Percutaneous vertebroplasty

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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. However, 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.

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.

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

This guidance should be read in conjunction with CG75.

1 Guidance

- 1.1 Current evidence on the safety and efficacy of percutaneous vertebroplasty appears adequate to support the use of the 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 when there are arrangements for good access to a spinal surgery service, and with prior discussion between a specialist multidisciplinary team that includes a radiologist and a spinal surgeon.
 - 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.
 - The procedure should be limited to patients whose pain is refractory to more conservative treatment.

2 The procedure

2.1 Indications

- 2.1.1 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).
- 2.1.2 Vertebral compression fractures are a common cause of pain and disability. Osteopenia, associated with ageing or chronic steroid use, and metastatic disease are the most common causes of vertebral compression fractures. Nearly all people experience pain. Most people are treated conservatively with analgesics, bed rest and bracing, but a small percentage are left with persistent pain and limited mobility.

2.2 Outline of the procedure

2.2.1 Percutaneous vertebroplasty is the injection of bone cement into the vertebral

body to relieve pain, and to stabilise the fractured vertebrae.

2.3 Efficacy

- 2.3.1 The evidence reviewed indicated some level of pain relief in 58–97% of patients, with an associated reduction in medication usage in 50–91% of patients. One study indicated that 93% of patients had improved mobility and that 100% of patients were satisfied with the procedure and would have it again.
- 2.3.2 The opinions of the Specialist Advisors were divided about this procedure. Some believed that the procedure was proven to work, with numerous publications proving benefit. They believed that the procedure could have a major impact in the future as the incidence of osteoporotic spinal fractures increases in an ageing population. One Advisor suggested that it is effective in the majority of patients. Other Advisors suggested that the procedure is unnecessary, that the fractures will heal of their own accord, and that the procedure causes further fractures at a higher level of the spine.

2.4 Safety

- 2.4.1 Reported complications of this procedure were uncommon. They included damage to neural or other structures by needle misplacement or migration of cement. One study observed cement leakage in up to 27% of patients. However, this event was often without sequelae and required further intervention in only 1% of patients in that study.
- 2.4.2 The Specialist Advisors offered different estimates of risk but stated that the procedure carried a low risk in experienced hands. Some listed paraplegia as a risk (less than 5%), as well as the potential for nerve root damage and infection.

2.5 Other comments

2.5.1 The Medicines and Healthcare products Regulatory Agency (MHRA) has recently issued a <u>safety notice on the use of cement in percutaneous</u> <u>vertebroplasty (MDA/2007/088)</u>.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

Interventional procedure overview of percutaneous vertebroplasty, December 2003.

Information for patients

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

4 Other NICE recommendations on percutaneous vertebroplasty

Further recommendations have been made as part of the clinical guideline on metastatic spinal cord compression published in November 2008, as follows:

Vertebroplasty or kyphoplasty should be considered for patients who have vertebral metastases and no evidence of MSCC or spinal instability if they have either:

- mechanical pain resistant to analgesia, or
- vertebral body collapse.

Vertebroplasty or kyphoplasty for spinal metastases should only be performed after agreement between appropriate specialists including an oncologist, interventional radiologist, and spinal surgeon, and in facilities where there is good access to spinal surgery.

Clinical and cost-effectiveness evidence was reviewed in the development of this guideline which has led to this more specific recommendation. For more information see the <u>NICE guideline on</u> <u>metastatic spinal cord compression in adults</u>.

The IP guidance on percutaneous vertebroplasty remains current, and should be read in conjunction with the clinical guideline.

The <u>Medicines and Healthcare Products Regulatory Agency (MHRA)</u> has issued safety notices relating to this procedure (Reference No. MDA/2003/021).

Update information

Minor changes since publication

January 2012: minor maintenance.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.