

Two unilateral puncturation comparative analyses of multiple-level fresh osteoporotic vertebral body compression fractures treated with percutaneous vertebroplasty guided by C-arm fluoroscopy or in senile patients

J.-C. XU¹, G.-H. WU², L.-L. ZHOU³, X.-J. YANG², J.-T. LIU¹

¹Department of Orthopaedics, Xiangyang Hospital, Hubei University of Medicine, Xiangyang, Hubei Province, China

²Department of General Surgery, Affiliated Hospital of Xiangyang Vocational and Technical College, Xiangyang, Hubei Province, China

³Department of Obstetrics and Gynecology, People's Hospital of Yicheng, Xiangyang, Hubei Province, China

The five authors contributed equally to this article

Abstract. – OBJECTIVE: To compare the curative effects of two unilateral puncturation percutaneous vertebroplasty (PVP) for the pain caused by multiple-level osteoporotic vertebral body compression fractures (OVCF) in senile patients.

PATIENTS AND METHODS: From June 2008 to November 2014, eighty-nine cases suffering from fresh multiple-level OVCF were randomly divided into experimental group (n=51) and control group (n=38). Patients underwent PVP guided by C-arm fluoroscopy in the prone position. We monitored and recorded the visual analgesic scale (VAS) at pre-operation and 2 days post-operation, operation time, exposure duration, bone cement injection amount and extraosseous cement leakages.

RESULTS: PVP procedures were successful in both groups without serious complications. The VAS scores in both two groups at 2 days post-operation were significantly lower than VAS scores at pre-operation ($p<0.05$). The operation time and exposure duration in the observational group were significantly lower than those in the control group ($p<0.05$). However, bone cement injection amount and extraosseous cement leakages in the observing group were similar to those in control ($p>0.05$).

CONCLUSIONS: The curative effects of two unilateral puncturation PVPs were satisfactory. However, puncturation method had lower operation time and lower X-ray exposure dose. We concluded that puncturation method was a suitable method to be considered for clinical application.

Key Words

Unilateral puncturation, Osteoporosis, Compression fracture, multiple-level, Percutaneous vertebroplasty.

Introduction

Society is aging and the incidences of osteoporosis are getting higher. Osteoporosis is a condition that causes bones to become thin and porous, reducing bone strength and increase the risk of bone fractures^{1,2}. The thoracic and lumbar spine is the most common osteoporotic fracture sites, with the possibility of multiple vertebral compression fractures. This can cause severe pain in the thoracic and lumbar back, spinal deformity and even nervous dysfunction, which negatively influences the quality of life in seniors. Safe, convenient and effective pain-relieving is an important part of the treatment for individuals suffering from this condition³. Currently, percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP) treatment methods are considered the most effective ways for treating osteoporotic vertebral compression fractures (OVCF) in seniors⁴. Nevertheless, implementation of these types of surgeries in patients with multiple vertebral compression fractures is still considered a big challenge.

Patients and Methods

Patients

From June 2008 to November 2014, eighty-nine cases suffering from fresh multiple-level OVCF were randomly divided into experimental group (n=51) and control group (n=38). The number of fresh vertebral fractures was ≥ 2 , and

the course of disease was within 3 weeks (MRI results confirmed that fractures were fresh). We used CT to verify the completeness of posterior wall of vertebral body.

The Ethics Committee of Xiangyang Hospital, approved the study. Patients and their families provided written informed consent.

Both groups received unilateral pedicle of vertebral arch piercing cement injection with surgeries completed in the first phase. We received the approval from the Ethic Committee of our University. Differences between the two groups in the aspects of gender, age, duration of disease, number of vertebral fractures, fracture site, and the types of diseases in the Department of Internal Medicine, such as combined hypertension, diabetes mellitus and coronary heart complications were not statistically significant ($p > 0.05$) (Table I).

Surgical Methods

Preoperative preparation

We performed routine blood tests, coagulation time, ECG, pulmonary function and bone mineral density test for all patients. Also, comprehensive assessment of patients' general condition along with, conventional thoracic and lumbar spine X-ray, CT, thoracic and lumbar spine MRI was done. Patients with internal diseases received preferential treatment for their complications. All patients received antibiotics intravenously, 30 min before the operation.

Surgeries

Patients were in prone position with a pillow under their abdomen. In experimental group there was one case who could not tolerate heart function grade 3 prone position surgery, therefore patient's position was changed to lateral position.

Puncture and bone cement infusion

Using C-arm fluoroscopy we determined body surface projection in pedicle of fractured vertebra and marked it. Conventional disinfection and draping was performed. For left approach, we chose the bow's outer edge of responsible and normal vertebrae, 10 o'clock position, as the entry point. Similarly, for right approach, the outer vertebral pedicle at the 2 o'clock position was chosen. Lateral opening was 5 to 10 mm for puncture point and for each puncture point we used 5 ml of 1% lidocaine with the local infiltration anesthesia of intradermal, subcutaneous and muscle to facet. Puncture needle and the sagittal plane of the vertebral body were 10 to 25 degrees. The operator and the assistant in the observation group stood at both sides and punctured at the same time. Puncture needles penetrated into bone injury and was fixed with keeping the C arm machine still (normally it was not necessary to move C arm machine with 3 vertebral body). Processing lateral roentgenoscopy immediately after normal roentgenoscopy created a good viewing position. When puncture needle was penetrating into vertebral body through pedicle depth, it was necessary

Table I. Comparison of the preoperative clinical data in 89 patients.

Index	Group		Test statistic χ^2/t	p	
	Observation group (n=51)	Control group (n=38)			
Gender	Male	16	14	0.098	0.754
	Female	35	24		
Age (years old)	$\bar{x} \pm s$	73.032 \pm 20.2	71.865 \pm 18.34	-0.280	0.780
		17	6		
Course of disease (days)	$\bar{x} \pm s$	6.473 \pm 2.896	7.942 \pm 2.503	2.506	0.014
Fracture site	Thoracic vertebra	51	32	0.783	0.377
	Lumbar vertebra	86	69		
Fracture number	2	25	19	0.071	0.877
	3	17	13		
	4	9	6		
	0	3	4		
	1	15	12		
Types of diseases in the Department of Internal Medicine	2	20	13	0.807	0.848
	≥ 3	13	9		

*For counting data, we used the χ^2 -test for; for measuring data we used the t -test.

to confirm that the puncture needle was placed in a good position (under lateral roentgenoscopy the needle tip was at the back of vertebral body, and under normal position roentgenoscopy the needle tip did not exceed the medial wall of pedicle of vertebral arch). We withdrew all puncture needles, under the lateral position drilling through the bone to the junction of 1/3 in front of the vertebral body by turns, and used C arm machine for an X-ray examination to verify the needle and confirm the correct puncture position.

Bone cement was modulated to the viscous state and was injected into the vertebral body through a push rod under the fluoroscopy monitor. Injection was stopped immediately if there was a bone cement infiltration into the posterior margin of the vertebral body or leakage out of the vertebral body. After the bone cement was completely hardened, puncture needle was pulled out. For patients in the control group C-arm machine was adjusted continuously in order to have a roentgenoscopy at the front and lateral positions. Bone cement injection was repeated until a complete fill was achieved.

Postoperative processing

After operation, patients were placed on the bed wearing oxygen masks while their vital signs were monitored for 6 hours. On the second day post-operation, patients could stand and walk with waist protection. We performed X-ray examination for thoracic and lumbar vertebrae. On the third day post-operation, patients left the hospital. Patients received anti-osteoporosis medicine treatment for 6-18 months and had regular examinations.

Clinical Assessing Index

Visual analogue pain scale: operation effects were assessed with visual analogue scale (VAS) 2 days before and after operation.

Average operation time for a single vertebral body: counting by total operation time of every case dividing diseased vertebral body numbers.

Average X-ray times for single vertebral body: We assessed the safety degree of medical staff by the average s of single vertebral body, and count by the total C arm machine roentgenoscopy times of every case dividing diseased vertebral body number.

Average bone cement injection volume for single vertebral body: counted by the total amount of bone cement injection dividing diseased vertebral body number.

Bone cement leakage: We assessed safety of operation according to whether there was bone cement leakage.

Statistical Analysis

We used SPSS13.0 statistic software (SPSS Inc., Chicago, IL, USA) to analyze the data. For count data we used χ^2 -test, and for measurement data we used *t*-test. $p < 0.05$ was considered statistically significant.

Results

Operation situation

All surgeries were uneventful, without any symptomatic pulmonary embolism, nerve root and spinal cord compression symptoms caused by leakage, or local infection and hemorrhage.

VAS assessment

We compared VAS assessment scores in both groups 2 days before and after operation. The latter had obvious improvement compared with the former and the difference had statistical meaning ($p < 0.05$). Patients in both groups had similar VAS assessment scores 2 days after operation, and the difference was not statistically significant ($p > 0.05$) (Table II).

Comparison of the average operation time for single vertebral body, roentgenoscopy times, bone cement injection amount and bone cement leakage situations

Table II. Comparison of the VAS scores in both groups 2 days before and after operation.

Groups	Before operation	2d 2 days after operation	<i>t</i>	<i>p</i>
Observation group (n=51)	8.874±3.452	2.439±0.736▲	13.020	0.000
Control group (n=38)	9.023±3.327	2.652±0.492▲	-9.207	0.000
<i>t</i>	0.205	1.544		
<i>p</i>	0.834	0.126		

▲ Compared with pre-operation, $p < 0.05$; *compared with control group, $p < 0.05$

In the observation group, the average operation time for single vertebral body and the roentgenoscopy times were less than those in the control group and differences had statistical significant ($p < 0.05$). When the bone cement injection amount in single vertebral body and bone cement leakage situation were compared between the two groups, the difference showed no statistical significance ($p > 0.05$) (Table III).

Discussion

The thoracic and lumbar vertebrae of osteoporosis patients may suffer from immediate compression fracture under the effect of slight external force. Multiple vertebral bodies in senior patients are usually destroyed and compressed at the same time because of their physical features and the pathological characteristics of osteoporotic compression fractures⁵. Most of the authors believed that the best course of action in these cases is an immediate surgical intervention once a definite diagnosis is achieved. The clinical symptoms in multiple vertebral compression are more serious than those in single vertebral compression, which normally requires a higher demand for treatment. Patients with this type of disease are mostly seniors with poor heart and lung function and their operations usually adopt local anesthesia prone position. This may negatively affect patients' comfort. Treatment during the perioperative period of a primary disease and a careful assessment before the operation and the length of operation are all important matters that require close atten-

tion while processing multiple vertebral fractures PVP treatment. Reducing the operation time as much as possible is the key to avoid cardiovascular and cerebrovascular complications in senior patients and to achieve a successful surgery.

Diagnosis of multiple vertebral bodies OVCF

Making a definite diagnosis is the key to get a beneficial treatment effect. Multiple vertebral bodies OVCF showed by X-ray may have happened once or multiple times, and may be all fresh, or some may be fresh with the others old. Thus, having a MRI prior to operation is crucial. The main diagnosis evidence is the signal change and shape of vertebral body showed by MRI, and using ECT radionuclide scanning for those who cannot receive MR can determine "responsible vertebra" and the number of vertebral bodies involved.

Reading films before operation

To realize quick and accurate operative location, careful study on X-ray, MRI and CT images before operation is very important. It is essential to determine the features of the front and lateral position for every vertebral body, identify the feature and location of the 12th rib and make sure whether the lumbar Di and Di vertebra waist have changed and whether any other spinal deformities have occurred. Thoracic vertebra is usually vaguely shown under C arm machine because of tissue overlapping and disturbance. This situation makes the features of positive lateral images in

Table III. Comparison of the preoperative clinical data in 89 patients.

Index		Group		Test statistic quantity χ^2/t	p
		Observation group (n=51)	Control group (n=38)		
The average operation time of single vertebral body (min)	$\bar{x} \pm s$	27.551±10.483*	44.219±20.035	5.086	0.000
The average roentgenoscopy times of single vertebral body	$\bar{x} \pm s$	8.647±2.582*	14.039±3.670	8.138	0.000
The bone cement injection amount of single vertebral body (ml)	$\bar{x} \pm s$	2.943±1.262	3.105±1.179	0.616	0.540
The bone cement leakage situations	Soft tissue of vertebral body	6	4	0.497	0.920
	Intervertebral space	11	6		
	Venous plexus	8	6		
	Spinal epidural	3	1		

For counting data, we used the χ^2 -test for; for measuring data we used the t -test. *compared with control group, $p < 0.05$

diseased vertebral body and adjacent vertebral body before operation particularly important. Vertebral body CT mainly explores whether vertebral pedicle is sound and varied, whether posterior wall of vertebral body has fractures and whether spinal canal is narrow.

Methods and approaches of puncture

For the same injured vertebra, there are two normal puncture approaches: (i) single-side and (ii) both-sides. Strengthening effects of these two injection approaches are still inconclusive. Theoretically both-sides puncture approach can achieve the uniform distribution of bone cement, while it increases the incidence of complications. We improved the puncture approaches and made the puncture points slightly closer to the outside to enlarge the sagittal angle. This way, more bone cement could spread towards the opposite sides, which reduced the operation time and patients as well as operators under-laser time. Furthermore surgical trauma was also reduced compared with the standard both-sides puncture approach.

Usually single-side puncture approach is adopted when diseased vertebral body doesn't collapse seriously and bone fractures are limited to one side of the vertebral body. Diseased side puncture approach is used when the diseased vertebral body collapses evenly and the collapsing level is not lower than the half of the original level. When we adopt the multi-vertebral body puncture approach on PVP at the same time, the operator and the assistant should stand respectively at the left and the right sides, puncturing different injured vertebral bodies at the same time⁶.

Our investigation showed that the two puncture approaches demonstrated good treatment effects⁷, and puncture multiple vertebral bodies at the same time reduced the operation time and fluoroscopy times. However, we experienced the similar bone cement leakage complications compared with the section-by-section puncture approach.

Bone cement amount

According to the previous studies, there was no proportional relation between the injection amount of bone cement and the clinical treatment effects⁵. To avoid the bone cement reaction, the injection amount of bone cement for every vertebral body in each group was only 2.0 to 4.0 mL, which also gained relatively good clinical treatment effects.

Avoid leakage

The most common complication of PVP is bone cement leakage, and to avoid leakage we respected the following principles: (i) strict adopting certification, which means the patients with the seriously-destroyed posterior wall of vertebral body are not suitable for PVP approach; (ii) the perfusion under the monitor of X-ray interrupted fluoroscopy during the operation should be immediately stopped, when it is going to reach the posterior wall of vertebral body; (iii) control the stickiness degree, the perfusion pressure and the perfusion timing of bone cement. If the bone cement is too diluted, in the case of bone cement leakage there is a risk of venous thrombosis, which can easily hurt nerves and blood vessels. If the bone cement is too thick then only one diseased vertebral body can be injected which increases the operation cost and time. Thickness also leads to the solidification of bone cement inside the needle tube thus failing the operation⁸.

Choose PVP or PKP

To reduce leakage and correct back protruding deformity, many scholars adopt PKP. Using PKP for multiple vertebral body OVCF contributes to the higher treatment cost, longer operation time, more radiation exposure and bigger surgical wound⁹. We suggest adopting PVP approach for multiple vertebral body OVCF.

Guarding and processing during the operation

Although it's a local anesthesia operation, venous channels should still be opened and electrocardiograph monitoring should still be carried out during the operation. Keeping patient conscious during the operation makes it easier for operator to tell the reactions and the activity situations of lower limbs during the process of puncturing and injecting the bone cement. In order to reduce the toxic and allergic reactions of bone cement, it's required to inject 10 mg dexamethasone intravenously 10 minutes before the bone cement perfusion.

Conclusions

Multiple vertebral body OVCF adopts conservative treatments, which usually leads to long bedding time, bad pain-relieving effects and easy co-occurrence of kyphosis deformity and bedding complications. It also increases the

mortality rate. Compared with the open operation, PVP approach offers quick pain relieve as well as reinforcement of vertebral body to avoid further collapses. Adoption of PVP approach with multiple vertebral body puncturing at the same time can complete puncturing operation in one shot, save operation time, reduce laser radiation and reduce costs. Patient will have small scars, and suffer only from slight influences on their cardio-pulmonary function and will enjoy quick recovery. This enables patients to enjoy a normal life in a short term and gain long-term satisfactory results.

Acknowledgements

This study is supported by the Hubei Provincial Department of Education (contract grant number: B2015481).

Conflict of Interests

The Authors declare that they have no conflict of interests.

References

- 1) DONG CH, GAO QM, WANG ZM, WANG AM, ZHEN P. Vitamin D supplementation for osteoporosis in older adults: Can we make it help better? *Eur Rev Med Pharmacol Sci* 2016; 20: 4612.
- 2) ZHANG Y, WANG N, MA J, CHEN XC, LI Z, ZHAO W. Expression profile analysis of new candidate genes for the therapy of primary osteoporosis. *Eur Rev Med Pharmacol Sci* 2016; 20: 433.
- 3) LI HD, XU CJ, WANG H, LIU W, JIANG XJ, ZHU XQ. Percutaneous vertebroplasty for single osteoporotic vertebral body compression fracture: results of unilateral 3-D percutaneous puncture technique. *Indian J Orthop* 2015; 49: 245-250.
- 4) KOBAYASHI K, SHIMOYAMA K, NAKAMURA K, MURATA K. Percutaneous vertebroplasty immediately relieves pain of osteoporotic vertebral compression fractures and prevents prolonged immobilization of patients. *Eur Radiol* 2005; 15: 360-367.
- 5) WANG E, YI H, WANG M, HUANG C. Treatment of osteoporotic vertebral compression fractures with percutaneous kyphoplasty: a report of 196 cases. *Eur J Orthop Surg Traumatol* 2013; 23: S71-S75.
- 6) CHANG X, LV YF, CHEN B, LI HY, HAN XB, YANG K, ZHANG W, ZHOU Y, LI CO. Vertebroplasty versus kyphoplasty in osteoporotic vertebral compression fracture: A meta-analysis of prospective comparative studies. *Int Orthop* 2015; 39: 491-500.
- 7) GAO W, MI S, GAO J. [Percutaneous vertebroplasty to treat osteoporotic vertebral compression fractures combined with intravertebral clefts by unilateral approach]. *Zhongguo Xiu Fu Chong Jian Wai Ke Za Zhi* 2012; 26: 1330-1335.
- 8) KIM HW, SONG JW, KWON A, KIM IH. Extreme multi-level percutaneous vertebroplasty for newly developed multiple adjacent compression fractures. *J Korean Neurosurg Soc* 2009; 45: 378-380.
- 9) TU PH, LIU ZH, LEE ST, CHEN JF. Treatment of repeated and multiple new-onset osteoporotic vertebral compression fractures with teriparatide. *J Clin Neurosci* 2012; 19: 532-535.