Pain after cholecystectomy
Navigating a clinical minefield

Peter B Cotton MD, FRCP, FRCS
Professor of Medicine
Digestive Disease Center
Medical University of South Carolina
Digestive Disease Center

Patient-friendly care

A springboard for the research and education needed to improve it
The pinball patient

- Gastroenterology
- Oncology
- Radiology
- Surgery
- Pathology
- Medicine
if you have only a hammer
everything looks like a nail
Putting patients first

Solly Marks
(sage of SAGES)

“Consider the whole patient, not just the hole in the patient”
Cholecystectomy

- > 0.5 million/year in USA
- 10-15% unhappy afterwards
- Some have pathology (eg stones, strictures, leaks) detected by labs and scans
- Many have no objective evidence for biliary or pancreatic disease, and dysfunction of the sphincter of Oddi is considered
Sphincter of Oddi Dysfunction (SOD)

Over- or in-appropriate activity of the sphincter can cause pain attacks by increasing the pressure in the biliary and/or pancreatic ducts.
Current treatment
Recommended by NIH conference in 2002

ERCP (Endoscopic Retrograde CholangioPancreatography), with sphincter manometry leading to sphincterotomy of the biliary and/or pancreatic sphincters
ERCP sphincterotomy
The problem

• Lots of patients coming to “experts” at MUSC
• Published results are unimpressive
  – Cohort studies claim only modest improvement
  – One small randomized trial
• Manometry is unproven as a predictor
• Risks are substantial
  – Pancreatitis rate at least 15%. Perforations occur
  – Slippery slope of more procedures, even resections
The EPISOD study

- Evaluating
- Predictors and
- Interventions in
- Sphincter of
- Oddi
- Dysfunction

A multi-center trial funded by NIDDK
Does sphincterotomy help?

How to measure “help”?  
• Patients impression (PGIC) – too subjective  
• Quality of life – too general  
• Change in the pain burden
Measuring pain

• Most pain scoring systems (eg McGill) deal with chronic daily pain (cancer), and simple intensity (VAS) is a sufficient measure
• Rome III consortium defines biliary pain as episodic, “not daily”
• How to measure intermittent pain, and changes in it?
Measuring episodic pain

- Daily diaries?
  - Problem with lead-in data, and compliance for follow-up of one to three years
- Retrospective recall
  - Days of pain and intensity; not validated
- MIDAS
MIDAS for migraine

• Number of days in the prior 3 months that work/school, household and social activities were compromised by pain.
• Grades
  1 = <5 days; 2 = 6-12 days; 3 = 13-20 days; 4 = >20 days
• Validated by test-retest and against 90 day diaries

RAPID
Recurrent Abdominal Pain Interference and Disability

- Number of days in the prior 3 months that work/school, household and social activities were compromised by pain
  - Maximum score 270
- Also, number of days pain and average severity
- Pilot studies showing
  - Good test-retest correlation
  - 80% grade 3 or 4 before treatment, and 65% grade 1 after treatment

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1. On how many days in the last 3 months did you miss work or school because of your episodes of abdominal pain? ____ days

2. On how many days in the last 3 months was your productivity in work or school reduced by half or more because of your episodes of abdominal pain (Do not include days you counted in question 1 where you missed work or school.)? ____ days

3. On how many days in the last 3 months did you not do household work because of your episodes of abdominal pain? ____ days

4. On how many days in the last 3 months was your productivity in household work reduced by half or more because of your episodes of abdominal pain (Do not include days you counted in question 1 where you did not do household work.)? ____ days

5. On how many days in the last 3 months did you miss family, social or leisure activities because of your episodes of abdominal pain? ____ days

_____________________________________________________________________

6. On how many days in the last 3 months did you have episodes of abdominal pain (If the abdominal pain lasted more than 1 day, count each day.)? ____ days

7. On a scale of 0-10, on average, how painful were these episodes _______
**EPISOD Current Status**

- Completed enrollment March 2012
  - 214 randomized
  - 72 enrolled in observational study

- Last subject completed 12-month follow up March 2013

- Executive Committee Unblinded Aug 2013
Overall RAPID Data

• EPISOD Baseline Rapid (3-mo recall)
  – Median RAPID Score: 74 days of disability
  – Ave intensity of pain episodes (10-pt scale): 7

• EPISOD Mo12 Change from Baseline
  – Median Change in RAPID Score: 44 day decrease
Questions on the RAPID

• Accuracy of 90 day recall?
• Do patients exaggerate to gain entry/sympathy?
• And maybe minimize after “treatment”?
• Are they at peak burden at entry?
EPISOD study

- The results of the sham-controlled study will be announced shortly.
- And will have a big impact on practice in this minefield.