NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of percutaneous cementoplasty

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in December 2005.

Procedure names

- Percutaneous cementoplasty.
- Percutaneous cement osteoplasty.
- Percutaneous acetabuloplasty.

Specialty societies

- British Orthopaedic Association.
- British Society of Interventional Radiology.
- British Society of Skeletal Radiologists.
- British Society of Orthopaedic Oncology.
- Royal College of Radiologists.

Description

Indications

The procedure is indicated for patients with painful bone metastases, often lytic lesions, resulting from primary tumours at another site in the body, or occasionally in situ bone sarcoma. Other candidates are patients with benign bone cysts. The procedure aims to reduce pain and also stabilise bones. Cementoplasty is the generic term for this procedure, however its use in vertebrae is commonly termed vertebroplasty, and when treating the sacrum may be described as sacroplasty.

Current treatment and alternatives

Most patients with bone lesions experience pain, which can be of varied duration. Standard interventions include; radiation therapy to treat the pain of bone lesions, but the pain relieving effect can be delayed for up to 2 weeks and the effect on bone reconstruction is partial and requires several weeks to develop. Conservative therapy includes analgesia often with narcotic drugs, and bed rest. However some patient remain refractory to both pharmacological and radiation treatment

What the procedure involves

Percutaneous cementoplasty is the injection of acrylic bone cement (commonly polymethylmethacrylate; PMMA) into malignant or benign bone cavities in order to relieve pain and/or stabilise the bone.

Percutaneous cementoplasty may be performed under general anaesthetic or more commonly, using conscious sedation and local anaesthesia affecting the skin, subcutaneous tissue and the periosteum of the bone into which the needle will be introduced. Access to the bone is percutaneous. A small incision is made with a scalpel and an 10 to 12 gauge trocar or needle, under fluoroscopic guidance, is passed into the bone being treated.

The cement is mixed with barium sulphate or other agent to enhance radio-opacity. The cement is allowed to thicken to the consistency of toothpaste, to lessen the risk of extra-osseous leakage upon injection. Visualisation of the cement during injection, via fluoroscopy (multi-plane), is essential to ensure safety, as every attempt should be made to avoid extra-osseous leakage of cement. If leakage outside the bone occurred the injection can be halted for a couple of minutes to allow the cement to harden and plug the leak, or the needle repositioned and the bevel reoriented. Mean procedure time was found to be 25 minutes per lesion in one case series[1]

Once the procedure is complete, the patient should remain recumbent to prevent weight bearing whilst the cement hardens, mean hospital length of stay has been reported to have been 6 days among 11 patients treated with cementoplasty in one case series [2].

Efficacy

Pain score (as measured by self reported visual analogue scale) was improved after cementoplasty in 14 patients in a case series from a mean 8.8 points at baseline to 1.9 points post operatively ($p<0.0016$)[1]. In another two studies good pain relief was achieved in between 82% (9/11)[2] and 92% (13/14)[1] of cases. In another case series 22% (4/18) of patients had total improvement in pain, while 39% (7/18) had clear improvement at 72 hours follow up[3].

Two studies reported on mobility outcomes: One has shown overall mobility to improve in 92% (13/14) of cases at one week follow up[1], and another study showed mean walking score (on an 0 to 4 scale) to improve from 1.1 at baseline to 2.1at 1 month follow up[4].

Method of evaluation of technical success varied across the studies included. In one case series this was achieved in 100% (14/14) cases[1], and in another 39% (7/18) of cases demonstrated good filling on postoperative computed tomography scans[3].

Safety

Among 4 case series leakage of injected cement was reported in between 6 % (1/18)[4], 14% (2/14)[1], 27% (3/11)[2], and 50 % (9/18)[3] of patients, the definition of leakage (either established intra-operatively or post operatively on imaging) varied between studies . However, symptomatic cases relating to cement leaks were only reported in between 6% (1/18)[4] and 11% (2/18)[3] of patients. One case report detailed an incident of sudden intra-articular cement leak which led to a covering of part of the femoral head. The patient suffered intense pain in the first 48 hours following the intervention and functional incapacity, and athroscopic ablation of the cement was undertaken at 5 days postoperatively. Subsequent chondrolysis in 75% of the joint space required total hip replacement at 12 weeks[5].

Transient worsening of pain was recorded in 73% (8/11) of cases in one study[2], however, most patients experienced improvement in pain at follow up.

Other reported complications included fever (below 39C) in 45% (5/11) of patients following the intervention and an increase in serum creatinine level in 9% (1/11) of cases[2].

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to percutaneous cementoplasty. Searches were conducted via the following databases, covering the period from their commencement to 13 December 2005: Medline, PreMedline, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches. (See appendix C for details of search strategy.)

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. If these criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded if no clinical outcomes were reported, or if the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients with painful metastatic bone lesions.
Intervention/test	Percutaneous cementoplasty (vertebroplasty not considered).
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on four case series and two case reports.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Existing reviews on this procedure

There were no published reviews identified at the time of the literature search.

Related NICE guidance

NICE has published the following guidance related to this procedure. Appendix B details the recommendations made in the guidance listed below.

- Percutaneous vertebroplasty. *NICE interventional procedures guidance* no.12 (2003). Available from www.nice.org.uk/IPG012

Table 2 Summary of key efficacy and safety findings on percutaneous cementoplasty

Abbreviations used: CT – computed tomography, MRI – magnetic resonance imaging, VAS – visual analogue score			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Kelekis A (2005)[1] Case series (retrospective) Switzerland n=14 October 1999-2003 Patients with painful bone metastses refractory to medication and radiation therapy and unable to tolerate surgery. Presence of bone lysis was based on standard radiography plus CT or MRI imaging. A total of 23 lesions treated. Cementoplasty on superior and inferior pubic rami n=15, or ischial tuberosity lesions n=8. Lesions with displaced pathological fractures n=10, or visible bone lysis n=13) Percutaneous cementoplasty with PMMA cement (mean 8 ml per lesion) mixed with sterile barium powder. Patients were hospitalised overnight. Mean age = 68 years, Male =29%. Mean follow-up = 9 months (range 2 days to 2 years) Disclosure of interest: One author is a consultant for a commercial interventional pain company	**Technical success** Cementoplasty was technically successful in 100% (14/14) cases with stabilisation of the lesion achieved. The mean procedure time was 25 minutes per lesion **Symptomatic relief** Significant pain relief (VAS score 0 to 2) was achieved at 24 hours post operatively in 92% (13/14) cases Pain score dropped from a mean 8.8 (range 7 to 10) at baseline to 1.9 (range 0-2) at 12 hours postoperatively ($p<0.0016$) Overall mobility was improved in 92% (13/14) cases at 1 week follow up	**Complications** No major complications reported during follow up Leakage in the obdurator foramen occurred in 7% (1/14) of cases, resulting in continued pain and requiring radiation therapy of the pudendal nerve 7% (1/14) of cases showed leakage in the hip joint, but was asymptomatic to 3 months follow up	Clinical follow up was evaluated retrospectively immediately after the intervention and by telephone questionnaire at up to 2 years. No loss to follow up Analysis of change in VAS score from baseline might have excluded the 1 non responder, as numbers presented are inconsistent with intention to treat analysis No details given of independent outcome assessment Patient selection by mean of multidisciplinary committee Many outcomes are patient self reported No definition given of measure of mobility. Criteria used to determine unsuitability for surgery are not reported Duration of symptoms at baseline not reported Although outcomes reported include pain and mobility, not quality of life or survival outcomes are reported.

Abbreviations used: CT – computed tomography, MRI – magnetic resonance imaging, VAS – visual analogue score

Study details	Key efficacy findings	Key safety findings	Comments
Marcy P-Y (2000)[4] Case series (retrospective) France (multicentre) n=18 September 1996-1998 Patients with painful bone metastases that could not be treated surgically due to location, extent, number, or poor general health. Patients grouped into; Group1 pain recurrence after radiation therapy n=6, Group 2 no relief after radiation therapy n=6, Group 3 intense pain / extensive lytic lesion before radiation therapy n=6. Cementoplasty with bone cement (Shering –Plough) mean 6 ml Acetabular lytic lesion n=12, iliac n=2, sacral n=4. Mean age =58 years, Male =22%. Mean follow-up = 4.6 months Disclosure of interest not stated	**Symptomatic benefit** Pain relief was evaluated by patient reported score on a scale from 1 mild to 5 excruciating. Mean pain status scores Overall: Baseline 3.2, I month FU 1.6 Group 1: Baseline 2.8, I month FU 1.6 Group 2: Baseline 3.3, I month FU 2.7 Group 3: Baseline 3.6, I month FU 1.3 Walking ability was evaluated by patient reported score on a scale from 0 no walking to 4 normal Mean walking scores Overall: Baseline 1.1, I month FU 2.1 Group 1: Baseline 1.3, I month FU 2.5 Group 2: Baseline 1.6, I month FU 2.3 Group 3: Baseline 0.5, I month FU 2.3 89% (16/18) of cases experienced pain relief and improvement in walking. At 12 month follow up 3 patients were available for analysis, 11 had died, and 4 were lost to follow up (reasons not given)	**Complications** There were no major complications linked to the procedure. There was no cement leakage into the joint space or nerve compression during follow up 6% (1/18) of patients suffered a leak of cement into the gluteus muscle, resulting in worsening of pain at 7 days postoperatively. At 15 days after the procedure 6% (1/18) of the cases reported pain, this was found to be due to an acetabular fracture.	Measurement of statistical significant not provided for any outcome Method of case selection not defined Duration of symptoms at baseline not reported Outcome measures not reported to have been validated prior to use in the study.

Abbreviations used: CT – computed tomography, MRI – magnetic resonance imaging, VAS – visual analogue score

Study details	Key efficacy findings	Key safety findings	Comments
Weill A (1998)[3] Case series (retrospective) France n=18 Cases with acetabular malignancies. 17 cases with metastases of different origin, and 1 case of multi-focal bone sarcoma. In three cases the operative intent of cementoplasty was for stabilisation of the hip in addition to pain relief. Some included patients included were refractory to radiation therapy whilst some were de novo cases. Cementoplasty under fluoroscopic control with local analgesia, and sedation. Surgical cement (surgical simplex P radioplaque with tungsten powder). Mean 9.9 ml injected into lytic lesions Patient allowed to stand at one day after the procedure. The superior section of the acetabulum was filled in 17 cases and the posterior part in 1. Mean age = 60 years, Male =44%. Mean follow-up = 9.4 months Disclosure of interest: not stated	**Operative success** 39% (7/18) of cases demonstrated good filling (more than 2 of 3 lesions filled) on post operative CT scan. 28% (5/18) had partial filling (1 or 2 of 3 lesions filled), and 33% (6/18) had poor filling (less than 1 of 3 lesions filled). **Analgesic effect** Results on pain were classified as follows: Total improvement – no pain (without analgesic drugs) even when walking Clear improvement – Reduction in analgesic drug >50% or change to a non-narcotic Moderate improvement – decrease in pain but no improvement in autonomy <50% reduction in analgesic drugs. At 72 hours postoperatively Outcome — Percent of patients (n=18) Total improvement — 22% (4/18) Clear improvement — 39% (7/18) Moderate improvement — 22% (4/18) Unchanged — 6% (1/18) Worsening — 11% (2/18) In 2 cases pain recurred at 6 and 39 months respectively, both were found to have local tumoral extension on CT scan. **Stabilisation** Of the 3 patients treated for hip instability. One patient died at 7 months without displacement or dislocation. One patient did not present with any modification, and one patient underwent surgery at 10 months due to progression of the lesion. 6 patients died, at between 2 and 7 months following the procedure	**Operative complications** Cement leakage towards the hip joint space was recorded in 22% (4/18) of cases. One case was symptomatic with acute pain reported, this was relieved with surgical extraction of the cement fraction. Cement leakage towards the adjacent soft tissue or veins was recorded in 28% (5/18) of cases. One case was symptomatic with worsening of existing sciatica, the patient died 5 months postoperatively. No hypotension was reported during the cement injection procedure. Why does this matter, comment please, why is this information “parachuted” here, while no such “warning” exists in safety section in text? Does it require inclusion as potential complication in safety section of main text, and/or is it reported elsewhere? If on the other hand not an issue why report here?	There was no apparent correlation between the degree of filling and the analgesic benefit. No pre-procedure assessment of pain presented.

Abbreviations used: CT – computed tomography, MRI – magnetic resonance imaging, VAS – visual analogue score

Study details	Key efficacy findings	Key safety findings	Comments
Cotten A (1995)[2] Case series (prospective) France n=11 January 1990 to February 1993 Patients with acetabular bone lesions that could not be treated surgically due to location, extent, number, or poor general health. Patients with articular cortical destruction fo eth acetabular roof >5 mm, or with excessive soft tissue involvement were excluded from the study. Origin of osteolyses metastasis n=8, myeloma n=3 Sedatives and local analgesia given. Under floruscopic guidance methylmethacrylate polymer (sulfix 6) with tantalum powder was injected (mean 7 ml). Nonsteroidal anti-inflammatory drugs given for 2 to 4 days. Radiation therapy given at 15 to 32 days after cementoplasty. Combination cementoplasty and radiation therapy Mean age =61 years, Male =73%. Mean follow-up = 7.2 months Disclosure of interest: not stated	**Operative parameters** Mean length of stay was 6 days (range 4 to 15). **Symptomatic relief** Pain relief (score of ≤2 on a 5 point scale) was achieved in 82% (9/11) of cases immediately after cementoplasty. All patients experienced an improved walking at a mean time of 3 days. At 1 month postoperatively 25% (2/8) of cases available for evaluation had experienced an increase in hip pain compared to immediate post injection score	**Complications** Leak of cement in to the acetabular fossa occurred in 18% (2/11) of cases, and leak into the joint space occurred in 9% (1/11) of cases. Complication — Frequency (n=11) Serum creatinine leval increased >3.5 mg/dl (spontaneously resolved) — 9% (1/11) Fever <39C — 45% (5/11) Transient worsening of hip pain — 73% (8/11)	Inclusion criteria and outcome evaluation used very similar to Marcy (2000) although this appears to be a separate cohort of cases. Outcomes not analysed as a group vs. baseline individual patient scores presented Careful patient selection that would have excluded cases where benefit was less likely Duration of symptoms at baseline not reported Outcome measures not reported to have been validated prior to use in the study

Abbreviations used: CT – computed tomography, MRI – magnetic resonance imaging, VAS – visual analogue score			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Hart J A (2003)[6] Case report Ireland Secondary acetabular lesion, unable to bear weight for 2 weeks. Lytic lesion on the superior surface of the left acetabulum 3 X 2.5 cm. Radiotherapy had failed to control pain. Multidisciplinary team decided minimally invasive management was required General anaesthesia administered. cementoplasty with PMMA mixed with phenol under fluoroscopic guidance, and 48 antibiotic prophylaxis. Age = 39, female Follow-up to 10 days Disclosure of interest: not stated	**Symptom outcomes** The patient was pain free at 48 hours postoperatively Length of stay was 1 week Patient was walking unaided at 10-day follow-up Despite further image-confirmed aggressive pelvic metastases, the patient was pain free and able to perform all activities of daily living at outpatient follow-up	**Surgical complications** There was no evidence of intra-articular leakage of cement	Not clear how case was selected. No details whether this was the first case treated at the centre. Length of final follow-up not reported. Case was younger than the mean of other reported series.
Leclair A (2000)[5] Case report France Patient with a CT-confirmed cystic lesion (3.5 cm) of left acetabulum, producing mechanical pain for 6 months, refractory to analgesia. Age=49, male Cementoplasty with bone cement (not defined) (2.5 cc) Mean follow-up = 12 weeks Disclosure of interest: not stated	None presented – report of a complication	**Operative complications** After injection of 2.5 cc of cement a sudden intra-articular leak led to coverage of a third of the femoral head, leading to immediate cessation of the injection Patient suffered intense pain for 48 hours with total functional incapacity. Arthroscopic ablation of the cement was undertaken 5 days postoperatively Patient able to walk but in pain at 2 weeks. Radiographs taken at 8 weeks due to increasing pain showed chondrolysis in > 75% of the joint space. Total hip replacement carried out at 12 weeks after initial cement injection	Benign not metastatic acetabular lesion. Type of cement used is not described. No details of whether this was the first case treated at the centre.

Validity and generalisability of the studies

- Most of the evidence reviewed relates to a variety of sites on the pelvis were treated, and some with displaced pathological fractures and some with bone lysis.
- No standardisation of cement produced employed across the studies with some centres using their own preparations
- Some (but not all) patients had previous radiotherapy of the same lesions.
- No comparative studies to open surgery or radiotherapy

Specialist Advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their specialist society or Royal College.

Dr R Edwards, Dr R Campbell, Mr R Tillman, Mr D Wilson, Dr N Ashford

- The majority of the Advisers considered cementoplasty to be a minor variation on the existing procedure of vertebroplasty. However, one Adviser considered the use of this technique to treat malignant bone metastases to be novel and of uncertain safety and efficacy.
- The aim of the procedure is to achieve pain relief and lesion stabilisation, and allow greater patient mobility.
- Theoretical adverse events may include death from cement venous embolus, and nerve or vascular injury relating to local cement leak. Pathological fracture may occur. Infection, bleeding, and thermal damage caused by the cement are additional concerns
- There are few cases followed up to date, and a UK registry would be useful. It may be possible to expand a vertebroplasty database that is being established to include cementoplasty cases.
- The procedure is technically complex and requires knowledge of cement preparation and delivery as for vertebroplasty, but no training is available in the UK at present. The intervention also requires high-quality imaging facilities.
- The use of cementoplasty in lesions of the long bones has been presented only at scientific meetings to date and, with the potential for pathological fractures, the need for concomitant surgical fixation should be considered.
- The intervention may be undertaken by radiologists, orthopaedic surgeons or pain specialists.

- There are few cases annually that are refractory to other treatments and may be suitable for cementoplasty.
- In patients with malignant lesions, pain relief may be more important than long term safety.
- There may be an upper limit on the size of lesion that can be treated.
- The Advisers warned that the name ‘cementoplasty’ has often been used interchangeably with ‘vertebroplasty’ in the literature.

Issues for consideration by IPAC

Searching was sensitive, and produced a majority of studies using vertebroplasty.

Poor prognosis for many patients may limit the relevance of long-term outcomes.

Lesions may develop over time, and thus benefit from this intervention may be only temporary.

References

1 Kelekis A, Lovblad KO, Mehdizade A et al. (2005) Pelvic osteoplasty in osteolytic metastases: Technical approach under fluoroscopic guidance and early clinical results. *Journal of Vascular & Interventional Radiology* 16: 181–88.

2 Cotten A, Deprez X, Migaud H et al. (1995) Malignant acetabular osteolyses: Percutaneous injection of acrylic bone cement. *Radiology* 197: 307–10.

3 Weill A, Kobaiter H, and Chiras J (1998) Acetabulum malignancies: technique and impact on pain of percutaneous injection of acrylic surgical cement. *European Radiology* 8: 123–9.

4 Marcy PY, Palussiere J, Descamps B et al. (2000) Percutaneous cementoplasty for pelvic bone metastasis. *Supportive Care in Cancer* 8: 500–3. (erratum appears in *Supportive Care in Cancer* 8: 510).

5 Leclair A, Gangi A, Lacaze F et al. (2000) Rapid chondrolysis after an intra-articular leak of bone cement in treatment of a benign acetabular subchondral cyst: An unusual complication of percutaneous injection of acrylic cement. *Skeletal Radiology* 29: 275–278.

6 Hart RA (2003) Percutaneous treatment of osteoporotic spinal compression fractures [Review]. *Current Women's Health Reports* 3: 72–4.

Appendix A: Additional papers on percutaneous cementoplasty not included in summary table 2

The following table outlines the studies that are considered potentially relevant to the overview but are not included in the main data extraction table (Table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Hokotate H, Baba Y, Churei H et al. (2001) Pain palliation by percutaneous acetabular osteoplasty for metastatic hepatocellular carcinoma. *Cardiovascular and Interventional Radiology* 24: 346–8.	n = 1	Patient obtained sufficient pain relief and improved walking ability, which continued for 3 months	Could not obtain a copy of the study report.
Wallace MJ, Ross M (2005) Bone lymphangiomatosis: treatment with percutaneous cementoplasty. *Spine* 30: E336–9.	n = 1	The patient reported substantial pain relief within several hours of the procedure	Could not obtain a copy of the study report.

Appendix B: Related published NICE guidance for percutaneous cementoplasty

Guidance	Recommendations
Interventional procedure guidance no. 12	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.
Technology appraisals	None applicable
Clinical guidelines	None applicable
Public health	None applicable

Appendix C: Literature search for percutaneous cementoplasty

Procedure number: 304	Procedure name: percutaneous cementoplasty	
Databases	**Version searched (if applicable)**	**Date searched**
The Cochrane Library	2005 Issue 4	14/11/2005
CRD		14/11/2005
Embase	1980 to 2005 Week 46	14/11/2005
Medline	1966 to November Week 1 2005	14/11/2005
Premedline	November 11, 2005	14/11/2005
CINAHL	1982 to November Week 1 2005	14/11/2005
British Library Inside Conferences (limited to current year only)		14/11/2005
National Research Register	2005 Issue 4	14/11/2005
Controlled Trials Registry		14/11/2005

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in other databases.

1. exp methylmethacrylates/
2. Radiography, Interventional/
3. cementoplast$.tw.
4. exp bone cements/
5. injections, intralesional/
6. pmma.tw.
7. methylmethacrylate$.tw.
8. polymethylmethacrylate$.tw.
9. (cement$ adj3 (acrylic or bone$ or injection$)).tw.
10. or/1-9
11. bone neoplasms/
12. fractures, spontaneous/
13. humeral fractures/
14. femoral fractures/
15. osteolysis/
16. femoral neoplasms/
17. osteolys$.tw.
18. multiple myeloma/
19. or/11-18
20. 10 and 19
21. percutan$.tw.
22. 20 and 21
23. animal/ not human/
24. 22 not 23