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Management of malignant biliary obstruction: Technical and clinical results using an expanded polytetrafluoroethylene fluorinated ethylene propylene (ePTFE/FEP)-covered metallic stent after 6-year experience

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Abstract To evaluate the efficacy and safety of an expanded polytetrafluoroethylene-fluorinated ethylene-propylene (ePTFE/FEP)-covered metallic stent in the management of malignant biliary obstruction. Eighty consecutive patients with malignant common bile duct strictures were treated by placement of 83 covered metallic stents. The stent-graft consists of an inner ePTFE/FEP lining and an outer supporting structure of nitinol wire. Clinical evaluation, assessment of serum bilirubin and liver enzyme levels were analyzed before biliary drainage, before stent-graft placement and during the follow-up period at 1, 3, 6, 9 and 12 months. Technical success was obtained in all cases. After a mean follow-up of 6.9±4.63 months, the 30-day mortality rate was 14.2%. Survival rates were 40% and 20.2% at 6 and 12 months, respectively. Stent-graft patency rates were 95.5%, 92.6% and 85.7% at 3, 6 and 12 months, respectively. Complications occurred in five patients (6.4%); among these, acute cholecystitis was observed in three patients (3.8%). A stent-graft occlusion rate of 9% was observed. The percentage of patients undergoing lifetime palliation (91%) and the mid-term patency rate suggest that placement of this ePTFE/FEP-covered stent-graft is safe and highly effective in achieving biliary drainage in patients with malignant strictures of the common bile duct.

Keywords Biliary · Stricture · Malignant · Stent · Covered

Introduction

Malignant biliary strictures can be palliated by percutaneous or endoscopic stenting. Because of the short average life expectancy of these patients, the purpose of these techniques is to enhance the patient's quality of life.

Plastic stents present a high rate of occlusion and a high incidence of complications due to misplacement. To overcome these problems, metallic stents have been introduced [1, 2] and have improved patency, with a 6-month rate ranging between 43% and 81% [3, 4]. The first experience with expandable metallic stents in dogs was reported in 1985 [5]. Since then, a variety of metal stents have been used, and percutaneous or endoscopic stenting has become a standard palliative treatment for inoperable malignant biliary obstructions.

Expandable metallic stents have a large inner lumen, as compared with plastic stents, and occlude less frequently [2, 6, 7]. However, metallic stent occlusion due to hemobilia, tumor overgrowth, accumulation of sludge and tumor ingrowth has been reported [8, 9].

We report our 6-year experience in the treatment of malignant biliary stenosis with a dedicated self-expandable covered stent-graft (Viabil WL Gore & Associates Flagstaff, AZ) evaluating technical aspects, patency rate and complications.

Materials and methods

Patient population

Between January 2000 and November 2006, 80 consecutive patients (33 men, 47 women) with malignant biliary obstruction were treated (mean age 69.9 years; range 48–

90 years). Jaundice was secondary to pancreatic carcinoma in 46 patients, cholangiocarcinoma in 8 patients, gallbladder cancer in 2 patients and metastatic lymphadenopathy in 24 cases. Strictures were located in the upper third of the common bile duct (CBD) in 8 patients, in the middle third in 9 cases, and in the lower third in 63 patients. Malignancy was always confirmed by endoluminal or percutaneous biopsy.

All patients underwent insertion of a polytetrafluoroethylene and fluorinated ethylene propylene (ePTFE) covered self-expandable stent-graft (Viabil-WL Gore & Associates, Flagstaff, AZ) dedicated to biliary diseases.

Inclusion criteria was obstruction of the CBD below the hilar confluence due to unresectable malignancy. Criteria for non-resectability were estabilished by CT or by laparoscopy. Exclusion criteria were: previous biliary surgery, previous insertion of metallic stents or uncontrollable coagulopathy (INR >3.0). Written informed consent was obtained from all patients before stent insertion.

Stent design and placement

The stent-graft used can be considered a hybrid of metallic and plastic biliary stents, consisting of an inner tubular lining and a supporting nitinol structure (Fig. 1). The inner lining is made of ultrathin, low-porosity ePTFE/FEP, while the supporting structure consists of a helically wound nitinol (nickel-titanium alloy) wire, bound to the outer surface of the lining along its entire length.

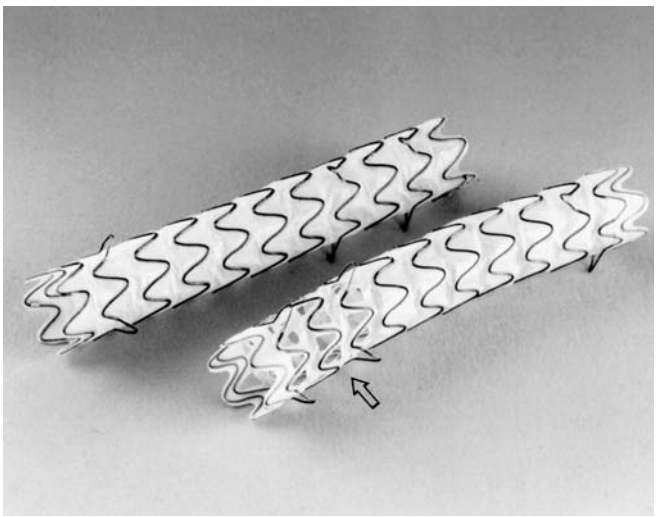

Fig. 1 Viabil biliary endoprosthesis (WL Gore & Associates Flagstaff, AZ). Stent structure consists of a helically wound nitinol wire with anchoring fins at each end that are bound to the outer surface of the ePTFE-FEP tubular lining. The 6- and 8-cm-long stent-grafts are available with transmural drainage holes at 1.5 cm along the proximal lining (arrow). Multiple sections of the wires near each end of the nitinol stent are elevated from the external surface of the tubular lining and act as anchoring fins

To prevent migration of the stent-graft, especially in those cases where the distal portion of the stent protrudes into the duodenum, multiple sections of the wires near each end of the device are elevated from the external surface and act as anchoring fins.

The device is available in two different diameters, 8 mm and 10 mm, and various lengths: 4, 6, 8 and 10 cm. The 6-, 8- and 10-cm-long stent-grafts are available in two different versions: with or without drainage side-holes cut in the lining for 1.5 cm, only along the proximal end of the stent. Thirty-two holes should provide drainage of bile coming from the cystic duct or from biliary side branches, when these branches are covered by the proximal portion of the stent-graft.

Radiopaque gold markers are incorporated into each end of the stent-graft to increase its visibility under fluoroscopy. In the version with side holes, an additional gold marker is placed to define the junction between the two portions of the stent-graft.

Procedure

The procedures were performed in two different steps (i.e., biliary drainage and stent-graft deployment, so-called secondary stenting) in 76 cases. In our practice we prefer secondary stenting in order to avoid bleeding related to the initial procedure and to perform a better morphological evaluation of the lesion. Only four patients received a stent-graft in the same session of the biliary drainage (primary stenting). These four patients were from an outside hospital, and no bleeding had occurred during the biliary drainage; therefore, we preferred to complete the procedure in 1 day. Antibiotic prophylaxis was administered intravenously in 74 patients and orally in 6. All patients continued antibiotic treatment for 5–6 days after the initial procedure.

- Biliary drainage: performed under sedo-analgesia. After opacification of the biliary tree, typically a biliary duct of hepatic segment VI was punctured using a 5-F catheter needle. The stricture was then managed with a hydrophilic guide wire (0.035” angled tip, Terumo, Tokyo, Japan) and a 10-F biliary drainage (FLEXIMA, Boston Scientific Co, Natick, MA) was placed with its distal portion into the duodenum (Fig. 2). In case of tight stenosis, the stricture was dilated with a 6-mm or 8-mm balloon catheter. The drainage was left in place for 4–6 days according to the patient’s clinical condition.
- Stent-graft deployment: performed under local anesthesia. A 9 or 10 Fr, 25 cm long, introducer sheath (Radifocus-Terumo-Tokyo-Japan) was advanced over a stiff-hydrophilic guide wire (0.035” Terumo, Tokyo, Japan) across the stenotic tract into the duodenum in order to facilitate stent deployment. We generally use a

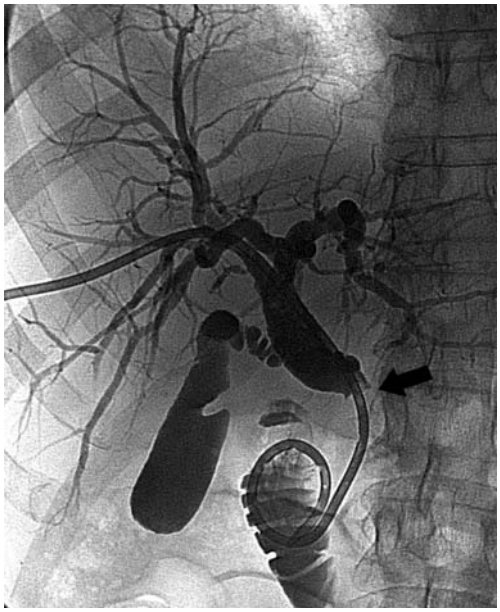

Fig. 2 Percutaneous transhepatic cholangiogram in a 78-year-old man with pancreatic cancer. Three days after biliary drainage, contrast media injection shows a severe stricture in the lower portion of the CBD (arrow). There is still some residual dilatation of the common hepatic duct and the cystic duct appears patent. A normal anatomical variant is also present: segment 6 duct drains into the left hepatic duct

long introducer to inject contrast media and better evaluate the papilla (Fig. 3).

The diameter of the stent was selected according to the diameter of the CBD with 1-mm oversize. The length was selected in order to cover the whole stricture and a portion of normal CBD at least 5 mm below and above the lesion to avoid tumor overgrowth.The stent was inserted through the introducer and deployed 1.5 cm below the papilla. An angiographic 5-F pigtail catheter was left in place for 24 h to evaluate the correct functioning of the stent (Fig. 4).

Eighty-three stent-grafts with different sizes were implanted: 8 mm ×4 cm (*N*=1), 8 mm ×6 cm (*N*=8), 8 mm ×8 cm (*N*=44), 10 mm ×4 cm (*N*=2), 10 mm ×6 cm (*N*=3) and 10 mm ×8 cm (*N*=25). In 64 cases, a stent-graft with transmural holes was used due to the presence of a patent cystic duct that needed be covered by the stent. In the remaining 16 patients a Viabil without side holes was implanted (those represented the first 16 patient treated in our experience) [17].

In 78/80 (97.5%) patients, the distal end of the stent was deployed 1.5 cm in to the duodenum. In the remaining two cases (2.5%), the stenosis was located in the upper third of the CBD, and the distal stent end was positioned above the papilla; in these two cases it was unlikely that the stricture involved the papilla since it was due to hilar metastatic lymphadenopathy.

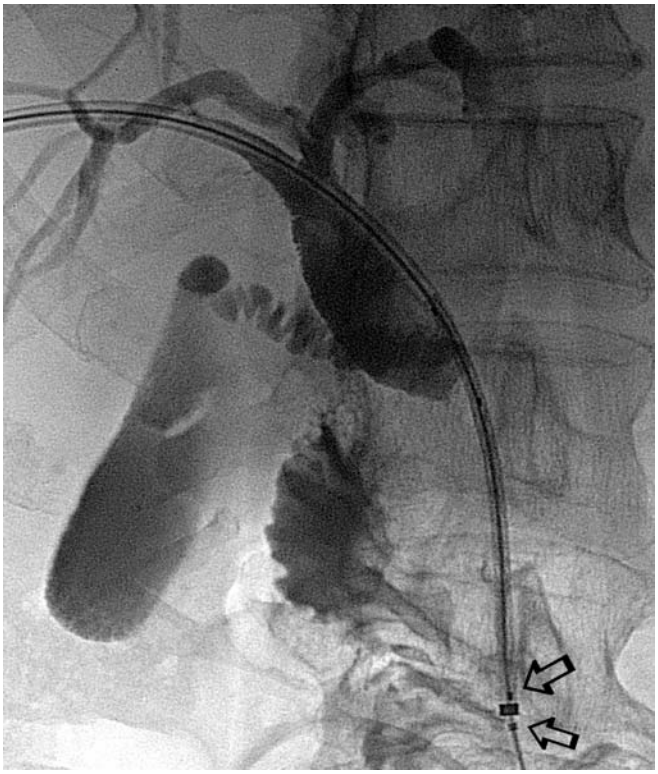

Fig. 3 A 78-year-old man with pancreatic cancer; Viabil deployment. A 9-F/25-cm introducer was advanced into the duodenum to correctly visualize the papilla. Afterward a Viabil (8 mm ×80 mm) was inserted into the introducer. Two radiopaque markers are incorporated into the delivery system (arrows) to better visualize the stent-graft during the deployment phase. The larger radiopaque marker is placed on the distal tip of the outer sheath of the delivery system

Follow-up

Follow-up evaluation included assessment of serum bilirubin and liver enzyme levels (alkaline phosphates, aspartate aminotransferase, alanine aminotransferase and γ-glutamyl transpeptidase) performed before percutaneous drainage, before and after stent deployment.

Clinical assessment and serum bilirubin and liver enzyme assays were also performed at 1, 3, 6, 9 and 12 months after stent-graft placement unless there was clinical evidence of jaundice, cholangitis or other complications. Between these assessments, monthly control examinations were also performed by telephone interviews to evaluate the patient's general clinical conditions.

Complications such as cholangitis, cholecystitis and pancreatitis were diagnosed by clinical signs and symptoms and by laboratory tests (WBC count and CRP). In case of jaundice, ultrasonography (US) or computed tomography (CT) of the liver was performed to determine whether the jaundice was caused by advanced metastatic disease or if the intrahepatic ducts were dilated and repeat intervention was required.

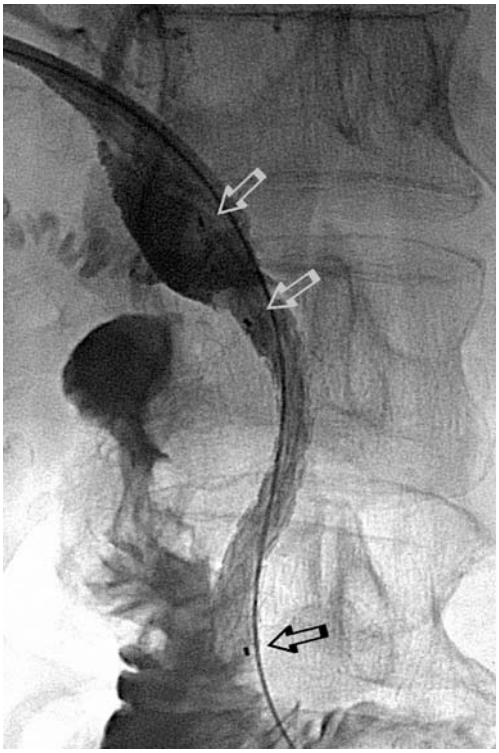

Fig. 4 Cholangiogram obtained after complete deployment of the Viabil stent-graft. Two radiopaque markers indicate the side-holes area (white arrows) for drainage of the cystic duct. Another radiopaque marker indicates the distal end of the Viabil (black arrow)

Study endpoints and definitions

Major study endpoints were represented by the assessment of technical success, safety of stent implantation, patient survival, stent patency at 6 months and 1-year follow-up.

Technical success was achieved when the stent-graft was correctly deployed in the expected location with a residual stenosis at the end of the procedure <30%.

Safety of stent implantation was correlated to the incidence of peri-procedural and intra-procedural complications. Minor complications were events that required nominal therapy or observation without sequelae. Major events were those complications that required patient hospitalization.

Stent patency corresponds to the absence of recurrent symptomatic biliary obstruction. Primary patency of the stents was defined as the time interval between initial placement and recurrence of obstruction. If there was no evidence of obstruction during the patient's life, the patency period was considered equal to the survival period, but censored.

Statistical analysis

The results of continuous variables are expressed as means. Patient survival and stent patency were calculated according to the actuarial cumulative curve of Kaplan and Meier, which allows an adequate analysis despite differences in follow-up intervals [10]. All calculations were made with the NCSS 97 statistical package (NCSS Statistical Software, Salt Lake City, UT).

Results

Stent placement

Stent placement was successful in all 80 patients. The radiopaque markers of the stent-graft were clearly visible under fluoroscopy and permitted correct deployment of the device. No migration of the stent-graft occurred during deployment. A single stent-graft was used to relieve the CBD obstruction in 77 patients (96.2%), while two stent-grafts were inserted in 3 patients (3.8%) due to a long stricture.

All patients showed clinical improvement and relief of jaundice after drainage and stent placement (average bilirubin level was 12.7±7.81 mg/dl before drainage; 7.02±3.41 mg/dl before stent placement and 4.4±2.13 mg/dl 1 week after stent placement) (Table 1).

In the patients who survived at least 1 month after stent insertion, bilirubin levels decreased to below 2.5 mg/dl in all but seven cases (9%) in which the bilirubin serum level increased as a result of stent occlusion.

In all patients a reduction of alkalin phosphatase (average level from 576 U/ml to 297 U/ml), aspartate aminotransferase (average level from 134 U/l to 37 U/l), alanine aminotransferase (average level from 186 U/l to 45 U/l) and gamma glutamintransferase (average level from 520 U/l to 182 U/l) were observed.

Table 1 Laboratory values before and after Viabil stent-graft deployment

	Pre-procedure (mean) 7 days after PBD	Post-procedure (mean) 5 days after stenting
Bilirubin (mg/dl)	12.7	4.4
Alkaline phosphatase (U/l)	576	297
Hemoglobin (g/dl)	11.7	12.1
Aspartate aminotransferase (U/l)	134	37
Alanine aminotransferase (U/l)	186	45
Gamma-glutamintransferase (U/l)	520	182

Survival

After a mean follow-up of 6.9+4.63 months (range 1 to 15 months), five patients (6.5%) are alive and in good clinical conditions. Three patients (3.75 %) were lost to follow-up after 1 month and therefore were not included in the survival analysis. Eleven patients died within 30 days, with a 30-day mortality rate of 14.2%. Death was caused by advanced cancer and poor clinical condition in nine cases (11.6%), but not directly related to the drainage procedure, and in two cases (2.6%) by massive pulmonary embolism.

The survival rates were 40% and 20.2% at 6 and 12 months, respectively. (Table 2; Fig. 5)

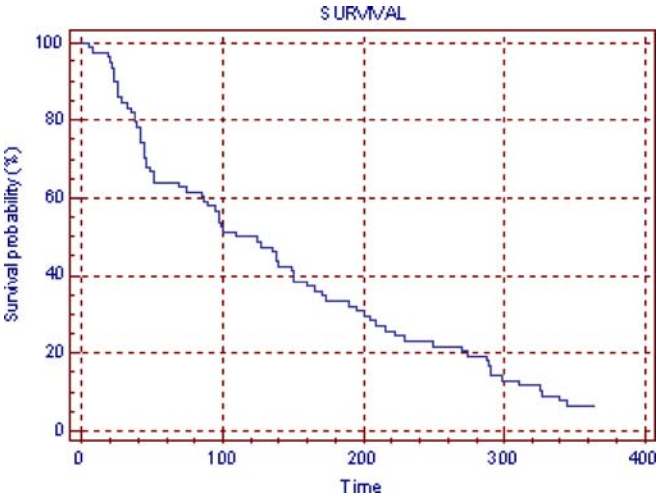

Fig. 5 Survival curve (Kaplan-Meier analysis). Time is expressed in days

Patency

According to the Kaplan-Meier analysis, the primary patency rates of the endoprostheses at 3, 6 and 12 months were 95.5%, 92.6% and 85.7%, respectively (Table 3; Fig. 6). Calculation of the composite endpoint (i.e., either obstruction or death with patent stent) by means of Kaplan-Meier analysis (Table 4, Fig. 7) revealed a median period of patency of 117 days.

During the follow-up period, stent obstruction occurred in seven patients (7/77, 9%) (Table 5). Percutaneous transhepatic cholangiography demonstrated obstruction caused by tumor overgrowth (N=6) or tumor ingrowth (N=1) that were considered the most probable causes of recurrent jaundice. Tumor ingrowth and tumor overgrowth were diagnosed by means of biopsy under cholangioscopy, biopsy/cytology under fluoroscopy and evidence at fluoroscopy of filling defects within or above the stent that did not move during bile duct flushing or after PTA in two consecutive fluoroscopic controls.

In one patient a proximal occlusion of the stent-graft occurred at 5.3 months consequent to tumor extension into the biliary bifurcation. A reintervention was performed by deployment of two additional bare stents (Wallstent, Boston Scientific, Corporation, Natick, MA) from the right and left hepatic ducts. Adequate bile flow was maintained for the following 2.5 months and then re-occlusion occurred at the level of the hilum. Bilateral drainage catheters were positioned, and the patient died 12 months later of advanced cancer without evidence of jaundice.

In the other five patients, stent occlusion was seen after 22 days, 26 days, 2.1 months, 2.8 months and 3 months, respectively, in all cases caused by proximal tumor overgrowth. An internal-external biliary drainage was performed in all patients, but all of them died after 1 to 3.6 months for their own pathologies, without either obstructive jaundice or cholangitis.

In another patient obstruction occurred at 4.8 months due to tumor ingrowth trough the side holes in the proximal portion of the stent-graft. An external-internal biliary drainage was also performed with complete disappearance of jaundice; the patient died 10 months later.

The secondary patency at 12 months, including re-interventions, was 100%.

Complications

Early complications occurred within 7 days after stent insertion and were observed in 3/77 patients (3.9%). A perihepatic biloma was treated with percutaneous drainage in one patient 6 days after stent implantation; the patient improved, and no stent revision was needed. Another patient presented with a drop of hemoglobin level (3 g/dl) 5 days after stent insertion; CT showed a peri- and intrahepatic blood collection, which was successfully drained percutaneously and completely resolved after 28 days. CT findings suggested that the hematoma had

Table 2 Survival rate of the 77 patients treated with the Viabil stent-graft for malignant biliary strictures

Survival rate	
30 days	85.8%
6 month	40%
12 months	20.2%

Table 3 Patency rate evaluated at 3, 6 and 12 months

Patency rate	
3 month	95.5%
6 month	92.6%
12 month	85.7%

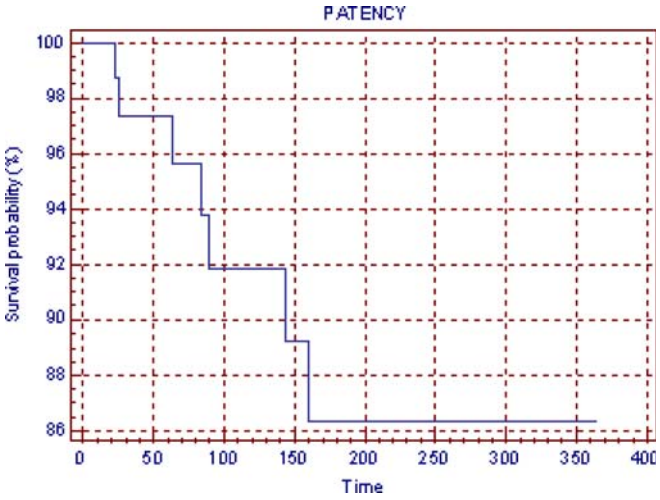

Fig. 6 Patency curve (Kaplan-Meier analysis). Time is expressed in days

originated from the outer portion of the intrahepatic tract; bleeding was self-limiting, and the hemoglobin level remained stable. The third early complication occurred in a patient who developed acute acalculous cholecystitis 5 days after insertion of a stent-graft without side holes. After percutaneous cholecystostomy, it was proven that the cystic duct orifice was occluded by the stent-graft.

Late complications occurred in 2/77 (2.6%) patients. We observed two patients who presented with acute cholecystitis 4.5 and 4 months after stent insertion and were treated by percutaneous cholecystostomy and cholecystectomy, respectively.

The overall complication rate was 6.5% (5/77 cases). The overall acute acalculous cholecystitis rate was 3.9% (3/77 patients).

Discussion

Expanding metallic stents have solved most of the problems that occur when using plastic endoprostheses and are mainly represented by migration and occlusion [11]. However, metallic stents do occlude, and their occlusion has been attributed to hemobilia, distal or proximal tumor overgrowth, accumulation of biliary sludge and tumor ingrowth through the stent meshes [8, 9].

To overcome stent obstruction due to tumor ingrowth, metallic stents covered with different synthetic materials have been developed [12] and used in several clinical trials. Saito et al. [13] in 1994 reported quite good medium- to long-term results in six patients using a homemade Gianturco-Rosch stent covered with a Gore-Tex membrane. In this small series stent-graft migration occurred in two patients, while in the other four patients stents remained patent during a follow-up period of 1–12 months.

Thurnher et al. [5] in 1996 reported their initial experience in five patients with a Wallstent fully covered by polyurethane. They observed early stent migration in one case and one obstruction at 3 months likely caused by bile sludge formation. This experience suggested to modify the covered Wallstent design with the introduction of a bare portion at both ends in order to prevent migration.

Miyayama et al. [14] in 1997 reported the use of polyurethane-covered Gianturco-Rosch stents and spiral "Z" stents. Both ends of the stents were uncovered and wider than the stent body to prevent dislocation. In a series of 15 patients, they observed patency rates of 79% at 24 weeks and 66% at 48 weeks. No occlusions secondary to tumor ingrowth occurred.

These two studies have shown that the polyurethane covering membrane presents good biocompatibility and is also resistant to bile and gastric secretions in vivo.

Different results were reported by Rossi et al. [15] who indicated that the covering membrane of the Wallstent was not resistant to bile and gastric secretions. In their prospective study, which included 21 patients followed for 23 months, the covering membrane of a stent that had migrated into the stomach through a gastroenteric anastomosis was found partly dissolved. In addition, in four other patients with stent obstruction, contrast medium injected within the occluded segment leaked outside the margins of the covering, indicating the presence of fissures into the polyurethane membrane. In this study, the primary patency rate at 6 months was 46.8%. Comparing this result to larger series of patients treated with bare Wallstents, no advantages were therefore observed [8, 15].

Table 4 Composite endpoints

Kaplan-Meier analysis of composite endpoints				
Interval (d)[a]	No. of patients at start[b]	No. of deaths or obstructions	Cumulative survival/patency rate (%)	Standard error (%)
0–30	77	12	86	6.7
31–180	65	41	43	7.8
181–365	24	19	24	7.2

Note: For the purposes of this analysis, the composite endpoint was defined as obstruction or death with a patent endoprothesis
[a]Time interval after endoprosthesis placement
[b]Number of patients alive with patent stents at start of given interval

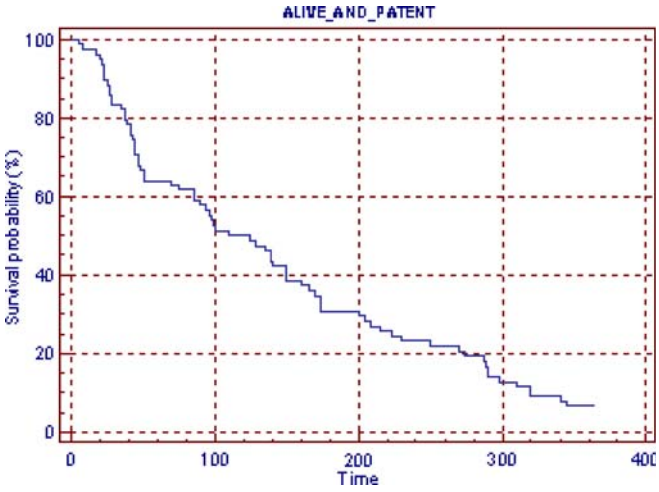

Fig. 7 Cumulative results of Kaplan-Meier analysis of time (in days) to composite endpoint (i.e., stent obstruction or death with patent stent) after implantation of biliary endoprosthesis

Hausegger et al. [16] in 1998, using polyurethane-covered Wallstents, reported an occlusion rate of 37% and 6- and 12-month patency rates of 47% and 31%, respectively. The authors reached the same conclusions as Rossi et al. [15] and stated that polyurethane-covered stents did not provide better results than the uncovered stent because the membrane was not effective in preventing tumor ingrowth, which was observed in two patients in their series [16].

Bezzi et al. [17] in 2002 reported 26 patients with inoperable malignant biliary strictures treated with Viabil stent-graft, the same device used in this study. A 30-day mortality rate of 11.5% was reported. Survival rates were 40% and 15% at 6 and 12 months, respectively. Eighty-four percent of patients had adequate palliative drainage during their lifetime. Stent-graft patency rates were 91%, 77% and 77% at 3, 6, and 12 months, respectively. Stent-graft occlusion occurred in four patients (16%), and a reintervention was required in all of them. No migrations were reported. Complications occurred in five patients (19%), and acute cholecystitis was observed in three patients (12%).

Kuo et al. [18] in 2006 reported their experience in the placement and retrieval, using a retrograde percutaneous technique, of the Viabil. The stent-graft was retrieved by placing an endoscopic grasping forceps parallel to the safety wire used to grab the proximal edge of the stent-graft. The stent was then pulled out through a large sheath. In this experience six Viabil were successfully removed from five patients after a mean time of 38 days. This study concludes that the Viabil can be safetely removed percutaneously.

Device migration is a potential risk of covered stent-grafts, as reported by several authors [5, 13, 15]. The specific design of the Viabil minimizes this risk with the presence of an anchoring mechanism. This consists of looped metal wires protruding from the external stent surface, which produce a direct mechanical resistance to migration. In our opinion this solution should be preferred to leaving the distal ends of the stents uncovered, since the uncovered portions may facilitate tumour ingrowth, as reported by Hausegger et al. [16].

Another key point to be considered is the high rate of acute cholecystitis. This complication is related to the impaired bile flow through the cystic duct, covered by the stent-graft. In order to avoid this complication, after our initial experience, we decided to use only Viabil with side holes. The holes, in the proximal portion, should hypothetically allow for drainage of cystic or branch biliary ducts when their orifice is covered by the stent-graft.

In our series, acute cholecystitis occurred in three cases (3.8%). In one case, early cholecystitis developed in the first part of our experience using a Viabil without side holes. In the other two cases, where stents-grafts with side holes had been implanted, cholecystitis occurred after 4 and 4.5 months. The most likely reason is that, despite the presence of holes, the duct orifice was occluded. As a matter of fact, approximately 65% of the stent external area at the proximal end remains uncovered for the presence of holes, whereas 35% remains covered by the residual graft material. During stent-graft placement it is not possible to align the side holes exactly with the cystic duct orifice; therefor,e it is possible that the orifice remains partly covered by the ePTFE lining.

Table 5 Viabil occlusions: causes and timing

	Occlution (months after deployment)	Cause of occlusion	Death (months after deployment)
Patient 1	5.3 months	Tumor extension into biliary bifurcation	12 months
Patient 2	26 days	Tumor overgrowth at proximal end	1 month
Patient 3	22 days	Tumor overgrowth at proximal end	1.5 months
Patient 4	2.1 months	Tumor overgrowth at proximal end	2.6 months
Patient 5	2.8 months	Tumor overgrowth at proximal end	3.6 months
Patient 6	3 months	Tumor overgrowth at proximal end	3.2 months
Patient 7	4.8 months	Tumor in-growth through the holes	10 months

In our study with ePTFE-FEP-covered stents, the patency rates with the endoprostheses at 3, 6 and 12 months were 95.5%, 92.6% and 85.7%, respectively. These rates are higher than the patency rates reported for uncovered metal stents, which at 6 months range between 67% and 81% [3, 4, 8]. Interestingly, the 12-month patency rate of 85.7% also represents a better result than the rate we observed at 12 months in patients treated with bare stents (range, 51–68%) [3, 4, 8]. Covered stents probably do not prevent reocclusion from tumor overgrowth in the first 4–5 months, particularly in rapidly growing tumors, because their patency rates are similar to those of bare stents. Their usefulness probably remains to be seen in patients with longer survival, in whom no ingrowth and bile incrustation occurred. Only 7 out of 77 patients required re-intervention as a result of recurrent jaundice, which accounts for a reintervention rate of 9%. Adeguate palliation until death was therefore provided to 91% of patients without need for further percutaneous or endoscopic intervention.

Schoder et al. [19] reported similar results in a study published in 2002 where they used the same endoprostheses implanted in our experience. Primary patency rates at 3, 6 and 12 months were 90%, 76% and 76%, respectively, while recurrent obstructive jaundice occurred in six (15%) patients.

Hatzidakis et al. [20], on the other end, in a paper published in 2007, reported lower patency rates. Using the same ePTFE-FEP-covered stent, they observed primary patency rates of 100%, 55.5%, 28.5% and 25% at 3, 6, 9 and 12 months, respectively. The authors identified stent occlusion in 6 of 35 (17%) patients after a mean time of 148.1 days and attribute this higher occlusion rate to tumor ingrowth caused by the use of stents with transmural holes. We used stents with transmural holes in 64 out of 80 patients, but we did not observe tumor ingrowth.

The absence of tumor ingrowth confirms that ePTFE/FEP is resistant to neoplastic penetration and to the action of body fluids in a clinical setting. Because of this feature, ePTFE/FEP seems to be a promising material for future applications in the treatment of biliary pathologies.

All obstructions were seen above the proximal end of the stent-graft and were caused by tumor overgrowth, a condition that can be prevented by "over-stenting." Schoder et al. [19], who observed an obstruction rate of 15%, suspected that the extension of the endoprosthesis beyond the stenosis and into the normal duct above the obstruction was inadequate, and, therefore, tumor overgrowth caused the stent obstruction.

In conclusion, our results suggest that placement of this ePTFE/FEP-covered stent-graft is feasible and effective in achieving biliary drainage. The percentage of patients undergoing lifetime palliation is high, and the midterm patency is very promising. However, the incidence of acute cholecystitis is troublesome. A larger group of patients is mandatory to validate these midterm results and provide more data on the issue of cystic duct obstruction. A randomized controlled trial comparing bare and covered stents should be conducted to verify if better palliation can be obtained using covered stent-graft.

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