



Effect of Low-Energy Shockwave Therapy Versus Platelets Rich Plasma Therapy in Patients with Erectile Dysfunction

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Authors' contributions

This work was carried out in collaboration among all authors. Authors KS, MS designed the study, performed the statistical analysis, wrote the protocol, and wrote the first draft of the manuscript. Author HAM, RAS, MN, SA, MAR and AB managed the analyses of the study. Authors MMH and QA managed the literature searches. All authors read and approved the final manuscript.

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ABSTRACT

Phosphodiesterase 5 inhibitors (PDE5Is) and low-energy shock wave therapy (LESWT) have created a revolution in the treatment of erectile dysfunction (ED). However, they are not able to restore the actual changes in the penis. An emerging new therapy called platelet-rich plasma (PRP) is believed to be more beneficial in treating ED. The objective of this study is to evaluate and compare the efficacy of LESWT and PRP in treating ED. A total of sixty participants of pathological ED was included in the study and divided into two groups. Group A received the LESWT, whereas

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Group B received the PRP. The benefits were measured by the International Index of Erectile Function (IIEF), an erection hardness score (EHS) and Self-Esteem And Relationship (SEAR) questionnaires. The results of this analysis demonstrated a larger effect in treatment group B in percentage terms, but there were no statistical differences in the two groups. In the near future, PCP may be a new modality for treating ED, especially PDE5I non-respondents with organic ED. However, more extensive preclinical and applied research needs to be conducted.

Keywords: Erectile disfunction; low-energy shock wave therapy; platelets rich plasma therapy; international index of erectile function; erection hardness score.

1. INTRODUCTION

Erectile dysfunction (ED), also referred to as impotence, is the type of sexual dysfunction in which the penis does not manage to become or stay erect during sexual activity. This is the most frequent sexual issue among men. Because of its connection to self-image and sex problems, erectile dysfunction can cause psychological harm. In approximately 80 percent of cases, physical causes can be identified [1]. This includes cardiovascular disease, diabetes mellitus, neurological problems, such as those following prostatectomy, hypogonadism and medication side effects. Approximately 10% of cases are psychologically impotent, caused by thoughts or feelings here, there is a strong response to placebo treatment [2]. In addition to penile implants and lifestyle changes, techniques that include drugs and injections provide treatment options upon request. Shock wave therapy could be a possible alternative [3]. Insufficiency of blood supply to the penis is a common underlying cause of ED, known as vascular ED. Shock wave therapy can work better for individuals with this condition, as experts believe it increases the blood supply [4]. Platelet-rich plasma (PRP) found its use in the treatment of various conditions and diseases, because PRP concentrated plasma consists of numerous growth factors. Their interaction with surrounding cells, the intracellular matrix and the mediators at the injection point leads to tissue regeneration. Angiogenic, vasculogenic, and regenerative impacts of PRP may be used for erectile dysfunction (ED) treatment [5]. A very little clinical data is available on PRP for the treatment of ED. The current study was design to analyze the effectiveness of PRP as compare to the low energy shock wave therapy.

2. MATERIALS AND METHODS

The current prospective clinical trial was conducted in Lahore General Hospital from Jan 2019 to dec 2020 till the completion of sixty response. Total of sixty (n=60) participants of

diagnosed cases of pathological erectile dysfunction were included in the study after taken the informed consent written consent. Study was approved by the institutional review board. Participant were divided into two groups according to the treatment options. Both groups have equal number of participants with no confounding factors. Group A was treated with low-energy shock wave therapy whereas Group B was given PRP for the treatment of ED.

2.1 Protocols of Treatment

After a 4-week elimination period of previous treatment and a detailed explanation, participants entered one of the two active treatment groups, either a 6-week LESWT or PRP therapy.

2.2 LESWT

The LESWT protocol comprised of 2 sessions per week for 3 weeks, which were repeated after a 3-week interval (5). LESWT was applied to each treatment session for 3 minutes at 5 different anatomical sites of the penis (3 positions on the penis stem and 2 on the penis cross). Each LESWT contained 300 shocks per treatment point at a power density of 0.09 mJ/mm² and a frequency of 120/min. Participants in the LESWT arm were not allowed to take sildenafil or other types of PDE5i tablets for the duration of the trial.

2.3 PRP

At each visit 9ml of venous blood was taken and placed in a 9ml vacuum tube with 3.8% sodium citrate solution. Then it was centrifuged to 500 G for 5 minutes, then to 1500 G for 3 minutes. 1 ml of plasma was collected and activated by 0.1 ml of 10% calcium chloride solution. The treatment procedure using PRP consists of a complex of injections performed using a syringe (1.0 ml capacity) along the lateral surface of the penis: proximally, distally 1.0 ml per each locus; further 1.0 ml approaching albuginea (Multifocal); further

on 0.5 ml of PRP in both ischia-cavernous muscles; and 1.0 ml per each peduncle of the penis. This process was repeated every week for 6 weeks.

In the beginning and after 12 weeks of procedure, efficacy of treatment was assessed by three main parameters, the International Index of Erectile Function (IIEF), an erection hardness score (EHS) and Self-Esteem And Relationship (SEAR) questionnaires. Statistical analysis was done by using SPSS software (version 21) and p value less the 0.05 considered statistically significant.

3. RESULTS

This study included the sixty male participants of erectile dysfunction. Group A had thirty males with mean age of 42.56 ± 7.44 years whereas group B included males with mean age 45.89 ± 9.11 .

Table 1. Percentage of participants showed Positive results after 12 weeks in both groups

VARIABLES	GROUP A	GROUP B
IIEF-5	80.4%	81.3%
EHS	78.3%	78.1%
SEAR	71.7%	62.5%

Improvements were reported at third month follow-up, the response with 80.4% in IIEF-5, 78.3% in EHS, and 71.7% in SEAR in the LESWT group. Similarly positive response was seen in PRP group, with 81.3% in IIEF-5, 78.1% in EHS, and 62.5% in SEAR. (Table 1).

At baseline, the IIEF-5 score was equal in both groups in the LESWT group (Group A) and in the PRP group (Group B). The mean (SD) score in IIEF-5 for LESWT and PRP was 20.21 and 21.26 at 12th week ($P > 0.05$) with no statistically significant difference. The EHS and SEAR were similar to IIEF-5, which was equal at baseline and showed similar improvement after 12 weeks in erectile dysfunction with no statistical difference (Table 2).

4. DISCUSSION

Based on our study and analysis, PRP showed similar or statistically non-significant efficacy in patients with ED in general compared to LESWT.

We observed that LESWT had a treatment result similar to the PRP measured by IIEF-5 and other instruments in patients with ED. During the 12-

week follow-up, similar results were observed in both groups, as measured by IIEF-5, EHS and SEAR post-treatment. In previous studies, oral treatment with phosphodiesterase type 5 (PDE5i) inhibitors (sildenafil) was found to improve immediately following administration of the drug. A longer duration may be required by the LESWT and PRP to demonstrate its efficacy, which, on the other hand, has been maintained over a longer period. Improvements to the IIEF-5 and EHS measures indicated that both treatments were effective in improving erection function. The increase in SEAR's score also indicated that regular and voluntary treatment may improve psychological status, particularly with respect to SEAR with the partner.

More time was needed for LESWT and PRP to reach their therapeutic effect. we observed continuous improvements in both groups with 12 weeks of follow-up over the baseline, which was particularly reflected by the SEAR score. Rather than taking pills just before sexual intercourse, both PRP and LESWT provided a new treatment model that was more stable and proactive, helping participants to re-establish their confidence. These new therapeutic approaches partially addressed the unmet needs of ED patients, including those who could not take oral drugs due to clinical concerns or subjective rejection [6].

Our findings showed that LESWT and PRP were an alternative to PDE5i in ED patients. Compared to sildenafil, LESWT and PRP has shown more potential to achieve a long-term therapeutic effect due to its addressing underlying neovascularization mechanisms [7], which is advantageous to these novel therapies, but the results of our study indicated both of these therapies had almost similar efficacy in the treatment of ED.

We have included ED patients of pathological origin, but with improved erection hardness could also significantly increase confidence during intercourse [8]. It is therefore reasonable to expect that LESWT and PRP should also be effective in psychogenic ED [9].

The two therapies were considered safe for the study participants. None of them discontinued the study as a result of adverse events, despite the various adverse events observed in both groups. Few participants reported local transient penile pain.

Table 2. The mean score after 12 weeks in both groups

PARAMETERS	GROUP A	GROUP B	P- VALUE (CL=95%)
IIEF-5	20.21	21.26	>0.05
EHS	3.04	3.89	>0.05
SEAR	45.25	48.33	>0.05

This prospective non-randomized interventional comparison study summarized clinical practice relative to a well-designed placebo-controlled trial. All patients in this study received free counselling and regular visits, which improved participant compliance.

However, treatment outcomes in participants were multifactor and determined by more than therapy. Other factors such as ED severity and duration, comorbidities, lifestyle and relationship affected compliance and treatment outcome [10]. A successful intercourse is an act of collaboration among partners. Moreover, the heavy work of patients can contribute to an unhealthy lifestyle, which results in unsuccessful or unsustainable erections.

5. CONCLUSION

LESWT and PRP are possible alternative treatments for ED. It is still under investigation and has not yet received FDA approval as a treatment option. Our study showed that LESWT had the same effectiveness as PRP for patients with general ED, as measured by validated devices. Consequently, Li-ESWT offers another option to ED patients. However, further studies are required to explore changes in regimens and improved endpoints. The only legitimized LESWT for ED currently available is through clinical trials.

6. RECOMMENDATIONS

These new therapies can play an outrageous role as long-term therapeutic strategies, and we can also assume that the combination of LESWT and PRP can produce additive effects in the treatment of ED.

7. LIMITATIONS

There were some limitations in this study. First, our study focused on one patient, most patients in a hospital, which might have introduced a selection of participants. Second, the number of participants was insufficient to compare subgroups for psychogenic, vascular and mixed causes. Participants with ED from different causative factors could have had

different responses and improvements to each treatment.

CONSENT

As per international standard or university standard, Participants' written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

Ethical approval for the study has been collected and preserved by the author

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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