

# Quality in Endoscopy

Why half of you should stop doing ERCPs



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# Ensuring Quality in ERCP

## Some statements for discussion

- The best way to avoid procedural complications is not to perform an ERCP...
- ERCP training to fellows is mostly not properly assessed, inadequate, and incomplete
- There is a direct relation between the numbers of ERCPs performed, the number of successful cannulations, and the incidence of complications
- The daily practice and quality of GIs performing ERCPs is largely unknown and highly variable

# Ensuring Quality in ERCP

## The issue at hand

- ERCP is one of the most challenging procedures in gastroenterology practice
- Setting quality standards for endoscopy in general, but for ERCP in particular, have been slow
- Mainly focused on numbers and only for trainees
- There is a renewed interest pertaining quality standards for ERCP which is driven by:
  - ✓ heightened interest and awareness of the regulatory authorities
  - ✓ developments regarding quality registries in other endoscopic and surgical procedures

# Is ERCP a Dangerous Procedure?

## Complication rates

Complication	Rate	Prevention and/or management
Pancreatitis	5%-7%	Avoidance of ERCP for equivocal indications; use of temporary pancreatic stent in high-risk situations
Postsphincterotomy hemorrhage	1%-2%	Withholding anticoagulation for up to 3 d after sphincterotomy; endoscopic therapy; angiography (rare); surgery (rare)
Cholangitis	<1%	Obtaining complete and successful biliary drainage
Perforation	<1%	Meticulous sphincterotomy technique; endoscopic therapy and antibiotics for localized post-ES or wire perforation; surgical management for luminal perforations; early recognition is key to good outcome
Sedation related	Minor (transient hypoxemia, hypotension) 5%-10%; major (aspiration, cardiac arrest, death) 0.03%-0.5%	Use of supplemental oxygen; use of electrocardiogram in selected cases; reversal agents; consider anesthesiology-assisted sedation in patients with higher American Society of Anesthesiologists (ASA) classification and/or hemodynamic instability



# Ensuring Quality in ERCP

## Training of GI fellows

- Should all GEs learn ERCP?
- How does an optimal ERCP training look like?
  - ✓ which institution?
  - ✓ how many procedures?
  - ✓ special techniques?
  - ✓ level of competency to be reached before certified to do procedures on their own?
- Should a person's competence be monitored once trained and working in the field and how (e.g. minimal number of procedures per year, outcome)?

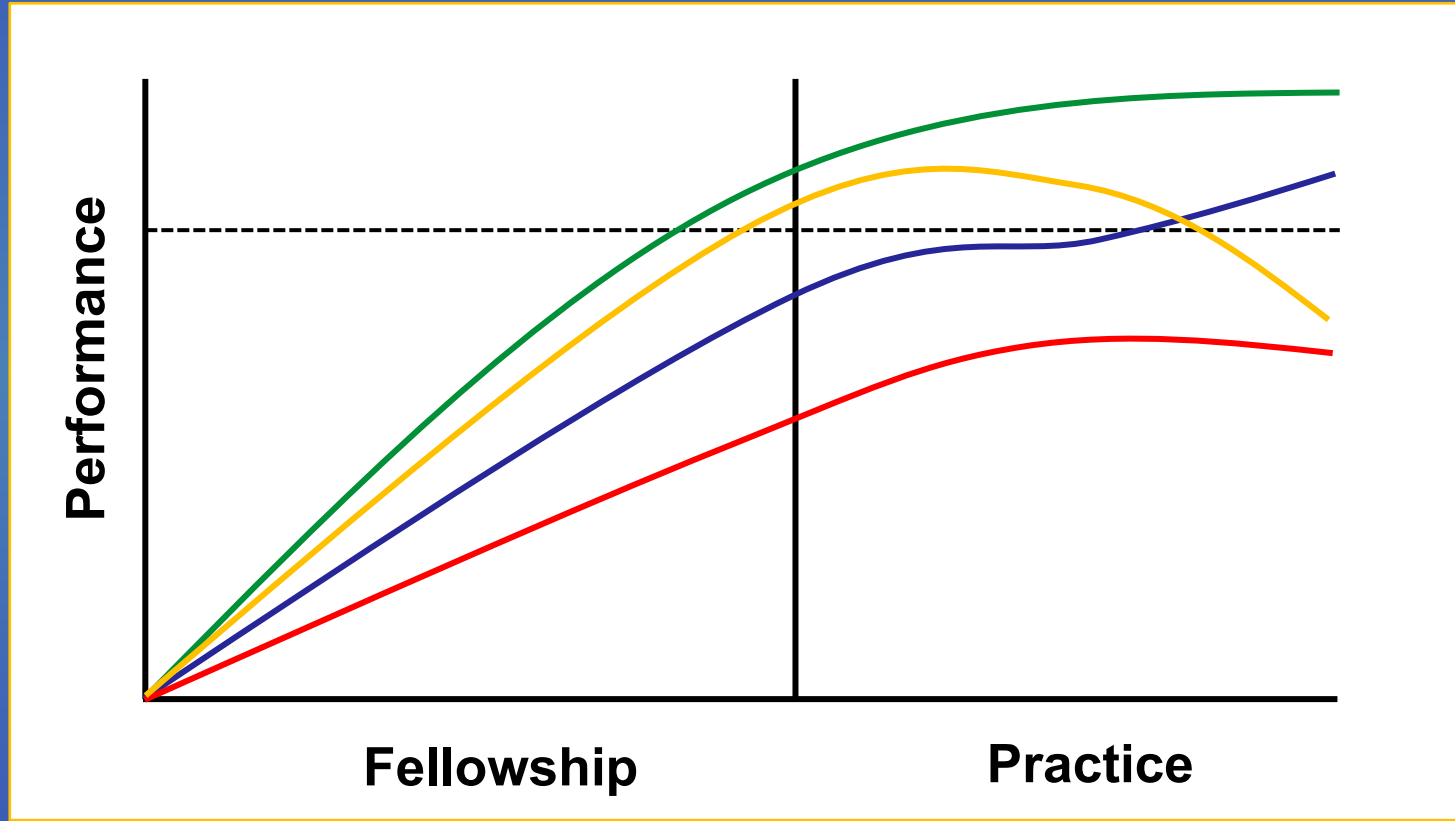
# Theory of Learning

## From 'Novice' to 'Master' and beyond



# Theory of Learning

Individual performance From 'Novice' to 'Master' and beyond



# Training in ERCP

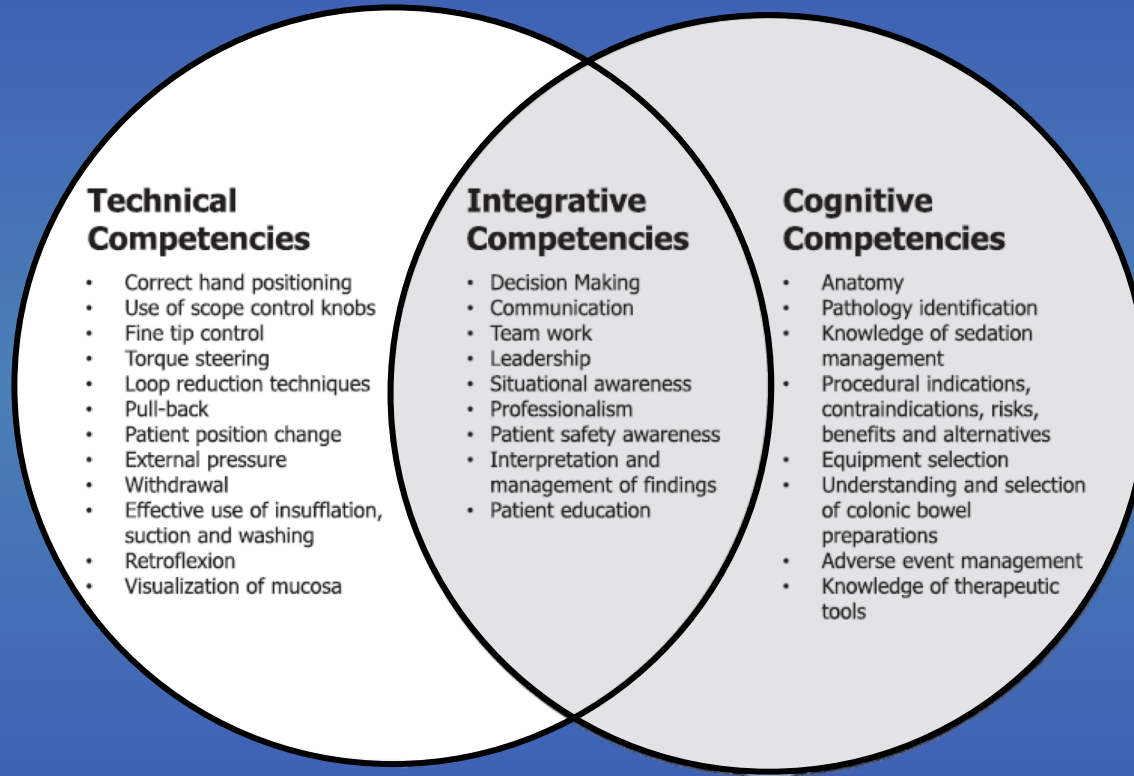
## Competency outcomes of published studies

Study	Competency marker	Competency results
Pancreatic duct cannulation		
Jowell et al <sup>7</sup>	80%	Achieved by 160 ERCPs
Watkins et al <sup>12</sup>	85%	Achieved by 70 ERCPs
Selective duct cannulation		
Schlup et al <sup>13</sup>	90%	Achieved by 120–150 ERCPs
Biau et al <sup>14</sup>	90%	Achieved by 79–300 ERCPs
Kowalski et al <sup>15</sup>	80%	Achieved by 180 ERCPs
Vitale et al <sup>16</sup>	85%	Achieved by 102 ERCPs
Waller et al <sup>18</sup>	80%*	Achieved by 100 ERCPs
Common bile duct cannulation		
Jowell et al <sup>7</sup>	80%	Not achieved by 200 ERCPs
Watkins et al <sup>12</sup>	85%	Not achieved by 100 ERCPs
Verma et al <sup>17</sup>	80%*	Achieved by 350 – 400 ERCPs
Ekkelenkamp et al <sup>19</sup>	80%	Achieved by 160 ERCPs

- Nine studies, assessing 137 trainees and 17,100 ERCPs, were included in the analysis
- Overall, competency was achieved among the included studies between 70 to 400 ERCPs
- In the 2 studies that used pancreatic duct cannulation rate, competency was achieved by 70 to 160 ERCPs

# Endoscopic Competence

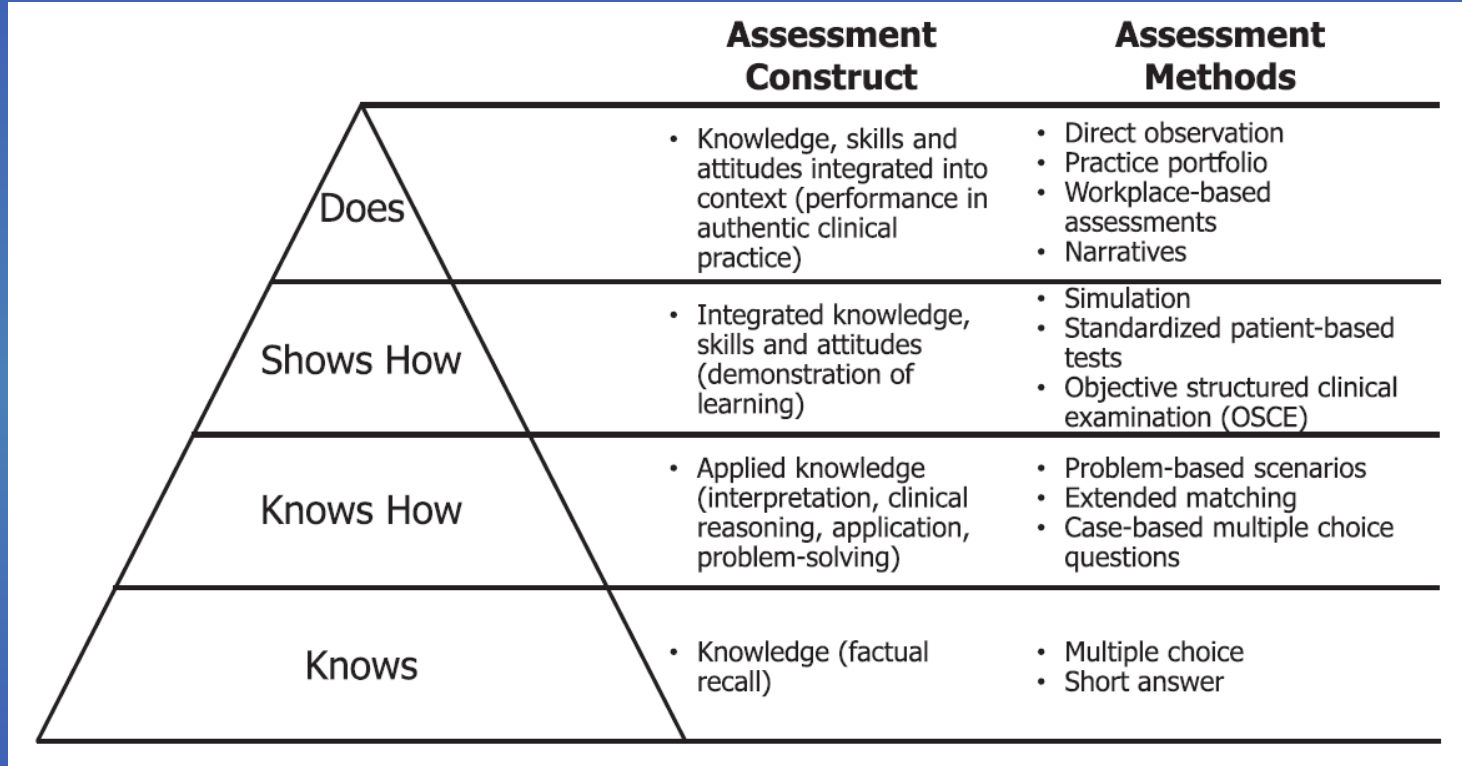
## Conceptual framework competencies within domains





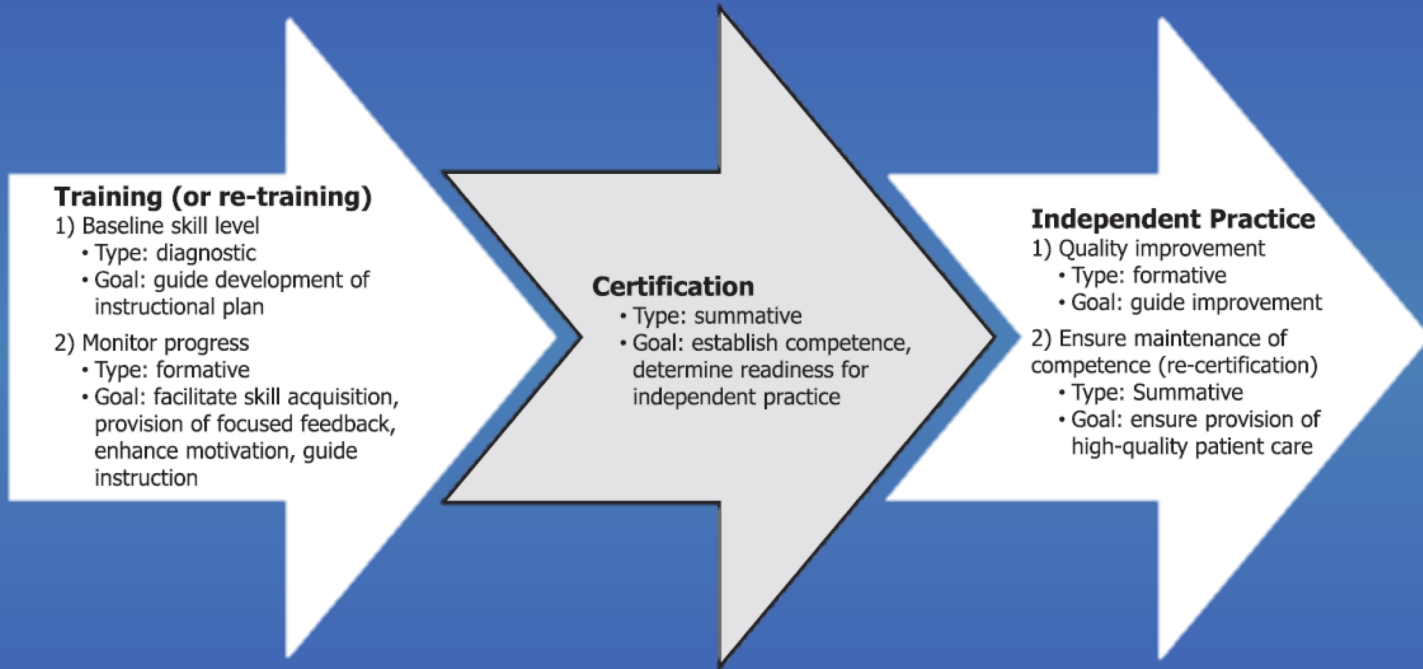
# Endoscopic Competence

## Learning assessment pyramid



# Endoscopic Competence

## Framework for the integration of assessment



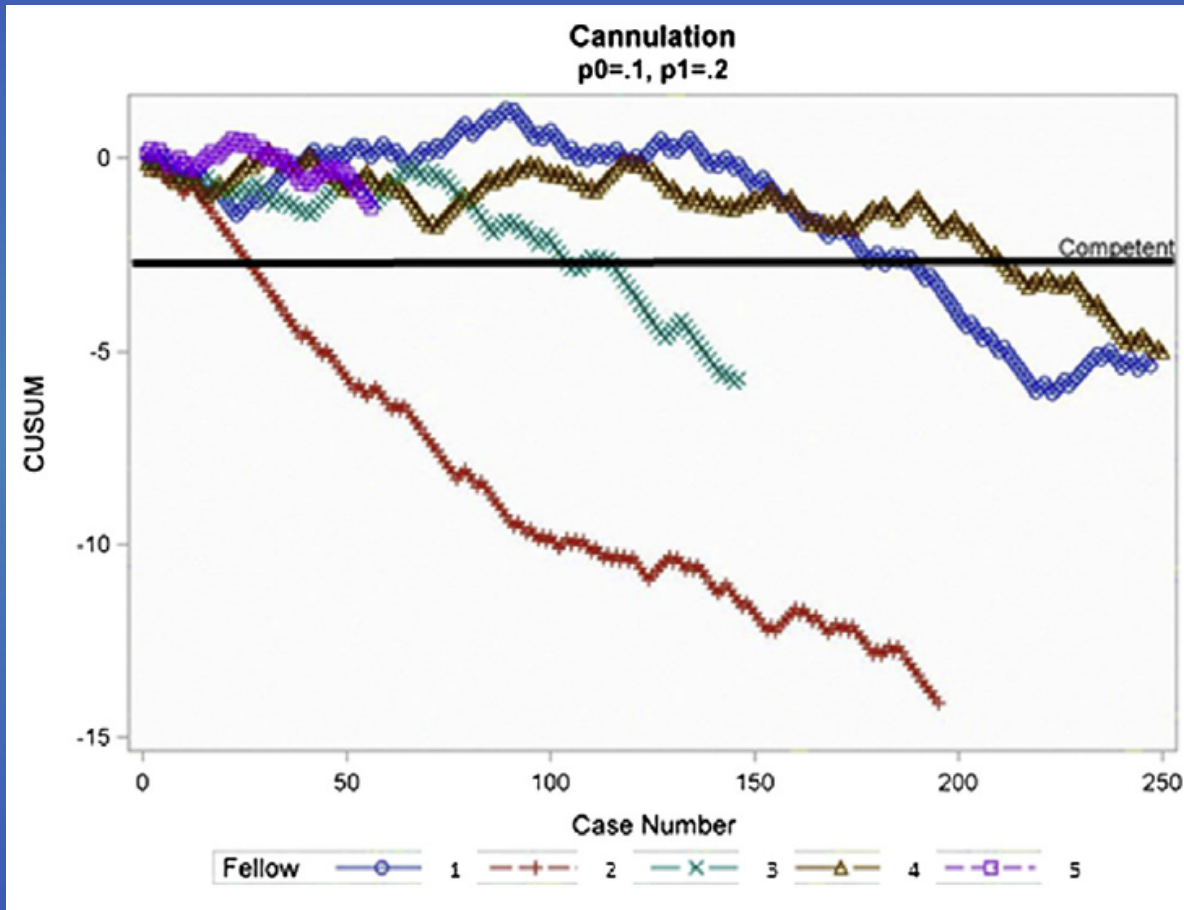
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## Recommendations of professional bodies

- American Board of Internal Medicine position paper 1988: 35
- The American Society for Gastrointestinal Endoscopy 1986: 100
- European Diploma of Gastroenterology 1995: 150
- Australian Conjoint Committee for Recognition of Training in Gastrointestinal Endoscopy 1997: 200

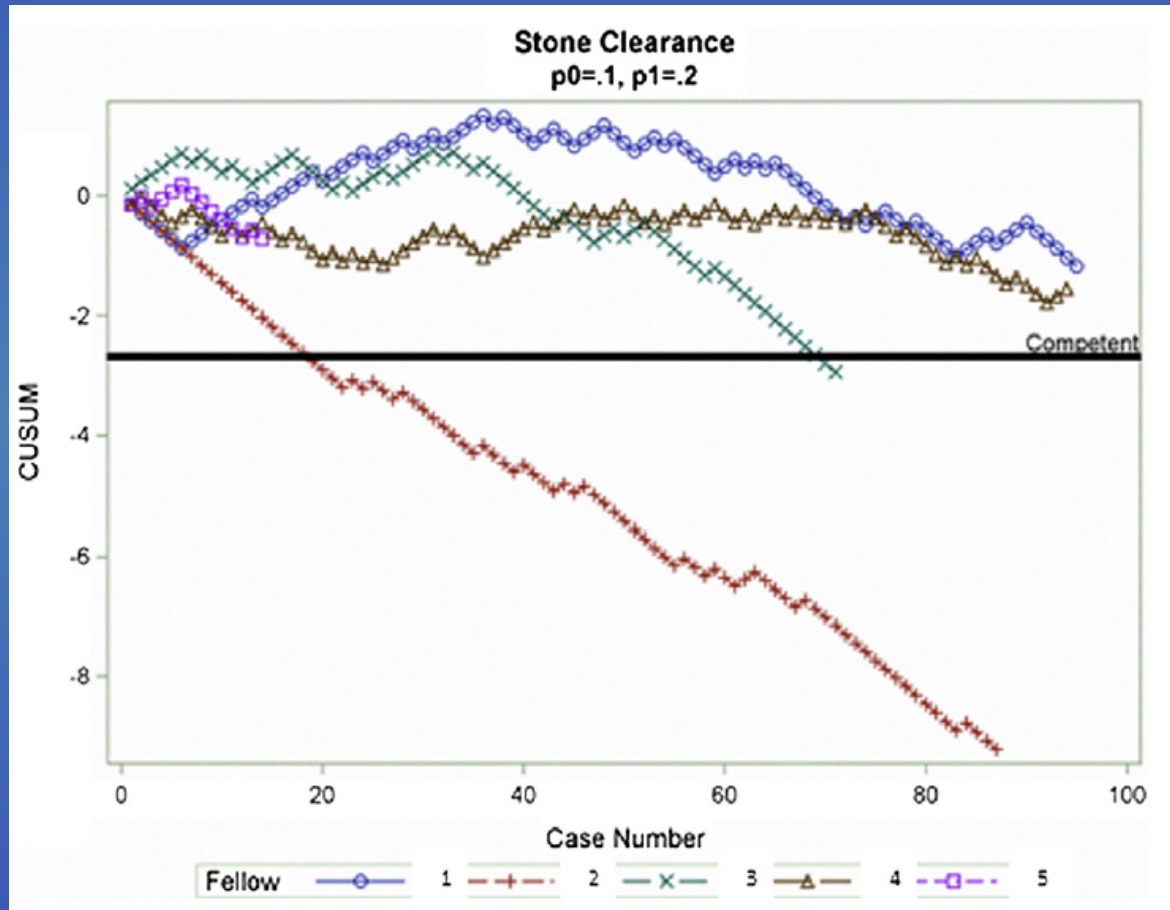
# Endoscopic Competence

Cumulative sum (CUMSUM) analysis for overall cannulation



# Endoscopic Competence

Cumulative sum (CUMSUM) analysis for stone clearance





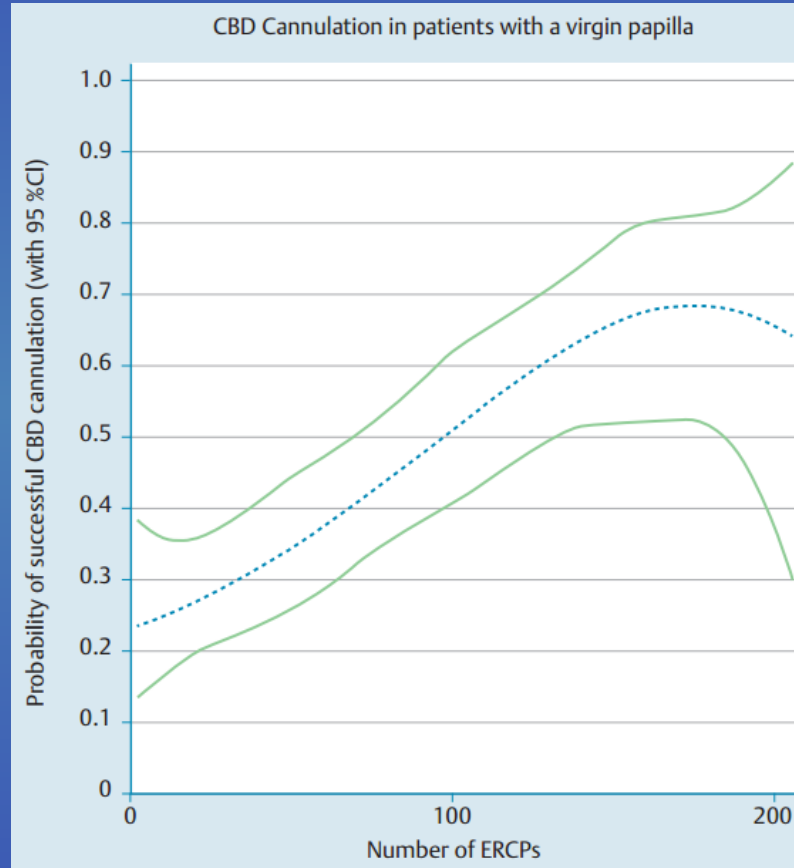
# Endoscopic Competence

Cumulative sum (CUSUM) analysis for overall performance



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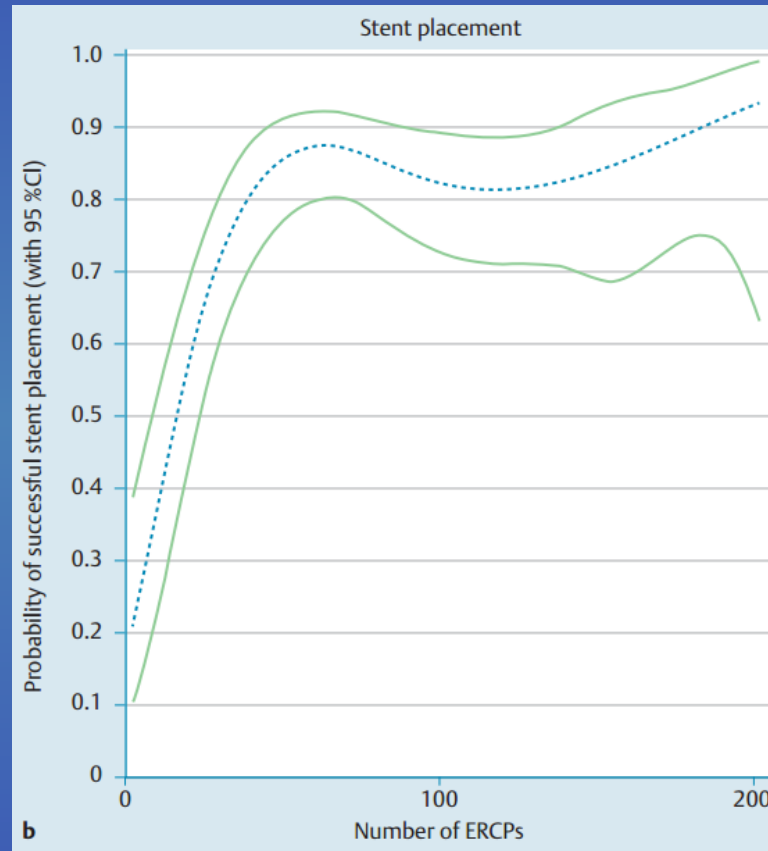
## Learning curve and probability of success by trainees in ERC



N = 15

# Ensuring Quality in ERCP

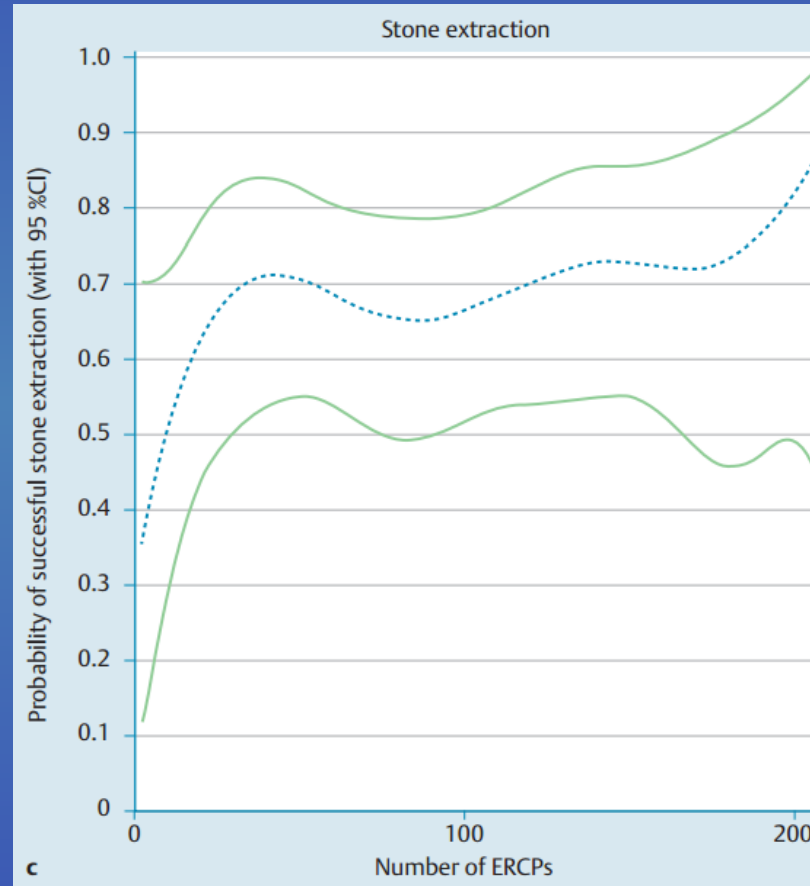
## Learning curve and probability of success by trainees in ERC



N = 15

# Ensuring Quality in ERCP

## Learning curve and probability of success by trainees in ERC



N = 15

# Ensuring Quality in ERCP

## Exposure & procedural competency

- Endoscopists performing 25 or fewer ERCPs report only 38% success at bile duct cannulation as compared with 85% for endoscopists performing 200 procedures or more<sup>1</sup>
- At tertiary referral centers, where endoscopists perform a high volume of ERCPs, success rates of 95% or better are reported, even in patients who have previously undergone unsuccessful procedures <sup>2,3</sup>



# Ensuring Quality in ERCP

## Getting more grip on the matter – The PERK study

- To investigate the procedural quality of ERCP practice in the Netherlands
- To identify endoscopist-related predictors of procedural outcome
- All gastroenterologists performing ERCP in the Netherlands were invited
- Web-based voluntary registration of all ERCPs for a period of one year using the RAF-E form

# Ensuring Quality in ERCP

## Rotterdam Assessment Form for ERCP (RAF-E)

Examination date: --20

Patient number

L  J

**1. Objective assessment:**

Indication: ☐ Stones (1) ☐ Bile leak/ Trauma (5)  
☐ Benign stenosis (2) ☐ Stent exchange (6)  
☐ Malignant stenosis (3) ☐ Chronic pancreatitis (7)  
☐ PSC (4) ☐ Other (8)

Virgin papilla ☐ Yes ☐ No  
 Previous ERCP failure ☐ Yes ☐ No ☐ NA  
 ERCP difficulty grading: ☐ 1 ☐ 2 ☐ 3

**2. Subjective assessment:**

S=success, P=partial, F=failure

Visual Analogue Scale  
Self-assessment for ERCP for

	S	P	F	0	10
CBD cannulation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>	<input type="text"/>
PD cannulation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>	<input type="text"/>
sphincterotomy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>	<input type="text"/>
precut	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>	<input type="text"/>
stone extraction	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>	<input type="text"/>
stent placement	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>	<input type="text"/>
PD intervention	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>	<input type="text"/>

**3. Improvement plan:** (Define potential points for improvement)

What is the situation? \_\_\_\_\_

What is the problem? \_\_\_\_\_

How should it be addressed? \_\_\_\_\_

What is the improvement strategy? \_\_\_\_\_

Was this self-assessment helpful in solving potential problems during ERCP?

0  10

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# Ensuring Quality in ERCP

## Rating the degree of difficulty

Degree of difficulty	Biliary procedures	Pancreatic procedures
Grade 1	Diagnostic cholangiography Biliary cytology Stone extraction $\leq 10$ mm Dilation of stenosis/stent placement/ nasobiliary drain in extrahepatic strictures	Diagnostic pancrea- tography Pancreatic cytology
Grade 2	Stone extraction $> 10$ mm Dilatation of stenosis/stent placement/nasobiliary drain in hilar tumors or benign intra-hepatic strictures	Cannulation of minor papilla
Grade 3	Billroth II anatomy Intrahepatic stone extraction Stone extraction with lithotripsy	Therapeutic pancreatic procedures including pseudocyst drainage

# Ensuring Quality in ERCP

## PERK study – Methods - Outcome parameters

- Procedural success in:
  - ✓ difficulty degree 1 procedures
  - ✓ naïve papillary anatomy
  - ✓ intent for complete stone extraction
- Procedural outcome
  - ✓ identification of factors associated with success or failure

# Ensuring Quality in ERCP

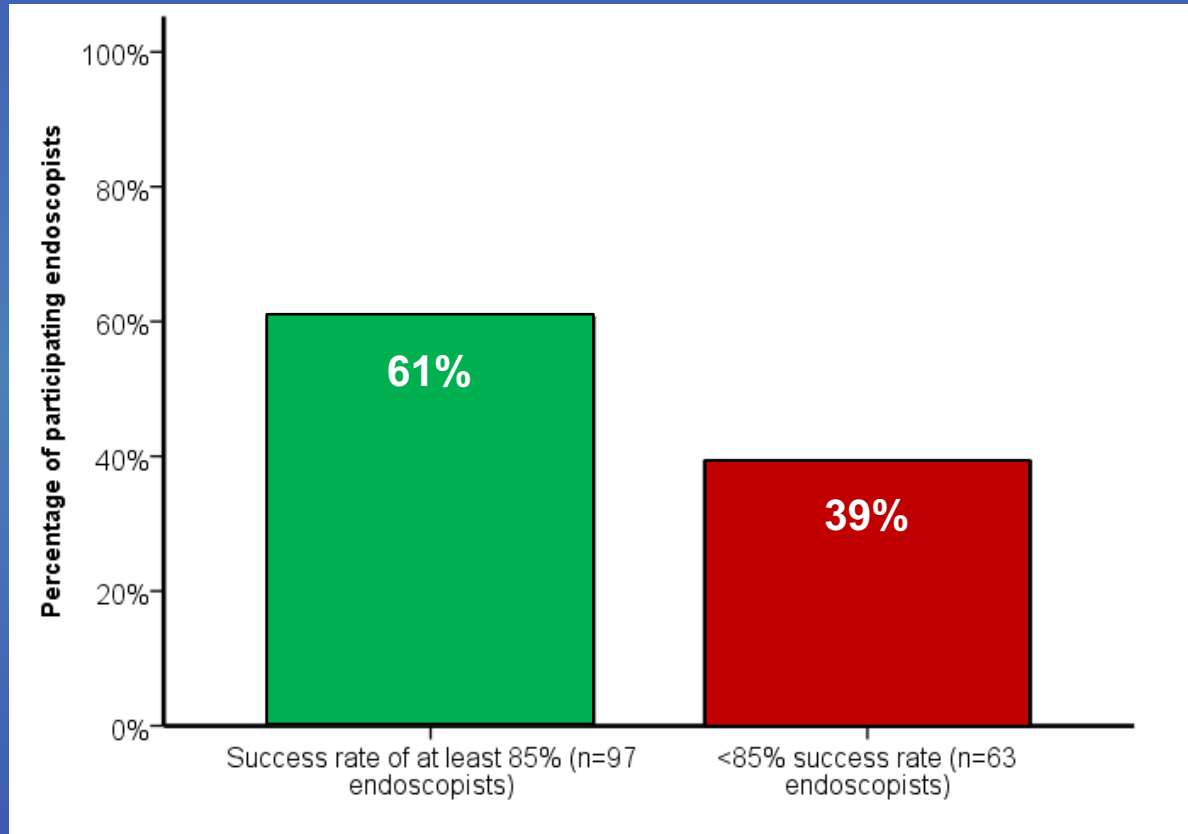
## PERK study – Results - Number of ERCPs

- Procedures were collected from 171 endoscopists
- Working in 61 hospitals
- With a total number of 8575 registered ERCPs
  - ✓ difficulty degree 1 procedures: n = 4891 (57%)
  - ✓ patients with naïve papillary anatomy: 3261 (67%)



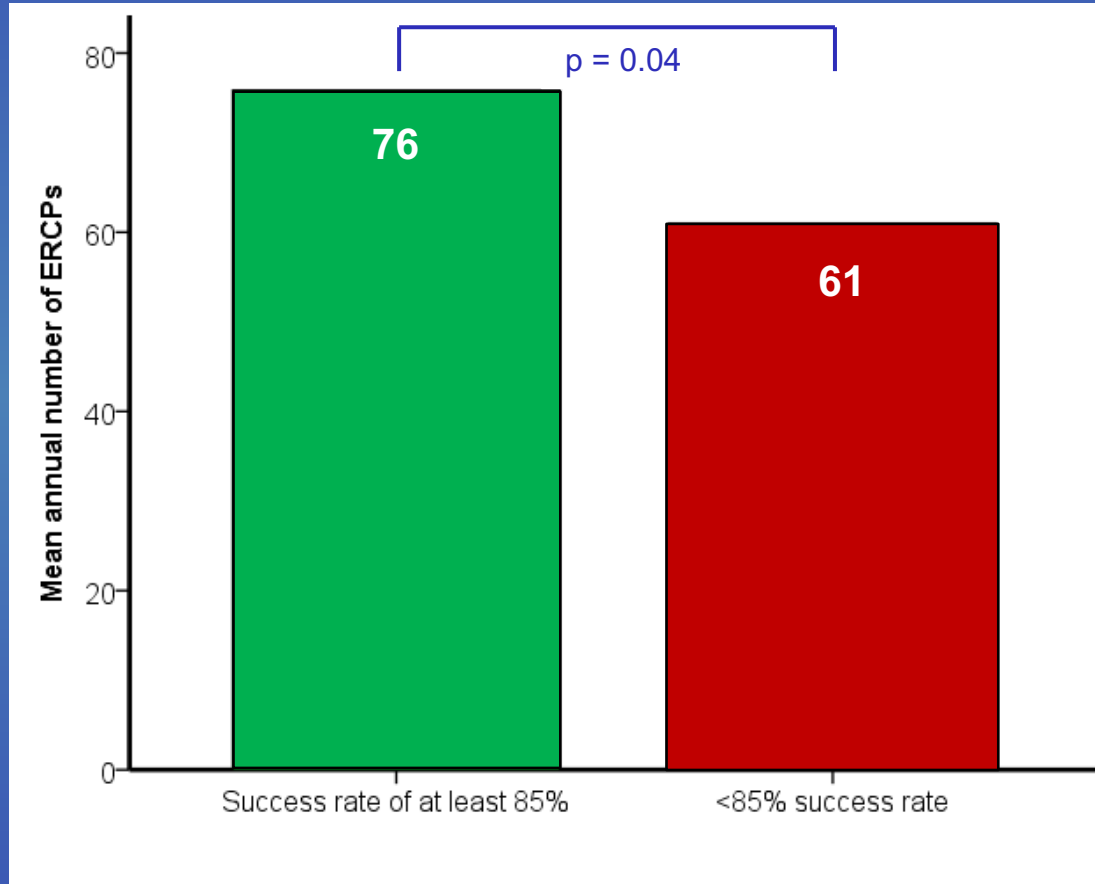
# Ensuring Quality in ERCP

## PERK study – Results - Procedural success per endoscopist



# Ensuring Quality in ERCP

## PERK study – Results - Mean annual number of ERCPs per group



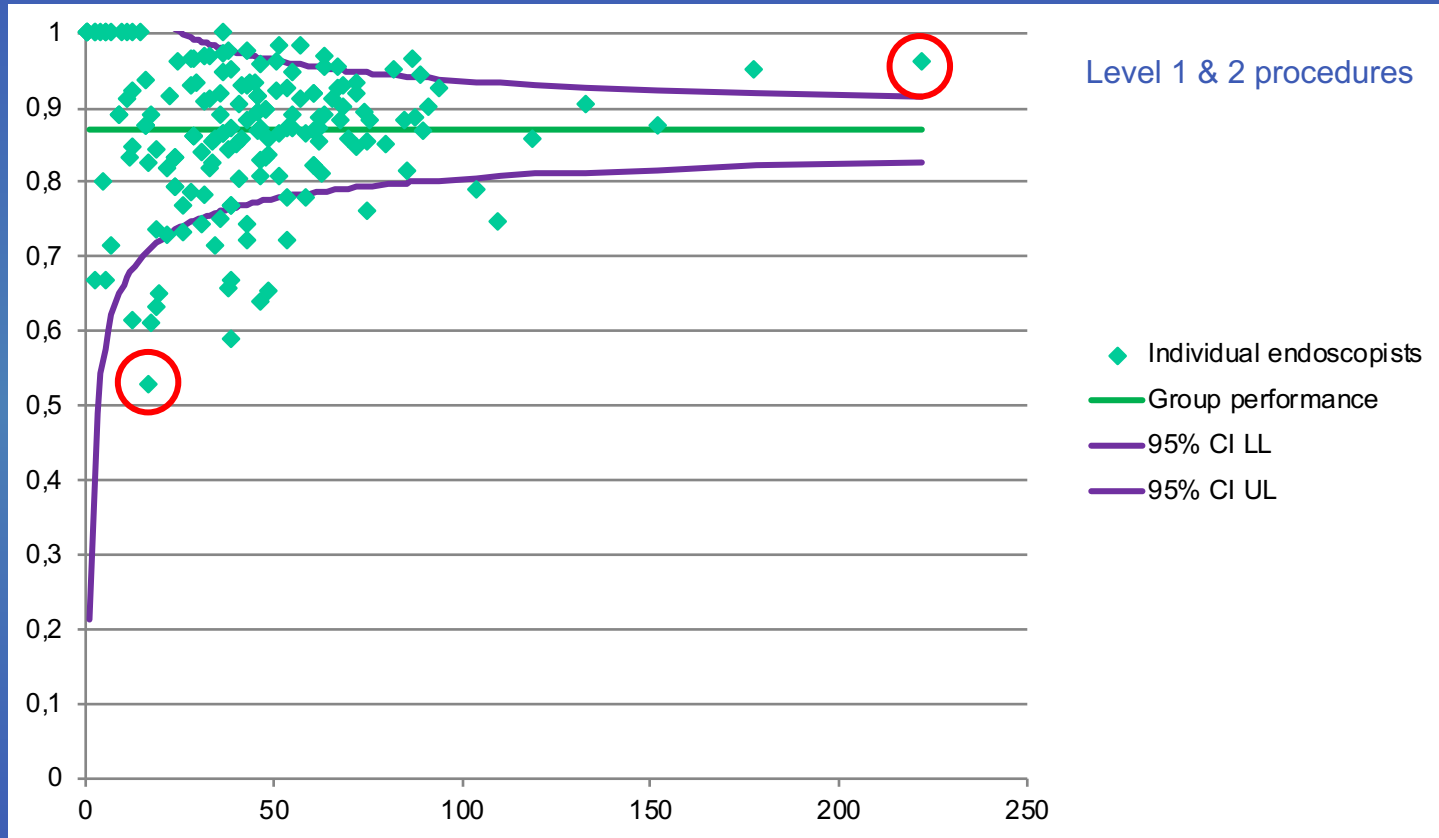
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## PERK study – Results - Predictors of procedural success

Variable	Odds ratio	95% CI	P-value
number of years as a certified gastroenterologist	0.921	0.868-0.979	0.008
number of ERCPs performed yearly	0.985	0.971-0.999	0.038
lifetime number of ERCPs >500	0.488	0.239-0.998	0.049

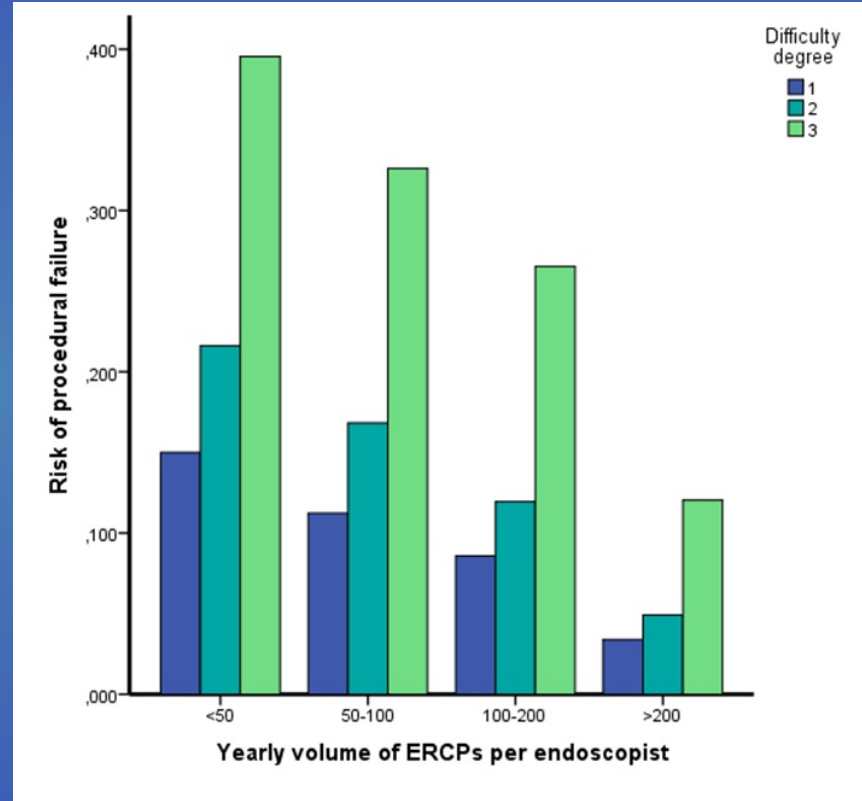
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## PERK study – Results - Individual vs. group performance



# Ensuring Quality in ERCP

Relation between volume, degree of difficulty & outcome



# Ensuring Quality in ERCP

## Summary & conclusions

- Procedural success rates of at least 85% are achieved more frequently by endoscopists performing larger numbers of ERCPs per year
- Quality in ERCPs will increase when fewer endoscopists perform more ERCPs
- ERCPists have the obligation to monitor and report the outcome of ERCP procedures
- The RAF-E form provides a meaningful insight into the procedural competence of practicing GEs and is a valuable tool to promote self-reflection of ones own competence
- Cumulative Sum curves are an excellent tool to monitor progression of skills and competence of trainees and practitioners alike

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