

Clinical and paraclinical characteristics and treatment outcomes of endoscopic retrograde cholangiopancreatography (ercp)-guided biliary stent placement in patients with malignant biliary obstruction

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Abstract

Objective: To describe the clinical and paraclinical characteristics and evaluate the treatment outcomes of ERCP-guided biliary stenting in patients with malignant biliary obstruction due to cancer. **Subject and method:** A prospective, non-randomized, longitudinal, convenience-sample interventional study was conducted on 97 patients with malignant biliary obstruction due to cancer who underwent ERCP-guided biliary stenting from December 2019 to January 2024. **Result:** The study included 97 patients with malignant biliary obstruction due to cancer, with a mean age of 63.1 ± 11.8 years, and 68.0% were male. All patients presented with jaundice, accompanied by anorexia (94.8%), weight loss (88.7%), and abdominal pain (83.5%). Pre-procedure, 100% had elevated total bilirubin, with 58.8% $>256.5\mu\text{mol/L}$; elevated liver enzymes (AST, ALT, GGT); and hypoalbuminemia in 59.8%. The technical success rate of the initial stent placement was 95.9%, with a higher usage of metal stents (56.7%). After one month, significant improvements were observed in bilirubin, liver enzymes, and creatinine levels ($p<0.001$); albumin and prothrombin time also increased significantly. **Conclusion:** ERCP-guided biliary stenting is an effective and safe method for palliating malignant biliary obstruction due to cancer, leading to improved clinical symptoms and liver function, with a high technical success rate and minimal severe complications.

Keywords: Malignant biliary obstruction, endoscopic retrograde cholangiopancreatography, biliary stent.

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I. Đặt vấn đề

Malignant biliary obstruction, also known as malignant biliary stricture, refers to mechanical blockage of the bile ducts caused by tumor compression or invasion. The obstruction may occur in the common bile duct (CBD), common hepatic duct, biliary confluence, or in the right and left hepatic ducts. Common causes include extrahepatic cholangiocarcinoma, pancreatic head cancer, hepatocellular carcinoma, gallbladder carcinoma, intrahepatic cholangiocarcinoma, and cancer of the ampulla of Vater or periampullary region. In addition, certain other cancers can lead to biliary obstruction through local invasion, hepatic metastases, or regional lymph node involvement.

Endoscopic biliary stenting is an effective palliative treatment for patients with malignant biliary obstruction. Studies have reported a technical success rate ranging from 90-95% [1]. This procedure significantly reduces serum bilirubin levels and improves liver function [2]. Two commonly used types of stents include plastic and metal stents, with the straight, uncovered type being the most frequently used [3].

In Vietnam, endoscopic retrograde cholangiopancreatography (ERCP) with biliary stent placement is increasingly utilized at both central and provincial hospitals for managing malignant biliary obstruction. In recent years, this technique has undergone numerous advancements and refinements. However, there remains a scarcity of domestic studies assessing the technical efficacy and long-term outcomes of this approach.

Therefore, we conducted the study titled:

“Clinical, paraclinical characteristics and treatment outcomes of endoscopic retrograde biliary stenting in patients with malignant biliary obstruction”, with the following objectives: (1) To describe the clinical and paraclinical features of patients with malignant biliary obstruction, (2)

To evaluate the treatment outcomes of biliary stenting via ERCP in patients with malignant biliary obstruction.

2. Subjects and Methods

2.1. Subjects

The study included 97 patients with malignant biliary obstruction who underwent endoscopic retrograde biliary stenting (ERBS) between December 2019 and January 2024.

Inclusion Criteria:

Age ≥ 18 years.

Confirmed diagnosis of malignant biliary obstruction due to tumors in the common bile duct or hilar region.

Indication for ERBS either for preoperative decompression or palliative treatment.

Informed consent provided by the patient.

Exclusion Criteria:

General contraindications for ERCP or when ERBS was technically unfeasible for biliary drainage.

ECOG performance status > 3 , advanced disease with life expectancy < 1 month; Child-Pugh class C cirrhosis or severe hepatic failure due to extensive tumor infiltration.

Tumor invasion causing occlusion of the main portal vein or both right and left portal vein branches, or Bismuth-Corlette type IV hilar obstruction with $< 30\%$ of the liver volume drainable by a single stent.

-Patient refusal to participate.

2.2. Methods

Study Design:

Prospective, interventional, non-controlled, longitudinal follow-up study.

Sample Size:

All patients diagnosed with malignant biliary obstruction who underwent ERBS at our institution from December 2019 to January 2024 and met the inclusion/exclusion criteria were enrolled. A total of 97 patients were analyzed.

Data Collection and Procedure:

Stenting Procedure (based on Ministry of Health Vietnam, 2014 and Peter B. Cotton, 2000):

Step 1: Cannulation of the major duodenal papilla into the biliary tract.

Step 2: Cholangiography with contrast injection to assess the lesion and plan the stenting technique and type.

Step 3: Deployment of the biliary stent.

Study Parameters:

Clinical indicators: age, sex, history of hepatobiliary intervention, abdominal pain, obstructive jaundice syndrome, time of jaundice onset prior to stenting (days), fever, poor appetite, weight loss, ascites, ECOG performance status.

Paraclinical indicators: biochemical, hematological, and immunological tests.

Treatment outcomes: success/failure rate, reasons for failure; technical characteristics in successful cases: ease of cannulation, whether sphincterotomy was performed, stent position relative to the sphincter of Oddi, unilateral vs bilateral hilar drainage, procedural time, stent features, and liver/kidney function tests one month post-stenting.

Data Processing and Statistical Analysis:

Data were analyzed using SPSS version 22.0. Quantitative variables were presented as mean $\pm$ standard deviation. Qualitative variables were expressed as percentages. T-test was used to assess differences between two means, with $p < 0.05$ considered statistically significant.

III. Results

3.1. Clinical and Paraclinical Characteristics

Table 1. Selected Clinical Characteristics of the Patients

Characteristic		Number (n)	Percentage (%)
Mean age (years)		63,1 $\pm$ 11,8 (range: 36–88)	
Gender	Male	66	68,0
	Female	31	32,0
Age group	<40	4	4,1
	40 - 59	38	39,2
	60 - 79	42	43,3
	>80	13	13,4
History of surgery or intervention	Hepatic surgery or procedures	9	9,3
	Biliary interventions	10	10,3
	No prior intervention	78	80,4

Comment: The mean age of patients was 63.1 $\pm$ 11.8 years. Males were predominant, accounting for 68.0% (male-to-female ratio: 2.1:1). The majority of patients (80.4%) had no history of prior hepatobiliary intervention.

Table 2. Clinical Symptoms Prior to Stent Placement

Clinical Feature (n = 97)	Number (n)	Percentage (%)
Jaundice	97	100,0
Anorexia	92	94,8

Clinical Feature (n = 97)	Number (n)	Percentage (%)
Weight loss	86	88,7
Abdominal pain	81	83,5
Pruritus	62	63,9
Pale stools	40	41,2
Fever	18	18,6
Ascites	15	15,5
Nausea/Vomiting	28	28,9
ECOG Performance Status		
- Score 1	25	25,8
- Score 2	53	54,6
- Score 3	19	19,6
Duration of jaundice (days)	30,2±14,5 (5 - 92)	

Comment: As shown in the table, all patients presented with jaundice. The majority also experienced anorexia (94.8%), weight loss (88.7%), and abdominal pain (83.5%). Pruritus was observed in 63.9% of cases. Less common symptoms included pale stools, fever, ascites, and nausea/vomiting. Most patients had an ECOG performance status of 2 (54.6%). The average duration of jaundice before stent placement was 30.2 ± 14.5 days.

Table 3. Paraclinical Characteristics Before Biliary Stent Placement

Parameter	Value (Mean ± SD)	Range	Patients with Abnormal Values n (%)
Total Bilirubin (μmol/L)	318,6 ± 132,7	43,5 - 625,0	97 (100%)
Bilirubin levels		42,9 - 85,4 μmol/l	2 (2,1%)
		85,5 - 170,9 μmol/l	13 (13,4%)
		171,0 - 256,4 μmol/l	25 (25,8%)
		> 256,5 μmol/l	57 (58,8%)
AST (U/l)	118,4 ± 92,1	34,0 - 610,0	89 (91,8%)
ALT (U/l)	133,7 ± 158,3	12,0 - 1180,0	85 (87,6%)
GGT (U/l)	662,5 ± 512,6	48,0 - 2180,0	93 (95,9%)
Albumin (g/l)	34,2 ± 5,4	21,5 - 43,8	58 (59,8%)
Ure (mmol/l)	4,7 ± 1,8	1,3 - 10,3	22 (22,7%)
Creatinin (μmol/l)	72,1 ± 19,3	37,0 - 146,0	15 (15,5%)
Hb (g/l)	120,9 ± 17,5	75,0 - 158,0	41 (42,3%)
White Blood Cell (G/L)	8,9 ± 3,6	3,2 - 24,0	29 (29,9%)
Platelets (G/L)	288,3 ± 104,8	108,0 - 545,0	18 (18,6%)
PT (%)	90,2 ± 19,1	57,0 - 144,0	11 (11,3%)

Comment: All patients had elevated total bilirubin, with 58.8% exceeding 256.5 μmol/L. Liver enzyme abnormalities (AST, ALT, GGT) were highly prevalent, particularly GGT, which was elevated

in 95.9% of patients. Hypoalbuminemia and anemia were observed in 59.8% and 62.9% of cases, respectively. Coagulopathy, indicated by reduced PT, was seen in 11.3% of patients.

3.2. Treatment Outcomes

Table 4. Technical Characteristics in Cases of Successful Biliary Stent Placement via ERCP

Technical Characteristics	First Stent Placement		Second Stent Placement	
	Patients (n = 97)	Rate (%)	Procedure (n = 30)	Rate %
Technical success	93	95,9	29	96,7
Procedural difficulties				
- Difficult cannulation	25	25,8	2	6,7
- Sphincterotomy (Oddi incision)	80	82,5	0	0,0
- Biliary dilation	5	5,2	0	0,0
Stent position				
- Stent tip distal to sphincter of Oddi	65	67,0	22	73,3
- Hilar region (n = 45), unilateral stent	43	95,6	22	100,0
Stent type				
- Plastic	42	43,3	14	46,7
- Metal	55	56,7	16	53,3
Procedure time (minutes)	39,2 ± 15,8 (20-100)		31,6 ± 8,9 (15-60)	

Comment: The technical success rate was 95.9% for the first procedure and 96.7% for the second. The most common procedural challenge was sphincterotomy (82.5%), while difficult cannulation and biliary dilation were less frequent. The majority of stents were placed distal to the sphincter of Oddi (67%). Metal stents were used more frequently (56.7%). The mean procedure time was approximately 39.2 minutes.

Table 5. Changes in Liver and Kidney Function Tests One Month After Biliary Stent Placement

Parameter	n	Before Stenting (Mean ± SD)	After 1 Month (Mean ± SD)	p (Paired t-test)
Bilirubin TP (μmol/l)	89	328,7 ± 135,2	45,2 ± 29,8	<0,001
AST (U/l)	89	122,5 ± 98,4	54,3 ± 42,5	<0,001
ALT (U/l)	89	129,6 ± 165,3	41,8 ± 28,9	<0,001
GGT (U/l)	82	648,3 ± 510,2	265,4 ± 310,6	<0,001
Albumin (g/l)	75	34,1 ± 5,3	37,8 ± 4,1	0,002
PT (%)	68	89,5 ± 19,8	97,6 ± 13,9	0,004
Creatinin (μmol/l)	88	72,8 ± 20,1	58,3 ± 17,5	<0,001
Ure (mmol/l)	88	4,6 ± 1,7	4,4 ± 1,8	0,910

Comment: After biliary stent placement, total bilirubin, AST, ALT, and GGT levels showed a significant reduction ($p < 0.001$), indicating marked improvement in liver function. Albumin, prothrombin time (PT), and creatinine also improved significantly, while urea levels did not show a statistically significant change ($p > 0.05$).

V. Discussion

Our study involving 97 patients who underwent endoscopic retrograde biliary stenting (ERBS) demonstrated a high technical success rate of 95.9%, which aligns with previous studies reporting success rates between 93.8% and 100% [2], [4], [5]. This confirms the effectiveness and safety of this method in managing malignant biliary obstruction.

In terms of clinical characteristics, the majority of patients were male (68.0%) with a mean age of 63.1 ± 11.8 years (range: 36-88), consistent with prior studies on malignant biliary obstruction [6]. The most common symptoms were jaundice (100%), anorexia (94.8%), and weight loss (88.7%), reflecting prolonged cholestasis and the nutritional decline commonly seen in patients with biliary tract malignancies [7].

Paraclinical findings showed that all patients had elevated total bilirubin, with 58.8% exceeding $256.5 \mu\text{mol/L}$. Liver enzymes (AST, ALT, GGT) were elevated in most patients, particularly GGT, which was increased in 95.9% of cases indicative of significant hepatobiliary damage. Hypoalbuminemia and anemia were also common, found in 59.8% and 62.9% of patients respectively, reflecting malnutrition and compromised liver function [8].

One month after stenting, there was a marked improvement in liver function parameters: Total bilirubin decreased from $328.7 \pm 135.2 \mu\text{mol/L}$ to $45.2 \pm 29.8 \mu\text{mol/L}$; AST, ALT, and GGT levels also significantly declined ($p < 0.001$); Albumin and prothrombin time (PT) increased

significantly, indicating improved hepatic synthetic function; Serum creatinine dropped from $72.8 \pm 20.1 \mu\text{mol/L}$ to $58.3 \pm 17.5 \mu\text{mol/L}$, suggesting improved renal function, likely due to reduced cholestasis and enhanced systemic circulation [8].

From a technical perspective, endoscopic sphincterotomy was performed in 82.5% of patients to facilitate access and stent placement. Metal stents were used more frequently (56.7%) than plastic stents, consistent with current recommendations favoring self-expandable metal stents (SEMS) for malignant obstruction due to their longer patency and lower complication rates [8].

Compared to earlier research, our study showed comparable or superior rates of technical and clinical success, supporting the efficacy of ERBS in treating malignant biliary obstruction [2]. However, long-term follow-up is essential to assess stent patency and late complications such as stent occlusion or recurrent cholangitis [8].

V. Conclusion

Our study demonstrates that endoscopic retrograde biliary stenting (ERCP-guided) is a safe and effective interventional approach for the treatment of malignant biliary obstruction. This method results in significant improvement in biochemical markers and liver function within just one month of intervention. Nevertheless, further long-term studies are needed to fully evaluate the impact of this treatment on patient quality of life and overall survival.

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