

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

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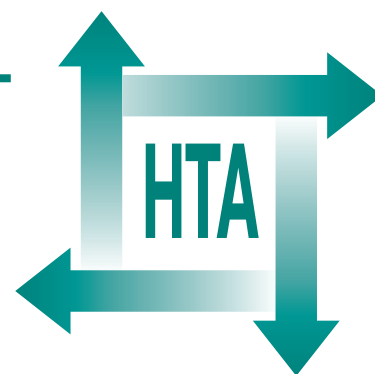
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## *Executive summary*

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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

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