

Endoscopic ultrasound guided biliary drainage in malignant biliary obstruction and failed ERCP-Initial experience of tertiary Hepato-pancreato-biliary center in Sri Lanka

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Abstract

Introduction

The traditional primary method for treating biliary blockage is endoscopic retrograde cholangiopancreatography (ERCP) and percutaneous transhepatic cholangiography and biliary drainage (PTBD). In centers with expertise in Endoscopic ultrasound (EUS), it is increasingly being used to drain obstructed biliary tracts especially in patients with failed ERCP. The biliary tract can be drained to the stomach (Hepatico-gastrostomy-HGS) or duodenum (Choledoco-duodenostomy-CD) with EUS and fluoroscopy guidance using a self-expandable metal stent.

Materials and methods

This is a retrospective descriptive study among 18 patients with malignant biliary obstruction who underwent EUS-BD after failed ERCP from 2019 to 2023 in a tertiary HPB center in Sri Lanka. All procedures were performed by a single gastroenterologist (NF).

Results

The mean age was 63 years (range 35–78) with the male: female ratio 1: 1. The commonest indications for the procedure was obstructive jaundice with failed ERCP due to failed biliary cannulation (13/18). CD and HGS techniques were performed on nine patients each. CD was performed in patients with distal bile duct obstruction (Pancreatic head cancer n= 7/9) and HGS in patients with proximal bile duct obstruction (Hilar cholangiocarcinoma n=7/9). The technical success was 100% in our experience and the clinical success was 94%. One patient died on day 1 of a myocardial infarction while post-procedure cholangitis was inevitable for all the

patients. The success rates and adverse events were comparable between both CD and HGS groups.

Conclusion

EUS-BD is an effective and efficient procedure to achieve biliary drainage in patients with malignant biliary obstruction after ERCP failure with minimal complications.

Introduction

Malignant biliary obstruction (MBO) occurs in advanced cancers, such as pancreatic cancer and cholangiocarcinoma, which are often diagnosed at stages where surgical intervention is not feasible. MBO significantly impairs patients' quality of life, and presents with symptoms like obstructive jaundice, pruritus, and recurrent cholangitis. Effective biliary decompression is crucial for providing symptomatic relief and enabling oncological therapies like chemotherapy, which require improved liver function and reduced bilirubin levels [1], [2]. Beyond symptom relief, the importance of palliative care in MBO extends to preventing complications such as recurrent cholangitis and hepatic dysfunction, which commonly arise due to prolonged bile duct obstruction [3].

Historically Endoscopic Retrograde Cholangiopancreatography (ERCP) has been the primary treatment modality for biliary drainage in malignant biliary obstruction, demonstrating high clinical success rates. However, ERCP fails in 10-20% of cases, often due to several key factors: (1) Tumor Invasion: Advanced cancer infiltration obstructing the ampulla or duodenum. (2) Duodenal Stenosis: Tumor-induced narrowing that prevents passage of the endoscope to the ampulla. (3) Post-Surgical Anatomy: Altered gastrointestinal anatomy that negates the standard ERCP approach.[1], [2], [4]

When ERCP fails, clinicians may turn to alternative methods like Percutaneous Transhepatic Biliary Drainage (PTBD). However, PTBD has notable drawbacks, including patient discomfort from external drainage systems and an elevated risk of complications such as bile leaks and infections, which

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can diminish the patient's quality of life [1]. In such scenarios, EUS-guided biliary drainage has emerged as a minimally invasive and a transformative technique for biliary decompression especially in malignant biliary obstruction. Initially developed as a rescue option [5], EUS-BD has evolved into a well-established alternative, offering internal drainage and providing superior patient comfort while reducing adverse event rates compared to PTBD. Furthermore, the development of advanced techniques, including lumen-apposing metal stents, has enhanced the technical success and safety of EUS-BD. [1], [4], [6], [7].

The primary advantage of EUS-BD is its capacity to directly access the biliary system by circumventing obstructions stemming from malignancy or altered anatomy. Utilizing a linear echoendoscope, clinicians can visualize and puncture the biliary system with remarkable precision. Once accessed, drainage is achieved through two principal approaches: (1) Intrahepatic Access: EUS Guided hepatic gastrostomy (EUS HGS) This method establishes a fistula between the left intrahepatic bile duct and the stomach, rendering it well-suited for proximal obstructions or altered anatomy. (2) Extrahepatic Access: EUS Guided choledoco- duodenostomy (EUS CDS): This technique creates a connection between the common bile duct and the duodenum. [2], [3], [6], [8]

Technological advancements, including the development of electrocautery-enhanced lumen-apposing metal stents, have simplified these procedures. These devices allow for single-step, secure stent placement, thereby reducing procedure time and minimizing complications such as bile leakage [1], [5].

EUS-guided biliary drainage offers several significant advantages compared to traditional methods like ERCP and PTBD: (1) High Success Rates: EUS-BD demonstrates high technical and clinical success rates, often surpassing or equaling those of ERCP and PTBD in cases where the primary drainage method has failed [1], [2] (2) Internal Drainage: Unlike PTBD, EUS-BD avoids the need for external drainage systems, significantly improving patient comfort and quality of life. The internal drainage approach reduces the psychological and physical burden associated with external tubes and mitigates the risk of infection and catheter displacement [1], [3]. (3) Reduced Complications: By bypassing the ampulla of Vater, EUS-BD eliminates the risk of post-procedural pancreatitis, a common complication of ERCP. Additionally, EUS-BD is associated with fewer adverse events, such as cholangitis and bile leakage, compared to PTBD [1], [2], [9].

This study evaluates the feasibility and efficacy of EUS-BD for managing malignant biliary obstruction in a resource-limited South Asian setting. Given the high prevalence of advanced biliary cancers and the limitations of ERCP and PTBD, EUS-BD offers a minimally invasive and effective alternative. The study aims to provide critical insights to the global literature on the applicability of EUS-BD in settings with constrained resources and limited access to advanced technology.

Materials and Methods

This retrospective descriptive study was conducted at a tertiary Hepatopancreatobiliary (HPB) center in Sri Lanka between 2019 and 2023. Eighteen patients with malignant biliary obstruction who underwent Endoscopic ultrasound-guided biliary drainage (EUS-BD) following failed Endoscopic retrograde cholangiopancreatography (ERCP) were included. Data were collected from patient medical records, endoscopy reports, and follow-up records.

The study evaluated technical success, clinical success, and post-procedure complications. Patients were followed for at least eight weeks to monitor bilirubin levels and complications. The study primary outcome included technical and clinical success of EUS-BD. Technical success was defined as the successful placement of the stent at the end of the procedure in proper position; with one end in the biliary tree and the other in the alimentary tract. Clinical success was defined as a 50 % or more decrease in serum total bilirubin two weeks after the procedure. [10]

Adverse Events were defined, and classification of endoscopic adverse events (AEs) were adopted from the lexicon by American Society for Gastrointestinal Endoscopy [11]. AE was defined as an event causing interruption of the procedure and/or requiring medical consultation, hospitalization, endoscopic or surgical intervention. When there was more than one AE, the most serious was the one to be counted.

Endoscopic procedure

All procedures were performed by the first author (NF). A linear echoendoscope (Olympus ME1) was used in all procedures to visualize and access the biliary system, followed by stent placement. Initially a 19G EUS-FNA needle (Echotip needle, EXPECT needle Boston Scientific, Natick, MA, USA) was used to access the dilated bile duct (Left Intra hepatic ducts for HGS and Common bile duct for CDS). A 0.035 or 0.025 ERCP guidewire (Jagwire; Boston-

Scientific) was inserted through the needle into the bile ducts to railroad the future accessories and stent. A 6 French cystotome (Endo-flex) was used to dilate the puncture tract.

Following tract dilatation, a partially covered self-expandable metal stent (Niti-S™ GIOBOR™ Biliary Stent) for HGS and standard fully covered self-expandable metal stent for CDS (Wall Flex™ Biliary RX Stents) was used to create the enterostomy. Stent length varied from 6 – 10cm. Immediate passage of bile through the stent confirmed the correct stent placement. (Figure 1)

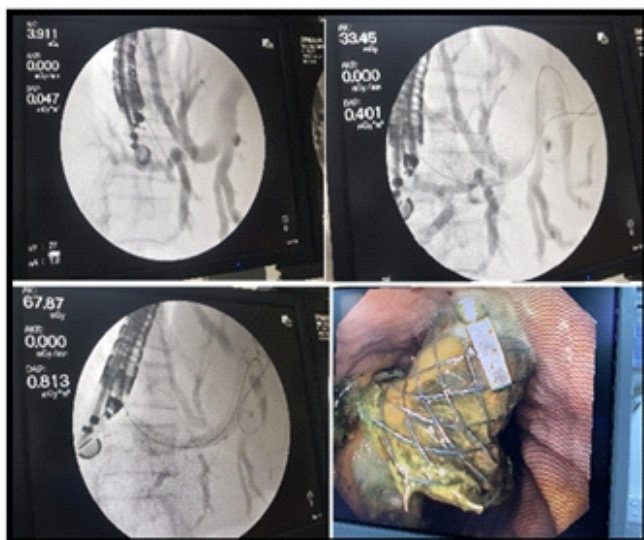


Figure 1

Results

The mean age was 63 years (range 35–78) with the male: female ratio of 1:1. As shown in figure 2, the indications for EUS BD were obstructive jaundice with failed ERCP either due to failed biliary cannulation (13/18), inaccessible ampulla (4/18), or post-PTC stenting obstructive jaundice (1/18).

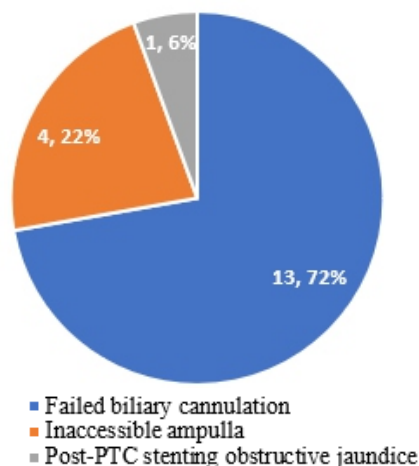


Figure 2: Indications for EUS-BD following failed ERCP

CD and HGS techniques were performed on nine patients each. As illustrated in figure 3, CD was performed in patients with distal bile duct obstruction (i.e., pancreatic cancer n = 7/9 and periampullary cancer n = 2/9) and HGS in patients with proximal bile duct or hilar obstruction (i.e., hilar cholangiocarcinoma n = 7/9 and gallbladder cancer n = 2/9).

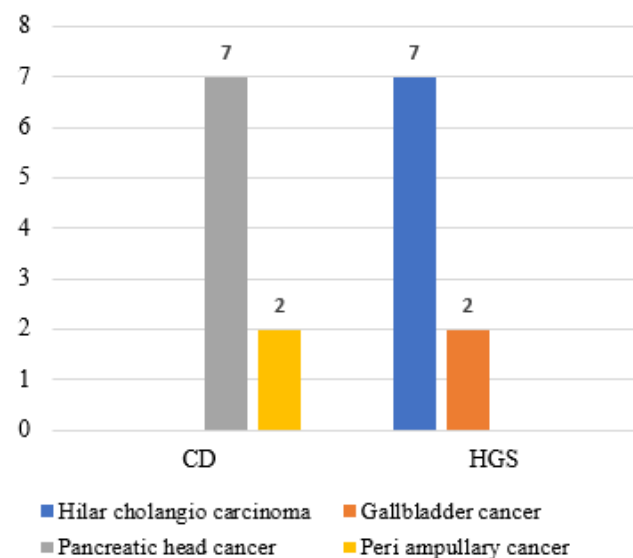
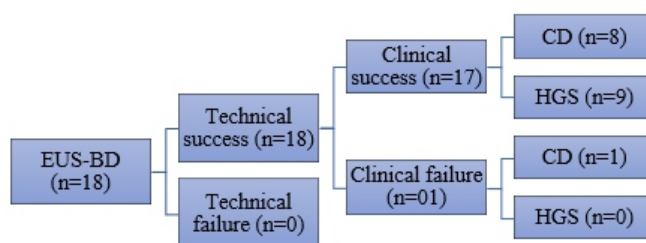


Figure 3: Causes for malignant biliary obstruction

The technical success of this procedure was 100% while the clinical success was achieved in 88% of the patients (50% Total bilirubin reduction in two weeks). Figure 4 summarizes the success rates of EUS BD. During the eight weeks post-procedure follow up period, one patient died on day 1 of a myocardial infarction. Post-procedure cholangitis was inevitable in all patients and needed antibiotics. Table 1 summarizes the comparison of outcome between CD vs HGS groups which shows comparable success rates and adverse event profile between the two groups.



CD: Choledoco- duodenostomy, HGS: Hepatic gastrostomy

Figure 4: Summary of EUS-BD success rates for malignant biliary obstruction

Table 1: Outcome of CD vs HGS procedures

Item		CD	HGS	Total	Significance
Technical success	Yes	9/9 (100%)	9/9 (100%)	18/18 (100%)	NS
	No	0	0	0	
Clinical Success	Yes	8/9 (89%)	9/9 (100%)	17/18 (94%)	NS
	No	1/9 (11%)	0	1/18 (6%)	
Adverse events	Mild	9/9 (100%)	9/9 (100%)	100 (100%)	NS
	Moderate	0	0	0	
	Severe	0	0	0	
	Fatal	1/9 (11%)	0	1/18 (6%)	

CD: Choledoco- duodenostomy, HGS: Hepatic gastrostomy, NS: Not significant

Discussion

Our study, being the first conducted in Sri Lanka, revealed high efficacy and safety of EUS-BD, with notable reductions in bilirubin levels and manageable complications. These findings provide a crucial perspective, particularly in a South Asian context where data on this advanced technique are limited.

The study demonstrated a 100% technical success rate for creating enterobiliary fistulas and stent placement, with all procedures achieving effective biliary decompression. This is consistent with the high technical success rates reported by Paduano et al. (98.2%) and Kawakubo et al. (95%) in their multicenter investigations, suggesting that EUS-BD is a dependable alternative when ERCP fails [1], [3].

The clinical success of our patient cohort was demonstrated by a 50% reduction in bilirubin levels within 2-4 weeks and a 90% reduction at 8 weeks, which aligns with the findings reported by Paik et al. [2] who observed a comparable timeline of bilirubin reduction. Furthermore, the comparative effectiveness of Choledochoduodenostomy and Hepaticogastrostomy was evident in our study, where each technique was applied based on anatomical considerations. This is consistent with other studies like Paduano et al.[1], which emphasizes that CD is the preferred approach for distal obstructions, while HGS is more suitable for proximal or hilar blockages. This mirrors international practice underscoring the adaptability of EUS-BD to varied anatomical changes.

The patients in our study cohort included a spectrum of failed ERCP cases, including failed biliary cannulation in 13 cases (72.2%), inaccessible ampulla in 4 cases (22.2%), and post-PTC stenting-related jaundice in 1 case (5.6%). These findings are consistent with previous research, by Tyberg et al. [6], where tumour involvement of the ampulla and altered surgical anatomy were common reasons for the failure of endoscopic retrograde cholangiopancreatography.

All patients in our study experienced post-procedure cholangitis, which was effectively managed with antibiotics. This complication rate contrasts with the overall adverse event rate of less than 20% reported in previous studies [3], [6], [7], [12]. This difference may suggest higher susceptibility among our patient population, potentially related to patient demographics, procedural nuances, or the relatively small sample size of our study. Furthermore, the day one mortality due to myocardial infarction observed in one of study patients was similar to the early complication rates reported by Poincloux et al. in the initial learning phase of the procedure. Specifically, their study found a mortality rate of 10.5% during the initial cases, which declined to 2.0% in later cases.[7]

The study examined a cohort of 18 patients over a four-year period. The mean age of the participants was 63 years, which aligns with the 60–70 years age range reported in similar studies.[6], [8]

Our study stands out for being the first to report on EUS-BD outcomes in Sri Lanka, highlighting its feasibility in a resource-limited environment. But the relatively smaller size of the sample may not reflect the broader trends due to the lack of multicenter data and restrict the generalizability of findings.

Conclusion

This study shows that Endoscopic Ultrasound-Guided Biliary Drainage is a feasible and effective alternative to ERCP and PTBD for managing malignant biliary obstruction when standard approaches fail. The findings highlight the high technical success and significant clinical efficacy of EUS-BD, as demonstrated by a substantial reduction in bilirubin levels. While all patients experienced post-procedure cholangitis, it was manageable with antibiotics, indicating the overall safety of the procedure. The mortality rate due to myocardial infarction aligns with international data on early

complications during the learning phase of EUS-BD. EUS-BD represents a promising option for palliative biliary decompression in malignant obstruction, offering advantages such as internal drainage, high patient comfort, and reduced adverse events compared to traditional alternatives. The study's findings support the integration of EUS-BD into clinical practice, especially in resource-limited settings.

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