Vertebroplasty is not a do-not-do treatment

"The evidence for and against vertebroplasty is inconclusive"

Vertebroplasty has been controversial but remains clinically useful and new evidence awaits publication

Duckett and colleagues have classified vertebroplasty as a do-not-do treatment.[1] They referenced two randomised controlled trials (RCTs)[2,3] as definitive proof of this. However, the authors failed to heed our clinical opinion published in the *MJA* that these two trials were "not relevant to the patient group that we treat with vertebroplasty".[4] We have the largest clinical vertebroplasty experience in Australia, yet our published advice was apparently ignored. In the article by Duckett and colleagues, Box 1 illustrated the selection process that the authors used to determine do-not-do procedures. The process supposedly excluded evidence which was "contested" or "which was not supported by consulted clinical experts". Accordingly, vertebroplasty should have been deleted from the list.

The authors used the United Kingdom National Institute for Health and Care Excellence (NICE) for clinical guidance. Current NICE guidance[5] states that "vertebroplasty and kyphoplasty can be considered appropriate interventions for people with recent, unhealed osteoporotic vertebral compression fractures in whom the pain is severe and ongoing despite optimal pain management".

From 1208 potential treatments, the authors excluded 1200, leaving five apparently incontrovertible do-not-do treatments. The fact that at least one of the five is wrongly included (by the authors' own criteria) demonstrates the failure of the proposed model and the danger of adopting this kind of formula to influence clinical practice in hospitals.

The evidence for and against vertebroplasty is inconclusive. There is disparity in measured outcomes between blinded RCTs[2,3] of vertebroplasty for fractures up to 12 months old and a larger, open-label RCT[6] of fractures less than 6 weeks in duration. The blinded trials found no significant benefit of vertebroplasty over placebo, whereas the open-label RCT found significant benefit of vertebroplasty over conservative care. This disparity is well described in the NICE guidance.[5]

For the past 10 years, my vertebroplasty practice has been confined to treating fractures less than 6 weeks old.[7] It is clear to me that the published blinded trials tested a different approach and are not relevant to the patient group that my practice treats with vertebroplasty for two principal reasons: the fractures were mostly non-acute; and the volume of cement used in these trials (2.6 cm^3 on average in both trials) would have been insufficient to stabilise an acutely collapsing vertebral fracture.

Attempting to answer the acute fracture conundrum, the authors of the blinded RCTs published a meta-analysis of 52 patients from both trials with fractures less than 6 weeks duration.[8] Only outcomes at 2 weeks and 1 month were presented and the evidence is hardly definitive.

The onus was placed on vertebroplasty practitioners to provide high-quality blinded data in this group of patients. For this purpose, my co-investigators and I embarked on the Vertebroplasty for Acute Painful Osteoporotic fractURes (VAPOUR) trial.[9] Five years ago, we reconfigured the protocol from the INvestigational Vertebroplasty Efficacy and Safety Trial (INVEST),[2,10] the larger of the two blinded vertebroplasty trials. We excluded crossover, which was permitted at 1 month in INVEST. We changed the selection criteria to include only fractures less than 6 weeks duration (average fracture age in the VAPOUR trial was 2.6 weeks compared with 18 weeks in INVEST) with pain scores greater than 7/10 and with either magnetic resonance imaging or single-photon emission computed tomography evidence of acute fracture. In-patients, already hospitalised with acute fractures, comprised 59% of the VAPOUR trial enrolment but were excluded in INVEST. The procedural technique was different in the VAPOUR trial, where we attempted maximum fill of the vertebral body to stabilise the fracture and prevent ongoing collapse. The average cement volume of 7.5 cm^3 in the VAPOUR trial was three times that in INVEST. The method of blinding and data collection was similar for the two trials.

Our trial team included four Sydney centres with established vertebroplasty programs. The VAPOUR trial completed enrolment of 120 patients in December 2014 and is the largest RCT and the only acute fracture RCT of vertebroplasty in Australia. Statistical assessments of outcomes are nearing completion and the results of the trial will soon be published.

Acknowledgements: Optimus Clinical Research, an independent research company, collected the data and conducted the trial. The biostatistics section of the National Health and Medical Research Council Clinical Trials Centre (University of Sydney) provided trial guidance and statistical analysis. We obtained an independent research grant from CareFusion, the company that manufactures the vertebroplasty kit used for the trial. CareFusion had no input on trial protocol or conduct.

Competing interests: No relevant disclosures.

Provenance: Commissioned; not externally peer reviewed. ■

References are available online at www.mja.com.au.

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doi: 10.5694/mja15.01201

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