Original Article

Treatment of osteoporotic vertebral compression fractures with percutaneous vertebroplasty under local anesthesia: clinical and radiological results

Hüseyin Balkarli¹, Hakan Demirtaş², Mesut Kılıç³, İbrahim Oztürk⁴

¹Department of Orthopaedics and Traumatology, School of Medicine, Akdeniz University, Antalya, Turkey; ²Department of Radiology, School of Medicine, Süleyman Demirel University, Isparta, Turkey; ³Department of Orthopaedics and Traumatology, School of Medicine, Samsun 19 Mayıs University, Samsun, Turkey; ⁴Department of Anesthesiology, Medeniyet University Göztepe Education and Research Hospital, Istanbul, Turkey

Received June 18, 2015; Accepted August 6, 2015; Epub September 15, 2015; Published September 30, 2015

Abstract: Background: Vertebroplasty (VP) is a commonly used method for the treatment of osteoporotic vertebral fractures (OVF). The aim of this study is to analyze retrospectively the efficacy of VP in symptomatic osteoporotic spine fractures. Methods: Patients with symptomatic osteoporotic spine fractures were included in our study. Visual analog scale and demographic characteristics were used for clinical examination, local wedge angle and the central height of the vertebral body were measured preoperatively and postoperatively. Results: 95 patients (72 female, 23 male) were included and 118 level vertebroplasty were performed. There was statistical significance in the differences of preoperative VAS scores compared to postoperative first day, first month and sixth month. The radiologic assessment of the mean local wedge angle correction at the postoperative sixth month, was 13.9 and mean increase of mid height of vertebral body was 7.9 mm, but it was not statistically significant. Conclusion: VP is at an important point as a minimally invasive method, that provides rapid pain relief in symptomatic osteoporotic vertebral fractures and that prevents the patient being bed-dependent. It is a reliable surgical method, being an alternative to open surgery with minimal complications in patients with comorbidities, which can be applied and decreases the potential spinal deformity after the fracture and prevents the progression of deformity.

Keywords: Vertebroplasty, osteoporotic vertebral fractures, local wedge angle, the central height of the vertebral body, visual analogous scale

Introduction

Osteoporosis is characterized by the progressive loss of bone mass in the skeletal system. This bone loss often occurs in proportion to aging, causes alterations in bone microstructure, and increases the risk of fractures. The most common presentations of osteoporotic fractures include severe lumbar and/or back pain, spinal deformities, muscle atrophy, decrease in physical functioning, prolonged hospitalization, potentially increased mortality and new osteoporotic vertebral fractures (OVFs).

The classical treatment options for the management of OVFs include bed rest, brace use, non-steroidal analgesic drugs, and physical therapy. However, prolonged bed rest may lead to complications, including muscle atrophy, progression of osteoporosis due to immobilization, pressure ulcers, and thromboembolism. In addition, non-steroidal anti-inflammatory drugs (NSAIDs), which are used for pain management, have significant side effects on the gastrointestinal system and kidneys, while opioid analgesics might also cause nausea, drowsiness, and tolerance development. Under appropriate conditions, open surgery can be considered, although it is rarely used due to the potential complications of general anesthesia.

The most common surgical techniques currently used are vertebroplasty (VP) and kyphoplasty [1]. VP technique is performed under local anesthesia, and involves a percutaneous injection of cement into a fracture line in the spine [2]. The primary goal of this method is to obtain rapid analgesia and early mobilization of the
Clinical and radiological effectiveness of percutaneous vertebroplasty

Patient. VP technique was first used by Galibert et al. in 1984 in a case of painful vertebral hemangioma [3]. During the following years, it was used for the treatment of malignant and benign spine tumors, and particularly, in cases with painful OVFs [4, 5].

In this study, we aimed to determine the efficacy, complications, utility and radiologic outcomes of VP technique, which was applied to patients with lumbar/back pain who came to our clinic, were diagnosed as OVFs after clinical and radiologic examinations, and followed-up with for at least 6 months.

Materials and methods

We investigated the files of patients who underwent the VP technique in our institution between April 2011 and June 2013. A total of 95 patients (72 women and 23 men) were included in the study. Demographic features of the patients and their preoperative visual analogue scale (VAS) values were compared with those at postoperative day 1, and months 1 and 6. Radiographic evaluations were performed in order to calculate the preoperative local wedge angle and the vertebral corpus height, and these results were compared with the findings at postoperative day 1 and in the 6th month.

Inclusion criteria of patients

Inclusion criteria of patients required the presence of back and/or lumbar pain in the patient’s medical history and during a physical examination. Other inclusion criteria were tenderness to palpation at the site of the fracture and the presence of ≥15% compression relative to the upper adjacent vertebra with marrow edema seen via lateral direct film and/or MRI. Patients were excluded from the study if they had neurologic deficits, bleeding diathesis, osteomyelitis, active infection in a body site, lack of orientation and cooperation (e.g. Alzheimer’s disease and other forms of dementia), and/or pathologic fractures in X-Rays and MRI.

Surgical method

All procedures were carried out with sterile equipment. Patients were placed in a prone position on operating table, and sedation was achieved with 1.5 cc intravenous midazolam. The fracture line was identified with fluoroscopy. Local anesthesia with 2% prilocaine hydrochloride (8 cc) was administered from the pedicle of fractured vertebra to subcutaneous tissue. An 11-gauge needle was inserted into the pedicle via fluoroscopy. Using anteroposterior and lateral imaging, the pedicle was passed through the body to reach the corpus vertebræ. Then, cementing was performed, and a lateral X-ray showed the distribution of the cement inside the corpus. The amount of cement added was determined via lateral imaging. After the procedure, the patients remained motionless in a prone position until the cement polymerized. When the cement was fully polymerized, the patients were moved to the inpatient ward, where they rested for 2 hours. The patients underwent a neurological examination at every stage of the procedure. All of the patients stayed in the hospital for 1 day, and none of them had to wear a cast after discharge.

Evaluation of the results

The demographic features of the patients were retrieved from medical records, and data were recorded in standard forms prepared by the investigators. Age, sex, level of fracture, and duration of symptoms were included in the analysis. The types of fractures were defined as either wedge, concave or biconcave. The following data were recorded and evaluated: pre- and postoperative VAS scores, the affected vertebral levels and the number of operated levels, complications, re-fractures, local wedge angle and vertebra corpus height, which was obtained from pre- and postoperative direct lateral films. The shortest duration of follow-up was 6 months.

Statistical methods

Descriptive statistics included frequency, percentage, mean and standard deviation values. The relationship between VAS scores and radiological evaluations was determined with a paired sample t-test and a Pearson correlation test. All statistical analyses were performed with SPSS version 17.0 (Chicago). P values lower than 0.05 were accepted as significant.

Results

A total of 95 patients (72 women and 23 men) were included in this study. Ten women and 2 men had two-level surgery while 1 woman had
Clinical and radiological effectiveness of percutaneous vertebroplasty

Table 1. The clinical characteristics of the study populations

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Mean-Range) yr</td>
<td>68±1.8</td>
</tr>
<tr>
<td>Gender</td>
<td>Female 72 (75.7%), Male 23 (24.3%)</td>
</tr>
<tr>
<td>Fracture Age</td>
<td>3±0.5 Days</td>
</tr>
<tr>
<td>Refracture</td>
<td>8 (6.7%)</td>
</tr>
<tr>
<td>Cement Volume</td>
<td>6.2±1.4 cc</td>
</tr>
<tr>
<td>Stay in Hospital (Mean) Day</td>
<td>1.4</td>
</tr>
<tr>
<td>Follow-up Period</td>
<td>6 months</td>
</tr>
</tbody>
</table>

triple-level surgery, therefore bringing the total number of VP levels to 118. The mean age of the patients was 68±1.8 years and the duration of symptoms was 3±0.5 days (Table 1).

The levels of fracture included L1 in 42 cases (35.5%), L2 in 12 (10.1%), L3 in 8 (6.8%), L4 in 5 (4.2%), L5 in 1 (0.8%), T12 in 37 (31.3%), T11 in 9 (7.6%), T10 in 3 (2.5%) and T9 in 1 (0.8%) cases. Fifty-six fractures (47.4%) were wedge type, 38 (32.2%) were concave type, and 24 (20.3%) were biconcave type.

The average amount of cement applied to the patients was 6.2±1.4 cc. The mean preoperative VAS score was 7.6 and the mean postoperative scores were 3.8 at day 1, 3.3 at the 1st month, and 3.7 at the 6th month. The decrease in all three postoperative VAS scores was statistically significant when compared to the preoperative values (p<0.001). The VAS scores are shown in Table 2. Seventy-nine of 95 patients (83.2%) had a dramatic decrease in pain on postoperative day 1, while 16 patients (16.8%) had no decrease in pain after VP. The mean preoperative VAS score of these 16 patients was 7.8, and it was 6.8 at postoperative day 1, 5.7 in the postoperative 1st month, and 4.1 in the postoperative 6th month (Table 2). There was no significant difference between the preoperative VAS scores and the postoperative scores of these 16 patients at day 1 and in the 1st month, while the decrease in the VAS scores at the 6th month was statistically significant (P<0.05).

The radiologic local wedge angle and the vertebral corpus height were 29.6° and 12.2 mm, respectively. The local wedge angle at postoperative day 1 was 13.4°, and was 15.7° at the postoperative 6th month. Vertebra corpus heights were 21.3 mm and 20.1 mm at postoperative day 1 and at the 6th month, respectively (Table 3). There were no statistically significant differences between the pre- and postoperative radiologic measurements (P>0.05).

VP was performed in 118 levels of the 95 patients enrolled in the study, and it was not complicated with neurological damage, pulmonary embolism or vascular injury in any of these cases. There were no major complications in the study cohort, except for cement leak into the upper disk in 2 cases and into the epidural space in 1 case. These complications were totally asymptomatic. Eight patients (6.7%) had fracture of the adjacent vertebra upon follow-up. Two of these fractures were treated with VP, while 6 patients refused to have VP and were treated conservatively.

Discussion

This study is significant because it used both radiological and clinical data to assess the efficacy of VP in OVFs. In addition, all of our patients underwent the procedure with local anesthesia (none received general anesthesia) and none of them required a second open surgery. Taken together, these results indicate that VP is a minimally invasive surgical option. Since both the clinical and radiological data were evaluated in the same study population, the present study helps to clarify this debated topic in the literature.

VP has gained popularity in the last 20 years due to its minimally invasive nature for the treatment of OVF and its efficacy in eliminating or substantially decreasing the pain experienced by this patient group. Retrospective evidence indicates that VP has significant clinical efficacy for painful OVF cases [6-11]. However, the exact nature of this success remains to be elucidated. During VP, cement composed of polymethylmethacrylate (PMMA) is injected into a weakened vertebral corpus with a percutaneous needle to support and stabilize the area. There are various speculations regarding its mechanism of decreasing pain. One theory is that the polymerization of the cement creates heat, which dissipates into the surrounding tissues. This heat is sufficient to cause protein denaturation, cell necrosis, and nerve ablation [12, 13]. After the cement is polymerized, the fracture fragments are stabilized, which prevents mechanical stimulation of in-
traosseous sensory endings, resulting in analgesic effects [15, 16]. Both of these mechanisms are believed to be involved in the mechanism of how VP decreases OVF-related pain.

The efficacy of VP in decreasing pain has been reported to be 60-90% [17, 18]. A meta-analysis also reported a success rate of 87% [35]. In our cohort, only 16 patients did not have a decrease in VAS scores during early follow-up, while 79 patients (83.1%) had significant decreases in their early-term VAS scores. These results indicate our study had an 83% success rate, which is consistent with the current literature. It also supports that VP is an effective method in symptomatic OVF. In addition, the 16 patients that did not have a significant decrease in their VAS scores at postoperative day 1 and at the 1st month did have substantial reductions at the 6th month follow-up. However, the latter did not reach statistical significance. For patients with no clinical improvement after VP, clinicians must be alert to the nature of the back pain, as it may be related to regional muscular atrophy or a secondary fracture that was not visible in the imaged field. In addition, detailed clinical and radiological studies are needed for these unsuccessful cases.

The amount of cement applied during the VP procedure is critical to the procedure's success. Currently, there are no studies reporting the exact amount of cement that should be applied during VP. Despite this lack of clarity, it has been reported that 16% of the vertebral corpus volume should be augmented in order to balance the distribution of stress over the vertebra [19-21]. The average amount of cement applied in our patients was 6.2±1.4 cc, which was measured by inspecting the corpus filling under fluoroscopy during intraoperative cement injection. The amount of cement applied in our study is sufficient and consistent with the literature.

The mean age of our study population was 68±1.8 years, which was consistent with the literature [22, 23]. It has been shown that the incidence of vertebral fracture increases with age, and women are more prone to fractures [24]. In our study, 72 of the 95 patients were women (75.8%). It should be kept in mind that older patients with back pain might have OVF despite the lack of trauma history. A careful physical examination and radiological imaging are necessary to properly diagnose OVF.

The major indication of VP in OVF patients is to obtain a rapid decrease in pain and early mobilization of the patient. Two studies published by Buchbinder et al. [25] and Kallmes et al. [26] in 2009 reported that VP caused no difference between the OVF and sham groups. However, there are various limitations of these studies with regards to patient selection, the application of the procedure, the insufficient amount of cement applied, inter-group patient changes, and awareness of patients in which group they had been. In our series, the difference between the preoperative and day 1 postoperative VAS score was 4.3. The statistical significance of this change highlights that VP is an effective method for OVF patients. In addition, the further decrease in the VAS scores at the 6th month follow up indicates that VAS may be a successful measure for long-term control.

Potential complications of VP procedures include pulmonary embolism, cardiac perfora-
Clinical and radiological effectiveness of percutaneous vertebroplasty

Table 3. The results of radiological assessments

<table>
<thead>
<tr>
<th></th>
<th>Preoperative</th>
<th>Postoperative 1. day</th>
<th>Postoperative 6. month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Wedge Angle (°)</td>
<td>29.6°</td>
<td>13.4°</td>
<td>15.7°</td>
</tr>
<tr>
<td>The Central Height of The Vertebral Body (mm)</td>
<td>12.2</td>
<td>21.3</td>
<td>20.1</td>
</tr>
</tbody>
</table>

... extension, epidural cement extravasation causing spinal cord or nerve root compression, cement leak into paraspinal, intradiskal or venous systems, infections, and fractures in adjacent vertebrae [27-31]. There were no major complications in our study cohort, except for cement leak into the upper disk in 2 cases and into the epidural space in 1 case. These results indicate that VP is generally a safe procedure for OVF patients.

Lateral direct X-ray should be used in OVF patients to determine the loss of height in the fractured vertebra relative to the adjacent vertebra at the point of tenderness. In patients with tenderness who do not have pathological findings by X-ray, an MRI evaluation is needed to determine the fracture and bone marrow edema. In our study, MRI was performed to assess potential fractures that were not visualized by direct X-ray and to select patients at risk for pathological fractures. One potential limitation of this study is that MRI was not performed in all patients. Although there is a low probability, it is possible that patients with pathological fracture may have been included in this study.

One potential complication after VP is a new fracture in the adjacent vertebra. Despite previous reports indicating higher fracture risk after VP [36], recent systematic reviews reported no association between VP and new fracture risk [37]. However, meta-analyses demonstrated that there was a 21% frequency of new fractures after VP, with a range between 2% and 50% [38]. In our series, only 8 patients (8.4%) had new OVF, which is consistent with the literature. It has been shown that the occurrence of new fractures after VP is associated with bone mineral density [39].

After OVF, vertebral corpus height decreases and local kyphosis develops, which results in sagittal imbalance and a shift of the vertebral loading to the anterior portion. Since these phenomena cause the momentum arm to lengthen, the load on the vertebral column increases, causing the risk of fracture in local kyphosis to increase. In addition, local kyphosis might lead to complications related to respiration and the intra-abdominal organs. One study showed that the kyphosis angle (Cobb angle) was inversely correlated with forced expiratory volume (FEV), indicating that increased kyphosis angle leads to a decrease in FEV [40]. The dynamic fracture mobility is the fracture height gained after positioning the patient. The preoperative dynamic fracture mobility often determines the effect of VP on increasing the height of the vertebra corpus [41]. In our study, at 6 months after VP, dynamic fracture mobility helped the local wedge angle to improve 13.9 and the vertebral corpus height to increase 7.9 mm. Although these changes were not statistically significant, they prevented the progression of kyphotic deformity and corrected the sagittal imbalance caused by dynamic fracture mobility. Using VP to prevent the progression of kyphotic deformity might decrease respiratory and intra-abdominal complications. Further studies evaluating pulmonary and intra-abdominal function are needed to clarify this point.

In conclusion, VP is an important and minimally invasive procedure that causes rapid pain relief and prevents immobility in patients with symptomatic osteoporotic vertebral fractures. It is a safe surgical option with minimal complications and it decreases spinal deformity, restored sagittal alignment and prevents its progression caused by fracture. This procedure can be performed rapidly and is an alternative to open surgery in patients with comorbidities.

Disclosure of conflict of interest

None.

Address correspondence to: Dr. Hüseyin Balkarli, Department of Orthopaedics and Traumatology, School of Medicine, Akdeniz University, Dumlupinar Bulvan 07058 Kampus, Antalya, Turkey. Tel: +(90)-(242)-249 60 00; Fax: +(90)-(242)-249 69 03; E-mail: hbalkarli@gmail.com

References


Clinical and radiological effectiveness of percutaneous vertebroplasty


