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REVIEW ARTICLE

Establishment and validation of a nomogram and web calculator for the risk of new vertebral compression fractures and cement leakage after percutaneous vertebroplasty in patients with osteoporotic vertebral compression fractures

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Abstract

Purpose The aim of this work was to investigate the risk factors for cement leakage and new-onset OVCF after Percutaneous vertebroplasty (PVP) and to develop and validate a clinical prediction model (Nomogram).

Methods Patients with Osteoporotic VCF (OVCF) treated with PVP at Liuzhou People's Hospital from June 2016 to June 2018 were reviewed and met the inclusion criteria. Relevant data affecting bone cement leakage and new onset of OVCF were collected. Predictors were screened using univariate and multi-factor logistic analysis to construct Nomogram and web calculators. The consistency of the prediction models was assessed using calibration plots, and their predictive power was assessed by tenfold cross-validation. Clinical value was assessed using Decision curve analysis (DCA) and clinical impact plots.

Results Higher BMI was associated with lower bone mineral density (BMD). Higher BMI, lower BMD, multiple vertebral fractures, no previous anti-osteoporosis treatment, and steroid use were independent risk factors for new vertebral fractures. Cement injection volume, time to surgery, and multiple vertebral fractures were risk factors for cement leakage after PVP. The development and validation of the Nomogram also demonstrated the predictive ability and clinical value of the model.

Conclusions The established Nomogram and web calculator (https://dr-lee.shinyapps.io/RefractureApp/) (https://dr-lee.shinyapps.io/LeakageApp/) can effectively predict the occurrence of cement leakage and new OVCF after PVP.

Keywords Osteoporotic compression fractures · Percutaneous vertebroplasty · Bone cement leakage · Risk factors · Nomogram · Web calculator

Introduction

With the aging of the population and the increase of average life expectancy, osteoporosis shows an increasing trend. Osteoporotic vertebral compression fractures (OVCF) are among the main complications, where there are about 1.4 million new OVCF around the world every year [1, 2]. OVCF is a common disease for elderly patients. Usually, OVCF causes long-term back pain in older adults and affects their mobility and daily activities, reducing their quality of life and bringing heavy financial burdens on their family [3, 4]. Percutaneous vertebroplasty (PVP) has been widely used in clinical practice due to its advantages in relieving pain and partially restoring vertebral height [5, 6]. However, as with other invasive procedures, there are risks associated with PVP, the most common of which are leakage of bone cement and new OVCF [7].

New OVCF is common in osteoporosis patients receiving PVP [8]. When occurring new OVCF, it may require reoperation or conservative treatment, both of which will seriously affect the quality of patient's life [9]. According to

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related studies, the incidence of new OVCF (both adjacent and non-adjacent) is 5.5–52.0%. 17.4% of patients with VCF have a new fracture within a year, which may be related to osteoporosis's natural course [10]. Some studies have pointed out that more than two OVCF are risk factors for developing new OVCF after PVP [11]. Bone cement leakage may cause higher incidence of new OVCF. Some other potential risk factors also did, including age, sex, Bone mineral density (BMD), Body mass index (BMI), and cement injection volume [4, 12, 13].

Bone cement leakage is the most common complication associated with PVP, whose incidence ranges from 5 to 80% [14–16]. At the same time, bone cement leakage may present a risk factor for new OVCF after PVP [4, 17, 18], and the pain caused by the leak will seriously reduce the quality of patient's life [19, 20]. Currently, risk factors about bone cement leakage are not completely confirmed and still controversial, including age, sex, Bone mineral density (BMD), Body mass index (BMI), injection volume of bone cement, steroid use, and some underlying chronic diseases [21, 22]. Considering that the existence of underlying diseases may lead to longer preoperative preparation, length of hospital stay and surgery duration, some other factors such as time from injury to surgery, time from hospitalization to surgery, and surgery duration are also included as predictors.

Nomogram is used worldwide to calculate the possibility of generating clinical events through complex computational formulas [23]. With the help of Nomogram, clinicians can assess the risk of clinical events, develop individualized treatment plans and follow-up more aggressively [24]. Considering the additional burden that post PVP bone cement leakage and new OVCF places on patients, this study evaluates OVCF patients treated with PVP using the Nomogram for identifying patients at high risk of bone cement leakage and new OVCF. To facilitate clinicians and others, a web-based calculator was created to facilitate use in assessing risk.

Materials and methods

Clinical data and selection criteria

Patients with OVCFS who underwent PVP surgery in Liuzhou People's Hospital from June 2016 to June 2018 were retrospectively analyzed. All patients were followed up for two years. The Institutional Review Board of Liuzhou People's Hospital has approved the plan. All patients had undergone PVP procedure interpretation and clinical data processing. Furthermore, written informed consents were received from all patients.

Bone mineral density (BMD) of L2 ~ L4 vertebral bodies was measured. Bone mineral density was measured by dual-energy X-ray absorptiometry (Osteocore 3, Medilink, Mauguio, France), and corresponding *t*-scores were calculated. The height and weight of each patient were also recorded to calculate BMI.

Inclusion criteria include primary osteoporosis whose bone density met the World Health Organization diagnostic criteria for osteoporosis, pain or local tenderness consistent with imaging findings, preoperative spinal X-ray and Magnetic resonance imaging (MRI) results, initial treatment with PVP, and new fractures detected by MRI after PVP. Exclusion criteria were non-osteoporotic VCF or compression fracture stress secondary to other factors, such as pathological fractures caused by metastatic tumors or hemangiomas, no PVP treatment, preoperative nerve root symptoms or spinal cord compression symptoms and clear history of trauma or no MRI examination for the new fracture after PVP.

Percutaneous vertebroplasty (PVP)

In this study, all PVP operations adopted the unilateral lateral approach to the vertebral arch. The amount of bone cement injection was determined by the size of the vertebral body and the degree of compression and leakage of the vertebral body. The C-arm X-ray machine was adjusted preoperatively. The patient's vertebral body's lower endplate was presented as a one-line shadow through the anteroposterior film. Bilateral pedicles were equidistant from the spinous process. Laterally, the endplate and the upper and lower edges of the pedicle were in line. Vital signs were monitored intraoperatively, and patients were in the prone position with regular skin disinfection. The puncture point was 3–4 cm near the spine with 5–10 ml 1% lidocaine anesthesia infiltrates until the periosteum. The cement needle puncture point was 3–4 cm near the spine with 30–45° abducent angles. Needle to the anterior 1/3 and adjust according to the location and depth of the needle. The puncture needlepoint should be in the vertebral body up and down the upper one-third of level and computer direction first 1/3. Pull out the pillow core observation after the presence of active bleeding. The bone cement powder ratio is 1:1, which was pumped into 10 ml syringes, gently pushed the pressor to the bone cement to the syringe mouth, and gradually injected under pressure when the bone cement filaments. A fluoroscope was used to monitor whether the bone cement was leaking or exceeding the midline of the vertebral body. The movement of the patient's lower limbs was also monitored. After 2–5 min, the pressurizer and syringe were removed and inserted into the needle core. After 2 min, the needle was pulled out, and the sterile dressing was applied under pressure for 3 min. The operation was over.

New OVCF identification criteria

The recurrence of patients with chest and lumbago was related to obvious tenderness in the corresponding site. X-ray examination showed corresponding partial wedge changes in OVCF, and MRI examination confirmed the presence of a new fracture. MRI showed low signal intensity on T1-weighted images and high signal intensity on T2-weighted images. MRI was also used to rule out other spinal diseases, including infections and malignancies.

Postoperative bone cement leakage

X-rays or CT scans were performed on all patients within three days after PVP surgery to assess the presence of cement leakage.

Statistical analysis

Risk factors

Univariate and multivariate analyses were performed on the occurrence of bone cement leakage and new OVCF after PVP to identify the related factors and risk factors. In univariate analysis, the t-test was performed on the samples to analyze quantitative data, and the chi-square test was used to analyze qualitative data. Logistic regression was used to analyze the occurrence relationship among bone cement leakage and age, sex, BMI, BMD, injection volume, injury to surgery, hospitalization to surgery, surgery time, and multiple vertebral fractures and steroid use. Besides, the possible relationship among the occurrence of new OVCF and age, gender, BMI, BMD, bone cement dosage, bone cement leakage, time from injury to surgery, time from admission to surgery, duration of surgery, multiple vertebral fractures, and steroid use were also analyzed. Univariate logistics regression analysis was used to determine its risk factors, and multivariate logistics regression analysis was further used to determine its independent risk factors.

Construction, validation and clinical application of nomogram

The Nomogram and web calculator were built as predictive models based on the results of logistic regression analysis and previous literature reports. Calibration plots of the clinical prediction models were plotted to determine the consistency of the models. The predictive power of the Nomogram was tested using tenfold cross-validation. The larger the area under the ROC curve (AUC), the stronger the predictive power of the model. The group with the largest AUC value was selected to plot the ROC curve. Decision curve analysis (DCA), where the Net benefit (NB) was plotted within a reasonable risk threshold consistent with clinical reality, could also be used to assess the clinical utility of the Nomogram for PVP risk and benefit. Based on DCA, clinical impact curve plots were developed to visually estimate the number of patients at risk for each risk threshold.

Statistical methods and software

Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were ratios. Continuous and categorical variables were compared by independent sample *t*-test and chi-square test. IBM SPSS Statistics version 26.0 (SPSS Inc, Chicago, IL, USA) and R Software version 3.6.2 performed the above statistical methods and applied multiple R packages, including regplot, RMS, RMDA, and Proc, to plot graphs such as Nomogram, Calibration Plot, DCA plots, and ROC curves. $P < 0.05$ was considered statistically significant.

Results

Patient baseline characteristics

A total of 385 patients met the inclusion criteria. There were 58 patients with new OVCF after surgery and 327 patients without OVCF. There were 81 patients with bone cement leakage after surgery and 304 patients without it. Chi-square test and independent-sample T-test were conducted, where detailed results were shown in Tables 1 and 2.

Baseline characteristics of the refracture group

The mean age of patients in the non-newly diagnosed OVCF group was 73.9, and that in the newly diagnosed OVCF group was 75.41 years. There was no statistical difference between the two groups ($P = 0.254$). In the non-newly developed OVCF group, the number of male patients (68 cases, 20.8%) was much lower than that of female patients (259 cases, 79.2%). The number of male patients (9 cases, 15.5%) in the newly developed OVCF group was also much lower than that of female patients (49 cases, 84.5%), which also showed no statistical difference between the two groups. Furthermore, there was no significant differences in height, injection volume, leakage, injury to surgery, hospitalization to surgery, and operation time between the two groups ($P < 0.05$). There was significant differences in body weight between the two groups ($P < 0.01$). The mean weight of the non-newly diagnosed OVCF group was significantly lower than that of the newly diagnosed OVCF group. The BMI was also significantly different ($P < 0.01$). In the newly developed OVCF group, the degree of osteoporosis (lower BMD

Table 1 Baseline characteristics of patients with no refracture and refracture

Variable	No refracture group ($N=327$)	Refracture group ($N=58$)	P value
Age (years)	73.9 ± 9.6	75.4 ± 6.9	0.254
Sex			0.356
Male	68 (20.8%)	9(15.5%)	
Female	259 (79.2%)	49(84.5%)	
High (cm)	154.6 ± 8.3	154.9 ± 8.2	0.809
Weigh (kg)	49.6 ± 13.3	54.8 ± 10.7	< 0.01
BMI	20.7 ± 5.3	22.8 ± 3.8	< 0.01
BMD	−4.3 ± 0.8	−4.6 ± 0.6	< 0.01
Hospitalized date (days)	9.3 ± 4.7	10.1 ± 4.3	0.218
Injection volume (ml)	4.1 ± 1.0	4.14 ± 1.2	0.862
Leakage			0.531
No	260 (79.5%)	44 (75.9%)	
Yes	67 (20.5%)	14 (24.1)	
Surgery time (min)	53.2 ± 20.3	57.1 ± 19.6	0.188
Hospitalization to surgery (days)	5.2 ± 2.9	6.1 ± 3.6	0.053
Injury to surgery (days)	29.4 ± 45.3	26.5 ± 27.0	0.634
Anti-osteoporosis therapy			< 0.01
No	199 (60.9)	46 (79.3%)	
Yes	128 (39.1)	12 (20.7%)	
Multiple vertebral fracture			< 0.01
No	185 (56.6%)	20 (34.5%)	
Yes	142 (43.4%)	38 (65.5%)	
Steroid use			< 0.01
No	281 (85.9%)	39 (67.2%)	
Yes	46 (14.1%)	19 (32.8%)	

value) was higher, the proportion of standard anti-osteoporosis therapy was lower, and multiple vertebral fractures and Steroid use were higher in the initial OVCF group ($P < 0.01$). The detailed results were shown in Table 1.

Baseline characteristics of the bone cement leakage group

There was no significant differences in age, sex, height, weight, BMI, BMD, time from admission to surgery, time from injury to surgery, and steroid use between the two groups ($P < 0.05$). The injection amount of bone cement was significantly different between the two groups ($P < 0.05$). The injection amount of bone cement in the no-leakage group was lower than that in the leakage group. Duration of surgery also varied significantly ($P < 0.01$), where the leakage group's operation time was longer. Additionally, multiple vertebral fractures were more common in the leakage group ($P < 0.001$). The detailed results were shown in Table 2.

Risk factors for new OVCF after surgery

Logistic regression analysis results were shown in Table 3. Analysis results of univariate Logistic analysis showed that BMI, BMD, postoperative use of anti-osteoporosis therapy, primary OVCF multi-vertebral fracture, and steroid use were related to the risk factors of postoperative new OVCF (all $P < 0.05$). The OR value (odds ratio) showed the relative risk of newly developed OVCF.

In multivariate Logistic regression analysis, higher BMI (OR = 1.094, 95% CI = 1.035–1.156, $P < 0.01$) and more severe osteoporosis (OR = 1.894, 95% CI = 1.181–3.038, $P < 0.01$) patients were with higher risk. Primary multi-vertebral fracture of OVCF (OR = 1.929, 95% CI = 1.028–3.620, $P < 0.05$) and steroid use (OR = 4.070, 95% CI = 2.005–8.264, $P < 0.05$) patients were with higher risk. In addition, patients with postoperative standard use of anti-osteoporosis were with lower risk (OR = 0.385, 95% CI = 0.187–0.792, $P < 0.05$). Therefore, high BMI, low BMD, primary multi-vertebral fracture of OVCF and steroid use were independent risk factors for newly diagnosed OVCF after surgery. Furthermore, after surgery, standardized use of anti-osteoporosis after surgery was an independent factor for reducing newly diagnosed OVCF.

Risk factors for postoperative bone cement leakage

Logistic regression analysis results were shown in Table 4. The univariate logistic analysis results showed that the injection amount of bone cement, the duration of operation, and whether the multiple vertebral fractures were related to the risk factors of bone cement (all $P < 0.05$). The OR value (odds ratio) showed the relative risk of cement leakage.

In multivariate logistic regression analysis, higher injection volume of bone cement (OR = 1.283, 95% CI = 1.004–1.640, $P < 0.05$), longer operation time (OR = 1.0.15, 95% CI = 1.003–1.027, $P < 0.05$) and multiple vertebral fractures (OR = 2.456, 95% CI = 1.461–4.130, $P < 0.05$) patients were at greater risk. Therefore, higher injection volume of bone cement, longer operation time, and multiple vertebral fractures were independent risk factors for postoperative bone cement leakage.

Development and validation of the nomogram for the risk of new OVCF after PVP

Based on the results of the logistic regression analysis in Table 3 ($p < 0.2$) combined with previous literature, a Nomogram (Fig. 1) and web calculator (https://dr-lee.shinyapps.io/RefractureApp/) were developed to predict the new OVCF postoperatively. Calibration curves were used to evaluate the predicted results and observed results, showing good agreement (Fig. 2A). The predictive ability of the Nomogram was

Table 2 Baseline characteristics of patients in the non-leakage group and the leakage group

Variable	Non-leakage group (*N* = 304)	Leakage group (*N* = 81	*P* value
Age (years)	74.3 ± 8.7	74.3 ± 8.6	0.885
Sex			0.493
Male	63 (20.7%)	14 (17.3%)	
Female	241 (79.3%)	67 (82.7%)	
High (cm)	154.3 ± 8.5	155.7 ± 14.3	0.187
Weigh (kg)	50.32 ± 12.77	50.86 ± 10.7	0.741
BMI	21.1 ± 5.2	20.9 ± 5.5	0.758
BMD	−4.38 ± 0.8	−4.54 ± 0.5	0.180
Hospitalized date (days)	9.3 ± 4.7	9.8 ± 4.4	0.392
Injection volume (ml)	4.1 ± 1.0	4.4 ± 1.2	< 0.05
Surgery time (min)	52.3 ± 18.7	59.5 ± 24.5	< 0.01
Hospitalization to surgery (days)	5.28 ± 2.9	5.86 ± 3.3	0.128
Injury to surgery (days)	29.4 ± 46.0	27.44 ± 27.8	0.712
Multiple vertebral fracture			< 0.001
No	177 (58.2%)	28 (34.6%)	
Yes	127 (41.8%)	53 (65.4%)	
Steroid use			0.119
No	248 (81.6%)	72 (88.9%)	
Yes	56 (18.4%)	9 (11.1%)	

Table 3 Univariate and multivariate Logistic regression analysis of recurrent vertebral compression fractures after percutaneous Vertebroplasty in patients with osteoporosis

Variable	Univariate OR (95% CI)	*P* value	Multivariate OR (95% CI)	*P* value
Age (years)	1.019 (0.987–1.053)	0.252	–	–
Sex				
Male	Ref	Ref	–	–
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 (days)	1.033 (0.981–1.088)	0.223	–	–
Injection volume (ml)	0.976 (0.747–1.276)	0.976	–	–
Leakage				
No	Ref	Ref	–	–
Yes	1.235 (0.639–2.386)	0.530	–	–
Surgery time (min)	1.009 (0.996–1.022)	0.188	1.894 (1.181–3.038)	0.181
Hospitalization to surgery (days)	1.081 (0.998–1.171)	0.057	1.071 (0.981–1.169)	0.124
Injury to surgery (days)	0.998 (0.991–1.006)	0.634	–	–
Anti-osteoporosis therapy				
No	Ref	Ref	Ref	Ref
Yes	0.406 (0.207–0.795)	< 0.01	0.385 (0.187–0.792)	< 0.05
Multiple vertebral fracture				
No	Ref	Ref	Ref	Ref
Yes	2.475 (1.38–4.43)	< 0.01	1.929 (1.028–3.620)	< 0.05
Steroid use				
No	Ref	Ref	Ref	Ref
Yes	2.976 (1.584–5.592)	< 0.05	4.070 (2.005–8.264)	< 0.001

Table 4 Univariate and multivariate Logistic regression analysis of the risk of bone cement leakage after percutaneous vertebroplasty in patients with osteoporosis

Variable	Univariate OR (95% CI)	*P* value	Multivariate OR (95% CI)	*P* value
Age (years)	1.000 (0.972–1.029)	0.996	–	–
Sex				
Male	Ref	Ref	–	–
Female	1251 (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 (days)	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 (days)	1.059 (0.983–1.140)	0.130	–	–
Injury to surgery (days)	0.999 (0.993–1.005)	0.711	–	–
Multiple vertebral fracture				
No	Ref	Ref	Ref	Ref
Yes	2.638 (1.582–4.400)	< 0.001	2.456 (1.461–4.130)	< 0.01
Steroid use				
No	Ref	Ref	–	–
Yes	0.554 (0.261–1.173)	0.123	–	–

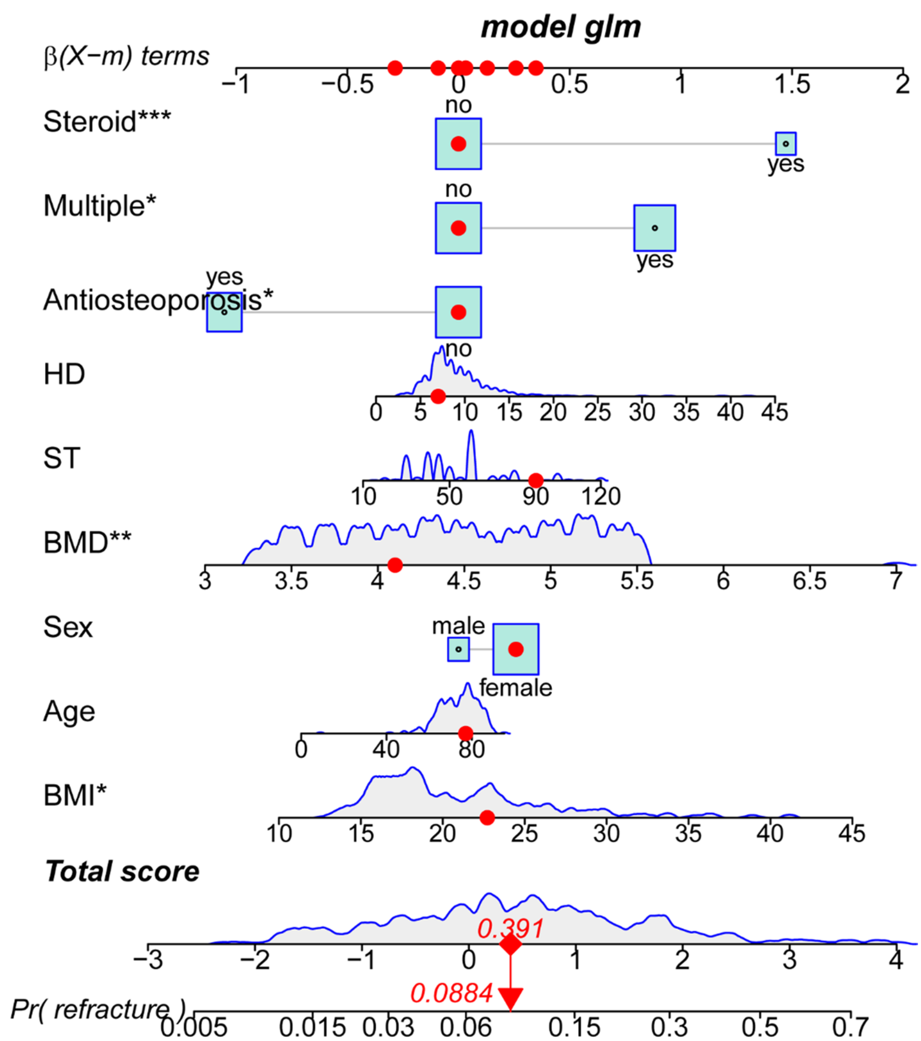


Fig. 1 Nomogram for predicting new-onset OVCF after PVP

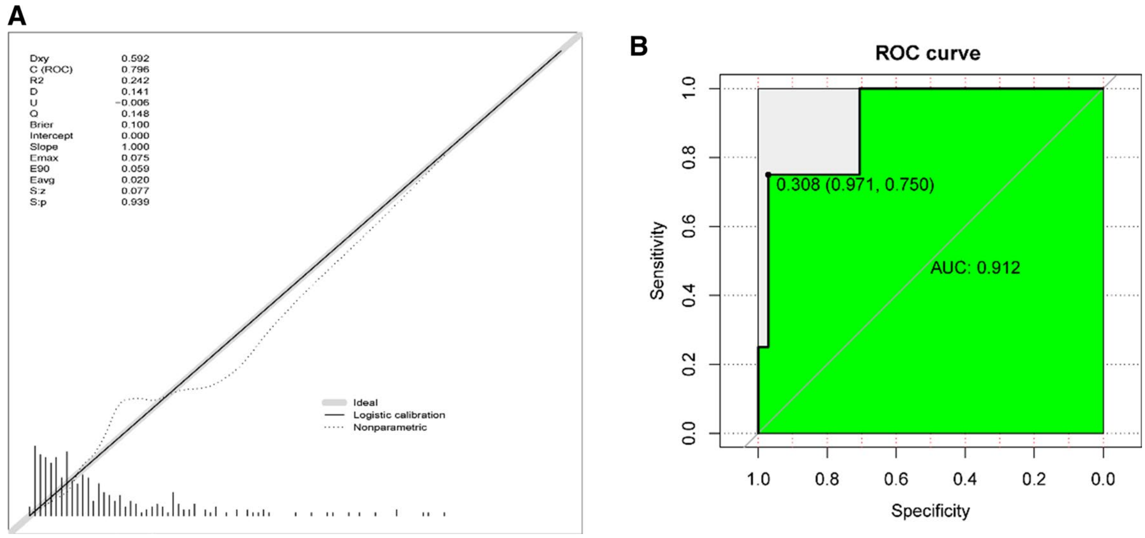


Fig. 2 Calibration plots and ROC curves for predicting new OVCF Nomogram after PVP. **A** Calibration plot of the Nomogram, showing very good agreement **B** ROC curve for the highest AUC (0.912) of the predicted refraction nomogram after tenfold cross-validation. The mean AUC for tenfold cross-validation was 0.726

validated using tenfold cross-validation with a maximum AUC of 0.912 (Fig. 2B) and a mean AUC of 0.726, indicating that the Nomogram had a good predictive ability.

Figure 1, Nomogram approach: place the values for each patient on each variable axis and draw lines upwards to determine the number of points for each variable value. The sum of these numbers is placed on the total number of points axis. Draw a line down to the probability axis to determine the probability of a new OVCF after surgery. ST: time to surgery; HD: time from admission to surgery.

Development and validation of a nomogram for bone cement leakage risk after PVP

Based on the results of the logistic regression analysis in Table 4 and previous literature reports, a Nomogram (Fig. 3) and web calculator (https://dr-lee.shinyapps.io/LeakageApp/) were created for the risk of postoperative bone cement leakage. Calibration plots were used to assess the agreement between the predicted and observed actual results (Fig. 4A). The predictive ability of the Nomogram was validated using tenfold cross-validation with a maximum AUC of 0.793 (Fig. 4B) and a mean AUC of 0.656, indicating that the Nomogram had a good predictive ability.

Clinical utility of nomogram for new OVCF risk after PVP

As shown in the DCA curve (Fig. 5A), the threshold value of about 0.1–0.8 had the maximum return. Furthermore, the clinical impact diagram of the training set (Fig. 5B) showed that there were always more expected high-risk patients than actual newly developed OVCF within the most favorable threshold probability range, which was also accompanied by an acceptable cost–benefit ratio.

Clinical applicability of nomogram for bone cement leak during PVP

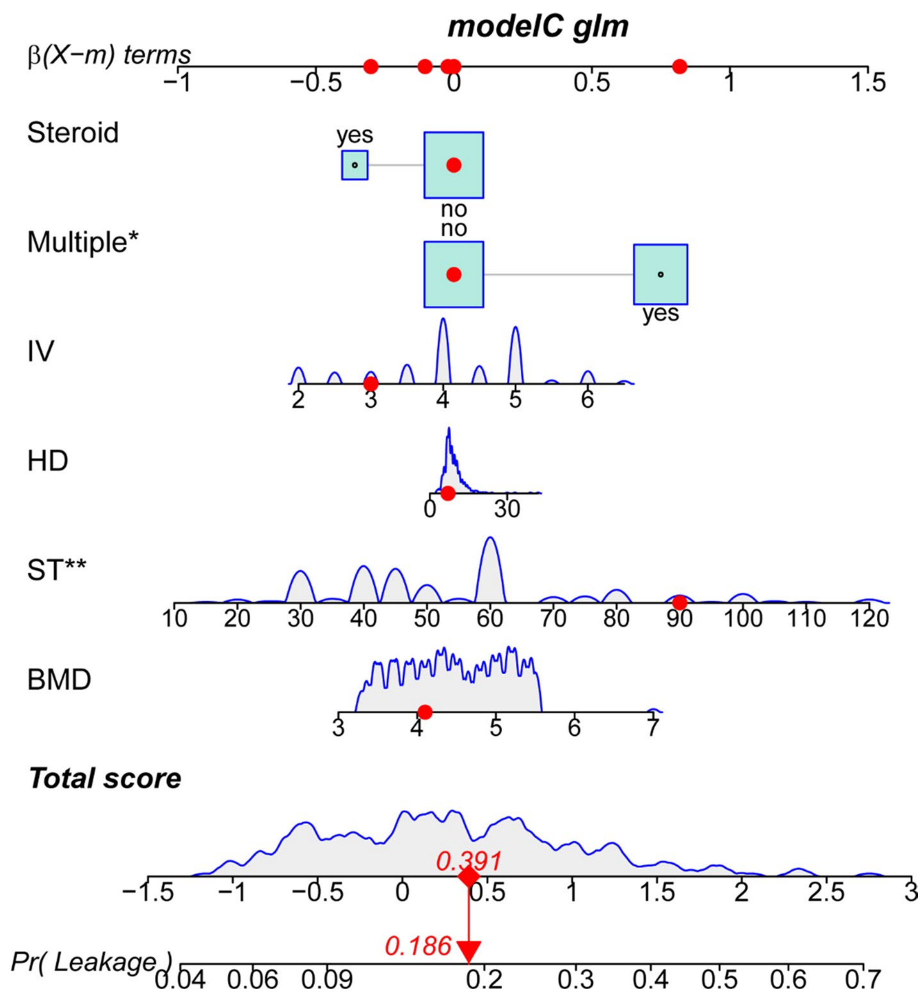
As shown in the DCA curve (Fig. 6A), the threshold value of about 0.1–0.7 had the maximum return. Furthermore, the clinical impact diagram of the training set (Fig. 6b) showed that there were always more expected high-risk patients than actual bone cement patients within the most favorable threshold probability range, which was also accompanied by an acceptable cost–benefit ratio.

Discussion

The nomogram has now been applied to a variety of conditions, including in the field of spine surgery, such as the nomogram for spine surgery evaluation using patient symptoms, baseline disease, demographics and prior spine care developed by Zach Pennington et al. and the development of prediction calculator about a non-routine discharge and length of stay after spine surgery by Daniel Lubelski et al. [25, 26].To the best of our knowledge, our study may be the first to examine the effect of operation duration on postoperative complications of PVP and to use a nomogram to assess the risk of postoperative cement leakage and new compression fractures.

With the aging of the population worldwide, osteoporosis has become a common disease that threatens the health

Fig. 3 Nomogram of the risk of bone cement leakage after percutaneous Vertebroplasty in patients with osteoporosis



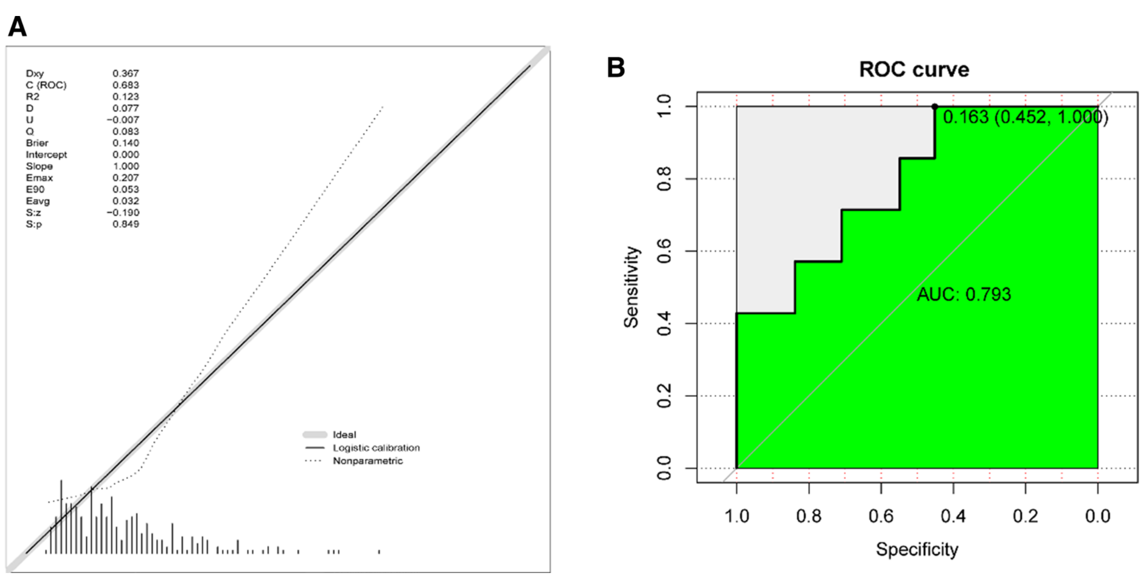


Fig. 4 Calibration plot and ROC curve for predicting bone cement leakage Nomogram **A** Calibration plot of the predicted bone cement leakage nomogram, showing that it had a good agreement **B** ROC curve of the highest AUC (0.793) of the Nomogram for predicted bone cement leakage after tenfold cross-validation. The mean AUC for tenfold cross-validation was 0.656

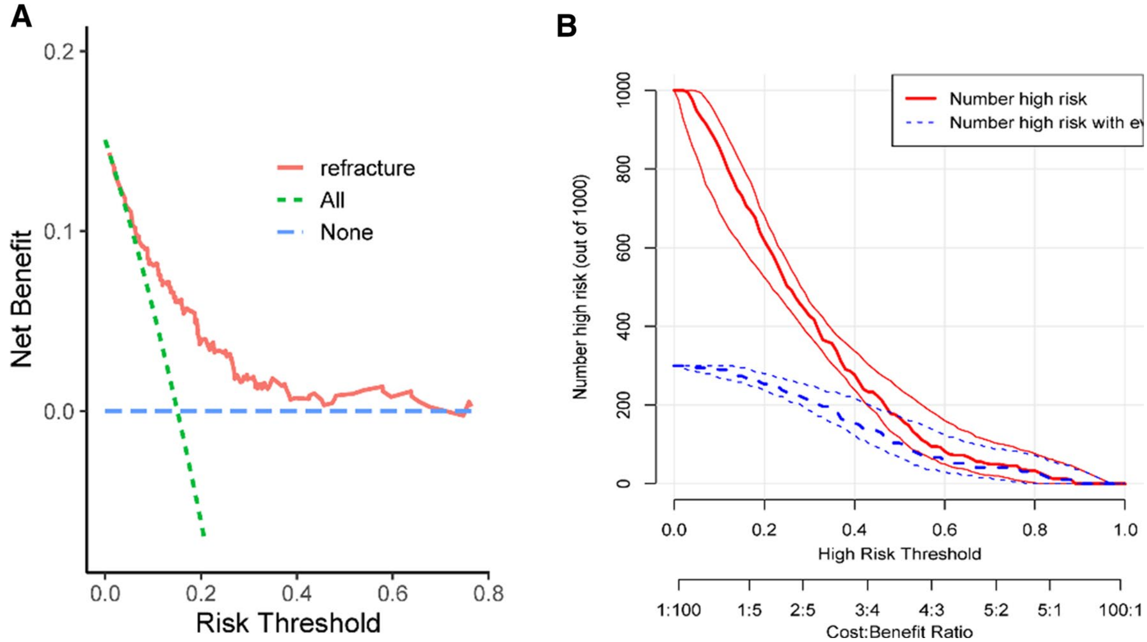


Fig. 5 DCA and clinical impact maps for predicting refacture Nomogram **A** Nomogram decision curve (DCA) and clinical implications for the risk of new compression fracture after percutaneous osteoplasty. **B** The red curve (Number of high risks) indicated the number of people classified as positive (high risk) by Nomogram for each threshold probability. The blue curve (Number of high risks with the outcome) representd the number of true positives under each threshold probability

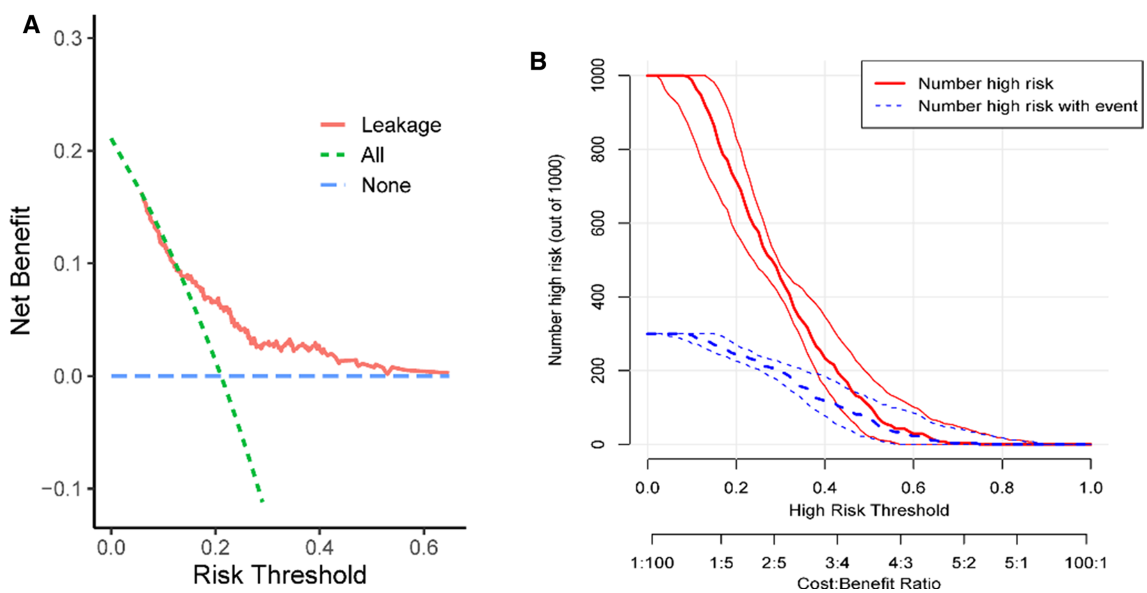


Fig. 6 DCA and clinical impact maps for predicting bone cement leakage. **A** Nomogram decision curve (DCA) and clinicalimplications for bone cement leakage risk for percutaneousosteoplasty. **B** The red curve indicated the number of peopleclassified as positive by Nomogram for each thresholdprobability. The blue curve represented the number of truepositives under each threshold probability.

of older people, especially postmenopausal women. One of the main complications of this disease is vertebral compression fracture [27]. Considering the high incidence of OVCF and PVP surgery's popularity, it was of great clinical significance to screen out high-risk patients with bone cement leakage and newly developed OVCF before PVP. Bone cement leakage was a major complication of PVP, which was asymptomatic in most cases. However, cement leakage in the spinal canal or the foramina may result in nerve compression symptoms. If the symptoms are severe, additional decompression surgery may be required [28]. Besides, intervertebral cement leakage may increase the risk of fracture of adjacent vertebrae [29].

The injection volume of bone cement was a concern for the spine surgeon. Studies have demonstrated that the greater the injection amount of bone cement, the higher pain relief caused by OVCF. Therefore, it was recommended to inject more bone cement as much as possible [30]. However, another meta-analysis results suggest that patients who inject large amounts of bone cement may be at a higher risk of bone cement leakage [31]. It was likewise the same as the results of this study. One study recommended the injection of less than 3.5 mL for the thoracic vertebrae and less than 4.2 mL for the lumbar vertebrae to avoid cement leakage [32].

The results of this study showed that patients with cement leakage tended to have longer operative time. Longer operation time meant a more difficult operation or more vertebrae need to be operated, which in some ways meant more severe fracture. Simultaneously, the increased severity of the fracture made the operation more difficult, which meant that the surgeon had difficulty getting the needle into the desired location, thus affecting the distribution of the bone cement [32]. Therefore, whether the duration of the operation itself or the influence of other factors (such as fracture severity) led to an increase in the risk of bone cement leakage further needed further study and analysis.

Studies had shown that when the first OVCF was diagnosed, and new multi-vertebral OVCF would repeatedly occur [33]. MS OVCF causes the spine to shorten and bend forward, which can develop into scoliosis or kyphosis, even with severe lower back pain. The kyphosis not only made it difficult to walk and reach objects but also caused chronic back pain and loss of height over time [34]. It has been proved by relevant clinical practice that PVP is an effective method for the treatment of OVCF and is widely used in clinical practice. However, newly developed OVCF is common after surgery. Related studies indicated that the incidence of OVCF is about 6.5–51% [35], which was one reason that seriously affects the postoperative quality of life of patients with PVP [17, 36, 37]. The cause of the new OVCF was currently controversial. Some scholars believed that the emergence of new OVCF one year after PVP might be a natural process of senile osteoporosis [29]. Whether PVP can lead to an increased risk of new OVCF in adjacent vertebral bodies has not been confirmed yet [38, 39]. Some scholars believed that PVP was not a risk factor for new OVCF and can prevent further height loss [40]. A meta-analysis concluded that PVP as a minimally invasive procedure for the treatment of OVCF was a better option than conventional treatment because these techniques provided not only immediate relief of back pain but also avoided many complications in patients who became bed-bound due to conservative treatment, and might not increase the incidence of new OVCF in the adjacent vertebral body [41].

In previous studies, women, older age, and low BMD have been identified as significant risk factors for OVCF [42]. Elderly patients and postmenopausal women usually had lower BMD, which might be why new OVCF and low BMD always appeared together after PVP. Logistic regression analysis was performed on gender, age and BMD in this study. There was no statistical difference between gender and age ($P < 0.05$), while BMD had a significant difference ($P < 0.01$). Considering the limited sample size and the single-center retrospective study, there was a risk of bias in the data.

The results of statistical analysis showed that the average body weight and BMI of the newly developed OVCF group were (54.86 ± 10.7) kg and (22.8.77 ± 2.16) kg/m2, which were significantly higher than those of the non-newly developed OVCF group (49.65.40 ± 13.13) kg and body mass index (20.74 ± 5.38)kg/m2. Compared to body weight, BMI can reflect the degree of body obesity more objectively and reduce the error caused by different heights. Thus, BMI was included in the Logistic regression correlation analysis. Most OVCF patients were postmenopausal women and older adults who was usually overweight and had a higher than normal BMI [43]. Considering dietary habits, lack of exercise and use of hormonal medications, estrogen levels in postmenopausal women tent to drop sharply, which leads to a gradual decline in BMD, as in older adults [44]. These patients with high BMI had a higher incidence of severe osteoporosis and new-onset OVCF after PVP surgery, which was consistent with this study's results. Similarly, logistics analysis results show that the OR value of standard anti-osteopathic therapy was 0.385, 95% CI is 0.187–0.792, $P < 0.05$, where there was a statistically significant difference (Table 2). Therefore, it was suggested that postoperative standard anti-osteoporosis treatment, increasing patient BMD, and lowering BMI can effectively reduce the risk of new OVCF after surgery.

Older patients tent to have more underlying medical conditions, resulting in longer hospital stays, and often had a longer surgical duration due to difficulty in cooperating with doctors during surgery [45]. Considering these factors, this study collected the time from admission to surgery and surgery duration for analysis. Analysis results showed no significant statistical difference ($P > 0.05$). The amount of cement injection and the presence of leakage were also factors of concern. Whether these factors increased the risk of newly diagnosed OVCF, various studies were different in different cases and different regions, which had no straightforward conclusion. In this study, the authors compared the injection volume and leakage of bone cement between the newly diagnosed OVCF group and the non-newly diagnosed OVCF group. There was no statistically significant difference between the two groups ($P > 0.05$). Although this finding did not support the hypothesis that excessive cement and leakage increased the risk of adjacent fractures, reliable conclusions could not be drawn due to the small sample size of this study's cases. A further focus was required on this point, and a larger sample size was needed to draw reasonable conclusions.

Multiple vertebral fractures during the first OVCF were regarded as a risk factor for new OVCF after PVP. A clinical study found no difference in the incidence of new OVCF between PVP and conservative treatment. The number of initial OVCF was the only risk factor for new OVCF after surgery [9]. Simultaneously, some studies found that the presence of more than two preexisting OVCF was the only independent risk factor for new OVCF [46]. However, some studies believed that the occurrence of new fractures after PVP was not related to the number of initial OVCF [47]. The results of this study confirmed that multiple initial OVCF segments had a 1.92-fold higher risk of new OVCF than single postoperative ones (OR = 1.929, 95% CI = 1.028–3.620, $P < 0.05$).This may be related to the fact that patients with multiple vertebral compression fractures may have a more severe osteoporosis. Meanwhile, whether the cemented strengthening of multiple vertebrae leads to an increased force in the remaining uncemented vertebrae had no firm conclusion [48]. A meta-analysis and a review concluded that there was no increased risk of compression fractures in the remaining uncemented vertebrae after the cemented strengthening of the vertebrae [49]. Considering the advantages of PVP in terms of vertebral height restoration and avoiding the serious consequences of prolonged bed rest due to pain in the elderly, an analysis of insurance claims data showed that patients treated with PVP had lower mortality and morbidity rates compared to conservative treatment [50].Therefore, taking into account the possible complications of their PVP, such as new-onset OVCF, we still recommend seeking the opportunity to undergo PVP treatment when possible.

This study attempted to use a new Nomogram to predict the likelihood of bone cement leakage and new OVCF in OVCF patients after PVP. This Nomogram approach had been proved to be a reasonable and feasible approach in multiple disease models [51]. The screening of Nomogram predictors has not been confirmed. Standard criteria included statistical analysis ($P < 0.2$), clinical experience, literature reports and other factors [52]. In this study, statistics, relevant literature and clinical experience were integrated. Nomogram was constructed by incorporating predictors with univariate logistics analysis integrated into $P < 0.2$ and previous research results. The ROC curves, as well as the AUC values of the two nomograms, demonstrated excellent predictive performance of the two nomograms.

However, ROC has some shortcomings, as it only predicts the model's accuracy and is not a guide to the value of the model in clinical practice. DCA is a method of assessing the benefits of treatment in a range of patients and is used to analyze the risk of under- and over-treatment to facilitate the choice of treatment modality. As could be visually observed in Figs. 5A and 6A, the DCA was represented as a curve with a gain score on the vertical axis and a probability threshold on the horizontal axis. Predicting the risk of new compression fractures after surgery (Fig. 5A) at 0.1 to approximately 0.8 and predicting the risk of cement leakage after PVP (Fig. 6A) at 0.1 to approximately 0.7 both had good gain values. Therefore, clinicians need to look at whether to continue treatment with PVP when the patient's risks outweigh the benefits when performing PVP.

Based on previous studies, clinicians could not calculate the probability of postoperative bone cement leakage and new OVCF based on the identified risk factors. With this Nomogram, clinicians could use an accurate and easily implemented method to calculate the probability of bone cement leakage and new OVCF after PVP, which was of profound significance for postoperative prevention, treatment, and targeted follow-up. It also guides further prospective studies.

This study has some limitations: (1) The clinical data are from the orthopedics department of our hospital, and lack of comparison with various centers; (2) Compared to inpatients, the compliance of out-of-hospital patients decrease to a greater extent, which may lead to the loss of follow-up data to a certain extent. (3) As a retrospective study, there may be a certain degree of selection bias. Therefore, it is necessary to conduct a prospective study to verify the accuracy of this Nomogram.

Conclusions

This study showed that the independent risk factors for new OVCF after PVP in OVCF patients were BMI, BMD, multiple vertebral fractures in primary OVCF, failure to receive anti-osteoporosis treatment, and steroid use. The independent risk factors for bone cement leakage after PVP in OVCF patients were higher cement injection volume, longer operative time, and multiple vertebral fractures. The creation of a Nomogram and webpage calculator can objectively and accurately predict the probability of new OVCF and the likelihood of postoperative cement leakage and can help clinicians to conveniently assess the risk of clinical events and personalize treatment plans.

Authors' contributions CLY and ZHH designed the study. WLL, CLY and HSW performed the study and analyzed the data. WLL, HSW and STD wrote the manuscript. ZRT provided the expert consultations and clinical suggestions. LHC, XTC and ZHH conceived of the study, XTC participated in its design and coordination, ZRT helped to draft the manuscript. All authors reviewed the final version of the manuscript.

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Data availability All data in this article can be requested by communicating with the author of the communication.

Declarations

Conflict of interest The authors declare that they have no competing interests.

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