

Risk and Survival Benefits of Percutaneous Transhepatic Biliary Drainage (PTBD) & Diagnostic Utility of Endobiliary Brush Cytology

Research Article

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Abstract

Objective: Patients of malignant biliary obstruction were prospectively & retrospectively analyzed to identify factors related to bile output and reduction of serum bilirubin after PTBD and stenting. We also compared the survival of these patients after PTBD to investigate if biliary drainage had any impact on the long-term survival.

Materials and methods: 41 patients of malignant obstructive jaundice in whom PTBD was attempted were followed up at regular interval of 2, 6 & 12 months. Data on post-stenting complications, stent patency and patient survival were collected. Endobiliary brush cytology was performed in 18 patients prior to dilatation and stenting.

Results: Mean age of presentation was 55 years for males and 52 years for females. Most common cause of biliary obstruction was cholangiocarcinoma. There was significant decrease in bilirubin on postoperative day 5 with p-value less than 0.0001. Patients with dilated IHBR had better post procedural outcome as compared to those with non-dilated IHBR. No significant association was found between extra or intra hepatic biliary dilatation and intra or postoperative complications and long-term outcome. There was increase in postoperative survival in patients with internal drainage as compared to external drainage. Cytology report showed malignant cells in 13 out of 14 patients.

Conclusion: PTBD is an effective procedure in malignant obstructive jaundice to reduce the bilirubin load. Long-term survival rate in case of patients of malignant obstructive jaundice undergoing PTBD was significantly increased with 2,6 and 12 months survival rate 88.2%, 67.6% and 50%. Patients with non-dilated system are at an increased risk of intra and postoperative bleeding as compared with the patients with dilated system. Metastasis and ascites in case of patient with malignant obstructive jaundice are bad prognostic factors for PTBD. Endobiliary brush cytology is an important alternative to have histopathological diagnosis in case of malignant obstructive jaundice undergoing PTBD.

Keywords: PTBD; Survival; Diagnostic; Endobiliary; Brush; Cytology

Introduction

Malignant Biliary Obstruction (MBO) is usually caused by cholangio-carcinoma, gall bladder and pancreatic malignancies, and metastatic lymphadenopathy and infrequently by hepatic and advanced gastric and duodenal malignancies [1]. Where the tumors are unresectable at diagnosis only palliative treatment is possible to improve patient's quality of life. The key purpose of biliary interventions in these patients is to decompress the obstructed biliary

system. 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 neo-adjuvant chemotherapy [2-4]. Surgery has been traditionally considered the treatment of choice in patients with biliary malignancies. However a large number of these patients are found unresectable. Among these patients reported median survival is 3 to 10 months [5]. Endoscopic stenting in patients with low biliary obstruction is the preferred method. However, high

obstructions, bilateral or multiple strictures, as well as previous upper gastrointestinal tract surgery may render endoscopic stent placement difficult or impossible and in such cases percutaneous technique is preferred [6]. Percutaneous Trans-Hepatic Biliary Drainage (PTBD) and metallic stent insertion has been practiced since the early reports of percutaneous trans-hepatic cholangiography in the 1960s. It is an effective preoperative risk-reducing modality and an effective palliative procedure in patients who are not surgically drainable [7]. It is now a common procedure for the interventional radiologists [8]. Although stenting can be performed with either Plastic Stents (PS) or Self-Expandable Metallic Stents (SEMS), the benefit of the latter is manifested by higher rates of successful drainage and longer survival [9,10]. In this study we prospectively & retrospectively analyzed the clinical and imaging characteristics of these patients in an attempt to identify the factors related to bile output and reduction of serum bilirubin after PTBD. In addition, we also compared the survival of patients with different bile output and reduction rates of bilirubin after PTBD to investigate if the short-term effectiveness of biliary drainage had any impact on the long-term survival. Previous studies that analyzed patient survival present outcomes that are controversial, there is as yet no general agreement regarding either the technique of the procedure or the selection of patients. The aim of our study was to assess short- and long-term outcomes of malignant biliary stricture treatment by Percutaneous Trans-Hepatic Bile Duct Stenting (PTBS) with uncovered self-expandable metallic stents, and to identify predictors of patient survival. It is necessary to elucidate which features patients possess in order to ensure the maximum possible benefits for survival. Malignant strictures of extra-hepatic duct cannot be easily distinguished from benign strictures [11]. Biliary brush cytology can be alternative method in the evaluation of patients with biliary tract stricture.

Material and Methods

The study was carried out prospectively on 41 patients of MBO in whom PTBD procedure was attempted and patients were followed up at regular interval of 2, 6 & 12 months. Duration of study was 2 years. Ethical clearance was obtained from ethical committee of the institution. Well informed consent was obtained in all cases after explaining about the procedure and its complications in detail. All patients with surgical obstructive jaundice were assessed with multiphase Contrast Enhanced Computed Tomography (CECT) and Magnetic Resonance Cholangio Pancreatography (MRCP) prior to percutaneous management, for identifying the level and cause of obstruction and defining the extent of the disease. Ultrasonography was done as a screening procedure prior to percutaneous intervention to assess biliary dilatation, presence of ascites, volume of the liver lobes/segments and patency of biliary confluence (primary and secondary) as this decided the approach used and lobe to be drained. Patient's coagulation profile was checked before the procedure to avoid bleeding complications. If Prothrombin Time and International Normalized Ratio (PT/INR) values were deranged, vitamin K injection was given for three days and the procedure was done after normalization. In case of emergencies where the patient had cholangitis with risk of septicaemia, if PT/INR was deranged, fresh frozen plasma was given before and during the procedure.

The procedure was usually performed under local anesthesia in the presence of anesthetist. The segmental duct was punctured by spinal needle and percutaneous cholangiogram was performed slowly to define the biliary anatomy and type of obstruction (Figure 1). Later on the radicals were punctured with 18 G Chiba needle or 18G spinal needle, under fluoroscopy /ultrasonography guidance. Once there was backflow of bile, a 0.032/0.035 inch soft "J" tip guide wire is passed through the needle, which was then exchanged for a 5F or 6F dilator followed by removal of the guide-wire. Subsequently, the dilator was exchanged for 7F Angiosheath or an angled tip angiographic catheter over the wire. When the catheter tip was at the site of obstruction, the soft hydrophilic guidewire was manipulated to cross the stricture. Once the wire was across the stricture, the catheter was pushed over the wire into the duodenum (Figure 2). The soft wire was then replaced by Ultra Stiff Amplatz guidewire over which the tract and stricture was dilated. Then, an 8F/8.5F internal-external drainage catheter was positioned across the stricture and the position was confirmed with contrast injection. In patients where initial attempt to cross the stricture failed, an external drainage catheter was left with tip proximal to the obstruction and internalization was attempted after a gap of two-four days. This two-step procedure helped in reduction of inflammation and edema and enhanced the likelihood of negotiating the obstruction. For strictures distal to the hilum, with patent primary biliary confluence, single drainage was sufficient. Drainage of single or both systems was done when the primary biliary confluence was completely occluded. Endobiliary Double Lumen brush was used for sampling prior to dilatation and stenting by agitating the brush in between the stricturous segment (Figure 3). Samples were then taken on slides and sent to cytology department. Once the obstruction was traversed, stenting was done in the same sitting to reduce the incidence of procedure related complications. Self expandable metallic stents (Zilver Flex by Cook medical services/ WallFlex metallic stent by Boston) were used (Figure 4). The stricture was dilated with plastic dilators, if necessary, so that the stent apparatus could be passed. The metallic stents have thermal memory and expand to their maximum width when they reach the body temperature, this usually occurs in 24-48 hr. If the expansion was not adequate after 48 hr, dilatation of the stent with balloon catheter was done for successful drainage (Figure 5). Data on post-stenting complications, stent patency and patient survival were collected retrospectively from patient's medical records &

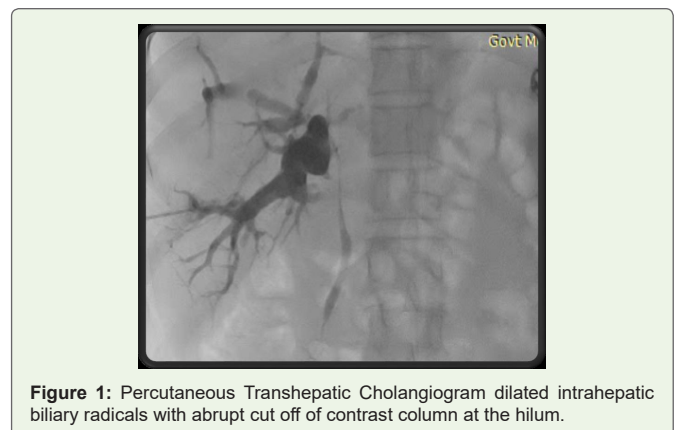


Figure 1: Percutaneous Transhepatic Cholangiogram dilated intrahepatic biliary radicals with abrupt cut off of contrast column at the hilum.



Figure 2: Percutaneous transhepatic access through the biliary tract into the duodenum using guide wire with catheter placed across stricture in the proximal duodenum.



Figure 3: Endo-biliary brush cytology at the level of common bile duct stricture.

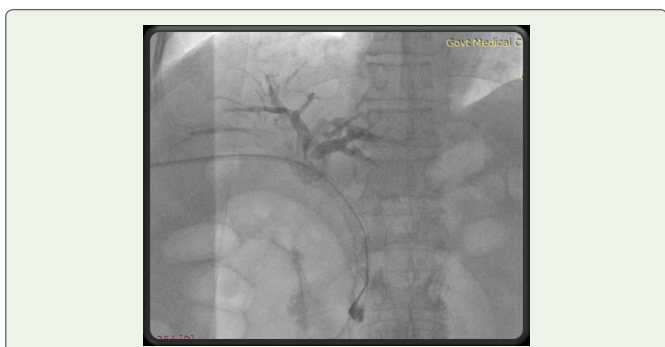


Figure 4: Stent in situ in CHD & CBD across the stricture.

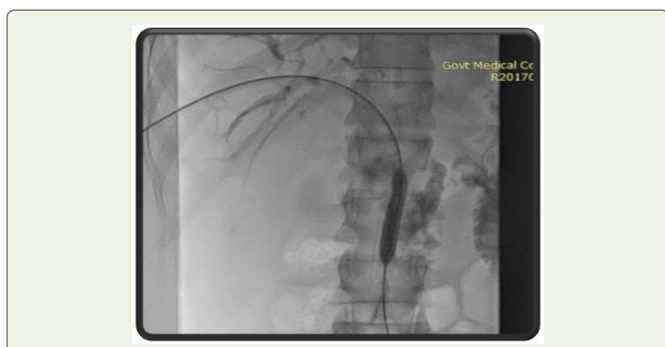


Figure 5: Balloon dilatation at the level of distal common bile duct.

postoperative CT scans taken before patient was discharged. Further follow up of patients was taken telephonically at regular interval of 2 months, 6 months and 1 year. Continuous variables were presented as mean +SD. Categorical variables were expressed in frequency and percentage. Paired T test was performed to compare preoperative and postoperative bilirubin levels. Categorical variables were compared by performing chi-square test. For small numbers, Fisher's exact test was applied wherever required. All the tests were two-sided. $p < 0.05$ was considered as statistically significant. Statistical software Stata version 14.0 was used for data analysis.

Results

Most of the population in this study was above the age of 40 years with maximum patients in the age group of 51-60 years. Mean age of presentation was 55 years for males and 52 years for females. Most common cause of biliary obstruction on preoperative imaging in our study was cholangiocarcinoma followed by carcinoma head of pancreas (Figure 6). Mean bilirubin level of the patient at the time of presentation was 24.10 mg/dl. Almost all of the patients experienced decrease in clinical jaundice and associated symptoms (e.g. pruritus) after PTBD with mean postoperative bilirubin value being 10.5 mg/dl. There was a statistically significant decrease in the postoperative bilirubin value done at postoperative day 5 with a p-value less than 0.0001, which is highly significant (Table 1). As most of the patients presented late and in advanced stage, severe Intrahepatic Biliary Radical (IHBR) dilatation (>2 mm) was seen in 32 patients. In 9 patients IHBR was found to be non-dilated. These findings were correlated with the intra and postprocedural complications (e.g. Bleeding and sepsis). It was found that patients with dilated IHBR had a better post-procedural outcome as compared to the patients with non-dilated IHBR. This can be correlated with difficulty in puncture of the biliary radical in a non-dilated biliary system with more chances of vascular injury by multiple punctures. Out of the 32 patients with dilated IHBR 29 (90.6%) patients survived till 2 months, 20 (62.5%)



Figure 6: CECT axial section in a patient of Hilar cholangiocarcinoma showing dilated biliary radicles with an abrupt cut-off at the level of the hilum

Table 1: Comparison of Bilirubin level before and after operation (N=39).

Mean	Pre-op	Post-op	t-value	p-value
	24.10	10.56	11.9140	<0.0001, HS
SD	5.28	5.13		

NOTE: Two patients were excluded from the table as in one patient the procedure was not done and in another patient immediate intraoperative death of the patient had occurred.

patients survived by 6 months and 17 (53.1%) patients had survival of more than 1 year. Out of the 9 patients with non-dilated system 2 patients (22.2%) had intraoperative or postoperative bleeding. No significant association was found between the Extrahepatic Biliary Radical (EHBR) dilatation and intra or postoperative complications & postoperative long-term outcome. Out of 41 patients, 22(53.6%) patients had hilar obstruction, which was correlated with the post-operative outcome. There was significant improvement in long-term survival in patients with hilar obstruction as compared to patients without hilar obstruction with post operative 2,6 and 12 months survival rate of 86%, 63% and 45% respectively. Level of obstruction was also correlated with intraoperative and post-operative complications. Out of 22 patients with hilar obstruction 2 patients had severe bleeding and 1 patient landed in sepsis in postoperative period. Out of 22 patients with infrahilar obstruction 2(9.5%) patients had severe bleeding in intra-postoperative period and 1 patient had sepsis in postoperative period. 15 (36.5%) patients had metastatic lesions (in the liver and/or lymph nodes). These patient's post operative outcomes were compared with those of patient's without metastatic lesions. One patient with metastasis was excluded from the postoperative outcomes because of failure of the procedure in this patient. There was significant decline in the survival of patients with metastasis with postoperative long-term survival at 2,6 and 12 months of 85%, 46.6% and 33.3% as compared with that of 88%, 72% and 56% in patients without metastasis. However no statistical significance was demonstrable. So metastasis in case of patient with MBO is bad prognostic factor for PTBD patients. Out of 10 patients with gross ascites 4 patients (36.4%) had episodes of bleeding intra or postoperative period. 1 patient (9.1%) landed in severe sepsis in postoperative period (Figure 7). There was significant statistical correlation between ascites and intra or post operative bleeding. One patient was excluded from the calculation, as PTBD was not performed even after repeated attempts. In 6 (14.6%) cases it was not possible to put a self-expandable metallic stent (internal drainage) due to technical difficulty in crossing the stricture and due to non-affordability for the stents. In these patients PTBD was done with external drainage catheter. Long-term survival in these patients with external drainage in situ at 2,6 and 12 months was 66.7%, 33.3% and 33.3% respectively. Internal drainage was possible in 34(82.9%) patients. In these patients there was statistically significant increase in survival with 2,6 and 12 months survival rate 88.2%, 67.6% and 50%. There was increase in postoperative survival in patients with internal drainage as compared to the external drainage (Table 2). However this was not significant statistically. This can be due to less number of patients who had undergone external drainage only. There were incidents of displaced external drainage catheter, accidental removal of external catheter, pericatheter leak & abdominal discomfort etc. with the external drainage catheter. Out of 41 patients 39 patients were followed up for the post PTBD serum potassium levels at post operative Day 3. There was decrease in serum potassium levels below 3.5 in 9 (23.7%) patients. However there was no significant increase in the postoperative mortality noted in these patients. Out of 41 patients with MBO Endobiliary Brush Cytology (EBBC) was performed in 18 patients out of which in 14 patients (77.7%) cytology report showed sample adequate for reporting. In 4 patients sample was reported as

inadequate. Out of 14 patients with adequate samples 13 patients were reported to have malignant cells in the stained smears, however in 1 patient only fibrotic tissue was reported with none of the slides showing malignant cells. Out of 22 cases of hilar obstruction EBBC was performed in 10 patients out of which 8(80%) cases were reported to be adequate samples. Out of these 8 samples collected 7 samples were positive for malignant cells (Figure 8). Similarly in 22 cases of infrahilar obstruction EBBC was performed in 9 patients out of which 6 (67%) samples were reported to be adequate samples. Out of these 6 samples all 6 were reported to be positive for malignant cells.

Discussion

In 14th Aichi International Cancer Symposium on Pancreatobiliary Cancer Update -Prevention, Diagnosis and Treatment by Palepu Jagannath et al., it was observed that most of the Pancreatobiliary tract carcinomas are observed above the age group of 50 years [12]. Our study was in concordance with this as most of the patients in our study presented after the age of 50 years. In this study 67% of the population were males. These findings are consistent with the study of Zhang et al on clinical outcomes and prediction of survival following percutaneous biliary drainage for MBO in which most of the study

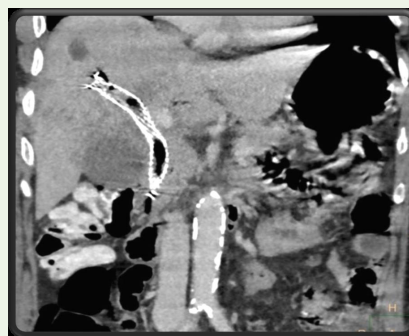


Figure 7: Coronal CT scan showing stent in situ with cholangitic abscess.

Table 2: Long term survival in PTBD patients.

Drainage procedure	2 months	6 months	12 months
Internal Drainage	88.2%	67.6%	50%
External Drainage	66.7%	33.3%	33.3%

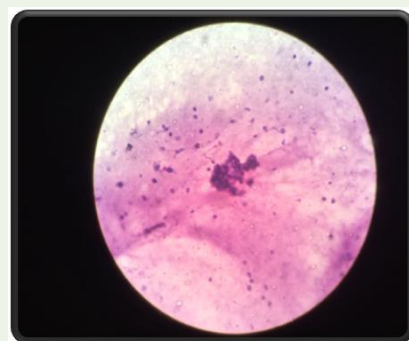


Figure 8: Cytopathology slides with high cellularity showing papilloid groups clusters of highly pleomorphic cells with high nucleus to cytoplasmic ratio. Nuclei are large and hyperchromatic with scanty cytoplasm.

population was male [13]. In our study both males and females were having nearly same age of presentation with males presenting slightly late age of presentation. This was also in concordance with the study of Katabi et al. and in most of the other previous studies in which incidence of MBO is more common in males than in females with nearly same age of presentation [14]. This may be attributable to the number of risk factors like alcohol, smoking etc. which are more common in males and also to the awareness of people about the disease. Most of the patient experienced statistically significant decrease in the level of total bilirubin. This was consistent with the study of Tuqan et al. in which significant decrease in post operative bilirubin was shown [15]. The technical success of PTBD in terms of internal or external drainage in 40 patients out of 41 (97.5%) was in concordance with the study of Pranculis et al. who reported success rate of 95.9% [16]. Out of 41 patients, 32 (78%) showed dilatation of IHBR and there was favorable 2, 6 & 12 months postoperative survival in them. However in non-dilated system there was increased chances of bleeding and postoperative mortality as compared to that with the dilated IHBR. This is in concordance with the study of Weber et al. concluding non-dilated intrahepatic bile ducts showed a higher risk for procedure related complications [17]. In our study we also compared the level of obstruction (hilar and infra-hilar) with the postoperative complications and long-term survival. There was no statistically significant improvement in long-term survival of the patients with hilar obstruction. Similarly no significant correlation was found between the level of obstruction and postoperative complications. There was significant decline in the survival of the patients with metastasis. Similarly study done by Li et al also concluded metastasis as one of the independent risk factor in case of patients undergoing PTBD in MBO [18]. Out of 41 patients in 9 patient with gross ascites (defined as patients with fluid in perihepatic region) there was significant reduction in the survival, which was also proven statistically (p-value-0.018). These findings were supported by studies done by Li et al and Tuqan et al. [15,18]. Long term survival in patients with external drainage in situ at 2, 6 and 12 months was 66.7%, 33.3% and 33.3% respectively. However no statistical significance was demonstrable (p value <0.407). In 33 patients of internal drainage done there was statistically significant increase in survival with 2, 6 and 12 months survival rate 88.2%, 67.6% and 50%. Double stents were placed in 14 patients and single self-expandable stent was placed in the 19 patients with infrahilar obstruction. This is in concordance with the Pranculis et al. in which post procedural 30 days mortality rate was 15.3% [16]. Our study also depicts the same result with post procedural survival rate at 2 months of 88.2%. This suggests the need of another comparative prospective study to compare internal and external drainage in terms of long-term survival. In 9 patients there was decrease in serum potassium levels below 3.5 at post operative day 3. However there was no significant increase in the postoperative mortality noted in these patients. The study was biased because of supplementation of serum potassium orally and intravenously hence no significant correlation between postoperative serum potassium level and postoperative mortality can be predicted from this study. Parildar et al. studied effects of PTBD on renal function in patients with obstructive jaundice using the estimated glomerular filtration rate (eGFR) and evaluated the factors

associated with renal dysfunction [19]. They observed eGFR was <60-mL/min/1.73 m² before PTBD in 27 patients (25%) and increased significantly 30 days after PTBD. Conclusion of the study was that obstructive jaundice is associated with renal dysfunction, and serum direct bilirubin is a significant predictor of renal function. However this can't be correlated with our study. Endobiliary brush cytology is an important alternative to have histo-pathological diagnosis in case of MBO undergoing PTBD. Endobiliary brush cytology was performed in 18 patients out of which in 14 patients (77.7%) cytology report showed sample adequate for reporting. Out of these 13 patients was reported to have malignant cells in the stained smears, however in 1 patient only fibrotic tissue was reported with none of the slides showing malignant cells. This was in concordance with the study of Xing et al in which percutaneous Trans-Hepatic Biliary Cytology (PTBC) was done during the procedure in 58 patients with obstructive jaundice [11]. Their results indicated that PTBC was very easy to manipulate and had a high sensitivity. Similarly in our study there was no difficulty in manipulating the procedure for EBCC and there was no increase in any intra operative complications noted. However sensitivity and specificity of this test cannot be determined due to lack definitive gold standard test.

Conclusion

Percutaneous Transhepatic Biliary Drainage is an effective procedure in malignant obstructive jaundice to reduce the bilirubin load. Long-term survival rate in case of patients of malignant obstructive jaundice undergoing PTBD was significantly increased with 2, 6 and 12 months survival rate 88.2%, 67.6% and 50% respectively. Patients with non-dilated system showed an increased risk of intra and postoperative bleeding as compared with the patients with dilated system. Metastasis and ascites were bad prognostic factors for PTBD. Endobiliary brush cytology is very easy to manipulate and is an important alternative for histo-pathological diagnosis.

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