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RESEARCH ARTICLE

Hypertonic saline solution 5% as an effective cost-beneficial alternative to normal saline for wound healing in patients with diabetic lower-extremity ulcers: a randomized controlled trial

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Abstract

Background Diabetic foot ulcer is among the most common complications and causes of mortality and morbidity in patients with diabetes. Herein, we propose using 5% Hypertonic Solution as an alternative to Normal Saline in treating patients with diabetic foot ulcers as an effective cost-benefit therapeutic approach.

Methods In this clinical trial, 100 patients with diabetic foot ulcers were divided into two groups. Foot ulcer was washed and treated three times a day with the 5% hypertonic saline solution in the first group, while the second group was treated with normal saline 0.9% and normal washing. Patients were examined for the size and depth of the wound weekly, and the results were recorded after six weeks.

Results The mean length and width of the wound in the experimental group significantly decreased six weeks after the start of treatment with hypertonic saline ($p < 0.05$). The wound healing rate was lower after treatment in both groups of patients who had a longer disease duration and higher HbA1c.

Conclusion Treating diabetic foot ulcers with hypertonic saline solution may help improve wound healing. Therefore, rinsing with hypertonic saline is a cheap, safe, simple, and non-invasive treatment protocol for these patients.

Keywords Saline Hypertonic · HbA1c · Diabetic foot ulcer · Wound healing

Introduction

Diabetes is one of the most common diseases in the health system, and its prevalence has been growing rapidly in recent decades [1, 2]. According to some studies, the number of patients with diabetes has been rised from 30 million in 1985 to 177 million in 2000 and is expected to reach 360 million by 2030 [3, 4]. Diabetic foot ulcer (DFU) is the most common complications for patients with diabetes, holding a considerable incidence throughout the past century [5–7]. Although the exact estimation is difficult, reports have suggested an incidence of 4–27% for DFU [8–11]. Furthermore, DFU is considered one of the most important causes of mortality in people with diabetes nowadays, and it is said that about 20% of patients with diabetes are hospitalized due to DFU [12, 13]. If no good and effective care is taken, DFU can lead to gangrene infection, amputation, and eventually death [12, 14].

Amputation is one of the major complications, and it is said that the rate of amputation in patients with diabetes is about 15 times more than those without the disease [9, 11]. On the other hand, DFU is a major problem in the quality of life, physical restrictions, and mental stress of patients with diabetes [15].

The management and treatment of DFU is a particular imperative for the medical system due to its high incidence, along with mortality and morbidity. Due to various treatment results and outcomes, researchers have examined

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inflammatory response secondary to intestinal ischemia-reperfusion injury. [33, 34]

In the context of the impact of simple, safe, inexpensive, and non-invasive treatments on patients with DFU, many cases have been investigated, such as honey, sugar, betadine, and normal water. Several studies showed that DFU treatment had a good result with the local topical administration of honey and improved the patient's wound healing [33, 35–39]. In a study by Biswas et al. [12], it was found that sugar might have a beneficial effect on wound healing in patients with DFU.

Usman Riaz et al. [40] compared VAC (Vacuum Assisted Closure) with normal saline in DFU patients. In this study, VAC had a better effect than normal saline. Bowling et al. [13] compared superoxidase with normal saline showed that this solution was not significantly different from normal saline but could substantially reduce the volume of bacterial wounds in patients.

According to the analysis of the current study results, it can be stated that the treatment of DFU patients with hypertonic saline may be helpful in faster wound healing. This study showed that cleansing with hypertonic saline is a cheap, safe, simple, and non-invasive treatment protocol in patients with DFU.

Hypertonic saline is available in 5% and 20% forms in our country. Since patients did not tolerate the 20% form, we used the 5% form. The solution of hypertonic saline was prepared by dissolving 50 g of salt per liter of cooled water and used three times a day. Furthermore, we assumed that based on the autolyze properties of hypertonic saline, higher concentrations would affect and damage normal and healthy tissue. We aimed to limit our intervention to the cell surface level to minimize the need for debridement since the loss of healthy vital tissues in diabetes patients could cause irreversible lesions and consequences. Because there is little information on the antibacterial activity of hypertonic saline, further research is needed to determine its impact on common wound pathogens. It's crucial to test the range of pathogens that hypertonic saline can inhibit using effective saline concentrations. Simultaneously, these concentrations should be tested for their toxicity on normal human cells, particularly in the presence of high osmotic action. Hypertonic saline is already used in wound irrigation, and its clinical application could be enhanced if it can be shown to have antibacterial activity against a wide range of bacteria at specific concentrations while causing no harm to normal host cells.

Questions remain as to which types of intervention, treatment, and dressing are suitable for wound healing and whether all treatments are necessary and cost-effective for therapies. DFU should be carefully examined, and appropriate treatment of wounds should be done to prevent amputation. Also, various percentages of hypertonic saline should be examined to obtained the most satisfactory results, since the optimal concentration (optimal osmolality) of hypertonic saline might be an important factor for the efficacy and safety. One of the limitations of our study is that we did not evaluate the offloading method of patients. Further clinical studies are needed to support the available evidence of the clinical benefits of a new approach in the treatment of DFU and consideration as a gold standard treatment for wound healing. Also, another limitation is the lack of histopathological evaluation of the wounds, which could provide better insight into the treatment modalities of DFU.

Conclusion

Our results demonstrated that hypertonic saline could be proposed as an optimal and cost-beneficial approach for the treatment of DFU, with significantly better results than normal saline in terms of the wound size. Utilizing hypertonic saline could positively impact the prognosis along with financial savings in the treatment of DFU.

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Authors' contributions B.Z, S.K, and A.A designed the study while M.E collected the data. K.R and R.S drafted the manuscript. All authors proofread the final version of the manuscript.

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Data availability SPSS data of the participants can be requested from the authors. Please write to the corresponding author if you are interested in such data.

Declarations

Ethics approval and consent to participate Shiraz University of Medical Sciences Human Ethics Committee approved the study (IR.SUMS.MED.REC.1395.12). This study was registered in the Iranian registry of clinical trials (trial number IRCT20200705048015N1; Date: 5/8/2020). Written informed consent form was obtained from all the participants enrolled in this trial. All patients' information was de-identified and documented confidentially, and patients were able to exit any time during the trial if they desired. All ethical principles of the Declaration of Helsinki were considered in this trial.

Consent for publication Not applicable.

Competing interests None.