Influence of lumbar epidural injection volume on pain relief for radicular leg pain and/or low back pain

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CRD summary
The authors concluded that preliminary results suggested a positive correlation between larger volumes of fluid injected in the epidural space and greater relief of radicular leg pain and/or low back pain. The conclusions reflected the results of the review, but need to be viewed with caution given potential for publication bias and substantial heterogeneity across included studies.

Authors' objectives
To assess the effect of epidural injection volume on relief of radicular leg and low back pain.

Searching
MEDLINE (1966 to January 2009), EMBASE (1980 to January 2009) and The Cochrane Library were searched. The searches were limited to English and Human subjects. Reference lists of retrieved articles were handsearched.

Study selection
Controlled clinical trials that compared epidural injections with control injections on pain relief in patients with low back pain with or without leg pain were eligible for inclusion. Only studies where the same approach to epidural space was used in both groups were included. Studies that measured pain relief for radicular leg and low back pain before and after epidural injections were included. Studies of low back pain associated with infection, inflammation, tumours or cauda equina syndrome were excluded. All data after crossover in trials with crossover design were excluded.

Most studies were in patients with lumbar radiculopathy. Mean age (where reported) ranged from 37.2 to 52.0 years. Duration of pain (where reported) ranged from 12 days to six months and more. The included studies compared different combinations of agents in treatment arms and sometimes used the same and sometimes different volumes of fluid in each treatment arm. A variety of injections (normal saline, steroid and local anaesthetic) were used; methylprednisolone (2mL, 80mg) was the most commonly used substance. Volumes of epidural injections varied and ranged between 2mL to 42mL. Pain measurement scales were varied; visual analogue scale (VAS) was the most commonly used.

One reviewer assessed studies for inclusion.

Assessment of study quality
Two reviewers independently assessed study quality using the 11-item criteria recommended by the Cochrane Back Review Group on adequacy of: randomisation; treatment allocation concealment; similarity of baseline characteristics; blinding of patients, care providers and outcome assessors; treatment of cointerventions; compliance; description of dropout rates; similarity in timing of outcome assessment across groups; and intention-to-treat analysis. Studies that fulfilled six or more criteria were considered high quality; those that fulfilled five or fewer criteria were considered to be lower quality.

Data extraction
Two independent reviewers extracted data on pain relief as relative risks (RR) for dichotomous data and standardised mean differences (SMDs) for continuous data. Data were extracted as four categories: immediate (six weeks or less); short-term (more than six weeks to three months); intermediate (three months or more to one year); and long-term (one year or more).

Methods of synthesis
Pearson correlation between volume difference and effect size at each data point was calculated. The Pearson correlation coefficient (r) was considered strong if r≥0.8, moderate if 0.8>r>0.5 and weak if r≤0.5. Average effect
sizes in the studies with same volume in both groups were compared to those with different volumes using a two-tailed t-test.

**Results of the review**
Fifteen studies were included (n=886 patients): 14 RCTs and one CCT. Twelve studies were of higher quality (score≥6) and three were of lower quality (score≤5).

Correlation between volume difference and pain relief was 0.8027 (p=0.002, 12 studies) for the immediate category, 0.5019 (p=0.168, nine studies) for the short-term category and 0.9470 (p=0.014, five studies) for the intermediate category. Insufficient data were available to calculate the correlation coefficient in the long-term category (one study).

There was a statistically significant difference when comparing the mean effect size where the volume injected was the same between the two groups (mean, standard deviation (SD): 0.07, ±0.26) with those where the volumes were different between comparison groups (mean, SD: 0.81, ±0.6) irrespective of the medications injected.

**Authors’ conclusions**
Preliminary results suggested a positive correlation between larger volumes of fluid injected in the epidural space and greater relief of radicular leg pain and/or low back pain.

**CRD commentary**
The review question was clearly stated. A number of relevant databases were searched. The search was restricted to papers published in English, which raised the possibility of language bias. No efforts were made to search for unpublished papers, hence some relevant papers may have been missed. Quality assessment and data extraction were done in duplicate, which reduced risks of reviewer error and bias; similar rigor was not applied in study selection. Quality assessment used appropriate criteria and results were used to inform the synthesis. Studies were clinically heterogeneous and pooling such diverse studies could be considered questionable.

The authors’ conclusions were supported by the evidence presented, but need to be viewed with caution given the potential for publication bias and substantial heterogeneity across included studies.

**Implications of the review for practice and research**
**Practice:** The authors stated that clinicians should not change their practice until high-quality clinical studies confirmed this review's findings.

**Research:** The authors stated that further randomised controlled trials are needed to investigate the effects of lumbar epidural injection volume on decreasing pain in patients with radiculopathy. Such studies should also aim to define an optimal lumbar epidural injection volumes.

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