

Hip-preserving treatment for osteonecrosis of the femoral head★

Evaluation criteria of quality of life

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Abstract

BACKGROUND: There are many criteria used to evaluate the curative effects of hip-preserving treatment for osteonecrosis of the femoral head (ONFH), and there have been no consistent criteria, so the curative effects of hip-preserving treatment lack comparability to some extent.

OBJECTIVE: To review and analyze a variety of criteria for evaluating the curative effects of hip-preserving treatment and to develop a specific quality of life scale of hip-preserving treatment.

METHODS: A computer-based retrieval of Pubmed database using key words "osteonecrosis, femoral head, quality of life", or "osteonecrosis, femoral head, curative effect" for manuscripts published from August 2000 to August 2010 and of CNKI database for manuscripts published from January 1994 to December 2009 using key words "femoral head necrosis, curative effect" or "femoral head necrosis, quality of life". Manuscripts that address hip-preserving treatment of ONFH and related quality of life or manuscripts that were recently published or in the high-impact journals were included in this paper. Finally, 31 manuscripts were reviewed.

RESULTS AND CONCLUSION: The current criteria for evaluating the curative effects of hip-preserving treatment focus on pain, function, and range of motion of hip joints, but do not lay emphasis on the local changes of hip joints or lower limbs, which can not sufficiently reflect the overall quality of life of patients. The SF-36 scale lack specificity to some extents and cannot be used to evaluate the curative effects of hip-preserving treatment systemically and specifically. Therefore, it is necessary to develop a specific quality of life scale for evaluating the curative effects of hip-preserving treatment of ONFH.

INTRODUCTION

Since osteonecrosis of the femoral head (ONFH) is first reported in 1738, scholars all over the world have done much work in this regard. ONFH is a pathological process that results from interruption or impairment of blood supply to bone, involving osteocyte and bone marrow component death and subsequent repair, which lead to structural changes, collapse, and dysfunction of the femoral head. ONFH is highly prevalent in young people aged 30–50 years, and it is primarily induced by trauma, alcohol, and hormone. With the progression of ONFH, subchondral fracture and femoral head collapse would occur, leading to severe osteoarthritis which makes patients to lose physical working capacity and eventually causing greatly decreased quality of life. The prevalence of ONFH has been recently found to be gradually increased. Total hip replacement for treatment of secondary severe hip osteoarthritis of advanced ONFH has acquired satisfactory effects and has become the standard method of treating advanced ONFH^[1]. For young patients with early-stage ONFH, hip-preserving treatment has been primarily recommended.

The currently used hip-preserving methods for adult ONFH primarily include the following: non-surgical methods: biophysical therapy, simple drug application therapy, and cocktail therapy; micro-invasive technology: interventional therapy, arthroscopic surgery; surgical methods: osteotomy, decompression of bone marrow, bone marrow decompression combined with strengthening of mechanical structure: a, simple bone transplantation,

vessels-containing bone transplantation, c, nickel-titanium shape-memory alloy balls combined with bone transplantation, d, support frame or biomaterials combined with screws, e, bone cement, f, porous tantalum implantation, bone marrow decompression combined with strengthening of mechanical structure and bone marrow or multipotent stem cell transplantation^[2].

There has been no consistent standard for evaluating success in hip-preserving treatment, so it is difficult to make proper evaluation of curative effects of hip-preserving treatment. The majority of studies report the success of hip-preserving treatment of ONFH primarily from two concerns, whether hip joint is preserved and whether hip joint replacement can be delayed^[3-4]. The curative effects of hip-preserving treatment for ONFH lack comparability because there have been no consistent evaluation criteria worldwide. In China, the clinical efficacy of hip-preserving treatment for ONFH is high, but the clinical evaluation criteria differ greatly, even the self-made criteria are used^[5], therefore, the clinical efficacy is a matter for argument^[6]. Up to date, the commonly used evaluation criteria worldwide are developed primarily based on the assessment criteria of curative effects of artificial joint replacement. This paper analyzed several frequently used criteria to develop a specific quality-of-life scale for assessing the curative effects of hip-preserving treatment.

MATERIALS AND METHODS

Data source

A computer-based retrieval was performed by the first author in PubMed (<http://www.ncbi.nlm.gov/>)

PubMed), Wanfang (<http://www.wanfangdata.com.cn>), and Weipu (<http://www.vmis.net.cn/yixue/index.asp>) databases for manuscripts published from August 2000 to August 2008 using the key words “osteonecrosis femoral head, quality of life” or “osteonecrosis femoral head, curative effect” in English and Chinese languages, respectively.

Data selection

Inclusion criteria: manuscripts with contents closely related to this paper; original manuscripts with reliable topics and evidence; manuscripts with clear points and all-round analysis.

Exclusion criteria: manuscripts with irrelevant contents, obsolete reference, or repetitive contents.

Literature type and data analysis

A total of 87 manuscripts regarding basic studies and animal experiment original studies, 48 Chinese, 39 English, were retrieved electronically. By screening titles and abstracts, 15 manuscripts were rejected for objective independence and 41 for repetitive contents. Finally, 31 manuscripts were retained for further analysis.

RESULTS

Basic information of included literature

Manuscripts focused on curative effects of ONFH and quality of life or manuscripts that were recently published or in high-impact journals were selected. Of 31 manuscripts retained for further analysis, 3 described the assessment criteria of hip-preserving treatment of ONFH^[1-3], 3 described the Merle d'Aubigné scoring modified by Charnley, 5 described the scoring criteria in North America (such as Harris hip score)^[7-11], 6 described the Oxford Hip Score, Andersson's Score, Visual Analog Scale (VAS) Score^[5], 12 summed up several scoring criteria in China, and 2 described the prospects of hip-preserving treatment of ONFH.

RESULTS DESCRIPTION

Charnley modified Merle d'Aubigné score

The Merle d'Aubigné score was first proposed in 1931 by Ferguson and Goworth and modified by d'Aubigné and Postel in 1954^[7]. In 1972, the Merle d'Aubigné score was re-modified by Charnley and widely accepted by many European countries. The scoring system consists of three domains, pain, range of motion, and walking ability, 6 points for each domain^[8]. Prior to scoring, the patients were assigned to three types: A, patients who suffered from trauma to one hip and had no other diseases that affect patients' walking ability; B, patients who suffered from trauma to two hips; C, patients who suffered from other diseases that affect patients' walking ability, such as rheumatoid arthritis, hemiplegic paralysis, aging and severe heart and lung diseases. Charnley considered that a 3-item measure should be used for type A patients and the type B patients who underwent bilateral hip arthroplasty, but for type B patients who underwent unilateral hip arthroplasty and all type C patients, only pain and range of motion are evaluated, and caution should be taken to

evaluate walking ability. The Charnley hip score is widely used in Europe. With the emergence of hip-preserving treatment, the Charnley hip score is also widely used for assess the curative effects of hip-preserving treatment^[9].

The Harris Hip Score

The Harris hip score, developed by William H. Harris, M.D., an orthopedist from Massachusetts, is one way to evaluate hip function following surgery^[10]. The simple and practicable Harris hip score has been widely accepted by clinicians in North America because it integrates the advantages of Shepherd and Larson hip evaluation systems, addresses the importance of pain and function, and measures all-round items, with reasonable points allocated to each item. The Harris hip score is suitable for assessing the curative effects of various hip diseases^[11]. It consists of four domains, pain, function, deformity, and range of motion. The total score of these four domains is 100 points and the pain domain contributes 44 points, function 47, range of motion 5 and absence of deformity 4 points. Excellent: 90–100 points, good: 80–90 points, fair: 70–79 points, poor: < 70 points. From the allocation of score ratio, the Harris hip score addresses as the domains of pain and function, while the weight of range of motion is relatively small. Harris considered that immovable and painless hip joints, rather than moveable and painful hip joints, are selected and that different clinicians obtained greatly different measurement outcomes of range of motion; in addition greater weight would lead to poorer outcome repeatability. Among the current criteria of assessing the curative effects of hip-preserving treatment, the Harris hip score is one of the mostly used criteria^[12-13].

The Hospital for Special Surgery (HSS) hip rating system^[14], proposed in 1972, is a 40-point scale that rates pain, walking ability, range of motion, and function. After adding imaging evaluation indices, a modified HSS score was developed, but its use in assessing the curative effects of hip-preserving treatment is relatively rare.

The Oxford Hip Score

The Oxford Hip Score is a 12-question scale, each question consisting of 5 answers. Each item was scored from 1–5, with 1 representing the best outcome/least symptoms and 5 representing the poorest outcome/most symptoms. Scores from each equation were added so the overall score was from 12 to 60 with 12 being the best outcome^[15]. The Oxford Hip Score is a questionnaire widely used to measure hip joint function, which primarily evaluates patients' pain and activities, but ignores the range of motion of hip.

The Andersson Hip Score

The Andersson hip score rates the dimensions of pain, range of motion, and function^[16]. The outcomes are graded as good, fair, and poor. The Andersson Hip Score is similar to the Harris Hip Score, but the difference is that the Andersson Hip Score focuses on the function dimension, and the weights of pain and range of motion are relatively small.

The Visual Analog Scale (VAS) Score^[17-19]

The VAS is usually a horizontal line, 10 cm in length, anchored by “no pain” at the left end and by “very severe

pain” at the right end, and there are no scales in the middle of the line. The patients mark on the line the point that they feel represents their perception of their current state immediate at the beginning, during, and after treatments. The VAS score is determined by measuring in millimetres from the left end of the line to the point that the patients mark. VAS was scored 0-10. After treatment, VAS score = 0 indicates complete relief of pain, VAS score < 3 indicates marked relief, $3 \leq$ VAS score \leq 5 indicates slight relief, and VAS score > 5 indicates no response to the treatment^[20]. The scale is simple and practicable, but its evaluation content only consists of pain domain and therefore its use in assessment of hip functions is limited. In addition, on one hand, different patients have different tolerance to pain, so the evaluation results could not be transversally compared; on the other hand, when one patient performed many measurements in succession, the results may lack validity to some extent due to potential discrepancy.

Scoring criteria in China

The scoring criteria in China for assessing the curative effects of hip-preserving treatment primarily include Standard Scheme for Assessment Criteria of Hip Joint Replacement (Beijing Trial version)^[3], Beidaihe Criteria and Chinese Medical Association Orthopedic Society 100-point Method^[4].

In 1982, Standard Scheme for Assessment Criteria of Hip Joint Replacement, Beijing Scheme for short, was proposed by Discussion Meeting of Hip Joint Replacement in Beijing organized by the Editorial Office of Chinese Journal of Surgery and Beijing Orthopedics Society. The scheme rates the domains of pain, function and range of motion. Each item consists of 6 grades, and the curative effects are graded from very poor to excellent. This scheme is comprehensive, practicable, and easy to compare. It has been widely used in some hospitals in China and can be also used for assessing the curative effects of hip-preserving treatment.

In September 1993, scholars in China hold a meeting in Beidaihe regarding avascular necrosis of the femoral head and formulated consistent staging criteria and curative effect evaluation criteria, named “Beidaihe scheme”. The scheme points out that the important function of hip joint is weight loading and walking and that stable, powerful and painless hip joints are more practicable than painful and hypodynamic hip joints with greater range of motion.

In August 1995, Chinese Medical Association Orthopedic Society hold the first academic assembly regarding bone necrosis in Liaoning Dandong. The meeting studies the cause, pathological mechanism, diagnosis, and various treatments of bone necrosis, and then develops new curative effect evaluation criteria after careful discussion and modification based on original curative effects of ONFH, *i.e.*, Chinese Medical Association Orthopedic Society 100-point Method^[21-23]. The scoring criteria consist of clinical evaluation and X-ray plain evaluation in one simple, practicable table for the first time. Among the total score (100 points), clinical evaluation accounts for 60 points, including pain 25 points, function 18 points, and range of motion 17 points, and X-ray evaluation accounts for 40 points and is developed based on Ficat/Arlet staging.

Function evaluation criteria of repair and reconstruction of ONFH

According to clinical practice, Wang^[23] formulated new scoring criteria based on Chinese Medical Association Orthopedic Society 100-point Method. The criteria consisted of 4 domains, each domain containing 5 grades, with a total score of 100 points: excellent: > 75 points; good: > 60 points; fair: > 45 points; poor: < 45 points. In the criteria, 70 points were allocated for the domains of pain, walking distance and range of motion and 30 points for X-ray examination. It should be pointed out that it is more difficult for X-ray plain, as an objective index of ONFH, to evaluate the curative effects in hip-preserving treatment than in total hip replacement. This is primarily because of different acceptance degrees by the clinicians owing to two cases: one is that after hip-preserving treatment, X-ray plain shows the presentations of unavoidable arthritis, which is more obvious with follow-up time going, and the other is that with the exception of preoperative non-collapsed femoral head, postoperative femoral heads nearly present standard spherical appearance, and oval-shaped or irregular appearance is unavoidable^[5]. Nonetheless, after hip-preserving treatment, pains obviously relieve and range of motion increases in many patients, thereby improving quality of life. Therefore, the use of X-ray plains in assessing the curative effects of hip-preserving treatment has advantages and disadvantages.

Quality of life scoring criteria

The 36-Item Short Form Health Survey (SF-36)^[24-27]

The SF-36, developed by RADA, is a part of the Medical Outcomes Study. It can distinguish the changes of different diseases and is widely used in North America. The scale consists of 36 questions from 8 sections, including physical functioning, physical role functioning, bodily pain, social role functioning, general health perceptions, vitality (energy/fatigue), emotional role functioning, and mental health. Each section is scored 0–100. The 36 questions would be short and easy to answer and would be accomplished within 15 minutes. The SF-36 scale significantly correlates strongly with the Harris hip score in terms of physical functioning, social role functioning, and vitality (energy/fatigue). With the exception of bodily pain and vitality (energy/fatigue), other factors including emotional role functioning, social role functioning, and mental health exhibit the same importance on postoperative patients. However, the SF-36 scale is a survey of systemic health and is not specially designed for evaluation of joint diseases. For this reason, the SF-36 scale lacks of specificity to some extent in assessing the curative effects of hip-preserving treatment.

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

The WOMAC is a specific scale used for assessing the curative effects of hip-preserving treatment. Different from other scales, the WOMAC is not only based on clinical results, but also retrieves data from patients’ telephone follow-up records, questionnaires and large-sized medical institution databases. The purpose of the WOMAC use is to investigate curative effects and potency ratio as well as improvement in

patient's quality of life with scientificity and efficacy. The WOMAC includes the following contents: baseline information (age, gender, race, education, marriage status, living standard, vocation, dysfunction degree and compensation), disease condition, expected value (symptom, function, sleep, return to work, and rehabilitation), satisfaction degree, general condition. Symptom alleviation and functional rehabilitation are core evaluation indices. The WOMAC scale, consisting of 24 items, puts more emphasis on the symptoms and function of patients in addition to the baseline information. However, the WOMAC is originally designed for hip and knee arthritis, so it lacks specificity to some extent in assessing the curative effects hip-preserving treatment^[28-29].

DISCUSSION

The current evaluation criteria for assessing the curative effects of hip-preserving treatment primarily include the Harris hip score, the Charnley hip score, 100-point method, and the SF-36 scale. Based on the concept that immovable and painless hip joints, rather than moveable and painful hip joints, are selected, scoring criteria taking the Harris hip score and the Charnley hip score as representatives all put weights on the domains of pain, function and range of motion. Although each scale has different weights in different parts, the consistency is to focus on the local change of hip joint (or lower limb) and not to sufficiently reflect the quality of life of patients^[30]. Similar limitations appear in several above-mentioned scoring criteria. With the transformation of biomedical model to biological-psychological-social medical model, in the current competing society, social and psychological factors play a great role in quality of life, and a simple evaluation of disease status is not sufficient. After hip-preserving treatment of ONFH, the recovery of patient's hip function may be limited, however, patients may acquire improvements to a large extent from the social, psychological and mental domains, therefore, concerning the improvement of patient's quality of life would be of significance for evaluating the curative effects of hip-preserving treatment. Quality of life is a multi-dimensional concept that contains biomedicine and social, psychological and mental factors and can be used to evaluate the general well-being of individuals. When chronic diseases cannot be cured, a relatively independent living ability of patients can be achieved only by improving symptoms, and the adverse psychological reactions caused by chronic diseases can be reduced by keeping a healthy and comfortable sense, the quality of life scales are extremely important for evaluating the therapeutic measures. At present, quality of life scales are widely used in assessing the curative effects of chronic diseases, such as tumor, diabetes mellitus, and cardio-cerebrovascular diseases, while the use of quality of life scales is relatively rare in the field of orthopedics. ONFH, as a chronic retractable disease, would accompany the whole life, so in addition to conventional biological evaluations (imaging evaluation and the Harris hip score), quality of life would better embody the general well-being of individuals in assessing the curative effects of hip-preserving treatment^[31]. Quality of life scales taking SF-36 as a representative rate the domains of pain, function, general physical health, social role functioning, viability, emotional role functioning, and mental health of patients, but the SF-36 scale is a universal scale and

lacks specificity to some extent in assessing the curative effects hip-preserving treatment of ONFH. The WOMAC scale is specially designed for hip and knee arthritis, so it lacks specificity to some extent in assessing the curative effect of hip-preserving treatment of ONFH. Therefore, it is imperative to develop a specific quality of life scale for assessing the curative effects of hip-preserving treatment of ONFH.

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保髋治疗股骨头缺血性坏死生存质量的评价标准★

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摘要

背景：目前评价保髋治疗的疗效标准较多，没有统一标准，因此保髋治疗的疗效缺乏一定的可比性。

目的：通过回顾及分析现有的用于保髋治疗疗效的各种评价标准，试图研制一款特异性的用于评价保髋治疗疗效的生存质量量表。

方法：应用计算机检索 Pubmed 数据库(2000/2010-08)，以“Osteonecrosis Femoral Head、quality of life”或“Osteonecrosis Femoral Head、curative effect”为检索词；应用计算机检索 CNKI 数据库(1994-01/2009-12)，以“股骨头坏死、疗效”或“股骨头坏死、生存质量”为检索词。选择与股骨头坏死保髋治疗疗效或生存质量相关，同一领域文献则选择近期发表或发表在权威杂志文章。根据纳入标准共 31 篇文章进行综述。

结果与结论：现有的评价保髋治疗的疗效标准过分的侧重髋关节的疼痛、功能、关节活动等方面，局限于髋关节或下肢的局部改变

情况，对患者整体的生存质量反应不够，而以 SF-36 为代表的生存质量量表评价标准却缺乏一定的特异性，都未能更全面更具特异性的用于评价保髋治疗的疗效。因此，研制一款特异性的用于评价股骨头坏死保髋治疗疗效的生存质量量表成一种必要。

关键词：股骨头缺血性坏死；保髋治疗；评价标准；生存质量；关节活动

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此问题的已知信息：保髋治疗已成为股骨头缺血性坏死早期及年轻患者的一种常规手段，对于保髋治疗的疗效评价标准，现有文献多使用 harris 评分标准、Charnley 髋关节功能评分、百分法及 SF-36 量表等，缺乏一个统一的评价标准。

本综述增加的新信息：文章通过回顾及分析现有的用于保髋治疗疗效的评价标准，指出现有的评价标准过分的侧重髋关节的疼痛、功能、关节活动等方面，局限于髋关节或下肢的局部改变情况，对患者整体的生存质量反应不够，而以 SF-36 为代表的生存质量量表评价标准却缺乏一定的特异性，都未能更全面更具特异性的用于评价保髋治疗的疗效，从而引发研制一款特异性的用于评价保髋治疗疗效的生存质量量表的设想。

临床应用的意义：随着保髋治疗手段的日渐丰富及保髋治疗的日益普遍化，研制一款特异性的用于评价保髋治疗疗效的生存质量量表有利于对保髋治疗疗效的统一评价及横向比较，有利于推进保髋治疗手段及疗效的进步。