

ERCP in a district general hospital in England: a review of 1550 procedures over nine years

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Citation

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Abstract

Objectives: To describe the practice of ERCP in a district general hospital. **Design:** Descriptive study with prospective data collection from all patients undergoing ERCP between 1997 and 2006. **Endpoints:** The main outcomes were technical success (cannulation rates and therapeutic success rates) and safety (complication rate). **Results:** Technical success rates were high: cannulation of common bile duct was achieved in 95% of all 1550 ERCPs, increasing to 98% during 2001-2006; high success rates were also achieved for sphincterotomy, pre-cut incision, stent insertion and stone removal. The complication rate was low: acute pancreatitis occurred in 3%, perforation in 0.3% and haemorrhage in 0.4%, with a decrease in complications over time; procedure-related mortality was 0.2%. During the study period, the success rates for cannulation and therapeutic procedures increased, while complications decreased. **Conclusions:** ERCP in a district general hospital was associated with a high degree of technical success and a low risk of complications.

INTRODUCTION

Endoscopic retrograde cholangio-pancreatography (ERCP) is a technically difficult procedure that is associated with a substantial risk of complications and may result in death. Awareness of these problems has led to recommendations designed to restrict the number of procedures by careful selection of patients and the use of alternative methods of investigation. ¹ However, there is evidence that patients continue to be subjected inappropriately to ERCP. ²

A recent extensive audit by the British Society of Gastroenterology ³ indicated that approximately 48,000 ERCPs are performed each year in the United Kingdom. Given that the risk of complications is 5-10% and the mortality is 0.3-1.0%, it follows that about 2400-4800 patients suffer adverse events and up to 480 die every year directly as a result of ERCP. If patients are to participate in decisions regarding their management, then they must be made aware of the success rates of the procedure, as well the magnitude of the risks of complications.

This study describes the practice of ERCP over a period of nine years in a district general hospital in England with particular emphasis on the success rates of the technical aspects of the procedure and the rates of complications.

METHODS

Since June 1997, patients undergoing ERCP have been assessed by the single consultant gastroenterologist performing the procedure (JP). This includes a detailed history and examination, together with a review of all relevant investigations. Patients are given a full explanation of the procedure and advised of the risks of complications. They are also provided with a booklet about ERCP and advised to read it carefully before giving their informed consent.

All patients are given prophylactic antibiotics, usually cefuroxime 750mg intravenously, approximately one hour before the procedure. ERCPs are performed in the radiology department using Pentax duodenoscopes. Patients receive a local anaesthetic with lidocaine throat spray followed by intravenous sedation with midazolam and pethidine. They are monitored with pulse oximetry throughout the procedure by a fully qualified nurse. Afterwards, they are transferred to the ward for observation.

Data have been collected prospectively on all patients who have undergone ERCP since 1997. Immediately after the procedure, demographic details, together with information related to indications, sedation, endoscopic and radiological findings, as well as a description of therapeutic

interventions, are recorded on a computer file. The number of data fields was increased in 2001 and, consequently, not all data are available for the entire study period. However, information relating to the most important aspects of ERCP – in other words, cannulation success rates, therapeutic procedure success rates and complications – are available in all cases.

All patients are reviewed by the consultant endoscopist 6-8 hours after the procedure and again the following morning. Data relating to complications are recorded in the medical records which are reviewed at intervals so that the computer files may be updated with this information.

Between 1997 and 2001, the data set was regularly assessed for accuracy by the audit department before presentation at internal audit meetings. Subsequently, information related to complications has been collected by both the consultant gastroenterologist and junior staff to check on the accuracy of the data.

All patients undergoing ERCP – defined as any attempt at intubation of the oesophagus with the duodenoscope – by a single gastroenterologist at Scunthorpe General Hospital between June 1997 and May 2006 have been included in this analysis. Therefore, this paper presents the results of an intention-to-treat analysis.

RESULTS

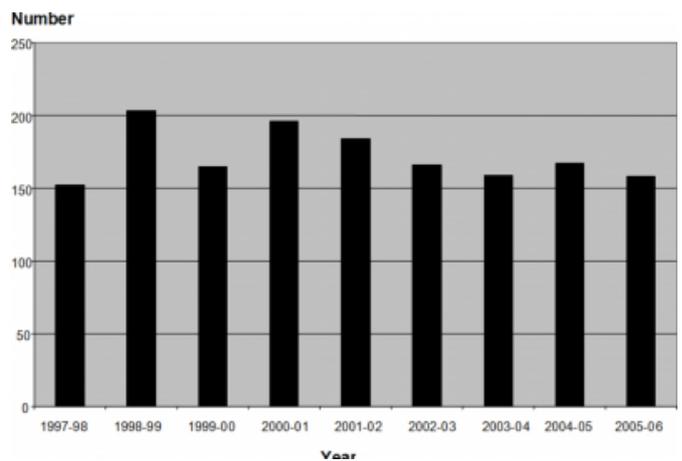
PATIENTS

The total number ERCPs performed during the period 1997-2006 was 1550 with a trend towards fewer procedures over time. (Fig. 1). The mean age of patients was 67 years (range 18-97 years) and 58% were female. Twenty-eight percent of ERCPs were repeat procedures.

Between 2001 and 2006, 96% of patients were reviewed by the consultant performing the ERCP before the procedure. In the remaining cases, the patients had been referred after assessment by another consultant gastroenterologist. All 1550 patients were reviewed by the consultant endoscopist 6-8 hours after ERCP.

Figure 1. Number of ERCPs performed per year, 1997 – 2006.

Figure 1



SEDATION

Data relating to sedation and patients' cooperation with the procedure were available between 2001 and 2006. All patients were sedated with intravenous midazolam and >95% also received pethidine. General anaesthesia was used in 3% of patients.

Sedation was judged to be effective in 41% of ERCPs. However, in more than half of cases, cooperation was recorded as either fair or poor, and the failure to achieve adequate sedation frequently hampered diagnostic cannulation and therapeutic procedures.

INDICATIONS

Data relating to the major indication for ERCP – without regard to the presence or absence of additional indications – were available for the entire study period. The most frequently recorded major indications were obstructive jaundice (41%) and abdominal pain (28%). Since 1999, no ERCPs were performed for abdominal pain except when accompanied by objective evidence of biliary tract obstruction, in particular, deranged liver function tests or dilated ducts.

When the data for major and minor complications were combined for the period 2001-2006, the most frequently observed indications for ERCP were obstructive jaundice (47%), abdominal pain (55%) and dilatation of the biliary tract (52%). Five per cent of procedures were performed for acute pancreatitis.

ENDOSCOPIC ASPECTS

The oesophagus was successfully intubated in all 1550 ERCPs. In six patients (0.4%), intubation was difficult but was successfully achieved by placement of a guidewire with

a gastroscope followed by intubation with the duodenoscope over the wire.

The second part of the duodenum was reached in 1545 procedures (99.7%). On one occasion, a benign stricture of the pylorus was dilated in order to gain access to the duodenum.

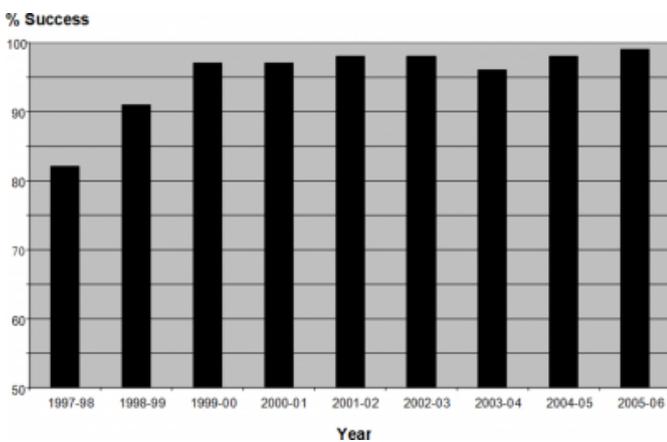
Data relating to the papilla are available only for the period 2001-2006. Excluding one case of a previous choledochenterostomy in which the common hepatic duct was successfully cannulated, the papilla was identified in 827/833 procedures (99.3%). The papilla was normal in appearance in 55%, while the remainder were recorded as showing inflammation or scarring (13%), tumour (4%) or a previous sphincterotomy (23%). The position of the papilla was normal in 73%; in 14%, it was located in an abnormal position, either high in the second part or displaced by underlying disease; the papilla was involved in a duodenal diverticulum in 12%.

CANNULATION AND DIAGNOSTIC FINDINGS IN THE BILIARY TRACT

In all ERCPs, the intention was to cannulate the common bile duct. Overall, this was successfully achieved in 1475/1550 (95%) procedures. However, there was a marked improvement in cannulation rates during the first three years from 82% to 97% and, over the last five years, the success rate in 834 ERCPs was 98% on a strict intention-to-treat analysis. (Fig. 2)

Figure 2. Success rate (%) for common bile duct cannulation by year

Figure 2

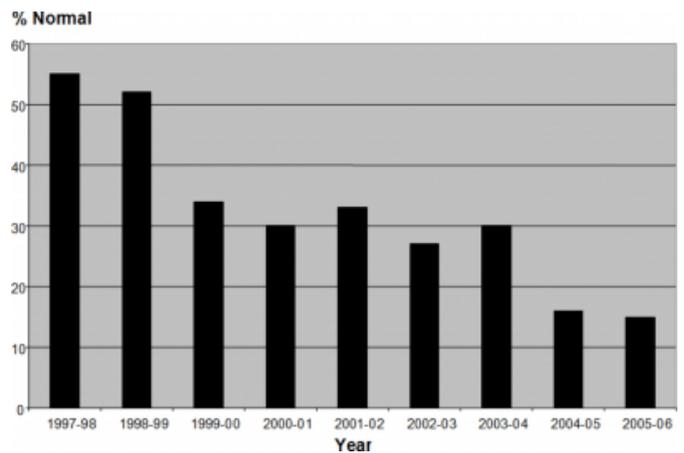


Between 1997 and 2006, there was a downward trend in the proportion of normal cholangiograms. (Fig. 3) Comparing the first two years with the final two years of the study

period, normal cholangiograms decreased from 54% to 16%. During the period 2001-2006, the most common abnormalities detected on cholangiography were biliary tract dilatation (65%), strictures (33%) and choledocholithiasis (38%).

Figure 3. Normal cholangiograms (% of procedures) per year.

Figure 3



CANNULATION AND DIAGNOSTIC FINDINGS IN PANCREAS

Given the developments in alternative diagnostic methods for investigation of the pancreas and the danger of ERCP-induced acute pancreatitis, cannulation of the pancreatic duct was usually not deliberately undertaken. However, pancreatograms were often obtained with the initial injection of contrast. Overall, visualisation of the pancreatic duct was obtained in 874/1550 (56%) procedures. There was, though, a fall in the frequency of pancreatograms from 70% in the first year to 55% in the final year of the analysis. Of 874 pancreatograms, 79% were normal, the remainder showing strictures of the pancreatic duct, changes of chronic pancreatitis or pancreas divisum.

THERAPEUTIC PROCEDURES

SPHINCTEROTOMY AND PRE-CUT INCISION

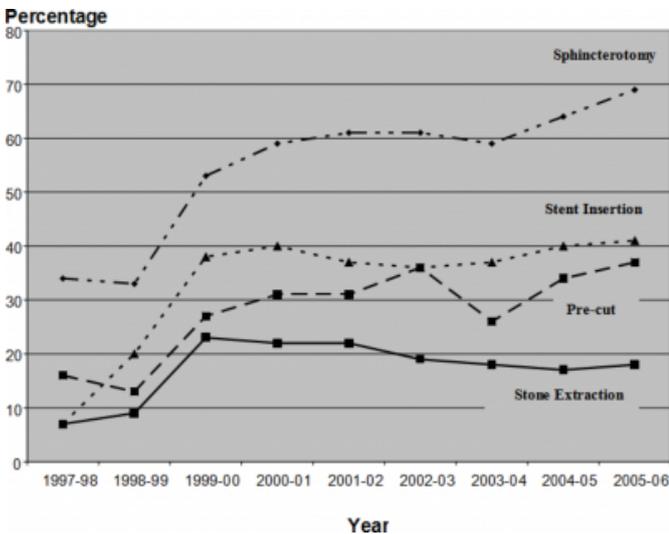
Sphincterotomy was attempted in 844 of 1550 (54%) procedures. This proportion increased from 44% in the period 1997-2001 to 63% in 2001-2006. (Fig 4)

Pre-cut, or needle-knife sphincterotomy, was attempted in 264 of 1550 (17%) procedures. (Fig. 4) Success, defined as obtaining access to the common bile duct, was achieved in 216 of 264 (82%) attempts. Successful pre-cut incision increased from 71% in the period 1997-2001 to 90% in

2001-2006. (Fig. 5)

Figure 4. Percentage of ERCPs involving therapeutic procedures by year

Figure 4

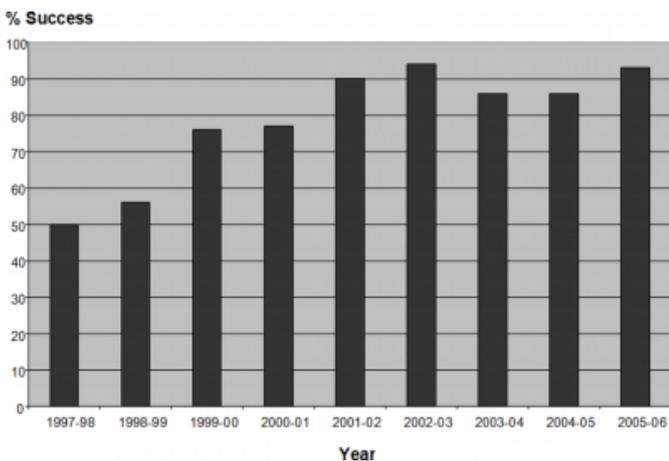


STENT INSERTION

Overall, stent placement in the biliary tract was attempted in 509 of 1550 (33%) procedures and this proportion increased over time. (Fig. 4) Successful insertion of the stent was achieved in 96% of ERCPs in which it was required.

Figure 5. Success rates (%) of pre-cut incision by year.

Figure 5



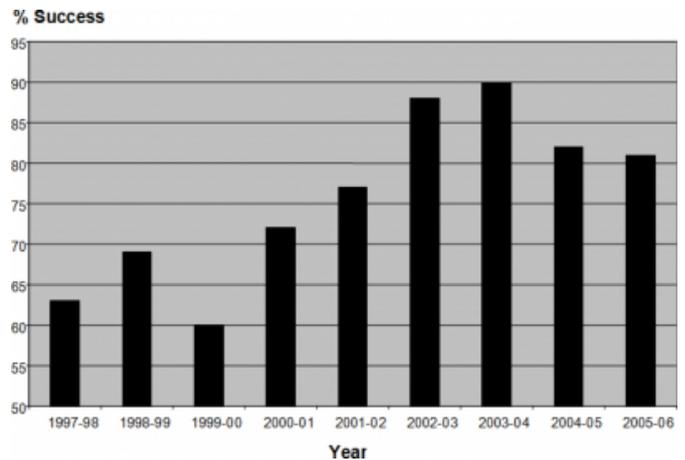
STONE EXTRACTION

Stone extraction was attempted in 432 of 1550 (27%) ERCPs and this proportion increased from 21% in the period 1997-2001 to 33% in 2001-2006. (Fig. 4) Complete or partial clearance were achieved in 300 (78%) and 59 (14%), respectively. Stone extraction failed in 32 (8%). There was

an improvement over time with complete clearance achieved in 68% of cases in 1997-2001 compared with 83% in 2001-2006. (Fig. 6)

Figure 6. Success rates (% complete clearance) of stone extraction

Figure 6



COMPLICATIONS

The complications of ERCP were graded as mild, moderate or severe in line with previous recommendations. 4

PANCREATITIS

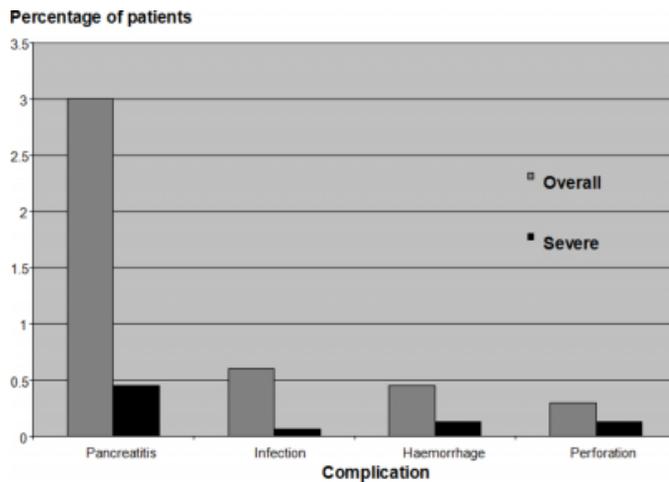
The most commonly observed complication of ERCP was acute pancreatitis which occurred in 51 of 1550 (3%) procedures. (Fig. 7) Of these 51 cases, 36 (71%) were mild and 7 (14%) were severe. One of the seven patients with severe pancreatitis died as a result of this complication. The proportion of ERCPs followed by this complication decreased sharply from 6% in the period 1997-2001 to 1% in 2001-2006.

INFECTION

Infection was recorded as a complication of ERCP in 10/1550 (0.6%) of procedures. (Fig. 7) In only one case was this classified as severe. There were no deaths due to infective complications of ERCP.

Figure 7. Complications during the entire study period, defined by type and severity

Figure 7



HAEMORRHAGE

Haemorrhage occurred after seven of 1550 (0.4%) ERCPs. (Fig. 7) In two of these cases, bleeding was severe and required surgery. There was no mortality from haemorrhage after ERCP.

PERFORATION

Perforation occurred after five of 1550 (0.3%) ERCPs. (Fig. 7) In three cases, this complication was mild or moderate and did not require surgical intervention. Of the remaining two patients with a severe perforation, one underwent successful laparotomy while the other died 18 hours after ERCP as a result of the complication.

MORTALITY

Two patients died directly as a result of ERCP, giving an overall mortality of 0.1% in 1550 procedures. One patient died within 24 hours due to a perforation; the other developed severe acute pancreatitis and died four months later after a protracted illness. A further patient developed mild acute pancreatitis and, although this resolved, she declined fluids and died due to renal failure. If this patient is included as a death due to ERCP, then the mortality from the procedure was 0.2%.

DISCUSSION

ERCP is an indispensable procedure for the management of patients with biliary tract disease. Although its diagnostic value has been reduced by the advent of MRI scanning and endoscopic ultrasound, it still remains useful in identifying lesions of the ampulla and determining the nature of strictures of the biliary tract when combined with histology or cytology. However, its primary value lies in the therapeutic procedures, namely, the removal of common bile

duct stones, the alleviation of obstruction by stent insertion and decompression of the biliary tract in the management of post-operative biliary leaks. The correct use of ERCP, though, must involve detailed assessment of patients to avoid unnecessary exposure to serious complications.

The present study describes the practice of ERCP in a district general hospital in the United Kingdom between 1997 and 2006. Its strengths include the large number of procedures reported, the prospective nature of most of the data collected, and the strict intention-to-treat analysis which avoids any selection of patients and, hence, provides a true reflection of the success rates of both diagnostic and therapeutic procedures. However, the study has weaknesses. The data relating to complications were collected retrospectively and relied, therefore, on the accuracy of medical records. While this would be unlikely to be a problem in terms of identifying complications of a moderate or severe degree, it may have led to some inaccuracy in terms of the frequency of minor complications. This is aggravated by the absence of any reliable criteria for the identification of the milder complications of ERCP.

THE SELECTION OF PATIENTS FOR ERCP

All patients referred for ERCP were assessed in detail by a consultant gastroenterologist and, in 96% of cases, this was carried out by the individual performing the procedure. This contrasts with the results of a recent large audit in the UK which reported that only 16% of endoscopists personally vetted all patients undergoing ERCP. ³ Thus, patients were carefully selected with due attention to their background medical illnesses and their suitability for the procedure; consideration was given to the indications in order to ensure that ERCP was the most appropriate investigation or treatment; and a comprehensive verbal explanation of the procedure was provided, together with written information to be read before giving informed consent.

During the period of the study, the indications for ERCP changed. In particular, after the first two years, patients without objective evidence of biliary tract disease were not considered for the procedure. This was reflected in the findings of the present study which showed a sharp reduction in the number of normal cholangiograms over time as well as a decrease in the rate of pancreatitis – a complication which is recognised to occur more often in patients with abdominal pain alone. ³⁵⁶⁷ The total number of ERCPs declined between 1997 and 2006, most probably due to both changes in clinical indications and the availability of

alternative methods of investigation of the biliary tract, particularly magnetic resonance cholangio-pancreatography.³

ENDOSCOPIC ASPECTS OF ERCP

Although difficulties were occasionally encountered with intubation of the oesophagus, all procedures were successful in reaching the stomach. Insertion of the duodenoscope over a guidewire placed with a gastroscope was required in only 0.4% of procedures. Passage of the side-viewer through the pylorus and duodenal bulb was not infrequently hampered by tumour infiltration but this seldom prevented further progression. The descending duodenum was reached in 99.7% and the papilla was successfully identified in 99.3% of ERCPs.

The appearance of the papilla was reported to be normal in 55% of cases, with evidence of previous sphincterotomy being the most commonly observed abnormality. The papilla was involved in a duodenal diverticulum in 12% of cases; this is a similar proportion to that observed previously.⁸⁹¹⁰¹¹¹² Although one study reported reduced cannulation rates when the papilla was related to a diverticulum,⁹ this finding has not been confirmed.¹¹¹² In the present study, a diverticulum often hindered, but did not prevent, successful cannulation.

CHOLANGIOPANCREATOGRAPHY

Between 2001 and 2006, the success rate for cannulation of the common bile duct in 834 patients was 98% on a strict intention-to-treat analysis. This compares favourably with previous reports. The cannulation rates in large studies range from 82-99%; most report less than 95% success and there are often uncertainties regarding exclusions.

¹¹¹²¹³¹⁴¹⁵¹⁶¹⁷¹⁸¹⁹²⁰²¹²²²³²⁴²⁵²⁶²⁷ A recent large UK audit reported successful cannulation in 86% of 5,264 procedures while 58% of ERCP endoscopists failed to achieve successful cannulation rates of $\geq 90\%$.³

The proportion of normal cholangiograms decreased from 55% to 16% during the period 1997-2006, a finding that reflected the changing clinical indications for ERCP. The frequency of normal cholangiograms, common bile duct stones and strictures were consistent with previous reports.²³²⁸

Pancreatograms were obtained in 56% of ERCPs, with a reduction in frequency over time. In most cases, filling of the pancreatic duct occurred during the initial attempts to cannulate the common bile duct. Overall, 79% of pancreatograms were normal.

THERAPEUTIC PROCEDURES

Sphincterotomy was performed in 54% of patients, a similar proportion to that reported in the literature.³¹⁵²⁹³⁰ Pre-cut, or needle-knife sphincterotomy, was attempted in 17% of ERCPs in the present study again consistent with previous reports.¹⁵³¹³²³³³⁴ Interestingly, the frequency of pre-cut sphincterotomies was inversely proportional to the occurrence of acute pancreatitis. Overall, pre-cut incision allowed deep access to the common bile in 82% of cases and this increased to 90% when the analysis was confined to the period 2001-2006. This figure is higher than most published reports.³¹³³¹³²³³³⁴³⁵³⁶³⁷³⁸³⁹⁴⁰⁴¹⁴²⁴³

In the period 2001-2006, the success rates for pre-cut incision (90%) and stent insertion (96%) were high when compared to other reports.³ Data for stone extraction, however, are more difficult to compare because clearance of the ducts was not always attempted. For example, in frail, elderly patients with extensive duodenal diverticula who might not survive a complication of ERCP, management with a biliary stent would be considered a sensible option compared with the traumatic removal of large stones from the common bile duct. Thus, the rate of 83% for complete clearance of stones from the common bile duct in the present study must be interpreted in the context of decisions not to attempt stone extraction in some patients for sound clinical reasons.

COMPLICATIONS

The overall risk of complications of ERCP – conventionally taken as the aggregate of acute pancreatitis, haemorrhage, perforation and biliary tract infection – is reported in large studies as being in the range of 3-16%,

⁵⁶¹⁴¹⁵¹⁶¹⁷²⁰²³²⁴²⁵²⁷²⁹³³⁵³⁶⁴⁴⁴⁵⁴⁶⁴⁷⁴⁸⁴⁹⁵⁰⁵¹ with an increased risk in therapeutic, compared with diagnostic, procedures.⁵² In the present study, complications occurred after 4.7% of ERCPs. This finding was very similar to the 5.1% of complications reported by a recent large audit in the UK.³

Acute pancreatitis is the most common complication of ERCP although the rates vary considerably. In large series, between 2% and 7% of procedures are followed by pancreatitis.³⁷¹⁴¹⁵¹⁶¹⁷²⁹⁴⁴⁴⁵⁴⁶⁴⁷⁵²⁵³⁵⁴⁵⁵⁵⁶⁵⁷⁵⁸⁵⁹ However, in randomised trials, where the reporting may be more accurate, 8-15% of procedures are associated with this complication.²²⁶⁰⁶¹⁶²⁶³⁶⁴⁶⁵⁶⁶⁶⁷⁶⁸⁶⁹⁷⁰ Variation in the rate of pancreatitis may also be related to the differences in risk factors which include multiple injections of contrast into the pancreatic duct usually associated with difficult cannulation,

⁷⁴⁶⁵⁹⁶⁰⁶⁵ small calibre ducts, ⁵⁹⁷¹ sphincter of Oddi dysfunction, ⁴⁶⁷¹⁷² female gender ⁷⁵⁹⁷³ and previous ERCP-induced pancreatitis. ⁷⁴⁶ Although sphincterotomy and pre-cut have been reported to increase the risk of pancreatitis, ⁴⁶⁵⁹⁶⁰⁷² the findings are not consistent. ⁵³²³³³³⁸⁷⁴⁷⁵ It seems, though, that differences in the definition of pancreatitis account for much of the variation in the data. ⁷⁶ In particular, since upper abdominal pain or increased amylase may each occur after the procedure without pancreatitis, ⁵⁸⁶⁰ it follows that the presence of both cannot be assumed to indicate the occurrence of this complication without further evidence. In the present study, 3% of ERCPs were complicated by pancreatitis but, more importantly, only 0.4% of cases were associated with severe pancreatitis, a finding which is similar to that reported elsewhere. ¹²⁸

Haemorrhage occurs in 0.5-2% of patients undergoing ERCP. ⁵⁶¹³¹⁴¹⁵¹⁶¹⁷²⁵²⁷³⁶⁴⁴⁴⁵⁴⁷⁴⁸⁵⁴⁵⁶⁵⁷⁷⁷ This complication is, as expected, related to sphincterotomy or pre-cut, with some studies suggesting an increased risk with the latter procedure. ²⁸³¹³²³³³⁵³⁷³⁸⁴⁰⁷⁵⁷⁸⁷⁹⁸⁰ Only 0.5% of ERCPs in the present study were complicated by haemorrhage and the risk of serious bleeding requiring surgery was 0.1%.

ERCP may be complicated by infection, either of the biliary tract or of other sites, including the chest. However, reports in the literature tend to focus on biliary tract infection and, in particular, cholangitis. Most of the large studies report that between 0.5% and 2% of ERCPs are complicated by cholangitis. ⁶¹⁷²⁵³⁶⁴⁴⁴⁵⁴⁶⁴⁷⁴⁸⁴⁹⁵¹⁵⁴⁶³⁷⁹⁸¹⁸²⁸³ In the present study, ERCP was complicated by infection in 0.6% of cases and in only one case (0.1%) was this classified as serious. These findings may be related to the routine use of antibiotic prophylaxis as studies suggest that this reduces the risk of bacteraemia ⁸²⁸⁴ and, more importantly, clinical sepsis ⁶³⁸⁵⁸⁶ following ERCP.

Perforation is the least common complication of ERCP. It may be related to endoscopic trauma to the oesophagus, stomach or duodenum – and, in the case of Polya gastrectomy, the jejunum – to sphincterotomy or pre-cut incisions, to manipulation of the common bile duct with balloons or baskets, or to damage to the biliary tract by guidewires. ⁸⁷ Large series report that between 0.1% and 1.8% of ERCPs are complicated by perforation.

⁶¹⁵¹⁶¹⁷²⁵²⁸²⁹³⁶⁴⁵⁴⁶⁴⁷⁴⁸⁴⁹⁵¹⁵²⁵⁴⁷⁷⁷⁹⁸¹⁸⁸⁸⁹⁹⁰⁹¹ In the present study, 0.3% of procedures resulted in perforation and, in all cases, this was the result of sphincterotomy or pre-cut. In three cases, this complication was mild or moderate and was managed

conservatively in line with accepted practice. ⁸⁷⁹⁰⁹² However, of the remaining two patients, one required laparotomy whilst the other died before undergoing surgery. Thus the proportion of ERCPs complicated by serious perforation was 0.1%.

The mortality as a direct consequence of ERCP in the present study was 0.1% although, if a further death less definitely related to the procedure were included, this would increase to 0.2%. This compares favourably with recently published data which reported a procedure-related mortality rate of 0.4%. ³

TRENDS OVER TIME

Scunthorpe General Hospital serves a population of about 160,000 and, given the number of procedures performed annually over recent years, this is equivalent to approximately one ERCP per 1000 of the population per year, a figure similar to that in the recent audit by the British Society of Gastroenterology. ³ As noted above, the number of ERCPs declined between 1997 and 2006. Improved selection of patients and the availability of new techniques for the investigation of the biliary tract resulted in both fewer unnecessary ERCPs – as judged by a reduction in the proportion of normal cholangiograms – and a decline in complications, particularly acute pancreatitis. Interestingly, although the proportions of procedures involving either sphincterotomy or pre-cut increased over time, the rate of complications actually decreased over the same period.

The reduction in the numbers of patients undergoing ERCP has implications for training. The general view is that trainees need to perform between 100 and 200 procedures before they achieve cannulation success rates approaching 80-85% ²¹⁹³⁹⁴⁹⁵ and the evidence indicates that, at least in the UK, such a degree of competence is not being achieved. ³ Moreover, the decline the number of ERCPs should lead to fewer consultant gastroenterologists performing this procedure in future.

CONCLUSIONS

This study describes the clinical outcomes of a single-handed, consultant-based ERCP service in a district general hospital over a period of nine years and involving 1550 procedures. Data, mostly collected prospectively, show that the consultant gastroenterologist performing ERCP assessed >95% of patients before, and reviewed all of them after, the procedure. The diagnostic and therapeutic success rates – by strict intention-to-treat analysis – were excellent while the

risk of complications was low. The data also draw attention to the changes that have taken place over the past decade, particularly in relation to the selection of patients, the decreasing numbers of patients undergoing ERCP, the reduction in normal cholangiograms and the frequency of therapeutic procedures.

ACKNOWLEDGEMENTS

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