



A COMPARATIVE STUDY BETWEEN THE EFFECTIVENESS OF AUTOLOGOUS PLATELET-RICH FIBRIN VERSUS SALINE DRESSING IN THE MANAGEMENT OF CHRONIC VENOUS LEG ULCERS

Surgery

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ABSTRACT

Background: Venous disease is responsible for around 85% of all chronic lower limb ulcers in resource-rich countries. Venous leg ulcer is a chronic condition, and various treatment modalities are available. Various adjunctive wound care therapies and procedures are available that can be utilized as part of a comprehensive approach to healing venous stasis ulcers. Platelet-rich fibrin (PRF) is one of the newer modalities and it contains fibroblast growth factor (FGF), VEGF, angiopoietin and platelet-derived GF which enhances the wound healing. We conducted a randomized controlled trial to compare the efficacy of PRF versus saline dressing in chronic venous leg ulcers.

Aim: To compare the efficacy of autologous PRF with saline dressing in patients with chronic venous leg ulcer in terms of mean reduction in ulcer area, presence of infection and cosmetic outcome at the end of 4 weeks.

Materials and Methods: Thirty patients with chronic venous leg ulcers of >6 months duration having an ulcer area of 1 cm × 1 cm to 5 cm × 5 cm were taken into the study and were randomly divided into two groups. Group 1: Patients received PRF dressing. 10 mL of patient's blood was taken and centrifuged at 3000 rpm for 15 min. A fibrin clot obtained in the middle of the tube was removed and used for dressing over the wound surface. It was repeated every week for 4 weeks. Group 2: Patients received saline dressings once a week for 4 weeks. The assessment of the ulcer size was done with the help of photographs, and ulcer area was measured.

Results: The mean reduction in the area of the ulcer size in PRF group was 81.84%, and the mean reduction in the area of the ulcer size in Saline group was 59.84%.

Conclusion: Platelet rich fibrin matrix is a novel modality and an ideal, safe, affordable therapeutic option for chronic venous leg ulcers.

KEYWORDS

Platelet-rich fibrin, saline, chronic venous ulcers, dressing

INTRODUCTION

Leg ulceration of venous origin accounts for over 70% of patients with chronic leg wounds. [1] It is the most severe manifestation of chronic venous insufficiency (CVI) owing to long standing venous hypertension. Venous hypertension is most commonly caused by reflux through incompetent valves, but other causes include venous outflow obstruction and failure of the calf-muscle pump. Other causes of leg ulceration include arterial ischemic ulcers, vasculitic ulcers, traumatic ulcers, neuropathic ulcers, neoplastic ulcers and infections, especially in resource-poor countries.

The majority of venous leg ulcers (VLU) will have a superficial component of venous reflux. [2] Therefore, treatment of the underlying source of venous hypertension should be sought for therapeutic intervention, when patient selection is appropriate. However, treatment of the VLU is often inadequate and poorly addressed, leading to disappointing healing rates and chronicity of the ulcer. When properly diagnosed, effective treatment of the VLU is available. External compression is the mainstay of treatment of the venous leg ulcer. When used in conjunction with corrective procedures for superficial venous reflux, ulcer recurrence is significantly reduced coupled with an extended ulcer-free time. [3] Various adjunctive wound care therapies and procedures are available that can be utilized as part of a comprehensive approach to healing venous stasis ulcers. These include wound disinfection and debridement using autolytic, chemical, and mechanical methods; pneumatic devices; negative pressure wound therapy; ultrasonic wound bed stimulation; pulsed electromagnetic field therapy; platelet leukocyte gel application; skin substitute grafts; auto skin grafts; tissue flap reconstruction; and use of systemic therapy with agents such as dafon and pentoxifylline.

Platelet-rich fibrin (PRF) is one of the newer modalities. It contains fibroblast growth factor (GF), vascular endothelial GF, angiopoietin and platelet-derived GF which enhances the wound healing. Community-based prevalence is 0.1–0.3% in adults (2–4% in the elderly). Various studies have been performed showing the efficacy of platelet gel on wound healing. Surgical wound healing in horses treated with platelet leukocyte gel demonstrated faster epithelial differentiation and increased organization of dermal collagen compared to controls. [4] Used on chronic venous stasis ulcers, platelet leukocyte gel has been noted to increase granulation tissue formation

and promote complete epithelialization of these ulcers. [5] A randomized controlled trial found that diabetic foot ulcers were statistically significantly more likely to heal with PLG application than ulcers treated with a control (saline) gel. [6] Platelet leukocyte gel has been used in conjunction with fibrin glue and skin grafting, [7] fat grafting, [8] and negative pressure wound therapy [9] to heal chronic ulcers.

Aim

To compare the efficacy of autologous PRF with saline dressing in patients with chronic venous leg ulcer in terms of mean reduction in ulcer area, presence of infection and cosmetic outcome at the end of 4 weeks.

MATERIALS AND METHODS

We included 30 patients with chronic venous leg ulcers of >6 months duration having an ulcer area ranging between 1×1 cm to 5×5 cm in the study. Patients were alternatively divided into two groups: Group 1 patients who received PRF dressing and group 2 patients who received saline dressing.

INCLUSION CRITERIA:

1. Patients suffering from chronic venous ulcers of the lower extremity for >6 months
2. Ulcer area between 1×1 cm to 5×5 cm
3. Patients willing to be part of the study

EXCLUSION CRITERIA:

1. Ulcers of >6 months duration
2. Ulcer size <1 sq cm or >5 sq cm
3. Neuropathic, arterial, diabetic or vasculitic ulcers
4. Patients with infected ulcers
5. Osteomyelitis affecting the area of the ulcer
6. Ulcers with exposed tendons or bones
7. Patients receiving anticoagulants/antiplatelet drugs/ bleeding diathesis
8. Patients not willing to be part of the study

Group 1: Patients who received PRF dressing. 10 ml of patient's blood was taken and centrifuged at 3000 rpm for 15 min. A fibrin clot obtained in the middle of the tube was removed and used for dressing over the wound surface. It was repeated every week for 4 weeks.

Group 2: Patients received saline dressings once a week for 4 weeks. Ulcer was covered with a sterile gauze soaked in saline (primary dressing), which was in turn covered with a sterile gauze pad (secondary dressing). Then ulcer was covered with a sterile roller bandage.

Measurements documentation: The greatest length and the greatest breadth were measured using a scale. This was done before starting the treatment, and before repeating the treatment each time at weekly intervals and after the treatment was completed (the final measurement). Digital photographs will be taken before starting the treatment, before repeating the treatment each time at weekly intervals and after the treatment is completed.

RESULTS

This study was conducted in Susheela Tewari Government Hospital Haldwani. Total number of patients studied were 30. Majority of the patients belonged to the age group of 18-40 years (n=8; 53.33%). Out of 15 patients, 11 were male and 4 were female.

Table 1: Distribution of study participants according to age.

Age Group	No.	Percentage
18 – 40 years	8	53.33
41 – 60 years	4	26.67
>60 years	3	20
Total	15	100.0

Table 2: Distribution of study participants according to Sex.

Sex	No.	Percentage
Male	11	73.33
Female	4	26.67
Total	15	100.0

All the patients were suffering from chronic venous ulcers. The greatest length and the greatest breadth were measured using a scale. This was done before starting the treatment, and before repeating the treatment each time at weekly intervals and after the treatment was completed (the final measurement). The mean ulcer area reduction after 1 week in the PRF group was 11.64%, after 2 weeks it was 24.15%, at 3 weeks it was 43.40% and after 4 weeks it was 81.84%. The mean ulcer area reduction after 4 weeks in the saline dressing group was 59.84%. There was a complete closure of the ulcer in 8 patients (53.33%) in the PRF group. There was a complete closure of the ulcer in 3 patients (20%) the saline group.



Figure 1: Patient 3 before treatment with platelet-rich fibrin dressing

Figure 2: Patient 3 after 2 weeks of treatment with platelet-rich fibrin dressing

Table 3: Patients treated with platelet rich fibrin dressing

Patient number	Initial measurement in sq. cm	After 1 st week	After 2 nd week	After 3 rd week	Final measurement in sq. cm	Percentage of improvement
1	1.7	1.2	1.2	1.0	0	100
2	2.2	2.2	1.9	1.6	0	100
3	4.5	4.1	3.4	3.2	0	100
4	12.5	11.4	10.8	6.8	4.2	66.4
5	15.8	13.9	11.4	9.4	8.2	48.1
6	22	20	17.1	14.8	10.5	52.3
7	16	14.5	13.1	9.5	6.8	57.5
8	9.3	9.2	9.2	4.0	0	100
9	10.9	9.7	9.0	6.1	2.3	78.9
10	11.4	9.9	8.7	5.1	3.2	71.9
11	2.5	2.2	1.5	1.5	0	100
12	2.2	2.2	1.5	1.1	0	100
13	13.1	10.1	7.3	7.0	6.2	52.6
14	1.8	1.6	1.2	1.0	0	100
15	2.6	2.0	1.5	1.1	0	100

Table 4: Patients treated with saline dressing

Patient number	Initial measurement in sq. cm	After 1 st week	After 2 nd week	After 3 rd week	Final measurement in sq. cm	Percentage of improvement
1	1.9	1.2	1.2	1.0	0	100
2	2.0	2.2	1.9	1.6	0	100
3	4.2	4.1	3.4	1.2	1.1	73.8
4	13.5	11.4	10.8	7.8	6.2	54
5	16.8	14.9	13.4	10.4	8.2	51.1
6	24	22	18.1	16.8	14.5	39.5
7	11	10.5	9.1	7.5	6.8	38.1
8	10.3	10	9.2	6.0	4.5	56.3
9	14.9	12.7	10.0	8.1	7.3	51
10	13.4	12.9	10.7	9.1	7.2	46.2
11	3.5	2.2	1.5	1.5	0.4	88.5
12	6.2	5.9	5.5	4.1	4.0	35.4
13	10.1	9.1	8.3	7.0	6.2	38.6
14	1.6	1.6	1.2	1.3	0	100
15	12.3	12.0	11.5	10.1	9.2	25.2



Figure 3: Patient 6 before treatment with platelet-rich fibrin dressing



Figure 4: Patient 6 after 3 weeks of treatment with platelet-rich fibrin dressing

DISCUSSION

PRF is an autologous platelet and leucocyte-rich fibrin material. It forms an organized network where the platelets and leucocytes are concentrated leading to the sustained release of various GFs, resulting in wound healing. Hence, it can also be used for the treatment of venous ulcers. [10]

In this study, there was a mean reduction of ulcer size of 81.84% in the group treated with PRF at the end of 4 weeks. In our study, 53.33% of patients treated with PRF had complete closure at the end of 4 weeks, whereas 20% patient treated with saline had complete closure. In our study, we found mean reduction of 85.51% in ulcer area at the end of 4 weeks in patients treated with PRF which is faster when compared to saline group. Our study showed 59.84% reduction in ulcer size when treated with saline dressing, however, this was less when compared to the 85.51% ulcer area reduction in the PRF dressing group. Neither adverse reactions nor in-situ recurrences were observed.

Choukroun et al first used PRFM in oral and maxillofacial surgery to improve bone healing.[11] Since then PRFM has been widely used with few modifications in the preparation protocol and also there have been few comparative studies between PRP and PRFM. The procedure is simple, cheap, safe day care using autologous blood without anticoagulants. [12,13] It can be done single handedly, without any downtime, without much training and assistance and no downtime required for the patient. Also, it can be practiced in small to large scale clinics with minimum equipment's even by beginners. All these advantages make it an ideal and affordable option for chronic non-healing wounds of varied causes.

CONCLUSION

This procedure is simple, patient-friendly, cost-effective, painless and can be performed as an outpatient procedure. We would like to conclude that the use of PRF dressings as an adjuvant therapy in the treatment of chronic venous ulcer shows great potential to achieve complete closure of ulcers and can successfully be used as a routine procedure in the management.

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