

Demonstrating competence in Endoscopic Retrograde Cholangiopancreatography (ERCP): Recently credentialed operator's performance for deep biliary cannulation over 1 year period from a tertiary care hospital in Pakistan

Om Parkash¹, Umar Bhatti², Hasnain Zafar³, Saeed Hamid⁴

Abstract

Objective: To measure the success rate of endoscopic retrograde cholangiopancreatography biliary cannulation of a recently credentialed endoscopist at a tertiary hospital.

Methods: The clinical audit was conducted at the Aga Khan University Hospital, Karachi, and comprised data of all patients who underwent endoscopic retrograde cholangiopancreatography under the care of a single operator during 2016. Data was retrospectively extracted from patient charts by an assistant blinded to the study. Data extracted included demographics, admission type, details and indication for the procedure, diagnosis, cannulation outcome, duct clearance, complications, follow-up surgical intervention, radiological imaging and mortality post-endoscopy. Data was analysed using SPSS 19.

Results: Of 143 procedures performed, 102(71.3%) were included. The mean age was 52±17 years and 54(52.9%) of them were females. Most common indication was choledocholithiasis in 70(68.6%). The average procedure time was 41.5±5.5 minutes. Cannulation success rate was 96(94.1%). Complications included post-procedure pancreatitis in 5(4.9%), minimal bleeding in 8(7.8%) and oesophageal perforation in 1(0.98%). There was no procedure-related mortality.

Conclusion: The success rate was high and complications were low with zero mortality.

Keywords: ERCP, CBD cannulation, Pancreatitis, CBD stones. (JPMA 71: 929; 2021) DOI: <https://doi.org/10.47391/JPMA.1219>

Introduction

The dramatic growth of gastroenterology and endoscopy over the past decade, with rigorous clinical trials investigating into novel pharmacological and interventional therapeutic strategies has resulted in a substantial improvement in the diagnostic and therapeutic potential of gastroenterology in the current era.¹ Technological advancements in the field of medicine have expanded the use of endoscopy in gastroenterology in many forms that include endoscopic retrograde cholangiopancreatography (ERCP), endoscopic ultrasound (EUS), colonoscopic polypectomy (CP), radiofrequency ablation (RFA), endoscopic mucosal resection (EMR), balloon-assisted enteroscopy (BAE) and luminal stenting (LS).

The patient demographics for endoscopic procedures have changed considerably over the recent years and there has been a significant increase in the number of elderly patients and patients with complex medical problems requiring endoscopic means of treatment.² The diversity of technical skills required to perform endoscopy makes it a challenging procedure for even the well-trained endoscopists. This mandates comprehensive training curricula during residency and fellowship training of

endoscopists that would ascertain that the independent prospective endoscopist possesses the skill-set required to perform the procedure efficiently with optimum patient outcomes.³

The American Society for Gastrointestinal Endoscopy (ASGE) defines competence as the minimum level of skill and knowledge acquired through training that is needed to perform a procedure safely.⁴ ERCP is considered one of the more technically challenging endoscopic procedures that are routinely performed by gastrointestinal endoscopists.⁵ ASGE recommends that a standard endoscopy training during gastroenterology fellowship is pre-emptive to acquiring training in advanced endoscopic procedures like ERCP.⁴ ASGE devises a count of 180-200 cases before competence is achieved by the fellows training for ERCP.⁶ This, however, was opposed by Verma et al., who proposed that around 350 ERCPs are required to be performed by an endoscopist on native papilla to acquire competence.⁷ Although a threshold number of procedures performed is integral to achieving competence, it is imperative to say that an arbitrary number of procedures performed does not guarantee competence. Current research proposes that a success rate of 80-85% in common bile duct (CBD) cannulation is required before trainees of advanced endoscopic procedures, like ERCP, are deemed competent in the technical skill.⁸

The training programmes and hospital credentialing

^{1,4}Department of Medicine, Aga Khan University, Karachi, Pakistan;

^{2,3}Department of Surgery, Aga Khan University, Karachi, Pakistan.

Correspondence: Om Parkash. e-mail: om.parkash@aku.edu

committees all around the world have been subjected to a lot of scrutiny in order to ensure that they produce adequately trained endoscopists.⁴ Clinical competence of endoscopists plays an important role in determining the patient outcomes. Currently, there are no recognised robust ERCP training fellowship programmes in Pakistan. Most endoscopists are either trained in a foreign country, or they gain experience from local training centres in Pakistan, which are not structured fellowship training programmes. Competence assessment is given little to no precedence during the credentialing process at different hospitals across the country. The Aga Khan University Hospital (ALUH), on the other hand, is a Joint Commission International (JCI)-certified facility that aims at determining competence before credentialing a trainee.

A paucity of data has been identified on ERCP success rates at health care centres in Pakistan. One of the few studies conducted has demonstrated an ERCP success rate of 88.5% in 200 patients at a tertiary care hospital in Rawalpindi.⁹ However, it took into account the gross success rate at the centre and not the success rates of individual endoscopists. The current study was planned to determine the competence of a single recently-credentialed operator regarding ERCP biliary cannulation.

Materials and Methods

The clinical audit was conducted at the AKUH, Karachi, and comprised data of all patients who underwent endoscopic retrograde cholangiopancreatography under the care of a single operator from January 1 to December 31, 2016. AKUH is a major tertiary care hospital with a staffed bed-count of 560. The gastroenterology training programme at the centre is approved by the College of Physicians and Surgeons of Pakistan (CPSP) for residency. There are three well-equipped endoscopy suites at the hospital and one fluoroscopy room for ERCP procedure in the Radiology Department.

Data collected related to all patients regardless of age or gender who underwent ERCP under the care of the operator.

Data excluded was related to patients with incomplete records, like no report or radiological images, and cases that involved altered anatomy of the biliary tree due to a prior sphincterotomy, pancreaticobiliary surgery or those that involved CBD stent removal.

Case files were retrieved with the help of the hospital's Health Information Management System (HIMS) by using The International Classification of Diseases Clinical Modification, 9th Revision (ICD) codes.¹⁰

Data extraction was done by a research assistant blinded

to the study. Data extracted comprised variables like demographics, admission type, details and indication for ERCP, diagnosis, cannulation outcome, duct clearance, complications, follow-up surgical intervention, radiological imaging and mortality post-endoscopy. Some of the missing information about imaging was collected from the comprehensive records in the AKUH radiology database.

Cannulation success was defined as complete cannulation in the setting of first 'pre-cut' incision on a duct with unaltered anatomy due to any prior procedure.

Duct clearance was considered to have been achieved when the free flow of bile was seen after cannulation of a duct in patients with choledocholithiasis and no residual stone was identified on imaging.

Complications included post-ERCP pancreatitis characterized by symptoms of severe pain in abdomen radiating to the back with associated nausea, in addition to an elevation in pancreatic enzymes following ERCP.

Bleeding was noted during ERCP at the time of sphincterotomy which is usually only minor and does not require any intervention. It was treated by serial observation and/or adrenaline sclerotherapy.

Perforation of the gut due to iatrogenic injury during the procedure was noted.

Mortality was defined as death within a week of ERCP due to procedural complications and not due to causes unrelated to the procedure.

Data was analysed using SPSS 19. Qualitative data was reported as frequencies and percentages, while quantitative data was reported as means±standard deviation (SD) or median with interquartile range (IQR) depending upon the distribution of data.

Results

Of 143 procedures performed, 102(71.3%) were included. The mean age was 52±17 years and 54(52.9%) of them were females.

In 70(68.6%) patients, the indication for ERCP was choledocholithiasis (Table 1).

Of the total, 74(72.5%) cases were elective admissions and 28(27.5%) were admitted via the emergency department (ED). Majority 98(96.1%) ERCPs were performed with therapeutic intent. Type of anaesthesia implied was monitored anaesthesia care (MAC) in 97(95.1%) cases and general anaesthesia (GA) in 5(4.9%). The average ERCP time was 41.5±5.5 minutes.

The cannulation success was the main outcome

Table-1: Indication of the Endoscopic Retrograde Cholangiopancreatography (ERCP) performed.

Indication	n (%)
Choledocholithiasis	70 (68.6)
Biliary Stricture	14 (13.7)
Ampullary carcinoma	16 (15.7)
Hydatid cyst	1 (1.0)
Bile leakage	1 (1.0)

Table-2: Complications after Endoscopic Retrograde Cholangiopancreatography (ERCP).

Complications	n (%)
Pancreatitis	5 (4.9)
Bleeding	8 (7.8)
Oesophageal Rupture	1 (1.0)
Mortality	0 (0)

investigated to determine competency and 96(94.1%) cases were completed with successful cannulation of the bile duct.

Among the 70(68.6%) cases of choledocholithiasis, complete duct clearance was achieved in 62(88.6%).

Post-ERCP pancreatitis was noted in 5(4.9%) patients who were managed during the hospital stay.

Post-ERCP minimal bleeding was reported in 8(7.8%) cases who did not require any intervention.

There was no duodenal perforation reported, and only 1(0.98%) case of oesophageal perforation. There was no ERCP-related mortality (Table 2).

Discussion

ERCP is considered the mainstay in the management of pancreatic and biliary pathology, but with the introduction of new comparatively less-invasive technologies, like EUS and magnetic resonance cholangiopancreatography (MRCP), the value of ERCP today mainly related to its therapeutic utility. Initially, ASGE had recommended a procedural 35-100 ERCP threshold before evaluating competency¹¹ but Jowell et al. demonstrated that 180 ERCPs were required before a gastroenterology fellow could be considered competent.¹² Moreover, according to the ASGE core curriculum, a successful cannulation rate of 80% is the threshold marker of competency in ERCP.¹³ Learning a new procedure is associated with the risk of acquiring unacceptable standards. All training institutions around the world should mandate rigorous supervision of trainees to ascertain that the trainee is credentialed to perform the procedure independently only after an acceptable level of performance has been achieved. The current study was conducted to investigate the competency of a recently-credentialed operator at a

tertiary care centre in Pakistan.

The operator concerned had a cannulation success rate of 94%. This is higher than the ASGE target of the successful bile duct or pancreatic duct cannulation before a trainee is considered competent at performing ERCP.^{4,10} This is also higher than the success rate of 88% reported in a study that evaluated the performance of multiple operators at a tertiary care centre in Pakistan.⁹

The average procedure duration in this study was 41.5±5.5 minutes, which is less than the mean duration of 45.6±30.1 minutes reported earlier.¹⁴ Mehta et al. suggested that the duration of ERCP procedure did not have a significant effect on the success rate of ductal cannulation, but a longer procedure may precipitate a higher risk of complication like post-ERCP bleeding.¹⁴

Recently, there has been a transition of interest from a diagnostic to almost a completely therapeutic application of ERCP in clinical medicine.⁷ These modifications in utilisation have also translated into change in the learning curricula pertaining to ERCP.¹⁵ About 96% of the ERCPs performed during the current study period had a therapeutic basis. Also, we used the successful cannulation of CBD as the main indicator of ERCP success, as recommended by ASGE.⁴

In addition to the varying procedural difficulty within different settings, it has been reported that deep biliary cannulation is considerably more difficult in patients with native papilla in comparison with those with a prior biliary sphincterotomy.^{16,17} In the current study, only those cases were analysed in which there had been no prior attempts of ERCP, or surgical interventions distorting the anatomical characteristics of the biliary tree.

Among the most common complications is post-ERCP pancreatitis, with an incidence of about 3.5%.¹⁸ Another study reported the incidence of post-ERCP pancreatitis of 4.2% in 13,513 procedures performed over 5 years in Austria.¹⁹ In our study, the rate of post-ERCP pancreatitis was 4.9%, and we think that a likely reason for it to be marginally higher than the rates reported earlier is that the sample size in our study was small.

During the course of the study, there was one case which was complicated by oesophageal rupture. The incidence of perforations related to ERCP is low (0.35%), and requires surgical intervention when large organs like oesophagus, stomach and duodenum are perforated. Advanced age, dilated bile duct, and a longer duration of procedure predispose the patient to undergo an iatrogenic perforation injury during ERCP.²⁰

The current study has its limitations. It did not look into the learning curve of the endoscopist during the training, which may have had an influence on competence. Also, it was a retrospective chart review over a period of 1 year, when a prospective analysis would have been more accurate, but that was not done owing to time and cost considerations. The current study relates to only one operator, and there is a need to have more studies comprising other operators at the centre to determine the overall level of competence.

Conclusion

The success rate of ERCP was found to be with few complications and zero mortality. Although it is a complicated procedure, competence in performing ERCP can be achieved during training by following a set criterion. The training programmes that credential prospective endoscopists should use algorithms to ensure that the trainees acquire competence in endoscopic procedures, like ERCP, before being credentialed to operate independently.

Disclaimer: None.

Conflict of Interest: None.

Source of Funding: None.

References

- Ladas SD, Novis B, Triantafyllou K, Schoeffl R, Rokkas T, Stanciu C, et al. Ethical issues in endoscopy: patient satisfaction, safety in elderly patients, palliation, and relations with industry. Second European Symposium on Ethics in Gastroenterology and Digestive Endoscopy, Kos, Greece, July 2006. *Endoscopy* 2007;39:556-65. doi: 10.1055/s-2007-966534.
- Beilenhoff U, Neumann CS. Quality assurance in endoscopy nursing. *Best Pract Res Clin Gastroenterol* 2011;25:371-85. doi: 10.1016/j.bpg.2011.05.005.
- James PD, Antonova L, Martel M, Barkun A. Measures of trainee performance in advanced endoscopy: A systematic review. *Best Pract Res Clin Gastroenterol* 2016;30:421-52. doi: 10.1016/j.bpg.2016.05.003.
- Faigel DO, Baron TH, Lewis B, Petersen B, Petrini J. Ensuring competence in endoscopy. [Online] 2005 [Cited 2020 June 12]. Available from URL: https://www.asge.org/docs/default-source/education/practice_guidelines/doc-competence.pdf?sfvrsn=6
- Rodrigues-Pinto E, Macedo G, Baron TH. ERCP competence assessment: Miles to go before standardization. *Endosc Int Open* 2017;5:e718-21. doi: 10.1055/s-0043-107780.
- Chutkan RK, Ahmad AS, Cohen J, Cruz-Correa MR, Desilets DJ, Dominitz JA, et al. ERCP Core Curriculum prepared by the ASGE Training Committee. ERCP core curriculum. *Gastrointest Endosc* 2006;63:361-76. doi: 10.1016/j.gie.2006.01.010.
- Verma D, Gostout CJ, Petersen BT, Levy MJ, Baron TH, Adler DG. Establishing a true assessment of endoscopic competence in ERCP during training and beyond: a single-operator learning curve for deep biliary cannulation in patients with native papillary anatomy. *Gastrointest Endosc* 2007;65:394-400. doi: 10.1016/j.gie.2006.03.933.
- Baron TH, Petersen BT, Mergener K, Chak A, Cohen J, Deal SE, et al. Quality indicators for endoscopic retrograde cholangiopancreatography. *Gastrointest Endosc* 2006;63(Suppl 4):s29-34. doi: 10.1016/j.gie.2006.02.019.
- Ghazanfor R, Liaqat N, Changeez M, Tariq M, Malik S, Ghazanfar KR, et al. Choledocholithiasis: Treatment Options in a Tertiary Care Setup in Pakistan. *Cureus* 2017;9:e1587. doi: 10.7759/cureus.1587.
- Centers for Disease Control and Prevention (CDC). International Classification of Diseases, Ninth Revision (ICD-9). [Online] 1999 [Cited 2020 June 12]. Available from URL: <https://www.cdc.gov/nchs/icd/icd9.htm>
- Clinical competence in diagnostic endoscopic retrograde cholangiopancreatography. Health and Public Policy Committee, American College of Physicians. *Ann Intern Med* 1988;108:142-4.
- Jowell PS, Baillie J, Branch MS, Affronti J, Browning CL, Bute BP. Quantitative assessment of procedural competence. A prospective study of training in endoscopic retrograde cholangiopancreatography. *Ann Intern Med* 1996;125:983-9. doi: 10.7326/0003-4819-125-12-199612150-00009.
- Training the gastroenterologist of the future: the Gastroenterology Core Curriculum. *Gastroenterology* 2003;124:1055-104. doi: 10.1053/gast.2003.50160.
- Mehta PP, Sanaka MR, Parsi MA, Albeldawi MJ, Dumot JA, Lopez R, et al. Association of procedure length on outcomes and adverse events of endoscopic retrograde cholangiopancreatography. *Gastroenterol Rep* 2014;2:140-4. doi: 10.1093/gastro/gou009.
- Jorgensen J, Kubiliun N, Law JK, Al-Haddad MA, Bingener-Casey J, Christie JA, et al. Endoscopic retrograde cholangiopancreatography (ERCP): core curriculum. *Gastrointest Endosc* 2016;83:279-89. doi: 10.1016/j.gie.2015.11.006.
- Johanson JF, Cooper G, Eisen GM, Freeman M, Goldstein JL, Jensen DM, et al. Quality assessment of ERCP. Endoscopic retrograde cholangiopancreatography. *Gastrointest Endosc* 2002;56:165-9. doi: 10.1016/s0016-5107(02)70172-7.
- Schutz SM, Abbott RM. Grading ERCPs by degree of difficulty: a new concept to produce more meaningful outcome data. *Gastrointest Endosc* 2000;51:535-9. doi: 10.1016/s0016-5107(00)70285-9.
- Andriulli A, Loperfido S, Napolitano G, Niro G, Valvano MR, Spirito F, et al. Incidence rates of post-ERCP complications: a systematic survey of prospective studies. *Am J Gastroenterol* 2007;102:1781-8. doi: 10.1111/j.1572-0241.2007.01279.x
- Kapral C, Mühlberger A, Wewalka F, Duller C, Knoflach P, Schreiber F. Quality assessment of endoscopic retrograde cholangiopancreatography: results of a running nationwide Austrian benchmarking project after 5 years of implementation. *Eur J Gastroenterol Hepatol* 2012;24:1447-54. doi: 10.1097/MEG.0b013e3283583c6f.
- Enns R, Eloubeidi MA, Mergener K, Jowell PS, Branch MS, Pappas TM, et al. ERCP-related perforations: risk factors and management. *Endoscopy* 2002;34:293-8. doi: 10.1055/s-2002-23650.