

# Guideline on training and credentialing in endoscopic retrograde cholangiopancreatography

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## ABSTRACT

**The aim of the Endoscopic Retrograde Cholangiopancreatography (ERCP) Working Group was to examine the issues of training, credentialing and quality control in ERCP in Singapore. Published guidelines and clinical trials concerning issues of training, complications and quality control in ERCP have been reviewed. The Working Group recommended that a trainee reach a minimum threshold of 200 cases before the assessment of competency. The target for achievement of competency was set at an 85 percent successful cannulation rate for native papilla. To perform advanced ERCP, endoscopists should have undergone dedicated training either in a recognised training centre or in conjunction with and under the guidance of a more experienced colleague, until technical competency is achieved. Precut should only be performed by endoscopists with experience and expertise in performing Levels II and III ERCP, who have been formally proctored. An audit of ERCP should examine parameters such as appropriate indication, success rates of selective cannulation, technical success rate of commonly performed procedures and procedure-related complications. To maintain technical competency, an individual should be performing ERCP on a regular basis. In conclusion, the innate risks of ERCP necessitate that all ERCP practitioners should be appropriately trained, practise within their expertise level and maintain regular practice in order to minimise risks and improve patient outcome.**

**Keywords: competency, credentialing, endoscopic retrograde cholangiopancreatography, guideline**

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## INTRODUCTION

The Endoscopic Retrograde Cholangiopancreatography (ERCP) Working Group was set up under the auspices of the Academy of Medicine, Singapore to examine the

issues of training, credentialing and quality control in ERCP in Singapore. ERCP is an effective modality for the diagnosis and treatment of pancreaticobiliary disorders, offering patients a minimally invasive alternative to surgery. It is generally regarded as the endoscopic procedure associated with the highest risk of potentially serious complications, such as pancreatitis, perforation, delayed bleeding and the need for salvage surgery. Even though these complications are uncommon, especially in experienced and trained hands, it is important to outline, on a national basis, the accepted standards of practice in ERCP so as to ensure consistent clinical standards in patient management. This article is formulated based on scientific evidence, and where such data is lacking, decisions are made on the basis of expert opinion from the Working Group members, who are all experts in the field.

## INDICATIONS FOR ERCP

The main role of ERCP is in the treatment of benign and malignant biliary tract and pancreatic duct disorders. Benign disorders include choledocholithiasis, benign biliary strictures, biliary leaks, pancreatic duct leaks, pseudocysts and chronic pancreatitis. Malignant disorders include cholangiocarcinoma, pancreatic cancer and ampulla cancer. The diagnostic role of ERCP in pancreaticobiliary disorders has been reduced significantly in current clinical practice, due to the availability of much less invasive alternative imaging techniques such as magnetic resonance cholangiopancreatography and endoscopic ultrasonography. Nonetheless, ERCP retains a small but important diagnostic role in selected cases such as suspected biliary or pancreatic duct leak, biliary stricture of indeterminate aetiology and suspected sphincter of Oddi dysfunction. In such instances, additional measures like brush cytology, biopsy, cholangioscopy, pancreatoscopy and intraductal ultrasonography may be required. The indications for ERCP are summarised in Table I.<sup>(1)</sup>

## LEVELS OF DIFFICULTY IN ERCP

It is now well recognised that the technical difficulty of ERCP varies according to the individual case. These differences in levels of difficulty reflect both

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**Table I. Appropriate indications for endoscopic retrograde cholangiopancreatography.**

	Biliary tract disorders	Pancreatic disorders
Benign diseases	Bile duct stones Benign biliary strictures with obstruction Biliary leak Suspected sphincter of Oddi dysfunction Choledochal cyst/cholechocele Papilla stenosis Sump syndrome	Chronic pancreatitis with pancreatic duct stones Pancreatic duct leak or fistula Pancreatic pseudocyst Pancreatitis of unknown aetiology Symptomatic pancreas divisum
Neoplastic diseases	Cholangiocarcinoma Ampulla adenoma Ampulla cancer	Pancreatic head cancer with obstruction
Others	Clinical and biochemical/imaging data suggestive of biliary tract disease	Clinical and biochemical/imaging data suggestive of biliary tract disease

underlying anatomical considerations as well as disease type. Anatomical factors that increase the level of difficulty include location of the major papilla within a diverticulum, the need to cannulate the minor papilla and post-surgical states such as previous Billroth II partial gastrectomy. Disease factors that increase the level of difficulty include the need to extract biliary stones larger than 1 cm, the treatment of perihilar strictures, cholangioscopic diagnostics and therapeutics as well as pancreatic therapeutics. The different levels of difficulty are summarised in Table II.<sup>(2)</sup>

### TRAINING IN ERCP

It is now accepted that additional subspecialty training for ERCP is required after completion of Advanced Specialist Training in Gastroenterology or Surgery, given the time constraints during specialist training. In general, an additional year of training is required in order to expose the trainee to an adequate variety and volume of cases, so as to develop both cognitive and technical skills. In exceptional cases in a high-volume training centre, six months of dedicated training may suffice. The American Society of Gastrointestinal Endoscopy (ASGE) ERCP Core Curriculum is a useful guide to the training syllabus, which should be considered by training programmes for ERCP.<sup>(3)</sup>

### BASIC COMPETENCY IN ERCP

When ERCP was first introduced four decades ago, the pioneers had no one to mentor them. Through repeated practice in a high-volume setting, mastery was achieved. Now that ERCP is a mainstream technique, formal training is a prerequisite in order to facilitate training and enhance patient safety. Indeed, as time goes by and more data is accrued, the threshold number of ERCP procedures that trainees are required to perform before competency assessment has increased. In 1996, the Gastroenterology

**Table II. Levels of difficulty in ERCP [modified from Chutkan et al<sup>(3)</sup>].**

Difficulty	Nature of procedure
Level I	Diagnostic cholangiogram Diagnostic pancreatogram Biliary brush cytology Pancreatic cytology Standard sphincterotomy Removal of bile duct stones < 10 mm Stricture dilation/stent/nasobiliary drain for extrahepatic stricture or bile leak
Level II	Diagnostic cholangiogram with Billroth II anatomy Diagnostic pancreatogram with Billroth II anatomy Removal of bile duct stones > 10 mm Minor papilla cannulation Stricture dilation/stent/nasobiliary drain for hilar tumours or benign intrahepatic strictures
Level III	Precut for selective cannulation Sphincter of Oddi manometry Cholangioscopy Pancreatoscopy Any therapy with Billroth II anatomy All pancreatic therapy, including pseudocyst drainage Removal of intrahepatic stones or any stones with lithotripsy

Core Curriculum stated that fellows were required to complete 100 ERCP procedures, 25 of which were therapeutic cases (20 sphincterotomies and five stent placement cases), before the competency assessment.<sup>(2)</sup> Subsequently, the ASGE ERCP Core Curriculum revised the threshold number required to achieve competency to 200 cases, with at least half being therapeutic cases.<sup>(3)</sup> This was related to publications that showed that the overall competency in ERCP could only be achieved by fellows after 180–200 cases.<sup>(4)</sup> However, the level of difficulty in cannulation of a native papilla is clearly higher than that with previous papillotomy. To this end, another recent study showed that successful deep cannulation of a native papilla was consistently achieved only after 350 cases.<sup>(5)</sup> The Working Group endorses the 200-cases threshold

for assessment of competency in a trainee. The target for achievement of competency is set at an 85% successful cannulation rate for native papilla.

### COMPETENCY IN ADVANCED ERCP

To achieve competency in Levels II and III ERCP, the endoscopist should ideally undergo further training in a recognised training centre in order to have adequate case exposure. In the absence of such further training, it is equally acceptable for an endoscopist who is already trained to perform Level I ERCP independently to undertake Levels II and III procedures in conjunction with and under the guidance of a more experienced colleague, until technical competency and confidence are achieved. The technique of precut is very useful for achieving deep cannulation when standard cannulation techniques fail.<sup>(6)</sup> In expert hands, it is a safe and effective technique, and the complication rates are similar to those of standard ERCP techniques.<sup>(7,8)</sup> However, it has also been associated with higher rates of perforation and pancreatitis, and as such, is clearly a dangerous technique if the endoscopist lacks sufficient experience. There is currently no consensus on what constitutes adequate training for precut. In fact, in all the publications concerning success and complications of precut to date,<sup>(9-13)</sup> the endoscopists had not undergone formal hands-on training before performing precut. However, these were experienced endoscopists who had previously trained in high-volume centres, but the results of a less experienced community ERCP practitioner who has not undergone dedicated training at a high-volume centre would most likely be worse. Thus, the Working Group recommends that precut should only be performed by endoscopists with experience and expertise in performing Levels II and III ERCP, and that they should have been formally proctored in precut.

### COMPETENCY TARGETS IN ERCP

The Working Group endorses the competency targets set by the ASGE Taskforce on Quality in Endoscopy.<sup>(14)</sup> There are two aspects to competency assessment, namely success in achieving deep cannulation of the desired duct and technical success of the procedure. Successful cannulation rates  $\geq 80\%$  are the minimum goal in training programmes. Most endoscopists should have successful cannulation rates of  $\geq 85\%$ . Overall success rates  $\geq 90\%$  should be the ideal target. Expert endoscopists should consistently achieve success rates above 95%. When cannulation rates are calculated, failed examinations due to inadequate sedation or prior abdominal surgery such as pancreaticoduodenectomy (Whipple operation), Billroth II anatomy, prior gastrojejunostomy and hepaticojejunostomy

**Table III. Important complications of ERCP [modified from Baron et al<sup>(14)</sup> and Rochester et al<sup>(16)</sup>].**

Complication	Risk of complication*
Acute pancreatitis	5 (range 1–15)
Delayed bleeding	0.76–3.20
Severe bleeding	0.3–0.5
Perforation	0.3–1.3
Mortality from perforation	8–14
Mortality	0–1
Cholangitis	0.3–1.3 (up to 5% reported)
Acute cholecystitis	0.1–0.7
Cardiopulmonary complications	2.3

\*All data is reported in percentage.

and obstruction to the duodenum should be excluded. Additionally, procedures that are aborted due to a high volume of retained gastric contents or inability to achieve adequate sedation should be excluded. Apart from successful cannulation, the technical success of ERCP is also dependent on other manoeuvres, including traversing of a stricture, extraction of stones and successful stent placement. Technical success for commonly performed procedures (stone extraction, relief of biliary obstruction, stent placement for bile leaks) should be achievable in more than 85% of cases, and this will serve as a useful audit tool. Additionally, prior to accreditation for independent performance of ERCP, an individual should demonstrate clinical maturity, i.e. being able to judge correctly the best course of action to take for a patient's condition and to assess whether he/she has the ability to perform the required procedure, or if he/she should seek the assistance of or refer the case to a more experienced colleague.

### QUALITY CONTROL IN ERCP<sup>(14)</sup>

Parameters to be assessed during quality control audit can be classified into three components: (1) pre-procedural; (2) peri-procedural; and (3) post-procedural. Pre-procedural considerations include documentation of an appropriate indication, obtaining of informed consent, appropriate assessment of procedural difficulty and the appropriate use of prophylactic antibiotics. Peri-procedural factors include success rate of selective cannulation, rate of the desired duct and technical success rate of commonly performed procedures, such as extraction of common bile duct stones and biliary stent placement. Post-procedural factors to be monitored consist of procedure-related complications, including adverse effects of sedation (e.g. cardiopulmonary depression) and local complications (e.g. pancreatitis, bleeding and perforation). The common complications are summarised in Table III;<sup>(14-16)</sup> a more detailed discussion of the definition, predisposing factors and means of

minimising these complications can be found in a study conducted by Rochester and Jaffe.<sup>(16)</sup> To facilitate audit, it is recommended that ERCP practitioners maintain a personal log. As an alternative, the centre should have in place data tracking mechanisms for the purpose of audit.

### MAINTAINING TECHNICAL COMPETENCY

The Working Group acknowledges that there are currently no scientifically validated published numbers for the maintenance of technical proficiency. Nonetheless, it is clear that if an individual stops performing a technical procedure or does it infrequently, the proficiency level would be affected. The Working Group is of the opinion that to maintain clinical competency, an individual should be performing ERCP on a regular basis. However, the issue remains complex, as the variability of an individual's motor skills, case-mix, anatomic variations and type of ERCP procedures all have an impact on the success or failure of the procedure. For example, the minimum number of procedures that a physician needs to perform before a significant deterioration in skills occurs is unknown. This needs to be addressed before a clear recommendation can be made.

### CONCLUSION

This document summarises the deliberations of the ERCP Working Group concerning the important issue of credentialing and maintenance of technical proficiency in ERCP. Although ERCP is a safe and highly effective technique for management of pancreaticobiliary disorders, it has a small risk of very serious complications. Hence, it is important that all ERCP practitioners are adequately trained, practise within their expertise level and maintain regular practice in order to minimise risks and improve patient outcome. The Working Group acknowledges that with technological advances, there may be a need to revise these recommendations in the future.

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