

Comparison of Autologous Platelet-Rich Plasma (PRP)-Soaked Dressing vs. Saline-Soaked Dressing in the Healing of Diabetic Foot Ulcer

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Abstract: Diabetic foot ulcer (DFU) remains one of the most debilitating complications of diabetes mellitus, contributing significantly to morbidity, disability, and healthcare costs. Impaired wound healing due to neuropathy, ischemia, and infection is a major clinical challenge. Platelet-rich plasma (PRP), an autologous source of concentrated growth factors, has emerged as a promising biological therapy to enhance wound repair and tissue regeneration. This study aimed to compare the efficacy of PRP-soaked dressings versus conventional saline-soaked dressings in promoting healing among patients with diabetic foot ulcers in a Pakistani population. **Methods:** This randomized controlled trial was conducted in the Department of Surgery, Bahawal Victoria Hospital, Bahawalpur, Pakistan, from January 2024 to July 2024. A total of 150 patients with Wagner Grade I or II DFUs were enrolled through non-probability consecutive sampling and randomly allocated into two equal groups. Group A received autologous PRP-soaked dressings, while Group B received saline-soaked dressings. Primary outcome measures included complete ulcer healing within six weeks and reduction in ulcer area; secondary outcomes were mean healing time and proportion of non-healing ulcers. Data were analyzed using SPSS 25.0, and a p-value < 0.05 was considered statistically significant. **Results:** The mean age of participants was 54.6 ± 8.9 years, with males comprising 64.7% of the sample. Baseline ulcer areas were comparable between the PRP (5.6 ± 2.2 cm²) and saline groups (5.4 ± 2.5 cm²; $p = 0.68$). After six weeks, the mean ulcer area reduced to 0.9 ± 0.7 cm² in the PRP group versus 2.7 ± 1.2 cm² in the saline group ($p < 0.001$). Complete healing was achieved in 86.7% of PRP-treated patients compared to 64.0% in the saline group ($p = 0.002$). The mean healing time was significantly shorter with PRP (28.3 ± 6.2 days) than with saline (35.9 ± 7.1 days; $p < 0.001$). Stratified analysis revealed consistent benefits across age, gender, and smoking subgroups, with the most significant effects in non-smokers ($p = 0.003$). **Conclusion:** Autologous PRP-soaked dressings markedly enhance healing outcomes in diabetic foot ulcers compared with saline-soaked dressings, offering a faster rate of epithelialization and higher complete-healing rates. PRP represents a cost-effective, biologically active adjunct that can be integrated into standard wound-care protocols to reduce morbidity associated with DFUs in resource-limited healthcare settings such as Pakistan.

Keywords: Diabetic foot ulcer, Platelet-rich plasma, Saline dressing, Wound healing, Randomized controlled trial

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Introduction

Diabetic foot ulcers (DFUs) represent a significant complication of diabetes mellitus and contribute to considerable morbidity and healthcare costs globally. Approximately 15% to 30% of diabetic patients will develop foot ulcers in their lifetime, often leading to severe outcomes such as infection, hospitalization, and even amputation (1, 2). The impaired wound healing associated with DFUs is largely attributable to factors such as neuropathy, ischemia, and abnormal immune responses, which complicate the healing process (3, 4).

Standard treatment options have traditionally included debridement, infection management, and moist wound dressings; however, these measures frequently yield inadequate results (5). In recent years, there has been an increasing focus on the application of regenerative medicine approaches, particularly the use of autologous platelet-rich plasma (PRP), in chronic wound management. Autologous PRP, which is derived from the patient's own blood and is rich in growth factors and cytokines, has been proposed to promote tissue regeneration, enhance angiogenesis, and facilitate the healing process in DFUs (6). Studies indicate that PRP may improve healing rates due to its ability to modulate inflammation, stimulate fibroblast activity, and promote collagen synthesis (7, 8). A systematic review of randomized controlled trials suggests that PRP may significantly accelerate healing compared to conventional dressings, particularly in chronic, non-healing ulcers (2, 9, 10).

As an alternative to PRP, saline solutions have been traditionally employed for wound management due to their availability and ease of application. Saline dressings serve primarily as moist wound healing agents but do not exhibit the biological activity attributed to PRP. Consequently, while saline dressings may control local infection and provide a moist environment, they fall short in promoting the cellular activity needed for accelerated healing (11, 12).

The objective of this study is to compare the efficacy of PRP-soaked dressings with saline-soaked dressings in the healing of diabetic foot ulcers. By evaluating clinical outcomes, including the rate of wound healing and patient-reported outcomes, we aim to elucidate the potential advantages of incorporating autologous PRP into standard wound care regimens.

In the context of Pakistan, where the prevalence of diabetes and associated complications is on the rise, this research holds particular significance. A substantial portion of the adult population is affected by diabetes, significantly increasing the burden of DFUs due to poor glycemic control and inadequate healthcare access (13). Cultural factors and limited awareness around diabetic self-care further complicate the management of these ulcers (14). By exploring innovative treatment modalities like PRP, this study seeks to contribute valuable insights into optimized management strategies, ultimately aiming to reduce the morbidity associated with diabetic foot ulcers in the Pakistani population.



Methodology

The present study was designed as a randomized controlled trial conducted in the Department of Surgery at Bahawal Victoria Hospital, Bahawalpur, Pakistan, from January 2024 to July 2024. The objective was to compare the efficacy of autologous platelet-rich plasma (PRP) soaked dressing with conventional saline-soaked dressing in the healing of diabetic foot ulcers (DFUs). The study was carried out over a period of six months following approval of the synopsis from the College of Physicians and Surgeons Pakistan (CPSP) and after obtaining ethical clearance from the institutional review board. Informed written consent was obtained from all participants prior to inclusion in the study, and all procedures were performed in accordance with the Declaration of Helsinki for research involving human subjects.

A total of 150 patients fulfilling the inclusion criteria were selected through non-probability consecutive sampling. The sample size was calculated at a 95% confidence level and 80% study power, assuming a healing rate of 60.3% with PRP-soaked dressing and 43.0% with saline-soaked dressing. Eligible patients were individuals aged between 30 and 70 years of both genders who had been diagnosed with diabetes mellitus (either good or poor glycemic control) and presented with Wagner Grade I or II diabetic foot ulcers. Patients with normal platelet counts were included. Exclusion criteria were applied to eliminate confounding factors and included patients with thrombocytopenia, peripheral arterial disease, varicose veins, malignancy, or foot ulcers secondary to trauma or other etiologies.

All patients who presented to the surgical outpatient and emergency departments with diabetic foot ulcers and met the inclusion criteria were enrolled. After obtaining informed consent, the participants were randomly divided into two equal groups using the lottery method. Group A received autologous PRP-soaked dressings, while Group B received conventional saline-soaked dressings. Both groups were managed under similar clinical and aseptic conditions to minimize bias. Each patient's demographic details, including name, age, gender, smoking history, body weight (kg), hemoglobin levels, fasting and postprandial blood glucose levels, HbA1c, blood urea, and serum creatinine, were recorded at baseline. The ulcers were classified according to Wagner's classification system, and the site (plantar, dorsal, heel, or toes), duration (in days), size (in centimeters), and area (in cm²) were documented at baseline and at subsequent follow-ups.

The preparation of autologous PRP was performed under aseptic conditions. Approximately 9 mL of venous blood was drawn from each patient into a sterile tube containing 1 mL of sodium citrate as an anticoagulant. The blood sample was centrifuged using a double-spin technique. The first centrifugation, a hard spin at 5000 rpm for 15 minutes, resulted in three distinct layers: platelet-poor plasma, buffy coat, and red blood cells. The supernatant plasma along with the buffy coat was carefully aspirated and subjected to a second centrifugation, a soft spin at 1000 rpm for 5 minutes, to separate platelet-poor plasma (upper layer) from platelet-rich plasma (lower layer). The PRP thus obtained was divided into two portions: one injected around the ulcer margins and the other applied directly over the wound bed and allowed to clot to form a platelet gel. The wound was then covered with sterile paraffin gauze followed by standard sterile dressing. The PRP dressing was changed every five days, and the application was repeated weekly for six weeks or until complete epithelialization occurred.

Patients in the control group received conventional saline-soaked dressings. The wound area was irrigated thoroughly with 0.9% normal saline and povidone-iodine solution before applying sterile saline-soaked gauze. Dressings were changed daily for six weeks or until the ulcer healed. All patients, regardless of group allocation, received standard medical management including glycemic control, antibiotic prophylaxis with oral moxifloxacin for one week, and counseling on proper foot hygiene and offloading techniques.

Data collection was performed using a predesigned proforma to ensure uniformity. The primary outcome measure was the rate and degree of

wound healing, defined as complete epithelialization of the ulcer without discharge or infection within six weeks. Secondary outcome measures included reduction in ulcer size, mean healing time, and proportion of non-healing ulcers. Patients were followed weekly for six weeks, and wound measurements were recorded using sterile calipers and transparent graph paper to determine ulcer area in square centimeters at each visit. Healing was considered complete when the ulcer achieved full epithelial coverage with no residual raw area.

All data were entered and analyzed using Statistical Package for the Social Sciences (SPSS) version 25.0. Normality of quantitative variables such as age, weight, ulcer duration, and ulcer area was assessed using the Shapiro-Wilk test. Normally distributed variables were presented as mean \pm standard deviation, whereas non-normally distributed variables were expressed as median and interquartile range. Qualitative variables such as gender, smoking status, ulcer site, Wagner grade, and healing status were presented as frequencies and percentages. The independent sample t-test was applied to compare mean healing times between groups, while the Chi-square or Fisher's exact test was used for categorical variables such as healing outcome and ulcer grade. Mann-Whitney U-test was employed for non-normally distributed data such as ulcer size reduction over time. Stratification was applied for potential effect modifiers, including age, gender, and duration of ulcer, smoking status, HbA1c levels, and ulcer site, to control for confounding. Post-stratification comparisons were made using appropriate statistical tests, with a p-value of less than 0.05 considered statistically significant.

Results

A total of 150 patients with diabetic foot ulcers were included in this study, divided equally into two groups: Group A (PRP-soaked dressing) and Group B (saline-soaked dressing). The mean age of participants was 54.6 ± 8.9 years, ranging from 38 to 70 years. Males were predominant in both groups (64.7%), reflecting the higher prevalence of diabetic complications among males in Pakistan. The mean body weight was 72.5 ± 10.3 kg. Smokers constituted 28% of the total sample. (Table 1).

At baseline, the mean ulcer area was 5.6 ± 2.2 cm² in the PRP group and 5.4 ± 2.5 cm² in the saline group ($p = 0.68$). The majority of ulcers were located on the plantar surface (46.7%), followed by toes (33.3%) and heel (20.0%). Most cases were Wagner Grade II ulcers (56%), while 44% were Grade I. (Table 2). After 3 weeks, the mean ulcer area reduced to 2.8 ± 1.4 cm² in the PRP group versus 4.1 ± 1.8 cm² in the saline group ($p < 0.001$). By 6 weeks, the mean ulcer area further decreased to 0.9 ± 0.7 cm² in the PRP group and 2.7 ± 1.2 cm² in the saline group, indicating a significantly faster healing process in patients treated with PRP dressings. (Table 3).

Complete ulcer healing at 6 weeks was achieved in 65 (86.7%) patients in the PRP group compared to 48 (64.0%) in the saline group ($p = 0.002$). The mean healing time was significantly shorter in the PRP group (28.3 ± 6.2 days) than in the saline group (35.9 ± 7.1 days, $p < 0.001$). (Table 4)

When stratified by age, gender, and smoking status, the advantage of PRP remained consistent across subgroups. The difference was particularly significant among male patients ($p = 0.004$) and non-smokers ($p = 0.003$), suggesting improved angiogenic and anti-inflammatory healing response with PRP dressings. (Table 5).

PRP-soaked dressings significantly improved wound healing rates compared with saline-soaked dressings. The mean reduction in ulcer area and complete epithelialization were achieved earlier in the PRP group. PRP therapy showed consistent benefits across demographic and clinical subgroups. No major adverse events were reported.

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Table 1: Demographic Characteristics of the Study Participants (n = 150)

Variable	PRP Group (n=75)	Saline Group (n=75)	Total (n=150)	p-value
Age (years), mean \pm SD	54.1 \pm 9.1	55.0 \pm 8.8	54.6 \pm 8.9	0.62
Gender (Male/Female)	50 (66.7%) / 25 (33.3%)	47 (62.7%) / 28 (37.3%)	97 (64.7%) / 53 (35.3%)	0.61
Body Weight (kg), mean \pm SD	72.1 \pm 9.8	72.9 \pm 10.7	72.5 \pm 10.3	0.73
Smoker, n (%)	20 (26.7%)	22 (29.3%)	42 (28.0%)	0.71
Duration of Diabetes (years), mean \pm SD	8.3 \pm 3.4	8.7 \pm 3.7	8.5 \pm 3.5	0.54
HbA1c (%), mean \pm SD	7.9 \pm 1.3	8.1 \pm 1.5	8.0 \pm 1.4	0.43

Table 2: Baseline Characteristics of Diabetic Foot Ulcers

Characteristic	PRP Group (n=75)	Saline Group (n=75)	Total (n=150)	p-value
Ulcer Duration (days), mean \pm SD	31.7 \pm 10.9	32.5 \pm 11.4	32.1 \pm 11.1	0.67
Ulcer Area (cm ²), mean \pm SD	5.6 \pm 2.2	5.4 \pm 2.5	5.5 \pm 2.3	0.68
Site of Ulcer				
• Plantar Surface	34 (45.3%)	36 (48.0%)	70 (46.7%)	0.75
• Toes	26 (34.7%)	24 (32.0%)	50 (33.3%)	
• Heel	15 (20.0%)	15 (20.0%)	30 (20.0%)	
Wagner Grade I	33 (44.0%)	33 (44.0%)	66 (44.0%)	1.00
Wagner Grade II	42 (56.0%)	42 (56.0%)	84 (56.0%)	1.00

Table 3: Comparison of Mean Ulcer Area Reduction over Time

Time Interval	PRP Group (mean \pm SD)	Saline Group (mean \pm SD)	p-value
Baseline (Day 0)	5.6 \pm 2.2	5.4 \pm 2.5	0.68
After 3 Weeks	2.8 \pm 1.4	4.1 \pm 1.8	< 0.001
After 6 Weeks	0.9 \pm 0.7	2.7 \pm 1.2	< 0.001

Table 4: Comparison of Healing Outcomes between Groups

Outcome Variable	PRP Group (n=75)	Saline Group (n=75)	p-value
Complete Healing (Yes), n (%)	65 (86.7%)	48 (64.0%)	0.002
Mean Healing Time (days), mean \pm SD	28.3 \pm 6.2	35.9 \pm 7.1	< 0.001
Non-healing Ulcers, n (%)	10 (13.3%)	27 (36.0%)	0.002

Table 5: Stratified Analysis of Complete Ulcer Healing

Stratum	PRP Group (Healed %)	Saline Group (Healed %)	p-value
Age < 55 years	88.9	66.7	0.006
Age \geq 55 years	84.6	61.5	0.009
Male	88.0	63.8	0.004
Female	84.0	64.3	0.032
Non-smoker	90.7	68.3	0.003
Smoker	80.0	57.1	0.041

Discussion

The results of this study present a compelling evaluation of the efficacy of autologous platelet-rich plasma (PRP) soaked dressings versus saline-soaked dressings in the treatment of diabetic foot ulcers (DFUs). The findings demonstrate a statistically significant improvement in healing rates, underscoring the potential of PRP as a therapeutic strategy in managing chronic non-healing ulcers.

The demographic information of our study participants reveals a sample primarily comprising males (64.7%), reflecting the higher prevalence of diabetic complications in male populations in Pakistan, as proposed by Ghayour et al (15). The mean age of 54.6 years and mean body weight of 72.5 kg are consistent with findings from Gupta et al (16). Who emphasized the association between demographic factors and healing outcomes in DFUs? Additionally, the ulcer area at baseline was comparable across both groups (PRP: 5.6 \pm 2.2 cm²; saline: 5.4 \pm 2.5 cm²), a trend correlated with other studies showing no significant variation in starting ulcer characteristics between treatment groups (17,18).

The most salient finding of this study is the marked difference in healing rates between the two treatment modalities. The PRP group demonstrated a substantial reduction in mean ulcer area from 5.6 \pm 2.2 cm² at baseline to 0.9 \pm 0.7 cm² at 6 weeks (p < 0.001). This finding aligns with prior studies, including that of Elbarbary et al. (19). Which documented significant improvements in healing rates from PRP treatments compared to standard saline dressings. Moreover, the findings by Deng et al. (20). Indicated that PRP treatments reduced healing times significantly across chronic and non-healing wound cases, corroborating the superior efficacy observed in our study's PRP group.

The reported complete healing rates—86.7% in the PRP group versus 64.0% in the saline group—further emphasize the effectiveness of PRP as a therapeutic option. These results are supported by findings from Bhatmule et al. (21). which showcased that PRP facilitated higher rates of complete healing when compared to conventional treatment methods. Similarly, Devesvar et al (22). Highlighted the advantages of PRP, noting enhanced rates of healing and recovery when managing chronic ulcers, reinforcing our conclusions.

Our stratification analysis indicated that PRP's advantages were particularly notable among male patients ($p = 0.004$) and non-smokers ($p = 0.003$). This finding is consistent with the observations by Rajendran et al. (23). Who found that gender played a crucial role in healing efficiency with varying treatment modalities. Furthermore, Gupta et al. Gupta et al (16). Indicated that demographic factors, such as smoking status and age, significantly influence healing outcomes, providing further justification for our stratified analysis outcomes.

While the results of this study are promising, it is crucial to acknowledge the inherent limitations associated with a single-center study, which may affect the generalizability of our findings. However, the clinical advantages of PRP treatments have been widely recognized, as established by Deng et al (20). Suggesting that our results support existing literature on this promising approach.

Thus, the findings of this study advocate for the integration of PRP soaked dressings as part of the standard care regimen for managing diabetic foot ulcers, particularly in populations with a high prevalence of such conditions. This study not only validates the regenerative potential of PRP but also underscores the necessity of further research to refine application techniques and establish standardized protocols for broader implementation.

Conclusion

This study demonstrates that autologous PRP-soaked dressings significantly accelerate wound healing and improve complete-healing rates in diabetic foot ulcers compared with saline dressings. The results support the inclusion of PRP as an effective adjunct in the management of chronic diabetic wounds, particularly in low-resource settings where rapid recovery can reduce healthcare burden and prevent amputation.

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. (IRBEC-24)

Consent for publication

Approved

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Conflict of interest

The authors declared the absence of a conflict of interest.

Author Contribution

HSG (PGR)

Manuscript drafting, Study Design,

MAI (SR)

Review of Literature, Data entry, Data analysis, and drafting article.

MHG (PGR)

Conception of Study, Development of Research Methodology Design,

MUA (MO)

Study Design, manuscript review, critical input.

All authors reviewed the results and approved the final version of the manuscript. They are also accountable for the integrity of the study.

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