Vertebroplasty appears no better than placebo for painful osteoporotic spinal fractures, and has potential to cause harm

Paul J Graziotti

To the Editor: The editorial by Buchbinder et al suggesting that the effectiveness of vertebroplasty has been determined by the two studies she and her co-authors published is misleading.

Both studies contain major flaws. In both, 70% of eligible patients declined to participate. No details of these patients are published, but they may have been the patients with more severe pain. The median duration of pain in the Australian study was 9 weeks (compared with 16 weeks in the US study); only 30% of patients had pain for less than 6 weeks. No information on the need for hospitalisation because of severe pain was given in either study. The average length of hospital stay was not published.

In the Australian study, the inclusion criteria were the presence of back pain of less than 12 months’ duration and the presence of one or two recent fractures. In this group of patients, whose average age was 74 years, there will be many possible causes of back pain. The fracture may be the main cause of pain, a part-player, or may not be significant. In patients with milder pain and longer duration of pain, non-fracture causes are more likely.

In the US study, patients were selected on the basis of x-ray unless the fracture “was of uncertain age”. I have performed an audit of my practice and found that in patients with an unequivocal x-ray diagnosis of fracture level, magnetic resonance imaging (MRI) identified another fracture not seen on x-ray in 23 of 63 patients (36%), and in 10 of the 63 patients (16%), a fracture that was presumed acute showed no oedema on MRI.

In the Australian study, the experience of the radiologists performing the vertebroplasty is not made clear; no details are given about the number of patients they had previously treated. The incidence of osteomyelitis (3.8% at best, 30% at worst, depending on which centre was involved), despite prophylactic antibiotic therapy, is unacceptable. In the US study, injury to the thecal sac in one of 78 patients suggests incompetence. The protocol stated that cement injection was ceased if “cement reached the posterior quarter of the vertebral body or leaked into intraosseous structures”. This sometimes happens after 1 mL of cement has been injected. Experienced operators will perform various manoeuvres to ensure an adequate spread of cement occurs throughout the vertebral body. It would appear this was not done. The volumes of cement injected are not published, except an estimate of “about 3 mL”.

The sham procedure was not a true placebo. Injection of local anaesthetic onto the pedicle would likely block the dorsal ramus nerve and provide partial analgesia of the fracture if the fracture extended into the pedicle.

Those who perform vertebroplasty regularly see patients who are bedridden, in severe pain, intolerant of analgesics, and who have undergone various procedures including epidural injections or facet joint injections without benefit, and who then respond to vertebroplasty within 24 hours. Efforts should be aimed at refining technique and patient selection, rather than throwing out the baby with the bathwater on the basis of inappropiate studies.

Competing interests: Stryker Pty Ltd (medical device company) paid my costs of travel and accommodation to participate in an instructional course on vertebroplasty.

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Kevin D Pile

To the Editor: Clinical trials study a restricted patient group, so their results may not be generalisable to a different population subgroup or the population as a whole. The editorial by Buchbinder, Osborne and Kallmes about their recent vertebroplasty studies concludes that vertebroplasty offers no benefit over placebo. They suggest, in light of their trials, the decision to list vertebroplasty on the Medical Benefits Schedule will be reviewed later this year. I understood the review to have been part of the original listing on the benefits schedule and not as a result of their studies, and I suggest that their editorial generalises results to a subpopulation of early acute vertebral fractures that they did not study.

The duration of symptoms in osteoporotic vertebral fracture is critical, as most fractures heal quickly with a good outcome by 3 months, and only a very small group of patients continue to experience pain. A fracture that is still painful months after the event is not a “normal fracture”, and I suggest is less likely to respond to the same management concepts as an acute fracture.

In the study by Buchbinder and colleagues, patients had persistent pain and were recruited up to 1 year after their vertebral fracture. Nearly three-quarters had significant ongoing pain for at least a month after their fracture, and most for at least 2 months. The study by Kallmes and colleagues also included symptomatic fractures up to 1 year old, with the interquartile range (8–38 weeks) suggesting that they had an even longer period between fracture and inclusion in the trial.

While vertebroplasty appears to be unhelpful for patients who continue to have chronic pain months after an acute osteoporotic fracture, the authors have not robustly excluded vertebroplasty as improving quality of life and pain management in those who undergo vertebroplasty within days to a month of the fracture. Such an outcome is suggested by Rousing et al, who showed that vertebroplasty within 2 weeks of fracture led to a rapid reduction in pain within 12–24 hours, similar to the result of conservative management at 3 months.

Any review of the role for vertebroplasty should consider the populations studied and, hence, should define the characteristics of patients in whom to intervene or not intervene.

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Rachelle Buchbinder, Richard H Osborne and David Kallmes

IN REPLY: The letters by Graziotti and Pile raise spurious issues that in no way threaten the key message of our trials. Participation rates in both trials were better than other controlled trials of vertebroplasty or kyphoplasty.1,2 Eligible patients who declined enrolment in the Investigational Vertebroplasty Efficacy and Safety Trial (INVEST) had similar levels of pain and disability to those who participated.3 Both trials adhered to stringent eligibility criteria, ensuring that only patients with pain due to acute or subacute fractures were included. All operators were trained and experienced, and the low incidence of serious adverse effects in both trials is consistent with the literature. There is no evidence that the outcome of vertebroplasty is influenced by cement distribution or volume.4 Local anaesthetic infiltration of the periosteum of the pedicles, as occurred in one trial,3 is unlikely to have a sustained effect.

As Pile points out, most osteoporotic vertebral fractures heal quickly; this implies that most people would be unlikely to benefit from early invasive intervention. Consistent with this, public funding for vertebroplasty in Australia only has interim approval for patients whose pain is not controlled by conservative medical therapy. While duration of medical therapy is not specified, historically, this has ranged from at least 4 to 6 weeks. Thus, both trials included patients similar to those who would qualify for government-subsidised funding of the procedure in Australia.

While Pile acknowledges that vertebroplasty appears to be of no value in patients with persisting symptoms (the group most likely to derive benefit), he seems to suggest that it may have a role in early treatment (within days to a month). As well as being at odds with his earlier statement, this is not supported by the available data. Many participants in both trials had short symptom duration (Australian trial, 32% < 6 weeks; INVEST, 20% < 6 weeks and 41% ≤ 13 weeks), and neither trial found evidence that symptom duration was a treatment effect modifier. The trial by Rousing et al reported comparable outcomes from vertebroplasty and conservative treatment in patients with acute symptoms (40 patients, <2 weeks; 10 patients, 2–8 weeks).5 While no data were presented, the immediate (12–24 hours) benefit from vertebroplasty reported in this open study, like clinical experience, could be attributable to many factors including local anaesthesia, regression to the mean, and expectation bias.

The onus remains on proponents of vertebroplasty to prove that any benefits of vertebroplasty outweigh the potential risks.

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