Prospective Evaluation

Percutaneous Vertebroplasty for Osteoporotic Fractures

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Background: Vertebral augmentation has been widely used to treat vertebral body compression fractures caused by varied pathologies. The lifetime risk of a vertebral body compression fracture is 16% for women and 5% for men, and exponential increase of osteoporotic fractures worldwide.

Purpose: To determine the efficacy and durability of percutaneous vertebroplasty for the treatment of back pain associated with osteoporotic vertebral fractures.

Design: A prospective study.

Materials and Methods: A prospective evaluation of pain relief in 30 patients, with mean age of 73.7 years, who underwent percutaneous injection of polymethyl methacrylate into 54 vertebrae under fluoroscopic guidance over a period of 35 months was done. Before the procedure and at follow up, patients were asked to quantify their pain on a visual analogue scale.

Results: The procedure was technically successful in all the patients. Mean duration of follow up was 21.5 months (6-44months). Ninety-seven percent of the patients reported a significant relief 24 hours after the procedure. Ninety-two percent reported significant improvement in back pain, previously associated with a compression fracture, as well as improved ambulatory ability. Before vertebroplasty, the VAS score was 8.91+/- 1.82 compared to a score of 2.02+/- 1.95 at follow up. The mean difference in VAS score was significant (p<.0001). One patient had an asymptomatic epidural leak of PMMA, however did not require any further intervention.

Conclusion: Percutaneous vertebroplasty of symptomatic osteoporotic vertebral compression fractures is a minimally invasive procedure that provides immediate and sustained pain relief in patients with refractory pain.

Key words: Compression fracture, osteoporosis; pain, vertebroplasty, polymethylmethacrylate

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Vertebral augmentation has been widely used to treat vertebral body compression fractures caused by varied pathologies including hemangioma, multiple myeloma, osteolytic metastases, and primary or secondary osteoporosis (1,2). The technique of vertebroplasty was originally developed by Deramond and Galibert, a French radiologist and a French neurosurgeon, in 1987, and it uses a percutaneous transpedicular approach to introduce polymethlymethacrylate (PMMA) cement into the vertebral body (3). The lifetime risk of a vertebral body compression fracture is 16% for women and 5% for men, and the incidence of osteoporotic fractures is anticipated to increase

fourfold worldwide in the next 50 years (4). In addition to pain, spinal column instability may also be present. Regardless of etiology, treatment for compression fractures has been largely conservative and directed toward pain control, usually consisting of narcotic analgesia, bedrest, and back bracing. For osteoporosis, current preventive drug regimens, including hormonal replacement therapy, bisphosphonates, and calcitonin, often are not prescribed until the disease has been diagnosed by the presence of a fracture. Percutaneous vertebroplasty has been used as a therapeutic alternative for the treatment of pain associated with compression fractures (5-7). Few prospective studies with long-term follow-up have been published. The purpose of our study was to determine the efficacy of percutaneous vertebroplasty for the treatment of back pain associated with vertebral body compression fractures and to evaluate the extent of pain relief afforded by the procedure.

Materials and Methods

A prospective study was undertaken over a 35-month period in which 30 consecutive patients with senile osteoporosis were treated with PVP. Institutional review board approval was obtained. Twenty-seven women and 3 men with a mean age of 73.7 years (57–90 y) were treated. Fifty-four vertebral bodies were treated (24 thoracic, 30 lumbar). The indication for percutaneous vertebroplasty was painful vertebral body compression fracture(s) refractory to medical therapy. Failure of medical therapy was defined by minimal or no pain relief with the administration of analgesics. All patients were neurologically intact and suffered from severe back pain refractory to analgesia. All patients were evaluated before the procedure. Medical history was investigated and a physical examination was performed. Plain radiographs or magnetic resonance images were evaluated in a preprocedural consultation; before therapy, the location of the patient's pain was correlated with physical examination under fluoroscopy. The amount of vertebral compression was determined by comparing the minimum height of the affected vertebral body on lateral radiographs to the expected normal height at that level, determined by substituting the vertical measurement of the closest adjacent normal vertebral body. The maximum degree of a compression fracture treated was 75%. The average degree of compression was 50% (range 25%–75%). Patients with a loss of vertebral height greater than 75% or significant spinal stenosis (>25%) at the level of the fracture were not considered for treatment. Our population consisted of three men and 27 women with a mean age of 73 years (range, 57–90 y). Fifty-four PPV procedures were performed for thoracic or lumbar compression fractures in these 30 patients. A single vertebral level was treated in 21 cases. Multiple levels were treated in 14 patients: 8 patients had 2 levels treated, 3 patients had 3 levels treated, 2 patients had 4 levels treated, and one patient had 5 levels treated. Two treatment sessions were necessary in 7 patients, and 3 treatment sessions were required in 2 patients.

Technique

Informed written consent was obtained from each patient before the procedure. The procedure was performed under intravenous conscious sedation. Blood pressure, electrocardiographic readings, and oxygen saturation were monitored continuously. The patients were given 1 g cefazolin intravenously before the vertebroplasty procedure. The technique employed in all cases was essentially that described by Jensen et al (6) and Deramond et al (7). The patients were placed in a prone position on the operating table. The involved vertebrae were identified fluoroscopically and the overlying skin was prepared and draped in the usual sterile fashion. Local anesthesia was applied to the skin and deep structures, including the periosteum of the bone at the intended site of entry by the bone needle. In our series, alternating and nearly simultaneous injection through both pedicles was performed instead of treating the hemivertebrae in sequential fashion. A total of 4–8 mL of PMMA were injected into each treated vertebral body. After the procedure, all patients were observed in the supine position for 1 hour, followed by sitting for 1 hour, and then standing as tolerated.

The patients' pain levels were assessed before vertebroplasty with use of a visual analog scale (VAS) of 0–10. Patients were asked, "on a scale of 0 to 10, with 0 being no pain and 10 being the most severe pain you have ever had, where is your pain level?" At 12–24 hours post-vertebroplasty, patients were seen and asked to subjectively report their pain as being improved, unchanged, or worse than before the procedure. Patients were seen in a clinic periodically thereafter for continued data collection. Patients were also asked whether the procedure had relieved the pain for which they were treated, if they were satis-

fied with the procedure, and, if needed, whether they would have vertebroplasty performed again. They were also asked whether they still took pain medications for back pain and if their ambulatory ability had improved. Finally, a VAS score was again obtained. Minor adverse events were defined as any unexpected or undesirable clinical occurrence within the first 2 weeks after vertebroplasty but which required no immediate or delayed surgical intervention. Serious adverse events were defined as any unexpected or undesirable clinical occurrence that required surgical intervention or which resulted in death or significant disability after vertebroplasty. One of our patients had a small epidural leak of PMMA, but being asymptomatic, did not require any further intervention. Data were analyzed with a paired Student t test to ascertain statistical significance.

Results

The etiological factors for vertebral compression fractures were osteoporosis in all our patients as was confirmed by pathologic examination of aspiration biopsies. Vertebral augmentation procedures were made to levels thoracic in 24 and 30 in lumbar vertebrae. We were technically successful in all treated vertebrae. At 12–24 hours, patients were seen and asked to subjectively report their pain as being improved, unchanged, or worse than before the procedure. Ninety-seven percent (29 of 30 patients) reported improvement and one patient reported his condition unchanged. There was one minor adverse event and no major adverse events in our patient population. One patient had a small epidural leak of PMMA which was asymptomatic. Follow-up was obtained in all the 30 patients with a mean follow-up of 21.5 months (6–44 months). Ninety-three percent (28 of 30 patients) reported improvement in their back pain for which vertebroplasty was performed. Ninety-three percent of patients also reported improved ambulatory ability after vertebroplasty. Ninety percent of patients (26 of 30 patients) were able to decrease the amount of oral pain medication that they required on a daily basis. All patients were satisfied with percutaneous vertebroplasty and all patients reported that they would undergo the procedure again. Before vertebroplasty, there was a mean VAS score of 8.91 $\pm$ 1.12. At 21.5 months follow-up, the mean VAS score was 2.02 $\pm$ 1.95. This difference was significant ($P \pm .0001$). Restoration of the VB heights was assessed by x-ray film; CT and MRI were taken when needed. In the patients treated the mean preoperative kyphotic angle was 11.2° ± 8, whereas the mean postoperative kyphotic angle was 8.3° ± 9. We achieved an average of 2.9° of improvement in the kyphotic angle of the VB after the procedure. The percentage of the vertebral compression improved from 30.8% ± 22 to 21.6% ± 24 after the procedure.

Discussion

Osteoporosis is a systemic disorder characterized by decreased bone mass, loss of bone strength, and micro architectural deterioration of the skeleton, leading to bone fragility and increased fracture risk. A steep increase in the incidence of vertebral fractures with increasing age and a higher incidence of vertebral fractures in women than in men has been observed (8). Osteoporotic compression fractures may result in severe persistent back pain. The pain can often limit mobility and impact the patient's quality of life. Conservative treatment with external bracing, analgesics, and bedrest may be all that is required for pain control in certain patients. However, patients with severe osteoporosis may continue to experience protracted pain despite these conservative measures. Conventional treatment of vertebral fractures is typically nonoperative, and, until recently, has focused on the alleviation of acute pain with narcotic and nonsteroidal anti-inflammatory agents. Pharmacologic intervention to improve bone marrow density has gained widespread acceptance in recent years (9). Because of significant risk caused by comorbid conditions that are common in this elderly patient population, as well as technical difficulty achieving adequate fixation of hardware within osteoporotic bone, surgical intervention is rarely undertaken (10). Pain and diminished mobility, loss of employment, and narcotic addiction are not the only potential sequelae of vertebral compression fractures. Patients may develop urinary retention, ileus, or spinal cord compression. Long-term effects can include kyphosis, insomnia, and depression (11). The actual cost related to this illness may therefore be underreported. PMMA has been used in spine stabilization for metastatic disease in earlier series (12-14) and for treatment of primary bone lesions such as angiomas and giant cell tumors (16,17). The percutaneous injection of PMMA into collapsed or partially destroyed vertebrae is a relatively new procedure first described in the French literature (17). Complications after percutaneous vertebroplasty occur with extremely low frequency. The complication rate in osteoporotic fractures is 1%–3% and as high as 10% in treatment

of metastatic lesions (3,18). Jensen et al (7) studied 29 patients with 47 vertebral body levels treated and reported only 2 complications in this series. The complications were single nondisplaced rib fractures (7). Potential complications include migration of cement into the epidural venous plexus or leakage through a fracture in the spinal canal resulting in spinal canal or nerve root compression, a complication that can be mitigated by careful biplane fluoroscopic observation during PMMA deployment. Other possible complications include fractures of posterior elements or pedicles, hemorrhage, and infection. The results of percutaneous vertebroplasty are very exciting. Deramond and colleagues (3) reported on 80 patients with rapid and complete pain relief in more than 90% of osteoporotic cases. The follow-up in this patient population ranged from 1 month to 10 years with evidence of prolonged pain relief. Martin et al (19) reported on 40 patients with 68 treated vertebral body segments. They reported a success rate of approximately 80% and a very low complication rate. Recent small series have demonstrated consistent and significant success with use of PPV to relieve the pain that results from osteoporotic vertebral compression fractures (3,12). Significant pain relief is achieved in 75%–90% of patients with benign fractures (3,7,20). PPV has also resulted in increased mobility and a diminished requirement for analgesics (7). Whether pain relief is caused primarily by structural reinforcement of the fractured vertebral body or by analgesia associated with a chemical or thermal effect of the methacrylate has not yet been determined; however, the occurrence of a repeated fracture (20) at an adequately treated vertebral body level has not been reported and did not occur in our series. Most previous studies of PPV have been retrospective and have reported only short-term results. Previous reports on the efficacy of PPV suggest that the treatment effect does not decrease over time. At a mean follow-up of 281 days, Jensen et al (7) reported durable benefit in 23 of 26 patients who initially experienced pain relief and increased mobility in the few days after treatment with PPV. When followed for an average of 18 months (21) and 6 months (22) after PPV, some patients developed new pain, but none reported a return of the pain for which they had initially sought treatment. In another study, Grados et al (23) followed 25 patients for a mean of 48 months (range, 12–84 mo). Pain assessed by visual analog scale decreased significantly (P _ .05) from a mean of 80 mm at baseline to 37 mm at 1 month and 34 mm at the time of maximum follow-up. Cortet et al (24) found significant improvement in pain with a trend of decreasing scores over time (days 3, 30, 90, and 180 after PPV) in five of six dimensions of the Nottingham Health Profile: pain ($P \pm .01$), physical mobility ($P \pm .05$), emotional reactions ($P \pm .05$), social isolation ($P \pm .05$), and energy ($P \pm .05$). We followed patients in our series for a mean of 21.5 (6-44) months after treatment and assessed the durability of PPV with a brief long-term follow-up questionnaire. Our study includes 30 patients with follow-up obtained in all patients. Before vertebroplasty, there was a mean VAS score of 8.91 ± 1.12. At almost 22 months follow-up, the mean VAS score was 2.02 ± 1.95.

Conclusion

Percutaneous vertebroplasty is a minimally invasive therapy in the treatment of painful compression fractures that are refractory to conservative treatment. Although our series is a small one in size, we have shown in our prospective study of 30 patients, the procedure restores patient mobility and provides immediate and extended pain relief of symptomatic vertebral body compression fractures.

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