Research Article
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Intrabiliary pressure in obstructive jaundice
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Intrabiliary pressure in the pathophysiology of extra hepatic biliary obstruction

Dhananjay Saxena[1], Shridhar Vasantrao Sasturkar[1], Amar Mukund[2], Yashwant Patidar[2], Ashok Kumar Choudhury[1], Ragini Kilambi[1], Pratibha Kale[1]

[1]*Department of HPB and Liver Transplantation Surgery, Institute of Liver and Biliary Sciences, New Delhi, India;* [2]*Department of Intervention Radiology, Institute of Liver and Biliary Sciences, New Delhi, India*

Abstract

Background and Aim: The aim of this study was to evaluate the role of intrabiliary pressure (IBP) in the pathophysiology of extrahepatic biliary obstruction (EHBO) during percutaneous transhepatic biliary drainage (PTBD).

Materials and Methods: Adult patients with EHBO who underwent PTBD were prospectively enrolled. IBP was recorded during primary PTBD. The parameters of interest were age, gender, etiology of EHBO, baseline and post-PTBD liver function tests, duration for resolution of jaundice (decrease in total serum bilirubin ≥30% of baseline or <2 mg/dL), cholangitis, bile cultures, and serum albumin levels. The level of EHBO was divided into three types: Type 1 – secondary biliary confluence involved; Type 2 – primary biliary confluence involved; Type 3 – mid and distal common bile duct obstruction.

Results: IBP was measured in 102 patients, and finally, 87 patients, including 52 (59.77%) females, were analyzed. The mean age of the patients was 56.1±11.6 years. The most common etiology of EHBO was carcinoma of the gallbladder in 44 (50.6%) patients. The mean IBP was 18.41±3.91 mmHg. IBP was significantly higher in Type 3 EHBO compared to Type 1 and 2 (p=0.012). A significant correlation was seen between IBP and baseline total serum bilirubin (p<0.01). There was a negative correlation between IBP and baseline serum albumin (p=0.017). In 56.3% of patients, resolution of jaundice was observed by day 3, but this was not significantly associated with IBP (p=0.19). There was no correlation between IBP and cholangitis (p=0.97) or bacterial cultures (p=0.21).

Conclusion: IBP was significantly associated with the type of EHBO, baseline serum bilirubin, and albumin levels. IBP could not predict cholangitis or the resolution of jaundice after PTBD.

Keywords: Biliary manometry; cholangitis; percutaneous transhepatic biliary drainage.

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Corresponding author: Shridhar Vasantrao Sasturkar; Department of HPB and Liver Transplantation Surgery, Institute of Liver and Biliary Sciences, New Delhi, India

Phone: +9910461303; **e-mail:** svsasturkar@gmail.com

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Introduction

Most hepato-pancreatico-biliary cancers present with extrahepatic biliary obstruction (EHBO). These are routinely evaluated using cross-sectional imaging. However, all these imaging modalities provide morphologic data, with little or no functional information. The functional status of a distensible conduit system, such as the bile duct, is determined by physiological variables including flow, volume, and pressure. Intrabiliary pressure (IBP) has been implicated in the development of cholangio-lymphatic and cholangio-venous reflux,[1] but its role in the pathophysiology of development and resolution of EHBO is largely unknown. The understanding of the functional physiology of the obstructed biliary system and various factors that determine the resolution of jaundice might be helpful in aiding the management of patients with EHBO. Both animal and human studies demonstrate that the recovery of various metabolic and immune functions requires at least six weeks after the relief of biliary obstruction.[2–4] This time duration is valuable in planning further treatment.

The routine use of preoperative biliary drainage in resectable hepato-pancreatico-biliary malignancies is not recommended in current clinical practice. Nevertheless, drainage is still required in a significant proportion of patients presenting with EHBO, for various indications like cholangitis, chemotherapy, nutritional build-up, optimization of comorbidities, palliation of pruritus, etc. Data on whether elevated IBP has any predictive role in the resolution of jaundice is limited in clinical practice. Biliary manometry is described for predicting adequate treatment of strictures after bilioenteric anastomosis[5] or living donor liver transplantation[6] in recent literature. Previous studies have described IBP measurement during surgery[7] or endoscopy to access the sphincter of Oddi function.[8] Percutaneous transhepatic biliary drainage (PTBD) provides an opportunity to measure IBP directly.[9] The aim of this study is to evaluate the role of IBP in the pathophysiology of EHBO.

Materials and Methods

This prospective study was conducted in the Department of HPB and Liver Transplantation Surgery and the Department of Interventional Radiology at the Institute of Liver and Biliary Sciences, New Delhi. Consecutive adult (>18 years of) patients with EHBO who underwent PTBD at our institute from August 2020 to March 2022 were enrolled. The IBP was measured only during the first PTBD procedure, and patients who required a second PTBD or catheter change were excluded. Patients with a prior history of liver transplantation or liver resection were excluded. Patients with prior bilio-enteric anastomosis were not included in view of altered anatomy. Informed consent was obtained from the patients. Patients not willing for committed follow-up or those who underwent metallic stent placement were excluded. The study was conducted in accordance with the Declaration of Helsinki. The study was approved by the Institutional Review Board and Institute of Liver and Biliary Sciences Ethics Committee IEC/2020/81/MA17 (Aug 27, 2020).

The IBP was measured at the time of PTBD catheter insertion by using the central venous pressure (CVP) transducer (Truwave™, Edwards Lifesciences). The patient was placed in a supine or right anterior oblique position with the arm elevated above the head or extended to the side. PTBD was performed using all aseptic precautions and local anesthesia. With ultrasound guidance, a biliary duct was accessed with an 18G Cheeba needle. Bile was aspirated for confirmation. The CVP transducer was connected to the needle and IBP was measured. Bile samples were collected for aerobic culture. The PTBD was then completed using fluoroscopic guidance.

The various demographic and clinical parameters of interest were the age and sex of the patient, presence of diabetes mellitus, total leucocyte count ($x10^9$/L), serum total bilirubin (mg/dL), and serum albumin (g/dL) recorded at the time of PTBD. Clinical normalization of bilirubin was defined as the decrease in the serum total bilirubin level of more than 30% relative to the baseline value or a serum bilirubin level of less than 2 mg/dL.[10] Cholangitis was defined by recent Tokyo guidelines (TG18).[11]

All patients undergoing IBP measurement were followed up with serial evaluation of serum bilirubin and albumin at day 3, 7, 14, 21, or till normalization of bilirubin as defined, or the patient taken up for definitive treatment, whichever is earlier. The trend of liver enzymes, including aspartate transaminase, alanine transaminase, alkaline phosphatase, and gamma glutamyl transpeptidase, was recorded. Serum albumin levels were used as a parameter of nutrition. International normalization ratio and serum creatinine levels were measured at baseline.

The anatomy of EHBO was categorized into three types based on the level of biliary obstruction. Type 1 included EHBO with both primary and secondary biliary confluences involved. Type 2 included EHBO with primary biliary confluence involved but secondary confluence not involved. Type 3 included all patients with patent primary and secondary biliary confluences, mid and distal common bile duct blocks. Presence of vascular involvement, cholangiolar abscesses, and presence of imaging features of CLD were recorded.

The role of IBP in the pathophysiology of EHBO was evaluated by correlating with serum bilirubin, cholangitis, and albumin before PTBD and whether it predicts clinical resolution of jaundice after PTBD. IBP was correlated with the type of EHBO.

Statistical Analysis

The presentation of the categorical variables was done in the form of number and percentage (%). The quantitative data were presented as the means±SD as median with 25th and 75th percentiles (interquartile range). The association of the variables which were quantitative in nature was analyzed using the independent t-test (for two groups) and ANOVA test (for more than two groups). Paired t-test was used for comparison across follow-up. The association of the variables which were qualitative in nature was analyzed using Fisher's exact test as at least one cell had an expected value of less than 5. Pearson correlation coefficient was used for correlation of quantitative parameters with each other. The analysis was done with the use of Statistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, ver. 21.0. For statistical significance, p-value of less than 0.05 was considered statistically significant.

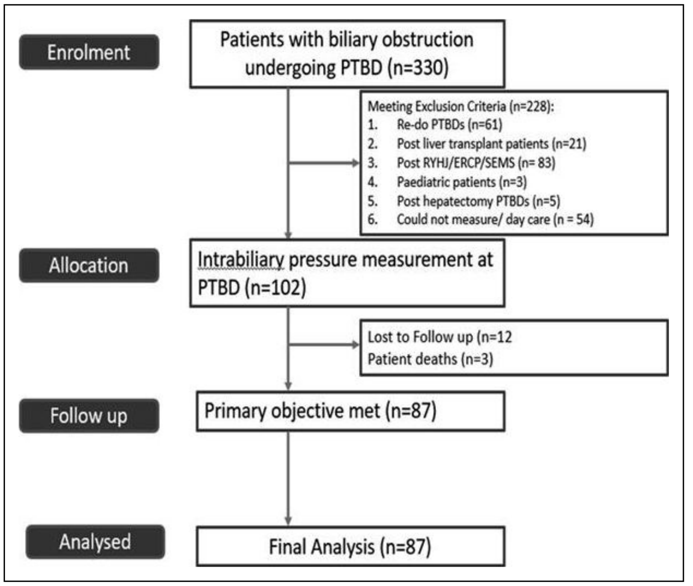

Figure 1. Study population and patient enrolment.

Results

A total of 330 PTBD procedures were performed during the study period. After satisfying the inclusion and exclusion criteria, IBP measurement was done in 102 patients. Twelve patients were lost to follow-up and 3 patients expired before the primary objective was achieved. Finally, 87 patients were included in the study (Fig. 1). The demographic and clinical parameters of the enrolled patients are presented in Table 1. The mean age (years) of the patients was 56.08±11.6. In the cohort, 52 (59.77%) patients were females. Type 2 diabetes mellitus was present in 15 (17.2%) patients. Carcinoma of the gallbladder was the most common etiology of EHBO, 44 (50.6%), followed by perihilar cholangiocarcinoma, 24 (27.6%). The distribution of types of EHBO was type I, 32 (36.8%), type II, 39 (44.8%), and type III, 16 (18.4%). Out of 16 patients in the type III group, 6 patients had gastric outlet or duodenal obstruction with ERCP scope not negotiable, 2 patients had advanced carcinoma gall bladder with a block just proximal to the cystic duct level, 2 patients underwent emergency PTBD in ICU due to severe cholangitis, 1 patient was not fit for the ERCP procedure under sedation, ERCP was not attempted due to risk of bleeding in 2 patients, and ERCP was attempted but CBD cannulation was not possible in 3 patients; hence all these patients with mid to distal CBD blocks underwent primary PTBD. PTBD catheter was inserted on the left side in 68 (78.2%). Right-sided catheter was inserted in 14 (16.1%) patients, while bilateral PTBD was done in 5 (5.7%) patients. The mean value of IBP (mm of Hg) of study subjects was 18.41±3.91, with a median (25th-75th percentile) of 18 (16-21). In 77 (88.51%) patients, bilirubin levels normalized as per definition. Percutaneous self-expanding metallic stent placement was done before normalization of bilirubin in 8 patients (9.20%), and 2 patients (2.30%) underwent surgery.

In 49 (56.3%) patients, the bilirubin normalized by day 3 after PTBD; in 13 patients (14.9%) by day 7; in 11 (12.6%) it normalized by day 14. It took 21 days for bilirubin to decrease to normalization levels in 3 patients, while 1 patient was lost to follow-up. The mean duration for bilirubin normalization of study subjects was 7.6±4.96 days. A decreasing trend was seen in total bilirubin across time periods. Total bilirubin was significantly lower at all post-PTBD time intervals when compared with pre-PTBD total bilirubin ($p<0.0001$) (Fig. 2a).

Table 1. Demographic and clinical parameters

Variable	Mean±SD/n (%)
Age (years)	56.08±11.6
Sex (M:F)	35:52
Diabetes	15 (17.2 %)
Liver function tests total bilirubin (mg/dL)	16.64±7.80
AST (IU/L)	135.15±71.65
ALT (IU/L)	115.20±97.19
SAP (IU/L)	538.65±348.73
GGT (IU/L)	360.60±402.69
Albumin (g/dL)	3.13±0.505
Total leukocyte count (x10^9/L)	10.24±4.52
International normalization ratio	1.28±0.359
Serum creatinine (mg/dL)	0.78±0.32
Etiology	
Carcinoma gallbladder	44 (50.6%)
Perihilar cholangiocarcinoma	24 (27.6%)
Periampullary/Distal CBD	10 (11.5 %)
Intrahepatic cholangiocarcinoma	5 (5.7%)
Metastatic tumor	3 (3.4%)
Hepatocellular carcinoma	1 (1.1%)
Type of EHBO	
Type I	32 (36.78%)
Type II	39 (44.83%)
Type III	16 (18.39%)
Vascular involvement	38 (43.7%)
Cholangiolar abscess	7 (8%)
Chronic liver disease	6 (6.89%)

SD: Standart deviation; AST: Aspartate transaminase ALT: Alanine transaminase; SAP: Serum alkaline phosphatase; GGT: Gamma glutamyl transpeptidase; CBD: Common bile duct; EHBO: Extra hepatic biliary obstruction.

Albumin levels at post-PTBD day 3 (p<0.0001), post-PTBD day 7 (p=0.001), and at final follow-up (p=0.007) were significantly lower as compared to pre-PTBD levels. The serum albumin levels showed a decreasing trend until Day 14 after PTBD, after which they started rising (Fig. 2b). The trend of liver enzymes is shown in Figure 2 (Fig. 2c, d). There was a decrease in the liver enzymes on day 3 after PTBD.

Six patients had background CLD. In 5 of them, bilirubin was decreased to endpoint levels on day 3 post-PTBD, while in 1 patient the primary endpoint was surgery. Cholangitis was observed in 26 (29.9%) patients. Out of 26 patients with cholangitis, 14 (53.8%) had Grade 1 cholangitis, 8 (30.76%) had Grade 2, and 4 (15.38%) had Grade 3 cholangitis. Bile culture was positive in 16 patients (18.4%). Out of the 16 patients with positive culture, 8 (50%) had Escherichia coli, followed by Klebsiella pneumoniae in 6 (37.5%) patients. One patient each had Enterococcus and Pseudomonas species. There was no significant association between IBP and the presence of vascular involvement (p=0.838) or the development of cholangiolar abscesses (p=0.054).

Association of Pressure with Baseline Bilirubin and Albumin Levels: Baseline serum bilirubin was found to have a significant positive correlation, while baseline serum albumin was found to have a significant negative correlation with intrabiliary pressure (Table 2). Thus, patients with higher intrabiliary pressure are expected to have higher levels of serum bilirubin and lower levels of serum albumin, i.e., they are more nutritionally depleted (Fig. 3a,b).

Table 2. Correlation between intrabiliary pressure and baseline serum bilirubin and albumin levels

Variables	Baseline total bilirubin (mg/dL)	Baseline serum albumin (g/dL
Pressure (mm of Hg)		
Correlation coefficient	0.409	-0.255
p	<0.01	0.017

Pearson correlation.

A weak positive correlation was observed between IBP and baseline serum creatinine and INR values. Thus, patients with higher IBP had a slightly higher risk of developing renal dysfunction and coagulopathy. The correlation coefficient was 0.14 and 0.82, respectively.

Association of Pressure with Type of Block: The mean±SD IBP in type 3 block was 20.25±2.46, which was significantly higher as compared to type 2 (18.87±3.47) and type 1 block (16.94±4.54) (p=0.012) (Table 3).

A mild positive correlation was seen between IBP and duration of normalization of bilirubin, with a correlation coefficient of 0.113. There was no correlation seen between IBP and percentage change in albumin (g/dL), with a correlation coefficient of 0.016. The mean±SD IBP in patients with cholangitis was 18.38±3.6, and in patients without cholangitis it was 18.43±4.07, with no significant association between them (p=0.964). Thus, the occurrence of cholangitis was not associated with IBP in our study.

Discussion

There is limited data in the literature on the association of IBP with recovery of bilirubin levels after drainage. Most of the studies are performed in animal models, as discussed above. This study was conducted with the hypothesis that IBP might play an important role in the pathophysiology of EHBO both before and after drainage. Various methods of measurement of IBP are described in the literature. IBP measurement can be performed during endoscopic procedures, intraoperative measurement by direct cannulation of bile ducts, and PTBD.[7–9]

Measurement of IBP is invasive but does not pose any additional risk when performed as the first step of PTBD. The mean value of IBP (mm of Hg) recorded was 18.41±3.91, with a median (25th-75th percentile) of 18 (16-21). This is equal to approximately 25 cm of H_2O, which is similar to that recorded in previous studies. Huang et al. and Mixter et al.[1,12] have shown that normal biliary pressure ranges between 5-20 cm of H_2O and that cholangio-lymphatic and cholangio-venous reflux occurs at pressures above 25 cm of H_2O.

In our study, IBP was measured during only the first PTBD as subsequent biliary interventions may not reflect true IBP. The patients enrolled in the study were having EHBO due to various underlying etiologies. In view of the size of the ducts and the amount of liver parenchyma expected to be drained, we divided the patient population into three groups based on the level of blocks. That enabled us to evaluate whether these factors affect the IBP. Though there might be an inverse relation between the diameter of the duct and pressure across it, the volume of the bile as determined by the amount of liver parenchyma

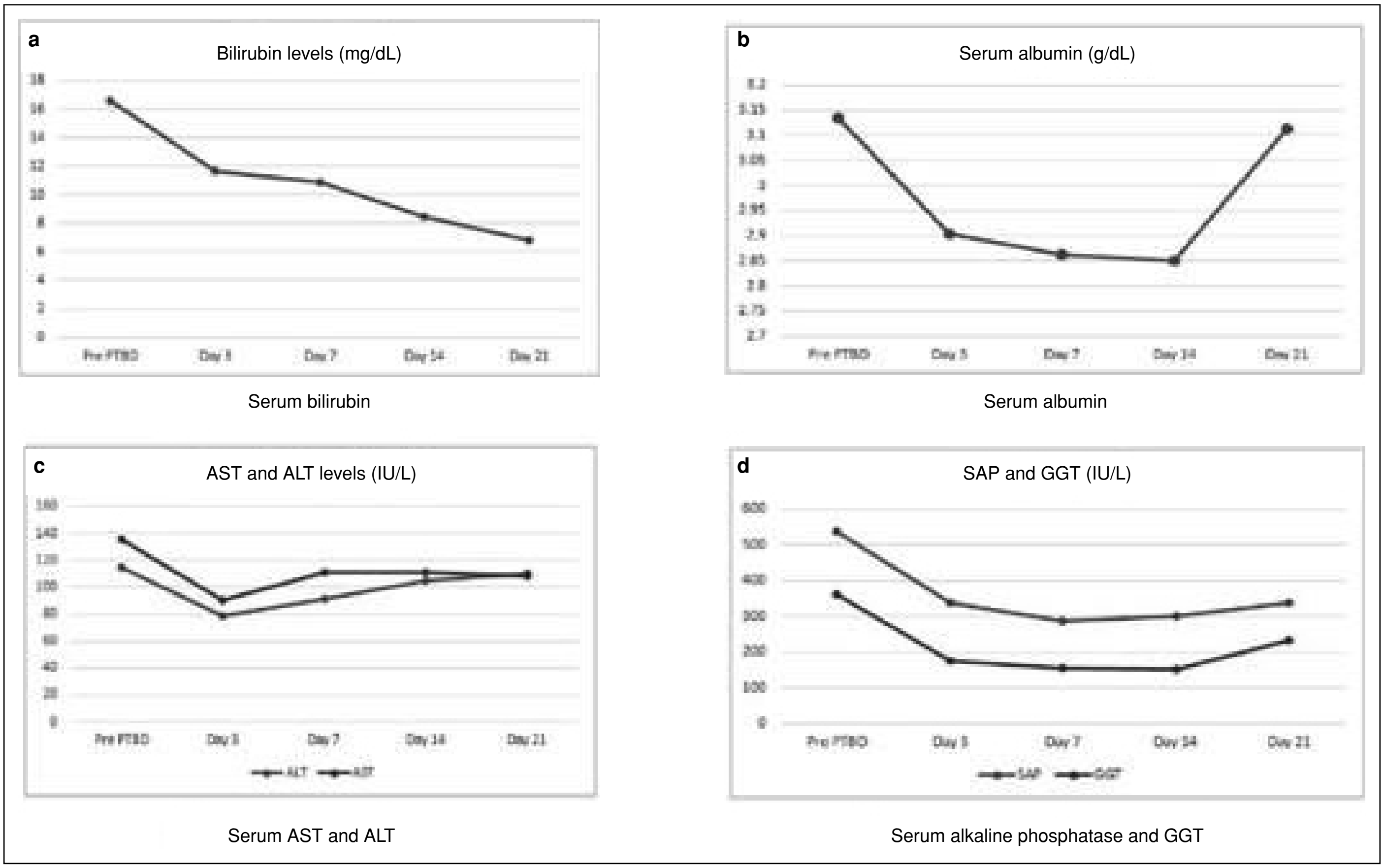

Figure 2. Trend of liver function tests before and after PTBD.

Table 3. Association of intra biliary pressure (mm of Hg) with type of EHBO

Intra biliary pressure (mm Hg)	Type 1 (n=32)	Type 2 (n=39)	Type 3 (n=16)	Total	p
Mean±SD	16.94±4.54	18.87±3.47	20.25±2.46	18.41±3.91	0.012‡
Median (25th–75th percentile)	17 (14.75–20)	19 (16–20)	20.5 (18–22)	18 (16–21)	
Range	9–28	12–28	17–26	9–28	

‡: ANOVA (Analysis of variance); EHBO: Extrahepatic biliary obstruction; SD: Standar deviation.

might have an important role. IBP was significantly higher in distal block as compared to hilar block without secondary confluence involved and hilar block with secondary confluence involved (p=0.012). Thus, if any part of the biliary system is isolated, the intrabiliary pressure rises slowly. We found a significant difference in IBP across the three levels of EHBO that is expected as per the physiology. The IBP measurement at different levels of EHBO is being reported for the first time to the best of our knowledge.

Total bilirubin was significantly lower at all post-PTBD time intervals when compared with pre-PTBD total bilirubin (p<0.0001). In the majority of the patients (56.3%), the bilirubin normalized by day 3 after PTBD as per definition. This indicates that adequate biliary drainage was achieved. Mild positive correlation was seen between IBP and duration for normalization of bilirubin, with a correlation coefficient of 0.15 that did not reach statistical significance. Resolution of jaundice after biliary drainage is multifactorial.[13–16] Scoring systems have been developed to address this issue but do not incorporate IBP.[13] Our study has not addressed the other factors in the resolution of jaundice, as our aim was to explore the role of IBP in the pathophysiology of EHBO.

Albumin levels at post-PTBD day 3 (p<0.0001), post-PTBD day 7 (p=0.001), and at final follow-up (p=0.007) were significantly lower as compared to pre-PTBD levels. Various authors have shown, both in animal and human studies, that the recovery of various metabolic and immune functions requires at least 6 weeks to pass after the relief of biliary obstruction. In our study, the serum albumin levels showed a decreasing trend until Day 14 after PTBD, after which they started rising. No correlation was seen between IBP and percentage change in albumin (g/dL), with a correlation coefficient of 0.016. IBP was not directly associated with nutritional recovery, as multiple factors such as the presence of cholangitis, premorbid nutritional status, underlying disease, etc. are involved.

The mean IBP (mm of Hg) in patients with cholangitis was 18.38±3.6 and in patients without cholangitis was 18.43±4.07, with no significant

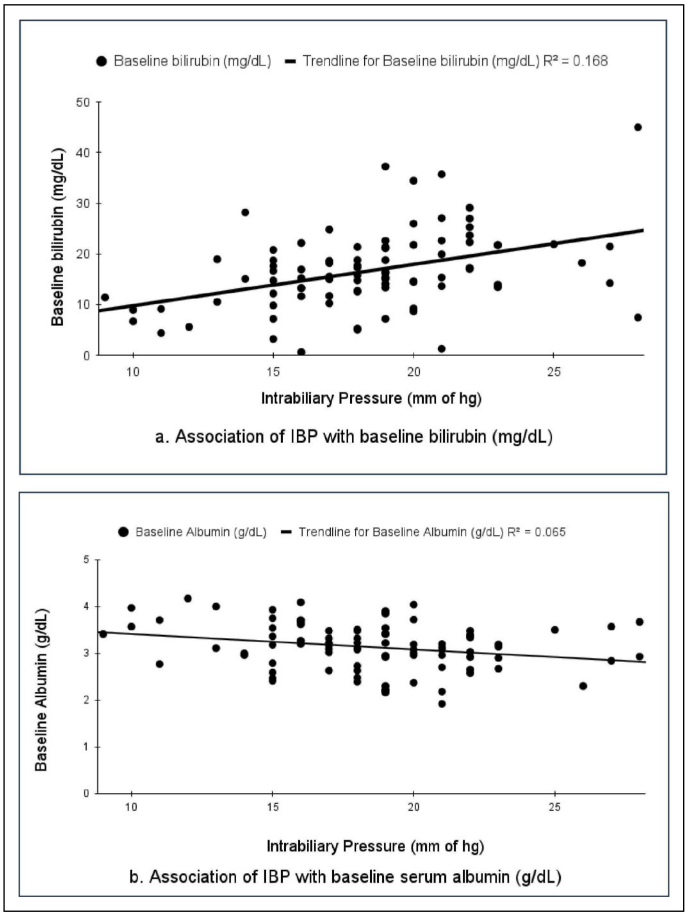

Figure 2. (a) Association of intrabiliary pressure with baseline bilirubin and **(b)** albumin levels.

association between them (p=0.964). Thus, IBP was not associated with predicting episodes of cholangitis in our study population. One explanation of this observation might be that mean pressure in our study population was 18.41±3.91, which is roughly equal to 25 cm of H_2O. As many authors have previously stated that cholangio-venous and cholangio-lymphatic reflux occurs at this pressure, most of the subjects in our study population were at risk for reflux, and significance could not be achieved. We have not taken into account the pre-PTBD antibiotic treatment received by these patients, as most of the patients are expected to have received the antibiotic treatment when presented with cholangitis. Bile culture was positive in 16 out of 87 patients (18.39%). Cholangitis was present or developed in 26 out of 87 patients (29.89%).

Conclusion

There is limited data available in the literature, to the best of our knowledge, as to how the IBP affects the rate of normalization of bilirubin levels. Though our study also did not show significant correlation, this is an interesting aspect of IBP dynamics and pathophysiology that is mostly unexplored. Though it is intuitive that IBP should correlate with the rate of resolution of jaundice, a small sample with heterogeneous etiology and level of block may have resulted in negative results. The role of IBP may be more apparent in a larger sample size, homogenous patient population in respect to anatomy and etiology of EHBO. Though this is a heterogeneous study population, we stratified patients according to the level of EHBO. Further studies with a more homogenous population may further elaborate the role of IBP. As initially shown by Beinart et al.,[17] biliary manometry can be a useful tool to assess the adequacy of biliary drainage. Subsequent studies described manometric perfusion tests by balloon dilatation of biliary strictures.[18,19] Thus, by incorporating IBP into clinical practice, we might redefine the further course in the resolution of jaundice and time the next therapeutic intervention accordingly. In conclusion, in the pathophysiology of EHBO, PTBD is a reliable and easy modality to measure IBP. IBP was significantly associated with the level of biliary obstruction. Patients with high IBP have high baseline total bilirubin levels and low baseline serum albumin levels.

Ethics Committee Approval: The Institutional Review Board and Institute of Liver and Biliary Sciences Ethics Committee granted approval for this study (date: 27.08.2020, number: IEC/2020/81/MA17).

Author Contributions: Concept – SVS, AM, YP; Design – DS, SVS, AM, YP, AKC; Supervision – DS, SVS, AM, YP, RK, PK; Materials – DS; Data Collection and/or Processing – DS, SVS, AM, YP, AKC; Analysis and/or Interpretation – SVS, AM, YP, AKC, RK, PK; Literature Search – DS, SVS, RK, PK; Writing – DS, SVS, RK; Critical Reviews – DS, SVS, AM, YP, AKC, RK, PK.

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