

EFFECTIVENESS OF TOPICAL INSULIN DRESSINGS VS NORMAL SALINE DRESSING IN THE MANAGEMENT OF DIABETIC FOOT ULCER

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Abstract: Diabetic foot ulcers (DFUs) represent a significant complication of diabetes mellitus, often leading to severe morbidity and increased healthcare costs. **Objectives:** The main objective of this study is to evaluate the effectiveness of topical insulin dressings versus normal saline dressings in the management of diabetic foot ulcers. **Methods:** This randomized controlled trial was conducted at Khyber Teaching Hospital, Peshawar, from 13th August 2023 to 3rd December 2023. Data were collected from 245 patients suffering from diabetic foot ulcers. Patients in group A received dressings with regular insulin (at a concentration of 0.1 U/cm² of ulcer area) applied directly to the ulcer, and patients in group B received dressings soaked in normal saline. Both groups received standard diabetic foot care, including debridement, offloading, and management of blood glucose levels. **Results:** Data were collected from 245 patients. The mean age of patients in the topical insulin group was 58.2 ± 10.4 years, and in the normal saline group, it was 59.1 ± 11.2 years. The mean duration of diabetes mellitus was 12.6 ± 6.3 years in the insulin group and 13.1 ± 5.9 years in the saline group. Baseline ulcer size was 4.5 ± 2.1 cm² in group A and 4.7 ± 2.3 cm² in group B. The insulin group showed a 65.3% reduction in ulcer size compared to 45.8% in the saline group (p<0.001), and ulcers healed faster, averaging 9.2 weeks versus 12.8 weeks (p<0.001). **Conclusion:** Topical insulin dressings are significantly more effective than normal saline dressings in the management of diabetic foot ulcers.

Keywords: Diabetic foot ulcer, insulin dressing, normal saline dressing, wound healing, randomized controlled trial.

Introduction

Diabetic foot ulcers (DFUs) represent a significant complication of diabetes mellitus, often leading to severe morbidity and increased healthcare costs. Effective management of these ulcers is crucial to prevent infections, and amputations, and improve the quality of life for affected individuals. Among the various treatment strategies, wound dressings play a pivotal role. Traditional methods such as normal saline dressings have been widely used due to their simplicity and cost-effectiveness(1). However, innovative approaches, including the application of topical insulin, have shown promise in enhancing wound healing through insulin's potential trophic effects on skin cells (2). Diabetes is a chronic and systemic disease that affects the metabolism and is defined by elevated levels of blood glucose or blood sugar, and therefore, significant harm, to microvascular, and macrovascular diseases (3). The two main varieties are type 1, usually among the young, where the body does not produce adequate insulin, and type 2, in adults, where the body tries to resist the insulin impressed upon it. The increase in the incidence of Type 2 diabetes over the last three decades has been observed in all nations of developed, developing, and even the least developed (4). To be precise, the global trend to cut down the rise of diabetes and obesity by the year 2025 has been set. A large number of people are from South Asia, which has a much higher prevalence of type-2 diabetes mellitus (T2DM) (5). Specifically, South Asians have 50% higher rates of diabetes than the remainder of the global population Group. Diabetic foot ulcers with infection are always a challenge for the surgeon and also a

cost factor for the patient and state in the aspect of the increase of stay in the hospital and cost of the medicines and dressings. There have been different techniques used in treating infected wounds in history with diversities in the effects being produced on different patients (4). Consequently, the goal of the present research is to examine the efficacy of adopting topical insulin on diabetic foot ulcers compared to Pyodine® povidone iodine dressing. Diabetic foot disease is one of the topics that many patients in surgical wards present with and can be the first indication of this devastating condition (6). There is an acknowledgement that patients with diabetes mellitus have a higher likelihood of developing complications in their lower limbs than people without diabetes (7). It has been estimated that for diabetic patients 5% of them are likely to develop foot ulcers every year. About 15 per cent of diabetic patients are affected by some or the other foot problems in the course of their sickness. The complications of foot ulcers are that they could lead to major amputation affecting 25% of patients (8). Thus, diabetic foot disease has considerable health, social and economic implications. Stretching demands, and a thorough adherence to measures if not followed, will take a longer period in the hospital. According to various research, it has been determined that this complication has the longest duration of hospital admission compared to other forms of diabetes complications (9).

Thus the main objective of the study is to find the effectiveness of topical insulin dressings vs normal saline dressings in the management of diabetic foot ulcers.

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Methodology

This randomized controlled trial was conducted at Khyber Teaching Hospital, Peshawar, from 13th August 2023 to 3rd December 2023. The study aimed to compare the effectiveness of topical insulin dressings versus normal saline dressings in managing diabetic foot ulcers. The inclusion criteria were: age ≥ 18 years, diagnosed with type 1 or type 2 diabetes mellitus, presence of at least one diabetic foot ulcer classified as Wagner grade 1 or 2, ulcer duration of at least 4 weeks, and adequate blood supply to the affected limb confirmed by an ankle-brachial index (ABI) between 0.7 and 1.3. Exclusion criteria included ulcers classified as Wagner grade 3 or higher, active infection or osteomyelitis at the ulcer site, systemic infection, and known allergy to insulin.

Data were collected from 245 patients who met the inclusion criteria and agreed to participate in the study. Patients were randomly assigned to one of two groups: Group A (Topical Insulin Dressing Group) with 122 patients, and Group B (Normal Saline Dressing Group) with 123 patients. Patients in Group A received dressings with regular insulin applied directly to the ulcer at a concentration of 0.1 U/cm² of the ulcer area. Patients in Group B received dressings soaked in normal saline. Both groups received standard diabetic foot care, including

debridement, offloading, and management of blood glucose levels.

Ulcer size, including area and depth, was measured at baseline and weekly using digital planimetry and standardized depth measurement tools. Infection rates were monitored through regular clinical assessments and microbiological cultures as needed. Pain levels and patient satisfaction were recorded at baseline, midpoint, and the end of the study. Statistical analysis was performed using SPSS version 29. A p-value of < 0.05 was considered statistically significant. Data analysis included comparisons of ulcer size reduction, healing time, infection rates, pain levels, and patient satisfaction between the two groups. This comprehensive methodology ensured a thorough evaluation of the effectiveness of topical insulin dressings compared to normal saline dressings in the management of diabetic foot ulcers.

Results

Data were collected from 245 patients. The mean age of patients in the topical insulin group was 58.2 ± 10.4 years and the normal saline group was 59.1 ± 11.2 years. The mean duration of DM was 12.6 ± 6.3 years and 13.1 ± 5.9 years respectively in both groups. Baseline ulcer size was 4.5 ± 2.1 cm² in group A and 4.7 ± 2.3 cm² in group B. (Table 1)

Table 1: Demographic data of patients

Characteristic	Topical Insulin Dressing (n=122)	Normal Saline Dressing (n=118)
Age (years)	58.2 ± 10.4	59.1 ± 11.2
Male (%)	65 (53.3%)	63 (53.4%)
Duration of diabetes (years)	12.6 ± 6.3	13.1 ± 5.9
Baseline ulcer size (cm ²)	4.5 ± 2.1	4.7 ± 2.3
Ulcer duration (weeks)	8.4 ± 3.5	8.6 ± 3.8

The insulin group showed a 65.3% reduction in ulcer size compared to 45.8% in the saline group (p<0.001), and ulcers healed faster, averaging 9.2 weeks versus 12.8 weeks (p<0.001). Additionally, the insulin group had a greater reduction in ulcer depth (58.7% vs. 39.5%, p<0.001), fewer

infections (9.8% vs. 21.2%, p=0.01), lower pain levels (VAS score 2.3 vs. 4.1, p<0.001), higher patient satisfaction (8.4 vs. 6.9, p<0.001), and better quality of life scores (7.8 vs. 6.5, p<0.001). (Table 2)

Table 2: Reduction in ulcer size and outcomes

Reduction in ulcer size	Topical Insulin Dressing	Normal Saline Dressing	p-value
Percentage reduction in ulcer size (%)	65.3 ± 15.4	45.8 ± 18.7	<0.001
Outcome Measure			
Time to complete healing (weeks)	9.2 ± 3.1	12.8 ± 4.4	<0.001
Percentage reduction in ulcer depth (%)	58.7 ± 14.2	39.5 ± 17.5	<0.001
Incidence of infections (%)	12 (9.8%)	25 (21.2%)	0.01
Pain level (VAS score)	2.3 ± 1.1	4.1 ± 1.6	<0.001
Patient satisfaction score	8.4 ± 1.2	6.9 ± 1.7	<0.001
Quality of life score	7.8 ± 1.5	6.5 ± 1.9	<0.001

Mild skin irritation occurred in 4.1% of patients in the topical insulin dressing group and 5.9% in the normal saline dressing group (p=0.56). No severe adverse events were

reported in either group. This indicates that both treatments were generally well-tolerated by patients. (Table 3)

Table 3: Adverse events in both groups

Adverse Event	Topical Insulin Dressing (n=122)	Normal Saline Dressing (n=118)	p-value
Mild skin irritation (%)	5 (4.1%)	7 (5.9%)	0.56
Severe adverse events (%)	0 (0%)	0 (0%)	

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Discussion

The results of this randomized controlled trial demonstrate that topical insulin dressings are significantly more effective than normal saline dressings in the management of diabetic foot ulcers (DFUs). As for the anabolic and growth-promoting effects of insulin, they have been closely related to the regular application of topical insulin which has resulted in improved healing rates (1). Insulin facilitates glucose and amino acids transport and protein synthesis in various human cells; which is pertinent to tissue repair. These effects probably translate to earlier closure of wounds as well as better results as evidenced by the insulin-treated group. Our results conform with previous studies in showing that insulin may be an advantage in matters related to wound healing (10). It should be noted that previous research has revealed the ability of topical insulin to stimulate granulation tissue formation, decrease inflammation and stimulate angiogenesis. It is also a fact that insulin has anti-inflammatory effects in its repertoire that could help one prevent infection and reduce bacterial load in case of ulcer-causing bacteria and therefore, there being lesser incidence of what can be attributed to infections that the bacteria under discussion caused in the insulin group (11). Diabetes mellitus, as defined by the American Diabetes Association, is a metabolic disorder of multiple etiologies with disturbed glucose homeostasis leading to high blood glucose levels that can cause significant harm over time through microvascular and macrovascular complications. The type most often seen is type 2 diabetes more common in adults where the body is unable to produce the necessary insulin or cannot use properly the insulin that is produced. More alarming is the fact that, over the past three decades, the rate of type 2 diabetes has increased across developed, developed, and developing countries (12). Diabetes, obesity and other non-communicable diseases are increasing substantially; according to the United Nations sustainable development goals, there is an objective to stop the rise in diabetes and obesity by 2025. South Asians constitute about 1/5th of the total population of the global community and they are known to have a higher prevalence of type-2 diabetes mellitus (T2DM) (13). About the general population, South Asians are considered to have a 1.5 times higher propensity of having type 2 diabetes. Research has indicated differing outcomes when insulin-containing dressings are applied as opposed to other dressing types with improved results in definitive statistical status (14). Duration of Topical Insulin Dressing is taken around about 5 days in every patient. 68 ± 2.45 days. While there is honey dressing which totals 14.4 ± 6 . Salad type Duration Tomato dressing 5 days Cucumber dressing 3 days Scramble dressing 12 days Other dressing 25 days Papaya dressing 6 days 23 ± 3 (14). The number of days taken to prepare hydrochloric acid solution is 62 whereas that of povidone is 12 and the concentration of povidone is 15.4 ± 6.4 days. Nonetheless, there is no direct contact made with any form of topical insulin dressing with any of these dressings available here. Normal saline is a commonly used dressing in our set-up (15).

Conclusion

It is concluded that topical insulin dressings are significantly more effective than normal saline dressings in

the management of diabetic foot ulcers. The insulin dressings enhance wound healing, reduce infection rates, alleviate pain, and improve patient satisfaction and quality of life. These findings support the potential of topical insulin as a superior therapeutic option for diabetic foot ulcer care.

Declarations

Data Availability statement

All data generated or analyzed during the study are included in the manuscript.

Ethics approval and consent to participate.

Approved by the department concerned. (IRB/KTHBA/823 dated 22-10-21)

Consent for publication

Approved

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Conflict of interest

The authors declared an absence of conflict of interest.

Authors Contribution

Afra Khan (Resident Surgeon)

Final Approval of version & Design of Study

Muhammad Zarin (Professor)

Revisiting Critically

Khadeeja (Resident Surgeon)

Data Analysis & Drafting & Concept

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