Research Article

Pain Relief in Patients Treated With Percutaneous Vertebroplasty: An Evaluation Cement Volume

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Summary

Background: To evaluate the correlation between the injected volume of cement and pain-relief in patients with single level of osteoporotic compression fractures treated by percutaneous vertebroplasty (PVP).

Material and Methods: A total of twenty-three patients comprising 13 women and 10 men who received a one level vertebroplasty were consecutively enrolled in this study. The injected volume of PMMA ranged from 2 mL to 8 mL. Depend on the volume of injected cement, these patients divided into two groups. The relevant injected volume of cement and the pre-operative and post-operative visual analogue scores of pain were analyzed.

Conclusions: There was no significant correlation between the injected volume of cement and pain-relief. Only 4 mL could reduce the pain and achieve good clinical results. Percutaneous vertebroplasty is an effective treatment for patients with a painful single level osteoporotic compression fracture.

Key words: vertebroplasty, pain relief, polymethylmethacrylate, osteoporotic fracture, cement volume

Perkütan Vertebroplasti ile Tedavi Edilen Hastalarda Ağrı Tedavisi: Dolgu Hacmi Değerlendirmesi

Özet

Amaç: Perkütan vertebroplasti (PKV) ile tedavi edilen tek seviye osteoporotik kompresyon kırıklarında enjekte edilen dolgu hacmi ile ağrı tedavisi arasındaki iliskinin değerlendirilmesi.

Materyal ve Metod: Bu çalışmaya tek seviye vertebroplasti uygulanan 13 kadın ve 10 erkek olmak üzere toplam üç hasta alındı. Enjekte edilen PMMA hacmi 2-8 mL idi. Enjekte edilen dolgu volümüne bağlı olarak bu hastalar iki ayrı gruba ayrıldılar. Enjekte edilen dolgu hacmi ve işlem öncesi ve sonrası görsel analog ağrı skorları analiz edildi.

Sonuç: Enjekte edilen dolgu maddesi hacmi ile ağrıın geçmesi arasında önemli bir ilişki saptanmadı. Yalnızca 4 mL dolgu maddesi ağrıının azalmasına ve iyi bir klinik sonuç elde etmeye yeterli bulundu. Perkütan vertebroplasti tek seviye ağrılı osteoporotik kompresyon fractürü olan hastalarda etkili bir tedavidir.

Anahtar Kelimeler: vertebroplasti, ağrı tedavisi, polimetilmetakrilat, osteoporotik kırık, dolgu hacmi
INTRODUCTION

Osteoporotic compression fractures, occurring in 20% of patients over the age of 70 years and 16% of postmenopausal women, remains a devastating problem resulting in impairment of morbidity and a reduction in quality of life. Despite traditional treatments such as bed rest, analgesics, muscle relaxants, local injection, physical therapy or rehabilitation programs, percutaneous vertebroplasty is a new and minimal invasive technique to treat collapsed vertebrae. Due to the biochemical, thermal, and toxic effects of bone cements [polymethylmethacrylate (PMMA)], pain-relief is significantly observed in series studies. Therefore, percutaneous vertebroplasty has become (PVP) the mainstay of therapy for selected patients with osteoporotic compression fractures. A larger amount of cement to increase the stiffness and strength of the collapsed vertebrae has been advocated, but more risk of extravasation remains as a devastating clinical complication. The optimal injected volume of bone cement to reduce the pain remains obscure. Therefore, in our study, a total of twenty-three patients with one level of osteoporotic compression fracture were analyzed for the relationship between cement, volume, and pain-relief.

MATERIAL AND METHODS

Patients

Between January 2005 and April 2007, twenty-three patients comprising of 13 women and 10 men who received a one level vertebroplasty, by the same neurosurgeon (Dr. D.T. Ju), were consecutively enrolled in this study. The mean age was 73 ± years (range, 62 to 87 years). The inclusion criteria were (1) acute severe back pain resulting from osteoporotic compression fractures, (2) painful sensation localized to the fracture level. Exclusion criteria included (1) existence of progressive neurological deficits such as weakness in lower extremities, urinary incontinence, loss of anal tone and radiculopathy, (2) pathological fractures due to malignance or osteomyelitis, (3) multiple level compression fractures, (4) previous spinal surgery, including PVP. Complete laboratory examinations including blood count, electrolyte, bleeding time and coagulation time and systemic screening were performed on all patients. Except anterioposterior and lateral radiographs, pre-operative magnetic resonance images of the spine with contrast were performed on all patients. The level of acute compression fracture and the collapsed cavity were recognized in the T1-weighted images, as the enhancement of collapsed vertebra after gadolinium injection.

Procedure

The patients were placed in a prone position on the examination table. Positional reduction with double barrel placed in the anterior chest wall and hip joint region were performed. The blood pressure, pulse and oxygen saturation were monitored continuously. The optimal injection point was identified by the mobile fluoroscope. After intravenous general anesthesia (no intubation) and local injection, both 3-mm linear incisions were made over the planned sites. Steimann pins were introduced into the vertebral body via the bilateral transpedicular routes under fluoroscopic imaging. A 8-gauge bone marrow biopsy needle was then inserted via the approach routes formed by the previous pin. When the needle was in the optimal position, venography using 5-10ml Isovist was performed via bilateral bone marrow needle under the fluoroscopic imaging before the injection of bone cement. After visualizing of the patent of opacification, PMMA was prepared for optimal viscosity. The PMMA was injected and monitored under mobile fluoroscopy. The injection was immediately stopped if a backflow opacification was observed. During intraoperative venogram, if the contrast could be accumulated in intravertebral body and no leakage of contrast via venous
return or backflow opacification was observed, more low-viscosity bone cement was injected into the intravertebral space. On the contrary, less high-viscosity bone cement was needed if absent of intravertebral cavity or present of leakage of contrast via venous return or backflow opacification. After the PMMA became hot, the bone morrow needles were removed. The incision sites were covered with skin closures.

Data acquisition
The pain level was assessed before PVP with use of a visual analog score (VAS) of 0-10. The VAS is rated from 0 to 10, representing a 0 for no pain and 10 for the worst pain. About 24 hours after vertebroplasty, the VAS of pain was re-assessed by the same method. Postoperative plain X-ray was performed to evaluate the extravasation of the PMMA.

Statistical analysis
The VAS of pain in the all group data before and after the procedure was statistically analyzed using a Student's t-test. The level of statistical significance was set at 0.05

RESULTS
A total of twenty-three patients were enrolled in this study. The patients comprised 13 women and 10 men. The mean age was 73 ± 6.2 years, ranging from 62 to 87 years. A total of twenty-three collapsed vertebrae were treated by PVP. The general data and level of treated fractures were summarized in Table 1. The most common collapsed vertebra was located at T12 (39%), followed by T11 (13%) and L1 (13%). The injected volume of PMMA ranged from 2 mL to 8 mL, with a mean volume of 4.74 mL. Pain relief was archived in all patients (100%). The mean VAS decreased from 8.13 to 2.26 after this procedure (p<0.001).

Table 1. Summary of 23 patients with compression vertebral fractures treated by PVP.

<table>
<thead>
<tr>
<th>Number of patients</th>
<th>Male</th>
<th>Female</th>
<th>Mean age (Range)*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10</td>
<td>13</td>
<td>73 ± 6.2 (62~87)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Level</th>
</tr>
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<tbody>
<tr>
<td>T11</td>
</tr>
<tr>
<td>T12</td>
</tr>
<tr>
<td>L1</td>
</tr>
<tr>
<td>L2</td>
</tr>
<tr>
<td>L3</td>
</tr>
<tr>
<td>L4</td>
</tr>
</tbody>
</table>

*: years, values are mean ± SEM.

Table 2. Pain-score in patients treated by PVP.

<table>
<thead>
<tr>
<th>Group</th>
<th>A (n=11)</th>
<th>B (n=12)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>74 ± 6.0</td>
<td>72 ± 6.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Injected volume</td>
<td>3.55 ±0.69</td>
<td>5.83 ± 0.83</td>
<td>0.52</td>
</tr>
<tr>
<td>Pre-op VAS</td>
<td>8.00 ± 0.77</td>
<td>8.00 ± 0.75</td>
<td>0.44</td>
</tr>
<tr>
<td>Post-op VAS</td>
<td>2.27 ± 0.79</td>
<td>2.25 ± 1.06</td>
<td>0.95</td>
</tr>
<tr>
<td>Change of VAS</td>
<td>5.73 ± 1.01</td>
<td>6.00 ± 0.95</td>
<td>0.51</td>
</tr>
</tbody>
</table>

Group A: injected volume of PMMA less than 5 mL; Group B: injected volume of PMMA 5 mL or more.

Valued are means ± SEM. (Two tailed, unpaired-t test, P<0.05)
These twenty-three patients were divided into two group dependent on the amount of PMMA injected. Group A had an injected volume ranging from 2 mL to 4 mL whereas Group B, 5 mL to 8 mL. In the Group A, there were 11 patients including 6 women and 5 men. The mean age was 74 ± 6.0 years (Range, 65 to 82 years). The mean injected volume of PMMA was 3.55 ±0.69 mL. The preoperative mean VAS of pain was 8.00 ± 0.77. The postoperative mean VAS of pain was 2.27 ± 0.79. The mean decreased VAS of pain was 5.73 ± 1.01. There was a significant difference in Group A with regard to VAS of pain between pre- and post-operative periods (t=18.8, p<0.001), after it was quantified by the paired t-test. Group B consisted of 12 patients including 7 women and 5 men. The mean age was 72 ± 6.5 years. The mean volume of injected PMMA was 5.83 ± 0.83 mL. The mean preoperative VAS of pain was 8.00 ± 0.75. After PVP, the mean postoperative VAS of pain decreased to 2.25 ± 1.06. The mean decreased VAS of pain was 6.00 ± 0.95. Using the paired t-test, there was a significant difference in Group B with regard to the VAS of pain between pre- and post-operative periods (t=21.8, p<0.001), after being quantified by the paired t-test. However, there was no significant difference in the decrease in VAS of pain between Group A and Group B after PVP.

Extravasation of PMMA into the disc space was only observed in three of twenty-three patients (13%). These three patients (25%), all in the Group B, received the injected volume of cement more than 5mL. There was no obvious major postoperative complications such as cement leakage into spinal canal or neurological deficits in any patients.

DISCUSSION
Osteoporotic compression fracture is a common disease leading to severe lower back pain with disability and morbidity, especially in elderly and postmenopausal women(3). In past period, conservative treatment such as bed rest, analgesic medications or physical therapy was the mainstream theory for compression fractures of the spine. With the development of PVP in the mid 1980s(2), it has been proved very efficient in reducing pain from symptomatic vertebral compression fractures(6). Previous studies have shown that PVP is effective and safe in patients with painful compression fractures, with a reported pain relief of 75% to 90%(5,6,9). In our study, 13 of 23 patients (57%) were women. The most common level of compression fractures occur at the thoraco-lumbar junction such as T12 (39%), T11 (13%) and L1 (13%). One day post- PVP, pain-relief was significantly observed in all of our patients (100%). The mean VAS of pain decreased from 8.13 to 2.26 after this procedure. Our results hypothesized that the PVP is considered to be an effective method of reducing pain resulting from compression fractures.

Although the complication rate of PVP accounts for approximately 0-5.4%, it remains a devastating problem for clinical physicians(3). These complications include bleeding, infection, pain, cement leakage, nerve root compression, paralysis, and pulmonary embolization; these are most commonly related to the amount of injected cement(5). Because some authors found no correlation between the injected volume of cement and the therapeutic benefits(3), the optimal amount of injected cement, which is essential to reduce pain and the risk of cement extravasation, remains obscure. In the anatomically accurate finite-element models, Liebschner et al.(4) demonstrated a small amount of bone cement filling, about 14% (3.5mL), was essential to restore the stiffness of a damaged vertebral body to the pre-damaged value, and overfilling would result in cement extravasation. In a study of forty percutaneous vertebroplasties performed for metastases and myelomas,
Cotten et al.\(^1\) found that pain relief could be achieved in 36 of 37 patients despite insufficient lesion filling with smaller volumes of cement (about 2.1 mL). In another series of 70 patients with osteoporotic compression fractures, Yang et al.\(^{10}\) demonstrated that less than 5 mL of PMMA could achieve a positive clinical outcome of pain-relief. In our study, there was no significant difference between these two groups in the decreased pain score. Only 4 mL could reduce the pain score and achieve a positive clinical outcome. Our findings are compatible with previous reports. However, 13\% of patients who were sustained with postoperative cement leakage into the disc space, but no obvious neurological deficit such as neuropathy, radiculopathy or myelopathy was observed.

These cases included in this study were performed by one neurosurgeon and safety is the most important concept in this procedure. Therefore, the injected volume of cement was depended on the texture of the vertebral bodies which demonstrated by the preoperative MR images and intraoperative venogram during operation\(^5\). More cement is needed if vertebral bodies with a large cavity (avascular necrosis) inside and no leakage of contrast medium in the intraoperative venogram\(^1,10\). The space inside the bone marrow is small and thus less bone cement is needed in a patient with no osteoporosis and no avascular necrosis. Otherwise, other factors such as toxic effect, thermal effect, distribution of cement, the percentage of bone cement to vertebra, presence of intravertebral cleft, or anesthesia effect were not discussed in our study, which were considered as the important role in pain-relief in patients with osteoporotic compression fractures treated by vertebroplasty\(^8,10\).

There are limitations to the study. First, the sample size was small and this is a retrospective study. Second, only the VAS of the first postoperative day was assessed. Long-term effects of PVP for the pain-relief were not measured in the longer follow-up. Third, the goal of PVP does not only focus on the fracture-related pain, but also the further kyphotic deformity. Although a reduction in cement injection could reduce the risk of cement extravasation and archive a positive clinical outcome, the restoration of strength and stiffness to prevent adjacent fractures was not determined. Therefore, further large, prospective and longer follow-up studies may be helpful in determining the optimal cement volume for the pain-relief of osteoporotic compression fractures.

**CONCLUSION**

Percutaneous vertebroplasty is an effective treatment in relieving pain in patients suffering with osteoporotic compression fractures. There was no significant difference between the injected volume and the therapeutic effect. Our results demonstrated that a vertebroplasty with only 4 mL of PMMA could achieve a positive clinical outcome.

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