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Original Article

Comparison of Oxoferrin (Tetrachlorodecoxide) Drops Dressing versus Normal Saline Dressings in Management of Diabetic Foot Ulcers

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ABSTRACT

Objective: To compare the wound outcome of "Oxoferrin (Tetrachlorodecoxide) drops dressing" versus "normal saline dressings" in management of diabetic foot ulcers.

Study Design: Quasi-experimental study.

Place and Duration of Study: Pakistan Air Force Hospital Mushaf, Sargodha Pakistan, from May 2023 to Feb 2024.

Methodology: We included 210 patients with diabetic foot ulcers. 10 patients were excluded making final sample of 200 which were divided into "Oxoferrin (Tetrachlorodecoxide) drops dressing" & "normal saline dressings" Groups. Patients were treated for four weeks and were then assessed for outcomes.

Results: No difference was observed between Groups for baseline size of wound (p=0.809). "Size of wound" after four weeks of therapy in "Oxoferrin (Tetrachlorodecoxide) drops dressing" Group (A) was 131.70±11.83 cm^2 while in "normal saline dressings" Group (B) it was 151.74±13.22 cm^2, (p<0.001). Mean reduction in size of wound and % reduction in size of wound was significantly greater in "Oxoferrin (Tetrachlorodecoxide) drops dressing" Group, (p<0.001). Median patient satisfaction VAS in "Oxoferrin (Tetrachlorodecoxide) drops dressing" Group (A) was 9(7-9) while in "normal saline dressings" Group (B) it was 6(3-9), (p<0.001).

Conclusion: "Oxoferrin (Tetrachlorodecoxide) drops dressing" provides better wound outcomes and patient satisfaction in management of "diabetic foot ulcers".

Keywords: Diabetic Foot, Granulation Tissue, Oxoferrin, Wagner Grade.

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INTRODUCTION

"Diabetic foot ulcers" are a devastating consequence of diabetes mellitus that drastically lowers a patient's life quality.[1] The most prevalent factors contributing to the development of "diabetic foot ulcers" include inadequate control of the patient's blood sugar levels, preexisting diagnoses of "diabetic vasculopathy" or "diabetic neuropathy" in conjunction with diabetes and inadequate foot hygiene.[2] Amputations of the lower extremities and "osteomyelitis" of the foot are additional devastating complications associated with these ulcers. "Diabetic foot ulcers" tend to manifest predominantly in regions of the foot that experience repeated trauma.[3] The prevalence of diabetes foot has exhibited an upward trend over the years, resulting in an estimated annual occurrence of roughly 26.1 million cases of diabetic foot ulcers at healthcare institutions worldwide.[4,5]

In the management of diabetic foot ulcers, surgical debridement is often the preferred treatment option selected by healthcare professionals to enhance patient outcomes. The effectiveness of this approach is contingent upon several factors, such as the patient's age, duration for which patients have diabetes and the severity of co-existent diabetes-related complications. When these factors coexist, they can have a detrimental effect on both wound healing and the overall well-being of the patient.[6] Another significant aspect that exerts a substantial impact on the outcome of a wound is the selection of type of wound dressing following the debridement process.[7] The principal objective of optimizing the selection of wound dressings is to enhance the healing process, as impaired healing significantly contributes to increased morbidity and death rates in patients with complex diabetes.[8] In this instance, modern dressings like vacuum dressings with negative pressure have been reported to have the potential to improve the wound outcomes, however, in Pakistan, such advanced dressing facilities unfortunately lack in most healthcare centers in periphery. Alternatively, "Oxoferrin (Tetrachlorodecoxide) drops dressing"

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have been reported to be effective in management of diabetic foot ulcers[9] but when it comes to its comparison with standard "normal saline dressings" not much research has been done. In fact, to best of our knowledge this is the first head to head comparison in Pakistani population that is comparing the wound outcome of "Oxoferrin (Tetrachlorodecoxide) drops dressing" versus "normal saline dressings" in management of diabetic foot ulcers. Results from this study will help adding to the existing knowledge regarding the efficacy of alternative and cheaper dressing types that can improve the outcomes of wound and reduce the diabetic foot ulcer related disability in Pakistani population.

METHODOLOGY

This Quasi experimental study was conducted at "PAF Hospital Mushaf, Sargodha" from May 2023 to 10 February 2024 after obtaining approval from the ethical review committee of the "PAF Hospital Mushaf, Sargodha"; ERC #: _MSF(H)/308/3/1/trg). To calculate sample size following parameters were used: 5% level of significance, 98% power, anticipated frequency of excellent wound outcome with Oxoferrin dressing as 48/137(35.03%) and frequency of excellent wound outcome with normal saline dressing as 16/134(11.94%).[10] Formula used for this calculation was:

$$n = \frac{\left(z_{1-\alpha/2}\sqrt{2\bar{P}(1-\bar{P})} + z_{1-\beta}\sqrt{P_1(1-P_1)+P_2(1-P_2)}\right)^2}{\left(P_1-P_2\right)^2}$$

Based on these calculated sample size was 210. However, out of these, 10 patients left against the medical advice so were excluded from the study which led to a total of 200 patients (100 in each Group) from which study data was obtained.

Inclusion Criteria: We included patients who were adults having an age above 18 years, either of male or female gender, had diabetes "(HbA1C% ≥6.5%)"[11] for a year or more and presented with a "Wagner grade 2 and 3" diabetic foot ulcer defined as "a deep ulcer without presence of any abscess or involvement of the bone".

Exclusion Criteria: We excluded patients who had evidence of co-morbidities (like hypertension, ischemic heart disease and chronic renal failure), systemic sepsis, "Wagner grade 1, 4 and 5", peripheral arterial disease, previous history of diabetic foot ulcer surgery and hypersensitivity to "Oxoferrin".

After patient selection through "non-probability consecutive sampling" baseline characteristics of patients including age, gender, Wagner grade and duration of diabetes were recorded. Subsequently, all the enrolled patients received diligent ulcer debridement performed by a team of skilled surgeons. Additionally, all patients were administered oral antibiotics for a duration of seven days, namely "linezolid tablets at a dosage of 600mg twice daily". Following the surgical procedure, a measuring scale was positioned adjacent to the wound and the "size of wound" was documented. Patients were then divided into two equal Groups based on their MR number. Patients having MR number ending at an even number were placed in Group A (n=100) who were treated with "Oxoferrin (Tetrachlorodecoxide) drops dressing" for which commercially available formulation of "Oxoferrin" was used. This solution was sprinkled onto the gauze piece used for dressing by spraying bottle and wound was covered. Dressing was done twice a day for a period of two weeks. Patients having MR number ending at an odd number were placed in Group B (n=100) who were treated with "normal saline dressings" in which a surgical gauze piece soaked with normal saline was placed over the debrided wound (Figure).

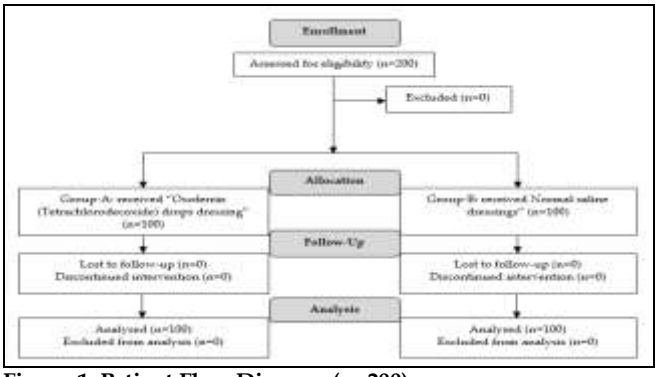

Figure-1: Patient Flow Diagram (n=200)

Both the dressings were prepared by a single member of research team using the same gauze material to ensure uniform quality of dressings. In both the Groups, after a period of four weeks, "size of wound" was measured again. Along with this percentage reduction of wound and patient satisfaction VAS was documented. Formula for calculation of % reduction was as follows:

% Reduction of wound = (baseline wound size – post-therapy wound size) x 100 Baseline wound size.

For patient satisfaction assessment "numeric visual analogue scale (VAS)" was used with 1 labelled as unsatisfied and 10 labeled as completely satisfied.

"The statistical package for social sciences (SPSS) version 22 software was used for statistical analysis of the data. Normality of data was assessed by Shapiro-Wilk test. Age, duration of diabetes, size of wound and wound size reduction were represented using Mean±SD while patient satisfaction was represented using median (IQR). Categorical variables (gender and Wagner grade) was expressed as frequency and percentages. Categorical variables were compared between Groups by using chi-square test. All quantitative variable were compared between Groups using Student independent sample t-test while for patient satisfaction VAS, Mann-Whitney U-test was used. The *p*-value of ≤0.05 was considered significant".

RESULTS

A total of 200 patients [100 in "Oxoferrin (Tetrachlorodecoxide) drops dressing" Group and 100 in "normal saline dressings" Group] were included. Mean age of the patients was 50.45±10.24 years. 119(59.50%) of the patients were male while 81(40.50%) of the study participants were female. Mean duration of diabetes was 9.97±5.57 years. 112(56.00%) patients had "Wagner grade 2" ulcer and 88(44.00%) had "Wagner grade 3" ulcer. Comparison of baseline characteristics between Study Groups is shown in Table-I.

Table-I: Comparison of Baseline Characteristics (n=200)

Parameters	Study Groups		*p*-value
	"Oxoferrin (Tetrachlorodecoxide) Drops Dressing" Group-A (n=100)	"Normal saline Dressings" Group-B (n=100)	
Mean age (years)	49.94±10.64	50.96±9.85	0.483
Gender			
Male Female	61(61.00%) 39(39.00%)	58(58.00%) 42(42.00%)	0.666
Mean Duration of Diabetes (years)	9.93±5.68	10.01±5.49	0.920
Wagner Grades			
2 3	56(56.00%) 44(44.00%)	56(56.00%) 44(44.00%)	1.000

Baseline "size of wound" (in cm^2) in "Oxoferrin (Tetrachlorodecoxide) drops dressing" Group (A) was 174.13±13.49 cm^2 while in "normal saline dressings" Group (B) it was 174.60±14.05 cm^2, (p=0.809). "Size of wound" after four weeks of therapy in "Oxoferrin (Tetrachlorodecoxide) drops dressing" Group (A) was 131.70±11.83 cm^2 while in "normal saline dressings" Group (B) it was 151.74±13.22 cm^2, (p<0.001). Similarly, mean reduction in size of wound in "Oxoferrin (Tetrachlorodecoxide) drops dressing" Group (A) was 42.42±16.50 cm^2while in "normal saline dressings" Group (B) it was 22.86±17.72 cm^2, (p<0.001). Percentage (%) reduction of wound in "Oxoferrin (Tetrachlorodecoxide) drops dressing" Group (A) was 24.01±7.99% while in "normal saline dressings" Group (B) it was 12.64±9.38%, (p<0.001). Median patient satisfaction VAS in "Oxoferrin (Tetrachloro-decoxide) drops dressing" Group (A) was 9(7-9) while in "normal saline dressings" Group (B) it was 6(3-9), (p<0.001). This data is tabulated below in Table-II.

Table-II: Comparison of Wound Outcomes between Groups (n=200)

Parameters	Study Groups		*p*-value
	"Oxoferrin (Tetrachlorodecoxide) Drops Dressing" Group-A (n=100)	"Normal Saline Dressings" Group-B (n=100)	
Mean Baseline Size of Wound	174.13±13.49 cm^2	174.60±14.05 cm^2	0.809
Mean Size of Wound after Four Weeks of Therapy	131.70±11.83 cm^2	151.74±13.22 cm^2	<0.001
Mean Reduction in Size of Wound after Four Weeks of Therapy	42.42±16.50 cm^2	22.86±17.72 cm^2	<0.001
% Reduction in Size of Wound	24.01±7.99%	12.64±9.38%	<0.001
Median Patients Satisfaction VAS	9(7-9)	6(3-9)	<0.001

DISCUSSION

Diabetic foot ulcers pose significant challenges in therapy due to compromised peripheral blood flow, particularly in the feet with a reported burden of 51.5%.[12] This condition increases the susceptibility to infection, diminishes the efficacy of therapeutic interventions, and notably hampers wound healing.[13] Therefore, it is imperative to implement necessary interventions that might effectively enhance the wound healing capabilities of individuals with diabetes. One such intervention is appropriate choice of dressing to be placed over wound. There are several types of dressing that can be used in this regard including medicated/non-medicated standard contact wound dressings, absorbent dressings, hydrogel dressings, polymer dressings, alginate dressings, plasma dressings, vacuum dressings with negative pressure and material impregnated dressings.[14-16] One such type of dressing is "Oxoferrin (Tetrachlorodecoxide) drops dressing". To the best of our knowledge, this is the first study in Pakistan that is comparing the wound outcome of "Oxoferrin (Tetrachlorodecoxide) drops dressing" versus "normal saline dressings" in management of diabetic foot ulcers.

No difference of statistical significance was observed in terms of baseline characteristics between the study Groups. It was observed that duration between the diagnosis of diabetes and development of diabetic foot ulcer in our study was almost a decade. This was close to the finding of a study conducted by Adeniyi *et al.*,[17] who found this duration to be just around seven years. For assessment of severity of diabetic foot ulcer, we used "Wagner grading" which a well-established and validated tool for assessing and grading diabetic foot ulcer severity.[18-20] In terms of wound outcomes, it was found that final size of wound at the completion of two weeks of therapy was significantly reduced from baseline wound size in "Oxoferrin (Tetrachlorodecoxide) drops dressing" Group as compared to "normal saline dressing" Group. In addition, mean reduction in size of wound as well as % reduction in the size of wound was also significantly higher in "Oxoferrin (Tetrachlorodecoxide) drops dressing" Group as compared to "normal saline dressing" Group. Previously, a study conducted by Ramarao *et al.*,[21] have found "normal saline dressing" to be effective option in diabetic foot ulcer management but present study states "Oxoferrin (Tetrachlorodecoxide) drops dressing" to be much more efficacious. Similarly, in one study conducted by Rashid *et al.*,[22] Oxoferrin dressing has been reported to be highly effective to reduce size of wound after therapy but in this study comparison was made with honey dressing. In another study by Parikh *et al.*,[9] Oxoferrin has been reported to improve healing of the wound and having the capacity of early induction of the granulation tissue. Despite extensive literature search, not much data was available regarding the role of "Oxoferrin dressing" in diabetic foot. Thus this study will serve the purpose as a pioneer of research regarding this useful local therapy for managing diabetic foot.

Based on the evidence provided by the findings of this study, "Oxoferrin (Tetrachlorodecoxide) drops dressing" can be considered as preferred management option that the standard "normal saline dressing" for treating patients who have had debridement of their diabetic foot ulcers. However, due to lack of previous comparative studies on these particular types of dressings, we strongly recommend that further studies with much larger sample size should be conducted in future to strengthen the evidence in favor of "Oxoferrin (Tetrachlorodecoxide) drops dressing".

LIMITATION OF STUDY

Although the present study had a decent sample size, more accurate results may be achieved by sampling from diverse healthcare centers with an even larger sample size across the country.

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CONCLUSION

"Oxoferrin (Tetrachlorodecoxide) drops dressing" is an effective intervention for the management of "diabetic foot ulcer" as it provides much more favorable outcomes compared to standard "normal saline dressing" in terms of greater reduction in size of wound after therapy.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

MZNK & SAA: Data acquisition, data analysis, critical review, approval of the final version to be published.

NT & MNBT: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

SRM & SA: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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