Medico-legal aspects of ERCP

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Personal potential conflicts

- Consultant to Olympus America
- Royalties from Cook Medical
- Board member
  - Apollo Endosurgery
  - SE Healthcare Quality Consulting
Personal qualifications

• 40 years in ERCP practice
• Medical expert in 150 ERCP lawsuits

Frakes JT, Cotton PB. Medicolegal issues in ERCP, in ERCP, eds Baron t, Kozarek R, Carr-Locke D. Elsevier 2012

Cotton PB. Analysis of 59 ERCP lawsuits; mainly about indications. Gastrointest Endosc 2006; 63(3):378-82.

Lawsuits for gastroenterologists

• 5th likeliest out of 25 specialties
• 12% of gastroenterologists are sued each year
• 75-99% of specialists will be sued in lifetime
• Missed diagnosis, meds, complications
• 20% of claims result in a payment

Cotton PB. Medicolegal issues in ERCP, in ERCP, eds Baron T, Kozarek R, Carr-Locke D. Elsevier 2012
Patients may be unhappy because

• The ERCP was technically unsuccessful
• Technically successful, but no benefit
• Went great, but problems with the process
• Something bad happened
  – Complications, adverse events

People sue because

• Poor outcome (usually a severe adverse event)
• Can’t afford the resulting costs
• Assume someone screwed up
• POOR COMMUNICATIONS
  – Before and afterwards
ERCP is dangerous

- Adverse events occur in 5-15%
- 1 in 100 are severe
- 1 in 1000 are fatal

Adverse events can occur
Before the procedure

- Medication adjustments
  - Anti-coagulants etc
During the procedure

- Over sedation
  - Guidelines doses, monitoring, anesthesia for ASA 3+
- Stressed cardio-pulmonary systems
- Bleeding
  - Usually stops or can be stopped with clips, injection, loops
- Perforation
  - Obvious wrong territory, subtle X-ray changes
- Injury
  - Electrical, skeletal, impaction

During recovery

- Pain
  - Over-distension (CO2)
  - Luminal perforation
    - Chest/abdominal X-rays, CT
    - Treatment usually surgical
  - Pancreatitis (not for 8-12 hours)
  - Retro-duodenal perforation
    - May be managed conservatively with surgical input
- Cardio-pulmonary compromise
- Injury
After leaving

• Pain
  – Perforation
  – Pancreatitis
• Bleeding, up to 14 days
• Infection
  – Cholangitis
  – Nosocomial infection
• Early treatment failures
  – Blocked biliary stent

Defining adverse events

Lack of agreed definitions of adverse events
  – And co-morbidities and other correlates with risk
Means that it is difficult to compare
  – different endoscopic series
  – endoscopy with surgery and other interventions
Computer report writers need structured datasets
What is the threshold beyond which an “incident” becomes an “adverse event”?

When does “bleeding” count?

For how long afterwards?

• For ever?
• 30 days?
• Something less?
  – 7 or 14 days?
Consensus conference on ERCP complications (Cotton PB et al. GIE 1991)

- An unwanted outcome
- Attributable to the procedures
- Requiring treatment in hospital (or prolongation of planned admission)

Severity grades (1991)
Mainly determined by patient burden

- Mild: 1-3 nights in hospital
- Moderate: 4-9 nights
- Severe: 10 or more nights, ICU or surgery
- Fatal
ASGE Quality Committee Workshop on Adverse events 2010

Multi-disciplinary input


ASGE workshop recommendations

An adverse event is one that
- Prevents completion of the procedure, or
- Within 14 days, has clinical sequelae that need
  - Unplanned or prolonged admission, or
  - Another procedure (requiring sedation/anesthesia), or
  - Consultation with other specialist

Attributable?
- Definite, probable, possible, unrelated
Events vary in severity

**Trivial**
- Procedure completed, no sequelae
- Procedure aborted (or not started)
- Post-procedure medical consultation
- Unplanned anesthesia/ventilation support
- Unplanned hospital admission ≤3 nights
- Unplanned admission 4–10 nights
- ICU admission
- Transfusion
- Repeat endoscopy for AE
- Interventional radiology for AE
- Surgery for AE
- Permanent disability (specify)
- Death

**Fatal**

Severity table

<table>
<thead>
<tr>
<th>Consequence</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incident</td>
<td>Mild</td>
</tr>
<tr>
<td>x procedure completed, no sequelae</td>
<td></td>
</tr>
<tr>
<td>x procedure aborted (or not started)</td>
<td></td>
</tr>
<tr>
<td>x post-procedure medical consultation</td>
<td></td>
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<td></td>
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<tr>
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<td></td>
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<tr>
<td>x transfusion</td>
<td></td>
</tr>
<tr>
<td>x repeat endoscopy for AE</td>
<td></td>
</tr>
<tr>
<td>x interventional radiology for AE</td>
<td></td>
</tr>
<tr>
<td>x surgery for AE</td>
<td></td>
</tr>
<tr>
<td>x permanent disability (specify)</td>
<td></td>
</tr>
<tr>
<td>x death</td>
<td></td>
</tr>
</tbody>
</table>
Incidents

Events not reaching threshold for AE
  – e.g. transient hypoxia, controlled bleeding
Should be documented
  – For quality improvement purposes
  – To show which incidents predict AEs (bleeding)

Collecting delayed AEs

• Wait to hear about them?
• Chase them?
  – Give patients a reminder card to call/email
  – Call all patients at 2-4 weeks (30% yield)
    • Computer calls?
  – Check hospital/national records for re-admissions/re-procedures/deaths
• Document the results and the methods used
• The harder you look the worse you appear
There are higher risk

• Procedures
  • Ampullectomy, pseudocysts

• Patients
  • Young, with healthy pancreas
  • Acutely ill (cholangitis)
  • Comorbid illness
    • Coagulopathy, obesity, ASA 3+, immunosuppressed

59 ERCP lawsuits GIE 2006
Spectrum of complications

• Pancreatitis  30 (6 deaths)
• Sph perforation 16 (3)
• Infection  10 (6)
• Esophageal perf  2
• Lost stent  1
• Total  59 (15)
Clinical contexts of cases

28 Pain (21 post-cholecystectomy)
16 Known biliary stones
11 Suspected duct damage or leak
2 Possible pancreatic tumor
1 Pancreatitis therapy


Alleged deviations from standard of care

Indications 32 + 16
ERCP 15
Sphincterotomy 8
Pre-cutting 9

Technique 19 + 4
Assumed 11
Documented 8

Post-ERCP care 5 + 10
Declined/delayed ERCP 2
Consent 0 + 15
Credentialing 0 + 1
• 48 F saw PA “to establish care with PCP”
• c/o fatigue, no pain. Normal labs (inc LFTs)
• US = small liver cyst, refer to GI
• GI repeat US = mild prominence pancreatic duct (“likely incidental”)
• ERCP. Normal pd, failed bd
• PEP 3 months in hospital

PA consult
• 50F post-chole
• LLQ pain, bloats cramps; colonoscopy neg
• Pain also in RUQ 2 weeks, mild no meds
• LFTs normal. CA 19-9 = 40 (<35)
• CT bile duct 9-10 mm
• Scheduled ERCP

GI sees patient on table before ERCP
PEP, died at 4 weeks
• 40F; chole 20 years ago
• RCM pain, “possibly skeletal”
• Normal LFTs and CT
• ERCP, difficult “marked stenosis of papilla”
• Precut then biliary sph
• Pain for 7 days “PEP”, discharged hurting, fed
• Readmitted at 10 days, plain Xray “mottling”
• CT perf

• 55 M recurrent bile duct stones
• Pain at midnight, ER at 3 am
  – afebrile, WBC 11.7, AST X 2; sent home
• ER at 11 am, afebrile, WBC 21,000, LFTs +++
  – Antibiotics, admit, IVF consult GI
• 7pm T 39, chills, p 122
• 10.30 Urgent ERCP; “ASA IV”
  – Demerol 50, versed 6
  – Hypoxia, code
  – Spinal infarction, paraplegia
Pancreatic stents

3 cases of “pushed in” stents requiring major surgery

Malpractice or bad luck?

Consent

• A process, not a paper
• Provide explanatory brochures, web sites
• Sit down, dressed, discussion with the ERCPist
• Prior day except in emergency
• Documented in writing
Consent quotes

“I never saw the doctor before the ERCP”
“I can’t remember the case from 4 years ago, but I always spend at least 20 minutes......”
“Is there any risk doctor?”
“Less than the risk of you driving here today!”
“Mum would never have accepted the procedure if she knew this could happen”

Risk reduction strategies

Maximize technical expertise and knowledge
Know your limits, work in your comfort zone
Follow national standards of care
    Keep updated on professional society guidelines
    NIH State of the Science conference 2002 (Cohen GIE)
Recognize and manage specific risks (eg coagulopathy)
Fully inform patients and families
Dealing with adverse events

• Recognize quickly
• Explain to the patient and family
• Refer back to the consent process
• Apologize
  – “Sorry it happened to you”
  – (not, “I must have pushed too hard, cut too far”)
• Consult as needed
• Explain the plan
• Document carefully

Lessons from 150 lawsuits

• Consider benefit/risk ratio very carefully
• Ensure truly informed consent (well annotated)
• Avoid risky behavior (pre-cutting)
• Document carefully and legibly
  – But never retrospectively
• COMMUNICATE and show that you CARE
Show that you care

- “Patients do not sue doctors they like”
- Seek out family members
- Give them your cell phone number
- Continue to visit/call regularly, even (especially) after they have been transferred

Higher risk endoscopists?
Competence = independent practice

How skilled are your graduates?

Would you let him work on your mother

(mother-in-law)?

Would YOU submit to ERCP by an “80%” doctor?

How would you know?

Data; report cards
Report card caveats

• Data quality?
• May promote avoiding difficult risky cases
• Little evidence that their use (e.g., cardiac surgery) has influenced patients or payers

But I still think it is a great idea and will be much easier, and believable, when the data are extracted directly from report writers.

Real performance data

• What rates of success and adverse events are desirable/acceptable?
• Accountability
  – Report cards, benchmarking
  – ASGE/ACG GIQUic for colonoscopy
  – ERCP Quality network
On-going numbers in practice?

Are low-volume ERCPists a problem in USA?

Cotton PB. GIE 2011
Certification?

• Cars, trucks, trains, planes
• Endoscopes?

Endoscopists and teams who

• Practice within the standard of care
  – With good indications and techniques
• Educate and communicate well

May still get sued, and lose some sleep, but not the lawsuit
I have not been sued, but....... 

“The tunnel at the end of the light; my endoscopic journey in six decades”  www.peterbcotton.com