

## NICE Technology Appraisal

### Vertebroplasty and Kyphoplasty

Personal Statement on behalf of the British Society of Skeletal Radiologists:

[REDACTED]

I am a musculo-skeletal radiology consultant of 16 years with an interest in spinal intervention. I have been performing vertebroplasty and kyphoplasty for over 10 years.

Below are my thoughts from observations during that time and based on reading the current literature on the subject:

Osteoporosis is a complex demineralising condition with a wide spectrum of clinical severity which affects many, predominantly elderly patients with 750,000 new vertebral fractures occurring in the United States per year. The majority of osteoporotic vertebral fractures will heal without long term sequelae and a significant number will have occurred sub-clinically, but a small proportion remain painful and in some cases result in severe debilitating pain and progressive deformity. It is these cases which need to be recognised at an early stage and treated more aggressively with vertebral cement augmentation to prevent progressive deformity and to relieve the severe pain.

Epidemiological studies support the fact that osteoporotic vertebral compression fractures are not as benign a clinical entity as perhaps originally thought. Mortality rates are observed to increase significantly when the number of vertebral fractures increase, (Kado DM et al) and the conclusion from the study by Suzuki et al was that, instead of the generally believed good prognosis for the greater majority of those with vertebral fractures, the acute vertebral body fracture was the beginning of a long lasting severe deterioration of their health.

It is this heterogeneity of the clinical spectrum which has made evaluating the efficacy of treatments such as vertebroplasty and kyphoplasty for osteoporotic vertebral fractures difficult.

The studies by Buchbinder and Kallmes are both randomised, controlled, double blinded trials but are significantly under-powered studies and certainly in the case of the Kallmes study, the inclusion criteria are not as stringent as might appear at first glance. The original power calculation suggested that 294 patients should be included in the study and when the study was terminated prematurely only 131 patients had been enrolled, and it should be noted that 1682 patients were excluded from the study for a variety of different reasons.

What can be concluded from these two studies?

In the Kallmes study, at one month, clinical improvement in patients with painful osteoporotic vertebral fractures was similar among those treated with vertebroplasty and those treated with local anaesthetic injections in and around the posterior elements of the painful segment. Similarly, the Buchbinder study concluded that there was no significant early benefit from vertebroplasty over a sham procedure (local anaesthetic injection into the posterior para-spinal tissues among patients with recent osteoporotic fractures).

It should be noted that potential trial participants for both studies, when presented with a choice between an apparently established treatment (vertebroplasty) and a clinical trial which might mean no effective treatment, are likely not to enter either trial. It is therefore probable that this will result in exclusion of the most symptomatic patients who are perhaps most likely to benefit from vertebroplasty.

My concern, therefore, is that these studies do not address satisfactorily the sub-population of patients with vertebral compression fractures at the severe end of the spectrum who may progress to rapid deformity and multiple vertebral compression fractures over a short period of time.

The Vertos and FREE studies are also not without their limitations. These are not placebo-controlled trials and there is therefore still doubt about the mechanism of the effect of the intervention being evaluated. On the other hand these are adequately powered studies looking at patients with more clearly defined early vertebral fractures with higher pain scores, compared to the randomised controlled trials of Kallmes and Buchbinder.

Perhaps the unifying conclusion from all of these studies is that at the very least, patient selection is critical if vertebroplasty is to be found to be effective and that if at all possible, more (ideally better powered) randomized controlled trials are required.

Spinal pain in the setting of vertebral compression fractures is a complex, multifactorial phenomenon. As well as pain from the micro-movement at the fracture plane, it is likely that sagittal imbalance from the kyphotic deformity results in operation of the biomechanical stresses on the posterior elements and paraspinal muscles, and it is therefore logical to understand that local anaesthetic injections into these areas may have a short term effect on pain and potentially a more intermediate term effect by breaking complex pain cycles.

Further well designed studies will be difficult to orchestrate and complete, but are essential to understand more comprehensively the complexities of vertebral compression fractures.

What is most important is to identify the subset of patients in whom early intervention with percutaneous cement augmentation is likely to be beneficial both in terms of pain relief and prevention of progressive deformity.

#### References:

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