ORIGINAL ARTICLE

Covered metal versus plastic stents for malignant common bile duct stenosis: a prospective, randomized, controlled trial CME

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Background: Most patients with malignant common bile duct strictures are suited only for palliation of jaundice by placement of a polyethylene (PE) stent using an endoscopic retrograde cholangiographic technique. Occlusion of these stents occurs after 3 to 4 months, whereas uncovered self-expanding metal stents (SEMS) remain open twice as long. The initial higher cost of the latter might be balanced by a decreased need for repeat intervention.

Objective: To compare the patency of 10F PE stents and covered 30F steel SEMS (Wallstent; Boston Scientific Nordic AB, Helsingborg, Sweden).

Design: Single–center, prospective, randomized, controlled trial.

Setting: General hospital in Stockholm, Sweden, which has a catchment area of 0.6 million people.

Patients: Non-referred, unresectable malignant common bile duct strictures.

Interventions: Endoscopic retrograde cholangiography with plastic stents or covered SEMS.

Main Outcome Measurements: Time to stent failure, requiring a new stent.

Limitations: Similar setting and patients, and costs in Scandinavia.

Results: Fifty-one and 49 patients were allocated to the PE stent and SEMS groups, respectively. Fifty-six patients died without stent failure within 10 months (median, 2.6 months). Twenty-two PE stent and 9 SEMS patients ($P = .009$) developed failure after a median of 1.1 and 3.5 months, respectively ($P = .007$). Median patency times were 1.8 and 3.6 months in the PE and SEMS groups, respectively ($P = .002$). Median survival was 4.5 months; in 35 patients with distant metastases, the median survival was 2.5 months ($P = .002$)(PE group, 1.9 months).

Conclusions: The more-effective SEMS are recommended in unresectable patients with malignant common bile duct strictures, who survive a median of 4.5 months. Less costly plastic stents are preferable in the one third of patients who have distant metastases. In our study, the cost was equal. (Gastrointest Endosc 2006;63:986-95.)

Fewer than 20% of patients with a malignant stricture of the common bile duct can be offered a cure by resection.[1,2] In the others, the best method for palliation of jaundice is the placement of a polyethylene (PE) endoprosthesis (EP) by using an endoscopic retrograde cholangiographic (ERC) technique.[3,4] However, partial or total occlusion of the EP, frequently accompanied by cholangitis, usually occurs 3 to 4 months after the insertion of a standard 10F PE stent,[4,5] and it must then be replaced.

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Stent dysfunction mainly is associated with the diameter of the EP lumen. In 4 randomized controlled studies (RCTs), wide-bore self-expanding metal stents (SEMS) have remained patent up to a median of 9 months.[6-9] SEMS are much more expensive, but if they stay open about twice as long as conventional plastic stents, the high initial cost will be offset by a reduction in the need for endoscopic repeat intervention and/or rehospitalization. Therefore, the choice of a plastic or metal EP may be dependent on an estimate of the patient survival rate, ie, prognostic factors that are not fully understood.[10,11] SEMS, such as the Wallstent (Boston Scientific Nordic AB, Helsingborg, Sweden), are inserted using an 8F catheter system and are composed of a wire mesh that expands to a maximum of 30F when released across the stricture.

Metal EPs are also available in a silicone polymer-covered version (C-SEMS). The plastic covering of the mesh may counteract tumor ingrowth, one of the known mechanisms for dysfunction of the metal stent.[12]

Our aim was to compare the patency of conventional endoscopically inserted 10F plastic stents with that of C-SEMS in our Scandinavian setting of a large urban district general hospital. Therefore, we conducted a prospective RCT in patients with malignant distal bile duct strictures unsuitable for radical surgery.

Capsule Summary

What is already known on this topic

- When used for malignant common bile duct strictures, wide-bore, self-expanding metal stents (SEMS) remain patent longer than plastic stents, but are more expensive.
- Plastic-covered SEMS counteract tumor ingrowth, the main cause of occlusion.

What this study adds to our knowledge

- In a single-center, randomized, prospective study comparing plastic stents to plastic-covered SEMS, the plastic stent group had significantly more stent failures and shorter patency times than the SEMS group.
- Because the survival period in patients with distant metastases and the patency time in the plastic stent group are similar, the more-expensive SEMS may be reserved for patients who do not have distant metastases.

PATIENTS AND METHODS

The study eligibility and exclusion criteria are shown in Table 1. Between August 2001 and April 2003, 100 patients fulfilled our criteria for randomization. A Consolidated Standards for Reporting Trials (CONSORT) flowchart is shown in Figure 1.

Randomization

When the patients met all the inclusion criteria and none of the exclusion criteria, and after informed consent was obtained, the patients were randomized (without blocking or stratification) to one of two groups: the PE stent or the C-SEMS group. The randomization process, which used the opaque, sealed envelope and random table technique, was done by one of the authors when the patient was in the ERCP suite, after the guidewire was in place. The stent then was immediately inserted. Blinding at or after randomization was not applied.

Stent insertion

A traditional straight, PE plastic, 10F EP (5, 7, or 10 cm in length) with distal and proximal side flaps and adjacent side holes, or a silicone polymer-covered (5 mm bare ends), self-expandable, steel metal (4, 6, or 8 cm in length) Wallstent (both from Boston Scientific Nordic AB, Helsingborg, Sweden) was inserted by the ERC transduodenal route. If the patient had not been investigated adequately (eg, with CT or evaluated for possible radical surgery), a 8.5F thin PE stent was inserted first. At a second session (as soon as possible, but always within 1 month), after the patient was enrolled in the study, randomization was done, and the stent was switched to a 10F PE EP or C-SEMS. Endoscopic sphincterotomy was performed routinely before stent insertion.

Follow-up and end points

The patients attended the outpatient clinic at 1 month, 4 months, and 10 months (end point), where we performed a physical examination, obtained blood samples for tests including liver function tests, and assessed them with the World Health Organization performance classification and the Visick grading system. Our main aim was to look for signs or a history of stent occlusion and to decide whether ERCP or other investigations should be done to confirm or intervene because of stent dysfunction.

The study end points were an uneventful follow-up for 10 months, death, and confirmed (ERC with intervention) stent failure. Survival data and stent patency data also were available after 10 months. Stent failure was defined as clinical (cholangitis) and laboratory (S-bilirubin >50 μmol/L, previously normal) signs of stent occlusion confirmed by ERC (dilation of bile ducts proximal to the stricture, occluded or dislocated stent with little, if any, passage of contrast dye) and requiring insertion of a new stent.

The patients and caregivers were told about the symptoms of cholangitis and were asked to contact our hospital immediately in case of signs of obstruction. If stent obstruction was suspected, ERC was performed. The stent was switched to a SEMS in cases of an occluded PE stent; in those with occlusion of a metal EP, a PE stent was inserted inside the SEMS. Records from hospices and other primary care facilities were also evaluated for signs of stent dysfunction.

Evaluation

Our main outcome measure was the time to proven stent failure, as defined earlier. The primary aim was to compare the two groups for stent patency (ie, episodes of cholangitis) detected clinically, subsiding spontaneously, or confirmed and requiring repeat intervention (stent failure was the end point).

The secondary aims were to determine the technical success rate for insertion of the 2 types of stents, the complications at insertion, and the need for one or more sessions, as well as a simple cost calculation. The criteria for a successful stent insertion included the views of the endoscopist and radiologist (not involved in the trial)