Suspected sphincter of Oddi dysfunction Type II: empirical biliary sphincterotomy or manometry-guided therapy?

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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 techniques were examined:

endoscopic retrograde cholangiopancreatography (ERCP) with manometry, followed by biliary endoscopic sphincterotomy (ES) if the basal pressure was equal to or greater than 40 mmHg (strategy 1), versus ERCP with biliary ES, without manometry (strategy 2).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised a hypothetical cohort of patients with clinical criteria meeting suspected biliary Type II SOD according to the modified Milwaukee classification. To meet the inclusion criteria, the patients had to suffer from "biliary-type" pain and have a common bile duct diameter larger than 10 mm and/or serum alanine aminotransferase, aspartate aminotransferase, or alkaline phosphatase levels of at least twice the upper limit of normal on any occasion. Patients with suspected biliary SOD Types I and III were excluded, as were patients with suspected pancreatic SOD.

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

Dates to which data relate
The effectiveness and resource use data were derived from studies published between 1989 and 2002. The price year was 2001.

Source of effectiveness data
The effectiveness evidence was derived from a review of completed studies and authors' assumptions.

Modelling
A decision model, based on a deterministic tree, was constructed to assess the costs and clinical outcomes associated with the two strategies in a hypothetical cohort of 100 patients. The structure of the tree was reported. The model considered procedural complications and mortality over one year.
Outcomes assessed in the review
The health outcomes assessed were the probabilities of the following:

- prevalence of Type II SOD;
- the patients experiencing improvements over a one-year period with abnormal pressure (with ES) or normal pressure (with or without ES);
- procedural complications with manometry, ES, and manometry plus ES; and
- deaths due to complications.

Study designs and other criteria for inclusion in the review
Not stated.

Sources searched to identify primary studies
MEDLINE was searched using the keywords "SOD", "endoscopic retrograde cholangiopancreatography" and "SOM" (sphincter of Oddi manometry). Other relevant data were derived from two studies of the authors' experiences in their own setting.

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 data were derived from 11 primary studies.

Methods of combining primary studies
Not stated.

Investigation of differences between primary studies
Not stated.

Results of the review
The prevalence of Type II SOD was 41% (range: 15.9 - 60).

The probabilities of patients experiencing improvements over a 1-year period were 91% (range: 85 - 93) with abnormal pressure (with ES), 42% (range: 40% - 60) with normal pressure (with ES), and 33% (range: 30 - 50) with normal pressure (without ES).

The rates associated with procedural complications were 15% (range: 5 - 30) for manometry, 10% (range: 5 - 25) for ES, and 15% (range: 5 - 30) for manometry plus ES.

The rate of death due to complications was 5% (range: 0 - 50).
Methods used to derive estimates of effectiveness
The authors made some assumptions that were based on their own experiences and on data derived from the literature, although not explicitly derived from the review.

Estimates of effectiveness and key assumptions
It was assumed that the proportion of patients that experienced improvements after ES in the absence of prior manometry would be similar to that found for ES in a published study. In addition, 5% of patients who underwent ES would undergo manometry for persistent pain. Finally, prophylactic pancreatic stents would be used in both groups with similar complication rates.

Measure of benefits used in the economic analysis
The summary benefit measure was the proportion of patients experiencing an improvement after one year. This was derived from the decision model.

Direct costs
Discounting was irrelevant due to the short time horizon of the study. The unit costs and the quantities of resources used were not presented separately. The health services included in the economic evaluation were manometry, ES, manometry plus ES, clinic visits and procedural complications. The cost/resource boundary of the third-party payer was adopted. Resource use was estimated on the basis of published rates and the authors' assumptions. The costs were derived from current procedural terminology and diagnosis-related groups at the University of Alabama at Birmingham (AL), USA. The price year was 2001.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
The indirect costs were not included.

Currency
US dollars ($).

Sensitivity analysis
To address variability in the data, one-way sensitivity analyses were conducted on the key model inputs. A two-way sensitivity analysis was also performed, in which the probability of an abnormal manometry (based on the prevalence of Type II SOD) and the proportion of patients who improved after ES with normal sphincter pressures were varied simultaneously. Finally, the decision tree was modified to incorporate the need for manometry in patients who had undergone ERCP with ES, without manometry, with ongoing symptoms. The ranges used were derived from the literature.

Estimated benefits used in the economic analysis
The proportion of patients experiencing an improvement after one year was 55% with strategy 1 and 60% with strategy 2.

Cost results
The estimated total costs were $2,790 with strategy 1 and $2,244 with strategy 2.
Synthesis of costs and benefits
An incremental cost-effectiveness ratio was calculated to combine the costs and benefits of the two strategies. However, it was not really required since strategy 2 dominated strategy 1, being both more effective and less costly.

The results of the sensitivity analysis suggested that strategy 2 was cost-saving most of the time. However, the costs associated with strategy 2 were higher than those associated with strategy 1 when the cost of ES was higher than $1,728, the probability of complications due to ES was higher than 19%, and the probability of complications associated with manometry was less than 6%.

The two-way sensitivity analysis revealed that ES became the preferred strategy, even as the proportion of patients improving decreased, due to the high probability of improvements in patients with documented high pressures.

Authors’ conclusions
Compared with endoscopic retrograde cholangiopancreatography (ERCP) with manometry followed by endoscopic sphincterotomy (ES), empirical ES without manometry was the preferred strategy for treating patients suspected of having Type II sphincter of Oddi dysfunction (SOD).

CRD COMMENTARY - Selection of comparators
The choice of the comparators appears to have been appropriate, as both procedures represented standard approaches for treating patients with suspected Type II SOD. The authors noted that the strategy of “doing nothing” was not considered because the clinical question revolved around manometry. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The analysis of effectiveness used data derived from a review of the literature. However, details of the primary studies, and the methods used to extract the data and combine the studies, were not provided. More information would therefore be needed to assess the quality of the review. Only the sources searched were provided. Some assumptions were also made. It would appear that all the effectiveness estimates were varied in the sensitivity analysis, which was appropriate for increasing the robustness of the conclusions.

Validity of estimate of measure of benefit
The summary benefit measure was specific to the interventions considered in the study. Thus, it would be difficult to compare with the benefits of other health care interventions. The benefit measure was derived from the decision model.

Validity of estimate of costs
The authors explicitly reported the perspective adopted in the study and it appears that all the relevant categories of costs have been included. The cost estimates were derived from sources consistent with the perspective adopted. However, the unit costs and the quantities of resources used were not reported, and statistical tests on the costs were not conducted. The price year was reported, which facilitates reflation exercises in other settings. The cost estimates were varied in the sensitivity analysis.

Other issues
The authors made some comparisons of their findings with those from other studies. They partially addressed the issue of the generalisability of the study results to other settings. Sensitivity analyses were conducted to address variability in the data. The authors noted that their results should be limited to the population of patients considered in the study. Caution is required when interpreting the conclusions of the analysis in other contexts.

Implications of the study
The authors stressed that clinical trials should be conducted before recommending the use of empirical biliary ES (without manometry) for patients with suspected Type II SOD.

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**Other publications of related interest**


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