

Efficacy and Safety of Percutaneous Transhepatic Biliary Drainage in Malignant Biliary Obstruction – A Single Tertiary Centre Experience

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ABSTRACT

Background and Aim of the study:

Percutaneous Transhepatic Biliary Drainage (PTBD) is performed as a preoperative procedure for resectable malignancies, prior to neo adjuvant chemotherapy or as a palliative technique. This prospective study was done to evaluate technical success, clinical success, stent/catheter patency rate, survival rate and complications of PTBD in patients with malignant obstructive jaundice.

Materials and method: All patients from June 2018 to November 2019, with malignant obstructive jaundice who have undergone PTBD were included in this study.

Results: One Hundred and One patients were planned for PTBD, technical success was achieved in 93 (92.07%) patients. 97 (96%) patients underwent PTBD for palliation and 4 (4%) for preoperative drainage. Unilateral approach was used in majority of our patients (97.8%). 3 patients (2.9%) underwent internalization with 7 Fr plastic stent. 55 patients were female (54.45%). Mean age was 55.35± 22 years. Cause for malignant biliary obstruction was carcinoma gall bladder (77.7%), cholangio carcinoma (9.9%), carcinoma head of pancreas (6.9%), periampullary (3.9%), and metastatic lymphadenopathy at porta (3.2%). Type of block was hilar in 90 patients (89.1%) and lower end block in 11 patients (10.89%). Endoscopic Retrograde Cholangiopancreatography (ERCP) failure was in 25 patients (24.75%). Clinical success was achieved in 88

patients (94.6%). The difference in the pre and post intervention bilirubin levels at 1 month as estimated with wilcoxon signed rank test is found to be statistically significant. Successful biliary drainage had a positive impact on Quality of Life (QOL). Stent/catheter patency period in our study was 51± 46 days (range 14 -120 days). Survival in our patients was 74± 90 days (Range 15- 270 days).Kaplan-Meier log rank survival analysis showed that there was no statistical significance between the survival rates of the patients when they were grouped according to the post PTBD bilirubin levels.16.1% of our patients had minor complications. Major complications in our centre were 45.15%.

Conclusion: Percutaneous management of malignant biliary obstruction is a good method for palliation with good technical success (92%) and clinical success (94.6%). Unilateral approach was used in majority of our patients (97.8%) as drainage of 25%-30% of normal liver is adequate to improve jaundice and liver functions. PTBD is an effective alternative in ERCP failure patients (25% in our study). Successful biliary drainage alleviates jaundice, improves liver function, and has a positive impact on QOL.

INTRODUCTION

Biliary obstruction is caused by many conditions, including benign and malignant diseases. Malignant biliary obstruction (MBO) is usually caused by gall bladder, cholangiocarcinoma and pancreatic malignancies, metastatic lymphadenopathy and infrequently by hepatic and advanced gastric and

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duodenal malignancies. Frequently the tumors are unresectable at diagnosis and only palliative treatment is possible to improve patients' quality of life¹. The key purpose of biliary interventions in these patients is to decompress the obstructed biliary system and if possible to develop a communication between the biliary tree and the bowel allowing physiological bile flow. This decreases pain, jaundice and occurrence of cholangitis by relieving the obstruction. As hepatic dysfunction is a risk factor for major hepatic resection, biliary drainage helps in improving the liver function prior to surgery or neoadjuvant chemotherapy^{2,3}. For a long time, the relief of obstructive jaundice was accomplished with surgical bilioenteric bypass^{4,5}. However, percutaneous transhepatic biliary drainage (PTBD) or endoscopic drainage are less invasive alternatives and has been used for several decades. Endoscopic stents in the common bile duct is today the first choice to alleviate symptoms and prolong life by decreasing hyperbilirubinemia before surgery, chemotherapy, or as palliation⁶. However, when endoscopic stenting fails in palliative patients, one option is to recommend PTBD and another is to offer best supportive care.

Drainage of 25%-30% of normal liver is adequate to improve jaundice and liver functions^{7,8}. Nevertheless, as bile stasis in any dilated biliary segment can result in infection, drainage of such segments is necessary. Baseline imaging is important to evaluate the extent and severity of biliary dilatation and level of obstruction. Any dilated biliary tree which gets opacified on preliminary cholangiogram needs separate drainage if the communication is narrow, as there is very high incidence of post intervention cholangitis^{9,10}. Hence, cholangiogram should be carefully done in cases hilar obstruction of unilateral drainage to prevent infection¹¹⁻¹³. The PTBD is performed as a preoperative procedure for resectable malignancies, prior to neoadjuvant chemotherapy or as a palliative technique⁷. Indications of percutaneous management of malignant biliary obstruction include high biliary obstructions, failed endoscopic drainage, post-operative cases with biliary obstruction, recurrent malignancies and multiple segment strictures¹⁴. There are no absolute contraindications for PTBD of MBO. Relative contraindications are hemorrhagic disorders, allergy to iodinated contrast agents and ascites¹⁴. Although safe, PTBD of malignant biliary obstruction is

associated with complications, which can be immediate or late⁷. The incidence of complications of PTBD ranges from 8%-42%¹⁵. The complications can be categorized into early (occurring within 30 days) and late. Early complications, with exception of pain, are seen in about 25%-50% of patients of which about half were procedure related¹⁶⁻²⁰. The complications include pain at the site of puncture (more common with rightsided punctures), bile leak with risk of biliary peritonitis and biloma formation, hemorrhage including haemobilia, biliovenous fistula, arterial injury, cholangitis and septicaemia, acute pancreatitis and catheter related problems like kinking or dislocation. The right lobe punctures are painful as the needle has to traverse the intercostal space. Left lobe punctures are associated with higher risk of bile leak and thus biliary peritonitis which may cause acute abdomen. Right sided punctures are also associated with the risk of pneumothorax and hemothorax. The rates of complications are lower with metallic stents compared with plastic stents (16% vs 29%)²¹. Vascular injury during the procedure can be arterial or venous. Arterial injury occurs in 1%-2% of cases and is more commonly associated with 18-gauge puncture needles and placement of three or more catheters in a single day^{22,23}. Left sided punctures are associated with higher incidence of hemorrhagic complications and is due to the lack of tamponading effect in left lobe punctures^{22,24}. The hemorrhage usually resolves spontaneously, and may need temporary clamping of the catheter. If it is persistent, CT angiography should be done and if it shows active contrast extravasation or pseudoaneurysm, treatment by embolization is needed. Biliovenous fistulas present with hemorrhage in the catheter or hemobilia and can be diagnosed on cholangiogram with filling of portal venous or hepatic venous radicles. They can be managed by temporary catheter clamping or by changing the catheter to a larger bore catheter¹⁶. Late complications include cholangitis, liver abscess, septicaemia, drainage catheter or stent blockage. Stent occlusion could be due to tumor ingrowth, tumor overgrowth or sludge.

The data of PTBD procedure in MBO from India are limited.

So we planned a prospective study to evaluate the efficacy and safety of PTBD in patients with malignant biliary obstruction.

MATERIALS AND METHOD

Aims and objective:

- 1) To study the efficacy and safety of percutaneous transhepatic biliary drainage in malignant biliary obstruction.
- 2) To evaluate the technical and clinical success of the procedure

Inclusion criteria:

- 1) Confirmed diagnosis of malignant biliary obstruction
- 2) Patients who gave consent for the procedure

Exclusion criteria:

- 1) Refusal to participate in the study
- 2) Patients with massive ascites
- 3) Patients with bleeding diathesis

Study design, study period and sample size:

From June 2018 to Nov 2019, data of all patients with malignant obstructive jaundice, who have undergone PTBD was analysed.

Statistical analysis:

The Wilcoxon signed rank test was used for comparison of non categorical variables (pre and post intervention bilirubin levels). The Kaplan–Meier survival curves will calculate the cumulative overall survival and the primary patency rates. The level of statistical significance is set at $P \leq 0.05$.

Following data was analysed:

A) History

Clinical history was analysed with particular reference to abdominal pain, pruritus, fever, anorexia, weight loss, and duration of symptoms. The patients underwent quality of life (QOL) assessment as well as performance status assessment using the European Organisation for Research and Treatment of Cancer QOL questionnaire version 3.0, based on 30 questions (EORTC QLQ C30)²⁵ and ECOG performance status scale²⁶ respectively

B) Laboratory

Complete blood count, Liver function tests (LFTs) (total bilirubin, direct bilirubin, indirect bilirubin, alanine transferase, aspartate transferase, alkaline phosphatases and total protein) and coagulation profile was analysed in all patients.

C) Imaging

Ultrasonography (USG), triple phase computed tomography and/or magnetic resonance imaging with magnetic resonance cholangiopancreatography was also analysed. Images were analyzed for: cause of obstruction (gallbladder carcinoma, cholangiocarcinoma, pancreatic/periampullary carcinoma, recurrent/post cholecystectomy gall bladder carcinoma and peri portal nodes) and level of obstruction whether hilar or nonhilar obstruction. For hilar obstruction Bismuth-Corlette classification was used. The criteria used for unresectability are those as described by Kumaran *et al*²⁷.

The diagnosis of obstructive jaundice was established on the basis of LFTs (increased serum bilirubin and alkaline phosphatase levels) and an abdominal USG showing dilated intrahepatic radicals. The diagnosis of malignancy was established preoperatively by clinical features, imaging studies and was confirmed by either an USG guided fine needle aspiration cytology (FNAC) / trucut biopsy from mass whichever possible. After the clinical, laboratory, and radiological investigations were completed, patients were offered the option of PTBD, a palliative method of treatment. Patients were informed about the procedure and related complications in detail and written informed consent were obtained. The procedures were performed with USG and fluoroscopic guidance. After the completion of the procedure, the patients were kept under observation in the gastroenterology department and closely followed for any immediate procedure related major or minor complications.

Follow up:

After the placement of catheter / stent and if there was no major complication during observation, the patients were discharged and called for regular follow up at 1 week, 1 and 6 months. Follow up of each patient was based on outpatient examinations and telephone interviews.

Analysis:

Technical success, clinical success, stent patency, survival and complication rates were recorded.

Technical success:

Technical success was defined as the successful deployment of the stent / internal external drainage tube in

the appropriate position resulting in drainage of the respective bile ducts.

Clinical success:

Clinical success was defined by a decrease in serum bilirubin level of more than 20% relative to baseline within 1 week after stent insertion.

Stent / catheter patency:

Stent/catheter patency period was defined as the interval between PTBD / stent placement and obstructive jaundice recurrence. Stent / Catheter block was diagnosed if the reappearance of jaundice after it had subsided. It was confirmed by one of the following:

- a) USG or CT demonstration of redilatation of bile duct
- b) Cholangitis

If stent / catheter occlusion does not occur during a patient's lifetime, the patency was considered equal to the period of survival.

Survival:

Survival (in days) was calculated from the day of intervention until death or last follow up.

Complications:

These were divided into major and minor categories according to the reporting standards of the Society of Interventional Radiology.

- a) Major complications included sepsis or cholangitis, hemorrhage requiring blood transfusion, abscess formation, peritonitis, cholecystitis, pancreatitis, pneumothorax, pneumonia, pleural infection, sepsis, stent / catheter migration and death.
- b) Minor complications included pain, self limiting haemorrhage, biliovenous fistula, sub capsular biloma.

Quality of life assessment:

QOL was assessed by EORTC QLQ C30 prior to the treatment and after 1 month of the treatment. The QLQ C30 is composed of 30 questions with a scale range from mild to severe measured on a scoring scale, and the questions are grouped together into two groups as described below.

- Functional 15 questions are under functional group
- Symptom 13 questions are under symptomatology group

- Global 2 questions are under global group.

Interpretation of quality of life scoring system :

A high score for a functional scale represents a poor level of functioning and an improvement in functional status is determined by a decrease in score.

A high score for the global health status / QOL represents a high QOL and an improvement in global status is determined by an increase in score.

A high score for a symptom scale / item represents a high level of symptomatology / problems and an improvement in symptomatology status is determined by a decrease in score.

The QOL questionnaire has been translated into Hindi and validated for use among Indian patients. The QOL was assessed at 1 month post treatment.

RESULTS

101 patients were planned for PTBD during the study period.

Females were 55 (54.45%) and males were 46 (45.55%).

Mean age was 55.5±22 years.

97 patients (96%) underwent PTBD for palliation, four (4%) underwent as required for pre-operative drainage.

Indications for PTBD:

- a) Severe pruritus refractory to medical management in 68 patients (67.3%).
- b) Cholangitis in 33 patients (32.6%)
- c) Pre-operative drainage (4%) as there was expectant delay in surgery

Cause of biliary obstruction:

Cause of malignant biliary obstruction (MBO) was carcinoma gallbladder in 77 patients (77.7%), cholangiocarcinoma in 10 patients (9.9%), carcinoma head of pancreas in 7 patients (6.9%), periampullary carcinoma in four patients (3.9%) and secondaries at porta in three patients (3.2%). (Table 1)

Type of block:

Type of block was hilar in 90 patients (89.1%) and lower end block in 11 patients (10.89%). Hilar block was type 1 in 3 (2.9%) patients, type 2 in 36 (35.6%) patients, type 3 in 42 patients (41.6%) and type 4 in nine patients (8.9%). (Shown in table 1)

Table 1: Distribution of patients according to cause of MBO and type of hilar block

Cause of MBO	Number (percentage)	Block –Type (Number)
Carcinoma gallbladder	77(77.7%)	Type 2 hilar block- 33
		Type 3 hilar block- 38
		Type 4 hilar block-6
Cholangiocarcinoma	10 (9.9%)	Type 1 hilar block- 3
		Type 2 hilar block-3
		Type 3 hilar block -1
		Type 4 hilar block- 3
Carcinoma head of pancreas	7 (6.9%)	Lower CBD block -7
Periampullary carcinoma	4 (3.9%)	Lower CBD block-4
Secondaries at porta	3 (3.2%)	Type 3 hilar block-4

Table 2: Baseline laboratory parameters

Serum bilirubin	19.9 ±12 mg%
Conjugated fraction	9.5±7.4 mg%
AST	119± 200 U/L
ALT	88± 110 U/L
ALP	666±940 IU/L
Haemoglobin	10.64±2.5 gm%
TLC	12670±13900 mm ³
Prothrombin time	19±6 seconds

97 patients had unresectable disease. Most common criteria for unresectability was metastatic disease followed by locally advanced disease (shown in table 3)

Table 3: Distribution of patients according to unresectability on imaging

<u>Criteria for unresectability</u>	<u>Number of patients ,n=97(percentage)</u>
Vascular invasion	20 (20.6%)
Locally advanced disease	34 (35.05%)
Metastasis	43 (44.3%)

PTBD approach:

Right anterior approach in 54 patients (58%) and subxiphoid in 37 patients (39.7%). So unilateral approach was used in majority of our patients (97.8%), whereas bilateral approach was used in 2 (2.15%) patients in our study. The bilateral approach was used in those patients with blocked confluence, in which the contralateral ducts were inadvertently opacified during cholangiography, as these patients were at high risk of cholangitis if left undrained. The majority of patients had a high obstruction involving the primary confluence and hence there was unilateral drainage in the majority of the patients.

PTBD and stent internalization with 7 Fr DPT stent was done in 3 patients (2.9%) with lower CBD block.

PTBD guided rendezvous in 4 patients (3.96%).

ERCP Failure:

ERCP failure was in 25 patients (24.75%).

Gastric outlet obstruction (11), failed CBD cannulation (9), tight stricture at hilum (4) and altered anatomy (1) were reasons for ERCP failure

Technical success:

93 patients underwent the successful deployment of the stent / internal and external drainage tube in the appropriate position resulting in drainage of the respective bile ducts. So technical success in our centre is 92.07%.

Clinical success:

88 patients had decrease in serum bilirubin level of more than 20% relative to baseline within 1 week after stent insertion. Five patients had catheter mis-placement within one week resulting in increase in serum bilirubin, thus not fulfilling criteria for clinical success. So clinical success is 94.6%.

Complete follow up was available in 85 patients at 1 month, and 8 patients expired within 1 month either due to disease progression or co morbid conditions. Among 8 patients who died within one month, the latest bilirubin levels were available for 6 patients only, just before death and so these values were recorded as 1 month follow up. Hence, a total of 91 patients were analyzed at 1 month.

Serum bilirubin levels were measured before and after treatment. The pre-interventional values and the final post-interventional values at 1 month were recorded. Mean serum bilirubin level before PTBD was 19.9±12 mg/dl (range 10–34.5 mg/dl) and after the procedure at 1 month was 4.2 ± 6 mg/dl (range 2–16 mg/dl). The mean difference in total bilirubin was 15.7 mg/dl, and the percentage reduction of total bilirubin level was 78.9% from the baseline total bilirubin level. The difference in the pre and post intervention bilirubin levels as estimated with Wilcoxon signed rank test is found to be statistically significant with 95% confidence interval as estimated by Hodges Lehmaan estimator (Std. W= -8.3, CI=-17.2- -14.5, P<0.05).

For the analysis of patency rates and survival rates, patients were stratified into the two groups based on the post PTBD bilirubin levels at 1 month (serum bilirubin <4mg / dl vs. 4mg / dl or more).

Around two third (64.8%) patients had serum bilirubin level less than 4mg / dl and 35.2% patients had serum bilirubin levels ≥ 4 mg / dl post PTBD at 1 month (Table no. 4).

Table 4: Distribution of patients according to the absolute bilirubin level at 1 month

Bilirubin Level (mg/dl)	No. of patients	Percentage
<4	59	64.8
≥4	32	35.2
Total	91	100

Stent/catheter patency:

Stent/catheter patency period was defined as the interval between PTBD/stent placement and obstructive jaundice recurrence. As PTBD was successfully carried out in 93 patients, recurrence of jaundice occurred in 82 patients due to stent blockage. 11 patients had functional stent and did not experience any rise in the bilirubin during the study period.

The range and mean patency of PTBD catheter were 14 to 120days and 51± 46 days.

Table 5: Distribution of the patients according to the patency.

Patency (Days)	Number of Patients (%)	Percentage
<30 days	11	13.4
30-59	35	42.7
60-119	35	42.7
≥120	1	1.2
Total	82	100

Relation between patency rate and amount of bilirubin reduction.

In the patients with serum bilirubin level < 4mg / dl the mean patency was 54.1 ± 6.6 days and in the patients with serum bilirubin level ≥ 4mg/dl the mean patency was 49.8 ± 8.4 days. There is mean difference of 4.3 days and it is statistically insignificant at 95% confidence level ($\lambda^2=0.54$, $df=1$, $p=0.46$). The Kaplan-Meier curve is shown in the graph. (Figure 1)

Quality of life assessment

Of the 8 patients who died within 30 days, the latest QOL scores were not available for these patients, just before death. Hence the QOL scores were calculated for 85 patients at 1 month follow up. The pre-interventional values and the final post-interventional values were recorded. There was an improvement in the QOL symptomatic, which was statistically significant (P 0.04). QOL functional also improved after PTBD significantly (p 0.037.) but QOL global improves after PTBD but difference was not statistically significant. Pre and post PTBD QOL values are depicted in Table 6.

Table 6: Quality of life assessment before and after PTBD

Status	QOL Functional	QOL symptomatic	QOL global
Pre- PTBD	41.67±13	38.8±13.48	4.8±3.4
Post- PTBD	24.73±8.4	23.12 ±7	9.46±2.5
P value	0.037	0.04	0.2

Stent / catheter patency:

Stent / catheter patency period was defined as the interval between PTBD / stent placement and obstructive jaundice recurrence.

Stent / catheter patency period in our study was 51±46 days (range 14 -120 days).

Complications:

A) Early complications:

Minor complications:

Pain at puncture site in 22 patients (21.8%), mild hemorrhage in 7 patients (7.5%), transient blood tinged bile in 8 patients (8.6%), so excluding pain at puncture site, 16.1% of our patients had minor complications.

Major complications:

Accidental removal of PTBD catheter in 5 patients (5.4%). Accidental removal of PTBD catheter leads to cholangitis and recurrence of symptoms. This was managed with repeat PTBD.

B) Late complication:

All of these complications were major. Late complications were accidental removal of PTBD 28 times (30.1%) in 21 patients, meaning thereby some patients had PTBD misplacement multiple times.

Catheter blockage in 7 patients (7.5%), stent migration in 2 patients (2.15%).

Accidental removal of PTBD leads to cholangitis (21 patients), perihepatic collection (2 patients) and leak from PTBD site (5 patients). Cholangitis was managed with repeat PTBD in 18 patients, ERCP and biliary SEMS placement in 3 patients. 2 patients with perihepatic collection underwent percutaneous drainage for perihepatic collection along with repeat PTBD.

Catheter blockage leads to cholangitis (6 patients) and perihepatic collection (1 patient). Catheter blockage was managed with flushing of PTBD catheter with normal saline in 2 patients and upsizing of PTBD catheter in 3 patients, stent internalization with 7 Fr DPT in 2 patients. One patient required additional percutaneous drainage for perihepatic collection.

Stent migration leads to cholangitis (2 patients) which was managed with placement of PTBD catheter and removal of internally migrated stent.

So major (both early and late major) complications in our centre were 45.15%.

Survival:

81 patients out of 93 who underwent PTBD, died during the study period (Table no.5); the mean length of survival in study group was 74±90 days (Range 14- 270

days). 12 patients were alive till last follow up on 31st December 2019. Calculated median survival time was approx 70 days.

Table 7: Distribution of patients according to the survival (n=93)

Survival (days)	Number of Patients	Percentage
≤30	8	8.6
31-180	70	75.3
>180	15	16.1
Total	93	100

Relationship between survival rates of patients and reduction of serum bilirubin levels

In 59 patients (64.8%) with post PTBD bilirubin levels of less than 4mg/dl at 1month, the mean survival was 81.4 ± 15.6 days and in the remaining 32 patients (35.2%) with post PTBD bilirubin levels of ≥ 4 mg/dl at 1month, the mean survival was 70.4 ± 7.6 days. Kaplan-Meier log rank (Mantel-Cox) survival analysis showed that there was no statistical significance between the survival rates of the patients when they were grouped according to the post PTBD bilirubin levels ($\lambda^2=0.39$, $df=1$, $p=0.532$) (Figure 2).

DISCUSSION

Malignant obstructive jaundice is a common clinical problem and can occur due to variety of causes as described earlier¹. GBC is the most common cause of malignant biliary obstruction in our country. Most of these patients present with obstructive jaundice caused by biliary obstruction²⁸. As majority of the patients are not candidates for curative resection, the therapeutic goal is often palliative, given the short life expectancy.

PTBD is a well established procedure used in patients with malignant biliary obstruction for decompression of intra and extra hepatic bile ducts^{15,29}.

In our study, most frequent diagnosis was GBC (77.7%), followed by cholangiocarcinoma (9.9%), pancreatic (6.9%), periampullary carcinoma (3.9%), and secondaries at porta from unknown primary (3.2%). Our results were similar to study conducted by Shivanand Gamanagatti et al³⁰.

Unilateral approach was used in majority of our patients (97.8%), similar to study conducted by Shivanand Gamanagatti et al³⁰.

Technical success in our centre is 92.07%. In the study reported by Saluja et al¹⁹ the technical success achieved was 93% in the PTBD group, whereas it was 82% in the endoscopic stenting group.

Technical success was 100% in a study done by Shivanand Gamanagatti et al³⁰.

Clinical success

Clinical success was assessed in 93 patients in which there was technical success. 88 patients had decrease in serum bilirubin level of more than 20% relative to baseline within 1 week after stent insertion. Also five patients had catheter misplacement within one week resulting in increase in serum bilirubin, thus not fulfilling criteria for clinical success. So clinical success was 94.6%. The overall clinical success rate was 89.97% in a study done by Shivanand Gamanagatti et al³⁰.

We also assessed the difference in the pre and post-intervention bilirubin levels as estimated was Wilcoxon signed rank test, which was statistically significant similar to the study done by Shivanand Gamanagatti et al³⁰.

Quality of life

Successful biliary drainage alleviates jaundice, improves liver function, and has a positive impact on QOL²⁸. There was an improvement in the QOL symptomatic, which was statistically significant (P 0.04). QOL functional also improved after PTBD significantly (p 0.037) but QOL global improves after PTBD but difference was not statistically significant.

Relation between patency rate and amount of bilirubin reduction:

In the patients with serum bilirubin level < 4 mg / dl the mean patency was 54.1 ± 6.6 days and in the patients with serum bilirubin level ≥ 4 mg / dl the mean patency was 49.8 ± 8.4 days. There is mean difference of 4.3 days and it is statistically insignificant at 95% confidence level.

However in a study done by Shivanand Gamanagatti et al³⁰ patients with serum bilirubin < 4 mg / dl, the mean overall patency was 150.2 days, whereas in patients with serum bilirubin > 4 mg / dl, the mean overall patency was 79.89 days with a mean difference of 70.1 days, which was statistically significant ($P < 0.001$). This may be due to frequent misplaced PTBD catheter in our patients and less internalizations in our patients.

Survival:

81 patients died during the study period, survival in these patients was 74 ± 90 days (Range 15- 270 days). The estimated mean length of survival for the entire patient population was 116.8 days (range 2–445 days) in a study done by Shivanand Gamanagatti et al³⁰.

Kaplan-Meier log rank (Mantel-Cox) survival analysis showed that there was no statistical significance between the survival rates of the patients when they were grouped according to the post PTBD bilirubin levels ($\lambda^2=0.39$, $df=1$, $p=0.532$) (Figure 1).

However in a study by Shivanand Gamanagatti et al³⁰, univariate Kaplan–Meier (log rank) survival analysis revealed a statistically significant difference in the survival rate when patients were stratified according to the post-stenting bilirubin levels (serum bilirubin < 4 mg/dl vs > 4 mg/dl) ($P=0.007$).

We did not see such survival benefit, may be because PTBD is a palliative procedure, improves quality of life but not survival. And survival in MBO is related to underlying malignancy.

Stent / catheter patency:

Stent / catheter patency period in our study was 51 ± 46 days (range 14 -120 days)

Mean primary patency was 113.2 days (range 2–445 days) in a study done by Shivanand Gamanagatti et al³⁰.

Complications:

16.1% of our patients had minor complications similar to a study done by Shivanand Gamanagatti et al who reported them to be 14.3%³⁰.

We also reported cholangitis as early major complications in five patients (5.4%) due to accidental misplacement of PTBD. Our patients were successfully managed with repeat PTBD.

Major complications occurred in four patients (8.1%) in a study by Shivanand Gamanagatti et al³⁰. In all the patients, complications developed 2–3 days after the procedure: All four patients developed severe sepsis leading to death, and all were caused by severe cholangitis, not responding to antibiotics.

No immediate major complications in the form of hemorrhage requiring a blood transfusion, shock, or procedure related death were observed in our study,

similar to study done by Shivanand Gamanagatti et al³⁰, thus highlighting safety of the procedure in expert hands.

Catheter blockage was noticed in 7 patients (6.5%) of our patients. Time to occlusion ranged between 30 to 60 days (mean 45 ± 40 days). Catheter blockage was managed with flushing of PTBD catheter with normal saline in 2 patients and upsizing of PTBD catheter in 3 patients, stent internalization with 7 Fr DPT in 2 patients. One patient required additional percutaneous drainage for perihepatic collection.

In a study done by Shivanand Gamanagatti et al³⁰ eight patients developed catheter occlusion in the total duration of 6 months (16.3%). Time to occlusion ranged between 10 and 135 days (mean 52.6 days). All occlusions were managed conservatively. None of the patients underwent pre intervention.

In the literature, rates of minor and major complications range between 8% and 23% and between 2% and 20%, respectively^{15,16}.

CONCLUSION

Most common cause of malignant biliary obstruction is still carcinoma gallbladder. Percutaneous management of malignant biliary obstruction is a good method for palliation with good technical success (92%) and clinical success (94.6%). The difference in the pre and post intervention bilirubin levels at 1 month as estimated with wilcoxon signed rank test is found to be statistically significant. Unilateral approach was used in majority of our patients (97.8%) as drainage of 25%-30% of normal liver is adequate to improve jaundice and liver functions. PTBD is a good alternative in ERCP failure patients (25% in our study). Successful biliary drainage alleviates jaundice, improves liver function, and has a positive impact on QOL. Stent / catheter patency period in our study was 51 ± 46 days (range 14 -120 days). Survival in our patients was 74 ± 90 days (Range 15- 270 days). Kaplan-Meier log rank survival analysis showed that there was no statistical significance between the survival rates of the patients when they were grouped according to the post PTBD bilirubin levels. However complications reported by us were higher than reported in literature.

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Efficacy and Safety of Percutaneous Transhepatic Biliary Drainage in Malignant Biliary Obstruction – A Single Tertiary Centre Experience

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**Efficacy and Safety of Percutaneous Transhepatic Biliary Drainage in Malignant Biliary Obstruction –
A Single Tertiary Centre Experience**

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