Economic evaluation of a randomized trial comparing Helicobacter pylori test-and treat and prompt endoscopy strategies for managing dyspepsia in a 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 study compared a Helicobacter pylori (H. pylori) test-and-treat strategy (i.e. testing for H. pylori and treating the positive patients) with prompt endoscopy strategies for managing dyspepsia in a primary-care setting.

Type of intervention
Diagnosis and treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised patients who presented with symptoms of dyspepsia that were severe enough to warrant endoscopy or the prescription of acid-suppressive medication. The exclusion criteria were symptoms suggestive of gastroesophageal reflux disease, age younger than 18 years, and the presence of high-risk symptoms (these were fully outlined in the paper). Patients were also excluded if any malignancy was diagnosed or if the patient became pregnant.

Setting
The setting was primary care. The economic study was carried out in the Netherlands.

Dates to which data relate
Data on the effectiveness and resources used were collected between September 1998 and 2001. The price year was 1999.

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 in the effectiveness study.

Study sample
Limited information on the sample size was provided since the clinical trial (SENSE) had been reported elsewhere (Arents et al. 2003, see ‘Other Publications of Related Interest’ below for bibliographic details). Of the 281 patients who consented to participate in the study, 11 were excluded as they failed to meet the inclusion criteria. The remaining 270 patients were randomly assigned to two groups, 141 patients to test-and-treat and 129 to prompt endoscopy.
Study design
The analysis was based on a randomised controlled trial that appears to have been conducted in a multi-centre setting. It was randomised by supplying 4 sealed envelopes to each of the 56 general practitioners (GPs) who participated in the study. Adverse events were not recorded in the SENSE study. Follow-up lasted one year. Follow-up data were not available for 23 patients in the intervention group and 24 patients in the control group.

Analysis of effectiveness
The analysis of the clinical study included all patients for whom follow-up data were available (per protocol). The demographic variables and disease-specific variables of the patient groups were compared, and no statistically significant differences were observed. Quality of life was measured at the beginning and the end of the study, using the RAND-36 questionnaire. The authors did not report the other outcomes, but stated that the details were presented elsewhere (Arents et al. 2003).

Effectiveness results
The authors did not report the results of the clinical trial, but stated that the details were presented elsewhere (Arents et al. 2003).

Clinical conclusions
The authors did not describe the clinical conclusions, but stated that the details were presented elsewhere (Arents et al. 2003).

Measure of benefits used in the economic analysis
The summary benefit measure used was the quality-adjusted life-years (QALYs). The QALYs were derived by transferring the quality of life individual scores of the RAND-36 into one overall score, the Health Utilities Index Mark 2 (HUI2).

Direct costs
The economic analysis was carried out from the perspective of the third-party payer. The categories of costs included in the economic evaluation were dyspepsia-related drugs, dyspepsia-related GP visits, diagnostic tests, and dyspepsia-related referrals to specialists. The authors stated that over-the-counter antacids and histamine2-receptor antagonists were not included in the economic study since they were not reimbursed. The unit costs were presented separately from the quantities of resources used. The quantities of resources used were likely to be derived from patient-level data for the sample of patients included in the effectiveness study, however this was not explicit. The unit costs were derived from typical published sources. Discounting was not relevant, as the costs were incurred during less than two years, and was not carried out. The price year was 1999.

Statistical analysis of costs
The groups were compared using an independent sample Student t-test.

Indirect Costs
The indirect costs were not reported.

Currency
Euro (EUR). The conversion rate to US dollars ($) was EUR 1 = $1 on December 31, 1999.

Sensitivity analysis
Parametric bootstrap with angular transformation was also used to assess uncertainty in the cost-effectiveness. Confidence limits were based on 10,000 simulations from the estimated bivariate normal distribution.

**Estimated benefits used in the economic analysis**
The QALYs gained per patient were 0.037 in the test-and-treat group and 0.032 in the endoscopy group, with incremental QALYs gained of 0.005, (p non significant).

**Cost results**
The total costs per patient were EUR 511.02 in the test-and-treat group and EUR 748.08 in the endoscopy group, with incremental costs of EUR -237.06, (p<0.001).

**Synthesis of costs and benefits**
In the comparison with the prompt endoscopy strategy, the test-and-treat strategy yielded cost-savings and QALYs gained. Parametric bootstrap confidence limits indicated cost-savings per QALY gained in 75.7% of the bootstrap simulations.

**Authors' conclusions**
The Helicobacter pylori (H. pylori) test-and-treat strategy was more cost-effective than prompt endoscopy in the initial management of dyspepsia in general practice, from the perspective of a third-party payer.

**CRD COMMENTARY - Selection of comparators**
The justification for choosing prompt endoscopy as the comparator was clear as it was identified as a possible alternative to the test-and-treat strategy in recent studies. You should decide if this is relevant technology in your own setting.

**Validity of estimate of measure of effectiveness**
The clinical evaluation was based on a randomised controlled trial. This design minimises systematic differences between the groups, reducing the possibility that confounding variables have influenced the results. The study sample was representative of the study population. Baseline demographic and clinical characteristics patients were comparable, with no statistical differences observed between the trial and control groups. Appropriate statistical analyses were carried out. However, the limited reporting in this paper makes a full critique of the clinical study impossible. To fully assess the internal validity of the study, the reader should refer to the clinical paper (Arents et al. 2003).

**Validity of estimate of measure of benefit**
QALYs were appropriately used as the measure of benefits, as they are broadly comparable with other treatments. The authors acknowledged that, by transforming the individual scores of the RAND-36 into HUI2, they may have introduced a limitation into the study since the conversion formula and the uncertainties of the RAND-36 might have affected the results. Bootstrapping was conducted to help assess this issue.

**Validity of estimate of costs**
The analysis was performed from the perspective of a third-party payer. It appears that all the cost categories relevant to this perspective have been considered in the analysis, and all relevant costs for each category seem to have been included. A detailed breakdown of the cost items, and the sources of the unit costs, was provided. This enhances the reproducibility of the study in other settings. Appropriate statistical and parametric bootstrap analyses of the costs were performed, which adds to the reliability of the results. The price year was reported, thus aiding reflation exercises.
Other issues
The authors made appropriate comparisons of their results with findings from other studies. In this respect they pointed
out and discussed the similarity and differences between their study and other published studies. The issue of
generisability was not addressed and the results were not presented selectively. The authors’ conclusions accurately
reflected the design and scope of the study. A number of limitations were reported.

Implications of the study
The study suggests that the test-and-treat strategy is preferable in the initial management of dyspepsia in clinical
practice.

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The SENSE study was supported by an unrestricted grant from Aventis Pharma, Hoevlaken, the Netherlands.

Bibliographic details
randomized trial comparing Helicobacter pylori test-and-treat and prompt endoscopy strategies for managing dyspepsia
in a primary-care setting. Clinical Therapeutics 2005; 27(10): 1647-1657

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Other publications of related interest

Bytzer P, Hansen JM, Schaffalitzky de Muckadell OB. Empirical H2-blocker therapy or prompt endoscopy in

Delaney BC, Moyyedi P, Forman D. Initial management strategies for dyspepsia. Cochrane Database of Systematic


Lassen AT, Pedersen FM, Bytzer P, Schaffalitzky de Muckadell OB. Helicobacter pylori test-and-eradicate versus

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Subject indexing assigned by NLM

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