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Effect of Endoscopic Metallic CBD Stenting on Quality of Life in Malignant Biliary Obstruction

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Abstract: ***Background**: Malignant biliary obstruction commonly presents late, and many patients are unsuitable for curative resection; hence palliation should focus on symptom relief and quality of life. **Methods**: This prospective observational study evaluated whether endoscopic metallic common bile duct stenting improves quality of life in patients with inoperable malignant biliary obstruction. Thirty adults admitted to a tertiary care centre with malignant biliary obstruction and fulfilling predefined inclusion criteria underwent endoscopic metallic CBD stenting. Quality of life was assessed using FACT-Hep version 4 at baseline, 1 month and 3 months after intervention. Mean age was 58.93 ± 10.00 years; 18 patients were female and 12 were male. **Results**: The common diagnoses were carcinoma gallbladder (26.7%), periampullary carcinoma (23.3%), cholangiocarcinoma (23.3%) and carcinoma head of pancreas (23.3%). Mean quality-of-life score improved from 83.93 ± 5.83 at baseline to 91.60 ± 5.97 at 1 month and 98.80 ± 9.82 at 3 months ($P < 0.001$). Improvement was seen across age, gender and diagnosis groups, without statistically significant intergroup differences. **Conclusion**: Endoscopic metallic CBD stenting offers clinically meaningful palliation and improved quality of life in selected patients with inoperable malignant biliary obstruction.*

Keywords: malignant biliary obstruction; CBD stenting; metallic biliary stent; FACT-Hep; quality of life

1. Introduction

Malignant biliary obstruction (MBO) results from intrinsic or extrinsic obstruction of the biliary tract by pancreaticobiliary and hepatobiliary malignancies, including carcinoma head of pancreas, periampullary carcinoma, cholangiocarcinoma, carcinoma gallbladder, hepatocellular carcinoma and metastatic nodal disease. Patients commonly present with progressive jaundice, pruritus, anorexia, weight loss, abdominal pain and cholangitis. These symptoms contribute directly to poor functional status and reduced quality of life (QOL), particularly because many patients present at an advanced or unresectable stage.

The primary goal in unresectable disease is palliation. Surgical bypass can provide durable drainage, but it is associated with greater physiological stress and postoperative morbidity. Endoscopic biliary drainage by endoscopic retrograde cholangiopancreatography (ERCP) with biliary stent placement is less invasive and is widely used for palliation in patients who are elderly, malnourished, have co-morbidities, decline surgery, or are not candidates for curative resection. Metallic stents, particularly self-expandable metallic stents (SEMS), have better patency than plastic stents and can reduce repeated interventions when survival is expected to exceed a few months. Although relief of jaundice is often considered the procedural endpoint, the most patient-centred endpoint is improvement in daily functioning and well-being. Quality-of-life instruments provide a structured method to quantify this benefit. The present study was undertaken to evaluate the impact of endoscopic metallic CBD stenting on QOL in patients with inoperable malignant biliary obstruction using the FACT-Hep questionnaire.

2. Literature Survey

Historically, operative biliary bypass procedures such as cholecystojejunostomy, choledochojejunostomy and hepaticojejunostomy were the principal palliative options for malignant obstructive jaundice. With the development of ERCP and transpapillary endoprosthesis placement, endoscopic drainage became an accepted minimally invasive approach for patients with surgically incurable disease. Current evidence and guidelines support SEMS insertion for palliative drainage in malignant extrahepatic biliary obstruction, particularly when longer patency is desirable.

Quality-of-life improvement after biliary drainage has been reported in several prospective studies. Ballinger et al. observed relief of jaundice and pruritus and improvement in anorexia and indigestion after stenting in malignant bile duct obstruction. Luman et al. reported improvement in EORTC QLQ-C30 domains one month after endoscopic stenting. Abraham et al. showed that successful biliary drainage was associated with improvement in social function and mental health, although very high baseline bilirubin predicted a less consistent response. The Functional Assessment of Cancer Therapy-Hepatobiliary (FACT-Hep) questionnaire is a validated patient-reported outcome tool for hepatobiliary and pancreatic malignancies. It includes the general FACT-G domains and a hepatobiliary subscale addressing disease- specific symptoms and concerns. Its use is suitable for assessing the palliative value of biliary intervention in MBO.

The choice of drainage modality in malignant biliary obstruction depends on anatomical level of obstruction, expected survival, performance status, local expertise and

the need for future oncological therapy. Endoscopic drainage is generally preferred when the papilla is accessible and the obstruction is technically amenable. Percutaneous drainage has an important role when ERCP fails or in complex hilar obstruction, while operative bypass is reserved for selected fit patients or when unresectability is discovered at laparotomy. Stent-related outcomes are influenced by stent diameter, covering, tumour ingrowth, tumour overgrowth, sludge formation and migration. Metallic stents are more expensive initially, but may reduce repeat procedures because of longer patency. In a palliative setting, reduced reintervention is relevant because each unplanned admission can worsen nutritional status, delay chemotherapy and reduce time spent at home. Therefore, QOL assessment complements conventional procedural outcomes.

3. Problem Definition

In inoperable malignant biliary obstruction, palliation should be judged not only by technical drainage success or reduction in serum bilirubin, but also by the patient's perceived improvement in symptoms, activity and well-being. Many patients are elderly, nutritionally depleted or medically unfit for major surgery, making endoscopic stenting an attractive option. However, local data evaluating QOL after metallic CBD stenting remain limited. This study addresses whether endoscopic metallic CBD stenting produces statistically and clinically meaningful QOL improvement over three months in selected patients with inoperable malignant biliary obstruction.

4. Methodology and Approach

Study design and setting: This was a prospective observational study conducted in the Department of General Surgery at a tertiary health care centre in Mumbai over an 18-month period.

Study population: Thirty adult patients with malignant biliary obstruction were included. Patients were considered eligible if they had inoperable disease based on patient factors such as advanced age, malnutrition or co-morbidities, tumour factors, or refusal of surgery; presented with jaundice, cholangitis or cholestasis; had an expected survival of more than one month; and consented to participate.

Exclusion criteria: Patients younger than 18 years, those with prior biliary drainage, impending duodenal obstruction, malignant hilar obstruction not amenable to ERCP drainage, fitness for surgical bypass, significant coagulopathy (INR > 1.40 or platelet count < 70,000/cumm), or unwillingness for study participation were excluded.

Intervention and follow-up: Eligible patients underwent endoscopic metallic CBD stenting as a palliative biliary drainage procedure. No additional intervention was introduced as part of the study protocol. Baseline clinical details, diagnosis, symptoms, hospital stay and bilirubin levels were recorded. QOL was assessed before intervention and repeated at 1 month and 3 months after stenting using FACT-Hep version 4. Higher scores indicated better QOL.

Statistical analysis: Data were entered in Microsoft Excel and analysed using SPSS version 22. Continuous variables were expressed as mean and standard deviation; categorical variables were expressed as frequency and percentage. Data normality was assessed using the Shapiro-Wilk test. Paired t-test was used for within-patient QOL comparisons over time. Unpaired t-test or ANOVA was used for subgroup comparisons. A P value less than 0.05 was considered statistically significant.

5. Results and Discussion

Thirty patients were analysed. The mean age was 58.93 ± 10.00 years, with a range from 33 to 73 years. The largest age group was above 60 years (46.7%). There were 18 females (60.0%) and 12 males (40.0%). The leading diagnoses were carcinoma gallbladder (26.7%), periampullary carcinoma (23.3%), cholangiocarcinoma (23.3%) and carcinoma head of pancreas (23.3%). Most patients presented with yellowish discolouration of eyes (70.0%) and abdominal pain (66.7%), followed by loss of appetite (43.3%) and weight loss (23.3%). Mean hospital stay was 10.43 ± 2.38 days. The clinical profile reflects the late symptomatic presentation typical of pancreaticobiliary malignancy.

Table 1: Demographic and diagnostic distribution profiles of the study population

Characteristic Matrix (N = 30)	Value Representation / Proportions
Age ≤ 50 years	8 (26.7%)
Age 51-60 years	8 (26.7%)
Age > 60 years	14 (46.7%)
Mean Age (Years)	58.93 ± 10.00 years
Female Cohort	18 (60.0%)
Male Cohort	12 (40.0%)
Carcinoma Gallbladder	8 (26.7%)
Periampullary Carcinoma	7 (23.3%)
Cholangiocarcinoma	7 (23.3%)
Carcinoma Head of Pancreas	7 (23.3%)
Hepatocellular Carcinoma	1 (3.3%)

More than half of the cohort had high bilirubin values above 10 mg/dL, and the symptoms most likely to affect daily living were jaundice, abdominal pain, anorexia, weight loss and pruritus. The short mean hospital stay suggests that endoscopic palliation can be delivered without prolonged admission in appropriately selected patients. Carcinoma gallbladder was the most frequent diagnosis, which is relevant in the Indian surgical setting where gallbladder cancer often presents late and may be unresectable at diagnosis. However, the cohort also included periampullary carcinoma, cholangiocarcinoma and carcinoma head of pancreas, allowing the QOL effect of stenting to be observed across a broad malignant biliary obstruction spectrum.

Table 2: Clinical baseline characteristics, symptoms, and biological markers

Symptom & Clinical Parameters	Observed Quantities & Baselines
Jaundice Presence	21 (70.0%)
Abdominal Pain Report	20 (66.7%)
Loss of Appetite	13 (43.3%)
Significant Weight Loss	7 (23.3%)
Pruritus (Severe Itching)	5 (16.7%)
Mean Hospital Stay (Days)	10.43 ± 2.38 days
Total Bilirubin Profile	12.43 ± 6.57 mg/dL
Direct Bilirubin Sub-fraction	8.76 ± 4.68 mg/dL

The mean QOL score increased progressively after endoscopic metallic CBD stenting. Baseline score was 83.93 ± 5.83. It improved to 91.60 ± 5.97 at 1 month and to 98.80 ± 9.82 at 3 months. The mean improvement from baseline was 7.67 points at 1 month and 14.87 points at 3 months. These changes were statistically significant ($P < 0.001$), indicating sustained improvement after drainage.

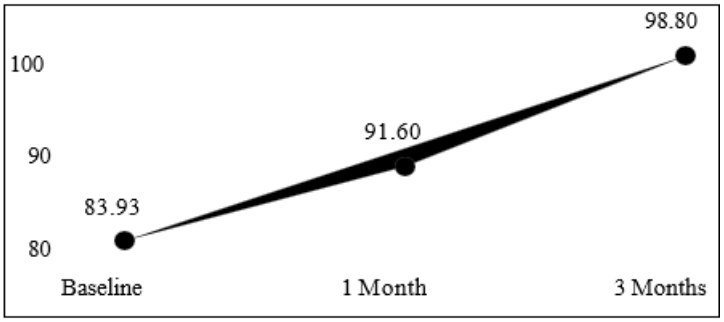

Figure 1: Progressive timeline growth in mean FACT-Hep Quality of Life ratings (N=30)

On subgroup analysis, periampullary carcinoma showed the highest mean absolute QOL improvement, followed by carcinoma gallbladder, hepatocellular carcinoma, cholangiocarcinoma and carcinoma head of pancreas. Patients aged 51-60 years showed greater improvement than those ≤ 50 years and > 60 years. Female patients showed a higher mean improvement than male patients. However, differences across diagnosis, age and gender were not statistically significant (diagnosis $P = 0.737$; age $P = 0.568$; gender $P = 0.322$), suggesting that the palliative benefit of biliary decompression was broadly distributed in the study population.

These findings are consistent with previous reports that relief of biliary obstruction improves symptoms beyond jaundice. Ballinger et al. documented relief of jaundice and pruritus and improvement in appetite and indigestion after stenting. Luman et al. reported significant improvement in global health and multiple functional domains after endoscopic stenting. Abraham et al. found that successful biliary drainage was associated with better social functioning and mental health at one month. The present study adds local experience using FACT-Hep assessment and metallic stents. From a general surgery perspective, these results support early multidisciplinary discussion once unresectability or high operative risk is established. When the therapeutic goal shifts from cure to palliation, the selected intervention should relieve obstruction with minimal interruption to nutrition, pain control and family support. Metallic CBD stenting is aligned with these goals when anatomy permits safe ERCP-guided placement.

The study also highlights the importance of recording patient-reported outcomes in surgical practice. Laboratory improvement alone may not capture whether the patient eats better, sleeps better, resumes routine activity or experiences less distress from visible jaundice. Incorporating QOL instruments into palliative biliary care can help clinicians counsel families, select patients for intervention and audit the real benefit of procedures performed in advanced malignancy. The improvement in QOL can be explained by multiple mechanisms: reduction in cholestatic symptoms, relief of pruritus, improved appetite, better sleep, recovery of functional activity and the psychological benefit of visible reduction in jaundice. Endoscopic metallic stenting also avoids the morbidity of operative bypass in patients with limited life expectancy or poor surgical fitness. The absence of significant differences across subgroups should be interpreted cautiously because the sample size was small and one diagnosis group included only one patient.

Clinical interpretation of the outcome: The observed mean improvement of 7.67 points at 1 month and 14.87 points at 3 months suggests that decompression was associated not only with early symptomatic relief but also with continued functional recovery during follow-up. In patients with advanced malignancy, a modest numerical change can be clinically relevant when it reflects better appetite, reduced itching, improved sleep, reduced treatment-related anxiety and improved ability to perform routine activities. Because the intervention was performed for palliation rather than cure, sustained QOL improvement is an important endpoint in itself.

Patient selection and practical implications: The study population represented a common real-world surgical scenario: patients with malignant biliary obstruction who were not suitable candidates for curative resection or major bypass because of disease extent, frailty, co-morbidity, malnutrition, advanced age or preference against surgery. In such patients, endoscopic metallic stenting provides internal drainage without an external tube, avoids laparotomy and can allow earlier recovery. The procedure may also facilitate nutritional improvement, reduce

cholangitis risk after decompression and improve suitability for palliative oncological treatment when clinically appropriate.

Interpretation of subgroup findings: The statistically non-significant subgroup comparisons should not be interpreted as absence of biological differences. Rather, the study was underpowered for diagnostic subgroup analysis. The finding that each major subgroup improved supports the practical view that symptomatic decompression can benefit a range of malignant biliary obstruction patients, provided the obstruction is drainable and expected survival is sufficient for benefit to be experienced.

Strengths and limitations: The strengths of this study include prospective assessment, predefined inclusion and exclusion criteria, use of a validated QOL instrument and serial follow-up at clinically relevant time points. Its limitations include small sample size, single-centre design, heterogeneous diagnoses, absence of a control group, and lack of detailed assessment of stent type, technical success rate, procedure-related adverse events, serial bilirubin fall, chemotherapy initiation, survival and stent patency. Therefore, the results support QOL benefit in selected patients but should not be interpreted as evidence of overall survival benefit or comparative superiority over other drainage modalities.

6. Conclusion

Endoscopic metallic CBD stenting significantly improved quality of life in selected patients with inoperable malignant biliary obstruction. The mean QOL score increased from 83.93 at baseline to 91.60 at 1 month and 98.80 at 3 months, with statistically significant improvement over time. The benefit was observed across age, gender and diagnostic groups. Endoscopic metallic CBD stenting is therefore an effective, minimally invasive palliative option for symptom relief and QOL improvement in malignant biliary obstruction.

7. Future Scope

Future studies should include larger multicentre cohorts, longer follow-up, comparison between covered and uncovered SEMS, plastic stents, percutaneous drainage and surgical bypass, and analysis of bilirubin decline, stent patency, stent-related adverse events, survival, chemotherapy eligibility and cost-effectiveness. Incorporating standardized symptom scores with FACT-Hep can better define which patient groups gain the greatest palliative benefit.

Ethical Considerations: Written informed consent was obtained from all participants. Institutional ethics committee approval details should be inserted before submission.

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