Vertebroplasty

Dear Editor

We read with concern Guduguntla and Subramaniam’s (AJP May 2006) claim that vertebroplasty is a safe, effective and cost effective treatment for osteoporotic spinal fractures. To be able to make such a claim, there should be either Level I (summaries of well conducted RCTs), or at least Level II (at least one properly conducted RCT) evidence. There are no completed RCTs of vertebroplasty and so its effectiveness including the ability to relieve pain, as well as both short and long term safety remains unproven. The promotion of vertebroplasty in routine care is therefore both premature and potentially dangerous.

There are many examples of seemingly beneficial therapies found to be ineffective or harmful when tested in rigorous studies. Nonrandomised studies may produce biased results for a range of reasons. The natural history of painful osteoporotic spinal fractures is to improve over time, often rapidly; the concept of ‘regression to the mean’ indicates that on average pain is likely to have improved or regressed to an average, regardless of treatment; and placebo responses may vary 30-70% and the placebo response of an invasive procedure is likely to be accentuated. Furthermore, volunteers who agree to have the new therapy are likely to be different to those either who either refuse or are not offered it.

Several recent studies have suggested that vertebroplasty may increase the risk of further spinal fractures, particularly in vertebrae adjacent to treated spinal fractures or if cement leakage into the adjacent disc has occurred. Trout et al reported that the relative risk of having a new spinal fracture adjacent to a treated spinal fracture was 4.62 (95% CI: 4.36-4.89). Time to fracture was also significantly faster. In another study, 58% of vertebrae adjacent to discs containing cement subsequently fractures compared with 12% vertebrae not adjacent. In a multivariate study of predictors of new vertebral body fracture, cement leakage into the disc was the only significant predictor of vertebral fracture. Unfortunately none of these studies were controlled or provided information about osteoporosis treatment.

The authors also state that the Medical Services Advisory Committee’s (MSAC) has recommended Medicare funding for vertebroplasty. We understand that this is an interim rebate, for limited indications. When further evidence becomes available, the MSAC recommendation will be reviewed and the rebate may be continued, expanded, restricted or withdrawn depending on the results of current trials. Several technology appraisals undertaken by international health policy makers have reported inadequate high quality evidence on which to base such a reimbursement decision.

A multicentre NHMRC funded RCT is currently underway in Melbourne (ACTRN012605000079640) to provide much needed evidence of the efficacy and safety of vertebroplasty for painful osteoporotic fractures. All trial participants are being followed for 2 years so that the question of long term safety and, in particular, risk of future fractures can be assessed. Unrestricted Medicare funding has the potential to seriously undermine the success of this and other trials by not only providing easy access to an unproven treatment but also by lending implicit support to its use. This may result in a situation where the true effects of this treatment may never be established. At present, the trial has recruited almost a quarter of the required sample and is expected to be complete within 4 years. It will provide pivotal evidence regarding the value of vertebroplasty.

Vertebroplasty may be a highly efficacious and safe treatment for painful osteoporotic spinal fractures but at the present time, in the absence of RCTs, promotion, dissemination and routine use of this procedure outside of the research setting remains unjustified.

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References