

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Proposed Health Technology Appraisal

Vertebroplasty and kyphoplasty for the treatment of osteoporotic vertebral fractures

Draft scope (Pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of percutaneous vertebroplasty and balloon kyphoplasty for the treatment of osteoporotic vertebral fractures.

Background

Vertebral fracture refers to a break in any of the bones (vertebrae) of the spinal column. There are several types of vertebral fractures based on the mechanism of injury. Vertebral compression fractures occur when the front portion of the vertebral column is compressed. Vertebral compression fractures may be due to trauma or due to a weakened vertebra, most commonly a result of osteoporosis. Other causes include malignancy in the vertebrae or, more rarely, in vertebral haemangiomas.

Vertebral compression fractures can be associated with curvature of the spine and loss of height and can result in pain, breathing difficulties, gastrointestinal problems and difficulties in performing activities of daily living. However, it is thought that the majority (50–70%) of vertebral compression fractures are asymptomatic.

Prevalence of vertebral compression fractures is difficult to estimate as not all fractures come to the attention of clinicians and they are sometimes overlooked on X-rays. It is estimated that, annually, there are 25,000 osteoporosis-related clinical (symptomatic) vertebral fractures in England and Wales. The prevalence of vertebral fracture increases with age.

Non-invasive treatment (such as painkilling medication, bed-rest and the use of back braces) for vertebral compression fractures is focused on the alleviation of symptoms and spinal support. The majority of patients become symptom free through these measures and the majority of fractures will repair within weeks. Surgery is rarely indicated, but may be considered in patients whose condition is refractory to medical therapy and in whom there is continued vertebral collapse and severe pain.

Hospital episode statistics indicate that approximately 800 percutaneous vertebroplasty procedures and 500 balloon kyphoplasty procedures were undertaken in England and Wales in 2008/09.

NICE Interventional Procedure guidance supports the use of percutaneous vertebroplasty (IPG No. 12) and balloon kyphoplasty (IPG No. 166) as options for the treatment of vertebral fractures. The guidance notes that these

procedures should only be undertaken after prior discussion with a specialist multidisciplinary team and in an appropriately resourced facility, which has access to a spinal surgery service. For percutaneous vertebroplasty, the guidance also states that the procedure should be limited to people whose pain is refractory to more conservative treatment. NICE clinical guideline 75 provides guidance on the use of percutaneous vertebroplasty and balloon kyphoplasty in the management of vertebral metastases.

The technologies

Percutaneous vertebroplasty involves the injection of bone cement, typically polymethacrylate (PMMA) into the vertebral body (the large, cylindrical part of the vertebra). The procedure may relieve pain and stabilise a fracture, but it does not directly restore vertebral body height. It can be performed with the patient under sedation and with an analgesic.

Percutaneous vertebroplasty may be used to provide pain relief for people with severe painful osteoporosis with loss of height and/or compression fractures of the vertebral body, and also for people with symptomatic vertebral haemangioma and painful vertebral body tumours (metastases or myeloma).

Balloon kyphoplasty is a variation of vertebroplasty. It involves the insertion of a balloon-like device into the vertebral body. The balloon is then slowly inflated until the normal height of the vertebral body is restored or the balloon reaches its maximum volume. When the balloon is deflated the space is filled with bone cement. The procedure can potentially restore vertebral body height and reduce curvature of the spine, but requires that the patient is anaesthetised (either by local or general anaesthetic).

Indications for kyphoplasty are generally the same as those for vertebroplasty and include painful vertebral compression fractures due to osteoporosis or osteolytic lesions. In addition, kyphoplasty may be used to prevent the sequelae of immobility and deformity due to vertebral compression fractures, such as decreased lung function, decubitus ulcers, urinary tract infections, and deep vein thromboses. In general, balloon kyphoplasty is indicated in patients with recent fractures and curvature of the spine.

A variety of bone cements, along with delivery equipment for both procedures, have received CE mark authorisation.

Interventions	<ul style="list-style-type: none"> • Percutaneous vertebroplasty • Balloon kyphoplasty
Population(s)	People with osteoporotic vertebral fractures whose pain is refractory to more conservative treatment

Comparators	<ul style="list-style-type: none"> • The interventions should be compared with each other • Non-invasive management (without the use of either intervention)
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • pain • functional status/mobility • vertebral body height and angular deformity • Rate of new fractures • adverse effects of treatment • health-related quality of life.
Economic analysis	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>
Other considerations	<p>Guidance will only be issued in accordance with the instructions for use.</p>
Related NICE recommendations	<p>Related Guidelines:</p> <p>Clinical guideline No. 75, Nov 2008. 'Metastatic spinal cord compression: diagnosis and management of adults at risk of and with metastatic spinal cord compression'.</p> <p>Related Interventional Procedures:</p> <p>Interventional Procedure Guidance No. 12, Sep 2003, 'Percutaneous vertebroplasty'</p> <p>Interventional Procedure Guidance No. 166. (Apr 2006) Updated Jan 2008, 'Balloon kyphoplasty for vertebral compression fractures'</p>

Questions for consultation

Should people who have traumatic vertebral fractures also be included in the population for this scope?

How should non-invasive management (without the use of either intervention) be defined?

Should different types of bone cement be considered? If so, which bone cements are routinely used in the UK for percutaneous vertebroplasty or balloon kyphoplasty procedures?

Among fractures that would be considered suitable for vertebroplasty and/or kyphoplasty, what proportion are caused by osteoporosis, and what proportion are associated with other causes?

Is the population in the scope defined appropriately? Do the populations considered for percutaneous vertebroplasty and balloon kyphoplasty differ?

Are there any other subgroups of people in whom these technologies are expected to be more clinically effective and cost effective or other groups that should be examined separately?

Are there any issues that require special attention in light of the duty to have due regard to the need to eliminate unlawful discrimination and promote equality?

Do you consider vertebroplasty and/or kyphoplasty to be innovative in their potential to make a significant and substantial impact on health-related benefits and how they might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of these technologies can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.

NICE intends to appraise these technologies through its Multiple Technology Appraisal (MTA) Process. Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology_appraisal_process_guides.jsp