A pragmatic cost-effectiveness study of routine epidural corticosteroid injections for lumbosciatic syndrome requiring inpatient management

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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
Routine epidural corticosteroid injections for lumbosciatic syndrome requiring in-hospital management.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Male and female patients aged 18 to 60 years with lumbosciatic syndrome unresponsive to outpatient treatment but not requiring invasive therapy.

Setting
Hospital (multicentre). The economic study was conducted in Lyon, France.

Dates to which data relate
The main effectiveness data were obtained from a single trial conducted in 1997. Resource and cost data were taken from 1991-93 sources. The price year was 1993.

Source of effectiveness data
The proportion of patients who required additional therapy and the clinical improvement at the second visit (based on the difference in pain scores between the first and second visit) were derived from a single study.

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

Study sample
Overall, 108 patients (mean age: 42.1 years) with common lumbosciatic syndrome were randomly allocated to treatment with (53 patients: 38 males; mean age: 41.6 +/- 10.5 years; work-related sciatica: 24.5%) or without (55 patients: 28 males; mean age: 42.6 +/- 10.6 years; work-related sciatica: 21.8%) routine epidural corticosteroids. Sample size was estimated at 139 patients assuming a 5% gamma risk and a 10% between-group difference in the proportion of patients requiring additional treatment.
Study design
Randomised controlled trial. The duration of the follow-up was 90 days. The loss to follow-up was not given.

Analysis of effectiveness
The analysis of the clinical study was based on intention to treat. The primary health outcome used in the analysis was the proportion of patients who required additional therapy and the clinical improvement at the second visit based on the difference in pain scores between the first and second visit. The two groups were comparable at baseline except for a larger proportion of males in the routine epidural corticosteroid group. Patients in the routine epidural corticosteroid group were more likely to require other treatments, but the difference was only of borderline significance after adjustment for gender.

Effectiveness results
The proportion of patients who required additional therapy was 93% (97% male, 86% female) overall, 98% in the epidural injection group and 87% in the comparison group. The 11% between-difference (similar to the 10% difference used in the sample size estimation) in the proportion of subjects given additional therapy fell below the significance threshold when the results were adjusted for gender (P=0.08). Only pain score at baseline was reported (58.4 +/- 22.0mm in the epidural and 59.8 +/- 19.0mm in the no epidural group). However, as reported by the authors, no significant differences were found between the two groups in terms of pain score.

Clinical conclusions
The results showed that physicians based their treatment decision primarily on whether an improvement in the clinical status of the patient was apparent at the second visit. None of the other factors studied influenced treatment decisions.

Measure of benefits used in the economic analysis
The benefits were the secondary evaluation criteria used (pain score, Schober's index, straight leg raising test and overall assessment).

Direct costs
Mean standard costs of invasive procedures (nucleolysis, percutaneous discectomy and surgery), hospital stay and outpatient health care costs (visits, drugs, physiotherapy, epidural corticosteroid injections) were included in the analysis. Mean standard costs of invasive procedures and of the attendant hospital stay were evaluated from a specifically-designed hospital-based study and from a literature review. Costs associated with hospital stays were evaluated based on a CREDES survey. Estimations of outpatient health care costs were based on official documents, the Vidal dictionary and the Interministerial Price List for Health Care Procedure. Resources were reported separately from the prices. The quantity/cost boundary adopted was the hospital. Discounting was not undertaken due to the short study period. The price year was 1993. Direct costs were determined based on data recorded in the case report forms during the first 30 days and on any hospitalisations and invasive procedures that occurred between 30 and 90 days of follow-up.

Statistical analysis of costs
Not undertaken.

Indirect Costs
Not considered.

Currency
French francs (Ffr).
Sensitivity analysis
Not undertaken.

Estimated benefits used in the economic analysis
As reported by the authors, no significant differences were found between the two groups in terms of secondary evaluation criteria.

Cost results
The total costs were Ffr 19,815 for the epidural and Ffr 17,231 for the no epidural group. The mean total costs per patient was Ffr 18,492 (range: 7,125 - 62,959). Mean costs per patient in each of the seven centres were reported.

Synthesis of costs and benefits
Not combined.

Authors' conclusions
The study shows that adding an epidural injection as a first-line treatment to rest and a non-steroidal anti-inflammatory drug for the treatment of lumbosciatic syndrome requiring inpatient management results in additional costs and no gain in efficacy.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator is clear. Widely accepted treatments for lumbosciatic syndrome include analgesics, systemic anti-inflammatory agents, epidural corticosteroid injections and use of a lumbar belt or corset. Rheumatologists remain divided regarding the efficacy and optimal modalities of use of epidural corticosteroid injections.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis and as such the authors conducted a cost and outcomes study. The secondary criteria used to evaluate patients would appear to be valid.

Validity of estimate of costs
Resource quantities were reported separately from the prices. Adequate details of methods of quantity/cost estimation were given. Important cost items do not appear to have been omitted. However, no statistical analysis (see below) was conducted. As the study was retrospective, the costs need to be treated with a degree of caution. As noted by the authors, a high percentage of the total cost was paid for by the French national health insurance system which covers all costs of inpatient management.

Other issues
The authors' adopted a "pragmatic" methodology which they state does not require statistical analysis of the results but may involve a weighting of alternative options. The issue of generalisability to other settings was not addressed even though it could have been applicable as the French national health insurance system covers all costs of inpatient management. Comparisons with other studies were not undertaken by the authors. Results do not appear to have been presented selectively.

Source of funding
None stated.
Bibliographic details

PubMedID
9385692

Indexing Status
Subject indexing assigned by NLM

MeSH
Adolescent; Adult; Cost-Benefit Analysis; Female; Follow-Up Studies; Glucocorticoids /administration & dosage /economics /therapeutic use; Hospital Costs; Humans; Injections, Epidural /economics; Length of Stay; Male; Middle Aged; Prednisolone /administration & dosage /economics /therapeutic use; Sciatica /drug therapy /economics; Syndrome; Treatment Outcome

AccessionNumber
21997001475

Date bibliographic record published
30/06/1999

Date abstract record published
30/06/1999