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Proof of concept to portray management of early and mid-stage avascular necrosis with bone marrow aspirate concentrate and high concentrate plasma augmentation, post percutaneous core decompression-an ortho biologics approach

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ABSTRACT

Background: Avascular necrosis (AVN) or osteonecrosis of the femoral head portray as a progressive disease affecting hip joints particularly in younger and middle-aged individuals and if left untreated precipitate to secondary complications. Percutaneous core decompression (PCD) has been the first line treatment for AVN in view of its beneficial effects to remove necrotic lesion, non-invasive, compression lessened with revascularization. Ortho biologics explore the application of autologous bone marrow aspirate concentrate (BMAC) and high concentrate platelet rich plasma (HCP) found naturally in body to improve healing, reduce inflammation with very good safety profile and require minimal post-procedural time for recovery. Present study explores the synergistic effect of autologous BMAC and HCP post PCD, as an interventional therapy to treat AVN patients.
Methods: We recruited (prospective study) 45 AVN patients (mean age: 37.8 years, range, 15-52 years, 38 males and 7 females). Treatment included PCD followed by augmentation with autologous BMAC and HCP injection via fluoroscopy in femoral head guided. The patient's follow-up was for two years by telephonic survey post therapy (2023-2025) and were assessed using standard Ficat and Arlet scoring.
Results: Patients in stage I (3.8%), stage II (55.7%) and stage III (16.45%) showed greater improvement(s) as very good/good/satisfactory compared to stage IV (12.65%) which required total hip replacement (THR).
Conclusions: We advocate promising line of treatment for management of stage I-III of AVN patients (Ficat and Arlet scoring) using combination of BMAC and HCP augmentation post PCD.

Keywords: Avascular necrosis, Femoral head, Bone marrow concentrate, Platelet-rich plasma, Percutaneous core decompression

INTRODUCTION

Avascular necrosis (AVN)/ osteonecrosis of femoral head is a disabling, multifactorial condition that effects typically the younger group of population causing degenerative and death of the bone tissue, inadequate vascularization, leading to collapse in femoral head, which if untreated would result in secondary complications including osteoarthritis (OA).[1,2] Although initial presentations appear painless, imaging (structural) has been vital and shows limitation of both active and passive hip movements which under chronic conditions lead to debilitating

condition.[3] The confounding factors are not very clear, nevertheless AVN poses substantial challenge in public health owing to the pathophysiology of the functional impairment evidenced differentially with stages of AVN.[4,5] Ortho biologics have emerged as an alternative therapy to treat musculoskeletal diseases (MSDs) and include BMAC, HCP (autologous) and studies do document better recovery (injured tendons, ligaments, cartilage, injured muscles) using these interventional line of therapies.[6] Beneficial effects in AVN with BMAC following post PDC has been well documented owing to its enriched regenerative milieu of stem cell pool, growth factors, and paracrine factors which orchestrate to replace and restore marrow of the necrotic femoral head.[7,8] If AVN is not treated at stage 1-III, it eventually would harp on irreversible stage IV (Ficat and Arlet) with trauma of hip replacement in young adults. Several approache(s) have been relooked into for the management of AVN patients including PCD per se, PCD post bone grafting and osteotomies, morselized bone grafting, BMAC post PCD etc to accelerate bone repair process and suppress the activation of necrosis. Amongst these, PCD with BMAC augmentation with scaffold or morselized bone graft have been beneficial with better functional outcomes in managing early and mid-stages of AVN.[9]

The pathophysiology of AVN is complex, and has been associated with a decrease turnover of the osteoprogenitor cells in femoral head, activation of necrotic process vis a vis down regulation of repair cascade.[6] Further, studies by Hashimoto et al have shown for a quantitative increase in fat-based marrow at the proximal end of the femur to make it more inflammatory unlike the healthy red marrow. The therapeutic signature of stem cells inherent in BMAC have been primarily documented for its multipotent lineage/osteogenic, anti-inflammatory, activate growth factors including angiogenic, paracrine effects, immunomodulatory and to enhance mitochondrial biogenesis.[10] Thus potent beneficial functions of BMAC to alleviate early and mid AVN stages have been documented with supporting findings.[4,7,8,11] In similar lines, impetus obtained from our earlier study in knee OA patients showed significant efficacy with BMAC to improve pain and restore moments similar to seen in spinal OA.[12-15] The merit of using HCP (Ortho biologics) to address MSDs is noteworthy and emerging as an new line of treatment as it is non-invasive procedure, autologous, ease of collection and better functional outcomes to release the growth factors and cytokines at the site of injection.[16] Supporting data from early, middle and late stages of knee OA have improvement also improved with PRP intervention, probably due to the interplay of PRP at chondrogenesis site.[17,18]

The present study has been undertaken in 45 AVN patients primarily to assess therapeutic potential of combining BMAC and PRP (autologous) with augmentation post PCD. This study form prospective and not randomized and has been investigated only to establish proof of concept to assess the beneficial functions of BMAC and PRP. Further, literature survey show no reports till date for a combination approach (BMAC and HCP) as line of intervention post PCD.

We therefore hypothesize that intervention of AVN patients with PCD, followed by augmentation with BMAC and HCP would negate necrosis, inflammation and restore vascularity of the femoral head owing to regenerative potential of BMAC/HCP to normalize the femoral head architecture. The functional outcomes were monitored telephonically as a two-year follow up study by Ficat and Arlet scoring (2023-2025).

METHODS

Study design and patients

This was a prospective study, to assess the outcomes of treating PCD followed with BMAC and HCP in AVN patients. The patients were followed up for two years and outcomes evaluated telephonically post intervention (two years), classified stage I-IV/Ficat and Arlet 2025.[4] A total of 45 patients consisting of 79 hips (Table 1), were classified for age 15-52 years/mean 37.8 (38 males and 7 females) showed bilateral involvement of 86.07% (34 patients). All the patients were questioned for hip pain and AVN with idiopathic etiology were included for the study (inclusion criteria). The exclusion criteria included patients exposed to steroids, alcoholic, epileptic drugs and suffering with sickle cell diseases. The study was undertaken as a single centre at RegenOrthoSport-Movva health care Hospital at Jubilee Hills, Hyderabad.

Table 1: Distribution of hips according to grade of osteonecrosis of the femoral head (ONFH).

Stage of hip (Ficat and Arlet classification)	No. of hips (%)
I	3 (3.8)
II	44 (55.7)
III	21 (26.58)
IV	11 (13.92)

Outcome measures

The follow-up was conducted telephonically in September 2025 (approximately two years post-procedure) and the patients were asked to self-report their outcomes as very good, good, fair/minimal change, no improvement/ replaced (hip arthroplasty). Parallelly, baseline follow up by MRI staging data were also reviewed as and when required during post operative care.

Non-invasive technique

The patients were educated adequately regarding the procedure and after the needful consent by patients, BMAC was aspirated as minimal non-invasive technique, and PCD was also done as minimal non-invasive approach (ipsilateral and bilateral).[23]

BMAC and HCP processing procedure

Bone marrow aspirate was harvested from the patient's iliac crest under ultrasound guidance and PRP was prepared by two step differential centrifugations and was processed.[23]

Statistical analysis

Descriptive statistics were used and outcomes were analysed as per disease stage for-early: Ficat and Arlet (I-II-III) or equivalent and advanced Ficat and Arlet (IV) or equivalent.

RESULTS

The follow-up studies on all recruited patients were by telephonic survey for a period of two years post-procedure. In a total of 45 patients recruited (79 hips) with mean age of 37.8 years, constituting 38 males and 7 females. Among them, 34 patients/75.55% (69 hips) showed bilateral involvement of AVN and who were subjected for PCD followed by BMAC and HCP. Interestingly, the patients showed stage specific improvement as per Ficat and Arlet as very good (Stage I/3-3.79%), good (Stage II/53-67.08%) and satisfactory (stage III/13-16.45%), and advanced stage (Stage-IV/11-12.65%) showed poor outcome requiring THR (Table 2). The data indicates the stage specific/prognosis carried out by telephonic means as indicated above.

Table 2: Clinical outcomes of the follow-up i. e., at 2 years (Ficat and Arlet).

Ficat and Arlet-stage at onset of treatment	Clinical outcome	Total hip arthroplasty
I (n=3)	Very good: 3 (3.79%)	0
II (n=53)	Good: 53 (67.08 %)	0
III (n=13)	Satisfactory: 13 (16.45%)	0
IV (n=11)	No improvement: 10 (12.65%)	10

DISCUSSION

Our present findings show the effective management of AVN patients' stages I-III with autologous BMAC and HCP post PCD predominant in pre-collapse phases (Ficat and Arlet scoring) with less desirable results noted in advanced stages (Ficat stage IV). Interestingly, PCD forms a widely used intervention therapy for AVN patients since times to reduce intra-osseous pressure and to increase vascularization due to multiple drill holes made in necrotic area of the femoral head. Several studies including Ficat et al have also documented the beneficial effects of core decompression in stage I and II AVN patients who were followed up for a long-term study.[19] However, at the clinical level despite its improvement noted in some patents/suboptimal outcomes or resistance, could be due to inadequate osteo progenitor cells to curb the repair process leading to necrotic changes.[16-19] In recent times, Ortho biologics has emerged as an alternate cellular therapy to include autologous BMAC, HCP and mesenchymal stem cells/MSCs (Placenta, umbilical cord, Wharton jelly, adipose tissue, bone marrow, dental pulp etc) to treat several disease conditions including musculoskeletal.[12,20-24] Indeed, combined effects of BMAC with PRP as compared to PCD per se can be attributed to the enriched stem cell pool in BMAC helping in multilineage potential, paracrine function, mitochondrial biogenesis, immunomodulatory and also to orchestrate regeneration and repair in AVN, akin to similar reports noted with MSCs intervention for KOA, diabesity, diabetes and wound healing etc.[10,23-29] The beneficial effects of our approach merit owing to increase in osseous pressure by PCD, enhance blood supply through the drill channels vis-à-vis followed by augmentation with BMAC and HCP to enhance regenerative milieu, vascularization and restore almost the normal architecture of the femoral head.[30] In a randomised control study intervention with BMAC showed significant decrease in the lequesne index 38.7% by six months of treatment in addition to WOMAC score which showed a reduction to 60% suggesting its efficacy and safety to address the early stages of AVN.[31]

As the AVN progresses, the femoral head undergoes necrotic changes of the articular surface and bone marrow grafting pose as a long-lasting regenerative effect although still debatable.[19] Hence, further investigations should aim to enhance the femoral head integrity by enriching the femoral head milieu by stimulating the osteoblast and remodel to upscale the regenerative process. In similar lines different studies reinstate that the combination with BMAC and morselized bone grafting with core decompression as a promising treatment modality and to increase the survival grafts against only the core decompression.[8,32,33] Several studies undertaken to assess the post pain relief using Harris hip score (HHS) index undoubtedly report for a positive co-relation with the approach of core decompression with BMAC.[8,34] The significant improvement exhibited by their functional outputs including range of motion, gait, day to day activity does evidence the positive outcomes of the minimal non-invasive surgical intervention. Regulatory norms like FDA have approved the therapeutic efficacy of using the BMAC as a minimally invasive procedure for treatment of MSDs/OA due to inherent regenerative potential of BMAC.[35] Further, intervention with PRP probably would exacerbate the repair process.[36-38] Similar to our present approach.

Hence, our study demonstrates for the first time that combination approach with BMAC and HCP injections facilitates hip management in AVN patients appreciable from stage I-III. The regenerative intervention was effective over 70% in patients reported very good/good/ and satisfactory outcomes followed up for a year of two

years (Ficat and Arlet scoring) which is consistent with published reports of stem cell augmentation to delay the disease progression. The patients treated at stages I>II> and >III derived the greatest benefit, whereas advanced stages 1V had minimal or no improvement requiring THR.

Limitations

Multicentric studies are required to arrive at conclusive line of evidence with BMAC and HCP augmentation post PCD. Also supporting with imaging (structural) evidence would have further added strength to the data and functional outcome measurements using HHS and WOMAC would have added further strength to the data obtained.

CONCLUSION

We advocate beneficial line of treatment in the management of stage I-III of AVN patients (Ficat and Arlet scoring) using combination of BMAC and HCP augmentation post PCD.

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