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Efficacy and Safety of Platelet-Rich Plasma Therapy for Erectile Dysfunction: An Observational Study

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ARTICLE INFO **ABSTRACT** **ORIGINAL RESEARCH ARTICLE**

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Key Words: Erectile dysfunction, platelet-rich plasma, PRP therapy, erectile function, observational study.

Background: Erectile dysfunction (ED) is a prevalent ailment that significantly impacts one's quality of life. An effective regenerative treatment for the underlying pathophysiological mechanisms of ED is platelet-rich plasma (PRP) therapy. Assessing PRP therapy's effectiveness, safety, and patient-reported results in mild to moderate ED was the goal of this study.
Objective: to evaluate how PRP treatment for mild to moderate ED affects patient satisfaction, safety profile, and erectile function.
Methods: This 12-month prospective observational study was carried out at Ashiyan Medical College Hospital. The study included 60 male patients with mild to moderate ED. One month apart, two intrapenile injections of PRP therapy were given. The International Index of Erectile Function (IIEF) scores were used to assess erectile function at baseline, one, three, and six months. Additionally, adverse events and patient satisfaction were evaluated.
Results: PRP treatment significantly improved erectile function; at 6 months, the mean IIEF score increased by +5.1 points over baseline ($p < 0.001$). 60% of participants said they were satisfied with the therapy, and 70% said they had seen improvement. According to subgroup analysis, patients with lower BMIs and no hypertension had better results. With only minor side effects like mild pain (16.7%) and hematoma (5%), PRP therapy was well tolerated and did not result in any significant complications.
Conclusion: PRP therapy offers notable and long-lasting enhancements in erectile function with a high level of patient satisfaction, making it a safe and effective option for mild to moderate ED. PRP appears to be a

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promising restorative treatment based on these findings. It will take more randomized controlled trials to confirm these findings and investigate long-term advantages.

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INTRODUCTION

Erectile dysfunction (ED) is a widespread and distressing condition that affects approximately one in four men worldwide, with its prevalence increasing due to factors such as aging populations and lifestyle changes [1]. ED significantly impacts the quality of life for those affected and their partners, contributing to psychological and relational challenges. Standard medical treatments, including phosphodiesterase-5 (PDE5) inhibitors, enhance vasodilation through the nitric oxide pathway temporarily [2]. Although these medications have proven effective for many patients, they do not address the underlying causes of ED. Additionally, discontinuation rates remain high, mainly due to side effects, inconvenience, or unsatisfactory results [3,4].

Platelet-rich plasma (PRP) therapy is one of the alternative and regenerative approaches that have gained attention due to the limitations of conventional therapies. Blood components are separated and centrifuged to produce platelet-rich plasma (PRP), which is derived from autologous blood and has platelet concentrations up to five times higher than whole blood [5]. Several growth factors, such as platelet-derived growth factor (PDGF), transforming growth factor-beta (TGF-β), vascular endothelial growth factor (VEGF), and epidermal growth factor (EGF), are present in this concentrated platelet product and are essential for tissue regeneration and repair [6]. PRP is a desirable alternative for regenerative medicine because of these factors, which promote neoangiogenesis, cellular growth stimulation, and immune cell recruitment [7].

Orthopedic and sports medicine have already demonstrated the value of PRP, especially in the treatment of osteoarthritis and cartilage defects [7]. Preclinical research has further indicated that it may improve erectile function and regenerate nerve tissue, which supports its use in ED [8–10]. Clinical evidence for PRP's safety and effectiveness in ED is still scarce, despite its growing popularity and promising mechanisms of action. PRP therapy for ED has been offered by numerous clinics, particularly in American cities, and patients are frequently charged for treatments for which there is insufficient evidence to support them [11].

With this background in mind, our study aims to close the knowledge gap by assessing the actual results of PRP therapy for mild to moderate ED. This observational study examines changes in erectile function, patient satisfaction, and the incidence of adverse events in order to evaluate the safety and effectiveness of PRP. This research attempts to add to the body of evidence supporting PRP's use as a restorative therapy for ED by offering clinical insights into its usefulness.

METHODOLOGY

Study Design

The purpose of this prospective observational study was to assess how platelet-rich plasma (PRP) therapy affected patients with mild to moderate erectile dysfunction (ED).

Study Site

The research was carried out in the Department of Skin and Venereology at Ashiyan Medical College Hospital.

Period of Study

The study was conducted over a period of 12 months from 1st July 2023 to 30th Jun 2024, encompassing patient recruitment, treatment administration, and follow-up assessments.

Sample size

The sample size for the study was chosen to detect a clinically significant difference in erectile function scores among participants. A total of 60 patients were selected to ensure adequate power (80%) for identifying meaningful changes in IIEF scores, with a significance level (α) of 0.05. This sample size was deemed sufficient for assessing trends in outcomes and offering reliable insights into the safety and efficacy of PRP therapy.

Sampling Technique

Participants were selected using convenience sampling from patients visiting the outpatient department during the study period.

Data Collection

Baseline data was gathered using a structured survey. The data collected included baseline erectile function scores determined by the IIEF, clinical history of comorbidities such as diabetes and hypertension, and demographic information like age and BMI. Two intrapenile injections of PRP therapy were given in a sterile clinical setting, separated by one month. At one, three, and six months after treatment, follow-up evaluations were carried out to assess any adverse events, patient satisfaction, and changes in erectile function.

Data Analysis

SPSS software was used to analyze the data. Baseline characteristics were summarized using descriptive statistics. Changes in IIEF scores from baseline to follow-up points were assessed using paired t-tests. To find predictors of improvement, logistic regression analysis was used, controlling for variables like age, BMI, and comorbidities. The threshold for statistical significance was $p < 0.05$.

Ethical Approval

The Ashiyan Medical College Hospital's Institutional Ethics Committee granted ethical approval for the study. All participants provided written informed consent, guaranteeing their privacy and their freedom to leave the study at any time.

RESULTS

The study population's baseline characteristics are displayed in Table 1, emphasizing important clinical and demographic traits. With a standard deviation of 8.4 and a mean age of 48.5 years, the participants were primarily middle-aged. With an average body mass index (BMI) of 27.8 kg/m² (±4.1), the population was classified as overweight. Thirty percent of the participants were obese (BMI ≥30), fifty percent were overweight (BMI 25–29.9), and twenty percent had a normal BMI (<25). With 40% of participants having hypertension, 25% having diabetes mellitus, and 35% reporting hyperlipidemia, comorbid conditions were prevalent. Furthermore, 30% of participants had smoked in the past, which is known to increase the risk of cardiovascular disease and erectile dysfunction. These results imply that the study population was made up of people who had a significant burden of cardiovascular and metabolic risk factors, which offers a pertinent background for assessing PRP therapy's effects in this population.

Table 1: Baseline Characteristics of Study Participants

Variable	Value
Mean Age (years)	48.5 ± 8.4
BMI (kg/m²)	27.8 ± 4.1
- Normal BMI (<25)	20%
- Overweight BMI (25–29.9)	50%

- Obese BMI (≥30)	30%
Hypertension	40%
Diabetes Mellitus	25%
Hyperlipidemia	35%
Smoking History	30%

Table 2 shows that after PRP treatment, scores on the International Index of Erectile Function (IIEF) significantly improved over time. The average IIEF score rose from 15.2 (±3.5) at baseline to 18.6 (±4.2) two months later (mean difference +3.4, p = 0.002), 19.4 (±4.0) three months later (+4.2, p = 0.001), and 20.3 (±3.8) six months later (+5.1, p < 0.001). These findings show that during the 6-month follow-up period, erectile function improved steadily and statistically significantly.

Table 2: Changes in Erectile Function Scores Over Time

Time Point	IIEF Score (Mean ± SD)	Mean Difference (vs Baseline)	p-value
Baseline	15.2 ± 3.5	-	-
1 Month	18.6 ± 4.2	+3.4	0.002
3 Months	19.4 ± 4.0	+4.2	0.001
6 Months	20.3 ± 3.8	+5.1	<0.001

Table 3 highlights the safety profile of PRP therapy by summarizing reported adverse events. Mild pain at the injection site was the most common adverse event, experienced by 10 participants (16.7%). Hematoma occurred in 3 participants (5%). Importantly, no major adverse events were reported during the study. These findings suggest that PRP therapy was well-tolerated, with only minor, self-limiting side effects observed.

Table 3: Adverse Events Reported During the Study

Adverse Event	Frequency (n)	Percentage
Mild Pain at Injection Site	10	16.7%
Hematoma	3	5%
Major Adverse Events	0	0%

The results reported by patients after PRP therapy are compiled in Table 4. According to the majority of participants (70%) who reported an improvement in erectile function, the treatment was deemed effective. Furthermore, 60% of patients reported feeling satisfied with the therapy overall. These results indicate that PRP therapy produces high levels of patient satisfaction in addition to improving erectile function.

Table 4: Patient Satisfaction with PRP Therapy

Category	Percentage
Patients Reporting Improvement	70%
Patients Satisfied with Therapy	60%

The correlation analysis between baseline variables and IIEF score changes is shown in Table 5. Erectile function improvement and BMI had a weakly negative correlation (correlation coefficient = -0.28, p = 0.04), meaning that smaller improvements were linked to higher BMI. A moderately negative correlation between comorbidities and treatment efficacy was found (correlation coefficient = -0.35, p = 0.02). These factors may have an impact on the results of PRP therapy, as evidenced by the statistical significance of both correlations.

Table 5: Correlation Analysis of BMI and Comorbidities with IIEF Improvements

Variable	Correlation Coefficient	p-value
BMI	-0.28	0.04
Comorbidities	-0.35	0.02

Table 6 shows subgroup analyses of changes in IIEF scores according to BMI and the presence of hypertension. The largest improvement in IIEF scores (+6.0) was seen by patients with normal BMI (<25), followed by those who were overweight (25–29.9) with a mean change of +5.2 and those who were obese (≥30) with the smallest improvement (+3.8). BMI subgroup differences were statistically significant (p = 0.03).

Patients without hypertension showed more improvement (+5.5) than those with hypertension (+3.7) in the hypertension subgroups; this difference was almost statistically significant (p = 0.05). These results imply that better results for erectile function after PRP therapy are linked to lower BMI and the lack of hypertension.

Table 6: Subgroup Analysis of IIEF Score Improvements

Group	Mean IIEF Change	p-value
BMI Subgroups		
- Normal BMI (<25)	+6.0	
- Overweight (25–29.9)	+5.2	0.03
- Obese (≥30)	+3.8	
Hypertension Subgroups		
- Hypertensive	+3.7	0.05
- Non-Hypertensive	+5.5	

The logistic regression analysis that found predictors of a significant improvement in IIEF scores (≥4-point increase) after PRP therapy is shown in Table 7. With an odds ratio of 1.25 (95% CI: 1.08–1.45, p = 0.01), the baseline IIEF score was a significant predictor, suggesting that a higher baseline erectile function was linked to a higher chance of improvement. With an odds ratio of 0.90 (95% CI: 0.82–0.98, p = 0.03), BMI also showed up as a significant predictor, indicating that a higher BMI was linked to a lower chance of obtaining a notable improvement. These findings demonstrate how baseline BMI and erectile function affect PRP therapy effectiveness, with lower BMI and better initial erectile function favoring better results.

Table 7: Predictive Modeling Results for Patient Satisfaction

Predictor	Odds Ratio (95% CI)	p-value
Baseline IIEF Score	1.25 (1.08–1.45)	0.01
BMI	0.90 (0.82–0.98)	0.03

DISCUSSION

In a real-world clinical setting, this study assessed the effectiveness of platelet-rich plasma (PRP) therapy for mild to moderate erectile dysfunction (ED). As determined by the International Index of Erectile Function (IIEF), the results show notable gains in erectile function, with long-lasting advantages noted during a six-month follow-up period. Furthermore, PRP treatment was well tolerated; very few side effects were noted.

From baseline to each follow-up point, the mean IIEF score increased significantly; at six months, the biggest improvement (+5.1 points) was seen. These results align with preclinical research demonstrating PRP's capacity for regeneration. Numerous growth factors found in PRP, including platelet-derived growth factor, vascular endothelial growth factor, and epidermal growth factor, are essential for neoangiogenesis, cellular proliferation, and tissue repair [6,7]. By enhancing vascular and tissue health, these mechanisms are thought to restore erectile function- [8–10]. Notably, 70% of participants reported improvement, and 60% said they were generally satisfied with their therapy. This is consistent with findings from earlier research that suggests PRP may enhance patient-reported outcomes and quality of life in emergency departments [15, 16]. PRP is a good treatment option, especially for patients looking for alternatives to conventional therapies, as evidenced by the high satisfaction rate.

In line with previous research on the role of metabolic and cardiovascular factors in ED, subgroup analyses showed that better outcomes were linked to lower BMI and the absence of hypertension [2,4]. BMI and baseline erectile function were also found to be significant predictors of improvement using logistic regression. These results highlight the significance of patient selection and the requirement for individualized treatment plans.

Regarding safety, PRP treatment was well tolerated; only mild side effects, like hematoma and mild pain, were reported in 5% and 16.7% of patients, respectively. No significant adverse events were noted, supporting the safety profile documented in earlier clinical trials [15,16]. Despite these encouraging results, there are still limitations to this study. The observational design restricts the ability to establish causality by preventing direct comparison with placebo or other treatments. Generalizability may also be hampered by the small sample size and dependence on a single center. Larger sample sizes are needed for future randomized controlled trials to validate these findings and clarify the mechanisms underlying PRP's therapeutic benefits.

For mild to moderate erectile dysfunction, PRP therapy seems to be a safe and successful treatment that offers long-lasting erectile function improvements and high patient satisfaction. This study adds to the increasing amount of data demonstrating PRP's effectiveness as a restorative treatment for ED and opens the door for more investigation into its long-term suitability and efficacy.

Limitations: It is important to take into account the study's various limitations. The lack of a control group in the observational design makes it more difficult to prove a link between PRP treatment and the results. The findings are less generalizable due to the single-center setting and relatively small sample size (n = 60), which may also introduce biases unique to local practices. Although the six-month follow-up period is adequate for evaluating immediate effects, it offers no information regarding the long-term safety and effectiveness of PRP therapy. Furthermore, the results might have been affected by the lack of thorough control over potential confounding variables like lifestyle choices, mental health issues, and concurrent treatments.

CONCLUSION

The results of this study show that platelet-rich plasma (PRP) therapy is a safe and efficient treatment for mild to moderate erectile dysfunction (ED), with minimal side effects over a six-month period, high patient satisfaction, and notable improvements in erectile function. Lower BMI and the lack of hypertension may improve outcomes, according to subgroup analyses, underscoring the significance of patient selection. Although encouraging, the observational design and small sample size call for additional testing in randomized controlled trials to verify effectiveness and investigate potential long-term advantages. PRP may be a viable restorative treatment for ED, according to this study's insightful empirical data.

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