

Comparison of Efficacy of Autologous Platelet Rich Plasma Dressing versus Conventional Dressing in Healing of Chronic Non-healing Ulcer - A Prospective, Randomised and Controlled Study

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Abstract:

Background: Long-term morbidity is linked to chronic non-healing ulcers, which frequently do not improve with traditional wound care. Growth factor-rich autologous platelet-rich plasma (PRP) has become a popular biological supplement to improve wound healing.

Aim: To evaluate the effectiveness of conventional and autologous platelet-rich plasma dressings for the treatment of persistent, non-healing ulcers.

Methods: Over the course of a year, this prospective, randomized, controlled trial was carried out at IGIMS, Patna. PRP dressing (Group P, n = 60) and conventional dressing (Group C, n = 60) were randomly assigned to 120 patients with chronic non-healing ulcers. While traditional dressings were used every two days, PRP was created using a double-spin centrifugation method and applied once a week. For 20 weeks, patients were monitored. Rate of healing, ulcer size decrease, granulation tissue creation, epithelialization, necessity for surgery, and complications were among the outcomes evaluated.

Results: Compared to the standard dressing group, the PRP group showed considerably faster wound healing, higher reduction in ulcer size, earlier granulation tissue development, and earlier epithelialization ($p < 0.05$). The PRP group required less surgical intervention and had a much shorter mean healing time. There were no significant negative effects noted.

Conclusion: Autologous PRP dressing is a safe and effective modality that significantly improves healing outcomes in chronic non-healing ulcers.

Keywords: Platelet-rich plasma; Chronic non-healing ulcer; Wound healing; Conventional dressing; Randomized controlled study

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Introduction

Wounds that do not go through the typical stages of healing and do not significantly improve after four to six weeks of regular

wound care are known as chronic non-healing ulcers. The lower extremities are frequently affected by these ulcers, which

are linked to significant morbidity, pain, a worse quality of life, and higher medical expenses [1]. In the general population, the prevalence of chronic leg ulcers is reported to be between 0.18% and 1%, with higher rates seen in patients with systemic comorbidities and the elderly [2].

The most common etiologies of chronic non-healing ulcers include diabetic foot ulcers, venous insufficiency ulcers, pressure ulcers, and arterial ulcers. Diabetes mellitus remains a major contributor due to peripheral neuropathy, microvascular disease, and impaired immune response, all of which delay wound healing and increase susceptibility to infection [3]. Venous ulcers result from chronic venous hypertension and valvular incompetence, leading to tissue hypoxia and persistent inflammation [4]. Chronic wounds are characterized by prolonged inflammatory phases, reduced fibroblast activity, impaired angiogenesis, and decreased growth factor availability, which collectively hinder normal tissue regeneration [5].

Conventional management of chronic ulcers includes meticulous wound assessment, infection control, regular debridement, pressure offloading, optimization of glycemic control, and use of appropriate dressings. Despite these measures, many ulcers fail to heal completely and may eventually require surgical interventions such as skin grafting, flap coverage, or even amputation [6]. Hence, there is a growing interest in adjunctive biological therapies that can accelerate wound healing and reduce complications.

An autologous concentration of platelets suspended in a tiny amount of plasma is called platelet-rich plasma (PRP), and it has drawn interest as a possible treatment for chronic wounds. Growth factors, such as platelet-derived growth factor, transforming growth factor- β , vascular endothelial growth factor, epidermal growth factor, and insulin-like growth

factors, are highly concentrated in PRP and are essential for angiogenesis, fibroblast proliferation, collagen synthesis, and epithelialization [7]. Because of these characteristics, PRP is a desirable technique for improving wound healing and tissue restoration.

When compared to traditional dressing techniques, PRP has been shown to promote granulation tissue production, speed up wound closure, and shorten healing times in a number of trials on chronic non-healing ulcers [8,9]. Nevertheless, the research now in publication demonstrates variation in study design, PRP preparation procedures, and outcome measurements, which results in conflicting findings. Furthermore, there is a dearth of high-quality randomized controlled data from Indian tertiary care facilities [8,9].

In order to produce solid clinical evidence and support standardized wound care procedures, the current prospective, randomized, controlled study was conducted at a tertiary care facility to compare the effectiveness of autologous platelet-rich plasma dressing with conventional dressing in the healing of chronic non-healing ulcers.

Materials and Methods

Study Design and Setting

The Indira Gandhi Institute of Medical Sciences (IGIMS) in Patna, India, was the site of this prospective, randomized, controlled, and comparative investigation. The trial lasted for a full year.

Ethical consideration

After receiving approval from the Institute Ethics Committee at IGIMS, Patna, the study was started. Prior to recruitment, each subject provided written informed consent, and the study was carried out in compliance with the Declaration of Helsinki's tenets.

Research Population

Patients with persistent, non-healing ulcers who visited General Surgery's outpatient and inpatient departments were evaluated for eligibility. Ulcers that were at least four weeks old and did not heal while receiving conventional wound care were classified as chronic non-healing ulcers.

Inclusion Criteria

Patients aged between 18 and 60 years of either gender with long-standing non-healing ulcers, including diabetic ulcers, venous ulcers, and pressure ulcers, were included. Only ulcers measuring up to 8 × 8 cm in size and patients willing to participate in the study were enrolled.

Exclusion Criteria

Patients unwilling to participate, those with lower limb ischemia, severe wound infection characterized by visible pus or copious exudates, cellulitis, gangrene, or ischemic changes were excluded. Patients with platelet counts less than 1 lakh/ μL and those receiving anticoagulant or antiplatelet therapy were also excluded from the study.

Sample Size and Randomization

Based on a prior study by Rainys et al. that showed platelet-rich plasma treatment reduced healing times by around 20%, the sample size was determined. The minimum needed sample size was 111 with a 95% confidence interval and a 0.05 margin of error. A total of 120 patients were enrolled to account for potential dropouts. A computer-generated random number table was used to divide participants into two groups at random, and the sealed envelope method was used for distribution. There were sixty patients in each group.

Baseline Assessment

At enrollment, detailed demographic and clinical data were recorded, including age, sex, comorbidities, type and site of ulcer, duration of ulcer, hemoglobin level (g/dL), fasting blood sugar (mg/dL), platelet count, wound size (cm^2), and bacteriological

culture report. Doppler ultrasound of the affected limb was performed where indicated to assess venous incompetence or exclude ischemia.

Intervention

Group P (Platelet-Rich Plasma Dressing)

A double-spin centrifugation method was used to create autologous platelet-rich plasma. Sodium citrate anticoagulant was used to draw twenty milliliters of venous blood. Red blood cells were separated by centrifugation at 1000 rpm for 10 minutes, and platelets were concentrated by centrifugation at 3000 rpm for 10 minutes. After discarding platelet-poor plasma, 10% calcium gluconate was added to the final PRP at a ratio of 1 mL to 9 mL.

A part of activated PRP was injected around and beneath the wound base following complete wound debridement, and the remaining PRP was placed topically over the wound surface to produce a gel. After that, a sterile dressing and petrolatum gauze were applied to the wound. Dressing changes were done every two days, and PRP application was repeated weekly for up to 10 weeks or until complete healing occurred. If healing was incomplete after 10 applications, conventional dressing was continued for a total duration of 20 weeks.

Group C (Conventional Dressing)

Patients in the control group underwent wound debridement and offloading similar to Group P. The wound was irrigated with normal saline and dressed with petrolatum gauze and sterile dressing. Dressings were changed every two days for a maximum period of 20 weeks.

Follow-Up and Outcome Measures

Patients were followed up at two-week intervals up to the 10th week and subsequently at the 15th and 20th weeks. At each follow-up visit, hemoglobin level, fasting blood sugar, platelet count, wound size, culture report, presence of granulation tissue, and epithelialization were recorded. Digital photographs of the wounds were

taken at baseline and during follow-up to document healing progression.

The primary outcome was the rate of wound healing. Secondary outcomes included reduction in ulcer size, need for surgical intervention such as skin grafting or flap coverage, and occurrence of any complications or adverse effects.

Failure of healing was defined as non-closure of the ulcer after 20 weeks of treatment, following which patients were managed surgically as required.

Statistical Analysis

Data were analyzed using IBM Statistical Package for the Social Sciences (SPSS) version 24. Quantitative variables were expressed as mean and standard deviation and analyzed using the paired t-test. Qualitative variables were analyzed using the Pearson chi-square test. A p-value of less than 0.05 was considered statistically significant.

Results

A total of 120 patients with chronic non-healing ulcers were enrolled in the study and randomized into two equal groups: Group P (autologous platelet-rich plasma dressing) and Group C (conventional dressing), with 60 patients in each group. All patients completed the follow-up period of 20 weeks and were included in the final analysis.

Baseline Demographic and Clinical Characteristics

The demographic profile and baseline clinical parameters of patients in both groups were comparable. There was no statistically significant difference between the two groups with respect to age, gender distribution, type of ulcer, duration of ulcer, hemoglobin level, fasting blood sugar, platelet count, and baseline ulcer size. This indicated successful randomization and homogeneity of the study population.

Table 1: Baseline Demographic and Clinical Characteristics of Study Participants

Parameter	Group P (PRP) (n=60)	Group C (Conventional) (n=60)	p-value
Mean age (years)	46.8 ± 8.9	47.3 ± 9.1	0.74
Male/Female	38 / 22	36 / 24	0.70
Mean duration of ulcer (weeks)	7.6 ± 2.1	7.9 ± 2.4	0.52
Diabetic ulcers	34 (56.7%)	36 (60.0%)	0.71
Venous ulcers	18 (30.0%)	16 (26.7%)	0.68
Pressure ulcers	8 (13.3%)	8 (13.3%)	1.00
Hemoglobin (g/dL)	11.4 ± 1.2	11.3 ± 1.1	0.66
Fasting blood sugar (mg/dL)	156.2 ± 38.5	159.4 ± 41.2	0.64
Platelet count (×10 ⁵ /μL)	2.45 ± 0.52	2.48 ± 0.49	0.78
Mean ulcer size (cm ²)	26.4 ± 8.3	27.1 ± 7.9	0.63

Reduction in Ulcer Size

Both groups showed progressive reduction in ulcer size during follow-up; however, the reduction was significantly faster and more pronounced in the PRP group. From the second week onward, Group P

demonstrated a greater decrease in mean ulcer area compared to Group C. This difference became statistically highly significant from the 4th week and persisted throughout the follow-up period up to 20 weeks.

Table 2: Comparison of Mean Ulcer Size (cm²) at Different Follow-up Intervals

Follow-up interval	Group P (PRP)	Group C (Conventional)	p-value
Baseline	26.4 ± 8.3	27.1 ± 7.9	0.63
2 weeks	21.8 ± 7.5	24.9 ± 7.6	0.04
4 weeks	16.3 ± 6.2	21.7 ± 7.1	<0.001
6 weeks	10.4 ± 5.1	17.6 ± 6.8	<0.001
8 weeks	5.6 ± 3.8	13.2 ± 6.1	<0.001
10 weeks	2.1 ± 2.9	9.4 ± 5.7	<0.001
20 weeks	0.4 ± 1.2	4.1 ± 3.9	<0.001

Granulation Tissue Formation

Early appearance of healthy granulation tissue was observed more frequently in the PRP group. At the end of the 2nd week, a significantly higher number of patients in Group P had developed granulation tissue

compared to Group C. By the 6th week, almost all patients in the PRP group showed healthy granulation tissue, whereas a substantial proportion of patients in the conventional dressing group still lacked adequate granulation.

Table 3: Comparison of Granulation Tissue Formation

Follow-up	Group P (n=60)	Group C (n=60)	p-value
2 weeks	36 (60.0%)	22 (36.7%)	0.01
4 weeks	52 (86.7%)	34 (56.7%)	<0.001
6 weeks	58 (96.7%)	44 (73.3%)	<0.001

Epithelialization

The appearance of epithelialization was significantly earlier in patients treated with PRP. By the 4th week, nearly half of the patients in Group P demonstrated

epithelialization compared to less than one-fourth in Group C. This difference widened with subsequent follow-up, and by the 8th week, epithelialization was observed in more than 90% of patients in the PRP group.

Table 4: Comparison of Epithelialization Between the Two Groups

Follow-up	Group P (n=60)	Group C (n=60)	p-value
4 weeks	28 (46.7%)	14 (23.3%)	0.008
6 weeks	44 (73.3%)	26 (43.3%)	0.001
8 weeks	56 (93.3%)	38 (63.3%)	<0.001

Duration of Complete Healing

The mean duration required for complete wound healing was significantly shorter in the PRP group compared to the

conventional dressing group. A majority of patients in the PRP group achieved complete healing within 10 weeks, whereas most patients in the conventional group required a longer duration.

Table 5: Comparison of Healing Duration

Parameter	Group P	Group C	p-value
Mean healing time (weeks)	7.8 ± 2.6	12.9 ± 3.4	<0.001
Complete healing ≤10 weeks	48 (80.0%)	22 (36.7%)	<0.001

Requirement of Surgical Intervention

The requirement for secondary surgical intervention such as skin grafting or flap coverage was significantly lower in the

PRP group. No patient in the PRP group required amputation, whereas two patients in the conventional dressing group underwent amputation due to progression of disease.

Table 6: Requirement of Surgical Intervention

Intervention	Group P (n=60)	Group C (n=60)	p-value
Skin grafting / flap	6 (10.0%)	18 (30.0%)	0.006
Amputation	0	2 (3.3%)	0.15

Complications

Overall complication rates were lower in the PRP group. Minor infections and wound

necrosis were more commonly observed in the conventional dressing group. No allergic or anaphylactic reactions related to PRP application were noted.

Table 7: Comparison of Complications

Complication	Group P (n=60)	Group C (n=60)
Infection	4 (6.7%)	9 (15.0%)
Necrosis	1 (1.7%)	5 (8.3%)
Gangrene	0	3 (5.0%)
Allergic reaction	0	0

Discussion

Due to extended inflammation, poor angiogenesis, and delayed epithelialization, chronic non-healing ulcers remain a major therapeutic issue. By delivering concentrated growth factors directly to the wound bed, biological treatments like autologous platelet-rich plasma (PRP) have drawn interest recently due to their potential to improve wound healing. The current prospective, randomized controlled trial assessed PRP dressing's effectiveness in treating chronic, non-healing ulcers in comparison to traditional dressing.

In order to ensure that differences seen during follow-up could be ascribed to the intervention rather than confounding factors, both groups in this trial were comparable at baseline in terms of demographic variables, ulcer features, and biochemical indicators. The study's internal validity is improved by this methodological strength.

This study's main conclusion was that patients treated with PRP treatment healed ulcers much more quickly than those treated with traditional dressing. From the first few weeks of therapy, there was a noticeable decrease in the size of the ulcers in the PRP group, and starting in the fourth week, there were statistically significant differences. The high concentration of growth factors in PRP, which promote rapid

wound contraction and tissue regeneration by stimulating fibroblast proliferation, collagen deposition, and angiogenesis, is responsible for this accelerated healing [10].

Another significant finding in the PRP group was the early and strong development of granulation tissue. Nearly all PRP-treated patients had good granulation tissue by the sixth week of follow-up, but a sizable percentage of patients in the standard dressing group had insufficient or delayed granulation. Other authors have reported similar results, noting that PRP facilitates the shift from the inflammatory to the proliferative phase of healing by improving neovascularization and oxygen and nutrient delivery to the wound bed [11,12]

The PRP group also showed noticeably earlier epithelialization, a critical factor in wound healing. In contrast to the traditional dressing group, which showed delayed epithelialization, most patients receiving PRP treatment showed epithelialization by the eighth week. Epidermal growth factor and insulin-like growth factors generated from active platelets, which quicken keratinocyte migration and proliferation, are probably responsible for this action [13].

In the PRP group, the average time needed for full wound healing was considerably

shorter. When compared to patients getting traditional dressings, a significantly greater percentage of patients treated with PRP experienced full healing after ten weeks. These results are in line with other controlled trials that showed PRP-based therapy improved wound outcomes and shortened healing times [14,15].

Another clinically relevant outcome was the reduced requirement for secondary surgical interventions in the PRP group. Fewer patients treated with PRP required skin grafting or flap coverage, and none required amputation. In contrast, a higher proportion of patients in the conventional group required surgical management due to delayed or inadequate healing. This suggests that PRP therapy may not only accelerate healing but also reduce the overall treatment burden and risk of limb-threatening complications [16].

The complication rate was lower in the PRP group, with fewer cases of infection, necrosis, and gangrene observed. Importantly, no allergic or anaphylactic reactions related to PRP application were noted, highlighting the safety of autologous PRP therapy. The autologous nature of PRP minimizes immunogenic reactions and reduces the risk of disease transmission, making it a safe adjunct in wound care [17].

Despite the encouraging results, certain limitations should be acknowledged. The study was conducted at a single center, and the sample size, although adequate, limits the generalizability of the findings. Additionally, variations in PRP preparation techniques and platelet concentration may influence treatment outcomes. Future multicenter studies with standardized PRP preparation protocols and longer follow-up durations are recommended to validate these findings [18].

Overall, the findings of this study support the role of autologous PRP dressing as an effective and safe modality for enhancing healing in chronic non-healing ulcers. Incorporation of PRP into standard wound

care protocols may significantly improve patient outcomes and reduce the need for surgical interventions.

Conclusion

The results of this prospective, randomized, controlled study show that autologous platelet-rich plasma dressing is a safer and more successful treatment option for chronic non-healing ulcers than traditional dressing. Compared to patients receiving conventional dressing, patients treated with PRP dressing demonstrated a considerably faster rate of wound healing, larger reduction in ulcer size, earlier emergence of healthy granulation tissue, and more rapid epithelialization.

Additionally, the use of PRP dressing was linked to a reduced requirement for secondary surgical procedures such as skin grafting or flap coverage, as well as a shorter overall healing period. The safety profile of autologous PRP therapy is further highlighted by the decreased frequency of wound-related problems and the lack of treatment-related side effects.

Incorporation of platelet-rich plasma into standard wound care protocols may improve clinical outcomes, reduce morbidity, and decrease the burden of prolonged treatment in patients with chronic non-healing ulcers. Larger multicentric studies with standardized PRP preparation protocols and longer follow-up are recommended to further validate these findings and establish definitive clinical guidelines.

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