Percutaneous polymethylmethacrylate vertebroplasty in the treatment of osteoporotic vertebral body compression fractures: technical aspects.

M E Jensen, A J Evans, J M Mathis, D F Kallmes, H J Cloft and J E Dion

AJNR Am J Neuroradiol 1997, 18 (10) 1897-1904
http://www.ajnr.org/content/18/10/1897
Percutaneous Polymethylmethacrylate Vertebroplasty in the Treatment of Osteoporotic Vertebral Body Compression Fractures: Technical Aspects

Mary E. Jensen, Avery J. Evans, John M. Mathis, David F. Kallmes, Harry J. Cloft, and Jacques E. Dion

PURPOSE: To describe a technique for percutaneous vertebroplasty of osteoporotic vertebral body compression fractures and to report early results of its use. METHODS: The technique was used over a 3-year period in 29 patients with 47 painful vertebral fractures. The technique involves percutaneous puncture of the involved vertebra(e) via a transpedicular approach followed by injection of polymethylmethacrylate (PMMA) into the vertebral body. RESULTS: The procedure was technically successful in all patients, with an average injection amount of 7.1 mL PMMA per vertebral body. Two patients sustained single, nondisplaced rib fractures during the procedure; otherwise, no clinically significant complications were noted. Twenty-six patients (90%) reported significant pain relief immediately after treatment. CONCLUSION: Vertebroplasty is a valuable tool in the treatment of painful osteoporotic vertebral fractures, providing acute pain relief and early mobilization in appropriate patients.

Index terms: Interventional materials; Spine, fractures


With the aging of the American population, increasing numbers of elderly persons are sustaining vertebral compression fractures due to osteopenia. Other individuals, such as transplant recipients, suffer fractures as a result of chronic steroid use. These vertebral fractures frequently cause persistent, often excruciating pain, which significantly impairs mobility and quality of life. External bracing, analgesics, and observation may be all that is necessary for pain control in some patients, but in others, a constant requirement for narcotics can be as life-altering as the fracture itself.

Neoplastic vertebral compression fractures (1–3), giant cell tumors of the long bones (4, 5), and vertebral hemangiomas (6) have been treated in the past by surgical decompression and instillation of polymethylmethacrylate (PMMA) cement. Recently, percutaneous puncture of vertebral compression fractures, by the transpedicular or paravertebral approach under computed tomography (CT) and/or fluoroscopic guidance, has been described (7–10) (H. Deramond, R. Galibert, C. Debussche-Depriester, “Percutaneous Vertebroplasty with Methylmethacrylate: Technique, Method, Results” [abstract], Radiology 1990;117[suppl]:352).

Over the past 3 years, we have treated 29 patients with 47 age-related or steroid-induced osteoporotic compression fractures of the lumbar or thoracic vertebrae via percutaneous puncture and injection of PMMA. We describe the process for patient selection, the therapeutic technique, complications, pitfalls, technical results, and immediate clinical results. Long-term clinical outcomes will be described in a separate publication.

Materials and Methods

Twenty-nine patients (19 women and 10 men) with 47 compression fractures (17 thoracic, 30 lumbar) who were suffering from disabling back pain refractory to analgesic therapy were treated. Referral sources included orthope-
dics, neurosurgery, rheumatology, organ transplant service, family practice, and the pain management clinic. All patients had plain film evidence of progressive or new vertebral body compression fractures that corresponded to the level of the pain. Seventeen patients had fractures associated with age-related osteopenia and 12 patients were receiving oral steroids as part of an immunosuppressive regimen after cardiac or lung transplantation, or for chronic conditions. All patients had severe pain that limited their mobility; nine (31%) required assistance to ambulate, 10 (34%) were wheelchair bound, and 10 (34%) were limited to sitting in a chair or remaining in bed. Pain medication use varied, with eight patients (27%) using oral narcotics on an as-needed basis, 16 (55%) using oral narcotics on a 4- to 6-hour schedule, and five (17%) requiring parenteral narcotics.

Patient Selection and Preparation

Patient selection was limited to persons with focal, intense, deep pain associated with plain film evidence of a new or progressive vertebral compression fracture. Often the pain radiated along the ribs to the chest or abdomen, but lower extremity radicular pain was not reported.

Physical examination determined the patients’ general health and their ability to tolerate lying prone for 1 to 2 hours. Neurologic examination was performed to evaluate possible radicular symptoms. Once the patient was accepted for treatment, an unenhanced CT scan was obtained to assess continuity of the posterior vertebral wall and to exclude other causes of pain, such as a herniated nucleus pulposus or an adjacent tumor mass.

The procedure was discussed with the patient, and the potential benefits and risks were outlined. The potential complications specified were bleeding at the puncture site, bone infection or fracture, damage to the nerve roots or cord, extravasation of material into the surrounding epidural or paravertebral spaces, and passage of material into the venous system with embolization to the pulmonary vasculature or compression of neural tissue.

Vertebroplasty Technique

The technique described below is that which we currently use, and is the result of the experience we have gained over 3 years.

Upon completing the informed consent process, the patient is placed in the prone position on the angiography table. Monitoring of blood pressure, heart rate, and pulse oximetry is done continuously throughout the procedure. Oxygen supplied via a nasal cannula is used when necessary. Neuroleptic analgesics in the form of fentanyl (Sublimaze, Abbott Labs, North Chicago, Ill) and midazolam (Versed, Roche Pharma, Manati, Puerto Rico) are administered by the angiography nurse under the direction of the operating physician. The procedure is performed under strict sterile conditions. All personnel wear surgical masks and caps in addition to gowns and gloves for the operators, to minimize the risk of infection. The vertebral body to be treated is localized under fluoroscopic control and the skin overlying this area is prepped and draped. Biplane fluoroscopy is recommended, as it allows near simultaneous imaging of the stylet tip position in two planes, thus decreasing the overall procedure time. The anteroposterior tube is angled in such a way as to maximize the oval appearance of the pedicle (“looking down the barrel”) (Fig 1). The skin over the center of the pedicle oval is anesthetized with bupivacaine hydrochloride (0.25%) (Abbott Labs) followed by deep injection of bupivacaine to and including the periosteum. A small skin incision is made with a #11 scalpel blade. A disposable 11-gauge Jamshidi needle (Manan Medical, Northbrook, Ill) is positioned with
its tip in the center of the oval and advanced until the stylet tip abuts the bone. Lateral fluoroscopy shows the tip at the level of the upper to midpoint of the pedicle such that advancement of the needle is within the midportion of the pedicle. A slight twisting motion is used to advance the tip through the cortex, and frequent checking of needle placement in both planes is required. The anteroposterior view shows the needle shaft end-on as a circle within the center of the pedicle oval to indicate that the needle is proceeding parallel to the X-ray beam (Fig 2). The lateral view shows the needle moving roughly parallel to the superior and inferior edges of the pedicle (Fig 3) or in a slightly descending course through the pedicle. Minor adjustments in either plane may be required during needle advancement.

Once the needle tip has traversed the cortex and the pedicle and is located within soft bone marrow, less pressure may be required to advance the needle into the vertebral body. Care must be taken not to abrogate the anterior vertebral wall or the endplates. The stylet tip is placed at or near the junction of the anterior and middle third of the vertebral body line. Because the stylet tip projects beyond the end of the needle shaft, removal of the stylet will position the needle end in the middle or anterior half of the vertebral body (Fig 3).

Before injecting the PMMA, venography is done to exclude needle placement directly within the basivertebral venous complex and to ensure continuity of the posterior vertebral wall as evidenced by containment of the contrast material within the bony trabeculae (Fig 4). We use a hand injection of 5 mL of iohexol (Omnipaque 300, Nycomed, Princeton, NJ) and film in both planes at a rate of two frames per second. Rapid flow of contrast material into the vena cava and/or perivertebral veins without visibility of intervening bone marrow indicates direct communication of the needle tip with a major venous outlet and requires needle advancement. Once correct placement of the needle is confirmed, treatment is begun. If a bone biopsy is warranted, a variety of standard, commercially available biopsy needles can be passed through the Jamshidi shaft to obtain tissue samples before vertebroplasty.

In our experience, the Codman Cranioplastic, Type 1 (slow setting) material (CMW Laboratories, Blackpool, England) is the most suitable for vertebroplasty. The contents consist of a powder PMMA component (methylmethacrylate polymer with or without styrene copolymer and benzoyl peroxide) and a liquid PMMA component (methylmethacrylate monomer, ethylene dimethacrylate monomer, dimethyl p-toluidine and hydroquinone).

The powder is placed into a disposable plastic bowl and mixed with 1 g sterile tungsten powder (Nycomed) and 1.5 teaspoons (5 to 6 g) of sterile barium sulfate powder (E-Z-EM, Westbury, NY). The barium powder usually needs to be pulverized more completely before mixing, as it has a tendency to clump. The tungsten and barium are ground together with a pestle. The opacification agents are mixed thoroughly with the powdered PMMA and, for patients who are immunocompromised, 1.2 g of tobramycin (Nebcin, Eli Lilly, Indianapolis, Ind) is added to the powder mixture. A single dose of PMMA powder is divided into two equal parts to curb waste. The total powder volume (about 48 cm$^3$ without tobramycin, 55 cm$^3$ with) is measured in a 60-mL syringe and equal amounts are placed into two separate plastic bowls. Once the powder is divided, an additional 5 to 7 cm$^3$ are removed from each half and set aside. One half of the liquid agent (8.5 mL) is aspirated into a plastic syringe, and the unused portion is left in the glass bottle, since prolonged contact with the syringe wall will create a residue. The liquid agent is added to the powder and the slurry is mixed using a tongue blade until a thin "toothpaste" or "cake-glaze" consistency is achieved. If the material appears too thin after adding the liquid, the powder that was set aside is used to thicken the mixture. Once the desired consistency is reached, the material is poured into the back end of a 10-mL syringe, and the plunger is replaced, and the material is advanced to the Luer-Lok end.

One-milliliter Luer-Lok syringes are filled from the end of the barrel. The plunger is removed and the syringe tip is held upright while 0.5 to 0.7 mL PMMA is injected into the 1-mL syringe from the 10-mL syringe. With the 1-mL
Fig 5. Injection of the hemivertebra is best seen on the lateral view (A) as the radiopaque material passes down the needle and disperses throughout the vertebral body. In most patients, the PMMA respects the midline (B), although in severely osteoporotic vertebrae, material may pass to the opposite side.

One operator injects the material as the second loads the syringes. The stylet is removed and, unless blood fills the dead space in a retrograde manner, the dead space is injected with PMMA using a long 18-gauge spinal needle. The 1-mL syringe is attached tightly to the shaft port of the Jamshidi needle and injection begins. The injection pressure required to push the material will increase over time as the vertebral body fills and the PMMA polymerizes. Injection is performed under lateral or anteroposterior oblique fluoroscopy (Fig 5) and particular attention must be paid to the region of the vena cava and the epidural space as seen on the venogram. If passage of material into the venous system is noted, the injection is slowed or halted while the material attains a thicker consistency. Injection is continued until hemivertebal or holovertebral filling is achieved, no more material can be pushed into the body, or extravasation into veins or the disk space is noted. Repositioning of the needle is not recommended, as the location of the tip will be unknown, and unwanted vascular embolization may occur. Upon completing the injection, the needle is removed and hemostasis at the puncture site is achieved by gentle pressure. The contralateral hemivertebra is then treated in the same fashion. More than one vertebra can be treated at the same time, depending on the patient’s tolerance (Fig 6).

After the procedure, the patient is placed supine and asked to remain flat for 3 hours to allow complete curing of the PMMA prior to axial loading. Although patients usually remain overnight, those from our local area have been allowed to return home the same day, when appropriate.
Procedural Pitfalls and Helpful Hints

Several pitfalls and caveats have been discovered throughout our experience. It is helpful to have the patient attempt the prone position on a firm table before beginning the procedure to check for tolerance. Because most patients are receiving high doses of narcotics, the usual amount of neuroleptics needed to achieve adequate sedation may be insufficient. A dedicated nurse or other qualified person must be responsible for monitoring the patient, as respiratory distress or depression may occur quickly. Patients who experience difficulty with ventilation or who are unable to tolerate the prone position may require general anesthesia or deep sedation.

A recent CT scan to detect extension of the fracture into the posterior wall and to assess pedicle size is preferred whenever possible, particularly if the plain films show progressive collapse. In patients with questionable histories, the CT scan may also uncover other causes of pain, such as a herniated disk or a neoplastic lesion. Often, scans are obtained the same day as the initial consultation or just before treatment. Recently, we have found magnetic resonance (MR) imaging to be helpful in determining the site of an acute fracture in patients with multiple compression fractures, particularly when serial plain films are not available. The involved vertebra(e) have typically shown edema within the bone at the fracture site.

A variable degree of kyphosis may be associated with the fracture, and craniocaudal angulation may be required in addition to obliquity to attain the optimal pedicular appearance. In some instances, a significant amount of downward force may be required to advance the needle, and patients with diffuse osteopenia are at risk for rib fracture, especially with thoracic vertebral procedures. Often, the most force is needed to penetrate the pedicular cortex; thereafter, the tip usually advances easily, particularly in patients with severe osteoporosis. The needle position should be checked frequently in both planes to avoid exiting through the endplate. Once endplate penetration occurs, the needle may have to be removed and repositioned.

If the venogram shows rapid, direct filling of the basivertebral complex, the tip should be advanced into the bone instead of withdrawn. Once a track has been made, contrast material should be flushed with saline to remove any residual contrast material that may be confused with the embolic agent.

When adding opacification powders to the PMMA, using more than 1.5 teaspoons of barium sulfate results in a stiffer, faster-curing material that is difficult to inject. Barium powder alone does not provide as good visibility as the barium/tungsten combination. The powdered material should be mixed thoroughly to avoid clumping of the tungsten or barium. Powdered barium preparations designed for gastrointestinal work contain gums and flavors that may act as nutrients for bacteria, and should not be used. Pure barium sulfate powder is available, but needs to be sterilized by using dry heat.

The liquid agent is extremely volatile and should be opened only when needed. Inhalation of the fumes should be avoided, as the odor has occasionally induced headache and eye irritation in the operators. The package insert recommends double gloving, as there is inadequate information to determine if the PMMA resin might affect fertility in humans or have a teratogenic potential or other adverse effects on fetuses.

After mixing for approximately 1 minute, the material is relatively thin. At this point it is loaded into the 10-mL syringe. Further mixing seems to speed the polymerization and if one waits until the material appears to be of correct consistency in the bowl, it will be too thick to inject by the time the syringe is loaded. Filling the 1-mL syringes from the bowl by aspiration clogs the Luer-Lok threads, and adequate attachment to the Jamshidi stylet port may not be obtained. The dead space of the Jamshidi needle must be filled from the tip to the hub with a long 18-gauge needle, as the material does not readily drip into the hub. Injection of the air within the dead space may cause a venous air embolus.

Owing to the viscosity of the material, injection may be difficult, and the best results are obtained by using small amounts (0.5 to 0.7 mL) with the force of the injection applied parallel to the syringe cylinder. Excessive force may result in bending of the plunger. Injection through 3-mL syringes is difficult, and maximal vertebral body filling has been obtained consistently using 1-mL syringes. Non-Luer-Lok syringes do not give an adequate seal with the Jamshidi port. Care must be taken not to bear down on the Jamshidi handle, as the tip may advance further into the vertebral body.

Injection is performed under fluoroscopic control, paying particular attention to the epidural space, the spinal canal, and the perivertebral veins visible on the venogram. The lateral projection is best but may be useful for only the initial vertebral hemisphere, since the opaque cement from the first hemivertebral injection obscures the entire vertebral body in the lateral view. The anteroposterior oblique view for the contralateral hemisphere is recommended; however, the lateral plane should be checked frequently to ensure no epidural leakage. Occasionally, in severely osteoporotic vertebrae, it is possible to attain adequate filling of both sides from a single transpedicular injection (Fig 7). We consider an injection that fills the majority of the hemivertebra to be adequate. We continue the injection as long as the material remains within the vertebral body and there is no continuous leakage into paravertebral veins or into the disk space. Once adequate...
filling is obtained, the needle is removed without replacing the stylet to prevent injection of the dead-space material.

In some patients, PMMA will traverse endplate fractures and enter the disk space, which, in our experience, is of no clinical significance. When leakage occurs, delaying further injection for a minute allows the material to thicken and form a plug before proceeding. This technique is also useful when material enters the paravertebral veins. If continued injection shows filling only of the disk space or veins, the procedure is terminated in that hemisphere.

Results

The procedures were technically successful in all patients, as defined by effective transpedicular puncture of the vertebral body with instillation of PMMA. The amount of PMMA injected per vertebral body varied from 2.5 mL to 11 mL, with an average injection amount of 7.1 mL. Four vertebral bodies were treated from a single, unipedicular approach as the PMMA flowed across the midline to adequately fill both vertebral hemispheres. All remaining patients were treated via bipedicular punctures.

Two patients undergoing thoracic vertebral punctures sustained a nondisplaced rib fracture, which caused limited chest pain that subsequently resolved. No other clinical complications were noted. In two patients, a small amount of PMMA escaped to the inferior vena cava with presumed embolization to the lungs, but no respiratory changes were seen. In nine patients, radiographs showed evidence of PMMA leakage through the endplate fracture into the disk space, with no discernible clinical effect. A follow-up CT scan in one patient with pain associated with a new fracture showed PMMA in the anterior internal venous plexus at L-4, causing flattening of the thecal sac. There was no history of radicular pain and no radicular findings on neurologic examination.

Immediate clinical response to the procedure was assessed by monitoring patients’ verbal expression of perceived pain, amount and/or type of pain medication given, and changes in activity level. Two patients reported resolution of back pain immediately after vertebroplasty. Twenty-six patients (90%) described pain relief and improved mobility within 24 hours after treatment. All patients who had required parenteral narcotics were changed to oral medications on an as-needed basis. Three patients had no significant relief of pain and were continued on their pretreatment medical regimen. No worsening of pain was reported.

Discussion

PMMA has been used in anterior and posterior stabilization of the spine for metastatic disease in multiple surgical series (1–3), for bone packing after curettage of giant cell tumors of the long bones (4, 5), and in the surgical treatment of vertebral hemangiomas (6). Recently, percutaneous injection of PMMA into vertebral compression fractures via the transpedicular or paravertebral approach under CT and/or fluoroscopic guidance has been described (7–10) (Deramond et al., “Percutaneous...”). In patients being treated for chronic pain, the initial results of these small series were good, with relatively low complication rates. We believe our experience in performing vertebroplasty safely in 29 patients with 47 osteoporotic compression fractures with no significant clinical complications further validates these earlier studies. As noted above, the majority of our patients reported ini-
tial improvement in their quality of life as determined by decreased pain, increased mobility, and decreased reliance on analgesics immediately after the procedure.

Our technique is somewhat different from that used by European investigators (7–10) (Deramond et al, “Percutaneous...”). The materials we used are approved by the Food and Drug Administration; however, our use of them for percutaneous vertebroplasty would qualify as an “off-label” application. Instead of using the CT/fluoroscopic technique described by Gangi et al (9), we found the fluoroscopically guided transpedicular approach to be the easiest, safest, and least time-consuming procedure. Stringham et al (11) demonstrated that half the vertebral body can be reached via the transpedicular approach in bone biopsy specimens without compromising the anatomic structure of the pedicle. We noted that injection of PMMA spreads through the ipsilateral hemivertebra first, followed by progression across the midline in some patients.

Other authors (7–10) (Deramond et al, “Percutaneous...”) did not perform venography before injecting the PMMA. We found venography to be of great use, as it confirmed needle placement within the bony trabeculae, outlined the venous drainage pattern, and delineated fractures in the bony cortex. Knowledge of the venous anatomy allowed the operator to pay particular attention to those areas during dynamic injection of the PMMA.

In our initial experience, we terminated the injection whenever filling of a paravertebral vein or extravasation through an endplate fracture was noted. However, we encountered no clinical complications from PMMA situated in either location. We terminated the injection if filling of the anterior internal venous plexus was seen, as these veins abut the dura along its anterior surface and could compress the spinal cord or nerve roots. We also terminated the injection if the PMMA continued to seek the intervertebral space or progressed through paravertebral veins.

The complication rate for this procedure has been very low in other series (7–10) (Deramond et al, “Percutaneous...”), ranging from 0% to 10%. Complications have included transient dysphagia or radiculopathy, presumably due to extravasation of PMMA with nerve root or esophageal compression (10). We know of no reports of infection in any series, including our own. We decided to add tobramycin to the PMMA when treating immunocompromised patients after reviewing several reports that described the addition of antibiotics to PMMA in an attempt to decrease surgical infection rates (12–14). One series reported a decrease in infection from 5% to 1% when tobramycin-impregnated PMMA was used for cranioplasty, vertebral body replacement, or spinal fusion (12). Although regional tissue concentrations of the drug were noted, no incidents of renal toxicity were reported nor were significant systemic levels of tobramycin detected. Aminoglycosides should not be used in any patient with a known sensitivity.

Potential toxicities of PMMA have been described. McLaughlin et al (15) found decreased pulmonary function in dogs only when the dosage of PMMA monomer was more than 35 times the amount liberated in humans during total hip replacement. Phillips et al (16) described a fall in systemic arterial blood pressure after implantation of acrylic cement into the femoral shaft, but not the acetabulum, during hip arthroplasty. These authors speculated that the hypotension may have been due to absorption of monomer or additives into the circulation. We have not seen this phenomenon during injection of vertebral bodies. Convery et al (17) studied the safety of PMMA during total hip replacement, and, like Phillips et al, noted a fall in systemic pressure that was temporally related to the implantation of the acrylic in the femoral canal. There was no evidence of pulmonary function alteration or change in liver enzyme levels that could be related to the PMMA, indicating that liver toxicity is probably not an issue.

Another potential mechanism for injury is from the thermal reaction that occurs during polymerization. A significant amount of heat is generated, which potentially could be damaging to adjacent neurologic structures. In an in vivo experiment, Wang et al (18) found no spinal cord injury occurring in dogs undergoing cervical fusion with PMMA, even when gelatin sponge was not used as an insulator. The presence of intervening ligaments and vascular-rich dura along with cerebrospinal fluid flow may act as natural insulators to dissipate any heat that is created.

This technique has possible use as a means of delivering different substances to the bone. We have done some preliminary work with naturally occurring bone materials, such as hy-
droxyapatite, for use as a bone cement and think it is conceivable that bone growth hormones or other biologically active substances could be injected percutaneously into vertebral bodies to induce new bone growth.

**Conclusion**

We performed percutaneous vertebroplasty in 29 patients with 47 thoracic or lumbar compression fractures that were the cause of significant pain and/or immobilization. The procedure resulted in immediate subjective improvement in pain and in increased mobility for the majority (n = 26) of the patients. The long-term outcome in this patient population is currently being analyzed and will be the subject of a future publication. Complications appear to be rare. Vertebroplasty is a valuable new tool in the treatment of osteoporotic vertebral compression fractures, providing pain relief and early mobility in appropriate patients.

**References**