Cost analysis of magnetic resonance cholangiography in the management of inoperable hilar biliary obstruction

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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 use of magnetic resonance cholangiopancreatography (MRCP) to visualise Klatskin tumours and to identify the hepatic duct suitable for stent placement without the injection of contrast material, in the treatment of patients with advanced and incurable Klatskin tumours of Bismuth type II, III, and IV. The use of MRCP avoided bilateral contrast injection and decreased the risk of postprocedural bacterial cholangitis caused by undrained contrast material.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study sample comprised a hypothetical cohort of patients with malignant hilar obstruction involving both hepatic ducts (Bismuth type II, III or IV). It was assumed that the patients had not yet undergone ERC or MRCP.

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

Dates to which data relate
The effectiveness and resource use data were derived from studies published between 1976 and 2001. The price year appears to have been 2001.

Source of effectiveness data
The effectiveness evidence was derived from a non-systematic review of published studies and the authors’ assumptions.

Modelling
A deterministic decision model was constructed to estimate the costs of the two alternative strategies considered in the study. The model was based on a decision tree, whose main branches represented the two alternative strategies. One alternative was the use of MRCP to determine the most suitable hepatic duct (left or right) across which to place a biliary stent, and then to proceed to ERC without injecting contrast material and to place the biliary stent across the preferred side. The other alternative was to proceed with ERC by injecting contrast material in both hepatic ducts and attempt bilateral biliary stent placement. The structure of the decision tree was reported graphically. The time horizon of the model was not explicitly reported, but it reflected the short natural history of the disease.
Outcomes assessed in the review
The model inputs estimated from the primary studies were:

- the rates of technical success of unilateral biliary stent placement, bilateral stent placement, and plasma thromboplastin component (PTC) after failed ERC;
- the postprocedural complication rates for unilateral stent placement after bilateral contrast injection, for bilateral contrast injection, and for unilateral stent placement without contrast injection;
- the median survival after unilateral stent placement with bilateral contrast injection, after bilateral stent placement with bilateral contrast injection, and after unilateral stent placement without contrast injection;
- the postsurgical complication rate; and
- the surgical mortality rate.

Study designs and other criteria for inclusion in the review
The review of the literature does not appear to have been systematic, but the authors stated that all peer-reviewed articles from 1976 to 2001 were considered. The designs of the primary studies used to provide the model parameters were not reported.

Sources searched to identify primary studies
Not reported.

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

Methods used to judge relevance and validity, and for extracting data
Not stated. However, the authors stated that the data were extracted from studies with comparable study populations.

Number of primary studies included
The effectiveness evidence was derived from 39 primary studies.

Methods of combining primary studies
Not stated.

Investigation of differences between primary studies
Not stated.

Results of the review
The rate of technical success was 92% (range: 70 - 100%) for unilateral biliary stent placement, 77% (range: 40 - 90) for bilateral stent placement, and 70% (range: 60 - 80) for PTC after failed ERC.

The postprocedural complication rate was 34% (range: 20 - 50) for unilateral stent placement after bilateral contrast injection and 15% (range: 2 - 25) for both bilateral contrast injection and for unilateral stent placement without contrast injection.

The median survival was 106 days after unilateral stent placement with bilateral contrast injection, 160 days after...
bilateral stent placement with bilateral contrast injection, and 115 days after unilateral stent placement without contrast injection.

The postsurgical complication rate and surgical mortality rate were both 20% (range: 5 - 30).

**Methods used to derive estimates of effectiveness**
The authors made some assumptions in the decision model.

**Estimates of effectiveness and key assumptions**
The authors assumed that:

- the patients referred for ERC or MRCP were similar;
- the patients had not yet undergone ERC or MRCP;
- the tumour was unresectable and the patient inoperable;
- no evidence existed that biliary stent placement would be technically easier before performing MRCP/ERC;
- contrast material was injected in both hepatic ducts;
- MRCP and ERC had equal sensitivity for the detection of malignant bile duct strictures
- the reintervention rates for stent occlusion, migration, or obstruction were similar in both arms of the decision tree.

Low procedural-related mortality for ERC and PTC were not considered in the model. Some of the assumptions were made on the basis of data coming from the literature, but it seems that the authors have not extracted these data from the literature review.

**Measure of benefits used in the economic analysis**
The summary benefit measure used in the economic evaluation was survival. This was derived from the effectiveness analysis and not from the decision model.

**Direct costs**
Discounting was not relevant due to the short time horizon of the model. The health services included in the economic evaluation were ERC with biliary stent placement, the treatment of ERC complications, PTC, choledochojjunostomy, choledochojjunostomy with complications, and MRCP. For each category of costs, the inpatient/outpatient reimbursement rates and the corresponding physician fees were reported when diagnosis-related group (DRG) estimates were not available from the Medicare reimbursement system. The cost/resource boundary of the study appears to have been that of the reimbursement system, although it was not explicitly reported. Resource use was mainly estimated from the probability rates evaluated in the review of the literature and from the authors’ assumptions. The price year appears to have been 2001. The total estimated costs were obtained through the decision model.

**Statistical analysis of costs**
The costs were treated deterministically, but ranges were reported and were calculated by adding or subtracting 25% to or from the baseline estimates.

**Indirect Costs**
The indirect costs were not included.
Currency
US dollars ($).

Sensitivity analysis
One- and two-way sensitivity analyses were carried out to evaluate the robustness of the estimated costs to variations in the main model inputs. The ranges used in the analysis were those reported in the literature for probability values and were the +/-25% changes for the costs. A threshold analysis, in which patient survival was varied, was conducted to determine the limits of survival that influence the cost-effectiveness of the study intervention.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The estimated total costs per patient were $3,806 with MRCP and $4,275 with double stent placement. Thus, in a cost-minimisation framework, MRCP offered the most convenient option with cost-savings of $469. This result was sensitive to the complication rate of bilateral stent placement. MRCP remained the least costly approach, provided that the complication rate of bilateral stent placement was greater than 3%.

Synthesis of costs and benefits
An incremental cost-effectiveness ratio was calculated to combine the costs and benefits of the two study interventions. The incremental cost per life-year gained with double stent placement relative to MRCP was $3,908 per life-year gained. This figure was sensitive to survival duration. The threshold analysis showed that double stent placement could only become the most cost-effective option with a gain in survival, relative to MRCP, of greater than 7 days.

Authors' conclusions
The use of magnetic resonance cholangiopancreatography (MRCP) to guide biliary stent placement in inoperable hilar obstruction reduced the costs of the intervention. The gain in terms of survival was not clearly defined.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. Placement of bilateral biliary stents using ERC was selected as the basic comparator because it represented the standard approach for stent placement required for inoperable malignant hilar obstruction. The authors justified their choice of plastic stents in place of metallic ones. You should decide whether it represents a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The analysis of effectiveness used data derived from a non-systematic review of published studies. The method and conduct of the review were not reported. The search method and design of the primary studies were not described, and neither was the method used to combine the estimates extracted from the primary studies. The authors only reported that the data were extracted from studies with comparable study populations. Intervals for the sensitivity analysis, which investigated variability in the data and uncertainty in the probability values used, were defined using ranges of values observed in the literature. The assumptions made were not investigated, which represents a weakness of the effectiveness study.

Validity of estimate of measure of benefit
The benefit measure was derived from the data obtained from the review of the literature used for the effectiveness analysis (see previous section for comments in relation to its validity). However, it is worth noting that the use of survival as a summary benefit measure enables comparisons to be made with the benefits of other health care
interventions.

Validity of estimate of costs
The perspective adopted in the study was supposed to be societal, although the indirect costs were not included. It was unclear whether the reimbursement rates represented actual opportunity costs from a societal perspective. A detailed breakdown of the costs was not provided as macro-categories (DRG) were reported. A decision model was constructed to estimate the overall costs of the two alternative strategies considered. The price year appears to have been implicit, thus facilitating reflation exercises in other settings. The authors acknowledged that geographic variations were observed and ranges of cost estimates were considered in the sensitivity analysis. The authors stated that the extra costs associated with antibiotic use were not considered.

Other issues
The authors made several comparisons with other studies and discussed the flaws and strengths of the results obtained in the other articles. The authors stated that, in the presence of conflicting results (above all those concerning the survival gain with MRCP over the standard approach), some caution should be maintained when interpreting the results of the cost-effectiveness analysis, while the conclusions of the cost-minimisation approach are more reliable. The issue of the generalisability of the study results to other settings was partially addressed through the sensitivity analysis, especially on the cost side of the analysis.

Implications of the study
The authors suggested that their findings should be confirmed in prospective trials, in particular the evaluation of the impact of the two strategies on patient survival.

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