Safety and Efficacy of Percutaneous Vertebroplasty in Lateral Decubitus Position: A Retrospective Evaluation

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Abstract

Background and Purpose: During a percutaneous vertebroplasty (PVP) procedure, patients typically lie in the prone position. However, some elderly patients have difficulty in maintaining the prone position. Therefore, we aimed to investigate the safety and efficacy of PVP in a lateral decubitus position in patients experiencing difficulty in maintaining the prone position.

Materials and Methods: A total of 123 PVP procedures performed consecutively on 117 patients for symptomatic vertebral fractures caused by bone tumors or osteoporosis were studied. The patients were divided into prone (n=113) and decubitus groups (n=10) according to their positions during the PVP procedures. The factors related to the patients’ background, procedures, therapeutic effects, and adverse events were compared between the 2 groups. Univariate analysis was performed using Student’s t-test, Mann-Whitney’s U-test, chi-squared test, or Wilcoxon signed-rank test.

Results: In the decubitus group, the average age was 6.7 years older (p<0.05), the average set-up time was 1.6 times longer (p<0.01), the average fluoroscopic exposure dose was 1.37 times greater (p<0.05), the average dose-length product of interventional computed tomography was 1.78 times greater (p<0.05), and mobility restoration on the 7th day after the PVP was less (p<0.05) compared to the prone group. There were no significant differences in bone cement leakage, pulmonary embolism, recurrence of compression fractures, or pain relief.

Conclusion: Although some disadvantages were observed, decubitus PVP seemed to be completed safely and successfully. Decubitus PVP can become a treatment option for patients with vertebral fractures and difficulty in maintaining the prone position.

Key words: vertebroplasty, spinal fractures, osteoporosis, bone neoplasms, prone position (Interventional Radiology 2018; 3: 115-120)

INTRODUCTION

Percutaneous vertebroplasty (PVP) is a treatment method used to achieve improvement in back pain and ambulation difficulty due to vertebral fractures caused by bone tumors or osteoporosis [1, 2]. PVP involves injecting bone cement into a fractured vertebral body through bone needles that are punctured directly through the skin into the bone under local anesthesia [3-5]. Since its first performance in France in 1984 [3], the PVP has spread into many developed countries because of its safety, prompt efficacy, wide indication range, and lower level of invasiveness.

However, one of the restrictions of the PVP is that the patient should be in the prone position during the operation [4-6]. Meanwhile, some elderly patients have difficulty in maintaining a prone position even for one hour or more approximately as required for the PVP because of the comor-
Table 1. List of the patients in the decubitus group:

| Patient No. | Age/ Sex | Cause                     | Dementia | Reasons for prone position difficulty                                                                 | Direction of decubitus position |
|-------------|----------|---------------------------|----------|-------------------------------------------------------------------------------------------------------|---------------------------------|
| 1           | 93/F     | Falling                   | No       | Abdominal incisional hernia                                                                           | left side                      |
| 2           | 90/F     | Falling from a sofa       | No       | Breathing difficulty due to pleural effusion                                                          | left side                      |
| 3           | 89/F     | Unknown cause             | No       | Risk of liver giant cyst rupture                                                                       | left side                      |
| 4           | 92/M     | Falling                   | Yes      | Difficulty maintaining a safe prone position due to dimentia                                           | left side                      |
| 5           | 97/F     | Back pain for 3 years     | Yes      | Difficulty maintaining a safe prone position due to dimentia                                           | left side                      |
| 6           | 86/F     | Falling                   | No       | Concurrent left humeral bone fracture                                                                  | right side                     |
| 7           | 80/F     | Falling from a bed        | No       | Breathing difficulty due to sputum excretion                                                           | left side                      |
| 8           | 66/F     | Metastasis from gallbladder cancer | No       | Colostomy and percutaneous                                                                             | left side                      |
| 9           | 80/M     | Forward stoop             | Yes      | Bilateral knee joints contracture                                                                      | left side                      |
| 10          | 87/M     | Colonoscopic examination  | No       | Gibbous deformity due to prevalent vertebral fractures                                                | right side                     |

bilities or other past histories. Such patients underwent a PVP in a lateral decubitus position (decubitus PVP) in our hospital. We hypothesized that decubitus PVP would provide pain relief and mobility function restoration safely. Therefore, we conducted the present study to examine retrospectively the safety and efficacy of the PVP in the decubitus position for the vertebral fractures in the patients with difficulty in maintaining the prone position.

MATERIALS and METHODS

1. Study Design

We performed a retrospective analysis to determine the safety and efficacy of the decubitus PVP in the patients with difficulty maintaining the prone position. This research was approved by our Institutional Review Board, and the need for the written informed consent from each patient was waived based on the retrospective nature of this study.

2. Patients

A total of 123 procedures performed consecutively on 117 patients who were diagnosed with unhealed symptomatic vertebral fractures, and treated with a PVP procedure between May 2015 and April 2017 at our hospital were classified into 2 groups according to the patients’ position during the procedure: the prone group (n = 113) and the decubitus group (n = 10). Table 1 shows the list of the decubitus group patients.

3. PVP procedure

(1) Operators and equipment

All the procedures were performed in our hospital’s angiographic examination room by 2 or more radiologists including at least one board-certified interventional radiologist who was familiar with our PVP procedure using a 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).

(2) Procedure

First, the patient was placed in a prone or lateral decubitus position on the examining bed. The area of interest, which was confirmed with fluoroscopy as well as physical examination by means of percussion tenderness, was marked and sterilized. Then, the puncture site was addressed via a transpedicular route according to the iso-center puncture (ISOP) method [7]. In the ISOP method, a marker was placed in the center of a fluoroscopy monitor; the fluoroscopic C-arm was rotated in an arbitrary puncture direction; a needle was placed endways in an anterior-posterior (A-P) position; and a pinpoint puncture was performed. After inducing local infiltration anesthesia, a Cattelan needle was inserted into the posterior arch according to the Cattelan-needle-assisted puncture (CAP) method. In the CAP method, the Cattelan needle, used during the local infiltration anesthesia, was introduced into the posterior arch and placed to guide for the bone biopsy needle (Figure 1). One or more 11- or 13-gauge bone biopsy needles (Osteo-Site Bone Biopsy Needle Set; Cook Medical, Indianapolis, IN) were hammered into the vertebral body by a unilateral or bilateral transpedicular approach in parallel with the Cattelan needle under a fluoroscopic monitoring. Cone beam CT or IVR-CT was performed at least twice in order to implement a puncture planning and affirmation of pathway (PPAP) method [8]. The PPAP method involved performing CT in order to plan a puncture route after the Cattelan needles were placed and placed to guide for the bone biopsy needle.
which was necessarily not suitable for the cone beam CT. Bone cement (VertaPlex Bone Cement; Stryker) was slowly injected into the vertebra using a bone cement injector (PCD System; Stryker, Mahwah, NJ) under continuous fluoroscopy. The injection was terminated when the bone cement adequately diffused in the vertebrae, leaked into the extravertebral structures, or migrated into the veins. We limited the total maximum dose up to 12.5 mL of the bone cement per patient, which is the amount contained in one set of the bone cement product. Prophylactic augmentation to adjacent vertebrae [9] was performed in the patients who presented with a vertebral fracture caused by events other than falling or trauma, who had a widened air- or fluid-filled cleft that seemed to be a mass-like distribution after the PVP, or who had a concomitant pre-existing compression fracture in another vertebra [10-12]. In addition to the PVP, a pedicu- loplasty [13] was also performed by injecting the bone cement along the needling paths to brace the pedicles of the fractured vertebrae after confirming by CT that the bone biopsy needle passed through the pedicle. After the PVP, the distribution of the bone cement was assessed by the IVR-CT, and then the patient was held in a supine or lateral decubitus position for 120 minutes in the patient’s hospital bedroom.

4. Clinical Outcome Assessment

All patients performed a self-assessment of their back pain on a scale of 0 to 10 (with 0 indicating no pain, and 10 indicating the maximum imaginable pain) known as the pain Numeric Rating Scaling (NRS) scores [2, 14]. We retrospectively determined the patients’ mobility activities of daily living (ADL) scores using the following 5-point scale, which is a modification of the Yokoyama’s ADL scores [2, 15]: 0 points = complete independence; 1 point = light assistance, being able to walk with walking equipment; 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 to 90 degrees; and 4 points = total assistance, mostly staying in a bed-ridden state and being upright under 60 degrees.

The patients’ pain ratings and mobility scores were estimated on the day before the PVP and on the 7th day after the PVP. If there were any lost or missing score data after 7 days of the PVP, we used the scores that were rated nearest to that of the lost data. We also assessed post-PVP complications and adverse events among the patients. All the data were identified using our institution’s Hospital Information System.

5. Data Analyses

Factors related to the patients’ background, including age, sex, vertebral fracture, presence of dementia, history of the PVP, and presence of neoplastic fracture were examined. As the factors regarding the PVP procedure, the rate of proc- dural success, (defined by the completion of an appropriate injection of the bone cement into the target vertebrae), set-up time (from the arrival to the administration of local infiltration anesthesia), procedure time (from the administration of local infiltration anesthesia to the needle removal), fluoroscopic exposure dose, Dose-Length Product (DLP) of CT, number of bone punctures, and the volume of bone cement were examined. As the factors regarding the adverse events,
the number of punctures through the spinal canal, presence of the bone cement leakage (evaluated by a spinal CT after the PVP), presence of pulmonary embolism (confirmed by an additional chest CT with slice thickness of 1.5-mm after the PVP, performed when the bone cement leakage through the paravertebral veins was found on fluoroscopy), and recurrence of vertebral fracture were examined.

Statistical analyses were performed using Excel 2013 (Microsoft, Seattle, WA, USA) with the add-in software Statcel-3 [16]. Univariate analyses were performed using the Student’s t-test, Mann-Whitney’s U-test, chi-squared test, or Wilcoxon signed-rank test. The level of significance was set at P <0.05 for all the tests.

RESULTS

Table 2 presents results of the comparisons of the patients’ background, surgical outcomes, therapeutic effects, and adverse events between the 2 groups:

| Item | Prone group | Decubitus group | p value |
|------|-------------|-----------------|---------|
| No. of procedures | 113 | 10 | |
| No. of Pts | 107 | 10 | |
| Age (year) | 79.2±9.6 | 85.8±8.9 | p<0.05 |
| Sex (Male/Female) | 46/67 | 3/7 | n.s. |
| Vertebral fracture (No. of Pts with 1 to 5 vertebral fractures) | 73/34/3/1/1 | 4/5/1/0/0 | n.s. |
| Procedural success rate (%) | 100% | 100% | n.s. |
| Setup time (Minute) | 30±7 | 48±32 | p<0.01 |
| Procedure time (Minute) | 82±27 | 90±30 | n.s. |
| Fluoroscopic exposure dose (mGy) | 1077±443 | 1472±610 | p<0.05 |
| DLP of IVR-CT (mGy) | 619±254 | 1101±613 | p<0.05 |
| Volume of bone cement (mL) | 4.9±2.1 | 4.2±1.5 | n.s. |
| Puncturing through spinal canal (No. and (%) of punctures) | 9 (3%) | 3 (11%) | n.s. |
| Bone cement extravasation (No. and % of Pts) | 59% | 59% | n.s. |
| Pulmonary embolism (No. and (%) of Pts) | 3 (3%) | 0 (0%) | n.s. |
| Recurrence of vertebral fracture (No. and % of Pts) | 8 (7%) | 0 (0%) | n.s. |
| Pain NRS score | | | |
| Score at one day before PVP (mean±SD) | 6.3±3.1 | 6.6±2.6 | n.s. |
| Score at 7th day after PVP (mean±SD) | 2.2±2.3 | 2.7±2.8 | n.s. |
| Mobility ADL score | | | |
| Score at one day before PVP (mean±SD) | 2.5±1.3 | 2.9±0.9 | n.s. |
| Score at 7th day after PVP (mean±SD) | 1.4±0.9 | 2.3±1.3 | p<0.05 |

DLP: Dose-Length Product, No.: number, Pts: patients, SD: standard deviation, n.s.: not significant

follow-up period of 319 days (range: 29 to 813 days). Furthermore, the pain NRS scores on the 7th day after the PVP revealed no differences in the treatment effect.

Both pain NRS scores and mobility ADL scores in the decubitus group tended to improve after the PVP, but this difference did not attain a statistical significance; whereas, both the scores significantly improved after the PVP (p<0.01) in the prone group.

No significant difference was observed in the presence of dementia (25 and 2 patients in the prone and decubitus groups, respectively), a history of PVP (5 and 0 patients, respectively), the presence of neoplastic fracture (5 and 1 patients, respectively), or the mean number of the bone punctures (3.1 and 2.7, respectively).

DISCUSSION

As the aging of the global population progresses, the number of patients with vertebral fractures due to neoplasms or osteoporosis continues to increase. PVP is a beneficial treatment method for patients with vertebral fractures, since it is a minimally invasive procedure and has a quick-acting pain relief effect. PVP is likely to become much more popular in the future throughout the world compared with balloon kyphoplasty, which is generally performed under general anesthesia [17]. In addition, with the aging of the society, the number of elderly patients with the vertebral fractures who cannot maintain a prone position (which is essential for the PVP), due to a pre-existing disease or concurrent complications, has increased. In our study, indeed, the patients in the decubitus PVP group were significantly older than those in the prone PVP group.

Few reports on the decubitus PVP have been published to
date. A PVP under general anesthesia is typically recommended for patients who have difficulty in maintaining the prone position [4, 6]. However, the use of general anesthesia would reduce the advantage of the PVP as being minimally invasive, and it is not practical in many patients who have difficulty in maintaining a prone position. Therefore, it would greatly benefit the patients with a symptomatic vertebral fracture, if a decubitus PVP is performed more commonly.

However, in the decubitus PVP, the maintenance of a safe position, fluoroscopic monitoring, and puncturing with a needle during the procedure can all create difficulties. The patients in the lateral decubitus position can more easily change their position than those in the prone position and have difficulty in maintaining a safe position. On lateral fluoroscopy, the vertebrae may sometimes overlap with the upper limbs, electrode cords, infusion lines, positioning instruments, and so on. Needles should be held horizontally during the puncturing, but they may sometimes fall to the floor. In our study, these difficulties with the lateral decubitus position might have resulted in significant prolongation of the set-up time, the fluoroscopic exposure dose, and the DLP of the IVR-CT. In particular, the larger radiation exposure in our decubitus patients seems to be related to a more frequent use of the IVR-CT for the PPAP method, which might have increased the current automatically to maintain the imaging quality in the decubitus patients because the decubitus position increases the thickness of the body.

All decubitus PVP procedures in this series were successfully completed. This achievement was greatly supported by use of the ISOP, CAP, and PPAP methods. The ISOP method easily indicated the initial direction in which the Cattelan needle was required to be inserted. The Cattelan needle was inserted into the posterior arch according to the CAP method, which precisely guided the bone biopsy needle to the puncture site even if the target vertebra was obscured due to osteoporosis or was deformed due to a compression fracture. The PPAP method provided the mapping and the orientation, and thus, allowed us to perform the puncturing confidently.

However, some disadvantages were observed, such as the irradiation exposure dose, the rates of complications and the pain relief effects in the decubitus group patients were comparable to those in the prone group patients. A decubitus PVP can be a treatment option for improving the quality of life in patients with difficulty in maintaining the prone position. In our study, 8.5% (10/117) of the patients experienced such difficulty. If the indications for a PVP can be expanded by making it possible to perform a PVP in the lateral decubitus position, many more patients can be benefited from the PVP.

Our study proved that the decubitus group patients reported higher mobility ADL scores on the 7th day after the PVP as compared to the prone group, which indicated that the decubitus group patients manifested less mobility restoration on the 7th day after the PVP. This suggested that the patients with difficulty in maintaining a prone position might be physically weaker and might experience more difficulty in recovering to their initial performance level. In the decubitus group, the pain NRS and mobility ADL scores on the 7th day after the PVP revealed a trend of improvement after the PVP, but the change did not reach a statistical significance as compared to the scores obtained on the day before the PVP. This result might be due to the small sample size.

Our study has some limitations. First, the number of patients in our series was too small to provide any definitive conclusions. Second, the factors that we investigated were insufficient as the indicators to evaluate the difficulty to perform puncturing in the decubitus PVP, and therefore, more concrete indices are needed. Third, the pain and mobility were evaluated only in 7 days after the PVP, which limited our evaluation of the efficacy of the PVP. Forth, a long-term follow-up validation was not performed in the current study. Fifth, while performing a decubitus PVP, an irregularity in the alignment of the spine might have occurred due to the vertebral body fixation in the lateral decubitus position, and this might have caused a secondary lumbar spine disorder.

Finally, this retrospective study might have involved a selection bias. Therefore, a prospective study with a larger number of subjects and long-term follow-up should be performed to confirm our findings.

In summary, we retrospectively examined the efficacy and safety of the PVP procedures performed on the patients in the decubitus position. Our analysis clarified that a decubitus PVP has disadvantages, such as a prolongation of high-dose radiation exposure. However, no disadvantages such as a higher complication rate or lower pain relief effect were observed. This indicated that decubitus PVP can be a treatment option for the patients with vertebral fractures and difficulty in maintaining the prone position, if the solutions to the problems associated with the decubitus PVP are obtained.

FUNDING INFORMATION

This work was supported in part by Grants-in-Aid for Research from the National Center for Global Health and Medicine (28A5003) and Grants-in-Aid for Scientific Research from Japan society for the promotion of science (16K10333)

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