Dyspepsia management in primary care: a management trial

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
Four dyspepsia-management strategies were compared:

- empirical medical therapy for dyspepsia, as determined by the primary physician;
- Helicobacter pylori (HP) serology test;
- carbon-13 urea breath test (UBT) for HP; and
- oesophagogastroduodenoscopy (EGD).

Type of intervention
Screening and treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised adult patients presenting with dyspepsia at the authors' primary care clinic (General Internists and Family Physicians of the Mayo clinic). All patients meeting the "Rome" criteria for dyspepsia and experiencing symptoms of more than mild severity (such as upper abdominal pain, nausea, vomiting, or a feeling of fullness after eating for more than 4 weeks), and for at least 25% of the time, were included in the study. Patients who met the following criteria were excluded from the study:

- investigation or treatment of dyspepsia within the past year;
- history of radiographically or endoscopically diagnosed peptic ulcer within 5 years;
- prior attempt to treat proven HP infection;
- alarm symptoms suggestive of malignancy (e.g. new dyspepsia over age 60, bleeding, weight loss, anorexia);
- symptoms of gastroesophageal reflux disease (GERD) (e.g. postprandial substernal burning, nocturnal or postprandial regurgitation of food);
- symptoms of irritable bowel syndrome (IBS) according to the "Rome" criteria for IBS;
- significant intra-abdominal disease, surgery, radiation or history of any medical disorder which could explain symptoms of dyspepsia (i.e. inflammatory bowel disease, chronic pancreatitis, atherosclerosis or vasculitis affecting the splanchnic vasculature, malignancy, cirrhosis, end-stage renal disease, musculoskeletal disorders or neurogenic sources of pain).
Setting
The setting was primary care. The economic study was carried out in Rochester, USA.

Dates to which data relate
The effectiveness data were collected between June 1998 and June 1999. The price year was 1999.

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

Link between effectiveness and cost data
It appears that the costing has been carried out prospectively on the same sample of patients as that used in the effectiveness study.

Study sample
The sample size was not determined in the planning phase of the study. In addition, power calculations were not conducted retrospectively. Of the 100 primary care patients investigated initially, 73 were found eligible for the study according to the inclusion and exclusion criteria. Thirty of these refused to participate. The authors compared participants and non-participants at their baseline characteristics and found the non-participants to be, on average, 8 years older (mean age 60 years versus 52 years) and more often male (37% versus 33%). The non-participants were also less likely to have any health care visit in general (37% versus 49%) or for stomach trouble (5% versus 21%) in the last month. However, the authors reported that there were no differences in health-related quality of life (HR-QOL) generic or disease-specific measures between participants and non-participants. The sample comprised 43 patients overall. Eleven were assigned to the empirical medical therapy group, 8 to the HP serology group, 11 to the HP UBT group and 13 to the initial EGD group.

Study design
The basis of the analysis was a single-centred prospective randomised trial. An independent pharmacy unit conducted the computer-generated randomisation. The patients were followed up at 6 weeks and 6 months through mailed questionnaires, while every 6 weeks the patients underwent a structured telephone interview on clinical outcomes and medical resource use in order to reduce recall bias. Neither the patients nor the physicians were blinded to the intervention. The authors reported that there were no patients lost to follow-up during the 6-month period.

Analysis of effectiveness
It was not reported whether the analysis was conducted on an intention to treat basis or on treatment completers only. The primary clinical outcome was symptom-free status of the patients at 6 weeks. It was reported that symptom severity was assessed with the modified Bowel Disease Questionnaire, a specific instrument that distinguishes between diseases with overlapping symptoms (e.g. GERD and IBS). Further outcomes included over-the-counter and prescription medication use, and the number of health care visits for stomach trouble or for any reason in the past month. HR-QOL was evaluated using a dyspepsia-specific instrument. Reduced time spent on, or restriction in, usual work or activities was also evaluated. The Medical Outcomes Study short Form-36 (SF-36) was used to assess the general health status of the participants, while the Somatic Symptom Checklist was used to measure psychological distress.

The authors reported that the patients in the four groups were shown to be comparable at baseline and demographic characteristics (e.g. psychological distress, measured using the symptoms checklist and the somatic symptom checklist, and the frequency of health care visits during the month before randomisation).

Effectiveness results
Overall, there were no significant differences between treatment group in terms of symptom-free status, (p=0.49).
average overall percentage of symptom-free patients varied from 16% to 28% during the follow-up period.

Similarly, there were no statistically significant differences between different groups in terms of downstream medication use or health care visits.

Differences in work or activity measures, the SF-36-physical and the Somatic Symptoms Checklist among management groups were found to be statistically insignificant over the 24-week period after randomisation.

The SF-36-mental scores varied among groups. Pairwise analysis demonstrated that those in the HP UBT group had lower scores than the HP serology group, (p=0.045), the empirical group, (p=0.01), and the EGD group, (p=0.027).

The overall management effect on dyspepsia-specific HR-QOL was statistically significant, (p=0.02, simultaneous test for weeks 6 and 24). The pairwise analysis demonstrated that the HP UBT group had better dyspepsia-specific HR-QOL scores than those in the HP serology group, (p=0.01), the empirical group, (p=0.007), and the EGD group, (p=0.02).

**Clinical conclusions**
The authors concluded that, independently of the initial management method, most patients remained symptomatic but did not seek additional medical care. Significant differences in HR-QOL were observed in mental and overall management effects.

**Measure of benefits used in the economic analysis**
The authors did not derive a summary measure of benefit in the economic analysis. As such, a cost-consequences analysis was performed.

**Direct costs**
The patient costs included in the analysis were laboratory and radiology tests, lower endoscopies, inpatient and outpatient visits, and prescription drugs. The costs associated with initial management at randomisation were not included so that the variation in downstream utilisation among treatment groups could be demonstrated. The quantities of resources used were extracted using structured telephone interviews every 6 weeks, and were confirmed by review of the medical and administrative records. The authors reported that they used charges to proxy prices in order to account for those resources used outside of their health care system (i.e. they used per unit local fees and made appropriate adjustments for patient demographics and condition-severity). All charges were appropriately adjusted to reflect 1999 dollars. Discounting was not relevant since the costs were incurred during a short time (less than two years).

**Statistical analysis of costs**
The authors provided median and mean values of costs. In addition, they conducted a generalised linear regression (with log link and gamma distribution) in order to evaluate the overall treatment effects on direct downstream medical charges over a 6-month period in each group. The confidence intervals (CIs) of mean dyspepsia-related charges were calculated using non parametric bootstrap techniques. Pairwise mean differences in dyspepsia-related charges among the treatment groups were summarised based on unadjusted bootstrap CIs (alpha -0.05).

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

**Currency**
US dollars ($).
Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
Owing to the cost-consequences approach, the reader is referred to the 'Effectiveness Results' section.

Cost results
The costs were reported per patient. There were no overall treatment group effects on total downstream medical charges. (p=0.097). The patients in the EGD group had downstream mean billed charges of $2,077 versus $512 in the empirical group (95% CI for mean difference: 78 - 3,986).

Patients in the HP serology group and in the UBT arms were billed with higher charges than those in the empirical treatment group ($898 and $1,726 versus $512, respectively). However, the 95% CIs for mean differences contained the value of zero, which proves the high variation in estimated charges used in the analysis.

Synthesis of costs and benefits
The costs and benefits were not combined.

Authors' conclusions
Owing to its high cost, oesophagogastroduodenoscopy (EGD) does not represent the optimal choice for non high-risk patients who present to primary care with new dyspepsia.

CRD COMMENTARY - Selection of comparators
The selection of the comparators was explicitly justified. You should decide if they represent a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a prospective randomised trial, which was appropriate for the study question. The study sample was representative of the study population and the patient groups were shown to be comparable at analysis. The methods of randomisation and loss-to-follow up were reported, suggesting that the internal validity of the study was relatively good. In addition, an appropriate statistical analysis was undertaken to take potential biases and confounding factors into consideration. However, no power calculations were conducted and, as the authors acknowledged, there was only adequate power (at 80%) to identify large differences which may limit the interpretation of a causal relationship between the interventions and the results.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of benefit. In effect, a cost-consequences analysis was performed. The comments in the 'Validity of estimate of measure of effectiveness' field (above) therefore apply.

Validity of estimate of costs
The perspective of the patient was adopted in the analysis but costs such as travel costs for inpatient or outpatient visits were not included. The unit costs were reported, thus enhancing the reproducibility of the results in other settings. The quantities of resources used were obtained from a single study, while the unit costs were obtained from the authors' setting. An appropriate statistical analysis on the costs was conducted. Appropriate price adjustments were performed and the price year was reported. Discounting was not relevant since the costs were incurred during a short time. Charges were used to proxy prices, which was appropriate given the patient perspective adopted in the economic analysis, although it should be noted that charges do not reflect true opportunity costs.
Other issues
The authors compared their results with those from other studies, but some differences that were reported were not justified. The issue of generalisability of the results to other settings was not directly addressed. The authors do not seem to have presented their results selectively. The study enrolled non-high-risk patients who presented to primary care settings with new dyspepsia and this was reflected in the authors’ conclusions. Apart from the limited number of participants, and hence the low power of the study, the authors did not report any further limitations to their study.

Implications of the study
The authors did not make any recommendations for changes in policy or practice, nor did they make any recommendations pertaining to the need for future research.

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