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Original Article

Clinical observation of percutaneous vertebroplasty in the treatment of senile osteoporosis complicated with vertebral compression fractures

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Abstract: Objective: To compare the effects of conservative treatment and vertebroplasty in the treatment of senile osteoporosis complicated with thoracic or lumbar vertebral compression fractures. Methods: Sixty-eight patients with osteoporosis complicated with thoracic or lumbar vertebral compression fractures admitted to Jining NO.1 People's Hospital from March 2016 to March 2017 were selected and randomized into control and experimental groups, and subjected to conservative treatment and percutaneous vertebroplasty respectively. One month after treatment, the effective rate of clinical treatment, pain scores and mobility of the two groups were evaluated by follow-up observation. Results: The total clinical effective rate of the experimental group was better than that of the control group. The post-treatment pain scores in Visual analogue scoring of both groups were significantly improved compared to the pre-treatment scores, and the experimental group scores were superior to those of the control group. The vertebroplasty group also showed significantly better post-operative mobility scores compared to the control group (all $P<0.05$). Finally, imaging evaluation revealed significantly greater vertebral height and smaller recovery wedge angle in the vertebroplasty group compared to the control group (both $P<0.05$). Conclusion: Compared to conservative treatment, vertebroplasty can effectively reduce the pain in patients with compression thoracolumbar fractures, improve clinical treatment and prognosis, and can be considered for the treatment of senile osteoporosis with vertebral compression fractures.

Keywords: Osteoporosis, compression fracture, vertebroplasty, conservative treatment, clinical efficacy

Introduction

Osteoporosis is largely manifested as continuous whole body bone loss. The elderly population is at greater risk of developing osteoporosis, which can easily lead to fractures. Some studies have found osteoporosis to be the most common cause of thoracolumbar vertebral compression fractures [1]. In the United States, approximately 1.5 million osteoporotic patients with fractures are hospitalized each year. Although no such statistical results are available in China, based on existing data, osteoporotic fractures in the elderly population is predicted to increase by 6 times in the next 40 years [2]. Therefore, osteoporosis-related fractures have become a major public health concern in the elderly population [3].

The main clinical manifestations of osteoporotic compression fractures include chronic pain in the thoracolumbar spine, spinal deformity, muscle atrophy, insomnia, anxiety, and limited mobility. In the absence of timely intervention, the mortality risk and incidence of new fractures may increase [4, 5].

The classic treatment options for osteoporotic compression fractures include absolute bed recuperation, non-steroidal anti-inflammatory drugs and functional exercises in the later stages. However, conservative treatment is associated with various complications like muscle atrophy caused by long-term inactivity, bedsores, pressure ulcers caused by local fixation and even a potential risk of thromboembolism, all of which weaken the effectiveness of the treatment [6, 7]. Surgical approaches, such as vertebroplasty and kyphoplasty, are therefore gradually replacing conventional treatments for osteoporotic compression induced thoracolumbar fractures because of their good clinical effi-

cacy [8]. However, there are still some controversies related to vertebroplasty in terms of pain reduction, improvement in mobility and the recovery of vertebral height in patients [9, 10].

The objective of this study was to compare the therapeutic effects of conservative treatment and percutaneous vertebroplasty on osteoporotic thoracolumbar vertebral compression fractures, in terms of their clinical efficacy.

Materials and methods

Research subjects

Sixty-eight elderly patients with osteoporotic thoracolumbar vertebral compression fractures admitted from March 2016 to March 2017 were prospectively selected and divided into observation (n=34) and control (n=34) groups according to the order of the patients admission numbers. Inclusion criteria were age >60 years, presence of osteoporosis diagnosed by MRI, thoracolumbar fracture diagnosed by imaging and pain location consistent with imaging results. Patients with major organ (liver, kidney or heart) dysfunctions, pathological fractures caused by bone tumors, hyperparathyroidism, lesions resulting from multiple myeloma, lymphoma etc., and spinal cord and nerve root compression and those refusing to participate in were excluded. All patients gave informed and signed consents and the study was approved by the Ethics Committee of Jining NO.1 People's Hospital.

Treatment methods

Control group: Patients in the control group were given conservative treatments such as lying on a hard bed with partial braking (absolute bed rest for one week), celecoxib analgesia, functional recovery exercises, etc. A cylindrical soft pillow was placed on the thoracolumbar fracture segment at a height of about 10 cm above the bed. Exercises in the first week mainly included straight leg raises and other functional upper limb exercises. After one week, the functional training of the lower back muscles was increased as per the patients' abilities, and the patients were given necessary vitamins and calcium supplements (take the medicine according to the instructions).

Vertebroplasty group: Local anesthesia was conducted. Routine preoperative examination consisted of measuring blood pressure, heart rate, oxygen saturation etc., and establishment of intravenous access. The patient was placed prone on the operating table and sedated with intravenous midazolam. After the fracture line was confirmed by X-ray, the surgical site was locally anesthetized with 1% lidocaine hydrochloride (China Otsuka Pharmaceutical Co., Ltd.), whose range extended from the fractured vertebral pedicles to subcutaneous tissues. A puncturing needle 11 was inserted into the vertebral pedicle with front, rear and side imaging provided by X-ray fluoroscopy. The needle was drilled into the anterior edge of the vertebral body through the pedicle. Then after the needle was removed with the channel remain, the vertebral drill was used to reach the anterior part of vertebral body. After the balloon was expanded, the bone cement was injected carefully to prevent any leakage. The patient was instructed to remain in the supine position till the bone cement polymerized. Lateral X-rays were taken that showed the amount and distribution of the cement in the body. At every stage during the operation, the patient underwent neurological examination [1].

Patients were advised to get out of bed after 6 hours of surgery. After confirming that there were no additional debilities like fever or infection, the patient was discharged on the following day and routine oral calcium was prescribed.

Observation and evaluation index

Primary observation indicators were postoperative pain and clinical efficacy. The latter was graded into three types: 1) Remarkably effective if the pain disappeared and the X-rays showed completely healed fractures; 2) Effective if the pain was relieved and the fractures were healed to an extent; 3) Ineffective in the absence of pain relief and no significant healing of fractures. The total effective rate was calculated as (remarkable effective + effective)/total number of subjects *100%. Visual analogue scoring (VAS) was used to evaluate the pain changes before and after operation in the two patient groups [11]. VAS is 0 for no pain, 1 to 3 for mild pain, 4 to 6 for moderate pain, 7-9 for severe pain, and 10 for intense pain.

Secondary observation indicators included changes in vertebral body height and wedge

Table 1. Comparison of the basic data of two groups of patients ($\bar{x} \pm sd$)

Item	Experimental group (n=34)	Control group (n=34)	t/χ^2	P
Age (year)	62.5±10.1	63.1±9.7	0.250	0.803
Gender (male/female)	7/27	10/24	0.706	0.401
Fracture time (day)	3.1±0.1	3.0±0.2	1.844	0.070
Secondary fractures (case)	5	6	0.108	0.742
Thrombosis (case)	1	1	0.515	0.473

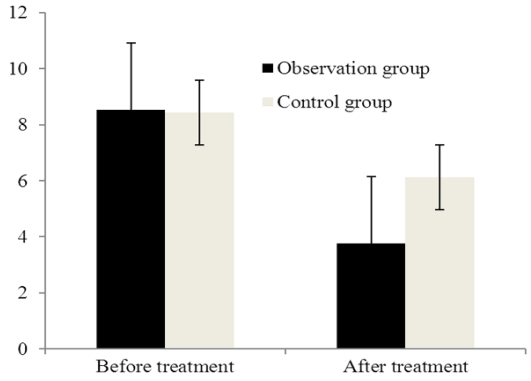

Figure 1. Comparison of VAS scores in two groups. Patients in the control group (34 cases) were treated conservatively, and patients in the observation group (34 cases) were treated with vertebroplasty. The VAS scores for two groups before and after treatment were significantly different (▲P<0.001); the post-treatment VAS scores between the two groups were significantly different (*P<0.001). VAS, Visual analogue scoring.

angle. The pre- and post-operative wedge angle and the height of the vertebral body were evaluated with the help of X-rays. The mobility of the patients of the two groups were evaluated according to previously described mobility scores where a score of 1 implied no significant difficulty in action, 2 implied difficulty in walking that required external force, 3 was assigned to wheelchair assisted or seated patients, and 4 for those completely unable to move [12].

One month after treatment, the treatment efficacy was judged based on the patient's clinical performance and X-ray examination.

Adverse reactions and treatment measures

The main complication of vertebroplasty is bone cement leakage. If there is no clinical symptom, follow-up can be done for a small amount of leakage. If the patient has radation pain, bed rest and Methycobal can achieve good therapeutic effect.

Statistical methods

SPSS20.0 statistical software was used for analysis. All data were expressed as mean ± standard deviation. Since the two groups showed normal distribution and with equal variance, paired t-tests were used for intra-group and independent t-tests were used for inter-group comparisons. Count data were compared using Chi-Square test and Fisher's exact probability method. Rank variables were ranked using the H-test. P<0.05 is considered statistically significant.

Results

Comparison of general information in the two groups of patients

There were no differences in age, fracture time, thrombosis, and case numbers of secondary fractures between the two groups. Although the proportion of older women with osteoporosis was more than the men (51:17), there was no statistical difference between the two groups (all P>0.05; **Table 1**). Thus, they were comparable.

Comparison of VAS scores before and after treatment in the two groups of patients

No significant difference was seen in the pre-treatment pain scores between the two groups (P=0.153). For both groups, the post-treatment pain scores were significantly lower compared to the pre-treatment scores, and the score of the experimental group was superior to the control group (P<0.001; **Figure 1**).

Changes in vertebral height and wedge angle before and after treatment in both groups of patients

There was no significant difference in vertebral body height and wedge angle between the two groups before treatment. After one month of treatment, the vertebral body in the experimental group was significantly higher and the wedge angle was also smaller compared to the control group (P<0.05; **Table 2**).

Table 2. Changes in vertebral height and wedge angle in both groups of patients ($\bar{x}$ ± sd)

Items	Vertebral height (mm)		Wedge angle (°)	
	Before treatment	After treatment	Before treatment	After treatment
Experimental group	17.23±2.09	23.98±2.32	28.77±3.49	15.72±2.19
Control group	17.11±2.23	21.74±2.11	28.92±3.13	19.38±2.40
t	0.229	4.165	0.187	6.569
P	0.820	<0.001	0.853	<0.001

Table 3. The clinical efficacy of the two groups (n, %)

Group	Treatment efficacy			Clinical effective rate
	Remarkably effective	Effective	Ineffective	
Control group	14 (41.2)	12 (35.3)	8 (23.5)	26/34 (76.5)
Experimental group	24 (70.6)	8 (23.5)	2 (5.9)	32/34 (94.1)
χ^2/H	7.032			4.220
P	0.050			0.040

Table 4. Life ability scores and hospitalization time in two groups ($\bar{x}$ ± sd)

Items	Hospitalization time (day)	Life ability scores	
		Before treatment	After treatment
Experimental group	3.2±1.2	3.13±1.06	1.73±0.97
Control group	11.5±2.8	3.21±0.99	2.34±1.03
t	15.887	0.322	2.514
P	<0.001	0.749	0.014

The clinical efficacy of the two groups

The clinical efficacy of the two groups was observed. The effective rate and the remarkably effective rate of patients in the experimental group (76.5% vs. 94.1%) were higher than that of the control group (P<0.05). See **Table 3**.

Life ability scores and hospitalization time in both groups

The mobility of the two groups was compared before and after treatment. There was no significant difference between the control group and the experimental group before treatm ent (P>0.05). After the treatment, both groups showed significantly increased mobility, with the experimental group performing better than the control group. Furthermore, the duration of hospitalization of the patients in the experimental group was also significantly shorter than the control group (P<0.05). See **Table 4**.

Discussion

Thoracolumbar compression fractures are one of the most common complications of osteoporosis. Epidemiological studies show that elderly women are at high risk of the disease, which has a great impact on their survival and quality of life. This may be due to changes in hormone levels in postmenopausal women, resulting in a much greater loss of bone mass than that in older men, and a decrease in bone density with age [13, 14]. A study have shown that the indence of osteoporosis in women aged 85-89 years is 8 times higher than that of people aged 60-64 [15]. Our patient group also had a high proportion of older women (75.0%), consistent with the previous study [16]. Therefore, even a routine case of back pain among elderly women should be followed up with an X-ray examination for early diagnosis and treatment for possible osteoporosis.

At present, the evaluation of the therapeutic effects of osteoporotic thoracic and lumbar vertebral compression fractures are based on clinical outcomes. The results however are complicated by the existence of certain biases, which in turn make the treatment of osteoporotic thoracolumbar compression fractures (conservative or surgical) difficult to evaluate [17]. A novel combination of objective X-ray and clinical data provides a comprehensive and objective assessment of the clinical efficacy of both treatments.

Pain is the most important clinical manifestation of fractures and is a direct form of evaluation of treatment efficacy. The reason that vertebroplasty became popular in the last 20 years is largely attributed to its ability to effectively reduce this pain. Our results showed that pain was reduced in both groups after treatment, and the degree of reduction in pain scores was significantly greater in the experi-

mental group, consistent with another study [18].

In the evaluation of fractures, we adopted a combination of clinical treatment efficiency and imaging. The results showed that the effective rate, the remarkable effective rate and the total effective rate of the experimental group were significantly better than the control group, which proved the superior therapeutic efficacy of vertebroplasty over conventional therapy. At the same time, X-rays showed that the vertebral body height and wedge angle of the experimental group were also better than the control group, further verifying the above conclusions. However, the other studies have only used imaging to evaluate the effectiveness of vertebroplasty without using conservative treatment as a reference [19].

The recovery of exercise capacity is an important part of the patient's prognosis. Our results showed that the postoperative life ability score of the experimental group was better than that of the control group. The average hospitalization duration was two weeks for the control group and only three days for the experimental group, also in line with other published reports [20]. However, long-term follow-up on the results, larger patient cohorts, and multi-center cooperation are needed to validate our findings. Finally, the potential risk of leakage caused by the use of bone cement in vertebroplasty will be the focus of our next study.

In conclusion, vertebroplasty is more effective than conservative treatment in the treatment of osteoporotic thoracolumbar compression fracture.

Disclosure of conflict of interest

None.

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