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INTERVENTIONAL RADIOLOGY

Complication rates of percutaneous biliary drainage in the presence of ascites

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Abstract

Background Ascites is a relative contraindication to percutaneous biliary drainage (PBD), but patients with biliary obstruction presenting with ascites may still undergo PBD insertion. We hypothesized that ascites increases the major complication rate of PBD.

Materials PBDs placed between January 2005 and August 2016 were identified ($n=491$). Etiology and location of obstruction, the presence, and distribution of ascites based on abdominal imaging within 2 weeks of PBD, INR, WBCE, and periprocedural complications were reviewed in the EMR.

Results A total of 491 PBD were placed during the study period of which 26.2% had ascites ($n=129$), and 73.7% did not have ascites ($n=362$). Ascites was categorized as perihepatic in 41 patients (32%), diffuse in 82 patients (64%), and non-perihepatic in 6 patients (4%). Overall, a significantly higher rate of major complications occurred in patients with ascites (19%) compared to that in patients without ascites (7.7%, $P=0.0004$). Diffuse ascites was associated with a significantly higher major complication rate (26%) when compared to perihepatic ascites (7.3%, $P=0.014$). In ascites patients, no association between the etiology of biliary obstruction or laterality of the PBD and the rate of major complications was identified.

Conclusions The major complication rate in patients with ascites not only exceeds SIR suggested threshold of 10% but is also significantly higher than that patients without ascites. The distribution of ascites had a significant effect on complication rate, with diffuse ascites being associated with increased major complication rates compared to those with perihepatic. These findings suggest careful consideration of patients for PBD with ascites, particularly diffuse ascites.

Keywords Biliary obstruction · Percutaneous biliary drainage · Ascites · Interventional radiology

Introduction

Percutaneous transhepatic biliary drainage (PBD) procedures are an accepted part of the treatment algorithm for biliary obstruction. PBD has largely replaced surgical interventions to decompress the biliary system due to the complications and morbidity associated with open surgical decompression procedures [1]. Although less invasive than open surgery, PBD does still pose the potential for frequent complications related to bleeding or bacteremia/sepsis [2, 3]. Thus, since the dissemination of endoscopic biliary drainage, PBD is now the most often performed in patients who have failed endoscopic drainage or in whom biliary system is anatomically inaccessible from an endoscopic approach.

Several risk factors have been identified, which increase the likelihood of complications following PBD such as an uncorrectable coagulopathy or active cholangitis; however, PBD still maybe indicated in these settings if it were anticipated to have a lower expected risk than alternative methods of treatment. One risk factor which has been suggested to increase complications following PBD is the presence of ascites [4–6]. This has led to ascites being viewed as a relative contraindication to PBD. Despite this relative contraindication, patients with ascites still may undergo PBD as the alternative to allowing an obstructed biliary system

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to remain undrained may pose even greater risks to the patient. The purpose of the current study is to review all PBDs inserted in the presence of ascites to better elucidate the absolute risk of complications in this population.

Methods

Patient selection and data collection

Approval from the institutional review board was granted for this study. A retrospective review of all patients who underwent a PBD at an academic medical center from January 2005 to June 2016 was performed by examining the records from a dedicated interventional radiology database(Hi-IQ, ConexSys, RI). A total of 491 patients were identified. All drains were placed by interventional radiologists ($n = 14$) in an inpatient fluoroscopy suite. Exact method of PBD insertion depended on the operating interventionalist. However, all were performed under fluoroscopy with or without the assistance of ultrasound guidance using a 21G needle to perform percutaneous transhepatic cholangiography (PTC) to delineate the site of biliary obstruction and the optimal sight for insertion of the PBD. For PBD insertion, the peripheral most duct that could be accessed was chosen, and PBD insertion was performed with a 21G needle and tri-axial system (Jeffrey Set, Cook Medical, Bloomington, IN.) The mean of years of experience of the interventionalists performing the procedures was 12 years (range 1–23 years) at the time of publication. Institutional guidelines regarding management of coagulopathy and thrombocytopenia for PBD insertion require an INR ≤ 1.5 and platelet count $\geq 50{,}000/\mu L$.

Patients were reviewed for the presence of ascites at the time of, or within 2 weeks before or after PBD placement. The presence of ascites was determined from available diagnostic radiology studies (abdominal US, MRI, CT) obtained during the hospital encounter at the time of, or within the two-week window of PBD placement. From the available imaging, the ascites was classified as diffuse or peri-hepatic as previously described. *Diffuse ascites was defined as fluid interspersed throughout the abdomen and pelvis without mass effect or abdominal distention* [7]. Perihepatic ascites was characterized by the presence of fluid at least 1 cm deep, on the axial or transverse axis, of non-loculated fluid around the liver without contiguous fluid in the pelvis.

The electronic medical records (EMR) were examined for procedure details, including technical success, type of drain (internal/external or external), side of drainage approach, INR, WBC, and concurrent stenting. The indication for PBD was reviewed and characterized as either malignant or benign. The location of the obstruction was also characterized as either proximal, distal, neither, or other. As per *Boulay and Birg*, proximal and distal were defined relative to cystic duct insertion [8]. Proximal referred to any obstruction superior to cystic duct insertion, which included etiologies such as metastases to the liver, cholangiocarcinoma, strictures resulting from primary sclerosing cholangitis (PSC) or postsurgical strictures at the hepaticojejunal-jejunal anastomosis following Whipple Procedure or anastomotic strictures post liver transplant. Distal obstructions included etiologies resulting in obstructions inferior to the insertion of the cystic duct which included pancreatic tumors, impacted CBD stones, and extrahepatic tumors causing distal compression. Obstructions were characterized as "Neither" if they were the result of surgical complications which included CBD injury during cholecystectomy procedures. Finally, if the location of the obstruction could not be ascertained from radiology reports and available imaging at the time of PBD insertion, the location was characterized as "Unknown." For INR and WBC, the value closest to time of insertion was used up to 1 week preceding PBD placement.

Follow-up reports from cholangiograms and PBD exchanges were recorded in addition to information about additional drain placements and drain removals. Furthermore, all encounters in patients' EMR up to 30 days following PBD placement were examined for complications related to PBD insertion. The primary outcome of interest was PBD complications, which included, biliary sepsis, abscess formation, catheter discontinuation requiring tube change or reinsertion, bile peritonitis, and hemorrhage. Complications were considered related to PBD if included in the EMR and clinically suspected. Complications were assessed using SIR Practice Guidelines and Quality improvement guidelines for percutaneous transhepatic cholangiography, biliary drainage, and percutaneous cholecystostomy. Major hemorrhagic complications included events requiring additional interventions to treat bleeding such as embolization or bleeding requiring transfusion and increased level of care with transfer to ICU. Similarly, major sepsis complications were new onset sepsis following biliary drainage resulting in an increased level of care with transfer to ICU for invasive monitors, pressers, and/or mechanical ventilation.

Data interpretation and statistical analysis

Statistical analysis was performed using SPSS statistical software (version 18; SPSS, Chicago, Illinois). Categorical variables were analyzed by χ^2 test and Fisher exact test as appropriate based on sample size. Continuous variables were analyzed by two-sided Student t test or analysis of variance as appropriate. The significance level was defined as $P = 0.05$ on two-tailed tests. When analyzing the association of complications with ascites, patients with diffuse or perihepatic ascites were categorized as having ascites present, whereas those with or no fluid were categorized as having no ascites.

Results

Of the 491 PBD patients, 129 were performed in the presence of ascites, while 362 occurred in patients without ascites. In the 129 patients undergoing PBD in the presence of ascites, the median age was 62(range 19–89 y, Table 1). 82 patients were considered to have diffuse ascites (63.5%), while 41 patients had perihepatic ascites (31.7%), and 6 were characterized as neither perihepatic nor diffuse (4.7%). In total, 86 of the biliary obstructions in patients with ascites were malignant in origin (66.7%), while 43 were of benign etiology (33.3%). PBD placement was completed using a right-sided approach in 64 patients (50%), a left-sided approach in 59 patients (46%), and a bilateral approach in 6 patients (4%). There were a total of 362 patients in the Non-Ascites group with a median age of 62 (range 20–89). In the non-ascites group, 204 patients had biliary obstructions of malignant origin(56%), compared to 158 patients which had benign obstructions (44%). PBD placement was completed using a right-sided approach in 176 patients (49%), a left-sided approach in 169 patients (47%), and a bilateral approach in 17 patients (4%).

Table 1 Patient demographics with percentages listed in parentheses except where noted

	Non-ascites	Ascites
Age (years)	62 (20–89)	60 (19–89)
Sex		
Male	206 (57%)	72 (56%)
Female	156 (43%)	57 (44%)
Etiology of obstruction		
Malignant	204 (56%)	86 (67%)
Benign	158 (44%)	43 (33%)
Location of obstruction		
Proximal	198 (55%)	61 (47%)
Distal	143 (40%)	66 (51%)
Neither	20 (5.5%)	1 (0.78%)
Other	1 (0.27%)	1 (0.78%)
Fluid location		
Perihepatic	N/A	41 (32%)
Diffuse	N/A	82 (64%)
Non-Perihepatic	N/A	6 (4.6%)
Laterality		
Right	176 (49%)	64 (50%)
Left	169 (47%)	59 (46%)
Bilateral	17 (4%)	6 (4.6%)
Drain type		
Internal/external	272 (75%)	94 (73%)
External	83 (23%)	24 (19%)
Both/converted	7 (1.9%)	11 (8.5%)
Median INR (IQR)	1.2 (0.2)	1.3 (0.3)
Median WBC (IQR)	7.8 (5.2)	8.3 (7)

The overall incidence of major complications in patients with ascites was 21% (27/129), while the major complication rate in the non-ascites group was 7.7% (28/362), which was significant ($P=0.0004$). Additionally, the presence of ascites, compared to that in patients without ascites, was associated with a significant increase in the incidence of both sepsis/septic shock (6.2% vs 2.2%; $P=0.028$) and hemorrhagic complications (6.2% vs 1.4%; $P=0.004$). In the ascites group, the overall incidence of septic/septic shock and hemorrhagic complications exceeded the suggested threshold values set forth in the Society of Interventional Radiology Practice Guidelines [2]. The incidences of other major complications reported in the literature, such as periprocedural death, abscess formation, and catheter discontinuation, have been further detailed in Table 2, but no differences were observed between the ascites and non-ascites group. The hemorrhagic complications occurring in the ascites patients most often were subcapsular hematomas/liver lacerations ($n=3$, 38%), hemobilia requiring arterial embolization ($n=2$, 25%), and one patient with hemobilia and subcapsular hematoma. The other two hemorrhagic complications occurred in the right flank and anterior abdominal wall along the path of the biliary drain. The most common etiology of sepsis was bile peritonitis and infection of the ascites ($n=4$, 50%). In contrast, sepsis secondary to peritonitis occurred only once in the non-ascites subjects.

Complication rates were significantly different in patients with diffuse ascites verses perihepatic ascites. Diffuse ascites was associated with an increased the rate of

Table 2 Total and subclassification of major complications in non-ascites and ascites group

	Non-ascites ($N=362$)	Ascites ($N=129$)	P value
Total complications	28 (7.7%)	24 (19%)	0.0004
Sepsis	8 (2.2%)	8 (6.2%)	0.028
Hemorrhage	5 (1.4%)	8 (6.2%)	0.004
Inflammatory/infectious	5 (1.4)	3 (2.3%)	0.49
Abscess requiring drainage	4 (1.1%)	3 (2.3)	0.32
Death	1 (0.28%)	0 (0)	0.55
Catheter discontinuation	5 (1.4%)	2 (1.6%)	0.87

major complications compared to perihepatic ascites (26% vs 7.3%, *P* 0.014). A right-sided approach was associated with a higher rate of complications compared to a left-sided approach; however, this difference was not significant in the ascites group (14% vs. 22%; $P=0.25$). On the other hand, a significant difference in complication rates was observed in the non-ascites group between right-sided and left-sided approaches (11% vs 4.7%; $P=0.03$). In both ascites and non-ascites group, patients with benign strictures had a complication rate similar to that of malignant etiologies which is detailed in Table 3.

Discussion

PBD is a common intervention to treat biliary obstructions, in patients with significant comorbidities or risk-factors precluding surgical interventions or preventing endoscopic drainage [1, 9]. The presence of ascites has been cited as a relative contraindication for PBD, since the presence of ascites theoretically will impair tract maturation and thus increase the risk of peri-procedural complications [4, 5]. Although ascites is viewed as a relative contraindication to PBD placement, it is not directly addressed in the SIR standards for management of biliary obstruction and the expected complication in this setting remains unclear. Several studies have evaluated the safety of PBD procedures, looking at various patient factors that may contribute to poor outcomes [4–6, 9–13]. The current study hypothesized that not only the presence of ascites but also relative volume of the ascites would be associated with a higher incidence of complications then small volume ascites.

Table 3 Analysis of complication rates by subgroup

	Non-ascites ($N=362$)		Ascites ($N=129$)	
Etiology				
Malignant	14 (6.9%)	$P=0.48$	19 (22%)	$P=0.17$
Benign	14 (8.9%)		5 (12%)	
Location of obstruction				
Proximal	16 (8.1%)	$P=0.92$	14 (23%)	$P=1$
Distal	12 (8.4%)		15 (23%)	
Neither	0 (0%)		0 (0%)	
Unknown	0 (0%)		0 (0%)	
Fluid location				
Diffuse	N/A	N/A	21 (26%)	$P=0.014$
Perihepatic			3 (7.3%)	
Laterality				
Left approach	8 (4.7%)	$P=0.03$	8 (14%)	$P=0.25$
Right approach	19 (11%)		14 (22%)	
Bilateral	1 (5.9%)		2 (33%)	
Drain type				
Internal/external	18 (6.6%)	$P=0.11$	19 (20%)	$P=0.429$
External	10 (12%)		3 (13%)	
Converted/both	0 (0%)		2 (18%)	

In the 129 patients with ascites who underwent PBD placement, 19% developed major complications related to the procedure within 30 days of drain placement, while 7.7% of patients without ascites developed major complications and this difference was significant. Additionally, the overall incidence of major complications in patients with ascites is almost double the 10% threshold set by the SIR consensus guidelines. More importantly, the presence of large volume diffuse ascites was associated with an even greater rate of complications compared to those with less ascites (26% vs. 7.3%, $P=0.014$). In the subgroup analysis of complications, the difference was largely driven by increased rate of sepsis and hemorrhagic complications compared to subjects without ascites. When examining these complications, sepsis related to bile peritonitis or infection of the ascites was the most frequent cause of sepsis which was found to only happen once in subjects without ascites. Similarly, a large proportion of the bleeding complications were related to subcapsular hematomas which was not observed in the non-ascites groups. These hematomas may be a result of the mobility of the liver in ascites making PBD insertion more traumatic.

Other studies have conducted multivariate analysis of patient factors associated with the increased complication rates and found ascites to be associated with an increased odds of post procedural complications [4–6]. For example, Lucatelli et al. demonstrated that in a cohort of 97 patients who were afebrile at the time of PBD placement, the presence of ascites was associated with an OR 4.207 of developing fever within 10 days of the procedure; however, this did not reach statistical significance or quantify the number of subjects treated with ascites. When looking at hilar obstructions of malignant etiology, ascites was found to have an OR of 2.994 of developing major complications within 30 days of PBD placement in a study of 159 patients, which similarly failed to reach statistical significance [5]. One of the largest PBD studies by Tapping et al. involving 704 patients requiring PBD found the procedure related mortality to be 2%. In this study's multivariate analysis, the presence of ascites at the time of PBD insertion was identified as the one factor predisposing patients to complications leading to mortality (OR 2.4) [6].

Despite these studies suggesting ascites being a factor predisposing patients to increased complications following PBD, these studies did not sub-categorize patients based on volume or distribution of the ascites. In comparing the distribution of the ascites at the time of PBD placement, a significant difference in complication rate was identified between patients with ascites limited to the perihepatic space and those with diffuse ascites. Patients characterized as having

diffuse ascites were found to have a 26% major complication rate, while patients with perihepatic ascites were found to have a 7.3% major complication rate ($P = 0.014$). These data suggest that the amount and location of the abdominal fluid matters when assessing which patients with ascites are acceptable candidates for the procedure recognizing that the major complication rate in this group is at the upper threshold for the procedure. Furthermore, the data suggest that careful consideration and acknowledgement of increased risk must be made when consulting with patients with diffuse ascites prior to undergoing PBD.

While the laterality of the drain placement has been cited as a factor affecting complication rates in the setting of ascites, we did not observe any association of side of drain insertion or type of drain inserted with the rate of complications in patients with ascites. Covey et al. suggested that PBD in ascites patients should be performed employing a left-sided approach, because the right-sided approach more often leads to peri-catheter leakage, and because the left-sided approach is usually subcostal, rather than mid-axillary, the volume of ascites leakage can be minimized [1]. However, the results of this study did not corroborate this distinction between the laterality of drain placement. In all, 14% of patients with a left-sided drain placement suffered major complications, while 22% of patients with a right-sided drain had a major complication. While the right-sided drain was associated with a higher rate of major complications, the difference was not found to be significant in the ascites subgroup. Together, the data suggest that the laterality of drain placement does not have a significant effect on the incidence of major complications.

The current study is not without its limitations. Patients referred to the IR service for PBD, who were not deemed good candidates for the procedure because of any factor, including the presence of ascites, were not included in the study and this creates the possibility of selection bias. However, this selection bias more likely minimizes the negative effect of ascites on PBD complications. Additionally, the amount of abdominal fluid was not recorded for any of the patients because this information was only available in the medical record in the small minority of patients who received paracentesis around the time of PBD insertion. Therefore, the characterization of ascites as either diffuse or peri-hepatic is based on individual radiology reports which could vary depending on who was interpreting the imaging. Abdominal fluid is also mobile and can relocate depending on patient position during abdominal imaging, so there is a chance that it was not properly characterized in some patient records. Transient fluctuations in abdominal ascites also occur in patients with liver failure and biliary obstructions depending on the volume status of the patient. For this reason, the patients with diffuse ascites were grouped together. Finally, as is the case in any retrospective study in a large academic medical center, a modest number of patient complications may have been lost to follow up. Patients may have undergone the PBD at our hospital and then have followed up or presented with complications relevant to the study at local providers after PBD placement.

Conclusions

The complication rate following PBD placement in patients with ascites was 19% compared to 7.7% in patients without ascites, and this difference was significant. Additionally, we observed a significant increase in complication rate for patients who presented with either diffuse ascites compared to those with peri-hepatic ascites. These findings can help to guide interventional radiologists and referring physicians when considering PBD in patients with ascites. Preoperative ultrasounds to characterize the ascites may be warranted, and if diffuse ascites is found, prophylactic paracentesis may need to be performed in order to proceed with the procedure.

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