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ORIGINAL STUDY

Does timing matter in performing kyphoplasty ? Acute versus chronic compression fractures

Serkan ERKAN, Taçkın R.ÖZALP, Hüseyin S. YERCAN, Güvenir OKCU

From Celal Bayar University, School of Medicine, Manisa, Turkey

The objective of this prospective consecutive cohort study was to compare the clinical outcomes, the radiographic outcomes and the complication rates of symptomatic acute (< 10 weeks) and chronic (> 16 weeks) osteoporotic vertebral compression fractures (VCFs) treated with kyphoplasty. Twenty-eight consecutive patients had 52 symptomatic osteoporotic VCFs treated with kyphoplasty ; 5 of these patients were treated in two sessions. The Oswestry Disability Index (ODI) for back pain, a Visual Analog Scale for pain assessment, a patients' satisfaction scale, and medication usage served to evaluate the clinical outcomes. All these variables improved significantly in both groups, and more so in the acute group, but the difference was most often not significant. Vertebral height, local kyphosis angle, global sagittal alignment and dynamic fracture mobility significantly improved in both groups (except global sagittal alignment), and again more so in the acute group (except global sagittal alignment) ; the difference between groups was significant regarding radiological variables, except global sagittal alignment. Timing of kyphoplasty certainly matters, as the clinical and radiological outcomes were mostly better in acute fractures than in chronic fractures, which somehow responded satisfactorily. Controlled studies (kyphoplasty versus natural history) are needed to establish the real value of the procedure.

Keywords : kyphoplasty ; fracture age ; height restoration ; cement leakage.

INTRODUCTION

Osteoporotic vertebral bodies are fragile and are prone to compression fracture following minor trauma, as a result of reduced bone mineral density (*14*). Every standard deviation of decrease in bone mineral density increases the risk of compression fracture by a factor 2.3. The incidence of osteoporotic vertebral compression fractures (VCFs) is reportedly 117 per 100,000 persons per year in Rochester, Minnesota, USA (*3*) ; they account for 41,000 hospitalizations per year in the United States, with an average length of stay of 20 days. Nineteen percent of the women with a confirmed incidental VCF have a second fracture within one year (*32*). VCF may produce pain about the fracture site, loss of height, spinal instability, and, in many

■ Serkan Erkan, MD, Assistant Professor.
■ Taçkın R.Özalp, MD, Assistant Professor.
■ Hüseyin S. Yercan, MD, Associate Professor.
■ Güvenir Okcu, MD, Associate Professor.
Department of Orthopaedics and Traumatology, Celal Bayar University School of Medicine, Manisa, Turkey.
Correspondence : Serkan Erkan, Department of Orthopaedics and Traumatology, School of Medicine, Celal Bayar University, Izmir Cad. No.10, 45050, Manisa, Turkey.
E-mail : serkanerkan73@yahoo.com

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cases, kyphotic deformity (*34*). Chronic pain and kyphotic deformity may cause depression, impaired mobility, decreased pulmonary function, and a reduction in the quality of life, the eventual consequence being a noteworthy increase in morbidity (*6,17,21*). It has been reported that one thoracic VCF can lead to enough overall sagittal kyphosis to produce a 9% loss of forced vital capacity (*33*).

Conservative management of the acute VCF episode includes analgesics, bed rest, external support, and rehabilitation (*30,35*). However, such treatments are only moderately efficient in addressing symptoms, and about one third of the patients have been reported to complain of unrelenting pain, progressive functional limitation and loss of mobility (*25*).

Surgical treatment can be considered for patients with progressive neurological deficit (*29*). Decompression and instrumentation are extensive procedures, involving prolonged operation time, blood loss, and associated complications (*21*). Percutaneous cement augmentation of vertebral bodies with compression fracture using either vertebroplasty (without balloons) or kyphoplasty (with balloons) is recommended to treat patients who do not require operative decompression of the neural elements but have intractable pain or significantly diminished pulmonary function .

Reduction of post-fracture kyphosis, restoration of the overall spinal sagittal alignment and restoration of the vertebral body height include the theoretical advantages of correcting sagittal deformity, restoring lost height, improving pulmonary and gastrointestinal function, improving cosmetic appearance, and reducing the risk of a neurologic deficit caused by the progression of the deformity .

The treatment strategy for patients with chronic (> 4 months) symptomatic VCF, not responding to conservative treatment, has not been clarified yet. Minimally invasive techniques (vertebroplasty, kyphoplasty) might be an option. Osteoporotic VCFs treated with kyphoplasty within 10 weeks are more than five times as likely to be reducible to 80% of their normal height as fractures older than 4 months (*5*). The objective of this prospective consecutive cohort study was to compare the clinical and radiographic outcomes, as well as the complication rates of symptomatic acute (< 10 weeks) and chronic (> 16 weeks) osteoporotic VCFs treated with kyphoplasty. The authors hypothesized that restoration of local kyphosis and overall sagittal alignment would be better in the acute VCFs than in the chronic VCFs, while clinical improvement would probably be similar.

MATERIALS AND METHODS

Twenty-eight consecutive patients underwent kyphoplasty for 52 symptomatic osteoporotic VCFs between February 2006 and July 2007 ; 5 of these 28 were treated in two sessions. Their mean age was 72 years, ranging from 66 to 80 years. The average follow-up was 24 months, ranging from 14 to 28 months. Patients were re-examined after 6 weeks, 12 weeks, 6 months, 12 months and 18 months. The final follow-up rate at the 18th month was 90.5% in the acute fracture group and 90.9% in the chronic fracture group.

The time interval between the onset of symptoms and the kyphoplasty procedure was accepted as the age of the fracture. VCFs were categorized as acute fractures if they were younger than 10 weeks, as subacute fractures if they were between 10 and 16 weeks, and chronic fractures if they were older than 16 weeks. There were 6 patients with 10 subacute fractures ; they were excluded from the study in order to obtain clear-cut groups, so that possible differences between acute and chronic fractures would become more distinct. Two other patients, who had both acute and chronic fractures, were also excluded, leaving a total of 28 patients.

All patients suffered from severely disabling back pain, which was reproduced by deep palpation over the spinous process at the involved level. Bed rest, activity modification, bracing and analgesics were recommended as a non-operative treatment for at least two weeks. VCFs not responsive to the above mentioned treatment modalities were accepted for kyphoplasty procedure. But only fractures, acute or chronic, which were oedematous on T2-weighted chemical fat suppression images were considered persistent or active, and consequently treated with kyphoplasty. Fractures without oedema on appropriate MR sequences were considered healed.

The kyphoplasty procedure has been described by several authors . All procedures were performed under general anaesthesia in a single institution by one experienced spine surgeon. The patient was positioned prone and the spine was extended with chest and pelvis bolsters. This assured a partial reduction : dynamic fracture

mobility. Two 11-gauge Yamshidi needles were inserted percutaneously into the vertebral body through a transpedicular approach, under fluoroscopic control. The biopsy needles were replaced with working cannulas via a guide wire. KyphX Inflatable Bone Tamps (Kyphon, Inc., Sunnyvale, CA, USA) were subsequently inserted into the vertebral body through the working cannulas. They were inflated to further reduce the fracture and to create a void. Inflation continued until the vertebral body height was maximally restored. The balloons were now deflated and withdrawn. Polymethylmethacrylate (PMMA) cement (Simplex P, Stryker Howmedica Osteonics, Allendale, NJ, USA) was finally injected into the void. Patients were allowed to ambulate on the evening of surgery and were discharged the day after the kyphoplasty procedure. None of the patients wore a brace.

Clinical outcomes

Four clinical variables were studied :

The *Oswestry Disability Index (ODI*) for back pain (*8*) and a *Visual Analog Scale (VAS*) for pain assessment were used preoperatively and postoperatively at the dates mentioned above. *Patients' satisfaction* : patients evaluated themselves as either 1) fully satisfied (pain absent at all times ; unimpaired activities of daily living), or 2) satisfied (slight pain requiring no medication and occurring no more than once a day ; minimal impairment in daily activities) or 3) unsatisfied (pain occurring more than once a day, requiring medication ; changes in daily activities). *Medication usage* was rated as zero (1), occasional (once per day) (2), or regular (more than once a day) (3). The *body mass index* was also recorded.

Radiological outcomes

Four radiological variables were studied. Standing anterior-posterior and lateral radiographs obtained before and after the procedure were evaluated by one author who did not perform the surgery. This limited the possible intervariability among the surgeons that might affect the results of the current study. *Height restoration* represented a percentage increase from the preoperative height. The height of each fractured vertebral body was measured at the most compressed point (anterior or central), before and after the kyphoplasty. *Local kyphosis* across the fractured level was measured using the Cobb method, as the angle between the superior endplate of the proximal adjacent vertebra and the inferior endplate of the distal adjacent vertebra. If adjacent vertebrae were injected, a single Cobb angle was calculated. Intraobserver variability from multiple measurements of all vertebrae was ± 1.5 mm in height and ± 1.8º for the Cobb method. *Global sagittal alignment* was analyzed by measuring the distance between the plumb line (a vertical line drawn through the center of the C7 vertebra) and the posterior superior corner of the sacrum. The plumb line fell anterior to the posterior superior corner of the sacrum on all radiographs. *Dynamic fracture mobility* (spontaneous reduction) was determined by comparing preoperative standing lateral radiographs with intraoperative prone lateral radiographs before inflation of the balloons : a measurable decrease in local kyphosis angle or increase in vertebral height was characteristic of a mobile fracture. Fractures without measurable changes were considered fixed (*38*).

Complications

Complications were carefully noted : cement leakage, among others, was traced by means of fluoroscopic and radiographic images.

Statistical analyses were performed using a paired samples *t* test, a Wilcoxon signed-ranks test, an independent samples *t* test and a chi-square test. Statistical analyses were performed using SPSS version 11.0 (SPSS, Chicago, IL).

RESULTS

Patient demographics and fracture characteristics

There were 15 patients in the acute fracture group and 13 in the chronic fracture group (table I) ; 20 (71.4%) women and 8 (28.6%) men. Their mean age was 72 years (range, 66 to 80 years). The average duration of symptoms was 6.2 weeks in the acute fracture group, and 27.5 weeks in the chronic fracture group. Eleven VCFs (61%) in the acute fracture group and 9 VCFs (60%) in the chronic fracture group had a single-level procedure (table I). Three "acute" and 2 "chronic" patients were treated in two sessions. All the VCFs occurred between the levels T11 and L4. Statistically no significant difference was observed between the fracture type (acute versus chronic) and the level of the fracture ($p > 0.05$). The average operative time was 64 minutes (range, 38 to 78 minutes) in the acute

Table I. — Patient demographics and fracture characteristics

Factors	Acute	Chronic	Total
Patients	15	13	28
Fractures	28	24	52
Sessions	18	15	33
Gender : female (%)	11(73.3%)	9 (69.2%)	20 (71.4%)
Gender : male (%)	4 (26.7%)	4 (30.8%)	8 (28.6%)
Average age, years (range)	70 (62-79)	74 (67-82)	72 (66-80)
Mean duration of symptoms, weeks (range)	6.2 (4-11)	27.5 (18-46)	17 (4-46)
No. of single-level procedures	11	9	20
No. of 2-level procedures	4	3	7
No. of 3-level procedures	3	3	6
Mean body mass index	25	23	24

Table II. — Mean improvement (%) in ODI and VAS scores at different follow-up periods for acute and chronic fracture group. Mean preoperative values : 86/100 and 8.2/10 (*Significant difference between groups)

	Acute ODI (%)	Chronic ODI (%)	Acute VAS (%)	Chronic VAS (%)
6 wks	54 *	44 *	59 *	48 *
12 wks	46	42	50	46
6 mos	43	39	47	43
12 mos	39	35	44	41
18 mos	36	32	42	37

group and 71 minutes (range, 43 to 86 minutes) in the chronic group ; the difference was not significant ($p > 0.05$).

Clinical outcomes

The *ODI score* (table II) improved significantly from a mean preoperative value of 86/100 by an average of 36% ($p < 0.001$) in the acute fracture group, and by an average of 32% ($p < 0.001$) in the chronic fracture group at the 18-month follow-up. Similarly, the *VAS for pain* (table II) improved significantly from a mean preoperative value of 7.9/10 by an average of 42% ($p < 0.001$) in the acute fracture group and by 37% ($p < 0.001$) in the chronic fracture group at the 18-month follow-up. Statistically significant improvements were maintained from the 6-week follow-up to the 18-month follow-up ($p < 0.001$ for ODI and $p < 0.05$ for VAS). The acute group did always better than the chronic group, but the difference was significant only at the 6-week follow-up ($p < 0.05$). *Patients' satisfaction* (table III) : 89% of the patients in the acute group were completely satisfied or simply satisfied at the 18 months follow-up, and 86% in the chronic group ($p < 0.001$). Again, the acute group did better at all follow-ups, but the difference was not significant ($p > 0.05$). *Medication usage* (table IV) decreased significantly in both the acute and the chronic fracture groups at all follow-up periods ($p < 0.05$). The number of patients using medication was always lower in the acute group than in the chronic VCF group, but the difference was only significant at 6 and 12 weeks ($p < 0.05$). The average *body mass index* was 24, which confirms the statement that osteoporotic women are mostly thin.

Radiographic outcomes

Vertebral body height : there was no significant difference between the preoperative vertebral heights of the two groups ($p > 0.05$). Height (fig 1)

Table III. — Mean patient satisfaction (%) for the acute and chronic VCF groups

Patient Satisfaction (%)	6 wks		12 wks		6 mos		12 mos		18 mos	
	Acute	Chronic	Acute	Chronic	Acute	Chronic	Acute	Chronic	Acute	Chronic
Fully satisfied	72	60	70	58	67	57	66	55	66	54
Satisfied	22	30	23	29	24	30	24	31	23	32
Unsatisfied	6	10	7	13	9	13	10	14	11	14

Table IV. — Mean medication usage (%) at different follow-up periods

Medication usage (%)	6 wks*		12 wks*		6 mos		12 mos		18 mos	
	Acute	Chronic	Acute	Chronic	Acute	Chronic	Acute	Chronic	Acute	Chronic
None	78	62	75	60	66	59	63	57	61	56
Episodic	17	26	18	24	23	26	24	27	25	27
Regular	5	12	7	16	11	15	13	16	14	17

* Significant difference between groups.

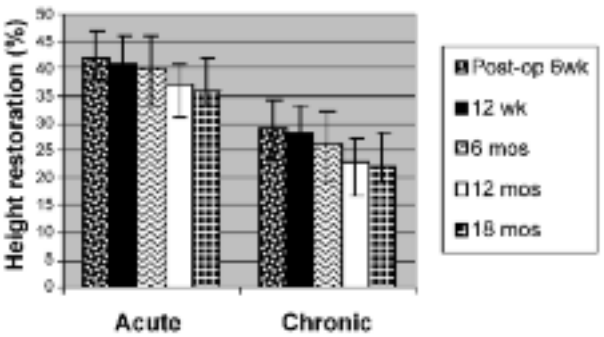

Fig. 1. — The mean height restoration was significant in the acute and in the chronic groups, at all follow-ups. Restoration was more pronounced in the acute group : this difference was also significant at all follow-ups.

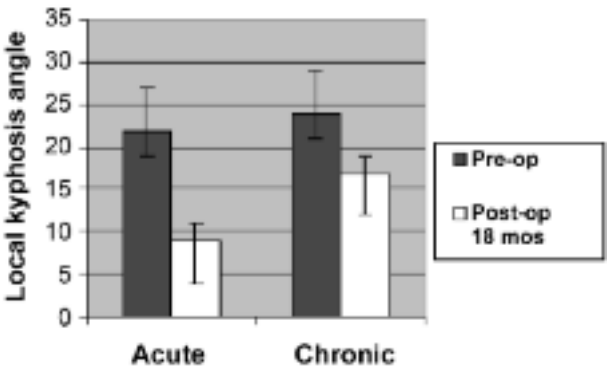

Fig. 2. — The mean local kyphosis angle improved significantly in the acute and in the chronic group at the final follow-up. Improvement was greater in the acute group ; this difference was also significant.

was significantly restored in both groups at all follow-ups ($p < 0.001$). The mean height restoration was 42% for the acute VCFs and 29% for the chronic VCFs at the 6-week follow-up. However, these percentages decreased to 36% and 22% at the 18-month follow-up. Seven percent of the acute and 21% of the chronic fractures had important loss of height restoration. The mean height restoration for the acute group was significantly higher than that of the chronic group at all follow-ups ($p < 0.05$). The mean *local kyphosis angle* (Cobb angle) (fig 2) improved significantly in both the acute and the chronic group at all follow-ups ($p < 0.001$). The Cobb angle improved from $22.2° \pm 4.7°$ preoperatively to $9.7° \pm 3.2°$ in the acute fracture group and from $24.6° \pm 5.3°$ preoperatively to $17.4° \pm 3.7°$ for the chronic group at the 18-month follow-up. This improvement was significantly greater in the acute group than in the chronic group at all follow-ups ($p < 0.05$). *Global sagittal alignment* (fig 3) : the mean distance between the plumb line and the posterior superior corner of the sacrum improved, but not significantly, from 83 ± 7 mm preoperatively to 74 ± 6 mm in the acute group ($p > 0.05$) and from

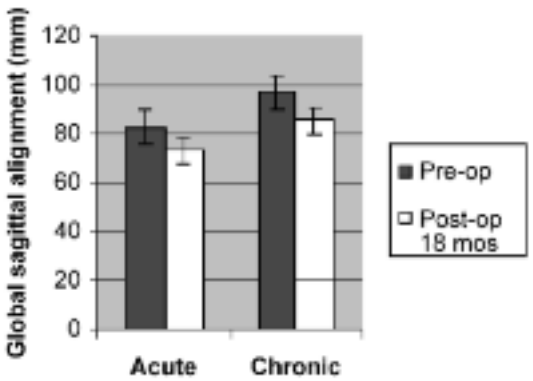

Fig. 3. — Global sagittal alignment improved in the acute and in the chronic group, but not significantly. The chronic group did better, but the difference was not significant.

97 ± 9 mm preoperatively to 86 ± 7 mm in the chronic group ($p > 0.05$) at the 18-month follow-up. The chronic group performed better, but the difference was not significant ($p > 0.05$). *Dynamic fracture mobility* : positioning the patients prone on the operating table provided a significant spontaneous correction, before inflation of the balloons : height improved significantly with 22% (range, 2%-32%) and 10% (range, 0%–21%) in the acute and chronic group, respectively. Similarly, the local kyphosis angle improved by 6.2° ± 3.7° (range, 3° to 14°) and 4.6° ± 2.8° (range, 1° to 8°) in the acute and chronic group, respectively. The acute group did better, and the difference was significant ($p < 0.05$).

Complications

Two patients (13%) in the acute group and 4 patients (30%) in the chronic group sustained a vertebral fracture on top of the cemented vertebra. Cement leakage was noted in three cases (10%) in the acute group and in one patient (4%) in the chronic group : all into the disc space without causing any symptoms. Neither neurologic deficits, infections, embolic/ pulmonary events, nor balloon-related complications were observed.

DISCUSSION

The effectiveness of kyphoplasty for VCFs less than 3 months old has been claimed by several authors, but controlled studies versus the natural evolution are needed. On the other hand, the literature on the results of kyphoplasty in the chronic period (> 4 months) is sparse, with only one study reported by Crandall *et al* (*5*). Although this study provides valuable information about the results of kyphoplasty for acute and chronic fractures, the number of follow-ups is insufficient (2nd and 6th week only) to delineate the difference in outcomes between the acute and chronic cases. In the current study more detailed clinical and radiographic data were provided at five different follow-up periods (6 weeks, 12 weeks, 6 months, 12 months, and 18 months).

Clinical variables

Kyphoplasty significantly improved the clinical variables in both acute and chronic VCFs at all follow-ups, and more so in the acute group, but the differences were mostly not significant between the two groups. The degree of clinical improvement in this study is comparable to previous studies (*2,4,10, 12,27*).

Radiographic outcomes

Height restoration : Height was better restored in the acute group than in the chronic group at all follow-ups, a finding consistent with the study of Crandall *et al* (*5*). Generally speaking, the difference between groups was more pronounced in the radiological outcomes than in the clinical outcomes. Besides, the percentage of height restoration for the acute group was in agreement with other studies (*2,10,19,25-27*). The *local kyphosis angle* was significantly better restored in the acute group than in the chronic group at all follow-ups, while no significant difference was noted in the study by Crandall *et al* (*5*). In the current study the restoration of local kyphosis angle in the acute group was comparable to other studies (*2,10,18,31,37*). *Global sagittal spinal alignment w*as not significantly improved, neither in the acute nor in the chronic group. This finding is consistent with a study published by Pradhan *et al* (*28*). They observed +/-7.3º of correction for local kyphosis, but this correction did not

translate into a similar correction in the overall sagittal alignment. The authors agree with Pradhan *et al* (*28*) and attribute this to the relatively softer disc material, which can absorb a significant amount of the local reduction before transmitting it to the adjacent vertebral body and restoring the global sagittal spinal alignment. *Dynamic fracture mobility :* it has been stated recently that proper positioning of the patient can lead to an important reduction of VCFs (*7,23*). Voggenreiter *et al* (*38*) emphasized the importance of dynamic fracture mobility when performing vertebral augmentation. They observed the contribution of fracture mobility to the improvement of sagittal alignment (at least 5º) in 57% of the patients treated with kyphoplasty. However, most of the patients in their study had acute fractures, and they did not compare acute and chronic fractures as to spontaneous reduction. In the current study, fracture mobility led to improvement in the local kyphosis angle in 60% of the acute and in 30% of the chronic fractures. It is obvious that spontaneous reduction was more striking in the acute group, which might explain the better restoration of local kyphosis angle in this group. It is important to state that an important part of the height restoration is due to the spontaneous correction by positioning the patient and not to the inflation of the balloons.

Complications

In the current study, the acute group tended to have less subsequent adjacent level fractures than the chronic group (13% versus 30%), although this was not statistically significant. Previous studies also mention subsequent adjacent level fractures. Fribourg *et al* (*9*) observed subsequent vertebral fractures in 26% of the patients after kyphoplasty, mostly within 2 months. Harrop *et al* (*13*) reported that 19% of 115 patients had new compression fractures within ten months after the index procedure. The current study demonstrated that all the adjacent level fractures were observed at the 12-week follow-up in patients who had more than a single-level fracture. This confirms biomechanical studies which show that cement augmentation places additional stress on the adjacent levels (*1,39*). We assume that the effects of this stress can be higher for multi-level VCFs treated with kyphoplasty. In contrast, Kayanja *et al* (*19*) claimed that subsequent adjacent level fractures were a result of the low bone mineral density and the kyphotic alignment, and not a result of the augmentation. Nevertheless, surgeons should be aware of possible adjacent level fractures following multi-level kyphoplasty procedures. *C*ement leakage tended to be observed more often in the acute group than in the chronic group. However, this difference was not significant. All the cement leakages occurred into the disc space without causing any symptoms. These findings were comparable to those of Hulme *et al* (*16*) : in a systematic review of 69 clinical studies about vertebroplasty and kyphoplasty they observed that most of the cement leakages were intradiscal and that only 1.3% of the patients were symptomatic after the kyphoplasty procedure performed for acute fractures.

Limitations inherent to this study include the relatively small number of patients, the lack of long-term follow-up and the lack of a control group (kyphoplasty versus natural evolution). However, this study provides valuable information about the differences in outcomes and complication rates between the acute and the chronic group at five consecutive follow-ups.

CONCLUSION

Kyphoplasty improves clinical and radiological outcomes in patients having either acute (< 10 weeks) or chronic (> 16 weeks) VCFs. The outcomes are mostly better in the acute group, but not always significantly. This means that timing of kyphoplasty really matters, although the difference between acute and chronic fractures is more striking from a radiological view-point than from a clinical view-point. Controlled studies (kyphoplasty versus natural history) are needed to establish the real value of the procedure.

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