Costs of managing Helicobacter pylori-infected ulcer patients after initial therapy

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
Three alternative approaches to managing patients previously treated for peptic ulcer disease and Helicobacter pylori infection were considered in the study: urease breath test (UBT), a non-invasive test to detect Helicobacter pylori infection; endoscopy and a rapid urease test, to detect the presence of ulcer and Helicobacter pylori infection; and antimicrobial and antisecretory therapy (based on omeprazole, metronidazole, bismuth subsalicylate, and tetracycline).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population included patients with peptic ulcer disease and Helicobacter pylori infection and who had already completed initial antimicrobial and antisecretory therapy.

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

Dates to which data relate
Effectiveness data were derived from studies published between 1993 and 1999. Resource use data were gathered between 1992 and 2000. The price year was 1999.

Source of effectiveness data
The effectiveness evidence was derived from a review of published studies and from the opinion of an expert panel of physicians.

Modelling
A decision analytic model was constructed in order to compare the costs and outcomes of alternative approaches to managing a cohort of Helicobacter pylori-infected patients following completion of initial antimicrobial and antisecretory therapy in a one-year time horizon. The model was subdivided into two main branches according to the patient symptoms as follows:

for symptom-free patients (model 1), UBT was compared to observation with no further testing or treatment;

patients with persistent symptoms (model 2) received UBT, repeated endoscopy, or repeated antimicrobial and antisecretory therapy without any testing.
The model was constructed on the basis of a specific clinical status of the patients, which was carefully described.

Outcomes assessed in the review
The outcomes assessed in the review and used as parameters in the model were as follows:

- the rates of duodenal or gastric ulcer and of Helicobacter pylori infection (with or without ulcer);
- the probabilities of erosive oesophagitis and cancer;
- the specificity and sensitivity of rapid urease test, histology, and UBT;
- the probabilities of ulcer healing and Helicobacter pylori cure with initial antimicrobial and antisecretory therapy after initial therapy.

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

Sources searched to identify primary studies
Not stated.

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
Five primary studies were used as sources of effectiveness evidence.

Methods of combining primary studies
Effectiveness estimates were not combined given that each estimate was derived from only a single published paper.

Investigation of differences between primary studies
Not reported.

Results of the review
The results of the review were as follows:

- The rate of duodenal or gastric ulcer was 0.09; the rate of Helicobacter pylori infection was 0.73 given an ulcer, and 0.50 given no ulcer.
- The probabilities of erosive oesophagitis and cancer were respectively 0.14 and 0.03.
- The specificity and sensitivity were respectively 0.90 and 1 for the rapid urease test, 0.93 and 0.99 for the histology, and 0.95 and 0.96 for UBT.
- The probabilities of ulcer healing and Helicobacter pylori cure with initial antimicrobial and antisecretory therapy were
0.73, both after initial therapy and at one year.

**Methods used to derive estimates of effectiveness**
Several effectiveness measures were derived from a panel of six physicians with expertise in treating dyspepsia and peptic ulcer disease. The panel comprised four gastroenterologists, a general internist, and a family practitioner, representing academic, private practice and managed care settings.

**Estimates of effectiveness and key assumptions**
The panel estimated several effectiveness outcomes.

- The sensitivity and specificity for ulcer detection with endoscopy were 0.95 and 1 respectively.
- The probability of initial antimicrobial and antisecretory therapy at one year was 0.73.
- The probability of repeat antimicrobial and antisecretory therapy at one year was 0.70.
- The effectiveness of antisecretory therapy at one year was 0.04.

In symptomatic patients the rates of persistent ulcer was 0.05 after initial therapy, and 0.70 at one year.

It was also assumed that all patients with a healed ulcer would be symptom free, both following initial therapy and at one year.

**Measure of benefits used in the economic analysis**
The benefit measure used in the economic analysis was the rate of symptomatic ulcer at one year associated with each approach in the two models.

**Direct costs**
Discounting was not relevant because costs occurred over a period of time less than two years. The costs included in the study were drug prices, charges for physician’s visits and wholesale prices for the diagnostic tests. Quantities and costs were not reported separately and their estimation was based on actual data derived from average charges and retail prices. Costs of severe adverse events associated with endoscopy were also included and were based on the national average Medicare operating payment. The boundary adopted was that of the third party payer. Resource data were gathered between 1992 and 2000. The price year was 1999.

**Statistical analysis of costs**
No statistical analysis of costs was reported.

**Indirect Costs**
Indirect costs were not included.

**Currency**
US dollars ($).

**Sensitivity analysis**
One-way sensitivity analyses were carried out to investigate variability in cost and effectiveness data in both models.
Estimated benefits used in the economic analysis
In model 1, the rate of symptomatic ulcer at one year was 6.1% for the UBT strategy and 18.2% for the observation option.

In model 2, the rate of symptomatic ulcer was 23.3 for the UBT, 23.8 for the endoscopy, and 21.0 for the repeat therapy.

Cost results
In model 1, the expected total cost per patient over one year was $591 for the UBT and $480 for the observation strategy.

In model 2, the expected total cost per patient was $1,122 for the UBT, $1,787 for the endoscopy, and $766 for the repeat therapy.

Synthesis of costs and benefits
In model 2, the repeat therapy was dominant, because it was associated with lower expected total costs and resulted in a lower rate of symptomatic ulcer than the other approaches.

In model 1, costs and benefits were not combined. However, the authors stated that the cost of UBT was only $111 greater than the cost of the observation strategy and the rate of symptomatic ulcer at one year was almost three times lower for the UBT compared with observation.

The results of the sensitivity analyses showed that in model 1 the benefit measure was particularly sensitive to changes in the effectiveness of the initial antimicrobial and antisecretory therapy, and that the cost estimates were influenced by the effectiveness of the initial therapy and the price of the UBT.

In model 2, although the results were sensitive to changes in costs and probability parameters, the repeat therapy continued to dominate the other two approaches.

Authors' conclusions
The authors concluded that, according to the model results, symptom-free patients should undergo UBT. For symptomatic patients, on the other hand, repeat antimicrobial therapy should be prescribed, rather than UBT or endoscopy.

CRD COMMENTARY - Selection of comparators
The selection of the health technologies considered in the study was based on the commonly used strategies for managing Helicobacter pylori-infected ulcer patients.

Validity of estimate of measure of effectiveness
The validity of the effectiveness measures could be limited given that a systematic review of the literature was not undertaken and that some estimates were derived from experts' opinion. The authors acknowledged that some probability estimates (especially those regarding specificity and sensitivity of the diagnostic tests) could not be correct and therefore the model outcomes may not have been precise. Several sensitivity analyses were performed in order to overcome this limitation.

Validity of estimate of measure of benefit
The benefit measure was derived from the analytic decision model and seems appropriate to the disease considered.
Validity of estimate of costs
The estimations of the costs were limited to direct costs. The adoption of a societal perspective and the inclusion of indirect costs could have changed the model findings. Given that cost estimations were mostly based on average retailer prices, the values used in the model were likely to be specific to the US setting.

Other issues
The main limitation of the study was that costs and benefits were not combined and an incremental analysis was not carried out. This could have been very useful in model 1, where no strategy dominated the other. In addition, although several sensitivity analyses were performed, the issue of the generalisability to other settings was not specifically addressed.

Implications of the study
The current standard of care for Helicobacter pylori-infected ulcer patients was the prescription of an initial course of antimicrobial and antisecretory therapy. The implication of the study indicates that it is necessary to distinguish between symptom-free and symptomatic patients: the former should undergo UBT, the latter should be prescribed repeat therapy.

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