Cost effectiveness of initial endoscopy for dyspepsia in patients over 50 years: a randomised controlled trial in primary care


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
Initial endoscopy in the management of dyspeptic patients aged over 50 years presenting to their primary care physicians. Endoscopies were carried out according to usual practice at open access services.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of dyspeptic patients aged over 50 years presenting to their primary care physicians. Dyspepsia was defined as epigastric pain or heartburn with or without nausea and bloating. Those who had undergone endoscopy, had a positive barium meal in the past 3 years, were unable to give informed consent, or were unfit for endoscopy, were excluded.

Setting
The setting was primary care and hospital. The economic analysis was carried out in the West Midlands, UK.

Dates to which data relate
Effectiveness and resource use data corresponded to the period between 1 April 1995 and 31 May 1998. The price year was 1998.

Source of effectiveness data
The evidence for the final outcomes was based on a single study.

Link between effectiveness and cost data
Costing appears to have been conducted retrospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were used to determine the sample size (a sample of 430 patients would detect differences of 2 units (SD 4) in dyspepsia score, 9 (22) in quality-of-life pain dimension, 8 (20) in emotion and social dimension, and a reduction in general practice consultation rates for dyspepsia from three to one per year (SD 3); these estimates were based on a power of 90% at the 5% significance level and assumed 25% loss to follow-up). Of 442 eligible patients, a
total of 256 were randomly assigned to receive initial endoscopy and 186 to receive the standard management. Of these patients, 254 in the endoscopy group with a mean (SD) age of 62.2 (8.4) years completed the trial versus 184 patients with a mean (SD) age of 62.7 (8.6) years in the control group.

**Study design**
This was a randomised-controlled trial, carried out in 31 practices. Endoscopies were performed in six local hospitals. Primary care doctors in the study area were invited to take part in the study. The duration of the follow-up was 15-18 months after recruitment. Regarding the number of patients who were lost to follow-up, it was reported that 16% of patients (41) assigned to initial endoscopy did not undergo this procedure, 20 declined, 6 cancelled or failed to attend and 15 were not referred by their physicians. Only one patient in the control group did not receive standard treatment as assigned. Furthermore, records of four patients could not be traced and 6 (2%) in the intervention and 4 (2%) in the control group died. For postal follow-up, 73% of patients returned a usable symptom score, and 74% quality-of-life scores. Randomisation was conducted by means of sealed, sequentially numbered envelopes containing the treatment allocation. The randomisation schedule was carried out on a 60/40 basis (intervention/control), with a computer generated random number sequence without blocking or stratification. Patients requesting an alternative treatment (no endoscopy, private referral, etc.) subsequent to group allocation were retained in the study.

**Analysis of effectiveness**
The principle used in the analysis of effectiveness was intention to treat. The primary clinical outcome measure was effect of treatment on dyspepsia symptoms. Secondary outcomes were quality of life and patient satisfaction. Diagnoses of patients at endoscopy were also reported. Symptoms were measured at recruitment and at 15-18 months, with the Birmingham dyspepsia symptom score (four questions scored on a Likert scale of frequency), which had been validated in the local population. A questionnaire was derived from a validated measure for patients with peptic ulcer disease and used to measure quality of life as: pain, emotion, and social function. Patient satisfaction was assessed by a validated measure of satisfaction with the primary care consultation, supplemented by additional questions relating to secondary care and endoscopy. An adjustment was made for the factors associated with questionnaire response rates (age and smoking). The study groups were reported to be comparable in terms of the baseline characteristics, although the intervention group had endoscopy sooner than the control group (Chi², p<0.0001).

**Effectiveness results**
The initial endoscopy group showed a greater improvement in symptom scores (mean difference 1.2 (95% CI: 0.1-2.3; p=0.03) and in the pain dimension of quality-of-life measurement (mean difference 6.4 (95%CI: 0.7-12.1; p=0.03). There was no evidence of a difference between groups in emotion or social dimensions, (p=0.46 and p=0.69, respectively).

The findings did not change on adjustment for factors associated with questionnaire response rates.

There were no differences in satisfaction with the primary care consultation between the two study groups.

For participants referred to secondary care, more patients in the initial endoscopy group than in the control group felt that endoscopy was very unpleasant, (p=0.035).

There were no significant differences between diagnoses of the two groups of study patients at endoscopy.

**Clinical conclusions**
Although the change in dyspepsia score was small, clinically important effects, including an improvement in the quality-of-life pain dimension accompanied it.

**Measure of benefits used in the economic analysis**
The measure of benefits adopted was the number of patients who were symptom-free at 12 months. The economic analysis classed patients as having symptoms only if they had symptoms at least every week.

**Direct costs**
Costs were not discounted due to the one-year time frame of the cost analysis. Quantities were reported separately from the costs. Cost items were not reported separately. The cost analysis covered the costs of endoscopy, barium meal, outpatient attendance, inpatient visits, H pylori test, primary care consultation, and H pylori eradication. The perspective adopted in the cost analysis was not explicitly specified. Total costs were calculated from individual patient use of resources with unit costs applied from national data. Resource use for dyspepsia in primary and secondary care for 12 months following recruitment was assessed from primary care case records. To reduce the effect of high inpatient cost outliers, costs were trimmed at the 95th percentile for total cost. The price year was 1998.

**Statistical analysis of costs**
Statistical analysis was not used to compare the study groups in terms of costs; however resource use per patient was compared using the Wilcoxon rank-sum test.

**Indirect Costs**
Indirect costs were not considered.

**Currency**
UK pounds sterling (£).

**Sensitivity analysis**
The effect of differing ceiling ratios of cost-effectiveness (Willingness to Pay) and the uncertainty around the sampling estimate of the incremental cost-effectiveness ratio (ICER) was shown as a cost-effectiveness acceptability curve, calculated by the net benefit approach. The probability of the ICER being less than the ceiling ratio (net benefit greater than 0) for a series of ceiling ratios was estimated from a normal distribution for net benefit. A sensitivity analysis was carried out on unit costs for endoscopy, and the cheapest and most expensive drugs in class.

**Estimated benefits used in the economic analysis**
The number of patients who were symptom-free in the initial endoscopy patients was 75/188 (40%) compared with 47/133 (35%) in the control group.

**Cost results**
Total costs per year were higher for initial endoscopy than for usual management (420 versus 340).

**Synthesis of costs and benefits**
The incremental cost-effectiveness ratio (ICER) for the initial endoscopy versus the usual practice was 1,728 per patient symptom-free at 12 months. The ICER was very sensitive to the cost of endoscopy, and could be reduced to 165 if the unit cost of this procedure fell from 246 to 100. All of the ICERs were those at which the probability that the ICER was less than this value was equal to 0.5. An alternative way of expressing these results is that changing the cost of endoscopy from 246 to 100 would increase the probability that the ICER was less than 1000 from 30% to 74%.

**Authors’ conclusions**
Initial endoscopy in dyspeptic patients aged over 50 might be a cost-effective intervention.
CRD COMMENTARY - Selection of comparators
The strategy of usual practice was regarded as the comparator; it allowed the active value of the intervention to be evaluated.

Validity of estimate of measure of effectiveness
The internal validity of the effectiveness results is likely to be high given the randomised nature of the study design, the performance of power calculations, and the fact that the effectiveness analysis was based on intention to treat. The study groups were comparable in terms of baseline characteristics and adjustment was made for the factors associated with questionnaire response rates (age and smoking). The study sample appears to have been representative of the study population, although comparability could have been tested other than simply by time to endoscopy.

Validity of estimate of measure of benefit
The estimate of the benefit measure was directly derived from the effectiveness analysis and the choice of the benefit measure was justified.

Validity of estimate of costs
The following features of the analysis enhanced the validity of the cost analysis: quantities were reported separately from the costs; the price year was specified; statistical analysis was conducted on resource use; and sensitivity analysis was performed on some of the cost data. However, the cost breakdown was not fully reported; it is not entirely clear whether the cost data were based on true costs or on charges (although it is likely to be actual costs); the perspective adopted in the cost analysis was not explicitly reported; statistical analyses were not performed on the cost data; and the effects of alternative preventive methods on indirect costs were not addressed.

Other issues
The authors’ conclusions appear to be justified. Regarding the issue of generalisability to other settings or countries, it was deemed that initial endoscopy is likely to be more costly in the USA than in the UK (due to higher expense of upper gastrointestinal endoscopy). Appropriate comparisons were made with other studies. The authors did not discuss, in this paper, the issue of the degree to which the study sample was representative of the study population.

Implications of the study
Healthcare service purchasers and hospitals should consider innovative methods of decreasing the cost of upper gastrointestinal endoscopy, such as the use of nurse endoscopists. If the unit cost of endoscopy cannot be decreased, further evidence of the cost-effectiveness of initial endoscopy in improving survival with gastric cancer will be required before initial endoscopy can be accepted as cost-effective. However, whether the procedure is cost-effective depends on comparison with other interventions. For example, a study was cited which reported 422 per symptom free patient treated for oesophagitis.

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