ORIGINAL RESEARCH PAPER

Volume-8 | Issue-7 | July - 2019 | PRINT ISSN No. 2277 - 8179

INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

SAFETY AND EFFICACY OF PERCUTANEOUS TRANSHEPATIC BILLIARY DRAINAGE- A STUDY IN EASTERN INDIA

Radiology

Dr. Surajit Das Assistant Professor, Department of Radiology, Midnapore Medical College and Hospital, West Bengal.

Dr. Iman Sinha* Assistant Professor, Department of Anatomy, Institute Of Post Graduate Medical Education & Research, Kolkata, West Bengal. *Corresponding Author

ABSTRACT

Malignant biliary obstruction is often inoperable at presentation and has a poor prognosis. Percutaneous Transhepatic Biliary Drainage has been widely used for palliation of malignant biliary obstruction as an alternative to major bypass surgery or when endoscopic drainage is not technically feasible. The fundamental objectives of palliative transhepatic biliary drainage are to improve quality of life by relieving jaundice and pruritus, prevent cholangitis, and avert liver failure caused by progressive biliary obstruction. Our present study aimed to evaluate safety and efficacy of percutaneous transhepatic billiary drainage in Eastern Indian population. Following the selection criterias and baseline clinical workup & laboratory investigations, the patients are allowed to undergo the procedure of PTBD. Then evaluations are done regarding reduction in total serum bilirubin level 1 month after procedure and the rate of procedure related complications.

KEYWORDS

Percutaneous transhepatic biliary drainage, safety, efficacy.

INTRODUCTION:

While surgical resection provides the best chance of long term survival and quality of life, the majority of patients with malignant biliary obstruction are not candidates for curative resection due to advanced disease at the time of diagnosis (locally advanced, vascular invasion, metastasis) and/or poor general condition of the patient. Prognosis of these patients is dismal. Among these patients, some survive for only a few weeks, most die within six months, but some may survive in a fairly good condition for one or even several years. Untreated biliary obstruction may lead to hyperbilirubinemia, pruritus, anorexia, cholangitis, septicemia, and liver failure.

In this situation therapeutic goal is often palliative. The objective of palliation is to relieve biliary obstruction related symptoms and complications such as jaundice, pruritus and cholangitis, and to improve quality of life. Main benefits of well-functioning drainage of biliary tract are-

1) Marked recovery of liver parenchyma.
2) Relief of severe pruritus.
3) Improvement of general condition of patient

Palliative biliary drainage can be provided by surgical bypass, endoscopic stent placement or percutaneous transhepatic biliary drainage (PTBD) [1].

Although ***surgical bilioenteric bypass*** has been the traditional palliative approach, however it is associated with considerable morbidity and mortality. Therefore, there was a need for minimally invasive and clinically satisfying procedure to replace the more morbid surgical procedures.

Endoscopic stenting is the preferred method of biliary drainage in patients with low biliary obstruction [2]. However, high biliary obstructions, bilateral or multiple strictures, as well as previous upper gastrointestinal tract surgery may render endoscopic stent placement difficult or impossible [3].

Percutaneous transhepatic biliary drainage (PTBD) is an effective preoperative as well as an effective palliative procedure in patients who are not surgically/endoscopically drainable [3,4,5]. It has been reported that PTBD is the preferred method of biliary drainage in patients with high biliary obstruction and also it is associated with lower complication rates [1,2,4]. PTHBD can be 1) retrograde, where bile is drained externally through a catheter and collected in a bag; 2) antegrade, where the obstructing lesion, usually a carcinoma of the pancreas, is bypassed with a catheter and bile is drained internally into the duodenum; or (3) a combination of both[6].

PTBD may be a definitive palliative procedure or a preoperative biliary decompressive modality when subsequent surgery or radiation therapy is planned. PTBD can be performed by either catheter drainage or by stenting.

There are two forms of catheter drainage – external drainage and internal-external drainage. In external drainage, catheter is placed proximal to the obstruction and bile is drained outside into the connector bag. In internal-external drainage, catheter is placed in such a way that few holes of the catheter are above and few holes below the stricture, so as to allow the bile to drain into duodenum, as well as outside into the connector bag. However, the catheter drainages are associated with many disadvantages and complications such as infections, catheter dislodgement, blockage, pain, bile leakage. They are also associated with catheter maintenance problems as well as cause discomfort for the patient as there is a need for regular catheter flushing and dressing [7]. However, they are inexpensive and they give an advantage of access to the biliary system in case of blockage without the need of repeat puncture.

PTBD is also done by placement of stents across the stricture, which is called as biliary stenting and serves as internal drainage. There are two types of stents – metallic and plastic stents. Biliary stenting has lower rate of complications, provides more effective biliary drainage and better comfort for the patient as compared to catheter drainage. Self-expanding metal stent, is associated with low risk of migration, efficient bile drainage and re-stenosis rate due to tumor ingrowth is also low [2, 8]. Metallic stents have been found superior to plastic stents, with longer patency rates, improved quality of life for the patient and lower complication rates. In contrast, the plastic stents have higher migration rate, are more traumatic and because of smaller inner lumen, the risk of re-stenosis is also high. Because of these advantages and lower complication rates, metallic stents are being more widely used as compared to plastic stents and catheter drainage, as a method of palliation. The major disadvantage of the metallic stents is that they are expensive and are known to undergo fractures. The few contraindications of percutaneous bile duct drainage include -- Clinically significant coagulopathy and voluminous ascites [8]. The procedure is relatively contraindicated in obese and uncooperative patients. Immediate morbidity following PTBD (bleeding, septicaemia, and bile leakage) is rare (1–5%).

PTBD-related complications are categorized into major and minor complications, based on outcome of the complication.

Major complications result in admission to a hospital for therapy, an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. Sepsis, haemorrhage (requiring blood transfusion), abscess, peritonitis, cholecystitis, pancreatitis, pneumothorax, fluid collection, death are described as major complications [4,8].

Minor complications are not associated with any significant morbidity; they may require nominal therapy or a short hospital stay for observation[8] . Minor complications include mild haemorrhage, biliary-venous fistula, bile leakage, subcapsular biloma. Patients with

coagulopathies, cholangitis, stones, malignant obstruction, or proximal obstruction will have higher complication rates . Most complications can be treated conservatively, and procedure related mortality is less than 3% [4].

Materials and method:

STUDY DESIGN

A descriptive observational study.

PATIENTS

This study was conducted in the department of Radiodiagnosis, in collaboration with Gastrointestinal Surgery and Surgery Departments, in a Government Medical College in Kolkata. History and investigations of all patients were noted before and after the procedure and regular follow up was done at one week and one month after the procedure.

All patients with malignant obstructive jaundice, who were not suitable for resection and referred for PTBD were analyzed as per the inclusion and exclusion criteria described below and accordingly recruited in the study. A total of 34 patients with malignant obstructive jaundice were treated in the Department of Radio-Diagnosis with PTBD, during the study period. 3 patients were lost to follow-up and 1 patient refused to participate in the study. So, finally a total of 30 patients (age range 32 to 75 years) were recruited in the study. The study protocol was approved by the institutional ethics committee. Written informed consent was obtained from all patients before inclusion in the study. A Case Record Proforma was filled for each patient giving the history, investigations and clinical details of the patient and relevant information of the patient.

SAMPLE SIZE

30 patients

INCLUSION CRITERIA

- Surgically irresctable histopathologically proven Carcinoma (Gallbladder/Bile duct) with obstruction of Intra & Extra Hepatic ductal system.
- Symptomatic patient of Cholangio Carcinoma
- Periampullary obstruction either due to Periampullary Carcinoma Or Carcinoma Head of Pancreas with failed attempt of ERCP.
- Metastatic tumor involvement of Porta hepatis & Portal lymphadenopathy.

EXCLUSION CRITERIA

- Documented benign biliary stricture.
- Massive ascites.
- Uncontrolled coagulation.
- No access to bile duct
- Refusal to participate in the study.

CLINICAL WORKUP

A detailed clinical history was obtained from all patients with particular reference to abdominal pain, pruritus, fever, anorexia, weight loss and duration of symptoms.

Laboratory investigations

All patients were subjected to the following investigations:

- Liver Function Tests (Total Bilirubin, Direct Bilirubin, Indirect Bilirubin, Alanine Transferase (ALT), Aspartate Transferase (AST), Alkaline Phosphatase (ALP), Total Proteins.
- Coagulation profile – Prothrombin Time (PT).

Imaging

All patients were evaluated with Ultrasonography (USG) and either Dual or Tripple Phase Computerised Tomography (DPCT)/ Contrast Enhanced Computerised Tomography (CECT) or Magnetic Resonance Imaging (MRI) with Magnetic Resonance Cholangio Pancreaticography (MRCP).

Images were analyzed to identify:

1. The cause of obstruction (gallbladder carcinoma, cholangiocarcinoma, pancreatic/peri ampullary carcinoma, recurrent/ post cholecystectomy gall bladder cancer, peri portal nodes).
2. The level of obstruction whether hilar or non-hilar obstruction.
3. The criteria for unresectability on imaging. The criteria used for unresectability were those as described by Kumaran V et al [9]: distant metastasis (liver, peritoneum, lymph nodes), extensive local contiguous organ spread (liver, duodenum, pancreas or hepatic flexure), contiguous involvement of greater than two segments each in both lobes of the liver, involvement of secondary biliary confluence of both lobes of liver, tumoural invasion of main portal vein or proper hepatic artery or simultaneous invasion of one side hepatic artery and the other side portal vein or simultaneous involvement of ipsilateral hepatic artery and/or portal vein along with contralateral secondary confluence of bile ducts.

After the clinical, laboratory and radiological investigations were completed, patients were offered the option of PTBD as a palliative method of treatment and were informed about the procedure in detail. Written informed consent was obtained from all patients. After the placement of catheter/stent and if there was no major complication during observation, the patient was discharged and called for regular follow up at 1 week & 1 month. Follow up of each patient was based on outpatient examinations and telephone interviews. Serum Bilirubin(Total, Direct & Indirect) was assessed at 1 month after drainage.

Objectives:

- To evaluate reduction in serum total bilirubin level 1 month after procedure of Percutaneous Transhepatic Billiary Drainage.
- To evaluate the rate of procedure related complications

RESULTS:

1.Age: Age of patients in study population were varying in a range between 32 yrs to 75 yrs.

Mean	51.5
Standard Error	2.21
Median	51
Mode	60
Standard Deviation	12.13
Sample Variance	147.02
Range	43
Minimum	32
Maximum	75
Sum	1545
Count	30

Table 1 depicts the descriptive data analysis of distribution of age in the study population.

2.Sex: The numbers of male patients were 10 and female patients were 20 in study population.

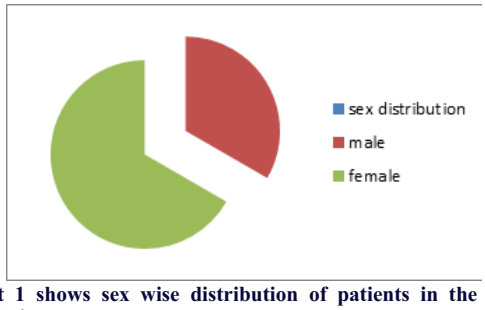

Chart 1 shows sex wise distribution of patients in the study population

3.Diagnosis: Diagnosis of patients in study population was noted. In our study group we found Gallbladder carcinoma as most common cause of malignant biliary obstruction.

Table 2 depicts the number and percentage distribution of the diagnosis in the study population.

diagnosis	Number of patients	Percentage distribution
gall bladder carcinoma	13	43.3%
cholangio carcinoma	5	16.7%
Pancreatic/ ampullary carcinoma,	7	23.3%
recurrent/post cholecystectomy gall bladder cancer	3	10%
peri portal nodes	2	6.7%

4.Level of Biliary Obstruction: Level of biliary obstruction(High or

Low) of patients in study population and their outcomes was evaluated. High obstruction denotes obstruction above the level of insertion of cystic duct and low obstruction denotes obstruction below the level of insertion of cystic duct. In our study we found high obstruction in **20** patients and low obstruction in **10** patients.

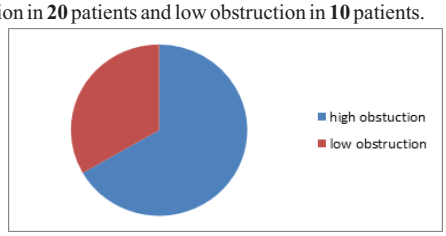

Chart2: shows high/low level of obstruction in the study population.

5. Bilirubin Level: Total serum bilirubin level of individual patient was assessed prior to procedure and 1 month after procedure. Percentage of reduction of total bilirubin level after procedure was evaluated in individual patient.

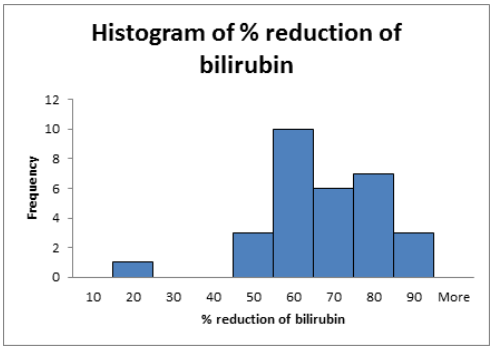

Chart 3 shows frequency of % reduction of total bilirubin following procedure

6. Complication Rate: Complication rate was evaluated in study population. Complication was divided into major and minor groups as described before.

complications	Number of patients	Percentage of patients
Minor	3	10%
Major	2	6.7%

Table 3 depicts the number and percentage distribution of complications seen in the patients undergone the procedure.

DISCUSSION

In our study group we found Gallbladder carcinoma as most common cause of malignant biliary obstruction. Study of Malkan et al [10], which says that, the most common cause of malignant biliary obstruction in our country is carcinoma of the gall bladder, supports our result. Carriaga et al [11] who found GB Carcinoma as the most common cause of malignant hilar biliary obstruction also supports our result. The peak occurrence of gall bladder carcinoma is in the sixth and seventh decades of life and there is a female predilection of 2:1 to 3:1 [12] . our study also comply with this.

Regarding Technical Success Rate [13,14,15], in our study, procedure was technically successful in all 30 cases. ACR Appropriateness criteria [16] says that technical success rate of PTBD is 90-95%. Lawson et al[17] found technical success rate of 100% in his study.

Clinical improvement and a decrease in serum bilirubin of 1 to 3 mg/dL/day or to 50 percent or less of the initial value within 10 days are reliable indicators of a successful drainage, whether external, internal, or combined[18]. Young-Min et al[19] found that, mean bilirubin level decreased from 11.1 mg/dL ±6.86 standard deviation (SD) before the procedure to 5.12 mg/dL ±4.6 SD at the first follow-up, and this difference was statistically significant. Mcgrath et al[20] also found a significant reduction in bilirubin level after biliary drainage procedure. In our study,mean bilirubin level decreased from 16.81mg/dL ±6.58 standard deviation (SD) before the procedure to 6.22 mg/dL ±3.17 SD at the follow-up after 1 month . Furthermore mean of the percentage of bilirubin reduction is 62.21 mg/dL ±14.17 SD after 1 month.

Rates of minor and major complications are in the range of 8–23% and 2–20%, respectively[4]. The recommended overall threshold for all major complications of percutaneous transhepatic biliary drainage is 10%[8].Our present study records major complications in 6.7% 0f cases and minor complications in 10% of cases.

CONCLUSION:

Thus evaluating the safety and efficacy of the procedures done in our present study among the 30 patients, it can be concluded that Percutaneous Transhepatic Biliary Drainage is an effective palliative procedure in unresectable cases of malignancies causing biliary obstruction.

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