CONTROVERSIES IN ADVANCED ENDOSCOPY
DDW 2019 UPDATES

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OBJECTIVES

- Updates in EUS:

a. EUS-guided tissue acquisition – needle gauge, FNA vs. FNB

b. Quality indicators and pragmatic approach to sampling pancreatic masses

c. Advances in evaluation of pancreatic cysts

d. Interventional EUS

EUS-GUIDED TISSUE ACQUISITION

- EUS-TA by EUS-FNA or EUS-FNB sampling – pivotal role in the diagnosis of GI and other non-GI malignancies and numerous non-malignant processes
- Obtaining adequate samples, arriving at accurate diagnosis (avoid false negative diagnosis) and ultimately improve patient outcomes – fundamental endpoints of EUS-TA

EUS GUIDED TISSUE ACQUISITION DEFINITIONS

- Specimen adequacy: Percentage of lesions sampled in which obtained material is representative of the target site and sufficient for diagnosis
- Diagnostic yield: Percentage of lesions sampled for which a tissue diagnosis is obtained
- Accuracy: Percentage of lesions sampled by EUS-TA techniques that correspond to final diagnosis (surgical histopathology or clinical follow up of at least 12 months with non-diagnostic sampling)
- Core specimens: Defined by presence of a tissue sample that allows for histologic and tissue architectural assessment

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Wani S et al. GIE 2014, Wani et al CGH 2018

VARIABLES

- **EUS-TA Technique:**
  - Use of suction (wet, dry, and no suction), use of a stylet, fanning, capillary technique, number of passes
- **Needle type:**
  - FNA vs. FNB, needle gauge
- **Endosonographer:**
  - Training and competency, experience and volume
- **Cytopathologist:**
  - Training, experience, and volume
- **Cytotechnologist:**
  - Experience in slide preparation and tissue processing
- **Center variables:**
  - Availability of on-site cytopathology evaluation (OCE) and volume

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Wani S et al. GIE 2014, Wani et al CGH 2018

FNA vs. FNB

- **Potential advantages of FNB (core biopsy)**
  - Larger specimens
  - Improving diagnostic yield especially for non-pancreatic lesions and cases with prior non-diagnostic EUS-FNA (salvage technique)
  - Assessment of tissue architecture and performing ancillary studies (autoimmune pancreatitis, GI stromal tumors, metastasis, lymphoma)
  - May obviate need for on-site cytopathologist
  - Achieve the endpoint with fewer passes
  - Role in personalized medicine (NGS, organoids)

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Tiriac et al, GIE 2018; Wani et al CGH 2018

FNB Needles

- Designs:
  - **Fork shaped tip:** cutting needle with a fork shaped distal tip including 6 cutting edges and an opposing bevel (SharkCore – 19G, 22G, 25G, Medtronic)
  - **Reverse bevel:** modified Menghini type needle with a beveled side slot near needle tip (ProCore 19G, 22G, 25G, Cook)
  - **Anterograde core trap**: modified Menghini type needle with a beveled side-slot near needle tip (ProCore 20G, Cook)
  - **Franseen tip geometry:** end cutting needle with a crown shaped distal tip (Acquire, 22G, 25G, Boston Scientific)

COMPARISON OF FNA vs. FNB AND NEEDLE GAUGE

- Systematic review with network meta-analysis
  - Comparison of diagnostic performance of FNA and FNB needles (based on needle gauge)
  - Secondary outcomes were sample adequacy, histological core procurement rate, and number of needle passes
  - Pairwise and network meta-analysis using frequentist approach
    a. informs comparative effectiveness of multiple interventions and synthesize evidence across a network of RCTs,
    b. strong evidence against the null hypothesis often and earlier than conventional pairwise meta-analysis
  - Quality of evidence appraised using GRADE methodology

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Facciorusso et al, DDW 2019

COMPARISON OF FNA vs. FNB AND NEEDLE GAUGE

Clinical Question	
Is there a difference in diagnostic accuracy between different EUS-FNA and FNB needles?	
Population:	Patients with pancreatic masses who underwent EUS-TA using FNA or FNB needles
Intervention:	EUS-FNA (22G, 25G, 19G) and EUS-FNB (22G, 25G) Franseen tip, Reverse-bevel, Fork-shaped tip
Comparator:	Each other
Outcomes:	Diagnostic accuracy (critical)

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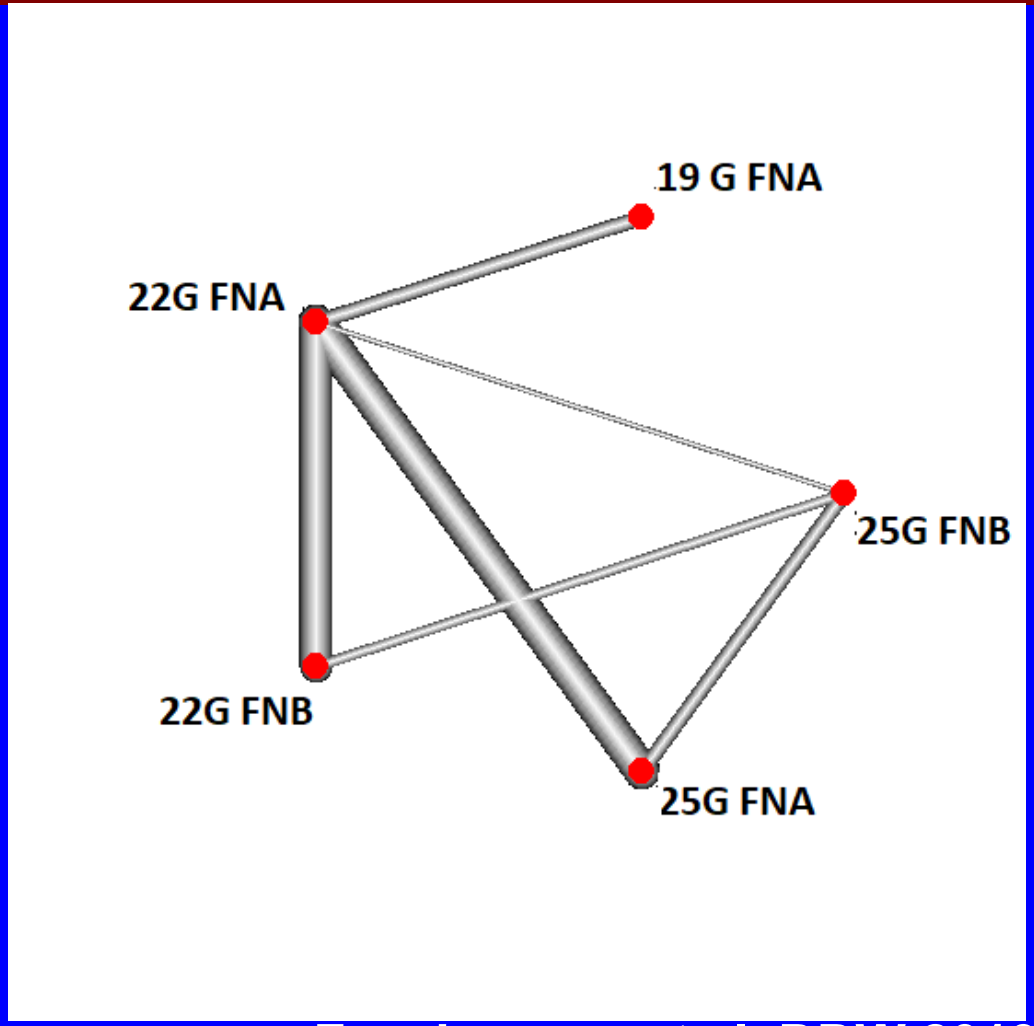
Facciorusso et al, DDW 2019

COMPARISON OF FNA vs. FNB AND NEEDLE GAUGE



Facciorusso et al, DDW 2019

COMPARISON OF FNA vs. FNB AND NEEDLE GAUGE

	Diagnostic Accuracy				
Sample Adequacy	**19G FNA**	**22G FNA**	**22G FNB**	**25G FNA**	**25G FNB**
	19G FNA	1.06 (0.8-1.41)	1.10 (0.8-1.5)	1.10 (0.81-1.51)	1.16 (0.58-1.69)
	0.87 (0.66-1.14)	**22G FNA**	1.03 (0.89-1.18)	1.03 (0.91-1.17)	1.09 (0.85-1.39)
	0.85 (0.63-1.15)	0.98 (0.86-1.11)	**22G FNB**	1.00 (0.83-1.20)	1.05 (0.82-1.36)
	0.84 (0.62-1.13)	0.96 (0.86-1.08)	0.98 (0.83-1.15)	**25G FNA**	1.05 (0.82-1.33)
	0.83 (0.58-1.18)	0.95 (0.76-1.19)	0.97 (0.77-1.23)	0.99 (0.79-1.23)	**25G FNB**

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Facciorusso et al, DDW 2019

COMPARISON OF FNA vs. FNB AND NEEDLE GAUGE – WITHOUT ROSE

	Diagnostic Accuracy				
Sample Adequacy	19G FNA	22G FNA	22G FNB	25G FNA	25G FNB
	19G FNA	1.06 (0.8-1.41)	1.09 (0.79-1.5)	1.06 (0.73-1.52)	1.13 (0.76-1.67)
	0.87 (0.66-1.14)	22G FNA	1.02 (0.87-1.19)	0.99 (0.78-1.24)	1.06 (0.81-1.39)
	0.85 (0.63-1.16)	0.98 (0.85-1.13)	22G FNB	0.97 (0.74-1.25)	1.03 (0.79-1.36)
	0.85 (0.6-1.2)	0.97 (0.78-1.21)	0.99 (0.77-1.27)	25G FNA	1.07 (0.83-1.37)
	0.84 (0.58-1.21)	0.96 (0.74-1.24)	0.98 (0.75-1.27)	0.98 (0.78-1.23)	25G FNB

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Facciorusso et al, DDW 2019

ESGE GUIDELINES FOR EUS-TA

For routine EUS-guided sampling of solid masses and LNs, ESGE recommends 25G or 22G; FNA and FNB needles are equally recommended

Strength of recommendation: Strong

Quality of evidence: High

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Polkowski M et al. Endoscopy 2017

QUALITY INDICATORS FOR
GI ENDOSCOPIC PROCEDURES

Quality indicators for EUS

Quality indicators for EUS

Sachin Wani MD, Michael B. Wallace MD, MPH, Jonathan Cohen MD, Irving M. Pike MD, Douglas G. Adler MD, Michael L. Kochman MD, John G. Lieb MD, Walter G. Park MD, MS, Maged K. Rizk MD, Mandeep S. Sawhney MD, MS, Nicholas J. Shaheen MD, MPH and Jeffrey L. Tokar MD

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QUALITY INDICATORS FOR GI ENDOSCOPIC PROCEDURES

nature publishing group

Quality Indicators for EUS

Sachin Wani, MD[1], Michael B. Wallace, MD, MPH[1], Jonathan Cohen, MD, Irving M. Pike, MD, Douglas G. Adler, MD, Michael L. Kochman, MD, John G. Lieb II, MD, Walter G. Park, MD, MS, Maged K. Rizk, MD, Mandeep S. Sawhney, MD, MS, Nicholas J. Shaheen, MD, MPH and Jeffrey L. Tokar, MD

Am J Gastroenterol 2015; 110:102–113; doi:10.1038/ajg.2014.387; published online 2 December 2014

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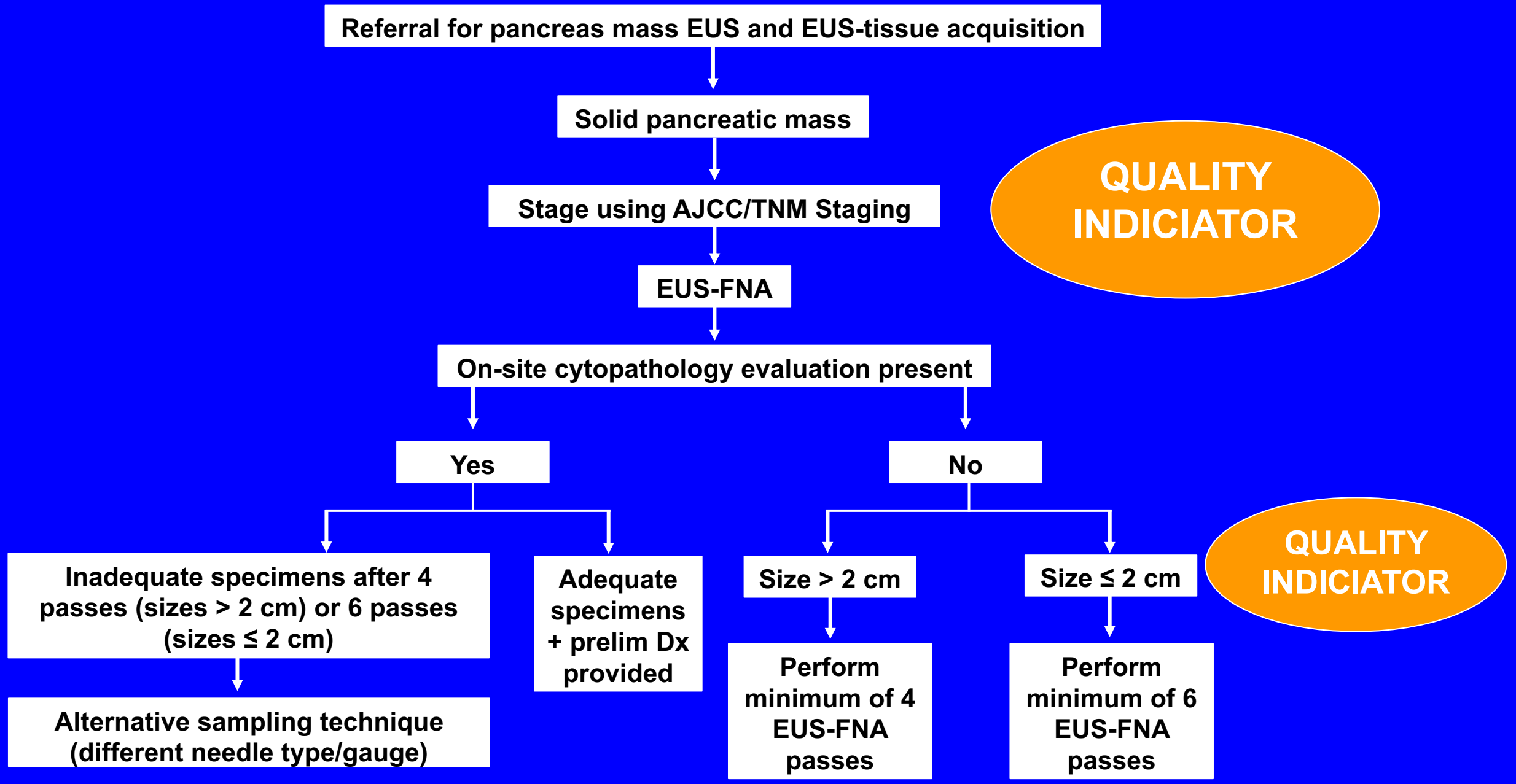
QUALITY INDICATORS

PRIORITY INDICATORS

- Frequency with which all GI cancers are staged with the AJCC/UICC TNM staging system
- Diagnostic rates of malignancy and sensitivity in patients undergoing EUS-FNA of pancreatic masses
- The incidence of adverse events after EUS-FNA (bleeding, perforation and acute pancreatitis)

Wani S et al. Quality Indicators in EUS, GIE and Am J Gastroenterol 2015



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Mohamadnejad M, Wani S. CGH 2017

MULTIMODALITY TESTING IN PANCREATIC CYSTS

- Pancreatic cysts are common and pose a management dilemma
- International multicenter study
- Developed a comprehensive test (CompCyst) that combined clinical, imaging, and molecular markers
- Molecular markers: (i) mutations in 11 genes associated with specific cysts, (ii) LOH of chromosome regions containing cyst-specific tumor suppressor genes, (iii) aneuploidy, (iv) CEA and VEGF

Dal Molin et al, DDW 2019

MULTIMODALITY TESTING IN PANCREATIC CYSTS

- Total of 862 cysts were analyzed
- CompCyst used to train half the cohort (those that could be observed, require surgery and no further surveillance) and tested in validation set
- Clinical management informed by CompCyst superior to conventional clinical and imaging criteria
- Spared >50% of unnecessary surgeries

Dal Molin et al, DDW 2019

MULTIMODALITY TESTING IN PANCREATIC CYSTS

- Cost-effectiveness
- Performance in a prospective cohort

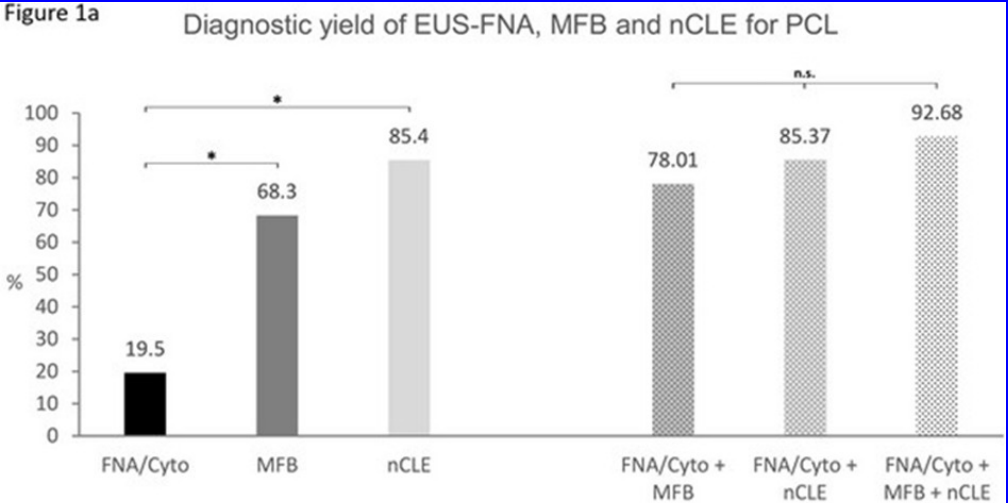
Dal Molin et al, DDW 2019

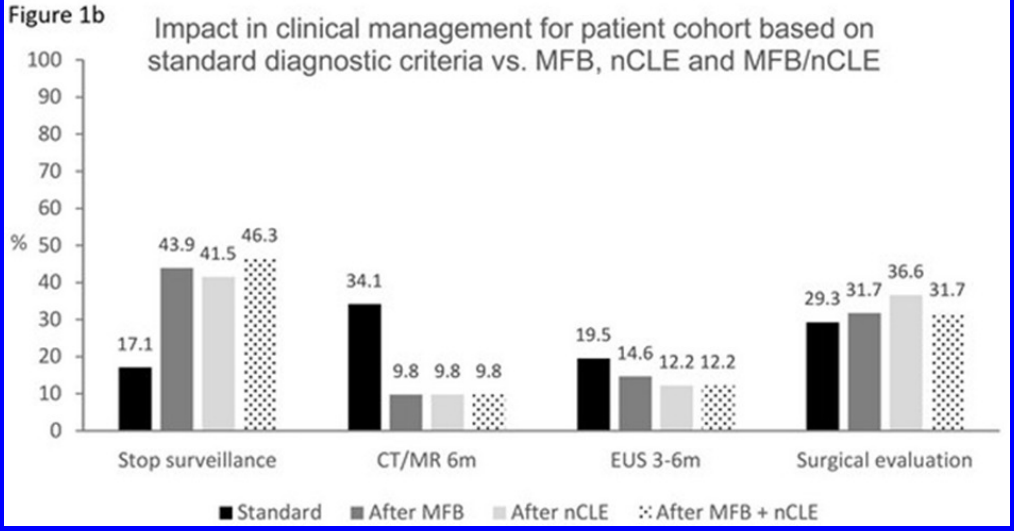
MULTIMODALITY TESTING IN PANCREATIC CYSTS MICROFORCEPS AND nCLE

- EUS-FNA has suboptimal diagnostic yield in pancreatic cysts
- EUS-guided microforceps and nCLE emerging techniques
- Primary aim – compare diagnostic outcomes and changes in clinical management using these novel techniques
- Retrospective study – 41 patients

Cheesman et al, DDW 2019

MULTIMODALITY TESTING IN PANCREATIC CYSTS MICROFORCEPS AND nCLE





- Diagnostic yield for combined testing higher than EUS-FNA cytology
- Compared to standard criteria, MFB, nCLE and combination led to change in clinical management in 32-44% of cases
- Changes included discontinuation of surveillance, reduction in imaging

Cheesman et al, DDW 2019

INTERVENTIONAL EUS

- Numerous advances in diverse areas
- Shifting the needle from staging and diagnosis
- Potentially disruptive techniques and technology
- Increasingly used as an alternative to interventional radiology or surgery

EUS CLASSIFICATION – BASED ON COMPLEXITY

Diagnostic and Staging EUS

↓

EUS-guided Tissue Acquisition [EUS-FNA, FNB]

↓

EUS-guided CPB, CPN
EUS-guided fiducial marker placement
EUS-guided cyst ablation

↓

EUS-guided drainage of pancreatic fluid collections (pseudocyst/WON)

↓

EUS-guided biliary and pancreatic drainage
Rendezvous < Antegrade < Transluminal drainage
Biliary (extrahepatic) < Intrahepatic < Pancreatic

EUS-guided vascular therapy

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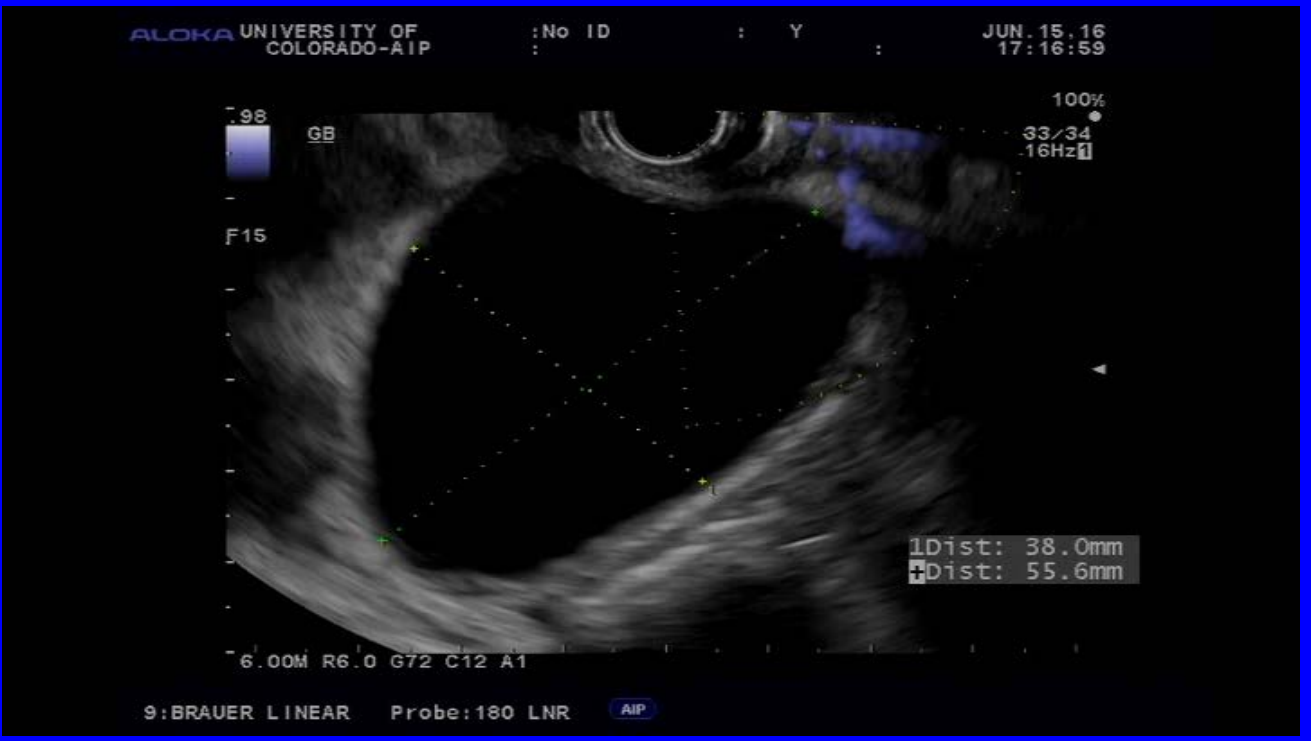
EUS GUIDED GALLBLADDER DRAINAGE vs. PERCUTANEOUS DRAINAGE



- Multicenter retrospective study
- EUS-GBD vs. PT-GBD
- Acute cholecystitis – not candidates for surgery
- EUS-GBD (LAMS)
- No difference in technical & clinical success, adverse events
- EUS-GBD – shorter LOS, re-interventions

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Irani et al, Clin Gastroenterol Hepatol 2017

EUS GUIDED GALLBLADDER DRAINAGE vs. PERCUTANEOUS DRAINAGE

- Randomized controlled trial
- High-risk patients with acute cholecystitis
- 5 high-volume institutions (Hong Kong, Japan)
- Inclusion criteria: age >18 years, acute calculous cholecystitis and not candidates for cholecystectomy
- Primary outcome: 1-year morbidity rate
- Secondary outcomes: technical and clinical success, unplanned readmissions, reintervention and mortality

Teoh A et al, DDW 2019

EUS GUIDED GALLBLADDER DRAINAGE vs. PERCUTANEOUS DRAINAGE

	EGBD N=39	PC N=40	P value
Age (years)	81.9 (9.6)	79.8 (9.6)	0.214
Sex (M/F)	22/17	20/20	0.654
ASA grading (I/II/III/IV)	2/4/28/5	3/3/27/7	0.891
Size of gallstones (mm)	10.3 (8.9)	13.8 (8.2)	0.154
Procedural time (minutes)	22.9 (13.1)	27.7 (17.1)	0.360

Teoh A et al, DDW 2019

EUS GUIDED GALLBLADDER DRAINAGE vs. PERCUTANEOUS DRAINAGE

	EGBD N=39	PC N=40	P value
Technical Success (%)	38 (97.4)	40 (100)	0.494
Clinical Success (%)	36 (92.3)	37 (92.5)	1
30-day adverse events (%)	4 (10.3)	12 (30)	0.048*
30-day mortality (%)	2 (5.1)	3 (7.5)	1
Hospital stay (days)	8 (2-53)	9 (1-1153)	0.175
1-year adverse events (%)	4 (10.3)	20 (50)	<0.001*
Unplanned admissions (%)	10 (25.6)	14 (35)	0.465
Recurrent acute cholecystitis (%)	2 (5.1)	5 (12.5)	0.432

Teoh A et al, DDW 2019

EUS GUIDED GALLBLADDER DRAINAGE vs. PERCUTANEOUS DRAINAGE

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Recurrent acute cholecystitis (%)	2 (5.1)	5 (12.5)	0.432

Teoh A et al, DDW 2019

EUS GUIDED GALLBLADDER DRAINAGE vs. PERCUTANEOUS DRAINAGE

- Did not assess the role of ERCP-guided transpapillary cystic duct stent placement
- Blinded assessment of outcomes

Teoh A et al, DDW 2019

EUS GUIDED GALLBLADDER DRAINAGE vs. PERCUTANEOUS DRAINAGE

- Did not assess the role of ERCP-guided transpapillary cystic duct stent placement
- Blinded assessment of outcomes

Teoh A et al, DDW 2019

SAFETY AND EFFECTIVENESS OF EARLY AND VERY EARLY DRAINAGE OF POST-OPERATIVE FLUID COLLECTIONS

Early EUS-POD of POFC technically feasible, effective and safe compared to delayed EUS-POD

	Very early EUS-POD (n=20)	Early EUS-POD (n=42)	Delayed EUS-POD (n=33)	P-value*
Technical success	20	42	33	-
Clinical success	19 (95%)	39 (93%)	31 (94%)	0.99
Adverse Events (AE)	3 (15%)	9 (21.4%)	10 (30.3%)	0.43
Early AE	0	2 (4.8%)	1 (3%)	0.99
Nausea/vomiting	-	2 (4.8%)	-	-
Stent maldeployment	-	-	1 (3%)	-
Late AE	3 (15%)	7 (16.7%)	9 (27.3%)	0.39
Fever	1 (5%)	2 (4.8%)	-	-
SIRS	-	-	2 (6.1%)	-
Recurrent collection	-	2 (4.8%)	2 (6.1%)	-
Hemorrhage	1 (5%)	2 (4.8%)	2 (6.1%)	-
Nausea/vomiting	1 (5%)	1 (2.4%)	-	-
SMV thrombosis	-	-	1 (3%)	-
Pericarditis	-	-	1 (3%)	-
Stent migration	-	-	1 (3%)	-

Storm et al, DDW 2019

THERAPEUTIC EUS – OTHER EMERGING TECHNIQUES

- EUS-guided portal vein sampling of circulating tumor cells
  - provide prognostic assistance for progression free survival in pancreaticobiliary cancers
- EUS-guided radiofrequency ablation plus chemotherapy superior to chemotherapy alone in unresectable pancreatic cancer (prelim results) in reducing morphine dosage requirement

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Swei et al DDW 2019; Kongkam et al, DDW 2019

THERAPEUTIC EUS – INCORPORATION INTO CLINICAL PRACTICE

- Informed consent (indications, benefits, risks, management of adverse events)
- Consider impact on definitive surgery, malignant vs. benign disease, ductal dilation, resectable vs. unresectable, success and risks of other treatment options
- Multidisciplinary approach with input from IR/surgery
- Under the guidance of experienced mentors
- Ensure that all devices available, skilled assistants
- Maintain a log and follow up on outcomes

THANK YOU

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ERCP Abstracts at DDW 2019

Simon K. Lo, MD

Director of Endoscopy

Head, Pancreatic Diseases Program

F. Widjaja Family Chair in Digestive Diseases

Clinical Professor of Medicine

Cedars-Sinai Medical Center

Los Angeles, California

CEDARS-SINAI

SAFETY & COMPLICATIONS

Post ERCP De Novo Fever and De Novo Bacteremia

- Aim: Assess the incidence of post ERCP fever and bacteremia in the national cohort; Evaluate the in-hospital mortality, LOS and total hospitalization charges
- Methods: Retrospective cohort study using the 2016 Nationwide Inpatient Sample (NIS). Patients with ICD-10 CM procedure codes for ERCP were included. Post-ERCP bacteremia was defined as an ICD-10 CM code for a secondary diagnosis of infection or septic shock or fever in patients who received an ERCP
- Results: 152,924 ERCP procedures, which were performed in hospitals in 2016, in the US.
  - Fever alone (without bacteremia or sepsis) after ERCP 0.2%
  - Post ERCP bacteremia 0.5% of all the procedures
  - 9% of patients with sepsis progressed to septic shock

*Abhishek Bhurwal*1, Hemant R. Mutneja4, Khwaja F. Haq5, Michal Bartel3, Bhaumik Brahmbhatt2 1Gastroenterology, Rutgers RWJ, New Brunswick, NJ; 2Gastroenterology, Mayo Clinic, Jacksonville, FL; 3Gastroenterology, Fox Chase Cancer Center, Philadelphia, PA; 4Gastroenterology, Cook County Hospital, Chicago, IL; 5Gastroenterology, Henry Ford Hospital, Detroit, MI*

Post ERCP De Novo Fever and De Novo Bacteremia

- Biliary stenting and pancreatic stenting was associated with increased odds of developing sepsis by 3X and 5X
- No significant difference in terms of post ERCP percutaneous cholecystectomy or bile duct exploration in the two cohorts.
- Fever alone did not increase the odds of mortality, but sepsis did (OR 2.96 (1.36-6.46), p< 0.006)
- Mean length of stay was significantly higher in patients with bacteremia as compared to fever alone (8 days vs 16 days, p<0.001)
- Post ERCP bacteremia is associated with higher total hospitalization charges (114,381 $ vs 188,835 $, p<0.001)

*Abhishek Bhurwal*1, Hemant R. Mutneja4, Khwaja F. Haq5, Michal Bartel3, Bhaumik Brahmbhatt2 1Gastroenterology, Rutgers RWJ, New Brunswick, NJ; 2Gastroenterology, Mayo Clinic, Jacksonville, FL; 3Gastroenterology, Fox Chase Cancer Center, Philadelphia, PA; 4Gastroenterology, Cook County Hospital, Chicago, IL; 5Gastroenterology, Henry Ford Hospital, Detroit, MI*

Prophylaxis with Diclofenac+SL-Nitrate is superior to Diclofenac in PEP: a Multicenter, RCT

- Rectal administration of NSAIDs decreases the incidence of PEP. However, the combined effect of sublingual nitrate and NSAIDs is currently unknown
- Methods: multicenter, prospective, RCT. Patients with native papilla who underwent ERCP at 12 units in Japan were randomly medicated with 50 mg diclofenac supp <15 minutes post-ERCP either alone (diclofenac alone group) or with 5 mg SL-isosorbide dinitrate 5 min Pre-ERCP (combination group). Primary endpoint was PEP <24 h after an ERCP
- Results: Between 3/2015 and 5/2018, 900 patients were enrolled. 14 excluded after randomization (combination group: 444; diclofenac alone group: 442)

*Toru Ueki*1, Takeshi Tomoda2, Hironari Kato2, Soichiro Kawahara1, Yutaka Akimoto3, Hidenori Hata4, Masakuni Fujii5, Ryo Harada6, Tsuneyoshi Ogawa7, Masaki Wato8, Masahiro Takatani9, Minoru Matubara11, Yoshinari Kawai10, Hiroyuki Okada2 1Department of Internal Medicine, Fukuyama City Hospital, Fukuyama, Japan; 2Department of Gastroenterology andHepatology, Okayama University Graduate School of Medicine, Okayama, Japan; Department*

Prophylaxis with Diclofenac+SL-Nitrate is superior to Diclofenac in PEP: a Multicenter, RCT

- PEP developed in 25 patients (5.6%) in the combination group and in 42 patients (9.5%) in the diclofenac alone group (relative risk, 0.59; 95% CI, 0.37–0.95; p<0.03)
- Moderate-to-severe pancreatitis developed in 4 patients (0.9%) in the combination group, and in 10 patients (2.3%) in the diclofenac alone group (p < 0.12)
- Patients at high PEP-risk: PEP occurred in 24/288 patients (8.3%) in the combination group, and in 39/301 (13.0%) in the diclofenac alone group (P<0.08)
- 35 patients (7.9%) in the combination group and 13 (2.9%) in the diclofenac alone group presented mild transient hypotension during ERCP, which improved within several minutes (P<0.002)
- There was no serious AEs related to the additional administration of sublingual nitrate

*Toru Ueki*1, Takeshi Tomoda2, Hironari Kato2, Soichiro Kawahara1, Yutaka Akimoto3, Hidenori Hata4, Masakuni Fujii5, Ryo Harada6, Tsuneyoshi Ogawa7, Masaki Wato8, Masahiro Takatani9, Minoru Matubara11, Yoshinari Kawai10, Hiroyuki Okada2 1Department of Internal Medicine, Fukuyama City Hospital, Fukuyama, Japan; 2Department of Gastroenterology andHepatology, Okayama University Graduate School of Medicine, Okayama, Japan; Department*

IV Ibuprofen for Prevention of PEP in Pediatric Patients: A Randomized DB, Placebo-Controlled Pilot Study

- Post-ERCP pancreatitis (PEP) is reported to occur in up to 10% of pediatric patients. To date, no study has prospectively evaluated a prevention intervention
- Aim: To obtain preliminary data evaluating the effectiveness of IV Ibuprofen at preventing PEP in the pediatric population
- Methods: From 12/2014-3/2017, consecutive pts <19 yrs were randomized to 10mg/kg of IV Ibuprofen (800mg max) or equivalent amount of saline at ERCP
- **Results:** 58 patients were randomized and received IV Ibuprofen or placebo. Pre-procedure and procedure related factors were not significantly different except that the placebo patients tended to weigh less (48.7kg vs 63.7kg, p<0.03)

- 7 episodes of PEP (6 mild, 1 mod, 0 severe) for a rate of 12%. PEP was less frequent in the Ibuprofen group than the controls (7% vs. 17%), but it was not statistically significant (p<0.42)
- Mean postprocedural abdominal pain scores were significantly lower in the IV Ibuprofen group than the control group (1.1 vs 3.1, p<0.01)
- # patients who had increased abdominal pain after the procedure was significantly lower in Ibuprofen group than the control group (3% vs. 38%, p<0.002)
- No significant differences in procedure related or drug related adverse events

*David M. Troendle*1,2, Bhaskar Gurram1,2, Rong Huang2, Bradley Barth1,2 1 UT Southwestern Medical Center, Dallas, TX; 2Children's Health Children's Medical Center, Dallas, TX*

IV Ibuprofen for Prevention of PEP in Pediatric Patients: A Randomized DB, Placebo-Controlled Pilot Study

	All Patients (n=58)	IV Ibuprofen (n=29)	Placebo (n=29)	p-value
Pre-procedure factors				
Age yrs, mean (IQR)	12.8 (10.6-15.7)	13.6 (11.1-16.0)	11.9 (9.9-14.8)	0.13
Weight kg, mean (IQR)	56.2 (39.5-65.8)	63.7 (48.3-78.1)	48.7 (33.5-56.6)	0.03
Female	41 (69%)	20 (69%)	21 (72%)	1.00
Hispanic	29 (49%)	15 (52%)	14 (48%)	1.00
Hx of recurrent acute pancreatitis	11 (19%)	4 (14%)	7 (24%)	0.50
Hx of chronic pancreatitis	9 (16%)	3 (10%)	6 (21%)	0.47
Previous episode of PEP	1 (2%)	0 (0%)	1 (3%)	1.00
Native papilla	40 (69%)	22 (76%)	18 (62%)	0.40
ASA >2	11 (19%)	6 (21%)	5 (17%)	1.00
ASGE difficulty grade >2	16 (28%)	5 (17%)	11 (38%	0.14
Therapeutic indication	55 (95%)	27 (93%)	28 (97%)	1.00
Pancreatic indication	13 (22%)	4 (14%)	9 (31%)	0.21
Procedure factors				
Biliary sphincterotomy performed	35 (60%)	19 (66%)	16 (55%)	0.59
Pancreatic sphincterotomy performed	6 (10%)	2 (7%)	4 (14%)	0.67
Minor papillotomy performed	1 (2%)	0 (0%)	1 (3%)	1.00
Pancreatic injection	21 (36%)	8 (28%)	13 (45%)	0.27
Pancreatic stent placed	4 (7%)	3 (10%)	1 (3%)	0.61
Therapeutic stent	2 (3%)	1 (3%)	1 (3%)	1.00
Prophylactic stent	2 (3%)	2 (7%)	0 (0%)	0.49
Pain Scores				
Pre-ERCP, mean (IQR)	2.6 (0-4.5)	2.9 (0-4.5)	2.2 (0-4.0)	0.32
24 hour post-ERCP, mean (IQR)	2.1 (0-4.0)	1.1 (0-2.0)	3.1 (0-6.0)	0.01
Increased pain score	12 (21%)	1 (3%)	11 (38%)	0.002
Adverse Events				
Any	12 (21%)	3 (8%)	9 (31%)	0.10
PEP	7 (12%)	2 (7%)	5 (17%)	0.42
Pain, not PEP	3 (5%)	0 (0%)	3 (10%)	0.24
Bleeding	2 (3%)	2 (7%)	0 (0%)	0.49
Cholangitis	1 (2%)	0 (0%)	1 (3%)	1.00
Perforation	1 (2%)	1 (3%)	0 (0%)	1.00
Drug related AEs	0 (0%)	0 (0%)	0 (0%)	1.00

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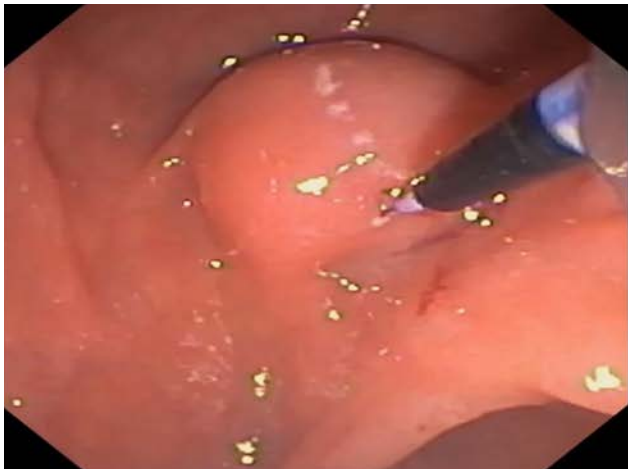
Early Precut Sphincterotomy and Risk of ERCP Related Complications: an Updated Meta-Analysis

- Deep biliary cannulation can fail in 5-10% of ERCP. Precut has emerged as a rescue technique, but has been associated with higher complications in some studies. More recent studies have reported lower risk of complications
- Methods: Databases and abstracts of recent GI meetings were searched. There were no language restrictions. Data was extracted regarding the adverse events including pancreatitis, cholangitis, bleeding, perforation rates, cannulation success rates and need for repeat ERCP



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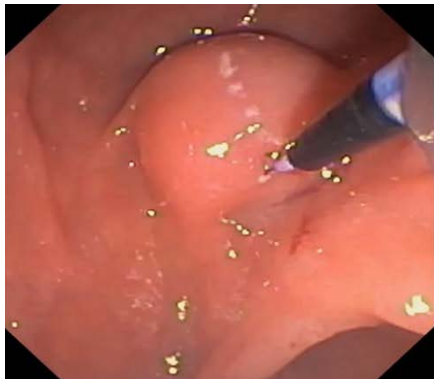
Early Precut Sphincterotomy and Risk of ERCP Related Complications: an Updated Meta-Analysis

- **Results:** 11 RCTs met the criteria. 10 were full publications; 1 was an abstract. All studies compared early precut to the standard techniques of cannulation. Sample size ranged from 62 to 375 patients
- Early precut was associated with a decreased PEP risk (RR 0.47; p<0.0001). PEP occurred in 3.6% (32/884) of early precut patients; in 8.7% (81/933) of conventionally treated pts
- Cannulation rates were similar in both groups (RR 1.03; 95% CI 0.72-1.46, p<0.88)
- There was no difference in the need for repeat ERCP and risks of cholangitis, bleeding or perforation between the 2 groups



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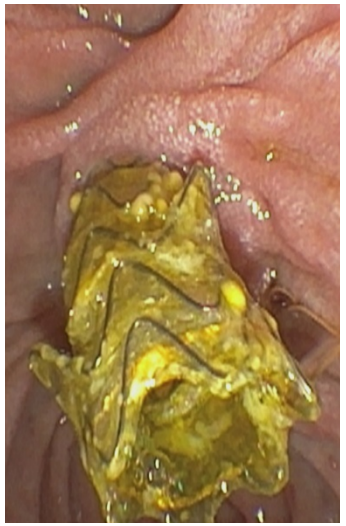
A Prospective, RCT Comparing SEMS Placement with and without Biliary Sphincterotomy in Patients with Malignant Biliary Obstruction: An Interim Analysis

- There is controversy regarding the benefit of ES before placement of biliary SEMS
- Aim: to investigate the outcome SEMS placement with and without ES
- Methods: This is an interim analysis of an ongoing multicenter RCT conducted in four international centers from 3/2016 to 10/2018 in patients with malignant distal biliary obstruction with indication to SEMS placement. Patients were randomized to ES prior to fully covered (FC) SEMS placement (ES, G1) versus FCSEMS placement leaving the papilla without (No ES, G2)
- Results: 152 patients with distal malignant biliary obstruction were included. FCSEMS were successfully deployed in all patients in both groups



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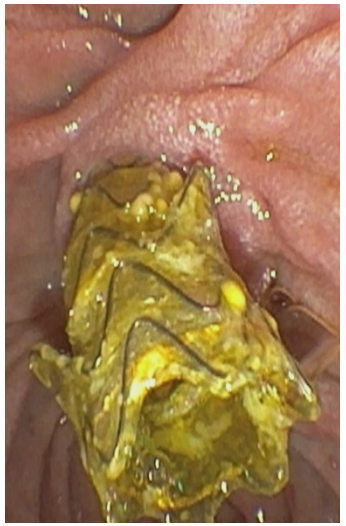
A Prospective, RCT Comparing SEMS Placement with and without Biliary Sphincterotomy in Patients with Malignant Biliary Obstruction: An Interim Analysis

- 76 (G1) were randomized to perform ES before placement of SEMS, and 76 patients to no ES (G2)
- Complications occurred in 24 (31.5 %) patients in G1(ES) and in 17 (22.3%) patients in G2 (no ES) (p=0.2008). Although not statistically significant there was a trend toward increased risk of PEP in the G2 (no ES) compared to the G1 (ES)(15.8% vs 11.8%, p= 0.4807). Fatal AEs occurred in 1 patient because of cholangitis in G1 and in 1 patient because of post ERCP pancreatitis in G2
- Conclusions: At interim analysis, placement of biliary FCSEMS without prior ES in patients with distal common bile duct obstruction showed a lower rate of cumulative AEs. On the other hand patients in G2 (no ES) reported an higher incidence of PEP (although not statistically significant)



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A Prospective, RCT Comparing SEMS Placement with and without Biliary Sphincterotomy in Patients with Malignant Biliary Obstruction: An Interim Analysis

Adverse events in patients with malignant biliary obstruction who underwent SEMS placement with and without endoscopic sphincterotomy

AEs	Group 1 (ES)	Group 2 (no ES)	p
PEP	9 (11.8%)	12 (15.8%)	0.4807
Cholangitis	7 (9.2%)	2 (2.6%)	
Bleeding	5 (6.6%)	1 (1.3%)	
Stent migration	2 (2.6%)	/	
Cholecystitis	1 (1.3%)	2 (2.6%)	
Total	24 (31.5 %)	17 (22.3%)	0.2008

AEs: adverse events; SEMS: self-expandable metallic stents; ES: endoscopic sphincterotomy; PEP: post-ERCP pancreatitis

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Predictors of Increasing Patient Radiation Exposure During ERCPs

- Introduction: Use of fluoroscopy during ERCP, exposes patients to ionizing radiation. Increasing procedure complexity and low volume (< 200 ERCP per year) have been identified as predictors for increasing radiation exposure
- Aim: examine patient radiation exposure within large hospital system
- Methods: Retrospectively evaluated a prospectively maintained database of ERCP within a hospital system from 2015-2017. We evaluated volume of endoscopists, volume of given facility, procedure factors such as interventions during the procedure. Each intervention during ERCP was given 1 point and composite score for each procedure was calculated to design fluoroscopy complexity score

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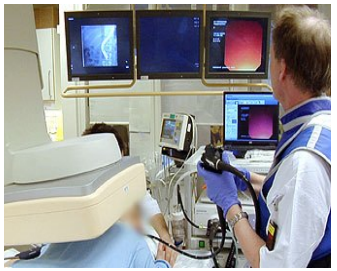
Predictors of Increasing Patient Radiation Exposure During ERCPs

- **Results:** 7400 ERCPs were performed during the study period in 12 facilities by 66 gastroenterologists
- Fluoroscopy Time: median fluoroscopy time was 1.9 minutes
- Low yearly ERCP volume at facility (< 250 ERCP per year) and high fluoroscopy complexity (Fluoroscopy score > 3) significantly increased fluoroscopy time (2.12 minutes and 3.5 minutes, respectively)
- Total Radiation Dose: Overall median total radiation was 33.37 mGy. Once again, Low yearly ERCP volume at facility and high fluoroscopy complexity significantly increased total radiation dose (36.9 mGy and 49.33 mGy, respectively)



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BILIAR ABLATION

ERCP Biliary Ablation Prolongs Survival in Pts with Unresectable Hilar Cholangiocarcinoma Versus Stenting Alone

- Perihilar CCA is surgically unresectable at the time of diagnosis in up to 80% of patients. Palliative chemoradiation is of limited benefit. Limited data have suggested that endobiliary ablation of perihilar CCA using photodynamic therapy (PDT) or radiofrequency ablation (RFA) might improve biliary patency as well as overall survival
- Hypotheses: patients with unresectable perihilar CCA who had any combination of ERCPdirected endobiliary ablation (PDT and/or RFA) and stenting had superior survival (primary outcome) and no difference in post-procedural adverse events (secondary outcomes) compared to biliary stenting alone
- Methods: All patients undergoing ERCP for unresectable perihilar cholangiocarcinoma from July 2011 to August 2018 at a center were identified and their records reviewed
- Results: 30 patients underwent endobiliary ablation (10 had PDT alone, 18 had RFA alone, and 2 had both PDT and RFA) followed by stenting; 29 underwent biliary stenting alone
- There was no significant difference in age, Eastern Cooperative Oncology Group (ECOG) scores, Bismuth-Corlette classification, levels of serum total bilirubin, albumin, or CA-19-9 between any of the groups
- Multivariate Cox modeling showed superior median survival time for patients undergoing ablation followed by stenting (10.0 months) compared to stenting alone (6.1 months, $p<0.010$)
- No difference in rates of adverse events between the two groups
- When the RFA+stenting cohort was compared to the stenting alone group in a similar analysis, the combination group had superior survival (10.0 months vs 6.7 months, 95% CI: 5.4-8.8, HR 3.5, $p<0.012$)
- Multivariate modeling revealed a significantly increased risk of death in patients who did not undergo endobiliary ablation (HR 3.2, $p<0.010$), in older patients (HR 1.7, $p<0.007$), and in those needing more frequent ERCP (HR 1.8, $p<0.001$); however, the frequency of stent placement did not impact risk of death ($p<0.692$). ECOG scores and metastatic disease status did not impact survival

Post-DDW2019
ERCP Review

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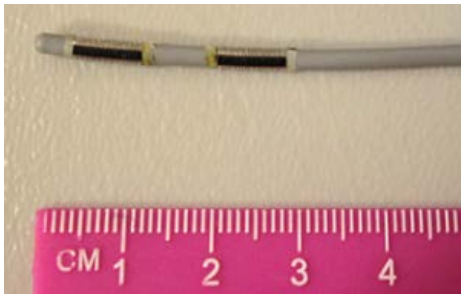
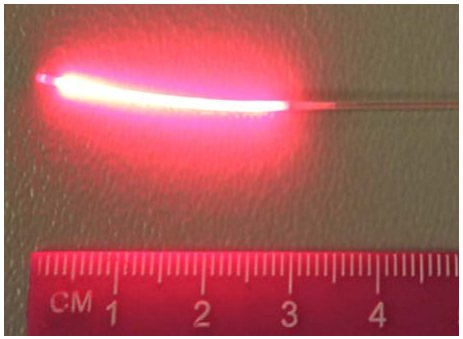
Background

- **Endobiliary ablation options**
  - **Radiofrequency Ablation** (RFA)*
    - Thermal energy delivered via bipolar probe
  - **Photodynamic Therapy** (PDT)*
    - Photosensitizer infused
    - 48-72 hours later: ERCP with specialized fiber
    - Emits light of specific wavelength





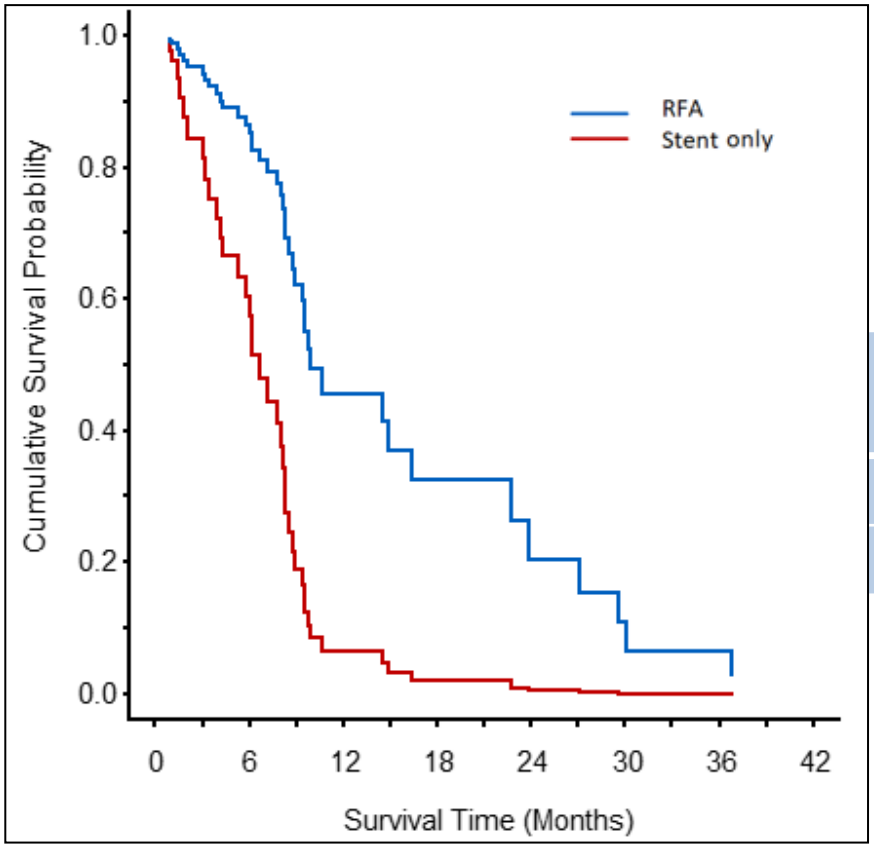
* *Both are typically followed by biliary stenting*

Buerlein RCD, Wang AY. Gastrointest Endosc Clin N Am 2019;29:351-367

Hilar cholangiocarcinoma, Patient Data

	Ablation (n=30)	Stent (n=29)	p-value
Bismuth-Corlette Classification: n (%)			
B1	1 (3.3)	1 (3.4)	0.253
B2	3 (10.0)	2 (6.9)	
B3a	3 (10.0)	4 (13.8)	
B3b	7 (23.3)	1 (3.4)	
B4	16 (53.3)	21 (72.4)	
ECOG: n (%)			
0	9 (36.0)	5 (21.7)	0.689
1	9 (36.0)	8 (34.8)	
2	4 (17.4)	5 (21.7)	
3	3 (13.0)	5 (21.7)	
Initial AJCC Tumor Staging: n (%)			
N0	**14 (46.7)**	**2 (6.9)**	**0.001**
N1	9 (30.0)	9 (31.0)	1
NX	**7 (23.3)**	**18 (62.1)**	**0.004**
M0	**14 (46.7)**	**3 (10.3)**	**0.003**
M1	**5 (16.7)**	**12 (41.4)**	**0.047**
MX	11 (36.7)	14 (48.3)	0.438

RFA was Associated with Improved Survival



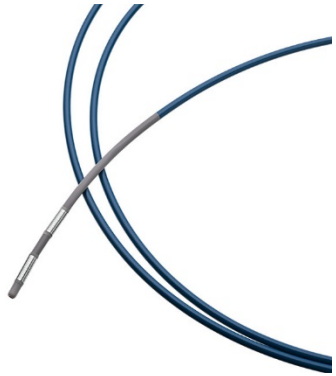
Multivariate Cox model estimating survival time from diagnosis for patients treated with RFA vs Stent alone

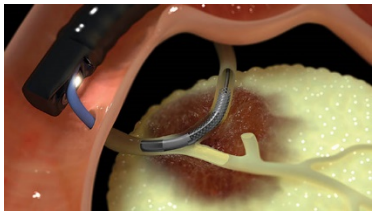
	Estimated Median Survival	95% CI
RFA Group	10.0 months	8.5 – 36.8
Stent Group	6.7 months	5.4 – 8.8

Adjusted HR: **3.50**, 95% CI: 1.32–9.29, **p = 0.012**

The Efficacy and Safety of Papillectomy Plus Endobiliary RFA for Ampullary Neoplasm with Biliary Ductal Extension

- Endoscopic papillectomy is the preferred approach for management of ampullary adenomas. Endobiliary radiofrequency ablation (RFA) has been used as an adjunctive therapy
- Aim: to evaluate the efficacy and safety of papillectomy plus endobiliary RFA for ampullary neoplasms with intraductal biliary extension
- Methods: A retrospective analysis of all patients with histologically proven ampullary neoplasms with intraductal biliary extension treated with endoscopic papillectomy and RFA between 2/2013 and 2/2016 at 2 sites. RFA (HabibTM, Boston Scientific; Effect 8, power 8 Watts, 90 seconds) was performed at a subsequent ERCP after papillectomy failed to remove the intraductal lesion.





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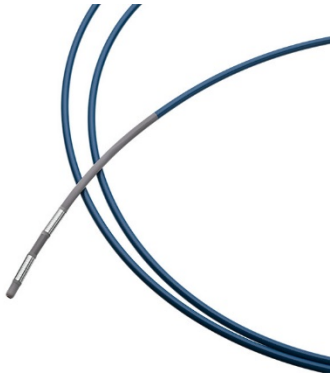
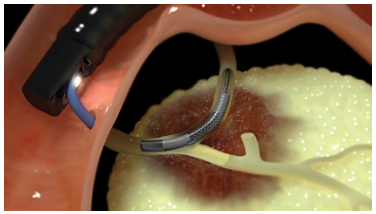
The Efficacy and Safety of Papillectomy Plus Endobiliary RFA for Ampullary Neoplasm with Biliary Ductal Extension

- **Results:** 8 patients were included and were deemed non-operative due to comorbidities. The mean size was 29.7 (SD 12.6) mm with a mean intraductal extension of 14.4 mm.
- Histology: Adenocarcinoma 5 (67.5%); adenoma with HGD 3 (37.5%)
- 1-3 RFA sessions was performed with or without biliary stent placement. Two (25%) patients also received pancreatic duct stenting for prophylaxis.
- A mean 4.1 ERCP/biopsy sessions were done for surveillance after completion of Rx over a mean follow-up of 28.5 months. In those with initial malignancy, recurrence occurred in 3 (37.5%) patients at 14, 20, and 30 months, respectively
- There were no adverse events.





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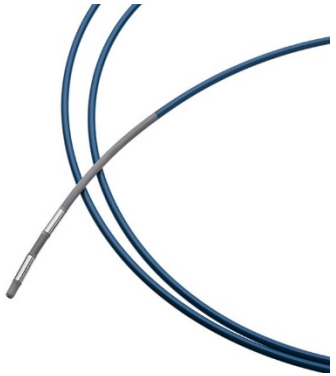
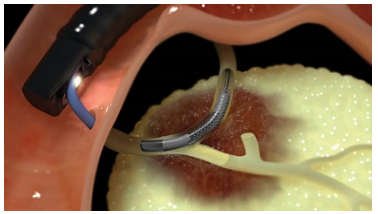
The Efficacy and Safety of Papillectomy Plus Endobiliary RFA for Ampullary Neoplasm with Biliary Ductal Extension

Patient	Age	Sex	Size (mm)	Extension length (mm)	Lesion Pathology	(Time to Recurrence)
1	78	Female	22.9 x 15.7	20	Adenocarcinoma	Yes (14 months)
2	73	Male	35.8 x 24.5	20	Adenocarcinoma	None
3	78	Female	25.5 x 15.5	15	Adenoma with high-grade dysplasia	None
4	75	Male	43.4 x 28.5	10	Adenocarcinoma	Yes (30 months)
5	80	Female	50.7 x 32.9	15	Adenocarcinoma	None
6	82	Male	32.5 x 15.5	15	Adenocarcinoma	Yes (20 months)
7	66	Male	14 x 7	10	Adenoma with high-grade dysplasia	None
8	75	Male	13 x 11	10	Adenoma with high-grade dysplasia	None





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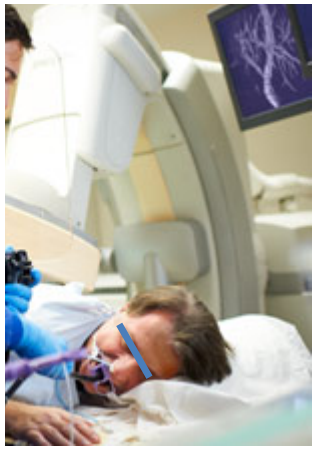
PERFORMANCE OF ERCP

Does ERCP Position Matter? A RCT Comparing Efficiency and Complications of Left Lateral vs Prone Position During ERCP

- Aims: We evaluate if LL position is non-inferior to PP for ERCP
- Methods: Randomised trial on adult patients with native papillae undergoing ERCP between 3/2017 and 11/2018. Patients >18 years of age requiring a therapeutic ERCP were offered enrollment and randomized in a 1:1 ratio. Exclusion criteria included 1) patients unable to provide informed consent, 2) critically unwell, 3) previous sphincterotomy, and 4) physical limitations preventing adequate positioning. All patients received MAC/general anaesthesia
- Results: 253 (135 females) of 308 patients were enrolled. 132 randomised to LL (52.2%) and 121 to PP (47.8%)
- Drug requirements were similar
- Cannulation rates were 97.0% in LL vs 99.2% in PP ($p<0.372$)



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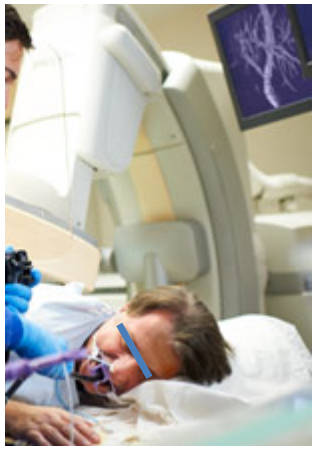
Does ERCP Position Matter? A RCT Comparing Efficiency and Complications of Left Lateral vs Prone Position During ERCP

- Median time to biliary cannulation was 3:84 mins in LL vs 2:96 mins in PP (p<0.62)
- There was no difference between # of cannulation attempts and pancreatic duct cannulations. Pancreatitis rates were 2.3% in LL vs 5.8% in PP (p<0.20)
- There were significantly lower radiation doses used in PP (0.23mGmy2 in LL vs 0.16mGmy2 in PP, p<0.008)
- Conclusion: Comparable outcomes including rates of biliary cannulation, pancreatitis and cardiorespiratory complications. There was significantly lower radiation exposure in prone position



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Does ERCP Position Matter? A RCT Comparing Efficiency and Complications of Left Lateral vs Prone Position During ERCP

	Left Lateral (n=132)	Prone (n=121)	p-value
Age, mean (±SD)	66.7 (±17.4)	65.43 (±18.23)	0.48
Gender, n (%)			
- Male	64 (48.5)	55 (44.6)	0.54
- Female	68 (51.5)	66 (55.4)	
Indication, n (%)			
- Choledocholithiasis	88 (66.7)	93 (76.9)	0.07
- Benign stricture	3 (2.3)	1 (0.8)	0.62
- Malignant stricture	27 (20.5)	10 (8.3)	**0.006**
- Bile leak	6 (4.6)	3 (2.5)	0.50
- Other	8 (6.1)	13 (10.7)	0.18
Cannulation Attempts			0.55
- Median (IQR)	3 (1-6)	2 (2-7)	
Number of PD Cannulations			
- Median (IQR)	0 (0-1)	0 (0-1)	0.35
Biliary Cannulation, n (%)			
- Successful	128 (97.0)	120 (99.2)	0.37
- Unsuccessful	4 (3.0)	1 (0.8)	
Time to Cannulation			
- Median (IQR)	3.84 (1.54-7.25)	2.96 (1.43-7.57)	0.62
Total Procedure Time, mins:secs			
- Median (IQR)	21:00 (13.77-31.00)	20:58 (13.75-28.83)	0.35
Radiation Dose, mGy			
- Median (IQR)	13.65 (6.84-21.6)	9.52 (5.32-17)	**0.03**
Radiation Dose, mGmy2			
- Median (IQR)	0.23 (0.12-0.38)	0.16 (0.08-0.28)	**0.008**
Total Fluoroscopy Time, mins:secs			
- Median (IQR)	01:46 (1:04-2.54)	01:38 (1.04-2.38)	0.38
Cardiorespiratory Events, n (%)	5 (3.8)	4 (3.3)	1.00
- Mild respiratory	0	1 (0.8)	0.49
- Severe respiratory	0	1 (0.8)	0.49
- Tachycardia	0	1 (0.8)	0.49
- Bradycardia	3 (2.3)	2 (1.7)	1.00
Immediate Complications, n (%)	2 (1.5)	5 ()	0.26
- Bleeding	1 (0.8)	1 (0.8)	1.00
- Perforation	1 (0.8)	0	1.00
- Pancreatitis	0	3 (2.5)	0.11
- Significant pain	0	1 (0.8)	0.48
Delayed Complications, n (%)	13 (9.8)	11 (9.1%)	1.00
- Bleeding	1 (0.8)	2 (1.7)	0.61
- Pancreatitis	3 (2.3)	4 (3.3)	0.71
- Cholangitis	6 (4.5)	4 (3.3)	0.75
- Other	3 (2.3)	1 (0.8)	0.62
Propofol Dose, median (IQR)	380 (255-500)	300 (235-465)	0.14
Antispasmodic Need, n (%)	40 (30.3)	32 (26.4)	0.58

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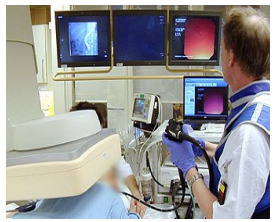
Who Should Administer Sedation During ERCP – Anesthesiologist, Intensivist or Endoscopist?

- The proper training in sedation and who should administer it during ERCP is still unknown
- Objective: To compare safety and effectiveness of ERCP sedation by different specialists
- Method: Comparative prospective non-randomized study. Consecutive patients who underwent ERCP were collected at 2 centers between 1/17 – 5/18. Sedation was directed by an endoscopist using propofol (EDP) on Monday, by an intensivist-administered propofol (IAP) on Wednesday, and by an anesthesiologist (MAC) on Thursday
- Results: 454 pts (147 to EDP, 137 to IAP and 170 to MAC)



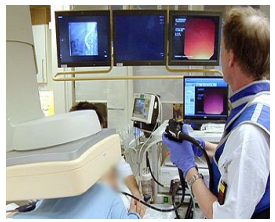
*Marco Alburquerque*1,2, Alba L. Vargas1,2, Nati Zaragoza Velasco3, Marina Pechkova1, Jose Miñana3, Montserrat Planella3, Raquel Ballester3, Montserrat Figa1, Ferran González-Huix1,3 1Gastroenterology, Clinica Girona, Gerona, Spain; 2Gastroenterology, Hospital de Palamós, Palamós, Spain; 3Gastroenterology, Hospital Arnau de Villanova, Lleida, Spain*

Who Should Administer Sedation During ERCP – Anesthesiologist, Intensivist or Endoscopist?

- The endoscopist administered only propofol in 81.9%, the intensivist administered propofol plus midazolam in 78.7% and anesthesiologist used propofol plus other agents (i.e. opioids, ketamine) in 86.2%, p<0.0001

- Sedation was deepest in MAC, Observers's Assessment of Alertness–Sedation score (OAAS): 5.19 0.6, p<0.0001

- Overall SAE rate: 8.6%, lowest in EDP 4.8%, p<0.042 (SpO2 <70% was most frequent -4.5% and highest in MAC: 6.1%, p<0.085). Respiratory resuscitation measures (chin-lift, increasing FIO2 or airway insertion) were needed more in MAC and IAP than EDP, p<0.003



- MAC had the highest cancelled rate (2.9%, p<0.015), most frequent left lateral decub position (31.6%, p<0.000), and had the worst radiologic image (17.8%, p<0.0001)
- Sedation time was shortest in IAP: 44.4 1.8 min, p<0.023

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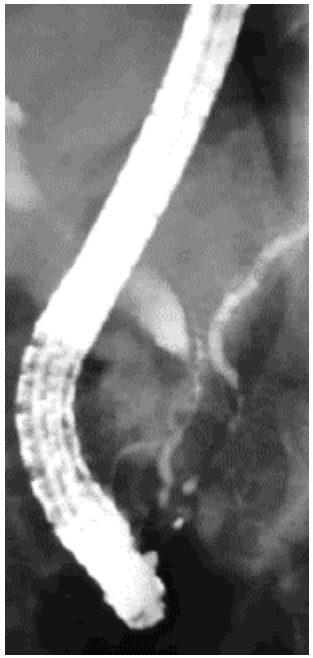
Difficult Biliary Cannulation in Patients with Distal Malignant Biliary Obstruction: An Under-estimated Problem?

- Background: No available data on difficult cannulation in malignant distal CBD obstruction
- Aim: investigate the incidence and outcome in pts with distal malignant biliary obstruction
- Methods: Retrospective multicentric analysis of a prospectively maintained database in 4 Italian centers from 9/2014 to 10/2017
- Results: 522 pts with distal biliary obstruction for ERCP were included. Difficult cannulation occurred in 277 (53%)
- Cannulation techniques: Precut/fistulotomy in 191 (69%), double guidewire in 10 (3,6%), transpancreatic biliary sphincterotomy in 25 (9%); more than one of these techniques 15 pts (5,4%); several attempts with standard technique in 15 pts (5,4%)



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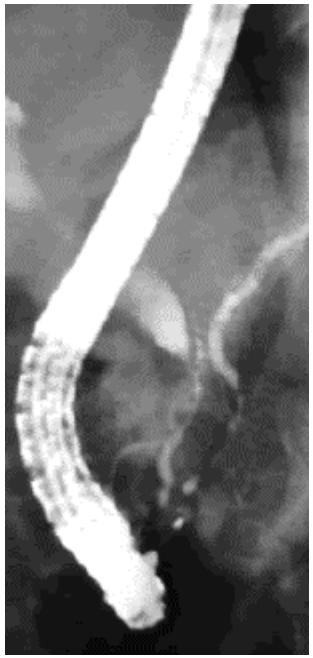
Difficult Biliary Cannulation in Patients with Distal Malignant Biliary Obstruction: An Under-estimated Problem?

- Failure of biliary cannulation occurred in 53 pts, requiring following options:
  - EUS-guided placement of lumen apposing metal stent in 36 pts (67,9%)
  - EUS guided rendez-vous with transpapillary stent placement in 2 (3,8%)
  - PTC drainage in 8 (15,1%)
  - Second successful ERCP after pre-cut in 6 (11,3%)
  - Surgical bypass in 1 (1,9%)
- Overall AEs rate was 15.7% (82/522) (19.8% in pts with difficult cannulation and 11,02% in pts without (p=0,0056). Severe AEs in pts with difficult cannulation were severe PEP (1%, with 1 exitus), bleeding (1.4%, with 1 exitus), acute cholecystitis (1.8%), cholangitis (3, 1%), sepsis (2, < 1%) and perforation (1, <1%)
- Conclusions: Patients with distal biliary malignant obstruction have a high rate of difficult cannulation (53%) requiring alternative techniques for biliary drainage. This translates to higher rates of AEs in patients with DBC



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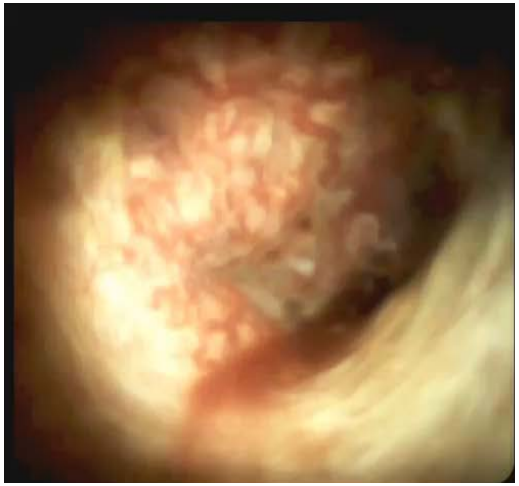
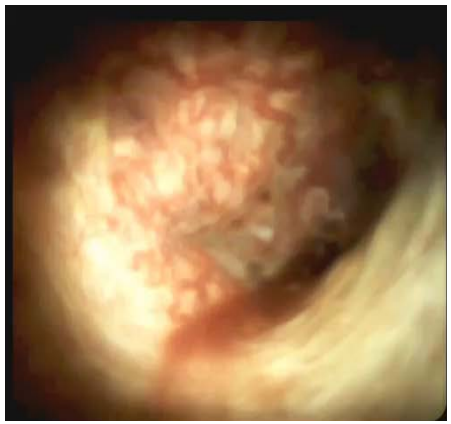
Optimizing Outcomes of Single Operator Cholangioscopy-guided Biopsies: Results of a Randomized Trial

- Aim: To determine the optimal method of specimen processing and to identify the number of biopsies required to establish a definitive diagnosis in patients undergoing SOC biopsies of IBDS
- Methods: Pts with IBDS (defined as failed prior Dx attempts) were randomized to undergo specimen processing using the onsite (touch imprint cytology [TIC]) or offsite (cell block) method. A max 7 biopsies (SpyBiteTM, Boston Scientific) were performed in each cohort. In the onsite cohort, biopsies were performed until diagnosis was established. In the offsite cohort, 3 biopsies were placed in the first container and 4 in the second. Final Dx was established at surgery or FU of 18 m
- Results: 62 pts were randomized: onsite=32, offsite=30. Location of stricture was common bile duct (19), common hepatic duct (16), hilum (18) and intrahepatic ducts (9)



Ji Young Bang, Muhammad K. Hasan, Udayakumar Navaneethan, Robert H. Hawes, Shyam Varadarajulu. Center for Interventional Endoscopy, Florida Hospital, Orlando, FL*

Optimizing Outcomes of Single Operator Cholangioscopy-guided Biopsies: Results of a Randomized Trial



- Final Dx was benign disease in 34 and malignancy in 28 patients
- A diagnosis was established with a median of 1 biopsy (IQR 1-1.5) in the onsite cohort; false positives were encountered in 1 patient and false negatives in 3. The diagnostic accuracy was identical (90.0%) whether patients underwent 3 or 4 biopsies in the offsite cohort; false negatives were encountered in 3 patients, there were no false positives
- There was no significant difference in diagnostic accuracy (90.6 vs. 90.0%, p=0.99), sensitivity (80.0 vs. 76.9%, p=0.99), specificity (100 vs. 100%, p=0.99), positive predictive value (100 vs. 100%, p=0.99) or negative predictive value (85.0 vs. 85.0%, p=0.99) between the onsite versus offsite cohorts, respectively
- Conclusion: For centers without onsite cytopathology support, performing three SOC-guided biopsies of the biliary stricture and processing the specimen offsite yields a diagnostic accuracy of 90%.

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Early versus Late ERCP in Acute Cholangitis: A Systematic Review and Meta-Analysis

- **Introduction:** The current guidelines of Tokyo recommend urgent biliary drainage depending on the severity without any specified timing
- Aim: Conducted a systematic review and meta-analysis to evaluate the impact of early biliary drainage on in-hospital mortality (IHM) and length of stay (LOS) compared to delayed ERCP
- **Methods:** A comprehensive literature review was conducted by searching the Embase and PubMed databases from inception to September 2018 to identify all studies that compared outcomes of early ERCP with delayed ERCP
- **Results:** Seven studies included. 63,147 underwent biliary drainage within 48 hours while 19,530 underwent after 48 hours

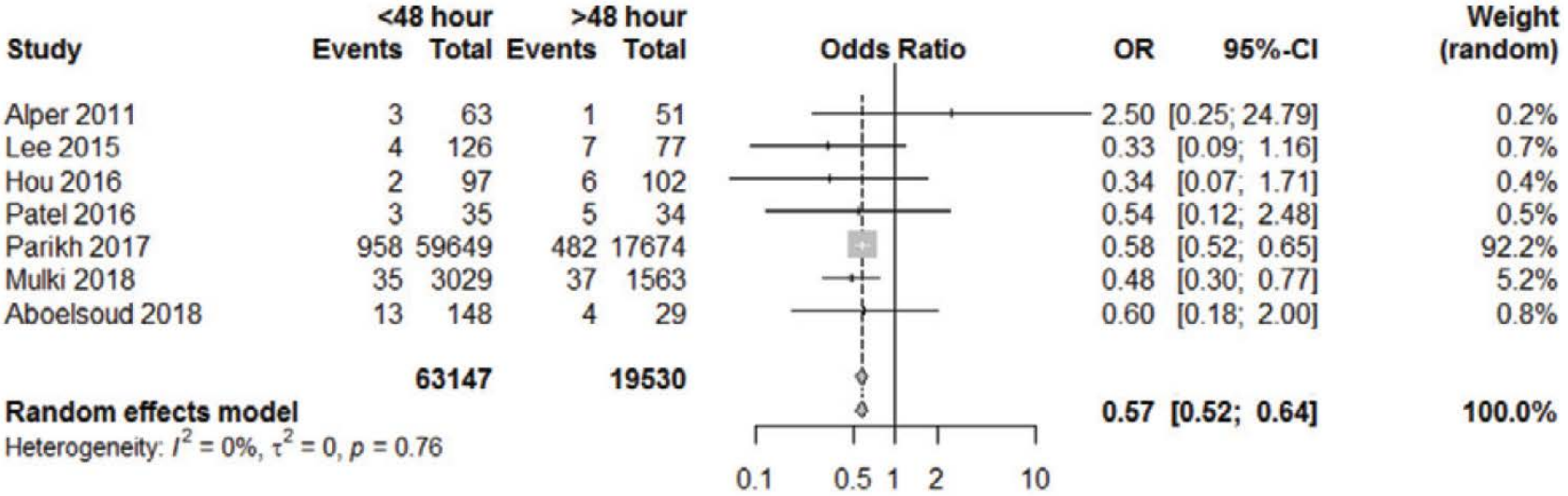
Umair Iqbal, Muhammad Ali Khan, Yirui Hu, Osama Siddique, Anais Ovalle, Haiyan Sun, M. J. Shellenberger

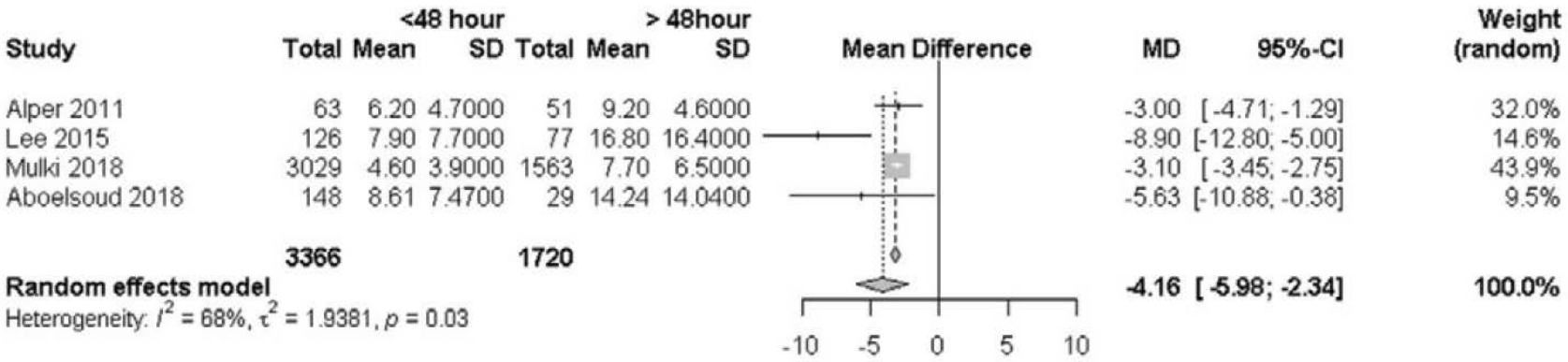
Early versus Late ERCP in Acute Cholangitis: A Systematic Review and Meta-Analysis

- IHM was significantly lower in patients who underwent biliary drainage within 48 hours OR= 0.57 [95% CI: 0.52 – 0.64] (Fig 1)
- 4 studies were included in evaluating the MDs in LOS between two groups. LOS was also significantly lower in patients who underwent ERCP within 48 hours of 4.16 days (Fig 2)
- A subgroup analysis showed IHM trended significantly lower in patient who underwent ERCP for AP within 24 hours, OR=0.83 [0.75-0.92] compared to patients who had the procedure after 24 hours
- **Conclusion:** Mortality of acute cholangitis is around 10%. Early ERCP within 24 to 48 hours had decreased odds of IHM and had shorter LOS

Umair Iqbal, Muhammad Ali Khan, Yirui Hu, Osama Siddique, Anais Ovalle, Haiyan Sun, M. J. Shellenberger

Early versus Late ERCP in Acute Cholangitis: A Systematic Review and Meta-Analysis





Umair Iqbal, Muhammad Ali Khan, Yirui Hu, Osama Siddique, Anais Ovalle, Haiyan Sun, M. J. Shellenberger

Laparoscopy-assisted versus Enteroscopy-assisted ERCP in patients with RYGB: a Meta-analysis

- ERCP in RYGB can be performed with a surgical approach or enteroscopyassisted ERCP (EA-ERCP)
- **AIMS:** conducted a meta-analysis comparing LA-ERCP versus EA-ERCP in RYGB patients
- **Methods:** Performed a search of PubMed, EMBASE and the Cochrane library from inception to 10/2018 for studies reporting outcomes of LA- or EA-ERCP in RYGB patients. Single, double balloon or spiral systems were included in the EA-ERCP arm.
- **Results:** 3,859 studies were identified, of which 26 met the inclusion criteria (14 LA-ERCP and 12 EA-ERCP) and were included in the analysis

Fares Ayoub, Tony Brar, Debdeep Banerjee, Ali M. Abbas, Dennis Yang, Peter V. Draganov

Laparoscopy-assisted versus Enteroscopy-assisted ERCP in patients with RYGB: a Meta-analysis

- The pooled therapeutic success rate for LA-ERCP (97.8%) was higher than with EAERCP (73.2%); with little heterogeneity (I2: 0%) among LA-ERCP as compared to the high degree of heterogeneity (I2: 80.2%) among EA-ERCP studies
- The pooled mean total procedure time for LA-ERCP (laparoscopy+ERCP time) was significantly longer when compared to EA-ERCP (158 min versus 100 min)
- Adverse events were more commonly reported with LA-ERCP (19%) than with EA-ERCP (6.5%)
- **CONCLUSIONS:** LA-ERCP has a higher therapeutic success rate compared to EA-ERCP in RYGB patients. However, LA-ERCP is associated with a higher rate of adverse events and a longer total procedure time. High quality, prospective comparative studies of the two modalities remain needed

Fares Ayoub, Tony Brar, Debdeep Banerjee, Ali M. Abbas, Dennis Yang, Peter V. Draganov

Early ERCP or Conservative Treatment in Predicted Severe Acute Biliary Pancreatitis: A Multi-Center RCT

- Early biliary decompression for severe acute pancreatitis by ERC may ameliorate the disease course, but previous randomized trials have shown conflicting results
- Aims & Methods: randomized 232 patients in 26 Dutch hospitals with predicted severe acute biliary pancreatitis (based on APACHE II score of ≥8, an Imrie score of ≥3 or a C-reactive protein level of >150 mg/L within 24 hours) and without cholangitis, to early ERC within 24 hours or conservative treatment
- **Results**: 112 patients (96%) in the early ERC group underwent ERC at a median of 20 hours after presentation, and after a median of 29 hours after symptom onset. Biliary sphincterotomy was performed in 91 patients (81%)

Group, Nora D. Hallensleben, Marc Besselink, Marie-Paule Anten, Thomas Bollen, Foke van Delft, Hendrik M. van Dullemen, Marcel Dijkgraaf, Casper H. van Eijck, G. Willemien Erkelens, Nicole S. Erler, Paul Fockens, Erwin-Jan M. van Geenen, Hein G. Gooszen, Janneke van Grinsven, Jeanin E. Van Hooft, René W. van der Hulst, Jeroen Jansen, Frank J.G.M. Kubben, Sjoerd D. Kuiken, Robert Laheij, Rutger Quispel, Rogier de Ridder, Marno C.M. Rijk, Tessa Romkens, Carola H.M. Ruigrok, Erik. J. Schoon, Matthijs P. Schwartz, Marcel Spanier, Adriaan C. Tan, W. Thijs, Robin Timmer, Niels Venneman, Robert C. Verdonk, Frank P. Vleggaar, W van de Vrie, Ben Witteman, Hjalmar C. van Santvoort, Olaf Bakker, Marco J. Bruno

Early ERCP or Conservative Treatment in Predicted Severe Acute Biliary Pancreatitis: A Multi-Center RCT

- In 35 of the 113 patients (31%) allocated to conservative treatment, ERC was performed for cholangitis or persisting cholestasis after a median of 8 days after randomization
- In the early ERC group, cholangitis occurred less often compared with conservative treatment (2% versus 10%; P=0.01) without significant differences in other related complications (new-onset organ failure [19% versus 15%; P=0.45], death [7% versus 9%; P=0.57] or other components of the primary end point)
- Conclusion: In patients with predicted severe acute biliary pancreatitis without cholangitis, early ERC with biliary sphincteromy within 24hours did not reduce the primary end point of death or major complications

Group, Nora D. Hallensleben, Marc Besselink, Marie-Paule Anten, Thomas Bollen, Foke van Delft, Hendrik M. van Dullemen, Marcel Dijkgraaf, Casper H. van Eijck, G. Willemien Erkelens, Nicole S. Erler, Paul Fockens, Erwin-Jan M. van Geenen, Hein G. Gooszen, Janneke van Grinsven, Jeanin E. Van Hooft, René W. van der Hulst, Jeroen Jansen, Frank J.G.M. Kubben, Sjoerd D. Kuiken, Robert Laheij, Rutger Quispel, Rogier de Ridder, Marno C.M. Rijk, Tessa Romkens, Carola H.M. Ruigrok, Erik. J. Schoon, Matthijs P. Schwartz, Marcel Spanier, Adriaan C. Tan, W. Thijs, Robin Timmer, Niels Venneman, Robert C. Verdonk, Frank P. Vleggaar, W van de Vrie, Ben Witteman, Hjalmar C. van Santvoort, Olaf Bakker, Marco J. Bruno (Netherlands)

NEW STENTS

Anew Anti-reflux Plastic Stent for Patients with Unresectable Distal Malignant Biliary Obstruction: A Prospective, RCT

- There is no ideal design of anti-reflux plastic stent (ARPS) for prolonging stent patency. We developed a new ARPS with a “duckbilled” valve attached to the duodenal end of the stent
- Aim: to compare the patency of this new ARPS with that of traditional plastic stent (TPS) in patients with unresectable distal malignant biliary obstruction (MBO)
- Methods: A single center, prospective, randomized, controlled, double-blind study. Patients with nonhilar, extrahepatic MBO were enrolled

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Anew Anti-reflux Plastic Stent for Patients with Unresectable Distal Malignant Biliary Obstruction: A Prospective, RCT

- Results: Between 2/2016 and 12/2017, 38 patients were randomized to receive an ARPS or TPS (19 in each group). Stent insertion was technically successful in all patients
- There was no significant difference between two groups in the rate of clinical success or in the rate of either adverse event (p=0.660; p=1.000; p=1.000)
- Median cumulative duration of stent patency in ARPS group was 285 days, which was significantly longer than that in TPS group (median, 130 days) (p=0.005)
- No significant difference in patient survival was noted between two groups (p=0.900)

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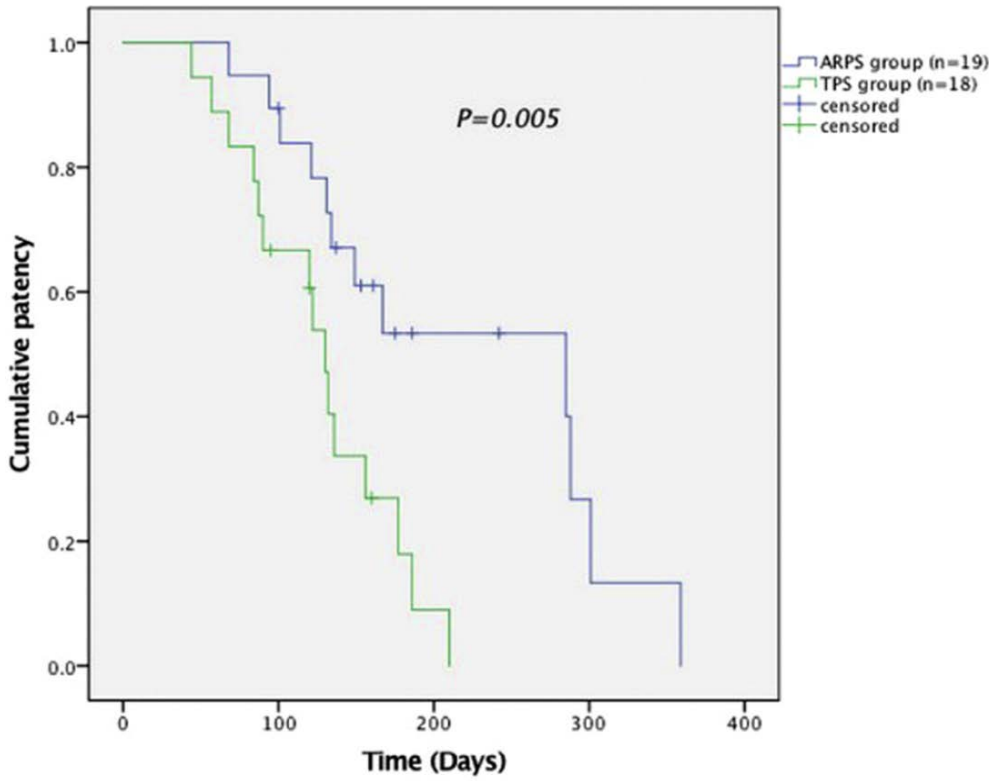
Anew Anti-reflux Plastic Stent for Patients with Unresectable Distal Malignant Biliary Obstruction: A Prospective, RCT

Figure 2. Kaplan-Meier curve comparing the cumulative patency of stent between the anti-reflux plastic stent (ARPS) group and the traditional plastic stent (TPS) group (p=0.005, log-rank test)



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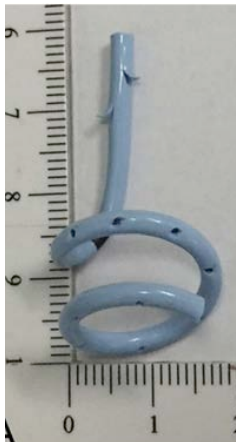
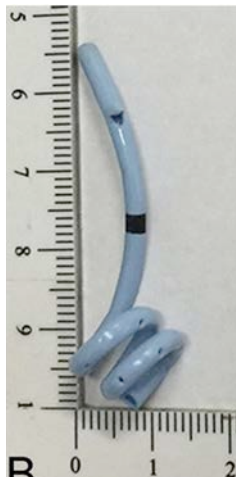
Placement of a Biliary Spontaneous Dislodgement Spiral Stent for Short-term Biliary Drainage: a Prospective Pilot Study

- Papillary edema may block biliary drainage, and many endoscopists routinely insert an endoscopic nasobiliary drainage (ENBD) tube after endoscopic clearance of CBD stones. Two types of 7-Fr biliary spontaneous dislodgement spiral stents (BSDSS) were developed
- Aim: to identify which was more suitable for further evaluation and widespread application.
- Patients and methods: Between May and October 2017, a total of 34 patients underwent BSDSS placement after endoscopic clearance of CBDS (17 patients in the 18-mm-spiral group; 17 patients in 12-mm-spiral group). Dislodgement time and clinical outcomes were compared





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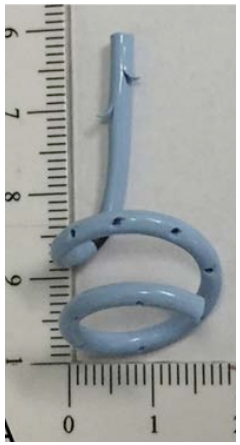
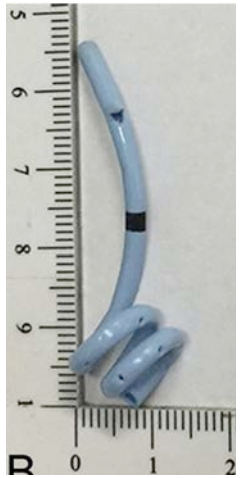
Placement of a Biliary Spontaneous Dislodgement Spiral Stent for Short-term Biliary Drainage: a Prospective Pilot Study

- Results: All BSDSSs were dislodged and evacuated spontaneously after short-term biliary drainage. There were no significant differences in dislodgement time (p=0.305), but a relatively small variation of dislodgement time was noted in the 12-mm-spiral group (95% confidence interval: 3.0-5.4 days vs. 3.0-7.4 days). There were no cases of post-ERCP cholangitis, pancreatitis, or BSDSS related adverse events in either group. The rate of CBDS recurrence and postoperative stay were also similar in two groups (p=0.562 and p=0.540, respectively)
- Conclusions: Both stents can be inserted for short-term biliary drainage after complete CBDS removal in selected patients. The 12-mm-spiral BSDSS is suggested for further investigation





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NOVEL BIODEGRADABLE STENT IN PATIENTS WITH CHRONIC PANCREATITIS

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Hyderabad, India

Introduction

- Stents placed at ERCP for management of pancreatic duct obstruction may occlude.
- Follow up ERCP required for
  - stent removal
  - stent exchange

Aim

Primary endpoint

– Technical success: Bio-degradable stent placement.

– Safety

Methods

- Pilot study
  - Symptomatic pancreatic duct disease subjects requiring endoscopic stenting were enrolled, after consent.
  - Biodegradable stents with 3 different degradation profiles were used.

Stent

ARCHIMEDES Biodegradable Stent

– Biodegradable stent made of proprietary blend of complex carbohydrate to drain obstructed pancreatic duct.

– $BaSO_4$ is embedded in stents for fluoroscopic visualization.

ARCHIMEDES Biodegradable Stent

– 3 different polymeric materials (according to bio-degradation rate)

– Degradation time *(minimal strength retention)*

- Fast degrading 12 days
- Medium degrading 25 days
- Slow degrading 11 weeks.

Biodegradable Stent Features

- Slightly curved shape, Fluted surface.
- Tapered tip
- Outer diameter: 6 F (pancreatic); Length: 40-225 mm.
- Anti-migration Features: Split-end (6 F), Flaps (8, 10F)
- Central lumen for 0.035” guidewire.
- Cross-section: 2 channels spiral as double helical in the entire length of stent.

Biodegradable Stent Design

6 F

8, 10 F

Methods:
Clinical Follow up & X-Ray abdomen

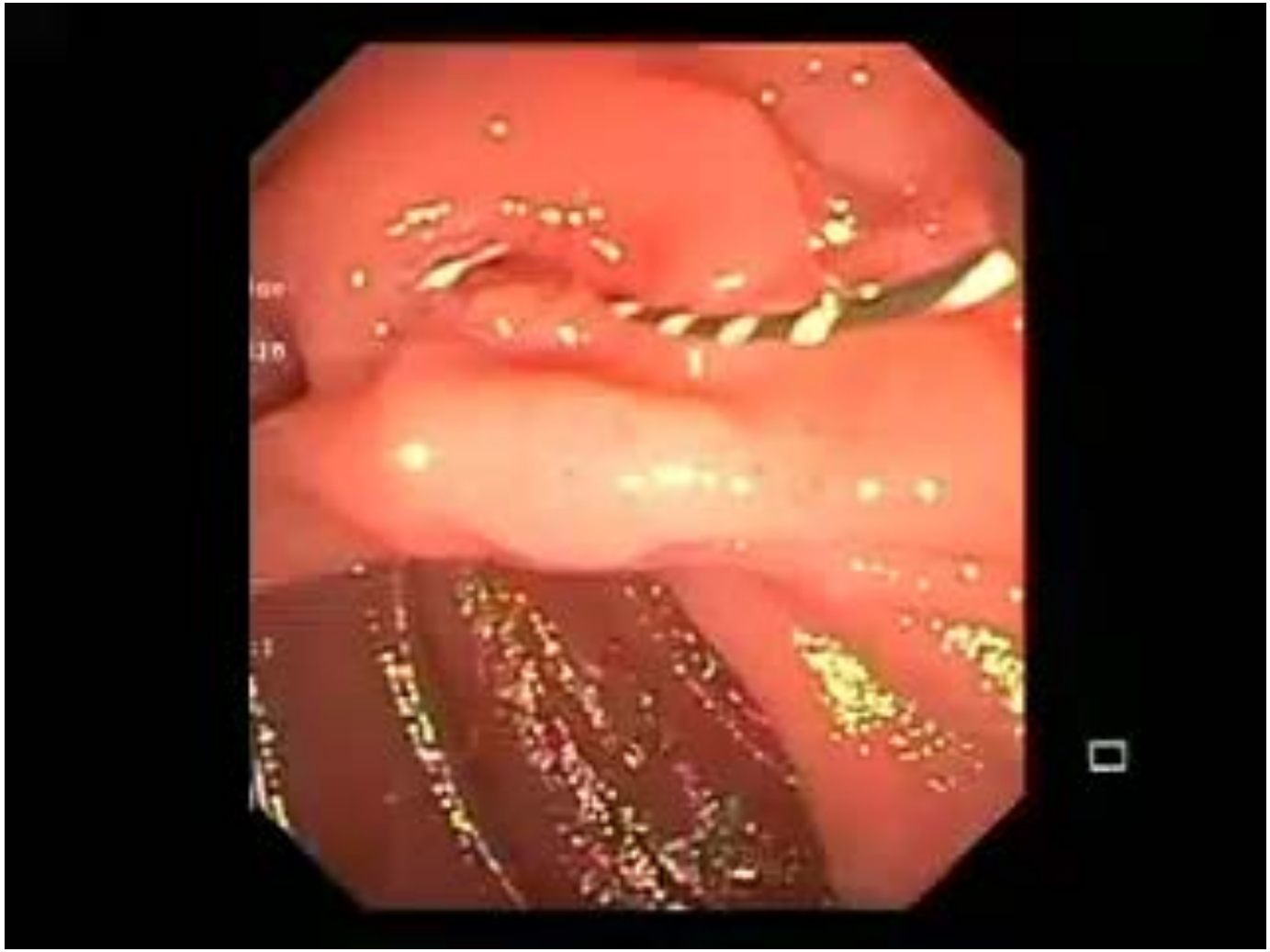
Variant	Day 1	Day 7	Day 14	1 mo.	3 mo.	6 mo.	9 mo.	12mo.
Fast	x	x	x	x	x			
Mediu m	x	x		x	x	x		
Slow	x	x		x	x	x	x	x

- Serial abdominal X-rays schedule based on degradation profile:

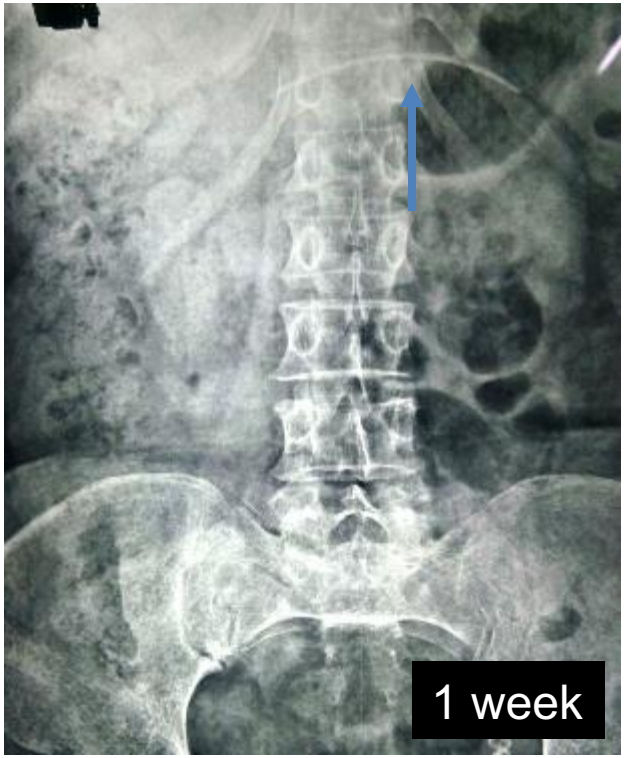
  @ 14 days, 1, 3, 6, 9, and 12 months.

- If stent not seen on X-ray on any FU, further X-rays abandoned.

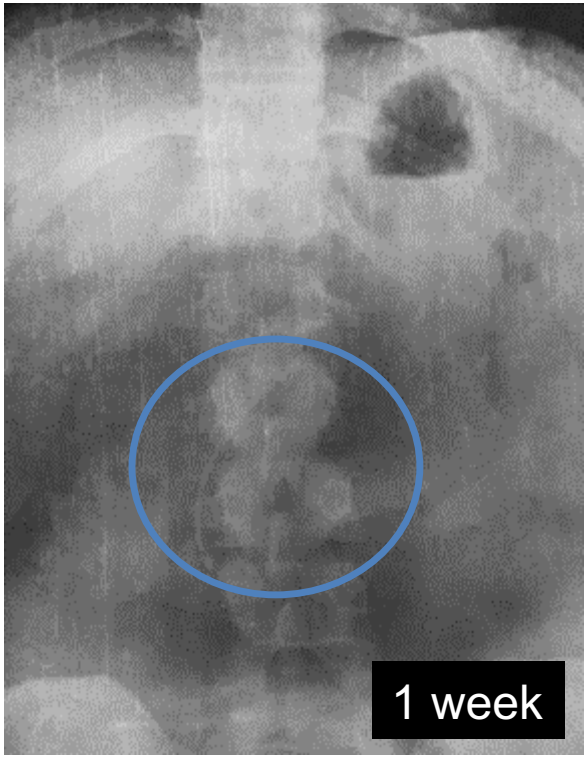
Insertion of Biodegradable stent



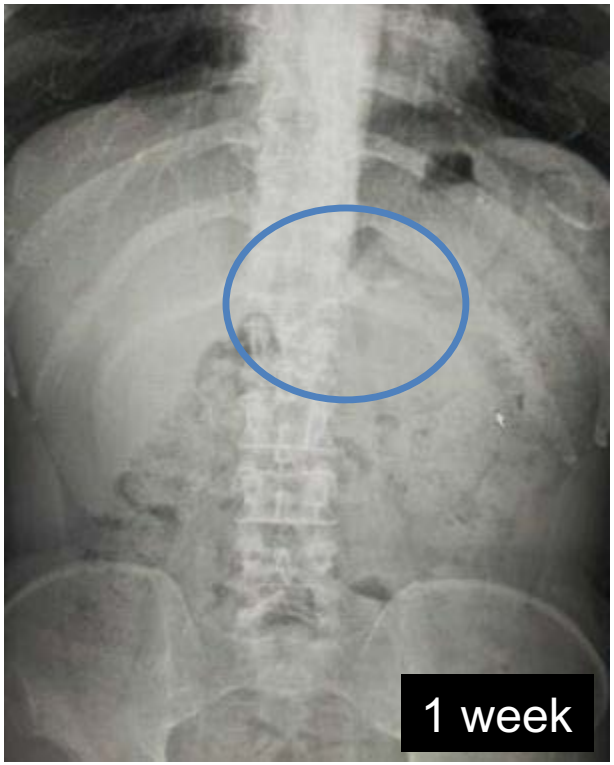
Pancreatic duct stent @1 week



Slow degrade



Medium degrade



Fast degrade

Results

Technical success: n=23 (100%).

- No requirement of early re-stenting.
- No repeat ERCP for device retrieval in the study.
- Stent visualisation rate
  - Excellent – 23%
  - Good – 64%
  - Fair – 13%

Results: Procedural Success

Device Rating: Excellent-1, Good-2, Fair-3, Poor-4

Device Rating	N=23
Loadability	**1.2**
Trackability Over Guide Wire	**1.8**
PushabilityWith Push-Catheter	**1.0**
Force Required To Implant Device	**1.1**
Stent Flexibility	**1.5**
Visualisation by Fluoroscopy	**2.0**
Stent Repositioning (If applicable)	**1.5**
Stent Deployment Accuracy	**1.3**
Device Average Rating	**1.4**

Results: Stent Characteristics

Number of stents implanted	n=24
Degradation	
Fast	3 (12.5)
Medium	7 (29.2)
Slow	14 (58.3)
Diameter (mm)	
2.0	24 (100)
2.6	0
3.4	0
Length (mm)	
40	2 (8.3)
60	1 (4.2)
80	1 (4.2)
100	20 (83.3)

Results

- Mean QOL score improved from 4.82 at baseline with rise up to 7.47 at day 1, & improved further up to 8.09 at 30 days period.

Adverse events

	Mild	Severe
Procedural	0	0
Non-Procedural (late)	1	0
SAE	0	0
Total	1	0

Feasibility of New Biliary and Pancreatic Biodegradable Stent Placement: Interim Analysis of an Ongoing Single Center Pilot

- New biliary and pancreatic biodegradable stents have been developed. They came in different sizes and with different polymeric mixtures allowing three expected rates of biodegradation: slow(11 wks), medium(20 d) and fast(12 d)
- Aim: to evaluate biodegradation time, safety and technical success of these stents.
- Methods: This is an interim analysis of an ongoing single-center, prospective, pilot study. Stents were inserted during ERCP. The primary outcome was the evaluation of biodegradation time, which was controlled by abdominal x-ray at 2 and 4 weeks for fast-degrading stents, 3 and 6 weeks for medium-degrading stents, and 3 and 6 months for slow-degrading stents

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Feasibility of New Biliary and Pancreatic Biodegradable Stent Placement: Interim Analysis of an Ongoing Single Center Pilot

- Results: 22 patients were enrolled, with placement of a total of 32 stents (Panc and biliary stents)
- Stents were successfully placed in all patients, with good loadability and pushability in all cases
- Fluoroscopic visualization was good in 85% and medium in 15% of the patients
- All fast-degrading pancreatic stents showed partial degradation after 2 weeks and complete degradation after 4 weeks in 4 out of 5 patients, with early migration in one patient
- 6 (2 with medium and 4 with slow degradation stents) have completed their follow-up evaluation showing complete disappearance of the stent at the expected time

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Feasibility of New Biliary and Pancreatic Biodegradable Stent Placement: Interim Analysis of an Ongoing Single Center Pilot

Indications	Number	Number of stent (degradation time)
Post-cholecystectomy bile duct stricture	5	7 (slow) + 2 (medium)
Prevention of post-ERCP pancreatitis	5	5 (fast)
Benign biliary stricture	3	4 (slow)
Bridge to cholecystectomy	3	4 (slow)
Malignant biliary stricture	2	3 (slow)
Pancreatic duct stenosis in chronic pancreatitis	2	1 (slow) + 1 (medium)
Bile duct stenosis in chronic pancreatitis	1	2 (medium)
Bile duct stenosis in PSC	1	1 (slow)
Post-ampullectomy	1	1 (slow)
Cholangitis	1	1 (slow)

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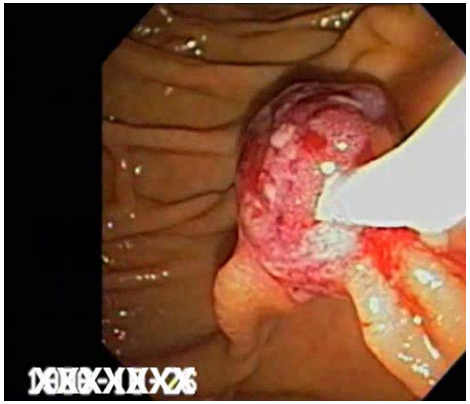
Risk Factors for Recurrence after Endoscopic Papillectomy

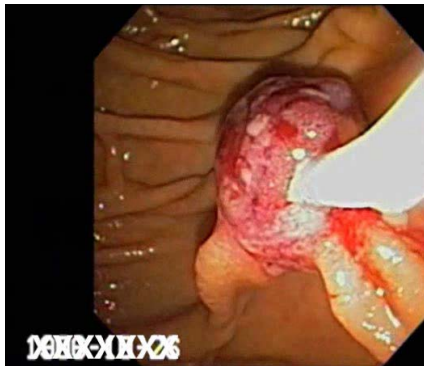


- Background: Endoscopic papillectomy (EP) for ampullary neoplasms is associated with recurrence rates up to 33%. Data on risk factors is limited
- Aim: Report EP efficacy and identify risk factors for recurrence
- Methods: Single-center retrospective review from 8/2000-1/2018
- Results: 165 patients. Mean size 20.6 mm
- Histology: TA 57.3%, TA with HGD 28.1%, and cancer 14.6%
- Resection method: En-bloc 53.1% and piecemeal 41.6%. Aborted 5.3% (intraductal extension >1cm [7] and sedation failure [1]). Thermal ablation of residual adenoma was performed in 36% of index EPs

Brian C. Brauer, Steven A. Edmundowicz, Hazem T. Hammad, Mihir S. Wagh, Sachin B. Wani, Raj J. Shah Gastroenterology, University of Colorado, Denver, CO

Risk Factors for Recurrence after Endoscopic Papillectomy

- Of the 157 EP patients, follow-up was 375 person years (PY, mean follow up of 2.4 years), during which recurrence occurred in 16 (10.2%) patients (incidence rate of 4.3 per 100 PY) at a mean of 3.4 (SD 3.1) years. 13/16 (81.3%) recurrences were managed endoscopically and three required surgery. Multivariate analysis revealed that incomplete resection (=thermal ablation at index EP for adenomatous-appearing tissue or residual adenoma on index surveillance), was associated with recurrence (OR 6.1, 95% CI: 1.6, 23.2) while lesion size and piecemeal resection were not
- AEs in 23.6%: bleeding (15.1%), pancreatitis (6.1%, 3 severe), and perforation (4.2%; 3 required surgery)
- Conclusions: 95% underwent EP with a recurrence rate of 10.2%. Incomplete resection was an independent risk factor for recurrence but piecemeal technique and lesion size were not.



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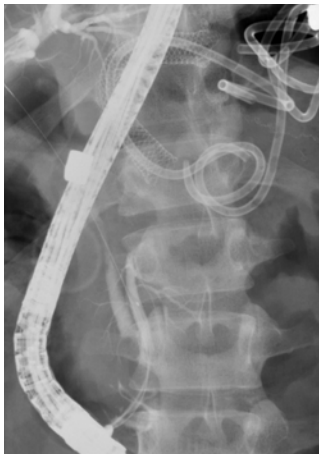
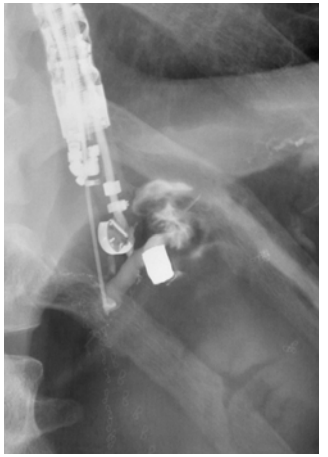
Disconnected Pancreatic Duct Syndrome Affects Endoscopic Management of Pancreatic Fluid Collections

- Limited data suggest that disconnected pancreatic duct syndrome results in more primary failures of endoscopic therapy with an increased need for percutaneous drainage
- Aim: to determine its impact on endoscopic management of PFCs.
- Methods: Retrospective cohort of consecutive patients who had EUS-guided transmural drainage for PFCs from 7/2012 to 1/2018
- Results: 159 patients included. Acute pancreatic fluid collections (3.8%), pseudocysts (38.4%), and walled-off necrosis (57.9%)
- Most patients had a single PFC (62.3%) with a median size of 105mm (IQR 72-156mm)
- Transgastric drainage was the most common approach (56.6%); Technical success 99.4%
- Disconnected duct did not affect technical success, # of index stents placed, or total # of therapeutic endoscopies. Patients were more likely to undergo concurrent MPD stenting (23% vs 8%, P=0.029), prolonged duration of index stent placement (129 vs 74 days, P=0.006), and placement of permanent transmural double pigtail stents (37% vs 8%, P<0.001)





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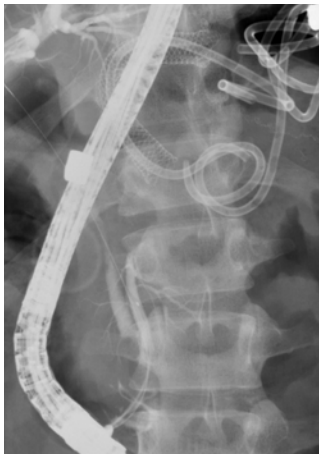
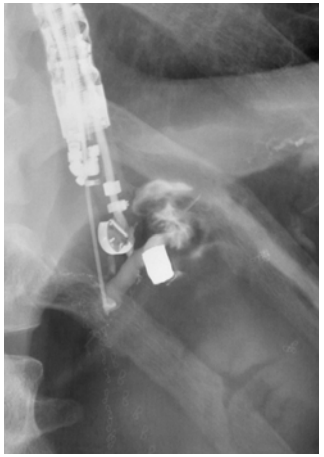
Disconnected Pancreatic Duct Syndrome Affects Endoscopic Management of Pancreatic Fluid Collections

- Although PFCs in patients with DPDS were located in body instead of head (P=0.005), smaller (82 vs 120mm, PZ0.002), and preferably drained via double pigtail stents instead of LAMS (P=0.002), there was no difference in days until PFC resolution (70 vs 66.5, P=0.21) or need for early or any reintervention (P=0.54, PZ1). DPDS was associated with increased PFC recurrence after stent removal (9% vs 1%, PZ0.040), but not persistence (P=0.71).
- Paracolic extension (OR 25.78, P<0.001), DPDS (OR 8.55, P=0.021), persistent PFC (OR 8.09, P=0.007), and infected PFCs (OR 5.08, PZ0.046) were associated with an increased need for hybrid IR-guided percutaneous management on multivariate analysis (Table 2)
- Conclusions: Presence of DPDS does not significantly prolong time until PFC resolution, increase rates of PFC persistence, or require more frequent therapeutic endoscopic interventions. DPDS is more often treated with permanent indwelling double pigtail stents, but when stents are removed, DPDS is associated with increased rates of PFC recurrence. On multivariate analysis, the presence of DPDS, paracolic extension, persistent, and infected PFCs were associated with an increased need for hybrid therapy





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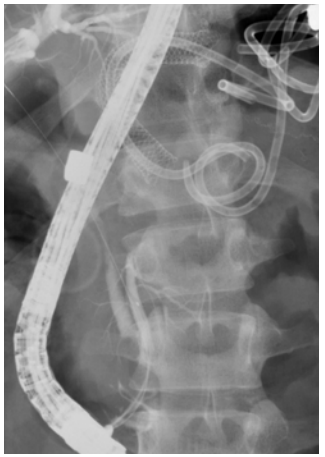
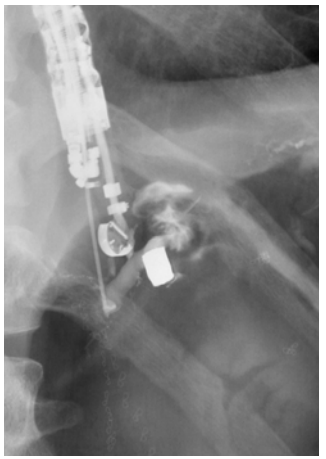
Disconnected Pancreatic Duct Syndrome Affects Endoscopic Management of Pancreatic Fluid Collections

Table 2. Univariate and multivariable analysis of potential factors associated with Hybrid IR Treatment

	Univariate Analysis		Multivariable Analysis	
Variable	**Odds Ratio (95% CI)**	**P-value**	**Odds Ratio (95% CI)**	**P-value**
Multiple PFCs	5.63 (2.06 - 15.39)	0.001	2.19 (0.52 - 9.22)	0.283
Paracolic Extension	17.28 (6.07 - 49.16)	<0.001	25.78 (4.13 - 160.65)	**<0.001**
Walled-Off Necrosis	0.21 (0.06 - 0.76)	0.017	0.44 (0.07 - 2.55)	0.358
Age >= 50 years	2.02 (0.74 - 5.47)	0.168	1.59 (0.33 - 7.59)	0.557
Infected PFC	4.47 (1.77 - 11.37)	0.002	5.087 (1.023 - 25.13)	**0.046**
Persistent PFC	10.38 (3.72 - 28.96)	<0.001	8.09 (1.78 - 36.87)	**0.007**
Recurrent PFC	2.64 (0.48 - 14.53)	0.265	1.99 (0.14 - 28.86)	0.613
PFC >= 100mm	1.93 (0.74 - 5.04)	0.177	0.94 (0.17 - 5.29)	0.944
Index stent: pigtail	1.42 (0.57 - 3.55)	0.449	3.41 (0.72- 16.06)	0.120
DPDS	1.41(0.56 - 3.58)	0.468	8.55 (1.38 - 52.93)	**0.021**





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Thank
You!

True or False

- Precut sphincterotomy for biliary access is less likely to cause acute pancreatitis than trying more cannulation when encountering difficulty in accessing the bile duct during ERCP

True or false answer

- True

Which statement is correct (may choose more than one answer)

1) Emergency ERCP should always be attempted in severe biliary pancreatitis
2) There is strong evidence that NSAIDs may prevent post-ERCP pancreatitis
3) Radiofrequency ablation therapy may prolong patient survival in unresectable hilar cholangiocarcinoma
4) The currently tested biodegradable biliary or pancreatic stents are unsuitable for clinical use because of their tendency to disorganized degradation

Which statement is correct (may choose more than one answer)

- 2 and 3

True or False

- Metal biliary stent placement without a sphincterotomy protects the patient from developing post procedure acute pancreatitis

True or False

- False