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Analysis of therapeutic effect of high focused extracorporeal shock wave comprehensive therapy on femoral head bone marrow edema syndrome

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Abstract

Purpose: This study explored the clinical therapeutic effect of high-focused extracorporeal shock wave therapy (HF-ESWT) combined with exercise rehabilitation and drug therapy on femoral head bone marrow edema syndrome (BMES).

Materials and Methods: This study systematically reviewed and analyzed the clinical data of 43 patients with femoral head bone marrow edema who were treated in our hospital from January 2017 to June 2022. Twenty-three patients received HF-ESWT comprehensive treatment. Twenty patients received general treatment including medication and exercise rehabilitation treatment. The treatment methods for Group B patients were the same as Group A, except for not receiving shock wave therapy. Changes in visual analog scale (VAS), Harris score of the hip, and the edema area of region of interest area (ROIA) on hip magnetic resonance imaging (MRI) were analyzed before and after treatment.

Results: Our research found that patients receiving HF-ESWT had significantly reduced VAS compared with general treatment at 1, 2, and 3 months ($P < 0.05$). We found that HF-ESWT comprehensive treatment had significantly improved hip Harris score compared with general treatment at 2 and 3 months ($P < 0.05$). HF-ESWT comprehensive treatment had significantly reduced edema area of ROIA on hip MRI compared with general treatment at 1, 2, and 3 months ($P < 0.05$). In addition, the healing rate was significantly higher in the HF-ESWT comprehensive treatment group compared with general treatment group ($P < 0.05$). One of the patients in the group treated with shockwaves developed hip pain that worsened after treatment, three patients developed local skin ecchymosis, and the other patients had no adverse events.

Conclusion: HF-ESWT comprehensive treatment significantly reduced hip pain symptoms, quickly shortened the time for femoral head edema to dissipate, and significantly improved hip function for affected limbs with bone marrow edema syndrome. HF-ESWT comprehensive treatment may be an effective therapeutic strategy for HF-BMES.

Keywords: Extracorporeal shock wave therapy, Bone marrow edema syndrome, Traditional Chinese medicine, Osteonecrosis of the femoral head

Introduction

Femoral head bone marrow edema syndrome (FH-BMES) is also known as transient osteoporosis of the hip or transient demineralization syndrome of the hip [1, 2]. Bone marrow edema syndrome (BMES) is considered a self-limiting disease, commonly seen in males aged 40–60, and typically self-heals within several months [3].

At present, the diagnosis of hip BMES is difficult. The typical manifestation of femoral head BMES is edema on magnetic resonance imaging (MRI) without signs of ischemic necrosis, accompanied by hip pain [4, 5]. BMES of the femoral head is usually distinguished from osteonecrosis of the femoral head (ONFH) [5]. ONFH usually occurs due to excessive use of hormones, alcohol abuse, trauma, and other factors that lead to bone marrow tissue ischemia and hypoxia, leading to avascular necrosis of the femoral head [6]. ONFH appears as a characteristic "double line sign" under the cartilage on MRI images, with low signal on T1-weighted images and medium intensity signal on T2-weighted images [7].

There is no consensus on the treatment of FH-BMES, and the main treatment methods used in clinical practice include weight reduction, regulation of vitamin D and vitamin C metabolism, and the use of non-steroidal anti-inflammatory drugs [8]. In recent years, extracorporeal shock wave therapy (ESWT) has been well applied in the treatment of bone non-union, bone necrosis, and tendon injury [9]. At the same time,

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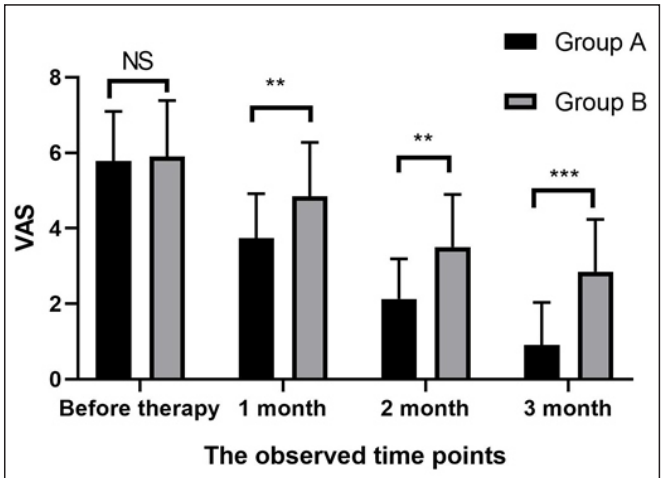

Figure 1: The development of the VAS during therapeutic intervention between two groups. NS P>0.05, **P<0.01, ***P<0.001, VAS: Visual analog scale.

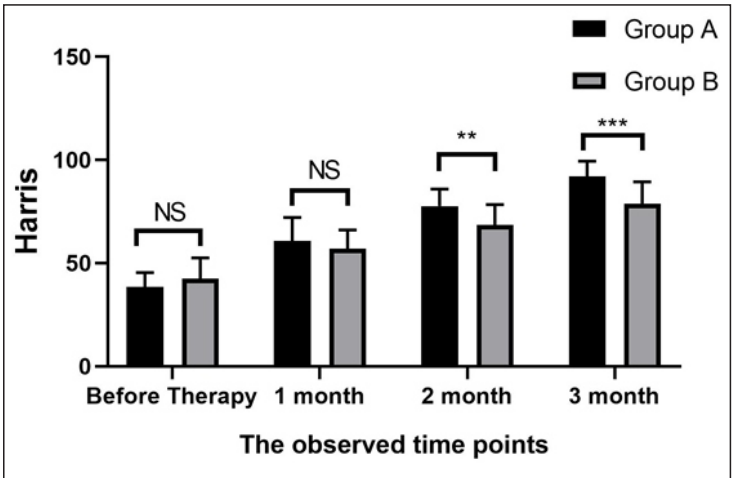

Figure 2: The development of the Harris during therapeutic intervention between two groups. (NS P>0.05, **P<0.01, ***P<0.001)

more and more scholars applied HF-ESWT to treat bone and joint BMES achieving good therapeutic effects [10, 11].

Traditional Chinese medicine (TCM) plays a positive role in treating osteonecrosis. Drugs that promote blood circulation and remove stasis can significantly reduce whole blood viscosity, reduce peripheral vascular resistance, improve blood supply to the femoral head, inhibit osteocyte apoptosis, and promote osteoblast activity [12-14]. The TCM preparation "femoral head necrosis healing capsule" has a good therapeutic effect in the treatment of ONFH. In clinical observation, it could significantly reduce the area of bone marrow edema in patients with femoral head necrosis and alleviate their pain symptoms. Bisphosphonates could bind with hydroxyapatite in bones, significantly inhibiting the activity of osteoclasts, preventing bone resorption, and thus reducing bone loss after femoral head bone marrow edema [15].

Based on previous research, this study reviewed the clinical data of 43 cases of FH-BMES admitted to our department from January 2017 to December 2022, analyzed the therapeutic effect of HF-ESWT comprehensive therapy on FH-BMES, and provided advices for the clinical treatment of FH-BMES.

Methods

Patients

We retrospectively selected 43 patients with FH-BMES who were treated in our hospital outpatient and inpatient departments from January 2017 to December 2022 as the research subjects, including 43 hip joints. As it was a retrospective study, the selection of the groups was not random. Twenty-three patients received the HF-ESWT comprehensive therapy, known as Group A. Twenty patients, received general treatment, known as Group B. All patients sought their wishes and signed informed consent before treatment.

Group A included 16 (70%) males and 7 (30%) females, with a mean age of 41.35 ±11.33 (range 25–59) years and a mean body mass index (BMI) of 25.29 ± 3.31 (range 19.57–31.22) (Table 1). Twenty patients received the general therapy, including 14 (70%) males and 6 (30%) females, with a mean age of 44.15 ± 11.50 (range 26–59) years and a mean BMI of 25.29 ± 3.31 (range 17.90–30.44). Group B patients received medication and exercise rehabilitation treatment. The treatment methods for Group B patients were the same as Group A, except for not receiving shock wave therapy.

There was no statistical difference between the two groups of patient's characteristics (P > 0.05) (Table 1).

Diagnostic criteria

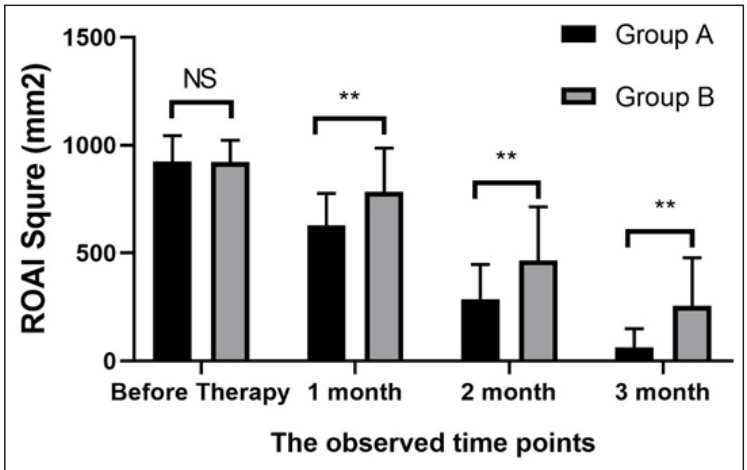

Figure 3: The bone marrow edema area in MRI of the region of interest area of MRI during therapeutic intervention between two groups. (NS P>0.05, **P<0.01). MRI: Magnetic resonance imaging.

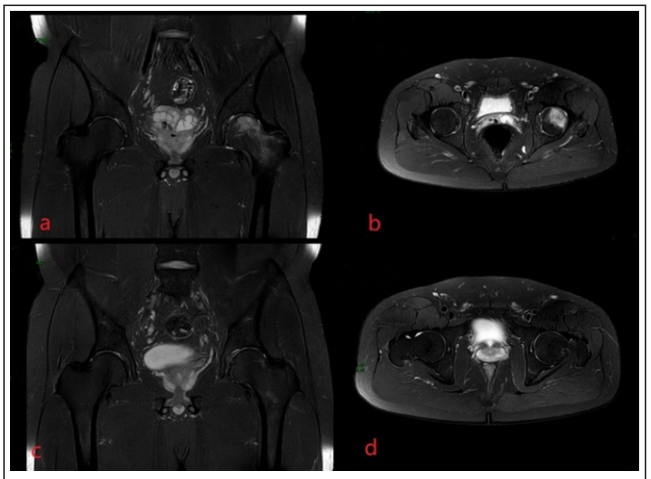

Figure 4: MRI showed that extensive bone edema of the femoral head and neck before treatment (a and b). Bone marrow edema disappeared on MRI images 2 months after treatment (c and d). MRI: Magnetic resonance imaging.

The diagnosis of FH-BMES followed the diagnostic criteria proposed by Miyanishi et al. [1]:

1. Pain in the hip joint without any obvious history of infection or trauma.
2. Radiographic imaging suggesting demineralization of the femoral head or neck.
3. The signal intensity of bone marrow in femur decreased in T1-weighted images, and increased in T2-weighted images compared with normal bone marrow.
4. Spontaneous resolution of symptoms and radiographic demineralization.

Inclusion and exclusion criteria

Inclusion criteria

1. Definitely diagnosis of FH-BMES.
2. Age range from 20 to 60 years old.
3. Complete clinical records.

Exclusion criteria

1. Patients with malignant tumors, serious medical diseases, and infectious diseases; use of other related drugs or patients receiving other related treatments that could affect research results.
2. Patients unable to effectively cooperate with treatment.
3. Contraindications for HF-ESWT and drug therapy.

Treatment methods

All patients in this study were treated inpatient or outpatient in our hospital. The patients in Group A received HF-ESWT 3 times in hospital, once every 3 days. Then, they received HF-ESWT once a month until the clinical symptoms completely disappeared. During the treatment period, the patient took our hospital's TCM preparation "femoral head necrosis healing capsule", 5 capsules per time, 2 times daily. The patient took risedronate, 35 mg per time, 1 time a week. During the treatment period, patients were asked to use crutches to reduce weight, and we encouraged them to make resistance exercises such as cycling and swimming exercises.

Scores

1. VAS (full score of 10) was used to evaluate the degree of pain. The pain scores were assessed before and after treatment at 1, 2, and 3 months.
2. Hip joint function score: The Harris scale was used to evaluate the hip joint function before and after 1, 2, and 3-month treatment.
3. Bone marrow edema area measurement: Two physicians measured the range of bone marrow edema on T1 and T2 -weighted image of the hip joint MRI, and the maximum area of bone marrow edema was the ROIA.

Statistical analysis

All data analyses were performed using SPSS version 20.0.0 software (SPSS; Chicago, USA). Measurement data were expressed as mean±standard deviation (x±s). The comparison of the mean of two samples that conformed to the normal distribution was conducted using independent samples t-test for statistical analysis, otherwise using Mann–Whitney U for statistical analysis. Comparison of proportion and correlation analysis was evaluated by Chi-square test. A probability $P < 0.05$ was considered to be of statistical significance.

Results

Clinical efficacy observation

There was no difference in VAS scores between Group A (5.78 ± 1.31) and Group B (5.90 ± 1.48) before treatment ($P > 0.05$) (Fig. 1). The VAS scores in Group A and Group B decreased at 1 month after treatment, 3.74 ± 1.18 and 4.85 ± 1.42, respectively. Compared with Group B, patients in Group A had a lower VAS at 1 month after treatment ($P < 0.01$) (Fig. 1). Analysis of the VAS after 2 months treatment in both groups (Fig. 1) revealed a significant decrease in Group A (2.13 ± 1.06) as compared with the Group B (3.50 ± 1.40) ($P < 0.01$, Fig. 1). After 3-month treatment, the pain in Group A patients was mild or had disappeared, with a VAS of 0.091 ± 1.13, and there was a significantly difference compared with Group B ($P < 0.001$, Fig. 1).

The Harris scale was used to assess the level of hip function. There was no difference in Harris scores between the two groups of patients before treatment ($P > 0.05$) (Fig. 2), 38.52 ± 6.87 and 42.40 ± 10.16, respectively. At 1 month after treatment, hip function improved in both Groups A and Group B, with Harris scores of 60.78 ± 11.46 and 56.90 ± 9.12, respectively, however, no significant differences were found in the level of Harris between Group A and Group B ($P > 0.05$) (Fig. 2). At 2-month and 3-month post-treatment of HF-ESWT comprehensive therapy, we observed a significant increase in hip Harris score (77.65 ± 8.30 and 92.04 ± 7.46, respectively). Importantly, Group A patients have a higher Harris score compared to Group B patients ($P < 0.01$ and $P < 0.001$, respectively) (Fig. 2).

MRI results

The MRI findings demonstrated the area of bone marrow edema of femoral head gradually decreased (Fig. 3). Patients in Group A and Group B had extensive bone marrow edema before treatment, with ROIA areas of 924.1 ± 120.48 and 920.55 ± 102.66, respectively, and there was no difference between the two groups ($P > 0.05$) (Fig. 3). At 1, 2, and 3 months after treatment, MRI examination showed that the area of femoral head bone marrow edema gradually decreased in both groups of patients. Compared with Group B, the area of bone marrow edema in Group A decreased more significantly at 1, 2, and 3 months after treatment ($P < 0.01$, $P < 0.01$, and $P < 0.01$, respectively) (Fig. 3). If MRI examination showed complete disappearance of bone marrow edema and no obvious pain symptoms in the hip after treatment, it was considered cured. After 3 months of treatment, the cure rate of Group A (52.17%) patients was significantly higher than Group

Table 1: Patients characteristics

Characteristics	Group A (*n*=23)	Group B (*n*=20)
Male, *n*	16	14
Female, *n*	7	6
Age, years	41.35±11.33	44.15±11.50
Height, m	1.68±0.08	1.70±0.09
Weight, kg	71.43±10.87	73.75±12.25
Body mass index, kg/m^2	25.29±3.31	25.34±3.33

B (20.00%), and the difference was statistically significant ($X^2 = 4.740, P < 0.05$).

Complications

Three patients (13.04%) in Group A developed transient skin erythema after HF-ESWT treatment that alleviated after 2 days of rest. One patient (5.00%) in Group B developed fever after taking risedronate and returned to normal temperature 1 day later. No severe complications such as infection and skin necrosis were found during treatment. In addition, no patients developed osteonecrosis or collapse during the follow-up period.

Case Report

A 35-year-old male patient had left hip pain for 1 month, with no history of trauma, hormone use, or alcohol abuse. BMES of the left femoral head was diagnosed (Fig. 4a and b). The combination of HF-ESWT with drugs and exercise rehabilitation quickly and effectively reduced the patient's pain and bone marrow edema area. The VAS score dropped from 7 points prior treatment to 2 points at 1-month post-treatment. Symptoms of pain were significantly alleviated. The function of the hip joint was significantly improved. MRI showed that bone marrow edema almost disappeared at 2 months after treatment (Figure 4c and d).

Discussion

At present, there are certain limitations in the research of the pathological mechanism of BMES. Hofmann believed that BMES is a precursor of ONFH, but it does not progress to ONFH, or BMES could self-heal when the degree of local ischemia is below a critical value [16].

Schweitzer found that the sustained action of external forces reduces the normal load-bearing capacity of bones, leading to biological effects in the bone marrow, causing partial bone marrow congestion and excessive capillary bed perfusion, leading to bone marrow edema [17]. In addition, external forces caused microfracture of bone trabeculae in cancellous bone and increased capillary permeability in bone, resulting in cell fluid extravasation, and increased local vascular perfusion volume in bone tissue resulting in BMES [18]. A study also found that a large amount of edema fluid in the bone marrow edema area fills in between the bone trabeculae, increasing the gap between the bone trabeculae, accompanied by fat necrosis and vascular fiber proliferation [19]. The decreased in BMD on the X-ray was mainly due to the increasing of osteoid and the decrease of hydroxyapatite content, but the bone trabeculae were continuous, bone cells survived, and bone formation was active in the edema area, which was also an essential difference from osteonecrosis [19]. In addition, most patients stayed up late for a long time and lacked sufficient sunlight, leading to vitamin D deficiency, accompanied by calcium and phosphorus metabolism disorders, exacerbating the progression of the disease [8, 20].

Although various clinical treatments for early osteonecrosis have been proposed, such as drug therapy, core decompression, minimally invasive surgery, and standardized joint replacement surgery [21], there is little scientific research on the treatment of BMES. The previous treatment strategies for BMES included weight reduction, oral low-dose painkillers, and non-steroidal anti-inflammatory drugs [22]. Although reducing weight-bearing is effective in alleviating local pain symptoms in the hip joint, prolonged non-weight bearing activities can cause muscle atrophy and osteoporosis [23].

Other therapeutic options include bisphosphonates that improve bone density and prostaglandin analogs that inhibit platelet aggregation [24, 25]. However, there are significant differences in therapy outcomes and issues with drug side effects.

Previous studies have reported that the natural course of hip BMES is 6–9 months [26]. We applied HF-ESWT combined with drug therapy and rehabilitation exercise treating FH-BMES. In the 3rd month after treatment, the clinical cure rate reached 52.17%, significantly shortening the course of hip bone marrow edema and effectively alleviating the patient's pain symptoms and improving hip joint function. More and more attentions have been paid to the effect of shock wave in the treatment of musculoskeletal injury, and shock wave has been widely used in the treatment of ONFH [27-29]. Studies have found that local ESWT could increase the number of bone trabeculae, promote osteoblast maturation through transforming growth factor (TGF)-β/SMAD2 signal transduction pathway, and help reduce bone loss and improve bone density [30]. ESWT has been shown to increase local levels of vascular endothelial growth factor, TGF-β1, bone morphogenetic protein, and alkaline phosphatase, which promotes bone tissue regeneration and repair [31, 32].

ESWT produces less trauma and is repeatability and easy operation, and it is easier to be applied and promote in clinical practice.

TCM had a good effect on improving the blood supply of femoral head and enhancing the ability of bone repair [33]. TCM theory held that "the liver governs the tendons, and the kidney governs the bones". Although the location of this disease was in the bone marrow, it was fundamentally in the liver and kidney. The TCM preparation of our hospital "Femoral head necrosis Yu capsule" had the effect of tonifying liver and kidney, invigorating qi and activating blood, warming meridians and collaterals, and can be used to repair the injury of femoral head. Bisphosphonates can bind to bone mineralized matrix, inhibit bone resorption, promote bone formation, and improve bone density [34], thus inhibiting bone loss in the course of BMES.

It has been reported that the treatment of FH-BMES should protect weight-bearing and avoid excessive external load that aggravates hip injury [2]. However, mechanical stress exerted an important influence on the bone microenvironment and bone metabolism [35]. Exercise could decrease inhibitory effects on bone mass by reducing both osteoclastogenesis and inhibition of osteoblast function [36]. Resistance exercise and supplementation with calcium and vitamin ameliorate bone loss and promote new bone formation [37]. In our treatment plan, we recommended patients use crutches to reduce weight bearing, while encouraging certain intensity of resistance exercises, such as swimming and cycling exercises, effectively reducing bone loss and improving hip joint function.

Conclusion

In our study, it was found that the comprehensive therapy of HF-ESWT combined with TCM, bisphosphate drugs, and exercise rehabilitation therapy can significantly reduce hip pain symptoms in patients with hip BMES, effectively shorten the time from femoral head edema to

dissipate, and significantly improve the function of the affected limb. It is a good strategy for treating hip BMES.

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his consent for his images and other clinical information to be reported in the Journal. The patient understands that his name and initials will not be published, and due efforts will be made to conceal his identity, but anonymity cannot be guaranteed.

Conflicts of Interest: Nil. **Source of Support:** None.

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