A pharmacoeconomic comparison of amoxicillin/clavulanate and cefpodoxime proxetil in the treatment of acute otitis media

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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
Treatment of acute otitis media in children with amoxicillin/ clavulanate potassium or cefpodoxime proxetil.

Type of intervention
Treatment

Economic study type
Cost-effectiveness analysis.

Study population
Children (males and females) were divided equally into two groups with an average age of 4.6 years in the cefpodoxime proxetil group, and 4.2 years in the amoxicillinavulanate group. There was no significant difference in severity of illness between the two groups.

Setting
The practice setting was primary care in the USA.

Dates to which data relate
The effectiveness and resource data were collected during 1993.

Source of effectiveness data
Evidence for final outcome was derived from a single study.

Link between effectiveness and cost data
Costing and effectiveness analyses were undertaken on the same patient sample. Costing was undertaken prospectively.

Study sample
No reason for selecting 50 children were given. 25 children were allocated in the intervention and control groups respectively. The sample was taken from patients treated by one physician during a 5 month period. The patients were all outpatients aged from 6 months to 12 years who had one of the two pharmaceuticals in question prescribed for the treatment of clinical signs and symptoms of acute otitis media. Children with a history of otitis media within the previous two months were excluded as were those with eardrum perforation, myringotomy, allergy to penicillin or cephalosporins, or any underlying disease causing the immune system to be compromised.
**Study design**
Case series. No details were given as to the method of allocation of patients to the two groups described in the study, however they were matched for age and diaper (nappy) use.

**Analysis of effectiveness**
Analysis was based on intention to treat. The primary health outcome was a clinical cure or improvement as detected by an otitis media severity score. The two groups of patients were matched for age and diaper (nappy) use and were shown to have no significant difference in severity of illness at the start of the study.

**Effectiveness results**
Of the 25 patients in the cefpodoxime proxetil group, 21 (84%) had clinical cure or improvement at the 14-day follow-up and 4 (16%) required treatment with another antibiotic. In the amoxicillin/ clavulanate group, 22 (88%) of 25 children had clinical cure or improvement after 14 days and 3 (12%) required treatment with another antibiotic. There was no significant difference in the clinical cure rates between the two groups. The incidence of the side effect of diarrhea was greatest in the group receiving amoxicillin/clavulanate (8 patients, 32%) compared to those receiving cefpodoxime (3 patients, 12%).

**Clinical conclusions**
There was no significant difference in clinical cures rates between the two groups, with the mean +/- SD otitis media severity scores at 14 days being 6.8 (+/-2.1) for cefpodoxime and 6.3 (+/-1.4) for amoxicillin/clavulanate.

**Measure of benefits used in the economic analysis**
Since the effectiveness analysis showed no difference in clinical benefit between the two pharmaceuticals, the economic analysis was based on the difference in costs only.

**Direct costs**
Direct costs to the parents of patients were used:

1. Drug acquisition costs were taken as average wholesale prices.
2. Physician visits (source of cost of visits not given).
3. Over the counter products for side effects (source diaries of parents).
4. Parents’ telephone calls to physicians enumerated but no cost was applied to them.

**Indirect Costs**
Parents’ time taken off work to deal with treatment failure or side effects was reported but no attempt to cost it was made. The data was derived from parents’ diaries.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was carried out.
Estimated benefits used in the economic analysis
Not applicable.

Cost results
The total cost of treatment was calculated as the sum of:

- initial antibiotics plus
- initial physician visits plus
- follow-up physician visits for additional treatment plus
- antibiotics for treatment failure plus
- medications and products required to manage side effects.

Results showed costs of $2713.80 ($108.55 per patient) for the cefpodoxime proxetil group, and $2732.47 ($109.29) for the amoxicillin/clavulanate group. These costs excluded the respective costs for telephone consultations and the indirect cost of parents' time taken off work to care for children with treatment failure.

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
Clinical cure was shown to be equivalent with both treatments, however, greater side effects were associated with amoxicillin/ clavulanate (not statistically significant). An additional study with a larger sample size may be warranted to determine drug related side effects. The results of the review confirm that there are many factors in addition to acquisition cost that must be considered when determining the cost of treating a patient with a specific drug.

CRD Commentary
Although this was a well-designed study it suffered from small numbers in the comparison groups and no attempt to calculate the numbers required to demonstrate significant differences between the two groups. Information on the method used to assign patients to the groups would have been useful. It would have been preferable for the economic analysis to have included the cost of the telephone calls and parents' time taken off work, rather than merely reporting them.

Implications of the study
The main implication of the study is that the true cost of treating a patient with a specific drug includes the cost of dealing with treatment failure and side effects as well as the drug acquisition costs.

Source of funding
Funded in part by the Upjohn Company, Kalamazoo, Michigan.

Bibliographic details

PubMedID
Other publications of related interest
Discussion in Clinical Therapeutics 1994;16(2):271-2.

Indexing Status
Subject indexing assigned by NLM

MeSH
Acute Disease; Amoxicillin /adverse effects /economics /therapeutic use; Amoxicillin-Potassium Clavulanate Combination; Ceftizoxime /adverse effects /analogs & derivatives /economics /therapeutic use; Child; Child, Preschool; Clavulanic Acids /adverse effects /economics /therapeutic use; Drug Therapy, Combination /adverse effects /economics /therapeutic use; Economics, Pharmaceutical; Fees, Medical; Fees, Pharmaceutical; Female; Humans; Infant; Male; Otitis Media with Effusion /drug therapy /economics; Parents; Prodrugs /adverse effects /economics /therapeutic use; Severity of Illness Index; Time Factors; Trimethoprim, Sulfamethoxazole Drug Combination /therapeutic use

AccessionNumber
21995007025

Date bibliographic record published
28/08/1997

Date abstract record published
28/08/1997