



Journal Homepage: - [www.journalijar.com](http://www.journalijar.com)

## INTERNATIONAL JOURNAL OF ADVANCED RESEARCH (IJAR)

Article DOI: 10.21474/IJAR01/18766  
DOI URL: <http://dx.doi.org/10.21474/IJAR01/18766>



### RESEARCH ARTICLE

#### IMPROVEMENT IN QUALITY OF LIFE FOLLOWING PERCUTANEOUS TRANSHEPATIC BILIARY DRAINAGE FOR MALIGNANT OBSTRUCTIVE JAUNDICE: AN INSTITUTION-BASED OBSERVATIONAL STUDY

Dr. Arkaprovo Roy<sup>1</sup>, Dr. Suchismita Chakraborty<sup>2</sup> and Dr. Ayusmati Thakur<sup>3</sup>

1. Associate Professor, Department of Surgery, Medical College Kolkata.
2. Senior Resident, Department of Surgical Oncology, Banaras Hindu University.
3. Consultant Gastroenterologist, DNB(General Medicine), MRCP UK.

#### Manuscript Info

##### Manuscript History

Received: 20 March 2024  
Final Accepted: 27 April 2024  
Published: May 2024

##### Key words:-

Quality of Life, PTBD, Obstructive Jaundice, Carcinoma Gall Bladder

#### Abstract

**Purpose:** Long-term prognosis of patients with obstructive jaundice due to malignant biliary disease is very dismal. These patients are treated mainly for palliation of symptomatic jaundice and related complications. To alleviate symptomatic jaundice, three modalities of treatment are generally employed – bilio-enteric bypass, Percutaneous Transhepatic Biliary Drainage (PTBD) and Endoscopic Retrograde Cholangiopancreatography guided stenting. However, minimal data is available comparing the pre-procedure and post-procedure Quality of Life (QOL) of these patients.

**Aims of the Study:** To study the pre-procedure & post-procedure QOL of patients undergoing PTBD.

**Methodology:** We studied patients who underwent PTBD in between January 2017 and June 2021, attending our tertiary-care hospital with malignant obstructive jaundice, with high-up biliary obstruction. An observational study was conducted to compare the QOL before and after procedure using the EORTC-QLQ-30 Symptom Scale Score.

**Results:** The majority (80%) had the diagnosis of carcinoma gallbladder. Maximum number of patients (75%) presented with a pre-procedure bilirubin value of more than 15 mg/dl. These patients showed significant bilirubin decrement by day 7. Follow-up at 1 month and 3 months following PTBD demonstrated significant improvement in global health status, physical status, emotional, cognitive and social QOL score. Some deterioration in the QOL score was noted at 6 months follow-up, which might be related to recurrence or stent blockade.

**Conclusion:** Overall improvement in post-procedure QOL was observed during follow-up analysis of the subjects. The increase in financial burden could be attributed to the maintenance of drainage catheter (wound management bags, treatment of infections) and cost of frequent hospital visits after the procedure.

Copy Right, IJAR, 2024,. All rights reserved.

**Corresponding Author:- Dr. Arkaprovo Roy**

Address:- Associate Professor, Department of Surgery, Medical College Kolkata.

**Introduction:-**

Quality of life (QOL) is a highly subjective measure of happiness, related to a number of variables that differ according to personal preferences. World Health Organization (WHO) defines quality of life as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad concept that is affected in a complex way by a person's physical health, psychological state, personal beliefs and social relationships.<sup>[1]</sup> Over the last decade, the focus of health care for patients with advanced malignancy has shifted from curative intent to hospice, which is basically a type of healthcare that focuses on the palliation of a terminally ill patient's distressing symptoms and attending to their emotional and spiritual needs.

Malignant obstructive Jaundice can develop due to direct involvement of CBD by carcinoma gall bladder, cholangiocarcinoma and pancreatic adenocarcinoma as well as due to external compression by metastatic lymph nodes at porta. However owing to the non-specific symptoms and lack of any widely accepted screening protocol, these malignancies tend to be diagnosed at an advanced, inoperable state and the patient is rendered to live rest of his life with distressing symptoms like jaundice, pruritus, pain abdomen, anorexia and malnutrition. Various palliative procedures remain the only treatment option for improvement of the Quality Of Life (QOL) including alleviation of cholangitis and pruritus. Reduction in serum bilirubin level below 3 mg/dl is also mandated before initiating chemotherapy or intrabiliary brachytherapy. Various methods of biliary drainage include surgical bypass and minimally invasive procedures like Percutaneous Transhepatic Biliary Drainage (PTBD) and Endoscopic Retrograde Cholangiopancreatography (ERCP).

For the patients with symptomatic malignant obstructive jaundice those are deemed unfit for surgery, urgent treatment is required to improve hepatic function, in order to facilitate the addition of subsequent chemotherapeutic regimen. In this context van researchers have evaluated the role Percutaneous Transhepatic Biliary Drainage (PTBD) and stenting as emerging alternative treatment of malignant biliary obstruction (MBO). It exhibited good clinical efficacy and fewer complications and lead to limited patient suffering as compared to surgical bypass. Among the study subjects, reported technical success in >90% and clinical success in >75%, with procedure related mortality <2%<sup>[2]</sup>. Palliative value of PTBD was shown in another prospective study.<sup>[3]</sup> It was found to reduce the severity of pruritus significantly. However, mixed results have been obtained with regards to the effect of PTBD on the quality of life and majority of such studies performed were based on some arbitrary quality of life scores.

Common complications following the procedure of PTBD include drain dislodgement and the need for re-intervention, pain and biliary leakage around the puncture site, haemorrhage, perforation, haemobilia, cholangitis and stent migration. Therefore, it is really important to weigh the potential benefits and risks of this procedure in patients with MBO<sup>[4,5,6]</sup>. Factors able to predict long and short-term survival after PTBD are scarcely reported in the medical literature and have not yet been well established. In our study, we attempt to document the short and long-term improvements in the QOL of patients with MBO following PTBD.

**Methodology:-**

It is an observational retrospective-prospective study done on 155 patients with malignant obstructive jaundice, who attended the Interventional Radiology department of our institution, between January 2017 and June 2021, after taking informed consent from the patients. The study was approved by the institutional ethics committee. We included unresectable cases of carcinoma gall bladder and cholangiocarcinoma with obstruction at the level of upper CBD, causing jaundice (serum bilirubin more than 10mg/dl), cholangitis and/or pruritus. They were subjected to PTBD with external drainage and/or internal stenting. Patients with resectable tumours, poor performance status (Karnofsky index less than 60) or those with severe sepsis and hepatocellular failure were excluded. Figure 1 depicts the proforma for pre-procedural data collection from the patients.

The efficacy of biliary drainage was determined in terms of daily reduction in serum bilirubin value till day 7 and bilirubin values at 1 month, 3 months and 6 months follow-up visits. We also took into consideration in-hospital mortality, 30-day mortality, post-procedure survival, duration of stent patency (i.e. requirement of repeat PTBD due to stent blockade) and any other post-procedural complication including cholangitis. Improvement in post-procedural QOL was assessed using the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire 30 (EORTC-QLQ-30) (Figure 2). This questionnaire incorporated 30 questions altogether, to assess five functional scales – physical (Q1-5), role (Q6-7), cognitive (Q20, 25), emotional (Q21-24), social (Q26-27); three

symptom scales – fatigue (Q10, 12, 18), pain (Q9, 19), nausea-vomiting (Q14, 15) and a global health and QOL scale (29, 30) with financial impact score (Q28).<sup>[7,8]</sup> Scores were calculated before the procedure and at the 7<sup>th</sup> post-procedural day, 1-month, 3-month and 6-month visits. They were compared using a series of paired t-tests. All of the statistical analyses were performed using Microsoft Excel 2016 and SPSS software version 6.0.

### Results:-

Total of 155 unresectable cases of malignant obstructive jaundice were selected during the study period and patients were predominantly from West Bengal and neighbouring states.

After thorough history taking, physical examination and investigations, 124 (80%) of them were found to have a carcinoma gall bladder, whereas the remaining 31 (20%) were diagnosed with hilar cholangiocarcinoma. We observed that among those diagnosed with cholangiocarcinoma, 15 (48%) patients were male, whereas 16 (52%) patients were female. Therefore, the female: male ratio came up to be 1.06:1. On the other hand, among those with carcinoma gall bladder, 46 (37%) were male and 78 (62.9%) were female. The female: male ratio in gall bladder carcinoma was calculated as 1.69:1. These ratios, however, do not correlate with the female: male ratio found in studies conducted worldwide, which is close to 1:2 and 2-2.25:1 respectively.<sup>[9,10]</sup> It was also found that 45 (29%) out of 155 patients were between the age group of 41-50 years, followed by 42 (27%) patients in 51-60 years of age group. The age incidence is much lower than that described in western literatures (SEER Cancer Statistics Review, 1975-2017).<sup>[11]</sup> The reason behind this lower age incidence of both carcinoma gall bladder and cholangiocarcinoma could be a genetic predisposition in the subcontinental population.

41 (26.4%) patients were identified as vegetarian. None of them were obese (i.e. BMI > 30). Out of 155 patients, 35 (22.8%) were smokers, whereas 13 (8.57%) gave history of regular alcohol intake. 13 patients (8.57%) were both smokers as well as alcoholics. None of the female patients were smoker or alcoholic. We saw that 40 (25.7%) patients had previous history of gall stone disease and/or choledocholithiasis.

Conjugated hyperbilirubinemia of more than 15mg/dl was observed among 117 (75%) patients and remaining 38 (25%) patients had less than 15mg/dl bilirubin value. In the latter group of patients the indication for performing PTBD was palliative chemotherapy, intractable pruritus, deranged hepatic function or recurrent cholangitis. Mean value of serum bilirubin was calculated immediately before the procedure, as well as on day 7, 1 month, 3 months and 6 months follow up visits. It was observed that mean pre-procedure serum bilirubin value was 19.2mg/dl with a standard deviation of 6.05. Post-procedure bilirubin values at 7<sup>th</sup> day, 1 month, 3 months and 6 months (as mean  $\pm$  standard deviation) are, respectively 10.89 SD 6.46, 4.98 SD 1.01, 2.6 SD 0.81 and 1.5 SD 0.77. Serial paired t-tests were applied to compare the decrease in bilirubin value in each follow-up visit concerning pre-procedure value. All the p values were well below 0.00001, which signifies the efficacy of PTBD in lowering serum bilirubin value. Table 1 depicts the mean and standard deviation of serum bilirubin value in various time frames.

All the patients were given the EORTC-QLQ-C30 questionnaire to be filled up before the procedure and in each follow-up visit. It was observed that the mean functional score of patients in the pre-procedure period and post-procedure day 7, 1 month, 3 months and 6 months follow-up visits were 52.7 SD 6.1, 34.08 SD 9.82, 20.9 SD 8.13, 9.1 SD 4.13 and 13.5 SD 5.13 respectively. On the other hand, mean symptom scale scores were 25.6 SD 2.1, 12.8 SD 6.9, 9.2 SD 3.99, 7.45 SD 3.89 and 8.89 SD 2.12 respectively. We obtained respective financial scores in different periods as 3.7 SD 0.23, 3.2 SD 0.61, 1.9 SD 0.9, 1.5 SD 0.34 and 0.78 SD 0.11. The mean of pre-procedure quality of life and global health score was 3.24 SD 2.39. It improved on post-procedure day 7 to a score of 8.11 SD 5.01, 12.09 SD 1.56 at 1 month, 12.99 SD 1.9 at 3 months and 11.99 SD 1.78 at 6 months. Again, we applied serial paired t-tests onto the data set comparing post-procedure data sets on day 7, 1 month, 3 months and 6 months follow up to pre-procedure values and in every instance, the p-value was statistically significant (less than 0.001). Figure 3a and 3b show a composite bar diagram comparing mean values of the several components of the EORTC-QLQ-C30 questionnaire as measured at different follow-up visits.

We have included the complications following PTBD in our collected data. 28 (18.06%) out of 155 patients had suffered from some complication after the procedure and required repeat hospital admission. Among these 28 patients, 13 (46%) had the problem of stent block, 10 (36%) suffered from cholangitis, 4 (14%) were diagnosed to have peri-drain wound infection and 1 (4%) patient presented with biloma.

We documented survival rate for each patient after the procedure and regularly followed them up. It was observed that 5 (3%) out of 155 patients died during the initial hospital admission. 14 (9.03%) patients survived for less than 30 days

following PTBD, another 19(12.2%) remained alive upto 3 months. 91 (58.7%) patients survived upto 180 days and 25 (16.1%) for more than 6 months. 6 (3.8%) patients were still living at the end of the study time. We also found that 30-day mortality rate was 64.7% among patients requiring repeat hospital admission, whereas only 2.4% among those without any history of repeat hospital admission.

### Discussion:-

According to a paired t-test performed between QLQ scores in the pre-procedure and post-procedure follow-up visits, significant improvement was found in the mean score of the study population at Day 7, 1 month and 3 months follow-up visits ( $p = 0.001$ ). Scores at 6 months follow-up visit deteriorated, however. At the same time, it was observed that the mean serum bilirubin level of the study population was decreasing significantly till the 3-month follow-up visit, only to rise again at the 6-month visit. These can be attributed to the progression of primary tumours and/or the development of metastases leading to stent blockade. A randomised controlled trial conducted in India on carcinoma gall bladder patients with obstructive jaundice, in 2008, concluded that PTBD has higher chances of successful drainage ( $p = <.001$ ), equivalent 30-day mortality ( $p = .61$ ) and a similar rate of stent occlusion ( $p = .63$ ) as compared to endoscopic stenting (ES). Emotional functioning score as per the EORTC QLQ-C30 questionnaire was better in the ES group and cognitive score better in the PTBD group at 1 month. Global QOL score was better in the PTBD group at 3 months. The symptom scale score was improved in both arms, with considerable improvement of fatigue in the PTBD group.<sup>[12]</sup> A systematic review and meta-analysis conducted in 2017 compared the efficacy and complication rate of PTBD and endoscopic biliary drainage (EBD). Incidence of cholangitis and pancreatitis were lower in patients undergoing PTBD, whereas rate of bleeding and tube dislocation were lower in EBD.<sup>[13]</sup> A randomised controlled trial was undertaken to compare the quality of life of patients following 'right' and 'left' access PTBD using the QLQBIL-21 questionnaire. Those having undergone PTBD through RHD access had higher intercostal pain, respiratory difficulties, greater amount of tiredness, anxiety and more difficulty in drain bag management. Therefore, patients with PTBD via LHD had a better post-procedure quality of life.<sup>[14]</sup> There were a few negative reports regarding quality of life improvement following PTBD procedure. A prospective study done by in India in the year 2021 showed at least one complication in 68% patients and at least two complications in 30% patients. Significant decrease was observed in post-procedure quality of life at 4-6 weeks, when assessed by SF-36 questionnaire.<sup>[15]</sup>

There has hardly been any observational study, conducted on quality of life assessment of patients with malignant obstructive jaundice undergoing PTBD based on the EORTC QLQ C-30 questionnaire. Hence, our study can be considered as one of the pioneers in this aspect. Results of this study reflected similar data as that of the other previously mentioned studies. In future, similar other studies could be conducted on a multi-centre basis and using a larger sample size.

### References:-

1. Yao G, Chung CW, Yu CF, W JD. Development and verification of validity and reliability of the WHOQOL-BREF Taiwan version. *J Formos Med Assoc* 2002;101(5):342-351.
2. Kloek JJ, van der Gaag NA, Aziz Y, Rauws EA, van Delden OM, Lameris JS, et al. Endoscopic preoperative biliary drainage in patients with suspected hilar cholangiocarcinoma. *J Gastrointest Surg*, 2010 Jan;14(1):119-25.
3. Robson PC, Heffernan N, Gonen M, Thornton R, Brody LA, Covey AM, et al. Prospective study of outcomes after percutaneous biliary drainage for malignant biliary obstruction. *Ann Surg Oncol*. 2010 Sep;17(9):2303-2311.
4. Nennstiel S, Weber A, Frick G, Haller B, Meining A, Schmid RM, et al. Drainage –related complications in percutaneous transhepatic biliary drainage: an analysis over 10 years. *J Clin Gastroenterol*. 2015 Oct;49(9):764-770.
5. Weber A, Gaa J, Rosca B, Born P, Neu B, Schmid RM, et al. Complications of percutaneous transhepatic biliary drainage in patients with dilated and nondilated intrahepatic bile ducts. *Eur J Radiol*. 2009 Dec;72(3):412-417.
6. Venkatanarasimha N, Dampdharan K, Gogna A, Leong S, Too CW, Patel A, et al. Diagnosis and management of complications from percutaneous biliary tract interventions. *Vascular/Interventional Radiology*. 2017 Mar. Doi: 10.1148/rg.2017160159.
7. Kaasa S, Bjordal K, Aaronson N, Moum T, Wist E, Hagen S. The EORTC core quality of life questionnaire (QLQ-C30): validity and reliability when analysed with patients treated with palliative radiotherapy. *Eur J Cancer*. 1995 Dec;31A(13-14):2260-2263.

8. Aaronson NK, Ahmedzai S, Bergman B, et al. The European Organisation for Research and Treatment of Cancer QLQ-C-30: a quality-of-life instrument for use in international clinical trials in oncology. *J Natl Cancer Inst* 1993;85:365-376.
9. Rawla P, Sunkara T, Thandra KC, Barsoul A. Epidemiology of gall bladder cancer. *ClinExpHepatol*. 2019 May;5(2):93-102.
10. Kirstein MM, Vogel A. Epidemiology and risk factors of cholangiocarcinoma. *Visc Med*. 2016 Dec;32(6):395-400.
11. Howlander N, Noone AM, Krapcho M, Miller D, Brest A, Yu M, et al. SEER cancer statistics review, 1975-2017, National Cancer Institute, Bethesda, MD. Available on: [https://seer.cancer.gov/csr/1975\\_2017](https://seer.cancer.gov/csr/1975_2017).
12. Saluja SS, Gulati M, Garg PK, Pal H, Pal S, Sahni P, et al. Endoscopic or percutaneous biliary drainage for gallbladder cancer: a randomised trial and quality of life assessment. *ClinGastroenterol and Hepatol*. 2008;6:944-950.
13. Duan F, Cui L, Bai Y, et al. Comparison of efficacy and complications of endoscopic and percutaneous biliary drainage in malignant obstructive jaundice: a systematic review and meta-analysis. *Cancer Imaging* 17. 2017. Doi: 10.1186/s40644-017-0129-1.
14. Castiglione D, Gozzo C, Mammino L, Failla G, Palmucci S, Basile A. Health-related quality of life evaluation in “left” versus “right” access for percutaneous transhepatic biliary drainage using EORTC QLQ-BIL-21 questionnaire: a randomised controlled trial. *Abdomradiol (NY)*. 2020 Apr;45(4):1162-1173.
15. Subramani VN, Avudaiappan M, Yadav TD, Kumar H, Sharma V, Mandavdhare H, et al. Outcome following percutaneous transhepatic biliary drainage in carcinoma gallbladder: a prospective observational study. *J Gastrointest Cancer*. 2021 Jun 26. Doi: 10.1007/s12029-021-00655-5.