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

K. Ramarao¹, L. Ramu²

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 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 envelope 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 mm²) 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 mm²) (p=0.001).

Conclusion: Overall, topical insulin dressing provided favorable 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.¹⁻³ Diabetic effects range from asymptomatic presentation to its major effects like retinopathy, neuropathy and nephropathy.¹ Diabetes also reduces the immune status and makes the person susceptible to various infections like Staphylococcus aureus and Pseudomonas Aeroginosa.⁴ 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 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 foot ulcer is offloading the by using appropriate therapeutic footware⁵⁻⁷ daily saline or similar dressings to provide a moist wound environment,⁸ debridement when necessary, antibiotic therapy if cellulitis is present⁹⁻¹⁰ 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.¹¹⁻¹³ Insulin stimulates the growth and development of keratinocytes, endothelial cells and fibroblasts and help proliferation, and tissue healing.¹₂⁻¹⁶ 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

• Patients with grade IV and V ulcers of Wegener's classification.
• Patients who were not on regular follow-up.
• Patients with grade III, IV and V ulcers of Wegener's classification.

Exclusion

• Patients with blood glucose levels between 110 and 130 gm/dL.
• Patients with grade I and II ulcers of Wegener's classification.
• Patients with absent peripheral pulses in dorsalis pedis artery, posterior tibial artery, anteriotibial artery.

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 were given empirically.

Conclusion

Overall, topical insulin dressing provided favorable 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.

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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 cm² 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. SSPS software and Microsoft excel software are used in this analysis. Chi-square test is used 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 mm²) 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 mm²). 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 individuals 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 aeroginosa.

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 not 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.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Group A (n=30)</th>
<th>Group B (n=30)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduction in area (mm²)</td>
<td>307.23</td>
<td>144.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Percentage reduction (%)</td>
<td>35.19</td>
<td>18.82</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Table-1: Comparison of reduction of ulcer size

DISCUSSION
Wounds that result 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 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.

CONCLUSION
Based on the results in table 1 of the present study it is be 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.

REFERENCES
factsheet national estimates and general information on diabetes and prediabetes in the United States, 2011.


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