Cost-effectiveness of routine endoscopic biopsies for Helicobacter pylori detection in patients with non-ulcer dyspepsia

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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
Routine biopsies for the detection of Helicobacter pylori (H. pylori) at upper endoscopy in patients with nonulcer dyspepsia (NUD) were examined. Two main strategies at diagnostic endoscopy were compared. One involved performing a biopsy for the detection of H. pylori with a rapid urease test (RUT), while the other did not involve taking a biopsy. The biopsy strategy had 2 sub-strategies. The gastroenterologist had the choice to confirm a negative RUT result by sending the biopsy for histopathologic examination, or to rely solely on the result of the RUT.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients younger than 45 years of age without heartburn-predominant symptoms of dyspepsia. Patients presenting with symptoms of gastroesophageal reflux disease, alarm symptoms (e.g. weight loss, recurrent vomiting, dysphagia, bleeding, or anaemia), biliary pain, or irritable bowel syndrome were excluded. Also excluded were those taking non-steroidal anti-inflammatory drugs.

Setting
The setting was unclear but it was either secondary care or tertiary care. The economic study was conducted at McGill University Health Centre and the Department of Clinical Epidemiology, Montreal (PQ), Canada.

Dates to which data relate
The effectiveness data were derived from studies published between 1966 and 2003. The price year was 1999.

Source of effectiveness data
The effectiveness data were derived from a review and synthesis of published studies, supplemented by assumptions made by an expert panel.

Modelling
A clinical decision-making model was conducted to compare the costs and effectiveness of the two strategies (taking a biopsy for the detection of H. pylori with an RUT, or not taking a biopsy). A 12-month time horizon was adopted.

Outcomes assessed in the review
The outcomes assessed were:

relief of symptoms, defined as the absence of symptom persistence or recurrence over the 12 months;
the sensitivity and specificity of the RUT for H. pylori diagnosis;
the sensitivity and specificity of histology for H. pylori diagnosis; and
the sensitivity and specificity of the urea breath test (UBT) for diagnosis.

Study designs and other criteria for inclusion in the review
A systematic review was carried out to identify relevant studies. The study designs and inclusion criteria for the review were not reported.

Sources searched to identify primary studies
MEDLINE and Current Contents were searched for relevant 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
Approximately 25 studies were included in the review.

Methods of combining primary studies
Although the authors did not report how the primary studies were combined, it would appear that the results of different primary studies were pooled using a meta-analysis.

Investigation of differences between primary studies
Not stated.

Results of the review
The prevalence of H. pylori among adults under 45 was 36% (range: 33 - 39.4).

The H. pylori negative rate after H. pylori eradication at 1 year was 62.1% (range: 58.8 - 77).

The H. pylori negative rate before and after antisecretory treatment at 1 year was 62.1% (range: 50 - 100).

The H. pylori negative rate before and after H. pylori eradication attempt at 1 year was 72% (range: 76 - 93). Note that a different source was used for the baseline figure and the range, hence the fact that the baseline is not in the range.

The sensitivity of the RUT for H. pylori diagnosis was 94.5% (range: 87.7 - 99) and the specificity was 97% (range: 92.6 - 100).

The sensitivity of histology for H. pylori diagnosis was 94% (range: 91.1 - 96) and the specificity was 98% (range: 95 - 100).
The sensitivity of the UBT for H. pylori diagnosis was 96% (range: 90.2 - 100) and the specificity was 97% (range: 89 - 100).

**Measure of benefits used in the economic analysis**
The primary outcome measure used was the proportion of patients "cured". This was defined as patients remaining symptom-free over a 12-month period after initial therapy.

**Direct costs**
The costs were not discounted, which was appropriate as the time horizon of the study was only 12 months. Only the direct medical expenses were included since the chosen cost perspective was that of a public payer. The direct costs were for pharmacologic treatments, physician visits and diagnostic tests. The quantities and the costs were reported separately. The quantities and costs were estimated from actual data. These were measured in 1999 Canadian dollars.

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

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

**Currency**
Canadian dollars (Can$). An approximate exchange rate was US$1.00 = Can$1.50.

**Sensitivity analysis**
One- or two-way sensitivity and threshold analyses were performed on all probability assumptions and cost variables.

**Estimated benefits used in the economic analysis**
Endoscopy without biopsy cured 34.34 patients per 100 NUD patients.

Endoscopy with biopsy and an RUT cured 37.06 patients per 100 NUD patients.

Endoscopy with biopsy and an RUT, plus histology if the RUT result was negative, cured 37.21 patients per 100 NUD patients.

The incremental effectiveness of endoscopy with biopsy over endoscopy without biopsy was 2.72 more patients cured per 100 NUD patients.

The RUT plus histopathologic evaluation cured 0.15 more patients per 100 NUD patients than with the RUT alone.

**Cost results**
The total cost per 100 NUD patients was $74,601 for endoscopy without biopsy, and $85,317 for endoscopy with biopsy and the RUT.

The incremental cost of endoscopy with biopsy over without biopsy was $10,716 per 100 NUD patients.

The incremental cost of the RUT plus histopathologic evaluation over the RUT alone was $3,829 per 100 NUD patients.
Synthesis of costs and benefits
Average and incremental cost-effectiveness ratios were calculated to combine the costs and benefits of the treatment strategies. The average cost per patient cured was $2,172 without biopsy at endoscopy, $2,302 with biopsy and an RUT, and $2,396 with biopsy and an RUT plus histopathologic evaluation. The incremental cost per additional patient cured was $3,940 with biopsy and an RUT over without biopsy. Compared with biopsy and the RUT alone, the incremental cost per patient cured was $25,529 with biopsy and an RUT plus histopathologic evaluation.

The results were sensitive to the difference in symptomatic recurrence rates at 1 year between patients in whom H. pylori were successfully and unsuccessfully eradicated, which in this study was set at 9.9%. Only when the difference in symptomatic recurrence in patients with successful versus unsuccessful eradication fell to less than 4% was endoscopy with biopsy over $10,000 per cured patient greater than endoscopy without biopsy. Otherwise, the results for the base-case were generally robust to variations in all probability and cost variables across clinically relevant ranges.

Authors' conclusions
In adults with nonulcer dyspepsia (NUD) who were undergoing endoscopy and were younger than 45 years, the routine procurement of a biopsy specimen for the detection of Helicobacter pylori (H. pylori) was more costly yet more effective than not obtaining a specimen. The cost-effectiveness of a biopsy was dependent on the benefits of H. pylori eradication in the patient population. The less likely a patient with NUD is to become asymptomatic after successful H. pylori eradication, the more costly a strategy involving routinely obtaining a specimen at endoscopy would be. The additional cost of sending a specimen for histopathologic analysis if the rapid urease test (RUT) results were negative does not appear warranted based on cost-effectiveness considerations.

CRD COMMENTARY - Selection of comparators
The authors did not provide an explicit justification for their choice of the comparators.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from data derived from the literature. A systematic review of the literature was conducted to identify model inputs. The most commonly used electronic databases were searched, but the methods and conduct of the review were not reported. In addition, no information on the primary studies was provided.

Validity of estimate of measure of benefit
The patients cured were used as the summary measure of health benefit. This was taken directly from the effectiveness analysis.

Validity of estimate of costs
The authors limited their analysis to direct medical costs to a public payer. Charges to the patients were not included. The costs relating to the possibility of developing oesophagitis after H. pylori eradication, or any resulting increased antibiotic resistance in the community, were not considered. The differences in practice patterns and resource costs between the USA and Canada were taken into consideration in the sensitivity analyses.

Other issues
The authors made extensive comparisons of their findings with those from other studies. They did not address the issue of the generalisability of their results to other settings.

Implications of the study
The authors concluded "The cost-effectiveness of a biopsy is dependent on the benefits of H. pylori eradication in this patient population... The additional cost of sending a specimen for histopathologic analysis if the rapid urease test is negative does not appear warranted based on cost-effectiveness considerations”. However, the authors did not make any
recommendations for policy or practice. No further research was explicitly identified.

**Source of funding**
Supported in part by an "at arms length" grant from AstraZeneca, Canada.

**Bibliographic details**

**PubMedID**
12838214

**DOI**
10.1067/mge.2003.295

**Other publications of related interest**


**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Adult; Biopsy, Needle /economics /methods; Breath Tests; Canada; Cohort Studies; Cost-Benefit Analysis; Dyspepsia /diagnosis /economics /microbiology; Female; Gastroscopy /economics /statistics & numerical data; Health Care Costs; Helicobacter Infections /diagnosis /economics; Humans; Male; Middle Aged; Sensitivity and Specificity

**AccessionNumber**
22003001014

**Date bibliographic record published**
31/05/2005

**Date abstract record published**
31/05/2005