Expandable metal biliary stents before pancreaticoduodenectomy for pancreatic cancer: a Monte-Carlo decision analysis
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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 study examined the endoscopic placement of plastic stents or self-expandable metal biliary stents via endoscopic retrograde cholangiopancreatography (ERCP) for the treatment of obstructive jaundice in patients with pancreatic cancer.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The hypothetical study population comprised patients presenting with obstructive jaundice from pancreatic cancer. Following staging of disease, some patients were considered potential surgical candidates for the Whipple procedure. The authors excluded patients with ampulla of Vater or auto-immune disease, cholangiocarcinoma, cholelithiasis, cystadenoma, gallstones, hepatocellular carcinoma, pancreatitis or sclerosing cholangitis.

Setting
The setting was secondary care. The economic study was carried out in Alabama, USA.

Dates to which data relate

Source of effectiveness data
The effectiveness data were derived from a review of published studies.

Modelling
A Markov model was used to estimate the costs and outcomes associated with the four treatment strategies evaluated. The model had a cycle length of 1 month and a timeframe of 2 years. Death and Whipple surgery were absorbing states in the model. From the health state of pancreatic cancer with obstructive jaundice, patients could move to complications from cholangitis, complications from ERCP, have patent biliary stent, death from pancreatic cancer and co-morbid conditions, death from cholangitis, death from ERCP-related complications, or have Whipple surgery if their cancer was resectable. The model was analysed using patient-level simulation where 10,000 individual patients were simulated through the model using Monte-Carlo simulation. This analysis propagates patient-level variability (first-order uncertainty) through the model results.
Outcomes assessed in the review
The outcomes assessed were:

- the occlusion rates with initial and subsequent stents,
- the rates of cholangitis and complications,
- the percentage of patients that would be candidates for Whipple surgery, and
- the mortality rates.

Study designs and other criteria for inclusion in the review
The authors did not specify the study designs for inclusion in the review, but did specify the keywords used in the literature search.

Sources searched to identify primary studies
The authors searched Ovid MEDLINE from 1996 to week 4 of 2004. They also checked the references of the included studies.

Criteria used to ensure the validity of primary studies
Not reported.

Methods used to judge relevance and validity, and for extracting data
The authors did not describe the methods used to judge the relevance of the primary studies, or the method used to extract the data. Of 85 potentially relevant articles, 11 were deemed clinically relevant to the decision analysis; the others were classified as unrelated topics.

Number of primary studies included
The review identified 11 English language papers that were determined to be clinically relevant. A further 15 papers were identified from the references of these articles.

Methods of combining primary studies
The data from the primary studies were pooled, weighted by sample size. The precise method used was not reported.

Investigation of differences between primary studies
Not reported.

Results of the review
The occlusion rate with a metal stent was 5.3% (Range: 3.9 to 14.7) for the initial stent and 9.4% (Range: 6.3 to 20.0) for subsequent stents. Following placement of a metal stent, the rate of cholangitis was estimated to be 14% (Range: 6 to 25), the rate of complications 5% (Range: 0 to 12), and the 30-day mortality rate 8% (Range: 2 to 14).

The occlusion rate with a plastic stent was 13% (Range: 6.3 to 35.7) for the initial stent and 17% (Range: 14 to 19) for subsequent stents. Following placement of a plastic stent, the rate of cholangitis was estimated to be 17% (Range: 5.5 to 30), the rate of complications 11% (Range: 0 to 30), and the 30-day mortality rate 6% (Range: 1 to 15).
Measure of benefits used in the economic analysis
There was no summary measure of benefit. The paper reported comparative clinical outcomes for plastic and metal stents. These are reported in the Results of the Review section (above).

Direct costs
The study included the direct inpatient and outpatient costs, as well as the costs of death from cholangitis and death from complications. The costs were those of the hospital and a third-party payer. The costs for each health state were reported separately. The prices were based on Medicare charges and hospital costs from the University of Alabama at Birmingham Hospital. This will affect the generalisability of the study results. Although the timeframe of the model was 2 years, the median survival of the hypothetical cohort was less than 1 year and so the authors did not perform any discounting. The price year was 2004. The authors did not report any methods used to adjust for inflation.

Statistical analysis of costs
Since patient-level data were not available, a statistical analysis of the costs was not relevant.

Indirect Costs
The indirect costs were not included in the analysis.

Currency
US dollars ($).

Sensitivity analysis
A one-way sensitivity analysis was conducted to identify the thresholds for each parameter at which the results of the analysis would change.

Estimated benefits used in the economic analysis
See the Results of the Review section.

Cost results
The mean simulated costs were $20,878 (standard deviation, SD=36,452) for plastic f/u plastic, $20,157 (SD=35,986) for plastic f/u metal, $20,871 (SD=36,890) for metal f/u plastic, and $19,935 (SD=36,494) for metal f/u metal.

The difference in costs was found to be statistically significant using an F-test, (p<0.01).

Although the costs from cholangitis and complications were included, the cost of death from pancreatic cancer and co-morbid conditions was not.

The study also did not include the procedural or subsequent costs associated with Whipple surgery.

Synthesis of costs and benefits
Not relevant.

Authors’ conclusions
Initial metal stent with subsequent metal stents for subsequent occlusions (metal f/u metal) is the optimal strategy in patients with advanced disease, or who are not surgical candidates, and who have a life expectancy of greater than 5 months. Initial metal stent followed up with plastic stents (metal f/u plastic) may be preferred in patients with less than
5 months- life expectancy.

**CRD COMMENTARY - Selection of comparators**
Plastic stents were identified as current practice in the study setting. Metal stents were included in the analysis as they are considered to be more effective than plastic stents but more expensive. The authors acknowledged that another potentially relevant comparator might be covered metal stents, but these were not included in the analysis. You must consider whether these technologies are relevant in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness data were based on a review of the published literature. The review was not reported in sufficient detail to show that biases were minimised. The study designs included and the methods of synthesis were not reported in detail, and this may limit the validity of the study results. However, the authors did weight the studies by sample size. The authors did not consider the effect of differences between the primary studies. This might be particularly important if the effectiveness data were drawn from single arms of separate studies, as differences in the study population could introduce bias.

**Validity of estimate of measure of benefit**
The authors’ main aim was to conduct a cost-minimisation analysis. They therefore did not make a detailed comparison of the health benefits of the different interventions. However, they reported comparative clinical effectiveness results for plastic and metal stents, which were informative. The authors stated that they did not calculate quality-adjusted life-years because of the lack of reliable estimates of utility weights.

**Validity of estimate of costs**
The authors did not specify a perspective for the analysis. The perspective appears to have been that of a third-party payer. The authors omitted the costs of death due to pancreatic cancer and co-morbid conditions, but as the rates of these were similar for plastic and metal stents this might not have affected the study conclusions. The unit costs were reported separately. A threshold analysis was used to determine the costs or rates of events at which the study conclusions would change. The price data were based on Medicare charges and hospital costs. These make the study results very specific to a US setting. The price year was reported, but the methods used to inflate cost data from published studies were not. The authors did not perform discounting, but this is unlikely to have affected the study results because few patients in the model would have survived beyond 1 year. The authors acknowledged that despite the statistical significance of the cost-difference, the absolute difference may be considered small.

**Other issues**
The authors made appropriate comparisons of their findings with those from other studies. The issue of generalisability to other settings was not addressed. The authors do not appear to have presented their results selectively, and they presented extensive results of the one-way sensitivity analyses. The authors’ conclusions reflected the scope of their analysis and they stressed that the results do not apply to patients without pancreatic cancer. The authors acknowledged that their assumption that all metal stents have equivalent patency might not be true. However, they stated that the bias could be in either direction.

**Implications of the study**
The authors did not make any recommendations for research.

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None stated.
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