Effectiveness of therapeutic lumbar transforaminal epidural steroid injections in managing lumbar spinal pain

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CRD summary
The authors stated there was good evidence for transforaminal epidural injections for chronic low back and lower extremity pain caused by disc herniation with radiculitis; the evidence was fair for spinal stenosis, and limited for axial pain and post surgery syndrome. Whilst the relative effectiveness of different types of transforaminal epidural injections is unclear, the authors' broad conclusion seems reliable.

Authors' objectives
To determine the effects of transforaminal epidural injections with or without steroids to treat people with lower back and lower extremity pain.

Searching
PubMed, EMBASE, The Cochrane Library, the United States Guideline Clearinghouse, clinical trials.gov, previous systematic reviews and reference lists were searched for relevant studies. Search dates ranged from 1966 to December 2011. A search strategy was referred to, but not reported.

Study selection
Eligible for inclusion in the effectiveness review were randomised controlled trials (RCTs) and non-randomised observational studies of participants (aged 18 years or over) with chronic low back and lower extremity pain lasting for at least three months, and for whom other management techniques (for example, pharmacotherapy and exercise therapy) had failed. Non-randomised observational studies had to have at least 50 participants in total or for comparative studies at least 25 participants in each study group. All studies had to have at least one month of follow-up. The intervention of interest was lumbar transforaminal epidural injection (with or without steroids) performed with an appropriate image guidance technique. The primary outcome of interest was pain relief, defined as short-term (up to six months) and long-term (more than six months). Secondary outcomes of interest were functional, psychological, return to work, and reduction or elimination of other interventions, including opioids. Complications were also assessed.

Most included studies evaluated participants with disc herniation; other studies included those with spinal stenosis, disc-related axial pain without disc herniation or radiculitis or those with post surgery syndrome. Most studies had active controls, for example comparing local anaesthetic versus local anaesthetic with steroid; technical variations (preganglionic versus postganglionic); types of steroids, transforaminal versus interlaminar or caudal injections; or nucleoplasty (plasma disc compression). Only one placebo-controlled trial was considered by the review authors to be truly placebo (comparing transforaminal epidural steroid injections or intramuscular injection with or without steroids). Various outcome measures were used.

Two reviewers were involved in the selection of studies.

Assessment of study quality
The quality of included trials was assessed using Cochrane criteria, and quality of observational studies was assessed with the Newcastle-Ottawa Scale. Clinical relevance was evaluated using criteria recommended by the Cochrane Back Group. Included in the effectiveness analysis were RCTs meeting at least six of 12 criteria, cohort studies meeting seven of 13 criteria, and case-control studies meeting five of 10 criteria. The overall strength of evidence was assessed using modified United States Preventive Services Task Force criteria.

Quality assessment was carried out by two independent reviewers. Disagreements were resolved with the involvement of a third reviewer and by consensus.

Data extraction
Data were extracted on the various outcomes of interest. Positive results were defined as clinically relevant and
effective (for RCTs) and effective at one month, three months, six months and one year (for non-randomised studies).

Two independent reviewers were involved at this stage. Disagreements were resolved by discussion, or with the involvement of a third reviewer. Authors were contacted for additional information, where necessary.

**Methods of synthesis**
A meta-analysis was not considered feasible. A narrative synthesis was presented by type of condition.

**Results of the review**
Fifteen RCTs and 10 non-randomised studies (three case-control studies; seven cohort studies) were included in the review. Sample sizes for RCTs ranged from 26 to 239; for non-randomised studies this was 55 to 233. Six good quality, and eight moderate quality RCTs were included in the analysis. All cohort studies were low quality; the case-control studies were moderate quality. Most studies represented long-term follow-up (over six months). Twenty-three studies were considered to be clinically relevant.

For participants with disc herniation or radiculitis, transforaminal epidural injections were associated with significant improvements from baseline to follow-up for pain relief, and particular improvements were reported with the addition of a steroid (eight RCTs; four non-randomised studies). One good quality placebo-controlled trial found significantly greater pain relief and function improvements following transforaminal epidural steroid injections, although pain relief diminished in all groups over time. Other studies showed advantages of transforaminal epidural injections in preventing surgery.

In terms of managing participants with spinal stenosis, three RCTs showed positive results for pain in the short-term, when different techniques or types of drugs were compared. Conflicting results were reported for short and long-term pain in two non-randomised studies.

The authors stated there were insufficient data to evaluate the effectiveness of transforaminal epidural injections for axial pain (three non-randomised studies). Evidence of effectiveness for post surgery syndrome was limited to one active controlled trial comparing transforaminal injections with multiple drugs; this trial did not show any statistically significant difference for pain between groups.

There were no major complications reported in any of the studies contributing to the effectiveness analysis. Results from other studies were reported in the paper.

**Authors' conclusions**
There was good evidence for transforaminal epidural injections in managing chronic low back and lower extremity pain caused by disc herniation with radiculitis; the evidence was fair for spinal stenosis and limited for axial pain and post surgery syndrome.

**CRD commentary**
The review question and inclusion criteria were clear. The search strategy included relevant sources of published and unpublished studies. The review process was conducted with steps to minimise reviewer error and bias, and appropriate quality assessment criteria were applied to the included studies. Study characteristics were presented, demonstrating high level of clinical variation which justifies the authors' decision to provide a narrative synthesis. Most of the included trials were good quality. Wide variation in the included studies makes it difficult to identify the relative effectiveness of different types of transforaminal epidural injections and their comparators. However, the authors' broad conclusion reflects the evidence presented and seems reliable.

**Implications of the review for practice and research**
**Practice:** The authors stated that results of this systematic review can be considered generalisable if appropriate selection criteria are used, and may be applied to interventional pain management practices using appropriate evaluations.

**Research:** The authors stated that future research should include clear case definition with consistent selection criteria, technical consideration, frequency, type and volume of injectate, outcome measures, appropriate study design, and reporting of randomised trials.
Funding
Not stated.

Bibliographic details

PubMedID
22622912

Original Paper URL

Indexing Status
Subject indexing assigned by NLM

MeSH
Clinical Trials as Topic; Humans; Injections, Epidural; Low Back Pain /drug therapy; Spine; Steroids /administration & dosage /therapeutic use; Treatment Outcome

AccessionNumber
12012029829

Date bibliographic record published
15/01/2013

Date abstract record published
19/02/2014

Record Status
This is a systematic review that meets the criteria for inclusion on DARE.