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Long-term observations of vertebral osteoporotic fractures treated by percutaneous vertebroplasty

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Abstract

Objective. To assess the immediate and long-term efficacy and safety of percutaneous vertebroplasty with polymethylmethacrylate (PMMA) for the treatment of refractory pain resulting from osteoporotic vertebral fractures.

Methods. A retrospective, open study of percutaneous vertebroplasty (PV) was conducted with long-term follow-up. PV with PMMA was carried out between 1990 and 1996 in 40 patients with symptomatic osteoporotic vertebral fracture(s) that had not responded to maximum medical therapy. In 1997, each patient was asked to come back to our institution for a physical and spinal X-ray examination. Efficacy was assessed by changes over time in pain on Huskisson's visual analogue scale (VAS).

Results. Thirty-four vertebrae treated by PV in 25 patients were evaluated with long-term follow-up. The mean duration of follow-up was 48 months (range 12–84 months). Pain assessed by the VAS significantly ($P < 0.05$) decreased from a mean of 80 mm $\pm$ 16 (S.D.) before PV to 37 $\pm$ 24 mm after 1 month and 34 $\pm$ 28 mm at the time of maximal follow-up. There was no severe complication related to this treatment, and no progression of vertebral deformity in any of the injected vertebrae. However, there was a slight but significantly increased risk of vertebral fracture in the vicinity of a cemented vertebra (odds ratio 2.27, 95% confidence interval 1.1–4.56). The odds ratio of a vertebral fracture in the vicinity of an uncemented fractured vertebra was 1.44 (0.82–2.55).

Conclusion. PV appears to be a safe and useful procedure for the treatment of focal back pain secondary to osteoporotic vertebral fracture when conservative treatment has failed.

KEY WORDS: Vertebroplasty, Osteoporosis, Polymethylmethacrylate, Vertebral crush fracture, Interventional radiology.

Percutaneous vertebroplasty (PV) is a radiologically guided therapeutic procedure that consists of injecting polymethylmethacrylate (PMMA) into a vertebral lesion to relieve pain and structurally reinforce the vertebrae. This technique was pioneered in 1985 by Deramond *et al.* [1] for the treatment of symptomatic or aggressive vertebral angiomas [1, 2]. Subsequently, it has been used successfully in the treatment of pain due to vertebral malignant tumours [3–8] and vertebral osteoporotic compression fractures [4, 9–18]. The early clinical results using PV for osteoporotic vertebral crush syndrome were encouraging. The initial results of small series [4, 9–15] were good, with rapid regression of pain and a low rate of complications. Recent papers [16–18] have corroborated these preliminary findings. Jensen *et al.* [16] safely treated 47 osteoporotic vertebral fractures in 29 patients with PV and noted that 90% of the patients described pain relief within 24 h after treatment. In a series of 16 patients, Cortet *et al.* [17] found a mean 53% decrease of pain assessed by a visual analogue scale 3 days after PV ($P < 0.0005$). In a series of 20 patients, Cyteval *et al.* [18] reported complete relief of pain in 15 patients (75%) within 24 h after PV. However, data supporting the widespread use of PV in this indication remain sparse, and the long-term effects of such a procedure have not been described. The aim of this study was to report the long-term follow-up of patients complaining of back pain related to vertebral compression fracture and treated by PV.

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Materials and methods

Vertebroplasty technique

The procedure can be performed under conscious sedation and local anaesthesia or under general anaesthesia. Luer-Lock needles (10–15 cm long, 10-gauge) are used.

The procedure has to be performed under sterile conditions. A percutaneous, transpedicular approach to the vertebral body is used (Fig. 1). The needle is introduced under fluoroscopic control. Fluoroscopic C-arm or biplane guidance is essential. Once the needle has been inserted into the vertebral body, the cement is prepared: 20 ml of methylmethacrylate powder is mixed with 5 ml of methylmethacrylate monomer liquid (Surgical Simplex P; Howmedica, Shannon, Ireland), and 2 g of tantalum powder is added to give good radio-opacity. The preparation is mixed until it becomes like toothpaste, and the cement is then injected through the needle using a 3 ml Luer-Lock syringe (Fig. 2). The cement is pushed manually into the vertebral body under continuous lateral fluoroscopic control to prevent leakage of cement into the spinal canal. If necessary, a second needle is inserted into the contralateral part of the vertebral body and the procedure is repeated. Two or three vertebrae may be treated during the same procedure. Three to six millilitres of PMMA is injected into each vertebral body. Patients are given bed rest for 24 h and are allowed to stand up the next day.

Methods

PV with PMMA was carried out between January 1990 and April 1996 in 40 osteoporotic patients who had been complaining of focal back pain refractory to rest and analgesics for 4–12 weeks. In 1997, each patient was asked by direct mail or telephone to return to our institution for a physical and spinal X-ray examination. Adverse effects, pain and radiographs were evaluated by a physician different from the one who performed the procedure. The patients were asked in 1997 to quantify their degree of pain on Huskisson's visual analogue scale (VAS; 0 mm = no pain; 100 mm = worst pain possible) before vertebroplasty, 1 month after vertebroplasty and at the present time. Radiographs of the thoracic and lumbar spine were performed 1–3 days before the procedure and in 1997. Baseline and follow-up radiographs were viewed simultaneously in order to facilitate the detection of changes. They were analysed using the semiquantitative visual method devised by Genant *et al.* [19]. Vertebrae were graded as normal (grade 0), mildly deformed (grade 1 with 20–25% reduction in anterior, middle and/or posterior height), moderately deformed (grade 2 with 25–40% reduction in any height) and severely deformed (grade 3 with 40% or greater reduction in any height). Incident fractures were defined when vertebrae showed a distinct alteration in morphology resulting in a higher deformity grade on the follow-up radiographs. We had previously verified, in 39 postmenopausal women who had at least one osteoporotic vertebral fracture, that Genant's semiquantitative grading scheme was reproducible. The agreement between one trained reader and a consensus reading of three experts was 98%, with a corresponding κ score of 0.95

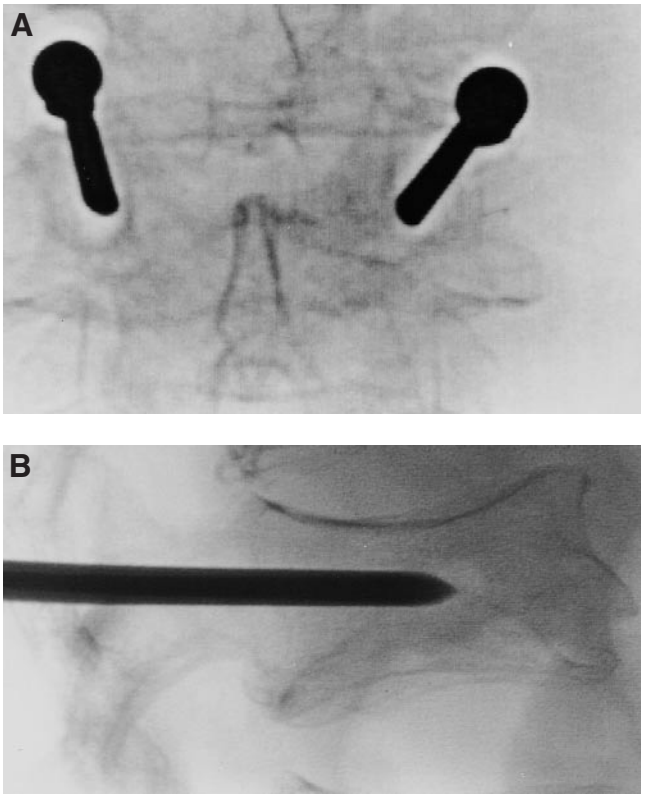

FIG. 1. L2 osteoporotic vertebral collapse. Frontal (A) and sagittal (B) views. Two 10-gauge needles are placed in the vertebral body via a bilateral transpedicular approach.

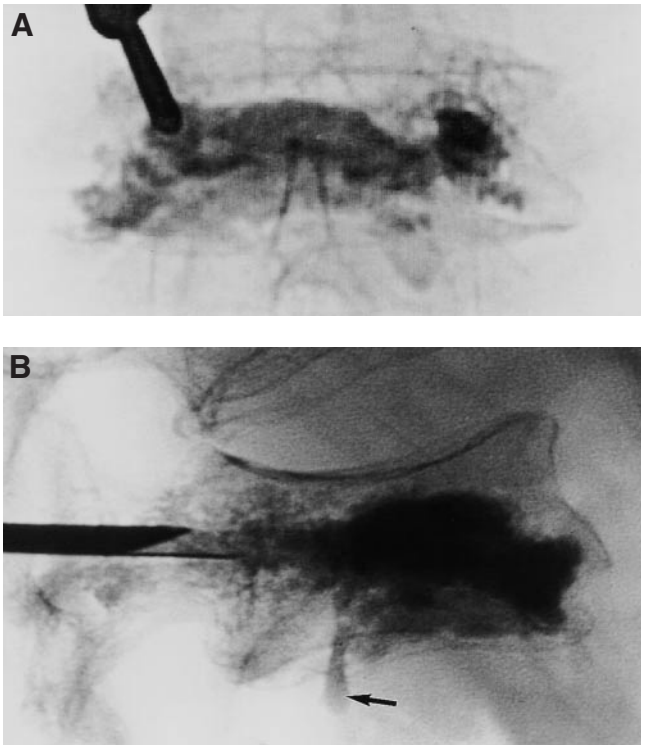

FIG. 2. Frontal (A) and sagittal (B) views after bilateral cement injection and before removal of the needles. Note the leakage in the inferior disk (arrow in panel b); it had no clinical consequence.

for the dichotomous fracture (grade 1 or greater)/non-fracture diagnosis; it was 91.6% with a corresponding κ score of 0.80 for the whole grading scale (F. Grados, C. Roux, M.C. de Vermejoul, G. Vtrard, J.L. Sebert and P. Fardellone, submitted for publication).

Statistical analysis

The VAS values before PV, 1 month after PV and at the last follow-up visit were compared using the Wilcoxon signed rank non-parametric test for paired data. The relative risks of fracture in the vicinity of a cemented vertebra and of an uncemented fractured vertebra were estimated as odds ratios with 95% confidence intervals (CI).

Results

Characteristics of the patients

Of the 40 patients treated by PV between January 1990 and April 1996, 15 could not be evaluated in 1997. Ten patients were dead (eight from cardiovascular accident and one from a traffic accident; the cause of one death was not known). All these deaths occurred more than 6 months after PV. The mean age of the patients who died was 82 yr. None of these deaths could be related to PV. Two patients had returned to their country of origin and could not be contacted. Three patients were lost to follow-up. Thirty-four vertebrae, treated by PV in 25 patients (19 women, six men), could be evaluated with long-term follow-up. The mean duration of follow-up after treatment was 48 ± 21 months (range 12–84 months). These patients, aged 48–78 yr (mean age 66 yr), suffered from severe primary (16 patients) or secondary osteoporosis (seven had corticosteroid-induced osteoporosis and two had alcoholism-induced osteoporosis). The average number of vertebral fractures at baseline was 3.36 per patient. The mean T score for the bone mineral density of the femoral neck, measured by dual-energy X-ray absorptiometry (Hologic QDR 2000; Hologic, Waltham, Massachusetts, USA), was -3.1. In eight patients, two (seven patients) and three (one patient) vertebrae were treated during the same procedure. The spinal segment involved was the thoracic spine in 13 cases and the lumbar spine in 21 cases.

Analgesic effect

Pain decreased from 80 ± 16 mm at baseline to 37 ± 24 mm at 1 month and 34 ± 28 mm at the long-term follow-up. The reductions in pain from baseline to 1 month and to long-term follow-up were statistically significant ($P < 0.05$). There was no statistical difference between the degree of pain at 1 month and at the long-term follow-up. Only one patient described no improvement in pain after the procedure.

Safety

Few complications occurred in the immediate post-operative period. Two patients complained of transitory nerve root pain (intercostal neuralgia, cruralgia), which was treated with non-steroidal anti-inflammatory drugs and resolved within 2 days, two patients had transitory fever ($<38.5^{\circ}$) which resolved spontaneously after 2 days, and transitory (<2 days) exacerbation of pain occurred in one case. No other clinical complication was noted. In seven patients, radiographs showed evidence of leakage of PMMA through the endplate fracture into the disk space, but there was no clinical effect (Fig. 2B). In one patient, chest radiographs demonstrated cement embolism with no respiratory changes. Comparison between baseline and long-term follow-up radiographs showed no evidence of progression of vertebral collapse at the level of the treated vertebra. During the follow-up, 13 patients (52%) developed at least one new vertebral fracture and 34 vertebral fractures occurred. The odds ratio of a vertebral fracture in the vicinity of a cemented vertebra was 2.27 (95% CI 1.11–4.56) compared with 1.44 (95% CI 0.82–2.55) for a vertebral fracture in the vicinity of an uncemented fractured vertebra.

Discussion

Previous open studies [4, 9–18] have demonstrated that percutaneous injection of PMMA into osteoporotic vertebral fractures rapidly produces significant pain

Table 1. Immediate complications of PV for the treatment of osteoporotic vertebral fractures

	Present study	Jensen *et al.* [16]	Cortet *et al.* [17]	Cyteval *et al.* [18]	Chiras and Deramond [20]
Number of patients	25	29	16	20	67
Number of vertebroplasties	34	47	20	23	76
Transitory[a] worsening of pain	1 (2.9%[b])	0	0	0	NS
Transitory[a] fever	2 (5.9%[b])	NS	0	0	NS
Transitory[a] nerve root pain	2 (5.9%[b])	0	0	0	NS
Durable nerve root pain	0	0	0	1 (4.3%[b])	1 (1.3%[b])
Rib fracture	0	2 (4.3%[b])	0	0	NS
Cement pulmonary embolism on chest radiographs	1 (2.9%[b])	2 (4.3%[b])	0	0	NS
Infection	0	0	0	0	0
Spinal cord compression	0	0	0	0	0

NS, not specified.
[a]Less than 2 days.
[b]Percentages of complications were calculated using the number of vertebroplasties as the denominator.

relief and improves mobility. Our study suggests that this rapid analgesic effect is persistent.

The immediate rate of complications of PV appears to be low in this indication according to the data from our study. All symptomatic complications (nerve root pain, fever, exacerbation of pain) were transitory. Non-steroidal anti-inflammatory drugs can be given for a few days to minimize these symptoms. These results are similar to those of previous studies [16–18, 20, 21] (Table 1). There is no report of infection or spinal cord compression induced by PV in the treatment of osteoporotic vertebral compression fractures. Cement embolism was demonstrated on the chest radiograph of one patient in our study and two patients in the study of Jensen *et al*. [16]; however, no respiratory symptoms occurred.

Even with a long follow-up period, we did not observe any modification of the vertebral bodies that had been treated. Therefore, we suggest that PV can prevent the progression of vertebral collapse at the level of the treated vertebrae. Our long-term follow-up showed a slight but significant increase in the incidence of fracture in the vicinity of a cemented vertebra in comparison with the incidence in the vicinity of an uncemented fractured vertebra. PV with PMMA might increase the risk of fracture of adjacent vertebrae by shifting the normal load transmission through the spine. This risk should be weighed against the benefit of PV in preventing further collapse at the level of the treated vertebrae.

PMMA was chosen because it has been used over a long period to seal orthopaedic prostheses with a good safety record, and because biomechanical testing in cadaveric vertebral bodies has shown a significant increase in the load-bearing ability of PMMA-injected vertebral bodies compared with controls [2, 22]. It is conceivable that in the future more physiological substances capable of inducing bone conduction and/or bone formation could be substituted for PMMA.

The pain of acute vertebral osteoporotic fracture can usually be relieved by bed rest, analgesics, the injection of calcitonin or external bracing [23, 24]. Therefore, we suggest that PV should be considered in patients who suffer from a persistent high level of pain despite at least 3 weeks of conservative treatment. PV should be performed within this period in patients with a high risk of decubitus complications.

We conclude that PV with PMMA appears to be a safe and useful procedure for the treatment of refractory focal back pain secondary to osteoporotic vertebral fracture. A prospective, randomized, controlled trial comparing PV with the best conservative treatment is needed to confirm its efficacy and to define precisely the role of this new technique in the management of pain and functional disability produced by osteoporotic vertebral fracture.

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