Treatment of Malignant Biliary Obstruction with a PTFE-Covered Self-Expandable Nitinol Stent

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Objective: We wanted to determine the technical and clinical efficacy of using a PTFE-covered self-expandable nitinol stent for the palliative treatment of malignant biliary obstruction.

Materials and Methods: Thirty-seven patients with common bile duct strictures caused by malignant disease were treated by placing a total of 37 nitinol PTFE stents. These stents were covered with PTFE with the exception of the last 5 mm at each end; the stent had an unconstrained diameter of 10 mm and a total length of 50–80 mm. The patient survival rate and stent patency rate were calculated by performing Kaplan-Meier survival analysis. The bilirubin, serum amylase and lipase levels before and after stent placement were measured and then compared using a Wilcoxon signed-rank test. The average follow-up duration was 27.9 weeks (range: 2–81 weeks).

Results: Placement was successful in all cases. Seventy-six percent of the patients (28/37) experienced adequate palliative drainage for the remainder of their lives. There were no immediate complications. Three patients demonstrated stent sludge occlusion that required PTBD (percutaneous transhepatic biliary drainage) irrigation. Two patients experienced delayed stent migration with stone formation at 7 and 27 weeks of follow-up, respectively. Stent insertion resulted in acute elevations of the amylase and lipase levels one day after stent insertion in 11 patients in spite of performing endoscopic sphincterotomy (4/6). The bilirubin levels were significantly reduced one week after stent insertion ($p < 0.01$). The 30-day mortality rate was 8% (3/37), and the survival rates were 49% and 27% at 20 and 50 weeks, respectively. The primary stent patency rates were 85%, and 78% at 20 and 50 weeks, respectively.

Conclusion: The PTFE-covered self-expandable nitinol stent is safe to use with acceptable complication rates. This study is similar to the previous studies with regard to comparing the patency rates and survival rates.

Index terms:
Biliary tract, malignant obstruction
Biliary tract, interventional procedures
Prosthesis, stent

Korean J Radiol 2007;8:410-417
Received August 24, 2006; accepted after revision December 18, 2006.

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This paper was supported by research funds (2005-46) of Chonbuk National University in 2005.

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The treatment for malignant biliary obstruction includes performing surgery and interventional procedures such as insertion of a self-expanding metal stent under fluoroscopic and/or endoscopic guidance (1–6). Self-expanding metal stents have become a well-accepted palliative procedure for relieving inoperable malignant biliary obstruction. The most common causes of occlusion of an uncovered stent are sludge formation, proximal and distal tumor overgrowth, tumor ingrowth and stone formation (1, 7, 8). The obstruction rates for uncovered stents in a previous study varied from 5% to 100% (mean: 22%) during a 0.7 to 19 month period following stent placement (9).

To improve the patency rates of metallic stents, many studies have been performed

to investigate polyurethane- and expanded polytetrafluoroethylene-fluorinated ethylene propylene (ePTFE-FEP)-covered stents (10 –20). The obstruction rate for these covered stents has varied from 0% to 37% (mean rate: 15%). The cause of polyurethane-covered stent occlusion was previously reported to be due to a degraded polyurethane membrane and subsequent tumor ingrowth into the stent (10). In animal studies, PTFE has been shown to be quite useful for reconstructing the common bile duct (21). Schoder et al. reported that using an ePTFE-FEP covered stent produced good clinical results with no stent obstruction; this type of stent has anchoring fins at its ends (19). We hypothesized that a PTFE membrane forms a successful barrier against future tumor ingrowth, and so this might improve the stent patency rates.

We present here the results of a pilot study of implanting PTFE-covered Niti-S stents in patients suffering with malignant biliary obstruction. This is a prospective, non-randomized clinical study that's intended to determine the technical efficacy and safety of implanting a PTFE-covered self-expandable nitinol stent for the management of malignant biliary obstruction. We evaluated the clinical efficacy of this stent design by determining the stent patency rate and the patient survival rate.

MATERIALS AND METHODS

Patient Population

Thirty-seven subjects were enrolled in this study; there were 19 men and 18 women with a mean age of 70 years (age range: 47−85 years). The study protocol was approved by the Institutional Review Board of our university and also by the Ethics Committee of the Institute for Medical Science. The procedure was explained in detail to all the prospective patients, and a written consent was obtained from all the subjects before the procedure. The study inclusion criteria were (i) the presence of malignant obstruction of the common bile duct below the hilar confluence, and this was caused by unresectable malignant tumor or reocclusion of a previously inserted self-expandable uncovered biliary stent, and (ii) obtaining an informed consent. The exclusion criteria included surgical resectability of the tumor, hilar obstruction or postoperative anastomotic site obstruction due to malignant recurrence, or the presence of a generally fatal patient condition such as sepsis or disseminated intracoagulopathy. Thirty-seven patients had percutaneous biliary drainage performed, of which 34 were treated with a covered stent as the first stent, and three were treated for failure of a standard uncovered stent. Six patients underwent sphincterotomy via endoscopic guidance before stent insertion.

In our study, 14 patients had biopsy-confirmed adenocarcinomas and 23 patients lacked a confirming biopsy, but these 23 patients had been diagnosed by the findings on abdominal spiral computed tomography (CT), magnetic resonance (MR) imaging, percutaneous cholangiography and endoscopic retrograde cholangiopancreatography (ERCP). Thirteen patients had common bile duct carcinoma, eight patients had pancreatic head carcinoma, four patients had gallbladder carcinoma, six patients had periampullary carcinoma and six patients had gastric carcinoma. The site of obstruction was the proximal common bile duct (CBD) in three patients, the middle CBD in six patients and at the distal CBD in 28 patients.

Stent Device and Placement

The stents used in this study were self-expanding biliary PTFE covered Niti-S stents (Taewoong Medical Corporation, Seoul, Korea), as are described in Figure 1. The Niti-S stent we used was made of 0.007-inch single nitinol wire, which has excellent biocompatibility and expansile force, and the stent was also self-expanding without any sharp spurs at either end (low trauma ends).

To prevent stent migration, a PTFE membrane covered the stent on the inside of the metal wire. Thus, the outer surface of the stent had a rough texture. The stents were 5−8 cm long when fully expanded to a maximum diameter of 10 mm, and they were positioned using a 9-Fr introducer system. The stent was held, compressed and elongated on the delivery catheter by a cylindrical rolling membrane (the outer sheath). The delivery catheter had three markers: one at a first-proximal portion (the proximal marker), the second at the actual stent length position (the stent length marker), and the third at the distal position of the loaded stent (the stent marker). Stent

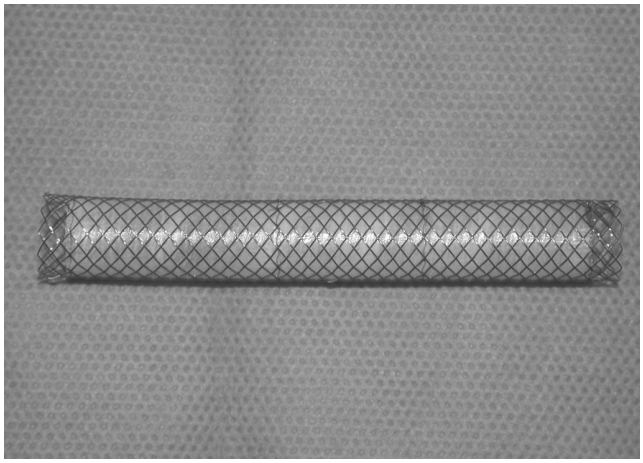

Fig. 1. The PTFE-covered self-expanding Niti-S stent endoprosthesis. The stent is a woven, monofilament structure composed of nitinol, and it is covered on its interior surface by PTFE.

deployment was accomplished by withdrawing the outer sheath while fixing the inner catheter. The devised Niti-S stent became shortened by 51% after deployment, which is similar to that of Wallstents (50%); the Nitis-S stent had tungsten markers on its proximal and distal ends that helped with manipulation during deployment (13).

Fluoroscopic Guidance Procedure

The fluoroscopic guidance procedure was performed as previously described by Han et al. (20). In most patients, stent placement was accomplished within two weeks after performing percutaneous transhepatic biliary drainage (PTBD). Stent placement was accomplished in three patients during the follow-up tubogram after protracted PTBD or stent placement. A right intercostal and/or left epigastric approach was chosen depending on the extent of tumor. Stent insertion was performed over an extra stiff Amplatz guidewire (180 cm, 0.035 inch, curved tip; Cook Inc., Bloomington, IN). Care was taken to precisely locate the covered mid-portion of the stent exactly at the stricture. The distal end of the stent protruded 2−3 mm into the duodenum. Balloon dilation after stent insertion was not performed in any of our patients; instead, an 8.5-Fr or 10.2-Fr biliary drainage catheter was left in place for seven days. This catheter was used only for flushing and maintaining access to the biliary tree, and not for drainage. Thereafter, imaging was repeated via the drainage catheter to check the stent's patency, function and position. The catheter was removed if free bile flowing into the duodenum was documented or if the bilirubin level was normalized or markedly reduced.

All the patients received 200 mg of prophylactic antibiotics that were administered intravenously over a period of 12 hours (Flomoxef sodium; Flumarin®, Ildong, Ansung, Korea; or Fosfomycin sodium; Fonofos®, Chong Keun Dang, Chunan, Korea) before and usually 48−72 hours after the procedure. Coagulation tests were performed before the procedure, and if a patient had disseminated intravascular coagulopathy, then stent placement was not performed.

Study Endpoints and Definitions

A hospital discharge report was obtained for each patient. The study endpoints were followed at monthly intervals for two years. Sonography of the upper abdomen was performed, and the bilirubin levels were checked at each examination. The patients were also followed by conducting telephone interviews with the referring physicians or with the patients when the patients failed to appear at the follow-up examinations. If stent occlusion was suspected, then the stent was revised percutaneously using a 10-Fr drainage catheter. Finally, the cause of death was ascertained for all the patients who died within the observation period.

Successful decompression of the biliary system was defined by a decrease of the serum bilirubin level of more than 30% versus the baseline value within a week of stent insertion (10). We measured the distance from the bifurcated line between the right and left intrahepatic ducts to the end of the biliary stent. Stent migration was divided into proximal and distal stent migration. Proximal stent migration was defined as a stent that migrated into the common hepatic duct, and distal stent migration was defined as a stent that migrated into the duodenum or out of the patient's body. The extents of these migrations were established by comparing the stent ends with the stent positions seen on the initial images. Early migration was defined as migration that occurred within one week of deployment, and delayed migration was defined as migration that occurred from one week to one month after stent placement. For the cases of recurrent jaundice, any stent occlusion was confirmed by sonography or CT, which showed dilation of the intrahepatic duct and the presence of soft tissue density inside the stent. Recurrent episodes of inexplicable fever were defined as cholangitis. At the time of death, a stent was assumed to be patent if the patient had normal or only mildly elevated serum bilirubin levels (< 3 mg/dl). If the patients had obvious jaundice or if they had a higher bilirubin level than that before stent placement, then the stent was assumed to be obstructed. Ultrasonography (US) was used to examine the degree of stent occlusion. Echogenic materials in the stents, as were determined by US, were considered to represent sludge, and floating material in the stent, as determined by percutaneous transhepatic cholangiography, was also considered to represent sludge formation.

The bilirubin and amylase/lipase levels before and during follow-up were statistically analyzed by using the Wilcoxon signed-rank test. The stent patency rate and the patient survival rate were calculated by performing Kaplan-Meier survival (life-table) analysis. The duration of primary patency was defined as the interval between stent placement and the recurrence of obstructive jaundice. If obstruction was not evident during a patient's life, then the patency period was considered to be equal to the survival duration, but this data was censored.

RESULTS

Stent deployment was successful in all 37 patients, and this was performed via transpapillary placement of the covered stent (37/37, 100%) (Fig. 2). No proximal or distal

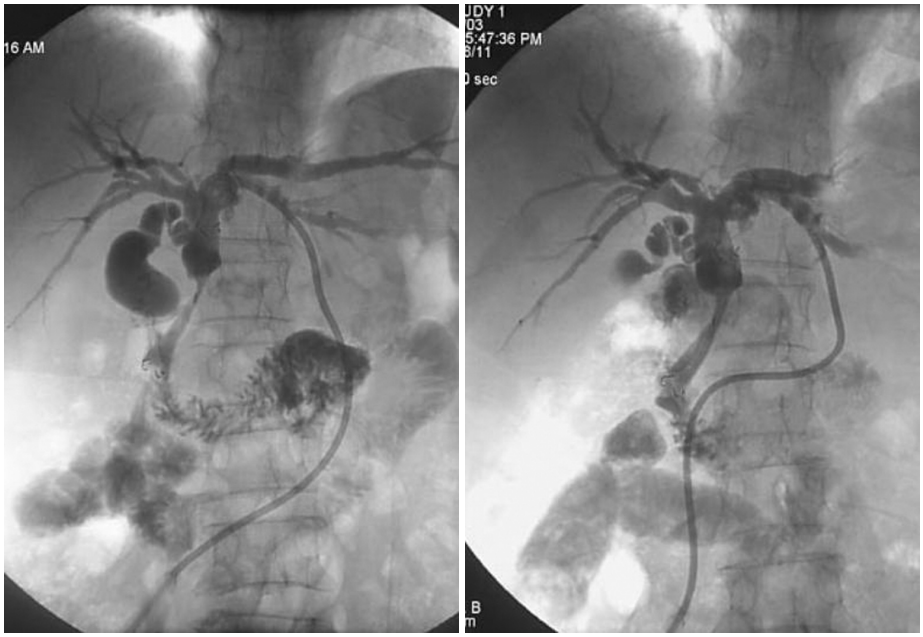

Fig. 2. A 68-year-old female with common bile duct carcinoma.
A. The tubogram taken immediately after stent insertion shows good stent patency and correct positioning.
B. This one-week follow-up tubogram shows good stent function. The distance between the end of the stent and the bifurcation of the common hepatic duct shows no change.

stent migration occurred during the procedures. Two patients showed that the stent had migrated completely out of the biliary duct during the 7-week and 27-week follow-up period, respectively. The distance between the bifurcated line and the end of the stent immediately after stent placement was 6 –35 mm (mean: 15 mm). One week later, follow-up tubography showed no change of this distance (range: 6 –35 mm: mean: 15 mm). The follow-up plain films showed no changes in any of the stents in the right upper quadrant areas except for two patients who experienced delayed stent migration.

The mean bilirubin level decreased from 11.1 mg/dL ± 6.86 standard deviation (SD) before the procedure to 5.12 mg/dL ±4.6 SD at the first follow-up, and this difference was statistically significant (Wilcoxon test: $p < 0.01$). Significant changes in the bilirubin levels were observed between the baseline and the most recent follow-up after stent placement ($p < 0.05$). The amylase and lipase levels were 110.5 IU/L ±150.6 and 133.4 IU/L ±187.3, respectively, before the procedure; they were 94.0 IU/L ±90.6 and 135.2 IU/L ±185.0, respectively, one week after the procedure, and they were 48.6 IU/L ±38.1 and 50.3 IU/L ±54.2, respectively, at the last follow-up (Fig. 3). The amylase and lipase levels did not increase at one week and at the last follow-up day after the insertion ($p > 0.01$). The amylase and lipase levels were found to be severely elevated one day after stent insertion in 11/37 patients (29%); that is, the amylase/lipase level was 505 IU/L (range: 107 –1,455)/520 IU/L (range: 77 –1,019). Despite endoscopic sphincterotomy that was done in six patients, four patients revealed severe elevations of their amylase

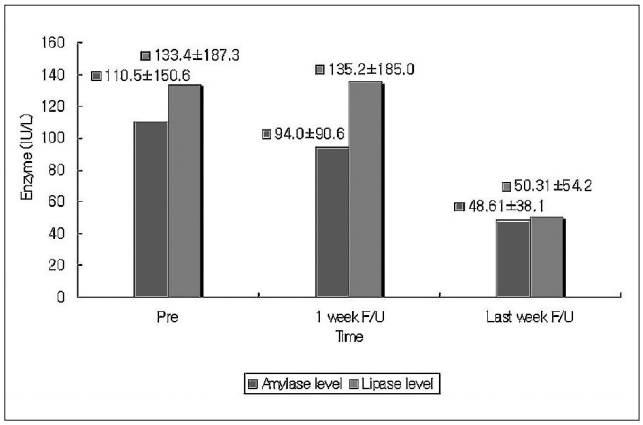

Fig 3. The graph shows the changes of the amylase and lipase level before and after stent placement and during the last follow-up.

and lipase levels one day after stent insertion. These 11 patients had pancreatitis symptoms such as pain; however, their amylase and lipase levels stabilized within seven days. The 30-day mortality rate was 8% (3/37), which reflected fatal septic conditions in two patients and death from an unknown cause in one patient. Three patients showed good patency of their biliary stent, according to one-week follow-up ultrasound sonography. However, the bilirubin level of two patients before stent insertion was from 11.0 mg/dl to 11.5 mg/dl and 13.5 mg/dl to 14.4 mg/dl, respectively, on the one-week follow-up, and one other patient showed a bilirubin level from 24.7 mg/dl to 22.0 mg/dl. The discrepancies between the image findings and lab findings were related to each patient's conditions.

The lesion was completely covered by the stent in four

patients who received a 5-cm-long stent, in 12 patients who received a 6-cm-long stent, in 11 patients who received a 7-cm-long stent, in nine patients who received an 8-cm-long stent and in one patient who received a 9-cm-long stent. The stent was sufficiently long to cover the lesion in all the patients. No case of biliary side-branch obstruction occurred, except for at the cystic duct.

Seventy-six percent (28/37) of the study patients experienced adequate palliative drainage for the remainder of their lives. Three patients displayed stent sludge occlusion, and PTBD showed some filling defect in these stents (Fig. 4). However, good stent patency was achieved via irrigation for two patients who both underwent PTBD two times during the follow-up. Two patients had PTBD performed:

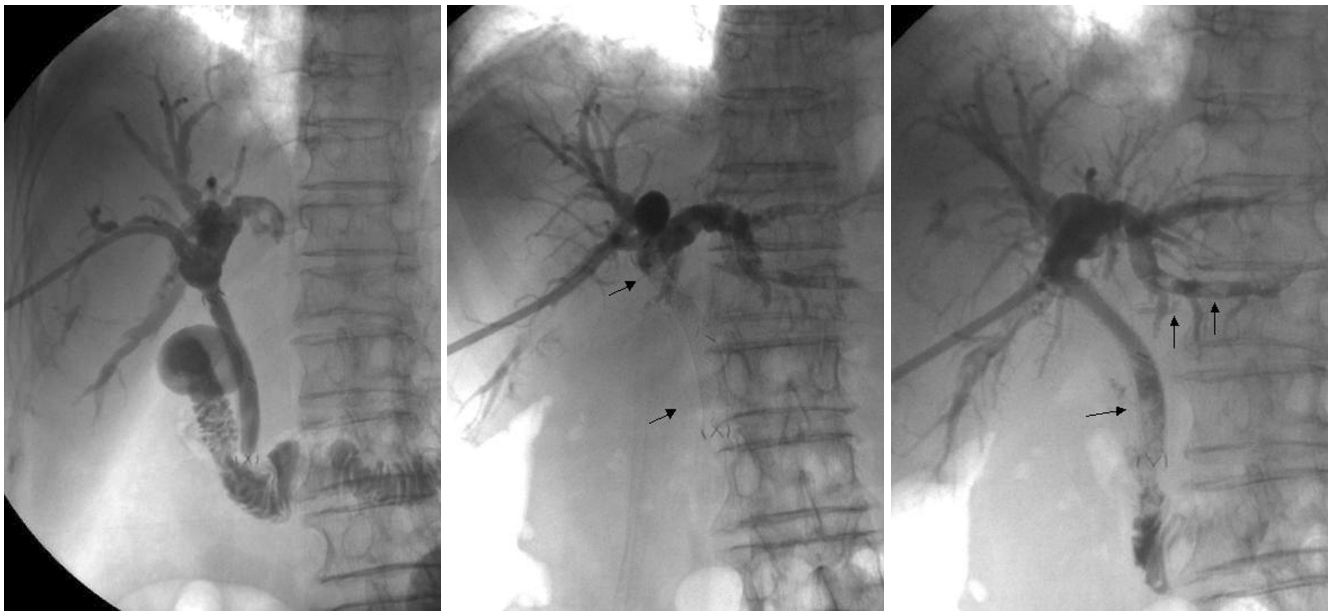

Fig. 4. A 78-year-old female with common bile duct carcinoma.
A. The one-week follow-up tubogram shows a well functioning stent.
B. This 33-week follow-up tubogram after percutaneous transhepatic biliary drainage shows no contrast medium, due to food reflux, in the stent (arrows).
C. The tubogram after stent irrigation shows good passage of contrast medium into the duodenum. Small remnants of food material (arrows) were observed in the left intrahepatic duct and in the distal portion of the stent.

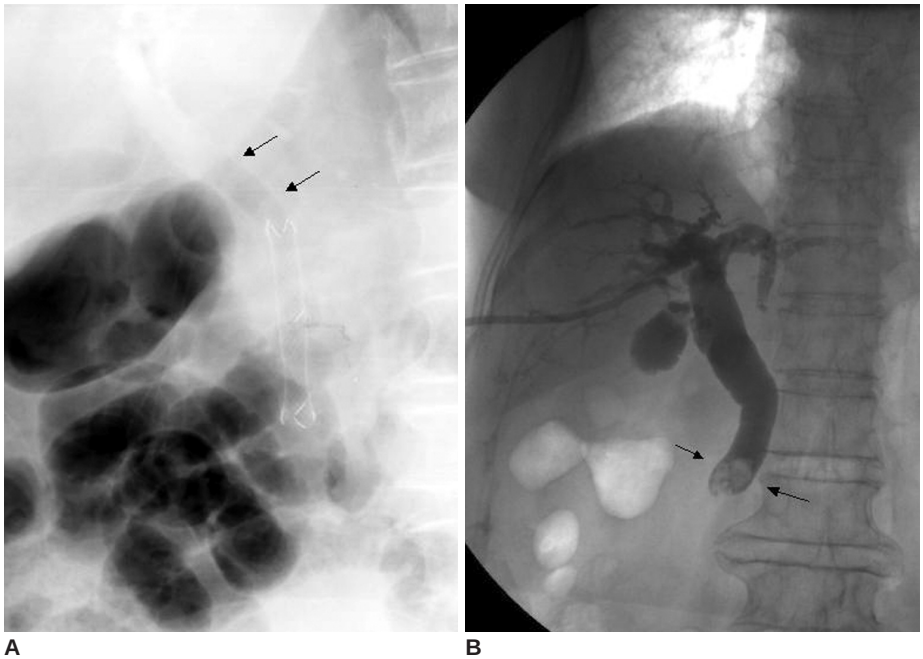

Fig. 5. A 76-year-old female with Ampulla of Vater carcinoma.
A. The five-day follow-up plain film after stent insertion shows good stent positioning on the air-biliary gram (arrows).
B. The 27-week follow-up tubogram after percutaneous transhepatic biliary drainage shows no evidence for the presence of a stent, and there is a small filling defect in the distal common bile duct, which may be a common bile duct stone (arrows).

one patient due to tumor ingrowth (34 weeks) and another due to stent migration (7 weeks). One patient had biliary obstruction 27 weeks after stent insertion. The tubogram finding after PTBD showed stone formation, but we did not find the previously inserted PTFE stent in the abdomen (Fig. 5). One patient underwent percutaneous transhepatic gallbladder drainage at 19 weeks due to acute cholecystitis, and that patient also underwent PTBD at 24 weeks due to overgrowth that was noted at 24 weeks. Two patients had percutaneous transhepatic gallbladder drainage due to acute cholecystitis.

The duration of the follow-up study for all the patients was 2–81 weeks (mean: 27.9 weeks). Twenty-eight patients died during 2–81 weeks and nine patients lived until 43–80 weeks. According to the Kaplan-Meier survival analysis, the primary stent patency rates were 85% and 78% at 20 and 50 weeks, respectively; the survival rates were 49% and 27% at 20 and 50 weeks, respectively; and the mean survival and patency durations were 33 weeks and 64 weeks, respectively. No procedure-related patient deaths were identified, and all the deaths were attributed to the patients' natural course of disease. The covered stents showed patent lumens in 28 patients; this was confirmed by such laboratory values as the bilirubin levels at the final follow-up.

DISCUSSION

The reported follow-up durations and patency rates of covered stents in the medical literature have varied (10–19). Hausegger et al. (10) have reported that the patency rates after 1, 3, 6 and 12 months were 96%, 69%, 47% and 31%, respectively. Rossi et al. (16) have reported primary patency rates after 3, 6 and 9 months of 72%, 46% and 46%, respectively. Both of these investigations (10, 16) didn't report good patency rates because their stent occlusion rates were somewhat high (33–37%). Born et al. (14) noted that the mean survival of their patients was six months. Kanasaki et al. (12) reported that the mean patency period of their stents was 37.5 weeks. Schoder et al. (19), in a large series of covered stents, reported the primary patency rates at 3, 6 and 12 months to be 90%, 76% and 76%, respectively, and we previously reported stent patency rates of 71% and 48% at 20 and 50 weeks, respectively (20). In this present study, the primary and stent patency rates were 85%, and 78% at 20 and 50 weeks, respectively. Kanasaki et al. (12) and Born et al. (14) have reported good patency rates that were the result of lower stent occlusion rates. However, making comparison with those studies is difficult because each of their patients was treated at a different stage of disease, and the tumors differed for their histologic type, cellular growth and biological behavior (12).

The ePTFE/FEP-covered stent has several advantages. It is resistant to bacterial growth, and this reduces the risk of occlusion caused by bile incrustation (18, 22). Moreover, PTFE resists chemicals (acids and alkalies) and heat, and PTFE is self-lubricating and not prone to demolding. Moreover, although PTFE has a low coefficient of friction and therefore good patency, it has poor adhesion to other materials (23). In the present study, the PTFE stent offered several advantages. First, a 9-Fr introducer system was used for implanting the PTFE-covered stents, which is a much smaller system than that required for the Schoder et al. ePTFE-FEP covered stent. Second, in order to prevent stent migration, the end portion of the stent and the outside of the stent are not coated with PTFE. Third, the stent is designed to be covered with PTFE on the inner aspect of the stent. The stent wire surrounds the PTFE, and so the stent's outer surface is similar to that of an uncovered stent. In our study, two patients experienced delayed stent migration.

The disadvantage of the ePTFE/FEP-covered stent is that the fabric covering of the expanded stent may cause blockage of the cystic or pancreatic duct, and this can result in possible cholecystitis or pancreatitis (18, 19). In our study, three patients (3/37, 8%) underwent percutaneous transhepatic gallbladder drainage due to acute cholecystitis. The most obvious disadvantage of the PTFE stent was that stent insertion was followed by marked elevation in the amylase and lipase levels one day after insertion; these levels subsequently decreased and then fell to normalized levels within seven days. The other disadvantage of the stent is the occurrence of stent obstruction due to sludge formation. In our opinion, this elevation of the amylase and lipase levels was caused by pancreatic sphincter hypertension because there was no space between the stent and the sphincter of Oddi, as seen on post-endoscopic retrograde cholangiopancreatography (ERCP). The level of the lesion was the proximal CBD in one patient, the mid CBD in two patients and the distal CBD in eight patients. The cause of disease was CBD carcinoma in three patients, gastric carcinoma in three patients, ampulla of Vater carcinoma in two patients and pancreatic head carcinoma in three patients. Four patients underwent endoscopic sphincteromy. The second disadvantage of stenting is the possibility of stent occlusion due to food reflux from the duodenum into the proximal common bile duct.

There are many studies that have made comparisons between covered and uncovered stents (24–26). Isayama et al. reported have that covered stents successfully

prevented tumor ingrowth and they were significantly superior to uncovered stents for treating those patients suffering with distal malignant biliary obstruction (24). Stent occlusion occurred in covered stents for eight patients (14%) after a mean of 304 days (24). Yoon et al. reported that the stent patency rates were 83%, 78%, 67% and 54% at 100, 200, 300 and 400 days, respectively, for covered stents and 83%, 66%, 54% and 36%, respectively, for uncovered stents, which was not significantly different (25). Stent migration occurred in three patients (3/36, 8%) in that study. Park et al. have reported that the mean stent patency was 148.9 days for covered stents and 143.5 days for uncovered stents. The incidence of mild pancreatitis was 6.1% for covered stents and 1.9% for uncovered stents (26). Migration of stent occurred in 0.6% of the patients and sludge formation in stents occurred in 20% of the patients in the above study. In our study, the covered stent showed similar patency rates, a high incidence of mild pancreatitis and a low incidence of sludge formation and stent migration.

Our study has a few limitations. The study group was a somewhat small compared to other related studies. One patient had tumor ingrowth in the mid portion of their stent; however, the image finding was not confirmed by choledochoscopy. Tumor ingrowth may not occur in PTFE materials because the PTFE itself is a strong barrier. If it does occurs, it would be due to damage or natural degradation of PTFE.

In conclusion, the PTFE-covered self-expandable nitinol stent is safe with acceptable complication rates. This study is similar to previous studies in regard to comparing between the patency rates and the survival rates. Using the PTFE-covered self-expandable nitinol stent for treating malignant biliary obstruction was found to be a feasible and effective means of achieving biliary drainage.

Acknowledgements

The authors thank Kevin Condren, Harrisco Language Research Institute, for his editorial assistance in the preparation and revision of the manuscript.

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