The outcomes of percutaneous kyphoplasty in treatment of the secondary osteoporotic vertebral compression factures: a case-control study

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Background: To investigate the outcomes of using percutaneous kyphoplasty in the treatment of the secondary osteoporotic vertebral compression fractures.

Methods: Eighty-one patients had the secondary single segmental osteoporotic vertebral compression fractures after the initial fractures and treated by percutaneous kyphoplasty were reviewed, 74 of them had minimum 2 years follow-up were included in this study. The 74 patients with primary osteoporotic vertebral compression fractures treated by percutaneous kyphoplasty at the same time period were matched as control group in 1:1 ratio. Visual Analogue Scales (VAS) and Oswestry Disability Index (ODI) were used to assess the back pain and functional outcomes. The kyphotic angulation (KA) and compression ratio (CR) of the fractured vertebra was measured too.

Results: Both the secondary fracture group and control group had significantly relieved back pain, improved functional outcomes, corrected KA and restored CR after operation, but no difference was found between two groups.

Conclusions: Our findings suggest that percutaneous kyphoplasty is an effective and safe procedure for patients with secondary single segmental osteoporotic vertebral compression fractures; it can achieve similar clinical outcomes to the primary osteoporotic vertebral compression fractures.

Keywords: Percutaneous kyphoplasty; minimally invasive; osteoporosis; vertebral fractures; spinal trauma

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Introduction

Osteoporotic fracture is one of the major global burdens of diseases (1-3). Osteoporotic fractures could occur in hip, vertebrae, and limbs. Osteoporotic vertebral compression fractures are mostly caused by the lower energy trauma or without trauma (4), and commonly in the elderly population. It was estimated that there were approximately 1.5 million vertebral compression fractures in US population every year (5). The European prospective osteoporosis study (6) found that the incidence of morphometric vertebral fracture was 10.7/1,000 person years (pyr) in women and 5.7/1,000 pyr in men and vertebral fracture as assessed qualitatively by the radiologist was 12.1/1,000 pyr and 6.8/1,000 pyr, respectively.

Percutaneous kyphoplasty or vertebroplasty was reported had effective outcomes in treatment of osteoporotic vertebral compression fractures (7-10), had advantages of minimally invasive, quicker recovery and shortening the hospital stay (11).

However, some patients will have the secondary vertebral compression fracture after the initial treatment (12,13), the secondary vertebral fracture may associate with severe spinal deformity and worse bone quality. The aim of this study is to investigate the outcomes of using percutaneous kyphoplasty in the treatment of the secondary osteoporotic vertebral compression fractures.

Methods

Patient population

From August 2008 to December 2014, a total of 81 patients had the secondary single segmental osteoporotic vertebral compression fractures after the initial fractures and treated by percutaneous kyphoplasty from two medical centers were recorded and reviewed, the secondary multiple segmental vertebral fractures were excluded to avoid the mixed influence, 74 out of 81 patients with minimum 2 years follow-up were included in this study. Then, the 74 patients with primary osteoporotic vertebral compression fractures treated by percutaneous kyphoplasty at the same time period were matched as control group in 1:1 ratio, the matched principles include: (I) the same gender; (II) age difference to the matched case is less than 3 years old; (III) single segmental vertebral fracture; (IV) followed up more than 2 years; (V) the surgeries were performed by the same surgeon.

Operative procedure

The operative procedure was similar to the Wu *et al.* (14). Briefly, the patients were placed at prone position under local anesthesia or general anesthesia. C-arm X-ray fluoroscope was used to guide the pedicle punctures and cement injection. Balloon tamps were used to expand the compressed vertebral body, the inflation was stopped when the pressure reached 300 psi or when the balloon made contact with the endplate. Polymethylmethacrylate cement was injected when it reached the "toothpaste" viscosity. All patients were permitted to ambulate at 12–24 hours after operation.

Pain and functional outcomes

Visual Analogue Scales (VAS) was used to assess the back pain at pre-operation, post-operation, and final followup; Oswestry Disability Index (ODI) was used to assess the functional outcomes at pre-operation, 3 months after operation, and the final follow-up.

Radiographic images

All of the radiographic images were assessed by two researchers for diagnosis (15) and measurement. The kyphotic angulation (KA) and anterior vertebral body height of fractured vertebrae, adjacent upper and lower vertebrae were measured on lateral X film at preoperation, post-operation, and the final follow-up. The estimated normal anterior height of the fractured vertebra was calculated using the following formula: NV = $1/2 \times$ (UV + LV), (NV: the estimated normal anterior height of the fractured vertebra; UV: the anterior height of the adjacent upper vertebrae above the fractured vertebra; LV: the anterior height of the adjacent lower vertebrae below the fractured vertebra). At the secondary fracture group, some patients had fracture of the adjacent vertebrae to initial fractured vertebrae, the UV and LV were measured at the second adjacent vertebrae. Then, the values of NV, UV and LV were used to calculate to the compression ratio (CR) of the anterior height of the fractured vertebra using following formula (16): CR = (NV - FV)/NV ×100% (FV: the anterior height of the fractured vertebrae) (Figure 1).

Statistical analysis

The data were analyzed with the software of IBM SPSS

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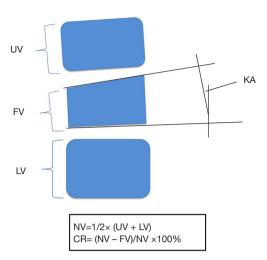


Figure 1 The measurement of kyphotic angulation (KA) and anterior vertebral body height of fractured vertebrae, adjacent upper and lower vertebrae. Compression ratio (CR) was calculated as CR = (NV – FV)/NV ×100%; NV =1/2× (UV + LV). FV, the anterior height of the fractured vertebrae; NV, the estimated normal anterior height of the fractured vertebra; UV, the anterior height of the adjacent upper vertebrae above the fractured vertebra; LV, the anterior height of the adjacent lower vertebrae below the fractured vertebra.

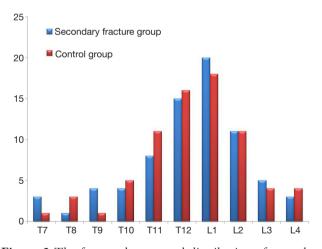


Figure 2 The fractured segmental distribution of secondary fracture group and control group.

Statistics (Version 22.0, IBM Corp., Armonk, NY, USA). The data of pre-operation, post-operation (or 3 months after operation of ODI), and the final follow-up of VAS, ODI, KA, and CR were tested by the repeated-measures analyses of variance, and the comparison of two groups was tested by two independent-samples t-tests. The level of significance was set at P<0.05.

Results

There were 26 males and 48 females at the secondary osteoporotic vertebral compression fractures groups, with the age of 74.3 ± 10.8 years old, and followed up 37.5 ± 12.9 months. Total 26 males and 48 females of primary osteoporotic vertebral compression fractures patients were matched as the control group, with the age of 74.6 ± 10.4 years old, and followed up 40.9 ± 16.3 months. No significant difference of age and follow up term between two groups (P=0.847 and 0.172, respectively). The segmental distribution of two groups was shown in *Figure 2*.

VAS and ODI outcomes

Both the secondary fracture group and control group had significantly relieved back pain after operation (P<0.05), with the changed VAS of 6.08 ± 1.53 and 6.11 ± 1.59 , respectively. The relieved pain maintained at the final follow up, no significant difference was found between the post-operation and final follow up. No significant difference was found between two groups in VAS at pre-operation, post-operation and final follow-up either (*Table 1*).

Both two groups had a significant improvement of ODI at 3 months after operation (P<0.05), with the changed values of 50.18 ± 15.60 and 53.61 ± 16.56 , respectively. No significant difference was found between the post-operation and final follow up. No significant difference was found between two groups in ODI at pre-operation, post-operation and final follow-up either (*Table 2*).

Radiographic outcomes

Both two groups had significant corrections of KA and CR after operation (P<0.05) (*Figure 3*). The changed KA of secondary fracture group and control group was $8.29^{\circ}\pm 5.95^{\circ}$ and $8.95^{\circ}\pm 7.22^{\circ}$ (*Table 3*), respectively; the changed CR of secondary fracture group and control group was $25.59\%\pm 12.32\%$ and $26.83\%\pm 13.44\%$ (*Table 4*), respectively. No significant difference of KA and CR were found between the post-operation and the final follow-up. And no significant difference between two groups in KA and CR at pre-operation, post-operation and final follow-up either.

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Groups	Pre-operation	Post-operation	Change	Final follow-up
Secondary fracture group	8.22±0.99	2.15±1.27*	6.08±1.53	1.87±1.22**
Control group	7.94±1.12	1.82±1.23*	6.11±1.59	1.75±1.26**
t	1.637	1.564	-0.142	0.597
Р	0.104	0.120	0.887	0.551

 Table 1 The comparisons of the VAS of back pain between two groups

*, the post-operative VAS is significant relieved when compared to the pre-operation (P<0.05); **, no significant difference was found between the post-operation and final follow-up (P>0.05). VAS, Visual Analogue Scale.

Table 2 The comparisons of the ODI between two groups

Groups	Pre-operation	Three months after operation	Change	Final follow-up
Secondary fracture group	76.94±13.34	26.75±7.60*	50.18±15.60	28.13±8.23**
Control group	80.69±14.67	27.08±8.04*	53.61±16.56	28.28±7.57**
t	-1.628	-0.253	-1.296	-0.116
Р	0.106	0.800	0.197	0.908

*, the post-operative ODI was significantly improved when compared to the pre-operation (P<0.05); **, no significant difference was found between the post-operation and final follow-up (P>0.05). ODI, Oswestry Disability Index.

Discussion

Secondary osteoporotic vertebral compression fractures after the initial fractures are not rare condition (17). Lee *et al.* (18) followed up 198 patients for 4-year, found 34 (17.2%) of them had secondary osteoporotic vertebral compression fractures. Lindsay *et al.* (12) analyzed data of four large 3-year osteoporosis treatment trials that conducted at 373 centers in North America, Europe, Australia, and New Zealand; they found that the incidence of secondary vertebral fractures of the participants who had developed an initial incident vertebral fracture was 19.2% in the subsequent year.

Many factors may contribute to the secondary vertebral fractures, including age, lower bone mineral density, lower activity level after the first operation, and bone cement distribution (19-21). The finite element analysis showed cement augmented vertebral bodies had more than 12 times stiffer and 35 times stronger than the un-augmented level, therefore, increasing the pressure of adjacent levels (22), however, there is still no high quality evidence supporting vertebroplasty would increase the risk of secondary vertebral fracture, neither adjacent nor total vertebral fracture (23). Lin *et al.* (24) reported that the cement leakage into the disc would increase the risk of secondary fracture of the adjacent vertebral body, maybe it is also associated with the increased

pressure on adjacent levels, to avoid the disc cement leakage may decrease the incidence of secondary vertebral fractures.

The prevention of secondary fractures after initial operation is also important. Black *et al.* (25) suggested that women with low bone mass and existing vertebral fractures, alendronate can reduce the frequency of morphometric and clinical vertebral fractures. The hormone-replacement therapy and parathyroid hormone (PTH) also can increase vertebral bone-mineral density (26). Proper intake of vitamin D, vitamin A, vitamin K, calcium and protein may also improve the bone-mineral density and reduce the risk of fracture (3,27-29).

However, once the secondary vertebral fractures happened, positive treatments would conduct. Conservative treatments have long-term bed rest, may induce further bone mineral loss, and high risk of deep vein thrombosis, pneumonia, urinary tract infection and pressure sores. Percutaneous vertebroplasty or kyphoplasty yielded faster, better pain relief and earlier ambulance (30-32). A prospective randomized controlled study conducted by Yang *et al.* (31), comparing the percutaneous vertebroplasty with the conservative treatment in treatment of the acute osteoporotic vertebral compression fractures, found that percutaneous vertebroplasty had much greater pain relief after operation, and fewer complications. Another

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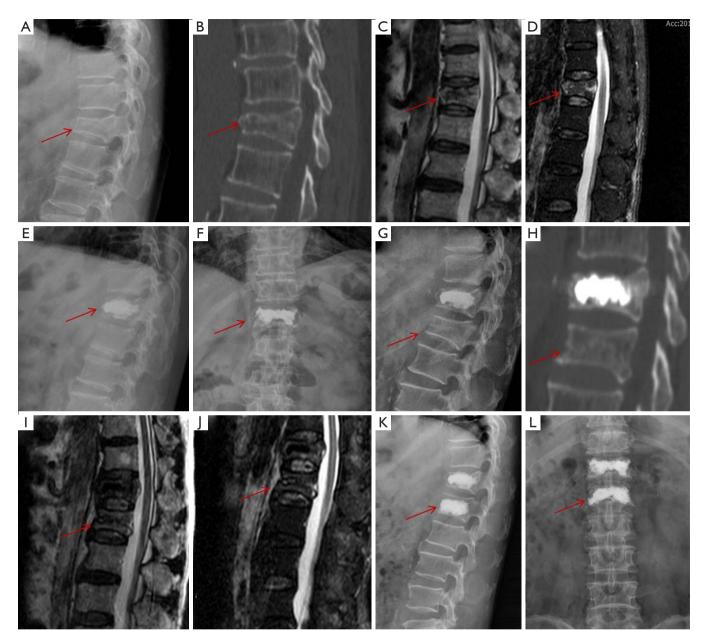


Figure 3 A typical secondary osteoporotic vertebral compression fracture patient. The patient had primary T12 osteoporotic compression fracture [(A) lateral film; (B) sagittal CT reconstruction; (C) MR T2 image; (D) MR fat suppress image], percutaneous kyphoplasty was performed [(E) lateral film; (F) anteroposterior film], the patient had significantly pain relief and back to the normal life. Unfortunately, he had pain re-occurred and secondary L1 osteoporotic compression fracture 2 months after the first operation [(G) lateral film; (H) sagittal CT reconstruction; (I) MR T2 image; (J) MR fat suppress image], percutaneous kyphoplasty was performed on him again [(K) lateral film; (L) anteroposterior film], the patient had significantly pain relief and went back to the normal life again, no pain re-occurred at the final 35 months follow-up. Red arrows indicate the primary T12 osteoporotic compression fracture in A–F, and the secondary L1 osteoporotic compression fracture in G–L.

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Groups	Pre-operation	Post-operation	Change	Final follow-up
Secondary fracture group (°)	14.93±5.88	6.64±2.73*	8.29±5.95	7.27±3.32**
Control group (°)	16.41±7.01	7.47±3.26*	8.95±7.22	7.59±3.19**
t	-1.398	-1.668	-0.609	-0.598
Р	0.164	0.098	0.544	0.551

 Table 3 The comparisons of the KA between two groups

*, the post-operative KA was significantly corrected when compared to the pre-operation (P<0.05); **, no significant difference was found between the post-operation and final follow-up (P>0.05). KA, kyphotic angulation.

Table 4 The comparison	is of the CR of back	k pain between two groups
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Groups	Pre-operation	Post-operation	Change	Final follow-up
Secondary fracture group (%)	44.45±14.33	18.86±9.81*	25.59±12.32	19.10±8.84**
Control group (%)	47.25±16.29	20.42±11.14*	26.83±13.44	20.91±10.02**
t	-1.110	-0.903	-0.585	-1.166
Р	0.269	0.368	0.559	0.246

*, the post-operative CR was significantly re-stored when compared to the pre-operation (P<0.05); **, no significant difference was found between the post-operation and final follow-up (P>0.05). CR, compression ratio.

randomized controlled study by Wardlaw *et al.* (10), found percutaneous kyphoplasty had better improvements in quality of life, disability measures and reduction of back pain than conservative treatment in follow-up time points <1 year, and trend to similar at 1 year, suggested percutaneous kyphoplasty is an effective and safe procedure and it could be considered as an early treatment option.

In our present study, all patients were permitted to ambulate at 12–24 hours after operation, the VAS of back pain was significantly relieved and the functional outcome was significantly improved after operation, the results were similar to the secondary fracture group and control group, we suggest the percutaneous kyphoplasty also has higheffective outcome for secondary vertebral fractures.

Both of percutaneous vertebroplasty and percutaneous kyphoplasty can significantly relieve the back pain and improve the function, however, percutaneous kyphoplasty with ball inflation may have a better correction of kyphosis. A systematic review and a meta-analysis (33) showed the kyphoplasty had lower risk of cement extravasation and greater correction of kyphosis than vertebroplasty. Since the secondary vertebral fracture associated with severe spinal deformity, therefore, we choose percutaneous kyphoplasty and hope it would be a better correction of kyphosis.

The limitations of this study include the nature of retrospective study, and non-randomized. All of the

involved patients were single segmental vertebral fractures; therefore the results and conclusion of this study should be limited to interpret the secondary single segmental vertebral fractures. Moreover, the control patients were treated by percutaneous kyphoplasty too, therefore, we still cannot conclude the percutaneous kyphoplasty had a better correction of kyphosis than the percutaneous vertebroplasty; further percutaneous kyphoplasty *vs*. percutaneous vertebroplasty in the treatment of secondary vertebral fractures may need to be conducted.

Conclusions

Our findings suggest that percutaneous kyphoplasty is an effective and safe procedure for patients with secondary single segmental osteoporotic vertebral compression fractures; it can achieve similar clinical outcomes to the primary osteoporotic vertebral compression fractures.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: This study was approved by Institutional Review Board (IRB) (No. 2015-30) of Ninth People's Hospital Shanghai Jiaotong University School of Medicine and The Second Affiliated Hospital and Yuying Children's Hospital of the Wenzhou Medical University. Informed consent was obtained from all participants.

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