

INVESTIGATION THE SAFETY OF AMNIOTIC MEMBRANE EXTRACTS To IMPROVE DIABETIC FOOT ULCERS (PHASE 1 CLINICAL TRIAL STUDY)

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Background: For nearly 100 years, amniotic membranes have been used to treat various types of skin wounds. Amniotic extract is one of the derivatives of amniotic membrane that contains all the properties of amniotic membrane. The aim of this study was to evaluate the safety of the amniotic membrane extract in the treatment of diabetic ulcers.

Methods: This study was an Open labeled clinical trial without control group. A total of 10 patients with Wagner Grade 2 diabetic foot ulcers were selected in both sexes. The extract was used every 48 hours in the first week and every 72 hours from the second week until the end of the wound treatment. Patients were followed up weekly until wound healing.

Results: In this study 80% of patients were men and 20% were women with mean age (56.7 ± 8.7) years. The ulcer duration was 8.9 ± 2.12 weeks. The mean area of ulcers at the time of entry into the wound group ≥ 500 mm², 977.5 ± 201.9 and in the wound group ≤ 500 mm² was 145.6 ± 36.4 . At 4 weeks post treatment, the wound healing rate in the wound group was ≤ 500 mm², 98.9 ± 2.40 % and in the wound group ≥ 500 mm² was 92.1 ± 7.23 %. In sixth week of treatment, ulcers were complete closure in both groups.

Conclusion: The results of this study suggest that the use of amniotic extract can be effective in the healing of diabetes foot ulcer without any side effects. DFUs are defined as foot lesions (ulcers) that may affect the skin, soft tissue, and bone in lower limbs, causing an aggravating infection in diabetic patients that can lead to very serious consequences such as lower-limb amputations. DFUs are caused by multifactorial etiologies as part of the microvascular complications of diabetes mellitus that can lead to major amputations, in most cases by the lack of the timely and correct management of diabetic feet. Indeed, diabetes is the leading cause of non-traumatic lower-extremity amputations worldwide. These serious consequences are mostly due to the absence of data on many subjects including diabetes education, preventive measures, glycemic control, comorbidities, inappropriate multidisciplinary assessment and treatment of ulcers, and later treatment failures in the prevention of ulcer recurrence. Based on the 2015 prevalence data from the International Diabetes Federation, it is estimated that foot ulcers develop in 9.1 million to 26.1 million people with diabetes annually worldwide. A systematic review and meta-analysis of the global prevalence of DFUs showed that the global prevalence of DFUs was 6.3%, higher in males than in females, and higher in type 2 than in type 1 diabetic patients. In Mexico, there are around 12 million cases of diabetes mellitus, and since the overall prevalence of DFUs is 6%, it is estimated that more than 700,000 people are affected with any grade of DFUs. DFU treatment has a high cost worldwide. In the United States (US), this cost ranges

from \$8000 to \$17,000, depending on the grade of infection and type of amputation, with the cost rising to \$43,000 in the case of partial amputation to \$63,100 after major amputation. All of these costs not only affect the patient's economic and psychological status but also the family's economy, the patient's disability and diminished quality of life, and the finances provided by the government and health insurance intended for diabetes treatment. In patients with diabetes, it is reported that, in most cases (60–80%), the ulcers become less aggressive, and, with the proper care, they heal. On the other hand, about 10% to 15% of these ulcers remain active and 5% to 24% lead to limb amputation in approximately 6–18 months. As many as 40% of patients have a recurrence within one year after ulcer healing, almost 60% have a recurrence within three years, and 65% have a recurrence within five years, making a previous incident of a foot ulcer the strongest predictor for diabetic foot ulceration. The median time to healing without surgery is about 12 weeks [4]. The five-year risk of death in diabetes patients is 2.5 times higher in those with DFUs than without them, and the five-year mortality after diabetes-related amputations exceeds 70%, which is worse than in many common cancers [3,4]. Osteomyelitis is another severe complication of DFUs, and it needs to be discarded in every patient with infected DFUs. A complete assessment with the measurement of blood pressure, and laboratory testing for complete blood cell counts, creatinine, glyated hemoglobin, erythrocyte sedimentation rate, C-reactive protein level, and ankle-brachial index (ABI, normal 0.8–1.2), as well as imaging (X-ray and MRI), needs to be done, and, in some cases, a bone biopsy may also be considered.

Keywords:

Diabetes Mellitus, Diabetic Foot Ulcer, Amniotic Membrane Extract, Amniotic Membrane, Wound Healing

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