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Platelet Rich Plasma for the Treatment of Erectile Dysfunction: A Prospective, Randomized, Double-Blind, Placebo-Controlled Clinical Trial

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Abstract

PURPOSE—To assess the safety and efficacy of two injections of platelet rich plasma for treating mild to moderate erectile dysfunction by conducting a prospective, randomized, double-blind, placebo-controlled, clinical trial.

MATERIALS AND METHODS—Men with mild to moderate erectile dysfunction (international index of erectile function scores 11–25) were randomized to receive either two injections of PRP or placebo separated by 1 month. Primary outcome was percentage of men meeting minimum clinically important difference (MCID) at 1 month after the second injection. Secondary outcomes were change in IIEF at 1, 3 and 6 months, and changes in penile vascular parameters and adverse events at 6 months.

RESULTS—We randomized 61 men: 28 into PRP and 33 into placebo. There was no difference between groups in percentage of men meeting MCID at 1 month: 14 (58.3%) in PRP vs. 15 (53.6%) in placebo (P=0.730). Mean IIEF-EF changed from 17.4 (95% CI 15.8–19.0) to 21 (17.9–24.0), at 1 month in men receiving PRP, vs 18.6 (17.3–19.8) to 21.6 (19.1–24.1) in the placebo; however, there was no significant difference between groups (P=0.756). There were no major adverse events, only one minor adverse event in each group. There were no changes in penile Doppler parameters from baseline to 6 months.

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DISCLOSURES

No disclosures

CONSENT FOR PUBLICATION

All authors have provided their consent for publication.

COMPETING INTERESTS

The authors declare no competing interests.

CONCLUSION: The results of our prospective, double-blind, randomized, placebo-controlled clinical trial suggest that two injections of intracavernosal PRP separated by one month in men with mild to moderate ED is safe but we found no difference in efficacy between PRP and placebo.

Keywords

Clinical Trial; Erectile Dysfunction; Platelet-Rich Plasma

INTRODUCTION

Erectile dysfunction (ED) affects as many as 1 in 4 men, and the incidence appears to be increasing[1]. Guideline-supported medical treatments for ED work through transient vasodilation by way of augmentation of the nitric oxide pathway[2]. While these treatments are effective for many men suffering from ED, they are incapable of reversing the underlying pathology. Furthermore, many men will discontinue medical therapies due to lack of efficacy and side effects[3, 4]. Therefore, there is increasing interest in restorative therapies such as shockwave therapy and platelet rich plasma (PRP) that may be capable of reversing underlying pathology and reestablishing natural spontaneous erections.

PRP is an autologous blood product created by centrifugation and separation of whole blood. The PRP layer contains 5x the concentration of platelets as whole blood and is injected into an area of pathology[5]. PRP contains growth factors, including platelet-derived growth factor (PDGF), transforming growth factor β (TGF-β), vascular endothelial growth factor (VEGF), epidermal growth factor (EGF), insulin-like growth factor (IGF), and fibroblast growth factor (FGF)[6] These growth factors are involved in complex healing processes, most notably neoangiogenesis, stimulation of cellular growth, and recruitment of immune cells. These properties have made PRP an attractive treatment for orthopedic injures and sports medicine, and it is widely used for treating osteoarthritis and cartilage defects[7]. Pre-clinical studies also suggest that these growth factors may be beneficial in ED[8–10]. Despite the hypothesized mechanisms and benefits that may make PRP an attractive treatment, there is remarkably little clinical evidence supporting its use in ED. Even without supporting data, numerous clinics in largest metropolitan areas of the Unites States are charging patients for PRP treatments for ED[11].

Our objective was to assess the safety and clinical efficacy of PRP for treating mild to moderate ED through a prospective, randomized, double-blind, placebo-controlled, clinical trial. We hypothesized that PRP would improve erectile function in men with mild to moderate ED as compared to placebo.

METHODS

Study design:

This study was a prospective, randomized, double-blind, placebo-controlled, clinical trial performed at the outpatient clinic of the Desai Sethi Urology Institute, Miami, Florida, United States of America. The study protocol was approved by our institutional review

board (protocol number: 20200373) and registered at ClinicalTrials.gov (ClinicalTrials.gov Identifier: NCT04396795). This study was performed in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement, and all participants provided written informed consent before enrollment. Patients were recruited from May 2020 to August 2022, and the results were obtained in November 2022.

Selection Criteria:

Eligible men were between age 30–75 (inclusive) with organic ED, defined as IIEF score of 11–25 (inclusive) for at least 6 months, with normal testosterone levels, and hemoglobin A1c (HbA1c) less than 9%. Men using intracavernosal injections or urethral suppositories for ED treatment were excluded from participation due to severity of ED. Men were allowed to take and continue PDE5 inhibitors at their same dosage if they were taking them during screening and asked to report either discontinuation or increase in dosage during as well at the end of the study period. No dosage adjustments were allowed during the study period. Men with suspected psychogenic ED based on clinical history as determined by the investigators, with any planned urological surgeries during the study period, or who were deemed unfit for the trial by the principal investigator were excluded.

Study protocol:

Men were prescreened with a thorough history and physical exam, IIEF-EF and SEP3 questionnaires, and measurement of serum testosterone using LC-MS/MS before 10AM, HbA1c, and complete blood count. Eligible men underwent a baseline penile duplex ultrasound to measure penile vascular parameters: peak systolic velocity (PSV), end diastolic velocity (EDV), and resistive index (RI). After signing consent, participants were sequentially randomized 1:1 to receive treatment or placebo. Randomization was performed using RedCap. Only one member of the study team (MM) was aware of the treatment allocations, and that researcher was not involved with data collection and outcome analysis. This study member did not have access to pre- or post-treatment data.

Regardless of randomization, patients underwent two sessions of intracavernosal injections separated by 28± 7 days. Sessions began by obtaining 120ml of autologous blood via phlebotomy of the brachial vein. The blood was processed in a separate room using the Arthrex Angel PRP system. Arthrex Angel is an automated PRP system that contains an optical sensor to separate out the platelet rich layer[5]. Approximately 5ml of PRP was extracted from 120ml whole blood. For the treatment group, the PRP was placed into two 5 ml syringes (2.5ml PRP in each) covered with foil to maintain blinding (supplemental figure 1). In the sham group, the PRP was saved and frozen for future laboratory studies. To prepare for injection, the patient was positioned supine, and ice was applied to the penis for 5 minutes to reduce injection site pain prior to injection. A sterile field was created on the penis. A 1/4-inch Penrose drain was placed at the base of the penis to create a tourniquet and maintained in place under tension with a sterile clamp for 20 minutes. Approximately 2.5 ml of PRP (treatment) or normal saline (sham) was injected into the right and left corpus cavernosum for a total of 5ml (regardless of the amount of PRP that was obtained from 120mL of blood). After 20 minutes, the tourniquet was removed, and the subject released from the clinic. To ensure fair enrollment in the clinical trial, we provided men who were

randomized to placebo during the trial with PRP free of charge after the 6-month follow-up timepoint.

Outcomes:

Primary outcome was percentage of men attaining minimum clinically important difference (MCID) at 1 month after the second injection. MCID is an increase of 2 points for mild ED (starting IIEF-EF 17–25) and 5 points for moderate ED (starting IIEF-EF 11–16)[12]. We continued data collection out to 6 months to assess for safety and durability.

Secondary outcomes were changes in IIEF-EF scores, changes in penile vascular parameters (PSV, EDV) and adverse events. Patients were followed up at 1, 3 and 6 months after last injection to assess for long term side effects and durability of response.

Scientific Rigor and Reproducibility:

We employed a double-blind design to reduce bias and increase the validity of the results. Neither the participants nor the investigators knew the treatment assignment of the participants.

To achieve this, we had only one person in the study team in charge of preparing both the PRP and placebo injections, that were then packaged and labeled in an identical-looking way that the investigators and participants were not able to identify the treatment group. The allocation of participants to the treatment or control groups was done by this same person using a computer-generated randomization schedule.

Additionally, we took steps to ensure that the investigator who was blinded was not involved in the outcome analysis. This was accomplished by assigning the outcome assessment to an independent third party not aware of the participants' treatment assignment. This further helped to reduce bias and increase the validity of the results.

Sample size calculation:

Previous studies on the effect of placebo show about a 15% attaining MCID in men with mild to moderate ED[13]. In the interventional PRP group, we expected 50% of patients would meet MCID. Sample size of 27 patients in each group achieves 80% power to detect a difference of 35% between PRP and placebo, using a two-sided Z-test with pooled variance at 5% significance level. Assuming a 10% dropout rate, we planned to recruit a total of 60 subjects.

Statistical Analysis:

Descriptive statistics were used to summarize demographic and baseline patient characteristics, and primary and secondary outcomes. In general, two groups were compared using chi-square test or Fisher's exact test for categorical variables, and two-sample t-test or Wilcoxon rank-sum test for continuous variables; paired data in each group was compared using the paired t-test or the Wilcoxon signed-rank test for continuous variables or the McNemar's test for categorical variables.

The Wilcoxon signed-rank test was used for comparison of changes in penile vascular parameter PSV from baseline to 6-month follow-up visit in each group, while the Wilcoxon rank-sum test was used for comparisons between groups. Since majority of values for EDV was value 0, we analyzed EDV as a categorical variable (0 vs >0) using the McNemar's test to compare proportions between baseline and 6 months in each group and the chi-square test to compare two proportions between groups at a specific time visit.

For outcome IIEF-EF score, we also performed longitudinal data analysis using a linear mixed model for assessing effects of group, time and their interaction (group×time), using residual maximum likelihood estimation (REML) and assuming any missing data are missing at random. We assumed an unstructured covariance for the time correlated data structure.

The statistical significance was set as P<.05 and analyses were performed in SAS 9.4.

RESULTS

We recruited and randomized 61 men: 28 into PRP and 33 into placebo. We had complete 1-month data for 24 men receiving PRP and 28 receiving placebo. Additionally, we had complete 6-month data for 20 men receiving PRP and 24 receiving placebo (Figure 1). There were no differences in baseline demographics or characteristics between men who received treatment and those who received placebo, except that there were more men with prediabetes receiving placebo compared to PRP (8 vs 1) despite similar median A1c level (Table 1).

For primary outcome, there was no difference between groups in percentage of men attaining MCID at 1 month: 14/24 (58.3%) in PRP group compared to 15/28 (53.6%) in placebo (P=0.730). For secondary outcome, mean IIEF-EF score changes from baseline to 1 month were statistically significant in both groups (mean increases of 3.7, 95% CI 0.5–6.9, P=0.026 in PRP vs 3.1, 95% CI 0.8–5.4, P=0.009 in placebo), but there was no statistically significant difference between groups (P=0.765). Means changes from baseline to 3 months were not statistically significant in each group, and there was no difference between groups at 3 months (P=0.662). However, the mean changes from baseline to 6 months were statistically significant in both groups (mean increases of 5, 95% CI 1.9–8.1, P=0.003 in PRP vs 2.2, 95% CI 0.1–4.3, P=0.045 in placebo), but no difference between groups (P=0.116) (Table 2).

Figure 2 reports the estimated mean of IIEF-EF score obtained from a linear mixed model including group, time, and their interaction effect. The estimated mean scores were very similar to the observed mean scores in Table 2. The interaction effect (P=0.832) and the group effect (P=0.512) were not statistically significant, while the time effect (P=0.002) was significant. Pairwise mean comparison in each group indicated significant increase in IIEF-EF scores at 1- and 6-month follow-up visits relative to baseline.

Supplemental Table 1 reports scores for IIEF intercourse and overall satisfaction domains. There was no difference between groups in both satisfaction scores at any visit time or over time compared to baseline in each group.

Incidence of anticipated adverse events in all patients was recorded during the study period. There were 2 minor adverse events: one patient with new plaque in PRP and one patient with hematoma in placebo. There were no differences in adverse events between groups, and importantly, there were no major adverse events (Table 3).

There were no significant changes in penile Doppler parameters between baseline and 6-month visit in each group (PRP: P=0.927 for PSV and P=0.059 for EDV; Placebo: P=0.210 for PSV, P=0.655 for EDV). Note however, that there was a statistically significant difference between groups in PSV at baseline (means 47.2 in PRP vs 40.5 in placebo, P=0.028), but the difference was not significant at 6 months post-treatment (means 48.8 in PRP vs. 44.7 in placebo, P=0.366). There was no significant difference between groups in EDV at baseline (proportion with EDV>0 in PRP and placebo, respectively, of 21.4% vs. 33.3%, P=0.301) or at the 6 months assessment (37.5% vs 30.8%, P=0.616) (Table 4).

DISCUSSION

We set out to determine if PRP is a safe and effective treatment for men with mild to moderate ED by performing a prospective, randomized, double-blind, placebo-controlled, clinical trial. Our results suggest that PRP is safe as we had almost no adverse events. Importantly, however, we found no difference in efficacy between PRP and placebo. PRP is currently marketed online as a treatment for sports injury, facial aging, hair loss, and ED. Consequently, PRP may be offered in myriad clinical settings for multiple conditions regardless of the evidence[11]. This has resulted in clinics offering PRP for ED long before clinical human studies supported its use or before validated treatment protocols were established. An unfortunate consequence of PRP's rapid adoption is an extreme heterogeneity in treatment protocols, all of which are unsupported by evidence [11]. Therefore, studies such as this are critical to ensuring that men with ED are receiving treatments that are both safe and effective.

The first human study of PRP for the treatment of ED in the United States was published by Matz et al. in 2018. They assessed the safety of PRP in 17 patients with different urological complaints, including five with ED. While not powered to detect any changes in IIEF, their study found that none of the subjects reported worsening ED or adverse events[14]. Since this observational study, there have been two additional clinical trials assessing the safety and efficacy of PRP in ED, both published in 2021. The first was a case series including 31 men with ED associated with metabolic syndrome by Tas et al. They assessed three injections of 3.0ml intracavernosal PRP, administered at intervals of 15 days. At 6-month follow up, 19 (61%) had improved IIEF-EF scores suggesting potential efficacy[15]. Poulios et al. published their double-blind, randomized, placebo-controlled clinical trial in Greece that included 60 men with mild to moderate ED randomized to either two intracavernosal injections of 10ml PRP or 10ml normal saline separated by 1 month. They found that 22/29 (76%) reached IIEF MCID in the PRP group, compared to only 7/28 (25%) in placebo at 6 months[16]. Both studies reported only minor, and very few, adverse events. Based on these earlier studies, we were surprised to find that PRP was no different than placebo in our study. It is possible that differences in patient population and trial design led to these differences. For example, men in our trial were able to continue PDE5 inhibitors without

dose modification throughout the trial to mimic real-world experience; whereas in the other trials, men had to discontinue PDE5 use. Additionally, we used a smaller volume of PRP; 5ml x 2 treatments in our study, vs 6ml x3 treatments vs 10ml x 2 treatments.

To our knowledge, this is the first prospective, randomized, double-blind, placebo-controlled, clinical trial conducted in the United States assessing the safety and efficacy of PRP for ED. We are also the first to utilize the Arthrex Angel centrifuge system, with its optical sensor, to create a more concentrated and less variable PRP product. Despite the strengths of our study, there are notable limitations. The first is the short duration of follow up (6 months) which may be inadequate to assess long-term differences. We also had a dropout rate of nearly 15% for 1 month follow-up in a relatively small study, which may affect outcome data. Additionally, the protocol we utilized was based on prior PRP studies, and it is possible that our protocol of 2 injections, one month apart, will not yield optimal results. It is possible that more injections or a different interval between injections may yield greater changes in IIEF-EF. More research into patient selection, protocol optimization, and PRP dosing is needed.

CONCLUSION

The results of our clinical trial suggest that two injections of intracavernosal PRP separated by one month in men with mild to moderate ED is safe, but no more effective than a placebo. More research is needed into patient selection and treatment protocol to assess for efficacy.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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References

1. Derby CA, et al. , Measurement of erectile dysfunction in population-based studies: the use of a single question self-assessment in the Massachusetts Male Aging Study. Int J Impot Res, 2000. 12(4): p. 197–204. [PubMed: 11079360]
2. Burnett AL, et al. , Erectile Dysfunction: AUA Guideline. J Urol, 2018. 200(3): p. 633–641. [PubMed: 29746858]
3. Kim SC, et al. , Reasons and predictive factors for discontinuation of PDE-5 inhibitors despite successful intercourse in erectile dysfunction patients. Int J Impot Res, 2014. 26(3): p. 87–93. [PubMed: 24305610]
4. Carvalheira AA, et al. , Dropout in the treatment of erectile dysfunction with PDE5: a study on predictors and a qualitative analysis of reasons for discontinuation. J Sex Med, 2012. 9(9): p. 2361–9. [PubMed: 22616766]
5. Baria M, et al. , Cellular Components and Growth Factor Content of Platelet-Rich Plasma With a Customizable Commercial System. Am J Sports Med, 2019. 47(5): p. 1216–1222. [PubMed: 30848659]
6. Pavlovic V, et al. , Platelet Rich Plasma: a short overview of certain bioactive components. Open Med (Wars), 2016. 11(1): p. 242–247. [PubMed: 28352802]

7. Zhu Y, et al. , Basic science and clinical application of platelet-rich plasma for cartilage defects and osteoarthritis: a review. Osteoarthritis Cartilage, 2013. 21(11): p. 1627–37. [PubMed: 23933379]

8. Campbell JD and Burnett AL, Neuroprotective and Nerve Regenerative Approaches for Treatment of Erectile Dysfunction after Cavernous Nerve Injury. Int J Mol Sci, 2017. 18(8).

9. Ding XG, et al. , The effect of platelet-rich plasma on cavernous nerve regeneration in a rat model. Asian J Androl, 2009. 11(2): p. 215–21. [PubMed: 19151738]

10. Wu CC, et al. , The neuroprotective effect of platelet-rich plasma on erectile function in bilateral cavernous nerve injury rat model. J Sex Med, 2012. 9(11): p. 2838–48. [PubMed: 22906160]

11. Shahinyan GK, et al. , Analysis of Direct-to-Consumer Marketing of Platelet-Rich Plasma for Erectile Dysfunction in the US. JAMA Netw Open, 2022. 5(5): p. e2214187. [PubMed: 35616943]

12. Rosen RC, et al. , Minimal clinically important differences in the erectile function domain of the International Index of Erectile Function scale. Eur Urol, 2011. 60(5): p. 1010–6. [PubMed: 21855209]

13. Montorsi F, et al. , A randomized, double-blind, placebo-controlled, parallel study to assess the efficacy and safety of once-a-day tadalafil in men with erectile dysfunction who are naive to PDE5 inhibitors. J Sex Med, 2011. 8(9): p. 2617–24. [PubMed: 21707928]

14. Matz EL, Pearlman AM, and Terlecki RP, Safety and feasibility of platelet rich fibrin matrix injections for treatment of common urologic conditions. Investig Clin Urol, 2018. 59(1): p. 61–65.

15. Tas T, et al. , Early Clinical Results of the Tolerability, Safety, and Efficacy of Autologous Platelet-Rich Plasma Administration in Erectile Dysfunction. Sex Med, 2021. 9(2): p. 100313. [PubMed: 33529814]

16. Poulios E, et al. , Platelet-Rich Plasma (PRP) Improves Erectile Function: A Double-Blind, Randomized, Placebo-Controlled Clinical Trial. J Sex Med, 2021. 18(5): p. 926–935. [PubMed: 33906807]

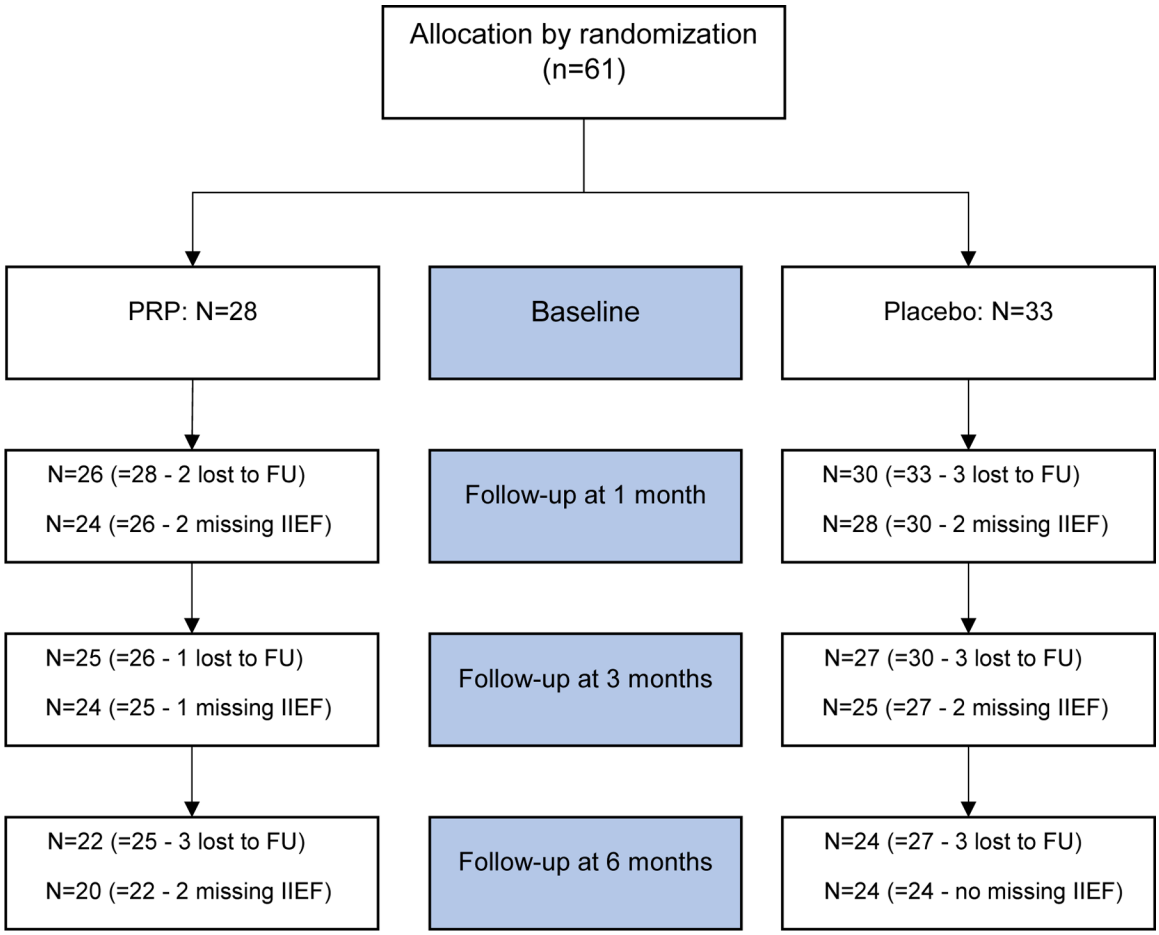

Figure 1.
Patient flow diagram

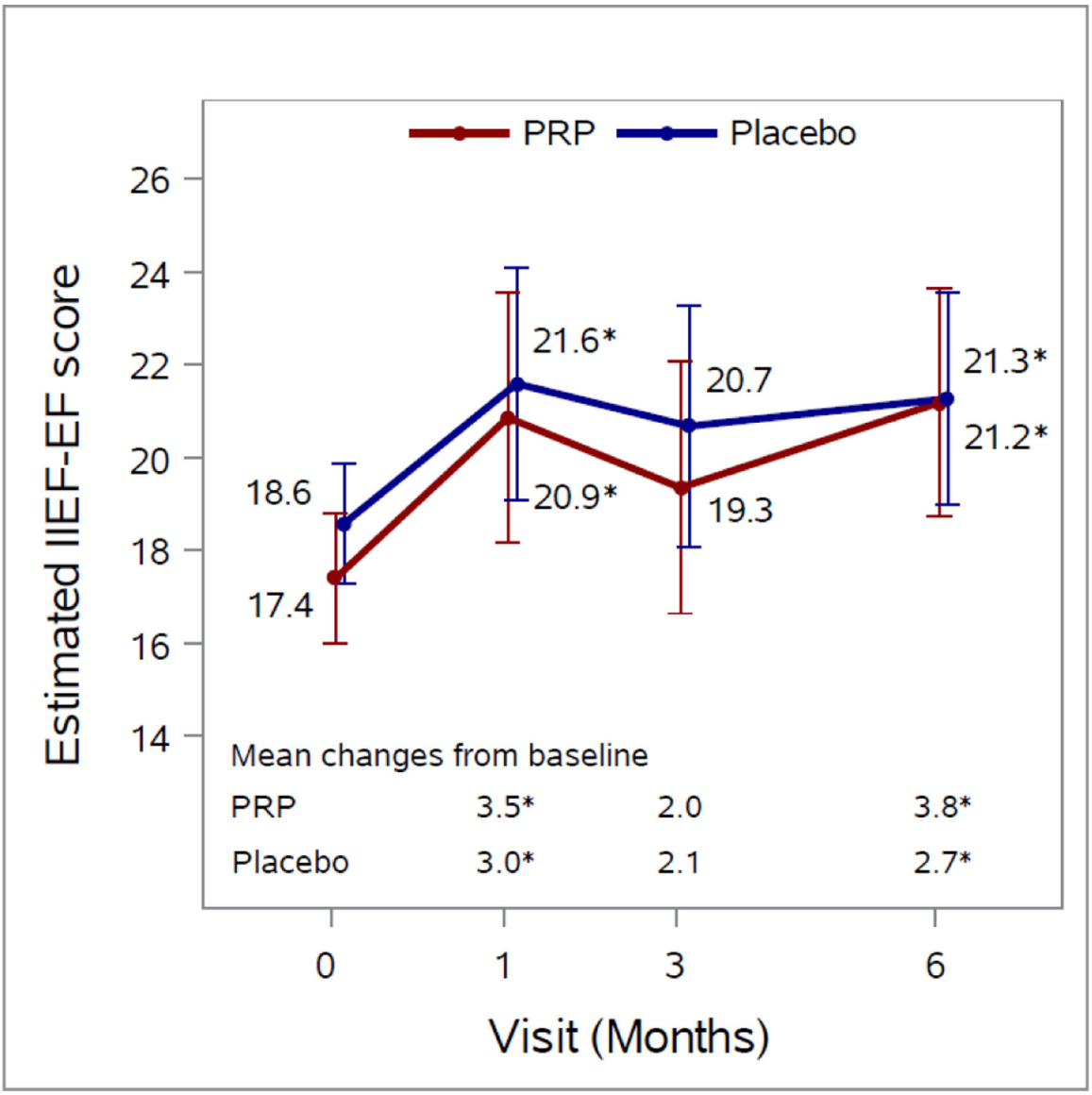

Figure 2.

Estimated IIEF-EF score means with corresponding 95% confidence intervals from longitudinal data analysis. Asterisks (*) indicate statistically significant difference between baseline and a specific follow-up time in each group (P<0.05). There were no significant differences between groups at any visit (P>0.05).

Table 1.

Baseline characteristics

Characteristic	PRP	Placebo
Total patients, n (%)	28 (100)	33 (100)
Age in years, median (p25, p75)	49 (38.5, 55)	46 (42, 56)
BMI in kg/m^2, n (%)		
<25 (healthy)	8 (28.6)	4 (12.1)
25–29.9 (overweight)	13 (46.4)	16 (48.5)
≥30 (obese)	7 (25)	13 (39.4)
Median (p25, p75)	27.9 (24.5, 30.3)	28.5 (25.7, 31.1)
Not current smoker, n (%)	26 (92.9)	33 (100)
CAD, n (%)	3 (10.7)	3 (9.1)
HTN, n (%)	8 (28.6)	10 (30.3)
HLD, n (%)	7 (25)	8 (24.2)
DM, n (%)	3 (10.7)	3 (9.1)
No. of comorbidities, n (%)		
0	14 (50)	18 (54.5)
1	7 (25)	10 (30.3)
2+	7 (25)	5 (15.2)
Hemoglobin A1c at baseline, n (%)		
<5.7% (normal)	24 (85.7)	24 (72.7)
5.7–6.4% (pre-diabetes)	1 (3.6)	8 (24.2)
≥6.5% (diabetes)	3 (10.7)	1 (3)
Median (p25, p75)	5.4 (5.2, 5.6)	5.3 (5.1, 5.7)
T-level in ng/dL, median (p25, p75)	493 (388.5, 605.5)	520 (383, 699)
Erectile dysfunction, n (%)		
Mild (IIEF-EF scores 17–25)	16 (57.1)	21 (63.6)
Moderate (IIEF-EF scores 11–16)	12 (42.9)	12 (36.4)

BMI: body mass index; CAD: coronary artery disease; HTN: hypertension; HLD: Hyperlipidemia; DM: diabetes mellitus; No. of comorbidities: count of history of CAD, HTN, HLD, and DM; T-level: testosterone-level; IIEF-EF: International Index of Erectile Function-Erectile Function domain.

p25, p75: 25 and 75 percentiles.

Note: There were no significant differences between the two groups with respect to all baseline characteristic except for Hemoglobin A1c at baseline as 3 categories (P=0.046).

Table 2.

MCID, ED, and IIEF-EF scores

	Baseline		1 month		3 months		6 months	
	PRP	**Placebo**	**PRP**	**Placebo**	**PRP**	**Placebo**	**PRP**	**Placebo**
MCID based on IIEF-EF, n (%)								
Yes	NA	NA	14 (58.3)	15 (53.6)	10 (41.7)	13 (52)	12 (60)	10 (41.7)
No	NA	NA	10 (41.7)	13 (46.4)	14 (58.3)	12 (48)	8 (40)	14 (58.3)
P_1	NA	NA	NA	0.730	NA	0.469	NA	0.226
ED, n (%)								
No	NA	NA	7 (29.2)	9 (32.1)	7 (29.2)	6 (24)	7 (35)	4 (16.7)
Mild	16 (57.1)	21 (63.6)	12 (50)	13 (46.4)	8 (33.3)	15 (60)	9 (45)	15 (62.5)
Moderate	12 (42.9)	12 (36.4)	3 (12.5)	4 (14.3)	4 (16.7)	2 (8)	2 (10)	5 (20.8)
Severe	NA	NA	2 (8.3)	2 (7.1)	5 (20.8)	2 (8)	2 (10)	NA
P_1	NA	0.605	NA	0.989	NA	0.247	NA	0.152
IIEF-EF score								
N	28	33	24	28	24	25	20	24
Mean	17.4	18.6	21	21.6	19.2	20.6	22.2	20.5
95% CI	(15.8, 19.0)	(17.3, 19.8)	(17.9, 24.0)	(19.1, 24.1)	(15.9, 22.4)	(18.1, 23.2)	(18.9, 25.4)	(18.5, 22.6)
Median	18.0	18.0	23.5	24.0	21.5	21.0	24.0	21.0
P25, P75	14, 20	15, 22	17.5, 26.5	17.5, 27.0	13, 26	17, 25	18.5, 28.0	17, 24
Mean diff.	NA	−1.2	NA	−0.7	NA	−1.4	NA	1.6
(95% CI)		(−3.1, 0.8)		(−4.5, 3.2)		(−5.5, 2.6)		(−2.0, 5.2)
P_2	NA	0.231	NA	0.722	NA	0.466	NA	0.376
IIEF-EF score changes from baseline								
N	NA	NA	24	28	24	25	20	24
Mean	NA	NA	3.7*	3.1*	1.4	2.2	5*	2.2*
95% CI	NA	NA	(0.5, 6.9)	(0.8, 5.4)	(−1.6, 4.5)	(−0.2, 4.6)	(1.9, 8.1)	(0.1, 4.3)
Median	NA	NA	4.5	2.0	1.0	2.0	3.5	2.0
P25, P75	NA	NA	0.0, 8.5	−0.5, 8.0	−3.0, 7.5	−1.0, 6.0	0.0, 9.5	−2.5, 7.0
Mean diff.	NA	NA	NA	0.6	NA	−0.8	NA	2.8
(95% CI)				(−3.2, 4.4)		(−4.6, 2.9)		(−0.7, 6.4)
P_2	NA	NA	NA	0.765	NA	0.662	NA	0.116

MCID: minimum clinically important difference; MCID based on IIEF-EF score was defined as an increase of ≥2 for patients with baseline mild ED (baseline IIEF-EF score of 17–25), and ≥5 for patients with baseline moderate ED (score of 11–16).

ED: erectile dysfunction; ED categories based on the IIEF-EF score: no ED (26–30), mild (17–25), moderate (11–16), and severe (0–10). IIEF-EF: International Index of Erectile Function-Erectile Function domain.

95% CI: 95% confidence interval. P_1: p-value from chi-square test, P_2: p-value from two-sample t-test.

*: significant difference from baseline ($p<0.05$) from paired t-test in each group. NA: not applicable.

Table 3.

Adverse events of PRP and placebo injections

	PRP	Placebo
N	28	33
Mean Pain with Injection 1 (score 1 to 10)	3.7	3.5
Mean Pain with Injection 2 (score 1 to 10)	4.1	4
Adverse Events, n (%)		
Major (grade 3+) Adverse Events	0 (0%)	0 (0%)
Minor (grade 1, 2) Adverse Events	1 (3.6%)	1 (3.0%)
Hematoma	0 (0%)	1 (3.0%)
New Plaque	1 (3.6%)	0 (0%)

Note: No patient had any of the following per-protocol anticipated adverse events: infection, swelling, and local injection site reaction, such as bruising, edema, and allergy.

Table 4.

Penile vascular parameters (PSV and EDV)

	PRP			Placebo		
	Baseline	**6 months**	**Change**	**Baseline**	**6 months**	**Change**
PSV						
N	28	24	24	33	26	26
Mean	47.2	48.8	0.4	40.5	44.7	4.7
95% CI	(42.1, 52.4)	(42.1, 55.4)	(−7.8, 8.5)	(36.9, 44.1)	(38.3, 51.1)	(−2.8, 12.2)
Median	44.2	48.8	0.8	37.6	43.1	1.5
P25, P75	36.8, 58.0	42.5, 56.7	−9.6, 15.3	34.5, 44.6	36.5, 55.8	−3.4, 14.8
$P_{1\ (between\ groups)}$	0.028	0.366	0.425	NA	NA	NA
$P_{2\ (change\ in\ a\ group)}$	NA	NA	0.927	NA	NA	0.210
EDV, n (%)						
EDV=0	22 (78.6)	15 (62.5)	NA	22 (66.7)	18 (69.2)	NA
EDV>0	6 (21.4)	9 (37.5)	NA	11 (33.3)	8 (30.8)	NA
$P_{1\ (between\ groups)}$	0.301	0.616	NA	NA	NA	NA
$P_{2\ (change\ in\ a\ group)}$	NA	NA	0.059	NA	NA	0.655

PSV: Peak Systolic Velocity; EDV: End Diastolic Velocity; 95% CI: 95% confidence interval; NA: not applicable.

$P_{1\ (between\ groups)}$: p-value from two-sample t-test for PSV and from chi-square test for EDV.

$P_{2\ (change\ in\ a\ group)}$: p-value from paired t-test for PSV and from McNemar's test for EDV.