NEW YORK SOCIETY FOR GASTROENTEROLOGY & ENDOSCOPY
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Complications of Therapeutic EUS: Prevention and Management

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Disclosures

Boston Scientific

Cook

Olympus

Surgical Intuitive

Not all videos are mine ☺, but compiled by loads of friends with a lot of experience

What is interventional EUS? -- *'more than taking a look'...*

utilizing through the scope instruments for image-guided procedures and treatments

- EUS-guided vascular therapy
  - Insertion of embolization coils
  - Image-guided sclerosant/glue injection
- Oncologic treatments
  - Pancreatic cyst ablation
  - EUS directed treatment
    - FNI of anti-tumor agents directly into malignancy (phase I trials)
    - Ethanol injection into pancreatic neuroendrocrine tumors (case reports/series)
    - EUS-guided ablation (RFA, cryotherapy, PDT)
  - EUS fiducial placement
- Anastomosis creation
  - EUS gastro-jejunostomy
    - Gastric outlet obstruction
    - Bariatric therapy
  - EUS gastro-gastric fistula to facilitate ERCP in RYGB (EDGE)
- Advances in Hepatologic EUS
  - Core liver biopsy
  - Portal pressure gradient measurement
- Pancreatic fluid collections
- Biliary access/drainage

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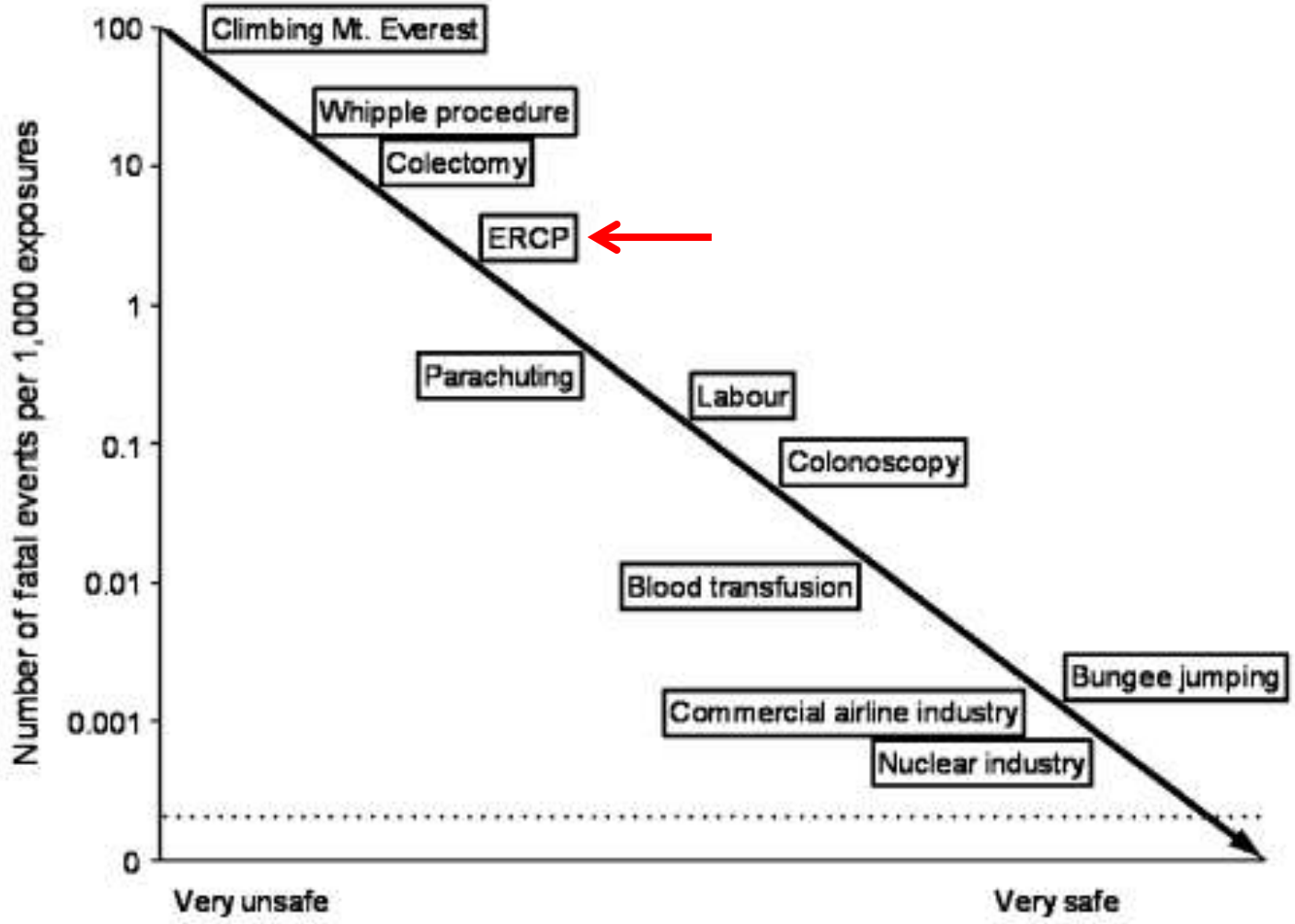
Adverse events happen

Part of the course

They will occur

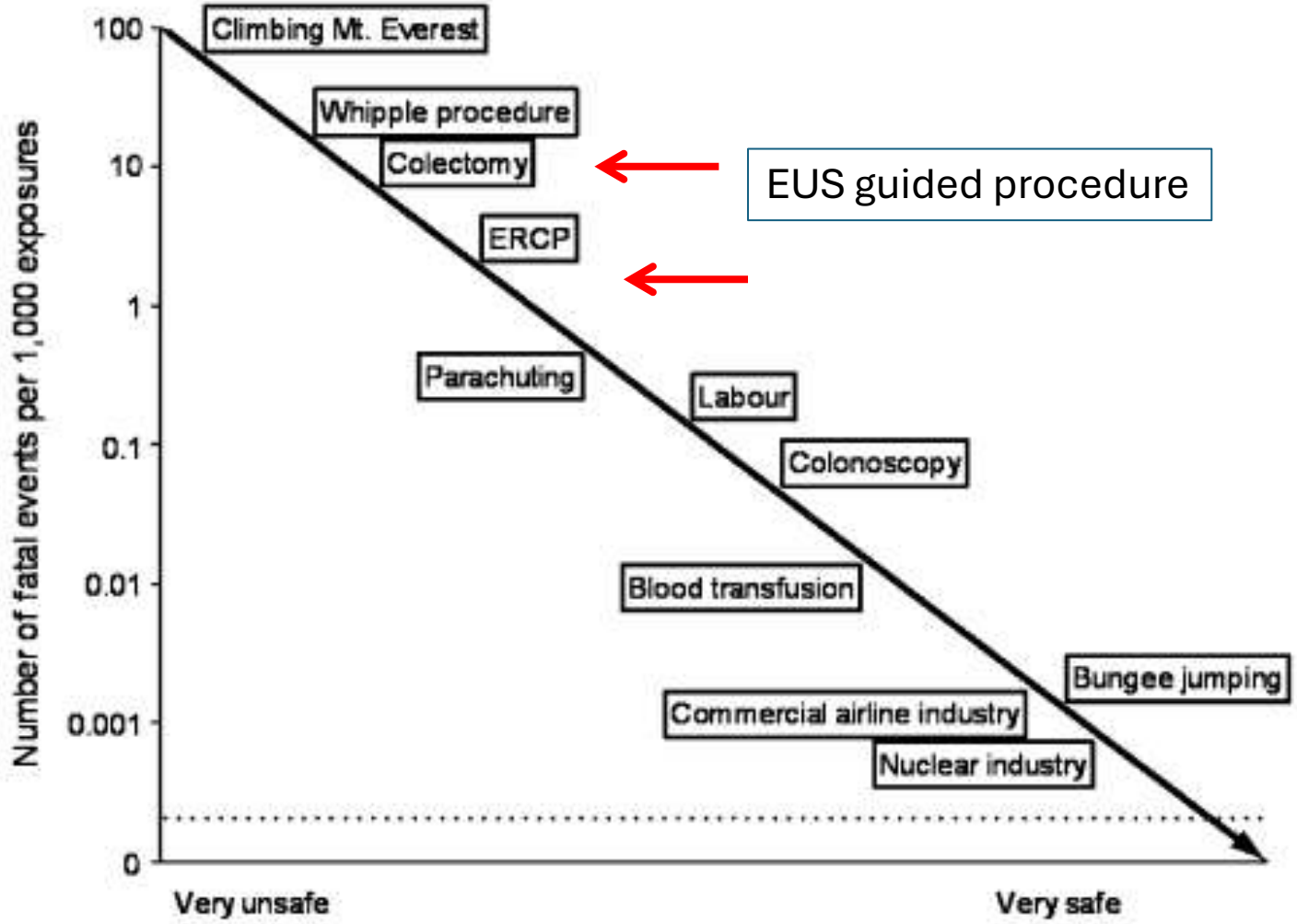
Know how to deal with it

ERCP is risky



Safety based on number of fatal events. Courtesy of Dr. Firas Al-Kawas and J. Elmunzer.

EUS guided is risky

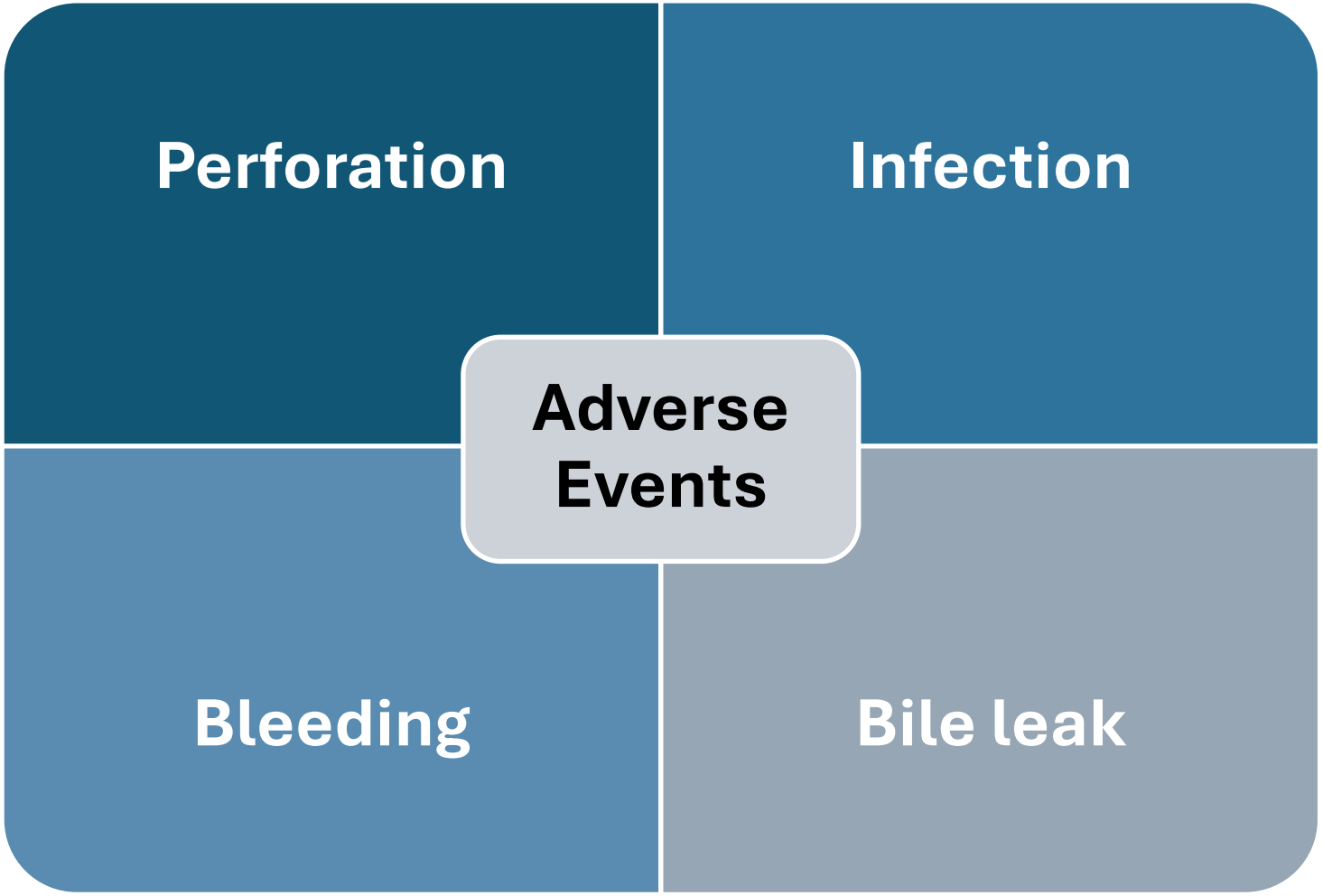


Safety based on number of fatal events. Courtesy of Dr. Firas Al-Kawas.

When do Adverse events occur?

- Immediate
  - During the case
  - Recognize it
  - How to deal with it

- Within 24 hours
- > 24 hours, likely >7 days later



Cardiopulmonary events /Pancreatitis
Rare events

Indications

- Most important
- When you have a complication ***it is*** the question most often asked
- Always discuss risks and benefits and alternatives

Not all post-inflammatory, pancreatic fluid collections (PFCs) need treatment, but some do…

Indications	Comments
Infection or suspected infection	~20% in necrotizing pancreatitis Routine FNA not needed- clinical signs predict in >90%
Ongoing organ failure	~40% will have infected PFC
Mass effect causing GOO, biliary/bowel obstruction	Less common
Refractory pain, wt loss, >8wks	
Bleeding into PFC	Rare
Abdominal compartment syndrome	
Bowel ischemia	

Pseudocyst → DRAIN

Walled off necrosis (WON) → DEBRIDE

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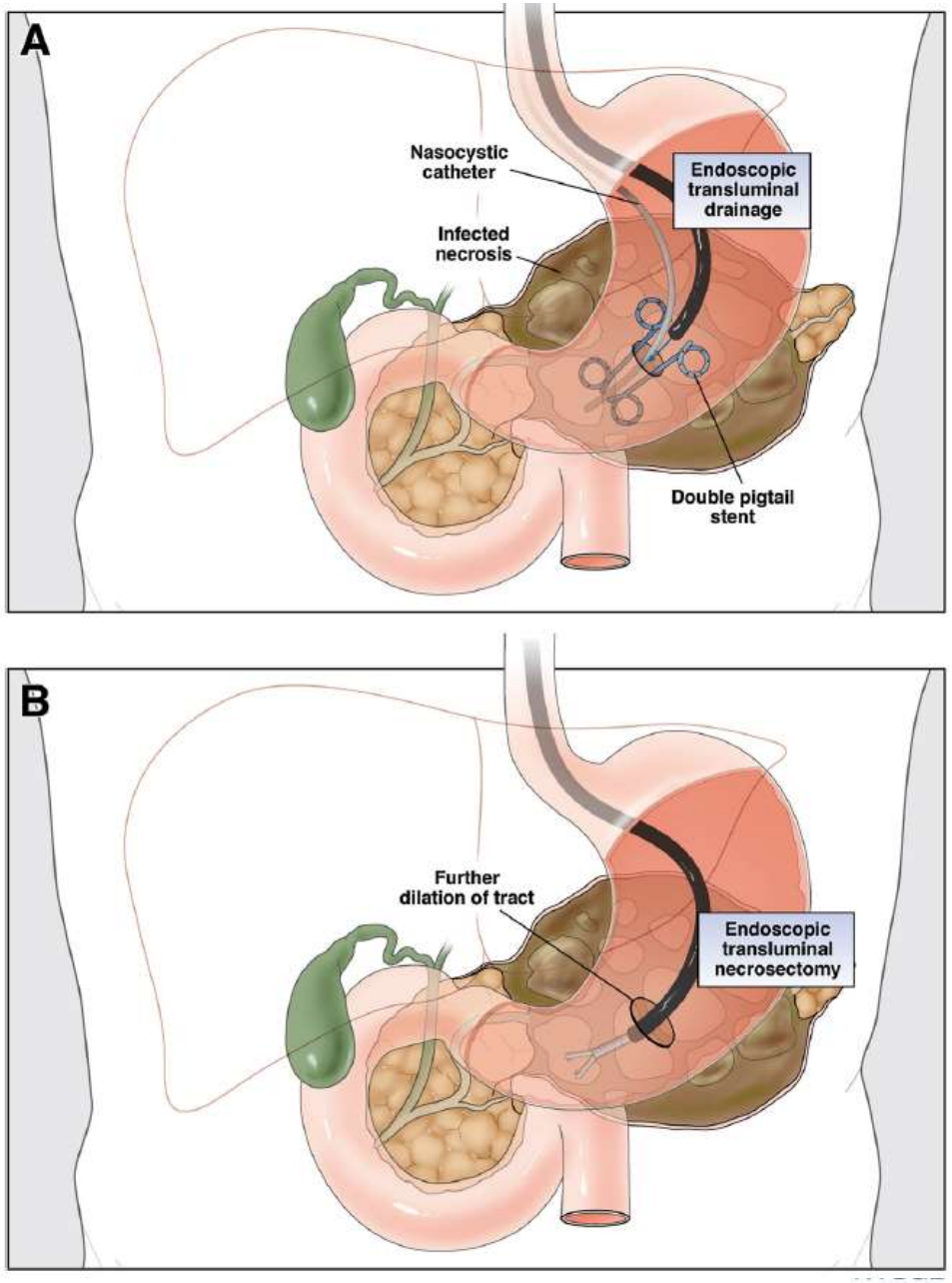
Endoscopic debridement of WON: challenges with conventional technique

- Large diameter tract dilation-> perforation, bleeding, leak
- Removal of necrotic tissue-> multiple repeat procedures, bleeding, perforation
- Maintaining cystgastostomy tract-> stent clogging, infection

* Complications in 20-35% (infection, bleeding, perforation) in MA / systematic reviews

Puli S. Can J Gastro Hep 2014
Brunschot S. Surg Endosc 2014



From Brunschot. BMC Gastroenterol 2013

Next Step: Drainage

- Choice of
  - Access technique
  - Stent type
- Selection based on
  - Type of collection (etiology, contents, etc)
  - Size
  - Location

Pancreatic collection: Outcomes ASGE|ACG New Quality indicators

WON and LAMS:

-High technical success rate >94-97%

-High resolution rate >92%

-Low adverse event rates <14%

Shah R, et al. CGH 2015;
Walter D, et al. Endoscopy 2015;
Itoi T, et al. GIE 2012
Rinella E, et al. GIE 2012;
Sharaiha R, et al. CGH 2016

Pancreatic collections- Adverse events

- **Bleeding**: This can occur due to the vascular nature of the pancreas and surrounding tissues.
- **Perforation**: early intervention, more common in the multistep process.
- **Infection**: if there is inadequate drainage of fluid or removal of solid debris.
- **Stent migration**: or buried LAMS

1. Peng S, Yao Q, Fu Y, et al.Surgical Endoscopy. 2023;37(8):6246-6254.

2. Varadarajulu S, Christein JD, WCMGH. 2011;26(10):1504-8.

3. Muthusamy VR, Chandrasekhara V, Acosta RD, et al.GIE. 2016;83(3):481-8

VIDEO: Direct Access CE-LAMS

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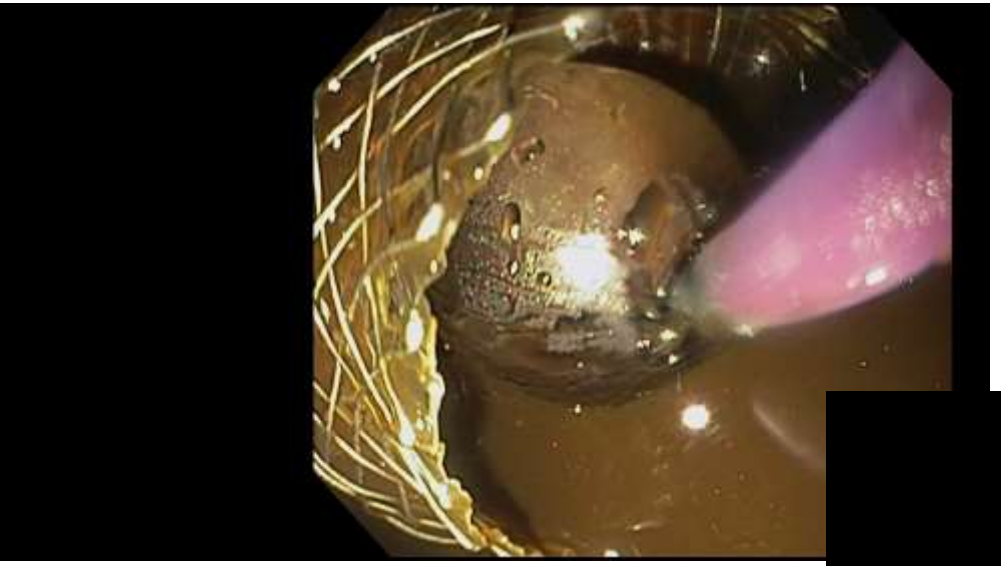
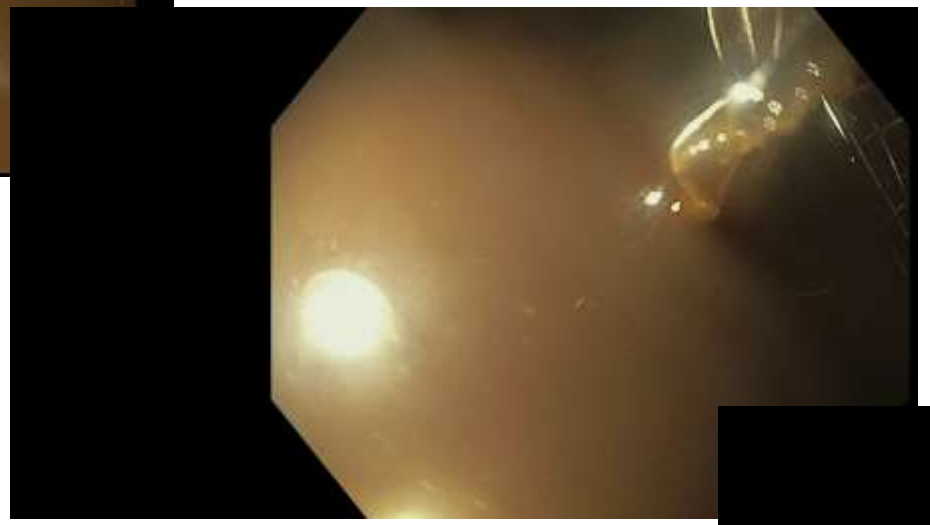
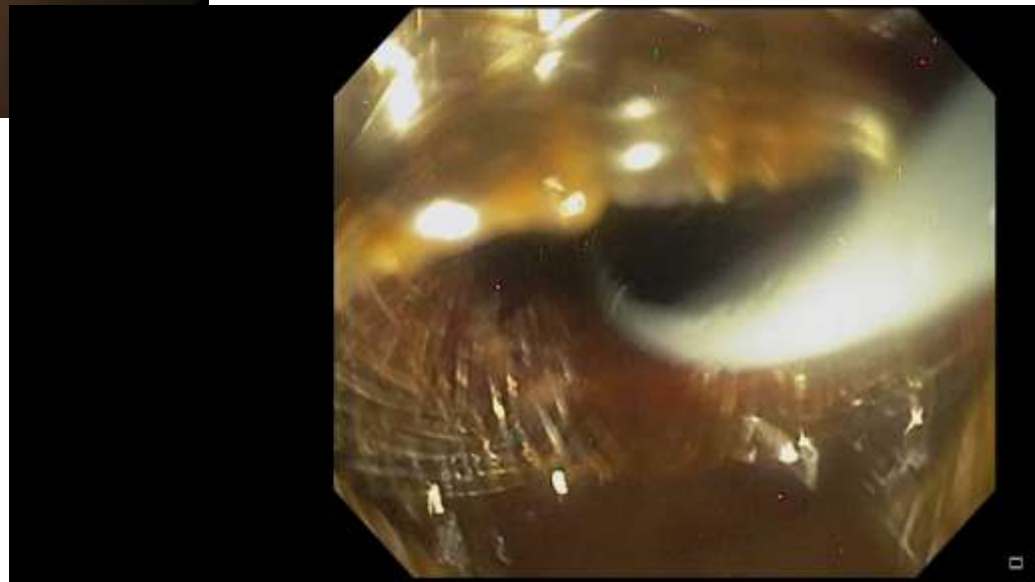
Next Step?

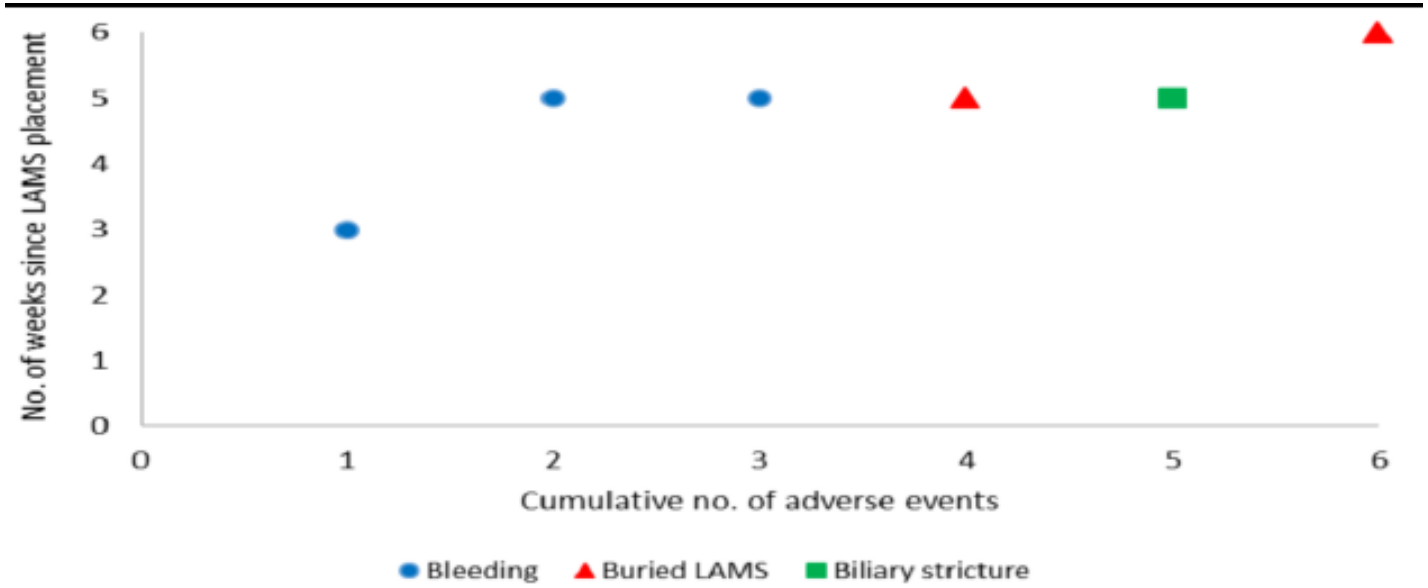


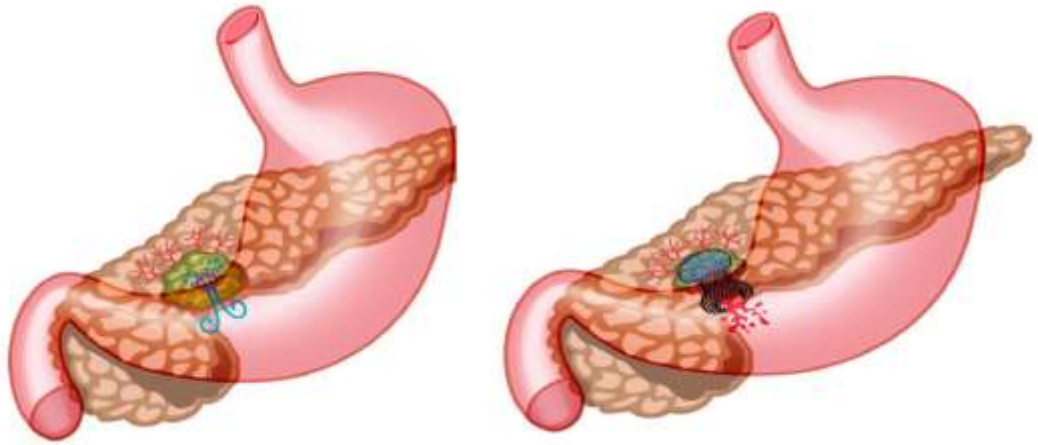




Lumen-apposing metal stents (LAMS) for pancreatic fluid collection (PFC) drainage: may not be business as usual

Ji Young Bang, Muhammad Hasan, Udayakumar Navaneethan, Robert Hawes, Shyam Varadarajulu





Follow-up CT to assess Rx response: 3-4 weeks
WON Resolution = LAMS removal

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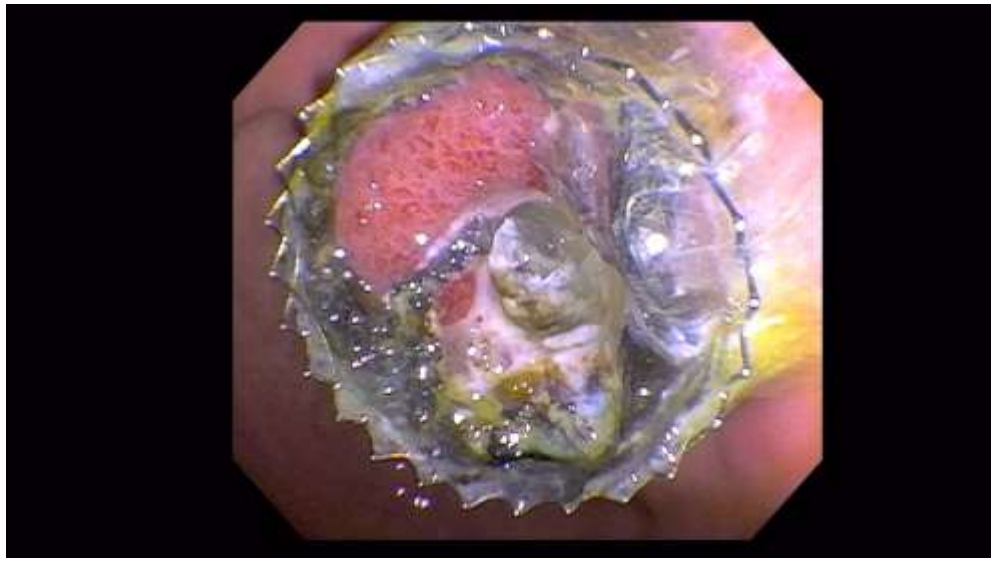
LAMS: Reported Adverse Events

- Delayed bleeding
- Tissue overgrowth
- Stent occlusion by food
- Large distance between collection and GI tract
  - Peritonitis
  - Perforation



Seerden T, et al. Endoscopy 2016
Bang JY, et al. Gut 2016
Fabbri C, et al. GIE 2015
Shah R, et al. CGH 2015

LAMS: Caution

WON and LAMS:

- Look for Vessels
- ?pre op CTA
- Remove after resolution
  - 2 week imaging
  - 4 weeks maximum
  - Replace with plastic

Shah R, et al. CGH 2015;
Walter D, et al. Endoscopy 2015;
Itoi T, et al. GIE 2012
Rinella E, et al. GIE 2012;
Sharaiha R, et al. CGH 2016

CASE

Courtesy of Uzma Siddiqui

Endoscopy (ERCP) is first line therapeutic modality for biliary drainage but fails in 3-10%

Cote GA, Clin Gastroenterol Hepatol. 2012

Approach for Biliary Drainage

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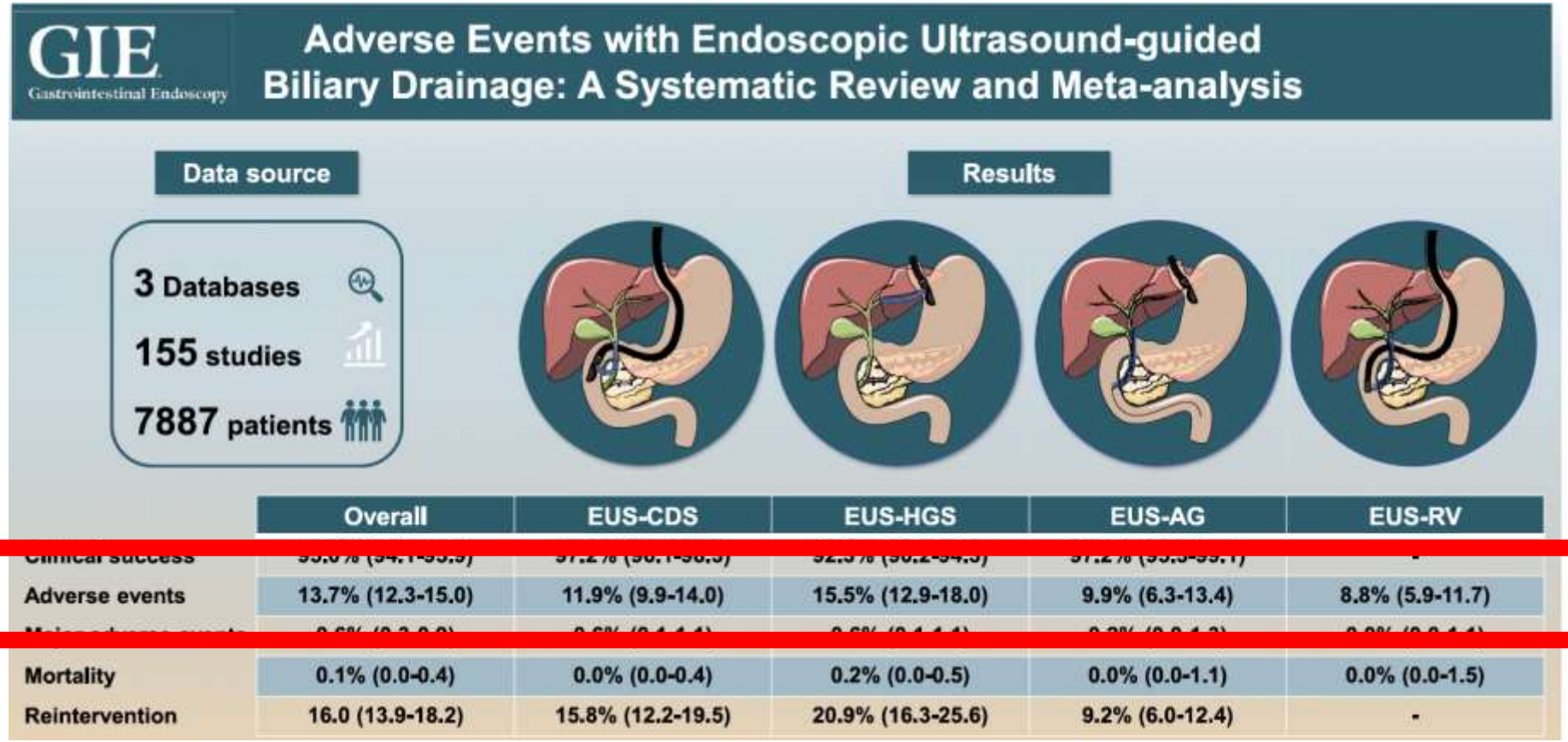
So what is difficult?

- Failure
- Bile leak
- Wire sheering
- Wire exchanges
- Multiple devices
- Stent misdeployment
- Salvage
- Staff training

Meta-analysis of 155 studies



	Overall	EUS-CDS	EUS-HGS	EUS-AG	EUS-RV
Clinical success	[illegible]	[illegible]	[illegible]	[illegible]	-
Adverse events	13.7% (12.3-15.0)	11.9% (9.9-14.0)	15.5% (12.9-18.0)	9.9% (6.3-13.4)	8.8% (5.9-11.7)
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Mortality	0.1% (0.0-0.4)	0.0% (0.0-0.4)	0.2% (0.0-0.5)	0.0% (0.0-1.1)	0.0% (0.0-1.5)
Reintervention	16.0 (13.9-18.2)	15.8% (12.2-19.5)	20.9% (16.3-25.6)	9.2% (6.0-12.4)	-

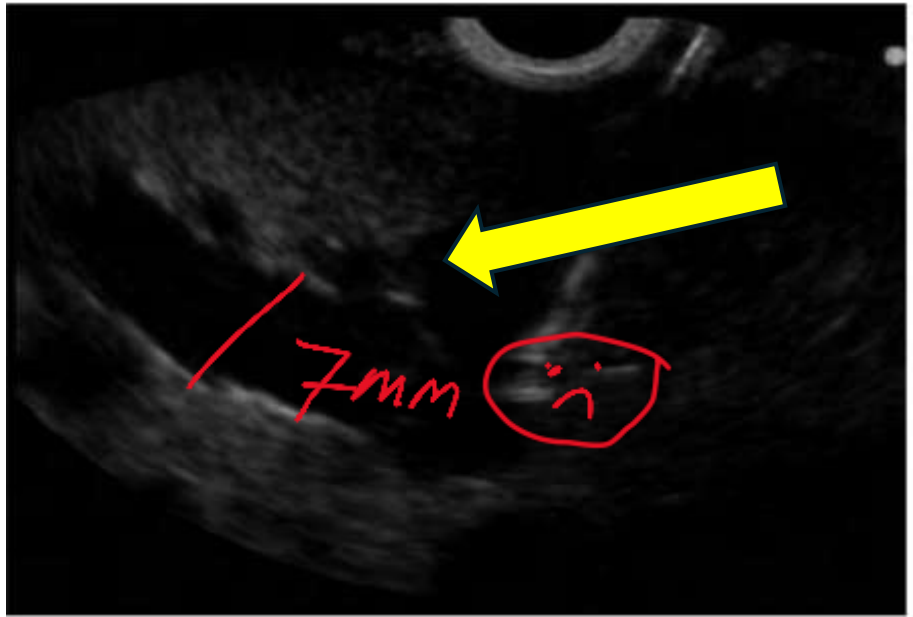
Gastrointest Endosc 2023;98:515-23

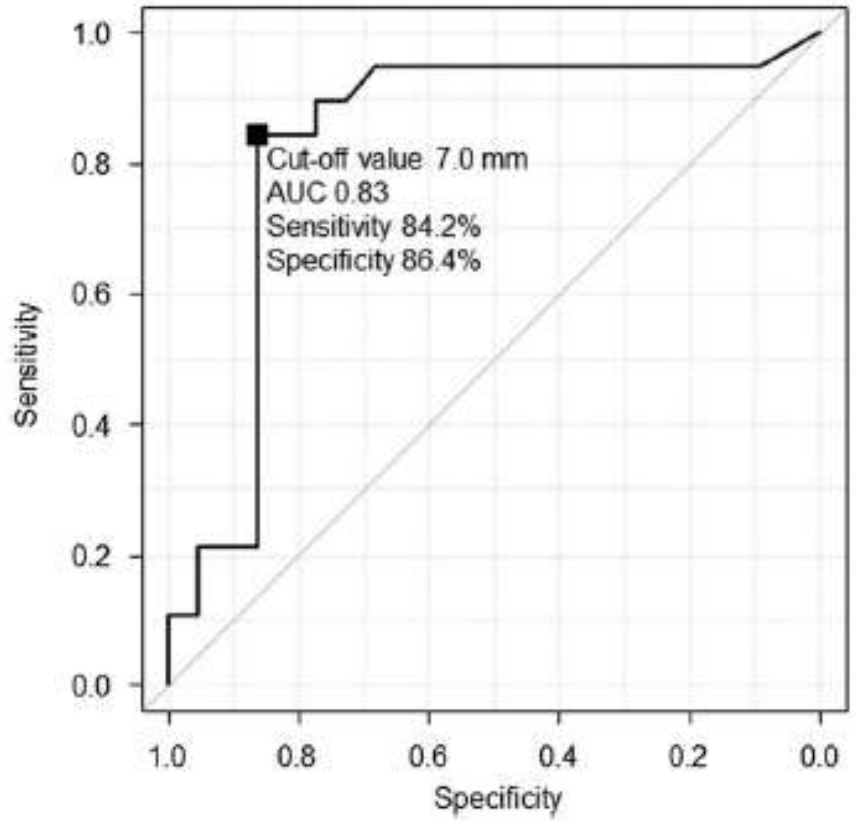
Factors associated with difficulty

TABLE 4. Factors Associated with a Difficult EUS-BD

	Univariate		Multivariate	
Factors	**OR (95% CI)**	***P***	**OR (95% CI)**	***P***
Age	1.01 (0.94-1.08)	0.84		
Male sex	0.64 (0.18-2.3)	0.50		
Past history of gastrectomy	5.60 (0.57-55.3)	0.14		
Primary lesion	0.18 (0.018-1.76)	0.14		
Oral administration of antithrombotic medicine	0.25 (0.025-2.46)	0.24		
Duodenal stent placement	1.61 (0.36-7.1)	0.53		
Distal bile duct stricture	0.86 (0.05-14.7)	0.92		
Procedure among the first 19 cases	0.49 (0.14-1.70)	0.26		
22 G needle used	0.67 (0.18-2.42)	0.54		
Diameter of punctured bile duct	0.73 (0.60-0.89)	<0.01	0.65 (0.46-0.91)	0.012
Length of puncture route	1.11 (0.99-1.25)	0.072		
One-time puncture	<0.01 (0-inf)	0.99		
0.018" guidewire used	0.81 (0.22-2.96)	0.75		
Cautery dilator used	1.20 (0.26-5.6)	0.82		
7 Fr dilator used	0.98 (0.28-3.5)	0.98		
Multiple dilators used	1.21 (0.29-5.06)	0.79		
EUS-HES performed	5.33 (1.2-23.7)	0.028	0.29 (0.009-9.5)	0.49
EUS-AGS performed	5.70 (1.25-25.9)	0.024	1.07 (0.06-17.6)	0.96
Metallic stent used	4.04 (1.07-15.3)	0.039	6.44 (0.51-81.0)	0.15

ed biliary drainage; EUS-HES, endoscopic





J Clin Gastroenterol 2023;00:000–000

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My take..

- **THE more steps**
- **The more exchanges**
- **The more chances of failure**

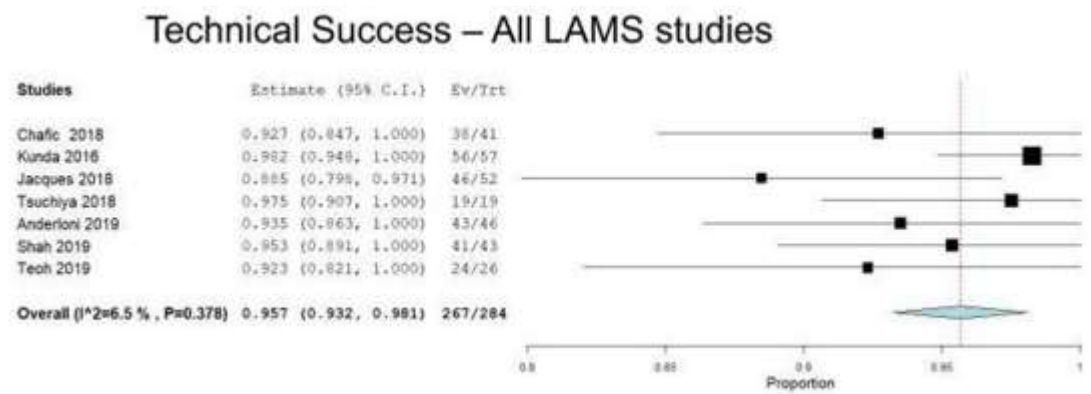
EUS-CDS drainage

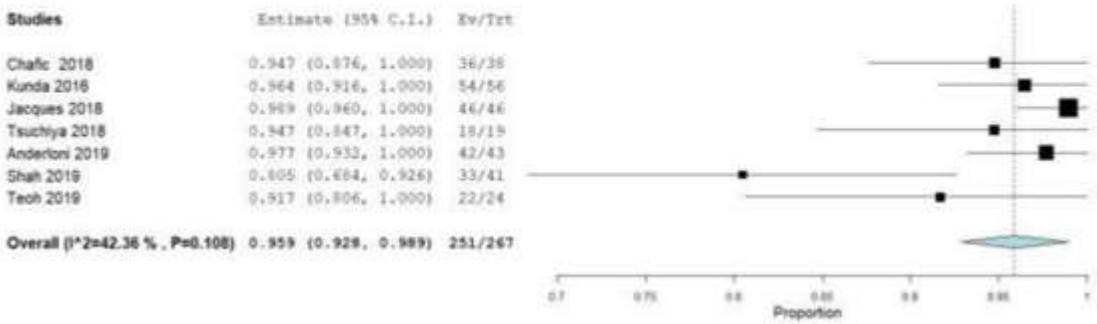
Established second line modality after failed ERCP

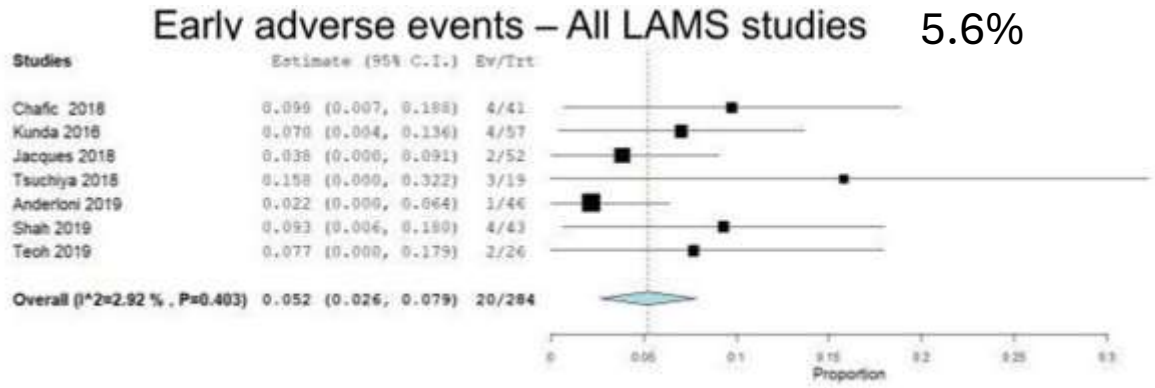
Level I evidence supporting its use as first line modality (ELEMENT trial[1] and DRA-MBO[2])

Chen YI *et al.* ELEMENT. Gastroenterology 2023

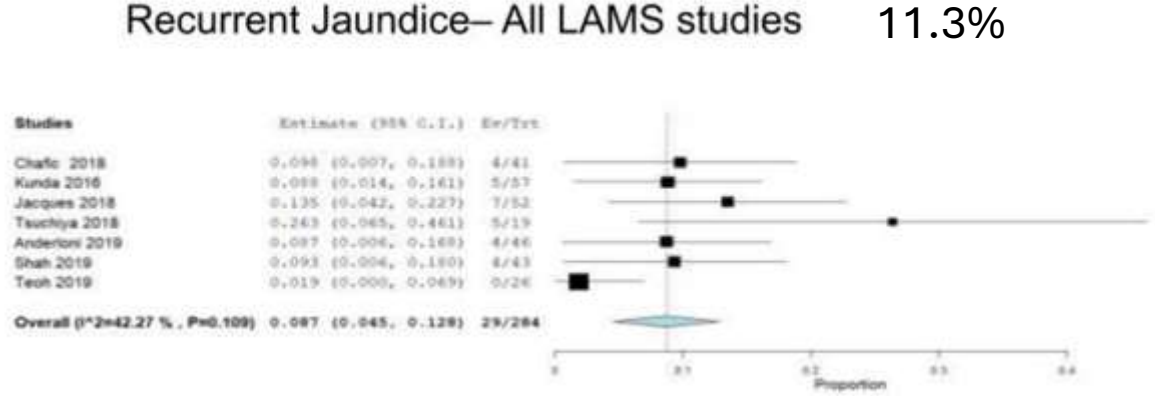
Effectiveness and safety of EUS-guided choledochoduodenostomy using lumen-apposing metal stents (LAMS): a systematic review and meta-analysis







5.6%



11.3%

Surgical Endoscopy (2020) 34:2866–2877

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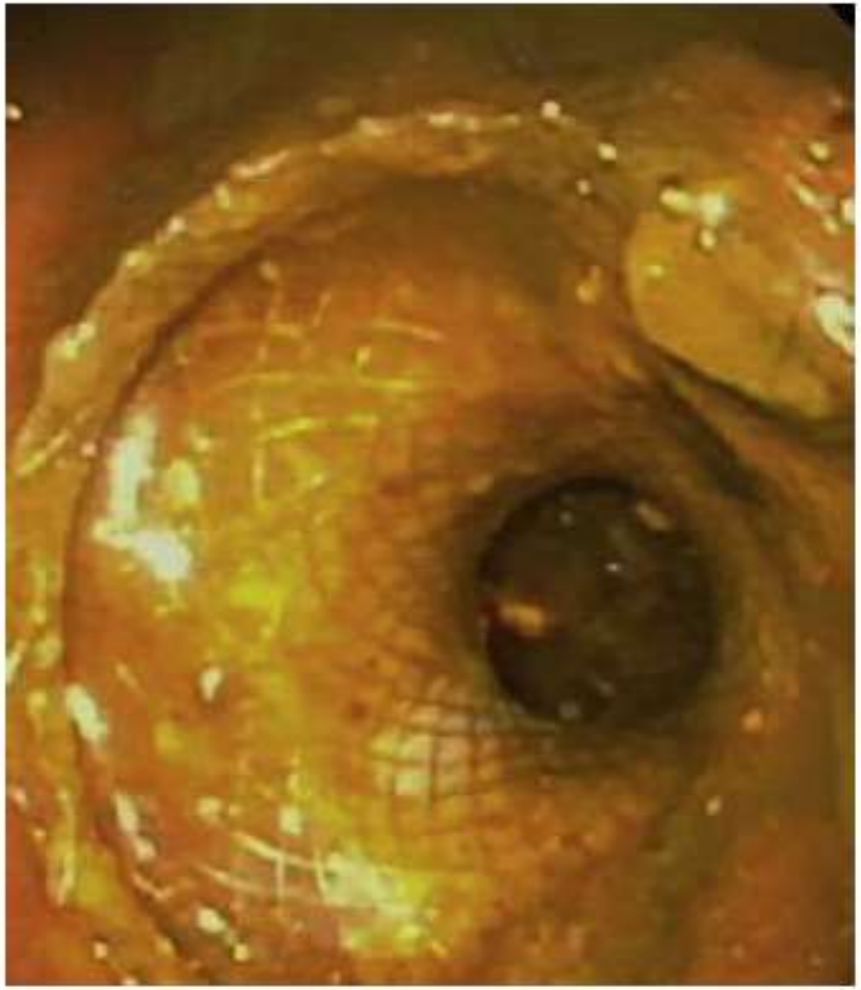
Adverse events



- Bile leak / peritonitis
- Misdeployment
- Migration
- Perforation
- Occlusion / Infection
- Bleeding

Adverse events	No of studies	Pooled rate (%) (95% CI)	I^2 (%)
CDD using LAMS			
Perforation	7	1.5 (0.1–3)	0
Bile leak	7	1.2 (0.1–2.4)	0
Bleeding	7	2.5 (0.7–4.3)	0
Cholangitis	7	1.5 (0.1–2.9)	0
Abdominal pain	7	1.2 (0–2.5)	0
CDD using EC-LAMS			
Perforation	5	1.3 (0.3–2.9)	0
Bile leak	5	1.3 (0.3–2.9)	0
Bleeding	5	2.5 (0.4–4.7)	0
Cholangitis	5	1.5 (0.2–3.1)	0
Abdominal pain	5	1.4 (0.2–3.0)	0

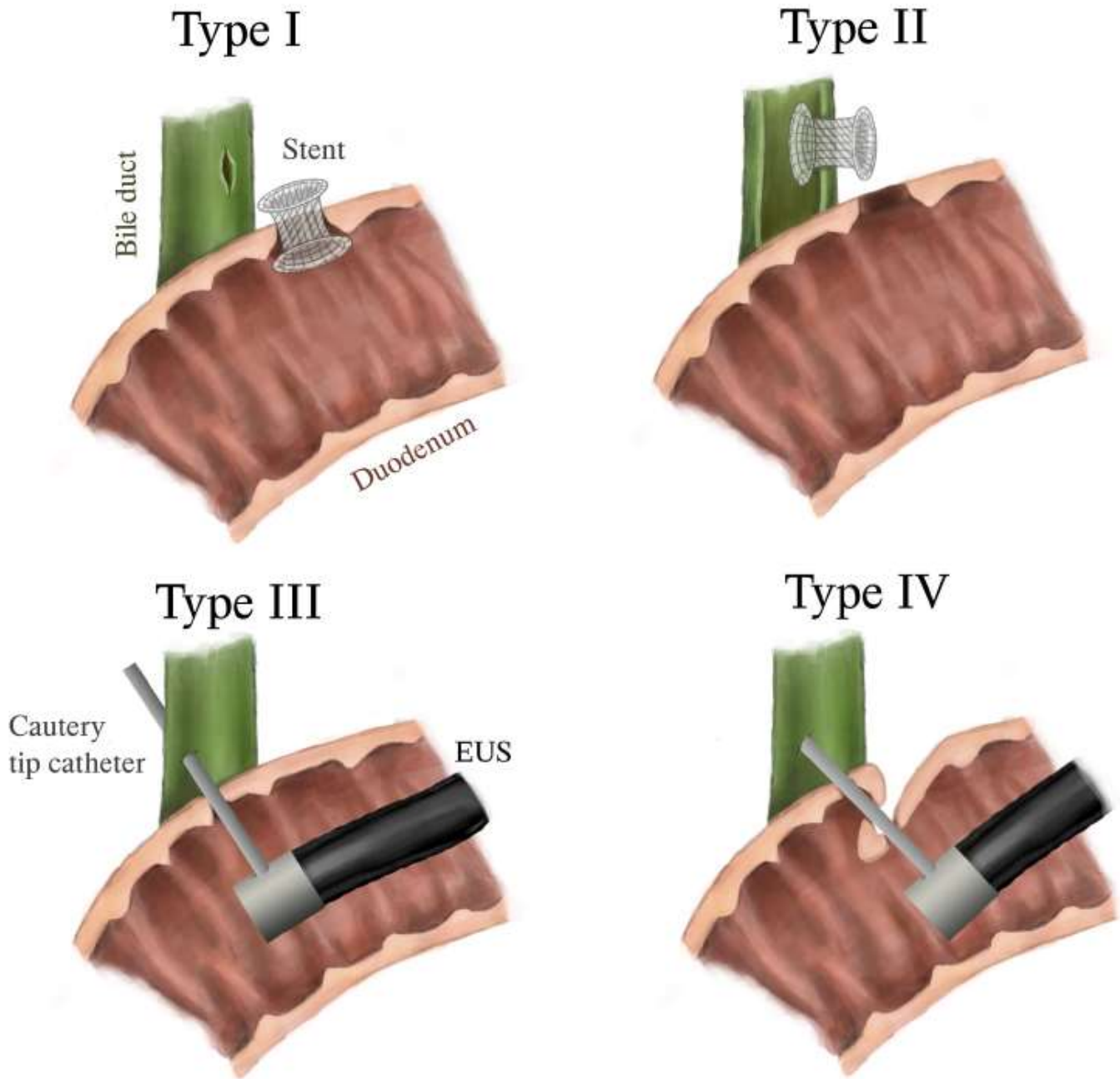
**Ensure multidisciplinary back-up support prior to procedure*

Surgical Endoscopy (2020) 34:2866–2877

Adverse events **EUS-CD similar to ERCP**

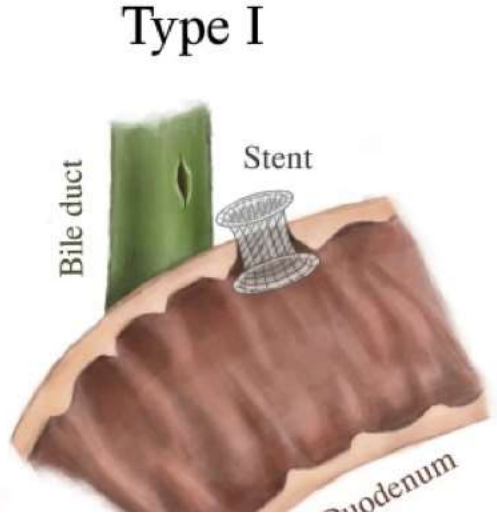
Severity Grading	EUS-CDL 11%	ERCP-M 11%	p-value
Mild	5 (6.8%) Cholangitis n=2 Perforation n=1 Misdeployment n=1 Leukocytosis n=1	3 (4.2%) Cholangitis n=1 Pancreatitis n=2	0.49
Moderate	3 (4.2%) Cholangitis n=2 Bleeding n=1	2 (2.8%) Pancreatitis n=2	1.00
Severe	0 (0.0%)	2 (2.8%) Cholangitis n=1 Bleeding n=1	0.24
Fatal	0 (0.0%)	1 (1.4%) Cholangitis n=1	0.49

Chen YI Gastroenterology 2023



Chen YI, Larghi A, Teoh AYB *et al.* DDW 2024

Type 1 Salvage



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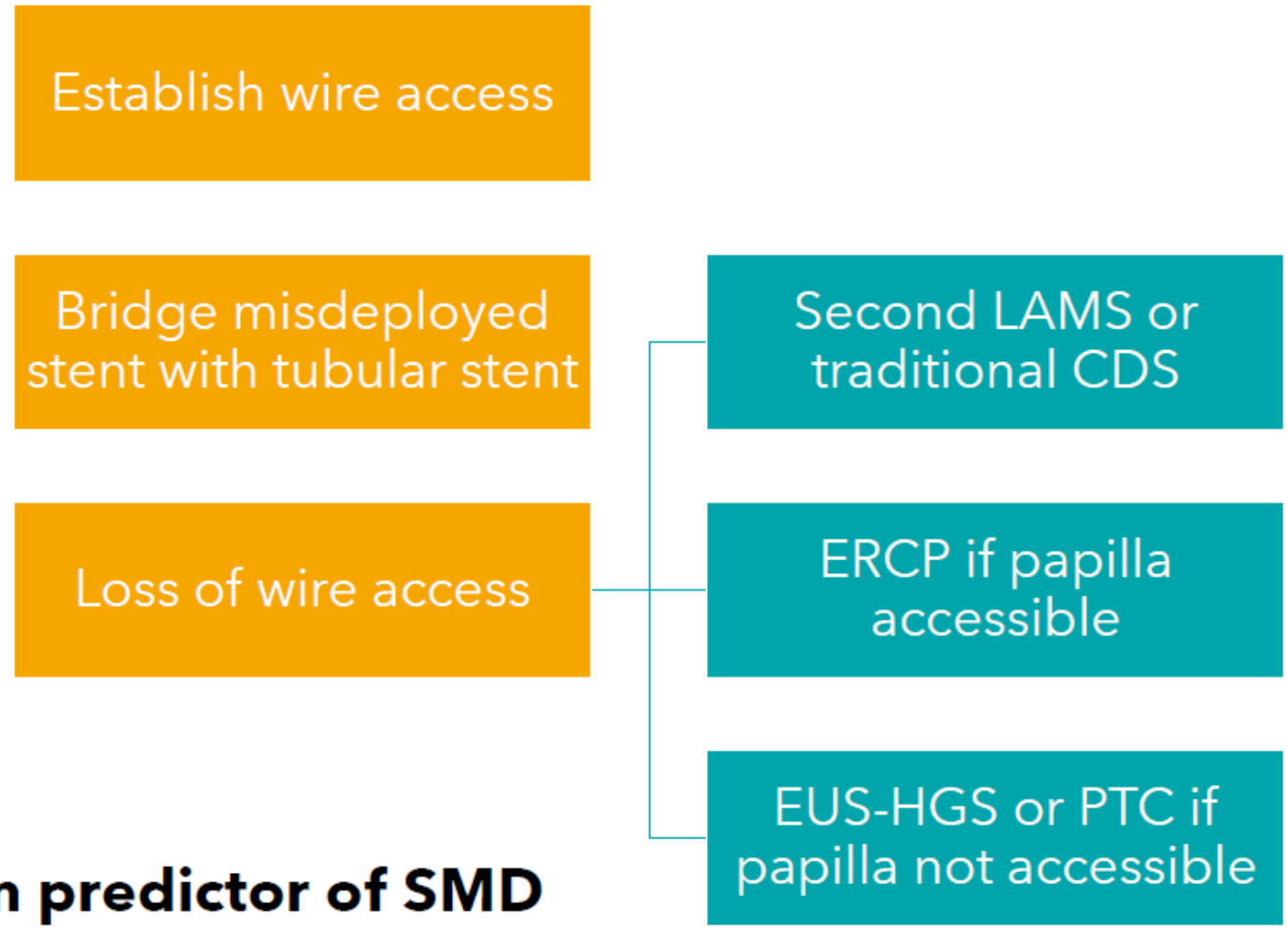
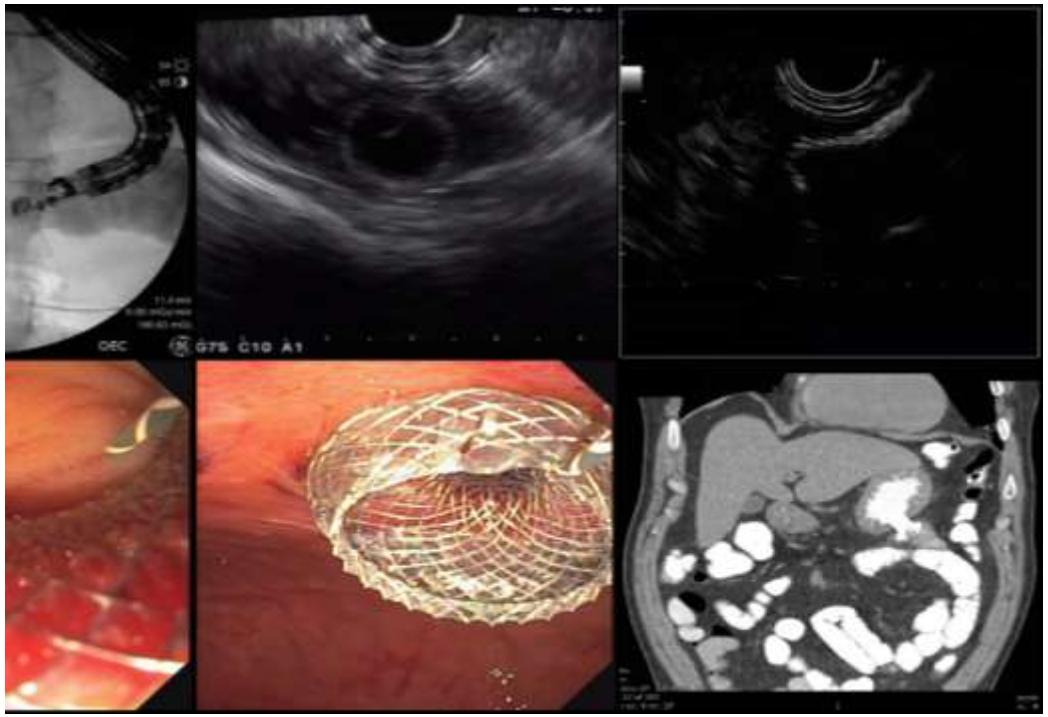
ELEMENT + DRA-MBO 152 patients: 7% Misdeployment

Approach to Misdeployed Stents EUS-CDS



15 mm predictor of SMD

Techniques of EUS-GJ



- Balloon-assisted EUS-GJ
- Direct (Free-hand) EUS-GJ
- Balloon-occluded gastrojejunostomy bypass (EPASS)

KHASHAB, BARON, BINMOELLER,

ITOI. GIE 2015;81:1234-6

ITOI ET AL. GUT 2016;65:193-5

Be prepared

GJ

equipment

Scopes
- upper
- linear EUS
- double channel & available only
- peds colonoscope

Devices
- 19 G Boston
- Visiglide 0.025
- Axios 15/20 (Hot) & 7F x5cm double pigtail
- ERBE
- CRE balloon 12-15 & 15-18 & Inflation device x2
- Taewoong (18x60 & 20x66)
- Ovesco 12
- Rat tooth forceps
- 60cc syringe x4 & 12cc syringe x6

Meds
- 2gm glucagon
- Methylene blue
- Antibiotics
- Contrast
- 500cc of sterile water.

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EUS-GJ with long-axis view

- Know your devices
- Know your setting
- Know the landing zone

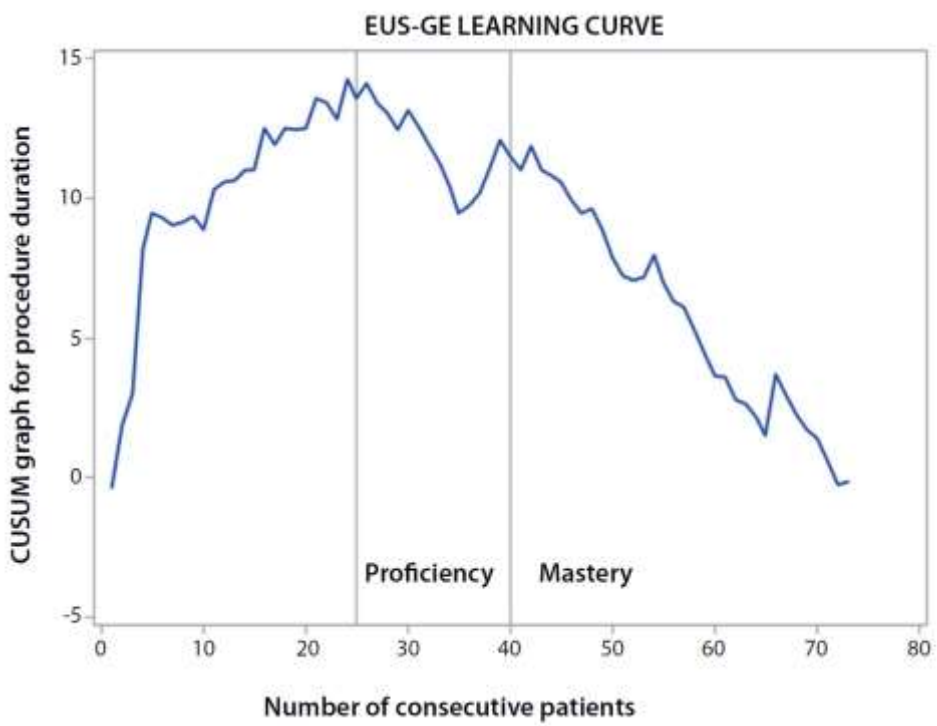
Lumen diameter mm	Saddle Length (mm)	Flange diameter (mm)	Runway required for stent deployment
8	8	17	24
10	10	21	32
15	10	24	35
20	10	29	38

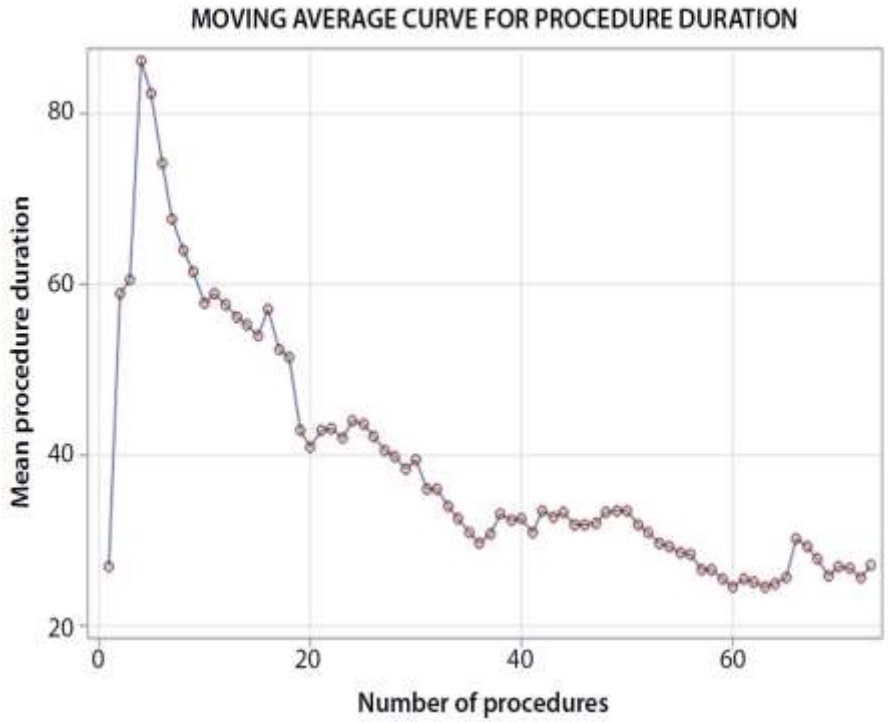
Sundaram, Giri, Binmoeller LAMS a primer

Assessment of the learning curve for EUS-guided gastroenterostomy for a single operator

Manol Jovani, MD, MPH,[1] Yervant Ichkhanian, MD,[1] Nasim Parsa, MD,[2] Sahiljeet Singh, MD,[3] Olaya I. Brewer Gutierrez, MD,[1] Margaret G. Keane, MBBS, MSc MRCP,[1] Sarah S. Al Ghamdi, MD,[1] Saowanee Ngamruengphong, MD,[1] Vivek Kumbhari, MBBS, PhD,[1] Mouen A. Khashab, MD[1]

25 cases → Proficiency
40 cases → Mastery





AEs 5.5% → none severe, none after 39 cases

GIE 2021

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Classification, outcomes, and management of misdeployed stents during EUS-guided gastroenterostomy

Bachir Ghandour, MD,[1] Michael Bejjani, MD,[1] Shayan S. Irani, MD,[2] Reem Z. Sharaiha, MD,[3] Thomas E. Kowalski, MD,[4] Douglas K. Pleskow, MD,[5] Khanh Do-Cong Pham, MD,[6] Andrea A. Anderloni, MD,[7] Belen Martinez-Moreno, MD,[8] Harshit S. Khara, MD,[9] Lionel S. D'Souza, MD,[10] Michael Lajin, MD,[11] Bharat Paranandi, MBBS,[12] Jose Carlos Subtil, MD, PhD,[13] Carlo Fabbri, MD,[14] Tobias Weber, MD,[15] Marc Barthet, MD, PhD,[16] Mouen A. Khashab, MD,[1] on behalf of the EUS-GE Study Group*

Baltimore, Maryland; Seattle, Washington; New York, Stony Brook, New York; Philadelphia, Danville, Pennsylvania; Boston, Massachusetts; La Mesa, California, USA; Bergen, Norway; Rozzano, Forli-Cesena, Italy; Valenciana, Navarra, Spain; Leeds, UK; Bayern, Germany; Marseille, France

Total # GE procedures	N= 467	
Stent Misdeployment	N= 46	9.85%
Mild	N= 28	85%
Moderate	N= 11	
Severe	N= 6	13%
Fatal	N= 1	2%
Required surgery	N=5	10.9% (1.1% overall)

Gastrointest Endosc 2022;95:80-9

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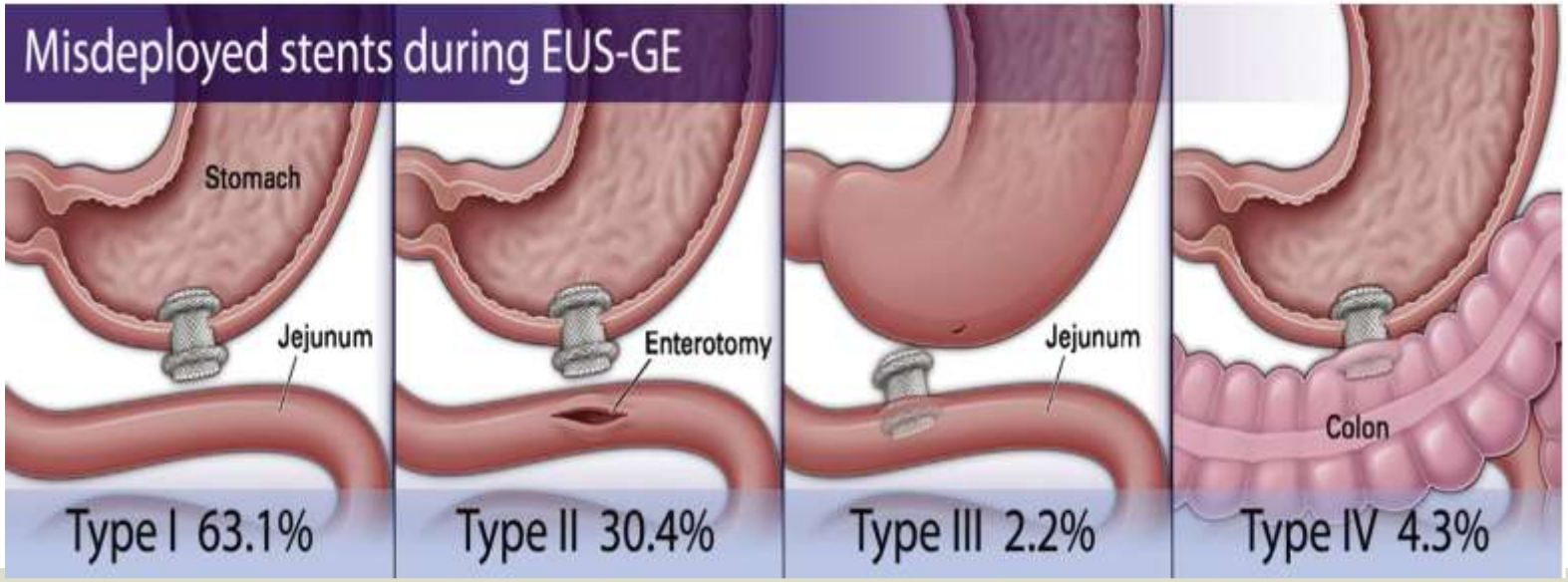
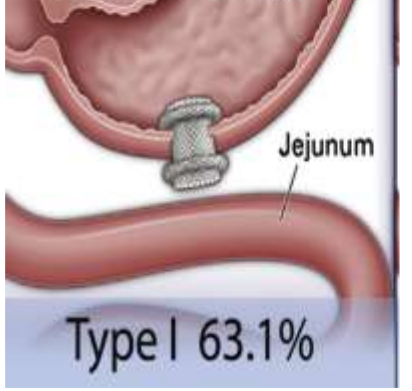


	Type I SM (n = 29)	Type II SM (n = 14)	Type III SM (n = 1)	Type IV SM (n = 2)	Total (n = 46)
SM management					
Conservative management (with or without antibiotics)	2 (6.9)	1 (7.1)	N/A	N/A	3 (6.5)
Over-the-scope clips	17 (58.6)	3 (21.4)	N/A	N/A	20 (43.5)
Through-the-scope clips	5 (17.2)	2 (14.3)	N/A	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)

Type 1 misdeployment



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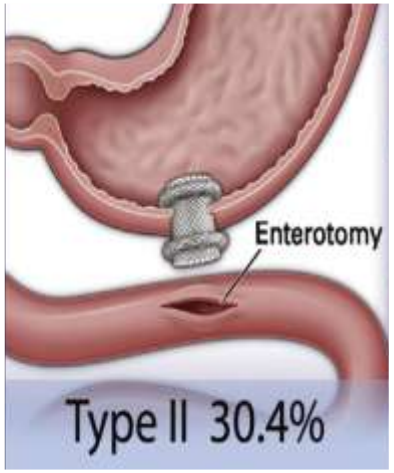
Type2 misdeployment



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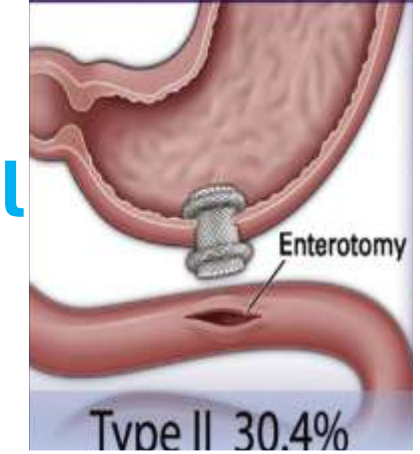
Type2b misdeployment – contralateral wall



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Delayed EUS-GE Perforation Cases - *RARE*

Authors, et al	Years	Study Type	N	Delayed Perforation	Wall Type	Suspected Etiology	Timing after EUS-GE	Management
Abbas	2016-2020	Prospective (single center)	50	1 (2%)	Into colon (gastrocolonic fistula)	Stent erosion	6-8 weeks	Conservative
McKinley	2021	Case Report	1	1	Contralateral jejunal wall	Adhesions → ulceration	3 months	Surgery
Taibi	2020	Case Report	1	1	Contralateral jejunal wall	Delayed stent removal / erosion	6 months	Surgery
Perez-Cuadrado-Robles	2020–2022	Retrospective case-control study	28	1 (3/6%)	Into colon (gastrocolonic fistula)	Colon crossing during stent deployment	12 days	Conservative (passed)
Genere	2023	Case Report	1	1	Ipsilateral jejunal wall	Carcinomatosis, smoker	4 weeks	Surgery → comfort measures (passed)

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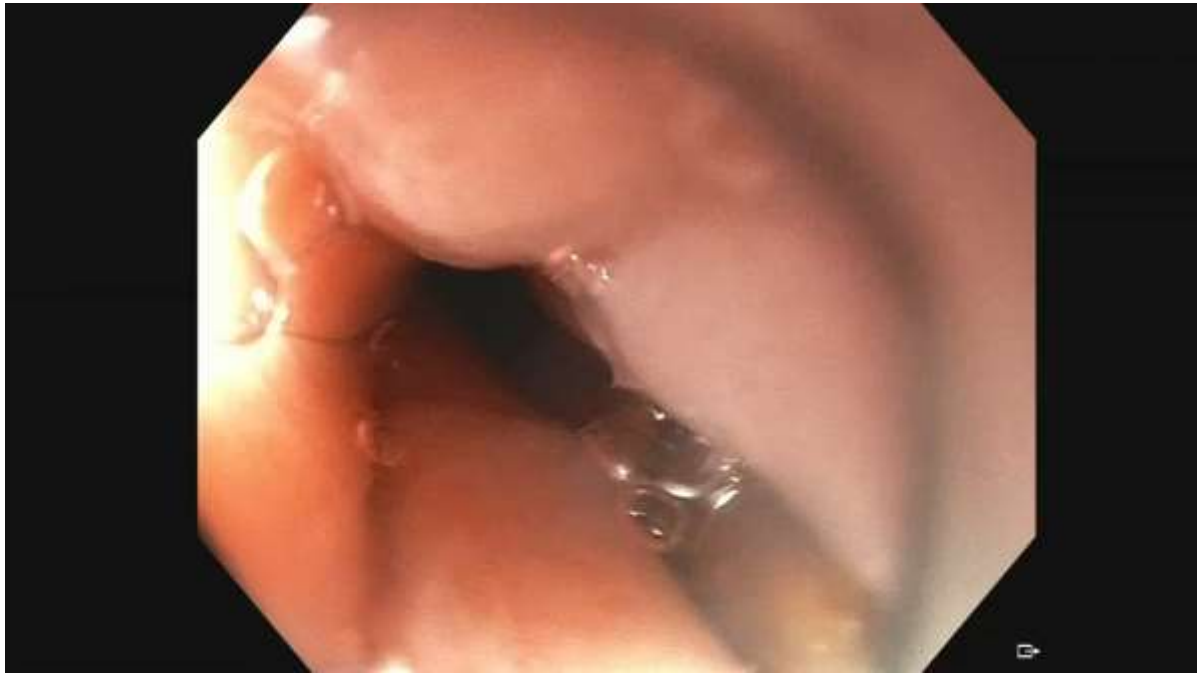
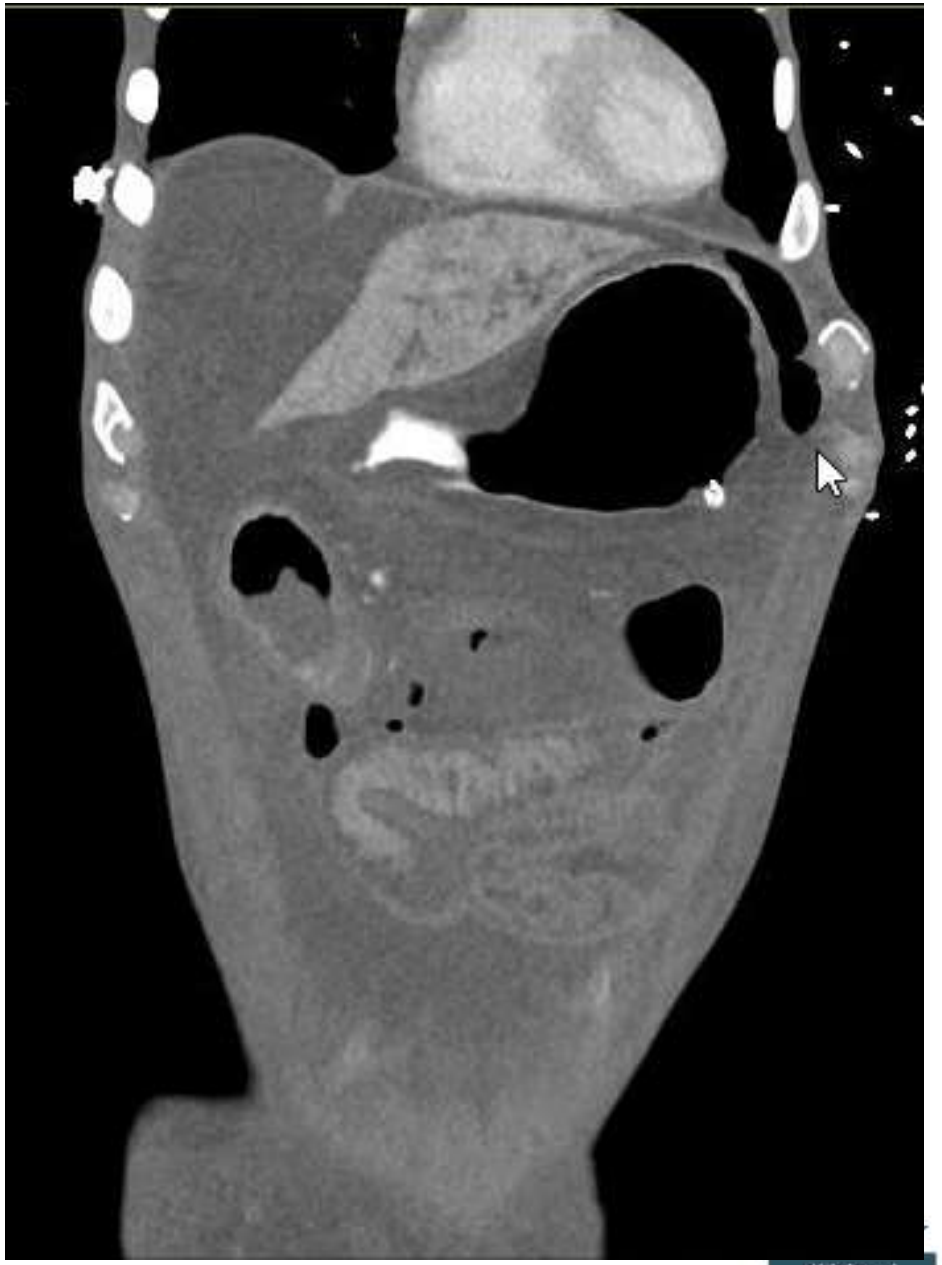
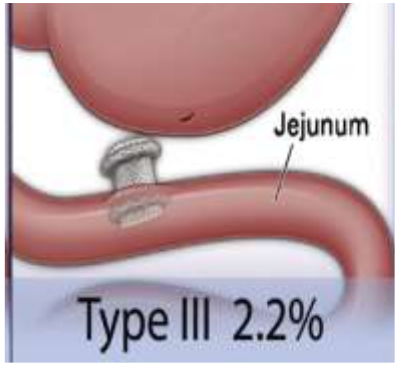
Representing with Gastric outlet syndrome – buried LAMS





Delayed Type 3 – GJ Dehisence



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Delayed Dehiscence

Delayed dehiscence of the EUS-GE anastomosis is rare and serious complication of EUS-GE

We demonstrated novel endoscopic management of a delayed EUS-GE dehiscence by tethering the separated ends of the anastomosis with endoscopic suturing

Reestablishing the GE anastomosis facilitated LAMS replacement to seal the tract and place reinforcements.

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Venting saves lives…

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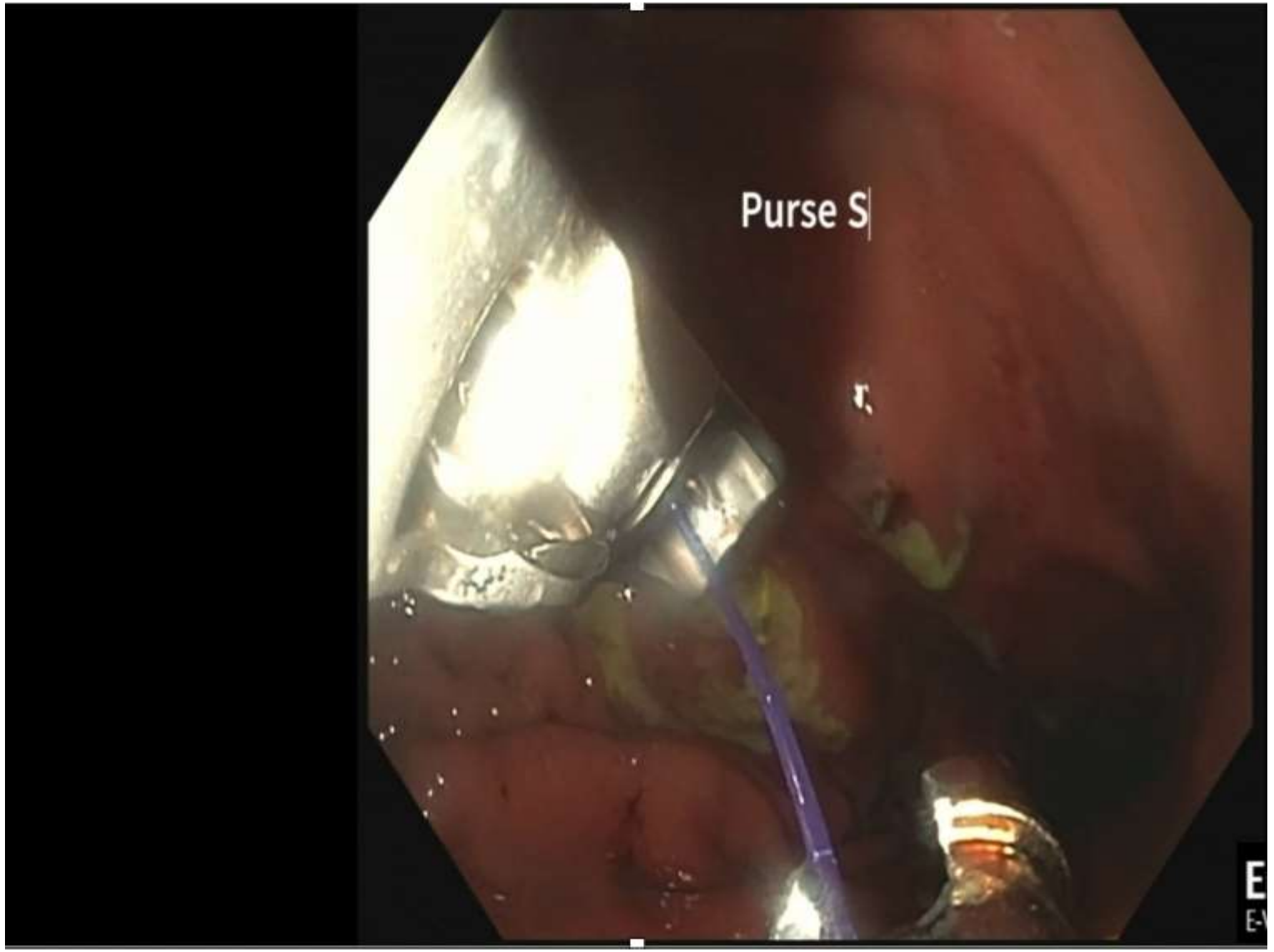
The future?

- **How do we scale this?**
- EPASS
- Stability
- New device
- **Long-term**
- Minimise stent exchanges
- Can we keep stent free?

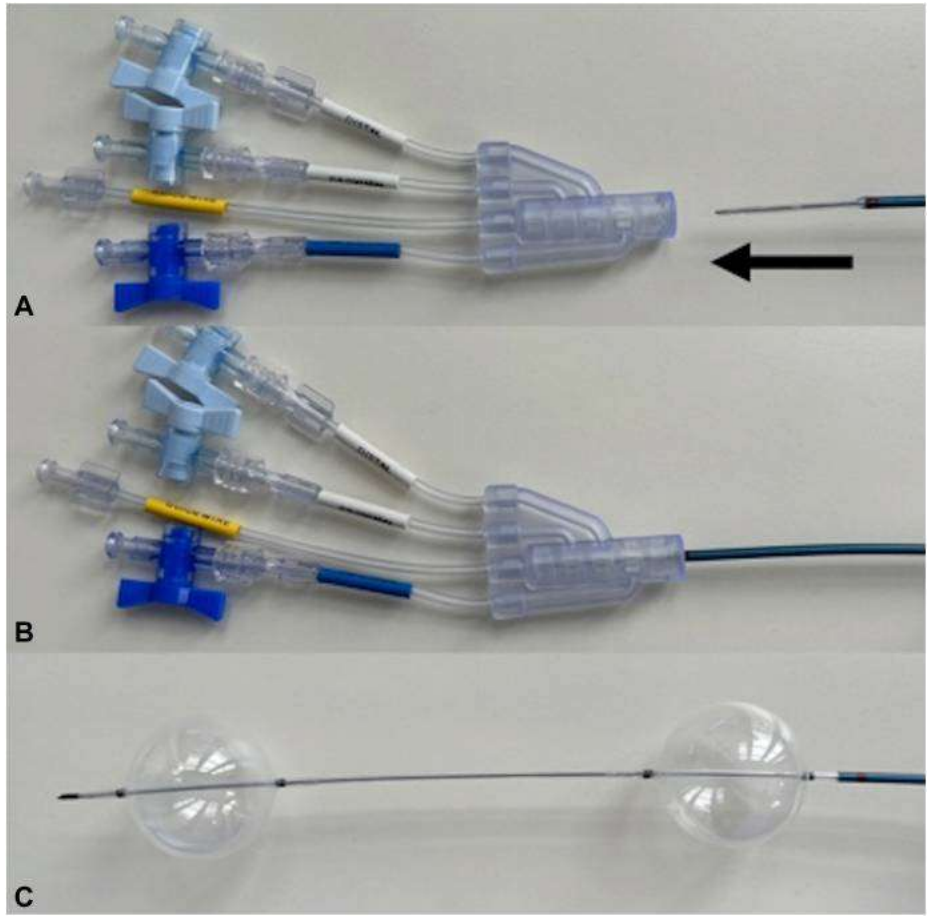
No need to pray when you do a GJ

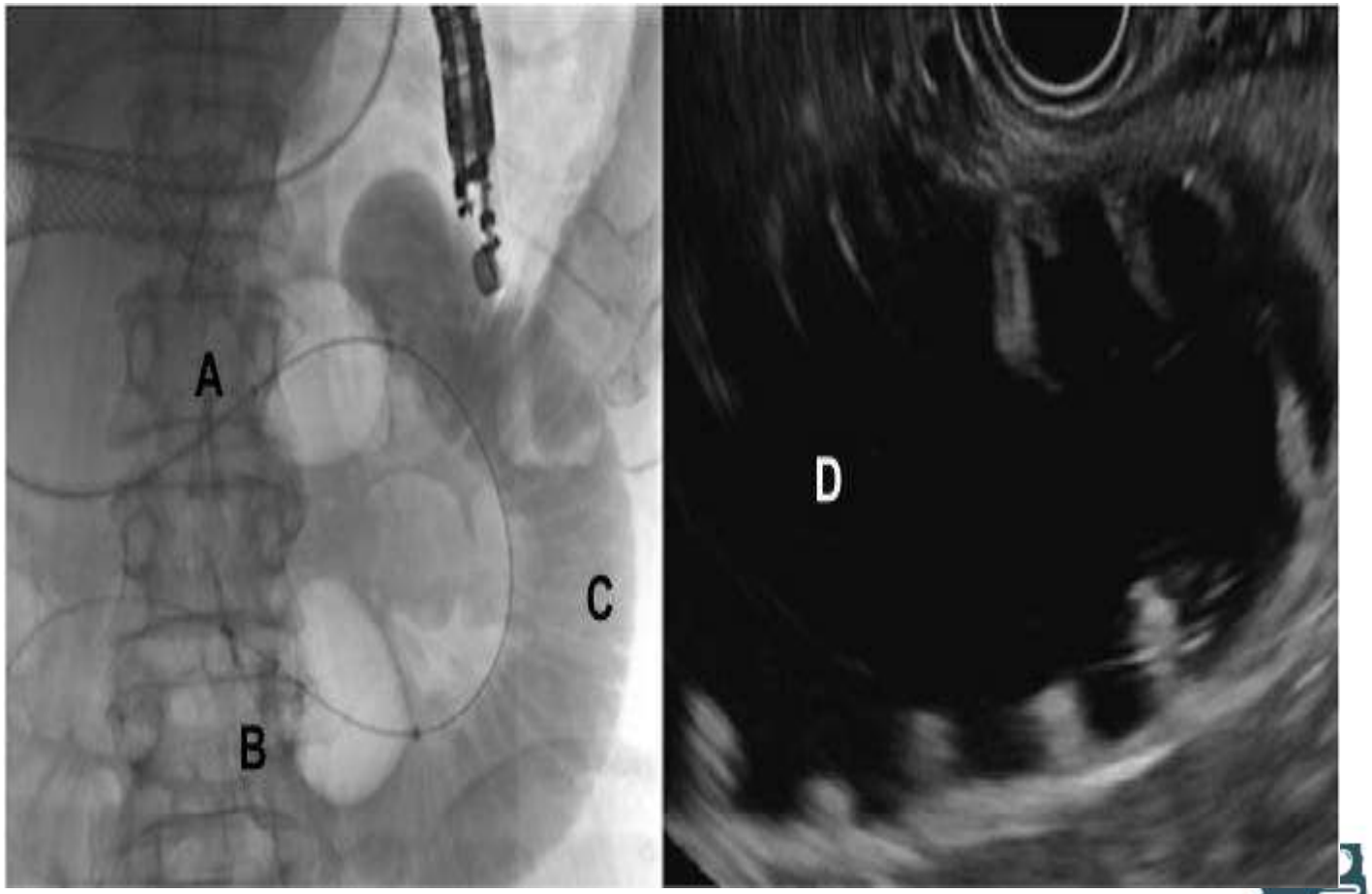
Salgado.. Sharaiha Mahadev Endoscopy 2023

Making a permanent GJ



Novel Device- Chess Medical





Yen-I Chen

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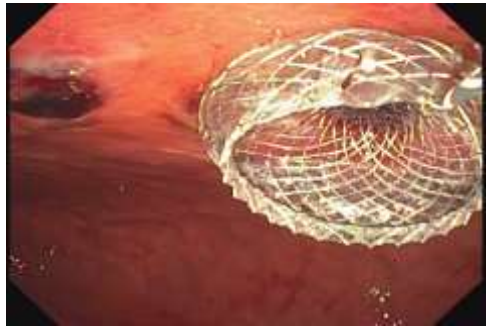
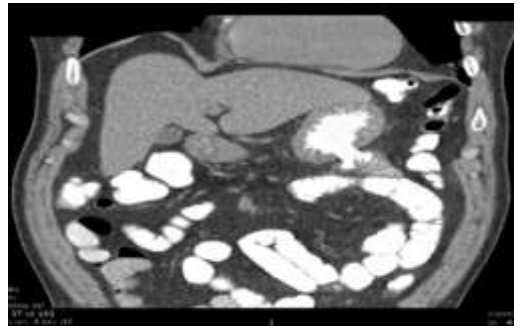
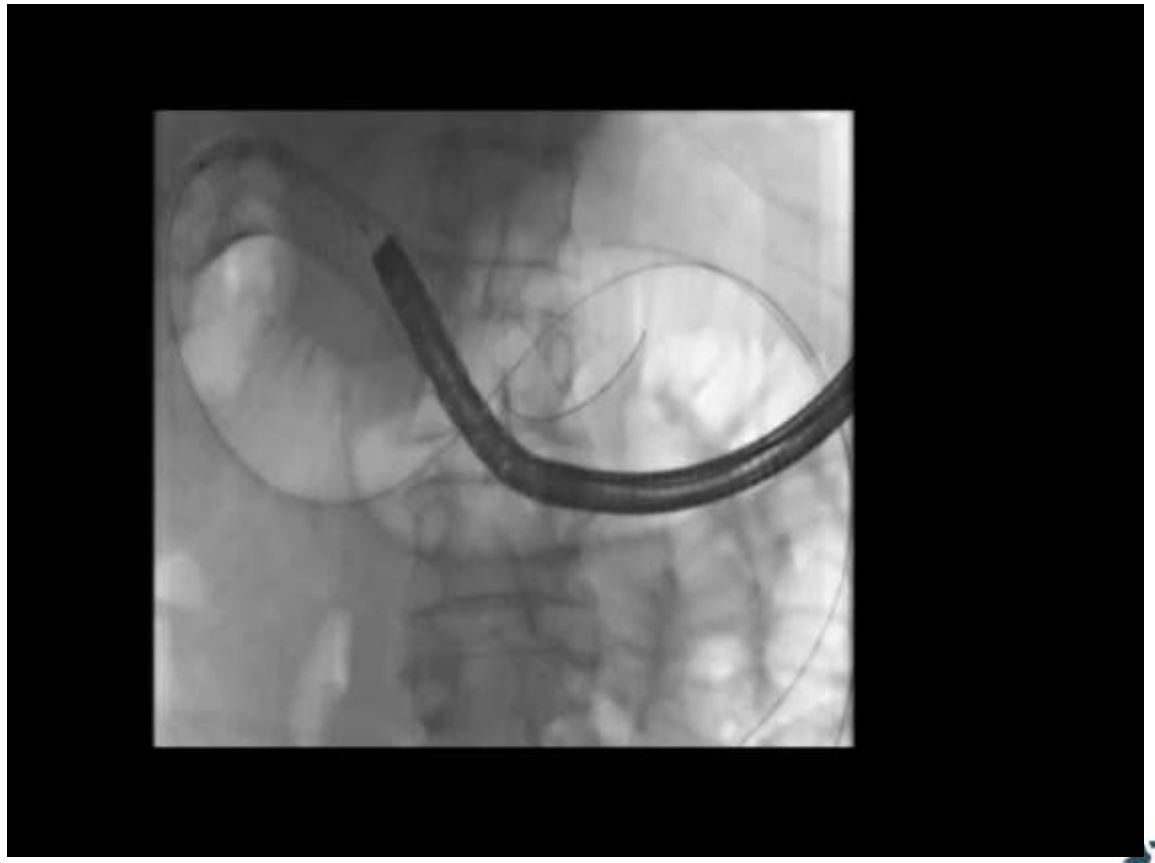


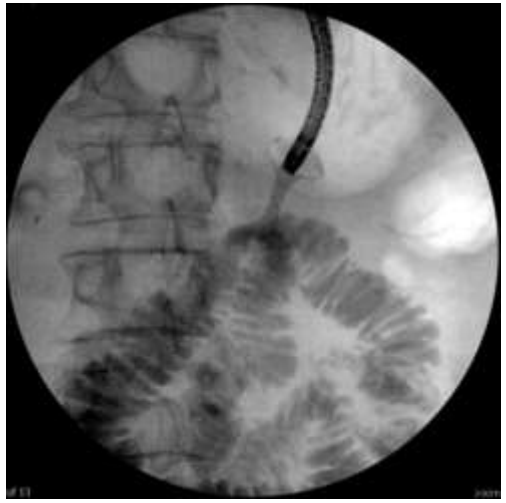
Conclusions



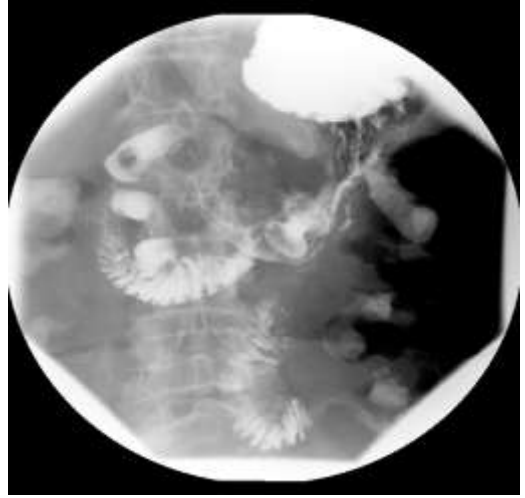
- Main issue with EUS-GJ: Stent Misdeployment/technically difficult → has not scaled

→ Solution: Dedicated devices that renders the target (jejunum): Large, stable and apposed to the stomach.





Conclusions



- EUS-GJ is safe and effective for palliation of malignant GOO
- Endoscopists should have expertise in interventional EUS
- Technical challenges can be overcome with several endoscopic techniques and experience
- Be prepared for the worst, and Hope for the best
- Know your tools to be able to manage Adverse events

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Limitation of Published Literature

- Studies at high volume tertiary care centers
- Highly skilled and expert endoscopists
- Limited data from prospective trials
- Limited data from randomized controlled trials
- Considerable heterogeneity in included patients, approaches, study endpoints
  - technical and clinical success definitions),duration of follow-up

Therapeutic EUS – Training and Credentialing

- No training or credentialing guidelines
- Endoscopists interested in these techniques should:
  - Regularly perform pancreaticobiliary EUS and FNA
  - Extensive experience with EUS and ERCP (annual volume: 200-300 for 4-5 years)
  - High success rates with ERCP (>95%)
  - Perform cases at centers with IR +/- pancreaticobiliary surgery access
  - Complete >20-25 pseudocyst drainage procedures prior to EUS-BD and EUS-PD, start with EUS-RV

Maple et al. GIE 2017

Therapeutic EUS - Where we need to go?

- Define the ideal treatment algorithm
- Need outcomes data from lower volume centers
- But also need more comparative data from India
- Improvement in devices is required
- Long-term follow-up studies of individual procedures are needed, **read new quality indicator document.** Phone call two weeks out. Make this standard
- Training pathways, learning curves and competency thresholds need to be defined

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Leave you with this ---It happens to all of us..