malignant biliary obstruction were included. The most common cause of obstruction was pancreatic cancer, which occurred in 76% and 77% in the cSEMS group the uSEMS group, respectively. The trial compared a polycarbonate-polyurethane covered nitinol stent with an uncovered nitinol metal stent (Nitinella; ELLA-CS, Hradec Kralove, Czech Republic).The membrane of the covered stent was placed inside of the metal mesh, and only the distal 5 mm of the covered stent was uncovered. The endoscopist decided the length of SEMS to use- either 52 or 72 mm. All stents had an inner diameter of 10mm.

The criteria for a successful stent insertion included radiological confirmation (at ERCP), and at least a 30% decrease in bilirubin level during the first 5 days after stent insertion. Clinical follow-up was performed once per month, starting at 1 month, and the endpoint was 12 months after randomization.

The investigators found that patient survival times were 116 days and 174 days in the cSEMS and uSEMS groups, respectively (p=0.320). The first quartile stent patency time (the day when 25% of the stents had occluded) was 154 days in the covered stent group and 199 days in the uncovered stent group (p =0.326). There was no difference in the incidence of pancreatitis or cholecystitis between the 2 groups. Stent migration occurred in 6 patients (3%) in the covered group and in no patients in the uncovered group (p=0.030).The majority of patients in both groups died within 12 months with a patent stent. Ten percent of the patients in the cSEMS group and 15% in the uSEMS group were alive at 12 months with a patent stent.

The authors concluded that there was no significant difference in patient survival or stent patency time between cSEMS and uSEMS in the palliative treatment of malignant distal biliary obstruction.There was no increase in risk of cholecystitis or pancreatitis when using cSEMS.

Commentary

The primary objective of the study was stent patency, and no difference was found in this end point between the uSEMS and cSEMS. The frequency of observed stent failure also occurred in nearly equal proportion - 24% and 23% for cSEMS and uSEMS, respectively. Important mechanisms causing stent occlusion are tumor overgrowth and ingrowth, which in this series occurred in 27 patients (13%) in the cSEMS group and in 31 patients (15%) in the uSEMS group. However, a significant difference in the frequency of ingrowth was found between cSEMS in 9 patients (5%) and uSEMS in 21 patients (11%), as would be expected. Stent obstruction by sludge formation and encrustation occurred more often with cSEMS (6% vs 2%). This is in agreement with findings by others who have reported sludge formation, with or without food impaction, to be the most common cause of stent occlusion in cSEMS.

One must remember that it is notoriously difficult in most cases to distinguish between overgrowth, ingrowth, and encrustation. In the present study the mechanisms of stent dysfunction was mainly based on cholangiographic findings, which may be subject to observer error.

There has been an apprehension that cSEMS might increase the prevalence of cholecystitis and pancreatitis by blocking the cystic duct and the pancreatic duct orifice However in this study cholecystitis occurred in 2 patients (1%) in each group, which is similar to previously reported incidence. Similar findings were reported in the second study described below.

Migration of cSEMS has been reported to occur in 6% to 12% of cases, more often with stents made of stainless steel than in those made with nitinol. In this series also migration of cSEMS occurred in 6 of 200 patients (3%) compared with none in the uSEMS group- a significant but small difference.

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A randomized trial comparing uncovered and partially covered self-expandable metal stents in the palliation of distal malignant biliary obstruction

Telford JJ, Carr-Locke DL, Baron TH, Poneros JM, Bounds BC, Kelsey PB, Schapiro RH, Huang CS, Lichtenstein DR, Jacobson BC, Saltzman JR, Thompson CC, Forcione DG, Gostout CJ, Brugge WR.

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This second multicenter RCT was conducted in 4 teaching hospitals in Canada and US. Adults with inoperable distal malignant biliary obstruction were included. From

October 2002 to May 2008, 129 patients were randomized. Distal obstruction was defined in this study, as being ≥1 cm distal to the biliary hilum. As in the previous study, subjects were randomized at the time of the ERCP after successful placement of a guidewire across the malignant stricture, using sealed envelopes. Either an uncovered Wallstent or a Permalume membrane partially covered Wallstent (Boston Scientific Corporation, Natick, Mass, USA) was used. Follow-up data were collected by telephone interview conducted by a research assistant, 1 week after stent insertion and then monthly until patient death.The primary study outcome was time to recurrent biliary obstruction, and secondary outcomes of interest were patient survival, serious adverse events, and the mechanism of recurrent biliary obstruction.

Recurrent biliary obstruction was observed in 11 of 61 uSEMS (18%) and 20 of 68 cSEMS (29%). The median times to recurrent biliary obstruction were 711 days and 357 days for the uSEMA and cSEMS groups, respectively (p=0.530). Median patient survival was 239 days for the uSEMS and 227 days for the cSEMS groups (p=0.997). Serious adverse events occurred in 27 (44%) and 42 (62%) patients in the uSEMS and cSEMS groups, respectively (p=0.046). None of the uncovered and 8 (12%) of the partially covered SEMS migrated (p=0.0061). Cholecystitis developed in 3 patients in each treatment group.

The authors concluded that there was no significant difference in time to recurrent biliary obstruction or patient survival between the partially covered and uncovered SEMS groups. Partially covered SEMS were associated with more serious adverse events, particularly migration.

Commentary

A previously published randomized trial in 2004 demonstrated improved stent patency and an absence of tumor ingrowth with a cSEMS compared with an uSEMS.[1] However, the cSEMS used in this study is not commercially available. A subsequent retrospective cohort study[2] and a prospective cohort with a retrospective comparison group[3] did not demonstrate a difference in stent patency between uncovered and partially covered SEMS. Hence although there is some suggestion that covering a SEMS may increase the duration of stent patency, there is no firm data in this regards. In addition, there is some concern that cSEMS may be associated with an increased incidence of cholecystitis, pancreatitis, and distal migration due to lack of tissue embedding.

The planned sample size for this study was 136 patients, but the study was closed before reaching this goal because of slow accrual. The results of this study did not demonstrate a difference in the time to recurrent biliary obstruction or patient survival between the two stents, but did demonstrate a higher incidence of serious adverse events in those patients who received a cSEMS. Migration of the covered stents contributed to recurrent biliary obstruction in 6 cases. Migration caused duodenal perforation in two cases and contributed to upper GI hemorrhage in one. Duodenal perforation secondary to biliary SEMS migration has not been reported previously. Cholecystitis after cSEMS placement may occur in up to 10% of patients, but was not seen at an increased rate in this study (7% in both cSEMS and uSEMS groups).

In an accompanying editorial in the same issue Willingham states that although not currently indicated for late removal, it is possible that the covered stents, with their inherent propensity to migration and prevention of ingrowth, could be of benefit when the quality of late removability is desired, and the diagnosis of malignancy is not definitely established.[4] In conclusion, the message from these two studies is that cSEMS, although safe, offer no real advantage for patients with distal biliary obstruction.

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Prediction of drainage effectiveness during endoscopic stenting of malignant hilar strictures: the role of liver volume assessment

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The optimal endoscopic approach to the drainage of malignant hilar strictures remains controversial, especially with regards to the extent of desirable drainage and unilateral or bilateral stenting. In this study the records of all 188 patients who underwent endoscopic stenting for malignant