

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for the treatment of osteoporotic vertebral fractures

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of percutaneous vertebroplasty and percutaneous balloon kyphoplasty (with or without vertebral body stenting) 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 usually 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.

Osteoporotic 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. Osteoporotic vertebral compression fractures can also interfere with sleep and people with these fractures can have side-effects from high doses of analgesics. However, it is thought that the majority (50–70%) of vertebral compression fractures are not identified at the time of occurrence.

It is estimated that more than 2 million women in England and Wales have osteoporosis. Prevalence of osteoporotic 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 at least 25,000 osteoporosis-related clinical (symptomatic) vertebral fractures in England and Wales. The prevalence of vertebral fracture increases with age. Clinically evident osteoporotic vertebral compression fractures are associated with an increase in mortality.

Non-invasive treatment (such as medication for pain relief, 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 percutaneous 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 percutaneous 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 percutaneous 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 painful osteoporotic vertebral compression fractures.

Percutaneous 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 highest achievable volume. When the balloon is deflated the space is filled with bone cement. Vertebral body stents can also be inserted before the cement is added. The procedure can potentially restore vertebral body height and reduce curvature of the spine, and requires that the patient is anaesthetised (either by local or general anaesthetic).

Indications for percutaneous balloon kyphoplasty are generally the same as those for percutaneous vertebroplasty and include painful vertebral compression fractures due to osteoporosis or osteolytic lesions. In general, percutaneous 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 • Percutaneous balloon kyphoplasty with or without vertebral body stenting
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Population(s)	People with painful osteoporotic vertebral fractures
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 • progression of treated fracture • rate of new vertebral fractures • mortality • 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>

<p>Other considerations</p>	<p>The assessment of evidence should also include consideration of clinical trials where sham procedure was performed in the comparator arm.</p> <p>If evidence allows, consideration will be given to subgroups defined by</p> <ul style="list-style-type: none"> • time between fracture and treatment • people with and without fracture-related deformity before treatment • people receiving inpatient care before treatment and those who were not. <p>People with malignancy-related vertebral fractures and those with neuropathy in the absence of osteoporotic compression fractures are outside the scope of this appraisal.</p> <p>Guidance will only be issued in accordance with the instructions for use.</p>
<p>Related NICE recommendations</p>	<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>