



## Original Research Article

# COMPARATIVE EFFICACY OF RECOMBINANT HUMAN PLATELET-DERIVED GROWTH FACTOR, HYDROGEL, AND NORMAL SALINE DRESSINGS IN DIABETIC FOOT ULCER HEALING: A PROSPECTIVE RANDOMIZED CONTROLLED TRIAL

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### ABSTRACT

**Background:** Diabetic foot ulcers (DFU) are a major complication of diabetes mellitus and contribute significantly to morbidity, hospitalization, and lower limb amputations. Advanced wound therapies such as recombinant human platelet-derived growth factor (rh-PDGF) and hydrogel dressings have been proposed to enhance healing compared to conventional normal saline dressings. The aim is to compare the efficacy of rh-PDGF, hydrogel, and normal saline dressings in the healing of diabetic foot ulcers.

**Materials and Methods:** This prospective randomized controlled trial included 75 patients with Wagner grade I and II diabetic foot ulcers. Participants were randomly allocated into three groups: standard care with rh-PDGF (n=25), standard care with hydrogel dressing (n=25), and standard care with normal saline dressing (n=25). Ulcer size was measured at baseline, 1st, 4th, and 10th weeks. Outcomes assessed included reduction in ulcer size, time to complete healing, duration of hospital stay, need for secondary intervention, and days absent from work. Statistical analysis was performed using ANOVA and chi-square tests, with  $p < 0.05$  considered significant.

**Results:** Baseline characteristics were comparable among groups ( $p > 0.05$ ). The rh-PDGF group demonstrated significantly greater ulcer size reduction by Week 4 and Week 10 ( $p < 0.001$ ). Mean time to complete healing was significantly shorter in the rh-PDGF group ( $34.6 \pm 11.2$  days) compared to hydrogel ( $44.8 \pm 13.6$  days) and normal saline ( $55.7 \pm 15.1$  days) groups ( $p < 0.001$ ). Hospital stay was significantly reduced in the rh-PDGF group ( $p = 0.001$ ). Complete healing by 10 weeks was highest in the rh-PDGF group (84%), followed by hydrogel (68%) and normal saline (48%) ( $p = 0.030$ ). Secondary interventions were more frequent in the normal saline group. Days absent from work were significantly lower in the rh-PDGF group ( $p < 0.001$ ).

**Conclusion:** Recombinant human platelet-derived growth factor significantly enhances healing of diabetic foot ulcers compared to hydrogel and normal saline dressings. It reduces healing time, hospital stay, and need for additional procedures, thereby improving patient outcomes and functional recovery.

**Keywords:** Diabetic Foot Ulcer. Recombinant Human Platelet-Derived Growth Factor. Wound Healing.

## INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic disorder characterized by persistent hyperglycemia

resulting from defects in insulin secretion, insulin action, or both. The global burden of diabetes has increased dramatically over the past decades, with a significant rise in developing countries. One of the

most debilitating complications of diabetes is the development of diabetic foot ulcers (DFU), which represent a major cause of morbidity, prolonged hospitalization, and lower limb amputation. Approximately 15-25% of diabetic patients are estimated to develop a foot ulcer during their lifetime, and DFU accounts for nearly 60% of non-traumatic lower limb amputations worldwide.<sup>[1]</sup>

The pathogenesis of diabetic foot ulcers is multifactorial, involving peripheral neuropathy, peripheral arterial disease, immunopathy, and repeated minor trauma. Impaired wound healing in diabetes is attributed to altered inflammatory response, decreased growth factor production, reduced collagen synthesis, and compromised angiogenesis. Standard care for DFU includes glycaemic control, infection management, debridement, pressure offloading, and appropriate wound dressings. However, despite optimal standard care, healing remains delayed in many patients, necessitating exploration of advanced wound therapies.<sup>[2]</sup>

Recombinant human platelet-derived growth factor (rh-PDGF-BB), commercially available as becaplermin gel, has been introduced as an adjuvant therapy to enhance wound healing. PDGF plays a crucial role in chemotaxis of neutrophils, macrophages, and fibroblasts, and stimulates collagen deposition and angiogenesis. Several randomized controlled trials have demonstrated improved healing rates and reduced time to closure with rh-PDGF compared to placebo when combined with good wound care.<sup>[3,4]</sup> However, some studies have reported variable or modest benefits, thereby necessitating further institution-based evaluation.<sup>[5]</sup>

Hydrogel dressings, on the other hand, are amorphous hydrophilic polymers that maintain a moist wound environment, facilitate autolytic debridement, and promote granulation tissue formation. Cochrane reviews suggest that hydrogel dressings may be more effective than basic wound contact dressings in certain low-grade diabetic foot ulcers, although the strength of evidence remains limited due to methodological heterogeneity.<sup>[1]</sup>

**Aim:** To compare the efficacy of recombinant human platelet-derived growth factor, hydrogel, and normal saline dressings in the healing of diabetic foot ulcers.

#### **Objectives**

1. To compare reduction in ulcer size among the three treatment groups at 1st, 4th, and 10th week.
2. To compare duration of hospital stay and time to complete ulcer healing among the three groups.
3. To evaluate need for secondary interventions and days of abstinence from work in each group.

## **MATERIALS AND METHODS**

**Source of Data:** The data were collected from patients presenting with diabetic foot ulcers to the Department of General Surgery at ESIC Medical College & PGIMS, KK Nagar, Chennai. Eligible

patients who satisfied the inclusion criteria and provided informed consent were enrolled in the study.

**Study Design:** The study was conducted as a prospective randomized controlled trial. Patients were randomly allocated into three treatment groups using simple randomization.

**Study Location:** The study was carried out in the Department of General Surgery, ESIC Medical College & PGIMS, KK Nagar, Chennai, a tertiary care teaching hospital catering to urban and semi-urban populations.

**Study Duration:** The study was conducted over a period of 18 months after obtaining Institutional Ethical Committee approval.

#### **Sample Size**

A total of 75 patients were included in the study. They were divided equally into three groups:

- 25 patients received standard care with Hydrogel dressing.
- 25 patients received standard care with rh-PDGF dressing.
- 25 patients received standard care with Normal Saline dressing once daily.

Sample size was calculated using nMaster software considering healing proportion difference, with allowance for possible loss to follow-up.

#### **Inclusion Criteria**

- Patients aged 20-80 years
- Diagnosed diabetic foot ulcers (Wagner Grade 1 and 2)
- Ulcer size <10 cm in greatest dimension
- Controlled blood glucose (FBS 90-110 mg/dl, PPBS 140-200 mg/dl, HbA1c 6.5-7.5)
- Willing to provide informed consent

#### **Exclusion Criteria**

- Critically ill patients
- Pregnancy
- Chronic venous or arterial insufficiency ulcers
- Malignant ulcers
- Severe anaemia (<7 g/dl)
- Immunosuppressive therapy within previous 6 months
- Peripheral vascular disease

**Procedure and Methodology:** All patients underwent detailed history taking and clinical examination. Baseline investigations included complete haemogram, fasting and post-prandial blood sugar, renal function tests, and HbA1c levels. X-ray of the foot was performed to rule out osteomyelitis. Doppler study was done to assess vasculopathy. Neurological examination was performed using tuning fork, hot/cold sensation testing, and ankle reflex assessment.

#### **Standard care included:**

- Strict glycaemic control
- Adequate infection management with antibiotics
- Surgical debridement when required

Ulcer area was measured by tracing the ulcer on cellophane paper and transferring to graph paper. Area was calculated in square centimeters.

Measurements were repeated at 1st, 4th, and 10th week.

#### Dressing Protocols:

- **Normal Saline Group:** Ulcer was cleaned with normal saline; saline-soaked gauze was applied and covered with sterile dressing.
- **Hydrogel Group:** Ulcer was cleaned; hydrogel applied and covered with sterile gauze and bandage.
- **rh-PDGF Group:** Ulcer cleaned with saline; 0.01% becaplermin gel applied as per formula: (Length × Width) / 0.4, then covered with sterile dressing.

Patients were followed up for 10 weeks.

#### Sample Processing

Ulcer size measurements were recorded in structured proforma. Rate of wound contraction was calculated using:

$$\frac{\text{InitialArea} - \text{FinalArea}}{\text{InitialArea}} \times 100$$

Secondary interventions (SSG, flap cover, repeated debridement) were documented.

**Statistical Methods:** Data were analyzed using SPSS version 21.0. Quantitative variables were expressed as mean ± SD. Categorical variables were expressed as frequencies and percentages. Student's unpaired t-test and ANOVA were used for comparison of means among groups. Chi-square test was used for categorical variables. A p-value <0.05 was considered statistically significant.

**Data Collection:** Data were collected using a pre-designed structured proforma including demographic details, ulcer characteristics, treatment group,

duration of hospital stay, days absent from work, need for secondary intervention, and ulcer size at baseline and follow-up visits. Confidentiality of patient data was strictly maintained throughout the study.

## RESULTS

[Table 1] presents the baseline demographic and clinical characteristics of participants across the three treatment groups (Hydrogel, rh-PDGF, and Normal Saline). The mean age of participants was comparable among the hydrogel (54.2 ± 10.8 years), rh-PDGF (53.6 ± 11.4 years), and normal saline groups (55.1 ± 10.2 years), with no statistically significant difference (ANOVA, p = 0.872). Male predominance was observed in all groups (56.0%, 60.0%, and 52.0%, respectively), but this difference was not significant (p = 0.776).

The mean duration of diabetes mellitus was similar across groups (11.7 ± 5.2, 12.3 ± 5.5, and 11.1 ± 4.8 years; p = 0.749). Glycemic control, assessed by HbA1c levels, was comparable (7.12 ± 0.42%, 7.18 ± 0.39%, and 7.09 ± 0.44%; p = 0.728). Distribution of Wagner grade II ulcers showed no significant difference among groups (p = 0.788).

Baseline ulcer area was nearly identical in all three groups (6.84 ± 1.92 cm<sup>2</sup>, 6.91 ± 2.05 cm<sup>2</sup>, and 6.76 ± 1.88 cm<sup>2</sup>; p = 0.972), indicating effective randomization. Similarly, the proportion of patients with clinical infection, neuropathy, and mild peripheral arterial disease (PAD) was statistically comparable (all p > 0.05).

**Table 1: Baseline profile of participants (N=75)**

Parameter	Hydrogel (n=25) n(%) / Mean±SD	95% CI	rh-PDGF (n=25) n(%) / Mean±SD	95% CI	Normal Saline (n=25) n(%) / Mean±SD	95% CI	Test of significance	p-value
Age (years)	54.2 ± 10.8	49.7-58.7	53.6 ± 11.4	48.9-58.3	55.1 ± 10.2	50.9-59.3	One-way ANOVA (F=0.14)	0.872
Male sex	14 (56.0)	36.2-74.7	15 (60.0)	39.7-78.4	13 (52.0)	32.7-70.7	χ <sup>2</sup> test (χ <sup>2</sup> =0.51)	0.776
Duration of DM (years)	11.7 ± 5.2	9.6-13.8	12.3 ± 5.5	10.0-14.6	11.1 ± 4.8	9.1-13.1	One-way ANOVA (F=0.29)	0.749
HbA1c (%)	7.12 ± 0.42	6.95-7.29	7.18 ± 0.39	7.02-7.34	7.09 ± 0.44	6.91-7.27	One-way ANOVA (F=0.32)	0.728
Wagner grade II	11 (44.0)	24.4-65.1	10 (40.0)	21.1-61.3	12 (48.0)	28.4-68.2	χ <sup>2</sup> test (χ <sup>2</sup> =0.48)	0.788
Baseline ulcer area (cm <sup>2</sup> )	6.84 ± 1.92	6.05-7.63	6.91 ± 2.05	6.07-7.75	6.76 ± 1.88	5.98-7.54	One-way ANOVA (F=0.03)	0.972
Clinical infection present	8 (32.0)	15.0-53.5	9 (36.0)	18.0-57.5	7 (28.0)	12.1-49.4	χ <sup>2</sup> test (χ <sup>2</sup> =0.47)	0.790
Neuropathy present	16 (64.0)	42.5-82.0	15 (60.0)	39.7-78.4	17 (68.0)	46.5-85.1	χ <sup>2</sup> test (χ <sup>2</sup> =0.47)	0.790
Doppler abnormal (mild PAD)*	6 (24.0)	9.4-45.1	5 (20.0)	6.8-40.7	7 (28.0)	12.1-49.4	χ <sup>2</sup> test (χ <sup>2</sup> =0.55)	0.759

\*Mild PAD only (severe PVD excluded as per criteria).

**Table 2: Ulcer size reduction across follow-up (N=75)**

Time point / outcome	Hydrogel (n=25) Mean±SD	95% CI	rh-PDGF (n=25) Mean±SD	95% CI	Normal Saline (n=25) Mean±SD	95% CI	Test of significance	p-value
Baseline ulcer area (cm <sup>2</sup> )	6.84 ± 1.92	6.05-7.63	6.91 ± 2.05	6.07-7.75	6.76 ± 1.88	5.98-7.54	One-way ANOVA (F=0.03)	0.972
Week 1 ulcer area (cm <sup>2</sup> )	5.76 ± 1.84	5.00-6.52	5.12 ± 1.71	4.41-5.83	6.08 ± 1.90	5.29-6.87	One-way ANOVA (F=2.21)	0.117
Week 4 ulcer area (cm <sup>2</sup> )	3.82 ± 1.55	3.18-4.46	2.96 ± 1.44	2.37-3.55	4.56 ± 1.62	3.89-5.23	One-way ANOVA (F=7.92)	0.001*
Week 10 ulcer area (cm <sup>2</sup> )	1.64 ± 1.20	1.15-2.14	0.72 ± 0.88	0.36-1.08	2.54 ± 1.46	1.94-3.14	One-way ANOVA (F=14.86)	<0.001*
% reduction at Week 10	76.1 ± 18.4	68.5-83.7	89.3 ± 12.6	84.1-94.5	61.7 ± 21.2	52.9-70.5	One-way ANOVA (F=16.02)	<0.001*

\*Significant at p<0.05.

[Table 2] compares ulcer size reduction among the three treatment groups at baseline and during follow-up. Baseline ulcer area was statistically similar (p = 0.972). At Week 1, although the rh-PDGF group demonstrated relatively smaller ulcer area (5.12 ± 1.71 cm<sup>2</sup>) compared to hydrogel (5.76 ± 1.84 cm<sup>2</sup>) and normal saline (6.08 ± 1.90 cm<sup>2</sup>), the difference was not statistically significant (p = 0.117). By Week 4, a significant difference emerged (p = 0.001), with the rh-PDGF group showing greater reduction (2.96 ± 1.44 cm<sup>2</sup>) compared to hydrogel

(3.82 ± 1.55 cm<sup>2</sup>) and normal saline (4.56 ± 1.62 cm<sup>2</sup>). This trend became more pronounced at Week 10, where the rh-PDGF group had the smallest residual ulcer area (0.72 ± 0.88 cm<sup>2</sup>), followed by hydrogel (1.64 ± 1.20 cm<sup>2</sup>) and normal saline (2.54 ± 1.46 cm<sup>2</sup>), with highly significant differences (p < 0.001).

The percentage reduction at Week 10 further confirmed superior efficacy of rh-PDGF (89.3 ± 12.6%), compared to hydrogel (76.1 ± 18.4%) and normal saline (61.7 ± 21.2%) (p < 0.001).

**Table 3: Hospital stay and time-to-heal outcomes (N=75)**

Outcome	Hydrogel (n=25) n(%) / Mean±SD	95% CI	rh-PDGF (n=25) n(%) / Mean±SD	95% CI	Normal Saline (n=25) n(%) / Mean±SD	95% CI	Test of significance	p-value
Length of hospital stay (days)	12.7 ± 4.3	10.9-14.5	10.4 ± 3.8	8.8-12.0	14.6 ± 4.9	12.6-16.6	One-way ANOVA (F=7.41)	0.001*
Time to complete healing (days)**	44.8 ± 13.6	39.2-50.4	34.6 ± 11.2	30.0-39.2	55.7 ± 15.1	49.5-61.9	One-way ANOVA (F=16.93)	<0.001*
Complete healing by 10 weeks	17 (68.0)	46.5-85.1	21 (84.0)	63.9-95.5	12 (48.0)	28.4-68.2	χ <sup>2</sup> test (χ <sup>2</sup> =7.02)	0.030*
Wound infection during follow-up	4 (16.0)	4.5-36.1	3 (12.0)	2.5-31.2	7 (28.0)	12.1-49.4	Fisher's exact	0.236

\*\*Among those achieving complete closure; otherwise censored at 70 days for summary.

**Table 4: Secondary interventions and abstinence from work (N=75)**

Outcome	Hydrogel (n=25) n(%) / Mean±SD	95% CI	rh-PDGF (n=25) n(%) / Mean±SD	95% CI	Normal Saline (n=25) n(%) / Mean±SD	95% CI	Test of significance	p-value
Repeat debridement required	6 (24.0)	9.4-45.1	4 (16.0)	4.5-36.1	10 (40.0)	21.1-61.3	χ <sup>2</sup> test (χ <sup>2</sup> =3.66)	0.160
Split-skin graft (SSG) required	5 (20.0)	6.8-40.7	2 (8.0)	1.0-26.0	8 (32.0)	15.0-53.5	Fisher's exact	0.082
Flap cover required	2 (8.0)	1.0-26.0	1 (4.0)	0.1-20.4	3 (12.0)	2.5-31.2	Fisher's exact	0.603
Minor amputation (toe)	1 (4.0)	0.1-20.4	0 (0.0)	0.0-13.7	2 (8.0)	1.0-26.0	Fisher's exact	0.353
Any secondary intervention (composite)	8 (32.0)	15.0-53.5	5 (20.0)	6.8-40.7	13 (52.0)	32.7-70.7	χ <sup>2</sup> test (χ <sup>2</sup> =5.28)	0.071
Days absent from work (days)	18.6 ± 7.1	15.7-21.5	14.2 ± 6.3	11.6-16.8	23.4 ± 8.2	20.0-26.8	One-way ANOVA (F=10.84)	

[Table 3] compares hospital stay and healing outcomes across the groups. The mean duration of hospital stay was significantly shorter in the rh-PDGF group ( $10.4 \pm 3.8$  days) compared to hydrogel ( $12.7 \pm 4.3$  days) and normal saline ( $14.6 \pm 4.9$  days) ( $p = 0.001$ ).

Similarly, mean time to complete healing was significantly lower in the rh-PDGF group ( $34.6 \pm 11.2$  days) compared to hydrogel ( $44.8 \pm 13.6$  days) and normal saline ( $55.7 \pm 15.1$  days) ( $p < 0.001$ ).

The proportion of complete healing by 10 weeks was highest in the rh-PDGF group (84.0%), followed by hydrogel (68.0%) and normal saline (48.0%), with statistically significant difference ( $p = 0.030$ ).

Although wound infection during follow-up was relatively higher in the normal saline group (28.0%) compared to hydrogel (16.0%) and rh-PDGF (12.0%), this difference did not reach statistical significance ( $p = 0.236$ ).

[Table 4] evaluates the need for secondary interventions and days absent from work. Repeat debridement was more frequent in the normal saline group (40.0%) compared to hydrogel (24.0%) and rh-PDGF (16.0%), although the difference was not statistically significant ( $p = 0.160$ ).

Similarly, the requirement for split-skin graft (SSG) was higher in the normal saline group (32.0%) compared to hydrogel (20.0%) and rh-PDGF (8.0%), showing a trend toward significance ( $p = 0.082$ ). Flap cover and minor amputation rates were numerically higher in the normal saline group but did not show statistical significance ( $p > 0.05$ ).

When analyzed as a composite outcome, any secondary intervention was required in 52.0% of normal saline patients compared to 32.0% in hydrogel and 20.0% in rh-PDGF groups ( $p = 0.071$ ), suggesting a clinically relevant but statistically borderline difference.

Importantly, mean days absent from work were significantly lower in the rh-PDGF group ( $14.2 \pm 6.3$  days) compared to hydrogel ( $18.6 \pm 7.1$  days) and normal saline ( $23.4 \pm 8.2$  days) ( $p < 0.001$ ), indicating faster functional recovery.

## DISCUSSION

**Baseline Characteristics [Table 1]:** In the present study, baseline demographic and clinical characteristics were comparable across the hydrogel, rh-PDGF, and normal saline groups ( $p > 0.05$  for all variables), indicating effective randomization and homogeneity. The mean age of participants (approximately 54-55 years) is consistent with earlier studies reporting that diabetic foot ulcers predominantly affect middle-aged and elderly individuals, as observed by Younan et al. (2021).<sup>[6]</sup> Similarly, the male predominance noted in our study aligns with findings by Yang et al. (2025),<sup>[7]</sup> who reported higher incidence of DFU among males, possibly due to occupational exposure and delayed healthcare seeking.

The mean duration of diabetes (11-12 years) corresponds with established risk profiles indicating that chronic hyperglycemia contributes to neuropathy and vasculopathy, predisposing to ulcer formation. Tian et al,<sup>[4]</sup> (2025) also noted a similar duration in patients included in their network meta-analysis of growth factor trials. HbA1c levels were comparable among groups and were within moderately controlled range, similar to the cohort studied by Wang et al,<sup>[5]</sup> (2025) who reported favorable healing outcomes in patients with controlled glycemic status.

Baseline ulcer size and Wagner grading were statistically similar in all groups, comparable to inclusion characteristics reported by Güiza-Argüello et al,<sup>[8]</sup> (2022) in studies evaluating hydrogel-based dressings. The prevalence of neuropathy and mild PAD in our cohort mirrors epidemiological patterns described by Tan et al,<sup>[9]</sup> (2025) where neuropathy was identified as the predominant underlying pathology in low-grade diabetic foot ulcers.

**Ulcer Size Reduction [Table 2]:** Our study demonstrated significantly greater reduction in ulcer size in the rh-PDGF group at Week 4 and Week 10 ( $p = 0.001$  and  $p < 0.001$ , respectively). The mean percentage reduction at Week 10 was highest in the rh-PDGF group (89.3%), followed by hydrogel (76.1%) and normal saline (61.7%).

These findings are consistent with Bhatnagar et al,<sup>[2]</sup> (2022) who reported enhanced wound contraction and tissue regeneration with platelet-derived growth factor delivery systems. Similarly, Devesvar et al,<sup>[1]</sup> (2025) demonstrated improved wound closure rates with PDGF-based therapies compared to conventional saline dressing. In their updated network meta-analysis, Tian et al,<sup>[4]</sup> (2025) concluded that growth factors significantly improve healing rates in diabetic foot ulcers.

Hydrogel dressings also showed moderate improvement compared to normal saline, supporting findings by Verma et al,<sup>[10]</sup> (2023) who suggested that moist wound environments enhance granulation and epithelialization. However, hydrogel did not achieve the magnitude of reduction seen with rh-PDGF, consistent with comparative analyses by Yang et al,<sup>[7]</sup> (2025) who found regenerative growth factor therapies to be superior adjuncts to standard care.

The relatively slower reduction in the normal saline group reflects the lack of active biological stimulation of fibroblast proliferation and angiogenesis, mechanisms emphasized by Mahdipour et al,<sup>[3]</sup> (2020) in their systematic review of recombinant proteins in chronic wound healing.

**Hospital Stay and Time to Healing [Table 3]:** The rh-PDGF group demonstrated significantly shorter hospital stay ( $10.4 \pm 3.8$  days) and reduced time to complete healing ( $34.6 \pm 11.2$  days), compared to hydrogel and normal saline groups ( $p < 0.001$ ). The proportion of complete healing by 10 weeks was highest in the rh-PDGF group (84%).

These findings are in agreement with Devesvar et al,<sup>[1]</sup> (2025) who reported faster wound closure and improved clinical outcomes with PDGF therapy.

Bhatnagar et al.<sup>[2]</sup> (2022) also highlighted the enhanced bioavailability and regenerative potential of PDGF delivery systems. Furthermore, Tian et al.<sup>[4]</sup> (2025) demonstrated that growth factors significantly accelerate healing compared to conventional therapy. The hydrogel group showed intermediate outcomes, consistent with Dixon et al.<sup>[11]</sup> (2021) who reported improved moist wound healing compared to dry gauze but without acceleration comparable to biologically active growth factors.

Although wound infection rates during follow-up were numerically higher in the normal saline group, the difference was not statistically significant, aligning with findings by Mullin et al.<sup>[12]</sup> (2024) where infection rates did not significantly differ when appropriate debridement and antibiotic management were provided alongside adjunctive therapies.

**Secondary Interventions and Functional Recovery [Table 4]:** The requirement for repeat debridement, split-skin grafting, and composite secondary interventions was numerically lower in the rh-PDGF group and highest in the normal saline group. Although some differences did not reach statistical significance, the trend suggests clinical superiority of rh-PDGF in reducing surgical intervention.

These observations are consistent with Bhatnagar et al.<sup>[2]</sup> (2022) who reported improved granulation and reduced complication rates with PDGF-based systems. Yang et al.<sup>[7]</sup> (2025) similarly concluded that regenerative growth factor therapies significantly improve healing rates and reduce the need for advanced procedures.

Importantly, days absent from work were significantly lower in the rh-PDGF group ( $p < 0.001$ ), reflecting faster functional recovery. This socioeconomic benefit has been highlighted in growth factor-based wound healing studies emphasizing earlier ambulation and reduced morbidity, as noted by Tian et al (2025).<sup>[4]</sup>

## CONCLUSION

The present prospective randomized controlled trial demonstrated that recombinant human platelet-derived growth factor (rh-PDGF), when used as an adjunct to standard care, significantly improved healing outcomes in patients with diabetic foot ulcers compared to hydrogel and normal saline dressings. Patients treated with rh-PDGF showed greater reduction in ulcer size, faster time to complete wound healing, shorter hospital stay, and higher proportion of complete ulcer closure by 10 weeks. Additionally, the rh-PDGF group required fewer secondary interventions and had significantly fewer days of work absenteeism, indicating improved functional recovery and socioeconomic benefit.

Hydrogel dressings demonstrated better outcomes than normal saline in terms of ulcer contraction and healing duration; however, their efficacy was inferior to rh-PDGF. Normal saline dressing, while cost-

effective and widely available, showed comparatively slower healing rates and higher need for additional procedures.

Overall, rh-PDGF appears to be a superior adjunctive therapy in the management of Wagner grade I and II diabetic foot ulcers, promoting accelerated wound healing and reducing morbidity when combined with standard wound care practices.

## Limitations of the study

1. The sample size was relatively small ( $n = 75$ ), which may limit the generalizability of the findings.
2. The study was conducted at a single tertiary care center, potentially affecting external validity.
3. Follow-up duration was limited to 10 weeks; long-term recurrence rates were not assessed.
4. Blinding of participants and investigators was not feasible due to the nature of interventions, introducing potential performance bias.
5. Cost-effectiveness analysis of rh-PDGF compared to hydrogel and saline dressings was not formally evaluated.
6. Only Wagner grade I and II ulcers were included; results cannot be extrapolated to advanced grade ulcers.
7. Microbiological profiles and detailed vascular assessment beyond mild PAD were not analyzed in depth.

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