Vertebroplasty: for whom and when

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INTRODUCTION

Vertebral compression fractures (VCF) are the most common type of fragility fracture, with about 1.4 million people affected annually, worldwide.¹ The risk of VCF increases with age, up to 25% in women and 18% in men by age 75 according to the European Vertebral Osteoporosis Study (EVOS).² VCF can result in severe and disabling back pain, especially in elderly patients. Patients may experience significant morbidity and decreased quality of life, are at higher risk of chronic back pain and have increased mortality rates.³ VCF is most commonly caused by osteoporosis but can be caused by primary and metastatic malignancies, trauma, haemangioma and osteonecrosis.

The current first-line therapy for symptomatic VCF comprises analgesics, bed rest and bracing. Patients generally improve in 4-6 weeks with this conservative treatment; however, up to a third of patients may require alternative therapy.⁴

Percutaneous vertebroplasty (PV) is the percutaneous injection of specially formulated acrylic bone cement under pressure into the cancellous bone of vertebra under image guidance. This procedure was first used by Galibert and colleagues, who published their findings in 1987.⁵ Since then, PV has become a standard treatment for VCF, although there is some controversy regarding its status, as discussed below.

PV is most commonly indicated for osteoporotic VCF;⁶ however, it can also be used for metastatic disease, multiple myeloma and aggressive haemangiomas. PV is contraindicated in...
patients with asymptomatic VCF and patients who improve with conservative treatment. It is also contraindicated in patients with allergies to bone cement products, patients with disruption of the dorsal wall of the vertebral body and patients with severely compressed VCF, as these are associated with increased risk of complications. Complications of PV include leakage of bone cement into adjacent structures, allergic reactions, infection, bleeding, transient neuropathy and pulmonary embolism.

DISCUSSION

Before 2009, PV was generally accepted as an efficacious treatment for VCF. Multiple observational studies reported significant pain relief in up to 75-95% of patients. However, Buchbinder et al. believe that there is a bias to overestimate the benefits of treatment, for several reasons, including the placebo effect. In 2009, the first two randomized blinded trials comparing PV and a sham intervention were published in the New England Journal of Medicine, and showed no statistically significant benefit of PV over placebo. These two trials have received much criticism, however, including allowing crossover at one month between the two groups in the study done by Kallmes et al. Further, Bono et al. suggested a possible selection bias within these two trials. The patients who would benefit from PV, namely patients with crippling pain and those at risk of increased immobilization, were less likely to consent to randomization, as evidenced by the low enrolment numbers compared with the number of screened patients. Kallmes did not enrol enough patients to disprove the effectiveness of PV and Buchbinder’s study was also insufficient to power a subgroup analysis to assess effectiveness in those with acute fractures (≤ 6 weeks).

In 2011, Staples et al. published a meta-analysis of two multicentre randomized controlled trials. This study had a larger sample size (n=209) and therefore increased power. The study showed similar results, with no significant difference in pain between PV and the sham procedure, including for the subgroup of patients with acute VCF (≤ 6 weeks) and severe pain (pain score ≥8). The meta-analysis, though, met similar criticism as the first two randomized controlled trials.

In 2016, results from VERTOS II, a randomized multicentre study, were published; however, it is important to note that there was no blinding. In this trial, 202 patients with acute VCF (≤ 6 weeks) were randomly assigned to PV or conservative treatment. At one month and at one year, the study found a statistically significant decrease in pain in the patients treated with PV. The authors concluded that the subgroup of patients with acute VCF who experienced significant pain had quicker and more effective pain relief with PV than patients treated conservatively.

Rousing et al. have published the results of a randomized study with 50 patients with acute VCF (≤ 8 weeks) which also compared PV with conservative treatment. They found a statistically significant decrease in pain 12-24 hours after the procedure and 1 month after discharge. However, there was no significant difference in pain at 6 months or 12 months. The authors concluded that patients with acute VCF who do not respond to conservative treatment or who are at increased risk of immobilization could benefit significantly from PV.
More recently, the results of VERTOS IV\textsuperscript{20} have been published. This is a double-blind randomized controlled trial with 180 patients assigned to either PV or a sham procedure. This study recruited only patients with acute VCF and did not allow cross-over at follow-up. The study found no significant difference in pain between the sham procedure and PV immediately after the procedure and at follow-up after 1, 3, 6, and 12 months. The authors did admit that they failed to include a group receiving conservative treatment with which to compare the results.

CONCLUSIONS

It is clear from the above studies that there is still much debate over the efficacy of PV and its benefits over sham therapy. However, the studies do appear to agree that PV does result in significantly more pain relief than is afforded by conservative treatment. It is the authors’ opinion that PV can provide short-term pain relief for patients with acute VCF who fail to respond to conservative treatment or who are at increased risk of immobilization. Acute intervention with VP allows earlier mobilization and earlier rehabilitation. Future studies should experiment with periosteal infiltration of local anaesthetics (the sham procedure used by Buchbinder et al.,\textsuperscript{13} Kallmes et al.,\textsuperscript{14} and Staples et al.,\textsuperscript{17} and in VERTOS IV\textsuperscript{20}) as a viable treatment option for VCF and as an alternative to vertebroplasty.

Contributors

Manjiri Ranade wrote the first draft and performed the literature search.

Ruben Geeraert edited the draft and revised the manuscript.

Hemant Pandit revised the draft and advised on structure and contents of the paper.

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REFERENCES


