



A COMPARATIVE STUDY OF PLATELET RICH PLASMA DRESSING VS NORMAL SALINE DRESSING IN THE MANAGEMENT OF DIABETIC FOOT ULCER

General Surgery

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ABSTRACT

90 patients with diabetic foot ulcer admitted in Department of General Surgery R. L. JALAPPA HOSPITAL, TAMAKA, KOLAR, in between the study period of December 2017 to June 2019.

The study is estimated to include diabetic foot ulcer patients satisfying inclusion criteria who are admitted in surgical wards of RLJH and RC.

A complete detailed history, as per standard proforma will be obtained and documented. All patients will undergo clinical examination with relevant investigations after obtaining an informed consent. Patients are divided into 2 groups using even-odd method to include similar type of cases in both groups, where even group is study group and odd group is control group.

RESULTS: Predisposition of diabetic foot ulcer was common among males than in females, More number of diabetic patients presented with diabetic foot ulcer arising from trauma than those occurring spontaneously. The spontaneous onset ulcers healed better with PRP than those arising due to traumatic onset. The ulcers on dorsal aspect heal faster than on plantar aspect. PRP dressing improved the rate of healing in lower Wagner grade ulcer than in higher grade ulcer, Patients who were on insulin alone showed better healing than those on OHA. Over all PRP dressing group showed higher rate of ulcer size reduction than those on saline dressing.

CONCLUSION: The diabetic ulcer in the study group treated with PRP dressing contracted in wound size more than in the control group. This indicates that PRP dressing is an effective method to facilitate wound contraction in diabetic patients with foot ulcer. PRP dressing is found to be more effective, cost efficient and safe promoter of ulcer wound healing and can be used as an adjunct to saline dressings for enhanced healing of diabetic wounds.

KEYWORDS

PRP, Normal saline, Wagner grade, diabetic foot,

INTRODUCTION

Diabetes mellitus is defined by the WHO as a disorder of metabolism characterized by hyperglycemia with disturbance of carbohydrates, lipoproteins and amino acids metabolism which results from defects in secretion of insulin, insulin action or both.^[1]

Diabetic foot ulcer a major complication and concern of diabetes mellitus, it affects about 15% of population with diabetes. Studies have shown that up to 88% of all lower leg amputation are due to diabetic foot ulcer. According to, the World Health Organization, at least 171 million people in globe have diabetes the figure is sooner to double by 2030.^[2]

Diabetes mellitus causes 2 major vascular complications micro and macro vascular complications. Micro vascular complications include nervous system damage (neuropathy), renal system damage (nephropathy) and eye damage (retinopathy). Peripheral vascular disease may lead to bruises or injuries that do not heal, gangrene and ultimately amputation.^[3]

Conventional treatments like dressings, debridement of the wound and even skin grafting cannot provide a satisfactory healing since these were not able to provide necessary growth factors that can augment the healing process.^[4]

Autologous platelet-rich plasma (PRP) is an expensive methods used in treating non-healing ulcers as it provides growth factors which enhance healing. PRP functions as a tissue sealant and drug delivery system, with the platelets initiating wound repair by releasing locally acting growth factors via α -granules degranulation.^[5]

AIM OF STUDY

1. To evaluate the efficacy of platelet rich plasma dressings in the treatment of diabetic foot ulcers in study group.
2. To evaluate the efficacy of Normal saline dressing in management of diabetic ulcers in control group.
3. Comparing the effectiveness of study and control groups in terms of decrease in the size of ulcer and duration of ulcer healing in the treatment of diabetic foot ulcers.

MATERIALS AND METHODOLOGY

1. Study design: prospective Comparative study

2. Period of study: Dec 2017- June 2019

3. Study group: The study included 90 patients with diabetic foot ulcer admitted in wards or attending the outpatient departments who met the inclusion criteria

4. Sample size

Total patients : 90

Study group : 45

Control group : 45

INCLUSION CRITERIA:

1. Patients with type 2 diabetes mellitus with diabetic foot ulcers of Wagner's grade 1 and 2.

EXCLUSION CRITERIA:

1. Patients with uncontrolled diabetes i.e, HbA1c level more than 10.
2. Patients with peripheral vascular disorders and Chronic Venous Insufficiency.

The included patients were randomized into study and control group for our study using an open label randomization method. The history was taken and data was carefully entered in to the pretested and predesigned proforma.

Among the 90 patients in the study, 45 patients underwent treatment with conventional normal saline dressing and were assigned to control group, remaining 45 patients underwent PRP dressing and were assigned to group study.

Routine blood investigation was done and culture from the ulcer site was taken for both the groups, both group patients are strictly monitored and treated to obtain glycaemic control.

Ulcer is monitored closely and debridement of the wound is undertaken whenever necessary, X-ray foot was taken for both the group patients and any bone involvement is ruled out. The ulcer size is measured at the presentation and total initial area is calculated and

recorded. The size of the ulcer is again measured after respective treatment for each group was carried out for 30 days.

The final area of the ulcer is calculated and recorded for control group the dressing is changed on daily basis, whereas for the study group, the dressing is changed once in 5 days. The results are then calculated using student t-test.

DRESSING TECHNIQUE

For control Group-saline dressing:

After thorough debridement and cleaning of the wound with normal saline, a saline soaked gauze piece are placed over the ulcer and then covered with pad and roller bandage. Patient are advised to take appropriate care of the wound dressing.

For study group –PRP dressing:

The platelet rich site plasma is then applied over the ulcer area and covered with gauze and dressing done with pad and roller bandage. Patient are advised to take appropriate care of the wound dressing.

After recording the values in study and control group, we calculate the % of reduction in ulcer size after 30 days using the below formula for each patient in both groups

$$\text{Percentage of wound contraction} = \frac{(\text{initial wound area} - \text{final wound area})}{(\text{initial wound area})} \times 100$$

The values are noted in the chart for statistical analysis.

STATISTICAL ANALYSIS:

Data was entered into Microsoft excel data sheet and was analyzed using SPSS 22 version software. Categorical data was represented in the form of Frequencies and proportions. Chisquare test was used as test of significance for qualitative data. Continuous data was represented as mean and SD.

OBSERVATION AND RESULTS

1. Sex distribution in both groups

In Control group, 37 were males (82.2%) and 8 were females (17.8%) and in Study group, 34 were males (75.6%) and 11 are females (24.4%). The significant difference in sex distribution was not observed between two groups.

2. Mean Percentage of reduction of ulcer size in each group based on gender

Among females, in control group mean percentage reduction of ulcer size was $18.19 \pm 7.66\%$ and in study group was 36.29 ± 5.10 . The significant difference in mean percentage reduction of ulcer size between control and study group among females was observed.

Similarly among males, in control group mean percentage reduction of ulcer size was $19.94 \pm 6.72\%$ and in study group was 38.81 ± 6.03 . The significant difference in mean percentage reduction of ulcer size between control and study group among males was observed.

Table 3: Mean reduction of ulcer size in both groups based on onset

	Group				P value
	Control Group		Study Group		
	Mean	SD	Mean	SD	
Spontaneous	18.75	6.49	37.62	5.02	<0.001*
Traumatic	20.16	7.10	38.51	6.34	<0.001*

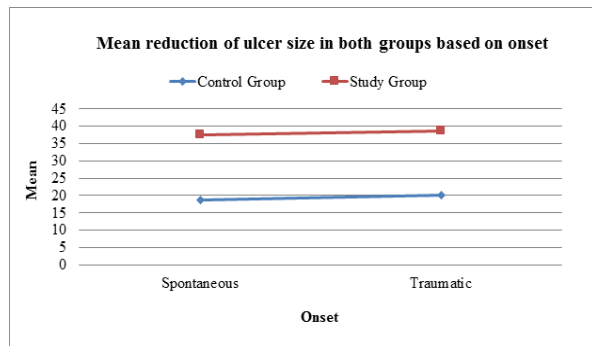


Chart 3: Line Diagram Showing Mean reduction of ulcer size in both groups based on onset

Table 4: Overall mean reduction in ulcer size between two diabetic treatment groups

Treatment		% reduction		
		Mean	SD	P value
	OHA	28.70	11.13	0.818
	Insulin	29.27	11.69	

In the study mean % reduction of ulcer size among those on OHA was $28.70 \pm 11.13\%$ and among those on insulin was $29.27 \pm 11.69\%$. The significant difference in % reduction with respect to treatment was not observed.

Table 5: Mean reduction of Ulcer among Wagner grade in each group

		% reduction				P value
		Control Group		Study Group		
		Mean	SD	Mean	SD	
Wagner grade	1	19.32	6.84	38.09	4.81	<0.001*
	2	19.84	6.95	38.28	6.69	<0.001*

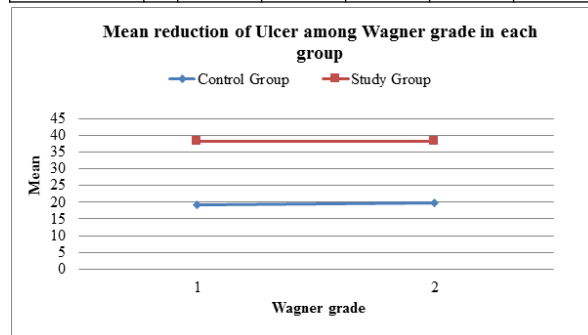


Chart 5: Line Diagram Showing Mean reduction of Ulcer among Wagner grade in each group

Table 6: Contraction of wound between 2 groups

Group		% reduction			P value
		Mean	SD	Median	
Control Group	Control Group	19.63	6.83	17.36	<0.001*
	Study Group	38.19	5.86	38.40	
Total		28.91	11.28	30.32	

In the control group, mean % reduction of ulcer size was $19.63 \pm 6.83\%$ and in study group was $38.19 \pm 5.86\%$. The significant difference in mean % reduction of ulcer size was observed between two groups.

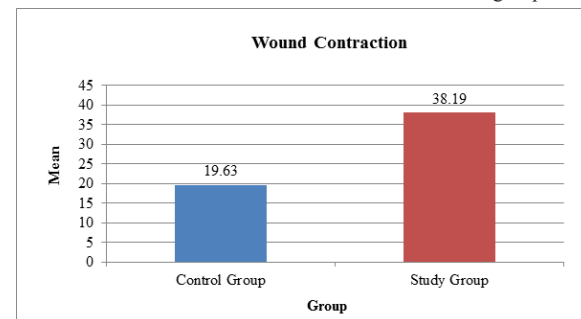


Chart 6: Bar Diagram Showing Contraction of wound between 2 groups

DISCUSSION

Platelet rich plasma is a useful adjunct in order to achieve ulcer healing in diabetic patients. These are biologically active polypeptides that act to alter the growth differentiation and metabolism of target cells stimulating cellular proliferation, chemotaxis and angiogenesis.

Patients admitted in department of general surgery, in female and male surgical wards of R.L Jalappa hospital and research centre Tamaka, Kolar from December 2017 to June 2019 to study the effect of use of PRP dressing in healing of diabetic foot ulcer.⁶

Age distribution

It was observed that of 90 patients with diabetic foot ulcers, 13 patients

were upto 40 years, 51 patients were between age group 41-50 years, 25 patients were age group of 65. This observation correlates with WHO reports which also shows that prevalence of diabetes increases with age and highest incidence occurs at age group of 45-65 years.^{7,8}

Kapur et al, also reported a similar findings where maximum number of cases were diagnosed between 40-60 years of age with no significant difference between genders.⁹

Gender distribution

It was observed that 80% of studied population were males and 20% were females. The male to female ratio was 4:1. This observation was similar to Jali et al and Flatau E et al, who reported, the diabetes was more prevalent in men than in women.¹⁰

This was in contrast to Arthur M. Michalek et al who reported that prevalence of diabetes among women was higher than in men. The occurrence of diabetic foot ulcer among male and middle aged patients which was confirmed by Merza et al and Unachukwu et al.¹¹

Onset of diabetic foot ulcer

It was observed that traumatic origin of the diabetic foot ulcer was the common cause (64%) followed by spontaneous onset, may be blister or minor unattended trauma.

Studies show that spontaneous ulceration is the main cause, but in our study, we found that diabetic foot ulcer due to trauma was more common, the opposite findings could be due to small sample size of our study.¹²

Diabetic management

It was observed that patients who were on OHA alone had (28.7%) mean reduction in ulcer size than compared to patients who were on insulin (29.27%).

This observation was contradictory to N.K Rai et al study which showed significant increase in apoptosis in diabetic wounds, which in turn contributes to delayed wound healing, more in patients on OHA's than those on insulin.¹³

Wagner grade

It was observed that 58% patients had Wagner grade 2 ulcer, 42% patients had Wagner grade 1 ulcer. The mean reduction of ulcer size was (19.32% in control group and 38.09 in study group) in Wagner grade 1 patients compared to mean reduction in Wagner grade 2 patients (19.84% in control group and 38.28%).

Yao hung et al reported similar observation that Wagner grade 1 has better rate of healing than other Wagner grades.¹⁴

Site of diabetic foot ulcers

It was observed that diabetic foot ulcer was more common on the plantar aspect (58%) than on the dorsal aspect. Mean reduction of ulcer size (in control group is 17.14% and study group is 36.81%) compared to plantar aspect (control group 22% and study is 38.96%).

This observation was similar to Edmonds et al study which showed foot ulcers occurred more commonly on plantar and fore foot region.^{15,16}

Wound dressing

It was observed that mean area of contraction of wound size was more in study group (38.19%) compared to control group (19.63%). The observation was similar to saad seta et al performed a randomized trail to compare the effects of platelet rich and platelet poor plasma (PRP and PPP), respectively, in ulcer healing demonstrating that this was significantly faster in the PRP group.

Anitua et al measured the mean percentage of ulcer surface area healed in the study population, which was 72.94% in patients treated with GFs versus 21.48% in those requiring standard care, a difference that was significant statistically.¹⁷

Steed studied the effects of topical recombinant human platelet derived Growth factor versus placebo. The study included 118 patients and suggested that the group treated with Growth Factors achieved significantly higher healing rate (48% vs 21%) while the median reduction in wound area was greater in the former group (98.8% vs 82.1%).¹⁹

We observed that irrespective of age, gender, onset of ulcer, site of diabetic foot ulcer, Wagner grading of ulcer and on diabetic management. The patients who were treated with PRP shows better healing and faster reduction in ulcer size and duration of treatment was also decreased. Hence autologous PRP is better option in treating diabetic foot ulcers.²⁰

We observed that there was significant improvement in wound healing between PRP dressing and normal dressing. The standard deviation for study group was 5.86 and 6.83 for control group. The median for study group was 38.4 and 17.36 in control group and on applying the unpaired t test, we obtained a p value of <0.001. since any value of p < 0.05 is significant, our study was also statistically significant.²⁰

CONCLUSION

1. The vulnerable age group for Diabetes is in 5th and 6th decade of life.
2. Male population is affected from diabetes and its complications are more compared to female population.
3. Foot ulcers following trauma is more common than spontaneous onset.
4. Ulcers on the sole of the foot is common than on the dorsal aspect.
5. Healing of ulcers with Wagner grade 1 > grade 2 > grade 3.
6. The patients who are treated with insulin has good glycemic control and shows good results in healing when compared to those on OHA.
7. The diabetic ulcer in the study group treated with PRP dressing contracted in wound size more than in the control group (38.19% vs 19.63% with p value < 0.001 which is statistically significant).
8. This indicates that PRP dressing is an effective method to facilitate wound contraction in diabetic patients with foot ulcer.
9. PRP dressing is found to be more effective, cost efficient and safe promoter of ulcer wound healing and can be used as an adjunct to saline dressings for enhanced healing of diabetic wounds.



Fig1 Before The Study



Fig2 During The Study



Fig3 During Follow Up

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