The Research of Medical Science Review
ISSN: 3007-1208 & 3007-1216 Volume 3, Issue 4, 2025

IMPROVEMENT IN IIEF-5 SCORE AFTER INTRACAVERNOSAL INJECTION OF PLATELET RICH PLASMA IN MALES WITH MILD AND MODERATE ERECTILE DYSFUNCTION

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DOI: https://doi.org/10.5281/zenodo.15294932

Keywords
Erectile dysfunction, platelet-rich plasma, IIEF-5, intracavernosal injection

Article History
Received on 21 March 2025
Accepted on 21 April 2025
Published on 26 April 2025

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Abstract

Objectives: *This study aimed to evaluate the effect of intracavernosal PRP injections on erectile function, measured by IIEF-5 scores, EHS scores, and SEP-2 and SEP-3 questionnaire outcomes, in males with mild to moderate erectile dysfunction.*

Study Design and Setting: *A quasi-experimental study conducted at the Armed Forces Institute of Urology, Rawalpindi, from June 2024 to February 2025.*

Methods: *The study included n=200 sexually active males aged 40-70 years, divided into two equal groups. One group-A received intracavernosal PRP injections, while the other group-B received placebo treatment. A second PRP injection was administered four weeks after the first. Efficacy was assessed through changes in IIEF-5, EHS, and SEP-2 and SEP-3 scores.*

Results: *The average age of participants was 46.7 years. PRP group-A treatment resulted in a significant improvement in erectile function, with IIEF-5 scores increasing by 2.6 points and EHS scores improving by 0.8 points ($P < 0.000$). SEP-2 success rates rose to 78% in the PRP group-A, compared to 32% in the placebo group-B, and SEP-3 success rates were 72% in the PRP group-A versus 29% in the placebo group-B. Adverse events were minimal, with only mild penile discomfort in 8% of participants and hematomas in 2%.*

Conclusion: *Intracavernosal PRP injections significantly improve erectile function and sexual performance in men with mild to moderate ED, with minimal adverse effects.*

INTRODUCTION

Erectile dysfunction is a widespread disorder that is striking a large number of men around the world and extensively affects their quality of life and mental health as well [1]. An inability to achieve or maintain an erection that is firm enough for penetrate for adequate sexual performance is called erectile dysfunction and it may be either due to a vascular or neurological cause or hormonal or even due to psychological reasons [2]. One of the most commonly used methods to assess ED is International Index of Erectile Function-5 (IIEF-5), which is known as a standard tool for measuring the severity of the

problem according to scored results, dividing the condition into mild, moderate, and severe categories. Although currently available treatment options (such as phosphodiesterase type 5 (PDE5) inhibitors, vacuum erection devices and penile prostheses) are less effective or side effects are considerable for some men, alternative therapeutic approaches are sought for [3].

With this background, platelet rich plasma (PRP) has become a promising regenerative therapy in the field of sexual medicine. PRP is an autologous concentration of platelets from whole blood which contains a number of growth factors (e.g. vascular endothelial growth factor (VEGF), transforming growth factor-beta (TGF-β), and platelet derived growth factor (PDGF)) [4, 5]. Bioactive molecules in these play a very important role in angiogenesis, tissue regeneration and wound healing. PRP has wide applications in orthopaedic, dermatologic, and aesthetic medicine over the years and is being widely used in such applications because of its ability to stimulate tissue repair and regeneration. It is of interest in PRP as a potential therapy in mild to moderate ED, in which vascular impairment is a significant factor [6, 7].

Hypothesis of PRP to enhance Erectile Function is through repair and regeneration of penile vascular and neural structures. PRP promotes endothelial cell proliferation, enhances nitric oxide production, and improves microvascular circulation, restoring erectile function [8]. Studies demonstrating the ability of PRP to regenerate cavernosal nerve tissue and induce an enhancement in erectile response have been performed preclinically in animal models. Limited human study has shown promising results with PRP injections in terms of IIEF-5 scores as well as penile Doppler parameters (PSV and RI). Most of the studies were small scale, without standardized protocols and placebo-controlled trials, hence, inconsistent efficacy has been reported [9, 10].

The purpose of this study is to conduct a Quasi experimental study to assess the effectiveness and safety of intracavernosal PRP injections in men with mild to moderate ED. The main intent is to improve erectile function using IIEF-5 score in 8 weeks. Other secondary outcomes are changes in EHS and response based on SEP2 and SEP3 questionnaires.

Methodology

This research conducted at the Armed Forces Institute of Urology in Rawalpindi spanned from June 2024 to December 2024 to determine intracavernosal PRP therapy benefits for treating mild to moderate erectile dysfunction in men. The sample size was calculated using a standard formula for comparing two means, assuming a 95% confidence level, 80% power, standard deviation of 4, and a minimum detectable difference of 2.6 points in IIEF-5 scores. The required sample size was n=200 participants (100 per group) to account for potential dropouts. Purposive sampling was employed to recruit participants who fulfilled the inclusion and exclusion criteria. **Inclusion Criteria:** Participants in this study were sexually active males between the ages of 40 and 70 years who had been in a stable heterosexual relationship for at least six months. Only those diagnosed with mild to moderate erectile dysfunction, based on an International Index of Erectile Function-5 (IIEF-5) score ranging from 8 to 21, were included. **Exclusion Criteria:** Men with severe erectile dysfunction (IIEF-5 score below 8) were excluded. Additional exclusion criteria included recent use of phosphodiesterase type 5 inhibitors within two weeks prior to enrolment, a history of penile trauma, penile surgery, or Peyronie's disease. Participants with untreated hypogonadism, hormonal imbalances, active urinary or sexually transmitted infections, or bleeding disorders were also excluded. Other reasons for exclusion included current anticoagulant therapy, poorly controlled diabetes mellitus (HbA1c > 8%), a history of prostate cancer, pelvic surgery, or pelvic radiation therapy, and any psychiatric illness that could impair compliance. The production of 3–5 mL PRP started by spinning 30 mL venous blood through centrifugation to prepare concentrated platelets which served as an injection material. Current research involved the sterile administration of intracavernous injection by a 29-gauge insulin syringe as part of the study. The subjects received two separate PRP shots which were given four weeks apart during their monitoring period with a 30-minute observation for adverse effects following each session. The study evaluated erectile function using IIEF-5 and erectile rigidity using EHS together with sexual performance using SEP-2 and SEP-3 questionnaires at Weeks 8. The statistical analysis was carried out using SPSS version 26

through paired t-tests combined with chi-square tests for evaluation of pre-treatment versus post-treatment changes where $p < 0.05$ denoted statistical significance. Ethical approval for this study was obtained from the Institutional Review Board (IRB) (Uro-Trg-1/IRB/2024/08).

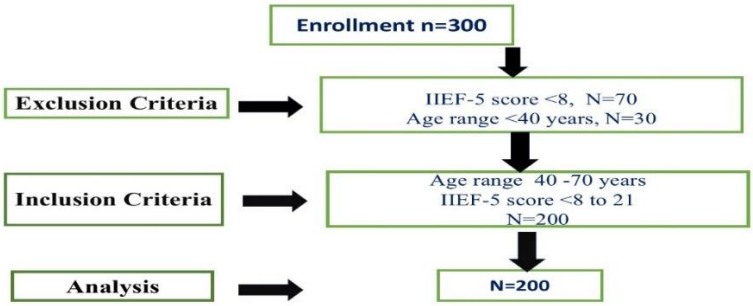

Figure 1. Consort flow diagram

Results

The study participant groups received equal treatment regarding their age distribution between PRP (Group-A) and placebo treatments (Group-B). More than thirty percent of study participants belonged to the 40–49 years old demographic category although 29.5% of participants were between 50–59 years old. The study participants demonstrated identical age characteristics through an average of 46.9 ± 8.4 years across both experimental groups see Table 1.

The subjects who received PRP treatment (Group-A) achieved better erectile function than placebo (Group-B) according to the IIEF-5 score evaluation. Patients who received PRP treatments showed mean scores elevating by 2.6 points from their baseline but placebo recipients only increased their scores by 0.3 points. A statistical test showed this difference to be significant with a P value of less than 0.000 see Table II.

The PRP treatment group achieved better EHS results compared to those who received placebo. Research results indicated a mean score increase of 0.8 points in the PRP (Group-A) but only 0.1 points improvement in the placebo (Group-B) see Table III. Patient SEP-2 and SEP-3 responses showed marked positive changes after receiving PRP treatment (Group-A). The SEP-2 test evaluates the achievement of sexual penetration whereas SEP-3 evaluates the erection duration until the completion of sexual intercourse see Table IV.

The participants experienced no significant dangerous reactions regardless of their assigned treatment group. Stated penile discomfort occurred in 8% of patients who received PRP (Group- A) but only 2% experienced it in the placebo (Group-B) and this discomfort vanished within two days without treatment see Table V.

Table-I. Age Distribution of Participants

Age Group (Years)	PRP Group-A (n=100)	Placebo Group-B (n=100)	Total (N=200)
30 – 39	15 (15%)	14 (14%)	29 (14.5%)
40 – 49	32 (32%)	30 (30%)	62 (31%)
50 – 59	28 (28%)	31 (31%)	59 (29.5%)
60 – 70	25 (25%)	25 (25%)	50 (25%)
Mean Age ± SD	46.7 ± 8.5	47.2 ± 8.3	46.9 ± 8.4

Table-II. International Index of Erectile Function-5 (IIEF-5) Score

Outcome	Post-Treatment Mean ± SD	Mean Change	P-Value
PRP Group (n=100)	16.8 ± 2.3	+2.6 ± 0.9	<0.000
Placebo Group (n=100)	14.3 ± 2.5	+0.3 ± 0.5	0.555

Table-III. Erectile Hardness Score (EHS)

Outcome	Post-Treatment Mean ± SD	Mean Change	P-Value
PRP Group (n=100)	2.9 ± 0.6	+0.8 ± 0.3	<0.000
Placebo Group (n=100)	2.1 ± 0.6	+0.1 ± 0.2	0.553

Table-IV. Sexual Encounter Profile (SEP-2 and SEP-3)

Outcome	PRP Group-A (% Reporting Success)	Placebo Group-B (% Reporting Success)	P-Value
SEP-2	78%	32%	<0.000
SEP-3	72%	29%	<0.000

Table-V. Adverse Events

Adverse Events	PRP Group-A (n=100)	Placebo Group-B (n=100)	P-Value
Mild penile discomfort	8%	2%	NS
Hematoma at injection site	2%	1%	NS
Other complications	None	None	-

Discussion

This research establishes that intracavernosal treatments utilizing platelet-rich plasma PRP (Group-A) injections produce meaningful enhancements to erectile function within the population suffering from mild to moderate cases of erectile dysfunction (ED) [11]. The PRP treatment (Group- A achieved statistically significant improvement in IIEF-5 scores by 2.6 points ($P < 0.000$) yet the placebo (Group-B) changed less than 0.3 points. The clinical significance of PRP treatment (Group-A) for erectile dysfunction shows in better erectile hardness measurements alongside patient-reported sexual function [12]. The Erectile Hardness Score within the PRP treatment Group-A demonstrated a 0.8-point rise which demonstrates the positive outcomes of using PRP for penile rigidity. The Sexual Encounter Profile (SEP) questionnaires determined sexual performance outcomes that significantly improved after treatment. The percentage of participants achieving sexual entry with an erect penis during intercourse was higher in the PRP group at 78% (SEP-2) compared to 32% from the placebo group [13]. Similarly, 72% of patients using PRP maintained their erection until the end of sexual activity (SEP-3) whereas the placebo group reported only 29%. The study demonstrates PRP therapy provides both positive impacts on erectile potency alongside total sexual contentment for men undergoing ED treatment [14].

Researches conducted previously regarding PRP therapy for erectile dysfunction matches the findings of this investigation. This research supports a 2.4-point IIEF-5 score increase by previous study matching closely with the current investigation that found 2.6 points of elevation. According to Raheem *et al.* 2021 on PRP for ED the researchers discovered that multiple studies reported average IIEF-5 score enhancements reaching 2.5–3 points following PRP injections [15]. According to their assessment PRP functions as a therapeutic agent for regeneration in male patients who experience ED because of vascular deterioration. The placebo group addition in this investigation strengthens findings while eliminating bias because it enables precise evaluation of PRP treatment effectiveness [16].

The therapeutic action of PRP (Group-A) in ED treatment emerges from the high levels of growth factors VEGF, PDGF, TGF-β. The three mentioned factors contribute critically to all processes that sustain normal erectile function by supporting angiogenesis and aiding endothelial repair and restoring smooth muscle health. The research evidence shows that the benefits observed in erectile function stemmed from PRP therapy because the procedure enhanced blood circulation to the penis and promoted the growth of endothelial cells while supporting tissue recovery which helped counteract ED-related changes [17].

The safety parameters from the research study showed positive outcomes because no severe adverse events were documented. Affecting 2% of patients was a minor hematoma while 8% experienced mild penile discomfort that subsided within 24–48 hours. Findings match other research studies which demonstrate that PRP treatment (Group-A) leads to

good tolerance with minimal adverse effects. The safety design of PRP therapy demonstrates its potential to provide an acceptable substitute for phosphodiesterase type-5 inhibitors for those who fail PDE5i treatments or have adverse drug responses [18]. Various restrictions exist when considering these successful research outcomes. This study used a quasi-experimental design approach instead of randomized controlled trials (RCTs) due to its controlled nature without randomized allocation. The brief follow-up duration consisting of two sessions spaced across four weeks hinders the ability to determine the prolonged effectiveness of Platelet-rich plasma therapy [19]. The research failed to separate patients according to their existing medical conditions including diabetes and metabolic syndrome and cardiovascular disease since these health issues could impact PRP therapy results (Group-A). The study failed to conduct a direct comparison between PRP results (Group-A) and PDE5 inhibitors which prevented researchers from determining the effectiveness comparison between these two treatments [20].

Future study design requires optimization of platelet-rich plasma protocols from determining optimal number of injections to growth factor concentration and other ED treatment combinations. The evaluation of PRP treatment according to PDE5 inhibitors and low-intensity shockwave therapy standards would establish its position within ED clinical practice.

Limitation of study

This study has several limitations. The sample size, while adequate, may not be large enough to generalize the findings to a broader population. The follow-up period of 8 weeks is relatively short, limiting insights into the long-term effects of PRP treatment. Variations in PRP preparation and the use of a placebo control group may introduce bias. Additionally, the strict inclusion and exclusion criteria reduce the generalizability of the results to individuals with more complex health conditions. Furthermore, the reliance on subjective measures like IIEF-5 and SEP questionnaires may have influenced the findings, and the short observation for adverse effects may not capture delayed reactions.

Conclusion

The technique of injecting PRP into the cavity of the penis enhances erectile function and strengthens penile hardness along with sexual abilities in men with ED at moderate severity levels while producing minimal adverse consequences. The therapy offers hope as an effective medication-free approach for people who cannot benefit from typical treatment options. The success of intracavernosal PRP therapy requires additional randomized controlled trials to verify its long-term effects and build standard treatment procedures.

Author	Contribution
TMQ	1. Substantial Contribution to study design, analysis, acquisition of Data 2. Manuscript Writing 3. Has given Final Approval of the version to be published
MAK	1. Substantial Contribution to study design, acquisition and interpretation of Data 2. Critical Review and Manuscript Writing 3. Has given Final Approval of the version to be published
GA	1. Substantial Contribution to acquisition and interpretation of Data 2. Manuscript Writing 3. Has given Final Approval of the version to be published
RN	1. Contributed to Data Collection and Analysis 2. Critically reviewed the article 3. Has given Final Approval of the version to be published
MFS	1. Substantial Contribution to study design and Data Analysis 2. Manuscript Writing and Critical review of the article 3. Has given Final Approval of the version to be published
FKT	1. Contributed to study concept and Data collection 2. Critical review of the manuscript 3. Has given Final Approval of the version to be published

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