ORIGINAL ARTICLE

Study of Outcome and Success Rate in Percutaneous Transhepatic Biliary Stent for Malignant Biliary Obstruction in Srinagarind Hospital, Khon Kaen University

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Background: Malignant biliary obstruction (MBO) is likely to be inoperable at first presentation. Palliative biliary drainage is essential to increase overall survival. Percutaneous transhepatic biliary stent (PTBS) is one of the most effective and safe procedure of biliary drainage in malignant biliary obstruction. However, there are no previous studies of outcome, success rate, and complications of PTBS insertion for biliary drainage of MBO in Thai population.

Objective: To determine outcome, success rate, and complications of PTBS insertion in MBO in tertiary care medical center in Thailand.

Materials and Methods: A retrospective cohort study was performed on 41 patients with MBO underwent PTBS insertion from 2015 to 2021. Technical data, success rate, and outcome data including survival analysis, occlusion rate, and complications were analyzed.

Results: Of 41 patients, PTBS insertion had technical success 82.93% and functional success 70.59%. Median survival time of patients was 95 days (95% CI 89.5 to 193). Occlusion rate occurred in only 22.6% of patients and all of them underwent percutaneous transhepatic biliary drainage (PTBD) as alternative palliative biliary drainage. Mean occlusion-free survival time was 77.14 days (95% CI 38.9 to115). Majority of patients (79.4%) did not have PTBS-related complications. The most common complication was acute cholangitis that found only in 6 patients (17.6%). Median complication-free survival was 91 days (95% CI 86.8 to 247). For the group of patients with functional success after PTBS insertion, the 30-day, 120-day, and 390-day cumulative survival rates and 30-day, 120-day, and 390-day cumulative occlusion-free survival rates were statistically significantly better than those with functional failure (p=0.030 and p=0.007).

Conclusion: Outcomes and success rate of PTBS insertion in Srinagarind Hospital were 82.93% in technical success and 70.59% in functional success. Functional success of PTBS insertion was the most important issue that related with better cumulative survival and occlusion-free survival.

Keywords: Percutaneous transhepatic biliary stent (PTBS); Malignant biliary obstruction (MBO)

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Malignant biliary obstruction (MBO) is often caused by periampullary cancer e.g. pancreatic head cancer and extrahepatic cholangiocarcinoma[1]. MBO is an essential condition because the disease is likely to be inoperable at the first presentation[2]. Nowadays, palliative management is an adequate biliary drainage for acute cholangitis prevention, improved quality of life, and prolonged survival. High level of serum bilirubin is a poor prognostic factor for survival[3]. Inadequate biliary drainage is associated with jaundice, cholangitis, sepsis, and subsequently death.

Adequate biliary drainage is essential to increase overall survival (OS) in patient with inoperable MBO[4]. Percutaneous transhepatic biliary stent (PTBS) is one of the most effective and safe procedure to ensure adequate biliary drainage in the patients with inoperable MBO[5-7]. PTBS is also cost-effectiveness procedure[8]. Occlusion of biliary stent can occur after PTBS placement. Various

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complications including acute pancreatitis[9], acute cholangitis, and abdominal wall abscess[10] are also found. When compare with another biliary drainage procedure such as endoscopic biliary stent, there is no significant difference in terms of success rate and survival[11].

Nowadays, PTBS is performed in some tertiary care center in Thailand. However, there are no previous studies to evaluate in outcome, success rate, and complications of PTBS in MBO in Thai population. Owing to high incidence rate of cholangiocarcinoma, which is one of most common causes of MBO in the northeastern region of Thailand[12], our research is intended to determine outcome and success rate of PTBS in MBO in tertiary care medical center.

Objective

We aimed to investigate outcome, success rate, and determine complications of PTBS insertion in patients with MBO.

Materials and Methods

We retrospectively searched the database of patients in Srinagarind Hospital, Khon Kaen University around 6 years between 1st January 2015 and 25th March 2021. During this period, PTBS drainage in MBO were performed in 41 patients. Inclusion criteria were patients with MBO underwent PTBS insertion with adequate radiological images data for evaluation of success rate of PTBS and medical records could be achieved from document and electronic system. Exclusion criteria were the patients who had inadequate radiological images and/or inadequate medical records. Finally, we included 41 patients in this study.

The study protocal was approved by Center for Ethics in Human Research, Khon Kaen University and did not require informed consent from patients.

PTBS procedure

Patient with MBO had initial external biliary drainage via PTBD as the first step for PTBS. For PTBD placement, ultrasonography was performed to evaluate dilatation of intrahepatic duct. Percutaneous transhepatic puncture into the more dilated IHD was done. Catheter of PTBD was placed in the dilated IHD and external drainage was obtained. Cholangiogram was done during procedure to evaluate possibility to perform PTBS, as internal biliary drainage procedure (Figure 1). If patient was eligible to insert PTBS, patient would plan to perform subsequently.

On the day of PTBS, patient received prophylactic antibiotic. Fluoroscopy was used to check position of initial PTBD placement. Cholangiogram was performed to choose the location and length of the biliary stent. Then, PTBS was performed using guidewire into the previous PTBD tract.

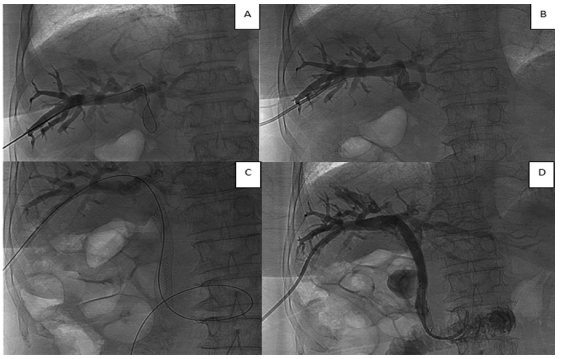

Figure 1. Cholangiogram during PTBD and PTBS insertion A and B) PTBD procedure by ultrasound-guidance punctured into dilated IHD and guidewire inserted to place drainage tube as initial step of PTBS. C and D) After initial PTBD, guidewire was used to place the metallic stent. After PTBS insertion, cholangiogram showed contrast could pass through duodenum.

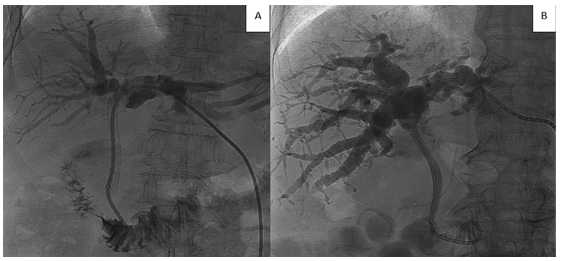

Figure 2. Cholangiogram during PTBS insertion A) Suprapapillary PTBS insertion. B) Transpapillary PTBS insertion. Both were patent by evidence of contrast pass through duodenum with external biliary drainage.

The stent was inserted either suprapapillary or transpapillary method depend on position of MBO (Figure 2). Uncovered, Niti S stent, TaeWoog Medical, Kimpo, Korea was used in length of 10 mm x 80 mm or 10 mm x 100 mm. In addition, a 8.5-Fr external drainage catheter was placed in all patients to divert from external biliary draiage. In case of inadequate internal drainage via stent, balloon cholangioplasty was performed (Figure 3).

After PTBS and/or balloon cholangioplasty, all patients were scheduled to perform cholangiogram to evaluate patency of stent. If the stent was patent, external drainage was removed (Figure 4).

PTBS procedural data and complications were obtained from the electronic medical record.

Outcome

Primary outcome was success rate of PTBS insertion which was evaluated in two aspects of technical success and functional success. Technical success was defined as stent placement in an appropriate position and in good contrast medium passage through the stent. Functional success was defined as decreased in serum total bilirubin more than 75% of pre-PTBS value in timespan of 1 month or serum

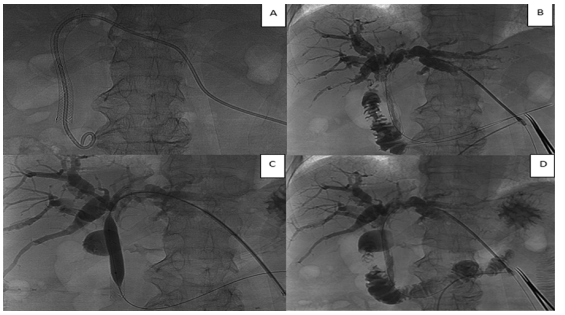

Figure 3. Balloon cholangioplasty A) PTBS with external drainage. B) Pre-procederal cholangiogram showed minimal contrast could pass through duodenum. C) Balloon cholangioplasty was used to dilate the stent. D) Post-procedural cholangiogram showed contrast passage into duodenum.

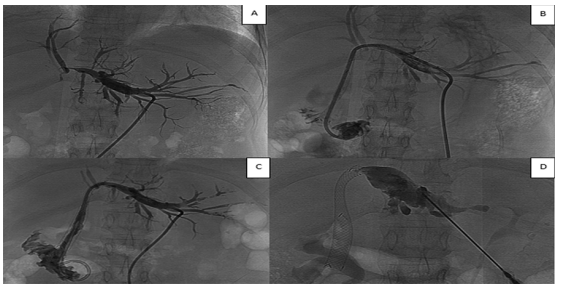

Figure 4. Cholangiogram during PTBS and follow-up post PTBS insertion A and B) PTBS insertion with patent of stent and placement of external drainage C) Follow-up cholangiogram showed patent of the stent. The external drainage was removed. D) At day159 after PTBS insertion, cholangiogram revealed contrast could not pass through duodenum due to stent obstruction..

bilirubin remain below 3 mg/dl after removal of external biliary drainage catheter for 1 month.

Secondary outcomes were complication, occlusion, and survival after PTBS. Death date of patient or last follow up date were obtained to analyze survival after PTBS. Occlusion rate was defined as occlusion whether on imaging method such as cholangiogram, CT, MRI, or ultrasound. Time interval between occlusion date and PTBS insertion date were acquired to analyze occlusion-free survival. Complications were reviewed from electronic medical records and radiological records. Complications of PTBS insertion might be found such as acute cholecystitis, acute cholangitis, acute pancreatitis, and liver abscess. Time interval between complication date and PTBS insertion date were acquired to analyze complication-free survival.

Study data were collected and managed using Research Electronic Data Capture (REDCap) which hosted by Khon Kaen University.

Statistical analysis

All data were analyzed using SPSS statistics version 19.0.2. For all statistical purposes, $p<0.05$ was considered statistically significant. A descriptive statistic was used to describe patient demographic data. Categorical data were presented as number and percentages. Continuous data were presented as mean, standard deviation, median, and range. Correlation test was used from either Pearson or Spearman correlation, as appropriate. Overall survival, occlusion-free survival rates, and complication-free survival rates were analyzed using Kaplan-Meier curve and Cox regression model with subgroup analysis by length of stent, route of stent placement, position of stent, or cholangioplasty.

Ethical consideration

The present study was approved by the Ethics Committee for Human Research, Khon Kaen University. The research number is HE661576. The patients were concealed the identities and sorted out by number.

Results

Demographic data

There were 41 patients underwent PTBS between 1st January 2015 and 25th March 2021. There were 20 (48.8%) men and 21 (51.2%) women with a mean age of 64±9 years (range, 55 to 73 years). Majority of them had no underlying disease (26 patients, 63.4%). There were 5 patients (12.2%) with underlying diabetes mellitus. Six patients (14.6%) had hypertension. Three patients (7.3%) had dyslipidemia. The most frequent tumor that caused MBO was cholangiocarcinoma, 33 patients (80.5%) (Table 1). Hilar cholangiocarcinoma was the most common encounter (32 patients, 97.0%). There were 3 patients (7.3%) each with either pancreatic cancer or ampullary cancer.

Table 1. Demographic data of study population

Characteristics	Patients (n=41)
Age (year), mean (SD)	64.02 (9.21)
Sex	
Male (%)	20 (48.78)
Female (%)	21 (51.22)
Underlying disease	
None (%)	26 (63.41)
Diabetes mellitus (%)	5 (12.20)
Hypertension (%)	6 (14.63)
Dyslipidemia (%)	3 (7.32)
Cause of MBO	
Cholangiocarcinoma (%)	33 (80.49)
Hilar (%)	32 (96.97)
Distal (%)	1 (3.03)
Pancreatic cancer (%)	3 (7.32)
Ampullary cancer (%)	3 (7.32)
Gallbladder cancer (%)	2 (4.88)

Outcome of PTBS insertion

The technical success rate of PTBS was achieved in 82.9% (Table 2). The stents were applied equally between 10 mmx8 cm and 10mmx10cm (47.0% in each) (Table 3). 10mmx6cm stent was used in one patient and double stents technique using two 10mmx8cm stents were used in another patient. About two-thirds of patients were underwent PTBS insertion via left PTBD (68.3%) and the rest via right PTBD (31.7%). Transpapillary technique was used in majority of patient (82.4%), while the rest underwent suprapapillary method (17.6%). 26 patients (76.5%) needed balloon cholangioplasty during PTBS placement. 6 patients had balloon cholangioplasty after PTBS placement with median time to cholangioplasty = 6 days (95% CI -2.1 to 44.1).

Functional success rate of PTBS insertion was 70.6% (Table 2). Median survival time of patients was 95 days (IQR 50 to 147 days). PTBS occlusion occurred in only 22.6%, all of them underwent PTBD as alternative palliative biliary drainage. Mean occlusion-free survival time of patient was 77.14 days (SD 51.68 days). Majority of patients (79.4%) did not have PTBS-related complications. The most common complication was acute cholangitis that found in 6 patients (17.6%) with median time to acute cholangitis = 56 days (95% CI 14.8 to 158) (Table 4). Two patients (5.8%) developed acute cholecystitis at 83 and 154 days after PTBS placement. Only one patient had combined liver abscess and abdominal wall abscess. Median complication-free survival was 91 days (IQR 60 to 155 days) (Table 5).

There was no significant correlation between technically successful outcome of PTBS insertion and route of placement via PTBD (right and left) (p>0.999). Functionally successful outcome of PTBS insertion did not relate with route of placement via PTBD (p=0.692), position (suprapapillary and transpapillary) (p=0.328), length of stent (p=0.253), or balloon cholangioplasty (both during procedure and post procedure) (p=0.666 and p=0.664, respectively).

The 30-day, 120-day, and 390-day cumulative survival rates in all patients were 95.1%, 52.7%, and 15.6%, respectively. In group of patients with functional success after PTBS insertion, the 30-day, 120-day, and 390-day cumulative survival rates were statistically significantly better than those with functional failure, 95.8%, 68.9%, and 24.2%, respectively, compared to 90.0%, 25.0%, and 0.0%, respectively (p=0.030) (Figure 5). For group of patients with transpapillary position of PTBS, the 30-day, 120-day, and 390-day cumulative survival rates were statistically significantly better than those with suprapapillary position, 96.4%, 61.2%, and 27.1%, respectively, compared to 83.3%, 33.3%, and 0.0%, respectively (p=0.045) (Figure 6).

The 30-day, 120-day, and 390-day cumulative occlusion-free survival rates in all patients were 87.1%, 52.9%, and 20.1%, respectively. For group of patients with functional success after PTBS insertion, the 30-day, 120-day, and 390-day cumulative occlusion-free survival rates were statistically significantly better than those with functional failure, 95.4%, 65.8%, and 28.2%, respectively, compared to 66.7%, 22.2%, and 0.0%, respectively (p=0.007) (Figure 7). The 30-day, 120-day, and 390-day cumulative complication-free survival rates in all patients were 91.2%, 51.0%, and 19.7%, respectively.

Many factors of PTBS procedure might related outcomes such as technical success, functional success, placement of PTBS via right or left IHD, position of PTBS, length of stent, cholangioplasty during PTBS procedure,

Table 2. Outcome of PTBS insertion

Outcome	n (%)
Technical success	34 (82.93)
Functional success	24 (70.59)

Table 3. PTBS procedure and techniques

PTBS data	n (%)
Placement of PTBS	
Right PTBD	13 (31.71)
Left PTBD	28 (68.29)
Length of stent	
10 mm x 8 cm	16 (47.06)
10 mm x 10 cm	16 (47.06)
Other+	2 (5.88)
PTBS position	
Transpapillary method	28 (82.35)
Suprapapillary method	6 (17.65)
Concurrent balloon cholangioplasty	26 (76.47)
Post procedural balloon cholangioplasty	6 (17.65)
Time to cholangioplasty (day), median (IQR)	6 (5 to 28)

+ One 10 mm x 6 cm and double 10 mm x 8 cm stent

Table 4. PTBS-related complications

Complications	n (%)	Time to complication (day), median (IQR)
None	27 (79.41)	-
Acute cholecystitis	2 (5.8)	118.5 (83 to 154)
Acute cholangitis	6 (17.6)	56 (45 to 82)
Abscess*	1 (2.9)	203

* Combine liver and abdominal wall abscess

Table 5. Time survival data after PTBS insertion

Survival data	Days
Overall survival; median (95% CI)	95 (89.5 to 103)
Occlusion-free survival; mean (95% CI)	77.14 (38.9 to 115)
Complication-free survival; median (95% CI)	91 (86.8 to 247)

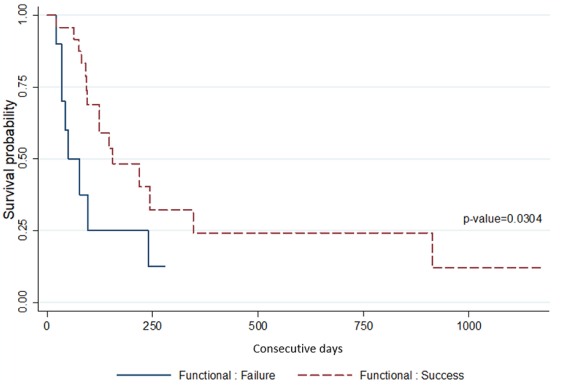

Figure 5. Comparison of cumulative overall survival rates after PTBS insertion between functional success and functional failure group. The 30-day, 120-day, and 390-day cumulative survival rates were 95.8%, 68.9%, and 24.2%, respectively, compared to 90.0%, 25.0%, and 0.0%, respectively (p=0.030).

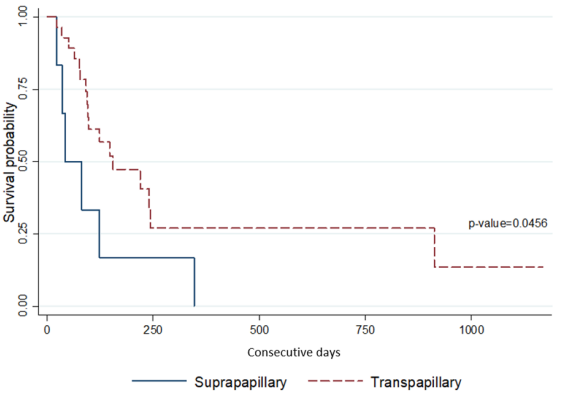

Figure 6. Comparison of cumulative overall survival rates after PTBS insertion between transpapillary and suprapapillary group. The 30-day, 120-day, and 390-day cumulative survival rates were, 96.4%, 61.2%, and 27.1%, respectively, compared to 83.3%, 33.3%, and 0.0%, respectively (p=0.045).

and cholangioplasty after PTBS procedure. Based on multivariate analysis to identify the prognostic factors, functional success was statistically significant independent prognostic factor associated with survival, occlusion-free survival, and complication-free survival (Adjusted HR=0.33; 95% CI 0.13 to 0.84; p=0.020, adjusted HR=0.26; 95% CI 0.10 to 0.68; p=0.006, and adjusted HR=0.38; 95% CI 0.15 to 0.96; p=0.040, respectively). Moreover, position of PTBS was also found to be statistically significant prognostic factor associated with overall survival (adjusted HR=0.33; 95% CI 0.12 to 0.89; p=0.028).

Discussion

The most common cause of MBO patients underwent PTBS insertion in Srinagarind Hospital was cholangiocarcinoma (80.49%), mostly hilar type, which is

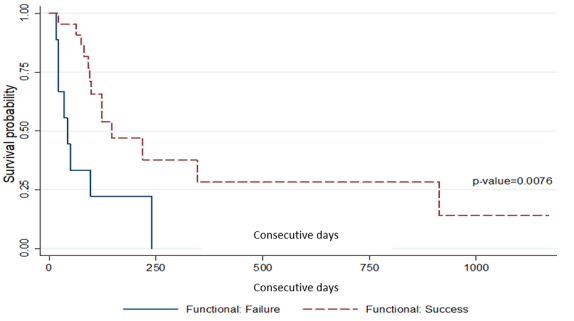

Figure 7. Comparison of cumulative occlusion-free survival rates after PTBS insertion between functional success and functional failure group. The 30-day, 120-day, and 390-day cumulative survival rates were 95.4%, 65.8%, and 28.2%, respectively, compared to 66.7%, 22.2%, and 0.0%, respectively (p=0.007).

higher proportion than most of the similar study (18.2 to 63.8%) due to higher incidence rate of cholangiocarcinoma in the northeastern region of Thailand.

In this study, the success rate of PTBS insertion in Srinagarind Hospital were 82.93% in technical success and 70.59% functional success similar to the study of Dambrauskas et al. (technical success 83% and functional success 80%)[6] and Li et al. (functional success 71.6%)[13], which was acceptable owing to relatively new procedure at Srinagarind Hospital which required learning curve and small population. Moreover, there was slightly low number compared to other studies which were performed in more advanced medical setting (technical success 99.4 to 100.0% and functional success 89.1 to 90.3%)[5,7].

Occlusion occured in 22.6% of patients, which was in the same range of previous studies (18.0 to 26.9%)[6,7]. However, our occlusion rate was lower than some studies, which showed occlusion rate as high as 48.2%[5].

Overall complication rate in our study was 20.6%, which was slightly high rate, but it was still the same range compared to prior studies (13 to 26.4%)[5,6,13]. Acute cholangitis was the most common complication, as same as previous study[6,13]. However, serious complications, which were reported by Shim et al.[5], included haemobilia due to arterial injury and required further transarterial embolization, severe cholecystitis which required cholecystectomy and biloma which required percutaneous drainage, were not found in our study. Indicating PTBS insertion was reliable and safe procedure.

Median survival time was 95 days, which was lower compared to similar studies which median survival time were 126 to 212 days[5,7,13]. Our median survival time was quite low which could be from higher proportion of cholangiocarcinoma in our study. Mean occlusion-free survival time and median complication-free survival were 77.1 and 94 days, respectively, which were still lower than

similar studies (130 to 192 days) too[5,7].

Functional success was statistically significant independent prognostic factor associated with overall survival, occlusion-free survival, and complication-free survival. Patients with functional success after PTBS insertion were significantly better than those with functional failure consistent with prior studies[13], which confirmed that PTBS insertion was an effective palliation procedure of biliary drainage in patient with inoperable MBO[4].

Our study found that cumulative survival probability was significantly different in patient with transpapillary and suprapapillary stent position (transpapillary was better than suprapapillary method) and furthermore multivariate analysis found that position of PTBS stent was statistically significant prognostic factor associated with survival, like the study of Li et al.[13]. However, there was no significant difference in study of Jo et al.[14]. Jo et al. study suggested that suprapapillary stent had significantly lower rate of pancreatitis. On the other hand, no pancreatitis was found in both suprapapillary and transpapillary groups in our study.

No significant difference in cumulative survival, cumulative occlusion-free survival, and cumulative occlusion-free survival probability between both groups by placement of PTBS via right or left PTBD, by balloon cholangioplasty (either during or post procedure), or length of stent, were found in the our study.

This study was able to show that functional success of PTBS insertion in inoperable MBO patients was effective and safe to provide better overall survival, similarly to previous studies[4-7,13].

A strength of this study was the first study in Thailand to report outcome, success rate, and complications in PTBS insertion. There was the highest prevalence of cholangiocarcinoma in the northeastern region of Thailand[12]. This disease had significant cause of MBO and the result of our study could be useful for palliation in these patients.

The limitation of this study was a retrospective cohort study occurring over a period of six years. Therefore, it was possible that learning curve of interventionist might provide some better outcome. The small number of population might affect to some significant results such as the correlation between underlying survival probability and transpapillary/suprapapillary position of stent.

Conclusion

Outcomes and success rate of PTBS insertion in Srinagarind Hospital were 82.93% in technical success and 70.59% in functional success. Functional success of PTBS insertion was the most important issue that related with better cumulative survival and occlusion-free survival.

What is already known on this topic?

PTBS insertion in inoperable MBO patients was effective and safe to provide better overall survival, similarly to previous studies

What this study adds?

First of all, it was the first study to report outcome, success rate, and complications in PTBS insertion in Thailand. Success rate was similar to previous international studies. Second, functional success of PTBS insertion was the most important issue that related with better cumulative survival and occlusion-free survival. Lastly, there was the highest prevalence of cholangiocarcinoma in the northeastern region of Thailand. This disease had significant cause of MBO and the result of our study could be useful for palliation in these patients.

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Conflicts of interest

The authors declare no conflict of interest.

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