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Prospective Study

Percutaneous Vertebroplasty Using a Rotary Cutter for Treating Kümmell's Disease with Intravertebral Vacuum Cleft

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Background: Reported data indicate that the curative effect of percutaneous vertebroplasty (PVP) on the patients with intravertebral vacuum cleft (IVC) is worse than on those without IVC.

Objectives: This study was to prospectively investigate the advantage of rotary cutter-PVP (RC-PVP) in patients with Kümmell's disease with IVC.

Study Design: A prospective outcome study.

Setting: A tertiary care hospital.

Methods: Patients who underwent conventional PVP served as the control group. For the RC-PVP group, the rotary cutters were applied before the cement injection to destroy the IVC structure and the surrounding necrotic bone. The following data were compared between the two groups: the cement filling patterns, effective therapeutic rate, the pre- to post-procedural changes of spinal geometry, and the subsequent fractures.

Results: This study included a total of 64 patients (30 and 34 patients in RC-PVP group and control group, respectively). In the RC-PVP group, the cement in 26 cases was filled as a mixed pattern, while the filling pattern in the control group was mainly the cystic type (n = 31). There were no significant differences in the height restoration rate between the RC-PVP and control groups (32.7 ± 13.6 and 32.4 ± 13.9, respectively, $P = 0.93$). The RC-PVP group had a higher effective rate during the first week and the first month (93.3% vs. 70.6%, $P = 0.02$) and at 3 months (90.4% vs. 73.9%, $P = 0.03$). Long-term follow-up indicated that vertebral recollapse of the same treated vertebral body occurred in 5 patients after conventional PVP, which was not observed in the RC-PVP group.

Limitations: The small number of included patients and no long-term follow-up.

Conclusions: RC-PVP, with the destruction of IVC, may lead to better clinical outcomes with fewer complications.

Key words: Back pain, bone cements, osteonecrosis, vertebroplasty

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Kümmell's disease (KD) is defined as microtrauma that leads to osteonecrosis and delayed vertebral collapse. It usually involves intravertebral avascular necrosis and an intravertebral vacuum cleft (IVC) (1-3). The difference between KD and vertebral acute compression fracture is that KD is usually associated with additional bone and fibrosis formation to repair osteonecrosis, forming a fibrocartilaginous membrane at the periphery of IVC (4).

Early reports focused on conservative treatment, but more recent studies favor percutaneous vertebroplasty (PVP) procedure (5,6). Reported data indicate that PVP's curative effect on the patients with IVC is worse than on those without IVC (7-9). Moreover, recollapse or refracture after PVP is related to IVC (10,11).

As the fibrocartilaginous membrane may lead to a pseudo synovium of a nonunion (4), it can prevent cement from diffusing into the surrounding spongy bone. Therefore, a cystic filling pattern of cement is frequently found. Besides the progressive collapse of osteonecrosis around the IVC, the vertebral body's structural stiffness caused by conglobated cement may lead to further collapse of the surrounding vertebral body (10).

We hypothesize that the destruction of the barrier of the IVC is the critical solution for a better outcome after PVP. In this study, we applied a novel rotary cutter to breach the IVC and the surrounding necrotic bone before cement injection. The diffused cement may effectively interdigitate with the healthy cancellous bone and lead to the better curative effect.

Methods

Study Population

We performed a prospective study regarding patients treated with PVP at our hospital. The approval was obtained from the institutional review board. We included the patients diagnosed with KD complicated with signs of IVC. The exclusion criteria were: (1) multiple osteoporotic vertebral compression fractures, (2) osteoporotic vertebral compression fractures caused by benign and malignant tumors, (3) patients with radicular pain or spinal cord compression syndrome.

Patients who underwent conventional PVP served as the control group. For the other group, the rotary cutters were applied before the cement injection to destroy the structure around the IVC. The group was classified as the rotary cutter-PVP (RC-PVP) group. From June 18, 2007 to October 21, 2018, conventional PVP was used to treat 34 patients, and 30 patients were included in the RC-PVP group from September 11, 2013 to April 14, 2019.

Surgical Procedure

The patients were laid in a prone, lordotic position for the reduction of the fractured vertebral body. 2% lidocaine was used for local anesthesia. A 4 ×126mm beveled puncture needle (Shandong Guanlong Medicinal Utensils Co., Ltd., Jinan City, Shandong Province, China) was advanced into the fractured vertebra through a unilateral transpedicular approach. After reaching the IVC of the collapsed vertebral body, bone needles were removed.

For the control group, 1 mL of polymethyl methacrylate (PMMA) during the dough period was injected. Then, PMMA was injected sluggishly to a maximal amount in a paste with high viscosity phase. The procedure was under the fluoroscopic guidance in increments of 0.2 mL to 0.3 mL. The cement injection was stopped if there was filling in the posterior quarter of the vertebra, the epidural vein, the paravertebral space, or the intervertebral disc space.

For the RC-PVP group, a bone drill was placed in to drill a circular hole in the vertebral body as a working channel. Then, a rotary cutter (3.4×190 mm, Shandong Guanlong Medicial Utensils Co., Ltd., Jinan City, Shandong Province, China) was inserted to destroy the IVC structure and the surrounding necrotic bone before the cement injection. The diameter of the cutter's tip could be adjusted from 3.4 mm to 12 mm. We rotated the cutter to breach the fibrocartilaginous membrane of the IVC and the surrounding cancellous bone (Fig. 1). The diameter was enlarged sequentially until the cutter reached nearly one-third to one-half of the vertebral body height. Then, the cement was injected according to the method described above.

Assessment Indices

The following patient data were recorded: age, gender, history of bisphosphonate therapy, baseline and post-procedural visual analog scale (VAS) score, lumbar bone mineral density (BMD) with a T-score. We classified the cement filling shape into 3 patterns: trabecular pattern (cement diffuse along the cancellous bone), solid pattern (cement forms a mass), and mixed pattern (cement forms a mass with diffusing into the cancellous bone) (12). We recorded the cement volume, incidence, and location of cement leakage during the procedure of PVP. The changes in spinal geometry from pre- to post-procedure were also measured. Pain intensity was quantified by numeric VAS with values ranging from 0 to 10 (0 representing no pain and 10 representing the worst pain). Patients with a VAS score lower than 3 were classified as an effective group.

The patients had routine follow-ups in the outpatient department at one week, one month, 3 months, and 6 months after PVP—or whenever there was recurrent back pain. All the patients received bisphosphonate therapy during the follow-up period. When subsequent fractures were suspected, computed tomography or magnetic resonance imaging examinations were performed. The fractures were divided into 3 categories: on the adjacent levels, on the nonadjacent levels, and on the augmented levels.

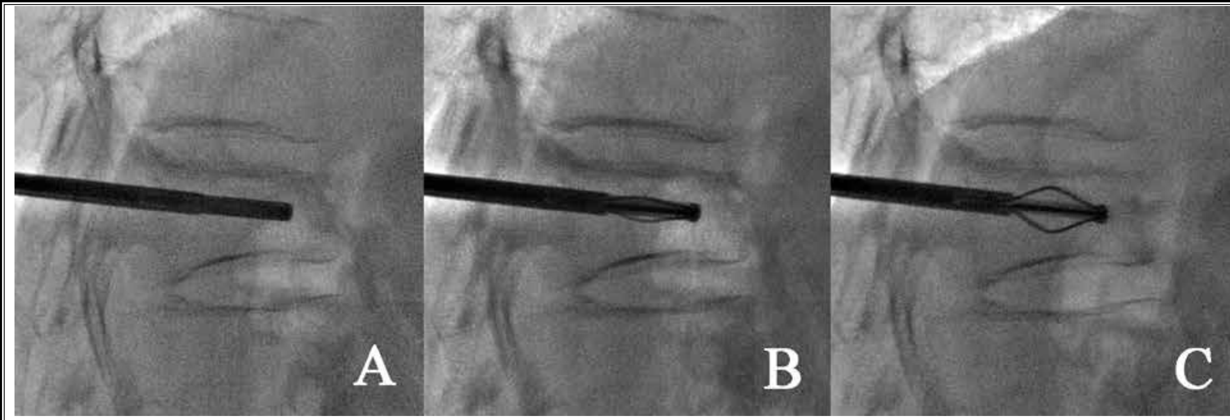

Fig. 1. *(A) The rotary cutter is placed around the cleft of the vertebra. (B) The cutter is enlarged and rotated to destroy the bone trabecula. Then, the diameter can be changed sequentially until the cutter reaches nearly one-third to one-half of the vertebral body height. (C) The IVC structure and the nearby trabecular with potential osteonecrosis can be destroyed.*

Statistical Analysis

All the data were analyzed by statistical software (SPSS for Windows, version 16.0; SPSS, Inc., Chicago, IL, USA). The baseline characteristics, such as age, bone density, were compared between the 2 groups. We analyzed the difference of the height restoration rate in the vertebral body and wedge angles to test the efficacy to recover the morphologic abnormity. Moreover, the volume of the injected cement and leakage rate were also compared. As the patients with a VAS score lower than 3 were classified as an effective group, we calculated the effective rate and evaluated the difference between RC-PVP and control groups. The quantitative data were compared by applying an independent sample t test and the categorical data were analyzed by using chi-square or Fisher's exact tests. For all statistical analyses, $P < 0.05$ was considered as statistical significance.

Results

The present study included a total of 64 patients. The patients' baseline characteristics are presented in Table 1. There was no statistical difference in the demographic data between the 2 groups.

Table 1. *Baseline characteristics of patients.*

Characteristic	RC-PVP (n = 30)	Control (n = 34)	*P* value
Age, years (mean ± SD)	79.1 ± 4.5	77.4 ± 3.5	0.09
Male/female (NO.)	19/11	22/14	0.96
BMD (T-score)	-3.5 ± 1.4	-3.6 ± 1.2	0.78
Baseline VAS- score	7.4 ± 1.8	7.9 ±1.5	0.79
Bisphosphonate use	25 (83.3 %)	29 (85.3 %)	1.00

Abbreviations: RC-PVP, rotary cutter-PVP; VAS, visual analog scale; BMD, bone mineral density.

Clinical Evaluation

The procedures were performed successfully in all patients without any symptomatic complications. In the RC-PVP group, the types of cements in 26 cases were classified as a mixed filling pattern (Fig. 2). As we can see from the figure, the cement diffused into the cancellous bone, which even reached to the endplate. The diffused cement could provide extra adhesive power and prevent micro-motion between cement and bone. The other 4 cases demonstrated a cystic filling pattern. The filling pattern in the control group was mainly cystic (n = 31) (Fig. 3). Another 3 vertebras with IVC were filled with mixed-type cement.

The amount of cement injected was 4.2 ± 1.3 mL in the control group, and more cement was injected in RC-PVP group (5.4 ± 1. 3, $P = 0.001$). The total cement leakage occurrences in the RC-PVP group were less than in the control group ($P = 0.02$) (Table 2). Asymptomatic cement leakages occurred in 2 cases with 2 locations and leaked into the intervertebral disc space (n = 1) and paravertebral space (n = 1), respectively. In the control group, cement leakages were found in 7 cases with 10 locations distributed among the intervertebral disc space (n = 5), puncture path (n = 1), and paravertebral space (n = 4).

There were no significant differences in height restoration rate between the RC-PVP and control groups (32.7 ± 13.6 and 32.4 ± 13.9, respectively, $P = 0.93$). The

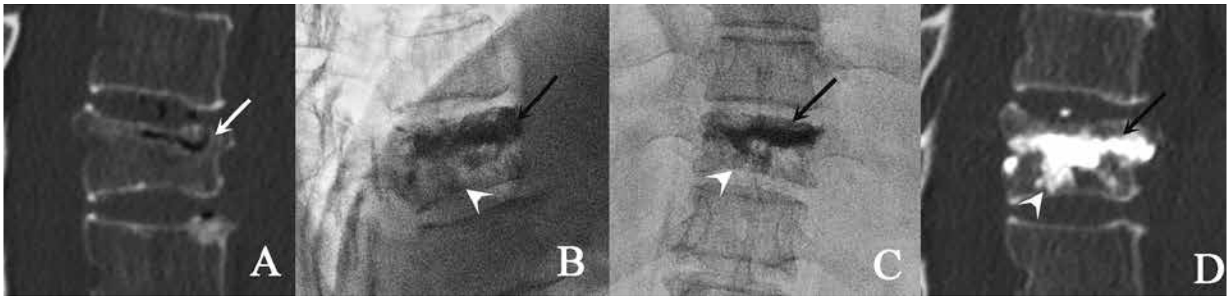

Fig. 2. *(A) A 65-year-old woman was admitted due to a severe backache for 2 years. She was diagnosed with IVC at the anterior one-third of T11 vertebra (white arrow). (B, C, D) A sagittal computed tomography image shows an IVC near the upper endplate. After RC-PVP, the IVC is filled mainly by a mass of cement (black arrows), spreading into the fine bone trabeculae (white arrowhead).*

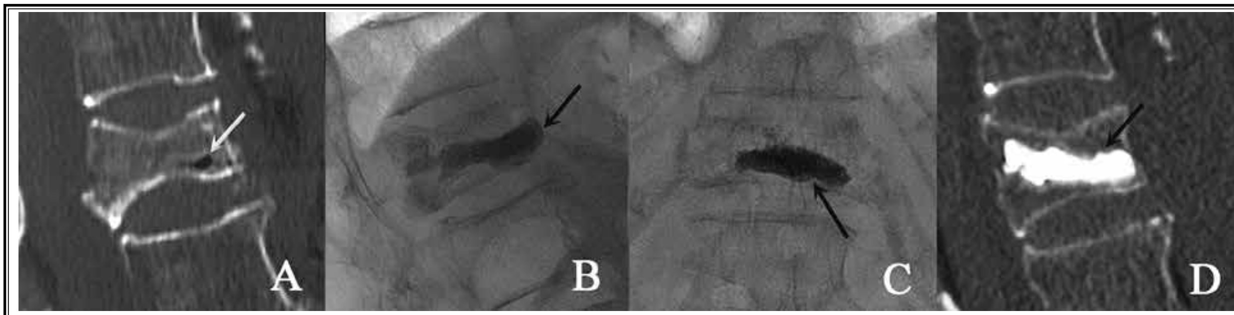

Fig. 3. *(A) A 77-year-old man was admitted due to persistent lumbago and progressive kyphosis for 3 months. He underwent conventional PVP with an IVC at the anterior one-third of L1 vertebral body near the lower endplate (white arrow). (B, C, D) As the cement cannot integrate with the trabecula (black arrows), a cystic filling pattern is observed.*

Table 2. *Clinical outcomes of the 2 groups.*

Outcome	RC-PVP (n = 30)	Control (n = 34)	*P* value
Cement volume (mL)	5.4 ± 1. 3	4.2 ± 1.3	0.001
Cement leakage	2 (2)	7(10)	0.02
Cement filling pattern			
Solid pattern	4	31	
Trabecular pattern	0	0	
Mixed pattern	26	3	< 0.001
Height restoration rate (%)	32.7 ± 13.6	32.4 ± 13.9	0.93
Wedge angle correction	5.2 ± 4.9	6.2 ± 5.9	0.46

Note — RC-PVP = the rotary cutters were applied before cement injection to destroy the structure around IVC.

wedge angle correction data in the RC-PVP and control groups were also similar (5.2 ± 4.9 and 6.2 ± 5.9, respectively, *P* = 0.46) (Table 2).

In the control group, 24 out of 34 patients (70.6%) qualified for the effective group after a week and a month, 17 out of 23 patients (73.9%) after 3 months, and 14 out of 19 (73.7%) patients after 6 months. From one month to 3 months, 11 patients stop attending follow-ups. From 3 months to 6 months, another 4 patients were lost to follow-ups. Eight patients showed aggravated pain due to subsequent fractures postoperatively, among whom 4 patients showed no improvement, 2 patients showed slight improvement, and 2 patients showed much improvement to aggravation. Three subsequent fractures were located in the adjacent level and 5 in the augmented levels (n = 5) (Fig. 3). In the 8 patients with subsequent fractures, the filling cement formed a mass in 7 patients, and a mixed filling pattern was found in one patient.

The RC-PVP group had a higher rate of patients classified as effective during the first week and the first month (93.3%, 28/30 patients, *P* = 0.02) and at 3 months (90.4%, 19/21 patients, *P* = 0.03). After 6 months, the RC-PVP group showed a non-statistically higher effective rate than the control group (89.5%, 17/19 patients, *P* = 0.2). Nine patients were lost to follow-up from one month to 3 months, and another 2 patients were lost to follow-up from 3 months to 6 months. In the RC-PVP group, subsequent fractures occurred in 2 cases (6.7%). One case was located in the nonadjacent levels and one case in the adjacent level. Both cases were filled with cement with a mixed filling pattern.

Discussion

The present study demonstrated that both conventional PVP and RC-PVP could achieve satisfactory kyphosis correction and vertebral height restoration. The filling pattern of cement in the control group was mainly cystic, while the cement was filled as a mixed type in the RC-PVP group. The RC-PVP group had a higher rate of patients classified as effective during the first week and at the one month and 3 month follow-ups. In addition, fewer vertebral recollapses were detected in the RC-PVP group after a long-term follow-up.

With the improved recognition of mechanisms of KD, the posttraumatic delayed vertebral collapse has received more attention in clinical work. It is usually challenging to make an initial diagnosis, as KD is often clinically occult at the early stage. Therefore, progressive kyphosis is generally found due to vertebral fracture at the time of diagnosis. It is usually accompanied by continuous intractable pain or neurologic deficit. The previous study indicates that the pathogeny is ischemic osteonecrosis leading to vertebra nonunion and pseudarthrosis formation (13). An effective treatment is needed for relieving intractable pain and for correcting kyphotic deformity (11,14). PVP is believed as an effective alternative for treating vertebral fractures and controlling the symptomatic pain.

Some authors noted that patients with IVC signs had obvious pain reduction immediately after PVP, and these authors believed that PVP was a reasonable option for the selected patients (14-17). Other studies, however, hold an opposite view of PVP. They found that the therapeutic benefit of PVP was less effective in patients with vacuum cleft than in those without IVC. Some patients with IVC had no pain relief after PVP or even suffered from depraved back pain (7-9). Therefore, some authors regard conventional PVP as a contraindication, if there is pseudoarthrosis or IVC in the fractured vertebra (10,11).

Our study is in accordance with the opinion that conventional PVP is inefficacious in more patients with IVC. In the control group, significant pain reduction was observed in 24 out of 34 patients (70.6%) at the one week and one month follow-up, which was worse than in patients without IVC (effective therapeutic rate range from 90% to 95%) (18,19). An early study showed a vertebral recollapse rate of approximately 3.2% after PVP (10,11). The present study mainly focuses on IVC, and the incidence of recollapse increased to 14.7%, which further proves the high risk of refracture for patients with IVC.

Conventional PVP injects cement directly into an IVC, which is covered by fibrous tissues. Although the cement could fill the IVC cavity, the fibrous tissues around the IVC will interfere with the bone cement expansion. The solid-filled cement only acts as a simple space-occupying material. The surrounding vertebral body remains unsupported and untreated, causing further pain—especially if there is a further collapse of the unfilled part of the treated vertebral body (7). Moreover, the concentrated and regular shaped cement will eventually increase the stress on the IVC's superior border and inferior border. The potential micro-motion at the bone-cement interface may cause tiny fractures, worsen the blood supply, and lead to osteonecrosis (20). When osteonecrosis is aggravated, the cement with a solid pattern may reduce the effect of conventional PVP treatment and even result in refracture in the augmented vertebra. It should be noted that more adjacent vertebral compression fracture is also found in the control group. It is easier to refracture with conventional PVP because the bone cement conglobates, which increases the stress in a pre-existing IVC. When concentrate stress transmits from the intervertebral disc to the adjacent vertebral body, a fracture may occur for the uneven force and elevated load (21,22).

Compared with patients treated with conventional PVP, a contiguous bone interdigitation is generally observed around a solid lump in the RC-PVP group (Fig. 2). The destruction of the fibrocartilaginous membrane by rotary cutter would make the bone cement diffuse into the cancellous bone with a healthy blood supply (Fig. 2). The internal stabilization created by the rotary cutter can effectively prevent micro-motion between cement and bone. It may eliminate the potential osteonecrosis process and may prevent the failure of PVP. A short-term follow-up indicates that RC-PVP has a higher success rate (93.3%) than the control group (70.6%), which is similar to osteoporotic compression fracture without IVC (90% to 95% success rate) (18,19). Moreover, the cement can diffuse into trabecula in the RC-PVP group, which may lead to less biomechanical stress and reduce the risk of subsequent refracture in the augmented and adjacent vertebrae.

A recent review indicates high rate of cement leakage (15.8%-75%) in the IVC group than in the non IVC group, which is another major complication for IVC treatment (23). The present study demonstrates that the cement leakage probability is significantly lower for vertebral bodies with the application of a rotary cutter (6.7%). As the structure of IVC and the surrounding vertebral body is destroyed, the cement can be injected into the fractured vertebral body with lower pressure. Thus, the cement leakage occurs less often within the treated vertebral body.

Limitation

First, some patients did not complete the follow-ups. Second, the number of patients in the study is limited, which may influence the statistical significance. Third, we did not enroll data of kyphoplasty, which will be studied in the future. Despite the limitations mentioned above, this study introduced and assessed the clinical outcome of new technology for a relatively tricky disease and provided valuable information.

Conclusion

This study indicates that PVP, combined with a rotary cutter, can safely and effectively relieve pain for patients with KD. Besides, the destruction of IVC and the peripheric trabecula may lead to better long-term outcomes with fewer complications.

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