

Study by using the endoscopic method for simultaneously placing biliary metal stents bilaterally

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【 Abstract 】

Objective	To evaluate the feasibility of the endoscopic method for simultaneously placing self-expandable metal biliary stents bilaterally.
Methods	Totally 9 patients with hilar biliary obstructive malignancy of Bismuth type II to IV were enrolled in the current study, with a mean serum bilirubin at 162.8 ± 193.8 $\mu\text{mol/L}$ before the procedure. Two guide wires were inserted into the left and right hepatic ducts and kept in site respectively. After aggressive dilatation of both ducts, the metal stents were deployed one by one bilaterally in the common hepatic duct. Success rate of the procedure, remission of jaundice, early stage complications and short-term clinical outcome were recorded.
Results	The procedure was succeeded in all patients with Y-type stent. Two cases were being placed with Y-type stents. One case was being placed with plastic stents transitionally. 6 cases were being placed with 2 stents bilaterally. The average time of procedure is 38.1 ± 14.8 min. The most convenient way was the bilateral method with proximal ends of the stents remaining at outside of papilla. The serum bilirubin of all patients returned to normal level within 3 weeks except one case, and no major complications were observed.
Conclusion	The endoscopic method for simultaneously placing self-expandable metal biliary stents is technically feasible and safe, with the benefit of prompt and effective control on jaundice reduction and biliary infection, caused by hilar biliary malignancy. A more ideal method is to place specially designed endoprosthesis bilaterally and leave the proximal ends of the stents outside the papilla.

【 Key words 】

Biliary tract neoplasms; Cholangiopancreatography; Endoscopic retrograde; Self-expandable metallic stent

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Background:

Endoscopic placement of self-expandable metal biliary stent has been widely applied in clinical treatment of malignant biliary obstruction. In comparing with traditional plastic biliary stent, the self-expandable metal biliary stent features in larger diameter, accurate positioning, better drainage effects and longer stent patency. Its efficacy having been well confirmed by large numbers

of clinical researches^[1-3], the treatment has gained wide acceptance by clinical physicians and patients. However, in case of malignant hilar biliary obstruction of Bismuth type II or more advanced stage, both the right and left hepatic ducts have been obstructed, unilateral metal stent placement usually results in poor jaundice reduction due to incomplete biliary drainage, and may develop biliary infection or pyemia. As a result, surgery or further intervention may be needed. Simultaneous placing biliary

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metallic stents bilaterally, if any, may result in facilitating biliary drainage, reducing postoperative infectious complications and enhancing the effectiveness of endoscopic treatment. However, owing to limitation of the current skills and medical device conditions, technically it is rather difficult to practice bi-stents placement, which results a low success rate. The reference cases or publications were limited in China & overseas^[4-5]. Recently the author tried to cure patients with advanced biliary tract neoplasms by using simultaneously endoscopic bilateral placement of biliary metal stents, which were successfully implemented in 9 cases. This paper reviews clinical data from such patient group as a pilot study of a feasible technical method and operational experiences as concerned.

Data & Methods

1 Clinical Data

A review was made of a group of 9 cases, (consisting of 6 males and 3 females, aged from 44 to 82 with a mean age of 60) accepted the endoscopic method of simultaneous placing biliary metal stents bilaterally due to malignant hilar biliary obstruction from May, 2007 to February, 2009 in Eastern Hepatobiliary Hospital/EHBH. According to clinical diagnosis, 5 cases were suffered from biliary tract neoplasms, 3 cases were suffered from gall bladder carcinoma, 1 case was suffered from hepatocellular carcinoma. Bismuth Type II, III, IV each occurred in 3 cases. All the patients infected with jaundice to different extents, with TBIL (serum total bilirubin) value of 162.8 ± 193.8 (Range: 36-603) $\mu\text{mol/L}$ before ERCP examination. Also among them, one case was placed with a unilateral stent, one case with a unilateral naso-biliary duct, and one case experienced unilateral percutaneous transhepatic cholangial drainage (PTCD), as well as one case accepted stent drainage (SD) on one side and PTCD on the other side. All cases were encountered poor jaundice reduction. While another case accepted bilateral plastic stent placement, the symptom of jaundice occurred again as the stent was being blocked.

2 Devices & Materials

Herein adopted were an Olympus JF-260V duodenoscope, with a 3.7mm biopsy channel, an Olympus KD•210Q Sphincterotome, Boston hydrophilic guide wire, Cook's dilating bougie with a port diameter of 6~9 FR, Cook's Quantum TTC dilating balloon (8mm (D) x 3cm (L)), Teawong's Y type metallic stent (10mm (D) x 80 mm (L)),

Boston's Wallstent metallic stent (10mm (D) x 80 mm (L)), Micro-Tech (Nanjing) MT metallic stents (6mm (D) x 80-110 mm (L)) and Boston's Flexima plastic stents (7 FR (D) x 12cm (L)) with frontal spine.

3 Methods

All patients accepted a MRCP examination for investigating the biliary obstruction site and range covered. After signing a letter of consent, a routine pre-operative ERCP preparation was carried out. After catheterization of bile duct via papilla was made, a small amount of contrast medium was injected for investigating biliary duct conditions near the obstruction site. A guide wire was inserted into the intra-hepatic bile duct on one side of the obstructive sites, choler was pumped out as much as possible. Contrast medium was injected for displaying the biliary branches. The guide wire was retained in the distal end of biliary duct group. Then, the papilla was incised by sphincterotome and the guide wire was kept in place by locking with fingers. Another guide wire was introduced into the opposite side of the biliary duct, choler was pumped out similarly for investigating obstructive conditions inside the biliary duct. Then the guide wire was retained in the main tract of this duct group, the sphincterotome was withdrawn. A bougie or a dilation balloon was inserted for dilating the hepatic tract and the stricture section of right and left hepatic ducts. A bilateral metallic stent was placed as per one of the following methods.

1. Method of Y-shaped stent placement: Firstly, the 1st metallic stent was deployed with the distal end retaining in the left hepatic duct and the proximal end inside the common bile duct, respectively. Y-shaped stent was a specially made metallic stent with an opening formed by a loosely-woven metal mesh in such middle part of the stent. Two metallic markers were characterized at both ends. The markers are used to indicate the connections between two stents. So the mentioned opening should be placed at the junction between the right and left hepatic ducts. Then, the guide wire should be withdrawn half-way from the left hepatic duct and inserted into the right hepatic duct through the opening of loosely-woven portion of the above-mentioned stent. Attention should be paid on the guide wire as it must be kept in place throughout the procedure. Then, a dilating balloon inserted along the guide wire and re-dilated the right hepatic duct and the first stent's meshes. After the lumen of right hepatic duct was confirmed, the 2nd metallic stent

could be deployed with the distal end retaining in the right hepatic duct and the proximal end retaining inside the left stent cavity.

2. Method by using plastic stent as a transitional help: Firstly, a barb-free plastic stent was placed in the hepatic duct on one side, with the proximal end retaining outside the papilla. Then, the 1st metallic stent was inserted into another hepatic duct on the other side and released, with the proximal end retained outside papilla. Again the guide wire is inserted into the hepatic biliary duct where the plastic stent dwells. The 2nd metallic stent is placed and released it. Finally, the plastic stent could be removed.

3. Method of two stents bilaterally placement: Use a specially designed metallic stent which adopts nickel-titanium alloy filaments woven longitudinally in a closed pattern (6 mm (D) x 80-110 mm (L), after released). The 1st stent was inserted along a guide wire. The distal end should be retained in the hepatic biliary duct and the proximal end should be placed inside biliary duct or outside the papilla accordingly. 9 FR dilating bougie or dilating balloon should be inserted into the other side and dilated the stricture section. Finally, the 2nd metallic stent should be inserted on the opposite side and deployed (Fig. 1).

4 Post-operative Processing

A routine post-operative ERCP monitoring procedure was carried out. It included the monitoring of jaundice reduction, complication occurrence, and hepatic functional test weekly until the figures completely back to a complete normal state. Monthly checkup and surveillance were recommended. Once any occurrence of gall duct infection or any re-occurrence of jaundice was found, another endoscopic intervention was administered. In case of any obstruction, retaining a plastic stent in the original metallic stent cavity was necessary to restore drainage.

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Results

1. Totally, 9 cases had accepted simultaneously bilateral metallic stent placement, all had successfully placed, with an average consumption time of 38.1 ± 14.8 min. Among them, 2 cases had adopted Y-shaped stents, with time consumption of 45.6 min and 67.6 min, respectively. One case had adopted temporary plastic stent placement process, with time consumption of 46.1 min. The remaining 6 cases have adopted bilateral stent placement, with time consumption of 33.0-36.9 min averaged in 29.4 ± 9.9 min (including 4 cases adopted to place in the distal end in the biliary duct, or one in the biliary duct and another end at the papilla; and 2 cases in each end of bilateral stents outside the papilla).

2. Complications: One case had an amylase increment up to 978U. The amylase examination was made in the day 1 after operation, but no abdominal pain or fever was scored. The amylase value was reduced to the normal range 24 hr thereafter without any other complications. In another case, jaundice reduction occurred right after the operation, the jaundice reduction occurred continuously. The jaundice reoccurred on the 5th day and an ultrasonic examination revealed that a serious obstruction in left hepatic duct. The symptom released after left-side drainage via PTCO process. In the 7 remaining cases, all the patients had a rapid jaundice reduction. Bilirubin levels of all patients restored their normal range in 3 weeks' time.

3. Follow-up: One case did not come back for further follow-up after hospital discharge. Among those patients falling in the follow-up record, 2 cases met jaundice reoccurrence in 4 months' time with irregular fever, and were admitted for ERCP examination again. It was found that stent obstruction occurred as the ingrowth of neoplasm. The jaundice were under controlled once the re-placement of bilateral and unilateral plastic stents. The remaining patients were having surveillance and no jaundice reoccurred. One patient scored no syndromes in 10 month's time (Table1).

Discussions

The biliary tract tumor is the most frequently occurring in the hilar region. Besides, the metastasis of gall bladder carcinoma, liver cancer and the other neoplasm are commonly invading the hilar biliary region. In case of malignant hilar obstruction of Bismuth subtype II or higher, the neoplasm's invasion into the junction of right and left hepatic ducts or advanced positions may result in

blockage between the right and left hepatic ducts. Therefore, unilateral hepatic duct drainage is unable to function properly in the hindered region. Although there is a dispute as to necessity of bilateral drainage in patients inflicted with hilar carcinoma, some scholars believed that unilateral hepatic duct drainage may also effectively control jaundice level with less complication.^[6] A clinically incomplete drainage often leads to poor jaundice control and patients manifest infection, fever, etc. Let's take this patient group as an example, among the whole group, 4 cases had a medical history of unilateral stent placement and PTCO drainage with poor jaundice reduction and some had fever; 1 case accepted bilateral plastic stent drainage resulting satisfactory effects although the neoplastic ingrowth occurred in the stent. Also among the whole group, 9 cases experienced bilateral metallic stent drainage yielded a very rapid jaundice reduction and the jaundice level fell into the normal range within 3 weeks, except one patient having a poor effects. If the condition permits, the author believes that an aggressive attempt of simultaneous bilateral drainage still has significant clinical advantage to the patients, who inflicted with malignant hilar duct obstruction.

In comparison with placing bilateral plastic stents, retaining a bilateral metallic stents is more difficult to achieve. Owing to the restriction by the diameter of biopsy channel of a duodenoscope, it is incapable of simultaneously inserting both two metallic stent delivering systems into the same biopsy channel. The metallic stents shall be inserted and released from one side to another side in turn. When the 1st metallic stent is released in position, the fully dilated metallic stent has occupied almost all the space in the hepatic duct. It increases the difficulty to insert the 2nd stent along the 1st stent. It is the reason why some scholar had designed a Y-shaped metallic biliary stent,^[4-5] the first 2 cases in this trial group adopted this method. However, there are rather complicated steps in the placement of Y-shaped metallic stents, which requires a fully dilation of stricture sections at both sides, i.e., besides dilating with a bougie, dilation balloons shall be introduced to dilate both sides completely. After the 1st stent is released, it is necessary to selectively relocate the guide wire into the other hepatic duct through the opening of loosely-woven meshes of the stent. In fact, it is not easy to success in every placement. And in case of any failure to locate the guide wire in place, percutaneous and transhepatic punctures were needed for compensation

thereof.^[4] In addition, the most serious intrinsic problem of "Y-shaped" stents is that the dilating power is not strong enough in the middle part of the stent. It cannot dilate the duct completely. So the neoplasm tissue may easily invade therein and lead to ingrowth and stent blockage. Furthermore, the interlacement of stents at both sides unavoidably affects the bilateral drainage rate. Y-shaped stents are adopted in 2 cases of this group and evidently much time is required in this process. Moreover, one patient had an incomplete dilation of Y-shaped stents and gave rise of continuous fever in the 5th day post-operation. The jaundice reduction ceased itself and the compensation via PTCO had to be made (Fig.2). All of these shortcomings prompt us to explore a new process for simultaneously placing bilateral metallic stents, so as to bring the stents to lie in bilateral way and enhance drainage effects accordingly.

The difficulty of adopting bilateral metallic stents in parallel position is mainly due to the limited spaces inside the common hepatic duct and stricture section. After releasing the 1st stent, there is a great difficulty to insert the 2nd stent. Therefore, some scholar proposed that a plastic stent should be inserted first to occupy certain space for serving a transitional purpose.^[7] Herein we had also adopted similar process for trial usage in one case and gained success. However, this process was still rather complicated and needed to waste one piece of plastic stent and there was a doubt of the metallic stent migration upon removing plastic stent. To simplify the operation, we had cooperated with related departments in specially designing a 6 mm diameter stent woven in a closed pattern longitudinally, which was slimmer than the ordinary stent in order to occupy little space. A considerably drainage was being improved from the hepatic duct once this stent applied. Longitudinally woven filaments reduced the resistance during insertion of the 2nd stent. The stent deformation was not occurred. After guide wires at both sides were selectively put in place and stricture sections at both sides had dilated, the stents were inserted and released in turn. Clinical trials indicated that our proposed procedure was a feasible one, which was characterized in that the operation was rather smooth with evidently less time consumption and a satisfactory drainage may be acquired as no mutual interference occurs between bilateral stents lining in parallel.

In the first instance, we had adopted an 80 mm long metallic stent with the distal end retaining in a biliary

duct. However, we encountered a certain difficulty in inserting the 2nd stent's delivering system, especially for those patients who had thinner hepatic ducts. In addition, jaundice reoccurred in 2 patients, who inflicted with cholangiocarcinoma about 4 months following stent placement and another endoscopic interference was made. Under the contrast examination, it showed that neoplasm tissues had invaded into the stent cavity and resulted obstruction. We tried once again to retain a plastic stent in the stent cavity at either side (Fig. 3). However, in one of them, the stent lumens could be clearly identified, so only a unilateral plastic stent could be retained. Therefore, our materials and methods were modified to adopt 2 extra long stents (6 mm x 110 mm) with both ends retaining outside the papilla (a small incision had been made on the papilla by using a sphincterotome.). Thereby smoother insertion of the 2nd

stent had come true, with a higher rate of success and less time consumption (respectively 32.1 min and 11.8 min). At the same time, if any stent blockage occurred, the compensation procedure could be easily carried out from this stent opening to either side of the hepatic ducts. No stent blockage occurred among patients in our study. In conclusion, simultaneously endoscopic bilateral placement of self-expanding metallic stents is a feasible process for a patient inflicted with malignant hilar obstruction. It is beneficial by facilitating drainage of the biliary tract system and may effectively control jaundice and biliary duct infection, thereby improving quality of life. The method by using a specially designed two metallic stents, characterized with parallel positioning and released each of them simultaneously, with the proximal end retained outside the papilla, is a rather simple and easy process. It is worth to promote and apply.

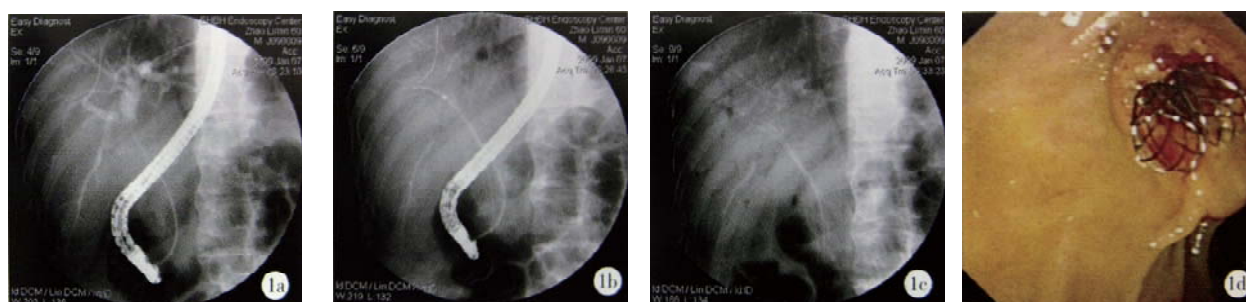


Fig. 1



Fig. 2

Patient No. 2, accepted Y-shaped stent placement. An incomplete dilation occurred due to the middle portion of the left stent, which gave rise to poor drainage.



Fig. 3

Patient No. 5, inflicted with cholangiocarcinoma-induced biliary duct obstruction.

3a: Adoption of parallel placement of bilateral metallic stents and effective jaundice level control;

3b: Jaundice reoccurred 4 months later, and neoplasm tissues invaded into the stent lumen and resulted in stent blockage under a contrast examination;

3c: Separately insertion of guide wires into right and left hepatic ducts through both stent lumens.

3d: Once again retaining bilateral plastic stents.

Table 1 Patient conditions and endoscopic therapy for the whole group

No	Sex	Age	Diagnosis (Yr)	Bismuth subtype	Preoperative bilirubin ($\mu\text{mol/L}$)	Stent type/ position of the distal end	Operating time (min)	Postoperative adverse effects	Jaundice reduction	Follow-up
1	M	52	#	IIIb	36	Y / IN	45.6	N/A	fine	*
2	F	52	#	IV	445	Y / IN	67.6	Fever	poor	**
3	M	52	#	IV	159	Plastic Stent/ IN & OUT	46.1	Transitional Amylase increase	fine	***
4	M	52	#	IV	95	Bilateral / IN	33.0	N/A	fine	****
5	M	52	#	IIIa	340	Bilateral / IN	36.9	N/A	fine	****
6	F	52	##	II	95	Bilateral / IN & OUT	34.9	N/A	fine	***
7	M	52	#	IIIa	234	Bilateral / IN	35.3	N/A	fine	***
8	M	52	#	II	426	Bilateral / OUT	32.1	N/A	fine	***
9	M	52	#	II	603	Bilateral / OUT	11.8	N/A	fine	***

#=Cholangiocarcinoma; ##=hepatic cancer; *= out of follow-up; **=adopt left side PTCD; ***=in follow-up, normal in hepatic function; ****=jaundice reoccurrence after 4 months.

IN = inside the common bile duct; OUT = Outside the papilla

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