



Effect of Robot-Assisted Surgery on Clinical Outcomes in Patients with Osteoporotic Vertebral Compression Fractures after Percutaneous Vertebral Augmentation: a Meta-Analysis and a Validation Cohort

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Background: The objective of this study was to investigate the impact of robot-assisted surgery (RA) on the risk of new vertebral compression fracture (NVCF) and bone cement leakage in patients with osteoporotic vertebral compression fractures (OVCF) after percutaneous vertebral augmentation (PVA), including percutaneous kyphoplasty (PKP) and percutaneous vertebroplasty (PVP).

Methods: A meta-analysis was performed to evaluate the clinical outcomes and adverse effects of RA-PVA versus fluoroscopy-assisted (FA)-PVA in patients with OVCF. A validation cohort of 385 patients who underwent PVP or PKP was retrospectively analyzed. In addition, we attempted to create well-calibrated nomograms to estimate the risk of NVCF and bone cement leakage.

Results: The meta-analysis revealed that the incidence of NVCF and bone cement leakage was significantly lower in RA-PVA than in FA-PVA. The validation cohort confirmed that RA-PVA provided better results than FA-PVA in terms of NVCF and bone cement leakage.

Conclusions: The meta-analysis and the validation cohort suggest that RA reduced the risk of NVCF and bone cement leakage in patients with OVCF after PVA. The nomograms are accurate and easy-to-implement methods for clinicians to estimate the risk of NVCF and bone cement leakage after PVA.

Keywords: *Spinal Fractures, Vertebroplasty, Robot-assisted surgery, Bone cements, Osteoporosis*

Osteoporotic vertebral compression fractures (OVCF) often occur in older people with osteoporosis, a common metabolic disease of the bone characterized by decreased bone mineral density (BMD) and bone mass and increased

bone fragility.¹⁾ Vertebral compression fractures can occur due to low forces as a result of decreased bone density and weakened bone mass.²⁾ OVCF can cause significant pain at the vertebral fracture site and restricted mobility, which are detrimental to the quality of life of older people. Hence, early diagnosis and treatment of OVCF are crucial for maintaining their health and quality of life.³⁾ At present, the main goal of treating OVCF is to relieve pain, prevent postoperative fractures, restore physical function, and improve quality of life.

Percutaneous vertebral augmentation (PVA), including percutaneous kyphoplasty (PKP) and percutaneous vertebroplasty (PVP), is one of the first-line treatments

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for pain relief and kyphosis correction in OVCF patients. In both procedures, the surgeon injects bone cement into the vertebral body to increase stability and relieve pain.⁴⁾ However, as these techniques become more common, the disadvantages are gradually becoming apparent, such as new vertebral compression fracture (NVCF) and bone cement leakage. In both cases, reoperation or conservative treatment may be required, which can significantly affect the patient's quality of life. Therefore, it is necessary to identify the patients with a high risk of NVCF or bone cement leakage.

Currently, the puncture point of PVA mainly depends on intraoperative C-arm fluoroscopy. Surgeons often require repeated radiographs to determine a safe puncture route. Due to the deviation from fluoroscopy, the accuracy of the puncture may be compromised. To avoid injuries caused by inaccurate puncture points during puncture, robot-assisted surgery (RA) technology was applied to PVA,^{5,6)} which improves the safety and accuracy of Kirschner wire placement. RA has high accuracy and stability and can help spine surgeons improve the accuracy of puncture needle placement.⁷⁾ Several studies have reported the clinical outcomes of RA-PVA in OVCF. However, due to the limited sample size of these studies, the results are conflicting, which have not been systematically confirmed.

The nomograms can help clinicians to calculate the likelihood of clinical events, design individualized treatment plans, and more actively manage follow-up. Here, we developed and validated nomograms to predict the risk of NVCF and bone cement leakage via exploring the independent risk factors through univariate and multivariate logistic regression analyses. In this study, we performed a meta-analysis to evaluate the clinical outcomes of RA-PVA compared with conventional fluoroscopy-assisted (FA)-PVA for OVCF and to provide a scientific basis for spine surgeons to use RA-PVA in OVCF. In addition, a validation cohort was retrospectively analyzed to assess the potential risk factors for NVCF and bone cement leakage in patients with OVCF after PVA. Furthermore, we attempted to create well-calibrated nomograms to predict the risk of NVCF and bone cement leakage.

METHODS

The Institutional Review Board of Tianjin Hospital Medical Ethics Committee approved the study. Informed consent was obtained from patients.

Meta-Analysis

A meta-analysis was conducted to assess the clinical outcomes of RA-PVA compared to FA-PVA in patients with OVCF, according to the updated guidelines.⁸⁾ A detailed description of the meta-analysis methods can be found in Supplementary Materials 1-3.⁹⁻¹²⁾

Clinical Subjects

A validation cohort of 385 OVCF patients, who underwent PVP or PKP surgery at Tianjin University Tianjin Hospital from October 2019 to October 2022, was retrospectively analyzed. A detailed description of the retrospective analysis can be found in Supplementary Material 2.

Identification of NVCF and Bone Cement Leakage

Low-signal intensity of T1-weighted magnetic resonance imaging (MRI) and high-signal intensity of T2-weighted MRI indicated the occurrence of NVCF. Other spinal conditions were ruled out, including infection and malignancy. On the other hand, x-ray was used to assess bone cement leakage.

Logistic Regression to Determine Risk Factors

Quantitative data were analyzed by the sample *t*-test, and qualitative data were analyzed by the chi-square test. Univariate analysis was performed to screen out the potential risk factors, and multivariate analysis was conducted to determine the independent risk factors.

Nomogram Construction

The nomograms for NVCF and bone cement leakage in patients with OVCF after PVA were constructed based on the independent risk factors determined in the logistic regression analysis. Calibration plots were used to assess the consistency of the models. The predictive power of the nomogram was evaluated by the area under the curve (AUC) of receiver operating characteristic (ROC). Decision curve analysis (DCA) was used to explore the clinical utility of the nomograms. The data were randomly distributed into a training set (75%) and a validation set (25%). The training set was used to build a nomogram, and the testing set was used to validate the efficacy of the nomogram.

Statistical Analyses

Continuous and categorical variables were analyzed via the independent sample *t*-test and the chi-square test. R 3.6.2 was used to display nomograms, calibration plots, DCA, and ROC curves with several R packages. A *p* < 0.05 was considered to be statistically significant.

RESULTS

Meta-Analysis of RA-PVA and FA-PVA in OVCF

Patients

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart for the selection process of included studies is shown in Supplementary Figs. 1-3. Thirteen articles with 1,094 patients were involved in the meta-analysis. Table 1 provides an overview of the basic characteristics of included studies. Seven articles investigated the clinical outcomes of PVP, and 6 articles focused on PKP. The overall quality of evidence is shown in Supplementary Fig. 4.

The results of this meta-analysis showed that the RA group had lower cement leakage rates, a lower number of fluoroscopic procedures and a lower incidence of NVCF, a greater inclination angle, and better improvement of short-term pain and Cobb angle than the FA group (Table 2, Supplementary Figs. 5-17). However, no significant difference was found in operative time, injection volume, Oswestry disability index, vertebral midline height, and post-operative pain relief at long-term follow-up between the 2 groups. It is worth mentioning that RA holds a promise for spinal surgery, but further validation of the efficacy and safety of RA is still needed.

Baseline Characteristics of OVCF Patients in the Validation Cohort

Baseline characteristics of OVCF patients are shown in Table 3. There were significant differences in body weight, body mass index (BMI), BMD, anti-osteoporosis therapy, multiple vertebral fractures, and steroid use between the NVCF group and the non-NVCF group (all $p < 0.01$). In addition, there were significant differences in injection volume, surgery time, and multiple vertebral fractures between the leakage group and the non-leakage group (all $p < 0.05$).

Nomogram for the Risk of NVCF after PVP

As shown in Table 4, univariate analysis revealed that BMI, BMD, assistant type (RA/FA), primary OVCF multiple vertebral fracture, and steroid use were potential risk factors for postoperative NVCF after PVP (all $p < 0.05$). Multivariate analysis revealed that patients with higher BMI (odds ratio [OR], 1.094; 95% CI, 1.035–1.156; $p < 0.01$) and BMD (OR, 1.894; 95% CI, 1.181–3.038; $p < 0.01$) were at higher risk. Patients with primary OVCF multiple vertebral fracture (OR, 1.929; 95% CI, 1.028–3.620; $p < 0.05$) and steroid use (OR, 4.070; 95% CI, 2.005–8.264; $p < 0.05$) were also at higher risk. Notably, RA significantly

reduced the risk of NVCF after PVP (OR, 0.385; 95% CI, 0.187–0.792; $p < 0.05$). Thus, high BMI, low BMD, primary OVCF multi-vertebral fracture and steroid use were independent risk factors for NVCF after PVP. Furthermore, RA was a beneficial factor for NVCF after PVP.

A nomogram was developed to predict the risk of NVCF after PVP (Fig. 1A). The predictive ability of the nomogram was validated using ROC with a mean AUC of 0.829, indicating a good predictive ability (Fig. 1B). Calibration curves and DCA were used to assess the predicted outcomes and observed outcomes and showed good agreement (Supplementary Fig. 18).

Nomogram for the Risk of Bone Cement Leakage after PVP

Univariate analysis revealed that the injection amount of bone cement, the duration of surgery, and assistant type (RA/FA) were potential risk factors for bone cement leakage after PVP (Table 5). Multivariate analysis revealed that patients with higher injection volume of bone cement (OR, 1.283; 95% CI, 1.004–1.640; $p < 0.05$), longer operation time (OR, 1.015; 95% CI, 1.003–1.027; $p < 0.05$), and assistant type FA (OR, 2.456; 95% CI, 1.461–4.130; $p < 0.05$) were at greater risk. A nomogram was constructed to assess the risk of bone cement leakage after PVP (Fig. 2A). The predictive ability of the nomogram was validated by tenfold cross-validation with a mean AUC of 0.842, indicating a good predictability (Fig. 2B). Calibration curves and DCA were used to assess the predicted outcomes and observed outcomes and showed good agreement (Supplementary Fig. 19).

Nomogram for the Risk of NVCF after PKP

As shown in Table 6, univariate analysis showed statistically significant differences in age, BMD, assistant type (RA/FA), and fracture history between the 2 groups (all $p < 0.05$). Multivariate analysis revealed that sex (OR, 2.621; 95% CI, 1.030–6.673; $p = 0.043$), assistant type RA (OR, 0.706; 95% CI, 0.507–0.707; $p < 0.001$), fracture history (OR, 12.298; 95% CI, 6.250–24.199; $p < 0.001$), and cemented intervertebral leakage (OR, 2.501; 95% CI, 1.029–6.082; $p = 0.043$) were independent risk factors positively associated with NVCF. These predictors derived from multivariate analysis were used to create a nomogram to predict the risk of NVCF after PKP, and 4 predictors were finally included in the model: female sex, fracture history, assistant type (RA/FA), and cemented intervertebral leakage (Fig. 3A). The ROC curve showed that the nomogram had a good discriminatory ability with an AUC of 0.986 (Fig. 3B), suggesting that it could more accurately predict

Table 1. Patient Characteristics of the Studies in the Meta-Analysis

Study	Study type	Robot type	Surgery type	RA/FA			Risk of bias		
				Sample size	Sex (male ratio)	Age (yr)		BMI (kg/m ²)	BMD (T score)
Guo et al. (2021) ¹³	R	Mazor	PVP	23/27	6/8	72.17 ± 7.02/72.15 ± 7.36	-	-	Low
Shi et al. (2021) ¹⁴	R	ZOEZEN	PVP	14/16	4/7	71.00 ± 8.81/5.75 ± 5.93	22.62 ± 2.66/24.18 ± 2.85	-2.89 ± 0.29/-2.89 ± 0.45	Moderate
Tan et al. (2023) ¹⁵	R	ZOEZEN	PVP	42/42	11/6	69.9 ± 9.1/68.3 ± 6.2	23.3 ± 4.4/22.0 ± 4.2	-3.2 ± 0.4/-3.3 ± 0.3	Low
Xie et al. (2021) ¹⁶	RCT	TiRobot	PVP	95/85	43/39	75.2 ± 3.7/77.4 ± 2.8	-	-	Low
Yang et al. (2022) ¹⁷	R	TiRobot	PVP	40/50	18/22	69.3 ± 9.0/71.0 ± 7.5	23.7 ± 6.1/24.2 ± 4.2	-2.74 ± 0.23/-2.84 ± 0.24	Moderate
Zhang et al. (2018) ¹⁸	R	TiRobot	PVP	40/40	16/12	61.1 ± 8.6/63.2 ± 5.9	-	-	Low
Zheng et al. (2021) ¹⁹	R	TiRobot	PVP	19/21	5/6	73.4 ± 10.7/75.2 ± 11.2	-	-4.7 ± 1.2/-4.2 ± 1.5	Moderate
Jin et al. (2022) ²⁰	R	TiRobot	PKP	81/131	36/59	75.44 ± 8.25/2.65 ± 9.14	22.16 ± 5.98/23.92 ± 6.31	-	Low
Li et al. (2022) ²¹	R	TiRobot	PKP	15/15	2/3	69.7 ± 8.1/69.3 ± 8.4	-	-3.4 ± 2.1/-3.4 ± 1.5	Moderate
Lin et al. (2022) ²²	R	TiRobot	PKP	87/68	19/15	71.7/69.6	23.42 ± 3.69/22.70 ± 4.02	-3.20 ± 0.53/-3.15 ± 0.55	Low
Sun et al. (2022) ²³	RCT	AIOOR	PKP	12/12	5/6	64.22 ± 5.70/5.07 ± 4.91	28.67 ± 1.62/27.96 ± 1.35	-4.46 ± 0.48/4.37 ± 0.38	Low
Wang et al. (2021) ²⁴	R	TiRobot	PKP	30/30	14/13	69.5 (61–89)/70 (61–86)	-	-3.6 ± 0.7/-3.5 ± 0.6	Low
Yuan et al. (2022) ²⁵	R	TiRobot	PKP	37/22	3/3	69.9 ± 8.7/73.4 ± 8.4	-	-2.9 ± 0.5/-3.0 ± 0.5	Low

Values are presented as mean ± standard deviation.

RA: robot-assisted, FA: fluoroscopy-assisted, BMI: body mass index, BMD: bone mineral density, R: retrospective, RCT: randomized controlled trial, PVP: percutaneous vertebroplasty, PKP: percutaneous kyphoplasty.

Table 2. The Meta-Analysis of RA or FA-PKP or PVP for OVCF

Outcome	RA-PVP vs. FA-PVP				RA-PKP vs. FA-PKP				RA-PVA vs. FA-PVA				
	No. of studies	Risk ratio (95% CI)	P-value	I ²	No. of studies	Risk ratio (95% CI)	P-value	I ²	No. of studies	Risk ratio (95% CI)	P-value	I ²	Egger's test
Leakage rate	6	0.36 (0.21 to 0.619)	<0.01	0	6	0.279 (0.159 to 0.492)	<0.01	0	12	0.319 (0.216 to 0.472)	<0.01	0	0.664
Operation time	7	-18.781 (-19.301 to -18.261)	<0.01	99%	5	-6.591 (-7.847 to -5.334)	<0.01	97%	12	-17 (-17.48 to -16.52)	<0.01	99%	0.026
Number of fluoroscopic procedures	4	-11.842 (-12.91 to -10.775)	<0.01	99%	4	-11.833 (-12.783 to -10.883)	<0.01	97%	8	-11.837 (-12.547 to -11.127)	<0.01	97%	0.410
Injection volume	4	-0.577 (-0.798 to -0.357)	<0.01	92%	4	0.248 (-0.066 to 0.561)	0.12	84%	8	-0.304 (-0.484 to -0.123)	<0.01	91%	0.602
NVCF	3	0.392 (0.133 to 0.65)	<0.01	68%	3	0.256 (0.073 to 0.439)	<0.01	36%	6	0.301 (0.152 to 0.451)	<0.01	50%	0.931
VAS < 3 days	6	-0.189 (-0.269 to -0.109)	<0.01	27%	4	-0.186 (-0.336 to -0.036)	0.01	0	10	-0.189 (-0.259 to -0.118)	<0.01	4%	0.080
VAS > 1 month	6	-0.132 (-0.182 to -0.109)	<0.01	84%	5	-0.067 (-0.192 to 0.058)	0.3	43%	11	-0.123 (-0.169 to -0.076)	<0.01	75%	0.638
ODI < 3 days	5	-1.019 (-1.519 to -0.519)	<0.01	63%	1	1.14 (-0.227 to 2.507)	0.1	-	6	-0.765 (-1.234 to -0.295)	<0.01	74%	0.460
ODI > 1 month	5	-0.228 (-0.816 to 0.36)	0.45	0	1	-0.62 (-2.413 to 1.173)	0.5	-	6	-0.266 (-0.825 to 0.292)	0.35	0	0.021
Cobb angle < 3 days	1	-0.9 (-1.236 to -0.564)	<0.01	-	2	-2.146 (-3.636 to -0.656)	<0.01	33%	3	-0.96 (-1.288 to -0.632)	<0.01	50%	0.605
Cobb angle > 1 month	2	-0.834 (-1.16 to -0.508)	<0.01	66%	3	-1.662 (-2.505 to -0.819)	<0.01	44%	5	-0.942 (-1.246 to -0.638)	<0.01	59%	0.854
Midline height < 3 days	1	0.58 (-1.771 to 2.931)	0.63	-	2	2.927 (2.664 to 3.189)	<0.01	97%	3	2.898 (2.636 to 3.159)	<0.01	95%	0.293
Midline height > 1 month	1	0.22 (-1.919 to 2.359)	0.84	-	3	2.865 (2.691 to 3.04)	<0.01	94%	4	2.848 (2.674 to 3.022)	<0.01	93%	0.114

RA: robot-assisted, FA: fluoroscopy-assisted, PKP: percutaneous kyphoplasty, PVP: percutaneous vertebroplasty, OVCF: osteoporotic vertebral compression fracture, NVCF: new vertebral compression fracture, VAS: visual analog scale, ODI: Oswestry disability index.

Table 3. Baseline Characteristics of OVCF Patients

Variable	Non-NVCF group (n = 58)	NVCF group (n = 327)	p-value	Non-leakage group (n = 304)	Leakage group (n = 81)	p-value
Age (yr)	75.4 ± 6.9	73.9 ± 9.6	0.254	74.3 ± 8.7	74.3 ± 8.6	0.885
Sex			0.356			0.493
Male	9 (15.5)	68 (20.8)		63 (20.7)	14 (17.3)	
Female	49 (84.5)	259 (79.2)		241 (79.3)	67 (82.7)	
Height (cm)	154.9 ± 8.2	154.6 ± 8.3	0.809	154.3 ± 8.5	155.7 ± 14.3	0.187
Weigh (kg)	54.8 ± 10.7	49.6 ± 13.3	< 0.01	50.32 ± 12.77	50.86 ± 10.7	0.741
BMI (kg/m ²)	22.8 ± 3.8	20.7 ± 5.3	< 0.01	21.1 ± 5.2	20.9 ± 5.5	0.758
BMD (kg/m ²)	-4.6 ± 0.6	-4.3 ± 0.8	< 0.01	-4.38 ± 0.8	-4.54 ± 0.5	0.18
Hospitalized date (day)	10.1 ± 4.3	9.3 ± 4.7	0.218	9.3 ± 4.7	9.8 ± 4.4	0.392
Injection volume (mL)	4.14 ± 1.2	4.1 ± 1.0	0.862	4.1 ± 1.0	4.4 ± 1.2	< 0.05
Surgery time (min)	57.1 ± 19.6	53.2 ± 20.3	0.188	52.3 ± 18.7	59.5 ± 24.5	< 0.01
Hospitalization to surgery (day)	6.1 ± 3.6	5.2 ± 2.9	0.053	5.28 ± 2.9	5.86 ± 3.3	0.128
Injury to surgery (day)	26.5 ± 27.0	29.4 ± 45.3	0.634	29.4 ± 46.0	27.44 ± 27.8	0.712
≤ 24 hr	19 (32.8)	89 (27.2)	0.428	92 (30.3)	16 (19.8)	0.071
> 24 hr	39 (67.2)	238 (72.8)		212 (69.7)	65 (80.2)	
Anti-osteoporosis therapy			< 0.01			0.531
No	46 (79.3)	199 (60.9)		44 (75.9)	260 (79.5)	
Yes	12 (20.7)	128 (39.1)		14 (24.1)	67 (20.5)	
Multiple vertebral fracture			< 0.01			< 0.001
No	20 (34.5)	185 (56.6)		177 (58.2)	28 (34.6)	
Yes	38 (65.5)	142 (43.4)		127 (41.8)	53 (65.4)	
Steroid use			< 0.01			0.119
No	39 (67.2)	281 (85.9)		248 (81.6)	72 (88.9)	
Yes	19 (32.8)	46 (14.1)		56 (18.4)	9 (11.1)	

Values are presented as mean ± standard deviation or number (%).

OVCF: osteoporotic vertebral compression fracture, NVCF: new vertebral compression fracture, BMI: body mass index, BMD: bone mineral density.

the risk of NVCF after PKP. Calibration curves and DCA showed good agreement (Supplementary Fig. 20).

Nomogram for the Risk of Bone Cement Leakage after PKP

Univariate analysis revealed that delayed surgery, assistant type, and vertebral compression ratio were the potential risk factors for bone cement leakage after PKP (Table 7). Multivariate analysis indicated that delayed surgery (OR, 2.74; 95% CI, 1.35–5.59; $p = 0.005$), preoperative vertebral

compression ratio (OR, 0.13; 95% CI, 0.02–0.84; $p = 0.032$), and assistant type (RA/FA) (OR, 2.74; 95% CI, 1.14–6.56; $p = 0.024$) were independent risk factors for bone cement leakage after PKP. A nomogram was constructed to assess the risk of bone cement leakage after PKP (Fig. 4A). The ROC curve showed that the nomogram had good discriminatory power with an AUC of 0.987 (Fig. 4B), indicating that it could more accurately predict the risk of NVCF after PKP. Calibration curves and DCA showed high agreement between the prediction of the nomogram

Table 4. Univariate and Multivariate Logistic Regression Analysis of NVCF after PVP in OVCF Patients

Variable	Univariate	<i>p</i> -value	Multivariate	<i>p</i> -value
	OR (95% CI)		OR (95% CI)	
Age	1.019 (0.987–1.053)	0.252	-	-
Sex				
Male	Reference	Reference	-	-
Female	1.429 (0.669–3.054)	0.356	-	-
BMI	1.070 (1.019–1.123)	< 0.01	1.094 (1.035–1.156)	< 0.01
BMD	1.914 (1.238–2.960)	< 0.01	1.894 (1.181–3.038)	< 0.01
Hospitalized date (day)	1.033 (0.981–1.088)	0.223	-	-
Injection volume (mL)	0.976 (0.747–1.276)	0.976	-	-
Surgery time (min)	1.009 (0.996–1.022)	0.188	1.016 (0.818–1.157)	0.181
Hospitalization to surgery (day)	1.081 (0.998–1.171)	0.057	1.071 (0.981–1.169)	0.124
Injury to surgery (day)	0.998 (0.991–1.006)	0.634	-	-
Assistance type				
FA	Reference	Reference	Reference	Reference
RA	0.406 (0.207–0.795)	< 0.01	0.385 (0.187–0.792)	< 0.05
Multiple vertebral fracture				
No	Reference	Reference	Reference	Reference
Yes	2.475 (1.38–4.43)	< 0.01	1.929 (1.028–3.620)	< 0.05
Steroid use				
No	Reference	Reference	Reference	Reference
Yes	2.976 (1.584–5.592)	< 0.05	4.070 (2.005–8.264)	< 0.001

NVCF: new vertebral compression fracture, PVP: percutaneous vertebroplasty, OVCF: osteoporotic vertebral compression fracture, OR: odds ratio, BMI: body mass index, BMD: bone mineral density, FA: fluoroscopy-assisted, RA: robot-assisted.

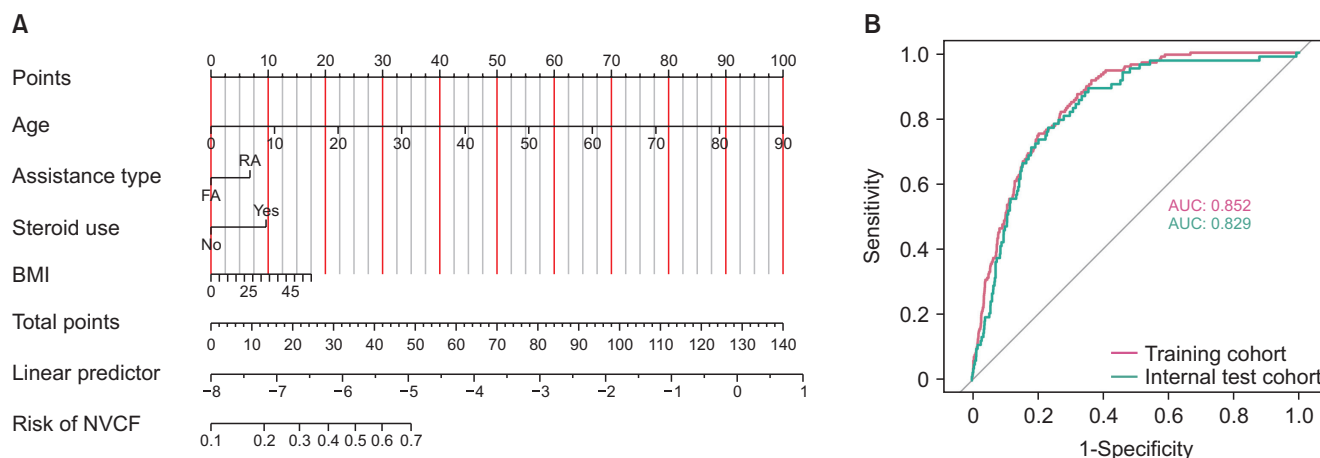


Fig. 1. Nomogram for the risk of new vertebral compression fracture (NVCF) after percutaneous vertebroplasty (PVP). (A) Nomogram for predicting NVCF after PVP. (B) Receiver operating characteristic curve of tenfold cross-validation for predicting NVCF after PVP based on the nomogram. BMI: body mass index, RA: robot-assisted, FA: fluoroscopy-assisted, AUC: area under the curve.

Table 5. Univariate and Multivariate Logistic Regression Analysis of Bone Cement Leakage after PVP in OVCF Patients

Variable	Univariate	<i>p</i> -value	Multivariate	<i>p</i> -value
	OR (95% CI)		OR (95% CI)	
Age	1.000 (0.972–1.029)	0.996	-	-
Sex				
Male	Reference	Reference	-	-
Female	1.251 (0.660–2.371)	0.496	-	-
BMI	0.993 (0.946–1.041)	0.758	-	-
BMD	1.283 (0.897–1.833)	0.172	-	-
Hospitalized date (day)	1.281 (1.004–1.634)	0.394	-	-
Injection volume (mL)	0.976 (0.747–1.276)	< 0.05	1.283 (1.004–1.640)	< 0.05
Surgery time (min)	1.017 (1.005–1.028)	< 0.01	1.015 (1.003–1.027)	< 0.05
Hospitalization to surgery (day)	1.059 (0.983–1.140)	0.13	-	-
Injury to surgery (day)	0.999 (0.993–1.005)	0.711	-	-
Assistance type				
FA	Reference	Reference	Reference	Reference
RA	0.379 (0.227–0.632)	< 0.001	0.497 (0.242–0.684)	< 0.01
Multiple vertebral fracture				
No	Reference	Reference	Reference	Reference
Yes	2.505 (1.233–5.062)	< 0.01	1.731 (1.159–4.633)	< 0.05
Steroid use				
No	Reference	Reference	-	-
Yes	0.554 (0.261–1.173)	0.123	-	-

PVP: percutaneous vertebroplasty, OVCF: osteoporotic vertebral compression fracture, OR: odds ratio, BMI: body mass index, BMD: bone mineral density, FA: fluoroscopy-assisted, RA: robot-assisted.

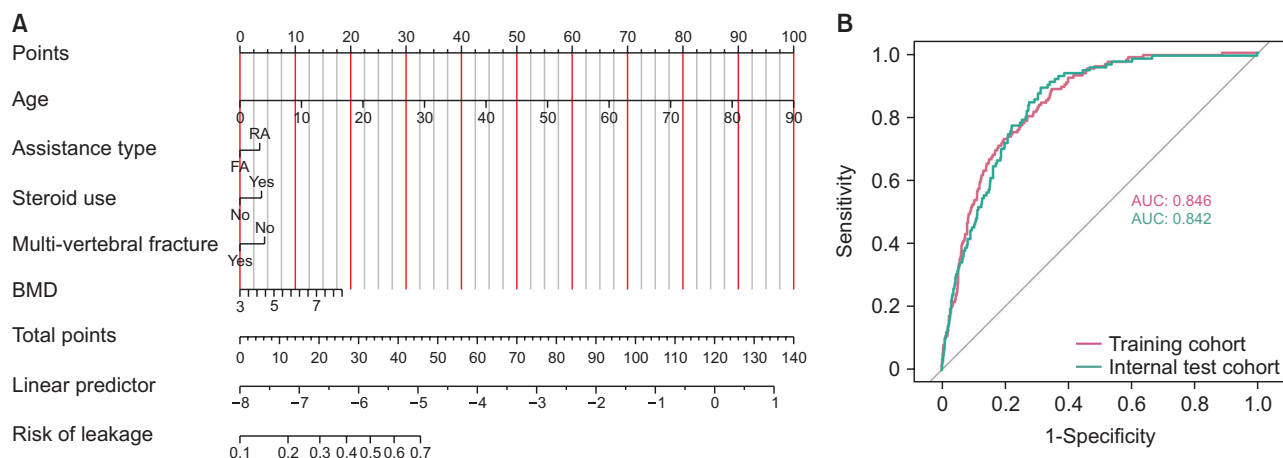


Fig. 2. Nomogram for the risk of bone cement leakage after percutaneous vertebroplasty (PVP). (A) Nomogram for predicting bone cement leakage after PVP. (B) Receiver operating characteristic curve of tenfold cross-validation for predicting bone cement leakage after PVP based on the nomogram. BMD: bone mineral density, RA: robot-assisted, FA: fluoroscopy-assisted, AUC: area under the curve.

Table 6. Univariate and Multivariate Logistic Regression Analysis of NVCF after PKP in OVCF Patients

Variable	Univariate analysis	p-value	Multivariate analysis	p-value
Age	1.896 (0.903–3.981)	0.091	-	-
Sex	1.032 (1.001–1.064)	0.041	2.621 (1.030–6.673)	0.043
BMI	1.029 (0.947–1.119)	0.498	-	-
BMD	0.235 (0.091–0.609)	0.003	-	-
Assistance type (RA/FA)	0.509 (0.224–0.536)	< 0.001	0.706 (0.507–0.707)	< 0.001
Time of injury	0.985 (0.970–1.001)	0.07	0.985 (0.969–1.001)	0.065
Time from admission to surgery	0.995 (0.892–1.111)	0.931	-	-
Number of fractured vertebrae	0.926 (0.607–1.414)	0.722	-	-
Location of the fractured vertebrae	1.192 (0.740–1.920)	0.47	-	-
Operation approach	1.651 (0.829–3.287)	0.154	-	-
Fracture history	10.471 (5.747–19.081)	< 0.001	12.298 (6.250–24.199)	< 0.001
New fracture	1.028 (0.465–2.270)	0.946	-	-
Paravertebral leakage	1.979 (0.964–4.063)	0.063	-	-
Intervertebral leakage	0.000 (0.000–Inf)	0.983	2.501 (1.029–6.082)	0.043
Spinal leakage	0.982 (0.947–1.018)	0.311	-	-
Bone cement distribution	1.209 (0.802–1.821)	0.364	-	-
Bone cement in contact with the endplate	1.111 (0.554–2.225)	0.767	-	-
Fracture type	1.151 (0.754–1.757)	0.515	-	-
Anti-osteoporosis (yes/no)	0.667 (0.349–1.275)	0.22	-	-
Vertebral height after recovery	0.995 (0.974–1.017)	0.66	-	-

NVCF: new vertebral compression fracture, PKP: percutaneous kyphoplasty, OVCF: osteoporotic vertebral compression fracture, BMI: body mass index, BMD: bone mineral density, RA: robot-assisted, FA: fluoroscopy-assisted, Inf: infinite.

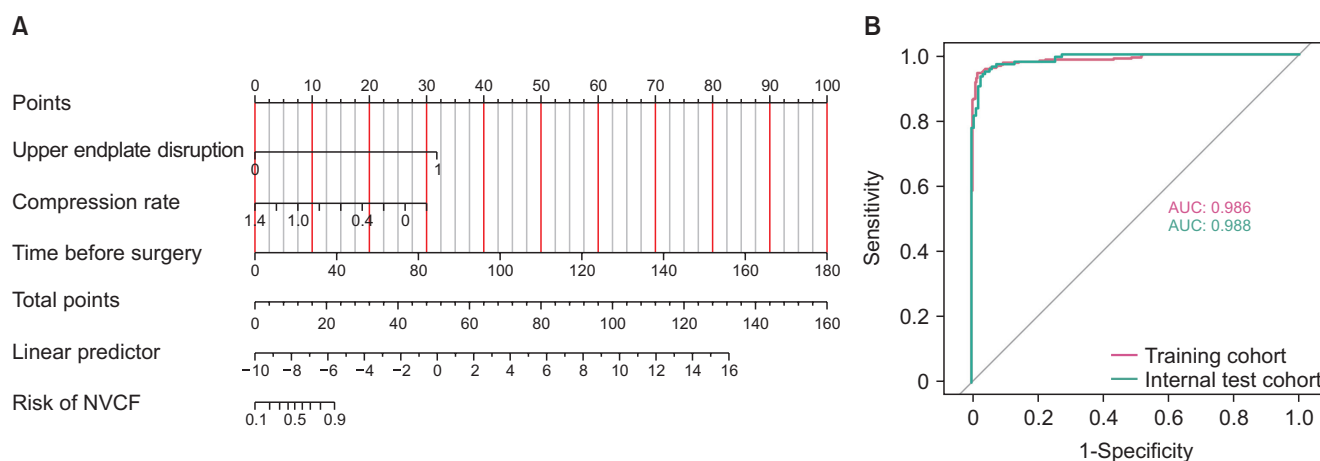


Fig. 3. Nomogram for the risk of new vertebral compression fracture (NVCF) after percutaneous kyphoplasty (PKP). (A) Nomogram for predicting NVCF after PKP. (B) Receiver operating characteristic curve of tenfold cross-validation for predicting NVCF after PKP based on the nomogram. AUC: area under the curve.

Table 7. Univariate and Multivariate Logistic Regression Analysis of Bone Cement Leakage after PVP in OVCF Patients

Preoperative factor	Univariate analysis			Multivariate analysis	
	Cement leakage	OR (95% CI)	<i>p</i> -value	OR (95%CI)	<i>p</i> -value
Dichotomous factor					
Sex			0.653		
Male (n = 65)	23 (35.4)	Reference			
Female (n = 230)	73 (31.7)	0.85 (0.48–1.52)			
Time before surgery			0.033		0.005
Early stage (n = 218)	63 (28.9)	Reference		Reference	
Delayed stage (n = 77)	33 (42.9)	1.85 (1.08–3.16)		2.74 (1.35–5.59)	
Preoperative fracture severity			0.104		0.017
Grade 1 (n = 132)	36 (27.3)	Reference		Reference	
Grade 2 (n = 163)	60 (36.8)	1.27 (0.76–2.12)		2.82 (1.20–6.61)	
Preoperative IVC			0.184		
No (n = 227)	69 (30.4)	Reference			
Yes (n = 68)	27 (39.7)	1.51 (0.86–2.65)			
Assistance type			0.001		0.024
FA (n = 198)	61 (30.8)	Reference		Reference	
RA (n = 97)	35 (36.1)	5.52 (2.05–14.89)		2.74 (1.14–6.56)	
Continuous factor					
Age (yr)		1.02 (0.99–1.05)	0.144		
Preoperative Cobb angle		1.01 (0.99–1.04)	0.398		
Preoperative compression ratio (%)		0.23 (0.65–0.83)	0.025	0.13 (0.02–0.84)	0.032
Cement volume (mL)		0.99 (0.76–1.28)	0.935		

Values are presented as number (%) unless otherwise indicated.

PVP: percutaneous vertebroplasty, OVCF: osteoporotic vertebral compression fracture, OR: odds ratio, IVC: intravertebral vacuum cleft, FA: fluoroscopy-assisted, RA: robot-assisted.

and the actual observation (Supplementary Fig. 21).

DISCUSSION

RA-PVA and FA-PVA are important methods for treating OVCF, though it is still unclear which is superior. The purpose of this study was to evaluate the effect of RA technology and construct nomograms for predicting NVCF and bone cement leakage in OVCF patients after PKP and PVP. The meta-analysis evaluated clinical outcomes and imaging improvements of RA-PKP or RA-PVP for OVCF and analyzed complications of RA-PVA and FA-PVA for OVCF, providing a scientific basis for spine surgeons to

use RA treatment for OVCF. There was a high degree of heterogeneity between studies included in the meta-analysis, and different robot types and learning curves may have caused risk of biases, potentially influencing the results. Hence, a validation cohort could verify the results from the meta-analysis and provide a basis for future randomized controlled trials (RCTs) and prospective studies. To the best of our knowledge, our study may be the first to examine the effect of RA technology on postoperative complications of PVA and to use nomograms to assess the risk of postoperative cement leakage and new compression fractures.

Given the high incidence of OVCF and the popular-

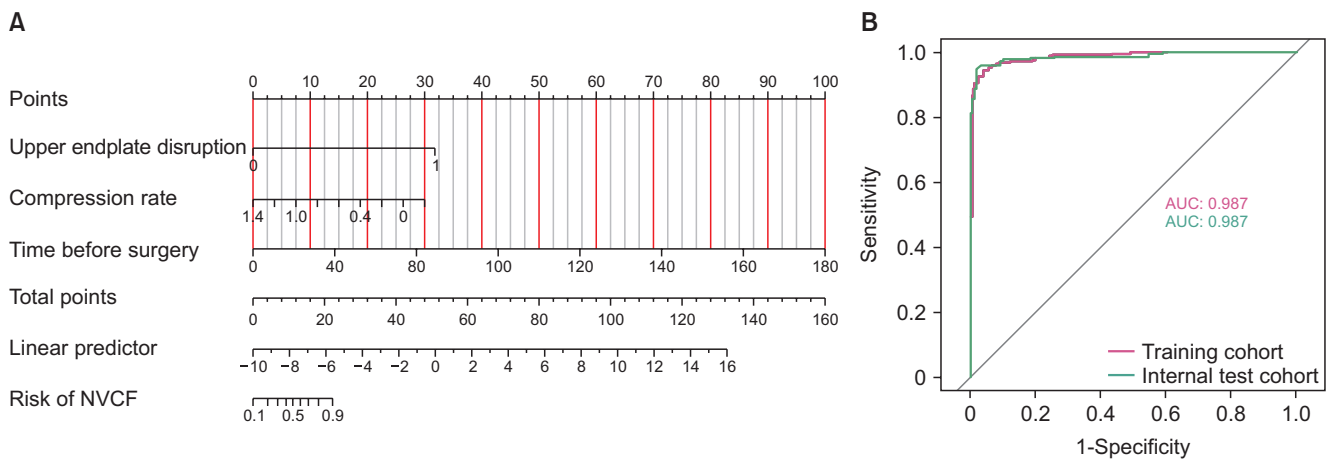


Fig. 4. Nomogram for the risk of bone cement leakage after percutaneous kyphoplasty (PKP). (A) Nomogram for predicting bone cement leakage after PKP. (B) Receiver operating characteristic curve of tenfold cross-validation for predicting bone cement leakage after PKP based on the nomogram. NVCF: new vertebral compression fracture, AUC: area under the curve.

ity of PVA, it was of great clinical importance to identify patients with high-risk of NVCF and bone cement leakage after PVA. Additional surgery may be needed if the symptoms are severe. In addition, the risk of fracture of adjacent vertebrae exists due to intervertebral cement leakage.²⁶⁾ When the hollow bony structures of the vertebral body are filled with cement, it can leak into the surrounding soft tissues or vasculature. Several factors may contribute to cement leakage in PVP, including the shape of bone cement, type of bone cement dispersion, basivertebral foramen, cortical disruption, severity of fracture, age, and sex.²⁷⁻²⁹⁾ The risk of bone cement leakage after PKP may also increase by low BMD, cortical bone defects, and inappropriate timing of cement injection.³⁰⁾ The results of both the meta-analysis and the validation cohort showed that RA is effective in reducing the risk of bone cement leakage in patients with OVCF after PVA. Precise puncture in RA could minimize damage to the pedicle wall and vertebral body. Therefore, the use of RA techniques may effectively increase the safety of PVA in OVCF.

It is generally believed that endplate cortical disruption is a crucial risk factor for bone cement leakage,^{28,31-33)} which was also confirmed by this study. Most OVCF patients had endplate cortical disruption. We suspected that endplate cortical disruption might be a prerequisite for bone cement leakage in patients with OVCF after PVA, rather than just a risk factor. However, we cannot draw an arbitrary conclusion and further pathophysiological studies are needed.

When the first OVCF has been diagnosed, NVCF may recur. Multi-vertebral OVCF leads to shortening and forward bending of the spine. The occurrence of NVCF

could be regarded as a natural process of senile osteoporosis,³⁴⁾ However, no consensus has been reached on whether the occurrence of NVCF in the cases treated by PVA is related to mechanical variations or is a complication related to the patient's age and development of osteoporosis.³⁵⁾

Postmenopausal women and older adults with a higher than normal BMI are in the majority of OVCF patients.³⁶⁾ Unhealthy dietary habits and the use of hormone supplements lead to the drop of estrogen levels in postmenopausal women, resulting in a gradual decline in BMD. Hence, these patients are at high risk of NVCF after PVA. In this study, lower BMD and higher BMI were found in the NVCF group than the non-NVCF group. Hence, increasing BMD and decreasing BMI can effectively reduce the risk of NVCF after PVA. In addition, it is generally believed that endplate cortical disruption is a crucial risk factor for intradiscal leakage. However, although slightly more endplate cortical disruptions were found in the intradiscal leakage group in this study, the difference did not reach statistical significance. The main reason for this may be because all patients enrolled in this study were with intravertebral vacuum cleft (IVC), while IVC was found to be communicated with the endplate cortical disruption in 89.0% patients. This resulted in the high incidence of endplate cortical disruption, which may weaken its effect on contributing to the discrepancy in the 2 groups. Moreover, all intradiscal cement leaks occurred through the cortical disruption at the endplates. We also found all endplate cortical disruptions were communicated with IVC in the intradiscal leakage group. Therefore, we inferred that endplate cortical disruption may be a requisite for intradiscal leakage in patients with IVC, rather

than just a risk factor. However, we cannot draw an arbitrary conclusion, and further pathophysiological studies are required.

The cement viscosity has not been assessed. The cement viscosity was regarded as a risk factor influencing the cement leakage.^{31,37)} However, it was difficult to objectively evaluate the cement viscosity because multiple factors could influence it, such as surgeon experience, cement property, and mixing method.³³⁾ The administration of high-viscosity bone cement in PVP/PKP could be a potential option for improving the complications of leakage in OVCFs, while the clinical efficacy of pain relief is not certain.³⁸⁾ A meta-analysis showed that although high- and low-viscosity cement had similar clinical outcomes, high-viscosity cement had a lower risk of leakage in the disk space or vein.³⁹⁾ Another network meta-analysis also supported the lower risk of leakage for high-viscosity cement in vertebral compression fractures.⁴⁰⁾

Orthopedic robots are characterized by high stability, easy and convenient operation, high accuracy, and repeatability. In PVA, it is difficult to control the accuracy puncture point and angle, and the end of the working sleeve may not reach the ideal position, leading to poor distribution of bone cement.⁴¹⁾ With the assistance of a robot, the accuracy puncture point and angle can be significantly increased.^{42,43)} The end of the working sleeve can reach the ideal position as close as possible. This avoids the risk of damaging the inner wall of the pedicle by the puncture needle, as well as nerve damage and dural sac rupture due to accidental penetration into the spinal canal. The results of the meta-analysis and the validation cohort also showed that RA effectively reduced the incidence of NVCF in OVCF patients after PVA.

In addition, RA-PVA requires only 1 radiograph prior to planning the intraoperative puncture route, thus avoiding repeated exposures. This would significantly reduce the radiation dose for surgeons and patients. On the other hand, the learning curve of RA-PVA is short, and the total operation time and the operation time of the robot decrease as the operation frequencies increase.⁴⁴⁾ Therefore, orthopedic robots could help in PVA for the treatment of OVCF.

Herein, we attempted to create nomograms to assess the risk of bone cement leakage and NVCF in patients with OVCF after PVA. Nomograms were constructed by including predictors that were filtered out by logistic regression analysis. The ROC curves, as well as the AUC values, showed good predictive performance of these nomograms. With the nomograms, clinicians could use an accurate and easy-to-implement method to calculate the

risk of NVCF and bone cement leakage after PVA, which was important for postoperative prevention, treatment, and targeted follow-up.

In this study, we created a nomogram model based on a single cohort and successfully tested the model in a validation cohort. By calculating scores for each of the potential risk factors, orthopedic surgeons can easily assess the risk of NVCF and cement leakage after PVA. Based on the assessment results, patient management strategies can be improved to reduce the risk of NVCF and cement leakage. Similarly, in low-risk patients, some preventive measures can be taken to reduce the financial burden.

Several limitations exist in the current study. First, the reliability of the meta-analysis is limited by the quality of the included studies. Included studies largely focus on non-RCTs, and more high-quality RCTs are required in the future. Second, the validation cohort was a retrospective study from a single center, which could lead to the selection bias. Although the nomograms were validated in a validation cohort, the incidence of postoperative NVCF and bone cement leakage varies by hospital, region, and country, which may limit the application of this model in the other hospitals. Multi-center retrospective studies or prospective RCTs can further improve the sensitivity and specificity of the nomograms, providing high-level evidence for future clinical applications. Last but not least, because some data were lost in the retrospective study, BMD, time of hospitalization to surgery, and steroid use were not fully considered in the multivariate regression analysis. Therefore, higher quality studies are needed to clarify our results.

In conclusion, the meta-analysis and the validation cohort suggest that fewer NVCF and bone cement leakage occur in patients with OVCF after RA-PVA. Evidence of small or moderate improvement, a sufficiently large sample size, and adequate follow-up should be considered. Although RA brings improvements for spinal surgery, the efficacy and safety of RA need to be further evaluated. In the future, further prospective studies and RCTs are needed to assess the results of this study.

CONFLICT OF INTEREST

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

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SUPPLEMENTARY MATERIAL

Supplementary material is available in the electronic version of this paper at the CiOS website, www.ecios.org.

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