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Vertebroplasty: Clinical Experience and Follow-up Results

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This study was undertaken to report the clinical experience with percutaneous minimal invasive vertebroplasty using polymethyl-methacrylcate (PMMA) for a consecutive group of patients. Over the period of the last 4 years, 40 patients were treated at 68 vertebral segment levels with the intention to relieve pain related to vertebral body lesions. Reduced vertebral body height and destruction of the posterior vertebral wall were not considered to be exclusion criterias. The vertebroplasty procedure was performed under general anesthesia and in prone position with imaging control using mostly biplane DSA fluoroscopic guidance, and rarely with single-plane mobile DSA combined with computed tomographic guidance. Unilateral, but more frequently bilateral, transpedicular introduction of a 2–3-mm OD needle was followed by an injection of polymethyl-methacrylcate (PMMA). PMMA preparation involved a diluted mixture (20 mL powder for 5 mL liquid) allowing for an extended polymerization time of up to 8 min. The PMMA was mixed with metallic powder to enhance its radio-opacity. Before PMMA injection, a vertebral phlebography was obtained to evaluate the filling pattern and identify sites of potential PMMA leakage. Injection of opacified PMMA was performed under continuous visual control with fluoroscopy to obtain adequate filling and to avoid important PMMA leakage. Clinical follow-up involved an evaluation using a questionnaire for assessment of pain, pain medication, and mobility. One to six levels were treated in one to three treatment sessions for patients with metastatic, osteoporotic, and hemangiomatous lesions of the vertebral bodies who presented with pain. The results observed matched those reported previously with a success rate of approximately 80% and a complication rate below 6% per treated level. Treatment failure and complications observed were related to leakage, insufficient pretreatment evaluation, anesthesia, or patient position during treatment. Image guidance with fluoroscopy was efficient both for precise transpedicular approach and PMMA implantation control. Vertebroplasty is very efficient for treatment of pain. Treatment failure was mostly related to insufficient pretreatment clinical evaluation, and complication due to excessive PMMA volume injection. Control of PMMA volume seems to be the most critical point for avoiding complications. A good fluoroscopy control is therefore mandatory. (Bone 25:11S–15S; 1999) **© 1999 by Elsevier Science Inc. All rights reserved.**

Key Words: Clinical follow-up, Percutaneous; Polymethyl-methacrylcate; Vertebroplasty.

Introduction

The technique of percutaneous minimal invasive vertebroplasty was introduced a little over decade ago[10] and has found increasing recognition. The current indication for treatment is management of pain, likely caused by structural instability of the vertebral body. This condition is encountered in vertebral metastatic disease,[3,4,6,14,18] vertebral osteoporotic fracture,[5,7,13,15] and presence of nondegenerated vertebral hemangioma.[3,8,12,17] Vertebroplasty procedure leads in 80%–90% to a durable partial or complete pain reduction. Pain relief is usually observed within the first 72 h after treatment.[2,5] Destruction of the posterior vertebral wall, with or without compression of the spinal canal, complete loss of vertebral body height, and presence of osteoblastic metastatic lesion, was considered as a relative contraindication.[2,5] Procedural complications were mostly related to leakage of polymethyl-methacrylcate (PMMA) into adjacent structures because of vertebral cortical destruction or fracture, or injection into the vertebral venous plexus. Such venous leaks caused compression of spinal cord or nerves or could also cause pulmonary embolism.[1–4] Risk of damaging nerve roots or the spinal cord was mostly considered due to compression or by damage due to exothermic effect.[2,5] The overall complication rate was reported to range from 1% to 10%, with a higher incidence of complications in cases with metastatic lesions.[1] Mortality was observed with periprocedural complications, including broncho-aspiration and pneumonia, or complications related to advanced cancer stage.

The treatment was performed in prone patient position and under local or general anesthesia.[5] The treatment protocol involved a percutaneous, transpedicular access.[2,5] The direction and advancement of the needle was controlled under fluoroscopy, computed tomography (CT), or both, and 1–5 mL of methyl-methacrylate polymer (Simplex P, Methyl-methacrylate; Howmedica Inc., Rutherford, NJ) was injected.[5] Metallic powder was added to PMMA in order to enhance the visibility of the implant. Injection was done under fluoroscopy control in order to perform the vertebral filling and to detect PMMA leak.[2,5] PMMA filling going from inferior to superior vertebral plates allowed for immediate stabilization, even if the filling was only partial.[5] Vertebroplasty was combined with surgery or with radiotherapy for the management of metastatic lesions.[2,16]

We report the clinical experience with percutaneous minimal

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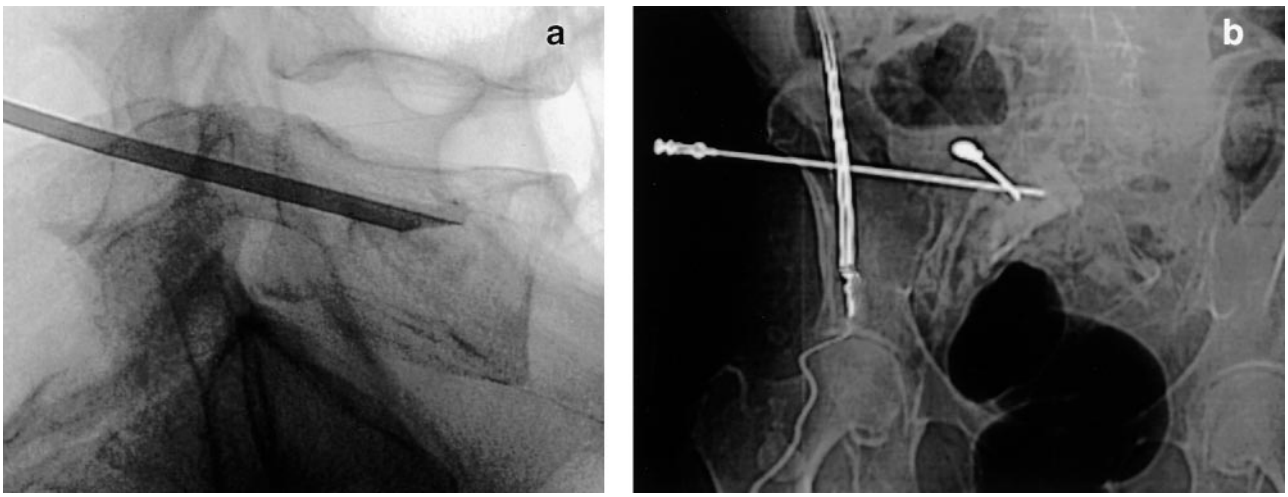

Figure 1. (a) Lateral fluoroscopy with needle tip ideally placed in the anterior third of the vertebral body. (b) For treatments involving S1 levels, a complementary trans-illiac bone access may be performed in order to reach the center of the vertebral body.

invasive vertebroplasty using PMMA[5–7,9,10] for a consecutive group of 40 patients.

Materials and Methods

Over the period of the last 4 years, 40 patients were considered for vertebroplasty with the intention to relieve pain related to vertebral body lesions. Reduced vertebral body height and destruction of the posterior vertebral wall were not considered to be exclusion criterias. Pretreatment imaging evaluation was performed within 21 days preceding the procedure, using standard radiography, CT, and, if possible, magnetic resonance imaging (MRI). In the presence of tumor extension with lysis of the posterior wall, involvement of the pedicle, and of the epidural or foraminal spaces, an increased risk to produce PMMA contact with nerve roots or the spinal cord was considered. Such anatomical conditions were, however, not excluded from treatment, but lead to particularly caution during cement injection to avoid complication by compression. All the procedures were performed under general anesthesia and in prone position of the patient.

Transpedicular Approach

For all but two of the cases, the control of the percutaneous procedure was performed by visualization with biplane DSA fluoroscopy (Integris BV/BN 3000; Philips, Netherlands). Only in two cases was a combined use of DSA and CT (HiSpeed CT/I-TiP; General Electrics, Milwaukee, WI) required to assure correct position of the needle and the PMMA implant. Percutaneous access was gained under sterile conditions with a needle of 2–3 mm OD, with a length of 10–15 cm and a beveled tip (Trocart Vertebroplastie; Escoffier, Thonon-les-Bains, France). Needle length was chosen according to the length of the planned percutaneous pathway. Introduction of the needle was performed with positioning of the needle in the same axis as the central X-ray beam. Concentric alignment with the contours of the pedicle allowed to direct the needle coaxially through the pedicle. At the level of the pedicle, the bevel was oriented towards the spinal canal, with the tip pointing outwards. This orientation was used to avoid penetration into the spinal canal. When the depth of the vertebral body was reached, the needle tip was rotated and oriented in the direction of the vertebral body center. Advancement was also controlled in the lateral projection, and the needle tip was ideally placed in the anterior third of the vertebral body (**Figure 1**a) before PMMA injection.

Complementary and Alternative Approaches

For treatments involving S1 levels, most of the time, a complementary trans-illiac bone access was performed in order to treat the center of the vertebral body (Figure 1b). In a case in which previous surgical stabilization with transpedicular surgical fixation screws had been done, a lateral approach was chosen to perform complementary vertebroplasty.

PMMA Implantation Procedure

Before injection of PMMA, the bevel of the needle was oriented to primarily address the region of interest. In this position, a pretreatment phlebographic study was performed and evaluated. The phlebographic information was used to predict the risk of early leakage into main venous outflow of the vertebral body or leakage in the intervertebral and paravertebral spaces. In the presence of direct venous outflow visualization and concomitant lack of filling of osseous compartments, the needle was placed at a different depth or with a different orientation of the needle tip. In the presence of early venous drainage, the PMMA was injected very slowly and already partially polymerized. In addition, the phlebographic studies were evaluated in regard to their filling pattern. PMMA preparation involved use of a diluted mixture (20 mL powder for 5 mL liquid), allowing for an extended polymerization time of up to 8 min.[2,5] Before the admixture of the liquid, 1 g of metallic powder was added (tungsten powder; Nycomed, Paris, France) to the PMMA powder. The PMMA mixture was injected with 1–3-mL syringes under continuous fluoroscopic control, and injection was interrupted as soon as a cement leak into venous structures was recognized. In cases with tumor extension towards the spinal canal or with destruction of the posterior wall of the vertebral body, the PMMA injection was interrupted as soon as the implant reached a 5-mm distance from the assumed posterior wall. After 30–60 sec, the PMMA injection was slowly continued, either in the same needle position or after advancing, withdrawing, or rotating the needle according to the lesion. A PMMA leak towards the intervertebral space was of no

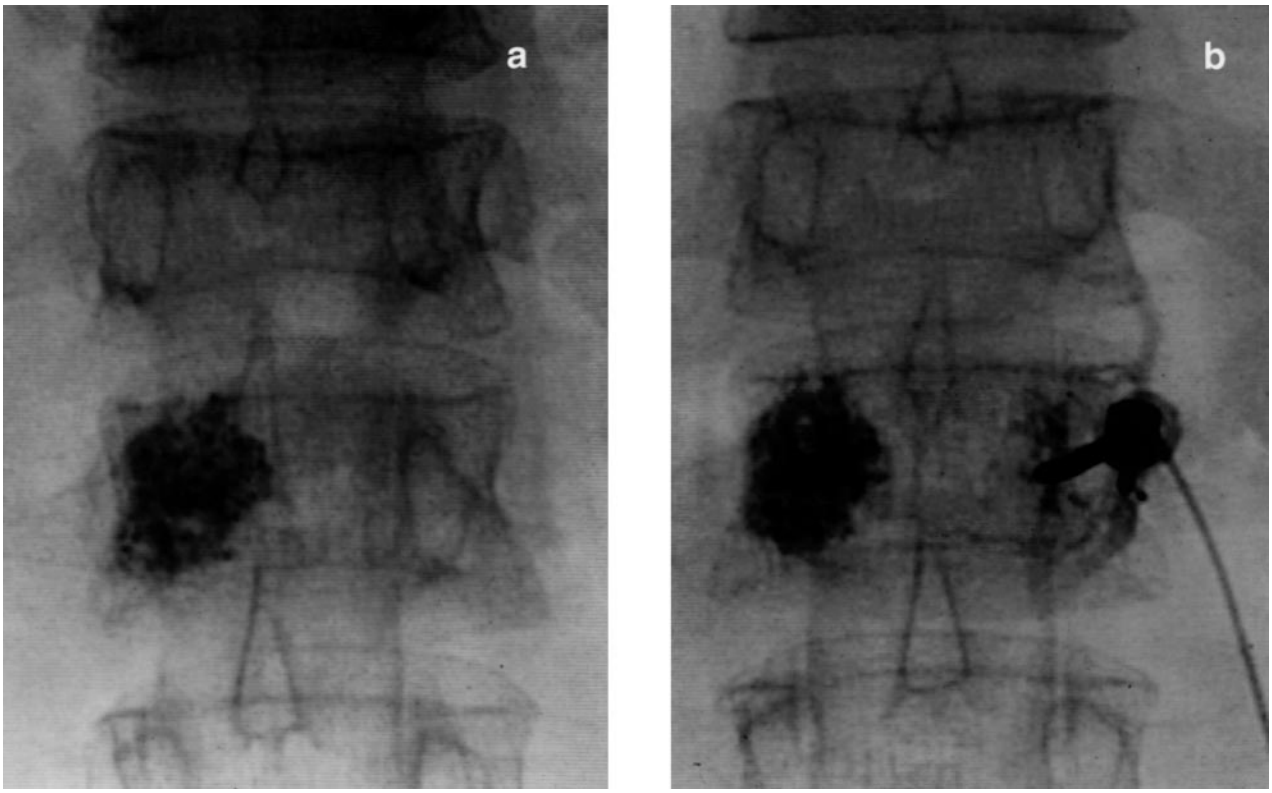

Figure 2. Bilateral transpedicular approach to achieve symmetric filling.

concern and did not lead to interruption of the injection. Minimal satisfactory filling was considered when the cast reached the superior and inferior vertebral plates. In cases with a symmetric extension of the lesion within the vertebral body, bilateral transpedicular approach (**Figure 2**a,b) was often used. In all the cases, an immediate postprocedural CT was performed. Clinical follow-up included next-day evaluation, recording of patient chart notes, and patient phone inquiries using a questionnaire. The clinical evaluation occurred in a retrospective fashion, and total follow-up period ranged from 2 weeks to 4 years, with a mean of 14 months. Evaluated parameters included subjective pain felt in the follow-up period, pain medication used in the follow-up period, and mobility in comparison with pretreatment status.

Results

Treatment was performed for all 40 patients considered and involved PMMA injection at 67 vertebral levels in the region Th4 to S1. Twenty women and 20 men with an average age of 67 years (range 32–87 years) were treated for vertebral lesions at spine levels that corresponded to the back pain. Eleven patients were treated for osteoporotic collapse, 7 for hemangioma, 19 for metastasis, 2 for myeloma, and 1 for bone lymphoma. The number of levels treated per patient ranged from one to six, treated in one to three sessions. The minimal treatment involved a unilateral access with PMMA filling at one level. The maximal treatment involved PMMA filling at six levels performed in one session for osteoporosis (**Figure 3**a,b). The average procedure time was approximately 40 min (±15 min) for one level, not including the anesthesia care.

The techniques described by Deramond et al.[1–3,5,6] allowed for rapid and successful access without complications. Biplane fluoroscopy was considered very useful for the puncture procedure. Before PPMA injection, a vertebral phlebography was performed allowing for correct assessment of the sites of potential leak and to predict the pattern of PMMA distribution (Figure 3a,b). Two types of intralesional casts were found. The first type showed speckled distribution and subsequent venous drainage. The second type represented contrast material deposition within a necrotic tissue mass. This type rarely showed venous filling, but readily leaked into perivertebral structures, when cortical destruction was present. Minor PMMA leaks occurred in the majority of the cases, since used to indicate satisfactory filling.

Follow-up

Immediate CT evaluation was considered useful for the analysis of the spatial distribution of PMMA, and to exclude major compression of nerve roots or spinal cord that could have been overlooked with fluoroscopy. No spinal cord compression was observed in our case material. Presence of PMMA leak towards epidural veins and close to the foraminal segment of the nerve roots was frequently found, however, only in one case was an infiltration of this area necessary to treat radicular pain.

Early clinical follow-up showed that pain relief occurs mostly within 3 days. Complications were found in the early posttreatment phase with cancer patients. One patient with retroperitoneal infiltration at the L5/S1 level presented with deep thrombosis of the left leg, likely due positional venous stasis during the vertebroplasty procedure. One patient contracted broncho-aspiration pneumonia after general anesthesia and died within 1 week. One patient with extensive pulmonary metastasis and cachexia experienced not only pain increase, but also died 3 days after treatment (same case as **Figure 4**).

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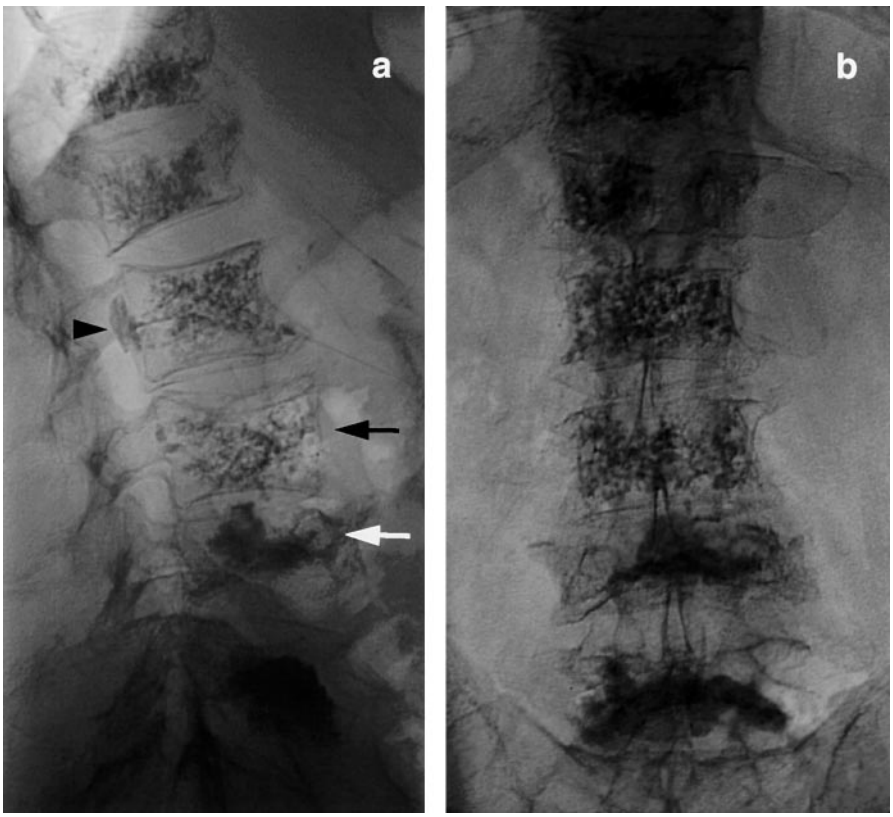

Figure 3. Lateral and ap view of PMMA distribution. Six levels were treated for osteoporotic disease. Two types of intralesional casts were found. A speckled distribution (black arrow) and contrast material deposition are within a necrotic tissue mass in type two (white arrow). Note presence of leakage in the region of the basivertebral vein (arrowhead).

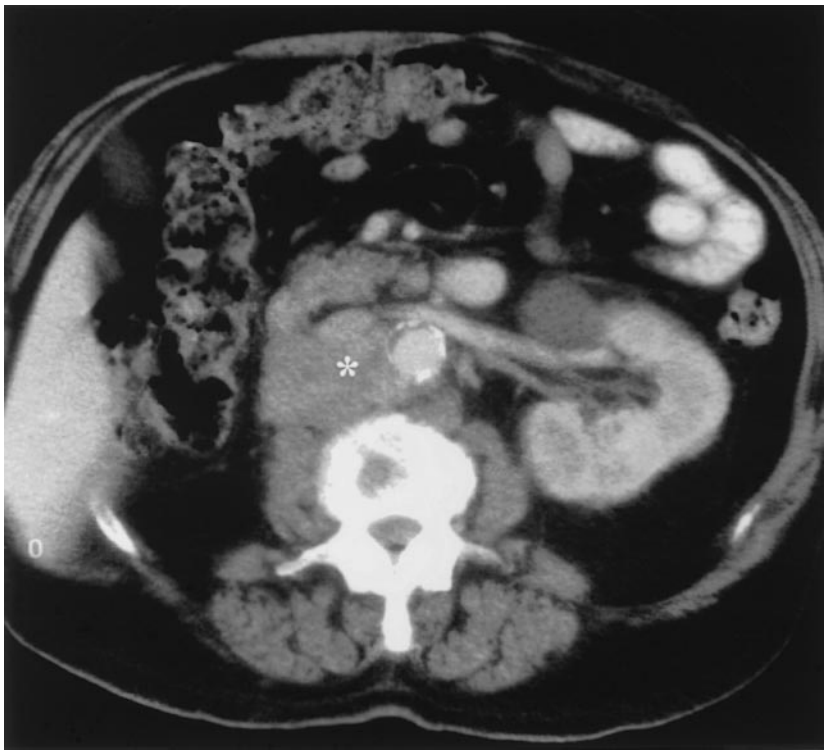

Figure 4. Metastatic disease may produce pain by other lesions such as associated retroperitoneal invasion (asterisk).

No late complications due to the vertebroplasty procedure were observed. Later follow-up in patients treated for hemangioma revealed pain reduction, with interruption of pain medication. Only 1 out of 5 cases reported residual back pain.

In cases of osteoporosis, complete pain relief was observed in 7 out of 9 cases. Pain medication was stopped in all but 1 patient, and all patients reported recovery of mobility. No pain relief occurred in 2 out of 9 cases.

Patients with metastatic lesions showed complete pain relief and recovery of mobility in 11 out of 18 of cases. Intakes of narcotic analgesics were stopped in all these cases. Two out of 18 patients experienced partial pain relief and could be taken off narcotic analgesic treatment. The pain remained unchanged in 4 out of 18 patients.

In the patient with myeloma, where follow-up was achieved, there was good pain relief. The patient with bone lymphoma also presented with a very good result, including recovery of mobility and interrupted pain medication.

Six patients were lost to follow-up, including 2 patients with hemangioma, 1 with myeloma, 2 with osteoporotic collapse, and 1 with metastasis.

Discussion

Our results reproduced published data,[1–3,5,6] and we can recommend use of vertebroplasty for painful vertebral lesions. Although some authors advocate needle placement and PMMA injection under CT control,[11] or a combination of CT and fluoroscopy control,[1] we agree with Deramond et al.[7] that the procedure is efficient and safe with fluoroscopy only. In addition, we advocate use of vertebral phlebography to identify potential leakage sites and filling type. This information may change the timing and preparation of the PMMA injection. In cases with necrotic cavities, postphlebography contrast residues have the disadvantage of making control of PMMA injection more difficult. To overcome these difficulties, we used irregular contrast of the PMMA achieved by aggregated metallic particles. This technique also allowed us to differentiate still fluid from already polymerized PMMA by identification of particle movement. To overcome the risks associated with excessive PMMA injection, we consider phlebographic studies as useful and the use of a good fluoroscopic equipment as mandatory.

In our opinion, the greatest difficulty lies in denying the treatment to patients with advanced metastatic disease, where other concomitant medical conditions may increase the treatment risk. Lack of pain relief was mostly observed in advanced stages of metastatic disease. In such cases, pain may be related to other secondary lesions such as associated retroperitoneal carcinomatosis (Figure 4).

In conclusion, vertebroplasty is very efficient for pain treatment. In cases of treatment failure, there was generally a problem with identifying the correct origin of the pain because of insufficient clinical evaluation, or pain syndrome with questionable relation to the observed vertebral lesion. Complications were mostly related to excessive PMMA injection, underlining the need of optimal conditions to control PMMA implant injection.

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