Long-term follow-up study of osteoporotic vertebral compression fracture treated using balloon kyphoplasty and vertebroplasty

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OBJECT Long-term follow-up study is required for verifying whether the clinical outcomes of kyphoplasty and vertebroplasty are altered. The authors' findings showed only subtle differences between these operations within a 5-year period. However, they still suggest the use of vertebroplasty over kyphoplasty in view of the treatment costs. In their previous study, the authors performed a short-term prospective comparison between vertebroplasty and kyphoplasty. Vertebroplasty was recommended instead of kyphoplasty for the treatment of vertebral compression fractures (VCFs) because of the subtle differences between this procedure and kyphoplasty and the treatment costs. To determine whether these clinical outcomes persist in the long term, they continued to observe the patients from their short-term study over a longer-term period.

METHODS One hundred cases of VCF were assigned randomly to either the kyphoplasty or the vertebroplasty group. In cement augmentation, the authors used polymethylmethacrylate as bone filler. Pain was assessed by using a visual analog scale (VAS). For each patient, vertebral body height and wedge angle were measured from reconstructed CT images.

RESULTS The duration of the follow-up period was 5 years. Vertebral body height, kyphotic wedge angle, and VAS score were not evidently altered. Eight patients in the kyphoplasty group had an adjacent fracture after the procedure, whereas 7 patients in the vertebroplasty group had an adjacent fracture after the procedure. These adjacent fractures occurred within 1 year of surgery in both treatment groups except in 1 kyphoplasty-treated patient in whom the adjacent fracture was noted 16 months after treatment. Three patients in the vertebroplasty group had a nonadjacent fracture, and 4 patients in the kyphoplasty group had a nonadjacent fracture. The link between angular correction and the occurrence of adjacent fracture was statistically significant in the vertebroplasty group.

CONCLUSIONS Excessive angular correction is a critical concern in the risk of adjacent fracture after vertebroplasty. Given the subtle differences between vertebroplasty and kyphoplasty observed over the course of 5 years, vertebroplasty remains the preferred option in view of the costs.

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KEY WORDS angular correction; cement augmentation; kyphoplasty; osteoporosis; vertebral compression fractures; vertebroplasty; deformity

THE incidence of osteoporotic vertebral compression fractures (VCFs) is an increasing health care problem. The common manifestations of osteoporotic VCFs are bone pain and kyphotic deformity, which affect physical function, psychosocial ability, and quality of life.^{6,7} Two augmentation treatments, namely, vertebroplasty and balloon kyphoplasty, were first reported in 1987 and 1988,

respectively. Vertebroplasty was initially performed for the treatment of angioma through consolidation of the vertebral column by injecting bone cement, most commonly polymethylmethacrylate (PMMA).⁵ Kyphoplasty was developed to treat kyphotic deformity and involved the use of an inflatable bone tamp placed into the vertebral body to restore body height.¹⁴

ABBREVIATIONS PMMA = polymethylmethacrylate; RCT = randomized controlled trial; VAS = visual analog scale; VCF = vertebral compression fracture.

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Vertebroplasty and balloon kyphoplasty are both safe and efficient procedures that are used to relieve pain, but recent reports have shown that both procedures are associated with an increased risk of new fractures.^{16,21} The subsequent fractures are mostly adjacent to the initial operative site because of bone cement augmentation and the transfer of greater load to adjacent vertebral levels, which leads to collapse of the adjacent vertebrae.^{1,19} A retrospective study showed that wedge angle changes affect the incidence of new symptomatic VCF after vertebroplasty.¹⁵ Moreover, adjacent-level fractures often occur within a shorter time period than nonadjacent fractures.^{4,27,28,30} Therefore, deciphering the correlation between risk factors and the onset of subsequent fractures is important for preventing the occurrence of subsequent fractures after each procedure.

Several recent studies have reported the clinical outcomes and complications of kyphoplasty and vertebroplasty.^{18,26,32} However, a comparative study of the occurrence of subsequent fracture after treatment has not been conducted. Questions about which of these two procedures provides a better clinical outcome and reduced complication rates and whether long-term outcomes are as favorable as short-term outcomes cannot be answered with certainty given the lack of data. Therefore, a long-term comparative and randomized study needs to be conducted to address these issues. After our previous short-term study, we investigated pain relief in and clinical outcomes of patients between 6 months and 5 years after surgery.

Methods

Patients

This study was performed at Chung-Shan Medical University Hospital and approved by the local institutional review board. Each patient provided informed consent before participating. One hundred patients diagnosed with an osteoporotic VCF at the thoracolumbar junction (T12–L1) were assigned to either the kyphoplasty or vertebroplasty group using permuted block randomization ($n = 50$ for each group). The kyphoplasty group was treated with balloon kyphoplasty, and the vertebroplasty group was treated with percutaneous vertebroplasty. The patients' demographic data and clinical characteristics (e.g., mean age, sex, operative time, amount of PMMA, location of osteoporotic VCF, and time between the injury and surgery) were reported in our previous study.¹⁶ Vertebral body height and kyphotic wedge angle, as well as the 10-point visual analog scale (VAS) pain score, were recorded before and after surgery. In this study, we used the well-known horizontal 10-point VAS, anchored on the left by "no pain" (score of 0) and on the right by "maximum pain" (score of 10). Radiographic measurements were obtained by technicians who were blinded to the treatment group status. Variability was controlled via interobserver and intraobserver comparisons. The follow-up period was 5 years.

Operative Technique

The indications for balloon kyphoplasty and vertebroplasty have been described previously.¹² The vertebroplasties were performed via a bipedicular approach. In terms

of the surgical procedures, intravenous general anesthesia (propofol) with 2% Xylocaine was injected locally. A special bone needle (Angiotech) was inserted percutaneously and slowly through each side of the pedicle into the vertebral body. The bone filler, PMMA (Zimmer), was prepared and mixed with an antibiotic (gentamicin) to reduce the risk of infection and a powder containing barium to enable x-ray visualization. An optimal amount of bone filler was injected into the vertebral body via the needles inserted on both sides. All procedures were performed under mobile C-arm x-ray monitoring. The kyphoplasties were performed with the same anesthetic protocol as for the vertebroplasties. Using image-guided radiography, 2 small incisions were made and a probe was placed into the vertebral space at the fracture site. The bone was drilled, and an inflatable balloon tamp (VCF-X Central Medical Tech.) was inserted into each side. The balloon tamp was then inflated with contrast medium to facilitate image guidance until the tamp expanded to the desired height. Once the desired height was achieved, the balloon tamp was removed. The spaces created by the balloon were then filled with PMMA (prepared as for vertebroplasty) to bind to the fractured vertebral body. Each patient was placed on an orally administered treatment regimen to protect bone density after surgery.

Statistical Analysis

Data plotting and statistics were processed using Prism (GraphPad software). The values shown represent means $\pm$ SDs of the mean. Vertebral body heights, kyphotic wedge angles, and VAS scores were statistically compared between the treatment groups using the paired Student t-test. Preoperative and postoperative vertebral body heights, kyphotic wedge angles, and VAS scores were assessed using the unpaired Student t-test. Kyphotic wedge angle differences and new incidences of adjacent fractures were statistically assessed with the Mann-Whitney U-test. Significance was set at a p value of < 0.05 .

Results

A total of 100 patients were equally divided into the kyphoplasty or the vertebroplasty group. None of the 100 patients manifested evident clinical complications because each procedure was performed under C-arm monitoring with barium. When the PMMA was near extravasation into the vein or the epidural space, we stopped the injection. In some cases there was even asymptomatic cement leakage into the epidural space or venous embolization; however, no adverse events were found. In our previous study, we found no statistical differences between the treatment groups in terms of age, sex, location of osteoporotic VCF, or duration between injury and surgery. Compared with the vertebroplasty group, the kyphoplasty group required a 1.13-fold-greater amount of PMMA (5.56 ± 0.62 ml vs 4.91 ± 0.65 ml; $p < 0.001$) and a 1.05-fold-longer operative time (46.2 ± 4.5 minutes vs 44.0 ± 4.4 minutes; $p < 0.05$).¹⁶

A previous study also reported an increase in vertebral body heights, a decrease in kyphotic wedge angles, and significant improvements in VAS pain scores after each operation. However, no statistical difference in VAS pain

scores was observed between the treatment groups in the short-term study.¹⁶ To verify if this outcome persisted in the long-term analysis, we continually followed the findings of a previous study and extended the observation from 6 months to 5 years. The vertebral body heights, kyphotic wedge angles, and VAS pain scores were not evidently altered in either treatment group after 1 year or at the final follow-up (5 years) compared with those after surgery (at 3 days) (Figs. 1–3). Consistent with results of a previous study, no statistical difference in VAS pain scores between the treatment groups was observed, even at the extended 5-year follow-up period (Fig. 3).

Eight patients had an adjacent fracture after kyphoplasty, and 7 patients had an adjacent fracture after vertebroplasty. Adjacent fractures occurred within 1 year in both treatment groups, except for a patient in the kyphoplasty group in whom an adjacent fracture occurred 16 months after treatment. A nonadjacent fracture was documented in 4 patients in the kyphoplasty group and in 3 patients in the vertebroplasty group. However, no statistical difference in the incidence of VCF was observed between the surgical groups. The difference in kyphotic wedge angles and the risk of adjacent fracture in the vertebroplasty group ($2.84^\circ \pm 2^\circ$ vs $6.2^\circ \pm 3.91^\circ$, $p < 0.05$) showed a significant relationship, demonstrating that excessive angular correction increased the risk of adjacent fracture after vertebroplasty (Fig. 4).

Discussion

Several articles have reported that both kyphoplasty and vertebroplasty offer a safe and efficient way to treat osteoporotic VCF.^{8,11,31} However, the efficacy of the treatments is coupled with the risk of multiple complications. For instance, cement leakage and new symptomatic VCF are commonly diagnosed postoperatively. Although comparative studies between the 2 treatments have been performed, whether kyphoplasty or vertebroplasty provides a better clinical outcome and reduced complications is still debatable.^{8,11,20,22,31} Thus, a randomized controlled trial (RCT) is necessary to settle this controversial issue. A short-term RCT was established in our previous study.¹⁶

FIG. 1. Vertebral body height before and 3 days, 1 year, 2 years, and 5 years after kyphoplasty and vertebroplasty. Values represent mean $\pm$ SD. *** $p < 0.001$ (Student t-test).

FIG. 2. Kyphotic wedge angle before and 3 days, 1 year, 2 years, and 5 years after kyphoplasty and vertebroplasty. Values represent mean $\pm$ SD. *** $p < 0.001$ (Student t-test).

To determine if the results of our short-term RCT were altered by time, we followed the patients for 5 years. In this study, we found that vertebral body heights, kyphotic wedge angles, and VAS pain scores were not evidently altered in the kyphoplasty or vertebroplasty group, and no statistically significant difference was observed between the VAS pain scores of both groups. Because of similar intergroup clinical outcomes and long-term pain relief and because of the higher cost of the balloon-tamp procedure, we believe that vertebroplasty is a better choice than kyphoplasty for the treatment of osteoporotic VCF. Furthermore, vertebroplasty's prevention of excessive angular correction could provide a better clinical outcome compared with kyphoplasty.

Vertebral body height restoration and wedge angle correction are thought to be the main purposes of treating osteoporotic VCF with kyphoplasty or vertebroplasty.^{2,9,12,17} Recent studies found that kyphoplasty has superior capability in restoring vertebral body height.^{23,29} Moreover, we found that kyphoplasty restored more vertebral body height than vertebroplasty. The inflated balloon tamp most likely created a space wherein the cement was injected into the center, thereby facilitating the restoration of the verte-

FIG. 3. VAS pain score before and 3 days, 1 year, 2 years, and 5 years after kyphoplasty and vertebroplasty. Values represent mean $\pm$ SD. *** $p < 0.001$ (Student t-test).

FIG. 4. The wedge angle difference affects the incidence of adjacent fracture after vertebroplasty. Wedge angle difference is the wedge angle before the procedure minus the wedge angle after the procedure. Values represent mean $\pm$ SD. * $p < 0.05$ (Mann-Whitney U-test).

bral body height. In wedge angle correction, the wedge angle is reduced by 3.5° – 7.4° after vertebroplasty^{2,24} and by 4° – 10° after kyphoplasty.^{3,25} Our procedures resulted in an 8.0° reduction in wedge angle after kyphoplasty and a 3.3° reduction after vertebroplasty.

Regarding complications associated with kyphoplasty and vertebroplasty, the incidences of new symptomatic VCFs were 24% (16% adjacent and 8% nonadjacent) and 20% (14% adjacent and 6% nonadjacent), respectively. No evident difference in the incidence of new VCF between surgical procedures was observed. Adjacent fractures occurred within 1 year after the completion of treatment in both groups, except for one in a patient in the kyphoplasty group who had a nonadjacent fracture 16 months after treatment. The nonadjacent fractures were observed 24.5 months after kyphoplasty and 27 months after vertebroplasty. These results reflect the findings of a previous study, which demonstrated that adjacent fractures were observed sooner than nonadjacent fractures.²⁷

Although kyphotic wedge angle corrections can relieve pain, previous studies have demonstrated that wedge angle changes affect the incidence of new symptomatic VCF after vertebroplasty.¹⁵ In line with these observations, our results show a statistically significant relationship between kyphotic wedge angle and risk of adjacent fracture after vertebroplasty. This relationship was likely the result of the greater load transferred to adjacent vertebral levels. However, this relationship did not reach statistical significance after kyphoplasty. Therefore, the correct amount of PMMA augmentation is still unknown and should be verified. Several studies have reported that other risk factors, such as initial wedge angle, restoration rate of vertebral height, lower body mass index, and bone mineral density, are associated with new symptomatic VCF after vertebroplasty.^{10,13,15}

In addition to even better clinical outcomes and reduced complications associated with vertebroplasty and kyphoplasty, with subtle differences, the correlation between wedge angle correction and new occurrence of adjacent fracture clearly suggests that prevention of excessive angular correction can provide a better clinical outcome via

vertebroplasty than via kyphoplasty. In view of the high cost of the balloon-tamp procedure and the advantages of vertebroplasty, we conclude that vertebroplasty is a better option than kyphoplasty for treating osteoporotic VCFs. Our study provides a strategy for choosing the optimal procedure considering safety, pain relief, and reasonable cost.

Conclusions

Excessive angular correction is a critical concern in the risk of adjacent-level fractures after vertebroplasty. Given the subtle differences between vertebroplasty and kyphoplasty viewed over 5 years, vertebroplasty is preferred in view of the costs.

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Author Contributions

Conception and design: all authors. Acquisition of data: Liu. Analysis and interpretation of data: Liu. Drafting the article: Liu. Critically revising the article: Liu. Reviewed submitted version of manuscript: Liu. Study supervision: Liu.

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