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A delphi-based model for prognosis of femoral head collapse in osteonecrosis: a multi-factorial approach

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Abstract

Background Osteonecrosis of the femoral head (ONFH) is a progressive and debilitating condition characterized by the death of bone tissue due to inadequate blood supply. Despite advances in diagnostic imaging and treatment strategies, predicting the risk of femoral head collapse remains a significant clinical challenge. This study seeks to address this gap by developing a robust prognostic model that integrates clinical, imaging, and laboratory data to improve early diagnosis and guide therapeutic decision-making.

Methods We conducted a qualitative systematic review and employed the Delphi method to select key prognostic factors from clinical data, imaging findings, and laboratory indicators. The study included ONFH patients treated from January 2014 to December 2021. We used univariate and multivariate Cox regression analyses to develop a nomogram for predicting the risk of femoral head collapse. The model's performance was evaluated using the concordance index (C-index), calibration plots, and decision curve analysis (DCA).

Results The study included 297 patients (454 hips) with ONFH. Key prognostic factors identified included pain presence ($p < 0.001$, $RR = 0.185$, 95% CI: 0.11–0.31), JIC classification (C1: $p < 0.001$, $RR = 0.096$, 95% CI: 0.054–0.171; C2: $p < 0.001$, $RR = 0.323$, 95% CI: 0.215–0.487), necrotic area ($3 < MNAI < 6$: $p < 0.001$, $RR = 0.107$, 95% CI: 0.061–0.190; $MNAI \geq 6$: $p < 0.001$, $RR = 0.466$, 95% CI: 0.314–0.692), weight-bearing reduction ($p < 0.001$, $RR = 0.466$, 95% CI: 0.323–0.672), preservation of the anterolateral pillar ($p < 0.001$, $RR = 0.223$, 95% CI: 0.223–0.473), and subchondral bone fracture on CT ($p < 0.001$, $RR = 0.32$, 95% CI: 0.217–0.472). The nomogram demonstrated a high C-index of 0.88, indicating excellent predictive accuracy. Calibration plots showed good agreement between predicted and observed outcomes, and DCA confirmed the model's clinical utility.

Conclusions The prognostic model developed in this study provides a reliable tool for predicting femoral head collapse in ONFH patients. It allows for early identification of high-risk patients, guiding personalized treatment strategies to improve patient outcomes and reduce the need for invasive surgical procedures.

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Introduction

Osteonecrosis of the femoral head (ONFH) is a debilitating condition that leads to the death of bone tissue due to inadequate blood supply. It is a notable factor leading to hip pain and disability, primarily affecting adults between the ages of 20 and 50 [1]. The global incidence of ONFH continues to rise, with an estimated 50,000 to 100,000 new cases annually in China alone, making it one of the highest rates in the world and significantly increasing the economic burden on healthcare systems [2, 3]. In addition to established risk factors such as steroid use and alcohol consumption [4], certain occupations, such as deep-sea diving, have been associated with an elevated risk of developing osteonecrosis of the femoral head due to exposure to rapid pressure changes [5]. Effective early diagnosis and treatment are crucial to prevent progression to femoral head collapse and subsequent hip replacement surgery [6–8]. However, the complexity of ONFH's etiology and the variability in its clinical presentation pose challenges for early diagnosis and effective treatment [9], underscoring the urgent need for comprehensive prognostic models to guide clinical management and improve patient outcomes.

Several studies have identified various factors influencing the prognosis of ONFH, including patient demographics, clinical presentations, and imaging findings [10–13]. Despite extensive research, there remains a lack of consensus on the most critical prognostic indicators and their relative importance [2]. Current prognostic models vary in their predictive accuracy and clinical utility, highlighting the necessity for a robust and comprehensive model tailored to specific patient populations.

This study aims to develop and validate a clinical prognostic model for ONFH, utilizing a Delphi method to systematically identify and prioritize prognostic factors based on expert consensus. By incorporating a combination of clinical data, imaging findings, and laboratory indicators, this study seeks to create a reliable tool for predicting the risk of femoral head collapse and guiding clinical decision-making. The ultimate goal is to enhance the early diagnosis and management of ONFH, thereby improving patient outcomes and reducing the need for invasive surgical procedures.

Methods

This section consists of two parts. The first part uses the Delphi method to identify prognostic factors for ONFH. The second part develops and validates a clinical prognostic model based on these factors, ensuring a comprehensive and reliable approach.

Delphi method for screening prognostic factors

Data collection and indicator pool selection

A qualitative systematic review was conducted on May 3, 2023, with literature searches performed in PubMed, Web of Science, China National Knowledge Infrastructure (CNKI), Wanfang Data Knowledge Service Platform, Chinese Biomedical Literature Database (CBM), and Chinese Science and Technology Journal Database (VIP). The search strategy was: ((“osteonecrosis of the femoral head”) OR (“avascular necrosis of the femoral head”) OR (“ONFH”) OR (“ANFH”)) AND ((“prognostic factors”) OR (“prognoses”) OR (“risk factors”) OR (“factors affecting prognosis”)). The search period ranged from January 1, 2013, to May 3, 2023.

Delphi method

Expert selection Given the specifics of this study, experts were selected based on the following criteria: affiliation with a provincial-level public tertiary hospital, a minimum of 5 years of experience in diagnosing and treating osteonecrosis, and an intermediate or higher professional title.

Questionnaire preparation and distribution A dedicated database for this study was created using Excel 2016. The judgments of experts on the importance of each item were recorded in the database after being cross-checked by two individuals and then verified by a third person. The database also documented expert modification suggestions, proposed additional items, and reasons for the perceived importance of certain items. A 9-point Likert scale was used to develop the expert consultation form. Consensus was defined as 75% or more of experts rating an item between 7 and 9, ensuring agreement on the importance of the item [14]. To enhance the response rate, the expert consultations were conducted in person. The first-round questionnaires were distributed from May 27, 2023, to May 28, 2023, and the second-round questionnaires were distributed from July 14, 2023, to July 16, 2023. The first round included 29 items, while the second round consisted of 27 revised items.

Data processing and quality control Expert questionnaire results were analyzed using Excel 2016 and SPSS 26.0. Calculations included activity coefficient, authority coefficient, opinion coordination degree, opinion concentration degree, and item weight coefficient. For example, indicators such as ‘pain presence’ and ‘JIC classification’ showed high authority and coordination, with activity coefficients exceeding 80%. These indicators were retained due to their strong expert consensus and relevance to the outcome variables. Conversely, ‘BMI’ was eliminated due

to a low opinion coordination degree ($CV > 25\%$) in the first round, indicating a lack of expert agreement.

The activity coefficient reflects the level of participation of the experts. It is usually represented by the ratio of participating experts to the total number of experts consulted, which indicates whether experts are highly engaged in the study. The specific formula is: Activity Coefficient = (Number of Participating Experts / Total Number of Experts Consulted) $\times 100\%$. An activity coefficient $\geq 70\%$ ensures the accuracy of the questionnaire [15].

The authority coefficient depends on the basis of expert judgment (four dimensions: practical experience, theoretical analysis, literature basis, intuitive feeling) and the level of familiarity (three levels: high, medium, low). Details are shown in Table 1. The arithmetic mean is the authority coefficient, with a value greater than 0.7 indicating a relatively high authority [16].

The opinion coordination degree indicates whether experts can reach a consensus on the importance of one or more items, composed of the coefficient of variation (CV) and Kendall's coefficient of concordance (W) [17]. A $CV < 15\%$ is considered highly concentrated. In this study, the first round selected items with $CV \leq 25\%$, and the second round selected items with $CV \leq 15\%$ [18]. The coordination degree ranges from 0 to 1, with values closer to 1 indicating higher coordination. The χ^2 test was used to analyze the coordination degree.

The opinion concentration degree includes the mean, standard deviation, and full score ratio for the importance of single items. A higher mean indicates greater importance, and the full score ratio supplements the mean, with a higher ratio indicating greater importance. The standard deviation reflects the concentration of expert opinions [19].

The item weight coefficient, evaluated by experts, was calculated through mean normalization: Item Weight Coefficient = Mean / Sum of Means.

Development and validation of the clinical prognostic model

Study population

Through a retrospective analysis of previous cases, we selected ONFH patients treated in the third Department of Orthopedics at Wangjing Hospital from January 2014 to December 2021. This study was approved by

the Ethics Committee of the Wangjing Hospital, China Academy of Chinese Medical Sciences (Approval No.: CI2021A05406).

Inclusion criteria

- (1) Age ≥ 18 years;
- (2) Meeting the diagnostic criteria for ONFH [2];
- (3) Classified as ARCO (Association Research Circulation Osseous) stage I, II, or IIIA according to the 2019 version [20];
- (4) Patients with available X-ray and MRI imaging. X-rays, including anteroposterior and frog-leg lateral views.

Exclusion criteria

- (1) Patients with traumatic ONFH or other hip joint diseases;
- (2) Patients with incomplete medical histories or follow-up imaging data.

Primary endpoint events

Based on the final follow-up imaging results, patients were categorized into two groups: those with femoral head collapse changes ≥ 2 mm [2] (endpoint group) and those without. The occurrence of endpoint events was defined as the first time the endpoint was met, and an early ONFH patient database was established.

Sample size estimation and data collection

Multiple simulation studies [21, 22] indicate that Logistic and Cox models should use at least 10 events per predictor variable to ensure accurate results when the number of events is less than 10. This means the number of events should be at least ten times the number of predictor variables. In our study, the number of patients experiencing femoral head necrosis should be at least ten times the number of prognostic factors included.

We extracted patient data from the HIS system of Wangjing Hospital, China Academy of Chinese Medical Sciences, and followed up with the patients. Based on the results of the first part of the clinical study, we collected general case data, clinical data, imaging data, and follow-up data. We recorded the timing of each follow-up imaging examination and the occurrence of femoral head collapse (≥ 2 mm change). Due to clinical follow-up constraints, the final data collected included patient age, gender, BMI, side of femoral head necrosis, etiology, pain status, JIC classification, necrosis area, bone marrow edema degree, weight-bearing reduction (use of crutches ≥ 1 year), preservation of the anterolateral pillar, necrosis area, and subchondral bone fracture on CT.

Age was categorized into two groups: young and middle-aged (≤ 44 years) and middle-aged and elderly (> 44 years) [23]. Etiology was classified according to current

Table 1 Quantitative assignment of Expert Authority Degree

Judgment Basis	Familiarity Level		
	High	Medium	Low
Practical Experience	0.5	0.4	0.3
Theoretical Analysis	0.3	0.2	0.1
Literature Basis	0.1	0.1	0.1
Intuitive Feeling	0.1	0.1	0.1

mainstream academic concepts into steroid-induced, alcohol-induced, and idiopathic [24].

Bone marrow edema on MRI was classified into four grades based on the extent [25]: Grade 0: normal; Grade 1: edema involving the femoral head; Grade 2: edema involving the femoral head and neck; Grade 3: edema involving the femoral head, neck, and trochanteric region. Feng et al. demonstrated that this grading system correlates with disease progression in avascular necrosis of the femoral head, making it an effective tool for staging and monitoring in clinical practice [25].

The Japanese Investigation Committee (JIC) classification based on MRI divided necrotic lesions into four types, as shown in Table A1. It is particularly useful for estimating the risk of femoral head collapse, especially in advanced cases such as C2, where early surgical intervention is often indicated [26].

Preservation of the anterolateral pillar was determined using the China-Japan Friendship Hospital Classification for ONFH (CJFH Classification for ONFH), as shown in Table A2. This system has demonstrated reliability and consistency, proving valuable for evaluating necrotic lesions and guiding treatment decisions [27].

The necrosis area was assessed using the “quartile method” [28]. The femoral head was divided into 4 parts by the central axis of the femoral head and neck on each transverse T1WI MRI image, with each area accounting for 25% (2.5 points) of the total area. The score increased as necrosis reached the corresponding area, with the total percentage increasing. The mean necrotic area index (MNAI) was defined as the average score across all layers and was categorized into three groups: $MNAI \geq 6$, $3 < MNAI < 6$, and $MNAI \leq 3$. This method demonstrated potential for consistent results in quantifying necrotic involvement, offering a standardized approach for assessment in the study [28].

The degree of collapse was assessed using the concentric circle method on anteroposterior and frog-leg radiographs. This approach has shown high intraobserver and interobserver reliability, offering consistent measurements for assessing femoral head deficiency [29].

All imaging evaluations were independently performed by two experienced orthopedic surgeons in our department. In case of disagreement, a third senior surgeon participated and determined the final result.

Data standardization procedures

To ensure the consistency and reliability of the collected data, standardized protocols were applied across all clinical, imaging, and laboratory assessments. Clinical data were systematically recorded using structured forms to maintain uniformity. Imaging studies, including X-rays and MRIs, followed standardized protocols and were performed using the same equipment. Two experienced

orthopedic specialists independently reviewed the imaging results, and any discrepancies were resolved by consensus, ensuring accurate and consistent interpretations.

Laboratory data were collected under standardized conditions, with blood samples drawn in the morning after an overnight fast to minimize variability. All laboratory analyses were conducted in a certified facility, using calibrated equipment and adhering to strict quality control procedures. These measures ensured the accuracy and consistency of the laboratory data, contributing to the overall robustness and reliability of the prognostic model.

Statistical methods

Data were statistically analyzed using SPSS 26.0 and R 4.3.30. Categorical variables were grouped based on clinical findings and determined before modeling. The chi-square test or Fisher’s exact test was used to compare categorical variables. Continuous variables were expressed as mean $\pm$ standard deviation and were subjected to normality and homogeneity of variance tests before analysis. Independent samples t-test was used for data following a normal distribution, while non-parametric tests were used for non-normally distributed variables.

Univariate Cox regression analysis was performed to screen prognostic factors. Based on the results of the multivariate analysis, a nomogram and Kaplan-Meier survival curves were constructed. The Kaplan-Meier survival curves were used to assess survival differences between groups, and the log-rank test was employed to evaluate the statistical significance of these differences, with a significance level set at $P < 0.05$. The performance of the nomogram was assessed by the concordance index (C-index) and calibration plots comparing predicted versus observed outcomes. The nomogram was further validated using 100 bootstrap resamples to calculate the adjusted C-index; a higher C-index indicates more accurate prognostic prediction. Finally, decision curve analysis (DCA) was conducted to evaluate the clinical utility of the model. A P-value of < 0.05 was considered statistically significant.

Results

Results of Delphi method

Selection of evaluation indicators

A total of 119 articles were included in the study. Prognostic factors influencing ONFH were extracted from the original literature and standardized. These factors were categorized into three aspects: clinical data, imaging findings and laboratory indicators, forming the core indicators for the ONFH prognostic factors expert survey questionnaire.

Clinical data included age, gender, body mass index (BMI), occupation, strict use of crutches (crutch use ≥ 1 year), duration of pain, Visual Analog Scale (VAS) pain score, hip joint range of motion, affected side, etiology (triggering factors), underlying diseases, cumulative duration of steroid use/alcohol consumption, and whether steroids were discontinued/alcohol abstinence was achieved. Imaging findings included the ARCO staging, JIC classification, CJFH classification, preservation of the anterolateral pillar, bone marrow edema grading,

necrotic area, subchondral bone fracture on computed tomography (CT), cystic changes, and joint effusion. Laboratory indicators included abnormalities in ≥ 2 coagulation factors, lipid levels, homocysteine (HCY) levels, alkaline phosphatase (ALP), vitamin D levels (Vd), bone mineral density (BMD), and uric acid (UA).

Demographics and participation rate of experts

All experts participating in the survey are senior professionals engaged in the clinical practice, teaching, and research of orthopedics in China. Detailed information about the experts is shown in Table A3.

Summary of responses from the first and second rounds

A total of 30 expert consultation forms were distributed in the first round, and all 30 were returned and deemed valid, resulting in an expert participation rate of 100%. The authority coefficient of the experts was 0.903. The expert coordination coefficient was $W=0.713$ ($\chi^2=748.711$, $P<0.001$). The degree of CV, opinion concentration and weight coefficients of expert opinions are shown in Table 2.

After completing the first round of expert consultation, some experts provided suggestions for item modifications. We collected and organized these suggestions, as detailed in Table A4. Based on these recommendations, the following adjustments were made for the second round of expert consultation. Items with a $CV \leq 25\%$ were selected, and the following nine indicators were added: patient gait, hip trauma history, hip preservation surgery, patient treatment compliance, patient mental and emotional changes, bone metabolism indicators, rehabilitation exercises, treatment duration, and confirmation of bone necrosis time.

A total of 40 expert consultation forms were distributed in the second round, and all 40 were returned and deemed valid, resulting in an expert participation rate of 100%. The authority coefficient of the experts was 0.872. The expert coordination coefficient was $W=0.689$ ($\chi^2=964.359$, $P<0.001$). The degree of consensus, coefficient of variation, and weight coefficients of expert opinions are shown in Table 3.

Final list of prognostic factors

Items with a $CV \leq 15\%$ from the second-round survey were selected as key prognostic factors, resulting in 9 indicators: strict use of crutches, pain presence, hip joint range of motion, confirmation of bone necrosis time, ARCO staging, JIC classification, preservation of the anterolateral pillar, necrotic area and subchondral bone fracture on CT.

Table 2 The degree of CV, Opinion Concentration and Weight coefficients of Expert opinions in the First Round of Expert Consultation

Item	CV	Mean	Standard Deviation	Full Score Ratio (%)	Weight Coefficient
Age	0.245	6.70	1.64	20.00	0.0268
Gender	0.438	4.33	1.90	3.33	0.0173
BMI	0.177	6.93	1.23	16.67	0.0277
Occupation	0.263	6.17	1.62	13.33	0.0247
Strict Use of Crutches	0.135	8.27	1.11	66.67	0.0331
Pain Presence	0.159	7.93	1.26	53.33	0.0317
VAS Pain Score	0.198	7.67	1.52	50.00	0.0307
Hip Joint Range of Motion	0.172	7.93	1.36	56.67	0.0317
Affected Side	0.307	6.50	1.20	20.00	0.0260
Etiology (Triggering Factors)	0.253	6.87	1.74	33.33	0.0275
Underlying Diseases	0.207	7.47	1.55	43.33	0.0299
Duration of Steroid Use/Alcohol Consumption	0.182	7.47	1.36	36.67	0.0299
Steroid Discontinuation/Alcohol Abstinence	0.159	7.87	1.25	50.00	0.0315
ARCO Staging	0.140	8.13	1.14	60.00	0.0325
JIC Classification	0.186	7.80	1.45	53.33	0.0312
CJFH Classification	0.186	7.80	1.45	53.33	0.0312
Preservation of Anterolateral Pillar	0.115	8.33	0.96	66.67	0.0333
Bone Marrow Edema Grading	0.173	7.80	1.35	50.00	0.0312
Necrotic Area	0.137	8.20	1.13	63.33	0.0328
Subchondral Bone Fracture on CT	0.115	8.33	0.96	66.67	0.0333
Cystic Changes	0.194	7.13	1.38	26.67	0.0285
Joint Effusion	0.239	6.63	1.59	16.67	0.0265
≥ 2 Coagulation Factor Abnormalities	0.277	6.13	1.70	10.00	0.0245
Lipid Levels	0.259	6.20	1.61	6.67	0.0248
HCY	0.308	5.57	1.72	6.67	0.0223
ALP	0.361	4.87	1.76	3.33	0.0195
Vd	0.307	5.73	1.76	13.33	0.0229
BMD	0.263	6.17	1.62	13.33	0.0247
UA	0.347	5.23	1.81	3.33	0.0209

Table 3 The degree of CV, Opinion Concentration and Weight coefficients of Expert opinions in the Second Round of Expert Consultation

Item	CV	Mean	Standard Deviation	Full Score Ratio (%)	Weight Coefficient
Age	0.227	7.18	1.63	32.5	0.0338
BMI	0.231	7.28	1.68	37.5	0.0343
Strict Use of Crutches	0.146	8.15	1.19	62.5	0.0384
Pain Presence	0.125	7.40	0.93	22.5	0.0349
VAS Pain Score	0.207	7.50	1.55	45.0	0.0348
Hip Joint Range of Motion	0.121	7.48	0.91	25.0	0.0353
Confirmation of Necrosis Time	0.129	7.60	0.98	27.5	0.0358
Underlying Diseases	0.182	7.80	1.42	52.5	0.0367
Duration of Steroid Use/Alcohol Consumption	0.151	7.90	1.19	50.0	0.0372
Steroid Discontinuation/Alcohol Abstinence	0.182	7.75	1.41	50.0	0.0365
Patient Gait	0.191	7.65	1.46	47.5	0.0360
Hip Trauma History	0.255	6.63	1.69	22.5	0.0312
ARCO Staging	0.150	8.00	1.20	55.0	0.0377
JIC Classification	0.126	8.05	1.01	52.5	0.0379
CJFH Classification	0.191	7.70	1.47	50.0	0.0363
Preservation of Anterolateral Pillar	0.099	8.53	0.85	75.0	0.0402
Bone Marrow Edema Grading	0.161	7.95	1.28	55.0	0.0375
Necrotic Area	0.131	8.25	1.08	65.0	0.0389
Subchondral Bone Fracture on CT	0.127	7.80	0.99	40.0	0.0367
Cystic Changes	0.254	6.95	1.77	27.5	0.0327
Joint Effusion	0.297	6.03	1.79	12.5	0.0284
Rehabilitation Exercises	0.151	7.95	1.19	52.5	0.0375
Hip Preservation Surgery	0.182	7.75	1.41	50.0	0.0365
Treatment Duration	0.181	7.65	1.39	45.0	0.0360
Bone Metabolism Indicators	0.262	6.30	1.65	12.5	0.0297
Patient Treatment Compliance	0.160	7.60	1.22	37.5	0.0358
Patient Mental and Emotional Changes	0.175	7.40	1.30	32.5	0.0349

Results of prognostic model development

Baseline characteristics of patients

This study ultimately included 454 hips from 297 patients, with an age range of 18 to 76 years and an average age of 45.74 ± 13.21 years. Additional details are provided in Table 4. For this study, the non-endpoint group was followed for 24 to 109 months, while the endpoint group was followed for 2 to 101 months. The average follow-up duration was 71.99 ± 20.89 months for the non-endpoint

Table 4 Baseline characteristics

Variable	Non-Endpoint Group (N=339)	Endpoint Group (N=115)	P Value
Age			0.141
≤ 44	150 (44.2%)	60 (52.2%)	
> 44	189 (55.8%)	55 (47.8%)	
Gender			0.526
Female	108 (31.9%)	33 (28.7%)	
Male	231 (68.1%)	82 (71.3%)	
Side			0.133
Left	173 (51%)	68 (59.1%)	
Right	166 (49%)	47 (40.9%)	
BMI (Kg/m ²)	24.99 ± 3.27	25.77 ± 3.91	0.038
Etiology			0.016
Steroid-induced	121 (35.7%)	58 (50.4%)	
Alcohol-induced	138 (40.7%)	39 (33.9%)	
Idiopathic	80 (23.6%)	18 (15.7%)	
Pain			< 0.001
No	179 (52.8%)	16 (13.9%)	
Yes	160 (47.2%)	99 (86.1%)	
Bone Marrow Edema			0.455
Grade 0	268 (79.1%)	94 (81.7%)	
Grade 1	25 (7.4%)	4 (3.5%)	
Grade 2	23 (6.8%)	7 (6.1%)	
Grade 3	23 (6.8%)	10 (8.7%)	
JIC Classification			< 0.001
A	122 (36%)	0 (0%)	
B	106 (31.1%)	17 (14.8%)	
C1	91 (26.8%)	60 (52.2%)	
C2	20 (5.9%)	38 (33%)	
Necrotic Area			< 0.001
MNAI ≤ 3	179 (52.8%)	15 (13%)	
3 < MNAI < 6	100 (29.5%)	45 (39.1%)	
MNAI ≥ 6	60 (17.7%)	55 (47.8%)	
Weight-Bearing Reduction			< 0.001
Yes	238 (70.2%)	57 (49.6%)	
No	101 (29.8%)	88 (50.4%)	
Subchondral Bone Fracture on CT			< 0.001
Yes	116 (34.2%)	77 (67%)	
No	223 (65.8%)	38 (33%)	
Preservation of Anterolateral Pillar			< 0.001
Yes	237 (69.9%)	45 (39.1%)	
No	102 (30.1%)	70 (60.9%)	

group and 27.87 ± 18.77 months for the endpoint group. Ultimately, 115 hips reached the endpoint outcome, accounting for 25.3% of the total hips included.

Construction and validation of the prognostic model

Based on the results from the Delphi method, clinical experience, and baseline data, we included six factors: pain presence, JIC classification, necrotic area,

weight-bearing reduction, preservation of the anterolateral pillar and subchondral bone fracture on CT.

Table 5 presents the results of the univariate Cox regression analysis, where all six variables (pain presence, JIC classification, necrotic area, weight-bearing reduction, preservation of the anterolateral pillar, and subchondral bone fracture on CT) were evaluated for their potential predictive value for femoral head collapse in ONFH patients (all P values<0.001). Type A was utilized as the reference category for the JIC classification, facilitating a clear comparison of the relative risks among different types.

Table 6 displays the results of the multivariate Cox regression analysis, where four key prognostic factors were identified: necrotic area (≥6), weight-bearing reduction, preservation of the anterolateral pillar, and subchondral bone fracture on CT. These factors were found to be statistically significant predictors of femoral head collapse.

The comprehensive display of these variables in Tables 5 and 6 includes the coefficients, standard errors, p-values, and hazard ratios (HRs), ensuring a clear and complete presentation of all relevant data for the Cox regression analyses.

Although pain presence and JIC classification did not show significant results in the multivariate Cox regression analysis, we included them in constructing the clinical

Table 5 Univariate Cox Regression Analysis Results

Variable	P Value	RR (95% CI)
Pain Presence	<0.001	0.185 (0.11, 0.31)
JIC Classification		
A		
B	0.869	
C1	<0.001	0.096 (0.054, 0.171)
C2	<0.001	0.323 (0.215, 0.487)
Necrotic Area		
MNAI ≤3		
3 < MNAI < 6	<0.001	0.107 (0.061, 0.190)
MNAI ≥6	<0.001	0.466 (0.314, 0.692)
Weight-Bearing Reduction	<0.001	0.466 (0.323, 0.672)
Subchondral Bone Fracture on CT	<0.001	0.32 (0.217, 0.472)
Preservation of Anterolateral Pillar	<0.001	0.223 (0.223, 0.473)

Table 6 Multivariate cox regression analysis results

Variable	P Value	HR	95% CI
Necrotic Area (≥6)	<0.001	4.219	(2.552, 6.975)
Weight-Bearing Reduction	<0.001	3.008	(1.916, 4.723)
Subchondral Bone Fracture on CT	<0.001	6.495	(4.017, 10.504)
Preservation of Anterolateral Pillar	<0.001	22.11	(3.888, 125.696)

prognostic nomogram based on clinical experience and the results of univariate Cox analysis (see Fig. 1). This decision was guided by the importance of these factors in

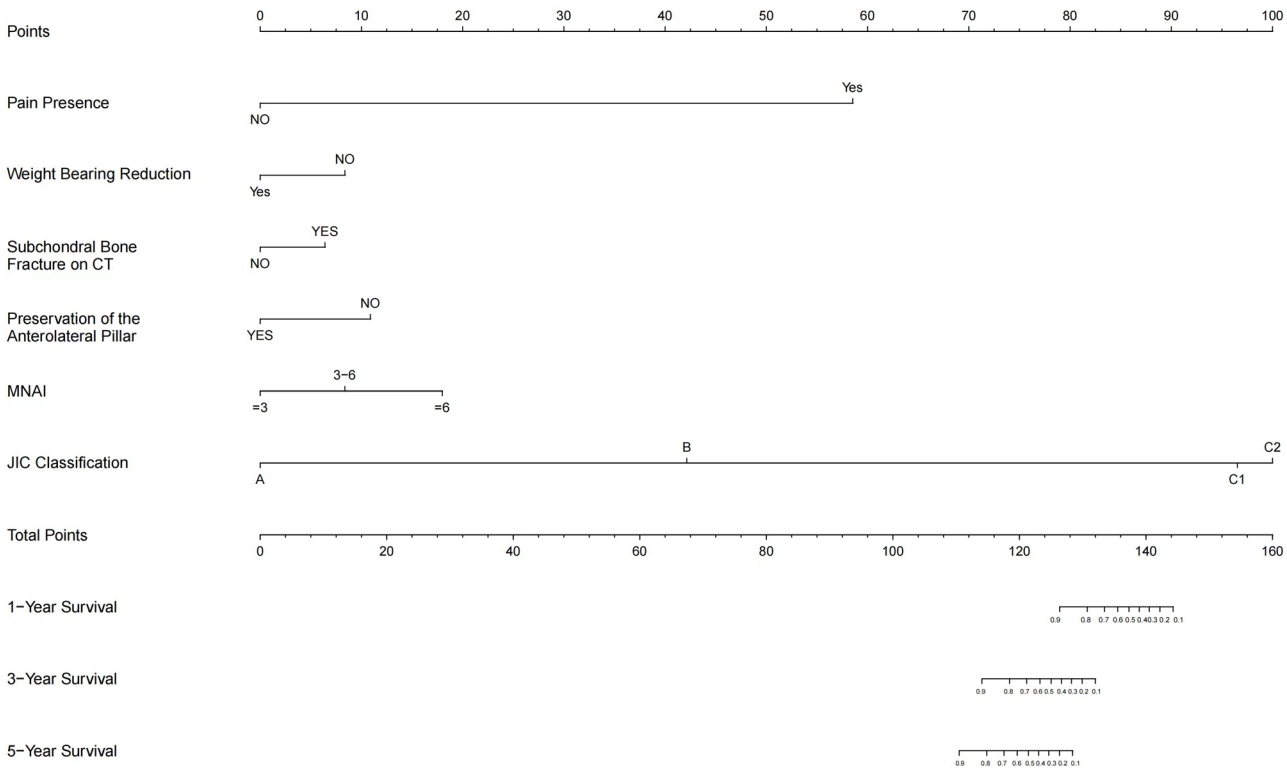


Fig. 1 Nomogram for predicting the survival rate of ONFH

the univariate analysis and their recognized relevance in clinical settings [26, 30].

A nomogram is essentially a visual representation of the Cox regression results. It begins with the “Points” line at the top, representing the score for each prognostic factor. After integrating and analyzing all the factors included by the researchers, each factor is plotted proportionally. For instance, the presence of pain (Yes) contributes a specific score, as does the absence of pain (No). Similarly, weight-bearing reduction (Yes or No), subchondral bone fracture on CT (Yes or No), preservation of the anterolateral pillar (Yes or No), the MNAI categories (≤ 3 , 3–6, > 6), and the JIC classification types (A, B, C1, C2) each contribute to the total score. Summing these individual scores provides a cumulative score, which is used to predict survival rates. The total points are mapped against the survival probabilities at 1, 3, and 5 years, where higher total points correlate with lower survival probabilities.

In addition to the nomogram, we constructed Kaplan-Meier survival curves to evaluate these six factors, as shown in Fig. 2, which comprises six curves, each depicting the impact of a different prognostic factor on patient survival over time. Figure 2A focuses on pain

presence, showing that patients experiencing pain have a lower survival rate compared to those without pain. Figure 2B illustrates the survival rates across different JIC classifications, indicating that higher severity classifications (C1 and C2) are associated with lower survival rates. Figure 2C illustrates survival based on the extent of necrosis, with patients having greater necrotic areas exhibiting lower survival rates. Figure 2D compares survival between patients who have reduced weight-bearing and those who have not, showing that patients who reduced weight-bearing have higher survival rates. Figure 2E shows that patients with preserved anterolateral pillars have higher survival rates. Finally, Fig. 2F indicates survival differences between patients with and without subchondral bone fractures, with the presence of subchondral bone fractures correlating with lower survival rates. Log-rank test results showed statistically significant differences between the groups in all Kaplan-Meier survival curves ($P < 0.05$).

The model's ability to correctly distinguish between patients who experienced the clinical outcome and those who did not is typically represented by the concordance index (C-index), essentially the area under the ROC curve (AUC), with a range of 0.5–1.0. The closer the value

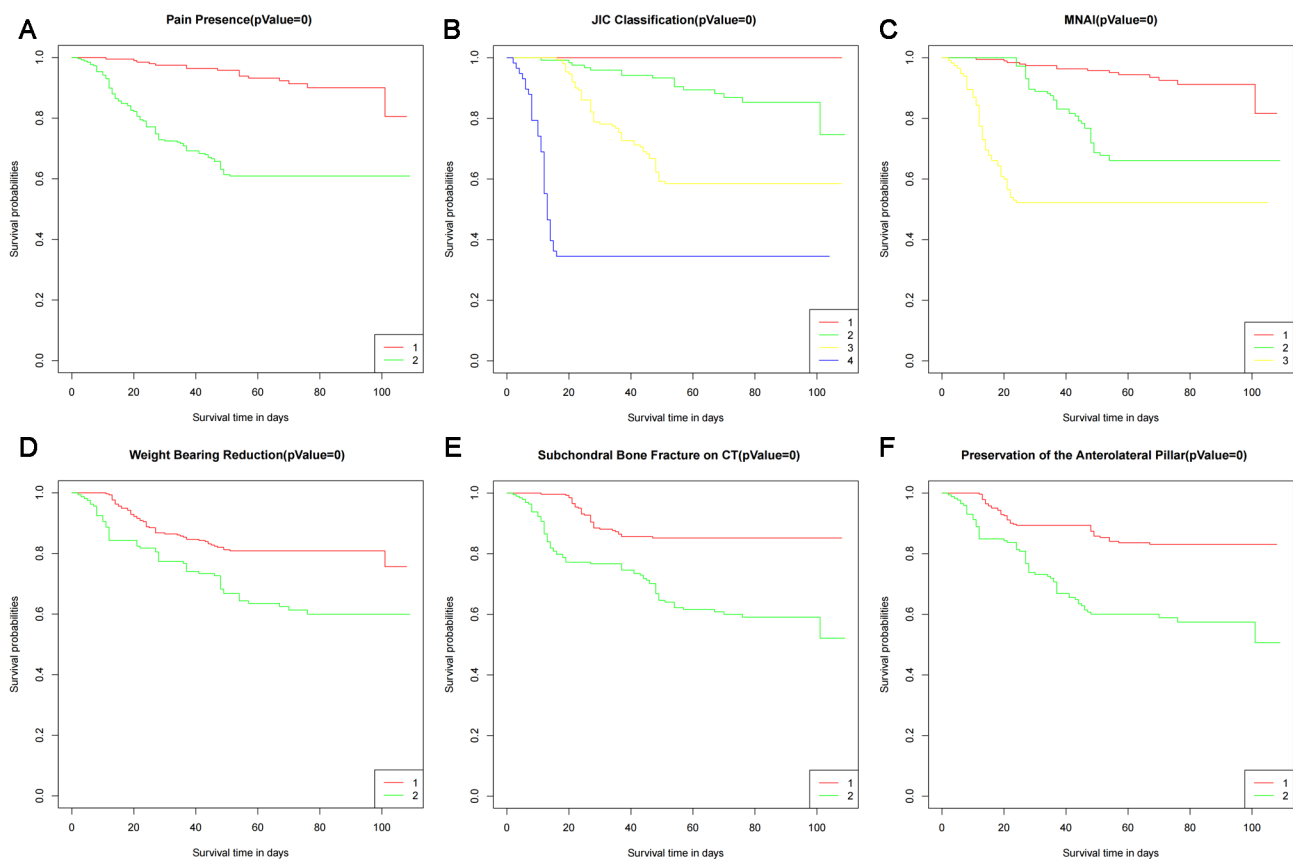


Fig. 2 Kaplan-Meier survival curves for pain presence (A), JIC classification (B), necrotic area (C), weight-bearing reduction (D), preservation of the anterolateral pillar (E), and subchondral bone fracture on CT (F)

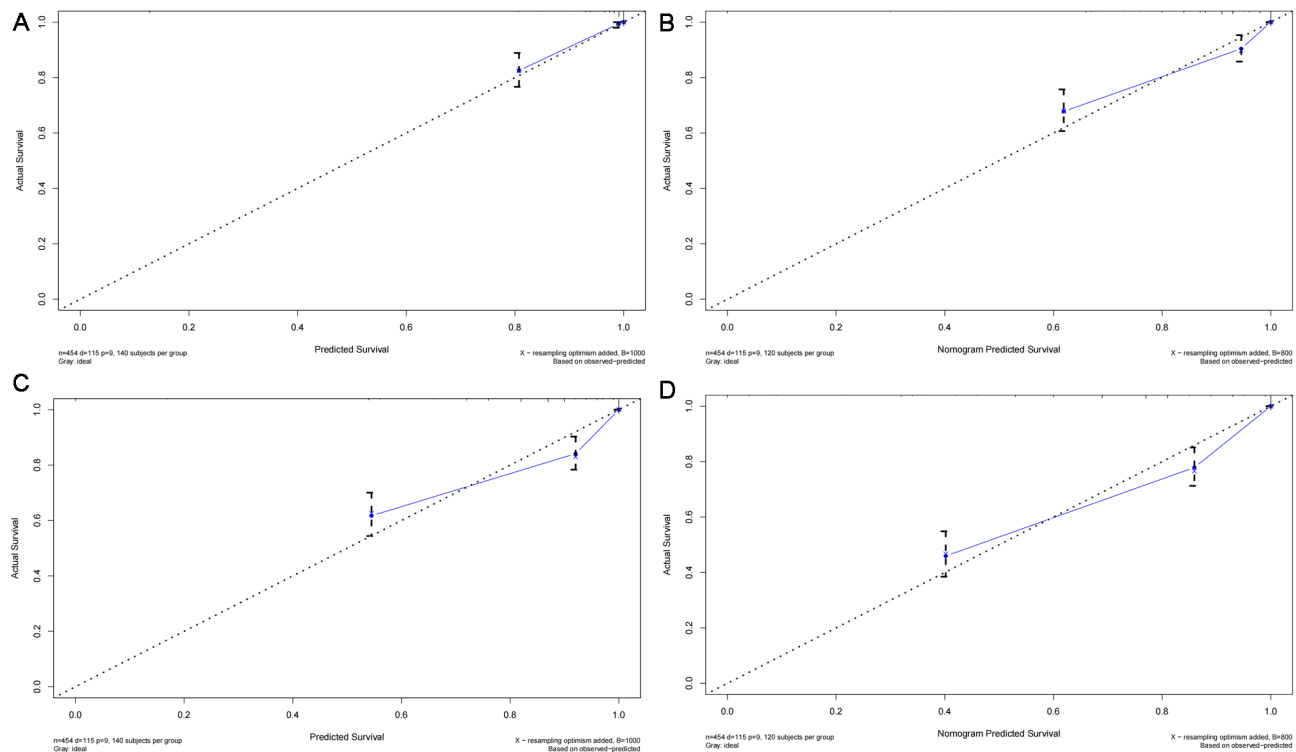


Fig. 3 Calibration curves of the prediction model at 12 months (A), 24 months (B), 36 months (C), and 60 months (D) Fig. 4. Clinical decision curve of the prognostic model

is to 1.0, the better the consistency between the predicted and actual results. The C-index of the nomogram, derived using R, was 0.88 (95% CI, 0.606–0.907).

We evaluated the accuracy of the model's prediction of individual endpoint event probabilities using calibration curves. The calibration curve provides insight into how well the model's predictions align with actual patient outcomes. The horizontal axis represents different endpoint event probabilities predicted by the model, while the vertical axis reflects the observed probabilities of patient endpoint events. Ideally, a calibration curve would follow a straight line with a slope of 1, indicating perfect agreement between predicted and observed probabilities. The closer the actual calibration curve is to this ideal line, the more accurate the model is, with smaller deviations suggesting a higher predictive performance (see Fig. 3). Figure 3A presents the calibration curve for 12 months, Fig. 3B for 24 months, Fig. 3C for 36 months, and Fig. 3D for 60 months, showing a strong alignment between the predicted and actual outcomes across all time intervals. We performed Bootstrap internal validation (1000 bootstrap resamples) to calculate the relatively corrected C-index, obtaining a CI of 0.88, indicating that the model demonstrates a high degree of consistency between predicted survival rates and actual outcomes for ONFH patients at most time points.

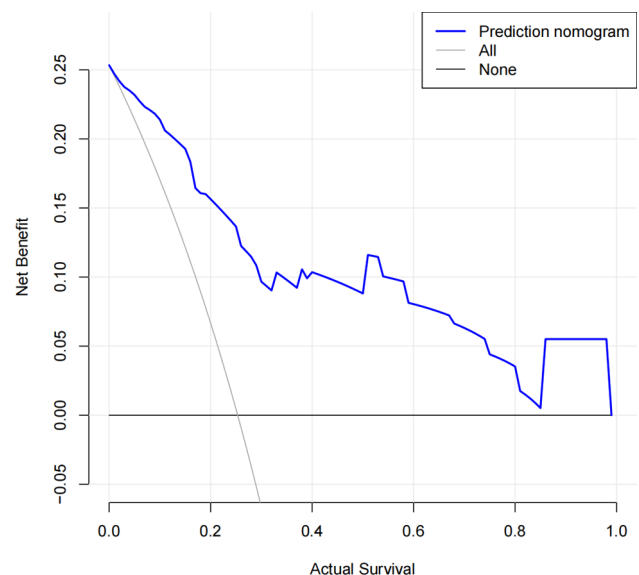


Fig. 4 Clinical decision curve of the prognostic model

Finally, we assessed the clinical utility of the model by drawing the Decision Curve Analysis (DCA) (see Fig. 4). The DCA helps evaluate the practical benefit of applying the prognostic model in clinical settings by considering the trade-offs between true positive and false positive results. The horizontal axis of the graph represents the threshold probability—the probability at which a patient

would opt for an intervention—while the vertical axis shows the net benefit, balancing the advantages of correctly identified patients against the risks of unnecessary treatments.

In this analysis, the No Intervention Line represents the net benefit when no patients receive treatment, and the All Intervention Line indicates the net benefit if all patients are treated regardless of their risk. The Model Curve illustrates the net benefit provided by the prognostic model across different threshold probabilities, demonstrating superior performance compared to both the No Intervention and All Intervention lines. This result suggests that using the prognostic model offers a clear clinical advantage, particularly in identifying patients who would benefit most from specific interventions at various risk thresholds.

Discussion

Interpretation of results

Delphi method and expert consensus

The Delphi method not only enabled us to systematically identify key prognostic factors, but it also ensured the clinical relevance and reliability of our findings through expert consensus. The high level of expert participation and strong authority coefficients enhanced the credibility of the identified indicators. Moreover, the consistency of expert agreement throughout the process underscores the robustness of our approach. By incorporating expert feedback, we ensured that the identified prognostic factors are directly applicable and clinically relevant for predicting femoral head collapse in ONFH patients. This expert-driven approach provides a practical framework that can be confidently utilized in clinical settings for decision-making and patient management.

In summary, the Delphi method contributed both scientific rigor and practical utility to our model, ensuring that the selected prognostic factors are grounded in expert consensus and can meaningfully guide clinical practice in the management of ONFH.

Key prognostic factors

Our study identified several key prognostic factors for ONFH, each contributing uniquely to the risk of femoral head collapse.

The presence of pain is a critical prognostic factor in ONFH. Pain correlates strongly with the extent of bone necrosis and the mechanical instability of the femoral head. Clinical studies indicate that pain often precedes structural changes, serving as an early warning sign of disease progression [31]. Biologically, pain is thought to result from increased intraosseous pressure and the release of inflammatory mediators in response to bone necrosis [30]. These factors not only explain the

occurrence of pain but also highlight its importance in clinical prognosis.

The JIC classification, necrotic area size, anterolateral pillar integrity, and subchondral bone fractures on CT scans are critical imaging indicators for predicting the prognosis of ONFH. The JIC classification system categorizes the extent of necrosis. Higher JIC grades correlate with more extensive necrosis, a higher risk of femoral head collapse, and compromised structural integrity of the femoral head [26]. This standardized method aids in clinical decision-making and patient stratification for treatment, and it has been validated as a reliable predictor of disease progression and femoral head collapse [12]. The necrotic area size is a direct indicator of disease severity. Larger necrotic areas suggest more extensive bone death, which compromises the structural integrity of the femoral head and increases the risk of collapse. This aligns with the biomechanical understanding that the loss of viable bone tissue reduces the femoral head's ability to withstand normal physiological loads [32]. Previous studies have consistently shown that a larger necrotic area is associated with worse clinical outcomes, reinforcing its significance as a key prognostic factor in ONFH [13]. Based on the mechanical structure of the femoral head, the primary weight-bearing region is located on the anterolateral aspect of the femoral head. When pathology occurs in this area, the mechanical support capacity of the femoral head is compromised, leading to impaired normal stress transmission [33]. Regardless of the lesion size, the risk of femoral head collapse is significantly elevated under these conditions [13]. Furthermore, studies using metrics like the lateral and combined preserved angles (LPA and CPA) have demonstrated their predictive value for femoral head collapse, highlighting the critical importance of this region [34]. Subchondral bone fractures on CT scans provide critical insights into the structural integrity of the femoral head and are strong predictors of disease progression and collapse. Bone microstructure analyses using multi-detector row computed tomography (MDCT) have revealed that changes in subchondral trabecular bone are associated with an increased risk of collapse, highlighting the importance of early detection [35]. Additionally, the predictive value of necrotic lesion boundaries, measured through specific intact ratios in AP and frog-leg views, has been demonstrated in studies, indicating that precise measurement of these boundaries can help assess the extent of damage and structural risk [36].

The reduction of weight-bearing plays a crucial role in the management of ONFH. Orthopedic devices such as crutches and canes help reduce mechanical load on the femoral head. This approach delays the need for total hip arthroplasty (THA) and reduces the risk of femoral head collapse [37]. In addition, reducing mechanical stress

promotes bone recovery by facilitating bone remodeling, a process supported by pathways like OPG/RANK/RANKL [38].

Development and validation of the predictive model

We synthesized these critical prognostic factors into a nomogram for predicting ONFH survival rates (see Fig. 1). With a high C-index of 0.88, our nomogram demonstrates superior predictive accuracy and clinical robustness. Unlike Zheng et al., who focus on factors like Garden alignment and surgery timing, our model includes a broader range of indicators for a more comprehensive prognosis [39]. Similarly, while Qu et al. emphasize anatomical preservation, their model is limited to specific ONFH etiologies, whereas ours is broadly applicable across various clinical settings [40].

The Kaplan-Meier survival curves in Fig. 2A and F complement the nomogram by providing a visual representation of patient survival probabilities based on the identified prognostic factors. The curves validate the nomogram's predictions, showing how factors like pain presence, high JIC classifications, and larger necrotic areas correlate with decreased survival rates, thus underscoring the necessity for targeted clinical strategies. Figure 3A and D show calibration curves that validate the model's predictive accuracy over different time intervals (12, 24, 36, and 60 months). The close alignment with the ideal reference line across these intervals confirms the model's reliability in real-world clinical settings. This high level of calibration accuracy means that clinicians can trust the model to provide consistent and accurate predictions, thereby improving decision-making in the management of ONFH. Building on the predictive accuracy established in Figs. 1, 2, 3 and 4 presents a DCA to evaluate the clinical utility of the prognostic model. The DCA reveals the model's net benefit compared to standard practices, highlighting its importance in clinical decision-making.

Clinical implications

The model allows for the early identification of patients at high risk of femoral head collapse, which is crucial for implementing personalized treatment plans. For example, high-risk patients can be closely monitored and may benefit from early surgical interventions, such as core decompression, to prevent collapse [41, 42]. Furthermore, the model enhances patient management by stratifying patients based on their risk levels. This stratification ensures that those with the highest risk receive the most intensive management and follow-up, optimizing resource allocation and ensuring timely and appropriate care for high-risk patients.

In addition, the model identifies key prognostic factors such as pain presence, JIC classification, necrotic area,

weight-bearing reduction, preservation of the antero-lateral pillar, and subchondral bone fracture on CT. Clinicians can target these areas in their treatment plans, such as encouraging weight-bearing reduction through supportive devices or prioritizing surgical techniques aimed at preserving the anterolateral pillar for high-risk patients. By accurately predicting the progression of ONFH, the model also helps reduce the need for invasive surgical procedures like THA. Early intervention based on the model's predictions can slow disease progression and maintain joint function, thereby delaying or preventing the need for hip replacement surgery.

Finally, the model serves as a guide for future research and clinical trials by identifying patients who are most likely to benefit from new treatments or interventions. This targeted approach enables researchers to design more effective studies, accelerating the development of new therapies and improving the overall understanding of ONFH progression and management.

Limitations

Future research should prioritize external validation of the prognostic model in diverse patient populations and clinical settings. Large-scale, prospective multicenter studies are critical to confirming the model's predictive accuracy across different demographics, healthcare systems, and geographic locations. Including a broad range of patient profiles will enhance the model's generalizability. Additionally, long-term prospective studies with extended follow-up are necessary to observe the disease's natural history and better assess the impact of prognostic factors on femoral head collapse. Such longitudinal data will improve the timing and effectiveness of interventions, enabling more tailored treatment strategies.

Evaluating the effectiveness of various interventions based on the model, along with cost-effectiveness analyses, is also important. Comparative clinical trials involving pharmacological treatments, surgical interventions, and rehabilitation strategies will help identify the best management plans for patients with different risk levels. Furthermore, understanding the economic impact of the model, including potential cost savings from preventing femoral head collapse, will support its broader clinical adoption.

Incorporating emerging technologies such as artificial intelligence (AI) and exploring new prognostic factors can further improve the model's predictive power. AI-driven analysis of large datasets can identify complex patterns and refine the model. Additionally, research into genetic markers, biomechanical assessments, and advanced imaging techniques may help identify and validate new prognostic indicators, contributing to a more comprehensive understanding of ONFH.

Future research directions

Future research should prioritize the external validation of the prognostic model in diverse patient populations and clinical settings. Prospective multicenter studies are crucial to confirm the model's predictive accuracy and reliability across different demographics, health-care systems, and geographic locations. Including a wide range of patient profiles in these studies will ensure the model's generalizability and applicability in various clinical contexts. Furthermore, to understand the long-term outcomes and progression of ONFH, it is necessary to conduct prospective studies with longitudinal follow-up. Tracking patients over extended periods will help observe the natural history of the disease and the impact of identified prognostic factors on femoral head collapse. Detailed longitudinal data will provide insights into the timing and effectiveness of different interventions, allowing for more precise and tailored treatment strategies.

Additionally, evaluating the effectiveness of various treatment interventions based on the prognostic model and conducting cost-effectiveness analyses are crucial. Clinical trials comparing different therapeutic approaches, such as pharmacological treatments, surgical interventions, and rehabilitation strategies, will help determine the most effective management plans for patients at different risk levels. Future research should also assess the economic implications of implementing the prognostic model in clinical practice, including the potential cost savings from preventing femoral head collapse and reducing the need for invasive surgeries. These analyses will support the broader adoption of the model and justify investments in its development and application.

Incorporating emerging technologies and investigating additional prognostic factors can significantly enhance the predictive power and accuracy of prognostic models. Future research should explore the use of AI algorithms to analyze large datasets, identify complex patterns, and refine the prognostic model. Additionally, studies should investigate factors such as genetic markers, detailed biomechanical assessments, and advanced imaging techniques. Identifying and validating new prognostic indicators will contribute to a more comprehensive understanding of ONFH and improve the accuracy of prognostic models.

Conclusion

This study successfully developed a prognostic model to predict femoral head collapse in patients with ONFH. Key prognostic factors identified include pain presence, JIC classification, necrotic area, weight-bearing reduction, preservation of the anterolateral pillar, and subchondral bone fracture on CT. The model demonstrated high predictive accuracy, offering a reliable tool for

clinicians to identify high-risk patients early and guide personalized treatment interventions. Implementing this model in clinical practice can enhance patient stratification, optimize resource allocation, and improve early diagnosis and management of ONFH, ultimately contributing to better patient outcomes and reducing the need for invasive surgical procedures.

Appendices

Table A1 JIC classification

JIC Classification	MRI Manifestation
Type A	Necrotic area < one-third of the weight-bearing portion
Type B	Necrotic area < two-thirds of the weight-bearing portion
Type C1	Necrotic area > two-thirds of the weight-bearing portion but not extending to the acetabular edge
Type C2	Necrotic area extends laterally to the acetabular edge

Table A2 CJFH classification

CJFH Classification	MRI Manifestation
M Type (Medial)	Necrotic area occupies the medial column, with central and lateral columns intact
C Type (Central)	Necrotic area occupies the central and medial columns, with the lateral column intact
L Type (Lateral)	Necrosis occupies the medial, central, and lateral columns
L1 Type (Sub-Lateral)	Necrosis occupies all three columns, but part of the lateral column remains intact, with at least some cortical retention
L2 Type (Extreme Lateral)	Necrotic area occupies only the lateral column or part of the central column, with the rest of the central column and the entire medial column intact
L3 Type (Total Head)	Necrotic band penetrates the cortex and marrow of all three columns of the femoral head

Table A3 Expert Information statistics

Item	First Round (n, %)	Second Round (n, %)
Gender		
Male	30 (100.00)	35 (87.50)
Female	-	5 (12.50)
Years of Experience		
5–10 years	7 (23.33)	10 (25.00)
11–20 years	15 (50.00)	20 (50.00)
21–30 years	7 (23.33)	9 (22.50)
31–40 years	1 (3.34)	1 (2.50)
Professional Title		
Intermediate	7 (23.33)	10 (25.00)
Associate Senior	9 (30.00)	14 (35.00)
Senior	14 (46.67)	16 (40.00)

Table A4 Summary of Expert suggestions from the First Round of Consultation

No.	Expert Suggestion	Adopted
1	Add “patient gait” item	Yes
2	Can some “intervention measures” be merged?	Yes
3	Consider the impact of “early diagnosis”	Yes
4	Add “bone metabolism indicators” item	Yes
5	Add “hip trauma history” item	Yes
6	Add “surgical timing” item	No
7	Add “surgical method” item	Yes
8	Consider the impact of “patient treatment compliance”	Yes
9	Consider the impact of “patient mental and emotional changes”	Yes

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Author contributions

T.J.Y. and S.Y.S. contributed equally to this work. T.J.Y. and S.Y.S. designed the study and wrote the main manuscript text. X.P.Z. and L.Z. conducted the data analysis and prepared the figures. H.J.H. supervised the project and provided critical revisions to the manuscript. All authors reviewed and approved the final manuscript.

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Data availability

The data supporting the findings of this study, including de-identified individual participant data, data dictionaries, clinical data, imaging findings, laboratory results, and relevant documents such as the study protocol and statistical analysis plan, will be available from the corresponding author Hai-jun He, upon reasonable request. The data will be accessible starting 6 months after publication for a period of 5 years. Researchers who submit a methodologically sound proposal with ethical approval may request access by contacting Hai-jun He and signing a data access agreement. Data will be shared through secure transfer mechanisms.

Declarations

Ethics approval and consent to participate

This study was approved by the Ethics Committee of Wangjing Hospital, China Academy of Chinese Medical Sciences (Approval No.: WJEC-KT-2022-043-P001; Project No.: CI2021A05406). All procedures involving human participants were conducted in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments. The ethical review included a fast-track process, and it was determined that the research adhered to all required ethical guidelines, ensuring that participants were fully informed of the research, and any adverse events were to be reported promptly to the ethics committee.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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