

PERFECT OR FAILED ERCP: WHAT MAKES THE DIFFERENCE?

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Disclosure: The authors have declared no conflicts of interest.

Received: 19.05.15 **Accepted:** 25.09.15

Citation: EMJ Gastroenterol. 2015;4[1]:108-113.

ABSTRACT

Endoscopic retrograde cholangiopancreatography (ERCP) has become an effective and safe therapeutic method, providing clinical success in more than 80% of cases. As ERCP has evolved from a diagnostic to a therapeutic procedure, technical demands have risen. Furthermore, it is an invasive procedure that can be potentially harmful when administered improperly. Quality of ERCP and procedural outcome are dependent on various factors that are related to the patient, procedure, and endoscopist. These factors are reviewed in detail and their contribution to ERCP quality is presented and discussed. Preventive therapies through procedural techniques and medical management to avoid complications are available. Proper and organised training and ERCP outcome reporting are essential for further quality improvement.

Keywords: Endoscopic retrograde cholangiopancreatography (ERCP), failure, cannulation, precut, efficiency, complications.

INTRODUCTION

Advances in endoscopic retrograde cholangiopancreatography (ERCP), sphincterotomy, and related techniques have progressively created a comprehensive grouping of therapeutic procedures. These have substantially changed the approach to diseases of the bile ducts and pancreas, and their impact can now be compared with that of laparoscopic surgery. ERCP and its associated methods have quickly spread throughout clinical practice in developed countries, are readily available, and can respond to demand without delay. Today, the majority of the interventions required in diseases of the bile ducts and pancreas can be performed by these methods and usually in a smart way - or at least we endoscopists assume so. How much do we know of the clinical experience with ERCP? How representative and reproducible are the data on these methods? How effective are they? How often do they fail when applied in the general population, and what makes the difference between success and failure? We are concerned that our data are still selective and fragmentary,

and cover the issue like a mostly incomplete mosaic. Results are systematically reported only by tertiary care centres, with the data focussed on technical achievements because the overwhelming majority of procedures are done on an outpatient basis with limited patient follow-up. Consequently, our awareness of complications is also limited. We can only speculate that the less active centres and less experienced practitioners are understandably reluctant to share their possibly inferior results and numerous side effects. The achievements and complications of endoscopic methods are not consistently defined, described, classified, or researched. Admittedly, the willingness to report and share data might also be influenced by the security of personal and patient data and legal obstacles.

OUTCOME MEASUREMENT

As with other therapeutic strategies, ERCP-related methods are only meaningful if they provide consistent, sustained relief and cure. The clinical outcomes are difficult to measure because ERCP is used to treat different diseases with different

therapeutic needs, often on an outpatient basis. Therefore, surrogate characteristics are usually utilised in order to evaluate the efficacy of these procedures, including procedural technical achievements and short-term occurrence of complications. According to recently published American Society for Gastrointestinal Endoscopy practice guidelines, technical achievements and other quality indicators are classified as pre, intra, and postprocedural process measures. The most important of these include appropriateness of indication, obtaining informed consent, use of antibiotics, whether the procedure has been performed by a trained and credentialed endoscopist, volume of ERCPs performed per endoscopist, deep cannulation of the ducts of interest in a naïve papilla without altered anatomy, extraction of common bile duct stones <1 cm in diameter, stent placement in obstructions below the bifurcation, completeness of the ERCP report, all adverse events with particular emphasis on pancreatitis, perforation, and bleeding, and contact with the patient with the aim to detect delayed complications. Perhaps surprisingly, prevention of post-ERCP pancreatitis (PEP) is not addressed.

In general, our aim is a perfect ERCP, which can be characterised using the quality indicators as making a significant contribution to the diagnosis, immediate access to treatment within a single session, acceptable tolerability for the patient, successful treatment without complications, and a complete report including the indication, analgosedation, prevention of complications, details of the technique and accessories used, outcome, and recommendation. Outcomes assessed should include stone extraction rate, fluoroscopy time, and rate of successful stent placement. Conversely, a failed procedure means that deep cannulation was not achieved, diagnosis was not established, treatment was not completed, or side effects occurred.¹

The outcome of each procedure is affected by several factors, including the indication, American Society of Anesthesiology (ASA) Grade Estimated Comorbidities score, sedation, anatomy of the upper gastrointestinal tract, equipment, technique, experience and skill of the provider, prevention of complications, and the reporting method.

ERCP EFFICIENCY

The intraprocedural quality of ERCP has been evaluated in several multicentre assessments.

A retrospective analysis by DeBenedet et al.² selected 52 of 8,005 retrieved publications for evaluation and showed that bile duct cannulation was achieved in 89.3% (77–98.6%), the precut utilisation rate was 10.5%, common bile duct stones were successfully removed in 88.3% of procedures, and biliary stenting below the junction was achieved in 97.5%. A subgroup analysis showed no statistically significant differences between academic and community settings and in trainee participation. Peng et al.³ prospectively analysed anonymous, self-reported procedures in a web-based registry of cases involving 3 continents, 85 endoscopists (60 USA, 16 UK, and 9 in other countries), and 13,018 ERCPs including 6,732 outpatient procedures. A total of 3,746 procedures (28.8%) were described as difficulty level 3; 30.5% were labelled as ASA score III–V, either propofol with anaesthesiologist monitoring or general anaesthesia was used in 55.3%, and trainees participated in 31.6% of the procedures. Initial deep cannulation without precut was achieved in 89.9% (63.9–100%), and precut was performed in 6.7%, giving a final cannulation rate of 95.6%. The mean duration of the procedures was 25 minutes. The experience of endoscopists with ERCP was a median 12 years (range: 0–36), the median lifetime volume was 1,200 procedures (range: 175–15,000), and the median annual volume was 150 procedures (range: 10–940). Success was more likely in outpatients (odds ratio [OR]: 1.21) and with trainee involvement. The major factors predicting failure included high ERCP difficulty level (OR: 0.59), ASA score III–V (OR: 0.77), obstructive jaundice without stones (OR: 0.51), postsurgically altered bile duct anatomy (OR: 0.51), teaching cases (OR: 0.53), and certain indications (e.g. strictures or acute pancreatitis).

As expected, reports from less developed countries, where expertise and availability of instruments and medical devices are limited, are relatively rare. A study from Peru reported the results of 202 ERCPs performed within 2 years, with a failure rate of 17.3% and overall complication rate of 5.9%.⁴ Peñaloza-Ramírez et al.⁵ reported a success rate of 79.6% and a complication rate of 7.6% in 381 ERCPs performed over a period of 2 years in Bogota, Colombia. Gurung et al.⁶ retrospectively analysed the results of 423 ERCP procedures conducted from August 2011 to August 2013 at a centre in Nepal. The cannulation rate was 94.1%, with PEP occurring in 4%.

CANNULATION TECHNIQUE

The cannulation rate can be influenced by the cannulation technique used, which can be by contrast injection (CI), with the assistance of a guidewire (GW), the 'double-wire' technique, or after precut. The contrast-assisted method and wire-guided cannulation have been compared in many studies and meta-analyses. Two meta-analyses published in 2009 showed better cannulation rates and less PEP with GW assistance (cannulation with GW: 85.3%, cannulation with CI: 74.9%; PEP OR: 0.23;⁷ cannulation with GW: 89%, cannulation with CI: 78%; rate of PEP with GW: 3.2%, rate of PEP with CI: 8.7%).⁸ Five comparative studies and one meta-analysis have subsequently been published. Two randomised controlled studies reported equal cannulation success and PEP rates (cannulation with GW: 83%, cannulation with CI: 87%; rate of PEP with GW: 6.1%, rate of PEP with CI: 6.3%;⁹ rate of PEP with cannulation with or without GW: 5.9% and 4%, respectively; rate of PEP with sphincterotome with or without GW: 2.1% and 2%, respectively).¹⁰ In a meta-analysis published in 2013, incidence of PEP was lower in GW groups (OR: 0.51), the cannulation rate was higher (OR: 1.07), and need for precut was lower (OR: 0.75).¹¹

With the so-called double-wire technique, involving primary inadvertent but repeat cannulation of the pancreatic duct, the first wire remains in the pancreatic duct and the second wire is inserted in the presumed direction of the biliary orifice. As the PEP rate is likely to be higher with this technique, temporary pancreatic stenting is recommended.¹²

FAILED CANNULATION

In procedures involving difficult cannulation, the options to consider include: a repeat procedure 1 or 2 days later; referral to another endoscopist; continuation with the technique used; switching to another cannulation technique or precut.

Desirable deep cannulation by an experienced endoscopist using standard techniques is successful in approximately 85–90% of cases. Cannulation becomes difficult in about 5–10% of cases, especially in patients with altered anatomy, ampullary tumours, inflammatory changes of the intestine due to pancreatitis, juxtapapillary diverticula, and particularly with a modulated papillary shape. In the latter case, access to the bile duct can be achieved

by a blind cut performed using either the Erlangen sphincterotome with or without the GW inserted into the pancreatic duct, or by the needle knife, in which case the precut can start either in the orifice or on the plica longitudinalis above the orifice (fistulotomy). PEP can be prevented by the temporary insertion of a pancreatic stent. There is debate regarding the optimal technique and the timing and safety of the precut. Many studies found an increased risk of PEP with this technique, but it remains unclear whether the increased rate of PEP is related to the precut itself or to prolonged cannulation. Recently, two meta-analyses were published in the same year. A review by Navaneethan et al.¹³ aimed to study the cannulation rate and complications of early precut compared with persistent attempts at standard cannulation. The cannulation rate with the first technique was 90% versus 86.3% with the second. The PEP rates were not significantly different (3.9% versus 6.1%), and the overall occurrence of complications was nearly the same with the two techniques. In the seven studies reviewed, timing varied between 5 and 12 minutes; a needle knife was used in six studies, and a sphincterotome was used in one. Choudhary et al.¹⁴ analysed the same seven randomised trials plus an additional seven non-randomised comparative trials. The analyses differ in the terminology of precut techniques (needle knife: six, sphincterotome: one in the study by Navaneethan et al.,¹³ papillotomy: four, fistulotomy: two, and both techniques: one in the study by Choudhary et al.).¹⁴ Similarly to the first study, Choudhary et al.¹⁴ found a nonsignificant trend in favour of precut.

CASE VOLUME

Other important issues including the endoscopist's experience, case volume, and case mix have been addressed in several studies. Varadarajulu et al.¹⁵ examined health-related outcomes after ERCP in relation to hospital procedure volume using the National Inpatient Sample database. Data from 2,629 hospitals and 199,625 ERCPs in the USA were evaluated. The median number of ERCPs performed in participating hospitals was 49 per year (range: 1–1,004), with 25% of hospitals performing ≥ 100 ERCPs per year and 5% performing ≥ 200 per year. Multivariate regression analysis found significant negative relationships between procedure volume and procedure failure rates, but did not find a significant effect on inpatient mortality.

Williams et al.¹⁶ aimed to identify the principal risk factors for ERCP complications in a prospective analysis of results from 66 study centres and 5,264 ERCPs at the institutional level. Neither the number of ERCPs performed annually nor the hospital type (i.e. district versus university hospital) was significantly associated with overall complication rates. Nevertheless, in a subgroup of patients with pancreatitis, the risk of PEP was significantly lower in university hospitals. Loperfido et al.¹⁷ prospectively studied the complication rates reported by small and large centres stratified by a threshold volume of 200 procedures performed annually. Small centres (i.e. <200 procedures per year) and precut technique were found to be independent risk factors for major complications overall; age <70 years, pancreatic duct opacification, and nondilated common bile duct were identified as risk factors for PEP.

Testoni et al.¹⁸ compared high and low-volume centres (median: 257 versus 45 procedures per year) to identify the risk factors for PEP. There were more procedures of Grade 3 difficulty performed in the high-volume centres, but the PEP rates in the two centre types or according to expert and non-expert operators were not significantly different (3.8% versus 5.5%). Univariate and multivariate analyses of data from the high-volume centres found a significant association of PEP with a history of pancreatitis, young age, absence of bile duct stones, >10 attempts to cannulate Vater's papilla, pancreatic duct cannulation, and precut technique.

An Austrian nationwide voluntary benchmarking project collected data from both academic and community-based endoscopy centres. Fourteen were high-volume centres performing more than 200 procedures per year and 28 were low-volume centres with fewer than 200 procedures per year. A total of 13,513 procedures were analysed. The patient population included 36% with severe comorbidities and 26.9% on anticoagulation medications. The common bile duct was visualised in 88.7% of the procedures; nevertheless, the percentage of naïve papillae was not mentioned and nor was the difference in bile duct visualisation between low and high-volume centres. The overall therapeutic and diagnostic targets were achieved in 84.8% and 80.3%, respectively. Precut sphincterotomy was associated with an increased risk of PEP (7.9% versus 4.1% in other patients), but use of the needle knife was not. GW-assisted cannulation was used in 84.6% and PEP rates were significantly higher with this technique (4.3% versus 1.3%). High-volume centres had increased rates of bleeding and cardiopulmonary complications, but there were no differences in PEP and cholangitis rates.¹⁹

Perhaps surprisingly, the influence of the individual shape of the papilla is rarely questioned. Swan et al.²⁰ analysed 51 referred, primarily unsuccessful ERCPs. The reasons for failure included a long and mobile (floppy) papilla with a long intraduodenal segment of the common bile duct (8.29%), unstable position (9.32%), a small papilla (4.14%), or periampullary diverticulum (7.25%).

Table 1: Independent risk factors for PEP according to ESGE guidelines.¹²

Patient-related	Procedure-related
<i>Definitive risk factors</i>	
Sphincter of Oddi dysfunction	Cannulation attempts duration >10 minutes
Female gender	Pancreatic guidewire passages >1
Previous pancreatitis	Pancreatic injection
<i>Likely risk factors</i>	
Previous PEP	Precut
Younger age	Pancreatic sphincterotomy
Nondilated extrahepatic bile ducts	Biliary balloon sphincter dilation
Absence of chronic pancreatitis	Failure to clear bile duct stones
Normal serum bilirubin	Intraductal ultrasound

PEP: post-endoscopic retrograde cholangiopancreatography pancreatitis; ESGE: European Society of Gastrointestinal Endoscopy.

ALTERED ANATOMY

For very obvious reasons, the success rate of ERCP is lower in patients with an altered upper gastrointestinal anatomy. In some patients, for example those with a Billroth II gastrectomy, ERCP can often be successfully performed using the standard technique. In other situations, the success rate can be increased with the use of overtube-assisted enteroscopy techniques. Skinner et al.²¹ performed a systematic review of published articles on this issue, which included 23 relevant reports and 945 procedures. Among patients with Roux-en-Y gastric bypass, the ERCP success rate was 70%, and in patients with Roux-en-Y surgery with either a pancreaticoduodenectomy, pylorus-preserving pancreaticoduodenectomy, or hepaticojejunostomy, the ERCP success rate was 76%. In patients after Billroth II resection, the success rate of ERCP was 90%. All kinds of deep enteroscopy with either a single or double balloon, or with a spiral overtube, can be applied. Representative, prospective comparative studies are not realistic due to the characteristics of the procedure and the small number of ERCP procedures in patients with altered anatomy.

Smart, standard cannulation of the duct can also be prevented by juxtapapillary diverticula, particularly if the papilla is hidden inside. Numerous studies have been published and numerous approaches have been proposed for overcoming this anatomical obstacle. Techniques include use of biopsy forceps or clipping an approaching papilla, a forward-viewing endoscope with a cup, simultaneous use of two endoscopes, or two accessories in one scope; but a precut is effective in most difficult scenarios.

TRAINING

Everyone has the right to receive qualified healthcare, including advanced endoscopy, but this legitimate requirement can be difficult to meet. Ideally, the advanced endoscopist should undergo a fellowship programme not only in ERCP, but also in endoscopic ultrasound. This should involve more than 200 ERCPs under supervision and might take several years to complete. Nevertheless, to become fully comfortable with the procedure requires, according to the authors' experience, approximately 1,000 ERCPs; and, in order to maintain a high standard, more than 100 procedures completed annually without long intervals. Several countries have strict national control over the

practice, while others have a system based, more or less, on free competition.²² The measures of competence during training and final accreditation are poorly defined. Ekkelenkamp et al.,²³ using the Rotterdam Assessment Form for continuous self-assessment by a group of 15 trainees, documented improvement of cannulation from 36–85% after 200 procedures, and from 22–68% after 180 procedures in patients with naïve papillae. Competence should be credited on learning curves rather than on threshold numbers alone.²³

COMPLICATIONS

ERCP is a highly demanding technique and understanding of the potential complications is a must. PEP is the most frequent harmful complication and has a frequency of 5–10% in most studies; the risk factors are shown in [Table 1](#). In its recently published guidelines for PEP prevention, the European Society of Gastrointestinal Endoscopy recommends routine rectal administration of non-steroidal anti-inflammatory drugs (NSAIDs), keeping the number of cannulation attempts as low as possible, restricted use of pancreatic GW backup technique, and precut after the insertion of a pancreatic stent in difficult cannulations. The risk of bleeding according to a meta-analysis of 21 studies was 1.3%, with 70% of the episodes classified as mild. Besides sphincterotomy, precut technique, low-volume centres, papillary stenosis, cholangitis, coagulopathy, and recent use of anticoagulation, aspirin, and other NSAIDs do not increase risk of PEP. The rate of perforation is reported to vary from 0.1–0.6%. Risk factors include sphincterotomy, precut technique, dilation, and, particularly, B II resection. Risk factors for cholangitis, which has a rate of less than 1%, include icterus, incomplete drainage, complicated strictures, and low-volume centres. PEP and complications together serve as a surrogate criterion, as mentioned above.²⁴

SUMMARY

It can be concluded that ERCP itself and its related therapeutic methods are obviously extremely effective and safe, ensuring full and sustained clinical success in more than 80% of cases. The breadth and quality of the armamentarium can satisfy most demands, and comprehensive knowledge of the complications results in their effective prevention. The procedure has reached a peak and cannot be significantly improved in

tertiary centres. Nevertheless, it remains invasive and is thus potentially hazardous when done improperly. Most of our knowledge of and experience with ERCP has been obtained from several regularly publishing centres and may be prone to bias. How then to proceed? The relevant professional societies should use their influence to organise training programmes in advanced endoscopy, respecting the needs of the patient population, local healthcare systems, and legal principles. The training and continuing education programmes must be precisely and transparently organised, allowing all trainees the opportunity to

fully master the procedure before performing it on their own, and must allow qualified endoscopists to maintain their skills and expand their knowledge. To obtain representative information about what we do is a principal goal. Countries with high standards of healthcare and endoscopy should begin building a web-based, online central registry of their procedures, beginning with the leading centres. Continuing participation by community units would follow, respecting local legislation, data security, and voluntary principles. Reporting should take into account the universally accepted definitions, classifications, and terminology.

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