

Clinical Study

Comparative analysis of clinical outcomes in patients with osteoporotic vertebral compression fractures (OVCFs): conservative treatment versus balloon kyphoplasty

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Abstract

BACKGROUND CONTEXT: Most osteoporotic vertebral compression fractures (OVCFs) can be treated conservatively. Recently, kyphoplasty has become a common treatment for painful osteoporotic compression fractures and has shown numerous benefits, such as early pain control and height restoration of the collapsed vertebral body. In spite of being a simple procedure, numerous complications related to kyphoplasty have been reported. Moreover, there is limited evidence to support its superiority.

PURPOSE: To compare the clinical outcomes of patients with OVCF according to different treatment modalities and identify clinical risk factors related to failure of conservative treatment of OVCF.

STUDY DESIGN: A prospective study consisting of a review of case report forms.

PATIENTS SAMPLE: We prospectively enrolled 259 patients who had one or two acute painful OVCFs confirmed by magnetic resonance imaging. All patients were treated conservatively in the initial 3 weeks. Kyphoplasty was performed in 91 patients who complained of sustained back pain and disability in spite of conservative treatment for the initial 3 weeks.

OUTCOME MEASURES: Pain score using visual analog scale (VAS) and the Oswestry Disability Index (ODI).

METHODS: Participants were stratified according to age, sex, level and number of fractures, bone mineral density, body mass index (BMI), collapse rates, and history of spine fractures. Pain scores using VASs were assessed at 1 week and at 1, 3, 6, and 12 months.

RESULTS: A total of 259 patients were enrolled, and 231 patients (82 of 91 patients in the kyphoplasty group [KP] and 149 of 168 patients in the conservative treatment group) completed the 1-year follow-up. About 65% of patients were treated successfully with conservative treatment. Risk factors for failure of 3 weeks of conservative treatment were older age (older than 78.5 years), severe osteoporosis (*t* score less than –2.95), overweight (BMI more than 25.5), and larger collapse rates (more than 28.5%). There were significant reductions in VAS and ODI scores in both groups at each follow-up assessment. At the first month, better clinical results were observed in KP. However, there were no significant differences in outcome measures between the two groups at 3, 6, or 12 months. Thirteen subsequent compression fractures (five in KP and eight in the conservative treatment group) occurred during the 1-year follow-up period.

CONCLUSION: Both treatments of OVCF showed successful clinical results at the end of the 1-year follow-up period. Kyphoplasty showed better outcomes in the first month only. Given these results, prompt kyphoplasty should not be indicated in the case of a patient with OVCF that has no

FDA device/drug status: Approved (Balloon Kyphoplasty).

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risk factors for failure with conservative treatment. Rather, a trial of conservative, 3-week treatment would be beneficial. © 2012 Elsevier Inc. All rights reserved.

Keywords: Acute fracture; Vertebral compression fracture; Osteoporosis; Kyphoplasty; Risk factor analysis

Introduction

Osteoporotic vertebral compression fractures (OVCFs) are the most common fractures seen in patients with osteoporosis. The prevalence is increasing as populations age; about 1.4 million new fractures occur every year [1,2]. Osteoporotic vertebral compression fracture usually causes pain and deformities and can even cause mortality in elderly populations [3,4].

Although most patients with OVCF are managed with conservative treatments, including pain management, short periods of bed rest, and a brace, the pain because of vertebral fractures may last for weeks or months [5,6]. Some patients who fail conservative treatment may require hospitalization, long-term care, and surgical interventions [7].

Percutaneous cement augmentation techniques, such as the injection of polymethylmethacrylate (PMMA) into the fractured vertebral body, have shown effectiveness in terms of early pain relief and relatively low complications [8–10]. Guidelines only recommend cement augmentation techniques for fractures that have pain that has not responded to conservative treatment [11]. Recently, two randomized clinical studies about vertebroplasty for painful osteoporotic compression fractures failed to show better clinical outcomes of vertebroplasty compared with conservative treatment [12,13]. Balloon kyphoplasty is another minimally invasive cement augmentation technique that is intended to reduce pain, disability, and vertebral deformity by the use of an inflated balloon inside the vertebral body [14,15]. However, this technique has also had numerous problems, such as complications and socioeconomic burdens. Moreover, there is limited evidence to support its superiority over conservative treatment [16–21]. Numerous other controversies about when and for whom procedures should be performed have not been resolved. In this study, we aimed to compare the clinical outcomes of patients with OVCF according to different treatment modalities and identify clinical risk factors related to failure of conservative treatment of OVCF.

Methods

Study design and participants

We undertook a prospective study in our hospital between March 2005 and May 2009. All participants were aged 50 years or older and were admitted via the emergency room because of acute severe back pain after minor trauma. One or two vertebral compression fractures were confirmed by low-intensity signal changes on T1-weighted image, high-intensity changes on T2-weighted image, and bone edema

on short-tau inversion recovery sequence images of magnetic resonance imaging [22]. Other inclusion criteria were as follows: level of fracture at T8 or lower, focal tenderness on the back after minor trauma, and anterior wedge compression fractures [23]. Exclusion criteria were the following: severe cardiopulmonary comorbidity, major coagulopathy, spine infection, suspected neoplasm in the target vertebral body, retropulsion of bony fragments, spinal cord compression syndrome, dementia, and fractures related to major trauma. All participants who agreed to be involved in this prospective observational study provided written informed consent. The institutional review board at our hospital approved the study protocol.

Assignments and procedures

All participants received conservative treatment for the initial 3 weeks, which included analgesics, bed rest, a back brace, and walking aids, according to the standard practices of our hospital. After 3 weeks, we divided all the participants into two groups according to their symptoms: the conservative group and kyphoplasty group (KP). If the patient (KP) complained of intolerable pain in spite of conservative treatment, the patient underwent kyphoplasty using a balloon. If the patient (conservative group) tolerated conservative treatment, the patient received prolonged conservative treatment.

Kyphoplasty was performed with introducer instruments, inflatable bone balloons, and PMMA bone cement (about 3 cc per vertebral body) using a percutaneous bilateral transpedicular approach. All procedures were performed under local anesthesia and sedation [24]. All participants also received the same standard practices of our hospital after allocation to their respective group. In all participants, calcium supplements and antiresorptive agents were started during the first month after the treatment decision was made. During follow-up, subsequent fractures were treated according to the original assignment. If the participants complained of sustained pain after 3 weeks of conservative treatment, kyphoplasty using a balloon was also performed in a routine manner (Fig. 1).

Outcome measures

At baseline, participants completed self-assessment questionnaires and provided demographic and clinical information, including age, sex, height, and weight. Back pain intensity was recorded using a 100-mm visual analog scale (VAS), on which a score of 0 indicates no pain and a score of 100 indicates the worst conceivable pain. Serial

EVIDENCE & METHODS

Context

Despite controversy over efficacy derived from vertebroplasty trials, kyphoplasty continues to be commonly used to treat symptomatic osteoporotic vertebral compression fractures. This study aims to delineate in which patients this intervention is most beneficial.

Contribution

In this prospective analysis of 259 patients who were all treated nonsurgically for a compression fracture for 3 weeks, 91 ultimately underwent kyphoplasty. The authors found that older patients, those with more severe osteoporosis, those who are overweight, and those with more severe vertebral collapse had slower recovery with nonoperative care and might benefit more from kyphoplasty. There was little apparent benefit from kyphoplasty beyond the very early postoperative period (1 month).

Implication

Delineating subgroups that would benefit most from an invasive treatment such as kyphoplasty is vital. Many patients with this condition recover without the risk or expense of the procedure. This study provides some insight into patient subgroups that are better candidates for kyphoplasty. That being said, conclusions regarding kyphoplasty versus nonsurgical care cannot be drawn from this paper given the methodology. For instance, the two groups were developed based on an arbitrary selection bias (better or not at 3 weeks). This question would be more rigorously evaluated by randomizing those not better after 3 weeks of nonsurgical care to more nonsurgical care or kyphoplasty.

—The Editors

evaluation measures were performed before group assignment and at various times, including once a week for 1 month and then once every 3 months for 1 year. Standing lateral radiographs of the spine were taken at each period. Three authors independently assessed the percentage compression of the vertebral body using the PACS system (PiView STAR; INFINITT Healthcare Co., Ltd). The collapse rate was calculated using Genent's method [25]. Bone densitometry of the spine and hip joint was also evaluated using dual X-ray absorptiometry at baseline. The lowest *t* scores from the spine and hip joint were recorded and used for the diagnosis and measurement of osteoporosis [26].

The primary focus of this study was pain and health-related quality of life, assessed using the Korean version of the Oswestry Disability Index (ODI) at each of the follow-up visits [27]. The secondary focus was risk factors associated with the failure of conservative treatment for the initial 3 weeks in patients with OVCF.

Statistical analysis

This study initially had 95% power ($\alpha=0.05$ and $\beta=0.20$) to detect differences in the pain score and ODI in 230 patients [10,12,13,15]. To compensate for possible loss, 259 patients were enrolled. The end points were analyzed by per-protocol analysis, including all data available from patients who were followed up at 1 year. Differences in mean VAS and ODI scores between the baseline and 1 month and 1 year were assessed with the paired *t* test. Repeated analysis of covariance was performed to compare VAS and ODI scores between the two groups at each of the follow-up periods. To identify the risk factors affecting failure of conservative treatment, which resulted in kyphoplasty after 3 weeks of conservative treatment, receiver operating characteristic curve analysis and binary logistic regression analysis (tree analysis) were done. The SPSS version 18.0 for Windows (IBM, Armonk, NY, USA) was used for all statistical analyses.

Results

Two hundred fifty-nine patients were enrolled and assigned to conservative treatment ($n=168$) or balloon kyphoplasty ($n=91$). Fig. 1 and the Table show the number of participants involved in the trial from assessment for eligibility through the 1-year follow-up. At the 1-year assessment, complete data were available for 231 of 259 participants (89%). One hundred forty-nine patients (65%) were treated successfully with conservative treatment. Only seven participants progressed to balloon kyphoplasty in spite of success of 3 weeks conservative treatment. The final success rate of conservative treatment in patients who showed favorable result at the initial 3 weeks was estimated as 95% (149/156).

The Table shows the demographic characteristics of the enrolled participants. Older participants, participants with more severe osteoporosis, participants who were more obese, and participants with higher rates of initially having a collapsed vertebral body characterized the participants in KP ($p<.05$). After a 1-year follow-up, five subsequent fractures were reported in patients treated with kyphoplasty and eight new fractures in 149 conservatively treated patients. This difference was not significant ($p>.05$).

Figs. 2 and 3 show the change in clinical outcomes, including VAS and ODI, at each follow-up assessment. Baseline VAS and ODI scores were similar in both groups. Participants of both groups had improved clinical outcomes at the final follow-up (1 year) compared with those at the baseline ($p<.001$). Comparing the two groups, the VAS and ODI scores of participants who underwent balloon kyphoplasty were significantly lower only at the first week and first month assessments compared with the scores of participants who received conservative treatment ($p<.05$). However, there were no significant differences in scores between the two groups after the first month.

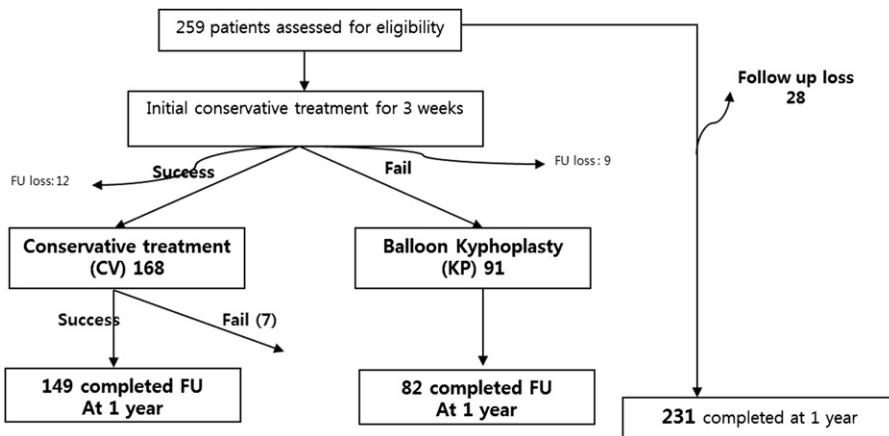


Fig. 1. Trial profile. CV, conservative treatment group; KP, kyphoplasty group; Success, patient tolerated pain; Fail, patient complained of intolerable pain; FU, follow-up.

Receiver operating characteristic curve analysis revealed cutoff values for four factors (aged older than 76.5 years, less than -2.8 in t score of bone densitometry, more than 24.8 of body mass index [BMI], and more than 27.2% of collapse rate of vertebral body) affecting failure of conservative treatment, necessitating balloon kyphoplasty (Fig. 4). Fig. 5 shows the result of tree analysis of risk factors and their contributions to the failure of conservative treatment.

Discussion

Our results showed that both balloon kyphoplasty and conservative treatment led to well-controlled pain and improved quality of life at the 1-year follow-up after acute OVCF. In fact, balloon kyphoplasty showed more rapid improvement of pain and disability than conservative treatment, with significant differences in scores of the VAS and ODI between the treatment groups up until the first month. However, these differences diminished, and there were no

significant differences between the two groups after 1 month throughout the 1-year follow-up period because the conservative treatment group improved over time, most likely as a result of fracture healing. These findings were similar to the results of other studies [12,13,15,18,28–30]. Because kyphoplasty does not promote biologic processes and also inhibits normal physiological bone healing, we should avoid it if clinical success is expected without kyphoplasty.

So far, almost all studies, randomized or nonrandomized, have compared and reported only clinical outcomes of surgical or nonsurgical treatment regardless of the surgical indication for cement augmentation, including vertebroplasty and balloon kyphoplasty. There has not been obvious consensus about surgical indications for balloon kyphoplasty in treating OVCFs except for after failure of conservative treatment. There are also numerous controversies

Table
Demographic data

	CV (149)	KP (82)	p
Age (y)	66.2±6.3	76.8±11.5	<.05
Sex (M:F)	61:88	29:53	NS
Levels			NS
Thoracic spine (~T9)	33	10	NS
TL junction (T10–L1)	91	61	NS
Lumbar spine (L2~)	25	11	NS
History of OVCF (%)	16.1	20.2	NS
Number of fractures			NS
Single/double	112/37	70/12	
BMD (t score)	-2.4±0.5	-3.1±0.6	<.05
BMI	21.8±2.3	23.5±3.2	<.05
Initial collapse rates (%)	20.7±11.5	36.5±11.7	<.05
Subsequent fractures	8	5	NS

CV, conservative treatment group; KP, kyphoplasty group; M, male; F, female; NS, not significant; TL, thoracolumbar; OVCF, osteoporotic vertebral compression fracture; BMD, bone mineral density; BMI, body mass index.

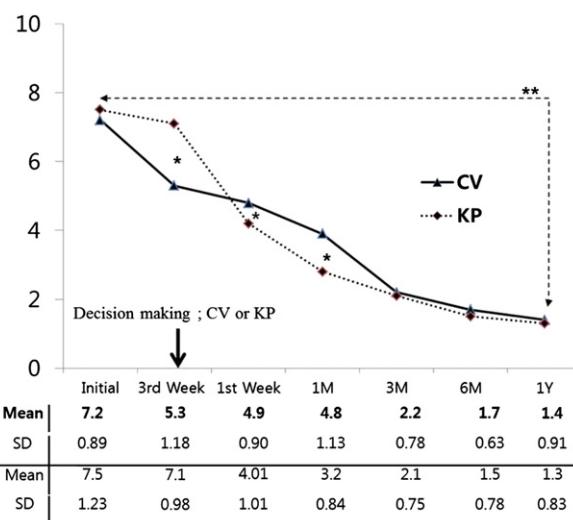


Fig. 2. Clinical outcomes—visual analog scale. *Repeated analysis of covariance revealed a p value of less than .05 between the two groups; **paired t test: p value less than .05 between the two periods. CV, conservative treatment group; KP, kyphoplasty group; SD, standard deviation.

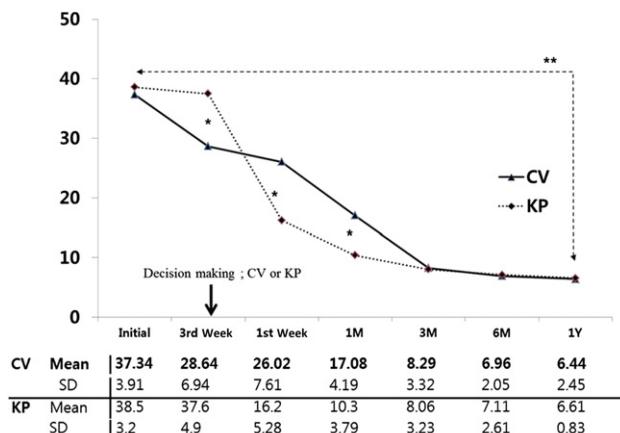


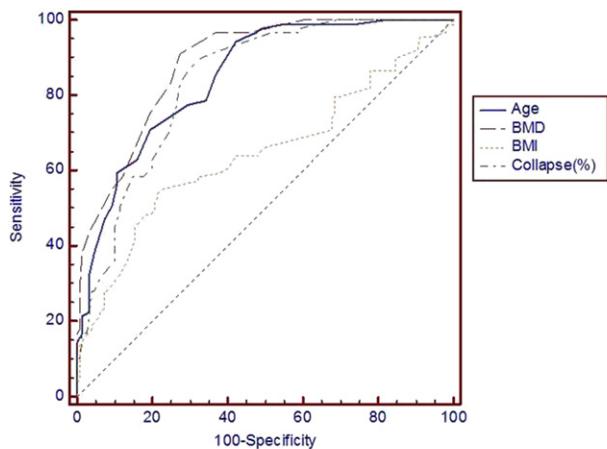
Fig. 3. Clinical outcomes—Oswestry Disability Index score. *Repeated analysis of covariance revealed a p value of less than .05 between the two groups; **paired t test: p value less than .05 between the two periods. CV, conservative treatment group; KP, kyphoplasty group; SD, standard deviation.

about the duration of conservative treatment and risk factors affecting failure of conservative treatment in patients with OVCF. In our study, conservative treatment showed excellent success rates of more than 95% in patients who had success with 3 weeks of conservative treatment. Therefore, the initial 3 weeks were a sufficient amount of time to delay the decision to pursue surgical interventions.

The Free study showed favorable clinical results of kyphoplasty compared with conservative treatment in patients with OVCF [15]. However, other randomized double-blind clinical trials failed to demonstrate superiority of vertebroplasty over conservative treatment [12,13,28,30]. Kyphoplasty showed an effect on pain relief that is similar to that

of vertebroplasty, with rapid and sustained improvement. Because kyphoplasty involves the use of an inflated balloon that forms a space in the vertebral body into which cement can be injected, advantages of kyphoplasty over vertebroplasty include a lower chance for cement leakage during the procedure and the ability for the restoration of collapsed vertebral body height. However, there are also many reports detailing subsequent fractures that developed more frequently after kyphoplasty than vertebroplasty [23,31]. The subsequent fractures were related to PMMA cement, which was inserted into the vertebral body during cement augmentation procedures, vertebroplasty, and kyphoplasty. The vertebral body treated with PMMA became stiffer than the adjacent vertebra. The subsequent fracture at the adjacent level was thought to be a result of load transfer to the less stiff vertebral body [32,33]. Fribourg et al. observed that most of the fractures subsequent to kyphoplasty occurred within 2 months. After this period, they found dramatic declines in the incidence of subsequent fractures, which more closely resembled the natural history of OVCFs [34]. These studies emphasized the importance of postoperative care, including immobilization with a back brace and anti-osteoporotic medications. Our study showed a similar rate of subsequent fractures in KP and conservative treatment group. This result might be because of the use of a rigid back brace for 2 months and proper anti-osteoporosis medications, such as bisphosphonates, calcium, and vitamin D metabolites.

One third of our participants failed our conservative management protocol. They underwent balloon kyphoplasty because of sustained and intolerable back pain and disabilities. These 82 patients also showed good clinical outcomes, not only in the early period but also at 1 year



Variable	AUC	95% CI	P-value	Cut-off value	PPV	NPV
Age	0.848	(0.795, 0.891)	<0.0001	76.5	57.1	94.5
BMD	0.886	(0.838, 0.923)	<0.0001	-2.8	66.4	93.1
BMI	0.645	(0.581, 0.706)	0.0002	24.8	60.0	74.1
Collapse(%)	0.836	(0.783, 0.881)	<0.0001	27.2	62.0	91.7

Fig. 4. Receiver operating characteristic curve analysis of risk factors affecting failure of conservative treatment. AUC, area under the curve; CI, confidence interval; PPV, positive predictive value; NPV, negative predictive value; BMD, bone mineral density; BMI, body mass index.

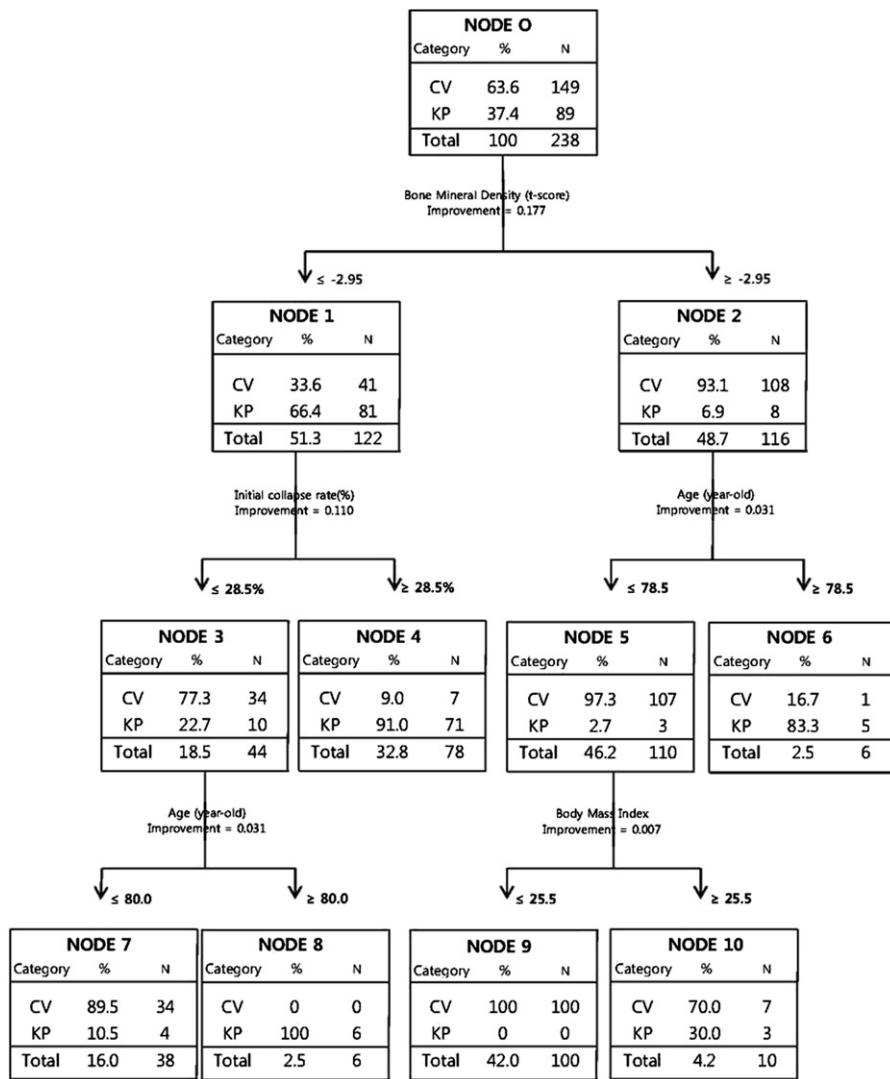


Fig. 5. Tree analysis (CART algorithm). CV, conservative treatment group; KP, kyphoplasty group.

after kyphoplasty. There were no significant complications affecting clinical outcomes except for minor cement leakages that were subclinical. Therefore, balloon kyphoplasty was a very useful treatment option when patients with acute OVCF failed to have symptom improvement in spite of proper conservative treatment. Receiver operating characteristic analysis revealed that age, bone densitometry, BMI, and initial collapse rates were independent risk factors for failure of conservative treatment. However, because all factors were correlated with each other very closely, tree analyses were also performed.

Tree analysis (event or fault) is a systemic, deductive, top-down method of analyzing system design and performance. It involves specifying a top event followed by identifying all the associated elements in the system that could cause that top event to occur. It also clearly identifies fault relationships and provides a methodical approach to predict the probability that some top-level events will or will not occur [35]. In

our study, tree analysis (Fig. 5) revealed that the most important factor related to failure of conservative treatment was the *t* score from bone densitometry, the severity of osteoporosis. The cutoff value of bone mineral density *t* score was -2.96 . According to the World Health Organization definition of osteoporosis, this *t* score means patients had severe osteoporosis. Moreover, bone density is the most important parameter involved in the development of osteoporotic fractures [36,37]. Obesity, defined as a BMI more than 25.5, was also an important factor in failure of acute OVCF treatment. Nielson et al. [38] revealed that obesity was associated with an increased risk of fracture because of worse physical activity. Obesity might also be associated with poor compliance with the rigid back brace used in conservative treatment because fitting the rigid back brace to the body is very difficult in obese patients. The rigid back brace is the most important conservative treatment for acute spine fractures [39,40]. Poor compliance might decrease treatment success rates

similar to the results of bracing in scoliosis [41]. Age more than 78.5 years was also an important factor. Older age is also closely associated with osteoporosis and a high risk of falls [42]. Higher initial rates of collapsed vertebra, especially when more than 28.5%, might cause more kyphotic deformity and a forward shift of the center of gravity, producing further collapse of the vertebral body and failure of proper conservative treatments [43]. Lindsay et al. [34] reported that the risk of another vertebral compression fracture was about fivefold higher after the first fracture has occurred. A collapsed vertebral body may cause higher stress on other vertebral bodies and also on itself. From the results of the tree analysis, if the patient with acute OVCF had a *t* score of less than –2.95 and an initial vertebral collapse rate of more than 28.5%, the failure rate of conservative treatment was 91.0%. Therefore, earlier performance of kyphoplasty in these patients would be justified. However, if the patient had a *t* score greater than –2.95 and was younger than 78.5 years and had a BMI less than 25.5, the success rate of conservative treatment was 100% (Fig. 5). Therefore, more vigorous conservative treatment would be appropriate.

Despite the fact that our study has some methodological problems, including nonrandomization and relatively large dropout rates (10%) during follow-up, it is one of the few studies that compared conservative treatment and kyphoplasty in a reasonable number of patients with acute OVCF using per-protocol analysis. We identified factors that predict poor results of conservative treatment in this prospective study.

In summary, in this prospective study, most of the patients who had a favorable clinical result with conservative treatment in the initial 3 weeks after fracture showed successful clinical results at 1 year after fracture. However, if the patient failed conservative treatment, kyphoplasty also resulted in excellent results at 1 year after trauma. The risk factors for failure of conservative treatment were severe osteoporosis, older age, obesity, and higher rates of initial vertebral collapse. Therefore, when patients have no risk factors, conservative treatment for an initial 3 weeks will be helpful in the treatment of acute OVCFs.

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