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# ADVANCED DIGESTIVE ENDOSCOPY: ERCP

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EDITED BY  
PETER B. COTTON  
AND  
JOSEPH LEUNG



**Blackwell**  
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# Preface

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There was a time, long ago, when endoscopy was a small off-shoot of gastroenterology, and when most of what budding endoscopists needed to know could be covered in a slim book. Thus *Practical Gastrointestinal Endoscopy* was conceived by Christopher Williams and myself over 25 years ago, and had a successful run through four editions. The field has expanded enormously over that time. The number and variety of procedures, and the relevant scientific literature, have proliferated, and there is now a hierarchy within endoscopy. There are ‘standard’ procedures which most clinical gastroenterologists master during their training. These constitute routine upper endoscopy and colonoscopy, with their common therapeutic aspects, which may be needed at work every day (and some nights). Then there are recognized ‘advanced’ procedures, such as ERCP and EUS, and the more adventurous therapeutic aspects of upper endoscopy and colonoscopy, such as fundoplication, EMR, and tumor ablation. These are practiced by only a small percentage of endoscopists, who need more focused and intensive training. In addition, for a few of the leaders, there is much to be learned in related fields, such as unit design, management, teaching, and quality improvement. It is clear that no one person (or two) can speak or write about all of this territory with any authority. Advice and instruction are best given by acknowledged experts in each specific area.

My publishing journey reflects these changes. Thus, the latest (5<sup>th</sup>) Edition of *Practical Gastrointestinal Endoscopy*, sub-titled ‘The Fundamentals’, published in 2003, is devoted solely to the basic facts which all trainees need in their first year or two. It is accompanied by 2 practical CDRoms, one devoted to each ‘end’. We removed all of the ‘advanced stuff’, such as ERCP, teaching methods, and unit management.

We then sought to serve the needs of the established endoscopists, and of those learning more advanced aspects, with a new series called ‘Advanced Digestive Endoscopy’. Reflecting the acceleration of our world, we saw this primarily as a virtual ‘ebook’, presented electronically for speed of posting and for easy updating. This is now evolving on the comprehensive Blackwell Publishing website [www.gastrohep.com](http://www.gastrohep.com). It has 5 separate sections:—Endoscopic Practice

and Safety, Upper Endoscopy, Colonoscopy, ERCP, and EUS. I was delighted to be joined in this endeavor by new partners; Joseph Leung, Joseph Sung, Jerry Wayne, and Rob Hawes. Between us we have persuaded over 40 distinguished colleagues from all over the world to make contributions.

Despite the multiple benefits of electronic publishing, there is still a demand for print books. Jerry Wayne's book on Colonoscopy, co-edited with Doug Rex and Christopher Williams, is already in print (the ebook version consists of a selection of those chapters).

Here we present the print version of ERCP. I am enormously grateful to Joseph Leung and to the 12 other contributors who have labored long and hard to bring it to fruition. The fact that most of the authors are based in the USA should not be misinterpreted, for the expertise and methods of ERCP are now truly international. The electronic version will continue, and will be updated every year or so. We welcome your criticism and suggestions for improvement.

Joseph and I offer our sincere thanks to our families for their support and forbearance, and to our colleagues and trainees who have taught us so much, not least how much we still have to learn.

Peter B Cotton MD FRCP FRCS February 2005  
Digestive Disease Center, Medical University of  
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# ERCP Overview—A 30-Year Perspective

PETER B. COTTON

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## Historical background

Endoscopic cannulation of the papilla of Vater was first reported in 1968 [1]. However, it was really put on the map shortly afterwards by several Japanese groups, working with instrument manufacturers to develop appropriate long side-viewing instruments [2–5]. The technique (initially called ECPG—endoscopic cholangiopancreatography—in Japan) spread throughout Europe in the early 1970s [6–13]. Early efforts were much helped by a multinational workshop at the European Congress in Paris in 1972, organized by the Olympus company. ERCP rapidly became established worldwide as a valuable diagnostic technique, although doubts were expressed in the USA about its feasibility and role [14], and the potential for serious complications soon became clear [15–18]. ERCP was given a tremendous boost by the development of its therapeutic applications, notably biliary sphincterotomy in the mid-1970s [19–21] and biliary stenting 5 years later [22,23].

It is difficult for most gastroenterologists today to imagine the diagnostic and therapeutic situation 30 years ago. There were no scans. Biliary obstruction was diagnosed and treated surgically, with substantial operative mortality. Non-operative documentation of biliary pathology by ERCP was a huge step forward. Likewise, ERCP was an amazing development in pancreatic investigation at a time when the only available test was laparotomy. The ability to ‘see into’ the pancreas, and to collect pure pancreatic juice [24], seemed like a miracle. We assumed that ERCP would have a dramatic impact on chronic pancreatitis and pancreatic cancer. Sadly, these expectations are not yet realized, but endoscopic management of biliary obstruction was clearly a major clinical advance, especially in the sick and elderly. The period of 15 or so years from the mid-1970s really constituted a ‘golden age’ for ERCP. Despite significant risks [25], it was obvious to everyone that ERCP management of duct stones and tumors was easier, cheaper, and safer than available surgical alternatives. Large series were published, including some randomized trials [26–31]. Percutaneous transhepatic cholangiography (PTC) and its drainage applications were also developed

during this time, but were used (with the exception of a few units) only when ERCP failed or was not available. The ‘combined procedure’—endoscopic cannulation over a guidewire placed at PTC [32,33]—became popular for a while, but was needed less as both endoscopic and interventional techniques improved.

## **The changing world of pancreatico-biliary medicine**

The situation has changed in many ways during the last two decades. ERCP has evolved significantly, but so have many other relevant techniques.

### **The impact of scanning radiology**

Imaging modalities for the biliary tree and pancreas have proliferated. High quality ultrasound, computed tomography, endoscopic ultrasonography, and MR scanning (with MRCP) have greatly facilitated the non-invasive evaluation of patients with known and suspected biliary and pancreatic disease. As a result, the proportion of ERCP examinations now performed purely for diagnostic purposes has diminished significantly. However, it remains a very accurate diagnostic tool, and continues to shed important light in selected cases where all of the non-invasive tests have been inconclusive.

### **Extending the indications for therapeutic ERCP**

The second major change has been the attempt of ERCP practitioners to extend their therapeutic territory from standard biliary procedures into more complex areas such as pancreatitis and suspected sphincter of Oddi dysfunction. The value of ERCP in these contexts remains controversial [34].

### **Improvements in surgery**

The third major change is the substantial and progressive reduction in risk associated with conventional surgery (due to excellent perioperative and anesthesia care), and the increasing use of less invasive laparoscopic techniques [35]. It is no longer correct to assume that ERCP is always safer than surgery. Sadly, serious complications of ERCP (especially pancreatitis and perforation) continue to occur, especially during speculative procedures performed by inexperienced practitioners, often using the needle-knife for lack of standard expertise [36].

### **Risk reduction**

These facts are forcing the ERCP community to search for ways to reduce the risks. Important examples of this preoccupation are the focus on refining

indications [34], prospective studies of predictors of adverse outcomes [37], and attempts to remove stones from the bile duct without sphincterotomy [38], at least in younger patients with relatively small stones and normal sized ducts.

### **Patient empowerment**

Another important driver in this field is the increased participation of patients in decisions about their care. Patients are rightly demanding the data on the potential benefits, risks, and limitations of ERCP, and the same data about the alternatives. Report cards are one response [39].

### **Current focus**

The focus in the early twenty-first century is on careful evaluation of what ERCP can offer (in comparison with available alternatives), and on attempts to improve the overall quality of ERCP practice [40]. Equally important is the increasing focus on who should be trained, and to what level of expertise. How many ERCPists are really needed? (See Chapter 2.)

These issues are important in all clinical contexts, but come into clearest focus where ERCP is still considered somewhat speculative, e.g. in the management of chronic pancreatitis and of possible sphincter of Oddi dysfunction [34].

### **Benefits and risks**

Evaluation of ERCP is a complex topic [41,42]. Its role is very much dependent on the clinical context (Table 1.1), and colleagues contributing to this resource provide guidance about the current state of practice in their main topic areas. This discussion focuses on the general difficulties in defining the role and value of ERCP [41]. Figure 1.1 attempts to illustrate all the elements of the ‘intervention equation’. There is much talk about ‘outcomes studies’, but ‘outcomes’ cannot be assessed without detailed knowledge of the precise ‘incomes’. Thus, a patient with certain demographics, disease type, size, and severity causing a specific level of symptoms, disability, and life disruption is offered an ERCP intervention, by a certain individual with a particular experience and skill level, with certain expected, planned, burdens (i.e. pain, distress, disruption, and costs). All of these metrics need clear and agreed definitions if we are to make any sense of the evaluation. The conjunction of the patient and that intervention results in the ‘outcomes’ (Fig. 1.1). Ultimately, we are most interested in the clinical outcome (reduced burden of symptoms and disease), but there are many factors along the way, including the technical results (influenced by the ‘degree of difficulty’), and the occurrence of unplanned events (or complications), which add to the actual burden.

**Biliary**

- Jaundice
- Abnormal LFTs
- Suspected/known duct stone

**Pancreatitis**

- Chronic
- Acute gallstone related
- Idiopathic recurrent
- Complicated

**Pain**

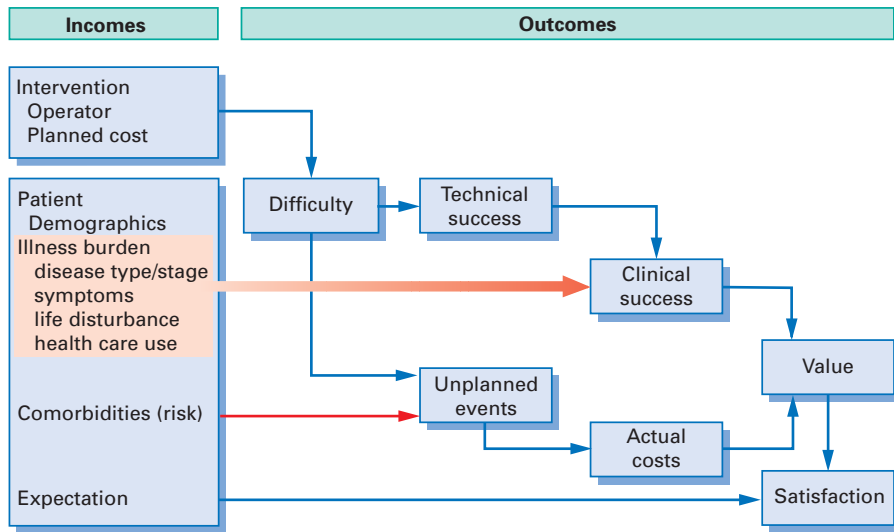
- Chronic
- Acute intermittent (includes postcholecystectomy)
- Early postsurgical

**Imaging findings** (papilla, pancreas, biliary)

**Stent service**

**Other**

**Table 1.1** Clinical contexts for possible ERCP use.



**Fig. 1.1** The intervention process: data elements required.

**Unplanned events**

The word ‘complication’ is emotive, raising issues of medical error and legal liability. We prefer to discuss ‘unplanned events’, since they are best described simply as deviations from the plan which had been agreed with the patient. The phrase ‘adverse events’ has been used too, but not all unplanned events are



negative. A patient with suspected cancer may be delighted to wake up from a procedure with an unexpected cure (sphincterotomy and stone removal). All unplanned events should be documented in a standard format, as an aid to efforts at quality improvement. Some are relatively trivial, such as transient hypotension or self-limited bleeding. At what level of severity do they become ‘complications’? An influential consensus conference [43] set the threshold at the need for hospital admission, and defined levels of severity by the length of stay, as well as the need for surgery or intensive care. Details of complications, and their avoidance and management, are addressed in Chapter 13.

### **Clinical success and value**

Clinical success may sometimes be relatively obvious, e.g. removal of a stone or relief of jaundice with a stent. However, in many cases (e.g. chronic pancreatitis, sphincter dysfunction), the judgement can be made only after long periods of follow-up. This greatly complicates evaluation studies in just the clinical circumstances where the knowledge is needed most. Patient satisfaction is another important parameter. It is determined partly by the clinical results (and how that compares with the patient’s expectation), but also by patients’ perception of the process (accessibility, courtesy, etc.). The cost (burden) of the intervention is obviously a key consideration. This consists of the planned burden, plus the result of any unplanned events. The ratio between the clinical impact (benefit) and the burden (cost) determines the ‘value’ of the procedure in that individual patient (Fig. 1.1). Attempts to provide definitions for all of these metrics are advancing slowly. Their incorporation in endoscopy reporting databases will allow ongoing useful outcomes evaluations to guide further decisions. If the same or similar metrics are also used by those performing alternative interventions such as surgery, we will obtain a clearer idea of the relative roles of these different procedures [44]. In some cases randomization will be necessary to make a final judgement. However, the issue of ‘operator dependence’ will always exist. A randomized trial of two techniques performed by experts may not be the best guide to the choice of intervention in everyday community practice.

### **The future**

The trends which we have outlined are likely to continue and to accelerate in the coming years. Quality is the big issue. That means making sure that we are doing the right things, and doing them right. It has been clear for a long time (but is only now becoming generally accepted) that ERCP is a procedure that should be undertaken only by a minority of gastroenterologists. The amount of training and continuing dedication in practice needed to attain and maintain high levels

of competence, and to improve, means that the procedures should be focused in relatively few hands. The increasing variety and safety of alternative procedures, and the vigilance of our customers, will drive that agenda. The other imperative is to pursue the research studies necessary to improve current methods, and to evaluate all of them rigorously. This is best performed in collaboration with colleagues in surgery and radiology to establish the best methods for approaching patients with known or suspected biliary and pancreatic disease. The dynamics between specialists will change with time, which is one excellent reason for organizing care to be patient-focused, rather than in traditional technical silos. Multidisciplinary organizations, like our Digestive Disease Center, attempt to provide that perspective and a platform for the unbiased research and education that aim to improve the quality of service [45].

## References

- 1 McCune WS, Shorb PE, Moscovitz H. Endoscopic cannulation of the ampulla of Vater: a preliminary report. *Ann Surg* 1968; 167: 752–6.
- 2 Oi I, Takemoto T, Kondo T. Fiberduodenoscope: direct observations of the papilla of Vater. *Endoscopy* 1969; 1: 101–3.
- 3 Ogoshi K, Tobita Y, Hara Y. Endoscopic observation of the duodenum and pancreatocholedochography using duodenofiberscope under direct vision. *Gastrointest Endosc* 1970; 12: 83–96.
- 4 Takagi K, Ideda S, Nakagawa Y, Sakaguchi N, Takahashi T, Kumakura K *et al*. Retrograde pancreatography and cholangiography by fiber-duodenoscope. *Gastroenterology* 1970; 59: 445–52.
- 5 Kasugai T, Kuno N, Aoki I, Kizu M, Kobayashi S. Fiberduodenoscopy: analysis of 353 examinations. *Gastrointest Endosc* 1971; 18: 9–16.
- 6 Classen M, Koch H, Fruhmorgen P, Grabner W, Demling L. Results of retrograde pancreaticography. *Acta Gastroenterologica Japonica* 1972; 7: 131–6.
- 7 Cotton PB. Progress report: cannulation of the papilla of Vater by endoscopy and retrograde cholangiopancreatography (ERCP). *Gut* 1972; 13: 1014–25.
- 8 Cotton PB, Salmon PR, Blumgart LH, Burwood RJ, Davies GT, Lawrie BW *et al*. Cannulation of papilla of Vater via fiber-duodenoscope: assessment of retrograde cholangiopancreatography in 60 patients. *Lancet* 1972; 1: 53–8.
- 9 Gulbis A, Cremer M, Engelholm L. La cholangiographie et la wirsungographic endoscopiques. *Acta Endoscopica Radiocinetomogr* 1972; 2: 78–80.
- 10 Heully F, Gaucher P, Laurent J, Vicari F, Fays J, Bigard M-A, Jenpierre R. La duodenoscopie et la catheterisme de voies biliares et pancreatiques. *Nouv Presse Med* 1972; 1: 313–18.
- 11 Safrany L, Tari J, Barna L, Torok I. Endoscopic retrograde cholangiography: experience of 168 examinations. *Gastrointest Endosc* 1973; 19: 163–8.
- 12 Liguory C, Gouero H, Chavy A, Coffin JC, Huguier M. Endoscopic retrograde cholangiopancreatography. *Br J Surg* 1974; 61: 359–62.
- 13 Cotton PB. ERCP. *Gut* 1977; 18: 316–41.
- 14 Morrissey JF. To cannulate or not to cannulate [Editorial]. *Gastroenterology* 1972; 63: 351–2.
- 15 Blackwood WD, Vennes JA, Silvis SE. Post-endoscopy pancreatitis and hyperamylasuria. *Gastrointest Endosc* 1973; 20: 56–8.
- 16 Classen M, Demling L. Hazards of endoscopic retrograde cholangio-pancreaticography (ERCP). *Acta Hepatogastroenterol (Stutt)* 1975; 22: 1–3.
- 17 Nebel OT, Silvis SE, Rogers G, Sugawa C, Mandelstam P. Complications associated with endoscopic retrograde cholangio-pancreatography: results of the 1974 A/S/G/E survey. *Gastrointest Endosc* 1975; 22: 34–6.

- 18 Bilbao MK, Dotter CT, Lee TG, Katon RM. Complications of endoscopic retrograde cholangiopancreatography (ERCP): a study of 10 000 cases. *Gastroenterology* 1976; 70: 314–20.
- 19 Classen M, Demling L. Endoskopische sphinkterotomie der papilla Vateri und steinextraktion aus dem ductus choledochus. *Dtsch Med Wochenschr* 1974; 99: 496–7.
- 20 Kawai K, Akasaka Y, Murakami K, Tada M, Kohill Y, Nakajima M. Endoscopic sphincterotomy of the ampulla of Vater. *Gastrointest Endosc* 1974; 20: 148–51.
- 21 Cotton PB, Chapman M, Whiteside CG, LeQuesne LP. Duodenoscopic papillotomy and gallstone removal. *Br J Surg* 1976; 63: 709–14.
- 22 Soehendra N, Reijnders-Frederix V. Palliative bile duct drainage: a new endoscopic method of introducing a transpapillary drain. *Endoscopy* 1980; 12: 8–11.
- 23 Laurence BH, Cotton PB. Decompression of malignant biliary obstruction by duodenoscope intubation of the bile duct. *Br Med J* 1980; I: 522–3.
- 24 Robberrecht P, Cremer M, Vandermers A, Vandermers-Piret M-C, Cotton PB, de Neef P *et al.* Pancreatic secretion of total protein and three hydrolases collected in healthy subjects via duodenoscopic cannulation: effects of secretin, pancreozymin and caerulein. *Gastroenterology* 1975; 69: 374–9.
- 25 Byrne P, Leung JWC, Cotton PB. Retroperitoneal perforation during duodenoscopic sphincterotomy. *Radiology* 1984; 150: 383–4.
- 26 Vaira D, Ainley C, Williams S, Caines S, Salmon P, Russell C *et al.* Endoscopic sphincterotomy in 1000 consecutive patients. *Lancet* 1989; 2: 431–4.
- 27 Cotton PB. Endoscopic management of bile duct stones (apples and oranges). *Gut* 1984; 25: 587–97.
- 28 Leung JWC, Emery R, Cotton PB, Russell RCG, Vallon AG, Mason RR. Management of malignant obstructive jaundice at The Middlesex Hospital. *Br J Surg* 1983; 70: 584–6.
- 29 Cotton PB. Endoscopic methods for relief of malignant obstructive jaundice. *World J Surg* 1984; 8: 854–61.
- 30 Speer AG, Cotton PB, Russell RCG, Mason RR, Hatfield ARW, Leung JWC *et al.* Randomized trial of endoscopic versus percutaneous stent insertion in malignant obstructive jaundice. *Lancet* 1987; 2: 57–62.
- 31 Smith AC, Dowsett JF, Russell RCG, Hatfield ARW, Cotton PB. Randomised trial of endoscopic stenting versus surgical bypass in malignant low bile duct obstruction. *Lancet* 1994; 344: 1655–60.
- 32 Shorvon PJ, Cotton PB, Mason RR, Siegel HJ, Hatfield ARW. Percutaneous transhepatic assistance for duodenoscopic sphincterotomy. *Gut* 1985; 26: 1373–6.
- 33 Dowsett JF, Vaira D, Hatfield AR, Cairns SR, Polydorou A, Frost R *et al.* Endoscopic biliary therapy using the combined percutaneous and endoscopic technique. *Gastroenterology* 1989; 96: 1180–6.
- 34 Cohen S, Bacon BR, Berlin JA, Fleischer D, Hecht GA, Loehrer PJ *et al.* NIH State of the Science Conference Statement: ERCP for diagnosis and therapy. *Gastrointest Endosc* 2002; 56: 803–9.
- 35 Cotton PB, Chung SC, Davis WZ, Gibson RM, Ransohoff DF, Strasberg SM. Issues in cholecystectomy and management of duct stones. *Am J Gastroenterol* 1994; 89: S169–76.
- 36 Cotton PB. ERCP is most dangerous for people who need it least. *Gastrointest Endosc* 2001; 54: 535–6.
- 37 Freeman ML, DiSario JA, Nelson DB, Fennerty MB, Lee JG, Bjorkman DJ *et al.* Risk factors for post-ERCP pancreatitis: a prospective, multicenter study. *Gastrointest Endosc* 2001; 54: 425–34.
- 38 Huibregtse K. Endoscopic balloon dilation for removal of bile duct stones: special indications only. *Endoscopy* 2001; 33 (7): 620–2.
- 39 Cotton PB. How many times have you done this procedure, Doctor? *Am J Gastroenterol* 2002; 97: 522–3.
- 40 Quality and Outcome Assessment in Gastrointestinal Endoscopy. *Gastrointest Endosc* 2000; 52: 827–30.
- 41 Cotton PB. Income and outcome metrics for objective evaluation of ERCP and alternative methods. *Gastrointest Endosc* 2002; 56 (Suppl. 6): S283–90.

- 42 Cotton PB. Therapeutic gastrointestinal endoscopy: problems in proving efficacy. *N Engl J Med* 1992; 326: 1626–8.
- 43 Cotton PB, Lehman G, Vennes J, Geenen JE, Russell RCG, Meyers WC *et al.* Endoscopic sphincterotomy complications and their management: an attempt at consensus. *Gastrointest Endosc* 1991; 37: 383–93.
- 44 Cotton PB. Randomization is not the (only) answer: a plea for structured objective evaluation of endoscopic therapy. *Endoscopy* 2000; 32: 402–5.
- 45 Cotton PB. Fading boundary between gastroenterology and surgery. *J Gastroenterol Hepatol* 2000; 15: G34–7.

## ERCP Training, Competence, and Assessment

PETER B. COTTON

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### ERCP is challenging, and not for all gastroenterologists

ERCP is the most challenging endoscopic procedure performed regularly by gastroenterologists. It is often difficult technically, and may fail. Optimal practice requires considerable manual dexterity, a broad knowledge of pancreatic and biliary diseases, and familiarity with the many alternative diagnostic and therapeutic approaches. Furthermore, it carries substantial risks, even in the hands of experts [1,2].

ERCP has been seen also as rather glamorous, so that most gastroenterology trainees have aspired to master the techniques, and to practice them independently. Many factors make that inappropriate. Firstly, it has become obvious (as detailed below) that attaining competence takes far more training and experience than previously appreciated. This is time consuming, and also detracts from time needed to study other specialist fields of gastroenterology and hepatology. Secondly, the increasing refinement and availability of imaging techniques such as CT scanning, MRCP, and EUS have rendered diagnostic ERCP to be (almost) obsolete [1]. This means that any endoscopist offering ERCP must be geared up to provide therapy for the likely problem. Thirdly, it is now clear that less experienced practitioners have more failures, and also have more complications. Fourthly, many ERCP endoscopists have been trained (albeit not all very well) in the last two decades, and very few more are needed each year to maintain the ranks. Finally, consumer empowerment will be an important driver. Patients are beginning to understand that not all endoscopists are alike, and are seeking out experienced practitioners when they need more aggressive procedures.

All of these facts mandate that only a few people should be trained, and that they should be trained well. This is far from a new idea, having been stated clearly and repeatedly over the years by many individuals [3–7] and endoscopy organizations [8–14]. The problem is that no one has paid attention, as is brutally obvious from a recent survey of 69 graduates from US fellowship programs [15]. Most had had some experience of ERCP (range 12–320 cases, median 140).

One-third stated that their training was inadequate, yet 91% of them proposed to practice ERCP. This is bad medicine, and embarrassing for our profession [16]. We must ensure that those offering ERCP services are competent to do so.

### What is ‘competence’ in ERCP?

There is a wide spectrum of expertise in the performance of ERCP. Competence traditionally describes the point at which a trainee can practice independently. What are the criteria for independent practice? Sadly, our understanding of the complexity of that issue has been slow to develop, and opinions vary widely [17]. Only now are attempts being made to develop meaningful objective methods of assessment.

Issues of training, competence, and assessment for all aspects of endoscopy have been well reviewed recently by Cohen [18] and Freeman [19].

The first ASGE guidelines for ERCP relied almost solely on the numbers of cases experienced during training, and suggested that 100 (including 25 therapeutic) would be adequate [8]. That guideline attempted to put the onus on the training program directors, suggesting that they should not be asked to advise or to arbitrate competency until those ‘threshold’ numbers had been reached. But this sensible concept was ignored, and formal assessments were rare events. Even when logbooks became routine, it was difficult to assess what contribution the trainee had made (or indeed could have made independently).

A study of the learning curve for ERCP at Duke University was a turning point in the debate. Even after 180–200 cases, trainees were scarcely performing at an 80% level [20].

The latest guideline from the ASGE in 2002 [21] mentions that 200 procedures are not adequate for most trainees to achieve competence, and emphasizes objective end points (such as an 80% biliary cannulation rate) as better minimal standards. The Australians have set the highest hurdle so far, i.e. completion of 200 procedures, unassisted [22]. The British authorities suggested a 90% hurdle in 1999 [13], but the 2004 version [23] replaced numbers completely in favor of a list of needed skills (without precise goals), stating rather quaintly that ‘although trainees must aspire to internationally accepted standards for cannulation success—a 90% success rate for uncomplicated cases has been proposed—it is unreasonable to demand this level of performance from trainees by the end of their training . . .’.

Whilst these concepts and guidelines are logical and well-meaning, there have been few attempts so far to document what skill levels are really being achieved. Nor do we know how performance in the training environment translates into independent practice. It is one thing to complete a procedure in the training environment with faculty advice and encouragement, and familiar

assistants and equipment, but quite another to do so unaided in a new unfamiliar environment, with pressure to succeed. We need to collect meaningful objective data during training, but also in the early phases of practice.

### Cognitive competence

The safe and effective practice of ERCP clearly requires far more than technical skills, as has been well stated repeatedly. Documenting technical competence is difficult, but proving the acquisition of the necessary cognitive skills may be even more so [24]. It has been assumed that formal training in Gastroenterology and Hepatology (e.g. Board certification in the USA) is likely to cover the necessary territory [25], but the specifics of pancreaticobiliary medicine have not been assessed formally. Furthermore, the field is in constant flux and requires ongoing study.

### Degree of difficulty and expertise

Not all ERCP examinations are equal. Any case can prove challenging on the day (e.g. due to a duodenal diverticulum), but some are *predictably* more difficult (e.g. known prior Billroth II resection, hilar tumors, or suspected sphincter dysfunction). A five-level scoring system for predicted degree of difficulty was developed [26], and later simplified to three grades (Table 2.1) [26,27]. Grade 1 procedures are those (mainly biliary) interventions which anyone offering ERCP should be able to achieve to a reasonable level of expertise. Grade 2 cases include more complex cases, such as minor papilla cannulations and larger

Table 2.1 Degrees of difficulty in ERCP.

	Diagnostic	Therapeutic
Standard, grade 1	Selective deep cannulation Diagnostic sampling	Biliary sphincterotomy Stones < 10 mm Stents for leaks Low tumors
Advanced, grade 2	Billroth II diagnostics Minor papilla cannulation	Stones > 10 mm Hilar tumors Benign biliary strictures
Tertiary, grade 3	Manometry Whipple Roux-en-Y Intraductal endoscopy	Billroth II therapeutics Intrahepatic stones Pancreatic therapies

Endoscopist	Grade of difficulty		
	1	2	3
Competent	80–90	–	–
Proficient	90+	80+	–
Expert	98+	95+	90+

**Table 2.2** Likely success rates (%) of ERCP, correlating the endoscopist's level of skill with the grade of difficulty.

stones. Grade 3 procedures are the most difficult, such as treatments for pancreatitis and intrahepatic stones, and are performed mainly in tertiary referral centers.

The above discussion about competence refers primarily to grade 1 procedures, which are the 'garden-variety' cases that will be encountered in everyday practice. Endoscopists with more training (e.g. a dedicated fourth year in the USA), and those who have honed their skills in practice with the aid of community and academic colleagues, will attempt more complex cases. So-called experts, working in referral centers, will tackle all comers, but will also have very high success rates in the easier cases. These concepts of case difficulty and individual expertise can usefully be combined (Table 2.2).

### ERCP training at MUSC

Our trainees select from three levels of training in pancreatico-biliary medicine and ERCP. The simplest is exposure to the service for 2 months, which shows them approximately 80 cases, and the thinking that goes with them. They learn to use side-viewing endoscopes, but are not expected to perform ERCP. The second level is offered to selected fellows in the GI training program (which lasts 3 years). They experience over 300 cases and appear reasonably competent in standard (mainly biliary) procedures when they leave. The third option requires a dedicated fourth year, with another 300+ cases. These endoscopists have mastered standard grade 1 cases, and know enough to attempt some of the more complex procedures.

### Towards more structured training

Together, all of these issues in training and assessment point to the need for a much more structured approach, including formalized curricula and enhanced educational resources. The need to be personally involved in so many live cases could be reduced substantially in the future as computer simulators mature and become more widely available [18].



## Ongoing competence and re-credentialing

It is logical that endoscopists need a certain ongoing volume of cases to maintain their skills, if not to improve them. There have been no studies to provide guideline figures, but my guess is that it is difficult to remain sharp with less than 50–100 cases per year, even if prior experience has been substantial. Few endoscopists achieve that annual volume in Britain [7], and a survey of US gastroenterologists in 1987 revealed a median number of only 30 ERCPs per year [28].

There is also the issue of the number of ERCP cases in an individual endoscopy unit or hospital. Continuing experience is needed to maintain the necessary nursing skills and equipment; my guess would be a minimum of 100–200 cases per year. Few hospitals achieve those numbers. A British survey reported that only 25% of units performed > 200 cases per year in 1997 [7]. A search of the National Inpatient sample in the USA revealed that ERCPs were done in 2629 hospitals. The average number was 49 per year; only 25% of hospitals performed more than 100, and only 5% more than 200 [29].

Hopefully, ongoing privileging (credentialing) in the future will be based on more than numbers alone [21,23]. Outcomes data should be available, and computer simulators are also likely to play an increasing role. The ASGE suggested in 1995 that intermittent ‘proctoring’ should be considered [21], a sensible idea that has been ignored completely.

One promising tool is the endoscopy ‘report card’.

### Report cards

The ASGE has recommended the use of report cards, i.e. summaries of the ongoing practice of individual endoscopists [30], a concept that I support strongly [31]. Endoscopists should keep track of their case volumes and case mix, and their outcomes, and be prepared to share the data when requested (whether by payers, privileging authorities, or patients) [21]. We are becoming accustomed to seeing hospital ‘league tables’ of the outcomes of major procedures such as cardiovascular surgery and pancreatico-duodenectomy. However, it is clear for endoscopy [32], as for surgery [33], that outcomes are more dependent on the case volume of individual practitioners than on the institutions in which they work. An example of a report card for one long-time ERCPist is shown in Table 2.3. The increasing use of electronic reporting systems will make this process easier, even automatic. Sharing the data between endoscopists eventually will provide benchmarks, and will be a powerful stimulus to improvement.

Report cards are likely to be voluntary at least initially. What is the incentive for less experienced endoscopists to collect data and advertise the fact that they are not super-experts? The answer lies with our patients, who are advised

**Table 2.3** Lifetime experience of ERCP > 15 000 cases since 1971. Certifications: Gastroenterology boards (UK); ACLS.

	2002	2003	2004
Annual procedures	422	386	342
Therapy performed	80%	85%	88%
Disease spectrum			
Pancreatitis	115 (27%)	106 (21%)	98 (29%)
Sphincter dysfunction	84 (20%)	118 (27%)	84 (25%)
Tumors	64 (15%)	42 (11%)	43 (13%)
Stones	57 (13%)	52 (13%)	52 (15%)
Benign biliary	54 (13%)	40 (10%)	38 (11%)
Normal	20 (5%)	6 (2%)	10 (7%)
Difficulty scores			
Grade 1	38%	30%	33%
Grade 2	18%	12%	12%
Grade 3	44%	58%	55%
Time taken (minutes)	37 ( $\pm$ 19)	39 ( $\pm$ 21)	39 ( $\pm$ 19)
Biliary cannulation rate	98%	98%	97%
Minor papilla cannulation rate	75%	86%	87%
Stone extraction success	100%	100%	100%
Complications			
<i>Total</i>	5 (1.2%)	15 (4%)	17 (5%)
Mild	4	13	13
Moderate	1	1	2
Severe	0	1	2
Fatal	0	0	0
Pancreatitis	3	11	12
Infection	2	3	2
Bleeding	0	1	1
Other	0	0	2

increasingly to ask their potential interventionists about their experience. Some patients will certainly hesitate if their practitioners are not able or willing to provide data when requested. Well-trained and skillful practitioners should wear their data as badges of quality.

### **An ERCP diploma?**

A strong case can be made for a diploma which attests to ERCP competence. Eventually this will be accepted and embraced by the standard national examination authorities, but we should show the way. I envisage three main elements.

- 1 A written examination covering
  - a knowledge base of pancreatic and biliary medicine;
  - safety issues in ERCP practice;
  - endoscopic and radiological interpretation.
- 2 Logbook documentation of all cases and achievement of defined threshold standards (e.g. cannulation rates, risks, etc.).
- 3 Proctoring of three cases by an outside expert, covering all aspects of the cases, including preparation, consent, performance, and documentation.

This examination would focus on standard grade 1 procedures, and be used to certify completion of training. It could be applied either at the training unit, or, by default, at the institution at which privileges are sought. A shorter version could be used also (along with the report card data and maybe computer simulation testing) for re-credentialing. One could envisage also an analogous diploma in 'Advanced ERCP' for those aspiring to recognition as expert referral resources. These examinations would be voluntary, like the report cards, but the acquisition of a diploma would provide the individual endoscopist with a significant practice advantage.

## Conclusion

ERCP has tremendous potential for benefit, but can cause devastating complications. We must provide the training and credentialing framework to ensure that it is offered optimally. Structured training and continuing objective assessment of competence (through collection of real data) will be key elements for future success.

A diploma of competence in ERCP could become a powerful force for improving the quality of ERCP services.

## References

- 1 NIH State-of-the-Science Conference Statement. ERCP for diagnosis and therapy, 14–16 January 2002. *Gastrointest Endosc* 2002; 56: 803–9.
- 2 Cotton PB, Williams CB. (1996). *Practical Gastrointestinal Endoscopy*, 4th edn. Blackwell Science, Oxford.
- 3 Sivak MV, Vennes JA, Cotton PB, Geenen JE, Benjamin SB, Lehman GA. Advanced training programs in gastrointestinal endoscopy. *Gastrointest Endosc* 1993; 39: 462–4.
- 4 Wicks ACB, Robertson GSM, Veitch PS. Structured training and assessment in ERCP has become essential for the Calman era. *Gut* 1999; 45: 154–6.
- 5 Baillie J. ERCP training for the few, not for all. *Gut* 1999; 45: 9–10.
- 6 Hellier MD, Morris AI. ERCP training—time for change. *Gut* 2000; 47: 459–60.
- 7 Allison MC, Ramanaden DN, Fouweather MG, Davis DKK, Colin-Jones DG. Provision of ERCP services and training in the United Kingdom. *Endoscopy* 2002; 32: 693–9.
- 8 American Society for Gastrointestinal Endoscopy. (1986). *Guidelines for Advanced Endoscopic Training*. ASGE, Publication no. 1026. ASGE, Manchester, MA.
- 9 American Society for Gastrointestinal Endoscopy. (1991). *Principles of Training in Gastrointestinal Endoscopy*. ASGE, Manchester, MA.

- 10 American Society for Gastrointestinal Endoscopy. Maintaining competency in endoscopic skills. *Gastrointest Endosc* 1995; 42: 620–1.
- 11 American Society for Gastrointestinal Endoscopy. Guidelines for credentialing and granting privileges for gastrointestinal endoscopy. *Gastrointest Endosc* 1998; 48: 679–82.
- 12 American Society for Gastrointestinal Endoscopy. Quality improvement of gastrointestinal endoscopy. *Gastrointest Endosc* 1999; 49: 842–4.
- 13 Joint Advisory Group on Gastrointestinal Endoscopy. (1999). *Recommendations for Training in Gastrointestinal Endoscopy*. British Society of Gastroenterology, London ([www.bsg.org.uk/training/jag\\_99.html](http://www.bsg.org.uk/training/jag_99.html)).
- 14 American Society for Gastrointestinal Endoscopy. Guidelines for advanced endoscopic training. *Gastrointest Endosc* 2001; 53: 846–8.
- 15 Kowalski T, Kanchana T, Pungpapong S. Perceptions of gastroenterology fellows regarding ERCP competency and training. *Gastrointest Endosc* 2003; 58: 345–9.
- 16 Sivak MV Jr. Trained in ERCP. *Gastrointest Endosc* 2003; 58: 412–14.
- 17 Waye JD, Bornman PC, Chopita N, Costamagna G, Ganc AJ, Speer T. ERCP training and experience. *Gastrointest Endosc* 2002; 56: 607–8.
- 18 Cohen J. (2004). Endoscopic training and credentialing. In: *Advanced Endoscopy*, e-book/annual (ed. Cotton, PB) ([www.gastrohep.com](http://www.gastrohep.com)).
- 19 Freeman ML. Training and competence in gastrointestinal endoscopy. *Rev Gastroenterol Disord* 2001; 1: 73–86.
- 20 Jowell PS, Baillie J, Branch S, 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.
- 21 American Society for Gastrointestinal Endoscopy. Methods of granting hospital privileges to perform gastrointestinal endoscopy. *Gastrointest Endosc* 2002; 55: 780–3.
- 22 Conjoint Committee for Recognition of Training in Gastrointestinal Endoscopy. (1997). *Information for Supervisors: Changes to Endoscopic Training*. The Conjoint Committee for Recognition of Training in Gastrointestinal Endoscopy, Sydney.
- 23 Joint Advisory Group on Gastrointestinal Endoscopy. (2004). *Guidelines for the Training, Appraisal and Assessment of Trainees in Gastrointestinal Endoscopy, 2004* ([www.Thejag.Org.Uk/JAG\\_2004.pdf](http://www.Thejag.Org.Uk/JAG_2004.pdf)).
- 24 Wigton RS. Measuring procedural skills. *Ann Intern Med* 1996; 125: 1003–4.
- 25 The Gastroenterology Leadership Council. Training the gastroenterologist of the future: the gastroenterology core curriculum. *Gastroenterology* 1996; 110: 1266–300.
- 26 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.
- 27 Cotton PB. Income and outcome metrics for objective evaluation of ERCP and alternative methods. *Gastrointest Endosc* 2002; 56 (Suppl. 2): S283–90.
- 28 Wigton RS, Blank LL, Monsour H, Nicolas JA. Procedural skills of practicing gastroenterologists: a national survey of 700 members of the American College of Physicians. *Ann Intern Med* 1990; 113: 540–6.
- 29 Varadarajulu S, Kilgore M, Wilcox CM, Eloubeidi M. Relationship between hospital ERCP volume, length of stay and technical outcomes. *Gastrointest Endosc* [in press].
- 30 American Society for Gastrointestinal Endoscopy. Quality assessment of ERCP. *Gastrointest Endosc* 2002; 56: 165–9.
- 31 Cotton PB. How many times have you done this procedure, Doctor? *Am J Gastroenterol* 2002; 97: 522–3.
- 32 Petersen BT. ERCP outcomes: defining the operators, experience, and environments. *Gastrointest Endosc* 2002; 55: 953–8.
- 33 Birkmeyer JD, Stukel TA, Siewers AE, Goodney PP, Wennberg DE, Lucas FL. Surgeon volume and operative mortality in the United States. *N Engl J Med* 2003; 349: 2117–27.

# Fundamentals of ERCP

JOSEPH LEUNG

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## Synopsis

*Endoscopic retrograde cholangiopancreatography (ERCP) was first described in 1968 and we have recently celebrated the 30th anniversary of endoscopic sphincterotomy. This diagnostic and therapeutic modality has impacted significantly in the management of patients with many different benign and malignant pancreatico-biliary problems. A successful ERCP requires the coordination and cooperation of a dedicated and committed team of endoscopists, nurses, and assistants, as well as an organized and functioning unit. It takes many years to learn, and repeated practice, in order to master the skill of ERCP and to do it safely. It is important to understand the indications, contraindications, limitations, and complications of individual procedures when offering ERCP to our patients. Although successful ERCP has replaced surgery as a treatment option for some difficult pancreatico-biliary diseases, we have also seen problems and complications arising as a result of endoscopic treatment. Prospective collection of data and selected randomized controlled studies with long-term follow-up are necessary to evaluate the true value of this technology in the overall care of our patients.*

## Introduction

### Imaging of the pancreatico-biliary system

Methods for imaging the pancreatic and biliary ductal systems continue to evolve. Correct application of ERCP (and other procedures) requires an up-to-date knowledge of all of these modalities.

### ERCP

ERCP is a direct contrast study of the pancreatico-biliary system. It is useful in

the diagnosis and treatment of diseases involving the pancreas and bile ducts, such as stones, benign and malignant strictures, and developmental anomalies.

It is superior to indirect cholangiography (oral or IV), especially in cases with obstructive jaundice, which leads to raised intrabiliary pressure and impaired biliary excretion of contrast.

Moreover, intrahepatic bile duct pathologies can be demonstrated by ERCP using occlusion cholangiography. Pathology in the gallbladder and cystic duct abnormalities can also be visualized, although ERCP is not the best imaging study for gallbladder disease.

#### *ERCP vs. PTC*

Comparative investigation of direct cholangiography studies, i.e. ERCP and percutaneous transhepatic cholangiography (PTC), should take into consideration the individual patients and the expertise of the operator; however, ERCP is considered less invasive than PTC.

ERCP has the added advantages of allowing duodenoscopy and pancreatography, which are helpful in the diagnosis of ampullary pathology and pancreatic abnormalities. ERCP can be performed in the presence of ascites and/or malignancies involving the liver, contraindicating PTC. In addition, bile and pancreatic juice can be collected for cytological and microbiological examination during ERCP procedures.

#### *MRCP*

The development and refinement of magnetic resonance cholangiopancreatography (MRCP) have produced excellent quality pictures of the anatomy of the pancreatobiliary system. It is non-invasive and can give images comparable to ERCP when performed well. Limitations are few and the diagnostic value is high, and it may replace diagnostic ERCP, especially in the investigation of jaundice. MRCP, however, lacks therapeutic potential.

#### *EUS*

Endoscopic ultrasonography (EUS) allows good visualization of the distal common bile duct (CBD), with an excellent diagnostic accuracy for ductal stones. It provides superb views of the pancreas, and is useful in defining underlying pancreatic pathology. Fine-needle aspiration cytology further complements the diagnostic capability of EUS in pancreatobiliary diseases.