CASE REPORT

From Risk of Amputation to Complete Wound Healing: The Role of Diperoxochloric Acid in Diabetic Foot Ulcer Treatment

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ABSTRACT

Patients with diabetes mellitus are at risk for developing diabetic foot ulcers (DFUs), which significantly affect the quality of life and can lead to lower limb amputation. This report describes a case of a nonhealing DFU, treated successfully with a topical solution containing 'Diperoxochloric acid' (DPOCL). A 46-year-old female with uncontrolled type 2 diabetes mellitus and hypertension came with a nonhealing abscess on her left great toe, for which amputation had been initially recommended. The use of DPOCL reduced the wound size by approximately 70% in 1 week and complete wound closure was observed in 28 days. This demonstrates the potential of DPOCL as an alternative therapy in DFU in wound care.

Keywords: Diabetes management, diabetic foot ulcers, diperoxochloric acid, wound healing

Diabetes mellitus (DM) can lead to several complications, of which diabetic foot ulcers (DFUs) are one of the most challenging; approximately one-third of patients develop a DFU during their lifetime. They represent a significant health care burden in India affecting approximately 6.2% of the patients with DM[1]. Immune dysfunction along with peripheral artery disease (PAD) and diabetic neuropathy (DNP) are the main pathophysiological factors that predispose to DFUs. The decreased pain and pressure sensation due to DNP predisposes to formation of ulcer and is present in about 80% of patients with DFUs. This can lead to formation of anatomic deformities such as prominent plantar metatarsal heads, hammer toes, Charcot foot. About 50% of the patients with DFUs have PAD, which is significantly associated with the increased risk of adverse limb events. DFUs are associated with increased mortality risk and the 5-year survival rate in patients with DM having DFUs is less than that associated with the most common cancers[2].

Over the past few decades, numerous novel dressings have been developed and tested to combat the challenge of impaired healing in diabetic ulcers. Basic dressings just provide moist surface to the ulcer bed or act as a physical barrier that prevents the contamination. The basic wound dressing materials like honey, saline, etc. do not cover all the aspects of wound healing such as stimulation of ulcer bed for healing or antibacterial activity or both[3].

Modern or advanced dressings help to balance moisture of the wound bed; they possess protease action, stimulate growth factors, improve permeability of oxygen and autolytic debridement, support granulation and re-epithelialization process. The main disadvantage of advanced dressings such as growth factors is that they require special storage conditions and have the potential to develop malignancy; majority of these are expensive, which adds to the financial burden on the patient[4].

CASE HISTORY

A 46-year-old housewife with a history of hypertension and poorly managed type 2 diabetes mellitus presented with a nonhealing abscess close to the metatarsal joint of the left great toe. There was a foul smelling, purulent discharge from the abscess. Another podiatrist had

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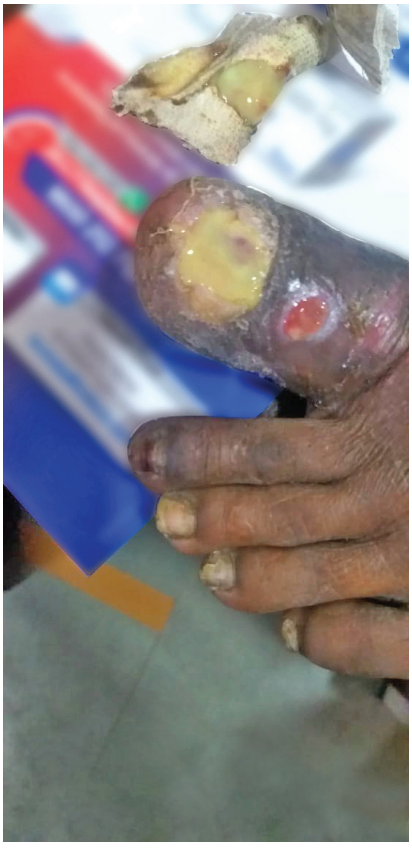

Figure 1. Day 0

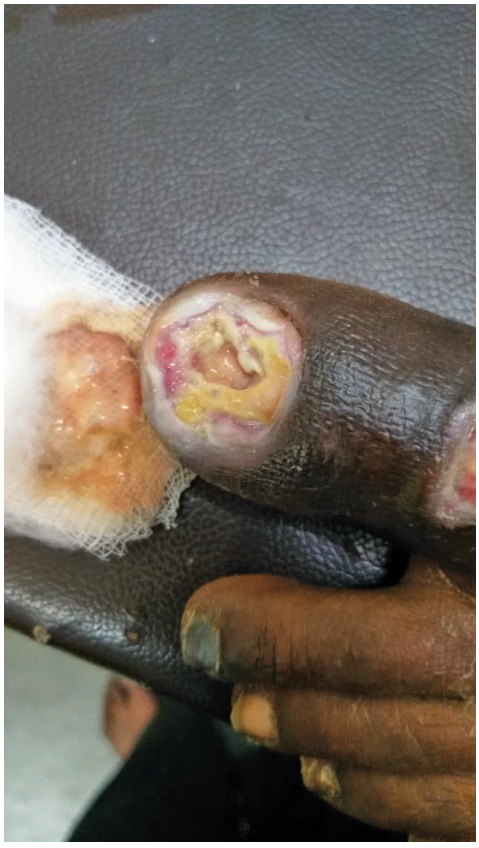

Figure 2. Day 07

Figure 3. Day 14

recommended amputation of the great toe, even though the perfusion of the affected extremity was intact. Upon examination, the surface area of the wound was measured at 48 cm² (longest length 8 cm × longest width 6 cm), with minimal osteomyelitis observed (Fig. 1).

The treatment procedure began with cleansing of the wound with 0.9% normal saline. To attain tight glycemic control, the patient received oral antidiabetic drugs, which included metformin 1 g twice daily, glimepiride 2 mg twice daily, and teneligliptin 40 mg once daily. Offloading was also advised to reduce pressure on the afflicted foot.

A brief course of broad-spectrum antibiotics was given to control the infection which included amoxicillin 500 mg plus clavulanic acid 125 mg twice daily plus metronidazole 400 mg 3 times daily for 10 days.

A topical solution of DPOCL was used to treat the local wound.

Following a week of treatment, the wound shrank by 68.75% and its surface area, which measured 5 cm in length and 3 cm in width decreasing to 15 cm². The edges were starting to close, and the granulation tissue was clean and healthy (Fig. 2). Debridement was not required as there were no signs of wound infection or discharge. Considering the improved wound condition, the antibiotics were discontinued, and attention was directed toward controlling the blood glucose and local dressing with DPOCL.

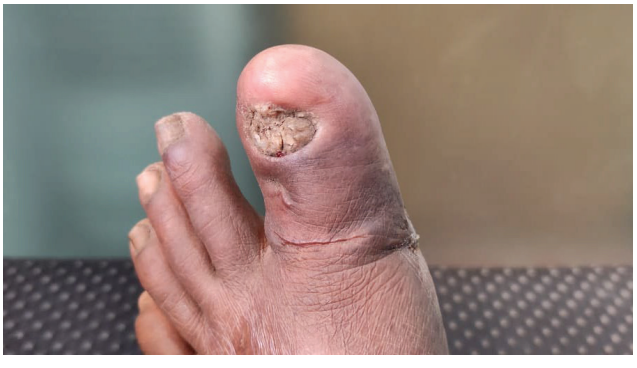

Figure 4. Day 28

On day 14, the wound continued to have healthy granulation tissue, was free of infection and abscess, and showed further reduction in size (Fig. 3). The same treatment was continued for an additional 2 weeks. Complete wound closure was seen by day 28 (Fig. 4). The patient had no local side effects from the topical solution of DPOCL over the course of treatment.

DISCUSSION

As per the Indian Council of Medical Research-India Diabetes (ICMR-INDIAB) national cross-sectional study, the prevalence of diabetes in India was 101 million in 2021[5]. Peripheral nerve degeneration is common in patients with diabetes leading to loss of pain perception and skin damage from pressure or injury. This can cause ulceration without the patient's knowledge[6]. Diabetic foot affects around 15% to 25% of patients with diabetes over their lives[7]. Foot ulceration and inadequate treatment lead to 85% of diabetes-related lower limb amputations[8].

Diabetic foot ulcers have a global prevalence of 6.3% and are commonly caused due to severe infections by multidrug-resistant microorganisms such as *Staphylococcus aureus*, *Klebsiella* species, *Enterococcus*, *Pseudomonas aeruginosa*, *Escherichia coli*, and *Proteus* species, as well as filamentous fungi such as *Candida* spp. and *Fusarium solani*[7].

Uncontrolled blood glucose levels weaken the body's defense against possible infections and disrupt the healing process[9]. Lack of proper foot care education, poor foot care practices, insufficient monitoring of blood glucose levels, inadequate management of diabetes, and challenging socioeconomic conditions collectively lead to various complications such as foot deformities, skin and bone infections, Charcot foot, gangrene, and foot amputation in developing countries like India[10,11].

It has been observed that despite tight glycemic control and offloading, healing may be delayed in DFUs. Certain wounds do not achieve complete wound closure and the persisting infection as well as requirement of surgical or mechanical debridement affect the quality of life of the patient, needless to say loss of working days. Due to the risk of resistance and adverse effects, systemic antibiotics cannot be administered for a longer duration of time. Topical antibiotics like mupirocin, fusidic acid effectively control the infection; however, healthy granulation tissue may not be achieved and subsequently can lead to amputation of the affected part.

DPOCL topical solution has 2 unique properties, i.e., a) bactericidal action against Gram-positive and Gram-negative bacteria due to reactive chloride [Cl^-] ions and reactive oxygen species; b) fibroblast cell growth promoting due to reactive O^- ions, which results in complete wound closure. The efficacy and safety of DPOCL topical solution in the treatment of DFU has been established in phase II and phase III trials[12].

In a phase III clinical trial, the efficacy and safety of DPOCL versus active-control solution i.e., isotonic normal saline (0.9%) was investigated in 280 Indian patients with DFU for a period of 10 weeks. Results showed that 71.03% of the patients on WOXheal achieved complete wound closure versus 57.53% in active controls, which was statistically significant ($p = 0.0156$). Time taken for complete wound closure in DPOCL group was 42 days as compared to 56 days in the active control group. More than 90% of the patient treated with DPOCL had positive response compared to 66% of the active-control group (treatment response defined by at least 50% wound reduction in 4 weeks). No serious adverse events or drug-drug or drug-lab interaction were noted in DPOCL group. Results of the clinical trial indicate that DPOCL can be considered as an effective and safe treatment option for DFU compared to isotonic normal saline[12].

CONCLUSION

This case illustrates the successful management of a DFU through effective glycemic control, offloading, antibiotic therapy, and the use of DPOCL leading to complete wound healing within 4 weeks without the need for amputation. It supports DPOCL as a promising alternative in the management of DFUs.

Key Messages: Diperoxochloric acid as a DFU therapy substitute, offering a significant advancement in wound care.

Declaration of Patient Consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published, and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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