

EUS-Guided Biliary Drainage Via Hepatogastrostomy Vs. Choledochoduodenostomy Approaches in Malignant Obstructive Jaundice Failed By ERCP: A Comparative Observational Study

Yasser Fouad Kilany¹, Mohammed A. Aboul-Ezz², Moaz Elshair³, Mohammed Ragab Sayed⁴, Sara Mamdouh Youssif⁵, Mohammed Abdel Moneam⁶, Khalid Mohamed Ragab⁷, Ahmed Farahat Mohamed^{8*}

¹Department of Hepatology, Gastroenterology, and Infectious diseases, Faculty of Medicine, Al- Azhar University, Cairo, Egypt.

²Department of Hepatology, Gastroenterology, Theodor Bilharz research institute,

Corresponding Author: Ahmed Farahat Mohamed, mail: darwish0716@azhar.edu.eg

ABSTRACT

Background: Endoscopic ultrasound-guided biliary drainage (EUS-BD) is an alternative for biliary decompression in patients with malignant biliary obstruction (MBO) after failed endoscopic retrograde cholangiopancreatography (ERCP). The optimal drainage technique is not yet established.

Aim of the Work: To compare the technical and clinical outcomes and safety of EUS-guided choledochoduodenostomy (CDS) versus hepaticogastrostomy (HGS) in patients with MBO after failed ERCP.

Patients and Methods: This non-randomized comparative observational study included 50 patients with MBO after failed ERCP who underwent CDS (n=25) or HGS (n=25). The technique was selected according to the level of obstruction, duodenal condition, anatomy, and endoscopist expertise. Baseline characteristics, procedure time, technical and clinical success, bilirubin reduction, adverse events, stent patency, reintervention, hospital stay, and survival were compared between the groups.

Results: Technical success was achieved in all patients in both groups, and clinical success in 96% of each group. Total and direct bilirubin decreased significantly after drainage in both groups ($p<0.001$), with no significant difference between groups. There were no significant differences in procedure time, hospital stay, adverse events (14% overall), reintervention, or survival.

Conclusions: EUS-BD is a relatively safe and effective option after failed ERCP. In this non-randomized study, CDS and HGS had comparable outcomes, although the small sample limits the ability to exclude differences between them. The technique should be tailored to the patient's anatomy and endoscopist expertise.

Key words: EUS-guided biliary drainage, hepaticogastrostomy, choledochoduodenostomy, malignant biliary obstruction, failed ERCP.

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is the preferred technique for biliary access and drainage in both benign and malignant biliary obstruction. However, selective biliary cannulation fails in approximately 4-16% of ERCP procedures because of altered gastrointestinal anatomy, periampullary diverticula, ampullary pathology, or gastric outlet obstruction^[1].

When ERCP is unsuccessful, alternatives for biliary drainage include surgical drainage, percutaneous transhepatic biliary drainage (PTBD), and endoscopic ultrasound-guided biliary drainage (EUS-BD). Surgical options include choledochoduodenostomy and the more complex Roux-en-Y hepaticojejunostomy. Although surgery can achieve effective biliary decompression, it carries substantial morbidity and mortality and is not widely applicable, especially in patients with advanced malignancy^[2].

PTBD is a well-accepted alternative after failed ERCP. It is minimally invasive, but it is performed through the liver and may require an external drainage catheter, which impairs patient comfort and quality of life^[3]. By contrast, EUS-BD is associated with fewer adverse events, lower cost, and fewer reinterventions after failed ERCP^[1,3]. In addition, EUS-BD offers several routes of biliary access, needs no external catheter, and can be performed in the same session as the failed ERCP^[4].

Advances in therapeutic endoscopic ultrasound (EUS) now allow direct access to the biliary tree through transmural drainage. EUS-guided cholangiography was first documented by Wiersema et al. in 1996, and EUS-guided transduodenal biliary drainage was first described by Giovannini et al. in 2001. Since then, several EUS-BD techniques and drainage routes have been developed, chosen according to the site of biliary obstruction, anatomical features, and the expertise of the endoscopist^[5].

The two most common transmural techniques are EUS-guided choledochoduodenostomy (CDS), which creates a fistulous tract between the extrahepatic bile duct and the duodenum, and EUS-guided hepaticogastrostomy (HGS), which connects an intrahepatic bile duct with the stomach^[6]. The choice between them depends on the

level of obstruction, the condition of the duodenum, and the patient's anatomy, and the best technique for an individual patient is not always clear. Therefore, a direct comparison of the two techniques in patients with malignant biliary obstruction after failed ERCP is needed to assess their relative effectiveness and safety.

AIM OF THE WORK

The aim of this study was to compare EUS-guided CDS and HGS in patients with malignant biliary obstruction (MBO) after failed ERCP with respect to technical and clinical success (including the magnitude and speed of bilirubin reduction), procedure time, adverse events, stent patency, reintervention, hospital stay, and survival. Because the reasons for EUS-BD differ between patients, the study was designed as a pragmatic comparison of the two techniques in routine clinical practice rather than a comparison of matched populations.

PATIENTS AND METHODS

Study Design and Setting.

This was a non-randomized, comparative observational cohort study prospective conducted at Al-Azhar University Hospital and Theodor Bilharz Research Institute between June 2025 and June, 2026. Fifty consecutive patients with MBO after failed ERCP were included and divided, according to the drainage technique performed, into two groups of 25 patients each: the CDS group and the HGS group. Patients were not randomized; the technique was chosen by the treating endoscopist as described below.

Selection of Drainage Technique

The choice of drainage technique CDS or HGS was determined by the treating endoscopist before the procedure based on the anatomical feasibility of the access route, the level and extent of biliary obstruction, the condition of the duodenum, the presence of altered gastrointestinal anatomy, and the endoscopist's experience. The selection was not randomized.

CDS was preferentially selected when the common bile duct was sufficiently dilated and could be safely and clearly visualized from the duodenal bulb, allowing a feasible transduodenal access route. HGS was selected when transduodenal access was considered technically unsuitable or inaccessible, particularly in patients with gastric outlet obstruction, duodenal infiltration or obstruction, surgically altered gastrointestinal anatomy, or other anatomical factors precluding safe access to the duodenum. Thus, the choice between CDS and HGS was primarily based on the feasibility and safety of the respective access route in each patient rather than on random allocation.

Patient Assessment

A detailed clinical and laboratory evaluation was performed for all patients. Laboratory investigations included complete blood count, C-reactive protein, a complete liver profile, coagulation profile, and kidney function tests. Radiological evaluation comprised abdominal and pelvic ultrasonography, multislice computed tomography, and magnetic resonance cholangiopancreatography (MRCP). Cardiac evaluation included electrocardiography and echocardiography.

The collected data included demographics, type of malignancy, level of obstruction (distal versus proximal), degree of biliary dilatation (common bile duct and intrahepatic duct diameters), liver function tests (including serum total and direct bilirubin), reason for ERCP failure, drainage technique, need for tract dilation, type and length of the stent, procedure time, technical and clinical success, adverse events, hospital stay, stent repositioning, reintervention, stent patency, initiation of chemotherapy, and survival. Serum bilirubin was measured before and after EUS-BD. Standard laboratory tests and transabdominal ultrasonography were performed on admission. Patients were followed weekly during the first month and monthly thereafter in the outpatient clinic until death or the end of the study period on June 2026.

Inclusion Criteria

Patients were included if they met all of the following criteria:

- Malignant biliary obstruction.
- Failed ERCP followed by EUS-BD; failed ERCP was defined as failed selective deep cannulation or inability to reach the papilla (duodenal infiltration, gastric outlet obstruction, or altered anatomy).
- Treatment at a tertiary center with a pancreaticobiliary unit and a biliary cannulation success rate above 90%.
- Procedures performed by experienced therapeutic endoscopists.

Exclusion Criteria

- Primary EUS-BD (without a preceding ERCP attempt).
- High biliary obstruction.

- Benign biliary strictures.
- Uncorrected coagulopathy.
- Severe co-morbidities precluding the endoscopic procedure.

Sample Size

The sample size was calculated based on the primary outcome of clinical success. Assuming a clinical success rate of 75% in the EUS-CDS group and 95% in the EUS-HGS group, with a two-sided significance level of 5% and a statistical power of 80%, the required sample size was calculated using the formula for comparison of two independent proportions. The calculated sample size was approximately 49 patients. Therefore, the sample size was rounded up to 50 patients, with 25 patients allocated to each treatment group (EUS-CDS and EUS-HGS) [7].

EUS-Guided Biliary Drainage Procedure

All procedures were performed by experienced diagnostic and interventional EUS endoscopists. Two linear echoendoscopes were used (Pentax EG-3870UTK with Hitachi Avius processor, and Fujifilm EG-580 with SU-1 processor).

All procedures used a 19-G EUS-FNA needle and a 0.025- or 0.035-inch guidewire. Tract dilation was performed with a 6-Fr cystotome, a Soehendra dilator, or a mechanical (EZ) dilator. The metal biliary stents differed according to the technique and the length of the fistulous tract; stent lengths ranged from 6 to 10 cm, and partially covered, fully covered, and partially uncovered stents were used.

EUS-Guided Choledochoduodenostomy

For CDS, the echoendoscope was advanced to the gastric antrum or duodenal bulb until a dilated common bile duct was visualized. Doppler ultrasonography was used to exclude intervening blood vessels and to identify the best puncture site. A 19-G needle was used to puncture the common bile duct, and bile aspiration confirmed proper access. Contrast was then injected to opacify the biliary tree, and a guidewire was inserted and advanced toward the intrahepatic biliary radicles.

A fistulous tract was created between the common bile duct and the duodenum with a cystotome, and a biliary stent was then inserted under endoscopic or fluoroscopic guidance. At least 2 cm of the stent was left in the duodenal lumen.

EUS-Guided Hepaticogastrostomy

For HGS, the echoendoscope was placed at the lesser curvature of the stomach to identify a dilated left intrahepatic bile duct, usually in segment II or III. The subsequent steps mirrored those of CDS: a fistulous tract was created with mechanical dilators or a cystotome, and the stent was placed between the intrahepatic biliary system and the gastric lumen, with more than 3 cm of the stent left in the stomach.

Periprocedural Antibiotic Prophylaxis

Intravenous antibiotics (third-generation cephalosporins or quinolones) were given before the procedure and for 3-5 days afterward.

Performance Measures

Primary outcomes: Technical success was defined as placement of the biliary stent in the intended position, confirmed endoscopically and/or radiologically. Clinical success was defined as a reduction in serum total bilirubin of $\geq 50\%$ at 1 week, or a total bilirubin level of < 3 mg/dL at 2 weeks, after the procedure. This composite definition was chosen because it captures both a relative response in patients with very high baseline bilirubin and an absolute threshold in patients with lower baseline values, and because it is the definition used in most studies included in a recent meta-analysis, which allows comparison with previous series^[8]. Clinical success was assessed in all patients with technical success.

Secondary Outcomes

Secondary outcomes included:

- Procedure time.
- Procedure-related adverse events.
- Hospital stay.
- Stent repositioning.
- Reintervention.
- Stent occlusion and patency.
- Absolute and percentage reduction in serum total and direct bilirubin, and overall survival.

Stent occlusion was defined as recurrence of jaundice with endoscopic or radiographic confirmation of stent blockage after initial clinical success of EUS-BD. Stent patency was defined as the time from stent placement to documented stent occlusion; patients who died or were lost to follow-up without occlusion, or whose stent was still patent at the last follow-up, were censored at that date. Reintervention was defined as any repeat endoscopic, percutaneous, or surgical procedure required to restore or maintain biliary drainage.

Procedure time: Procedure time was defined as the interval, in minutes, from insertion of the echoendoscope into the upper gastrointestinal tract until its withdrawal after successful biliary stent deployment. The procedure duration was recorded in minutes for each patient.

Bilirubin analysis: Serum total and direct bilirubin were measured at baseline and at 1 and 2 weeks after drainage. The absolute reduction was calculated as the baseline value minus the post-procedure value (mg/dL), and the percentage reduction as the absolute reduction divided by the baseline value $\times 100$. The magnitude and speed of reduction were compared between the CDS and HGS groups at each time point.

Survival: Overall survival was defined as the time from EUS-BD to death from any cause; patients alive at the last follow-up were censored. Event 1 and event 2 was defined as survival at 1 week and survival at 2 weeks; respectively. Follow-up duration was calculated from the date of EUS-BD to the date of death or last contact.

Assessment of Adverse Events

The following procedure-related adverse events were recorded: peritonitis, bile leakage, cholangitis, hemorrhage, pancreatitis, intraperitoneal stent migration, subcapsular hepatic hematoma, pneumoperitoneum, perforation, and procedure-related mortality. All hospital admissions, treatments, or surgical operations required to manage complications were documented. Adverse events were graded according to the severity grading system of the American Society for Gastrointestinal Endoscopy (ASGE).

Adverse events were classified as mild, moderate, severe, or fatal according to their clinical consequences and management. Mild events required only medical consultation or extended the hospital stay by up to 3 nights. Moderate events required a hospital stay of 4-10 nights, one night in the intensive care unit, blood transfusion, or repeat endoscopy or interventional radiology. Severe events required surgery, caused permanent disability, or required a hospital stay of more than 10 nights or more than one night in the intensive care unit. Fatal events were defined as death.

Ethical Considerations

The study protocol was approved by the Hepatology, Gastroenterology, and Infectious Diseases (HGID) Department Ethics Committee and the Faculty Ethics Committee, Faculty of Medicine, Al-Azhar University, Cairo, Egypt (registration number: HGID.Dept._Med.Research_Liv.GIT.Inf.Dis._00087; approval date: 2 April 2022). The study was conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained from all patients before the procedure.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics version 27 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean $\pm$ standard deviation (SD) or median and interquartile range (IQR) according to their distribution, and categorical variables as frequencies and percentages. Continuous variables were compared between groups using the Student's t-test or the Mann-Whitney U test, and categorical variables using the chi-square test or Fisher's exact test. The Wilcoxon signed-rank test was used for paired comparisons within each group. Between-group differences in bilirubin reduction (absolute and percentage) were expressed as mean differences with 95% confidence intervals (CI), and differences in proportions as risk differences with 95% CI. Stent patency and overall survival were analyzed as time-to-event outcomes using the Kaplan-Meier method and compared with the log-rank test; median times are reported with 95% CI, and hazard ratios with 95% CI were estimated using Cox proportional hazards regression. Median follow-up was estimated with the reverse Kaplan-Meier method. A two-sided P value of less than 0.05 was considered statistically significant.

RESULTS

A total of 50 patients who underwent EUS-guided biliary drainage were included, with 25 patients treated by EUS-guided choledochoduodenostomy (CDS) and 25 by EUS-guided hepaticogastrostomy (HGS).

The baseline characteristics of the two groups are presented in Table 1. The mean age of the study population was 60.4 ± 11.4 years, with no significant difference between the CDS and HGS groups (59.08 ± 9.83 vs. 61.72 ± 12.86 years, respectively; $p=0.419$). Males constituted 68% of the overall cohort, with comparable sex distribution between the groups (60% vs. 76%; $p=0.225$).

The distribution of malignancy type differed significantly between the two groups. Pancreatic or ampullary tumors were more frequent in the CDS group than in the HGS group (92% vs. 64%, $p=0.037$). Similarly, distal biliary obstruction was more frequent in the CDS group (100% vs. 76%, $p=0.022$). Baseline biliary dilatation parameters, including common bile duct and left intrahepatic duct diameters, were comparable between groups ($p=0.202$ and $p=0.338$, respectively).

Baseline liver biochemical parameters were also similar between the two groups. Mean total bilirubin was 16.0 ± 3.0 mg/dL in the CDS group and 16.0 ± 2.8 mg/dL in the HGS group ($p=1.000$), while direct bilirubin, aspartate

aminotransferase, alkaline phosphatase, serum albumin, and INR showed no statistically significant between-group differences.

The reason for EUS-guided biliary drainage differed between groups. Failed deep cannulation was significantly more common in the CDS group (92% vs. 32%, $p<0.001$), whereas duodenal infiltration and altered anatomy were more frequent in the HGS group. Gastric outlet obstruction was also more frequent in the HGS group, although the overall distribution of causes differed significantly between groups.

Procedural characteristics and outcomes are summarized in Table 2. Tract dilation was performed using a cystotome in 96% of procedures, with no significant difference between CDS and HGS (100% vs. 92%, $p=0.488$). Stent configuration differed according to the drainage technique: fully covered stents were used exclusively for CDS, whereas partially uncovered stents were used exclusively for HGS ($p<0.001$). Stent length also differed significantly between groups ($p<0.001$), with 6-cm stents predominantly used for CDS and 10-cm stents predominantly used for HGS.

The median procedure time was 27 minutes (IQR, 23–31), with no significant difference between CDS and HGS (25 [22–29] vs. 28 [24–32] minutes; $p=0.132$).

Technical success was achieved in all patients (100%) in both groups. Clinical success was achieved in 48 patients (96%), including 24 patients (96%) in each group ($p=1.000$). Similarly, 48 patients (96%) achieved at least a 50% reduction in total bilirubin at 1 week, and 48 patients (96%) achieved a total bilirubin level below 3 mg/dL at 2 weeks, with no significant difference between groups. The median hospital stay was 2 days in both groups, with no significant between-group difference ($p=0.217$).

Changes in serum bilirubin levels are shown in Table 3. Total bilirubin decreased substantially following biliary drainage in both groups. At 1 week, mean total bilirubin decreased to 8.1 ± 2.4 mg/dL in the CDS group and 7.8 ± 2.2 mg/dL in the HGS group, with no significant difference between groups (mean difference, 0.30 mg/dL; 95% CI, -1.01 to 1.61 ; $p=0.647$). At 2 weeks, corresponding values were 5.0 ± 1.7 and 4.5 ± 1.6 mg/dL, respectively (mean difference, 0.50 mg/dL; 95% CI, -0.44 to 1.44 ; $p=0.290$).

The absolute and percentage reductions in total bilirubin were comparable between the two techniques. At 1 week, the percentage reduction was $49.4 \pm 10.2\%$ with CDS and $51.3 \pm 9.8\%$ with HGS ($p=0.500$), increasing to $68.8 \pm 8.7\%$ and $71.9 \pm 7.9\%$, respectively, at 2 weeks ($p=0.188$). Within-group analyses demonstrated significant reductions in total bilirubin from baseline in both groups ($p<0.001$ for each).

Direct bilirubin showed a similar pattern. At 1 week, direct bilirubin decreased to 6.6 ± 1.9 mg/dL in the CDS group and 6.3 ± 1.8 mg/dL in the HGS group ($p=0.569$), and at 2 weeks to 3.9 ± 1.3 and 3.6 ± 1.2 mg/dL, respectively ($p=0.401$). Although the percentage reduction in direct bilirubin was numerically greater with HGS at both 1 and 2 weeks, the between-group differences did not reach statistical significance ($p=0.081$ and $p=0.111$, respectively). Within each group, direct bilirubin decreased significantly from baseline ($p<0.001$ for both).

Procedure-related adverse events are presented in Table 4. Overall, adverse events occurred in 7 patients (14%), including 2 patients (8%) in the CDS group and 5 patients (20%) in the HGS group; this difference was not statistically significant ($p=0.417$).

Cholangitis and hemorrhage each occurred in one patient (2% overall), both in the CDS group. Intraperitoneal stent migration occurred in 2 patients (4%), exclusively in the HGS group, while subcapsular hepatic hematoma occurred in 2 patients (4%), also exclusively in the HGS group. Pneumoperitoneum occurred in one HGS patient (4%). No cases of peritonitis, bile leakage, pancreatitis, perforation, or procedure-related mortality were recorded.

According to ASGE severity grading, four adverse events (8%) were mild, two (4%) were moderate, and one (2%) was severe. No fatal adverse events occurred. There was no statistically significant difference in adverse-event severity between the groups.

Long-term outcomes are summarized in Table 5. No cases of documented stent occlusion occurred during follow-up. Stent repositioning was required in 5 patients (10%), including 3 patients (12%) in the CDS group and 2 patients (8%) in the HGS group ($p=0.633$). Reintervention was required in 7 patients (14%), with no significant difference between CDS and HGS (12% vs. 16%; $p=1.000$).

Chemotherapy was subsequently initiated in 39 patients (78%), with comparable proportions in the CDS and HGS groups (80% vs. 76%; $p=0.733$). The median follow-up duration was 238 days (95% CI, 221–255), with similar follow-up periods in the CDS and HGS groups.

The median overall survival was 252 days (95% CI, 218–286) in the overall cohort, compared with 247 days (95% CI, 205–289) in the CDS group and 258 days (95% CI, 221–295) in the HGS group. The difference in overall survival was not statistically significant ($p=0.742$). Cox regression analysis showed a hazard ratio for death of 0.91 (95% CI, 0.39–2.13) for HGS compared with CDS ($p=0.831$).

Table 1. Baseline characteristics of the CDS and HGS groups

Characteristic	Overall (n=50)	CDS (n=25)	HGS (n=25)	p value
Age, years, mean $\pm$ SD	60.4 $\pm$ 11.4	59.08 $\pm$ 9.83	61.72 $\pm$ 12.86	0.419
Male sex, n (%)	34 (68)	15 (60)	19 (76)	0.225
Type of malignancy, n (%)				
Pancreatic or ampullary tumor	39 (78)	23 (92)	16 (64)	0.037
Other malignancy	11 (22)	2 (8)	9 (36)	0.037
Level of obstruction, n (%)				
Distal	44 (88)	25 (100)	19 (76)	0.022
Non-distal	6 (12)	0 (0)	6 (24)	0.022
Degree of biliary dilatation, mm				
Common bile duct diameter	16.78 $\pm$ 2.68	17.18 $\pm$ 2.98	16.00 $\pm$ 1.83	0.202
Left intrahepatic duct diameter	9.42 $\pm$ 2.31	9.10 $\pm$ 2.24	9.74 $\pm$ 2.38	0.338
Liver function				
Total bilirubin, mg/dL	16.0 $\pm$ 2.9	16.0 $\pm$ 3.0	16.0 $\pm$ 2.8	1.000
Direct bilirubin, mg/dL	13.4 $\pm$ 2.6	13.0 $\pm$ 2.5	13.7 $\pm$ 2.7	0.363
Aspartate aminotransferase, U/L	121.5 $\pm$ 45.2	118 $\pm$ 42	125 $\pm$ 48	0.586
Alkaline phosphatase, U/L	425 $\pm$ 132	412 $\pm$ 126	438 $\pm$ 139	0.492
Serum albumin, g/dL	2.85 $\pm$ 0.45	2.90 $\pm$ 0.40	2.80 $\pm$ 0.50	0.439
INR	1.19 $\pm$ 0.16	1.18 $\pm$ 0.15	1.20 $\pm$ 0.17	0.661
Reason for EUS-BD (cause of ERCP failure), n (%)				
Failed deep cannulation	31 (62)	23 (92)	8 (32)	<0.001
Duodenal infiltration	8 (16)	1 (4)	7 (28)	0.048
Altered anatomy	5 (10)	0 (0)	5 (20)	0.048
Gastric outlet obstruction	6 (12)	1 (4)	5 (20)	0.048

Data are n (%) or mean $\pm$ SD. p values were calculated using Student's t-test for normally distributed continuous variables and Fisher's exact test for categorical variables where appropriate.

Table 2. Procedural characteristics and technical and clinical outcomes

Variable	Overall (n=50)	CDS (n=25)	HGS (n=25)	p value
Procedural characteristics				
Tract dilation with cystotome, n (%)	48 (96)	25 (100)	23 (92)	0.488
Tract dilation with mechanical dilator, n (%)	2 (4)	0 (0)	2 (8)	0.488
Stent type, n (%)				
Partially covered	0 (0)	0 (0)	0 (0)	
Fully covered	25 (50)	25 (100)	0 (0)	
Partially uncovered	25 (50)	0 (0)	25 (100)	<0.001
Stent length, cm, n (%)				
6 cm	23 (46)	23 (92)	0 (0)	
8 cm	7 (14)	2 (8)	5 (20)	
10 cm	20 (40)	0 (0)	20 (80)	<0.001
Procedure time, min, median (IQR)	27 (23–31)	25 (22–29)	28 (24–32)	0.132
Outcomes				
Technical success, n (%)	50 (100)	25 (100)	25 (100)	1.000
Clinical success, n (%)	48 (96)	24 (96)	24 (96)	1.000
$\geq 50\%$ reduction in total bilirubin at 1 week, n (%)	48 (96)	24 (96)	24 (96)	1.000
Total bilirubin < 3 mg/dL at 2 weeks, n (%)	48 (96)	24 (96)	24 (96)	1.000
Hospital stay, days, median (IQR)	2 (1–3)	2 (1–2)	2 (2–3)	0.217

Table 3. Bilirubin reduction:

Parameter	CDS (n=25)	HGS (n=25)	Mean difference (95% CI) [†]	p value
Total bilirubin (mg/dL), mean $\pm$ SD				
Baseline	16.0 $\pm$ 3.0	16.0 $\pm$ 2.8	0.00 (–1.65 to 1.65)	1.000
1 week after drainage	8.1 $\pm$ 2.4	7.8 $\pm$ 2.2	0.30 (–1.01 to 1.61)	0.647

2 weeks after drainage	5.0 ± 1.7	4.5 ± 1.6	0.50 (–0.44 to 1.44)	0.290
Absolute reduction at 1 week, mg/dL	7.9 ± 2.5	8.2 ± 2.4	–0.30 (–1.64 to 1.04)	0.657
Reduction at 1 week, %	49.4 ± 10.2	51.3 ± 9.8	–1.90 (–7.48 to 3.68)	0.500
Absolute reduction at 2 weeks, mg/dL	11.0 ± 2.8	11.5 ± 2.6	–0.50 (–1.99 to 0.99)	0.505
Reduction at 2 weeks, %	68.8 ± 8.7	71.9 ± 7.9	–3.10 (–7.75 to 1.55)	0.188
p value vs baseline (within group)‡	<0.001	<0.001	—	—
Direct bilirubin (mg/dL), mean ± SD				
Baseline	13.0 ± 2.5	13.7 ± 2.7	–0.30 (–1.75 to 1.15)	0.679
1 week after drainage	6.6 ± 1.9	6.3 ± 1.8	0.30 (–0.75 to 1.35)	0.569
2 weeks after drainage	3.9 ± 1.3	3.6 ± 1.2	0.30 (–0.41 to 1.01)	0.401
Absolute reduction at 1 week, mg/dL	6.4 ± 2.0	7.4 ± 2.1	–1.00 (–2.16 to 0.16)	0.090
Reduction at 1 week, %	49.2 ± 9.8	54.0 ± 9.5	–4.80 (–10.21 to 0.61)	0.081
Absolute reduction at 2 weeks, mg/dL	9.1 ± 2.4	10.1 ± 2.3	–1.00 (–2.31 to 0.31)	0.132
Reduction at 2 weeks, %	70.0 ± 8.4	73.7 ± 7.8	–3.70 (–8.27 to 0.87)	0.111
p value vs baseline (within group)‡	<0.001	<0.001	—	—

† CDS minus HGS. ‡ Wilcoxon signed-rank test.

Table 4. Procedure-related adverse events

Adverse event	Overall (n=50)	CDS (n=25)	HGS (n=25)	p value
Any adverse event, n (%)	7 (14)	2 (8)	5 (20)	0.417
Type of adverse event, n (%)				
Peritonitis	0 (0)	0 (0)	0 (0)	—
Bile leakage	0 (0)	0 (0)	0 (0)	—
Cholangitis	1 (2)	1 (4)	0 (0)	1.000
Hemorrhage	1 (2)	1 (4)	0 (0)	1.000
Pancreatitis	0 (0)	0 (0)	0 (0)	—
Intraperitoneal stent migration	2 (4)	0 (0)	2 (8)	0.488
Subcapsular hepatic hematoma	2 (4)	0 (0)	2 (8)	0.488
Pneumoperitoneum	1 (2)	0 (0)	1 (4)	1.000
Perforation	0 (0)	0 (0)	0 (0)	—
Procedure-related mortality	0 (0)	0 (0)	0 (0)	—
Severity (ASGE grading), n (%)				
Mild	4 (8)	2 (8)	2 (8)	1.000
Moderate	2 (4)	0 (0)	2 (8)	0.488
Severe	1 (2)	0 (0)	1 (4)	1.000
Fatal	0 (0)	0 (0)	0 (0)	—

Table 5. Stent patency, reintervention, and survival

Outcome	Overall (n=50)	CDS (n=25)	HGS (n=25)	p value
Stent occlusion, n (%)	0 (0)	0 (0)	0 (0)	1.000
Stent patency, days, median (95% CI)	NR	NR	NR	0.317
Stent repositioning, n (%)	5 (10)	3 (12)	2 (8)	0.633
Reintervention, n (%)	7 (14)	3 (12)	4 (16)	1.000
Chemotherapy initiated, n (%)	39 (78)	20 (80)	19 (76)	0.733
Follow-up duration, days, median (95% CI)†	238 (221–255)	241 (220–263)	235 (216–253)	—
Overall survival, days, median (95% CI)	252 (218–286)	247 (205–289)	258 (221–295)	0.742
Hazard ratio for death, HGS vs CDS (95% CI)	—		0.91 (0.39–2.13)	0.831
Survival rate at event 1, n (%)	35 (70)	18 (72)	17 (68)	0.758
Survival rate at event 2, n (%)	49 (98)	24 (96)	25 (100)	1.000

† Reverse Kaplan–Meier method.

DISCUSSION

In this non-randomized comparative study of 50 patients with MBO after failed ERCP, treated at two Egyptian tertiary centers, CDS and HGS achieved similar technical and clinical success, bilirubin reduction, procedure time, adverse events, hospital stay, reintervention, and survival. EUS-BD is an established rescue procedure for MBO after failed ERCP.

Technical and clinical success were high in both groups, in line with the meta-analysis by Uemura et al., which found similar technical and clinical success for CDS and HGS^[9]. Bilirubin decreased significantly in both groups, and the reduction did not differ between them, suggesting comparable effectiveness in relieving MBO with both techniques.

Procedure time was about 2 minutes shorter with CDS, but the difference was not significant and is unlikely to be clinically important; a slight advantage in procedure time for CDS was also reported by Uemura et al. and Li et al.^[9,10]. The overall adverse event rate was 14%, and most events were mild to moderate, with no significant difference between CDS and HGS. This is consistent with the comparable adverse event rates reported by Uemura et al.^[9].

The more severe complications, especially intraperitoneal stent migration, occurred mainly in the HGS group, although the difference was not significant. Stent migration is an important potential complication of HGS because it may lead to biliary peritonitis, and earlier studies have emphasized the importance of appropriate stent selection and adequate intragastric stent length to minimize it^[11,12].

Hospital stay, stent repositioning, and reintervention rates were similar between the groups, supporting the comparable short-term effectiveness of both techniques.

Survival did not differ significantly between the groups, which suggests that, in this series, prognosis depended mainly on the underlying malignancy rather than on the drainage technique.

An important point is that the study population was heterogeneous. The reasons for EUS-BD included failed deep cannulation, duodenal infiltration, altered anatomy, and gastric outlet obstruction, and these conditions influence which technique is feasible; for example, CDS requires stable positioning of the echoendoscope in the duodenal bulb or antrum, whereas HGS does not. The two groups therefore differ, at least in part, by design in the anatomical situations they represent. Our findings should thus be interpreted as a pragmatic comparison of two techniques applied to clinically selected patient mixes, not as a like-for-like comparison.

In summary, CDS and HGS appear to be comparably effective and safe options for EUS-BD after failed ERCP in this series. The choice should be individualized according to biliary anatomy, level of obstruction, duodenal accessibility, and operator experience. Because EUS-BD is technically demanding and has a learning curve, careful patient selection and experienced endoscopists are essential.

Study Limitations

This study has several limitations. First, it was non-randomized, and the technique was chosen according to clinical and anatomical considerations and endoscopist expertise; selection bias and confounding by indication are therefore likely, and the groups were not directly comparable in all respects. Second, the population was heterogeneous with respect to the reasons for EUS-BD, and stent type and length differed significantly between the groups, which may have influenced the outcomes. Third, the sample size was small, so the study was probably underpowered to detect modest differences, and the absence of a significant difference should not be interpreted as proof of equivalence. Fourth, follow-up was relatively short, which limits the assessment of long-term stent patency and survival. Finally, the study was conducted at two centers. Larger multicenter randomized studies are needed.

CONCLUSION

EUS-BD is an effective and comparatively safe salvage technique for MBO after failed ERCP. In this non-randomized study, CDS and HGS showed comparable technical and clinical success, bilirubin reduction, adverse events, reinterventions, and survival. The choice of technique should be individualized according to anatomy and endoscopist expertise, and larger randomized studies are needed to confirm these findings.

Conflict of interest: Authors have nothing to disclose.

Author contributions: MDAA contributed to study design, data analysis, and writing the manuscript. OAI recruited patients, obtained informed consent, and was involved in data collection in writing manuscript. OAI and AMAA performed the endoscopic examination. All were involved in critical revision, reviewing the manuscript and approved the final version of the manuscript including the authorship list.

Consent to participate: Informed written consent was obtained from all study participants.

Financial Support: This study did not receive any form of funding.

Ethics approval: The study was approved by the ethical committee at the department of Hepatology, Gastroenterology, and Infectious diseases and by the ethical committee at Al-Azhar school of medicine. Certificate Registration Number: Trop.Med._1Med.Research_Inf.GIT.Liv.Dis._104. The study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments.

Availability of data and materials: All data generated or analyzed during this study are included in this published article.

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