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EUS-Guided Biliary Drainage Vs. Percutaneous Transhepatic Biliary Drainage Following Failed ERCP In Malignant Biliary Obstruction: A Pilot Comparative Study

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Abstract

Background:

Malignant biliary obstruction (MBO) is a common complication of biliopancreatic malignancies, often requiring endoscopic retrograde cholangiopancreatography (ERCP) for biliary decompression. However, ERCP fails in up to 15% of cases. Percutaneous transhepatic biliary drainage (PTBD), traditionally used in such cases, is associated with high morbidity. Endoscopic ultrasound-guided hepaticogastrostomy (EUS-HGS) has emerged as a promising alternative. This study compares the safety, efficacy, and survival outcomes of EUS-HGS versus PTBD following failed ERCP.

Methods:

In this single-center, ambispective pilot study conducted from January 2021 to January 2025, we included 18 patients with histologically confirmed MBO and failed ERCP. Twelve underwent PTBD, and six underwent EUS-HGS. Primary outcomes included clinical success (≥50% reduction in bilirubin at 2 weeks). Secondary outcomes included technical success, delayed complications (>24h), and overall survival.

Results:

Technical success was comparable between PTBD and EUS-HGS groups (83.3% each). Clinical success was 100% in the EUS-HGS group vs. 83.3% in the PTBD group ($p = 0.53$). Delayed complications were significantly lower in the EUS-HGS group (16% vs. 70%; $p < 0.001$). PTBD was associated with external drain discomfort, dislodgment, and abscess formation. No deaths were reported in the EUS-HGS group during follow-up, whereas the PTBD group showed a median survival of 26 days ($p < 0.001$).

Conclusion:

EUS-HGS is a safe and effective alternative to PTBD following failed ERCP in MBO, offering superior clinical outcomes, fewer complications, and improved survival. While technically demanding and best performed in specialized centers, EUS-HGS may represent a preferable strategy in selected patients. Larger randomized controlled trials are warranted to validate these findings and inform clinical practice.

Keywords: *Malignant biliary obstruction; Endoscopic ultrasound-guided hepaticogastrostomy; EUS-HGS; Percutaneous transhepatic biliary drainage; PTBD; ERCP failure; Biliary drainage; Pancreatic cancer; Cholangiocarcinoma; Interventional endoscopy*

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I. Background

Malignant biliary obstruction (MBO) is a frequent and serious complication of biliopancreatic malignancies such as pancreatic head adenocarcinoma, perihilar cholangiocarcinoma, gallbladder carcinoma, and ampulloma. Endoscopic retrograde cholangiopancreatography (ERCP) remains the first-line modality for biliary decompression; however, cannulation failure occurs in up to 15% of cases due to anatomical or pathological challenges. In such scenarios, percutaneous transhepatic biliary drainage (PTBD) has traditionally served as the fallback option, but it is associated with considerable morbidity, particularly related to external drains and infection risk.

In recent years, endoscopic ultrasound-guided hepaticogastrostomy (EUS-HGS) has emerged as a promising alternative to PTBD following failed ERCP. This minimally invasive approach enables internal biliary drainage while preserving physiological bile flow and potentially improving patient comfort and clinical

outcomes. However, evidence comparing EUS-HGS to PTBD, particularly in real-world clinical settings, remains limited.

The present study aims to to provide preliminary data and to compare the safety, efficacy, and survival outcomes of EUS-HGS versus PTBD in patients with MBO after failed ERCP. By evaluating technical and clinical success, complication rates, quality of life, and overall survival.

II. Patients And Methodes

1. Patient selection and study design

We performed a single-center, ambispective analytical pilot study between January 2021 and January 2025. We included all consecutive patients with histologically confirmed biliopancreatic malignancies—pancreatic head adenocarcinoma, perihilar cholangiocarcinoma, gallbladder cancer, or ampulloma— who presented with obstructive jaundice and who experienced failed selective cannulation of the major papilla during ERCP. Patients underwent either percutaneous transhepatic biliary drainage (PTBD) or endoscopic ultrasound-guided hepaticogastrostomy (EUS-HGS).

2. Procedures

Endoscopic ultrasound-guided hepaticogastrostomy

A second-generation Pentax curved linear echoendoscope (EG-3870UTK, Pentax Medical, Tokyo, Japan) was used to access the left hepatic ducts from the proximal stomach or cardia. The ducts were punctured with a 19-gauge needle (19G, EchoTip® Access Needle, Cook Ireland Ltd., Limerick, Ireland), avoiding vessels with color Doppler guidance. Bile was aspirated for culture, then contrast was injected for cholangiography. A 0.035-inch guidewire (Jagwire, Boston Scientific, USA) was advanced into the bile ducts. The needle was exchanged for a 6-Fr cystotome (Endo-Flex®, Germany) to dilate the tract. a dedicated hepaticogastrostomy stent was introduced (MI Tech, South Korea); this stent is a partially covered metallic stent (70% covered to prevent the bile leakage and 30% uncovered to prevent the migration; the uncovered part is introduced in the bile duct). We left about 2 cm of the stent inside the stomach (figures 1 to 3)

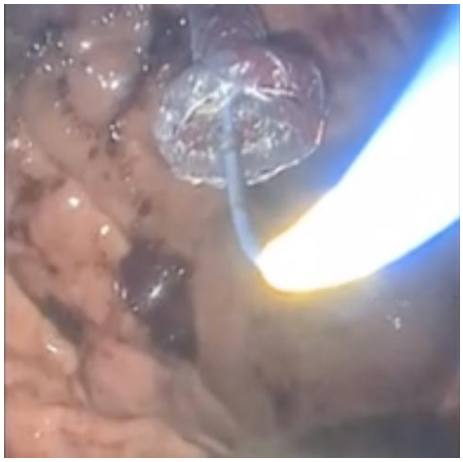

Figure 1. Endoscopic view showing the intragastric portion of the stent traversing the posterior and proximal gastric wall

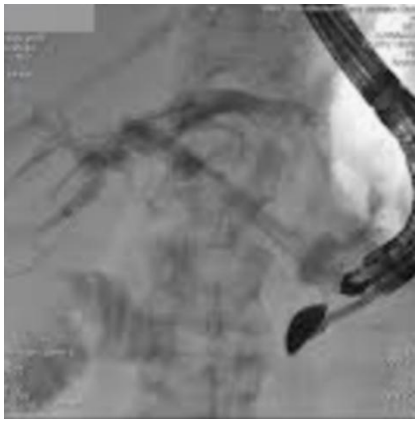

Figure 2. Fluoroscopic image demonstrating EUS-guided hepaticogastrostomy (EUS-HGS).

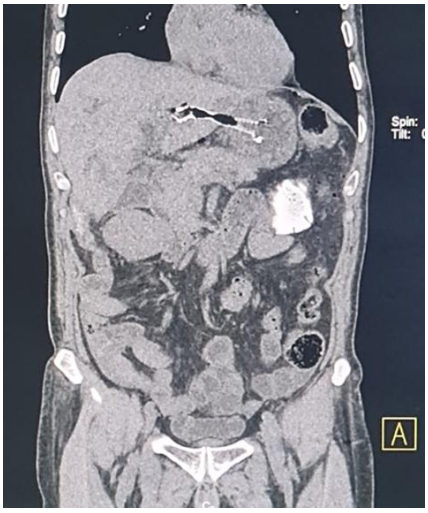

Figure 3. Coronal CT image demonstrating successful deployment and patency of the transhepaticogastric stent, extending from the left intrahepatic bile ducts through the hepatic parenchyma into the gastric cavity, ensuring effective internal biliary decompression without evidence of bile leak or migration.

Percutaneous transhepatic biliary drainage

The biliary tree was punctured under ultrasound guidance. Contrast injection was performed to obtain a cholangiogram. The biliary tree was then catheterized with a guide wire under fluoroscopic guidance and a 7 Fr introducer placed at entry of the intrahepatic bile duct. An 8 Fr externally locked drain was placed. After 1 week, or if the patient improved, an attempt of metallic stent placement was performed. In case of lower bile duct obstruction, the distal end of the stent was placed across the ampulla in order to ensure maximal biliary drainage and reduce the risk of post-procedure cholangitis. An 8 Fr external drain was left along the PTB track following stent placement and removed 7 days later if the drainage from the metallic stent was effective.

III. Data Collection

Patient demographics, histopathological diagnosis and procedural details were collected and analyzed. Data sources included medical history, biochemical parameters at baseline and during follow-up, imaging studies, procedural documentation, and both clinical and pathological follow-up records. Information regarding failed ERCP attempts—including failure characteristics and underlying causes—was recorded, along with technical and clinical success, adverse events throughout follow-up, and overall survival. Patients were monitored until death or until the conclusion of the study period, whichever occurred first

IV. Study Endpoints

The primary outcome measure was the clinical success rate. Secondary outcome measures were the technical success rate, procedure-related delayed complications, improvement in quality of life and overall survival.

Outcomes were defined as follows : Technical success was defined as successful puncture of the hepatic bile duct, followed by guidewire insertion and accurate placement of the stent or drain at the intended site, confirmed by endoscopic and/or radiographic imaging. Clinical success was defined as a drop in serum bilirubin level of more than 50% at two weeks post-procedure. Procedure-related delayed complications were defined as adverse events occurring more than 24H post-procedure.

V. Statistical Analysis

Statistical analyses were conducted using Jamovi software. Continuous variables were expressed as mean ± standard deviation (SD) or median with interquartile range (IQR), depending on the distribution, which was assessed using the Shapiro–Wilk test. Categorical variables were summarized as counts and percentages. Group comparisons for categorical data were performed using Fisher's exact test. Continuous variables were compared using either the Student's *t*-test or the Mann–Whitney *U* test, as appropriate. Survival analysis was conducted using the Kaplan–Meier method, and differences between groups were evaluated using the log-rank test. A p-value < 0.05 was considered statistically significant.

VI. Ethics Approval Statements

This study was conducted in accordance with the ethical standards of the Mohammed V Military Teaching Hospital Ethics Committee and with the 1964 Helsinki Declaration and its later amendments. Informed consent was obtained from all individual participants included in the study

VII. Results

Among 124 patients referred for ERCP due to malignant obstructive jaundice, 18 patients (15%) experienced failed cannulation and were subsequently included in this study. Of these, twelve patients underwent percutaneous transhepatic biliary drainage (PTBD group), while six patients received endoscopic ultrasound-guided hepaticogastrostomy (EUS-HGS group).

Baseline characteristics showed no significant difference in pre-drainage total serum bilirubin levels between the PTBD and EUS-HGS groups (250 ± 12.1 mg/L vs. 210 ± 21.8 mg/L, respectively; $p = 0.40$), indicating comparable severity of biliary obstruction at the time of intervention. Technical success, defined as successful stent placement with adequate biliary decompression, was achieved in 83.3% of patients in both groups ($p = 1.00$).

In the PTBD group, two patients required repeat procedures due to inadequate intrahepatic ductal dilation, highlighting challenges related to procedural technicalities. In the EUS-HGS group, one patient experienced a significant adverse event of intraperitoneal stent misdeployment necessitating laparotomy and subsequent intragastric stent repositioning.

Among patients achieving technical success, clinical success was observed in 100% of the EUS-HGS group compared to 83.3% in the PTBD group ($p = 0.53$), suggesting a trend favoring EUS-HGS though without statistical significance.

Notably, the incidence of delayed complications was significantly higher in the PTBD group (70% vs. 16%; $p < 0.001$). All patients undergoing PTBD reported discomfort associated with the presence of an external drain. Additionally, drain dislodgment and bile leakage were observed in 50% of PTBD cases, with four patients (33.3%) developing perihepatic or abdominal wall abscesses, underscoring the morbidity linked to this approach. Conversely, all patients in the EUS-HGS group reported an improved quality of life post-procedure and were able to successfully initiate chemotherapy. One patient experienced recurrent jaundice after one year, which was effectively managed by endoscopic stent cleaning without further complications.

After a median follow-up period of 448 days (range: 200–779 days), median overall survival in the PTBD group was 26 days (range: 8–92 days). Remarkably, no deaths occurred in the EUS-HGS group during the follow-up period, with survival outcomes significantly favoring EUS-HGS ($p < 0.001$). Table 1 resumes comparative outcomes between PTBD and EUS-HGS Groups

Table 1. Comparative Outcomes Between PTBD and EUS-HGS Groups

	PTBD group n = 12	*EUS-HGS group n = 6*	*p*
Technical success, n(%)	10(83.3)	5(83.3)	1
Clinical success, n(%)	100(83.3)	6(100)	0.53
Mean total bilirubin level before drainage (mg/L)	250 ± 12.1	210± 21.8	0.4
Delayed complications, n(%)	8(70)	1(16)	<0.001
Median overall survival (days	26 [8-92]	No deaths recorded	<0.001

VIII. Discussion

Obstructive jaundice resulting from malignant biliary strictures is most commonly caused by pancreatic cancer, ampulloma, or cholangiocarcinoma [1]. If not promptly managed, obstructive jaundice may lead to serious complications including delayed oncologic treatment, acute cholangitis, diminished quality of life, and increased mortality. Effective biliary drainage in these patients plays a crucial role in mitigating such risks and enhancing overall clinical outcomes [2].

Endoscopic retrograde cholangiopancreatography (ERCP) with stenting remains the guideline-recommended first-line treatment for malignant distal biliary obstruction (MBO). However, ERCP-guided biliary access fails in approximately 5–10% of cases, due to duodenal invasion, or gastric outlet obstruction [3]. Even with native anatomy, selective cannulation of the major papilla poses significant challenges. Failure rates may reach 15% despite expert endoscopists, influenced by papillary orientation, anatomical variations, and periampullary anomalies including diverticula, lipomas, or duplication cysts [4]. Surgical modifications, such as Billroth II gastrectomy or Roux-en-Y gastric bypass, further complicate or preclude the procedure [5].

Until recently, percutaneous transhepatic biliary drainage (PTBD) was the standard approach for biliary decompression in case of failed ERCP [6]. Though effective, the procedure is technically demanding and may lead to adverse events in up to 40% of cases [7].

Endoscopic ultrasound (EUS) offers several alternative approaches for biliary drainage in the management of obstructive jaundice, including transduodenal (EUS-guided choledochoduodenostomy), transgastric (EUS-guided hepaticogastrostomy), and, more recently, transcholecystic access (EUS-guided gallbladder drainage). In contrast to the single-access technique of ERCP, EUS enables a more flexible and individualized therapeutic strategy [8].

EUS-guided biliary drainage (EUS-BD) was first described in 2001 [9]. A multicenter randomized controlled trial compared the efficacy of EUS-guided biliary drainage (EUS-BD) and percutaneous transhepatic biliary drainage (PTBD) following failed primary ERCP in patients with unresectable malignant distal biliary obstruction. The study demonstrated comparable efficacy and quality of life between the two approaches. Notably, EUS-BD was associated with fewer procedure-related adverse events and required significantly fewer unplanned re-interventions compared to PTBD [10].

Many recent meta-analysis further demonstrated that EUS-BD following failed ERCP is associated with higher clinical success, reduced adverse event rates, and fewer reinterventions [11,12]. Giri et al. conducted a meta-analysis of 23 studies including 1,376 patients comparing EUS-guided biliary drainage (EUS-BD) and percutaneous transhepatic biliary drainage (PTBD) after ERCP failure. Technical success rates (96.9% vs. 97.1%; OR = 1.12, 95% CI: 0.67–1.88) and major adverse event rates (1.3% vs. 1.0%; OR = 0.66, 95% CI: 0.31–1.42) were similar between groups. However, EUS-BD showed a significantly higher clinical success rate than PTBD (90.6% vs. 78.4%; OR = 2.55, 95% CI: 1.63–4.56) [13].

The European Society of Gastrointestinal Endoscopy now recommends EUS-guided biliary drainage over percutaneous transhepatic drainage for distal malignant biliary obstruction, contingent on the availability of local expertise. And current data favor EUS-guided choledochoduodenostomy over hepaticogastrostomy, given its lower incidence of adverse events [14]. However, choledochoduodenostomy may not be feasible in cases of surgically altered anatomy or duodenal invasion [15].

First described in 2003 [16], EUS-guided Hepaticogastrostomy (EUS-HGS) appears to be as effective and safe as the conventional PTBD technique, with the added benefit that it can be performed immediately after a failed ERCP, eliminating the discomfort and inconvenience caused by an external catheter. Moreover, EUS-HGS preserves the natural bile flow into the digestive tract, which is important for nutrient absorption and prevents the loss of alkali that occurs with external drainage. Conversely, PTBD frequently necessitates repeated interventions, especially when an external drain is initially placed, which is a significant limitation compared to EUS-HGS [17]. EUS-HGS offers specific advantages over other EUS-guided biliary drainage techniques, particularly in patients with gastric outlet obstruction. Moreover, the hepaticogastric stent is positioned away from the site of tumor involvement, reducing the risk of dysfunction due to tumor ingrowth [18].

EUS-HGS is also a technically complex procedure that requires advanced endoscopic skills and is typically limited to specialized centers. Its use is restricted to patients with dilated intrahepatic bile ducts accessible via the gastric wall, which may not be feasible in all cases due to anatomical variations or obstructions [14]. Compared to other biliary drainage methods, EUS-HGS carries a higher risk of adverse events such as bile leakage, peritonitis, pneumoperitoneum, bleeding, and stent-related complications including migration and occlusion, which may necessitate additional interventions. The procedure also tends to require longer operative times and may be challenging in patients with altered anatomy or gastric outlet obstruction [19,20]. Another drawback of the EUS-HGS technique is its reliance on access through the left liver lobe, which may be inadequate or ineffective in cases of advanced hilar obstruction [21]. Furthermore, despite promising outcomes, the existing clinical data for EUS-HGS are relatively limited, with fewer large randomized controlled trials compared to ERCP or percutaneous transhepatic biliary drainage (PTBD), thus constraining definitive conclusions on its long-term safety and efficacy [22].

Besides EUS-based methods, enteroscopy-assisted ERCP is used for pancreatobiliary diseases in patients with altered anatomy. A multicenter comparative study showed that EUS-BD outperformed enteroscopy-assisted ERCP, with higher technical (98% vs. 65.3%) and clinical (88% vs. 60.4%) success rates, as well as shorter procedure times, highlighting its advantages in this setting [23].

More recently, EUS-guided biliary drainage (EUS-BD) has even been proposed as a potential first-line treatment for malignant biliary obstruction (MBO) [24]. Three randomized controlled trials have shown that EUS-BD achieves comparable technical and clinical success rates to ERCP. Moreover, while the overall incidence of procedure-related adverse events was similar between the two techniques, post-procedural pancreatitis occurred significantly more often with ERCP [25-27]. And a more recent multicenter randomized controlled trial also demonstrated that EUS-guided choledochoduodenostomy (EUS-CDS) is non-inferior to ERCP as an initial treatment approach [28]. These findings have further sparked the debate over which approach should be preferred as the initial drainage strategy in MBO [29].

Our pilot study comparing EUS-guided hepaticogastrostomy (EUS-HGS) and percutaneous transhepatic biliary drainage (PTBD) after failed ERCP in malignant biliary obstruction demonstrates comparable technical success (83.3%) but a higher clinical success rate with EUS-HGS (100% vs. 83.3%). Notably, EUS-HGS showed

significantly fewer delayed complications (16% vs. 70%), likely due to the avoidance of external drains and associated morbidities, resulting in better patient comfort and timely chemotherapy initiation. The survival advantage observed with EUS-HGS, despite potential confounders, suggests added clinical benefit beyond palliation. Although EUS-HGS carries procedural risks, such as stent misdeployment, its overall safety profile favors its use in experienced centers. Limitations include the study's small size, single-center scope, and non-randomized design, necessitating more randomized controlled trials for confirmation. Overall, EUS-HGS emerges as a safe, effective, and potentially superior alternative to PTBD for biliary drainage after ERCP failure in malignant obstruction.

IX. Conclusion

This pilot study provides important insights into the comparative performance of EUS-guided hepaticogastrostomy (EUS-HGS) and percutaneous transhepatic biliary drainage (PTBD) following failed ERCP in malignant biliary obstruction. While both techniques demonstrated equivalent technical success, EUS-HGS achieved higher clinical success and was associated with significantly fewer delayed complications. Patients undergoing EUS-HGS also reported improved quality of life and exhibited superior overall survival, highlighting the clinical advantages of internal over external biliary drainage. Despite these promising findings, EUS-HGS remains a technically demanding procedure that should be reserved for experienced centers. The small sample size and non-randomized design of this study limit the generalizability of the results. Nonetheless, our data support the growing body of evidence that EUS-HGS is a safe, effective, and potentially superior alternative to PTBD in appropriately selected patients. Larger randomized controlled trials are warranted to confirm these findings and to refine the selection criteria for optimal biliary drainage strategies after ERCP failure.

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Conflict Of Interest: The authors declare they have no conflict of interest

Consent To Participate: The study was conducted in accordance with the Declaration of Helsinki and with our local ethics committee. All patients were informed about the surgical procedure, its benefits and its risks. They gave informed consent to be included in this study.

Availability Of Data And Materials: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Authors' Contributions:

Jihane Benass, Hassan Seddik and Fedoua Rouibaa was responsible for study concept and planning. Hassan Seddik and Fedoua Rouibaa supervised the statistical analysis and the redaction of the manuscript. Jihane Benass, Akram Benass and Samir Mrabti were involved in performing the statistical analysis and writing the manuscript, with input from all authors. Jihane Benass, Akram Benass, Samir Mrabti and Reda Berraida were involved in patient enrollment and data collection and were involved in the preparation of the manuscript. All authors reviewed the manuscript.

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