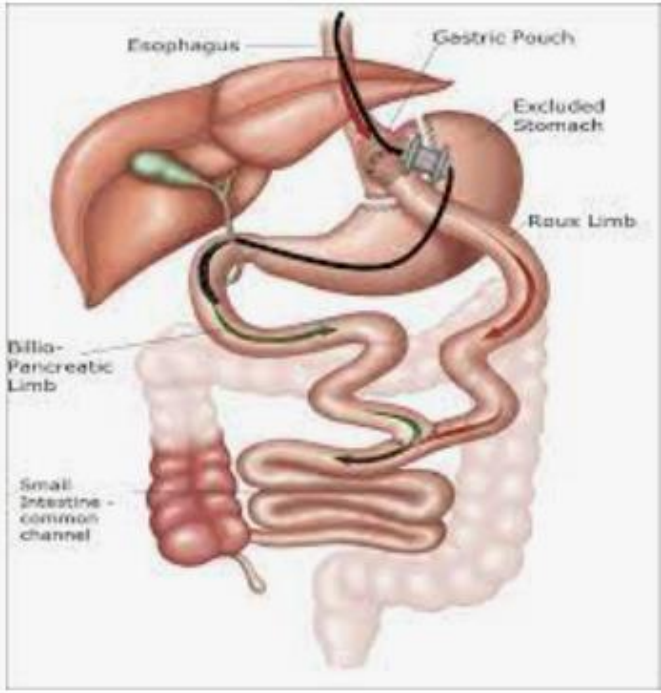
- EUS-BD appears non-inferior (and possibly superior) to conventional ERCP for biliary drainage prior to hepatobiliary surgery

- EUS-BD should not impede patients from undergoing surgical intervention; surgical candidacy should not impede patients from undergoing EUS-BD

EUS-Directed Transgastric ERCP (EDGE)

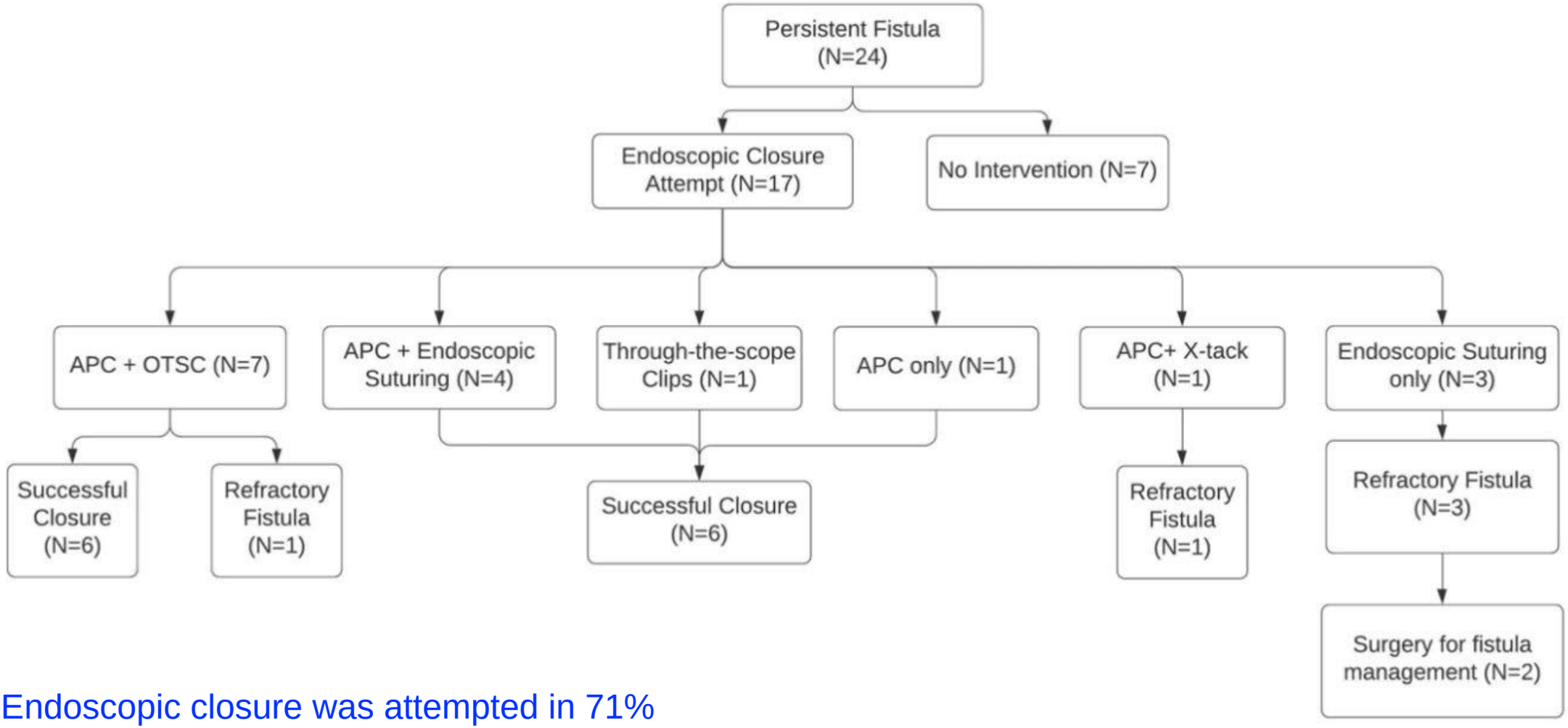
1. Factors Predictive of Persistent Fistulas in EUS-Directed Transgastric ERCP (EDGE), A Multicenter Case-Control Study –Bachir Ghandour et al

- EDGE is an established method for managing pancreaticobiliary pathology in RYGB patients.
- ~ 20% risk of persistent fistula after LAMS removal, leading to weight gain and marginal ulceration
- Aim:
  - Assess factors associated with the development of persistent fistulas
  - Technical success of endoscopic fistula closure
- Case-control study in 8 US centers, 2/2015-9/2021
  - Patients with persistent fistula >8 weeks after LAMS removal vs patients who did not develop fistula
  - Mean f/u of 19.8 +/- 16.7months



	Persistent Fistula (N=24)	No Persistent Fistula (N=60)	Total (N=84)	p-value
Female; n (%)	20 (83.3)	53 (88.3)	73 (86.9)	0.7
Mean age (mean ± SD)	57.5 ±10.6	60.3 ±12.3	59.5 ± 11.8	0.3
Diabetes; n (%)	6 (27.3)	14 (27.5)	20 (27.4)	0.9
Active Smoker; n (%)	1 (4.5)	3 (5.9)	4 (5.5)	0.9
LAMS Location				0.8
GG; n (%)	20 (83.3)	47 (78.3)	67 (79.8)	
JG; n (%)	4 (16.7)	13 (21.7)	17 (20.2)	
LAMS Size				0.8
15-mm; n (%)	10 (41.7)	23 (38.3)	33 (39.3)	
20-mm; n (%)	14 (58.3)	37 (61.7)	51 (60.7)	
LAMS Dwell Time days (mean ± SD)	97.3 ±139.6	36.5 ±17.6	54.3 ± 80.8	**0.04***
Primary Closure; n (%)	9 (37.5)	17 (28.3)	26 (31.0)	0.4
APC treatment; n (%)	19 (79.2)	38 (63.3)	57 (67.9)	0.2
Weight gain >5% TBW; n (%)	8 (33.3)	5 (9.8)	13 (17.3)	**0.02***

- N=84 patients underwent EDGE
- 28.6% developed persistent fistula
- Mean LAMS dwell time was 54 days
- No diff in age, sex, smoking status, fistula site, LAMS size or primary closure frequency
- Fistula group had longer LAMS dwell time (OR=4.7 after >33 days in situ, p=0.001)
- The odds of developing a persistent fistula *increased by 39% for every 7 days that LAMS was left in situ*

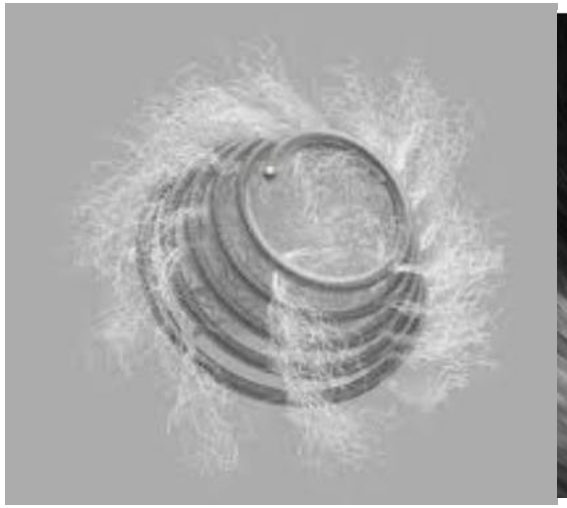


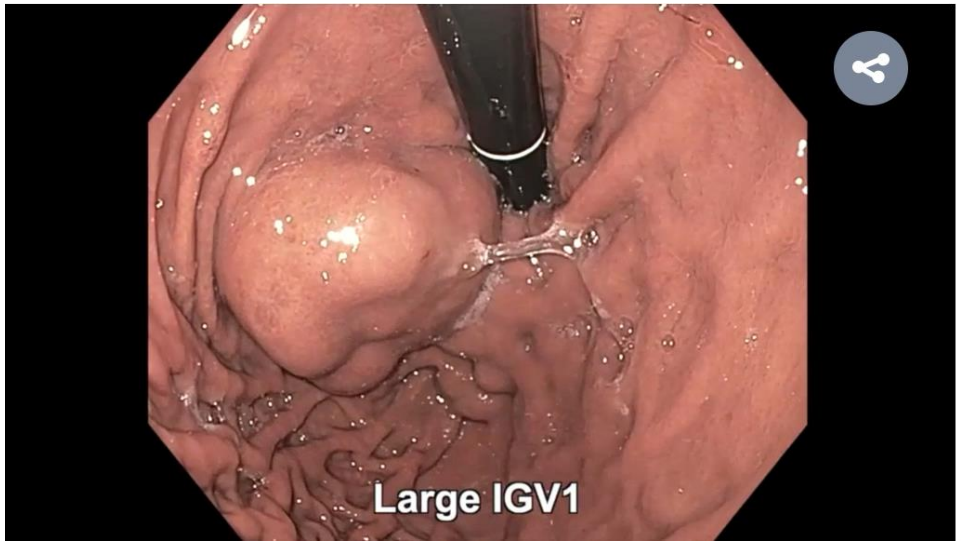
Endoscopic closure was attempted in 71%
Successful resolution of fistula in 70.6%

EndoHepatology

1. EUS-Guided Treatment of Gastric Fundal Varices With Coil And Glue Injection Is Safe And Fares Better Than Endoscopic Glue Injection: An International Multicenter Experience –Jayanta Samanta et al

- 4 tertiary care centers in Italy and India
- Aim: compare efficacy and safety of endoscopic glue with cyanoacrylate (CYA) vs EUS-guided coil+glue
- N=170 (glue n=118, coil+glue n=52)
- EUS-coil/glue group:
  - Complete obliteration during the index procedure was noted in all cases
  - 92.3% had obliterated varices at 4weeks f/u
  - At median f/u of 703 days, 15.4% had rebleeding. Lower rebleeding rate (15.4% vs 31.3%, p=0.03)
  - Fewer # of sessions required for varix obliteration
  - Lower re-intervention rate



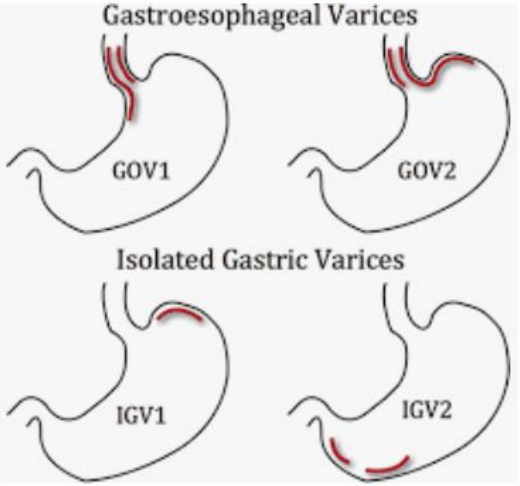


Bhat et al. Gastrointest Endosc 2016 Jun;83(6)1164-72.

Table 1: Comparison of the procedure details and outcome between EUS -guided and endoscopic management of gastric varices

	EUS-Guided (n=52)	Endoscopic (n=118)	p value
Size of varix F2 F3	 28 (53.8%) 24 (46.2%)	 65 (55.1%) 52 (44.1%)	
Maximum diameter of varix on EUS/Endoscopic (mm) *	21.09±8.1#	16.17±4.6#	<0.0001
Past history of glue	10 (19.2%)	17 (14.4%)	
RCS on GV	44 (84.6%)	56 (47.5%)	
Amount of glue injected on first session	2.0 (1.0)	2.0 (1.0)	0.07
Technical Success	52 (100%)	117 (99.2%)	1.00
Adverse events Abdominal pain Embolisation	 0 (0%) 0 (0%)	 16 (13.9%) 1 (0.9%)	 0.018 1.00
Number of sessions required for complete obliteration	1.0 (0)$	2.0 (2.0)$	<0.0001
Rebleeding rate	8 (15.4%)	36 (31.3%)	0.03
Re-intervention required for GV	7 (13.5%)	58 (49.6%)	<0.001

*Data available for 77 cases of endoscopic arm
#Represented as mean± standard deviation
$Represented as median (interquartile range)
Abbreviations: EUS Endoscopic ultrasound; RCS red color signs; GV Gastric varices



Comparison of treatments	Technical success	Clinical success	Rate of adverse events	Rate of reintervention	Rate of re-bleeding
EUS CYA alone *versus* EUS CYA + Coil (*P*)	97% *versus* 100% (<0.001)	96% *versus* 98% (<0.001)	21% *versus* 10% (<0.001)	26% *versus* 15% (<0.001)	30% *versus* 14% (<0.001)
EUS CYA alone *versus* EUS Coil alone (*P*)	97% *versus* 99% (0.005)	96% *versus* 90% (0.146)	21% *versus* 3% (<0.001)	26% *versus* 25% (0.846)	30% *versus* 17% (<0.001)
EUS CYA + coil *versus* EUS Coil alone (*P*)	100% *versus* 99% (<0.001)	98% *versus* 90% (<0.001)	10% *versus* 3% (0.057)	15% *versus* 25% (0.047)	14% *versus* 17% (1.00)

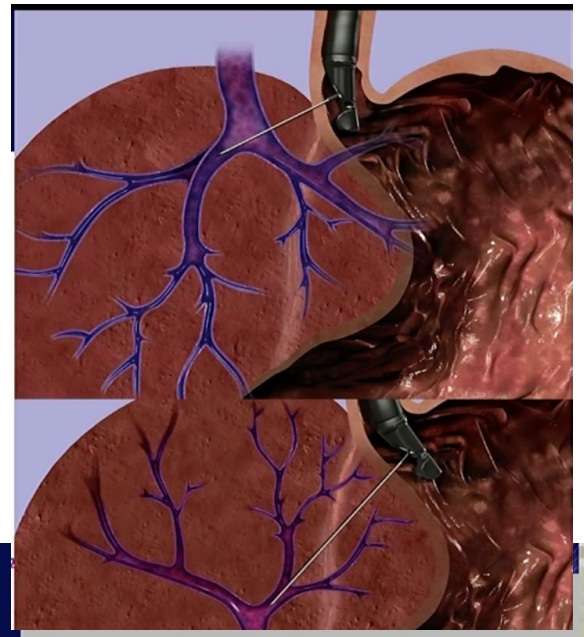
CYA: Cyanoacrylate, Coil: Coil embolization

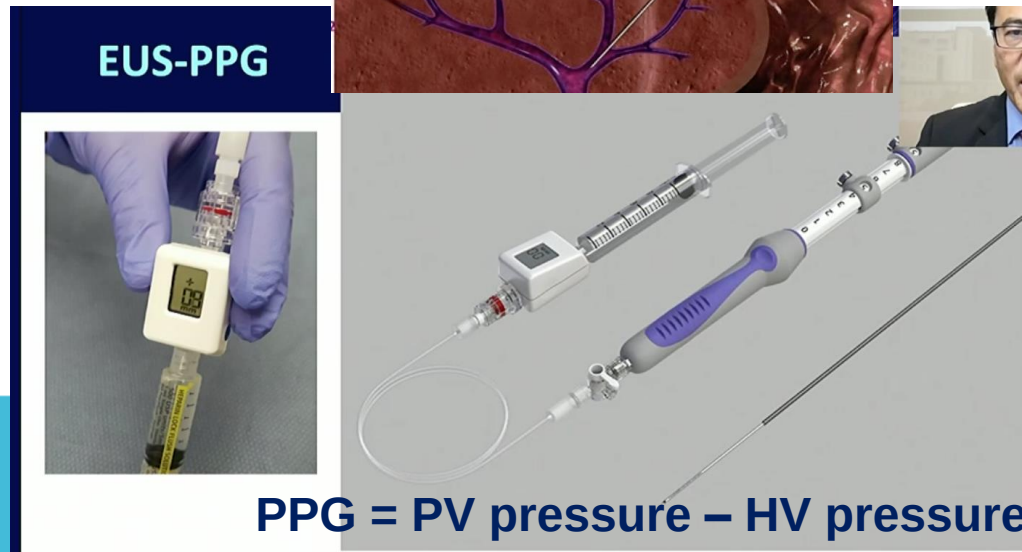
Reem Sharaiha EUS-guided management of Variceal Bleeding

McCarty et al Endosc Ultrasound. 2020

2. EUS-Guided Porto-Systemic Pressure Gradient (EUS-PPG) Evaluation Predicts Liver Histology and Clinical Parameters of Liver Disease: A Large Multicenter Endohepatology Study –Marc Monachese et al

- Aim: evaluate correlation between EUS-PPG and clinical markers of portal HTN, non-invasive marker of liver disease (FIB-4, APRI, MELD), and liver histology
- N=159
- Technical success 98.1%
- AE 1.2% (bleeding)
- Mean PPG 5.73 mmHg (0-26mmhg)
- Higher PPGs were measured in patients with esophageal varices, PHG, thrombocytopenia
- Concurrent histology available in 49%
  - PPG>5 mmHg (compared to <5mm) were more likely to have stage 3 or 4 fibrosis (OR 6.043, CI 1.797-22.582)





EUS-Guided Porto-Systemic Pressure Gradient (EUS-PPG) Results

- PPG correlated well with FIB-4 (R=0.484, p<0.01), APRI (R=0.30, p=0.0003), and MELD (R=0.28, p=0.006)
- PPG did not correlate with transient elastography (R=0.005, p=0.54)
  - In 19 patients (48.7%), PPG<5mmhg accurately characterized patients with false positive elastography
- 5 patients (6.4%) with no clinical marker of liver disease had PPG>5mmhg and advanced histology on biopsy

Thank You

EUS-Guided Ablation of Pancreatic Cyst

Surgery

- Surgery is considered the gold standard for malignant or high-risk lesions in patients who are surgical candidates.
- Lesions in the head and neck or the body and tail can be resected with pancreaticoduodectomy or distal pancreatectomy, respectively.
  - Technically challenging surgeries, and ideally, should be performed in high-volume centers. Even then, pancreatic resection is associated with perioperative morbidity of 20-40% and mortality of 1-5%.*
- In patients who carry higher risks for surgical complications and have higher risk cysts (but do not have overt signs of malignancy), a less invasive alternative would be very attractive.

* Tanaka M, et al. Fukuoka guidelines. *Pancreatology*. 2017.
* Elta GH, et al. ACG Clinical Guideline. *Am J Gastroenterol*. 2018.

EPIC (EUS-Guided Pancreatic Injection of Cyst) Trial

- Prospective, double-blinded RTC at two tertiary care centers 2004-2007
- 58 pts with 1cm -5cm unilocular pancreatic cysts were randomized into ethanol (n=25) vs saline (n=17) lavage for pancreatic cysts.
- Repeat EUS in 3 months for cyst size, 76% second ETOH ablation
- ETOH resulted in greater decrease in cyst surface area (-42.9 vs -11.4, p=0.009)
- 33.3% had resolution of cysts on f/u CT scan
- Histology of 4 resected cysts demonstrated epithelial ablation ranging from 0% (saline alone) to 50-100% (1-2 ETOH)
- Adverse events ~10%

DeWitt et al. Gastrointest Endosc. 2009 Oct;70(4):710-23

EUS-guided ethanol ablation

TABLE 1. Studies of EUS-guided ethanol ablation

Author	Year	No. of subjects	Average cyst diameter (mm)	Ablative agent	Median follow-up (mo)	Complete resolution (%)	No. of procedure-related adverse events
Gan[24]	2005	25	19.4	5%-80% ethanol	12	35 (8/25)	None
DeWitt[25]	2009	42	22.4	80% ethanol or saline, followed by ethanol	3-4 after second lavage	33 (12/36)	10 (abdominal pain), 1 (intracystic hemorrhage), 1 (pancreatitis),
DiMaio[26]	2011	13	20.1	80% ethanol	3-6	38 (5/13)	1 (abdominal pain)
Caillol[27]	2012	13	24	99% ethanol	26	85 (11/12)	None
Gomez[28]	2016	23	27.5	80% ethanol	40	9 (2/23)	1 (abdominal pain), 1 (pancreatitis)
Park[29]	2016	91	30	99% ethanol	40	45 (41/91)	18 (abdominal pain), 3 (pancreatitis)

Canakis et al. Gastrointest Endosc 2020;91:520-6

EUS-guided ethanol-paclitaxel ablation

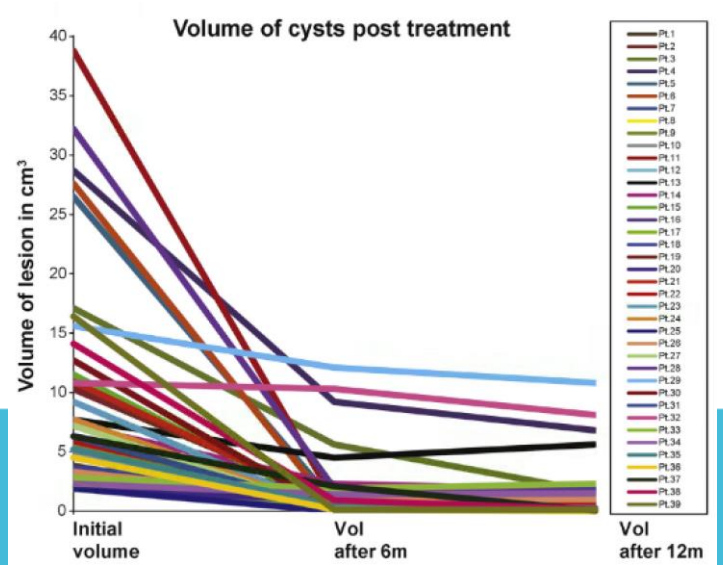
TABLE 2. Studies of EUS-guided paclitaxel ablation

Author	Year	No. of subjects	Average cyst diameter (mm)	Ablative agent	Median follow-up (mo)	Complete resolution (%)	No. of procedure-related adverse events
Oh[30]	2008	14	25.5	99% ethanol, paclitaxel	9	79 (11/14)	1 (pancreatitis), 1 (abdominal pain)
Oh[31]	2009	10	29.5	99% ethanol, paclitaxel	8.5	60 (6/10)	1 (pancreatitis)
Oh[3]	2011	47	31.8	99% ethanol, paclitaxel	20	62 (29/47)	1 (pancreatitis), 1 (abdominal pain), 1 (fever), 1 (splenic vein obliteration)
DeWitt[32]	2014	22	24	99% ethanol, paclitaxel	12	50 (10/20)	4 (abdominal pain), 3 (pancreatitis), 1 (peritonitis), 1(gastric wall cyst)
Moyer[9]	2016	10	29	80% ethanol or saline + paclitaxel and gemcitabine	12	ethanol free 67 (4/6) ethanol 75 (3/4)	1 (pancreatitis)
Kim[38]	2017	36	25.8	100% ethanol (n= 8) or ethanol + paclitaxel (n = 28)	22.3	56 (19/34)	4 (pancreatitis), 4 (abdominal pain), 1 (intracystic hemorrhage)
Moyer[21]	2017	39	25	80% ethanol or saline + paclitaxel and gemcitabine	12	thanol free 67 (14/21) ethanol 61 (11/18)	4 (abdominal pain), 1 (pancreatitis)
Choi[33]	2017	164	32	99% ethanol, paclitaxel	72	72 (114/158)	6 (pancreatitis), 2 (pseudocyst), 2 (abscess), 1 (intracystic hemorrhage), 1 (pericystic spillage), 1 (pancreatic duct stricture) 1 (splenic vein obstruction) 1 (portal vein thrombosis)

Canakis et al. Gastrointest Endosc 2020;91:520-6

CHARM (Chemotherapy for Ablation and Resolution of Mucinous Pancreatic Cysts) Trial

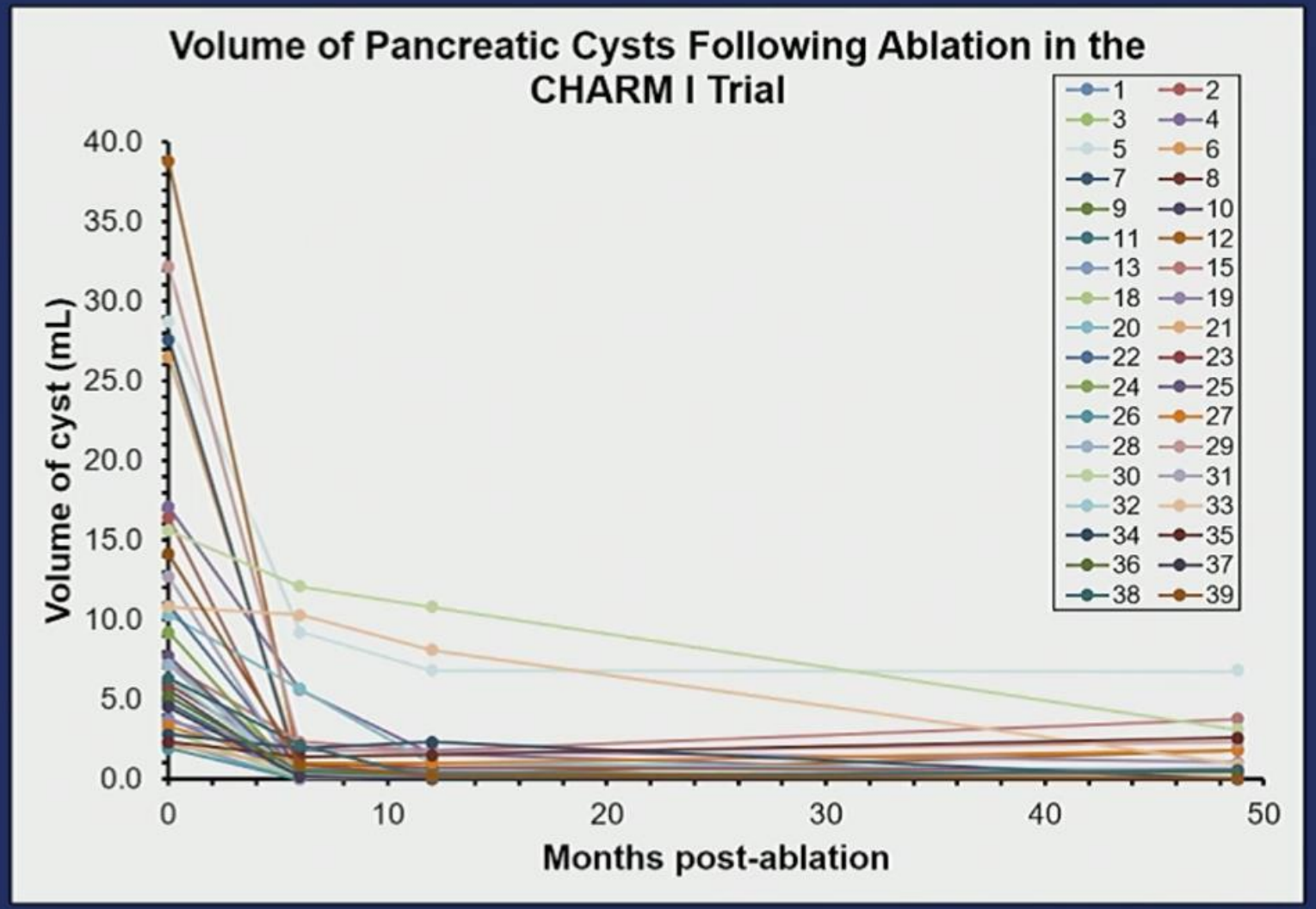
- Prospective double-blinded RTC, 2011-2016
- 39 pts with 1.5-5cm mucinous cysts were randomized to saline + paclitaxel/gemcitabine (n=21) vs ETOH + paclitaxel/gemcitabine (n=18)
- F/u CT scan at 3, 6, and 12 months
- 67% (ETOH–free) vs 61% complete responders at 12 months
- AE pancreatitis: 0% (ETOH-free) vs 6%, p=0.01



	Mean % reduction in cyst volume at 12 months (pancreatitis)	Complete response at 12 months, n (%) (abdominal pain)	Serious adverse events, n (%)	Minor adverse events, n (%)
Alcohol lavage (n=18)	85.0	11 (61.0)	1 (6.0)	4 (22.0)
Alcohol-free lavage (n=21)	84.0	14 (67.0)	0 (0.0)	0 (0.0)
TOTAL (n=39)	84.5	25 (64.0)	1 (3.0)	4 (10.0)

Moyer MT, et al. *Gastroenterology* 2017.

CHARM Long-Term Follow-Up Results



Lester C, et al. *Clin Gastroenterol Hepatol*. 2021.

- 87% of patients who achieved complete ablation at CHARM 12-month assessment maintained complete ablation 36.5 months later
- No treated patients developed high-grade pathology
- 4 partial or non-responders improved to complete ablation at long-term follow-up

EUS-Guided Pancreatic Cyst Chemoablation Summary

- ETOH alone:
  - EUS-guided cyst ablation with ETOH alone is relatively ineffective with 9-35% efficacy rates and carries the 3-10% risks of AE
- ETOH+paclitaxel:
  - Increased complete ablation rates to 50-79% but still carried similar AE felt to be due to toxic/inflammatory effects of dehydrated ETOH (pancreatitis, thrombosis, peritonitis)
- ETOH-free chemoablation paclitaxel/gemcitabine
  - Resulted in 67% complete ablation rate at 12 months with much lower AE

Which pancreatic cysts are appropriate for EUS-guided chemoablation?

- Most mucinous pancreatic cysts are low risk, <2cm, and best managed by surveillance per accepted guidelines.
- Mucinous cysts with stigmata of malignancy or multiple high-risk features are best evaluated by a MDC at a high-volume center, with surgery considered if appropriate.*
- However, for pancreatic cysts that are in the middle ground (and amenable to ablation), alcohol-free chemoablation offers a minimally invasive treatment option with a 67% rate of complete ablation and very low rate of AEs.
- For details, see the recently published *Position Statement on Pancreatic Cyst Ablation* and recent review articles in the citation section of this presentation.

Elta GH, et al. ACG Clinical Guideline. *Am J Gastroenterol*. 2018.

Extra Slides

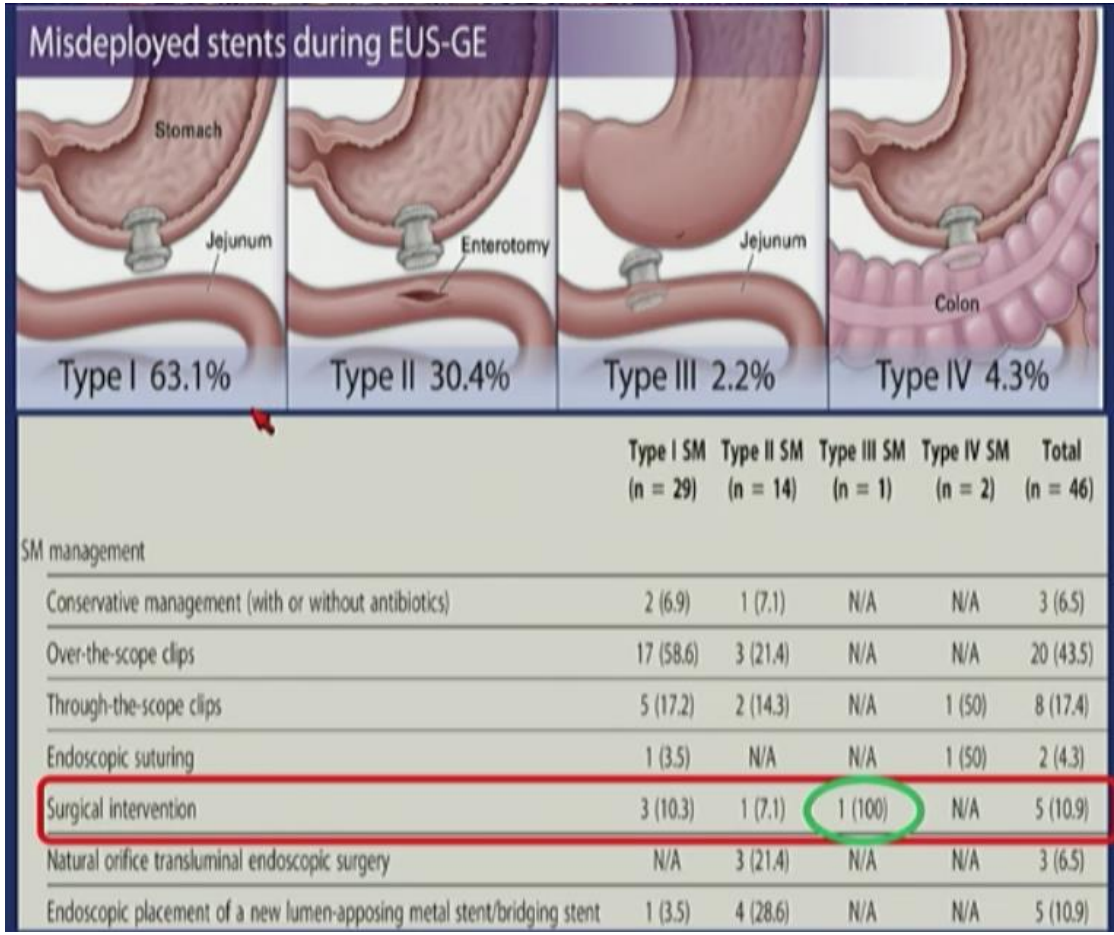
Results – Patient characteristics

Baseline characteristic	
Age, years [mean ± SD (range)]	75.2 ± 14.1 (34.0,94.0)
Male	63.3% (19/30)
Days since onset of first AC symptoms (median QR)	
First treatment	4.5 (3-13)
Relapsing cholecystitis	3.5 (2-12)
Current abdominal pain visual analog scale (VAS) score (0-10)	4.5 ± 2.7 (28) (0.0, 10.0)
Calculous cholecystitis	83.3% (25/30)
Acute cholecystitis grade	
Grade I	23.3% (7/30)
Grade II	76.7% (23/30)
History of acute cholecystitis	
First treatment	80.0% (24/30)
Relapsing cholecystitis	20.0% (6/30)
Prior percutaneous drainage	3.3% (1/30)
Days subject free of AC between treatment with prior drain and date of enrollment	78.0

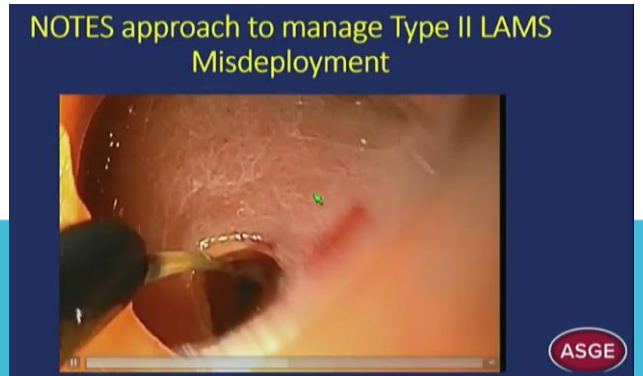
4. J.Edward Berk MD, DSC, FASGE Endowed Lecture on LAMS --

Mouen Khashab

- Proficiency for EUS-GJ is 39 cases
  - Stent mis-deployment ~10% risk
    - 10% of these 10% patients (1% overall) required surgical repair
- Type 1 misdeployment most common – gastric clip closure
- Type II NOTES approach/surgery
- Type III surgery
- Type IV – leave the tract to mature 4 weeks, remove stent and suture defect



	Type I SM (n = 29)	Type II SM (n = 14)	Type III SM (n = 1)	Type IV SM (n = 2)	Total (n = 46)
SM management					
Conservative management (with or without antibiotics)	2 (6.9)	1 (7.1)	N/A	N/A	3 (6.5)
Over-the-scope clips	17 (58.6)	3 (21.4)	N/A	N/A	20 (43.5)
Through-the-scope clips	5 (17.2)	2 (14.3)	N/A	1 (50)	8 (17.4)
Endoscopic suturing	1 (3.5)	N/A	N/A	1 (50)	2 (4.3)
Surgical intervention	3 (10.3)	1 (7.1)	1 (100)	N/A	5 (10.9)
Natural orifice transluminal endoscopic surgery	N/A	3 (21.4)	N/A	N/A	3 (6.5)
Endoscopic placement of a new lumen-apposing metal stent/bridging stent	1 (3.5)	4 (28.6)	N/A	N/A	5 (10.9)



3. Robotic GJ vs EUS-Guided GJ for Malignant GOO

–Robert Dorrell et al

- Retrospective study of 25 patients with malignant GOO
  - 11/2016-10/2021
- Technical and clinical success achieved in all patients.
- EUS-GJ group had:
  - shorter procedure duration
  - faster time to oral intake
  - shorter postop stay
  - Lower AE

	EUS-GJ (n=11)	R-GJ (n=14)	p-value
Age, mean, SD	64.5, 13.0	63.6, 14.0	0.91
Female, n, %	2, 18%	6, 42.9%	0.23
Preoperative BMI, mean, SD	23.1, 4.1	26.9, 5.8	0.16
Presence of ascites, n, %	6, 55%	8, 57%	0.70
Age-adjusted Charlson comorbidity index, mean, SD	9.8, 1.9	7.1, 1.3	0.0014
Malignant etiology, n, %			
Pancreatic cancer	7, 64%	9, 64.3%	
Metastatic disease	1, 9%	1, 7.1 %	
Duodenal cancer	1, 9%	2, 14.3%	
Cholangiocarcinoma	1, 9%	0, 0%	
Gastric cancer	1, 9%	2, 14.3%	
Procedure duration (min), mean, SD	66.0, 31.6	147.1, 41.0	0.0002
Technical success, n, %	11, 100%	14, 100%	>0.99
Time from GJ to oral intake (days), mean, SD	1, 0	6, 3.8	<0.0001
Tolerating soft mechanical diet at discharge	11, 100%	5, 36%	0.001
Length of postoperative stay (days), mean, SD	4.2, 2.8	8.2, 4.5	0.0075
GOOSS score at 1 month, mean, SD	2.9, 0.3	2.1, 1.2	0.057
BMI at 1 months, mean, SD	22.3, 3.8	25.7, 5.5	0.14
Average BMI change	-1.2, 2.1	-2.2, 3.1	0.44
Adverse events, n, %	0, 0%	5, 36%	0.001
Bleeding		2 (@17, 48 days postop)	
Sepsis		1 (@5 days)	
Anastomotic occlusion		1 (@5 days required EGD w/NJ tube)	
GJ volvulus		1 (@8 days required surgical reintervention)	
Clinical success, n, %	11, 100%	14, 100%	>0.99

2. EUS-Directed Transgastric Interventions (EDGI) In RYGB Anatomy: A Multicenter Experience –Bachir Ghandour

- Aim: evaluate outcomes and safety of EDGI
- Multicenter retrospective study in 8 US centers
- Consecutive RYGB patients who underwent EDGI 6/2015-9/2021
- 52 EDGI performed in 45 patients
  - 20mm LAMS in 55.6%, 15mm LAMS in 44.4%
  - 66.7% patients underwent 2 stage EDGI (17 d between procedures)
  - Diagnostic EUS (+/-FNA), EUS-guided cystgastrostomy, gastric mass, ulcer/bleed

	EDGI (N=45)
Technical Success; n (%)*	50 (96.2)
Single Session EDGI; n (%)	15 (33.3)
Mean Procedural Time (mean ± SD)*	94.5 ±76.4
Anastomosis Created	
Gastrogastrostomy; n (%)	35 (77.8)
Jejunogastrostomy; n (%)	10 (22.2)
LAMS Size	
15-mm; n (%)	20 (44.4)
20-mm; n (%)	25 (55.6)
Intervention Performed*	
Diagnostic EUS; n (%) • FNA/FNB Pancreas • Diagnostic only	28 (53.8) 19 (36.5) 9 (17.3)
EUS-guided Cystgastrostomy; n (%)	7 (13.5)
Choledochoduodenostomy; n (%)	3 (5.8)
EUS-guided jejuno-jejunostomy for afferent loop syndrome; n (%)	1 (1.9)
Pancreatic Mass Fuicidal Placement; n (%)	1 (1.9)
Gastroduodenal Ulcer treatment and luminal biopsy; n (%)	6 (7.7)
Push Enteroscopy evaluation of obscure bleeding; n (%)	2 (11.5)
PEG tube removal and gastrocutaneous fistula closure with OTSC; n (%)	3 (5.8)
Esophageal stent insertion across pyloric stricture; n (%)	1 (1.9)
Adverse events; n (%)	8 (15.4)
Adverse event severity#	
Mild; n (%)	3 (37.5)
Moderate; n (%)	4 (50)
Severe; n (%)	1 (12.5)
Adverse event nature#	
LAMS migration/dislodgment; n (%)	5 (62.5)
Abdominal Pain requiring hospitalization; n (%)	1 (12.5)
Postprocedural infection; n (%)	1 (12.5)
Pancreatitis; n (%)	1 (12.5)

*: Denominator is total EDGI procedures performed

#: Denominator is total number of adverse events

- 96.2% technical success
  - 1 misdeployment
  - 1 LAMS dislodgement during EUS
- Most common AE was LAMS migration
- 20% developed persistent fistula after LAMS removal