There Is No Role for ERCP in the Setting of Abdominal Pain of Pancreatobiliary Origin

P.J. Pasricha

Division of Gastroenterology and Hepatology

University of Texas Medical Branch

Galveston. TX

OBJECTIVES and OVERVIEW

- Primary Focus:
  Role of ERCP in abdominal pain of suspected pancreatobiliary origin
  - "Structural" Disease
  - "Functional" Disorders
- What is **not** the Primary Focus:
  - Role of ERCP in patients with pain and "objective" clinical, biochemical or radiological abnormalities
  - Validity of Sphincter of Oddi Dysfunction as a clinical syndrome

Aims of ERCP in Unexplained Abdominal Pain

- Discover subtle “structural” abnormalities
- Diagnose sphincter of Oddi dysfunction
- Others
  - Bile collection?

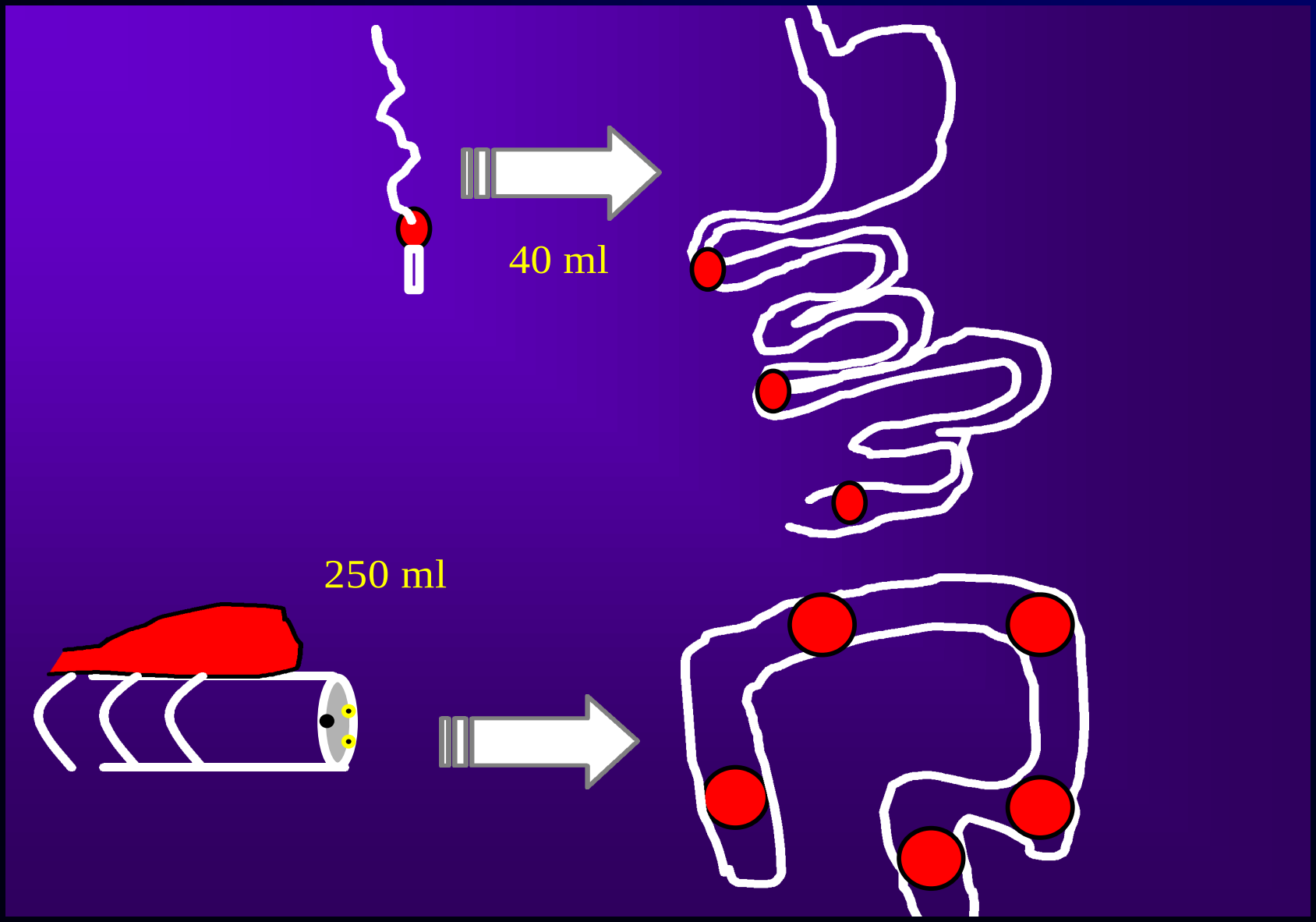
ERCP and Pain: Underlying Assumptions

- ✓ The clinical pattern of chronic pain can reliably indicate pancreatic or biliary disease, even in the absence of “objective” findings
- ✓ In the absence of morphological changes, it is important to exclude functional changes in the pancreatobiliary sphincter in these patients
- ✓ These morphological or functional changes correlate with pain and their detection leads to effective treatment

Origin of Chronic Right Upper Quadrant Pai

- 22 consecutive patients with severe chronic RUQ pain
- Average work-up:
  - 3.5 consultations
  - 7.3 procedures
  - 1.7 operations
  - >20 blood tests

Kingham and Dawson Gut 1985;26:783-788



Kingham and Dawson Gut 1985;26:783-788

Balloon Distention Sites and Reproduction of Spontaneous RUQ Pain

- Esophagus 0
- **Duodenum 6**
- **Jejunum 15**
- **Ileum 12**
- **Right colon 9**
- Left colon 0

21 of 22
at least one site

12 of 22
> one site

Diagnostic Yield of ERCP in Abdominal Pain

Carlson et al (Br J Surg 1992;79:1342-45)

- 5000 ERCPs (1976-1989)
- 384 patients with *post-cholecystectomy* *pain
- 4 groups:
  - Pain only*
  - Pain and clinical/biochemical abnormality
  - Pain and Imaging Abnormality
  - Pain and both clinical/biochemical or imaging abnormality
- *Caveats:
  - Presumably for gallstone disease
  - Imaging may not have been done in every patient

Diagnostic Yield of ERCP in Abdominal Pain

	N	CBD stones	Others
Pain Only	150	20 (13%)	9 (CP = 2; “Amp stenosis” = 2)
Pain + C/B	140	76 (54%)	15
Pain + imaging	57	34 (60%)	8
Pain + C/B + Imaging	33	28 (76%)	5

Carlson et al

Diagnostic Yield of ERCP in Abdominal Pain

Thornton et al (Gut, 1992; 33:1559-61)

- 138/1005 ERCPs between 1989 and 1990 for evaluation of abdominal pain
- 130 patients analyzed
- Findings

– Bile stones	10
– CP	5
– Ca	1
TOTAL	**16 (12%)**

Diagnostic Yield of ERCP in Abdominal Pain

Thornton et al (Gut, 1992; 33:1559-61)

- Every patient with stones had abnormal US and/or alk phos (Negative Predictive Value of combined tests = 100%)
- 3 of 5 patients with CP had abnormal US (Negative Predictive Value = 60%)
- If these patients are excluded, yield of ERCP in this setting is 3 (about 2%)

Diagnostic Yield of ERCP in Abdominal Pain

Chen et al, Am J Gastroenterol 1993;88:1355-58

- Prospective study of 86 patients with idiopathic pain
- Group I: Normal Alk Phos and Bili
  Group II: Abnormality in one or both
- Only 6% of Group I had abnormal cholangiogram (dilation alone, no stones) vs 30% of Group II (18% stones)

  Normal pancreatograms

Subtle or Minimal Change

Ruddel et al, Br J Surg,1983;70:74-75

- 140 patients with “obscure” abdominal pain
- CP diagnosed in 20 (14%)
  - Gross changes in 6 (4%)
  - Minimal change (“side branches only”) in 14 (10%)

Subtle or Minimal Change

- Clinical significance of subtle ductographic changes controversial
  - May be found in elderly or at autopsy in the absence of any evidence for pancreatitis (Anand et al, Gastrointest 1989;35:210; Schmitz-14)
  - Of 20 patients with normal secretin-pancreozymin test and abnormal ERCP 17 remained free of any evidence of pancreatitis after a mean follow-up of 84 months (Lankisch et al, Pancreas 1996;12:149-52)
- Conversely, ERCP may miss “true” CP not involving the ducts (Walsh et al, Gut 1992;33:1566-71)

ERCP in “Functional Disorders”

phincter of Oddi Dysfunction (Hogan and Geenan)

Type I:

- sGOT or > 2 x normal (> twice)
- Delayed drainage of contrast (>45 minutes)
- Dilated CBD (> 12 mm)

Type II

– One or more of the above

Type III

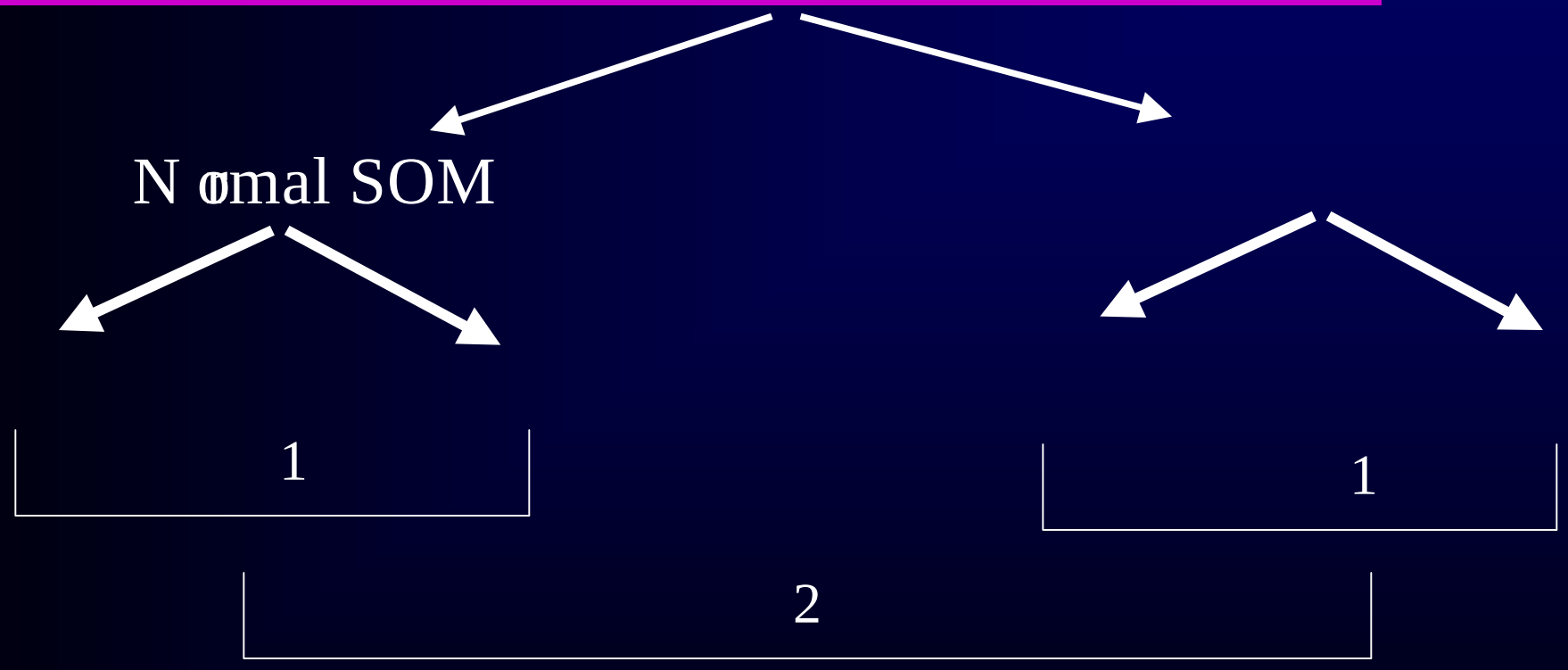
– None of the above (pain only)

Sphincter of Oddi Dysfunction

Clinical presentation	Incidence of SOD	Response to ES	
		SOM+	SOM-
Type I	75-95%	90-95%	90-95%
Type II	55-65%	85%	35%
Type III	25-55%	?	?

Lehman and Sherman 2000

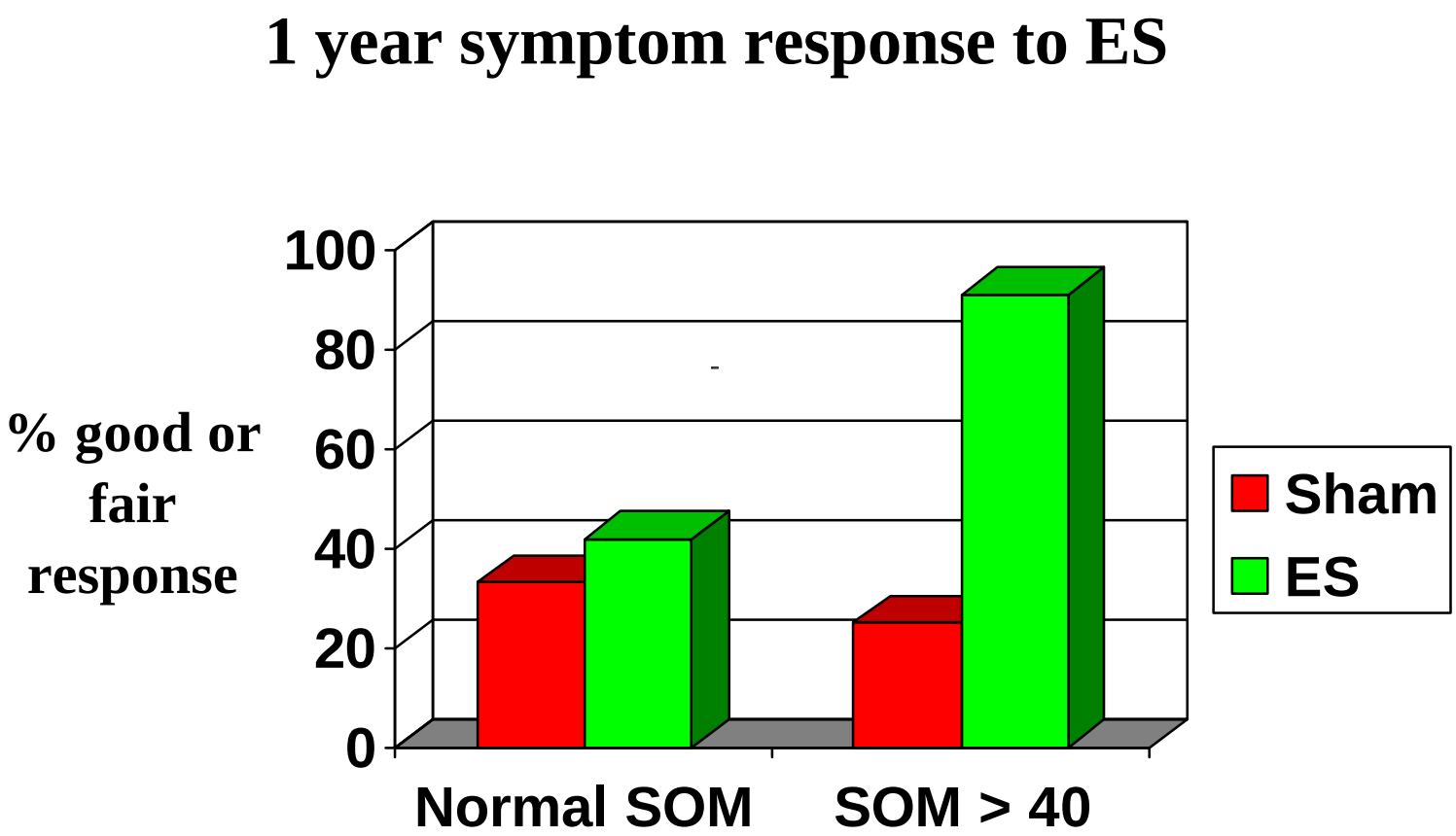
Methodology to Determine Utility of SO Manometry



1 = Does sphincter activity cause pain ?

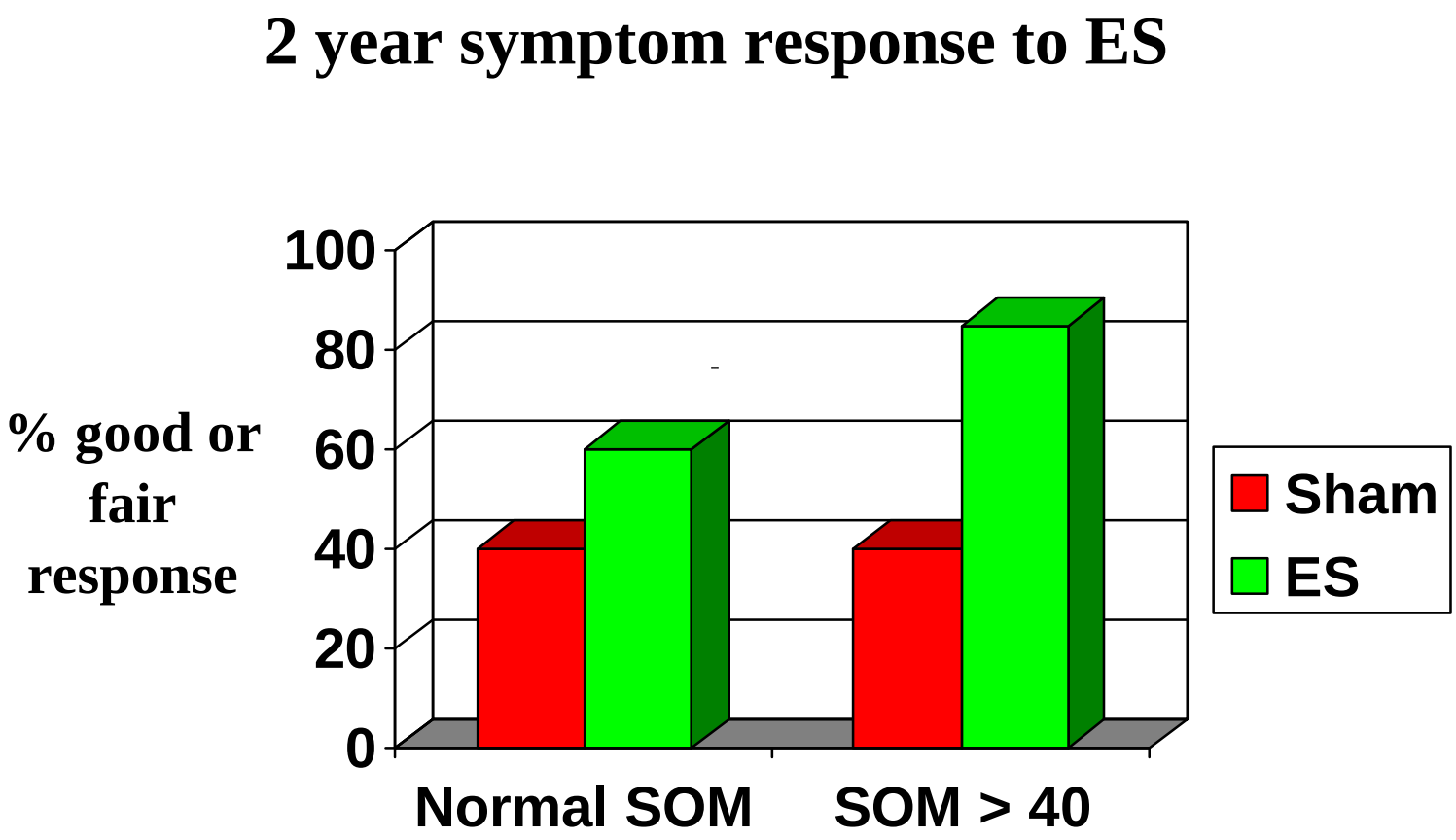
2 = Does SOM select patients in whom sphincter activity causes pain ?

Type II SOD: Randomized before SOM



Geenen et al. NEJM 1989;320:82-7

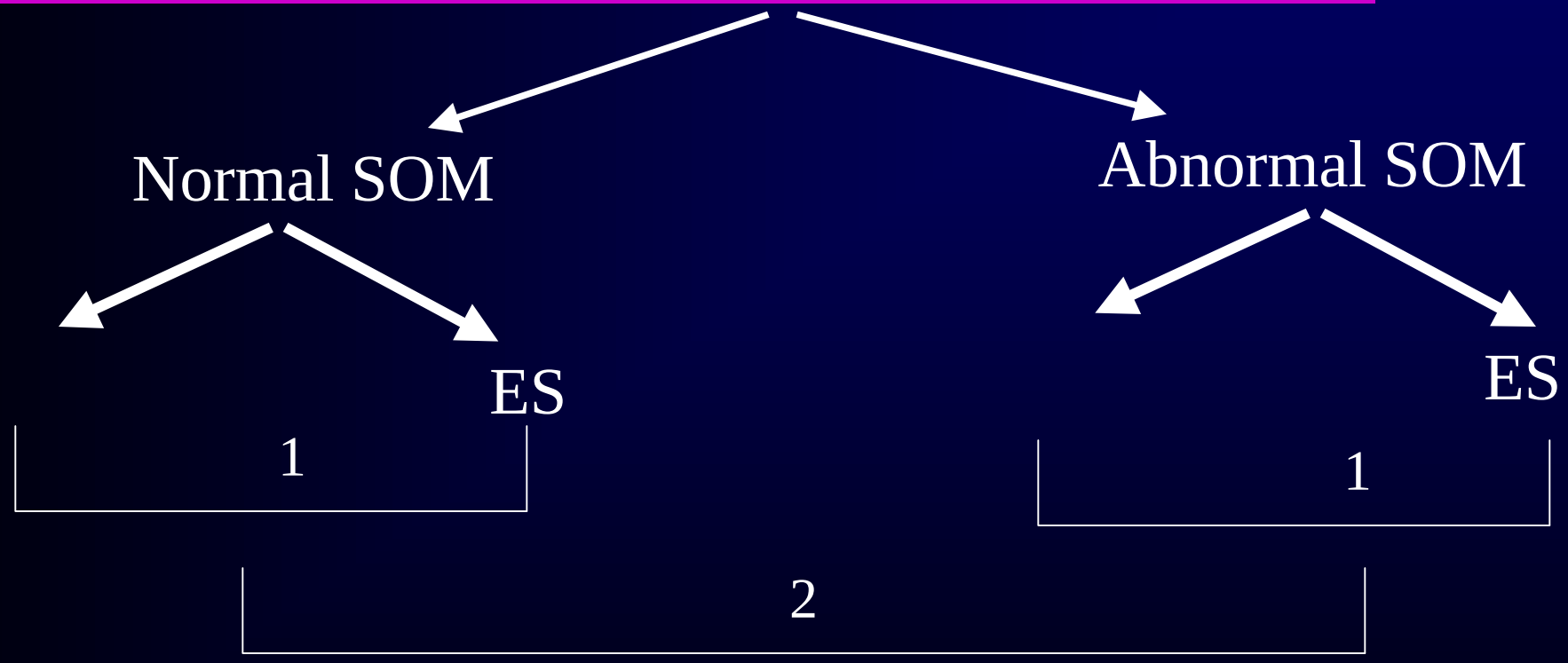
SOD*: Randomized after SOM



Toulli et al Gut 2000;46:98-102

* 80% type I or II

What about Type III SOD?



1 = Does sphincter activity cause pain ?

2 = Does SOM select patients in whom sphincter activity causes pain ?

SOD Type III: Experience-based Reports

	Follow-up	Response Type II	Response Type III
Wehrmann et al, Eur J Gastroenterol & Hepatol 1996;8:251-56	2.5 years	60%	8%
Botoman et al, Gastrointest Endosc 1994;40:165-70	3.1 years	68%	56%

SOD Type III: pain only

- Assuming that 50% of these patients will have a positive SOM
- Even assuming the “best” response rate of 50%, and a conservative placebo response of 35%, this translates into an NNT of 13

Poor Correlation Between SOM and Response to ES

Two broad explanations

- SO Dysfunction is a marker but not a cause for pain in Type III patients
  - Overlap with other functional pain syndromes: NCCP, IBS
  - Similar psychosocial profiles
  - Visceral hyperalgesia
- SO Dysfunction plays a causative role in a subset of patients in Type III patients, but SOM cannot accurately detect this
  - Not physiological
  - Does not provide correlation with pain

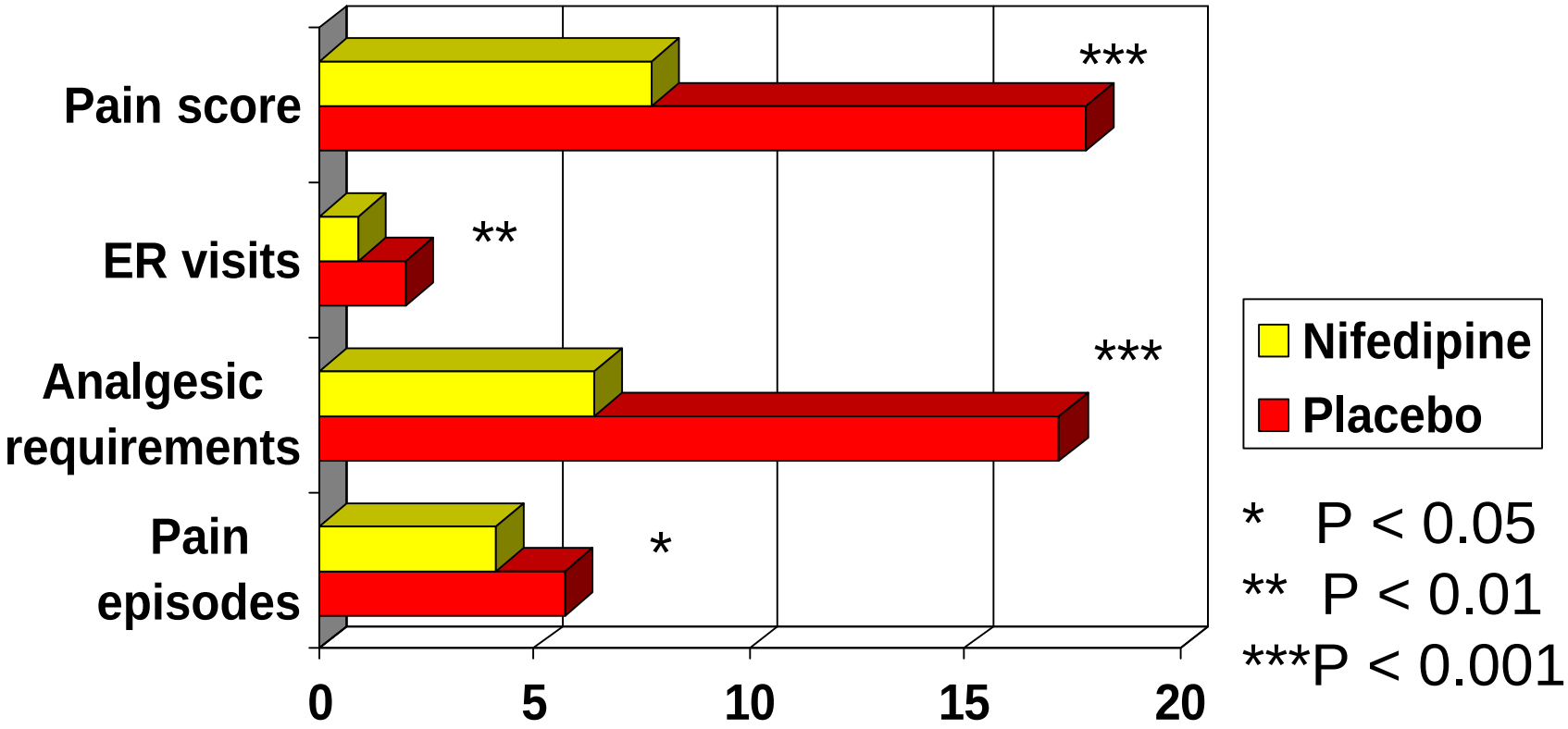
Alternatives to SOM

- Imaging Tests: ? More physiological
  - Fatty Meal Sonography (FMS)
    sensitivity: 74%
    specificity: 100%
  - Quantitative Hepatobiliary Scintigraphy (QHBS)
    sensitivity: 67-100%
    specificity: 80-100%
- Problems
  - comparison to “invalid” gold standard (SOM)
    True gold standard should be response to ES at 1 year
  - Limited data on Type III patients

Alternatives to SOM

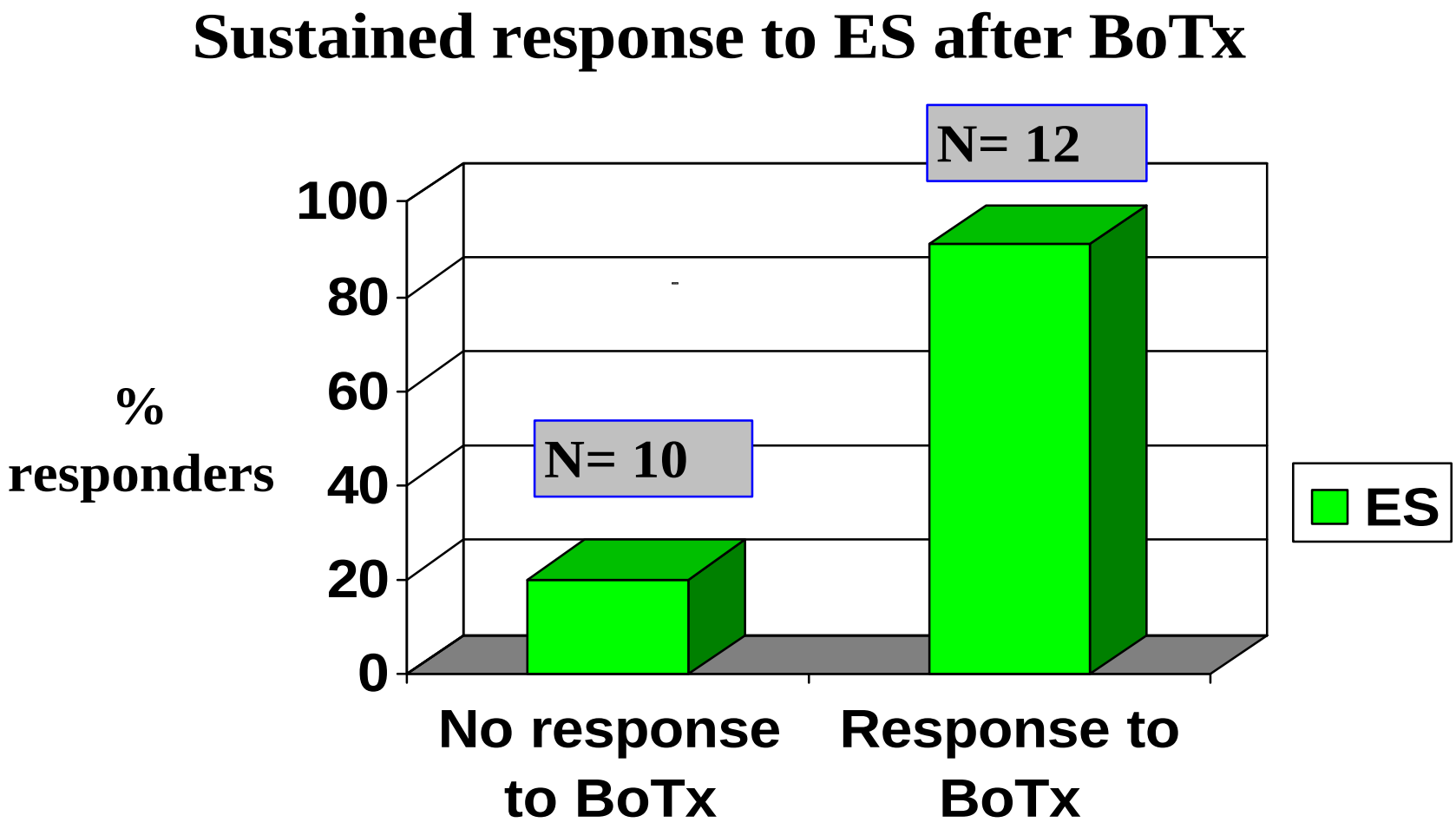
- Therapeutic Trials: Requirements
  - A reliable and safe means of lowering SO pressure
  - Relief of pain implies sphincter at fault: patient may benefit from ES
  - If not, ES not necessary
- Possible candidates:
  - Calcium channel antagonists
  - BoTox

S Type II: Response to



Khuroo et al. Br J Clin Pharmac 1992;33:477-85

BoTx As a Therapeutic Trial for SOD



Wehrmann

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Summary

- Clinical criteria do not reliably indicate the true site of origin of pain
- “Structural Disease”
  - In patients with pain only, the yield of ERCP for gross structural abnormalities such as biliary stones, chronic pancreatitis and cancer is negligible
  - Modern imaging (US, spiral CT, MRCP) are able to detect most if not all such cases
  - abnormalities that may be detected remains unclear

Functional Disorders

No evidence base to support utility of SOM in

- High complication rate and degree of difficulty
- Obsession with implicating sphincter distracted

Directions for Research

- Better understanding of minimal change pancreatitis
  - Ability to acquire pancreatic tissue at ERCP
- Need for Randomized Control Trials in Type III SOD
  - ES
  - Tricyclic antidepressants
  - Cognitive behavioral therapy
- Need to develop more reliable ways to predict SOD as cause of pain
  - More physiologic imaging with pain response as gold standard
  - Therapeutic Trials