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Application of unilateral multiple channels approach in percutaneous vertebroplasty for osteoporotic vertebral fractures

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Abstract: This study aimed to investigate the application valuable of percutaneous vertebroplasty (PVP) with unilateral multiple channels approach in osteoporotic vertebral fractures patients. A retrospective review was conducted on 685 consecutive patients with osteoporotic vertebral fracture from March 2003 to October 2012. Among them, 82 cases were given PVP procedure by unilateral multiple channels approach. The timing of surgery, bone cements injection, and complications were analyzed. By using the X-ray film, the distribution of cement was detected and scored. The visual analogue scale (VAS) score and Oswestry disability index (ODI) system were used to evaluate the pain relief and improvement of daily activity function after operation. The excellent and good rate of cement distribution was 98.8% (98/99). Before surgery, the VAS score was 2.5 ± 0.43 . After surgery, the VAS score was significantly decreased to 2.0 ± 0.33 at 1 h. Before surgery, ODI was 40.94 ± 2.72 . ODI was significantly decreased at 1 month after surgery (9.64 ± 2.60) and at the final follow-up (7.77 ± 2.15). No spine or nerve injury, bone cement leakage, pulmonary embolism, pneumothorax, bleeding or infection occurred intraoperatively. Thus, the PVP with unilateral multiple channels approach effectively relieve the pain and improve the functional activity, without occurrence of complications.

Key words: Percutaneous vertebroplasty; Unilateral approach; Multiple channels.

Introduction

Percutaneous vertebroplasty, which is an effective method for the treatment of osteoporotic vertebral fractures, has become the main method for the treatment of osteoporotic vertebral fractures in Europe and America, and has been widely used in China, in recent years (1, 2). Double transpedicular percutaneous vertebroplasty is the most commonly used approach in operation, its disadvantage is high cost, anesthesia operation in patients with difficult to tolerate. With the increased skills of puncture, unilateral puncture has been widely used in treatment, but was still limited by its safety, poor bone cement distribution, and other problems in the traditional unilateral transpedicular percutaneous vertebroplasty (3, 4). In addition, bone cement leakage from the fracture line occurred in the operation process of both the bilateral approach and unilateral approach (5-7). In the present study, we demonstrated the therapeutic efficacy of unilateral multiple channels approach in percutaneous vertebroplasty (PVP) for osteoporotic vertebral fractures in 82 cases (99 vertebral fractures) from March 2003 to October 2012.

Materials and Methods

General Data

A total of 685 patients, 885 osteoporotic vertebral fractures underwent percutaneous vertebroplasty (PVP) were admitted. Bone cement leakage was observed in cases (99 fractures) when injection of bone cement less than 0.3ml to treat the fracture, including 38 males (45 fractures), and 33 females (54 fractures), were given PVP procedure by unilateral multiple channels approach. The average age was 75.4 years old (from 69 to 92). The sites of vertebral fractures: T6, 3 cases; T7, 7 cases; T8, 9 cases; T9, 9 cases; T10, 10 cases; T11, 13 cases; T12, 15 cases; L1, 14 cases; L2, 11 cases; L3, 4 cases; L4, 4 cases. The X ray film of lumbar positive lateral, and thoracic vertebra lateral positions showed obvious wedge change, so all the patients were carried out MRI examination and data showed that the injured vertebra T1 WI low signals, anti-fat phase high signal, and the spinal canal was not affected. This study is approved by the ethics committee of China-Japan Friendship Hospital and informed consent was signed by patients.

Surgical Methods

Patients taken prone bit, ECG monitoring. The surface projection of the vertebral pedicle and bilateral transverse end surface projection was determined by a C Arm X-ray machine, and marked. Conventional disinfection shop towels, layer infiltration with 1% lidocaine, and full infiltration of zygapophysial (thoracic transverse and infiltration small joint, lumbar facet joint infiltration and transverse root), with transverse surface projection marks as the entry point, the needle points to the lumbar transverse root, thoracic transverse process in middle to lower thoracic transverse end. With the perspective of C Arm X-ray machine, the trocar soft rotary screw in until the tip reached the medial wall of pedicle, make sure the lateral tip through the posterior margin of the vertebral body is about 3mm, then continue to screw into the puncture needle of vertebral body, pull out the puncture needle core, put the guide needle, arrived in the vertebral body. When it was shown the end of the needle over the midline by X-ray machine, pull out the needle. Blunt separator and casing was inserted along with the needle, pull out the needle and separator after rotating screw into 1/4 vertebral body and leave the work casing, drill to spin up anterior transposition in the middle, pull out the hand, modulation of bone cement, bone cement filling in the drawing period to push through work in the casing will be inserted into the vertebral bone before the middle, slow injection of bone cement. When bone cement leakage after injection of 0.3 ml bone cement, pull out the bone cement filling rod, exit the front end of the sleeve pipe to the lateral to the posterior margin of the vertebral body under the perspective, swing the casing to change the direction of puncture to drill hole and change the vertebral puncture channel. After re implantation of bone cement filling rod, bone cement was slowly injected. Repeated adjustment angle of drill casing according to the need, and injected bone cement in a plurality of channels to control the distribution of bone cement in the vertebral body. After bone cement solidification, removed the push rod and the casing, cover the incision, end of operation (Figure 1). Postoperative treatment: bed rest for half an hour.

Assessment Methods

The operation time, amount of injected bone cement, and complications were recorded. Excellent and good rate of cement distribution was studied by the X-ray film (8, 9). According to the X-ray, bone cement distribution was calculated. The distribution of $70\% \sim 100\%$ is excellent, $50\% \sim 70\%$ is good, and below 50% is poor. The patients were followed up. The visual analogue scale (VAS) score (10) and Oswestry disability index (ODI) system (11) were used to evaluate the pain relief and improvement of daily activity function respectively at preoperation and 1 hour, 1 month, 3 months and 6 months after operation.

Statistical Analysis

Statistical analysis was performed by using SPSS17.0, quantitative data was described as the number of cases (percentage). The measurement data was described using standard deviation. Analysis of VAS and ODI was performed by single factor variance. SNK-q test was performed at each time point after operation compared with the preoperative. There was statistically significant difference with P < 0.05.

Results

A total of 885 vertebrae were involved in this study. Among them, 82 cases (99 fractures) were bone cement leakage when injection of bone cement less than 0.3ml to treat the fracture, including intradiscal cement leakage in 66 fractures (66.7%), paraspinal soft tissue leakage in 24 fractures (24.2%), and paravertebral venous leakage in 9 fractures (9.1%). It included 38 males (45 fractures), and 33 females (54 fractures), and the average age was 75.4 years old (from 69 to 92). After the successful completion of the operation by PVP with



Figure 1. Operation methods. 1, Bone cement leakage after a small amount injection; 2, Extract push-bar to the vertebral rear and change the direction of cannula; 3, Drill a new channel; 4, Inject bone cement in the new channel; 5, Bone cement well diffused; 6, Non leakage.

unilateral multiple channels approach, no spine or nerve injury, bone cement leakage, pulmonary embolism, pneumothorax, bleeding, infection, or other complications occurred.

In the ninety-nine fractures treated by PVP with unilateral multiple channels approach, the average operation time was 33 minutes (20~45 minutes). The average injection volume of bone cement was 6.5 ml (4~9.0 ml). The excellent and good rate of cement distribution was 98.8% (98/99; 74 excellent, 24 good, and 1 poor). Only 1 case with L1 vertebral fracture with bone cement leakage in the front of the vertebral body. The resets the casing had delayed the operation time. Although poor distribution of bone cement (less than 50%) in this case, the distribution still over the midline.

The visual analogue scale (VAS) score and Oswestry disability index (ODI) system were used to evaluate the pain relief and improvement of daily activity function respectively at preoperation and 1 hour, 1 month, 3 months and 6 months after operation. The VAS score was 8.4 ± 0.73 before surgery, and 2.5 ± 0.43 , 2.0 ± 0.33 , 1.8 ± 0.28 , 2.1 ± 0.17 at 1 hour, 1 month, 3 months and 6 months respectively after operation. ODI was 40.94 ± 2.72 before surgery, 9.64 ± 2.60 at 1 month after surgery, 8.52 ± 2.30 at 3 months after surgery and 7.77 ± 2.15 at the final follow-up. The differences of the VAS and ODI between pre-operation and post-operation had statistical significance (P < 0.01) (Table 1).

Discussion

Percutaneous vertebroplasty (PVP) and kyphoplasty with little trauma, short operation time, pain improved obviously, has become a common method for the treatment of osteoporotic vertebral fractures. Although PKP has an advantage in the theory on the recovery of the vertebral height, kyphosis correction side has over PVP, the fracture site pillow can also make fracture effectively reset by PVP taking hyperextension position (12). Studies have shown that there are no significant differences in pain relief, and occurrence of complications in adjacent vertebral fractures after surgery between PKP and PVP (13, 14). In clinic, it was confirmed that more than

Table 1.	Preoperative a	and postoperative vis	ual analogue scale	(VAS) score and Os	westry disability index (ODI).
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	Drooporativo	Postoperative				
	rreoperative	1 h	1 month	3 months	6 months	
VAS score	8.4±0.73	2.5±0.43***	2.0±0.33***	$1.8 \pm 0.28^{***}$	2.1±0.17***	
ODI	40.94 ± 2.72	N/A	9.64±2.60***	8.52±2.30***	7.77±2.15***	
Degree of Pain	4.38 ± 0.64	N/A	$0.97 {\pm} 0.82$	0.89 ± 0.64	0.78 ± 0.67	
Ability of daily activity	4.82 ± 0.38	N/A	1.06 ± 0.91	$0.93 {\pm} 0.74$	$0.84{\pm}0.72$	
Life a heavy object	4.51±0.39	N/A	1.16 ± 0.78	1.03 ± 0.86	0.93 ± 0.61	
Sit	4.40 ± 0.86	N/A	$0.78 {\pm} 0.58$	0.64 ± 0.42	$0.59{\pm}0.48$	
Stand	4.96±0.66	N/A	1.01 ± 0.71	$0.92{\pm}0.67$	$0.89{\pm}0.69$	
Walk	4.70 ± 0.48	N/A	1.03 ± 0.66	$0.87 {\pm} 0.62$	$0.79{\pm}0.50$	
Sleep	3.60±1.27	N/A	$0.82{\pm}0.65$	0.75 ± 0.53	0.63 ± 0.41	
Social activities	4.59 ± 0.58	N/A	1.34 ± 0.93	1.22 ± 0.96	1.13 ± 0.91	
Travel	4.98±0.20	N/A	$1.47{\pm}0.90$	1.27 ± 0.86	1.19±0.83	

Note: ***P<0.001, compared with preoperative data.

90% of patients with osteoporotic vertebral fractures could be partial or complete relieve pain by PVP. For patients, PKP is more suitable for fresh vertebral fractures, and reduction effect for semi fresh or relatively old vertebral fractures is not good (15). In general, fresh vertebral fractures with less than 50% was suitable for PKP, and PVP has a good clinical efficacy for vertebral fracture in greater degree even more than 2/3 (16). From the cost of treatment, the cost of PKP in our country is 2~3 times of PVP (14). The same conclusion had drawn from a multi-center study (17). Whether it is from the correction of the deformity or from the analgesic effect, PVP and PKP showed similar effects, and the cost of PVP treatment is far less than PKP, which means that the application of PVP is more extensive. In this study, all patients underwent PVP surgery, hospitalization day surgery, fresh compression fractures using conventional hyperextension position pad postural reduction, vertebral height were recovery in different degrees by intraoperative and postoperative radiographs obtained by Xray film. And patients with PVP was relieved pain, and discharge 1 day postoperative with the maximum reduction of treatment costs.

In traditional view, the PVP with bilateral approach can make bone cement well filled, but increased trauma, surgical time and radiation exposure. The study confirmed that the unilateral approach on the basis of no increase in trauma can also be satisfied with the filling of bone cement (18). Some scholars believe that the unilateral approach is better in the relief effect of the pain (19, 20).

In the present study, 82 cases with 99 vertebral bodies were operated by PVP with unilateral approach, the pain and function were improved obviously, and the excellent and good rate of bone cement distribution was 98.8%. The key for good distribution of bone cement by unilateral approach is the correct choice of the biopsy needle point. Unlike the needle point of pedicle screw in open surgery, the needle point in PVP with unilateral approach was more outside. In the X-ray film, thoracic puncture needle point is in the middle of the upper edge, next to the transverse oval shadow pedicle lateral edge about 10 mm. The needle point enters into the vertebral body through pedicle and pedicle rib complex. The tip can often reach even to the side of the midline of the vertebral body without spinal canal. Because of the lower thoracic transverse process is short and the end is a bone, the puncture needle and the needle probe is easily to enter the lower thoracic puncture point at upper lateral transverse root. The traditional open pedicle screw pedicle screw entry point is in the edge facet (pedicle oval shadow lateral side in X-ray film). If this point was used as the needle point for PKP or PVP, the puncture tip will not reach the midline of the vertebral body. The forceful puncture of the vertebral midline and increase in development angle, the puncture tip is easily to perforate pedicle of the inner wall of spinal canal, and to injury the spinal and nerve.

PVP has good clinical efficacy in the treatment of osteoporotic vertebral fractures, but the related reports of complications have gradually increased (21, 22). The bone cement leakage is one severe complication (23, 24). The timing of bone cement leakage, fracture of vertebral cortex and endplate integrity, as well as the choice of operation and the surgeon operating proficiency of bone cement, will influence the bone cement leakage. Most of bone cement leakage will not cause the clinical symptoms, do not need special treatment. Only a few leakages will cause clinical symptoms. Literatures reported how to prevent bone cement leakage. However, bone cement leakage rates in PVP and PKP were still as high as $19\% \sim 65\%$ (25, 26). The leakage of bone cement by injection of a small volume of bone cement is possible due to the fracture of the vertebral body (27). The occurrence of bone cement leakage rate by vertebral fractures is about 79%. Less is known about the prevention of the bone cement leakage. Researchers take to stop the injection of bone cement to termination surgery, stop the needle injection of bone cement and reinjected the mixture after bone cement curing (28). Due to insufficient filling and poor bone cement distribution by termination surgery, it is difficult to achieve the analgesic effect. Increased leakage of bone cement in the vertebral body with large fracture will increase the injection time and the bone cement, as well as prolong the operation time and cost. Although the injection volume of bone cement is not correlated with pain relief (29), but the biomechanical studies show that the recovery of stiffness of vertebral fracture needs 4 ~ 6ml or 29.8% bone cement (30). Therefore, a sufficient amount of bone cement injection has become a key for pain relieving and vertebral height maintaining. The ideal state

of bone cement in the vertebral body fully filled fracture and permeability dispersion to play an anchorage effect on trabecular bone. If the injection volume is insufficient, bone cement will inevitably not fully disperse into the trabecular bone without ideal fixed and analgesic effects. In theory, more bone cement injection, higher the probability of leakage. In order to solve the contradiction of bone cement leakage and injection, patients with leakage after the injection of a small dose of bone cement (less than 0.3ml) were collected. We found that the adjustment of the angle of casing within a short time and change the vertebral puncture channel, re-injection of $4 \sim 9.0$ ml bone cement is sufficient and could disperse from bone trabecula to the end of fracture. There are no new cases of bone cement leakage. The excellent and good rate of cement distribution was 98.8% (98/99; 74 excellent, 24 good, and 1 poor). Only 1 case with L1 vertebral fracture with bone cement leakage in the front of the vertebral body. The resets the casing had delayed the operation time. Although poor distribution of bone cement (less than 50%) in this case, the distribution still over the midline.

Taken together, the unilateral multiple channels approach in percutaneous vertebroplasty can obviously relieve the pain and effectively improve the functional activity without occurrence of adverse events, provide a satisfied cement distribution in vertebral body with cement leakage after a small amount infusion. However, this study taken fewer cases and shorter follow-up time, further prospective randomized controlled study is needed.

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