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Vertebroplasty: for whom and when

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INTRODUCTION

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

The current first line therapy for symptomatic VCF is treatment with 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 to improve.[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 alternative treatment for VCF.

PV is most commonly indicated for osteoporotic VCFs[6], however, it can also be used for metastatic disease, multiple myeloma, and aggressive haemangiomas. PV is contraindicated in patients with asymptomatic VCF or patients improving 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[7], and patients with severely compressed VCFs as these are associated with increased risk of complications.[8] 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.[9,10,11] However, Buchbinder et al[12] 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 sham intervention were published in the NEJM and showed no statistically significant benefit of PV over placebo.[13,14] The two NEJM trials have received much criticism, however, including allowing crossover at one month between the two groups in Kallmes et al study.[14] Bono et al[15] also reports a possible selection bias within these two trials. The patients who would benefit from PV, patients with crippling pain and those at risk of increased immobilization, are less likely to consent to randomization as evidenced by the low enrollment numbers compared to the number of screened patients. Kallmes also did not enroll 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).[16]

In 2011, Staples et al[17] published a meta-analysis of two multi-center randomized controlled trials. This study comprised of a larger sample size (n=209) and an increased power. The study showed similar results with no significant difference in pain between PV and sham procedure including for the subgroup of patients with an acute VCF (≤ 6 weeks) and severe pain (pain score ≥8). The meta-analysis met similar criticism as the first 2 randomized controlled trials, however.

In 2016, VERTOS II[18] a randomized multi-centre study was 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 the PV or conservative treatment group. At one month and 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 an acute VCF who experienced significant pain had quicker and more effective pain relief with PV than patients treated conservatively.[18]

Rousing et al.[19] also recently published a randomized study with 50 patients with acute VCF (≤ 8 weeks) which compared PV with conservative treatment. The study found a statistically significant pain decrease 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 that fail conservative treatment or are at increased risk of immobilization could benefit significantly from PV.

Most recently, the results of VERTOS IV[20] have just been published. This is a double blinded randomized controlled trial with 180 patients randomly assigned to either PV or sham procedure. This study followed only acute VCFs and did not allow cross-over at the follow up. The study found no significant difference in pain between the sham procedure and PV immediately after the procedure and at the 1, 3, 6, and 12 month follow ups. The authors did admit that they failed to include a conservative treatment group with which to compare the results.

CONCLUSIONS

It is clear from the current studies that there is still much debate over the efficacy of PV over sham therapy. However, the studies do appear to agree that PV does result in significant pain relief over conservative treatment. As a result, it is still the author's opinion that PV can provide short-term pain relief for patients with acute VCFs who are failing conservative treatment or are at increased risk of immobilization. Acute intervention with VP allows earlier mobilization and earlier rehabilitation. Future studies should experiment with using periosteal infiltration of local

anesthetics (sham procedure used in Buchbinder et Al, Kallmes et Al, Staples et Al, and VERTOS IV) as a viable treatment option for VCFs and a possible replacement for vertebroplasty in the future.

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Manjiri Ranade wrote the first draft and performed the kit 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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