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Original Research Article

Outcomes of ERCP – Retrospective Series from a District General Hospital

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Abstract: Endoscopic retrograde cholangiopancreatography (ERCP) is a technically demanding procedure and carries one of the highest risks of serious complications. The success and safety of ERCP are strongly influenced by both the experience of the endoscopist and the procedural volume of the centre. Evidence have shown that higher case volumes are associated with improved outcomes and lower complication rates. However, this does not imply that low-volume centres are incapable of performing safe and effective ERCPs. This study aims to evaluate the outcomes of ERCPs performed by a single operator at a district general hospital. The results are compared with recognized international standards to assess the safety and efficacy of ERCP in a lower-volume setting. This retrospective study reviewed ERCP procedures performed in the General Surgery Department of Hospital Pakar Sultanah Fatimah, Muar, between 1 January 2021 and 31 October 2023. Data analysis included patient demographics, cannulation success rates, and procedure-related complications. Patients with missing or incomplete source documentation were excluded. A total of 137 ERCP procedures were analysed, of which 102 were first-time ERCPs. Most patients were Malay females. The overall common bile duct (CBD) cannulation success rate was 93.4%. Stone-related indications accounted for 94 procedures, with successful stone clearance during the first ERCP achieved in 58 cases (59.6%). The incidence of post-ERCP pancreatitis was 10.2%. These findings highlight opportunities for improving the ERCP service. In response, targeted changes have already been implemented to enhance patient safety and procedural outcomes.

Keywords: Endoscopic Retrograde Pancreatography, ERCP, Endoscopy, Choledocholithiasis, Outcome, Complication.

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is a complex and technically demanding procedure. Over the last three decades, ERCP has become almost exclusively therapeutic. Of all the widely performed endoscopic modalities, ERCP carries the greatest risk of serious complications with a recognized complication rate of between 10 and 14%, and a death rate of 0.1 to 1% (Cohen S *et al*, 2002, Vandervoort J *et al*., 2002). This is mostly due to the more technically demanding skills required to perform ERCP. Among the complications of ERCP are post ERCP pancreatitis (PEP), cholangitis, cholecystitis, bleeding and duodenal perforation.

The incidence of PEP has been reported to be ranging from 3.5% to 9.7% in meta-analysis study (Kochar B *et al.*, 2015). The 2020 ESGE guideline on ERCP-related adverse events defines PEP as a condition that is associated with new or worsened abdominal pain combined with elevated pancreatic enzymes (amylase or lipase ≥ 3 times upper limit of normal), thus prolonging a planned hospital admission or necessitating hospitalization after an ERCP (Dumonceau JM *et al.*, 2020).

Duodenal perforation most frequently happens following sphincterotomy but balloon dilation, guidewire maneuvers, and tip of the endoscope may also cause this. The rate of this happening has been quoted to be ranging from 0.1-0.6% (Adler DG *et al*, 2025, Freeman ML *et al.*, 1996). American Society for

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Gastrointestinal Endoscopy has set the standard to be 0.2% (Howard TJ *et al.*, 1999).

According to British Society of Gastroenterology (BSG) ERCP Framework Standard (Wilkinson M *et al.,* 2014), there should be a minimum of 75 cases per annum for ERCP endoscopists. The minimum standards for independent practitioners should be based on intention to treat and include a ≥ 85% cannulation rate of virgin papillae, CBD stone clearance for ≥ 75% of those undergoing 1st ever ERCP, and for patients with an extra-hepatic stricture, successful stenting with cytology or histology where appropriate at 1st ERCP in ≥ 80% (8). BSG also advocates that there should be a national registry of ERCP cases to monitor practice and outcomes, which will aid a cycle of continuous improvement and provide research data to plan better care in the future (Wilkinson M *et al.,* 2014).

Joint Advisory Group (JAG) on GI Endoscopy accreditation is awarded to high-quality gastrointestinal endoscopy services. According to JAG criteria, all trainees for ERCP should demonstrate over the last 50 cases, and as an intention to treat, a cannulation rate of >80%; successful stone clearance (≤1cm) ≥70% and successful distal biliary stenting ≥75% (Siau K *et al.*, 2022). American Society for Gastrointestinal Endoscopy, on the other hand, has set the standard for stone clearance for stone <1 cm to be >90% (Adler DG *et al.*, 2025).

In Malaysia, ERCP procedures are generally performed by hepatobiliary surgeons and gastroenterologists, with a small proportion carried out by general surgeons. Hospital Pakar Sultanah Fatimah (HPSF) Muar is a district hospital with a capacity of 560 beds, where ERCP services are provided by a general surgeon. During the study period, a single consultant general surgeon was responsible for all ERCP procedures at this centre. It should be noted that all suspected malignant cases and technically complex procedures were referred to the nearest hepatobiliary centre.

Currently, there are no established national standards for ERCP practice in the Malaysian healthcare setting, and limited data exist regarding the safety and outcomes of ERCP at HPSF Muar.

This study was conducted to evaluate whether our centre is providing high-quality ERCP services that are safe, effective, and aligned with best practice standards. Specifically, we aimed to assess four key outcome measures: common bile duct (CBD) cannulation rate, stone clearance rate at the first ERCP, incidence of post-ERCP pancreatitis (PEP), and the rate of duodenal perforation.

Objective

The general objective of this study is to ascertain whether we are providing a high quality ERCP that is safe, effective and adheres to the best practice. The specific objective is to evaluate the outcome of ERCP procedure performed in the General Surgical Department of HPSF Muar, namely CBD cannulation rate, stone clearance rate at first ERCP, incidence of PEP, and the rate of duodenal perforation.

METHODOLOGY

This is a retrospective study of ERCP procedures performed in the General Surgery Department of Hospital Pakar Sultanah Fatimah, Muar, between 1 January 2021 to 31 October 2023. Data were collected and reviewed for all patients who underwent ERCP during the study period. The analysis included patient demographics, cannulation success rate and procedure-related complications. Patients with missing or incomplete source documentation were excluded from the study.

Statistical Analysis

Statistical analysis was done using IBM® SPSS® Statistics Version 26. All continuous variables were expressed as mean and standard deviation and categorical variables expressed as frequencies and percentages.

Ethics

This study was conducted as per ethical standards of the Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia with registration number of NMRR ID-24-02153-BJY. Patient's privacy and confidentiality was protected throughout the data collection, analyses, interpretation, and publication processes as patients' identifiers were not included.

RESULTS

A total of 137 ERCP procedures performed at our centre from 1 January 2021 to 31 October 2023. Most patients were Malay female. Majority of procedures were conducted under sedation using midazolam and pethidine, with only 0.7% performed under general anaesthesia. The characteristics of the study population are summarized in Table 1.

Table 1: Characteristics of study population

Parameters	Value
Age (years)	
Mean	50.57 ± 16.66
Min	22
Max	86
Median	51
Race (number, %)	
Malay	109, 79.6
Chinese	25, 18.2
Indian	1, 0.7
Others	2, 1.5
Gender (number, %)	
Male	57, 41.6
Female	80, 58.4
Indication (number, %)	
Choledocholithiasis	122, 89.1
Pancreatitis	5, 3.6
Ascending Cholangitis	35, 25.5
Redo (stones/stent change)	35, 25.5
Unspecified Obstruction	3, 2.2
Pancreatic Head Mass	2, 1.5
Others	5, 3.6
Findings (number, %)	
Stone	94, 68.6
Stricture	18, 13.1
Others	5, 3.6
Failed	9, 6.6
Procedure (number, %)	
Sphincterotomy	97, 70.8
Stone Extraction	55, 40.1
Stent Insertion	39, 28.5
Stent Exchange	6, 4.4
Stent Removal	28, 20.4
Others	4, 2.9
Complications (number, %)	
Bleeding	16, 11.7
Pancreatitis	14, 10.2
Duodenal Perforation	0, 0
Cholangitis	14, 10.2
Sedation-related Adverse Effect	9, 6.6
Cholecystitis	0, 0
Others	0, 0
Unintentional PD cannulation	30, 21.9

Cannulation of the common bile duct (CBD) was unsuccessful in 9 out of 137 procedures, yielding a CBD cannulation success rate of 93.4%. Among the total procedures, 102 were first-time ERCPs. Stone-related indications accounted for 94 cases. Of these, successful stone clearance during the first ERCP was achieved in 58 cases (59.6%).

Of the 137 ERCP procedures, 14 patients (10.2%) developed post-ERCP pancreatitis (PEP). Unintentional pancreatic duct cannulation occurred in 30 patients, of whom 3 (10.0%) developed PEP. Among the remaining 107 patients without unintentional cannulation, 11 (10.3%) developed PEP. Statistical analysis using Fisher's exact test showed no significant association between unintentional PD cannulation and the development of PEP (p=1.0).

Table 2: Comparison to Standard

	Standard	Performance
Cannulation Rate	≥ 80%	93.4%
Stone Clearance at 1st ERCP	≥ 70%	59.6%
Post ERCP Pancreatitis	≤ 5%	10.2%
Duodenal Perforation	≤ 0.2%	0%

DISCUSSION

Common Bile Duct Cannulation Rate

The overall CBD cannulation rate at our centre was 93.4%. This exceeds both the Joint Advisory Group on Gastrointestinal Endoscopy (JAG) recommended minimum standard of >80% (Siau K *et al.*, 2022) and the Britis Society of Gastroenterology (BSG) benchmark of ≥ 85% (Wilkinson M *et al.,* 2014). This performance demonstrates a high level of technical competence within our ERCP team and aligns with outcomes reported from high-performing endoscopy units.

Stone Clearance at First ERCP

Stone clearance during the first ERCP is known to be influenced by both the size and number of bile duct stones, with larger and multiple stones presenting greater technical challenges for complete clearance. However, due to the retrospective nature of this study, stone size data were unavailable for more than half of the cases. This was attributed to incomplete documentation and the absence of stone size measurements in some imaging reports.

According to Joint Advisory Group (JAG) on GI Endoscopy, a first-attempt stone clearance rate of over 70% is expected for stones measuring 1 cm or smaller (Siau K *et al.*, 2022). As stone size was not accounted for in this study, it is postulated that this limitation may have contributed to our lower first-attempt clearance rate of 59.6%.

Duodenal Perforation

Reported cases of duodenal perforation in the literature range from 0.1-0.6% (Adler DG *et al.*, 2025, Freeman ML *et al*, 1996), commonly associated with sphincterotomy or difficult cannulation attempts. American Society for Gastrointestinal Endoscopy has set the standard to be 0.2% (Howard TJ *et al.*, 1999). During the study period, no cases of duodenal perforation were observed. This outcome underscores the procedural safety in our centre and reflects adherence to careful cannulation techniques.

Pancreatitis

Resource constraints at our centre have necessitated the reuse of certain ERCP equipment, including guidewires, endoscopic balloons, and sphincterotomes. This practice may compromise the efficiency and precision of the instruments, potentially contributing to inadvertent pancreatic duct cannulations. This, in turn, could be one of the factors associated with the higher-than-expected rate of post-ERCP pancreatitis (PEP) observed in our series.

Another contributing factor is the lack of routine pharmacological prophylaxis. The European Society of Gastrointestinal Endoscopy (ESGE) recommends the rectal administration of 100 mg of diclofenac or indomethacin immediately before ERCP in all patients without contraindications to non-steroidal anti-inflammatory drugs (Dumonceau JM *et al.*, 2020). The ESGE also advises prophylactic pancreatic duct stenting in selected high-risk patients (Dumonceau JM *et al.*, 2020). However, as a district hospital with limited resources, our centre currently does not have access to pancreatic stents, and rectal NSAID prophylaxis is not routinely administered.

These limitations may have contributed to the observed PEP rate and highlight the need for improved resource allocation and adherence to guideline-based preventive measures where feasible.

Another recognised risk factor for post-ERCP pancreatitis (PEP) is difficult cannulation of the common bile duct (CBD), which often results in prolonged attempts and repeated instrumentations (Freeman ML *et al.*, 2004). According to Halttunen *et al*., difficult cannulation is defined as more than five minutes of attempted cannulation, five or more cannulation attempts, or more than two unintended pancreatic duct guidewire insertions (Halttunen J *et al.,* 2014). Due to the retrospective design of our study, we were unable to determine whether difficult cannulations were a contributing factor in patients who developed PEP, as detailed procedural timings and cannulation attempts were not consistently documented.

From this study, we found that our centre did not meet half of the performance standards set for the study. We postulate that this may be attributed to the relatively small sample size, as well as the fact that our centre is a low-volume unit—defined as performing fewer than 200 ERCP cases per year.

The relationship between ERCP success, complication rates, and procedural volume has been explored in previous studies. Syren *et al*., (Syren EL *et al.*, 2022) demonstrated that higher endoscopist and centre case volumes are significantly associated with improved safety and procedural success. However, it is important to note that low-volume centres are still capable of performing safe and effective ERCPs, as highlighted by other studies (Testoni PA *et al.,* 2010), particularly when there is adherence to best practices and ongoing quality improvement efforts.

This study has provided valuable insight into areas for service improvement. In response, we have implemented the routine administration of prophylactic rectal diclofenac for eligible patients prior to ERCP, in accordance with international guidelines. Furthermore, the findings from this study support our ongoing efforts to advocate for increased funding from hospital administration, particularly for single-use consumables. With better resource allocation, we aim to enhance the safety, efficiency, and overall quality of our ERCP services.

Limitations

There are several limitations to this study. Firstly, data collection was conducted retrospectively, which inherently limits the completeness and accuracy of the data. As a result, some source documents were untraceable or incomplete, leading to the exclusion of certain cases from the analysis.

Additionally, some patients were referred from other hospitals, and the documentation of post-ERCP complications in these cases was less detailed and not standardized, potentially affecting the accuracy of complication reporting.

Another important limitation was the lack of consistent documentation of common bile duct stone size in pre-procedural imaging reports. This prevented us from analysing the correlation between stone size and the success rate of stone clearance during the first ERCP attempt. Consequently, we were unable to assess one of the key factors known to influence procedural outcomes.

CONCLUSION

The results of this study highlight several areas where our ERCP service can be improved. In response, targeted changes have already been implemented to enhance patient safety and procedural outcomes.

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