

### **A Comparative Study of Platelet Rich Plasma Versus Normal Saline Dressing In Diabetic Foot**

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#### **Abstract**

**Aim:** The aim of the study is to compare the effectiveness of platelet rich plasma dressing versus normal saline dressing in patients with diabetic foot ulcer

**Method:** This randomised control study was conducted in 80 patient who got admitted at Government Villupuram medical college & hospital with diabetic foot ulcer over a period of 2 years

**Results:** In this study 50 patients were included of which 25 received PRP and other 25 was treated with normal saline for a period of four weeks. The two groups are comparable with respect to age, sex, family history, type of onset, site of ulcer, blood sugar and was found to have no significance. Mean  $\pm$  SD duration of hospital stay is less in PRP group (35.41 $\pm$ 4.67) compared to normal saline group (45.92 $\pm$ 7.82) (P<0.05) Mean  $\pm$  SD reduction in wound area is more in PRP group (34.30 $\pm$ 6.21)

compared to normal saline group (14.43 $\pm$ 2.12) (P<0.05).

There is statistically significant association in Wound culture among study participants after dressing (P<0.05)

**Keywords:** Diabetic foot ulcer, platelet rich plasma, saline dressing.

#### **Introduction**

Diabetes affects more than 400 million people globally. Diabetes mellitus a disease characterised by Chronic hyperglycemia and abnormalities in the metabolism of carbohydrates as a result of deficiencies in insulin secretion, insulin action. Banting & Best showed that pancreatic extracts reduce blood sugar levels in 1921. Antonio made the discovery of oral hypoglycemic drugs in 1936. W. R. Jordan discussed the link between diabetic foot sores and the disease. Diabetics have a 15-fold increased risk of lower extremity amputations compared to non-diabetics. These diabetic ulcers are

known to be resistant to conventional therapy and, if left untreated, could signal serious problems. It has been discovered that PDGF to be low in or absent from resistant diabetic wounds, it is of substantial value to diabetics. PDGF is essential for angiogenesis. Platelet rich plasma contains various growth factors which is Chemotactic, Mitogenic, Angiogenic which makes them an efficient treatment option. DFU accounts for 20% or so of hospital admissions among DM patients. The length hospital stays in patient with DFU is the primary cause for increased cost of care. The mortality rate is in those patients suffering from DFU is twice as high as those not suffering from DFU.

### Materials And Methods

A randomised control study was conducted at Government Villupuram Medical college & hospital, Tamil Nadu, India for a period of 2 years.

**Study Design:** Randomized control study

**Study Centre:** Government Villupuram medical college & hospital

**Study Population:** All patients who fulfill the inclusion criteria were included in the study after obtaining informed written consents.

**Sample Size:** 50. It is calculated using open epi software. It is calculated as 25 patients in each group with 95% Confidence interval and Power as 95% considering a contingency of 20 %.

**Study Period:** 2 years

### Inclusion Criteria

1. Type II Diabetes mellitus.
2. Diabetics between 40 to 70 years of age.
3. Have documented wound etiology resulting from complications of DM
4. Duration of the ulcer more than 4 weeks.
5. Size of ulcer less than 10 x 10 cm

6. Fasting blood glucose levels measured in two occasions 24 hours apart between 140mg/dl- 200mg/dl

### Exclusion Criteria

1. Pulseless limb
2. Immunocompromised patients
3. Associated Osteomyelitis
4. Skin malignancy
5. Cellulitis
6. Diabetic Ketoacidosis
7. Exposed bone and tendon in ulcer

### Methodology

All patients who fulfilled the inclusion criteria were enrolled. Written informed consents were obtained. The present study was carried out in Govt Villupuram Medical College Hospital where 50 patients with diabetic foot ulcers participated. A pretested and predesigned Proforma was used and randomized into either study group or control group population using randomization chart. All patients have undergone detailed examination according to the Proforma approved by the institutional Ethical committee.

### Statistical Analysis

Data collected was entered in Microsoft excel and analysed using SPSS version 24. Qualitative variables were expressed in percentage. Quantitative variables were expressed in mean and standard deviation. Chi square test was used to test significance of difference in proportion. Independent t test was used to test significance of difference in means

### Results

Table 1: Age Distribution of Study Groups

Group	Number	Mean	SD	t	P-value
PRP	25	51.22	6.3	0.08	0.93
Normal Saline	25	52.86	8.4		

Mean age of Platelet rich plasma group is 51.22 and normal saline group is 52.86. The two groups are comparable with respect to age.

Figure 1: Age Distribution of Study Groups



Table 2: Sexwise distribution of study groups

Group	Male	Female	Total	df	CHI square	P value
PRP	14	11	25	1	0.577	0.44
Normal Saline	16	9	25			
Total	30	20	50			

There are 14 males and 11 females in Platelet rich plasma group and 16 males and 9 females in normal saline group. The two groups are comparable with respect to sex.

Figure 2: Sex wise distribution of study groups

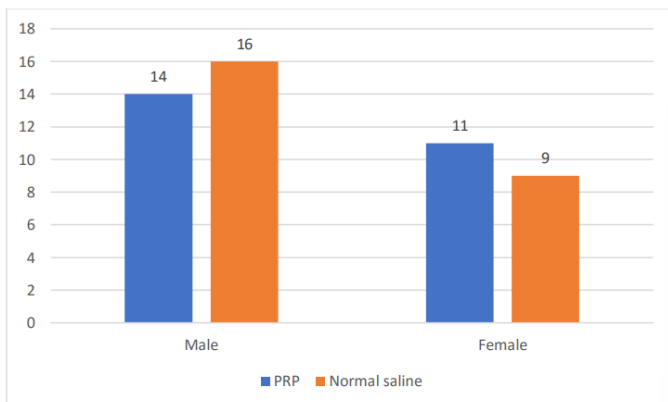


Table 3: Distribution of study participants according to family history

Group	Yes	No	Total	df	CHI square	P value
PRP	12	13	25	1	0.87	0.96
Normal Saline	13	12	25			
Total	25	25	50			

Family history is positive in 12 participants in Platelet rich plasma group and 13 in normal saline group. The two groups are comparable with respect to family history.

Figure 3: Distribution of study participants according to family history

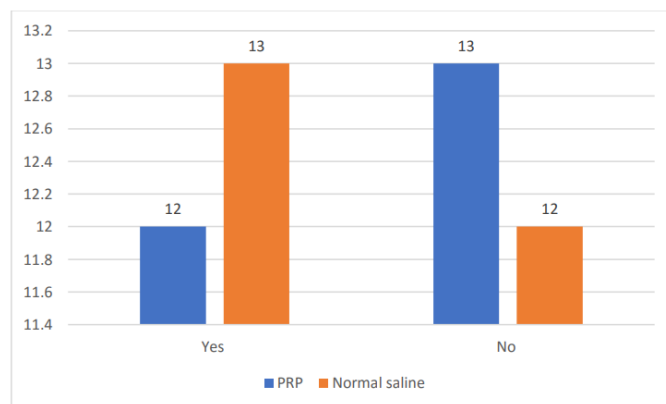


Table 4: Type of onset among study participants

Group	Spontaneous	Traumatic	Total	df	CHI square	P value
PRP	10	15	25	1	0.78	0.84
Normal Saline	8	17	25			
Total	18	32	50			

Onset is spontaneous in 10 patients in Platelet rich plasma group and 8 patients in normal saline group. The two groups are comparable with respect to type of onset.

Figure 4: Type of onset among study participants

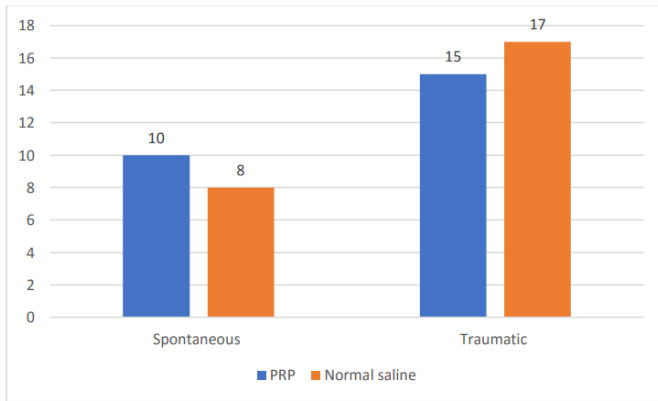


Table 5: Site of ulcer among study participants

Group	Dorsum	Plantar	Total	df	CHI square	P value
PRP	10	15	25	1	0.62	0.33
Normal Saline	11	14	25			
Total	21	29	50			

About 10 patients had ulcer in dorsum part in Platelet rich plasma group and 11 patients had ulcer in dorsum in normal saline group. The two groups are comparable with respect to site of ulcer.

Figure 5: Site of ulcer among study participants

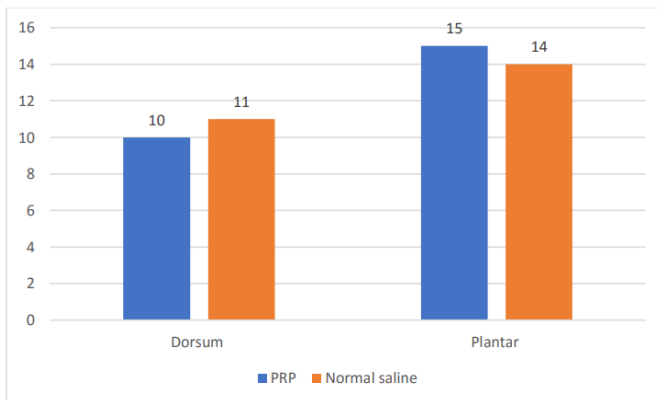


Table 6: Fasting blood sugar among study participants before dressing

Group	Number	mean	SD	t	P value
PRP	25	154.12	16.3	0.07	0.86
Normal Saline	25	156.21	18.4		

Table 7: Fasting blood sugar among study participants after dressing

Group	Number	Mean	SD	t	P value
PRP	25	164.16	18.3	1.12	0.42
Normal Saline	25	166.82	19.4		

The two groups are comparable with respect to fasting blood sugar.

Figure 6: Comparison of blood sugar among study participants

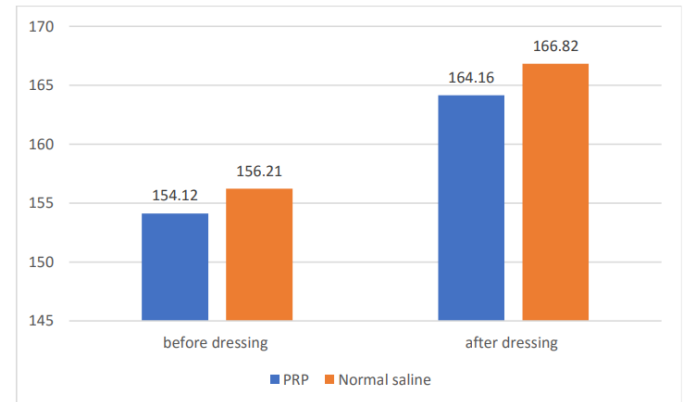


Table 8: Mean duration of hospital stay among study participants

Group	Number	mean	SD	t	P value
PRP	25	35.41	4.67	5.26	0.01
Normal saline	25	45.92	7.82		

Mean duration of hospital stay is less in Platelet rich plasma group compared to normal saline group (P<0.05)

Figure 7: Mean duration of hospital stay among study participants

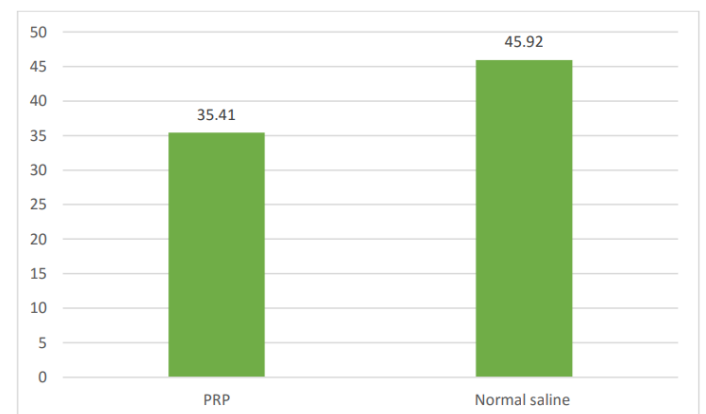


Table 9: Mean reduction in wound area among study participants

Group	Number	Mean	SD	t	P value
PRP	25	34.30	6.21	9.42	0.0001
Normal Saline	25	14.43	2.12		

Mean reduction in wound area is more in Platelet rich plasma group compared to normal saline group (P<0.05)

Figure 8: Mean reduction in wound area among study participants

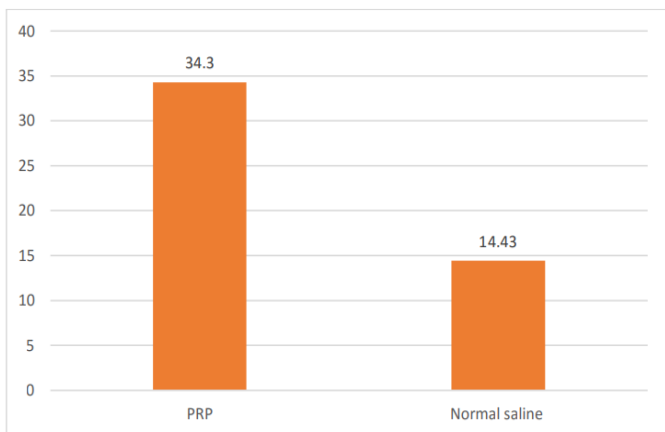
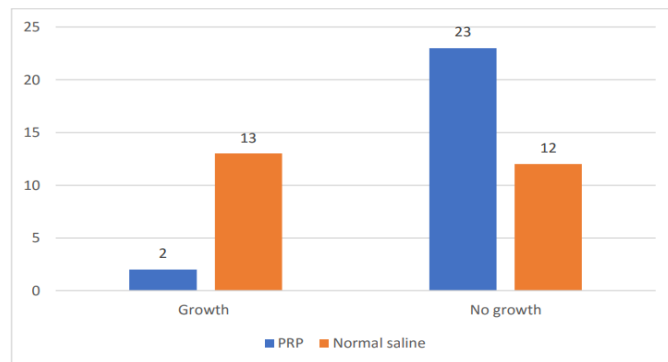


Table 10: Wound culture among study participants after dressing

Group	Growth	No growth	Total	df	CHI square	P value
PRP	2	23	25	1	5.48	0.01
Normal Saline	13	12	25			
Total	15	35	50			

There were 2 organisms cultured from Platelet rich plasma group and 13 organism cultured from normal saline group. There is statistically significant association in Wound culture among study participants after dressing(P<0.05)

Figure 9: Wound culture among study participants after dressing



**Discussion**

Hyperglycemia, a state brought on by absolute or relative impairment in insulin secretion and/or action, characterises diabetes mellitus (DM). The prevalence of diabetes has been increasing as people's living standards and lifestyles have changed. The modified 2010 prevalence estimates rise to 10.3% for the USA, 9.2% for Canada, 7.8% for India, and 10.8% for Mexico when these cases are also taken into account.

The platelet-derived growth factors and cytokines that PRP uses to mediate the therapeutic mechanisms of wound healing are responsible for controlling the immune system and inducing cellular regeneration processes in all tissues.

Diabetes induced Peripheral neuropathy and peripheral vascular disease, specifically, have a role in the development of foot ulcers, which can result in surgical debridement or lower limb amputation.

72 patients were randomly assigned to one of two groups of 36 patients each— the PRP group—or the standard dressing group in Orban et al 's prospective randomised controlled trial on the use of PRP for the treatment of DFUs.<sup>57</sup> In comparison to the traditional dressing group, the PRP group's ulcer healing time was considerably shorter (P =.01). Additionally, the PRP group experienced a greater rate of healing than the traditional

dressing group (31 patients (86.11%) compared to 23 patients (63.89%;  $P = .029$ ). In the PRP group compared to the conventional dressing group, there was no difference in healing rates according to ulcer site ( $P = .67$  vs.  $P = .544$ , respectively). However, individuals in the PRP group experienced a higher rate of plantar ulcer healing than those in the conventional dressing group (23/26 [88.46%] and 15/24 [62.5%], respectively).

Villela and Santos<sup>58</sup> published a systematic review and meta-analysis in 2010 that detailed the scientific evidence supporting positive outcomes, particularly the healing rate in PRP-treated patients, which demonstrated the value of PRP in the treatment of diabetic ulcers. 100 patients with persistent DFUs participated in a prospective, controlled study that Jeong et al published that same year. When compared to the control treatment with topically applied fibrinogen and thrombin (79% and 46%, respectively;  $P = .05$ ), they discovered that individuals treated with blood bank platelet concentrate had a considerably greater percentage of complete recovery.

Hirase et al observed that topical administration of PRP for 79 management of diabetic foot ulcers led to significantly better healing rates and decreased complication rates compared with a control group ( $p = .001$  and  $P = .115$ , respectively) in a systematic review that was published in 2018.

One young woman who has had infected heel ulcers for three years and is a juvenile diabetic. For the treatment of diabetic foot ulcers, she underwent PRP. Her first ulcer was entirely cured, while her second ulcer was just 40% healed. A significant achievement in this field of wound care is the full healing of a diabetic ulcer in a patient with uncontrolled diabetes without surgery, medication, or intensive dressing. An novel procedure for such instances is PRP therapy led by platelet regeneration.

In a multicenter, prospective, clinical randomised controlled trial, Driver VR treated diabetic foot ulcers using autologous PRP gel. 40 eligible participants in all took part in the trial. They were split into two groups at random: PRP gel was applied topically to one treatment group. The saline gel therapy was given to the control group. Every 12 weeks for a total of 12 weeks, the extent of ulcer healing was evaluated. In the treatment and control groups, 13 (68.4%) and 9 (42.9%) ulcers recovered, respectively. The PRP therapy group fared noticeably better than the control group, according to a Kaplan-Meier time-to-cure study. Throughout the PRP procedure, there were no severe adverse effects. The study found that PRP treatment for diabetic foot ulcers was very successful.

Release of plasma-free platelets from healthy donors and patients with diabetes both displayed comparable amounts of in vitro angiogenic activity, according to a study by Miao et al.<sup>63,24</sup> people were enrolled in the trial. The patients' average age was  $55.2 \pm 6.4$  years. Compared to none of the patients in group II, just three (25%) patients in group I experienced full healing. 8.3% of patients in group I and 41.6% of patients in group II overall did not respond to treatment. The longitudinal and horizontal DFU decrease percentages in group I were significantly higher than those in group II (43.2% vs. 4.1% and 42.3% vs. 8.2%, respectively). Maximum healing took place in group I far more quickly than in group II (6.3  $\pm$  2.1 vs. 10.4  $\pm$  1.7 weeks,  $P = 0.0001$ ). When compared to conventional saline dressing, the size of the ulcer was significantly reduced when PRP gel was applied as a dressing for chronic DFU. Additionally, when PRP was used as a dressing treatment, the time it took to achieve the point of maximum healing with the smallest wound dimensions was considerably reduced.

## Conclusion

Diabetics have a 15-fold increased risk of lower extremity amputations compared to non-diabetics. Diabetic ulcers are known to be resistant to conventional therapy. standards of care for diabetic foot ulcer include wound debridement pressure relief in the wound area, appropriate wound management, infection management, ischemia management, medical management of co morbidities, and surgical management as needed. PRP is considered to be viable and secure therapeutic option for treating diabetic foot ulcer hence it can be used as an biological adjuvant agent for treating non healing ulcers. More studies are required to evaluate the effectiveness of PRP.

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