Analisis coste-efectividad del uso de espironolactona en el tratamiento de la insuficiencia cardiaca cronica [Cost-effectiveness of the use of spironolactone in the treatment of chronic heart failure]
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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
The health intervention under examination was spironolactone 25 mg daily as adjunct therapy for the treatment of patients with chronic heart failure (CHF).

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients suffering from CHF, with systolic dysfunction of the left ventricle in functional class III-IV.

Setting
The setting was not explicitly stated, but appears to have been primary care. The economic study was carried out in Spain.

Dates to which data relate
Effectiveness evidence and data on resource use were derived from studies published in 1993 and 1999. The price year was 2000.

Source of effectiveness data
Effectiveness data were derived from a review of the literature.

Modelling
A decision tree model was constructed to compare costs and life expectancy of spironolactone plus standard therapy with those of placebo plus standard therapy. The time horizon of the model was 4.2 years and two hypothetical cohorts of 1,000 patients (administered spironolactone and placebo, respectively) were considered.

Outcomes assessed in the review
The outcomes assessed from the literature were the life expectancy of patients included in the study population and the following probabilities: mortality and survival in patients hospitalised and not hospitalised with spironolactone and placebo.
Study designs and other criteria for inclusion in the review
One of the primary studies was a randomised controlled trial.

Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Not stated.

Number of primary studies included
Two primary studies were used to derive the effectiveness evidence.

Methods of combining primary studies
Primary studies were not combined.

Investigation of differences between primary studies
Not stated.

Results of the review
The results of the review were as follows:

Life expectancy of patients included in the study population was 4.3 years.

Probability of hospitalisation was 75% with spironolactone and 83% with placebo.

Mortality and survival rates of hospitalised patients were 33% and 67% with spironolactone and 39% and 61% with placebo.

The probability of no hospitalisation was 25% with spironolactone and 17% with placebo.

Mortality and survival rates of no hospitalised patients were 39% and 61% with spironolactone and 78% and 22% with placebo.

Measure of benefits used in the economic analysis
The benefit measure used in the economic analysis was the number of life-years gained with spironolactone over placebo, which was obtained using modelling. A 3% discount rate was used.

Direct costs
Unit costs and quantities of resources were reported separately. The costs included were hospitalisation, drugs, physician visits, and diagnostic tests. Future non-medical costs were also included since the intervention extended life expectancy: the annual value of the average pension in Spain was used to estimate the cost of each year of life gained. The cost/resource boundary for direct costs was not clearly stated, but appears to have been that of the Spanish National
Health Service. Costs were estimated on the basis of a published database and official drug acquisition costs. The estimation of quantities was derived from published studies and authors’ assumptions. Total costs were obtained using modelling. A 3% discount rate was used as costs were incurred over a period of time longer than 2 years. The price year was 2000.

Statistical analysis of costs
No statistical analysis of costs was carried out.

Indirect Costs
Indirect costs were not included.

Currency
Spanish pesetas (Ptas).

Sensitivity analysis
One-way sensitivity analyses were carried out to assess the robustness of the results to variations in cost of hospital day (Pta 34,000 - Pta 57,000), annual value of average pension (+/- 10%), and average life expectancy (+/- 1 year).

Estimated benefits used in the economic analysis
Undiscounted life-years gained with spironolactone were 1.506, and with placebo, 1.249. When discounted, life-years gained with spironolactone were 1.407, and with placebo, 1.167.

Cost results
Discounted total costs were Pta 2,759,429,260 in the spironolactone group and Pta 2,617,479,356 in the placebo group, with a difference of Pta 141,950 in favour of the placebo group.

Synthesis of costs and benefits
Costs and benefits were combined by performing average and incremental cost-effectiveness analyses. The average cost per life-year gained was Pta 1,961,214 with spironolactone and Pta 2,242,912 with placebo. The additional cost per extra life-year gained with spironolactone over placebo was Pta 591,457. The estimated cost-effectiveness of spironolactone was robust to model input variations performed in the sensitivity analyses.

Authors’ conclusions
The authors concluded that spironolactone as adjunct therapy for the treatment of patients suffering from CHF proved to be a cost-effective intervention. The incremental cost per extra life-year gained was very low in comparison with placebo and far lower than other widely accepted health care interventions.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator was clear. Placebo (plus standard therapy) was selected to permit the active value of spironolactone as adjunct therapy to be assessed. You, as a user of this database, should assess whether placebo represents a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence was derived from published data, mainly based on a randomised clinical trial, thus the internal validity of the analysis is likely to be high. However, a formal review of the literature was not carried out and it
was not clear whether the differences in terms of study population and sample size between the two primary studies used were taken into account in the analysis. Sensitivity analyses were carried out on the average survival rate, which represented the most important model input.

Validity of estimate of measure of benefit
Life-years gained with the intervention were used as the benefit measure in the economic analysis. They were discounted and were derived using a decision tree model. Quality of life issues were not considered.

Validity of estimate of costs
It appears that all categories of costs relevant to the perspective adopted in the study were included in the analysis. Indirect costs were not included as patients in the study were unable to work, due to the severity of the disease. Unit costs and quantities of resources used were reported separately. The price year was reported. The authors made some assumptions to assess the quantities of resources. Cost estimates appear to be specific to the Spanish setting. Costs were treated deterministically, but sensitivity analyses were carried out on key parameters.

Other issues
The authors did not compare their findings with those from other studies. The generalisability of the study results to other settings was enhanced by performing some sensitivity analyses, and reporting unit costs and quantities separately. The authors noted that their conclusions should be limited to the specific population considered in this study.

Implications of the study
Spironolactone should be used as adjunct therapy for the treatment of patients with CHF, since it proved to be a cost-effective intervention from the perspective of the Spanish National Health Service.

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None stated.

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