J Musculoskelet Neuronal Interact 2018; 18(1):55-61

Journal of Musculoskeletal and Neuronal Interactions JMNI

Original Article

Efficacy of fibula fixation in the early treatment of Osteonecrosis of the femoral head and its effects on local microcirculation, articular surface collapse, joint pain and function

Baijun Hu[1], Dawei Gao[1], Yihe He[2]

[1]Department III of Orthopaedics, Zhongshan Hospital of Traditional Chinese Medicine;
[2]Department of Internal Medicine, Zhongshan Hospital of Traditional Chinese Medicine

Abstract

Objectives: The aim of this study is to investigate the efficacy of fibula fixation in the early treatment of osteonecrosis of the femoral head (ONFH). **Methods:** 130 patients with ONFH were selected and randomly divided into control group and observation group. Patients in the control group received core decompression treatment, while patients in the observation group received fibula fixation. The local microcirculation was observed by dynamic contrast-enhanced MRI, necrotic volume was measured using MRI, articular surface collapse by using X-ray, McGill pain questionnaire was used to understand and compared the joint pain condition. **Results:** The total effective rate of the observation group was significantly higher than that of the control group ($p<0.05$). Necrosis volume of observation group was significantly smaller than that of control group ($p<0.05$). Degree of joint pain was significantly lower in observation group than in control ($p<0.05$). Harris scores were higher in observation group than in control group ($p<0.05$). All life scores of observation were significantly higher than those of control group ($p<0.05$). **Conclusion:** fibula fixation seems to be not superior to core decompression n preventing articular surface collapse, but it can effectively relieve the joint pain in patients with early ONFH.

Keywords: Osteonecrosis of the Femoral Head (ONFH), Fibula Fixation, Articular Surface Collapse, Local Microcirculation, Joint Pain

Introduction

Osteonecrosis of the femoral head (ONFH) is the disrupted blood supply to the femoral head caused by various causes, and the poor blood supply can cause orthopedic diseases. The ONFH is characterized by trabecular bone fracture, bone cell necrosis, and femoral head collapse[1]. The incidence of the ONFH is high in young and middle-aged people. Without timely and effective treatment, the ONFH will develop into severe hip osteoarthritis, resulting in loss of labor capacity. Efforts should be made to keep patients' femoral head during treatment, and joint replacement should be avoided or at least delayed[2]. The etiology and pathogenesis of the ONFH are not fully understood yet, and no ideal clinical treatment is available[3]. Therefore, the ONFH is still a big problem for orthopedic communities. Hip-preserving can be performed for patients with early ONFH. Core decompression treatment is often used in clinical practice to relieve the disease by reducing the pressure inside the femoral head to improve the revascularization, but this method cannot be used to repair necrotic area[4]. Fibula fixation can be used to increase blood supply to the femoral head, to prevent collapse and deformation, to repair necrotic area and to extend the use of autologous hip[5]. In this study, fibula fixation was used in the early

The authors have no conflict of interest.

Corresponding author: Dawei Gao, Department III of Orthopaedics, Zhongshan Hospital of Traditional Chinese Medicine, No. 3 Kangxin Road, West District, Zhongshan, Guangdong province, 528400, China
E-mail: gu96z8@163.com

Edited by: G. Lyritis
Accepted 9 February 2018

Table I. General information of objects.

Items	Control group (n=65)	Observation group (n=65)	t/x^2	*p*
Gender(male/female)	44/21	46/19	0.036	0.849
Age (years)	30~50	30~55		
Average age (years)	40.38±6.63	40.83±6.73	0.384	0.702
Duration of disease (months)	11.65±5.46	11.28±5.37	0.390	0.698
BMI (Kg/m^2)	23.63±3.25	23.89±3.48	0.440	0.661

treatment of the ONFH to provide a scientific basis for the treatment of the ONFH.

Materials and methods

General information

A sample of 130 patients with the ONFH were selected from March 2003 to December 2012 in Zhongshan Hospital of Traditional Chinese Medicine and were randomly divided into control group and observation group each consisted 65 patients Inclusion criteria:the patients who met the diagnosis criteria of the ONFH established by the International Association on Bone Circulation and Bone Necrosis (ARCO), without femoral head collapse before surgery with duration of pain <6 months, patients who signed informed consent. Exclusion criteria: the patients with severe heart, brain, liver or mental diseases, the patients with severe coagulation dysfunction, and the patients combined with knee and ankle deformity. There was no significant difference in general data between two groups (p>0.05) (Table I).

Preoperative preparation

Comprehensive assessment before surgery was done on patients. Surgical contraindications were excluded and the appropriate timing for surgery was determined. Antibiotic treatment was given two hours before surgery to prevent infection. Intravenous injection of methylprednisolone was given 30 minutes before surgery. Epidural anesthesia was also given to the patients in both groups.

Surgical methods

Patients in two groups were allowed to lie down on traction table with supine position, and lower limbs were kept in lap position. After conventional disinfection, core decompression treatment was performed on the patients in control group. After the positioning of the central line of femoral tunnel, a guide needle (2.5 mm) was inserted into the femoral head. With X-ray monitoring, guide needle was pushed to reach necrotic area and puncture was performed for 3 to 5 times for the core decompression.

Patients in observation group were treated with fibula fixation. Guide needle was pushed to reach the necrotic area, and a tunnel was made along the guided needle. Reaming was performed according to the shape and diameter of the allogeneic fibula. Necrotic bone tissue was removed along the tunnel and saline was used to wash the tunnel. Complete decompression was performed. The allogeneic fibula was pushed to reach the necrotic area of the femoral head through the tunnel. A hollow titanium screw can be used to fix the allogeneic fibula if necessary. The incision was sutured layer by layer.

Postoperative care

After the operation, bed rest was suggested to the patients. Routine infection prevention treatment was performed. After operation, activities of hip joint were allowed with patients in bed, but walking was not allowed for 6 months after surgery. Patients' recovery was check at 6, 12, 24 and 48 months after operation using X-ray and MRI, and a long-term follow-up was also carried out.

Evaluation criteria

Efficacy evaluation: The efficacy at 6 months after the operation was evaluated using X-ray. The evaluation criteria: Firstly, cure, that is the density of necrotic bone was recovered and bone structure was reconstructed. Tension trabeculae and weight-bearing trabeculae showed normal geometric structure that is no femoral head collapse. The femoral head showed normal weight-bearing capacity. Secondly, markedly effective, that is, the necrotic bone tissue was almost absorbed, the density of trabeculae was improved, tension trabeculae and weight-bearing trabeculae showed near-normal geometric structure, the collapse of the femoral head was compared to preoperative level <2 mm and the femoral head showed near-normal weight-bearing capacity. Thirdly, effective, that is, destruction of necrotic bone was stopped, the necrotic bone tissue was partially absorbed, the collapse of the femoral head was compared to a preoperative level between 2 and 4 mm and the trabeculae showed a trend of reconstruction. Finally, ineffective, that is, the necrotic area was not improved or even enlarged, the collapse of femoral head compared with preoperative level >4 mm. Effective rate of treatment= (cure + markedly effective + effective)/total number. The articular surface collapse was observed using X-ray and collapse rate was calculated.

Evaluation 6 months after surgery: A dynamic contrast-enhanced MRI was used to observe femoral

Table II. comparison of treatment efficacies between groups (n, %).

Groups	N	Cure	markedly effective	effective	ineffective	Total efficiency
Observation group	65	30(46.15)	17(26.15)	15(23.08)	3(4.62)	62(95.38)
Control group	65	12(18.46)	16(24.62)	23(35.38)	14(21.54)	51(78.46)

Table III. Comparison of MRI results between groups.

Groups	Cases	Ktrans (min^{-1})	Kep (min^{-1})	Ve	iAUC
Observation group	65	0.021±0.008	4.036±1.213	0.032±0.012	0.713±0.102
Control group	65	0.039±0.009	1.738±0.325	0.186±0.017	2.016±0.307
T		29.881	34.258	50.758	50.758
P		<0.0001	<0.0001	<0.0001	<0.0001

head necrosis. The volume of necrosis for each layer is equal to the necrotic area multiplied by the thickness of the layer. The necrotic volume of each layer was added up to get total necrotic volume. Original image data of MRI was transmitted to the workstation. After processing using a professional software, time-signal intensity curve is generated, pseudocolor images were displayed, and parameters of blood vessel function of observation area were calculated by (a) Ktrans which is the amount of small molecule contrast agent spread from the inside of blood vessels to the outside of the blood vessels within a unit time. (b) Ve that is the volume of extracellular space in a unit volume of the tissue, (c) Kep: the amount of small molecule contrast agent spread from interstitial space back to blood vessels within a unit time and (d) iAUC: the initial area under multiplier curve.

Evaluation of joint-pain conditions: McGill pain questionnaire (SF-MPQ) was used to evaluate the joint-pain conditions of patients at 6, 12, 24 and 48 months after operation where (a) the Pain Rating Index (PRI) was used to obtain scores using sensory items (11 entries) and the emotion items (4 items), and the resultant scores ranged from 0 to 3 points. In otherwords, PRI total score = total score of sensory item + total score of emotion items (b) visual analogue scale (VAS) was used and scores were obtained that ranged from 0 to 10 (0 point represents painless and 10 points indicates unbearable pain), (c) present pain intensity (PPI) scores ranged from 0 to 5 were measured where 0 point represents painless, 1 point represents light pain, 2 points represents uncomfortable feelings, 3 points represents painful and irritable feelings, 4 points represents terrible pain and 5 points represents extremely painful feelings. Total scores were obtained by adding scores of the three tests. The total score was positively correlated with the degree of pain.

Evaluation of hip joint function: The Harris score of the hip joint function was evaluated at 12, 24, and 48 months after operation, and Harris scores at 48 months after operation were compared: The scores were categorized by (a) excellent when Harris score> 90 points (b) good when Harris score was between 80 and 90 (c) pass if Harris score were between 70 to 79 and (d) poor when Harris score <70 points.

Quality of life evaluation: Life quality of patients in two groups was evaluated using Chinese SF-36 health survey at 48 months after the operation. Higher scores indicated better life quality.

Statistical analysis

Data were processed using the SPSS 19.0 (SPSS Inc., Chicago, IL, USA) software. Measurement data were expressed as mean ± standard deviation and t-test was performed for comparisons. The count data was expressed as a rate, and chi-square test was performed. Furthermore, F-test was used for the comparisons between the preoperative and the postoperative data. Treatment efficacy was tested using rank sum test. For all tests, $p<0.05$ was considered to be statistically significant.

Results

After 3 months of treatment, the effective rate in the observation group was found 95.38% which was significantly higher than that in the control group with 78.46% ($p<0.05$). (Table II). Furthermore, the MRI analysis performed at 6 months after the operation showed that, Ktrans, Ve and iAUC values from the observation group were significantly lower than those of the control group, while Kep value was significantly higher than that of the control group ($p<0.05$) (Table III). Moreover, the necrotic volume, in observation group was significantly lower than that of the control group at 3, 6, 12 and 24 months after operation ($p<0.05$) (Table IV). Also, the X-ray was used to observe the postoperative articular surface collapse. Results showed, which there were

Table IV. Comparison of postoperative necrotic volume between groups (cm^3).

Groups	Cases	3 months after operation	6 months after operation	12 months after operation	24 months after operation
Control group	65	12.95ol gr	11.36ol gr	10.13ol gr	8.133ol g
Observation group	65	10.16vatio	8.736vati	7.266vati	6.766vati
T		13.414	4.699	5.202	2.483
P		<0.001	<0.001	<0.001	0.014

Table V. postoperative articular surface collapse in both groups (n, %).

Groups	Cases	3 months after operation	6 months after operation	12 months after operation	24 months after operation
Control group	65	5(7.69)	11(16.92)	15(23.08)	18(27.69)
Observation group	65	7(10.77)	13(20.00)	17(26.15)	20(30.77)
x^2		0.091	0.051	0.041	0.037
P		0.763	0.821	0.839	0.848

Table VI. Comparison of postoperative MPQ pain scores between two groups.

Groups	Cases	3 months after operation	6 months after operation	12 months after operation	24 months after operation
Control group	65	36.95ol gr	18.36ol gr	9.136ol g	6.036ol g
Observation group	65	48.16vatio	24.73vatio	16.26vatio	13.47vatio
T		8.544	6.138	9.494	9.938
p		<0.001	<0.001	<0.001	<0.001

no significant differences in the articular surface collapse between the two groups at 6, 12, 24 and 48 months after the operation ($p>0.05$) (Table V).

The postoperative pain in the two groups of patients was analyzed. The MPQ pain scores from the observation group were significantly lower than those of the control group at 3, 6, 12 and 24 months after operation ($p<0.05$) (Table VI). The hip function of patients in the two groups was assessed using the Harris score. The Harris score of the two groups of patients was significantly increased after the operation. In addition, the Harris score of the observation group was significantly higher than that of the control group at 12, 24 and 48 months after operation ($p<0.05$), see Table VII, and excellent rate of hip function in the observation group was significantly higher than that in the control group ($p<0.05$) (Table VIII). Finally, the quality of life between the patients of the two groups was compared at 48 months after operation. Results showed, which the sF-36 scores of the observation group were significantly higher than that of the control group ($p<0.05$) (Table IX).

Discussion

ONFH, which is a refractory disease of orthopedics, can be divided into two types namely, traumatic and non-traumatic ONFH[6]. Without effective treatment, the disease will progress rapidly, leading to the hip dysfunction and high morbidity[7]. Note that ONFH can be induced by many factors including trauma (posterior hip dislocation, a femoral neck fracture, etc.), drinking, smoking, blood disease, decompression sickness, radiotherapy, connective tissue disease and use of glucocorticoid and other factors[8]. At present, the pathogenesis of ONFH is not yet fully understood and many physiological theories including the intravascular coagulation theory, increased intraosseous pressure theory and fat embolism theory was developed to explain the occurrence of ONFH[9]. Early intervention regarding treatment of ONFH with the necrotic site in non-weight-bearing sites can achieve low occurrence ate of collapse, less necrosis and better treatment efficacy[10].

Many treatments, including drug therapy and surgical treatment, can be used to treat ONFH. Hip-preserving including

Table VII. Comparison of preoperative and postoperative Harris scores between two groups.

Groups	Cases	Before operation	12 months after operation	24 months after operation	48 months after operation	F	*p*
Control group	65	66.95ol gr	89.36ol gr	91.13ol gr	93.73ol gr	56.347	<0.001
Observation group	65	67.16vatio	81.73vatio	83.26vatio	85.46vatio	37.736	<0.001
T		0.376	13.633	14.265	13.884		
p		0.708	<0.001	<0.001	<0.001		

Table VIII. Comparison of hip function between 2 groups (n, %).

Groups	Case	Excellent	Good	Pass	Porr
Control group	65	32 (49.23)	26 (40.00)	6 (9.23)	1 1.54)
Observation group	65	14 (21.54)	24 (36.92)	16 (24.62)	11 16.92)
x^2				14.378	
p				<0.001	

drilling decompression (small channel decompression), core decompression (big channel decompression) combined with bone transplantation, fibular transplantation with or without vascular anastomoses, transplantation using bone with vascular pedicle and osteotomy, is the focus of surgical treatment[11]. Although simple decompression treatment can decrease pressure and improve revascularization to a certain extent, but the necrotic area cannot be repaired with this method[12]. Core decompression combined with the allogeneic fibula, which can play a satisfactory supporting role, is more affordable for the patient and has become an effective method in the treatment of early ONFH[13]. Results of this study showed that effective rate of treatment in observation group was significantly higher than that in control group (p<0.05). The possible explanation is that the method used in the observation group can achieve better decompression, and fibula fixation can support articular surface of femoral head and fill the necrotic areas. Fibula fixation can also create space for repairing which in turn delays the progress of ONFH and joint replacement[13].

Studies showed that allogeneic fibula fixation could interrupt the high pressure in the femoral head, promote local blood circulation, thereby improving blood perfusion, and stimulate the growth of capillaries[14]. Dynamic contrast-enhanced MRI scanning can reflect the characteristics of intravascular angiogenesis and hemodynamics. Ktrans value, which is one of the vascular function parameters, can be affected by the blood circulation, microcirculation structure, the transportation of contrast agent through the vascular wall and the diffusion of contrast agent through the intercellular space[15,16]. Under certain vascular wall permeability in the microcirculation, Kep can effectively reflect the status of circulation[17]. Results of our study showed that Ktrans, Ve and iAUC values of observation group were significantly lower than those of control group, while Kep value was significantly higher than that of control group (p<0.05). Increase of Ktrans value after operation indicated that the newly formed capillaries are not mature and thus resulting in increase of the vascular wall permeability at corresponding area. Higher Ve values indicate higher vascular permeability of the corresponding region, and higher AUC values represent richer blood supply. The higher values of those three scores in control group indicated the existence of different degrees of vascular wall damage. Lower Kep value in the control group indicated the existence of the posterior circulation stasis, which may be associated with the large area of femoral head edema.

Fibula fixation can provide a mechanical environment for the early repair, induce the reconstruction of subchondral cancellous bone, regulate lipid metabolism, and induce osteogenesis[18]. Under normal conditions, abnormal changes in the hemodynamic characteristics of a local microcirculation will happen after the occurrence of ONFH, which in turn lead to the hip pain in patients, and at the same time, venous blood flow obstruction will lead to further increase in bone pressure, resulting in a vicious cycle to accelerate the development of ONFH[19-20]. Our study showed that necrotic volume and MPQ pain scores were significantly lower in the observation group compared to the control group at 3, 6, 12 and 24 months after the operation, the Harris score of the two groups increased after operation, and Harris score of the observation group was significantly higher than that of the control group at 12, 24 and 48 months after the operation, the excellent rate of hip joint was also significantly higher in observation group than in control group (p<0.05). The possible explanation is that the fibula fixation can improve hypoxic-ischemic state of the necrotic area so that the blood flow will move to the balanced state, thereby improve bone marrow cycle, increase the density of necrotic area and promote the bone marrow repair and regeneration. Decompression treatment, postoperative bed rest and the avoidance weight-bearing of limbs can relieve joint pain symptoms caused by bone marrow pressure. The pressure on the other side was also reduced, so rest pain in patients was relieved. Establishment of the bone tunnel relieved the pressure inside the joint capsule. Implantation of the allogeneic fibula can replace necrotic bone tissue and created a better environment for the formation of the new bone, in order to improve and avoid the decline of mechanical properties of trabeculae, to prevent the deformation of femoral head cortical bone, and as a result to enhance the hip joint function in patients[18]. In our study we found that the follow-up for 48 months, sF-36 scores in the observation group was significantly higher than those in the control group ($p<0.05$) which indicate that the fibula fixation can delay the progress of disease, so patients can quickly recover, joint replacement can be delayed or avoided, and the quality of life can be improved.

This study also showed that fibula fixation was not superior to core decompression in the prevention of the articular surface collapse which may suggest that implanted fibula had no effect of supporting articular surface, patients had postoperative joint pain relief and increased ability of activity, however, the possibility of the articular surface collapse still exist. Many scholars have stressed that the importance of articular surface collapse, while ignoring the degree and duration of the pain. Patients with ONFH usually visit a doctor due to the joint pain but not because of the articular surface collapse. It is therefore general thinking that the degree and the duration of the pain should also be considered. The mechanisms of the satisfactory efficacy of fibula fixation possibly include removal of local necrotic bone, better core decompression and local microcirculation improvement.

In conclusion, the early treatment of ONFH patients with fibula fixation is easy for operation, and clinical efficacy is satisfactory. It can improve local microcirculation and reduce the joint pain symptoms, which is conducive for early recovery of the joint function.

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