From Womb to Wound: Amniotic Fluid and Diabetic Ulcer Healing

(MSN EBP Poster, Spring 2023)

Veronica Cromwell, Jody Peterman, Natasha Doughty

I. Introduction
- A. Diabetes Prevalence in adults-6.4%
  1. Estimated to reach 17.7% in 2030
- B. Comorbidities of Diabetes
  1. Peripheral neuropathy
  2. Ischemia
  3. Callus formation
  4. Deformities
  5. Edema
  6. Peripheral arterial disease (PAD)
     a) Well established risk factor for foot ulcers
- C. Diabetic Foot Ulcers
  1. Most common cause of hospitalization in diabetic patients
  2. Global prevalence 6.6%
  3. More common in men
  4. Type 2 Diabetes more likely to develop foot ulcer
- D. Consequences of Diabetic Foot Ulcers
  1. Diabetics 15X more likely to have lower limb amputation
     a) Most initially caused by foot ulcers
  2. Increased treatment costs
  3. Reduce quality of life
  4. Reduce self esteem and independence
  5. Higher rates of mortality
- E. Treatment of Diabetic Foot Ulcers
  1. Glycemic control
  2. Antibiotic therapy
  3. Debridement of necrotic tissue
  4. Pressure reducing- restore blood flow
  5. Negative pressure wound therapy
  6. High pressure oxygen
  7. Wound vac devices
- F. Regenerative Medicine
  1. “Replacing or regenerating cells, tissues, organs to restore normal function”
  2. Amniotic fluid contains high amount of stems cells
     a) used in regenerative medicine
  3. AF contains other elements that promote healing
     a) Prostaglandins, carbs, peptides, lipids, lactate, amino acids, proteins, enzymes, minerals, hormones (GH and prolactin)
        (1) Stimulate cutaneous fibroblast reproduction
     b) Antibody elements to fight infection
        (1) Broad spectrum-bacteria, fungi, protozoa, viruses

II. Purpose

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A. "The aim of this study was to evaluate the effect of a gel made with amniotic fluid (AF) formulation on wound healing in diabetic foot ulcers."

III. Method

A. Triple Blind Study
    1. 2019-2020
B. 92 Type 2 Diabetics were included
    1. Diagnosed with grade 1 or 2 pressure ulcer
    2. Exclusions from Study
        a) Use of IV antibiotics, immunosuppressants, corticosteroids
        b) Gangrenous ulcer requiring amputation
        c) Use of alcohol, drugs, tobacco
        d) Non compliance with study
C. Preparation of Wound
    1. Initial examination by doctor
    2. Debridement performed if indicated
    3. Washed in 0.9% NS
    4. Skin patch test to determine sensitivity
        a) Disqualified if sensitive to AF
D. Preparation of AF Solution
    1. Extracted during prescribed amniocentesis
        a) 20-30 mL of fluid
        b) 14-20 weeks pregnant
        c) Negative for HIV, Hepatitis B & C
    2. Storage
        a) Transported in cold box, stored 1C
        b) Centrifuged and added to gel base in 5%, 10%, 15% concentrations
            (1) Base: 15% propylene glycol, 2% hydroxypropyl methyl cellulose
E. Participants divided between 4 groups
    1. 3 intervention groups, 1 placebo group
    2. Groups decided randomly
        a) Intervention groups dressed wound with AF impregnated petrolatum gauze
            (1) Intervention groups: 5%, 10%, 15% solution
        b) Placebo group dressed wound with petrolatum gauze
F. Wagner System
    1. Assess depth, osteomyelitis, gangrene
        a) Grade 0
            (1) Pre or post ulcer lesion
        b) Grade 1
            (1) Partial-full thickness ulcer
        c) Grade 2

(1) Ulcer to tendon, ligament, bone
d) Grade 3
(1) Deep abscess, osteomyelitis, joint sepsis
e) Grade 4
(1) Partial gangrene
f) Grade 5
(1) Full foot gangrene

2. Scoring
a) Wagner Grade, color, drainage, surrounding tissue
(1) Up to 100 points in each category
b) Higher score, better healing
c) Week 8 score was compared to Week 0
(1) Full Recovery: 400 points
(2) Partial: 30X improvement
(3) No Recovery: no change, below 30X improvement
(4) Worsening: score decreased 10X

IV. Results
A. All groups showed initial improvement, then decreased
B. Discharge: AF 5%had greatest effect (p=0.048)
C. Surrounding Tissue: AF 15% greatest effect (P=0.038)
D. Wound Color: AF 5% had greatest effect (P= 0.004), 10 & 15% matched control
E. Overall status: 15% (0.048) 5% (0.024)

V. Conclusion
A. AF is a useful and safe option to treat foot ulcers
1. 5% solution has best results
2. Placebo had no effect on healing
B. Amniotic gel should be promoted to improve diabetic ulcer healing
1. Reduce rate of amputation
2. Improve physical, mental, social and economic implications.

Reference: 1. Niami, F., Molavynejad, S., Hemmati, A. A., Bijan Nejad, D., Yazdanpanah, L., Maram, N. S., Saki Malehi, A., & Mahmoudi, M. (2022). Evaluation of the effect of a gel made with amniotic fluid formulation on the healing of diabetic foot ulcers: A triple-blind clinical trial. *Frontiers in Public Health*, *10*. https://doi.org/10.3389/fpubh.2022.1025391