DOI: https://doi.org/10.53350/pjmhs0202418132

ORIGINAL ARTICLE

Comparative Analysis of Topical Insulin Dressing Vs Normal Saline Dressing in Diabetic Foot Ulcers Wound Healing

LYBA GHAYOUR[1], FAIZA IREM[2], BASEERULLAH[3], ADNAN RIAZ[4], ABRAR ASHRAF ALI[5]
[1]*Senior Registrar General Surgery, Fatima Memorial Hospital Lahore*
[2]*Assistant Professor, Biochemistry Department, Fatima Jinnah Medical University, Lahore*
[3]*Registrar General Surgery, Cancer Care Hospital, Lahore*
[4]*Assistant Professor, Department of Biochemistry, Islam Medical College Sialkot*
[5]*Professor of General Surgery, South Surgical ward Mayo Hospital/King Edward Medical University Lahore*
Correspondence to Dr Lyba Ghayour, Email: Lyba_ghayour@hotmail.com, Cell:+923316340731

ABSTRACT

Background: Foot ulcers, a dangerous and common consequence of diabetes, currently have no particular therapeutic options. There are many topical medicines and ointments available for wound management.It has been observed that topical insulin dressings effectiveness is better than other dressings.
Aim: To determine the effectiveness of Topical Insulin dressing VS Normal saline dressing in diabetic ulcer in terms of rate of reduction in ulcer area in days and need for re debridement
Methods: A randomized control trial conducted in Emergency and Outdoor Department of South Surgical ward, Mayo Hospital, Lahore.Study was carried out insix months from Sept 2022 to March 2023. A total 86 patients fulfilling the selection criteria presented to outdoor/Emergency of South surgical department of general surgery of Mayo Hospital, Lahore falling in Wagner's classification I and IIwere enrolled in the study after taking informed consent. Patients were divided by method of random allocation (lottery method) to Group A (Topical insulin dressing) and Group B (Normal saline soaked dressing) after explaining the procedure. Rate of reduction in ulcer area was measured in days. Need of re-debridement was labeled as 'yes' if patient needed re-debridement or 'no' if patient did not need re-debridement.
Results: Baseline mean wound area in Group A and in Group B was 34.87±29.23 cm^2 and 27.45±24.00cm^2. After 2 weeks the wound area reduced to 9.35±10.75 cm^2 and 7.33±9.29 cm^2 respectively. Mean days for rate of reduction in ulcer areas was significantly less in Group A patients than in Group B patients (p-value<0.001). Rate of re-debridement for Group B patients was significantly higher than patients in Group A (Group A: 18.6% vs Group B: 46.5%, p-value= 0.006). Improved wound healing will reduce need of redebridement and minor to major foot amputations.
Conclusion: This study concludes that topical insulin dressing is more effective as that of normal saline soaked dressing for management of diabetic ulcer in terms of rate of reduction in ulcer area in term of days and need for re debridement.
Keywords: Effectiveness, Normal saline Dressing, Topical Insulin dressing, Diabetic foot ulcer, Ulcer area, Re-debridement.

INTRODUCTION

Diabetes is on rise worldwide[1]. Patients with diabetes have a 15-20% lifetime chance of having a diabetic ulcer[2]. The prevalence of foot ulcers in diabetic patients is 6.3% globally, with males having a rate of 4.5% vs females' 3.5%, and rate of 6.4% in diabetes mellitus type II patients and rate of 5.5% in diabetes mellitus type I patients. In Pakistan, 13.9% of diabetic foot ulcers have been observed[3]. Non-healing ulcers leading to non-traumatic lower extremity amputations are becoming more prevalent in diabetic patients.

Diabetic foot ulcer is multi factorial in nature. Diabetic foot ulcers of about 45-60% are neuropathic, while the remaining 45% are of mixed ischemic and neuropathic components. It is believed that 15-27% of diabetic patients require limb amputations, the majority of which are secondary to infection[2]. It is expected that effective education regarding risk factors and foot care can prevent 50% of the foot ulcers in diabetic patients[4].

The importance of wound healing and patient's physiological status in diabetic patients mandates the use of the best treatment options depends on the type and complexity of wound[2].

Chronic diabetic wounds, in our setup are treated with debridement if necessary, regular wound dressing following a thorough wash with hydrogen peroxide, povidone iodine, normal saline and empirical antibiotics after culture and sensitivity testing[5].

Normal Saline is commonly used irrigating agent which helps in wound cleansing. Thorough wound wash with normal saline helps in cleaning wound, removing dead and necrotic surface and removing debris and bacteria. It also provides moist environment which helps keratinocytes to travel across wound surface and helps in wound healing.

Received on 12-08-2023
Accepted on 03-01-2024

Topical Insulin dressing help in healing of wound by accelerating growth, development and proliferation of different kind of cells which include endothelial cells, keratinocytes and fibroblasts[6,7].

Studies have shown the results with topical insulin dressings are encouraging and statistically significant as compared to other dressing types[8,9]. Average healing time of topical insulin dressing is 5.68±2.45 days.[10] Whereas, honey dressing is 14.4±6.6 days[11], Papaya dressing is 19.23±3.62 days[12] and povidone is 15.4±6.4 days.[11] However, there is no direct comparison of topical insulin dressing with any of these dressings available. The commonly used dressing in our setup is normal saline. The randomized control trial studies available nationally and internationally had patients with wide range of foot ulcer disease (Wagner's classification 1-4) and use of normal saline in both control and experimental groups in addition to topical insulin dressings.

Hence, the study is being carried out by eliminating both these factors and to find evidence in our setting and support literature for utility in the wider prospective.

MATERIALS AND METHODS

The study was carried out in South Surgical Ward, Mayo hospital ward, Lahore from March 2022 to Sept 2022. After IRB permission, a Sample Size (estimating the difference of two population propositions) of 86 patients was calculated. Non probability convenient sampling employed to collect data as per inclusion and exclusion criterion after taking informed consent.

Inclusion Criteria

- Type II diabetic patients between age group of 25-70 years.
- Patients of either gender.
- Patients having foot ulcers falling in grade I and II of Wegner's classification.
- Patients with random blood glucose level between 110-200mg/dl.

Exclusion Criteria

- Patients not willing to join study.
- Patients with peripheral vascular disease.
- Patients on immunosuppressive agents.
- Patients with uncontrolled diabetes random blood glucose level more than 200mg/dl.
- Patients with IHD, hypertension, CLD, chronic renal disease.

Bio-data and clinical history was taken from all the patients, investigations were checked. Patients falling in Wagner's classification I and II with a random blood glucose range from 110-200mg/dl were enrolled. Patients were then divided by method of random allocation (lottery method) to either Group A or Group B after explaining the procedure, where Group A patients underwent topical insulin dressing and Group B patients underwent normal saline dressing.

Rate of reduction in ulcer area was measured in days when the ulcer area starts reducing that day is noted and results were interpreted at the end of two weeks. Ulcer area was measured by placing a disposable ruler adjacent to it but not covering the wound edge, and perpendicular to the camera lens and taking the photographic evidence. Need of re-debridement was labeled as 'yes' if patient needs re-debridement or 'no' if patient do not need re-debridement. All the information was noted on proforma.

Data was entered in SPSS–26. Quantitative variables like age, and reduction in ulcer area was presented as mean ±SD. Qualitative variables like gender and need for re-debridement was presented as frequency & percentages. Comparison of two groups (control and experimental) was done with the help of Chi-square test. P-value ≤ 0.05 was taken as significant.

RESULTS

Mean age of patients in Group-A and in Group-B in Fig 1

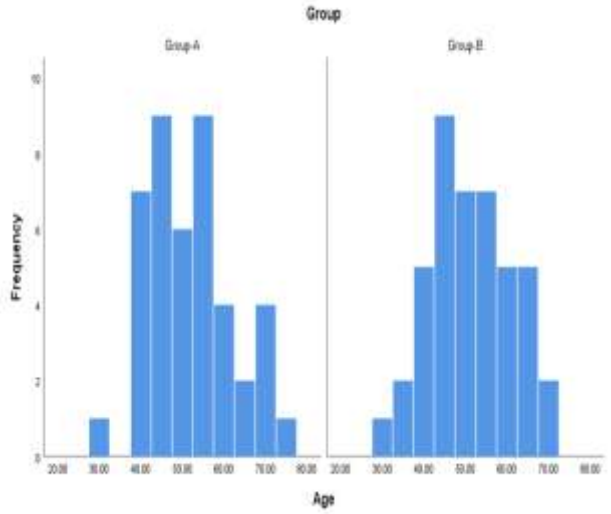

Table-I: Gender of Patients in Treatment Groups

	Group A	Group B	Total
Male	36(83.7%)	32(74.4%)	68
Female	7(16.3%)	11(25.6%)	18
Total	43	43	86

Group A: Topical Insulin dressing Group B: Normal Saline dressing

Table-II: Wound Area at baseline in Treatment Groups(cm^2)

	Group A	Group B
N	43	43
Mean	34.87	28.73
SD	29.23	23.07
Minimum	4	4
Maximum	91	77

Group A: Topical Insulin dressing Group B: Normal Saline dressing

In Group-A 36(83.7%) were male and 7(16.3%) were female. While in Group-B 32(74.4%) were male and 11(25.6%) were female (Table I). Mean wound size at baseline in Group-A and in Group-B was 34.87±29.23 and 28.73±23.07 (Table II). Mean wound size in Group-A and in Group-B when granulation tissue starts was 26.27±23.76 and 21.95±19.33 respectively (Table-III).

Table-III: Wound Area when granulation starts appearing(cm^2)

	Group A	Group B
N	43	43
Mean	26.27	21.95
SD	23.76	19.33
Minimum	1.80	2.25
Maximum	71.38	64.50

Group A: Topical Insulin dressing Group B: Normal Saline dressing

Mean wound size at the end of two weeks in Group-A and in Group-B was 8.21±7.02 and 11.34±7.00 respectively. Table-IV

Table-IV: Wound Area at the end of two weeks in Treatment Groups(cm^2)

	Group A	Group B
N	43	43
Mean	8.21	11.34
SD	7.02	7.00
Minimum	1.44	5.84
Maximum	24.56	32.40
p-value	0.042	

Group A: Topical Insulin dressing Group B: Normal Saline dressing

Mean days for rate of reduction in ulcer area in Group-A and in Group-B was 3.20±1.24 and 4.95±2.01 respectively. Mean days of for rate of reduction in ulcer areas was significantly lower for Group-A patients as that of Group-B patients i.e., (p-value<0.001) (Table-V).

Table-V: Rate of reduction in ulcer area (Days) in Treatment Groups

	Group A	Group B
N	43	43
Mean	3.20	4.95
SD	1.24	2.01
Minimum	1	2
Maximum	7	10
p-value	<0.001	

Group A: Topical Insulin dressing Group B: Normal Saline dressing

Rate of re-debridement was significantly higher for Group-B patients when compared with Group-A patients. i.e. (Group-A: 18.6% vs. Group-B: 46.5%, p-value=0.006) (Table-VI).

Table-VI: Re-debridement in Treatment Groups

	Group A	Group B	Total
Yes	8(18.6%)	20(46.5%)	28
No	35(81.4%)	23(53.5%)	58
Total	43	43	86
p-value	0.006		

Group A: Topical Insulin dressing Group B: Normal Saline dressing

DISCUSSION

Foot ulcers are prevalent in diabetic patients and they commonly result in lower extremity amputation until and unless a wise and timely multidisciplinary approach is implemented. Foot ulceration is a resource intensive, debilitating illness that is frequently the first step toward lower limb amputation in diabetic patients. The best therapy is prevention[6]. Topical dressings are the first line of treatment options for diabetic foot ulcers.

In our study, we compared topical insulin dressing to standard saline dressing in diabetic foot ulcers in terms of rate of ulcer area reduction in days and requirement for re debridement. The rate of reduction in ulcer area in days (Group-A: 3.20 vs Group-B: 4.95, p-value 0.001) and incidence of re-debridement (Group-A: 18.6% vs Group-B: 46.5%, p-value=0.006) was

substantially greater for patients who were treated with standard saline dressing in our study.

In terms of mean reduction in ulcer surface area, studies have found that insulin yield better results than normal saline dressing.[7] In our study the mean ulcer area at the start of study was 34.87cm^2 in topical insulin group and 28.73cm^2 in normal saline group and at the end of two weeks it reduced to 8.21cm^2 in topical insulin group and 11.34cm^2 in normal saline group. The mean difference in reduction area at the start of our study was 6.1 cm^2 which reduced to 3.1cm^2 at the end of two weeks which is statistically significant. Whereas, in a study conducted by Parsad et al (2018)[8], the mean ulcer area at the start of study was 13cm^2 in topical insulin group and 14.5cm^2 in normal saline group measured by visual scoring. The mean difference before treatment was 1.51cm^2 and after treatment (at the end of two weeks) the mean surface areareduced to 8.94cm^2 and 11.6cm^2 respectively with a mean difference of 2.66cm^2 which was statistically significant[8]. In results are comparable & significant and difference in results may be due to difference in selection criterion. We used Wagner's classification of diabetic foot ulcergrade I and II whereas; he has used University of Texas classification in his study. Moreover, he has debrided every wound whereas, we have debrided only those wound that needed debridement and he has estimated wound size by visual scoring whereas, we have used disposable scale to minimize the measuring error.

In another study conducted by Sanjay P et al, 2018, the effectiveness of topical insulin was compared with normal saline dressing. In their study the mean percentage reduction in ulcer area at the end of two weeks was 70% in topical insulin group and 25% in normal saline group. Whereas, in our study the mean percentage reduction in ulcer area at the end of two weeks was 76.5% in topical insulin group and 60.5% in normal saline group. Our study yields better results in term of percentage reduction in ulcer area than their study as we have specified Wagner's I and II grade of diabetic foot ulcer[13] whereas,he used grade I to grade IV of Wagner's ulcers which include gangrene of forefoot which leads to variable results. Moreover, they used 4IU of insulin in 1ml of normal saline and compared with normal saline dressing as control group.[9] whereas, we have used 10 units of regular insulin in one ml of distilled water for each 10 cm^2 area of wound and covered it with cling film. The use of distilled water in study group in our study reduces the bias when compared with saline group as a control.

In another study, Zhang Z and LVL in 2016, effectiveness of local insulin injection in wound vascularization in diabetic foot ulcer. He observed growth of granulation tissue which was13.38% at day 5, and 59.06% at day 12 in insulin treated group whereas, in normal saline group it was 12.98% at day 5, and 23.61% at day 12 of his study[14]. Whereas, in our study the growth of granulation tissue was 24.7% observed at day 3 in topical insulin group and 23.5% in normal saline treated group at day 5. By the end of two weeks, it was 76.5% in topical insulin group and 60.5% in normal saline group.

Our study yields better results in terms of early appearance of granulation tissue in term of days as mean days for reduction in ulcer area and was significantly lower in insulin treated group vs. saline treated wounds i.e. ($p<0.001$)and we have achieved more percentage reduction of ulcer area as compared to his study within same duration. The main reason was in their studythey injected half of insulin diluted in normal saline at the base of the ulcer and rest half of insulin subcutaneously in abdominal wall.Whereas, we have used 10 units of regular insulin in one ml of distilled water for each 10 cm^2 area of wound and covered it with cling film. The use of distilled water in study group in our study reduces the bias when compared with saline group as a control. Thus, our study yields better outcome when insulin was applied topically on the wound, without causing hypoglycemia or other side effects.

In terms of need for re-debridement,our study yields better results as in our study the rate of re-debridement was significantly higher for Group-B (normal saline) patients when compared with Group-A (topical insulin) patients i.e., (Group-A: 18.6% vs. Group-B: 46.5%, p-value=0.006) whereas, in study conducted by Sanjay P and et al, 2018[9], 40% of insulin group needed re-debridement and 18% in saline group needed re-debridement. These results are comparable and significant[9]. In their study, they included grade I-IV ulcers of Wagner's classification which include gangrene of forefoot where as we have included grade I and II diabetic ulcers of Wagner's classification which yields better outcome.

CONCLUSION

As per results obtained it can be concluded that topical insulin dressing proved to be more effective as that of normal saline dressing in the management of diabetic foot ulcer in terms of rate of reduction in ulcer area in days and need for re debridement.

Authorship and contribution declaration: Each author of this article fulfilled following Criteria of Authorship:

1. Conception and design of or acquisition of data or analysis and interpretation of data.
2. Drafting the manuscript or revising it critically for important intellectual content.
3. Final approval of the version for publication.

All authors agree to be responsible for all aspects of their research work.

Conflict of interest: None
Funding: None

REFERENCES

1. Lim JZM, Ng NSL, Thomas C. Prevention and treatment of diabetic foot ulcers. Journal of the Royal Society of Medicine. 2017;110(3):104-9.
2. Kavitha KV, Tiwari S, Purandare VB, Khedkar S, Bhosale SS, Unnikrishnan AG. Choice of wound care in diabetic foot ulcer: a practical approach. World journal of diabetes. 2014;5(4):546.
3. Khan A, Junaid N. Prevalence of diabetic foot syndrome amongst population with type 2 diabetes in Pakistan in primary care settings. JPMA. 2017;67(1818).
4. Yazdanpanah L, Nasiri M, Adarvishi S. Literature review on the management of diabetic foot ulcer. World journal of diabetes. 2015;6(1):37.
5. Kulkarni SB, Venkatesh S, Kruthi S. Saline dressing versus povidone iodine dressing in chronic diabetic foot ulcer healing: a prospective comparative study. International Surgery Journal. 2019;6(5):1524-7.
6. Kamat VV, Sunil C. A comparative study between topical insulin versus normal saline dressings in wound healing in diabetic foot ulcers. International Journal of Surgery. 2019;3(1):26-32.
7. Swaminathan R. Effectiveness of topical insulin in management of chronic diabetic foot ulcers. Indian Journal of Basic and Applied Medical Research. 2014;3(3):455-9.
8. Prasad A, Thomas AA, Mahadevan D. To Study The Efficacy of Topical Insulin Vs Conventional Dressing on Wound Healing In Diabetic Foot Ulcers. Journal of Dental and Medical Sciences. 2018;17(4):33.
9. Sanjay P, Sandeep K, Vishal M, Sumit K, Avirl T, Ankit G. Efficacy of Topical Insulin Dressings V/S Normal Saline Dressing on Diabetic Foot Ulcer-A Hospital Based Study. IOSR J Dent Med Sci. 2018;17:47-50.
10. Thakur PB, Ramachandrudu T, Takalkar AA. A study of effectiveness of topical insulin on healing of diabetic ulcers at tertiary health care centre: a cross sectional study from Puducherry. International Surgery Journal. 2020;7(3):857-60.
11. Shukrimi A, Sulaiman A, Halim A, Azril A. A comparative study between honey and povidone iodine as dressing solution for Wagner type II diabetic foot ulcers. Med J Malaysia. 2008;63(1):44-6.
12. Ch IM. Role of papaya dressings in the management of diabetic foot ulcers. Journal of Rawalpindi Medical College. 2014;18(1):87-9.
13. Jalilian M, Shiri S. The reliability of the Wagner Scale for evaluation the diabetic wounds: A literature review. Diabetes & Metabolic Syndrome: Clinical Research & Reviews. 2021 Dec 13:102369.
14. Zhang Z, Lv L. Effect of local insulin injection on wound vascularization in patients with diabetic foot ulcer. Experimental and therapeutic medicine. 2016 Feb 1;11(2):397-402

This article may be cited as: Ghayour L, Irem F, Baseerullah, Riaz A, Ali AA: Comparative Analysis of Topical Insulin Dressing Vs Normal Saline Dressing in Diabetic Foot Ulcers Wound Healing. Pak J Med Health Sci, 2024;18(1): 32-34.