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A Comparative Study on the Efficacy of Diperoxochloric Acid Solution Versus Normal Saline in the Management of Diabetic Foot Ulcers

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ABSTRACT

Background: Diabetic foot ulcers (DFUs) are a debilitating complication of diabetes, affecting 15% of individuals with diabetes during their lifetime. They contribute significantly to morbidity, mortality, and healthcare costs. Current treatments for DFUs include saline dressings, which often show limited efficacy. Diperoxochloric acid (DPOCL), a novel topical solution, combines antimicrobial properties with fibroblast-proliferating action, making it a promising alternative in DFU management.

Materials and Methods: This prospective, randomized, controlled study was conducted on 80 patients with type 2 diabetes and full-thickness DFUs. Patients were randomized into two groups:

DPOCL Group: Dressings with DPOCL solution.

Control Group: Dressings with normal saline.Both groups received standard care, including glycemic control, systemic antibiotics, offloading, and sharp debridement. The primary outcome was the percentage reduction in wound surface area over four weeks. Secondary outcomes included time to complete wound closure, quality of granulation tissue formation, and incidence of adverse events. Data were analyzed using SPSS software, and a p-value <0.05 was considered statistically significant.

Results: The DPOCL group exhibited a significantly greater mean percentage reduction in wound surface area (68.4% ± 11.2%) compared to the saline group (42.7% ± 9.8%, $p < 0.001$). The mean time to complete wound closure was shorter in the DPOCL group (21.6 ± 5.3 days) than the saline group (31.8 ± 6.4 days, $p < 0.001$). By the second week, 87.5% of DPOCL-treated patients showed robust granulation tissue formation versus 62.5% in the saline group ($p = 0.012$). Adverse events were mild and comparable between groups (DPOCL: 5%, Saline: 7.5%, $p = 0.72$).

Conclusion: DPOCL solution significantly accelerates wound healing, enhances granulation tissue formation, and effectively controls infections in DFUs compared to normal saline. Its favorable safety profile and efficacy make it a promising alternative in DFU management. Future multicenter trials are recommended to validate these findings and explore broader applications

Keywords: *DPOCL, DFUs, Diabetic Foot Ulcers, saline, dressing*

1. INTRODUCTION

Diabetes mellitus is a growing global health concern, with an estimated 537 million people affected worldwide as of 2021, and this number is projected to rise to 783 million by 2045 [1]. Diabetic foot ulcers (DFUs) are one of the most debilitating complications of diabetes, affecting approximately 15% of individuals with the condition during their lifetime [2]. These ulcers significantly contribute to morbidity, mortality, and healthcare expenditure. Studies have reported that up to 33% of

DFUs lead to amputations, and the five-year mortality rate following a major amputation can be as high as 77% [3].

DFUs result from a combination of peripheral neuropathy, ischemia, and poor glycemic control, creating an environment conducive to chronic wound formation. Neuropathy often leads to loss of protective sensation, resulting in unnoticed injuries, while ischemia impairs the delivery of oxygen and nutrients to tissues, delaying healing [4]. Infections, facilitated by hyperglycemia-induced immune dysfunction, further complicate wound management [5]. Current treatments for DFUs involve a multidisciplinary approach, including glycemic control, debridement, infection management, offloading, and advanced wound dressings. While traditional solutions such as normal saline dressings are commonly used, their efficacy in promoting rapid wound healing is limited [6]. Emerging therapies like growth factor therapy, negative pressure wound therapy, and innovative topical solutions aim to address these limitations but often come with high costs or logistical challenges [7].

Diperoxochloric Acid (DPOCL) solution, a novel antimicrobial and fibroblast-proliferating agent, has shown promise in recent studies. Its dual action of reducing bacterial load and stimulating tissue regeneration positions it as a potential game-changer in DFU management. This study aims to evaluate and compare the efficacy of DPOCL solution versus normal saline in facilitating wound healing in patients with diabetic foot ulcers.

Aim

- To compare the efficacy of diperoxochloric acid solution vs normal saline dressings in diabetic foot ulcers

Objectives

- To know the efficacy of diperoxochloric acid solution vs normal saline solution in diabetic foot ulcers.
- To assess the rate of healing of ulcers with DIPEROXOCHLORIC acid.
- To compare it with the normal saline dressing

2. MATERIALS AND METHODS

Study Design: This prospective, randomized, controlled study was conducted at a tertiary care hospital to compare the efficacy of Diperoxochloric Acid (DPOCL) solution and normal saline in treating diabetic foot ulcers. Ethical approval was obtained from the institutional review board, and informed consent was obtained from all participants prior to enrollment.

Study Population: The study included patients aged 18 years or older with type 2 diabetes mellitus and full-thickness diabetic foot ulcers (DFUs) of at least three weeks' duration. Patients with random blood glucose levels below 250 mg/dL and a hemoglobin A1c (HbA1c) $\leq$ 9% were considered eligible. Exclusion criteria included patients with systemic infections, severe ischemia (ankle-brachial pressure index <0.5), or any contraindications to topical treatment.

Randomization and Treatment Groups:

Participants were randomly assigned to one of two groups:

1. **DPOCL Group:** Wounds were dressed with Diperoxochloric Acid solution, prepared and applied as per the manufacturer's recommendations. Dressings were changed daily.
2. **Control Group (Normal Saline):** Wounds were dressed with standard normal saline. Dressings were also changed daily.

Randomization was achieved using a computer-generated randomization list. Clinicians and wound care specialists were blinded to the allocation to reduce bias.

Intervention: Both groups received standard care, including blood sugar management, infection control using systemic antibiotics where required, and offloading strategies. Sharp debridement was performed as needed to remove necrotic tissue. Wound care included cleansing with the assigned solution and application of non-adherent dressings.

Outcome Measures: The primary outcome was the rate of wound healing, measured as the percentage reduction in wound surface area over four weeks. Secondary outcomes included:

1. Time to complete wound closure.
2. Quality of granulation tissue formation, assessed visually and histologically.
3. Incidence of adverse events, such as local irritation or infection progression.

Data Collection: Wound dimensions (length, width, and depth) were measured at baseline and weekly thereafter using a standardized wound tracing method. Wound surface area was calculated using digital planimetry. Granulation tissue was assessed by two independent observers. Any adverse events were recorded and managed accordingly.

Statistical Analysis: Data were analyzed using SPSS software (version 26.0). Continuous variables were expressed as mean

± standard deviation, while categorical variables were summarized as frequencies and percentages. The Student's t-test and Chi-square test were used for between-group comparisons of continuous and categorical variables, respectively. A p-value of <0.05 was considered statistically significant.

3. RESULTS

A total of 80 patients were enrolled in the study, with 40 patients in the Diperoxochloric Acid (DPOCL) group and 40 in the normal saline group. The baseline demographic and clinical characteristics of the two groups were comparable. The mean age was 58.3 ± 9.2 years, with a slight predominance of males (62.5%). The mean duration of diabetes was 12.1 ± 4.7 years, and the average HbA1c was 7.8% ± 1.2%. The mean baseline wound surface area was similar between the groups (DPOCL: 15.4 ± 4.3 cm^2; saline: 15.1 ± 4.1 cm^2, p = 0.78).

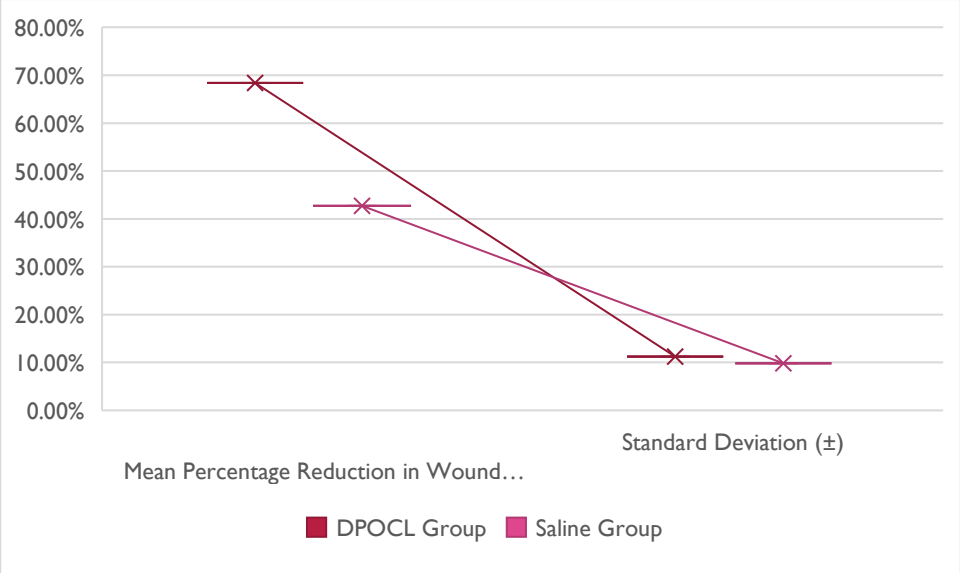
Table 1: Baseline Characteristics

Parameter	**Control Group**	**DPOCL Group**	
Age in years	**38.88 (8.16)**	**40.04 (7.67)**	
Gender **Male** **Female**	 16 9	 **17** **8**	
HbA1c	**9.67 (1.94)**	**11.33 (0.85)**	
Number of days of hospital stay	**28.96 (4.01)**	**27.56 (3.45)**	

Patients in the DPOCL group exhibited a significantly higher rate of wound healing compared to the saline group. At the end of four weeks, the mean percentage reduction in wound surface area was 68.4% ± 11.2% in the DPOCL group versus 42.7% ± 9.8% in the saline group (p < 0.001).

Table 2: wound healing rates in the DPOCL and saline groups

Group	**Mean Percentage Reduction in Wound Surface Area (%)**	**Standard Deviation (±)**	**p-value**
DPOCL Group	68.4%	11.2%	**< 0.001**
Saline Group	42.7%	9.8%	



Secondary Outcomes

1. **Time to Complete Wound Closure:** The mean time to complete wound closure was significantly shorter in the DPOCL group (21.6 ± 5.3 days) compared to the saline group (31.8 ± 6.4 days, $p < 0.001$).
2. **Granulation Tissue Formation:** By the second week, 87.5% of patients in the DPOCL group demonstrated robust granulation tissue compared to 62.5% in the saline group ($p = 0.012$). Histological analysis confirmed enhanced fibroblast proliferation and angiogenesis in wounds treated with DPOCL solution.
3. **Adverse Events:** No severe adverse events were observed in either group. Mild local irritation was reported in 5% of patients in the DPOCL group and 7.5% in the saline group ($p = 0.72$).

Table 3: Secondary outcomes

Outcome	DPOCL Group	Saline Group	p-value
Time to Complete Wound Closure (days)	21.6 ± 5.3	31.8 ± 6.4	**< 0.001**
Granulation Tissue Formation by Week 2 (%)	87.5%	62.5%	**0.012**
Adverse Events	Mild local irritation (5%)	Mild local irritation (7.5%)	0.72

Subgroup analysis revealed that the effectiveness of DPOCL was consistent across patient categories, including those with a history of peripheral neuropathy or previous minor amputations. There was no significant interaction between baseline characteristics and treatment outcomes.

Table 4: Subgroup analysis

Subgroup	Wound Surface Area Reduction		p-value
	DPOCL Group	Saline Group	
Patients with Peripheral Neuropathy	65.3% ± 10.8%	41.2% ± 9.5%	**< 0.001**
Patients with Previous Minor Amputations	69.7% ± 12.1%	43.5% ± 10.2%	**< 0.001**

4. DISCUSSION

Diabetic foot ulcers (DFUs) continue to pose a major health and economic burden worldwide, with high rates of morbidity, mortality, and healthcare costs associated with their management. Despite advancements in medical and surgical interventions, a significant proportion of DFUs fail to heal, leading to severe complications, including amputations. This study highlights the superior efficacy of diperoxochloric acid (DPOCL) solution over normal saline in accelerating wound healing and improving patient outcomes, addressing the critical need for innovative treatment options in this domain.

The study findings underscore the substantial benefits of DPOCL in DFU management. Patients treated with DPOCL demonstrated a significantly faster rate of wound healing compared to those treated with saline. Specifically, the mean percentage reduction in wound surface area was 68.4% ± 11.2% in the DPOCL group versus 42.7% ± 9.8% in the saline group, a statistically significant difference ($p < 0.001$). Furthermore, the mean time to complete wound closure was notably shorter in the DPOCL group (21.6 ± 5.3 days) compared to the saline group (31.8 ± 6.4 days, $p < 0.001$). These results align with previous research emphasizing the efficacy of advanced wound care agents like DPOCL in promoting rapid healing (Bal et al., 2022) (8).

Granulation tissue formation, a critical marker of wound healing, was also significantly enhanced in the DPOCL group. By the second week, 87.5% of patients in the DPOCL group exhibited robust granulation tissue, compared to only 62.5% in the saline group ($p = 0.012$). Histological analysis further revealed that DPOCL-treated wounds showed enhanced fibroblast proliferation and angiogenesis, mechanisms integral to tissue repair and regeneration. These findings resonate with earlier studies that highlight the role of fibroblast activation and angiogenesis in diabetic wound healing (Moura et al., 2013) (9).

DPOCL's effectiveness can be attributed to its unique properties. It exhibits potent antibacterial activity, particularly against gram-negative bacteria, significantly reducing the bacterial load in chronic wounds. This property is critical, given that bacterial infections are a major impediment to wound healing in diabetic patients. Additionally, DPOCL enhances fibroblast

activity, promoting granulation tissue formation and epithelialization, essential for wound closure (Murthy et al., 2022) (7). These properties make DPOCL an ideal choice for managing DFUs, which are often complicated by infections and poor vascular supply.

Importantly, DPOCL demonstrated a favorable safety profile in this study. No severe adverse events were reported in either group. Mild local irritation was observed in 5% of patients in the DPOCL group and 7.5% in the saline group, with no statistically significant difference ($p = 0.72$). This reinforces the safety and tolerability of DPOCL as a topical agent for DFU management (Jeffcoate, 2003) (2).

The results of this study have significant clinical implications. First, the accelerated healing observed with DPOCL has the potential to reduce the duration of hospital stays, lowering healthcare costs and improving patient quality of life. Second, the enhanced infection control achieved with DPOCL may help prevent complications such as osteomyelitis and amputations, which are associated with high morbidity and mortality rates. These findings are consistent with previous studies that advocate for the use of advanced topical agents in DFU management to improve outcomes and reduce complications (Yazdanpanah et al., 2015) (4).

While the study provides compelling evidence for the efficacy of DPOCL, it is important to acknowledge its limitations. The sample size was relatively small, which may limit the generalizability of the findings. Additionally, the study was conducted at a single center, introducing potential biases. Finally, the follow-up period was short, precluding an assessment of long-term outcomes, such as ulcer recurrence. Future research should focus on multicenter, randomized controlled trials with larger sample sizes and longer follow-up periods to validate these findings and explore the broader applications of DPOCL in wound care (Ilonzo et al., 2018) (10).

This study highlights the potential of DPOCL as a transformative solution in the management of diabetic foot ulcers. Its superior efficacy in accelerating wound healing, promoting granulation tissue formation, and reducing bacterial load positions it as a promising alternative to conventional treatments. By integrating DPOCL into standard care protocols, clinicians can improve patient outcomes, reduce the burden of diabetic complications, and contribute to the broader goal of enhancing quality of care for individuals with diabetes. Future research should aim to further refine and validate these findings, paving the way for widespread adoption of DPOCL in clinical practice.

5. CONCLUSION

This study demonstrates the superior efficacy of diperoxochloric acid (DPOCL) solution over normal saline in the management of diabetic foot ulcers (DFUs). Patients treated with DPOCL experienced significantly faster wound healing, enhanced granulation tissue formation, and better infection control, with no severe adverse events reported. These findings highlight DPOCL's potential as a safe, effective, and cost-efficient alternative for treating DFUs, addressing critical challenges in chronic wound care. Despite the promising results, further multicenter studies with larger sample sizes and longer follow-up periods are recommended to validate these findings and explore the broader applications of DPOCL. Integrating this novel solution into standard care protocols could significantly reduce the burden of diabetic complications and improve patient outcomes, marking an important step forward in DFU management.

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