Percutaneous Vertebroplasty for Acute Osteoporotic Vertebral Fracture Contributes to Restoration of Ambulation

Yoshitaka Shida\textsuperscript{1)}, Tomoyuki Noguchi\textsuperscript{1)}, Takashi Okafuji\textsuperscript{1)}, Kanako Murakami\textsuperscript{1)}, Tomotaka Iraha\textsuperscript{1)}, Kota Yokoyama\textsuperscript{1)}, Tsuyoshi Tajima\textsuperscript{1)}

Abstract

Purpose: To retrospectively determine the effectiveness of percutaneous vertebroplasty (PVP) for patients with ambulation difficulties due to acute osteoporotic vertebral fractures.

Materials and Methods: We enrolled 62 patients who met the following criteria: almost normal ambulation before osteoporotic vertebral fracture, ambulation difficulties after onset, and a first-time PVP performed within 4 weeks. The patients were divided into Earlier (n = 46) or Later groups (n = 16) in which patients underwent PVP within 2 weeks or later, respectively. Mobility scores 7 days post-PVP in the Earlier group were compared with those 1 day before PVP in the Later group, that is, the conservatively waiting state. Earlier group values were also compared with those at 7 days post-PVP in the Later group to estimate the effectiveness of later PVP.

Results: Mobility scores at 7 days post-PVP in Earlier group were significantly better than those 1 day before PVP in the Later group, suggesting that PVP provided mobility improvements sooner than the conservatively waiting state. Meanwhile, the lack of a difference in mobility scores at 7 days post-PVP between the Earlier and Later groups indicated that later PVP provided improvement comparable to earlier PVP.

Conclusion: Earlier PVP contributes to earlier recovery from ambulation difficulties due to acute osteoporotic vertebral fractures than later PVP, while earlier and later PVP show equivalent efficacy in restoration of ambulation.

Key words: vertebroplasty, acute compression fracture, osteoporosis, ambulation

INTRODUCTION

Two previous randomized control trials demonstrated that percutaneous vertebroplasty (PVP) was comparable to the sham study for osteoporotic vertebral fractures regarding pain relief and quality of life (QOL) improvement at 3 months post-PVP with the high evidence levels\cite{1, 2}. These results suggest that although there is no broad indication for PVP among patients with osteoporotic vertebral fractures, patients who are appropriate candidates for PVP should be selected based on a more precise therapeutic policy for PVP. On the other hand, Clark et al proved the safety and efficacy of vertebroplasty for acute painful osteoporotic fractures in a randomized control study\cite{3}. They recruited patients with one or two osteoporotic vertebral fractures of <6 weeks’ duration and Numeric Rated Scale (NRS) back pain $\geq$ 7 of 10.

However, patients with acute vertebral fractures develop back pain and often experience locomotion disability. Rather, prolonged bed rest due to vertebral fracture requires monitoring because the bedridden state sometimes cause serious secondary disorders such as aspiration pneumonia, pulmonary thromboembolism, or disuse syndrome\cite{4}. We
speculated that the use of PVP might help avoid such diseases after osteoporotic vertebral fractures by facilitating an early recovery from back pain or ambulation difficulty[3, 5-10]. In the present study, we retrospectively investigated the effectiveness of PVP for patients who had difficulty walking due to acute osteoporotic vertebral fractures, and our analysis revealed that early treatment with PVP expedited the patients’ recovery of ambulation, which is of clinical importance.

**METHODS**

1. Study Design

We performed this retrospective analysis to determine the effectiveness of PVP in patients with walking difficulties due to acute osteoporotic vertebral fractures. 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.

2. Patients

A total of 139 consecutive patients who were diagnosed with vertebral fractures and treated with PVP between June 2013 and the end of July 2016 at our hospital underwent PVP. We enrolled the 62 patients who met the following criteria: (1) almost-normal ambulation before the onset of an osteoporotic vertebral fracture (their mobility scores, which are described later in the outcome assessment section, were estimated as 0 or 1 point), (2) inability to ambulate on admission (mobility scores were estimated as 2, 3, or 4 points), and (3) a first-time PVP treatment performed within 4 weeks after the fracture onset. We excluded patients with vertebral fractures with non-osteoporotic causes, with an unclear onset date, or who frequently used a wheelchair before onset. We divided the 62 patients into Earlier and Later groups in which patients underwent PVP within 2 weeks (n = 46) or later (n = 16) after fracture onset, respectively[8, 9].

3. Intervention

All procedures were performed in our hospital’s angiographic examination room by experienced interventional radiologists. Under biplane fluoroscopic guidance, one or more 11- or 13-gauge needles were inserted into the vertebral body using a uni- or bilateral transpedicular approach after the administration of local infiltration analgesia. Under continuous fluoroscopy, the thermoplastic polymer polymethylmethacrylate (PMMA) was slowly injected into the vertebra. The injection was terminated when PMMA adequately diffused in the vertebrae, leaked into the extravertebral structures, or migrated into the veins. Prophylactic augmentation of the adjacent vertebra[11] was performed for patients with a widened air- or fluid-filled cleft or concomitant old compression fracture(s) found in other vertebra since such patients were predisposed to the recurrent fractures after PVP. After PVP, the patient remained in a supine position for 120 minutes.

4. Clinical Outcome Assessment

Each of the patients assessed his or her back pain on a scale of 0-10 (with 0 indicating no pain, 10 indicating the maximum imaginable pain) [1-3]. We retrospectively determined the patients’ mobility scores using the following five-point scale, a modification of Yokoyama’s Activities of Daily Living (ADL) scores: 0 points = complete independence; 1 point = light assistance, able to walk with a walking aid; 2 points = moderate assistance, needing a wheelchair for locomotion; 3 points = major assistance, mostly staying in bed and being able to sit upright at 60-90 degrees; and 4 points = total assistance, mostly staying in a bed-ridden state and able to sit upright at <60 degrees.

The patients’ pain ratings and mobility scores were estimated as: (1) the maximum points during the pre-PVP period; and (2) the points at 1 day before PVP, and (3) 7 days post-PVP. If there were any lost or missing score data at 7 days post-PVP, we used the points that were rated nearest to them. We also assessed post-PVP complications and adverse events among the patients. All data were identified using our institution’s hospital information system.

5. Data Analyses

We assessed the differences between the Earlier and Later PVP groups in demographics, number of vertebral fractures, and degree of PMMA augmentation provided. We also made the following four comparisons of the pain rating and mobility scores in the two groups: (1) Intragroup comparisons of the maximum points before PVP with points at 1 day before PVP to determine the degree of improvement during the conservative waiting period; (2) Intragroup comparisons of points 1 day before PVP with points 7 days post-PVP to estimate the efficacy of PVP; (3) An intergroup comparison of points 7 days post-PVP of the Earlier group with the Later group’s points 1 day before PVP as an alternative comparison of the PVP treatment group with the conservative treatment group; and (4) An intergroup comparison of points 7 days Post-PVP between the Earlier and Later groups to estimate the effectiveness of PVP by surgical timing. The other two following comparisons were also performed: (5) An intergroup comparison of the incidence of adverse events after PVP between the Earlier and Later groups; and (6) An intergroup comparison of survival rates after PVP.

The statistical analyses were performed using Excel 2013 (Microsoft, Seattle, WA, USA) with the add-in software Statcel-3[12]. Both continuous and non-continuous data are expressed as mean ± standard deviation of the mean in the table and figures because this format seemed more comprehensible than median and range. The intergroup comparisons with non-normally distributed continuous data (i.e., patient age, number of vertebral fractures, and degree of PMMA augmentation) were analyzed using the Mann-Whitney U test.
Table 1. Results of the Earlier and Later groups

| Item                                | Earlier group | p value | Later group |
|-------------------------------------|---------------|---------|-------------|
| Number of patient                   | 46            |         | 16          |
| Sex (male/female)                   | 21/25         | n.s.    | 5/11        |
| Age (years)                         | 80.5±10       | n.s.    | 82.9±8.2    |
| Vertebral fracture Number of patients with 1, 2, or 3 vertebral fractures | 38/6/2        | n.s.    | 12/2/2      |
| PMMA augmentation Volume per vertebrae | 3.5±1.5       | n.s.    | 3.2±1.5     |
| PMMA augmentation Volume per patient | 4.7±1.9       | n.s.    | 4.5±1.7     |
| Elapsed time Period from onset to hospital admission | 2.2±3.3       |         | 5.9±6.1     |
| Days from onset to 1 day before PVP  | 8.1±3.2       |         | 19.1±2.8    |
| Days from onset to 7 days after PVP  | 16.1±3.2      |         | 27.1±2.8    |
| Pain score Number of available patients | 40            |         | 13          |
| Maximum scores before PVP           | 7.6±2.1       | **      | 7.7±2.1     |
| Scores at 1 day before PVP          | 5.7±3.1       | *       | 3.9±2.8     |
| Scores at 7 days post-PVP           | 1.9±2.2       | n.s.    | 1.1±1.3     |
| Mobility score Number of available patients | 46            |         | 16          |
| Maximum scores before PVP           | 3.5±0.8       | *       | 3.6±0.7     |
| Scores at 1 day before PVP          | 3.3±0.9       | **      | 2.8±0.9     |
| Scores at 7 days post-PVP           | 1.3±1         | n.s.    | 1.1±0.8     |

Data are mean ± standard deviation, n.s.: not significant, PMMA: polymethylmethacrylate

RESULTS

No differences between the Earlier and Later groups were observed in demographics, number of vertebral fractures, or degree of PMMA augmentation (Table 1).

Pain scores for six patients in the Earlier group and three patients in the Later group failed to be recorded, but no mobility scores were identified. The time courses of the two groups, mobility scores, and pain scores (Fig. 1A and 1B, respectively) were plotted by three points as follows: (x, y) = (average elapsed time from onset to hospital admission, average of maximum points before PVP), (average of elapsed time from onset to 1 day before PVP, average of points at 1 day before PVP), and (average of elapsed time from onset to 7 days post-PVP, average of points at 7 days post-PVP).

The intragroup comparisons of the Earlier and Later groups showed the same tendencies: (1) Pain and mobility scores 1 day before PVP were significantly improved compared to the maximum points before PVP; (2) Pain and mobility scores 7 days post-PVP were further improved compared to those before PVP. Notably, the averaged mobility scores at 7 days post-PVP in both groups were <2, suggesting that most of the patients were able to leave their beds and use a wheelchair or even practice walking during the daytime within 7 days post-PVP.

The results of the intergroup comparisons between the Earlier and Later groups were as follows: (3) Pain and mobility scores at 7 days post-PVP in the Earlier group were significantly improved compared to the scores at 1 day before PVP in the Later group, suggesting that earlier PVP could provide pain relief and improve mobility compared to the conservatively waiting state; (4) There were no significant differences in the pain or mobility scores at 7 days post-PVP between the Earlier and Later groups, suggesting that later PVP could also provide pain relief and improve mobility comparable to those provided by earlier PVP; (5) One of the Earlier group patients and one of the Later group patients had a recurrent vertebral fracture after PVP, and no significant difference was observed between the two groups; and (6) One Earlier group patient and one Later group patient were lost to follow-up. The follow-up period for the other patients was 3.5-38 months. Five Earlier group patients (two with infectious pneumonia and one each with a ruptured brain aneurysm, renal failure, and lung cancer) and four Later group patients (one each with fatal cardiac dysrhythmia, lung cancer, infectious pneumonia, and suffocation) died of causes other than vertebral fractures or PVP within 1 year post-PVP. No significant difference in survival rates was observed between the two groups (Fig. 2).

DISCUSSION

As noted in the Introduction, acute vertebral fractures often cause locomotion disability, require prolonged bed augmentation) were performed using Mann-Whitney’s U-test. The intergroup comparison of the categorical data (i.e., sex and incidence of adverse events) was performed using the chi square test. The intra- or intergroup comparisons of non-continuous data were performed using the Wilcoxon signed-rank test or Mann-Whitney’s U-test, respectively. The survival rates were determined using Kaplan-Meier plots, while the intergroup comparisons were performed using the log rank test. The level of significance was set at P < 0.05 for all tests.
Figure 1. Pain scores (A) and mobility scores (B) show significant improvement from before to post-PVP treatment. Both scores 7 days post-PVP in the Earlier group were significantly more improved compared to the scores 1 day before PVP in the Later group, suggesting that PVP can result in earlier recovery than the conservatively waiting state. No significant differences were observed in pain or mobility scores 7 days post-PVP between the Earlier and Later groups, suggesting that the later performance of PVP was also effective for pain relief and mobility improvement. PVP, percutaneous vertebroplasty.

Our series clarified that earlier PVP can provide pain relief and improve mobility compared to the conservatively waiting state, although we did not confirm that PVP prevents the secondary disorders that are caused by long-term bed rest. We also observed that delayed PVP also effectively provided pain relief and locomotion recovery when performed within 4 weeks of the fracture onset. However, we still recommend "striking while the iron is hot," that is, performing PVP as soon as the patient can undergo it to immediate ambulant restoration.

Previous investigations of patient QOL after PVP were evaluated with the following systems: Quality of Life Questionnaire of the European Foundation for Osteoporosis, Assessment of Quality of Life questionnaire, European Quality of Life, 5 Dimensions scale, Roland Morris Disability Questionnaire, Bartel Index, or Oswestry Disability Index[1, 8, 9]. These tests can comprehensively assess an individual’s ADL proficiency including eating, dressing, moving, toileting, grooming, and bathing in addition to low back pain. While the tests have proved to be valid for various QOL evaluation studies, they usually show a non-specific score because the scores of the question items are averaged; in addition, it was difficult to determine the specific pathological conditions (such as ambulation ability) in those earlier investigations, although the pathological condition of a patient is an essential factor in acute vertebral fractures.

Our study adopted the mobility scoring system that was first proposed as ADL scores by Yokoyama et al[13]. This scoring system has several advantages including the modest daily fluctuation, ease of use, simple and objective estimation by medical staff, and direct relationship of mobility...
scores to the physical status of patients with acute vertebral fractures. In addition, the clinical problems that are associated with these mobility scores are easily predicted. For example, a score of 3 or 4 points, indicating that a patient must usually stay in bed, is likely to be associated with difficulties such as defecation while bedridden, frequent need for medical staff assistance, and a high risk of secondary illness and long-term hospitalization. A score of 2 points, indicating that the patient usually uses a wheelchair, is likely to be associated with the autonomous use of the bathroom, undergoing advanced rehabilitation for walking but still needing assistance and going on limited outings. A score of 1 or 2 points indicates that the patient may be able to walk and can be expected to leave the hospital, return home, and expand his or her activity level.

In contrast, the pain evaluation remains challenging because a subjective internal feeling and patients’ self-rating of pain often change with psychological factors and different environments. No completely objective evaluation method for pain has been proposed to date. It is also often difficult to evaluate pain in patients who have communication difficulties, such as those with dementia.

The mortality rates in previous reports were 0-17% of patients with a mean age of 68-81 years old in follow-up periods of 3 months to 1.7 years.[3, 6-9] In the present study, 14.5% of the 62 patients died of causes other than vertebral fractures or PVP within 1 year after treatment. One of reasons for the current relatively high mortality rate might be that we enrolled elderly patients (mean age, >80 years); elderly individuals often have several preexisting diseases and, therefore, a high risk for mortality. However, further investigations are needed to clarify whether potential risk factors for mortality might exist in our procedure or patient care after PVP.

The limitations of our investigation are its retrospective nature, the relatively small number of cases, the lack of an objective evaluation of pain relief, the detailed examination of mobility improvement only up to 7 days post-PVP (rather than several weeks or months), and the need for other comparisons of PVP-treated patients versus conservatively treated patients. Prospective studies of greater numbers of subjects are desired.

CONCLUSIONS

We retrospectively examined the effectiveness of PVP performed in patients who had only ambulation difficulty due to acute osteoporotic vertebral fractures. Our analysis clarified that earlier PVP (within 2 weeks after fracture onset) can provide pain relief as well as mobility improvement compared to the conservative treatment. Delayed PVP was still effective for providing pain relief and locomotion recovery when performed within 4 weeks.

Conflict of interest: All authors have no relevant financial relationships.

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