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# Comparison of Wound Healing with 'Autologous Platelet-Rich Plasma' versus Conventional Dressing in Chronic Diabetic Foot Ulcer

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Submitted for Publication: 04-03-2025 Accepted for Publication 14-08-2025

How to Cite: Iqbal MS, Abbas MA, Mujahid D, Haral MA, Rashid S, Rohili SA. Comparison of Wound Healing with 'Autologous Platelet-Rich Plasma' versus Conventional Dressing in Chronic Diabetic Foot Ulcer. APMC 2025;19(3):203-207. DOI: 10.29054/APMC/2025.1737

#### **ABSTRACT**

**Background:** Innovative approaches, such as cellular therapies like platelet-rich plasma (PRP), are emerging to enhance wound healing in diabetic foot ulcers. **Objective:** To compare the effectiveness of autologous PRP with conventional dressing for chronic diabetic foot ulcers. **Study Design:** Randomized controlled trial. **Settings:** Allied Hospital, Faisalabad Pakistan. **Duration:** January 2024 to June 30, 2024. **Methods:** 124 diabetic patients aged 18-80 with non-healing foot ulcers were included. Exclusions were made for those with bleeding disorders, uncontrolled diabetes (HbA1c > 9), and severe infections, among others. Group A received PRP treatment, while Group B underwent conventional dressing. The wound area was measured weekly for 3 weeks. **Results:** Mean age was similar between groups (Group A: 52.92 ± 9.21 years; Group B: 52.63 ± 9.86 years). Most patients (70.97%) were aged 46 to 80. Out of 124 patients, 37.90% were male, and 62.10% were female. PRP showed an efficacy of 88.71%, compared to 67.74% for conventional dressing, with a p-value of 0.0034. **Conclusion:** Platelet-rich plasma is more effective than normal saline dressing for treating chronic diabetic foot ulcers.

Keywords: Diabetic foot ulcer, Platelet-rich plasma, Healing.

#### **INTRODUCTION**

More than 366 million people have diabetes globally, and this number may increase to half a billion by 2030.¹ Diabetic foot ulcers (DFU) are among the major complications, and the pathogenesis is multifactorial. Diabetic foot complications are considered preventable. The new diabetic foot ulcers incidence is 2.2%/year, increasing to 5.8% in 03 years.¹ The lifetime risk of foot ulcer is around 25%.² Important risk factors for developing diabetic foot problems are poor information and defective foot care practices.³ Adequate and timely foot care is mandatory to prevent foot complications in patients with diabetes.⁴

The development of diabetic foot ulcers is a significant health issue posing a lot of economic burden on patients' families and health departments. It is the main reason for repeated and prolonged hospital admissions and ultimately amputation. Approximately 6.3% is the incidence of DFU. Healing is hampered in DFU wounds, and 40% is the five-year mortality post-amputation.<sup>3</sup>

The primary purpose of treatment in DFU is to expedite wound closure as early as possible. Different measures commonly used in this regard include wound debridement, pressure-free wound area, moist wound healing, infection prevention, Adequate perfusion, correction of co-morbidities, and surgical intervention as needed.<sup>4</sup> New methods with appreciable outcomes are under consideration to improve healing in DFU. Plateletrich plasma (PRP) is one of the newest techniques in this regard.<sup>5,6</sup>

An autologous PRP is a serum extracted from whole blood by centrifugation and is a source of platelets, defense factors, anti-bacterial agents, growth agents, and cytokines, which encourage the growth of stem cells and tissue remodeling. PRP is an effective treatment for decreasing the recovery time of ulcers, ultimately leading to an improvement in quality of life and a reduction in the healthcare burden of wound treatment.<sup>7</sup>

A recent meta-analysis about PRP therapy in cutaneous wounds showed that PRP promoted wound healing and the ulcers improved significantly in both acute and chronic wounds.<sup>8-10</sup>

A RCT analyzing Autologous PRP with traditional dressing for DFU demonstrated complete wound healing rate as 95% (n = 38) and result obtained earlier (6<sup>th</sup> week) in group A (PRP), in contrast to 77.8% (n = 28) & (9th week) for Group B (traditional dressing) (P < 0.001).<sup>11</sup>

The Rationale of this study was to find the efficacy of autologous PRP over conventional dressing for wound healing, as there is no such study in our setup. A better technique will be recommended in the future.

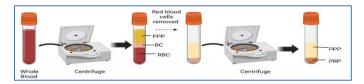
# **OBJECTIVES**

To find the outcome of autologous PRP and conventional dressing in chronic diabetic foot ulcers regarding wound healing.

# **OPERATIONAL DEFINITIONS:**

**Efficacy:** The technique was labelled as effective when there was  $\geq 50\%$  reduction in the wound.

**Platelet-Rich Plasma Preparation:** PRP is obtained in a 2-step. Centrifugation of blood yields 03 layers: RBC, WBC, platelets layer (buffy coat), and a layer of platelet plasma. 2<sup>nd</sup> centrifugation concentrates platelets into PRP.



#### **METHODS**

This randomized controlled trial was conducted at the Department of Surgery, Allied Hospital, Faisalabad Pakistan. The duration of the study was six months from January 2024 to 30 June 2024.

The sample size was 124 patients. 62 patients (group A) underwent PRP dressing and 62 patients (group B) underwent conventional dressing. Non-probability, consecutive sampling technique was used.

Age group of both sexes from 18 - 80 years, Patients with non-healing diabetic foot ulcers with HbA1c of <9 gm%, Diabetic foot Ulcer  $\geq 6$  weeks duration and Ulcer  $\leq 10$  cm2 in size was included in the study.

Patients of known bleeding diathesis, HbA1c >9 gm%, diabetic nephropathy and severe local infection & ischemia was excluded from the study

Approval was taken from the Institutional Ethical Review Board & after informed consent, patients were enrolled according to the inclusion criteria. Patients were divided into 02 groups based on a lottery method. Group A underwent PRP therapy while group B received traditional dressing. After clinical evaluation ulcer size was measured before starting the intervention. Both groups were given dressings. PRP dressing was administered 2 times/ week. The follow-up period was 3 weeks in both groups. Wound size was measured at regular intervals weekly basis in both groups of patients. All the data was recorded on a specially designed proforma (Annexure-I).

**Figure 1: Before intervention** 



Figure 2: After Debridement



Figure 3: Injecting PRP on wound Margins

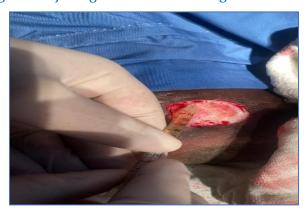


Figure 4: Injecting PRP in wound bed



Figure 5: Injecting PRP on wound Margins



Figure 6: Healed wound



SPSS 25 was utilized for statistical analysis. Frequency and percentages were estimated for qualitative variables like sex & efficacy. Mean with SD were estimated for quantitative variables like age, weight, height, BMI, HbA1C level, duration of diabetes, duration of ulcer, size of ulcer. Chi-square test was applied to determine efficacy in both groups.

Effect modifiers such as age, gender, BMI, HbA1C level, duration, and initial size of ulcer were managed via stratification. Post-stratification chi-square test applied &  $P \le 0.05$  was taken as significant.

# **RESULTS**

The age ranges from 18 - 80 years with a mean of  $52.69 \pm 9.43$  years. In A-group mean age was  $52.92 \pm 9.21$  years & B-group was  $52.63 \pm 9.86$  years. 88 patients (70.97%) were from 46 -80 years. From 124 patients, males were 47 (37.90%) & females 77 (62.10%) with a male to female ratio of 1:1.6. Mean DM duration was  $12.21 \pm 2.20$  years. The mean ulcer duration was  $4.60 \pm 1.15$  months (Table 1). The mean size of the ulcer was  $5.22 \pm 1.20$  cm (Table 2). The mean height was  $162.34 \pm 14.32$  cm. The mean weight was  $78.54 \pm 8.43$  kg. Mean BMI was  $27.21 \pm 3.34$  kg/m² (Table X). Mean HbA1c was  $6.73 \pm 1.22\%$ .

The efficacy of PRP was found to be 88.71% & conventional dressing was 67.74% for chronic diabetic foot ulcers with a p-value of 0.0034 (Table 3). Stratification is shown in Table 4.

Table 1: Distribution concerning Ulcer duration.

Ulcer Duration (months)	A (n=62)		B (n=62)		Total (n=124)	
	Number	%	Number	%	Number	%
≤4	31	50.0	34	54.84	65	52.42
>4	31	50.0	28	45.16	59	47.58
Mean ± SD	4.69 ± 1.22		4.50 ± 1.13		4.60 ± 1.15	

Table 2: Distribution by ulcer size

Ulcer Size (cm)	A (n=62)		B (n=62)		Total (n=124)	
	Number	%	Number	%	Number	%
≤5	32	51.61	38	61.29	70	56.45
>5	30	48.39	24	38.71	54	43.55
Mean ± SD	5.32 ± 1.21		5.11 ± 1.20		5.22 ± 1.20	

Table 3: Efficacy comparison of autologous PRP & conventional dressing

	A (n=62)		B (n	P-	
	Yes	No	Yes	No	value
Efficacy	55 (88.71%)	07 (11.29%)	42 (67.74%)	20 (32.26%)	0.0034

Table 4: Efficacy stratification with different Parameters.

		A (n	=62)	B (n	P-		
Variables		Effi	cacy	Effi			
		Yes	No	Yes	No	value	
Age	18-50	15	02	07	12	0.0016	
(years)		(88.24%)	(11.76%)	(36.84%)	(63.16%)		
(y curs)	51-80	40 (88.89%)	05 (11.11%)	33 (76.74%)	10 (23.26%)	0.129	
		22	04	17	04	0.739	
	Male	(84.62%)	(15.38%)	(80.95%)	(19.05%)		
Gender	т 1	33	03	23	18	0.0005	
	Female	(91.67%)	(8.33%)	(56.10%)	(43.90%)		
Duration	≤12	30	03	18	15	0.0000	
of DM	<b>\\ \)</b> 12	(90.91%)	(9.09%)	(54.55%)	(45.45%)	0.0009	
(years)	>12	25	04	22	07	0.315	
(years)		(86.21%)	(13.79%)	(75.86%)	(24.14%)		
Duration	≤4	24	07	23	11	0.379	
of ulcer		(77.42%)	(22.58%)	(67.65%)	(32.35%)		
(months)	>4	31	00	17	11	0.0001	
(IIIOIIIII)		(100.0%)	(0.0%)	(60.71%)	(39.29%)		
Size of	≤5	28	04	27	11	0.095	
ulcer		(87.50%)	(12.50%)	(71.05%)	(28.95%)	0.095	
(cm)	>5	27	03	13	11	0.0028	
(CIII)		(90.0%)	(10.0%)	(54.17%)	(45.83%)	0.0028	
BMI (kg/m²)	≤25	22	03	14	08	0.049	
		(88.0%)	(12.0%)	(63.64%)	(36.36%)	0.049	
	>25	33	04	26	14	0.012	
		(89.19%)	(10.81%)	(65.0%)	(35.0%)	0.012	
HbA1c (%)	≤6	19	02	12	06	0.066	
		(90.48%)	(9.52%)	(66.67%)	(33.33%)		
	6.1-9	36	05	28	16	0.009	
		(87.80%)	(12.20%)	(63.64%)	(36.36%)	0.009	

# **DISCUSSION**

The common complication of diabetes is Diabetic foot ulcers ultimately pose a great burden on the health system and may lead to limb amputation. Quality of life is disrupted in patients having chronic ulcers. Lifetime risk of having DFU in diabetics is around 15% & ultimately amputations in 88 %. Diabetic foot ulcers prevalence is 4-10% & 40-80% of subjects develop mortality and morbidity due to infections. Traditional techniques include normal saline dressing, but it may cause delayed healing and provoke an infection. Emerging methods are cellular therapies such as PRP & collagen wound dressing. Platelets are the source of

epidermal growth factors & angiogenesis factors. Several studies proved the effectiveness of PRP for wound healing.<sup>3,12</sup>

A study was conducted to find the benefits of autologous PRP and conventional dressing in chronic diabetic wound healing. The mean age was 52.92 ± 9.21 years and 52.63 ± 9.86 years for group A & group B, respectively 88 patients (70.97%) were from 46-80 years. From 124 patients, males were 47 (37.90%) and females 77 (62.10%) vielding ratio of male to female as 1:1.6. In this study, the efficacy of platelet-rich plasma was found to be 88.71% and the conventional dressing was 67.74% for chronic diabetic foot ulcers, with p-value of 0.0034. A metaanalysis regarding PRP therapy in cutaneous wounds demonstrated that PRP promoted wound healing and the ulcers improved significantly.8 A randomized controlled trial comparing Autologous PRP with conventional dressing for diabetic Foot Ulcers showed that the complete wound healing rate was 95% (n = 38) in 6th week in group A (PRP), contrary to 77.8% (n = 28) in 9th week for Group B (conventional dressing) (P < 0.001).11

After the second and fourth weeks, Abd El-Mabood *et al* found that the PRP group was more effective than traditional care. According to Takashi Hirase *et al*, the PRP group saw faster healing (7.8 weeks vs. 8.3 weeks) and better healing rates ( $0.68 \pm 0.56 \text{ cm}/\text{week}$  vs.  $0.39 \pm 0.09 \text{ cm}/\text{week}$ ; p < 0.001) than the standard care group. According to the current study, PRP patients recuperate more quickly than those receiving traditional treatment. Ullah *et al* discovered that the PRP group had a greater rate of wound reduction (80%) than the standard therapy group (46.25%) (P<0.001). In contrast to 60.6 days with conventional care, Singh SP *et al* saw full healing after 36.7 days of PRP therapy.

Elsaid *et al*<sup>17</sup> found that at 20 weeks, the complete healing rate was significantly higher at 20 weeks with PRP therapy compared to the normal saline dressing group (3/25 vs. 0/25, p = 0.03). The maximum healing time is also shorter for the PRP group, averaging  $6.3 \pm 2.1$  weeks versus  $10.4 \pm 1.7$  weeks for the saline group (P < 0.0001).

#### **CONCLUSION**

This study concluded that the effectiveness of plateletrich plasma is better for the management of chronic diabetic foot ulcers as compared to conventional dressing. So, we recommend that PRP should be used routinely in treating chronic non-healing ulcers in diabetics for improved healing and thus reducing the morbidity.

# **LIMITATIONS**

The study is limited by its single-centre trial.

# SUGGESTIONS / RECOMMENDATIONS

It is recommended to conduct larger-scale multicenter studies to confirm and validate these findings.

# CONFLICT OF INTEREST / DISCLOSURE

The authors declare no conflict of interest.

#### **FUNDING SOURCE**

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors

# **ACKNOWLEDGEMENTS**

We acknowledge and thank all residents and faculty of the surgery department for their cooperation regarding the completion of this project.

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