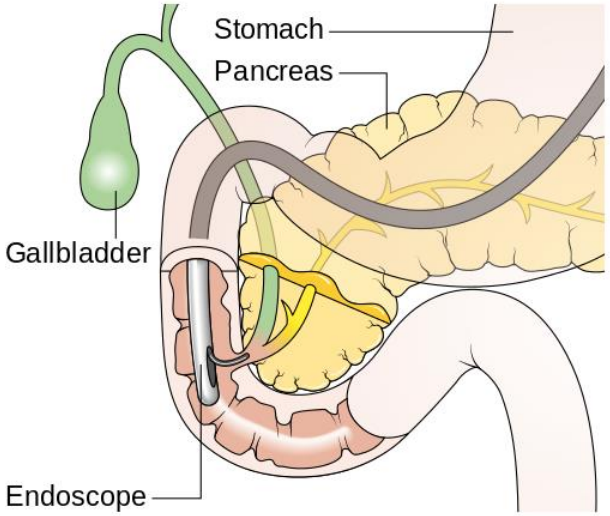
Biliary Tract Disorders and ERCP



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Relevant Disclosures

- Ambu Inc

Abstracts

1. The Exalt Model D Single-Use Duodenoscope is Safe and Effective in Post-Market Experience at a Tertiary Medical Center

2. Tri-Modality Sampling with Cytology, FISH, and Transpapillary Forceps Biopsies Improves Detection of Malignant Biliary Strictures

3. A Randomized Trial of Aggressive Fluid Hydration to Prevent Post-ERCP Pancreatitis (FLUYT)

The Exalt Model D Single-Use Duodenoscope is Safe and Effective in Post-Market Experience at a Tertiary Medical Center

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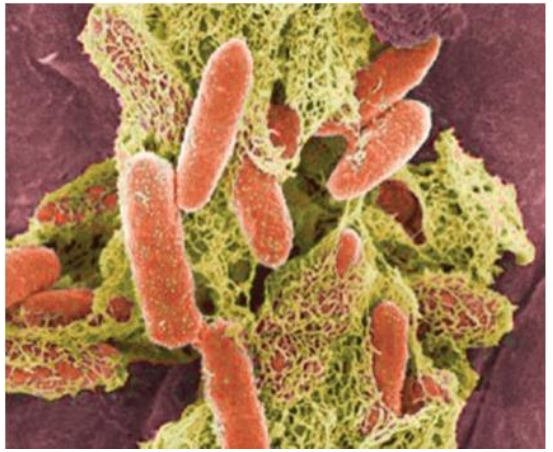
AIM: Assess the technical performance of the SUD in real-world practice

Background

- Outbreaks of multi-drug resistant organisms and infections have been linked to the use of duodenoscopes in ERCP- especially carbapenem-resistant *Enterobacteriaceae (CRE)* and *Pseudomonas aeruginosa*

- Patient to patient cross contamination has been documented despite appropriate scope reprocessing due to the mechanical complexity in the distal cap



- More than 660,000 ERCPs are performed annually in the US

Background

- Several strategies have been proposed to avoid the risk of duodenoscope-related contamination and infections.
  - serial microbiologic tests
  - thorough reprocessing schedules
  - use of removable scope cap have been adopted
- Unfortunately, those strategies did not completely eliminate the potential risk of infection
- 2019 the FDA cleared the first single use duodenoscope (SUD)
- In vivo trials with technical success rate without need to convert to reusable scope

Methods

- Retrospective Analysis
- Inclusion Criteria – all patients who underwent ERCP with SUD between June 12th 2020 – November 12th 2020 at UCLA
- 5 attendings and 2 fellows performed procedures

EXALT Model D Single Use Duodenoscope

EXALT Model D Control Box

Criteria for SUD Use

- Criteria for SUD use
  - If patient has known MDRO
  - Critically ill patient that would not withstand a duodenoscope acquired infection
  - Procedure high risk for bacteremia or infection
    - Cholangitis, cholangioscopy, biliary RFA, stent placement

  - To facilitate use –
    - no reusable scopes available
    - Weekend or evening procedure
    - OR procedure
    - Low volume/off-site centers

Outcomes

- Main outcome:
  - Completion of ERCP for intended clinical indication and cross over to reusable duodenoscope

- Secondary outcomes
  - Maneuver assessment
  - Adverse events
  - Procedure Time
  - Necessity for Pre-cut

Results

Baseline Characteristics of the Study Population

	ERCPs with SUD (n = 36)
Age (Mean; range)	65 years; 31 – 94
Female Gender	44.4% (16/36)
Pregnant	0% (0/36)
Altered ERCP Anatomy	0% (0/36)
Prior Biliary Sphincterotomy	63.9% (23/36)
Prior Pancreatic Sphincterotomy	0% (0/36)
Prior Liver Transplant	8.3% (3/36)
Indication for ERCP (Can be >1 indication)	
Bile Duct Stricture / Obstruction (non-stone)	66.7% (24/36)
Bile Duct Stent Exchange	36.1% (13/36)
Bile Duct Stone	25% (9/36)
Bile Duct Leak	2.8% (1/36)
Pancreatic Duct Stone	5.6% (2/36)
Ampullectomy	2.8% (1/36)
ASGE Grade for Complexity of ERCP Procedure	
Grade 1	11.1% (4/36)
Grade 2	50% (18/36)
Grade 3	27.8% (10/36)
Grade 4	11.1% (4/36)
Fellow-Assisted with Procedure	58.3% (21/36)

Results

Characteristics of the Procedures Performed

	ERCPs with SUD (n = 36)
Maneuvers Performed (can be > 1 maneuver per case)	
Biliary Stent Exchange	36.1% (13/36)
Removal of Biliary Stent	5.6% (2/36)
Placement of Biliary Stent	19.4% (7/36)
Balloon Dilation of Biliary Stricture	16.7% (6/36)
Clearance of Bile Duct Stone	50% (18/36)
Evaluation of a Biliary Stricture/Filling Defect	36.1% (13/36)
Placement of Pancreatic Stent	11.1% (4/36)
Clearance of Pancreatic Duct Stone	5.6% (2/36)
Evaluation of a Pancreatic Stricture/Filling Defect	2.8% (1/36)
Cholangioscopy	25% (9/36)
Pancreatoscopy	2.8% (1/36)
Ampullectomy	2.8% (1/36)
Completion of ERCP for Intended Clinical Indication	91.7% (33/36)
Procedure Time (mean; range)	48.6 minutes; 18 – 126
Pre-Cut Technique Performed	5.6% (2/36)
Cross-Over to Standard Reusable Scope	8.3% (3/36)
Adverse Events (for data available)	
72 hours post procedure	3.2% (1/31)
Cholangitis	3.2% (1/31)
7 days post procedure	0% (0/29)

Conclusion

- SUD eliminates device related transmission of infection
- SUD comparable to those of a reusable duodenoscope – only 3 patients requiring crossover to reusable duodenoscope
- SUD could be used for several ERCP indications and maneuvers with optimal operators' satisfaction
- Similar adverse event rates to reusable duodenoscope

Tri-Modality Sampling with Cytology, FISH, and Transpapillary Forceps Biopsies Improves Detection of Malignant Biliary Strictures

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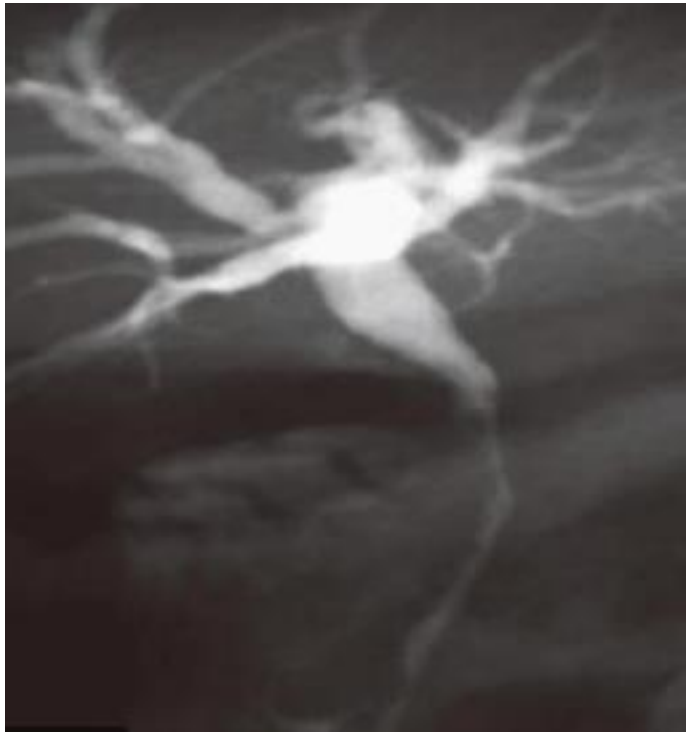
AIM: to determine the performance characteristics of the various sampling techniques in isolation or in combination for the detection of malignancy in biliary strictures in select patient cohorts.

Background

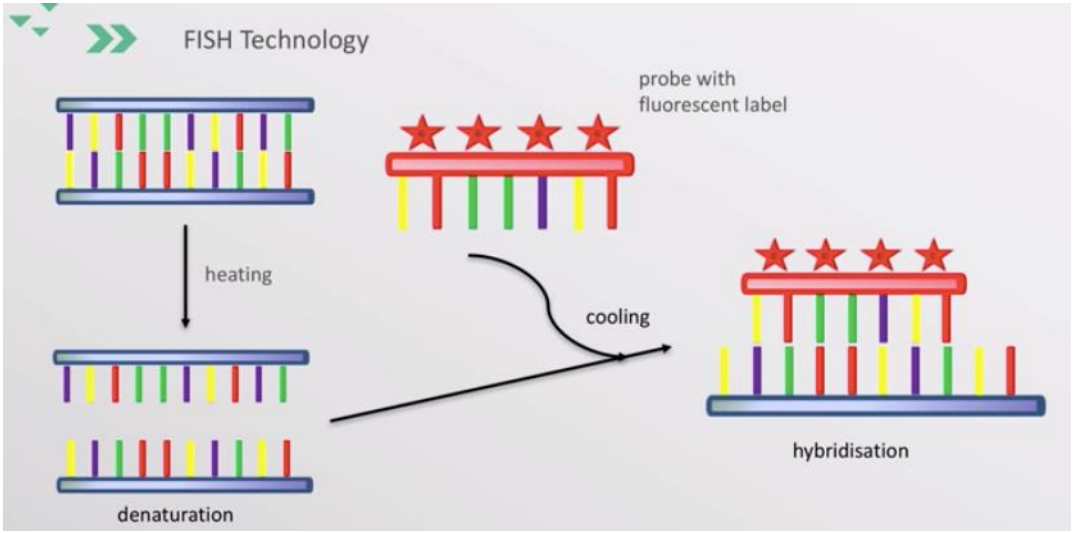
- Indeterminate biliary strictures pose a diagnostic and therapeutic challenge with the primary concern of diagnosing malignancy
- 20% labeled as indeterminate after initial sampling modality when imaging, ERCP, and brushing non-diagnostic
- Balancing risk of failing to detect malignancy and potential morbidity caused by unnecessary surgery in benign etiologies
- Transpapillary biopsy (TPB) or fluorescence in situ hybridization (FISH) increases detection of biliary malignancy when added to brush cytology (BC)

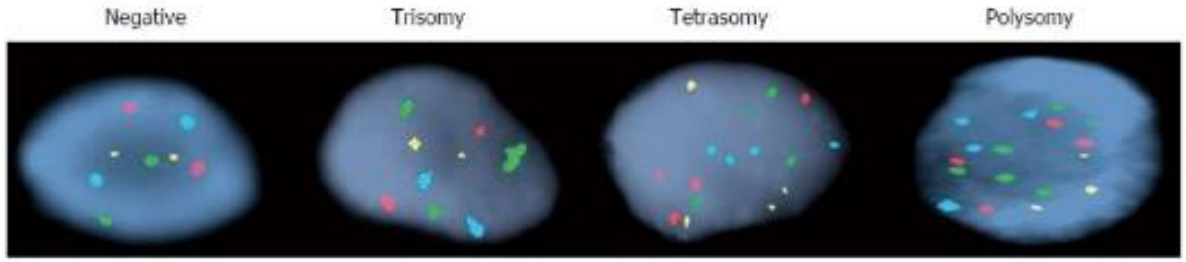


FISH

- Fluorescently labeled probes hybridize with DNA of individual cells

- It is used to detect and localize the presence or absence of specific DNA sequences on chromosomes that would be highly suspicious for malignancy





Methods

- Single-center retrospective cohort study
- Adult patients with biliary strictures who underwent ERCP with tri-modality sampling between 9/2014 and 4/2019
- Performance characteristics for each diagnostic test alone and in combination were evaluated overall and in each subset: cholangiocarcinoma (CCA), pancreatic cancer, and primary sclerosing cholangitis (PSC)

Results

- 204 patients underwent tri-modality sampling
- 104 (51.0%) with malignancy

Sensitivity	Overall	PSC	CCA	PC
BC	48.1 %	60%	61%	33.3%
BC+FISH	69.2%	95%	83.1%	58.3%
BC+TPB	64.4%	75%	48%	45.8%
Trimodality	76.9%	95%	89.8%	66.7%

Conclusions:

- Tri-modality sampling improves the diagnostic sensitivity for the detection of malignant biliary strictures
- ERCP with tissue sampling is more sensitive for detecting CCA than pancreatic cancer
- Patients with PSC, tri-modality sampling was not superior to BC+FISH
- Future – incorporating modalities such as cholangioscopy, confocal microscopy

A Randomized Trial of Aggressive Fluid Hydration to Prevent Post-ERCP Pancreatitis (FLUYT)

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AIM: To investigate whether aggressive IVF in addition to rectal indomethacin leads to decreased rates of post-ERCP pancreatitis

Background

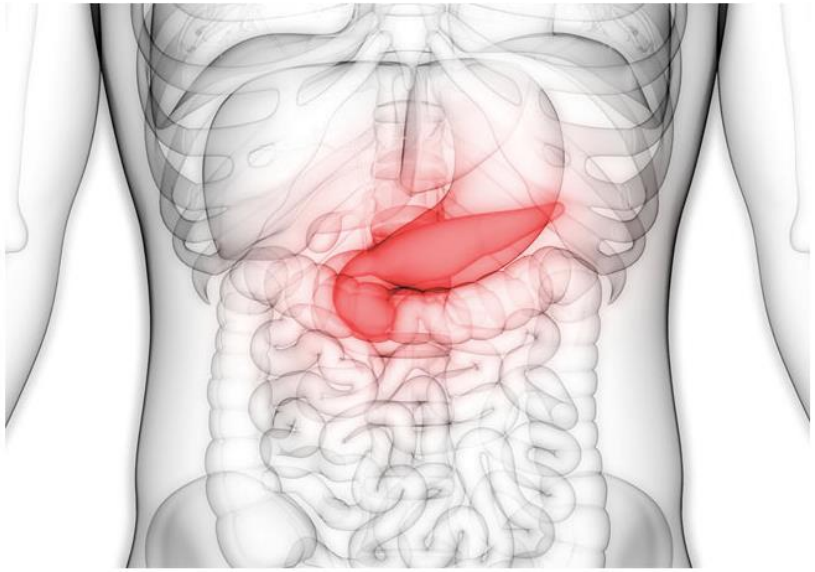
- Post-ERCP pancreatitis (PEP) a common and feared complication of endoscopic retrograde cholangiopancreatography (ERCP)

	Mild	Moderate	Severe
Cotton et al.[5]	• Clinical pancreatitis, • Amylase at least three times normal at more than 24 h after the procedure, • Requiring admission or prolongation of planned admission to 2-3 d.	• Pancreatitis requiring hospitalization of 4-10 d	• Hospitalization for more than 10 d, • Hemorrhagic pancreatitis, phlegmon, or pseudocyst, or intervention (percutaneous drainage or surgery).
Revision of the Atlanta classification and definitions	Two of three features: 1. Abdominal pain consistent with acute pancreatitis; 2. Serum lipase activity (or amylase activity) at least three times greater than the upper limit of normal; 3. Characteristic findings of acute pancreatitis on contrast-enhanced computed tomography (CECT) AND no organ failure and no local or systemic complications	• Organ failure that resolves within 48 h (transient organ failure) and/or • Local or systemic complications without persistent organ failure	Persistent organ failure (>48 h)

Background

- PEP occurs from a combination of insults that result from papillary instrumentation and/or hydrostatic injury from contrast material within the pancreatic duct

- This combination leads to premature intracellular activation of pancreatic proteolytic enzymes, auto-digestion, and the release of inflammatory cytokines causing local and systemic effects



	Patient-related	Procedure-related	Operator-related
Risk factors	• Suspected or known sphincter of Oddi dysfunction(SOD) • History of prior PEP • Female gender • Younger age • Normal serum bilirubin • Prior history of acute recurrent pancreatitis	• Difficult cannulation • Precut biliary sphincterotomy • Pancreatic sphincterotomy, • Cannulation and/or opacification of pancreatic duct • Endoscopic papillectomy • EPBD/EPLBD (ever)	• Previous experience • Case volume • Trainee involvement

Background

- Several modalities are used to decrease the rates of post-ERCP pancreatitis – rectal indomethacin and pancreatic duct stenting if accessed

- But what about hydration??

- A few studies evaluated the role of peri-procedural hydration, but its efficacy in the prevention of post-ERCP pancreatitis remains unclear especially when given along with rectal indomethacin.

Methods

- Multicenter, parallel-group open-label randomized controlled superiority trial of patients moderate- to high-risk of post-ERCP pancreatitis
- Randomly assigned (1:1) by a web-based module to a combination of aggressive hydration and rectal NSAIDs (hydration group) or rectal NSAIDs monotherapy (control group)
- Aggressive hydration - 20mL/kg lactated Ringer's intravenously from the start of ERCP within 60 minutes, followed by 3mL/kg/h for 8 hours.
- Control group - normal saline with a maximum of 1.5mL/kg/h and 3L/24h.

Outcomes

- The primary outcome - post-ERCP pancreatitis

- The secondary outcomes –
  - Pancreatitis severity
  - Hydration related complications

Results

- 826 patients were randomized
- Post-ERCP pancreatitis
  - 30 of 388 patients (8%) in the hydration group
  - 39 of 425 patients (9%) in the control group
- Severity of pancreatitis moderate to severe
  - 21 patients (5%) in the hydration group
  - 32 patients (8%) in the control group

Conclusion

- Aggressive periprocedural hydration and rectal NSAIDs was not superior in reducing the incidence of post-ERCP pancreatitis, as compared to rectal NSAID monotherapy in patients with moderate- to high- risk of post-ERCP pancreatitis

Thank you!
Questions?