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Balloon kyphoplasty for vertebral compression fractures

Understanding NICE guidance –
information for people considering
the procedure, and for the public

Ordering information

You can download the following documents from www.nice.org.uk/IPG166

- this booklet
- the full guidance on this procedure.

For printed copies of the full guidance or information for the public, phone the NHS Response Line on 0870 1555 455 and quote:

- N1016 (full guidance)
- N1017 (information for the public).

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About this information

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. One of NICE's roles is to produce guidance (recommendations) on whether interventional procedures are safe enough and work well enough to be used routinely in the NHS in England, Wales and Scotland.

This information describes the guidance that NICE has issued on a procedure called balloon kyphoplasty for vertebral compression fractures. It is not a complete description of what is involved in the procedure – the patient's healthcare team should describe it in detail.

NICE has looked at whether balloon kyphoplasty is safe enough and works well enough for it to be used routinely for the treatment of vertebral compression fractures.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of balloon kyphoplasty for vertebral compression fractures and how well it works
- asked experts for their opinions
- asked the views of the organisations that speak for the healthcare professionals and the patients and carers who will be affected by this guidance.

This guidance replaces the previous guidance on balloon kyphoplasty for vertebral compression fractures (which was interventional procedure guidance number 20). To produce this guidance, NICE undertook a review of all the published studies on balloon kyphoplasty for vertebral compression fractures.

This guidance is part of NICE's work on 'interventional procedures' (see 'Further information' on page 10).

About the procedure

Osteoporotic fractures are unexpected breaks or cracks in weakened bones, and are common in older people. These fractures often happen in the bones (vertebrae) that make up the backbone or spine. Osteoporotic fractures in the backbone cause the vertebrae to collapse – they are known as vertebral compression fractures.

Osteoporotic fractures are especially likely in women after their periods have stopped completely (postmenopausal women). They can also happen in other people such as those who have taken drugs called steroids for a long time. Osteoporotic fractures in the backbone can happen for other reasons such as tumours affecting the backbone and a type of non-cancerous growth called a haemangioma.

Fractures in the backbone often cause pain. They also sometimes make the spine gradually change shape and become abnormally curved or 'hunched' (known as kyphosis). These changes in shape may cause more fractures in nearby vertebrae leading to more changes in shape and more pain. People affected usually lose some height. They are also more likely to have falls as the problem gets worse.

Standard treatments for people with vertebral compression fractures are pain killers (analgesics) and back supports. Most people do not have pain or other problems after they have this treatment and do not need an operation.

For some patients the standard treatments do not work – more vertebrae may collapse, and they may have severe pain. These patients may be helped by treatments that do not need a major operation. Two of these new treatments (kyphoplasty and vertebroplasty) are ways of strengthening with cement the bone that has collapsed.

For balloon kyphoplasty a small opening is made in the patient's back. A small channel is drilled into the spine and one or two special balloons (inflatable bone tamps) are placed into the bone (vertebra) that has collapsed.

A special X-ray method (fluoroscopy) is used to see what is happening during the procedure. The balloons are filled with a substance (radiopaque contrast medium) that makes them show up on the X-ray.

The balloon is blown up slowly until the vertebra is back to as near its normal height as possible. The balloon is then let down and removed. The space left in the vertebra is then filled with special cement to strengthen the bone. More than one part of the spine can be treated in one session.

How well the procedure works

What the studies said

Three studies compared what happened to patients who had balloon kyphoplasty with what happened to patients who had other treatments. After up to 2 years, patients who had balloon kyphoplasty had less pain than those who had standard treatment (physical therapy and pain killers) or another treatment to strengthen the bone (called vertebroplasty).

In two studies patients were more physically able a year after balloon kyphoplasty than they were before treatment. However, in one of these studies, after 2 years, patients who had balloon kyphoplasty (and those who had vertebroplasty) were no more able than they were before treatment.

In a study of 222 patients about two-thirds of patients regained more than a fifth of the height they had lost because of vertebral collapse. In this study the curvature of the spine (kyphosis) was also generally improved. In another study patients who had balloon kyphoplasty regained more height than those who had standard treatment.

What the experts said

The experts said they could not be sure whether the improvements in pain and height after balloon kyphoplasty would last in the long term.

Risks and possible problems with the procedure

What the studies said

The most common problems after balloon kyphoplasty were cement leaks and new fractures. In one study cement leaks happened after 11% of procedures (11 in every 100). In one patient a cement leak damaged the nerve roots but the patient recovered after treatment and rehabilitation. In another study cement leaks occurred after 7% of procedures but they did not cause the patients any problems.

New fractures happened after the procedure in 23% of patients (225 procedures) in one study. In another study 7 out of 40 patients (18%) who had balloon kyphoplasty had new fractures compared with 10 out of 20 patients (50%) who had standard treatments.

Other problems have happened occasionally during or after balloon kyphoplasty. The balloon burst in two cases, there was bleeding around the spine in another case and in another case a nerve was damaged and the patient lost the use of one leg.

The US Food and Drugs Administration has been told about 33 major problems out of roughly 40,000 to 60,000 balloon kyphoplasty procedures. These included one death, five cases of paralysis or other major problems with nerves resulting in loss of physical function, and 13 cases of damage to the spinal cord (the nerves in the spine).

What the experts said

The experts said that cement leakage was the most common problem after balloon kyphoplasty. They said that infection, allergy and injury to the spinal cord or nerve root because of the needle being put in incorrectly were possible problems that could occur.

What has NICE decided?

NICE has considered the evidence on balloon kyphoplasty. It has recommended that when doctors use this procedure for people with vertebral compression fractures, they should be sure that:

- the patient understands what is involved and agrees (consents) to the treatment, and
- the results of the procedure are monitored.

NICE has also said that balloon kyphoplasty should only be done:

- when it has first been discussed by a team of specialist doctors that includes a specialist in imaging techniques (a radiologist) and a spinal surgeon
- when there are facilities for getting good images of the area to be treated, and
- when access to a spinal surgery service can be arranged.

Doctors who do this procedure should be thoroughly trained to do it beforehand. In particular, they must follow the manufacturer's instructions for making the cement, to reduce the risk of blood vessels being blocked by cement leaks.

Other comments from NICE

The Medicines and Healthcare products Regulatory Agency (MHRA) has issued a safety notice relevant to the use of cement in balloon kyphoplasty (MDA/2004/027 – ‘Injectable polymeric cements used in percutaneous vertebroplasty, balloon kyphoplasty and pedicle screw augmentation’). See www.mhra.gov.uk

What the decision means for you

Your doctor may have offered you balloon kyphoplasty. NICE has considered this procedure because it is relatively new. NICE has decided that the procedure is safe enough and works well enough for use in the NHS. Nonetheless, you should understand the benefits and risks of balloon kyphoplasty before you agree to it. Your doctor should discuss the benefits and risks with you. Some of these may be described above.

Further information

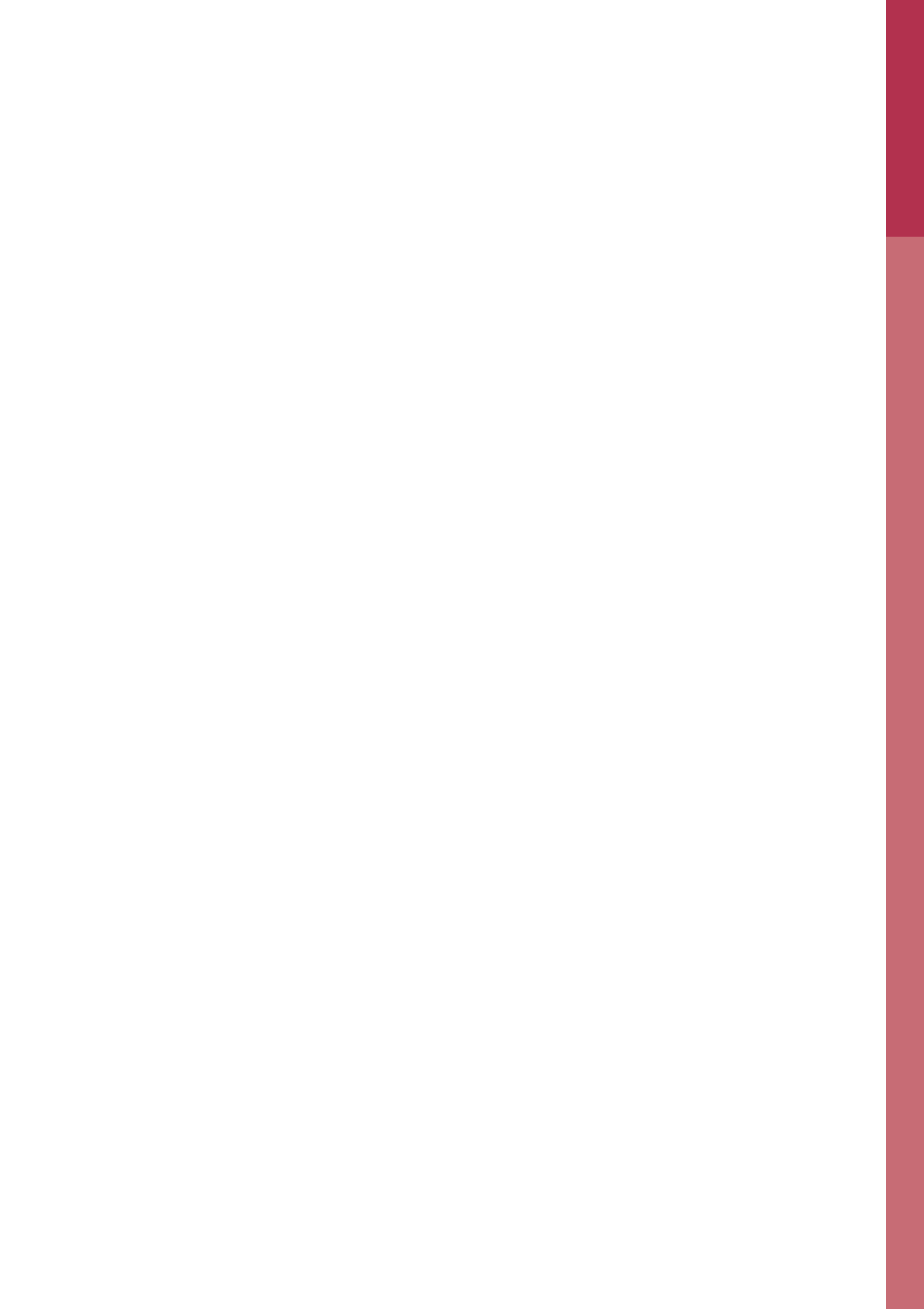
You have the right to be fully informed and to share in decision-making about the treatment you receive. You may want to discuss this guidance with the doctors and nurses looking after you.

The NICE website (www.nice.org.uk) has further information about NICE, the Interventional Procedures Programme and the full guidance on balloon kyphoplasty that has been issued to the NHS. The evidence that NICE considered in developing this guidance is also available from the NICE website.

NICE has also issued guidance on percutaneous vertebroplasty (see www.nice.org.uk/IPG012).

If you have access to the internet, you can find more information on osteoporosis on the NHS Direct website (www.nhsdirect.nhs.uk).

You can also phone NHS Direct on 0845 46 47.





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