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# Percutaneous Vertebroplasty with the Polymethyl Methacrylate - Gelatin Sponge Complex in the Treatment of Patients with Osteoporotic Vertebral Compression Fractures Accompanied by Superior Endplate Injuries

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## ABSTRACT

**AIM:** To explore the clinical efficacy of percutaneous vertebroplasty (PVP) combined with the polymethyl methacrylate-gelatin sponge (PMMA-GS) complex in the treatment of patients with osteoporotic vertebral compression fractures (OVCFs) accompanied by superior endplate injuries

**MATERIAL and METHODS:** A total of 77 OVCF patients with superior endplate injuries who were treated with PVP from January 2017 to December 2020 were retrospectively analyzed. The visual analogue scale (VAS) score, Oswestry disability index (ODI), and injured vertebral height ratio at one day (1d) before surgery, three days (3d) after surgery, and one year (1y) after surgery were compared between both groups. Besides, the surgical duration, PMMA (polymethyl methacrylate) injection volume, PMMA leakage rate, and adjacent vertebral fracture rate were compared between these two groups.

**RESULTS:** Among these patients, there were 39 individuals treated with PVP combined with the PMMA-GS complex (the observation group) and 38 individuals treated with PVP (the control group). These patients in both groups completed the surgery successfully. There were no such complications as pulmonary embolism, hemopneumothorax, rib fracture, spinal cord nerve injuries, and vital organ injuries. In these two groups, the VAS score, ODI, and injured vertebral height ratio 1d before surgery were significantly different from those 3d and 1y after surgery ($p<0.05$). However, there was no significant difference in these indexes between both groups ($p>0.05$). There was no significant difference in the surgical duration and PMMA injection volume between both groups ($p>0.05$). However, the PMMA leakage rate and adjacent vertebral fracture rate in the observation group were significantly lower than those in the control group ($p<0.05$).

**CONCLUSION:** Compared with traditional PVP, this therapy PVP combined with PMMA-GS complex in the treatment of OVCF patients with superior endplate injuries can effectively reduce the incidence of PMMA leakage and the incidence of adjacent vertebral fracture rate.

**KEYWORDS:** Osteoporotic vertebral compression fracture, Superior endplate injury, Percutaneous vertebroplasty (PVP), Polymethyl methacrylate - gelatin sponge complex, PMMA leakage

**ABBREVIATIONS: OVCFs:** Osteoporotic vertebral compression fractures, **PVP:** Percutaneous vertebroplasty, **PMMA-GS:** Polymethyl methacrylate - gelatin sponge, **PMMA:** Polymethyl methacrylate, **VAS:** Visual analog scale, **ODI:** Oswestry Disability Index

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## INTRODUCTION

With the aggravation of social aging, the incidence of osteoporotic vertebral compression fractures (OVCFs) is increasing with each passing year. Percutaneous vertebroplasty (PVP) has been widely used in the treatment of OVCFs and achieved satisfactory efficacy (2). Because the wedge shape of the compressed vertebral body is prone to induce superior endplate injuries, the PMMA leakage in the intervertebral space occurs frequently during PVP. As is demonstrated in an increasing number of studies, PMMA leakage in the intervertebral space may increase the risk of adjacent vertebral fractures (17). Therefore, reducing PMMA leakage contributes to favorable efficacy of PVP treatment. The authors applied the traditional standard PVP and the PVP combining the PMMA-GS complex to the treatment of 77 OVCF patients with superior endplate injuries from January 2017 to December 2020. It was confirmed that the intravertebral filling with the PMMA-GS complex can significantly reduce the occurrence of PMMA leakage during PVP. The specific circumstances would be reported as follows.

## MATERIAL and METHODS

This study was approved by the ethic commitee (Date: 04.02.2017, No: 0516-85326137).

### General Data

#### *Inclusion and Exclusion Criteria*

The inclusion criteria are presented as follows: 1) patients with osteoporosis, with the T-score of bone mineral density (BMD) ≤-2.5 SD; 2) patients aged ≥ 65 years; 3) patients without obvious trauma or intractable pain in chest, waist and back after minor trauma; 4) patients with a low signal intensity on $T_1$-weighted images and a high signal intensity on $T_2$-weighted images or fat-suppression sequence images from the MRI scan on the injured vertebra, and with edema, angulation or degenerative changes in the superior endplate; 5) patients with compressive deformation in the injured vertebra and degenerative changes and angular subsidence in the superior endplate cartilage from the CT scan; 6) patients with the single vertebral disease; 7) patients with no spinal cord nerve damage caused by compression and no contraindications related to PVP. The exclusion criteria are presented as follows: 1) patients with malignant tumors in the spine; 2) patients with spinal infection; 3) patients with a high-sensitivity allergic constitution; 4) patients with coagulation dysfunction; 5) patients with mental function diseases.

#### *Grouping Data*

A total of 77 eligible patients were included in the study. They were randomly divided into the traditional PVP group (the control group, n=38) and the PVP + the PMMA-GS complex group (the observation group, n=39). The surgery for patients in both groups was completed by experienced surgeons.

#### *Imaging Data*

X-ray films of 77 patients revealed the compression signs with the compression degree ranging from 20% to 60%. The two dimensional (2D) CT scan displayed clear cortical fracture signs in the superior endplate of the injured vertebra in all patients, including 15 patients with intravertebral vacuum cleft signs.

### Methods

#### *Preoperative Preparation*

The patient lay in a prone position, with both hands lifted and cushions placed under the shoulders and pelvis. The injured vertebra was located at the waist bridge of the operating table. According to the compression degree of the injured vertebra, the waist bridge was set at a downward concave angle in a V shape, so that the patient's spine could be hyperextended at a degree from 10° to 30°. The reduction of compressed vertebrae was positioned and observed with the G-arm surgical fluoroscopy system. After relevant requirements were met, routine disinfection and surgical drape were applied to conduct surgery under local anesthesia. Then, the puncture and surgical instruments with proper diameters were selected according to the thoracolumbar puncture site. Specifically, a puncture needle with a diameter of 3.0mm can be used for lumbar vertebrae and lower thoracic vertebrae.

#### *Surgical Procedure and A Case Report*

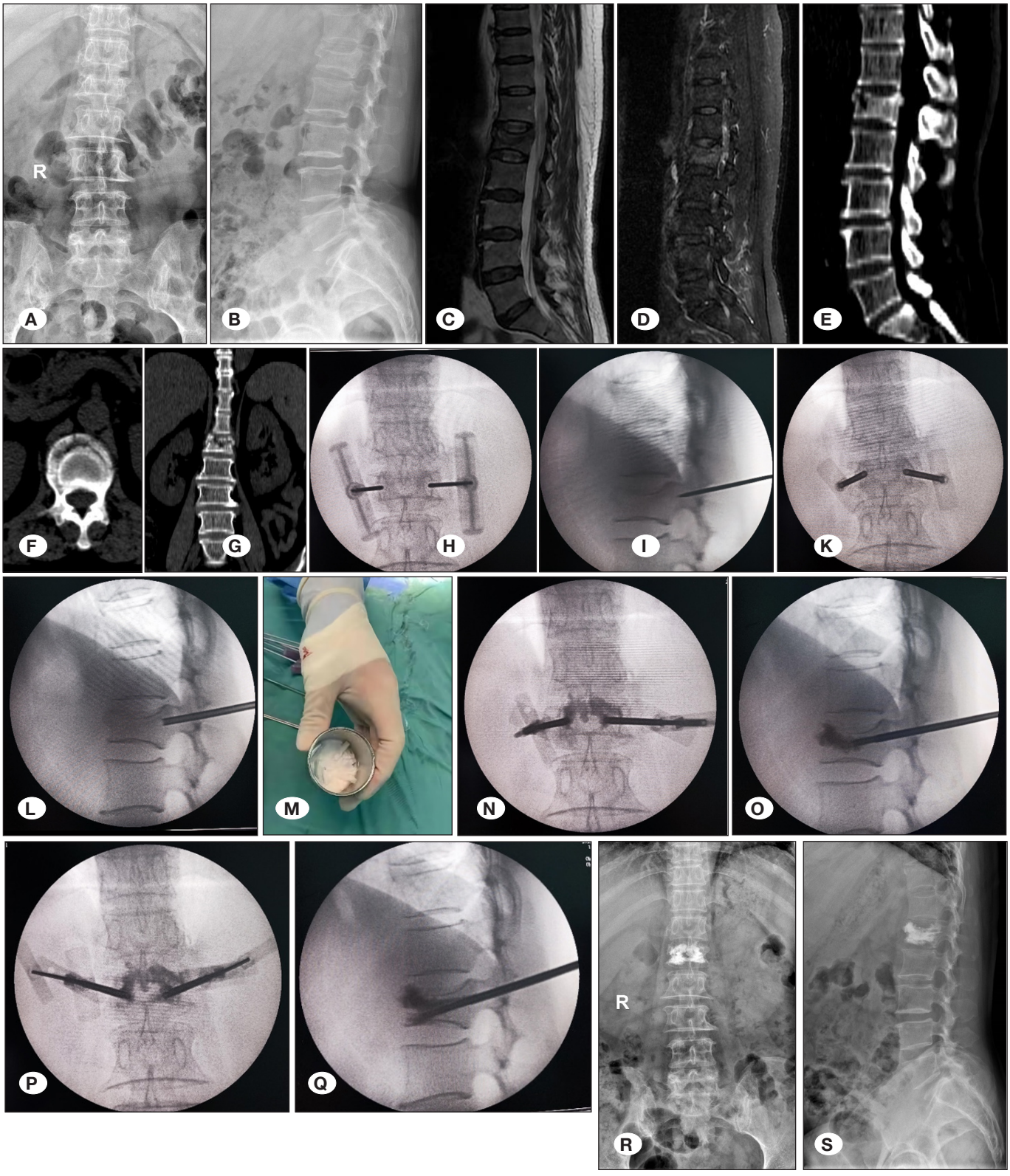
A 70 years old patient suffered from back pain for 2 days. As shown in figure (A-G), L1 OVCF is definite and the superior endplate injuries is evident. The puncture was stopped when it reached 1/2 to 2/3 of the vertebral pedicle, as shown in figure (H-I). A 1.5mm guide needle with a round head slowly entered the injured vertebra under fluoroscopy. The guide needle can be withdrawn in case of adjustment, and the puncture needle can be tilted to the head, tail, inside, and outside through stress, as shown in figure (J). After the puncture was completed successfully, a 4.2mm working sleeve was replaced, and was inserted to the front of the vertebra, as shown in figure (K-L).

#### *The Control Group*

The patients in the control group were treated with traditional PVP. PMMA was injected to conduct reinforcement after the puncture. The surgery was performed in strict accordance with relevant surgical norms to prevent PMMA leakage.

#### *The Observation Group*

The patients in the observation group were treated with modified PVP. The PMMA-GS complex was prepared with absorbable gelatin sponges, with a volume of 0.5-1 $cm^3$ for each sponge. The PMMA in the thinning stage was extracted and mixed with gelatin sponge strips to prepare the PMMA-GS complex, as shown in figure (M). The complex was filled under the endplate through the working sleeve, and the complex filling position can be adjusted according to the fluoroscopic images. The focus of filling was placed on the superior endplate, the cortical bone fracture, and the intravertebral vacuum cleft. The filling volume was determined based on the complete filling and covering of the part under the superior endplate and the cortical bone injury, as shown in figure (N-O). After the filling was completed, the reinforcement




**Figures: A, B)** The preoperative lumbar X-rays of this patient. **C, D)** The preoperative lumbar MRIs of this patient showed new-onset OVCF. **E-G)** The preoperative lumbar CT scans of this patient showed that there were superior and inferior endplate injuries in the lumbus with OVCF. **H, I)** The intraoperative puncture. **M)** The PMMA-GS complex. **N, O)** The focus of filling was placed on the superior endplate. **P, Q)** The focus of filling was adjusted direction towards the inferior endplate. **R, S)** Postoperative images showed the vertebral body was well filled with no PMMA leakage.

was performed with PMMA with adjusted direction towards the inferior endplate under fluoroscopic monitoring, as shown in figure (P-Q). The injection position of PMMA should be adjusted to avoid PMMA leakage. Postoperative images showed in figure (R-S), the vertebral body was well filled with no PMMA leakage.

### *Postoperative Treatment*

The detumescence and alleviation pain treatment was performed routinely after surgery. Patients were allowed to get out of bed after staying in bed for 4-24h. In addition, the anti-osteoporosis treatment was applied routinely after discharge.

### Observation Indexes

The VAS score, ODI, and injured vertebral height ratio 1d before surgery, 3d after surgery, and 1y after surgery were compared between both groups. Besides, the surgical duration, PMMA leakage rate, and adjacent vertebral fracture rate were compared between both groups. The injured vertebral height ratio was calculated as per the value measured at the most significant point of vertebral compression / the average value measured at the same point of adjacent upper and lower vertebrae × 100%. The surgical duration was calculated from the initiation of local anesthesia to the withdrawal of the working sleeve after PMMA reinforcement.

### Statistical Analysis

The data were analyzed with SPSS 25.0. The measurement data conforming to normal distribution were expressed as mean ± standard deviation ($\bar{x}\pm s$) and subject to two-sample independent t-test. The enumeration data were compared by the $\chi^2$ test. P<0.05 indicated that the difference was statistically significant.

## RESULTS

These patients in both groups completed the surgery successfully. There were no such complications as pulmonary embolism, hemopneumothorax, rib fracture, spinal cord nerve injuries, and vital organ injuries. The follow-up duration ranged from 6 months to 3 years, with an average of 1.7 years.

In the control group, there were 17 males and 21 females, with an average age of (74.2 ± 2.3) years, ranging from 65 to 89 years. The onset duration ranged from 2 days to 34 days, with an average of (7.5 ± 6.3) days. There was 1 patient with a compression fracture at $T_7$, 1 patient at $T_8$, 2 patients at $T_9$, 3 patients at $T_{10}$, 3 patients at $T_{11}$, 8 patients at $T_{12}$, 10 patients at $L_1$, 6 patients at $L_2$, 2 patients at $L_3$, and 2 patients at $L_4$. In the observation group, there were 16 males and 23 females, with an average age of (73.6 ± 2.3) years, ranging from 66 to 87 years. The onset duration ranged from 2 days to 36 days, with an average of (7.7 ± 6.7) days. There were 2 patients with a compression fracture at $T_8$, 2 patients at $T_9$, 3 patients at $T_{10}$, 4 patients at $T_{11}$, 7 patients at $T_{12}$, 9 patients at $L_1$, 7 patients at $L_2$, 2 patients at $L_3$, 1 patient at L4, and 1 patient at $L_5$. There was no significant difference in gender, age, and course of disease between both groups. These patients in both groups had a history of hypertension, diabetes, lung diseases, mild cerebral infarction, lumbar spinal stenosis, and other conditions with varying degrees. Nevertheless, these conditions would not affect the surgical treatment after strict preoperative evaluation.

There was no significant difference in the VAS score, ODI, and injured vertebral height ratio at 1d before surgery, 3d after surgery, and 1y after surgery between the observation group and the control group. In these two groups, the VAS score, ODI, and injured vertebral height ratio 1d before surgery were significantly different from those 3d and 1y after surgery (p<0.05). However, there was no significant difference in the VAS score and injured vertebral height ratio of both groups between 3d after surgery and 1y after surgery (p>0.05). There were significant differences in ODI of both groups between 3d after surgery and 1y after surgery (p<0.05). Please refer to Table I for more details.

There was no significant difference in the surgical duration and PMMA injection volume between the observation group and the control group (p>0.05). There were significant differences in the PMMA leakage rate and adjacent vertebral fracture rate between the observation group and the control group (p<0.05). Please refer to Table II for more details.

**Table I:** Comparison of the VAS Score, ODI, and Injured Vertebral Height Ratio of Both Groups

| | | 1 day before surgery | 3 days after surgery | 1 year after surgery | p-value |
|---|---|---|---|---|---|
| VAS Score (points) | Observation | 7.821 ± 1.023 | 2.333 ± 0.701* | 1.385 ± 0.847*Δ | **<0.05** |
| | Control | 7.290 ± 0.956 | 2.158 ± 0.594* | 1.290 ± 0.732*Δ | **<0.05** |
| ODI (%) | Observation | 75.606 ± 11.145 | 25.053 ± 4.703* | 17.948 ± 6.966*# | **<0.05** |
| | Control | 74.934 ± 10.877 | 25.395 ± 4.762* | 18.356 ± 7.136*# | **<0.05** |
| Injured Vertebral Height Ratio (%) | Observation | 59.793 ± 10.635 | 83.523 ± 6.103* | 82.969 ± 6.095*Δ | **<0.05** |
| | Control | 60.533 ± 10.490 | 84.021 ± 5.565* | 83.003 ± 5.471*Δ | **<0.05** |

***VAS:*** *visual analogue scale;* ***ODI:*** *Oswestry disability index.* ******* *Compared with 1 day before surgery, the difference was statistically significant (p<0.05);* **Δ** *Compared with 3 days after surgery, the difference was not statistically significant (p>0.05);* **#** *Compared with 3 days after surgery, the difference was statistically significant (p<0.05).*

**Table II:** Comparison of Surgical Duration, PMMA Injection Volume and Complications between Both Groups

| | Observation | Control | p-value |
|---|---|---|---|
| Surgical Duration (min) | 48.462 ± 5.399 | 47.105 ± 6.229 | >0.05 |
| PMMA Volume (ml) | 3.944 ± 0.335 | 4.026 ± 0.357 | >0.05 |
| PMMA Leakage | 7.692% (3/39) | 28.947% (11/38) | **<0.05** |
| Adjacent Vertebral Fracture | 5.128% (2/39) | 23.684% (9-38) | <0.05 |

***PMMA:*** *Polymethyl methacrylate. The difference was statistically significant (p<0.05).*

## DISCUSSION

As a common complication of osteoporosis, OVCF would induce severe pain in the chest, waist and back, the height loss of vertebral body, and kyphotic angle. These conditions would seriously restrict the mobility of patients, cause a series of complications, and even endanger their lives. Percutaneous vertebroplasty (PVP) has been recognized as a minimally invasive technique that can be effectively applied to the treatment of OVCF. It shall be noted that PMMA leakage is a major complication of PVP. Most researchers maintain that the concomitant injuries involving the fracture line of the cortical bone and endplates in the fractured vertebra are the leading factor affecting PMMA leakage (15). According to an MRI imaging analysis of OVCF patients conducted by Ortiz and Bordia (12), about 68% of OVCF patients are accompanied by superior endplate injuries with varying degrees. The main reason for this phenomenon is that the superior endplate is sunken and displaced with the compression and flattening of the vertebra, which would destroy the trabecular bone under the endplate and induce the loss of effective support, thereby causing the fracture and defect of the superior endplate cartilage and cortical bone. As is revealed in a study conducted by Zong et al. (18), the PMMA leakage rate of OVCF patients treated with PVP is 28.2%. The multivariate regression analysis results demonstrate that superior endplate injury is a risk factor for PMMA leakage in the intervertebral space. Besides, some OVCF patients may present with intravertebral vacuum cleft signs, and the stress injury is prone to occur due to the decreased effective support for the superior endplate. The PMMA leakage rate of these patients after PVP can reach as high as 66.7%, with the PMMA leakage in the intervertebral space accounting for a large proportion (8). According to a report of Lin et al. (9), the PMMA leakage in the intervertebral space after PVP will significantly increase the risk of re-fracture of adjacent vertebrae, with the incidence being 58%. While the incidence of adjacent vertebral fractures is 12% in those without PMMA leakage. Therefore, it is required to pay attention to and prevent PMMA leakage for the PVP treatment of OVCF patients with superior endplate injuries.

Currently, the PMMA leakage during the PVP treatment is mainly prevented by high-viscosity PMMA, puncture technology improvement, and PMMA injection in stages (14), which contributes to partially reducing PMMA leakage caused by technical factors. In recent years, many researchers have reported the PVP based on bone filling mesh containers (BFMCs) for the treatment of OVCF patients with superior endplate injuries (5,6,10,16). They maintain that this therapy is more effective in preventing PMMA leakage. However, according to a research report of Jing et al. (7), the poor prognosis rate of BFMC-based PVP is 37% in the treatment of patients with osteoporotic vertebral compression fractures accompanied by vertebral body wall incompetence, the PMMA leakage rate is 26%, and the incidence of sustained moderate pain is 21%. Therefore, it is recommended that the indications of surgery shall be fully understood, and it is required to pay attention to potential adverse complications. The BFMC-based PVP has the defects of complex technology and high cost of consumables, which hinders its routine promotion in clinical practice. It is necessary to explore a low-cost and simple technical method to prevent PMMA leakage. In the PVP treatment of OVCF patients with superior endplate injuries, PMMA leakage may occur due to its flow to the intervertebral disc through the endplate fracture cleft. PMMA leakage can be reduced by blocking the fracture cleft by technical methods during PVP. In recent years, it has been reported that gelatin sponge particles can reduce the occurrence of leakage by improving the viscosity of PMMA, reducing its fluidity, and shortening solidification time (1,11). Vancomycin combined with gelatin sponge can effectively prevent wound infection (4). And, gelfoam barrier appears to provide partial protection of the spinal cord against thermal injury (13). However, the position of the gelatin sponge filled into the injured vertebra cannot be traced by X-ray-based fluoroscopy, which would affect the accuracy of leakage prevention and treatment effects. The PMMA during PVP can be visualized by fluoroscopy. Therefore, the PMMA-GS complex prepared by combining polymethyl methacrylate with gelatin sponge can overcome the defect that the gelatin sponge could not be traced during PVP with GS alone. In this study, therefore, the intravertebral filling with the PMMA-GS complex is applied to the PVP treatment of OVCF patients with superior endplate injuries. There is no significant difference in improving the analgesic effect, ODI, and injured vertebral height ratio between the traditional PVP and this combined therapy. In addition, there is no significant difference in the surgical duration and PMMA injection volume between both therapies. However, there are significant differences in the PMMA leakage rate and adjacent vertebral fracture rate between both therapies. It can be maintained that this therapy combining PVP and the intravertebral filling with the PMMA-GS complex in the treatment of OVCF patients with superior endplate injuries can effectively reduce the PMMA leakage rate and the adjacent vertebral fracture rate. Meanwhile, this

surgical method would not increase the surgical duration and the poor prognosis of patients. Moreover, the effects of the intravertebral filling with the PMMA-GS complex on reducing PMMA leakage during PVP can be specifically interpreted from the following aspects. 1) The position of the PMMA-GS complex filled into the injured vertebra can be traced by intraoperative fluoroscopy, which is convenient for pushing the complex to the superior endplate and other bone defects during surgery, thus achieving accurate filling and occlusion. 2) The PMMA in the complex can block the bone defects and clefts in the superior endplate and the anterior edge of the vertebra through diffusion, which can reduce PMMA leakage via PMMA injection in stages. 3) The condition that whether there will be serious PMMA leakage can be predicted by the diffusion of PMMA, which conduces to taking preventive measures in time. 4) The temperature change can accelerate the solidification of PMMA in the complex, which is more conducive to limiting the flow of PMMA. In terms of the selection of PVP or PKP for OVCF patients with superior endplate injuries, the author recommends that PVP shall be given priority. The reason is that PVP can shorten the surgical duration, decrease medical expenses, and reduce the original defect enlargement or new clefts caused by excessive expansion of the superior endplate during PKP balloon expansion. Furthermore, PVP can reduce the incidence of PMMA leakage, and it can also reduce the incidence of adjacent vertebral fractures (3).

It is necessary to pay attention to the following aspects during the treatment of OVCF patients with PVP combining the PMMA-GS complex. 1) The injured vertebra reduction shall be performed based on specific conditions during PVP, and complete recovery shall not be imposed on the injured vertebral height. 2) The puncture shall be performed at the middle or upper 1/3 of the injured vertebra side parallel to the superior endplate. Besides, the puncture channel shall not be angled with the superior endplate, nor should it be too close to the superior endplate. 3) The gelatin sponge shall be prepared with a proper width. An excessive large width may induce excessive extrusion of PMMA during the complex injection through the working sleeve, which would affect the efficacy. 4) The PMMA-GS complex can be filled under the endplate through the working sleeve from the anterior edge to the middle and posterior parts of the vertebra in turn under X-ray-based fluoroscopy. The complex filling position and volume can be adjusted according to the fluoroscopic images. The proper filling volume can be determined based on the complete filling and covering of the part under the superior endplate or the injured part of the bone cortex in the anterior and lateral fluoroscopic images of the vertebra during PVP. 5) As for those patients with superior endplate injuries accompanied by intravertebral vacuum cleft signs or bone defects in other vertebral parts, the cleft cavity or bone defect shall be filled with the complex via targeted puncture. 6) After the filling is completed, the reinforcement shall be performed with a PMMA syringe with a lateral outlet towards the inferior endplate under fluoroscopic monitoring. The injection position of PMMA shall be adjusted to reduce leakage in case of PMMA leakage signs.

## CONCLUSION

Compared with traditional PVP, this therapy combining PVP and the intravertebral filling with the PMMA-GS complex in the treatment of OVCF patients with superior endplate injuries can effectively reduce the incidence of PMMA leakage in the intervertebral space and the incidence of adjacent vertebral fracture.

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**AUTHORSHIP CONTRIBUTION**

Study conception and design: HL, YW
Data collection: LQ, BW
Analysis and interpretation of results: XT
Draft manuscript preparation: YL
Critical revision of the article: CZ
Other (study supervision, fundings, materials, etc...): ZC
All authors (YW, LQ, BW, XT, YL, CZ, ZC, HL) reviewed the results and approved the final version of the manuscript.

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