

EFFECTIVENESS OF TOPICAL OXYGEN THERAPY IN WOUND HEALING FOR PATIENTS WITH DIABETIC FOOT ULCER

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ABSTRACT

Objectives: Non-healing wounds have been one of the major challenges in health care because of increased morbidity, especially for those who have diabetes mellitus. Numerous regimens are being innovated to produce an evidence-based practice that would minimize complications and promote healing. Topical oxygen therapy is an innovation in wound care that has been considered influential in the wound healing process. This intervention aims to increase the oxygen concentration in the affected limb to promote wound healing. **Methods:** This research applied an experimental design that targeted a total of 60 adult patients aged 45–64 years with diabetic foot ulcers. A randomized systematic sampling technique was used to allow equal chances and prevent bias. In total, 30 patients in the control group received usual care for diabetic foot ulcers, and the remaining 30 patients in the experimental group received topical oxygen therapy together with standard care for diabetic foot ulcers. Subjects were assessed using the Wagner-Meggitt Wound Classification System.

Results: The result proved that there was a significant difference in the wound grade of patients in the experimental group after the application of the usual wound care plus the topical oxygen therapy using Friedman’s test. The control and experimental groups were compared using Mann–Whitney statistical analyses, and the results showed that there was a significant difference between the control and experimental groups after the application of topical oxygen therapy.

Conclusions: Topical oxygen therapy was demonstrated to be effective to aid in the wound healing process of patients with diabetic foot ulcers. Further research was recommended to improve the application of topical oxygen therapy to patients with chronic wounds and promote the wound healing process.

Keywords: diabetic foot ulcer, localize oxygenation, neuro ischemic foot ulcer, neuropathic ulcer, oxygenation, topical oxygen therapy, wound healing

INTRODUCTION

In today’s health care system, wounds are taken more seriously with specialties utilizing different bodies of knowledge to develop proper care for wound management. Several studies and treatment regimens are being innovated to develop an evidence-based practice that would minimize complications of wounds and promote healing since diabetic foot ulcer is one of the major challenges in wound management and the healthcare society.

According to Rice et al.¹ foot ulcers have been estimated to affect 1%–4% of patients with diabetes annually and as many as 25% of the patients with diabetes over their lifetime. Studies have estimated that foot ulceration is one of the major sources of hospitalization among patients with diabetes, and it leads to 84% of amputations of lower limbs in these patients. In addition, diabetic foot ulcer patients have a low survival prognosis, with a 3-year cumulative mortality rate of 28% and rates among amputated patients approaching 50%. Because of this, several studies have been conducted to develop an effective plan of care for diabetic foot ulcers.

During wound healing, the presence of oxygen takes on additional importance because of the increased demand for reparative processes like cell proliferation and the synthesis of collagen. Increase in blood viscosity and hardening of capillaries due to prolonged high concentrations of glucose in the blood leads to the development of peripheral vascular disease. These complications cause poor perfusion to the peripheral cells, making wound healing prolonged and even worse, developing infection or necrosis. Wound oxygenation is dependent on the perfusion status of the tissue. This is the reason why wounds of patients with diabetes mellitus take a longer time to heal.²

Topical oxygen therapy is a method that is derived from hyperbaric oxygen therapy where the wound is exposed to a high concentration of oxygen using a plastic bag or an improvised device to aid in wound healing. By using this method, the healing process of wounds can be improved even for patients with poor peripheral perfusion. Oxygen therapy is localized preventing the possible systemic adverse reaction in patients. Despite having good feedback in the literature, topical oxygen therapy is still not the standard practice in wound care here in the Philippines. This research determines the effectiveness of topical oxygen therapy in wound healing of patients with diabetic foot ulcers. This intervention can be beneficial to diabetic patients with chronic wounds and may even prevent amputation.

RESEARCH METHOD

The researcher used an experimental design to determine the effectiveness of topical oxygen therapy in patients with diabetic foot ulcers. The researcher selected the chosen population to be included in the study to address the issue of the non-healing wound of was given the new therapy together with the usual care, and the control group was given the standard care alone. The study was conducted in a government hospital that is readily accessible to the researcher and has a patient population with diabetic feet. The data were gathered in a period of 4 months from September 2019 to December 2019 to attain the target population and to execute the research protocol. The population of this study consisted of 60 adult patients with an age range of 45–64 years, with diabetic foot ulcers, who were admitted to the hospital. A total of 30

patients were categorized into the control group, and the remaining 30 patients were in the experimental group. Patients who were categorized based on the inclusion criteria were randomly assigned under the control group where the usual wound care for diabetic foot ulcers was rendered, and the treatment group received the standard wound care for diabetic foot ulcers together with topical oxygen therapy. The researcher acquired samples from the population who met the inclusion criteria: (1) patients who were medically diagnosed to have diabetes mellitus type 2 for >1 year, (2) patients who were suffering from a diabetic ulcer for >1 month and do not go beyond grade 3 in the Wagner-Meggitt Wound Classification System. Patients with grade 4 (forefoot gangrene) and grade 5 (whole foot gangrene) level in the Wagner Meggitt Wound Classification System were excluded. (3) Patients who have regular food intake, (4) patients who were non-smokers or quit smoking for at least 6 months, and (5) patients who were not scheduled for limb amputation in the affected area. The selected subjects who agreed to participate in the study were randomly assigned through a systematic sampling technique. The total number of participants was divided into subjects per group to determine the interval in which patients would be assigned to the experimental group.

The researcher together with the physician counterpart assessed the patients that were included in the study through the application of the Wagner Meggitt Wound Classification System. The wound grades of the patients have been recorded prior to the implementation of topical oxygen therapy for a more accurate evaluation during the post-intervention phase. The application of topical oxygen therapy was implemented by the researcher after the application of the usual care for wound ulcers in the experimental group.

RESEARCH RESULTS

Table 1 shows the grade status of patients in the control and experimental groups. A total of 60 patients who qualified for the inclusion criteria were included in this study. Using the Wagner Meggitt Wound Classification tool, the results show that at the beginning of the study (day 0), most of the patients in both the control and the experimental groups have a grade 2 wound (deep ulceration). Both groups have the same number of patients with grade 3 wound (deep ulceration with bone involvement). The results of the tool show that, at the beginning of the study (day 0), most of the patients in both the control and the experimental groups have a grade 2 wound (deep ulceration). Both groups have the same number of patients with grade 3 wound (deep ulceration with bone involvement).

On the 7th day of the study, the control group has 1 patient that was reclassified grade 4 wound group (forefoot gangrene). Patients in the experimental group were unable

to grade and quantify wounds. Subsequently, on the 14th day of the study, patients in the control group showed an increase in grade 4 wound (forefoot gangrene) by 13.3%. In comparison with the experimental group, results showed that a total of 6% or 20% of patients had totally closed wounds and were classified as grade 0 wound group (pain/swelling/no lesion).

Assessment of the wound status of patients before the implementation of the study is very important in order to attain the homogeneity of the subject and to provide an accurate evaluation after the implementation of the study. The researcher and the physician counterpart used the same tool in evaluating the wound status of patients in the pre-assessment phase until the 14th day of the study in order to have a more accurate description of wound status.

According to Mutluoglu et al.,⁶ the advantage topical oxygen therapy is its lower cost and safety as compared with hyperbaric oxygen therapy. He also states that topical oxygen therapy uses the concept of diffusion, leading to the exchange of gasses superficially. This is one of the main factors as to why this study focuses on patients with grade 3 wound or less based on the Wagner Wound Classification Stem. The study done by Hayes et al.⁷ concluded that ambulatory topical oxygen delivery devices showed a significant beneficial effect on wound size. This poses practical advantages over currently existing oxygen-based wound therapies such as hyperbaric oxygen therapy due to its continuous oxygen delivery, ease of use, safety, and lower cost.

Table 2 shows the patients' wound grades before and after the implementation of usual wound care and topical oxygen therapy. On day 0, patients from the control group (n = 30) had a mean of 2.40 with a standard deviation (SD) of 0.563, while the experimental group had a mean of 2.33 with a SD of 0.661. Both groups on day 0 or prior to the application of topical oxygen therapy and the usual wound care had a mean and SD of wound grade classification 2 which is deep ulceration.

After 7 d since the study was initiated, both groups fell under the classification of grade 2 wound or deep ulceration. Despite having the same classification, the mean difference between the control group and the experimental group on day 0 is 0.07; which is lower than the mean difference on day 7 which is 0.5. This result shows that the control and experimental groups show significant changes during day 7 compared with day 0. On the 14th day of the research with the application of usual care for 14 consecutive days, the mean of the wound grades of the control group was 2.67 with a SD of 0.802, classified as deep ulceration with abscess/osteomyelitis as grade 3 wound. On the other hand, after receiving the same usual wound care along with the implementation of topical oxygen therapy for 14 consecutive days, the experimental group had a mean of

1.47 and a SD of .937, classified as grade 1 wound classification, which was superficial lesion. The mean difference between the 2 groups on day 14 is 1.20.

It is essential to assess the wound grades of patients included in the study because one of the significances of this research is to prevent amputation and permanent complications. The presence of necrotic tissues which is defined as permanent irreversible cell death will inevitably result in amputation and, if not, may cause severe complications. The study done by Mutluoglu et al.⁶ stated that one of the disadvantages of using topical oxygen therapy is the inability of the oxygen molecules to penetrate deep wounds. This was the reason why topical oxygen therapy was applied after the application of the usual care to remove purulent discharges and dead cells in the affected area that may hinder the effect of topical oxygen therapy. This also supports the research done by Winfield⁴ where among the 22 patients with healed wounds examined, 11 patients were treated with topical oxygen therapy, and 11 patients were treated with hyperbaric oxygen therapy. Those 11 patients treated with hyperbaric oxygen therapy healed faster with an average wound closure of 47.09 d compared with other 11 patients treated with topical oxygen therapy with an average wound closure of 61.82 d (Table 3).

A Friedman test shows that there is a statistically significant difference in the wound grades of patients in the experimental group on day 0, day 7, and day 14 after the implementation of topical oxygen therapy and usual care. The null hypothesis which states that there is no significant difference in the wound grade after the implementation of topical oxygen therapy in the experimental group is rejected based on the actual data gathered. Statistical analysis revealed that differences in the wound grades are evident during day 14 as compared with day 0 after the intervention. The result shows that after the implementation of usual care and topical oxygen therapy, most of the patients showed improvements in their wound grades. In the research done by Kaufman et al.,⁸ it was revealed that optimal wound healing occurred after using topical oxygen therapy to stimulate wound healing of chronic wounds for >25 d. A wound area reduction of 83% and 47% wound closure was seen in patients with venous leg ulcers, and a 74% reduction and 57% closure rate in arterial wound ulcers was observed as well. The study done by Hayes⁷ revealed that after using topical oxygen therapy, the median ulcer size decreased from 1.8 cm² at the start of the study to only 0.15 cm² at the end of the study. At week 8, the median ulcer size had decreased by 48%. By week 24, 42% had healed completely, with another 14% exhibiting >80% re-epithelialization. Although not all wounds were closed, this represented a significant benefit in the closing of recalcitrant diabetic foot ulcers under long-term specialist treatment (Table 4).

In the control group, Friedman's test result shows that there was no significant difference in the wound grades of patients after the implementation of usual care for 14

consecutive days. The result of Friedman's test reveals that the control group has a score of 0.058, which is greater than the significant level of 0.05. The result means that the control group has no significant changes in their wound grade from day 0 to day 14, hence accepting the null hypothesis of this study. The mean score of the control group during day 0 of the study was classified as grade 2 (deep ulceration) using the Wagner Meggitt Wound Classification tool. After the implementation of the usual care in the control group for 14 consecutive days, the wound grades of the group reveal that instead of lowering the grade of the wound, the wound status of patients in the control group deteriorated into grade 3 (deep ulceration with bone involvement) status at day 14.

Table 5 illustrates the comparison between the experimental and control groups. The statistical method that was used to compare data was the Mann–Whitney U-test in which the P value of <0.05 , which is a standard to denote significance. During day 0, the P value of 0.788 which is greater than the standard significant value of 0.05 showed no significant difference between the experimental and the control groups. Subsequently, on day 7, the P value was 0.019, which denoted a significant difference in the result, rejecting the null hypothesis. Lastly, on day 14 of the study, the P value of 0.000 showed significant results which conclude the rejection of the null hypothesis.

This supports the study of Niederauer et al.⁹ whose results indicated that there were more people who were healed using continuous oxygen therapy compared with sham (46% vs 22%, $P = 0.02$). The results proved that continuous diffusion oxygen therapy has higher rates of closure and a faster time for closure compared with similarly treated patients receiving standard therapy. Hayes⁷ found that ambulatory topical oxygen delivery is proven to have decreased the mean ulcer size of diabetic foot ulcers by 51% within 8 weeks.

DISCUSSION

Despite having differences in the mean, both control, and experimental groups, the research with mean wound status falls under grade 2 (deep ulceration) using the Wagner-Meggitt Wound Classification System. As stated in the study of Mutluoglu et al.,⁶ it is essential to categorize patients according to their wound status to allow the diffusion of oxygen to promote wound healing. The wound grade status of patients on the 7th day since the application of usual care had started revealed that the mean average wound status of patients in the control group was 2.43, which is higher compared with the wound status of patients in the experimental group with a mean wound grade of 1.93. The difference between the control and experimental groups was significantly evident on the 14th day of the experiment. The mean wound grades of patients in the control group increased to 2.67 compared with the wound grade of the experimental

group with a mean wound grade of 1.47. The wound grade status of patients in the control group alone that received the usual care for diabetic foot ulcer increased from Wagner wound classification grade 2 (deep ulceration) on day 0 of the study to Wagner wound classification grade 3 (deep ulceration with bone involvement) on day 14 of the study. This result shows that the wound status of most of the patients under the control group if not improved had worsened since the study was conducted.

The experimental group which received the same usual wound care for diabetic foot ulcers but with the application of topical oxygen therapy showed a significant difference in the wound grade status of patients from day 0 of the study to day 14. The average wound grade of the patients in the experimental group on day 0 falls under the Wagner wound classification of grade 2. This result is further supported by the research of Nierdruer et al.⁹ wherein there are more people that benefit from continuous diffusion therapy as compared with sham therapy, which promotes a faster healing rate as compared with patients receiving the usual wound care. Compared with day 14 of the study, the wound status of the experimental group falls under the Wagner wound classification of grade 1 which shows that the application of topical oxygen therapy has been effective as an aid in the wound healing of patients with a chronic diabetic foot ulcer.

The effectiveness of topical oxygen therapy was emphasized with proper statistical analysis of data to compare how significant the differences were between the control and the experimental groups. Using the Mann–Whitney test in assessing the significant differences between the control and the experimental groups, the P value of 0.05 was used to assess the level of significance. The result shows that on day 0, the P value = 0.788 > 0.05, which means that there were no significant differences between the control and the experimental groups. On day 14 of the study, the Mann–Whitney P value was 0.000, which is < 0.05, that is, there was a significant difference in the wound status of patients in the control and experimental groups.

The result emphasized that the wound status between the control and the experimental groups shows a significant difference to conclude that the application of topical oxygen therapy is effective in wound healing of patients with diabetic foot ulcers. Hayes⁷ also state in their study that topical oxygen therapy has been decreasing the mean wound grade of the patient that received the treatment in promoting wound healing for diabetic foot ulcers by 51% within 8 weeks.

This study is limited to patients with a known history of diabetes mellitus admitted to the selected hospital. For this reason, patients who were not admitted may have difficulty in the intervention during the allotted period. Only adult patients aged 45–64 years suffering from a chronic non-healing wound but with no schedule of amputation are included in the study. The researcher did not have control over the nutritional factors of the participants, as well as the prescribed medication. Hence, this research did not

control for such factors. However, health teaching and encouraging participants to adhere to the prescribed diet plan were done by the researcher. The researcher also encouraged all participants to take the prescribed medications by the physician to maintain a normal blood sugar level.

CONCLUSION

The result of this study shows that there was a significant difference in the wound status of patients between the control and experimental group after the application of the usual care and the topical oxygen therapy. Therefore, topical oxygen therapy has been shown to be effective in promoting wound healing of patients with diabetic foot ulcers if patients are compliant with their medications and normal blood sugar is maintained. This evidence-based study can be a reference to create a more effective nursing care plan to improve conditions of patients, specifically those who are suffering from diabetic foot ulcers. Providing an innovative yet accessible treatment may improve the holistic being of patients who are on a verge of amputation due to diabetic foot ulcers.

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