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The Synergistic Role of Topical and Oral Therapies in Chronic Wound Management: A Study Proposal for Diabetic Foot Ulcers and Pressure Injuries

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1. Introduction & Objectives

Diabetic Foot Ulcers (DFU) and Decubitus wounds represent significant complications of diabetes and immobility, often exacerbated by poor glycemic control and prolonged pressure exerted over specific areas of the body. Ulcers are prevalent at the sacrum, ischial tuberosity, greater trochanter, plantar surface, and great toe. A crucial thing to consider during wound healing is adequate nutrition. While traditional treatments focus on symptom management, recent research suggest that biologically active compounds like zinc, vitamins (A, B6, B12, C, D, and folate), copper, aloe vera, leech saliva, and myrrh may synergistically accelerate wound healing. This paper aims to review existing literature on these compounds in wound care and proposes a study to evaluate combined effect. A literature review of these compounds' efficacy and purposes, a study assesses their combined effect in novel topical formulations and oral supplementation for patients with both controlled and uncontrolled glycemic indices.

2. Literature Review

The current literature highlights the benefits of zinc, vitamins (A, B6, B12, C, D, folate), and copper in promoting cellular repair, reducing inflammation, and supporting immune responses. Aloe vera offers hydration and anti-inflammatory properties and antimicrobial activity. Aloe vera has also shown to prompt polycosaminoglycan synthesis and epithelial regeneration all while also amplifying integrin expression, platelet endothelial cell adhesion molecule-1 (PECAM-1) and transforming growth factor beta (TGF-β) all of which are crucial in tissue repair (5). Leech saliva promotes enzymatic debridement and angiogenesis, and myrrh exhibits antimicrobial activity. While these ingredients are effective individually, limited studies explore their synergistic effects combined topical application and oral supplementation.

3. Proposed Methods

The preprocessed randomized controlled trial will enroll 120 participants diagnosed with diabetic foot ulcers or pressure injuries. Participants will be stratified into two groups of 60 patients: receiving the proposed topical formulation and undergoing standard wound care. Subgroup analyses will evaluate differences in efficacy between patients with controlled and uncontrolled glycemic indices. Blood samples will be drawn at initial intake to measure baseline zinc levels, vitamins (A, B6, B12, C, D, and Folate), copper, and inflammatory markers. Also decubitus wounds will be assessed and documented upon intake using the Bates-Jensen Wound Assessment Tool (BWAT), while DFUs will be assessed and documented using the Diabetic Foot Ulcer Assessment Scale (DFUAS), Wagner Grading Scale, and Deep, Maceration, Infection, Size, Tunneling (DMIST). Outcomes to be assessed include wound healing rates, reductions in wound size, pain levels, and infection rates over 12 weeks. Statistical analyses, including repeated measures ANOVA, will be used to evaluate the effectiveness of the intervention.

5. Discussion

The proposed study addresses the multifaceted wound healing challenges in diabetic and decubitus ulcer populations. By combining evidence-based ingredients with a focus on systemic and local factors, this formulation could improve outcomes regardless of glycemic control. Identifying differences in response between glycemic groups will provide critical insights into optimizing care.

6. Conclusion

This literature review and proposed study offer a comprehensive approach to advancing chronic management and integrating evidence-based components known for their roles in wound healing. By addressing systemic nutritional deficiencies and leveraging the localized benefits of biologically active compounds, the study aims to advance the understanding of synergistic effects in chronic wound management. Including patients with controlled and uncontrolled glycemic indices ensures applicability to diverse outcomes across a broader spectrum of patients.