Sphincter of Oddi Dysfunction: What’s the Verdict in 2014?

Evan L. Fogel, M.D.
Professor of Clinical Medicine
ERCP Fellowship Director
Division of Gastroenterology/Hepatology
Indiana University Hospital
Indianapolis, Indiana
Disclosures

- Consultant: Cook
  Olympus
  Boston Scientific
Objectives

Attendees will:

• be able to recognize how patients with suspected sphincter of Oddi dysfunction may present in clinical practice;

• gain an understanding of the appropriate evaluation and management of patients with post-cholecystectomy abdominal pain;

• be able to explain the risks and potential benefits to patients undergoing ERCP with sphincter of Oddi manometry (SOM).
OUTLINE

• sphincter of Oddi dysfunction: definition
• case presentation
• manometry
• outcomes
Sphincter of Oddi

- regulates flow of bile/pancreas enzymes into duodenum
- maintains sterile intraductal milieu
Major Papilla
Cannulation

Biliary

Pancreatic
Sphincter of Oddi Dysfunction (SOD)

- an abnormality of SO *contractility*

- it is a benign, noncalculous, relative obstruction to flow of bile or pancreatic juice through the pancreatobiliary junction

- most common in young women

- may be manifested clinically by “pancreaticobiliary” pain, pancreatitis, abnormal LFTs, or abnormal pancreatic enzymes
Case: 30-year-old woman with RUQ pain

- six-month history
- constant discomfort, rated 2/10, with intermittent attacks of debilitating pain, identical to pain prior to cholecystectomy last year (“wasn’t functioning”)
- pain lasts 30-90 minutes, radiates to upper back, associated with nausea/vomiting
• Past medical history: cholecystectomy, otherwise negative

• Physical exam: upper abdominal tenderness, otherwise unremarkable

• ER visit: AST 82 (normal < 45), ALT 90 (<40), alkaline phosphatase 150 (<125), bilirubin 0.6 (<1.0), amylase 100 (< 89), lipase 60 (< 51)
  • all return to normal when pain-free

• CT scan unremarkable
  • normal pancreas and biliary tree
• referred to a local gastroenterologist

• EGD normal

what is your next step in the diagnostic evaluation of this patient?
• post-cholecystectomy pain resembling the patient’s pre-operative biliary colic occurs in at least 10-20% of patients

• Here, the pain is similar to gallbladder-type pain, with mildly elevated LFTs, amylase/lipase
  – suggestive of pancreaticobiliary origin
Chronic abdominal pain of pancreaticobiliary origin

• Consider:
  – structural causes of biliary and pancreatic ductal obstruction (stones, tumors, strictures)
  – chronic pancreatitis (scarring/fibrosis)
  – sphincter of Oddi dysfunction (SOD)
Initial evaluation

- History, physical examination
- Labs: LFTs, amylase and/or lipase (during an attack of pain)
- Imaging: ultrasound and/or CT scan
• Consider MRI/MRCP or endoscopic ultrasound (EUS) if available

• may detect pathology (stones, sludge, chronic pancreatitis, tumors) not visualized by other modalities
MRCP

pancreatic duct

bile duct
Proceed with ERCP!
Chronic Pancreaticobiliary Pain

What do I do when the MRCP and EUS are normal?
Chronic pancreaticobiliary pain: normal MRCP

- The residual group of patients has a high frequency of SOD
SOD Evaluation:

Non-Invasive vs Invasive
Non-invasive Evaluation

- cholescintigraphy (nuclear med scan)
- secretin-MRCP, secretin-EUS

- Not sensitive
  - miss too many cases of SOD

- Not specific
  - suggest SOD when it isn’t there!
Diagnostic Evaluation

• Invasive tests
  – ERCP - provides structural evaluation of the pancreatic duct and bile duct
  – Sphincter of Oddi manometry – directly assesses pressure profile of the sphincter of Oddi
Indications for SOM 2013

• Unexplained, *disabling* pancreaticobiliary pain ± LFT and/or pancreatic enzyme abnormalities

• Idiopathic pancreatitis

- SOM
  - 5352 pts

- Abnormal SOM
  - 3520 (65%)

- Normal/Equivocal SOM
  - 1832 (35%)
### SOD: Classification

<table>
<thead>
<tr>
<th>Type</th>
<th>Biliary/Pancreatic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>pain</td>
</tr>
<tr>
<td>I</td>
<td>+</td>
</tr>
<tr>
<td>II</td>
<td>+</td>
</tr>
<tr>
<td>III</td>
<td>+</td>
</tr>
</tbody>
</table>

- **Objective evidence**
- **Some objective evidence**
- **No objective evidence**
OK, we’re going to proceed with ERCP / SOM!

How do we do it?
SOM Procedure Overview

• requires special equipment

• requires a cooperative, motionless patient

• a physician-driven procedure (failed cannulation → failed SOM)

• requires a knowledgeable, skilled endoscopist and an experienced manometrist to perform a successful study

• requires constant communication and teamwork

• computer and software program for SOM to view waveform
EQUIPMENT

• Water-perfused probe ("Lehman catheter")
SOM Procedure

- The manometry catheter is advanced through the scope to the duodenum -- the duodenal baseline pressure is set to zero.

- The pancreatic/bile duct is cannulated.

- The catheter is withdrawn one band at a time.
  - When a high-pressure zone is found, the pressure is recorded for 30 seconds.
  - Basal pressure must be elevated in both recording leads for a diagnosis of SOD.
Figure 4. (A) An abnormal station pull-through at SO manometry: The study has been abbreviated to fit onto one page. (B) Schematic representation of one lead of the above tracing. (a) Baseline duodenal 0 reference. (b) Intraductal (pancreatic) pressure of 20 mm Hg (abnormal). (c) Basal pancreatic sphincter pressure of 45 mm Hg (abnormal). Phasic waves are 155–175 mm Hg in amplitude and 6 seconds duration (normal).
Aim of Therapy for SOD: Reduce Resistance to Flow of Bile or Pancreatic Juice

- Medical
- Surgical
- Endoscopic
Aim of Therapy for SOD: Reduce Resistance to Flow of Bile or Pancreatic Juice

- Medical
  - antispasmodics (smooth muscle relaxants, calcium channel blockers)
  - PPIs, tricyclic anti-depressants
Aim of Therapy for SOD: Reduce Resistance to Flow of Bile or Pancreatic Juice

• Medical
• Surgical
• Endoscopic
  ─ Sphincterotomy (cutting the muscle)
  ─ Botulinum toxin injection
  ─ Dilation
  ─ Stent
What is the long-term outcome after biliary sphincterotomy (BES) in SOD?
### Long-term Outcome after BES: Type I SOD

<table>
<thead>
<tr>
<th>Author/year</th>
<th>n</th>
<th>Improved (%)</th>
<th>Mean follow-up (months)</th>
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</thead>
<tbody>
<tr>
<td>Rosenblatt/2001</td>
<td>11</td>
<td>9 (82)</td>
<td>57.6</td>
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<tr>
<td>Cicala/2002</td>
<td>6</td>
<td>6 (100)</td>
<td>12</td>
</tr>
<tr>
<td>Thatcher/1987</td>
<td>15</td>
<td>15 (100)</td>
<td>28</td>
</tr>
<tr>
<td>Boender/1992</td>
<td>24</td>
<td>18 (77)</td>
<td>12.5</td>
</tr>
<tr>
<td>Sherman/1991</td>
<td>11</td>
<td>9 (82)</td>
<td>24</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>67</strong></td>
<td><strong>57 (85)</strong></td>
<td><strong>25.2</strong></td>
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</table>
### Long-term Outcome after BES: Type II SOD

<table>
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<tr>
<th>Author/year</th>
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<th>n Improved (%)</th>
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<tr>
<td>Rosenblatt, 2001</td>
<td>30</td>
<td>22 (73)</td>
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<tr>
<td>Pereira, 2006</td>
<td>16</td>
<td>14 (88)</td>
<td>35.1</td>
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<tr>
<td>Cicala, 2002</td>
<td>8</td>
<td>7 (88)</td>
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<tr>
<td>*Toouli, 2000</td>
<td>13</td>
<td>11 (85)</td>
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<tr>
<td>Thatcher, 1987</td>
<td>15</td>
<td>7 (47)</td>
<td>20</td>
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<tr>
<td>*Geenen, 1989</td>
<td>18</td>
<td>17 (94)</td>
<td>48</td>
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<tr>
<td>*Sherman, 1994</td>
<td>6</td>
<td>5 (83)</td>
<td>39.6</td>
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<tr>
<td>Botoman, 1994</td>
<td>35</td>
<td>21 (60)</td>
<td>36</td>
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<td>Wehrmann, 1996</td>
<td>22</td>
<td>13 (59)</td>
<td>30</td>
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<tr>
<td>Linder, 2003</td>
<td>5</td>
<td>2 (40)</td>
<td>18.1</td>
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<tr>
<td>Bozkurt, 1996</td>
<td>22</td>
<td>14 (64)</td>
<td>32.5</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td>190</td>
<td>133 (70)</td>
<td>36.8</td>
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</tbody>
</table>

*Randomized controlled trial
Long-term Outcome after BES: Type III SOD

<table>
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<tr>
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<tr>
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<td>9 (28)</td>
<td>57.6</td>
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<tr>
<td>Pereira, 2006</td>
<td>11</td>
<td>2 (18)</td>
<td>30.2</td>
</tr>
<tr>
<td>Wehrmann, 1998</td>
<td>22</td>
<td>11 (50)</td>
<td>15</td>
</tr>
<tr>
<td>*Sherman, 1994</td>
<td>13</td>
<td>8 (62)</td>
<td>40</td>
</tr>
<tr>
<td>Botoman, 1994</td>
<td>38</td>
<td>21 (55)</td>
<td>36</td>
</tr>
<tr>
<td>Wehrmann, 1996</td>
<td>29</td>
<td>2 (8)</td>
<td>30</td>
</tr>
<tr>
<td>Linder, 2003</td>
<td>15</td>
<td>6 (40)</td>
<td>18</td>
</tr>
<tr>
<td>Bozkurt, 1996</td>
<td>9</td>
<td>3 (33)</td>
<td>36.4</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td><strong>169</strong></td>
<td><strong>62 (37)</strong></td>
<td><strong>34.7</strong></td>
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</tbody>
</table>

*RCT
Causes for Persistent Symptoms after Biliary Sphincterotomy in SOD

- Residual or recurrent biliary SOD
- Pancreatic SOD
- Chronic pancreatitis
- Other untreated pancreaticobiliary disease
- Non-pancreaticobiliary diseases especially gut motility disorders
Does the addition of a pancreatic sphincterotomy to biliary sphincterotomy in SOD patients improve outcome?
Symptomatic Improvement in Pancreatic SOD Patients after Pancreatic Sphincterotomy

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<th>n Improved (%)</th>
<th>Mean follow-up (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pereira, 2006</td>
<td>13</td>
<td>7 (54)</td>
<td>30.2</td>
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<tr>
<td>Okolo, 2000</td>
<td>15</td>
<td>11 (73)</td>
<td>16</td>
</tr>
<tr>
<td>Elton, 1998</td>
<td>43</td>
<td>31 (72)</td>
<td>36.4</td>
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<tr>
<td>Soffer, 1994</td>
<td>25</td>
<td>16 (64)</td>
<td>13.7</td>
</tr>
<tr>
<td>Guelrud, 1995</td>
<td>27</td>
<td>22 (81)</td>
<td>14.7</td>
</tr>
<tr>
<td>TOTAL</td>
<td>123</td>
<td>87 (71)</td>
<td>23.9</td>
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Role for ERCP and SOM?
2013

<table>
<thead>
<tr>
<th>SOD Type</th>
<th>ERCP</th>
<th>SOM</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Yes</td>
<td>Not necessary</td>
</tr>
<tr>
<td>II</td>
<td>Yes</td>
<td>Highly recommended</td>
</tr>
<tr>
<td>III</td>
<td>Yes</td>
<td>Mandatory</td>
</tr>
</tbody>
</table>
SOD

- Approximately 60-80% achieve benefit from sphincterotomy
- Mostly small, retrospective studies
- Little prospective data in Type III patients
- High complications rates (10-20% PEP)
NIH State of the Science Conference: ERCP

- diagnosis and management of Type III SOD patients are most difficult

- invasive procedures should be delayed or avoided if possible …… the risk of complications exceeds potential benefit in many cases

- ERCP with SOM and sphincterotomy should ideally be performed at specific referral centers and in randomized controlled trials………. 

Cohen GIE  2002
Evaluating Predictors & Interventions in Sphincter of Oddi Dysfunction: The EPISOD Trial
“EPISOD”

Medical University of South Carolina
Indiana University
Virginia Mason
University of Minnesota
Dallas
Yale University
St. Louis
Study Design

- a multi-center, randomized, sham-controlled study

- designed to assess the value of sphincterotomy as treatment in SOD III

- likelihood of finding SOD (by SOM) in these patients approaches 66% -- need 2:1 randomization in favor of treatment

- assuming a 30% placebo (sham) response rate, and 60% treatment response rate, 214 subjects required
RAPID Score
(Recurrent Abdominal Pain Intensity and Disability)

• modeled after migraine research
• captures, in past 3 months, days lost due to abdominal pain in 3 domains:
  – work
  – household activities
  – social/leisure activities

Durkalski, et al, WJG 2010
RAPID score

- Grade 1: 0-5 days missed (little or no disability)
- Grade 2: 6-10 days (mild disability)
- Grade 3: 11-20 days (moderate disability)
- Grade 4: >21 days (severe disability)

Minimum score for eligibility: 11 days missed
Primary outcome

- sphincterotomy will result in a higher success rate than the sham intervention

- Success (definition):
  - Grade 1 disability as measured using the RAPID scale at months 9 and 12 post-randomization
  - no referral for possible re-intervention during the follow up period
  - no prescription analgesic use during months 10, 11 and 12 unless prescribed for pain other than abdominal pain (and then no more than 14 days)
Secondary Outcomes

• Is there an association between manometry result and treatment outcome?

• does addition of a pancreatic sphincterotomy improve outcome in patients with pancreatic sphincter hypertension (PSH)?
<table>
<thead>
<tr>
<th>Treatment</th>
<th>Number</th>
<th>Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sphincterotomy</td>
<td>141</td>
<td>31 (22.0%)</td>
</tr>
<tr>
<td>Sham</td>
<td>73</td>
<td>26 (35.6%)</td>
</tr>
</tbody>
</table>

p-value 0.03
## Secondary outcome

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Number</th>
<th>Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biliary Sphincterotomy</td>
<td>94</td>
<td>18 (19.1%)</td>
</tr>
<tr>
<td>Pancreatic and Biliary (Dual) Sphincterotomy</td>
<td>47</td>
<td>13 (27.7%)</td>
</tr>
<tr>
<td>Sham</td>
<td>73</td>
<td>26 (35.6%)</td>
</tr>
</tbody>
</table>
Median change in RAPID (days): Biliary=33 Dual=53 Sham=38
Success criteria too strict? Reducing the pain burden by half

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Number</th>
<th>Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biliary sphincterotomy</td>
<td>94</td>
<td>30 (32%)</td>
</tr>
<tr>
<td>Dual sphincterotomy</td>
<td>47</td>
<td>21 (45%)</td>
</tr>
<tr>
<td>Sham</td>
<td>73</td>
<td>32 (44%)</td>
</tr>
</tbody>
</table>
Manometry data

- Panc and Bil both abnormal: 35%
- P abnormal, B normal: 21%
- P abnormal, B not measured: 9%
- B abnormal, P normal: 11%
- Both normal: 24%

65% Panc abnormal
Does manometry predict success?

<table>
<thead>
<tr>
<th>Manometry</th>
<th>Number</th>
<th>Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreas</td>
<td>Biliary</td>
<td>Biliary sph</td>
</tr>
<tr>
<td>+</td>
<td>any</td>
<td>7/7 (5/50 16%)</td>
</tr>
<tr>
<td>any</td>
<td>+</td>
<td>98</td>
</tr>
<tr>
<td>-</td>
<td>- or ?</td>
<td>52</td>
</tr>
</tbody>
</table>

NO!
Potential criticisms

• Wrong subjects?

• Wrong definition of success?
  – too strict
  – wrong pain assessment tool (RAPID)

• Inadequate sphincterotomies?
Too strict?

Rates higher, but patterns the same with

• 50% reduction in RAPID
• 25% reduction in RAPID
• excluding the narcotics reason
• using re-intervention only
Wrong pain tool?

- RAPID measured pain-related disability
- Same results using SF 36 pain scores
## SF 36 pain assessment

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Disability</th>
<th>Baseline</th>
<th>11-12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biliary</td>
<td>Pain; Moderate, severe, very severe</td>
<td>88%</td>
<td>44%</td>
</tr>
<tr>
<td></td>
<td>Work interference; extreme, quite a bit</td>
<td>51%</td>
<td>16%</td>
</tr>
<tr>
<td>Dual</td>
<td>Pain; Moderate, severe, very severe</td>
<td>89%</td>
<td>36%</td>
</tr>
<tr>
<td></td>
<td>Work interference; extreme, quite a bit</td>
<td>38%</td>
<td>6%</td>
</tr>
<tr>
<td>Sham</td>
<td>Pain; Moderate, severe, very severe</td>
<td>91%</td>
<td>32%</td>
</tr>
<tr>
<td></td>
<td>Work interference; extreme, quite a bit</td>
<td>31%</td>
<td>10%</td>
</tr>
</tbody>
</table>
Conclusions

• sphincterotomy is not better than a sham procedure in Type III SOD, and manometry is NOT helpful in predicting treatment response

• these results should eliminate the use of ERCP in these patients, and thereby prevent many attacks of pancreatitis
Conclusions

• Further studies of the source of pain are needed in SOD III, with careful evaluation of other treatment options
  – behavioral and neuromodulator therapies

• Should we discard the term “SOD type III”, to divert attention away from the sphincter?
Questions

• Are the results all due to placebo?

• Was our sham arm (ERCP/manometry/stent) actually therapeutic?
  – Would a no-touch blinded endoscopy have the same effect?

• Why did sphincterotomy patients do less well?

• How will GI docs and SOD patients respond?
  – Half the patients did get half better
  – Will patients keep coming?
  – *Would the patients do it again? Re-do Type IIIs?*
Indications for SOM: 2013

• Unexplained, *disabling* pancreaticobiliary pain ± LFT and/or pancreatic enzyme abnormalities

• Idiopathic pancreatitis
Defining idiopathic recurrent acute pancreatitis (IRAP)

**H&P**
- Alcohol
- Medications
- Trauma
- Family history

**Laboratory**
- Calcium
- Triglycerides
- Liver tests

**Imaging**
- Tumors (PDAC, IPMN)
- Pancreas divisum
- Stone, Stricture

**Miscellaneous testing**
- Genetics
- Empiric cholecystectomy
- Microcrystals
ERCP for diagnosis and treatment

• The diagnostic yield of ERCP (ductography alone) ranges from 32-80%

• Elevated basal sphincter pressure has been reported in 30-65% of patients with idiopathic AP
  – Is this cause or effect?

• The therapeutic role of sphincterotomy is debated
IRAP and SOD: Therapy

Results of SOM predict outcome from sphincter ablation

→ limited data
→ no long-term F/U
→ small sample size
→ no randomized controlled trials
→ no outcome data of empiric sphincterotomy without SOM
IRAP and SOD: Prospective Randomized Trial

Coté et al. Gastro 2012;143:1502-9
Enrollment criteria

**Inclusion**

- Idiopathic recurrent acute pancreatitis (IRAP)
  - two or more episodes
- ERCP with SOM planned

**Exclusion**

- Chronic pancreatitis
  - Cross sectional imaging
  - Pancreatogram
- Pancreas divisum
- Alternate etiology identified (e.g., CBD stone, mucinous tumor)
- Inability to perform pancreatic manometry
- Pregnancy, age < 18, incarceration
- Inability to provide informed consent
Randomization

ERCP with pancreatic SOM

Elevated (≥40mmHg) basal pancreatic sphincter pressure
- Biliary sphincterotomy
- Biliary + Pancreatic sphincterotomy

Normal basal biliary and pancreatic sphincter pressure
- Sham
- Biliary sphincterotomy

1:1
Study Aims

**Primary**
- Measure the incidence of recurrent acute pancreatitis (RAP) post-ERCP

**Secondary**
- Interval development of chronic pancreatitis
- Results and impact of repeat ERCP, if performed

Screen failure (n=50, 36%)
- Pancreas divisum (n=17)
- Chronic pancreatitis (n=12)
- Other (CBD stone, IPMN) (n=21)

Elevated pancreatic SOM (n=69, 78%)
- BES (n=33)
- DES (n=36)

Normal SOM (n=20, 22%)
- Sham (n=9)
- BES (n=11)

Preliminary data

RAP (n=139)
IARP: RCT of biliary sphincterotomy vs biliary+panc sphincterotomy for Pancreatic SOD (f/u 7 years)

Recurrent Pancreatitis

- Biliary ES (n=33): 49%
- Biliary + pancreatic ES (n=36): 47%

p = 1

Coté et al. Gastro 2012
Development of chronic pancreatitis

<table>
<thead>
<tr>
<th>Variable</th>
<th>Normal SOM</th>
<th>Pancreatic SOD</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Sham (n=9)</td>
<td>BES (n=11)</td>
</tr>
<tr>
<td>Median follow-up (months)</td>
<td>85 (72, 108)</td>
<td>36 (22, 73)</td>
</tr>
<tr>
<td>Chronic pancreatitis</td>
<td><strong>20.0%</strong></td>
<td><strong>15.9%</strong></td>
</tr>
</tbody>
</table>

*P* values: <0.03 (0.98)
Repeat ERCP during follow-up

• 43% of patients underwent a repeat ERCP
  – normal SOM (32%) and pancreatic SOD (46%)

• pancreatic sphincterotomy performed (initial or repeat) in 76% of patients

• RAP occurred (again) after repeat ERCP in 68%
SOD in IRAP

- pancreatic SOD represents an independent predictor of future AP episodes, but does not necessarily predict the development of CP

- among patients with pancreatic SOD, pancreatic sphincterotomy affords *no* added benefit to biliary sphincterotomy alone
  - the role of ANY sphincter therapy remains unclear
Conclusions: ERCP in iRAP

• among patients with normal SOM, empiric BES may not impact on natural history

• in all patients with IRAP, the interval development of chronic pancreatitis is notable (16.9%)
Conclusion:
ERCP and SOM

What’s the final word in 2014?
Role for ERCP and SOM? 2013

<table>
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<tr>
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<th>ERCP</th>
<th>SOM</th>
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<tr>
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<td>Not necessary</td>
</tr>
<tr>
<td>II</td>
<td>Yes</td>
<td>Highly recommended</td>
</tr>
<tr>
<td>III</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>
SOM in IARP

• SOD is commonly identified in patients with IARP when detailed endoscopic evaluation is done

• the best therapy awaits further study
  – at present, the role of sphincter therapy remains unclear
Thank-you!

YOU'RE EATING TOO MUCH FIBER!