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Prospective study of outcomes after percutaneous biliary drainage for malignant biliary obstruction

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Abstract

Purpose—Percutaneous biliary drainage (PBD) is used to relieve malignant bile duct obstruction (MBO) when endoscopic drainage is not feasible. Little is known about the effects of PBD on the quality of life (QoL) in patients with MBO. The aim of this study was to evaluate changes in QoL and pruritus after PBD and to explore the variables that impact these changes.

Patients and Methods—Eligible patients reported their QoL and pruritus before and after PBD using the Functional Assessment of Cancer Therapy – Hepatobiliary instrument (FACT-HS) and the Visual Analog Scale for Pruritus (VASP). Instruments were completed pre-procedure and at one and four weeks following PBD.

Results—One hundred and nine (60 male/49 female) patients enrolled, 102 (94%) had unresectable disease. PBD was technically successful (hepatic ducts cannulated at the conclusion of procedure) in all patients. There were two procedure-related deaths. All-cause mortality was 10% (N=11) at 4 weeks and 28% (N=31) at 8 weeks post PBD with a median survival of 4.74 months. The mean FACT-HS scores declined significantly ($P<.01$) over time (101.3, 94.8, 94.7 at baseline, 1 week, 4 weeks, respectively). The VASP scores showed significant improvement at 1 week with continued improvement at 4 weeks ($P<.01$).

Conclusion—PBD improves pruritus but not QoL in patients with MBO and advanced malignancy. There is high early mortality in this population.

Keywords

Quality of life; percutaneous biliary drainage; outcomes; malignant biliary obstruction; hepatobiliary cancers

Introduction

Percutaneous biliary drainage (PBD) is performed in patients with malignant biliary obstruction (MBO) to address clinical problems resulting from the obstruction. PBD may be performed to relieve cholangitis or pruritus or to lower serum bilirubin to allow the administration of chemotherapy.^{1–4} Severe pruritus can be debilitating and rapid relief after biliary decompression has been reported.⁵ Other clinical benefits remain unproven.

Endoscopic stent placement (ESP) is the preferred method for treating bile duct obstruction because it does not require an exteriorized catheter. In some patients, ESP is either technically infeasible or does not succeed.^{6–8} PBD is an alternative approach, albeit one with significant risks, including procedure-related pain, bleeding, and sepsis.^{3–4} Patients undergoing PBD often require an exteriorized catheter with possible catheter-related pain, leakage, and/or accidental dislodgement. The patient may have recurrent cholangitis, and the procedure may fail to lower the serum bilirubin.^{2, 4–6, 9}

The potential effect on quality of life (QoL) is an important consideration when deciding whether to attempt PBD. To date, there is only one study of QoL in patients undergoing drainage of MBO.⁸ The primary objective of this study was to describe changes in QoL after PBD for MBO. The secondary objective was to explore variables that may influence the changes in QoL.

Patients and Methods

Subjects

Consecutive adult patients with MBO scheduled for PBD between October 15, 2004 and December 15, 2006 were invited to participate in this Institutional Review Board-approved, prospective, longitudinal study. Eligible patients had radiologic evidence of MBO, Karnofsky performance status (KPS) >50%, spoke and read English, and could give informed consent. Patients were not candidates for endoscopic drainage, but were eligible for this study if they had failed prior endoscopic, percutaneous, or surgical drainage.

Instruments

Functional Assessment of Cancer Therapy–Hepatobiliary (FACT-HS) is a 45-item self-report instrument designed to measure QoL in patients with hepatobiliary cancers.¹⁰ It is comprised of the FACT-General (FACT-G) and the hepatobiliary subscale (HS). The FACT-G consists of 27 items which measure 4 domains of well-being in cancer patients: physical well-being (PWB), social/family well-being (SWB), functional well-being (FWB), and emotional well-being (EWB). The instrument employs a Likert-type format (0- ‘not at all’ to 4- ‘very much’). Lower total scores reflect lower QoL. The FACT-G score is a total

of the subscale scores. The FACT-G has demonstrated internal consistency, score stability, reliability, and validity.^{11–16} The HS is a reliable and validated disease-specific subscale consisting of questions relating to pruritus, jaundice, and drainage catheters.^{10, 17}

Visual Analog Scale for Pruritus Assessment (VASP) is a four item analog scale measuring the sensation of itch.^{18–20} Each question is on a 10 point scale with zero correlating to no itch and ten equating to very strong itch. During completion of the instrument, the level of pruritus is reported at four time points: current intensity, worst intensity, lowest intensity, and the intensity of pruritus felt with a mosquito bite, which is used as a normalizing benchmark for pruritus. The instrument has demonstrated validity and reliability.^{19–20}

Methods

Patients referred for PBD were evaluated by the Interventional Radiology Service, in consultation with the Gastroenterology Service, when appropriate, to confirm that endoscopic management of MBO was not feasible. Before PBD, subjects provided informed consent for participation in this study and completed the FACT-HS questionnaire and the VASP. PBD procedures were performed by one of eight Interventional Radiologists.

In the original study design, patients were asked to complete instruments at baseline, one week (+/- 2 days), 4 weeks (+/- 1 week), 9 weeks (+/- 1 week), and 14 weeks (+/- 1 week) post PBD. Follow-up instruments were completed at clinic visits whenever possible, or by mail. The initial group of 69 subjects had low response rates at 9 and 14 weeks due to disease progression, so the protocol was amended to exclude these assessments.

Clinical follow-up was obtained by patient interview and chart review. Retrospective chart review was used to identify adverse outcomes occurring within 30 days of PBD. Complications were graded by the published guidelines of the Society of Interventional Radiology, categories defined in Table I.²¹ Vital status was monitored through February, 2009.

Two interventional radiologists (GIG and LAB) retrospectively determined the anatomic level of biliary blockage, or level of obstruction (LO), by reviewing the cholangiogram obtained at PBD. The LO was recorded as

- Low/mid bile duct obstruction (LBDO): Obstruction occurs between the ampulla and a level 2 centimeters below the confluence of the right and left bile ducts.
- High bile duct obstruction (HBDO) with isolation: Obstruction occurs at or above (more cranial to) the union of the left and right hepatic ducts (HD) resulting in lack of communication of one or more bile ducts. This can cause *complete isolation* in situations where the segment of the un-drained liver is not visualized on percutaneous transhepatic cholangiogram (PTHC); or *impending/incomplete isolation* in situations where it is possible to instill but not remove contrast into one of the HD during PTHC resulting in a HD with stagnant, contaminated bile increasing the infection risk.

- HBDO without isolation: Obstruction occurs within the common HD up to the confluence of the biliary tree, not impairing the flow of bile between the right and left HD.

Analysis/Biostatistics

FACT-HS instruments were scored following published guidelines.¹⁰ Changes in QOL and pruritus from baseline were calculated for each time-point. For statistical analysis, all subscale scores were scaled to make them range from 0–100. Total and subscale QOL scores were summarized for each time-point. Longitudinal analysis of scores across time used piecewise linear regression functions for each patient and the repeated nature of the data was taken into account using random effects modeling. This approach was used to adjust scores for baseline covariates and to test for various subgroup differences. In order to account for the potential effect of missing data points the group of patients who completed all time points was separately analyzed using repeated measures analysis.

Serum bilirubin values were collected at baseline and during follow-up. Distribution of time to bilirubin normalization was estimated using the Kaplan-Meier method in order to account for early death and short follow-up. All analyses were performed using SAS version 9.2.

Six individual items from the FACT-HS were analyzed separately for change over time. They were selected to represent frequently verbalized complaints from the study patient population. These items assessed QoL, side effects of treatment, appetite, pruritus, pain, and jaundice. The purpose of this item assessment was to determine if the individual items were consistent with the overall FACT-HS results.

Results

Patient Sample

Over the 26 month study period, 109 patients enrolled (Figure I). Of these, 102 patients (94%) had metastatic or locally advanced disease, and the other seven had potentially curable disease. HBDO with or without isolation was present in 70 patients (64%). Sixty patients (55%) were primarily referred to IR for PBD. The remainder were referred after diagnostic endoscopy (n=2, 2%), unsuccessful attempt at ESP (n=23, 21%) or after an ESP failure (n=24, 22%). Indications for PBD included hyperbilirubinemia precluding chemotherapy administration (generally > 2 mg/dl) (53%), pruritus (18%), and cholangitis (10%). Baseline patient characteristics are summarized in Table II.

Procedure Outcomes

All procedures were technically successful, in that the obstruction was relieved by placement of a catheter or a primary stent (PS). The initial procedures performed are summarized in Table 2. PS were placed in 23 patients (21%), but required conversion to an externally draining catheter in three patients (13% of 23). Including the PS failures, 89 patients (82%) had an exteriorized catheter (either external biliary drain (EBD) or internal-external biliary drain (EBD/IBD)) after the initial procedure. Of these, 25 (28%) were converted to an internal stent at a median of 33 days after the initial procedure (range 3–204

days). Overall, 41% (45 of 109) of patients ultimately had internal biliary stents without any external catheter.

After PBD, 21 patients required an additional drainage catheter. Including routine catheter changes, 85 patients out of 109 had additional procedures; each patient underwent an average of 3.1 procedures per patient (median 2, range 1–14) in the six months following the procedure.

Complications and adverse events are presented in Table I. Overall, 19 (17.4%) patients had no post-procedure complications documented in their medical record, 35 (32.1%) had at least one minor complication reported, while 55 (50.5%) had at least one major complication. Of these 55, 38 patients had at least one major and at least one minor complication reported. One patient developed chronic renal insufficiency related to dehydration from his biliary output and requiring intermittent IV hydration.

Survival

Median survival was 4.8 months. Eleven patients (10%) died within 4 weeks, and 31 patients (28%) died within 8 weeks of biliary drainage. Two deaths were directly related to PBD (1 sepsis, 1 hemorrhage) (Table I). One year mortality was 68.8% (n=75) (Figure II).

Instrument Response Rates

Instrument response rates declined over time. All patients completed the baseline instruments. At one week, 64 patients completed the instruments (59% of total enrolled, 60% of survivors). At four weeks, 43 patients completed the instruments (39% of the total enrolled, 43% of survivors). Thirty-four patients completed all time points (31% of total enrolled, 34% survivors).

FACT- HS results

Baseline scores in all subscale and combined measures were all less than 67% of the highest possible score for each measurement except in SWB (Table III). From baseline to 4 weeks, there was a statistically significant decline in the FACT-HS ($P<.01$). There was also a statistically significant decline noted in the following subscales: FWB ($P<.01$), SWB ($P<.01$) and HS ($P<.01$). There was no significant change in the EWB, PWB, or FACT-G subscales (Table III). Repeated measures analysis showed similar changes in QoL in subjects who did or did not complete all time points. There was no significant interaction between QoL trajectory and the occurrence of procedure-related complications (data not shown).

Analysis of specific questions within the scales addressing QoL, treatment side effects, pain, and appetite-related questions demonstrated no significant change from baseline to 4 weeks. There was statistically significant improvement noted in the items addressing jaundice and pruritus (Table III).

VASP results

The VASP instrument documented a significant improvement in pruritus after PBD in all intensity categories. Although 96 (88%) patients reported some degree of pruritus on the

baseline VASP assessment, only 20 patients underwent PBD for that reason alone. Patient ratings of current pruritus intensity declined from 2.26 to 0.75 over the four week period ($p<.01$). Lowest intensity ratings declined from 1.18 to 0.58 during that time period ($p<.01$). Worst pruritus rating declined from 4.92 to 3.88 ($p<.01$).

Patient Outcomes: Decrease in Total Bilirubin

At presentation, the median bilirubin was 11.8 mg/dl (range 0.8–51.6). Two patients (2%) had a serum bilirubin less than 2 at the time of initial drainage, both having had surgical bypass in the past and presenting for PBD with symptoms of cholangitis. Of the 107 patients whose bilirubin was greater than 2 mg/dl at the time of drainage, fifty-seven (53%) had their bilirubin decrease to less than 2 mg/dl after initial drainage. Of the 58 patients whose sole indication for drainage was to lower bilirubin to receive chemotherapy, 33 (57%) achieved a serum bilirubin less than 2 mg/dl. Out of these 58 patients, 26 (44.8%) went on to receive chemotherapy at this institution. The median time to achievement of serum bilirubin less than 2 mg/dL was 2.8 weeks (Figure III). For the 50 patients whose serum bilirubin did not decline to below 2 mg/dl, the last recorded bilirubin was drawn at a median of 1.2 weeks after drainage (range 0.1 to 12.1 weeks), mostly due to early death due to malignancy.

Patient Outcomes: Level of Obstruction (LO)

Based on the LO, patients were divided into two groups: patients with HBDO with isolation ($n=50$) and patients with either HBDO without isolation or with LBDO ($n=59$). Among those patients with HBDO and isolation, the pattern of biliary obstruction and catheter placement permitted drainage of a hemi- liver in 34 patients (15 right sides and 19 left sides); drainage of more than a hemi- liver in 9 patients, and drainage of less than a hemi- liver in 7. The presence of duct isolation did not correlate with changes in QoL. The FACT-HS scores significantly declined in both groups ($p<.01$) with a similar rate of decline between the groups ($p=0.267$).

Serum bilirubin decreased significantly in the four weeks after PBD independent of LO (data not shown). The nadir bilirubin in patients with HBDO with isolation was greater than 6mg/dl in 32% of the cases (16 of 50). On the other hand, only 5% of patients with LBDO (2 out of 39 patients) and 10% of patients with high obstruction without isolation (2 out of 20 patients) had their nadir bilirubin greater than 6 mg/dl following drainage ($p=0.005$, chi-square test).

Discussion

The present study is the largest prospective evaluation in the literature describing QoL outcomes of individuals undergoing PBD for MBO. The results demonstrate that PBD improves pruritus and often reduces hyperbilirubinemia to a level that does not contraindicate the administration of chemotherapy. However, PBD is associated with a significant rate of complications and does not halt the inexorable decline in QoL experienced by patients whose median post-procedure survival is less than 5 months. As the goal of biliary drainage is palliation, several authors emphasize the need to document the effect of drainage on QoL.^{17, 22–24} Recent QoL studies in MBO populations have reported

improvement in QoL after ESP as well as declining QoL related to hepatobiliary cancers in general.^{25–26} Evaluating the effect of PBD, Saluja *et al.* investigated post-procedure QoL in a population of gallbladder cancer patients with MBO randomized to receive endoscopic or percutaneous placed plastic stents.⁸ The patients with percutaneous stents were more likely to have a successful procedure, fewer episodes of cholangitis and improved QoL three months post procedure. However, all the patients in this study were eligible for consideration of ESP and may have had less advanced malignancy than those in the present study. PBD is usually not recommended until surgical bypass and ESP have been deemed infeasible.^{3, 6, 9} Another possible explanation for the differences between our results and those of Saluja is that the outcomes of patients with gallbladder cancer may not be representative of the broader population of patients with MBO.

The patients in this study had a high complication rate but within the range of previous reports.^{4, 9, 27–28} This paper is the first to employ SIR standards for reporting complications which represent the full scope of problems related to PBD, including commonly overlooked and unreported complications such as catheter malfunction or dislodgement requiring intervention. As there was no association between complications and changes in QoL, the occurrence of complications does not explain the inability of PBD to arrest the declining QoL in the subjects of this study.

We were unable to identify specific predictors of success of PBD in improving QoL. We hypothesized that patients with HBDO would have more complex procedures than patients with LMO, leading to more complications, less technical success, and lower QoL relative to patients with LMO. While it is possible that our study lacked sufficient power to detect a difference in outcome based on LO, none was demonstrated. Despite the high KPS at enrollment (mean 74%), the patients uniformly had a declining QoL with high morbidity and mortality. Therefore, KPS is also not a reliable predictor of successful outcome in this patient population.

Instrument completion rates were lower than expected, but consistent with other reports of QoL assessments in hepatobiliary cancer.^{21, 25} The results were statistically similar whether interpreted for the 31% of patients who completed all three time points or analyzed by methods that allowed the inclusion of data from patients with missing time points. This suggests that our conclusions were not sensitive to particular modeling assumptions.

The most common indication for drainage was to reduce the serum bilirubin to permit delivery of chemotherapy. Since patients did not experience an improvement in their QoL after PBD it is important to determine whether the procedure facilitated the delivery of palliative systemic treatment. Twenty-six patients out of the 58 patients (44.8%) whose indication for PBD was specifically to lower bilirubin went on to receive chemotherapy at this institution. Treatment data was collected retrospectively so the possibility exists that some of the remaining 32 could have received chemotherapy at another institution. For this reason, a serum bilirubin less than two was used as a surrogate indication that the procedure achieved the intended outcome of the original indication for the procedure. Of the 58 patients with this indication, 33 (57%) achieved post-drainage bilirubin values less than 2 mg/dl, the level required to allow the administration of optimal chemotherapy, though

chemotherapy may not have been ultimately possible because of a deteriorating clinical presentation. Among all subjects, the actuarial estimate of the proportion attaining a bilirubin less than 2 mg/dL was approximately 49.9%. The robustness of this estimate may be reduced by the loss of patients to follow-up and discontinuation of laboratory evaluation of patients with progression of their underlying disease.

Since pruritus is an important indication for PBD, a separate assessment tool was included to address this symptom. The results of the VASP instrument demonstrated a decline in pruritus that correlated with the FACT item on pruritus. From these data, it is clear that one of the most reliable outcomes of PBD is the relief of pruritus.

The analysis of the FACT-HS instrument suggests that PBD itself does not lead to an overall improvement in QoL. Before undergoing PBD, baseline QoL was already markedly reduced in all subscales and combined measures except for SWB. Although there was a further significant, uniform decrease in QoL over a relatively short period of time in FWB, SWB, HS, and the overall FACT-HS, the changes may not have been clinically significant. It remains possible that PBD decreased the rate of this decline. This benefit may have been obscured by the negative impact of progression of the underlying disease. The randomized trial by Saluja *et al.* suggested a potential positive impact of PBD in face of overall decline in QoL when the group compared percutaneous plastic stents and endoscopic stents.⁸ However, it is also possible that PBD contributed to the rapid decline in QoL. Whether PBD modifies the rate of QoL decline or improves survival cannot be addressed by this single-arm study.

The results of this study highlight the fact that patients with MBO presenting for PBD have high early mortality and a declining QoL, likely due to progression of the underlying disease. QoL does not increase after PBD regardless of technical success. Palliation of pruritus is probable, whereas the procedure is less successful in lowering the serum bilirubin to a level that permits the administration of chemotherapy. Performance of PBD without a clear clinical indication is not supported. The findings of this study might form the basis of discussion during informed consent for PBD. Additional studies are necessary to further delineate parameters for optimal patient selection and to determine the value of PBD relative to other strategies for management of MBO.

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Synopsis

Percutaneous biliary drainage improves pruritus but not quality of life in patients with malignant biliary obstruction and advanced malignancy. There is high early mortality in this population.

Figure I.
Patient enrollment results

Figure II. Overall survival curve for 109 patients undergoing PBD for MBO
Median survival 4.74 months.

Figure III. Probability of decrease in bilirubin to below 2 mg/dl post procedure (solid line)
Dashed line provides the 95% CI. Patients with early death or short follow up were censored. Curve truncated past 12 weeks because of no change in probability.

Table I

Total occurrences of complications 30 days following procedure

Procedural Complications	Number of patients experiencing given complication	Percentage of total patients* N=109
No Reported Complications	19	17.4%
<u>Minor Complications Level A (no therapy required) & Level B (minimal therapy, includes admission for overnight observation)</u>		
Pain	34	31%
Leaking around catheter requiring no intervention	31	28%
Fever post procedure	23	21%
Other: hemobilia (8), minor abscess (1), elevated creatinine (2), biliary tree thrombus (4), rigors (4), pruritus (2), hypotension (3)	24	22%
Total minor complications: 112 incidences		
<u>Major Complication Level C & D (resulting in hospitalization longer than overnight or increased level of care)</u>	63	58%
Catheter malfunction	8	7%
Peri-catheter Leakage requiring catheter change	17	16%
Infectious complication	27	25%
Stent occlusion or non-functional stent	4	4%
Bleeding complications	5	5%
Pain	1	0.9%
Dislodged metal stent during placement	1	0.9%
Chronic renal insufficiency due to dehydration from drainage catheter	1	0.9%
<u>Major Complication Level E (permanent change)</u>	3	3%
Persistent Unresolved Leaking	1	0.9%
Persistent unresolved fevers with sepsis	2	2%
<u>Major Complication Level F (death)</u>	2	2%
Arterial Bleed	1	0.9%
Septic Shock	1	0.9%
Total Major Complications: 69 incidences		

* Percentages do not total 100% because some patients experienced more than one complication.

Table II

Demographics, patient and procedure characteristics

Variable	N in parentheses	%
Gender	Male (60)	55%
	Female (49)	45%
Age	Median 66 (range 21–85 years old.)	
Diagnosis	Cholangiocarcinoma (32)	29.4%
	Pancreatic adenocarcinoma (32)	29.4%
	Metastatic colorectal carcinoma (19)	17.4%
	Gallbladder carcinoma(10)	9.1%
	Other (16)	14.7%
Bilirubin at presentation	Mean 12.9 mg/dl; standard deviation 7.7	
	Median 11.8 mg/dl (range 0.8–51.6 mg/dl)	
Indication for performing procedure	Lower bilirubin to receive chemo (58)	53.2%
	Relieve pruritus (20)	18.3%
	Suspected or proven cholangitis (11)	10.1%
	Other and multiple indications (20)	18.4%
Stage of Disease	Unresectable (100)	94%
	<ul style="list-style-type: none"> Metastatic (86) Locally advanced/unresectable (16) 	
	Potentially curable/Operable (7)	6%
Level of Obstruction	High with Isolation (50)	46%
	High without Isolation (20)	18%
	Low/mid (39)	36%
Previous instrumentation of biliary tree	Prior biliary tract surgery (23)	21%
	<ul style="list-style-type: none"> Biliary bypass (11) Cholecystectomy (11) Operative excision of intra-ductal tumor (1) 	
	ERCP for diagnosis only (2)	1.8%
	ERCP stent- plastic or metal (24)	22.0%
	ERCP failure (23)	21.1%
	Direct referral to IR (60)	55.1%
Karnofsky performance status at baseline	Mean: 74%	
	Median: 80% (range 60 –100)	

Variable	N in parentheses	%
Initial procedure performed	Right EBD *	2.8%
	Right EBD-IBD **	40.4%
	Left EBD	7.3%
	Left EBD-IBD	28.4%
	Primary stent ***	21.1%

* EBD: External biliary drainage catheter. Placement of the catheter into a bile duct proximal to the obstruction. Exteriorized drainage bag required.

** EBD/IBD: Internal–External biliary drainage. Placement of a catheter into the bile ducts that crosses the obstruction terminating in the duodenum. Drainage bag not required because catheter can be capped for internal drainage.

*** Primary stent: Metal stent(s) are placed across the obstructing lesion permitting the free flow of bile (internal drainage) into the bowel at time of initial biliary drainage.

Mean FACT and subscale scores at each time point and the significance to the changes. Specific item analysis demonstrating significant improvement in jaundice and itching.

Table III

	Highest possible score	Baseline N= 109	Week 1 N=64	Week 4 N=43	p mixed effect model
Subscale	(percentage of highest possible score indicated in parentheses)				
Emotional Well-being	24	15.14 (64%)	16.02	15.84	0.3
Functional Well-being	28	14.89 (53%)	11.85	13.49	<.01
Physical Well-being	28	16.17 (60%)	16.46	17.31	0.6
Social/Family Well-being	28	25.64 (92%)	24.84	23.40	<.01
Hepatobiliary	72	28.98 (40%)	25.43	23.93	<.01
Combined measures					
FACT general	108	72.19 (67%)	69.42	71.37	0.1
FACT hepatobiliary	180	101.27 (56%)	94.83	94.71	<.01
Specific item analysis	(N for each item indicated in parentheses)				
Bothered by side effects of treatment *	4	2.7 (81)	2.8 (58)	2.9 (41)	0.6
Content with QoL right now	4	1.6 (107)	1.3 (63)	1.6 (42)	0.9
Good appetite	4	1.6 (109)	1.7 (62)	1.8 (43)	0.7
Bothered by jaundice *	4	1.9 (109)	2.7 (64)	2.9 (43)	<.01
Itching *	4	2.1 (108)	3.0 (64)	3.3 (43)	<.01
Pain *	4	2.5 (108)	2.3 (64)	2.6 (42)	0.3

* Subscales were inverted per analysis guidelines for FACT instruments so higher numbers correlate with improved condition.