NICE National Institute for Health and Care Excellence

NICE guidance

Balloon kyphoplasty for vertebral compression fractures

HealthTech guidance
Published: 26 April 2006

www.nice.org.uk/guidance/htg108

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces IPG20 and IPG166.

1 Recommendations

1.1 Current evidence on the safety and efficacy of balloon kyphoplasty for vertebral compression fractures appears adequate to support the use of this procedure provided that normal arrangements are in place for consent, audit and clinical governance.

1.2 The following are recommended.

- This procedure should only be undertaken with prior discussion by a specialist multidisciplinary team that includes a radiologist and a spinal surgeon, and when there are facilities for good imaging, and arrangements for good access to a spinal surgery service.
- Clinicians should receive training to reach an appropriate level of expertise before carrying out this procedure. In particular, they must follow the manufacturer's instructions for making the cement, to reduce the risk of embolisation.

2 The procedure

2.1 Indications

2.1.1 Vertebral compression fractures are one of the most common types of osteoporotic fracture. Osteoporotic fractures are common in the elderly and particularly in postmenopausal women, but they can also be associated with other factors such as chronic steroid usage. Other causes of vertebral compression fracture include malignancy in the vertebrae or, more rarely, haemangioma.

2.1.2 Pain is the most common symptom in patients with vertebral compression fractures. Fractures can also cause progressive spinal deformity with abnormal curvature (kyphosis). This can lead to increased risk of further fracture at adjacent levels and progressive malalignment, deformity and pain. There is also an increased risk of falls.

2.1.3 Conventional treatment for vertebral compression fractures is focused on the alleviation of symptoms with analgesic medication and spinal support. The majority of patients become symptom free through these measures and surgery is rarely indicated.

2.1.4 Surgery may be considered in patients whose condition is refractory to medical therapy and in whom there is continued vertebral collapse and severe pain. Recently there has been increased interest in minimally invasive procedures, including balloon kyphoplasty and vertebroplasty.

2.2 Outline of the procedure

2.2.1 Balloon kyphoplasty is performed under local or general anaesthesia assisted by fluoroscopy. One or more levels of the spine can be treated in one session.

2.2.2 The fractured vertebra is accessed through a small incision in the patient's back.

A hand drill is used to create a channel through which one or two balloon-like devices (inflatable bone tamps) can be inserted into the medullary space. The inflatable tamp is positioned in the vertebral body and filled with a radiopaque contrast medium for visualisation. The balloon is slowly inflated until the normal height of the vertebral body is restored or the balloon reaches its maximum volume. The balloon is then deflated and the cavity created filled with cement (typically polymethylmethacrylate, PMMA) at a low pressure.

2.3 Efficacy

2.3.1 Three non-randomised studies were reviewed: two compared balloon kyphoplasty with conventional medical care (physical and analgesic therapy) and one compared the procedure with vertebroplasty. All three studies found that patients who had undergone balloon kyphoplasty had improved pain scores compared with the control group at a maximum follow-up of 24 months.

2.3.2 In two non-randomised controlled studies, physical function following balloon kyphoplasty, as measured by the European Vertebral Osteoporosis Study Group questionnaire or Oswestry Disability Index (ODI), was shown to be significantly improved from baseline at 12 months. However, in one of these trials physical function (ODI) at 2 years was not found to be significantly different from preoperative values in either the balloon kyphoplasty group (61% vs 56%) or the vertebroplasty group (61% vs 52%).

2.3.3 In a study of 222 patients (360 procedures), a greater than 20% restoration of lost vertebral height was achieved in 63% and 69% of fractures at the anterior and midline, respectively, and the kyphosis angle decreased from 22° to 15°. In a study comparing balloon kyphoplasty with conventional medical care, midline vertebral body height was significantly increased in the balloon kyphoplasty group compared with that at baseline and at 12 months was significantly greater than in the controls (67% vs 56%). For more details, see the overview.

2.3.4 The Specialist Advisors expressed uncertainties about whether the improvements following balloon kyphoplasty (reduced pain and height restoration) are maintained in the long term.

2.4 Safety

2.4.1 The most commonly reported complications following balloon kyphoplasty were cement leaks and new fractures. One study of 360 procedures in 222 patients reported 38 cement leaks (11% of procedures), with one resulting in an episode of radiculopathy (the patient recovered with selective nerve block and rehabilitation). In another study of 192 procedures in 102 patients, cement leaks were reported from eight vertebral bodies (7%), all of which were asymptomatic.

2.4.2 In one study of 115 osteoporotic patients (225 procedures), 26 patients (23%) developed a post-procedure fracture. In the non-randomised controlled study comparing balloon kyphoplasty to standard medical care, seven new fractures were observed in 7 of 40 (18%) patients in the balloon kyphoplasty group, compared with 11 fractures in 10 of 20 (50%) patients in the control group. In another non-randomised controlled study (28 patients undergoing balloon kyphoplasty, 35 fractures), six fractures to adjacent vertebrae were observed within 4 months from the procedure.

2.4.3 Other reported adverse events during or after balloon kyphoplasty included balloon rupture (two cases), motor deficits caused by faulty puncture (one case) and epidural bleeding (one case).

2.4.4 In a review of complications reported to the US Food and Drug Administration (Center for Devices and Radiological Health), there were 33 major complications in patients (denominator estimated at between 40,000 and 60,000 procedures) following balloon kyphoplasty. These included one death; five cases of permanent paralysis, radiculopathy, paraesthesia or loss of motor function; and 13 cases of canal intrusion or cord compression. For more details, see the overview.

2.4.5 The Specialist Advisors listed cement leakage as the most common complication following balloon kyphoplasty. They also listed infection, allergy and spinal cord or nerve root injury caused by incorrect needle placement as potential complications.

2.5 Other comments

2.5.1 The Medicines and Healthcare products Regulatory Agency has issued a safety notice on injectable polymeric cements used in percutaneous vertebroplasty, balloon kyphoplasty and pedicle screw augmentation.

3 Further information

Sources of evidence

The evidence considered by the committee is in the overview.

Information for patients

NICE has produced information for patients and carers on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 166 has been migrated to HealthTech guidance 108. The recommendations and accompanying content remain unchanged.

ISBN: 978-1-4731-9128-0

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.