ROLE OF PLATELET RICH PLASMA IN HEALING OF CHRONIC VENOUS LEG ULCER: A RANDOMIZED CONTROLLED CLINICAL TRIAL

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ABSTRACT:

Background: *Venous ulcers leg account for 80% of leg wounds caused by chronic venous insufficiency. Autologous platelet-rich plasma is used for wound healing treatment as it contains great variety of growth factors.*

Aim of the work: *To appraise the role of PRP for healing of chronic active venous ulcers.*

Patients and methods: *This prospective randomized controlled clinical trial was conducted at Ain Shams University Hospitals and Mataria Teaching Hospital on 20 patients. The participants were divided into two groups; the intervention group included 10 patients managed by compression therapy plus PRP injection, control group included 10 patients managed by compression therapy only. Follow up visits were scheduled at 1 week, 1, 3 and 6 months. The endpoint of the study was healing of the ulcer.*

Result: *Comparison between the study and control groups as regards change in Ulcer size after treatment we found that after one and four weeks the change was statistically significant higher in the study group than the controls, then after 3 months there was no statistically significant difference between the two groups, and 6 months after treatment the change was statistically significant higher in the control group than the study group where the study group were all healed but the controls were still completing their healing.*

Conclusion: *PRP showed to be useful in promoting wound healing in chronic venous leg ulcer without any harmful events.*

Keywords: *Platelet rich plasma, ulcer healing, venous leg ulcers, clinical trial, Ain Shams University.*

INTRODUCTION:

Venous leg ulcers (VLUs) are active lesions between the knee and ankle joint that occur due to venous disease. They account for 60-80% of leg ulcers. The prevalence of VLUs is between 0.18% and 1%. Increasing up to 4% above the age of 65. in 33-60% of these ulcers they persist for more than 6 weeks. These ulcers reflect advanced form of chronic venous insufficiency (deep or superficial) like varicose veins and lipodermatosclerosis according to CEAP classification (C5, C6) **(1).**

Identifying underlying etiology is an important step in the management of (VLUs). Clinical presentation and physical examination findings can help to differentiate venous leg ulcers from other ulcers. Dull aching pain in the lower extremities, swelling that decrease with limb elevation, surrounding skin eczematous

changes, and varicose veins are common symptoms of venous stasis [(2)].

Venous ulcers commonly occur over bony prominences, mostly the gaiter area (over the medial malleolus). Recurrence of an ulcer in the same area increases suspension of venous ulcer [(3)].

Clinically by examination, venous ulcers present as irregular and shallow ulcers. Ulcer base shows granulation tissue and fibrin. lower extremity varicosities, edema, venous dermatitis correlating with hyperpigmentation and hemosiderosis or hemoglobin deposition in the skin and lipodermatosclerosis associated with thickening and fibrosis of normal adipose tissue under skin may be present. Morphological or functional venous abnormalities could be detected by duplex ultrasound. Venous ulcer treatment has two objectives: to heal the ulcer and prevent ulcer recurrence. The standard first-line treatment is compression therapies and if failed, multiple second-line treatments can be considered, but there is no established standard second-line treatment[(4)].

The cornerstone of the conservative management of chronic venous insufficiency is the use of compression therapies[(5)].

Four-layer bandage techniques achieve healing in 68-83% in 24 weeks, but are associated with high recurrence rates[(6)]. Therefore, correction of underlying etiology plays an important role in management of venous ulcer so the Society for Vascular Surgery and the American Venous Forum recommended the following protocol in management of venous ulcer. Ablation of the incompetent veins together with compression therapy for patients with a venous leg ulcer (C6) and incompetent superficial veins that have axial reflux directed to the bed of the ulcer, to promote ulcer healing and to prevent recurrence. There are multiple RCTs showing increasing evidence that modern open surgery, radiofrequency, and laser ablation are equipollent in effect and safety for saphenous ablation[(7)].

Over the past fifteen years, platelet rich plasma (PRP) has been progressively used clinically for cutaneous ulcers treatments[(8)].

PRP promotes the healing process secondary to its growth factors (GFs) which include platelet-derived GF (αα, ββ, and αβ), fibroblast GF, vascular endothelial GF, epidermal GF, insulin-like GF, and transforming GF. Mesenchymal cell recruitment, proliferation, extracellular matrix degenerateion, and cell differentiation for tissue regeneration are stimulated by these GFs. These factors are released by α granules in response to platelet activation by inducers of platelet aggregation[(9)].

Society for Vascular Surgery and the American Venous Forum recommended the following protocol in management of venous ulcer. Ablation of the incompetent veins together with compression therapy for patients with a venous leg ulcer (C6) and incompetent perforators, to promote ulcer healing and to prevent recurrence. There are multiple RCTs showing increasing evidence that modern open surgery, radiofrequency, and laser ablation are equipollent in effect and safety for saphenous ablation [(7)].

AIM OF THE STUDY:

This study aims to evaluation of efficacy of PRP upon the healing of active venous ulcers in patients with chronic (VLUs).

PATIENTS AND METHODS:

This is a prospective randomized controlled clinical trial which was conducted at the Department of General Surgery, Faculty of Medicine, Ain Shams University.

This clinical trial was carried out on 20 patients with active venous ulcers.

Inclusion criteria: 1) Adults from 18 to 65 years old. 2) Both genders. 3) Patients presenting with chronic venous insufficiency active venous ulcers diagnosed clinically CEAP classification C6 (active venous ulcer) with superficial or deep venous reflex. 4) Patients with competent saphenofemoral and saphenopopliteal junctions.

Exclusion criteria: 1) Age <18 years old. 2) Patient with superficial venous reflux which can be treated surgically. 3) Patient with history of peripheral arterial disease (Ankle-Brachial Index <0.8). 4) Exposed tendon or bone in ulcer. 5) Patient with history of acute and chronic DVT without leg ulcer. 6) Patients with co-morbidities like uncontrolled DM, cardiac diseases, liver cell failure, immunodeficiency, collagen diseases, and anemia with hemoglobin level below 10 gm %. 7) Patients with low platelet count below normal level (e.g. ITP and blood dyscrasias).

Patients were subjected to the following protocol:

Personal data and history: Age, gender, smoking, medical comorbidities, history of recurrent venous ulcers and history of recent DVT.

Clinical Examination:

I) General examination: Included cardiovascular, respiratory and abdominal examinations.

II) Local examination of venous ulcer:

a) Presence of ulcers at the gaiter area (C6).
b) Number and size of the ulcers.
c) Skin around ulcer. Edges, floor of the ulcer.
d) Signs of inflammation or dermatitis.
e) Ankle Brachial Index.

Investigations: Complete blood picture, random blood sugar, and prothrombin time, activity and INR were done for patients.

Imaging: Duplex scanning with comments on competency of saphenofemoral junction, saphenopopliteal junction and perforators, patency and competency of deep venous system up to iliac vein, and reflux from deep system to superficial system.

Participants were randomly assigned into two groups:

A) The intervention group included 10 patients who were managed by compression therapy plus PRP injection. Our endpoint was the healing of the ulcer.

B) The control group included 10 patients who were managed by compression therapy only.

Additional procedure for the intervention group:

Preparation of PRP: PRP prepared by using a desktop centrifugation system. Withdrawing 45ml of blood from the patient, mixing it with 5ml citrate is first step in preparing PRP. Then blood transferal to disposable tube which is placed in a desktop centrifuge. It is spun at 2500 rpm for 10 minutes. During centrifugation blood is separated into three different fractions; platelets-poor plasma, platelets and white blood cells in addition to red blood cells. The platelets poor plasma and the concentrated platelets and white blood cells are collected from the tube using different ports, and then transferred to other disposable tube which is put in a desktop centrifuge. It is spun at 3500 rpm for 5 minutes. During centrifugation, plasma is separated into two different fractions; the top of tube is platelet-poor plasma and the bottom is platelet rich plasma. Thereafter, PRP is drawn from the bottom of the tube using separate ports. Finally, PRP is activated by $CaCl_2$ with concentration 2%.

Method of application: Debridement of necrotic tissue at ulcer. Thereafter, the activated platelet rich plasma was applied on wound as dressing for 4 days. Wound dressing and evaluation of the wound at one

week, 1 month, 3 months and 6 months. Bandaging and walking after procedure.

PRP risks to participants and measures needed to minimize these risks:

Application of PRP is a minimally invasive procedure performed without anesthesia, and was done under complete aseptic condition. Any unexpected risks were cleared to the Ethical Committee and patients.

Post procedure follow-up schedule:

Patients were followed up at one week, 1,3 and 6 months.

Post procedure clinical evaluation:

1) Change of ulcer size was assessed (percentage of healing expressed in surface area).
2) Ulcer complete healing.

Ethical consent:

This study was ethically approved by the Institutional Review Board (IRB) of the Faculty of Medicine, Ain Shams University. Every patient signed an informed written consent for acceptance of participation in the study. This work has been performed in accordance with the Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical analysis:

For all statistical tests, the Statistical Package for Social Sciences (IBM SPSS) version 23 was used. The parametric distribution of the quantitative variables was expressed by the mean, standard deviations (SD), and range, while the non-parametric distribution was expressed by the median. The qualitative variables were represented by numbers and percentages. The chi-square test was used to compare qualitative data between study groups. The independent t-test was used to compare two independent groups with quantitative data and parametric distribution, while *the Mann-Whitney test* was performed to compare two independent groups with quantitative data and non-parametric distribution. P value ≤ 0.05 was considered significant.

RESULTS:

As regarding demographic data, there was no notable difference between both groups. Males were more prevalent in both groups; where there were 6 (60%) males in the intervention group and 7 (70%) males in the control group. The age of the patients ranged from 26 to 60 years, with median of 37.5 and mean 40.2 (SD 10.71) years in the intervention group, and ranged from 25 to 48 years, with median of 37.5 and mean 36.6 (6.42) years in the control group.

Table 1 compares the intervention group with the control groups regarding the comorbidities. No significant differences were found between the two groups.

Table (1): Comparison between study group and control group as regards comorbidities.

Variable	Study group (n = 10)		Control group (n = 10)		Test of significance	P-value
	No.	%	No.	%		
Smoking						
Yes	6	60%	5	50.0%	$\chi2 = 0.202$	0.653
No	4	40%	5	50.0%		
Hypertension						
Yes	5	50%	3	30%	$\chi2 = 0.833$	0.361
No	5	50%	7	70%		
Diabetes						
Yes	1	10%	1	10%	$\chi2 = 0.000$	1.00
No	9	90%	9	90%		

COPD						
Yes	1	10%	0	0.0%	χ2 = 1.035	0.305
No	9	90%	10	100%		
H\o recurrent venous ulcers						
Yes	5	50%	6	60%	χ2 = 0.202	0.653
No	5	50%	4	40%		
H/o of recent DVT						
Yes	7	70%	5	50%	χ2 = 0.833	0.361
No	3	30%	5	50%		
BMI						
Median	30		31		U = 47.50	0.849
(Min. – Max.)	(20 – 37)		(20 – 35.5)			
Mean ± SD.	28.62 ± 5.32		27.73 ± 5.22			
Ankle Brachial Index						
Median	1.00		1.05		U = 43.50	0.631
(Min. – Max.)	(0.80 – 1.2)		(0.80 –1.2)			
Mean ± SD.	1.02 ± 0.131		1.0 5 ± 0.134			

(χ2): Chi-square Test. U: Mann-Whitney U test. P-value: P value for comparing between the studied groups.

Table 2 differentiates the intervention group with the control groups according to the ulcer's side, site, number, size, duration and previous intervention. No significant differences were found between both groups.

Table (2): Comparison between study group and control group as regards ulcer.

Variable	Study group (n = 10)		Control group (n = 10)		Test of significance	P-value
	No.	%	No.	%		
Side						
Right	6	60%	8	80%	χ2 = 0.952	0.329
Left	4	40%	2	20%		
Site						
Medial	7	70%	7	70%	χ2 = 0.000	1.00
Lateral	3	30%	3	30%		
Number						
One	8	80%	10	100%	χ2 = 2.22	0.136
Two	2	20%	0	0.0%		
Size (cm^2)						
Median	7.80		7.68		U = 44.50	0.684
(Min. – Max.)	(5.0 – 9.3)		(5 – 9.8)			
Mean ± SD	7.55 ± 1.32		7.81 ± 1.54			
Duration (Year)						
Median	2.75 year		2.5 years		U =36.50	0.315
(Min. – Max.)	(6 months – 17 years)		(4 months – 15 years)			
Mean ± SD	6.04 ± 5.79		4.10 ± 4.72			
Previous Intervention						
No	1	10%	5	50%	χ2 = 4.485	0.214
Compression	7	70%	4	40%		
Stripping of GSV	1	10%	0	0.0%		
Skin grafting of VLU	1	10%	1	10%		

(χ2): Chi-square Test. U: Mann-Whitney U test. P-value: P value for comparing between the studied groups.

Table (3): Comparison between Ulcer size before and after treatment with PRP at 1 week, 4 weeks, 3 months, and 6 months between the study and control groups.

Ulcer size	Groups		U	P-value
	Study group (n = 10) Mean ± SD	Control group (n = 10) Mean ± SD		
Basal 1 week Z P1	7.55 ± 1.32 6.06 ± 1.00 2.831 0.005*	7.81 ± 1.54 7.77 ± 1.40 -0.957 0.339	44.5 14.5	0.684 0.007*
4 weeks Z P2	3.45 ± 0.41 2.821 0.005*	6.05 ± 1.39 2.805 0.005*	3.0	0.000**
3 months Z P3	0.67 ± 0.72 2.812 0.005*	3.49 ± 1.54 2.803 0.005*	7.5	0.000**
6 months Z P4	0.00 ± 0.00 2.805 0.005*	0.96 ± 2.31 2.805 0.005*	20.0	0.023*

P1: Basal vs 1 week, P2: Basal vs 4 weeks, P3: Basal vs 3 months, P4: Basal vs 6 months.
U: Mann-Whitney U test for comparing between the studied groups.
Z: Wilcoxon Signed Ranks Test for comparing between the studied periods for each group.
* P-value ≤0.05 is significant **P- value ≤0.001 highly significant.

Table 4 compares the intervention group with the control groups regarding the change in ulcer size in centimeters during the follow up periods. Significant improvements were found in the intervention group after 1 week, 4 weeks, and 6 months.

Table (4): Comparison between change in ulcer size in centimeters at 1 week, 4 weeks, 3 months, and 6 months after treatment between the study and control groups.

Ulcer size Change	Study group (n = 10)	Control group (n = 10)	U	P-value
	Mean ± SD	Mean ± SD		
1 week	1.49 ± 0.98	0.076 ± 0.096	3.00	0.000
4 weeks	2.61 ± 0.75	1.73 ± 0.39	17.50	0.013
3 months	2.78 ± 0.43	2.56 ± 0.60	33.50	0.208
6 months	0.74 ± 0.68	2.53 ± 2.09	18.00	0.015

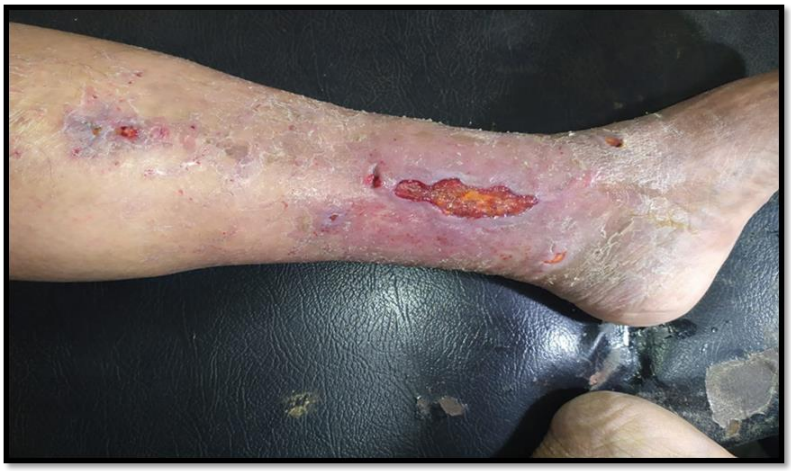
U: Mann-Whitney U test
*P-value <0.05 is significant **P- value ≤0.001 highly significant
Change in ulcer size by centimeters: calculated as the difference between periods.

Compared to our study, all cases have venous ulcers, so they are classified as post-thrombotic syndrome (PTS). According to Villalta score system, 4 cases were mild, 6 cases were moderate and 10 were severe, and after treatment there was 12 cases were nil, 5 cases were mild, one case was moderate, and 2 cases became severe (Table 5).

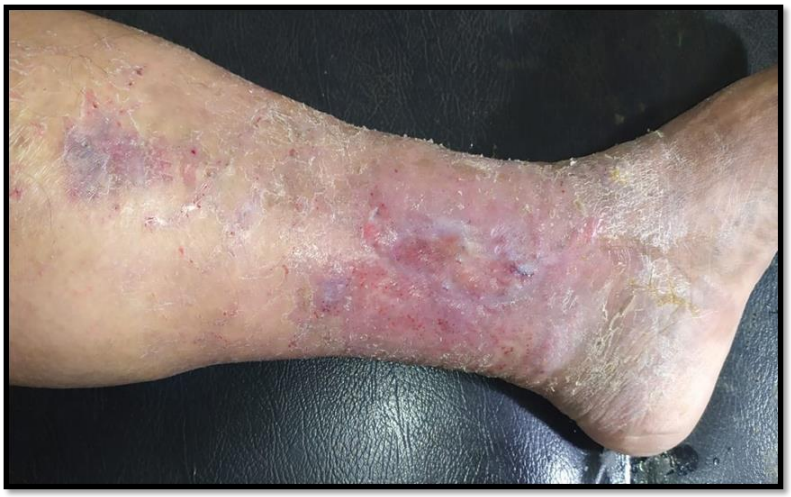
Table (5): Comparison between patients before and after treatment according to Villalta Score.

Patients PTS severity Before Treatment %			Patients PTS severity after treatment							
	Total		Nil		Mild		Moderate		Severe	
	No	%	No	%	No	%	No	%	No	%
Nil 0 %	0	0 %	0	0 %	0	0%	0	0%	0	0%
Mild 20%	4	20%	4	20%	0	0 %	0	0%	0	0%
Moderate 30%	6	30%	2	10%	4	20%	0	0%	0	0%
Severe 50%	10	50%	6	30%	1	5%	1	5%	2	10%
Total 100%	20	100%	12	60%	5	25%	1	5%	2	10%

Some selected cases from the study :



Case 1: (A) Male patient with chronic venous ulcer on right leg; ulcer at baseline measuring area 7.21



Case 1: (B) Ulcer on the third visit after treatment with platelet-rich plasma, area = zero.

Ulcer completely healed

DISCUSSION:

The most common form of chronic leg ulcers is VLUs, which results from long standing venous hypertension **(10)**.

There is no gold standard for the diagnosis of PTS. A number of clinical scales based on features can help support the diagnosis. These include the Villalta score**(11)**.

VLUs are mainly treated by compression therapy plus local debridement. It resulted in healing of 50% of VLUs within 4 months and approximately 60% to 80% within 6 months. 5 years after compression therapy alone, healing resistance and recurrence reached up to 30% and 70%, respectively, after**(12)**.

The idealistic treatment targets to rapid ulcer healing with low recurrence rate. Optimization of the resistant wound environment should proceed in the same time with cutaneous venous hypertension eradication by axial saphenous vein ablation and/or reticular or perforator veins foam sclerotherapy or thermal ablation, together with continuous compressive therapy**(13)**.

Different dressing materials, antimicrobials, hyperbaric oxygen therapy, negative pressure wound therapy, intermittent pneumatic compression, lasers, and infrared light in addition to PRP are local wound care modalities that showed to promote (VLUs) healing but still none of them is considered efficient**(14)**.

Healing resistance is related to an imbalance of some factors that lead to excessive prolongation of the inflammatory phase of normal wound healing. This includes an increase in cytokines, proteolytic activity, and metalloprotease activity together with decreased fibrin and growth factors content and activity. It is essential to shut down the prolonged phase and to turn on further phases of wound healing; proliferation, and regeneration **(15)**.

Autologous platelet factors are used to accelerate epithelialization of granulation tissue leading to complete healing of chronic non-healing ulcers. This was the first clinical illustration that locally acting factors derived from autologous blood enhance healing of chronic cutaneous ulcers**(16)**.

Autologous PRP contains concentrated platelets, fibrin, and growth factors (GFs), that enhances cellular migration, angio-genesis, proliferation, and differentiation and boosts epithelialization, granulation tissue, and collagen formation(17).

The use of topical PRP lead to reduction in healing time compared with conventional treatments particularly in diabetic foot ulcers, but the use of PRP on VLU showed conflicting results about healing**(18)**.

72 (80.0%) males and 18 (20.0%) females aging from 22 to 66 years were included in this study with a body mass index ranging from 17 to 37 kg/m^2.

In our study, comparison between intervention group and control group as per comorbidities, there were comorbidities in the patients of each group, where in the intervention group 6 (60%) were positive smoking, 5 (50%) had hypertension, 1 (10%) had diabetes, 1 (10%) had Congestive heart diseases, 5 (50%) had history of recurrent venous ulcers, and 7 (70%) had recent DVT, and in the control group 5 (50%) were positive smoking, 3 (30%) had hypertension, 1 (10%) had diabetes, 0 (0%) had congestive heart diseases, 6 (60%) had history of recurrent venous ulcers, and 5 (50%) had recent DVT.

The body mass index of the patients ranged from 20 to 37 years, with median of 30 in the intervention group, and ranged from 20 to 35.5 years, with median of 31 in the control group.

The ankle brachial index ranged from 0.8 to 1.2, with median of 1 in the intervention group, and ranged from 0.8 to 1.2, with median of 1.05 in the control group.

The comparison between the two groups showed that there was no statistically significant difference between the two groups as regards comorbidities.

In concordance with our results, Elbarbary et al, reported that, more than one-third of the study patients gave a history of previous deep venous thrombosis (DVT) (37/90, 41%), and (20/90, 22.2%) patients had pervious great saphenous vein (GSV) stripping surgically (n = 19) or using radiofrequency ablation (n = 1)**(12).**

Previous DVT is the most cause of venous ulcers, in the study of, Suryanarayan et al, they studied the role of the mean age of the patients was 42.5 years (SD 12.48). Of 33 ulcers, there were 19 (57.75%) venous ulcers due to previous DVT, 7 (21.2%) traumatic ulcers, 2 (6%) pyoderma gangrenosum ulcers, 2 (6%) diabetic ulcers, 2 (6%) trophic ulcers, and 1 (3%) vasculitis ulcer(16).

The in PRP contains anti-inflammatory factors that play an important role in wound healing due to presence of high levels of leukocytes **(21).**

Fibronectin, vitronectin, and sphingo-sine 1-phosphate are important factors in wound healing released by platelets. PRP is preferred over the use of single recombinant human GF delivery due to the release of multiple GFs and differentiation of factors upon platelet activation**(16).**

In our clinical trial, we estimated the role of PRP in treating venous ulcers. Our results revealed that, comparison between the intervention and control groups as regards the ulcer size showed that the basal size of the ulcer was almost equal in the two groups with no statistically significant difference, after treatment, there was statistically significant decrease in ulcer size in the intervention group than the control group every follow up period after one and four weeks and three and six months, and we found that after three months all cases of the intervention group had completed heal, where the control groups completed heal in the sixth month.

Additionally, in the intervention group there was statistically significant decrease in the ulcer size from the first week till the end of the follow up period, where in control group the decrease began to be statistically significant from the fourth week.

Comparison between the intervention and control groups as regards change in ulcer size after treatment we found that after 1 and 4 weeks the change was statistically significant higher in the intervention group than the controls, then after 3 months there was no statistically significant difference between the two groups, and 6 months after treatment the change was statistically significant higher in the control group than the intervention group where the intervention group were all healed but the controls were still completing their healing.

Also in concordance with our results, in a study done by *Yilmaz et al. 2015***(22)** they reported the results on a case series of 19 patients receiving PRP injection in treatment of patients with chronic un-healing venous leg ulcers. They stated that complete wound healing occurred in 18 of 19 patients (94.7%) within a mean of 4.82 (SD 2.16) weeks. There were significant reductions in wound area among all consecutive measurements except for first week. A significant decrease in wound volume was manifest even in first week and sustained among consecutive measurements.

Earlier experimental studies on use of PRP suggested that PRP has potential of accelerating the healing process by enhancing neovascularization in

reconstruction of transected tendons having poor vascularity **(23).**

In a larger prospective study done by *Roubelakis et al. 2014***(24),** they reported their study of 17 patients with chronic wounds of different etiologies including dehiscent sternal wounds and ischemic neuropathic wounds. In this study, the majority of wounds was exudative or necrotic and was located in the lower extremity. The authors reported an average volume reduction of 34.1% in all types of ulcers within 8 weeks by applying an average of 9.5 separate PRP sessions. This clinical study supported that PRP has potential of regulating wound healing by acting on cell migration and proliferation. Based on our findings and those above, we think that patients with VLU may respond better to PRP treatment than those having ischemic and neuropathic wounds in terms of faster recovery and higher amount of the closure.

In another study done by *Sarvajnamurthy et al. 2013***(10)**, they evaluated the role of PRP application in treating venous ulcers 12 patients with 17 ulcers were treated with PRP. The mean age of the patients was 33.5 (SD 9.82) years; 10 were males and 2 were females. The mean duration of the healing of the ulcers was in 5.1 (SD 3.1) weeks. The mean percentage improvement in the area and volume of the ulcer was 94.7% (SD 11.12) and 95.6% (SD 10.19) respectively.

From all the aforementioned results we can conclude that, chronic venous leg ulcers aggravate cost and morbidity for patients and society also. PRP is a safe, simple, inexpensive and biocompatible procedure. PRP enhances the wound healing in chronic venous leg ulcers without any side effects. there is no standardization of the procedure, so more randomized control studies are needed to achieve a standard protocol for the preparation of PRP.

In conclusion, PRP was found to be useful in promoting wound healing in chronic venous leg ulcer without any harmful effects.

Conflicts Of Interest:

The authors state that the publishing of this paper is free of any conflicts of interest.

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دور البلازما الغنية بالصفائح الدموية فى التئام قرحة الساق الوريدية المزمنة

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المقدمة : يعتبرالعلاج بالضغط حجر الاساس فى العلاج التحفظى وعند حدوث فشل يتم التوجه للعديد من طرق العلاج الأخرى لذلك يعد معالجة السبب الرئيسى للقرحة له أهمية كبيرة .

وتعتبر البلازما الغنية بالصفائح الدموية احدى مشتقات الدم والتى تحتوى على كميات مركزة من الصفائح الدموية التى تلعب دوراً مهماً فى علاج القرح الوريدية المزمنة من خلال احتوائها على كميات كبيرة من عوامل النمو. تلك العوامل المسئولة عن الالتهابات المصاحبة للجروح وتنظيم عملية هدم وبناء الأنسجة.

الهدف من العمل : الهدف من هذا العمل هو تقييم فاعلية استعمال البلازما الغنية بالصفائح الدموية فى علاج القرح الوريدية المزمنة بالساق.

المرضى وطرق البحث : سيتم اجراء هذا البحث فى مستشفيات جامعة عين شمس عن طريق اختيار مجموعة من المرضى الذين يعانون من قرح وريدية مزمنة بالساق وعددهم ٢٠ مريض ويستثنى من هؤلاء مرضى القرح الوريدية المزمنة الذين يعانون من قصور بالدورة الدموية الشريانية أو الذين يعانون من حساسية للعلاج الرغوى التصلبي أو المرضى الحوامل أو أولئك الذين يعانون من تخثر حديث بالأوردة أو القرح التى تكون الأوتار أو العظام مكشوفة بها.

الطرق : سوف يخضع جميع المشاركون فى الدراسة للأتى :

١. أخذ التاريخ المرضي .

٢. التقييم الاكلينيكي .

٣. الفحوصات : صورة دم كاملة وسكر عشوائي بالدم وزمن ونشاط البروثرومبين .

٤. سوف يتم عمل أشعة دوبلكس على أوردة الطرف السفلي .

٥. سوف يتم علاج المرضى باستخدام ضمادة البلازما الغنية بالصفائح الدموية المعدة باستخدام أجهزة الفصل .

٦. سيتم متابعة المرضى خلال زيارات بعد أسبوع ثم شهر ثم ثلاثة اشهر.

٧. ستكون المتابعة شاملة متابعة تغير حجم القرحة الوريدية أو حدوث التئام كامل للقرحة أو رجوع القرحة مرة أخرى بعد شفائها.

النتائج : كان الحجم القاعدي للقرحة متساويًا تقريبًا في المجموعتين مع عدم وجود فرق معتد به إحصائيًا وبعد العلاج ، كان هناك انخفاض معتد به إحصائيًا في حجم القرحة في مجموعة الدراسة عن مجموعة التحكم كل فترة متابعة بعد أسبوع وأربعة أسابيع وثلاثة و ستة أشهر ، ووجدنا أنه بعد ثلاثة أشهر ، اكتملت جميع حالات مجموعة الدراسة الشفاء ، حيث أكملت المجموعات الضابطة الشفاء في الشهر السادس.

أيضا في مجموعة الدراسة كان هناك انخفاض معتد به إحصائيا في حجم القرحة من الأسبوع الأول حتى نهاية فترة المتابعة ، حيث في مجموعة التحكم بدأ الانخفاض يعتد به إحصائيا من الأسبوع الرابع.

فيما يتعلق بالتغير في حجم القرحة بعد العلاج وجدنا أنه بعد أسبوع وأربعة أسابيع كان التغيير ذا دلالة إحصائية أعلى في مجموعة الدراسة من مجموعة التحكم، ثم بعد ٣ أشهر لم يكن هناك فرق ذو دلالة إحصائية بين المجموعتين ، و ٦ أشهر بعد العلاج كان التغيير ذا دلالة إحصائية أعلى في مجموعة التحكممن مجموعة الدراسة حيث تم شفاء مجموعة الدراسة جميعًا ولكن الضوابط كانت لا تزال تكمل شفاءها.

خلاصة الدراسة : في الختام إن التأثير المفيد للبلازما الغنية بالصفائح الدموية في حالات قرح الساق الوريدية المزمنة واضح بذاته لكل من الحالة الأكلينيكية وعلامات الألتهاب وتنظيم عملية بناء الأنسجة.