



Original Article

Efficacy of Autologous Platelet-Rich Plasma in the Treatment of Chronic Nonhealing Leg Ulcers: A Prospective Observational Study

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ABSTRACT

Introduction: Chronic nonhealing leg ulcers (CNLUs) are wounds persisting beyond four weeks that fail to progress through normal healing phases. They represent a significant healthcare burden, particularly in India where diabetes and peripheral vascular disease are endemic. Conventional therapies often fail to replenish the growth factors essential for tissue regeneration. Autologous platelet-rich plasma (PRP)- concentrated in platelet-derived growth factor (PDGF), vascular endothelial growth factor (VEGF) and transforming growth factor-beta (TGF- β)- offers a promising autologous, cost-effective adjunct.

Aim: To evaluate the clinical efficacy and safety of autologous PRP in chronic nonhealing leg ulcers with respect to complete healing rate, ulcer size reduction, one-year recurrence and adverse events.

Material and Method: A prospective observational study was conducted in the Department of General Surgery, VIMS, Gajraula, over two years (2023–2025). Sixty-five patients with chronic nonhealing leg ulcers of ≥ 4 weeks duration received intralesional autologous PRP injections every two weeks. PRP was prepared by double-centrifugation ($300 \times g/5$ min then $700 \times g/17$ min) of 10 mL venous blood with 3.2% sodium citrate and activated with 10% calcium chloride. Weekly assessments included ulcer dimensions, granulation tissue scoring, laboratory parameters and patient satisfaction via Visual Analogue Scale (VAS 0–10). Follow-up extended to 12 months post-healing.

Results: Complete healing occurred in 80.0% of patients (52/65) with a mean ulcer size reduction of $91.8\% \pm 5.3\%$ at 12 weeks ($p < 0.001$). Traumatic ulcers healed fastest (91.7% ; 7.4 ± 1.5 weeks), followed by venous (89.5% ; 8.7 ± 1.9 weeks) and diabetic ulcers (85.7% ; 10.3 ± 2.1 weeks). One-year recurrence was 13.5%. Granulation $\geq 50\%$ was achieved in 90.8% of patients by week 8. Adverse events occurred in 24.6% and were minor and self-limiting. Multivariate analysis identified ulcer area < 10 cm², serum albumin > 3.5 g/dL, non-smoking status, and upper/lower-middle socioeconomic status (SES) as independent predictors of healing.

Conclusion: Autologous PRP is a safe, effective and reproducible therapy that significantly accelerates healing of chronic nonhealing leg ulcers, reduces recurrence and maintains a favourable safety profile, supporting its incorporation as a standard adjunctive intervention in wound management.

Keywords Chronic ulcer, Wound healing, Growth factors, Diabetic foot ulcer, PRP.

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INTRODUCTION

Chronic nonhealing leg ulcers are defined as wounds persisting beyond four weeks that fail to progress through the three phases of healing- inflammation, tissue formation and remodelling (1). They impose a substantial clinical and economic burden globally and their incidence is rising in parallel with the twin epidemics of diabetes mellitus (DM) and peripheral vascular disease (PVD) (2). In India, approximately 8.9% of the adult population is affected by diabetes, translating to millions at risk of diabetic foot ulcers (DFUs)- the most common and refractory subtype of CNLUs (3). Rural and Tier-II regions face compounded challenges including delayed diagnosis, limited access to specialised wound care and poor glycaemic control (4).

The pathophysiological hallmark of CNLUs is a deficiency of key growth factors- including PDGF, VEGF, epidermal growth factor (EGF) and TGF- β — that disrupts fibroblast proliferation, angiogenesis and re-epithelialisation (5). Conventional therapies such as wound debridement, compression dressings and antibiotics address symptoms but do not replenish these molecular mediators (6).

Autologous PRP, derived by centrifuging the patient's own blood to yield a platelet concentrate 3–5 times baseline levels, delivers a physiological bolus of these growth factors directly to the wound bed (7). Its autologous origin eliminates the risk of immunological rejection or disease transmission and preparation is achievable at the bedside with minimal equipment- critical advantages in resource-limited settings (8). Despite growing international evidence, its systematic evaluation in the Indian demographic remains limited, with most studies conducted in Western populations with differing comorbidity profiles (9).

This present study provides prospective clinical evidence regarding the use of autologous Platelet-Rich Plasma (PRP) therapy in chronic non-healing leg ulcers from a tertiary care centre in North India. Unlike many previous studies that focused primarily on short-term ulcer closure, the present study evaluated multiple clinically relevant outcomes including ulcer area reduction etc. The study included different ulcer aetiologies such as diabetic, venous, traumatic and pressure ulcers within the same cohort, allowing comparison of healing response across ulcer types. The study also assessed clinical correlates and risk factors influencing healing outcomes, thereby providing a more comprehensive understanding of wound healing dynamics in real-world surgical practice. Furthermore, the study contributes data from a resource-constrained Indian tertiary care setting where chronic wounds are often associated with delayed presentation, poor nutrition and significant comorbidity burden. The findings therefore add practical clinical evidence regarding the feasibility, safety and potential utility of autologous PRP as an adjunctive modality in chronic wound management in developing healthcare settings.

OBJECTIVE

To evaluate the efficacy and safety of autologous PRP and quantifying healing rates, ulcer size reduction, recurrence and identifying patient-level predictors of outcome.

MATERIAL AND METHOD

Study Design and Setting

A prospective observational study was conducted in the Department of General Surgery, Venkateshwara Institute of Medical Sciences (VIMS), Gajraula, Amroha, Uttar Pradesh, over a two-year period (2023–2025). Ethical approval was obtained from the Institutional Ethics Committee (Ref: VIMS/IEC/2024/83; IEC/2024/AIR/66) and written informed consent was obtained from all participants.

Inclusion Criteria:

- Age above 16 years and below 60 years (Male, Female & Transgender).
- Non healing ulcers.
- Serum platelet counts more than 150000/dl.
- Hb >9g/dl.
- INR <1.5g/dl.
- Serum albumin >3.5 g/dl
- Patients compliant to appropriate offloading procedure recommended by investigator.

Exclusion criteria:

- Wounds with signs of active local or systemic infection (Surrounding redness, local warmth, fever)
- Diabetic patients with HbA1C > 7%.
- Radiological evidence of osteomyelitis of the underlying bone.
- Immunocompromised states, uncontrolled systemic illnesses.
- Patients on antiplatelet drugs.eg warfarin
- Patients with mental illness or not able to give consent.

- Patient refused to participate in study

Sample Size

Based on the prevalence of complete healing with autologous PRP (P = 80%) reported by Jaseem et al. (9), the sample size was calculated using the formula $n = Z^2Pq/r^2$, where $Z = 1.96$ (5% significance), $q = 20$, and $r = 10\%$ (absolute error), yielding a minimum of 62; a target of 65 was enrolled to account for attrition.

Data Collection

All patients' demographic details including age, sex and size of chronic ulcers of at least four weeks duration treated with autologous Platelet-Rich Plasma (PRP) were recorded. Detailed patient history, clinical examination findings and routine investigations including complete blood count, coagulation profile etc were obtained.

PRP Preparation and Administration

Under aseptic conditions, 10 mL of venous blood was drawn from the antecubital vein into sterile tubes containing 3.2% sodium citrate. A double-centrifugation protocol was employed: first at $300\times g$ for 5 minutes at $18^\circ C$ to separate erythrocytes, followed by transfer of the platelet-rich supernatant and second centrifugation at $700\times g$ for 17 minutes at $18^\circ C$ to yield 2–3 mL of platelet pellet concentrate. Activation was performed immediately by adding 0.3 mL of 10% calcium chloride per mL of PRP. The ulcer was irrigated with physiological saline before intralesional injection at the wound edges and floor. A non-absorbent dressing was applied and maintained for one week. Reinjection was repeated every two weeks until complete healing.

Outcome Assessment

The primary outcome was complete ulcer healing. Secondary outcomes included percentage reduction in ulcer area at weeks 4, 8, and 12; granulation tissue formation ($\geq 50\%$ coverage); one-year recurrence rate; adverse events; and patient satisfaction (VAS 0–10). Laboratory parameters (haemoglobin, platelet count, serum albumin) were compared pre- and post-treatment.

Statistical Analysis

Data were analysed using SPSS v23.0. Continuous variables are presented as mean \pm SD and categorical variables as frequency and percentage. Comparisons were made using appropriate parametric and non-parametric tests. Multivariate logistic regression was performed to identify independent predictors of healing. A p-value < 0.05 was considered statistically significant.

RESULTS

Table 1: Baseline Demographic and Clinical Characteristics (n=65)

Parameter	Category / Value	n (%) / Mean \pm SD
Age (years)	16–30	14 (21.5%)
	31–45	27 (41.5%)
	46–60	24 (37.0%)
Gender	Male	38 (58.5%)
	Female	27 (41.5%)
Ulcer Etiology	Diabetic Ulcers	28 (43.1%)
	Venous Ulcers	19 (29.2%)
	Traumatic Ulcers	12 (18.5%)
	Pressure Ulcers	6 (9.2%)
Ulcer Duration (weeks)	Diabetic Ulcers	18.7 \pm 3.2
	Venous Ulcers	22.4 \pm 4.1
	Traumatic Ulcers	14.3 \pm 2.8
	Pressure Ulcers	26.5 \pm 5.7
Ulcer Area (cm ²)	Baseline	14.7 \pm 3.8
Comorbidities	Diabetes Mellitus	28 (43.1%)
	Hypertension	21 (32.3%)
	PVD	17 (26.2%)
	Venous Insufficiency	19 (29.2%)

The study enrolled 65 patients. Table 1 illustrates that majority of participants were in the 31–45-year age group (41.5%) with a male preponderance (58.5%). Diabetic ulcers were the most frequent aetiology (43.1%), followed by venous (29.2%), traumatic (18.5%) and pressure ulcers (9.2%). Diabetes mellitus was the predominant comorbidity (43.1%), followed by hypertension (32.3%), venous insufficiency (29.2%) and PVD (26.2%). Baseline mean ulcer area was 14.7 ± 3.8 cm² (range 5.2–32.6 cm²).

PRP Treatment Sessions

Of the 65 participants, 18.5% required 2 sessions (mean volume 2.3 ± 0.4 mL), 53.8% required 4 sessions (2.5 ± 0.3 mL, $p=0.008$) and 27.7% required 6 sessions (2.8 ± 0.5 mL, $p<0.001$), reflecting the expected correlation between ulcer size/chronicity and treatment intensity.

Table 2: Overall Efficacy Outcomes of PRP Therapy (n=65)

Outcome	Value	95% CI	p-value
Complete Healing Rate	80.0% (52/65)	68.4–88.9%	<0.001
Mean Ulcer Size Reduction (12 weeks)	$91.8\% \pm 5.3\%$	89.7–93.9%	<0.001
1-Year Recurrence Rate	13.5% (7/52)	5.6–25.8%	0.007
Adverse Event Incidence	24.6% (16/65)	14.8–37.1%	0.112
Granulation $\geq 50\%$ by Week 4	63.1% (41/65)	—	<0.001
Granulation $\geq 50\%$ by Week 8	90.8% (59/65)	—	<0.001
Patient Satisfaction VAS (post-treatment)	8.3 ± 1.1	—	<0.001

VAS: Visual Analogue Scale; CI: Confidence Interval

Overall efficacy outcomes are summarised in Table 2. Complete healing was achieved in 80.0% of patients (52/65; 95% CI: 68.4–88.9%; $p<0.001$). Mean ulcer size reduced from 14.7 ± 3.8 cm² at baseline to 9.3 ± 2.6 cm² at week 4 (36.7% reduction), 4.1 ± 1.3 cm² at week 8 (72.1%), and 1.2 ± 0.7 cm² at week 12 (91.8%), all changes statistically significant ($p<0.001$).

Table 3: Complete Healing Rates and Time by Ulcer Etiology (n=65)

Etiology	n	Healed (%)	Healing Time (weeks \pm SD)	p-value
Diabetic Ulcers	28	85.7%	10.3 ± 2.1	0.003
Venous Ulcers	19	89.5%	8.7 ± 1.9	<0.001
Traumatic Ulcers	12	91.7%	7.4 ± 1.5	<0.001
Pressure Ulcers	6	66.7%	12.6 ± 2.8	0.021

Table 3 shows that traumatic ulcers demonstrated the highest and fastest healing (91.7%; 7.4 ± 1.5 weeks), followed by venous (89.5%; 8.7 ± 1.9 weeks), diabetic (85.7%; 10.3 ± 2.1 weeks), and pressure ulcers (66.7%; 12.6 ± 2.8 weeks).

Granulation Tissue and Recurrence

Granulation tissue coverage of $\geq 50\%$ was observed in 63.1% of patients at week 4, increasing significantly to 90.8% by week 8 (both $p<0.001$). Among the 52 healed patients, the one-year recurrence rate was 13.5% (7/52; 95% CI: 5.6–25.8%; $p=0.007$). Pressure ulcers had the highest recurrence (25.0%), while traumatic ulcers had the lowest (9.1%).

Socioeconomic and Behavioural Predictors

A clear socioeconomic gradient in outcomes was demonstrated: upper-class patients achieved 100% healing in 7.2 ± 1.1 weeks versus 61.5% healing in 13.8 ± 3.1 weeks among lower-class patients. Smokers had significantly lower healing rates (68.2% vs 86.0%; $p=0.019$) and higher recurrence (26.7% vs 8.1%; $p<0.001$). Full offloading compliance yielded a 90.5% healing rate versus 55.6% with partial compliance.

Table 4: Multivariate Predictors of Complete Ulcer Healing

Factor	Adj. OR	95% CI	p-value
Ulcer Area <10 cm ²	4.32	1.87–10.01	0.001
Serum Albumin >3.5 g/dL	3.78	1.52–9.41	0.004
Non-Smoking Status	3.21	1.24–8.32	0.016
Upper/Lower Middle SES	2.95	1.17–7.42	0.022

OR: Odds Ratio; CI: Confidence Interval; SES: Socioeconomic Status

Multivariate logistic regression (Table 4) identified four independent predictors of complete healing: ulcer area <10 cm² (OR 4.32; 95% CI: 1.87–10.01; $p=0.001$), serum albumin >3.5 g/dL (OR 3.78; 95% CI: 1.52–9.41; $p=0.004$), non-smoking status (OR 3.21; 95% CI: 1.24–8.32; $p=0.016$), and upper/lower-middle SES (OR 2.95; 95% CI: 1.17–7.42; $p=0.022$).

Adverse Events and Laboratory Parameters

Adverse events occurred in 24.6% of patients: mild injection pain (12.3%, resolving in 24.3 ± 3.1 hours), local erythema (7.7%, resolving in 48.2 ± 6.7 hours) and superficial infection (4.6%, resolving in 6.5 ± 1.2 days). No serious adverse events were recorded. Serum albumin demonstrated a statistically significant improvement from 3.8 ± 0.4 g/dL to 4.0 ± 0.3 g/dL post-treatment ($p=0.026$), while changes in haemoglobin and platelet counts were non-significant. Patient satisfaction scores (VAS) were high at 8.3 ± 1.1 post-treatment and sustained at 7.8 ± 1.3 at 12-week follow-up (both $p<0.001$).

DISCUSSION

The present study demonstrates that autologous PRP therapy is highly effective in the management of CNLUs, achieving an 80.0% complete healing rate and 91.8% mean ulcer size reduction over 12 weeks — outcomes that are consistent with, and in several respects superior to, those reported in prior literature.

The complete healing rate of 80.0% aligns closely with Suranarayan et al. (10) who reported 76% complete healing across 33 ulcers and a mean area reduction of 91.7% after six weekly PRP treatments, and with Prabhu et al. (8) who achieved 81.73% healing in 104 chronic ulcers using homologous PRP dressings. Our 12-week protocol with biweekly injections is further supported by Raslan et al. (11) who reported 100% healing in 24 patients with a mean healing time of 6.11 weeks using an identical injection schedule and by Wanniang et al. (12) who demonstrated 74% complete healing at one month with weekly PRP in a randomised controlled trial (RCT). The slight differences in healing rates may reflect heterogeneity in patient demographics, wound protocols, and PRP preparation techniques.

The stepwise ulcer area reduction observed in our cohort — 36.7% at week 4, 72.1% at week 8, and 91.8% at week 12—mirrors the kinetics described by Gade et al. (13) (PRP group showing 43.96% reduction at 3.68 weeks versus 13.81% with conventional dressings) and underscores the sustained biological activity of sequentially applied PRP. Stacey et al. (14) notably found no significant reduction with topical platelet lysate in a randomised controlled trial, highlighting that activated, injected autologous PRP— rather than inactivated platelet preparations— is essential for biological efficacy.

The differential healing rates by aetiology— traumatic > venous > diabetic > pressure— parallel findings from Suthar et al. (7) and Jaseem et al. (9), and are mechanistically explicable. Traumatic ulcers occur in otherwise well-perfused tissue with intact growth factor signalling, making them most responsive to exogenous PRP. Pressure ulcers, by contrast, exist in chronically ischaemic, mechanically stressed tissue, explaining the lowest healing rate (66.7%) and highest recurrence (25.0%).

The identification of serum albumin >3.5 g/dL as an independent predictor of healing (OR 3.78) is of particular clinical significance. Albumin serves as a proxy for nutritional and anabolic status; hypoalbuminemia impairs fibroblast proliferation and collagen synthesis, directly antagonising PRP's regenerative effects (8). This finding argues strongly for nutritional optimisation as a prerequisite to, or concurrent with, PRP therapy. Similarly, the SES gradient— from 100% healing in upper-class patients to 61.5% in lower-class— reflects access to adequate nutrition, adherence, and comorbidity management, consistent with socioeconomic determinants of wound healing described in global literature (12).

The adverse event profile (24.6% minor events, no serious adverse events) is consistent with the established safety record of autologous PRP across all prior studies (7,8,11), reinforcing its suitability for outpatient use. The statistically significant improvement in serum albumin post-treatment may reflect the systemic anabolic effects of wound healing and improved nutritional intake prompted by clinical improvement.

Our one-year recurrence rate of 13.5% compares favourably with conventional wound care, where recurrence rates of 30–70% are commonly reported, and is consistent with the durable outcomes described by Suthar et al. (7) and Jaseem et al. (9). The substantially higher recurrence in smokers (26.7% vs 8.1%) reiterates the importance of smoking cessation counselling as an integral component of wound management. Autologous PRP should be considered as part of a comprehensive wound-healing strategy rather than an isolated intervention. Its effectiveness is greatest in patients with adequate nutrition, good glycaemic control, smoking cessation, proper offloading and optimised vascular status. The study highlights the importance of identifying and correcting modifiable risk factors before PRP administration to improve healing outcomes. These findings support a personalised and evidence-based approach to chronic non-healing leg ulcer management, particularly in resource-limited settings. Wider implementation of such strategies may help reduce amputations, shorten hospital stay and improve quality of life among underserved populations.

Limitations

This study is limited by its single-centre, non-randomised design which precludes causal attribution and limits generalisability. The absence of a concurrent control group makes it difficult to definitively isolate PRP's contribution from concurrent offloading and nutritional optimisation. Longer-term outcomes remain unknown. Self-reported offloading compliance may introduce reporting bias. Variations in PRP platelet yield while minimised by standardised protocol, may affect reproducibility across settings.

CONCLUSION

Autologous PRP is a safe, effective and practically feasible therapy for chronic nonhealing leg ulcers, yielding an 80.0% complete healing rate, 91.8% ulcer size reduction, and a low 13.5% one-year recurrence over a 12-week treatment protocol. Healing was most rapid in traumatic and venous ulcers and was independently predicted by smaller ulcer area, adequate serum albumin, non-smoking status, and higher socioeconomic class— emphasising that PRP efficacy is optimised when systemic and behavioural factors are concurrently addressed. These findings support the integration of autologous PRP as

a standard adjunctive intervention in the surgical management of chronic lower-limb ulcers, particularly in settings where advanced wound care options are limited. Multi-centre randomised controlled trials are warranted to validate these findings and establish standardised protocols.

Ethical approval and consent to participate

Ethical approval from Institutional Ethics Committee (Ref: VIMS/IEC/2024/83; IEC/2024/AIR/66) was sought before the conduct of the study. Written consent from the participants was obtained after informing them about the purpose of the study; voluntary participation; and no harm to the participant. All methods were performed in accordance with the relevant guidelines and regulations. To protect the confidentiality of participants, no names or positions have been reported in the manuscript.

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