## **Original Research Article**

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# Management of extra hepatic biliary obstruction, in a rural tertiary care hospital India

Divyanshu Joshi<sup>1</sup>, Y. P. Monga<sup>1\*</sup>, Shashank Mishra<sup>1</sup>, Rani Bansal<sup>2</sup>, Sachin Agrawal<sup>3</sup>

<sup>1</sup>Department Of General Surgery, <sup>2</sup>Department of Pathology, <sup>3</sup>Department of Radio Diagnosis, SMC, Meerut, India

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# \*Correspondence: Dr. Y. P. Monga,

E-mail: mongayash@yahoo.co.in

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#### **ABSTRACT**

**Background:** Extra hepatic biliary obstruction (EHBO) is not a rare surgical problem; our experience in managing 36 patients over a period of two years at a tertiary care hospital in a rural setting in India. The objective was to study the etiology and clinical presentation of patients with EHBO, role of various investigative modalities and management strategies in these patients and their outcome.

**Methods:** This was a prospective study conducted between September 2018 to August 2020 in the department of surgery in tertiary care center Subharti medical college (SMC) Meerut. Data was taken in a pre-formed performa and the results were tabulated and analyzed (descriptive analysis).

**Results:** Out of 36 patients, 2 (5.5%) patients underwent choledochoduodenostomy, 1 (2.7%) exploratory laparotomy with CBD exploration with t tube drainage, 1 (2.7%) ERCP with pigtail drainage; 17(47.2%) ERCP (endoscopic retrograde cholangiopancreatography) followed by cholecystectomy, 1 (2.7%) open cholecystectomy with t tube drainage, 4 (11.1%) ERCP alone, 2 (5.5%) hepaticojejunostomy, 1 (2.7%) ERCP followed by diverticulectomy, 2 (5.5%) PTBD (percutaneous transhepatic biliary drainage) followed by a triple bypass surgery, 2 (5.5%) PTBD, 1 (2.7%) pylorus preserving pancreaticoduodenectomy, 1 (2.7%) ERCP with sphincterotomy, 1 (2.7%) PTBD followed by whipples procedure. Patients were followed up and 5 (13.8%) patients had recurrence of the disease.

**Conclusions:** EHBO is a hepatobiliary surgical condition caused by both neoplastic and non-neoplastic etiology. Benign pathologies common in younger patients whereas neoplastic conditions in older age. Ultrasonography is the most common investigative modality followed by ERCP with PTBD/ENBD playing an important role in decompression of biliary obstruction as a palliative measure in advanced malignancies.

Keywords: CBD, EHBO, Jaundice, ERCP, PTBD

#### INTRODUCTION

EHBO encompasses all those etiological conditions/diseases which cause obstruction of the biliary tree from its beginning in the liver till the opening in the duodenum. Patient most commonly present to the hospital with yellowish discoloration of the skin, abdominal pain. EHBO management in a resource limited rural tertiary care hospital is still a grey area in India. EHBO is one of the most common hepatobiliary surgical

conditions managed by general surgeons and hepatobiliary surgeons. The condition can be caused by either benign or malignant conditions.<sup>1</sup>

Benign pathologies which occur relatively more in younger patients include biliary stones (choledocholithiasis), benign biliary strictures (iatrogenic or sclerosing), parasite infestations (ascaris, liver flukes and hydatid cysts). Malignant causes of EHBO include pancreatic head tumors, tumors of the biliary tree, tumors

of the second part of the duodenum, ampulla of Vater tumors and others. $^2$ 

The symptoms include pain abdomen, yellowish discoloration of skin, urine and clay coloured stools. Itching is also one of the symptoms of the patient. Tenderness is a common sign in the abdomen but in malignant (neoplastic) causes of EHBO it is more of a painless progressive jaundice with or without a per abdominal mass and loss of weight.<sup>3,4</sup>

#### Laboratory investigations

Laboratory investigations such as liver function test, in which serum total bilirubin is raised with raised direct bilirubin and alkaline phosphatase levels. Serum amylase and lipase are also done to rule out patients with pancreatitis.<sup>5,6</sup>

Imaging modality ultrasonography (US)

Abdominal US is valuable as an initial investigation and for differentiation of patients with these presentations. Colour Doppler sonography CDS is a noninvasive method in liver hemodynamic studies.

Computed tomography (CT)

Although CT is useful in patients with obstructive biliary disease, axial CT is not an effective method of demonstrating biliary anatomy.

Direct cholangiography

Although sonography and CT are sensitive in detecting biliary tract obstruction, direct cholangiography including percutaneous transhepatic cholangiography (PTC) and ERCP remains the standard procedure to delineate the presence and level of biliary obstruction.<sup>7-9</sup>

*Magnetic resonance cholangiopancreatography (MRCP)* 

It completely avoids the formidable complications inherent to conventional cholangiographic examinations. Both primary liver tumors and dilatation of the biliary system could be demonstrated in MRCP.<sup>10</sup> The type of treatment for EHBO can be minimally invasive procedures or open surgery depending on the diagnosis and the hospital setting.<sup>11</sup>

In a well-developed country, interventions like laparoscopy, transesophageal ultrasonography and ERCP are the main modality of treatment. However, in a resource limited country like India where patient affordability is one of the main factors for the type of intervention that can be done in a tertiary care setting. In both neoplastic and non-neoplastic conditions minimally invasive and open surgical techniques prevail. As neoplastic conditions are often diagnosed at an advanced stage when the patient visit the hospital for a complain of

pain and abdomen or yellowish discoloration of skin very few operative procedures can be undertaken and mostly palliative surgery is done.

#### **METHODS**

This was a prospective study conducted between September 2018 to August 2020 in the department of surgery in tertiary care center Chhatrapati Shivaji Subharti medical college Meerut. Data was taken in a preformed performa and the results were tabulated and analyzed. Ethics committee registration no. was SMC/IEC/2018/613049.

The data that was collected was checked for correctness, entered and coded and was analyzed with SPSS version 2.1.

#### Inclusion criteria

All patients with obstructive jaundice due to EHBO as diagnosed by deranged liver function tests, USG, whole abdomen, CECT, whole abdomen, ERCP/MRCP and patients giving informed consent were included in the study.

#### Exclusion criteria

Patients with obstructive jaundice due to intra-hepatic calculi, patients with haemolytic and hepatocellular jaundice, patients who did not complete the follow up (abscond\expired) and patients who did not give informed consent were excluded from the study.

#### Sample size

Study included a sample of 36 participants calculated using the formula,

Sample size (N)=
$$\frac{Z^2 P (1-P)}{d^2}$$
,

where,

$$Z^2P = Z^{\frac{0.05}{2}} = 1.96 = 2$$
 (from Z table),

n is the sample size,

Z is the statistic corresponding to level of confidence,

P is expected prevalence (that can be obtained from same studies or a pilot study conducted by the researchers),

d is precision (corresponding to effect size).

Relevant data was obtained using detailed history and thorough clinical examination, hematological investigations, complete hemogram, liver function tests including serum alkaline phosphatase, serum proteins and albumin, blood urea and serum electrolytes. Radiological investigations were done like US abdomen and CECT abdomen. MRCP and ERCP to assess pathology of biliary tree whenever required. Any other special investigation was done if required. intervention/radiological intervention was done for the management of the disease. Histopathological examination of the tissue specimen from patients who underwent surgery/ERCP/pre-op lymph node biopsy. Follow up of the patients was done for 1st week, 2nd week, 1st month, 2nd month and third month.

#### **RESULTS**

Out of 36 patients 18 (50%) were diagnosed as a case of cholelithiasis with choledocholithiasis. 5 (13.8%) of the patients were diagnosed as carcinoma gallbladder. 2 (5.5%) were diagnosed as case of cholelithiasis with

choledocholithiasis with pancreatitis. 2 (5.5%) patients with CBD stricture.

1 (2.7%) patient of cholangiolar abscess with CBD stricture, 2 (5.5%) patients of cholangiocarcinoma, 1 (2.7%) patient of lemmel syndrome, 3 (8.3%) patient of periampullary carcinoma and 2 (5.5%) patients of choledochal cyst (Table 1).

Patient were followed up for 3 months.

Non-malignant causes of EHBO were in the age group of 21-40 years of age and neoplastic causes were in older age group.

In this study, 11 (30.5%) out of 36 patients were male while 25 (69.4%) were female (Table 2).

Table 1: Diagnosis in pathological conditions (N	=36).
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Pathology	Diagnosis	Frequency	Percentage
	CBD stricture	2	7.7
	CBD stricture with cholangiar abscess	1	3.8
<b>N</b> T	Choledochal cyst	2	7.7
Non neoplastic	Cholelithiasis with choledocholithiasis	18	69.2
пеоріаѕис	Cholelithiasis with choledocholithiasis with pancreatitis	2	7.7
	Lemmel syndrome with CBD entrapment	1	3.8
	Total	26	100
Neoplastic	Carcinoma gallbladder	5	50
	Cholangiocarcinoma	2	20
	Periampullary carcinoma	3	30
	Total	10	100

Table 2: Age and gender in pathological conditions (N=36).

Parameters	Non neoplastic (%)	Neoplastic (%)	Total (%)
Age groups (in years)			
21 to 30	10 (38.5)	0 (0)	10 (27.8)
31 to 40	8 (30.8)	1 (10)	9 (25)
41 to 50	2 (7.7)	3 (30)	5 (13.9)
51 to 60	4 (15.4)	1 (10)	5 (13.9)
>60	2 (7.7)	5 (50)	7 (19.4)
Total	26 (100)	10 (100)	36 (100)
Gender			
Male	4 (15.4)	7 (70)	11 (30.6)
Female	22 (84.6)	3 (30)	25 (69.4)
Total	26 (100)	10 (100)	36 (100)

Table 3: HPE in neoplastic condition (before surgery) (N=10).

Pathology	HPE	No. of patients	Percentage
	Adenocarcinoma (L. N.)	4	44.4
	Intestinal type of periampullary carcinoma	1	11.1
Naanlastia	Metastatic adenocarcinoma (L. N.)	2	22.2
Neoplastic	Poorly diff adenocarcinoma (L. N.)	1	11.1
	Adenocarcinoma (biopsy)	1	11.1
	Total	9	100

Table 4: Management was done in neoplastic and non-neoplastic (N=36).

Pathology	Diagnosis	N (%)	Surgery	N (%)
			Choledochoduodenostomy	1 (3.8)
	CBD stricture	2 (7.7)	Exploratory laparotomy with CBD exploration and t tube drainage	1 (3.8)
	CBD stricture with cholangiar abscess	1 (3.8)	ERCP with pigtail drainage	1 (3.8)
	Cholelithiasis with		ERCP f/b cholecystectomy	17 (65.4)
Non neoplastic	choledocholithiasis	18 (69.2)	Cholecystectomy with CBD exploration with t tube drainage	1 (3.7)
	Cholelithiasis with choledocholithiasis with pancreatitis	2 (7.7)	ERCP	2 (7.7)
	Choledochal cyst	2 (7.7)	Choledochoduodenostomy	1 (3.8)
	Choledochai cyst 2 (7.7)	2 (1.1)	Hepaticojejunostomy	1 (3.8)
	Lemmel syndrome with CBD entrapment	1 (3.8)	ERCP f/b diverticulectomy	1 (3.8)
	Total	26 (100)	Total	26 (100)
	Carcinoma gallbladder	5 (50)	ERCP	2 (20)
			Hepaticojejunostomy	1 (10)
			PTBD with triple bypass	2 (20)
	Cholangiocarcinoma	2 (20)	PTBD	2 (20)
Neoplastic	Periampullary carcinoma	3 (30)	Pylorus preserving pancreaticoduodenectomy	1 (10)
			ERCP with sphincterotomy	1 (10)
			PTBD with pancreaticoduodenectomy	1 (10)
	Total	10 (100)	Total	10 (100)

Table 5: Descriptive analysis of ERCP in the study population (N=27).

ERCP	Frequency	Percentage
Stent placed	19	70.4
Stent placed with sphincterotomy	7	25.9
Visible mass at ampulla of vater stent not passed brush biopsy taken.	1	3.7
Total	27	100

Table 6: Follow up with or without recurrence between non-neoplastic and neoplastic (N=36).

Follow up with or without recurrences	Non neoplastic	Neoplastic	Total
1 week			
Fever	0 (0)	2 (20)	2 (5.6)
Pain abdomen and fever	0 (0)	1 (10)	1 (2.8)
SSI	2 (7.7)	1 (10)	3 (8.3)
No symptoms	24 (92.3)	6 (60)	30 (83.3)
2 weeks			
Fever	1 (3.8)	1 (10)	2 (5.6)
Pain abdomen	0 (0)	1 (10)	1 (2.8)
Pain abdomen and fever	1 (3.8)	0 (0)	1 (2.8)
No symptoms	24 (92.3)	8 (80)	32 (88.9)
1 month			
Fever	2 (7.7)	1 (10)	3 (8.3)
Pain abdomen	3 (11.5)	6 (60)	9 (25)
Pain abdomen and fever	1 (3.8)	1 (10)	2 (5.6)
No symptoms	20 (76.9)	2 (20)	22 (61.1)
2 month			
Cholecystectomy done	1 (3.8)	0 (0)	1 (2.8)

Continued.

Follow up with or without recurrences	Non neoplastic	Neoplastic	Total
Jaundice ascites	1 (3.8)	2 (20)	3 (8.3)
Pain abdomen	0 (0)	3 (30)	3 (8.3)
Pain abdomen and fever	3 (11.54)	2 (20)	5 (13.9)
No symptoms	21 (80.8)	3 (30)	24 (66.7)
3 months			
Ascites and jaundice	0 (0)	1 (10)	1 (2.8)
Cholecystectomy done	2 (7.7)	0 (0)	2 (5.6)
Fever	0 (0)	1 (10)	1 (2.8)
Jaundice	1 (3.8)	4 (40)	5 (13.9)
Pain abdomen and fever	1 (3.8)	0 (0)	1 (2.8)
No symptoms	22 (84.6)	4 (40)	26 (72.2)

Diffuse pain abdomen was most common in almost 50% (18) patients next being right hypochondrium 44.4% (16).

Loss of weight, that is, a loss of more than 5 kg in 6 months was present in 12 patients presenting to the hospital (33.3%). 1 (2%) patients had a complaint of diarrhea and 16 patients (44.4%) had a history of clay colored stools.

21 patients (58.3%) came to complain of yellowish discoloration of skin/urine/eyes. Itching with scratch marks were also noted in 11 (30.6%) of those having jaundice. 13 (36.1%) of the patients had different comorbidities like DM/HTN/DM and HTN. Similarly 10 (27.7%) patients had a previous history of surgery. Murphy's sign was positive in 15 patients (41.7%).

In the coagulation profile of the patients being deranged with chronic obstruction similar features were also found in the renal function of the patients affected by chronic EHBO.

In liver function test total bilirubin 18 (50%) patients had total bilirubin in range of 0-5 mg/dl. 6 (16.6%) patients had bilirubin in rage of 6-10 mg/dl. 1 (2%) patient had bilirubin in rage of 11-15 mg/dl. 5 (13.8%) patients had bilirubin in range of 16-20 mg/dl. 2 (5%) patient had bilirubin in range of 21-25 mg/dl. 3 (8.3%) patients had bilirubin in range of 26-30 mg/dl and 1 (2%) patient had bilirubin more than 30 mg/dl.

Taking into account direct bilirubin only 1 (2.7%) patient had direct bilirubin less than 0.2 mg/dl rest of the patients the direct bilirubin was increased up to 30.0 mg/dl.

25 (69.4%) had amylase less than 125 U/l and 13 (36.1%) patients had amylase value more than 125U/l. Pancreatitis can be a standalone cause of EHBO or an associated entity. Serum alkaline phosphatase was also increased, 14 (38.8%) patients had ALP in rage of 0-500 U/l, 16 (44.4%) patients had ALP in range 501-1000 U/l, 1 (2%) patient had ALP in range of 1001-1500 U/l, 4 (11.1%) patients had ALP in range of 2001-2500 U/l and 1 (2%) patient had ALP in range of 3001-3500 U/l, showing bile duct and common bile duct involvement (Table 3).

Following the diagnosis, the patients were reviewed on the basis of surgical fitness, availability and affordability management was as follows. 2 (5.5%) patient underwent choledochoduodenostomy, 1 (2.7%) patient underwent exploratory laparotomy with CBD exploration with t tube drainage, 1 (2.7%) patient underwent ERCP with pigtail drainage, 17 (47.2%) patients underwent ERCP followed by cholecystectomy, 1 (2.7%) patient underwent open cholecystectomy with t tube drainage, 4 (11.1%) patients underwent ERCP alone, 2 (5.5%) patient underwent hepaticojejunostomy, 1 (2.7%) patient underwent ERCP followed by diverticulectomy, 2 (5.5%) patient underwent PTBD followed by a triple bypass surgery, 2 (5.5%) patients underwent PTBD, 1 (2.7%) patient underwent pylorus preserving pancreaticoduodenectomy, 1 (2.7%) patient underwent ERCP with sphincterotomy 1 (2.7%) patient underwent PTBD followed by pancreaticoduodenectomy (whipples procedure) (Table 4 and 5). No patient was operated in the postoperative period. Patients were followed up in 1st week, 2nd week, 1st month, 2nd month and 3rd month in which 5 (13.8%) patients had recurrence of the disease (Table 6).

No new patients were included in this study from March 2020 up to August 2020, only follow ups were attended.

### **DISCUSSION**

Non-malignant causes of EHBO were in the age group of 21-40 years of age and neoplastic causes were in the older age group.

In this study, 11 (30.5%) out of 36 patients were male while 25 (69.4%) were female. Madhu et al in 2010 reported a study in which 502 patients were included for the final analysis, of which 212 (42.3%) were male and 290 (57.7%) female, with male to female ratio of 1:1.36.<sup>12</sup>

Diffuse pain abdomen was most common in almost 50% (18) patients, next right hypochondrium 44.4% (16). 1 (2%) patient had complaint of diarrhea 16 patients (44.4%) had history of clay colored stools. 21 patients (58.3%) came with complain of yellowish discoloration of skin/urine/eyes. Itching with scratch marks were also

noted in 11 (30.6%) of those having jaundice. Murphy's sign was positive in 15 patients (41.7%). In the work done by Sharma et al in 2016 presenting symptoms were cholestatic jaundice, pain right hypochondrium, fever followed by weight loss, anorexia, vomiting and debility. Palpable gallbladder lump was present in 52% of gallbladder carcinoma 50% of carcinoma head of pancreas, 48% of periampullary carcinoma and 20% of cholangiocarcinoma patients.

In the liver function total bilirubin 18 (50%) patients had total bilirubin in the range of 0-5 mg/dl, 6 (16.6%) patients had bilirubin in range of 6-10 mg/dl, 1 (2%) patients had bilirubin in range of 11-15 mg/dl, 5 (13.8%) patients had bilirubin in range of 16-20 mg/dl, 2 (5%) patient had bilirubin in range of 21-25 mg/dl, 3 (8.3%) patients had bilirubin in range of 26-30 mg/dl and 1 (2%) patient had bilirubin more than 30 mg/dl.

Taking into account direct bilirubin, only 1 (2.7%) patients had direct bilirubin less than 0.2 mg/dl while rest of the patients, direct bilirubin was increased up to 30.0 mg/dl.

25 (69.4%) had amylase less than 125 U/l and 13 (36.1%) patients had amylase value more than 125U/l. Pancreatitis can be a standalone cause of EHBO or an associated entity. Serum alkaline phosphatase was also increased, 14 (38.8%) patients had ALP in range of 0-500 U/l, 16 (44.4%) patients had ALP in range 501-1000 U/I, 1 (2%) patient had ALP in range of 1001-1500 U/l, 4 (11.1%) patients had ALP in range of 2001-2500 U/l and 1 (2%) patient had ALP in range of 3001-3500 U/l, showing bile duct and common bile duct involvement which was also noted by Irabor in 2009. 7 patients were observed in this study. Four patients had carcinoma of the head of the pancreas (CAHOP); 3 males and 1 female. The three patients with ductal stones were all females. The age range was 36 to 81 years. Five of the patients were in the sixth decade. The total serum bilirubin ranged from 7.1 to 24.2 mg% with the majority between 11.5 to 17.1 mg% (5 patients). The conjugated bilirubin levels were between 3 to 17.6 mg% with a mean level of 11.6 mg%.

18 (50%) were diagnosed as a case of cholelithiasis with choledocholithiasis. 5 (13.8%) of the patients were diagnosed as carcinoma gallbladder, 2 (5.5%) were diagnosed as case of cholelithiasis with choledocholithiasis with pancreatitis, 2 (5.5%) patients with CBD stricture.

1 (2.7%) patient with cholangiolar abscess with CBD stricture, 2 (5.5%) patients of cholangiocarcinoma, 1 (2.7%) patient of lemmel syndrome, 3 (8.3%) patient of periampullary carcinoma and 2 (5.5%) patients of choledochal cyst (Table 1).

Following the diagnosis the patients were reviewed on the basis of surgical fitness availability and affordability management was as follows. 2 (5.5%) patient underwent choledochoduodenostomy, 1 (2.7%) patient underwent exploratory laparotomy with CBD exploration with t tube drainage, 1 (2.7%) patient underwent ERCP with pigtail drainage, 17 (47.2%) patients underwent ERCP followed by cholecystectomy, 1 (2.7%) patient underwent open cholecystectomy with t tube drainage, 4 (11.1%) patients underwent ERCP alone, 2 (5.5%) patient underwent hepaticojejunostomy, 1 (2.7%) patient underwent ERCP followed by diverticulectomy, 2 (5.5%) patient underwent PTBD followed by a triple bypass surgery, 2 (5.5%) patients underwent PTBD, 1 (2.7%) patient underwent pylorus preserving pancreaticoduodenectomy, 1 (2.7%) patient underwent ERCP with sphincterotomy 1 (2.7%) patient underwent PTBD followed by pancreaticoduodenectomy (whipples procedure). No patient was operated in the postoperative period. In 2019 Gelan et al in his study found that a total of 116 patients, 62 (53.4%) females were operated for extra-hepatic biliary tree obstruction. Their age ranged from 21 to 80 years with a mean (±SD) of 40.3 (11.2) years. Abdominal pain seen in 107 (92.2%) of the patients and jaundice in 98 (84.5%) were the two most common presented complaints. Abdominal ultrasound was the main imaging modality used to identify the etiology in 88.8% of the patients. Benign conditions accounted for 79 (68.1%) of the underlying etiology, common bile duct stone being the most common, 70 (60.3%). Pancreatic head tumor was the commonest malignant cause, 19 (51.3%), followed by cholangiocarcinoma, 15 (40.5%). For benign conditions, the most common intervention cholidochodoudenostomy 45 (64.3%), followed by cholidochotomy with t tube insertion, 13 (18.6%). with strictures were managed hepaticojejunostomy. In malignant EHBO, the most common surgery was cholecystojujunostomy with brain's anastomosis. Pylorus preserving pancreaticodoudenectomy was done only for 4 (12.9 %) of the patients who can be managed by that surgery.1

Patients were followed up in 1st week, 2nd week, 1st month, 2nd month and 3rd month in which 5 (13.8%) patients had recurrence of the disease with presentation of jaundice abdominal distention and pain.

#### Limitations

Limitations of the study was for projection of outcome further studies were required to enlarge the sample size. Financial burden over the patients, an expertise guiding system was lacking for patients to understand what specialty doctor was needed for their care.

#### **CONCLUSION**

EHBO is a hepatobiliary surgical condition caused by both neoplastic and non-neoplastic etiology.

Benign pathologies are more common in younger patients such as biliary stones and congenital diseases whereas neoplastic conditions generally occur in older age groups. US is the most common investigative modality followed by ERCP (diagnostic and therapeutic) with PTBD/ENBD playing an important role in decompression of biliary obstruction in a minimally invasive manner whenever required especially as a palliative measure in cases of advanced malignancies.

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Institutional Ethics Committee

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