



Virginia Mason™

News Flash: Type III SOD Does Not Exist

Richard Kozarek, MD

State-of-the-Art in Gastrointestinal Endoscopy
Pacific Northwest Gastroenterology Society
February 27, 2016

Biliary Dyskinesia/Sphincter of Oddi Dysfunction

Small AJ, Kozarek RA. GIE Clin N Am 2015;25:749-63.

- SOD benign, acalculous disease that can result in PB obstructive symptoms
- Modified Milwaukee classification (SOD I-III) still used WW
- Chronic, unrelenting narcotic-dependent RUQ or epigastric pain is not SOD

Table 1
Modified Milwaukee classification scheme

Classification	Diagnostic Criteria
<i>A. Biliary SOD</i>	
Type 1	<ol style="list-style-type: none"> 1. Biliary-type pain 2. Elevated ALT, AST, AP more than 1.5–2.0 times the upper limit of normal on at least 2 or more occasions 3. Bile duct diameter ≥ 10 mm
Type 2	Biliary-type pain with either B or C in the aforementioned criteria
Type 3	Biliary-type pain only with no other abnormalities
<i>B. Pancreatic SOD</i>	
Type 1	<ol style="list-style-type: none"> 1. Pancreatic-type pain 2. Elevated serum amylase or lipase more than 1.5–2.0 times the upper limit of normal on at least 2 or more occasions 3. Pancreatic duct diameter ≥ 6 mm in the head and ≥ 5 mm in the body
Type 2	Pancreatic-type pain with either B or C in the aforementioned criteria
Type 3	Pancreatic-type pain only with no other abnormalities

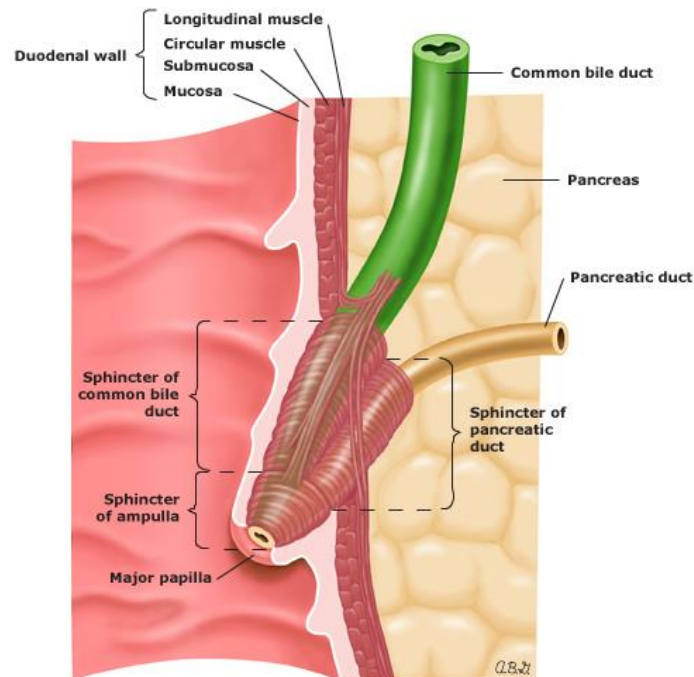
Abbreviations: ALT, alanine aminotransferase; AP, alkaline phosphatase; AST, aspartate aminotransferase.

Dx Type III SOD

Pain Pain Pain (episodic epigastric/RUQ)

Normal imaging

Normal or minimally abnormal LFTs/
amylase-lipase



Yield of EUS in Patients With Suspected Type III SOD

Siddiqui et al. J. Gastrointestin Liver Dis 2012;21:271

- 143 patients suspected SOD III
- 12 (8%) abnormal EUS as possible etiology of pain
 - CP-5/mucinous neoplasm of pancreas-3 / pap stenosis-2 / biliary stricture-1 / IPMN-1

Conclusions: Despite low yield, EUS should be done prior to ERCP-mano

Low Yield of ERCP in Patients with Pancreaticobiliary Pain and No Objective Findings

Imler et al. Dig Dis Sci 2012;57:3252

- 265 patients with Type III SOD
- 7 (2.6%) significant findings
 - Anom PB union-2 / IPMN-2 / CP-2 / choledochoceles-1

*SOD diagnosed 77.7%

Conclusions: Diagnostic ERCP should not be done unless SOM available

EPISOD Trial

Does SOM define response to ES?

Do patients respond to biliary/dual ES?

Multicenter, sham-controlled trial

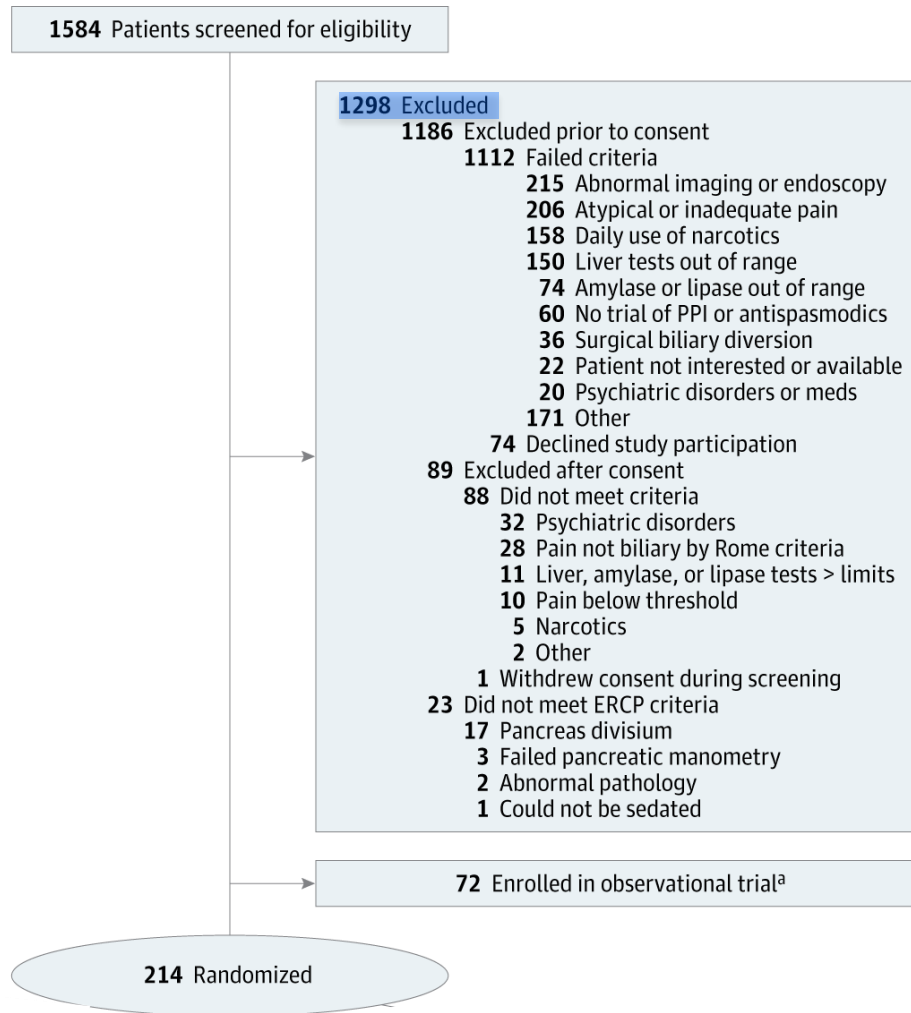
214 post-CCK patients (92% female, \bar{x} age 34), randomized 7 referral centers to ES (biliary/dual), vs. sham (2:1) irrespective of manometry findings.

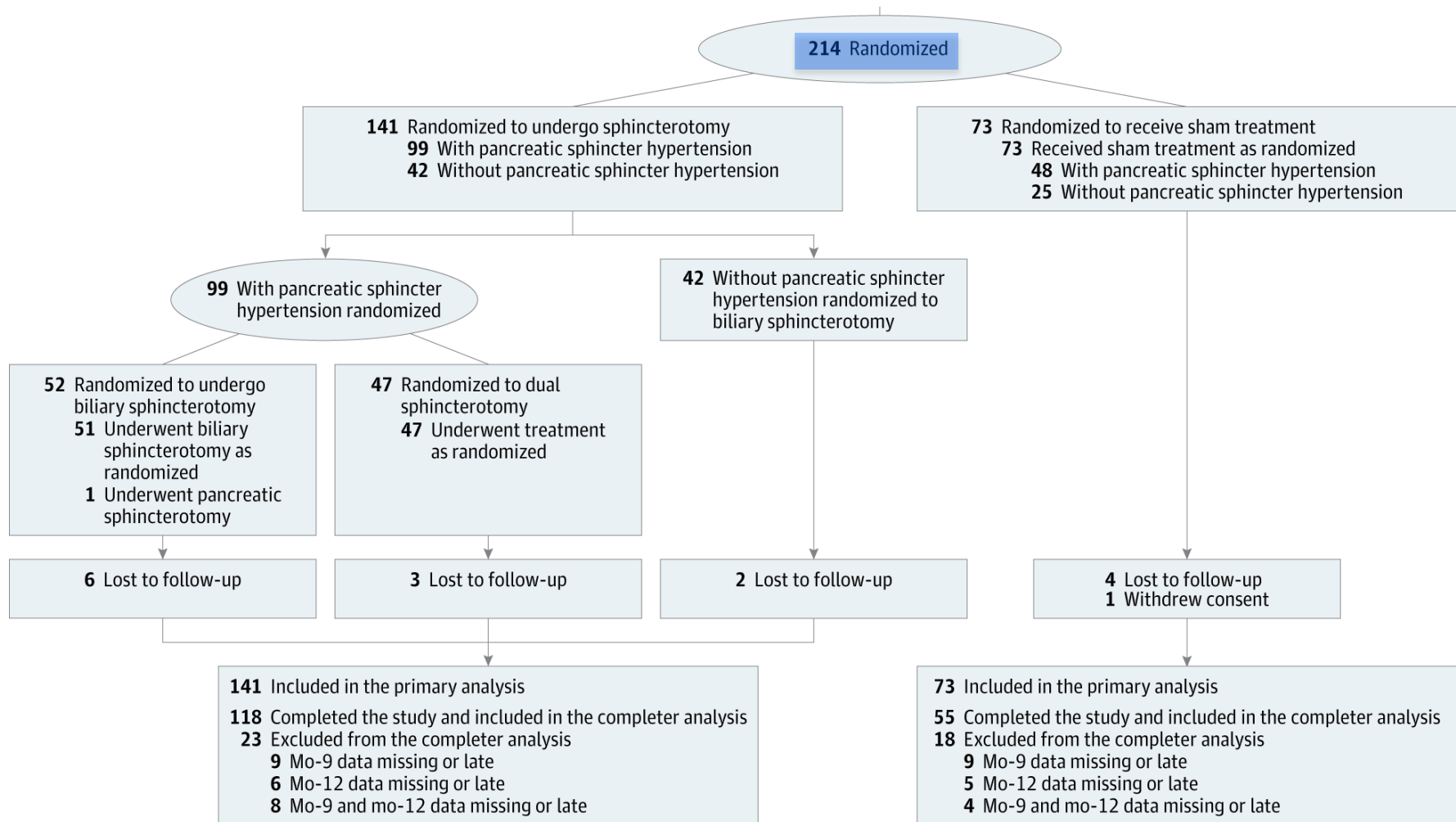
EPISOD RCT

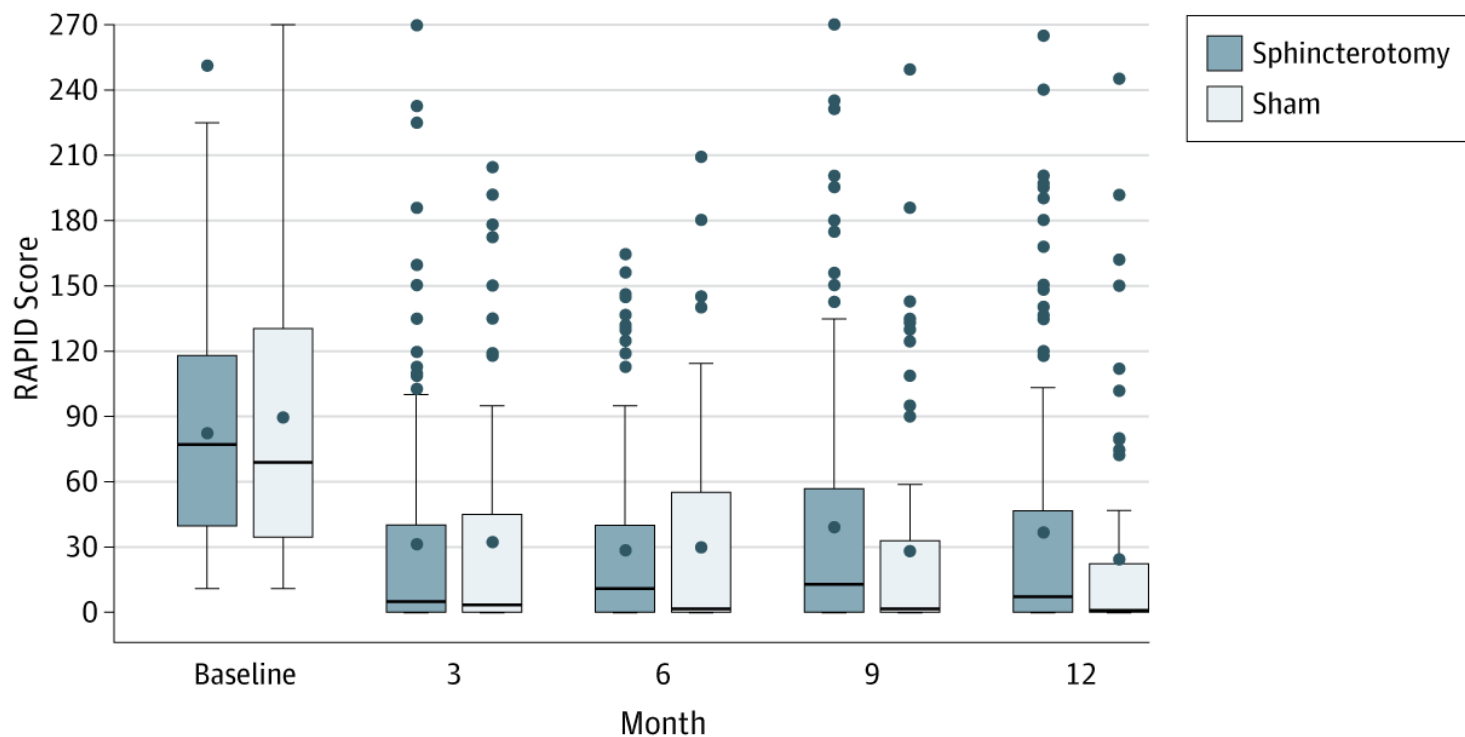
Cotton et al. JAMA 2014;311:2101

Primary outcome measure = RAPID score
(Recurrent Abdominal Pain and Disability
Instrument)

- Lost productivity in past 90 d in 3 domains:
work/school, household activities, non-work
activities
 - Gr 1 ≤ 6 d
 - Gr 2 = 7-10 d
 - Gr 3 = 11-20 d
 - Gr 4 ≥ 20 d
- Rx success defined as RAPID 1 @ 9 and 12
months, no narcotic requirement, no repeat ERCP







No. of participants 141 73 130 67 129 67 135 69 131 65

The boxes indicate interquartile ranges; circle within box, mean; horizontal line within box, medial; error bars, 1.5 times the interquartile range; and circles, outliers. RAPID indicates Recurrent Abdominal Pain Intensity and Durability.

EPIOD RCT

Improvement in pain/disability in all groups

Successful primary outcome (RAPID 1 and no narcotics/repeat ERCP at 9 and 12 months, 23% ES / 37% sham ($p = .01$))

Manometry mild LFT/amylase-lipase elevations, daily pain did not define outcome

Comparable pancreatitis rates (11% ES/15% sham), 1 ES perf requiring surgery

Table 2. Primary Outcome by Treatment Group and Success Rate for the Secondary Comparison of Biliary vs Dual Sphincterotomy for the Pancreatic Sphincter Hypertension Subgroup

	Treatment	No. of Patients	No. (%) [95% CI] of Treatment Success	Risk Difference (95% CI)	
				Adjusted ^a	Unadjusted
Primary outcome	Sham	73	27 (37) [21.6 to 33.6]	-15.7 (-28.0 to -3.3)	-14.3 (-27.3 to -1.2)
	Sphincterotomy (any)	141	32 (23) [15.8 to 29.6]		
Secondary outcome	Pancreatic sphincter hypertension with biliary sphincterotomy	51	10 (20) [8.7 to 30.5]		-10.2 (-27.2 to 6.8)
	Pancreatic sphincter hypertension with pancreatic and biliary sphincterotomy	47	14 (30) [16.7 to 42.9]		

^a Sham vs sphincterotomy *P* value adjusted for site and pancreatic sphincter hypertension status is .01; unadjusted *P* value, .03.

Table 3. Secondary Outcomes Month-12 Change From Baseline^a

	Sphincterotomy			Sham		
	No.	Mean (95% CI)	Median	No.	Mean (95% CI)	Median
RAPID score	131	-45 (-56.0 to -33.9)	-40	65	-62 (-83.3 to -40.1)	-38
HADS						
Anxiety	131	-1 (-1.7 to -0.2)	-1	68	-1 (-2.2 to -0.4)	-1
Depression	131	-1 (-1.7 to -0.3)	-1	68	-1 (-2.0 to -0.3)	-1
SF-36						
Physical	130	7 (5.2 to 8.6)	7	68	8 (5.8 to 10.3)	8
Mental	130	3 (1.5 to 5.1)	3	68	4 (1.8 to 7.1)	4

Abbreviations: HADS, Hospital Anxiety and Depression scale; RAPID, Recurrent Abdominal Pain Intensity and Disability; SF-36, 36-Item Short Form Health Survey.

^a There were no statistical differences between sphincterotomy and sham for each outcome; data include patients with reinterventions and narcotic use but exclude patients with missing outcome data at month 12.

Type III SOD

Post-cholecystectomy PB type pain likely multifactorial

- Fatty liver
- Motility disorder
- IBS
- Visceral hyperalgesia
- (this space available...)

Type III SOD

EUS findings uncommon in this patient population

ERCP with or without manometry should not be offered to these patients

EPISOD trial raises multiple questions re manometry directed ES

- Type II SOD
- ARP

No Pain.

No gain.

