

## Endoscopic Ultrasound–Guided Biliary Drainage Versus Ercp in Inoperable Malignant High–Grade Distal Bile Duct Obstruction: A Randomized Study; Preliminary Analysis

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### Abstract:

**Objective:** To compare the efficacy and safety of Endoscopic ultrasound–guided choledochoduodenostomy (EUS–CDS) and Endoscopic retrograde cholangiopancreatography (ERCP) for biliary drainage of high–grade malignant distal bile duct obstruction (HGMDBO).

**Material and Methods:** Patients with inoperable HGMDBO were randomized to undergo either: EUS–CDS or ERCP. HGMDBO was defined as total bilirubin  $\geq 15$  mg/dl and/or a common bile duct size  $\geq 12$  mm. The other procedure was performed if the utilized surgery failed: success rates, procedure time and complication rates were assessed.

**Results:** Preliminary analysis included 10 patients (5 per group); from August 2018 to January 2019, whose demographic data were similar. Technical success rates were at 60% (3/5) vs. 80% (4/5) for EUS–CDS and ERCP, respectively. Clinical success rates were at 80% (4/5) for both. The mean (S.D.) procedure times were 33.72 (14.5) and 45.22 (26.74) min for EUS–CDS and ERCP, respectively, without any significant difference ( $p$ -value=0.498). Adverse events in the EUS–CDS group included one case of mild biliary peritonitis and one case of post–sphincterotomy bleeding, while the ERCP group included one case of cholangitis with liver abscess and one case of mild bleeding.

**Conclusion:** Preliminary data showed similar technical and clinical success rates. EUS–CDS had a shorter mean procedure time than that of ERCP; however, statistical significance was not reached. Further comprehensive studies are needed to validate the role of EUS–CDS as a primary drainage procedure.

**Keywords:** Canale and Kelly view, osteoporosis, superimposition, talar neck, tarsal bones

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## Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) with stent placement is the standard treatment of choice for malignant distal bile duct obstruction (MDBO) when curative surgery is not an option<sup>1-5</sup>. Selective biliary cannulation is the first essential procedure step for successful ERCP. However, biliary cannulation can fail in some cases due to high-grade biliary obstructions, tumor invasion of the duodenum, ampulla of Vater, ampullary distortion, and surgically altered gastrointestinal anatomy<sup>6</sup>. Endoscopic ultrasound-guided biliary drainage (EGBD) is always reserved as a rescue procedure when ERCP fails<sup>7-8</sup>. Three previous randomized studies have shown comparable technical success and clinical success rates between EGBD and ERCP when performed at high-volume centers by an experienced endoscopist (technical success rates ranged from 90.6–92.8% vs. 90.2–100% in EGBD vs ERCP, clinical success rates ranged from 90–100% vs. 92.8–94.5% in EGBD vs. ERCP, respectively<sup>9-11</sup>). We previously published our center's experience in EUS-guided biliary interventions as of 2012<sup>12</sup>. Our previous technical success rate was 77% (24/31), which has since increased to 89% (16/18) within the last 2 years, which is higher than that documented 3 years earlier at 61.5% (8/13);  $p$ -value=0.072. Clinical success was 96% (23/24), defined as technical success for stent placement and subsequent symptom improvement. Complications were major in four (13%) and minor in seven (23%) patients; which are overall comparable to those of other studies<sup>12</sup>.

High-grade biliary (HGBO) is not well defined in the literature; herein, we defined HGBO as total bilirubin (TB)  $\geq 15$  mg/dL and/or size of the common bile duct (CBD) being  $\geq 12$  mm: according to our center's experience. For this study, high-grade malignant distal bile duct obstruction (HGMDBO) was defined as distal bile duct obstruction-related cancer, with TB  $\geq 15$  mg/dL and/or the size of CBD being  $\geq 12$  mm. Biliary drainage in HGMDBO is challenging

in ERCP, and in such situations EGBD may be less time-consuming than ERCP. However, data regarding the efficacy and safety of EUS-CDS as a primary procedure compared to ERCP in drainage for palliative treatment in HGMDBO are still limited. Hence, we conducted a prospective randomized study to compare the efficacy and safety of EUS-CDS and ERCP for biliary drainage of HGMDBO

## Material and Methods

### Patients

A prospective study was conducted from August 2018 to January 2019 at the NKC Institute, Faculty of Medicine, Prince of Songkla University. All patients were  $>18$  years of age, with an initial diagnosis of MDBO involving greater than 2 cm distal to the hepatic hilum. The initial diagnosis of MDBO was based on clinical features, biochemistry, and cross-sectional imaging, with or without cytological and/or histological confirmation. The patients were enrolled if they met the following inclusion criteria: i) inoperable MDBO due to advanced stage of malignancy based on NCCN guidelines<sup>13</sup>, accompanied with significant co-morbidities, or patients' wishes ii) HGBO defined as total bilirubin  $\geq 15$  mg/dL and/or common bile duct dilation  $\geq 12$  mm. Exclusion criteria included: i) pregnancy, ii) uncorrectable coagulopathy (international normalized ratio  $\geq 1.5$  and/or platelet count  $<50,000$ ), iii) extremely poor general condition rendering ERCP with stent insertion impossible for ethical reasons, iv) co-existence of obstructive duodenal invasion, v) active suppurative cholangitis, vi) surgically altered anatomy, vii) previous treatment with biliary drainage.

### Study protocol

This study was approved by the Faculty of Medicine Ethics Committee. Informed consent was obtained from each patient before study enrollment. Participating patients were randomized to undergo ERCP or EUS-CDS. Preoperative tests included, a complete blood count

(CBC), prothrombin time (PT), liver function test (LFT), renal function test, computed tomography, and magnetic resonance imaging. Randomization codes were generated by a computer, using a random mixing box (combination box set) and concealed in envelopes.

### Intervention

All procedures were performed by a single, experienced endoscopist (NN), who has performed ERCP in over 400 cases/diagnostic and EUS in over 200 cases. All patients underwent the procedure under our institute's conscious sedation protocol of conscious sedation, using intravenous midazolam, pethidine, and/or propofol<sup>14</sup>. Antibiotic prophylaxis was not administered before the procedure.

EUS-CDS was performed using a linear echoendoscope (GF-UCT240, Olympus Ltd., Tokyo, Japan), with a working channel of 3.7 mm. The extrahepatic bile duct was identified from the duodenal bulb under real-time EUS and Doppler guidance. A 19-gauge needle (Echotip; Cook Corp., USA) was inserted into the dilated common bile duct; confirmed by aspiration of the bile and cholangiogram. A 0.025-inch VisiGlide (Olympus Corp., Tokyo, Japan) was advanced further to form loops within the proximal CBD or intrahepatic duct. The biliary-enteric fistula was initially dilated with a 6 French (Fr) Soehendra biliary dilator catheter (SBDC); if this failed, the fistula tract was dilated with a 6 Fr cystotome (Wilson, Cook Medical) and then subsequently dilated with a 7 Fr SBDC. Finally, a 7 Fr diameter, 7-cm double-pigtail stent (Cook Medical) was placed across the biliary-enteric fistula under endoscopic and fluoroscopic guidance. We had to choose Plastic Stents (PSs) owing to economic constraints and lack of funding.

ERCP was performed using a duodenoscope (TJF-160 R, Olympus). Selective bile duct cannulation was performed using a sphincterotome and a 0.035-inch Jagwire

(Boston Scientific Corporation, USA) or 0.025-inch Visiglide. If the standard technique failed, a precut papillotomy was performed using a needle knife; either by freehand or over a pancreatic duct stent. A cholangiography was performed to assess the location and length of the biliary obstruction. A biliary sphincterotomy was performed, and a 10 Fr straight biliary PS was placed across the stricture.

If the assigned biliary drainage technique was unsuccessful, the patient underwent the other endoscopic drainage procedure as a crossover treatment on the same day.

### Follow-up

All patients were admitted for at least 24 hours to monitor any complications after the procedure. Telephone follow-ups were conducted on days 3 and 7 after discharge. A hotline was established to address all concerns. Patients were scheduled for outpatient visits to evaluate clinical symptoms and liver function tests at 2, 4, and 12 weeks. If patients missed their appointments, phone calls were made during the follow-up.

### Outcome measures and definition

The primary outcome was the technical success rate of the assigned procedure, which was defined as successful stent placement at the desired location; as confirmed by fluoroscopy. The secondary outcomes were clinical success rates, total procedure times, complications, procedure-related deaths, and additional interventions during follow-up. The clinical success rate was defined as a total bilirubin decline of >50% of the initial value at 4 weeks postoperatively<sup>15-16</sup>. Procedure time was defined as the interval between duodenoscopic and echoendoscopic intubation until the placement of a biliary stent. The procedure-related complications were classified according to the classification proposed by Cotton et al. in 1991<sup>17</sup>.

### Sample size calculation

From our literature review, the technical success rate of EUS-CDS was 94% for PSs and 98.2% for metallic stents (MSs)<sup>18-19</sup>, while the technical success rate of ERCP with biliary stenting ranged from 69–90%<sup>20</sup>. The primary analysis was a non-inferiority comparison between EUS-CDS and ERCP in terms of technical success rates. Sample size was calculated using the following parameters:  $p\text{-value}=0.95$ , non-inferiority margin=15%, Beta=0.2 and alpha=0.05, which required a sample size of 27 in each group. Allowing for an approximate 10% drop-out rate, the total number of participants required for this study was 60.

### Statistical analysis

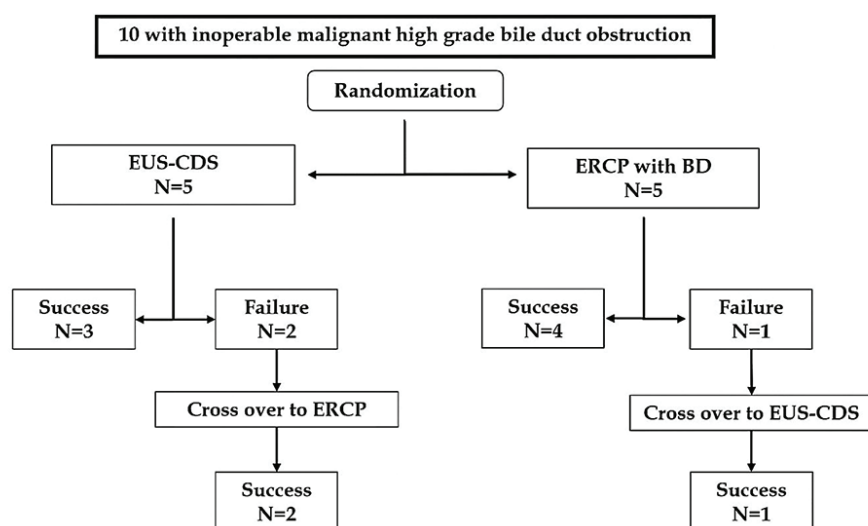
Baseline characteristic data of the patients are expressed as means and standard deviations for continuous variables and as percentages for discrete variables. Comparisons between the two groups were assessed using

the Student's  $t$ -test for parametric data, and the chi-square or Fischer's exact test for nonparametric data. Statistical significance was set at  $p\text{-value}<0.05$ . All statistical analyses were performed using R version 3.5.2 package "Epicalc."

## Results

### Study enrollment

Between August 2018 and January 2019, 10 patients were equally randomized into the EUS-CDS and ERCP groups. The EUS-CDS group comprised five patients (two males and three females), with a median age  $\pm$ S.D. of  $66.2\pm 8.3$  years old; whereas, the ERCP group comprised five patients (three males and two females), with a median age  $\pm$ S.D. of  $56.4\pm 7$  years (Figure 1). Baseline characteristics, tumor type and stage, tumor size, presence of liver metastasis, vascular invasion, total bilirubin level, and CBD size were not significantly different between the two groups (Table 1).



BD=Biliary drainage, EUS-CDS=Endoscopic ultrasound-guided choledochoduodenostomy, ERCP=Endoscopic retrograde cholangiopancreatography

**Figure 1** The consort flow of this preliminary study

**Table 1** Comparison of baseline characteristics for the EUS-CDS and ERCP groups

Factors	EUS-CDS (n=5)	ERCP (n=5)	p-value
Age (years)	66.2 (8.3)	56.4 (7)	0.08
Male: Female, sex, n (%)	3:2 (60)	2:3 (40)	1
ASA (I:II:III)	0:3:2	1:4:0	0.44
Type of cancer, n (%)			1
Pancreatic cancer	5 (100)	4 (80)	
Metastatic cancer	0	1 (20)	
Stage III:IV	1:4	0:5	0.44
Liver metastasis, n (%)	4 (80)	5 (100)	1
Vascular invasion, n (%)	3 (60)	3 (60)	1
Size of tumor (mm)	48±14.1	46.6±18	0.90
Total bilirubin (mg/dl)	20.1±6.9	23±8.8	0.57
Size of CBD (mm)	15.3±4.5	15.3±4.8	0.98

BD=Biliary drainage, EUS-CDS=Endoscopic ultrasound-guided choledochoduodenostomy, ERCP=Endoscopic retrograde cholangiopancreatography, mg/dl=milligram per deciliter, mm=millimeter, n=number

## Outcome

### Primary outcome

The technical success rate of the first procedure, before rescue therapy, was similar between the EUS-CDS and ERCP groups (three out of five patients [60%] vs. four out of five patients [80%], p-value=1.000). Two patients in the EUS-CDS group and one in the ERCP group were crossed over to other procedures for rescue therapy. All three patients underwent successful biliary drainage. The overall technical success rate was, therefore, 4/5 (80%) in the EUS-CDS group and 5/5 (100%) in the ERCP group (p-value=1.000) (Table 2).

### Secondary outcome

The overall clinical success rates were similar between the EUS-CDS and ERCP groups (4/5 [80%] for EUS-CDS vs. 4/5 [80%] for ERCP; p-value=1). The mean ±S.D. procedure time was 34.54±14.3 min for EUS-CDS, which was less than 45.22±26.74 min for ERCP; however, the difference was statistically not significant (p-value=0.498). No significant difference in the rate or severity of complications was observed between the two

groups (2/5 [40%] for EUS-CDS vs. 2/5 [40%] for ERCP; p-value=1.000) (Table 3).

### Complications

EUS-CDS-related complications occurred in two patients. One patient developed mild biliary peritonitis, which could be recovered with conservative treatment. The other had immediate post-sphincterotomy bleeding, which was controlled with an endoscopic adrenaline injection.

ERCP-related complications occurred in two patients. One patient faced immediate post-sphincterotomy bleeding, which was managed using a combination of balloon tamponade and adrenaline injections. The other patient developed cholangitis with a subsequent liver abscess two weeks after ERCP due to biliary stent occlusion that required re-ERCP for stent exchange, resulting in an uneventful recovery upon follow-up.

## Discussion

Our preliminary randomized study showed no statistically significant differences in technical or clinical successes between EUS-CDS and ERCP in HGMDBO.

**Table 2** Comparison of outcomes for the EUS-CDS and ERCP groups

Outcome measures	EUS-CDS (n=5)	ERCP (n=5)	p-value
Technical success, n (%)	3 (60)	4 (80)	1
Clinical success, n (%)	4 (80)	4 (80)	1
Total bilirubin at 2 weeks (mg%)	10±5.5	9.2±5.2	0.82
Total bilirubin at 4 weeks (mg%)	6.4±0.6	4.9±3.5	0.51
Procedure time (min)	33.72±14.5	45.2±26.7	0.61
Hospitalization >48 hours	1 (20)	1 (20)	1
30-days reintervention rate	0	1 (20)	1
30-days mortality	1 (20)	0	1

BD=Biliary drainage, EUS-CDS=Endoscopic ultrasound-guided choledochoduodenostomy, ERCP=Endoscopic retrograde cholangiopancreatography, mg=milligram, min=minute, n=number

**Table 3** Comparison of adverse events for the EUS-CDS and ERCP groups

Outcome measures	EUS-CDS (n=5)	ERCP (n=5)	Cross-over to ERCP (n=2)	Cross-over to EUS-CDS (n=1)	p-value (ITT)
Adverse events, n (%)	2 (40)	2 (40)			1
Bile leakage, n (%)	1 (20)	0	0	0	
Cholangitis, n (%)	0	1 (20)	0	1	
Bleeding(mild), n (%)	1 (20)	1 (20)	1	0	

EUS-CDS=Endoscopic ultrasound-guided choledochoduodenostomy, ERCP=Endoscopic retrograde cholangiopancreatography, EUS=Endoscopic ultrasound, ITT=intention to treat, n=number

These results showed the technical success of EUS-CDS as 60% and ERCP as 80%, whilst the clinical success rate of EUS-CDS was 80% and ERCP as 80%. These are lower than that of the previously published randomized studies, wherein the technical success rate of EUS-CDS ranged from 90.9–100%, ERCP ranged from 90.2–100%, the clinical success rate of EUS-CDS ranged from 91.2–100%, and ERCP ranged from 91.2–94.5%<sup>9–11</sup>. The lower performance outcomes of our study may be due to the very small number of enrolled patients in addition to the low experience of the endoscopist in performing EGBD. A French experience showed that there is a significant correlation between the learning curve and technical success rate of EUS-guided cholangiopancreatography<sup>21</sup>. Oh et al.'s studied the learning

curve for EUS-HGS in a prospective study involving 129 patients having undergone 174 attempts of EUS-HGS after ERCP failed by a single endoscopist experienced in both EUS and ERCP, which demonstrated that the procedure time and adverse events were shorter after 24 cases and stabilized after 33 cases of EUS-HGS, respectively<sup>22</sup>. Our study showed that the mean procedure time was 33.7±14.5 min for EUS-CDS, which was less than 45.2±26.74 min for the ERCP group; however, the difference was statistically not significant (p-value=0.498). Additionally, Paik et al. showed a significantly shorter procedure time in the EGBD group than that in the ERCP group (4.8 min in EGBD vs. 14 min in ERCP, p-value<0.001)<sup>11</sup>, which was one of the advantages of EGBD. Unlike ERCP, EGBD does not need

to pass the tumor in this circumstance, EGBD was predicted to have a shorter procedure time than ERCP in HGMDBO, wherein the tumor infiltrates the ampulla of Vater.

Owing to the small number of enrolled participants, the difference in complication rates between the two groups could not be demonstrated. All complications were classified as mild to moderate in severity, with one mild bile peritonitis and one mild bleeding in EUS-CDS; and one moderate cholangitis and one mild bleeding in ERCP. A meta-analysis (three RCTs and seven retrospective studies; including 756 patients) reported similar adverse event rates for EGBD and ERCP (16.3% [54/331] in EGBD vs. 18.3% [78/425] in ERCP); bile peritonitis was 2.4% in EGBD, and post-ERCP pancreatitis was 7.3% in ERCP<sup>23</sup>. Paik et al. revealed a lower rate of adverse events and intervention as well as a higher rate of stent patency in EGBD than those in ERCP, which was attributed to the use of dedicated stents (DEUS; Standard Sci Tech Inc., Seoul, South Korea) and endoscopist experience<sup>11</sup>.

Regarding the choice of stent, MSs offer several advantages over PSs. These include their self-expanding nature, decreasing the risk of bile leakage, as well as their larger diameter, which offers longer stent patency. However, they are more expensive: costing more than 10 times as much as PSs. Studies on EGBD-related complications with respect to the type of stent (PSs versus MSs) are conflicting. A meta-analysis (42 studies, 14 prospective studies, and 28 retrospective studies, including 1,192 patients) showed lower adverse event rates of EGBD with MSs than those with PSs (17.5% in MS vs. 31.0% in PS,  $p$ -value=0.013)<sup>24</sup>. However, Gupta et al., in a study involving 240 patients having undergone EGBD, found no significant difference in complication rates between the two types of stents. However, patients that underwent EGBD with the placement of MSs showed a trend toward improved outcomes ( $p$ -value=0.09)<sup>25</sup>. In our study, PSs rather than MSs were chosen because of limited funding and the economic status

of the patients. To minimize the risk of bile leaks following EGBD using PSs, non-cautery devices (SBDC) were used as the primary tool for biliary-enteric fistula dilation prior to stent placement. However, non-cautery fistula tract dilation was unsuccessful in all patients undergoing EGBD. Subsequent tract dilation was performed using a cautery device (6-Fr cystotome). Only one of these developed bile peritonitis, which was managed conservatively.

Previously published studies indicated that EGBD is comparable to ERCP in terms of technical success, clinical success rates, and overall adverse events. EGBD may be a safe and feasible first-line palliative treatment for inoperable malignant bile duct obstruction. However, it is important to note that all the published studies were conducted in high-volume centers by experienced endoscopists, and these results may not be reproducible in community practice. Our study results underscore the importance of endoscopists' skills and expertise in maximizing successful outcomes.

A major limitation of our study was the small number of cases, which was unable to provide adequate analytical power.

## Conclusion

These preliminary data show similar technical and clinical success rates for EUS-CDS and ERCP as primary drainage procedures for malignant high-grade distal bile duct obstruction. Although the mean procedure time was shorter for EGBD, the difference was not statistically significant. More comprehensive studies are required to validate the role of EGBD as a primary drainage procedure for HGMDBO.

## Ethics approval

Ethical approval was obtained from the Institutional Review Board and Ethics Committee of Songklanakarind Hospital, Prince of Songkla University (REC. 60-277-21-1)



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## Conflict of interest

The authors declare no conflicts of interest

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