

The use of intra-biliary uncovered self-expanding metallic stent as a palliative intervention for patients with unresectable malignant hilar stricture

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ABSTRACT

Malignant hilar strictures are generally revealed by cholestatic jaundice; Malignant biliary obstruction at the liver hilum is caused by a heterogenous group of tumors that include primary bile duct cancers (Klatskin's tumors), gallbladder cancers, and metastatic cancers. **Patients and method:** 28 patients with malignant hilar stricture proved by ultrasonography, CT, EUS, and brush cytology when available and needed have been chosen between august 2009-january 2011 from the patients who were visiting the outpatient clinic in the gastroenterology and hepatology teaching hospital. **Result:** 28 patients with non curable malignant hilar strictures have been chosen to perform the intrabiliary metallic stenting. 14 of them were male and 14 were females with male:female ratio 1:1. Mean age of presentation was 60.3 years, the youngest patient was 32 years old, and the oldest was 75 years old. 71% was cholangiocarcinoma.

Key word: metallic stent, malignant hilar stricture

Introduction:

Malignant hilar strictures are generally revealed by cholestatic jaundice; Malignant biliary obstruction at the liver hilum is caused by a heterogenous group of tumors that include primary bile duct cancers (Klatskin's tumors), gallbladder cancers, and metastatic cancers (1,2,3). These tumors are commonly unresectable at the time of diagnosis and therefore, they are associated with a very poor prognosis (4); Regardless of tumor histology, less than 30% of the patients are suitable for curative resection (5). Endoscopic biliary drainage is now the treatment of choice for inoperable hilar biliary obstruction (6,7). To relieve the obstruction many procedures are available as palliative measures which includes:

1-surgical drainage methods.

2-percutaneous drainage method

3-endoscopic internal drainage The endoscopic drainage method is the preferred first line palliative procedure because it is less invasive with less complication (6); Whether to use unilateral or bilateral metallic stent drainage is controversial (7).

Patients and methods:

28 patients with malignant hilar stricture proved by ultrasonography, CT, EUS, and brush cytology when available and needed have been chosen between august 2009-january 2011 from the patients who were visiting the outpatient clinic in the

gastroenterology and hepatology teaching hospital.

All the patients decided to be non curable and need palliative drainage procedure after surgical consultation. Informed consent was obtained from all patients before the procedure;

Baseline liver function test and clinical status documented, and after the procedure 4 variables have been documented and these are:

1-technical success:

successful stent deployment (passage of the stent across the stricture, along with flow of bile through the stent).

2-clinical success: successful drainage (decrease in bilirubin to more than 75% of the pretreatment value within 1 month).

3-procedure related complications: (Any adverse event occurring within 30 days was considered a procedure-related complication); Cholangitis within 14 days of the procedure was considered procedure-related and disease-related thereafter; A diagnosis of cholangitis was made if fever associated with leukocytosis and recurrence of jaundice and cholestasis developed and persisted for longer than 48 hours.

4- mortality: Procedure-related mortality was defined as death directly related to a complication from stent insertion and 30-day mortality, or death occurring within 30 days of the first attempt at

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endoscopic stent insertion, whether successful or unsuccessful.

Stent occlusion or failure was defined as the persistence or recurrence of jaundice (bilirubin level ≥ 5 mg/dL) and/or cholestasis (level of alkaline phosphatase, and alanine aminotransferases ≥ 3 times the normal value) and/or evidence of dilated biliary system on US requiring reintervention. The classification of the hilar malignant stricture was according to the Bismuth-Corlette classification:

1-Type I cholangiocarcinomas: involve the common hepatic duct distal to the union of the right and left hepatic ducts.

2- type II tumors involve the union of the right and left hepatic ducts.

3- type IIIa tumors involve the union of the right and left hepatic ducts and extend up the right hepatic duct; type IIIb tumors involve the union of the right and left hepatic ducts and extend up the left hepatic duct.

4- type IV tumors are multifocal or involve the biliary confluence and extend up the right and left hepatic ducts (8).

Technique:

Prophylactic treatment with broad-spectrum intravenous antibiotics (cefotaxime) initiated 1 day before the procedure, and continued with oral antibiotics for 5 days after the procedure.

Under good sedation (pethidine and diazepam) ERCP is performed with the use of Olympus or pentax duodenoscope, after successful cannulation (whether by standard guidewire-assisted or by precut) the type of stricture is documented by fluoroscopy and with the use of contrast medium.

Intrabiliary self-expanding uncovered metallic stent is deployed under fluoroscopy.

Technical success is assessed immediately by fluoroscopic documentation of overcoming the stricture and by free bile drainage.

Results:

28 patients with non curable malignant hilar strictures have been chosen to perform the intrabiliary metallic stenting. 14 of them were male and 14 were females with male:female ratio 1:1.

Mean age of presentation was 60.3 years, the youngest patient was 32 years old, and the oldest was 75 years old. The cause of hilar stricture was:

1-Hilar cholangiocarcinoma (Klatskin tumor) 20 (71.4%) patient:

2-Gall bladder tumor 4 (14.3%) patients

3-Cancer of the head of pancreas 4 (14.3%) patients

Technical success is achieved in all the patients (100%) by standard guide wire assisted cannulation except for 2 of the patients in whom the cannulation is achieved by precut.

cannulation is achieved by precut.

In one of the patients with cancer of the head of the pancreas who had duodenal infiltration and stenosis by malignant growth, duodenal metallic stenting is done in one session and after one week another session is done for the deployment of the intrabiliary metallic stent (2 step procedure).

Regarding the clinical success all the patients (100%) achieved the target of 75% reduction of TSB from the base line after 4 weeks, 9 patients (32%) achieved normalization of the TSB after 4 weeks. No major complication occurred in the patients, only one of them developed transient mild right upper quadrant pain and right shoulder pain for 3 days after the procedure, he underwent full investigations regarding biochemical and radiological and sonographic investigation to exclude minor perforation or pancreatitis or cholangitis and all proved to be negative. Mortality rate was 0% after 3 months of follow up.

Discussion:

Malignant hilar obstruction carries a very poor prognosis, with only 5% to 20% being resectable (1). By the time of diagnosis most of the patients have no curative solution that can be offered, with the palliative intervention is the last resort for them.

Palliative surgery is usually difficult and often impossible. Furthermore, operative mortality is high; approximately 20% (3). The endoscopic stent deployment seems to be a reasonable accepted palliative intervention.

A lot of debate about the most suitable method of stent placement, regarding: Plastic versus metallic stenting (7), unilateral versus bilateral stent placement (7), the use of contrast medium (1), using uncovered or partially covered metallic stents (9).

All the studies are designed to facilitate the selection of the appropriate method of palliation; usually the trial of bilateral stent deployment is associated with less success rate due to high technical demand and theoretical drainage impedance. Patients with bilateral drainage had a significantly lower rate of successful stent insertion and a significantly higher rate of early cholangitis than patients with unilateral drainage. They concluded that insertion of more than one stent would not appear justified as a routine procedure (7); this was regarding plastic stents. In a prospective and randomized controlled study comparing bilateral metal stenting and bilateral plastic stenting, Wegener *et al.* concluded that metal stents gave higher success and patency rates than plastic stents and were more cost-effective because they required fewer re-

interventions, thus reducing the period of hospitalization(10).In conclusion the most effective method is the one that provides the patients the best drainage with the least complications and the least mortality rate ,taking into account how easy it is performed and how much experience it needs. For sure unilateral deployment of a stent is easier than bilateral technically.In our study we used short self-expanding metallic stents 4-6 cm in length and we tried to deploy it across the malignant hilar stricture, this enables us to overcome the obstructed area without the need to extend the length of the stent into the papillary orifice , the success rate was excellent , in all the patients we managed to deploy the stent without technical failure, even in the patient with duodenal deformity and narrowing because of the tumor infiltration we managed to deploy the metallic stent after 1 week of duodenal stenting(2 step procedure).

The clinical success is confirmed by the follow up of the patients for more than 12 weeks , all patients show durable reduction of TSB >75% of the base line for more than 4 weeks, and this seems to be a reasonable target.

All this achievement is gained with no significant procedure related complication, despite the use of contrast material none of the patients developed cholangitis even after 4 weeks of follow up.

The result achieved seems not to be affected by the type of malignant stricture.In conclusion , intrabiliary metallic stenting using uncovered metallic stents seems to be a reasonable option for hilar malignant strictures with good outcome and no significant complication, it needs experience but it is easier than bilateral metallic stenting , and we do not need long metallic stents .

This is a pilot study in Iraq and Another study to directly compare the intrabiliary metallic stent with trans-papillary metallic stent is recommended.

	No.(%)
Total number	28
male	14(50%)
female	14(50%)
Mean age(yrs)	60.3
<u>Cause of obstruction</u>	
I. Hilar cholangiocarcinoma (klatskin tumor)	20(71.4%)
II. Gall bladder tumor	4(14.3%)
III. Cancer of the head of pancreas	4(14.3%)
<u>Procedure results</u>	
I. Technical success	28(100%)
II. clinical success	28(100%)
III. complication	1(3.6%)
IV. mortality	0(0%)

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