Quality of life and cost-effectiveness of combined therapy for reflux esophagitis
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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
Two triple combination therapies for the treatment of patients with reflux oesophagitis (RE) were examined. Lansoprazole (30 mg once daily) plus cisapride (10 mg three time times daily) and sulcrafate (1.0 g three times daily) was compared with ranitidine (150 mg twice daily) plus cisapride (10 mg three times daily) and sulcrafate (1.0 g three times daily).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with RE. The inclusion criteria specified oesophageal erosion under endoscopy and one or more of the following three symptoms: heartburn, sour regurgitation, and chest pain. The main exclusion criteria were the presence of peptic ulcer, caner or systemic disease, and the use of acid suppression H2 receptor antagonists, proton-pump inhibitors, or other prokinetic drugs in the past 2 weeks.

Setting
The setting was secondary care. The economic study was carried out in China.

Dates to which data relate
The effectiveness and resource use data were gathered from May 2000 through May 2001. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was 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 used in the clinical study.

Study sample
Power calculations were not reported. Of the 327 patients initially identified, 248 agreed to participate. There were 155 patients (113 men) in the lansoprazole group and 93 patients (61 men) in the ranitidine group. The mean age of the patients was 48.95 (+/- 14.45) years in the lansoprazole group and 47.98 (+/- 13.67) years in the ranitidine group.
Study design
This was a prospective cohort study that was carried out in 10 hospitals in 5 regions in Zhejiang province in China. The length of follow-up was 8 weeks. No patient was lost to the follow-up assessment, although QoL data were available for 265 patients only.

Analysis of effectiveness
The analysis of the clinical outcomes considered all patients included in the initial study sample, whereas only those patients with available data were considered in the analysis of QoL data. The outcome measures used were total efficacy, healing rates after endoscopy at 8 weeks, and changes in QoL. Efficacy was composed of two aspects, symptom remission and symptom improvement. Symptom remission was defined as symptom disappearance. Symptom improvement was defined as a 50% reduction or more in symptom score. QoL was assessed using a 5-item questionnaire that evaluated the severity and frequency of symptoms related to eating, daily sleeping disturbance, anxiety, family life and social activities. QoL level was defined as good, fair, or poor according to the average score of the questionnaire. The study groups were comparable at baseline in terms of gender, age, Helicobacter pylori infection, RE symptoms and RE severity.

Effectiveness results
The rate of total efficacy was 92.3% (remission rate 55.5%; improvement rate 36.8%) with lansoprazole and 78.4% (remission rate 36.5%; improvement rate 41.9%) with ranitidine, (p<0.01).

The healing rates after endoscopy at 8 weeks were 90.8% in the lansoprazole group and 82.9% in the ranitidine group, (p>0.05).

The analysis showed that RE strongly reduced QoL.

The proportion of patients in the 'good' state was significantly higher in the lansoprazole group than in the ranitidine group (64.5% versus 45.6%; p<0.01).

There was a close correlation between symptom remission and QoL in both groups.

Clinical conclusions
The effectiveness analysis showed that the two treatments were equally effective, but QoL improved significantly with lansoprazole in comparison with ranitidine.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic evaluation. In effect, a cost-consequences analysis was carried out.

Direct costs
Discounting was not relevant because of the short timeframe of the analysis. The unit costs were not presented separately from the quantities of resources used, and a detailed breakdown of the costs was not given. Thus, it was unclear which categories of costs had been included in the economic evaluation. The cost/resource boundary for the analysis of direct costs was unclear. The costs and resource use data were estimated using a 3-item questionnaire, which was administered to the sample of patients involved in the clinical study. The price year was not reported.

Statistical analysis of costs
The costs were treated deterministically. Statistical analyses were carried out to examine the relationship between effectiveness, QoL and medical costs.
Indirect Costs
The indirect costs were included in the analysis, although there was limited information on the source and quantities of such items. The authors stated that both indirect costs and family income were considered. As in the analysis of direct costs, the unit costs were not provided, no discounting was carried out, and the price year was not reported.

Currency
Chinese yuan (Y).

Sensitivity analysis
Sensitivity analyses were not carried out.

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

Cost results
The costs between the groups were not significantly different.

Synthesis of costs and benefits
A synthesis of the costs and benefits was not relevant since a cost-consequences analysis was performed.

Authors' conclusions
Lansoprazole combination therapy for the treatment of reflux oesophagitis (RE) was more cost-effective than ranitidine combination therapy.

CRD COMMENTARY - Selection of comparators
The selection of the comparators reflected two widely used options for the treatment of RE. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from a prospective cohort study. The study groups were comparable at baseline in terms of their demographic and clinical characteristics. However, confounding factors and selection bias could have affected the results of the analysis, owing to the lack of random treatment allocation. Further, power calculations were not carried out and there was no evidence that the study sample was appropriate. These issues might limit the internal validity of the analysis.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted. Please refer to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
The cost analysis appears to have been conducted from a societal perspective, although information on the items included in the analysis was limited. The cost estimates were specific to the study setting. The unit costs were not presented separately from the quantities of resources used. The price year was not reported, which limits the possibility of performing reflation exercises in other settings. The source of the data was unclear.
Other issues

The authors compared their findings with those from other studies and stated that consistent results were observed. The issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not carried out, which reduces the external validity of the analysis.

Implications of the study

The study results supported the use of lansoprazole combination therapy for the treatment of RE.

Source of funding

None stated.

Bibliographic details


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Other publications of related interest


Indexing Status

Subject indexing assigned by NLM

MeSH

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