

# “ASSESSING THE EFFECT OF PLATELET RICH PLASMA (PRP) AMONG PATIENTS WITH CHRONIC DIABETIC FOOT ULCERS ATTENDING DERMATOLOGY OPD FROM A PRIVATE MEDICAL INSTITUTE IN KANCHEEPURAM DISTRICT, TAMILNADU”

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## ABSTRACT

**Background:** One of the most common complications of diabetes mellitus is diabetic foot ulcer. Autologous platelet-rich plasma (PRP) has garnered the greatest interest among the wound-healing methods that have advanced greatly in recent years. Locally active growth factors are released by platelets, which is known to initiate the healing process after a wound. Autologous PRP studies have not shown strong data to support its utility in wound healing, hence more meticulously planned blinded trials are required.

**Methodology:** Patients visiting the department of Dermatology in a private medical institute from 2020 to 2021 who had been diagnosed with a chronic, non-healing diabetic foot ulcer and who met the inclusion criteria were recruited and randomly divided into two groups. One group (PRP Group) received care for glycemic control, wound cleaning, wound debridement, infection therapy, application of PRP, and appropriate dressings. For the second group (Control Group), glycemic control therapy, wound cleaning, wound debridement, infection management, and appropriate dressings were administered.

**Results:** Out of the 42 respondents, majority were between age group 51-60, nearly 71.4% were male. Study respondents were from various occupations. The mean HbA1c was 6.86% with standard deviation 0.68 in PRP group. In control group the mean HbA1c was 6.69% with 0.85 as standard deviation

**Conclusion:** The PRP group experienced better and quicker healing of the ulcer than the control group, demonstrating the higher efficacy of platelet rich plasma therapy. Throughout the trial, no unfavourable impacts were noticed. To sum up, platelet rich plasma therapy is an easy, affordable, and reliable therapeutic method that can be used to safely treat persistent diabetic foot ulcers.

## Introduction:

Diabetes mellitus has become a global health problem, affecting all groups of people irrespective of their race, social conditions, or gender. It can cause a wide range of complications, causing remarkable morbidity and mortality for the patient. Lower extremity

ulcers are one of the serious complications causing significant health concern in patients with diabetes mellitus. Several factors like poor glycaemic control, peripheral neuropathy, peripheral vascular disease and immunosuppression contribute in their aetiology.<sup>1</sup> Diabetes predisposes to several systemic and cutaneous complications causing significant morbidity and mortality. Its global prevalence is estimated over 200 million.<sup>2</sup> About 80% of the total cases of diabetes mellitus are from developing countries, of which China and India have the highest number.<sup>3</sup> India is thus said to be the diabetes capital of the world and every fifth diabetic person in the world is said to be an Indian.<sup>4</sup>

The real problem arises when the wound becomes chronic and non-healing in nature, which may cause disability, reduced quality of life and may even lead to amputation of few to most part of the lower limb. It is worthy to note that diabetic foot ulcers are the major cause of non-traumatic amputation occurring around the world.<sup>5</sup> These are the skin diseases associated with diabetes mellitus like xerosis, pruritus, diabetic dermopathy, necrobiosis lipoidica, diabetic bullae, granuloma annulare, acanthosis nigricans, acquired perforating disorders, diabetic thick skin, yellow skin, lichen planus, rubeosis faciei, and acrochordons.<sup>6,7</sup>

There are a wide range of medical and surgical treatment modalities available for the management of diabetic foot ulcers, ranging from patient education, using appropriate foot wear, conventional dressings with wound debridement, pressure reducing wound therapy to surgical methods like split skin grafting. Ulcer of the skin is defined as complete loss of epidermis and portion of dermis; sometimes it may involve the subcutaneous fat layer too. A chronic leg ulcer is said to be any ulcer below the knee level persisting for a duration of more than six weeks<sup>8</sup> that does not show tendency to heal even after three months of prompt treatment or which does not heal completely in 12 months.<sup>9</sup>

The prevalence of chronic leg ulcer in adult population ranges from 1.9% to 13.1% in the community.<sup>8</sup> In population over 60 years of age the prevalence ranges from 0.6% to 3% and in over 80 years, it is more than 5% .<sup>10</sup> About 10% of the population are estimated to develop chronic wound in their lifetime with wound related mortality rate estimated to be 2.5%.<sup>11</sup> In India, there are several studies regarding chronic wounds. One study showed a prevalence of 4.5 per 1000 population for chronic wounds, and 10.5 per 1000 population for acute wounds.<sup>12</sup>

Among the list of ten nations with most cases of Diabetes mellitus, India is ranked in the first place with a prevalence of 42 million cases.<sup>13</sup> Foot ulceration is one of the most serious and dreaded complications in patients with diabetes mellitus. It contributes as one of the major cause of mortality in diabetic patients and is responsible for prolonged periods of hospital stay.<sup>14,15</sup> About 15% of the patients with diabetes mellitus develops foot ulcer<sup>16</sup> and 85% of diabetic patients who undergo lower limb amputation have a preceding foot ulcer.<sup>17</sup> The annual incidence of diabetic foot ulcer is estimated to be 2 to 3%.<sup>18</sup>

Unfortunately, it is very challenging to treat diabetic wounds in spite of all the available treatment methods, and the desired positive result is often not obtained or observed in many patients. One novel method, emerging and currently becoming popular in the treatment of diabetic leg ulcers is the autologous platelet rich plasma therapy. Blood contains plasma, which is a protein rich fluid. All the cellular elements are suspended in this plasma. The cellular components are red blood cells, white blood cells and platelets. In a human body the circulating blood constitutes about 8% of the total body weight of which 55% is plasma<sup>19</sup>.

Here, using the patient's own blood, a high concentration platelet extract is obtained and is delivered to the wound, causing release of several essential growth factors which ultimately leads to an enhanced or accelerated wound healing.

In view of the above background, this study was planned with the aim to study the clinical effectiveness and the therapeutic response to Platelet Rich Plasma (PRP) in chronic diabetic foot ulcers and to observe for any side effects of PRP in patients with chronic diabetic foot ulcers.

## Materials and Methods

The approval was obtained from the ethical committee.

Patients diagnosed with chronic non-healing diabetic foot ulcer and fulfilling the inclusion criteria visiting the department of Dermatology, Venereology and Leprosy in a private medical institute from 2021 to 2022 were chosen and were randomly divided into two groups. For one group (PRP Group), treatment for glycemic control, cleansing of the wound, wound debridement, treatment of infection, application of PRP and suitable dressings were done. For the other group (Control Group), treatment for glycemic control, cleansing of the wound, wound debridement, treatment of infection and suitable dressings were done.

Informed consent (including in their mother tongue) was obtained from the patients. A detailed history on onset, duration of ulcer, associated pain, swelling of the feet and regional lymphadenopathy were noted. Duration of diabetes mellitus and treatment history for the same was noted. Other co-existing medical illnesses like hypertension if any were noted.

Ulcer was thoroughly examined and measurement was taken using the "clock face" method by Sussman, with the help of disposable paper rulers. Area of the ulcer was calculated using the formula for an ellipse – length x width x 0.7854. Baseline digital photography was taken.

## DATA COLLECTION

Complete blood count (including haemoglobin, total count, differential count, erythrocyte sedimentation rate, platelet count), Fasting blood sugar, Post prandial blood sugar, glycosylated haemoglobin (HbA1c), Peripheral smear, Bleeding time, clotting time, Liver function test, Renal function test, Swab for pus culture and sensitivity, X ray foot, Doppler study of the affected limb, Screening for HIV, Hepatitis B, C and VDRL were done as pre-treatment workout protocol.

In the treatment of PRP group, the PRP was applied over the ulcer and occlusive dressing was done. The dressing was removed the next day. PRP was applied once a week. Cleansing and dressing was done using normal saline for the remaining six days of the week. In the control group, cleansing and dressing using normal saline was done every day. The normal saline used in this study is isotonic normal saline (0.9% NaCl)

For both groups ulcer measurement and digital photographs were taken at the end of each week. This was carried out either for a maximum of five weeks or till there was complete re-epithelialisation of the ulcer, whichever was earlier. At the end of treatment, the percentage improvement in area was assessed and compared for both groups. The patient will be asked for any adverse events occurred during previous weeks, during each follow up.

**INCLUSION CRITERIA:**

Patients of either sexes aged 31 to 80 years and those who were willing to participate and give written informed consent, Patients with Wound diagnosed as chronic non-healing diabetic foot ulcer >6 weeks duration and with HbA1c less than 8% and Hemoglobin more than 9g/dl were included in the study.

**EXCLUSION CRITERIA:**

Patients with Presence of osteomyelitis or if osteomyelitis is suspected (x-ray), Evidence of gangrene in ulcer or any part of the foot, Presence of bleeding disorder, Subjects with thrombocytopenia and nursing or pregnant or plans to become pregnant during trial were excluded from the study. Those not willing to participate and those who were critically ill or bed ridden due to other chronic illnesses were excluded from the study.

**MEASUREMENT OF ULCER:<sup>[94]</sup>**

The ulcer was measured using disposable paper rulers. The length and width of the ulcer was measured using the standard “clock face method” described by Sussman. Length was 12:00 to 6:00 with 12:00 towards the head and the width was 3:00 to 9:00 side by side. Area was calculated using the formula for an ellipse length x width x 0.7854. The treatment outcome was defined as a percentage improvement in area of the ulcer.

**PREPARATION AND PROCEDURE FOR PRP:****Instruments required were**

- Centrifuge machine
- Sterile conical centrifuge tubes
- Sterile pipettes
- Anticoagulant acid citrate dextrose
- 10% Calcium chloride
- Normal saline
- Sterile gauze and pads
- Disposable paper rulers
- Digital camera

**Preparation of PRP:<sup>[89], [95]</sup>**

- 10ml of venous blood was collected from the patient in a conical centrifuge test tube containing anticoagulant ACD at ratio 10:1.5.
- First centrifugation was carried out at 1500 revolutions per minute for 6 minutes
- The plasma, buffy coat and upper layer of RBCs are collected into another empty sterile conical centrifuge tube.
- The second centrifugation is at 2500 revolutions per minute for 15 minutes.
- The lower one third plasma is collected which is the platelet rich plasma.
- It is activated by adding 10% calcium chloride (9 parts of PRP and 1 part of calcium chloride).
- Adequate wound debridement and cleansing with normal saline was done.
- Without much delay the activated PRP is applied over the surface of the ulcer by spraying.

- Occlusive dressing was done using sterile gauze and pads.
- Digital photographs were taken and compared at the end of every week.
- Improvement in ulcer area is the percentage improvement in area.

$$\text{Percentage improvement in area} = \frac{\text{Initial area} - \text{final area}}{\text{Initial area}} \times 100$$

- The dressing was opened the next day, and the wound was cleansed and dressed using normal saline for the remaining 6 days of the week.

#### **FOLLOW UP:**

Patients were asked to continue their diabetic management. They were all followed up every week for a maximum of 5 weeks or till there was complete re-epithelialization, whichever was early. At every visit, wound area was calculated and digital (serial) photographs were taken.

#### **STATISTICAL ANALYSIS:**

All statistical analysis was performed using Statistical Package for Social Science (SPSS, version 21) for Microsoft windows. The data were not normally distributed. And therefore parametric / Non Parametric tests were performed. Descriptive statistics were presented as numbers and percentages. The data were expressed as Mean and SD. Independent sample student t-test / Mann Whitney test were used to compare continuous variables between two groups. A chi-square test was used for comparison between two attributes. A two sided p value < 0.05 was considered statistically significant.

#### **SOURCE OF DATA:**

Patients visiting the department of Dermatology, Venerology and Leprosy from a private medical College in Kancheepuram District, Tamilnadu.

#### **SAMPLE SIZE:**

42 patients

#### **STUDY DESIGN:**

Comparative cross-sectional study

#### **SAMPLING METHOD:**

Convenient sampling method

#### **RESULTS:**

The findings from this study are illustrated below as tables and figures. Table 1 shows the various determinants among study respondents. From table 1 majority of them belonged to age group 51-60. Nearly 71.4% of the study participants were males while the remaining were females. In view of their occupation, there was a wide distribution and of which 28% were farmers.

**TABLE 1:VARIOUS DETERMINANTS AMONG STUDY RESPONDENTS**

SNO	Determinant	Frequency	Percentage
1	<b>Age</b>		
	<b>31-40</b>	<b>3</b>	<b>7.1</b>
	<b>41-50</b>	<b>11</b>	<b>26.2</b>

	<b>51-60</b>	<b>21</b>	<b>50</b>
	<b>&gt;60</b>	<b>7</b>	<b>16.7</b>
<b>2</b>	<b>Sex</b>		
	<b>Male</b>	<b>30</b>	<b>71.4</b>
	<b>Female</b>	<b>12</b>	<b>28.6</b>
<b>3</b>	<b>Occupation</b>		
	Carpenter	<b>3</b>	<b>7.1</b>
	Construction worker	<b>7</b>	<b>16.7</b>
	Farmer	<b>12</b>	<b>28.6</b>
	Housewife	<b>9</b>	<b>21.4</b>
	Shop owner	<b>6</b>	<b>14.3</b>
	Unemployed	<b>5</b>	<b>11.9</b>

From Table 2 it is noticed that most common age group seen in both PRP group and control group was 51 to 60 years. The difference between both the groups was not statistically significant. Male gender was encountered more than female in both the groups. The difference between two groups was not statistically significant. Most of the patients were farmers in both the groups and there was no statistical significance in both the groups. Most of the patients had total duration of ulcer between 8 to 16 weeks in both the groups. The difference between the groups showed no statistical significance. The most common site involved was the sub-metatarsal area of the foot in both the groups. There was no statistical difference between both the groups.

**TABLE 2: ANALYTICAL STATISTICS SHOWING ASSOCIATION BETWEEN BOTH GROUP**

SNO	DETERMINANTS		Group		Total	P value
			PRP Group	Control Group		
<b>1</b>	<b>AGE</b>					
	<b>31-40</b>	<b>Frequency</b>	2	1	3	<b>0.893</b>
		<b>% in Group</b>	9.5%	4.8%	7.1%	
	<b>41-50</b>	<b>Frequency</b>	5	6	11	
		<b>% in Group</b>	23.8%	28.6%	26.2%	
	<b>51-60</b>	<b>Frequency</b>	10	11	21	
		<b>% in Group</b>	47.6%	52.4%	50.0%	
	<b>&gt;60</b>	<b>Frequency</b>	4	3	7	
		<b>% in Group</b>	19.0%	14.3%	16.7%	
	<b>Age total</b>	<b>Frequency</b>	21	21	42	
<b>% in Group</b>		100.0%	100.0%	100.0%		
<b>2</b>	<b>SEX</b>					
	<b>Male</b>	<b>Frequency</b>	16	14	30	<b>0.495</b>
		<b>% in Group</b>	76.2%	66.7%	71.4%	
	<b>Female</b>	<b>Frequency</b>	5	7	12	
<b>% in Group</b>						

		<b>% in Group</b>	23.8%	33.3%	28.6%		
	<b>Total</b>	<b>Frequency</b>	21	21	42		
		<b>% in Group</b>	100.0%	100.0%	100.0%		
<b>3</b>	<b>OCCUPATION</b>						
	Carpenter	<b>Frequency</b>	2	1	3	<b>0.978</b>	
		<b>% in Group</b>	9.5%	4.8%	7.1%		
	Construction worker	<b>Frequency</b>	4	3	7		
		<b>% in Group</b>	19.0%	14.3%	16.7%		
	Farmer	<b>Frequency</b>	6	6	12		
		<b>% in Group</b>	28.6%	28.6%	28.6%		
	Housewife	<b>Frequency</b>	4	5	9		
		<b>% in Group</b>	19.0%	23.8%	21.4%		
	Shop owner	<b>Frequency</b>	3	3	6		
		<b>% in Group</b>	14.3%	14.3%	14.3%		
	Unemployed	<b>Frequency</b>	2	3	5		
		<b>% in Group</b>	9.5%	14.3%	11.9%		
	<b>Total</b>	<b>Frequency</b>	21	21	42		
		<b>% in Group</b>	100.0%	100.0%	100.0%		
<b>4</b>	<b>DURATION OF ULCER</b>						
	< 8 Weeks	<b>Frequency</b>	6	7	13	<b>0.675</b>	
		<b>% in Group</b>	28.6%	33.3%	31.0%		
	8 - 16 Weeks	<b>Frequency</b>	11	12	23		
		<b>% in Group</b>	52.4%	57.1%	54.8%		
	> 16 Weeks	<b>Frequency</b>	4	2	6		
		<b>% in Group</b>	19.0%	9.5%	14.3%		
	<b>Total</b>	<b>Frequency</b>	21	21	42		
		<b>% in Group</b>	100.0%	100.0%	100.0%		
<b>5</b>	<b>SITE OF ULCER</b>						
	T	<b>Frequency</b>	6	5	11		<b>0.645</b>
		<b>% in Group</b>	28.6%	23.8%	26.2%		
	SMT	<b>Frequency</b>	8	7	15		
		<b>% in Group</b>	38.1%	33.3%	35.7%		
	MF	<b>Frequency</b>	1	0	1		
		<b>% in Group</b>	4.8%	.0%	2.4%		
	H	<b>Frequency</b>	3	2	5		
		<b>% in Group</b>	14.3%	9.5%	11.9%		
	BMM	<b>Frequency</b>	2	3	5		
		<b>% in Group</b>	9.5%	14.3%	11.9%		
	BLM	<b>Frequency</b>	1	4	5		
		<b>% in Group</b>	4.8%	19.0%	11.9%		
	<b>Total</b>	<b>Frequency</b>	21	21	42		
		<b>% in Group</b>	100.0%	100.0%	100.0%		

At the end of fifth week, the mean area was reduced from 11.03 cm<sup>2</sup> (SD 4.42) to 2.89 cm<sup>2</sup> (SD 2.12) in PRP group and the mean area reduced from 10.64 cm<sup>2</sup> (SD 4.76) to 6.41 cm<sup>2</sup> (SD 2.65) in the control group. There was significant statistical difference from second week to fifth week in both the groups. The percentage improvement in area at the end of fifth week was 82.19% (SD 9.15) in the PRP group and 37.50% (SD 13.16) in the control group. The difference between both the groups was statistically significant.

The mean HbA1c was 6.86% with standard deviation 0.68 in PRP group. In control group the mean HbA1c was 6.69% with 0.85 as standard deviation. The difference was not found to be statistically significant. The mean post prandial blood sugar was 169.33 mg/dl for the PRP group and 169.04 mg/dl for the control group, with the standard deviation 38.05 for PRP group and 38.73 for control group. The difference between both groups was not statistically significant. The mean fasting blood sugar was 111.19 mg/dl and standard deviation was 25.87 for PRP group. The mean feasting blood sugar was 110.95 mg/dl and standard deviation was 25.33 for control group. The difference between both the groups was not statistically significant.

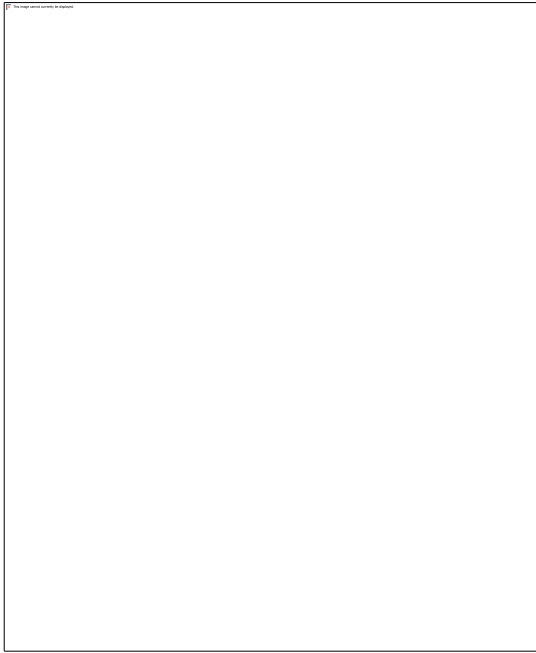
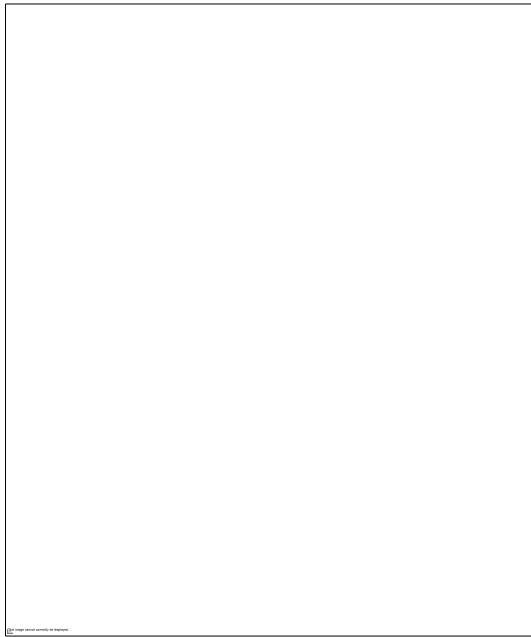
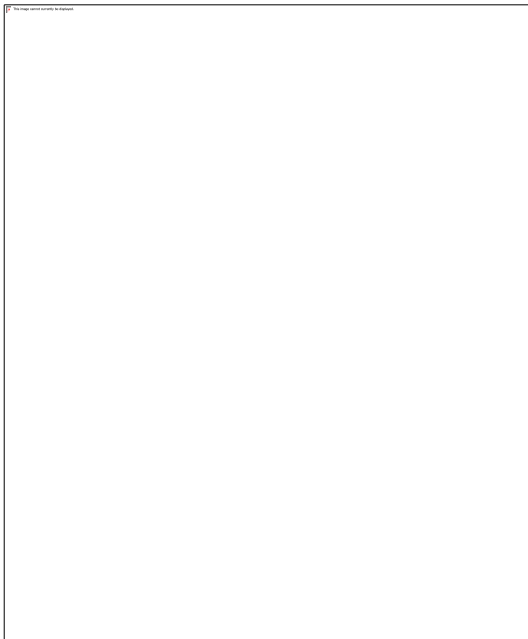
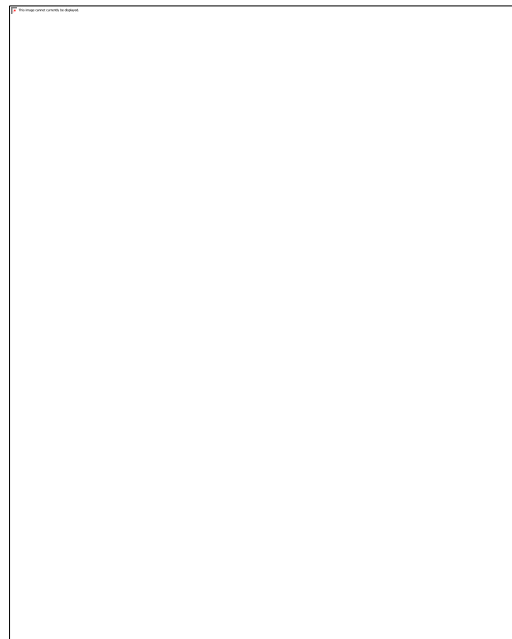
**TABLE 3: ASSOCIATION BETWEEN PRP GROUP AND CONTROL GROUP WITH GLYCEMIC VALUES**

SNO	DETERMINANT	GROUP	N	MEAN	Std.Dev	p value
1	<b>GLYCEMIC VALUES</b>					
	Fasting blood sugar (mg/dl)	PRP GROUP	21	111.1905	25.87396	0.976
		CONTROL GROUP	21	110.9524	25.33471	
	Post prandial blood sugar (mg/dl)	PRP GROUP	21	169.3333	38.05697	0.981
		CONTROL GROUP	21	169.0476	38.73819	
	HbA1c	PRP GROUP	21	6.862	.6895	0.491
		CONTROL GROUP	21	6.695	.8564	
	2	<b>AREA IMPROVEMENT</b>				
Area Initial		PRP GROUP	21	11.0352	4.42094	0.783
		CONTROL GROUP	21	10.6414	4.76695	
Area 1 week		PRP GROUP	21	8.2933	4.08514	0.242
		CONTROL GROUP	21	9.8800	4.27607	
Area 2 weeks		PRP	21	5.5610	3.54262	0.003



		GROUP				
		CONTROL GROUP	21	9.0052	3.82793	
	Area 3 weeks	PRP GROUP	19	3.8758	2.98121	0.000
		CONTROL GROUP	21	8.0314	3.31448	
	Area 4 weeks	PRP GROUP	15	2.8560	2.54377	0.0003
		CONTROL GROUP	21	7.1371	2.92388	
	Area 5 weeks	PRP GROUP	7	2.8914	2.12796	0.006
		CONTROL GROUP	21	6.4143	2.65189	
<b>3</b>	<b>Improvement in PRP</b>					
	% Improvement in area in 1 week	PRP GROUP	21	27.1124	9.18064	
		CONTROL GROUP	21	6.5829	3.74241	
	% Improvement in area in 2 weeks	PRP GROUP	21	52.9986	12.99445	
		CONTROL GROUP	21	14.3600	5.76106	
	% Improvement in area in 3 weeks	PRP GROUP	19	69.9647	13.67674	
		CONTROL GROUP	21	23.1290	9.14958	
	% Improvement in area in 4 weeks	PRP GROUP	15	79.7773	12.39780	
		CONTROL GROUP	21	30.9633	11.54647	
	% Improvement in area in 5 weeks	PRP GROUP	7	82.1901	9.15512	
		CONTROL GROUP	21	37.5019	13.16572	

FIG 1:

**PRP GROUP PRE TREATMENT****AT 3<sup>rd</sup> sitting****FIG 2:****PRE TREATMENT****4th sitting****DISCUSSION**

The total number of patients in the study was 42. They were randomly divided into two groups. The PRP group had 21 patients (50%) and the control group had 21 patients (50%). Out of 42 patients, 30 patients (71.4%) were male with 16 patients (76.2%) in the PRP group and 14 patients (66.7%) in the control group. Male patients were observed more than female patients in both the groups this was in concordance with several studies conducted in the past.<sup>20,21</sup> This could be due to the fact that males are more prone for injuries and females

having restricted outdoor activities. Another reason could be less hospital seeking behavior among the females, than that of the male population.

The most common age observed in both PRP and control group was the same (51 to 60 years) with a total of 21 patients (50%). In PRP group it was 10 patients (47.6%) and in control group it was 11 patients (52.4%). This was in concordance with a study conducted by Vickie R Driver<sup>20</sup> on 129 patients, where the mean age observed was 56.4 years and 57.5 years in test group and control group respectively. Another study by G Saldalamacchia showed similar observation in age group with mean age of  $61.1 \pm 9.4$  years in test group and mean of  $58.1 \pm 7.8$  years in control group.<sup>21</sup>

Most of the patients were farmers with a total number of 12 patients (28.6%) in both the groups. They were 6 in number (28.6%) in each group. This could be attributed to the fact that farmers are more prone for trauma. The duration of ulcer observed in most of the patients was 8 to 16 weeks with a total of 23 patients (54.8%) in both the groups. There were 11 patients (52.4%) in PRP group and 12 patients (57.1%) in control group. There was no significant statistical difference between the two groups.

The most common site affected was the sub-metatarsal region with a total number being 15 (35.7%) in both the groups. In PRP group it was 8 patients (38.1%) and in control group it was 7 patients (33.3%). The second most common site observed was toes in 11 patients (26.2%), 6 in PRP group and 5 in control group (28.6% and 23.8%). This was in concordance with a study conducted by G E Reiber on 92 patients, where the most common site affected was the plantar toes, forefoot and midfoot.<sup>18</sup>

The mean fasting blood sugar was 111.19 mg/dl with a standard deviation (SD) 25.87 in the PRP group and a mean of 110.95 with standard deviation 25.33 in control group. There was no significant statistical difference between the PRP group and the control group. The mean post prandial blood sugar level was 169.33 mg/dl with a standard deviation of 38.05 in PRP group and a mean of 169.04 mg/dl with standard deviation 38.73 in the control group. The difference in post prandial blood sugar level between the two groups was not statistically significant.

The mean HbA1c level in PRP group was 6.86% with standard deviation being 0.68 and in control group it was 6.69% with a standard deviation of 0.85. There was no significant statistical difference between the PRP group and the control group. This lack of significant statistical difference in glycemic status between both the groups shows that the ulcer healing is attributed to the effect of platelet rich plasma only and is not influenced by the glycemic status of the patient.

The mean size of ulcer initially in PRP group was  $11.03 \text{ cm}^2$  with standard deviation of 4.42 and initial ulcer size in control group had a mean of  $10.64 \text{ cm}^2$  with standard deviation 4.76. There was no significant statistical difference in both the groups. At the end of 1 week, the mean area reduced to  $8.29 \text{ cm}^2$  in the PRP group and  $9.88 \text{ cm}^2$  in the control group. The standard deviation was 4.08 and 4.27 respectively. There was no significant statistical difference between the PRP group and control group.

At the end of second week, the mean area was  $5.56 \text{ cm}^2$  in PRP group and  $9.00 \text{ cm}^2$  in control group. The standard deviation was 3.54 and 3.82 in PRP group and control group respectively. There was significant statistical difference between the test group and the

control group. This shows that the PRP group starts to exhibit a higher healing rate compared to the control group. At the end of third week, the mean area of ulcer reduced to 3.87 cm<sup>2</sup> with standard deviation 2.98 in PRP group. In control group the mean area of ulcer was 8.03 cm<sup>2</sup> with a standard deviation of 3.31. The difference between the PRP group and control group was statistically significant.

At the end of fourth week, the mean area was reduced to 2.85 cm<sup>2</sup> (SD 2.54) and 7.13 cm<sup>2</sup> (SD 2.92) in the test group and the control group respectively. The difference in mean area of ulcer between the two groups was statistically significant. At the end of the study (5 weeks), the mean area of the ulcer was 2.89 cm<sup>2</sup> in the PRP group and 6.41 cm<sup>2</sup> in the control group. The standard deviation for PRP group and control group was 2.12 and 2.65 respectively. The mean area of ulcer between the PRP group and the control group showed significant statistical difference. This shows there is significant overall reduction in the mean area of the ulcer in PRP group than that of control group.

In the PRP group, out of 21 patients 2 patients showed complete re-epithelialization of ulcer at the end of 3 weeks, 4 patients at the end of 4 weeks and 8 patients at the end of 5<sup>th</sup> week. A total of 14 patients (66.67%) showed complete healing with PRP therapy. There was no complete closure of ulcer in remaining 7 patients (33.33%). In the control group, out of 21 patients none showed complete re-epithelialization of ulcer within the study duration (five weeks). The mean percentage improvement in the ulcer area at the end of 5 weeks was 82.19% (SD 9.15) in PRP group and 37.50% (SD 13.16) in control group with significant statistical difference between both the groups. This shows that the percentage of ulcer healing is significantly better and faster than that of control group.

Saldalamacchia G *et al*<sup>21</sup> (2004) conducted a study on diabetic foot ulcers with a total number of 14 patients for a period of five weeks. The percentage reduction in the wound area was 71.9 ± 22.5 % in the treatment group and 9.2 ± 67.8% in the control group. Reduction of atleast 50% in wound area or a complete healing of the wound was observed in 5 patients (71.4%) in treatment group and 2 patients (28.6%) in control group.

A study conducted by Driver *et al* (2006) on diabetic foot ulcers for a period of 12 weeks, showed a favorable outcome in diabetic lower limb wound healing with the use of autologous platelet rich plasma gel. Out of 19 patients in treatment group, 13 showed complete healing and out of 21 patients in control group, 9 showed complete healing. Also, the mean duration of ulcer healing was shorter in the treatment group than that of control group.<sup>20, 22</sup> Sankararaman B *et al*<sup>23</sup> conducted a study on diabetic foot ulcers on 50 patients, where 52% of the patients showed complete healing in the study group and 20% showed complete healing in the control group.

The following two studies show the use of autologous platelet rich plasma in chronic non-healing ulcers of various etiologies. Suryanarayanan S *et al*<sup>24</sup> studied 24 patients with 33 ulcers. The mean percentage of reduction in area of the ulcer was 91.7% and complete healing was observed in 24 ulcers (76%). Suthar M *et al*<sup>25</sup> conducted a study on 24 patients out of which 17 (70.83%) patients showed more than 90% reduction in ulcer size.

## CONCLUSION

The total number of patients in the study was 42. Out of this, 21 received PRP with normal saline dressing and 21 received normal saline dressing only. At the end of five weeks, the

mean percentage improvement in area was found to be 82.19% in the PRP group and 37.50% in the control group. The difference between both the groups was statistically significant. In my study, treatment with PRP is found to show significant improvement in ulcer healing, reduction in the duration of treatment and sustainability of improvement as well as shorter duration of hospital stay. It is a simple, safe, cost effective and a painless procedure, which also improves the quality of life in the patients. Hence, it is a more desirable treatment option for patients with chronic diabetic foot ulcers, especially when other modalities of treatment have failed or surgical management is contraindicated. Thus the healing of the ulcer was found to be better and faster in the PRP group than that of control group, proving the superior efficacy of platelet rich plasma therapy. There were no adverse effects observed during the study. In conclusion, Platelet rich plasma therapy is a simple, cheap and effective day care procedure which can be used safely for treating chronic diabetic foot ulcers.

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