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The safety and efficacy of percutaneous vertebroplasty for patients over 90 years old

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Abstract

Objective To retrospectively analyze the safety and efficacy of percutaneous vertebroplasty (PVP) for patients aged 90 or over.

Materials and methods We analyzed 130 consecutive patients with osteoporotic vertebral fractures who underwent a first-time PVP between May 2015 and September 2017 at our institution. We divided them into the elder patient group aged 90 years or over ($n=21$) and the younger patient group under 90 years ($n=109$). We compared the two groups' background, treatments, and outcomes using univariate analyzes and the log rank test.

Results A significant difference was observed in dementia (19% in the younger group vs. 48% in the elder group, $p < 0.01$). No significant difference was revealed in the procedure time or the rate of complications. The post-PVP mobility function and the pain level were significantly improved compared to before PVP in both groups ($p < 0.01$ each). No significant differences were observed between the two groups in the recurrence of vertebral fracture after treatment (17% vs. 14%) or the 1-year survival rate (79% vs. 86%), respectively.

Conclusion The results of our analyzes suggested that a PVP can safely and effectively contribute to pain relief as well as the restoration of ambulation for patients aged 90 or over.

Keywords Vertebroplasty · Elderly patient · Decubitus position · Prophylactic treatment

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Introduction

Immobilization, which indicates an individual's impaired status that requires continued lying in bed or using a wheelchair for locomotion [1], has a major adverse effect not only on the individual's quality of life (QOL), but also on society, as the proportions of elderly populations worldwide are rapidly increasing. The independent risk factors for immobilization are advanced age, the presence of bone fractures, pain, and dementia [1]. Many of these risks are present in elderly people with symptomatic vertebral fractures.

Conservative treatment is usually administered for patients with symptomatic vertebral fractures in the acute phase. Full recovery often requires 3 months or more [2]. These patients have difficulty becoming or remaining mobile, and they need care from family members or healthcare professionals during the recovery period. Moreover, approximately 10% of vertebral fractures are still unhealed even after 6 months, and the unhealed status may cause continuous pain and reduced mobility [2]. Elderly patients with vertebral fractures are often advised to leave

their beds as soon as safely possible to prevent sequelae. A percutaneous vertebroplasty (PVP) may prevent the immobilization of elderly patients and help reduce the social costs of caring for bedridden elderly patients.

The effectiveness of PVPs for the pain relief of patients with symptomatic osteoporotic vertebral fractures has been examined; two randomized sham-controlled trials indicated that PVP was not effective for osteoporotic painful vertebral fractures [3, 4]. However, in those trials, early intervention was not assessed as a primary outcome, and the question of whether the stability of the vertebral body was obtained by a relatively small amount of bone cement injection was not addressed [5].

The latest randomized trial showed a significant improvement in the numeric rating scaling (NRS) scores in the PVP treatment group [6]. The authors of that study defined the PVP procedure more strictly and focused on acute-stage patients within 6 weeks after fracture onset. Thus, the appropriate case selection and procedures are important in studies of PVP. A recent meta-analysis showed that PVP provided better pain relief as well as daily functional improvement than before [7].

Although the minimal invasiveness of PVP is widely known, the safety and efficacy of PVP for very elderly patients, i.e., those aged 90 years or over, have not been established. If patients in their 90s can be included in the indication criteria of PVP, almost all patients with vertebral fractures could be treated with a PVP, and this procedure could become a treatment option for regaining QOL lessened by symptomatic vertebral fractures even among the very elderly. We conducted the present study to retrospectively analyze the safety and efficacy of PVP for patients aged 90 or over.

Materials and methods

Study design

We performed the current retrospective investigation to clarify the safety and efficacy of PVP in patients with age of 90 years or older with symptomatic osteoporotic vertebral fractures compared with patients under 90 years. The patient series was drawn from a single hospital. This study was approved by our hospital's institutional review board, which waived the need for written informed consent from the patients in light of the retrospective study design.

Patients

Between May 2015 and September 2017 at our hospital, 252 patients including 29 patients aged 90 or over were revealed to have unhealed thoracic or lumbar vertebral fractures on spine CT or MRI. Of those, a PVP was performed for 145 patients, whose preoperative status met the following eligibility criteria: they had (1) one or more unhealed vertebral fractures in the 6th thoracic to 5th lumbar vertebra, (2) severe back pain or a remarkable decrease in activities of daily living (ADLs) due to the vertebral fracture, (3) no active infection, (4) no bleeding diatheses, and (5) they requested a PVP. Of those 145 patients, we enrolled the 130 patients who met the following criteria: (1) they had undergone a first-time PVP treatment and (2) their vertebral fractures were not caused by a neoplasm. We divided the 130 patients into the elder patient group with aged 90 years or older ($n = 21$) and the younger patient group with less than 90 years ($n = 109$) (Table 1).

Intervention

All procedures were performed in our hospital's angiographic examination room by two or more radiologists including at least one special interventional radiologist who was certified by the member boards of Japanese Society of Interventional Radiology (1–10-year experience performing PVPs) using biplane fluoroscopic angiography equipment (Axiom Artis dBA; Siemens Healthcare GmbH, Erlangen, Germany) and interventional computed tomography (IVR-CT) (SOMATOM, Sensation, OPEN; Siemens Healthcare GmbH, Erlangen, Germany). Under biplane fluoroscopic

Table 1 Patient demographics

Item	Younger group	Elder group	p value
No. of pts.	109	21	
Median age (range) (years)	79 (46–89)	91 (90–97)	< 0.001
Sex (male/female)	39/70	8/13	0.839
Multiple unhealed fractures [no. and (%) of pts.]	36 (33%)	8(38%)	0.653
Dementia [no. and (%) of pts.]	21 (19%)	10 (48%)	0.005
Period between onset and PVP (days)	19 (1–2208)	12 (5–1103)	0.259
Traumatic episode [no. and (%) of Pts.]	54 (50%)	13 (62%)	0.299
History of steroid treatment [no. and (%) of pts.]	25 (23%)	2 (10%)	0.134
Lumbar spine BMD as %YAM (mean ±SD)	75.7 ± 18.8	77.5 ± 17.3	0.690
Prevalent vertebral fractures [no. and (%) of pts.]	24 (22%)	4 (19%)	0.510

No. number, *Pts.* patients, *BMD* bone mineral density, *%YAM* a percentage of the young adult mean

guidance, 11- or 13-gage bone biopsy needles (Osteo-Site Bone Biopsy Needle Set; Cook Medical, Bloomington, IN) were inserted into the vertebral body using a transpedicular approach. Cone beam CT or IVR-CT was first performed to implement the puncture planning and secondarily to affirm the pathway of the bone biopsy needles after puncturing. Bone cement (VertaPlex Bone Cement; Stryker, Mahwah, NJ) was slowly injected into the vertebra using a bone cement injector (PCD System; Stryker) under continuous fluoroscopy. The endpoint of injection was determined when the bone cement adequately diffused in the vertebra, leaked into the extravertebral structures, or migrated into the veins. The total maximum dose of the bone cement per patient was limited to 13 mL, which was the dose contained in one set of the bone cement product. Prophylactic augmentation of the adjacent normal vertebra [8, 9] was performed if the patient had (1) a vertebral fracture that was not fall-or trauma-related (2) a likelihood of a mass-like accumulation of bone cement in the vertebra or (3) a concomitant old compression fracture in another vertebra [10–12]. The targeting of prophylactic PVP was also restricted to the following vertebrae: (4) normal adjacent vertebrae on the level from the tenth thoracic to the third lumbar spine or (5) normal vertebrae between a pre-existing vertebral fracture and the current fractured vertebra or between two current fractured vertebrae that were scheduled to undergo a therapeutic PVP. The most important principle was (6) the renunciation was considered at any time if it might be difficult. After PVP, the distribution of the bone cement was assessed on IVR-CT and the patient was then held in a supine or lateral decubitus position for 120 min in the patient's hospital bedroom.

Clinical outcome assessment

Each of the patients assessed his or her back pain by providing a numeric rating scale (NRS) score of 0 to 10 with 0 indicating no pain and 10 indicating the maximum imaginable pain. We determined the patients' mobility ADL scores using the following scale of 0–4 points, as a modification of Yokoyama's ADL scores [9, 13]: 0 points = complete independence; 1 point = light assistance, able to walk with a walking aid; 2 points = moderate assistance, needing a wheel chair for locomotion; 3 points = major assistance, mostly staying in bed and being able to sit upright at 60°–90°; and 4 points = total assistance needed, mostly staying in a bedridden state and able to sit upright at less than 60°. The patients' change scores in analgesic use were determined using the following scale of 0–3 points: 0 points = no analgesic use before and after treatment; 1 point = reduction of analgesic dose after treatment; 2 points = no change in analgesic or a change to another analgesic after treatment; and 3 points = increased analgesic dose after treatment. The patients' pain NRS scores were estimated as: (1) the number

of points at 1 day before PVP and (2) the points at 7-day post-PVP. The patients' mobility ADL scores were estimated as: (1) the number of points before onset; (2) the points at 1 day before PVP; and (3) the points at 7-day post-PVP. The patients' change scores in analgesic use were estimated with 1 day before PVP and 7-day post-PVP. If there were any lost or missing scores at 7-day post-PVP, we used the points nearest to that date. We also assessed post-PVP complications and adverse events among the patients. All data were identified using our institution's hospital information system.

Data analyzes

We assessed the difference in the procedural success rate of PVP procedures between the younger and elder groups as the study's primary endpoint. Procedural success was defined by a completed and proper injection of the bone cement into the vertebrae that were scheduled to undergo PVP. We also made intergroup comparisons of the following items: patient age, sex, history of steroid treatment, dementia, the period between fracture onset and PVP, traumatic episodes, the number of unhealed vertebral fractures, the lumbar spine bone mineral density (BMD) as a percentage of the young adult mean (%YAM), and prevalent vertebral fractures as background items; the patient's position while undergoing the procedure, prophylactic augmentation, procedure time, fluoroscopic exposure time, total fluoroscopic exposure dose, fluoroscopic exposure dose of cone beam CT, number of treated vertebra, and volume of cement as parameters of the PVP procedure.

Regarding adverse events, we compared the groups' incidence of puncturing through the spinal canal, cement leakage both of which were evaluated on cone beam CT or IVR-CT, neuropathy, pulmonary embolization which was confirmed on additional chest IVR-CT after the PVP when the bone cement leaked through paravertebral veins as shown by intraoperative fluoroscopy, and cardiac dysfunction. We compared the groups' pain NRS scores, mobility ADL scores, discharge to home or not, vertebral refractures confirmed on follow-up CT or MRI after a PVP performed depending on the patients' symptoms, and the survival rate in the post-PVP course. In regard to the change scores in analgesic use, the patients with point 0 were excluded, because they did not use the analgesic. Of residual patients, the rate of patients with point 1 was compared between the two groups.

We also made intragroup comparisons of pain NRS scores and mobility ADL scores in each of the patient groups to determine the degree of improvement after PVP procedures: (1) an intragroup comparison of NRS scores at 1 day before PVP with that of at 7-day post-PVP and (2) an intragroup comparison of ADL scores before onset, at 1 day before PVP, and at 7-day post-PVP.

The statistical analyzes were performed using the free software R version 3.4.3 (https://www.cran.r-project.org/). Some non-continuous data were expressed as the mean ± standard deviation (SD) of the mean in the tables when this format seemed more comprehensible than the median and range. Univariate analyzes were performed using Student's *t* test, Mann–Whitney *U* test, Chi-square test, Fisher's probability exact test, or Wilcoxon signed-rank test. The survival rates of both groups in which patients were followed up for more than 3 months were plotted using Kaplan–Meier method and compared using the log rank test. Particularly, the 1-year survival rate between the two groups was evaluated using Fisher's probability exact test.

The level of significance was set at $p < 0.05$ for all tests.

Results

Background characteristics

Table 1 summarizes the background characteristics of the patients in the younger and elderly groups. The age range, average, and median were 46–89, 77.7, and 79 years in the younger group, and 90–97, 91.9, and 91 years in the elder group, respectively. A significant difference was observed in the rate of dementia (19% and 48% in the younger and elder groups, respectively, $p < 0.01$), but not in the periods between the fracture onset and PVP [the median days

(range), 19 (1–2208), and 12 (5–1103)], the presence of a traumatic episode (50% and 62%), history of steroid treatment (23% and 10%), or the presence of prevalent vertebral fractures (22% and 19%). The between-group difference in the lumbar spine BMD as %YAM, which was available with 104 patients in the younger group and 20 in elder group, was also not significant (76% and 78%).

PVP procedures and complications

The procedural success rate as the primary point was 100% in both groups (Table 2). In the comparison of the younger and elder groups, a significant difference was seen in the rate of prophylactic augmentation (49% and 14%, $p < 0.01$), the total fluoroscopic exposure dose (1156 mGy and 990 mGy), the number of treated vertebra (2.2 and 1.5, $p < 0.05$), and the volume of bone cement (5.2 mL and 4.3 mL, $p < 0.05$), but not in the procedure time (89 min and 77 min), or fluoroscopic exposure time (32 min and 30 min), respectively. The fluoroscopic exposure dose of cone beam CT was available with 103 patients in the younger group and 20 in elder group were also not significant (358 mGy and 312 mGy).

Regarding the occurrence of major complications, as shown in Table 3, no significant difference was observed between the younger and elder groups in the rate of the pulmonary emboli (1% and 10%), the transient cardiac dysfunction (4% and 0%), or puncturing through the spinal

Table 2 PVP procedure data

Item	Younger group	Elder group	*p* value
Procedural success rate (%)	100%	100%	> 0.999
Lateral decubitus position [no. and (%) of pts.]	6 (6%)	2 (10%)	0.880
Prophylactic augmentation [no. and (%) of pts.]	53 (49%)	3 (14%)	0.003
Procedure time (min; mean ±SD)	89 ± 30	77 ± 24	0.087
Fluoroscopic exposure time (min; mean ±SD)	32 ± 12	30 ± 10	0.635
Total fluoroscopic exposure dose (mGy; mean ±SD)	1156 ± 462	990 ± 535	0.031
Fluoroscopic exposure dose of cone beam CT (mGy; mean ±SD)	358 ± 177	312 ± 171	0.064
No. of unhealed fractures (mean ±SD)	1.5 ± 0.8	1.5 ± 0.7	0.767
No. of treated vertebra (mean ±SD)	2.2 ± 1.1	1.5 ± 0.7	0.015
Volume of bone cement (mL)	5.2 ± 2.1	4.3 ± 1.9	0.038

No. number, *Pts.* patients, *SD* standard deviation

Table 3 Complication data during PVP procedure

Item	Younger group	Elder group	*p* value
Puncturing through spinal canal [no. and (%) of punctures]	10 (3%)	3 (5%)	0.313
Bone cement leakage [no. and (%) of pts.]	82 (75%)	16 (76%)	0.925
Neuropathy	0 (0.0%)	0 (0.0%)	> 0.999
Pulmonary embolism [no. and (%) of pts.]	1 (1%)	2 (10%)	0.067
Transient cardiac dysfunction [no. and (%) of pts.]	4 (4%)	0 (0%)	0.489

No. number, *pts.* patients, *SD* standard deviation

canal (3% and 5%), respectively. None of these complications needed any additional treatment. No spinal cord injury occurred in either group.

Pain NRS, mobility ADL scores, and change score in analgesic use

As summarized in Table 4, the pain NRS scores for two patients in the younger group and three patients in the elder group failed to be recorded, but mobility ADL scores were identified in all patients. Although the pain NRS scores showed no significant difference between the younger and elder groups, the mobility ADL scores of the elder group at all timepoints were significantly advanced compared to those in the younger group ($p < 0.01$). However, both the pain NRS and mobility ADL scores were significantly improved after PVP compared with those before PVP in each of the younger and elder groups ($p < 0.01$ each). Regarding the change scores in analgesic use, 20 patients in the younger group and one in the elder group, who had point 0, were excluded. Of residual patients, no significant difference in the rate of patients with point 1 was observed between the two groups at 21% and 40%, respectively.

Courses after PVP and survival rate

The rate of discharge to home in the elder group was significantly lower than that in the younger group (65% and 10%, respectively; Table 5). Four patients in the younger group patient and no patients in the elder group patient were lost to follow-up within 3 months. The follow-up period for the other patients ranged from 29 days to 38 months. 78 patients in the younger group and 14 patients in the elder group were followed at least 1 year. The recurrence of vertebral fractures by 1 year after PVP was not significantly different between the younger and elder groups at 17% and 14%, respectively.

Sixteen of 19 patients in the younger group (three with lung cancer, three with sigmoid colon cancer, three with unknown cause, two with lymphoma, and one each with a ruptured brain aneurysm, primary amyloidosis, pyothorax, respiratory failure, chronic heart failure, suffocation, pneumonia, and hypertrophic cardiomyopathy) and two of four patients in the elder group (two with decrepitude, one each with infectious pneumonia, and cerebral hemorrhage) died within 1 year after PVP treatment. As illustrated in Fig. 1, no significant difference in the survival rate was observed between the two groups (79% vs. 86% of 1-year survival rate, respectively).

Discussion

This study is the first to examine in detail PVP-treated patients in their 90s; to the best of our knowledge, no other studies have clarified the safety and efficacy of PVP for very elderly patients. There are a few studies that included patients over the age of 90 [14–16], but PVP is generally not used for very elderly patients at present. Although elderly patients with vertebral fractures are expected to recover with conservative treatment, some of them may suffer from immobilization, because many such elderly patients have almost all of the risk factors of immobilization including advanced age, the presence of bone fractures, pain, and dementia [1]. The early intervention of PVP for osteoporotic vertebral fractures shortens the period of ADL recovery and enhances pain relief [9]. Our present analyzes demonstrated that PVP can be effective and safe even for patients at advanced ages if their ADL levels before onset were basically independent or in need of minimal assistance. Even among elderly patients who are dependent on others for their ADLs, PVP could contribute to their pain relief. Our study shows the grounds to

Table 4 Data of pain NRS, mobility ADL scores, and change score in analgesic use

Item	Younger group	Elder group	p value
Pain NRS score			
Score at one day before PVP (mean±SD)	6.2±3.1	6.9±2.6	0.438
Score at 7th day after PVP (mean±SD)	2.2±2.3 (<0.001)	2.2±2.3 (<0.001)	0.682
Mobility ADL score			
Score before onset (mean±SD)	0.4±0.6	1±1.2	0.001
Score at one day before PVP (mean±SD)	2.7±1.4	3.3±1	0.007
Score at 7th day after PVP (mean±SD)	1.3±1 (<0.001)	2.1±1 (0.003)	0.001
Change score in analgesic use (No. of Pts with 1 to 3 points)	22/57/10	8/11/1	0.166

No. number, *pts.* patients, *SD* standard deviation

Table 5 Courses after PVP

Item	Younger group	Elder group	p value
Discharge to home [no. and (%) of pts.]	71 (65%)	2 (10%)	< 0.001
1-year recurrence of vertebral fracture [no. and (%) of pts.]	8/62 (13%)	2/12 (17%)	0.511
1-year survival [no. and (%) of pts.]	62/78 (79%)	12/14 (86%)	0.452

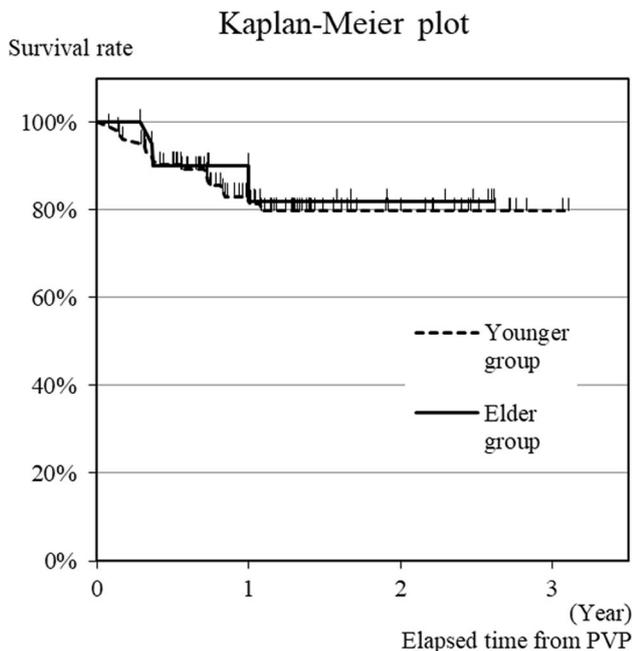*No.* number, *pts.* patients, *SD* standard deviation

Fig. 1 Survival rates of the younger and elder groups. Eighteen of the 92 patients (19.6%) who were followed up for 1 year after PVP treatment died of causes other than vertebral fractures or PVP

help determine the management of elderly patients aged 90 or over, which is a major concern in aging societies. Although balloon kyphoplasty (BKP) and vertebroplasty had similar long-term improvement in pain and disability with similar safety profiles and few device-related complications [17], the disadvantage of BKP is to be performed for patients with painful vertebral fractures after conservative management for at least 4–8 weeks [18], during which elderly patients are at risk of becoming bedridden. The general anesthesia during the operation is another disadvantage of BKP, because patients aged 90 or over tend to have comorbidities or other past histories.

The frequency of dementia was significantly higher in the present study's elder group, which might be a natural course, since the greatest risk factor of dementia is aging [19]. A PVP in the lateral decubitus position was carried out for the patients who had difficulty maintaining the prone position. However, our analyzes indicated that the contribution of dementia or the patient's position during PVP to the procedure's success rate was negligible.

The procedural success rate was 100% in both groups. Major complications were pulmonary embolization, cement leakage without any clinical symptoms, puncturing through the spinal canal, and transient cardiac dysfunction. The patients who experienced these complications were all asymptomatic at the completion of PVP and did not need any additional treatments afterwards, and no serious sequelae occurred. No considerable problems such as spinal cord or nerve root compression were observed, and thus, the strategy of minimal leakage as the treatment endpoint might be acceptable.

The performance of an intraoperative CT examination in our patient series, which was more accurate than fluoroscopy, revealed the precise course of puncture routes, and it demonstrated the occurrence of puncturing through the spinal canal. This adverse event is suspected to be due to causes such as the patient's movement, indistinctive visibility due to osteoporosis on fluoroscopy, and inexperience of the operator. The rate of puncturing through the spinal canal was slightly higher in our elder group, but there was no significant between-group difference. Our data would be of value for reviewing the procedural quality and attributing to the future improvement. Meanwhile, although the X-ray use depends on operators' requirement, the optimal radiation dose has not been discussed before, and our data would be valuable for its issue. The total fluoroscopic exposure dose in the younger group was significantly larger than that in the elder group without the more prolonged exposure time. This might be due to the difference of the body size and physical characteristics between them. Accordingly, the careful investigation should be performed when the optimal exposure doses are determined. Or, the fluoroscopic exposure time instead of the exposure dose might be usable for a surrogate indicator.

All instances of cardiac dysfunction in our series were transient, and they might have been the vagal reflex due to pain from the needle puncture and not pain from the bone cement injection. There was no tendency of transient cardiac dysfunction occurring in the elder group.

The treatment time was significantly shorter in the elder group. This result was greatly affected by the difference in the number of punctures. Although there was little difference in the number of unhealed vertebral fractures, the number of punctures was significantly larger in the younger group. The reason for this might be that the operator selected the

unilateral or bilateral approach for vertebra and tended to choose a lesser number of punctures for the more elderly patients.

In our study, the 1-year recurrence rate of vertebral fracture was almost the same in the two groups, although the rate of prophylactic PVP was higher in the younger group than the elder group. This might be because the younger group had a better recovery of mobility function and, earlier expose to a burden on the spinal vertebrae, and therefore, a higher risk for refractures than the elder group compared to the elder patients. However, the effect of prophylactic PVP is still unclear and further investigation is needed.

Our elder group had significantly more advanced mobilityADL scores compared to the younger group at all time-points. This suggests that the elder group, having declined ADL states before the fracture onset, might show a less remarkable recovery in mobility function even after PVP compared to the younger group. However, our intragroup comparisons clarified that the patients in both groups achieved significant improvement in pain relief and mobility restoration after PVP. Previous studies have not concluded whether PVP contributed to an improvement in patients' mobility functions [3, 4]. This discrepancy might be due to the differences in assessment methods among studies. We used a mobility ADL scoring system which was specific to ambulation ability [9, 13], whereas the prior studies used major QOL assessment tests such as Quality-of-Life questionnaire, European Quality-of-Life scale, Roland Morris Disability Questionnaire, or Oswestry Disability Index, all of which include eating, dressing, moving, toileting, grooming, and bathing in addition to low back pain and were thus not specific to ambulation ability [3, 20, 21]. Although the above-named tests have been confirmed as valid for various QOL evaluation studies, they usually show a non-specific score, because the scores of the question items are averaged; in addition, in those earlier investigations, it was difficult to determine specific pathological conditions such as ambulation ability, although the pathological condition of a patient is an essential factor in acute vertebral fractures [9].

We observed that the ratio of discharge to home was significantly inferior in the elder group. This may be due in part to social factors. There was no significant difference in the survival rate or the fracture recurrence after PVP between our two age groups. Even in terms of prognosis, it might thus be reasonable to consider a PVP for fracture patients in their 90s.

Our present findings clarified two points. First, there are more than a few patients over the age of 90 who require a PVP. Second, in light of our 100% success rate, such very elderly patients could undergo a PVP and achieve therapeutic effects similar to those of patients less than 90 years.

The limitations of our investigation are its retrospective nature, the relatively small number of patients in both groups, the lack of an objective evaluation of pain relief, and the detailed examination of mobility improvement and pain evaluation only up to 7-day post-PVP. In addition, the current retrospective series might have involved a selection bias. A prospective investigation with a larger number of patients and long-term follow-up should be conducted to test our findings.

Conclusion

The results of our analyzes suggested that a PVP can safely and effectively contribute to pain relief as well as the restoration of ambulation for patients aged 90 or over.

Compliance with ethical standards

Conflict of interest We wish to confirm that there are no known conflicts of interest associated with this publication, and there has been no significant financial support for this work that could have influenced its outcome.

Ethical statement This study was approved by our hospital's institutional review board, which waived the need for written informed consent from the patients in light of the retrospective study design.

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