Efficacy of Platelet Rich Plasma in Erectile Dysfunction: A Clinical Trial

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Abstract

Background: Platelet-rich plasma (PRP) is a treatment that uses a patient's own blood, processed to concentrate platelets and growth factors, to treat erectile dysfunction (ED). Erectile dysfunction (ED) is a common condition that affects men of all ages and can have a significant impact on quality of life. Platelet-rich plasma (PRP) is a newer treatment option that involves injecting a concentrated solution of platelets into the affected area to promote healing and tissue regeneration. Objective: The purpose of the present study was to evaluate the efficacy of platelet-rich plasma (PRP) in treating erectile dysfunction (ED). Methodology: A prospective study was conducted to evaluate the efficacy of platelet-rich plasma (PRP) in treating erectile dysfunction (ED) with a sample of 50 patients in Dhaka, Bangladesh during the period of January 2022 to June 2022. The patients received PRP treatment and the improvement in erectile function was measured through standardized questionnaires and scales. Data were collected predesigned data collection sheet. Results: The average age of the study subjects is 53.70 years. The mean scores of the IIEF-EF domain showed a statistically significant improvement from 18.50 ± 3.60 before the procedure to 20.71 ± 3.71 after 6 months (p = 0.002). Sexual satisfaction also showed a statistically significant improvement, with a mean score increasing from 6.00 ± 0.57 before the procedure to 8.00 ± 0.85 after 6 months (p = 0.016). However, there were no statistically significant changes in the mean scores for orgasmic function and sexual desire (p = 0.113 and p = 0.389, respectively). The mean score for general satisfaction showed a small but statistically significant increase from 5.00 ± 0.29 before the procedure to 5.38 ± 0.24 after the 1st month (p = 0.027). Conclusion: In conclusion platelet-rich plasma (PRP) application provides short-term improvement in erectile function. [Journal of National Institute of Neurosciences Bangladesh, January 2023;9(1):71-75]

Keywords: Efficacy; platelet rich plasma; erectile dysfunction

Introduction

Erectile dysfunction (ED) is described as an inability to achieve or maintain a penile erection that is sufficient for sexual intercourse. It is a common disease that may have a negative impact on male sexual health and quality of life¹. Previously, ED was seen as a completely psychogenic disease; however, current evidence suggests that ED pathogenesis is associated with a large number of factors. About 80.0% of patients have at least a partial organic etiology². ED is associated with many comorbidities and risk factors such as diabetes mellitus (DM), obesity, age, alcohol, smoking, cardiovascular disease, depression, previous pelvic surgery and spinal cord injuries, and other psychological variables³. Platelet-rich plasma (PRP) is an autologous plasma fraction produced from the centrifugation of whole blood that contains a 3- to 7-times higher mean platelet concentration compared to whole blood⁴. Due to the beneficial properties of growth factors contained in high concentrations in this fraction, numerous medical
specialties have included PRP injections in the quiver of their offered treatment options\(^1\). Currently, PRP intracavernosal injections emerged as a promising, angiogenic, vascogenic and regenerative treatment modality for ED\(^2\).

Despite the favorable outcomes of PRP and the exploding interest in regenerative medicine, limited data support its use as part of the established ED therapeutic algorithm\(^3\). Given the paucity of human clinical trials, there is currently an unmet need for high-quality studies exploring the use of PRP for the management of ED\(^4\). Over the past few years, the use of PRP as a therapeutic tool has led to significant progress in the field of regenerative medicine\(^5\). It has been reported that PRP has positive effects on ED in experimental studies\(^6\). This study to assess the efficacy and safety of PRP injections in patients with erectile dysfunction.

Methodology

Study Settings and Population: This study was a non-randomized clinical trial performed in the EW VM Health Bangladesh Ltd., Dhaka for a period of 6 month. Patients were sexually active patients with mild and moderate ED. At initial screening, all eligible patients underwent detailed medical history by two experienced physicians, extensive physical examination and appropriate medical tests.

Platelet-rich plasma (PRP) Preparation: All participants had their blood drawn into tubes containing 1.5 ml of anticoagulant citrate dextrose solution, which were then centrifuged at 2,800 rpm for 8 minutes. The resulting plasma layer was centrifuged again at 3,500 rpm for 10 minutes, and a solution containing 1,000-2,000 x 103/uL PRP was prepared in the laboratory. Using a 25 gauge needle, 3 cc of PRP (total amount = 3 x (1,000-2,000) x 106) was injected into each corpora cavernosa. Topical anesthetic cream was applied to the injection site, and a Stockmann penis clamp was used during injection to prevent PRP leakage without obstructing the dorsal artery and superficial/deep dorsal vein. The injection sites were spaced 1 cm apart in the mid-penile region.

Intervention and Follow Up: All included patients underwent the first session of PRP or placebo injections within the same visit. An additional administration was performed one month after the initial session. Accordingly, participants were assessed at 1, 3 and 6 months after completion of the treatment protocol.

Statistical Analysis: Data was collected using a pre-designed form and analyzed using SPSS version 25. Statistical tests such as two-tailed Student’s t-test and paired t-test were used to assess the efficacy of the treatment, with a p value measured between pre-treatment and post-treatment.

Ethical Consideration: All procedures of the present study were carried out in accordance with the principles for human investigations (i.e., Helsinki Declaration) and also with the ethical guidelines of the Institutional research ethics. Formal ethics approval was granted by the Ethics Review Committee of Local Institute. Participants in the study were informed about the procedure and purpose of the study and confidentiality of information provided. All participants consented willingly to be a part of the study during the data collection periods. All data were collected anonymously and analyzed using the coding system.

Results

This study showed that the average age of the study subjects was 53.70 years and the standard deviation was 7.91 years (Table 1).

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>41 to 50 Years</td>
<td>12</td>
<td>24.0</td>
</tr>
<tr>
<td>51 to 60 Years</td>
<td>23</td>
<td>46.0</td>
</tr>
<tr>
<td>61 to 70 Years</td>
<td>15</td>
<td>30.0</td>
</tr>
<tr>
<td>Mean±SD</td>
<td>53.70±7.91</td>
<td></td>
</tr>
</tbody>
</table>

The duration of ED was presented as a range, 5.0 (3.0-8.0), which indicated that the majority of the study subjects had an ED duration of between 3.0 and 8.0 years. The mean BMI of the study subjects was 25.39 ± 4.92, with a standard deviation of 4.92.

In terms of hypertension, 24 (48.0%) of the study subjects had hypertension, while 26 (52.0%) did not. In

<table>
<thead>
<tr>
<th>Base Line Characteristics</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of ED (Mean±SD)</td>
<td>5.11±0.67</td>
<td>48.0</td>
</tr>
<tr>
<td>Mean BMI (kg/m2)</td>
<td>25.39 ± 4.92</td>
<td></td>
</tr>
<tr>
<td>Hypertension, No (%)</td>
<td>24</td>
<td>48.0</td>
</tr>
<tr>
<td>Triglycerides (mg/dL), No (%)</td>
<td>48.0</td>
<td></td>
</tr>
<tr>
<td>&lt;150</td>
<td>24</td>
<td>48.0</td>
</tr>
<tr>
<td>≥150</td>
<td>26</td>
<td>52.0</td>
</tr>
<tr>
<td>HDL (mg/dL), No (%)</td>
<td>38.0</td>
<td></td>
</tr>
<tr>
<td>&lt;40</td>
<td>19</td>
<td>38.0</td>
</tr>
<tr>
<td>≥40</td>
<td>14</td>
<td>38.0</td>
</tr>
<tr>
<td>Dyslipidemia, No (%)</td>
<td>28.0</td>
<td></td>
</tr>
<tr>
<td>Impaired glucose tolerance, No (%)</td>
<td>16</td>
<td>32.0</td>
</tr>
</tbody>
</table>
organic etiology. ED is associated with many psychogenic diseases; however, current evidence suggests Erectile dysfunction (ED) is described as an inability to achieve or maintain an erection sufficient for satisfactory sexual performance. Platelet-rich plasma (PRP) is an autologous plasma modality for ED.

Accordingly, participants were assessed at 1, 3, and 6 months (p = 0.016). However, there were no statistically significant changes in the mean scores for orgasmic function and sexual desire (p = 0.113 and p = 0.389, respectively). The mean score for general satisfaction showed a small but statistically significant increase from 5.00 ± 0.29 before the procedure to 5.38 ± 0.24 after the 1st month (p = 0.027).

**Discussion**

Platelet-rich plasma (PRP) therapy is a treatment that uses a component of blood to promote healing and tissue generation, and it has been used to treat various conditions such as tendon or muscle injuries and stimulate hair growth. However, limited scientific evidence exists on the efficacy of PRP injections for treating erectile dysfunction (ED). The recent double-blind, randomized, placebo-controlled trial has assessed the efficacy and safety of PRP injections in patients with mild and moderate ED. The results showed that PRP injections significantly improved erectile function compared to the placebo group. PRP injections also had a favorable safety profile, with no major adverse events reported.

This study to evaluate the effectiveness of PRP injections in improving erectile function, as measured by changes in the International Index of Erectile Function (IIEF) score, in male patients with mild to moderate ED over a period of six months. The result of the study shows that the average age of the study subjects was 53.70 years, with a standard deviation of 7.91 years. This information can be used to understand the characteristics of the study population and to assess the generalizability of the study findings to other populations with similar age ranges. Previous studies show that ED is quite common, with about one-half of men over age 40 affected by it. The causes of ED can be physical, psychological, or a combination of the two, with physical causes being more common in older men. Physical causes of ED include diseases affecting blood flow, such as hardening of the arteries, and nerve disorders. ED affects about 35% of men over the age of 60 and 50% of men over the age of 70, highlighting the need for effective treatments for this condition.

The study found that the duration of ED in the majority of subjects ranged between 3.0 and 8.0 years. The mean BMI of the subjects was 25.39 ± 4.92, with a standard deviation of 4.92. 48.0% of the subjects had hypertension, while 52.0% had levels less than 40 mg/dL, while 19 (38.0%) had levels equal to or greater than 40 mg/dL. 14 (28.0%) of the study subjects had dyslipidemia, and 16 (32.0%) had impaired glucose tolerance (Table 2).

The mean scores of the IIEF-EF domain showed a statistically significant improvement from 18.50 ± 3.60 before the procedure to 20.71 ± 3.71 after 6th months (p = 0.002). This suggests that the procedure has a positive impact on the patients’ erectile function. Sexual satisfaction also showed a statistically significant improvement, with a mean score increasing from 6.00 ± 0.57 before the procedure to 8.00 ± 0.85 after 6th months.

However, there were no statistically significant changes in the mean scores for orgasmic function and sexual desire (p = 0.113 and p = 0.389, respectively). The mean score for general satisfaction showed a small but statistically significant increase from 5.00 ± 0.29 before the procedure to 5.38 ± 0.24 after the 1st month (p = 0.027).

**Table 3. International Index of Erectile Function Erectile Function (Mean±SD)**

<table>
<thead>
<tr>
<th>Values</th>
<th>Baseline</th>
<th>1st month</th>
<th>3rd month</th>
<th>6th month</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIEF-EF</td>
<td>18.50±3.60</td>
<td>20.71±3.71</td>
<td>20.71±3.71</td>
<td>20.71±3.71</td>
<td>0.002</td>
</tr>
<tr>
<td>Orgasmic function</td>
<td>7.12±0.67</td>
<td>7.12±0.67</td>
<td>7.12±0.67</td>
<td>7.12±0.67</td>
<td>0.113</td>
</tr>
<tr>
<td>Sexual desire</td>
<td>9.37±0.03</td>
<td>9.37±0.03</td>
<td>9.37±0.03</td>
<td>9.37±0.03</td>
<td>0.389</td>
</tr>
<tr>
<td>Sexual satisfaction</td>
<td>6.00±0.57</td>
<td>8.00±0.85</td>
<td>8.00±0.85</td>
<td>8.00±0.85</td>
<td>0.016</td>
</tr>
<tr>
<td>General satisfaction</td>
<td>5.00±0.29</td>
<td>5.38±0.24</td>
<td>5.00±0.29</td>
<td>5.00±0.29</td>
<td>0.027</td>
</tr>
</tbody>
</table>
improvement, with a mean score increasing from 6.00 ± 0.57 before the procedure to 8.00 ± 0.85 after 6 months. However, there were no statistically significant changes in the mean scores for orgasmic function and sexual desire. The mean score for general satisfaction showed a small but statistically significant increase from 5.00 ± 0.29 before the procedure to 5.38 ± 0.24 after the 1st month. Wu et al optimized the PRP production technology in humans. They concluded that human PRP, prepared in accordance with advanced technology, contains a large number of growth factors and consequently promotes the recovery of erectile function.9 Epifanova et al10. reported that PRP application improved IIEF-5 in patients with ED. The authors concluded that PRP contains an amount of growth factors required for therapeutic effect, and the method is reliable due to the absence of adverse effects. In another study conducted by Matz et al11. They reported that the IIEF-5 score increased after PRP injection in patients with ED and Peyronie disease (PD). At the same time, 80% (4/5) of patients with PD who were followed up reported a subjective improvement in their degree of curvature initially. However, there were few patients in this study. In our study, we determined that the IIEF-EF values of patients with ED who received PRP increased significantly compared with before the application. Our results are compatible with previous studies. However, even though IIEF-EF values increased numerically, median value remained within the mild-moderate classification. Therefore, we can only mention that there is a numerical improvement in IIEF-EF values rather than a clinical improvement. In addition, postprocedure sexual satisfaction scores were significantly higher than preprocedure values. The reason for the increased sexual satisfaction values may be related to the increased frequency of sexual intercourse, as determined by the question “How many times have you attempted sexual intercourse in the last 4 weeks?”. Fibrosis, a PD-like plaque and a penile curvature deformity are serious adverse reactions to intracavernous injection of vasoactive medication12-14. Due to limited research on PRP and ED, further studies are needed to establish a clear consensus on its effectiveness.

Conclusion
This study showed that two PRP intracavernosal injections were both safe and effective for improving erectile function in patients with mild and moderate erectile dysfunction (ED). PRP intracavernosal injection treatment is a promising new addition to the field of regenerative medicine and appears to be a viable option for urologists. However, more high-quality studies are necessary to support our findings before it can be fully accepted as part of the ED treatment.

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Conflict of interest: There is no conflict of interest relevant to this paper to disclose.

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Contribution to authors: Khan AT, Hashem MA, Hassan MK conceived and designed the study, analyzed the data, interpreted the results, and wrote up the draft manuscript. Jakia M, Sarkar N, Sakib MIU, Begum S involved in the manuscript review and editing. All authors read and approved the final manuscript.

Data Availability
Any inquiries regarding supporting data availability of this study should be directed to the corresponding author and are available from the corresponding author on reasonable request.

Ethics Approval and Consent to Participate
Ethical approval for the study was obtained from the Institutional Review Board. As this was a prospective study the written informed consent was obtained from all study participants. All methods were performed in accordance with the relevant guidelines and regulations.

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