



Comparison of insulin soaked dressing with the conventional dressing in diabetic ulcers.

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INTRODUCTION

Diabetic foot infections in our society cause a major clinical and financial burden to the diabetic patients.^{1,2} Diabetic foot ulcers are one of the most serious complications of diabetes that can progress very rapidly and turn into gangrene resulting in amputation of the limb.^{3,4} Healing of these ulcers takes dedicated and multidisciplinary efforts but preventing its recurrence is even greater challenge.⁵ These patients stay for longer duration in the hospital which is costly and causes a lot of burden to hospital, patient and family.^{6,7} In such patients the likelihood of lower limb amputation is 10 to 30 times greater amongst people with diabetes than those without diabetes. Diabetic foot ulcer constitutes a major part in all

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ABSTRACT... Objective: This study aims at demonstrating the benefits of insulin soaked dressing for the treatment and accelerating the healing process of diabetic ulcers thus helping the faster wound healing, reducing morbidity and also decrease the cost of management in patients with diabetic ulcers. **Study Design:** Randomized Controlled Trial. **Setting:** Surgical Unit 1, Holy Family Hospital, Rawalpindi Medical University, Rawalpindi. **Period:** November 2016 to May 2017. **Material & Methods:** The study was initiated after approval from the institutional research forum of Rawalpindi medical college. Patients fulfilling the selection criteria reporting at surgical unit – I, Holy Family Hospital, Rawalpindi were included in the study. Written informed consent was taken. Random allocation of the study participants to either study group was done by using lottery method, 60 patients were randomly allocated to either group A (insulin soaked dressing) or Group B (conventional dressing), each with 30 patients. **Results:** In Group A, insulin soaked dressing was applied whereas patients in Group B were applied with conventional dressing. Mean age (years) of patients was 48.04+13.45 whereas there were 32 (53.3) male and 28 (46.7) female patients. In the study, mean duration (day) of complete wound healing in patients with diabetic ulcers receiving insulin soaked dressing and conventional dressing was 39.80 + 8.04 and 47.60+6.52 respectively which was statistically significant (p-value 0.000). **Conclusion:** The study concluded that in patients with diabetic foot ulcer, average duration of complete wound healing was significantly less in patients with insulin soaked dressing as compared to conventional dressing.

Key words: Chronic Wound Care, Foot Ulcer, Insulin Dependent Diabetes Mellitus, Topical Dressings, Wound Healing.

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non-traumatic amputations ranging even up to 85%.⁸

The major constituents of pathophysiology of diabetic ulcer are diabetic neuropathy, vascular insufficiency and infections.⁹ Hyperglycemia is the back bone of the pathogenesis of diabetic ulcers.¹⁰ Over the years the main emphasis in the management of diabetic ulcer is on glycaemic control and the use of broad spectrum antibiotics.¹¹ But due to poor glycaemic control and multidrug resistance the outcome of chronic diabetic ulcers has not been improved significantly.

The basic aim in patients with diabetic ulcers is faster wound healing and saving the limb.¹² So the

cellular and molecular mechanisms that result in wound healing include cell adhesion, migration, proliferation, differentiation, and apoptosis. Any abnormality of these distinct factors can lead to delayed or defective wound healing. The other important aspects like decreased growth factor production, poor angiogenic response, defective macrophage function, faulty collagen accumulation, disruption of epidermal barrier function, and keratinocyte and fibroblast migration and proliferation dysfunction can lead to impaired wound healing.^{13,14} Despite these factors, the defective insulin action in the skin remains important mechanism leading to delayed wound healing in diabetic ulcers.

Recent studies have shown that the use of topical insulin in diabetic ulcers have resulted in faster healing of ulcer and shorter duration of hospital stay as the topical insulin accelerates wound healing in the skin of diabetic patients.^{15,16} The use of topical insulin decreases neutrophil infiltration and causes advanced neutrophil resolution thus promotes neutrophil functions.

Despite several studies and proven benefits of insulin soaked dressing in wound healing, traditional trends for treatment of diabetic ulcers continues. In comparison to conventional dressings, rate and time of healing in insulin soaked dressing is better. A study show that the mean duration of wound healing with insulin dressing was 41.65 days as compared to other dressings (43.50 days). The rate of healing in mm²/day was 46.09 in insulin dressing group as compared to other dressing group (32.24).

Furthermore there is not a single study done locally in Pakistan to demonstrate the beneficial effects of insulin soaked dressing on diabetic ulcers. This study aims at demonstrating the benefits of insulin soaked dressing for accelerating the healing process of diabetic ulcers, reducing morbidity and also decreasing the cost of management in patients with diabetic ulcers.

OBJECTIVE

To compare mean duration of complete wound healing in patients with diabetic ulcers receiving

insulin soaked dressing versus conventional dressing.

MATERIAL & METHODS

A randomized controlled trial was conducted from 6th November, 2016 to 5th May, 2017, after approval from the institutional research forum of RMC. Patients, fulfilling the selection criteria reporting at surgical unit – I, Holy Family Hospital, Rawalpindi were included in the study. Written informed consent was taken for participation in the research project. WHO sample size calculator was used for sample calculation: 60 patients were randomly allocated to either group A or Group B using lottery method, each with 30 patients. In group A patients, insulin soaked dressing was applied while in Group B, conventional dressing was done. Outcome variables were studied including wound healing or not, granulation tissue formation or not, color of wound from yellow or red to pink, edges of ulcer healed or not, area of wound in mm. Patient was followed daily for five days, on alternate days till ten days and then weekly till complete wound healing. All the findings were recorded for each patient on structured Performa. Diabetic patients of ages between 18-65 years, both genders and with diabetic ulcers of Grade I-II (Wegner grade) were taken as inclusion criteria whereas patients with severe infection and exposed bones (Wagner Grade III-V), patients requiring extensive debridement and skin grafting, limb amputations, severe uncontrolled diabetes mellitus and with terminal illnesses like end stage renal disease, decompensated liver disease, myocardial infarction were taken as exclusion criteria of the study.

HbA1c was used for assessment of diabetes control (the percentage of HbA1c of < 8% was considered controlled and > 8% was considered uncontrolled). Insulin Soaked Dressing was considered as a simple gauze piece soaked in regular insulin placed on infected diabetic ulcer and covered with surgical tape. Conventional dressing was considered as a simple gauze piece soaked in normal saline after cleaning with antiseptic material and covered with surgical tape. Diabetic Ulcers included Grade I-II (Wagner's Grading of

Ulcer) ulcers in diabetic patients showing signs of inflammation on clinical examination. Wound healing was defined as the formation of healthy granulation tissue, determined by assessing the clinical improvement, in color (from red or yellow to pink due to formation of healthy tissue), edges (healing of edges), area (decrease in area up to 50% of original ulcer area) and granulation tissue at the base of the ulcer followed up to complete wound healing. Mean number of days for complete healing were calculated. Wagner Grading system for diabetic foot infections includes following grades;

Grade 0 – intact skin.

Grade 1 – superficial ulcer of skin or subcutaneous tissue.

Grade 2 – ulcers extend into tendon, bone or capsule.

Grade 3 – deep ulcer with osteomyelitis or abscess.

Grade 4 – gangrene of toes or forefoot.

Grade 5 – mid foot or hind foot gangrene.

Data was analyzed on SPSS version 22. Descriptive statistics were calculated for both qualitative and quantitative variables. Qualitative variables like gender were expressed as frequencies and percentages. Quantitative variables such as age, controlled/ uncontrolled diabetes, grade of ulcer, type of anti-diabetic drugs, duration of diabetes mellitus and days when wound completely healed was calculated and expressed as means and standard deviation. To compare the mean duration in days till complete wound healing in both study groups, independent samples t-test was applied. P-value < 0.05 was considered statistically significant.

RESULTS

Mean age (years) of 60 patients included in the study was 48.04 SD+13.45. Out of these 60 patients 32 (53.3%) were male and 28 (46.7%) were female.

Distribution of patients with grade I and grade II ulcers were calculated. In group-A, out of 30 patients 18 (60%) had grade I ulcer and 12 (40%) had grade II ulcer, while in group-B out of 30 patients 22(73.33%) had grade I ulcer and 8 (26.66%) had grade II ulcers, Table-I.

Frequency of patient with controlled and uncontrolled diabetes was studied on the bases of HbA1c. Out of 30 patients in Group-A, there were 19 (63.33%) patients who had controlled diabetes while 11 (36.66%) had uncontrolled diabetes. Similarly in Group-B there were 15(50%) patients with controlled diabetes and 15 (50%) patients with uncontrolled diabetes, Table-II.

Frequency of the patients using oral anti-diabetic drugs as compared to subcutaneous insulin was studied in two groups. In group-A patients using oral hypoglycemic agents were 20 (66.66%) and those using insulin were 10(33.33%) while in group-B patients using oral hypoglycemic agents were 21 (70%) and those using insulin were 9 (30%).

Mean duration (years) of patients with diabetic mellitus in this study was 5.32 SD+2.01.

In the study, mean duration (days) of complete wound healing in group A and group B was 39.80 SD+8.04 and 47.60 SD+6.52 respectively. Independent sample t-test was used to compare mean duration (days) of complete wound healing in both the groups which was statistically significant (p-value 0.000), as shown in Table-III.

Grade of Ulcer	Group A	%	Group B	%
I	18	60	22	73.33
II	12	40	08	26.66
Total	30	100%	30	100%

Table-I. Frequency and percentage of Grade of ulcer.

BSR	Group A	%	Group B	%
Controlled	19	63.33	15	50
Uncontrolled	11	36.66	15	50
Total	30	100%	30	100%

Table-II. Frequency and percentage of patients with controlled and uncontrolled diabetes.

	Study groups	n	Mean	Std. Deviation	P-Value
Complete wound healing (days)	Group A (Insulin Dressing)	30	39.80	8.04	0.000
	Group B (Conventional Dressing)	30	47.60	6.52	

Table-III. Comparison of mean duration (days) of Complete Wound Healing in both groups.

DISCUSSION

Diabetic foot infections in our society cause a major clinical and financial burden to the diabetic patients. Diabetic foot ulcers are one of the most serious complications of diabetes that can progress very rapidly to and turn into gangrene resulting in amputation of the limb. Diabetic patients are 25 times more prone to lose a leg than those without diabetes and out of all leg amputations up to 70% occur in people with diabetes. Diabetic patients have much higher duration of hospitalization and cost of management for soft-tissue and bone infections of the foot than patients without diabetes.^{17,18} The different organisms cultured in diabetic ulcers vary not only from one patient to another, but also in different parts of the country. Different microbiological studies have proved that diabetic ulcers are polymicrobial in nature.¹⁹

Defective insulin action in the skin has been proposed as an important mechanism contributing to wound healing defects in this disease.^{20,21} Previous data, although not well controlled, showed that topical insulin accelerates wound healing in the skin of diabetics. It is known that insulin stimulates the growth and development of different cell types like endothelial cells and fibroblasts.^{22,23} At least part of the effects of insulin in the skin may be via canonical signal transduction and we suspect that upon reconstitution of normal insulin signaling in the wounded skin of diabetic subjects, healing may be corrected.²⁴⁻²⁶

In our study, mean age (years) in the study was 48.04 SD+13.45. Similarly, in a study conducted in 2012 found that mean age in year was 40.62 SD+17.37 years. In a study by Shah

et al, frequency and percentage of male and female patients were 15 (65.2) male and 8 (34.8) respectively.⁷ Likewise, in our study there were 32 (53.3) male and 28 (46.7) female patients. In our study, mean duration (in days) of complete wound healing in both the groups i.e. patients with diabetic ulcers receiving insulin soaked dressing and conventional dressing was 39.80 SD+8.04 and 47.60 SD+6.52 respectively. Similarly, in a study conducted by Rezvani et al, observed that mean duration of wound healing (in days) with insulin dressing was 41.65 SD+20.56 days and with conventional dressings was 43.50 SD+22.85 days.³ In another study by Goneka et al¹⁰ the mean duration (in days) of complete wound healing was 38 ± 17.03 days in Group A (insulin group) and 44.3 ± 17.5 days in Group B (normal saline group).²⁷

CONCLUSION

The study concluded that average duration of complete wound healing in patients with insulin soaked dressing group was significantly less as compared to conventional dressing group. Further studies must be done in the multiple setups to demonstrate the beneficial effects of insulin soaked dressing on diabetic ulcers for the improved treatment and accelerating the healing process. It will help to reduce the morbidity and the cost of management in patients with diabetic ulcers.

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











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3	Usman Qureshi	Material and methods data analysis.	
4	Usman Akram	Collection of data.	
5	Syed Waqas Hassan	Statistical expertise.	
6	Naqash Adnan	Discussion and conclusion.	
7	Ahmed Mujtaba Malik	Collection of data.	
8	Raheel Ahmad	Discussion and conclusion.	
9	Sara Malik	Introduction writing.	
10	Jahangir Sarwar Khan	Conception of idea, Final approval and guarantee.	
11	Gohar Rasheed	Proof reading, Statistical expertise.	
12	Munazzah Aziz	Introduction writing.	
13	Asma Mehr	Reference filing.	