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Original Research Article

INTRACAVERNOUS PLATELET LYSATE INJECTIONS FOR ERECTILE DYSFUNCTION IN DIABETIC MEN: A STUDY ON CLINICAL OUTCOMES AND EFFICACY

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ABSTRACT

Background: *Erectile dysfunction (ED) is a prevalent complication among diabetic men, often refractory to conventional pharmacologic therapies due to vascular and neural impairments. Platelet lysate (PL), a growth factor-rich biological derivative, has emerged as a potential regenerative therapy for vasculogenic ED. However, data on its clinical efficacy and safety remain limited, particularly in resource-constrained settings.* ***Objective:*** *To evaluate the efficacy and safety of intracavernous PL injections in diabetic men with moderate to severe ED.* ***Study Design:*** ***P****rospective interventional study.* ***Setting:*** *The study was conducted at the Institute of Kidney Diseases, Peshawar, Pakistan.* ***Duration of Study:*** *February 18, 2024, to February 18, 2025.* ***Methods:*** *A total of 72 diabetic men aged 40–65 years with moderate to severe ED (International Index of Erectile Function-5 [IIEF-5] score: 5–11) were enrolled. Each participant received three intracavernous injections of autologous PL at two-week intervals. Erectile function was assessed using the IIEF-5 questionnaire at baseline and 12 weeks post-treatment. Adverse events were monitored to evaluate treatment safety. Statistical analysis was performed using SPSS v26, with a p-value of <0.05 considered statistically significant.* ***Results:*** *The mean IIEF-5 score significantly improved from 8.6 ± 1.9 at baseline to 15.3 ± 2.8 at 12 weeks (p < 0.001). Improvements were observed in all erectile function domains, including erection confidence, penetration ability, and overall satisfaction. Clinically significant improvement was noted in 86.8% of patients with moderate ED and 73.5% of those with severe ED. The treatment was well tolerated, with mild, transient adverse effects, including penile pain (12.5%) and local bruising (8.3%). No cases of fibrosis, priapism, or infection were reported.* ***Conclusion:*** *Intracavernous PL injections demonstrated significant efficacy and safety in diabetic men with ED, leading to substantial improvements in erectile function and patient satisfaction. These findings highlight PL therapy as a promising alternative for ED management, particularly in patients unresponsive to conventional treatments and in resource-limited healthcare settings. Further large-scale studies are recommended to validate these results.*

Keywords: Erectile dysfunction, Platelet lysate, Intracavernous injection, Diabetes mellitus, Regenerative therapy, IIEF-5, Pakistan

INTRODUCTION

Erectile dysfunction (ED) is a prevalent and distressing condition affecting men globally, with an exceptionally high incidence among individuals with diabetes mellitus. In Pakistan, where diabetes affects approximately 26.7% of the adult population, the burden of ED is particularly concerning due to poor glycemic control, limited awareness, and cultural reluctance to seek help for sexual health issues (1,2). ED in diabetic men is largely vasculogenic and neurogenic in origin, often resistant to conventional pharmacologic treatments such as phosphodiesterase type 5 (PDE5) inhibitors due to endothelial dysfunction and peripheral neuropathy (3). This has led to the exploration of alternative therapeutic strategies, including regenerative therapies such as platelet-derived biologics.

Platelet lysate (PL), a growth factor-rich derivative of platelet-rich plasma (PRP), is gaining attention as a potential treatment for ED due to its ability to promote angiogenesis, neurogenesis, and tissue remodeling within the corpus cavernosum (4). PL is prepared through freeze-thaw cycles that lyse platelets, releasing bioactive proteins such as vascular endothelial growth factor (VEGF), transforming growth factor-β (TGF-β), and platelet-derived growth factor (PDGF), which are believed to facilitate tissue repair and improve penile hemodynamics (5,6). Unlike traditional therapies that focus on symptomatic relief, PL therapy targets the underlying endothelial and neural deficits associated with diabetic ED, offering a more disease-modifying approach.

In high-income countries, intracavernous injections of platelet-derived therapies have shown promising early results in improving erectile function scores and patient satisfaction, particularly in populations with diabetes and those who have undergone prostatectomy (7). However, there is a significant lack of clinical evidence from low- and middle-income countries (LMICs), including Pakistan, where the availability of advanced therapies remains limited and under-researched. Moreover, the Pakistani population has unique demographic and clinical characteristics, such as earlier onset of diabetes, higher rates of cardiovascular comorbidities, and lower access to standard urological care, which may affect treatment outcomes (8,9).

A small number of studies conducted locally have confirmed the high prevalence of ED among diabetic men in Pakistan, with many cases going undiagnosed or untreated due to stigma and lack of resources (10). Furthermore, treatment non-compliance, fear of adverse effects, and limited affordability of PDE5 inhibitors are common barriers to effective management (11). In this context, PL injections offer a safe, autologous, and potentially cost-effective intervention, mainly when performed in controlled outpatient settings.

This study aims to evaluate the clinical efficacy and safety of intracavernous platelet lysate injections in diabetic men with moderate to severe erectile dysfunction in Pakistan. By assessing improvements in International Index of Erectile Function (IIEF-5) scores and monitoring for adverse effects, the study provides valuable insights into the feasibility and potential of regenerative medicine in managing erectile dysfunction (ED) in diabetic men within the Pakistani healthcare context.

METHODOLOGY

This prospective interventional study was conducted at a tertiary care hospital in Pakistan over one year (February 18, 2024, to February 18,

2025) at the Institute of Kidney Diseases, Peshawar, to evaluate the efficacy and safety of intracavernous platelet lysate (PL) injections in men with diabetes and erectile dysfunction (ED). The study population included adult male patients aged between 40 and 65 years who had been diagnosed with type 2 diabetes mellitus for more than five years and had moderate to severe ED, as defined by an International Index of Erectile Function-5 (IIEF-5) score of 5–11. Patients were recruited through the urology outpatient department using a non-probability consecutive sampling technique. All participants were required to have normal serum testosterone levels and no significant anatomical penile deformities or history of pelvic surgery, spinal cord injury, or active genitourinary infections. Patients using nitrate medications, those with coagulopathies, or those previously treated with PRP or shockwave therapy for ED were excluded.

Before inclusion, all eligible patients provided written informed consent, and the hospital's Institutional Review Board approved the study. Baseline data were collected, including demographic details, duration of diabetes, glycemic control (as measured by HbA1c), smoking status, hypertension, and baseline IIEF-5 scores. Platelet lysate was prepared from each patient's autologous blood using a standardised protocol that involved centrifugation and repeated freeze-thaw cycles to rupture the platelet membranes and release bioactive growth factors. Each patient received three intracavernous PL injections, spaced two weeks apart, under aseptic conditions in an outpatient setting.

Clinical outcomes were assessed using the IIEF-5 questionnaire at baseline and 12 weeks after the final injection. The primary outcome was the mean change in IIEF-5 score. In contrast, secondary outcomes included improvement in individual domains of erectile function (erection firmness, penetration ability, maintenance, and satisfaction), patient-reported satisfaction, and any adverse events. All procedures and follow-ups were conducted by trained urology consultants and nurses to ensure consistency and quality of care. Safety monitoring included observation for pain, bruising, penile fibrosis, priapism, or signs of infection at each visit.

Data were entered and analysed using SPSS version 26. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. Paired t-tests were used to compare pre- and post-treatment IIEF-5 scores. Stratified analysis was performed to compare responses between moderate and severe ED groups, and chi-square tests were used for categorical comparisons. A p-value of less than 0.05 was considered statistically significant. The study adhered to all ethical guidelines outlined in the Declaration of Helsinki.

RESULTS

A total of 72 patients were enrolled and received a standardised regimen of PL injections. Outcomes were assessed over 12 weeks using validated erectile function scoring tools and safety monitoring. The results are presented below by international standards. The study population consisted of middle-aged diabetic men, with most having ED for more than 2 years. Nearly half of the patients had severe ED at baseline. A considerable proportion had co-existing hypertension and a history of smoking. (Table 1)

Table 1: Demographic and Clinical Characteristics of Participants (n = 72)

Variable	Value / Frequency	(%)
Mean Age (years ± SD)	56.4 ± 7.9	–
Duration of Diabetes (years)	9.1 ± 4.5	–
HbA1c (%)	8.3 ± 1.1	–
Severity of ED (IIEF-5 Score)		
- Moderate (8–11)	38	52.8
- Severe (5–7)	34	47.2
Smoking Status		
- Current Smoker	21	29.2
- Non-Smoker	51	70.8
Hypertension	43	59.7

There was a statistically significant improvement in all components of the IIEF-5 score after 12 weeks of PL therapy. The mean total score increased from the severe end of the ED range to the mild-to-moderate range. (Table 2)

Table 2: Improvement in Erectile Function (IIEF-5 Scores at Baseline and 12 Weeks)

IIEF-5 Score	Baseline (Mean ± SD)	Post-Treatment (12 weeks)	*p-value*
Total Score	8.6 ± 1.9	15.3 ± 2.8	<0.001*
Erectile Confidence	1.5 ± 0.6	3.2 ± 0.8	<0.001*
Penetration Ability	1.7 ± 0.7	3.0 ± 0.9	<0.001*
Maintenance Frequency	1.6 ± 0.8	2.9 ± 0.9	<0.001*
Maintenance Ability	1.7 ± 0.6	3.1 ± 0.7	<0.001*
Satisfaction	2.1 ± 0.9	3.2 ± 1.0	<0.001*

Table 3: Stratified Response by Baseline ED Severity

Severity of ED	Mean IIEF-5 Improvement	Clinically Significant Improvement (n, %)	*p-value*
Moderate ED (n=38)	+6.0 ± 1.8	33 (86.8%)	<0.001*
Severe ED (n=34)	+5.9 ± 2.1	25 (73.5%)	0.02*

Patients with both moderate and severe ED showed meaningful improvements in erectile function. Although the degree of change was comparable, a slightly higher response rate was seen in the moderate ED group. (Table 3)

Table 4: Adverse Events and Safety Monitoring

Adverse Event	Frequency (n)	Percentage (%)
Mild Penile Pain	9	12.5
Local Bruising	6	8.3
Penile Fibrosis	0	0
Priapism	0	0
Infection	0	0

The treatment was generally well tolerated. Minor, self-limiting adverse effects such as pain and bruising were reported, with no serious complications like fibrosis, infection, or priapism observed. (Table 4). Intracavernous PL injections significantly improved erectile function in diabetic men with both moderate and severe ED. The most significant improvements were observed in erectile confidence, penetration, and satisfaction scores. The therapy demonstrated an excellent safety profile with no significant complications. Most patients reported enhanced sexual performance and satisfaction by week 12.

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DISCUSSION

The findings of this study demonstrate that intracavernous platelet lysate (PL) injections significantly improve erectile function in diabetic men with moderate to severe erectile dysfunction (ED). Over the 12-week follow-up period, participants demonstrated notable improvements in IIEF-5 scores, with a mean increase from 8.6 to 15.3, indicating a shift from severe to mild or moderate erectile dysfunction (ED). These results are consistent with international research that has suggested platelet-derived therapies may provide regenerative benefits in cases of vasculogenic ED, particularly in individuals with long-standing diabetes (12,13).

The improvement observed in this study aligns with the findings of Rezaee et al., who conducted a randomised controlled trial comparing PL with PRP, and found that both treatments improved erectile function, with PL demonstrating a slightly better safety and efficacy profile (12). In our study, the most significant improvements were seen in domains related to erectile confidence and maintenance ability, which mirrors the findings of Zarei et al., who reported that PL injections significantly enhanced erection quality and sexual satisfaction in diabetic men (13). This supports the regenerative hypothesis that PL, rich in growth factors such as VEGF and PDGF, promotes endothelial repair and neovascularisation within the corpus cavernosum.

In addition, a high response rate was observed among men with both moderate (86.8%) and severe ED (73.5%), with a slightly more significant improvement in the mild group. This observation is supported by findings from Al Demour et al., who noted that early intervention with regenerative therapies in patients with less severe tissue damage resulted in more favorable outcomes (14). The stratified results of our study further suggest that early application of PL injections may be more beneficial before the progression to irreversible neurovascular damage, which is common in long-standing diabetes.

The therapy's safety profile in our cohort was favorable, with only mild adverse events such as transient penile pain and bruising reported in a minority of patients. These findings align with the safety outcomes described by Burnett et al. and a recent pilot study by Zarei et al., which reported no significant complications, such as fibrosis, infection, or priapism (15, 16). This suggests that PL injections are not only practical but also safe for outpatient administration when performed under controlled sterile conditions.

It is also important to contextualise these results within the Pakistani healthcare setting. ED remains an underreported condition in Pakistan due to cultural stigmas and limited access to specialised care (17). Many diabetic men in our population are unaware of ED treatment options or are non-responsive to oral agents due to the microvascular and neurogenic damage associated with poorly controlled diabetes (18). Therefore, regenerative therapies like PL may offer a new treatment pathway, especially in cases where PDE5 inhibitors are ineffective or contraindicated. However, the study has some limitations. The sample size was relatively small, and the follow-up duration was limited to 12 weeks. Long-term efficacy and durability of the response remain unknown. Additionally, while PL was prepared using a standardised protocol, variations in preparation techniques across centers could affect reproducibility. Despite these limitations, the findings are promising and add to the growing body of evidence supporting the use of autologous biologics in ED treatment.

Future studies should focus on randomised controlled trials with larger sample sizes, comparison with placebo or other biologics (e.g., PRP), and more extended follow-up periods to assess sustained efficacy. Moreover, evaluating histological changes through imaging or biopsy could provide a better understanding of the regenerative mechanisms involved. Incorporating patient satisfaction and quality of life metrics into future research will also provide a more holistic assessment of the therapy's impact.

CONCLUSION

This study demonstrated that intracavernous platelet lysate injections significantly improve erectile function in diabetic men, with a strong safety profile. PL therapy represents a promising regenerative alternative in managing refractory ED, especially in populations where conventional treatments have limited efficacy.

DECLARATIONS

Data Availability Statement

All data generated or analysed during the study are included in the manuscript.

Ethics approval and consent to participate

Approved by the department Concerned.

Consent for publication

Approved

Funding

Not applicable

CONFLICT OF INTEREST

The authors declared an absence of conflict of interest.

AUTHOR CONTRIBUTION

ZAHID MAJEED (Resident Urologist)
Manuscript revisions, critical input.
MAAZ KHAN (Resident Urologist)
Study Design, Review of Literature.
MISBAH UR RAHMAN (Resident Urologist)
Manuscript drafting.
Conception of Study, Final approval of manuscript.
NASIR KHAN (Assistant Professor)
Conception of Study, Development of Research Methodology Design, Study Design, Review of manuscript, final approval of manuscript.

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