Comparison of the clinical outcomes and cement distribution patterns after percutaneous vertebroplasty in the treatment of thoracolumbar Kümmell's disease and OVCFs

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Abstract

Background The purpose of this study is to investigate and compare the therapeutic effect and distribution characteristics of bone cement in the PVP treatment for thoracolumbar Kümmell's diseases and OVCFs.

Methods A prospective analysis of 35 patients with Kümmell ’s disease (K group) and 35 patients with OVCFs (O group) who underwent PVP treatment from February 2016 to February 2018 was conducted. The vertebral compression rate and degree of osteoporosis were more serious in the K group than in the O group ($P < 0.05$, respectively). Distribution pattern, volume and leakage rate of bone cement, operation time, VAS score, ODI, correction rates of vertebral compression and kyphosis, re-fracture rate of adjacent vertebrae in 2 years between the two groups were compared to assess clinical effect.

Results The follow-up time of the two groups was 24-48 months. The amount of intraoperative bone cement injection was significantly higher in the K group than in the O group ($P = 0.025$). The cement distribution pattern of local solid lump was dominant in the K group (65.71%), while intercalation with trabeculae was dominant in the O group (74.29%) ($P < 0.001$). VAS score and ODI were significantly lower both in the two groups at 1 day, 1 year and 2 years after surgery than before surgery (all $P < 0.05$), but significantly lower in the K group than in the O group at each time point after surgery (all $P < 0.05$). The correction rates of kyphosis and vertebral compression in both groups was significantly corrected ($P < 0.05$, respectively) and gradually lost with time ($P < 0.05$, respectively). The correction rates of kyphosis and vertebral compression were significantly higher in the K group than in the O group at each time point after surgery (all $P < 0.05$).

Conclusions PVP has the advantages of simple operation, short operation time, small trauma and quick recovery in treating both Kümmell's disease and OVCFs. However, PVP can better restore partial vertebral height and correct kyphosis in the treatment of Kümmell's disease, while can better alleviate pain and improve ODI in the treatment of OVCFs.

Background

Kümmell's disease is a special type of osteoporotic vertebral compression fractures (OVCFs) and relatively rare [1]. Persistent pain of low back persists several weeks or months after a minor injury. Radiological examination shows transversely or irregularly shaped transmittal areas of the vertebral body with peripheral sclerosis signals [2]. Some scholars also call it ischemic vertebral collapse or vertebral pseudarthrosis [3]. Thoracolumbar vertebra is the most common site of its occurrence. Kümmell's disease has the characteristic of "open sign", that is, the crack is obvious in the extension position of the body, while the crack can disappear in the flexion position [4]. The characteristic performance of Kümmell's disease is called intravertebral vacuum cleft (IVC) or intravertebral vacuum phenomenon (IVP) [5][6].

Percutaneous Vertebroplasty (PVP) is a minimally invasive approach to infuse bone cement into vertebral body for stabilizing fractured vertebra, which can quickly relieve the pain of low back, restore partial

vertebral height and correct kyphosis [7, 8]. PVP surgery can reduce the risk of vertebral wedge change and nerve injury in OVCFs patients with IVC, so early surgical treatment should be performed [9]. However, for OVCFs patients with or without IVC, the therapeutic effect, bone cement distribution and leakage, and postoperative refracture of adjacent vertebra in PVP treatment are still uncertain [10].

Therefore, in order to investigate the clinical effect, bone cement distribution and complications of PVP treatment in OVCFs patients with or without IVC, We prospectively analyzed the clinical data of patients with single-thoracolumbar Kümmell's disease and OVCFs admitted to our hospital from February 2016 to February 2018 to evaluate the clinical characteristics, clinical efficacy, bone cement distribution and postoperative refracture of adjacent vertebra for providing references for clinical practice.

Methods

Selection criteria

Inclusion criteria are as follows: (1) single-thoracolumbar Kümmell's disease or OVCFs patients without adjacent OVCFs; (2) physical examination of the location of the "pain vertebra" was consistent with imaging examination. (3) dual-energy X-ray bone mineral density(BMD) T value < -2.5; (4) bilateral pedicle PVP was performed; (5) follow-up time was more than 2 years; (6) Calcium supplementation and anti-osteoporosis drugs were used after the operation. Exclusion criteria are as follows: (1) severe cardiopulmonary dysfunction cannot tolerate the operation; (2) coagulation dysfunction affects the operation;(3) local or systemic infection; (4) nerve root or spinal cord compression symptoms; (5) pathological fractures other than osteoporosis.

General Information

From February 2016 to February 2018, 70 patients met the selection criteria to be included in the study, of which 35 cases of Kümmell's patients (K group) and 35 cases of OVCFs patients (O group) received PVP treatment (Fig. 1). This study was approved by the ethics committees of our hospitals. All clinical data and pictures of the patients were obtained with the written informed consent from the patients or their families.

There was no significant difference in gender, age, injury segment, preoperative VAS and Oswestry dysfunction index (ODI) between the two groups (all $P > 0.05$). The course of disease in the K group was significantly longer than that in the O group ($P = 0.000$). Most cases in the K group had no history of trauma, while most cases in the O group had a history of falls ($P = 0.001$). The vertebral compression rate and the degree of osteoporosis of the K group were more serious than those of the O group ($P < 0.05$, respectively). (Table 1)

Table 1
Baseline data of the two groups

Parameters	K group	O group	t/χ^2	P
Cases	35	35	0.396	0.567
Gender	11	9	-0.532	0.433
Male (cases)	24	26	-15.960	0.000
Female (cases)	76.0 ± 5.8	75.5 ± 5.9	11.209	0.001
Age (years)	8.4 ± 3.0	0.28 ± 0.17	0.484	0.922
Course of disease (months)	11	25	-1.124	0.037
Fall history	24	10	2.447	0.018
Yes(cases)	7	5		
No (cases)	12	13		
Injured vertebral segment	12	12		
T11(cases)	4	5		
T12(cases)	-4.25 ± 0.91	-3.88 ± 0.81		
L1(cases)	46.9 ± 8.79	41.5 ± 8.46		
L2(cases)				
BMD (T value)				
Vertebral compression rate(%)				

Surgery Technique

Both groups were performed by the same group of surgeons. The PVP procedure follows the principle of consistency. Patients were placed in the prone position to maintain posterior extension of spine for completing postural reduction. Under local anesthesia, C-arm X-ray machine fluoroscopy guided bilateral pedicle puncture. The working cannula reached the anterior 1/3 of the vertebral body or was adjacent to the IVC region. Polymethylmethacrylate (Tecres S.P.A., Verona, Italy) was injected into the vertebral body or the IVC region using a 3.5 mm lateral open bone cement injector (Shanghai Kinetic Medical Co., Ltd., Shanghai, China) until cement distributions were well dispersed and satisfactory.

Postoperative Management

After the operation, patients were kept in the horizontal position for 8–12 h, and the rest was mainly bed rest in the 1–2 months. For 1–2 months after the operation, the low back support was used to get out of bed. Drugs such as bisphosphonates, vitamin D and calcium tablets were given for anti-osteoporosis treatment.

Outcome Measurements

The dispersion morphology, leakage rate and injected amount of bone cement, operation time, VAS score of low back [11], ODI [12] and the incidence of new adjacent vertebral re-fracture in 2 years were recorded in the two groups.

Anteroposterior and lateral X-ray images were taken before and after the operation to measure the height of vertebral body at the anterior edge of the injured vertebra and kyphosis angle. The following indexes were calculated: (1) rate of vertebral compression, namely anterior edge vertebral height of the injured vertebra divided by the average anterior edge height of adjacent upper and lower vertebrae [13]; (2) correction rate of vertebral compression, namely (preoperative rate of vertebral compression - postoperative rate of vertebral compression) / preoperative rate of vertebral compression × % [13]; (3) correction rate of kyphosis =(preoperative kyphosis angle - postoperative kyphosis angle) / preoperative kyphosis angle × % [2].

Statistical analysis

SPSS19.0 (IBM Corp., Armonk, NY, USA) statistical software was used for statistical analysis. Measurement data are expressed as mean ± standard deviation. The Levene test was used to test the homogeneity of variance. Independent sample t test was used for inter-group comparison. One-way ANOVA (Bonferroni or Dunnett T3) was used for comparison between different time points between groups. Repeated measurement ANOVA was used for intra-group comparison between different time points. The counting data were tested with χ^2 test. $P < 0.05$ was considered statistically difference.

Results

The two groups were followed up for 24–48 months, and there was no statistically difference in follow-up time, operation time, intraoperative blood loss, or fluoroscopy times between the two groups (all $P > 0.05$). Intraoperative amount of bone cement injected was significantly higher in the K group than in the O group ($P = 0.025$). In the K group, 23 cases (65.71%) were local solid lump of distribution pattern of bone cement(Figure 2a), and 12 cases (34.29%) were embedded trabeculae of distribution pattern of bone cement. In the O group, 9 cases (25.71%) were local solid lump of distribution pattern of bone cement and 26 cases (74.29%) were embedded trabeculae of distribution pattern of bone cement（Figure 2b）. The comparison of bone cement distribution between the two groups was significantly different ($P < 0.001$).

Bone cement leakage occurred in 5 patients (14.29%) in the K group, including 2 cases of leakage to the anterior wall, 1 case of upper intervertebral space, 1 case of lower intervertebral space and 1 case of lateral wall. In the O group, bone cement leakage occurred in 3 cases (8.57%), including 1 case of leakage to the anterior wall, 1 case of upper intervertebral space and 1 case of lateral wall. However, none of the patients both in the two groups had any related clinical symptoms. There was no significant difference in the incidence of cement leakage between the two groups ($P > 0.05$).(Table 2)

Table 2

Comparison of clinical outcomes between the two groups

Parameters	K group	O group	t/χ^2	P
Follow-up time(months)	35.4 ± 6.89	35.9 ± 7.53	0.215	0.919
Amount of bone cement injected(ml)	4.2 ± 1.65	3.6 ± 1.35	1.875	0.025
Operation time (min)	36.8 ± 3.57	35.1 ± 5.15	0.132	0.696
Intraoperative blood loss (ml)	16.9 ± 3.45	16.2 ± 3.28	5.479	0.509
Fluoroscopy times	16.7 ± 3.50	15.9 ± 3.46	4.060	0.453
Bone cement distribution	23	9	11.283	0.001
local solid lump distribution	12	26	0.565	0.452
Nested distributions	5	3	0.458	0.186
Bone cement leakage	30	32	1.301	0.013
Yes (cases)	8.0 ± 0.77	7.8 ± 0.75	1.398	0.025
No (cases)	2.8 ± 0.73*	1.7 ± 0.81*	1.356	0.022
VAS scores	2.4 ± 0.68*	1.6 ± 0.84*	-2.293	0.662
Before surgery	2.5 ± 0.70*	1.5 ± 0.84*	3.533	0.026
At 1 day after surgery	84.1 ± 7.89	84.6 ± 7.73	3.407	0.024
At 1 year after surgery	29.4 ± 5.42*	25.4 ± 5.13*	3.872	0.034
At 2 years after surgery	29.8 ± 5.39*	24.9 ± 5.01*	0.255	0.243
ODI	29.9 ± 5.41*	25.0 ± 5.56*		
Before surgery	6	4		
At 1 day after surgery	29	31		
At 1 year after surgery				
At 2 years after surgery				
Adjacent vertebral fractures				
Yes (cases)				
No (cases)				

* Compared to before surgery, P = 0.000

VAS score and ODI were significantly lower in the two groups 1 day, 1 year and 2 years after surgery than before surgery (all $P < 0.05$), but significantly lower in the K group than in the O group at each time point after surgery (all $P < 0.05$). During the 2-year follow-up, 6 patients (17.14%) in the K group and 4 patients (11.43%) in the O group had adjacent vertebral fractures ($P = 0.243$).(Table 2)

The correction rates of kyphosis and vertebral compression were significantly corrected in both groups ($P < 0.05$, respectively), but gradually decreased significantly with time ($P < 0.05$, respectively), suggesting that vertebral height and kyphosis angle were gradually lost after the surgery. The correction rates of kyphosis and vertebral compression were significantly higher in the K group than in the O group at each time point after surgery (all $P < 0.05$). (Table 3)

Table 3

Comparison of the two groups of imaging data

Parameters	K group	O group	t/χ^2	P
Correction rate of vertebral compression	20.9 ± 5.54	13.8 ± 4.29	6.515	0.000
At 1 day after operation	17.8 ± 5.33*	12.5 ± 3.79	5.248	0.000
At 1 year after operation	16.7 ± 5.15*	12.1 ± 3.61*	5.290	0.001
At 2 years after operation	21.0 ± 5.34	14.6 ± 5.69	5.467	0.000
Correction rate of kyphosis	17.9 ± 5.24*	13.9 ± 5.26	6.093	0.001
At 1 day after operation	17.2 ± 5.17*	13.3 ± 5.19*	4.509	0.001
At 1 year after operation				
At 2 years after operation				

* Compared with 1 day after operation, $P < 0.05$

Discussion

Since 1984, Galiber et al. [14] applied PVP to treat a case of C2 vertebral invasive hemangioma, PVP has gradually become one of the effective methods to treat vertebral tumors and OVCFs due to its advantages of simple operation and definite effect [11, 15, 16]. Kümmell's disease is a special type of OVCFs. After minor trauma, vertebral collapse and kyphosis are gradually aggravated, which is related to vertebral ischemia and necrosis. Patients often suffer intractable lumbar and back pain, pseudarthrosis, and even nerve injury [17, 18]. Imaging examination shows IVC or localized fluid filling in the vertebral body [1, 3, 19]. IVC is mainly located in the thoracolumbar region, most of which are wedge fractures, and near the upper and lower endplates of the vertebral body [10, 20]. It suggests that the occurrence of the disease may be related to the repeated stress activity and high activity of thoracolumbar segments. In this study, patients with thoracolumbar segments were selected in this group. We found that the course of Kümmell's disease was significantly longer than the course of OVCFs. Kümmell's disease mostly has no obvious trauma, but OVCFs mostly has a history of trauma. The degree of osteoporosis and vertebral compression rate were more serious in Kümmell's disease than in OVCFs.

A small dose of bone cement can restore the mechanical properties of the fractured vertebrae, and the injection amount of bone cement has no significant correlation with the analgesic effect [21, 22]. 1.5 ml of bone cement injected into each vertebrae can obtain satisfactory analgesic effect [21, 22]. Biomechanical studies have confirmed that the strength of vertebral body can be restored by injecting about 2 ml bone cement and the stiffness of the vertebrae can be restored by injecting about 4 ml bone cement [22]. In this study, the average injection amount of bone cement in the K and O group were 4.2 ± 1.15 ml and 3.6 ± 1.35 ml, respectively. All of them met the requirements of restoring vertebral strength, and the K group met the requirements of restoring vertebral stiffness.

After filling the fissures with bone cement in the fractured vertebrae, the height of the vertebrae was partially restored and kyphosis deformity was partially corrected, and the abnormal activity of the fractured vertebrae was eliminated, which was an important reason for pain relief [2]. Previous studies have found that PVP can effectively relieve low back pain of Kümmell's disease and OVCFs, and partially

restore vertebral height and correct kyphosis [2, 23–30]. The ODI and VAS scores in both Kümmell's disease and OVCFs groups decreased after PVP treatment, but the mean score in Kümmell's disease group was higher than that in OVCFs groups [31]. Our study is consistent with the above studies, and the ODI and VAS scores in both groups can be maintained until the last follow-up.

Kümmell's disease is caused by the presence of IVC and pseudarthrosis due to vertebral collapse, ischemia and necrosis. When the spine flexes and bends, the injured vertebra can stretch and widen the cracks in the fractured vertebra. The height of the collapsed vertebrae can be reduced and kyphosis can be partially corrected in posterior extension of spine. In PVP treatment, bone cement is usually limited to diffusion in the fissures, which can maintain the effect of extension correction, without the further help of balloon dilation in PKP treatment. Patients with Kümmell's disease can achieve spontaneous reduction in the posterior extension position without further balloon expansion reduction [32, 33]. Heo et al. [34] reported that excessive reduction tends to accelerate the process of vertebral ischemia and necrosis, leading to severe recollapse. Therefore, excessive reduction intraoperatively of the injured vertebra should be avoided. Our study found that the correction rates of vertebral compression and kyphosis after PVP were significantly corrected in both groups, but significant correction was achieved at each time point in the K group compared with the O group, further confirming the view that "spontaneous reduction can occur in Kümmell's patients with posterior extension".

We found that the correction rates of vertebral compression rate and kyphosis in the two groups gradually decreased with time, suggesting that the vertebral height and kyphosis angle gradually lost after surgery, which was consistent with previous findings [16, 35]. In the treatment of OVCFs by PVP and PKP, the bone cement injected during the operation of the former is mainly embedded in cancellous bone, while the bone cement of the latter is mainly filled with clumps, so stress occlusion is more likely to occur after PKP and leads to recollapse [36]. In this study, it was found that local solid lump distribution pattern of bone cement was dominant in the K group (65.71%), while embedded trabeculae distribution pattern was dominant in the O group (74.29%). In the two groups, two years after the surgery, re-collapse and intervertebral height loss occurred in the enhanced vertebra, and the loss in the K group was more significant than that in the O group. As a "reservoir" of IVC region, bone cement was filled in the IVC region in the form of solid mass. The limited bone cement mass cannot connect with the adjacent endplates of the upper and lower levels to strengthen cancellous bone of the vertebrae, thus failing to support the normal physiological stress from the body and prone to collapse again [37].

The most common complications of PVP are bone cement leakage and adjacent vertebral fracture [38, 39]. Krauss et al. [40] reported that in OVCFs treated with IVC by PVP, the bone cement leakage rate was 18.2%. Wang et al. [41] reported that for OVCFs treated with IVC by PKP, the bone cement leakage rate was 7.4%. This study found that the leakage rate of bone cement in the K and O groups were 14.29% and 8.57%, respectively, which may be related to accurate preoperative surgical approach measurement, careful intraoperative operation and not pursue the maximum amount of bone cement. There was no significant difference in cement leakage rate between the two groups, which was consistent with previous research results [42, 43]. Among the 219 patients with single thoracolumbar OVCFs, 29 cases(13.22%)

occurred non-surgical vertebral fractures [44]. Eleven patients (14.1%) of OVCFs in the early PVP group (n = 78) and 18 patients (39.1%) in the late PVP group (n = 46) experienced an adjacent vertebral fractures during the first year following PVP [45]. In this study, the new adjacent vertebral fractures of the K group and O group were 17.14% and 11.43%, respectively, suggesting that postoperative restriction of premature activity, lumbar protection and sustained anti-osteoporosis treatment are very important for the prevention of re-fractures.

This study has some limitations. Firstly, the number of cases is small, which needs to be further analyzed and clarified by expanding sample size. Moreover, there is a lack of time biomechanical study on cement distribution in vertebrae to support the results. Patients and data collection researchers were not completely randomized double-blind. So, the current findings require further validation in multicenter clinical trials.

Conclusions

PVP has the advantages of simple operation, short operation time, small trauma and quick recovery in treating both Kümmell's disease and OVCFs. However, PVP can better restore partial vertebral height and correct kyphosis in the treatment of Kümmell's disease, while can better alleviate pain and improve ODI in the treatment of OVCFs.

Abbreviations

PVP: Percutaneous vertebroplasty; PKP: Percutaneous kyphoplasty; OVCFs Osteoporotic vertebral compression fractures; IVC: Intravertebral vacuum cleft; ODI: Oswestry disability index; VAS: Visual analogue scale. IVP: Intravertebral vacuum phenomenon

Declarations

Ethics approval and consent to participate

This study were approved by the institutional review boards/Ethics Committees of Wuhan Hanyang Hospital, and was conducted in compliance with the ethical principles of the Helsinki Declaration of 1975. Written informed consent was obtained from the patients or their family members.

Consent for publication

Not Applicable.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

No potential conflict of interest relevant to this article was reported.

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There is no funding for the current study.

Authors' contributions

All authors made substantive intellectual contributions in this study to qualify as authors. C JZ, L T and W CL designed this study. W CL participated in collecting and analyzing raw materials. An initial draft of the manuscript was written by W CL. C JZ and L T re-drafted parts of the manuscript and provided helpful advice on the final revision. All authors were involved in writing the manuscript. All authors read and approved the final manuscript.

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Figures

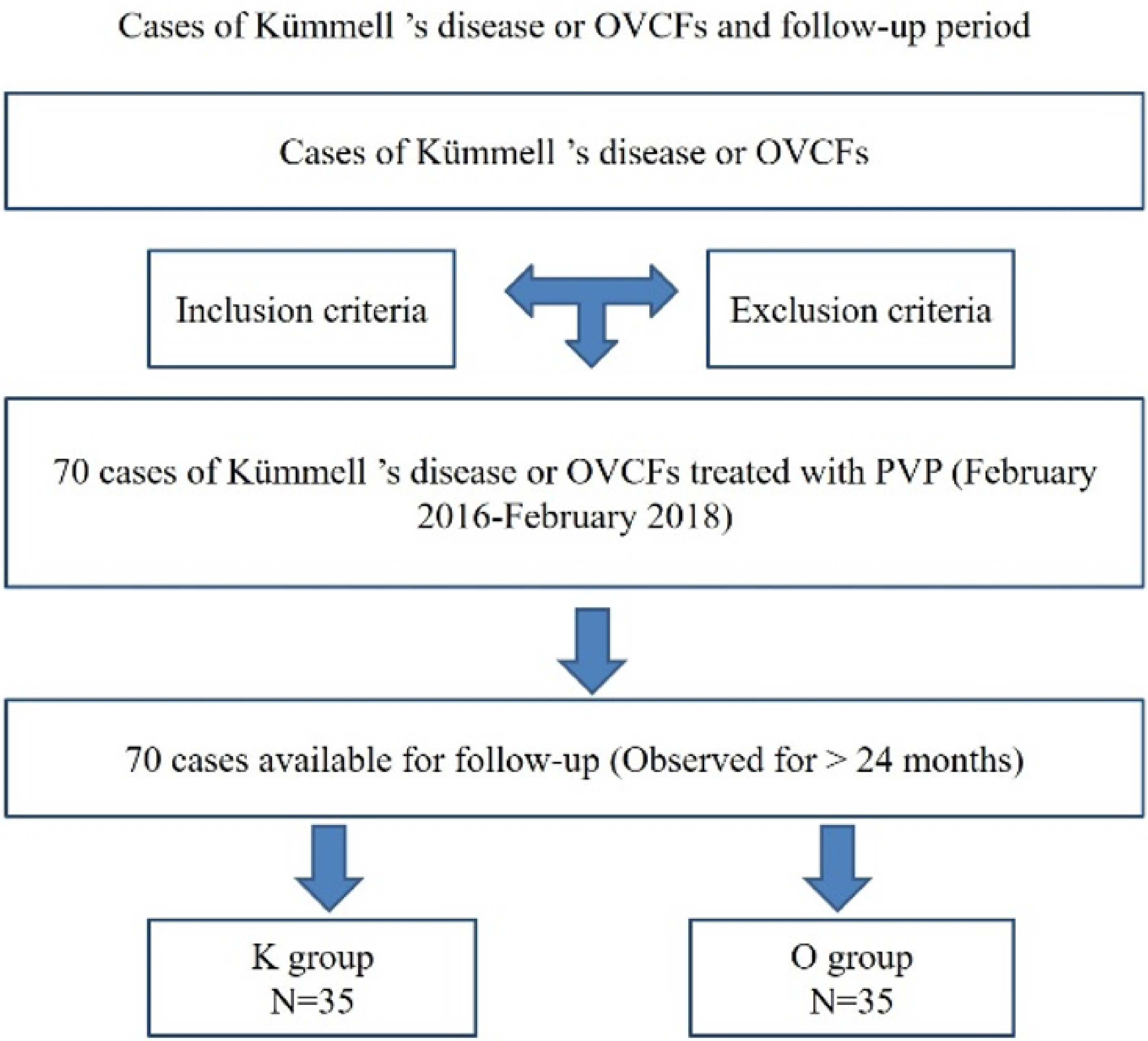

Figure 1

Cases of Kümmell 's disease or OVCFs and follow-up period

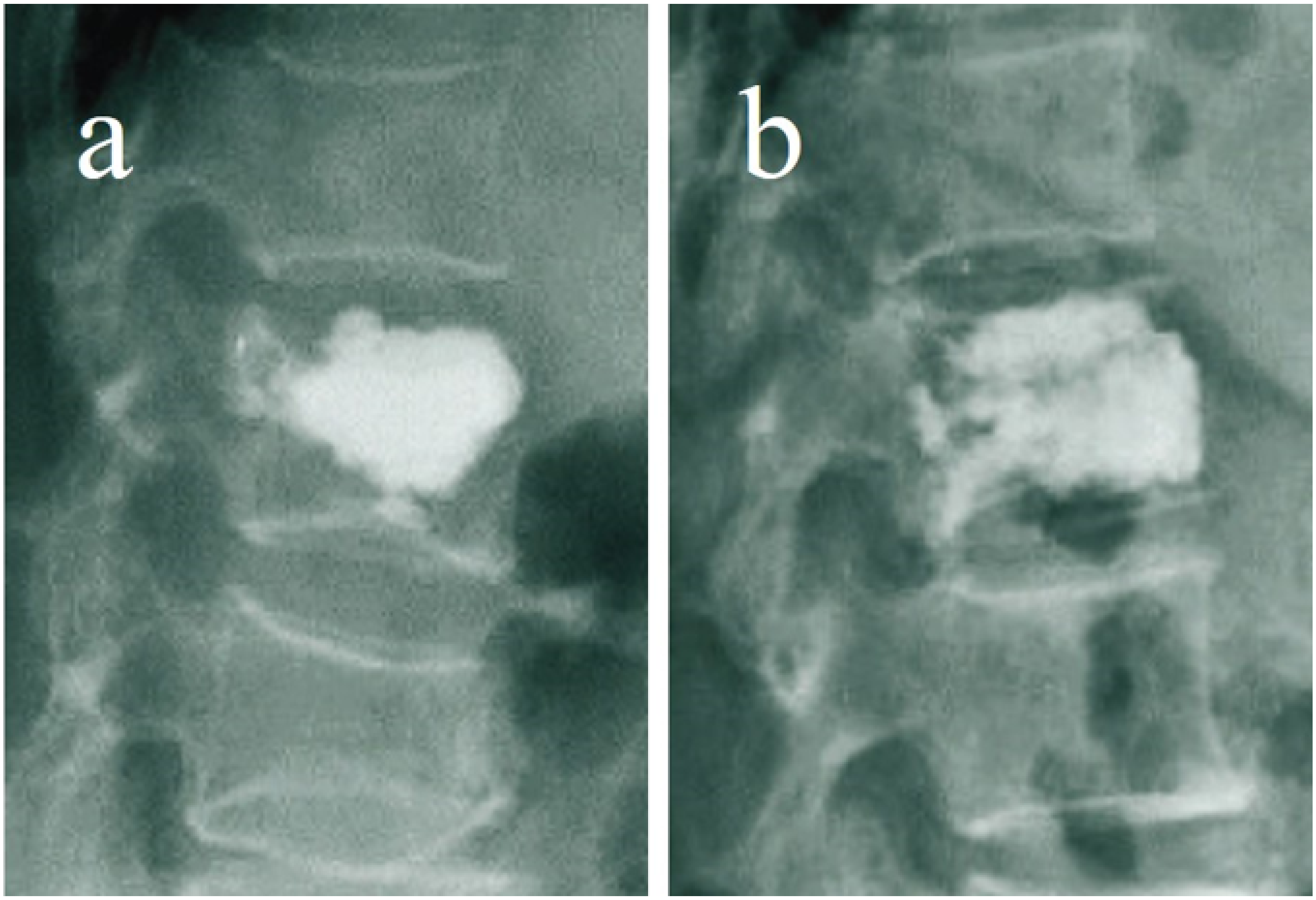

Figure 2

Distribution characteristics of bone cement: a local solid lump of distribution pattern; b embedded trabeculae of distribution pattern