



**ESGE SYMPOSIUM**

## **QUALITY IN ENDOSCOPY: ERCP**

**OCTOBER 6–8, 2011**


**VENUE: SHERATON ARABELLAPARK HOTEL  
MUNICH, GERMANY**

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Post-ERCP pancreatitis is best prevented  
by limiting the number of ERCP-ists...



well, it's not that easy...

# Risk factors

- Risk factors for the development of post-ERCP pancreatitis are based on:
  - the types of interventions carried out
  - the person undergoing the procedure
  - the person performing the procedure

# Patient-related Risk Factors

definite risk factors	adjusted odds ratios	pooled incidence of PEP
suspected SOD	4.09 (3.37-4.96)	10.3% vs. 3.9%
female gender	2.23 (1.75-2.84)	4.0% vs. 2.1%
previous pancreatitis	2.46 (1.93-3.12)	6.7% vs. 3.8%
likely risk factors		
younger age	1.09-2.87 (range 1.09 - 6.68)	6.1% vs. 2.4%
non-dilated extrahepatic bile ducts	NR	6.5% vs. 6.7%
absence chronic pancreatitis	1.87 (1.00-3.48)	4.0% vs. 3.1%
normal serum bilirubin	1.89 (1.22-2.93)	10.0% vs. 4.2%

Dumonceau JM, et al. European Society of Gastrointestinal Endoscopy (ESGE)  
Guideline: Prophylaxis of post-ERCP pancreatitis. Endoscopy 2010

# Procedure-related Risk Factors

definite risk factors	adjusted odds ratios	pooled incidence of PEP
precut sphincterotomy	2.71 (2.02 – 3.63)	5.3% vs. 3.1%
pancreatic injection	2.2 (1.60 – 3.01)	3.3% vs. 1.7%
likely risk factors		
high number of cannulation attempts	2.40 – 3.41 (range 1.07 – 5.67)	3.7% vs. 2.3%
pancreatic sphincterotomy	3.07 (1.64 – 5.75)	2.6% vs. 2.3%
biliary balloon sphincter dilation	4.51 (1.51 – 13.46)	9.3% vs. 1.9%
failure to clear bile duct stones	3.35 (1.33 – 9.10)	1.7% vs. 1.6%

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There is no evidence that hospital ERCP volume has an influence on the incidence of PEP; data about a potential relationship between PEP incidence and endoscopist case volume are conflicting. Low annual case volumes, of endoscopists and centers, are associated with higher ERCP failure rates (Evidence level 2+).

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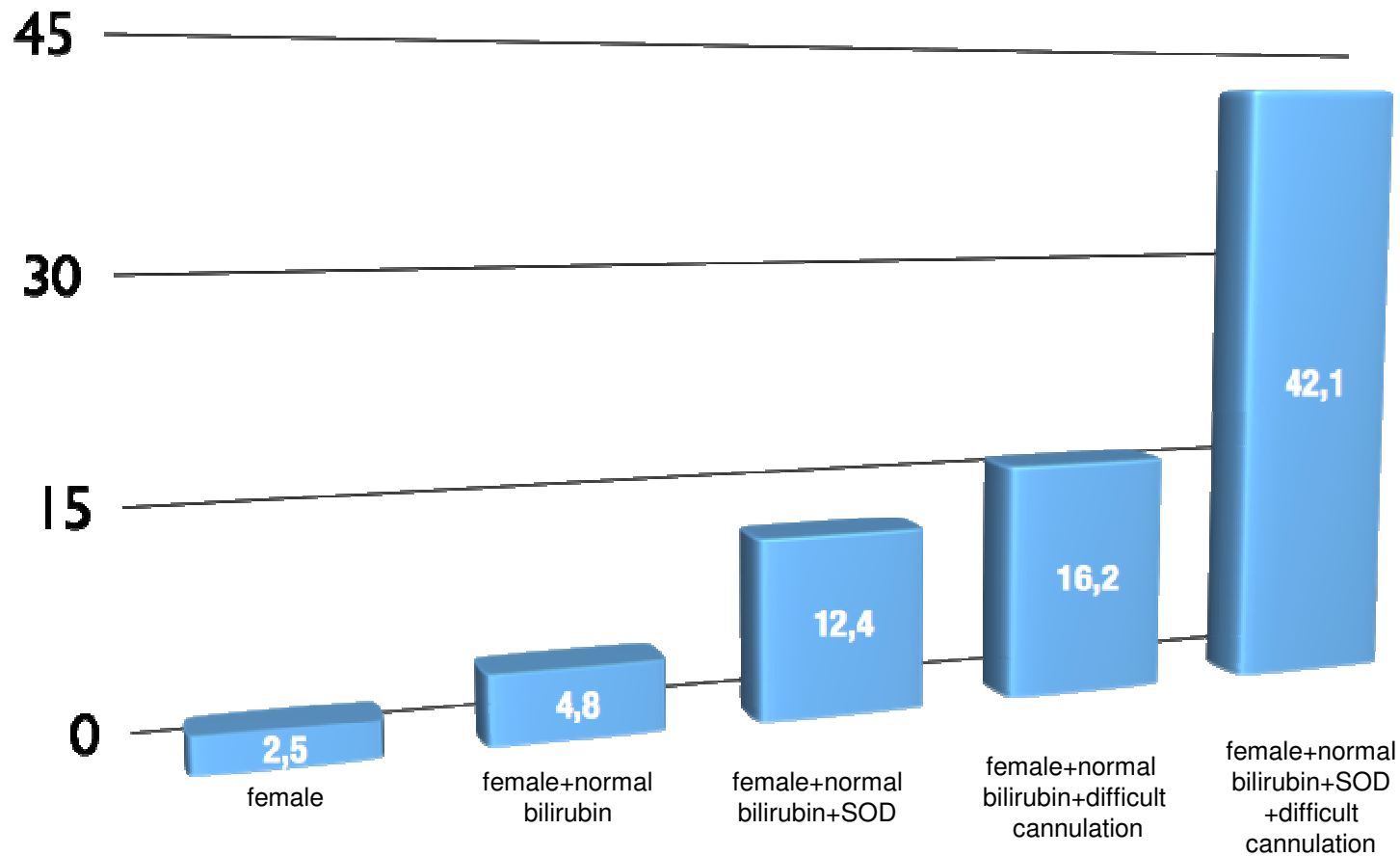
# Risk factors for Developing post-ERCP Pancreatitis

- prospective multicentre study investigating 32 variables for association with post-ERCP pancreatitis
- 11 participating centres (6 private, 5 academic) with 26 endoscopists, 1963 consecutive ERCPs
- pancreatitis occurred in 6.7% of all procedures (n=131)
  - mild pancreatitis in 3.6% (n=70)
  - moderate in 2.8% (n=55)
  - severe in 0.3% (n=6)

Freeman ML, et al. Risk factors for post-ERCP pancreatitis: a prospective, multicenter study. *GI Endosc* 2001



# Risk factors for Developing post-ERCP Pancreatitis



■ adjusted odds ratios for developing post-ERCP pancreatitis

Freeman ML, et al. Risk factors for post-ERCP pancreatitis: a prospective, multicenter study. *GI Endosc* 2001

## Risk factors for Developing post-ERCP Pancreatitis

- endoscopists' case volume had no independent significance on the development of post-ERCP pancreatitis in the multivariate model.
- case volume was not significant in the multivariate analysis even after excluding potentially linked technique-related variables such as difficulty of cannulation
- participation by a fellow trainee had no effect on pancreatitis rates (others found an increased risk)\*
- however:
  - success rates at bile duct cannulation were significantly higher for endoscopists performing more than 2 ERCPs per week than for those averaging 2 or fewer ERCPs per week (96.5% versus 91.5%,  $p = 0.0001$ )

Freeman ML, et al. Risk factors for post-ERCP pancreatitis: a prospective, multicenter study. GI Endosc 2001

\*Cheng CL, et al. Risk Factors for Post-ERCP Pancreatitis: A Prospective Multicenter Study. Am J Gastro 2006

# Impact of Endoscopist's Experience

- complications occurring within 30 days of endoscopic biliary sphincterotomy (EST) in 2347 patients
- complications were recorded in 229 patients (9.8%) including:
  - pancreatitis in 5.4%
  - bleeding in 2.0%
- mean number of EST performed per endoscopist ranged from 0.2 to 16.0 per week
- the experience of endoscopists with ERCP ranged from approximately 100 to 10,000 previous cases.

Freeman ML, et al. Complications of Endoscopic Biliary Sphincterotomy. NEJM 1996

# Risk Factors for Pancreatitis after EST

significant in multivariate analysis	odds ratio	p value
Suspected dysfunction of sphincter of Oddi	5.01 (2.73 – 9.22)	< 0.001
Younger age	2.14 (1.41 – 3.25)	< 0.001
Precut sphincterotomy	4.34 (1.73 – 10.88)	< 0.001
Difficulty of cannulation	2.40 (1.07 – 5.36)	< 0.001
No. of pancreatic contrast injections	1.35 (1.04 – 1.75)	< 0.001
not significant		p value
Use of multiple cannulation devices		0.57
Mean case volume of endoscopist $\leq 1$ /wk		0.81
Direction of incision 2 to 3 o'clock		0.99

Freeman ML, et al. Complications of Endoscopic Biliary Sphincterotomy. NEJM 1996

# Impact of Endoscopist's Experience

- prospective multicentre study investigating the impact of endoscopist's expertise, case volume and case mix on the outcome of ERCP procedures
- inclusion of 3635 ERCP procedures:
  - 2838 (78%) performed in 11 high volume centres (median 257 each)
  - 797 (22%) performed in 10 low-volume centres (median 45 each)
- there were significantly more grade 3 difficulty procedures in high-volume centers than in low-volume ones ( $P < 0.0001$ )
- post-ERCP pancreatitis occurred in 137 patients (3.8%); the rates did not differ between high- and low-volume centers (3.9% vs. 3.1%) and expert and non-expert operators (3.8% vs. 5.5%)

Testoni PA, et al. Risk Factors for Post-ERCP Pancreatitis in High- and Low-Volume Centers and Among Expert and Non-Expert Operators: A Prospective Multicenter Study. Am J Gastro 2010

# Risk Factors for post-ERCP pancreatitis (multivariate analysis)

risk factor	odds ratio (95% CI)	p value
>10 attempts to cannulate papilla	14.9 (10.5-21.26)	< 0.001
previous post-ERCP pancreatitis	8.7 (3.22-23.86)	< 0.0001
pre-cut technique	3.1 (2.06-4.76)	< 0.001
main pancreatic duct cannulation	2.1 (1.23-3.51)	0.006
biliary/pancreatic pain	1.9 (1.11-3.34)	0.01
low-ERCP volume (center)	1.3 (0.81-1.95)	0.30
low-ERCP experience (endoscopist)	0.7 (0.32-1.25)	0.19

Testoni PA, et al. Risk Factors for Post-ERCP Pancreatitis in High- and Low-Volume Centers and Among Expert and Non-Expert Operators: A Prospective Multicenter Study. Am J Gastro 2010

# Risk Factors for post-ERCP pancreatitis

Endoscopist level factors	odds ratio (95% CI)	p value
No. of ERCPs per year <50 vs. >200	0.82 (0.26-2.6)	0.057
50-100 vs. >200	1.63 (0.63-4.21)	
100-150 vs. >200	1.52 (0.19-1.4)	
150-200 vs. >200	0.95 (0.34-2.67)	
Hospital level factors	odds ratio (95% CI)	p value
Hospital Referral type local vs. regional	0.80 (0.4-1.6)	0.263
national vs. regional	2.00 (0.77-5.18)	
Hospital type District general vs. university	2.41 (1.08-5.41)	0.034
Hospital volume (log)	1.18 (0.67-2.07)	0.564

Williams EJ, et al. Risk factors for complication following ERCP; results of a large-scale, prospective multicenter study. *Endoscopy* 2007

# Quality of ERCP in a Community Setting



- data on quality outcome and complication rates usually originate from academic centres
- not much is known about the results obtained by smaller hospitals
- evaluation of outcome and 30-day complication rates in eight community hospitals in the Minnesota area (805 procedures by 13 physicians)
  - physician procedure volume ranged from 23-208 (median 50 / 6 months)
  - experience ranged from 6 to 28 years (median 17 yrs.)

Colton JB, et al. Quality indicators, including complications, of ERCP in a community setting: a prospective study. *GI Endosc* 2009



# Quality of ERCP in a Community Setting

- therapeutic ERCPs were performed in 78.4%
- overall complication rate was 5.0%
  - pancreatitis in 3.2%
  - infection 0.75%
  - bleeding 0.62%
  - perforation 0.12%
  - cardiopulmonary complications 0.25%
- no relationship between the years of experience, the number of procedures performed and the risk of a complication was discovered.

Colton JB, et al. Quality indicators, including complications, of ERCP in a community setting: a prospective study. GI Endosc 2009

## Post-ERCP pancreatitis is best prevented by limiting the number of ERCP-ists...

- endoscopist's expertise likely affects successful cannulation and overall performance of ERCP, including the risk for bleeding and perforation
- it seems unable to prevent post-ERCP pancreatitis, which seems more likely to depend on patient-related and technique-related risks than experience
- therefore selecting the patient carefully seems to be more important than the endoscopist's experience
- additionally, choosing the right technique, e.g. by placing a pancreatic stent, leads to a significantly reduced risk for developing post-ERCP pancreatitis