Evaluation of the efficacy and the cost-effectiveness of proton pump inhibitor-based dual and triple therapy regimens for H pylori eradication in peptic ulcer disease


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 dual and triple therapy regimens for Helicobacter pylori eradication in peptic ulcer disease.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients suffering from either gastric ulcer or duodenal ulcer or both.

Setting
Hospital. The economic study was conducted in Osaka, Japan.

Dates to which data relate
Dates to which the effectiveness and resource data relate were not given.

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

Link between effectiveness and cost data
The cost data were derived retrospectively from the same sample which formed the clinical study.

Study sample
The study sample comprised 124 gastric ulcer patients, 103 duodenal ulcer patients and 7 patients who were suffering both from gastric and duodenal ulcer. These patients were selected from those who were examined and found to have active ulcers by endoscopy and who were also diagnosed as being H. pylori positive either by culture method or other conventional methods. They also provided written consent after the explanation of the aim of the treatments and their possible side effects. From the total of 234 patients, 125 were treated with omeprazole 20mg bid + amoxicillin 500mg qid + clarithromycin 400mg bid (OAC) (69 gastric ulcer patients, 53 duodenal ulcer patients and 3 gastric/duodenal ulcer patients). 109 patients were treated with omeprazole 20mg bid + clarithromycin 400mg bid (OC) (55 gastric ulcer patients, 50 duodenal ulcer patients and 4 gastric/duodenal ulcer patients).
Study design
The study was a randomized controlled trial at a single centre. The trial lasted for 14 days. 3 out of 234 patients dropped out of the trial due to side effects (skin inflammation, headache, vomiting and tongue inflammation).

Analysis of effectiveness
The analysis of effectiveness appears to have been based on intention to treat. The outcome assessed was the H. pylori eradication rate. No significant differences were observed between the two groups in their age, gender, ulcer history or smoking habits.

Effectiveness results
Overall 202 out of 234 cases resulted in successful H. pylori eradication. The eradication rate with OAC was 87.6% (92/105) (95% Confidence Interval (CI): 81 - 94%), which was significantly higher than that with OC (61.9% (60/97) 95% CI: 52 - 72%),(p<0.001, chi-square test). Among gastric ulcer cases, the eradication rate with OAC was 83.9% (47/56) and with OC was 59.2% (29/49). Among duodenal ulcer patients the eradication rate with OAC was 91.5% (43/47) and with OC was 70.5% (31/44).

Clinical conclusions
As the eradication rate with OAC (omeprazole 20mg bid + amoxicillin500mg qid + clarithromycin 400mg bid) was significantly higher than that with OC (omeprazole 20mg bid + clarithromycin 400mg bid), OAC is more effective than OC.

Modelling
A Markov model was used to estimate the accumulated costs of treatments by the proton pump inhibitor based dual and triple therapy and the conventional method for a five year period. The cost results were based on the effectiveness results derived from the clinical trial.

Measure of benefits used in the economic analysis
The benefits are assumed to be equal to the effectiveness measure, namely the eradication rate. Meta-analysis was used to determine the probabilities and ranges used in the Markov model although no details concerning the review of the literature were given.

Direct costs
Based on the results of the clinical trial, the direct costs of including a H. pylori eradication regimen in the treatment of peptic ulcer diseases for one and five year periods were estimated using the Markov models. Estimated direct costs were shown in the total amount and therefore costs and quantities were not reported separately. Discounting was not applied and the price year was not stated.

Indirect Costs
Not included.

Currency
Japanese yen (Y).

Sensitivity analysis
Sensitivity analysis was carried out by varying the clinical probabilities, such as the H. pylori eradication rate and recurrence rate, to examine whether the estimates of clinical probabilities were stable and to determine the influencing...
factors for the estimates.

**Estimated benefits used in the economic analysis**
The estimated benefits are shown in the effectiveness results recorded earlier.

**Cost results**
The estimated direct cost for one year treatment was:

- OAC, approximately Y120,000
- OC, approximately Y125,000
- conventional methods, approximately Y120,000.

For five year estimates, OAC would cost approximately Y180,000 and OC approximately Y230,000 while the conventional methods would cost approximately Y310,000.

**Synthesis of costs and benefits**
Costs and benefits were not combined. The effects of eradication rates of OC and OAC on the five year estimates were examined and it was found that the more effective eradication is, the less costly the treatments can be in that period. When OC's eradication rate is 52% the five year costs would be approximately Y250,000 and when the eradication rate goes up to 72% the costs would be reduced to close to Y210,000. For OAC the costs would be reduced from approximately Y200,000 to Y175,000 when the eradication rate increases from 81% to 94%.

**Authors’ conclusions**
Proton pump inhibitor-based triple regimen is the most cost-effective treatment for patients suffering from peptic ulcers infected with H. pylori.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of comparator is clear. The treatments of peptic ulcers using proton pump inhibitor based H. pylori eradication regimen have been reported to be effective and have been adopted clinically outside of Japan. This trial aimed to examine the possibility of introducing the regimen in Japan by confirming the cost-effectiveness of the H. pylori eradication treatment for peptic ulcer patients.

**Validity of estimate of measure of benefit**
As the estimate of benefit (effectiveness) was based on a well conducted randomised controlled trial and patient samples were comparable the results are likely to have high validity.

**Validity of estimate of costs**
The 5 year costs were determined from a Markov model which employed other effectiveness data (for example recurrence rates) which were derived from a literature review/meta-analysis. However, no specific details concerning this review were given.

**Other issues**
The results are likely to be valid given the uncertainties in the data. The issue of generalisability was not specifically addressed and comparisons with other studies were not mentioned.
Implications of the study
The authors suggest that the proton pump inhibitor based triple therapy regimen for Helicobacter pylori eradication in peptic ulcer disease is the most cost-effective alternative.

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None stated.

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