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[Intervention Review]

Percutaneous vertebroplasty for osteoporotic vertebral compression fracture

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ABSTRACT

Background

Percutaneous vertebroplasty remains widely used to treat osteoporotic vertebral fractures although our 2015 Cochrane review did not support its role in routine practice.

Objectives

To update the available evidence of the benefits and harms of vertebroplasty for treatment of osteoporotic vertebral fractures.

Search methods

We updated the search of CENTRAL, MEDLINE and Embase and trial registries to 15 November 2017.

Selection criteria

We included randomised and quasi-randomised controlled trials (RCTs) of adults with painful osteoporotic vertebral fractures, comparing vertebroplasty with placebo (sham), usual care, or another intervention. As it is least prone to bias, vertebroplasty compared with placebo was the primary comparison. Major outcomes were mean overall pain, disability, disease-specific and overall health-related quality of life, patient-reported treatment success, new symptomatic vertebral fractures and number of other serious adverse events.

Data collection and analysis

We used standard methodologic procedures expected by Cochrane.

Main results

Twenty-one trials were included: five compared vertebroplasty with placebo (541 randomised participants), eight with usual care (1136 randomised participants), seven with kyphoplasty (968 randomised participants) and one compared vertebroplasty with facet joint

glucocorticoid injection (217 randomised participants). Trial size varied from 46 to 404 participants, most participants were female, mean age ranged between 62.6 and 81 years, and mean symptom duration varied from a week to more than six months.

Three placebo-controlled trials were at low risk of bias and two were possibly susceptible to performance and detection bias. Other trials were at risk of bias for several criteria, most notably due to lack of participant and personnel blinding.

Compared with placebo, high- to moderate-quality evidence from five trials (one with incomplete data reported) indicates that vertebroplasty provides no clinically important benefits with respect to pain, disability, disease-specific or overall quality of life or treatment success at one month. Evidence for quality of life and treatment success was downgraded due to possible imprecision. Evidence was not downgraded for potential publication bias as only one placebo-controlled trial remains unreported. Mean pain (on a scale zero to 10, higher scores indicate more pain) was five points with placebo and 0.6 points better (0.2 better to 1 better) with vertebroplasty, an absolute pain reduction of 6% (2% better to 10% better, minimal clinical important difference is 15%) and relative reduction of 9% (3% better to14% better) (five trials, 535 participants). Mean disability measured by the Roland-Morris Disability Questionnaire (scale range zero to 23, higher scores indicate worse disability) was 14.2 points in the placebo group and 1.7 points better (0.3 better to 3.1 better) in the vertebroplasty group, absolute improvement 7% (1% to 14% better), relative improvement 10% better (3% to 18% better) (three trials, 296 participants).

Disease-specific quality of life measured by the Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO) (scale zero to 100, higher scores indicating worse quality of life) was 62 points in the placebo group and 2.75 points (3.53 worse to 9.02 better) in the vertebroplasty group, absolute change: 3% better (4% worse to 9% better), relative change: 5% better (6% worse to 15% better (two trials, 175 participants). Overall quality of life (European Quality of Life (EQ5D), zero = death to 1 = perfect health, higher scores indicate greater quality of life) was 0.38 points in the placebo group and 0.05 points better (0.01 better to 0.09 better) in the vertebroplasty group, absolute improvement: 5% (1% to 9% better), relative improvement: 18% (4% to 32% better) (three trials, 285 participants). In one trial (78 participants), 9/40 (or 225 per 1000) people perceived that treatment was successful in the placebo group compared with 12/38 (or 315 per 1000; 95% CI 150 to 664) in the vertebroplasty group, RR 1.40 (95% CI 0.67 to 2.95), absolute difference: 9% more reported success (11% fewer to 29% more); relative change: 40% more reported success (33% fewer to 195% more).

Moderate-quality evidence (low number of events) from seven trials (four placebo, three usual care, 1020 participants), up to 24 months follow-up, indicates we are uncertain whether vertebroplasty increases the risk of new symptomatic vertebral fractures (70/509 (or 130 per 1000; range 60 to 247) observed in the vertebroplasty group compared with 59/511 (120 per 1000) in the control group; RR 1.08 (95% CI 0.62 to 1.87)).

Similarly, moderate-quality evidence (low number of events) from five trials (three placebo, two usual care, 821 participants), indicates uncertainty around the risk of other serious adverse events (18/408 or 76 per 1000, range 6 to 156) in the vertebroplasty group compared with 26/413 (or 106 per 1000) in the control group; RR 0.64 (95% CI 0.36 to 1.12). Notably, serious adverse events reported with vertebroplasty included osteomyelitis, cord compression, thecal sac injury and respiratory failure.

Our subgroup analyses indicate that the effects did not differ according to duration of pain ≤ 6 weeks versus > 6 weeks. Including data from the eight trials that compared vertebroplasty with usual care in a sensitivity analyses altered the primary results, with all combined analyses displaying considerable heterogeneity.

Authors' conclusions

Based upon high- to moderate-quality evidence, our updated review does not support a role for vertebroplasty for treating acute or subacute osteoporotic vertebral fractures in routine practice. We found no demonstrable clinically important benefits compared with placebo (sham procedure) and subgroup analyses indicated that the results did not differ according to duration of pain ≤ 6 weeks versus > 6 weeks.

Sensitivity analyses confirmed that open trials comparing vertebroplasty with usual care are likely to have overestimated any benefit of vertebroplasty. Correcting for these biases would likely drive any benefits observed with vertebroplasty towards the null, in keeping with findings from the placebo-controlled trials.

Numerous serious adverse events have been observed following vertebroplasty. However due to the small number of events, we cannot be certain about whether or not vertebroplasty results in a clinically important increased risk of new symptomatic vertebral fractures and/or other serious adverse events. Patients should be informed about both the high- to moderate-quality evidence that shows no important benefit of vertebroplasty and its potential for harm.

PLAIN LANGUAGE SUMMARY

Vertebroplasty for treating spinal fractures due to osteoporosis

Background

Osteoporosis is characterised by thin, fragile bones and may result in minimal trauma fractures of the spine bones (vertebrae). They can cause severe pain and disability.

Vertebroplasty involves injecting medical-grade cement into a fractured vertebra, under light sedation or general anaesthesia. The cement hardens in the bone space to form an internal cast.

Study characteristics

This Cochrane review is current to November 2017. Studies compared vertebroplasty versus placebo (no cement injected) (five studies, 541 participants); usual care (eight studies, 1136 participants); kyphoplasty (similar, but before cement is injected a balloon is expanded in the fractured vertebra; seven studies, 968 participants) and facet joint steroid injection (one study, 217 participants). Trials were performed in hospitals in 15 countries, the majority of participants were female, mean age ranged between 63.3 and 80 years, and symptom duration ranged from a week to six months or more. Eight trials received at least some funding from medical device manufacturers and only two reported that they had no role in the trial.

Key results

Compared with a placebo (fake) procedure, vertebroplasty resulted in little benefit at one month:

Pain (lower scores mean less pain)

Improved by 6% (2% better to 10% better), or 0.6 points (0.2 better to 1.0 better) on a zero-0 to 10-point scale.

• People who had vertebroplasty rated their pain as 4.4 points.

• People who had placebo rated their pain as 5 points.

Disability (lower scores mean less disability)

Improved by 7% (1% better to 14% better), or 1.7 points (0.3 better to 3.1 better) on a zero to 23-point scale.

• People who had vertebroplasty rated their disability as 12.5 points.

• People who had placebo rated their disability as 14.2 points.

Vertebral fracture or osteoporosis-specific quality of life (lower scores mean better quality of life)

Better by 3% (4% worse to 9% better), or 2.75 points better (3.53 worse to 9.02 better) on a zero to 100-point scale.

.• People who had vertebroplasty rated their quality of life related to their fracture as 59.25 points.

• People who had placebo rated their quality of life related to their fracture as 62 points.

Overall quality of life (higher scores mean better quality of life)

Improved by 5% (1% better to 9% better), or 0.05 units (0.01 better to 0.09 better) on a zero = death to one = perfect health scale.

• People who had vertebroplasty rated their general quality of life as 0.43 points.

• People who had placebo rated their general quality of life as 0.38 points.

Treatment success (defined as pain moderately or a great deal better)

9% more people rated their treatment a success (11% fewer to 29% more), or nine more people out of 100.

• 32 out of 100 people reported treatment success with vertebroplasty.

• 23 out of 100 people reported treatment success with placebo.

Compared with a placebo or usual care:

New symptomatic vertebral fractures (at 12 to 24 months)

1% more new fractures with vertebroplasty (7% fewer to 9% more), or one more person out of 100.

• 13 out of 100 people had a new fracture with vertebroplasty.

• 12 out of 100 people had a new fracture with placebo or usual care.

Other serious adverse events:

1% fewer people (5% fewer to 3% more), had other serious adverse events with vertebroplasty; relative change 36% fewer (64% fewer to 12% more).

• eight out of 100 people reported other serious adverse events with vertebroplasty.

• 11 out of 100 people reported other serious adverse events with placebo.

Quality of the evidence

High-quality evidence shows that vertebroplasty does not provide more clinically important benefits than placebo. We are less certain of the risk of new vertebral fractures or other serious effects; quality was moderate due to the small number of events.

Serious adverse events that may occur include spinal cord or nerve root compression due to cement leaking out from the bone, cement leaking into the blood stream, rib fractures, infection in the bone, fat leaking into the bloodstream, damage to the covering of the spinal cord that could result in leakage of cerebrospinal fluid, anaesthetic complications and death.