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

Soderlund C, Linder S

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of endoscopic retrograde cholangiography (ERC) with plastic stents, compared with silicone polymer-covered self-expanding metal stents (C-SEMS), in patients with malignant common bile duct structures for the palliation of jaundice. The study examined covered 30F steel SEMS.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The included patients were non-referred and had clinical data and history suggestive of malignant bile duct occlusion. They were also found to be unsuited to curative resection and had jaundice. Ten exclusion criteria were listed in the paper. For example, patient was a candidate for surgical resection, patient was in an extremely poor general condition, and proper investigations were not performed.

Setting
The setting was secondary care. Specifically, a general hospital in Stockholm, Sweden, with a catchment area of 0.6 million people. The study was conducted in Sweden.

Dates to which data relate
The effectiveness and resource use evidence was gathered from patients who met the inclusion criteria between August 2001 and April 2003 and were randomised into the study between August 2002 and March 2004. The date to which the prices referred was not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the effectiveness analysis.

Study sample
The authors expected a failure rate of up to 50% in the PE stent group at 3 months. Failure was defined as clinical cholangitis and/or confirmed stent occlusion with or without ERC intervention. To show a reduction to 15% (70%
reduction) with SEMS, with an alpha error of 0.05 and a power of 0.8, at least 75 patients would have to be included. It would appear that a convenient sample was taken. A total of 120 patients were assessed for eligibility. Of these, 1 refused, 16 had a Whipple resection and 3 did not fulfil all inclusion criteria. The study therefore included 100 patients, 49 of which were in the C-SEMS group and 51 in the PE stent group.

**Study design**
The study design was a single-centre, prospective RCT. The patients were randomised without blocking or stratification, using an opaque sealed envelope and random table technique. One of the authors did this while the patient was in the ERC suite, after the guidewire was in place, the stent being immediately inserted. Blinding at or after randomisation was not applied. The patients attended follow-up at 1, 4 and 10 months. Survival data and stent patency were also available up to 18 months. Loss to follow-up was nil in both groups, though 2 patients in the PE stent group discontinued after undergoing a Whipple operation.

**Analysis of effectiveness**
It was stated that an intention to treat analysis was performed, but 2 patients were censored at surgery because of a protocol violation. The analysis was also performed on a per-protocol basis. The primary outcome was the time to proven stent failure (i.e. stent patency). Episodes of cholangitis were detected clinically, subsiding spontaneously or confirmed and requiring repeat intervention. No differences were detected between the two groups at inclusion. Secondary aims were to determine the technical success rate for insertion of the two types of stent, the complications at insertion, the need for one or more sessions, and a simple cost calculation.

**Effectiveness results**
Nine C-SEMS and 22 PE stent patients developed stent failure in the 10-month follow-up, (p=0.009).

The time to proven stent failure was 3.5 months in the C-SEMS group and 1.1 months in the PE stent group, a relative hazard of 3.53 (95% confidence interval, CI: 1.41 to 8.87; p=0.007).

The median patency time was 3.6 months in the C-SEMS group versus 1.8 months in the PE stent group, a relative hazard of 1.94 (95% CI: 1.24 to 2.95; p=0.002). The difference was similar in the per-protocol analysis.

Survival differences were not statistically significant.

**Clinical conclusions**
The authors concluded that SEMS were more effective than PE stents in unresectable patients with malignant common bile duct structures.

**Measure of benefits used in the economic analysis**
No summary measure of benefits was used. In effect, a cost-consequences analysis was undertaken.

**Direct costs**
The study measured resource use, incorporating the costs of the stents themselves, together with costs of ERC and of hospitalisation. From these data and unit costs drawn from the authors' hospital setting, approximate direct costs were calculated. Discounting was not carried out, although in some cases the costs of stent failure occurred in the second year of the study. The resource use related to the same time period as the effectiveness estimates. The price year was not reported.

**Statistical analysis of costs**
The costs were treated deterministically.
Indirect Costs
Not relevant.

Currency
Euros (EUR). Neither the original results in Swedish kroner nor the exchange rate were reported.

Sensitivity analysis
No sensitivity analyses were conducted.

Estimated benefits used in the economic analysis
A cost-consequences analysis was conducted. See 'Effectiveness Results' section.

Cost results
The authors reported only the total initial cost in the C-SEMS group (EUR 46,060), and stated that this was more than that for the PE stent group. They also reported the incremental cost of stent failures in the PE stent group (EUR 48,610).

Synthesis of costs and benefits
Not relevant.

Authors' conclusions
The authors concluded that self-expanding metal stents (SEMS) were more effective, and recommended their use in unresectable patients with malignant common bile duct structures who survived a median of 4.5 months and did not have distant metastases. They also concluded that the costs were equal.

CRD COMMENTARY - Selection of comparators
The choice of the comparator was justified as representing common practice in the authors' setting. You should decide whether PE stents are a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on an RCT, which was appropriate for the study question. It would appear that the study sample was representative of the study population, although selection was based on convenience and the study took place within a single centre. The patient groups were shown to be comparable at analysis. In addition, power calculations were conducted to ascertain whether the results obtained were due to the intervention or to chance. The method of randomisation was reported, as was the loss to follow-up, suggesting that the internal validity of the study is likely to be good. The outcomes were analysed on both an intention to treat and per-protocol basis.

Validity of estimate of measure of benefit
The authors did not derive a measure of health benefit. The analysis was therefore categorised as a cost-consequences study.

Validity of estimate of costs
The cost categories relevant to the hospital perspective adopted were included in the analysis. Some relevant costs might have been excluded from the analysis. For example, consultations with specialists may have been more frequent in
patients with stent failure and the associated costs were not captured explicitly. These omissions might have affected the estimates of cost. However, the authors did caption the cost collection "approximate". Given the relatively expensive cost of hospital stays, it is unlikely that the conclusions would have been substantially different.

The costs and the quantities were reported separately but only median hospital stays were reported. No statistical analysis of the quantities or prices was performed. The authors did not acknowledge any uncertainty in their conclusions. Currency conversions were not reported and costs incurred beyond the first year were not discounted. Hospital charges might have been used to approximate the costs. The use of charges to proxy costs has the limitation of not reflecting true opportunity costs, thus restricting the external validity of the results. The price year was not given, which will hamper any possible inflation exercises.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. Generalisability was addressed by the authors noting that the total costs of stent insertion were mainly affected by local logistics (e.g. number of days in hospital and different reimbursement systems) rather than the cost of the stent itself. They noted that this could limit the study because of the unique Swedish setting, associated with close and complete follow-up. The authors appear to have presented their cost results selectively, as it would have been more transparent to present component and total costs for each group consistently. They chose not to conduct an incremental cost-effectiveness calculation but did not acknowledge this omission. The authors' conclusions reflected the scope of the study. However, their proposed implications for the distribution of SEMS versus PE stents among patients appear to go further than the evidence supported.

Implications of the study
Because the length of survival and the patency time in PE stent patients with metastases were very similar, the authors recommended PE stents for such patients. The more expensive SEMS should be reserved for patients who do not have metastases and survive a median of 4.5 months.

Source of funding
Supported by Boston Scientific Nordic AB, Helsingborg, Sweden.

Bibliographic details

PubMedID
16733114

DOI
10.1016/j.gie.2005.11.052

Indexing Status
Subject indexing assigned by NLM

MeSH
Aged; Aged, 80 and over; Bile Duct Neoplasms /complications /pathology; Bile Ducts, Intrahepatic; Cholangiocarcinoma /complications /pathology; Common Bile Duct /pathology; Constriction, Pathologic; Endoscopy, Gastrointestinal; Female; Humans; Jaundice, Obstructive /therapy; Male; Metals; Middle Aged; Palliative Care; Pancreatic Neoplasms /complications /pathology; Plastics; Prospective Studies; Prosthesis Design; Stents

AccessionNumber
22006001323