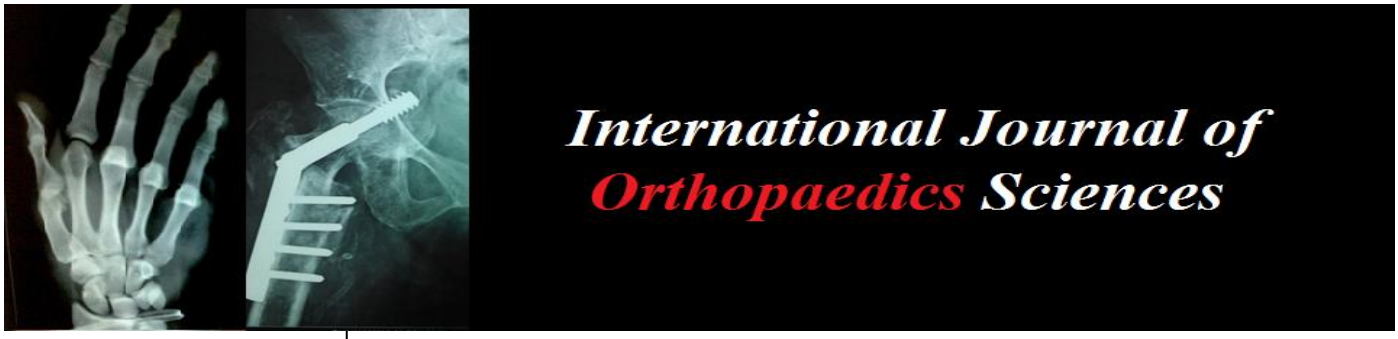

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Effects of bone marrow aspirate concentrates (BMACs) in tear size reduction in partial thickness tear of the supraspinatus tendon compared to platelet-rich plasma (PRP) injection

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Abstract
Objectives: The aim of this study is to compare the difference in tear size and functional scores between the intralesional PRP and BMAC injections for partial-thickness supraspinatus tears.
Methods: 30 patients with partial thickness tear of the supraspinatus tendon studied between May 1, 2021 to May 31, 2022 were randomised into two groups. 15 patients underwent extraction of BMACs and received BMAC injection at the tear site and 15 patients underwent extraction of PRP and received intralesional PRP injection, under the guidance of ultrasound. The American Shoulder and elbow surgeons (ASES) scores were recorded before injection, 3 weeks and 3 months after injection. Tear size reduction was measured at 3 weeks and 3 months after injection in two groups by ultrasound measuring the longitudinal tear length.
Results: There were 10 men and 5 women in BMAC group, whereas in the PRP group, there were 8 men and 7 women, with the right side being more frequently affected in 18 patients. In the BMAC group, the mean age of the patients was 52.6±7.3 years, whereas, in the PRP group, it was 52.6±5.4 years. The ASES scores in BMAC group changed from 37.1±7.3 (before injection) to 54.7±6.5 at 3 weeks and 75.6±5.2 at 3 months while those in the PRP group changed from 35.6±6.1 (before injection) to 51.4±6.6 at 3 weeks and 64.5±4.8 at 3 months. In the BMAC group, the mean tear size decreased from 5.7±1.4 (before injection) to 3.7±1.1 after 3 months, but in the PRP group, it changes from 6.3±1.3 (before injection) to 5.4±1.3 after 3 months.
Conclusion: BMAC injection reduced the tear size and improved the pain and functional scores in patients with partial thickness tears of the supraspinatus tendon when compared to PRP injection.

Keywords: Bone marrow aspirate concentrate, platelet-rich plasma, supraspinatus tear.

Introduction

Rotator cuff tears are a frequent shoulder ailment, affecting around 21% of the general population [1]. Although the pathogenesis of the rotator cuff tear is not entirely known, it is a complex condition caused by age-related degeneration, oxidative stress, and vascular changes [2-3]. Traumatic injury, degenerative changes, repetitive impingement, genetic predisposition, and smoking are some of the risk factors [4]. Supraspinatus tendon tears can be partial or full-thickness tears. A partial thickness tear is a non-communicating tear of the tendon that affects either the substance or articular side or bursal side of the tendon. Ellman classified supraspinatus tendon partial thickness tears into three grades based on the depth of the tendon thickness involved. Small partial thickness tears involve 3mm depth, medium tears involve 3 to 6 mm depth and large partial thickness tears are those that involve more than 6mm depth and thus involve more than 50% of tendon thickness. This grading method, however, does not account for natural variation in tendon thickness. So, Partial-thickness tears are classified as low grade if they occupy less than 50% of the tendon thickness and high grade if they occupy more than 50% of the tendon thickness. Pain and disability can develop from a partial tear of the supraspinatus tendon. Supraspinatus tendon tears can be treated non-surgically or surgically.

Non-surgical treatments include rotator cuff strengthening exercises, analgesics, and corticosteroid injections. All of these provide symptomatic alleviation rather than restoring shoulder function and preventing tears from progressing [5]. Surgical treatment of rotator cuff tears can restore shoulder function and prevent tear progression, but failure rates range from 0% to 78% [6]. Recent advances in the development of biological adjuvants such as platelet-rich plasma (PRP) and stem cells, which are utilised to relieve symptoms and increase the regeneration of torn rotator cuff tendons [7, 8]. Bone marrow mesenchymal stem cells and Bone marrow aspirate concentrate (BMAC) are ortho-biologic therapies considered an alternative to the current therapies for muscle, tendon, bone and cartilage pathologies [9]. In order to enhance regenerative processes, various biomaterial formulations have been employed as carriers for PRP and BMAC. PRP has gained popularity in tendon pathologies and its ability to enhance healing has led to its increased use [10, 11]. In preclinical studies, platelet-rich plasma (PRP) and stem cells improve the regenerative potential of tendon stem cells and the regeneration of torn supraspinatus tendon. As a result, regenerative biological treatment will be beneficial in restoring shoulder function and preventing tear progression. Magnetic resonance imaging (MRI) is the imaging modality of choice for determining the reduction of size in supraspinatus tear, because of its high accuracy and non-invasive nature [12]. The purpose of this study is to measure the reduction in tear size in supraspinatus partial thickness tears after Bone marrow aspirate concentrates (BMACs) and Platelets rich plasma (PRP) injections, as well as to evaluate the functional outcome before and after the BMACs and PRP injections.

Materials and Methods

This was a single centre randomised control trial of 30 patients with partial thickness tear of the supraspinatus tendon studied between May 1 2021 to May 31 2022 conducted at the Department of Orthopaedics, Saveetha medical college and Hospital, Thandalam, Chennai. This study was carried out after receiving approval from the institutional review board (IRB). Patients with symptomatic partial-thickness supraspinatus tendon tear who underwent conservative management for at least 3 months and were over the age of 18 were included in the study, whereas patients with complete supraspinatus tendon tear, previous history of steroid injection or shoulder surgery within 3 months, history of trauma to the affected shoulder, arthritis, glenohumeral joint infections, malignancy, and patient not willing to provide informed consent were excluded. All patients with symptomatic partial thickness tears of supraspinatus tendon, which was clinically diagnosed and thereafter an MRI study of the affected shoulder was interpreted by a radiologist for radiological diagnosis. All patients were presented at the outpatient department, and after admission, demographic data such as age, gender, and duration of symptoms were obtained and documented. Following informed consent, patients were randomly assigned to either the BMACs or PRP groups using computer-generated block randomization. Of the 30 patients, 15 were assigned to the plasma-rich platelets (PRP) group and 15 to the bone marrow aspirate concentrate (BMACs) group. All procedures were performed in an operating room. The injected substance was created once the assessor opened the envelope with information about the patient's group. All the injections were administered by a single well-trained surgeon under the guidance of ultrasound. Under strict aseptic precautions, the area to be injected was painted with beta-dine solution, patient was in modified crass position. The posterolateral technique was employed for all patients in both groups. All injections were guided by real-time ultrasonography using a 3 to 12 MHz linear array transducer covered with a sterile sleeve in plane method. For the PRP group, 15ml of peripheral blood was drawn from the left antecubital vein and centrifuged at 1,500 revolutions per minute for 5 minutes to extract the PRP, after which the freshly prepared leukocyte poor PRP was injected into the supraspinatus tear site with a 25-gauge needle under ultrasound guidance. For the BMACs group, the patient was made to lie prone for the extraction of BMACs. After palpating the iliac crest, the parts were painted with beta-dine solution and draped under strict aseptic precautions. 2% lignocaine was used to anaesthetize the skin and periosteum. The iliac crest was penetrated with a bone marrow aspiration needle, which was then advanced to the marrow site. The concentrated BMAC was isolated by aspirating bone marrow and centrifuging the aspirates. With ultrasound guidance, 2ml of bone marrow aspirate concentrate in a 5ml syringe was injected into the supraspinatus tear site. American Shoulder and elbow score (ASES) score and VAS score was calculated by one experienced surgeon who was blind to the group for all the patients before injection, 3 weeks, and 3 months post-injection. Supraspinatus tear size was assessed before injection, 3 weeks and 3 months later, using an ultrasound imaging equipped with a linear probe (3.0 to 12.0 MHz). The imaging of the supraspinatus tendon and muscle in modified crass position that exhibited the greatest longitudinal tear size (mm) along the long axis of the supraspinatus tendon and muscle was chosen. The torn area was defined as hypoechogenic or anechogenic with irregular margins, and the tear size was measured by greatest longitudinal tear length (mm) in several longitudinal sections of supraspinatus tendon. The statistical analysis was performed using IBM SPSS version 24.0. Armonk, NY: IBM Corp. Mann-Whitney U tests or unpaired t-tests were used to compare the difference in change of VAS score, ASES score and tear size between the groups. A P value of less than 0.05 were considered statistically significant.

Results

A total of 30 patients with partial thickness tears of the supraspinatus tendon were randomised into two groups and studied between May 1, 2021 and May 31, 2022. Group 1 received treatment with bone marrow aspirate concentrates (BMACs) injection, whereas group 2 received treatment with platelet-rich plasma (PRP) injection. In the BMAC group, the mean age of the patients was 52.6±7.3 years, whereas, in the PRP group, it was 52.6±5.4 years. In the BMAC group, there were 10 men and 5 women, whereas, in the PRP group, there were 8 men and 7 women, with the right side being more frequently affected in 18 patients. The mean ASES score for the BMAC group before administering the injection was 37.1±7.3 and for the PRP group, it was 35.6±6.1. The mean ASES score in the BMAC group increased from 37.1±7.3 (before injection) to 54.7±6.5 at three weeks, and 75.6±5.2 at three months. The mean ASES score in the PRP group increased from 35.6±6.1 (before injection) to 51.4±6.6 at 3 weeks, and 64.5±4.8 at 3 months (Figure 1). The change in the ASES score between the two groups at 3 months was differed significantly (P=0.01) but not at 3 weeks (P=0.71). The tear sizes before and after injections were tested to be normally distributed. In the BMAC group, the mean tear size

decreased from 5.7±1.4 (before injection) to 3.7±1.1 after 3 months, but in the PRP group, it changes from 6.3±1.3 (before injection) to 5.4±1.3 after 3 months (Figure 2). At 3 weeks, there was no significant difference in the change in tear size between the two groups, but at 3 months (1.75mm), there was a significant difference in the tear size reduction between the two groups. Difference in tear size from before injection to 3 months post-injection in BMAC and PRP was 2.0 and 0.9 respectively (Table 1). There were no complications seen in either group during the injection and the follow-up period. No patients were lost to follow-up in both the groups. (Table 2).

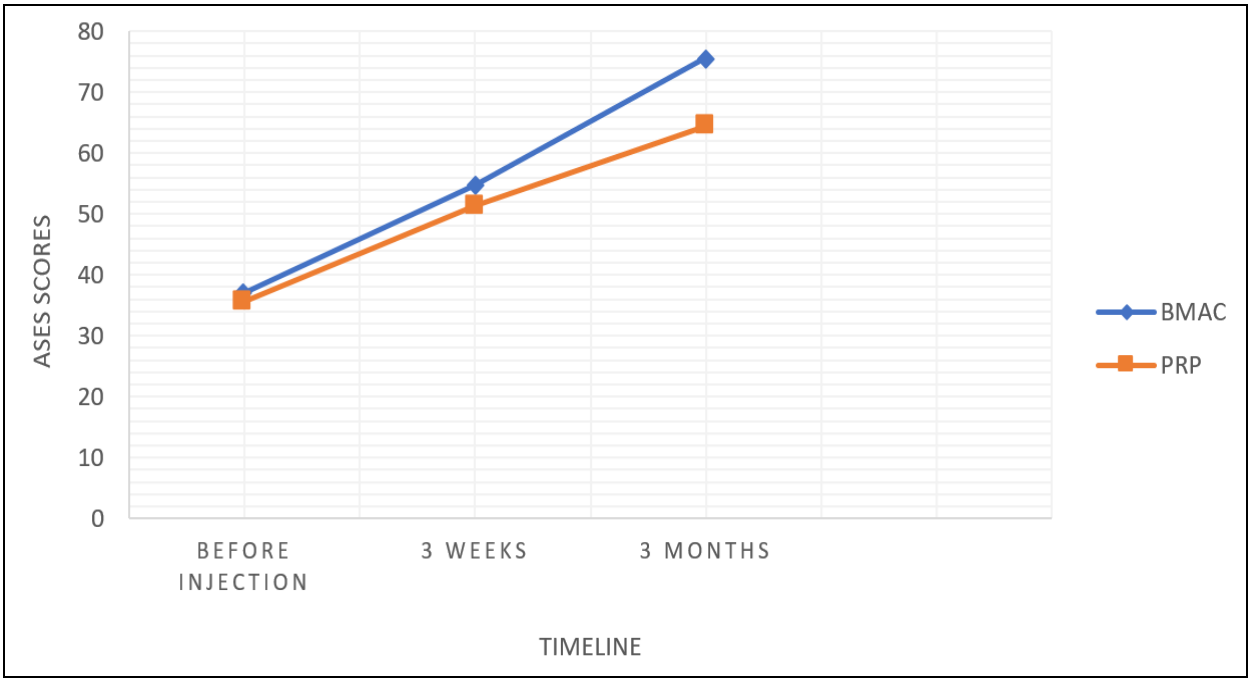

Fig 1: Mean ASES scores at before injection, 3 weeks and 3 months post-injection.

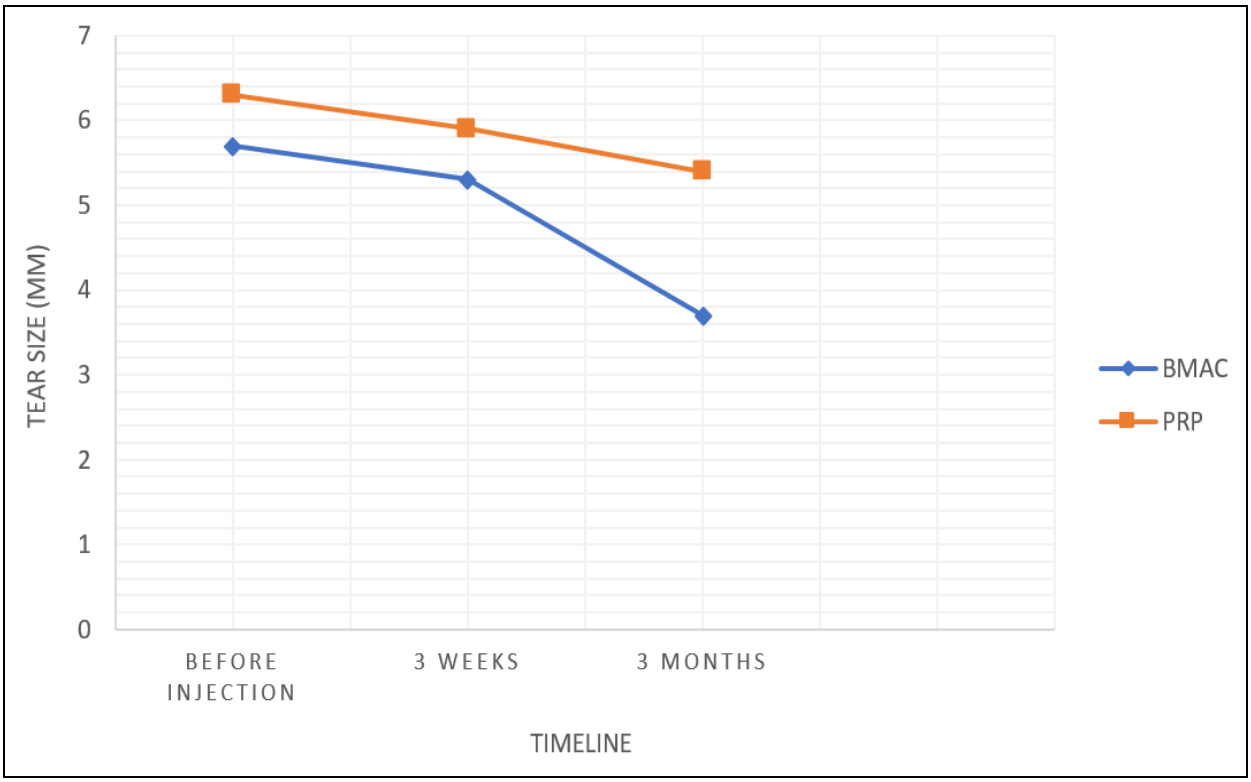

Fig 2: Changes in the tear size between BMAC and PRP groups are expressed as mean.

Table 1: Tear size of the two groups at baseline, 3 weeks and 3 months are expressed as mean with standard deviation

Tear Size (MM)	BMAC	PRP
Baseline	5.7 (1.49)	6.3 (1.38)
3 weeks	5.3 (1.46)	5.9 (1.38)
3 months	3.7 (1.16)	5.4 (1.32)
Tear size reduction	2.0	0.9

Table 2: Patient demographic details and data

S. No	Age	Sex	Side	Etiology	Treatment Given	Ases Score before injection	Ases score at 3 Weeks	Ases score at 3 Months	Tear size in mm before injections	Tear size reduction in mm at the end of 3 Weeks	Tear Size reduction in mm at the end of 3 Months
1.	45	M	L	TRAU	PRP	26	40	62	5.4 MM	4.9	4.3
2.	53	F	R	DEG	BMAC	37	54	76	5.1 MM	4.6	3.8
3.	49	M	R	TRAU	BMAC	33	52	78	4.3 MM	4.0	2.8
4.	63	M	R	DEG	PRP	29	41	60	7.2 MM	6.8	5.6
5.	58	F	R	DEG	PRP	33	49	61	4.5 MM	4.1	3.9
6.	44	M	L	DEG	BMAC	40	63	80	6.6 MM	6.1	4.9
7.	49	M	R	TRAU	PRP	39	59	65	4.6 MM	4.0	3.7
8.	58	F	L	DEG	BMAC	27	47	68	7.0 MM	6.6	5.7
9.	60	M	R	DEG	BMAC	43	55	78	4.3 MM	3.9	2.8
10.	57	F	L	DEG	PRP	49	60	75	5.9 MM	5.6	4.7
11.	48	F	R	TRAU	PRP	38	55	63	8.1 MM	7.8	7.2
12.	62	M	R	DEG	BMAC	42	59	79	5.0 MM	4.7	3.4
13.	55	M	L	TRAU	PRP	29	45	61	4.9 MM	4.5	4.3
14.	65	F	R	DEG	BMAC	21	43	65	4.5 MM	4.0	2.9
15.	48	M	L	DEG	BMAC	33	51	70	5.6 MM	5.2	3.1
16.	47	F	R	TRAU	PRP	33	51	69	7.8 MM	7.2	6.9
17.	58	M	L	DEG	BMAC	45	60	78	4.7 MM	4.1	2.7
18.	49	M	R	DEG	BMAC	38	55	76	5.1 MM	4.8	3.0
19	51	M	R	TRAU	PRP	36	53	59	6.8 MM	6.2	5.8
20.	43	F	L	TRAU	BMAC	41	59	80	4.5 MM	4.0	2.5
21.	59	M	R	DEG	PRP	39	51	64	7.4 MM	7.1	6.8
22.	44	M	L	TRAU	PRP	41	58	68	6.2 MM	5.8	5.4
23.	49	F	L	DEG	BMAC	28	43	68	5.1 MM	4.7	3.2
24.	55	F	R	DEG	PRP	37	54	70	6.8 MM	6.1	5.9
25.	61	M	R	DEG	BMAC	41	60	78	7.2 MM	6.7	5.1
26.	52	F	L	TRAU	PRP	29	44	59	5.9 MM	5.3	4.9
27.	46	M	R	TRAU	BMAC	40	56	79	9.1 MM	8.6	5.8
28.	54	F	R	DEG	PRP	33	51	62	5.2 MM	4.6	4.3
29.	45	M	L	TRAU	BMAC	48	64	82	8.1 MM	7.5	4.9
30.	53	M	R	DEG	PRP	43	60	71	9.2 MM	8.6	8.1

Discussion

Rotator cuff tears are a common shoulder problem, affecting around 21% of the general population. Although the pathogenesis of rotator cuff tears is unknown, it is a complex condition caused by age-related degeneration, oxidative stress, and vascular changes. Risk factors include traumatic injury, degenerative changes, repetitive impingement, genetic susceptibility and smoking [1-4]. Platelet-rich plasma (PRP) and bone marrow aspirate concentrate (BMAC) are ortho-biologic therapies considered an alternative to the current therapies for muscle, tendon, bone and cartilage pathologies. In order to enhance regenerative processes, various biomaterial formulations have been employed as carriers for PRP and BMAC.

When compared to PRP, the use of BMAC in the orthopaedic field is still relatively new, but the results are very promising. BMAC is made up of both progenitor cells and a vast number of growth factors [13, 14]. This combination makes BMAC a potent therapy. However, obtaining BMAC is invasive, needs closed systems during preparation, and positive results are substantially connected with the amount of stem cells.

In our study, BMAC injection was associated with higher ASES scores 3 months after injection as compared to the PRP group. The ASES scores did not differ considerably between the BMAC and PRP groups at three weeks, but they did at three months.

Ellera Gomes, *et al*. described a case series in which 14 patients (nine women and five men) with full-thickness rotator cuff tears were treated with trans osseous stitches enhanced with BMAC using a mini-open approach. All patients were followed for at least a year. Magnetic resonance imaging (MRI) scans were performed one year after surgery to determine tendon integrity. They found a considerable improvement in the University of California Los Angeles (UCLA) score at 12 months post-surgery, from 12±3.0 to 31±3.2. Tendon integrity was preserved in all cases, although six patients (42%) formed a high-signal intensity at the crucial zone. At the two-year follow-up, one revision was recorded. Authors found that BMAC could be safely implanted as a rotator cuff augment [15].

In 45 patients, Hernigou, *et al*. assessed the efficacy of BMAC in augmenting arthroscopic single-row rotator cuff repair. Their major goal was to compare tendon healing in the BMAC group to that of a matched control group of 45 patients who did not have BMAC augmentation. They discovered that patients treated with BMAC had better outcomes in terms of tendon healing rate and enhance repaired tendon quality, as measured by ultrasonography and MRI. By six months, 45 shoulders (100%) in the BMAC group had demonstrated tendon healing, compared to only 30 shoulders (67%) in the control group. Furthermore, at the most recent 10-year follow-up, the integrity of the repair was preserved in 39 (87%) of the BMAC group's shoulders compared to only 20 (44%) of the control group's shoulders. This study found that employing BMAC as an adjuvant to rotator cuff repair improved healing outcomes significantly. The authors observed no adverse outcomes of BMAC therapy after surgery [16].

Shams A, *et al*. studied sub-acromial injection of platelet-rich plasma (PRP) versus corticosteroid injection therapy in 40 patients with symptomatic partial rotator cuff tears in 2016 and discovered that sub-acromial autologous PRP injection significantly improves pain and ASES scores at 12 weeks but not at 6 weeks. The precise cause of the impact of PRP on

pain and function at 12 weeks is uncertain [17].

However, Geburek, *et al*. after clinical and ultrasonographic examination, studied twenty horses with naturally occurring tendinopathies of the forelimb superficial digital flexor tendon were randomly assigned to the PRP-treated group (n = 10) or the control group (N=10) and found that lameness of the tendon in tendinopathy began to decrease 8 weeks after PRP injection and higher performance occurred at 24 weeks, indicating that at least 8 weeks may be required to show functional improvements with PRP [18]. We also discovered that increasing ASES scores enhanced shoulder function in the BMAC group after 3 months. Several studies have found that BMAC and PRP improve the function of repaired rotator cuff tendons, which is consistent with our findings.

In our study, the BMAC group had a significant reduction in tear size compared to the PRP group on ultrasound imaging in the Modified crass position. Only a few research have looked at the size of tears following injection.

Niazi, *et al*. studied 30 patients with rotator cuff tendinopathy in 2020 and performed ultrasound-guided PRP injections. Patients were evaluated clinically using the SPADI scoring system and radiologically using ultrasonographic supraspinatus tendon thickness measurements at 4, 8, 12, and 24 weeks. The study discovered a statistically significant decrease in tendon thickness after 24 weeks (P value-0.043) [19].

Cai, *et al*. studied 184 patients who had partial-thickness rotator cuff tears that were detected through clinical examination and magnetic resonance imaging (MRI). Using MRI, they calculated the change in anteroposterior tear size between pre-treatment and 12 months following injection to determine the degree of healing. At 12 months, healing following PRP injection revealed a decreased tear size of 2.89 mm anteroposteriorly [20]. We believe that the BMAC injection approach was responsible for the considerable reduction in tear size seen in the current study.

The injected PRP, which resulted in a decreased tear size, could have been the result of inflammation, which aided in tendon repair. Hudgens, *et al*. conducted a controlled laboratory study in 2016, in which tendon fibroblasts or macrophages from rats were cultivated and treated with either platelet-poor plasma (PPP) or PRP and reported that tendon fibroblasts with PRP activated the cellular TNF-α and NF-κB signalling pathways. This resulted in a brief inflammatory response, which may have triggered the tissue regeneration response [21].

BMAC or PRP injection had no side effects or complications in our study. The pain associated with the bone marrow aspiration technique was not severe enough to end the research, and all patients in the BMAC group were satisfied with the BMAC injection. We were unable to conduct a double-blind study because bone marrow aspiration is an invasive procedure, and we could not discard BMAC after extracting it from patients for the sole purpose of blinding the PRP group due to ethical concerns. Although the sample size was computed based on the statistical method, the sample size in our study was 15 in each group, which was relatively small for a comparison study.

Conclusion

In this study, we observed that bone marrow aspirate concentrates (BMACs) injection in partial thickness supraspinatus tendon tears reduced the tear size, however, intralesional PRP injection had no significant effect on tear size. When compared to the baseline, both BMAC and PRP injections improved functional outcomes. However, BMAC injection resulted in better improvement at three months after injection.

Declarations

Funding

None

Conflicts of Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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