A randomized trial of an acid-peptic disease management program in a managed care environment

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
Patients with new dyspepsia and chronic users of antisecretory drugs, with acid-related disorders (ARD), were treated according to guidelines set down by a disease management programme. This programme included evidence-based practice guidelines derived from a search of the literature. Patients had an on-site Helicobacter pylori (H. pylori) serology test using the FlexSure HP (Quest Diagnostics, Collegeville) whole blood test. Pharmacists educated patients about H. pylori and the management of medication side effects, while nurses telephoned patients receiving H. pylori eradication therapy 3 days after therapy started to encourage compliance.

The guidelines included the identification of ARDs not related to the use of nonsteroidal anti-inflammatory drugs (NSAIDs), followed by a test and treat strategy. For those testing positive, treatment consisted of 1 week of triple therapy (omeprazole 20 mg or lansoprazole 30 mg daily plus clarithromycin 250 mg twice daily and metronidazole 500 mg twice daily). Those testing negative underwent 8 weeks of proton-pump inhibitor therapy (omeprazole 20 mg daily or lansoprazole 15 to 30 mg daily). After 8 weeks, patients with persistent symptoms were referred for endoscopy. The comparator group of patients were treated in accordance with ‘usual practice’. Usual practice was not described. It possibly varied by centre.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The patients in the study were those visiting the doctor with symptoms of epigastric pain or discomfort, indigestion, heartburn or belching or nausea, and those visiting the pharmacy for refills of antisecretory-drug prescriptions with records indicating they had used these drugs for more than 3 months. Patients were excluded if they had a history of gastrointestinal surgery, Barrett's oesophagus, oesophageal ulcers, vomiting, or upper gastrointestinal haemorrhage.

Setting
The setting was primary care. The economic study was carried out in Orlando, USA.

Dates to which data relate
The effectiveness evidence and resources used related to 1997 to 1998. No price year was given, but it can be assumed to have been 1997-98.

Source of effectiveness data
The effectiveness data were derived from a single study.
**Link between effectiveness and cost data**
The same patients who provided the cost data also provided the effectiveness data.

**Study sample**
The cluster-randomised trial was powered to detect a 25% difference in process-of-care measures between the disease management and usual practice groups. Eight clinics were randomised to give either normal care or to be part of the disease management programme. There were 200 patients in the disease management programme and 206 in the usual practice group. These were all the patients who met the inclusion criteria.

**Study design**
This was a multi-centre, cluster, randomised controlled trial in which the clinics were randomised to be part of the disease management programme or to offer usual care. The patients were followed up for 6 months after being enrolled in the study. There was a 50% loss to follow-up.

**Analysis of effectiveness**
The analysis appears to have been based on survey responders only. Self-reporting surveys were used to evaluate patients' health. The following information was used:

- over-the-counter medication use;
- days off work due to abdominal symptoms;
- the level of satisfaction with care;
- health-related quality of life, as derived from responses to the Medical Outcomes Study 12-Item Short-form Health Survey;
- an assessment of epigastric pain, heartburn and related symptoms at baseline using a survey adapted from a validated symptom index.

Process of care measures were also used:

- H. pylori testing in patients with ARDs;
- appropriate anti-H pylori therapy in patients testing positive;
- a trial of a proton-pump inhibitor in those patients testing negative;
- appropriate withdrawal of antisecretory therapy after a trial of empiric therapy; and
- referral of nonresponders for endoscopy.

There were no demographic or quality of life differences between the two patient groups. However, the disease management group had more painful and difficult swallowing than the control group, and more severe burning and pain in the stomach.

**Effectiveness results**
The patient surveys showed no difference between the two groups in terms of health-related quality of life or satisfaction with care.

The only ARD symptom that showed a statistically greater improvement in the disease management group was
nocturnal heartburn (-0.9 versus -0.5; p=0.03)

A sub-group analysis of patients in the disease management group who underwent serological testing was also undertaken, in order to compare the H. pylori positive and H. pylori negative groups. There were no significant differences at 6 months in the improvements in health-related quality of life or symptom severity.

Three of the 6 measures of the process of care showed an improvement.

Significantly more patients in the disease management group were adherent to the guidelines for H. pylori testing in cases of ARD (61% versus 9%; p=0.001).

Among the patients who tested positive, significantly more were prescribed appropriate anti-H. pylori therapy (96% versus 10%; p=0.001).

Physicians in the disease management group withdrew empiric trials of proton-pump inhibitors significantly more often then in the usual practice control group (70% versus 36%; p=0.04). They also tended to refer unresponsive patients more often for endoscopy, but the difference was not statistically significant.

Clinical conclusions
Although patients in the disease management group received better care than patients in the usual practice group, this did not translate into an improvement in quality of life or a statistically significant improvement in health symptoms.

Measure of benefits used in the economic analysis
No summary measure of health benefits was used. In effect, the authors carried out a cost-consequences analysis.

Direct costs
Discounting was not carried out, which was appropriate as the costs were only calculated for 6 months. The quantities and the costs were not analysed separately. The costs of medication, primary care visits, specialist visits, upper gastrointestinal radiography, endoscopy and anti-H. pylori therapy were calculated. Changes in the quantities of resources were given for days of antisecretory medication use, antacid use, over-the-counter NSAID use, and aspirin use. The costs were estimated from actual data. The data were derived from a review of patient charts and a database of information on pharmacy claims, medical encounters and procedures. The price year was probably 1997-98.

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

Indirect Costs
No indirect costs were calculated, although the authors had calculated the amount of time lost from work due to upper gastrointestinal symptoms.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.

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

**Cost results**
The total costs were $236.1 (+/- 225.36) for patients in the control group and $220.3 (+/- 211.21) for the intervention group (two-sided p=0.47). The costs of adverse effects were dealt with in the costing.

**Synthesis of costs and benefits**
The costs and benefits were not combined as the study was, in effect, a cost-consequences analysis.

**Authors’ conclusions**
Although the medical care received by patients in the disease management group was superior to that received by the control group, there was no evidence that their health was superior. However, the authors postulated various reasons why a health difference might not have been detected, even though it existed. Although one of the aims of the disease management programme had been to reduce the costs, no cost-reduction was detected.

**CRD COMMENTARY - Selection of comparators**
The choice of the comparator was justified by it being usual practice in the clinics under study. The comparator was not described. Hence, the meaning of the result for centres that did not participate in the trial is uncertain.

**Validity of estimate of measure of effectiveness**
The effectiveness data were derived from a single study. All patients who met the inclusion criteria were included in the study. Although the study design was appropriate for the hypothesis in many ways, the fact that the effectiveness analysis relied on patients self-reporting at 6 months was a drawback, as there was only a 50% response rate. The patients were shown to be different at baseline and this was not accounted for in the subsequent analysis.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of health benefit. The health benefits are, therefore, those associated with the effectiveness outcomes.

**Validity of estimate of costs**
The authors took the perspective of the health care organisation when calculating the costs, although they had obtained information on patients' medication use (which was not covered by the health care organisation) and on days lost from work. The authors used charges as a measure of the costs and the costs were not broken down into prices and quantities. This limits the generalisability of the results. The quantities were taken from a single study, while the prices were taken from the authors' setting. No statistical or sensitivity analyses of the prices or quantities were carried out.

**Other issues**
The authors compared their results with the findings from other studies. The issue of generalisability was touched on but not fully explored. The authors presented some of their results selectively, in that they paid attention to those areas where the disease management patients had better outcomes and ignored areas where the usual practice patients had better outcomes. Apart from that, the authors' conclusions reflected the scope of the analysis. The authors drew attention to several limitations of the study. In particular, the fact that the patients were not comparable at baseline, the poor response rate at 6 months, and the short duration of the follow-up. A further limitation was the fact that the study was concerned both with patients with “new dyspepsia” and those with a chronic complaint.

**Implications of the study**
The authors suggested that similar research on disease management programmes in different settings is needed. Any similar research should avoid the limitations outlined in the current study.

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