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Endoscopic retrograde cholangio-pancreatography practice in district general hospitals in North East England: a Northern Regional Endoscopy Group (NREG) study

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ABSTRACT

Aim: Endoscopic retrograde cholangio-pancreatography (ERCP) is an important tool for the management of pancreato-biliary disease. The aim of this study was to compare the current practice of ERCP in North East England against the key 2004 National Confidential Enquiry Report into Patient Outcome and Death (NCEPOD) recommendations and the standards set by the Joint Advisory Group on Gastrointestinal Endoscopy (JAG).

Methods: This was a prospective multicentre study involving all hospitals in North East England, coordinated through the Northern Regional Endoscopy Group (NREG).

Results: Fourteen endoscopy units submitted data for 481 ERCPs. Mean dose of midazolam was 3.24 mg (standard deviation 1.35; range 1–8 mg). Coagulation profile results were available on 469 patients (97%). Radiological investigations were documented in 96% of the procedures (463 of 481) prior to ERCP. The most common indication for ERCP was related to choledocholithiasis and its complications. All procedures were performed with a therapeutic intent. A total of 84% of all patients were either American Society of Anesthesiologists grade I or II. The selective biliary cannulation rate was 87.3%. The total completion rate of all procedures was 80.2% (381 of 475) and completion of therapy was 89.5% (425 of 475). The 30-day mortality rate was 2% (ten patients) and procedure-related complications occurred in 5% of patients. There were no deaths directly as a result of ERCP; all deaths were related to underlying medical conditions.

Conclusions: The practice of ERCP in North East England adheres to the key recommendations of the NCEPOD and the standards set by JAG. The rates of complications compare favourably with those reported internationally.

KEYWORDS Endoscopic retrograde cholangio-pancreatography, North East England.

DECLARATION OF INTERESTS No conflict of interests declared.

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INTRODUCTION

Endoscopic retrograde cholangio-pancreatography (ERCP) is an important diagnostic and therapeutic modality for the management of pancreato-biliary disease. In 2007, the British Society of Gastroenterology (BSG) published results of a prospective audit examining ERCP practice in five metropolitan regions of England.[1] This audit followed the 2004 report of the UK's National Confidential Enquiry into Patient Outcome and Death (NCEPOD) which had identified deficiencies in a number of areas.[2] The aim of our audit was to compare the quality of ERCP practice in district general hospitals (DGHs) in the north-east of England against the key recommendations of the NCEPOD report[2] (Table 1) and the standards set by the Joint Advisory Group on Gastrointestinal Endoscopy (JAG) for certification in ERCP.[3] The audit was coordinated through the Northern Regional Endoscopy Group (NREG).

METHODS

The hospitals in the north-east region serve a total population of 3.5 million. There is representation of all hospitals in NREG and through this organisation ERCP endoscopists were invited to participate and provide data on all ERCP procedures during the audit period (June–August 2009). An ERCP procedure was defined as any endoscopic procedure that was performed with an intention to cannulate the common bile duct (CBD) or the pancreatic duct. A questionnaire was developed to capture the relevant demographic, clinical and procedure-related data. Data were collected prospectively over a

TABLE 1 Key recommendations of the National Confidential Enquiry into Patient Outcome and Death[2] relevant to endoscopic retrograde cholangio-pancreatography (ERCP)

Area of practice	NCEPOD findings	NCEPOD recommendations
Consent	No written consent in 21% of patients who died; 16% of deaths in patients with acute confusion or dementia but written consent present in two-thirds of these	Risks/benefits to be explained to all patients The ability of those with dementia or acute confusion to provide consent to be tested
Patient preparation	In 80% of ERCPs there was no record of clotting tests	Bilirubin and clotting results to be available before ERCP
Sedation and monitoring	14% of cases inappropriately (excessively) sedated	Unit protocol for administration of sedation
Training and education	11% of deaths were related to ERCPs performed by an endoscopist performing <50 procedures per year	National guidelines for assuring continuing competency recommended All units to audit deaths within 30 days of ERCP
Patient selection, assessment and outcome	77% of deaths following ERCP were among those with American Society of Anesthesiologists grade III–V	Patients to be reviewed by consultant endoscopist before ERCP to ensure procedure is appropriate and optimised

Adapted from Williams EJ, Taylor S, Fairclough P et al. Are we meeting the standards set for endoscopy? Results of a large-scale prospective survey of endoscopic retrograde cholangio-pancreatograph practice. *Gut* 2007; 56: 821–829.

three-month period at the time of the procedures. Nurse-assessed sedation and comfort levels (see Appendix I; see online material at http://www.rcpe.ac.uk/journal/issue/41-2.php for Appendices) were recorded by the endoscopist immediately after the procedures.

The BSG have published a consensus document[3] regarding consent, and details about the consent process were also collected. The endoscopists were asked to review patients immediately after the procedure and then review case notes 30 days or more after the procedure to capture immediate and delayed adverse events. In the case of an adverse event, the endoscopist reviewed the hospital records in detail to identify the type, severity and outcome of the event. The criteria for the diagnosis of post-ERCP complications are summarised in Table 2. Anonymised patient data were analysed using the SPSS statistical software (Version 17.0 SPSS Inc).

TABLE 2 Definitions of post-endoscopic retrograde cholangio-pancreatography complications

	Mild	Moderate	Severe
Pancreatitis (abdominal pain and amylase >3x above normal after 24 hours)	Requiring admission or prolongation of planned admission to >2 nights	Requiring 4–10 days in hospital	Admission for >10 days; haemorrhagic pancreatitis; pseudocyst; intervention required; death
Infection (Cholangitis)	>38 °C for 1–2 days	Febrile or septic illness requiring >3 days in hospital or endoscopic/ percutaneous intervention	Septic shock or surgery; or resulting in death
Bleeding	Clinical (not just endoscopic), drop in Hb >3 gm%; no transfusion	Transfusion (4 units or less); no angiographic or surgical intervention	Transfusion >5 units; angiographic or surgical intervention; death
Perforation	Possible or slight leak of contrast – treated with fluids, suction for <3 days	Any definite perforation treated conservatively for 4–10 days	Hospitalisation for >10 days; need for intervention (percutaneous or surgical); death

Adapted from Cotton PB, Lehman G, Vennes J et al. Endoscopic sphincterotomy complications and their management: an attempt at consensus. *Gastrointest Endosc* 1991; 37:388–93.

RESULTS

Demographics of the patient population

Fourteen endoscopy units submitted data for 481 ERCP procedures. Of these, 303 procedures (63%) were carried out on females. The mean age of patients was 69 years with no difference between sexes. There were 139 patients with American Society of Anesthesiologists (ASA) grade I (mean age 60.8 years); 191 patients with grade II (mean age 71.91 years); 57 patients with grade III (mean age 77.88 years); and six patients with grade IV (mean age 80.5 years). A total of 88 questionnaires did not contain a record of patient ASA scores (see Appendix II).

Sedation

All but three procedures (which were performed with general anaesthesia) were performed with conscious

TABLE 3 Sedation at endoscopic retrograde cholangio-pancreatography

	No. of procedures	Dosage range (mg)	Mean dosage (mg)	Standard deviation
Midazolam	439	1–8	3.24	1.35
Fentanyl	145	10–100	48.43	21.12
Pethidine	310	12–75	36.45	13.29
Diazepam	29	5–30	12.33	6.37

sedation. Sedation was with benzodiazepine +/- opioid. Midazolam was the benzodiazepine used in 92% of sedated cases; mean dose administered was 3.24 mg (standard deviation 1.35; range 1–8 mg). The opioids pethidine and fentanyl were used (usually in conjunction with benzodiazepine) in 310 (65%) and 145 (30%) procedures respectively. Table 3 summarises the drugs used in all procedures. Buscopan was used in 385 (81%) procedures; mean dosage 27 mg (range 10–100 mg). No patient required reversal of benzodiazepine or opiate. In our patient population, 17% (82 patients) received additional throat spray along with sedation. This group did not suffer any additional complications related to the concurrent usage of sedation and throat spray.

Consent

Information regarding consent was available in 474 out of 481 procedures. Seven questionnaires did not document any information about the process of consent. Signed consent forms were available prior to the patient reaching the endoscopy suite/x-ray department in 415 patients (86.3%), and 59 patients (12.3%) had their consent process completed by the clinician performing the ERCP just prior to the procedure.

Investigations and pre-ERCP imaging

Coagulation profile results were available on 469 patients (97%), all less than seven days prior to the procedure. In the remaining questionnaires, there was no record of this having been checked. Platelet count was available in 466 patients (97%) and 15 questionnaires had missing data. Mean prothrombin time (PT) was 13.1 seconds (range 12–30) and mean platelet count was 308 (range 58–962).

Ultrasound of the abdomen was the most frequent radiology imaging modality performed prior to ERCP. In 390 out of 481 (82%) procedures, there was record of an ultrasound report in the notes prior to the procedure. Eighteen questionnaires had no record of radiology imaging and all these procedures involved stent removal, previous failed ERCP or stenting for bile duct injury. Table 4 summarises other radiological procedures performed in addition to transabdominal ultrasound prior to ERCP.

Indications, therapy and completion of procedure

The most common indication for ERCP in this study was choledocholithiasis (56%). The other indications were

TABLE 4 Radiological investigations prior to endoscopic retrograde cholangio-pancreatography (ERCP)

	Ultrasound prior to ERCP	No ultrasound prior to ERCP	Total
CT abdomen	123	30	153
Magnetic resonance cholangio-pancreatography	146	32	178
Endoscopic ultrasound	6	1	7
Previous ERCP	1	10	11
No other imaging	114	18	
Total	390	91	481

abnormal liver function tests (44%), cholangitis (21%), abdominal pain (19%), biliary dilatation on imaging (15%), pancreatic mass (8%), surgical bile duct injury (1.2%), recent acute pancreatitis due to stones (4%), stent removal (6.6%) and others (3%). In this audit, selective deep cannulation of the bile duct was achieved in 420 cases (87.3%). Therapeutic procedures were as follows: 300 sphincterotomies (71%), 163 biliary stent placements (38%), 65 balloon trawls (15%), 50 basket trawls (12%), 14 stent removals (3.4%), ten mechanical lithotripsies (2%), four needle knife accesses, two balloon sphincteroplasties and one pancreatic duct stenting were performed. Data regarding completion and difficulty grade of ERCP (Appendix III) were available in 475 procedures. Tables 5 and 6 summarise the success of the procedures against the difficulty grades of ERCP and ASA grade of patients.

TABLE 5 Endoscopic retrograde cholangio-pancreatography (ERCP) completion and difficulty grading of ERCP

Difficulty grade of ERCP	I (92%)	II (7.3%)	III (0.7%)	Total
Procedure complete	351	28	2	381
Incomplete but successful therapy or palliation	33	11	0	44
Unsuccessful	43	6	1	50
Total	427	45	3	475

TABLE 6 Endoscopic retrograde cholangio-pancreatography (ERCP) completion and American Society of Anesthesiologists (ASA) grading

	ASA I	ASA II	ASA III	ASA IV
Procedure complete	116	150	47	5
Incomplete but successful palliation	8	19	4	0
Unsuccessful	15	22	6	1
Total	139	191	57	6

TABLE 7 Sedation and comfort scores

Score	Sedation score (%)	Comfort score (%)
0	49 (10%)	29 (6%)
I	60 (12%)	174 (36.2%)
II	272 (56.5%)	183 (38.2%)
III	75 (15.6%)	70 (14.6%)
IV	8 (1.7%)	13 (2.7%)
V	5 (1%)	N/A

Procedure time, screening time and sedation/ discomfort scores

Procedure time was defined as the time from scope insertion to scope extubation and this was recorded in 383 questionnaires. Mean procedure time was 24 minutes (range 2–100 minutes). The screening time was defined as the total duration of time the fluoroscopy machine was active during the procedure. This was recorded in 356 procedures. Procedure screening time ranged from 6–890 seconds with a mean of 193 seconds.

Table 7 gives sedation and comfort score details of all procedures. Data relating to sedation and comfort scores were missing in 12 questionnaires.

Complications

There were ten reported deaths (2% of all procedures performed) within 30 days of ERCP procedure (see Table 8). Other complications noted were cholangitis (four; 0.8%), pancreatitis (five; 1%), bleeding (five; 1%), perforation (one; 0.2%), abdominal pain requiring hospital admission in nine patients (1.8%), hepatic abscess in one patient (0.2%), thought to be as a result of ascending cholangitis post-procedure.

DISCUSSION

This is the first audit of the current practice of ERCP in DGHs in North East England. It was arranged via NREG. Fourteen hospitals participated in the study which represents 95% of all endoscopists providing ERCP service in this region.

For the purposes of this study, ERCP was deemed 'complete' only if the intended intervention was fully performed. In certain situations, when this could not be completed but the endoscopist was able to do an intermediate intervention as a bridge to the final procedure at a later date (e.g. insertion of CBD stent when the duct could not be cleared of stones) it was termed 'incomplete but with successful therapy or palliation'. Deep cannulation of the bile duct was said to have been achieved when the distal CBD was entered sufficiently to be able to attempt the intended treatment. The minimum acceptable deep cannulation rate for a trained endoscopist for grade I ERCPs is between 80–90%.[3,4] The UK Joint Advisory group on Gastrointestinal Endoscopy has indicated that to be accredited as an independent ERCP endoscopist, an individual must show satisfactory completion of the intended therapeutic procedure in grade I ERCPs in more than 80% of cases.[3] In our study, the selective deep bile duct cannulation rate was 87.3% (420 out of 481). The total completion rate (see Table 5) for all procedures was 80.2% (381 out of 475) and completion of therapy was 89.5% (425 out of 475); both of which meet the standards set by JAG.

Most of the patients were either ASA grade I or II (a total of 330 out of 393 patients, 84 %). Only 63 patients (16%) were ASA grade III or IV. This reflects appropriate patient selection and is in sharp contrast to the NCEPOD report[2] that had inferred that potentially large numbers of inappropriate procedures are being carried out on 'high-risk' patients. There was no documentation of ASA grading in 88 questionnaires as three endoscopy units in the region did not routinely assess ASA grading.

There was a general supposition by the NCEPOD[2] which was also noted by Williams et al.[1] that ERCP is performed without appropriate checks such as clotting and radiological investigations. In this study, the converse was the case. Only 18 patients did not have documented imaging prior to ERCP and all of them were patients who had a previous ERCP and had come for either a stent removal or second attempt at therapy and repeat radiological investigations were not indicated. All patients had coagulation parameters checked prior to the procedure.

Now predominantly a therapeutic procedure, the diagnostic role of ERCP has been superseded by other radiological modalities. In this current study, all patients underwent ERCP with a therapeutic intent and 318 (72%) had some therapeutic intervention done. This is in keeping with the current belief that ERCP should not be routinely used for diagnostic purposes. In our study, the most common indication for ERCP was choledocholithiasis with most of the procedures being difficulty grade I (427 of 475; 90%).

The complication rates of ERCP have been studied in great detail previously both in the UK and in the United States.[1] Our study reported an overall complication rate of 5% which is similar to previous reports.[5–10] The 30-day mortality rate was 2% (10 patients) amongst all procedures performed. Four patients died of progressive malignancy within 30 days of the procedure. The other six deaths were all related to complications of the patients' medical condition, and there were no deaths as a direct result of the ERCP procedure itself such as bleeding, perforation, newly induced sepsis, or pancreatitis. This mortality rate and risk of complications are comparable to previously published data from the UK and North America.[5–9] Our study did not demonstrate a correlation between rate of complication with either the difficulty of the procedure or with ASA grade of the patient (p=0.8). This observation is due to correct patient selection (only a few patients were of ASA grade III and IV) and more difficult ERCPs (grade

III) are usually done in the regional referral unit and therefore not included in this study.

As there are no universally accepted comfort and sedation scoring systems, we used systems which were agreed by all the authors prior to the commencement of the audit (see Appendix I). The BSG has recommended[11] that the mean dosage of midazolam for ERCP should be less than 5 mg (3.24 mg in our study) and adverse events, such as usage of flumazenil for reversal of sedation should be recorded (not used in any of our patients in this study). This, we feel should be interpreted in conjunction with the sedation and discomfort scores and procedure times. Mean procedure time was 24 minutes with only 2.7% patients getting a sedation and comfort score of more than III.

This study faced some limitations. Firstly, some of the audit questionnaires were incomplete. Secondly, the study failed to investigate the influence of trainees on ERCP lists. In North East England since the publication of the BSG audit[1] there has been a definite move towards training only a few nominated registrars (as per its recommendations) and there was no trainee performing or being trained in ERCP during the study period. Thirdly, it was not possible to compare the performance of participating centres due to a possibility of different case mix and small numbers of procedures in this study. Also, the number of procedures performed by each endoscopist was too small to make an individual assessment of their performance.

TABLE 8 Causes of mortality

Age (yrs)	Indication for endoscopic retrograde cholangio-pancreatography (ERCP)	Cause of death
70	Choledocholithiasis, proven cholangitis prior to ERCP	Sepsis
69	Malignant biliary stricture with cholangitis due to biliary obstruction	Sepsis
84	Choledocholithiasis	Sepsis (pneumonia three weeks later)
85	Choledocholithiasis with cholangitis	Sepsis
85	Choledocholithiasis with cholangitis	Sepsis
65	Malignant biliary stricture	Progressive pancreatic malignancy
78	Ampullary tumour	Progressive pancreatic malignancy
80	Malignant biliary stricture	Progressive pancreatic malignancy
87	Pancreatic cancer	Progressive pancreatic malignancy
83	Choledocholithiasis with cholangitis	Frailty of old age

It is well known that publication of national audits gives us much needed insight into our daily practice. Deliberate introduction of practice changes in the post-audit era help us improve, and follow-up audits like this current one reassure ourselves of continued compliance with national standards. We believe that this audit has effectively reported current practice of ERCP in DGHs in North East England. It is clear that their endoscopy units have incorporated the findings (which have been audited in this study) of the NCEPOD enquiry report[2] into their daily practice, to enable them to deliver the safest patient care.

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APPENDICES

APPENDIX I Clinical guide to the Sedation and Discomfort Score

Comfort definition	Comfort score	Sedation definition	Sedation score
No/minimal discomfort	1	Fully awake; clear eyes; no ptosis	1
Mild discomfort – easily follows verbal instructions	2	Slightly drowsy; mild slowing/'thickening' of speech, ptosis	2
Moderate discomfort – mild movements, can be calmed by verbal instructions	3	Asleep – easily rousable by directed voice. Slurred, slowed speech	3
Severe discomfort–violent/ struggling, not obeying instruction leading to abandonment.	4	Deeply asleep – responds only to prodding/ shaking/ shouting their name	4
		Unconscious – no response to noxious stimuli	5

APPENDIX II American Society of Anesthesiologists (ASA) scoring system[#]

ASA grade	Description of grade
I	Normal healthy patient
II	Mild systemic disease
III	Severe systemic disease
IV	Severe systemic disease which is a constant threat to life
V	Moribund patient who is not expected to survive with or without operation
VI	A declared brain dead patient whose organs are being removed for transplant purposes.

[#]Adapted from the American Society of Anesthesiologists grading system. Saklad M. Grading of patients for surgical procedures. *Anesthesiology* 1941; 2:281–4.

APPENDIX III Grading of difficulty of endoscopic retrograde cholangio-pancreatography (ERCP)[*]

Grade	Type of ERCP
I	Diagnostic cholangiogram, Brush cytology, standard sphincterotomy, stone removal (≤10 mm), stricture dilatation, common duct stenting, naso-biliary drain, sphincteroplasty, diagnostic pancreatogram
II	Billroth diagnostics, hilar stenting, removal of stones (>10 mm)
III	Sphincter of Oddi manometry, Billroth therapeutics, intrahepatic stone removal, all pancreatic therapy

[*]This grading system is modified from the one proposed by Schutz SM, Abbott RM. Grading of ERCPs by degree of difficulty: a new concept to produce more meaningful outcome data. *Gastrointest Endosc* 2000; 51:535–539.