Estudio farmacoeconomico del tratamiento antibioticode las agudizaciones de la bronquitis cronica en atencion primaria [A pharmacoeconomic study of the antibiotic treatment of the acute manifestations of chronic bronchitis in primary care]

The DAFNE Group

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
The use of several antibiotic treatments for crises of chronic bronchitis (CB) and chronic obstructive pulmonary disease (COPD). The antibiotics studied were cephixime (400 mg/day), amoxycillin (1,500 mg/day), amoxycillin-clavulanic acid (1,500 to 375 mg/day), cefaclor (1,500 mg/day), erythromycin (1,000 mg/day), azithromycin (500 mg/day), clarithromycin (500 mg/day), monolid (1,000 mg/day), ciprofloxacin (1,500 mg/day), and cefuroxime-axetil (1,000 mg/day).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients presenting to the general practitioner (GP) office with CB or COPD. CB was diagnosed on the basis of a cough persisting for at least 3 months per year for two years. COPD was diagnosed the basis of a forced expiratory volume in 1 second (FEV1) of less than 80% of the basic value and a FEV1/FVC of less than 70%. Patients with crises presented with increased habitual dyspnoea and increased forced expiratory volume.

Setting
The setting was primary care. The economic study was carried out in the 15 autonomous regions of Spain.

Dates to which data relate
The effectiveness and resource use data were gathered from September 1996 to May 1997. The price year was 1997.

Source of effectiveness data
The effectiveness evidence was derived from a single study, whose design and main results were published elsewhere (see Other Publications of Related Interest).

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

Study sample
The first 10 patients attending the office of the 268 GPs participating in the study for consultation, with a diagnosis of a
crisis for CB or COPD, were enrolled in the study. An initial sample of 2,597 patients was selected, but 183 patients did not provide complete data. Thus, the final sample included in the analysis comprised 2,354 patients (90.6% of the initial group). The three study groups considered were patients treated with cephixime (1,438 individuals), patients treated with the remaining antibiotics (885 individuals), and patients treated with amoxycillin-clavulanic acid (363 individuals). Power calculations to determine the sample size were not performed.

**Study design**
This was a prospective cohort study comparing patients in the three study groups. It was carried out in several health districts in all Spanish regions. The patients were enrolled randomly, as the first 10 patients presenting at the primary care office were included in the study. The follow-up period was 30 days. No patient was lost to follow-up. The outcome assessment was conducted using a face-to-face questionnaire, which was completed at the end of the follow-up period.

**Analysis of effectiveness**
All patients included in the study were accounted for in the analysis. The primary health outcome was treatment failure. This was defined as the percentage of patients who required care within the 30-day follow-up period. The study groups were comparable at baseline.

**Effectiveness results**
The percentage of patients who required care within the 30-day follow-up period was 17.5% for those treated with cephixime, 26.5% for those treated with the remaining antibiotics (the average value was selected), and 25.6% for those treated with amoxycillin-clavulanic acid. The differences in the comparisons between cephixime and all other antibiotics, and between cephixime and amoxycillin-clavulanic acid, were statistically significant, (p<0.001).

**Clinical conclusions**
The cephixime-based treatment was more effective than all the other antibiotic treatments for CB and COPD.

**Measure of benefits used in the economic analysis**
The benefit measure used in the economic analysis was the success rate of the antibiotic treatments. It was represented by the opposite of the treatment failure assessed in the effectiveness analysis.

**Direct costs**
The health costs included in the analysis were visits to the GP and the hospital emergency department, hospital stay (pneumology ward), and drug acquisition costs. The cost/resource boundary of the cost analysis was not stated. The unit costs and the quantities of resources were reported separately. The source of the cost data was a Spanish database (SOIKOS). The price year was 1997. Discounting was irrelevant due to the short time horizon of the study.

**Statistical analysis of costs**
Statistical analyses of the costs were not carried out.

**Indirect Costs**
The indirect costs were not included in the analysis.

**Currency**
Spanish pesetas (Pta).
Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
The success rate was 82.8% for patients treated with cephixime, 73.4% for those treated with the remaining antibiotics (the average value was selected), and 74.4% for those treated with amoxycillin-clavulanic acid.

Cost results
The total costs of the treatments were Pta 14,388 for patients treated with cephixime, Pta 19,775 for those treated with the remaining antibiotics (the average value was selected), and Pta 18,647 for those treated with amoxycillin-clavulanic acid. Cephixime was associated with a lower total cost, due to the smaller number of GP and emergency department visits and hospital stay in comparison with the other study groups.

Synthesis of costs and benefits
An incremental analysis was not performed. The cephixime-based treatment was dominant (less costly and more effective), both over all the other treatments and over amoxycillin-clavulanic acid.

Authors' conclusions
The antibiotic cephixime represented a cost-effective intervention for patients with chronic bronchitis (CB) and chronic obstructive pulmonary disease (COPD, compared with other commonly prescribed treatments.

CRD COMMENTARY - Selection of comparators
The treatments compared in the analysis were selected because they represented interventions commonly prescribed for the treatment of CB and COPD. You should assess whether they are widely used in your own setting.

Validity of estimate of measure of effectiveness
The study used a cohort of patients followed for 30 days. The first ten patients presenting to a GP office were enrolled, but a formal randomisation was not carried out. The authors noted that this could have limited the internal validity of the analysis. The study groups were comparable at baseline, but potential selection bias and confounding factors could have affected the study results. The study sample was representative of the study population.

Validity of estimate of measure of benefit
The benefit measure was the success of the treatments. This was derived from the effectiveness analysis.

Validity of estimate of costs
The perspective from which the study was conducted was not stated. Only the direct medical costs were included in the analysis. The unit costs and the quantities of resources were reported separately. The price year was reported. No statistical analyses of the costs or quantities was carried out. The unit costs used in the analysis were derived from a Spanish database, thus the estimated costs were specific to the study setting.

Other issues
The authors compared their results with those from other studies. The generalisability of the analysis to other settings was low, as sensitivity analyses were not carried out. The study enrolled patients with CB or COPD and this was reflected in the conclusions of the analysis.
Implications of the study
The study results should be take into account when decision makers select the optimal antibiotic treatment for CB or COPD in primary care.

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Other publications of related interest

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