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## Percutaneous vertebroplasty immediately relieves pain of osteoporotic vertebral compression fractures and prevents prolonged immobilization of patients

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**Abstract** To assess the immediate efficacy of percutaneous vertebroplasty (PVP) in relief of pain and improving mobility of patients with vertebral compression fractures (VCF) secondary to osteoporosis, 205 cases (175 patients) underwent 250 percutaneous injections of polymethylmethacrylate (PMMA; unilateral, 247 levels; bilateral, 3 levels) into vertebrae under CT and fluoroscopic guidance for 34 months. Patients were prospectively asked to quantify their pain on a visual analog scale (VAS) before and a day after PVP. The interval to mobilization was recorded in those who were immobilized because of pain and/or bed-rest therapy (115 cases). PVP was technically successful in all patients, with three cases of minimal complications.

The mean VAS score available for 196 cases was improved from  $7.22 \pm 1.89$  (range, 3–10) to  $2.07 \pm 1.19$  (range, 0–10) by PVP. Ninety-four of 115 immobilized cases (81.7%) were mobile by 24 h after PVP, and the mean value was  $1.9 \pm 2.8$  days. The incidence of recurrent and new fractures was 15.6% in 4–25 months (mean, 15.3 months). PVP is a safe and effective treatment for relieving the pain associated with osteoporotic VCF and strengthening the vertebrae, avoiding refractures. This therapy leads to early mobilization and avoidance of the dangers of conservative therapy of bed-rest.

**Keywords** Osteoporosis · Interventional procedures · Spine · Fractures · Vertebroplasty

### Introduction

The prevalence of osteoporotic vertebral fracture is increasing with the aging of the population. Some epidemiological investigations indicate its higher prevalence especially in Japan compared with that in Western countries [1].

The vertebral fractures frequently cause persistent back pain, which significantly impairs mobility and quality of life. External bracing, narcotics and analgesics have been conventionally used for pain control; therefore, some patients are confined bed-rest, and the pain generally continues for 4 weeks to a few months. Long-term immobilization may accompany high hospitaliza-

tion expense, functional impairment of the musculoskeletal system and/or progression of dementia in elderly patients. As in femoral neck fracture, osteoporotic vertebral fracture is also becoming one of the socioeconomic problems in advanced countries [2].

Since the first percutaneous vertebroplasty (PVP) was reported in 1987 for treatment of a painful hemangioma in the cervical spine of a young female patient [3], the indications of PVP have extended to vertebral compression fractures (VCF) secondary to osteoporosis [4–6].

Recently accumulating evidence indicates that PVP provides both early pain relief and strengthening of the bone of the vertebrae, with long-lasting effectiveness, and that it has the potential to become the standard therapy in-

stead of the present conventional one [7–9]. PVP is now well accepted in the treatment of osteoporotic vertebral fractures, painful hemangiomas and metastatic vertebrae. Although PVP seems to be promising in solving the socioeconomic problems that osteoporotic vertebral fractures have, this procedure is still performed in a restricted number of institutions because of doubt about its safety and concern about its technical difficulty. Therefore, the procedure should be simple and safe in order to spread widely.

In this study we performed PVP on a large series of patients with poor mobility from painful VCF associated with osteoporosis and demonstrated its high efficacy, analyzing the degree of pain relief in each case. We also found an advantage to the guidance of computed tomography (CT) on the safety and technical easiness in the circumstance of a fractured pedicle, although active fluoroscopy is necessary to determine whether a cement leak has occurred.

## Materials and methods

### Patient population

Two hundred and fifty PVP were performed in our institution between December 2001 and August 2003 on 205 consecutive cases with thoracic and/or lumbar VCF because of osteoporosis. The total number of patients was 175, and 25 underwent PVP twice or more because of recurrent fractures. The patient population was composed of 150 women and 55 men [age range, 52–99 years; mean and standard deviation (SD), 77.9±8.5 years]. All patients were referred because their pain was resistant to conventional medical management, including bed-rest, analgesics and/or external bracing. The delay between fracture documentation and PVP was 1–255 days (mean and SD, 18.7±34.3 days). The distribution of vertebral levels was as follows: T5, 2; T6, 1; T7, 4; T8, 5; T9, 6; T10, 9; T11, 21; T12, 53; L1, 59; L2, 48; L3, 23; L4, 12; L5, 7 (Table 1). PVP was approved by our institutional review board, and informed consent was obtained from each patient after a detailed review of the potential risks and benefits of the procedure.

### Patient selection

Patient selection was limited to persons with focal, intense, deep pain associated with the evidence of plain X-ray films and magnetic resonance (MR) images, which were routinely taken prior to the procedure in all patients but one who was implanted with a cardiac pacemaker. In this case, a bone scan was performed to confirm a new vertebral fracture. The patients had demonstrated a less-than-satisfactory response to conservative therapy consisting of bed-rest, external bracing and/or analgesics for more than 1 week. In some cases, PVP was performed a few days after suffering the fractures because the intense pain was not reduced by the conservative therapy, and the patients could not tolerate it. The diagnosis of osteoporosis was made mainly by plain X-ray films and combined with the analysis of bone mineralization in some cases.

MR imaging criteria were to be acute or subacute compression fractures with a high signal band in a vertebral body on fat-suppressed, T2-weighted images (Fig. 1), which reflects bone edema, or chronic ones with osteonecrosis or a cavity secondary to pseudoarthrosis and with bone edema to some degree (Fig. 2). The posterior vertebral wall appeared intact in all cases.

**Table 1** Levels of fracture

Vertebral level	Number of fracture
T5	2
T6	1
T7	4
T8	5
T9	6
T10	9
T11	21
T12	53
L1	59
L2	48
L3	23
L4	12
L5	7
Total	250

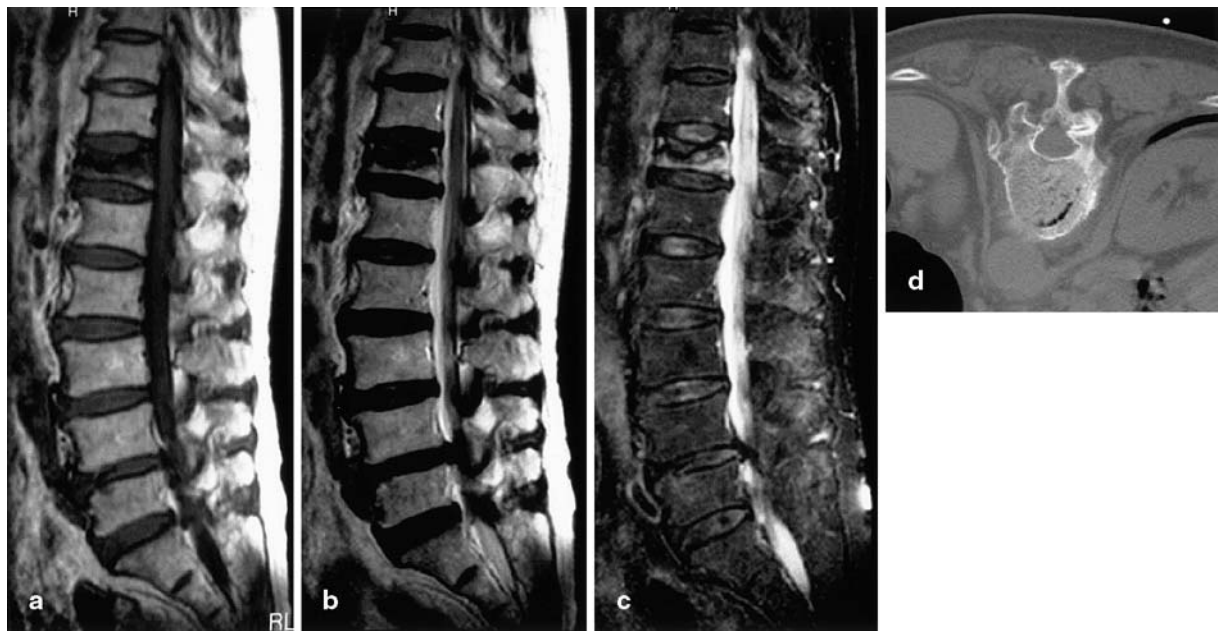
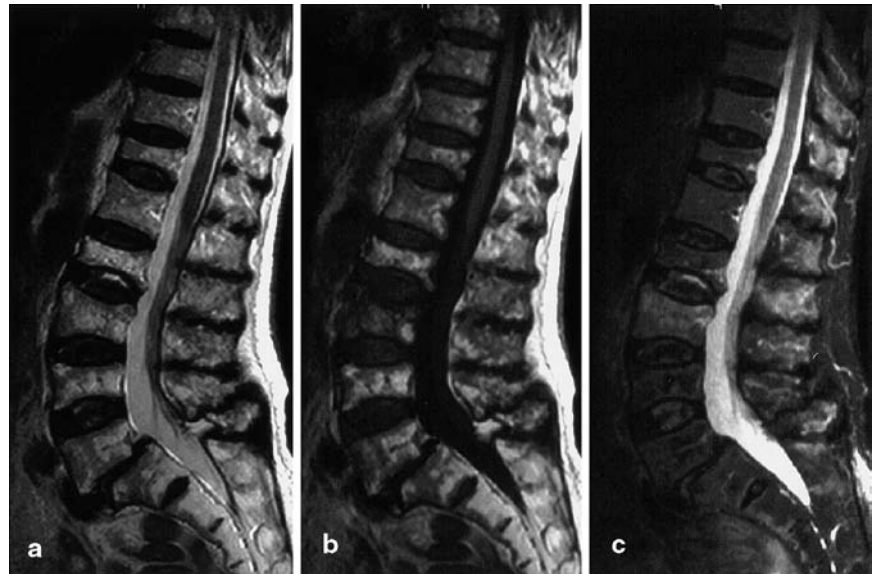
Often the accompanying radiating pain obscured the level of vertebral collapse on physical examination, and multiple preexisting compression fractures made it difficult to define the responsible vertebrae on plain X-ray films. Thus, MR imaging was useful in determining the appropriate site to be treated.

Exclusion criteria were bleeding disorders, systemic infection, lack of a definable level of vertebral collapse on physical and imaging examinations or a patient's disagreement with receiving PVP. Relative contraindications included the patient's inability to lie prone for about 1 h, which was required for the procedure, or neurological symptoms or signs because of compression from vertebral body collapse.

### PVP technique

All procedures were performed in a consistent manner at each site. After administration of analgesics in the form of a suppository (25-mg diclofenac sodium, Voltaren; Novartis Pharma, Tokyo, Japan) 30 min prior to the procedure, the patients were placed in a prone position on the CT table without fluoroscopic facility (HiSpeed Dx/i; GE Medical Systems, Milwaukee, WI) in sterile conditions. General anesthesia, sedation or prophylactic antibiotics were not used in each case. Cushions were placed under the patients' shoulders and waists so that the pain might be eased. Monitoring of heart rate and pulse oximetry was carried out continuously throughout the procedure. The blood pressure was monitored externally and recorded automatically at 3-min intervals. A single-plane mobile C-arm (Stenoscope; GE Medical Systems, Milwaukee, WI) was positioned in front of the CT gantry. The needle puncture was done using a unilateral, transpedicular approach under CT guidance, except in three cases using the bilateral approach. The treated vertebral body was localized with CT images, and the puncture point was determined by placing a radio-opaque marker on the skin overlying the responsible vertebra. The end point for needle placement was set within the anterior one-third of the vertebral body, close to the midline. After calculating the angle and depth for the presumed needle route, local anesthesia was fully administered using a 23-gauge, 6-cm long needle with 1% lidocaine. Leaving the needle used for local anesthesia inserted into the puncture site, a CT image was again obtained to check the angle and depth of the needle. Then, a small skin incision was made at the puncture site. According to the calculated angle and depth, a 13-gauge bone biopsy needle (Osteo-Site Bone biopsy needle; Cook, Bloomington, IN) was advanced half way to the cortex of the pedicle, its direction checked with CT, and then it was further advanced to the vertebral body with a slight twisting motion. If the needle was out of the presumed route, correction of the needle angle was made.

**Fig. 1** Sagittal MR images obtained in an 80-year-old woman. **a** T2-weighted image (WI), **b** T1WI and **c** fat-saturated T2WI. She was hospitalized for control of low back pain and immobilization secondary to a recent osteoporotic compression fracture of the L3 vertebral body. Plain films showed the fractures at multiple levels, and it was difficult to localize the level responsible for pain. T2WI demonstrated fractures at T12, L2, L3 and L4. MRI was helpful in identifying acute or subacute fracture, indicated by a low signal on T1WI with a corresponding high signal on fat-saturated T2WI at L3



**Fig. 2** Sagittal MR images obtained in a 74-year-old woman with continuous back pain. **a** T1-weighted image (WI), **b** T2WI and **c** fat-saturated T2WI. A low signal band was observed at T12 body in each MR image, corresponding to small gas in **d** CT image. Fat-suppressed T2WI demonstrated a high signal area around it, indicating that a pseudoarthrosis with vacuum cleft induced by osteo-necrosis (so-called Kummell disease) was acutely injured. PVP reduced the VAS score from 8 to 1, and made it possible to walk the next day

Verifying that the needle tip was within the proper position of the vertebral body using CT, the CT venogram was then obtained just after injection of 3 ml of contrast medium (iopamidol, Iopamiron 300; Schering, Berlin, Germany) through the needle to check for extravertebral leakage and/or drainage into perivertebral veins.

If direct communication of the needle tip with major venous outlets indicated by unopacification of intervening bone marrow was supposed, correct replacement of the needle was required. Therefore, the needle tip should be placed within the anterior one-third of the body. Intraosseous CT venography was also useful in determining the rate of the following bone cement injection. Usually, we injected the cement at the rate of 1.5–3.0 ml/min. When the venography revealed abundant paravertebral veins and/or leakage around the vertebral body, nevertheless the needle tip was in the proper position, and polymethylmethacrylate (PMMA) was injected more slowly than usual. Biopsy was not performed in each case.

We used PMMA cement (Surgical Simplex P; Howmedica, Rutherford, NJ) for vertebroplasty. After fully mixing the powder PMMA component and the liquid PMMA component at a 2:1 ratio, the mixture was divided into 1-ml syringes and cooled with cold water to avoid rapid polymerization of the mixture. There were nei-

ther antibiotics nor additives to increase radio opacity in the PMMA. Under continuous lateral fluoroscopic control using a single-plane, mobile, C-arm unit, the PMMA mixture was injected slowly, with particular attention to the region of the disc space, the vena cava and the epidural space, until the PMMA reached the posterior one-quarter of the vertebral body, or the PMMA leaked into the paravertebral tissue or the disc space.

Finally, CT was carried out in all cases to assess the extent of filling and to look for cement leaks, and then the procedure was completed.

A single pedicle approach was used in each case, but in three cases, the PMMA did not pass the midline of the vertebral body after the first injection; a second injection was done on the other side in the same manner. The second injection was done after having pulled the first needle in each case. A new needle was used for each pedicle.

The patients were placed in a supine position for 1 h after the procedures. They were permitted to stand and to walk a day after the procedure. They were recommended to resume normal daily activities as tolerated, but preferably to avoid lifting heavy objects.

#### Evaluation of the efficacy of PVP

We used a visual analog scale (VAS) with 11 levels ranging from 0 (no pain) to 10 (the strongest pain having ever been experienced) for clinical assessment. Each patient was prospectively asked to quantify his or her pain on a VAS before the treatment on the PVP day and a day after that by the same radiologists or nursing staff. Each patient was administered a separate sheet of VAS and evaluated the pain he or she felt most powerfully in an analgesic-free state. Delayed VAS score was not administered because the purpose of this study was to assess the immediate efficacy of PVP.

The efficacy was also evaluated retrospectively by comparing the intervals to mobilization in which the conservative therapy and PVP required in those who were immobilized because of pain and/or bed-rest therapy. The conservative therapy group was composed of 80 patients (male, 24; female, 56; mean age, 77.8 years) who were admitted to our hospital with vertebral fractures secondary to osteoporosis between December 1998 and November 2001, and they were treated only with the conservative therapy. Mobilization was determined with the patients' return to pre-fracture function.

The incidence of recurrent and new vertebral fractures after PVP was also evaluated. The patients who developed new back

pain during the follow-up period were brought back for MR imaging of the thoracic and lumbar spine. The new fractures were determined by the MR images and corresponding clinical findings.

#### Statistical analysis

Statistical analysis was performed by using the Wilcoxon signed rank test to assess the difference of mean VAS scores between pre- and post-procedure. The Mann-Whitney *U* test was used to compare the mean value of ambulation of the conservative therapy group with that of the PVP group. Differences were considered statistically significant at  $P < 0.05$ . All data were presented as mean  $\pm$  SD.

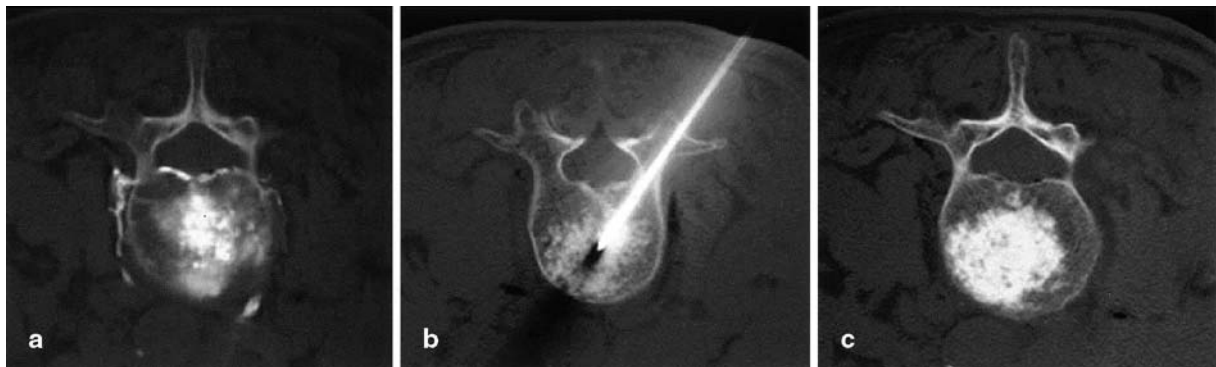
## Results

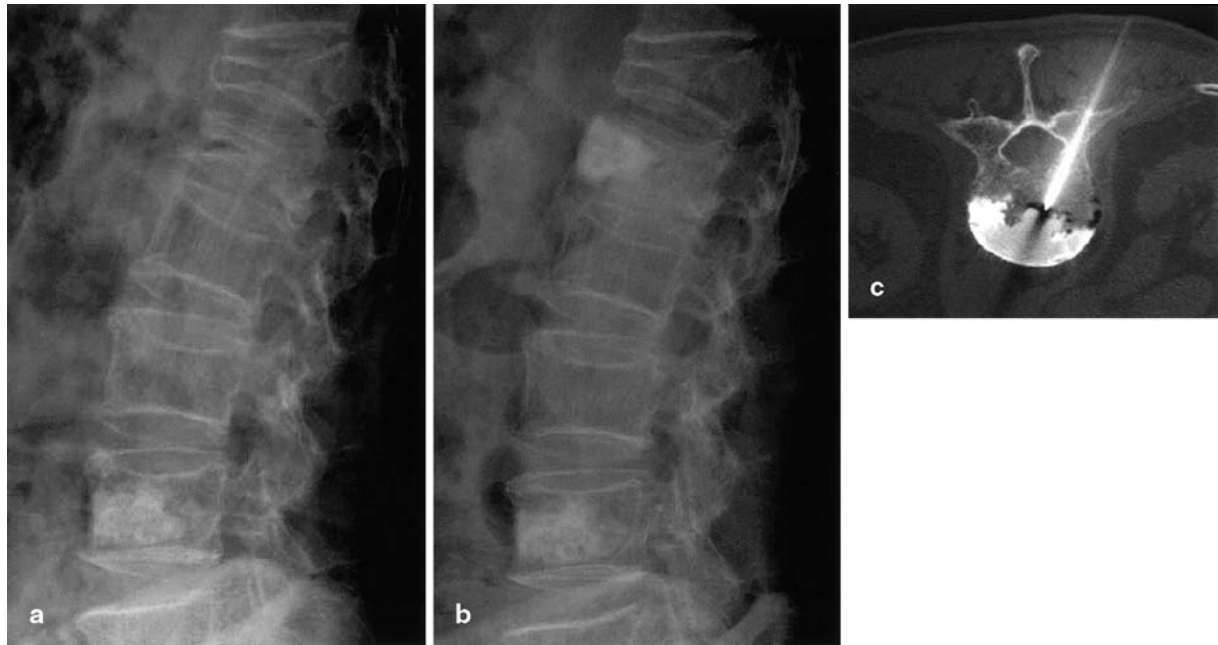
We were successful with the transpedicular approach in all cases. There was no exclusion because of technical difficulty, even in a case of severe vertebral collapse (Figs. 3, 4, 5). Paravertebral or costvertebral approaches were not necessary for optimal needle placement. The maximum number of levels treated in each session was three. The mean volume of PMMA injected in each vertebral body was  $3.9 \pm 1.0$  ml (range, 1.5–7.0 ml). The time required for the procedure of each vertebra was 30–40 min, and the total time for each case was 30–90 min.

Among the 205 patients treated, the VAS analysis was available for 196 cases, because nine patients found it difficult to understand this scaling system. As shown in Table 2, the mean VAS score for these 196 cases was  $7.22 \pm 1.89$  (range, 3–10) before PVP; however, it fell significantly to  $2.07 \pm 1.19$  (range, 0–10) a day after the procedure ( $P < 0.0001$ ). The pain was improved in 189 cases (96.4%) and disappeared completely in 44 of them. It did not change in six cases (3.1%) and increased in one case (0.5%) after PVP (Table 3). There was no case in which the dosage of analgesics was increased after PVP.

The mean value until ambulation of the conservative therapy group except for seven cases was  $23.9 \pm 27.5$  days (range, 1–175). The excluded seven cases (8.8%) became bed-ridden after suffering vertebral fractures. On the other hand, 115 cases in the PVP group became im-

**Fig. 3** A 69-year-old woman with acute multiple compression fractures. PVP was performed at L1, L2 and L4. **a** The intraosseous CT venogram showed abundant veins around L2 body. Therefore, we injected the cement more slowly than usual; the injection rate was 30 s/ml for first the 2 ml, then 50–60 s/ml for another 3 ml. **b, c** On CT scan after procedure, there was no cement leak, and the cement was distributed uniformly in the vertebral body

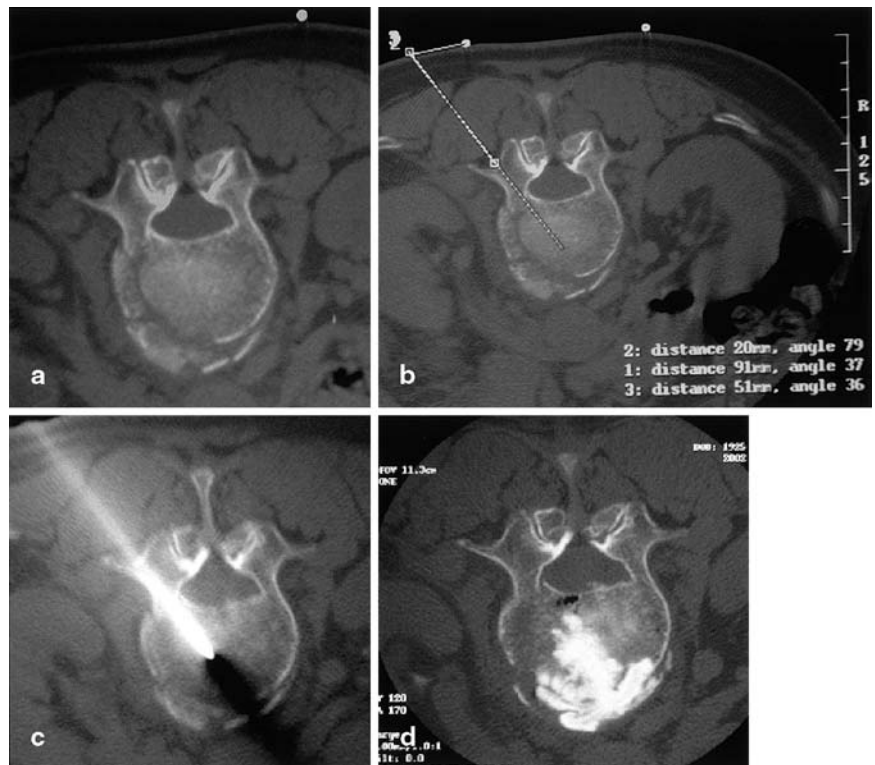




**Fig. 4** An 80-year-old man who had had PVP in the L4 body previously complained of continuous back pain with ineffective conservative therapy for 53 days. **a** The lateral radiograph showed a compression fracture with a vacuum cleft in the L1 body. The

VAS score was improved from 10 to 3 by injecting 5 ml of cement, and he could walk again the next day. **b** Lateral radiograph and **c** transverse axial CT after PVP showed distribution of the cement into the osteonecrotic area of the vertebral body

**Fig. 5** Axial CT obtained in a 77-year-old woman. **a** Pre-procedural CT showed a compression fracture of the L1 body, a fracture of the left pedicle and deformity of the right pedicle. **b** CT obtained to check the angle and depth. **c** CT demonstrated the needle through the left pedicle into the vertebral body. **d** CT after procedure showed the vertebral body filled with the cement. The pre-procedural VAS score was improved from 10 to 3, and she could walk again the next day after PVP



**Table 2** Pre-procedural and post-procedural VAS scores

VAS score	Number of cases	
	Pre-procedural	Post-procedural
10	30	1
9	19	1
8	46	3
7	37	1
6	16	6
5	35	15
4	7	10
3	6	26
2	0	38
1	0	51
0	0	44
Mean VAS $\pm$ SD	7.22 $\pm$ 1.89	2.07 $\pm$ 1.19*

\*  $P < 0.0001$  compared with pre-procedure (Wilcoxon signed rank test).

**Table 3** Evaluation of pain relief

Pain	No. of patients
Disappeared	44
Improved in some degree	145
No change	6
Increased	1
Total	196

mobilized because of fractures, and the mean value until ambulation was 1.9 $\pm$ 2.8 days after PVP ( $P < 0.0001$ ). All could walk again within 18 days after PVP (Table 4).

Three cases of minimal complications were observed including two cases of transient nausea immediately after the cement injection and one case of hematoma besides the treated vertebra. They required no medical treatment and improved with observation alone. Leakage of the bone cement outside the vertebral body was noted on post-procedural CT scan for 189 levels (75.6%). The site of the leakage was the epidural vein in 119 levels, the paravertebral vein in 42 levels, the paravertebral soft tissue in 23 levels and the adjacent disc in 73 levels. Despite the high incidence of leakage, no clinical symptoms were seen. No major complications such as pulmonary embolism, osteomyelitis or radicular neuritis were observed. There was no significant change in blood pressure, heart rate or blood oxygen saturation.

The recurrent and new fractures developed at 37 vertebrae in 32 of 205 cases during 4–25 months (mean 15.3 months) of the follow-up period. The recurrent fracture at the treated level occurred in one vertebra, and the new fractures at the different levels were at 36 vertebrae. Of 36 vertebrae, 21 were adjacent levels to the treated vertebrae.

**Table 4** The interval to mobilization in conservative therapy and PVP groups

Days	Number of cases	
	Conservative therapy group	PVP group
1	1	94
2	3	8
3	1	2
4	1	0
5	1	3
6–10	11	5
10–20	26	3
21–30	13	0
31<	16	0
Bedridden	7	0
Total	80	115
Mean $\pm$ SD (days)	23.9 $\pm$ 27.5	1.9 $\pm$ 2.8*

\*  $P < 0.0001$  compared with conventional therapy group (Mann-Whitney  $U$  test).

## Discussion

In this study, we clearly demonstrated that PVP has high efficacy in immediate pain relief. PVP is reported to reduce the pain of osteoporotic vertebral compression fracture in over 90% of patients [6, 10–15]. We also obtained a similar result (96.4% improvement rate) judging from the analysis of pre-procedural and post-procedural VAS scores and from the period until the resumption of ambulation. This effect was long lasting without a recurrence at the treated vertebra except in one case. Therefore, it has great potential to avoid various problems associated with prolonged bed-rest, including high medical expense, deterioration in osteopenia and function of the musculoskeletal system and progression of dementia in elderly patients. PVP also has benefits to prevent the development of delayed neural palsy and kyphosis induced by slowly progressing destruction of vertebrae without fundamental reinforcement. Persistent back pain may also cause psychological disorders such as sleep disorders or depression [16, 17]. Thus, PVP is likely to contribute to improving not only the quality of life of individual patients, but also the socioeconomic problems that VCF possess.

In Table 3, one case of “increased” and six cases of “no change” had radicular pain caused by degenerative spinal stenosis in addition to focal, deep pain related to the vertebral fractures (data not shown). After PVP, the pain from the vertebral fractures was reduced, however, the radicular pain was remained. Therefore, accompanying radicular pain caused by degenerative spinal stenosis is likely to predict the ineffective outcome of PVP, although PVP has the potential to relieve radicular pain from the fracture-induced vertebral instability.

In this study, the delayed VAS score was not administered. The pain at the puncture site continued for a few

days in some cases; thus, VAS scores would have improved further if VAS had been evaluated later.

One of the technical difficulties in this procedure is to position the needle tip in the proper area safely and surely. Generally, fluoroscopic guidance such as a single-plane C-arm unit or biplane fluoroscopy has been mainly used during needle insertion, and there are few reports on CT guidance [18, 19]. The use of CT was thought to be complex and costly. Moreover, routine CT examinations may have to be stopped during PVP in some institutions where a CT unit especially available for PVP is not installed. However, we took CT guidance in all cases because it had many advantages exceeding these disadvantages. As shown in this study, by taking CT images several times for making corrections of the needle position during PVP, we were able to minimize the complications associated with needle insertion into one case of paravertebral hematoma. The height loss of the vertebral body of more than 80% is generally considered to be one of the exclusion criteria because of technical reasons in some series [20]. In such a case, CT guidance was also useful in advancing the needle into a severely collapsed vertebral body accurately and safely as shown in Fig. 5. Therefore, if the possible route for advancing the needle is found on CT images, even a case of severely destroyed vertebra can become an indication for PVP.

A great portion of complications is associated with the needle insertion or with PMMA injection, and the incidence is believed to be 10% or less [6, 14, 21, 22]. There are many reports pointing out the adverse effect of PMMA on the cardiovascular and/or respiratory system in total hip arthroplasty [23–27], while Kaufmann et al. demonstrated no association between PMMA injection and systemic cardiovascular derangement in PVP [28]. Actually, we did not notice any significant change in blood pressure, heart rate or blood oxygen saturation during and after PVP. This difference may be partly due to the difference in the quantity of PMMA used between PVP and hip arthroplasty. Furthermore, we used a smaller quantity of PMMA (1.5–7.0 ml, average 3.9 ml per vertebra) than that reported in the literature [6, 12, 18, 29]. However, that did not change the efficacy of PVP as shown in this study. Uniform distribution of PMMA in a vertebral body is likely to be important to fix an unstable vertebra rather than

the quantity of PMMA. Partial distribution could induce a fracture at the treated vertebra, as seen in our study. From this point of view, the utilization of CT is also helpful in checking the distribution.

The other problem associated with PMMA injection is extravertebral cement leakage, the incidence of which has been reported to be 11–72.5% with CT or plain X-ray films [10, 13, 19, 29–33]. We checked the leakage using post-procedural CT, which detected even a very small quantity leakage, resulting in the high incidence (76.1%). Although we did not observe the leakage-associated complications such as myelopathy, radiculopathy or pulmonary embolism, special care should be taken to minimize the cement leakage by reducing the quantity of PMMA and/or its injection speed. To minimize the cement leakage, a bi-plane C-arm unit or CT fluoroscopy should be used while PMMA is injected. However, in case these are not available, a lateral fluoroscopic image is thought to be sufficient to check the leakage because the cement leakage to the lateral side of the vertebral body does not become a significant problem.

There has been some controversy about the potential risk of a new vertebral fracture adjacent to a cemented vertebra. Grados et al. showed a slight but significant increased risk of vertebral fracture in the vicinity of a cemented vertebra, compared with that in the vicinity of uncemented fractured vertebra (odds ratio 2.27 vs. 1.44) [11]. This phenomenon might occur by shifting the normal load transmission through the spine. We observed a similar incidence (12.4%) to that reported by Uppin et al. after PVP [34], whereas Lindsay et al. observed that women who developed a vertebral fracture have a risk for additional fracture within the next year of 19.2% [35]. Therefore, PVP may not necessarily increase the incidence of a new vertebral fracture. In the future, a more physiological substance capable of inducing bone induction and/or formation could be substituted for PMMA.

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