Pain Reduction in Patients with Painful Vertebral Compression Fractures undergoing Percutaneous Vertebroplasty

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Background: *Vertebral compression fracture (VCF) is the most common complication of osteoporosis. It results in significant mortality and morbidity. Percutaneous vertebroplasty (PVP) is a procedure that injects percutaneously bone cement into a collapsed vertebra.*
Objective: *To determine the results of PVP in pain reduction from osteoporosis VCF and its complications.*
Material and Method: *Thirty-five patients (34 women, 1 man, 48-98 years) with persistent back pain due to VCF underwent 66 percutaneous injection of polymethylmethacrylate (PMMA) into the vertebrae (27 thoracic levels, 39 lumbar levels) under fluoroscopic guidance between December 2003 and July 2005. Severity of back pain was assessed by using visual analog scale (VAS) before and after the operation.*
Results: *Thirty-two patients (91%) reported significant pain relief, the mean VAS of 35 patients, before PVP and after an 8-week period, post-operatively, were 6.9 $\pm$ 1.8 and 2.0 $\pm$ 1.8 ($p = 0.001$). There was only one minor complication. Two patients experienced intermittent sciatic shooting pain. This improved and disappeared within three months.*
Conclusion: *PVP is a minimally invasive procedure providing safe, immediate, and sustained pain reduction in patients with refractory pain and disability caused by painful VCF.*

Keywords: *Vertebral compression fracture, Percutaneous vertebroplasty*

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Percutaneous vertebroplasty is a percutaneous injection of low viscosity bone cement (Poly Methyl Meth Acrylate: PMMA) into an osteoporotic vertebral compression fracture or diseased vertebra under radiological guidance and local anesthesia. It was described by Galibert in 1987 for the treatment of aggressive vertebral angioma[1]. Presently, the indications have been extended to the treatment of osteoporotic compression fractures, vertebral myeloma, and vertebral metastasis[2,8]. Percutaneous vertebroplasty provides pain relief and strengthening of the weakened vertebra[9]. It is increasingly accepted as one of the alternative treatments for intractable back pain due to vertebral compression fracture. The purpose of the present study was to determine the effectiveness and safety of percutaneous vertebroplasty in patient with osteoporotic vertebral compression fracture induced pain.

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Material and Method

A retrospective review was conducted at the orthopedic division, Charoenkrung Pracharak Hospital in painful osteoporotic vertebral compression fracture between December 2003 and July 2005. Thirty-five patients (34 women 1 man) with an age range of 48 to 98 years (mean 71.6 $\pm$ 10.7 years) (Table 1) that underwent 66 vertebroplasty (27 thoracic levels, 39 lumbar levels) (Table 2) were enrolled. The duration of the painful fracture was extremely variable, ranging from a few weeks to more than one year. These patients did not respond to conservative treatments, including all types of medicines, exercises, and osteoporotic medications.

Indication for vertebroplasty was focal, intense and intractable back pain without definite neuro-

Table 1. Summary of demographic characteristics in patients undergoing vertebroplasty

Characteristic	Value
No. of patients	35
Sex (female : male)	34:1
Age range (yrs.)	48-98
Mean (yrs.)	71.6 $\pm$ 10.7
Duration of symptom: range (mos.)	2.5-24
Mean duration of symptom (mos.)	7.54
Severity of vertebral collapse (range and average)	20%-80% (54.0%)
Follow up: range (mos.)	3-20
Mean (mos.)	7.41

logical deficit, and progressive painful VCF. Retropulsed bone did not prohibit the procedure if the patient did not have radicular pain. The extent of vertebral collapse was measured from the height of the maximum collapse on lateral radiographs or mid-sagittal magnetic resonance images (MRI). The percentage of collapse compared with the average vertebral body height of the above and below, was then calculated. If they were unavailable, the height was estimated by measuring the next normal-appearing adjacent vertebral body. An MRI was performed routinely to see if there had been edema within the fracture vertebra except on patients identified with only one symptom and progressive vertebral compression fracture.

Percutaneous vertebroplasty was performed in the operating theater under sterile technique using C-arm image intensifier as guidance. The patient was placed prone for both thoracic and lumbar vertebroplasty. The skin, subcutaneous tissue, and periosteum over the pedicle were anesthetized by injection of 1% Lidocaine HCI with epinephrine 1:100,000. After creating a small skin incision, a 10-gauge needle was advanced until its tip reached in the pedicle ring under fluoroscopic guidance. The needle tip was pushed through the cortex and traversed the center of the pedicle, placing at anterior 1/3 of vertebral body, close to the midline. Bilateral pedicular injection was applied to fill the low viscosity PMMA in both sides of the vertebral body. By using a cement injector, the cement flow was steady and powerful. The extent of vertebral collapse, location of involved vertebra, clinical outcomes, VAS, complications on clinical, and radiographic appearance were concerned.

Patients were evaluated for pain using VAS before and after vertebroplasty at first and every 4 weeks. The VAS was calculated by analysis of variance and *post hoc* with repeated measurement by the pair t-test method. A p-value of less than 0.05 was considered statistically significant.

Results

The causes of vertebral compression fracture were fall 45.71% (16 of 35), traffic accident 5.71% (2 of 35), lifting or twisting 14.29% (5 of 35), and undetermined 34.29% (12 of 35) (Table 3). The average severity of vertebral body collapse was 54.0% (range 20%-80%) of the original height (Table 1). Involved vertebrae were located from T8 to L5 level (Table 2). Radiographic complications included PMMA leakage into the adjacent disc 14.29% (5 of 35), paravertebral soft tissue

Table 2. Level of vertebral compression fracture

Level	No. of vertebroplasty segment	Percentage
T8-10	7	10.61
T11-12	20	30.30
L1-3	29	43.94
L4-5	10	15.15
Total	66	100.00

Table 3. Causes of vertebral compression fracture

Cause	Case	Percentage
Fall	16	45.71
Traffic accident	2	5.71
Lifting or Twisting	5	14.29
Undetermined	12	34.29
Total	35	100.00

14.29% (5 of 35), epidural space 2.86% (1 of 35), and new adjacent vertebral compression fracture 5.71% (2 of 35) (Table 4). There were no major radiographic complications, and no patient required follow-up surgery. At complete clinical follow-up, 33 patients were still alive, while two patients died from other causes.

The follow-up period ranged from 3 to 20 months (mean 7.41 months). The mean VAS before vertebroplasty was 6.9 ± 1.8. The pain score decreased to 4.6 ± 2.3 (p = .001) at 1 week, 2.9 ± 1.8 (p = .001) at 4 week, 2.0 ± 1.8 (p = .001) at 8 weeks, and 1.3 ± 1.2 (p = .0001) at 16 weeks, post operatively (Table 5). Pain score was reduced to 0-3 in 34.29% (p = .001) of patients at 1 week, 68.57% (p = .001) at 4 weeks, 80.00% (p = .001) at 8 weeks and 91.43% (p = .0001) at 16 weeks (Table 6).

Table 4. Complications of vertebroplasty

Complication	Case	Percentage
Serious	0	0
Leakage of bone cement	11	31.43
- into disc space	5	14.29
- into epidural space	1	2.86
- into paravertebral soft tissue	5	14.29
Infection	0	0
New adjacent VCF	2	5.71

Discussion

Percutaneous vertebroplasty is performed in patients with vertebral compression fracture who presented with severe back pain, restricted mobility, and required potent analgesics. Especially, in patients with acute osteoporotic compression fracture in whom pain persisted despite full medical treatment for a period of time. Therefore, percutaneous vertebroplasty can be helpful[10-13]. Pain relief is expected in about 53%-97% after 24 hours, post operatively[14,15]. Marked or complete pain relief was demonstrated in more than 77% of patients with vertebral metastasis or Myeloma and 95% of patients with osteoporotic compression fracture[16]. In the series of 29 patients with osteoporotic

Table 5. Visual analog score in vertebral compression fracture patients

	Visual analog score					
	Pre-op+	Post-op+ (p-value)				
		1 week	4 week	8 week	16 week	24 week
Mean	6.9 ± 1.8	4.6 ± 2.3**	2.9 ± 1.8**	2.0 ± 1.8**	1.3 ± 1.2***	0.73 ± 0.9***
Minimum	4.0	0	0	0	0	0
Maximum	10.0	10.0	7.0	8.0	4.0	3.0

+ op = operation
** p-value = 0.001
*** p-value = 0.0001

Table 6. Number of patient grouping by degree of reducing pain after vertebroplasty

Visual analog score	Pre-op+	Post-op+ (p-value)			
		1 week	4 week	8 week	16 week
1. Marked to complete pain relief (VAS: 0-3)	1 (2.86%)	12 (34.29%)**	24 (68.57%)**	28 (80.00%)***	32 (91.43%)***
2. Moderate pain relief (VAS: 4-6)	15 (42.86%)	16 (45.71%)	7 (20.00%)	5 (14.29%)	3 (8.57%)
3. Reduction of pain (VAS: 7-10)	19 (54.28%)	7 (20.0%)	4 (11.43%)	20 (5.71%)	0

+ p = operation
** p-value = 0.001
*** p-value = 0.0001

compression fracture, Jensen et al[8,14] found marked pain relief in 90% of the patients within 24 hours. Barr et al[7] examined 38 patients with osteoporotic fractures and found complete pain relief in 63%, moderate pain relief in 32%, and no pain relief in 5%. The principle radiographic complication of PMMA leakage is epidural and foraminal extravasation[17,18]. Any resultant spinal cord or nerve root damage may require emergency surgical decompression. Neurological complications, however, is uncommon. Perivertebral, intravenous, paravertebral soft tissue, and intradiscal leakage are of no clinical importance in the short and midterm period[19]. Cyteval et al[20] found disc leakage in 5 of 20 patients (25%) none of whom had complications. In the series by Weill et al[21], PMMA leaked toward the disc, epidural space, perivertebral soft tissue, epidural veins and perivertebral veins were observed in 20 from 52 vertebroplasty (38%), leakage was symptomatic in only five vertebroplasty. These authors suggest that slight PMMA leak age, when not symptomatic, should not be considered as a complication. Deramond et al[3], however, stated that intradiscal PMMA leakage might have mechanical consequences on adjacent vertebrae, particularly in patients with osteoporosis who were at increased risk of secondary vertebral collapse. It was also reported that PMMA leakage into the disc is not uncommon (14%) but these patients did not have ill effects from leakage of small amounts of PMMA into the disc and paravertebral soft tissue. Kim et al[22] reported the risk to develop a new fracture of the adjacent to cemented vertebra was 7.1%.

In the present study, the results were similar to the preliminary studies. The majority of patients had pain relief after the procedure, marked or complete pain relief was demonstrated in 34.29% (12 in 35) within a week, 68.57% (24 in 35) within 4 weeks, 80.00% (28 in 35) within 8 weeks and 91.43% (32 in 35) within 16 weeks. Pain relief is expected after 24 hours post-operatively in acute fracture patients. The analgesics could be reduced or stopped after the procedure. In some patients, especially those who were bedridden from pain for a long period, pain gradually decreased within a few weeks.

In conclusion, percutaneous vertebroplasty is a useful technique for management of painful vertebral compression fractures. It provides pain relief and vertebral stabilization in the majority of these patients.

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การลดความเจ็บปวดในผู้ป่วยกระดูกสันหลังหักยุบด้วยการฉีดซีเมนต์เสริมกระดูกสันหลัง

บรรเทิง พงศ์สร้อยเพชร

ภูมิหลัง*: ภาวะแทรกซ้อนที่พบบ่อยที่สุดของโรคกระดูกพรุน คือการหักยุบของตัวกระดูกสันหลัง มีผลให้เกิดความเจ็บปวดบริเวณหลัง ผู้ป่วยบางรายมีอาการปวดต่อเนื่องและรุนแรงไม่สามารถเคลื่อนไหวได้เหมือนปกติ ทำให้เกิดโรคแทรกซ้อน และเสียชีวิตในอัตราสูง การฉีดซีเมนต์เสริมกระดูกสันหลังเป็นการใช้เข็มฉีดซีเมนต์เข้าไปในเนื้อกระดูกเพื่อเสริมความแข็งแกร่งให้ตัวกระดูกสันหลัง จุดมุ่งหมายของการรักษาวิธีนี้ คือ เพื่อลดความเจ็บปวดในผู้ป่วยที่มีการหักยุบของตัวกระดูกสันหลังที่ไม่ตอบสนองต่อการรักษาด้วยวิธีอนุรักษ์*

วัตถุประสงค์*: เพื่อศึกษาประสิทธิผลและความปลอดภัยของการฉีดซีเมนต์เสริมกระดูกสันหลัง ในการลดความเจ็บปวดที่เกิดจากการหักยุบของตัวกระดูกสันหลัง*

วัสดุและวิธีการ*: เป็นการศึกษาย้อนหลังในผู้ป่วยกระดูกสันหลังหักยุบได้รับการรักษาด้วยวิธีอนุรักษ์นานกว่า 4 สัปดาห์ แต่ยังคงมีอาการปวดหลังมากจำนวน 35 ราย (ชาย 1 ราย หญิง 34 ราย) อายุระหว่าง 48-98 ปี (เฉลี่ย 71.6 $\pm$ 10.7 ปี) ตรวจพบการหักยุบด้วยภาพถ่ายรังสี 20-80% ของตัวกระดูกสันหลัง ได้รับการฉีดซีเมนต์เข้าตัวกระดูกสันหลังที่หักจำนวน 66 ปล้องเป็นกระดูกระดับอก 27 ปล้อง กระดูกระดับเอว 39 ปล้อง ติดตามผลการรักษาตั้งแต่เดือนธันวาคม พ.ศ. 2546 ถึง กรกฎาคม พ.ศ. 2548 เป็นเวลา 3-20 เดือน (เฉลี่ย 7.4 เดือน) โดยวิเคราะห์ความเจ็บปวดเป็นคะแนนจากมาตรวัดความเจ็บปวด (Visual Analog Scale: VAS) เปรียบเทียบก่อนการรักษากับหลังการรักษาสัปดาห์ที่ 1, 4, 8 และ 16*

ผลการศึกษา*: ผู้ป่วย 32 ราย (91%) มีค่าคะแนนความเจ็บปวด (VAS) ลดลงอย่างมีนัยสำคัญอย่างยิ่งยวด ($p = 0.0001$) ภายในเวลา 16 สัปดาห์หลังได้รับการรักษา ค่าคะแนนความเจ็บปวดเฉลี่ยก่อนการฉีดซีเมนต์เสริมกระดูกสันหลัง 6.9 $\pm$ 1.8 เปรียบเทียบกับ 2.0 $\pm$ 1.8 ($p = 0.001$) 8 สัปดาห์หลังได้รับการรักษาภาวะแทรกซ้อน จากการฉีดซีเมนต์เสริมกระดูกสันหลังพบ 2 รายมีอาการปวดร้าวมาตามแนวเส้นประสาทไซอะติกแต่อาการทุเลาและหายภายในเวลา 3 เดือน*

สรุป*: การฉีดซีเมนต์เสริมกระดูกสันหลัง เป็นวิธีการรักษาที่ปลอดภัยและมีประสิทธิผลในการลดความเจ็บปวดได้อย่างรวดเร็ว ให้ผลการรักษาต่อเนื่องยาวนานในผู้ป่วยกระดูกสันหลังหักยุบที่มีอาการปวดไม่ตอบสนองต่อการรักษาด้วยวิธีอนุรักษ์*