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DIABETIC FOOT ULCER MANAGEMENT WITH INTRA-LESIONAL PRP THERAPY COMBINED WITH CONSERVATIVE MANAGEMENT VS CONSERVATIVE MANAGEMENT ALONE: A SINGLE-CENTER STUDY

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ABSTRACT

Introduction: Diabetic Foot Ulcers are a frequent chronic complication of DM and are linked with delayed wound healing, infection, hospitalization, and risk of lower limb amputation. Platelet-rich plasma can promote wound healing by providing local growth factors.

Objective: To evaluate the effectiveness of intralesional platelet-rich plasma therapy along with conservative treatment versus conservative treatment alone in diabetic foot ulcer patients.

Methods: The study was a randomized controlled trial carried out at the Department of Surgery, PNS Hafeez, from August 2025 to December 2025. Sixty-two patients were enrolled and split into two groups. Group A was treated with intralesional PRP and conservative management, and Group B was treated with conservative management alone.

Results: There was no statistically significant difference in the mean healing time, ulcer size reduction, or complete wound closure between Group A and Group B, but limb amputation occurred less often in the PRP group.

Conclusion: Intralesional PRP therapy is a viable complement to conservative treatment in the management of DFUs.

KEYWORDS: Diabetic foot ulcer, platelet-rich plasma, intralesional therapy, conservative management, wound healing.

INTRODUCTION

DFU is one of the most challenging and debilitating diabetic complications which contributes to high morbidity, frequent hospitalisation, infection, amputation of limbs, and reduced quality of life. The condition is a complicated mix of peripheral neuropathy, compromised immune system, microvascular dysfunction, peripheral arterial disease, repetitive trauma and delayed tissue repair. Once the initial ulcer forms, healing may be delayed as a result of the effects of diabetes on inflammatory response, collagen, angiogenesis and epithelial regeneration. The economic burden of DFU is substantial to patient and health system, due to frequent dressing changes, antibiotics, debridement, offloading devices, hospitalisation and in more severe cases, surgical treatment. Other advanced treatments, such as platelet-rich plasma (PRP), may be more affordable than traditional treatments alone, particularly when they reduce the length of treatment for DFUs and the overall disease burden over time due to faster healing (1).

Conservative treatment is the mainstay of diabetic foot ulcer therapy and includes glycemic control, infection control, wound cleansing, surgical/mechanical debridement, moist wound dressings, offloading of pressure areas, vascular assessment and education. All these are essential to make any of these advanced therapies work as long as they do not address pressure, infection, ischemia, and metabolic imbalance. Conservative treatment is indicated, but many ulcers are still chronic or do not heal completely, especially if they are long-standing or if the patient has neuropathy, recurrent trauma, poor tissue perfusion or long-standing diabetes. A network meta-analysis of the different treatments for DFUs found that a number of adjunctive treatments have been studied to improve healing, that different treatments work better in different groups of patients, and that different types of ulcers respond better to different treatments (2). Thus, simple, locally applicable and biologically appropriate adjuncts which can be integrated into the normal conservative treatment should be evaluated.

The rise of the movement for regenerative medicine in diabetic wounds is due to the fact that diabetic wounds are not only open wounds, but “stalled” biological healing environments. Diabetes disrupts the normal inflammatory and proliferative, granulation tissue, angiogenesis and remodeling process. Bone marrow-derived mesenchymal stem cells are a type of cellular therapy that has been investigated for the potential to promote tissue repair, control inflammation, and enhance vascular regeneration in chronic diabetic wounds (3). Stem cell therapy has been demonstrated to be very promising, but is often technically difficult, expensive, and not easily available in everyday clinical practice. By contrast, PRP is autologous, relatively simple to prepare, and can be applied locally, and therefore, is an appealing option for surgical and wound care environments.

Platelet rich plasma is a high concentration of platelets in plasma, that contains growth factors such as platelet-derived growth factor, vascular endothelial growth factor, transforming growth factor-β, epidermal growth factor and insulin-like growth factor. These mediators are important for chemotaxis, fibroblast activity, collagen synthesis, angiogenesis, and epithelial migration, which are all essential for ulcer healing. Clinical experience with other chronic ulcer conditions such as leprosy patients with neuropathic ulcers using platelet derived biological stimulation to improve the healing of these wounds with impaired healing potential supports the concept (4). Inflammation and infection control are also important in the management of DFUs, and recent reviews emphasise the importance of optimising the local wound biology in addition to the systemic diabetic management (5). PRP may help to optimize this wound environment, but cannot be used in lieu of debridement, antibiotic as necessary, or pressure offloading.

In current times, wound care is turning to therapies that emphasize immune regulation and tissue regeneration rather than wound covering. Autologous platelet and mononuclear cell therapies have been studied, and it has been suggested that biological preparations may have an impact on both inflammatory and repair mechanisms in musculoskeletal and tissue repair diseases (6). Likewise, the use of intralesional and perilesional recombinant epidermal growth factor (rEGF) in chronic ulcers has emphasized the need to directly target the growth-promoting agents to or around the active wound bed, where most of the cells are active (7). This is especially applicable to intralesional PRP, in which platelet-derived factors are injected into the ulcer base and edges, which might create a more powerful regeneration response than topical application.

The general principles that platelet-based preparations can be useful adjuncts in difficult healing situations are also supported by evidence from other surgical fields. The use of leukocyte-platelet-rich fibrin (L-PRF) with or without platelet-rich plasma (PRP) injection has been evaluated in complex oral surgical pathology and the application of autologous platelet products for tissue repair and regeneration has been growing (8). The biological effects of PRP therapy, such as angiogenesis, immunomodulation, remodeling of the extracellular matrix and paracrine signaling, have been shown to play a role in the healing process of diabetic foot wounds in studies of mesenchymal stem cells (9). The literature in the field of foot and ankle has also been devoted to the use of PRP for a number of clinical uses, given its potential to improve healing in tissues with limited healing potential, which makes it a suitable treatment for the care of diabetic foot ulcers (10).

Local therapies by injection are also being investigated in other musculoskeletal and pain conditions, and there is a need for controlled trials to compare biological or procedural treatments with proven conservative treatments. For instance, randomized controlled trials have been conducted in chronic plantar fasciitis and other painful conditions, and have shown that local treatment protocols need to be assessed using controlled comparison groups, not on theoretical grounds alone (11). Similarly, in disorders, clinical studies have shown that when new adjunctive treatment modalities are introduced, clinical improvement and biological repair need to be assessed. The cross-species interest in platelet-based healing and tissue repair mechanisms is also evident in the research into the use of autologous PRP for sole lesions and the expression of related biomarkers in dairy cattle (13).

This direction of targeted regenerative and molecular therapies is also seen in other fields of medicine, e.g., the use of biological markers to elucidate treatment effects in clinical trials of immune-mediated tissue regrowth (14). Experimental approach, such as gene therapy using the genes of bone morphogenetic protein and vascular endothelial growth factor, highlights the importance of osteogenesis and angiogenesis in tissue recovery (15). Diabetic foot ulceration is a chronic condition with multiple factors that can contribute to its chronicity and to treatment failure, such as metabolic dysfunction, aging-related degeneration, failure of bone repair, and failure of soft tissue repair, and failure of vascular response (16). Such advanced treatments would not be feasible in most clinical applications, but they further support the need for more widely available biological therapies like autologous PRP.

Intralesional PRP therapy has already shown promising results in the treatment of DFUs. Intralesional autologous PRP injection was proven to be an effective regenerative therapy in a case report of a chronic Wagner grade 2 diabetic foot ulcer, suggesting that direct local delivery may be beneficial in stimulating healing of a chronic diabetic wound (17). However, the care of a diabetic foot ulcer is not just a report, and, in a world where conservative care is always the care of choice. Thus, the clinical relevance of comparing intralesional PRP therapy with conservative management to conservative management alone is clinically important. This evaluation can help to see if there is any additional benefit from PRP to shorten healing, ulcer size and amputation risk. This study aims to address this by studying intralesional PRP as an adjunct to conservative treatment of DFUs in a single-center, randomized controlled trial.

Objectives: To compare the intralesional platelet-rich plasma therapy with conservative management versus conservative management alone in patients with DFUs, regarding the healing time, reduction in ulcer size, and frequency of limb amputation.

MATERIALS AND METHODS

Study Design: Randomized controlled trial.

Study Setting: The study was conducted in the Department of Surgery at PNS Hafeez.

Duration of the Study: March 2025 to August 2025.

Inclusion Criteria: Patients aged 30 to 75 years with a diagnosed diabetic foot ulcer (DFU) of Wagner grade 1 to 3 were included. Patients were eligible if they had an HbA1c ≤9%, had no previous foot surgery, and gave informed consent.

Exclusion Criteria: Exclusion criteria included uncontrolled diabetes (HbA1c >9%), peripheral vascular disease, immunosuppression, septicemia, hemodynamic instability, platelet dysfunction syndrome, critical thrombocytopenia, and contraindications to PRP therapy.

Methods

Written informed consent was obtained, and participants qualifying for the study were assigned sequential identification numbers. The participants were randomly allocated to two equal groups using simple randomization in Microsoft Excel. The intervention group was treated with intralesional autologous platelet-rich plasma therapy and conservative treatment, and the control group was treated with conservative treatment alone. PRP was prepared from the patient's own blood under aseptic conditions and injected into the base and margin of the ulcer using an insulin syringe to a maximum depth of 1 cm every 14 days for up to 6 weeks, or until complete healing. Conservative treatment comprised wound washing, surgical debridement if necessary, moist dressings, infection control, glycemic optimization, offloading, and vascular assessment. Wound size was assessed at baseline and every 2 weeks for a total of 6 weeks using a scale and measuring tape. The time of healing, percentage of reduction of the ulcer size, and amputation of the limb within six weeks after the completion of treatment were recorded.

RESULTS

Sixty-two patients with DFUs were enrolled and divided into two equal groups. The study comprised 62 patients, divided into two groups: Group A (31 patients) received intralesional platelet-rich plasma therapy plus conservative management, and Group B (31 patients) received conservative management alone. The treatment protocol and follow-up period were completed by all patients. Demographic and clinical parameters were similar between the groups, and there was no significant difference in age, gender distribution, diabetes duration, HbA1c level, or smoking status.

Table 1: Baseline demographic characteristics of study participants

Variable	PRP + Conservative Management (n=31)	Conservative Management Alone (n=31)	p-value
Mean age, years	54.8 ± 9.7	55.6 ± 10.2	0.75
Male gender	20 (64.5%)	19 (61.3%)	0.79
Female gender	11 (35.5%)	12 (38.7%)	0.79
Mean duration of diabetes, years	10.2 ± 4.1	10.8 ± 4.4	0.58
Mean HbA1c, %	7.8 ± 0.6	7.9 ± 0.7	0.54
Smokers	7 (22.6%)	6 (19.4%)	0.75

The baseline wound parameters were also comparable between the two groups. The mean ulcer surface area was 5.8 ± 1.7 cm² in Group A and 5.9 ± 1.8 cm² in Group B. The majority of ulcers were Wagner grade 2 in both groups. There was no difference in the distribution of ulcer location, ulcer duration, necrotic tissue, or baseline depth, suggesting that both groups were comparable prior to treatment initiation.

Table 2: Baseline wound characteristics

Wound Characteristic	PRP + Conservative Management (n=31)	Conservative Management Alone (n=31)	p-value
Mean ulcer duration, weeks	5.1 ± 1.6	5.3 ± 1.7	0.63
Mean ulcer surface area, cm²	5.8 ± 1.7	5.9 ± 1.8	0.82
Mean ulcer depth, cm	0.9 ± 0.3	1.0 ± 0.4	0.27
Wagner grade 1	9 (29.0%)	8 (25.8%)	0.88
Wagner grade 2	16 (51.6%)	17 (54.8%)	0.88
Wagner grade 3	6 (19.4%)	6 (19.4%)	1.00
Necrotic tissue present	12 (38.7%)	13 (41.9%)	0.79

Group A had superior wound healing results at the end of follow-up, with 25 patients (80.6%) achieving complete healing of the wound compared with 17 patients (54.8%) in Group B. The mean time to wound healing was significantly reduced in the PRP group (36.2 ± 5.4 days) compared to the conservative management group (41.1 ± 6.2 days). There was also a significantly higher mean percentage reduction in ulcer size, 78.4 ± 16.8% in Group A versus 56.9 ± 20.5% in Group B, but no difference was seen in the rate of amputation of the affected limb, with 1 patient (3.2%) in Group A and 4 patients (12.9%) in Group B.

Table 3: Treatment outcomes after follow-up

Outcome	PRP + Conservative Management (n=31)	Conservative Management Alone (n=31)	p-value
Complete wound healing	25 (80.6%)	17 (54.8%)	0.03

Mean healing time, days	36.2 ± 5.4	41.1 ± 6.2	0.002
Mean ulcer size reduction, %	78.4 ± 16.8	56.9 ± 20.5	<0.001
Limb amputation	1 (3.2%)	4 (12.9%)	0.16
Progression of infection	2 (6.5%)	7 (22.6%)	0.07

However, serial wound measurements revealed a gradual decrease in ulcer area in both groups, with a more pronounced decrease in the intralesional PRP group. The mean ulcer area in Group A was reduced from 5.8 cm² to 1.2 cm² by Week 6, while the mean ulcer area in Group B was reduced from 5.9 cm² to 2.6 cm² by Week 6.

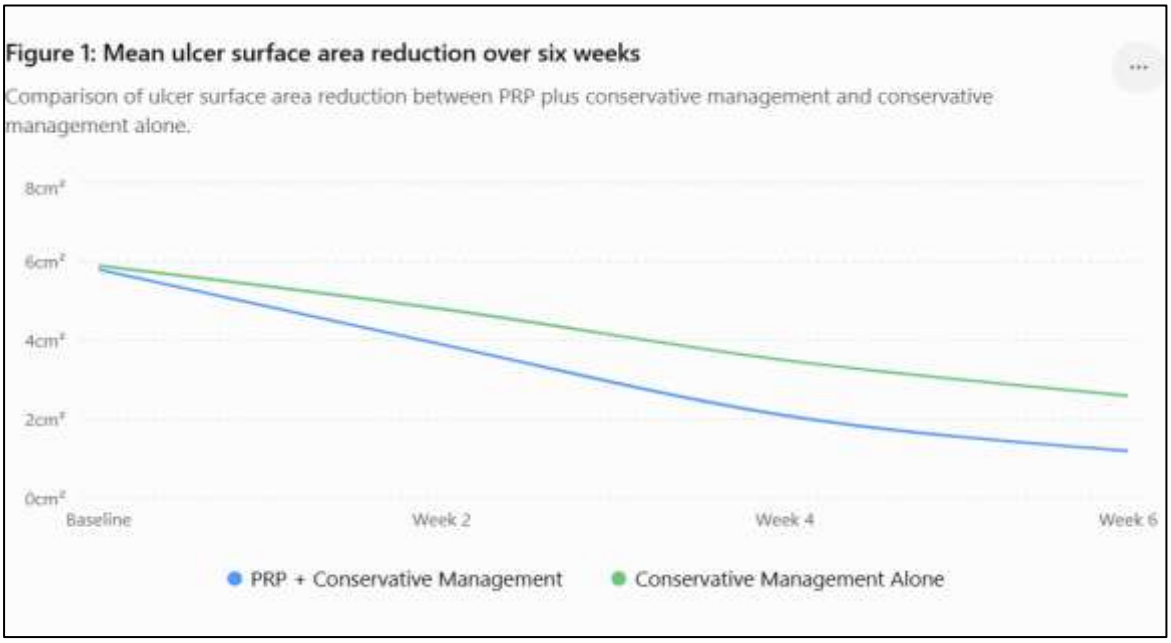

Figure 1: Mean ulcer surface area reduction over six weeks

In summary, intralesional PRP therapy, along with conservative treatment, was linked with quicker healing, larger reduction in ulcer size, and more frequent complete healing than conservative therapy alone.

DISCUSSION

In the present study, the effectiveness of intralesional PRP therapy was compared with conservative management alone in DFU patients. The results indicated that the mean healing time was shorter, the ulcer size was reduced more, and complete healing occurred more frequently in patients treated with PRP in addition to conservative treatment than in those treated with conservative treatment alone. DFU is a major burden of disease and cost because of the long-term wound care required, multiple hospital visits, antibiotic treatment, debridement and sometimes amputation. Recent cost-effectiveness analyses have suggested that PRP may be a valuable adjunct to DFU treatment, and can reduce the length of treatment and enhance healing rates relative to standard treatment alone (1). Conservative management is the first line of treatment for DFUs and involves wound care, debridement, infection control, offloading, glycemic control, vascular evaluation and frequent wound dressings.

However, conservative therapy alone is not always effective, as diabetic wounds frequently enter a chronic inflammatory state where there are poor angiogenesis and delayed epithelialization. A network meta-analysis of different treatments for DFU concluded that adjunctive treatments might be useful in combination with standard care, but the results were variable according to the type of wound and the treatment method (2). In our study, the intralesional PRP appeared to provide a biological advantage, and accelerated healing rates compared to conservative treatment alone. The platelets' ability to regenerate and the presence of high levels of growth factors in the PRP group may explain the improved wound healing. Platelet-rich plasma is rich in mediators that stimulate the proliferation of fibroblasts, collagen production, angiogenesis, granulation tissue formation and epithelial migration.

These processes are particularly important in diabetic wounds where cells' repair is impaired. The role of bone marrow-derived MSC in the management of DFUs has also highlighted the importance of regenerative and angiogenic stimulation in wound healing in recent years (3). Stem cell therapies are not readily available in the clinic, however, PRP treatment is an autologous treatment that can be injected directly into the wound site. PRP has also been clinically proven to be beneficial in other chronic neuropathic ulcer diseases. An interventional study on PRP in neuropathic ulcers of leprosy patients revealed that platelet therapy can help heal wounds with reduced local healing capacity (4). This is in line with the biological basis for PRP therapy in DFUs, where microvascular compromise, repetitive trauma, and neuropathy are prevalent. At the same time, inflammation and infection are still the significant challenges in healing and optimal care of the diabetic foot ulcer requires careful management of the wound microenvironment.

Inflammation and infection control in the treatment of DFUs emphasize local wound care and systemic optimization throughout the course of treatment (5). Therefore, PRP should be considered as a complementary treatment and not as a substitute for conservative treatment. Another possible explanation for the improved results in the intervention group is the immune-modulating effect of platelet-based therapies. Recent reviews have reported a move towards immune-based regenerative therapies with the use of autologous platelet and mononuclear cell preparations, indicating that these therapies could have effects on inflammatory pathways as well as tissue regeneration (6). In diabetic foot ulcers, the inflammatory phase is either prolonged or excessive, delaying the transition to the proliferative phase. Intralesional PRP could promote a more favorable healing environment by delivering platelet-derived cytokines and growth factors to the ulcer margins and base. Likewise, the use of intralesional and perilesional recombinant epidermal growth factor in chronic ulcers has proven beneficial, suggesting that direct injection of a regenerative agent in the vicinity of viable tissue may stimulate local repair processes (7).

Results from other surgical and regenerative disciplines also confirm the use of autologous platelet products in challenging healing situations. Leukocyte-platelet-rich fibrin (LPRF), with or without PRP injection, has been investigated in the surgical treatment of medication-related osteonecrosis of the jaw (MRONJ) and has shown that platelet-based preparations can improve tissue recovery in complex wounds (8). Experimental and clinical research on MSC in DFW healing has also revealed that paracrine actions, angiogenesis, ECM remodeling, and immunomodulation are key mechanisms in wound healing (9). The action of PRP could be through related pathways, but mostly it is via platelet-derived growth factors and not stem cell activity. PRP has been used in the treatment of foot and ankle diseases in recent years, and reviews have outlined the clinical potential of PRP in a number of soft tissue healing and musculoskeletal repair disorders (10).

The pathobiology is unique, but there are some commonalities, such as mechanical stresses, limited soft tissue envelope, and delayed wound healing at the foot and ankle. For other foot conditions, like chronic plantar fasciitis, injection therapy has also demonstrated the importance of comparing local therapy with a proven conservative therapy in a randomized clinical trial (11). This is significant to the present study as it directly compared PRP combined with conservative care versus conservative care alone, not PRP alone. Other clinical trials have compared the effectiveness of local biological or physical therapies (e.g., injection with epidermal growth factor, laser therapy) and have shown that procedural therapies should be assessed on the basis of measurable clinical results, such as pain, function, and tissue response (12). In the present study, clinically relevant outcomes were selected such as wound size reduction, healing time, and amputation rate.

Studies on the use of PRP in lesions of the sole and studies on the expression of different biomarkers in dairy cattle (13) support the biological activity of platelet preparations in tissue repair. Animal studies cannot be directly applied to the human diabetic foot ulcer, but can be useful in elucidating the possible effects of platelet-based products on tissue regeneration. In other clinical trial programs, the immune-mediated regrowth of other tissues was used to predict the response to treatment and long-term tissue recovery, and this is becoming more common in the wider field of regenerative medicine (14). Similarly, experiments using gene therapy for bone morphogenetic protein and vascular endothelial growth factor have shown that the osteogenic and angiogenic pathways are important in tissue repair (15). These mechanisms can be used in DFUs, especially if there is deeper involvement of soft tissue and bone (Wagner grade ulcers). Diabetic foot wounds become chronic and difficult to treat – some of the aging and metabolic disease associated factors may be responsible for this and may contribute to degeneration, impaired healing and poor tissue integration (16).

The findings in this study align with previous clinical studies of intralesional autologous PRP for treating chronic diabetic foot ulcers. In a case report, the use of PRP for the direct injection into the wound of a patient with diabetic foot ulcer (DFU) grade 2 resulted in wound healing and regeneration, indicating its potential benefits (17). The advantages of the present study were that the groups were randomized and equal. Although promising results were obtained, there are limitations to this study. It was done in one centre with a small number of participants and a short follow-up period. Larger multicenter studies with longer follow up are recommended to confirm the effectiveness of intralesional PRP for recurrence, infection control, functional recovery, and prevention of amputation.

CONCLUSION

The present study showed that intralesional PRP therapy, along with conservative treatment, was more effective than conservative treatment alone for DFUs. Patients with PRP had more rapid wound healing, smaller ulcers, and more complete wound closure at follow-up. There was a lower incidence of amputation in the PRP group, but this difference was not significant, probably because of the relatively small number of patients. The results indicate that PRP can be a valuable complementary treatment alongside conventional diabetic foot care, promoting the regeneration of local tissues and potentially improving wound healing in diabetes. Treatment continues to include conservative measures such as infection control, debridement, offloading, glycemic control, and regular dressings. Therefore, intralesional PRP should be used as an adjunctive procedure and not as a substitute for conventional treatment. Further multicenter studies with longer follow-up are recommended to validate these findings and assess long-term results.

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