Quality of life measurement clarifies the cost-effectiveness of Helicobacter pylori eradication in peptic ulcer disease and uninvestigated dyspepsia

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 health technologies considered in the study were a strategy of screening for Helicobacter Pylori infection (urea breath test) and the empirical anti-secretory and antimicrobial therapy for the eradication of Helicobacter Pylori in patients suffering from dyspepsia and peptic ulcer.

Type of intervention
Diagnosis and treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised adult patients suffering from dyspepsia and peptic ulcer and at risk of Helicobacter pylori.

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

Dates to which data relate
The effectiveness evidence and resource use data were gathered from studies published between 1995 and 1999. The price year was 2000.

Source of effectiveness data
Effectiveness evidence was derived both from a single study and from a review of published studies. The single study provided the estimation of patients' utility values to calculate QALYs. The literature review was performed to derive cost-effectiveness ratios for different treatments. Several effectiveness outcomes (to be combined with utility estimates for the final calculation of the QALYs) were also derived from published papers.

Study sample
The patients enrolled in the study were members of a large Northern California Health Maintenance Organisation (HMO) who were participating in the STOMACH (Study of Management and Costs of Helicobacter pylori Infection) investigation. Subjects who were treated with drugs after a diagnosis of duodenal, gastric, and peptic ulcer, or gastritis, were identified through pharmacy record review and contacted by mail. Of the 650 people in the STOMACH study, a sample of 73 patients (average age 57 years, 59% female) was selected. Patients were excluded if they showed the presence of classic gastroesophageal reflux disease without a documented peptic ulcer, were aged under 18 years or over 80 years, had upper GI tract malignancy, a contraindication to endoscopy, or were pregnant.
Study design
The study was carried out in California. It aimed to elicit patients' utility values for different health states associated with various levels of dyspepsia (mild, moderate, and severe). Trained interviewers interviewed each patient.

Analysis of effectiveness
The outcomes of the study were the estimates of utility values based on patients' preferences. The time-trade off method was used to obtain utility values. Patients' time value estimations were discounted at a rate of 3%. All the subjects were included in the same study group. A subgroup analysis was also performed on the basis of the different level of dyspepsia.

Effectiveness results
Among the entire cohort of patients, the estimated utility score was 0.87 for severe dyspepsia, 0.91 for moderate dyspepsia, and 0.92 for mild dyspepsia. The score of severe dyspepsia was significantly lower than the scores of mild and moderate dyspepsia, (p<0.0001). The utility results did not change when the respondents were stratified by age or by the presence of a diagnostically confirmed ulcer.

Clinical conclusions
The utility values needed to calculate QALYs were found to be higher in patients with severe dyspepsia than in patients with mild or moderate dyspepsia.

Modelling
A decision-analytic model was constructed to assess the clinical outcomes and costs of H. pylori eradication in patients suffering from dyspepsia and peptic ulcer. A strategy of test-and-treat was compared with a "do nothing" option. Patients who were positive at the urea breath testing were then treated for the eradication therapy of H. pylori. Patients who tested negative were given an initial trial of H2-receptor antagonists. Baseline assumptions included a H. pylori prevalence of 33% and an ulcer prevalence of 20% (80% of these ulcers were ascribed to H. pylori). Further details of the design and assumptions of the model were reported in a previously published paper.

Outcomes assessed in the review
The effectiveness outcomes assessed from different published papers were the annual rate of complications, the number of GI bleeding episodes, perforations and deaths, the number of "restricted activity days" and "bed days" per year, and the average number-needed-to-treat to prevent one clinically apparent ulcer.

A formal literature review was undertaken to identify studies reporting cost-effectiveness analyses of different treatment in terms of cost per additional ulcer cured or prevented. Only the dominant strategy (least costly and most effective) from each study was considered.

Study designs and other criteria for inclusion in the review
The primary studies included in the review to derive the incremental cost-effectiveness analysis were some articles comparing strategies for the treatment of H. pylori that produced an explicit incremental cost-effectiveness ratio in terms of cost per ulcer-related clinical event. The inclusion criteria for the other primary studies for the effectiveness outcome measures were not reported.

Sources searched to identify primary studies
The MEDLINE database (from 1966 to 2000) was searched, as well as reference lists from published articles, to identify the primary studies included in the review. The sources searched for the remaining effectiveness estimates were 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
Four primary studies were used for the effectiveness outcomes assessed. Five primary studies were reported for the estimation of cost-effectiveness ratios in the review.

Methods of combining primary studies
The authors did not report the method of combination of the primary studies.

Investigation of differences between primary studies
Not reported.

Results of the review
Among the effectiveness measures used to calculate QALYs, the annual rate of complication was 5%. The number of GI bleeding episodes was 92%, perforations 6%, and deaths 2%. The number of "restricted activity days" was 23 days per year and the number of "bed days" per year was 12. The average number-needed-to-treat to prevent one clinically apparent ulcer was 10 patients.

With respect to the formal review, the incremental costs per recurrent ulcer prevented or cured in the five studies (in the original currency) were Can$383 (in 1995), US$4,155 (in 1995), SEK 7420 (in 1996), US$5,781 (in 1997), and 240 (in 1998).

Measure of benefits used in the economic analysis
The benefit measure used in the economic analysis was the quality-adjusted life year (QALY), estimated through the time-trade off method to elicit patients' utility values.

Direct costs
Several cost items were included in the model to compute the total cost of each strategy. Only the costs of endoscopy, urea breath testing, rapid urease testing, Helicobacter pylori eradication therapy, and monthly maintenance antisecretory therapy were reported. Overall, very few details of the costs included in the decision model were reported, because the model was presented and discussed in another paper.

Due to space constraints associated with the 'Currency' fields the currency conversion rates are reported here:

National currencies were converted to US dollars in different years, as follows: in 1995, Can$1 = $0.75; in 1996, SEK1 = $0.1504; in 1998, 1 = $1.631.

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

Indirect Costs
Indirect costs were not included.

**Currency**
Currencies reported were Canadian dollars (Can$), Swedish kroner (SEK), US dollars ($), and UK pounds sterling ($). See ‘Direct Costs’ for conversion rates.

**Sensitivity analysis**
A sensitivity analysis was performed, but neither the parameters varied nor the type of analysis were indicated.

**Estimated benefits used in the economic analysis**
The disutility of an ulcer was equal to 0.11 QALYs, of which about 0.09 were attributable to dyspeptic symptoms and 0.02 were associated with complications including death.

**Cost results**
The total intervention costs of each strategy were not reported.

**Synthesis of costs and benefits**
A cost-effectiveness analysis was performed to combine the costs and QALYs of different strategies. Of the five cost-effectiveness analyses reported from the literature, three studies dealt with the treatment of peptic/duodenal ulcer and two studies focused on uninvestigated dyspepsia. Converting the effectiveness measure from ulcer cured or prevented into QALYs, the treatment of duodenal ulcer patients had a cost-utility ratio between $3,100 and $12,500 per QALY gained (range: $1,800 - $27,300). Empiric treatment of uninvestigated dyspeptic patients cost between $44,700 and $58,300 per QALY gained (range: $25,500 - $129,700). The results of the updated decision model indicated that for the "test and treat" strategy the cost-utility ratio was $26,800 per QALY gained. By varying some parameters of the model in the sensitivity analysis the incremental cost-utility ratio ranged from $15,00 to $58,600 per QALY gained.

**Authors’ conclusions**
Strategies based on the early eradication of Helicobacter pylori were cost-effective for patients with peptic ulcer and potentially cost-effective in patients with uninvestigated dyspepsia.

**CRD COMMENTARY - Selection of comparators**
The criteria for the selection of the main health technology and the comparator were not clearly stated. Further details about the interventions would have been useful.

**Validity of estimate of measure of benefit**
The benefit measure (QALY) was calculated by combining the results of a single study and some estimates derived from the literature. However, the utility values were derived from patients with chronic dyspeptic symptoms and then applied to published cost-effectiveness ratios whose populations were represented not only by patients with peptic ulcer but also people with uninvestigated dyspepsia. Therefore the baseline characteristics of the "QALY-population" could not be appropriate to update the published study results.

**Validity of estimate of costs**
Very few details of the costs included in the study were reported, given that the complete decision model had already been published elsewhere. It would have been interesting to have indicated the resources used in the papers derived from the literature review.
Other issues
The main purpose of the study (to update previously published estimates) was reached by combining estimates of benefits and costs derived both from a literature review and from a single study. However, even if some doubts remain about the mix of different pieces of information, the results of the study confirm those of previous studies. The authors recognised several limitations of the study. The main problem was that some estimates derived from the literature could not represent the true value of that specific parameter (i.e. the average number of symptomatic days per ulcer) and this could have biased the final results.

Implications of the study
The authors recommended undertaking the eradication of Helicobacter pylori in patients with peptic ulcer disease. Further economic, clinical, and epidemiological studies are necessary better to assess the cost-effectiveness of early Helicobacter pylori eradication in dyspeptic patients.

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