The first prospective endoscopic experience with the ePTFE-covered Viabil stent in patients with a distal malignant biliary stenosis

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Abstract

Background and study aims. Endoscopic insertion of a biliary stent is standard practice in the palliative treatment of malignant biliary obstructions. Experience with the new ePTFE-covered Viabil stent is mainly limited to the percutaneous approach. We report our experience with its endoscopic application in patients with distal malignant biliary obstructions.

Patients and methods. Eleven patients with an inoperable tumour, without apparent metastatic disease, and with an ECOG score of 0 to 1, were included. All patients received an ePTFE-covered Viabil stent of 10 mm diameter, with transmural side-holes. Primary endpoints were stent patency and patient survival.

Results. Overall median patient survival was 220 days; 10 patients died free of jaundice from non-stent related causes. Due to malfunction of the prototype stents at insertion, the introduction of 2 Viabils was required in 3 patients to acquire complete bile duct drainage. Thus, a total of 14 stents was needed in 11 patients. Stent dysfunction occurred in 3/11 patients. It always resulted from massive stone impaction needing stone removal with additional stenting in two out of 3 patients. Stent patency was 80% at 3 and 6 months, and 63% at 9 and 12 months. Lifetime palliation was 73%.

Conclusions

Although the biliary Viabil device has been developed to minimize bacterial adherence and sludge formation, stent dysfunctions in this series always resulted from stone impaction. Moreover, malfunction of the prototype stents needed the insertion of a second stent in 3 patients. Overall life time palliation was 73%. Further experience with newer versions of the device as well as comparative studies versus other metallic stents are needed. (Acta gastroenterol. belg., **2010**, 73, **18-24**).

Key words : Cholangiopancreaticography, endoscopic retrograde, Bile duct diseases, Cholestatis, extrahepatic, Stent.

Introduction

In the palliative treatment of malignant biliary obstructions, endoscopic insertion of a biliary stent is the primary mode of therapy in most centres. Insertion of a 10 French plastic stent can be considered the treatment of choice in patients with a short expected survival of less than 3 to 6 months (1,2). In patients with a longer expected survival, a metal expandable stent can primarily be used (1-3). Obstruction of uncovered metal stents can occur by tumoural invasion via the meshes of the stent, whereas the function of covered biliary stents may be limited by tumor overgrowth, stent migration, acute cholecystitis, and sludge formation (3-7). In clinical practice, it remains unclear whether a covered stent confers a real advantage over its uncovered counterpart (1,8).

In clinical studies, most experience has been reported with the Permalume-covered Wallstent (Microvasive Endoscopy, Boston Scientific Corp) (3-8). The expanded polytetrafluoroethylene-fluorinated ethylene propylene (ePTFE/FEP)-covered stent graft (Viabil WL Gore & Associates, Flagstaff, AZ) is another type of covered stent, but reported experience with this type of stent in malignant biliary stenosis is mainly limited to percutaneous drainage procedures (9-11). The non-porous covering extends over the entire length of the stent to prevent tumor ingrowth, and is designed to resist bacterial attachment minimizing the risk of bio-sludge occlusion. Moreover, the Nitinol self-anchoring design reduces the risk of stent migration. We report our initial experience with the endoscopic insertion of the Gore Viabil stent in patients with malignant distal biliary obstruction, evaluating technical aspects, patency and survival rates, as well as potential complications.

Patients and Methods

This feasibility study was performed in 11 patients who were admitted to our hospital with a malignant distal biliary obstruction, and who were considered inoperable because of local tumour extension. The study protocol was approved by the ethical committee of our institute, and the study was performed in accordance with the declaration of Helsinki, European directive 2001/CE/20 and with the regulations of good clinical practice. All patients had given their written informed consent.

Inclusion criteria included the presence of a stenosis in the distal and/or middle third of the common bile duct, in a patient older than 18 years and presenting with obstructive jaundice by an inoperable biliopancreatic malignancy. Only patients without evidence for metastatic disease and with a good performance status, as expressed by an Eastern Cooperative Oncology Group (ECOG) score of 0 to 1, were included. These criteria were applied to select a group of patients with a presumed life expectancy of more than 3 to 6 months, in whom the characteristics of the stent could optimally be studied. Exclusion criteria included a hilar biliary stenosis, the presence of metastatic disease or of a duodenal obstruction preventing an endoscopic approach, an ECOG score 2 - 4, or the presence of a plastic stent for more than 1 month.

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Submission date : 14/08/2009
Acceptance date : 19/01/2010

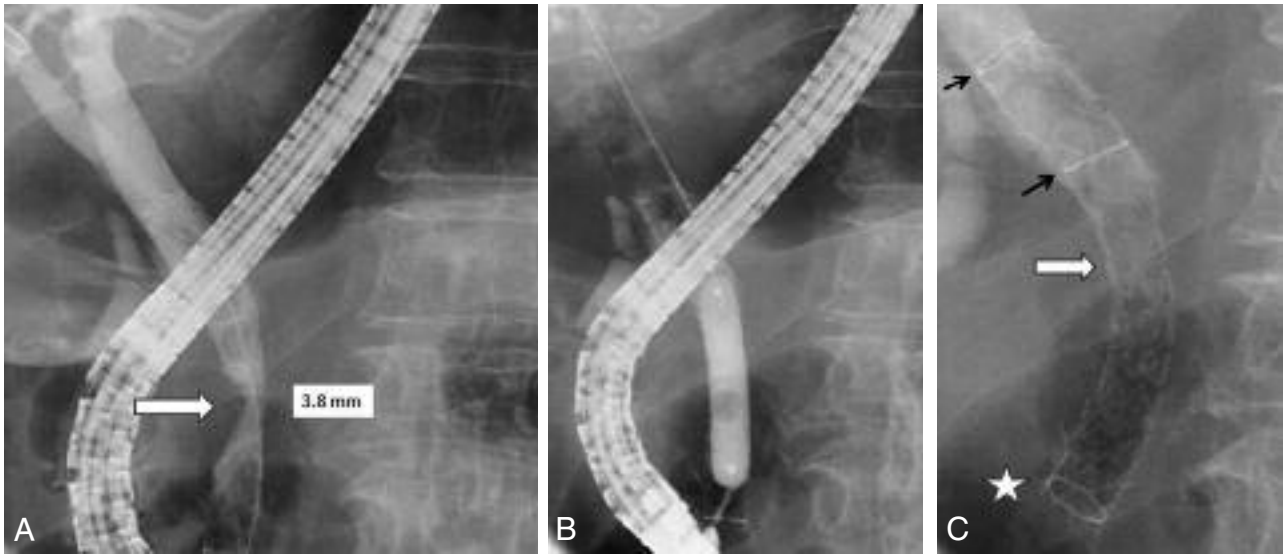

Fig. 1. — Insertion of an endoscopic Viabil stent in a patient with an inoperable pancreatic tumour. After insertion of the device, the diameter of the stent at the level of the stenosis (arrow) was only 3.8 mm and there was no good evacuation of bile and contrast (A); therefore it was decided to dilate the stenosis with an 8 mm Hurricane balloon (B). After dilatation, the diameter of the stent at the level of the stenosis was still slightly lower (arrow) than in the proximal bile duct (C). The latter picture that was obtained 48 hours after stent insertion, clearly shows the two proximal markers (arrows) and the distal marker (asterisk) of the device.

The ePTFE-covered stents, all with a diameter of 10 mm, were placed through the papilla and the stenosis over a 0.035-inch guidewire, using a therapeutic side-viewing endoscope (TJF160, Olympus, Tokyo, Japan). Stent insertion was always preceded by endoscopic sphincterotomy. Stents were positioned in the strictured area, with the distal end protruding beyond the papilla. They were progressively deployed under fluoroscopic control. If no proper drainage of contrast could be seen immediately after stent deployment, or if the diameter of the stent at the stenotic area was considered by the investigator to be insufficient for adequate bile drainage, dilatation of the stenotic area was performed with a balloon catheter up to 8 mm, mainly to prevent early cholangitis (Hurricane balloon, Microvasive Endoscopy, Boston Scientific Corp) (Figure 1). Stent lengths were 8 or 10 cm. All stents had transmural drainage side-holes along the proximal 1.5 cm of the stents to prevent a possible obstruction of the cystic duct, and hence to prevent acute cholecystitis.

Blood samples were obtained within 48 hours before the endoscopic procedure, and again 24 to 48 hrs after stent insertion. Later on, patients were evaluated on an outpatient basis every 3 months after stenting with clinical, biochemical, and sonographic examination. In case of evidence of stent obstruction, a repeat endoscopic retrograde cholangiography was performed to document the reason for stent dysfunction and to treat the recurrent cholestatic condition. The primary endpoint of the study was the presence of a well-documented stent obstruction requiring a therapeutic biliary reintervention. Stent patency was defined as the time interval in days between initial placement and documented stent obstruction. Patient survival was defined as the time interval in days between stent insertion and death.

Safety of stent insertion was evaluated according to post-procedural complications. For the definitions of post-ERCP complications, criteria were used as reported by Cotton et al (12).

Stent patency and patient survival were analyzed by the Kaplan-Meier life-table analysis. When there was no evidence for stent obstruction during the patient's life, stent patency was considered equal to survival period, but censored. Descriptive statistics was used for patient characteristics. Quantitative measurements are given by the means and standard deviations and by the ranges of observed values. For dichotomous and qualitative variables, absolute frequencies are given. Data management and descriptive statistics were done with Excel and with GraphPad. Survival analysis was done with the Graphpad version 4 software (GraphPad software Inc, San Diego, Cal, USA).

Results

Eleven patients were included, 8 females and 3 males, with a mean age of 68.7 ± 10.1 yrs (ranges 44-80 yrs). Ten patients had a pancreatic carcinoma and 1 patient presented with an ampullary adenocarcinoma. Stenosis of the distal third of the common bile duct was found in 10 cases whereas a stenotic area in the middle third of the bile duct was observed in 3 patients. An ECOG score of 0 and of 1 was found in 6 and in 5 cases, respectively. Marked jaundice was present in 10 cases and mild scleral jaundice in 1. Mean serum bilirubin was 10.4 ± 9.6 mg/dL (ranges 2.0-6.3 mg/dL). The median time interval

Table 1. — **Clinical and biochemical characteristics after biliary stenting with a Viabil stent in 11 patients with distal malignant biliary stenosis.**

	Pre-stent	Time after stent in months			
		3	6	9	12
Alive (n)	11	9	6	2	1*
Absence of jaundice (n)	0	9	6	2	0
On gemcitabine (n)	0	8	2	0	0
Bilirubin (mg/dL)	10.4 ± 9.6	0.7 ± 0.2	0.6 ± 0.2	0.5 ; 0.5	7.2
Alkaline. Phosphatase (U/L)	1770 ± 1053	441 ± 389	367 ± 335	278 ; 236	2220
Haemoglobin (g/dL)	11.8 ± 1.6	11.1 ± 1.7	11.8 ± 2.0	13.3; 13.2	12.8

* The patient with the longest survival suffered from recurrent jaundice and cholangitis at 12 months ; she was treated by plastic stenting and died free of jaundice at day 384 after primary stenting.

between the diagnosis of malignancy and insertion of the Viabil stent was 8 days (ranges 1-91 days).

A plastic stent had been in place for less than 1 month in 3 patients. None of our patients had clinical evidence of cholangitis prior to Viabil stent insertion.

Successful stent deployment was finally obtained in all patients, and in 8 cases only one stent had to be inserted. In three patients, however, two stents were needed because of technical problems. In one patient, during the pulling-release manoeuvre to open the metal stent, a break of the sheath occurred at the transition area of the sheath to the handle. Therefore, a second stent had to be used. In our two first patients, there was an incorrect positioning of the stent because of insufficient endoscopic visibility of the distal stent-marker. A second stent was needed to obtain complete stenting with a transpapillary position. Post-deployment balloon dilatation was performed in 7 out of the 11 cases.

No complications were observed after stent insertions. In nine patients, there was evidence of an improvement in cholestasis with less itching and a decrease in serum bilirubin within the first 24 to 48 hours after stenting. As compared to the pre-stent bilirubin concentration of 10.4 ± 9.6 mg/dL, the serum bilirubin at 24-48 hrs was significantly lower and reached 7.9 ± 10.1 mg/dL (P = 0.0038, two-tailed paired Wilcoxon test) (ranges 1.7-35.9 mg/dL). There were no significant changes in alkaline phosphatases, gamma-GT, haemoglobin, white blood cell count, and C-Reactive Protein. The median amylase concentration after stent insertion was 77 U/l (ranges 8-534 U/L) (normal < 100 U/L). Chemotherapy with gemcitabine was started in 8 patients after normalisation of their serum bilirubin.

Median patient survival time was 220 days with ranges between 58 and 384 days (Figure 2). All patients have already died with 1 “stent-related” and 10 ”non-stent related” deaths. The one patient with the “stent-related death” died 185 days after stent insertion from postoperative complications after hepaticojejunostomy that had to be performed because of repeated stent occlusions. All 10 patients who died from a “non-stent related death” were free of jaundice at time of death. Eight have died from progressive tumour evolution at a median of

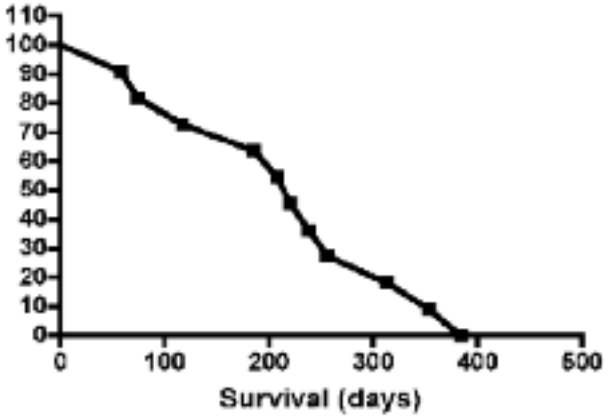

Fig. 2. — Patient survival rate as calculated by Kaplan-Meier analysis ; median patient survival was 220 days.

220 days (74 - 384 days) after stenting. One patient died from neutropenic septicaemia induced by chemotherapy at day 58, and one other case died from pulmonary oedema at day 238 after stent insertion. Main clinical and biochemical characteristics during the months after stent insertion are shown in Table 1.

Stent patency time, as estimated by life-table analysis, is shown in Figure 3. Stent dysfunction occurred in three patients. In all 3, stent occlusions that occurred at 49, 91, and 225 days, respectively, after primary stent insertion, were related to impaction by stones and sludge, and not to any tumoral ingrowth or overgrowth. All three primary episodes of stent dysfunction could be treated by balloon stone extraction techniques. Stent patency was 80% at 3 and 6 months, and 63% at 9 and 12 months. Overall, lifetime palliation was 73%.

In one patient, cholangitis by stent impaction occurred at 91 days. After succesful stone extraction, no further events occurred until he died 220 days after primary stent insertion. Secondary stent patency was 129 days. In this patient, two Viabil stents were present, the one inside the other.

In a second patient, that presented with cholangitis 225 days after stenting, stent impaction was found as well as a too long intraduodenal part of the stent, that

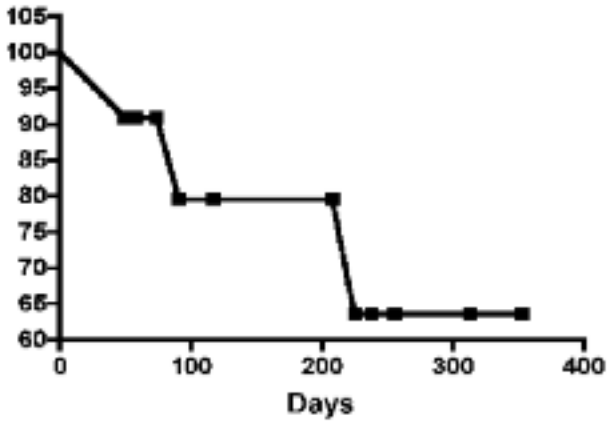

Fig. 3. — Kaplan-Meier estimation of stent patency rate. The median stent patency is not reached.

Fig. 4. — Insertion of a Viabil stent in a patient with an inoperable pancreatic tumour. At insertion of the stent in the bile duct that is filled with contrast, the proximal markers cannot be seen (A). As a result of a suboptimal positioning, the intraduodenal part of the stent is too long with a kinking at the level of the papilla (arrow) (B). Acute cholangitis occurred 225 days after stent insertion and was due to clogging of the stent by stones (C). The distal part of the stent is trimmed off with Argon Plasma Coagulation (APC) ; the distal marker of the stent can now be seen in the part of the stent (arrow) that has been cut away by APC and has been removed by snare (D). After a symptom free period of 66 days, the patient is readmitted with cholangitis and at that time, an upward intrabiliary migration of the stent that is impacted with stones can be observed (arrow) (E).

showed a kink at the level of the papilla. The distal kinked part of the stent, that was considered to be responsible for stone formation, was trimmed by argon plasma coagulation (APC) (13,14) (Figure 4). After a secondary patency time of 66 days, epigastric pain and abnormal liver tests were noticed. A that time, an upward intrabiliary migration of the metal stent as well as massive impaction of the stent with stones were observed (Figure 4). Balloon extraction of the stones was performed but again, two months later, stone impaction reoccurred. At that time, she was at 12 months follow-up after primary stent insertion (Table 1). A plastic stent was inserted through the metallic stent and she remained free of cholestasis until she died 384 days after Viabil stenting. In this patient, a plastic stent had been present prior to Viabil stent insertion.

A third patient developed repeated impaction from 49 days after stent insertion onwards. Stent impaction was treated by stone extraction, and, after a secondary patency time of 57 days, by endoscopic stent removal and insertion of a new Viabil stent at day 105. At day 136 a plastic stent was inserted through the new Viabil stent. At the occasion of the fourth episode of stent dysfunction, at day 157, a surgical biliodigestive bypass procedure was performed. The patient died from postoperative complications at day 185 after the first endoscopic stenting. Also in this patient, a plastic stent had been present in the bile duct before metallic stent insertion.

Discussion

In the palliative treatment of malignant biliary obstructions, endoscopic insertion of a biliary stent is the primary mode of therapy in most centres. Plastic stents as well as uncovered and covered metal stents can be used, and each of them have their own advantages and disadvantages.

In clinical studies on covered stents, most experience has been reported with the Permalume-covered Wallstent. However, other types of stents with other characteristics, such as the design of the stent and the length of the covering membrane on the metal mesh, might behave differently in patients with malignant biliary strictures. The ePTFE/FEP Viabil stent graft is a covered stent in which the non-porous covering extends over its entire length to prevent tumor ingrowth, and is designed to resist bacterial attachment minimizing the risk of sludge occlusion. This type of stent is available either with or without drainage side holes cut in the lining for 1.5 cm along the proximal end of the stent. Moreover, the Nitinol self-anchoring design reduces the risk of stent migration. Published experience with this type of stent in patients with malignant biliary stenosis is mainly limited to its percutaneous insertion (9-11). In the Fanelli paper (9) on 77 patients with malignant biliary obstructions, primary patency rates at 3, 6, and 12 months were 95.5%, 92.6%, and 85.7%, with survival rates of 40% and of 20% at 6 and 12 months, respectively. Stent obstruction occurred in 7/77 (9%) patients with tumor overgrowth in 6 and tumour ingrowth through the proximal side holes in 1 patient. The percentage of patients undergoing life time palliation was 91%. Acute acalculous cholecystitis was the most important complication. It occurred in 3/77 (3.9%), as well in one patient treated with a stent without side holes as in two patients treated with stents with side holes.

Excellent patency rates of 100%, 98%, and 91% at 3, 6, and 12 months (15), and of 100%, 100%, and 85% at 3, 6, and 12 months (16) were reported in abstract form.

In the Hatzidakis paper (10), 35 patients were included with distal as well as with proximal biliary strictures, and most patients were in a poor clinical condition with the presence of diffuse metastases in 5 of them. Poor general condition led to a median survival time of only 48 days. In that study, stent dysfunction due to sludge incrustration was observed in 4/35 (11%) after a mean time of 22.3 days, whereas stent occlusion either by tumour overgrowth in 2 cases and by tumor ingrowth in 4 cases led to a stent occlusion rate of 17% (6/35 patients) after a mean of 148 days. Patency rates were in favour of the fully covered stent. Primary stent patency rates at 3, 6, and 12 months were 100%, 55.5%, and 25%, respectively.

In a recent randomized controlled trial comparing percutaneously inserted bare Wallstents and covered Viabil stents, the latter type of stents proved to be significantly superior to the Wallstents with regard to stent dysfunction and survival rate (11). Stent dysfunction occurred in 30% of the patients in the Wallstent group and in 13% of the cases in the Viabil stent group. Median survival was 180 days for the Wallstent group and 243 days for the Viabil group. Tumour ingrowth could only be observed in the Wallstent group, whereas stent dysfunction in 4 Viabil stented patients was due to tumour overgrowth and sludge formation in 2 and in 2 cases, respectively.

In our, as well as in most centres for biliopancreatic diseases, the palliative treatment of a distal biliary stenosis consists of an endoscopic stent insertion, whereas the percutaneous approach is mainly reserved for failures of endoscopic therapy. After we had gathered experience with the percutaneous Viabil stent, we had the opportunity to study its first endoscopic version in patients with inoperable malignant distal bile duct strictures.

In order to fully explore the intrinsic properties of the stent, a group of patients were selected with a good performance status, as expressed by an ECOG score 0 or 1, and without evidence of distant metastases. This selection corresponded to a median survival time of 220 days or 7 months which is longer than median survival rates of 4 to 5 months reported by others (2,3,17,18). Lifetime palliation in this group of patients was 73%. Unlike the percutaneous Viabil devices reported by others (9,10), our endoscopically inserted stents were not complicated by tumour ingrowth or overgrowth in any of our 11 treated patients. Stent dysfunction, however, occurred in 27% (3/11) of the patients by the accumulation of sludge and

stones in the stent and in the proximal bile duct. In one patient, this complication occurred only once and was easily treated by endoscopic balloon sweeping; in two patients however, sludge accumulation repeatedly occurred, even after stent removal and insertion of a new Viabil prosthesis. The accumulation of sludge in covered stents is not limited to this type of prosthesis but has also been reported in studies using the covered Wallstent. Reported figures range from 1/49 (3), 20/98 (4), 2/36 (5), 1/80 (7), and 2/57 (6), with a total incidence of 8.1% (26/320). In a study of Familiari et al, the presence of debris as a cause of stent dysfunction occurred in 30% and in 9% of covered and of uncovered cases, respectively (19). Postmortem examination in 19 patients revealed no tumour ingrowth but small amounts of sludge in all 9 covered cases, and tumour ingrowth and even greater amounts of sludge in all 10 uncovered cases (6).

As such, for covered stents and in particular for the Viabil stent, the advantage of being protected against tumour ingrowth is partially lost by its propensity to sludge formation, which is exactly the mechanism of dysfunction of plastic stents. The mechanism of sludge formation in covered stents might be similar to that in plastic stents with the adherence of bacteria and proteins to the lining membrane, leading to the accumulation of biofilm on the membrane (20-22). It has been suggested that uncovered stents might be less prone to sludge formation. Wire meshes of uncovered stents become deeply embedded in the biliary mucosa, leading to an inflammatory reaction and the formation of a layer of collagenous material that separates the stent from the luminal contents, preventing the development of concretions on the stent wall (23,24). By contrast, the wires of covered stents penetrate less deeply in the bile duct wall (25). Therefore, a protective layer is not formed, allowing the accumulation of bacteria and of proteins on the wall of the stent.

To prevent migration of the Viabil stent, multiple sections of the wires near each end of the device are elevated form the external surface to act as anchorin fins. In Fanelli's series with 83 stents grafts in 80 patients, no cases of stent dislocation were noticed (9). Also other investigators using the Viabil stent did not encounter any case of stent migration (10,11,15,16). In our series, the distal intraduodenal end of the stent with its anchoring fins was trimmed by APC in one patient. Only in that particular case, an upward migration of the stent was observed. By contrast, dislocation of covered Wallstents has been reported in 3/49 (3), 6/98 (4), 1/36 (5), 5/80 (7), and 1/57 (6), with a total incidence of 5% (16/320).

In one of our patients, the Viabil stent was easily removed from the bile duct because of massive stone impaction about 3 months after its insertion. Retrieval of a Viabil stent via the percutaneous route has also been reported with an endoscopic grasping forceps through a large percutaneous introduction sheath (26,27).

As such, the intrinsic patency properties of the Viabil stent together with its lack of spontaneous migration and its potential to be retrieved either by the endoscopic or by the percutaneous route might allow its application in a number of benign biliopancreatic diseases. The use of the endoscopic Viabil stent has recently been reported in patients with benign biliopancreatic problems, as well for benign biliary strictures and postoperative biliary leaks (28-30), for drainage of pancreatic fluid collections (31), as for benign strictures of the pancreatic duct in chronic pancreatitis (32). In these preliminary studies, endoscopic removal of the Viabil stent was succesful in all patients in whom stent removal was attempted. In the experience of Wang et al (29), seven out of their 13 patients who had received a Viabil stent because of complex biliary leaks had their stent removed at the time of analysis, and all of them showed evidence of de novo choledocholithiasis or debris within the common bile duct at the time of stent removal.

We used the first prototype of the endoscopic Viabil stent in our first 8 patients. In two of them, there was an incorrect positioning of the stent because of insufficient endoscopic visibility of the distal stent-marker. Our last 3 patients were treated with an "improved" version of the stent with a better visibility of the distal stent markers. According to our limited experience with this second type of delivery catheter, there was a increased propensity for rupture of the catheter shaft at its fixation point to the hub assembly during the release manoeuvre. These technical problems led to the necessity for a second stent insertion in three of our patients. In order to overcome these technical problems, a new gastrointestinal delivery catheter for endoscopic application of the Viabil stent has been developed with a special deployment knob for an easy stent release. Future experience with this new device will hopefully lead to a more optimal approach of our patients with malignant as well as with benign biliary strictures.

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