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Effectiveness of Ultrasound-Guided Platelet-Rich Plasma Injection in Comparison with Standard Conservative Treatment on Improving Pain and Function Among the Athletes with Partial Tear of Anterior Talofibular Ligament of Ankle: A Randomized Controlled Trial

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ABSTRACT

Background: Ankle sprain is the most common injury in the world of sports and anterior talofibular ligament (ATFL) is most commonly affected. It is often underestimated, mismanaged and often result in delayed treatment, prolonged recovery times and long-term sequela. PRP may have enhancing effect on healing of partial tear of ATFL. Thus, the purpose of this study is to determine the role of PRP on partial tear of ATFL.

Methods: A randomized controlled trail was done among athletes with partial tear of ATFL who visited Department of Sports Medicine, RIMS, Imphal during January 2021 – June 2022. Patients with MRI diagnosed partial tear of ATFL (N=48) randomized into PRP injection plus rehabilitation, (n=24) and rehabilitation alone, (n=24) groups. The outcomes were compared using Foot and Ankle Disability Index (FADI) score for function and Visual analogue scale for pain at baseline, 2nd, 6th, 12th and 24th weeks respectively.

Results: Baseline characteristics were not statistically significant. There was statistically significant improvement seen in within the group comparison from baseline to 2nd, 6th, 12th and 24th weeks in both FADI and VAS in both the groups. There were statistically significant difference in mean changes of VAS and FADI score between the two groups from baseline to 2nd (p=0.007);(p=0.012), 6th (p=0.018);(p=0.009) and 12th (p=0.004); (p=0.001) follow-ups respectively with PRP group having more improvement however no significant difference at 24th weeks.

Conclusion: Ultrasound guided PRP injection along with standard rehabilitation program might be a treatment of choice for partial ATFL tear.

Keywords: ATFL tear, PRP, FADI, VAS, USG-guided.

INTRODUCTION

Ankle is the most commonly affected joint in the world of sports and its injuries accounts for 10% to 30% of all injuries.[1,2,3] Among all ankle injuries, ankle sprains are the most common accounting for approximately 80% of which 77% are lateral ankle sprains.[4,5,6,7] 73% of lateral ankle sprains are due to rupture or tear of the anterior talofibular ligament (ATFL) and ATFL is the weakest ligament in the lateral collateral complex of the ankle.[1,6] Its main function is to resist inversion and plantarflexion.[6,8] Mechanically, ATFL is injured due to forced supination in plantarflexion movement.[9] It is commonly seen in sports where there is involvement of frequent jumping, running, pivoting, sudden stopping, acceleration and lunging movement like in football, field hockey, basketball tennis, badminton, ballet/dance etc.[2,6,10]

The symptoms of ATFL injury includes pain, swelling, weakness and instability of ankle joint and typically results in a temporary period of reduced functioning and disability.[5,8] It has numerous sequelae that contribute to a substantial healthcare burden from the indirect cost of follow up care, loss of productivity, time loss of activity and care of its long-term consequences.[4,5] It has been reported that up to 70% of individuals with history of ankle sprain have some type of residual and chronic symptoms like chronic pain, recurrent swelling, recurrent ankle sprains and perceived instability.[4,6] Compounding the high percentage of the population that reports a history of lateral ankle sprain, is evidence of early onset post-traumatic osteoarthritis of the ankle; along with decreases in physical activity levels and health-related quality of life.[5] Physical examination for ATFL injury is ankle anterior drawer test. It helps to identify excessive anterior displacement of the talus on the tibia. Ultrasound can be a valuable instrument for ATFL injury, but it is operator-dependent.[8] Ruptures of lateral ligaments of the ankle can be diagnosed on MRI with a sensitivity of 75–100%.[11]

Most of the patients with acute isolated ATFL injury can be treated conservatively. The managements include protection, rest, ice packing, compression, and elevation for the first 3 days. Thereafter, functional rehabilitation program should be started as soon as possible.[4,8]

Rehabilitation programs should be structured and individualized. In the acute phase, the focus should be on controlling inflammation, re-establishing full range of motion and gaining strength. Once the athlete achieves a pain-free range of motion and weight-bearing, balance-training exercises should be included to regulate neuromuscular control. Advanced-phase rehabilitation exercises should focus on regaining normal function. These should include sports-specific exercises specific to the particular sport played by the athlete.[2] Although the initial line of management remains a functional rehabilitation, surgery should be considered if the symptoms persist.[2] A previous study revealed that patients who underwent acute surgical treatment took longer to return to work. Also, studies revealed that surgery was not helpful in reducing additional complications, costs and risks.[1]

Lateral ankle sprain (LAS) are often underestimated and mismanaged and often result in delayed treatment, prolonged recovery times and long-term sequela.[6] The negative consequences of LAS are concerning and improved efforts to address these conditions is essential.[4] Continued research is needed to determine the optimal treatment of LAS with ultimate goal to improve global musculoskeletal health, to encourage return to activity levels and to lessen the chance for reinjury. It is believed that timely intervention and early restoration of biomechanical deficits will be the optimal treatment of LAS and prevention of chronic

ankle instability (CAI) and post-traumatic osteoarthritis (PTOA).[5,12]

Some studies supported PRP injection for ATFL injury as an alternative non-surgical treatment option with the potential to prevent the development of chronic ankle instability and post-traumatic ankle osteoarthritis.[8] Case series have shown the beneficial effect on the partial thickness rotator cuff tear.[13] Randomized controlled trial has demonstrated positive effect of PRP on patella tendinopathy and the strongest level one evidence of PRP is found in the management of refractory tennis elbow with long term pain reduction and functional improvement.[14,15] A systematic review (SR) conducted in 2014 evaluated the role of PRP in different foot and ankle pathologies; however, all the seventeen included studies did not include LAS as the pathology for treatment.[16]

Platelet rich plasma is the superfluous concentration of platelet in plasma. Platelets contain alpha granules that is rich in various growth factors like vascular endothelial growth factors (VEGF), epidermal growth factors (EGF), platelet derived growth factors (PDGF), insulin like growth factor (IGF), transforming growth factor (TGF), interleukin (IL) and chemokines, cytokines which helps in healing of injured tissue by enhancing healing by stimulating cell proliferation, migration and differentiation, alongside interaction with the immune system, inflammation, and angiogenesis.[17] PRP injection helps in creating a biological environment internally that is most conducive for restoration of injured tissue by providing numerous signaling cytokines and growth factors that are important in repair of the damaged tissue.[7] Ultrasonic guidance injection can be a valid tool to perform a procedure with a proper selection of injection site, to increase the efficacy and reduce complications of blind injection.

We also suggest the possible beneficial effect of PRP in regaining ligamentous strength, reducing ligament laxity and achieving early ankle stability, which are essential elements in the management of LAS and which will ultimately allow the athletes for sooner returning to their sports activities and preventing risk of reinjury.[4]

Despite its popularity, little was understood about PRP research's significance in LAS treatment. There are very less studies determining the role and effectiveness of PRP injection in the treatment of ATFL injury. Therefore, a randomized controlled trial is conducted to determine the effectiveness of ultrasound guided platelet rich plasma injection in comparison with standard conservative management among athletes with anterior talofibular ligament injury of ankle.

MATERIALS AND METHOD

A randomized controlled trial was done among athletes with partial tear of ATFL of ankle who visited Department of Sports Medicine, RIMS, Imphal during January 2021-June 2022. Patients with lateral ankle pain were clinically examined and sent for MRI. Partial tear of ATFL in MRI is the partial discontinuity of ATFL reaching up to the surface but not involving the entire thickness of ligament.[18]

Inclusion criteria: Patient of age between 18 to 35 years, with history of lateral ankle pain within 1 month duration, MRI diagnosed partial ATFL tear.

Exclusion criteria: MRI diagnosed other associated ligamentous injuries of ankle, any associated fracture around the ankle, patients who received corticosteroid injection within last 12 weeks, history of platelet dysfunction syndromes, malignancy, thrombocytopenia.

A sample size of 48 was calculated using formula

$N=(Z\alpha + Z\beta)^2(S1^2+S2^2)/(m1-m2)^2$

According to a study conducted by Dhaundiyal S et al[17] considering 90% power, and 5% level of significance and 10% for drop outs to counter attrition bias.

Outcome measures:

Pain measured by Visual analogue scale, function measured by Foot and Ankle Disability Index (FADI) Score.

Patient who met inclusion and exclusion criteria and gave consent for participation in the study were randomized (N=48) into PRP injection plus rehabilitation, (n=24) and rehabilitation alone (n=24) groups by block randomization technique. After taking informed consent, all subjects were evaluated for FADI score and VAS at baseline before starting any intervention. And after starting the interventions, at the end of 2^{nd}, 6^{th}, 12^{th} and 24^{th} weeks, patients were evaluated with FADI score and VAS.

Interventions:

Study group: PRP injection plus rehabilitation

PRP was prepared using Double spin method. 18ml whole blood was drawn under proper aseptic and antiseptic precautions, and put in 2 vials containing acid citrate dextrose anticoagulant. The two vials were centrifuged at 2400 revolutions per minute for 10 minutes. The clear supernatant fluid was taken out using a 20-gauge spinal needle and put in plain vials and centrifuged again at 3600 rpm for 15 minutes. The lower $1/3^{rd}$ is PRP and upper $2/3^{rd}$ is platelet-poor plasma (PPP). 2 ml of PRP was procured by removing the PPP.

The patient was in supine position with knee flexed in 45 degrees and foot was planted on the couch and slightly internally rotated. Sterile skin preparation was done. 2ml of PRP as given into the ligament under ultrasound guidance using in-plane technique.

After the injections, patients were asked to withdraw from using any non-steroidal anti-inflammatory drugs (NSAID). Patients were instructed to take affected ankle rest for the next 2 days. Acetaminophen and cold therapy were allowed for pain control.

Control group: Rehabilitation alone

Rehabilitation programs should be structured, individualized and re-evaluated throughout the program. It consists of three phases: acute phase, sub-acute phase and maturation phase.

Acute phase:

Goals:

- Protection of the area from further injury, encourage tissue healing, limit pain, swelling, spasm, maintain function of non-injured tissues, maintain overall body conditioning

Methods:

- Rest, protection with brace, crutch as needed, cryotherapy, compression, ankle pumps, pain free range of motion (ROM), partial or full weight bearing as tolerated, stationary bike, trunk and upper body exercises

Sub-acute phase:

Goals:

- Prevent further injury, promote tissue healing, minimize pain and inflammation, restore ROM and flexibility, re-establish neuromuscular control and restore muscular strength and endurance, re-establish proprioception, agility and coordination, maintain overall body conditioning

Methods:

- Continue bracing, joint mobilizations, progress with pain-free ROM, heel cord stretches, isometric strengthening exercises, progressing to isotonic strengthening exercises with elastic bands, PNF patterns, heel raises, toe raises, squats and lunges, progress from static stances to dynamic activities and with perturbations, gradually introduce functional activities in later weeks

Maturation phase:
Goals:

- Prevent re-injury, restore ROM and flexibility, improve muscular strength, endurance, and power, improve proprioception, agility, and coordination, improve functional (sport-specific) skills, maintain overall body conditioning

Methods:

- Continue bracing, more aggressive stretching, isotonic exercises, PNF, closed kinetic chain exercises, plyometrics, functional exercises like jumping, running, changes of direction, dynamic exercises, stances with perturbation, jumping rope, side-to-side hops, shuttle runs, forward running, backward running, lateral shuffles, carioca, figure of eight running, cutting, hopping, return to sport/activity drills, upper body and trunk conditioning exercises

The goal of the rehabilitation program should be to return the patient to full sports activities. The criteria for returning to sports are

- Ankle should have full, pain free functional ROM
- Ankle should have full, functional muscle strength, endurance, and power
- Patient should have adequate proprioception, balance, agility, and coordination to safely and effectively participate in the activity
- Patient should be psychologically ready to return to activity

Informed Consent and Ethics Approval:
All the participants were informed about the nature of the study and those who agreed to participate were asked to sign the informed consent form. Participants were assured that they could withdraw from the study at any time. The study was approved by Institutional Ethics Committee.

STATISTICAL ANALYSIS

Data were entered and analyzed by using SPSS version 21. The baseline characteristics between the PRP plus rehabilitation group and rehabilitation alone group were studied by chi-square test for categorical variables and independent t-test was used for continuous variables. For descriptive statistics, mean and standard deviation were used. For outcome measures, the mean changes from baseline to 2^{nd}, 6^{th}, 12^{th} and 24^{th} weeks follow-ups for each group were compared by repeated measure ANOVA test followed by post hoc analysis (Bonferroni). For comparison between the groups, independent t- test was used. p-value < 0.05 was taken as significant.

RESULT

The baseline characteristics of the patients in intervention and control groups were not statistically significant. (Table 1) Outcome measures at baseline were not statistically significant. (Table 1) There was statistically significant improvement seen in within the group comparison from baseline to 2^{nd}, 6^{th}, 12^{th} and 24^{th} weeks in both FADI and VAS in both the groups. (Table 2) There was statistically significant difference in both mean changes of FADI ($p=0.012$) and VAS ($p=0.007$) from baseline to 2^{nd} week in between the groups with more improvement is seen in PRP plus rehabilitation group. At the end of 6^{th} and 12^{th} weeks, there was also statistically significant difference in both mean changes of FADI score and VAS from baseline to 6^{th} and 12^{th} weeks in between the groups with more improvement in PRP plus rehabilitation group however no significant difference at 24^{th} week. (Table 3)

Table 1: Comparison of baseline characteristics between the groups, (N=48)

Baseline Characteristics	PRP + Rehabilitation (n=24) (Mean±SD)	Rehabilitation(n=24) (Mean±SD)	p-value
Age 18-25 26-35	 14(58.3%) 10(41.7%)	 13(54.2%) 11(45.8%)	0.500*
Gender Male Female	 11(45.8%) 13(54.2%)	 10(41.7%) 14(58.3%)	0.500*
BMI 18.5-<20.5 20.5-<22.5 22.5-24.5	 5(20.8%) 7(29.2%) 12(50.0%)	 6(25.0%) 7(29.2%) 11(45.8%)	0.935*
Side of affection Right Left	 15(62.5%) 9(37.5%)	 14(58.3%) 10(41.7%)	0.500*
Type of Sports Soccer Badminton Hockey Judo Basketball Sprinter Volleyball	 10(41.7%) 5(20.8%) 2(8.3%) 3(12.5%) 2(8.3%) 1(4.2%) 1(4.2%)	 10(41.7%) 6(25.0%) 2(8.3%) 2(8.3%) 2(8.3%) 1(4.2%) 1(4.2%)	1.000*
VAS	8.67±0.51	8.65±0.66	0.886#
FADI	76.33±1.52	76.08±1.50	0.570#

***chi-square test #Independent t-test p-value<0.05 is taken as significant**

Table 2: Within the group comparison of outcome measures in both groups

	Group	Baseline	2nd week	6th week	12th week	24th week	p-value*
VAS	PRP + Rehabilitation	8.67±0.51	6.25±0.23	4.47±0.40	3.15±0.23	2.02±0.29	0.00
	Rehabilitation	8.65±0.66	7.00±0.51	5.31±0.60	3.72±0.50	2.38±0.34	0.00
FADI	PRP + Rehabilitation	76.0±1.50	96.6±2.66	111.6±4.60	120.7±2.91	125.9±1.92	0.00
	Rehabilitation	76.3±1.52	93.8±4.64	108.2±3.94	117.2±3.21	125.1±2.32	0.00

***Independent t-test p-value<0.05 is taken as significant**

Table 3: Comparison of mean changes of VAS and FADI score between the two groups from baseline to 2nd, 6th, 12th and 24th weeks follow up, (N=48).

	Mean changes from base line		
VAS score	**PRP + Rehabilitation (n=24) (Mean ± SD)**	**Rehabilitation (n=24) (Mean ± SD)**	**p-value***
2nd week	-2.22±0.58	-1.64±0.82	0.007
6th week	-3.90±0.70	-3.33±0.86	0.018
12th week	-5.51±0.50	-4.92±0.81	0.004
24th week	-6.65±0.70	-6.26±0.73	0.065
FADI score	**PRP + Rehabilitation (n=24) (Mean ± SD)**	**Rehabilitation (n=24) (Mean ± SD)**	**p-value***
2nd week	20.54±3.00	17.50±4.83	0.012
6th week	35.54±5.02	31.87±4.18	0.009
12th week	44.70±3.16	40.95±3.62	0.001
24th week	49.87±2.23	48.79±2.26	0.102

***Independent t-test p-value<0.05 is taken as significant**

DISCUSSION

In our study, we gave PRP injection into the torn region of ATFL under ultrasound guidance which was followed by functional rehabilitation program and in the control group, patients received the same rehabilitation program. There was significant difference in the mean changes from baseline to 2nd, 6th and 12th weeks follow-ups in between the two groups with more improvement was seen in the PRP plus rehabilitation group.

ATFL is the most common ligament of ankle to be injured in sports as well as in general population with often underestimated and mismanaged and result prolonged recovery times, long-term sequela and 70% of them re-injured.

Conservative management and early functional rehabilitation remain to be the standard of care for all grades of ATFL sprain. However, the negative consequences of ATFL are concerning, and improved efforts to address these conditions is essential.

Lai MWW et al[4] reported a case of LAS with complete tear of ATFL which showed complete healing of ligament and early ankle stabilization after PRP. The healing is supported by dynamic ultrasound images and magnetic resonance imaging. They proposed that PRP might serve as an alternative non-surgical treatment option in LAS in future research, with the potential to prevent the development of CAI and PTOA. Zhang J et al[19] concluded that PRP injection helped relieve early symptoms of LAS, although all patients saw a similar development after 6 months. Naidu A et al[7] conducted a study and gave single dose of PRP along with walking cast application in acute ankle sprains and showed improvement in VAS, FADI and AOFAS score at 6 months. Dhaundiyal S et al[17] concluded that addition of PRP to the conservative treatment has a definite benefit in the management of ATFL tear and conservative treatment in addition to PRP for ATFL tear results in early relief in symptoms and ankle function started at 4 weeks as tested by FADI scale. In long term follow-up, more outcome measures were improved and much significant difference obtained in two groups.

Because of the rising prevalence of ATFL damage, there is a considerable interest in developing innovative techniques to improve the biological healing response of ATFL.[19] In our study, we have found that both PRP plus rehabilitation and rehabilitation alone groups provided significant improvement in subsequent follow ups. However, more statistically significant improvements were seen in PRP plus rehabilitation group when comparing with Rehabilitation alone. At the end of 24th weeks, there was no significant difference between the groups however better improvement is seen in PRP plus rehabilitation group.

The utilization of PRP for the treatment of musculoskeletal conditions has become more prevalent in recent years. PRP treatment helps to create a biological environment internally that is very conducive for restoration of injured tissue by providing numerous signaling cytokines and growth factors that are important in repair of the damaged tissue by diverse mechanisms including the regulation of inflammation angiogenesis and remodeling of new tissue.[7] Healing process starts with platelet aggregation and clot formation and forms a scaffold, which acts as a temporary matrix for cell growth and differentiation. Platelets actively secrete pre-synthesized growth factors (GF) and synthesize more GFs for several days during their life span.

Our report suggested that PRP not only allows healing of the torn ligament, but also hastens its strength recovery. We believed that together with appropriate rehabilitation training, PRP may enhance early ankle stabilization in LAS, prevent the development of CAI and PTOA; it may also serve as an alternative non-surgical treatment option in the management of high-grade LAS not responding to conservative therapy.

Limitation of the study:

The study could have been more reproducible if done with bigger sample size and longer follow ups.

CONCLUSION

Platelet-rich plasma is a less invasive and safe procedure due to its autologous nature. Injection under ultrasound guidance gives the injection at exact location and probably gives better outcomes. We believe that PRP injection should be considered as a better alternative for the treatment of partial tear of ATLF for early ankle stabilization, faster and safe return to sports and prevention of chronic ankle instabilities.

Declaration by Authors

Ethical Approval: The study was approved by the Institutional Ethics Committee.

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