Also some other studies have also shown that LBD is safe with low risk of pancreatitis as the biliary and pancreatic orifices are separated by previously performed EST.[4] The authors also left the balloon inflated for 10 to 12 seconds only after obliteration of the waist and they believed that this shorter time of inflation could also have decreased the risk of pancreatitis. However, this hypothesis is contrary to an earlier published randomized study comparing 1 minute vs. 5 minute of endoscopic balloon dilatation of intact biliary sphincter where the authors have shown that 5 minute balloon dilatation is associated with better efficacy of stone extraction and reduced risk of pancreatitis.[5] The authors of this study hypothesized that post-ERCP pancreatitis is primarily related to postprocedure papillary edema and outflow obstruction rather than intraprocedural occlusion of the pancreatic sphincter by the balloon and therefore dilations of up to 1 minute, as is typically done, are inadequate and produce excessive postprocedure edema.

Also, the authors have demonstrated that ML is associated with more risk of complications like cholangitis when compared to LBD where none of the patients developed cholangitis. The authors believed that higher cholangitis rate in patients in ML group could be because of trauma to the CBD wall by the lithotriptor wires as well as edema at the sphincterotomy site and / or inadequate sphincterotomy could also contribute to the higher cholangitis rate. The current prospective randomized study has shown that LBD is safe and effective and is associated with fewer complications than ML and importantly the risk of pancreatitis is low and comparable between the two groups.

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Self expanding metal stents (SEMS) are a great advance over plastic stents for the palliation of malignant biliary obstruction. A systematic review comparing plastic stents and SEMS found a median plastic stent patency ranging from 62 to 165 days compared with a metal stent patency of 111 to 273 days.[1] *Generally, plastic stents last approximately 3 months and metal stents last approximately 6 to 12 months. There is still a 13% to 44% reintervention rate with SEMS attributed to stent failure.*[2-4] *A number of factors have been suggested to explain this relatively high failure rate, including epithelial hyperplasia, tumor ingrowth and overgrowth, dislocation, debris formation, and clot accumulation. To better counteract tumor ingrowth in uncovered SEMS (uSEMS), covered SEMS (cSEMS) were developed by placing a thin nonporous membrane on the inside of the metal mesh. However there are few comparative studies to answer the question as to whether cSEMS offer a more durable biliary drainage compared with uSEMS. In the November 2010 issue of Gastrointestinal Endoscopy, there are two randomized trials (RCTs) comparing uSEMS and cSEMS for palliation of malignant biliary obstruction.These studies are remarkable in having a rigorous prospective design, a powered pre-enrollment sample size target, and a priori specification of outcomes and endpoints.*

Covered versus uncovered self-expandable nitinol stents in the palliative treatment of malignant distal biliary obstruction: results from a randomized, multicenter study

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The first study was a RCT conducted to compare differences in stent patency, patient survival, and complication rates between covered and uncovered nitinol stents. in patients with malignant biliary obstruction. This multicenter trial was conducted between January 2006 and October 2008, at 10 sites in Sweden. A total of 21 endoscopists with 4 to 25 years of experience performing ERCP participated.

The randomization process, was done in blocks of 20 (10:10) when the patient was in the ERCP suite and after the guidewire had passed the stenosis. The endoscopist opened an opaque sealed envelope with computer-generated random numbers. A total of 400 patients with unresectable distal

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