

Original Article**Endoscopic retrograde cholangiopancreatography; a single tertiary care centre experience from Northern Sri Lanka.**¹Gobishangar S, ²Charles JC, ¹Shathana P¹ Department of Surgery, Faculty of Medicine, University of Jaffna² Teaching Hospital, Jaffna**Abstract**

This study evaluated endoscopic retrograde cholangiopancreatography's safety, efficacy and outcomes in a single tertiary care centre.

This retrospective analysis used data from clinical records of patients who underwent ERCP from 2019 to 2022 at Teaching Hospital Jaffna. Demographic and historical characteristics, indications, and data related to cannulation, interventions, procedural difficulties, and complications were extracted from BHT. The mean age of participants was 57.99 ± 15.33 (23 – 90 years). 52 (49.1%) were males. 54 (50.9%) were females. The procedural success rate was 95.3% (101/106). All procedures were carried out under sedation or general anaesthesia. Common indications for ERCP were biliary stones (76.4%, n=81) and neoplasms involving the biliary tract and pancreas (19.8%). Standard sphincterotomy was performed in the majority of patients (97.2%). Successful retrieval of stones was achieved in 67 (82.7%) patients, predominantly using the balloon extraction method. Duct dilatation and stenting were performed on patients with neoplasm and stricture. The primary procedural difficulty encountered was difficult cannulation. 89.6% of patients did not experience any post-procedural complications, and the ten patients who did develop complications were successfully managed. Procedural mortality of ERCP was 0.9% (n=1).

ERCP can be effectively and safely performed at centers with low procedural volumes in well-experienced hands.

Keywords: ERCP, distal cholangiocarcinoma, Choledocholithiasis, Sphincterotomy

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is a diagnostic or therapeutic procedure for biliary stones, stricture, and pancreatic pathologies [1,2]. The success rate of endoscopic retrieval of biliary tract stones is as high as 90%, as evidenced by previous studies [3]. Sometimes, difficult extraction occurs when multiple stones or distal common bile duct variations are present [4]. The success rate of the ERCP procedure may vary with the anatomical factors of the biliary tract, the experience of the interventionist, and interpersonal techniques between different endoscopists [3]. A trainee is expected to do a reasonable amount of ERCP procedures under supervision before carrying out an ERCP procedure alone to ensure the procedure's safety [5]. Post-ERCP complications are biliary tract injuries, cholangitis, perforation, bleeding, sepsis, and post-ERCP pancreatitis [6]. But, these complications are avoided by the operator's experience [7].

Causes for the difficult cannulation are perampullary diverticulum, perampullary tumour, surgically altered anatomy of the biliary tract, sphincter of Oddi dysfunction (SOD), and difficult approach to papilla [8]. When difficult cannulation is present, precut papillotomy is done as an alternative technical approach [9]. Teaching hospital Jaffna is the only tertiary care centre in the Northern Province of Sri Lanka with the availability of

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multiple endoscopists catering to the needs of surrounding district general and base hospitals. Annually, 50-60 patients undergo ERCP in THJ, and details have been maintained since 2019. This study evaluates ERCP's efficacy, indications, complications, safety, procedural difficulties, and outcomes. So far, there is no study carried out on the safety, efficacy, and outcomes of ERCP in Sri Lanka. Identifying and correcting gaps in the current practice of ERCP through this retrospective analysis will help improve the outcomes.

Methods

A retrospective observational descriptive study was conducted on 106 patients who underwent ERCP at the teaching hospital Jaffna from 2019 to 2023. Ethical approval was obtained from the Ethics Review Committee of the Teaching Hospital Jaffna, with reference number (Reg No- S06/08/2022). Of the 106 patients, 101 completed the ERCP procedure successfully. Patients from all age groups who underwent ERCP were included. No one was excluded. Indications of ERCP have adhered to the International Hepato- Pancreato Biliary Association (IHPBA) guidelines. Indications, technical difficulties, complications, procedural safety, reasons for difficult cannulation, and outcomes of ERCP were extracted from bed head tickets (BHT) after obtaining permission from the institutional ethical review committee. All ERCP procedures were performed by an experienced general surgeon trained in ERCP. Written informed consent was obtained from the patients who were underwent ERCP.

Procedures were performed using Olympus endoscopes. Endoscopic sphincterotomy was performed in patients with stone impaction with the obstructed bile duct, stricture, and obstruction due to neoplasms involving the biliary tract and pancreas. In patients with failed standard sphincterotomy, the precut approach was used. The standard procedure used for biliary stone retrieval included balloon extraction, dormia baskets, and mechanical lithotripsy. Stents were inserted for biliary drainage. Successful cannulation is considered

selective deep cannulation to the common bile duct. Failed cannulation is difficulty in cannulating the biliary tree using an endoscopist's regular technique within a certain time limit or multiple attempts. However, heterogeneity of definitions exists for failed cannulation from different stakeholders. Complications following ERCP were defined according to IHPBA guidelines. Finally, data were analysed by descriptive statistics using SPSS version 26.0.

Results

Totally 106 patients underwent ERCP from 2019 to 2023. Of the 106 patients, 52 (49.1%) were males, and 54 (50.9%) were females. The mean age group of patients was 57.99 ± 15.33 . (23 – 90 years). The common presentation on admission was obstructive jaundice (n=56, 52.8%). The demographic and historic characteristics of patients are listed in Table 01. Common indications for ERCP are illustrated in Figure 01.

Table 1 Demographic and historic characteristics

Gender	Male	52	49.1%
	Female	54	50.9%
Age	Mean	57.99 ± 15.33	
	Range	23 – 90 years	
Presentation on admission	Obstructive Jaundice	56	52.8%
	Acute cholecystitis	16	15.1%
	Acute Pancreatitis	6	5.6%
	Isolated RHC pain	28	26.4%

Standard sphincterotomy with sphincterotome was performed in 103 (97.2%) patients, and precut sphincterotomy using a needle knife was done on three patients (2.8%). Out of the 81 patients diagnosed with biliary stone disease, a single common bile duct (CBD) stone was detected in 43 patients (53%), while multiple stones were identified in 38 patients (47%). The predominant method used for stone retrieval was balloon extraction on 79 (97.5%) patients. 82.7% of stone retrievals were successful.

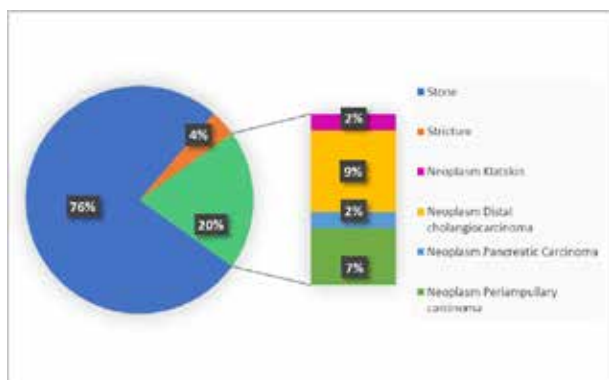


Figure 01: Indications for ERCP

The main reasons for the failed extraction of CBD stone (17.2%, 14) are large stones >2cm (5%), irregular shape (3.7%), periampullary diverticula (1.8%) altered anatomy of the biliary tract by previous surgery (3.7%), and tumour impingement (2.5%). Stents were placed for biliary drainage in 47 (44.3%) patients. Stone retrieval methods and stenting methods are summarised in Table 02. Standard sphincterotomy was done in 97.2% of patients and remaining were cannulated by precut sphincterotomy (2.8%) (Figure 2). Balloon sweep was done in 98.1% and stone retrieval done in 76.4%.

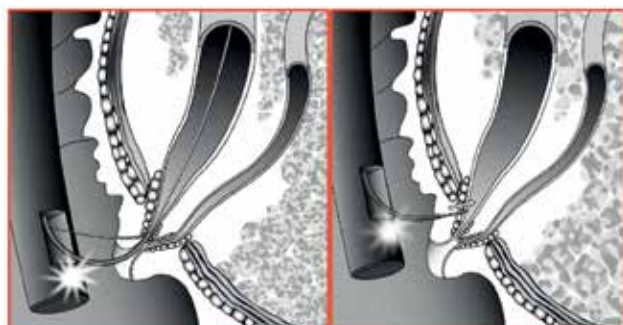


Figure 02 (A) Standard sphincterotomy with sphincterotome (B) precut sphincterotomy

There were minimal complications following ERCP, as 90% of the patients had no complications. Bile leak (n=2, 1.8%), perforation (n=1, 0.9%), and cholangitis (n=2, 1.8%) were the observed complication in our study (Figure 3). Observed procedural mortality rate was (n=1, 0.9%), attributed to sepsis with multi-organ failure. Failed cannulation (n=18, 16.9%), accidental pancreatic duct cannulation (n=5, 4.7%), difficult extraction (n= 14 , 13.2%) of the stones,

Table 2 Stone retrieval and stenting

Single/ Multiple stones	Single	43	53.0%
	Multiple	38	47%
Stone retrieval methods	Balloon extraction	79	97.5%
	Balloon + Lithotripsy	1	1.25%
	Dormia basket	1	1.25%
Stone extraction	Successful	67	82.7%
	Failed	14	17.3%
Type of stents in stent placed	JJ	7	6.6%
	Metal	6	5.6%
	Plastic	34	32.1%
	No Stent	59	55.7%

periampullary diverticulum (n=2, 1.8%) were the main problems noted during ERCP. (Figure 4)

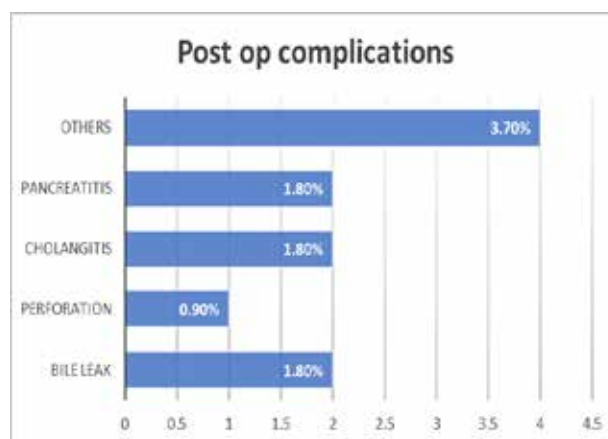


Figure 3 Post op complications

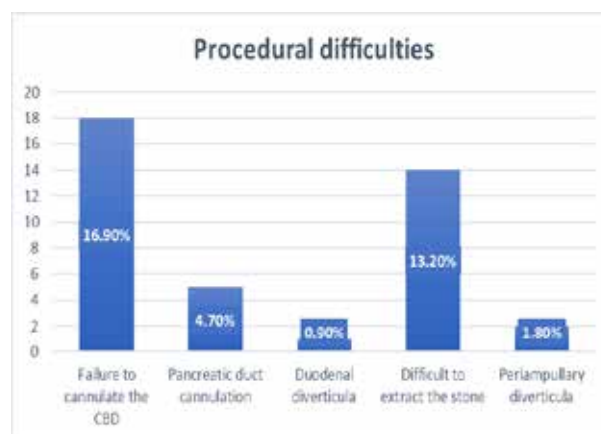


Figure 4 Procedural difficulties

Subsequent cholecystectomy was done in 49 (46%) patients with stone disease. CBD dilation and stenting was done for 24 patients (22.7%) with neoplasm and stricture.

Discussion

ERCP can be a diagnostic and therapeutic method for pancreatic and biliary conditions [5]. It is safe and effective in experienced hands [10]. This is the first study from Northern Sri Lanka to assess the safety, efficacy, and procedural challenges associated with ERCP.

ERCP is commonly indicated for benign conditions affecting the biliary or pancreatic ductal system, with some cases involving malignant conditions [11]. Our study also revealed that 80% of the cases were related to benign conditions, while 20% were attributed to malignant conditions. Numerous studies worldwide have consistently shown that choledocholithiasis is the most prevalent indication for ERCP [12-14].

In a multicenter study conducted in the United States, the most common ERCP indication was suspected or established uncomplicated common bile duct stones in 1470 (61.5%), followed by the management of existing biliary or pancreatic stent in 370 (15.5%) and acute biliary pancreatitis in 173 (7.2%) [15]. Similarly, our study revealed that the most prevalent benign indication was biliary stones (76%), followed by strictures (4%). Hence, stents were placed for biliary drainage in 47 (44.3%) patients in our study.

A study dealing with malignant indications for ERCP conducted in North India reported perihilar lesions being the most common (32.9%), followed by distal cholangiocarcinoma (23%), periampullary carcinoma (15.7%), and pancreatic carcinoma at 13.5% [13]. In contrast, our study found distal cholangiocarcinoma to be the most frequently observed malignant condition, followed by periampullary carcinoma.

Therapeutic ERCP requires selective cannulation of the biliary tract [16]. The success rate of cannulation in ERCP is influenced by the patient's factors and the endoscopist's experience [7]. Different studies have yielded different cannulation success rates in ERCP ranging from 65% to 100% [2]. A randomised controlled trial conducted in Australia unveiled that the success rate of cannulation was 97.3% [7]. Also, an Indian study revealed a success rate of 93% [13]. Despite encountering

difficulties, our study also demonstrated a cannulation success rate of 95.3% (n=101). Standard sphincterotomy was the preferred technique in 1244 (52.0%) cases, and precut sphincterotomy was performed only in 22 (0.9%) cases in a study conducted in the United States. Similarly, the predominant method used in our setting was standard sphincterotomy (97.2%).

ERCP is an effective method for managing common bile duct (CBD) stones compared to open and laparoscopic CBD exploration, as evidenced by previous studies [17]. A study on the epidemiology and characteristics of choledocholithiasis concluded that CBD stones found in Sri Lankan patients were predominantly single, located in the distal portion of the duct, and of small size. These characteristics are conducive to successful retrieval through ERCP [18]. However, it's noteworthy that although many characteristics were in line with the findings of our study, our research demonstrated an almost equal percentage of single and multiple stones.

A study in Pakistan focusing on CBD stone extraction using ERCP reported a successful extraction rate of 81.08% for CBD stones. 90.42% of the patients underwent balloon extraction, while 9.58% had dormia basket retrieval [19]. When comparing these findings to our study, we observed a 82.7% success rate in CBD stone removal, with the majority of our patients also undergoing balloon extraction (n=104, 98.1%), similar to that study.

Older age >85, Periampullary diverticula, multiple stones (>4), and stones more than 1.5cm were found to be the primary reasons for the failed stone retrieval in a Greece study recruiting 1390 ERCP stone extraction [20]. Similarly, large stones (>2cm) and periampullary diverticula were the primary reasons for the failure in our study. Additionally, altered anatomy resulting from previous surgery and tumour impingement were identified as other reasons for the failure.

The challenges encountered during ERCP procedures can arise even before the endoscope is introduced, including factors that heighten the risks of sedation, bleeding tendencies, anatomical variations in the biliary system, and difficult cannulation [23]. Our study primar-

ily noted minor difficulties, with difficult cannulation being a commonly encountered issue. Nevertheless, we successfully navigated these challenges without experiencing any major complications.

Post-ERCP complications are known and mostly include pancreatitis, cholangitis, haemorrhage, and perforation [24]. In a recent study conducted in South India, 8% of patients experienced post-ERCP complications, with pancreatitis being the most common (3.06%), followed by cholangitis and bleeding (1.14%), and perforation (0.76%) [16]. Similarly, a European study also yielded comparable results, with 12% of patients experiencing complications [25]. Despite our setting having limited facilities, our study also demonstrated findings consistent with global literature, reporting a 10.4% rate of complications

Post-ERCP pancreatitis is a particularly concerning complication in ERCP as it contributes to mortality [26]. Difficult cannulation of the biliary tract has been associated with a higher risk of PEP [16]. Worldwide trials have reported PEP incidence rates ranging from 8% to 15%. In our study, two patients were developed PEP after normal cannulation, not in difficult cannulation. Other risk factors for PEP were female sex and advanced age [16]. A Chinese study involving 4234 patients reported post-ERCP cholangitis in 2.4% of cases (n=102) [27]. Compared to that study and the currently available literature on post-ERCP cholangitis, a minimal incidence was noted in our study (1.8%).

Unfortunately, our study experienced one procedure-related mortality attributed to sepsis. This particular patient had infiltrative distal cholangiocarcinoma and pre-existing cholangitis before undergoing ERCP. Cannulation could not be achieved, and the ERCP procedure failed due to the inability to identify the ampulla.

The primary limitations of our study include its retrospective nature, a relatively small number of patients, and the lack of data on long-term follow-up. Furthermore, we could not thoroughly explore complications and efficacy due to the limited sample size. A comprehensive five-year study on efficacy and safety involving multiple large-volume centres in Sri Lanka would provide valuable additional evidence.

Conclusion

ERCP is a safe and effective procedure in experienced hands. Choledocholithiasis is the commonest indication for ERCP in the northern part of Sri Lanka, followed by distal cholangiocarcinoma. Pancreatic duct cannulation, duodenal diverticula, and periampullary diverticula are the most common periprocedural problems. Further studies have to be done to identify the reasons for cannulation failure and complications in many participants.

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