Randomized, multicentre comparison of sodium alginate and cisapride in the symptomatic treatment of uncomplicated gastro-oesophageal reflux

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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
Using sodium alginate in the treatment of patients experiencing reflux symptoms, without severe oesophagitis.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients ranging from 18 to 50 years, who were suffering from symptoms of uncomplicated gastro-oesophageal reflux.

Setting
Hospital. The economic study was carried out in Paris, France.

Dates to which data relate
The effectiveness and resource use data were collected between November 1994 and December 1995. The fiscal year was not explicitly reported.

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

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

Study sample
Power calculation was used to determine the sample size: a sample of 260 patients was required to identify a 15% difference between the therapeutic modalities with an estimate of 75% for cisapride efficacy rate, 5% alpha risk, 10% beta risk, and a bilateral formulation. The sample size consisted of 353 patients randomly allocated to either the intervention (sodium alginate) group (n=180) with an average age of 39.7 (SD, 9.3) years or the control (cisapride) group (n=173) with an average age of 39 (SD, 8.6) years.

Study design
The study was a randomised controlled trial, carried out in 59 centres. The duration of the treatment was 4 weeks.
Thirteen patients in the intervention group and 18 in the control group discontinued treatment.

**Analysis of effectiveness**

The analysis of effectiveness was based on intention to treat. The chief clinical outcome was the change in the severity of the reflux symptoms measured by a visual analogue scale (VAS) at 4 weeks. The adverse effects of the treatment modalities were reported. The study groups were shown to be comparable except in terms of the number of cigarettes per day; it was reported that an adjustment for this factor did not change the results.

**Effectiveness results**

In terms of VAS at 4 weeks, the intervention group experienced an average improvement of 62 versus 53 in the control group, (p=0.005). The adverse effects were reported to be rare and not serious (22 events in 13 patients in the intervention group as opposed to 27 events in 23 patients in the control group).

**Clinical conclusions**

"The results are very homogenous, with all the evaluation criteria in favour of the alginate".

**Measure of benefits used in the economic analysis**

The measure of benefit was the change in the severity of the reflux symptoms measured by a visual analogue scale (VAS) at 4 weeks. The patients evaluated their own state of health.

**Direct costs**

Discounting of costs was not required due to the short period of treatment. Resource use data were not reported separately from the costs. Cost items were reported in two general categories. The cost analysis consisted of the administration costs of the treatments and the costs associated with co-prescriptions, prescription for treatment failures, side-effects, and intercurrent effects. The perspective adopted in the cost analysis was not explicitly specified. The source of resource and cost data was actual data. The cost analysis did not include the costs of consultations, endoscopies, blood analyses, and electrocardiograms as these were similar for both alternatives. The date of the price data was not explicitly specified.

**Indirect Costs**

Costs were not required to be discounted due to the short period of treatment. Quantities were not reported. The number of working days lost was registered during the trial. Details of the methods of cost calculations for the lost earnings were not given. The date of the price data was not explicitly specified.

**Currency**

French francs (Ffr). No conversion to other currencies was reported.

**Sensitivity analysis**

Sensitivity analyses, including a per protocol analysis, were reported to have been performed, but they did not affect the results.

**Estimated benefits used in the economic analysis**

In terms of VAS at 4 weeks, the intervention group experienced an average improvement of 62 versus 53 in the control group, (p=0.005).
Cost results
The average costs of the treatment in the intervention group was FFr130 versus FFr175 in the control group.

Synthesis of costs and benefits
A synthesis was not performed since the use of sodium alginate was the dominant strategy. It was reported that sensitivity analyses did not in any way change the results.

Authors' conclusions
The authors concluded that "sodium alginate is more effective, and costs less, than cisapride for the treatment of symptoms presented by patients suffering from reflux without severe oesophagitis".

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator is clear.

Validity of estimate of measure of effectiveness
It is likely that the estimates of effectiveness are internally valid given the use of a randomised design, a sufficient sample size, and analysis of effectiveness based on intention to treat.

Validity of estimate of costs
Quantities were not reported separately from the costs and insufficient detail was provided on the methods of cost estimation.

Other issues
Details of the sensitivity analysis were not given. The issue of generalisability to other settings or countries was not addressed.

Implications of the study
"Because of numerous drugs approved for the treatment of reflux it is mandatory to assess their cost-effectiveness".

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