

A Pilot Comparative Study of Endoscopic Ultrasound-guided Biliary Drainage (EUS-BD) with Percutaneous Transhepatic Biliary Drainage (PTBD) in the Treatment of Malignant Biliary Obstruction

Jongboonyanuparp T¹ Attasaranya S¹
Sottisuporn J² Netinatsunton N²
Rookkapan S³ Pakdeejit S³
Hongsakul K³ Sungsiri J³
Sangthong R⁴ Ovarltanporn B²

ABSTRACT

Background: Biliary obstruction is a common complication of malignant diseases involving biliary tract. Endoscopic retrograde cholangiography (ERC) with biliary stenting is accepted as the standard treatment of unresectable malignant biliary obstruction. Percutaneous transhepatic biliary drainage (PTBD) is an alternative option when failed standard endoscopic drainage. Endoscopic ultrasonography (EUS)-guided cholangiography and EUS-guided biliary drainage (EUS-BD) have been reported in case series as another alternative treatment option in malignant biliary obstruction. However, there was no reported comparative study between PTBD and EUS-BD for biliary drainage in this patient population.

Aim: To compare the success and complication rate of EUS-BD and PTBD in unresectable malignant biliary tract obstruction who failed standard endoscopic biliary drainage

Patients and Methods: Ten patients with unresectable malignant biliary obstruction were enrolled from Songklanagarind hospital to this prospective randomized trial. Only those who failed ERC with biliary stenting were randomized to one of two treatment groups, EUS-BD or PTBD. All patients were hospitalized for at least 24 hrs following the procedure. Technical success, treatment success and complication were recorded. Further follow up was scheduled at day 7, day 28 and then every 4 week after the procedure.

Results: Technical success was achieved in 4/5 cases in EUS-BD group and in 5/5 cases in PTBD group. All patients with technical success achieved treatment success in term of relieving obstructive jaundice. One fatal complication with bile leak and intraabdominal sepsis occurred following failed EUS-BD. Two cases of minor complications; bile leak and cholangitis, occurred in EUS-BD and PTBD group respectively. All stents in EUS-BD group were patent until patients died with the longest duration of 184 day.

Conclusions: EUS-BD and PTBD appeared to offer comparable efficacy in treatment of patients with malignant biliary obstruction who failed ERC with biliary stenting. However, EUS-BD is a technically demanding procedure rendering potentially serious complications. Further studies are required to define the "rescue" treatment options in this difficult situation.

Key words : Endoscopic retrograde cholangiography, EUS-BD, percutaneous transhepatic biliary drainage, PTBD, biliary obstruction

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¹Division of Gastroenterology/Hepatology, Department of Medicine, ²NKC Institute of Gastroenterology and Hepatology, ³Intervention Radiology Unit, Department of Radiology, ⁴Department of Epidemiology, Faculty of Medicine, Prince of Songkla University, Songkla, Thailand.

Address for Correspondence: Buncha Ovarltanporn, M.D., Faculty of Medicine, Prince of Songkla University, Songkla, Thailand.

INTRODUCTION

Biliary obstruction is one of common problems encountered, particularly, in dealing with advanced stage of malignancies involving biliary tree. Potential consequences including acute cholangitis, pruritus, anorexia, and secondary liver damage may result in significant deterioration in the patient's quality of life^(1,2).

Endoscopic retrograde cholangiography (ERC) with biliary stenting is widely accepted as the standard treatment of unresectable/inoperable malignant biliary obstruction due to the high success rate (95-100%) with lower complication rate (RR 0.60, 95% CI 0.45-0.81) while providing similar improvement of quality of life as compared with palliative surgery^(1,2).

However, certain limitations of ERC with biliary stenting do exist. These include failure of transversing the scope to approach the major papilla due to significant pyloric/duodenal stenosis from tumor invasion or surgically altered anatomy, and failed biliary cannulation. In these circumstances, percutaneous transhepatic biliary drainage (PTBD) is frequently used as an alternative tool for providing biliary drainage⁽³⁾.

Recently, endoscopic ultrasonography (EUS)-guided cholangiography and EUS-guided biliary drainage (EUS-BD) in malignant biliary obstruction have been reported in a small number of case series. At present, the optimal choice; PTBD versus EUS-BD; for biliary drainage in those who failed standard endoscopic biliary drainage is still unknown. We herein performed a randomized trial to compare EUS-BD with PTBD in patients with malignant biliary obstruction. The primary aim is to compare the efficacy and complications between the two modalities.

METHODS

Study Patients

All patients with >18 years of age who presented with unresectable malignant biliary obstruction at Songklanagarind hospital between October 2009-January 2011 were enrolled. Malignant biliary obstruction was diagnosed based upon clinical and laboratory data in consistent with imaging studies including CTscan, MRI, MRCP, Endoscopic ultrasonography (EUS), or ERCP, with or without histopathology. The unresectable disease was defined as an advanced disease with invasions of neighboring vital organs or with distant metastasis. The patients who were considered high surgical risk or those who denied surgery were also

enrolled. ERC with biliary stenting were performed by one of two authors (SA, BO) as the first line therapy. Only the patients who failed ERC with biliary drainage would be included for randomization per study protocol. Patients with an uncorrectable coagulopathy were excluded. This study was approved by The Institutional Review Board of the Faculty of Medicine, Prince of Songkla University. All patients provided a written informed consent for participation in this study.

Study Design

This was a prospective randomized control trial in a university hospital. Patients were randomly assigned in a 1:1 ratio using block of four randomization technique. The first treatment group was assigned to EUS-BD and the second treatment group was assigned to PTBD. In patients with hilar lesion randomized for EUS-BD, EUS-guide hepaticogastrostomy (EUS-HGS) was performed. Otherwise, the choice of performing EUS-HGS or EUS-guided choledochoduodenostomy (EUS-CDS) was at discretion of the individual endoscopists. The assigned treatment will be performed within 3 days following failed ERC with biliary drainage.

Intervention

EUS-guide biliary drainage

The EUS guided intervention was performed by using the Olympus EUS scope (GF-UCT160OL5) with a 3.7 mm working channel by two authors (SA and BO). All the procedures were accomplished under conscious sedation with midazolam and pethidine supplemented with propofol when necessary. Under EUS, the upstream dilated bile duct segment was identified for biliary access. The bile duct was then accessed using a 19 gauge needle (Echotip[®] Wilson-Cook). After the confirmation of the proper position of the needle in the bile duct by aspiration for bile and contrast injection, a 0.035" guide-wire (Jagwire[®] Boston Scientific) was inserted through the needle until several loops of the wire were coiled in the bile duct, the needle was removed and the tract was then dilated over the guidewire using ERCP catheter followed by dilators with 6 and 7 Fr. diameter respectively. If the tract dilation with dilating catheter was unsuccessful, then a needle knife over the guidewire was used to accessing into the bile duct followed with 6 and 7 Fr. dilators. A 7 Fr. 10 cm double pigtailed plastic stent was inserted. The proper stent position was confirmed fluoroscopi-

cally and by endoscopic visualization of bile flow through the stent.

PTBD

The PTBD was performed under local anesthesia and aseptic technique. Preprocedural sonography was performed to evaluate the connection of the right and left intrahepatic duct (IHD). If the left and right IHD were not connected, the right lateral intercostals approach; aiming for the right intrahepatic duct; was preferred. However, when both IHDs were connected, left upper abdominal approach; aiming for the left intrahepatic duct was preferred due to the ease of technical aspect. An 18G trocar needle was advanced in to the dilated bile duct under real time sonographic guidance. Bile was firstly aspirated and sent for microbiologic study if indicated. Cholangiogram using diluted ionic contrast medium was then performed for the road mapping and to identify the point of obstruction. A 0.035 stiff guide wire was then inserted through the needle into the biliary system followed with serial tract dilations with the 5 upto 8 Fr. plastic dilators over the guide wire. At last, an 8 Fr. pigtail catheter with multiple side holes was advanced over the guide wire into the upstream dilated bile duct, preferably in common bile duct or common hepatic duct. Bleeding and draining were checked. The catheter was sutured at the skin insertion site.

Follow-up

All patients were hospitalized for at least 24 hrs after the procedure for close monitoring of any potential complications. Prior to discharge home, all patients and their accompanied relatives were advised to be aware of symptoms related to infection, bleeding and stent occlusion. Direct phone call access to the investigators was provided in case of any questions or concerns. Liver function test was obtained at baseline (within 72 hrs prior to the procedure), day 7, day 28, and then every 4 wk after the procedure. In the EUS-BD group, stent exchange would be performed only if there was clinical and laboratory or imaging evidence of stent occlusion. In the PTBD group, the patients were scheduled for PTBD exchange every 2 months according to the interventional radiology protocol.

End points

Primary end point

The primary end points were technical success, treatment success, and complication rate. Technical

success was defined as a proper position of drainage tubes/stents above stricture area confirmed by contrast injection or visualized bile flow via drainage tubes/stents. Treatment success was defined as total bilirubin value declined from baseline at least 30% at day 7 or 75% at day 28 post procedure.

Procedure-related complications were defined as the following criteria:

- 1) Bile peritonitis - fever or abdominal pain with billous ascites defined as total bilirubin in ascites >6 mg/dL and higher than in serum.
- 2) Pneumoperitoneum confirmed by imaging study
- 3) Cholangitis⁽⁴⁾ defined as fever >38.5°C following procedure and last longer than 24 hours and/or increasing in white blood count more than 20% from baseline
- 4) Bleeding⁽⁴⁾ defined as the presence of clinical evidence of bleeding with endoscopic confirmation (visualized bleeding from puncture site/per PTBD tube) or intraabdominal bleeding confirmed by imaging study with decreasing of Hb at least 2 g/dL.
- 5) Sepsis - following International Sepsis Definitions Conference 2001⁽¹⁵⁾
- 6) Perforation⁽⁴⁾ including retroperitoneal or bowel perforation confirmed by imaging studies.
- 7) Pancreatitis as defined in the 1991 consensus⁽¹⁷⁾.

Secondary end point

The secondary end point was time interval between biliary drainage to stent occlusion. The stent occlusion was defined as one of the following criteria: the presence of recurrent symptoms and/or signs of cholestasis (worsening pruritus, dark urine, acholic stool, elevation of bilirubin/alkaline phosphatase value ≥ 3 times baseline value), presence of cholangitis, or newly developed radiographic evidence of bile duct dilation (common bile duct >10 mm)

Statistical analysis

The trial was designed as non inferiority to detect a significant absolute difference in rate of technical success, treatment success, and complication between the two procedures. Statistical power of 80% was considered to detect a significant absolute difference in rates of technical and treatment success of 8% between EUS-BD and PTBD group with statistically significant difference of <0.05.

For demographic data; student *t*-test was used for

continuous data while Fisher's exact test was used for categorical data. In comparing for technical success, clinical success, and complication between two groups, data analysis using Chi-squared; bivariate analysis, and multivariate analysis were performed.

RESULTS

Patient characteristics

There were 5 patients in each treatment group. All patients presented with jaundice without cholangitis at the time of intervention. All, but one with hilar cholangiocarcinoma, biliary, obstructions were confined to distal/mid common bile duct. There was no statistical difference between the two groups in term of age, mean baseline bilirubin value and disease onset. Pancreatic head cancer was the most common cause of biliary obstruction (5/10; 50%), while the reasons of failed ERC with biliary stenting was due to failed biliary cannulation in 8 cases (80%) and inac-

cessible major papilla due to duodenal stenosis in 2 cases (10%) (Table 1, 2).

Treatment outcomes

Technical and treatment success

Technical success was achieved in 4 (80%) and 5 (100%) of patients in EUS-BD and PTBD group respectively. In EUS-BD group, EUS-HGS and EUS-CDS were performed in 3 and 2 cases respectively. Technical success was achieved in all cases of EUS-HGS, and in one out of two cases of EUS-CDS. In PTBD group, the biliary drainages were performed via right intrahepatic ducts (IHDs) in all but one patient. Patients who underwent successful biliary drainage in both group achieved treatment success in all (Table 3, 4). The percentage of declined bilirubin value at week 1 and 4 as compared to the baseline value was insignificantly different between two groups (Figure 1).

One case (case No. 3) in EUS-BD group was originally planned for EUS-CDS but unsuccessful due

Table 1. Patient characteristics in EUS-BD group.

Patient no.	Age	Sex	Diagnosis	Main symptoms	Duration (wks)	Reason for fail ERCP	Baseline bilirubin
1	45	Male	PNET	Abdominal pain	40	Duodenal stenosis due to tumor invasion	5.76
2	57	Male	CA pancreas	Abdominal pain, jaundice	4	Failed biliary cannulation	11.63
3	64	Male	CA pancreas	Abdominal pain, jaundice, weight loss	3	Duodenal stenosis due to tumor	24.02
4	39	Male	CA ampulla	Jaundice	12	Failed biliary cannulation	24.4
5	44	Male	CA pancreas	Jaundice	8	Failed biliary cannulation	19.86

Table 2. Patient characteristics in PTBD group.

Patient no.	Age	Sex	Main symptoms	Duration (wks)	Diagnosis	Reason for fail ERCP	Baseline bilirubin
6	79	Female	Jaundice	8	CCA	Failed biliary cannulation	32.37
7	59	Male	Jaundice, anorexia, weight loss	4	HCC	Failed biliary cannulation	19.21
8	51	Male	Jaundice, weight loss	4	Metastasis SCC	Failed biliary cannulation	19.68
9	64	Female	Abdominal pain, jaundice	2	Metastasis adenocarcinoma	Failed biliary cannulation	35.63
10	69	Female	Jaundice	3	CA pancreas	Failed biliary cannulation	23.19

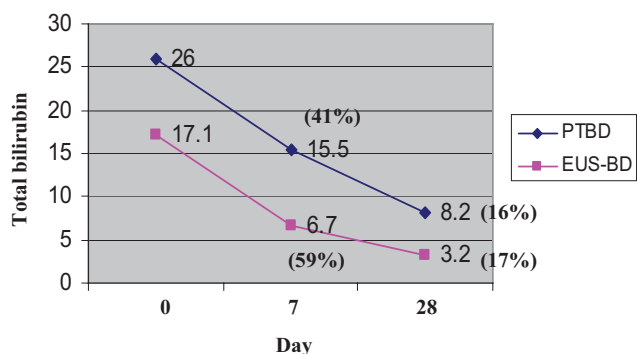
Table 3. Results of EUS-BD.

Case	Procedure	Tract dilatation	Stent	Technical success	Baseline TB	TB at day 7	TB at day 28	Treatment success	Complication(s)	Stent patency at death	Time until death (days)
1	EUS-HGS	Dilating catheter 6,7 Fr	Double pigtail stent 7 Fr 10 cm.	yes	5.76	1.58	N/A	yes	Bile peritonitis, suspected bleeding at puncture site	Patent	33
2	EUS-CDS	Dilating catheter 6 Fr, Balloon dilation 6 mm	Double pigtail stent 7 Fr 10 cm.	yes	11.63	5.29	1.91	yes	None	Patent	184
3	EUS-CDS, EUS)-ChDS*	Balloon dilation, 6 mm	Missed position of stent placement	no	24.02	N/A	N/A	N/A	Bile peritonitis followed with sigmoid perforation and intra-abdominal sepsis	N/A	21
4	EUS-HGS	Dilating catheter 7 Fr	Double pigtail stent 7 Fr 10 cm.	yes	24.4	8.54	3.93	yes	None	Patent	28
5	EUS-CDS	Dilating catheter 7 Fr	Double pigtail stent 7 Fr 10 cm.	yes	19.86	11.45	3.62	yes	None	Patent	37

*EUS-ChDS: EUS-guided cholecystoduodenostomy

Table 4. Results of PTBD.

Case	Access	Technical success	Baseline TB	TB at day 7	TB at day 28	Treatment success	Complication(s)	Time until death (days)
6	Rt IHD	yes	32.37	22.58	6.38	yes	cholangitis	344
7	Rt IHD	yes	19.21	12.37	2.27	yes	None	Still alive (Procedure date 19/2/2010)
8	Lt IHD	yes	19.68	10.99	3.06	yes	None	160
9	Rt IHD	yes	35.63	20.9	21.27 (on day 20)	yes	None	21
10	Rt IHD	yes	23.19	10.74	N/A	yes	None	24



() = percentage of bilirubin value at that time point as compared to the baseline value

Figure 1. Mean bilirubin level.

to inability to identify the dilated common bile duct segments. EUS-HGS was infeasible in the absence of significantly dilated IHDs. Attempting EUS-guide cholecystoduodenostomy (EUS-ChDS) was then pursued. In details, the gallbladder was successfully accessed with a proper needle position confirmed by bile aspiration and contrast injection. The needle tract was further dilated using an ERCP catheter and a 6-mm dilating balloon. However, the proximal end of the stent located in gallbladder was inadvertently dislodged into abdominal cavity after deployment. The stent was then removed. Due to the collapsed gallbladder presumably following bile leak, further attempting EUS-

ChDS was unsuccessful.

Complications

Two cases (40%) developed complications following EUS-BD. One encountered bile peritonitis following stent dislodgement while attempting EUS-ChDS (case No. 3). An urgent PTBD was infeasible due to the insignificantly dilated intrahepatic ducts. Vigorous fluid resuscitation with broad spectrum antibiotics was promptly started. Surgical exploration for cholecystectomy and cutaneous drain placement to convert the intraabdominal billous ascites was then performed. Unfortunately, the hospital course was prolonged and complicated with sigmoid perforation leading to uncontrolled intraabdominal sepsis. The patient was finally expired despite emergency surgical correction for bowel perforation and intensive care.

One minor complication (case No. 1) occurred following EUS-HGS. The patient developed bile peritonitis documented by CT scan and abdominal paracentesis. He was fully recovered with conservative treatment including parenteral antibiotics.

In PTBD group, only one patient (20%) developed acute cholangitis following the procedure, and was successfully treated with antibiotic alone.

Stent patency

All patients, except for one with fatal complication, in EUS-BD group were followed until death due to disease progression. The mean duration of follow up was 61 days (range 21-284 days). There was no clinical evidence of cholangitis or recurrent jaundice detected during follow up period.

All five patients in PTBD were followed with a mean duration of 137 days, range 21-344. Four patients were followed up until death. Causes of death were due to sepsis of uncertain source (2), and disease progression (2). One patient was still alive and was regularly followed up. Patient's PTBD was periodically exchanged for 7 sessions over 344 days of follow up period in one patient (case No. 6, Table 4). During follow up period, two minor complications; cholangitis and accidental displacement of drainage tube; were documented in one patient (case No. 7).

DISCUSSION

Our preliminary study reported the technical success rate of 80% in EUS-BD and 100% in PTBD for

biliary drainage in malignant biliary obstruction who failed ERC with biliary stenting. All technical success by either EUS-BD or PTBD led to treatment success in term of relieving obstructive jaundice. The overall technical success rate of EUS-BD was reported of 50-100%^(3,8,10,12,13,16,18-44) while the success rate for EUS-HGS (91-100%) appeared to be higher than that of EUS-CHS (50-100%) in a literature review by Itoi *et al*⁽²⁸⁾. Our preliminary data showed that technical success was achieved in all 3 patients undergoing EUS-HGS, but only one of two patients who had EUS-CDS attempted. The technical advantage of one approach over the other was currently unclear. The approach option likely depends on multiple factors; such as point of biliary obstruction (hilar vs. mid-distal common duct), approximation of the dilated duct segment and the EUS probe, the stability of EUS scope, and the personal expertise to each approach.

The technical success of PTBD in previous studies was reported of 97-100%⁽⁹⁾, which appeared to be similar to that of EUS-CD. Our small series reported technical success of PTBD in all patients. Only one minor complication; cholangitis was encountered and was fully recovered with antibiotic therapy.

The overall complication rate of EUS guided intervention of 0-36% was reported in the literatures^(3,8,10,12,13,16,18-44). In our preliminary result, one fatal complication due to bile leak following attempting EUS-ChDS is of great concern. To the best of our knowledge, there was no reported case of EUS-guide drainage of malignant biliary obstruction via normal GB. Itoi *et al*⁽²²⁾, reviewed 24 reported cases undergoing EUS-guided gallbladder drainage in acute cholecystitis with 100% success rate and 25% complication rate. Of note, bile leak was the most common complication in this review. Theoretically, EUS-ChDS in non-inflamed GB might pose more risk for bile leak as compared to that performed in inflamed gallbladder due to the lacking of adhesion or GB stiffness to stabilize the GB while puncturing the needle, needle tract dilation and stent insertion. In our particular case, the step of mistakes occurred at stent placement. The stent inadvertently dislodged from the GB after deployment. We hypothesized that the mobile, non-inflamed GB became collapsed following tract dilation resulting in "stepping away" from the inserted stent during deployment. EUS-ChDS, particularly in non-inflamed GB, should therefore be performed with great caution. Further refinement regarding the techniques and development

of accessories for the procedure are required before EUS guided drainage of GB can be accepted as a standard option.

Data concerning stent patency when placed via EUS-BD was scarce. The average stent patency was reported of 211.8 day in a previous study with small patient population ($n = 5$)⁽¹⁶⁾. The longest stent patency of 184 days following EUS-BD was shown in our series. However, the true overall stent patency of EUS-BD could not be estimated in our series given the rather short disease survival and small number of patients. The advantage, if any, of transmural biliary stent placement per EUS-BD over the transpapilla stent placement per ERC in term of stent patency is currently unknown. Theoretically, creating a permanent transmural tract with stent in place might facilitate “para-stent” bile flow independent on stent patency per se. This may be particularly encouraging if more than 1 plastic stents are placed to create a larger tract.

Due to the small numbers of patients in our preliminary series, any significant difference of outcomes between the two treatment groups could not be concluded. PTBD appeared to be less technically challenging in these somewhat fragile patients. However, PTBD also have some limitations and risks. Firstly, it is an external drainage system that causes patients’ discomfort and inconvenience of care resulting in impaired quality of life. Secondly, it is non-physiologic and the externally drained bile, fluid, and electrolyte via PTBD may result in maldigestion and metabolic disturbance. Thirdly, technical difficulty could be encountered in some circumstances such as in the presence of massive ascites or minimally dilated intrahepatic bile ducts⁽⁷⁾. Fourthly, some potential complications including cholangitis, bile peritonitis, hemo-peritoneum, intraperitoneum abscess, liver abscess do exist^(5,6) with a substantial complication rate of 6-31%⁽⁹⁾. Further well designed studies involving a larger number of patients are required to define the treatment options in this scenario. At present, choice of biliary drainage in malignant biliary obstruction who failed ERC with biliary stenting should be individualized, basing upon patients’ profile and local expertise.

In conclusion, our preliminary report showed that EUS-BD was technically feasible but posed potentially serious complication. EUS-BD should therefore be performed in expert centers and as a multidisciplinary approach. Further refining in technique and accessories as well as gaining more expertise are necessary to

improve outcome. The optimal option for biliary drainage in patients with malignant biliary obstruction who failed standard endoscopic drainage is still unclear. Further studies are required to elucidate this issue.

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