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RESEARCH

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Screening risk factors for the occurrence of wedge effects in intramedullary nail fixation for intertrochanteric fractures in older people via machine learning and constructing a prediction model: a retrospective study

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Abstract

Purpose The wedge effect (V-effect) is a common complication in intramedullary nailing surgery for intertrochanteric fractures and can significantly affect postoperative outcomes. The purpose of this study was to screen risk factors for the intraoperative V-effect in intertrochanteric fractures and to develop a clinical prediction model.

Methods A total of 319 patients (77 patients who developed V-effects) from China were randomly divided into a training set ($n = 223$) and a validation set ($n = 96$) at a ratio of 7:3. The variables were screened via 3 machine learning methods, including least absolute shrinkage and selection operator (LASSO) regression, the Boruta algorithm, and recursive feature elimination (RFE). Variables that appeared in the three machine learning methods were included in multivariate logistic regression to construct predictive models. Spearman correlation analysis was used to exclude covariance between variables. Restricted cubic splines (RCSs) were used to analyze the relationships among femoral lateral wall thickness, BMI, and the V effect. The differentiation, calibration and clinical applicability of the model were assessed, and the reasonability of the model was analyzed.

Results Machine learning identified 8 variables that appeared in these 3 machine learning methods, and the covariance between these 8 variables was excluded ($r < 0.6$). BMI, surgical experience, a lesser trochanteric fracture, the thickness of the lateral wall, the insertion point, bone density, fracture classification, and holiday surgery were found to be risk factors for the occurrence of the V-effect via multivariate logistic regression. The RCS analysis revealed that the lateral wall thickness, BMI, and occurrence of the V effect were linearly related. The final predictive model had good differentiation, calibration and clinical applicability, and it had better predictive efficacy than the other models did.

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Conclusion This study employed three machine learning variable selection methods—the LASSO, RFE, and Boruta algorithms—to construct a V-effect predictive model. The model enables orthopedic surgeons to better understand the risk factors associated with the V-effect and provides a reference for surgeons to implement appropriate measures to reduce the incidence of the V-effect.

Keywords Machine learning, Older people, Prediction model, Intramedullary fixation, V-effect

Introduction

Intertrochanteric fractures occur mainly in older people [1–4]. As the aging population increases worldwide, the incidence of intertrochanteric fractures is increasing annually, thus placing serious economic and nursing burdens on the medical system and families [5–7].

Falling is a common form of injury that leads to serious intertrochanteric fractures [8, 9]. At present, the mainstream treatment schemes for intertrochanteric fractures include single-nail proximal femoral nail antirotation (PFNA) fixation, intertrochanteric antegrade nail (InterTAN) fixation, and extramedullary screw-plate devices [10–15]. However, coxa vara after intramedullary nail surgery is a concern, and the presence of coxa vara can greatly affect the tip apex distance (TAD) of the intramedullary nail, which in turn may affect the long-term survival of internal fixation. The reasons for this phenomenon are still unclear.

The V effect may play an important role in the failure of intramedullary nails [16, 17]. It refers to a wedge-shaped separation of the fracture site caused by the insertion of the main intramedullary nail, and the most common manifestation is hip varus (Fig. 1a, b); moreover, it can lead to the inability of the cervical nail to be inserted into the axial position of the femoral neck, which can easily lead to postoperative internal fixation failure [16, 18] (Fig. 1c, d, e). However, there is currently limited research on the V effect, and some studies suggest that insufficient bone removal at the entry point can lead to the V effect during the insertion of the main nail [19, 20].

In theory, the V-effect could be caused by multiple potential factors, such as a smaller femoral canal size, reduction quality, unstable fracture, and bone density [17, 20, 21], but there is currently almost no research on screening risk factors and constructing clinical prediction models for the V-effect in related studies on intertrochanteric fractures. If we can identify the relevant risk factors that lead to the V-effect in advance before surgery and predict whether a patient is at high risk for the V-effect, we can take some steps to prevent negative outcomes from the relevant risk factors in advance,

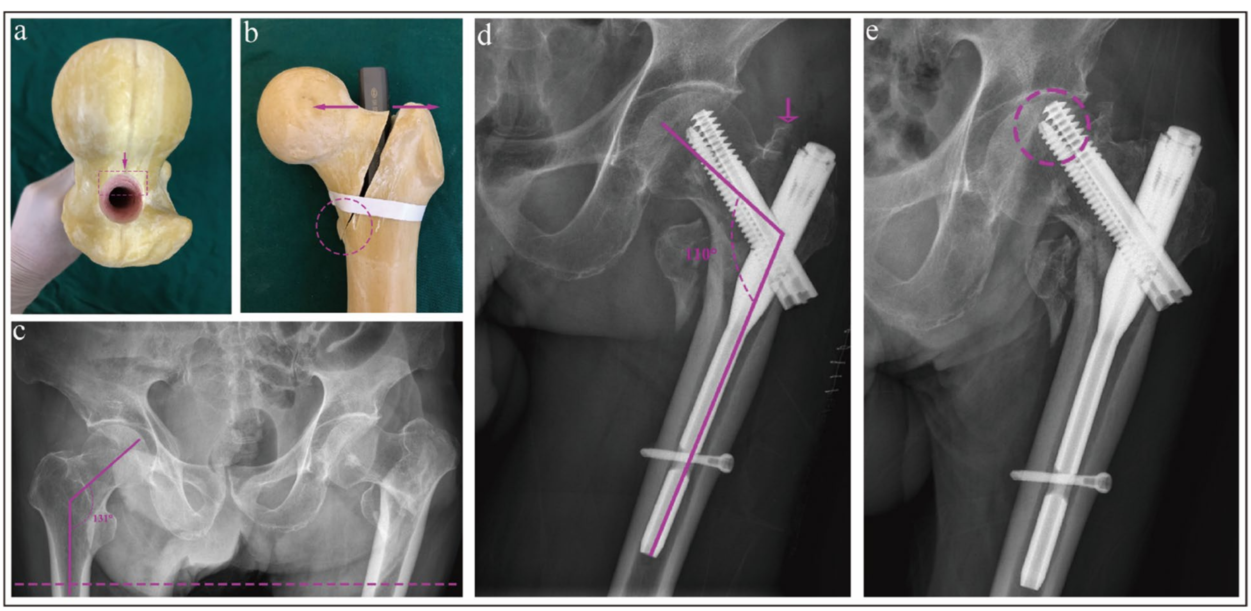

Fig. 1 **a** Hard bone at the base of the femoral neck. **b** Coxa vara caused by insufficient bone removal at the base of the femoral neck. **c** The femoral abduction angle on the healthy side of the patient before surgery was 131°. **d** Intraoperative use of intramedullary nails for fixation resulted in V-effect-induced coxa vara, and the patient's neck nail could not be fixed to the central axis of the femoral neck. **e** Six months after surgery, the patient's cervical nail was cut off

which will greatly reduce the probability of the V-effect occurring.

Therefore, this study utilized various machine learning methods to screen for risk factors that lead to the V-effect and constructed a clinical prediction model via multivariate logistic regression. This method can be used to analyze each patient quantitatively and provide valuable references for early interventions involving the V-effect.

Methods

Demographics

This study was approved by the Ethics Committee of Guihang Guiyang 300 Hospital (202304 A). All methods were carried out in accordance with relevant guidelines and the Declaration of Helsinki. In this retrospective study, we analyzed the clinical data of 391 older patients from 2019 to 2021. The trial was registered (ChiCTR2300071086) and included a training set ($n = 223$) and a validation set ($n = 96$) (Table 1). All the involved patients needed a plain pelvic film and an X-ray of the affected side of the hip joint before surgery. The inclusion criteria were as follows: 1) aged ≥65 years, 2) had a closed intertrochanteric fracture, and 3) complete case data. The exclusion criteria were as follows: 1) severe multiple fractures; 2) pathological fractures; 3) femoral neck fractures; and 4) serious basic diseases, including respiratory, circulatory, and endocrine system diseases (Fig. 2).

Variable selection

This study used 3 machine learning methods to screen the variables. In the baseline analysis, a lesser trochanter fracture refers to a complete fracture and displacement of the lesser trochanter. The doctor's surgical experience refers to whether the surgeon has performed more than 3 years of intramedullary nail surgeries for hip fractures. If the surgeon has performed more than 3 years of intramedullary nail surgery for hip fractures as an operator, we believe that the doctor has relatively rich surgical experience. The nail insertion points for intramedullary nail surgery can be divided into two main types: one uses the tip of the greater trochanter as the insertion point, and the second uses the tip of the greater trochanter 5 mm inward. The thickness of the lateral wall of the femur refers to a straight line that intersects with the intertrochanteric line, 3 cm below the unnamed nodule of the greater trochanter and 135° from the femoral shaft. The distance between these two points is the thickness of the lateral wall. The patients included in this study were all those who underwent surgery, and the surgical methods mainly included InterTAN and PFNA fixation. Through hip joint anteroposterior X-ray, the angle between the femoral neck axis and the femoral shaft axis is measured, and this angle is known as the neck–shaft angle. If it is less than 110°, it is defined as coxa vara. Bone density is primarily defined by the T score, where a T score ≥ − 1 is defined as normal bone density, − 2.5 < T score < − 1 is defined as osteopenia, and a T score ≤ − 2.5 is defined as osteoporosis. There are three time points for surgery: < 24 h after injury, 24 ~ 72 h, and > 72 h. The types of medullary cavities are classified according to the Dorr classification, with the main evaluation index being the canal flare index (CFI). The main evaluation method is the ratio of the width of the medullary cavity 2 cm above the lesser trochanter to the narrow part of the medullary cavity. Type A is a champagne-type medullary cavity with a CFI > 4.7, type B is a normal-type medullary cavity with a CFI 3.0 ~ 4.7, and type C is a chimney-type medullary cavity with a CFI < 3.0 [22]. The anesthesia methods are mainly divided into two types: spinal anesthesia and general anesthesia. Secondary surgery refers to surgery that has already been performed on the opposite side due to a hip fracture.

Data analysis

The data were analyzed with SPSS 25.0 (IBM, Chicago, USA) and R software (version 4.2.1). For baseline data analysis, all continuous variable data are expressed as the means ± standard deviations and quarters. Continuous variables associated with baseline characteristics were analyzed using the Mann–Whitney U test or independent samples t test, and the chi–square test or Fisher's exact probability method was used for categorical variables. This study used LASSO regression (glmnet package), the Boruta algorithm (Boruta package), and RFE (Carnet package) for univariate screening. Multivariate logistic regression was used for modeling (glm package), and a column chart (rsm package) was drawn. The RCSs and correlation heatmaps were drawn via the ggplot and Corrplot packages. ROC curves were drawn via the ggROC and pROC packages. Calibration curves were drawn via the rms and risk regression packages. The Hosmer–Lemeshow test was performed via the ResourceSelection package. DCA and CIC curves were drawn via the rmda package with dcurves and dca.

Results

Univariate selection

Three machine learning methods, namely, LASSO regression (Fig. 3a, b, c), the Boruta algorithm (Fig. 3d, e), and RFE (Fig. 3f, g), were employed. An analysis of each screening method via a Venn diagram (Fig. 3h) revealed that eight variables were present in all three variable

Table 1 Baseline characteristics

Variables	**All**	**Validation set (*n* = 96)**	**Training set (*n* = 223)**	***P* value**
Age (years)	82.0 (76.0, 87.0)	80.5.0 (76.0, 87.0)	83.0 (76.0, 87.0)	0.39
BMI (kg/m^2)	23.0 (21.0, 26.7)	22.9 (21.0, 25.7)	23.3 (21.0, 26.8)	0.40
Sex				0.55
● Female	193 (60.5%)	61 (63.5%)	132 (59.2%)	
● Male	126 (39.5%)	35 (36.5%)	91 (40.8%))	
Lesser trochanteric fracture				0.47
● Yes	274 (85.9%)	85 (88.5%)	189 (84.8%)	
● No	45 (14.1%)	11 (11.5%)	34 (15.2%)	
Fracture classification				0.25
● 31-A1	101 (31.7%)	36 (37.5%)	65 (29.2%)	
● 31-A2	182 (57.1%)	52 (54.2%)	130 (58.3%))	
● 31-A3	36 (11.3%)	8 (8.3%)	28 (12.5%)	
Surgical experience:				0.76
● Yes	261 (81.8%)	80 (83.3%)	181 (81.2%)	
● No	58 (18.2%)	16 (16.7%)	42 (18.8%)	
Thickness of lateral wall (mm)	23.0 (21.5, 26.0)	23.0 (21.2, 26.0)	23.0 (21.9, 26.0)	0.66
Insert point				0.39
● Tip of the greater trochanter (TGT)	269 (84.3%)	84 (87.5%)	185 (83.0%)	
● Medial deviation of TGT	50 (15.7%)	12 (12.5%)	38 (17.0%)	
Holiday surgery				0.54
● Yes	58 (18.2%)	15 (15.6%)	43 (19.3%)	
● No	261 (81.8%)	81 (84.4%)	180 (80.7%)	
Integrity of the lateral wall				1.00
● Yes	288 (90.3%)	87 (90.6%)	201 (90.1%)	
● No	31 (9.7%)	9 (9.4%)	22 (9.9%)	
Knee stiffness				1.00
● Yes	13 (4.1%)	4 (4.2%)	9 (4.0%)	
● No	306 (95.9%)	92 (95.8%)	214 (96.0%)	
Affected sides				0.38
● Left	196 (61.4%)	63 (65.6%)	133 (59.6%)	
● Right	123 (38.6%)	33 (34.4%)	90 (40.4%)	
Surgical method				0.96
● PFNA	82 (25.7%)	24 (25.0%)	58 (26.0%)	
● InterTAN	237 (74.3%)	72 (75.0%)	165 (74.0%)	
Surgical timing				0.64

Table 1 (continued)

Variables	All	Validation set (*n* = 96)	Training set (*n* = 223)	*P* value
● < 24 h	197 (61.8%)	62 (64.6%)	135 (60.5%)	
● 24 h ~ 48 h	81 (25.3%)	21 (21.9%)	60 (26.9%)	
● > 72 h	41 (12.9%)	13 (13.5%)	28 (12.6%)	
Bone density				< 0.001
● Normal	44 (13.8%)	7 (7.3%)	37 (16.6%)	
● Osteopenia	126 (39.5%)	55 (57.3%)	71 (31.8%)	
● Osteoporosis	149 (46.7%)	34 (35.4%)	115 (51.6%)	
Congenital hip varus				1.00
● Yes	17 (5.3%)	5 (5.2%)	12 (5.4%)	
● No	302 (94.7%)	91 (94.8%)	211 (94.6%)	
Intramedullary nail length (cm)	185 (180, 200)	185 (180, 200)	185 (180, 200)	0.13
Medullary cavity type				0.28
● A type	25 (7.8%)	9 (9.4%)	16 (7.2%)	
● B type	246 (77.1%)	77 (80.2%)	169 (75.8%)	
● C type	48 (15.0%)	10 (10.4%)	38 (17.0%)	
Emergency operation				0.31
● Yes	118 (37.0%)	40 (41.7%)	78 (35.0%)	
● No	201 (63.0%)	56 (58.3%)	145 (65.0%)	
Old fracture				1.00
● Yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	
● No	319 (100.0%)	96 (100.0%)	223 (100.0%)	
Anesthesia method				0.41
● Spinal anesthesia	224 (70.2%)	71 (74.0%)	153 (68.6%)	
● General anesthesia	95 (29.8%)	25 (26.0%)	70 (31.4%)	
Acetabular dysplasia				1.00
● Yes	3 (0.9%)	1 (1.0%)	2 (0.9%)	
● No	316 (99.1%)	95 (99.0%)	221 (99.1%)	
Secondary hip fracture				0.36
● Yes	13 (4.1%)	2 (2.1%)	11 (4.9%)	
● No	306 (95.9%)	94 (97.9%)	212 (95.1%)	
Hip revision surgery				1.00
● Yes	8 (2.5%)	2 (2.1%)	6 (2.7%)	
● No	311 (97.5%)	94 (97.9%)	217 (97.3%)	

TGT Tip of the greater trochanter

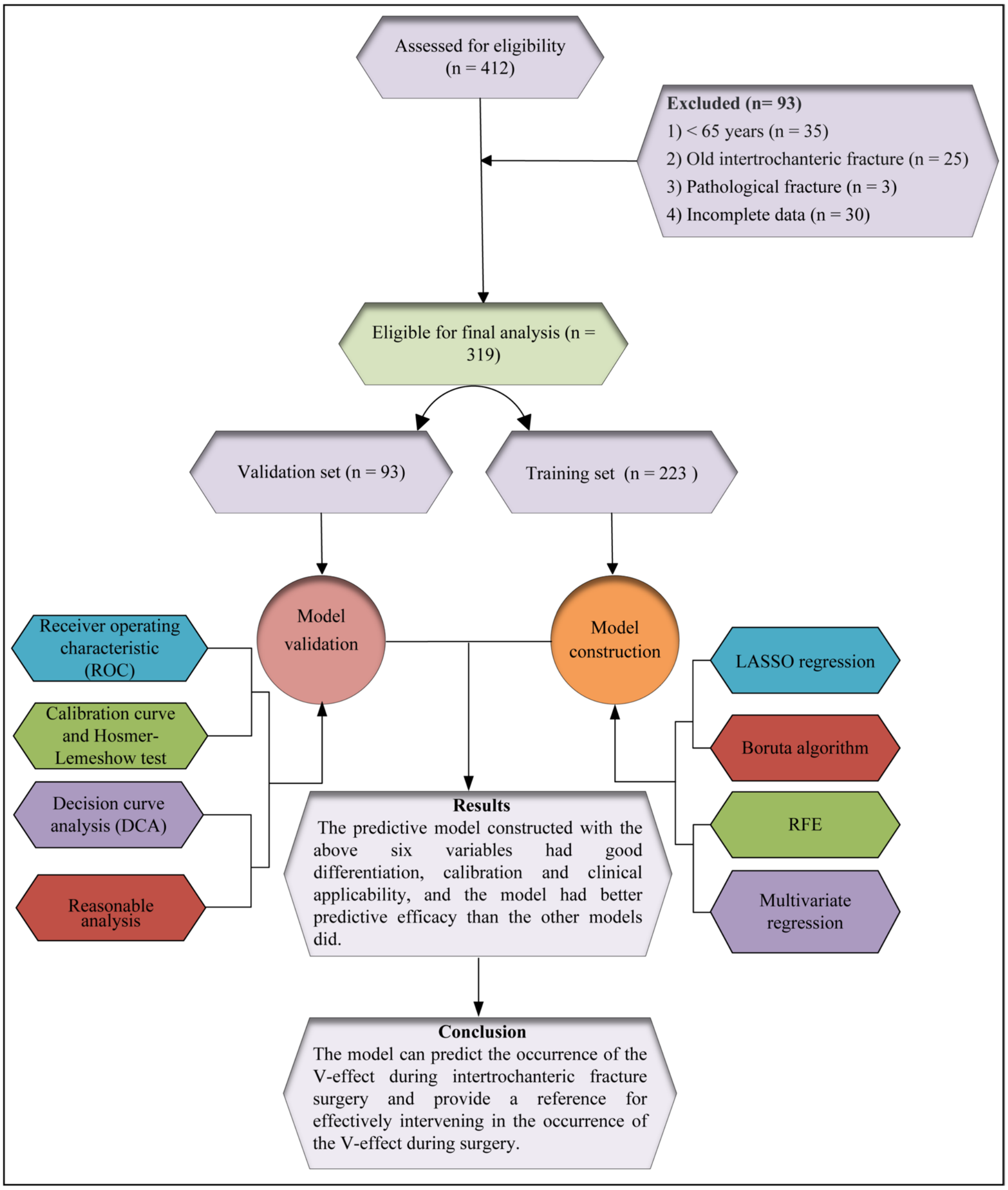

Fig. 2 Flow diagram

screening methods. A clinical prediction model was subsequently constructed utilizing these eight variables.

Model construction

Eight variables screened by the three machine learning methods were included in the multivariate logistic regression. Spearman correlation analysis revealed that there was no covariance problem among the variables ($r < 0.6$) (Fig. 4a). Finally, BMI, surgical experience, bone density, fracture classification, lesser trochanteric fracture, the insertion point, lateral wall thickness, and holiday surgery were modeled as final variables and plotted in columnar plots (Fig. 4b, e). The RCS analysis (Fig. 4c, d) revealed a linear relationship between BMI, lateral wall thickness, and the occurrence of the V effect, with cutoff values of 22.30 kg/m^2 and 22.96 mm, respectively. When the BMI is greater than 22.30 kg/m^2, the odds ratio (OR) value is greater than 1, which is a risk factor for the V effect. When the thickness of the lateral wall is less than 22.96 mm, its OR value is greater than 1, which is a risk factor for the occurrence of the V-effect.

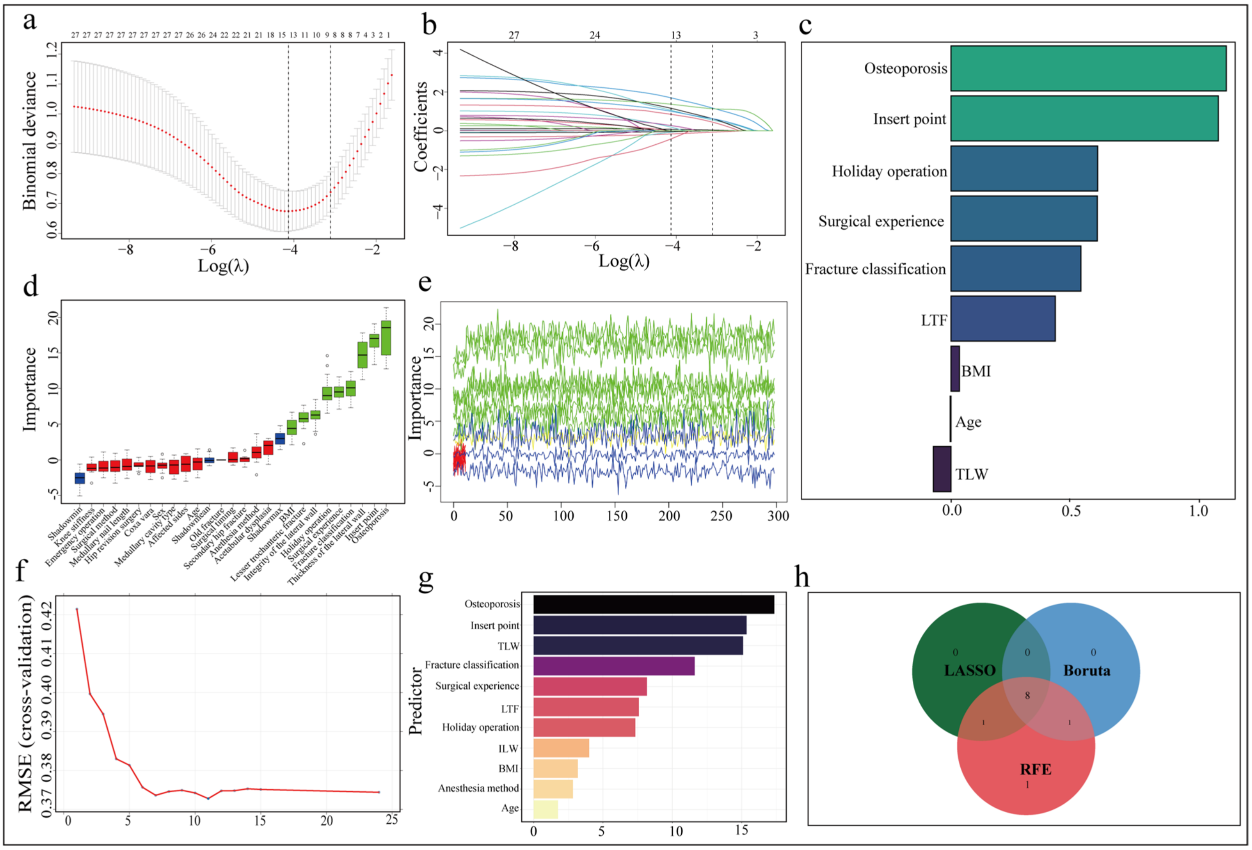

Fig. 3 **a** LASSO regression tenfold cross-validation plot using lambda. se (the second dashed line) was used as the screening criterion. **b** LASSO regression path coefficient graph. **c** Coefficients of the LASSO regression variables. **d** Boruta algorithm variable importance ranking (green are included variables). **e** After 300 iterations, the Boruta algorithm has good variable stability. **f** RFE has the smallest root mean square error (RMSE) value when the variable is 11, indicating the best predictive performance of the model. **e** Rank the importance of the 11 variables filtered out through RFE. **h** There are 8 variables screened in these three machine learning algorithms. LTF: Lesser trochanteric fracture; TLW: Thickness of the lateral wall; ILW: Integrity of the lateral wall

ROC curve
The 500-bootstrap area under the receiver operating characteristic curve (AUROC) values in the training and validation sets were 0.94 95% CI (0.91 ~ 0.98) and 0.86 95% CI (0.77 ~ 0.95), respectively (Fig. 5a, b).

Calibration curve
According to the calibration curve analysis, the calibration curves in the training and validation sets (Fig. 6a, b) deviate slightly from the ideal curve, but the model still has good accuracy.

Decision curve analysis
According to the 500-bootstrap decision curve analysis (DCA) results, when the threshold probability ranges in the training (Fig. 7a) and validation sets (Fig. 7b) were between 0.01 ~ 1.00 and 0.08 ~ 0.43, the clinical net benefit was greater than that of the completely intervention and completely nonintervention treatment strategies. According to the clinical impact curves (CICs), the clinical prediction model had good prediction efficiency in both the training and validation sets (Fig. 7c, d).

Reasonability analysis
A reasonability analysis revealed that the prediction model outperformed other univariate models in terms of AUROC and DCA in both the training (Fig. 8a, b) and validation sets (Fig. 8c, d).

Discussion
The predictive model constructed in this study can help orthopedic surgeons further understand the risk factors leading to the V-effect in intertrochanteric fractures in older people, and doctors can take some measures in advance to reduce the risk of the V-effect occurring. A total of 8 risk variables were identified in this study, among which lesser trochanteric fractures, fracture classification, and lateral wall thickness represent the

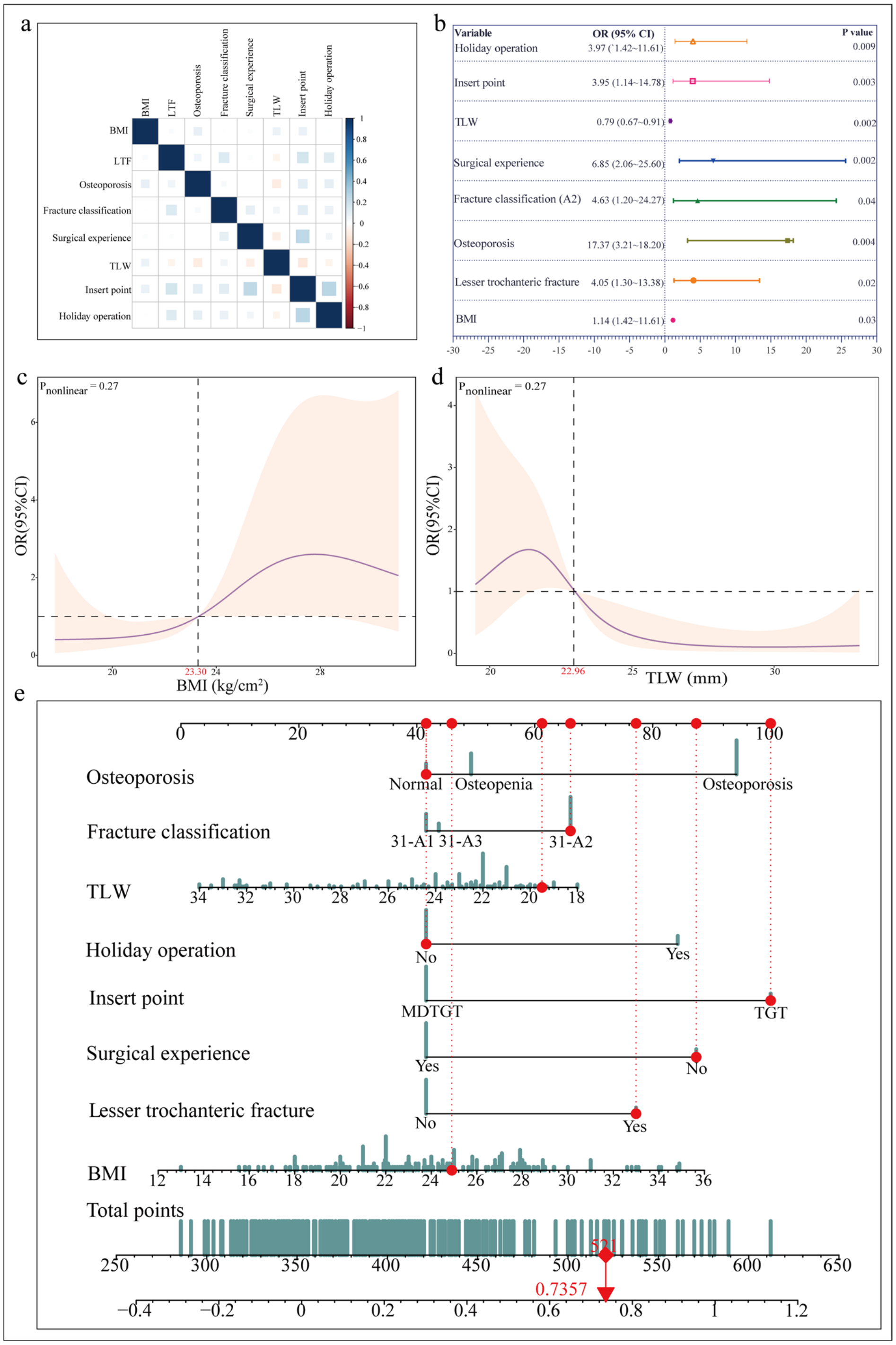

Fig. 4 **a** Correlations of the 8 variables included in the model. **b** The OR values of the 8 variables that ultimately establish the model. **c**, **d** RCSs were used to analyze the linear relationships between BMI, the thickness of the lateral wall, and the V-effect, with cutoff values of 22.30 kg/m^2 and 22.96 mm, respectively. **e** A dynamic column chart drawn using 8 variables in the model. TGT: Tip of the greater trochanter; MDTGT: Medial deviation of the TGT; TLW: Thickness of the lateral wall

morphological characteristics of the fracture itself; the insertion point and surgical experience represent the surgeon's technical skills; BMI and bone density represent the patient's own physical condition; and surgery during holidays represents an external factor. However, how these factors influence the V-effect in elderly individuals

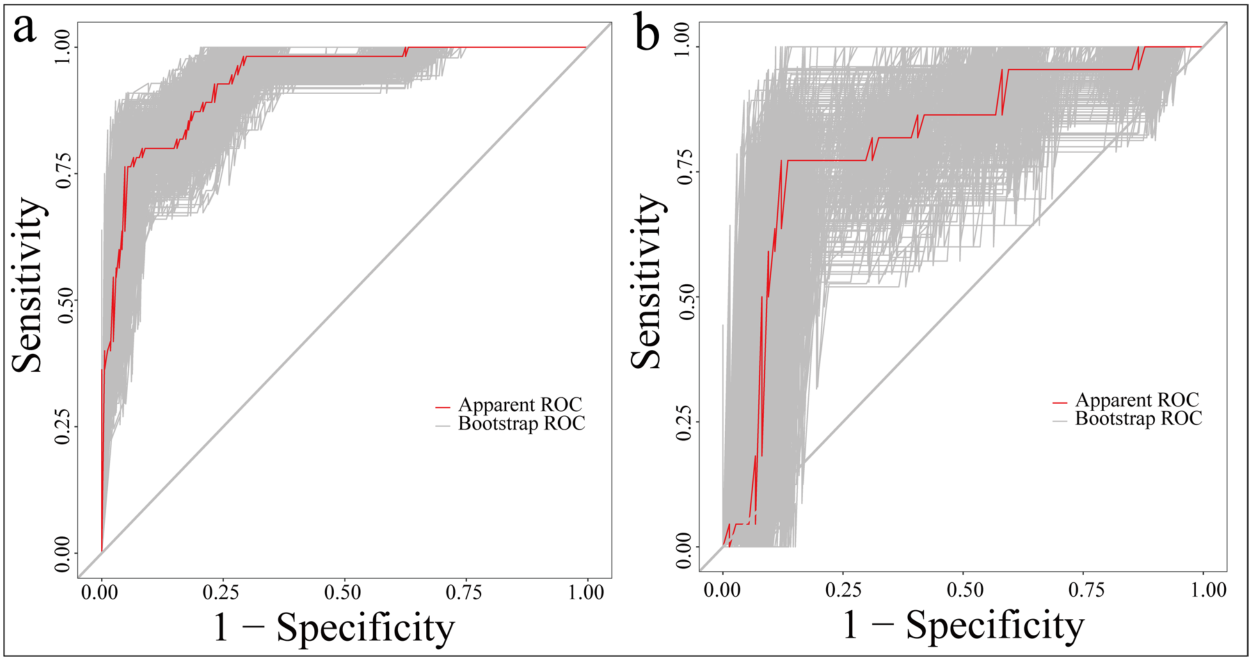

Fig. 5 **a** and **b** illustrate the 500—bootstrap AUROC in the training set and validation set respectively

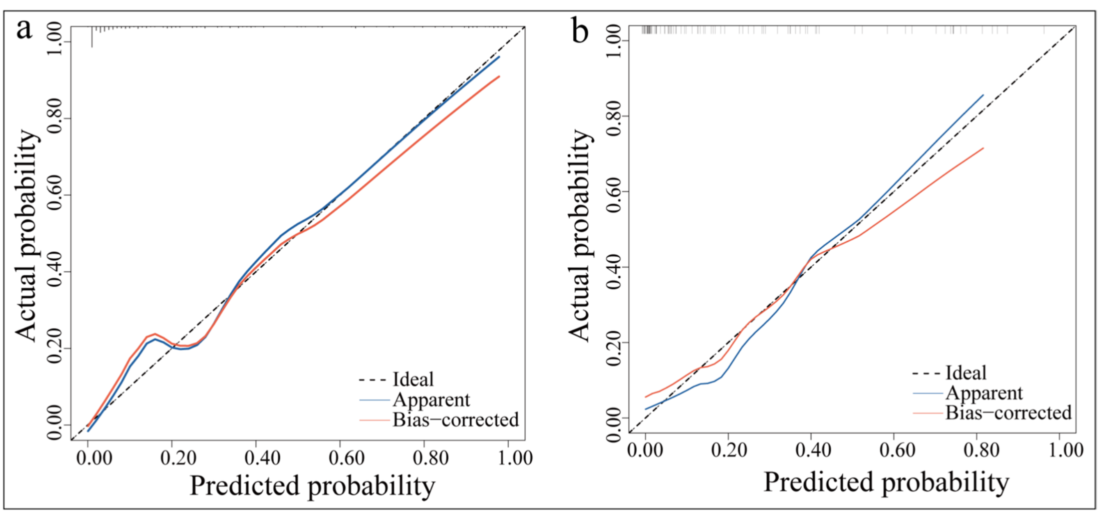

Fig. 6 **a**, **b** Calibration curves for 500 bootstraps in the training and validation sets

with intertrochanteric femur fractures is still worth further exploration.

First, we analyzed the impact of fracture morphological factors, such as lesser trochanteric fractures, fracture classification, and lateral wall thickness, on the V-effect. Since the medial femoral wall plays a very important mechanical supporting role, and the lesser trochanter is an important part of the medial femoral wall, a complete fracture of the lesser trochanter is likely to be an important risk factor for the occurrence of the V-effect for the following reasons: (1) The lesser trochanter is located in the distribution area of the femoral calcar, with a dense distribution of tension bone trabeculae. If the base of the femoral neck is not sufficiently removed, loss of support from the posterior medial wall is more likely to lead to postoperative complications, a conclusion that has been confirmed by some scholars [23, 24]. Several studies have shown that hip varus > 5° after reduction can lead to a poor prognosis [25]. (2) Due to the attachment of the lesser trochanter to the iliopsoas muscle, it is difficult to

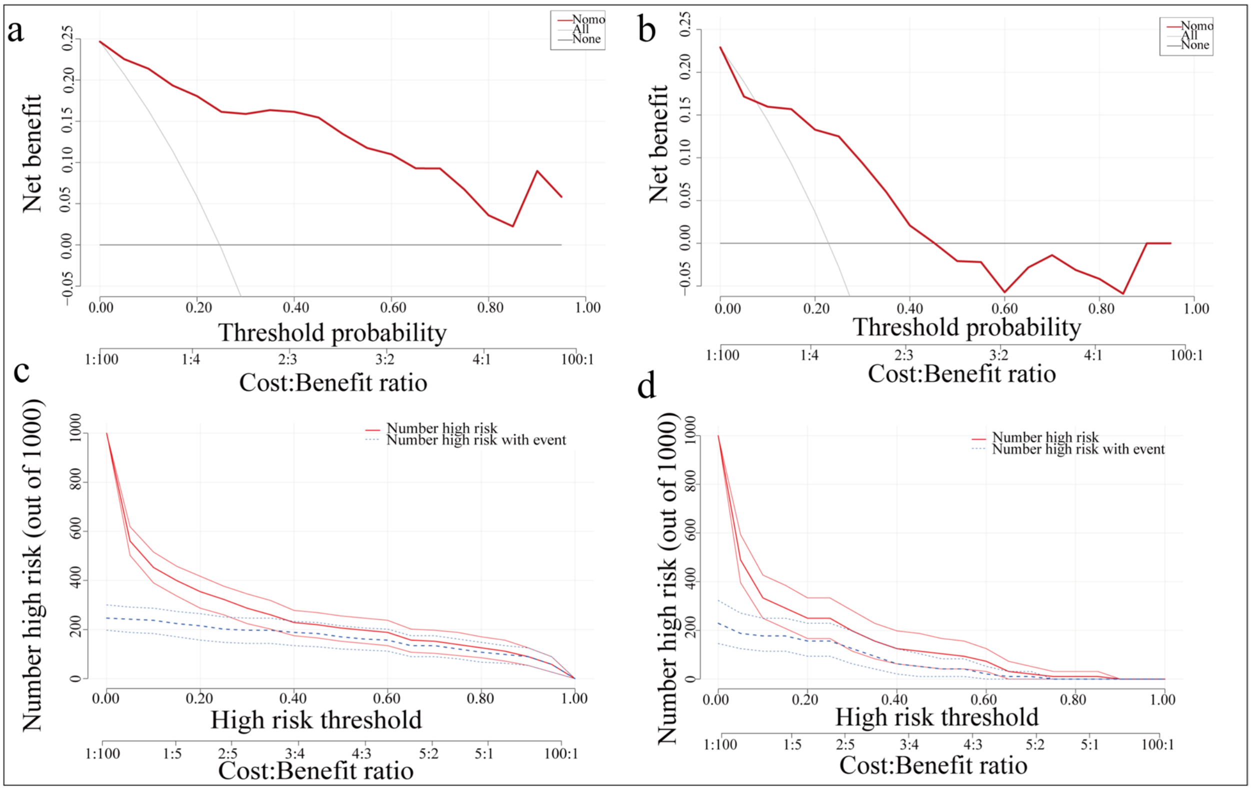

Fig. 7 **a**, **b** depict the 500-bootstrap decision curve analyses (DCA) in the training and validation sets. **c**, **d** reveal the CICs in the training and validation sets. The red dashed line in the CIC represents the number of high-risk individuals, whereas the blue dotted line represents the number of high-risk individuals who experience outcome events. The high-risk threshold in the training set is greater than 0.28, and when the validation set is greater than 0.10, the red and blue lines approach and intersect, indicating that the model has good predictive ability

maintain a reduction during surgery, making the anterior medial wall the only support [26, 27].

This study also revealed that type 31-A2 fractures are a risk factor for the V effect. The main reason is likely that type 31-A2 intertrochanteric femur fractures are unstable and complex, involving both the greater and lesser trochanters as well as the base. This fracture pattern is more prone to angulation and displacement when subjected to varus stress. Marmor M et al. reached a similar conclusion in their study [15]. The analysis revealed that when the lateral wall thickness is less than 22.96 mm, the OR value is greater than 1, indicating that it is a risk factor for the occurrence of the V-effect. Hsu CE et al. reported that a lateral wall thickness of less than 20.5 mm in intertrochanteric femur fractures increases the risk of failure of the dynamic hip screw [28]. Thinning of the lateral wall weakens its inherent mechanical strength and is a major cause of internal fixation failure. Similarly, in this study, a thinned lateral wall (< 22.96 mm) may have resulted in the inability of the lateral wall to effectively exert medial pressure on the drill, further exacerbating the insufficient removal of bone in the entry point and ultimately increasing the risk of the V-effect [29, 30].

Second, the surgeon's technical skill level also plays an important role. This study revealed that the selection of the insertion point for intramedullary nails also has a significant effect on the occurrence of the V effect [31, 32]. The risk of the V-shaped effect is reduced when the insertion point of the intramedullary nail is approximately 5 mm medial to the tip of the greater trochanter. The main reason is that leaning toward the inner opening of the greater trochanter can more effectively grind off the bone in the femoral neck crest area, avoiding the V effect caused by insufficient bone grinding in this area during the nail insertion process. This conclusion is very similar to that of Nakken ER et al. [33].

Moreover, inexperienced surgeons are also a risk factor for the V-effect. The reason is that inexperienced surgeons may lack experience in handling V-effects, and their awareness of V-effect prevention may not be as strong as that of experienced doctors. Studies by Authen AL et al. have shown that inexperienced surgeons are a risk factor for reoperation in hip surgery [34]. Since the V-effect is also an important factor affecting internal fixation failure, the conclusion that a

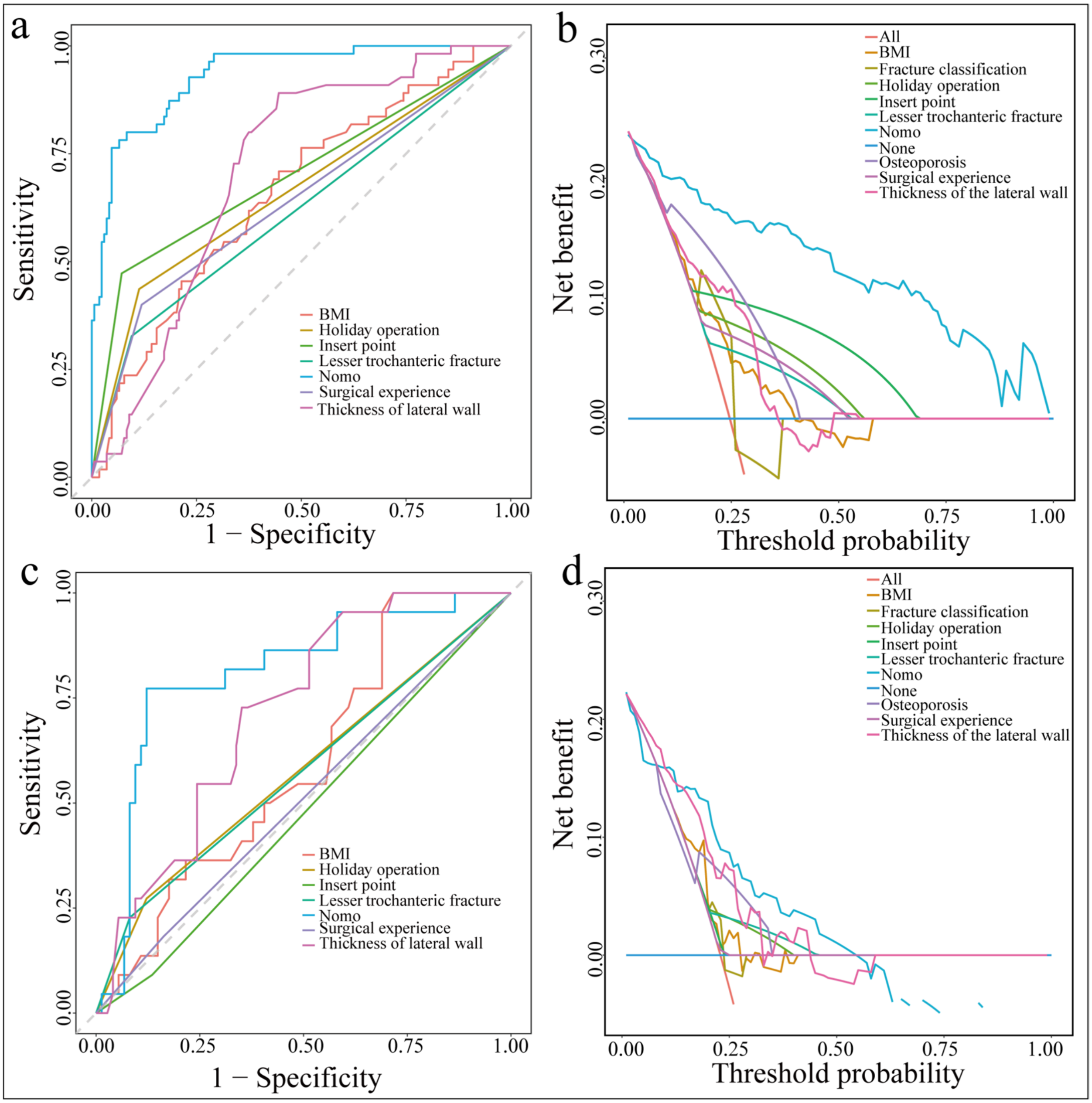

Fig. 8 **a**, **b** In the training set, this model has better discrimination ability and clinical applicability than other univariate prediction models do. **c**, **d** In the validation set, this model has better discrimination ability and clinical applicability than the other models do

lack of surgical experience is an important risk factor for the V-effect is well supported theoretically.

Third, the patient's own physical condition, including aspects such as BMI and bone density, is also a major factor affecting the V-effect. The analysis revealed that when BMI > 23.30 kg/m^2, the OR value was > 1, indicating that this indicator is a risk factor for the occurrence of the V effect. According to the consensus of Asian obesity experts, 23.30 kg/m^2 is close to being overweight in the Asian population. Therefore, individuals in this category often accumulate relatively high amounts of fat and muscle around their buttocks [35]. In this group of people, the fat and muscle in the gluteal region are relatively thick, which can cause the opening drill to be unable to align with the femoral axis, resulting in the inability to effectively remove the bone at the entry point.

Moreover, osteoporosis is also a risk factor for the V-effect. Osteoporosis means that the hip bone often has lower mechanical strength; therefore, it is more prone to complex hip instability fractures. Larrosa M et al. [36] reported that lower vitamin D levels in elderly patients predict more severe and complex types of hip fractures. Since vitamin D is an important substance involved in bone metabolism, lower vitamin D levels represent lower bone strength, which strongly supports the conclusions drawn in this study.

Finally, this study revealed that holiday surgery is also a risk factor for the occurrence of the V-effect. The reasons for this situation may be that there is a certain impact of the timing of the fracture on the occurrence of the V-effect [37]. Early treatment is recommended for older patients with hip fractures, which means that surgery within the golden 72 h can reduce patient mortality. Therefore, some patients need to undergo surgery during holidays, but surgeons also face high work intensity on weekdays [38, 39]. Most doctors who perform surgery on weekends are in a relatively tired state. A study by El Boghdady et al. revealed that fatigue and stress may affect the quality of surgery to a certain extent [40], which further supports our argument.

Therefore, for high-risk individuals with V-effects, we can try to reduce and bind the lesser trochanter as much as possible. For patients with a high BMI, we can appropriately extend the surgical incision to avoid soft tissue obstruction of the drill. Moreover, we chose 5 mm on the inner side of the greater trochanter as the insertion point for the intramedullary nail. If the surgery is performed by a relatively inexperienced doctor, it is best to discuss the surgical plan before the surgery and to have experienced and senior doctors develop the surgical plan. For patients undergoing surgery during holidays, it is best to arrange for a doctor with fewer surgeries on weekdays to perform the surgery and avoid fatigue. For patients with osteoporosis and type 31-A2 fractures, surgeons should be highly vigilant during the operation and take appropriate measures to reduce the risk of the occurrence of the V effect.

This study has several limitations. First, this was a retrospective study, and the level of evidence was lower than that of a prospective study. Therefore, prospective studies with larger sample sizes are needed. Second, this study lacks an external validation set, and later external validation is needed to test the generalizability of this model.

Conclusion

This study employed three machine learning variable selection methods—the LASSO, RFE, and Boruta algorithms—to construct a V-effect predictive model. The model enables orthopedic surgeons to better understand the risk factors associated with the V-effect and provides a reference for surgeons to implement appropriate measures to reduce the risk of the V-effect.

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Authors' contributions
Zhe Xu helped write the article and create the figures and tables. Qiuhan Chen and Zhi Zhou helped with the investigation and revised the figures and tables. Jianbo Sun helped collect and analyze the data. Guang Tian, Chen Liu performed the final analysis and review. Ruguo Zhang and Guangzhi Hou helped with the study design, conducted the study and reviewed and edited the article.

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Data availability
The datasets analyzed during the study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate
This study was approved by the Ethics Committee of Guihang Guiyang 300 Hospital (202304 A). All methods were conducted in accordance with relevant guidelines and the Declaration of Helsinki. This investigation was registered in the Chinese Clinical Trial Registry (ChiCTR2300071086; data of register: 04/05/2023). The requirement for informed consent was waived by the Ethics Committee of Guihang Guiyang 300 Hospital.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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