

CLINICAL OBSERVATION

Treatment of osteoporotic vertebral compressive fractures with percutaneous kyphoplasty and oral Zishengukang

Zhenjun Huang, Lijian Zhang

Zhenjun Huang, Lijian Zhang, Rehabilitation Centre of the 309th Hospital of the People's Liberation Army of China, Beijing 100091, China

Correspondence to: Prof. Zhenjun Huang, The 309th Hospital of the People's Liberation Army, Beijing 100091, China. mhuangzhenjun521@126.com

Telephone: +86-10-66780355

Accepted: June 26, 2012

Abstract

OBJECTIVE: To observe the therapeutic effect of percutaneous kyphoplasty (PKP) and oral Zishengukang (ZSGK) for the treatment of osteoporotic vertebral compression fractures (OVCFs).

METHODS: Seventy patients were randomly divided into a control group (PKP group) and an experimental group (PKP plus ZSGK group). The 35 patients in the experimental group were prescribed 6 g oral ZSGK three times a day for 90 days after PKP. Visual analog pain scale (VAS), Oswestry functional score, vertebral height and Cobb's angle were recorded and compared before treatment and at one week, one month and three months after treatment.

RESULTS: Vertebral height and Cobb's angle significantly improved and VAS and Oswestry functional score were significantly lower in both groups after PKP than pre-operatively ($P < 0.01$). Three months after treatment, VAS and Oswestry functional score in the experimental group were lower than controls ($P < 0.05$), even though vertebral height and Cobb's angle were comparable ($P > 0.05$).

CONCLUSION: PKP combined with oral ZSGK pro-

vide superior short-term and long-term symptom control after OVCF than PKP alone.

© 2012 JTCM. All rights reserved.

Key words: Osteoporosis; Fractures, Compression; Kyphoplasty; Zishengukang pill

INTRODUCTION

In an aging population it seems self-evident that the incidence of osteoporotic vertebral compression fracture (OVCF) will rise. OVCFs are mainly characterized by repeated vertebral fracture at many sites with little or no history of trauma.¹ Percutaneous kyphoplasty (PKP) has been an increasingly popular means of treating OVCFs since the 1990s; its positive impact on patient outcomes has led to its widespread adoption in clinical practice.^{2,3} Zishengukang (ZSGK) consists of Yinyanghuo (Herba epimedii), Danggui (Radix angelicae sinensis), Shudihuang (Radix rehmanniae praeparata), Tusizi (Semen cuscatae), Bajitian (Radix morindae officinalis), Shanzhuyu (Fructus corni) and Niuxi (Radix achyranthis bidentatae). It acts to reinforce the kidney, nourish blood, supplement essence and enrich marrow; therefore, the preparation would be expected to have therapeutic value in the treatment of OVCF.⁴ We hypothesized that an additional therapeutic advantage could be gained by adding a course of ZSGK for patients undergoing PKP.

METHODS

Patient characteristics

Seventy inpatients at our hospital diagnosed with OVCF consented to participate in the study between 2008 and 2011: 23 were male and 47 female; their mean age was 72 ± 18 years (range 60-82), and average duration of symptoms was (4.2 ± 1.5) days (range

1 day-12 days). The location of the fractures was T11 in five cases, T12 in 17, L1 in 10, L2 in 8, and in 30 cases there were two or more thoracolumbar vertebral fractures. The mechanism of injury was road traffic collision in 11 cases, fall from a height in four cases, fall and sprain in 32 cases, and traffic in 23 cases. The 70 OVCF patients were randomized into an experimental group ($n=35$) and a control group ($n=35$), which did not significantly differ on the basis of age, gender, duration of symptoms and fracture site ($P>0.05$).

Diagnosis and inclusion criteria

Patients were included in the study if they: complained of back pain and diminished function without nerve injury with or without a history of injury; had sufficiently reduced bone density ($T\leq 2.5$ standard deviations) to meet the diagnostic criteria for osteoporosis;⁵ had acute or sub-acute OVCF diagnosed on X-ray, computed tomography or magnetic resonance imaging without evidence of primary or metastatic spinal tumor; had no immediate contraindication to PKP such as recent myocardial infarction and were fit enough to tolerate the procedure lying prone under local anesthesia.

Therapeutic method

PKP was performed as described by Chi Yonglong.⁶ Briefly, patients adopted the prone position and under local anesthesia and using X-ray guidance, the compressed vertebra was entered using a unipedicular approach. A balloon was inserted into the vertebra using an introducer, which was inflated sufficiently to correct the deformity before it was filled with bone cement. The vital signs, pain and neurological function were monitored closely throughout the procedure. After the bone cement had completely set, the patient adopted the supine position. After six h, patients were permitted to turn under supervision. On the second postoperative day, they were permitted to get out of bed wearing a support garment, and to leave hospital three to four days after the procedure with instructions to exercise their back muscles. As outpatients, patients were followed up regularly for 12 months by telephone or in clinic for questionnaires, repeat X-rays and bone density scans. Patients in the experimental group were administered oral ZSGK 6 g three times daily immediately postoperatively for 90 subsequent days. ZSGK pills were provided by Henan Provincial TCM Hospital with the batch number 200060926.⁴

Outcome measures

A visual analog scale (VAS) of pain was recorded before treatment and at one week, one month and three months after treatment. A score of 1.0-3.9 represented mild pain, 4.0-6.9 moderate pain, and 7.0-10.0 severe pain.

Oswestry functional score measures nine items relevant to patients with back pain relating to activities of daily living, carrying items, walking, sitting, standing, sleeping, and engaging in social activities and travel. A score

of 0-5 is given for each item; 0 represents no dysfunction and 5 the most disabling dysfunction. A total score of 0-15 represents excellent functional rehabilitation, 16-30 good functional rehabilitation, and 31-45 poor functional rehabilitation.

Vertebral height and Cobb's angle were measured using X-ray images of the spine, obtained before the procedure and regularly during follow up. Vertebral height and Cobb's angle were measured from the images using Workstation V2.03. Cobb's angle of the spine is the intersection angle between the lines vertical to the lower plane of the upper vertebra and the upper plane of the lower vertebra.

Vertebral height and Cobb's angle were measured and compared with the pain VAS and Oswestry function scores before treatment and at one week, one month and three months after treatment.

Statistical methods

Experimental data were processed with SPSS 11.0 software. The Student's *t* test was used to compare continuous quantitative data. Results are expressed as the mean \pm standard deviation (SD). A *P* value <0.05 was considered statistically significant.

RESULTS

Most patients were treated successfully without complication: one patient had an asymptomatic leak of bone cement from the vertebra that did not enter the spinal canal or the intervertebral foramina; another developed fever that was successfully treated with anti-inflammatory drugs. After the procedure, most back pain was alleviated and quality of life enhanced.

Comparison of pain VAS scores before and after treatment

Pain VAS scores in both groups were significantly lower at one week, one month and three months after treatment than those before treatment ($P<0.01$), showing that both PKP and PKP plus ZSGK are an effective means of treating the pain of OVCF. Three months after treatment, the mean VAS score in the experimental group (PKP+ZSGK) was significantly lower than that in the control group ($P<0.05$), indicating that the long-term analgesic effect of PKP plus ZSGK was greater than that of PKP alone (Table 1).

Comparison of Oswestry functional scores before and after treatment

Oswestry functional scores in the both groups at one week, one month and three months after treatment were significantly lower than before treatment ($P<0.01$). Three months after treatment, the Oswestry functional score in the experimental group was significantly lower than that in the control group ($P<0.05$), indicating that PKP plus ZSGK improved function in the longer term more effectively than PKP alone (Table 2).

Table 1 Pain VAS scores in the two groups before and after treatment (score, $\bar{x} \pm s$)

Group	<i>n</i>	before treatment	1 week after treatment	1 month after treatment	3 months after treatment
Control group	35	8.2±1.0	2.2±1.1 ^a	1.8±1.0 ^a	1.5±0.9 ^a
Experimental group	35	8.2±1.1	2.2±1.3 ^a	1.8±1.0 ^a	1.1±0.7 ^{ab}

Notes: ^a*P*<0.01 as compared with VAS before treatment; ^b*P*<0.05 as compared with VAS at the same time in the control group.

Table 2 Oswestry functional scores (score, $\bar{x} \pm s$)

Group	<i>n</i>	Before treatment	1 week after treatment	1 month after treatment	3 month after treatment
Control group	35	41.3±5.8	20.4±5.0 ^a	19.3±5.1 ^a	18.3±6.2 ^a
Experimental group	35	42.2±6.1	20.2±5.3 ^a	18.3±5.0 ^a	15.2±5.0 ^{ab}

Note: ^a*P*<0.01 as compared with the score before treatment; ^b*P*<0.05 as compared with the score at the same time in the control group.

Table 3 Vertebral height and Cobb's angle ($\bar{x} \pm s$)

Group	<i>n</i>	Vertebral height (middle section)(cm)		Cobb's angle (degree)	
		Before treatment	3 months after treatment	Before treatment	3 months after treatment
Control group	35	0.73±0.15	0.82±0.18 ^a	8.02±5.56	5.53±5.07 ^a
Experimental group	35	0.72±0.17	0.83±0.19 ^a	8.04±6.24	5.45±5.11 ^a

Note: ^a*P*<0.01 as compared with before treatment.

Vertebral height and Cobb's angle before and after treatment

After treatment, vertebral height and Cobb's angle were significantly improved when compared with before treatment (*P*<0.01). There was no statistical difference in vertebral height and Cobb's angle between the two groups at all time points (*P*>0.05, Table 3)

DISCUSSION

OVCF mostly affects the elderly, the main symptoms are pain and limited activity. If severe, the fracture may also cause secondary dysfunction to the respiratory, gastrointestinal and cardiovascular systems, and the condition can be fatal.⁷ At present, PKP is generally considered to be one of the most safe and effective methods of treating OVCF, and it is widely used in clinical practice. Balloon kyphoplasty can restore the height of compressed vertebrae, improve the alignment of the spine and restore its anatomical and mechanical properties, thus offering a clear means of improving symptoms whilst remaining safe and relatively non-invasive.^{8,9} It is widely recognized that PKP can stabilize the spine, swiftly reduce pain, restore the height of compressed vertebrae and correct vertebral deformity.¹⁰⁻¹² Our findings are consistent with this understanding, in that our patients also experienced substantially reduced back pain, and improved function and quality of life.

TCM holds that OVCF is a consequence of atrophic debility of the bones due to renal deficiency, and that healing of fractures—particularly osteoporotic fractures in the elderly—depends on supplementing kidney essence.^{4,13,14} Therefore, OVCF should be treated with methods that nourish blood, generate marrow, rein-

force the kidney and connect bones. In the recipe of ZSGK, Shu Dihuang (Radix Rehmanniae Praeparata) can nourish kidney-*yin*, Shan Zhu Yu (Fructus corni) can nourish the liver and kidney and draws together *Qi* and blood, Danggui (Radix Angelicae Sinensis) can replenish blood and *yin*, Niuxi (Radix achyranthis) can nourish liver and kidney and strengthen tendons and bones, and Yinyanghuo (Herba Epimedii) and Buguzi (Fructus Psoraleae) can replenish kidney-*yang* and strengthen tendons and bones. When used in combination they can supplement kidney-essence to replenish marrow and strengthen bones. Oral ZSGK can increase the density and mineral content of bones to alleviate the clinical symptoms of osteoporosis.^{4,13} In addition, a study has found that ZSGK can effectively promote healing of fracture malunion or nonunion.¹⁵

We recorded and compared pain VAS score, Oswestry functional score, vertebral height and Cobb's angle of OVCF patients before treatment and at one week, one month and three months after treatment. We found that PKP plus ZSGK can also effectively alleviate back pain after OVCF, restore vertebral height and Cobb's angle and enhance quality of life. In the long-term, the benefits of PKP plus ZSGK are more obvious. Although there was no statistical difference in the improvement of vertebral height and Cobb's angle between the two groups after three months, we observed a trend that might suggest greater improvements in patients who took ZSGK. This observation warrants further study over a longer period.

PKP and ZSGK, a combination of TCM with Western Medicine, can effectively alleviate the pain experienced by OVCF patients, improve spinal function, promote fracture healing and enhance quality of life.

REFERENCES

- 1 **Zhang Q**, Zou DW, Hai Y, et al. Primary result on treatment of OVCFs with PKP. *Zhong Hua Chuang Shang Gu Ke Za Zhi* 2006; 8 (5): 497.
- 2 **Michael HL**, Mark D, Patrick C, et al. Percutaneous Treatment of Vertebral Compressive Fracture: A Meta-analysis of Complications. *Spine* 2009; 34 (11): 1228.
- 3 **Xu SJ**, Huang YM, Shi YX, et al. Influence of PKP on vertebral height and pain of OVCFs. *Guangdong Yi Xue* 2009; 30 (10): 1518.
- 4 **Huang ZJ**, Chen JX, Bai YB. Clinical research into treatment of osteoporosis with ZSGK pill. *Sheng Wu Ji Shu Tong Xun* 2008; 19 (2): 263-264.
- 5 **Liu ZH**, Yang YZ, Zhu HM, et al. Suggested standard for diagnosing osteoporosis of Chinese people. *Zhong Guo Gu Zhi Shu Song Za Zhi* 2000; 6 (1): 1.
- 6 **Chi YL**. Vertebral micro-traumatic surgery. Beijing: People's Press of Military Medicine, 2006: 553-566.
- 7 **Lin JT**, Lane JM. Osteoporosis: a review. *Clin Orthop Relat Res* 2004; 126-134.
- 8 **Zhou W**, Li LJ, Qian L, et al. Treatment of OVCFs with closed reposition PKP. *Zhong Guo Gu Shang Yu Guan Jie Sun Shang Za Zhi* 2010; 25 (1): 48-49.
- 9 **Wang WP**, Liu ZS. Observations on alleviating pain in treatment of OVCFs with PKP. *Zhong Guo Gu Shang Yu Guan Jie Sun Shang Za Zhi* 2007; 22 (1): 68-69.
- 10 **Mckiernan F**, Faciszewski T, Jensen R. Quality of life following vertebroplasty. *Bone Joint Surg Am* 2004; 86-A (12): 2006.
- 11 **Garfin SR**, Yuan HA, Reiley MA. New technologies in spine: kyphoplasty and vertebroplasty for the treatment of painful osteoporotic compression fracture. *Spine* 2001; 26: 1511.
- 12 **Rhyn A**, Banit D, Laxer E, et al. Kyphoplasty: report of eighty-two thoracolumbar osteoporotic vertebral fractures. *J Orthop Trauma* 2004; 18 (5): 294.
- 13 **Huang ZJ**, Chen JX. Experimental research into effect of ZSGK pill on osteoporosis of rats without ovary. *Henan Zhong Yi Xue Yuan Xue Bao* 2008; 23 (1): 37-38.
- 14 **Huang ZJ**, Chen JX. Clinical research into treatment of Gonitis with ZSGK pill. *Henan Zhong Yi Xue Yuan Xue Bao* 2009; 24 (4): 61-62.
- 15 **Huang ZJ**, Guan JZ, Xu YJ. Clinical Research on Zishengukang pill used to treat delayed union of fracture. *J Tradit Chin Med* 2011; 31(3): 189-190.