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Original Article

The application research of pedicle positioning network combination kit in vertebroplasty of thoracolumbar vertebral fracture

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Abstract: Objective: To explore the clinical application effect of pedicle positioning network combination kit in vertebroplasty of thoracolumbar vertebral fracture. Methods: 100 patients, who were confirmed of spinal vertebral compression fracture and performed unilateral PVP from January 2014 to December 2015, were selected in this study. According to digital table, these patients were randomly divided into pedicle positioning network combination kit group and conventional puncture group. Then, to compare the two group's puncture time, puncture frequencies, success rate of puncture, X-ray fluoroscopy frequencies, the dose of received radiation and accuracy of orientation. At last, we adopted Visual Analogue Scale (VAS) to evaluate the clinical curative effect and observed the occurrence of operation related complications at the same time. Results: The puncture time of pedicle combination kit localization method and free-hand puncture method were (7±1) min and (14±3) min respectively, the success rate of puncture were 96.8% and 79%, the location accuracy of pedicle were 100% and 86.7%. Therefore, combination kit localization method was significantly better than free-hand puncture method ($P<0.05$). The puncture frequencies of pedicle combination kit localization method and free-hand puncture method were (1.7±0.5) times and (3.8±1.1) times, fluoroscopy frequencies were (4.5±1.1) times and (7.7±0.7) times. Hence, the frequency of combination kit positioning method was significantly less than free-hand puncture method ($P<0.05$). The differences in radiation dose taken by two groups were statistically significant ($P<0.05$). There was no statistical significance in differences of VAS scores after operation between two groups ($P>0.05$). Conclusion: Pedicle positioning network combination kit localization is an ideal method with accurate pedicle puncture point in vertebro plasty positioning of thoracolumbar vertebral fracture.

Keywords: Vertebral compression fracture, percutaneous vertebroplasty, PVP, localization, pedicle

Introduction

Percutaneous vertebroplasty is an effective and commonly used approach to treat osteoporotic thoracolumbar vertebral compression fractures in Orthopaedics [1, 2]. It is widely applied in clinical practice currently. Meanwhile, it has advantages of small trauma, quickly reduction of patients' pain, good curative efficacy and the short hospitalization time [3, 4]. Percutaneous pedicle puncture is the key to the success of the operation. However, image navigation system and repeatedly X-ray fluoroscopy that commonly used in puncture process always produce increased radiation exposure to the medical staff. The risk of radiation exposure has attracted extensive attention [5, 6]. Therefore, how to effectively improve the safety as well as the accuracy of punctureand reduce the radiation damage has become a big question.

In recent years, scholars have committed to develop navigational aids of percutaneous vertebroplasty (PVP) for reducing fluoroscopy frequencies and enhancing puncture efficiency, but its practical application is rare in clinic. At present, the free-hand puncture method is a conventional way in clinic. This method, as time-consuming and requires repeated fluoroscopy and puncture, will cause enormous radiation injury to orthopaedic surgeons and patients. In consideration of these adverse conditions, our department has developed a new type of pedicle puncture positioning for thoracolumbar vertebral fracture, namely network

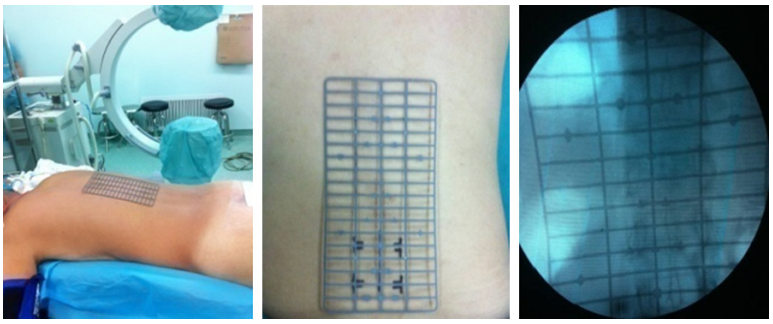

Figure 1. Locating grid of new percutaneous pedicle puncture.

device plus multiple needle positioning method (combination kit localization method) (Patent No. 20150164377.0), to enhance safety and accuracy of pedicle puncture and reduce X-ray fluoroscopy frequencies. From January 2014 to December 2015, we analyzed and compared the clinical efficacy of percutaneous vertebroplasty (PVP) with pedicle puncture combination kitpositioning method and conventional free-hand unilateral pedicle puncture, so as to provide a more convenient and safe method for the positioning in percutaneous vertebroplasty (PVP).

Materials and methods

Composition of pedicle positioning combination kit

Barium-containing polymer plastic grid devices were provided by Shandong Guanlong Company, with a size of 14 cm * 9 cm, as shown in **Figure 1**. The grid labeled with "▲ ●" is convenient to position the interval of injured vertebral pedicle under fluoroscopy. And the 1.5-2.0 mm sterile Kirschner wires were selected as standby.

General information

100 patients who underwent PVP in our hospital between January 2014 and December 2015 were randomly selected and divided into the pedicle combined kit positioning group as experimental group and the free-hand puncture group as control group. Each group had 50 patients. Inclusion criteria: Osteoporotic monosegmental vertebral compression fracture diagnosed by CT and other imaging examinations; PVP indications; And the consent of surgery signed by patients' family. Exclusion criteria: Infection, severe cardiopulmonary disease, abnormal coagulation, or spinal nerves compression after spinal fracture in patients. This experiment was approved by the ethics committee.

There were 20 males and 30 females with an average age of 65.4±5.6 years old in the experimental group, including 2 cases of T_9, 3 T_{10}, 5 T_{11}, 6 T_{12}, 16L_1, 8 L_2, 6 L_3, 2 L_4 and 2 L_5. There were 22 males and 28 females with an average age of 64.5±4.6 years old in the control group, including 1 case of T_9, 2 T_{10}, 6 T_{11}, 5 T_{12}, 17 L_1, 7 L_2, 7 L_3, 4 L_4 and 1 L_5. There was no significant difference in sex, age and thoracolumbar fractures of the sites between the two groups (P>0.05). Therefore, these two groups were comparable, as shown in **Table 1**.

Puncture method

Pedicle combined kit positioning group: The patient stook a prone position with abdomen suspended and the grid device was placed on the desired location before under going fluoroscopy. The skin tracings were performed on the injured pedicleinterval. Next, the required pedicle area for performing local anesthesia or general anesthesia was covered with aseptic towel after conventional disinfection of the skin and the percutaneous insertion of three Kirschner wires was arranged in an equilateral triangle. Afterwards, an optimal position of the Kirschner wire in the pedicle interval was observed through another fluoroscopy in the lateral position (by time positioning method: normotopia: 2 to 3 pointson the right, 9 to 10 points on the left). Later, only one Kirschner wire was kept in the optimal position while the remaining Kirschner wires were removed. In order to prevent Kirschner wire moving from the best position, the Kirschner wire was embedded into the bone within 2~3 mm. After that, the Kirschner wire was set into the pedicle working tube fixed by the assistant. A sit was pulled out, the matched pedicle drilled corewas inserted into the tube, screwing slowly into the pedicle according to its angle and direction, and then reaching the required depth. Subsequently, we took an X-ray fluoroscopy from the positive lateral position and injected the bone cement in correct locations required. If the percutane-

Table 1. The comparison of the basic clinical data of two groups

Groups	Cases	Gender (male/female)	Age (years)	The site of thoracolumbar compression fracture (cases)								
				T_9	T_{10}	T_{11}	T_{12}	L_1	L_2	L_3	L_4	L_5
Experimental group	50	20/30	65.4±5.6	2	3	5	6	16	8	6	2	2
Control group	50	22/28	64.5±4.6	1	2	6	5	17	7	7	4	1
P value		0.524	0.824	0.327								

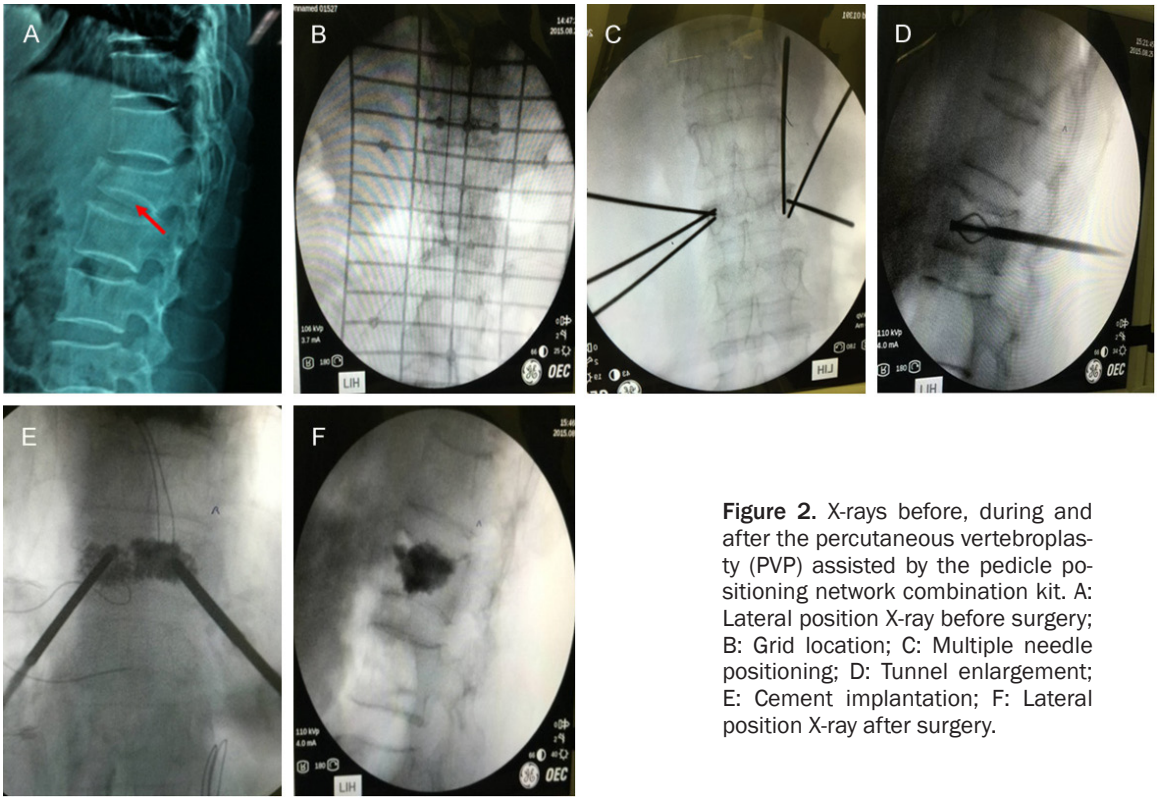

Figure 2. X-rays before, during and after the percutaneous vertebroplasty (PVP) assisted by the pedicle positioning network combination kit. A: Lateral position X-ray before surgery; B: Grid location; C: Multiple needle positioning; D: Tunnel enlargement; E: Cement implantation; F: Lateral position X-ray after surgery.

ous pedicle screw fixationneeded to be conducted, above mentioned steps should be repeated. And the following steps were taking out the pedicle drilled core, tapping the screw, ensuring the location was the bone tunnel, screwing the pedicle screw into the bone tunnel as required, mounting rod, enlarging the injured vertebral for reduction. Finally, the surgery was completed, as shown in **Figure 2**.

Free-hand puncture group

The traditional anterior superior illiac crest localization method was used to determine the injured vertebra and then the mark was made in the injured area. Afterwards, centered on the injured vertebra, several Kirschner wires of different thickness were placed in the surgical field vertically and horizontally. The distance between Kirschner wires and injured pedicle was calculated by taking X-ray flouroscopy from positive position. Having moved the Kirschner wires for a certain distance in horizontal, the flouroscopy would be performed again and again until the overlap between the intersection point of Kirschner wiresand the projection of pedicle was occurred and the puncture point was identified. At last, the following implantation of bone cement and the procedure of Kirschner wiresplacement were the same as pedicle combined kit positioning group.

Observation indicators

The one-time puncture success rate and the puncture frequency were compared between the above two groups. The differences about the puncture time and the X-ray frequen-

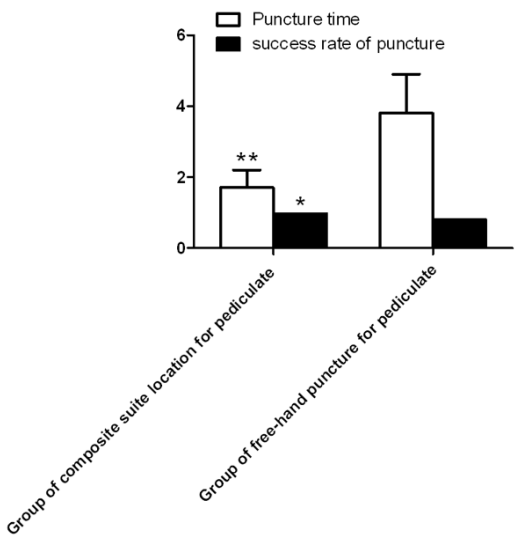

Figure 3. Comparison of successful puncture rate and puncture frequencyduring the surgery between the two groups. Compared with the control group, ** and *P<0.05.

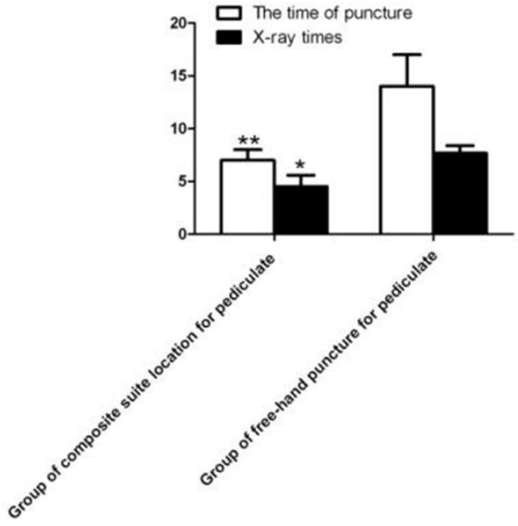

Figure 4. Comparison of puncture time and X-rayfrequency between the two groups. Compared with the control group, ** and *P<0.05.

cy between the two groups were observed. The localization accuracy and the accepted radiation dose in these two groups were recorded respectively, which could be verified by the anteroposterior and lateral position X-rays during and after surgery. Visual Analogue Scale (VAS) index was applied to score the reactions of patients in the two groups at pre-surgery and 1 month after surgery: 10 points for unbearable pain and 0 point for no pain. Patients' relevant complications occurred after surgeries in both groups were observed.

Statistical analysis

All the data were statistically analyzed by SPSS 19.0 software. Measurement data were expressed with mean ± standard deviation ($\bar{X}$ ±S). Comparison between two groups was examined by t test. Enumeration data were expressed with percentage, comparison between two groups was examined by Chi-square test. Difference was considered statistically significant when $P<0.05$.

Results

Comparison of puncture success rate and puncture frequency during surgery between two groups

The one-time puncture success rate in the experimental group was 98% and the average puncture frequency was (1.7±0.5) times. The one-timepuncture success rate in the control group was 79% and the average puncture frequency was (3.8±1.1) times. And comparison between the two groups had significant difference (P<0.05), as shown in **Figure 3**.

Comparison of the puncture time and X-ray frequency between two groups

The puncture time in the experimental group was (7±1) min while the control group was (14±3) min. The X-ray frequency in the experimental group was (4.5±1.1) times while the control group was (7.7±0.7) times. The differences were statistically significant (P<0.05), as shown in **Figure 4**.

Comparison of the localization accuracy and accepted radiation dose between two groups

X-rays during and after surgery presented that the localization accuracy in the experimental and control groups were 100% and 86.7% respectively, indicating that the differences were statistically significant (P<0.05). The accepted radiation dose in the experimental and control groups were (20.8±4.5) mGy and (38.5±5.2) mGy respectively, showing that the accepted radiation dose in the two groups were far less than the clinical safe radiation dose (100 mGy) and the differences between the two groups had statistical significance ($P<0.05$), see **Figure 5**.

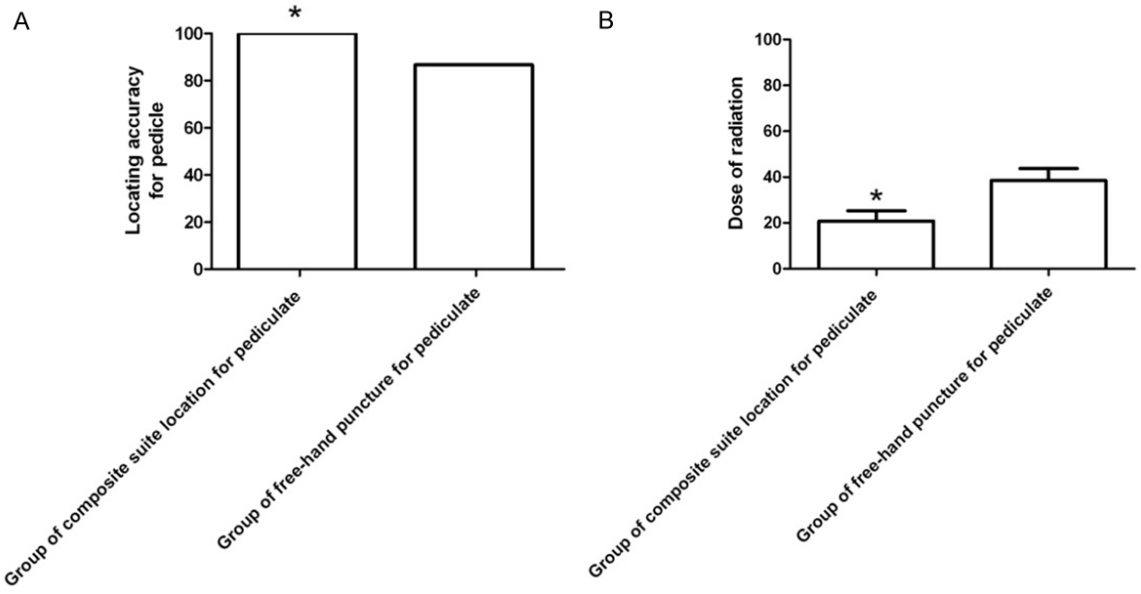

Figure 5. The comparison between the two groups about locating accuracy and dose of radiation. A: Locating accuracy; B: Dose of radiation. Compared with the group of free-hand puncture, *P<0.05.

Table 2. The comparison of the two groups' VAS score about pre-operation and one month after operation (mean ± standard deviation)

Groups	Cases	VAS score	
		Pre-operation	One month after operation
Group of composite suite location for pediculate	50	7.2±1.7	2.2±1.4*
Group of free-hand puncture for pediculate	50	7.6±1.1	2.4±1.3*

Note: Compared with pre-operation, *P<0.05.

The comparison of the postoperative VAS scores between the two groups

Compared with pre-surgery, the VAS scores one month after operation of the pedicle combined kit positioning group and the free-hand puncture groupwere significantly improved and had statistical significance (P<0.05). But the comparison of the two groups' VAS scores one month after operation had no statistical significance (P>0.05), see **Table 2**.

The comparison of complications incidence between two groups' patients

Both groups' patients showed no leakage of bone cement to spinal canal or nerve root. But each group had one case with cement leakage into intervertebral space. There's no symptom of nerve spinal cord injury, no complication like wound infection or bleed. And the wound healing rate was 100%.

Discussion

In recent years, osteoporosis has become a common disease with the aging of population. And the incidence of vertebral compressed fracture which is caused by osteoporosis also presents a significant increasing trend. At present, as a new spinal minimal invasive surgical technology, percutaneous vertebroplasty (PVP) has many advantages like simple operation, minimal trauma, few complications, high rate of postoperative pain relief and it can enhance the stability and stress of the injured vertebral. So, it is widely applied in clinical treatment at home and abroad [7, 8]. Vertebroplasty is the application of puncture tool which get through the narrow pedicle and into the injured thoracolumbar vertebral, and then inject bone cement [9, 10]. During the process, the key technology is puncture technology, and the quality of puncture is directly related to surgical prognosis. The traditional Kirschner wire pedi-

cle localization method is a commonly used method in pedicle positioning which needs to be carried out under strict X-ray monitoring. That means visual assessment should be performed according to bony landmarks under the perspective of C arm X-ray equipment and the sagittal plane, transverse plane and coronal plane puncture direction, centering on injured vertebral, should be repeatedly corrected, so as to ensure the safety and accuracy of percutancous pedicle puncture operation [11, 12]. But it increases patients and surgeons' absorption of radiation dose, causes serious body injury and extends operation time. And it has limited perspective view, only 3-4 vertebrae [13, 14]. Studies have reported that every surgeon can operate at most 34 cases of percutaneous vertebroplasty (PVP). If over this range, it will cause damage to surgeons [15]. And there's other studies showing that the assistance of X-rayfluoroscspy to the puncture operation of pedicle is limited and sometimes the puncture failure can still occur [16].

In order to reduce the risk of radiation and improve the success rate of puncture, many researchers have conducted a lot of work. The computer aided navigation system based on CT image has been applied in the operation, it helps to reduce the radiation and improve the accuracy of puncture, but it is only suitable for open operation [17, 18]. It has been reported that, optical positioning system and electromagnetic positioning system have been successfully applied in spinal surgery, but this method is too expensive [19]. Another study has shown that the error rate of computer surgical navigation system applied to pedicle puncture can reach 2.7%-8.5% [20]. Apparently, the implementation of these technologies requires not only advanced equipment and complex operation, but also fluoroscopy to determine the entrance point locations through CT and X-ray before being applied. And it can not significantly reduce the fluoroscopy times. Therefore, exploring a simple and practical method to determine the puncture point and puncture path is necessary and significant.

For these reasons above, this research developed a localization puncture method combined grid device with a localization method of a plurality of needle (combination kit positioning method) which could be used for percutaneous pedicle vertebroplasty in clinic. This method overcame the following shortcomings of the traditional Kirschner wirelocation method and the simple grid location method in determining the pedicle interval: It was difficult to place Kirschner wire on the surface of pedicle interval for the Kirschner wire localization method by only once. Therefore, it needed to change positions by moving many times for finding an accurate place. When it came to the surface projection, the simple grid device was superior to Kirschner wire localization method. However, it needed to puncture for positioning repeatedly when percutaneous pedicle was punctured because the slight movement of skin and thoracic dorsal soft tissue could cause puncture failures. In this study, compared to the freehand puncture group, the combination kit pedicle localization puncture method, which was based on horizontal and vertical online location pointer, identified the projection of pedicle, reduced the time of puncture, X-ray fluoroscopy times and the accepted radiation dose and improved the accuracy of positioning. Consequently, it made the puncture of pedicle and needle retention become safe and simple and it better played the advantages of the minimal invasive surgery.

To sum up, in performing vertebroplasty of percutaneous thoracolumbar, combination kit localization method can find the injured thoracolumbar vertebral pedicle conveniently and accurately under X-ray fluoroscopy. Meanwhile, it can reduce the surgical trauma and the risk of radiation. It can be considered as a ideal pedicle puncture localization method. And it is worth popularizing in clinical application. But the shortcoming of this study is that it does not set up a control group synchronously and randomly and not make a comparative study. In the future search, it needs to increase the number of cases and polycentric experiments in order to confirm the advantage of positioning puncture of pedicle network combination kit.

Disclosure of conflict of interest

None.

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