Cost-effectiveness of Helicobacter pylori eradication therapy at a company occupational health clinic in Japan

Yamasaki T

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
Proton-pump-inhibitor-based triple therapy for Helicobacter pylori (H. pylori) eradication was compared with H2-blocker maintenance therapy. H. pylori eradication therapy comprised omeprazole (20 mg once daily) plus amoxicillin (750 mg twice daily) and clarithromycin (200 mg twice daily), for 2 weeks. Maintenance therapy consisted of ranitidine (RAN), 150 mg daily for one year. Both alternatives were supplemented with omeprazole (20 mg once daily) when patients experienced ulcer recurrence.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised employees of a manufacturing industry in Japan who had been treated for dyspepsia at an on site clinic. The criteria for entry into the study included age 18 years or older, a diagnosis of active PUD, and H. pylori positivity confirmed by a rapid urease test.

Setting
The setting was tertiary care. The study was conducted in a company occupational health clinic in Japan.

Dates to which data relate
The effectiveness data were collected between October 1998 and March 2000. The dates during which the resource data were collected were not reported. The price year was also not reported.

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

Link between effectiveness and cost data
The costing was carried out retrospectively on a different sample of hypothetical patients to the actual sample used in the effectiveness study.

Study sample
The use of power calculations to estimate the influence of chance on the results was not reported. The sample was appropriate for the clinical study question since it comprised patients with H. pylori that could be eradicated.
nine patients participated in the study, of which 49 (28 with gastric ulcer and 21 with duodenal ulcer) received eradication therapy and 50 (27 with gastric ulcer and 23 with duodenal ulcer) received maintenance therapy. In the eradication therapy group, the male-to-female ratio was 48/1 and the age was 45.9 years (range: 19 - 61). In the maintenance therapy group, the male-to-female ratio was 50/0 and the age was 45.0 years (range: 20 - 62).

**Study design**
This was a prospective observational study. The patients effectively chose their preferred treatment. Patients who agreed and positively hoped for eradication therapy received this, while those that hesitated received maintenance therapy. The study was set in a single centre, the on-site occupational health clinic. Follow-up continued for 12 months. The author did not report any loss to follow-up.

**Analysis of effectiveness**
The basis of the analysis was the actual treatment received. The primary outcomes were the number of patients successfully eradicated, the number of patients remaining symptom free at the end of the 1-year observation period, and the lifetime probability of ulcer recurrence. The author reported that the two groups of patients had similar demographic and clinical characteristics.

**Effectiveness results**
For the H. pylori group, eradication was successful in 42 (86%) patients and remained successful after 1 year in 41 (84%) patients.

For the RAN therapy group, symptomatic ulcer recurrence occurred during continuous therapy for 12 months in 12 (24%) patients.

The lifetime probability of ulcer recurrence was 6.1% with H. pylori eradication and 24.0% with RAN alone.

**Clinical conclusions**
The author concluded that H. pylori was successfully eradicated in 86% of patients, and 98% of these patients remained symptom free for the 1-year study period. In addition, the lifetime probability of ulcer recurrence was significantly reduced with eradication therapy.

**Modelling**
A decision analytic model was constructed in Excel 5.0 to estimate the financial and clinical outcomes for 1 year after each initial management strategy, H. pylori eradication or RAN.

**Measure of benefits used in the economic analysis**
The author did not estimate a summary measure of benefit. In effect, a cost-consequences analysis conducted.

**Direct costs**
A perspective for the costing was not reported. The author did not state whether discounting was carried out, although discounting was not necessary since the time horizon was one year. The author estimated the cost of treating patients with H. pylori eradication and RAN maintenance therapy. Then identified likely patient pathways that included follow-up treatments and estimated the cost of H. pylori and RAN treatment strategies. The cost estimates were derived from direct payments identified by medical receipts for services received, and were therefore based on actual data. The direct medical costs included all medical tests and drugs. The unit costs were reported separately and the quantities were determined in the decision analytic model. A price year was not reported.
Statistical analysis of costs
A statistical analysis of the costs was not reported.

Indirect Costs
The indirect costs encompassed the charges for the patient's visit. These were calculated using the worker's wage.

Currency
Japanese yen (Y).

Sensitivity analysis
Sensitivity analyses were used to explore differences in the effectiveness estimates for the annual ulcer recurrence rate, probability of non-ulcer dyspepsia and the H. pylori eradication success rate. It was not stated whether one-way or multi-way sensitivity analyses were used. The ranges for the sensitivity analysis were identified from a review of the literature.

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

Cost results
The cost of treating a patient was Y 102,664 with H. pylori eradication therapy and Y 150,356 with RAN maintenance therapy.

Synthesis of costs and benefits
Not relevant as the study was a cost-consequences analysis.

Authors' conclusions
Compared with maintenance therapy with ranitidine (RAN), H. pylori eradication was a cost-effective therapy for patients with peptic ulcer disease (PUD).

CRD COMMENTARY - Selection of comparators
The author compared H. pylori eradication therapy with RAN maintenance therapy. These two alternatives were well justified with a discussion of currently available alternatives. Current practice in the author's setting was not reported.

Validity of estimate of measure of effectiveness
The basis of the study was a self-selected cohort design. Whilst this provides very useful initial results and an excellent basis for further work, the internal validity of the results would have been improved by randomising the patients to the possible treatments so as to avoid potential selection bias in the results. The study sample comprised patients who were diagnosed with PUD and were confirmed as H. pylori positive. Thus, it was representative of the study population. The author reported that the two groups demonstrated similar demographic and clinical characteristics. However, only gender, age, smoking status and alcohol intake appear to have been compared. Further comparisons in terms of clinical characteristics, which might highlight co-morbidities, would aid the reader in their understanding of the analysis presented and improve their confidence in the results. Appropriate sensitivity analyses were carried out to assess differences in the effectiveness estimates.

Validity of estimate of measure of benefit
The author did not estimate a summary measure of benefit. In effect, a cost-consequences analysis was conducted.

**Validity of estimate of costs**
A perspective for the cost analysis was not reported. However the author included estimates of relevant medical and drug costs, as well as the loss of employees’ work time, thus suggesting that a societal perspective was used. The unit costs were reported separately and the quantities were determined through a decision analytic model. This allows the reader to draw comparisons with their own setting and to assess the generalisability of the results.

**Other issues**
The author made appropriate comparisons of the findings with those from other published studies, suggesting that their own results and conclusions were in line with those of others. The issue of generalisability to other settings was not discussed, although the sensitivity analyses improved the extent to which the results might apply to other settings. In addition, the decision analytic frameworks allows the reader to re-estimate the results in their own setting for a particular population. The author did not present the results selectively. The conclusions drawn accurately reflected the results presented and the scope and design of the study.

Several limitations were discussed. For example, the short-term nature of the study, which was used to remove the need to extrapolate data beyond the length of the clinical study. Also, the inability to include less tangible benefits of treatment such as reduced ulcer pain, the convenience of not having to take medication once H. pylori is eradicated, and reduced patient anxiety.

**Implications of the study**
The results of the study lead eradication to be a dominant therapy. The author suggested that, on both clinical and economic grounds, H. pylori should be aggressively pursued in all patients receiving maintenance therapy (symptomatic or not) who have documented PUD. The need for future work was suggested in line with the limitations of the study that the author discussed.

**Source of funding**
None stated.

**Bibliographic details**

**PubMedID**
12066584

**Other publications of related interest**


Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Cost-Benefit Analysis; Female; Helicobacter Infections /drug therapy /economics; Helicobacter pylori; Histamine H2 Antagonists /economics /therapeutic use; Humans; Japan; Male; Middle Aged; Occupational Health Services /economics; Peptic Ulcer /drug therapy /microbiology

AccessionNumber
22002006417

Date bibliographic record published
30/11/2004

Date abstract record published
30/11/2004