A clinical and economic comparison of roxithromycin 150 mg twice daily vs amoxicillin 500mg/calvulanic acid 125mg three times daily for the treatment of lower respiratory tract infections in general practice


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
Roxithromycin 150mg twice daily or amoxicillin 500mg/clavulanic acid 125mg 3 times daily for 7 days, with a further 7 days if insufficient response was seen, in treating lower respiratory tract infections (LRTI).

Type of intervention
Treatment

Economic study type
Cost-effectiveness analysis

Study population
The study population consisted of patients aged 16 years or over who had a clinical diagnosis of bacterial LRTI. Several types of patient were excluded: lactating or pregnant women; those with serious illness; hypersensitivity to treatment components; liver or renal disease; terminal malignancy and so on.

Setting
Primary care in Australia and New Zealand.

Dates to which data relate
The data on effectiveness and resources used were collected between September 1991 and February 1993. Price date was not given.

Source of effectiveness data
Single study

Link between effectiveness and cost data
Resource data were collected prospectively on the same patient sample used in the effectiveness analysis.

Study sample
The study sample consisted of 242 patients. 126 were randomised to receive roxithromycin and 116 to amoxicillin/calvulanic acid. Sample size was calculated assuming 80% power to demonstrate a 15% difference in clinical response with a 5% risk assuming a clinical response rate of 90% for roxithromycin.
Study design
Randomized controlled trial. The study was performed on a multicentre basis by 40 general practitioners. Randomization was centralised by telephone and in blocks of four. The trial was observer (the panel of investigators) blinded.

Clinical response was assessed 7 days after the start of the medication and at the end of another 7 days in cases of extended treatment. Patients were examined no more than 4 days after completion of therapy.

The drop outs from final analysis were 9 for the intervention group and 6 for the comparator group.

Analysis of effectiveness
Effectiveness was based on treatment completers only. The outcome measures used in the study were treatment success rate, i.e. complete resolution of all signs and symptoms of infection and side-effects rates.

There was no difference between the groups in terms of sociodemographic and clinical characteristics but more patients randomised to roxithromycin had a proven bacterial infection.

Effectiveness results
Considering all evaluable patients, clinical response at study end was 91.5% for the roxithromycin group and 90.9% for the amoxicillin/clavulanic acid group. 9.8% of patients on roxithromycin and 17.1% of patients on amoxicillin/clavulanic acid were observed to have effects possibly related to the antibiotic (p=0.12).

Clinical conclusions
Clinical response at study end was high for both antibiotics.

Measure of benefits used in the economic analysis
The measure of benefits was the number of clinical successes at treatment end.

Direct costs
Quantities and costs were not reported separately. Only health service costs were considered. The costs included were medicine costs, additional general practitioner consultations and additional diagnostic tests needed over and above those required as part of the study protocol. Cost estimates were based on actual data.

Primary medicine costs were obtained by combining the average treatment duration, the average daily dose and the listed price per unit of the medicine. Price dates were not given.

Currency
Australian dollars.

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
The clinical successes at treatment end were 107 and 100 for roxithromycin and amoxicillin/clavulanic acid respectively.
Cost results
The total costs were $A 3,482 and $A 4,959 for the intervention and comparator respectively.

Synthesis of costs and benefits
The total incremental net benefit per clinical success was $A 17.04. The net cost per clinical success for roxithromycin was $A 32.55 and for amoxicillin/clavulanic acid was $A 49.59.

Authors' conclusions
The authors concluded that roxithromycin appeared to be a more appropriate choice than amoxicillin/clavulanic acid for the treatment of LRTI, given the more appropriate in vitro spectrum, the efficacy against all common pathogens, greater cost-effectiveness, the more convenient dosage regimen and better tolerance.

CRD Commentary
The study had certain problems from the clinical aspect:

(a) randomisation appeared to have failed, given that more proven bacterial infections were in the roxithromycin group they would have responded better to the antibiotics. (Some of the infections would be viral and would not respond).

(b) the analysis was based on "treatment completers", since the results did not relate to the original sample. Analysis of treatment completers my have biased the results.

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Roussel UCLAF

Bibliographic details

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