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Abstract- One hundred and fifty-six patients with 263 compression fractures and suffering from disabling back pain refractory to analgesic therapy were treated and included in this study. The age of the subjects ranged from 42 to 94 years (mean age: 72.8), and medical treatment period ranged from one to twelve months. The technique involves the percutaneous puncture of the involved vertebra via a transpedical approach followed by the injection of polymethylmethacrylate (PMMA) into the compressed vertebra. The patients were asked to quantify their degree of pain on the Huskisson's visual analogue scale and the clinical symptoms and surgical results were assessed. The procedures were technically successful for all patients, and no complications relating to either anesthesia or the surgical procedure arose. Pain decreased from 83 \pm 15 mm at baseline to 38 \pm 22 mm at the first postoperative day, and 34 \pm 19 at 3 month. The reduction in pain were statistically significant (P < 0.05). All patients were able to return to their previous activities and lift quality.

Key Words: Vertebroplasty, Osteoporosis, Vertebral compression fracture, Polymethylmethacrylate

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INTRODUCTION

With the aging of the Taiwanese population, the incidence of vertebral compression fractures due to preexisting primary or secondary osteopenia increases each year. Vertebral fractures frequently produce persistent, often excruciating, pain, which may significantly influence patients' morbidity and impair their quality of life. External bracing, analgesics and bed rest may be all that could have been prescribed for these patients in the past. However, for some patients, a constant need for narcotics and an extended period of bed rest may be neces-

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sary for effective pain control, and such activities can possibly induce further osteoporotic vertebral compression fractures^(1,2).

Polymethylmethacrylate (PMMA) vertebroplasty is a relatively new procedure by injecting PMMA into the vertebral body of a damaged vertebra for pain relief and strengthening previously weakened vertebra⁽³⁻⁷⁾. Vertebroplasty has been shown to be a promising novel technique for the treatment of aggressive angiomas, bone metastases, and multiple myeloma eliciting rapid and marked pain relief⁽³⁻⁷⁾. It is a useful and safe procedure for treating persistent, painful osteoporotic frac-

Reprint requests and correspondence to: Shih-Tseng Lee, MD. Department of Neurosurgery, Chang Gung Memorial Hospital, No. 5, Fu-Shin Street, Kweishan, Taoyuan, Taiwan. E-mail: yun0710@cgmh.org.tw tures of a vertebra⁽⁸⁾. The percutaneous vertebroplasty has previously reported a figure of 90-100% pain relief for the treatment of osteoporotic fractures^(5,9,10).

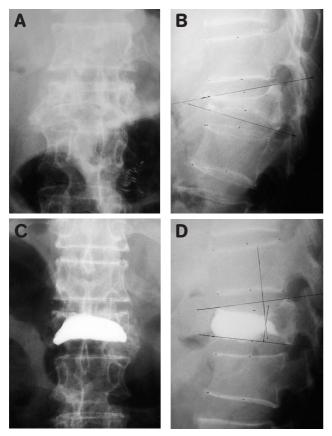


Figure . This is an example of an L1 osteoporotic compression fracture with the preoperative anteroposterior (A), lateral (B) views, and the postoperative anteroposterior (C), lateral (D) views.

PATIENTS AND METHODS

Patient selection was limited to those with focal, intense, and deep pain associated with plain-film evidence of a new or progressive vertebral compression fracture. Often, the experience of pain radiated along the ribs to the chest or abdomen. Physical examinations were conducted to determine each patient's general condition and the ability of the subject to tolerate lying in a prone position for one to two hours. Neurological examination was performed to evaluate possible radicular symptoms. All patients were subject to a set of anteroposterior, lateral, and dynamic radiographs and revealed evidence of progressive, or recently occurring, vertebral-body compression fractures. The relative dimension of fractures appeared to correspond well to the respective level of pain. Typically, patients with such injuries were initially managed with bed resting and analgesics for pain control. Afterwards, some of the patients became stable and could ambulate with bracing. If pain persisted and follow-up radiographs indicated an increased kyphotic deformity, vertebroplasty was considered to be a viable surgical option on a delayed basis. In such situations, spinal computer tomographic scans and/or magnetic resonance images were typically obtained to assess the relative degree of continuity of the posterior vertebral wall and to exclude the potential for other causes of pain.

Percutaneous vertebroplasty procedure was performed under strict sterile conditions in the hospital's operating rooms with monitoring. After general endotracheal anesthesia, the patients were putin the prone position. The vertebral body (to be treated) was localized using a digital fluoroscope and the skin overlying the area was sterile and draped. The fluoroscope was used to monitor the procedure in both anteroposterior and lateral directions if necessary. An 11-G Match-Ground Bevel-Tip introduction needle (Stryker Instruments, Kalamazoo, MI, USA) was positioned with its tip in the centre of the beam and the lateral fluoroscope should indicate the needle tip at the level of the upper and midpoint of the pedicle. The needle was progressively advanced through the pedicle and into the vertebra. Finallythe tip of the needle was typically placed within the anterior half of the vertebral body.

Following the formula of Deramond⁽¹⁰⁾ for the preparation of the cement, 5 ml of sterile barium sulfate powder was placed into a disposable plastic bowel and pulverized immediately prior to mixing, as the powder had a tendency to clump. PMMA powder (Osteobond, Zimmer, Warsaw, Indiana, USA) of 15 ml was mixed with the pulverized barium sulfate subsequently and grounded with a pestle. Later, PMMA liquid agent (monomer) of 10 ml was added to the powder (copolymer), and the slurry was mixed with a tongue blade until it became thin and semi-liquid. Once the material was sufficiently mixed and the desired consistency was obtained, the mix was poured into a 10 ml Luer-Lok syringe. With the 10ml syringe held upright, the plunger was reinserted and the contents were advanced to the syringe tip. After the air has been expelled, the filled 10 ml syringe was loaded into the screw syringe compressor. The injection of the cement was performed under lateral and/or anteroposteral fluoroscopic guidance. Injection was continued until the bone cement was either refluxing back from the syringe plunger or when cementing-material leakage was noted. With the injection was completed, the needle was removed and hematostasis at the puncture site was accomplished by gentle manual compressing the surgical site for 10 minutes.

The clinical symptoms and surgical results were assessed by asking the patients to quantify their degree of pain on the Huskisson's visual analogue scale (VAS: 0 mm for no pain; 100 mm for theworst pain possible) before vertebroplasty, on the third day after vertebroplasty, and 3 months after the procedure. The group data of VAS values were compared with Wilcoxon signed rank non-parametric test.

RESULTS

One hundred and fifty-six patients (with 263 compression fractures), who were suffering from disabling back pain refractory to analgesic therapy were treated and analysed for this study. The age of study subjects ranged from 42 to 94 years (mean: 72.8) and medical treatment period ranged from one to twelve months. All 156 patients exhibited fractures associated with agerelated osteopenia (Table 1), and experienced severe pain that limited their mobility and substantially altered their quality of life.

The surgical procedures used were technically successful for all patients, as defined by effective transpedicular puncture of the vertebral body and the injection of PMMA, resulted in no complications relating to anesthesia or the overall surgical procedure. The level and number of fractured vertebrae are shown in Table 2. The mean cementing-material injection time was 12 minutes. For forty-six vertebrae (17.5 %), postoperative radiographs revealed evidence of PMMA leakage through the endplate fracture site into either the disc space or the paravertebral space, without any evident

Table 1. Clinical summary of	156 patients treated with percuta-
neous vertebroplasty	

Factor	Cases	
	No.	%
Sex		
Male	37	23.7
Female	119	76.3
Age(Yrs)		
41-50	6	4
51-60	7	4
61-70	35	23
71-80	63	40
81-90	39	25
> 91	6	4
Offending level		
Single level	55	35
Double level	95	61
Triple level	6	4

Table 2. Level of treated compression fracture

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Level	Number	%	
T5	2	0.7	
T6	4	1.5	
T7	3	1.1	
T8	5	1.9	
Т9	5	1.9	
T10	8	3.0	
T11	24	9.1	
T12	55	20.9	
L1	71	27.0	
L2	34	12.9	
L3	19	7.2	
L4	23	8.7	
L5	10	3.8	

clinical symptoms.

Pain decreased from 83 ± 15 mm at baseline to 38 ± 22 mm on the first postoperative day, and 34 ± 19 on 3-month after the procedure. The reduction in pain were statistically significant (P < 0.05). There was no statistical difference between the degree of pain at the first postoperative day and after 3-month of follow-up. All patients were able to return to their pre-injury activities and the quality of life.

DISCUSSION

Osteoporosis is a major health problem, and fractures are the primary source of morbidity⁽¹¹⁾ in producing severe musculoskeletal pain in the elderly⁽¹²⁾. The true incidence of osteoporotic spine fractures is difficult to determine because many are asymptomatic and diagnostic criteria are not standardized. However, it is clear that the incidence of osteoporotic spine fracture is age and sex-dependent⁽¹³⁾. The pathophysiology of osteoporosis is unclear, and may represent a normal aging process, a consequence of senescence^(14,15). Osteoporosis can be broadly classified as primary or secondary depending on identifiable causes, such as immobilization or chronic corticosteroid therapy. The most commonly encountered form of osteoporosis is primary involution osteoporosis, which includes both postmenopausal osteoporosis and senile osteoporosis.

Osteoporotic compression fractures usually presents acute, excruciating back pain. The onset is not usually a result of an obvious trauma but is precipitated by minor stress such as bending forward. Loss of height and kyphotic deformity following osteoporotic compression fractures may produce muscle spasm, stress on ligaments, and/or nerve root irritation, which, in turn, produce chronic back pain. Severe neurological deficits following osteoporotic fractures are unusual but may develop in a delayed fashion. Fractures, which are frequently multiple, occur most commonly at the thoracolumbar junction, followed in order of frequency by the middle thoracic and lower lumbar vertebrae^(16,17).

PMMA vertebroplasty is a new procedure. Reported complications of the treatment ranged between 0 and 5.4%, most of which were relatively minor, with multidisciplinary approaches to patient selection and management being essential⁽¹⁸⁻²⁰⁾. Two classes of patients are considered to be appropriate for vertebroplasty treatment, those with chronic pain refractory to medical therapy and bracing and those with severe, disabling pain as elicited by the more acute fractures^(9,20). However, the treatment of ambulatory patients with acute fractures remains controversial. Very severe cardiopulmonary disease cases and uncorrectable coagulopathy are contraindications to vertebroplasty.

There are different hypotheses with respect to the pathophysiology of pain relief following vertebroplasty, including the stabilization of microfractures, the reduction of mechanical stress, the destruction of neural endings by the cement's mechanical, chemical, cytotoxic and thermal activity as well as by its anti-inflammation action^(8,21). For patients of this study, the symptoms improved via the stabilization of the fractured vertebral fragments, the enhancement of vertebral strength and a reduction in mechanical stress to the damaged vertebra. Therefore, percutaneous vertebroplasty is an alternative procedure for the treatment of osteoporotic compression fractures, especially in the elderly. When performed by experienced surgeons or neuroradiologist, percutaneous vertebroplasty can eliminate the need for major spinal surgery and, through prompt pain relief, the early mobilization and effective rehabilitation of a compression fracture patient remains a clear possibility for the elderly polymorbid patients.

Percutaneous vertebroplasty, however, is not an absolutely safe procedure. It inherits considerable dangers from the leakage of acrylic cement into the venous system or through a gap of the fractured vertebra into spinal canal. Cement leakage into the azygous vein or into the inferior vena cava with migration into the lung is a life-threatening complication of vertebroplasty^(19,21). Typically, cement spillage occurs through the basivertebral plexus into the anterior internal venous plexus leading to the progressive accumulation of acrylic material within the spinal canal. Bone cement leakage and consequent damage to neural structures by either compressive or thermal effects arising during the polymerization of the methyl methacrylate are well known sources of complications^(19,21). Although the pathophysiology of neural damage by a direct compressive effect of bone cement is probably the major source of neurological complication, the compromise of neurological function by thermal and chemical effects is still a controversal topic^(6,22,23). Paravertebral and disc spillage are asymptomatic and often arise in cases of severely compressed vertebrae. Malposition of the needle tip may lead to intradural filling of bone cement and subsequently damage of the neural tissue. The infection of treated vertebrae is another serious problem, and this can be eliminated by aseptic operative procedure. Usually, the posterior extrusion of bone cement into the spinal canal can be eliminated by assuming the appropriate needle position, and steady injection of cementing material, as well as the continuous and extensive monitoring of the surgical procedure

with the fluoroscope. In this study, percutaneous vertebroplasty procedure appeared weretolerated in all patients with no clinically-relevant side effects. Although leakage of the cement outside the vertebral body was observed for 46 patients (17.5%), the frequency was less than those were reported elsewhere, which ranged from 26% to $73\%^{(3-8)}$. Experience with vertebroplasty has indicated that the initial slow and steady introduction of acrylic cement and frequently fluoroscopic check might reduce the risk of leakage, probably by obliterating the major connection to the basivertebral venous plexus.

In conclusion, the study suggests that vertebroplasty provides the potential to actually achieve a good outcome for patients with a vertebral compression fracture due to osteoporosis, the condition causing severe and persistent pain. Percutaneous vertebroplasty is able to eliminate the need for and the risk of major spinal surgery. Because prompt pain relief, the early mobilization and effective rehabilitation of a vertebral compression fracture remains a clear possibility for elderly polymorbid patients. Further studies, particularly controlled studies incorporating the long-term follow-up, are required to establish consensus for indications of vertebroplasty.

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