Making ERCP training safe: A protocol-based strategy to minimize complications during selective biliary cannulation

Boon Eu Andrew KWEK, Tiing Leong ANG, Eng Kiong TEO, Kwong Ming FOCK

Department of Gastroenterology, Changi General Hospital, Singapore

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Abbreviations: ERCP, endoscopic retrograde cholangiopancreatography

Background and aims: Endoscopic retrograde cholangiopancreatography (ERCP) is an advanced procedure with significant complication rate of 5 to 10%. Scant data is available on quality indicators for trainee-involved ERCP. In our study, we evaluated the outcome of trainee-involved ERCPs in which a protocol-based strategy to minimize complications during selective biliary cannulation was adopted.

Patients and methods: Hands-on training was excluded if patients had ASA grade > 3. The trainee's attempts at selective biliary cannulation were stopped and the procedure taken over by the supervising expert endoscopist if the following factors were encountered: (1) failed cannulation after 5 attempts; (2) unsuccessful cannulation after 10 minutes; (3) edematous papilla; (4) pancreatic duct cannulation ≥ 2 times. After successful ductal cannulation, the trainee was allowed to continue additional hands on training in other aspects such as stone extraction and stenting.

Results: During the study period, 331 patients underwent ERCP. Trainee group (TG) consisted of 85 patients; mean age 70 (range 27-99). Expert group (EG) consisted of 246 patients; mean age 65 (range 19-98). The overall technical success rate was 97.9% and there was no significant difference between TG (98.8%) and EG (97.6%). The overall complication rate was 3.9% and there was no difference between TG (3.5%) and EG (4%). In TG, although inadvertent pancreatic duct cannulation occurred in 12/85 (14.1%), acute pancreatitis developed only in 3/85 (3.5%).

Conclusion: The high success and low complication rates in trainee-involved and expert-only ERCP procedures were similar. While using a protocol-based strategy, good clinical outcome during the provision of hands-on training for ERCP was observed.

Background and study aims

Endoscopic retrograde cholangiopancreatography (ERCP), an advanced endoscopic procedure with significant complication rate of 5% to 10%¹, is widely practised in the evaluation and management of pancreato-biliary diseases. To serve as a benchmark for quality assurance and improvement programs, quality indicators for ERCP have been introduced.^{2,3} Amongst these include appropriate indication, cannulation and precut rates, and complication rates.

Whilst numerous studies have described patient-related and procedure-related risk factors important in ERCP, scant data are available on these factors and quality indicators in trainee-involved ERCP. Known technical risk factors for post-ERCP pancreatitis are papillary trauma from high number of cannulation attempts (odds ratio 2.4-3.4) and pancreatic duct injections (odds ratio

2.2).⁴ Defining the effect of endoscopic training and expertise on ERCP outcomes is difficult due to a wide variation in factors such as case-mix, therapeutic intent, and technical success rates.⁵

In our study, we evaluated the outcome of trainee-involved ERCPs in which a protocol-based strategy to minimize papillary trauma and inadvertent pancreatic duct cannulation, during selective biliary cannulation was adopted.

Patients and methods

We analysed data from consecutive patients who underwent ERCP procedures between January 2009 and March 2010, at the Department of Gastroenterology, Changi General Hospital, Singapore. Demographic data and quality indicators were retrieved from our prospectively collected database.

ERCP was performed with all patients placed in prone position and under conscious sedation using intravenous midazolam and fentanyl. Supplemental oxygen was provided via intranasal prongs. Intravenous hyoscine or glucagon were given to reduce duodenal contractions. All patients received intravenous broad spectrum antibiotic (3rd generation cephalosporin or fluoroquinolone) prior to the procedure. Continuous monitoring of cutaneous oxygen

*Correspondence to: Boon Eu Andrew KWEK; Email: andrewkwek@gmail.com
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saturation, pulse rate, blood pressure and cardiac rhythm were available for all patients.

All trainee-involved procedures followed a standard protocol. Trainee involvement included papilla cannulation, sphincterotomy, stone extraction and stent insertion. By standard protocol, hands-on training was excluded if patients had ASA grade > 3. Trainee's attempts at selective biliary cannulation were stopped and the procedure taken over by the supervising expert endoscopist if the following factors were encountered: (1) failed cannulation after 5 attempts; (2) unsuccessful cannulation after 10 minutes; (3) edematous papilla; (4) pancreatic duct cannulation ≥ 2 times. After successful ductal cannulation by the expert endoscopist, the trainee was allowed to continue additional hands on training in other aspects such as stone extraction and stenting. Before embarking on ERCP training, the trainee (KBEA) had completed a 3-year specialist training in gastroenterology and had been credentialled for diagnostic and therapeutic upper/lower gastrointestinal endoscopy. During the study period, the trainee was at the start of his ERCP training. Expert endoscopists (TLA, EKT, KMF) have previously performed > 1000 ERCP procedures.

ERCP was performed using a therapeutic duodenoscope (TJF 160VR, Olympus, Tokyo, Japan). Guidewire within sphincterotome was the adopted initial cannulation technique. The outcome of ERCP among patients with trainee involvement was compared to those without trainee involvement. Technical success was defined as successful completion of procedure, after selective ductal access. Patients were followed-up till successful discharge from the hospital. Post-ERCP complications were defined as any adverse outcome that required hospital management. These included pancreatitis (new or worsened abdominal pain with three-fold rise in the serum amylase or lipase, and required at least 1 night in the hospital), bleeding (overt hemorrhage with drop in Hb > 2 g/dL, requiring endoscopic or surgical therapy) and perforation (radiological evidence of free or retroperitoneal air). ERCP difficulty grading was based on the described levels by the ASGE/ACG Taskforce on Quality in Endoscopy.²

Statistical analysis was performed using SPSS software version 17.0 (SPSS, Chicago, Illinois, USA). Categorical data were analyzed using chi-square or Fisher exact test, while continuous data were analyzed using student's t test. p value of < 0.05 was taken as statistically significant.

Results

During the study period, a total of 237 patients underwent 331 ERCP procedures. Of the 331 patient-procedures, mean age was 66.3 years (standard deviation [SD] 16.3, range 19-99). Male:Female ratio was 160:171. Indications for ERCP are shown in **Table 1**. Primary intent of the procedure was therapeutic biliary drainage in 315 patients (95.2%). Pancreatic endotherapy was performed in 13 patients (3.9%). Two patients had diagnostic cholangiography for evaluation of suspected primary sclerosing cholangitis, and 1 patient had diagnostic pancreatography for the evaluation of suspected pancreas divisum. Patient profile and demographics are shown in **Table 2**.

Trainee group (TG) consisted of 85 patient-procedures; ASA grade 1 to 3, mean age 70 (range 27-99). Expert group (EG)

consisted of 246 patient-procedures; ASA grade 1 to 5, mean age 65 (range 19-98). ERCP profile is shown in **Table 3**. The mean procedural time was similar for both groups (TG 24.4 mins, EG 23.9 mins; $p=0.768$). Trainee involvement included 72 cannulations (41 successful CBD cannulation, 12 inadvertent PD cannulation, 19 failed deep cannulation), 4 biliary sphincterotomy, 7 stone extraction and 19 biliary stent insertion (**Table 4**). Native papilla was present in 180 procedures (45 TG, 135 EG). Precut access was performed in 28 procedures (8.5%). 2/85 (2.4%) were in TG and 26/246 (10.6%) in EG ($p=0.019$). The overall technical success rate was 97.9% and there was no significant difference between TG (98.8%) and EG (97.6%) ($p=0.682$).

The overall complication rate was 3.9% and there was no difference between TG (3.5%) and EG (4.1%) ($p=1.0$). Post-ERCP pancreatitis occurred in 8 patients (2.4%). In TG, although inadvertent pancreatic duct cannulation occurred in 12/85 (14.1%), acute pancreatitis developed only in 3/85 (3.5%). There was no occurrence of perforation, bleeding or death in TG. In EG, post-ERCP pancreatitis occurred in 5 patients (2.0%). Bleeding, perforation and cardiopulmonary arrest occurred in 1 patient each. Two in-patient post-ERCP deaths were recorded in EG; both occurred within 30 days after the procedure. A 84-year-old patient with end-stage renal failure on peritoneal dialysis, triple vessel coronary artery disease, diabetes mellitus, hypertension and hyperlipidaemia, had acute cholangitis. ERCP was performed successfully and biliary stent inserted for drainage. A week later, during her recovery in the hospital she had a large territory acute non-hemorrhagic infarct. She died 10 days following that. The second death was that of a 78-year-old patient with ischaemic heart disease, atrial fibrillation, chronic renal impairment and hypertension. She had acute cholangitis for which ERCP and biliary stenting was performed. She developed acute duodenal ulcer with hemorrhage that recurred despite endoscopic treatment. Following surgical management, she succumbed to fulminant sepsis and multi-organ failure.

Univariate and multivariate analyses were used to identify risk factors for post-ERCP complications. Mean duration of procedure was longer in patients with post-ERCP complications; 36.85 mins vs. 23.49 mins ($p=0.029$). There were no significant differences for mean age, sex of patient, CBD size, the use of precut, ASA status and presence of trainee involvement.

Discussion

Safe and effective ERCP outcome relies on appropriate patient selection and the experience of the endoscopist, underscoring the importance of rigorous specialist training.⁶ In addition to achieving credentialing criteria, quality control during ERCP training is vital to minimize risks and improve patient safety.⁷ We aimed to preserve low complication rate and good procedural outcome during the provision of ERCP training. Our study demonstrated a high success rate, with 97.9% of ERCPs achieving ductal cannulation and therapeutics. Protocol-based strategy was implemented to minimize complications during selective ductal cannulation. There was no significant difference in the complication rates between ERCP procedures performed by trainee under supervision and those by expert specialists alone.

Table 1. Indications for ERCP

Indication for ERCP	n=331 (%)
Biliary stone	249 (75.2%)
Bile duct	243
Cystic duct (Mirizzi syndrome)	6
Neoplasm (biliary/pancreatic)	40 (12.1%)
Benign biliary stricture	13 (3.9%)
Papillary stenosis	7 (2.1%)
Obstructive jaundice	6 (1.8%)
Pancreatic endotherapy	13 (3.9%)
Pancreatic duct leak	4
Pancreatic duct fistula	4
Pancreatic duct stone	5
Diagnostic ERCP	3 (0.9%)
Suspected PSC	2
Suspected pancreas divisum	1

PSC: Primary Sclerosing Cholangitis.

Table 4. Trainee involvement in ERCP

Procedure	n
Cannulation	
Attempt	72
Common bile duct	41/72 (56.9%)
Pancreatic duct (inadvertent)	12
Failed deep cannulation	19
Stent insertion	
Attempt	22
Successful	19/22 (86.4%)
Stone extraction	7
Biliary sphincterotomy	4

Table 2. Patient profile and demographics

	Trainee-involved group	Expert group	p
n	85	246	-
Mean age (SD, range)[Years]	70.0 (15.3, 27-99)	65.0 (16.5, 19-98)	0.012
M:F	44:41	116:130	0.463
ASA (range, mode)	1-3, 2	1-5, 2	0.429

n=331 patient-procedures; Mean age 66.3 years, SD 16.3, range 19-99; M:F 160:171; ASA (range 1-5, mode 2); SD: Standard Deviation; ASA: American Society of Anaesthesiologist physical status classification system.

Table 3. ERCP profile, success rate and complication rate

	Trainee group	Expert group	p
ERCP grade (1/2/3)	14/ 65/ 6	145/ 72/ 29	< 0.001
Overall (159/ 137/ 35)			
Native papilla	45/85 (52.9%)	135/246 (54.9%)	0.757
Overall 180/331 (54.4%)			
Mean procedure time (mins)			
Overall 24.0	24.4	23.9	0.768
(SD 15.3, range 5-104)	(12.6, 7-85)	(16.2, 5-104)	
Mean CBD diameter (mm)			
Overall 12.6	13.1	12.4	0.308
(SD 5.6, range 3.2-43.0)	(5.2, 5.0-35.0)	(5.7, 3.2-43.0)	
Success rate	84/ 85	240/246	0.682
Overall 324/331 (97.9%)	(98.8%)	(97.6%)	
Complication rate			
Overall (13/331, 3.9%)	3/85 (3.5%)	10/246 (4.1%)	1.000
Pancreatitis	3/85 (3.5%)	5/246 (2.0%)	0.428
Bleeding	0	1/246 (0.4%)	0.743
Perforation	0	1/246 (0.4%)	0.743
Cardiorespiratory arrest	0	1/246 (0.4%)	0.743
Death	0	2/246 (0.8%)	0.552

CBD: common bile duct.

Overall complication rate was 3.9%; TG 3.5% vs. EG 4.1% (p=1.0).

The most common and serious complication following ERCP is acute pancreatitis, with an incidence of 3.47% based on a systematic review of 21 studies involving more than

16,000 patients.^{4,8,9} Existing data from meta-analyses identified patient-related and procedure-related risk factors for post-ERCP pancreatitis. Patient-related factors include suspected sphincter of Oddi dysfunction, female gender, previous pancreatitis, younger age, non-dilated extrahepatic bile ducts, absence of chronic

pancreatitis and normal serum bilirubin. Procedure related risk-factors include precut sphincterotomy, pancreatic injection, high number of cannulation attempts, pancreatic sphincterotomy, biliary balloon sphincter dilation and failure to clear bile duct stones.^{4,8} There is a paucity of data on effect of trainee involvement during ERCP. In our study, there was no significant difference in the post-ERCP pancreatitis rate between TG and EG; 3.5% vs. 2.0%, respectively ($p=0.428$). The only significant factor associated with a higher risk of complication was a higher duration of procedure; 36.85 mins vs. 23.49 mins (complications vs. no complications); likely reflecting a more difficult cannulation attempt or prolonged instrumentation.

We implemented a standard cannulation protocol in procedures with trainee involvement, based on principles to minimize papillary trauma and pancreatic ductal hypertension. Studies have shown that a higher number of cannulation attempts confers a higher risk of post-ERCP pancreatitis, with incidence of 3.3% when attempts were less than 5 and 14.9% when more than 20 attempts were made.¹⁰ Also, cannulation technique using wire-guided sphincterotome has a lower risk of inducing pancreatitis compared to other standard cannulation techniques, where inadvertent instillation of contrast medium into the pancreatic duct may occur.¹¹ Pancreatic duct contrast instillation, especially if it reaches the pancreatic tail region, has a tendency for increased risk of post-ERCP pancreatitis.¹⁰

Higher ERCP difficulty grade has also been associated with higher complication rates.^{2,12} However, in our study, despite having a higher proportion of patients with higher ERCP grade, TG had similar success and complication rates with EG.

Our study has several limitations. The study was a retrospective analysis of a single center ERCP procedures without randomized comparison against non-protocol based strategy. Also, patients in the expert group had higher ERCP difficulty grades, giving an inhomogeneous comparison with those in trainee group. During the study period, we had only one trainee for ERCP procedures. Future studies could involve more trainees, especially in centres with higher ERCP load, to determine if the results are reproducible. Despite these limitations, by formalizing a protocol, we hope to have uniform agreement between trainee

opportunity and supervisor interventions during ERCP training, while preserving good procedural outcome.

Conclusion

The outcome of ERCPs in this study compared favorably with international quality indicators. The high success and low complication rates in trainee-involved and expert-only ERCP procedures were similar. Using a protocol-based strategy, good clinical outcome during the provision of hands-on training for ERCP was preserved, providing quality assurance to our patients.

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