



Early results of kyphoplasty in osteoporotic vertebral compression fractures

Osteoporotik vertebra kompresyon kırıklarında kifoplasti sonrası erken dönem sonuçlar

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Amaç: Osteoporotik vertebra kompresyon kırığı (VKK) nedeniyle erken dönemde yapılan kifoplasti sonrası hastaların ağrı durumu, aktivite düzeyleri ve radyografik olarak vertebra cisminin restorasyonu değerlendirildi.

Çalışma planı: Çalışmaya lomber bölgede oluşan osteoporotik VKK nedeniyle erken dönemde kifoplasti uygulanan 16 hasta (4 erkek, 12 kadın; ort. yaş 63; dağılım 55-72) alındı. Kifoplasti uygulanan toplam seviye sayısı 21 idi ve seviye başına en az 3 ml (dağılım 3-6 ml) çimento enjekte edildi. Semptomların başlaması ile cerrahi işlem arasındaki süre ortalama altı gündü (dağılım 2-16 gün). İşlemin etkinliğini değerlendirmek için, tanı konduğunda, kifoplasti sonrası birinci günde ve bir ay sonra görsel analog skala (GAS: 0 hiç ağrı yok, 10 çok şiddetli ağrı) kullanıldı. Kifoplasti öncesi ve sonrasında vertebra gövdesinin ön, orta ve arka yükseklikleri direkt grafilerde ölçülerek vertebra restorasyonu değerlendirildi. Ortalama takip süresi 11 ay (dağılım 4-30 ay) idi.

Sonuçlar: Girişim öncesinde ortalama 8.8 (dağılım 7-10) olan GAS skoru girişim sonrası birinci günde 2.4 (dağılım 1-5), birinci ayda 1.6 (dağılım 0-3) bulundu ($p < 0.0001$). Tüm hastaların ilk bir ay içinde kırık öncesi aktivite düzeylerine geldiği görüldü. Kifoplasti uygulanan vertebra- lar da çökme veya yeni kırık görülmedi. Kompresyon kırığı olan vertebra- ların ön, orta ve arka cisim yükseklikleri girişim öncesine göre anlamlı değişim göstermedi. Komplikasyon olarak iki hastada komşu segmentte ek VKK gelişti ve bunlara yönelik yine kifoplasti uygulandı.

Çıkarımlar: Kifoplasti, osteoporotik VKK'de uygun hasta seçimiyle %80-95 gibi yüksek başarı oranlarına sahip güvenilir ve etkin bir tedavi yöntemi olarak kabul edilebilir.

Anahtar sözcükler: Kemik çimentosu/terapötik kullanım; enjeksiyon, spinal; kifoz/etyoloji; osteoporoz/komplikasyon; omurga kırığı.

Objectives: We evaluated early results of kyphoplasty for osteoporotic vertebral compression fractures with regard to the level of pain, activity levels of patients, and radiographic restoration of the vertebra bodies.

Methods: Sixteen patients (4 males, 12 females; mean age 63 years; range 55 to 72 years) with osteoporotic vertebral compression fractures in the lumbar spine were treated with kyphoplasty. The procedure was performed at 21 levels, with a minimum of 3 ml (range 3 to 6 ml) of cement per level. The mean time from the onset of symptoms to the application was six days (range 2 to 16 days). The effectiveness of the procedure was evaluated by a visual analog scale (VAS: 0 no pain; 10 very severe pain) before kyphoplasty, and after the first day and one month of the procedure. In addition, restoration of the vertebra bodies was assessed on pre- and postoperative radiographs by measuring the anterior, middle, and posterior heights. The mean follow-up was 11 months (range 4 to 30 months).

Results: The mean VAS scores were 8.8 (range 7 to 10), 2.4 (range 1 to 5), and 1.6 (range 0 to 3) before kyphoplasty, and after the first day and one month of the procedure, respectively ($p < 0.0001$). All the patients returned to preinjury levels of activity within the first month. No collapse or refracture occurred in the treated vertebrae. Changes in the anterior, middle, and posterior heights of the vertebra bodies after the procedure were not significant. The only complication was the development of an additional fracture in the nearby segment in two patients, for which kyphoplasty was performed.

Conclusion: With proper patient selection, kyphoplasty is an effective and reliable option for osteoporotic vertebral compression fractures, yielding 80% to 95% success rates.

Key words: Bone cements/therapeutic use; injections, spinal; kyphosis/etioloji; osteoporosis/complications; spinal fractures.

Osteoporosis, which is a serious public health problem at present, is a metabolic bone disease resulting in deterioration of the bone structure. It is also the most common cause of the vertebral compression fractures (VCF). It has been reported that frequency of VCF associated with osteoporosis significantly increased with an incidence of 117/100,000 people or 438,750 person-year per year.^[1] It is known that a patient with vertebral compression fracture has a fivefold increased risk of developing a VCF.^[2]

The major complaint of patients is the pain induced by the osteoporotic vertebral fractures; it may leave patients, who were previously functioning, bedridden. Additionally, it has been reported that complications such as depression, malnutrition, significantly reduced lung functions may occur in patients with VCF with a higher mortality rate compared to age-matched groups.^[3-6] Kado et al.^[7] reported that the mortality rate increased 23% in women with VCF, and 33% in patients with multiple VCF. Therefore, the primary treatment of osteoporotic VCF, which should not be underestimated, includes bed rest, bracing, painkillers and psychological support.^[8] The pain can be usually controlled by these methods. However, recently there has been increased interest in new minimally invasive procedures so called percutaneous vertebroplasty (PVP) as described by Galibert et al.^[9] and changed to kyphoplasty in the following years. PVP or kyphoplasty is indicated when non-surgical methods fail in patients with vertebral compression fracture over a 3-week treatment. The procedure can be applied earlier in some patients, including the ones with a risk of developing pneumonia or deep vein thrombosis if not mobilized early, and the patients with analgesic intolerance.

The present study objectively evaluated early results of the kyphoplasty for osteoporotic vertebral compression fractures with regard to the level of pain, activity levels of patients and radiographic restoration of the vertebral bodies.

Patients and method

The study included 16 patients (4 males, 12 females; mean age 63 years; range 55 to 72 years) who underwent early kyphoplasty for osteoporotic VCF between July 2003-December 2005. All of the

patients presented with low energy simple trauma as a result of falling onto hip or belly during daily activities. The total number of levels treated by kyphoplasty was 21. Only the fractures in the lumbar spine were included and treated (7 levels at L1, 6 levels at L₂, 3 levels at L₃, 3 levels at L₄, 2 levels at L₅). The mean duration between the onset of symptoms and the surgical procedure was six days (range 2 to 16 days). Each patient was evaluated by magnetic resonance imaging (MRI) and underwent the procedure under local anaesthesia following the diagnosis of newly established VCF. Kyphoplasty was performed at three segments in a single session in one patient, two segments in one patient and two patients in different sessions respectively while in a single segment in other patients. The cement was injected with a minimum of 3 ml (range 3 to 6 ml) per level. During the follow-up, a secondary VCF developed at two levels above the segment treated by kyphoplasty after 2 months in one patient, and one level below the segment in another patient after five months, which were also treated by kyphoplasty. The effectiveness of the procedure was evaluated using a visual analog scale (VAS; no pain 0; very severe pain 10). The patients with a score of 0-3 were considered significantly benefited from the treatment. The evaluations were carried out following the diagnosis, and at postoperative day 1 and month 1. Also, preoperative and postoperative activity levels of the patients were assessed. Furthermore, restoration of the vertebral bodies was assessed by pre- and post-operative plain radiographs measuring the anterior, midline and posterior heights. The mean follow-up was 11 month (range 4 to 30 months).

The change in the anterior, midline and posterior heights of the vertebral bodies was tested by the Student's t-test while the change in the early and month 1 results of the pre- and post-operative VAS scores was assessed by the ANOVA test.

Results

The mean VAS scores were 8.8 (range 7 to 10), 2.4 (range 1 to 5), and 1.6 (range 0 to 3) before the operation and the postoperative day 1 and month 1, respectively ($p < 0.0001$). All of the patients were mobilized on the same day after the operation, and discharged after 24 hours. All returned to their pre-

fracture levels of activity within the first month. No collapse or refracture was observed in the vertebrae treated by kyphoplasty during the follow-up. The pre- and post-operative anterior, midline and posterior heights of the vertebrae with compression fractures were measured by the same surgeon. No statistically significant change was observed in the change of height of these three different segments of the vertebra bodies (anterior $p=0.261$, midline $p=0.411$, posterior $p=0.114$). None of the patients in the study group developed a severe complication, which might have an influence on his/her overall health (embolus, myocardial infarction, spinal cord or stem symptoms). Additional VCF developed in two adjacent segments of two patients as complications, which were also treated by kyphoplasty.

Discussion

One of the major pathologies in the elderly populations, which increase the dependency to bed and morbidity, is osteoporotic VCF.^[10-12] Such injuries most frequently occur in the thoracolumbar junction or thoracic apex, and the interventional procedures are most frequently performed for the fractures in this region. The present study evaluated only the compression fractures of the lumbar spine and related kyphoplasty procedures. Approximately 50% of patients with vertebral fractures require personal assistance for daily activities.^[13] The sagittal vertebral deformity developed as well as the negative impact on daily activities deteriorate load bearing, increasing the risk of VCF fivefold in the lower or upper adjacent vertebrae.^[14] Furthermore, in the advanced period reduced lung capacity, chronic pain and depression may occur in the patient group with kyphotic deformity.^[12,15,16] Therefore, VCF associated with osteoporosis is a condition which should not be underestimated, requiring a serious management. The conventional treatment is conservative, and it includes bed rest, bracing, painkillers and psychological support.^[8,17] The pain can be usually controlled with these treatment methods; however the pain and immobilization of the patient can persist during the healing process of the fracture. Long term treatment may lead to gastrointestinal problems while long-term immobilization is associated with increased demineralization, increasing the risk of fractures. Besides, kyphotic deformity associated with the fracture is usually persistent.

First described by Galibert et al.^[9] in 1987 for the treatment of vertebral hemangiomas, the scope of vertebroplasty became wider to be also used in the treatment of osteoporotic VCF. This minimally invasive technique relieves the pain of patients early with higher rates up to 60-100% so that the patients become mobilized very soon and return to their daily activities.^[13,18-20] However, the procedure has its potential risks besides its significant clinical efficacy. One of the major risks is the leakage of bone cement given under a certain pressure out to the extravertebral region, leading to various complications depending on the location. Furthermore, it increases the risk of VCF in the adjacent vertebrae because of insufficiency in restoration of the height of the vertebral body and of the vertebral sequence.^[3,21,22] In recent years, vertebroplasty has been replaced by percutaneous balloon kyphoplasty technique, which has been reported to have several significant potential advantages over vertebroplasty. Different from vertebroplasty, kyphoplasty involves transpedicular guidance of a balloon catheter to the vertebra, followed by inflating the balloon to elevate the fractured endplate and filling the cavity created by inflation by cement. One of the advantages includes reduction of the fracture and sagittal deformity while another one is the inflation of the balloon and insertion of the trabecular bone and placement of cement to the cavity created with less pressure and more viscosity. With this advantage, risk of the extravertebral extravasation of the cement is reported to be substantially decreased compared to the vertebroplasty.^[18,23] The rates of extravertebral cement leakage are reported as low as 2.7-9% with this method.^[4,7,24] In the present study, we didn't experience any cement leakage in any of our patients. Therefore, we believe that the technique we used is highly safe.

The fracture pain is significantly relieved early in kyphoplasty compared to the vertebroplasty.^[22-25] Garfin et al.^[26] reported that the pain was reduced 90% within the first two weeks. We also obtained similar results in our study, and observed 90% relief in pain. We noted that the pain was significantly reduced at the postoperative day 1 for each patient, and the patients re-gained their previous functional levels during the 1-month follow-up.

Other than general indications, some pre-conditions are required for the success of vertebroplasty

and kyphoplasty. One of them is that the fracture should be recent or non-healed yet.^[10,11,15,16] At present it is widely accepted that MRI is the most effective method of evaluating the pain relief obtained by these methods. The pain was reduced 90% in patients with edema detected in the vertebral body in T2-weighted or fat suppressed sections while it is 40% in patients without edema.^[27] We used MRI for each patient enrolled in the study. However, we didn't perform kyphoplasty for all the levels detected by MRI. The kyphoplasty was applied at the levels with the extreme edema in the T₂-weighted and fat suppressed sections depending on the rate of sensitivity during the physical examination.

In the literature, there are several studies showing that following kyphoplasty the height of vertebral bodies was partly restored, and thus kyphotic deformity could be corrected.^[6,23-25] In a cohort of 70 patients, Lieberman et al.^[6] showed that the midline height of the vertebral body was increased by 46.8%, and Garfin et al.^[25] demonstrated that the anterior, midline and posterior heights of the vertebral bodies was increased, and the kyphosis was corrected by 50%. In the present study, we measured the preoperative and postoperative anterior, midline and posterior heights of the vertebral body with VCF in order to evaluate the restoration of the vertebral body; however, no significant increase was found in the heights following the kyphoplasty.

A minimum of 3 ml cement was used for each level during kyphoplasty. Although we could have used more cement for the compression fractures in the lumbar spine, we tried to minimise the potential complications, particularly using less cement after restoring the vertebral height. We believe that absence of a significant increase between the heights of levels by less cement and insufficiency of the vertebral height obtained by kyphoplasty didn't have an impact on the early clinical results.

In conclusion, in case of appropriate selection of patients, kyphoplasty can be considered a reliable and effective treatment method in the osteoporotic VCF with a success rate as high as 80-95%. It should be noted that potential complications may increase the morbidity, even they may become fatal in spite of a very low rate of severe complications. Some long-term, randomised, prospective and larger studies are

required in order to confirm the advantages offered by kyphoplasty.

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