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Comparison Between Intraoperative Target Area Cement-Enhanced Percutaneous Vertebroplasty and Conventional Percutaneous Vertebroplasty for Osteoporotic Thoracolumbar Non-Total Vertebral Fractures

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ABSTRACT

AIM: To compare the efficacy and feasibility of target area cement-enhanced percutaneous vertebroplasty (PVP) and conventional PVP in osteoporotic thoracolumbar non-total vertebral fractures.

MATERIAL and METHODS: Retrospective analysis of one hundred and two patients treated in our hospital from March 2020 to May 2021 and divided into groups A (targeted) and B (conventional PVP). The Visual Analogue Scale (VAS), Oswestry Disability Index (ODI), anterior vertebral height ratio, intraoperative bleeding, operative time, bone cement volume, complications, and refracture of the injured vertebra were evaluated in both groups.

RESULTS: The 2 days and 1-year post-operative VAS and ODI scores improved significantly in both groups ($p<0.05$). The 2 days post-operative VAS and ODI scores were better in group A ($p<0.05$), and there was no significant difference in the scores between the groups at the last follow-up ($p>0.05$). The anterior vertebral height ratios were significantly higher in both groups 2 days post-operatively ($p<0.05$); however, there was no significant difference in the 2 days and 1-year post-operative ratios in group A ($p>0.05$). The anterior vertebral height ratio reduced in group B after 1 year compared to the 2 days post-operative value ($p<0.05$). There was no statistical difference in intraoperative bleeding and the operative time between the groups ($p>0.05$), and the bone cement volume was lesser in group A ($p<0.05$). Six patients in group A and four patients in group B demonstrated cement leakage, the difference was not statistically significant ($p>0.05$). Three patients in group A and 11 patients in group B demonstrated refracture, the difference was statistically significant ($p<0.05$).

CONCLUSION: Target area cement-enhanced PVP can effectively relieve short-term pain and functional disability and reduce the long-term possibility of secondary collapse. Therefore, it is a technically feasible and efficacious method for the treatment of osteoporotic thoracolumbar non-total vertebral fractures.

KEYWORDS: Elderly, Incomplete Vertebra fracture, Innovation, Kyphoplasty, Minimally invasive, Osteoporosis, Precision, Percutaneous vertebroplasty, Targeted cement, Thoracolumbar

ABBREVIATIONS: PVP: Percutaneous vertebroplasty, **PKP:** Percutaneous kyphoplasty, **OVCF:** Osteoporotic vertebral compression fractures, **VAS:** Visual analogue scale, **ODI:** Oswestry disability index, **BMD:** Bone mineral density, **BMI:** Body mass index

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INTRODUCTION

Percutaneous vertebroplasty (PVP) or percutaneous kyphoplasty (PKP) provides rapid pain relief in osteoporotic vertebral compression fractures (OVCF) (15). The efficacy of vertebroplasty is associated with increased strength and stability of the fractured vertebral body after cement hardening (1,7). Clinically, non-total fractures of the vertebral body are frequently seen in OVCF. This type of fracture has certain characteristics, and it is common to inject the cement far from the fracture area when conventional PVP is performed. This leads to insufficient filling in the fracture area, thereby affecting the outcome of surgical treatment (9). Therefore, the treatment of patients with a non-total vertebral fracture is specific. However, there are few relevant research reports at present. In this study, a retrospective analysis was conducted to compare the efficacy of conventional PVP versus target area cement-enhanced PVP for the treatment of non-total vertebral fractures in patients with OVCF.

MATERIAL and METHODS

General Information

A total of 102 patients with single-segment thoracolumbar non-total vertebral fractures treated at our hospital from March 2020 to May 2021 were collected. The patients were divided into two groups: the target area cement-enhanced PVP group (Group A) and conventional PVP group (Group B). The inclusion criteria were: 1) bone mineral density (BMD) T value ≤ -2.5; 2) age ≥ 60 years; 3) no obvious trauma or intolerable symptoms of thoracolumbar pain after minor trauma; 4) a confirmed diagnosis of osteoporotic thoracolumbar fracture by MRI, and a high signal oedematous area ≤ 1/2 of the vertebral body on MRI fat suppression sequence imaging of the fracture; 5) single vertebral body fracture and height loss ≤ 1/3rd. The exclusion criteria were: 1) patients with coagulation disorders or bleeding tendency; 2) presence of serious diseases of the heart, liver, lung and nervous system that are contraindications for surgery; 3) long-term hormone therapy; 4) malignant tumours of the spine and spinal infection; 5) patients with hypersensitivity and mental disorders. The ethics committee of the hospital approved this study (approval number: 2022060302), and all patients signed a written informed consent before participating in the treatment.

Surgical Method

The patients were placed in the prone position with hands up, shoulder and pelvic pillows, and the injured vertebra was positioned at the lumbar bridge of the surgical bed, which was adjusted to be reversed, concave and form a V shape, resulting in a hyperextension position of the spine ranging from 10 to 30 degrees. G-arm fluoroscopic positioning was done, repositioning of the compressed vertebral body was assessed, and routine disinfection and towel laying procedures were performed, following which the surgery was performed under local anaesthesia. The conventional PVP procedure was as follows: The anterior lower 1/3rd of the vertebral body was used as the point to inject the bone cement, and the procedure was completed according to the standard operation path. Intraoperatively, the dispersion of the bone cement was monitored strictly to prevent leakage. The target area cement-enhanced PVP procedure was as follows: Target puncture was performed with the centre of the vertebral fracture as the puncture point, and no further entry was made when the puncture reached 1/2 to 2/3rd of the pedicle. A 1.5 mm round-tipped fine guide needle was used to slowly enter the injured vertebra under fluoroscopy guidance, and the relationship of the guide needle to the puncture target was observed. If any adjustment was required, only the guide needle was withdrawn and the direction of inclination of the puncture needle was changed to the head, tail, inside and outside areas through stress. When the fracture is located near the upper or lower endplate or the anterior and posterior ends of the vertebral body, it is important to take care not to damage the upper and lower endplates or the anterior end of the vertebral body with the puncture needle. After completing the puncture, the 4.2 mm working sleeve was replaced, the vertebral body drill was inserted into the mid-anterior part of the fracture, and cement hardening was completed according to the surgical procedure. For larger cystic cavities with liquid contents, the fluid should be aspirated while injecting the bone cement to reduce the pressure in the cavity. All patients were punctured bilaterally.

Group Data

A total of 102 patients were included, with 19 men and 32 women in group A (age 60-88 years, mean 68.47 ± 7.86 years), and 17 men and 34 women in group B (age 60-83 years, mean 69.86 ± 7.62 years). The fractures were located in T6 (one patient), T7 (two patients), T8 (two patients), T9 (five patients), T10 (ten patients), T11 (12 patients), T12 (17 patients), L1 (23 patients), L2 (15 patients), L3 (nine patients), and L4 (six patients) (Figure 1). The fractures involved the upper endplate combined with part of the vertebral body (42 patients), the lower endplate combined with part of the vertebral body (21 patients), the anterior 1/2 of the vertebral body (17 patients), the posterior 1/2 of the vertebral body (8 patients), and the vertebral body combined with the cleft sign (14 patients).

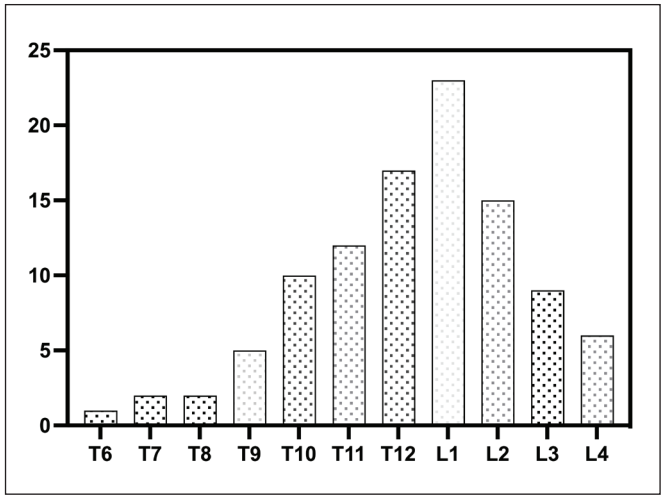

Figure 1: Fractured vertebral segments.

Observation Indicators

General baseline conditions, intraoperative bleeding, operative time (timed by the puncture after local anaesthesia until all the surgical instruments were taken out), and bone cement volume were recorded for both groups. The Visual Analogue Scale (VAS), Oswestry Disability Index (ODI), and anterior vertebral height ratio were recorded before operation, 2 days after operation, and 1 year after operation. At the same time, intraoperative and post-operative complications and refracture of the injured vertebra were also recorded.

Statistical Analysis

The data were statistically analysed using SPSS 26.0 software (IBM, Armonk, NY, USA). The count data were evaluated by the χ2 test and expressed as a rate (%). Measurement data were evaluated by the t-test and expressed as ($\chi \pm s$). Data were compared at different follow-up time points using one-way ANOVA. The SNK-q test was used for two-way comparisons, and the LSD t-test was used when the variance was not equal. The difference was considered statistically significant at $p<0.05$.

RESULTS

The surgeries were successful in all patients, and there were no serious post-operative complications, such as infection, pulmonary embolism or spinal nerve injury in either group. Six patients in group A and four patients in group B had cement leakage, the difference was not statistically significant ($p>0.05$). At the last follow-up, three patients in group A and 11 patients in group B had a re-collapse of the fractured vertebral body, and the difference was statistically significant ($p<0.05$) (Table I).

The 2 days and 1-year post-operative VAS and ODI scores of patients in both groups improved significantly compared with the pre-operative scores ($p<0.05$). The 2 days post-operative VAS and ODI scores were better in group A than in group B ($p<0.05$). There was no significant difference in the VAS and ODI scores between the groups at the final follow-up ($p>0.05$). In both groups, the 2 days post-operative anterior vertebral height ratio was significantly higher than that pre-operative ($p<0.05$). There was no significant difference between the anterior vertebral height ratio 2 days and 1 year post-operative in group A ($p>0.05$). The anterior vertebral height ratio decreased 1 year post-operative in group B compared with the 2 days post-operative value ($p<0.05$) (Table II).

Table I: Patient Conditions

	Group A	Group B	t/x²	p
Gender (M/F)	19/32	17/34	0.172	0.679
Age	68.47 ± 7.86	69.86 ± 7.62	-0.908	0.366
BMI	23.03 ± 2.55	22.81 ± 3.28	0.376	0.708
Fractured segments			0.282	0.869
≥T_{10}	11	9		
T_{11}~L_2	33	34		
L_{3-4}	7	8		
Fracture days	12.92 ± 5.60	14.04 ± 4.96	-1.068	0.288
BMD	-3.18 ± 0.43	-3.03 ± 0.53	-1.539	0.127
Cement leakage	6	4	0.443	0.505
Vertebral re-fracture	3	11	5.299	**0.021**

BMI: *Body mass index,* ***BMD:*** *Bone mineral density.*

Table II: Comparison of the Pre-Operative and Post-Operative VAS and ODI Scores and Anterior Vertebral Height Ratio Between the Two Groups

	VAS		ODI		Anterior vertebral height ratio	
	Group A	Group B	Group A	Group B	Group A	Group B
Pre-op	8.04 ± 1.23	8.29 ± 1.30	37.61 ± 2.65	37.47 ± 2.23	61.07 ± 10.48	59.64 ± 9.93
2 days post-op	2.12 ± 0.91[1]	2.59 ± 0.78[1,2]	18.06 ± 3.17[1]	19.53 ± 3.21[1,2]	83.85 ± 5.53[1]	82.33 ± 6.12[1]
1 year post-op	1.76 ± 0.84[1]	1.86 ± 0.78[1]	14.27 ± 2.87[1]	13.29 ± 3.61[1]	83.05 ± 5.48[1]	79.61 ± 6.48[1,2]

[1]p<0.05 compared with the same group pre-operative, [2]p<0.05 compared with group A at the same time point, ***VAS:*** *Visual analogue scale,* ***ODI:*** *Oswestry disability index.*

Intraoperative bleeding in group A ranged from 10 ml to 29 ml (mean, 16.69 ± 3.30 ml), operative time ranged from 36 min to 77 min (mean, 43.16 ± 5.88 min), and the bone cement volume ranged from 2 ml to 4.5 ml (mean, 3.31 ± 0.68 ml). Intraoperative bleeding in group B ranged from 12 ml to 26 ml (mean, 16.33 ± 2.65 ml), operative time ranged from 32 min to 62 min (mean, 41.98 ± 6.35 min), and the bone cement volume ranged from 2 ml to 5.5 ml (mean, 3.92 ± 0.73 ml). There was no statistical difference in intraoperative bleeding and the operative time between the two groups ($p>0.05$); however, the volume of bone cement in group A was less than that in group B, and the difference was statistically significant ($p<0.05$) (Table III). A typical case is shown in Figure 2.

DISCUSSION

PVP can provide rapid pain relief and promote early functional recovery in patients with OVCF (6,23). However, not all patients achieve satisfactory results after surgery, and some continue to experience poor pain relief and re-collapse of the vertebral body after treatment. A study reported that the success rate of PVP in the treatment of OVCF was 89% to 93%, indicating the scope for improvement in the clinical efficacy of the surgery (13). Many factors affect the efficacy of PVP. Relevant studies have confirmed that the diffuse distribution of bone cement in the fracture area is one of the main factors affecting the efficacy, and the main reason for poor post-operative outcomes is insufficient bone cement filling in the vertebral fracture area (11,21). In the treatment of OVCF by conventional PVP, the point at which the cement is injected lies in the anterior lower third of the vertebral body, which relies on the diffusion of the cement around the vertebral body to fix the fracture and prevent re-collapse (8). The surgeon can clinically observe that the bone cement generally tends to disperse in the direction of the intravertebral cavity and low-pressure areas and does not disperse uniformly in a spherical shape in all directions. In addition, factors such as the timing of bone cement injection, pushing force, degree of vertebral injury, time of injury and the different degrees of osteoporosis affect the degree of bone cement diffusion from the injection point to the surrounding area (14,16,17). In some patients with fracture areas far from the cement injection point, conventional PVP tends to concentrate the bone cement in the non-fracture area, resulting in underfilling of the fracture area and ultimately, poor efficacy of the surgery. In this study, the incidence of vertebral re-fracture in Group A was significantly lower than that in Group B ($p<0.05$), indicating that targeted cement augmentation can adequately fill the fracture area by directly

Table III: Comparison of Intraoperative Bleeding, Operative Time and the Bone Cement Volume Between the Two Groups

Group	Intraoperative bleeding (ml)	Operative time (mins)	Bone cement volume (ml)
Group A	16.69 ± 3.30	43.16 ± 5.88	3.31 ± 0.68
Group B	16.33 ± 2.65	41.98 ± 6.35	3.92 ± 0.73
T	0.596	0.971	-4.313
P	0.553	0.334	**<0.001**

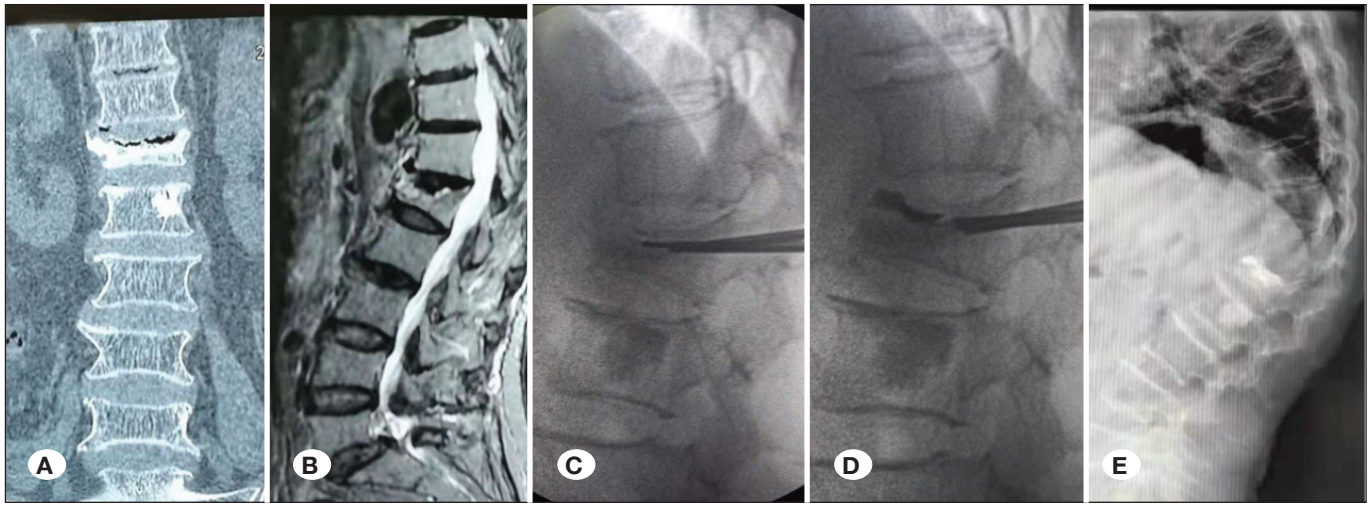

Figure 2: A 72-year-old woman. **A)** Pre-operative lumbar CT coronal view shows a compact bone compression zone at the inferior edge of the upper endplate of the L1 vertebral body. **B)** MRI T2WI of the lumbar spine shows low signal vertebral compression changes at the lower edge of the upper endplate, consistent with the fracture site in the CT scan. **C, D)** Intraoperatively, the target area cement-enhanced PVP puncture needle was precisely inserted into the vertebral fracture area, and the bone cement was injected. **E)** Post-operative lateral X-ray of the lumbar spine shows that the L1 vertebral body is well filled with bone cement along the fracture area.

injecting bone cement into the fracture area. In contrast, during conventional PVP injection, bone cement is relatively far away from the fracture area, which may lead to inadequate filling of bone cement and a higher incidence of vertebral re-fracture after surgery (22). Therefore, the conventional PVP approach should be modified in patients with osteoporotic non-total vertebral fractures. The bone cement injection point should be close to or located in the fracture area to implement precise target enhancement and optimize the efficacy of PVP.

Our research found that the bone cement leakage was higher in Group A compared to Group B. This may be due to the easy cement leakage into the intervertebral disc when the fracture line in Group A approached the endplate. However, there was no significant difference between the two groups ($p>0.05$). This could be attributed to the close intraoperative monitoring of cement leakage, the use of high-viscosity bone cement, and efforts to avoid excessive bolus pressure. Additionally, the small sample size in this study may have contributed to the lack of statistical significance. Therefore, in future research, we plan to increase the sample size to further validate our findings.

In this study, the 2 days post-operative VAS and ODI scores of patients in group A were better than those in group B. This could be attributed to the fact that reinforcement with bone cement in non-total vertebral fractures acts as a fixation mechanism for the fractured trabeculae, reduces micromovement in the fracture, enhances the immediate post-operative stability of the vertebral body and reduces the stimulation of nerve endings, which ultimately reduces pain (5). However, in some patients who underwent conventional PVP, the cement filling failed to strengthen the fracture end well, leading to a relatively poor immediate post-operative outcome. The poor outcome could be related to the displacement of the persistent fracture end (20). The anterior height ratio of the injured vertebrae was significantly higher in both groups post-operative compared to the pre-operative period, indicating that PVP is beneficial in reducing the risk of vertebral height loss. However, at the 1-year post-operative follow-up, we found that the anterior height ratio of the injured vertebrae in group B was significantly lesser than that in group A, and the probability of secondary collapse significantly increased. This phenomenon may be related to inadequate filling of the vertebral fracture area with bone cement, resulting in insufficient strengthening.

The use of targeted puncture techniques in vertebroplasty is gaining attention (19), especially in special cases, such as upper and lower endplate fractures with partial vertebral fractures, where targeted puncture allows the cement injection point to be in the fracture area and to be adequately diffused, which helps to prevent re-collapse (3). Target area strengthening can compensate for the disadvantages of conventional PVP cement injection points far from the fracture area, preventing inadequate cement filling and re-collapse of the fracture area, thereby providing complete pain relief (2,10). Pre-operative designing of a targeted puncture and target area bone cement hardening protocol is required. Detailed imaging is important, and it is clinically important to define the fracture type and severity and assess the risk (18). The combination of X-ray, CT 3D reconstruction and MRI is essential to identify the target area to be enhanced, design the puncture path and locate the fissure or cystic cavity. The key to the success of target enhancement is to ensure that the puncture can accurately reach the central area of the fracture or capsule to enable diffusion of the bone cement around the target area to achieve good filling of the fracture area or capsule with a small amount of the cement.

In this study, we found that there was no significant difference in intraoperative bleeding and the operative time of patients in group A compared with those in group B, while the amount of bone cement required was lesser in group A patients than in group B, and the difference was statistically significant. Belkoff et al. believed that the injection of a relatively small amount of bone cement (≥ 2 ml) could restore the strength of the vertebral body, promote healing and relieve pain (1). Several recent studies have not reported any significant correlation between the amount of bone cement used and the degree of post-operative pain relief (4,12). Kaufmann et al. suggested that it is not necessary to inject as much bone cement as possible when performing PVP but just the amount required to achieve pain relief while ensuring surgical safety (7). The surplus bone cement will diffuse into the non-fractured area, causing an increase in the elastic modulus of the vertebral body and exacerbating adjacent vertebral fractures. Therefore, after the bone cement is sufficiently diffused in the fracture area during target area strengthening treatment, it is not necessary to increase the amount to reduce the diffusion of bone cement into the non-fracture area. This is conducive to reducing the elastic modulus of the injured vertebrae after strengthening and reducing the fracture of the adjacent vertebrae in the middle and distant stages.

We have learnt the following aspects regarding puncturing: 1) ensure the accurate location of the affected vertebra and the entry point of the needle puncture by positioning and fluoroscopy; 2) the puncture needle does not penetrate further after it enters 1/2 to 2/3rd of the pedicle. At this point, a 1.5 mm diameter Kirschner needle can be used to enter the vertebral body, its deviation from the direction of the target area can be observed, following which the needle insertion direction can be adjusted; 3) it is not necessary to withdraw the puncture needle when adjusting the needle insertion direction. At this point, the puncture needle is in a shallow position within the pedicle, and it is easy to change the abduction of the needle, as well as the angle of inclination toward the head and tail end through stress until the Kirschner needle can be accurately located within the target area. Following this, the puncture needle can be placed in the vertebral body, and the working sleeve can be replaced according to the operational requirements; 4) after the vertebral body drill is inserted into the injured vertebra, fluoroscopy is performed again to confirm whether it is located in the target area. After reaching the fracture target area, fresh blood is usually seen to gush out. After reaching the intravertebral cavity, using Kirschner wire to probe often has a sense of falling, and a pale yellow or colourless liquid can be seen flowing out occasionally. A targeted puncture can be achieved by the above methods with little technical difficulty and without the need for more complex CT localization punctures; 5) to prevent the bone

cement from sinking into the vertebral body long after cement hardening in the target area, the needle on one side can be moderately shifted to the lower end of the oedematous area around the fracture during puncture, and part of the bone cement can be filled in the non-fracture area for "topping and rooting."

Our study has certain limitations. Firstly, the follow-up period for our patients was limited to one year, which may be considered relatively short. Additionally, the difference in vertebral height loss between the two groups may further increase over time. Secondly, the targeted puncture technique used in our study may pose an increased risk of cement leakage into the disc when the fracture is in close proximity to the endplate. Lastly, our study is a retrospective analysis conducted at a single center with a small sample size, which may introduce some bias in the conclusion. Therefore, future studies with larger sample sizes, conducted at multiple centers with prospective designs, are needed to further validate the findings of our study.

CONCLUSION

Target area cement-enhanced PVP can effectively relieve short-term pain and functional disability and reduce the long-term possibility of secondary collapse. Therefore, it is a technically feasible and efficacious method for the treatment of osteoporotic thoracolumbar non-total vertebral fractures in the elderly.

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AUTHORSHIP CONTRIBUTION

Study conception and design: YW, CZ
Data collection: YL, XM.
Analysis and interpretation of results: CZ, YL, XM
Draft manuscript preparation: YW, CZ
Critical revision of the article: YW
All authors (YW, CZ, YL, XM) reviewed the results and approved the final version of the manuscript.

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