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Original Article

Surgery Section

Quality of Life Assessment after Percutaneous Transhepatic Biliary Drainage in Patients with Advanced Gall Bladder Carcinoma: A Prospective Interventional Study

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ABSTRACT

Introduction: Gall Bladder Cancer (GBC) is associated with poor prognosis, particularly when presenting with jaundice. In these cases, jaundice often indicates advanced disease and precludes curative surgical options. Palliative management with biliary drainage may be the only available option to address symptom relief, restore liver function, and improve Quality Of Life (QOL). The impact of Percutaneous Transhepatic Biliary Drainage (PTBD) on QOL in such patients remains underexplored.

Aim: To evaluate the effectiveness of PTBD in improving QOL in patients with advanced GBC and obstructive jaundice, using two validated QOL indices.

Materials and Methods: A prospective interventional study in patients with unresectable GBC and jaundice undergoing PTBD was conducted on 70 patients at a tertiary care centre in northern India between 2019 and 2024. Just before and after PTBD, QOL was assessed using FACT-Hep and EORTC QLQ-BIL21/QLQ-C30 at three time points: preprocedure, one month postprocedure, and three months postprocedure. Data were analysed using descriptive statistics and repeated measures ANOVA.

Results: Significant improvements were observed in overall QOL and key domains-physical, social, emotional, and functional well-being- between baseline and follow-ups ($p<0.05$). Jaundice-related symptoms, eating ability, and fatigue showed marked improvement, though pain and anxiety scores remained unchanged. Complications included periprocedural leaks in 22 patients (31.4%), catheter blockage or pull-out in 16 (22.9%), and cholangitis in 8 (11.4%).

Conclusion: PTBD effectively improves QOL in patients with advanced GBC by alleviating jaundice-related symptoms and enhancing functional domains, despite procedural complications. Optimising post-procedural care and addressing complications are crucial for maximising palliative benefits in this patient population.

Keywords: Cholangitis, Gall bladder cancer, Jaundice, Lymph nodes

INTRODUCTION

The GBC typically carries a poor prognosis, especially when it presents with jaundice. The presence of jaundice in such cases often signals advanced stage disease, which generally precludes curative surgery. In these situations, palliative care-primarily through biliary drainage-may be the sole approach available to alleviate symptoms, restore liver function, and enhance the patient's QOL [1-5].

Biliary interventions are essential in managing jaundice by alleviating obstruction, improving hepatic function, and reducing complications such as cholangitis [6,7]. Jaundice in GBC results from several underlying mechanisms, including tumor invasion of the common bile duct, hilar infiltration, compression of the external biliary ductal system by metastatic lymph nodes, intraluminal tumor growth, extensive liver metastasis, and coexisting common bile duct stones [8,9].

Palliative care for jaundice in inoperable GBC involves surgical, endoscopic, and percutaneous methods. Due to lower risks and complications, minimally invasive procedures such as endoscopic and percutaneous biliary drainage have become preferred options over traditional surgical palliation [10-12]. Endoscopic drainage by Endoscopic Retrograde Cholangiopancreatography (ERCP) is a suitable treatment option for blockages located in the middle and distal parts of the common bile duct [13,14], while PTBD is the preferred treatment option for blockages near or involving the hilum and suprahilar regions in GBC patients [15,16].

PTBD involves the percutaneous insertion of a catheter into the biliary system to relieve obstruction. This technique not only alleviates jaundice but also prevents complications such as cholangitis and hepatic failure. Chronic cholestasis leads to systemic complications, including immune dysfunction, delayed wound healing, and organ impairment, which may be mitigated by PTBD [17-19]. By improving bile flow and normalising hepatic synthetic function, PTBD may significantly reduce infection risks and other systemic complications, thus potentially enhancing QOL [18,19].

Although PTBD plays a vital role in palliative care for GBC, its impact on QOL remains underexplored. A comprehensive assessment of QOL before and after PTBD is crucial for understanding its effectiveness, guiding clinical decisions, and optimising care for patients with advanced, inoperable GBC. Thus, this study aims to evaluate, statistically, the effectiveness of PTBD in improving QOL in patients with advanced GBC and obstructive jaundice, using two validated QOL indices. The objectives were to determine statistically the change in global QOL scores using the European Organisation for Research and Treatment of Cancer (EORTC) QLQ-BIL21 and the Functional Assessment of Cancer Therapy-Hepatobiliary (FACT-Hep) questionnaires after PTBD in patients with unresectable GBC and jaundice.

MATERIALS AND METHODS

A prospective interventional study of Unresectable Gall Bladder Cancer (GBC) patients undergoing PTBD for obstructive jaundice was conducted at the Department of Surgical Gastroenterology, a tertiary care and referral institute in northern India, between January 2019 and December 2022, with a minimum follow-up of three months postprocedure for each participant. Data analysis and interpretation were conducted between 2022 and 2024. The study was approved by the Institutional Ethics Committee (reference number: 202/22).

Inclusion criteria: The study included patients with inoperable gall bladder carcinoma with jaundice and no prior history of specific treatment for gall bladder malignancy.

Exclusion criteria: Patients were excluded if they did not give consent, had upfront resectable disease, had poor performance status (Karnofsky score <50) [20], uncontrolled ascites, duodenal obstruction, or if they underwent ERCP. Participants enrolled in the study who were lost to follow-up or those who died within three months of the procedure were excluded at the time of data analysis.

Consecutive sampling was planned for patients with non resectable GBC undergoing PTBD. All patients who fulfilled the inclusion criteria were informed regarding the purpose of the study. Only those who consented for participation were included. The decision was to include all such patients who presented to the department between January 2019 and December 2022.

Patients enrolled in the study were assessed for gall bladder malignancy resectability status and presence of metastasis based on liver biochemistry, abdominal ultrasonography (US), and Contrast Enhanced Computed Tomography (CECT). Additionally, MRCP was performed to assess the level of biliary obstruction using the Bismuth-Corlette grading system [21], in which Type I involves the common hepatic duct below the confluence; Type II reaches the confluence but does not extend into either the right or left hepatic duct; Type IIIa involves the confluence and extends into the right hepatic duct; Type IIIb involves the confluence and extends into the left hepatic duct; and Type IV involves both right and left hepatic ducts or presents as multifocal disease. This classification is required for treatment planning and prognostication, as a higher level of obstruction is associated with extensive disease and reduced resectability. Image-guided Fine Needle Aspiration Cytology or Fine Needle Aspiration Biopsy (FNAC/FNAB) was done to confirm the histopathological diagnosis once upfront resectability was ruled out. All eligible patients underwent PTBD as the primary palliative intervention. Patients with the financial means who underwent antegrade internalisation with self-expanding metallic stents (SEMS) were excluded from the analysis.

Study Procedure

Prior to the intervention, patients underwent baseline investigations, including Complete Blood Count (CBC), biochemical tests, prothrombin time, viral markers, and serum tumor markers (CEA and CA19-9). Additional preprocedure assessment included chest X-ray and electrocardiogram.

Validated questionnaires (in Hindi and English) were provided to the patients 1-2 days before the procedure. The instructions for completing the questionnaires were explained by the investigator to the patient and to the next of kin. Ample time was provided for completion of the survey, and specific issues or concerns of each patient were discussed in depth with the investigator. For illiterate patients, the investigator read the questions aloud and recorded responses.

Participation was voluntary, with no coercion, and refusal did not alter the management plan. The independent investigator was not part of the data analysis team. To prevent infection, a prophylactic antibiotic (cefoperazone-sulbactam) was administered two hours before the PTBD procedure.

As per institutional protocol, PTBD was performed in patients with serum bilirubin levels ≥3 mg/dL (range 3.2-29 mg/dL) who were expected to develop progressive jaundice. The number of PTBD catheters inserted was determined based on the Bismuth-Corlette classification of the biliary obstruction and the presence of cholangitis. Higher-grade obstructions or unresolved cholangitis required multiple catheters. PTBD was conducted using the Seldinger technique under ultrasound and fluoroscopic guidance, employing a Chiba needle (Cook Medical, Bloomington, IN). Following the procedure, patients received two additional doses of the antibiotic cefoperazone-sulbactam as part of their post-procedural care.

Quality of Life (QOL) Assessment: To assess QOL, scoring was performed based on patient responses to two validated tools—the EORTC QLQ-BIL21 and QLQ-C30—and the FACT-Hep version 4, by an investigator who was blinded to data analysis [22,23]. Follow-up assessments were scheduled at one month and three months postprocedure.

EORTC QLQ-BIL21: The questionnaire consists of three single-item assessments relating to treatment side effects, difficulties with drainage bags/tubes, and concerns regarding weight loss, in addition to 18 items grouped into five scales: eating symptoms (4 items), jaundice symptoms (3 items), tiredness (3 items), pain symptoms (4 items), and anxiety symptoms (4 items). Each item is scored on a 4-point Likert scale (1=not at all to 4=very much), with scores linearly transformed to a 0-100 scale [24].

FACT-Hep: The questionnaire consists of physical well-being, social well-being, emotional well-being, functional well-being, additional concerns, and hepatobiliary-specific concerns domains. It has 45 questions, divided into two parts: the FACT-G (27 questions) and the hepatobiliary subscale (18 questions). Higher scores on the FACT-Hep indicate better QOL [25]. Each item is rated on a 5-point Likert scale (0=not at all to 4=very much), with some items reverse-scored so that higher total scores consistently indicate better QOL. Subscale scores are summed to obtain the FACT-G total score, the hepatobiliary subscale score, and the overall FACT-Hep score, yielding a range of 0-180 points where higher scores represent better health status [23,25].

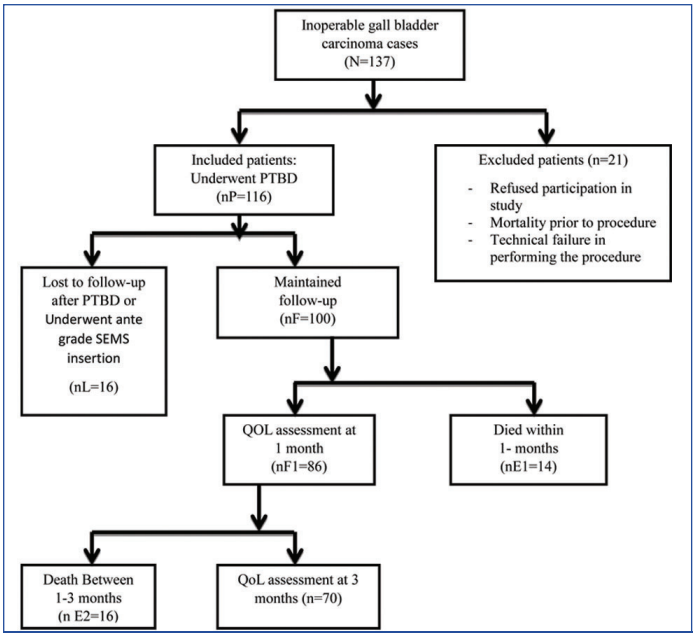
STATISTICAL ANALYSIS

Data analysis was performed using International Business Machines Statistical Package for the Social Sciences (IBM SPSS) Statistics version 12.0. Descriptive statistics included means with Standard Deviations (SD) or medians for numerical data, and percentages for categorical data. To compare QOL scores at different time points, repeated measures ANOVA was employed. Specifically, changes in scores between baseline and one month, baseline and three months, and one month and three months were analysed. A p-value of less than 0.05 was considered statistically significant.

RESULTS

During the study period, 137 patients with unresectable GBC and obstructive jaundice presented to the department. Of these, 116 underwent PTBD (N=116) and 21 were excluded from the study for various reasons as depicted in [Table/Fig-1]. Of the 116 patients, 70 completed the three month follow-up and their data were used for final analysis (n=70). Reasons for dropout/loss to follow-up of the remaining 46 patients are depicted in [Table/Fig-1]. Worsening of cholangitis and death occurred in four patients within one month of PTBD (all four patients had initially presented with GBC and cholangitis; hence, they were excluded from the final analysis) and 10 patients succumbed to progression of disease in the first month following PTBD. Another 16 patients died between one and three months after PTBD due to the primary malignancy [Table/Fig-1].

The mean age of the study participants (n=70) was 54.0±8.5 years, indicating that most patients were above 50 years, with moderate age variability reflected by the SD. The sex distribution showed a slight female predominance, with 42 females and 28 males (female:male ratio≈3:2). Demographic and clinical data are detailed in [Table/Fig-2]. The patients had elevated bilirubin, alkaline phosphatase, and tumour markers (CEA and CA 19-9). The majority presented with Bismuth-Corlette Type I n=33 (47.14%) and Type II n=26 (37.14%) biliary obstructions, with fewer cases of Type III n=11 (15.71%), and no cases of Type IV block. Postprocedure complications included PTBD catheter blockage/pull-out requiring PTBD reinsertion n=16 (22.86%), peri-PTBD leaks n=22 (31.43%), and cholangitis n=8 (11.43%).



[Table/Fig-1]: Flow Chart depicting patient recruitment in study planning and data analysis.

Parameters	Value in mean±SD
Age (years)	54.00±8.5
Sex ratio (female/male)	42:28
Haemoglobin (g/dL)	10.20±2.0
Total bilirubin (g/dL)	15.00±8.0
Alkaline phosphatase (IU)	872.00±324.0
Albumin (g/dL)	2.60±1.5
CEA(ng/mL)	21.00±9.
CA19.9(U/mL)	958.00±560.00
Bismuth-Corlette stricture Types	**n=number (Percentage)**
Type 1	33 (47.14)
Type 2	26 (37.14)
Type 3	11 (15.71)
Type 4	0 (0%)
Complications	
PTBD Block/pull out	16 (22.86%)
Cholangitis	8 (11.43%)
Peri PTBD Leak	22 (31.43%)
Perihepatic Bilioma	2 (2.86%)

[Table/Fig-2]: Baseline characteristics and complication rates (total patients=70).

Improvements in QOL over a three month period were assessed using EORTC QLQ-BIL21-C30 scores, detailed in [Table/Fig-3]. On analysis of overall scores, eating symptoms and jaundice symptoms showed the most significant changes, with p-values of 0.012 and 0.009 at one month and 0.011 and <0.001 at three months, respectively. However, pain and anxiety symptoms, while showing improvement, failed to reach statistical significance (p=0.069 and p=0.090). The "Other" symptoms, which include additional health factors, also showed no significant change (p=0.10 and p=0.09).

Parameters	Baseline scores	One month follow-up	p-value	Three months follow-up	p-value (0-3 months)
Overall score	72.28±6.3	48.49±6.93	<0.001	49.37±6.54	<0.001
Eating symptoms	75.67±4.0	54.3±4.2	0.012	52.6±4.0	0.011
Jaundice symptoms	71.0±6.1	37.67±6.3	0.009	41.6±4.0	<0.001
Tiredness	74.33±3.0	40.33±7.67	0.031	39.0±8.0	0.017
Pain	75.67±4.0	50.0±12.6	0.069	55.33±15.6	0.058
Anxiety symptoms	78.67±17.0	54.33±4.0	0.09	52.67±4.0	0.08
Others	58.33±8.0	54.3±13.30	0.1	55.0±11.6	0.09

[Table/Fig-3]: Symptom and Quality of Life (QOL) Scores in n=70 patients undergoing intervention, at baseline, 1 month, and 3 months using EORTC QLQ BIL21.

Improvements in QOL over three months according to FACT-Hep scores are highlighted in [Table/Fig-4]. The overall score rose from baseline (67.0) to one month (121.0) and three months (125.0) follow-ups, with p<0.001 indicating substantial and statistically significant improvement. Physical well-being, functional well-being, and emotional well-being showed significant improvements (p<0.001). These changes suggest that participants experienced marked improvements in their overall physical and emotional health over the study period. Social well-being improved as well, with p=0.011 at one month and p=0.007 at three months. The hepatobiliary subscale also showed significant improvement, with baseline scores rising from 31.71±4.8 to 51.85±5.7 at one month and 52.5±6.0 at three months (p=0.028 and p=0.020, respectively). Overall, the data indicate that most well-being measures-especially physical, functional, emotional, and social health-improved significantly over the three months period.

Parameters	Baseline scores	One month follow-up	p-value	Three months follow-up	p-value (0-3 months)
Overall score	67.0±7.7	121.0±11.2	<0.001	125.0±12.0	<0.001
Physical well-being	7.76±1.5	17.05±1.9	<0.001	18.0±2.0	<0.001
Social well-being	9.83±1.7	18.77±2.2	0.011	19.5±2.3	0.007
Emotional well-being	10.81±2.1	16.85±2.0	0.014	17.5±2.1	0.009
Functional well-being	7.59±1.7	17.08±1.4	<0.001	18.0±1.5	<0.001
Hepatobiliary subscale score	31.71±4.8	51.85±5.7	0.028	52.5±6.0	0.020

[Table/Fig-4]: Symptom and Quality of Life (QOL) Scores in n=70 patients undergoing intervention, at baseline, 1 month, and 3 months using Quality of Life (QOL) FACT-HEP tool.

DISCUSSION

The present study provides statistical insight into the impact of PTBD on QOL in patients with advanced GBC and jaundice. As evidenced by significant improvements in FACT-Hep and EORTC QLQ-BIL21-C30 scores, PTBD appears to be an effective palliative intervention for alleviating biliary obstruction and its associated symptoms. The procedure alleviates jaundice, one of the most debilitating symptoms in these patients, and significantly improves overall physical and emotional well-being, consistent with previous studies [21-23]. The ability of PTBD to reduce symptom burden is particularly crucial in advanced cancer, where interventions are often limited to symptom relief rather than curative treatments. PTBD, therefore, represents a critical part of the palliative care spectrum, allowing patients to achieve better symptom control and potentially improving their overall QOL without offering a statistically significant survival benefit.

Despite the apparent benefits of PTBD, it is important to acknowledge that this procedure is not without its risks. The relatively high complication rates observed in this study-including peri-PTBD leaks (n=22, 31.43%), blockages/catheter pull-out requiring reinsertion (n=16, 22.86%), and cholangitis (n=8, 11.43%)-align with the risks described in the literature [26]. These complications underscore the inherent challenges of PTBD, particularly in patients with advanced or inoperable cancers who may already be frail or suffer from multiple comorbidities. Such complications may worsen the patient's discomfort or lead to longer hospital stays, potentially diminishing the patient's ability to benefit from the palliative effects of PTBD. Despite these complications, the study's results suggest

that with appropriate follow-up care and prompt management of complications, overall QOL improvements can be substantial and sustained over time.

The study's findings also emphasise the role of symptom-specific assessments in capturing the nuanced effects of PTBD on various aspects of health. While the overall QOL improvement was significant, domain-specific analysis revealed interesting patterns. The most notable improvements were observed in symptoms related to jaundice, eating difficulties, and tiredness, which are often the most distressing symptoms for patients with advanced biliary obstruction. This aligns with prior research indicating that the alleviation of jaundice is one of the most immediate and significant benefits of PTBD [20-23]. The significant reductions in eating difficulties and tiredness further demonstrate the broad impact of the procedure on the patient's physical well-being. These improvements are clinically meaningful, as they allow patients to resume daily activities, eat more, engage in social activities, and manage daily tasks that are often disrupted by jaundice and fatigue.

Notably, pain and anxiety symptoms, while reduced, did not reach statistical significance in this study. This may reflect the multifactorial nature of these symptoms in patients with advanced cancer; pain can arise from cancer-related factors as well as the procedure itself. Anxiety may stem from the psychological burden of living with an incurable diagnosis, and it is not always directly alleviated by physical symptom management [27]. This suggests that while PTBD is highly effective for physical symptom relief, complementary psychological interventions—such as counselling or anxiolytic therapy—may be necessary to address emotional and psychological distress experienced by these patients.

The therapy-specific concerns reported by patients, such as dissatisfaction with the procedural aspects of PTBD, did not show significant improvement over the study period. This finding suggests that while PTBD is effective in symptom relief, it does not always address patients' treatment-related concerns, particularly regarding the invasiveness or recurrence of symptoms after treatment. Some studies have found that treatment-related dissatisfaction persists due to the perceived inconvenience of repeated interventions or the uncertainty about the long-term benefits of PTBD [26,28]. This finding highlights the importance of providing patients with clear communication and support throughout the treatment process. Ensuring that patients are well informed about the nature of the procedure, its potential benefits, and possible complications may help alleviate some of the dissatisfaction associated with the therapy.

The high technical success rate (uneventful insertion in a single attempt without the need for repeated attempts) of PTBD in this study further supports its role as a cornerstone in the management of proximal biliary obstructions. The ability to perform PTBD under minimal sedation and in unstable patients is a significant advantage, particularly in the context of advanced cancer where patients may not be fit for more invasive procedures. As noted, the incidence of procedural complications remains a significant concern. The study's findings align with those of other studies, such as those by Gamanagatti S et al., and Saluja SS et al., who reported high complication rates but also highlighted the effectiveness of PTBD in improving QOL when the complications were effectively managed [29,30]. These findings underscore the importance of a skilled and experienced interventional radiology team, as well as the need for robust post-procedural care.

When compared to the studies by Robson PC et al., Vaitiekunas L et al., and Subramani VN et al., this study offers a more optimistic view of the impact of PTBD on QOL, despite the high complication rates [31-33]. While these studies found limited improvement in overall QOL or significant complications, the structured follow-up care and management of complications in this study appear to mitigate some of the negative effects, resulting in significant QOL improvements.

Furthermore, the present study's use of two validated QOL indices allowed for a more comprehensive evaluation of the various symptom domains, revealing both the strengths and limitations of PTBD as a palliative procedure for symptoms like jaundice, eating difficulties, and pain.

Limitation(s)

The study is limited by the inability to statistically compare the two indices due to differences in scoring patterns and high attrition from disease progression. The study results are also limited by the exclusion of patients undergoing biliary drain internalisation by SEMS, patients who were lost to follow-up or who died within three months of the procedure, lack of assessment of overall survival, and the absence of stage-wise patient analysis.

CONCLUSION(S)

PTBD substantially enhances QOL for patients with advanced gall bladder carcinoma by relieving jaundice-related symptoms and improving physical, social, and functional well-being. Despite notable complications, it remains an effective palliative approach for managing proximal obstructions as seen in gall bladder malignancies. Addressing treatment-specific concerns and optimising post-procedural care are essential to further improve patient outcomes in this patient subset. Future research may focus on refining procedural techniques, analysing patients undergoing SEMS insertion, minimising complications, integrating holistic care approaches to optimise the benefits of PTBD, and studying the long-term impact of PTBD on QOL, particularly regarding survival and symptom recurrence.

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