Balloon Kyphoplasty using a Unilateral Approach for the Treatment of Osteoporotic Vertebral Compression Fractures

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Purpose: To evaluate the clinical results of a unilateral balloon kyphoplasty for the treatment of osteoporotic vertebral compression fractures (VCFs).

Materials and Methods: Twenty patients, 23 cases of osteoporotic VCFs who failed to respond to nonoperative treatments and who were confirmed by a consultant radiologist, were enrolled in this study. Times between injury and operation varied from 2 weeks to 2 months. All patients except two (18 female, 2 male patients), were female, and mean patient age was 71.7 (58-82) years. Follow-ups were conducted at least 12 months (12-27, mean 18.3). All patients underwent unilateral balloon kyphoplasty. Roentgenographic assessments were performed to evaluate fractured vertebra restoration and reduction loss. A ten-point visual analogue scale was used to measure pre- and postoperative pain severity.

Results: Preoperative anterior, middle and posterior heights of vertebra bodies were 57.8%, 66.1% and 85.3% of normal at presentation and these increased to 76.2%, 80.1%, 88.7% respectively at immediately after operation and at last follow-up, heights of each portion were 74.4%, 78.6%, 87.3%. Mean preoperative kyphotic angles of 17.6° at presentation improved to 8.9° at immediately after operations and to 9.1° at last follow-ups. Loss of reduction was 1.8%, 1.5%, 1.4% and 0.2°. Mean pain scores were 8.5 before surgery, 2.5 immediately after operations and 2.7 at last follow-ups. Statistical analysis showed a significant decrease in kyphotic angle (p=0.03) but VAS scores were no different (p=0.056). Anterior, middle and posterior body height was decreased with a statistical significance between two period (p<0.001). PMMA leakage occurred in 3 cases, but they did not cause neurologic deficits.

Conslusion: Balloon kyphoplasty using a unilateral approach is a good treatment method for osteoporotic vertebral compression fractures and an alternative to the substitute bilateral approach.

Key Words: Spine, Osteoporosis, Compression fracture, Balloon kyphoplasty, Unilateral approach

INTRODUCTION
Osteoporotic VCFs are not uncommon disease and thus, many patients may suffer from acute pain and from chronic symptoms and resultant osteoporotic spinal deformities due to these fractures. Osteoporotic VCFs restrict ambulation, reduce quality of life, and reduce lifespan. Their adverse affects on the activities of daily living are almost as great as those associated with hip fractures. Primary treatment for osteoporotic
VCFs is conservative and includes bed rest, analgesics, and early ambulation with a brace after relieving symptoms. However, some patients complain of severe pain that does not respond to these conservative treatments and even progressive collapse of vertebral bodies and kyphosis may occur with or without neurologic deficit. Even though more aggressive treatment may be needed in these cases, the majority of patients with osteoporotic VCFs are not good candidates for general anesthesia. During the past decades, vertebroplasty (VP), has been adopted as an optimal treatment of osteoporotic VCFs, and has the advantages of rapid pain relief and a long-lasting effect, but it cannot make fully restore the height of affected vertebra bodies. The introduction of a newly designed, minimally invasive technique, balloon kyphoplasty (BK), has allowed collapsed vertebral body to be restored using an inflatable bone tamp. Moreover a viscous polymethylmethacrylate (PMMA) is then introduced to the hollow cavity produced under low pressure.

Here the authors report our experience of balloon kyphoplasty using a unilateral approach, and describe the results of our evaluation and the efficacy of unilateral BK for the treatment of osteoporotic VCFs.

**MATERIALS AND METHODS**

Twenty patients, 23 cases of osteoporotic VCFs who failed to respond to conservative treatment confirmed by a consultant radiologist were enrolled in this study. Times between injury and operation varied from 2 weeks to 2 months. Twenty one women and two men were enrolled in this study (mean age: 71.7 (58–82) years). The minimum follow-up period was minimum 12 months. Average bone density (T-score) using DEXA (dual energy X-ray absorptiometry) was −4.8 (−3.9–−6.4). All patients were classified as more than grade III according to the ASA (American Society of Anesthesiology) classification. Before operations, plain anteroposterior (AP) and lateral views, radioscintigraphy, computed tomography (CT) or magnetic resonance imaging (MRI) were performed to confirm diagnosis and to exclude pathologic or metastatic disease. Whole procedures were performed under the local anesthesia. Based on operatively measured indexes, including angle of bone tamp and distance from the midline (Fig. 1), Balloon kyphoplasty using a unilateral approach were performed under fluoroscopic guidance. The operative indications for unilateral approach were the same as for the bilateral approach. However, unlike the bilateral approach, the bone tamp was advanced more across the midline on anteroposterior view. Also, to avoid great vessel injury, bone tamp entry was performed on the same side as great vessels. The remaining procedures were identical to those used during the bilateral approach. Postoperatively plain AP, lateral X-ray
and CT were performed. Anterior, middle and posterior heights of vertebral bodies and local kyphotic angles were measured at preoperatively, immediate postoperatively and at final follow-up. Vertebral body heights were measured as follows. Anterior, middle, and posterior vertebral heights were defined as the distances between the upper and lower endplates at the anterior, posterior cortical margin and center of the fractured vertebra body. Vertebral body heights were expressed as ratio of estimated prefracture heights. Prefracture heights were defined as average value of the sum of the heights of the two adjacent vertebrae. All patients were evaluated using a ten-point Visual Analogue Scale (VAS) for pre- and postoperative pain severity. Postoperative changes in vertebral body heights and in VAS scores were analyzed using the paired Student’s t-test, and the one sample t-test was used to compare the results of the present study with the results obtained by Berlemann et al.2) who used bilateral balloon kyphoplasty. Preoperative kyphosis, reductions in kyphosis and percentage reductions were not statistically significant (p=0.6265, 0.5582, 0.9082). The PMMA leakage occurred in 3 cases, but it did not cause neurologic deficits. No adjacent vertebra fractures occurred.

RESULTS

Preoperative anterior, middle and posterior heights of vertebra body of 57.8%, 66.1%, 85.3% was increased to 76.2%, 80.1%, 88.7% immediately after operation and at the last follow-ups, these heights had increased to 74.4%, 78.6%, 87.3%, respectively. The mean preoperative kyphotic angle of 17.6° improved to 8.9° at immediate after operations and to 9.1° at last follow-ups. Loss of reduction was 1.8%, 1.5%, 1.4% and 0.2°. Mean VAS pain score was 8.5 before surgery, decreased to 2.5 immediately after operations and was maintained at 2.7 at last follow-ups. Changes in vertebral body heights from immediately after operations to the last follow-ups were analyzed using the Student’s paired t-test. Statistical analysis showed a significant reduction in mean kyphotic angle (p=0.03) but no difference of VAS scores (p=0.056). Anterior, middle and posterior body heights decreased with statistical significance between these two times (p<0.001). The one-sample t-test was used to compare the results of the present study with the results obtained by Berlemann et al.2) who used bilateral balloon kyphoplasty. Preoperative kyphosis, reductions in kyphosis and percentage reductions were not statistically significant (p=0.6265, 0.5582, 0.9082). The PMMA leakage occurred in 3 cases, but it did not cause neurologic deficits. No adjacent vertebra fractures occurred.

DISCUSSION

Osteoporosis is defined as a diminished bone density of 2.5 standard deviations below the average bone density of healthy 25 year olds of the same sex. Using this criterion, 25% of postmenopausal women and 35% of women over 65 years of age in the United States suffer from osteoporosis1). The incidence of osteoporotic spine fractures in the United States is about 700,000 per year, of which more than one third are associated with chronic pain and 85% of these cases are due to primary osteoporosis3,15). Osteoporotic VCFs are an important cause of back pain and kyphotic deformity in the elderly. Osteoporotic VCFs occurs most commonly at the thoracolumbar junction, especially L111,12). Pain from acute osteoporotic vertebral compression fractures usually resolves over 6 to 8 weeks with conservative treatment, including medical and orthotic treatments. However, a few patients continue to complain of severe back pain, especially during motion of the trunk, and resultant kyphotic deformity. Such patients who are unresponsive to nonoperative treatment may be candidates for surgical treatment.

Vertebroplasty was developed during the late
1980s and Lapras first introduced this technique to treat fractured vertebra bodies\(^\text{10}\). Subsequently, it has gained wide acceptance for the treatment of osteoporotic vertebral compression fractures. In 2001, the first report on balloon kyphoplasty issued by Lieberman et al. Balloon kyphoplasty has several advantages over the vertebroplasty\(^\text{13,14}\) i.e., it offers immediate pain relief, stability and restores local kyphosis by reducing the fractured vertebrae with an inflatable bone tamp. In addition, more viscous PMMA is introduced under low pressure into the cavity made by the inflatable bone tamp, and as a result the rate of complications associated with this technique, such as, thromboembolism, and neurologic deficits due to extravertebral PMMA leakage are low. For this reason, balloon kyphoplasty has become popular. Moreover, nowadays, the indications for balloon kyphoplasty have expanded to pathologic fractures and even more revised cases\(^\text{6,15}\).

Several authors have reported the results for balloon kyphoplasty executed under general anesthesia\(^\text{4,5,11}\). However as mentioned above, all patients enrolled in the present study were debilitated (more than ASA grade III), and thus, operations were performed under local anesthesia. Also, during our earlier experiences of the technique, we treated patients using the bilateral approach under local anesthesia. However, when we tried to create access channels using the bone tamp, many patients complained of severe pain that was not controlled by local anesthetics or even parenteral sedatives and thus, we adopted unilateral approach to reduce pain. In the present study, all procedures were executed under local anesthesia.

Some authors have reported the results for the bilateral approach with those of present study, we found that results were similar. Several authors have reported that the clinical results of balloon kyphoplasty were not always positively correlated with the restoration of height or amount of PMMA introduced\(^\text{5}\).

### CONCLUSION

We may conclude that balloon kyphoplasty using the unilateral approach is a satisfactory treatment method for osteoporotic vertebral compression fractures and that it offers a substitute to the bilateral approach.

### REFERENCES

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= 국문초록 =

목적: 골다공증성 척추 압박 골절에서 일측 도달법을 이용한 풍선척추성형술의 임상 결과를 평가해보고자 한다.

재료 및 방법: 척추 골다공증성 압박 골절로 진단되었으며 보존적 치료에 반응을 보이지 않았던 20명, 23예를 대상으로 하였다. 이들은 수상일에서 수술시점까지 2주에서 2개월간 경과하였던 자들로 대부분이 여성 환자(여자 19명, 남자 2명)이었으며 평균연령은 71세였다. 최초 추시기간은 12개월(평균 18.3개월)이었다. 전체에서 일측도달법을 이용한 풍선척추 성형술을 시행하였으며 골절된 척추체의 회복 및 추체 정복의 소실을 측정하기 위해서 숭전 및 수술 직후, 최종 추시 시 전후면 및 측면 방사선 활영을 시행하였다. 또한 통증의 정도를 측정하기 위해 Visual analogue scale을 측정하였다.

결과: 각각의 부위에서 숭전 척추체 높이는 57.8%, 66.1%, 85.3%였으며 수술 직후 76.2%, 78.6%, 87.3%, 최종 추시 시 74.4%, 78.6%, 87.3%로 측정되었고 국소분절 후만각은 17.6도, 수술 직후 8.9도, 최종 추시 시 9.1도로 측정되었다. visual analogue scale은 숭전 8.5에서 수술 직후 2.5, 최종 추시 시 2.7로 유지되었다. 수술직후와 최종 추시를 비교한 통계 결과에서 전방, 중앙 및 후방 척추체의 높이(p<0.001)와 후만각(p=0.03)은 의미있는 감소를 보였으나 visual analogue scale (p=0.056)은 변화를 보이지 않았다. 3예에서 골시멘트의 유출이 있었으나 신경학적 합병증은 유발하지 않았다.

결론: 일측 도달법을 이용한 풍선척추성형술은 양측성 도달법을 대체할 수 있는 골다공증성 척추압박골절의 좋은 치료법으로 생각된다.

색인단어: 척추, 골다공증, 압박 골절, 풍선 척추 성형술, 일측 도달법