

An Evaluation of Endoscopic Retrograde Cholangiopancreatography: The Importance of Case Volume in Improving Outcome

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Citation

S Cawich, M Arthurs, J Plummer, D Mitchell, T Murphy, E Williams, M McFarlane, M Newnham, H Brown, M Frankson. *An Evaluation of Endoscopic Retrograde Cholangiopancreatography: The Importance of Case Volume in Improving Outcome*. The Internet Journal of Third World Medicine. 2008 Volume 7 Number 2.

Abstract

During the first three years after its introduction to Jamaica, ERCP was performed with high morbidity and poor therapeutic success. This study evaluates the effect of increased case volumes and accrued experience on ERCP outcomes at a tertiary level hospital in Jamaica.

We compared all ERCP procedures performed by a single endoscopist over eight years. The data were divided into two groups: Group A included patients who had ERCP performed during the first four years of its use (January 1, 1999 to December 31, 2002). Group B included patients who had ERCP performed during the latter four years of its use (January 1, 2003 to December 31, 2006). Outcomes were compared using Chi square statistics and Fisher's exact tests. Significance was considered present with a two-tailed P value < 0.05

There were 315 ERCPs performed in 299 patients during the study period. 14 patients were excluded from analysis, leaving 301 procedures in 285 patients. There were 79 males and 222 females, with ages ranging from 14 to 94 years (Mean +/-SD: 47 +/-20).

There has been a significant increase in case volume over the study periods (1.98 vs 4.29 cases monthly, $P < 0.001$). There has also been a change in the case mix profile, with significantly more ERCPs being performed for therapeutic indications (30.53% vs 59.71%, $P = 0.04$), attempted CBD stenting (4.21% vs 15.53%, $P = 0.005$) and successful stent placement (25% vs 96.88%, $P = < 0.001$).

Currently, ERCP is performed with acceptable morbidity (6.95%) and mortality (1.07%). Local endoscopists may have now passed the learning curve for ERCP, but they must have continued access to patient lists and equipment to maintain their competence.

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) was introduced to Jamaica in 1999. Plummer et al¹ documented the outcomes during the first three years of its use by a single endoscopist at the University Hospital of the West Indies (UHWI), a tertiary level hospital in Jamaica. During this time small numbers of cases were attempted with relatively high morbidity and poor therapeutic success.

The number of cases being attempted has since increased because the UHWI serves as a major referral centre for this service to several hospitals across Jamaica. This study assesses the impact of the increased case volume on ERCP outcomes.

METHOD

At the UHWI, patients requiring ERCP were admitted to hospital 24 hours prior to the procedure. All anticoagulant and antiplatelet medications discontinued 72 hours prior to the procedure. Normal coagulation status (PT, PTT and platelet count) was ensured pre-operatively.

We routinely administered a prophylactic dose of third generation cephalosporin one hour prior to ERCP. Hyoscine N-butyl-bromide (Buscopan, 20mg) was also given intravenously at the commencement of ERCP to prevent spasm of the sphincter of Oddi. The procedure was performed in the Radiology Department under fluoroscopic control. Intravenous sedation with midazolam and pethidine was employed when appropriate.

A complete upper gastrointestinal endoscopy was performed routinely. A catheter was advanced past the sphincter of Oddi into the common bile duct (CBD) for contrast injection. The pancreatic duct was selectively cannulated depending on the indications for ERCP and the endoscopic or radiologic findings. Sphincterotomy was selectively performed using the needle knife sphincterotome. When detected, stones were removed from the CBD with the use of a balloon and the wire basket.

All the patients who had ERCP by a single endoscopist between January 1, 1999 and January 1, 2007 were identified from the operative log. Their hospital records were retrieved and the relevant data extracted for analysis. We excluded patients who were transferred from other facilities for this service since their post ERCP hospital records would not be available for analysis. The data collected included patient demographics, indications, procedural details, complications and mortality.

We employed the definitions of ERCP complications proposed by Cotton et al² in order to standardize outcome evaluation. A perforation was defined as a retroperitoneal or bowel wall leak documented by any radiographic technique or at operation.

Post-ERCP pancreatitis was defined as new or worsened abdominal pain that was associated with a rise in serum amylase to at least three times the upper limit of normal (98 IU/L) requiring prolongation of the planned admission. At the UHWI, serum amylase was selectively measured in patients who were clinically suspected to have pancreatitis.

Hemorrhage was considered significant when there was clinical evidence of bleeding, such as melena or hematemesis, with an associated fall in the hemoglobin concentration by at least 2gm/dl.

Cholangitis was defined as elevated temperature greater than 38°C for longer than 24 hours that was thought to have a biliary cause without concomitant evidence of acute cholecystitis.

The data extracted from the hospital records during the study period were entered in a Microsoft Excel® worksheet. The data were divided into two groups: Group A included patients who had ERCP performed during the first four years after its introduction to the UHWI (January 1, 1999 to December 31, 2002). Group B included patients who had ERCP performed during the latter four years of its utility

(January 1, 2003 to December 31, 2006). Data were then analyzed using SPSS version 12.0. Outcomes were compared using Chi square statistics and Fisher's exact tests. Significance was considered present with a two-tailed P value ≤ 0.05.

RESULTS

There were 315 ERCPs performed in 299 patients during the study period. Fourteen patients were excluded from the final analysis because they were referred from other centres and returned to their respective hospitals after ERCP. Their hospital records were not available for detailed analysis of the post-ERCP period.

Hospital records were available for the remaining 301 procedures in 285 patients during the study period. There were 79 males and 222 females, with ages ranging from 14 to 94 years (Mean +/-SD: 47 +/-20). The indications for ERCP are recorded in table 1.

Figure 1

| Table 1: Indications for ERCP at the UHWI | | | |
|---|------------|----------------|-----------------|
| Indication for ERCP | Total (n) | Diagnostic (n) | Therapeutic (n) |
| Suspected choledocholithiasis | 176 | 105 | 71 |
| Relief of biliary obstruction | 60 | 17 | 43 |
| • Obstructive jaundice (not specified) | 22 | 9 | 13 |
| • Malignant obstruction | 13 | 3 | 10 |
| • Benign biliary stricture | 15 | 5 | 10 |
| • Stent change or removal | 10 | 0 | 10 |
| Pancreatitis | 54 | 22 | 32 |
| • Recurrent pancreatitis | 5 | 2 | 3 |
| • Mild gallstone pancreatitis | 39 | 19 | 20 |
| • Severe gallstone pancreatitis | 8 | 1 | 7 |
| • Chronic pancreatitis | 2 | 2 | 0 |
| Trauma | 1 | 1 | 0 |
| • Pancreatic duct injury after trauma | 1 | 1 | 0 |
| CBD injury after cholecystectomy | 7 | 4 | 3 |
| Pancreatic pseudocyst | 3 | 0 | 3 |

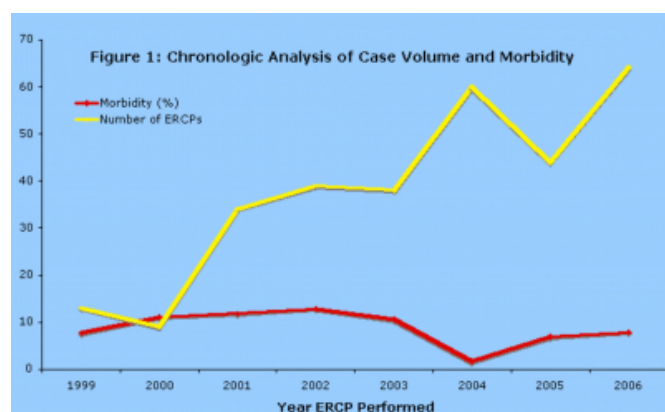
There was successful cannulation of the ampulla in 287 of 301 cases (95.4%). Common bile duct stones (CBDS) were identified in 72 patients. When detected, the CBD was successfully cleared of stones in 76.4% (55/72) of cases. The ERCP outcomes in both study groups are compared in Table 2.

Figure 2

| Table 2. Comparison of Outcomes of ERCP between study periods | | | | |
|---|--------------------|------------------------------|-------------------------------|---------|
| Parameter | Total Study Period | Group A 1999 - 2002 | Group B 2003-2006 | P Value |
| Complications from ERCP | | | | |
| Overall Mortality | 4/301 | 2.11 % (2/95) | 0.97% (2/206) | 0.59 |
| Overall Morbidity | 24/301 | 11.58% (11/95) | 6.31% (13/206) | 0.092 |
| Pancreatitis | 16/301 | 9.47% (9/95) | 3.40% (7/206) | 0.03 |
| • Mild pancreatitis | 11/301 | 66.66% (6/9) | 71.43% (5/7) | - |
| • Severe pancreatitis | 5/301 | 33.33% (3/9) | 28.57% (2/7) | - |
| • Mortality from pancreatitis | 1/301 | 11.11% (1/9) | 0 (0/7) | - |
| Cholangitis | 8/301 | 2.11% (2/95) | 2.91% (6/206) | 0.51 |
| Haemorrhage | 0 | 0 | 0 | - |
| Perforation | 0 | 0 | 0 | - |
| Therapeutic Outcomes from ERCP | | | | |
| Successful Cannulation | 287/301 | 87/95 (91.58%) | 200/206 (97.09%) | 0.47 |
| Successful Stone Clearance (in patients with CBD stones) | 55/72 | 13/19 (68.42%) | 42/53 (79.25%) | 0.257 |
| Attempts at Stenting | 36/301 | 4/5 (4.21%) | 32/206 (15.53%) | 0.005 |
| Successful CBD stent placement | 32/36 | 1/4 (25%) | 31/32 (96.88%) | <<0.001 |
| Indications for ERCP | | | | |
| Therapeutic Indication | 152/301 | 29/95 (30.53%) | 123/206 (59.71%) | 0.04 |
| Diagnostic Indication | 149/301 | 66/95 (69.47%) | 83/206 (40.29%) | |
| ERCP done to investigate or relieve Biliary Obstruction | 60/301 | 18/95 (18.95%) | 42/206 (20.39%) | 0.45 |
| ERCP done for suspected CBD Stones | 176/301 | 59/95 (62.11%) | 117/206 (56.80%) | 0.23 |
| ERCP done to investigate or treat Pancreatitis | 54/301 | 16/95 (16.84%) | 38/206 (18.45%) | 0.44 |
| Case Volume | - | 1.98 per month (95/48 Mo) | 4.29 per month (206/48 Mo) | <0.001 |

There was a major complication of ERCP in 24 (7.97%) patients. When ERCP was evaluated according to the year performed, there was a bimodal peak in the incidence of complications (Fig. 1).

Figure 3



Sixteen patients between the ages of 16 and 70 years (Mean \pm SD: 44 \pm 17.7;20) developed acute pancreatitis. Five patients had Acute Physiology and Chronic Health Evaluation (APACHE) II scores \geq 8, predicting a severe disease course. The endoscopist reported that all had

technically difficult therapeutic ERCPs with repeated attempts at cannulation: failed stent insertion (2); successful CBDS retrieval (1); and diagnostic ERCP for suspected CBDS (2).

Eleven patients had APACHE II scores <8, predicting a mild disease course. One patient had ERCP for suspected CBD injury after LC and the remainder had ERCP for suspected CBDS: Successfully extracted CBDS (3); Failed CBDS extraction (1); CBDS not confirmed (6).

Eight patients developed ascending cholangitis, all after technically difficult therapeutic procedures: Malignant obstruction (5); Change of indwelling biliary stent (1); Failed CBDS extraction (2).

There were four deaths directly resulting from ERCP complications in patients with: unconfirmed suspicion of CBDS (1); successful stenting of malignant stricture (2); and failed stenting of a malignant stricture across which the guidewire could not cross (1). Contrast enhanced computed tomography scans and serum amylase assays were performed in all cases. Nevertheless, the patients deteriorated rapidly, despite resuscitation and antibiotics. They demised before attempts at exploratory laparotomy and/or CBD decompression. Autopsies confirmed the cause of death to be septicemia from acute cholangitis in 3 cases and severe necrotizing pancreatitis in 1 case.

DISCUSSION

During the first three years of its use at the UHWI, ERCP was performed at a rate of only 1.98 procedures per month. This low volume of procedures reflected the long duration of individual cases (not objectively quantified) and limited availability of operating lists. There was high morbidity (12.5%), possibly because the endoscopist was still within the learning curve for this procedure.

The endoscopist became more experienced over the subsequent five years, having now performed a total of 315 ERCPs. Although the availability of operating lists remained unchanged, the case volume significantly increased to 4.29 cases per month. This was possibly due to increased proficiency at ERCP requiring less operating time, although it could not be quantitatively demonstrated from the study method.

In the current study period, there has been a reduction in overall morbidity from 11.58% to 6.31%. Although the trend has not attained statistical significance, the complication

rates have only now come down to accepted levels that range from 2% to 10%.^{2,3,4,5}

The bimodal peak in morbidity with time can probably be explained by the significant increase in attempts at technically difficult cases (stenting / therapeutic procedures) as the endoscopist became more experienced. There is an inherently greater risk of complications with these technically difficult cases, accounting for the second peak in morbidity. A similar pattern has been noted in the learning curve for laparoscopic cholecystectomy where bile duct injuries became commoner after experienced surgeons attempted increasingly difficult cases.^{6,7} With more experience, we expect the incidence of complications to fall once more. The evaluation of this part of the learning curve will require reassessment of future data.

Pancreatitis is the commonest complication of ERCP and is reported to occur in 3-5% of cases.^{2,3,4,5,8} During the latter study period, the incidence of pancreatitis has significantly declined and is now at accepted levels (3.40% vs 9.47%). Unfortunately there has been no significant change in the proportion of cases following a severe clinical course (28.57% vs 33.33%) or mortality from pancreatitis (0 vs 11.1%).

Although there were no reports of significant bleeding or perforations in either series, we continue to remain vigilant for these complications because when they do occur they are accompanied by disastrous complications.^{2,3,4,5}

There was a trend toward an increased incidence of cholangitis during the latter study period (2.11% Vs 2.91%), although this still compares well to the reported 3% incidence seen in high volume centres.⁸ We believe that this trend was partially due to a change in the case mix profile where significantly more attempts at CBD stenting were made (25% vs 96.88%). Incomplete CBD decompression in these cases can lead to continued cholangio-venous reflux and subsequent bacteremia.^{9,10} Three of the four deaths in our study were due to septicemia from cholangitis in patients who required repeated manipulation of the CBD to stent malignant strictures. These patients comprise a high-risk

group in whom a low threshold for operative CBD decompression may be warranted.

We have not been able to evaluate the long-term sequelae of ERCP, but it has been documented that 10-15% of patients will develop complications ten years after ERCP.^{11,12,13} These complications include sphincterotomy stenosis leading to cholangitis, bacterobilia leading to recurrent CBD stones and bile reflux causing mucosal metaplasia with potential neoplastic change.^{11,12,13} This may again require reassessment of future data.

With the advent of newer diagnostic modalities with lower complication rates, ERCP is now largely relegated to therapeutic indications.¹⁴ Magnetic resonance cholangio-pancreatography and endoscopic ultrasound have surpassed ERCP for diagnostic purposes.¹⁴ Unfortunately, these modalities are not universally available in developing countries such as Jamaica.

In addition to reduced morbidity, we have also witnessed improved therapeutic success. During the initial three year experience, Plummer et al reported that ERCP was limited in its therapeutic ability to clear stones from the CBD, with only 48% clearance rates.¹ There has been a significant improvement in stone clearance rates when the overall figures are compared to these initial results (48% vs 76.39%, $p=0.01$), although we have not quite achieved the 90% success rates reported from high volume centres.^{8,15} The improvement is still present when comparisons are made between our study periods (68.42% vs 79.25%), but the trend did not achieve statistical significance.

Cannulation has been used as a measure of competence in ERCP.^{16,17,18,19,20,21,22} There is a trend toward improved cannulation success in the latter study period (91.58 vs 97.09%), although both study periods have cannulation rates that are comparable to those from high volume centres.^{1,23,24}

It has already been noted that there was a trend toward increased use of ERCP to investigate or palliate biliary obstruction. There were significantly better success rates when stenting was attempted in these patients (25% vs 96.88%, $P<$