Cost utility analysis of caudal epidural injections in the treatment of lumbar disc herniation, axial or discogenic low back pain, central spinal stenosis, and post lumbar surgery syndrome

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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.

CRD summary
This study aimed to evaluate the cost-utility of caudal epidural injections, after conservative management failure, for chronic low back pain. The authors concluded that caudal epidural injections showed clinical and cost utility at less than $2,200 per quality-adjusted life-year. This was not a cost-utility analysis; several economic terms were misused. The reporting was poor and the methods were unclear. The economic and clinical results should not be relied on.

Type of economic evaluation
Not an economic evaluation

Study objective
This study aimed to evaluate the cost-utility of caudal epidural injections, after the failure of conservative management, for chronic low back pain.

Interventions
All patients, in four randomised controlled trials, received caudal epidural injections. One group in each trial received steroids and the other did not. All patients received drug therapy and a structured exercise programme, depending on their symptoms, which differed between the four trials. The two groups of each trial were merged, as there were no statistically significant differences in their outcomes; this resulted in one intervention being evaluated.

Location/setting
USA/secondary care.

Methods
Analytical approach:
The analysis was based on the four trials of subsets of patients with chronic low back pain. The time horizon was two years, which was the follow-up of each trial. No study perspective was stated.

Effectiveness data:
The primary clinical outcomes were pain measured on a numeric rating scale (from 1 to 10), and function assessed by the Oswestry Disability Index (from 0 to 50). These outcomes were combined to create treatment success, which was defined as significant pain relief and reduced disability status of 50% or more. The patients in each trial had failed to respond to conservative management. The subsets were diagnosed with lumbar disc herniation or radiculitis (120 patients), lumbar central stenosis (100 patients), lumbar post-surgery syndrome (140 patients), or axial or discogenic pain (120 patients). Intention-to-treat analyses were conducted, using outcomes at the start, and three, six, 12 and 24 months. Results were reported for six, 12 and 24 months.

Monetary benefit and utility valuations:
Not relevant.

Measure of benefit:
The measures of benefit were one week, one year, and two years of improvement in quality of life. Improvement was defined as treatment success (significant pain relief and reduced disability status of 50% or more). This improvement was called a quality-adjusted life-year (QALY).
Cost data:
Individual patient reimbursements, for each trial, were the actual payments from the facility and physician services during the trials (August 2006 to December 2011). Medical reimbursements over the 24 months after enrolment were collected. These included payments for physician assessment at each visit, and facility expenses for all procedures. The costs of oral drugs were excluded, as they were minimal compared with the epidural injections. All costs were in US $.

Analysis of uncertainty:
Standard errors and probabilities were reported for some outcomes.

Results
The average cost per procedure was $444.90. The number of weeks with significant improvement for all patients over two years was 24,949. The cost per week of quality of life improvement was $41.78. The cost per year of quality of life improvement was $2,172.50. The cost per two years of quality of life improvement was $4,344.99.

The cost per year of quality of life improvement by trial subset was $2,206 for disc herniation, $2,136 for axial or discogenic pain without disc herniation, $2,155 for central spinal stenosis, and $2,191 for post-surgery syndrome.

Authors’ conclusions
The authors concluded that caudal epidural injections showed clinical effectiveness and cost utility at less than $2,200 per year of QALY.

CRD commentary
Interventions:
The intervention was not well described. Only one intervention was assessed, as the intervention and comparator groups were combined. The authors noted that there were different types of epidural injection, and that there might have been alternative interventions, so the cost-effectiveness of treatment, accounting for all relevant alternatives, was not assessed.

Effectiveness/benefits:
The four trials included the primary author of this analysis, suggesting that the analysis was planned alongside the trials. As no systematic review of the literature was conducted, these trials cannot be considered to represent all the clinical evidence. Because the groups in each trial were combined no relative effectiveness data were presented. The trials were designed to evaluate the effectiveness of epidural injections for different patient groups. Other than being intention-to-treat, the method of analysis was unclear. It appears that the effectiveness data were pooled across trials, rather than conducting a meta-analysis or an individual patient data meta-analysis, which would have been appropriate. It is not possible to comment on the risk of bias in the included trials, as they were not described sufficiently; references were given. The outcomes were poorly defined – it was unclear what constituted a significant improvement in pain.

The term QALY was incorrectly used; in cost-utility analysis, it refers to an outcome valued using individual preferences for given states of health. The outcomes in this analysis were clinical outcomes, with no preference-based assessment; this cannot be considered to be a conventional cost-utility analysis.

Costs:
The study used reimbursement data, instead of costs. The amount that an organisation is reimbursed for a procedure, and the cost of that procedure often do not match. A cost-to-charge ratio can be applied to the reimbursement data to account for this difference. Without this, the results could mislead decision-makers and be inconsistent with those of other analyses. It appears that the costs were combined for the intervention groups. The categories seemed to be relevant, but oral drugs were excluded. The authors argued that this was conservative toward epidural drugs, as they were likely decrease oral drug consumption. As with the effectiveness data, meta-analysis does not appear to have been used to combine the data. This disregards the variation between the trials and their patients. A hierarchical regression, based on individual patient data, accounting for treatment group and trial, would have been appropriate, for both costs and effects.

Analysis and results:
The authors defined this study as a cost-utility analysis, but it does not meet the basic requirements for a cost-utility
analysis. A cost-utility analysis is a cost-effectiveness analysis that includes preference-based utility scores. A cost-effectiveness analysis compares two interventions, generally using clinical outcomes, in natural units, and costs. If treatments are or are assumed to be clinically equivalent, an analysis of the differences in costs may be conducted; this is called a cost-minimisation analysis. This study did not meet the requirements for any of these types of economic evaluation. There was only one intervention, so this was not an economic evaluation. The authors presented the average cost per unit of benefit. The analysis was poorly reported; the outcomes used to calculate the cost per year of quality of life improvement and per two years of quality of life improvement were not reported. The measure of benefit that the authors called a QALY was not the QALY normally used in health economics, so comparisons to society's willingness-to-pay for a QALY gained were spurious.

Concluding remarks:
This study was neither a cost-utility nor a cost-effectiveness analysis; several economic terms were misused. Its results are of no use for health economic decision making. The study was poorly reported and had unclear methods, and should not be considered reliable for clinical assessment.

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