

Prediction of osteonecrosis collapse of the femoral head based on the proportion of the proximal sclerotic rim

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Abstract

Purpose The purpose of this study was to predict ONFH-induced collapse based on the percentage of the proximal sclerotic rim.

Methods In total, 101 patients satisfying the inclusion criteria who received treatment at Guang'anmen Hospital were enrolled. Bilateral hip-joint computed tomography (CT) of the necrotic tissue was performed, and the largest layer within the coronal CT images was selected together with its anterior and posterior layers to calculate the proportion of the proximal sclerotic rim. The patients were divided into collapse and non-collapse groups, and the difference in the proportions of their proximal sclerotic rims was analysed. Specifically, a receiver operating characteristic (ROC) curve was created. The proportion of the proximal sclerotic rim represented by the maximal Youden's index was used as the reference value for collapse prediction, and its predictive value was assessed.

Results The proportion in the collapse group was 13.11 ± 10.65 %, whereas the proportion in the non-collapse group was 51.91 ± 21.29 % ($P < 0.01$). Additionally, the proportion corresponding to the maximal Youden's index (0.902) was 29.24 %. For clinical convenience, 30 % was selected as the reference value for collapse prediction, with 97.30 % sensitivity, 87.5 % specificity, 94.01 % accuracy, a positive likelihood ratio (LR) of 7.78, and a negative LR of 0.03. Therefore, the proportion of the proximal sclerotic rim is of great significance in predicting ONFH-induced collapse, and 30 % could be used as the critical value in clinical practice.

Conclusion When the proportion is >30 %, the collapse risk is low, whereas at <30 %, the risk is high, and effective mechanical support should be provided.

Keywords Femoral head · Osteonecrosis · Sclerotic rim · Collapse · Prediction

Introduction

Osteonecrosis of the femoral head (ONFH) is a common refractory condition in the field of orthopaedics. Approximately 80 % of patients with ONFH will progress to femoral head collapse (FHC) within one to four years if timely treatment is not provided [1–4]. After FHC occurs, osteoarthritis follows, which seriously affects hip joint function; consequently, joint replacement is unavoidable [5–8]. However, joint prostheses are not durable, and ONFH has a high incidence in young and middle-aged individuals [9]. Many patients are thus subjected to repeated joint replacement procedures [10–15], which cause great pain as well as a heavy economic burden on the family and on society. Therefore, a large number of ONFH-related studies have focused on identifying effective methods that can accurately predict the prognosis of ONFH and the risk of FHC.

Previously, researchers have proposed different methods for FHC prediction based on the necrotic range and area. Kerboul et al. used the radian sum method to predict the prognosis of ONFH and proposed that patients with a radian sum $>200^\circ$ have a large necrotic range and a poor prognosis, whereas patients with a radian sum $<160^\circ$ have a small necrotic range and a good prognosis [12, 13]. Koo et al. used the necrotic index method to predict the risk of FHC and proposed that patients with a necrosis index <30 % are at low risk of FHC, patients with an index between 30 and 40 % are at moderate risk, and patients with an index >40 % are at high risk [16, 17]. In contrast, Sugano used the necrosis area ratio method to predict the risk of FHC and proposed that a necrosis area ratio >43 % results in a high risk of collapse [18]. Hernigou et al. and Nishii et al. proposed that patients with a

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necrosis volume ratio > 30 % face a high risk of FHC [19, 20]. In addition to these methods, other methods, such as Japanese Investigation Committee (JIC) typing [21] and the China-Japan Friendship Hospital (CJFH) classification [22], have been reported. The majority of the aforementioned studies concluded that the femoral head tends to collapse when the necrotic range is large and when the necrotic area overlaps with the weight-bearing area. However, during the clinical diagnosis and treatment of ONFH, we observed several cases of ONFH that did not progress to collapse, although many of these cases had a large necrotic range or exhibited necrosis in the weight-bearing area. A further retrospective analysis revealed irregular mottling or a belt-like hyperdense shadow around the necrotic tissue (i.e., a sclerotic rim) in these patients on X-rays and computed tomography (CT) scans. Therefore, the current methods of FHC prediction may need to be revised.

The formation of a sclerotic rim is a phenomenon that occurs during the repair process after ONFH. In this process, new bone is deposited, the bone trabeculae thicken, the intertrabecular spaces become narrow, and the bone mineral density increases. This phenomenon is an indication that ONFH tissue is being repaired [23–26]. The rim is a special sclerotic margin that is formed in the femoral head by the new bone surrounding the reaction interface. The rim supports the subchondral bone and serves as a factor that prevents or delays FHC. Compared with normal bone, the sclerotic rim exhibits a different morphology; this difference is manifested by an increase in the thickness of the bone trabeculae as well as an increase in mechanical strength. Therefore, the sclerotic rim prevents FHC from occurring too early and creates conditions fostering prolongation of the persistence of the femoral head [23]. Certain scholars who have conducted studies on the relationship between the sclerotic rim and FHC have determined that FHC does not occur in patients with ONFH and a complete sclerotic rim in the subchondral bone and that the collapse rate among patients with ONFH and without a complete sclerotic rim is as high as 76 % [24, 25]. However, these studies employed only a qualitative classification based on whether the sclerotic rim has formed and whether the rim is complete. Therefore, relevant quantitative analyses are lacking.

Based on the aforementioned characteristics of the sclerotic rim, the present study quantitatively analysed the proximal sclerotic rim in patients with ONFH and subsequently calculated the proportion of the sclerotic rim. The main aim of the study was to explore the relationship between the proportion of the proximal sclerotic rim and the occurrence of FHC. The results of this study might provide a reference value for predicting the occurrence of FHC in clinical practice based on the proportion of the proximal sclerotic rim.

Materials and methods

General data

A total of 101 cases (170 hips) of ONFH were collected by the Chiefs of Orthopedics at Guang'anmen Hospital between August 2012 and February 2014. ONFH was diagnosed according to the diagnostic criteria of the 2012 Chinese Experts' Consensus on the Diagnosis and Treatment of Osteonecrosis of the Femoral Head in Adults [27]. Of these patients, 70 were males and 31 were females, with a gender ratio of 2.3:1. Their ages ranged from 20 to 64 years, with an average of 46 years. In total, 87 (86 %) were Han people, and 14 (14 %) were from minority groups. Moreover, 66 (65 %) were physical labourers. Their ONFH courses ranged from two to ten years, with an average of 3.8 years. Overall, 35 (35 %) of the patients suffered from unilateral ONFH, and 66 (65 %) suffered from bilateral ONFH. Additionally, alcoholic ONFH occurred in 52 patients (51 %), steroid-induced ONFH occurred in 31 patients (31 %), and idiopathic ONFH occurred in 18 patients (18 %). The severity of the involved hips was staged according to the 1993 Association Research Circulation Osseous (ARCO) staging criteria [28]: stage I, 3; stage II, 62; stage III, 73; and stage IV, 32.

The inclusion criteria were as follows: (1) stage II or higher according to ARCO staging, (2) patients without receiving systemic treatment, (3) bilateral hip joint CT scan, (4) a natural course \geq three years if FHC did not occur, and (5) informed consent provided by the patient. The exclusion criteria included the following: (1) traumatic ONFH, such as femoral head fracture, femoral neck fracture, or hip joint dislocation, (2) ONFH accompanied by other joint diseases, such as bone neoplasms, rheumatoid arthritis, ankylosing spondylitis, joint tuberculosis, or pyogenic arthritis, (3) severe congenital malformation of the hip joints, (4) history of an operation on the hip joint, (5) a comorbid mental disorder, and (6) non-cooperation of the patient.

Finally, 101 patients (167 hips) satisfied the inclusion criteria, with three hips from three patients with bilateral ONFH excluded for ARCO stage I disease according to magnetic resonance imaging.

ONFH at ARCO stage III or higher was defined as FHC. The enrolled hips were divided into collapse and non-collapse groups.

This study was conducted in accordance with the Declaration of Helsinki. Approval was obtained from the Ethics Committee of Guang'anmen Hospital of the China Academy of Chinese Medicine Sciences (2009S217). Written informed consent was obtained from the participants.

CT

Dual-source, 64-slice spiral CT (Siemens, Germany) was used to scan the bilateral hip joints in cross-sections using the

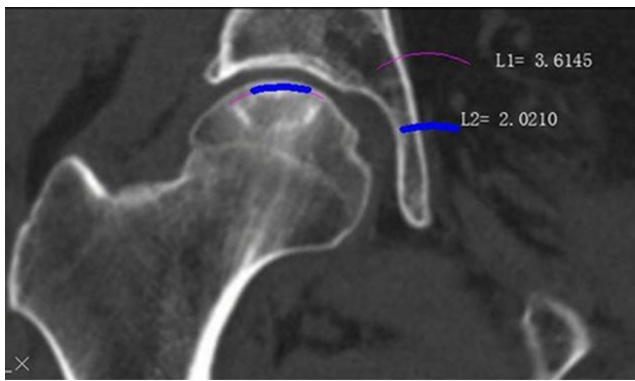


Fig. 1 Schematic diagram illustrating the calculation of the proportion of the sclerotic rim

following scanning parameters: a scanning voltage of 120 kV, a scanning current of 60 mA, bone tissue window scanning, and a slice thickness of 0.75 mm. All of the obtained images were exported in bmp format.

Calculation of the proportion of the sclerotic rim

The proportion of the sclerotic rim was calculated using the following steps:

- 1) Considering that larger slices would more accurately reflect the actual necrotic condition [29], the largest layer and the layers that were anterior and posterior to the largest layer (three layers in total) were selected from coronal CT images to calculate the proportion of the sclerotic rim.
- 2) The selected images were imported into AutoCAD software.
- 3) The proportion of the proximal sclerotic rim of the necrotic focus was measured. Considering that the majority of necrotic foci have an oval or round shape, the arc length (L1) of the upper hemicycle of the ellipse (the necrotic focus) and the length of the sclerotic rim within the upper hemicycle of the ellipse (L2) were measured based on the arc drawing and measurement functions of AutoCAD software. The proportion of the proximal sclerotic rim was specifically calculated based on the following formula: the proportion of the rim=L2/L1 (Fig. 1).

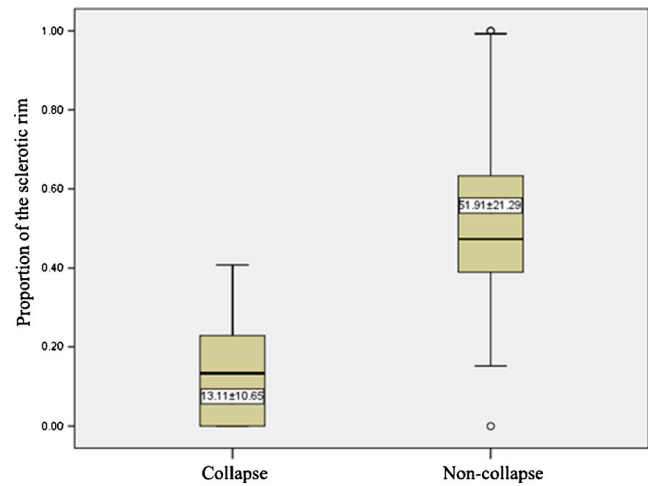


Fig. 2 Distribution of the proportions of the proximal sclerotic rims (%)

- 4) The proportions of the sclerotic rims in the three selected layers were calculated, and the mean value was used as the proportion of the sclerotic rim.

Prior to this study, we performed a preliminary experiment on 30 hips with ONFH. These cases were assessed every two weeks by three experienced orthopaedists. The orthopaedists measured the same case at the same time, and no significant differences were found among these measurements.

Observation indices

The proportions of the sclerotic rim were compared between the groups. To avoid diagnostic errors and insufficient knowledge regarding orthopaedics, the CT images were analysed by experienced orthopaedists. The orthopaedists were divided into three groups, namely, a group responsible for measuring the proportion of the sclerotic rim and blinded to the objective of the measurement, a group responsible for collapse judgment and blinded to the measurement event, and a group exclusively responsible for data collection and analysis. Using the proportion of the sclerotic rim as the test variable and whether collapse occurred as the state variable (collapse was defined as the state variable value), a receiver operating characteristic (ROC) curve was generated automatically, with sensitivity as the ordinate and 1–specificity as the abscissa. The proportion corresponding to the maximal Youden’s index

Table 1 Comparison of the proportions of the proximal sclerotic rims between groups

Group	Number of hips	The proportion of the proximal sclerotic rim (%)	Z	P
Collapse group	111	13.11±10.65	-9.88	<0.01*
Non-collapse group	56	51.91±21.29		

* Significant difference between the groups

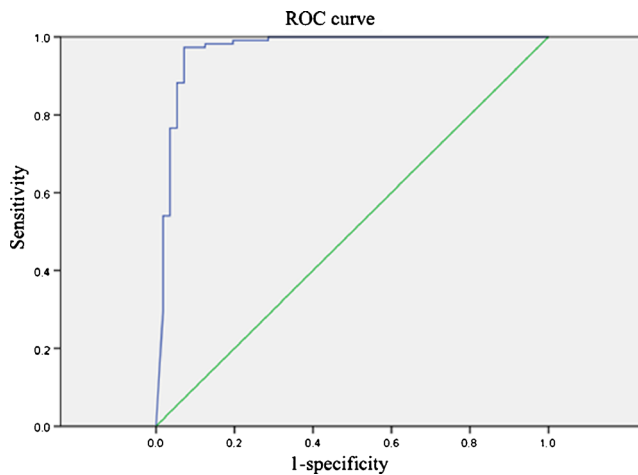


Fig. 3 Receiver operating characteristic (ROC) curve

value was used as the reference value to assess the value of the proportion of the proximal sclerotic rim for FHC prediction.

Statistical analysis

The data were processed using the SPSS 12.0 statistical package. First, normal distribution tests were performed. The data with normal distributions were compared between groups using *t*-tests. If a normal distribution was not observed, non-parametric tests were performed for comparisons between the groups. ROC curves were then created. All of the statistical tests were two sided, and differences with $P < 0.05$ were considered statistically significant.

Results

Comparison of the proportions of the proximal sclerotic rims between groups

One-sample Kolmogorov-Smirnov (K-S) tests showed that the proportion in the collapse group was $13.11 \pm 10.65\%$, with a P value of 0.001 (< 0.05), which did not reflect a normal distribution. In contrast, the proportion in the non-collapse group was $51.91 \pm 21.29\%$, with a P value of 0.33 (> 0.05), which reflected a normal distribution. The two groups were compared

Table 2 Area under the receiver operating characteristic (ROC) curve

Area	Standard error	Progressive sig	Progressive 95 % confidence interval	
			Lower limit	Upper limit
0.967	0.018	0.000	0.930	1.000

using a nonparametric test, and a significant difference was observed ($Z = -9.88$; $P < 0.01$; Table 1 and Fig. 2).

The ROC curve and the outcomes of prediction value assessment

The area under the ROC curve was 0.967 (Fig. 3 and Table 2). The proportion of the proximal sclerotic rim (29.24 %) corresponding to the maximal Youden's index value (0.902) was selected as the optimal critical point. For convenience in clinical applications, 30 % was selected as the reference value for prediction. The occurrence of FHC was predicted based on this value.

Of the 111 hips with FHC, 108 were successfully predicted. Of the 56 hips without collapse, 49 were successfully predicted (Table 3). The proportion of the proximal sclerotic rim had a sensitivity of 97.30 %, a specificity of 87.5 %, an accuracy rate of 94.01 %, a false-positive rate (misdiagnosis rate) of 12.5 %, a false-negative rate (omission diagnosis rate) of 2.70 %, a diagnostic odds ratio of 252, a positive likelihood ratio (LR) of 7.78, a negative LR of 0.03, a positive predictive value of 0.94, a negative predictive value of 0.94, and a Youden's index of 0.85 for predicting the occurrence of FHC.

Discussion

The relationship between the sclerotic rim and the occurrence of FHC remains controversial. The formation of a sclerotic rim is a manifestation of bone repair after ONFH, and it has a preventive effect against FHC. The incidence rates of FHC in hips with ONFH and a continuous sclerotic rim, a discontinuous sclerotic rim, and an obscure sclerotic rim of subchondral bone are 0, 76, and 63 %, respectively; however, the incidence rate of FHC in hips with ONFH that lack a noticeable sclerotic rim but exhibit a medium- or low-density shadow in the necrotic tissue is 100 % [25]. These findings suggest that the formation of a subchondral sclerotic rim (i.e., at the proximal end of the necrotic tissue) could prevent FHC.

Certain scholars have argued that the sclerotic rim is a reaction zone between the necrotic tissue and normal tissue and is therefore unfavourable for bone repair. In particular, the sclerotic rim may impede the growth of neovessels and the

Table 3 Femoral head collapse (FHC) prediction outcomes based on the proportion of the proximal sclerotic rim (30 %)

Predicted FHC	Actual FHC		Sum
	Yes	No	
Yes	108	7	115
No	3	49	52
Sum	111	56	167

advance of newly generated tissue toward the necrotic tissue [30–33]. However, in previous studies, the term “sclerotic rim” primarily referred to the disordered hyperplastic bone tissue located distal to the necrotic tissue. Therefore, the authors of these studies might have concluded that the sclerotic rim proximal to the necrotic tissue has a preventive effect on FHC, whereas the sclerotic rim distal to the necrotic tissue (at the juncture between normal bone tissue and necrotic tissue) impedes the repair of necrotic tissue.

The internal biomechanics of the femoral head are altered after ONFH, e.g. the buttress is destroyed, and the ability of the femoral head to resist stress decreases. If a sclerotic rim forms at the proximal end of the necrotic tissue, it could exert a mechanically supportive effect. In one of our previous studies (in press), we evaluated the mechanical role of a proximal sclerotic rim on stress on the femoral head by constructing three-dimensional finite element models with different proportions of proximal rim sclerosis. We found that the femoral deformity, the stress value in the compression direction, and the contact stress of the necrotic tissue gradually decreased with the increase in the proportion, which suggests that the sclerotic rim may improve the mechanical conduction and distribution of the femoral head, thereby preventing or delaying the occurrence of FHC. Therefore, in this study, we selected the sclerotic rim at the proximal end of necrotic tissue as an index for predicting the occurrence of FHC, and we explored the cutoff point for this index.

Our study showed that the proportion of proximal sclerotic tissue in the collapse group was 13.11 ± 10.65 %, whereas the proportion in the non-collapse group was 51.91 ± 21.29 % ($Z = -9.88$, $P = 0.00$). Based on the comparison between the measured proportions of the sclerotic rims and the actual occurrence of FHC, a ROC curve was created to determine the reference value of the proportion of the sclerotic rim for FHC prediction. The predictive value of the obtained index was then assessed. Our results showed that the area under the ROC curve was 0.967. According to the ROC curve evaluation criteria, the proportion of the sclerotic rim has high diagnostic value for predicting FHC.

The proportion of the proximal sclerotic rim corresponding to the maximal Youden’s index value was 29.24 %. Therefore, for convenience in clinical application, we used 30 % as the reference value for prediction. Of the 111 hips with FHC, 108 were successfully predicted. Of the 56 hips without collapse, 49 were successfully predicted (Table 3). The proportion of the proximal sclerotic rim (30 %) had a sensitivity of 97.30 %, a specificity of 87.5 %, an accuracy rate of 94.01 %, a false-positive rate (misdiagnosis rate) of 12.5 %, a false-negative rate (omission diagnosis rate) of 2.70 %, a diagnostic odds ratio of 252, a positive LR of 7.78, a negative LR of 0.03, a positive predictive value of 0.94, a negative predictive value of 0.94, and a Youden’s index of 0.85 for predicting the occurrence of FHC. These results suggest that the proportion

of the proximal sclerotic rim has high clinical value for FHC prediction. Previously, researchers conducted qualitative analyses to predict the occurrence of FHC based on whether a sclerotic rim had formed. It was found that patients with ONFH and a discontinuous subchondral sclerotic rim had an incidence of FHC of 76 % [24, 25]. These findings suggest that 24 % of patients with ONFH and a discontinuous subchondral sclerotic rim may still suffer from FHC, leading to great uncertainty about the application of our predictive index. Consequently, the specific proportion of the sclerotic rim that can be used as an index to predict FHC remains unclear. In the present study, we used a sclerotic rim proportion of 30 % as the quantitative index to predict the possible occurrence of ONFH, and the results showed that it had a sensitivity of 97.30 % and an accuracy of 94.01 %.

This study has certain limitations. First, we did not include a demographic comparison between the collapse and the non-collapse groups because the grouping was based on hips rather than patients. Second, although the proportion of the proximal sclerotic rim could accurately predict the prognosis of ONFH, it could not be applied for the prediction of the prognosis of ONFH at ARCO stages 0 and I because CT images do not reveal these conditions. Third, measurement of the proportion of the proximal sclerotic rim would be difficult to perform if the boundary of the focus was not clearly displayed for various reasons. Lastly, this study was cross-sectional, and all of the cases were from a single source. Multi-centre observational research studies will be better able to assess the predictive accuracy of the index used in this study.

The proportion of the proximal sclerotic rim has high clinical value for FHC prediction because the risk of FHC decreases as the proportion of the proximal sclerotic rim increases. In particular, when the proportion is >30 %, the risk of FHC is low, and the prognosis of ONFH is satisfactory. In contrast, when the proportion is <30 %, the risk of FHC is high, and effective mechanical support should be provided.

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Conflict of interest The authors declare no conflicts of interest.

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