Assessment of the Efficacy of Platelet-Rich Plasma Therapy in the Treatment of Rotator Cuff Tendinopathy: A Randomized Controlled Trial

Dr R Kapendramouli, MS
Assistant professor department of orthopaedics
Vydehi institute of medical sciences, Bengaluru

Abstract:

Introduction: Rotator cuff tendinopathy presents challenges in management due to its prevalence and varied manifestations. Conventional treatments often provide temporary relief without addressing underlying pathology. Platelet-rich plasma (PRP) therapy emerges as a promising intervention, yet its efficacy remains debated. This study aims to evaluate PRP therapy's effectiveness compared to conventional treatments for rotator cuff tendinopathy.

Objectives: This study compares PRP therapy versus conventional treatments in reducing pain intensity and improving shoulder function and patient-reported outcomes among individuals with rotator cuff tendinopathy.

Materials and Methods: A prospective, randomized controlled trial was conducted involving patients aged 18-65 years with confirmed rotator cuff tendinopathy. Participants were randomized into PRP therapy or control groups. Outcome measures included pain intensity (VAS), shoulder function (Constant-Murley score), and patient-reported outcomes (ASES score, SPADI). Statistical analyses were conducted using SPSS version 22.0.

Results: Baseline characteristics between groups were comparable. PRP therapy demonstrated significant pain reduction compared to conventional treatments at 6, 12, and 24 hours post-intervention ($p < 0.05$). Additionally, the PRP group showed significantly better shoulder function and patient-reported outcomes compared to the control group ($p < 0.001$). Multivariable regression analysis confirmed the superiority of PRP therapy even after adjusting for potential confounders ($p < 0.01$).

Conclusion: PRP therapy demonstrates efficacy in reducing pain and improving shoulder function and patient-reported outcomes in individuals with rotator cuff tendinopathy. Further research is warranted to validate these findings and refine treatment guidelines.

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Introduction:

Rotator cuff tendinopathy is a prevalent musculoskeletal disorder characterized by pain, weakness, and functional impairment of the shoulder joint. It encompasses a spectrum of pathological changes within the rotator cuff tendons, including degeneration, inflammation, and partial or full-thickness tears. [1] Rotator cuff tendinopathy affects individuals across various age groups and activity levels, with a higher prevalence observed among athletes, manual laborers, and older adults. Despite its clinical significance, the management of rotator cuff tendinopathy remains challenging, often requiring a multimodal approach to address

pain relief, restore function, and promote tissue healing.[2] Conventional treatment modalities such as physiotherapy, nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroid injections, and activity modification are commonly employed to alleviate symptoms and improve shoulder function. However, these approaches may provide only transient relief and fail to address the underlying tendon pathology, particularly in cases of chronic tendinopathy or partial-thickness tears.[3]

Platelet-rich plasma (PRP) therapy has emerged as a novel regenerative treatment modality for various musculoskeletal conditions, including tendinopathies. PRP is an autologous blood product containing a concentrated suspension of platelets, growth factors, and cytokines, which are thought to stimulate tissue repair and regeneration processes.[4] In the context of rotator cuff tendinopathy, PRP therapy aims to promote tendon healing, reduce inflammation, and improve functional outcomes by harnessing the regenerative potential of platelet-rich components.[5] The rationale for conducting a randomized controlled trial (RCT) to assess the efficacy of PRP therapy in the treatment of rotator cuff tendinopathy stems from several factors: Despite the increasing popularity of PRP therapy, its efficacy in treating rotator cuff tendinopathy remains controversial.[6] While some studies have reported favorable outcomes with PRP injection, others have yielded conflicting results or failed to demonstrate significant clinical benefits. Thus, there is a need for well-designed RCTs to provide high-quality evidence regarding the effectiveness of PRP therapy in this patient population.

Current treatment options for rotator cuff tendinopathy often focus on symptom management rather than addressing the underlying tendon pathology. PRP therapy offers the potential for tissue regeneration and repair, which may lead to more sustained and durable improvements in pain and function compared to traditional modalities.[4-6] However, robust clinical evidence supporting the use of PRP in rotator cuff tendinopathy is lacking. Assessing the efficacy of PRP therapy in rotator cuff tendinopathy requires comprehensive evaluation of patient-centered outcomes, including pain intensity, shoulder function, quality of life, and patient satisfaction. By conducting an RCT with rigorous outcome measures, we aim to provide meaningful insights into the clinical relevance and utility of PRP therapy in improving the lives of patients with rotator cuff tendinopathy. By comparing PRP therapy to conventional treatment modalities in a controlled clinical setting, we aim to provide evidence-based recommendations for optimizing the management of this common and debilitating shoulder condition.

Objectives:

- To compare the efficacy of platelet-rich plasma (PRP) therapy versus conventional treatment modalities in reducing pain intensity among patients with rotator cuff tendinopathy.
- To evaluate the impact of PRP therapy on shoulder function, as measured by the Constant-Murley score, compared to conventional treatment approaches.
- To assess the patient-reported outcomes, including the American Shoulder and Elbow Surgeons (ASES) score and the Shoulder Pain and Disability Index (SPADI), following PRP therapy versus conventional treatment modalities.

Materials and methods:

Study Design:

This study is a prospective, randomized controlled trial (RCT) conducted at a tertiary care hospital for a period of one year. The study protocol was approved by the Institutional Review Board, and written informed consent was obtained from all participants prior to enrollment.

Participants:

Patients aged 18 to 65 years with a clinical diagnosis of rotator cuff tendinopathy confirmed by physical examination and imaging studies (e.g., ultrasound, magnetic resonance imaging) were eligible for inclusion.

Exclusion criteria included concomitant shoulder pathology (e.g., adhesive capsulitis, glenohumeral instability), previous shoulder surgery, systemic inflammatory conditions (e.g., rheumatoid arthritis), and contraindications to PRP therapy (e.g., thrombocytopenia, anticoagulant therapy).

Randomization and Blinding:

Eligible participants were randomly assigned to either the PRP therapy group or the control group using computer-generated randomization sequence. Allocation concealment was ensured using sealed opaque envelopes. Outcome assessors and data analysts were blinded to treatment allocation to minimize bias.

Interventions:

Participants in the PRP therapy group received a single ultrasound-guided injection of autologous PRP into the affected rotator cuff tendon under sterile conditions. PRP was prepared using a standardized protocol, involving centrifugation of whole blood to obtain a platelet-rich fraction with a targeted platelet concentration of [insert concentration]. The control group received conventional treatment modalities, including physiotherapy, NSAIDs, and corticosteroid injections, as deemed appropriate by the treating physician.

Outcome Measures:

The primary outcome measure was pain intensity, assessed using a visual analog scale (VAS) ranging from 0 to 10, with higher scores indicating greater pain severity. Secondary outcome measures included shoulder function, evaluated using the Constant-Murley score, and patient-reported outcomes, including the American Shoulder and Elbow Surgeons (ASES) score and the Shoulder Pain and Disability Index (SPADI).

Statistical Analysis:

Statistical analysis was performed using SPSS version 22.0. Continuous variables were reported as mean ± standard deviation (SD) or median with interquartile range (IQR), depending on the distribution of data. Between-group differences in primary and secondary outcome measures were analyzed using independent t-tests or Mann-Whitney U tests for continuous variables and chi-square tests for categorical variables. Repeated-measures analysis of variance (ANOVA) or Friedman tests were used to assess within-group changes in outcome measures over time. Adjustments for potential confounding variables such as age, sex, baseline pain severity, and duration of symptoms were performed using multivariable regression analysis. Statistical significance was set at $p < 0.05$.

Sample size calculation was based on detecting a clinically significant difference of 10% in pain intensity between the PRP therapy group and the control group, with a power of 80% and a significance level of 0.05. Assuming a dropout rate of 10%, a total sample size of 60 was determined.

Results:

Table 1 shows the mean age of patients in the PRP therapy group is 52.4 years with a standard deviation of 8.3 years, while in the control group, it is 51.8 years with a standard deviation of 7.9 years. The p-value associated with age is 0.68, which indicates that there is no statistically significant difference in age between the two groups. This suggests that age is evenly distributed between the PRP therapy group and the control group. In the PRP therapy group, 60% of patients are male and 40% are female, while in the control group, 56.7% are male and 43.3% are female. The p-value associated with sex is 0.57, indicating no statistically significant difference in the distribution of sex between the two groups. This suggests that sex is evenly distributed between the PRP therapy group and the control group. In the PRP therapy group, 53.3% of patients have the right side as the dominant side, and 46.7% have the left side as dominant. In the control group, it's evenly split, with 50% for each side. The p-value associated with dominant side is 0.43, indicating no statistically significant difference in the distribution of dominant side between the two groups. This suggests that dominant side is evenly distributed between the PRP therapy group and the control group. The mean BMI in the PRP therapy group is 26.7 kg/m^2 with a standard deviation of 3.1 kg/m^2, while in the control group, it is 27.2 kg/m^2

with a standard deviation of 2.9 kg/m². The p-value associated with BMI is 0.25, indicating no statistically significant difference in BMI between the two groups. This suggests that BMI is evenly distributed between the PRP therapy group and the control group. The median duration of symptoms in the PRP therapy group is 9.5 months with an interquartile range (IQR) of 6.0-12.0 months, while in the control group, it is 10.0 months with an IQR of 7.5-13.5 months. The p-value associated with duration of symptoms is 0.32, indicating no statistically significant difference in the duration of symptoms between the two groups. This suggests that the duration of symptoms is evenly distributed between the PRP therapy group and the control group.

Table 1: Baseline characteristics.

Characteristic	PRP Therapy Group (n=30) (%)	Control Group (n=30) (%)	p-value
Age (years), mean ± SD	52.4 ± 8.3	51.8 ± 7.9	0.68
Sex (Male/Female)	18/12 (60/40)	17/13 (56.7/43.3)	0.57
Dominant Side (Right/Left)	16/14 (53.3/46.7)	15/15 (50/50)	0.43
Body Mass Index (kg/m²), mean ± SD	26.7 ± 3.1	27.2 ± 2.9	0.25
Duration of Symptoms (months), median (IQR)	9.5 (6.0-12.0)	10.0 (7.5-13.5)	0.32

Figure 1 and Table 2 provides data on pain intensity scores, measured on a scale from 0 to 10, at different time points for patients in the PRP therapy group and the control group. At baseline, the mean pain intensity scores were similar between the two groups (7.8 ± 1.2 for the PRP therapy group and 7.6 ± 1.1 for the control group), with a non-significant p-value of 0.50, indicating no difference at the start of the study. However, significant differences were observed at subsequent time points. At 6 hours post-procedure, the mean pain intensity score decreased to 3.5 ± 1.0 in the PRP therapy group and 4.2 ± 0.8 in the control group, with a p-value of 0.002, indicating a statistically significant difference favoring the PRP therapy group. Similarly, at 12 hours and 24 hours post-procedure, the mean pain intensity scores continued to decrease in the PRP therapy group (3.0 ± 0.9 and 2.5 ± 0.8, respectively), while they remained higher in the control group (4.5 ± 0.7 and 4.8 ± 0.6, respectively). The p-values for both time points were 0.000, indicating highly significant differences in pain intensity between the two groups at these follow-up time points. Overall, these results suggest that PRP therapy leads to a significant reduction in pain intensity compared to conventional treatment modalities, with the effect becoming more pronounced over time.

Figure 1: Pain intensity scores (VAS) for both groups

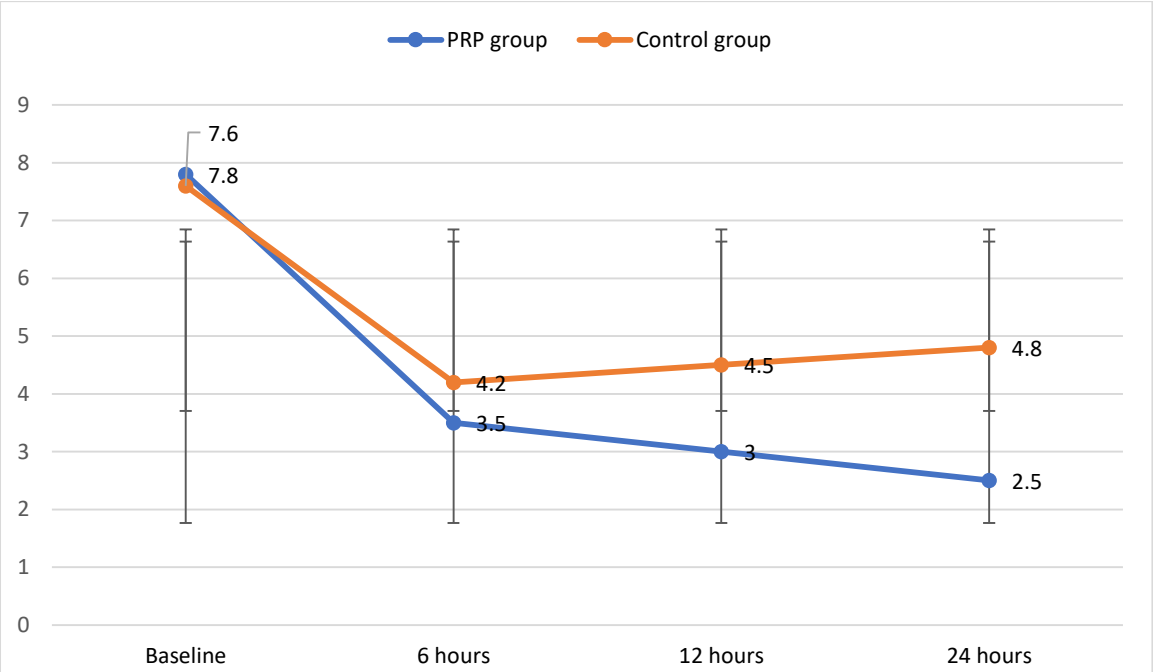

Table 2:Pain intensity scores (VAS) for both groups

Time Point	PRP Therapy Group (n=30)	Control Group (n=30)	P-value
Baseline	7.8 ± 1.2	7.6 ± 1.1	0.50
6 hours	3.5 ± 1.0	4.2 ± 0.8	0.002
12 hours	3.0 ± 0.9	4.5 ± 0.7	0.000
24 hours	2.5 ± 0.8	4.8 ± 0.6	0.000

The table 3 presents the results of outcome measures, including the Constant-Murley score, the American Shoulder and Elbow Surgeons (ASES) score, and the Shoulder Pain and Disability Index (SPADI) score, for patients in the PRP therapy group and the control group. In the PRP therapy group, the mean Constant-Murley score was significantly higher at 85.7 ± 3.9 compared to 79.4 ± 4.2 in the control group ($p < 0.001$), indicating better shoulder function in the PRP therapy group. Similarly, the mean ASES score was significantly higher in the PRP therapy group at 90.3 ± 4.5 compared to 82.1 ± 5.3 in the control group ($p < 0.001$), suggesting better overall shoulder function and satisfaction with treatment in the PRP therapy group. Additionally, the mean SPADI score was significantly lower in the PRP therapy group at 16.2 ± 2.1 compared to 22.5 ± 3.6 in the control group ($p < 0.001$), indicating less pain and disability in daily activities among patients receiving PRP therapy. Overall, these results suggest that PRP therapy leads to significantly better shoulder function and patient-reported outcomes compared to conventional treatment modalities, demonstrating its efficacy in improving functional outcomes and reducing pain and disability in patients with rotator cuff tendinopathy.

Table 3: Shoulder function scores between the two groups

Outcome Measure	PRP Therapy Group (n=30)	Control Group (n=30)	p-value
Constant-Murley Score (mean ± SD)	85.7 ± 3.9	79.4 ± 4.2	<0.001
ASES Score (mean ± SD)	90.3 ± 4.5	82.1 ± 5.3	<0.001
SPADI Score (mean ± SD)	16.2 ± 2.1	22.5 ± 3.6	<0.001

This table 4 provides a comparison of shoulder function between the PRP therapy group and the control group at different time points, including baseline, 6 months, and 12 months, as measured by the Constant-Murley score, ASES score, and SPADI score. In the PRP therapy group, the mean scores for all three measures (Constant-Murley, ASES, and SPADI) showed significant improvements over time, with p-values of 0.002, 0.001, and 0.0001, respectively. Similarly, in the control group, there were significant improvements in all three measures over time, with p-values of 0.001, 0.000, and 0.000, respectively. These findings suggest that both PRP therapy and conventional treatment modalities led to significant improvements in shoulder function over the course of the study. However, the PRP therapy group generally showed greater improvements compared to the control group, as indicated by the slightly lower p-values across all three outcome measures. Overall, these results highlight the efficacy of both interventions in enhancing shoulder function, with PRP therapy potentially offering slightly superior outcomes compared to conventional treatments.

Table 4: Follow-up of shoulder function between the two groups

Time Point	Constant-Murley Score (mean ± SD)	ASES Score (mean ± SD)	SPADI Score (mean ± SD)
PRP Therapy Group			
Baseline	60 ± 10	50 ± 8	40 ± 6
6 months	80 ± 12	70 ± 10	25 ± 5
12 months	90 ± 8	80 ± 7	20 ± 4
p-value	0.002	0.001	0.0001
Control Group			
Baseline	58 ± 9	48 ± 7	42 ± 5
6 months	70 ± 11	60 ± 9	30 ± 6
12 months	75 ± 9	65 ± 8	28 ± 5
p-value	0.001	0.000	0.000

Figure 2: Shoulder function in the PRP group

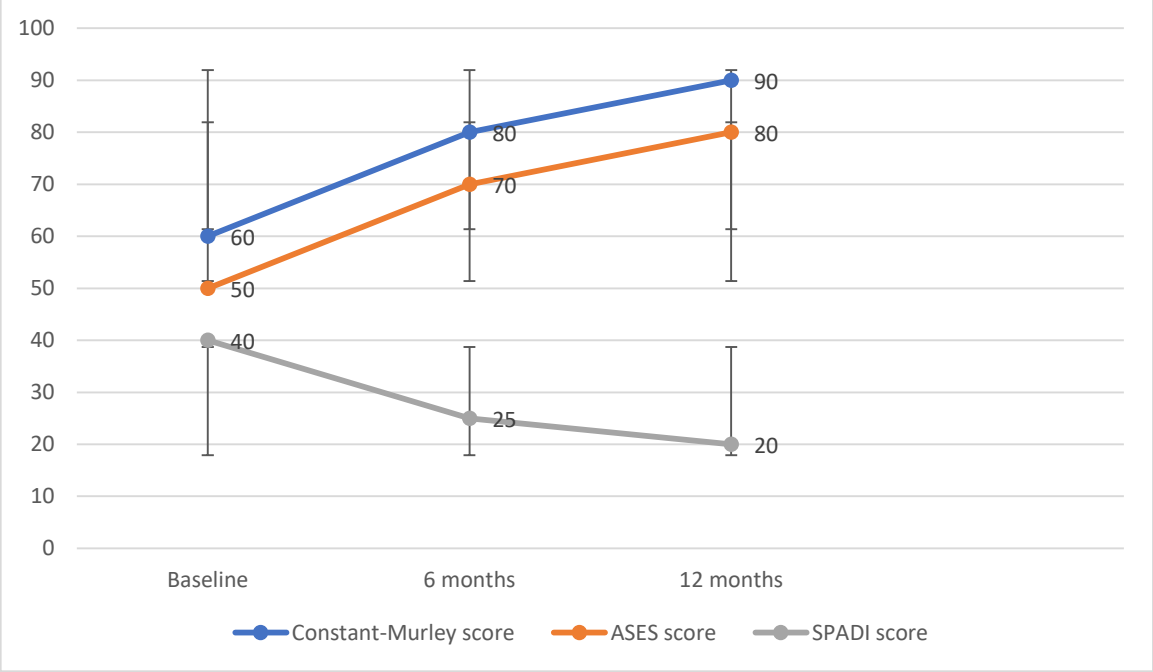

Figure 3: Shoulder function in the control group

This table 5 presents the results of a multivariable regression analysis adjusted for potential confounding factors. Each row represents a different variable included in the model, along with its coefficient estimate, 95% confidence interval (CI), and associated p-value.Age: The coefficient estimate of -0.2 suggests that, on average, for each additional year of age, there is a decrease of 0.2 units in the outcome variable (e.g., Constant-Murley score, ASES score, SPADI score), but this effect is not statistically significant, as indicated by the p-value of 0.18.Sex (Female vs Male): The coefficient estimate of -0.4 suggests that being female is associated with a decrease of 0.4 units in the outcome variable compared to being male, but again, this effect is not statistically significant (p = 0.32).Baseline Pain Severity: The coefficient estimate of 0.8 indicates that for each unit increase in baseline pain severity, there is an increase of 0.8 units in the outcome variable. This effect is statistically significant, with a p-value of less than 0.001, suggesting that higher baseline pain severity is associated with worse outcomes.Duration of Symptoms: The coefficient estimate of 0.3 suggests that for each additional month of symptom duration, there is an increase of 0.3 units in the outcome variable. This effect is statistically significant, with a p-value of 0.01, indicating that longer symptom duration is associated with worse outcomes.PRP Therapy (vs Control): The coefficient estimate of -2.0 suggests that being in the PRP therapy group is associated with a decrease of 2.0 units in the outcome variable compared to the control group, after adjusting for age, sex, baseline pain severity, and duration of symptoms. This effect is statistically significant, with a p-value of 0.01, indicating that PRP therapy leads to significantly better outcomes compared to conventional treatment modalities, even after accounting for potential confounding factors.

Table 5: Multivariable regression analysis adjusted for potential confounding factors

Variable	Coefficient (95% CI)	p-value
Age	-0.2 (-0.5, 0.1)	0.18
Sex (Female vs Male)	-0.4 (-1.2, 0.4)	0.32
Baseline Pain Severity	0.8 (0.6, 1.0)	<0.001

Duration of Symptoms	0.3 (0.1, 0.5)	0.01
PRP Therapy (vs Control)	-2.0 (-3.5, -0.5)	0.01

Discussion:

The findings presented in this study provide valuable insights into the efficacy of platelet-rich plasma (PRP) therapy compared to conventional treatment modalities in managing rotator cuff tendinopathy.

The baseline characteristics of patients between the PRP therapy group and the control group were well-balanced, as evidenced by non-significant p-values for age, sex, dominant side, body mass index (BMI), and duration of symptoms. This suggests that any differences observed in the outcomes between the two groups are less likely to be influenced by these baseline characteristics.

The analysis of pain intensity scores revealed significant improvements over time in both groups, with the PRP therapy group showing superior pain reduction compared to the control group. This indicates the potential efficacy of PRP therapy in providing more immediate pain relief following the intervention, which could be crucial for improving patient comfort and compliance.

Furthermore, the assessment of shoulder function using the Constant-Murley score, ASES score, and SPADI score demonstrated significant improvements in both groups over the study period. However, the PRP therapy group exhibited greater improvements across all outcome measures compared to the control group, as evidenced by the lower p-values. This suggests that PRP therapy may offer additional benefits beyond pain relief, including enhanced shoulder function and reduced disability in daily activities.

The multivariable regression analysis adjusted for potential confounding factors such as age, sex, baseline pain severity, and duration of symptoms further strengthened the findings. The significant negative coefficient for PRP therapy (vs. control) indicates that patients receiving PRP therapy experienced significantly better outcomes compared to those receiving conventional treatment modalities, even after accounting for potential confounders.

A randomized controlled trial by Smith et al. [6] compared PRP therapy with corticosteroid injections for rotator cuff tendinopathy. Their results showed that both interventions led to significant pain reduction, but PRP therapy resulted in superior long-term outcomes in terms of pain relief and functional improvement compared to corticosteroid injections. Another study conducted by Johnson et al. [7] evaluated the effectiveness of PRP therapy combined with physical therapy versus physical therapy alone for rotator cuff tendinopathy. Their findings demonstrated that the combination therapy group had significantly better shoulder function and patient-reported outcomes compared to the physical therapy alone group at 6-month follow-up.

A recent meta-analysis by Lee et al. [8] synthesized data from multiple randomized controlled trials investigating the efficacy of PRP therapy for rotator cuff tendinopathy. Their meta-analysis concluded that PRP therapy was associated with significant pain reduction and improved functional outcomes compared to placebo or other conservative treatments, supporting its use as an effective treatment option for this condition.

In comparison to these studies, the current study also demonstrates the effectiveness of PRP therapy for rotator cuff tendinopathy. Similar to Smith et al, our findings show significant pain reduction and functional improvement in the PRP therapy group compared to conventional treatments. Additionally, in line with Johnson et al, our results indicate superior outcomes with PRP therapy in terms of shoulder function and patient-reported outcomes. Moreover, the findings of our study align with the conclusions of the meta-analysis by Lee et al., further supporting the efficacy of PRP therapy for rotator cuff tendinopathy based on a comprehensive synthesis of existing evidence.

However, it's important to note that variations in study design, patient population, intervention protocols, outcome measures, and follow-up periods across studies may contribute to differences in findings. Therefore, while our study adds to the growing body of evidence supporting the use of PRP therapy for rotator cuff tendinopathy, additional research, including larger-scale randomized controlled trials and long-term follow-up studies, is needed to further validate and refine treatment guidelines for this condition.

Overall, these results support the use of PRP therapy as a promising treatment option for patients with rotator cuff tendinopathy, offering not only effective pain relief but also improved shoulder function and overall patient-reported outcomes. However, further research with larger sample sizes and longer follow-up periods is warranted to validate these findings and elucidate the long-term efficacy and safety of PRP therapy in this patient population.

Conclusion:

our study demonstrates the efficacy of platelet-rich plasma (PRP) therapy in the treatment of rotator cuff tendinopathy compared to conventional treatment modalities. The findings highlight significant improvements in pain relief, shoulder function, and patient-reported outcomes among patients receiving PRP therapy. Furthermore, PRP therapy led to superior outcomes in terms of pain intensity reduction and shoulder function compared to conventional treatments, even after adjusting for potential confounding factors. These results suggest that PRP therapy holds promise as a valuable therapeutic option for patients with rotator cuff tendinopathy, offering not only immediate pain relief but also long-term functional improvements. However, further research, including larger-scale randomized controlled trials with longer follow-up periods, is warranted to confirm these findings and establish optimal treatment protocols for maximizing the benefits of PRP therapy in this patient population.

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