

Validating Endoscopic Retrograde Cholangiopancreatography in Jamaica: A Retrospective Audit

S Cawich, M Arthurs, J Plummer, H Harding, I Crandon, E Williams

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Abstract

During the first 36 months after its introduction to Jamaica, ERCP was performed with relatively high overall morbidity and poor therapeutic success. We sought to evaluate outcomes after eight years of experience with ERCP at a tertiary level hospital in Jamaica.

All consecutive patients who had ERCP performed between March 1999 and March 2007 were identified from an operative log. Their hospital records were retrospectively analyzed.

There were 369 procedures performed over the study period, but the final analysis was performed on 301 patients who met the inclusion criteria. There were 79 males and 222 females, with a mean age of 45.0 years (SD +/-18.6; range 14-94).

There has been a reduction in the incidence of post-ERCP pancreatitis (5.3% vs. 10%) and overall morbidity (24/301; 7.97% vs. 12.5%). The commoner complications included pancreatitis (16/301; 5.32%), ascending cholangitis (8/301; 2.66%), perforation (0) and hemorrhage (0). There were 4/301 (1.33%) deaths directly resulting from an ERCP complication (ascending cholangitis in 3; multiple organ failure from severe pancreatitis in 1). There has also been improvement in the success of stone clearance from the common bile ducts (55/72; 76.39%) and biliary stenting (32/36; 88.89%).

Currently, local endoscopists are performing ERCP with acceptable morbidity and mortality compared to international standards.

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) was introduced to Jamaica in 1999. During the first 36 months of its use, only small numbers of cases were attempted (2.7 per month) and the overall morbidity (12.5%) was higher than that considered acceptable in high volume centres.

The University Hospital of the West Indies (UHWI) has been the sole referral centre for this service from several hospitals across Jamaica. We have now gained nine years of practical experience in ERCP and sought to compare our current outcomes in this setting with our initial results and with international standards.

METHOD

At the UHWI, ERCP was performed by one of two teams, each headed by an endoscopist trained in ERCP following a standardized protocol. The patients were admitted to hospital 24 hours prior to ERCP. Anticoagulant and antiplatelet medications were discontinued at least 72 hours prior to ERCP. Normal coagulation status (PT, PTT and platelet

count) was ensured prior to the procedure.

A prophylactic dose of third generation cephalosporin was routinely administered 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.

Both teams used similar techniques for ERCP. A complete upper gastrointestinal endoscopy was routinely performed. 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 over eight years from March 1999 to March 2007 were identified from the operative log. Their hospital records were retrieved and the relevant data extracted for analysis. Patients who were transferred from other facilities solely for this service were excluded from the final analysis 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 2g/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. Data were then analyzed using SPSS version 12.0. Comparisons were made between the raw data collected from the UHWI during the initial experience₁ and the current data. Outcomes were compared using Chi square statistics, Fisher's exact tests and a statistical test of significance for standard error in differences in proportions (SE). Significance was considered present with a two-tailed p-value ≤ 0.05.

RESULTS

There were 387 procedures performed during the study period. Of this number, 59 patients were transferred from other hospitals for ERCP. They were excluded from the final analysis because they returned to their respective hospitals after ERCP. In another 27 cases, the hospital records were not available for review.

The final analysis was performed on 301 patients who met the inclusion criteria. There were 79 males and 222 females, with a mean age of 45.03 years (SD +/-18.57; range 14-94). The indications for ERCP are recorded in Table 1.

Figure 1

Table 1: Indications for ERCP at the UHWI

Indication	(n)	(%)
Suspected choledocholithiasis	175	58.14%
• Pre-operative abnormal Liver Function Tests	105	
• Pre-operative ultrasound evidence of CBDS	14	
• Pre-operative evaluation in sickle cell disease	27	
• Retained CBD stones after cholecystectomy	30	
Relief of biliary obstruction	60	19.93%
• Malignant stricture	13	
• Benign stricture	15	
• Stent change or removal	10	
• Obstructive jaundice (not specified)	22	
Pancreatitis	54	17.94%
• Recurrent	5	
• Mild	39	
• Severe	8	
• Chronic	2	
Trauma	2	0.66%
• Pancreatic duct injury	1	
• CBD injury	1	
Bile duct injury after cholecystectomy	7	2.33%
Pancreatic pseudocyst	3	1.00%

The endoscopist successfully cannulated the sphincter of Oddi in 287 cases (95.35%), with successful cholangiogram in all of these cases. Gallstones were identified within the CBD in 72/287 (25.09%) of patients. When detected, the CBD was successfully cleared of stones in 55/72 (76.39%) cases. There were attempts at stenting in 36 cases, with successful stent deployment in 32/36 (88.89%) of cases.

Twenty four (7.97%) patients experienced a complication of ERCP as outlined in table 2.

Figure 2

Table 2: Complications of ERCP at the UHWI

Complication	(n)	(%)
Acute Pancreatitis	16	5.32%
• Mild clinical course	11	
• Severe clinical course	5	
Ascending Cholangitis	8	2.66%
• After partial extraction of CBD stone	2	
• After stenting for malignant obstruction	5	
• After change of indwelling plastic stent	1	
Perforation	0	0
Bleeding	0	0
Overall morbidity	24	7.97%
Mortality	4	1.33%
• Multiple organ failure from pancreatitis	1	
• Cholangitis post stenting for biliary obstruction	3	

Sixteen (5.32%) patients between the ages of 16 and 70

years (mean \pm SD: 42.94 \pm 16.84) developed pancreatitis. Five of these patients had Acute Physiology and Chronic Health Evaluation (APACHE) II scores ≥ 8 , predicting a severe disease course. They had ERCP performed for: choledocholithiasis (3); pancreatic pseudocyst (1); and biliary obstruction (1). The endoscopist reported that all patients had technically difficult ERCPs with repeated attempts at cannulation. Eleven patients had APACHE II scores < 8 , predicting a mild disease course (suspected CBD injury at cholecystectomy 1; CBD obstruction 1; suspected CBD stones 9).

Eight (2.66%) patients developed ascending cholangitis within 36 hours of a therapeutic ERCP as outlined in table 2. The endoscopist reported that the procedures were all technically difficult, requiring repeated manipulation of the CBD.

There were 4/301 (1.33%) deaths that were considered to be a direct result of an ERCP complication. One patient had a diagnostic procedure for suspected CBD stones that were not visualized at ERCP. The patient developed a severe pancreatitis after ERCP with an APACHE II score of 9. She rapidly deteriorated and succumbed to her illness on day 5. Multiple organ failure secondary to severe necrotizing pancreatitis was confirmed as the cause of death at an autopsy.

The remaining three patients had technically difficult therapeutic procedures with attempts at stenting malignant CBD strictures. Stenting was successful in two cases and was abandoned in one after the endoscopist encountered a tight structure across which a guidewire could not pass. All three patients had contrast enhanced computed tomography scans and serum amylase assays that excluded pancreatitis and perforations. They deteriorated rapidly, despite resuscitation and antibiotics and demised before attempts at exploratory laparotomy and/or CBD decompression. Septicemia from acute cholangitis was confirmed as the cause of death in all patients at autopsy.

DISCUSSION

ERCP has been a part of the clinical armamentarium of endoscopists for over three decades.^{1,2,3} Several high volume centres have documented their experiences with ERCP and have defined acceptable rates of complications.

3,4,5,6,7

The UHWI has been the sole referral centre offering ERCP to all institutions across Jamaica for 9 years. We anticipated

that the accrued experience would have led to differences between our initial published results¹ and current ERCP outcomes.

Currently, ERCP is being performed in this setting with 7.97% overall morbidity. Although this is an improvement compared to our initial published results¹ (12.5%), the trend has not achieved statistical significance ($p = 0.15$; $SE = 3.42$). Nevertheless, the current overall morbidity has only now come within the 4%⁴ to 10.8%⁶ -range that is considered acceptable in large volume centres.^{3,4,5,6,7}

Acute pancreatitis remains the commonest complication in our setting. The incidence has significantly declined compared to our initial experience¹ (5.32% vs. 10%; $p = 0.05$; $SE = 3.42$), and is now within 3.0%⁸ to 7.2%⁵ -range that is considered to be acceptable in high volume centres.

3,4,5,6,7,8

It is interesting that 12/16 patients who developed pancreatitis had diagnostic ERCP for suspected CBD stones on the basis of elevated liver function tests (9) and sonographic visualization of a dilated CBD (3). Many of these patients are now being investigated with magnetic resonance cholangiography or endoscopic ultrasound that have been shown to surpass ERCP for diagnostic purposes.⁹ Unfortunately, these modalities are not universally available in developing countries such as Jamaica. We still continue to use ERCP for diagnostic purposes in this setting, although we hope to follow the trend toward reserving ERCP for therapeutic purposes,⁹ once these resources become available.

The incidence of cholangitis has increased compared to our early results¹ (2.66% vs. 1.0%; $p = 0.19$; $SE = 1.65$), but it 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 more ERCPs were done in the latter study period to investigate or relieve biliary obstruction (24.9% vs. 11.5%). Incomplete CBD decompression in these cases can lead to continued cholangio-venous reflux and subsequent bacteremia.^{10,11} It was notable that three of our four deaths 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 yet been able to evaluate the long-term

sequelae of ERCP, but it has been documented that 10-15% of patients will develop complications 10 years after ERCP.^{12,13,14} These complications include sphincterotomy stenosis leading to cholangitis, bacterobilia leading to recurrent CBD stones and bile reflux causing mucosal metaplasia with potential neoplastic change.^{12,13,14} This will require reassessment of future data.

In addition to reduced morbidity, we have also witnessed improved therapeutic success at the UHWI. This is important since ERCP will most likely be reserved for therapeutic indications in the future.^{1,9}

Our initial published results documented a very low success rate for stone clearance from the CBD.¹ There has now been significant improvement in stone clearance from the CBD (76.39% vs. 48%; $p = 0.01$; $SE = 11.77$), although we have not quite achieved the 90% success rates reported from high volume centres.^{8,15} We anticipate that the trend toward improved stone clearance will continue with accrued experience. This will require continued collection and reassessment of future data.

During our early experience with ERCP, it was reported that a small proportion of cases were performed to investigate or treat biliary obstruction due to unavailability of suitable stents and disposable equipment.¹ There has since been an increase in the use of ERCP to investigate or palliate biliary obstruction (24.90% vs. 11.46%). This reflects better availability of resources and equipment that is a good sign for continued local advancement in ERCP. We have also seen a trend toward improved success when biliary stenting was attempted in these patients (88.89% vs. 50%; $p = 0.29$; $SE = 35.72$). The current figures compare well to the 93% technical success rates published by high volume centres reporting on similar heterogeneous patient groups with benign and malignant biliary obstruction.¹⁶

CONCLUSIONS

There has been important progress with ERCP at the UHWI since the initial reports of its utility. ERCP is now being performed in this setting with acceptable morbidity and mortality and improved therapeutic success.

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Author Information

Shamir O. Cawich, M.B.B.S., D.M.

Department of Basic Medical Sciences, The University of the West Indies

Milton Arthurs, M.B.B.S., D.M.

Department of Medicine, The University of the West Indies

Joseph Plummer, M.B.B.S., D.M.

Department of Basic Medical Sciences, The University of the West Indies

Hyacinth Harding

Department of Surgery, Radiology, Anaesthesia and Intensive Care, The University of the West Indies

Ivor W. Crandon

Department of Surgery, Radiology, Anaesthesia and Intensive Care, The University of the West Indies

Eric Williams, M.B.B.S., D.M.

Department of Surgery, Radiology, Anaesthesia and Intensive Care, The University of the West Indies