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Prospective Observational Study on the Functional and Radiological Outcome of Core Decompression with Bone Marrow Aspirate Concentrate in Osteonecrosis of Femoral Head

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Abstract:
Background: Osteonecrosis of the Femoral head is one of the most serious morbidity and several treatment methods are available for treating osteonecrosis. Most of these procedures are effective only in the early stages before the collapse of the femoral head. Hence this study was planned to evaluate the effectiveness of bone marrow aspirate in conjunction with core decompression in modifying the progression of the disease.
Materials and methods: This prospective interventional study was conducted in a College in Chennai among 32 patients selected consecutively from August 2022 to August 2024 fulfilling the inclusion and exclusion criteria. The pre-and post-operative follow-up was performed using the Visual analog scale (VAS), Harris Hip Score (HHS), and Association Research Circulation Osseous (ARCO) classification. The data was collected using MS EXCEL and analyzed using SPSS version 21.
Results: We analyzed 32 patients with osteonecrosis of the femoral head. The mean age of the patients was 37.8±11.5 years and 59.4% were males. Alcohol consumption(46.9%) was the primary etiology for the disease and the left side(37.5%) was mostly affected in the patients. Over the 12 months of follow-up the VAS and HHS improved gradually which was statistically significant with p-value <0.05. There was no change in ARCO score pre- and post-operatively.
Conclusion: In most cases, using bone marrow aspirate concentrate and core decompression at the pre-collapse stages of the disease improves function scores, slows the disease's radiological development, and eliminates the need for a total hip replacement. Hence effective use of these procedures can prevent or delay surgical intervention among the patients.
Keywords: Osteonecrosis of Femoral head, Visual analog scale, Harris Hip Score, Association Research Circulation Osseous classification

Introduction:

Osteonecrosis of the hip, commonly referred to as avascular necrosis (AVN), is characterized by the death of the femoral head due to vascular disruption. The resulting pain around the hip is insidious in onset, often affecting a younger demographic compared to osteoarthritis(1). Diagnosed at a rate of 20,000 to 30,000 new cases annually in the United States, AVN of the femoral head typically presents between the ages of 20 and 40, with a higher prevalence in men(2). Aseptic non-traumatic AVN is a complex, multifactorial disease, often leading to femoral head collapse and secondary osteoarthritis(3).

Approximately 10% of total hip arthroplasties (THA) are performed due to femoral head necrosis (FHN). The

management of AVN poses challenges, and various treatment options are available(4). In the early stages (ARCO stage I - II), the primary goal is joint preservation and preventing femoral head collapse(5). Core decompression, involving retrograde drilling into the necrotic zone, is a widely used approach. regeneration, offering a potential solution to the challenges posed by AVN(5,6).

The aetiology of AVN remains unclear, and the available treatments often fall short, leading to the exploration of alternative approaches(7). With a focus on preserving the joint and preventing femoral head collapse, this study addresses the existing gap by proposing an intervention that utilizes MSCs to potentially induce bone formation and regeneration(8,9). This study introduces a novel intervention involving the local application of autologous mesenchymal stem cells (MSCs) into the necrotic region(10). These cells, isolated from the mononuclear cell fraction of bone marrow, are expanded in-vitro and injected into the affected area(11,12).

This study is planned to evaluate the effect of concentrated bone marrow aspirate injections in conjunction with core decompression in Osteonecrosis of the femoral head and to investigate the clinical outcomes using the Visual Analog Scale (VAS) and Harris Hip Score (HHS), and the radiological outcomes through Magnetic Resonance Imaging (MRI).

Methodology:

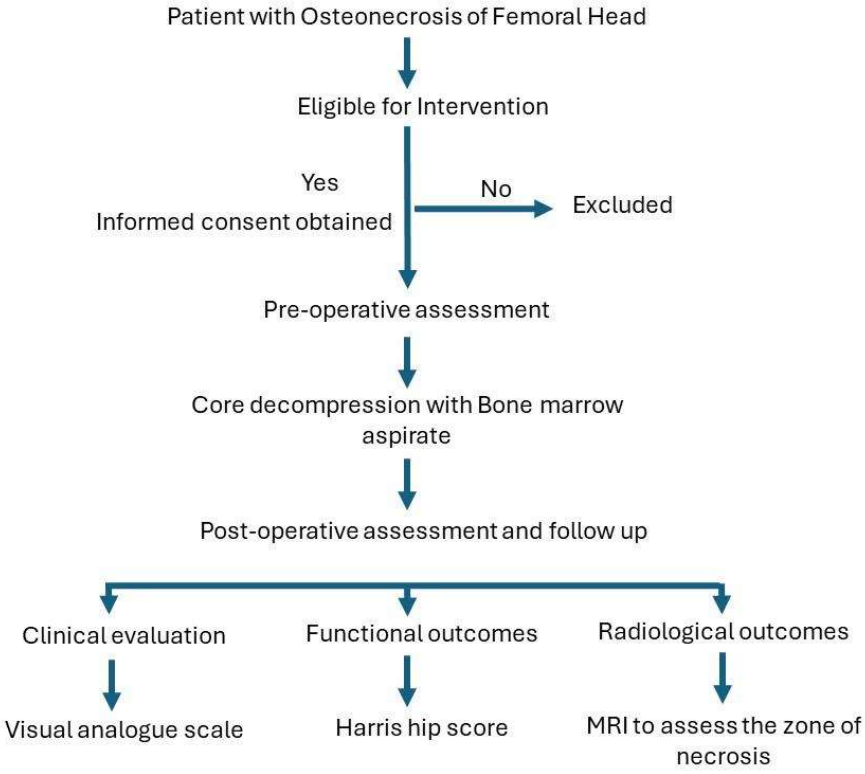
This prospective interventional study was conducted at SRM Institute of Medical Science and Research Center, Chennai from August 2022 to August 2024 among those patients who gave consent to participate in the study with the diagnosis of Osteonecrosis of Femoral Head. The sample size was calculated assuming the prevalence of better outcomes in Osteonecrosis of the femoral head by Pepke et al(12) following bone marrow aspiration in conjunction with core decompression as 71.4% with 95% confidence interval and 20% relative precision as 32 participants.

Based on the sample size, the sampling was done in a consecutive sampling method recruiting all patients reporting in SRM Medical College Hospital and Research Centre, Chennai diagnosed with Osteonecrosis of of Femoral Head until the desired sample size is achieved. The sampling and study methodology is explained in Figure 1. Inclusion criteria include all adult sex between 20-60 years of age giving consent with Ficat and Arlet Classification stage 1 and 2. Patients more than 60 years old with Ficat and Arlet Classification stage 3 and 4, psychologically ill patients, post-traumatic osteonecrosis of the femoral head, radiation-induced osteonecrosis of the femoral head, and osteonecrosis due to the hematological and metabolic process were excluded.

The pre-operative and post-operative evaluation included Clinical Assessment of Pain with Visual Analogue Scale (VAS), Functional Assessment with Harris Hip Score (HHS), and Radiological Assessment with Association Research Circulation Osseous (ARCO) classification(9)(13).

The collected data was entered in Microsoft EXCEL and data cleaning was done. The data was analyzed using SPSS version 21. Categorical data was presented as frequency and percentage. Continuous data was presented as mean and standard deviation. The outcome of patients during the postoperative follow-up period was analyzed with preoperative assessment using an independent sample t-test with a statistically significant p-value of 0.05.

Figure 1: Flow chart of the study process.



Informed written consent was obtained from each of the patients and they were assured that their identity will not be revealed, and they can withdraw from the study anytime they wish. They were also informed that its was voluntary participation. Official permission to conduct the study was obtained from the local institutional ethics committee.

Results:

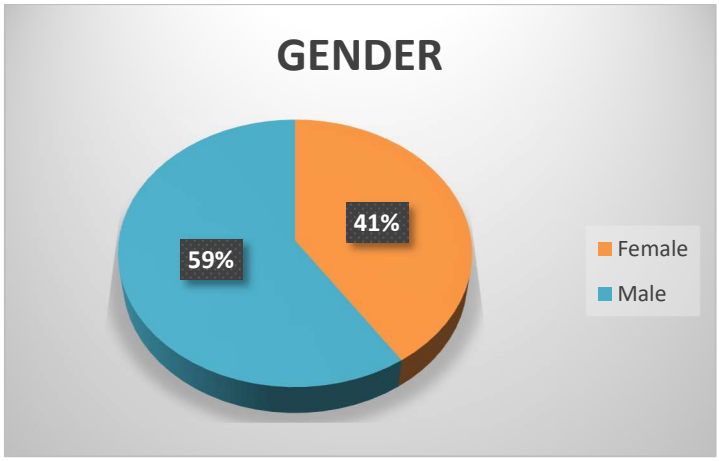
This study involved 32 patients selected consecutively presenting with Osteonecrosis of Femoral head. The mean age of the study participants was 37.8 ± 11.5 years. More than 50% (n=17) patients were between the age group of 25-45 years as showed in Table 1.

Table 1: Age distribution of the study participants (n=32)

Age	Frequency	Percent
<25 years	5	15.6
25-45 years	17	53.1
>45 years	10	31.3
Total	32	100.0

Figure 2 describes the gender distribution of the study participants. Males were the most common patients with 59.4% (n=19). Prevalence of osteonecrosis was almost evenly distributed on both sides.

Figure 2: Gender distribution of study participants (n=32)



Prevalence of Osteonecrosis based on the side is explained in the Figure 3. Osteonecrosis on left side was 37.5% and 31.3% on right side and bilateral distribution.

Figure 3: Distribution of study participants according to the side of injury (n=32).

Table 2: Distribution of study participants according to the duration of symptoms

Duration of symptoms	Frequency	Percent
8-10 months	14	43.8
10-12 months	18	56.3
Total	32	100.0

Table 4 depicts the distribution of study participants according to the duration of symptoms. Among the participants, 18 (56.3%) had a duration of 8-10 months, and 14 (43.8%) of patients had a duration between 10-12months.

Table 3: Distribution of study participants according to aetiology of disease (n=32)

Aetiology	**Frequency (n=32)**	**Percentage (%)**
Alcohol	15	46.9
Smoking	6	18.8
Steroid	3	9.4

Others	8	25.0
Total	32	100

The aetiology for osteonecrosis is presented in the table 2. The most common aetiology of the Osteonecrosis was alcohol (n=15, 46.9%) and 25% (n=8) had causes other than alcohol, smoking, and steroid use.

Table 4: Comparison of pre- and post-op VAS score at different follow-up period (n=32)

VAS	Mean	Std. Deviation	P value
Pre-op	8.38	1.100	0.006*
1 Month	7.59	1.266	
Pre-op	8.38	1.100	<0.001*
3 Months	5.31	1.120	
Pre-op	8.38	1.100	<0.001*
6 Months	2.19	0.821	
Pre-op	8.38	1.100	<0.001*
12 Months	1.75	0.440	

The classification of Osteonecrosis of the femoral head was by Association Research Circulation Osseous (ARCO) classification. Among the patients 56.25% (n=18) were classified as Class I pre-operatively and the assessment remained the same post-operatively. Similarly, 43.75% were classified as Class II pre-operatively and continued to remain the same. Majority of the patients (n=30, 93.8%) had no complication and 6.2% (n=2) had sub-trochanteric fracture.

Table 5: Comparison of Pre and Post Intervention Status of Hip by ARCO Classification (Radiological Evaluation)

ARCO Classification	Pre-intervention	Post-intervention
I	18	18
II	14	14
Total	32	32

The Visual analogue score (VAS) of the patients were compared with the pre-operative condition and follow-up periods during 1st, 3rd, 6th and 12th month. The mean pre-operative VAS was 8.38 which was more than VAS at each follow-up and this difference was statistically significant with p value <0.05. The maximum reduction in VAS was at 12th month follow-up (1.74).

Table 6: Comparison of pre- and post-op HHS score at different follow-up period (n=32)

HHS	Mean	Std. Deviation	P value
Pre-op	53.19	5.556	<0.001*
1 Month	68.59	6.283	
Pre-op	53.19	5.556	<0.001*
3 Months	84.09	3.532	
Pre-op	53.19	5.556	<0.001*
6 Months	89.09	2.607	

Pre-op	53.19	5.556	<0.001*
12 Months	89.63	2.600	

The Harris hip score (HHS) of the patients were compared with the pre-operative condition and follow-up periods during 1st, 3rd, 6th and 12th month. The mean pre-operative HHS was 53.19 which was less than HHS at each follow-up and this difference was statistically significant with p value <0.05. The maximum increase in HHS was at 12th month follow-up (89.63). The HHS increased gradually over the period of follow-up.

Discussion:

Osteonecrosis of the femoral head is a complex condition that can cause significant suffering for patients of all ages, including those who are young and active(14). When diagnosed early, surgical interventions can be attempted to preserve the hip joint, such as decompression of the femoral head coupled with concentrated bone marrow. Utilizing autologous stem cells has emerged as a promising approach to halt the progression of femoral head osteonecrosis, thereby avoiding the need for total hip replacement surgery in young patients(13,15).

The mean age of participants in our study was 37.8 years, consistent with findings from Moya et al. (2015) and Kennon et al. (2019), which reported mean ages of 38.2 years and 39.17 years, respectively(3,6). These similarities shows the prevalence of osteonecrosis of the femoral head within this age group, emphasizing the necessity for targeted interventions for this demographic.

In the current study, males constituted 59.4% of the participants, while in Kennon et al. (2019), the proportion was even higher at 70%. Conversely, females accounted for 40.6% of the participants in the current study and 30% in Desforges et al. (2019)(6,16). This similarity in gender distribution between the two studies suggests a potential trend towards a higher incidence or presentation of osteonecrosis of the femoral head among males.

The current study examined various factors potentially contributing to osteonecrosis of the femoral head, with 46.9% being alcohol consumers, 18.8% smokers, 25% experiencing other factors and 9.4% of participants using steroids. In contrast, Kennon V et al. (2019) and Martin et al (2013) found that 60% had idiopathic osteonecrosis, 30% had a history of steroid intake, and 10% had prolonged alcohol intake(6,11). Together, these findings show the complex interplay of various risk factors and etiological pathways in osteonecrosis of the femoral head, highlighting the need for tailored approaches to diagnosis, treatment, and prevention.

In the current study, 56.25% of the participants presented with ARCO- classification I both pre-operatively and post-operatively. Similarly, 43.75% of participants presented with ARCO- classification II pre-operatively and post-operatively. In contrast to our study the ARCO classification improved in most patients following surgery in studies conducted by Ganji et al (2011) and Pepke et al (2016)(12,15,17). These findings could be due to the various categories of avascular necrosis, duration of symptoms and lesser classification of ARCO classification.

In the current study, a substantial improvement in HHS from a baseline of 53.19 to 89.63 at 12 months follow-up was noted, indicating significant functional enhancement. Similar findings were observed by Ulusoy et al. (2023)(9), who reported a significant increase in HHS from a preoperative mean of 67.66 to a postoperative 18-month mean of 92.4. Conversely, Chang et al. (2010)(5) found a significantly lower HHS in the Core Decompression with Bone Marrow Aspirate Concentrate (CDBM) group compared to other treatment groups, suggesting potential limitations in certain therapeutic approaches(4,18). Overall, the collective evidence underscores the need for continued research to refine treatment protocols and optimize functional outcomes for patients with osteonecrosis of the femoral head.

In the current study, patients experienced a significant reduction in VAS scores from a baseline of 8.38 to 1.75 at 12 months follow-up, indicating substantial pain relief post-surgery. This improvement was consistent across all follow-up periods, highlighting the effectiveness of the intervention in alleviating pain. Conversely, Jain et al. (2021) observed divergent outcomes between treatment groups(8). While the Core Decompression + Bone Marrow Aspirate Concentrate (BMAC) group demonstrated a significant reduction in pain at the final follow-up, patients treated with Core

Decompression alone experienced a statistically significant increase in VAS score, indicating poorer pain outcomes in this subgroup(19,20). These findings showcase the importance of considering adjunct therapies such as BMAC in the management of osteonecrosis of the femoral head, as they may contribute to better pain outcomes compared to conventional treatment approaches alone.

Conclusion:

In conclusion, our study contributes to the growing body of evidence supporting the use of surgical interventions, particularly core decompression with BMAC, for the treatment of osteonecrosis of the femoral head. However, the variability in outcomes across studies emphasizes the need for continued research to refine treatment protocols and optimize functional outcomes for affected individuals.

Limitations:

The study was conducted in a specific geographic area and within a specific demographic group. Despite calculating the sample size, the study included a relatively small number of participants, which might limit the statistical power and generalizability of the results. Despite calculating the sample size, the study included a relatively small number of participants, which might limit the statistical power and generalizability of the results. The absence of a control group receiving standard treatment or a placebo limits the ability to attribute observed outcomes solely to the intervention being studied. Consecutive sampling technique might introduce selection bias, as it could exclude certain patients who do not meet the inclusion criteria. While the study investigates the effects of concentrated bone marrow aspirate injections and core decompression, it may not fully elucidate the underlying cellular mechanisms responsible for observed outcomes.

References:

1. Barney J, Piuzzi NS, Akhondi H. Femoral Head Avascular Necrosis. Radiopaedia.org [Internet]. 2023 Jul 3 [cited 2024 Jun 15]; Available from: https://www.ncbi.nlm.nih.gov/books/NBK546658/
2. Lespasio MJ, Sodhi N, Mont MA. Osteonecrosis of the Hip: A Primer. Perm J [Internet]. 2019 [cited 2024 Jun 15];23(1). Available from: https://pubmed.ncbi.nlm.nih.gov/30939270/
3. Moya-Angeler J, Gianakos AL, Villa JC, Ni A, Lane JM. Current concepts on osteonecrosis of the femoral head. World J Orthop [Internet]. 2015 [cited 2024 Jun 15];6(8):590–601. Available from: https://pubmed.ncbi.nlm.nih.gov/26396935/
4. Functional Outcome of Autologous Bone Marrow Concentrate Implantation in Osteonecrosis of Femoral Head-a Two Year Follow-up Study. [cited 2024 Jun 15]; Available from: https://www.researchgate.net/publication/338263518_Functional_Outcome_of_Autologous_Bone_Marrow_Concentrate_Implantation_in_Osteonecrosis_of_Femoral_Head-a_Two_Year_Follow-up_Study
5. Hua KC, Yang XG, Feng JT, Wang F, Yang L, Zhang H, et al. The efficacy and safety of core decompression for the treatment of femoral head necrosis: a systematic review and meta-analysis. J Orthop Surg Res [Internet]. 2019 Sep 11 [cited 2024 Jun 15];14(1). Available from: /pmc/articles/PMC6737645/
6. Kennon JC, Smith JP, Crosby LA. Core decompression and arthroplasty outcomes for atraumatic osteonecrosis of the humeral head. J shoulder Elb Surg [Internet]. 2016 Sep 1 [cited 2024 Jun 15];25(9):1442–8. Available from: https://pubmed.ncbi.nlm.nih.gov/27085764/
7. Lafforgue P, Dahan E, Chagnaud C, Schiano A, Kasbarian M, Acquaviva PC. Early-stage avascular necrosis of the femoral head: MR imaging for prognosis in 31 cases with at least 2 years of follow-up. Radiology. 1993;187(1):199–204.
8. Jain DA, Daultani DD, Doshi DK, Palanivel DA, Syed DT, Kumar DMA, et al. Bone marrow aspirate concentrate (Stem cells) therapy for pre-collapse stage of AVN of femoral head: An interventional comparative study. Int J Orthop Sci [Internet]. 2020 Oct 1 [cited 2024 Jun 15];6(4):974–9. Available from: https://www.orthopaper.com/archives/?year=2020&vol=6&issue=4&ArticleId=2448
9. Ulusoy İ, Yılmaz M, Kıvrak A. Efficacy of autologous stem cell therapy in femoral head avascular necrosis: a

comparative study. J Orthop Surg Res [Internet]. 2023 Dec 1 [cited 2024 Jun 15];18(1):799. Available from: /pmc/articles/PMC10598958/
10. Ficat RP. Idiopathic bone necrosis of the femoral head. Early diagnosis and treatment. J Bone Jt Surg - Ser B. 1985;67(1):3–9.
11. Martin JR, Houdek MT, Sierra RJ. Use of concentrated bone marrow aspirate and platelet rich plasma during minimally invasive decompression of the femoral head in the treatment of osteonecrosis. Croat Med J [Internet]. 2013 [cited 2024 Jun 15];54(3):219–24. Available from: https://pubmed.ncbi.nlm.nih.gov/23771751/
12. Pepke W, Kasten P, Beckmann NA, Janicki P, Egermann M. Core Decompression and Autologous Bone Marrow Concentrate for Treatment of Femoral Head Osteonecrosis: A Randomized Prospective Study. Orthop Rev (Pavia) [Internet]. 2016 Mar 21 [cited 2024 Jun 15];8(1):5–9. Available from: https://pubmed.ncbi.nlm.nih.gov/27114808/
13. Ko YS, Ha JH, Park JW, Lee YK, Kim TY, Koo KH. Updating Osteonecrosis of the Femoral Head. Hip pelvis [Internet]. 2023 Sep 1 [cited 2024 Jun 15];35(3):147–56. Available from: https://pubmed.ncbi.nlm.nih.gov/37727298/
14. Sen RK. Management of avascular necrosis of femoral head at pre-collapse stage. Indian J Orthop [Internet]. 2009 Jan 1 [cited 2024 Jun 15];43(1):6. Available from: /pmc/articles/PMC2739499/
15. Gangji V, Toungouz M, Hauzeur JP. Stem cell therapy for osteonecrosis of the femoral head. Expert Opin Biol Ther [Internet]. 2005 Apr [cited 2024 Jun 15];5(4):437–42. Available from: https://pubmed.ncbi.nlm.nih.gov/15934823/
16. Desforges JF, Mankin HJ. Nontraumatic Necrosis of Bone (Osteonecrosis). N Engl J Med [Internet]. 1992 May 28 [cited 2024 Jun 15];326(22):1473–9. Available from: https://www.nejm.org/doi/full/10.1056/NEJM199205283262206
17. Gangji V, De Maertelaer V, Hauzeur JP. Autologous bone marrow cell implantation in the treatment of non-traumatic osteonecrosis of the femoral head: Five year follow-up of a prospective controlled study. Bone [Internet]. 2011 Nov [cited 2024 Jun 15];49(5):1005–9. Available from: https://pubmed.ncbi.nlm.nih.gov/21821156/
18. Weinstein RS. Glucocorticoid-induced osteonecrosis. Endocrine [Internet]. 2012 [cited 2024 Jun 15];41(2):183–90. Available from: https://pubmed.ncbi.nlm.nih.gov/22169965/
19. Wu T, Jiang Y, Tian H, Shi W, Wang Y, Li T. Systematic analysis of hip-preserving treatment for early osteonecrosis of the femoral head from the perspective of bibliometrics (2010-2023). J Orthop Surg Res [Internet]. 2023 Dec 1 [cited 2024 Jun 15];18(1). Available from: https://pubmed.ncbi.nlm.nih.gov/38093378/
20. Marker DR, Seyler TM, McGrath MS, Delanois RE, Ulrich SD, Mont MA. Treatment of early stage osteonecrosis of the femoral head. J Bone Joint Surg Am [Internet]. 2008 Nov 1 [cited 2024 Jun 15];90 Suppl 4(SUPPL. 4):175–87. Available from: https://pubmed.ncbi.nlm.nih.gov/18984729/