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Endoscopic practice

Are we meeting the standards set for ERCP?

John Baillie, Pier-Alberto Testoni

ERCP practice today: implications for training

The study by Williams *et al.*,¹ published in this issue of *Gut* (see page 796), reports the findings of a UK National Confidential Enquiry into Patient Outcomes and Deaths relating to endoscopic retrograde cholangiopancreatography (ERCP). Approximately 48 000 ERCPs are performed annually in the UK. For this study, five metropolitan areas of England were surveyed. The authors estimate that about 20% of all the ERCP procedures performed in adults (>18 years of age) over a 6-month period were captured. The results offer a cornucopia of food for thought. In all, 94% (76/81) of endoscopy units polled responded. Personal questionnaires were returned by 89% of staff endoscopists and by 81% of their trainees. Aspects of ERCP that were examined ranged from the experience and success of the physicians performing the procedures, to indications, informed consent, adequacy of monitoring and resuscitation, and outcomes, including complications and mortality. More than a few of the findings are sobering, concerning and demand remedial action. But we acknowledge that it is easy to be an armchair critic of another country's ERCP practice. An in-depth look at ERCP practice in the US and Italy, for example, would probably reveal some, if not many,

of the same problems arising from marginal training, inexperience, inadequate volume of cases to maintain skills and so on.

The current study looked at the success rates of trainees as a function of their experience. Those with experience of >200 ERCPs had an unsupervised cannulation rate (to enter the duct of choice) of 66%; this fell to 40% for those with experience of <200 ERCPs. The overall trainee cannulation success rate with procedures whose trainee involvement was not documented, was reportedly 54%. The American Society for Gastrointestinal Endoscopy (ASGE) considers a selective cannulation success rate of 80% to be the bare minimum for credentialling to perform ERCP²; in the UK, the Joint Advisory Group on Gastrointestinal Endoscopy suggests that trainees aspire to a success rate of 90%.³ Until the 1996 publication of a large prospective study of ERCP training from the Duke University Medical Center,⁴ in which JB participated, ridiculously low numbers of procedures (eg, 25) were regularly touted as being adequate for credentialling to perform ERCP in the US. These numbers were usually suggested by gastroenterology training programme directors from hospitals with low ERCP

volumes. Keeping the credentialling threshold low was the only way to ensure that most or all their trainees could leave at the end of fellowship with a letter stating that they were “trained in ERCP”. The Duke University study showed that to attain minimum competence (80% success rate) in a variety of diagnostic and therapeutic ERCP skills, not less than 180–200 cases were required. Recognising that there is no “magic” number of ERCPs that guarantees competence, the ASGE has taken the stance that a trainee will rarely be ready for credentialling to perform unsupervised ERCP with fewer than these numbers. Indeed, some trainees are still struggling after 300 or more procedures. The decision to let a trainee “loose” to do ERCP on his or her own is inevitably quite subjective. But those of us who train endoscopists and write letters of support for them to get hospital credentials take this duty seriously. The Australians have set the highest “bar” for credentialling—namely, 200 unassisted ERCPs (<http://conjoint.gesa.org.au/information.htm>). Other countries have compromised by taking the “middle ground”—for example, requiring 150 procedures. The present study is further evidence—if any was needed—that 200 ERCPs performed under supervision are insufficient to achieve a credentialling threshold of 80% success at selective cannulation. A total of 77% of trainers reported a successful selective cannulation rate of >80%. This means that almost a quarter (23%) of the trainers failed to achieve the ASGE threshold for competence in diagnostic ERCP. The overall completion of intended treatment was only 70% (62%, if the aim was to clear the bile duct of stones). In all, 81% of pancreatograms were reportedly “unintentional”: this suggests difficulty in achieving selective cannulation of the

bile duct. It is surprising that the study's reported post-ERCP pancreatitis rate (1.6%) was not higher, given the frequency of unintended pancreatic duct opacification. Pre-cut papillotomy led to successful access to the duct of interest in only 66% of cases. In the current state of the pre-cut "art", experienced ERCP endoscopists should gain access to the desired duct in over 90% of cases.⁵

To ensure that only appropriate procedures are performed, some form of screening process for ERCP requests is necessary. In the current study, only 30/190 (16%) ERCP endoscopists reported personally vetting all patients scheduled for ERCP on their endoscopy lists. Possibly, this was the result of an open-access policy for ERCP scheduling. Nonetheless, we find this statistic alarming. In our opinion, the potential for complications and other negative outcomes is too great to allow most ERCPs to be scheduled without screening by a clinician experienced in hepatobiliary and pancreatic (HBP) disorders.

Only 1.5% of the ERCPs in this study were performed under general anaesthesia, with a few additional patients receiving propofol without endotracheal intubation (what would be considered monitored anaesthesia care (MAC) in the US). The rest of the ERCPs were performed using conscious (moderate) sedation. All respondents reported the use of oximetry during ERCP, but blood pressure (BP) monitoring and ECG were used in only 71% and 56% of units, respectively. Thirty-three percent of patients received >5 mg of midazolam during ERCP. Nineteen percent of units had no resuscitation cart on site. Antibiotics were administered in only 71% of cases in which they were indicated. Thirteen percent of ERCPs were performed on patients with American Society of Anesthesiology (ASA) scores ≥ 3 : only 36% of patients ≥ 75 years of age who had an ASA score of ≥ 3 had their BP monitored, and only 18% had an ECG monitor. There was no written consent for 21% of the patients who died. Sixteen percent of ERCP-related deaths occurred in patients who were confused or had dementia, but a surprising two thirds of these signed their own consent forms. There was no record of coagulation indices being checked in 80% of cases. Eleven percent of deaths from ERCP were associated with endoscopists doing <50 ERCPs a year. Only one third of the ERCPs in those who died were considered appropriate; the remaining two thirds were considered "futile". The overall complication rate of this study was reported to be 5.1%, with a mortality of 0.4%. The post-ERCP pancreatitis (PEP)

rate was 1.6% (≥ 2 nights of hospitalisation were required to be counted as a complication). Patients were not asked specifically to rate comfort level, but one third added comments to their questionnaires: 12% reported being "uncomfortable" during ERCP.

No survey is perfect, and this one is no exception. Too many patients were excluded because there was "inadequate time" to get their consent, and self-reporting, especially of something as subjective as procedural competence, is fraught with bias. However, this survey does provide a useful snapshot of the current state of ERCP in the UK. If this was a school report card, we would have to give British ERCP a "B minus" and send it to the headmaster's office for a stiff talking-to, if not a caning. The authors state that "Most ERCPs in the UK are performed on low-risk patients with therapeutic intent. Complication rates compare favourably with those reported internationally. However, quality suffers because there are too many trainees in too many low-volume centres". They opine that "...the implications for a low workload on the cannulation rates achieved by trainees appear clear. Consequently, it may be that overall success rates would be improved by concentration of greater numbers of ERCPs in a smaller number of centres, with greater restriction on who trains (and retrains)". The idea of limiting ERCP training to a small cadre of gastroenterology trainees to ensure adequate experience is not new: one of us (JB) wrote an editorial for *Gut* on this very subject in 1999.⁶ The current study suggests that nothing has changed in the last 8 years. Is the situation any different elsewhere in Europe? The problems with ERCP training and practice revealed by the National Confidential Enquiry into Patient Outcomes and Deaths study exist in Italy, and probably in most other European countries too. A minimum number of procedures that would be considered satisfactory for ERCP training has not been defined by either the scientific societies of gastroenterology and endoscopy in Italy or the public healthcare system. Most Italian gastroenterologists train in low ERCP volume settings. The Italian Society of Digestive Endoscopy and the Italian National Postgraduate Medical School Program are currently considering the problem. Minimum numbers of diagnostic and therapeutic upper gastrointestinal endoscopies (oesophagogastroduodenoscopies) and colonoscopies over 5 years are mandated for certification of training in gastroenterology in Italy. However, no standards have been set for more complex

procedures, including ERCP. As the proposed Italian National Postgraduate Medical School Program has no mechanism for assuring that ERCP endoscopists receive appropriate training, an additional period of apprenticeship is necessary for those who wish to attain expertise in ERCP (and endoscopic ultrasound). Only regional centres with a large volume of cases can provide the necessary environment for specialist HBP training. At present, plans for centralised ERCP training in Italy remain "on the drawing board" due to a variety of hurdles, including politics (how to select centres) and logistics (those wanting ERCP training may have to live away from home for a year or more).

ERCP training should be reserved for a select minority of gastroenterology trainees who have shown aptitude in endoscopic procedures and who wish to develop a career interest in managing HBP disorders. A dedicated period beyond standard gastroenterology fellowship is now customary in the US, typically a year for ERCP training. Endoscopic ultrasound (EUS) is the perfect complement to ERCP skills; EUS requires similar supervised training.⁷ In our opinion, future HBP specialists should be trained in both ERCP and EUS. This will probably require an additional 18 months to 2 years in a teaching centre with sufficient volume of cases and all the necessary support (including experienced mentors) to develop the necessary skills set. The current study suggests that too many ERCPs are being done in the UK, sometimes for marginal indications. We suspect that inexperience in managing HBP disorders, repeat procedures for earlier failures and the trainees' quest for ERCP numbers are contributing factors. As Cotton⁸ reminds us, those most at risk from ERCP are those who need it least. Fortunately, sphincter of Oddi dysfunction accounted for only 1% of cases in this study, which probably contributed to the commendably low complication and mortality rates. Young women with normal calibre bile ducts and normal liver serology who undergo ERCP for suspected sphincter of Oddi dysfunction are at very high risk for post-procedure pancreatitis.⁹ Moribund patients rarely benefit from ERCP. In the current study, two thirds of patients who died were considered to have undergone "futile" ERCPs. The recognition of futility is an important skill for every ERCP endoscopist.

The lack of basic vital sign monitoring, such as pulse oximetry, automated blood pressure readings and continuous ECG display, in many units in this study is concerning. Generally, monitors for these vital signs are inexpensive, so why not

use them, especially in high-risk patients (those with ASA grade ≥ 3 , regardless of age)? In our experience, routine measurement of coagulation indices before ERCP is a waste of time and money. Significant bleeding after endoscopic sphincterotomy is rare these days, even in the presence of therapeutic anticoagulation. This likely reflects improvements in the technology of electrocautery. The UK guidelines regarding coagulation screening for ERCP should be reviewed and revised. Informed consent is the keystone of safe ERCP practice. Every ERCP should be performed for a solid indication: it is not a game. When obtaining informed consent, the risks, benefits and alternatives need to be explained. Some experts are advocating that patients be given physician-specific "score cards" detailing the experience of the endoscopist, as well as his or her success and complication rates.¹⁰ Although it is hard to prove, the involvement of trainees in ERCP probably increases the risk of failure and complications, and it certainly prolongs the procedure. Patients' willingness to have trainees participate in ERCP should not be assumed. They should be asked "up front" whether they agree, and their wishes respected—without debate—should they decline.

This study casts a harsh spotlight on British ERCP. We commend those who participated, for their willingness to give honest answers. The results are first-and-foremost a "wake-up call" for British GI, but they also offer a unique opportunity for those who perform and teach ERCP around the world to look at their own practices. The way forward is clear: fewer, carefully selected trainees should be trained in the management of HBP disorders in regional specialist centres,

with ERCP being only one component of that training. The numbers being trained in ERCP should match the number of gastroenterology consultant posts requiring these skills that open up each year. All gastroenterology trainees should be taught how to use a duodenoscope. Those with interest and proven facility with endoscopes should compete for limited opportunities to learn ERCP. After an assessment period during which 50–100 ERCPs are to be performed, further selection should take place to identify those trainees most likely to benefit from a dedicated year (or more) of advanced training in HBP disorders, including the full range of diagnostic and therapeutic ERCP skills. With the availability of less- and non-invasive imaging techniques, such as EUS and magnetic resonance cholangiopancreatography, to look at the biliary tree and pancreas, solely diagnostic ERCP is becoming a rarity. We recommend that EUS be taught concurrently with ERCP, as these techniques are complementary. EUS is increasingly important in both the diagnosis and staging of biliary and pancreatic cancer, and its therapeutic applications are increasing daily. Finally, this study reveals that the sickest patients having ERCP in the UK do not always have the benefit of adequate monitoring. Monitored anaesthesia care using propofol and general anaesthesia increase the cost of ERCP, but enhance its performance and safety. We suggest that UK endoscopy units should look at alternatives to standard conscious sedation for the comfort and safety of their most vulnerable patients.

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Survival in cirrhosis

Cardiovascular determinants of survival in cirrhosis

Samuel S Lee, Hongqun Liu

Diastolic response as the strongest determinant of mortality after TIPS

My heart,
Where either I must live or bear no
life,
The fountain from which my current

runs
Or dries up

William Shakespeare, *Othello*

Cirrhosis is a fatal condition. Although mild cirrhosis can be associated with prolonged survival, most diseases that induce cirrhosis progress, at variable rates, to end-stage liver failure. Deaths from hepatic failure, variceal bleeding and infection are common in advanced cirrhosis, and even the rate of sudden unexplained death is increased compared with that in a normal population.¹ Moreover, patients with cirrhosis are well known to be fragile, and do poorly after invasive or stressful procedures. It is logical and intuitive to assume that the sickest patients—that is, those with the most advanced degree of liver failure—will have the poorest outcome after challenges. Indeed, this is what virtually all studies on risk factors for