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Comparative Study of Autologous Platelet Rich Plasma Versus Normal Saline Wound Dressing in Diabetic Foot Ulcer

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ABSTRACT

Introduction: Diabetic foot ulcers (DFUs) are a debilitating complication of diabetes mellitus, characterized by chronic non-healing wounds that may lead to hospitalization or amputation. Optimizing wound healing strategies is crucial to reduce morbidity. Platelet-rich plasma (PRP), rich in growth factors, has emerged as a novel therapeutic adjunct to promote wound healing.

Objective: This study compares the effectiveness of autologous PRP dressing versus conventional normal saline (NS) dressing in promoting wound healing among patients with diabetic foot ulcers.

Methods: A prospective randomized controlled study was conducted at the Department of Surgery, TMMC&RC, Moradabad, over 18 months. Seventy-four patients with diabetic foot ulcers (Wagner Grades 1–3) were randomized into two groups: Group A received PRP dressings; Group B received NS dressings. PRP was prepared via double centrifugation and applied weekly. Wound healing was assessed by reduction in ulcer size, granulation tissue formation, and duration of hospital stay.

Results: Patients in the PRP group demonstrated a statistically significant faster rate of wound healing compared to the NS group. On day 7, 100% of PRP patients showed granulation tissue versus 62% in the NS group. Mean healing time and hospital stay were significantly reduced in the PRP group. No adverse events were noted.

Conclusion: Autologous PRP dressing significantly accelerates wound healing in diabetic foot ulcers compared to normal saline. It is safe, easy to prepare, and cost-effective, offering a promising alternative for managing chronic wounds in diabetic patients.

Key words: *Platelet-Rich Plasma (PRP), Normal Saline Dressing, Diabetic Foot Ulcer, Wound Healing*

INTRODUCTION

Diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycemia resulting from defects in insulin secretion, insulin action, or both. One of the most severe and debilitating complications of diabetes is the development of diabetic foot ulcers (DFUs), which affect approximately 15–25% of diabetic patients during their lifetime. These ulcers, often precipitated by peripheral neuropathy, vascular insufficiency, and impaired immunity, significantly increase the risk of lower limb amputation, recurrent infections, and extended hospitalizations.

DFUs typically develop below the ankle and penetrate deep into the dermis, compromising blood vessels and collagen, and making them difficult to heal. In India, the prevalence of DFUs ranges from 4% to 5%, lower than in many Western nations, but still representing a substantial clinical burden. The multifactorial nature of DFU pathogenesis—ranging from poor glycemic control to mechanical trauma and secondary infections—complicates both prevention and management.
Standard treatment modalities include wound debridement, offloading, infection control, revascularization, and moist wound care using dressings such as normal saline, hydrogels, or antimicrobial agents. Despite these strategies, many DFUs exhibit a non-healing phenotype due to chronic inflammation and inadequate cellular response.

Recently, biological therapies like autologous platelet-rich plasma (PRP) have gained attention. PRP is a concentration of autologous platelets suspended in plasma, rich in growth factors such as platelet-derived growth factor (PDGF), vascular endothelial growth factor (VEGF), and epidermal growth factor (EGF). These factors play a crucial role in promoting angiogenesis, tissue regeneration, and wound healing.

Given its ease of preparation, low cost, and regenerative potential, autologous PRP may serve as an effective adjunct to conventional DFU management. This study aims to compare the efficacy of autologous PRP dressing with normal saline dressing in promoting wound healing in patients with diabetic foot ulcers.

Materials and Methods:

Study Design and Setting

This prospective, randomized controlled study was conducted in the Department of General Surgery, Teerthanker Mahaveer Medical College and Research Centre (TMMC&RC), Moradabad, over a period of 18 months. Ethical approval was obtained from the Institutional Ethics Committee (IEC) and the Clinical Research Committee (CRC) prior to initiation. Patients with diabetic foot ulcers (DFUs) were enrolled from both outpatient and inpatient services after obtaining informed consent.

Sample Size

The sample size was calculated using a formula for comparing two independent means based on previous literature. Assuming a mean healing time of 13.48 days for conventional dressing and 10.9 days for PRP, with standard deviations of 3.37 and 3.4 respectively, a 95% confidence interval, and 90% power, the sample size required was 37 patients per group, totaling 74 patients.

Inclusion Criteria

- Age 18 to 90 years
- Diagnosed cases of diabetic foot ulcer (Wagner Grades 1–3)
- Clean wounds with a healthy granulating bed
- Willing to provide informed consent and comply with follow-up

Exclusion Criteria

- Gangrenous or acutely infected wounds
- Uncontrolled diabetes (HbA1c > 90 mmol/mol)
- Patients with autoimmune disease, immunosuppression, or liver failure
- American Society of Anesthesiologists (ASA) grade >3
- Wagner Grade 4–5 ulcers

Randomization and Group Allocation

Eligible patients were randomized into two groups using computer-generated random numbers:

- Group A (n=37): Received autologous PRP dressing
- Group B (n=37): Received normal saline (NS) dressing

Intervention Protocol

Group A (PRP Dressing):

Twenty milliliters of venous blood was drawn using aseptic precautions. PRP was prepared by a double centrifugation method—first at 1500 rpm for 10 minutes and then at 3000 rpm for 10 minutes. The resulting PRP (2–3 ml) was activated using calcium chloride and applied topically to the ulcer once a week.

Group B (NS Dressing):

Ulcers were irrigated with 0.9% normal saline followed by saline-soaked gauze and dry sterile gauze covering, changed daily.

Both groups received standardized wound care including antibiotics (based on culture), glycemic control, pressure offloading, and nutritional support.

Outcome Measures

Primary Outcomes:

- Time to complete wound healing (in days)
- Rate of complete ulcer healing within 12 weeks

Secondary Outcomes:
- Reduction in wound surface area (via planimetry)
- Time to granulation tissue formation
- Improvement in Wagner Grade
- RESVECH 2.0 score
- Duration of hospital stay
- Presence of infection and complications

Follow-up and Statistical Analysis
Patients were followed weekly during the first month, then biweekly up to 12 weeks. Data were analyzed using SPSS version 26. Continuous variables were expressed as mean ± standard deviation; categorical data as frequencies and percentages. Group comparisons used independent samples t-test and chi-square test. Time to healing was analyzed using Kaplan-Meier curves and log-rank test. A p-value < 0.05 was considered statistically significant.

Patient Demographics and Baseline Characteristics
A total of 74 patients were included, with 37 in each group (Group A: PRP; Group B: Normal Saline). The two groups were comparable in terms of age, sex distribution, duration of diabetes, and Wagner ulcer grade at baseline. The mean age in the PRP group was 58.3 ± 7.6 years, and 59.1 ± 8.2 years in the saline group (p = 0.63). No statistically significant differences were observed in HbA1c levels or ulcer duration at enrollment.

Table1. Baseline Characteristics of Study Participants

Variable	PRP Group (n=37)	Saline Group (n=37)	p-value
Mean Age (years)	58.3 ± 7.6	59.1 ± 8.2	0.63
Male (%)	64.9%	62.1%	0.80
Mean Duration of Diabetes (yrs)	9.2 ± 2.8	9.7 ± 2.5	0.42
Mean HbA1c (%)	7.9 ± 0.9	8.1 ± 1.1	0.33
Wagner Grade 1/2/3 (%)	21.6/56.8/21.6	24.3/51.3/24.3	0.89

Wound healing outcome
By the end of 12 weeks, complete wound healing was observed in 36 patients (97.3%) in the PRP group versus 4 patients (10.8%) in the saline group, which was statistically significant (p < 0.001).

Table 2. Wound Healing at 12 Weeks

Healing Outcome	PRP Group (n=37)	Saline Group (n=37)	p-value
Completely Healed	36 (97.3%)	4 (10.8%)	<0.001
Partially Healed	1 (2.7%)	28 (75.7%)	
Non-Healed	0 (0%)	5 (13.5%)	

Time to Healing
The mean time to complete healing in the PRP group was 22.4 ± 5.8 days, compared to 46.7 ± 6.4 days in the saline group (p < 0.001), showing a highly significant reduction in healing duration with PRP.

Table 3. Mean Healing Time

Parameter	PRP Group	Saline Group	p-value
Mean Time to Healing (days)	22.4 ± 5.8	46.7 ± 6.4	

Wound Area Reduction
The PRP group showed greater wound area reduction compared to the control. The percentage reduction from baseline was significantly higher in the PRP group.

Table 4. Wound Surface Area Reduction

Time Point	PRP Group (cm²)	Saline Group (cm²)	p-value
Baseline	4.75 ± 0.9	4.62 ± 0.8	0.39
Day 7	3.11 ± 0.8	4.12 ± 0.7	<0.01
Day 14	2.04 ± 0.6	3.56 ± 0.7	<0.001
Day 21	0.91 ± 0.5	2.77 ± 0.8	<0.001

RESVECH 2.0 Score Comparison
The PRP group achieved a lower (better) RESVECH 2.0 score by week 3 (mean 2.73 vs 6.78; p < 0.001), reflecting faster healing and better wound bed characteristics.

Table 5. RESVECH 2.0 Scores (Week 3)

Group	Mean Score ± SD	p-value

PRP Group 2.73 ± 1.1
Saline Group 6.78 ± 1.5 <0.001
Hospital Stay Duration
Patients treated with PRP had significantly shorter hospital stays (13.3 ± 3.4 days) compared to the saline group (27.5 ± 5.2 days).

Table 6. Mean Hospital Stay

Group	Hospital Stay (days)	p-value
PRP Group	13.3 ± 3.4	
Saline Group	27.5 ± 5.2	<0.001

Summary of Key Findings:
- PRP significantly enhanced healing rates and reduced time to recovery.
- It improved granulation tissue formation, reduced wound size faster, and achieved better wound scores.
- Hospital stays were shortened significantly, implying lower healthcare burden.
- No adverse reactions or complications were reported with PRP application.

Diabetic foot ulcers (DFUs) remain a major health concern due to their chronicity, risk of infection, and high likelihood of leading to lower-limb amputations. Despite advances in wound care, many DFUs persist as non-healing lesions. This study aimed to evaluate whether autologous platelet-rich plasma (PRP), rich in growth factors and cytokines, offers a clinically superior alternative to conventional normal saline dressing.

The findings of our randomized controlled trial clearly demonstrate that autologous PRP significantly improves healing outcomes in DFUs. Patients treated with PRP showed a much higher complete healing rate (97.3%) compared to those treated with normal saline (10.8%) over 12 weeks. This aligns with the results of Orban et al. and Ali et al., who reported significantly improved healing rates and faster wound closure with PRP therapy in chronic diabetic wounds.

Mechanisms of PRP in Enhancing Wound Healing
PRP is rich in bioactive proteins including platelet-derived growth factor (PDGF), vascular endothelial growth factor (VEGF), and epidermal growth factor (EGF). These promote angiogenesis, fibroblast proliferation, collagen synthesis, and tissue regeneration. Activated platelets within PRP release these factors locally at the wound site, mimicking and enhancing the body's natural healing cascade. This mechanistic pathway explains the faster granulation tissue development and better RESVECH 2.0 scores observed in our PRP group.

Our study observed a mean healing time of 22.4 days in the PRP group compared to 46.7 days in the saline group, consistent with studies by Shao et al. and Deng et al., where PRP shortened healing duration and reduced ulcer area significantly . Moreover, the PRP group had a shorter hospital stay (13.3 days vs. 27.5 days), indicating faster recovery and lower treatment costs—an important consideration in resource-limited settings.

Comparison with Existing Evidence
The growing body of evidence—including multiple meta-analyses and RCTs—supports the use of PRP in DFU management. Ruiz-Muñoz et al. (2024) conducted a meta-analysis and found that autologous PRP significantly increased complete ulcer healing compared to conventional treatments (OR = 3.69) . Syafira et al. (2024) similarly reported that PRP doubled the healing rate and reduced wound area by nearly 0.5 cm^2.

However, some studies note heterogeneity in outcomes due to the variability in PRP preparation techniques and concentrations. In our study, we used a standardized double-spin method yielding 3–5× baseline platelet concentration, activated with calcium chloride. This approach is reproducible and cost-effective, making it feasible for widespread clinical adoption.

Strengths and Clinical Relevance
This study adds to the growing evidence supporting PRP use in diabetic foot care by employing a prospective, randomized design with clearly defined outcomes, regular follow-up, and robust statistical analysis. The significant improvements in healing rate, wound area reduction, granulation tissue, and shorter hospital stays make a compelling case for PRP as an adjunct to standard care.

From a clinical perspective, PRP is autologous, reducing the risk of immunogenicity or adverse reactions. It is simple to prepare, relatively inexpensive, and does not require advanced laboratory infrastructure, making it especially valuable in low-resource settings.

Limitations

Despite the positive outcomes, our study has limitations. The sample size, while statistically powered, was relatively small and drawn from a single center. Long-term follow-up beyond 12 weeks was not performed, so recurrence rates or delayed complications could not be assessed. Furthermore, although we used a standardized PRP preparation method, variations in PRP protocols across studies limit external comparability. Future studies should evaluate dose-response relationships and optimal PRP application frequency.

Implications for Future Research

Large-scale, multicentric RCTs are needed to establish standardized protocols for PRP preparation, dosing, and administration. Exploring combination therapies (e.g., PRP with collagen dressings or growth factor gels) could further optimize outcomes. Additionally, cost-benefit analyses are essential to justify widespread adoption in public health systems.

Conclusion

This study demonstrates that autologous platelet-rich plasma (PRP) is significantly more effective than normal saline dressings in the management of diabetic foot ulcers (DFUs). Patients treated with PRP experienced higher healing rates, faster wound closure, improved granulation tissue formation, better wound scores, and reduced hospital stays. The regenerative potential of PRP—attributed to its rich content of growth factors—offers a practical and biologically sound approach to accelerate wound healing in chronic diabetic ulcers.

Given its autologous nature, low cost, ease of preparation, and minimal risk of adverse events, PRP represents a valuable adjunct to standard diabetic wound care protocols. While further large-scale and long-term studies are warranted, our findings support the integration of PRP into routine clinical practice, especially in settings dealing with chronic, non-healing DFUs. It has the potential to reduce healthcare burden, prevent amputations, and improve patient quality of life.

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