Economic analysis of treatment with roxithromycin in comparison with erythromycin in patients with lower respiratory tract infections
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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 roxithromycin, a new macrolide, in the treatment of patients with lower respiratory tract infections.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with lower respiratory tract infections.

Setting
Primary care. The economic study was carried out in Sweden.

Dates to which data relate
Effectiveness and resource use data related to patients treated in a randomized trial carried out in 1990 and published in 1992. The price year was 1993.

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

Link between effectiveness and cost data
Costing was retrospectively performed on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. The study sample initially consisted of 84 patients, 5 of whom were found not to be evaluable, and were excluded, while the remainder were randomly assigned to receive either roxithromycin (n=40), 150 mg b.i.d. for 10 days or erythromycin stearate (n=39), 500 mg b.i.d. for 10 days.

Study design
This was a multicentre, double blind, randomized controlled trial, carried out in 3 centres. The duration of the follow-up was not specified. Loss to follow-up was not reported.
**Analysis of effectiveness**

The principle (intention to treat or treatment completers only) used in the analysis of effectiveness was not explicitly specified. The clinical outcome measures were cure rate and the rate of reported adverse events.

**Effectiveness results**

The roxithromycin-treated group had a cure rate of 85% (34/40) versus 79% (31/39) in the erythromycin-treated group (not significant). The corresponding values in terms of the rate of reported adverse events were 17.5% for roxithromycin-treated patients and 48.6% for erythromycin-treated patients, (p=0.003).

**Clinical conclusions**

The use of roxithromycin compared to erythromycin in the treatment of patients with lower respiratory tract infections was associated with comparable healing rate and better outcomes in terms of significantly reduced occurrence of adverse events.

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

The benefit measure was the cure rate.

**Direct costs**

Costs were not discounted. Some quantities were reported separately from the costs. Cost items were reported separately. The cost analysis covered the costs of initial treatment, second consultation and change of therapy, supplementary therapy, laboratory tests, and hospitalization due to adverse events or treatment failure. The perspective adopted in the cost analysis was not explicitly specified but is likely to be societal (indirect costs also included). The sources of resource use data were patients’ records and a questionnaire completed by the 3 centres participating in the trial. The 1989 price of erythromycin was inflated to an equivalent 1993 price using a price index of pharmaceutical specialities. 1993 price data were used. The cost of initial visits was not included in the cost analysis since they were deemed to be common to the two study groups.

**Statistical analysis of costs**

Not undertaken.

**Indirect Costs**

Costs were not discounted. Quantities were reported in terms of the number of days absent from work (reported sick-days). Cost items were not reported separately. The valuation of quantities of days absent from work into indirect costs using unit cost per day was not performed because the connection between the number of days absent from work and adverse events of drug therapy could not be established. One patient with 104 days of absence from work was excluded from the average number of sick-days. The source of data on sick leave was the Swedish National Board of Social Insurance.

**Currency**

Swedish kroner (SEK).

**Sensitivity analysis**

One-way sensitivity analysis was performed on cure rates and the number of patients requiring extra consultation. Threshold values were calculated.

**Estimated benefits used in the economic analysis**
The roxithromycin-treated group had a cure rate of 85% (34/40) versus 79% (31/39) in the erythromycin-treated group (not significant).

Cost results
The average total direct cost was SEK348 for the roxithromycin-treated group versus SEK385 in the erythromycin-treated group. The mean number of sick-days for patients with adverse events was 15 for the roxithromycin-treated group (n=5) versus 21 in the erythromycin-treated group (n=12), as compared to 21 days for patients with no adverse events (n=21).

Synthesis of costs and benefits
Average cost-effectiveness ratios were calculated using cost per patient healed, leading to a cost of SEK409 for the roxithromycin-treated group versus SEK488 in the erythromycin-treated group. Incremental analysis was not performed because there was no significant difference between the two study groups in terms of cure rate. The sensitivity analysis showed that "very small alterations would change the calculations completely".

Authors' conclusions
Roxithromycin was found to be more cost-effective than erythromycin stearate if cure rates from the follow-up visit were used.

CRD COMMENTARY - Selection of comparators
The reason for the choice of comparator (erythromycin stearate) was justified as it was already in use before the introduction of the new intervention. You, as a database user, should consider whether this is a widely used health technology in your own setting.

Validity of estimate of measure of benefit
The internal validity of the estimate of benefit is likely to be high given the randomized nature of the study design, although the relatively small sample size used should also be taken into consideration.

Validity of estimate of costs
Quantities were not fully reported separately from the costs (such as actual time spent by the physician, as mentioned by the authors). Adequate details of methods of cost estimation were given. The retrospective nature of the cost analysis may cast some doubt on its internal validity. Cost results may not be generalisable to other settings or countries.

Other issues
Caution should be exercised regarding the study results, due to limitations of the cost analysis and lack of extensive sensitivity analyses or statistical analysis of the costs. The issue of generalisability to other settings or countries was not specifically addressed although appropriate comparisons were made with other studies.

Implications of the study
A prospective study comparing the relevant current alternative therapies, including detailed information on alternative therapy in case of treatment failure or adverse events, and patient questionnaires, would add to the formulation of a more robust analysis.

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