

Prospective Study

New tapered metallic stent for unresectable malignant hilar bile duct obstruction

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Abstract

AIM: To examine the usefulness of a new tapered metallic stent (MS) in patients with unresectable malignant hilar bile duct obstruction.

METHODS: This new tapered MS was placed in 11 patients with Bismuth II or severer unresectable malignant hilar bile duct obstruction, as a prospective study. The subjects were six patients with bile duct carcinoma, three with gallbladder cancer, and two with metastatic bile duct obstruction. Stenosis morphology was Bismuth II : 7, IIIa: 3, and IV: 1. UMIN Clinical Trial Registry (UMIN000004758).

RESULTS: MS placement was 100% (11/11) successful. There were no procedural accidents. The mean patency period was 208.401 d, the median survival period was 142.000 d, and the mean survival period was 193.273 d. Occlusion rate was 36.4% (4/11); the causes of occlusion were ingrowth and overgrowth in 2 patients each, 18.2%, respectively. Patients with occlusion underwent endoscopic treatment one more time and all

were treatable.

CONCLUSION: The tapered MS proved useful in patients with unresectable malignant hilar bile duct obstruction because it provided a long patency period, enabled re-treatment by re-intervention, and no procedural accidents occurred.

Key words: Malignant hilar bile duct obstruction; Metallic stent; Tapered metallic stent

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Core tip: Placement of a tapered metallic stent in patients with unresectable malignant hilar bile duct obstruction proved useful because it allowed a longer patency period without procedural accidents.

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INTRODUCTION

The guidelines for biliary cancer diagnosis recommend drainage as frequent as possible in patients with unresectable malignant hilar bile duct obstruction for improvement of patient's quality of life or when performing chemotherapy^[1]. As an approach route for hilar bile duct occlusion, there are surgical, percutaneous, and transpapillary routes; and the region where drainage can be carried out differs depending on the location of the tumor, thus it is very difficult to establish treatment strategies. An endoscopic approach is recommended as the drainage route because of the low invasiveness and high success rate of internal drainage^[1]. Metallic stents (MSs) are considered useful for internal drainage in terms of patency period^[1]. Even past randomized controlled trials reported that MSs are associated with a longer patency period and lower occlusion rate than plastic stents (PSs)^[2,3]. Under such considerations, it may be necessary to set the strategies to use MSs in patients with unresectable malignant hilar bile duct obstruction. In this study we examine the usefulness of a new tapered MS developed for exclusive use in patients with unresectable malignant hilar bile duct obstruction.

MATERIALS AND METHODS

The patients with unresectable malignant hilar bile duct obstruction and showed a remarkable increase of hepatobiliary enzymes, had Bismuth II or higher

degree stenosis according to Bismuth classification^[4] and had been treated between July 2011 to December 2012 were included in this study (Table 1). There were 11 patients (7 men and 4 women) aged 72.273 ± 10.771 (59-85) years. The diagnosis was established based on a combination of images plus pathological findings. The cause of obstruction was bile duct carcinoma in 6, gallbladder cancer in 3, and metastatic bile duct obstruction in 2 patients. We evaluated the intrahepatic bile duct with a little contrast media. Stenosis morphology was Bismuth II in 7, IIIa in 3, and IV in 1 patient. The stenosis was 22.727 ± 8.545 (10-35) mm long. Remarkable increase of hepatobiliary enzymes was defined as a value double or more the normal value of ALT (IU/L), ALP (IU/L), or T-Bil (mg/dL), or a combination of them. ALT (IU/L) was 114.055 ± 96.915 , ALP (IU/L) was 1157.09 ± 420.250 , and T-Bil (mg/dL) was 5.427 ± 4.4365 prior to drainage. Inclusion criteria were: (1) Patients with unresectable malignant hilar bile duct obstruction; (2) No criteria on underlying disease, age or sex; and (3) Patients who gave their informed consent. Exclusion criteria were: (1) Patients in whom the endoscopic approach was difficult; (2) Patients with a bleeding tendency; (3) Patients who had suffered serious procedural accidents; (4) Patients who did not provide their informed consent; and (5) Patients who were determined not to be appropriate by the physician in charge. The MS was placed in all the patients *via* the endoscopic retrograde cholangiopancreatography (ERCP) route. Magnetic resonance cholangiopancreatography was performed in all of them before drainage. There was no case of cholangitis. Chemotherapy was performed in 6 patients and 5 received the best supportive care. The patients were followed up from MS placement to their death, and if patients were alive by March 2014 they were evaluated. Before ERCP, all patients were given the standard premedication consisting of intravenous administration of midazolam (3 to 10 mg), and the dose depended on age and tolerance. Scopolamine butylbromide or glucagon was used for duodenal relaxation. During ERCP, arterial oxygen saturation was continuously monitored using a pulse oximeter. Patients were kept fasting after the procedure for at least 24 h with drip infusion of 2000 mL and stayed in the hospital for at least 72 h. They received 8-h infusion of a protease inhibitor (nafamostat mesilate, 20 mg/d) and were prescribed antibiotics (SBT/CPZ, 2 g/d) for 2 d. For cannulation, catheters PR-104Q, R110Q-1 and PR233Q were used. Wire-guided cannulation was not performed. A 0.025-inch or 0.035-inch guidewire (Jagwire: Microvasive, Boston Scientific Corp., Natick, MA, Revo Wave: PIOLAX, or VisiGlide: Olympus Corp., Tokyo, Japan) was used. The endoscopes used were JF240, JF260V, TJF260V (Olympus Corp.), backward side-viewing endoscopes. After cholangiography, a guidewire was placed in the bile duct to conduct endoscopic sphincterotomy (EST). Clever-Cut3V

Table 1 Patient background

Case	Sex	Age	Disease	Stent no.	Stenosis morphology	Stenosis length (mm)	Treatment
1	Male	60	Intrahepatic bile duct carcinoma	2	Bismuth II	25	BSC
2	Male	59	Colon cancer	1	Bismuth IIIa	33	Chemotherapy
3	Female	85	Intrahepatic bile duct carcinoma	1	Bismuth IIIa	28	Chemotherapy
4	Female	85	Bile duct carcinoma	2	Bismuth IV	35	BSC
5	Male	67	Intrahepatic bile duct carcinoma	2	Bismuth II	18	Chemotherapy
6	Female	61	Gallbladder cancer	2	Bismuth II	17	BSC
7	Male	65	Gallbladder cancer	1	Bismuth II	18	Chemotherapy
8	Female	85	Gallbladder cancer	2	Bismuth II	22	BSC
9	Male	81	Colon cancer	1	Bismuth II	32	BSC
10	Male	79	Bile duct carcinoma	1	Bismuth IIIa	10	Chemotherapy
11	Male	68	Bile duct carcinoma	1	Bismuth II	12	Chemotherapy

BSC: Best supportive care.

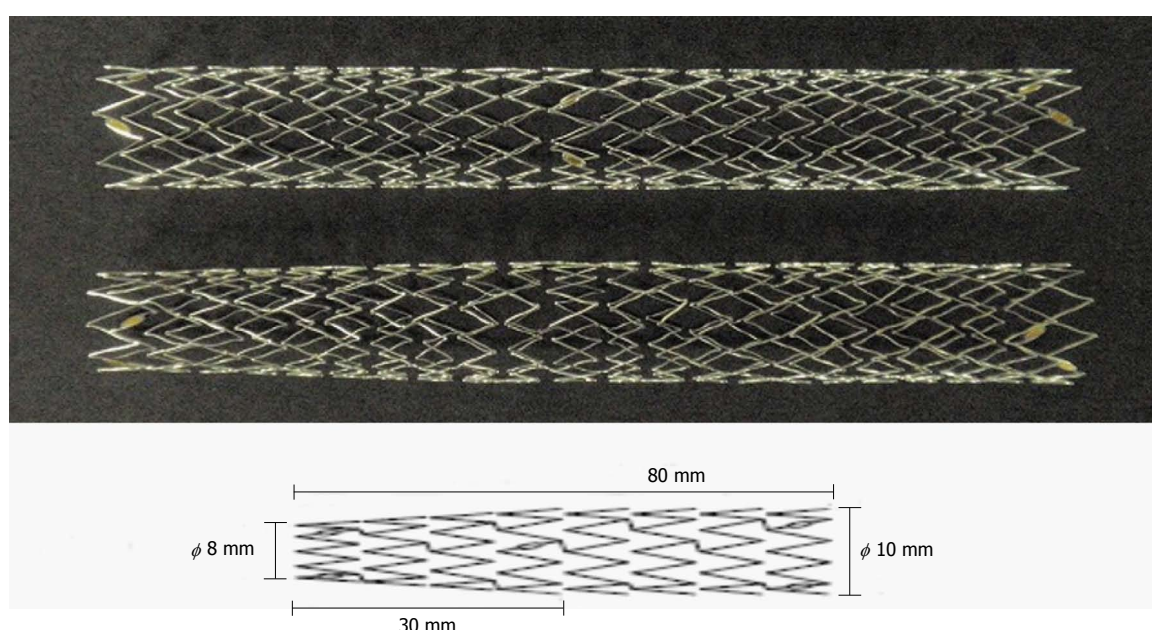


Figure 1 The metallic stent at the top is the ordinary laser-cut uncovered metallic stent. The one at the bottom is the laser-cut uncovered metallic stent (PIOLAX: Japan) created for exclusive use in the liver. This metallic stent is 8 cm in full size with a 3-cm tapered tip and a mesh space of 6-8 mm in the center of the stent; its internal diameter is 10 mm in the papillary side and 8 mm in the hepatic side.

(Olympus Corp.) was used as the knife for EST. EST was conducted using a single electrosurgical current generator (PSD-20, Olympus Corp.) at a power of 25 watts. EST was carried out in all the patients. The effect of drainage was determined by placing an endoscopic nasobiliary drainage (ENBD), or a PS in either the right or left bile duct. The effect of drainage was evaluated 7 d after drainage placement, and it was determined effective if the T-Bil was normal or 2/3 or less; then a tapered MS was placed. In patients without effective drainage, ENBD or PS was placed in the bile duct in the side where the drainage is not placed. An ENBD tube of 7 Fr. was used (FLEXIMA: Boston Scientific Corp., Natick, MA, or SD9: SILUX Straight type). Tube stents of 7 Fr., 8.5 Fr. and 10 Fr. were used (FLEXIMA: Boston Scientific Corp., or SD9: SILUX Straight type). And if the drainage was effective, the new tapered MS was placed in the region. As for tapered MSs, the delivery system

is a laser-cut MS created for use exclusively in the liver. These MSs are 7 Fr in size, with a full length of 8 cm and a 3-cm tapered tip. The mesh space is 6-8 mm at the center of the stent, and its internal diameter in the papillary side is 10 mm, while in the hepatic side it is 8 mm (PIOLAX: Japan) (Figure 1). In patients for whom two tapered MSs were required, stenting was performed in the partial stent-in-stent manner^[5-7]. The axial force and radial force of this MS were evaluated as follows. Axial force is the unbending force of the MS from the curved part. To measure the axial force, a portion of the stent was pushed perpendicularly by a force gauge (model DPX-5TR, Imada, Tokyo) until the angle became 60 degrees, and the force necessary to keep it in place was recorded. The measurement was made in an oven at 37 °C for 3 points distant 20, 40, and 60 mm from the bending point. Radial force is the dilating force of the MS. Radial force was measured using a radial force

Table 2 Comparison of alanine transaminase values before drainage and after metallic stent insertion

Case	ALT before drainage (IU/L)	ALT after MS insertion (IU/L)	P-value
1	63	54	
2	165	26	
3	182	32	
4	263	53	
5	75	14	
6	326	52	
7	69	25	
8	37	25	
9	115	25	
10	39	22	
11	212	35	
Average	114.055 ± 96.915	33.00 ± 13.892	P < 0.05

MS: Metallic stent; ALT: Alanine transaminase.

Table 3 Comparison of alkaline phosphatase values before drainage and after metallic stent insertion

Case	ALP before drainage (IU/L)	ALP after MS insertion (IU/L)	P-value
1	1524	1288	
2	1113	490	
3	1200	386	
4	1726	775	
5	605	354	
6	1289	254	
7	1524	956	
8	638	256	
9	1611	956	
10	610	238	
11	888	283	
Average	1157.09 ± 420.250	566.91 ± 365.157	P < 0.05

MS: Metallic stent; ALP: Alkaline phosphatase.

measurement machine (RX 500, Machine Solutions, Flagstaff, Ariz) in an oven at 37 °C. An MS sample in a fully expanded state was placed in the cylindric space of the machine, and the cylinder was contracted to shrink the MS to its minimum size of 2 mm. Then the force on the cylinder was reserved by an expansion force of the MS until it achieved its fully expanded state of 10 mm in diameter. The placement success rate, patency period, occlusion rate, and success rate of re-intervention of this MS were examined. Procedural accidents during ERCP-related procedures were evaluated according to Cotton's classification^[8]. When the jaundice level was T-Bil 3 mg/dL less, we started chemotherapy. This study was conducted under approval of our ethical committee, and was registered as prospective clinical trial. UMIN Clinical Trial Registry (UMIN000004758).

Statistical analysis

Fisher's exact probability test, student's *t*-test, and the Mann-Whitney *U*-test were used for statistical analyses to compare the blood test findings prior to drainage

Table 4 Comparison of T-Bil values before drainage and after metallic stent insertion

Case	T-Bil before drainage (mg/dL)	T-Bil after MS insertion (mg/dL)	P-value
1	13.9	3.8	
2	3	1	
3	12	1	
4	1.4	0.7	
5	3.1	0.9	
6	10.2	2.1	
7	2.3	1.3	
8	3	1	
9	1.8	1.3	
10	3.8	1	
11	5.2	1	
Average	5.427 ± 4.4365	1.373 ± 0.8833	P < 0.05

MS: Metallic stent.

insertion and post MS insertion. A *P* value < 0.05 was regarded as significant. Cumulative stent patency and survival were estimated using the Kaplan-Meier estimator. Data were analyzed using SPSS software version 17 (SPSS, Chicago, IL).

RESULTS

Initial drainage was successful in 6 (54.5%) of the eleven patients, and the remaining 5 (45.5%) had poor drainage thus drainage in the right and left bile ducts was performed. In the end, drainage was successful in all the patients. Since drainage was effective, MS was placed in all of them. In the six patients who underwent unilateral bile duct drainage one MS was placed, while in the five patients who underwent right and left bile duct drainage, two MS were placed; stenting was successful in all the patients. The mean number of MSs used was 1.545 ± 0.522 (1-2). All the parameters assessed at one week after stenting showed significant improvement compared with those before drainage insertion: ALT 33.00 ± 13.892 (IU/L), ALP 566.91 ± 365.157 (IU/L), and T-Bil 1.373 ± 0.8833 (mg/dL) (Tables 2-4). There were no procedural accidents due to stenting. The axial force of this MS was 0.156 ± 0.017 N when evaluated at bending point 20 mm, and radial force was 4.76 ± 0.18 N when evaluated at a dilated diameter of 4 mm. The patency of MS is shown in Table 5. The mean patency period was 208.401 d, the median survival period was 142.000 d (mean 193.273 d). The occlusion rate was 36.4% (4/11), and the occlusion causes were ingrowth in 2 (18.2%) patients and overgrowth in another 2 (18.2%). Patients with occlusion underwent endoscopic treatment one more time and in all of them it was 100% (4/4) successful. In patients who developed overgrowth in the contralateral hepatic side, an MS was placed in the partial stent-in-stent manner. In patients with an MS in each bile duct who developed overgrowth, an MS was additionally placed. In two patients with two MSs in the right and

Table 5 Achievements of metallic stent placement

Case	Survival period (d)	Alive or dead	Patency period (d)	Absence or presence of occlusion	Occlusion cause	Re-intervention
1	142	Dead	126	+	Ingrowth	PS
2	122	Dead	86	+	Ingrowth	PS
3	213	Dead	213	-	-	-
4	93	Dead	93	-	-	-
5	245	Dead	245	-	-	-
6	78	Dead	78	-	-	-
7	533	Alive	130	+	Overgrowth	MS
8	123	Dead	123	-	-	-
9	145	Dead	75	+	Overgrowth	MS
10	127	Dead	127	-	-	-
11	305	Dead	305	-	-	-
Mean	142		208.401	-	-	-
Median	193.273		-	-	-	-

MS: Metallic stent; PS: Plastic stent.

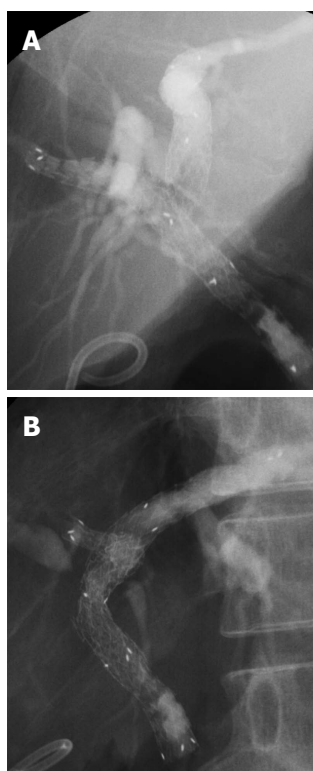


Figure 2 New tapered metallic stent (fluoroscopic image). A: Tapered laser-cut metallic stent placed in the liver. Stenting along the shape of the bile duct was possible (fluoroscopic image: front view); B: Fluoroscopic image: oblique view.

left bile duct who developed ingrowth, two PSs were placed in the right and left bile duct in the stent-in-stent manner. Re-treatment was successful in all the occlusion patients. The accidental occurrence symptom about the ERCP related procedures did not accept it.

DISCUSSION

In this study we evaluated a new tapered MS for unresectable malignant hilar bile duct obstruction. The MS used in this study was the laser-cut MS that enables precise stenting because shortening is structurally

less^[5]. Although evaluation may be partially difficult due to the small sample size, we experienced no procedural accidents during insertion, the patency period was long, and re-intervention was successful in all the patients; thus we consider this is a useful stent. This MS has moderate radial force at low axial force^[9]. With regard to procedural accidents, this MS has low axial force, which enables stenting along the bile duct and may prevent kinking. When an MS is placed, usually procedural accidents such as acute pancreatitis or acute cholecystitis do not occur, however, abdominal pain may occur^[10]. There may be various causes for this, including stress on the bile duct due to high axial force or strong radial force of the MS, or to a mismatch of the bile duct and MS regarding diameter, especially if the MS is of a diameter larger than that of the hepatic bile duct. The MS used in this study has a low axial force and a moderate radial force as shown in past reports; thus it is useful to treat stenosis and carry out stenting while applying low pressure on the bile duct. Furthermore, the tip is tapered, enabling good positioning of the stent (Figure 2). This may reduce the risk of abdominal pain due to stenting and of procedural complications such as hepatic abscess because the Glisson's sheath is not compressed. In this study no procedural accidents occurred; still if pancreatography is performed frequently during the procedure or it is difficult to catheterize the bile duct, pancreatitis might occur after ERCP^[11,12].

As for the patency period, the sample size was small and thus evaluation is difficult. However, the patency period was in the same range as that found in a previous report of similar sample size, and which was considered as satisfactory^[13]. The nature of the tumor, effect of chemotherapy, and characteristics of the MS itself may influence the patency period; yet, these should be evaluated in a study involving a large number of patients in the future.

Re-treatment was 100% (4/4) successful. Recent advancement of endoscopes and medical devices has enabled re-treatment in a comparatively easy

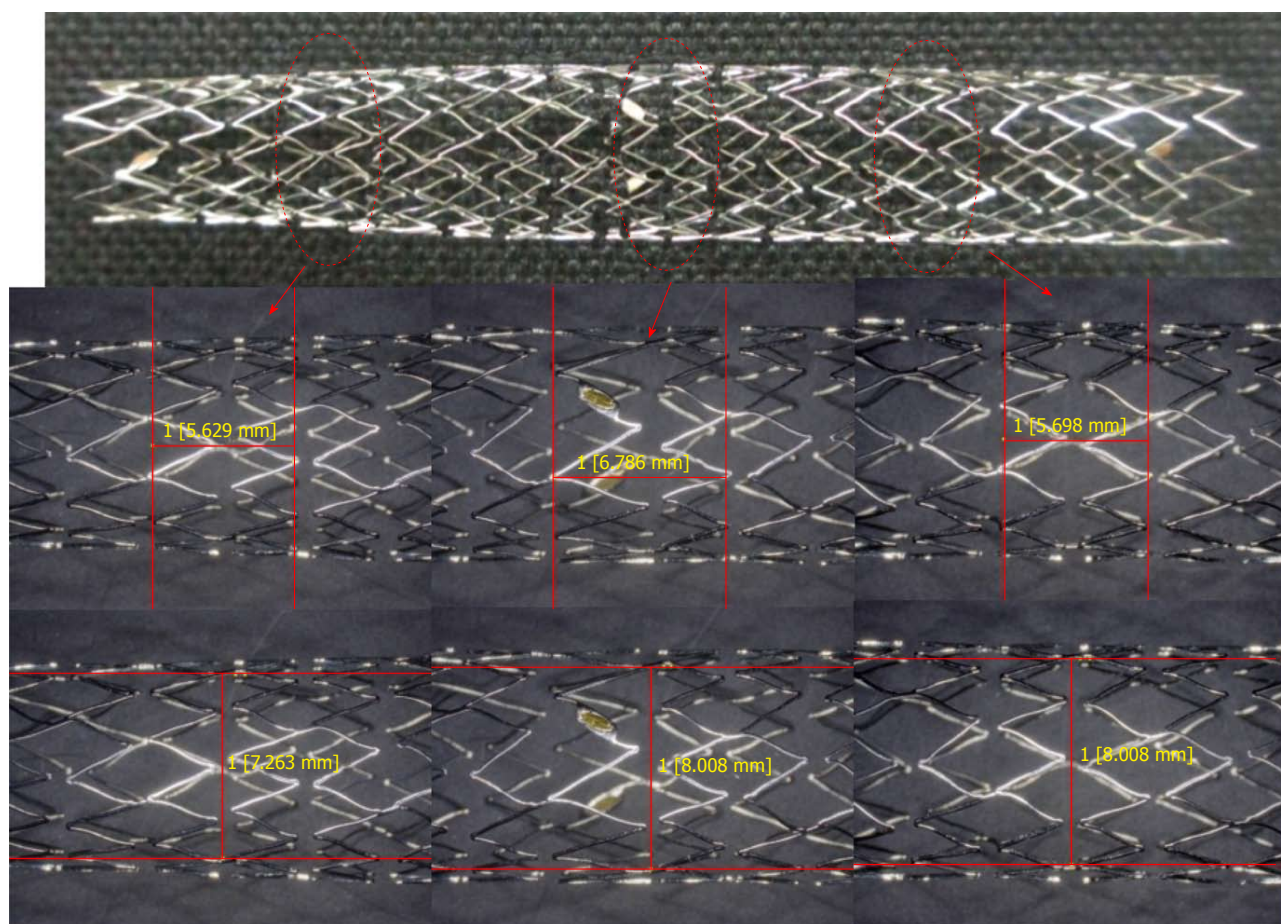


Figure 3 Laser-cut metallic stent with a comparatively large mesh space of about 6.8 mm × 8.0 mm in the center.

way. This MS has a large mesh space that facilitates re-intervention. Indeed, Mukai *et al.*^[14] reported that in the liver MSs with a large mesh space were an excellent choice because it was easier to re-intervene. Furthermore, other authors have also reported on the usefulness of MSs with a large mesh space that were created for exclusive use in the liver in patients with unresectable malignant hilar bile duct obstruction^[13,15]. The MSs used in these reports were of the braided type with a mesh space of 7 mm; that is, a space similar to that of the mesh space of the laser-cut tapered MS used in this study (Figure 3). The laser-cut tapered MS used in this study has a large mesh space, which facilitates manipulation through the mesh and re-intervention. From such results and reports, it is currently considered that MSs with a large mesh space may be an excellent choice for use in the liver. Compared with the braided MS, the laser-cut MS used in this study hardly suffered shortening and enabled precise placement. However, in the future it may be necessary a randomized clinical trial to assess which one is best regarding placement success rate and patency period.

Our results suggested that the new tapered MS was useful for patients with unresectable malignant hilar bile duct obstruction because the patency period was long, re-treatment was possible, and there were no

procedural accidents during their insertion.

COMMENTS

Background

Even past randomized controlled trials reported that metallic stents (MSs) are associated with a longer patency period and lower occlusion rate than plastic stents. Under such considerations, it may be necessary to set the strategies to use MSs in patients with unresectable malignant hilar bile duct obstruction.

Research frontiers

In this study, the authors examine the usefulness of a new tapered MS developed for exclusive use in patients with unresectable malignant hilar bile duct obstruction.

Innovations and breakthroughs

It may be necessary to set the strategies to use MSs in patients with unresectable malignant hilar bile duct obstruction.

Applications

A new tapered MS developed for exclusive use in patients with unresectable malignant hilar bile duct obstruction.

Terminology

The results suggested that the new tapered MS was useful for patients with unresectable malignant hilar bile duct obstruction because the patency period was long, re-treatment was possible, and there were no procedural accidents during their insertion.

Peer-review

This study prospectively estimated the efficacy of an uncovered metal stent with slightly tapered shape in its distal end for the patients with malignant biliary obstruction at the liver hilum.

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