Efficacy of Y-shaped bilateral self-expandable metallic stent placement for the management of malignant hilar biliary strictures

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Background
Malignant hilar stricture (MHS) is a clinical challenge because of the current therapeutic approach and poor prognosis. Although still controversial, bilateral stenting may be the best option for the palliative drainage of malignant hilar biliary obstruction. Recently, the self-expandable metallic stents have clarified more efficacy than plastic stents for the palliation of MHSs, with the bilateral stent-in-stent technique registering a high success rate. The aim of our investigation is to evaluate the technical and clinical efficacious of the endoscopic bilateral metal stenting using a biliary Y-stent for the management of MHS.

Patients and methods
Twenty-five patients with advanced hilar cholangiocarcinoma were managed by Y-shaped bilateral self-expandable metallic stent placement. The prospective analysis was performed over a period of 3 years from May 2015 to June 2018 at the Department of General Surgery, Zagazig University Hospitals.

Intervention
For bilateral metal stent placement, a biliary Y-stent with central wide-open mesh was used exclusively at first. A second stent was placed into the contralateral hepatic duct through the central open mesh of the Y-stent.

Results
Bilateral metal stenting using a Y-stent technique successful was achieved in 23 of 25 patients (technical success, 92%), and successful drainage was achieved in all patients (100%). Early complications rate was 0%, and the stent occlusion rate was two (9%) of 23 patients. Two patients were managed with the insertion of a plastic stent through the occluded metal stent, and the remaining patients were treated with percutaneous biliary drainage. The median stent patency period was 221 days (range, 102–480 days).

Conclusions
The Y-shaped endoscopic bilateral stenting using a Y-stent is more effective and feasible method with a high technical success rate of 92% and low stent-related complications for the management of MHS.

Keywords:
bilateral drainage, biliary strictures, endoscopic biliary drainage, malignant hilar strictures, self-expandable metal stent

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Introduction

The hilar biliary strictures are caused by various benign and malignant conditions. It is difficult to differentiate benign and malignant strictures. The endoscopic management of these strictures is challenging. An endoscopic method has been advocated that involves placement of an increasing number of stents at regular intervals to resolve the stricture. Malignant hilar strictures (MHS) are mostly unresectable at the time of diagnosis, and only palliation is possible [1].

MHSs, type more than or equal to 2 according to the Bismuth–Corlette classification of cancers of the human biliary tract [2], are a clinical challenge because of the current therapeutic approach (surgical or nonsurgical) and the poor prognosis associated with this form of cancer [3]. Although cholangiocarcinoma of the hilum accounts for most patients with hilar strictures, other etiologies include gallbladder carcinoma, lymph node metastasis, and pancreatic carcinoma [4,5].

Surgery, involving hepatic resection if necessary, offers the only chance of the cure, but most patients are not good candidates for curative resection [6,7].

In hilar cholangiocarcinoma, exclusively endoscopic placement of bilateral metal stents has been considered

very difficult and complex, and it may require multiple procedures, with an increased risk of complications and mortality [8–11].

The endoscopic biliary decompression is widely used to improve the survival and quality of the patient's life with advanced hilar cholangiocarcinoma. However, a consensus has not been reached regarding whether bilateral drainage or unilateral drainage is the better method. Bilateral stenting is required for adequate drainage of more than 50% of the liver volume and has become more feasible with more experienced endoscopists and the development of new devices [12].

Although the necessity of bilateral drainage for hilar biliary strictures is controversial, an increased risk of cholangitis has been described if only one side is drained when bile ducts of both hepatic lobes are contaminated [13,14]. Endoscopic bilateral stenting using conventional metal stents is considered technically difficult in patients with hilar biliary strictures because the second stent is not easily inserted once the first stent is deployed within the bile duct lumen. However, improvements in stents and devices for endoscopic intervention have led to increased use of endoscopic bilateral stenting [15].

Although the stent-in-stent method or stent-by-stent method can be used for bilateral stenting, the stent-in-stent method has been widely used since the introduction of various types of recently developed open-cell stents [16–18]. However, stent dysfunction develops in 3–45% because of tumor in growth, overgrowth, or debris as the disease progresses [15].

Despite the fact that multiple plastic stenting is a feasible and good curative, the self-expandable metallic stents (SEMS) have proven to be more effective than the plastic stents for the hilar tumor palliation [18,19], with bilateral stent-in-stent placement registering a high success rate [20].

A biliary Y-stent with a wider-mesh central portion has been recently introduced to facilitate passage of the second metal stent during bilateral stenting [21–23].

Aim

The aim of our investigation is to assess and evaluate the technical and clinical efficacy of endoscopic bilateral metal stent placement using a biliary Y-stent for the palliative drainage of MHS. Moreover, we report our experience on the feasibility and safety of Y-shaped endoscopic SEMS placement in advanced malignant hilar carcinoma.

Patients and methods

Study design

A prospective study was conducted in the Surgical Department at Zagazig University Hospitals to evaluate the efficacy of endoscopically inserted bilateral SEMS in 25 patients for advanced malignant hilar carcinoma over a period of 3 years (May 2015–June 2018).

Full and informed consent was obtained from all patients before the procedure. The study was approved by the Ethical Committee of our Internal Review Board.

Inclusion criteria were hilar stenosis of Bismuth type II, III, or IV. The lesions were staged according to the classification of Bismuth *et al.* [6] based on a review of all available cholangiograms, computed tomography (CT), and magnetic resonance cholangiopancreatography images.

Methods

Indication for stent placement was an increase in bilirubin levels with evidence of intrahepatic bile ducts dilatation (Fig. 1). Patients were treated within 48 h from the admittance. All patients were not treated previously.

All patients were diagnosed as having MHS based on ultrasound, CT, and magnetic resonance cholangiopancreatography imaging, CT and brushing cytology or endosonography-guided fine-needle aspiration cytology.

The studied group after clinical and radiological assessment was diagnosed as inoperable cholangiocarcinoma either due to locally advanced tumor invading portal vein or hepatic artery (stage III) or the presence of distant metastasis (stage IV); other patients had comorbidities that render them unfit for surgery.

All patients were hospitalized and underwent full blood count. Tumor markers including CEA, CA 19–9, and alpha-fetoprotein, liver and kidney functions, and coagulation parameters were obtained. Stent placement was discussed with the hepatobiliary surgeons, oncologists, and surgical endoscopists. Both tumor characteristics/location and the overall clinical condition were taken into account.

Figure 1

Magnetic resonance cholangiopancreatography showing normal common bile duct caliber with evidence of hilar obstruction with dilated both right and left hepatic ducts with marked intrahepatic biliary radical dilatation.

All patients in whom bilateral metal stenting was successful were followed up from stent insertion until death.

Technique

Prophylactic broad-spectrum antibiotics (third-generation cephalosporin) and vitamin K injections were initiated before the procedure and withdrawn 3 days later. All patients were operated under general anesthesia with appropriate cardiopulmonary monitoring.

The duodenoscopy used for this procedure was Pentax i-5000 with large working channels 4.2 mm. Endoscopic sphincterotomy was performed in all patients to facilitate stent placement.

The biliary Y-stent was produced with a single strand of nitinol wire, and its ends were formed to make a smooth, curved structure so as to not expose the sharp wire ends. The fully expanded stent was 10 mm in diameter and 10 cm in length, and the delivery system had a diameter of 8.5 F. The second stent, a conventional SEMS (biliary Niti-S stent; Taewoong Medical, Seoul, South Korea) which had 6–8 cm length and a fully expanded diameter of 10 mm can be introduced via the central mesh of the Y-stent [24] (Fig. 2).

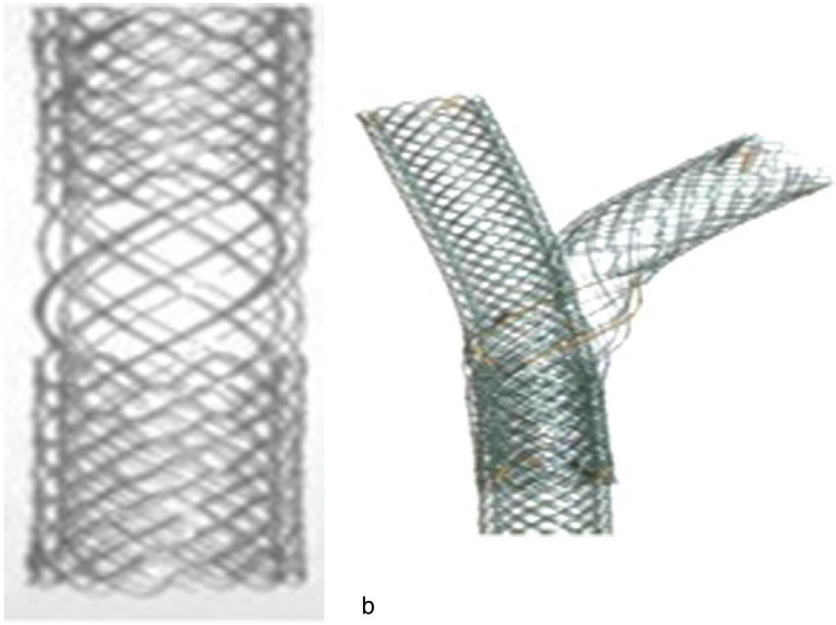
The length and size of SEMS were the same in all treated patients. After common bile duct cannulation, cholangiography, and subsequent sphincterotomy, a guide wire was placed, under the fluoroscopic guidance, across the left hepatic duct.

The stent placement technique was as follows: two stents were inserted in turn for the drainage of both liver lobes in a Y-shaped arrangement. After a guide wire was inserted across the hilar stricture, the Y-stent (i.e. the first stent) was endoscopically placed in the left or right hepatic duct, whichever was the more difficult side to access, using the standard method. The left stent is usually placed first as it is more difficult to access compared with the right stent (Fig. 3).

Evaluation of the severity of the stricture was made with contrast injection. The first uncovered SEMSs, with a wide-open central mesh, were placed across the hilar stricture. If needed, balloon dilation was performed before stent placement. Then, the guide wire was withdrawn slowly, and with the aid of a 5.5 F catheter, inserted under the fluoroscopic guidance into the wide-open central mesh of the first stent that was identified by the radiopaque markers. The second uncovered SEMS were placed through the central crossed mesh of the primary stent (Y-shaped configuration) to drain the right hepatic duct.

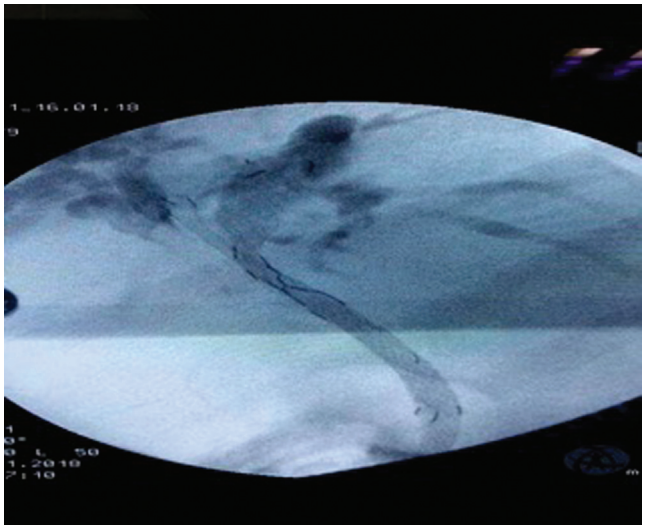
After dilation of the Y-stent with a biliary dilating balloon, a second guide wire was advanced from the inside of the Y-stent out through the central wider-mesh portion into the contralateral intrahepatic duct,

Figure 2



Pictures of the stent used in this study. (a) Nitis-S biliary Y-stent with central wide-open mesh; (b) Niti-S stent assembled (Y-shaped configuration).

Figure 3



Fully deployed Y-shaped stent.

and an attempt was made to insert the second stent along the guide wire (Fig. 2).

If the endoscopic access was not effective alone to pass through the stricture, we used rendez-vous technique (combined percutaneous ultrasound-guided and endoscopic access) to pass through difficult strictures.

If the bilateral stent placement failed, percutaneous transhepatic biliary drainage (PTBD) was performed for biliary decompression of the undrained contralateral hepatic lobe.

Follow-up

All patients' data on technical success, clinical success, and complications were collected. All patients were followed up, continued from stent insertion in the outpatient clinic until the death of the patient or to the end of the study. The median follow-up period was 221 days (range, 102–480 days).

After discharge from the hospital, patients were regularly followed at 1-month intervals. Biochemical parameters were assessed at 2 days, 1 week, and 1 month after stent placement, and every 3 months thereafter. Abdominal CT was checked every 3 months.

Successful stent insertion was defined as the passage of the stent across the stricture, along with the flow of contrast and/or bile through the stent. Successful drainage was defined as a decrease in bilirubin to less than 75% of the pretreatment value within the first month. Early and late complications were defined as any stent-related complication within 30 days and after 30 days of stent placement, respectively, including complications of endoscopic sphincterotomy, according to the criteria of Cotton *et al.* [25].

Statistical analysis

Data were collected in an electronic database and subsequently exported to the statistical software for final analysis. Data were analyzed using the software package SPSS 22 (SPSS Inc., Chicago, Illinois, USA).

The continuous variables were summarized as mean ±SD or median (range) according to their distribution. Categorical variables were summarized as frequency and percentage.

Results

We enrolled 25 patients, comprising 11 (44%) males and 14 (56%) female, with a mean age of 64.2±9.7 years (Table 1). All patients had primary cholangiocarcinoma. Regarding the types of MHS according to the Bismuth classification, there were six (24%) patients with type II, three (12%) patients with type III, and 16 (64%) patients with type IV. All patients showed a significant decrease in the serum bilirubin level. The mean bilirubin level in pretreatment period was 13.6±3.6 mg/dl (range, 3.5–30.4 mg/dl), and in the posttreatment period was 2.4±0.12 mg/dl (range, 0.37–7.4 mg/dl) (PZ.032). The diagnosis of malignancy was confirmed with tissue samples (brushing or endoscopic ultrasound-guided fine-needle aspiration).

During the study period, bilateral metal stent insertion by using the Y-stent method was attempted in all patients. Bilateral stents were placed in 23 of 25 patients (technical success, 91%). For 23 patients in whom bilateral metal stents were placed, initial insertion and deployment of the left-sided prosthesis, followed by insertion of the right-sided prosthesis was achieved in 23 patients and vice versa.

The endoscopic access was not effective alone to pass through the stricture in seven patients, so we used rendez-vous technique (combined percutaneous ultrasound-guided and endoscopic access) to pass through difficult strictures.

The remaining two patients needed stricture dilation. A unilateral stent with a Y-stent was placed in the remaining two patients. One of these two patients, both of whom failed the endoscopic second stent insertion through the Y-stent, received contralateral drainage by stent insertion via a percutaneous transhepatic approach, whereas the other was treated by PTBD.

Table 1 Baseline demographics and clinical characteristics of patients

	MHS (*N*=25)
Age (years)	
Mean±SD	64.2±9.7
Sex [*n* (%)]	
Male	11 (44)
Female	14 (56)
Bismuth type [*n* (%)]	
II	6 (24)
III	3 (12)
IV	16 (64)
Bilirubin	
Mean±SD	11.9±8.1

MHS, malignant hilar stricture.

Successful drainage was achieved in 23 of 23 patients (100%) in whom bilateral metal stents were placed by using a Y-stent. There was no procedure-related mortality, nor any early complication.

Late complications occurred in two (9%) of 23 patients and were related to stent occlusion from tumor ingrowth. Reintervention was required in these two (9%) patients. In one patient (case no. 1), tumor ingrowth occurred in the more proximal (peripheral) left intrahepatic duct than the central mesh portion and was managed by insertion of a plastic stent into the left duct through the SEMS (at 358 days). In one patient (case no. 4), tumor ingrowth occurred in the distal portion of the stent (proximal common bile duct) and was treated by left PTBD (at 180 days). The median stent patency period was 221 days (range, 102–480 days).

Discussion

Palliative biliary stenting has been the only option available for the treatment of patients with irresectable hilar obstruction as a result of the poor prognosis of these patients.

Drainage of obstructed ductal biliary systems has been strongly advocated as allowing for the reduction in morbidity and mortality because of better bile flow [12]. Although technically demanding, bilateral placement of two parallel metal expandable endoprosthesis has proven to be a safe and feasible procedure, with a high success rate and little need for further biliary reintervention in patients with unresectable hilar cholangiocarcinoma. Cheng *et al.* [26] reported, in 36 patients with Bismuth types II–III–IV lesions, an insertion success rate of 97%, with only 14% of complications at 30 days. The present study found that technical success rate was 100%, complication rate was 28.6%, and clinical success rate was 92.9%.Naitoh *et al.* [27], reported mean stent patency was 169 days, with a rate of stent occlusion at the end of the follow-up of 31%, whereas in this study, the median stent patency period was 221 days, which was slightly longer than that reported in patients who underwent percutaneous bilateral stent-in-stent placement using a T or Y configuration (range, 104–250 days) [22,28,29].

To have a high success rate, we used rendez-vous technique (combined percutaneous ultrasound-guided and endoscopic access) to pass through difficult strictures when the endoscopic access was not effective alone to pass through the stricture (seven patients). Neal *et al.* [30] reported the efficacy and feasibility for using rendez-vous technique for increasing success rate especially in hilar cholangiocarcinoma up to 94%.

Conclusion

In conclusion, endoscopic Y-shaped bilateral SEMS placement is safe and effective for the palliation of patients with irresectable and advanced hilar cholangiocarcinoma. This is because the technique was more similar to the normal physiological bilateral drainage state. These results should be confirmed by large prospective series and randomized controlled trials so this technique might gain consensus and become a gold standard for palliation of biliary obstruction in patients with advanced hilar cholangiocarcinoma.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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