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Randomized Controlled Trial

Effects of individual shock wave therapy *vs* celecoxib on hip pain caused by femoral head necrosis

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Abstract

BACKGROUND

Celecoxib has been used to treat hip discomfort and functional difficulties due to osteonecrosis of the femoral head (ONFH), although significant adverse reactions often follow long-term use. Extracorporeal shock wave therapy (ESWT) can delay the progression of ONFH, alleviate the pain and functional limitations it causes, and avoid the adverse effects of celecoxib.

AIM

To investigate the effects of individual ESWT in alleviating pain and dysfunction caused by ONFH, which is non-inferior to pharmacologic celecoxib.

METHODS

This was a randomized, controlled, double-blinded, non-inferiority trial. We examined 80 patients for eligibility in this study: eight patients were excluded because they did not meet the inclusion or exclusion criteria. A total of 72 subjects with ONFH were randomly assigned to group A (n = 36): celecoxib + alendronate + sham-placebo shock wave or

group B (n = 36): individual focused shock wave [ESWT based on magnetic resonance imaging three-dimensional (MRI-3D) reconstruction] + alendronate. The outcomes were assessed at baseline, a the end of treatment, and at an 8-wk follow-up. The primary outcome measure was treatment efficiency after two weeks of intervention [Harris hip score (HHS); improvement of 10 points or more from the baseline was deemed sufficient], and secondary outcomes were the HHS, visual analog scale (VAS), and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), after treatment.

RESULTS

After treatment, the pain treatment efficiency of group B was greater than that of group A (69% > 51%). The 95% confidence interval of the rate difference between the two groups was (-4.56%, 40.56%), with -4.56% > -10% (non-inferiority threshold). Furthermore, the HHS, WOMAC, and VAS in group B dramatically improved during the follow-up period (P < 0.001). After therapy, the VAS and WOMAC in group A were significantly improved from the second to eighth weeks (P < 0.001), although HHS was only significantly altered at two weeks (P < 0.001). On the first day and second week after treatment, the HHS and VAS performed statistical differences between the groups; the difference in HHS lasted until the fourth week. Neither group had severe complications, such as skin ulcer infection and lower limb motor-sensory disturbance.

CONCLUSION

Individual shock wave therapy (ESWT) based on MRI-3D reconstruction was non-inferior to celecoxib in managing hip pain and restrictions induced by ONFH.

Key Words: Extracorporeal shockwave therapy; Osteonecrosis of femoral head; Pain; Magnetic resonance imaging three-dimensional reconstruction; Celecoxib

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Core Tip: This is a randomized, controlled, and non-inferiority trial. To the best of our knowledge, the present study is the first to investigate the effectiveness of extracorporeal shock wave therapy (ESWT) in the short-term efficacy of osteonecrosis of the femoral head (ONFH). The traditional ESWT was innovated by magnetic resonance imaging three-dimensional (MRI-3D) reconstruction technology. The final results demonstrate that ESWT based on MRI-3D reconstruction is non-inferior to celecoxib in treating hip discomfort and restrictions induced by ONFH.

INTRODUCTION

Osteonecrosis of the femoral head (ONFH) is a prevalent condition in orthopedic clinics, characterized by the gradual loss of bone cells and bone structure. Ischemia, necrosis, and collapse are the characteristic pathological processes[1,2]. The hip joint is one of the most important weight-bearing joints in the human body[3]. The structural and pathological changes often lead to pain and dysfunction of the hip joint and even disability[4]. Those suffering from this condition are mostly young or middle-aged[5]. In the United States, more than 20000 individuals are afflicted by ONFH annually, and its prevalence continues to rise[6,7]. In China, it has been estimated that more than 8 million individuals have suffered from ONFH[2].

Currently, the treatment measures for ONFH mainly include the following: (1) Surgical treatment: artificial hip arthroplasty and drilling decompression are usually recommended for patients with ONFH; (2) Drug therapy: nonsteroidal anti-inflammatory drugs (NSAIDs) and alendronate are the mainstay drugs to improve hip pain and functional restrictions concerning ONFH; (3) Pharmacotherapy: potential physical therapies include extracorporeal shock wave therapy (ESWT) and high-pressure oxygen therapies; and (4) Lifestyle changes: mainly to control weight and reduce the impact of loading activities[2,8,9]. Because of the artificial joint's limited life in artificial hip arthroplasty, the difficulties of secondary revision, the inadequate impact of hip preservation surgery, and considerable trauma, most patients prefer oral drugs to alleviate their symptoms[10]. The main goal of pharmacotherapy is to relieve hip pain and improve joint function. It has achieved a particular effect on ONFH, but long-term use often brings severe side effects to the body[11-13]. Therefore, exploring a non-invasive treatment that can reduce side effects and replace traditional drug therapy was urgently needed. In treating ONFH, the biological effects of ESWT include improving microcirculation, promoting osteocyte proliferation and differentiation, and exerting analgesia[14-16]. A clinical study by Wang *et al*[17] in 2008 demonstrated that ESWT could delay the progression of necrosis, alleviate hip joint pain and recover hip joint function.

In terms of analgesia and improving activity, ESWT avoids the side effects of drugs and dramatically decreases the trauma and economic burden caused by surgery[18,19]. However, the effects of shock waves often cannot be maximized due to acetabular obstruction during the transmission of shock wave energy and its attenuation in bone conduction[20-22]. Magnetic resonance imaging three-dimensional (MRI-3D) reconstruction to strengthen extracorporeal shock wave (ESW) targeting may be a reasonable solution[23]. Thus, the primary aim of this prospective, randomized study was to determine the treatment efficiency and whether individual shock wave therapy (ESWT) based on MRI-3D reconstruction was non-inferior to NSAIDs in improving pain and dysfunction due to ONFH.

MATERIALS AND METHODS

Design and patients

This study was a prospective, double-blinded, non-inferiority randomized controlled trial designed per the principles of the Declaration of Helsinki. It was approved by the Ethics Committee of The Third Medical Center of Chinese People's Liberation Army General Hospital (ID: 001-R1) and registered on the Chinese Clinical Trial Registry (ChiCTR2100047844).

The study was conducted at the outpatient rehabilitation medicine department of The Third Medical Center of Chinese People's Liberation Army General Hospital. All consecutive subjects affected by ONFH associated with hip pain and hip dysfunction and referred to the hospital from June 2021 to October 2021 were screened for inclusion in an outpatient rehabilitative setting. The recruitment procedure was performed by two specialists, including a clinical examination of the affected hip, an MRI of the pelvis, an X-ray of the pelvis, and the patient's disease history and general condition.

Eligibility criteria were as follows: (1) Adult age (18-75 years); (2) Diagnosed as ONFH and Association Research Circulation Osseous staging I-IV, which were confirmed with plain radiographs and MRI; (3) Unwilling to accept surgical treatment and agreeing not to use non-research treatment related to hip pain during the study

period; and (4) Voluntarily participating in this clinical trial, complying with the requirements of this trial, and signing an informed consent form.

General contraindication: Shock wave therapy (pacemaker, pregnancy, bleeding disorders, anticoagulant drug usage, or cancer in the focal area); Use of anti-immune agents.

Finally, seventy-two patients were recruited for this study and randomly divided into two groups. All participants provided written informed consent after a detailed understanding of the objectives and procedures of the study. The randomization was performed using the IWRS central random system (https://iwrs.ymedical.net/#/projects/157/dashboard), generating group A and group B. The trial profile is synthesized in the flow diagram (Figure 1).

Interventions

Group A: Celecoxib was used once daily (200 mg daily) for nine consecutive days. Using sham focused ESWT, the protocol to be used is the same as that of "group B," except that the energy level is one grade (0.07 mJ/mm^2) and no coupling gel is used on the treatment site, whereas a thick gauze is placed between the skin and the instead, with no energy applied. Group B: Using personalized focused extracorporeal shockwave therapy (fESWT), the shock wave was generated by a focused shock wave generator (HK.SWT-007, Huikan AG, China), with a penetration depth between 0 and 70 mm and a focus diameter of 7.5 mm. All ESWT procedures were performed without general or regional anesthesia. Operation process: Firstly, according to the MRI imaging judgment of the subjects, the raw data of MRI scanning of bilateral hip joints (Digital Imaging and Communication in Medicine coronal T1-weighted MRI images of hip joints) were imported into the interactive medical imaging control system software (mimics) produced by Materialise Company. The three-dimensional view of the femoral head and its necrotic area was obtained by image segmentation, visualization, registration, and other functions. The size and spatial location of the necrotic area were determined using the 3D perspective of the reconstructed necrotic area. The junctional zone between

normal and necrotic bone within the femoral head was delineated under MRI-3D image guidance. Within the junctional zone, 2-3 points, approximately 1.0 cm apart, were chosen under MRI-3D imaging guidance, and the corresponding locations were marked on the skin in the groin area. Then physicians would adjust the treatment point through personalized posture, making the subjects take different lying positions. Furthermore, they place the treatment head in the hip's body surface corresponding to the necrotic area (locations should keep away from essential blood vessels and nerves), as shown in Figure 2. Next, adjust the water sac to an appropriate state, and apply the proper amount of medical coupling agent on the surface of the water bag in contact with the human body. Finally, when using 5-10 grade energy therapy (energy flow density: 0.20-0.6 mJ/mm^2), the energy should be increased from low to high according to the subjects' sensitivity to pain. Simultaneously, to ensure an exact site, the position should be monitored throughout treatment, and the drift of the treatment point should change in real-time.

The administering clinicians had extensive experience using extracorporeal shockwave therapy to treat various musculoskeletal disorders. Each treatment cycle included five sessions, with 1000 impulses per point, each administered at a frequency of 60 times per minute, at 48-72 h intervals.

During the trial, all the subjects were treated with basic treatment [oral alendronate sodium tablets during the study period (70 mg weekly)].

Outcome measurements

The primary outcome measure was treatment efficiency after the second week of treatment. Harris hip score (HHS) improved its score by 10 points compared to before therapy, which was deemed sufficient. The secondary outcome measure: Harris, visual analog scale (VAS), and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores were improved on the first day, second, fourth, and eighth week after treatment compared with the baseline. Pain recurrence (recurrence of symptoms): When completing therapy, the pain recurrence was evaluated if the subject's VAS pain score was equal to or higher than baseline during the follow-up period. Each subject was

instructed to record his VAS score on the first day, first week, second week, third week, fourth week, sixth week, and the eighth week following therapy during the experiment.

Sample size

This study computed a sample size of 64 patients, given an alpha error of 5% (two-sided) and a power of 80%, assuming that the pain improvement rate of group A and group B was 65% and 85%, respectively, with a non-inferiority limit of -10%. Thus, the non-inferiority would be demonstrated if the lower boundary of the 95%CI for the difference was higher than -10%. After considering potential dropouts (10%), the final sample was 72 patients (36 per group).

Randomization and blinding

Patients were randomized to group A or group B after providing written informed consent. Randomization was performed by a person not involved in the study, and a computer-generated list of random numbers was used. Patients and investigators were blinded to allocation. After the intervention, the results were recorded by a specialized physician. To maintain blinding, the statistical analyses were conducted by independent statisticians, and the results were not shared with the patients or other participants before the end of the study.

Statistical analysis

This experiment was a non-inferiority test; statistical analysis was Graphpad5.0 software; all statistical tests were bilateral, and $P < 0.05$ was considered statistically significant. The quantitative data were normally distributed by mean ± SD, and the skewed distribution was described by Median or interquartile range. The paired-sample *t*-test was used to compare the mean change of each evaluation indicator between the pre-treatment and scheduled follow-up time points. Two-sample independent *t*-test or Wilcoxon rank-sum test was used to compare the groups. The classified data distribution was described by rate or composition ratio. The main curative effect used the normal approximation

method, and the 95%CI of the rate difference between the two groups was compared with the non-inferiority boundary value of -10%.

Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

RESULTS

We examined 80 patients for study eligibility: 8 patients were excluded as they did not meet inclusion criteria or met exclusion criteria; 72 patients were randomized into the two groups, which received treatment for each group and completed all interventions. This was monitored and reported by the groups' physiotherapist at the end of the interventions. Finally, two participants were lost to follow-up, and the others were analyzed at all assessments (Figure 1). There were no differences in age, sex, height, weight, BMI, or symptom duration between the groups ($P > 0.05$) (Table 1).

The findings of the Harris, VAS, and WOMAC analyses were documented in Table 2 over the follow-up period. The analysis found no statistical significance in the baseline data of the two groups of patients, as shown (Table 2). Observing the continuous changes of VAS (Figure 3), the downward trend in group B was faster than in group A.

The treatment efficiencies of group A (18/35) and group B (24/35) were 51% and 69%, respectively. The 95%CI for the difference in rates between the two groups was (-4.56%, 40.56%), of which -4.56% > -10% (non-inferiority threshold) according to the primary outcome measure. In addition, the Harris, WOMAC, and VAS scores in group B were significantly improved at one day, two weeks, four weeks, and eight weeks after treatment (Table 2). In group A, the VAS and WOMAC scores were significantly improved at one day, two weeks, four weeks, and eight weeks after treatment ($P < 0.001$), while Harris scores were only quite different at two weeks after treatment ($P < 0.001$). On the first day and second week after receiving treatment, a comparison between the two

groups found that the HHS and VAS showed statistical differences; the difference in HHS lasted until the fourth week, as shown (Table 2).

Short-term side effects such as discomfort, edema, and bruising were similar in both groups. Heart rate, blood pressure, body temperature, blood routine, and blood biochemistry were unaffected by treatment. Both groups received no serious problems such as skin ulceration infection or lower extremity motor-sensory impairment

DISCUSSION

This study demonstrated that fESWT effectively and safely treats hip pain and functional restrictions caused by ONFH. The primary endpoint, the treatment efficiency of group B, was significantly higher than group A. Moreover, most secondary outcomes, including composite scores and response criteria, showed improvements favoring fESWT.

ONFH causes the collapse of the femoral head with severe pain and limited mobility[24]. Hip pain and functional limitations are the typical clinical manifestations[25]. Therefore, symptom alleviation and recovery of the hip joint function are essential references for the effectiveness of short-term treatment[1]. In this study, we proposed a hypothesis that individualized fESWT can be used for short-term symptomatic treatment of ONFH, and it is not weaker than NSAIDs, *e.g.*, celecoxib, in terms of analgesia and improving joint function[26]. After an eight-week follow-up, we found that individualized fESWT can alleviate hip joint pain and recover hip joint function during short-term applications. The therapeutic effect peaked one week after the intervention and was superior to celecoxib in both therapeutic efficiency and analgesic efficacy.

ONFH is likely to occur in young and active patients compared to osteoarthritis[4,27]. Therefore, most patients choose non-surgical treatments. In the short term, many non-operative treatments for ONFH are designed to relieve hip pain and improve joint function, while long-term treatments mainly aim to prevent the progression of necrosis[28]. Recent literature recommends using osteoclast inhibitors and NSAIDs for symptomatic treatment[2,29]. In 2009, a nationwide cohort study conducted in Denmark showed that NSAIDs were significantly associated with increased relative risks of

cardiovascular events and death, even in the low-risk population[30]. At the same time, Singh *et al*[31] also showed that NSAIDs drugs had severe gastrointestinal toxicity in another study. Therefore, drug treatment has significant adverse reactions; not all patients can tolerate it.

ESWT is mechanical stimulation and has great potential because it could avoid the adverse effects of drug therapy. In two clinical studies, scholars such as Wang *et al*[32] and Vulpiani *et al*[33] separately explored the long-term dose effects of ESWT in the treatment of ONFH. Finally, the research showed that ESWT could stimulate the growth of new bone at the site of necrosis and delay the progression of ONFH in the long-term application[33]. Some studies indicated that ESWT might relieve pain by suppressing inflammatory factors' release and down-regulate the expression of pain-related calcitonin gene-related peptides in dorsal root ganglion[34,35]. Additionally, it can directly act on the peripheral sensory nerve ending, improve the pain threshold, and prevent the production and propagation of pain signals[36]. Perhaps it shows that ESWT is useful in short-term symptomatic support therapy for ONFH.

To the best of our knowledge, this is the first study to investigate the effectiveness of ESWT on the short-term efficacy of ONFH. The final results showed that the Harris, WOMAC, and VAS scores of group B improved significantly at one day, two weeks, four weeks, and eight weeks after treatment ($P < 0.001$). In group A, the VAS and WOMAC scores were significantly improved at two, four, and eight weeks after treatment ($P < 0.001$), while Harris scores differed significantly only at two weeks after treatment ($P < 0.001$). Therefore, this study supports that the fESWT and celecoxib groups have short-term effects in improving hip pain and functional limitations caused by ONFH. However, the fESWT group was superior to celecoxib in onset speed and analgesic efficacy (a comparison of the two groups found statistical differences in HHS and VAS on the first day and second week after treatment; the difference in HHS lasted until the fourth week.). This finding suggests that, compared to medicines, ESWT avoids the lack of target and removes bone marrow edema induced by early ONFH. During the treatment, it can promote blood circulation and weaken the inflammatory effects, thereby partially

reducing factors associated with causing ONFH pain[14,37,38]. Traditional NSAIDs do not have these features.

Additionally, based on our prior ESWT treatment experiences, we discovered that the presence of the acetabulum frequently blocks the incoming shock wave and reduces the therapeutic impact because of the uniqueness of the hip joint anatomy. In a study of the energy decay of shock waves utilizing the femoral head of pigs, it was discovered that ESW would attenuate by 50% for every 10 mm penetration in the femoral head[20]. Coupled with acetabular blocking, traditional ESWT often fails to maximize the function[21]. Therefore, to reduce the unnecessary energy attenuation in ESW transmission, our team designed an individual fESWT treatment for each patient according to the patient's MRI-3D reconstructed image combined with posture adjustment, as shown in Figure 1. The three-dimensional picture of the MRI, as opposed to the conventional X-ray localization, can reflect the spatial location and size of the necrotic area, increasing the accuracy of our ESWT and improving the curative impact. At the same time, an important reason is that MRI is the gold standard for diagnosing early-stage ONFH, whereas X-ray and computed tomography are more difficult to diagnose it[1,2,39].

Study limitations

This study has some limitations. Because this trial used a new treatment method (ESWT) based on MRI-3D reconstruction, we only performed a non-inferiority test that was rather conservative. Furthermore, due to ethical concerns and a lack of relevant pathology tests and other objective markers, the study could not investigate the exact causes of pain induced by ONFH. At the same time, the lack of objective evaluation might lead to bias in experimental results. Therefore, our goals in the next phase are optimizing our treatment regimen and exploring the relevant mechanism of ESWT to improve ONFH-induced pain. Finally, this study was just a single-center clinical study, which was slow to collect subjects.

CONCLUSION

Short-term ESWT based on MRI-3D reconstruction can relieve hip pain caused by ONFH. It is non-inferior to celecoxib in terms of treatment efficiency and continuous analgesic effect. It also shows significant efficacy in improving the function of the hip joint, indicating that ESWT can be an effective alternative for the short-term analgesic treatment of ONFH.

ARTICLE HIGHLIGHTS

Research background

Hip pain and functional limitations are the two main symptoms of osteonecrosis of the femoral head (ONFH). Celecoxib's long-term use will often bring severe side effects to the body.

Research motivation

The motivation of this study was to explore a new treatment to replace drugs.

Research objectives

This study aimed to investigate the effect of individual extracorporeal shock wave therapy (ESWT) in improving pain and dysfunction caused by ONFH, which is non-inferior to pharmacologic nonsteroidal anti-inflammatory drugs.

Research methods

The eligible 72 ONFH patients were randomly assigned to two groups: the experiment group and the control group. All patients underwent clinical assessments and analysis during pre- and post-treatments.

Research results

The Harris hip score, Western Ontario and McMaster Universities Arthritis Index, and visual analog scale scores in both the experiment and control groups were significantly improved, but the experiment group improved more considerably.

Research conclusions

The ESWT based on magnetic resonance imaging three-dimensional reconstruction was non-inferiority to celecoxib in controlling hip pain and hip restriction caused by ONFH.

Research perspectives

This finding indicates that individual shock wave therapy might effectively alleviate pain symptoms caused by femoral head necrosis.

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