Effectiveness Of Normal Saline Versus Tetrachlorodecaoxide Dressing In The Management Of Diabetic Foot Wounds

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Abstract

Introduction: Pure solutions are used to produce an electrically treated aqueous solution high in reactive oxygen species (ROS). It is a potent anti-microbial. TCDO has been shown to be bactericidal in vitro. Wound healing is made possible by the mitogenic activities of TCDO on fibroblasts and new blood vessels. The primary goal of this study to Compare the effectiveness of Normal Saline Dressings versus Tetrachlorodecaoxide Dressings in the management of Diabetic Foot Wounds. The study was conducted at Department of Gen eral Surgery, Postgraduate Medical Institute/Shaikh Zayed Hospital, Lahore. Aim is to compare the effectiveness of normal saline versus tetrachlorodecaoxide dressing in the management of diabetic foot wounds.

Methods: A sample size of 40 (20 in each group) in group A, dressing was done with normal saline and in group B, dressing was done with tetrachlorodecaoxide solution. Statistical analyses were performed using IBM SPSS version 20. The mean difference was calculated using an independent t -test, and catego rical variables were stratified using a chi square test or a Fisher exact test as appropriate.

Results: Normal saline significantly shortened the healing duration and wound area after 8 weeks when added to a routine therapy for DFU. A comprehensive strategy is nece ssary to treat DFU effectively. To assist limit the number of patients who may eventually have to have their legs amputated due to DFU -related complications, it may be possible that normal salt water can be used as an alternate treatment option.

Conclusion: In conclusion, normal saline significantly shortened the healing duration and wound area after 8 weeks when added to a conventional therapy for DFU. A comprehensive strategy is necessary to treat DFU effectively. To assist limit the number of patients who may eventually have to have their legs amputated due to DFU -related complications, it may be possible that normal salt water can be used as an alternate treatment option.

Keywords: Diabetes, Normal saline, Tetrachlorodecaoxide, Diabetic foot, Foot ulcers, Super-oxidized solution

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1. Introduction

Diabetic foot wounds and other diseases are becoming increasingly common because of the rise in the prevalence of diabetes. Microvascular and macrovascular problems are all serious consequences of hyperglycemia (coronary artery disease, stroke and peripheral arterial disease). Non-healing ulcers are usually preceded by diabetes as a leading cause of non-traumatic lower extremity amputation. Patients with diabetes have a 15% to 20% lifetime chance of developing a foot ulcer(1).Amputation is required in more than 15% of cases with foot ulcers. The annual incidence of diabetic foot ulcers in the general population is estimated to be between 0.5 and 3 percent. Foot ulcers are reported to occur between 2% and 10% of the time. Neuropathic or ischemic foot ulcers account for more than half of all diabetic foot ulcers, with the latter accounting for around 45 percent of the total. Infection is the leading cause of lower limb amputations in people with diabetes, according to a recent study (2).

Peripheral vascular disease in the lower limbs is accompanied with deep tissue infection, ulceration, and destruction (3).Peripheral neuropathy, which causes the feet to become numb so that an injury goes unrecognized, is one reason that contributes to diabetic foot ulcers. Poor wound healing is also caused by vascular insufficiency, which makes the neuropathic ulcer more difficult to treat. High plantar pressure may be caused by foot deformities and calluses, increasing the risk (4). It is theorized that wound healing is affected by the presence of mechanical stress. Numerous additional factors can increase or decrease a diabetic's risk of developing a foot ulcer and subsequently contracting an infection (5).

Diabetic foot ulceration can be caused by uncontrolled hyperglycemia, long-term diabetes, trauma, incorrect footwear, callus, prior ulcers/amputations, old age, blindness/impaired vision, chronic renal illness, and poor nutrition(6). An infection in the feet of diabetics can lead to a wound that never heals. A recent study found that diabetic foot infections were more common among people with vitamin D deficiency (7).Recent advancements in wound management research have been fueled by the development of novel materials, procedures, and an improved knowledge of wound

healing biology. Topical wound dressings containing tetrachlorodecaoxide and super-oxidized solution are among the most recent, more effective, and more powerful options (SOS). For wounds of all kinds SOS is an effective and safe treatment that moistens, lubricates and debrides. It also decreases the bacteria load in the wound. Pure solutions are used to produce an electrically treated aqueous solution high in reactive oxygen species (ROS). It is a potent antimicrobial. 'It is a bactericidal, virucidal, fungicidal, and sporicidal solution that requires no additional dilution or mixing and is stable, non-flammable, and non-corrosive (8).

The use of tetrachlorodecaoxide (TCDO) is a stride forward in wound healing since it directly activates the macrophage system and increases the partial pressure of oxygen in the wound, both of which contribute to the healing process. If you have a persistent wound, this is critical for the healing process to take place. The wound is moistened using TCDO, an aqueous solution. The oxygen carrier is bio-activated (9).

It interrupts the cycle of hypoxia in a wound. When activated phagocytes need more oxygen, it helps to ensure that the hypoxic conditions necessary for neo-angiogenesis are not compromised. TCDO has been shown to be bactericidal in vitro. Wound healing is made possible by the mitogenic activities of TCDO on fibroblasts and new blood vessels. Toxicity is not generated during the degradation of TCDO via haem-activated decomposition (10).Both TCDO and SOS have been compared against other older options in numerous studies, both alone and in combination. As a direct comparison, these two medications will be compared in this research (11). The objective of this study is to compare the effectiveness of normal saline versus tetrachlorodecaoxide dressing in the management of diabetic foot wounds.

2. Materials & Methods

This After taking approval from Institutional Review Board (IRB) of Shaikh Zayed Hospital, Lahore. A total of 40 patients (20 in each group) fulfilling the inclusion criteria (both male and female gender, age from 30 to 70 years, patients with wound on pressure areas like heel, toes and ankle and patients with uncontrolled or poorly controlled diabetes mellitus) were evaluated by the surgical team in outdoor department. Patients Patients who were not willing to participate in study by giving written consent, those with known allergy to tetrachlorodecaoxide solution and patients who lost follow-up during this study were excluded from the study. Informed written consent was taken by explaining each patient about the purpose and the procedure of the study. All information regarding age, gender BSR, healing period, wound area was noted on prescribed proforma. Group A was represented as Normal saline Group (SOS) and group B was represented as tetrachlorodecaoxide solution group. Patients were following up at least 6-8 weeks in terms of dressing and wound healing.

3. Results

A total of 40 patients with an overall mean age and standard deviation of 56.65 ± 10.61 years and median of 58 with a range of (37-70) were included in this study. In addition, majority of the patients were male22 (55%). Additionally, all the patients were segregated as per diabetic wound grading system and majority of the patients had grade-1 (40%) and grade-2 (42.5), respectively. The overall mean healing time period and random blood sugar levels were 3.14 ± 0.66 and 252.55 ± 37.51, respectively. In addition, wound area was assessed at baseline and after 8 weeks and mean wound area baseline (cm2)143.13 ± 27.25 and 126.61 ± 29.30, respectively as shown in Table 1.

Furthermore, all the patients were equally divided into two groups; normal saline 20 (50%) and tetrachlorodecaoxide solution 20 (50%). Table 2 showed the bifurcation and mean difference all the independent variables with respect to normal saline versus tetrachlorodecaoxide solution groups. There is a statistically significant difference (p-value: 0.03) was observed in healing period in both groups. The healing period in normal saline groups was significantly lower 2.92 ± 0.53 than tetrachlorodecaoxide group 3.36 ± 0.71. Also, wound area after 8 weeks (cm2) was also statistically significant (p-value: 0.03) in both groups. Furthermore, wound area after 8 weeks (cm2) was also lesser in normal saline group versus tetrachlorodecaoxide group (123.47 ± 10.93 versus 129.76 ± 6.10) as shown in Table 2. Figure 1 showed the graphical presentation of mean difference of wound area at baseline (cm2) and wound area after 8 weeks (cm2) of all the patients with respect to normal saline versus tetrachlorodecaoxide solution groups.

Table 1: Baseline and overall characteristics of the patients

Variable Categories		Total n = 40 (%)
Age (years)		
Mean ± SD		56.65 ± 10.61
Median	(min-max)	(35-70)
Gender		
Male		(55.0)
Female		(45.0)
Groups		
Normal saline		(50.0)
Tetrachlorodecaoxide solution		(50.0)
Diabetic wound grading		
0		(7.5)
1		(40.0)
2		(42.5)
3		(10.0)
Healing period (months)		
Mean ± SD		3.14 ± 0.66
Median	(min-max)	3.10 (1.90-4.50)
Blood sugar random (mg/dL)		
Mean ± SD		252.55 ± 37.51
Median	(min-max)	(200-350)
Wound area baseline (cm^2)		
Mean ± SD		143.13 ± 27.25
Median	(min-max)	143.35 (127.25-157.0)
Wound area after 8 weeks (cm^2)		
Mean ± SD		126.61 ± 29.30
Median	(min-max)	125.20 (101.20-145.34)

4. Discussion

Conventional treatment for diabetic foot ulcer (DFU) patients includes wound care, glucose management, appropriate antimicrobial medication, and advice to rest and use therapeutic shoes to reduce foot pressure loading (28). If necessary, amputations and re-vascularization of ischemic limbs are carried out. On the basis of DFU's complex traits (29), such as low tissue oxygen tension and immunological abnormalities (30) that lead to uncontrolled infection and inflammation, conventional therapy has been able to achieve some partial success in treating DFU. Because DFU advances quickly and rigorous therapy is needed to limit the chance of amputation, it is imperative. Amputation rates for diabetic foot ulcers (DFUs) might increase by as much as 150% due to diabetes mellitus. There are more non-traumatic lower leg amputations in the industrialized world due to diabetic foot problems than any other medical condition. Furthermore, up to 25% of all diabetic admissions in the UK and the US are due to foot issues, making them the most common cause of hospitalization.[31]

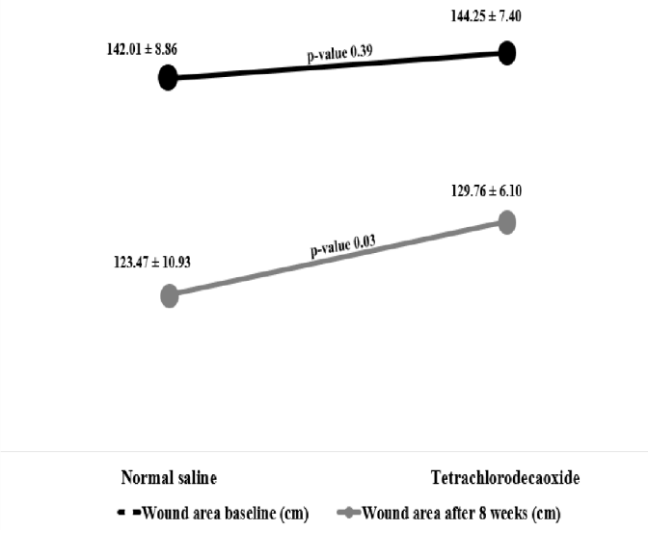
New therapeutic options have been tested in recent years in an effort to enhance patient outcomes. There has been modest success with recombinant platelet-derived growth factor in treating DFUs.[32] Wound healing has been slowed by the inability of other topical medicines

Table 2: Bifurcation and mean difference of all the independent variables with respect to normal saline versus tetrachlorodecaoxide solution groups

Variable Categories	Normal saline n = 20 (50.0)	Tetrachloro decaoxide n = 20 (50.0)	p-value
Age (years)			
Mean ± SD	54.15 ± 10.72	59.15 ± 10.15	0.14
Gender			
Male	(65.0)	(45.0)	0.20
Female	(35.0)	(55.0)	
Diabetic wound grading			
0	(15.0)	-	0.40
1	(40.0)	(40.0)	
2	(35.0)	(50.0)	
3	(10.0)	(10.0)	
Healing period (months)			
Mean ± SD	2.92 ± 0.53	3.36 ± 0.71	0.03
Blood sugar random (mg/dL)			
Mean ± SD	241.35 ±21.17	263.75 ±46.64	0.06
Wound area baseline (cm^2)			
Mean ± SD	142.01 ± 8.86	144.25 ± 7.40	0.39
Wound area after 8 weeks (cm^2)			
Mean ± SD	123.47 ± 10.93	129.76 ± 6.10	0.03

to penetrate the surrounding tissues and deeper infection sites.[33] The effectiveness of tetrachlorodecaoxide solution against normal saline as a topical wound care treatment is compared in this study. A wide range of ulcer types and etiologies were considered during this investigation. Using randomization as a technique of registration, researchers were able to minimize selection bias. Both groups have the same number of instances for each kind of ulcer, wound area score, gender, and diabetes status (diabetes mellitus). There are four main stages of wound healing, each of them overlapping and intertwined with the others: hemostasis, inflammation, granulation and remodeling. As blood cells, fibroblasts, keratinocytes and growth factors are coordinated during the healing of wounds, the healing process is accelerated. Diabetic wound healing may be delayed because of a lack of coordination between these cells and growth hormones and cytokines, which is not fully understood.[12] The wound healing process in diabetic foot ulcers is slowed, according to both clinical and experimental investigations (DFU). Reactive oxygen species (ROS) have been shown to increase apoptosis and delay wound healing in injured tissue. The delayed healing of wounds in diabetics is a result of diminished synthesis of several growth factors, including TGF-, EGF, PDGF, IGF-1, and VEGF, as well as lower collagen deposition and a delayed inflammatory response, which all contribute to the delay in wound healing.[13]

Figure 1: Mean difference of wound area at baseline (cm2) and wound area after 8 weeks (cm2) of all the patients with respect to normal saline versus tetrachlorodecaoxide solution groups.



Diabetes patients with tight glycemic control had a decreased long-term risk of microvascular and neurological complications, according to findings from the Diabetes Control and Problems Trial (DCCT) and the UK Prospective Diabetes Study (UKDPS), which may help with wound contraction speed. DFU presents a significant therapeutic challenge since it is associated to intrinsic issues such as hemodynamic irregularities, hypoperfusion, aberrant angiogenesis, and neuronal ischemia, as well as extrinsic variables such as infection and ongoing trauma that obstruct wound healing. Because traditional pharmaceutical therapy for DFU is lacking, it cannot be treated with a single technique.[14]

Therapies for treating diabetic wounds include the removal of dead, damaged, or diseased tissue; antibiotics; tissue grafts; proteolytic enzymes; corticosteroids; and other treatments. However, only a small percentage of patients benefit from these treatments, and their negative effects prevent them from being widely used. TGF-, EGF, PDGF, IGF-1, and VEGF have been shown in studies over the last few decades to speed wound healing by enhancing cell mitosis, migration, and neoangiogenesis. As a result, they aren't commonly utilized since they might cause problems with wound healing. Chronic, nonhealing DFU is connected with increased expenditures and a worse quality of life for patients. New treatment medicines with low side effects are needed as a result.[15] Nowadays, natural medicines produced from plants that may have hypoglycemic effects are more widely accepted, prompting clinical research based on evidence to be conducted in the regular practice of wound care. Triterpenes, alkaloids, and flavonoids, among other plant-derived active components, have been proven to have wound healing potential through modulating one or more healing stages.[16]

Because of its compatibility with human tissue, normal saline is often suggested as a wound cleaning solution for its ability to cleanse wounds. In the process of healing a wound, this fluid has no negative effects on fibroblasts or keratinocytes. It has not been shown to be beneficial in preventing infection. While many cleaning methods have shown to be safe and effective, others have the potential to harm or kill cells that are critical to the healing process. Nontoxic and isotonic, normal saline is regarded the best cleaning fluid since it does not harm healing tissue.[17] People with diabetes are more

vulnerable to wounds on the lower limbs and feet that don't heal for a variety of reasons. A diabetic's foot may become weak and numb as a result of nerve loss, which may cause discomfort. Numbness may put patients at risk for foot injuries, either by trauma or by walking on a blister or callus without experiencing any discomfort (18).

Diabetic skin is also more prone to breaking, which increases the chance of infection. As a result of diabetes, lower leg and foot blood arteries might stiffen and become obstructed by peripheral artery disease. Patients with this syndrome are more vulnerable to infection and ulcers because of impaired circulation (19). Wound healing can be hampered by inadequate tissue perfusion (the distribution of oxygen in the body), bacterial infection, starvation, and poor blood glucose control. A foot ulcer affects 15 to 25% of diabetics at some point during their life. Lower limb amputations are more common in diabetics than in non-diabetics because these wounds are more difficult to treat and heal(20).

Standard wound care is used to treat patients with diabetic foot ulcers. Hyperbaric oxygen therapy (HBOT) clinics may be recommended to many patients when normal wound treatment fails to heal them. As stated by Fedorko et al., the most important outcome was "freedom from having or meeting the criteria for amputation." One study's definition is different from the others. " There had been no significant improvement in wound healing over the follow-up period, indicating an ongoing threat of serious systemic infections from that particular injury; (2) a deep infection of the bone and tendons had persisted in spite of treatment with antibiotics, hospitalization, and/or the presence of a pathogen; (3) the affected limb was incapable of bearing weight and had seized; and (4) all three of the aforementioned conditions were present. Researchers utilized unverified digital images and vascular surgeons' recommendations to determine if a patient needed a leg amputation. It is only necessary to amputate the diabetic foot that can no longer be salvaged. Some of the circumstances that need the use of this therapy include wet gangrene (infection and ischemia), life-threatening sepsis and substantial muscle necrosis, as well as a bedridden or functionally useless limb(21). At three times, Abidia et al. assessed full ulcer healing. It took six weeks for the HBOT and conventional treatment groups to achieve full healing for five and one of eight patients, respectively. At six months, five patients in the HBOT group had fully healed ulcers, whereas two patients in the conventional therapy group had fully healed ulcers. After a year, five patients in the HBOT group were still exhibiting symptoms of complete recovery, but none in the standard treatment group. This led us to believe that both patients who had fully recovered after six months in the conventional treatment group had recurrences of their original ulcers after a year (22).

A total of two fatalities were recorded in the HBOT group, according to Kalani and colleagues. Multiorgan failure claimed the life of one patient, while increasing heart failure claimed the life of the other. Acute myocardial infarction was the cause of death for two patients in the standard-of-care group, whereas cerebral infarction (stroke) was the cause of death for a third patient (heart attack) (23). According to Londahl et al., one patient in the HBOT group died of multiple organ failure 20 days after the research began. Two patients in the usual care group died of myocardial infarctions after a median of 162 and 218 days, while a third patient died of sepsis caused by an infected foot ulcer, respectively (23).

According to Faglia and colleagues, the usual care group had four forefoot and eight toes amputated whereas the HBOT group had five forefoot and 16 toes amputated. There had been one minor amputation in the HBOT group but none in the conventional care group by an undetermined follow-up date (probably one year after the start of the study)(24). During an undefined amount of time, four minor amputations occurred in the HBOT group and 41 in the standard care group, according to Duzgun et al. time. Londahl et al. reported four minor amputations in the HBOT and conventional treatment groups after a year of follow-up(25). Due to the fact that Fedorko et al used the same criteria for minor amputations as they did for large ones, their results could not be included in the GRADE grading system. During the study's duration, just one minor amputation occurred in the conventional therapy group. After tracing the ulcers onto a clear sheet, Abidia et al transformed the tracings into digital pictures and measured the ulcer surface area reduction. A unique software tool was used to compute the total surface area. The depth of the ulcer was also measured, as were any visible evidence of infection (21). Kessler et al employed a computer programme to calculate the baseline wound ulcer surface

area in square centimeters, as well as the percent decrease in wound ulcer surface area from baseline to day 15, day 15 to day 30, and day 30 to baseline(26). Fedorko et al. used highresolution calibrated digital photographs to take manual measures of wound breadth and computational assessments of wound surface area and perimeter (27).

While the skin's potential to repair itself is enormous, the skin's ability to heal itself is limited by dryness of the wound surface and the presence of infections (34, 35). Normal saline showed better wound healing effect than tetrachlorodecaoxide solution in this study as is shown in table two. In addition, healing period and size of wound area is significantly lesser in normal saline group than that of tetrachlorodecaoxide solution. Because regular saline may keep the wound surface wet and does not interfere with the healing process, it may be to blame." This may explain why wounds treated with regular saline had a slightly better outcome than those treated with tetrachlorodecaoxide solution. Another study demonstrated a significant difference in the healing time of a lesion treated with regular salt water and tetrachlorodecaoxide solution, as well (36). The first step in evaluating a foot ulcer is to ensure that it has been adequately debrided. After removing necrotic tissue and surrounding callus, a healthy bleeding edge can be seen. It is common for patients (as well as doctors) to underestimate the necessity of debridement; therefore, they are often taken aback when the newly debrided ulcer first appears. The use of topical debriding enzymes is prohibitively costly and has yet to be shown effective. Thenon-toxic and isotonic property of normal saline may help in healing of the wound more efficiently than tetrachlorodecaoxide solution. The healing duration and wound area (after 8 weeks) were both statistically substantially (p-value <0.05) lower in normal saline compared to tetrachlorodecaoxide solution, according to this study. There are various flaws in this study. Because of the tiny sample size and the inclusion of only one institution. The findings did not represent the work of general surgeons and internists at other facilities. Despite the fact that these variables raise questions, the underlying conclusion remains sound.

5. Conclusion

In conclusion, normal saline significantly shortened the healing duration and wound area after 8 weeks when added to a conventional therapy for DFU. A comprehensive strategy is necessary to treat DFU effectively. To assist limit the number of patients who may eventually have to have their legs amputated due to DFU-related complications, it may be possible that normal salt water can be used as an alternate treatment option.

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