Improving the Safety of ERCP

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Indianapolis, Indiana

Disclosures

• None

Objectives

Attendees will:
• be able to list and understand the etiology of the most common complications of ERCP;
• understand the strategies employed to reduce the risk of post-ERCP pancreatitis;
• gain an appreciation of recent and ongoing research aimed at improving the safety of ERCP.
Complications of ERCP

- will occur
- do not automatically imply negligence
- informed consent
- predictable and preventable risk factors should be identified

ERCP complications

Common
- Pancreatitis
- Bleeding
- Perforation
- Infection
- Damage to teeth, lips, gums

Rare
- Cardiopulmonary event
- Air embolism
- Cholecystitis
- Technical problem (e.g. entrapped basket)
- Death

ERCP Complications

ERCP complications in large prospective series

<table>
<thead>
<tr>
<th>Author</th>
<th>Journal year</th>
<th>N</th>
<th>Pancreatitis</th>
<th>Bleed</th>
<th>Perforation</th>
<th>Infection</th>
<th>Cardiopulmonary</th>
<th>Air embolism</th>
<th>Cholecystitis</th>
<th>Technical problem</th>
<th>Death</th>
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<tbody>
<tr>
<td>Williams</td>
<td>EHubs 2007</td>
<td>3264</td>
<td>1.6%</td>
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</table>
Post-ERCP Pancreatitis (PEP)

- recent meta-analysis:
  - 108 randomized controlled trials
  - 13,296 patients
  - 9.7% overall incidence of PEP
    - 14.7% incidence in high-risk patients
  - majority of cases were mild (≤ 3 days in hospital)
  - mortality rate 0.7%
- 500,000 ERCPs performed/year in the USA
  - 50,000 episodes of PEP
  - 3500 deaths

Kochar et al. Gastrointest Endosc 2015;81:143-9

Post-ERCP Pancreatitis

- Most common major complication
- 3-10%, as high as 30%
- Varies with:
  - definition (Cotton et al. Gastrointest Endosc 1991)
  - methods of detection and follow-up
  - patient-related factors
  - procedure-related factors

Post-ERCP Pancreatitis: Risk Factors

**Patient**
- female
- suspected SOD
- normal bilirubin
- history of acute recurrent pancreatitis
- prior post-ERCP pancreatitis
- no chronic pancreatitis

**Procedure**
- difficult cannulation (> 10min)
- # of pancreatic injections
- repetitive pancreatic guidewire cannulation
- pancreatic sphincterotomy
- intact biliary orifice dilation
- degree of PD filling
  - (precut sphincterotomy)
Post-ERCP Pancreatitis: Risk Factors Are Cumulative

- 2.5
- 4.8
- 12.4
- 16.2
- 42.1

Adjusted risk of pancreatitis (%)

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Post-ERCP Pancreatitis: Methods of Prevention

- Avoidance of unnecessary or marginally indicated ERCP by using alternative imaging techniques (e.g. MRCP, EUS)

- Endoscopic
  - stents
  - limit amount/extent of PD injection
  - guidewire cannulation

- Pharmacologic

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Post-ERCP Pancreatitis: Methods of Prevention

- Avoidance of unnecessary or marginally indicated ERCP by using alternative imaging techniques (e.g. MRCP, EUS)

- Endoscopic
  - *stents*
  - limit amount/extent of PD injection
  - guidewire cannulation

- Pharmacologic
Pancreatic stenting to reduce pancreatitis risk after biliary sphincterotomy for SOD

- 80 pts with pancreatic sphincter hypertension, biliary ES for SOD
- Randomized to short-term PD stent or no stent after biliary ES

*P<0.01

Tarnasky. Gastroenterology 1998;115:1518
Cannulation positions

Upward approach favors biliary cannulation
En-face approach favors pancreatic duct cannulation

Cannulation Difficulty and Post-ES Pancreatitis

<table>
<thead>
<tr>
<th>Cannulation Difficulty</th>
<th># Attempts</th>
<th>Incidence of Pancreatitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Easy</td>
<td>≤ 5</td>
<td>30/924 (3.2%)*</td>
</tr>
<tr>
<td>Moderate</td>
<td>6-15</td>
<td>23/322 (7.1%)*</td>
</tr>
<tr>
<td>Difficult</td>
<td>&gt; 15</td>
<td>19/146 (13.0%)*</td>
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</tbody>
</table>

*Multivariate p < .05; Freeman. GI Endosc 1994;40:108A
PANCREATIC STENTING to reduce pancreatitis risk after difficult cannulation

- 74 pts w difficult access, SOD, ES
- randomized to short-term 5 Fr PD stent or nasopancreatic drain vs no stent after ERCP

Fazel et al. Gastrointest Endosc 2003;57:291

POST-ERCP PANCREATEITIS (%)

0 5 10 15 20 25 30
NO STENT PD STENT
P<0.05

PANCREATIC STENTING to reduce pancreatitis risk after precut papillotomy

- 93 needle-knife precut for biliary access after PD stent placed: randomized to stent left in >7 d vs removed immediately

Cha S-W et al. Gastrointest Endosc 2013;77:209-16

PANCREATEITIS (%)
Ampullary Adenoma Resection

PD Stenting after Snare Papillectomy of Ampullary Adenoma


Prophylactic Pancreatic Stents Prevent Post-ERCP Pancreatitis – Meta-analysis of 14 Trials (n=1541)

<table>
<thead>
<tr>
<th></th>
<th>Stent</th>
<th>No Stent</th>
<th>RR (C.I.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatitis</td>
<td>7%</td>
<td>19%</td>
<td>0.39 (0.29-0.53)*</td>
</tr>
<tr>
<td>Mild/Mod</td>
<td>7%</td>
<td>16%</td>
<td>0.45 (0.32-0.62)*</td>
</tr>
<tr>
<td>Severe</td>
<td>0%</td>
<td>2%</td>
<td>0.26 (0.09-0.76)**</td>
</tr>
</tbody>
</table>

P<0.001; **p=0.01
Mazaki et al., J Gastroenterol 2014;49:343-55
PD Stent-Induced Ductal Changes

A

B

PANCREATIC STENT DUCT INJURY

% with duct injury

Stent diameter

1 French 22/243
2 French 84/246
3 French 20/24
4 French 12/16


Guidewire Perforation

PEP...Mild
Pancreatic Stenting to Reduce Pancreatitis Risk after ERCP

- Overall pancreatitis risk greatly reduced, severe pancreatitis risk virtually eliminated
  however:
  - May be technically difficult
  - Failure may be worse than no attempt
  - Requires adaptation to new wires, stents
  - Must be documented to pass (x-ray) or removed (EGD)
  - May cause duct damage, especially if stent mismatched to duct or left in place too long

Post-ERCP Pancreatitis: Methods of Prevention

- Avoidance of unnecessary or marginally indicated ERCP by using alternative imaging techniques (e.g. MRCP, EUS)
- Endoscopic
  - stents
  - limit amount/extent of PD injection
  - guidewire cannulation
- Pharmacologic
Post-ERCP Pancreatitis: Methods of Prevention

- Avoidance of unnecessary or marginally indicated ERCP by using alternative imaging techniques (e.g. MRCP, EUS)
- Endoscopic
  - stents
  - *limit amount/extent of PD injection*
  - guidewire cannulation
- Pharmacologic

Pancreatitis After ES vs Number of PD Injections

<table>
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<tr>
<th>Number of PD Injections</th>
<th>Pancreatitis (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-5</td>
<td>2.7%</td>
</tr>
<tr>
<td>&gt;5</td>
<td>6.3%</td>
</tr>
<tr>
<td>&gt;5</td>
<td>16%</td>
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* *p<.05

Prevention of Post-ERCP Pancreatitis: Limit Pancreatic Duct Injections
Post-ERCP Pancreatitis:
Methods of Prevention

- Avoidance of unnecessary or marginally indicated ERCP by using alternative imaging techniques (e.g. MRCP, EUS)

- Endoscopic
  - stents
  - limit amount/extent of PD injection
  - guidewire cannulation

- Pharmacologic
GUIDEWIRE CANNULATION

to reduce pancreatitis risk

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<tr>
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<th>Standard cannulation</th>
<th>Guidewire cannulation</th>
</tr>
</thead>
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<tr>
<td>Pancreatitis</td>
<td>3.5%</td>
<td>6.7%</td>
</tr>
<tr>
<td>Cannulation of desired duct</td>
<td>83.6%</td>
<td>77.3%</td>
</tr>
<tr>
<td>Need for precut sphincterotomy</td>
<td>9.3%</td>
<td>12.4%</td>
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GW vs. Conventional Cannulation for Prevention of Post-ERCP Pancreatitis
(Meta-analysis of 12 Prospective RCT (n = 3450))

<table>
<thead>
<tr>
<th></th>
<th>GW</th>
<th>Conventional</th>
<th>RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatitis</td>
<td>3.5%</td>
<td>6.7%</td>
<td>0.51 (0.32-0.82)</td>
</tr>
<tr>
<td>Cannulation of desired duct</td>
<td>83.6%</td>
<td>77.3%</td>
<td>1.07 (1.00-1.15)</td>
</tr>
<tr>
<td>Need for precut sphincterotomy</td>
<td>9.3%</td>
<td>12.4%</td>
<td>0.75 (0.60-0.95)</td>
</tr>
</tbody>
</table>

* If additional techniques or rescue approaches were used, no difference was seen between the two techniques

Tse et al. Endoscopy 2013;45:605-18
Pharmacologic Prevention of Post-ERCP Pancreatitis

• ERCP provides a unique opportunity to administer a prophylactic therapy prior to the potential pancreatic injury.

Pharmacologic Interventions: Mechanisms

• Reduce sphincter spasm
• Prevent infection
• Reduce contrast toxicity
• Decrease pancreatic secretion
• Block enzyme-activated inflammatory cascade
• Reduce inflammatory mediators

Post-ERCP Pancreatitis: Pharmacological Prevention

<table>
<thead>
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<th>Effective likely</th>
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<tbody>
<tr>
<td>NSAIDs</td>
</tr>
<tr>
<td>Nitroglycerin</td>
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</table>

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<th>Possible under study</th>
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<tbody>
<tr>
<td>Secretin</td>
</tr>
<tr>
<td>Ulinistatin</td>
</tr>
<tr>
<td>Cephtazidine</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ineffective don’t work</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-ionic contrast</td>
</tr>
<tr>
<td>Octreotide</td>
</tr>
<tr>
<td>PAF inhibitors</td>
</tr>
<tr>
<td>Steroids</td>
</tr>
<tr>
<td>Allopurinol</td>
</tr>
<tr>
<td>Heparin</td>
</tr>
<tr>
<td>Ca²⁺ ch blockers</td>
</tr>
<tr>
<td>Lidocaine</td>
</tr>
<tr>
<td>IL-10</td>
</tr>
<tr>
<td>Somatostatin</td>
</tr>
<tr>
<td>Semapimod</td>
</tr>
<tr>
<td>Gabevate</td>
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**Post-ERCP Pancreatitis: Pharmacological Prevention**

**Effective likely**
- NSAIDs
- Nitroglycerin

**Possible under study**
- Secretin
- Ulinistatin
- Cephtazidime

**Ineffective don’t work**
- Non-ionic contrast
- Octreotide
- PAF inhibitors
- Steroids
- Allopurinol
- Heparin
- Ca^{2+} ch blockers
- Lidocaine
- IL-10
- Somatostatin
- Semapimod
- Gabexate

**NSAIDs**

- Inhibit prostaglandins, phospholipase A2 and neutrophil-endothelial interaction
  - all believed to play an important role in the pathogenesis of acute pancreatitis

- Reduce mortality from acute pancreatitis in animal models

**NSAIDs**

- Inexpensive
- Easily administered
- Favorable risk-profile when administered as a one-time dose
### Rectal NSAIDs and PEP Prevention

<table>
<thead>
<tr>
<th>Study</th>
<th>Inclusion Criteria</th>
<th>Intervention</th>
<th>% PEP Placebo</th>
<th>% PEP NSAID</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Murray 2003 (Scotland)</td>
<td>ERP, SOD</td>
<td>100 mg diclofenac in recovery</td>
<td>15.4% (17/110)</td>
<td>6.3% (7/110)</td>
<td>0.049</td>
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<tr>
<td>Sotoudehmanesh 2007 (Iran)</td>
<td>All-comers</td>
<td>100 mg indomethacin prior to ERCP</td>
<td>6.8% (15/221)</td>
<td>3.2% (7/221)</td>
<td>0.06</td>
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<tr>
<td>Khoshbaten 2007 (Iran)</td>
<td>ERP</td>
<td>100 mg diclofenac in recovery</td>
<td>26% (13/50)</td>
<td>4% (2/50)</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Montario Loza 2007 (Mexico)</td>
<td>Suspected bile duct obstruction</td>
<td>100 mg indomethacin prior to ERCP</td>
<td>16% (12/75)</td>
<td>5.3% (4/75)</td>
<td>0.034</td>
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</tbody>
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### A meta-analysis of rectal NSAIDs in the prevention of PEP

- Pooled relative risk reduction for PEP after NSAID administration: 0.36 (95% CI 0.22-0.60)
- NSAID patients: ↓ PEP 64%
  ↓ mod-sev PEP 90%
- NNT: 15 patients


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### Conclusions

- Meta-analysis results support the use of NSAIDs in the prevention of PEP
- Further prospective multicenter trials are needed
A Randomized Trial of Rectal Indomethacin to Prevent Post-ERCP Pancreatitis


N Engl J Med
Volume 366(15):1414-1422
April 12, 2012

Study Design

- multicenter, RCT
- enrolled only high-risk patients (82% SOD)
- randomized to rectal indomethacin 100 mg vs placebo
- 1st outcome: PEP
- 2nd outcome: moderate or severe PEP

Post-ERCP Pancreatitis

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>Indomethacin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (%)</td>
<td>16.8</td>
<td>9.2</td>
</tr>
<tr>
<td>p</td>
<td>0.005</td>
<td>0.03</td>
</tr>
<tr>
<td>Moderate or Severe PEP</td>
<td>8.8</td>
<td>4.4</td>
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</table>
Adverse Events

Summary

- prophylactic rectal indomethacin significantly reduced the incidence and severity of post-ERCP pancreatitis in high-risk patients

Is Rectal Indomethacin the Drug of Choice for PEP Prevention?

<table>
<thead>
<tr>
<th>Feature</th>
<th>Result</th>
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<tbody>
<tr>
<td>Easily administered</td>
<td>Yes</td>
</tr>
<tr>
<td>Inexpensive</td>
<td>Yes</td>
</tr>
<tr>
<td>Safe</td>
<td>Yes</td>
</tr>
<tr>
<td>Reduce incidence &amp; severity of PEP</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Should we administer rectal indomethacin to all patients undergoing ERCP?

- 1 RCT of 449 patients, 70% average risk: ✗
- 2 RCT of 2600 pts: universal pre-ERCP NSAID vs selective post-ERCP NSAID: ✓
- 3 Retrospective review of 4017 pts, including low-risk malignant biliary obstruction: ✓

Who Should Get Rectal Indomethacin?

- All patients at high risk for PEP
- Questions to be answered:
  - optimal dose?
  - value in patients at low risk for PEP?
  - added benefit to prophylactic PD stenting?
  - can it be used instead of PD stenting?
  - synergistic effect with other drugs focused on other pathways of pancreatitis cascade (combination therapy)?
Preventing Post-ERCP Pancreatitis in 2017: Are We There Yet?

- No – we can do better
- Despite pharmacologic and endoscopic methods
  - PEP occurs in 7-15% high-risk patients; 1% severe and rarely fatal
- Role in low-risk patients
  - PEP in 2-5%; occasional severe

Post-ERCP Pancreatitis: Strategy for Avoidance

- Avoid ERCP if low likelihood of biliary stone/stricture
  - especially in high risk patients
- Alternative imaging preferred:
  - laparoscopic CCX + intraoperative cholangiogram
  - MRCP
  - biliary obstruction found
  - biliary obstruction not found
  - ERCP/ES
  - Omit ERCP or refer to advanced ERCP center

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<td>5284</td>
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Bleeding at ERCP

- almost always post-sphincterotomy
- may occur in absence of identifiable risk factors
- may be:
  - immediate (noted during ERCP)
  - delayed (up to 2-3 weeks post-ERCP)

What to do with patients on anticoagulants pre- and post-ERCP?

- ASA
- warfarin
- clopidogrel (Plavix®)
- dabigatran (Pradaxa®), rivaroxaban (Xarelto®), Apixaban (Eliquis®)
- heparin (iv, sc)

Anticoagulants and ERCP

- Use your common sense!
- Stop the drug when you can
- Continue the drug when you can’t
- Resume post-procedure when possible
  - it may be easier to stop a GI bleed than salvage myocardium or survive a stroke
Risk Factors for post-ES bleeding

- **Definite**
  - Coagulopathy
  - Anticoagulation within 3 days of ES
  - Cholangitis
  - Bleeding during initial ES
  - Lower endoscopist case volume
- **Maybe**
  - precut ES
  - pure cut current

Consider balloon sphincteroplasty in coagulopathic patient in which correction is difficult or undesirable

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Types of Perforation

- All endoscopy
  - Bowel wall
- Exclusive to ERCP
  - Ductal
  - Retroduodenal
**Pathogenesis**

- Bowel wall - scope, accessory
- Ductal - balloon, catheter, guidewire
- Retroduodenal - sphincterotomy extends beyond intramural portion of bile duct or pancreatic duct

**Rx of Bowel Wall Perforation**

- Endoscopic clips

**Ductal Perforation**

- Contrast extravasation from BD or PD
- Guidewire outside duct
- PD - pancreatitis
- BD - usually no significant sequelae; may have bile peritonitis
- BD, PD stent or NBT, NPT may be necessary
- Conservative Rx - NPO, IVF, IV abx
- Outcome nearly always good
**Retroduodenal Perforation**

- may/may not be obvious at time of sphincterotomy
- contrast/air outside confines of bile duct and duodenum on fluoroscopy
- diversion of bile and GI secretions with nasobiliary tube and nasoduodenal (or nasogastric) tube

**Retroduodenal Perforation**

- endoclips
- delayed recognition - NDT or NGT
- NPO, IV antibiotics, IVF
- consider CT scan, surgical consultation - early surgery rarely needed

**Risk Factors for Retroduodenal Perforation**

- precut sphincterotomy*
- Billroth II*
- “big” sphincterotomy
- periampullary diverticulum
- SOD
- small CBD diameter
- sphincterotomy outside 11 - 1 o’clock position
- combined procedures
**Avoidance of Retroduodenal Perforation**

• proper sphincterotome orientation between 11 - 1 o'clock
• avoid "zipper cut" - stepwise incision
• sphincterotomy tailored to indication, size of papilla, bile duct
• judicious use of precut
• attention to technique in B-II, periampullary tic

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**ERCP Complications**

ERCP complications in large prospective series

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<th>Author</th>
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**Who needs prophylactic antibiotics?**

Any patient who:

1. may have difficult biliary drainage
   – biliary obstruction/jaundice (stone, tumor, benign stricture [PSC, chronic panc, liver transplant])
2. may have infected bile
   – biliary stent change
3. is immunosuppressed (e.g. liver transplant)
4. undergoes pseudocyst drainage
Cholangitis after ERCP

• Caveats
  – MRI or CT mandatory prior to intervention on hilar strictures ("roadmap")
  – wire access technique (avoids overfilling)
  – drain what you fill
  – unilateral drainage sufficient most of the time in resolving jaundice
**MRCP roadmap to minimize cholangitis risk**

- Poor technique

**Minimize cholangitis risk**

Plan: MRCP roadmap

Poor technique

**Who needs antibiotics after ERCP?**

- Undrained biliary segments which are filled with contrast
- PSC
- Pseudocyst drainage
Duodenoscope-related Transmission of infection

- first described nearly 30 years ago
- the elevator mechanism intrinsic to these devices is difficult to clean manually
- transmission of multidrug-resistant organisms, including carbapenem-resistant Enterobacteriaceae, has been reported
- optimal cleansing process is unknown

Diligent mechanical cleansing:

- Culturing of scopes
- Repeated high-level disinfection
- Gas sterilization
- Use of a liquid chemical sterilant

Duodenoscope Cleansing Process at Indiana University Hospital

- a commercially available cleaning solution and foam are used in the procedure room, prior to taking the scope to the reprocessing area
- all scopes are double-washed
- we culture 20 scopes/week: 10 Mon, 10 Wed
**Duodenoscope Cleansing Process at Indiana University Hospital**

- re-culture any scope with a positive culture from the prior week
- two positive cultures → gas sterilization
- if patient has known CRE → gas sterilization
- repeated positive cultures → “retirement”

**Complications of ERCP**

- will occur
- do not automatically imply negligence
- informed consent
- predictable and preventable risk factors should be identified

**Conclusion**

There’s only one way to avoid complications:

Don’t do the procedure!