Estudio comparativo coste eficacia ceftriaxona versus cefotaxima en el tratamiento de las infecciones urinarias complicadas [Cost-effectiveness comparative study of ceftriaxone versus cefotaxime in the treatment of complicated urinary infections]


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 two third-generation cephalosporin drugs for the treatment of patients with complicated urinary infection. The drugs examined were ceftriaxone (1 g daily, parenteral administration for 7 days) and cefotaxime (1 gram every 8 hours, parenteral administration for 7 days).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients diagnosed with complicated urinary infection.

Setting
The setting was a hospital. The economic study was carried out in nine hospitals in Spain. These were the Hospital Universitario La Fe (Valencia), Hospital de Basurto (Bilbao), Hospital 12 de Octubre (Madrid), Hospital Gregorio Maranon (Madrid), Hospital Miguel Servet (Zaragoza), Hospital Reina Sofia (Cordoba), Hospital Clinico Universitario San Carlos (Madrid), Hospital Jerez SAS (Jerez), and Hospital Carlos Haya (Malaga).

Dates to which data relate
The authors did not report the dates during which the effectiveness evidence and resource use data were gathered. The price year was not indicated.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

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
Power calculations were not performed to determine the sample size. A sample of 267 patients diagnosed with complicated urinary infection at the study hospitals was enrolled in the study. Of these, 119 patients were excluded for
various reasons:

- 48 patients did not follow the treatment protocol and did not undergo urine culture to assess the treatment efficacy;
- 19 had a negative initial culture;
- 18 used other antibiotics;
- 11 did not undergo the initial urine culture;
- 9 presented no complicated urinary infection;
- 7 interrupted the treatment;
- 5 were found with a microorganism resistant to the drug;
- 1 had an allergic reaction; and
- 1 presented with an episode of cardiac disease.

Of the remaining 148 patients, 75 (48 were men) were included in the ceftriaxone and 73 (48 were men) in the cefotaxime group. The mean age of the patients was 57.6 (+/-17.4) years in the ceftriaxone group and 53.9 (+/-19) years in the cefotaxime group. A different sample of 224 patients, who received the complete treatment, was enrolled in the study to assess the presence of adverse effects due to the treatments.

**Study design**

The study was an open, randomised multi-centre study carried out in nine hospitals. The patients were randomised according to their position at entry in the study, i.e. an odd position resulted in cefotaxime whilst an even position resulted in ceftriaxone. The patients were evaluated through clinical, analytical, and microbiological assessments. These were conducted before the treatment and 5 to 9 days and 1 month after the end of the treatment.

**Analysis of effectiveness**

The basis of the clinical analysis was not explicitly reported. It appears to have been treatment completers only, given that those patients who did not comply with the treatment were excluded from the sample. The primary health outcomes used in the analysis were microbiological and clinical efficacy. The microbiological efficacy was measured after the urine culture, in terms of eradication, persistence, re-infection from a different microorganism, or relapse after a negative culture. The clinical efficacy was measured by the treatment response, such as improvement, cure or failure. The rate of adverse effects was also reported. Statistical analyses were conducted to show the comparability of the groups in terms of the age, gender, alteration of the urinary tract, clinical characteristics, and type of microorganism.

**Effectiveness results**

In terms of microbiological efficacy, the microorganism was eradicated in 82.2% (60) of the patients in the cefotaxime group and in 81.3% (61) of those in the ceftriaxone group.

There were 4 episodes of improvement and 5 of failure in the cefotaxime group. In the ceftriaxone group, there were 4 episodes of improvement and 1 of failure.

In terms of clinical efficacy, a complete cure was obtained in 87.6% (64) of the patients in the cefotaxime group and in 93% (70) of those in the ceftriaxone group. The difference was not statistically significant.

There were 4 of episodes of persistence, 5 of re-infection, and 4 of relapse in the cefotaxime group. In the ceftriaxone group, there were 2 episodes of persistence, 4 of re-infection, and 8 of relapse.
The differences in both the microbiological and clinical efficacy did not reach statistical significance.

Mild adverse effects were found in 5% of the patients in each study group.

**Clinical conclusions**  
The effectiveness analysis indicated that cefotaxime and ceftriaxone were equally effective in terms of the clinical and microbiological outcomes. The side-effects were also similar.

**Measure of benefits used in the economic analysis**  
The health outcomes were not statistically different between the groups. Thus, a cost-minimisation analysis was conducted.

**Direct costs**  
Discounting was irrelevant. The analysis of the costs included only the price of drugs (retail price) and the cost of the equipment for administering them (syringe and disposable needle). The unit costs were not reported. The cost/resource boundary was not reported. The costs of hospital personnel were not included due to the high variability in these data. In addition, hospital stay was not considered because some patients may have had a longer hospital stay for the treatment of the urinary tract alteration. The source of the cost data was not reported. The quantities of resources used were estimated using data from the trial. The dates during which the resources use data were gathered were not reported. The price year was not indicated.

**Statistical analysis of costs**  
Statistical analyses were not conducted.

**Indirect Costs**  
The indirect costs were not included.

**Currency**  
Spanish pesetas (Pta). No currency conversions were performed.

**Sensitivity analysis**  
Sensitivity analyses were not carried out.

**Estimated benefits used in the economic analysis**  
See the 'Effectiveness Results' section.

**Cost results**  
The average cost of the treatment per patient was Pta 34,490 with cefotaxime and Pta 27,347 with ceftriaxone. The difference was statistically significant, (p<0.05).

**Synthesis of costs and benefits**  
Not relevant.

**Authors' conclusions**
Both cefotaxime and ceftriaxone were useful options for the treatment of complicated urinary infection, especially on the effectiveness side where both drugs proved to be highly efficacious and well tolerated by the patients. However, ceftriaxone was associated with two advantages over cefotaxime. Firstly, it was significantly less expensive and, secondly, it required only one injection per day.

**CRD COMMENTARY - Selection of comparators**
Cefotaxime and ceftriaxone were selected as the relevant therapies because they represented third-generation cefalosporins, commonly used as first-line treatments for complicated urinary infections. You should assess whether they represent widely used technologies in your own setting.

**Validity of estimate of measure of effectiveness**
The internal validity of the study is likely to be high due to the randomisation used in allocating the patients to the groups. Statistical analyses were also conducted on the sample to show the comparability of the groups in terms of their demographics and clinical characteristics. Also, to reduce the impact of confounding factors. The effectiveness analysis, however, appears to have used treatment completers only.

**Validity of estimate of measure of benefit**
No summary benefit measure was used as the outcomes were found to be similar in both groups. Therefore, a cost-minimisation analysis was conducted.

**Validity of estimate of costs**
The perspective of the study was unclear and the only items included in the analysis were the drugs and the equipment for the parenteral administration. The costs of hospital stay and personnel were not included. The dates during which the resource use data were gathered were not reported. In addition, the price year was not indicated. These factors made the generalisability of the cost results weak.

**Other issues**
The findings of the analysis appear to confirm those from published studies. The generalisability of the results to other settings was quite low, because no sensitivity analyses were conducted and the cost data were treated deterministically.

**Implications of the study**
Cefotaxime and ceftriaxone appear to have been highly effective and safe in the treatment of the patients in this study. Ceftriaxone was more convenient for its lower cost and greater ease of administration.

**Source of funding**
None stated.

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