



## RESEARCH

# Endoscopic retrograde cholangio-pancreatography services can be accessible and of a high standard in a district general hospital

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## Abstract

**Background** Endoscopic retrograde cholangio-pancreatography (ERCP) is an important tool in the management of pancreato-biliary disease.

**Objective** To compare the current practice of ERCP in a district general hospital with those reported in the 2007 British Society of Gastroenterology (BSG) ERCP audit and assess access to the service.

**Design** This was a service evaluation study. Data were collected retrospectively for all people who underwent ERCP. Demographic, clinical and procedure related data were collected and analysed.

**Setting** Sunderland Hospital.

**Results** 236 patients (median age 70 years, 56% women) underwent ERCP. The median period from referral to patient review was 1.0 day. The median period from the decision to carry out an ERCP to the actual procedure date was 3 days. All patients had radiological imaging before their first procedure. 96% patients had their bloods checked within 1 week of the procedure. The most common indication was related to choledocholithiasis and its complications. The mean doses of midazolam and diazepam used were 4.4 mg and 11.1 mg, respectively. The selective biliary cannulation rate was 92%. Sphincterotomy, biliary stent insertion and complete stone extraction were achieved in 94%, 85% and 88% of patients before the procedure. Complications that occurred as a result of ERCPs were as follows: bleeding (1.7%), pancreatitis (3.8%), cholangitis (0.4%) and renal failure (0.4%). The 30-day death rate was 4.6%. However, none of these were procedure related.

**Conclusions** The structure of the ERCP services at Sunderland Royal Hospital provides patients with a high-quality and accessible service. The technical success rate and sedation rate were better than those reported in the BSG ERCP

audit. The complication rate and procedure-related mortality were comparable to the BSG audit and much below the published figures.

## Introduction

Endoscopic retrograde cholangio-pancreatography (ERCP) is an important diagnostic and therapeutic tool in the management of pancreato-biliary disease. ERCP is diagnostically and therapeutically useful in the management of choledocholithiasis, pancreato-biliary malignancies and benign diseases of the pancreas.

However, the procedure carries a significant risk of complications, varying between 4% and 30%.<sup>1–5</sup> Because of the challenging nature of the procedure and a comparatively high rate of associated complications, various national endoscopic societies have developed recommendations for the minimum standards for training and accreditation. In 2002, the American Society for Gastrointestinal Endoscopy recommended that the success rate in required duct cannulation and/or basic treatment should be a minimum of 80% for attainment of competence.<sup>6</sup> In 2004, the Joint Advisory Group on Gastrointestinal Endoscopy recommended that trainees should aspire to a cannulation rate of 90% but did not specify an absolute mandatory cannulation and basic treatment rate or a minimum number of procedures that should be performed before achieving competence.<sup>7</sup> It is also expected that accredited ERCP endoscopists perform a minimum number of procedures a year to maintain competence and expertise.

Unlike other endoscopic procedures, the estimated national workload of ERCP has remained remarkably stable over the past decade. This was reflected in the British Society of Gastroenterology (BSG) national document<sup>8</sup> in 2004, which showed that the estimated national average of 48 000 ERCPs each year was comparable to the number reported by a BSG ERCP survey carried out in 1998.<sup>8</sup>

Because of this relatively low volume, there exists a tension between maintaining expertise and the provision of a readily accessible and timely service for patients requiring this procedure.

### Aims and methods

Sunderland Royal Hospital is a large district general hospital in northeast England. It serves a population of 330 000. There are two ERCP endoscopists in this hospital who perform a total of between 225 and 250 ERCPs each year. They are also designated ERCP regional trainers. Between them, they carry out two ERCP lists a week, providing cross-cover for all leave. They are both established and have a lifetime ERCP experience of over 2000 procedures. We carried out a retrospective audit of the ERCP practice in our hospital between 1 January 2009 and 31 December 2009. The main purposes of this audit were:

- To assess adherence to published guidelines with respect to technical success rate, complication rate and procedure-related mortality and to compare these rates with those reported in the national audit.<sup>6</sup>
- To assess access to the service for those patients requiring the procedure. This was done by assessing waiting times before a review of patients and before the procedure.

Approval for this audit was obtained from the trust audit committee. An audit proforma was designed by the ERCP endoscopists in collaboration with the clinical governance department. Data were collected by a trainee gastroenterologist (VM) using patients' clinical case notes, endoscopy reports, the international Olympus ERCP database, the hospital information support system, nursing records of procedures stored in the endoscopy department and the ERCP diary kept by the gastroenterology secretaries. Data were then transferred from the audit proforma to the Excel spreadsheet for subsequent analysis. The 't' test was used to analyse continuous data and Fisher's exact test was used to analyse categorical data.

### Results

The service in Sunderland is structured as two lists a week. If they fit the following criteria, patients have their procedure as day cases:

- patient is ambulant and self-caring;
- patient can be cared for after the procedure by a responsible adult who is able to bring them back to hospital if there are any complications.

A total of 236 ERCPs were carried out during the study period with the procedures being equally shared between the two ERCP endoscopists (118 ± 1). Eighty-

five (36%) of the procedures were carried out as day-case procedures. The median age of patients was 70 years (range 19–94) and a majority (56%) of the patients were women. All patients had a documented review by the medical gastroenterology team (usually an ERCP endoscopist) to assess appropriateness for the procedure and then to provide information to the patient and obtain their consent. The median period from referral (in case of inpatients, n=145) to patient review by gastroenterology team was 1.0 day (range 0–5). The median period from the decision to carry out an ERCP to the actual procedure date in the case of inpatients (n=145) was 3 days (range 0–19). Informed consent was obtained before all procedures (with appropriate procedures for patients without capacity).

Ninety-six per cent of patients had their blood count and coagulation screen checked within 7 days of the procedure, with the majority (93.6%) being checked within 72 h. All patients had radiological imaging before their first procedure. All ERCPs were performed with therapeutic intent. Thirty-six per cent of patients received preprocedure antibiotics. There was no clear indication for this in four patients.

Preprocedure indications for ERCP were as follows:

- common bile duct (CBD) stones 64.5%;
- gallstone pancreatitis 8%;
- pancreato-biliary malignancies 16.5%;
- possible sphincter of Oddi dysfunction 1.5%;
- postcholecystectomy bile leak 7%;
- stent change for recurrent CBD stones 1%;
- other 1.5%.

Forty-two (17.8%) procedures were repeat procedures for the following reasons:

- planned repeat for previous incomplete CBD stone clearance 26;
- occluded stent for pancreato-biliary malignancy 11;
- previous failed CBD cannulation 5.

**Table 1** Sedatives and analgesics used during ERCP

| Drugs used during ERCP       | SRH (n=number of patients) | BSG audit (n=number of patients) | p Value |
|------------------------------|----------------------------|----------------------------------|---------|
| Average midazolam dose (mg)  | 4.4 (n=112)                | 5.7 (n=4521)                     | <0.0001 |
| >5 mg of midazolam (%)       | 21 (n=24)                  | 33 (n=1484)                      | 0.0105  |
| Average diazepam dose (mg)   | 11.1 (n=118)               | 13.5 (n=520)                     | 0.0005  |
| General anaesthesia (%)      | 1.3 (n=3)                  | 1.5 (n=79)                       | 1.00    |
| Average fentanyl dose in µg) | 44.3 (n=225)               | 90.4 (n=1069)                    | <0.0001 |
| Reversal of sedation (%)     | 0 (n=231)                  | 7.6 (n=345)                      | <0.0001 |

ERCP, endoscopic retrograde cholangio-pancreatography; SRH, Sunderland Royal Hospital.

**Table 2** Grades of ERCP

| Grades of ERCP | Diagnostic                 | Therapeutic  |
|----------------|----------------------------|--|
| 1 – Standard   | Selective deep cannulation | Biliary sphincterotomy<br>Stones <10 mm<br>Stents for biliary leak |
| 2 – Advanced   | Biopsy and cytology        | Stents for low tumours   |
|                | Bilroth II diagnostics     | Stones >10 mm  |
|                | Minor papilla cannulation  | Hilar tumour stent placement                                       |
| 3 – Tertiary   | Sphincter manometry        | Benign biliary strictures  |
|                | Whipple                    | Bilroth II therapeutics  |
|                | Roux-en-Y                  | Intrahepatic stones  |
|                | Intra-ductal endoscopy     | Pancreatic treatments  |

ERCP, endoscopic retrograde cholangio-pancreatography.

**Table 3** Interventions used during ERCP

| ERCP intervention  | Sunderland Royal Hospital | BSG audit         | p Value        |
|--|---------------------------|-------------------|----------------|
| Deep bile duct cannulation (%)                                 | 92                        | 86.5              | 0.0140         |
| Sphincterotomy (% of intended preprocedure)                    | 94                        | 84                | 0.0004         |
| Biliary stent insertion (% of intended preprocedure)           | 85                        | 73                | 0.0094         |
| Complete biliary stone extraction (% of intended preprocedure) | 88                        | 62                | <0.0001        |
| Balloon sphincteroplasty of ampulla (% of total procedures)    | 12.7                      | No data available | Not applicable |
| Unintended pancreatogram (% of total procedures)               | 3.9                       | 27                | <0.0001        |

ERCP, endoscopic retrograde cholangio-pancreatography.

Midazolam or diazemul were used for sedation together with fentanyl. Table 1 compares our sedation figures with the BSG ERCP audit.

Other drugs used during the ERCP procedures were as follows: Buscopan in 198 patients (mean dose 30 mg), glucagon in 16 patients (mean dose 1 mg) and sublingual nitrate in 113 patients (mean dose 1.24 µg).

To assess the degree of difficulty of procedures, we used Cotton's grading system (table 2).<sup>9</sup> Most (66.5%) of our procedures were grade 1 ERCPs, with 31.5% grade 2 category and 2% of the procedures grade 3 category (these four cases were therapeutic procedures in patients with previous polya-gastrectomy). Deep bile duct cannulation rates for grade 1, grade 2 and grade 3 procedures were 91%, 94.6% and 100%, respectively, and completion of intended treatment was achieved in 93%, 83% and 75%, respectively.

The frequency of therapeutic interventions performed during the ERCP procedures is given in table 3.

**Table 4** ERCP related complications

| Complication      | SRH | BSG audit | p value |
|-------------------|-----|-----------|---------|
| Bleeding (%)      | 1.7 | 0.9       | 0.0616  |
| Pancreatitis (%)  | 3.8 | 1.5       | 0.0126  |
| Cholangitis (%)   | 0.4 | 1.1       | 0.5197  |
| Renal failure (%) | 0.4 | 0.03      | 0.0053  |
| Perforation (%)   | 0   | 0.5       | 0.6248  |

ERCP, endoscopic retrograde cholangio-pancreatography; SRH, Sunderland Royal Hospital.

**Table 5** ERCP related complications in day case procedures

| Complication                            | Number of patients | Mean additional bed days as a result of hospital admission |
|---|--------------------|--|
| Pancreatitis (3 mild, 2 moderate)       | 5                  | 2.0  |
| Bleeding (1 mild, 1 moderate)           | 2                  | 5.5  |
| Cholangitis                             | 1                  | 4.0  |
| Chest pain (ECG normal, troponin T neg) | 1                  | 1.0  |

ERCP, endoscopic retrograde cholangio-pancreatography.

The mean scope time and fluoroscopy time for the procedures were 24.5 min (range 4–60) and 2.8 min (range 0.1–15), respectively. A trainee was involved in 38.5% of the procedures.

Table 4 gives details of the complications of our ERCP procedures in comparison with those reported in the BSG audit.

If the complications are considered in terms of procedure difficulty, then in grade 1 procedures, 5% had post-ERCP pancreatitis and 1.9% had postsphincterotomy bleeding. The corresponding figures for grade 2 procedures were 1.3% and 1.3%, respectively, with an additional 1.3% having cholangitis. There were no complications in the grade 3 procedures.

To assess the impact of complications on bed occupation, we used data from day-case procedures (table 5)

## Discussion

Our audit provides complete, comprehensive data of all the ERCPs carried out in a district general hospital setting over a 1-year period. To the best of our knowledge, this is the first such non-tertiary referral centre comprehensive study comparing the ERCP practice in a UK district general hospital with the most recent BSG ERCP audit.

The main strengths of this audit are first, that notes were reviewed by a person who was not involved in the majority of procedures and second, the case notes review is likely to have comprehensively captured all complications as even day-case patients are unlikely to have been admitted to another institution (they are given an emergency contact number when discharged).

We feel that it is reasonable to compare our patient population with that reported in the BSG audit as the demographics of both populations were similar.

Several positive outcomes emerged from our study. All patients gave appropriate consent before undergoing the procedure. All patients had evidence of structural disease on radiological imaging before their first procedure (96% in the BSG audit). All ERCPs were performed with therapeutic intent (94% in the BSG audit). Most (96%) of the patients had their bloods checked within 7 days of the procedure (86% in the BSG audit). However, it is a concern that six patients did not have their coagulation checked within 7 days of the procedure. Of these six patients, two underwent sphincterotomy and one underwent balloon sphincteroplasty. However, none of them had complications. Of the patients who underwent ERCP, 8.5% belonged to the American Society of Anesthesiology (ASA) grade 3–5 category compared with 12.7% in the BSG audit, which confirms appropriate patient selection for the procedures. This is in contrast to the National Confidential Enquiry into Patient Outcome and Death report 2004, which concluded that potentially large numbers of inappropriate procedures were being performed on high-risk patients<sup>10</sup>. Our technical success rate was better than the figures from the BSG audit. Procedure-related complications were comparable to those of the BSG audit and much below published figures.<sup>1–5</sup>

The incidence of post-ERCP pancreatitis was higher than that reported in the BSG audit. However, our figures fall well within the range reported in the international literature, which is usually from referral centres and large multicentre studies.<sup>11 12</sup>

Overall, 30-day mortality was slightly higher than in the BSG audit (4.6% vs 3.4%). It is noted, however, that in the BSG audit, a number of endoscopists did not give permission for their data to be included. Also, patients who were considered too ill to give consent for their data to be used were excluded from that audit. Therefore, the reported complication rates and 30-day mortality probably did not accurately reflect the whole picture. There were no procedure-related deaths in our study population (eight died because of progression of underlying malignant disease and three died of pneumonia which was present before the ERCP). Twenty-seven per cent of deaths were in the ASA grade 3–5 categories compared with 33% in the BSG audit.

Our figures showed no adverse effect of procedure difficulty grade on bile duct cannulation success rates or indeed, on the incidence of complications. We accept, however, that the number of grade 3 procedures was small.

In this trust, wherever possible, we now attempt to perform as many procedures as possible as day-case procedures. This is after our previously published experience on safety<sup>13</sup> (after which a discharge

protocol was developed), which complies with the published literature.<sup>14 15</sup> In this audit, compliance with the protocol did not lead to any compromise of patient safety since in the day-case procedures, all complications were picked up within the 6 h observation period after the procedure.

There are only two, highly experienced ERCP endoscopists in our trust. This allows them to perform significantly more than the suggested minimum number of procedures required to maintain good clinical practice.<sup>16</sup> These factors may contribute to the good cannulation and completion rates and the relatively low complication rates. It therefore possibly supports the requirement for an annual minimum number of procedures to be performed by ERCP endoscopists.

This was a retrospective audit (in comparison with the national audit which was prospective). However, all patients who underwent ERCP in the year studied were identified and included in the data analysis.

We conclude that the structure of ERCP services at Sunderland Royal Hospital (a large district general hospital) provides patients with a high-quality and accessible service.

**Contributors** VM—first author conducted the whole study and wrote up the paper. HM—second author. DN—senior author and consultant. He supervised VM in carrying out the project and writing up the article

**Competing interests** None.

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