Percutaneous cementoplasty for palliative treatment of bony malignancies

Interventional procedures guidance
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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 assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

1.1 Current evidence on the safety and efficacy of percutaneous cementoplasty for the palliative treatment of bony malignancies is limited, but appears adequate to support the use of this procedure in patients for whom other treatments have
failed, provided that the normal arrangements are in place for consent, audit and clinical governance.

1.2 Patient selection should be carried out in the context of a multidisciplinary team, which may include specialists in radiology, oncology, radiotherapy, orthopaedics, pain management and palliative care.

2 The procedure

2.1 Indications

2.1.1 Radiotherapy is commonly used to treat patients with painful bony malignancy, although pain may not be relieved for up to 2 weeks after the procedure. Conservative therapy involves analgesia (often with narcotic drugs) and bed rest. However, in some patients, pain remains refractory to both pharmacological and radiation treatment.

2.1.2 Percutaneous cementoplasty is indicated for patients with painful bone metastases resulting from tumours elsewhere in the body or, less frequently, with primary bone tumours. The aim of the procedure is to reduce pain and stabilise bones. Cementoplasty is the generic term for this procedure. Its use in vertebrae is commonly termed vertebroplasty (see section 3.1), and when treating the sacrum it may be described as sacroplasty.

2.2 Outline of the procedure

2.2.1 Percutaneous cementoplasty involves the injection of acrylic bone cement into malignant bone cavities in order to relieve pain or stabilise the bone, or both.

2.2.2 Percutaneous cementoplasty may be performed under general anaesthesia or, more commonly, using conscious sedation and local anaesthesia. A small skin incision is made and a 10–12-gauge trocar or needle is passed into the bone under fluoroscopic guidance.

2.2.3 Cement containing a radiopaque agent is used for this procedure. Visualisation of the cement during injection via multi-plane fluoroscopy is essential in order to limit extra-osseous leakage of cement. If leakage outside the bone occurs, the
injection is halted while the cement hardens and plugs the leak, or for the needle to be repositioned.

2.2.4 Once the procedure is complete, the patient should remain recumbent and should not bear weight while the cement hardens.

2.3 **Efficacy**

2.3.1 In 14 patients in a case series, pain scores (measured using a self-reported visual analogue scale) improved from a mean 8.8 points at baseline to 1.9 points after cementoplasty ($p < 0.0016$). In another two studies, good pain relief was achieved in 82% (9/11) and 93% (13/14) of patients. In another case series, 22% (4/18) of patients had 'total improvement' in pain (no pain without analgesics), while 39% (7/18) had clear improvement at 72-hour follow-up.

2.3.2 Two studies reported mobility outcomes. One reported overall improvements in mobility in 93% (13/14) of patients at 1-week follow-up; the other study of 18 patients reported an improvement in mean walking score (on a 0–4 scale) from 1.1 at baseline to 2.1 at 1-month follow-up.

2.3.3 The evaluation of technical success varied across the studies. In one case series, cementoplasty was considered technically successful in all 14 patients; in another, good filling was demonstrated on postoperative computed tomography scans in 39% (7/18) of patients. For more details, refer to the 'Sources of evidence' section.

2.3.4 The Specialist Advisers noted that the procedure was a variation on the existing technique of vertebroplasty.

2.4 **Safety**

2.4.1 Among four case series, leakage of injected cement was reported in 6% (1/18), 14% (2/14), 27% (3/11) and 50% (9/18) of patients, although the definition of leakage varied between studies. Symptoms relating to cement leakage were reported in between 6% (1/18) and 11% (2/18) of patients. One case report described an incident in which sudden intra-articular cement leakage led to a covering of part of the femoral head. Subsequent chondrolysis in 75% of the joint space required total hip replacement at 12 weeks.
2.4.2 Transient worsening of pain was recorded in 73% (8/11) of patients in one study. Other reported complications included fever (below 39°C) following the intervention in 45% (5/11) of patients and an increase in serum creatinine levels in 9% (1/11) of patients. For more details, refer to the 'Sources of evidence' section.

2.4.3 The Specialist Advisers noted that theoretical adverse events may include death from cement venous embolus, and nerve or vascular injury as a result of local cement leakage. Pathological fractures may occur. Infection, bleeding and thermal damage caused by the cement are additional concerns. One Specialist Adviser noted that heat produced as the cement hardens may cause damage to neural structures.

2.5 Other comments

2.5.1 It was noted that the procedure has also been used to treat benign bone lesions such as cysts, but very little data were available.

2.5.2 It was noted that a variety of types of cement are available.

3 Further information

3.1 The Institute has issued guidance on percutaneous vertebroplasty.

Andrew Dillon
Chief Executive
June 2006

Sources of evidence

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

'Interventional procedure overview of percutaneous cementoplasty', December 2005.
Information for patients

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

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

We have produced a summary of this guidance for patients and carers. Information about the evidence it is based on is also available.

Changes since publication

19 January 2012: minor maintenance.

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Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.