



NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of Percutaneous vertebroplasty (methyl methacrylate)

Introduction

This overview has been prepared to assist members of IPAC advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by one or more specialist advisor(s) and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

Procedure name

Percutaneous vertebroplasty (methyl methacrylate)
- also known as percutaneous vertebroplasty, percutaneous polymethylmethacrylate vertebroplasty, vertebroplasty, transpedicular polymethylmethacrylate vertebroplasty or by the acronyms PV or PTPV, PPV.

SERNIP procedure number

76

Specialty society

British Orthopaedic Association
British Society of Skeletal Radiologists

Executive summary

Percutaneous vertebroplasty using polymethylmethacrylate (PMMA) appears to be efficacious in the treatment of pain associated with vertebral compression fractures of osteoporotic, metastatic or myeloma aetiology. It appears safe, with a low complication rate, although when complications occur they can be major, for example, pulmonary embolism or extravasation of cement into the spinal canal and spinal cord compression. A higher complication rate is observed in patients with metastatic disease, as those patients are compromised because of their disease. There is also a high death rate for patients with metastatic disease, but this is unrelated to the percutaneous vertebroplasty procedure.

Indication(s)

Vertebral compression fractures are a common cause of pain and disability, and each year over 270,000 painful vertebral fractures are clinically diagnosed in the USA, and numbers are increasing.¹ Osteopenia associated with aging or chronic steroid use and metastatic disease are the most common aetiologies of vertebral compression fractures. All patients experience pain, which can be of varied duration. Most patients are treated conservatively with analgesics, bedrest and bracing, but a small percentage is left with persistent pain and limited mobility². Percutaneous vertebroplasty

may be used to provide pain relief for patients with severe painful osteoporosis with loss of height and/or with compression fractures of the vertebral body and also for patients with symptomatic vertebral haemangioma and painful vertebral body tumours (metastasis and myeloma).

Summary of procedure

Percutaneous vertebroplasty is the injection of acrylic bone cement (polymethylmethacrylate; PMMA) into the vertebral body in order to relieve pain and/or stabilise the fractured vertebrae.

Percutaneous vertebroplasty may be performed under general anaesthetic or more commonly, using conscious sedation (e.g. fentanyl and midazolam) and local anaesthesia affecting the skin, subcutaneous tissue and the periosteum of the vertebral body into which the needle will be introduced. Access to the vertebrae is percutaneous, although an open technique has been described by Wenger *et al.*, 1999.³ The patient is placed prone, and local anaesthesia is administered. A small dermatotomy is made with a scalpel and an 11 or 12 gauge trocar or needle, under fluoroscopic guidance, is passed into the vertebral body. Access is usually transpedicular but the approach may change according to the vertebra under treatment, i.e. a single side transpedicular approach may be used at the thoracic level to avoid pleural tears, whereas a paravertebral approach may be used at lumbar levels. Unipediculate access may be sufficient, but contralateral access may be needed to obtain good vertebral filling. Venography may be performed to assess the risk of cement leakage outside the vertebral body. Computer tomography (CT) may also be used intraoperatively, which may be beneficial for cervical vertebra to allow visualisation of the carotid vessels. The polymethylmethacrylate (PMMA) is mixed with barium sulphate (or tantalum or tungsten) to enhance radio-opacity. The cement is allowed to thicken to the consistency of toothpaste, to lessen the risk of extravasation upon injection. Visualisation of the cement during injection, via fluoroscopy (biplane or single plane), is essential to ensure safety, as every attempt should be made to avoid extravasation of PMMA. Once the procedure is complete, the patient should remain recumbent to prevent weight bearing whilst the PMMA hardens. The procedure is commonly performed on an outpatient basis, but the patients should be observed for up to three hours post-operatively.

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,⁴ plus conservative therapy such as analgesia, bedrest and casts. The use of percutaneous vertebroplasty does not modify the long-term outcome compared to conservative therapy, but it facilitates analgesia and early mobility that is important in older patients who may suffer major complications with long-term bed rest.⁵

Literature review

A systematic search of MEDLINE, PREMEDLINE, EMBASE, Current Contents, PubMed, Cochrane Library and Science Citation Index using Boolean search terms was conducted, from the inception of the databases

until October 2002. The York Centre for Reviews and Dissemination, Clinicaltrials.gov, National Research Register, SIGLE, Grey Literature Reports (2002), relevant online journals and the Internet were also searched in October 2002. Searches were conducted without language restriction.

Articles were obtained on the basis of the abstract containing safety and efficacy data on percutaneous vertebroplasty in the form of randomised controlled trials (RCTs), other controlled or comparative studies, case series and case reports. Conference abstracts and manufacturer's information were included if they contained relevant safety and efficacy data. Foreign language papers were included if they contained safety and efficacy data and were considered to add substantively to the English language evidence base.

Studies were rejected for reporting no clinical outcomes, being review articles, or involving techniques other than vertebroplasty using PMMA. In the case of duplicate publications, the latest, most complete study was included. Studies were selected for extraction of data firstly if they were comparative, then case series were rated as to number of patients, breadth of study population (therefore multicentre studies were rated most highly) and length of follow-up. Included studies are highlighted in bold in the reference list. Studies for which data were not tabulated are listed in the annex following the reference list.

List of studies found

Total number of studies: 41

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|--------------------------------------|----|
| • Randomised controlled trials | 0 |
| • Systematic reviews | 1 |
| • Non-randomised comparative studies | 2 |
| • Case series | 32 |
| • Case reports | 6 |

RCTs in progress

- UK based – “A randomised controlled trial of vertebroplasty for treatment of osteoporotic vertebral crush factors”, currently ongoing (Dr Simon Dolin, Pain Service, St Richards Hospital, Spitalfield Lane, Chichester, PO19 4SE, West Sussex)
- Australian based – “Prospective, single site, randomised, controlled study to assess the performance of Cortoss Synthetic Cortical Bone Void Filler in percutaneous vertebroplasty compared to an injection with a local anaesthetic”. Cortoss overcomes a number of limitations of PMMA as Cortoss is ready as soon as mixed and is of appropriate consistency. It does not contain volatile monomers (which may be the cause of cardiovascular and respiratory effects, and hypersensitivity with PMMA use), is inherently opaque and does not need to be mixed with barium sulphate or other radio-opaque materials, and has a lower exotherm reducing the risk of thermal necrosis. Cortoss is also biomechanically stronger than PMMA. (Robert Fraser, Clinical Professor and Head of Spinal Unit, Royal Adelaide Hospital, The University of Adelaide, SA, 5005, Australia).

- A randomised trial comparing the use of Cortoss to conservative medical treatment is also underway in Europe.

Summary of key efficacy and safety findings

See following tables;

Abbreviations:

CT	computer tomography
N/A	not applicable
PV	percutaneous vertebroplasty
PMMA	polymethylmethacrylate
VAS	visual analogue scale

Authors, date, location, number of patients, length of follow-up, selection criteria	Key efficacy findings	Key safety findings	Appraisal/Comments
<i>Systematic review</i>			
Westesson⁶ 2001, USA 726 patients <i>Follow-up:</i> not stated <i>Selection criteria:</i> N/A	Complete pain relief: 26% Marked improvement: 58% No improvement: 14%	<i>Cement leakage into:</i> neural foramen 38/726 (5%) paraspinal region 27/726 (4%) spinal canal 21/726 (3%) adjacent discs 116/726 (16%) 9/726 (1% of total) [4.5% of those with leakage] required decompressive surgery	<i>Potential for bias:</i> reported only as a conference abstract. No details given about number or type of studies. <i>Outcome measures and their validity:</i> N/A <i>Other comments:</i>

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
Non-randomised comparative studies			
<p>Gaughen et al.⁷ 2002, USA</p> <p>Group 1; 24 consecutive patients with osteoporotic fractures at 42 vertebral levels between Aug 2000 and June 2001; all levels treated with venography prior to cement injection. Group 2; 24 consecutive patients with osteoporotic fractures at 42 vertebral levels without venography.</p> <p><i>Follow-up:</i> 1 month</p> <p><i>Selection criteria:</i> Retrospective review of consecutive vertebroplasty in patients with and without antecedent venography</p>	<p><i>Clinical improvement at 1 month follow-up</i></p> <p><u>With pain improvement</u>; Group 1; 19/20 (95%), Group 2; 21/22 (95%)</p> <p><u>Without pain</u>; Group 1; 14/20 (70%), Group 2; 14/22 (64%)</p> <p><u>With preoperative impaired mobility</u>; Group 1; 11/20 (55%), Group 2; 12/22 (55%)</p> <p><u>With mobility improvement</u>; Group 1; 11/11 (100%), Group 2; 12/12 (100%)</p> <p>(No significant difference detected between group 1 and 2)</p> <p><i>Cement extravasation</i></p> <p>Group 1; 22/42 levels (52%) and Group 2; 28/42 (67%) not statistically significant (p=0.266).</p>	<p>Perforation of thecal sac in 1/84 levels (1%), causing a cerebrospinal fluid leak and the patient had a postprocedural headache and left-sided pain</p> <p>No evidence of spinal cord compression or pulmonary embolism</p> <p>Cardiovascular and respiratory parameters remained within normal ranges</p>	<p><i>Potential for bias:</i> 20/24 (83%) Group 1 patients complied with 1 month follow-up. 22/24 (92%) Group 2 patients complied with 1 month follow-up. Total loss to follow-up 6/48 (12.5%).</p> <p><i>Outcome measures and their validity:</i> Pain (0-10) and mobility (0-5) ordinal scales were not validated.</p> <p><i>Other comments.</i></p>

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
<p>Kim et al.⁸ 2002, USA</p> <p>Group 1; 24 patients (29 vertebra) treated with a standard bipedicate approach.</p> <p>Group 2; 41 patients (68 vertebra) treated with a modified unipediculate approach.</p> <p><i>Follow-up:</i> not stated</p> <p><i>Selection criteria:</i> Retrospective review of consecutive cases of vertebroplasty between Jan 1999 and Sep 2000. Some patients were excluded for reasons stated in the text. Patients that met the inclusion criteria were telephoned and asked to identify their pre- and post-op. pain and medication usage.</p>	<p><i>Pain relief</i></p> <p>achieved in 16/17 (94%) of Group 1 and 28/32 (88%) of Group 2. No significant difference detected in pain level in patients treated with either the bipedicate or unipediculate approach (p=0.65)</p> <p><i>Medication usage</i></p> <p>decreased in 10/17 (59%) of Group 1 and 16/32 (50%) of Group 2. Neither the percentage of patients with a decrease in medication level nor the mean decrease in medication level was significantly different between bipedicate or unipediculate approaches.</p> <p><i>Cement deposition</i></p> <p>achieved in all vertebrae with both the bipedicate and unipediculate approaches. Mean filling of the width of the vertebral half was not significantly different (p=0.19) between the two approaches.</p>	<p>None stated.</p>	<p><i>Potential for bias:</i> Large number of patients excluded from study (Group 1: 24 down to 17 patients, Group 2: 41 down to 32 patients) – 8 patients lost to follow-up and therefore excluded, 4 patients underwent multilevel vertebroplasty and both unipediculate and bipedicate approaches were used, these were excluded. Imbalance between patient and vertebra numbers between treatment groups. Recall bias, with some patients unable recall to the exact extent of the pain. Conversions from unipediculate to bipedicate not recorded, which would falsely elevate the result of the unipediculate filling.</p> <p><i>Outcome measures and their validity:</i> 0-10 pain and 0-4 pain medication scales not validated. Pain was assessed quantitatively and qualitatively.</p> <p><i>Other comments:</i></p>

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
Case series			
<p>Gangi et al.⁹ 1999, FRANCE</p> <p>187 patients (289 vertebral bodies) osteoporosis 105/187 (56%), haemangiomas 11/187 (6%), metastasis and myeloma 69/187 (37%), postsurgical consolidation 2/187 (1%).</p> <p>Maximum follow-up was 7 years for osteoporosis (average 2.7 years, 1.2 years, average 7 months for tumoural lesions (metastasis and myeloma).</p> <p>Selection criteria: not stated.</p>	<p>Osteoporosis Satisfactory results were obtained in 82/105 (78%) of cases based on the reduction of analgesic doses</p> <p>Tumoural lesions Satisfactory results in 57/69 (83%) of cases based on the reduction of opiate doses</p> <p>Haemangioma Satisfactory results in 8/11 (73%) of cases</p>	<p>Epidural leak 14/187 (7.5%) - caused neuralgia in 3 cases without spinal cord compression. Cement leaks towards the disc were observed in 15/187 (8%) of cases, without clinical consequence.</p> <p>Asymptomatic pulmonary embolism 2/187 (1%)</p> <p>Inability to reinsert needle In 1/187 (0.5%) hardening of the glue didn't allow reinsertion of the needle and a paravertebral cement leak was detected. The glue fragment was extracted percutaneously two days later.</p>	<p>Potential for bias: No enough detail given.</p> <p>Outcome measures and their validity: Not stated.</p> <p>Other comments:</p>
<p>McGraw et al.¹⁰ 2002, USA</p> <p>100 patients (156 vertebroplasties) 92/100 (92%) osteoporotic, 5/100 (5%) neoplastic, 2/100 (2%) compression fractures and spinal canal stenosis, 1/100 (1%) osteogenesis imperfecta).</p> <p>Follow-up: 6-44 months follow-up (mean 21.5 months)</p> <p>Selection criteria: Prospective study of 100 consecutive patients over a 35 month period.</p>	<p>Pain relief - 12-24 hours post op. 97/100 (97%) reported improvement 3/100 (3%) reported no change.</p> <p>longer-term follow-up 92/99 (93%) improved 7/99 (7%) no change 0/99 (0%) worse Mean VAS score was significantly different (p<0.0001) between preop. to 21.5 months follow-up.</p> <p>Mobility 92/99 (93%) improved ambulatory ability</p> <p>90/99 (91%) were able to decrease their oral pain medication</p> <p>99/99 (100%) were satisfied with the procedure and would undertake it again.</p>	<p>1/100 (1%) sustained a sternal fracture while transferring herself from the stretcher to the procedure table</p> <p>1/100 (1%) experienced a 12-hour radiculopathy.</p>	<p>Potential for bias: 1/100 (1%) was lost to follow-up</p> <p>Outcome measures and their validity: The validity of 0-10 VAS pain scale and the questionnaire of the author's design was not stated.</p> <p>Other comments:</p>

Specialist advisor's opinion / advisors' opinions

Specialist advice was sought from the British Orthopaedic Association and British Society of Skeletal Radiologists

Percutaneous vertebroplasty is an established practice in some countries and in six centres in the UK, although is a novel technique elsewhere in the UK. It is estimated that less than 10% orthopaedic specialists/radiologists are performing the procedure, and is likely to be performed in a minority of hospitals. The potential impact on the NHS is likely to be moderate, as although the indications (spinal metastases and osteoporotic vertebral fractures) are common, they do not always cause uncontrollable pain. Currently symptomatic patients are treated. The main potential adverse effects of the procedure are extravasation of cement and spinal cord compression. Pulmonary embolism is rare, nerve damage <0.5% and infection <0.5%. Overall complication rate per indication is osteoporosis 1.3%, haemangioma 2.5% and metastases 10%. The procedure appears to be low risk in experienced hands. There is no training available in the UK but there is overseas. Advisors recommend that all cases are registered, as at present there frequency data are not available. In observational studies, the procedure appears to be effective for spinal metastases and osteoporotic fractures in 70-85% of cases. No RCTs have been performed, and there are practical difficulties as the intervention is offered as a "last resort", when other methods have failed. The procedure is reasonable easy to teach, but as there is no commercial interest in the procedure (unlike kyphoplasty which is the use of an inflatable bone tamp, manufactured by Kyphon Inc. Sunnyvale, USA, to compact the cancellous bone and increase vertebral height before PMMA is injected) it is harder to set up training. Two Advisors are trying to set up a RCT for vertebroplasty, but there may be difficulties as the Kyphon Company has funded a trial in the USA which closed due to poor recruitment as patients were not prepared to accept the alternative treatment (observation). It is understood that a trial is being established in Europe by Kyphon.

Only six centres in the UK are using the procedure and there is a strong feeling from those doing it that the previous SERNIP decision to 'ban' the procedure was not justified. Kyphoplasty is seen as expensive, possibly safety and efficacy remains to be proved. The advisors also suggested; 1) approach the Kyphon Company who have registered all their (kyphoplasty) interventions, 2) encourage NHS funding of the vertebroplasty trial.

Issues for consideration by IPAC

The studies included in this overview show possibly lower complication rates than those stated by the specialists. However this is based on a limited number of studies, and not a full systematic review. The numbers quoted by the specialist advisors appear to be from Chiras *et al.*, 1997.¹¹

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ANNEX: Studies that met the inclusion criteria but which were not tabulated.

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