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Clinical Profile of Extrahepatic Biliary Obstruction Cases Undergoing ERCP at an Indian Tertiary Care Centre

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Abstract

Background and Aims: Extrahepatic biliary obstruction (EHBO) is a common condition seen by gastroenterologist. We studied demographic, clinical, laboratory and endoscopic features of patients with EHBO undergoing Endoscopic retrograde cholangiopancreatography (ERCP) at our centre.

Material and Methods: We retrospectively analyzed our two year (2017-2018) data of ERCP. Diagnosis was based on laboratory parameters with imaging and cytological confirmation wherever possible.

Results: Our study comprises of 287 patients, among them 65.6% were female. Among them stones were found in 195 (67.9%) cases and strictures in 76 (26.4%) cases while other cases consisted of Sphincter of Oddi dysfunctioning (SOD), Bile duct leak, Hydatid cyst in 16 (5.5%) cases. Among the strictures, malignant strictures were seen in 52 (68.5%) cases, where most common cause was Carcinoma Gall bladder (GB) in 21 (40.4%) cases followed by Periampullary Carcinoma in 18 (34.6%), Carcinoma Head of Pancreas in 7 (13.5%), Cholangiocarcinoma in 6 (11.5%) respectively. Remaining 24 (31.5%) had either benign biliary strictures or indeterminate strictures. Presenting symptoms were cholestatic jaundice in 147 (51.2%) cases, in patients with stones it was 66 (33.8%) and in malignant strictures it was present in 50 (96.1%) cases. Other symptoms were pain, fever and pruritus. Cholangitis was seen in 58 (20.2%) cases. On investigating, 178 (62%) cases were found to have anemia (Hb <12), 70 (24.3%) cases had leucocytosis (TLC>12000), 21 (7.3%) cases had thrombocytopenia. During ERCP, Periampullary diverticulae was present in 27 (9.4%) cases. Among cases of choledocolithiasis, 105(53.8%) cases had single stone while 90 (46.2%) cases had multiple stones. About 129 (66.1%) cases had stone size <1cm while 66(33.9%) cases had stone size >1cm. After ERCP, 138(70.7%) cases had complete clearance, 18(9.3%) cases had partial clearance, 39(20%) cases had no clearance and stent was placed. Among patients with malignant stricture, 42(80.8%) had block below hilum (Type 1), 9(17.3%) had hilar block (Type 2), 1(1.9%) case had complex anatomy of block (Type 3).

Conclusions: Earlier in all Indian studies, malignancy was found to be the most common cause of EHBO. We have analyzed the cases undergoing ERCP, Common bile duct (CBD) stones were found to be most common cause followed by malignancy stricture. GB Carcinoma was most common cause of malignant EHBO.

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is a useful technique for the evaluation and management of biliary and pancreatic disease. ERCP is the procedure of choice undertaken for the evaluation & management of biliary tract if objective abnormalities pancreaticobiliary imaging or laboratory studies. The most common presentation of any obstruction in biliary tract is either pain or jaundice. A clear understanding of the etiology and presentation is a prerequisite for the management of obstructive jaundice. There is scant data from India about demography, clinical, laboratory & endoscopy features of patients with extrahepatic biliary obstruction (EHBO) undergoing ERCP. Our hospital is a tertiary care centre; patients with benign causes of EHBO such as stones are provided endoscopic clearance. Patients with unresectable malignant EHBO are provided biliary drainage through endoscopic percutaneous methods with or without metal stent placement, while resectable patients of malignant EHBO undergo preoperative biliary drainage in case of high bilirubin (>15mg/dl) or cholangitis. (1) We analyzed our last two year (2017-18) data procured from Indoor Patient files, HIS(Hospital Information System), Endoscopy software (Cutescopy Pro).

Materials and Methods

We retrospectively analyzed the hospital records of all patients who had undergone ERCP in Department of Gastroenterology, Mahatma Gandhi Medical College & Hospital, Jaipur, over a period of 2 years from January 2017 to December 2018. The diagnosis of EHBO was based on clinical presentation (jaundice, pain, pruritus, fever) and investigations which included Complete blood count (CBC), Liver function tests (LFTs), Renal function tests (RFTs), Blood sugar, Prothrombin time (PT/INR) & (Ultrasonography (USG) or Contrast enhanced computerized tomography [CECT] or Magnetic resonance imaging (MRI)/ Magnetic resonance cholangio-pancreatography (MRCP) abdomen) studies and was confirmed by a tissue diagnosis (imaging guided fine needle aspiration cytology (FNAC), Brush cytology, Post surgical histopathology) whenever available.

All the patients who underwent ERCP satisfied the given criteria⁽²⁾

- 1. Patient with or without jaundice who's clinical and biochemical or imaging data suggest biliary tract disease.
- 2. Choledocholithiasis on imaging
- 3. Sphincter of Oddi dysfunction (SOD) according to modified Milwaukee criteria
- 4. Stent placement across strictures and postoperative bile leak

The diagnosis of Benign biliary stricture (BBS)⁽³⁾ was made by the combination of history review, serum markers, imaging studies (4) and ERCP brush cytology reports. On MRCP⁽⁵⁾ benign biliary stricture is characterized by regular, symmetric and short segment narrowing, whereas malignant strictures usually present with irregular, asymmetric, and long-segment narrowing. Those biliary strictures in which basic work up, including transabdominal imaging and endoscopic retrograde cholangiopancreatography with conventional brush cytology⁽⁶⁾ is nondiagnostic for its etiology are classified as 'Indeterminate stricture'. (7) While stricture with mass lesion along with elevated serum CA 19-9, carcinoembryonic antigen $(CEA)^{(8)}$ characteristic imaging findings is classified as malignant stricture⁽⁹⁾. Malignant stricture is classified as Type 1 for strictures below hilum, Type 2 for hilar block, Type 3 & Type 4 for complex blocks above hilum. ERCP was done using Pentax scope under propofol sedation in prone or left lateral position.

Results

287 patients were included for final analysis. The etiology was CBD stone in 195(67.9%), stricture in 76(26.6%) and others (hydatid cyst, bile leak, SOD) in 16 (5.5%) cases. Among cases of CBD stones, 60 (30.77%) were male and 135 (69.2%)

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were female. About 76 (26.6%) cases undergoing ERCP were found to have stricture, among them 16(21%) had benign stricture, 52(68.5%) had malignant strictures and 8(10.5%) indeterminate cause. Those with malignant strictures, 42(80.8%) had block below hilum (Type1), 9(17.3%) had hilar block (Type 2), 1(1.9%) case had complex anatomy of block (Type 3). Cause of malignant stricture, 21(40.4%) cases had Ca GB, 18(34.6%) had Periampullary carcinoma, 7(13.5%) cases had Carcinoma Head Pancreas 6(11.5%) of and had Cholangiocarcinoma respectively.

Among the total cases, 99 (34.4%) were male and 188 (65.6%) female. In cases with CBD stones, 60 (30.7%) were male, 135 (69.2%) were female and the mean age was 48.2 yrs. In cases with malignant strictures, 24 (46.2%) were male while 28 (53.8%) were female and the mean age was 56.8 yrs. In cases with BBS/Indeterminate stricture, a male and female ratio was equal and mean age was 50 yrs. While in other cases (SOD, hydatid cyst, bile leak) 13 (81.25%) were females and the mean age was 38.5 yr (TABLE 1)

Table 1: Age and Sex distribution of EHBO cases undergoing ERCP.

	CBD Stones	Malignant strictures	Benign/ Indeterminate	Others	Total cases
	195(67.9%)	52(18.12%)	strictures 24(8.36%)	16(5.5%)	287(100%)
SEX	M=60(30.77%)	M=24(46.2%)	M=12 (50%)	M=3 (18.7%)	M=99(34.4%)
	F=135(69.2%)	F=28 (53.8%)	F=12 (50%)	F=13 (81.25%)	F=188(65.6%)
MEAN AGE	48.2	56.8	50	38.5	50.3

Clinical manifestations included pain which was present in 191 cases (66.5%). Jaundice was present in 147 (51.2%) cases, fever in 45 (15.6%) cases and pruritus in 63 (22%) cases. 58 (20.2%) cases presented with cholangitis. Those with CBD stones had pain, jaundice, fever, pruritus, cholangitis in 150 (76.9%), 66 (33.8%), 25 (12.8%), 19 (9.7%) and 33 (16.9%) cases

respectively. In malignant strictures pain, jaundice, fever, pruritus and cholangitis was present in 25 (48.07%), 50 (96.1%), 12 (23%), 28 (53.8%) and 15 (28.8%) cases respectively. In benign and indeterminate strictures pain, jaundice, fever, pruritus, cholangitis was present in 8 (33.33%), 20 (83.3%), 3 (12.5%), 14 (58.3%) and 3 (12.5%) cases respectively. (Table 2)

Table 2: Clinical manifestations of EHBO cases undergoing ERCP

	STONES	MALIGNANT	BENIGN/INDETERMINA	OTHERS	TOTAL CASES
		STRICTURE	TE STRICTURE		
PAIN	150 (76.9%)	25 (48.07%)	8 (33.33%)	8(50%)	191 (66.5%)
JAUNDICE	66 (33.8%)	50 (96.1%)	20 (83.3%)	11 (68.75%)	147 (51.2%)
FEVER	25 (12.8%)	12 (23%)	3 (12.5%)	5 (31.2%)	45 (15.6%)
CHOLANGITIS	33 (16.9%)	15 (28.8%)	3 (12.5%)	7 (43.7%)	58 (20.2%)
PRURITUS	19 (9.7%)	28 (53.8%)	14 (58.3%)	2 (12.5%)	63 (22%)

Among investigations, 178(62%) cases were anemic (Hb <12), 70 (24.3%) cases had leucocytosis (TLC>12000), 21 (7.3%) cases had thrombocytopenia, 38 (13.2%) cases had abnormal coagulation profile, 43 (15%) cases had deranged RFTs and 217 (75.6%) cases had raised alkaline phosphatase. Those with CBD stones 115 (60%) cases were anemic, 47 (24.1%) cases had TLC >12000.Thrombocytopenia was found in 17

(8.72%) cases and 18 (9.2%) had raised INR. Abnormal RFTs was found in 26 (13.3 %) cases and 134 (68.75%)had raised alkaline phosphatase. In malignant stricture anemia, raised TLC, thrombocytopenia, raised INR, abnormal creatinine was found in 37 (71.75%), 13(25%), 3(5.77%), 11(21.1%), 9(17.3%) cases respectively, raised alkaline phosphatase was seen in 48 (92.3%) cases. In cases with benign and

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indeterminate stricture anemia, raised TLC, thrombocytopenia, raised INR, abnormal creatinine was found in 16 (66.67%), 6 (25%), 1(4.16%), 5(20.8%), 3 (12.5%) respectively, raised alkaline phosphatase in 23 (95.8%) cases.

Mean bilirubin levels were 3.4 mg/dl in CBD stones, 11 mg/dl in malignant strictures, 10 mg/dl in BBS and indeterminate strictures and 5 mg/dl in other cases respectively. (Table 3)

Table 3: Laboratory investigations of EHBO cases undergoing ERCP

	STONES	MALIGNANT	BENIGN/INDETERMINATE	OTHERS	TOTAL
		STRICTURE	STRICTURE		CASES
Anemia	115 (60%)	37 (71.75%)	16 (66.67%)	10 (62.5%)	178 (62%)
(Hb <12)					
Leucocytosis	47 (24.1%)	13 (25%)	6 (25%)	4 (25%)	70 (24.3%)
(TLC >11000)					
Thrombocytopenia	17 (8.72%)	3 (5.77%)	1 (4.16%)	00	21 (7.3%)
(Platelets <1.5 lac)					
INR>1.2	18 (9.2%)	11 (21.1%)	5 (20.8%)	4 (25%)	38 (13.2%)
Deranged RF	26 (13.3%)	9 (17.3%)	3 (12.5%)	5 (31.25%)	43 (15%)
(S.Creat >1.5)					
Mean bilirubin	3.4	11	10	5	5.4
(mg/dl)					
Raised alkaline	134 (68.75%)	48 (92.3%)	23 (95.8%)	12 (75%)	217 (75.6%)
phosphatase					

During ERCP, Periampullary diverticulae was present in 27 (9.4%) cases. Needle knife was used in 46 (16%) cases. Lithotripsy was used in 30 (10.45%) cases (TABLE 4). In cases with stones, 105 (53.8%) cases had single stone while 90 (46.2%) cases had multiple stones. Among which

129 (66.1%) had <1cm size and 66 (33.9%) had >1cm size. 138 (70.7%) had their stones completely cleared, 18 (9.23%) had partial clearance and 39 (20%) cases had no clearance of stones and stent was placed. (Table 5)

Table 4: ERCP findings of EHBO cases

	Total cases (287)
PERIAMPULLARY DIVERTICULAE	27 (9.4%)
USE OF NEEDLE KNIFE	46 (16%)

Table 5: ERCP findings in cases with CBD stones

	CBD stones (195)
NUMBER OF STONES	Single: 105 (53.8%)
	Multiple: 90 (46.2%)
STONE SIZE	<1cm: 129 (66.1%)
	>1cm: 66 (33.9%)
USE OF LITHOTRIPSY	30 (10.45%)
CLEARANCE OF STONES	Partial: 18 (9.23%)
	Complete: 138 (70.7%)
	No clearance: 39 (20%)

Discussion

There are four studies from India about Etiological spectrum of EHBO. A large prospective study from AIIMS Delhi⁽¹⁰⁾ over a 10-year period from 1988 to 1997 consisted of 429 patients showed that malignant obstruction was

more common than benign (75.3% vs. 24.7%). Carcinoma of the gallbladder (Ca GB) and common bile duct (CBD) stones were the most common causes in the malignant and benign categories respectively. Another one from Rajasthan⁽¹¹⁾ that included 502 patients where the

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etiology was malignant in 318 (63.3%)cases, whereas 184 (36.6%) had benign cause. Carcinoma of Gall bladder was commonest in the malignant and common bile duct (CBD) stone in the benign group. Another study from Meerut⁽¹²⁾ comprising 110 patients reported malignancy in 62.7 % and benign causes in 37.2 % of cases, with Carcinoma Head of Pancreas as the most common malignant lesion (33.6%). Other study from Amritsar⁽¹³⁾ included 50 patients, showed malignant lesions in 48% and benign in 52% of cases, with periampullary carcinoma as the commonest malignant obstruction (14%). All studies documented CBD stone as the commonest benign etiology.

In our study, CBD stones were found to be most common cause followed by malignancy stricture as it was a laboratory based study rather than population based. GB Carcinoma was most common cause of malignant EHBO, which was consistent with the results of previous studies from AIIMS and Rajasthan. Pain was the most common presenting symptom among cases undergoing ERCP and there was a female predominance in those with CBD stones. While cases with strictures gender ratio was almost equal. Cases with strictures were found to be of older age group and jaundice was found to be the most common symptom. Among laboratory parameters, those with strictures were more anemic and had more deranged coagulation profile, higher bilirubin and raised alkaline phosphatase.

Most patients with malignant stricture had block below hilum as those with hilar and complex blocks were denied ERCPs in view of complex anatomy. Earlier all the studies were about clinical profile of patients presented as EHBO including all IPD and OPD patients while our study is a analysis of laboratory data of EHBO cases undergoing ERCP so benign causes like CBD stones has higher representation.

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