Cost-effectiveness and safety of epidural steroids in the management of sciatica

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Executive summary

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Executive summary

Background

Sciatica is a common cause of pain and disability. Epidural injections of corticosteroids (ESIs) commonly are used to treat sciatica. In 2002/03 there were 45,948 ESIs performed within the NHS. A systematic review and meta-analysis of previous trials found that there was weak benefit from ESIs, but most trials were underpowered. Safety and cost-effectiveness have not been evaluated.

Objectives

The objectives of this study were:

- to verify the clinical effectiveness of ESIs in the treatment of sciatica with an adequately powered study
- to identify potential predictors of response to ESIs
- to investigate the safety of lumbar ESIs in patients with sciatica
- to evaluate the cost-effectiveness of lumbar ESIs.

Methods

Design

A pragmatic, prospective, multicentre, double-blind, randomised, placebo-controlled trial with 12-month follow-up was performed. The study included 228 patients listed for ESI with clinically diagnosed unilateral sciatica, aged between 18 and 70 years, who had a duration of symptoms between 4 weeks and 18 months. Patients were stratified according to acute (<4 months since onset) versus chronic (4–18 months) presentation. All analyses were performed on an intention-to-treat basis with last observation carried forward used to impute missing data. Data were collected from dropouts, cross-overs and withdrawals at 52 weeks to give as much information as possible on long-term follow-up.

Setting

The study took place in rheumatology, orthopaedic and pain clinics in four participating centres: three district hospitals and one teaching hospital in the south of England.

Interventions

Patients received up to three injections of epidural steroid and local anaesthetic (active), or an injection of normal saline into the interspinous ligament (placebo).

Main outcome measures

The primary outcome measure was the Oswestry Disability Questionnaire (ODQ); measures of pain relief and psychological and physical function were collected. Health economic data on return to work, analgesia use and other interventions were also measured. Quality-adjusted life-years (QALYs) were calculated using the SF-6D, calculated from the Short Form (SF-36). Costs per patient were derived from figures supplied by Trust finance departments and a costings exercise performed as part of the study. A cost–utility analysis was performed using the SF-36 to calculate costs per QALY.

Results

ESI led to a transient benefit in ODQ and pain relief, compared with placebo at 3 weeks ($p = 0.017$, number needed to treat = 11.4). There was no benefit over placebo between weeks 6 and 52. Using incremental QALYs, this equates to an additional 2.2 days of full health. Acute sciatica seemed to respond no differently to chronic sciatica. There were no significant differences in any other indices, including objective tests of function, return to work or need for surgery at any time-points. There were no clinical predictors of response, although the trial lacked sufficient power to be confident of this. Adverse events were uncommon, with no difference between groups.

Costs per QALY to providers under the trial protocol were £44,701. Costs to the purchaser per QALY were £354,171. If only one ESI was provided then costs per QALY fell to £25,745 to the provider and £167,145 to the purchaser. ESIs thus fail the QALY threshold recommended by the National Institute for Health and Clinical Excellence (NICE).

Conclusions

Although ESIs are relatively safe, it was found that they confer only transient benefit in symptoms and self-reported function in a small group of patients with sciatica at substantial costs. ESIs do not provide good value for money to the NHS as determined by NICE guidelines.

Implications for healthcare

The results of this study suggest the following.

- There is little evidence to support the use of ESIs in acute sciatica; better patient education, reinforcement of analgesic strategies and the instruction to keep as active as possible are important.
- Owing to the short-term benefit from ESIs and lack of predictors of response, the routine use of ESIs in sciatica needs to be reviewed urgently and its place re-evaluated.
- Given the severity of impact on psychophysical functioning these patients require a multidisciplinary assessment and better analgesic and rehabilitation strategies.
- A national registry of all ESIs may be a suitable method for collecting appropriate safety data.
- The use of ESIs to defer surgery requires review.
- Repeat ESIs do not appear to be effective.
- The costs of ESIs to purchasers as used in their present form, do not, in the authors' opinion, represent good value for money and indeed fail the QALY threshold.

Recommendations for research

There are a number of areas that would benefit from additional research:

- Further work on the epidemiology of radicular pain is needed so that patients can be presented with better information on prognosis.
- A register of all ESIs should be developed so that the true incidence of major complications can be accurately determined.
- Subgroups who may benefit from ESIs may be identified through very large trials: these need not have long-term follow-up, but a wider range of assessment tools may be necessary to detect small changes in function. A subgroup analysis of acute and chronic patients may be one of these groups.
- Although previous studies have been inconclusive, the use of radiological imaging may improve accuracy and should be investigated further in larger studies with respect to outcome.
- Further work on the optimal early interventions may reduce the incidence of severe persistent sciatica. This is likely to require a multidisciplinary approach even at an early stage with involvement of vocational rehabilitation.
- A systematic review of analgesic agents and nerve root injections would determine the research agenda for these two potential analgesic strategies.
- The use of cognitive behavioural therapy in rehabilitation should be explored further.
- Exploration of improved methods of assessment to include investigation of cognitive content and processing in those with sciatica may better determine specific rehabilitative strategies.
- A comparative cost–utility analysis between various treatment strategies for sciatica would help purchasers in decision-making.
- Other more novel methods to reduce the effect of scarring and inflammation should be explored.

Publication

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NHS R&D HTA Programme

The research findings from the NHS R&D Health Technology Assessment (HTA) Programme directly influence key decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC) who rely on HTA outputs to help raise standards of care. HTA findings also help to improve the quality of the service in the NHS indirectly in that they form a key component of the 'National Knowledge Service' that is being developed to improve the evidence of clinical practice throughout the NHS.

The HTA Programme was set up in 1993. Its role is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care, rather than settings of care.

The HTA Programme commissions research only on topics where it has identified key gaps in the evidence needed by the NHS. Suggestions for topics are actively sought from people working in the NHS, the public, service-users groups and professional bodies such as Royal Colleges and NHS Trusts.

Research suggestions are carefully considered by panels of independent experts (including service users) whose advice results in a ranked list of recommended research priorities. The HTA Programme then commissions the research team best suited to undertake the work, in the manner most appropriate to find the relevant answers. Some projects may take only months, others need several years to answer the research questions adequately. They may involve synthesising existing evidence or conducting a trial to produce new evidence where none currently exists.

Additionally, through its Technology Assessment Report (TAR) call-off contract, the HTA Programme is able to commission bespoke reports, principally for NICE, but also for other policy customers, such as a National Clinical Director. TARs bring together evidence on key aspects of the use of specific technologies and usually have to be completed within a short time period.

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Reports are published in the HTA monograph series if (1) they have resulted from work commissioned for the HTA Programme, and (2) they are of a sufficiently high scientific quality as assessed by the referees and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reported in this monograph was commissioned by the HTA Programme as project number 96/31/05. The contractual start date was in January 1999. The draft report began editorial review in May 2004 and was accepted for publication in January 2005. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA Programme or the Department of Health.

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