Original Research Paper

Volume - 11 | Issue - 04 | April - 2021 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

Radiodiagnosis

"VARIOUS APPROACHES OF PERCUTANEOUS TRANSHEPATIC BILIARY DRAINAGE IN MALIGNANT BILIARY OBSTRUCTION AND THEIR CORRELATION WITH PATIENT CLINICAL AND BIOCHEMICAL OUTCOME"

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ABSTRACT **Background:** Common cause for malignant obstructive jaundice is Primary bile duct cancers[1] (Cholangiocarcinoma) Pancreatic carcinoma, Gall bladder carcinoma, Ampullary carcinoma, Duodenal carcinoma and secondary lymphadenopathy causing occlution at porta hepatis due to metastatic colonic and stomach cancers. Initial sign of presentation may be classic progressive painless jaundice and leads to progressive hepatic failure. Biliary drainage helps in improving the quality of life and reduces morbidity associated with the diseases. **Material and Method:** Percutaneous trans hepatic biliary drainage was done in 42 patients with malignant obstructive jaundice with bilateral IHBR dilatation, 23 patients (54.8%) Left sided and 19 (45.2%) Right sided approach with 6Fr biliary catheter and patient clinical and biochemical outcome were correlated. **Results:** All patients feel significant improvement in the symptoms which was statistically significant. There is a significant association between Pain scale and the side of the approach. Major, minor complications and reprocedure rates were more common on right sided than left approach but no statistical significant. **Conclusion:** Our study shows that PTBD causes significant reduction in the bilirubin level, irrespective of the side of approach (Left/ Right sided approach) or the type of drainage (external/internal). The reduction in bilirubin, SGOT and SGPT was more in the right sided approach compared to left sided approach but no statistically significant. Both minor and major complications are more common in right sided approach as compared to left sided approach. Percutaneous management of malignant biliary obstruction is a well-established method of treatment. Appropriate pre-procedure planning and interdisciplinary discussions are required for optimal patient management.

KEYWORDS : Percutaneous Transhepatic Biliary Drainage, Obstructive Jaundice, Malignant Biliary Obstruction.

INTRODUCTION:

Obstruction of bile flow causes debilitating symptoms such as severe pruritus, malabsorption, occasionally cholangitis and progressive hepatic failure and thus treatment is often recommended on this basis alone. Both cholangiocarcinoma and pancreatic cancers are notorious for presenting at the advanced stage in which immediate surgery is contraindicated [2]. Drainage of 25%-30%[3] of normal liver is adequate for improvement of jaundice and liver functions.

Both Endoscopic Retrograde Cholangio Pancreatography (ERCP) and Percutaneous Transhepatic Biliary Drainage (PTBD) are well established in palliation of unresectable cases. PTBD is preferred in cases of proximal and distal biliary obstruction however ERCP is usually performed in cases of distal common bile duct (CBD) obstruction beyond the hilum [4,5] in which after retrograde cholangiography is performed to localize the site of obstruction, the guide wire is maneuvered through the biliary obstruction followed by a catheter and endoprosthesis is placed. In recent times uses of these minimally invasive procedures has significantly increased due to higher success rates over surgical procedures.

The advantages of ERCP technique includes lesser pain, absence of discomfort caused by external catheter due to irritation and lower incidence of biliary peritonitis. But Pancreatitis is the main complication of this procedure. Also incidence of cholangitis is higher in ERCP when compared with percutaneous treatment (PCT) where some segments are non-drainage especially in cases of hilar obstructions.

The key purpose of biliary interventions in MBO patients is to decompress the obstructed biliary system and if possible to develop a communication between the biliary tree and the bowel allowing physiological enterohepatic circulation of bile flow.

MATERIALS AND METHODS:

Study design: It is an Interventional study conducted in the department of Radiodiagnosis at Government Stanley Medical College and Hospital, Chennai. The study was conducted for a period of one and half years after the approval of ethical committee between May 2019 and October 2020.

Subjects: The study group includes 42 patients with malignant obstructive jaundice with bilateral IHBR dilatation from the Surgical Gastroenterology Ward were included. Written consent was obtained from all the participants before the study.

Inclusion criteria: Patients of malignant obstructive jaundice not amenable to surgical treatment (inoperable), those requiring decompression of bile duct before going for definitive surgery and Unresectable malignant tumour with failed ERCP.

Exclusion criteria: Patients with preferential left / right sided IHBR dilatation, significant ascites, advanced cirrhosis and Uncorrected coagulopathy were excluded from the study.

PLANNING OF INTERVENTION

Imaging: Prior to the initiation of procedure, three dimensional cross sectional imaging, i.e., (computed tomography or magnetic resonance imaging ± magnetic resonance cholangiopancreatography) of patients were reviewed to identify the dilated ducts and the level of obstruction for the consideration of a target.

Laboratory analysis: Evaluation of the patient's coagulation profile, liver, and kidney functions were accessed.

Patient preparation: The patients were asked to be in nil per oral before the procedure along with good intravenous access. Informed consent was taken from each patient. Monitoring of vital signs (blood

pressure, pulse, and oxygenation status) was done during and after the procedure. The procedure is done with the patient in supine position, under strict aseptic precautions, after giving local anaesthesia (lignocaine 2%), under ultrasound guidance attempt was made to puncture the dilated bile duct. Site of puncture was decided after preliminary ultrasound.

Procedure: The skin area, depending on whether the right (11th intercostal space in the mid axillary line) or left (three finger breadths below the xiphoid) sided approach is cleaned and draped. Under ultrasonography guidance the sectoral duct (usually segment 3 for left side or segment 6 for right sided approach) is punctured by 18G Chiba needle, using at approximately 1-3 cm away from the secondary biliary confluence.

Once there is free backflow of bile, a 0.032/0.035 inch soft "J" tip guide wire is passed through the needle, which is then exchanged for a 5F or 6F dilator followed by removal of the guidewire. Cholangiogram is performed slowly to define the biliary anatomy and type of obstruction.

The dilator is exchanged for a biliary manipulation catheter or an angled tip angiographic catheter over the wire. When the catheter tip is at the site of obstruction, attempt is made to manipulate the soft hydrophilic guidewire (either straight or "J" tip) to cross the stricture. Once the wire is across the stricture and in the duodenum, the catheter is pushed over the wire into the duodenum. Then an 6Fr Internal-External drainage catheter (Ring biliary catheter) is positioned across the stricture and the position is confirmed with contrast injection. In patients where initial attempt to cross the stricture fails, an external drainage catheter is left with tip proximal to the obstruction and internalization is attempted after a gap of two-four days.

This two-step procedure frequently facilitates reduction of inflammation and edema and enhances the likelihood of negotiate the obstruction.

As the free flow of bile is noted, Proximal end is kept in the drainage bag. To Flush the catheter with 10ml of distilled water every day when bag is emptied is advised.

Table 1: Comparison between Right and Left sided PTBD approach

S NO	FEATURES	RIGHT SIDED APPROACH	LEFT SIDED APPROACH
1	Patients comfort	Painful, restricted patient movement	Less painful, increased patient comfort
2	Technical ease of puncture	Difficult	Easy
3	Associated risk	Pleural transgression, injury to intercostal neurovascular bundle, Accident slippage due to constant motion	Less segments of liver is covered
4	Radiation exposure	Less radiation to the operator	Higher radiation exposure to operators hands
5	Preferred duct	Anterior sectoral duct	Segment three duct antero-inferior to segment two duct
6	Puncture site	Below 10th rib at the mid axillary line	Subxiphoid or substernal
7	Imaging guidance for puncture	Blind puncture with fluoroscopic guidance	Ultrasonographic guidance

Statistical Analysis:

Table 2: Age distribution of study patients

Age Distribution		
	Frequency	Percent
Up to 30 yrs	1	2.4
31-40 yrs	2	4.8
41-50 yrs	7	16.7
51-60 yrs	13	31
61-70 yrs	14	33.3
71-80 yrs	5	11.9
Total	42	100
Mean ± SD = 59 ± 12 yrs		

Table 3: Gender distribution of study patients

Gender distribution		
	Frequency	Percent
Female	18	42.9
Male	24	57.1
Total	42	100

Table 4: Distribution of study patients according to diagnosis

Diagnosis		
	Frequency	Percent
Carcinoma Gall bladder	13	31.0
Hilar Cholangio carcinoma	17	40.5
Periampullary carcinoma	5	11.9
Carcinoma stomach with metastasis	6	14.3
Carcinoma colon with metastasis	1	2.4
Total	42	100.0

Table 5: Procedure comparison and Re procedure rates

Side of approach	Drainage type	Re - Procedure
Right 19 (45.2%)	Internal and External 28 (66.7%)	Yes 7 (16.6%)
Left 23 (54.8%)	External only 14 (33.3%)	No 35 (83.4%)
42 (100%)	42 (100%)	42 (100%)

Table 6: Comparison of Bilirubin and ALP reduction with PTBD Approach

Side of approach		N	Bilirubin			ALP		
			Mean	S.D	P value	Mean	S.D	P value
Pre	Right	19	14.7	4.5	0.763	855.0	272.1	0.717
	Left	23	15.1	4.5		888.2	308.4	
Day 1	Right	19	10.1	3.7	0.343	577.9	166.3	0.169
	Left	23	11.2	3.5		659.9	205.3	
Day 3	Right	19	6.1	13.5	0.392	428.6	129.2	0.100
	Left	23	7.4	2.2		513.4	184.7	
Unpaired t-test - Highly Significant at $p < 0.01$, Significant at $p < 0.05$ and No Significant at $p > 0.05$								

Table 7: Comparison of SGOT and SGPT reduction with PTBD Approach

Side of approach		N	SGOT			SGPT		
			Mean	S.D	P value	Mean	S.D	P value
Pre	Right	19	101.8	33.8	0.331	82.2	30.0	0.341
	Left	23	112.8	37.7		91.0	29.5	
Day 1	Right	19	69.5	13.4	0.042	60.5	16.8	0.107
	Left	23	82.7	24.5		70.3	21.0	
Day 3	Right	19	51.9	10.8	0.088	45.7	12.6	0.053
	Left	23	62.1	12.5		54.0	14.2	
Unpaired t-test - Highly Significant at $p < 0.01$, Significant at $p < 0.05$ and No Significant at $p > 0.05$								

Table 8: Comparison between Pain scale with Approach

Pain scale		Approach		Total
		Right	Left	
None	Count	2	17	19
	%	10.5%	73.9%	45.2%
Mild	Count	3	5	8
	%	15.8%	21.7%	19.0%
Moderate	Count	7	1	8
	%	36.8%	4.3%	19.0%
Severe	Count	7	0	7
	%	36.8%	0.0%	16.7%
Total	Count	19	23	42
	%	100.0%	100.0%	100.0%

Table 9: Comparison between post procedural Fever with side of Approach

Fever		Approach		Total
		Right	Left	
Yes	Count	3	1	4

	%	15.8%	4.3%	9.5%
No	Count	16	22	38
	%	84.2%	95.7%	90.5%
Total	Count	19	23	42
	%	100.0%	100.0%	100.0%

Table 10: Comparison between Pericatheteral leak with side of Approach

Pericatheteral leak		Approach		Total
		Right	Left	
Yes	Count	2	0	2
	%	10.5%	0.0%	4.8%
No	Count	17	23	40
	%	89.5%	100.0%	95.2%
Total	Count	19	23	42
	%	100.0%	100.0%	100.0%

DISCUSSION:

Patients who underwent PTBD in our study were in the age group of 27-85 years. Most of the patients fell in age group of 47-71 years with mean age of 59 years with 18 (42.9%) of them being females & 24 (57.1%) are males.

After taking proper history, clinical examination & required investigations, the diagnosis was established. Most of the patients with obstructive jaundice had Hilar cholangiocarcinoma (40.5%), followed by Gall bladder carcinoma (31%) and Periampullary carcinoma (11.9%). Some patients with carcinoma of stomach and colon with metastasis. Level of obstruction identified were 38.1% at hilum, 31.0%, CHD, 11.9% distal CBD, 9.5% CBD, 7.1% CD CHD junction and 2.4% at mid CBD. After checking & correcting the coagulation profile of the patient, Side of approach was determined of which 23 patients (54.8%) Left sided and 19 (45.2%) Right sided PTBD was done. For 2 patients (4.8%) emergency PTBD was done under USG guidance and for 40 (92.5%) patients under Fluroscopic guidance 6 Fr. pig tail catheter was inserted in the most prominent biliary duct & properly fixed with silk suture in all patients. For 28 patients (66.7%) we were able to manipulate across the obstruction internalisation was done with 6Fr 45cm catheter. Internalisation was done for 17 patients out of 23 patients through Left sided approach and 11 patients out of 19 patients through Right sided approach. For 14 patients (33.3%) only Externalisation of catheter was done with 6Fr 30cm catheter. Technological success (successful deployment of external/internal drainage catheter) rate was 100% in both side approaches. Van Delden OM et al. found that technical success of PTBD has been more than 90% [6].

Liver function tests of the patient were done with emphasis on Serum bilirubin, Serum glutamic oxaloacetic transaminase, Serum glutamic pyruvic transaminase & Serum alkaline phosphatase. Preprocedure values were compared with values on first and third postoperative days. Patients were asked about the symptoms of pruritus, nausea before & after intervention and Post procedure pain, fever and pericatheter leak.

There was a reduction in serum bilirubin, SGOT, SGPT and ALP levels after the procedure in both the approaches, but the decrease was more in the right-sided approach.

SERUM BILIRUBIN: Mean fall in Serum Bilirubin was 4.6mg% on right sided approach and 3.9 mg % on left sided approach on Postoperative day 1 and 4mg% on right sided approach and 3.8mg % on left sided approach on Postoperative day 3. The fall was No Statistical Significance at $p > 0.05$ level between the left and right sided approach.

S.G.O.T: The mean value of S.G.O.T fall after intervention was 32.3 and 30.1 on Day 1 and 17.6 and 20.6 on Day 3 between right and left sided approach respectively which shows statistical significant difference.

S.G.P.T: The mean value of S.G.P.T before intervention for right and left sided approach was 82 and 91 & after intervention was 60.5 & 70.3 on day 1 and 45.7 & 50.4 on day 3 respectively. Although fall was seen in most patients, but no statistical significant difference at $p > 0.05$ level.

SERUM ALKALINE PHOSPHATASE: Mean fall in Serum Alkaline Phosphatase was 278 IU/L and 150IU/L on right sided approach and 228 IU/L and 147IU/L on left sided approach on Postoperative day 1 and Postoperative day 3 respectively with No Statistical Significance. Most of the patients had improvement in both pruritus & nausea. All patients feel significant improvement in the symptoms, the improvement was statistical significant.

In left sided approach, 5 patients had mild and 1 patient had moderate pain. In right sided approach, 3 patient had mild, 7 patients had moderate and 7 patients had severe pain which shows highly statistical significant association between Pain scale and side of Approach.

Totally 4 patients out of 42 patients had postoperative fever of which 3 patients from right and 1 patient from left sided approach which shows no statistical significant association between Fever and side of approach. Patients with fever responded well to broad spectrum antibiotics.

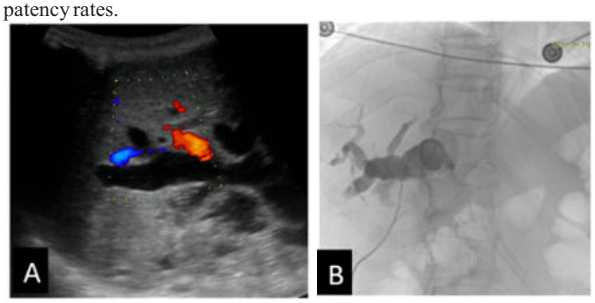
Kloek et al. found 48% infection rate with endoscopic biliary drainage and 9% with PTBD [7] which was 9.5% in our study. **Daniel Knap et al.** observed hemobilia (3.2%) was most common immediately postprocedure complication, which was not found in our study [8]. Re-procedure was done for 7 patients out of 42 patients in our study of which 4 patients from Right sided and 3 patients from Left sided approach which shows no statistical significant association between Re-Procedure and sided approach.

Pericatheter leak was seen in 2 patients from right sided approach. In two patients with pericatheter leak, catheter upsize to 10F was done in one patient and another patient had relief after drainage of ascites. The minor complications were not statistically significant in both the groups ($p > 0.05$). There was no procedure related death in our study. Two patients with minimal blockage of catheter responded to saline flushes. One patient with dislodgement of catheter underwent re-intervention for placement of ring biliary catheter. The major complications were also not statistically significant in both the groups ($p > 0.05$). **Turkington et al.** observed 3.3% of patients had pleural complications with bilious effusion called "bilothorax" or "cholethorax" on right side approach, because posteriorly the pleural reflections end at the level of L1[9]. No one from our study had biliothorax on right sided approach. **Hong et al.** suggests that although stent patency rate is better with bilateral drainage but there is no significant difference between the two in terms of technical success rate, complications or patient survival [10], in our study bilateral drainage was not done.

LIMITATIONS: PTBD can definitely improves quality of life in patients with malignant obstructive jaundice, however it could not prolong the survival time because of high mortality rate in these patients and fast progression of the underlying disease. Nevertheless, the deleterious effect of pruritus on quality of living can be eliminated by drainage of the biliary ducts.

CONCLUSION: PTBD causes a significant reduction in the bilirubin level, irrespective of the side of approach (Left/ Right sided approach) or the type of drainage (external/internal). In our study, the reduction in bilirubin, SGOT and SGPT was more in the right sided approach compared to left sided approach but no statistically significant. Both minor and major complications are more common in right sided approach as compared to left sided approach.

Percutaneous management of malignant biliary obstruction is a well-established method of treatment. Appropriate pre-procedure planning and interdisciplinary discussions are required for optimal patient management. A complete knowledge of the available techniques, success rates and risk of complications is needed for successful procedure. Further developments in intraluminal treatments for the malignancies would potentially improve the survival and long term patency rates.



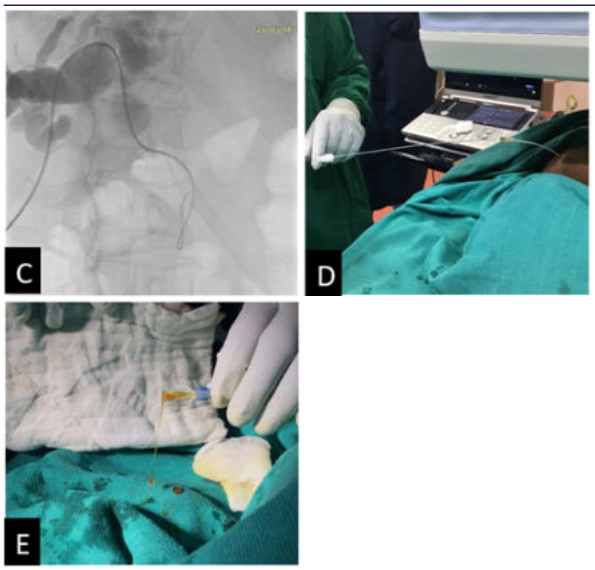


Figure 1: A. Ultrasound B. Fluoroscopic images showing dilated biliary radicles in patient with Hilar Cholangiocarcinoma, C& D. Right sided Internal and Externalisation of Biliary catheter done. E. Free flow of bile

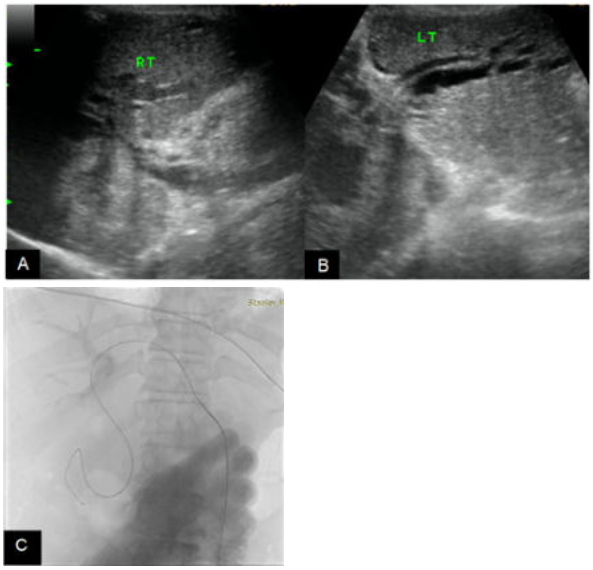


Figure 2: A, B. Ultrasound images showing dilated biliary radicles (Left> Right) in a patient with Carcinoma Gall Bladder Infiltrating CHD. C. Fluoroscopic images showing Left Sided Internal and Externalisation of Biliary catheter done.

Abbrevations: CBD- Common bile duct, CD- Cystic duct, CHD- Common Hepatic Duct, ERCP- Endoscopic Retrograde Cholangio Pancreatography, Fr- Fringe, G- Gauge, MBO- Malignant Biliary Obstruction, PTBD- Percutaneous Transhepatic Biliary Drainage, SGOT- Serum Glutamic Oxaloacetic Transaminase, SGPT- Serum Glutamic Pyruvic Transaminase.

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