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Evaluation of platelet-rich plasma (PRP) in the treatment of rotator cuff tendinopathy

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Abstract
Background: Rotator cuff tendinopathy is a common cause of shoulder pain and functional deficit. Platelet-rich plasma (PRP) has emerged as a potential non-surgical treatment option due to its ability to promote healing and improve blood flow to the affected area. This study aimed to evaluate the effectiveness of PRP in reducing pain and improving shoulder function in patients with rotator cuff tendinopathy.
Methods: A total of 30 patients with rotator cuff tendinopathy, who had failed conservative treatments, were enrolled in the study. They received a single subacromial injection of PRP and underwent a standardized rehabilitation protocol. Pain levels were assessed using the Visual Analog Scale (VAS), and functional outcomes were measured using the Disabilities of the Arm, Shoulder, and Hand (dash) score. Data were collected at baseline and after 8 and 12 weeks.
Results: Following PRP treatment, there was a significant reduction in resting pain levels, with the mean VAS score decreasing from 7.0 to 2.6 at 12 weeks. Functional improvement was also observed, as indicated by a decrease in the mean DASH score from 52.3 to 19.4 at 12 weeks. No major adverse events were reported, with only minor localized pain at the injection site being the most common side effect.
Conclusion: PRP injection combined with a standardized rehabilitation protocol resulted in significant pain reduction and functional improvement in patients with rotator cuff tendinopathy. This study supports the use of PRP as a non-surgical treatment option for this condition, providing pain relief and potentially avoiding the need for surgery.

Keywords: Platelet-rich plasma (PRP), rotator cuff tendinopathy, dash score, vas score

Introduction
Shoulder pain is one of the most common complaints in the orthopaedic outpatient department. Chronic shoulder pain and weakness are common reasons for individuals to seek medical attention, with a high occurrence rate of approximately 15% in men and 25% in women [1-3]. Moreover, the prevalence of shoulder pain tends to increase significantly in the population aged 50 years1 and above, leading to heightened levels of pain and severity. Among shoulder pathologies, rotator cuff tendinopathy is a common cause of shoulder pain and functional deficit. Rotator cuff tendinopathies are believed to be the most common cause of shoulder pain syndromes with one cross-sectional study reporting that 86% of all clinical diagnoses of shoulder pain were that of rotator cuff lesions. Rotator cuff injuries afflict patient populations in an age-dependent fashion. Rotator cuff tendinopathy accounts for about 86% of all clinical diagnoses of shoulder pain according to a cross-sectional study [4, 5].
Rotator cuff tendonitis refers to the inflammation of the tendons composing the rotator cuff, namely the supraspinatus, infraspinatus, teres minor, and subscapularis. This condition frequently coexists with shoulder impingement and can manifest suddenly after an injury or due to prolonged, repetitive activities that strain the shoulder. Injuries to the rotator cuff (RC) range from simple contusions and tendonitis to chronic tendinopathy, partial tears, and full-thickness tears. The etiopathology of rotator cuff tendinopathy is multifactorial, a combination of intrinsic factors (degeneration from overuse) and extrinsic factors (compression from anatomic structures) are implicated to cause inflammation and subsequent degeneration of the rotator cuff.

Patients often present with shoulder pain night pain, painful arc, and reduced movements (esp. External rotation and overhead elevation). Diagnosis can be made with shoulder MRI and ultrasound.

Treatment options for Rotator cuff tendinopathy vary from conservative, including physical therapy, to more invasive procedures such as shoulder injections and surgery. In the early inflammatory phase anti-inflammatory agents, rehabilitation exercise programs and electrotherapeutic modalities are often used for symptom control. Despite the availability of numerous treatment options, managing chronic tendinopathies remains challenging. Once the tendon is weakened, its biological and biomechanical properties are never fully restored. Chronic tendinopathies tend to have prolonged healing times due to the relatively low vascularity of tendons and reduced local blood flow to the muscles. As a result, platelet-rich plasma (PRP) and prolotherapy have emerged as recent treatment alternatives for rotator cuff tendinopathy [7, 8]. PRP can release biologically active proteins that facilitate cell recruitment, development and morphogenesis. Tendinopathy is characterized by a decrease in stem cell numbers, a disorganized matrix, and hypo-perfusion. PRP promotes healing by increasing the number of stem cells, improving the matrix, and increasing blood flow to the affected area. [8]. This study's objectives are to evaluate the effectiveness of PRP as a non-surgical treatment for rotator cuff tendinopathy and to assess its effectiveness in reducing pain and improving shoulder function.

Methods and Materials

The study protocol was approved by the Institutional Review Board. Participants were enrolled and followed from April 2021 to April 2022. Adult persons aged 18 to 70 years were recruited from the orthopaedic outpatient department. Inclusion criteria were a clinical diagnosis of RCT with symptoms for 3 months or more, failed conservative treatment of at least 4 weeks of formal physical therapy (including rotator cuff strengthening and scapular and proprioceptive stabilization), at least one corticosteroid injection, shoulder x-ray to rule out adhesive capsulitis, and magnetic resonance imaging (MRI) study indicating RCT but no significant acromioclavicular joint impingement, retracted tears, significant labral lesions, or significant glen humeral arthrosis. Exclusion criteria included joint instability defined by positive apprehension and relocation test, pregnancy, immune system compromise, significant upper extremity comorbidity, anticoagulation therapy, history of shoulder surgery, and corticosteroid injection within 3 months. Patients could have both shoulders injected if both shoulders met the criteria. The primary outcome measure for all participants was a score on a 0-10 visual analogue scale (vas) assessing current resting pain at baseline and at 8 & 12 weeks. The VAS is widely used in clinical medicine and as a research tool. Its utility as an outcome measure in chronic pain has been formally assessed. DASH score was also used in assessing the functional outcome at 8 &12 weeks. It is a self-reported questionnaire of 30 items, scoring 0 (no disability) to 100.

PRP Preparation:

Extraction of 40 mL of peripheral blood was performed using a 20-gauge needle for a Vacutainer holder system. It was placed in 8 tubes with 6 mL EDTA serum. Two of them were used to perform serology, haematology control, and immunohemato logical donor/patient, and the remaining 6 tubes, for a total of 30 mL of blood (5 mL blood per tube) with 6 mL EDTA (1 mL per tube), were devoted to obtaining PRP. We utilized a 2-spin protocol. First, the blood was centrifuged for 3 minutes at 1,400 rpm. The product obtained was separated using a laminar flow cabinet, where the buffy coat was obtained with the plasma and referred to a dry 10 ml tube, which was again centrifuged for 4 minutes at 3,000 rpm to achieve greater product concentration to yield 5 mL PRP. Process quality control was performed on the baseline blood and on the final PRP product through a haematology analyser (ROCHE XT) before the application of PRP.

PRP Injection

The injections were administered in the subacromial region. In the sitting position, the area to be injected was disinfected under strict aseptic precautions. A posterolateral approach was employed for all patients. The point of injection was a soft spot situated 1 to 2 cm distal and 1 cm medial to the posterolateral corner of the acromion (acromial angle) with the needle directed anteriorly, medially, and slightly superiorly for a depth of 3 to 4 cm directed anteriorly toward the coracoid process After injection, all patients were allowed to move their shoulders. All patients received a single subacromial injection of 5 mL PRP.

All patients were subjected to the same standardized rehabilitation protocol supervised by a physical therapist 2 times per week until the end of treatment. The rehabilitation protocol consisted of 3 phases: Passive pendulum and mild shoulder range of motion (ROM) exercises (phase 1), active assisted shoulder ROM exercises (phase 2), and resisted shoulder motion exercises (phase 3). Progression from 1 phase to another depended mainly on pain and ROM improvement. The exercises performed in the therapist's practice were complemented with a supervised home rehabilitation program that was explained to each patient at the first visit. Patients were advised to avoid sports activities for 4 weeks. Nonsteroidal anti-inflammatory drugs are encouraged.

All the follow-up data and scoring were documented in patient case records. The data were analysed using SPSS Version 22 statistical software and a P value of less than 0.05 was considered to be statistically significant.

Table 1: outcome scores

	VAS Score	DASH Score
Before PRP	7	52.3
After PRP by 12 weeks	2.6	19.4

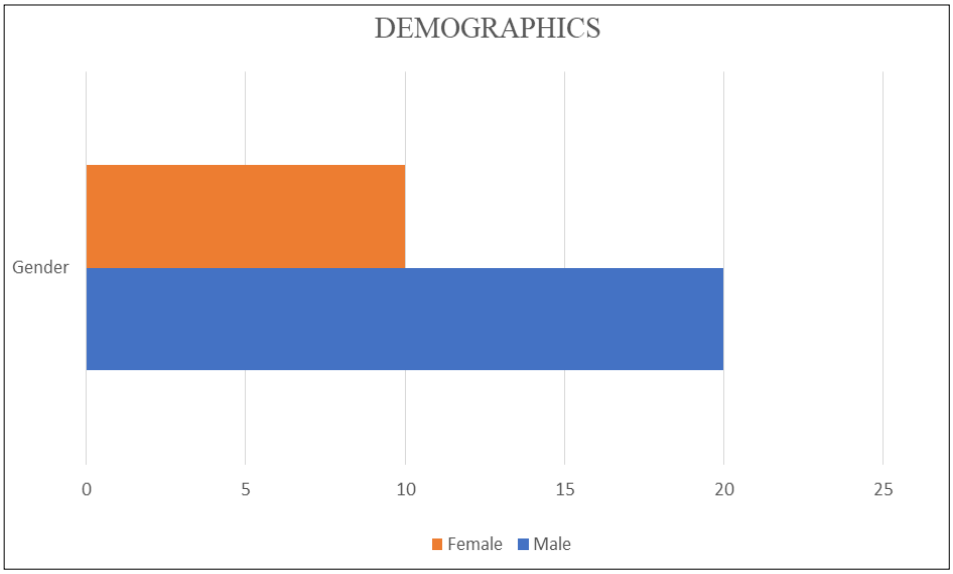

Fig 1: Distribution of gender among participants

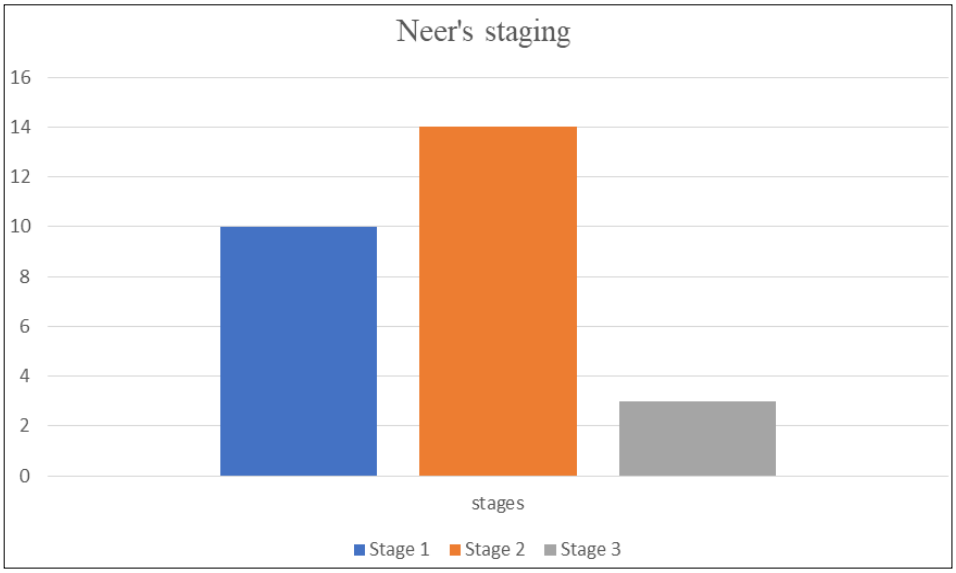

Fig 2: Classification according to Neer's staging

Table 2: Master Chart

S. No	Age	Sex	Side	Etiology	Neer's stage of impingement	VAS score before PRP	DASH Score before PRP	VAS score after PRP (12 wks.)	DASH Score (12 wks.)
1	36	M	R	Traumatic	Stage 1	7	48	3	12
2	44	M	R	Degenerative	Stage 2	6	54	2	18
3	38	M	R	Traumatic	Stage 1	8	58	3	19
4	45	F	L	Degenerative	Stage 2	7	50	4	14
5	52	M	R	Degenerative	Stage 3	8	58	1	22
6	48	F	L	Degenerative	Stage 2	6	55	2	18
7	56	M	R	Degenerative	Stage 3	7	60	3	25
8	39	M	R	Degenerative	Stage 1	8	54	2	18
9	46	M	L	Degenerative	Stage 2	8	62	4	24
10	33	F	R	Traumatic	Stage 1	7	58	3	22
11	60	M	L	Degenerative	Stage 3	6	52	3	17
12	53	M	R	Degenerative	Stage 2	5	56	2	21
13	43	M	R	Traumatic	Stage 2	6	60	2	19
14	38	M	R	Traumatic	Stage 1	8	48	2	14
15	40	F	L	Traumatic	Stage 1	7	61	3	21
16	51	M	R	Degenerative	Stage 2	7	52	2	16
17	49	F	R	Degenerative	Stage 2	6	60	4	21
18	43	M	R	Traumatic	Stage 1	7	58	3	18
19	51	M	R	Degenerative	Stage 3	8	62	3	24
20	50	F	L	Degenerative	Stage 2	7	60	2	22
21	57	M	R	Degenerative	Stage 3	7	61	2	21

22	49	M	L	Traumatic	Stage 2	6	59	3	14
23	62	M	R	Degenerative	Stage 3	5	64	2	28
24	58	M	L	Degenerative	Stage 3	7	66	4	27
25	43	M	R	Traumatic	Stage 2	6	56	3	19
26	52	M	R	Degenerative	Stage 2	7	64	2	26
27	47	F	R	Degenerative	Stage 2	8	52	3	21
28	39	M	L	Traumatic	Stage 1	8	50	2	21
29	38	F	R	Traumatic	Stage 1	7	48	2	16
30	49	M	R	Degenerative	Stage 2	5	56	3	18

Results

A total of 30 patients were included in the study, between June 2021 to June 2022 with their demographic and clinical data analysed to evaluate the outcomes of PRP treatment in Rotator cuff tendinopathy. The patient ages ranged from 33 to 62 years, with a mean age of 47.3 years. Out of the 30 participants, 20 were male and 10 were female (Figure 1). Among the participants, 19 had rotator cuff tendinopathy on the right side, while 11 experienced it on the left side.

Neer's staging system was employed to determine the severity of the condition (Figure 2). Stage 1 characterized by inflammation and oedema, was observed in 10 cases, while 14 patients had stage 2 indicating the presence of partial rotator cuff tears, and six patients presented with stage 3 which signifies complete rotator cuff tears.

The results of this study indicate that PRP injection combined with a standardized rehabilitation protocol resulted in a significant reduction in resting pain and improvement in functional outcomes, as assessed by the VAS and DASH scores respectively (Table 1). The study evaluated the effectiveness of PRP therapy in reducing pain levels using the Visual Analog Scale (VAS). The VAS scores were recorded before PRP treatment and after an 8-weeks & 12 weeks follow-up period. Before PRP therapy, the mean VAS score was 7.0, indicating moderate to severe pain. Following PRP treatment, the mean VAS score significantly decreased to 2.6, reflecting a substantial reduction in pain levels.

To assess functional improvement, the Disabilities of the Arm, Shoulder, and Hand (DASH) score was measured at baseline and after a 12-week follow-up period. The DASH score provides a measure of disability and its impact on daily activities. At baseline, the mean DASH score was 52.3, indicating a moderate level of impairment. After 12 weeks of PRP therapy, the mean DASH score improved to 19.4, demonstrating a significant enhancement in functional ability.

Throughout the study period, no major adverse events related to PRP injection or the rehabilitation protocol were reported. Minor localized pain at the injection site was the most commonly reported adverse event, with 12 patients experiencing this transient discomfort. No infections or severe complications were observed (Table 2).

Discussion

Rotator cuff tendinopathy has a complex origin involving both intrinsic and extrinsic factors. The intrinsic factors primarily consist of age-related degeneration of the cuff and changes in the vascularity of the tendon. On the other hand, extrinsic factors include biomechanical and anatomical dysfunctions that can lead to impingement, overuse, and excessive loading of the tendons. To effectively treat tendinopathy, it is crucial to address these underlying causes. Over the past decade, PRP (platelet-rich plasma) injections have been utilized for chronic tendon injuries due to their beneficial properties in promoting collagen synthesis, stimulating tendon cell proliferation, and enhancing vascularization of the affected tendon. In our study, we examined the outcomes of PRP injections and compared them with the results reported in various other studies available in the literature.

Our research revealed that rotator cuff tendinopathy was more prevalent among individuals in their fourth and fifth decades of life, with a mean age of 47.3 years. This average age aligns with the findings of previous studies conducted by Kesikburun *et al*. [12], Mautner *et al*.[9], Wesner *et al*.[10], and Scarpone *et al*. [11], where the average ages were reported as 45.5 years, 48.6 years, 44.6 years, and 46.2 years, respectively. Consequently, it can be inferred that rotator cuff tendinopathy is more frequently observed in middle-aged individuals, in contrast to rotator cuff tears, which tend to be more common among older adults

Our study had a male preponderance with 20 male and 10 female patients. Scarpone *et al* in their study of PRP for chronic tendinopathy had a higher male preponderance with 15 male and only 4 female patients. The higher male preponderance could be because males are more likely to be involved in heavy physical activities like manual labour, sports activities etc. Most of the males in our series of patients were either manual labourers or farmers.

Mautner *et al*. did a retrospective study where they studied 180 patients. Platelet-rich plasma injection for chronic tendinopathy was given in all these patients. In their study, the mean VAS score improved from 7 to 2 at the end of 6 months, whereas in our study mean VAS score reduce from 7 to 2.6 in the 12th week. They reported as moderate improvement in pain symptoms (> 50%) with multiple PRP injections for chronic tendinopathy, our study had good results with single PRP injections. There was significant improvement in pain in most of our patients and they were able to get back to their activities of daily living.

Wesner *et al*. did a randomised control trial on patients receiving PRP and reported clinical improvement in pain (> 1.5/10 on VAS), disability score (> 15 points DASH change), and tendon pathology while those receiving placebo injections did not. In the observational cohort, statistically and clinically significant improvements in pain and disability were observed [10].

Scarpone *et al.* in their prospective open-label study on 18 patients who received a single PRP injection, concluded that PRP resulted in safe, significant, and sustained improvement in pain and function. Twelve participants were "completely satisfied", five patients were "satisfied", and one participant was "unsatisfied". The mean VAS score improved from 7.5 to 0.5 in the 12th week. Our results were similar with mean VAS 7 to 2.6 in the 12th week, as they had good improvement in VAS scores and the majority of patients were satisfied [11].

Kesikburun *et al.* did a comparative study of PRP versus Saline injection in 40 patients with rotator cuff tendinopathy. In their study the SPADI score, which was 77.5 reduced to 27.6 at the end of the 12th week in the patients who were treated with PRP. In our study, the mean DASH score reduced from 52.3 to 19.4 demonstrating significant enhancement with

a p-value of < 0.05 at the end of the 12th week which is comparable with their outcome score. In their study mean VAS score reduction was from 8 to 3 at 12 weeks and in our study, the mean VAS score reduced from 7 to 2.6 at the 12th week [12]. They concluded at one-year follow-up, a PRP injection when compared to a placebo was no more effective in improving the quality of life, pain, disability, and shoulder range of motion in patients with chronic rotator cuff tendinopathy who were treated with an exercise program.

Jane Fitzpatrick, *et al.* their meta-analysis of randomised controlled clinical trials in which they included 18 studies, found that there is good evidence to support the use of a single injection of highly cellular leucocyte-rich PRP under ultrasound guidance in tendinopathy. The preparation and the technique of intra tendinous injection technique of PRP have a clinical significance. [13].

We used only a single injection of PRP. Serial injections are one of the controversial topics in PRP injection. A second injection can be performed at one to two months if no therapeutic effect is seen, but in most of our patients, a single injection was effective. All our injections were landmark guided, and given by a single surgeon trained in shoulder arthroscopy. Ultrasound guides may improve the accuracy of the injections, but the added cost was the reason we did not give the injections guided by ultrasound. PRP is an evolving treatment modality gaining momentum in primary care, rehabilitation, and sports medicine applications. PRP may provide a minimally invasive outpatient treatment for refractory rotator cuff tendinopathy thus providing a less expensive alternative modality to surgery with a reduced potential for operative side effects and adverse events. Physiotherapy is an important part of the treatment, post-PRP injection. Further studies with a larger number of patients will prove the efficacy of PRP in rotator cuff tendinopathy. Our study, fortunately, had no complications like needle breakage, local inflammation, or infection, except for the pain at the injection site for 24 to 48 hours.

The limitations of our study were that we had a smaller sample size and no controls, and we did not do a post-injection ultrasound or MRI to evaluate the tissue regeneration and healing. This may be, carried out in subsequent research efforts.

Conclusion

From our study it was evident that, in patients with rotator cuff tendinopathy who are refractory to initial physiotherapy management, intralesional PRP injections offer a promising approach for the management of rotator cuff tendinopathy, providing pain relief, functional improvement, and potentially avoiding the need for surgical intervention.

Our findings align with previous studies that have reported positive outcomes with PRP injections for rotator cuff tendinopathy. The use of PRP has been shown to promote collagen synthesis, stimulate tendon cell proliferation, and enhance vascularization, which is beneficial for tendon healing and recovery. Moreover, PRP injections are a minimally invasive outpatient procedure, providing a potentially cost-effective alternative to surgical interventions.

Declaration

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Conflict 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.

Ethical Approval: Not required.

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