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EDITORIALS

Vertebroplasty for vertebral fracture

On the basis of current evidence, cannot be recommended as the first line treatment

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In the linked meta-analysis of individual patient data (doi:10.1136/bmj.d3952), Staples and colleagues assess whether vertebroplasty for vertebral fracture is more effective than placebo in certain subgroups of people.[1]

Insufficiency fractures of the vertebra are a major cause of morbidity and are estimated to affect about one in four adults over the age of 50 years. Risk factors include age, low body mass index, smoking, alcohol misuse, family history, use of corticosteroids, and chronic illness. Although these associations may be used to predict the incidence of disease,[2] this remains a substantial problem in later life, and preventive treatment has yet to reduce the incidence.

Medical interventions, such as lifestyle changes, hormone replacement, and bisphosphonates, have been used to treat vertebral fractures. However, it is unclear how best to manage the fracture, to alleviate pain, and to reduce long term disability. Since the original description of vertebroplasty in 1987,[3] percutaneous cement augmentation has been widely advocated for pain management. Such procedures are normally performed on a day case basis and are undertaken using heavy sedation with fluoroscopy to guide an injection of cement into the fractured vertebra.

Many large unblinded trials have shown that cement augmentation results in a 70-90% improvement in symptoms within a few weeks.[4 5] However, imaging of acute fractures often shows multiple healed injuries even though patients have no recollection of the event, so spontaneous resolution must be common. Current guidance from the National Institute for Health and Clinical Excellence is that all patients with a symptomatic vertebral fracture confirmed by imaging should be treated conservatively for at least four weeks before considering spine augmentation.[6]

The first two randomised controlled trials comparing vertebroplasty with a control procedure were published in 2009.[7 8] The studies found startlingly similar results, with almost identical improvement in symptoms in patients treated by percutaneous augmentation of spinal fractures and those in whom local anaesthetic was infiltrated into the region of the fracture. The findings raised concerns among clinicians and patients that vertebroplasty is ineffective, although it has perhaps been overlooked that both studies gave over 85% recovery in a group of patients who had been in pain for many months. Some professional groups, such as the American Academy of Orthopaedic Surgeons, have recommended against vertebroplasty as a primary treatment for insufficiency fracture due to osteoporosis, whereas others have considered restricting spinal augmentation to subsets of patients, such as those who do not respond to anaesthetic injection. There is vigorous debate in the UK and Europe with no current consensus.

Given that many studies have shown lower success rates with simple conservative management than with vertebroplasty, something must have worked, the question is how? There are three possible reasons that the two trials found no benefit of vertebroplasty over the control procedure. Firstly, there may have been a high placebo response to any interventional procedure. Secondly, patients may have spontaneously recovered in both groups. Thirdly, the pain may have had more than one cause, one of which responded to the control intervention and the other to vertebroplasty.

The randomised controlled trials have been criticised for potential flaws, including the possibility that the patients were unblinded to the intervention, but this has been refuted by review of the data.[9] The authors of one of the trials also considered the possibility that the local anaesthetic injection was therapeutic, and in 19 patients they injected local anaesthetic at the site of the fracture before considering cement augmentation; they found little benefit.[10] They also suggest that vertebroplasty is essentially a potent placebo.[11] However, a recent prospective audit reviewed patients who were first treated by injecting local anaesthetic and steroid in the paraspinal region at the level of pain, sometimes two or three segments below the fracture.[12] About 34% of patients had immediate pain relief, which lasted at least two months. Therefore in a subgroup of about a third of patients, pain may come from other spinal structures as a result of loss of sagittal balance—the consequence of spinal deformity secondary to the fracture—rather than from motion at unhealed fractures. The patients who failed to respond were treated with cement augmentation, with success in 23 of 24 cases (94%), which suggests a role for vertebroplasty when other causes of pain are excluded. These findings may explain the difference

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in results between the two randomised studies and what is seen in clinical practice.

An alternative explanation for the findings of the randomised trials is that the different durations or severity of the pain might result in a different response to treatment. Staples and colleagues' meta-analysis of data from both papers analyses subgroups of patients to see whether the results would have been different if the selection criteria were more rigorous. Their analysis suggests that this is not the case and that the results stand.

Given that the prospective audit found that facet infiltration with cement augmentation in selected cases can relieve symptoms in more than 90% of cases [12] it would be hard to argue that we should revert to the old treatment of long term opiate analgesia with its associated morbidity in this age group. Should cement augmentation be abandoned or perhaps confined to subgroups of patients? [9]

What should clinicians do in the light of current evidence? It is sensible to use safer and less invasive techniques initially—infiltration of local anaesthetic, and perhaps steroids in the region of the pain, may alleviate symptoms sufficiently in a third of patients to break the pain cycle or potentially cover the period before spontaneous recovery. Cement augmentation may have a role in those who fail to respond.

Currently, there is probably insufficient evidence to reach a firm conclusion. A study to repeat the randomised trials using a more tightly controlled patient selection is under way. It may also be prudent to investigate further the mechanism of pain in vertebral fractures because it is likely to be multifactorial.

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