The Omega-Project: a comparison of two diagnostic strategies for risk- and cost-oriented management of dyspepsia

Brignoli R, Watkins P, Halter F

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
Diagnostic strategies (mandatory versus selective endoscopy) for risk- and cost-oriented management of dyspepsia.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Adult (male and female) patients with dyspeptic disorders (for at least one month) who were referred for upper gastrointestinal endoscopy. The average age was 41-42 and patients had a range of associated risk factors at initial examination.

Setting
Primary and secondary care. The economic study was conducted in Bern, Switzerland.

Dates to which data relate
The main effectiveness data were taken from a single study conducted in 1996. Resource and cost data were mainly derived from 1991-96 sources. The price year for indirect costs was 1991.

Source of effectiveness data
The estimates of response rates, mean incidence of relevant peptic and malignant lesions, development of symptoms and rates of absence from work, number of endoscopies, consultations and medication were derived from a single study.

Link between effectiveness and cost data
The costing was undertaken retrospectively on the same patient sample as that used in the effectiveness study.

Study sample
A cohort of 375 patients with chronic dyspeptic disorders was included in the analysis. 172 patients were included in the mandatory endoscopy arm (average age 41 years (+/- 15), 65% female) and 203 were included in the selective endoscopy arm (average age 42 years (+/- 16), 59% female): 125 had an endoscopy upon admission to the study and 78 during the observation period. The distribution of patients by number of risk factors for the mandatory and selective endoscopy groups respectively was as follows:0 risk factors, 32 and 226; 1 risk factor, 43 and 261; 2 risk factors, 54 and
76; 3 or more risk factors, 43 and 83. As such, the patients allocated to the two groups did not have similar risk profiles. Patients enrolled were treated with prokinetic drugs for 2 months. Power calculations to determine the sample size were not undertaken.

**Study design**
The study was a two-armed multicentre non-randomized with concurrent controls. The duration of follow-up was 2 months. The loss to follow-up was not stated.

**Analysis of effectiveness**
The analysis of the clinical study was based on treatment completers only. The primary health outcomes used in the analysis were response rate to treatment, mean incidence of relevant peptic and malignant lesions, development of symptoms and rates of absence from work, number of endoscopies, consultations and medication.

**Effectiveness results**
The response rates were 80% in the mandatory and 79% in the selective endoscopy group.

The mean incidence of relevant peptic and malignant lesions in the mandatory and selective endoscopy groups were:

- 10.7% and 10.7% (with 1-0 risk factors),
- 13.8% and 15.9% (with 2-3 risk factors)
- 33.3% and 33.3% (with > 3 risk factors)

The development of symptoms (expressed as the average symptom score) in the mandatory and selective endoscopy groups:

- 10.6 and 9.5 (Day 1),
- 4.7 and 4.7 (Day 7),
- 2.4 and 2.5 (Day 28),
- 1.6 and 1.5 (Day 56 and 84)

The rates of absence from work in the mandatory and selective endoscopy groups were:

- 19% and 17.5% (Day 1),
- 6.2% and 10.7% (Day 7),
- 1.3% and 3.6% (Day 28) (p<0.1),
- 2% and 0.4% (Day 56) (p<0.1)
- 0% and 1.3% (Day 84).

The number of endoscopies per patient performed was 1 and 0.35 in the mandatory and selective endoscopy group, respectively. The number of consultations per patient was 2.1 and 2.4 in the mandatory and selective endoscopy group, respectively. The number of medications per patient was 1.78 in the mandatory and 1.8 in the selective endoscopy group.

**Clinical conclusions**
The two management strategies achieved comparable clinical results.

**Measure of benefits used in the economic analysis**
No single benefit measure was developed. As such the benefits were assumed to be the same as the effectiveness results.

**Direct costs**
Endoscopies, consultations and medication costs were included in the analysis. The quantities were analysed separately from the costs. Discounting was not undertaken due to the short period of follow-up. The quantity/cost boundary adopted was the hospital. The price year was not stated.

**Statistical analysis of costs**
Mean and standard deviations.

**Indirect Costs**
The costs of loss of working hours were included in the analysis. The quantities were analysed separately from the costs. Discounting was not undertaken due to the short period of follow-up. The quantity/cost boundary adopted was the hospital. The price year for indirect costs was 1991.

**Currency**
Swiss francs (Sfr).

**Sensitivity analysis**
No sensitivity analysis was conducted.

**Estimated benefits used in the economic analysis**
The response rates were 80% in the mandatory and 79% in the selective endoscopy group.

The mean incidence of relevant peptic and malignant lesions in the mandatory and selective endoscopy groups were:

- 10.7% and 10.7% (with 1-0 risk factors),
- 13.8% and 15.9% (with 2-3 risk factors)
- 33.3% and 33.3% (with > 3 risk factors)

The development of symptoms (expressed as the average symptom score) in the mandatory and selective endoscopy groups:

- 10.6 and 9.5 (Day 1),
- 4.7 and 4.7 (Day 7),
- 2.4 and 2.5 (Day 28),
- 1.6 and 1.5 (Day 56 and 84)

The rates of absence from work in the mandatory and selective endoscopy groups were:
19% and 17.5% (Day 1),
6.2% and 10.7% (Day 7),
1.3% and 3.6% (Day 28) (p<0.1),
2% and 0.4% (Day 56) (p<0.1)
0% and 1.3% (Day 84).

The number of endoscopies per patient performed was 1 and 0.35 in the mandatory and selective endoscopy group, respectively. The number of consultations per patient was 2.1 and 2.4 in the mandatory and selective endoscopy group, respectively. The number of medications per patient was 1.78 in the mandatory and 1.8 in the selective endoscopy group.

Cost results
The total cost per week was Sfr 80 (+/- 16) and Sfr 55 (+/- 36) in the mandatory and selective group, respectively (P<0.01). Discounting was not undertaken due to the short period of follow-up.

Synthesis of costs and benefits
Costs and benefits were not combined. The selective strategy allowed a 31% cost reduction through a reduction in the number of endoscopies (67%). An incremental analysis was performed. The average costs per patient were reduced by Sfr 300.

Authors' conclusions
The authors concluded that selective UGE is cheaper and did not appear to compromise the response to prokinetics. However its diagnostic power was less than with mandatory UGE.

CRD COMMENTARY - Selection of comparators
The reason for the selection of the comparator is clear. A selective strategy is needed to attempt to create a potentially more economic management strategy for dyspepsia diagnosis. You, as a user of this database, should consider whether these are widely used health technologies in your setting.

Validity of estimate of measure of benefit
The estimate of measure of benefit used in the economic analysis is not likely to be internally valid. However, the authors highlighted that the study had a patient selection bias in that a considerable proportion of patients in the mandatory endoscopy group had a higher risk factor compared to the selective endoscopy group. This bias element appears to have been caused by a low acceptance of the concept of compulsory endoscopy by a large proportion of primary care physicians and led the authors to replace the randomised trial with two parallel trials before the of the study commenced.

Validity of estimate of costs
Resource quantities were reported separately from the prices. Adequate details of methods of quantity/cost estimation were given. Important cost items were not omitted.

Other issues
The authors' conclusions were justified given the uncertainties in the data. The issue of generalisability to other settings or countries was addressed in relation to comparisons with other studies' findings. However, appropriate comparisons
were made with other studies. Results were not presented selectively.

**Implications of the study**
More research is required from the patients’, providers’ and payers’ points of view.

**Source of funding**
Sponsored by Janssen Research Foundation, Baar, Switzerland.

**Bibliographic details**

**PubMedID**
9160195

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Adult; Cisapride; Costs and Cost Analysis; Domperidone /therapeutic use; Dopamine Antagonists /therapeutic use; Double-Blind Method; Dyspepsia /diagnosis /drug therapy /economics; Endoscopy, Digestive System /economics /methods; Female; Follow-Up Studies; Gastrointestinal Diseases /complications /diagnosis; Humans; Male; Mandatory Testing /economics /methods; Middle Aged; Parasympathomimetics /therapeutic use; Piperidines /therapeutic use; Prospective Studies; Recurrence

**AccessionNumber**
21997000687

**Date bibliographic record published**
31/12/1998

**Date abstract record published**
31/12/1998