Biliary stents in malignant obstructive jaundice due to pancreatic carcinoma: a cost-effectiveness analysis

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 two methods for endoscopic placement of biliary stents in patients with pancreatic carcinoma. The methods examined were plastic (polyethylene) stents and metallic stents. Plastic stents were widely used due to their ease of insertion and low costs. However, their major disadvantage was their tendency to clog because of bacterial biofilm formation and biliary sludge. Metallic stents were associated with lower occlusion rates. However, their major disadvantages were the high costs and the difficulty of repositioning or extraction once deployed.

Type of intervention
Palliative care.

Economic study type
Cost-utility analysis.

Study population
The study population comprised patients with unresectable pancreatic carcinoma.

Setting
The setting was a hospital. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness evidence and resource use data were derived from data published between 1992 and 2000. The price year was 1999.

Source of effectiveness data
The effectiveness evidence was mainly derived from published studies. Some effectiveness data were derived from the authors’ assumptions.

Modelling
A Markov decision model was constructed to simulate the natural history of the disease. Also, to compare the lifetime costs and benefits of the two stent strategies. Patients with pancreatic carcinoma and obstructive jaundice, presenting to an endoscopist for palliation, entered into the model and moved into five possible health states:

pancreatic carcinoma with obstructive jaundice,
pancreatic carcinoma without obstructive jaundice,
pancreatic carcinoma with obstructive jaundice complicated by cholangitis,
pancreatic carcinoma with procedure (endoscopic retrograde cholangiopancreatography, ERCP) complications, and
death from pancreatic cancer, cholangitis, and ERCP-related complications.

Each cycle was one month.

**Outcomes assessed in the review**
The outcomes assessed in the review and used as model inputs were:

- the probability of monthly plastic stent occlusion (first and subsequent stents);
- the probability of monthly metallic stent occlusion;
- the probability of monthly plastic in first metallic stent occlusion;
- the probability of procedure complications and ERCP death;
- the probability of monthly pancreatic carcinoma mortality;
- the probability of cholangitis (after stent occlusion); and
- the probability of cholangitis mortality.

**Study designs and other criteria for inclusion in the review**
The primary studies were generally randomised controlled trials.

**Sources searched to identify primary studies**
MEDLINE was searched for primary studies.

**Criteria used to ensure the validity of primary studies**
Not stated.

**Methods used to judge relevance and validity, and for extracting data**
Not stated.

**Number of primary studies included**
The effectiveness evidence was derived from seven primary studies.

**Methods of combining primary studies**
Narrative methods were used to combine the primary studies.

**Investigation of differences between primary studies**
Not carried out.

**Results of the review**
The probability values were:
0.125 (range: 0.10 - 0.20) for monthly plastic stent occlusion for first stent, and 0.16 (range: 0.06 - 0.19) for subsequent stents;

0.05 (range: 0.04 - 0.10) for monthly metallic stent occlusion;

0.0625 (range: 0.05 - 0.19) for monthly plastic in first metallic stent occlusion;

0.10 (range: 0.05 - 0.30) for procedure complications and 0.01 (range: 0 - 0.05) for ERCP death;

0.10 (range: 0.08 - 0.17) for monthly pancreatic carcinoma mortality;

0.18 (range: 0.10 - 0.75) for cholangitis (after stent occlusion); and

0.05 (range: 0.01 - 0.10) for cholangitis mortality.

Methods used to derive estimates of effectiveness
Due to the lack of published data, the authors made some assumptions that were used in the decision model. Fourteen health care workers at the study institution derived the health state utilities, on the basis of a computer-generated questionnaire utilising the standard gamble technique.

Estimates of effectiveness and key assumptions
The authors assumed that all patients would undergo ERCP with the successful placement of either metallic or plastic stents. The utility weights were 0.21 (range: 0.10 - 0.50) for pancreatic carcinoma with jaundice, 0.27 (range: 0.20 - 0.65) for pancreatic carcinoma without jaundice, 0.15 (range: 0.05 - 0.30) for ERCP complications, and 0.11 (range: 0.05 - 0.50) for occlusion complications.

Measure of benefits used in the economic analysis
The benefit measure used in the economic analysis was the number of quality-adjusted life-months (QALMs) associated with the two strategies. The values of the health states were derived from the utility values obtained from a sample of health care workers at the authors' institution.

Direct costs
Discounting was not carried out due to the short time horizon of the study. The unit costs were reported for the inpatient and outpatient costs involved in treating patients with unresectable pancreatic carcinoma and referred to ERCP with plastic or metallic stent placement. Unit costs were also reported for ERCP complications, cholangitis, and outpatients visits. These cost items were estimated using average Medicare reimbursement rates, and included hospitalisation, laboratory tests, drugs, and specialised home care. The cost data were obtained from published studies where possible. The cost/resource boundary appears to have reflected the perspective of the third-party payer. The price year was 1999.

Statistical analysis of costs
No statistical analyses of the costs were performed.

Indirect Costs
The indirect costs were not included.

Currency
US dollars ($).
Sensitivity analysis
One- and two-way sensitivity analyses were performed to investigate the uncertainty of data used in the decision model. Most of the model inputs were varied within the ranges already reported. Threshold analyses were also performed.

Estimated benefits used in the economic analysis
The estimated QALMs were 1.832 in the metal stent group and 1.799 in the plastic stent group. Thus, the metal stents resulted in a gain of 0.033 QALMs.

Cost results
The total costs were $13,446 in the metal stent group and $13,879 in the plastic stent group. Consequently, the metal stents resulted in cost-savings of $433.

Synthesis of costs and benefits
The costs and the benefits were combined using an incremental cost-utility analysis. However, the calculation of a cost-utility ratio was unnecessary as the metal stents dominated the plastic stents, that is, they were less effective and more costly. The sensitivity analyses indicated that expected survival with pancreatic cancer was the only variable that could affect the dominance of metal stents. The threshold analysis showed that metal stents were considered cost-effective (below the threshold of $8,333 per QALM, derived from the threshold of $50,000 per quality-adjusted life-years) if the expected patient survival was longer than 6 months.

Authors' conclusions
Initial endoscopic placement of metal stents proved to be a cost-effective intervention when compared with initial plastic stent placement. In particular, in those patients expected to survive longer than 6 months. The placement of plastic stents would only be cost-effective in patients who were expected to survive less than 3 months.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the technologies was clear. The authors justified the selection of the interventions, and described the advantages and disadvantages of the two types of stents. You should assess whether they represent widely used interventions in your own setting. In particular, would there be another established technology for comparison with endoscopic placement of metal stents?

Validity of estimate of measure of effectiveness
The effectiveness data were derived from a review of published studies. The authors reported the source searched and the design of the primary studies. However, the narrative methods used to combine the effectiveness estimates, and the impact of differences among the primary studies, were not discussed. In addition, assumptions were made in the decision model.

Validity of estimate of measure of benefit
The benefit measure was the number of QALMs gained with the two interventions. It was modelled using a Markov process, which was appropriate. The utility values were derived using a small sample of patients, but the results of the analysis were quite robust to variations in the estimated quality weights.

Validity of estimate of costs
The perspective of the analysis was incorrectly reported. It would appear that the cost/resource boundary of the third-party payer was selected, as reimbursement rates were used to estimate the costs included in the analysis. The price year was reported, and discounting was not carried out since the time horizon of the study was quite short. Statistical analyses of the costs and quantities were not carried out. However, several sensitivity analyses were performed, thus
demonstrating generalisability and robustness to bias.

**Other issues**
The authors made some comparisons of their finding with those from other studies. The issue of the generalisability of the study results to other settings was not specifically addressed. However, several sensitivity analyses were performed and the results were reported in detail. The authors pointed out that their findings should be limited to a population of patients with unresectable pancreatic carcinoma, in whom the major objective is palliative relief of obstructive jaundice.

**Implications of the study**
The analysis indicated that metal stents should be used for the treatment of patients with unresectable pancreatic cancer. However, the decision on which type of stent to place may depend on the local resources available, and the individual endoscopist’s expertise with a particular type of stent.

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