Prevention of Femoral Head Collapse In Osteonecrosis of Femoral Head by Core Decompression and Autologous Bone Marrow Aspirate Concentrate

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Abstract:
Objective : The objective of this study is preserving the joint by preventing the collapse of femoral head in Osteonecrosis of femoral head (ONFH)
Methods : In this study patients with early ONFH are treated with core decompression and augmented with bone marrow aspirate concentrate spread on a collagen scaffold.
Results : Core decompression augmented with bone marrow aspirate concentrate seems to be beneficial.
Conclusion: With the addition of autologous bone marrow along with core decompression, better results have been obtained.
Practice Implications: Core decompression when combined with bone marrow aspirate concentrate helps in preventing the collapse of femoral head.
Keywords: Osteonecrosis, femoral head, Core decompression, Bone marrow aspirate concentrate

I. Introduction

Osteonecrosis of femoral head (ONFH) or avascular necrosis of femoral head affects young population. Early presentation may be painless, but careful examination uncovers the painful limitation of hip movements. Passive movements of hip are also restricted. There is a high chance of bilateral presentation. Careful clinical history is important to find any of the risk factors.

Osteonecrosis is associated with a decrease in progenitor cells in the head of femur. In the adult, haematopoietic marrow is absent in the femoral head but red marrow persists. In some patients MRI studies have indicated that the conversion of red to fatty marrow occurs prematurely at the proximal end of the femur. This results in a decrease in intramedullary vascularity, predisposing to osteonecrosis. There is a decrease in osteogenic stem cells in the proximal femur. This decrease in stem cells can influence the bone repair in these patients with osteonecrosis. Better results have been obtained with the addition of autologous bone marrow cells along with core decompression.

If early ONFH is not treated at right time leads to collapse of femoral head eventually requiring total hip replacement in these young people which is not desirable. The surgical interventions have been performed in early ONFH with the intention of preserving the joint, like core decompression some times with bone grafting and osteotomies.

Bone grafting has been added to the core decompression to provide structural support. It may act as scaffold and help in repair and remodelling of subchondral bone. Autogenous or allograft cancellous bone have been used along with core decompression. Commonly used autogenous grafts are osteochondral grafts, muscle-pedicled bone grafts, free cortical grafts and free vascularized bone grafts with iliac or fibular bone. The principle of osteotomies in the treatment of ONFH is to rotate the necrotic segment of the hip out of the weight bearing zone and replace it with a segment of healthy articular cartilage supported by viable bone. Both these procedures ( bone grafting and osteotomies) have certain downsides. Harvesting bone graft is associated with donor site morbidity and osteotomies are cumbersome procedures for both the surgeon and the patient.

In this study 22 patients (24 hips) were treated with simple core decompression and augmenting with bone marrow aspirate concentrate on a collagen scaffold. Bone marrow aspirate concentrate has multipotent cells that can differentiate into osteogenic cells. These cells may also provide a potential therapy for bone repair. Autologous stem cell transplantation for early stages of ONFH has been standardized and should be instilled in concentration of 2X10^6 stem cells.

This effectiveness of bone marrow aspirate depends on the availability of stem cells with osteogenic properties. The injected marrow stromal cells also secrete angiogenic cytokines, which results in increased angiogenesis and subsequent improvement in osteogenesis.
II. Review Of Literature

Ficat and Arlet\(^1\) reported good or very good results on core decompression in Stage-I and in Stage-II avascular necrosis at an average follow-up of 7.9 years. Hungerford\(^6\) reported similar results. The rationale for the use of core decompression is based on the concept that increased intra-medullary pressure is involved in the pathogenesis of avascular necrosis. The aim of the proponents of core decompression is to decrease the intramedullary pressure and thus arrest or reverse the process of avascular necrosis before it is evident radiographically.\(^7\)

Wang et al.,\(^8\) have shown short-term effect of increased femoral-head blood flow due to core decompression in the rabbit model. The results of study showed that the decrease in femoral head blood flow due to prolonged steroid therapy was reversed by core decompression. Femoral head perfusion can return to a normal or slightly elevated state, four weeks after treatment. Core decompression is expected to relieve the pain and to allow creeping substitution to the necrotic area by bringing the blood supply through the drill channels.

Chan et al.,\(^9\) evaluated MRI of 32 hips with ONFH before and after the core decompression and bone grafting. Most lesions that appeared stable on MRI were clinically also stable or improved. It was also concluded that MRI can be used to demonstrate changes in size and signal characteristics as well as femoral head collapse after core decompression and bone grafting.

A meta-analysis\(^10\) of 24 reports analyzing 1,206 hips treated by core decompression with or without cancellous bone grafting revealed an overall clinical success rate of 63.5% (range 33 to 95%). Less than 33% of the hips required a replacement or salvage procedure during the follow-up period.

Gangji et al.,\(^11\) (2005 and 2009) performed a randomized control study, where patients were given bone marrow stem cells in addition to core decompression. The Lequesne index in stem cell group decreased from 7.7±1.5 to 3.0±1.1 at 6 months. The WOMAC score also reduced from 30±5 to 18±7 at 6 months.

Yan et al.,\(^12\) (2006) again reported the clinical efficacy and safety of the treatment of osteonecrosis of the femoral head by percutaneous decompression and autologous bone marrow mononuclear cell (BMACs) infusion in a study of 44 hips in 28 patients.

Deltroet al.,\(^13\) (2008) assessed the efficacy and safety of autologous bone-marrow mononuclear cells implantation in necrotic lesions of the femoral head in patients with sickle cell disease.

III. Material And Methods

The study population consisted of a patient group in early ONFH (Pre collapse- Stage I &II ) treated by Core decompression along with bone marrow aspirate concentrate (BMAC) in our hospital. All of these patients had documented ONFH and complained of hip pain due to ONFH. Only patients with idiopathic ONFH were included in the study. Patients, on steroids, anti epileptics, alcoholics, with sickle cell disease or any other secondary ONFH were excluded from the study. The diagnosis of ONFH was based on imaging examination (radiograph, CT or MRI). It also helped to map out the affected areas of the hip. They were also investigated by routine blood investigations (complete hemogram, ESR, CRP, liver and kidney function tests).

A total of 22 patients with 16 men and 6 women were included in this study. The mean age of these patients at the time of treatment was 35.8 years (23 to 45 years). The Ficat stage has been used to classify radiological results. Radiographs of all patients were classified into stage I (8 hips), stage II A (10 hips) and II B (6 hips) according to the Ficat stage system at onset of treatment. 8 of the 32 hips with stage 3 or 4 ONFH were excluded, leaving 24 hips.

<table>
<thead>
<tr>
<th>Stage of hip (Ficat classification)</th>
<th>No. of Hips</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>8 (33.33%)</td>
</tr>
<tr>
<td>II A</td>
<td>10 (41.66%)</td>
</tr>
<tr>
<td>II B</td>
<td>6 (25%)</td>
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</table>

Table1: Distribution of hips according to grade of ONFH.

Following adequate explanation about the procedure and necessary consent, patients were subjected to bone marrow aspiration, ipsilateral side followed by core decompression of the affected hip.

The bone marrow was harvested from anterior iliac crests using a beveled metal trocar of 8 cm length and a bore of 1.5 mm. The bone marrow was then aspirated using a 30 ml syringe that had been flushed with heparin. The aspirated bone marrow was pooled in a plastic bag containing an anticoagulant solution (citric acid, sodium citrate, and dextrose). The collected bone marrow was 100 ml to 200 ml. The bone marrow aspirate concentrate was done by density gradient centrifugation (BMAC – Harvest). After centrifugation, the red blood cells (the non-nucleated cells) and the plasma were isolated and removed. Finally, 30–60 ml of BMAC was collected and placed in syringes for injection.

This procedure of core decompression is briefly described as follows. All the patients were operated under spinal anesthesia in lateral position. Under sterile conditions, the guide-wire was inserted through lateral cortex just below the base of greater trochanter under image intensifier. Based on primary mapping of the area of necrosis, a beveled metal trocar of 8 cm length was used for decompression. After puncturing the femoral head, the guide-wire was inserted into the necrotic bone and decompression was done by drilling 3–4 holes of 1 cm in diameter and 1 cm in length at 1 cm apart from each other. The holes were drilled by means of a burr. After sufficient decompression, bone marrow aspirate concentrate was injected into the drill holes. The above procedure was repeated in the contralateral hip and both the hips were then fixed in a spica cast for four weeks after treatment.

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affected area in head and under image intensifier guidance, the guide pin was directed towards the affected area. The method of doing core decompression involves the use of an 8–10 mm trephine inserted under fluoroscopic guidance to penetrate the lesion. Serial reaming was done by DHS reamer to scrape out the necrotic sclerotic bone. The affected bone being sclerotic was harder to scrape and this gives an indirect confirmation of the affected area. The margins of the core created were thereafter curetted till normal feel of the bone is achieved and confirmed under image intensifier.

Finally the core thus created was filled by autologous bone marrow aspirate concentrate soaked in a collagen scaffold. The entry hole in the bone is sealed with bone wax.

Postoperatively, all patients stayed in hospital for 5 days. Functional training of hip started the first day after treatment. At the time of discharge patients were maintained at approximately 50% weight bearing for 5–6 weeks using a cane or crutch in the opposite hand from the hip that was operated. If the patient had bilateral core decompression, two crutches were used for a 4-point gait. After 5–6 weeks, the patients were advanced to full weight bearing as tolerated.

Patients were followed up at the onset of treatment and at 3, 6, 12, 24 months after treatment.

High-impact loading such as jogging and jumping was not permitted for 12 months. Rehabilitation throughout recovery to include hip abductor strengthening and Range of motion exercises was encouraged. If patients were asymptomatic at 10–12 months postoperatively with no radiographic evidence of collapse, they were allowed to resume all usual activities, including higher impact loading activities (such as running).

Clinical outcomes of all patients were assessed by two experienced orthopedic surgeons.

Harris hip scoring (HHS) system, which considers patients’ pain (44 points), joint function (47 points), deformity of hip joint (4 points) and motion of joint (5 points), was used for the clinical follow-up. Harris hip scores of patients were recorded at onset of treatment and at each follow-up visit and were graded as excellent when the Harris hip score was greater than 90 points, good when it was between 80 and 89 points, fair when it was between 70 and 79 points, and poor when it was less than 70 points, according to previous reports. Conversion to Total Hip Arthroplasty (THA) was considered as the end point in the evaluation of the efficacy of the treatment in the current study. It was considered to be a clinical failure when deterioration on the Harris score was severe enough to require THA. The hips which did not require THA were regarded as survived hips. Each hip of patients suffering from bilateral hip involvement was examined respectively. Complications of the treatment were registered at each follow-up visit.

**Radiological Assessment:** Anteroposterior radiographs or CT scans of the affected hips were taken at each visit. Due to the high cost, MRI could not be done in all the cases. All imaging examinations were analyzed by two experienced radiologists. Radiological progression was decided according to the development of the Ficat stage. Radiological collapse was defined as progression of Ficat stage I or II to Ficat stage III according to a previous report. Finally, our findings were compared with the previously reported data regarding the natural history of ONFH and the efficacy of Core Decompression.

**IV. Results**

In this study, we were able to do follow-up studies on all recruited patients. The mean duration of the follow-up was 18 months (12 to 24 months). No complications were observed during or after the treatment. Our data showed that none of hips in the Ficat stage-I and IIA required THA at 2 years, 1 of 6 hips in the Ficat stage-II B underwent THA at 2 years.

Majority of presenting patients had more restriction of cross leg sitting (10/24) and squatting (12/24) as compared to climbing stairs (9/24).

16/24 hips had flexion >90° but extension was restricted in 20/24 hips. Similarly, less than half of the hips (10 hips) had significant restriction of abduction (less than 30°) and 16/24 hips had appreciable restriction in adduction (less than 20°). Also two-thirds of the presenting hips had appreciable restriction in internal rotation, both in flexion (16/24) and extension (18/24), which was less than 10° and 18/24 hips had appreciable restriction (<30°) in external rotation in flexion and 16/24 had in extension.

Radiological assessment of all 8 hips which were diagnosed as grade I in MRI appeared completely normal on X-ray. However ONFH of II A and B had similar representation in both X-ray and MRI. Average follow-up of 22 patients was upto 18 months.

Majority of the patients (16) were immobilized for at least 12 weeks. However, 6 patients being non-compliant started weight bearing earlier. Out of 24, 20 hips had pain relief immediately after operation. In follow-up at 3 months, 22 hips had complete pain relief and at 6 months follow-up 19 had no pain. So it suggests that majority of patients had pain relief after the procedure.

Out of 24 hips, though 22 hips had internal rotation (in flexion) of less than 20° at 3 months of follow-up. Similar improvement was also seen in 5 hips having less than 10° internal rotation in extension at final.
follow-up. In 3 patients who had less than 30° of external rotation (in flexion) at 3 months improvement was seen at final follow-up. Appreciable improvement was also seen in 2 hips that had less than 30° of external rotation in extension.

Two hips had delayed wound healing due to superficial infection which subsided after debridement. According to Harris hip score, 19 hips (79.16%) had excellent outcome, 4 hips (16.66%) showed good result whereas 1 hip (4.16%) had poor outcome. However, for stage I, out of 8 hips, 7 hips (87.5%) improved, whereas for Stage IIA, out of 10 hips, 8 hips (80%) showed improvement and for stage IIB, out of 6 hips only 4 hips (66.66%) showed improvement. The one patient who did not do well had low pre-operative Harris hip score (<60).

Radiological outcomes were studied at 2 year follow up. The rates of radiological progression were 12.5% (1 of 8 hips), 20% (2 of 10 hips) and 16.66% (1of 6 hips) for Ficat stage-I, IIA and IIB, respectively. Clinically our procedure achieved better success for Ficat stage-I and IIA hips when compared with Ficat stage-IIB hips. The results showed a clinical failure rate of 4.16% (1 of 24 hips) at 2 years i.e., the patient who had to undergo total hip replacement at 2 years. Radiological outcomes also suggest delay of progression to collapse.

We compared our findings with previously reported data (historical control) with respect to the natural history of ONFH. It has been reported that the overall clinical progress for ONFH was 77% to 98%, and the radiological progress was 68% to 75% at a 3-year follow-up study. A radiological progress rate of 74% was observed in the follow-up of the 559 hips. In contrast, our study showed that 92.31% of hips achieved a satisfactory clinical result, while radiological progress rate was 16.66% at the end of 2-year study. Previous reports indicate that the rate of collapse of the femoral head were 75% and 80% at two and four years, respectively. However, our study showed a collapse rate of 16.66% (12.5% for stage I and 18.75% for stage II, includes both A and B) at the end of 2-year study. This study was designed to assess Total Hip Arthroplasty (THA) as an endpoint. 64% of the untreated hips requires THA at the end of 2-years, compared with our result of 4.16% at the end of 2years. Mont and Hungerford found that the rates of hips underwent THA were 65% and 69% for Ficat stage-I and II disease respectively. In the present study, THA was performed only in one patient (6.25%) for Ficat stage-II (A+B) disease.
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Table 2. Ficat stage of the hips and the rate of radiological progression for each Ficat stage

<table>
<thead>
<tr>
<th>Ficat stage at onset of treatment</th>
<th>Survival (number; %)</th>
<th>Total Hip Arthroplasty (THA) (number; %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I (n = 8)</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>IIA (n = 10)</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>IIB(n = 6)</td>
<td>5</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 3. Number of hips survived at the last follow-up i.e., at 2 years for each Ficat stage

V. Conclusion

Augmentation procedures in core decompression surgery with bone marrow aspirate concentrate are appearing to be better options than performing more invasive procedures like osteotomies and bone grafting. This effectiveness of augmentation with bone marrow aspirate concentrate may be related to the availability of stem cells endowed with osteogenic properties which help in bone repair and angiogenic cytokines in increased angiogenesis. The collagen scaffold which is used in this procedure helps in tethering, retaining the stem cells in the femoral head.

References

[1]. Mont MA, Jones LC, Hungerford DS. Non-traumatic osteonecrosis of the femoral head:

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