Clinical analysis of osteoporotic vertebral oblique compression fracture treated with bone cement combined with balloon

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Research Article

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Abstract

Objective： To explore the clinical effect of bone cement combined with balloon expansion in the treatment of osteoporotic vertebral oblique compression fracture.

Methods： This study retrospectively reviewed the patients who were diagnosed with osteoporotic vertebral oblique compression fracture between January 2017 and July 2019. According to the method of surgery, 41 patients received bone cement treatment alone (group A) and 44 patients received bone cement combined with balloon expansion (group B). The visual analogue scale (VAS), oswestry disability index (ODI), scoliosis angle (SA), height of long side (HL), height of short side (HS) and lateral height difference (LHD) before operation and 3 days and 1 year after operation were compared between the two groups. The operation time, fluoroscopic time, hospital stay, cement volume and complications were also compared between the two groups.

Results：The VAS and ODI differed significantly between the groups 1 year after operation($P<0.05$). Compared with the preoperative results, there were significant differences in SA, HL, HS and LHD 3 days and 1 year after surgery($P<0.05$). There were significant differences in SA, HS and LHD 3 days and 1 year after surgery between the two groups($P<0.05$). A total of 21 patients in group A and 6 patients in group B experienced scoliosis after operation, there were also significant differences between groups($P<0.05$).

Conclusions：Bone cement combined with balloon expansion and bone cement alone are all effective in the treatment of osteoporotic vertebral oblique compression fracture, but bone cement combined with balloon expansion had better long-term clinical efficacy.

Introduction

Osteoporosis is a systemic disease of the skeletal system that increases bone fragility due to the destruction of bone microarchitecture and reduction of bone mass, leading to fractures in various parts of the body[1,2], the most frequent disease is osteoporotic vertebral compression fracture (OVCF),they occur in 30–50% of people over the age of 50[3]. With the aging of the population and the prolongation of life expectancy, the prevalence of osteoporosis is increasing year by year[4]. The main symptom is low back pain, which will affect the function of the spine, produce scoliosis and kyphosis, and seriously affect the patient's daily life[5,6]. Osteoporotic vertebral oblique compression fracture (OVOCF) is a special type of OVCF. Usually, the anterior column of the vertebral body is compressed into a wedge shape on the lateral X-ray of OVCF patients. However, in patients with OVOCF, compression of the left and right vertebral bodies was mainly observed on the frontal X-ray. The main manifestation is that the vertebral body collapses sideways on the frontal X-ray, resulting in an oblique fracture of the vertebral body. If the lateral height of OVOCF vertebral compression is not corrected and the longitudinal pressure distribution of adjacent vertebral bodies is uneven, scoliosis deformity is highly likely to occur.

Treatment of OVCF with bone cement alone was first proposed by Deramand and Galibert in the 1980s[7]. It is an important technique in minimally invasive spine surgery, which can instantly stabilize fractures, strengthen vertebral bodies, and relieve pain[8–10]. The principle is to use bone cement (polymethyl methacrylate, PMMA) to quickly restore the strength and stiffness of the fractured vertebral body, rebuild the stability of the spine, and create a good healing environment for osteoporotic fractures[11,12]. Bone cement combined with balloon expansion that creates a cavity in the vertebral body with a balloon (inflatable bone tamp) before injecting polymethylmethacrylate (PMMA) bone cement, was first designed by Wong and Reiley and got approved by the FDA for clinical use in1998[7]. Liberman first reported the use of bone cement combined with balloon expansion in the clinic in 2001[13]. Bone cement combined with balloon expansion is a safe and effective technique for the treatment of OVCF, which can effectively relieve low back pain, restore vertebral body height, and improve the patient's sagittal plane sequence[14,15]. Both bone cement and bone cement combined with balloon expansion surgery are safe and effective surgical procedures for treating OVCF[16]. At present, more attention is paid to compare the clinical efficacy of bone cement and bone cement combined with balloon expansion for vertebral compression fractures with changes in the anterior column height, and less attention has been paid to the lateral height of vertebral body. Therefore, this research focus on comparing the clinical efficacy of bone cement and bone cement combined with balloon in the treatment of osteoporotic vertebral oblique compression fracture.

Methods

General Information

This study retrospectively reviewed the patients who were diagnosed with OVOCF between September 2015 and July 2019.All patients were treated with bone cement or bone cement combined with balloon expansion in our hospital. The inclusion criteria were as follows: (1) All patients and their families signed informed consent forms and approved by the medical ethics committee. (2) OVOCF was confirmed by imaging examination. MRI showed obvious edema signal in the vertebral body on T2-weighted image, and the frontal X-ray showed that the scoliosis angle was more than 11°. (3) Single-segment thoracolumbar fracture. (4) The follow-up time was over 2 years. The exclusion criteria were as follows: (1) Stale OVCF patients. (2) Pathologic vertebral lesions such as vertebral metastatic carcinoma, vertebral hemangioma and myeloma, etc. (3) Patients with severe liver and kidney dysfunction, cardiovascular and cerebrovascular diseases. (4) Patients who were lost to follow-up.

All patients underwent preoperative X-ray, computed tomography, and magnetic resonance imaging. Identify the fractured vertebra as the responsible vertebra for pain. The preoperative and follow-up X-rays for each patient were complete and available.

According to the methods of surgery, these patients were divided into group A and B. Group A: the method of surgery is bone cement alone. Group B: the method of surgery is bone cement combined with balloon expansion.

Surgical Technique

All patients were placed in prone position, and local or general anesthesia was selected according to the patient's physical condition and wishes.

Bone cement alone: Standard anteroposterior and lateral images of the vertebral body were captured by C-arm X-ray. Firstly, the position of the injured vertebra was located and the projection point of the pedicle on the body surface of the injured vertebra was marked. Unilateral or bilateral pedicle puncture approach was adopted to reach about 3mm in front of the posterior edge of the vertebra. After the puncture is positioned in place under fluoroscopy, the working cannula is replaced. After installing the working cannula, remove the expansion tube and guide wire, and push the fine drill along the working sleeve to the anterior edge of the vertebral body to establish a working channel. The polymethyl methacrylate (PMMA) bone cement was slowly injected into the anterior 1/3 of the vertebral body, and the injection was stopped after the bone cement was evenly injected into the vertebral body. After coagulation, the wound was pressed, and the incision was sutured 3 to 5 minutes later.

Bone cement combined with balloon expansion: Use the same method as bone cement surgery to establish a working cannula. The guide wire, expansion cannula and working cannula were placed in sequence, and then the inflatable balloon was placed into the vertebral body through the working cannula and inflated under fluoroscopic guidance. The prepared polymethylmethacrylate cement was slowly inserted into the vertebral body through a cannula under fluoroscopic monitoring. The injection was stopped as the cement was closed as the posterior wall of the vertebra. Finally, the cannula was removed.

All patients were given anti-osteoporosis drug treatment after operation and got out of bed on the day after operation to guide rehabilitation training and other postoperative treatment.

Assessed Parameters

The visual analogue scale (VAS) score was used to assess patients' subjective pain perception before surgery, 3 days after surgery and 1 year after surgery (0–10 scale, with 0 being painless and 10 being the most painful)[17]. In addition, the oswestry disability index (ODI) score was used to assess improvements in quality of life before surgery, 3 days after surgery and 1 year after surgery. Scoliosis angle (SA), height of long side (HL), height of short side (HS) and lateral height difference (LHD)of the injured vertebra were measured before surgery, 3 days after surgery and 1 year after surgery to the degree of reduction and correction. SA is the angle formed by the upper end plate and the lower end plate of the fractured vertebral body on the frontal X-ray. HS of vertebra is the height of the vertebral body on the heavily compressed side of the injured vertebral body. HL of vertebra is the height of the vertebral body on the slightly compressed side of the injured vertebral body. LHD of vertebra is the height of the long side of the vertebral body minus the height of the short side on the frontal X-ray.

Statistical Methods

SPSS26.0 software was used to analyze the data in our study. Statistic values are presented as mean ± standard deviation. The paired-samples T test was used to assess the changes of various parameters in both groups, and the independent-simple T test was used to assess difference between groups. The $\chi 2$ test was used for categorical data. $P < 0.05$ indicated the difference was statistically significant.

Results

Demographics

The demographic data of both groups is shown in Table1.This study reviewed 85 patients with OVOCF who meet all the above inclusion criteria in our hospital from January 2017 to July 2019.Female patients were more than male patients. There were 14 males and 27 females in group A and 16 males and 28 females in group B. The average age of these patients was 72.18±3.78 years old. The average age of 41 patients in group A was 71.80±4.05 years old, and the average age of 44 patients in group B was 72.52±3.52 years old. The average follow-up time was all more than 2 years. There were no significant differences between the two groups in terms of age, gender, bone mineral density (BMD), body mass index (BMI), previous trauma history, comorbidity and follow-up time.

Comparison of functional outcomes

The functional outcomes of patients in the two groups were shown in Table 2. There were no significant differences between group A and B when we compared VAS and ODI before surgery and 3 days after surgery($P>0.05$).However, we found that VAS and ODI differed significantly between the two groups 1 year after surgery($P<0.05$). In addition, compared with the preoperative results, ODI and VAS in both groups all decreased significantly 3 days and 1 year after surgery ($P<0.05$).

Comparison of radiographic outcomes

The radiographic outcomes of patients in the two groups were shown in Table 3 and Table 4. Compared with the preoperative results, there were significant differences in SA, HL, HS and LHD 3 days and 1 year after surgery($P<0.05$).Comparing A with B, there were no significant differences in SA, HL, HS and LHD in the preoperative results($P>0.05$). In addition, except that HL 3 days and 1 year after surgery were not significant differences between group A and B($P>0.05$), there were significant differences in SA, HS and LHD 3 days and 1 year after surgery between group A and B($P<0.05$).

Comparison of operational indicators and complications

The operational indicators and complications of patients in the two groups were shown in Table 5. It was found that there were significant differences in the operation time and fluoroscopic time between the two groups($P<0.05$), but there was no significant difference in the hospital stay and the cement volume. A total of 15 patients in group A and 6 patients in group B experienced cement leakage after operation, there were significant differences between groups($P<0.05$).Meanwhile, A total of 21 patients in group A and 6 patients in group B experienced scoliosis after operation, there were also significant differences between groups($P<0.05$).

Discussion

Osteoporosis is a complex disease characterized by loss of bone mass, resulting in increased bone fragility and destruction of bone outcomes. Older adults with osteoporosis often inadvertently develop OVCF. Sometimes it just happens after a sneeze. With the ascent of the ageing population, OVCF, which are mainly caused by osteoporosis, have become one of the most major health problems[14]. OVCF have been shown to adversely affect patients' quality of life, physical function, and mental health. These effects are related to the severity of the spinal fracture and the resulting deformity and pain[18]. Traditional treatment of OVCF consists of conservative management including bed rest, analgesia and braces, and physical therapy after symptom relief. However, due to long-term bed rest, patients are more likely to be accompanied by bone demineralization and disease progression[19], and lead to a series of complications, such as lower extremity deep vein thrombosis, pulmonary infection and urinary tract infection. It is generally believed that bone cement and bone cement combined with balloon expansion surgery, as the two most common minimally invasive surgical methods for the treatment of severe symptomatic OVCF, can effectively restore the compressed vertebral body and relieve pain[20]. The main difference is that bone cement combined with balloon is a new type of operation. During the operation, balloon reduction is placed into the injured vertebra and then bone cement is poured into the injured vertebra, which is more helpful to restore the height of the injured vertebra and enhance its stability[21]. However, there are different conclusions about the advantages and disadvantages of the two surgical methods in the treatment of OVCF.

Our research focuses on OVOCF, a special type of OVCF. The majority of OVCF patients mainly showed the loss of anterior vertebral height and the increase of kyphotic angle on X-ray lateral films, while OVOCF patients showed the serious loss of vertebral height and the increase of vertebral scoliosis angle on X-ray lateral films. Both bone cement and bone cement combined with balloon have achieved significant clinical efficacy in the treatment of OCVF induced spinal pain, and their main roles are to restore vertebral height and strength, correct kyphosis, and rebuild spinal stability[22,23]. In the past, when they were used to treat OVCF, only the sagittal height of vertebral body was restored, and kyphosis was corrected[24]. For spinal fractures with vertebral oblique compression fracture, not enough attention is often paid. If the vertebral compression scoliosis angle is not corrected, scoliosis deformity is highly likely to occur, resulting in uneven longitudinal pressure distribution of adjacent vertebrae, and even fracture of adjacent vertebrae. Therefore, which surgical method has better clinical effect for OOVCF is worthy of further discussion. In the present study, our results indicated that both functional and radiographic outcomes get significant improvement after bone cement and bone cement combined with balloon surgery. However, functional and radiographic outcomes obtained better improvement under bone cement combined with balloon expansion surgery when compared with bone cement surgery alone. Compared with bone cement surgery, the height of the short side of the vertebral body after bone cement combined with balloon expansion surgery was significantly recovered, and the height of the long side was almost the same to a large extent. The postoperative height difference between the two sides of the vertebral body is small, so that the vertebral body is almost balanced at the bilateral height. Therefore, the scoliosis angle after bone cement combined with balloon expansion surgery is also significantly smaller than that after bone cement alone. Many researchers believed that the most significant feature of bone cement combined with balloon expansion surgery lies in the placement of balloon reduction into the injured vertebra during the operation, followed by the perfusion of bone cement. The endplate is raised by percutaneous insertion of an expandable high-pressure bone pile into the fractured vertebra by creating a cement-filled cavity inside the vertebra to help restore and stabilize the height of the vertebra, which improves the problem that bone cement alone cannot improve the structural parameters of the vertebral body, and is more helpful to restore the height of the injured vertebra and enhance the stability of the vertebral body[25–27]. We believe that during the bone cement combined with balloon expansion operation for OVOCF patients, the height of the vertebral body on the heavily compressed side was effectively supported by placing a balloon in the vertebral body, so that the height of the bilateral vertebral body was as consistent as possible. when the height difference between the two vertebral bodies is large, the longitudinal pressure distribution of the vertebral body is uneven, and the scoliosis angle cannot be corrected, which will lead to scoliosis deformity in the long run. This also explains why patients after bone cement combined with balloon expansion surgery have lower VAS and ODI scores than patients in the treatment of bone cement alone one year after surgery, and fewer postoperative scoliosis complications in patients in the treatment of bone cement combined with balloon expansion surgery. At the same time, we also found that the complications of bone cement leakage after bone cement combined with balloon expansion surgery were significantly less than those of bone cement surgery alone. This is also consistent with the current research results of most scholars. It is generally believed that bone cement combined with balloon expansion surgery has a lower leakage rate than bone cement surgery alone[28].

Although our study found that bone cement surgery also has the advantages of short operation time, short fluoroscopy time, and recovery of vertebral height to a certain extent. However, we took the long-term recovery of vertebral height after surgery to reduce the occurrence of scoliosis and bone cement leakage into account. We believe that bone cement combined with balloon expansion surgery has better clinical outcomes. This surgery can be performed by unilateral and bilateral puncture methods. Many studies have shown that unilateral and bilateral bone cement combined with balloon expansion surgery can restore vertebral height and improve patients' pain, thus achieving good clinical benefits[29,30]. However, for OVOCF patients with vertebral compression scoliosis angle greater than 11°, it is required that the lateral angle can be corrected after bone cement combined with balloon expansion surgery, otherwise the spinal force line imbalance will lead to further aggravation of scoliosis, resulting in intractable pain. Then we should be more cautious in the choice of puncture methods. Some scholars believe that the use of unilateral pedicle approach will cause insufficient diffusion of bone cement in the vertebral body, resulting in unilateral load bearing of the vertebral body and spinal instability. Moreover, under constant load, it is easy to inject bone cement into the contralateral lateral buckling, resulting in compression deformation of the vertebral body[31]. Bilateral pedicle approach can make both sides of the injured vertebrae be reduced by balloon compression at the same time, avoiding the problem of unbalanced lateral stress caused by uneven diffusion of bone cement. We believe that bilateral pedicle approach can elevate both sides of the injured endplate by expanding the balloon, to restore the height of the vertebral body. In the unilateral pedicle approach, the short side with heavy compression was selected for puncture, and the balloon could also effectively raise the injured endplate and restore the height of the vertebral body.

Of course, there are some limitations to our study. The sample size of patients involved in our study was still too small, and we only conducted a simple retrospective study, not a prospective study. At the same time, the follow-up time of patients is relatively short, and the study of unilateral and bilateral bone cement combined with balloon dilation surgery relies more on clinical experience, and there is no systematic retrospective study and analysis of unilateral and bilateral puncture methods. This aspect should be further studied in the following research.

Conclusion

Bone cement combined with balloon expansion and bone cement alone are all effective in the treatment of osteoporotic vertebral oblique compression fracture, but bone cement combined with balloon expansion had better long-term clinical efficacy. For surgical treatment of OVOCF patients, bone cement combined with balloon expansion surgery should be considered.

Abbreviations

OVCF: Osteoporotic Vertebral Compression Fracture,

OVOCF: Osteoporotic vertebral oblique compression fracture,

VAS: Visual analogue Scale,

ODI: Oswestry Disability Index,

SA: Scoliosis angle,

HS: Height of short side,

HL: Height of long side,

LHD: Lateral height difference,

BMD: Bone mineral density,

BMI: Body mass index,

Declarations

Ethics approval and Consent to participate:

Approval was obtained from the ethics committee of Soochow University. The procedures used in this study adhere to the tenets of the Declaration of Helsinki. Informed consent was obtained from all individual participants included in this study.

Consent for publication:

All authors approved the manuscript and its publication.

Availability of data and material:

Data is available via a request to the corresponding author.

Conflicts of Interest:

All authors declare that they have no conflict of interest.

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Authors' contributions:

Lei Deng: Conceptualization, Methodology, Investigation, Software, Writing – original draft. Xia-Yu Hu**:** Methodology, Data curation, Investigation, Writing – original draft. **Xi-Hua:** Conceptualization, Methodology, Writing – original draft. **Ze-Jun Pan:** Methodology, Data curation, Investigation. **Quan Zhou:** Conceptualization, Methodology, Data curation. **Bao-Xin Li:** Methodology, Investigation, Software. **Nan-Ning Lv:** Conceptualization, Methodology, Data curation, Validation, Writing - review & editing. **Zhong-Lai Qian:** Conceptualization, Methodology, Data curation, Validation, Writing - review & editing, Funding acquisition.

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Tables

TABLE 1

Demographic data of both groups.

	Group A(n=41)	Group B(n=44)	*P*-value
Age (years)	71.80±4.05	72.52±3.52	0.385
Gender(male/female)	14/27	16/28	0.831
BMI(kg/㎡)	23.03±2.94	23.17±2.76	0.826
BMD(T-score)	-3.02±0.28	-3.05±0.29	0.622
Trauma history			
Yes	18	20	0.886
No	23	24	
Comorbidity(n)			
Hypertension	15	17	0.845
Diabetes	11	13	0.781
Hyperlipidemia	16	21	0.419
Somking	10	13	0.593
Follow-up(months)	27.93±4.04	26.77±3.15	0.144

BMI：Body mass index, BMD：Bone mineral density

TABLE 2

Comparison of functional outcomes

	Group A(n=41)	Group B(n=44)	*P*-value(A vs.B)
VAS			
Pre-op	7.37±0.97	7.27±0.82	0.632
Post-op 3 days	2.90±0.80	2.98±0.76	0.660
Post-op 1 year	2.49±0.78	1.86±0.70	**<0.001**
P. (pre. vs. 3 d.)	**<0.001**	**<0.001**	-
P. (3 d. vs. 1 y.)	**<0.001**	**<0.001**	-
ODI			
Pre-op	68.63±7.88	66.43±7.54	0.192
Post-op 3 days	35.27±4.07	34.34±3.65	0.271
Post-op 1 year	26.44±4.17	21.36±3.59	**<0.001**
P. (pre. vs. 3 d.)	**<0.001**	**<0.001**	-
P. (3 d. vs. 1 y.)	**<0.001**	**<0.001**	-

Pre-op., preoperative; Post-op.,postoperative.

TABLE 3

Scoliosis angle (Mean±SD)

	Group A(n=41)	Group B(n=44)	*P*-value(A vs.B)
Pre-op.	24.83±4.69	24.61±3.95	0.819
Post-op. 3 days	11.95±2.61	9.52±2.55	**<0.001**
Post-op. 1 year	12.05±2.78	9.61±2.64	**<0.001**
P. (pre. vs. 3 d.)	**<0.001**	**<0.001**	-
P. (pre. vs. 1 y.)	**<0.001**	**<0.001**	-

Pre-op., preoperative; Post-op.,postoperative.

TABLE 4

Comparison of radiographic outcomes

	Group A(n=41)	Group B(n=44)	*P*-value(A vs.B)
HL(mm)			
Pre-op.	22.49±1.03	22.24±1.09	0.283
Post-op. 3 days	24.26±0.94	24.32±1.24	0.797
Post-op. 1 year	24.00±0.91	24.25±1.20	0.514
P. (pre. vs. 3 d.)	**<0.001**	**<0.001**	-
P. (pre. vs. 1 y.)	**<0.001**	**<0.001**	-
HS(mm)			
Pre-op.	17.40±0.94	17.18±1.02	0.309
Post-op. 3 days	21.02±1.00	23.43±1.42	**<0.001**
Post-op. 1 year	20.98±0.94	23.35±1.44	**<0.001**
P. (pre. vs. 3 d.)	**<0.001**	**<0.001**	-
P. (pre. vs. 1 y.)	**<0.001**	**<0.001**	-
LHD(mm)			
Pre-op.	5.10±1.07	5.06±1.23	0.900
Post-op. 3 days	3.24±0.99	0.89±0.63	**<0.001**
Post-op. 1 year	3.02±1.06	0.90±0.73	**<0.001**
P. (pre. vs. 3 d.)	**<0.001**	**<0.001**	-
P. (pre.vs. 1 y.)	**<0.001**	**<0.001**	-

HL, height of long side;HS, height of short side; LHD, lateral height difference;Pre-op., preoperative; Post-op.,postoperative.

TABLE 5

Operational indicators and complications

	Group A(n=41)	Group B(n=44)	P-value
Operation time(min)	42.34±3.08	49.27±5.82	**<0.001**
Fluoroscopic time	30.66±3.51	40.05±3.92	**<0.001**
Hospital stay(days)	6.02±2.06	6.39±2.30	0.448
Cement volume(ml)	6.34±1.26	6.68±1.20	0.204
Complication			
Cement leakage	15	6	**0.014**
Scoliosis	21	6	**<0.001**