Does Sphincter of Oddi Dysfunction Even Exist Anymore?

Grace H. Elta, MD
Professor of Medicine
University of Michigan

Sphincter of Oddi Dysfunction

- Best studied clinical association:
  - Biliary pain post-cholecystectomy
- Less well studied:
  - Idiopathic acute recurrent pancreatitis
- Not studied: Biliary type pain with intact gallbladder
Classification of *Suspected* Biliary SOD

<table>
<thead>
<tr>
<th>Old Types</th>
<th>Characteristics</th>
<th>Rome IV Names</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biliary Type I</td>
<td>Biliary Pain&lt;br&gt;Duct &gt; 10 mm&lt;br&gt;ALT / AST elevation</td>
<td>Sphincter of Oddi stenosis</td>
</tr>
<tr>
<td>Biliary Type II</td>
<td>Biliary Pain&lt;br&gt;One of the above</td>
<td>Suspected biliary SOD</td>
</tr>
<tr>
<td>Biliary Type III</td>
<td>Biliary pain only</td>
<td>Functional pain</td>
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Reasons for Change in SOD Classification

- Type I cases benefit from sphincterotomy, no need for further testing, likely stenosis
- Type III cases no longer thought to have sphincter dysfunction based on EPISOD study*
- Uncertainty only in old Type II, “suspected SOD”

* Cotton JAMA 2015
Rome IV Definition of Biliary Pain

Pain located in the epigastrium and/or RUQ and all of the following:
1. Builds up to a steady level and lasts 30 minutes or longer
2. Occurring at different intervals (not daily)
3. Severe enough to interrupt daily activities or lead to an ED visit
4. Not significantly (<20%) related to bowel movements
5. Not significantly (<20%) relieved by postural change or acid suppression

Supportive Criteria:
The pain may be associated with:
- Nausea and vomiting
- Radiation to the back and/or right infra subscapular region
- Waking from sleep

*Biliary Pain definition based on expert opinion only
Suspected Biliary SOD (Prior Type II)

- Elevated liver enzymes: stronger evidence if associated with pain attack, level needed unknown
- Bile duct >10 mm (controversial size cut off), no narcotics
- “Strong” (classic pain, enzymes increase pain) vs. “Weak” (atypical pain, chronic mild transaminitis)
- Choice: empiric biliary ES vs. testing with manometry or HBS

Suspected Biliary SOD: based on labs, US, EGD, CT or MRCP

- EUS
- Strength of Evidence for Biliary Obstruction
  - strong
  - moderate
- Options: SOM or HBS
- Functional biliary-type pain
? Value of SO Manometry

- Normal SOM in 15-35% of old Type I, response to ES >90% so SOM has high false negative rate
- EPISOD trial in type III: SOM not predictive of response to ES
- 3 small RCTs (1 abst only) show SOM predicts response to ES in Type II: 70-90% (65% in case series) vs. 35% sham
  - Empiric BES commonly performed for SOD so meets SOC

Does SOM Increase Procedure-Induced Pancreatitis?

- Study of suspected SOD patients*
  - ERCP w. SOM vs. ERCP alone: No difference in pancreatitis rates (26%)
  - Compared to 3% rate in CBD stone pts at same site
  - Pancreatitis risk increased by ES and pancreatography

Conclusion: It’s the diagnosis of suspected SOD, not the manometry that increases risk

Singh GIE 2004
**Manometry Catheter Sales in US by State**

*Figures from Greg Cote*

- **2006**
- **2008**
- **2010**
- **2012**
- **2014**

**# of manometry catheters**

- 0
- 1000
- 2000
- 3000
- 4000
- 5000

- **2006**: 2/3 of sales
- **2014**: None in 13 states

**Value of Hepatobiliary Scintigraphy**

- Difficult to assess value due to varying techniques
- Value often compared to SOM although manometry may be weak “gold standard”
- Compared to response to ES: predicts outcome in Type I & “strong” Type II pts, where predictors are less needed
- More data needed on role
Treatment of Biliary SOD

- Conservative RX: nortriptyline, trimebutine, nitrates, reassurance: some reported success, always safe
- Biliary ES: Success in 70-90% with abn SOM in 3 small RCTs
- No outcome studies of empiric ES
- High risk ERCP: 10-15% pancreatitis even with prophylactic PD stent & indomethacin

SOD in Patients with an Intact GB

- Very, very few studies of SOD with intact GB
  - Less likely to respond to ES than s/p cholecystectomy pts
  - At best 43% benefit (similar to placebo response in EPISOD)
- ERCP, manometry, or ES should not be performed for possible SOD in pts with intact GB outside clinical trials
Pancreatic SOD: is it real?

- No role for ERCP / manometry / ES in pain only pts
- Idiopathic acute recurrent pancreatitis (IARP):
  - Must have > 1 episode of documented IARP
  - Other etiologies carefully excluded with negative EUS
  - If patient motivated despite low chance of benefit / high risk ERCP; SO manometry should be performed

Pancreatic SOD in IARP*

- Normal SOM: RCT of BES vs. sham
  - No benefit to BES
  - Better long term prognosis than abnormal SOM pts
- Abnormal SOM: no sham arm, BES vs. DES
  - 50% benefit in BES, DES not superior and is riskier

*Cote Gastroenterology 2012
**SOD Take Home Points**

- "Suspected Biliary SOD" Types I-III eliminated
  - I is not "suspected" and III is not real
- Empiric BES for suspected SOD accepted in "strong" cases; consider additional testing with SOM and/or HBS in "weak" cases
- No consideration of SOD in pts with intact GB outside clinical trials
- Consider SOM and BES for SOD in motivated pts with documented IARP

**Conclusion: Does Sphincter of Oddi Dysfunction Even Exist Anymore?**

- Sphincter of Oddi Dysfunction still exits, albeit in a simpler categorization system
- Sphincter of Oddi Manometry is barely hanging on