Management of Helicobacter pylori eradication: the influence of structured counselling and follow-up

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 use of a structured counselling and follow-up service for patients treated with a one-week regimen comprising lansoprazole (30 mg once daily), amoxycillin (1 g twice daily) and clarithromycin (500 mg twice daily), for the eradication of Helicobacter pylori (H. pylori). The patients were counselled by the hospital pharmacy that administered the medicines, on the disease and the importance of eradication, the therapy and possible side-effects, and the relevance of compliance. The patients received an information leaflet and a compliance diary chart, and were telephoned three days after therapy was initiated for further counselling on the importance of medication compliance.

Type of intervention
Treatment and counselling service.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised adult patients who were found by endoscopy to have macroscopic changes in gastritis, duodenitis or ulceration, with the presence of H. pylori in the stomach, using a rapid urease test. Patients found to be hypersensitive to any component of the combination therapy, or who were judged clinically unsuitable for eradication therapy, were excluded from the study.

Setting
The setting was a district hospital. The economic study was carried out at the endoscopy unit of the Antrim Area Hospital in Antrim, Northern Ireland.

Dates to which data relate
The dates during which the effectiveness and resource use data were collected were not given. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was performed prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations to determine the sample size were not performed. All eligible patients referred to the endoscopy unit of the study hospital were invited to participate. Eighty patients were included in the study and were divided into two groups of 40 patients each. Two patients in each group were excluded after randomisation, because of adverse effects, failing to attend study appointments, allergy episode, and being prescribed a longer eradication therapy. The final study groups included 38 patients in each group. The mean age of the patients in the intervention group was 49.3 (± 16.3) years, and 73.7% were men. The mean age of the patients in the control group was 50.7 (± 15.7) years, and 68.4% were men.

Study design
This was a prospective, randomised controlled study that was carried out in a single centre, the Antrim Area Hospital. Randomisation was performed using a sealed envelope technique. The patients were followed for 6 months. A urea breath test was conducted 4 to 6 weeks after the one-week therapy to assess the actual eradication. In addition, 10 days after the endoscopy, all patients were contacted by telephone to evaluate the potential side effects experienced during the eradication therapy. The loss to follow-up was 4 patients (two in each group).

Analysis of effectiveness
The analysis of the clinical study appears to have been conducted on the basis of treatment completers only. The primary health outcome was the eradication rate, which was defined as the absence of H. pylori after a urea breath test. The secondary health outcomes were:

- adverse drug effects such as nausea, vomiting, diarrhoea, taste disturbance, abdominal pain, headache, itching or rash;
- compliance, assessed indirectly through patient interviews by telephone and by pill counts after completion of the eradication therapy; and
- patient response to the therapy, measured on the basis of dyspeptic symptoms in eradicated versus persistent patients and the use of antisecretory medications. The presence and severity of dyspeptic symptoms were assessed using a modified version of the Gastrointestinal Symptom Rating Scale, patient interviews on the day of endoscopy and one month and 6 months after completion of the therapy, and consultations with general practitioners (GPs) for the treatment of dyspeptic symptoms.

The study groups were shown to be comparable in terms of age, gender, social habits such as smoking and alcohol intake, and the duration of dyspeptic symptoms prior to eradication therapy.

Effectiveness results
The eradication rate was 94.7% in the intervention group and 73.7% in the control group, (95% confidence interval of difference, 95% CI: 5.3% - 36.7%; p=0.027).

The overall eradication rate for the whole sample of 76 patients was 84.2% (64 eradicated and 12 persistent).

The number of patients experiencing adverse events was 19 (50%) in the intervention group and 17 (44.7%) in the control group, (p=0.81).

The compliance rate was 100% in 35 patients (91.2%) in the intervention group and in 9 patients (23.7%) in the control group (95% CI for the difference: 52.3% - 84.5%; p<0.001).

All H. pylori persistent patients took less than 60% of the prescribed regimen, while all eradicated patients took at least 65% of the prescribed medication.

In terms of the assessment of dyspeptic symptoms, the severity scores for individual dyspeptic symptoms were much lower for patients successfully eradicated than for persistent patients. Most of these differences reached statistical significance at both the one-month and 6-month follow-up assessments.
At the one-month follow-up, the use of antisecretory medications was significantly reduced in eradicated patients than in persistent patients. At the 6-month follow-up, the use of antisecretory medications in the eradicated patients had disappeared, while the persistent patients continued to receive the medication.

At the 6-month follow-up, 91.7% of persistent patients and 4.7% of eradicated patients visited their GPs, (p<0.001).

**Clinical conclusions**
The effectiveness analysis showed that the intervention comprising counselling and follow-up service and combined eradication therapy was more effective in improving eradication rates and reducing dyspeptic symptoms than the standard procedure (eradication therapy alone).

**Measure of benefits used in the economic analysis**
The health outcomes were left disaggregated. A cost-consequences analysis was therefore carried out.

**Direct costs**
Discounting was irrelevant due to the short timeframe of the analysis (6 months). The unit costs and the quantities of resources were not reported separately. The health services included in the economic evaluation were eradication therapy, urea breath test, patient counselling (only in the intervention group), and GP consultations. The cost/resource boundary adopted was not explicitly stated, but appears to have been that of the hospital. The quantities of resources used were estimated using the data from the trial, but the period during which the data were collected was not reported. The costs were estimated using actual data derived from the Monthly Index of Medical Specialties, Hospital Trust and Health Board sources. No price year was reported.

**Statistical analysis of costs**
The costs were treated deterministically.

**Indirect Costs**
The indirect costs were not included in the analysis.

**Currency**
UK pounds sterling ()

**Sensitivity analysis**
No sensitivity analyses were conducted.

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

**Cost results**
The per patient costs were 77.3 in eradicated patients and 200.9 in persistent patients. The authors stated that the costs required to eradicate 100 patients were 8,402 using the study intervention (therapy and counselling), whereas an additional 3,026 would be required to eradicate H. pylori in patients in the control group. Consequently, the study intervention led to cost-savings of 30 per patients in comparison with the standard intervention.

**Synthesis of costs and benefits**
Irrelevant as a cost-consequences analysis was carried out.

**Authors’ conclusions**
Structured counselling and follow-up combined with a one-week eradication regime consisting of lansoprazole, amoxycillin and clarithromycin, was more effective than the standard procedure (eradication therapy alone) in improving the success of eradication therapy for Helicobacter pylori (H. pylori). The economic evaluation showed that the study intervention was also associated with cost-savings.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparators was clear. Eradication therapy alone was selected as representing the routine treatment intervention for patients with H. pylori. You should decide whether it represents a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis used a prospective, randomised controlled trial, which was appropriate for the study question. The study sample appears to have been representative of the study population. The study groups were comparable at baseline and the method of randomisation was reported. However, power calculations were not performed, and the period during which the effectiveness data were collected was not reported. The basis for the analysis of the clinical study appears to have been treatment completers only, as patients lost to follow-up were not considered.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of health benefit. The analysis was therefore categorised as a cost-consequences study.

**Validity of estimate of costs**
All the categories of costs relevant to the presumed perspective seem to have been included in the analysis. The source of the cost data was reported. However, the unit costs and the resource quantities were not reported separately and no dates relating to the costs or prices were given. These factors limit the generalisability of the results and make any reflation exercises difficult.

**Other issues**
The authors made some comparisons of their findings with those from other studies. The issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not conducted. Thus, the external validity of the analysis was limited. The study enrolled patients requiring H. pylori eradication therapy, and this was reflected in the conclusions of the analysis.

**Implications of the study**
The authors highlighted the crucial role of counselling and follow-up for the successful eradication of H. pylori. Within the caveats highlighted, the study shows that well-structured counselling combined with therapy comprising lansoprazole, amoxycillin and clarithromycin, could be influential in the treatment of patients requiring H. pylori eradication.

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**Bibliographic details**
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