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Prospective Clinical Study to Compare the Effectiveness of Woundhealing by Platelet Rich Plasma versus Conventional Dressing in Chronic Diabetic Non Healing Ulcers in rmmch

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Abstract

Chronic Diabetic non healing ulcers are the frequent cause of amputation and substantial expenses to patient care. The purpose of management is to attain wound closure as soon as possible. Apart from old methods to facilitate wound closure, new methods are emerging such as cellular therapies like platelet-rich plasma (PRP). Platelets release certain factors from alpha granules which can be placed in thrombocyte cell membrane which include platelet derived growth factor (PDGF), platelet derived angiogenesis factor, epidermal growth factor (EGF), and platelet factor 4. These elements act regionally on wound and promote the recovery process. This was a prospective study conducted at Rajah Muthiah Medical College, Chidambaram. Total of forty six patients were assigned. They have been grouped into two groups randomization method. Patients in control group were treated with conventional dressing and patients in study group have been with PLATELET RICH PLASMA (PRP) dressing and observed for early wound closure. This have a look at intends to demonstrate the healing function of autologous platelet rich plasma in healing of chronic non-healing diabetic ulcers.

Keywords: Platelet rich plasma, chronic diabetic non healing ulcers.

Introduction

Chronic wounds are characterised by a long inflammatory period that delays wound healing. Chronic wounds, specifically in patients with diabetes mellitus (DM), are a prime fitness venture. Accepted therapeutic objectives and requirements for the care of diabetic foot ulcers are wound debridement, decompression in pressure points , good wound management , sepsis control , retain good vascularity , control of co-morbidities, and surgical management as

needed. Apart from these traditional strategies to facilitate wound healing many new methods are emerging consisting of cellular therapies which include platelet-rich plasma (PRP). This could have an important role in a standardized, quality and care. Platelets release growth factors from alpha granules which include platelet derived growth component (PDGF), epidermal growth factor (EGF), platelet derived angiogenesis factor and platelet component 4. These factors act regionally on wound and hasten the wound healing. Platelet extract has been used in lots of studies and has shown astonishing effects in healing of chronic non healing diabetic ulcers.

Objective

- To test the efficacy of wound closure and healing by autologous platelet rich plasma in chronic non-healing diabetic ulcers in comparison to conventional dressing.

Subjects and Methods

Study type; Prospective comparative study

Duration of study: 2 Year

Sampling method: Simple random sampling.

Inclusion criteria

1. Age: 20 to 65 years with chronic non healing diabetic ulcers.
2. Patients with diabetes [type 1 and 2]
3. Ulcer ≥ three weeks duration.
4. Ulcer ≤ 13 cm2 in size.
5. Hb ≥ 11 gm%.

Exclusion criteria

1. Screening platelet count < 100×10^9/l.
2. Patients with known or suspected osteomyelitis
3. Patients with other comorbid condition.
4. Severe infection (presence of obvious pusor copious wound exudates).
5. Presence of cellulitis, gangrene, insufficient perfusion, ischemia.
6. Patient not accepting the consent.

Methodology

Consent informed written on sent was obtained from allpatients willing for study.

For traditional dressing:

Ulcer was washed with normal saline and saline soaked gauze piece and was placed over the ulcer

And dressed with pad and roller bandage was applied.

For platelet rich plasma dressing:

The ulcer was washed with Normal Saline. Platelet rich plasma (PRP) was prepared from patients' blood and instilled over the ulcer twotimes weekly

The wounds in both the groups were examined. The dressings have been changed as informedbefore in both control and study groups and presence of healthy granulation tissue and wound closure was noted. Final ulcer area was measured and evaluated statistically.

Results

Table 1: Age Distribution

Age in years	Study group		Control Group	
	No	%	No	%
<30	1	4.3	1	4.3
31-40	3	13.0	3	13.0
41-50	7	30.4	8	34.8
51-60	8	34.8	9	39.1
61-70	1	4.3	0	0.0
71-80	3	13.0	2	8.7
Total	23	100.0	23	100.0
Mean ± SD	51.78±12.29		50.48±11.58	

The mean age in the study group was 51.78 years and in control group was 50.48 years. Samples are age matched with P=0.713

Table 2: Sex Distribution

Gender	Study group		Control Group	
	No	%	No	%
Female	10	43.5	8	34.8
Male	13	56.5	15	65.2
Total	23	100.0	23	100.0

Incidence of chronic lower limb ulcers was more in males in both the groups as compared to females.

Table 3: Onset

Onset	Study group		Control Group	
	No	%	No	%
T	14	60.9	15	65.2
S	9	39.1	8	34.8
Total	23	100.0	23	100.0

In this study, Traumatic ulcers were 60.9 % in study group and 65.2 % in control group and spontaneous ulcers were 39.1% in study group and 34.8 % in control group. It was observed traumatic ulcers were more in both the groups.

Table 4: Comparison of Initial Area and Final Area

	Study group	Control Group	P value
Initial Area(IA)	1328.57±128.68	1338.08±131.54	0.805
Final Area(FA)	749.99±99.97	1149.84±114.74	<0.001**
CA=IA-FA	579.03±63.55	214.39±148.20	<0.001**

Table 5: Percentage % area reduction in two groups of patients

% area reduction	Study group		Control Group	
	No	%	No	%
<15	0	0.0	17	73.9
15-30	0	0.0	6	26.1
>40	23	100.0	0	0.0
Total	23	100.0	23	100.0
Mean ± SD	43.40±3.74		14.03±3.45	

Study group (PRP dressing) had better wound contraction of Mean±SD43. 40±3.74 in comparison to control group (conventional dressing), the mean wound contraction was Mean±SD 14.03±3.45. These was observed to be statistically significant P<0.001**, in Student t test.

Discussion

Chronic diabetic non healing ulcers treatment remains difficult in this advanced clinical generation as it relies upon various factors. The main idea of wound dressing is to prevent the wound from infection and to provide the healthy environment for wound healing. The study was carried out at Rajah Muthiah Medical College and Hospital Chidambaram.

When platelets come into contact with exposed endothelium, factors are released and it act along with chemotaxis, cellular proliferation, angiogenesis, extracellular matrix deposit, and aids in Healing. Hence, adding platelet in an injured endotheliul could bring about increased growth factors and, eventually, aids in early healing. Platelet release therapy was used to deal with injuries since1985.PRP serves as a growth factor agonist and has both mitogenic and chemotactic action. PRP dressing acts as a sealant and medicine delivery system, and platelets initiate healing by releasing growth factors10, via α- degranulation. α- factors of platelets contains. Platelet- derived growth factor (PDGF-AA, BB, and AB isomers), Transforming growth factor-β (TGF-β), platelet factor-four (PF-4), Interleukin-1 (IL-1), platelet derived angiogenesis element (PDAF), Vascular endothelial growth factor (VEGF), epidermal growth factor (EGF), Platelet- derived endothelial growth factor (PDEGF), epithelial cell growth factor (ECGF), Insulin like growth factor (IGF), osteonectin (On), vitronectin (Vn), fibronectin (Fn),

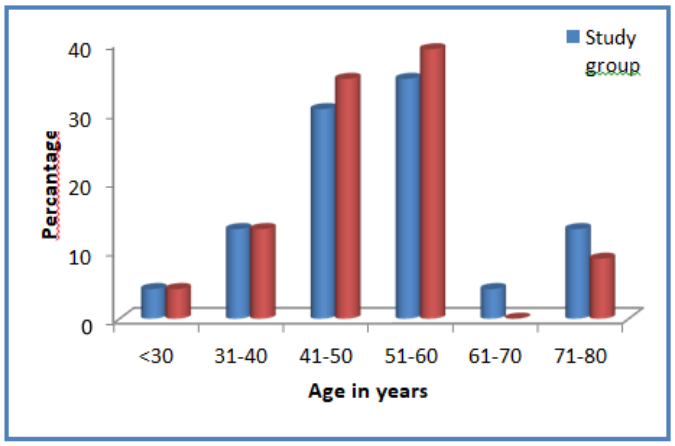
thrombospondin-1 (TSP-1), fibrinogen (Ff), osteocalcin (Oc). These factors aids in healing through attracting un-differentiated cells in the recently formed matrix and driving cellular division. PRP may also suppress cytokine release and limit inflammation, interacting with macrophages to enhance formation and regeneration of new capillary growth. And boost up epithelialization in non-healing wounds. No adverse effect or complication has been suggested PRP dressing. In this study PRP dressing was applied for study group and conventional dressing for control group. Result was compared. An aggregate of forty six cases was taken in this study. Cases with non-healing diabetic ulcers of more than three weeks, randomized into study group or control group grounded on motorized randomization map. The mean age in study group was 51.78 years and in control group was 50.48 years. In this study it was found that patients receiving Platelet rich plasma dressing had better wound contraction of 43.40% (S.D: 3.74) as compared to control group receiving conventional dressing (normal saline dressing). Mean wound contraction for conventional dressing was 14.03 % (S.D; 3.45). These were known to be significant on Student T test (p<zero.001) suggesting that Platelet rich plasma augments ulcer healing in chronic diabetic non healing ulcers. In this study the suggest time taken for complete healing of the ulcers had been 2.74weeks in study group (PRP dressing) as compared to 5.22 weeks in the control group(conventional dressing).

Table 6: Weeks for complete healing

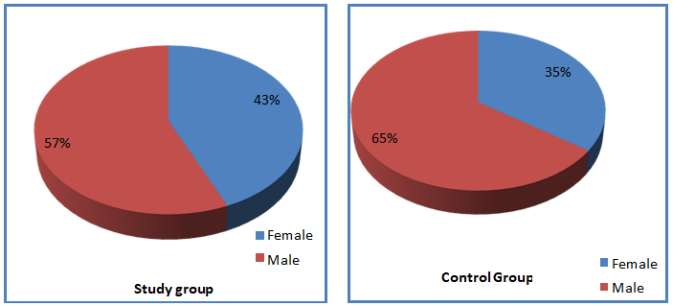
Weeks for complete healing	Study group		Control Group	
	No	%	No	%
1 week	0	0.0	0	0.0
2 weeks	6	26.1	0	0.0
3 weeks	17	73.9	0	0.0
4 weeks	0	0.0	1	4.3
5 weeks	0	0.0	16	69.6
6 weeks	0	0.0	6	26.1
Total	23	100.0	23	100.0
Mean ± SD	2.74±0.45		5.22±0.52	

The mean time taken for complete healing of the ulcers were 2.74 weeks in study group as compared to 5.22 weeks in the control group.

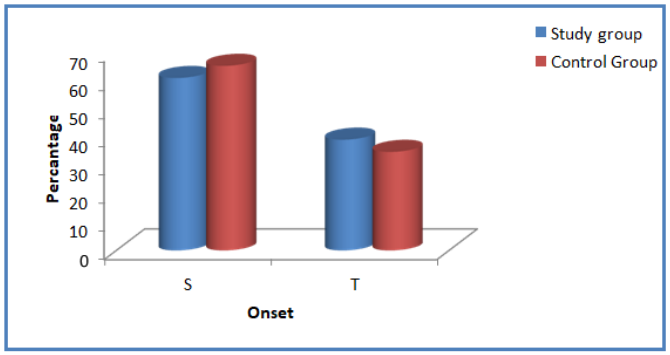
Graph 1: Age Distribution



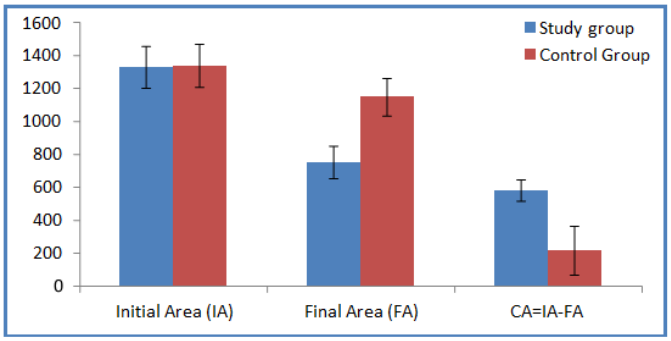
Graph 2: Sex distribution



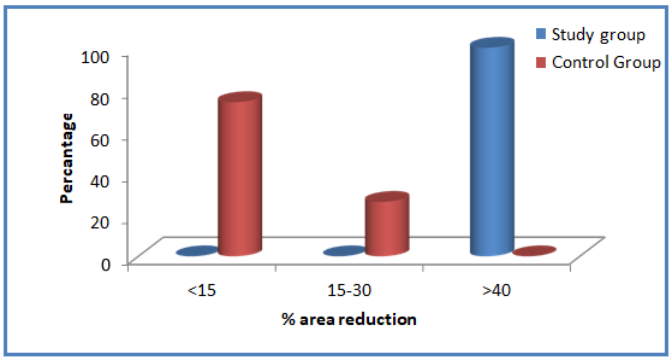
Graph 3: onset of ulcers



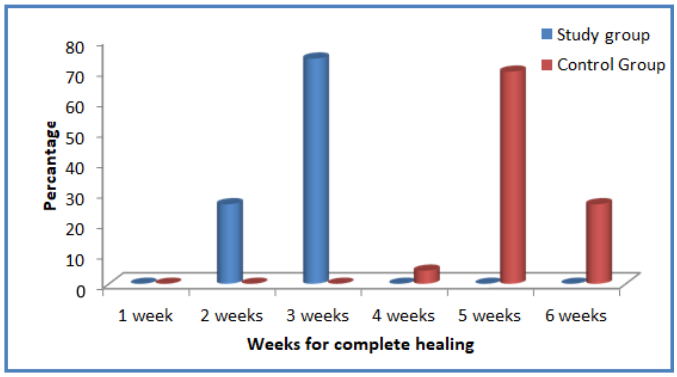
Graph 4: Comparison of Initial Area (IA) and Final Area (FA), CA contracted area



Graph 5: % area reduction in two groups of patients



Graph 6: Weeks for complete healing



Statistical Methods

Descriptive and inferential statistical evaluation has been done within the present look at. Results on continuous measurements are supplied on Mean ± SD (Min- Max) and measurements are provided in Number (%). Significance is classified at 5 % level of significance. The following assumption on records is made, Assumptions: 1.Dependent variables should be normally distributed, 2.Samples drawn from the population need to be random, Cases of the samples have to be independent. Chi-square/ Fisher Exact has been used to discover the significance of study parameters on categorical scale between two or greater groups.

Significant figures

+ Suggestive significant (P value: 0.05<P<0.10)

* Moderately significant (P value: 0.01<P <0.05)

** Strongly significant (P value: P<0.01)

Statistical software: The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc9.0.1, Systat 12.0 and R environment ver.2.11.1were used for the interpretation of the data andMicrosoft excel and word have been used togenerate graphs, tables etc.

Feasibility of this study

In the present study we have taken 46 patients suffering from chronic diabetic non-healing Ulcers (>3 weeks). Patients have been taken included based on inclusion and exclusion criteria. Out of forty six patients, 23 were study group (PRP dressing) and 23 were control group (conventional dressing). Participants included in study group have been managed with platelet rich plasma dressing. We have implemented the formula to calculate % reduction in area of ulcer after specific duration in both study and control group.

Rate of contraction of wound after treatment = Initial area – final area/ initial area * 100

We have observed 14.03% (S.D; 3.45) contraction of wounds in control group in comparison to 43.40% (S.D:3.74) contraction of wounds in study group. Therefore study group have a better percentage of ulcer contraction compared to the control group.

On applying student T test p<0.001 is significant. Hence platelet rich plasma dressing therapy promotes wound healing in patients with non-healing diabetic ulcers.

Conclusion

The ulcers in subjects managed with platelet rich plasma dressing contracted more than the ulcers in conventional dressing group (43.40% (S.D:3.74)Vs 14.03% (S.D; 3.45); P = < 0.001

Significant) which suggests platelet rich plasma dressing is an effective management to promote wound contraction in patients with diabetic non-healing ulcers.

Summary

The study is conducted on 46 patients to evaluate the efficacy of platelet rich plasma versus conventional dressing in chronic diabetic non- healing ulcers in Rajah Muthiah Medical College and Hospital between Oct 2019 to Sep 2021.

Patients had been divided into two groups of 23 patients each and detailed history was taken and required investigations were taken. All the 46 patients have been assessed .We concluded significant decrease in ulcer size in PRP dressing. There was no adverse effect seen in both groups.

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