The Journal of Arthroplasty 30 Suppl. 1 (2015) 11–15

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Combining Concentrated Autologous Bone Marrow Stem Cells Injection With Core Decompression Improves Outcome for Patients with Early-Stage Osteonecrosis of the Femoral Head: A Comparative Study

Reza Mostafavi Tabatabaee, MD [a,b], Sadegh Saberi, MD [a], Javad Parvizi, MD, FRCS [b], Seyed Mohammad Javad Mortazavi, MD [a], Mahmoud Farzan, MD [a]

[a] Joint Reconstruction Research Center (JRRC), Orthopedic Department of Imam Hospital, Tehran University of Medical Sciences, Tehran, Iran
[b] Rothman Institute, Thomas Jefferson University, Philadelphia, Pennsylvania

ARTICLE INFO

Article history:
Received 17 August 2014
Accepted 11 June 2015

Keywords:
femoral head osteonecrosis
core decompression
autologous bone marrow mononuclear cells
stem cells
avascular necrosis

ABSTRACT

The management of early-stage osteonecrosis of the femoral head (ONFH) remains challenging. This study aimed to evaluate the effects of core decompression and concentrated bone marrow implantation on ONFH. The study recruited 28 hips with early ONFH randomly assigned into two groups of core decompression with (group A) and without (group B) bone marrow injection. Patients were evaluated using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire, Visual Analogue Scale (VAS) pain index, and MRI. The mean WOMAC and VAS scores in all patients improved significantly ($P < 0.001$). MRI showed a significant improvement in group A ($P = 0.046$) and significant worsening in group B ($P < 0.001$). Bone marrow stem cell injection with core decompression can be effective in early ONFH.

© 2015 Elsevier Inc. All rights reserved.

Avascular necrosis (AVN) or osteonecrosis of femoral head (ONFH) is a relatively common disease that has multiple etiologies. The disease is usually bilateral. This condition usually affects the young [1]. The first presentation of ONFH may be painless, but ultimately severe pain and loss of movement occur. The disease usually advances with time and can result in the collapse of the femoral head and lead to end stage arthritis of the hip [1].

The pathogenesis and etiology of non-traumatic ONFH is not completely understood but stem cell involvement has been implicated as the initiating event [2].

There are various grading classifications of the disease with the Association Research Circulation Osseous (ARCO) proposing a new classification for ONFH based on magnetic resonance imaging (MRI) [3].

There is a number of treatment options proposed for this condition that includes the administration of bisphosphonates, anticoagulants, vasodilators, and biophysical modalities [4]. In addition, surgical treatment options such as the core decompression, vascularized cortical bone graft implantation, and femoral osteotomies have been described [5].

The exact mechanism by which core decompression works is unknown. It is believed that core decompression leads to a reduction in the intraosseous pressure and also stimulates stem cell regeneration. In recent years modified core decompression is one of the most reliable and most commonly used methods for treating the early stages of ONFH [6]. However, modified core decompression does not always have satisfactory results because of the inadequate bone remodeling and reconstruction of the necrotic area [7]. This may be related to the relative inadequacy of osteoprogenitor cells in the osteonecrotic proximal femur [2]. Using bone morphogenic proteins and demineralized bone matrix may improve the results of modified core decompression [8–10].

The undifferentiated bone marrow mesenchymal stem cells (BMSCs) have been used for tissue regeneration in recent years because of their ability to differentiate into multiple cell lineages, including osteoprogenitor cells [2,8,11]. There are reports of encouraging outcome related to the injection of the BMSCs into the femoral head of patients with after drilling a hole into the avascular area in patients having atraumatic osteonecrosis [2,12–15]. It is known that an adequate number of autologous stem cells need to be injected into the femoral head with 2 million cells being considered as optimal [11].

The aim of the current prospective, randomized study was to evaluate the effect of implanting concentrated autologous bone marrow containing mononuclear cells (MNCs) in combination with a core decompression procedure on patients with early stage ONFH.

One or more of the authors of this paper have disclosed potential or pertinent conflicts of interest, which may include receipt of payment, either direct or indirect, institutional support, or association with an entity in the biomedical field which may be perceived to have potential conflict of interest with this work. For full disclosure statements refer to http://dx.doi.org/10.1016/j.arth.2015.06.022.

Reprint requests: Reza Mostafavi Tabatabaee, MD, No. 5, Kaviani alley, Mojtabaei avenue, Shaiati St., Apt 03, Tehran 15418-67614, Iran.

http://dx.doi.org/10.1016/j.arth.2015.06.022
0883-5403/© 2015 Elsevier Inc. All rights reserved.

Table 1
Baseline Characteristics of the Patients.

Variable	Group A ($N = 14$)	Group B ($N = 14$)
Side of treated hip		
Left (%)	10 (71.4%)	4 (28.6%)
Right (%)	4 (28.6%)	10 (71.4%)
Age (mean ± SD)	31 ± 11.4	26.8 ± 5.8
Gender (male/female)	9/5	10/4
Etiology		
Corticosteroids (%)	10 (71.4%)	9 (64%)
Idiopathic (%)	4 (28.6%)	5 (36%)
MRI findings (ARCO classification)[a]		
Class I (%)	3 (21.4%)	2 (14.3%)
Class II (%)	9 (64.3%)	7 (50%)
Class III (%)	2 (14.3%)	5 (35.7%)
VAS score (mean ± SD)	35.9 ± 4.5	38.6 ± 4.6
WOMAC score (mean ± SD)	32 ± 3.8	35.9 ± 2.7

[a] At the baseline, the MRI findings in group A were not significantly different from the findings in group B. ($P = 0.24$).

Materials and Methods

This study was a prospective, randomized clinical trial, which included patients with non-traumatic ONFH with ARCO classification stages I, II, or III. The stages of ARCO classification are as follows:

Stage 0—Positive histology with normal radiograph, computer tomography (CT), MRI, or scintigraphy
Stage I—Positive MRI and/or bone scintigraphy with normal radiograph or CT
Stage II—Radiographic changes in the femoral head including sclerosis, cysts, or osteoporotic changes of the femoral head
Stage III—Radiographic sign of subchondral fracture ("crescent sign")
Stage IV—Radiographic sign of flattening of the femoral head
Stage V—Radiographic sign of flattening of the femoral head and osteoarthritic changes such as decreased joint space and acetabular changes
Stage VI—Complete joint destruction [3]

Patients with traumatic osteonecrosis and patients who were continuing steroid use were excluded from the study. All eligible patients were approached and consented for participation in the study. The hips were randomly assigned to two treatment groups: core decompression combined with injection of concentrated autologous bone marrow containing MNCs in to the femoral head (group A) or core decompression alone (group B). After inclusion, envelope technique was used to randomize the patients into either group. Only the surgeon and the operating room staff were aware of the group assignment and they were not involved in further follow-up of the patients. All surgical procedures were undergone under general anesthesia. So, the patients and physicians evaluating them were unaware of the group assignment. The study was approved by the ethical committee of the university and informed consent was obtained from the patients.

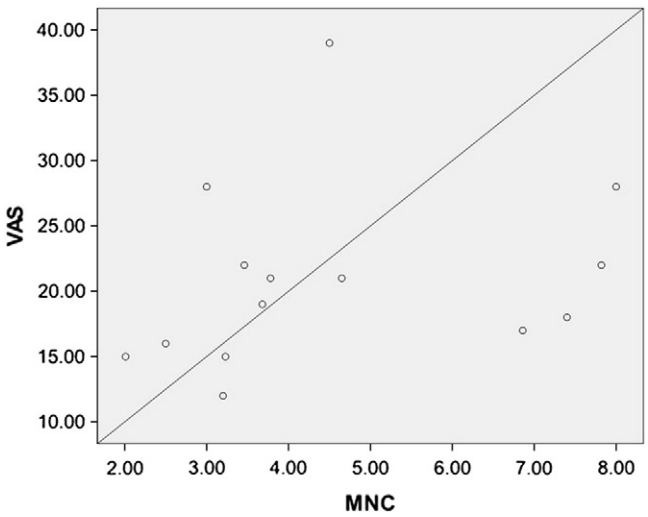

Fig. 1. The diagram showing the correlation between Total MNC count and VAS score. MNC, mononuclear cell; VAS, visual analogue scale.

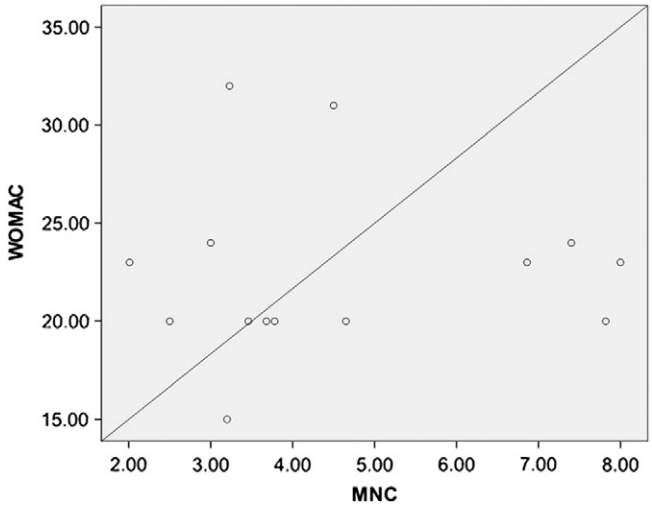

Fig. 2. The diagram showing the correlation between total MNC count and WOMAC score. MNC, mononuclear cell; WOMAC, Western Ontario and McMaster Universities.

Twenty-eight hips in 18 patients were enrolled in the study. Ten patients had bilateral ONFH. After inclusion, a nurse was asked to open an envelope containing the study-group assignment for each hip and reveal it to the surgeon. A statistician who was not involved in the trial prepared the sequentially numbered, sealed, opaque envelopes. Group A contained 14 patients (14 hips) with ONFH who underwent core decompression therapy combined with injection of concentrated autologous bone marrow containing MNC into the femoral head. Group B consisted of 13 patients (14 hips) who were treated with core decompression therapy alone. Ten patients had bilateral ONFH. Nine patients with bilateral ONFH had 1 hip in group A and 1 hip in group B. There were 9 men's and 5 women's hips in group A and 10 men's and 4 women's hips in group B, respectively. The mean age of the patients in the study was 29.08 years (range, 18 to 56 years) with no statistically significant difference between the two groups ($P = 0.22$) (Table 1).

Surgical Procedure

Stem cells were obtained by bone marrow aspiration of the iliac crest. Following the preparation of the skin, a small incision was made over the iliac crest and a needle was advanced between the cortical tables of the crest. Approximately 200 ml of bone marrow aspirate was obtained. The aspirated bone marrow was kept in a sterile bag containing cell anticoagulant solution (citric acid, sodium citrate, dextrose) and sent to the bone marrow transplantation laboratory for processing. The aspirated bone marrow was filtered and washed to remove fat, clot

Table 2
VAS Score At The Baseline and After Intervention.

	Group A (mm)	Group B (mm)	Difference (95% CI)	*P* Value
Preoperative	35.9 ± 4.5	38.6 ± 4.6	−2.7 (−6.2 to −0.8)	0.13
6 months	15.1 ± 3.6	28.2 ± 3.9	−13.1 (−16 to −10.2)	<0.001
12 months	20.2 ± 4.8	31.4 ± 5.1	−11.2 (−15 to −7.4)	<0.001
18 months	18.7 ± 3.2	31.5 ± 4.7	−12.8 (−15.9 to −9.7)	<0.001
24 months	16 ± 3.7	32.1 ± 4.1	−16.1 (−19.4 to −12.8)	<0.001

Note: The changing trend was significantly affected by intervention ($P < 0.001$). Group A, bone marrow graft group; group B, control group; VAS, visual analogue scale; CI, confidence interval.

Download English Version:

https://daneshyari.com/en/article/4060251

Download Persian Version:

https://daneshyari.com/article/4060251

Daneshyari.com