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Original Article

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Topical Application of Autologous PRP Dressing Versus Normal Saline Gauze Dressings in Management of Diabetic Foot Ulcer

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ABSTRACT

INTRODUCTION : Diabetes is a major health problem that is currently showing an alarming increase in its incidence and prevalence. Of Diabetic foot ulcers is a predominant complication of the disease.Appropriate treatment and wound careaccelerate the process of healing and prevents the infection and chronicity of the woundof which autologous platelet-rich plasma (PRP) has attracted a lot attention.
OBJECTIVE: To compare the efficacy between topical PRP dressings versus normal saline gauze dressing.
METHODOLOGY: This is a prospective study done in JSS HOSPITAL MYSURU for 18 months with sample size of 58 divided into 2 groups by using simple randomisation. Group A Underwent PRP and Group B- Sterile normal saline dressings were. Performa containing Questionnaire regarding medical history will be taken, general physical examination, local examination of ulcer, loco regional examination is done and noted . Wound Assessment was done to evaluate the rate of wound amongst the two groups.
RESULTS: The study showed significant decrease in size of the ulcer, decrease in exudate amount, peripheral tissue oedema and induration in patients treated with PRP dressing when compared with ulcers treated with Normal saline dressing. There was also significant increase in granulation tissue for the ulcers treated with PRP dressing. Most of the patients who underwent PRP dressing were found have no growth in the pus culture implying reduction in bacterial load of the ulcer.
CONCLUSION: The Approach of treatment to Diabetic foot ulcer is multidisciplinary which includes –local wound care with surgical debridement, regular dressings with infection control, use of offloading devices with proper vascular assessment and Good glycaemic control.
PRP Can be easily prepared using patients own blood and its Local application has significantly lead to faster healing by formation of granulation tissue and reducing the slough, discharge, bacterial load/ reducing the wound size. Thus, decreasing the duration of Hospital stay.

Key Words: *Diabetic foot Ulcer ,Topical PRP ,wound size*

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INTRODUCTION

Diabetes is a major health problem that is currently showing an alarming increase in its incidence and prevalence. Diabetic foot ulcers is a predominant complication of the disease. It is estimated that19-34% of the patients with diabetes are likely to be effected by diabetic foot ulcers in their lifetime and about 9.1 to 26.1million people annually worldwide**.** Also in India, it is a significant health care problem as it affects 15% of all diabetics during theirlifetime of which 15%-20% may require amputation as treatment . In India approximately 40,000lower limb amputations are done ,every year of which 75% are neuropathic with secondary infection which is potentially preventable causes**.**

Patients living with Diabetic foot ulcer have high morbidity, and have lesser quality of life with increased financial burden .Treatment of these foot ulcers is challenging and one must employ a multidisciplinary approach in its treatment. The approach towards treatment includes –local wound care with surgical debridement, regular dressings with infection control, use of offloading devices with proper vascular assessment and Good glycemic control

Diabetic foot ulcers require an environment that is moist which promotes granulation tissue production and angiogenesis and migration of epidermal cells across the wound for healing**.**

Wound healing can be explained as process of restoration of physicalintegrity of external and internal body structure by involving complex interactionbetween the cell and various other factors. Appropriate treatment and wound

careaccelerate the process of healing and prevents the infection and chronicity of the wound .The selected dressing should be able to do the same.

In recent years, great progress has made in the techniques of wound healing, among many one method is autologous platelet-rich plasma (PRP) which has attracted a lot attention. Platelets start the wound healing process by the release of locally active growth factors **.**The growth factors which it produces helps in formation of granulation tissue and to induce epithelialisation by the production of neovessels, it also attracts the fibroblasts and mesenchymal cells and produces the collagen fibres .Platelet rich plasma (PRP) also reduced the inflammation by suppressing cytokine release. PRP has also shown to be with some antimicrobial properties against microorganisms, such as Escherichia coli, MRSA, Candida albicans, and Cryptococcus neoformans.

Hence, If Platelet rich plasma hastens the wound healing, it can be implicated for regular use for treatment of the diabetic foot ulcer causing rapid healing of ulcer which in turn decreases the prevalence of Diabetic foot ulcer and also decreasing the morbidity in diabetic cases.

METHODOLOGY

STUDY DESIGN: PROSPECTIVE STUDY
STUDY PLACE: JSS HOSPITAL MYSURU
STUDY DURATION:ONE AND A HALF YEAR
SAMPLE SIZE:

Sample size estimated based on the SD healing rate area per week, as per (ref), in PRP group and normal dressing groups as 0.03 and 0.04 respectively, ability to differentiate at least 0.03 sq cm2 area of healing per week, 5% alpha error and 90% power, and one sided as 29 in each group. Total of **58.**

SAMPLING TECHNIQUE AND STUDY POPULATION

Simple randomization

Patient's getting admitted to JSS hospital, Dept of Surgery, Mysuru of >18yrs age
Patients will be followed up from the admission until the wound is completely healed or gets a definitive treatment (SSG)

Inclusion criteria

- Type 1 or 2 diabetes controlled by either medication or insulin.
- Patient aged >18yrs
- Presence of a foot ulcer for at least 4 weeks
- Wound surface area < 15cm2
- Wagner's classification 1,2
- In patients in JSS hospital

Exclusion criteria

- Non healing ulcers of other etiologies like varicose vein, arterial disease,burns.
- Grade 3,4,5 of Wagner's classification
- Evidence of gangrene in ulcer or on any part of the foot./ Patient has radiographic evidence consistent with diagnosis of acute Charcot foot/ Patient has known or suspected osteomyelitis.
- At Screening:
  Hemoglobin (Hb) of less than 10.5 mg/dl
  Platelet count of less than 100×109 /l
- Patient undergoing renal dialysis, has known immune insufficiency, liver disease, active cancer, nutritional, hematologic, collagen vascular disease, rheumatic disease, or bleeding disorders.
- Patients who did not complete their follow-up protocol.

STUDY SETTING AND METHOD OF COLLECTION OF DATA:

Patients in all groups are evaluated and after acquiring consent , with simple randomisation, study is performed .
Performa containing Questionnaire regarding medical history will be taken, general physical examination, local examination of ulcer, loco regional examination is done and noted .
At presentation one swab for culture and sensitivity was taken and Post debridement wound is cleaned with saline and swab for culture and sensitivity taken. With respective to the group the patient is in the following is done.

GROUP A:

After surgical debridement, the wound parameters were noted. 10-15 ml of venous blood from the patient is withdrawn into the vacutainer containing anticoagulant in it to avoid platelet disintegration.

The blood is centrifuged –SOFT SPIN (1000RPM) for 7-10 minutes which allows blood to separate into following layers-
a)Bottom 55% RBC
b)Top layer 40%Acellular plasma
c)Between the two -Buffy coat Layer 5% which has the PRP
This layer is extracted and a second centrifuge is run, HARD SPIN(3000RPM) for 10 minutes ,this allows PRP to settle.

This is mixed with 10% Cacl 0.1ml in a petri dish for about 10 minutes and later given to apply on the wound. It is applied/ injected to the wound and sterile dressing is done .

GROUP B:

After surgical debridement, the wound parameters were noted . Sterile Normal saline dressings are done.
Both groups culture and sensitivity reports are collected and started on oral /IV definitive antibiotic. Another swab is taken after one course of antibiotic to check for infection control.
Dressing done every 3rd day .
Wound is inspected for signs of healing , every 1nd,2nd week and every week until the wound is completely healed or has undergone SSG following,

a) Appearance of granulation tissue
b) Decrease in size of the wound
c) Type of discharge

ETHICS: Not Applicable

STATISTICAL ANALYSIS:

Data has been entered into Microsoft excel 2019. SPSS version 25 is used to carry out the statistical analysis. Descriptive statistics have been performed and represented in mean and standard deviation. The normality of the data has been checked using the Shapiro-Wilk test. The intergroup mean comparison was made using the independent sample t-test and Man Whitney U test based on the normality of the data. Chi-square analysis was used to find the association between the qualitative variables.

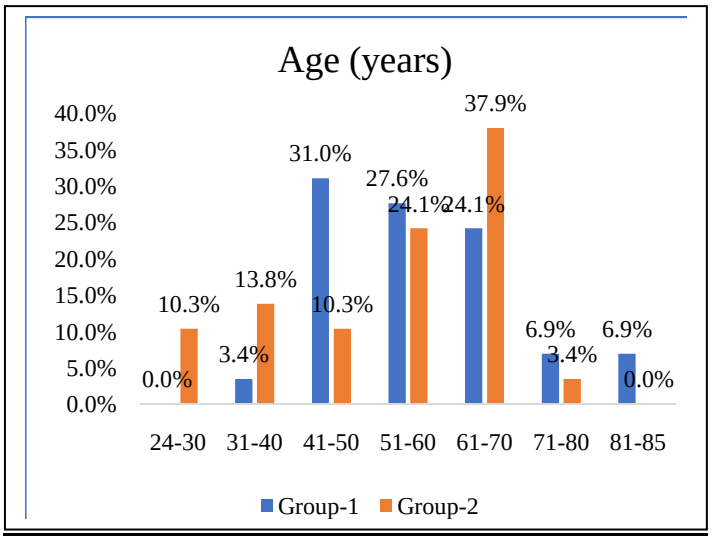
RESULTS

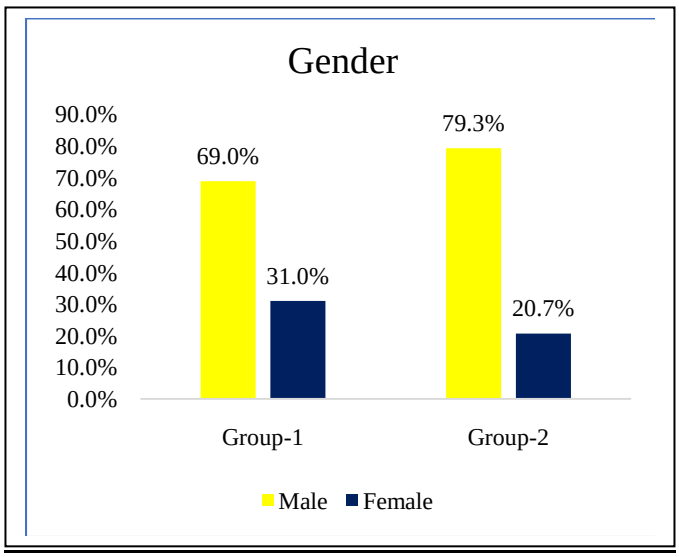
A .TOTAL STUDY SUBJECTS

Group Code	Group Description	No. of cases	% Of cases
Group 1	PRP Dressing	29	50.0
Group 2	Normal Saline Dressing	29	50.0
Total		68	100.0

Table /Diagram : 1

B. DEMOGRAPHIC DEATAILS





DURATION OF HOSPITAL STAY (IN DAYS):

Table /Diagram : 2Table /Diagram : 3

C. DURATION OF HOSPITAL STAY

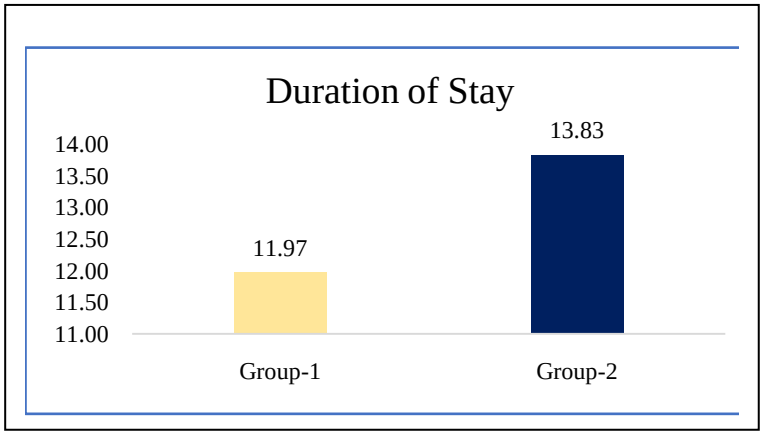


Table /Diagram : 4

D .DETAILS OF THE PATIENTS IN STUDY POPULATION:

		Dressing Method				
		PRP Dressing		Normal saline Dressing		
		Count	%	Count	%	P
Mode of Onset	Spontaneous	20	69.0%	20	69.0%	1.000
	Trauma	9	21%	9	21.0%	
Associated Symptoms (Fever)	Yes	5	17.2%	11	37.9%	0.078
	No	24	82.8%	18	62.1%	
Associated symptoms (Pain)	Yes	23	79.3%	19	65.5%	0.240
	No	6	20.7%	10	34.5%	
Associated Symptoms (Swelling)	Yes	18	62.1%	17	58.6%	0.788
	No	11	37.9%	12	41.4%	
Associated symptoms (Discharge)	Yes	7	24.1%	10	34.5%	0.387
	No	22	75.9%	19	65.5%	
Treatment for Diabetes	Insulin	24	82.8%	20	69.0%	0.428

	OHA	1	3.4%	1	3.4%	
	OHA +Insulin	4	13.8%	8	27.6%	
Personal History (Smoking)	Yes	15	51.7%	13	44.8%	0.599
	No	14	48.3%	16	55.2%	
Personal History (Alcoholic)	Yes	14	48.3%	13	44.8%	.79
	No	15	51.7%	16	55.2%	

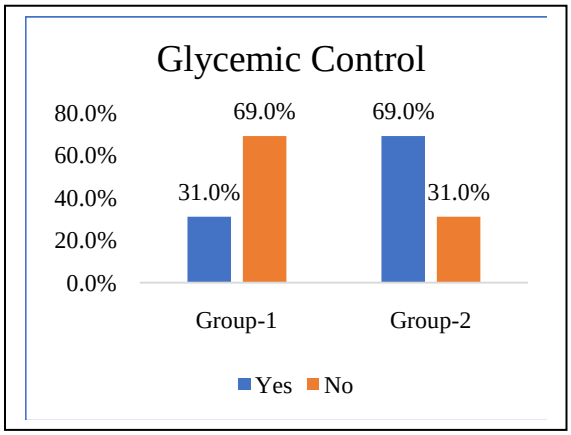
Table /Diagram : 5

E. ULCER DETAILS IN STUDY POPULATION: -D1

	PRP Dressing		Normal Saline dressing	
	Mean	SD	Mean	SD
Length (cm)	3.052	0.8382	3.355	0.9318
Breadth (cm)	3.190	0.9766	3.159	0.8781
Area (sq.cm)	9.03	3.31	10.15	2.46

Table /Diagram:6

F. GLYCEMIC CONTROL



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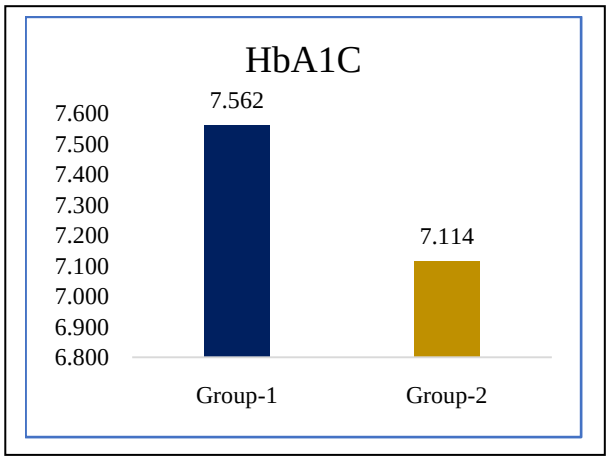
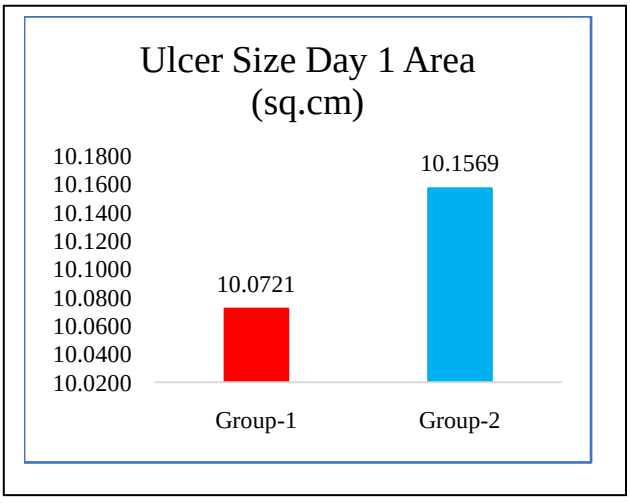
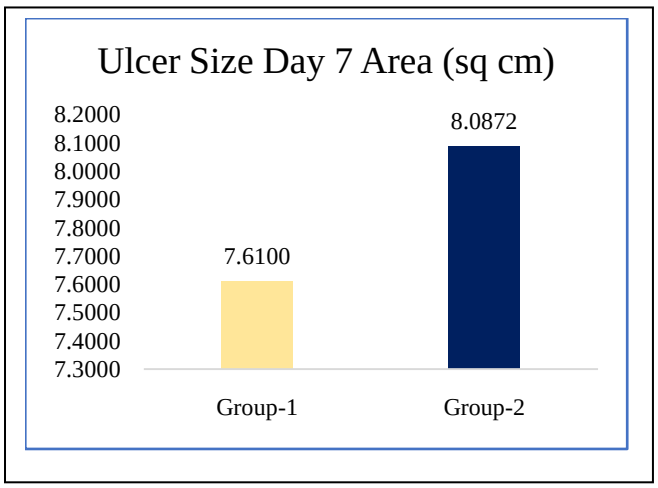


Table /Diagram: 8

G. AREA OF ULCER





Ulcer Size Day 14 Area (sq. cm): **Ulcer Size**

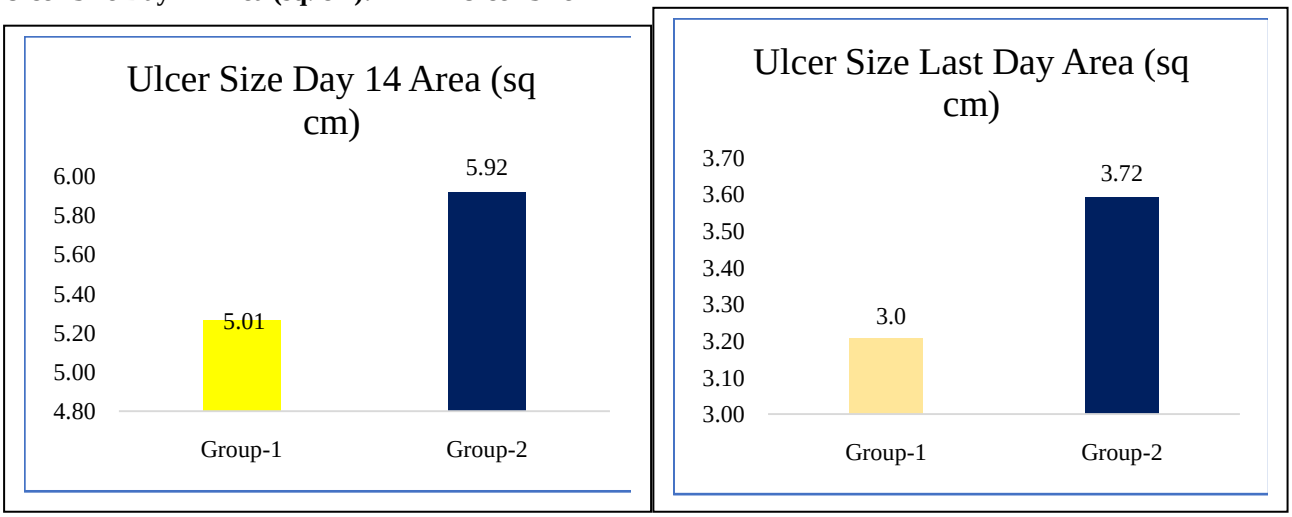


Table /Diagram: 9

DISCUSSION

The prevalence of Diabetic ulcers in India is rampant, causing significant morbidity and mortality. Though the mortality has reduced in recent times with the advent of higher generation antibiotics and more thorough wound debridement, nevertheless, extremity ulcers, are still associated with significant morbidity unless promptly and appropriately treated. A significant number of limb amputations is presently carried out nowadays, both in our hospital and elsewhere in India, due to sepsis secondary to infected extremity ulcers.

Local wound management assumes significance supported with systemic antibiotic therapy and supportive local treatment for wound healing.

This study attempted to use Platelet rich plasma obtained from patient own blood and its its topical application to determine its role in wound healing and was carried out over a period of 18 months and involved 58 subjects, randomly distributed into two equal subgroups of cases and controls. Cases (GROUP A) were managed with PRP and Controls(GROUP B) Underwent Normal saline dressing .

The results of the study show that Most subjects in GROUP A - belong to age group of 41-50 years, predominantly male (69%) with onset of ulcer to be spontaneous rather than trivial trauma .Control group is also demographically similar to Group A

Most common symptom patient with which patient presents is pain followed by other associated symptoms such as Discharge from ulcer , fever or swelling of foot .

In group A , the mean number of years of Diabetes is 16 years and all of them are on antidiabetic medication while the mean number of years of Diabetes in group B is 10 years .

Around 50% of both Cases and control have h/o of smoking and Alcohol in take which can be cause of delayed wound healing

Average duration of stay in hospital was marginally lower in the cases group (11.9days in Group A and 13.9 days in Group B,with a mean difference of 1.8)

ALL the patients who were considered for the study had Normal vitals at presentation with no other acute complication related to any other system.

65.5% of foot ulcers were on right foot in cases and none of them presented with abscess /gangrenous changes .

The mean hemoglobinin group A is 11.8g/dl and Total count 9792 cells/ *cubic* mm and mean HbA1Cin group 1 is 7.5 In group 2, the mean HbA1Cis 7.1 and all of them had good glycemiccontral Making both group equally comparable.

The common isolates from group A are Pseudomonas aeruginosa (20.7%), Klebsiella pneuomoniae (13.8) which showed antibiotics sensitivity to Linezolid (27.6%), followed by colistin (13.8%) and others Meropenem, Ceftazidime, Cefuroxime and Piperacillin (10.3%) which are considered Higher antibiotics .

While In Group B isolate had Acinetobacter species followed by Streptococcus Species and sensitivity to higher antibiotics

Most of the ulcers in Both Group A(55%) and GROUP B(62%)underwent debridement and after course of the antibiotic pus culture was taken again and 75.9% of the culture isolates in group A showed no growth. And 72.4% of the culture isolates in group B showed no growth.

Decrease in Surface area of the wound was considered as a marker for wound healing , The mean area of the ulcer in group 1 is 10.7 Sq.cm On DAY 1 to The mean area of the ulcer in group 1 is 3.0 sq. cms on last day of dressing causing 70% decrease in size of the wound which is significantly 10% more than the control group .

66.5% Of the wound in Group A healed by primary intention with mean number of days required was 35 days and rest of ulcers underwent Split skin grafting while in Group 2 around 50% of the ulcer wear healed by SSG .

In the current study, presence of slough and discharge was also noted and was found that there was significant decrease in both in group A to Group B that is at end of Day 14 no subject in group had slough and 83.7 % had no discharge while in group B 30% had slough and only about 44% did not have any discharge

Rate of granulation tissue formation was also significantly faster amongst cases in comparison with controls in the study as 100% of cases had presence of granulation tissue at end of day 14 while in group B it is 61%

Thus, Platelet Rich Plasma can be used as local application agent in case of Diabetic small ulcers to hasten the process of healing either by Secondary intention or By Split skin grafting

No side effects of local application /Injection from PRP was reported.

Table /Diagram: 10: Diabetic foot Ulcer on D1 and Day 7

CONCLUSION

Our study concluded that use of Platelet Rich plasma for local application/injection over the ulcer help in reduction of size of the ulcer, Reduction in exudate amount and most importantly Helps in production of granulation tissue and promotes epithelialisation. The study showed significant decrease in positive pus culture reports in patients treated with PRP dressing Also most of healed by secondary intention and few required SSG after a month of dressing . Autologous PRP is easier to prepare all that requires is a basic equipment in laboratory of pathology(Centrifuge)

To conclude, extremity Diabetic ulcers need aggressive local management in addition to systemic antibiotics and other supportive measures to promote wound healing.

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