



The influence of traditional Chinese medicine constitutions on the potential repair capacity after osteonecrosis of the femoral head



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ABSTRACT

Objectives: To explore the effects of traditional Chinese medicine (TCM) constitutions on repair capacity after osteonecrosis of the femoral head (ONFH).

Design and setting: Ninety-six patients with TCM constitutions of yang-deficiency, dampness-heat and/or blood-stasis were recruited from the orthopedic outpatient clinic of the Guang'anmen Hospital of the China Academy of Chinese Medical Science. Each patient underwent computed tomography (CT) examination of the hips, and CAD software was used to estimate proximal sclerosis ratios based on the CT images.

Main outcome measures: The proximal sclerosis ratios of subjects with different TCM constitutions were found to be significantly different ($P=0.046$): the ratios of subjects with the yang-deficiency, dampness-heat, blood-stasis, yang-deficiency plus dampness-heat, yang-deficiency plus blood-stasis, and dampness-heat plus blood-stasis constitutions were, respectively, 0.20 ± 0.25 , 0.24 ± 0.25 , 0.39 ± 0.29 , 0.29 ± 0.37 , 0.35 ± 0.29 , and 0.42 ± 0.28 . Differences among the three types of single, uneven constitutions were also observed ($P=0.042$).

Results: For each pairwise comparison, the yang-deficiency constitution was different from the blood-stasis constitution ($P=0.02$) and dampness-heat plus blood-stasis constitution ($p=0.02$). The proximal sclerosis ratio was lower in the yang-deficiency constitution group but higher in the blood-stasis constitution group.

Conclusions: TCM constitutions influence the capacity for ONFH repair. The blood-stasis constitution has a strong repair ability, but the yang-deficiency constitution has a poor repair ability and tends to collapse and require positive treatment. Furthermore, important therapeutic principles should reinforce the kidney and strengthen the spleen.

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1. Introduction

Collapse occurring after osteonecrosis of the femoral head (ONFH) plays a crucial role in the development and prognosis of ONFH. The potential for collapse is influenced by multiple factors, such as necrosis range, necrotic area, and self-repair ability. Repair ability and type are especially crucial factors affecting prognosis.

Sclerosis is generally caused by necrotic tissue repair and presents as irregular punctate or banded high-density shadows on computed tomography (CT) and X-ray scans. During the repair process after ONFH, the number of new bone deposits, bone trabeculae,

thickened and narrowed intertrabecular spaces, and bone mineral density increase, which causes the formation of the sclerotic rim. The sclerotic rim is the newly formed bone around the reactive interface that effectively forms a special sclerotic margin on the femoral head and plays a supporting role for subchondral bone.^{1–3} In our previous study, we analyzed the effect of the proximal sclerotic rim on the femoral head and necrotic tissue stress using the finite element method and found that the proximal sclerotic rim of the necrotic tissue mechanically supports the femoral head and the necrotic tissue. The rim effectively supports the stress load and increases the structural tolerance and anti-deformity capacities of the femoral head. The proximal sclerotic rim forms “a mechanical protective umbrella” on the surface of the necrotic tissue, thereby preventing the collapse of the ONFH.⁴ In another study, we used the ratio of the proximal sclerotic rim as an observational index to predict the collapse of ONFHs. We found that the ratio of the proximal sclerotic rim is of great significance for predicting the

Abbreviations: TCM, traditional Chinese medicine; ONFH, osteonecrosis of the femoral head; CT, computed tomography.

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collapse of ONFHs and that a ratio of 30% can be used as a critical threshold in clinical practice.⁵ The factors that influence the formation of the proximal sclerotic rim during repair after ONFH are currently unclear. Western medicine cannot provide a satisfactory explanation, and most scholars believe that the formation of sclerosis is affected by a combination of stress factors, changes in the microenvironment of the necrotic tissue, mutual regulation between various cytokines, and other factors.^{6–11}

According to traditional Chinese medicine (TCM) constitution theories, the occurrence, development and outcome of diseases are closely related to TCM constitutions. Therefore, individual differences in TCM constitutions may lead to different repair capacities for ONFH. TCM constitutions form during an individual's lifetime and are based on natural and acquired endowments.¹² These endowments are comprehensive and relatively stable, inherent qualities of morphological structure, physiological function and psychological state, and they include personality features that are adapted to the natural and social environment and that form during the process of growth and development. These features can trigger some pathogenic factors that increase the susceptibility or propensity to develop certain diseases. In addition, constitutions affect disease pathogenesis, syndromes and transfers, which are referred to as "transformation in accord with constitution". Constitutions are an important basis for predicting disease development, outcome and prognosis. The yang-deficiency, damp-heat, and blood-stasis constitutions are frequently susceptible to disease, as indicated by our previous research on susceptible TCM constitutions. In addition, in TCM, the current consensus regarding the etiology and pathogenesis of osteonecrosis states that phlegm and blood-stasis constitutions are the main pathogenic factors.¹³

Based on the aforementioned factors, in this study, we selected ONFH patients with yang-deficiency, damp-heat and blood-stasis constitutions to compare differences in the proximal sclerosis ratios among different TCM constitutions. The aim of the study was to investigate the effects of TCM constitution on the repair capacity after ONFH. The results of this study may shed new light on TCM treatment of ONFH.

2. Materials and methods

2.1. Criteria for the diagnosis and staging of ONFH and constitution determination

ONFH was diagnosed in accordance with the criteria described in the Chinese Experts' Consensus on the Diagnosis and Treatment of Osteonecrosis of the Femoral Head in Adults, which was published in 2012.¹⁴ The hips of the patients were classified as stage 0–IV according to the 1993 Association Research Circulation Osseous (ARCO) classification.¹⁵

Classification and determination of the TCM constitution was performed according to the standard Classification and Determination of Constitution in TCM (ZYYXH/T157-2009) that was published by the China Association for Traditional Chinese Medicine in 2009.¹⁶ Based on a completed TCM constitution questionnaire,¹⁶ ONFH patients with yang-deficiency, damp-heat, and/or blood-stasis constitutions were selected.

2.2. Inclusion and exclusion criteria

The inclusion criteria included the following: subjects met the diagnosis criteria for ONFH; patients of ARCO stages II–IV were selected; CT examinations of hips were performed; TCM constitutions met the definition of yang-deficiency, dampness-heat and/or blood-stasis constitutions; patients had not undergone systemic treatment; and informed consent was obtained.

The exclusion criteria included the following: traumatic necrosis of the femoral head; complications with other joint diseases, such as bone tumors, rheumatoid arthritis, ankylosing spondylitis, joint tuberculosis, or suppurative arthritis; severe congenital deformities of the hip joint; hip joint surgeries; inability to complete the TCM constitution questionnaire; complications with psychosis; or inability to cooperate.

2.3. Patients

Ninety-six patients with ONFH were recruited by the Outpatient Department of Orthopedics, Guang'anmen Hospital, China Academy of Chinese Medical Sciences from August 2012 to February 2014. Among these patients, 59 were male, and 37 were female; their ages ranged between 20 and 65 years, with an average age of 45 years. The duration of illness was between one month and 3 years, with a mean of 7 months. Thirty-eight cases (39.6%) were alcohol-associated, 41 (42.7%) were steroid-induced, and 17 (17.7%) were idiopathic ONFH.

Among the 96 patients, 38 (39.6%) had a yang-deficiency constitution, 14 (14.6%) had a dampness-heat constitution, 13 (13.5%) had a blood-stasis constitution, 11 (11.5%) had a yang-deficiency combined with dampness-heat constitution, 13 (13.5%) had a yang-deficiency combined with blood-stasis constitution, and 7 (7.3%) had a dampness-heat combined with blood-stasis constitution.

The proximal sclerosis ratios were estimated, and the differences among the TCM constitutions were compared. The researchers who measured the proximal sclerosis ratios were blinded to the TCM constitution results.

This study was approved by the Ethics Committee of Guang'anmen Hospital. Written informed consent was obtained from all participants.

2.4. Observational indices

CT scanning was performed first. All CT images were obtained using a dual-source, 64-slice spiral CT (Siemens, Germany). The scanning condition parameters were as follows: scanning voltage 120 kV, scanning current 60 mA, and bone scan window thickness 0.75 mm. The images were exported in BMP format.

To measure the proximal sclerosis ratios, the following steps were taken.⁵ (1) Three CT coronal section levels, including one showing the largest image of the femoral head and the sections before and after that section, were used for the measurements. (2) The three levels were imported into the CAD software. (3) Necrotic tissue was regarded as an approximate ellipse (circle); the arc length on the upper half of the ellipse (necrotic tissue) was measured as L1, and the sclerosis length on the upper half of the ellipse was measured as L2. (4) The proximal sclerosis ratio was calculated as L2/L1 (Fig. 1). (5) The proximal sclerosis ratios were measured on all three levels, and the averages were recorded.

2.5. Statistical analysis

The data were analyzed using SPSS 13.0 software, and they are expressed as the means \pm standard deviations. Normality tests were performed. If the data were normally distributed, one-way ANOVA was used to compare the differences among groups. Otherwise, the data were analyzed using a chi-square nonparametric test. All tests were two-sided, and $P < 0.05$ was regarded as a statistically significant difference.

3. Results

The respective proximal sclerosis ratios, results of normality tests and P values for the different TCM constitutions were

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