

Comparison of Uncovered Stent Placement across versus above the Main Duodenal Papilla for Malignant Biliary Obstruction

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ABSTRACT

Purpose: To evaluate the differences in efficiency and complications of metal stent insertion across versus above the main duodenal papilla (MDP) in patients with malignant obstruction of the common bile duct (CBD).

Materials and Methods: Records of 98 consecutive patients who underwent stent insertion for malignant CBD obstruction between 2004 and 2010 were retrospectively reviewed. Fifty-one patients (group 1) and 47 patients (group 2) were treated with stent insertion across and above the MDP, respectively. Primary stent patency, overall survival, complications, and changes in serum bilirubin level following stent insertion were assessed.

Results: Infection appeared in 12 and four patients, respectively, in groups 1 and 2. The respective mean primary stent patency times were 307.8 days \pm 20.2 and 490.7 days \pm 40.7, and mean survival times were 245.1 days \pm 17.4 and 286.3 days \pm 20.2. Bilirubin reduction rates were 55.7% \pm 16.6 and 61.1% \pm 13.7 at 1 week and 84.2% \pm 5.7 and 86.2% \pm 5.7 at 1 month in groups 1 and 2, respectively. In group 2, the rate of infection was significantly lower ($P = .044$) and primary stent patency was longer ($P = .019$). However, there was no significant difference between groups in survival time ($P = .074$) or bilirubin reduction rate at 1 week ($P = .083$) or 1 month ($P = .082$).

Conclusions: Bile stent insertion above the MDP may achieve longer stent patency and a lower infection rate compared with placement across the MDP. For patients with malignant CBD obstruction, biliary stents should be placed above the papilla if papillary lesions are not invaded.

ABBREVIATIONS

MDP = main duodenal papilla, CBD = common bile duct, PTBD = percutaneous transhepatic biliary drainage

Biliary stent placement is an effective treatment for unresectable malignant bile duct obstruction. Self-expanding metal stents are widely used because they provide longer patency times and greater cost-effectiveness than plastic stents (1,2). For patients with common bile duct (CBD) obstruction, the decision to insert a metal stent above or across the main duodenal papilla (MDP) is

controversial. Some studies (3,4) have recommended stent placement across the MDP because of low complication rates. However, other studies (5,6) described that disruption of the sphincter mechanism by transpapillary placement may be the most important etiologic factor in the propensity for cholangitis after metallic stent placement. The purpose of the present study was to compare the outcomes of metal stent insertion across the MDP versus above the MDP in patients with nonresectable malignant obstruction of the CBD.

MATERIALS AND METHODS

This study was approved by the committee on human research of the institutional review board at the authors' institution. The requirement for written informed consent was waived. Data from medical records and follow-up telephone calls were collected retrospectively.

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None of the authors have identified a conflict of interest.

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J Vasc Interv Radiol 2015; 26:432–437

<http://dx.doi.org/10.1016/j.jvir.2014.11.008>

Patient Population

From August 2004 to March 2010, 98 consecutive patients with unresectable malignant nonhilar biliary obstruction were treated with percutaneous placement of biliary bare self-expanding metal stents across the MDP (group 1; $n = 51$; tumor invaded the distal 2 cm of the CBD or papilla) or above the MDP (group 2; $n = 47$; tumor did not invade the distal 2 cm of the CBD or papilla). Accurate and definitive follow-up data were obtained in all 98 cases. All patients had a history of malignancy and a life expectancy of more than 3 months. Diagnoses of nonhilar biliary obstruction were established based on a serum bilirubin level greater than $17 \mu\text{mol/L}$ and enhanced computed tomography or magnetic resonance (MR) cholangiography. Patients with intestinal obstruction were not included.

Patient characteristics are presented in [Table](#). The etiologies of malignant biliary obstruction were diagnosed by surgical history in five and 10 patients, by biopsy in nine patients each, and by MR in 37 and 28 patients in groups 1 and 2, respectively. No patient had cholangitis or cholecystitis before the procedure.

Treatment Approach

Fifty-one patients underwent transpapillary stent placement (group 1), and 47 patients underwent stent placement above the MDP (group 2). Patients with hemobilia during operation required biliary drainage after stent insertion. The drainage catheters were irrigated after operation and removed 3 days after the catheters were closed without complication. Follow-up cholangiography was obtained via the drainage catheter before removal.

Prophylactic antibiotic treatment was given to patients with cholangitis and changed according to the results of bacterial culture of bile and a drug sensitivity test. Subsequent interventional percutaneous transhepatic biliary drainage (PTBD) was performed in patients with emerging biliary infections that were resistant to antibiotic treatment.

Procedures

Written consent was obtained from all patients before treatment. All procedures were performed under local

anesthesia with 0.5% lidocaine and conscious sedation with midazolam. Percutaneous biliary duct puncture was obtained from a right intercostal approach with a 21-gauge needle (Hakko, Tokyo, Japan) under ultrasound guidance for all patients. After a 4-F catheter (Cook, Bloomington, Indiana) was inserted through the obstruction into the duodenum, cholangiography was performed by injection of contrast material while pulling the catheter back slowly. The overall length of the obstruction and the distance from the end of obstruction to the papilla were confirmed. The guide wire was exchanged for a 0.035-inch guide wire (Amplatz Super Stiff; Boston Scientific, Natick, Massachusetts), and a self-expanding metal stent was inserted through the wire. Stents were placed across the papilla in patients with tumor obstruction the lower 2 cm of the CBD, and above the papilla in patients without peripapillary obstruction. The stent protruded 1 cm into the duodenum if it was inserted across the papilla. Postdilation of the stent was not necessary. An 8.5-F external biliary drainage catheter (Cook) was left above the stent if necessary. The drainage catheters were irrigated after the operation. Patients returned 1–2 weeks after stent insertion for tube cholangiography and removal of the drainage catheter if the stent was patent and infection was well controlled.

Study Endpoints and Definitions

Clinical follow-up was available in all patients until their death. The primary endpoint of the present study was overall survival. Survival time was assessed by follow-up telephone calls. A secondary endpoint was primary stent patency. Primary stent patency was defined as the time interval from first stent placement to stent dysfunction. If there was no evidence of stent malfunction during the patient's life, stent patency was considered equal to survival duration. The data of technical success, clinical success, complications, and serum total bilirubin levels before and after stent insertion were collected retrospectively. Technical success was defined as successful stent placement in the expected position via the percutaneous transhepatic route. Clinical success was defined as a decrease of serum bilirubin level of at least 20% between baseline and 7 days after stent placement. All early and

Table. Demographic and Disease Characteristics of the Study Population

Characteristic	Stent across MDP (n = 51)	Stent above MDP (n = 47)	P Value
Sex (M/F)	29/22	28/19	1.0
Age (y)	62.4 ± 15.2	60.1 ± 13.5	.448
Cause of biliary obstruction			1.0
Pancreatic carcinoma	21	14	
Extrahepatic cholangiocarcinoma	9	12	
Gallbladder carcinoma	4	6	
Metastatic carcinoma	7	15	
Carcinoma of ampulla	10	0	

MDP = main duodenal papilla.

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