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CLINICAL INVESTIGATION

ePTFE/FEP-Covered Metallic Stents for Palliation of Malignant Biliary Disease: Can Tumor Ingrowth Be Prevented?

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Abstract
Purpose To determine the application and clinical effectiveness of ePTFE/FEP-covered metallic stents for palliation of malignant biliary disease, and to evaluate the efficiency of stent coverage in preventing tumor ingrowth.
Methods During a 3-year period, 36 patients with malignant obstructive jaundice were treated with ePTFE/FEP-covered stents, with or without proximal side holes. The stricture was located in the lower common bile duct (CBD) in 18 cases, the upper CBD in 9, the lower common hepatic duct (CHD) in 6, and the upper CHD in 3 patients.
Results Thirty-seven covered stents were percutaneously implanted. The technical success rate was 97%. Reintervention was required in 6 cases. The 30-day mortality rate was 40%, not procedure-related. Mean survival was 128 days. Primary patency rates were 100%, 55.5%, and 25% at 3, 6, and 12 months, respectively, while the assisted patency rate was 100% at 12 months. Stents without side holes had higher primary patency rates compared with those with side holes, where occlusion was always due to tumor ingrowth. Tumor ingrowth did not occur in the completely covered stents. No stent dysfunction due to sludge incrustation was found. Complications were 1 case of arterial laceration that occurred during percutaneous transhepatic cholangiography, and a subcapsular hematoma and 1 case of bile peritonitis, that both occurred during primary stenting. No complications followed the secondary stenting technique.
Conclusion ePTFE/FEP-covered metallic stents are safe and effective for palliation of malignant biliary disease. The presence of the ePTFE/FEP coating is likely to prevent from tumor ingrowth.

Keywords Covered stents · Jaundice · Malignant biliary obstruction · Tumor ingrowth

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Placement of self-expanding metallic stents has been an established method of palliative treatment of inoperable biliary malignant strictures for more than 20 years [1–3]. Metallic stents have replaced the conventional plastic ones since they have shown higher patency and lower complication rates, providing the oncology patient with a better quality of life [4]. Nevertheless, jaundice may reoccur and, in most cases, this is due to tumor ingrowth and/or overgrowth, and occasionally due to bile sludge, food debris or stones [3]. In these cases, reintervention for the placement of a new stent is usually necessary [1, 2, 5].

Rossi et al. in a multicenter European study of 240 patients, all with malignant biliary strictures treated with percutaneous placement of four different types of uncovered metallic stents, reported a reintervention rate of 22% [5]. More recent studies with mesh metallic stents report reintervention rates between 11% and 40% [2, 3]. The most

common reason for stent malfunction is occlusion due to tumor over- or ingrowth. Whereas overgrowth might be prevented with overstenting, tumor ingrowth through the mesh of the uncovered stent may not [5].

Covered metallic stents, using a variety of covering materials, were developed in an effort to prevent tumor ingrowth and avoid reintervention [6–11]. Different materials have been tested but without great success. In particular polyurethane, which has been used by several authors as stent coverage in commercially available or self-made covered stents, has shown, in three different studies, limited efficiency in preventing tumor ingrowth [7, 9, 11].

Expanded polytetrafluoroethylene/fluorinated ethylene propylene (ePTFE/FEP)-covered stents have already been used in two studies and are likely to be effective in biliary drainage and associated with relatively low complication rates. Bezzi et al. in a study of 26 patients with malignant biliary obstruction treated with ePTFE/FEP-covered stents, reported a complication rate of 19% [12]. In a larger study of 42 patients treated with the same endoprosthesis Schoder et al. reported a complication rate of 10% [13]. In none of these studies was stent occlusion due to tumor ingrowth noted.

The purpose of the study was to determine the application and clinical effectiveness of ePTFE/FEP-covered metallic stents for the palliation of malignant biliary disease, as well as to evaluate the efficiency of stent coverage in preventing tumor ingrowth.

Materials and Methods

Between January 2003 and December 2005, 36 patients (37–88 years old, mean 67.4 years; 22 men, 14 women) were treated and followed-up until death.

The study was a retrospective clinical investigation. The procedure was explained in detail to all candidates and their written informed consent obtained before the procedure.

The inclusion criterion was the presence of obstructive jaundice from inoperable malignant biliary disease that could not be treated endoscopically. To avoid occlusion of the cystic duct or intrahepatic duct, stents with proximal side holes were used in cases where the tumor mass was adjacent to those regions. Exclusion criteria were significant ascites, a previously inserted biliary stent, previous biliary surgery or radiotherapy, an INR value >1.5, and a platelet count <70,000.

Biliary obstruction was attributed to pancreatic carcinoma in 17 patients, cholangiocarcinoma in 13, and gallbladder carcinoma, gastric cancer and enlarged lymph nodes due to metastases in 2 cases each. In 22 cases the tumor type was classified by biopsy as adenocarcinoma. In the remaining 14 the diagnosis was based on the computed tomography (CT) and percutaneous transhepatic cholangiography (PTC) findings. The stricture was located in the lower common bile duct (CBD) in 18 cases, the upper CBD in 9, the lower common hepatic duct (CHD) in 6, and the upper CHD in 3 patients.

Metallic Endoprosthesis

All patients were percutaneously treated with Viabil (W.L. Gore, Flagstaff, AZ, USA) covered metallic stents. The Viabil is a self-expanding covered endoprosthesis made of a 0.010 mm thick expanded polytetrafluoroethylene/fluorinated ethylene propylene (ePTFE/FEP) tubular lining, externally supported by a nitinol stent with radiopaque markers at both ends. The presence of lateral anchoring fins reduces the risk of stent migration and the delivery system consists of a 10 Fr outer sheath. The stent is available in a diameter of 8 or 10 mm and a length of 6, 8 or 10 cm. The endoprosthesis is also available with transmural drainage holes within the lining for a length of 2 cm along the proximal covered end. The purpose of these holes is to avoid obstruction of the existing side ducts/branches. The slotted part of the stent is identified by a third radiopaque marker, which is absent in the endoprosthesis lacking transmural holes. A total of 37 stents were implanted. Stent sizes were 10 mm × 10 cm (n = 1), 10 mm × 8 cm (n = 18), 8 mm × 8 cm (n = 1), and 10 mm × 6 cm (n = 17). Completely covered stents were implanted in 22 cases, where as 15 patients were treated with covered stents with transmural side holes, in order to prevent a consequent obstruction of the cystic duct (n = 13) or the left main bile duct (n = 2). In a single case, two covered stents were simultaneously implanted, one without and one with side holes, the second as an extension of the first.

Method

In all patients PTC through a 21G Chiba needle, always under local anesthesia and mild intravenously administered sedation and analgesia, was initially performed, in order to document the configuration of the stenosis. Percutaneous biliary drainage preceded placement of all stents in order to decongest the dilated biliary tree. The chosen drainage catheter was an 8 or 10 Fr biliary locking catheter (Flexima, Boston Scientific, Watertown, MA, USA). In 11 cases a primary stenting technique was performed with direct placement of the metallic stent. In the remaining 25 cases, the stent was implanted 3–23 days (mean 9.4 days) after initial drainage (secondary stenting technique).

No predilatation of the strictures was performed. A left liver lobe access was chosen in 1 case, due to the presence of excessive ascites. An 8 Fr percutaneous drainage catheter remained after stenting in all cases (Fig. 1).

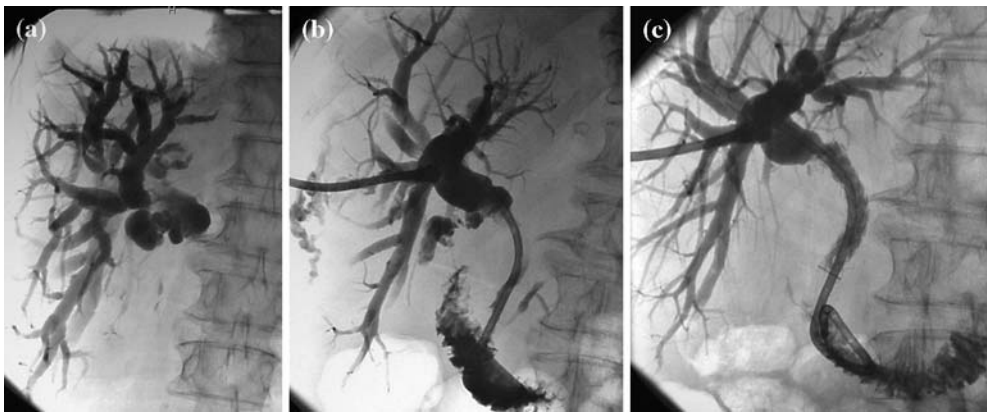

Fig. 1 **A** Percutaneous transhepatic cholangiography (PTC) shows dilatation of the biliary tree due to a stricture in the lower CHD. **B** Drainage catheter. **C** A 10 × 60 mm Viabil covered stent without side holes

A control cholangiography was performed 2–18 days after stent implantation (mean 3.5 days). Sufficient stent expansion was observed in all cases with no need for post-stenting balloon dilatation. The cholangiography catheter was subsequently removed.

Follow-up and Statistical Analysis

During follow-up, all patients underwent a thorough clinical evaluation, laboratory tests, and imaging (ultrasound, CT scan). We regularly recorded the serum bilirubin and liver enzyme levels (alkaline phosphatase, SGOT, SGPT, γ-GT) during the first 4 weeks after stenting. Patients were well informed about the signs and symptoms of jaundice, cholecystitis, and cholangitis before hospital release. Further follow-up was performed using telephone interviews with the referring physician or with the patient, monthly. In the case of an elevation of the serum bilirubin and imaging evidence of biliary dilatation, PTC was performed to confirm stent dysfunction and reintervention followed.

Where the occlusion level was seen only above the stent, this was characterized as a suspected ''overgrowth'' (Fig. 2), while if it was limited to inside the stent struts it was classed as a suspected ''ingrowth'' (Fig. 3). If cholangiography clearly revealed occlusion above and inside the stent, this was characterized as ''in- and overgrowth.''

To distinguish between stent dysfunction due to tumor ingrowth and that due to sludge incrustation, a semi-inflated 6 mm × 2 cm balloon was used. The semi-inflated balloon was initially inserted in the occluded stent lumen over the wire and was then carefully manipulated forwards and backwards, in order to ''clean'' any intraluminal debris or sludge. If the fluoroscopic image did not improve then tumor ingrowth was assumed. In all cases of stent dysfunction, where an angioplasty balloon was used, we gained cytologic material from the surface of the deflated balloon. This examination revealed the presence of debris or/and malignant cells. In comparison with the cholangiographic images, we were able to characterize the nature of the occlusion as ingrowth, overgrowth, or just due to bile sludge.

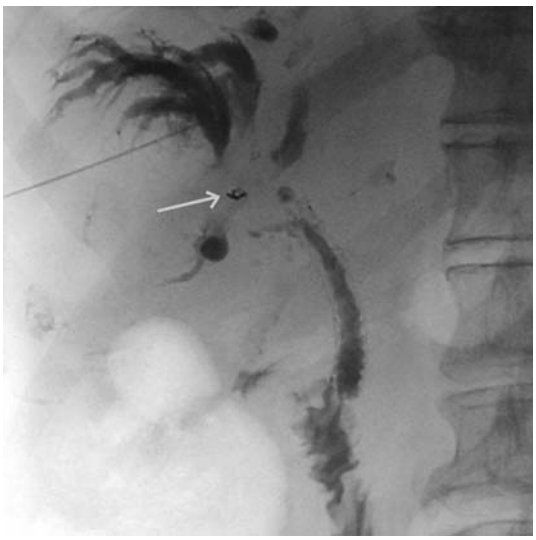

Fig. 2 Tumor overgrowth in a patient with CHD cholangiocarcinoma, 214 days after placement of a Viabil stent without side holes. Arrow shows the metallic coil used to embolize an injured right hepatic arterial branch

The period between initial stent placement and the recurrence of obstruction was defined as the primary stent patency. If there was no evidence of obstruction during the follow-up period, stent patency was considered equal with the patient's survival. Secondary (assisted) patency was defined as the period from initial stent placement until the end of follow-up, including reintervention and placement of a new stent. Stent patency and patient survival rates were calculated with Kaplan-Meier survival (life-table) analysis.

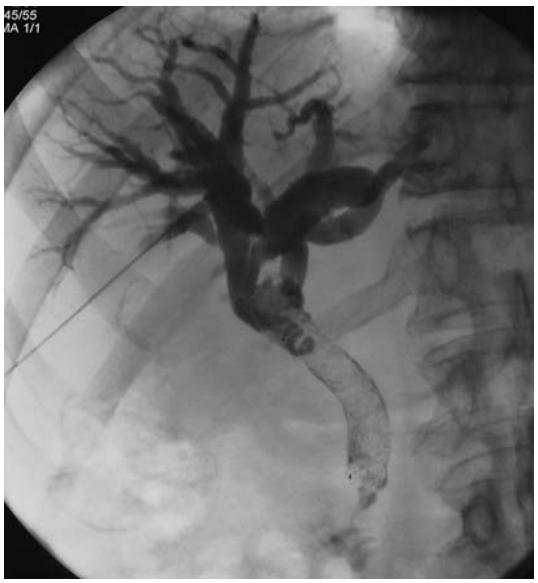

Fig. 3 Tumor ingrowth in a patient with CBD cholangiocarcinoma, 102 days after placement of a Viabil stent with side holes

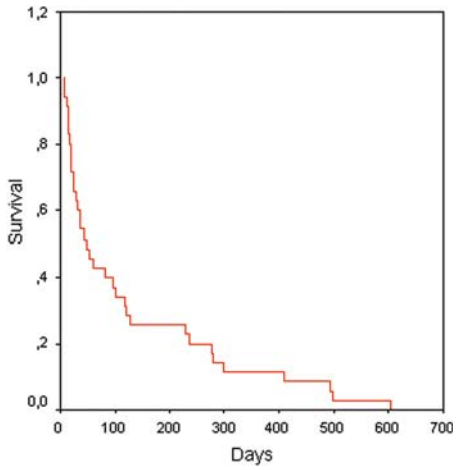

Fig. 4 Survival rates according to Kaplan-Meier life-table analysis

Results

A total of 37 Viabil stents were implanted in 36 patients with unresectable malignant biliary obstruction. Efficient placement of the endoprostheses was fluoroscopically verified by spotting the ultimate position of the radiopaque markers. Complete technical success of the implantation was achieved in all cases but 1 (technical success rate 97%) where, due to distal misplacement of the Viabil stent, an uncovered mesh stent was additionally used. This patient was excluded from the study and the follow-up.

In 6 of 35 patients (17%) reintervention became necessary and 6 new stents were implanted (2 ePTFE/FEP-covered stents and 4 bare stents).

Survival

Follow-up lasted 7–604 days (mean 128.2 days) and was complete in all 35 patients. The 30-day mortality rate reached 40%, as a result of the poor clinical condition of most of the patients, some of whom already had diffuse metastases (n = 5), cachexia (n = 4), or hepatorenal failure (n = 1). Survival rates were calculated as 40% at 3 months, 25.8% at 6 months, 20% at 9 months, and 11.4% at 12 months, according to the Kaplan-Meier life-table analysis. Mean survival rate during follow-up was 128 days, with median survival time 48 days (Fig. 4).

Patency

Stent dysfunction due to sludge incrustation was noted in 4 of 35 (11%) patients, after a mean time of 22.3 days, and was easily resolved by cleaning with a semi-inflated balloon.

Stent occlusion was identified in 6 of 35 (17%) patients after a mean time of 148.1 days. Five cases were cholangiocarcinomas and 1 was a pancreatic carcinoma. Primary patency rates were calculated as 100%, 55.5%, 28.5%, and 25% at 3, 6, 9, and 12 months, respectively. Secondary (assisted) patency rate was 100% at 6, 9, and 12 months (Table 1). Patency rates differed between the stents with and without side holes, always in favor of the fully covered stents (Table 2).

Stent occlusion was attributed to either tumor ingrowth or overgrowth (Table 3). Tumor overgrowth was observed in 2 of 6 (33%) patients, both with cholangiocarcinoma, who had been treated with a Viabil stent lacking side holes (Fig. 2). Tumor ingrowth was revealed 4 of 6 (67%) patients, 3 with cholangiocarcinoma and 1 with pancreatic carcinoma, in whom stents with side holes had been used (Figs. 3, 5). A combination of tumoral in- and overgrowth was not noted in any case.

Complications

Technique-related complications occurred in 3 of the 36 cases (8,3%). There was 1 case of arterial injury with subsequent severe hemorrhage that occurred during PTC needle insertion. Angiography was performed and revealed contrast extravasation from the right hepatic artery branch, which was immediately embolized with metallic coils (Fig. 2). The patient became hemodynamically stable within 24 hr and successful stenting followed 17 days later, once the patient's general condition had improved. In another case of primary stenting, bile leakage generated peritoneal irritation and subsequent bile peritonitis. Open surgical peritoneum lavage was decided on, with adequate results. Finally, the post-intervention hematocrit decrease

Table 1 Primary and secondary (assisted) patency at 3, 6, 9, and 12 months

Patency	3 months	6 months	9 months	12 months
Primary patency	9/9 (100%)	5/9 (56%)	2/7 (29%)	1/4 (25%)
Secondary patency	–	9/9 (100%)	7/7 (100%)	4/4 (100%)

Table 2 Primary patency at 3, 6, 9, and 12 months in patients with a Viabil stent with or without side holes

Primary patency	3 months	6 months	9 months	12 months
No side holes	4/4 (100%)	3/4 (75%)	2/3 (67%)	1/1 (100%)
With side holes	5/5 (100%)	2/5 (40%)	0/4 (0)	0/3 (0)

Table 3 Cause of stent occlusion in relation to the presence of side holes

Stent type	Ingrowth	Overgrowth	In- and overgrowth
No side holes (20 cases)	0	2/20 (10%)	0
With side holes (15 cases)	4/15 (27%)	0	0

in a patient who underwent primary stenting was attributed to a self-limiting subcapsular liver hematoma, as proven by ultrasound and CT imaging scans. The hepatic angiography that followed did not show any arterial injury (Table 4). Thus, technique-related morbidity was 8%, with a procedure-related mortality rate of 0.

Discussion

The use of metallic stents for the palliative treatment of inoperable malignant biliary obstruction has been extended during the last 20 years, having already been established as a safe and effective method of treatment [1–3, 14–16]. The advantage over plastic endoprostheses is documented by the reported lower occlusion rates and necessity for reintervention [4, 14, 17]. Nevertheless, the occasionally encountered problem of stent occlusion due to the growth of malignant or benign hyperplastic tissue still remains, leading to recurrence of jaundice or cholangitis [2, 3, 14]. Even less frequently, stent dysfunction as a result of sludge formation, impacted food debris or small biliary stones remains a reason for patient readmission and new stent placement [1, 5, 12].

The current literature differentiates between tumoral ''ingrowth'' through the metallic mesh and ''overgrowth'' centrally to the proximal stent end or even peripheral to the distal end [3, 12]. Tumoral ingrowth was present at autopsy in 29% of patients studied, with no end-stage recurrence of obstructive jaundice [18]. Other authors reported no mucosal hyperplasia in 22 autopsy specimens after implantation of bare self-expanding metallic stents, while adherent debris was always present along the lumen, without this being the reason for stent occlusion [19–22]. Schoder et al. did not encounter any benign hyperplasia and speculated that bacterial adherence, as well as tumor ingrowth, could be decreased in incidence or even prevented by utilizing a covering stent membrane [13].Thus, a theory was proposed assuming that the tumoral surface, which is compressed by the metallic mesh, is the basis for sludge formation [13, 23]. An alternative hypothesis is that the tumor itself promotes the formation of biliary sludge and debris [12]. It seems that the theories are not mutually exclusive.

An interesting approach to overcome these problems is the development of covered metallic stents. Tumoral ingrowth through the covering membrane is supposed to be excluded, minimizing stent lumen stenosis, also avoiding bacterial colonization of the metallic mesh and thus decreasing the risk of bile sludge formation. These stents should be a bare a metallic skeleton bound to the synthetic covering that is both biocompatible and resistant to the potentially deleterious effects of bile, gastric and pancreatic secretions [12]. The metallic mesh should comprise the outer surface, with the synthetic material lying within, so that better fixation can be guaranteed. The covering membrane should not prevent bile flow through the cystic or intrahepatic ducts, when these are not already obliterated by the tumor itself or some other cause.

A variety of such covered metallic stents have been manufactured and tested during the last decade. Different metallic mesh models with various covering materials, either self-made or commercially available, have been studied [6–13, 20, 24–26]. An accurate and justified comparison study has never been possible in the literature, given the great variety of material quality, mesh radial force, positioning of the coating, design, length and thickness of the covering material, as well as the French size of the delivery system. In practice, since the main goal of these stents is to reduce the reocclusion rate by providing longer patency with fewer technique-associated complications, measuring the parameters mentioned above and comparing covered and uncovered stents is currently the main way to come to conclusions.

A 6-month patency of 43–81% for uncovered stents has been reported in the literature [2, 3, 5, 15, 16, 27]. It seems that the extent of the range depends more on the tumor type, stage, and location than on the stent type and material. The reintervention rate varies even more, with

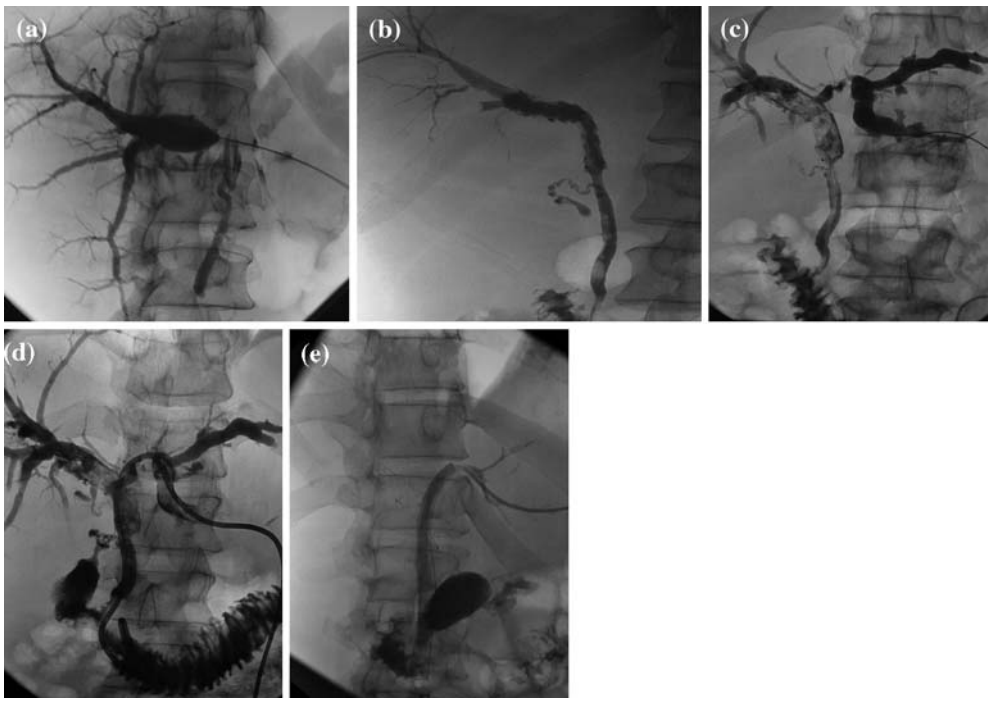

Fig. 5 **A** PTC showing a Bismuth type III obstruction in the upper CHD due to cholangiocarcinoma. **B** A 10 × 60 mm Viabil stent with transmural side holes was implanted, in order not to obstruct the right liver lobe biliary branches. The cystic duct lies lower than the distal end of the stent and remains patent. The left lobe was not stented, even though contrast opacified the dilated left biliary tree, in order to avoid further patient trauma and discomfort. **C** New PTC through the left liver lobe due to extensive ascites, 195 days later, reveals stent obstruction due to tumor ingrowth. Surprisingly, the left main bile duct remains patent despite the stent coverage. **D** An 8 Fr biliary drainage catheter was placed parallel to the obstructed stent. **E** A 10 × 69 mm Wallstent is placed from the left lobe to the duodenum. The right lobe was initially not drained due to the presence of ascites. Although contrast opacified the right lobe ducts, no cholangitis occurred

Table 4 Complications related to the intervention technique

Intervention technique	Arterial injury	Hematoma	Bile peritonitis
PTC	1/36 (3%)	1/36 (3%)	0
Primary stenting (11/35)	0	1/11 (9%)	1/11 (9%)
Secondary stenting (24/35)	0	0	0

reported rates of 11% to 100% [2, 3, 5, 15, 16]. The 6-month patency rates for covered stents range between 46.8% and 80.6% [7–13, 24, 25] and are comparable to those reported for bare stents. Regarding polyurethane-covered Wallstents, Rossi et al. reported a primary patency rate of 46.8% at 6 months in a study of 21 patients [7], while Hausegger et al. reported 47% in 30 patients [9]. Kanasaki et al., using a nitinol Strecker stent covered with 0.015 mm thick polyurethane in 18 patients, found a 6-month patency of 58% [10]. In these studies a relatively thin membrane was used. In contrast, better results have been reported when a 0.030–0.035 mm thick polyurethane membrane was used [8, 11]. Miyayama et al., using handmade Gianturco Z-stents covered with 0.035 mm thick polyurethane, reported a patency at 6 months of 79% in 19 patients, with all stent occlusions being attributed to tumor overgrowth [8]. Han et al. reported a 71% patency at 20 weeks using a Niti-S stent covered with 0.030 mm thick polyurethane (Taewoong, Seoul, Korea) [11]. The reasons for the low patency rates were mainly membrane erosion with subsequent tumor ingrowth [7, 9, 10]. Unfortunate Ely, Z-stents are no longer commercially available, while Niti-S stents are not widely accessible. Isayama et al., using Wallstents covered with 0.040–0.050 mm thick polyurethane in 21 patients, did not find any tumoral ingrowth [21]. They further improved their results by endoscopically implanting a Diamond nitinol stent covered with 0.050–0.060 mm thick polyurethane in 57 patients [22]. They reported an occlusion rate of only 14% after a mean of 304 days. Comparing this group with another of 55 patients treated with endoscopic placement of bare stents, they found stent occlusion in 38% after a mean of 166 days. Occlusion of covered stents was related to tumor overgrowth (in 4/57) or sludge formation (2/57), while in the uncovered stent group, occlusion was associated with ingrowth (in 16/55) or overgrowth (in 2/55). This leads us

to believe there is firm evidence that ingrowth can be prevented using a thick covering membrane, no matter what type of metallic stent is used. Finally, Kahaleh et al. reported an improved stent patency rate of 82% at 6 months, using Permalume-covered Wallstents in 80 patients; they did not report the thickness of the covering material [20].

In the last 5 years, the Viabil stent has been used clinically. The Viabil is a covered biliary stent consisting of an inner tubular lining supported on a helical nitinol wire structure. The inner lining is made of low-porosity, ultrathin (0.010 mm thick) ePTFE/FEP. Multiple sections of the wires near each end of the nitinol stent project outwards through the external surface of the tubular lining and act as anchoring fins to prevent migration. Two stent types are commercially available: a fully covered stent and one with side holes along the proximal 2 cm. The size of the introducer system is 10 Fr.

Bezzi et al. reported a 77% patency rate at 6 months using the Viabil stent in 26 patients [12]. Schoder et al., implanting the same stent in 42 patients, reported a similar 6-month patency of 76% [13]. Both investigator groups reported stent obstruction due to proximal tumor overgrowth. In our series of 36 patients, a 6-month primary patency rate of 56% was calculated, much lower than the two previously reported. Nevertheless, the previous investigators did not differentiate their results regarding the use of the fully covered stent versus the model with side holes. We found a 6-month patency of 75% using the fully covered model, while patency decreased to 40% when using the model with side holes (Table 2). In 2 of our 20 cases, stent occlusion resulted from tumor overgrowth (10%), while ingrowth accounted for stent occlusion in 4 of 15 patients (27%) with the stent with side holes, compared with no ingrowth for the group with the fully covered stent (Table 3). Given this differentiation, our stent patency rate is comparable with those in the other two series. Stent occlusion due to tumoral overgrowth remains an important issue. Unfortunately, due to the presence of a patent cystic duct or intrahepatic branches, the use of a greater length of covered stent proximally, with the aim of preventing overgrowth, is not efficient. Thus, we think that an intrahepatic extension, with help of a longer bare stent inserted into the Viabil, might make a difference.

Our study had a 30-day mortality rate of 40%, which is very high compared with other series (range 11.5–20%) [12, 13]. This meant the survival rates in our study were no better than 26% at 6 months and 11% at 12 months. We encountered complications in only 3 cases (8%). One arterial hemorrhage occurred during initial drainage and was successfully embolized. The other 2 complications occurred during primary stenting procedure, resulting in 1 subcapsular hematoma, which was conservatively treated and a case of bile peritonitis, where open peritoneum lavage was needed. The primary stenting technique combined with the relative wide 10 Fr delivery system could be responsible for these two complications.

Acute cholecystitis and pancreatitis are two complications attributed to the covering membrane, which may obstruct the cystic or pancreatic duct orifice. Isayama et al., in a prospective randomized controlled trial using uncovered versus covered Diamond stents, found an incidence of 4.8% of acute cholecystitis for covered stents versus 0 for uncovered stents, and 8.7% mild pancreatitis for covered stents versus 1.8% for uncovered stents [22]. Kahaleh et al. tried to eliminate the potential for cholecystitis by performing endoscopic gallbladder lavage through the cystic duct [20]. They reported 25 cases of cystic duct coverage with the stents: 15 after prophylactic endoscopic lavage and 10 without. Prophylactic lavage was found to prevent cholecystitis, whereas in its absence the rate of cholecystitis reached 20% (2/10 cases). Nevertheless, Carr-Locke believes that such ''prophylactic'' measures are not justified [14]. In any case, we think that Kahaleh's work provides more proof that obliteration of the cystic duct increases the risk of acute cholecystitis.

Bezzi et al., using Viabil stents, reported an incidence of acute cholecystitis in 12% of cases, perihepatic biloma in 4%, and peri-/intrahepatic hematoma in 4% of cases [12]. Schoder et al., using the same stent, reported acute cholecystitis in 7.5%, mild pancreatitis in 2.5%, perihepatic biloma in 2.5%, and peri-/intrahepatic hematoma in 2.5% [13]. They also reported device-related complications in 10% of patients, caused by the obstruction of bile duct side branches due to the covering material. Acute cholecystitis and intrahepatic duct obliteration are the two complications which can be prevented by using the stent model with side holes. We did not encounter such complications because we used this model when indicated. The price to be paid for this was the lower patency rate, due to tumor invasion through the intramural side holes. We also did not encounter any stent migration in our study. In a single case the Viabil stent was distally misplaced, failing to cover the entire malignant stricture. It was necessary to implant a second, uncovered Wallstent, since another Viabil stent was unavailable at the time. This patient was excluded from the study. Nevertheless, early or late migration of covered stents is frequently reported in the literature, mainly because of the smoother outer stent surface which enables dislocation [6, 20]. Partially covered metallic stents with bare distal and proximal ends have been manufactured to overcome this problem, and provide better anchoring and stabilization. This has resulted in an improvement of fixation with a lower incidence of distal migration [28]. Despite this, a migration rate of between 5.8% and 6.3% for covered Wallstents is reported [20, 25]. Stent migration

can be prevented with the aid of the lateral anchoring fins of the Viabil stent, which can be fixated on the normal biliary endothelium or on the tumor-infiltrated wall. In the normal duct, the fins become integrated with a thick layer of fibrous connective tissue [13]. The lateral-oblique shape of the fins also helps to improve stabilization by holding the stent against the malignant stricture. Comparable to our results, other investigators who used the Viabil stent did not encounter cases of migration [12, 13]. Despite the stent fixation to tissue, percutaneous retrieval still remains feasible following the special technique described recently by Kuo et al., though this was achieved within 49 days after stent implantation (mean 38 days) [26]. We can not predict how rigid stent incorporation into the surrounding tumor will be, since we encountered a case where recanalization around the stent was possible 7 months after Viabil implantation, followed by placement of a new Wallstent (Fig. 5).

Viabil stent placement seems to be safe and effective for the palliation of malignant obstructive jaundice. It does not increase complication rates despite the larger carrying catheter size. Although the number of cases in our series may be relatively small, stent patency rates do not seem to be significantly better than those with uncovered stents reported in the literature. The stent model with side holes can help prevent cholecystitis or cholangitis by keeping the cystic or the intrahepatic ducts patent. Nevertheless, it is likely that the side holes increase the possibility of tumor ingrowth leading to subsequent reocclusion. Finally, the Viabil stent provides better fixation to tissue, preventing distal migration, and at the same time its early percutaneous retrieval has been described as feasible. Further investigation is needed to decrease the incidence of tumor overgrowth. Perhaps use of an additional proximal bare stent extension could be the solution.

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