Conservative management of lumbar disc herniation with associated radiculopathy: a systematic review

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CRD summary
The review concluded that advice was less effective than microdiscectomy in the short-term but equally effective in the long-term for individuals with lumbar disc herniation with associated radiculopathy. The authors appropriately recommended that further research is required. However, the results should be interpreted cautiously, as they are based on trials that are small, varied and mostly not of high quality.

Authors' objectives
To determine the efficacy and safety of conservative treatments for people who have lumbar disc herniation with associated radiculopathy.

Searching
The following databases were searched for full papers published in English between 1971 and August 31, 2008: MEDLINE, CINAHL, EMBASE, PEDro, Current Contents, Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Database of Systematic Reviews, AMED, Web of Science, and Australasian Medical Index (Informit). Search terms were reported. Past relevant systematic reviews and the reference lists of all included trials were also searched. Citation tracking via the Web of Science was conducted on all included trials.

Study selection
Randomised controlled trials (RCTs) that included at least one treatment arm of adults in adults (>18 years) with referred leg symptoms who received a conservative treatment, and where at least 75% of participants had radiologic confirmation (computed tomography or magnetic resonance imaging) of a lumbar disc herniation were eligible for inclusion in the review. Included trials had to report data relating to treatment efficacy or adverse events. Conservative treatment was defined as one that did not involve penetration through the deep skin layers. Participants with symptoms of any duration could be included. Also excluded were trials were all groups received injection therapy or any type of surgical intervention, trials that verified lumbar disc herniation only with myelography, or trials in which over 25% of participants had previously undergone surgery or who had symptoms likely attributable to bony or ligamentous spinal stenosis.

Outcomes of interest included back specific functional status, pain intensity, global measures of improvement, and adverse events or complications potentially attributable to the intervention.

In included trials, conservative management included: stabilisation; manual autotraction; manipulation (osteopathic); oral herbal medication added to mobilisation, massage and mechanical traction; oral diclofenac sodium; inverted traction; herbal magnetic corset added to traction, electrotherapy and massage; sarpogrelate hydroxychloride; advice; and a multimodal program. Comparators varied across trials; six RCTs compared conservative treatment with surgery or injections. Most trials included participants with mixed symptom durations, but one RCT included only participants with acute symptoms (less than six weeks), two RCTs with only subacute symptoms (six to 12 weeks) and three RCTs included only chronic symptom (over 12 weeks) participants. A wide range of outcome measures were used but all trials included at least one measure of pain or global change; ten RCTs included measures of function. The most common measure of pain intensity was the visual analogue scale. The most common measure of function was the Oswestry.

Two reviewers independently selected trials for inclusion in the review. Any disagreements were resolved through discussion, where disagreements could not be resolved a third reviewer was consulted.

Assessment of study quality
Two reviewers independently assessed the quality of the included trials using the PEDro scale. A score of 6 or more (out of a possible 10) was considered to represent high quality. In addition, two reviewers independently evaluated the
clinical relevance of the included trials using five criteria recommended by the Cochrane Back Review Group.

**Data extraction**

Means and standard deviations were extracted (or estimated) to permit calculation of treatment effects and 95% confidence intervals (CIs) using the Hedges adjusted-g standardised mean difference (SMD) for continuous data. Standardised mean difference values of 0.2, 0.5, and 0.8 were considered to represent small, moderate and large effect sizes, respectively. For dichotomous data, the relative risk (RR) and 95% confidence intervals were calculated.

Two reviewers independently extracted data from the primary trials.

**Methods of synthesis**

Where at least two trials were considered to be both clinically and statistically similar, they were pooled in a fixed-effect meta-analysis; summary estimates were reported as standardised mean differences or relative risks, along with 95% confidence intervals. Statistical heterogeneity was assessed using $X^2$ and $I^2$ statistic (P-values of <0.1 or $I^2$ statistic >25% were considered significant).

Where quantitative pooling was considered inappropriate, effect sizes and 95% confidence intervals were reported for individual trials and a narrative synthesis was presented, using the levels of evidence criteria previously proposed by the Cochrane Collaboration; where less than 75% of trials were in agreement, the evidence was considered as contradictory.

**Results of the review**

Eighteen RCTs (n=1,671 patients) were included in the review. Quality scores ranged from 4 to 8, with seven trials considered to be of high quality. All but one RCT reported short-term follow-up (less than three months after randomisation), eight RCTs reported intermediate follow-up (between three and 12 months), and four trials reported long-term follow-up (at least one year).

Meta-analysis of two high quality trials found that advice was less effective than microdiscectomy surgery for back pain intensity at short-term follow-up (SMD -0.4, 95% CI -0.6 to -0.2). No between group differences were found at intermediate or long-term follow-up. Advice was found to be less effective than surgery for leg pain intensity at short-term follow-up (SMD -0.7, 95% CI -1.0 to -0.5) and intermediate follow-up (SMD -0.3, 95% CI -0.5 to -0.1), but no significant between group difference was found at long-term follow-up. A statistically significant effect of favouring surgery compared with advice was found for function (SMD -0.5, 95% CI -0.7 to -0.3) and global recovery (SMD 0.4, 95% CI 0.4 to 0.6) at short-term follow-up. No between group differences were found at intermediate or long-term follow-up.

Individual high-quality trials found moderate evidence that stabilisation exercises are more effective than no treatment, that manipulation was more effective than sham manipulation for individuals with acute symptoms and an intact anulus, but no difference among traction, laser and ultrasound. One trial found that some additional benefit from adding mechanical traction to medication and electrotherapy.

Adverse events were associated with traction (pain, lower limb weakness and fainting) and ibuprofen (gastrointestinal events).

**Authors’ conclusions**

In the short term, advice was less effective than microdiscectomy, but equally effective in the long term for individuals who had lumbar disc herniation with associated radiculopathy. Moderate evidence favoured stabilisation exercises over no treatment, manipulation over sham manipulation, and the addition of mechanical traction to medication and electrotherapy. No difference was found for traction, laser, and ultrasound treatments. Adverse effects were associated with traction and ibuprofen. However, further high-quality trials are required to allow firmer conclusions with regard to both efficacy and safety.

**CRD commentary**
The review question was supported by clear inclusion criteria. Several relevant databases were searched, but no specific attempts were made to identify unpublished literature, raising the possibility of publication bias. Appropriate steps were taken to minimise the likelihood of errors and bias for study selection, data extraction and validity assessment.

Trial quality was assessed using a standardised tool and summary scores were presented. Where possible the included trials were pooled but mostly a narrative synthesis was appropriately presented due to the clinical heterogeneity. Caution should be taken when interpreting these results as they are based on a number of small and largely heterogeneous trials, most of which were not considered to be of high quality. The authors' appropriately indicated that further research is required to more robustly determine the efficacy and safety of conservative treatments for adults with lumbar disc herniation with associated radiculopathy.

Implications of the review for practice and research

Practice: The authors did not state any implications for practice.

Research: The authors stated that additional high-quality trials are required to determine which conservative treatments are the safest and most effective for people with lumbar disc herniation with associated radiculopathy. They also stated that authors of future RCTs should take note of the revised CONSORT (Consolidated Standards of Reporting Trials) statement that recommends adverse events should be operationally defined and reported in all RCTs.

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