

**Rush University System for Health** 

# Interventional EUS: The endoscopic anastomosis is here to stay

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## **Disclosures**

**Boston Scientific (Speaker) US Endoscopy (Consultant)** 



## **Diagnostic EUS**

- Staging of luminal cancer
- Sub-epithelial masses
- Choledocholithiasis
- Pancreatic cysts
- Solid pancreatic lesions
- Biliary and gallbladder malignancy
- Chronic pancreatitis





## Interventional EUS

#### Drainage

- Pancreatic fluid collections
- Bile duct drainage
- Gallbladder drainage
- Peri-luminal abscesses

#### Bypass

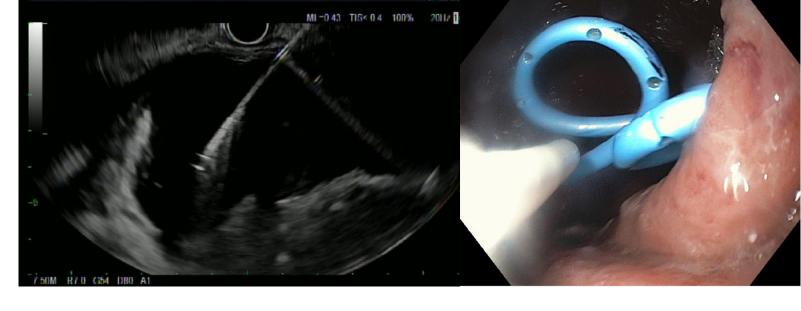
- RYGB/EDGE procedure
- Afferent loop syndrome
- Gastro-jejunostomy

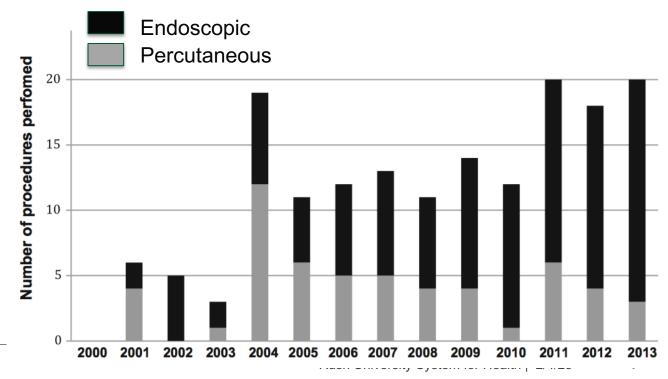
#### Ablation

- Pancreatic cysts
- Solid tumors
- Celiac plexus interventions

#### Endohepatology







Endoscopic anastomosis MI = 0.80 TIS < 0.4 100% Clinical evaluation of endosonography-gui drainage (with vide Takao Itoi, MD,<sup>1</sup> Kenneth Fumihide Itokawa, MD,<sup>1</sup> T Shujiro Tsuji, MD,<sup>1</sup> Nobuh Tokyo, Japan SDH

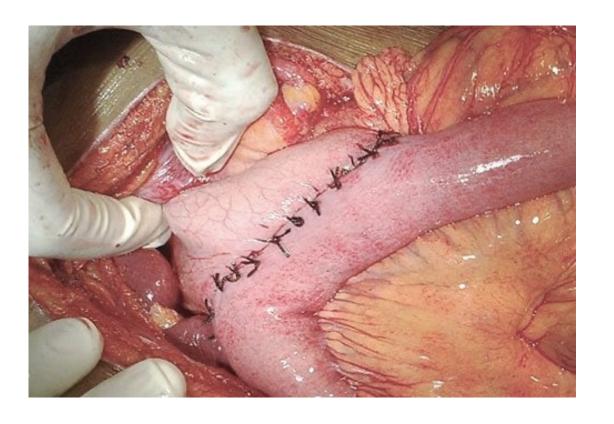
GIE 2012



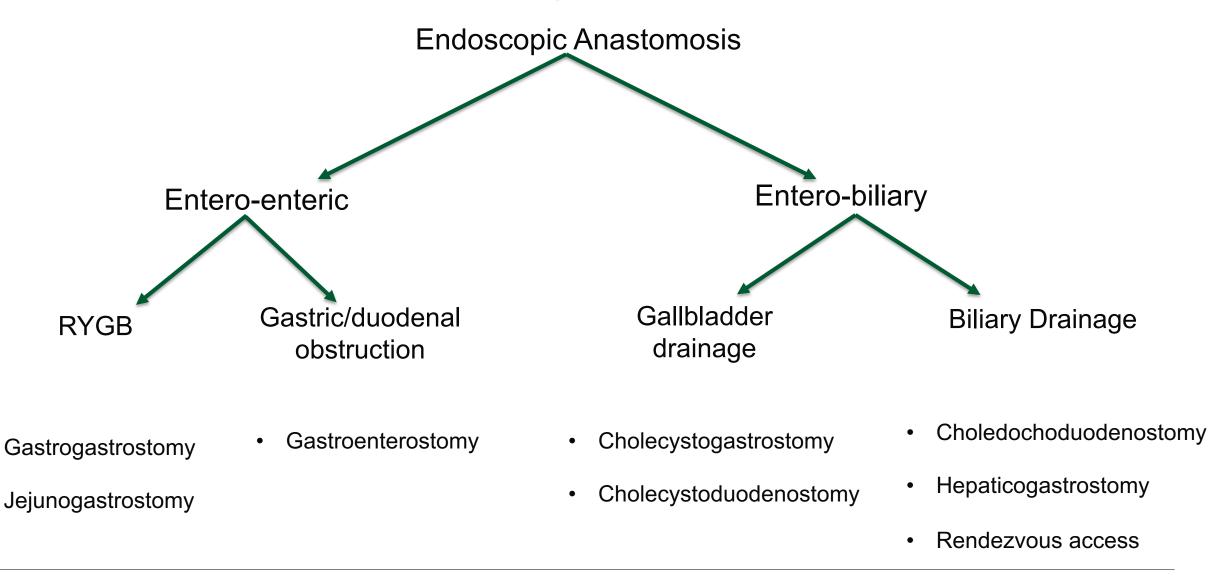


## Ideal bowel anastomosis

- Accurate/good approximation (no leaks)
- Lack of tension
- Good blood supply
- Clean (lack of peritoneal contamination)
- Connect viable tissue to viable tissue
- Patency (short and long term)
- Discomfort/QoL/comoribidities



## Interventional EUS: reaching the unreachable





# Post RYGB interventions: EDGE/EDGI





Khara at al. Current Gastroenterol Rep 2021



Biliopancreatic limb

### **EDGE** evolution to **EDGI**

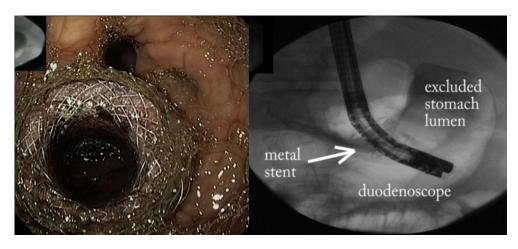
#### **GASTROENTEROLOGY IN MOTION**

Ralf Kiesslich and Thomas D. Wang, Section Editors

#### **Internal EUS-Directed Transgastric ERCP (EDGE): Game Over**

Prashant Kedia, Reem Z. Sharaiha, Nikhil A. Kumta, and Michel Kahaleh

Division of Gastroenterology and Hepatology, Weill Cornell Medical College, New York, New York



Gastroenterology 2014

## Endoscopic ultrasound-directed transgastric ERCP (EDGE) for Roux-en-Y anatomy: a novel technique

Authors

Prashant Kedia<sup>1</sup>, Nikhil A. Kumta<sup>1</sup>, Jessica Widmer<sup>2</sup>, Subha Sundararajan<sup>3</sup>, Mark Cerefice<sup>4</sup>, Monica Gaidhane<sup>1</sup>, Reem Sharaiba<sup>1</sup>, Michel Kabaleh<sup>1</sup>

Endoscopy 2014

## Endoscopic ultrasound-Directed transgastric ERCP (EDGE): A single center U.S. experience with follow up data on fistula closure

Theodore W. James, MD and Todd H. Baron, MD

Obesity Surg 2019

#### DYNAMIC MANUSCRIPT

Gastric access temporary for endoscopy (GATE): a proposed algorithm for EUS-directed transgastric ERCP in gastric bypass patients

Thomas J. Wang<sup>1,3</sup> · Christopher C. Thompson<sup>2,3</sup> · Marvin Ryou<sup>2,3</sup>

Surg Endosc 2019

The EDGI new take on EDGE: EUS-directed transgastric intervention (EDGI), other than ERCP, for Roux-en-Y gastric bypass anatomy: a multicenter study

Matthew R. Krafft<sup>1</sup>, William Hsueh<sup>1</sup>, Theodore W. James<sup>2</sup>, Thomas M. Runge<sup>3</sup>, Todd H. Baron<sup>2</sup>, Mouen A. Khashab<sup>3</sup>, Shayan S. Irani<sup>4</sup>, John Y. Nasr<sup>1</sup>

Endosc Int Open 2019



## **EDGI** technique

Consent, multi-disciplinary approach

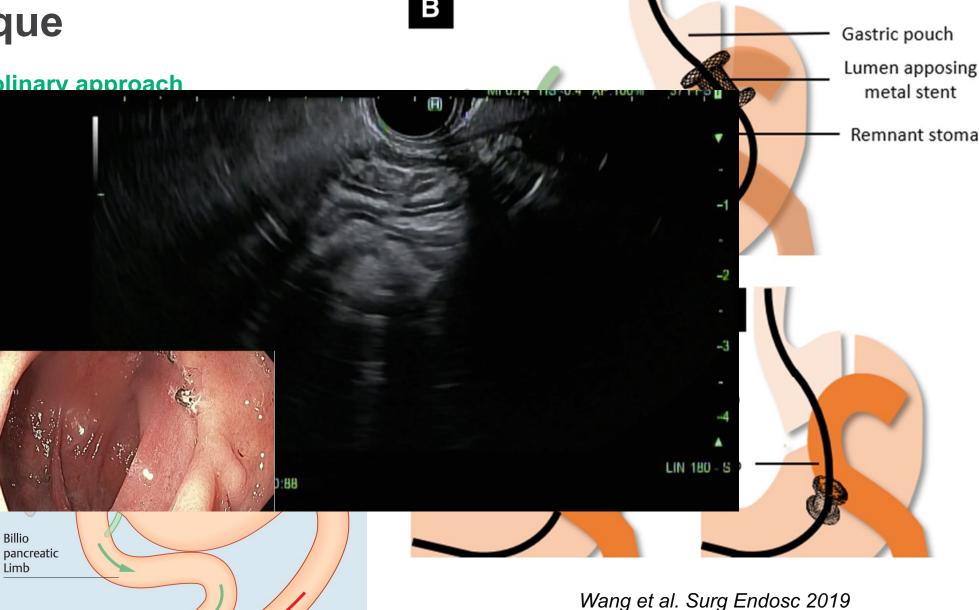
**General anesthesia** 

Make sure below the

Decide gastric vs. je anastomosis)

Glucagon, IV antibio

LAMS size







## **Outcomes for RYGB-ERCP**

Meta-analysis 76 studies, 3569 ERCPs

	**
*	

	DAE-ERCP	LA-ERCP	EDGE-ERCP
Technical Success	87.3	99.1	97.9
Cannulation Success	74.7	98.6	98
Therapeutic Success	69.1	98.5	97.9
Adverse Events	5.7	15.1	13.1

n.s.

No difference in outcomes between single and double balloon enteroscopy

Gfolfakis et al. Life. 2022



## Similar outcomes, then why EDGE

	LA-ERCP	EDGE-ERCP	Risk Diff.	P-value
Tech. success	98.3%	97.8%	0.00	0.96
Adverse Events	20.4%	13%	-0.08	0.09

Length of stay: -1.2 days (p=0.0004)

Procedure time: -98.2 mins (p<0.00001)

Modality		Minor AEs per patient	Cost per patient (US\$)	Cost per QALY
EDGE	0.06	0.01	4,877	5,188
DAE-ERCP	0.07	0.17	10,097	11,263
LA-ERCP	0.12	0.003	28,130	34,259

Meta-analysis 5 studies 268 patients (92/176)



Oliveira et al. Cureus 2022 James et al. Endoscopy 2019



## **EDGE: Clinical outcomes**

• 178 patients, 13 centers

• Technical success: 98.3%

Mean procedure time: 92 mins

Adverse events: 15.7%

	N (175)	Severity (mild/mod/severe)	Intervention
Perforation	6	3/2/1	Surgery:1 Endoscopic closure: 4
Symptomatic Pneumoperitoneum	3	1 / 0/ 2	Laparoscopy: 2 Needle decompression: 1
LAMS misdeployment	9	8/1/0	All bridging stent
Intra-procedural migration	2	1/0/1	Abort procedure: 1 Hypotension/intubation: 1
Delayed migration	2	2/0/0	No intervention
Bleeding	2	0/2/0	Transfusion & endoscopy: 2

Persistent Fistula: 10%

Runge et al. Endoscopy 2021 Shin et al. GIE 2021

## **EDGI lessons learnt: Issues and how to minimize**

#### Univariate analysis of factors associated with 11 total migrations

Stent size 15mm vs 20mm

Sutures vs no sutures

Dilation vs no dilation

Gastric route vs jejunal

Electrocautery vs no electrocautery

RR

5.271

0.221

1.972

0.300

0

95%CI

1.473-18.868

0.061-0.808

0.447-8.708

0.077-1.163

P value

0.007

0.033

0.084

0.502

0.141

#### Stent migration

- single vs. double session
- shortened interval
- <u>stent size (20 mm > 15mm)</u>
- securing the LAMS
- location of anastomosis

#### Persistent fistula

- shorter indwell time
- stent size (15 mm > 20 mm ??)
- gastric vs. jejunal access, avoid staple line
- APC treatment, DPS placement
- do we really need to worry about fistula

#### How to decide?

- Indication
  - · Benign vs. malignant disease
- Surgical needs
  - Needs cholecystectomy or not
- Anatomy
  - "Hostile" abdomen
- Local resources
  - Surgery support, endoscopic expertise

## Lap ERCP still has a role Patients with stones and gallbladder

Ghandour et al. GIE 2023



## Gastric outlet obstruction: Gastroenterostomy

#### **Surgical bypass**

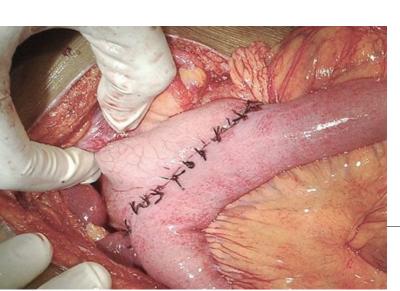
- High efficacy and technical success
- High long term patency

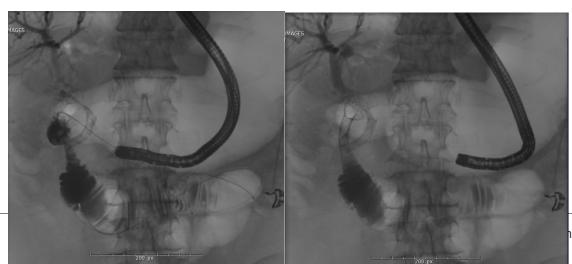
#### **Enteral stenting**

- High technical and short term clinical success
- Short LoS and very low morbidity

#### **EUS-gastroenterostomy**

 Long hospital stay and high morbidity - Long term stent patency (30% occlusion)





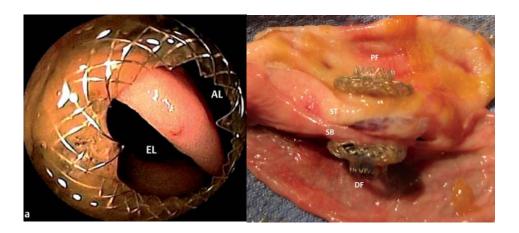


## Entero-enteric anastomosis: Gastrojejunostomy

Endoscopic ultrasound-guided gastroenterostomy using novel tools designed for transluminal therapy: a porcine study

Authors

K. F. Binmoeller, J. N. Shah



Binmoeller et al. Endoscopy 2012 Itoi et al. GIE 2013

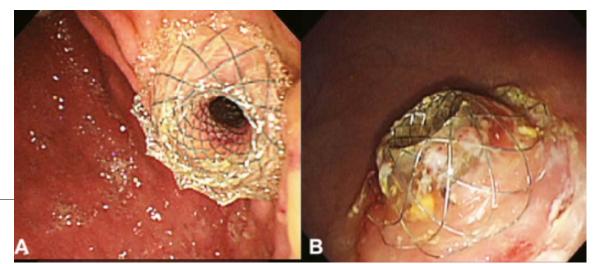


Novel EUS-guided gastrojejunostomy technique using a new double-balloon enteric tube and lumen-apposing metal stent (with videos)

Takao Itoi, MD, PhD, FASGE, <sup>1</sup> Fumihide Itokawa, MD, PhD, <sup>1</sup> Toshio Uraoka, MD, <sup>2</sup> Takuji Gotoda, MD, PhD, FASGE, <sup>1</sup> Joichiro Horii, MD, PhD, <sup>2</sup> Osamu Goto, MD, PhD, <sup>2</sup> Fuminori Moriyasu, MD, <sup>1</sup> Jong Ho Moon, MD, PhD, <sup>4</sup> Yuko Kitagawa, MD, PhD, <sup>3</sup> Naohisa Yahagi, MD, PhD







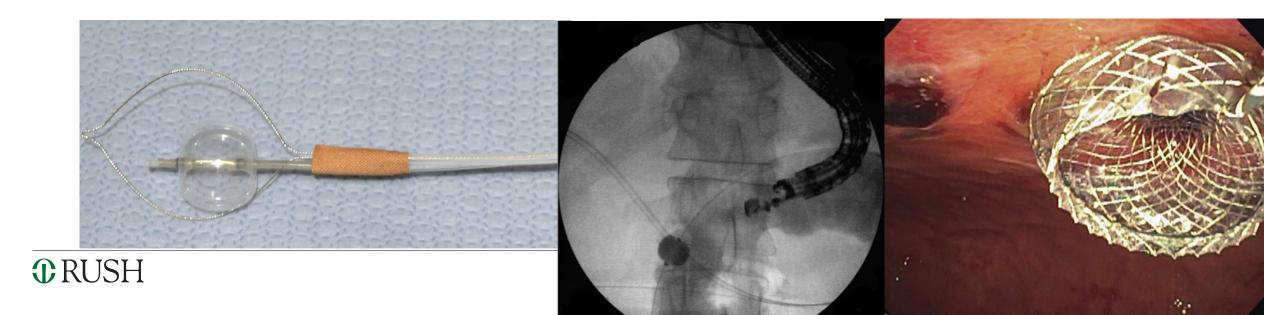
#### **NEW METHODS: Clinical Endoscopy**

## EUS-guided gastroenterostomy: the first U.S. clinical experience (with video)

Mouen A. Khashab, MD,<sup>1</sup> Vivek Kumbhari, MD,<sup>1</sup> Ian S. Grimm, MD,<sup>2</sup> Saowanee Ngamruengphong, MD,<sup>1</sup> Gerard Aguila, RN,<sup>1</sup> Mohamad El Zein, MD,<sup>1</sup> Anthony N. Kalloo, MD,<sup>1</sup> Todd H. Baron, MD<sup>2</sup>

GIE 2015

- 10 patients
- 7 with benign disease
- One free hand technique, all other balloon assisted
- Technical success: 90%
- One needed surgical bypass



## **EUS** guided gastroenterostomy

- Consent, surgical collaboration
- Anatomy, rule out ascites, make sure gastric mucosa healthy
- Approach
  - free hand, balloon assisted, jejunal drain assisted
- Glucagon, antibiotics
- Size of stent
- Surgical consult, surgeon available
- Back up plan....

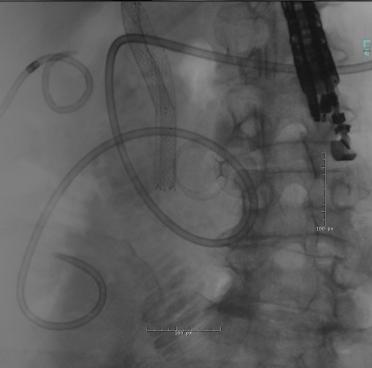






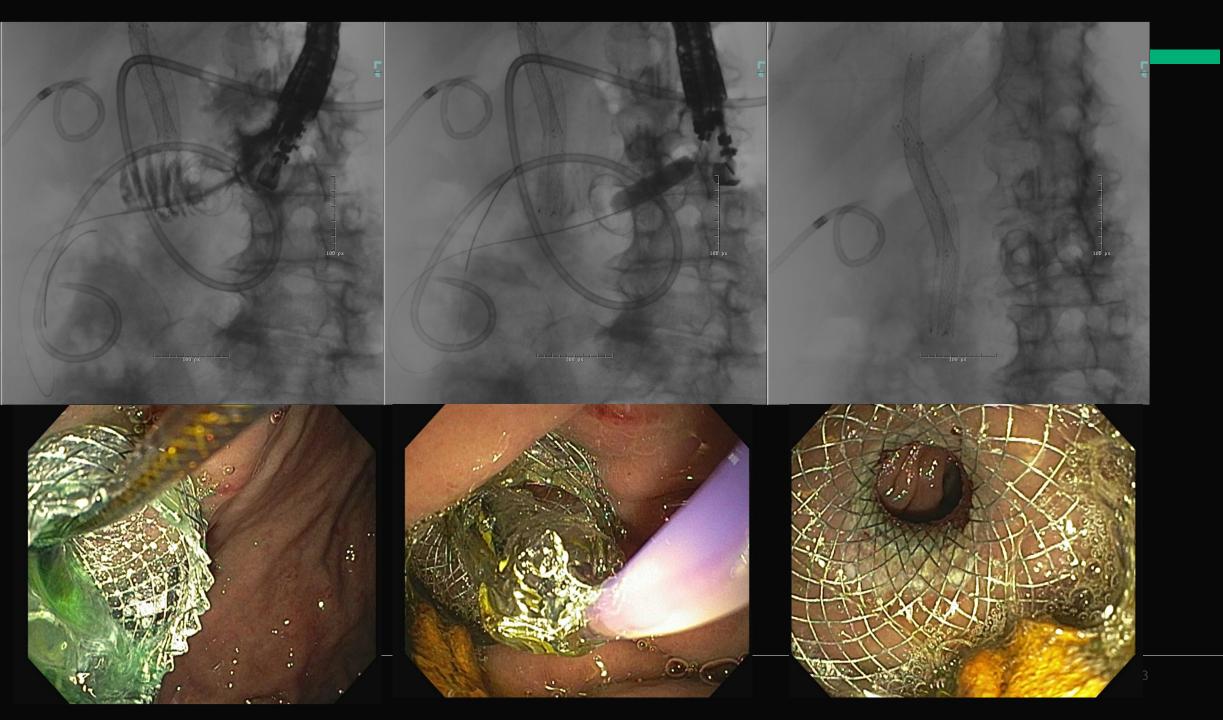


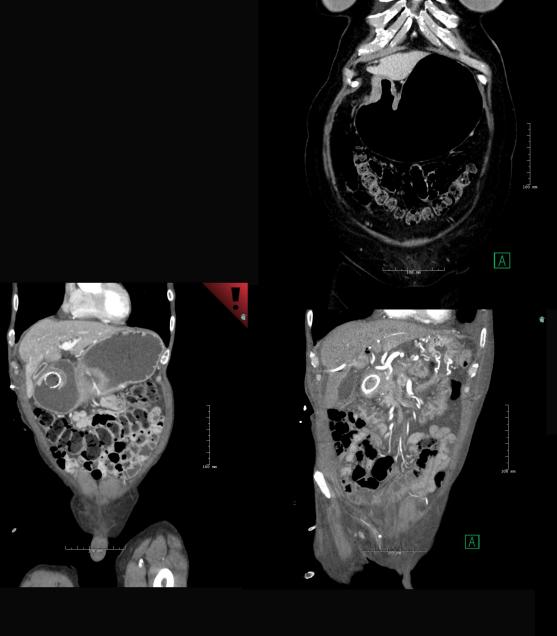


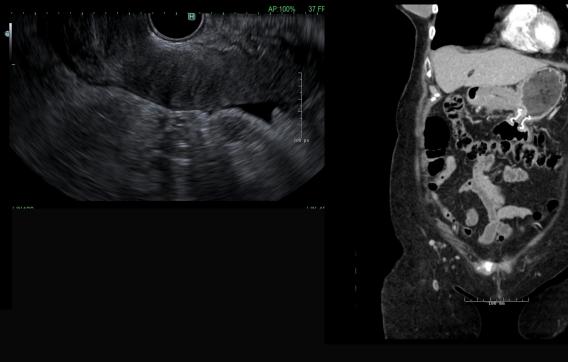


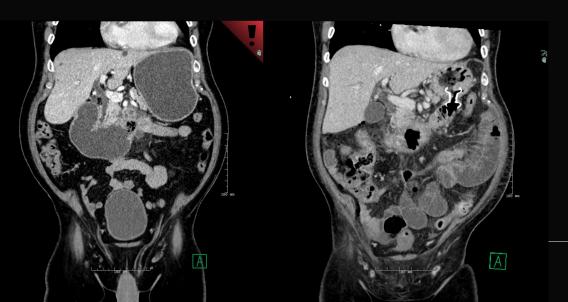














## Data starts coming in..... (2017)

International multicenter comparative trial of endoscopic ultrasonography-guided gastroenterostomy versus surgical gastrojejunostomy for the treatment of malignant gastric outlet obstruction

	EUS-GE (n=30), n(%)	Surgical GJ (n=63), n(%)	P value
Carcinomatosis	13 (43)	7 (11)	<0.001
Technical success	26 (87)	63 (100)	0.009
Clinical success	26 (87)	57 (90)	0.18
Recurrent GOO	1 (3)	9 (14)	0.08
Adverse events,	5 (16)	16 (25)	0.3
Mean LoS (days)	11.6±6.6	12±8.2	0.35*

Khashab et al. Endoscopy 2017

Only predictor of success: absence of carcinomatosis



## **EUS-GE vs. Lap-GE**

Retrospective study
International, multi-center study (Europe)

	EUS-GE (n = 77)	Lap-GE (n = 48)	P-value
Technical success	73 (94.8)	48 (100)	0.297
Clinical success	71 (92.2)	42 (87.5)	0.534
Time to oral intake, days	1 (0-1)	3 (1-5)	<.001
Time to full diet, days	2 (1-4)	8 (4-21)	<.001
Adverse events	5 (6.5)	15 (31.3)	<.001
Mild/moderate	3	6	1.000
Severe	2	9	0.007
Re-endoscopy	0	4	0.020
Surgical reintervention	N/A	3	N/A
Procedure duration, min	51	95	<0.001
Hospital stay, days	4	8	<0.001

Bronswijk et al. GIE 2021

## How does it compare with enteral stenting?

Meta-analysis 5 studies, 659 patients

	EUS-GE (n=278)	ES (n=381)	P value
Technical success	95.2%	96.9%	0.6
Clinical success	93.3%	85.6%	0.2
Reintervention	4%	23.6%	0.001
Adverse events	10.7%	19.7%	0.3
Major AEs	3.7%	2.8%	0.8

Mohan et al. Endosc Intl Open 2021



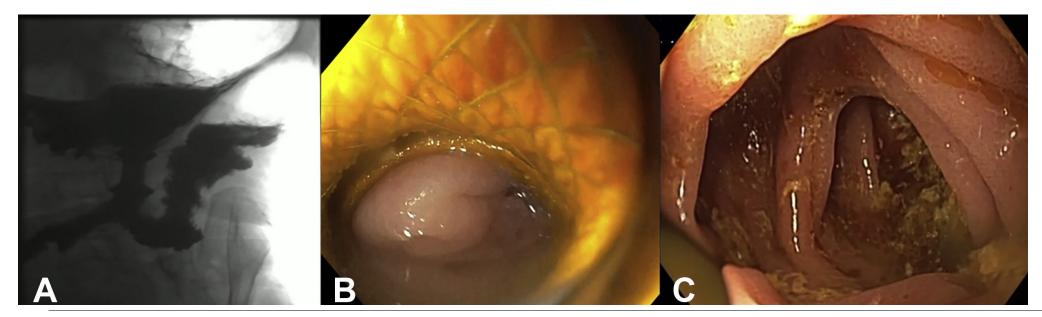
## **EUS** guided gastroenterostomy

	EUS-GE (n=232)	ES (n=131)	Surgical- GE (n=73)	Overall <i>P</i> -value	EUS-GE vs. ES †	EUS-GE vs. surgical-GE 1
Technical success	228 (98.3)	130 (99.2)	73 (100.0)	0.58	0.66	0.58
Clinical success	228 (98.3)	120 (91.6)	66 (90.4)	0.002*	0.002*	0.005*
Length of stay	2 (1–3)	3 (1–10)	5 (2–9)	<0.0001*	<0.0001*	0.018
Reintervention	2 (0.9)	16 (12.2)	10 (13.7)	<0.0001*	<0.0001*	<0.0001*
Adverse events	20 (8.6)	51 (38.9)	20 (27.4)	<0.0001*	<0.0001*	<0.0001*

Jaruvongvanich et al. Endosc Int Open 2023





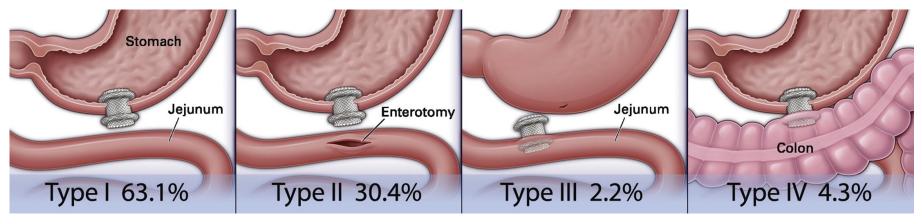




## EUS-GE: still not a walk in the park...

Retrospecitve, multi-center, international study 467 patients

**Stent misdeployment: 10% (46 patients)** 



- Expert centers
- Animal studies
- Surgical back up
- Off label use of LAMS
- Studies: 6-27%
  misdeployment rate

Severity

Mild: 61%

Moderate: 24%

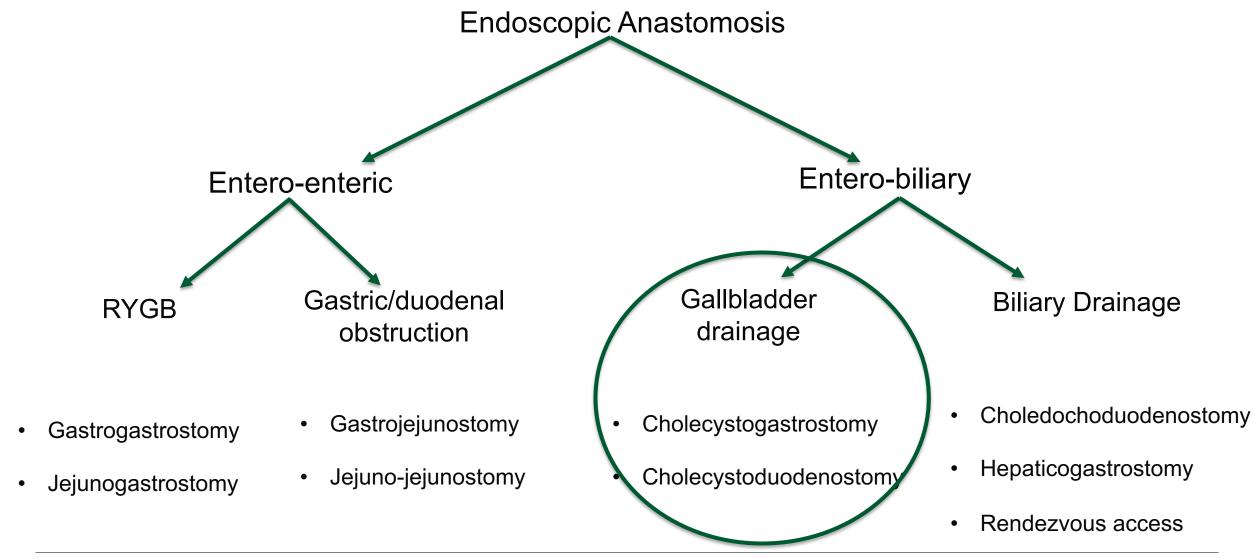
Severe: 13%

Fatal: 2%

Surgery: 11% (5/46)



## **Entero-biliary anastomoses**





## EUS guided gallbladder drainage Cholecystoduodenostomy / cholecystogastrostomy

#### Approach to non-surgical management of cholecystitis

- Percutaneous drainage
- Trans-papillary drainage (ERCP)
- EUS guided drainage
  - Cholecystoduodenostomy
  - Cholecystogastrostomy



## **EUS** guided GB drainage: Technique

- Proficient in use of LAMS and interventional EUS
- Correct indication (surgery, IR teams on board)
- Appropriate window
- Tap ascites if needed pre-procedure
- Stent size
- Antibiotics





## EUS-GBD vs. PC-GBD (DRAC 1 trial)

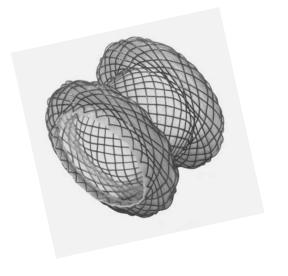
	EUS-GBD (39)	PTC-GBD (40)	p- value	80	EUS-GBD
Technical success	38 (97.4)	40 (100)	.494		
Clinical success	36 (92.3)	37 (92.5)	1	Pain score (VAS)	
Procedure time (mins)	22.7	27.4	.108	Pair s	
Hospital stay (days)	8 (4-13)	9 (7-14)	.181	0	
30-d mortality	3 (7.7)	4 (10)	1	0 1 2	3 4 procedural day
30-d adverse events	5 (12.8)	19 (47.5)	.001	<b>—</b>	
Unplanned admissions	6 (15.4)	20 (50)	.002	<b>—</b>	
30-d reinterventions	1 (2.6)	12 (30)	.029	<b>—</b>	
1-year AEs	10 (25.6)	31 (77.5)	<.001		
Recurrent AC	1 (2.6)	8 (20)	.029		



## EUS-GBD (only LAMS) vs. PC-GBD

Meta-analysis 5 studies 647 patients (278/369)

Outcome	EUS (%)	PC (%)	Risk difference	P value
Technical success	95.9%	99.6%	-0.03	0.1
Clinical success	91%	94.8%	0.04	0.1
Adverse events	19%	45.2%	-0.33	0.006
Recurrent cholecystitis	2%	6.8%	-0.05	0.02
Reintervention	1.7%	34.8%	-0.35	0.013
Readmission	7.3%	37.1%	-0.36	0.03



Candido Hemerly et al. Surgical Endoscopy 2022

## Why not ERCP and trans-papillary drainage?

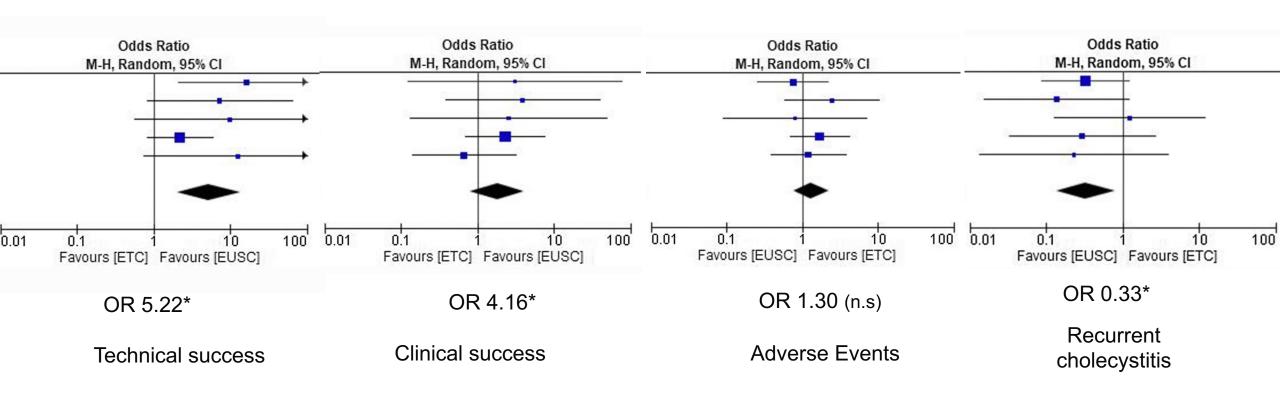
- Technically difficult
  - Cystic duct cannulation, tortuous cystic duct, duct obstruction
- Stent occlusion
  - Two side by side stents
- Stent removal, risk of recurrence
- Risk of pancreatitis





### **EUS-GBD vs. ERCP-GBD**

**Meta-analysis 5 studies, 857 patients** 





Krishanmoorthi et al. Surgical Endoscopy 2020

## **EUS GB** drainage: issues

- Transgastric vs. transduodenal
  - depends on the optimal position
  - less food impaction with duodenal
- Size of LAMS
- Double pigtail or not
- Stent removal/exchange
- Cholecystectomy after LAMS



## Just getting started !!

- Endo-hepatology
- Oncotherapy
  - sclerotherapy
  - chemotherapy
  - immunotherapy
  - gene therapy
- Vascular interventions
  - PPG measurement
  - pseudo-aneursyms
  - gastric variceal bleeding
  - CTCs sampling



### Conclusion

- Endoscopic anastomoses using lumen apposing metal stents are feasible, durable and safe in the right hands
- In patients with RYGB
  - EDGE/EDGI should be preferred over laparoscopic approaches in malignant disease
  - In benign disease, consider EDGI if no need for surgery
  - Lap CCY + CBDE and lap CCY with lap assisted ERCP still a reasonable option

Don't work alone !!!!

- In malignant GOO, EUS-GE should be done by expert endosonographers with adequate surgical back up. Consider enteral stent if expertise not available or short expected survival
- EUS guided GB drainage should be considered over percutaneous drainage in patients who are too high risk for surgery
- Future device development which minimizes risk will lead to wider adoption



## **Thank You**

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"We need practice to get good at what we do. There is one difference in medicine, though: it is people we practice upon."

— Atul Gawande

