Meta-analysis of vertebral augmentation compared with conservative treatment for osteoporotic spinal fractures

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CRD summary
This review concluded that there was strong support for cement augmentation for pain, functional difficulties, and health-related quality of life in patients with symptomatic vertebral compression fractures. The results seemed less significant in longer studies. Given the poor evidence and limited reporting of the results, these conclusions seem too strong.

Authors' objectives
To assess the effects of vertebral augmentation versus conservative treatment on pain relief, functional improvement, and quality of life for people with osteoporotic spinal fractures; and to assess whether any positive effects were maintained.

Searching
MEDLINE, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials (CENTRAL), CINAHL and EMBASE were searched for articles from 1980 to July 2011. No language restrictions were imposed. Search terms were reported. Reference lists of selected papers were handsearched to locate further studies.

Study selection
Randomised controlled trials (RCTs) of vertebroplasty or kyphoplasty, compared with conservative or sham treatment, for osteoporotic compression fractures, were eligible for inclusion. Trials had to have used a validated outcome measure, and be classed as level I or II by the criteria of the North American Spine Society. The outcomes of interest were pain, spine-specific function, health-related quality of life, and new fracture risk. Trials that evaluated the treatment of compression fractures as a result of neoplasm were excluded.

Most of the included trials evaluated vertebroplasty; comparators included sham treatments, non-surgical care, optimum pain treatment or medical therapy, gentle tapping, needle insertion, and conservative treatment. Most trials used a pain visual analogue scale as their primary outcome. Eligibility criteria, measurement time points, and secondary outcomes varied across the trials.

Two reviewers independently selected studies for inclusion in the review; any disagreements were resolved through discussion, with a third reviewer if necessary.

Assessment of study quality
Trial quality was assessed using the Cochrane risk of bias tool. The authors did not state how many reviewers assessed quality.

Data extraction
The data were extracted to calculate standardised mean differences and 95% confidence intervals for continuous outcomes (pain, functional outcomes, and health related quality of life), or odds ratios and 95% confidence intervals for dichotomous outcomes (adverse events). The data were extracted according to the intention-to-treat principle, and classified as being measured early (two to 12 weeks) or late (26 weeks or more).

The authors did not state how many reviewers extracted the data.

Methods of synthesis
The effect estimates and their 95% confidence intervals were pooled using random-effects models. Sensitivity analyses were performed by removing one trial at a time, and by adjusting the correlation between pre-operative and follow-up outcomes (ranging from 0.1 to 0.9). Publication bias was assessed using funnel plots; if asymmetry was observed the classic and Orwin's fail-safe N were calculated.
One trial did not report the confidence limits at the time points of interest; the intervals for this study were imputed according to those reported by the other trials. The analyses were repeated using 50% more error, and 50% less error.

**Results of the review**

Seven publications, reporting six RCTs, were included in the review and meta-analysis (827 patients, range 34 to 300). All of the trials were assessed as having a low risk of bias for randomisation, and five were found to have a low risk of bias for allocation concealment. The results for all other bias domains were variable (breakdown provided in the review).

**Pain:** In meta-analysis of six trials, statistically significant improvements in pain, favouring vertebroplasty over control, were shown at early assessment (SMD 0.73, 95% CI 0.35 to 1.10) and late assessment (SMD 0.58, 95% CI 0.19 to 0.97). Further results were reported.

**Spine-specific functional outcome:** In six trials, statistically significant improvements, favouring vertebroplasty over control, were shown at early (SMD 1.08, 95% CI 0.33 to 1.82) and late assessment (SMD 1.16, 95% CI 0.14 to 2.18). Publication bias was evident; the classic fail-safe N was 131 and Orwin's fail-safe N was 29, indicating that missing studies were unlikely to change the conclusions.

**Health-related quality of life:** In five trials, compared with control, statistically significant improvements were observed with vertebroplasty, at early (SMD 0.39, 95% CI 0.16 to 0.62) and late assessment (SMD 0.33, 95% CI 0.16 to 0.51).

**Adverse events:** In six trials, no statistically significant difference in the incidence of adverse events was found between groups. No statistically significant difference in the incidence of secondary fractures between two weeks and two years was found.

Sensitivity analyses did not substantially change any of the results. No further evidence of publication bias was found (data not shown).

**Authors' conclusions**

This meta-analysis supported cement augmentation for pain relief, functional recovery and improvement in health-related quality of life for patients with symptomatic vertebral compression fractures. The results seemed less significant in longer studies.

**CRD commentary**

The review questions were clear and supported by reproducible inclusion criteria. Relevant databases were searched, with no language restrictions. Some evidence of publication bias was found, but fail-safe tests showed that this was not likely to have influenced the findings. Study selection was performed by two people, but the process was unclear for data extraction and quality assessment, so reviewer error and bias cannot be ruled out.

Suitable quality assessment criteria were used; the results showed that trial quality was variable. Trial details were presented, revealing some clinical and methodological differences between them. The authors did not report the levels of statistical heterogeneity in the meta-analyses, and not all the forest plots for the meta-analyses were shown. The trials themselves had fairly small samples, and only a few trials were eligible for inclusion in the review.

Given the poor evidence and limitations in the reporting of the results, the authors' conclusions seem too strong.

**Implications of the review for practice and research**

**Practice:** The authors stated that the weighted mean difference in pain relief exceeded the minimum clinically important difference in the visual analogue scale for spine patients.

**Research:** The authors stated that research into the effects of cement augmentation and additional treatments for associated metabolic bone disease was needed.

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