Helicobacter pylori eradication for peptic ulceration: an observational study in a Scottish primary care setting

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 eradication of Helicobacter pylori (Hp) in patients with chronic peptic ulcer disease (PUD), who required maintenance acid suppression in primary care, was under evaluation. Hp eradication consisted of a 1-week course of omeprazole (40 mg/day), metronidazole (400 mg three times daily), and amoxycillin (500 mg three times daily). Maintenance acid suppression consisted of either histamine-2 receptor antagonists or proton-pump inhibitors.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who had received a prescription for acid suppression therapy. Patients who were receiving regular repeat prescriptions, or who had been prescribed more than two prescriptions per year during the last two years, were included. Also included were patients taking low-dose aspirin, and patients with concomitant gastro-oesophageal reflux disease or hiatus hernia noted at the time of upper gastro-intestinal investigation. Patients receiving non-steroidal anti-inflammatory drugs were excluded, as were patients who had received Hp eradication therapy within the last 12 months and pregnant women.

Setting
The setting was primary care. The economic analysis was conducted in Glasgow, UK.

Dates to which data relate
The dates to which the effectiveness and resource use data related were not reported. The price year was 1998.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations were not reported. Of the 450 patients identified, 243 attended (mean age 58.4 +/- 0.9 years; 95 (39%) women). No patients refused a Helisal Rapid Blood Test (HRBT). A total of 199 (81.9%) patients were HRBT
positive and were offered Hp eradication therapy, while the remaining 44 (18.1%) patients were HRBT negative and
did not receive Hp eradication.

Of the 243 who had the HRBT, 43 patients also had a C urea breath test (UBT). If the HRBT was positive but the UBT
negative, patients were not given eradication therapy.

**Study design**
This was a case series study (using longitudinal analysis) that was conducted in seven general practices. The outcomes
were assessed for three follow-up periods, namely, second dyspepsia clinic visit, 6-month review and 2-year review.
After 6 weeks, patients who had received Hp eradication were invited back to the dyspepsia clinic. At 6 months,
prescription records were reviewed. At 2 years, a postal questionnaire was sent to all patients who had received Hp
eradication.

Data from those who had both the HRBT and UBT were used to derive the sensitivity and specificity of the blood test.

**Analysis of effectiveness**
The results were based on those for whom data were available at follow-up. The primary study outcomes used in the
study were:

- the per protocol eradication rate,
- dyspeptic symptoms and side-effects over the previous 2 weeks, and
- the need for the prescription of maintenance acid suppression therapy over 2 years.

The secondary study outcomes were the sensitivity and specificity of the HRBT.

Although the ages of the positive and negative groups were not significantly different (mean ages 57.7 +/- 1.0 years
versus 61.3 +/- 1.9 years), the HRBT-positive patients had PUD diagnosed at a younger age than the HRBT-negative
patients (45.4 +/- 1.3 years versus 51.7 +/- 2.0 years; p<0.5). In addition, 61.3% of HRBT-negative patients had
oesophageal symptoms at the initial assessment compared with only 49.2% of HRBT-positive patients, (p=0.05).

**Effectiveness results**
At 6 weeks, the authors said that the per protocol eradication rate was 91.7% and the intention to treat eradication rate
was 71.8%. The difference between these was not clear.

Of the 196 patients prescribed Hp eradication therapy, 156 (79.6%) re-attended the dyspepsia clinic 6 weeks after
treatment.

Sixty-three patients (40.4%) experienced side-effects of their treatment. Only 6 patients did not complete their Hp
eradication because of side-effects.

The sensitivity of the HRBT was 0.58 and the specificity was 0.88.

After 6 weeks, 105 (67.3%) patients felt their symptoms had improved after eradication therapy and there was a
significant reduction in reports of nausea and vomiting.

Six weeks after Hp eradication 119 (76.3%) of the 156 patients re-attending no longer required maintenance acid
suppression.

After 6 months, patients who had received eradication therapy were less likely to require maintenance acid suppression
therapy than those to whom eradication was not given.
Two years after treatment, 76.5% of patients felt their symptoms were improved, but 42.2% were still receiving maintenance therapy.

Predictors of symptomatic response, or of no longer requiring acid suppression therapy after 2 years, were:

younger age at onset of PUD, (p<0.01);

absence of pre-documented gastro-oesophageal reflux disease or hiatus hernia, (p<0.005);

symptomatic improvement 6 weeks after eradication, (p<0.005); and

the absence of co-morbid illness, (p<0.05).

Clinical conclusions
Community-based Hp eradication for patients with chronic PUD is effective, improving patients' symptoms and reducing the requirement for maintenance acid suppression. However, it does not completely alleviate dyspepsia.

Methods used to derive estimates of effectiveness
No summary benefit measure was used in the economic evaluation. In effect, a cost-consequences analysis was performed.

Direct costs
The health service costs were evaluated. The direct costs included the cost of Hp eradication and maintenance acid suppression therapy. The costs were calculated from the British National Formulary, September 1998. The unit costs and the quantities of resources used were not presented separately. The resource use data were based on actual data derived from the sample of patients involved in the effectiveness study. The costs were estimated over one month and, appropriately, discounting was not conducted.

Statistical analysis of costs
No statistical analysis of the costs was carried out.

Indirect Costs
No indirect costs were included in the analysis.

Currency
UK pounds sterling ( ).

Sensitivity analysis
Sensitivity analyses were not performed.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The estimated cost per patient per month of maintenance acid suppression therapy prior to Hp eradication was 20.23.

The cost of Hp eradication treatment per month per patient was 17.73.
Two years after Hp eradication, the estimated cost per patient per month of maintenance acid suppression therapy had fallen to 9.39.

**Synthesis of costs and benefits**
A synthesis of the costs and benefits was not relevant as a cost-consequences analysis was carried out.

**Authors' conclusions**
Helicobacter pylori (Hp) eradication was cost-effective after 2 years' follow-up in patients with chronic peptic ulcer disease (PUD).

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparators (no Hp eradication treatment) was clear. You should decide whether it represents a currently used approach in your own setting.

**Validity of estimate of measure of effectiveness**
The study was based on a case series analysis. This ensured that there were no systematic differences between the two groups in terms of demographics, and will also have improved the internal validity. However, a randomised controlled trial would have been a more appropriate design for the study question, introducing a control group who did not receive the intervention. Power calculations were not carried out. Hence, the sample size may have been of insufficient magnitude to obtain robust results. The false-positive and -negative results with HRBT testing might have had a real impact on the cost-effectiveness of Hp eradication, but the authors did not analyse this.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the economic evaluation which was, in effect, a cost-consequences analysis. The reader is referred to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

**Validity of estimate of costs**
The authors did not explicitly report the perspective adopted in the study, thus making it difficult to decide whether all the relevant categories of costs were included. The costs of testing were not included and no justification was given for their exclusion. This exclusion might have led to the underestimation of the potential economic advantage of Hp eradication. Few details on the unit costs and quantities of resources were reported, which limits the generalisability of the economic analysis to other settings. The price year was unclear, but it was likely to have been 1998. Discounting was not relevant and, appropriately, was not performed. No statistical analyses of the quantities or prices were carried out. The authors did not carry out any sensitivity analysis to estimate the impact of changes in the cost values. Consequently, caution should be exercised when extrapolating the cost results to different contexts.

**Other issues**
The authors made appropriate comparisons of their findings with those from other studies, highlighting differences in effectiveness results and similarities in cost-effectiveness conclusions. The issue of generalisability to other settings was not addressed. The results were not reported selectively and the effectiveness conclusions reflected the scope of the study. The authors did not point out any limitations of the study. Sensitivity analyses were not performed to account for variability in the cost or effectiveness data. Consequently, the external validity of the study may be low.

**Implications of the study**
The authors did not make any specific recommendations for policy or practice. However, they suggested that the UBT used in the study should prove to be an effective means by which Hp status can be detected in the community.
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Other publications of related interest

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