

# Comparative Study between the Effect of Topical Insulin and Normal Saline Dressing in Healing of Diabetic Foot Ulcers

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## ABSTRACT

**Introduction:** Numerous topical medication and gels are promoted for ulcer care and healing. Relatively few have proved to be more efficacious than saline wet to dry dressings. The present study was aimed to compare the effect of topical insulin and normal saline dressing in healing of diabetic foot ulcers.

**Material and methods:** The present one year hospital based randomized controlled trial was conducted in the Department of General Surgery, Rangaraya medical college, Kakinada. A total of 60 patients with diabetic foot ulcers were studied. Based on the envelop method, patients were divided into two groups of 30 patients each that is group A (topical insulin) and group B (normal saline).

**Results:** In this males (66.67% in group A and 83.33% in group B) outnumbered females in both the groups with male to female ratio of 2:1 in group A and 4:1 in group B. The mean age in group A was 52.00 ± 11.00 years and in group B it was 57.00 ± 9.80 years (p=1.000). Among patients with group A significant reduction of mean ulcer area was observed (307.23 ± 169.87 mm<sup>2</sup>) with higher mean percentage reduction (35.19 ± 19.00 percent) whereas in group B the mean percentage reduction was significantly less (18.82 ± 4.06 percent) with less reduction of mean final ulcer area (149.90 ± 64.45 mm<sup>2</sup>) (p<0.001).

**Conclusion:** Overall, topical insulin dressing provided favourable outcome in patients with diabetic foot ulcer by significant reduction in wound area when compared to normal saline dressing and it had positive role in reducing the wound infection if present.

**Keywords:** Diabetic Foot Ulcers, Normal Saline, Topical Insulin, Wound Healing.

## INTRODUCTION

Diabetes results from either defective insulin production or defective action of insulin over the peripheral tissues.<sup>1-3</sup> Diabetic effects range from asymptomatic presentation to its major effects like retinopathy, neuropathy and nephropathy.<sup>4</sup> Diabetes also reduces the immune status and makes the person susceptible to various infections like Staphylococcus aureus and Pseudomonas Aeruginosa.<sup>5</sup> Diabetic foot ulcer is one of the commonest sequelae following trauma or infection mainly around the distal ends of limbs where the vascularity is relatively decreased due to effects of diabetes. Important step in managing diabetic ulcer is offloading the wound by using appropriate therapeutic footwear<sup>6,7</sup> daily saline or similar dressings to provide a moist wound environment,<sup>8</sup> debridement when necessary, antibiotic therapy if cellulitis is present<sup>8,9</sup> optimal control of blood glucose, evaluation and correction of peripheral vascular insufficiency. Numerous topical medication and gels are promoted for ulcer care and healing. Relatively few have proved to be more efficacious than saline wet to dry dressings.<sup>10,11</sup> Insulin stimulates the growth and development of keratinocytes, endothelial cells and fibroblasts and help proliferation, and tissue healing.<sup>12-16</sup> Hence

the present study was undertaken to compare the effect of topical insulin and normal saline dressing in healing of diabetic foot ulcers. The objective of the present study was to compare the effect of topical insulin with normal saline dressing in healing of diabetic foot ulcers.

## MATERIAL AND METHODS

A total of 60 cases from July 2016 to March 2017 were divided into two groups that is, 30 each in topical insulin (Purified human biosynthetic neutral plain insulin) and normal saline were studied. Based on the envelope method patients were randomized divided into two groups that is; Group A (n=30) - Patients in this group underwent dressing with topical insulin Group B (n=30) - Patients in this group underwent dressing with normal saline. Ethical committee approval has been taken from the ethics committee of Rangaraya medical college and government medical college Kakinada for conducting this study.

### Selection criteria

#### Inclusion

- Diabetic patients between the age group of 25 to 70 years.
- Patients having ulcers measuring more than one cm below ankle in dorsum of foot.
- Patients with blood glucose levels between 110 and 130 gm/dL.
- Patients with grade I and II ulcers of Wegener's classification.

#### Exclusion

- Patients with grade III, IV and V ulcers of Wegener's classification.
- Patients with absent peripheral pulses in dorsalis pedis artery, posterior tibial artery, anterior tibial artery.
- Patients who were not on regular follow-up.

#### Blinding

Syringes were filled with normal saline and insulin and were labelled by pharmacist and both patient and surgeon who did the dressing were blinded.

#### Procedure

Wound discharge was sent for culture and sensitivity if present. Empirical antibiotics namely ciprofloxacin and metronidazole

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were started and changed to sensitive antibiotics after sensitivity report. Debridement was done if necessary.

### Dressing

In Group A, one cc normal saline with 10 IU insulin for each 10 cm<sup>2</sup> wound was used.

In group B plain normal saline was used which was one of the standard procedure for ulcer dressings.

Ulcer was assessed by the investigator at the beginning of the study and at the end of the study (Investigator being the staff and residents who were blinded to study). Ulcer mapping was made and size was recorded.

Size was measured twice and mean of both the measurements were considered as size of the wound. The dressing was changed every day. Final wound area was measured on 14 day. During the course of dressing wound was observed for granulation, tissue quality, discharge and control of infection at the end of each week and recorded. Outcome was measured in terms of wound reduction between the two groups. Data was tabulated and the two groups were compared with reference to area and percentage of reduction.

### Statistical evaluation

The study data was analysed to evaluate the effect of topical insulin dressing over saline dressing. SPSS software and Microsoft excel software are used in this analysis. Chi-square test is used to evaluate the results and P value of <0.005 is considered significant.

## RESULT

In this study among patients with group A significant reduction of mean ulcer area was observed (307.23±169.87 mm<sup>2</sup>) with higher mean percentage reduction (35.19 ± 19.00 percent) whereas in group B the mean percentage reduction was significantly less (18.82 ± 4.06 percent) with less reduction of mean final ulcer area (149.90 ± 64.45 mm<sup>2</sup>). The difference between the percentage reduction and reduction of final ulcer area was statistically significant (p<0.001). Diabetic foot ulcers are common and estimated to affect 15% of all diabetic individual during their lifetime. Patient suffering from diabetic ulcer often require hospitalization. One of the major causes of non-healing of ulcer in diabetes is infection. It is caused by a variety of micro-organism. Most common are Staphylococcus aureus and Pseudomonas aeruginosa.

In the present study, the wound culture on day 14 was negative in 73.33% patients in group A compared 56.67% in group B. However no statistically significant difference was observed between the two groups (p=0.176). The most common isolate on day 14 was P. vulgaris in group B (33.33%) and in group A it was E. Coli and P.vulgaris (25%). Overall, in this study, topical insulin dressing provided favourable outcome in patients with diabetic foot ulcer by significant reduction in wound area when compared to normal saline dressing had positive role in reducing the infection if present.

## DISCUSSION

Wounds that results in limited tissue loss, such as surgical wounds, have a tendency to heal rapidly on the surface as opposing edges of the wound are in close proximity for cellular and structural repair. The wound is healed in about a week, but will continue to mature for a year or more. During this time the

Assessment	Group A (n=30)	Group B (n=30)	P value
Reduction in area (mm <sup>2</sup> )	307.23	144.9	<0.001
Percentage reduction (%)	35.19	18.82	<0.001

**Table-1:** Comparison of reduction of ulcer size

structural architecture of the wound changes, the scar usually flattens, and the skin regains most of its pre-wound tensile strength. In wounds where significant tissue loss occurs the damaged edges are usually unsuitable for primary closure. In this case, the tissue defect must be made up before the wound can heal. To facilitate healing, dressings are applied to try to protect the wound from contamination and keep the wound surface moist to maintain the integrity of the cells present in the defect. Where healing is protracted as a result of significant tissue loss (as in deep pressure sores) or due to underlying pathology (venous leg ulcers) chronic wounds occur.

Principles of Surgical Management in diabetic ulcer

1. Early recognition and prompt intervention.
2. Control of blood glucose
3. Complete rest of injured area.
4. Careful but complete debridement and drainage of all involved areas.
5. Appropriate antibiotic coverage
6. Wound care and dressings
7. Appropriate vascular reconstructions
8. Careful follow up including podiatric appliances and modified footwear.

Woost and colleagues have demonstrated an increase in the tensile strength of wounds following 3 daily applications of insulin.<sup>13</sup> The use of topical insulin strongly suggests accelerated wound healing in chronic ulcer, found to be safe and effective without any systemic side effect.<sup>14</sup>

Dressing is one of the important parts of the treatment of the diabetic ulcer. The types of wound dressing used in diabetic foot ulcer are;<sup>12</sup>

1. Traditional dressing--Gauze dressing
2. Modern wound dressing (Occlusive / moist wound dressing)
  - a. Alginate Dressings
  - b. Amorphous hydrogels
  - c. Hydrogel Dressings
  - d. Hydrocolloid Dressings
  - e. Composite Dressings
  - f. Transparent Films

## CONCLUSION

Based on the results in table 1 of the present study it is concluded that, topical insulin dressing provides favourable outcome in patients with diabetic foot ulcer by significant reduction in wound area when compared to normal saline dressing.

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