Original Research Paper

Volume - 13 | Issue - 12 | December - 2023 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

Dermatology

AUTOLOGOUS WHOLE BLOOT CLOT VS AUTOLOGOUS PLATELET RICH FIBRIN MATRIX(PRFM) THERAPY IN CHRONIC NON-HEALING ULCERS IN PATIENTS OFHANSEN`S DISEASE – A RANDOMISED OPEN LABELLED COMPARATIVE STUDY

Dr. B. Indira	Assistant Professor, Department of D.V.L.
Dr. S.S.Ravi	Assistant Professor, Department of D.V.L.
Dr. B. Hasini	Senior Resident, Department of D.V.L.
Dr. Sruthi. P*	Senior Resident, Department of D.V.L. *Corresponding Author

ABSTRACT Chronic nonhealing leg ulcer is defined as the "loss of skin and subcutaneous tissue on the leg or foot, which takes more than 6 weeks to heal. The present study was conducted with an aim to demonstrate the efficacy of autologous platelet rich fibrin matrix (PRFM) in chronic non-healing ulcers.40 cases were included for the study who are attending outpatient in DVL department, GGH Kakinada. The procedure was repeated once a week for a maximum of six sittings as per requirement.The mean percentage improvement in the area was 85.25% and the volume was 97.74% at the end of third sitting. Most of the ulcers were closed by sixth sitting. PRFM for the treatment of chronic non-healing ulcers is a feasible, safe, simple and inexpensive method leaving minimal residual side effects.

KEYWORDS : ulcers, PRFM, Leprosy

INTRODUCTION:

Chronic nonhealing leg ulcers are defined as skin and subcutaneous tissue loss on the leg or foot that takes longer than 6 weeks to heal[1]. Trophic ulcers of Leprosy are a significant clinical and public health issue in the disease, posing a therapeutic challenge to all those involved in ulcer care. The use of biologic scaffold materials, such as collagen, as a whole provisional ECM, as part of the ECM, or as part of a hybrid scaffold made of synthetic and biologic materials, is a new therapeutic option for wounds[2,3].

AIMS AND OBJECTIVES:

To compare the efficacy and safety of the continuous weekly application of the PRFM in one group and Autologous whole blood clot dressing weekly in another group for the management of chronic non-healing ulcers.

MATERIALS AND METHODS:

After Obtaining clearance and approval from the institutional ethical committee, 40 cases were included for the study who are attending outpatient in DVL department, GGH Kakinada. Informed and written consent should be taken from patients and clinical data was recorded as per proforma. Detailed history taking and complete examination was taken for study. Group A received Autologous whole blood clot dressings at weekly intervals for maximum of six sitting. Group B received PRFM dressings at weekly intervals for maximum of six sitting. The end point of study was complete wound epithelialization or appearance of granulation tissue.

Inclusion Criteria:

Patients between 18-70 years, non-healing trophic ulcers of more than 6 weeks duration in Hansen's disease patients who had already been released from MB-MDT treatment. Patients who are willing to participate in study.

Exclusion Criteria:

Patients with age group below 18 years, Patients having a history of bleeding disorders.Patients who are not willing to participate in study

PROCEDURE:

GROUP A – Autologous whole blood clot.10 ml of venous blood was taken under stringent aseptic conditions and put to a sterile centrifuge tube without the use of an anticoagulant. Two layers were produced after ten minutes of centrifugation at 3000 rpm (3824g, REMI R-8C model): the upper layer was Platelet Rich Fibrin Matrix Gel (PRFM), and the lower layer was a reddish fraction that contained red blood cells (RBCs). Using sterile forceps and scissors, PRFM was removed from red corpuscles at the base, preserving a thin RBC layer measuring about one millimetre in length, which was then transferred onto sterile gauze. The gel was then gently squished between two pieces of gauze, placed to a healthy wound, covered with a gauze pad, and bandaged. During the duration of treatment, the patients were urged to get enough sleep. After seven days, the patient's dressing was taken off. According to the requirements, this operation was repeated every week for a maximum of five sittings. Patients were instructed to refrain from standing for long periods of time, wear appropriate footwear (Microcellular rubber footwear) when walking, and leave the dressing in place until follow-up after one week(Figure1).

GROUP B - Whole blood clot matrix procedure and application. 10 ml of the patient's venous blood are taken in order to prepare the clot. Blood was drawn and handled in accordance with the hospital's safety regulations. In a clean glass petri plate, the blood is combined with either 2 mL of calcium gluconate. For 10 seconds, the suspension was gently blended. After injecting the coagulating blood into the previously chosen clotting tray, the formation of the clot was delayed for 10 minutes. Next, remove the sterile gloves from the clotting tray and carefully lift the entire blood clot matrix out. The clot was placed on the wound, with the embedded gauze pad facing upwards and anchored to the wound via the gauze edges. Primary and secondary dressings further affixed the clot to the wound. The follow-up schedule involved monitoring and reapplication visits, as required. Monitoring visits were conducted every 2 days. During these sessions, only primary and secondary dressings were removed and changed, while the whole blood clot matrix stayed on the wound. The visit included visual inspection of the exposed outer surface of the product to document the adherence of the clot to the wound and inspection of the wound periphery for adverse events such as infection. Reapplication visits occurred every 6 to 9 days, during which the clot matrix was removed, and a new clot was created and applied, as necessary. After removing the whole blood clot matrix, the wound was assessed and a digital photograph taken, as previously described. If the wound remained open, the wound bed was gently cleansed and prepped for clot reapplication, according to standard procedures using gauze and saline. The whole blood clot procedure and application was performed weekly for upto 6 weeks.

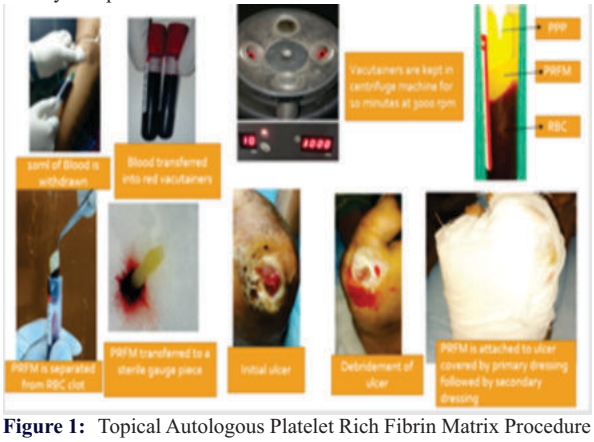

Figure 1: Topical Autologous Platelet Rich Fibrin Matrix Procedure In Clockwise Direction

RESULTS:

In this prospective, interventional, and comparative study, patients with chronic non-healing ulcers were treated using two distinct treatment modalities to examine the effectiveness and differences in the outcomes. Forty patients with chronic non-healing ulcers visiting the Department of Dermatology of Rangaraya Medical College and Government General Hospital during the period November 2014 to February 2015 and from January 2016 to July 2016 and satisfying the inclusion criteria were selected. All cases were assessed clinically and the necessary investigations required for diagnosis were carried out. Patients were then randomly divided into two treatment groups – topical autologous blood clot and topical autologous platelet rich fibrin matrix. The response to treatment in terms of healing of ulcer in the patients were assessed with serial measurements of the ulcer during the study period. All the data were documented, analyzed and the results were derived. Out the 40 eligible patients included in the study, 20 were randomly selected as GROUP A and the rest 20 patients were grouped under GROUP B.The mean age was 51.6 years, Range is 27-72 years with standard deviation of 12.23 years.Totally 40 patients with leg ulcers, who fulfilled the inclusion criteria were taken into the study, of which 37 were male accounting for 92.5% of the total study population.Out of 40 ulcers from 36 patients taken into study, the ulcers were predominantly in the lower two-third third of the leg (95%), followed by middle one third accounting for 5% of the total.Out of the 46 ulcers in the study, most of the ulcers were in the medial aspect (70%) of the leg, followed by lateral aspect (27.5%) and anterior aspect of the leg (2.5%).After every sitting of intervention in both the groups, the percentage of improvement in the area of the ulcer was calculated. In group A, at the end of six weeks, the percentage of improvement in the area was85.99% whereas in group B, the percentage of improvement in the area was 83.5%.After each sitting, the percentage of improvement in the volume of the ulcer was calculated in both the groups. In group A at the end of six weeks, the mean volume of the ulcer improved by 99.47% whereas in group B, the percentage of improvement in the mean volume was 98.8%(Figure 2).

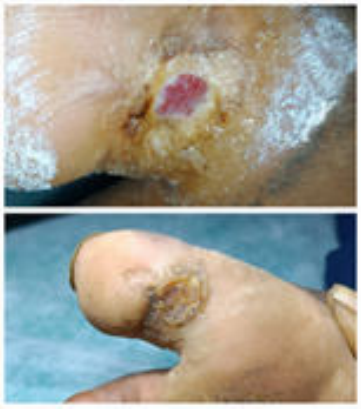

Figure 2: Complete Healing At The End Of 4th Sitting With PRFM

DISCUSSION

Topical platelet derived growth factors are FDA approved for wound healing, but their cost makes it unaffordable for use in developing countries[4,5].It is well recognized that platelets play a crucial role in the production of thrombi and hemostasis[6,7]. However, new research has demonstrated that these cells secrete cytokines, growth factors that support tissue regeneration and wound healing[8].The immediate requirement to reestablish hemostasis and initiate the other healing phases is addressed by the complete blood clot matrix through the production of a blood clot in vitro[9]. The best natural wound healing agent is a blood clot, which plays crucial roles in each stage of the healing process. Platelets release growth factors and other secretory proteins which influence tissue healing[10]. It is, therefore, logical to assume, that the presence of more platelets in the wound bed will aid healing[11,12].

CONCLUSION:

Though both topical autologous blood clot and topical autologous PRFM are safe, bio compatible, office-based procedures. Topical autologous blood clot is a simpler, cost effective, less time consuming procedure and does not require sophisticated equipment[13].Hence may be considered as a primary treatment modality in the management of chronic non-healing ulcers in resource poor settings.

REFERENCES

1. Gade, Ramakrishna & M., Venkata & Inamdar, Padmanabh. (2020). A comparative study between platelet rich plasma and conventional dressing in chronic non healing leg ulcers. International Surgery Journal. 7. 751. 10.18203/2349-2902.isj20200817.
2. Puri V, Venkateshwaran N, Khare N. Trophic ulcers-Practical management guidelines. Indian J Plast Surg. 2012 May;45(2):340-51. doi: 10.4103/0970-0358.101317. PMID: 23162234; PMCID: PMC3495385.
3. Yuvasri G, Rai R. Comparison of efficacy of autologous platelet-rich fibrin versus Unna's paste dressing in chronic venous leg ulcers: A comparative study. Indian Dermatol Online J 2020;11:58-61.
4. Davis VL, Abukabda AB, Radio NM, Witt-Enderby PA, Clafshenkel WP, Cairone JV, et al. Platelet-Rich Preparations to Improve Healing. Part I: Workable Options for Every Size Practice. J Oral Implantol. 2014;40(4):500-10.
5. Yazawa M, Ogata H, Nakajima T, Mori T, Watanabe N, Handa M. Basic studies on clinical applications of platelet rich plasma. Cell Transplant. 2003;12:509-18.
6. B Kahle., et al. "Evidence-based treatment of chronic leg ulcers".Deutsches Ärzteblatt International 108.14 (2011): 231-237.
7. Choukroun J., et al. "Platelet-rich fibrin (PRF): a second-generation platelet concentrate. Part IV: clinical effects on tissue healing". Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology,and Endodontology 101.3 (2006): e56-60.
8. Yazawa M, Ogata H, Nakajima T, Mori T, Watanabe N, Handa M. Basic studies on the clinical applications of platelet-rich plasma. Cell Transplant. 2003;12:509–18.
9. Sarvajnamurthy S, Suryanarayan S, Budamakuntala L, Suresh DH. Autologous platelet rich plasma in chronic venous ulcers: Study of 17 cases. J Cutan Aesthet Surg. 2013;6:97–9.
10. Kim SA., et al. "Application of platelet-rich plasma accelerates the wound healing process in acute and chronic ulcers through rapid migration and upregulation of cyclin A and CDK4 in HaCaT cells". Molecular Medicine Reports 7 (2013): 476-480.
11. Frykberg RG., et al. "Chronic wounds treated with a physiologically relevant concentration of plateletrich plasma gel: a prospective case series". Ostomy Wound Manage 56 (2010): 3644.
12. Madhan Jeyaraman., et al. "Management of Non-Healing Ulcers by Autologous Platelet Rich Fibrin (PRF)". Acta Scientific Orthopaedics 4.9(2021): 03-08.
13. Suthar M, Gupta S, Bukhari S, Ponemone V. Treatment of chronic non-healing ulcers using autologous platelet rich plasma: a case series. J Biomed Sci. 2017 Feb 27;24(1):16. doi: 10.1186/s12929-017-0324-1. PMID: 28241824; PMCID: PMC5327512.