



RESEARCH ARTICLE

A COMPARATIVE STUDY OF TOPICAL HUMAN PLACENTAL EXTRACT WITH TOPICAL SUCRALFATE IN THE MANAGEMENT OF DIABETIC FOOT ULCERS

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ABSTRACT

**Purpose:** To evaluate the efficacy of topical human Placental extract in the management of diabetic foot ulcers in comparison with topical sucralfate.

**Methods:** This prospective study included 100 patients with diabetic foot ulcers. Patients were randomized into two groups comprising 50 each. Group I received topical sucralfate, Group II received topical human placental extract dressing. Initial wound measurement was taken in both the groups before starting their respective treatment that is sucralfate in group II and human placental extract dressing in group I. After four weeks final wound area and percentage of wound reduction was assessed.

**Results:** We found that the mean reduction of wound area in patients treated with topical human placental extract was 14 sq cm and in patients treated with topical sucralfate was 8 sq cm which was statistically significant ( $p < 0.001$ ). The mean percentage reduction of wound area in human placental extract group was 39.04% and in sucralfate group was 29.04%, which showed statistical significance ( $p < 0.001$ ). In terms of granulation tissue which was assessed at 4 weeks, 48 patients in human placental extract group had 100-75% granulation tissue where as in sucralfate group only 36 patients had 100-75% granulation tissue ( $p = 0.002$ ).

**Conclusion:** Human placental extract dressing therapy in the treatment of diabetic foot ulcers was found to be more effective, safe, promoter of wound healing, and hence can be recommended for the treatment of diabetic foot ulcers.

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INTRODUCTION

Diabetes mellitus is characterized by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action or both. It is the leading cause of end stage renal disease, a major cause of non traumatic amputations, responsible for 30% of the preventable blindness and a leading cause of cardiovascular mortality. The prevalence of diabetes is rapidly rising all over the globe at an alarming rate. According to the world health organization, at least 171 million people worldwide have diabetes. The figure is likely to double by 2030 (Peter *et al.*, 2005). Diabetic foot is one of the major complications of diabetes mellitus. One in every six people with diabetes will have a foot ulcer during his /her life time (IDF, 2005). Currently there is a wound care revolution and a wide variety of dressings are available yet there is no ideal dressing. During the last two decades a wide variety of innovative dressings

have been introduced in wound healing, such as Benzoyl peroxide, collagen, insulin, oxygen therapy, sucralfate, honey and vinegar. Sucralfate is a commonly used antacid. It is a basic aluminium salt of sucrose octasulfate. It acts as a mechanical barrier because of a strong electrostatic interaction with proteins at the ulcer site (Frykberg *et al.*, 2006). Sucralfate has also been shown to have anti bacterial activity (Danesh *et al.*, 1987). Recent studies have also shown that it is structurally similar to heparin, and hence has angiogenic properties (Tryba and Mantey-Stiers, 1987). Recently a peptide fraction isolated from the placental extract, exhibited distinct collagenase activity and helps in achieving faster and better healing (De *et al.*, 2013). Placental extract is prepared from fresh term healthy human placenta, after delivery. It increases the synthesis of collagen, tissue protein, accelerates neo-angiogenesis, and epithelialization. It also has immunotropic effect, EGF and Fibroblastic growth factor, which supports ossification and reduces surrounding tissue inflammation and oedema (Fang and Xia, 2007). This study compares topical sucralfate with human placental extract in diabetic foot ulcers. They are highly efficacious in achieving faster and better

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healing. There is a need to optimize the ideal type of dressings in diabetic foot ulcers and thus the study was conducted.

## MATERIALS AND METHODS

This prospective study comprised of 100 patients with Wagner grade I & II diabetic foot ulcers during the period December 2013 and July 2015. The exclusion criteria were patients with chronic venous insufficiency of lower limbs with dermal changes and lymphedema and any other co-morbid conditions. The study was approved by the Ethical and Research Committee of Sri Devaraj Urs Medical College, Kolar. The selected patients underwent appropriate treatment for a period of one to two weeks. This was to stabilize the wound and institute appropriate medical and surgical treatment. The patients were randomly divided into two groups. Group I comprising 50 patients received topical sucralfate and Group II comprising 50 patients received human placental extract dressings. Initial wound measurement was taken in both the groups before starting their respective treatment that is sucralfate in group I and human placental extract dressing in group II. Wounds were inspected for Presence of slough as percentage of total ulcer surface area, Progress of granulation tissue as percentage of total ulcer surface area, Ulcer size as change in surface area and reduction percentages, Wound bed preparation for skin grafting, Infection of wounds. The amount of nonviable tissue, degree of wound granulation and overall wound response was evaluated on baseline, one week, two weeks, three weeks and four weeks.

The visual scores for the percentage of wound covered with necrotic tissues are

- 76-100% of wound covered by necrotic tissue.
- 51-75 of wound covered by necrotic tissue.
- 26-50% of wound covered by necrotic tissue.
- 11-25% of wound covered by necrotic tissue.
- 0-10% of wound covered by necrotic tissue.
- No necrotic tissue covering the ulcer.

The visual scores for the percentage of wound filled by granulation tissues are

- No granulation tissue covering the ulcer.
- Pink/dull <25% wound filled.
- Bright beefy 25-74% wound filled.
- Bright beefy red 75-100% wound filled.

The reduction of wound size area was measured in sq cm . We have applied the following formula to calculate % reduction in area of wound after four weeks period in both cases and controls.

$$\% \text{ Reduction of wound after four weeks} = \frac{\text{Initial area} - \text{Final area} \times 100}{\text{Initial area}}$$

### Statistical analysis

Data will be analysed using the statistical program for social sciences (SPSS) software. Comparison of categorical variables were done using Fischer's test. Comparisons of quantitative

variables were done using student t test. A probability value (p value) <0.05 will be considered statistically significant.

## RESULTS

In our study we found that the mean reduction of wound area in patients treated with topical human placental extract was 14 sq cm and in patients treated with topical sucralfate was 8 sq cm which was statistically significant ( $p < 0.001$ ). The mean percentage reduction of wound area in human placental extract group was 39.04% and in sucralfate group was 29.04%, which showed statistical significance ( $p < 0.001$ ). In terms of granulation tissue which was assessed at 4 weeks, 48 patients in human placental extract group had 100-75% granulation tissue where as in sucralfate group only 36 patients had 100-75% granulation tissue ( $p = 0.002$ ).

## DISCUSSION

Wound dressings have evolved from the status of providing physical protection to the raw surface, absorbing exudates and controlling local infections by local medications to the level of providing adequate environment promoting wound healing. This has been achieved by modern wound dressing agents which promote granulation tissue formation. Derived from folklore, human placental preparations show immense therapeutic value. The aqueous extract of human placenta is a scientifically proven potent wound healer. A fibronectin type III-like peptide present in the aqueous extract appears to be one of the key components for wound healing. Placental extract aids in absorption of exudates by controlling its formation, removal of unhealthy tissue by debridement and management of bacterial load that are required for good wound bed preparation. In this study on 100 subjects, 50 patients received sucralfate dressings and 50 patients received human placental extract dressings. Base line characteristics like age, sex, initial wound surface area, necrotic tissue or slough, granulation tissue and final wound area were matched.

Majority of patients in the study fell in the age group of 61-70 years showing that diabetic foot ulcers being common in the elderly age group. Male Sex distribution was more in comparison to female sex with male: female ratio of 3:1 in human placental extract group and 2 : 1 in sucralfate group. Mean initial wound area at the beginning of the study was  $29.45 \pm 14.58$  in sucralfate group and  $35.60 \pm 18.32$  in human placental extract group. There was no statistical difference between the initial wound surface areas with  $p = 0.066$ . After receiving the treatment for a period of four weeks in both the groups, the wound surface area considerably decreased in both the groups. The mean final wound area in the sucralfate group was  $20.10 \pm 10.11$  and in human placental extract group was  $21.56 \pm 12$ . Mean percentage reduction of wound area was calculated in both the groups. Human placental extract group showed considerable result in having better reduction percentage with 39.04% % and 29.04% in sucralfate group which was statistically significant ( $p < 0.001$ ). Base line necrotic tissue in both the groups were statistically similar. After receiving the dressings in both group there was considerable decrease in the necrotic tissue which was statistically significant ( $p < 0.001$ ).

Amount of good granulation tissue is a major indicator of healthy healing. During the study there was very good progression of granulation tissue in the human placental extract group when compared to the sucralfate group. There was high statistical significance ( $p=0.002$ ). Speeding up of granulation tissue thus provides faster healing and faster wound bed preparation which was shown in the study. This comparative study shows a significant reduction in final wound area when treated with human placental extract which is achieved obviously by its efficacy in drastically promoting granulation tissue formation. The Limitations of our study were smaller sample size- Though 100 patients is sufficient for statistical analysis, a randomized control comparative study with a much larger population may help to further substantiate findings, cost burden on patient not analyzed and it was not a blinded study.

### Conclusion

Human placental extract dressing therapy in the treatment of diabetic foot ulcers was found to be more effective, safe, promoter of wound healing, and hence can be recommended for the treatment of diabetic foot ulcers.

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