Pain reduction after percutaneous vertebroplasty for myeloma-associated vertebral fractures

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ABSTRACT
INTRODUCTION: Percutaneous vertebroplasty (PVP) is a minimally invasive procedure with cement augmentation of vertebral fractures. It was introduced in 1987 as a treatment for painful haemangiomas and is today mostly used for painful osteoporotic fractures of the spine. Two randomised, double-blinded trials published in 2009 have raised a debate about the efficiency of the PVP treatment. The aim of this study was to assess the safety and efficacy of PVP for vertebral body fractures in myeloma patients.

METHODS: A consecutive group of patients with multiple myeloma who underwent PVP were reviewed. A total of 64 levels were treated on 17 patients during 24 sessions. All procedures were performed in local anaesthesia; no patients complained about discomfort during the procedure.

RESULTS: The median preoperative visual analogue scale (VAS) score was 7.6. Improvement was observed in all patients. The median VAS pain score decreased to 3.2 at the three-month follow-up. The results are statistically significant. No complications were observed either during or after the treatment. We observed cement leakage in 12.5% of the patients, but no patients with cement leakage had clinical symptoms.

CONCLUSION: PVP is a safe and efficient procedure in the treatment of painful vertebral fractures in patients with multiple myeloma. The main advantages are the immediate stabilisation of the fractured vertebral body, reduction of the pain level and the fact that the patient can be discharged after two hours. The procedure can be repeated for several levels, and the pain relieving effect seems to be permanent.

FUNDING: not relevant.
TRIAL REGISTRATION: not relevant.

After the publication of two randomised, double-blinded trials there has been debate about the efficiency of percutaneous vertebroplasty (PVP) as a treatment for osteoporotic fractures in the spine [1, 2]. PVP is a minimally invasive procedure first described in 1987 when a group of French radiologists used the treatment for painful haemangiomas in the spine. During PVP, the vertebral body is instrumented, either transpedicularly or extra-pedicularly, under fluoroscopic guidance, and few cc of polymethyl methacrylate (bone cement) is inserted into the vertebral body [3].

Over the past decade, several studies have been published in which PVP was performed in patients with multiple myeloma or patients with solid tumours in the vertebral bodies. PVP is described as a safe procedure, and the procedure has been performed Th4-S1 in several studies [4-12].

Multiple myeloma is characterised by enhanced function of the osteoclasts, enhanced absorption of the bone, a lack of new bone formation and reduced fracture healing due to the poor osteoblast function [13]. These metabolic changes in the bone are created by the malignant plasma cells in the bone marrow. The incidence is 6/100,000 in Denmark, which equals 300 newly diagnosed patients annually. A third of these patients have a fracture at the time of diagnosis, and the risk of fractures is increased for the rest of their lives [14]. Even with optimal biphosphonate treatment, the annual risk of spontaneous fractures of the spine is 15-24% in myeloma patients [15-17].

The treatment of the painful vertebral body fractures has until now been limited to conservative care with bracing, analgesics and biphosphonate or radiation therapy [18].

PVP was introduced at the Spine Sector at Odense University Hospital (OUH), Denmark, in December 2000, and was initially used in the standard care for patients with osteoporotic fractures of the spine. In August 2004, the first patients with multiple myeloma were treated with a good pain-relieving effect.

The purpose of this study was to evaluate the pain-relieving effect and the complication rate of PVP in patients with multiple myeloma.

METHODS
This is a retrospective study, performed on 17 consecutive patients referred from the haematological department at OUH with vertebral body fractures and severe pain in the 2004-2010 period. The patient demographics are presented in Table 1. The mean age was 62.5 years (46-76 years), ten males and seven females.

A total of 64 levels were treated between Th6 and S2. One patient received PVP in ten levels, two patients in five or six levels.

All patients had X-ray of the spine and a magnetic resonance imaging (MRI) with Short TI Inversion Recov-
Pain levels were recorded with a visual analogue scale (VAS), marked on a 100-mm long ruler before the procedure.

Procedures were performed in local anaesthesia with lidocaine 20 mg/ml placed subcutaneously and at the periosteal border of the bone entry point, and the patients were in prone position on the surgical table. All patients were prepared for general anaesthesia if cement leakage occurred during the procedure.

Several patients had multiple fractures by the time of their first PVP procedure; but to reduce the procedure time and the patients’ discomfort, a maximum of four levels were treated at a time. Two patients in this study had PVP performed in 6-7 levels during two procedures.

At three-month follow-up, X-ray of the full spine was performed, the patients underwent a clinical examination and pain was recorded using the VAS ruler. Cement leakage was noted during the procedure and during examination of the post-operative X-rays. None of these led to neurological complications. One patient developed peroneal paresis 12 weeks after PVP treatment. X-rays did not show any cement leakage, MRI did not reveal any compression of the nerve structures, and the patient gained full function spontaneously. No pulmonary embolism, skin infections or bleeding occurred in this group of patients. The PVP treatment was performed with local anaesthetics, but two patients had their procedure performed in general anaesthesia because they suffered from anxiety. All patients tolerated the procedure well, and no patients reported discomfort due to the procedure.

**DISCUSSION**

Osteolytic lesions in the spine is a common and painful complication to multiple myeloma; even with chemotherapy and biphosphonate treatment, the annual risk of new fractures is 24% [16-17]. The osteolytic lesions are very painful and reduce the patient’s activity of daily living functions to a third of the age-matched levels [9]. A WHO pain study shows that conservative pain treatment is insufficient in 45% of the patients [19].

Multiple myeloma is considered as a chronic disease, but treatment has improved during the past decades so an increasing number of patients are long-term survivors. This increases the number of patients living with multiple myeloma and the annual number of fractures in these patients. Thus, an enhanced focus on pain relieving procedures is needed to ensure the patients’

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**TABLE 1**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yrs, mean (range)</td>
<td>62.6 (46-76)</td>
</tr>
<tr>
<td>Male/female, n</td>
<td>11/7</td>
</tr>
<tr>
<td>Treated levels, n (location)</td>
<td>64 (Th6-S2)</td>
</tr>
<tr>
<td>Levels per session, n, mean (range)</td>
<td>2.7 (1-4)</td>
</tr>
<tr>
<td>Levels per patient, n, mean (range)</td>
<td>3.6 (1-10)</td>
</tr>
<tr>
<td>VAS score, preoperatively, mean (range)</td>
<td>7.7 (6.9-8.3)</td>
</tr>
<tr>
<td>VAS score, post-operatively, mean (range)</td>
<td>3.4 (2.2-4.4)</td>
</tr>
<tr>
<td>Cement leakage, % (n/N)</td>
<td>12.5 (8/64)</td>
</tr>
</tbody>
</table>

**Trial registration:** not relevant.

**RESULTS**

VAS decreased from 7.7 preoperatively to 3.4 post-operatively with a p value < 0.005; see Figure 1.
Few publications are present on PVP treatment in patients with multiple myeloma, and none of them are randomised. The pain reduction in our study is equal to that reported in previously published studies, the numbers of cement leakages are lower, and some studies report a leakage rate of up to 75% [20]. We recorded 12.5% leakages, but our patients were only evaluated with X-ray and not CT, as used in other studies. Follow-up in this study was three months, but other studies show pain relief for a period of up to 41 months after the procedure [10]. Besides the pain-relieving effect, there seem to be a disease-controlling effect, since the PVP treatment stops the plasma cells from proliferating further in the vertebral body.

Serious complications to the PVP treatment is rare, but can occur. The PVP treatment should only be performed in a hospital with spine surgeons available because acute decompression of the spinal canal can be necessary in cases with severe leakage to the spinal canal, causing neurological complications. All patients should be prepared for general anaesthesia should such leakage occur. The patients in this study only reported minor discomfort during the procedure, and the procedure was performed with local anaesthetics in most of the patients to ensure a good monitoring of the nerve structures during the procedure. The only disadvantage associated with treating the patients in local anaesthesia is the four-level limit per procedure which is required to reduce the procedure time and the patient’s discomfort. The main advantage of this procedure is the immediate stabilisation of the fracture and the short procedure time, which allows the patients to mobilise within two hours after the PVP. All patients are discharged 2-4 hours after the treatment, and significant pain relief is achieved in all patients.

CONCLUSION

PVP is a very promising treatment for patients with multiple myeloma and painful vertebral fractures. Until now, this group of patients has only been treated with analgesics and bracing, which has reduced their daily function. The procedure is safe, there is no increased risk of cement leakage in this group of patients, and the procedure can be repeated at different levels if the patient suffers from fractures at other levels of the spine. One patient in this study was treated at ten levels, and has completed a five-year follow-up and reported back pain equal to a VAS score of two. MRI of the patient showed no signs of plasma cell proliferation in the treated levels. X-ray shows PVP performed in ten levels, and an acceptable sagittal balance (Figure 2).

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ACCEPTED: 2 September 2014
CONFLICTS OF INTEREST: Disclosure forms provided by the authors are available with the full text of this article at www.danmedj.dk.

LITERATURE
7. Pfugmacher R, Schleicher P, Schroder RJ et al. Maintained pain reduction in five patients with multiple myeloma 12 months after treatment of...