## ORIGINAL ARTICLE

# SUPERIORITY OF INTERNAL EXTERNAL DRAINAGE OVER EXTERNAL DRAINAGE IN PTBD IN PALLIATIVE BILIARY DECOMPRESSION: OUR EXPERIENCE IN A TERTIARY HOSPITAL (MEDICAL COLLEGE, KOLKATA)

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## ABSTRACT

BACKGROUND: There is a high burden of patients with malignant biliary obstructions presenting to our institute, PTBD has become the only means of palliation as the cases most often present beyond the stage of any curative treatment. Internal External Drainage (IED) being a comparatively newer technique to External Drainage (ED), there is little data studying the two methods in our patient population. **OBJECTIVES:** To show the techniques of PTBD, efficacy, complications and their management. To compare the two methods IED and ED regarding their efficacy, drawbacks, and complication rates. **METHODS:** A prospective study was done with 50 patients between September 2016 and August 2017. Following procedure, patients were followed up one week, two weeks and four weeks with clinical examination and biochemical evaluation. RESULTS: Out of 50 patients, 34 cases were female. Most common indication was gall bladder carcinoma. Overall, technical success achieved in 94% of cases. ED was done in 28 patients, 19 underwent IED. Stenting (SEMS) was performed in 8 cases after IED. IED reduced mean bilirubin levels by 67% one week post procedure, ED resulted in decrease by 39% at the same time. 22% of patients had complication during / after procedure. Two patients had sepsis post procedure. Chemotherapy could be initiated in two patients following IED in one week. CONCLUSION: PTBD is an effective procedure with high technical success. IED is better than ED in terms of rapid reduction of bilirubin, clinical improvement, possibility of stenting, less chances of expulsion and early initiation of chemotherapy. Keywords: Percutaneous transhepatic biliary drainage; Internal External Drainage; External Drainage; Palliation; Biliary obstruction

### Introduction

PTBD is a minimally invasive method of biliary decompression in which a peripheral biliary radicle is punctured followed by placement of catheter or stent for internal / external drainage of bile. As the patients with malignant biliary obstructions mostly present in an advanced stage, palliation becomes the only option. Percutaneous transhepatic biliary drainage was first carried out by Molnar et al,<sup>1</sup> in 1974, in the palliative treatment of malignant bile duct obstruction. Since

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then, PTBD with stenting has become one of the major palliative methods in such patients.<sup>2</sup>

There are two techniques in PTBD, when the catheter is placed proximal to the obstruction allowing the bile to drain externally into a bag, it is called External Drainage (ED). When the catheter is advanced beyond the obstruction into the duodenum allowing anterograde drainage into the duodenum as well, it is known as Internal External Drainage (IED). Our study was conducted with fifty patients undergoing PTBD in our institute to evaluate the therapeutic effect of PTBD in palliation of malignant obstructive jaundice as well as to compare between ED and IED with respect to their techniques, efficacy, complications and patient outcome.

### Materials and Methods

A prospective study was done at our institute between September 2016 and August 2017, 50 consecutive patients that were referred to us for PTBD were taken up and followed up.

*Institutional Ethics Committee:* Approval from institutional ethics committee obtained.

#### Inclusion criteria

FNA or Biopsy proved malignant biliary obstruction with-

Inoperable biliary obstruction Failed ERCP Preoperative distal biliary obstruction

#### **Exclusion Criteria**

Bleeding diathesis Massive ascites

#### Patient Preparation for biliary drainage procedure

**Preprocedural imaging** included Ultrasonography, this was usually followed by a CECT scan or an MRI with MRCP. This allowed us to determine the relevant anatomy, to define any aberrant biliary anatomy, consider any pitfalls during the procedure, and plan for the best site for approach and also for image guided FNA or Biopsy in some cases.

**Intravenous fluids** (2L of NS daily) started on the day of procedure as the patients are usually malnourished and dehydrated.

**Intravenous antibiotics**- Piperacillin/ Tazobactam 4.5 gm three times daily started on day of procedure. PTBD was done using standard techniques. USG guided puncture of biliary radicle was done by Arterial puncture needle or Chiba needle 18G followed by introduction of a 0.035 inch guidewire (Terumo) to gain access to the biliary system. If the guidewire could be manipulated beyond the obstruction to reach

the duodenum, IED was done. In the IED technique, the guidewire was followed by placement of 6F sheath and introduction of 5F KMP catheter over the guide wire to reach the duodenum, then exchanged by a stiff wire and KMP catheter removed. Finally PTBD catheter was deployed over the wire. If the obstruction could not be crossed, ED was done in the patient. This was done by serial dilatation of tract using fascial dilators followed by insertion of pigtail of malecot catheter (8F/10F).

Stenting was done in four cases in the same sitting and four cases one week after the IED technique. Stenting was done in the same sitting if the patient was stable, had no features of sepsis with normal total leukocyte counts. Otherwise, it was done one week later following control of sepsis, with antibiotics, and edema/ inflammation around the biliary radicles following decompression. Stenting was done with by Self Expanding Metallic Stents (SEMS) – Nitinol Stents (BARD)

**Post procedure,** immediate care included continuation of intravenous antibiotics, intravenous fluids for 48 hours, analgesics for pain and checking for signs of sepsis, bleeding. The patients were followed up by serum bilirubin estimation and clinical examination one week, two weeks and four weeks following PTBD. Statistical analysis was done using Unpaired t test on IBM SPSS 23.

### Results

Of the 50 patients included in the study, 34 cases were female (68%). Median age of the study group was 49.9 years, with youngest being 27 years and eldest age of 63 years. Maximum patients were in the 50-59 year age group - 18 cases.

Most common cause of malignant biliary obstruction in our study was gall bladder carcinoma - 22 cases (44%) followed by periampullary carcinoma - 13 cases (26%). Overall high technical success was achieved with biliary access and drainage being successful in 94% of cases.

External Drainage was done in 28 patients (56%), while the combined IED technique was done in 19 cases (38%). Stenting (SEMS) was performed in 8 patients following IED (16%), four patients in the

same sitting and four patients one week following IED.

Access to the biliary system was done with the left hepatic duct approach in 36 cases (72%), and via the right hepatic duct in 11 cases (22%).

Mean serum total bilirubin pre-procedure was 16.7mg/dl in ED group and 15.1 mg/dl in the IED group. Following IED mean bilirubin levels reduced to 4.9 mg/dl (reduction of 67%) one week post procedure, ED caused fall in mean bilirubin levels to 10.1 mg/dl (reduction of 39%) at the same time. Chemotherapy could be initiated in two patients following IED (10.5%) in one week. Comparing the two methods for fall in serum bilirubin using unpaired t-test showed a p value of 0.003 at one week, and p value of 0.05 at two weeks post procedure.

11 patients (22%) had some complication during or after procedure. Two patients (4%) had a major complication (sepsis) post procedure. Catheter expulsion occurred in 6% of patients.

Indication	Number of patients		
Gall bladder carcinoma	22		
Periampullary carcinoma	13		
Cholangiocarcinoma	11		
Metastasis	4		
Total	50		

Table 1: Indication for Procedure

Procedure	Mean Bilirubin	Post op 7 days	Post op 14 days	Post op 28 days
IED	15.1	4.9 (67% fall)	2.17	1.48
ED	16.7	10.1	2.56	1.52

Table 2: Serum bilirubin(mg/dl) trends on follow up

	Portal Fistula	Catheter Expulsion	Sepsis	Cath Block	Pneumo- thorax	IHBR collapse
ED	1	3		1		
IED	1		2			
Deferred	1				1	1

Table 3: Complications of the procedures







Figure 1(A,B,C): Image showing steps in IED with final placement of catheter in the duodenum

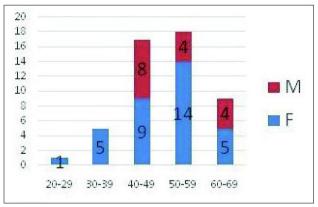


Figure 2: Distribution according to age groups





Figure 3(A,B): Case showing dilated biliary radicles and CBD with abrupt cut off. Obstruction could not be crossed and ED was done through left hepatic duct.

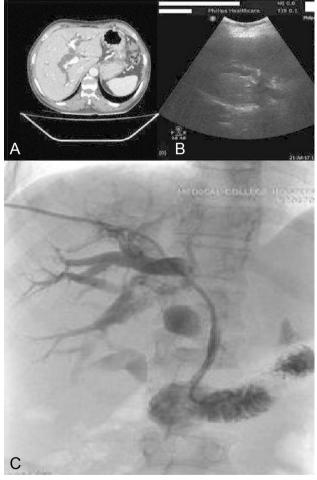


Figure 4(A,B,C): Case showing dilated biliary radicles in CECT, pre-puncture Ultrasound and finally placement of PTBD catheter. (IED done)

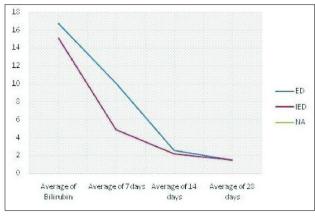


Figure 5: Bilirubin reduction trends in the two groups



Figure 6: Development of biliary portal fistula during puncture



Figure 7: Metallic stent deployed in patient following IED

### Discussion

Obstructive jaundice of malignant etiology can be caused by primary biliary carcinomas, such as gall bladder carcinoma, cholangiocarcinoma, and extra biliary carcinomas, such as periampullary carcinoma, hepatocellular carcinoma and metastasis. Most of the cases of malignant biliary obstructions are advanced by the time they are diagnosed and palliation becomes the only option left. PTBD, which has been practiced for some decades now has emerged as a safe way of palliation in such a patient group.3,4,5 PTBD can be used in obstructive jaundice for relief of cholangitis, pain, pruritus, to decrease serum bilirubin before the initiation of chemotherapy, to access biliary system for further palliative interventions such as stent placement or trans hepatic brachytherapy for cholangiocarcinoma.<sup>6</sup> Hyperbilirubinemia impedes the initiation/continuation of chemotherapy in certain malignancies. Pruritus, pain and anorexia deteriorate the quality of life which may be relieved by biliary drainage.

There are two techniques in PTBD. External drainage is a relatively simple, cheap easier technique, here the catheter is placed proximal to the obstruction and bile drains outside in a collection bag. This technique can be performed under ultrasound guidance alone even in rural areas and does not require high technical skill or expensive fluoroscopy/DSA suite. In the IED method, the obstruction is crossed using guidewire and finally catheter is placed in the duodenum.<sup>7</sup> IED allows for the natural enteric drainage as well, however this method requires a fluoroscopy system and a higher technical skill which can be available in a tertiary hospital/medical college like our institution.

Our study showed a female predilection for malignant biliary diseases, the majority of patients in our study being in the middle ages (50-59 years). Gall bladder carcinoma was the most common etiology, followed by periampullary carcinoma. There is a high incidence of gall bladder carcinoma in our population in the subcontinent,<sup>8</sup> although pancreatic carcinoma is the most common cause of biliary obstruction worldwide.

Access to the biliary system and drainage was successful in 47 cases (94%), this is on par with the success rate reported worldwide being in 90-95%.

External Drainage was done in 28 patients (56%),

while the combined IED technique could be done in 19 cases (38%). There are few technical difficulties for which IED could not be done. It is essential to identify the common bile duct and bypass the obstruction for IED, which is not always possible. Severe obstruction makes it impossible to manipulate the guidewire beyond the obstruction with the wire coiling up proximal to it.

Patients in the IED group showed rapid reduction of bilirubin at one week following procedure (67% reduction; p= 0.003) compared to ED group (34% reduction), which was statistically significant. IED patients showed faster relief of symptoms such as pruritis, pain and jaundice. Due to the comparatively rapid reduction in bilirubin levels, early chemotherapy could be started in 2 patients in the IED group, but no such patients in the ED group. Figure V shows quick downslope of the curve due to rapid fall in bilirubin levels in the IED group.

Although with increased expertise and better instrumentation, complication rates of PTBD have reduced in recent years,<sup>9</sup> certain major and minor complications can occur. They include pain, catheter block, catheter expulsion, hemothorax, hemoperitoneum, subcapsular hepatic hematoma, biliary peritonitis, hemobilia pneumobilia, injury to portal vein / hepatic artery / hepatic vein, biliary portal fistula.<sup>10</sup>

With the exception of pain, some complications were encountered in 22% of patients. In our group, we had 3 cases of catheter expulsion. All catheter expulsions occurred in cases of ED. This is most likely due to poor anchorage in this method and the patient during his daily activities may inadvertently tug the catheter leading to its dislodgement. It is also important to have correct catheter fixation to the skin as they are subject to the effects of movement of the liver during respiration. When the catheter is fixed too tightly at the skin entry, it cannot move in and out, and it tends to dislodge out of the liver as the patient breathes and forms a loop between the liver capsule and the abdominal wall. If the catheter migrates and injures a vein it may also lead to bleeding, hence a slack of 2 cm while suturing the catheter to the skin is recommended.

Two cases of sepsis occurred in the IED group. Although exact cause is unknown, it can occur due to three possible causes - retrograde infection of intestinal flora, infection tracking along the drainage catheter, or may be due to hematogenous spread.<sup>11</sup> As a patient of malignant obstruction is sick with weakened immune status, an invasive procedure increases the risk for further infection.<sup>12</sup> The patients with sepsis were managed with intravenous antibiotics and strict monitoring. ED maybe a better choice to reduce the chances of sepsis post procedure.<sup>13</sup>

A case of pneumothorax occurred due to puncture of pleura during procedure which was managed conservatively. There was no procedure related mortality in our study group.

In 8 patients, further stenting was done after IED. Stenting is done as a staged procedure as this allows the cholangitis, sepsis, edema of the biliary channels to subside. The IED method allows for stenting as the obstruction has already been crossed by the catheter.14 We used metallic stents in our cases as it has a better patency rate with regard to patient survival.<sup>15</sup> The mean stent patency rates is reported to be around six months.<sup>15</sup> In our study, four of the eight patients with stent could be followed up at four months. Stent patency was maintained in the four patients. Post successful stenting, the PTBD catheter is removed thus alleviating any further catheter related complications that can occur. If there is occlusion of stent due to tumor ingrowth, then another stent or external/internal drainage catheter can be placed through it. The use of metallic stents has been recommended for the palliation of malignant biliary obstructions.<sup>15</sup> The IED method also allows for intra luminal brachytherapy(ILBT) to be given to such patients. PTBD followed by ILBT has been shown to be a feasible procedure with good symptom control, definite impact on quality of life, and minimal complications.

**Limitations:** This study is done using a small number of patients followed up over a short period of time. A larger group followed up over a long time might assess the benefits and complications of the two techniques more accurately. As this is not a survival study, long term survival benefits of IED over ED, if any, is not assessed.

## Conclusion

In the role of Interventional Radiology in management of malignant biliary obstructions, PTBD has emerged

as a very safe and effective means of palliative biliary decompression and offers an improvement in the quality of life in such patients. It is the only method of biliary obstructions in case of high obstructions and failed ERCP. Although it requires experience and understanding of individual patient's anatomy and their limitations, PTBD has a high overall technical success rate.

ED is a cheap, simple technique which can be done using ultrasound only even in rural areas. However, it leads to less rapid reduction in serum bilirubin level, increased chance of catheter dislodgement. The IED technique offers rapid clinical and biochemical improvement, better catheter placement duration, and earlier initiation of chemotherapy, scope for further stenting as well as opportunity of intraluminal brachytherapy. But it is more expensive, requires a fluoroscopy unit, and has a steeper learning curve and increase chances of biliary sepsis. Although the long term prognosis is dismal in such patients due to the relentless growth of the primary, owing to its rapid relief of biliary obstructions, guicker relief of symptoms such as pruritus and pain, opportunity for stenting and earlier initiation of chemotherapy, IED with stenting seems to offer a better improvement in the quality of life and is a very safe and effective intervention for palliation.

Conflict of Interest: There are no conflicts of interest.

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