Cost-effectiveness analysis of alternative strategies for palliation of distal biliary obstruction after a failed cannulation attempt

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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
Two methods of metallic biliary stent placement for palliation of jaundice were examined. The methods were precut sphincterotomy (precut) and percutaneous transhepatic cholangiography (PTC).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The target population comprised patients with a confirmed inoperable distal malignant biliary obstruction for which ERCP cannulation had failed.

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

Dates to which data relate
Peer-reviewed articles published between 1976 and 2001 were included in the review, whereas the effectiveness data were derived only from studies published between 1977 and 1997. The dates to which resource use related were not reported. The costs appear to have been estimated for 2001.

Source of effectiveness data
The effectiveness data were based on evidence derived from the literature.

Modelling
A decision tree model was used to calculate the total costs associated with each treatment strategy.

Outcomes assessed in the review
The outcomes assessed in the review were:

the success of precut,
the success of second ERCP.
the success of PTC,

the complication rate of precut,

the complication rate of ERCP,

the complication rate of PTC, and

the surgical complication rate.

Study designs and other criteria for inclusion in the review
Details of the study designs included in the review were not reported. The probabilities for precut sphincterotomy, PTC and surgery were taken from studies that included patients with distal inoperable malignant biliary obstruction and a dilated common bile duct. Survival data were obtained from studies of patients with inoperable biliary malignancy of varying etiologies (pancreatic head adenocarcinoma, cholangiocarcinoma and gall bladder cancer).

Sources searched to identify primary studies
Not reported.

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

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

Number of primary studies included
The authors listed 20 studies as providing effectiveness data, but references were only supplied for 19 of these.

Methods of combining primary studies
Not reported.

Investigation of differences between primary studies
Not reported.

Results of the review
The success rates were 85% with precut, 90% with second ERCP, and 97% with PCT.

The complication rates were 10% with precut, 5% with ERCP, 5% with PTC, and 10% with surgery.

Measure of benefits used in the economic analysis
The life-years gained were reported separately in the economic analysis. However, details of how this measure was estimated, or how it was combined with the costs, were not given.

Direct costs
The resource costs and the quantities were not reported separately. Direct medical costs were estimated from the
Medicare Ambulatory patient classification plus professional fee for hospital-based outpatient procedures. These were converted to professional reimbursement payments with Medicare's 2001 national conversion factor. The costs included in the analysis were ERCP, diagnosis-related group (DRG) for ERCP complications, metallic biliary stent, PTC, DRG for PTC complications, DRG for choledochojejunostomy, and DRG for choledochojejunostomy complications. Discounting was not relevant. The study reported the average costs. The cost data appear to have referred to 2001.

**Statistical analysis of costs**
Statistical analyses of the costs or quantities were not reported.

**Indirect Costs**
The indirect costs were not reported.

**Currency**
US dollars ($).

**Sensitivity analysis**
A sensitivity analysis of the cost and effectiveness data was carried out to test the robustness of the model and to support the generalisability of the results. The costs were varied to account for variability in Medicare reimbursement rates between different regions, depending on local operating costs (+/- 25%). The effectiveness data were varied to account for variation in outcomes across practices. The outcomes varied were the success rates of precut (70 - 95%) second ERCP (80 - 100%) and PTC (90 - 100%), and the complication rates of precut (2 - 50%), ERCP (0 - 20%), PTC (0 - 20%), and surgery (2 - 20%). One- and two-way sensitivity analyses were conducted.

**Estimated benefits used in the economic analysis**
It was found that precut-PTC was marginally more effective than PTC, achieving a survival of 0.329 years (120 days) versus 0.326 years (119 days) for PTC.

**Cost results**
The costs of the different strategies were $1,595 for precut-PTC, $1,598 for precut-ERCP-PTC, $1,737 for precut-ERCP, and $1,843 for PTC.

It was also reported that, assessing costs alone, the precut-PTC approach was cheaper ($2,972) than PTC ($4,809).

Precut-PCT was found to be the most cost-effective strategy ($9,033/year) compared with PTC alone ($14,741/year).

**Synthesis of costs and benefits**
Reference was made to a cost per year of survival. However, the figures were not explicitly stated. An incremental analysis was not performed. The authors stated that the precut-PTC approach dominated the PTC approach, being both less costly and more effective.

**Authors' conclusions**
Precut sphincterotomy (precut) followed by percutaneous transhepatic cholangiography (PTC) (if necessary) was the most cost-effective strategy for palliative biliary stenting in the setting of malignant, distal, biliary obstruction after a failed endoscopic retrograde cholangio-pancreatography (ERCP) attempt.

**CRD COMMENTARY - Selection of comparators**
The choice of the comparator was not explicitly justified, although it would appear that the technologies chosen represented current practice. You should decide if this is a widely used health technology in your own setting.

**Validity of estimate of measure of effectiveness**
The authors did not state that a systematic review of the literature had been undertaken. The method used to combine the effectiveness measures was not reported. The authors recognised that the effectiveness estimates derived from different studies varied considerably, and consequently carried out sensitivity analyses around the baseline probability estimates.

**Validity of estimate of measure of benefit**
The estimation of benefits (years of survival) appears to have been obtained directly from the effectiveness analysis. No justification for this choice of estimate was provided. No details of how it was calculated were provided.

**Validity of estimate of costs**
It would appear that categories of cost relevant to the third-party payer perspective were included in the analysis. For each category of cost, the relevant costs were included. The costs and the quantities were not reported separately. A sensitivity analysis was conducted on the costs but not on the quantities. However, it was unclear how the cost per year was calculated. No details were given in the paper and the costs given appear to relate to a cost per x days being extrapolated to one year. The difference in effect of the two strategies was 1 day, and the authors claimed that this demonstrated that one strategy was marginally more effective than the other.

**Other issues**
The authors did not compare their results with findings from other studies. In addition, the issue of the generalisability to other settings was not addressed. The authors' conclusions reflected the scope of the analysis. They acknowledged that, in practice, precut might not be the optimal treatment strategy for all patients with inoperable distal malignant biliary obstruction. The authors did not report any further limitations to their study.

**Implications of the study**
The authors did not report any implications for policy or research.

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