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Original Article

Distance Electro Therapy Versus Low Pulsed Electromagnetic Field on Pressure Ulcer: Which is Safer and More Effective?

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Abstract

Purpose: Tens of thousands of individuals worldwide suffer from pressure ulcers (PUs), which are a global health hazard with highly cost management, so the trial targeted to compare between Distance Electro Therapy (DE) and Pulsed Electromagnetic Field (PEMF) efficacy in PU management in the form of minimizing wound surface area and volume.

Materials and Methods: 60 patients with pressure ulcers were recruited in this trial and subdivided at random to 3 equal groups. DE Group: received DE (Frequency: 72 Hz. Impulse: 340 microseconds. Time: 3000 microseconds. Intensity: 100%, for 20 min) and medical care. PEMF group: received Low intensity PEMF (Frequency: 10 Hz, Intensity: 60%, no thermal effect, for 20 min) and medical care. Control group: received medical care only. The treatment sessions were three times per week for 6 weeks. WoundDesk software application, and sterile gel injection were the assessment methods of wound surface area and volume respectively. All measurements were collected before the beginning of the study, and at 6th week of the trial termination.

Results: All groups reported improvement in measured variables, however more reduction of wound surface area and volume were reported in DE group compared to the other groups (p value < 0.05).

Conclusion: Distance Electro Therapy is a new intervention of contactless electrotherapy that achieved superior results in ulcer closure.

Keywords: Pressure Ulcer (PU); Distance Electro Therapy (DE); Pulsed Electromagnetic Field (PEMF).

Introduction:

A wound is a pathological process-induced impairment of the regular functioning and structure of the skin **(1,2).** The healing of a wound is a complicated tissue restoring procedure that requires multiple types of cells that work collectively to repair and rebuild tissue. In ulcer individuals, the healing process becomes

complicated, resulting in chronic ulcers that fail to heal. A chronic wound is one that fails to heal in the normal sequence of phases over a period of time that the majority of ulcers should. Chronic ulcers are those that fail to heal within a three-month period **(2-4).**

Non-healing wounds are mostly described as those that do not heal in a proper sequence in the appropriate amount of time. These wounds are occasionally assumed to be the result of carelessness, inadequacy, incorrect diagnosis, or ineffective treatment procedures. Yet, certain wounds are resistive to all strategies towards the healing process, and different outcomes should be focused on; interventions targeted at enhancing quality of life become essential in these cases **(5).**

A large percentage of chronic wounds fall into one of the following three groups: venous ulcers, diabetic ulcers, and pressure ulcers. A limited proportion of wounds that do not fit into one of these categories could be caused by ischemia or radiation exposure **(6,7).**

A pressure ulcer (PU) is a localized region of skin and underneath tissue injury that results from pressure, shear forces, or either of both. The extent of ulcers is tracked using a grading system ranging from Category 1 to Category 4. Category 1 describes superficial damage to the skin with no disruption in the skin consistency, often known as non-blanchable erythema. Severe damage, necrosis of tissue, or injury to muscle, bone, or underlying structures, either with or without full thickness skin loss, is classified as category 4 **(8).**

Pressure ulcer (PU) is connected to poor health and mobility. Due to their negative impact on the patient's quality of life and cost they impose on healthcare providers **(9),** the prevalence of PU is utilized as a quality indicator all around the world, serving as a standard for evaluating treatment in diverse contexts. According to studies, the prevalence of the disease in hospitals varies from 0% to 46%. Identifying patients who are at risk of developing a PU is a crucial part of clinical practice **(10).**

The causes of PU are complex and multifaceted. In critically ill patients who are already physiologically stressed, PU provide an extra risk. In fact, one of the most overlooked medical complications among critical care patients is PU. Despite developments in medical technology and the implementation of organized preventative measures based on clinical practice recommendations, the prevalence of PU during hospitalization continues to climb **(11).**

Many medical professionals and scholars have attempted on discovering supplementary or supportive interventions to help patients with PU. Surfaces for support and feeding, dressings for wounds, topical agents, and various supplementary therapies, such as electrical stimulation, therapeutic ultrasound, hyperbaric oxygen therapy, hydrotherapy, light therapy, and laser therapy, as well as vacuum-assisted devices and suction-assisted devices are all used in PU treatment **(12).**

Physical-based interventions, such as the use of low intensity pulsing electro-magnetic fields (PEMFs) and light emitting diodes, have received a lot of interest from researchers in recent years. PEMFs have been used effectively in a variety of disorders spanning neurological rehab to tissue healing, with mostly favorable outcomes **(13).** Experiences in healthcare facilities have supported the safety and efficacy of PEMFs provided using therapeutic magnetic resonance to stimulate repair of tissues in post-traumatic and chronic wounds, implementing this type of equipment potentially useful for the treatment of ulcers and post-surgical wounds **(14-15).**

Distance electrotherapy is an emerging method that includes medical equipment designed for use by professionals in the medical field with the aim to offer therapeutic techniques of distance, or non-contact (electrodeless), electrotherapy using the physical and therapeutic benefits of eddy electric currents, developed on the principles of Faraday electromagnetic induction, that are created in the tissues under treatment when the equipment applicator is

situated in close range of these tissues. The evident and well proven biological activity reaches up to the distance of approximately 25 cm from the applicator **(16).** It offers two fundamental forms of therapeutic electromagnetic currents: pulse magnetic currents and interference magnetic currents as well as light emitting LED diodes that represent secondary phototherapy applied simultaneously with distance electrotherapy in order to increase its effect **(17).**

The significance of this investigation lies in the fact that it will add to the body of evidence in the field of physiotherapy studies concerning the effectiveness of distance electrotherapy compared to low intensity PEMFs for the management of chronic PU by minimizing wound size and wound volumes.

Materials and Methods:

Subjects:

Sixty patients with chronic unhealed PU for longer than three months were participated in this study. They were divided into three equal-sized groups at random. Group A: distance electrotherapy group (20 patients) received distance electrotherapy (DE) and medical care. Group B: Low intensity PEMFs group (20 patients) received low intensity PEMFs and medical care. Group C: Control group (20 patients) received medical care only.

Criteria for entry to the study include (1) both genders male & female were included, (2) age ranged from 40 to 60 years, (3) patient with lower limb and foot ulcer, (4) Grade II or III pressure ulcers were included (European Pressure Ulcer Advisory Panel Grading System 2014), (5) Duration of ulcer was more than 3 months. Each subject received a detailed explanation of the study and a form of consent assigned prior to participation.

Participants were excluded because (1) they had diabetes, (2) cancer patients or those receiving radiation therapy or chemotherapy, (3) patients having necrotic tissue accompanied by eschar, (4) patients having a fistula to any organ or body cavity near the wound, (5) patients suffering from life-threatening conditions such as myocardial infarction, (6) patients who have recently had immunosuppressive or anticonvulsant medication, (7) patients who are also taking part in another clinical investigation, (8) patients experiencing psychological difficulties, (9) patients suffering from severe anemia, skin allergies, severe uncontrolled hypertension, and pregnant women.

Study Design and Randomization

This trial was a randomized, double-blind, pretest-posttest investigation conducted from July 2023 to July 2024. Throughout the process of randomization, Microsoft Excel was used to create a spreadsheet of random numerals, with each column representing one of the three groups A, B, or C based on the number of assignment codes. An investigator employed drawing techniques to select who was going to participate in group A, B, or C without notifying participants or assessors. As a consequence, both participants and assessors were uninformed of the therapy assignment.

Ethical Considerations

This study was approved by the research ethical council of Cairo University's Faculty of Physical Therapy before the examination took place, participants received details about the measurements and experimental methods, and they provided an informed consent agreement.

Procedure of the Study:

Measurement Procedures

The analysis was performed immediately before the beginning of treatment and again six weeks later.

1. Wound Surface Area Assessment

A smart app for measuring and assessing wounds. WoundDesk software application (version 0.06, digitalMedLab GmbH, Technoparkstrasse 2, Winterthur, Switzerland) is a tool that should only be used by medical experts. By providing a space for documentation as well as capabilities such as semi-automated wound surface measures, the programmer can help maintain track of all patients and chronic wound (18). Wound surface measurements using

the smartphone app +WoundDesk are accurate, reproducible, and repeatable, with intra- and inter-rater reliability values more than 0.98 (19,20). The ulcer surface area was calculated using these steps: A traditional metered sheet was positioned on the outer edge of the ulcer selected by the WoundDesk App, and a digital image was taken with a 64-megapixel mobile camera via a smart smartphone application called Digital MedLab's WoundDesk, that analyzes the image and accurately measures the surface area.

2. Wound Volume Assessment

The following steps were followed to determine the ulcer's volume: The surrounding skin was cleaned and dried before the sore was prepped. A transparent adhesive was applied securely over the sore along with the surrounding skin, with the film extending sufficiently far beyond the same boundaries to ensure good bonding. Following this, sterilized gel was administered into the ulcer via the film. We measured the amount of gel needed to fill the ulcer cavity. We developed two indicators based on the ulcer volume to quantify the effectiveness of treatment. The first is the percentage of change in ulcer volume, which is defined as the reduction in ulcer volume as a percentage of the starting volume. The second is the rate of change in ulcer volume, which is calculated by dividing the percentage of change over the total number of treatment weeks to obtain the change per week (21).

Treatment Procedures:

Participants were informed about the treatment procedures and its purpose. The procedures of the treatment were divided to three main categories.

Procedures of Medical Care:

Chronic wound medical treatment was done for all patients in the three groups and consists of: (1) Treatment of cause (e.g., using positioning, pressure distribution aids), (2) Mechanical debridement by whirlpool, (3) Wound cleansing by pressurized saline, (4) Wound dressing with appropriate dressing, (5) Nutritional support (22,23).

Procedures of Distance Electro Therapy (DE)

This procedure was applied for patients in group by EMBITRON VAS-007equipment (made in Czech Republic). Each participant was set in a relaxed and comfortable position. The device applicator place approximately above the treatment area about 25 cm2. Setting up the device parameters as following: (Frequency: 72 Hz. Impulse: 340 microseconds. Time: 3000 microseconds. Intensity: 100%). The treatment lasted 20 minutes, three times a week for six weeks.

Procedures of Low Pulsed Electromagnetic Field (LPEMF)

Low pulsed electromagnetic field (LPEMF) was applied for patients in group B (ASA device, Sri Via A, Voltage 9-36057, made in Italy). Patients were placed in a relaxed comfortable position. The device coil place around the treatment area. Setting up the device parameters as following: (Frequency: 10 Hz, Intensity: 60%, no thermal effect). The treatment lasted 20 minutes, three times a week for six weeks.

Statistical Analysis

A priori sample analysis was not performed since there was a shortage of relevant research and the inherent challenges in predicting the amount of the effect. Yet, the statistical power was estimated posteriori using the G power software tool (version 3.0.10, Made in Germany), which showed that every analysis performed had strong statistical power of 80%. The statistical package for social studies (SPSS) version 25 for windows (IBM SPSS, Chicago, IL, USA) was used for all statistical analysis. For age, WSA, and wound volume, descriptive statistics (mean, standard deviation, maximum, minimum, and range) were determined for all of the participants in all three groups. The chi-squared test was used to compare sex between groups. For all variables, the Shapiro-Wilk test was used to ensure that the data had a normal distribution. To assess group homogeneity, Levene's test for variance homogeneity was used.

ANOVA was used to examine the pre-treatment and post-treatment between the three study groups. Post Hoc tests were used for pairwise comparisons. For comparison of ulcer surface area and volume prior to and following intervention within groups, a paired t test was performed. The level of significance was fixed at $p < 0.05$ for all statistical tests.

Results:

Figure 1 shows a flow diagram for participants at each step of the trial. 75 patients were assessed for eligibility, and 60 of them met the inclusion requirements and were randomly assigned to one of three groups. Data for sixty patients were available for the final analysis. Data obtained from the three groups before initiation of treatment and at six weeks of treatment, regarding patients' demographic data, wound surface area and volume were statistically analyzed and compared.

Table 1 shows the demographics of the patients who completed the investigation. In terms of demographic features, three groups were comparable at their start.

As shown in **(Table 1),** there were no significant variances in average scores for age, height, weight, BMI and ulcer duration as well as sex distribution between the three groups ($p \geq 0.05$).

Table 2 shows a comparison of mean differences in wound surface area and wound volume between three groups before and after intervention.

As shown in **Table 2,** there were no significant variations in mean surface area scores between the three groups prior treatment (P value ≥ 0.05), however there were substantial differences between the three groups following treatment (P value < 0.05). The wound volume variations among all three groups indicated no significant changes before treatment (P value ≥ 0.05), however there were high significant differences following treatment (p value < 0.05).

The Bonferroni post hoc test was implemented to compare between groups. When group A or group B were compared to group C, the results revealed high significant differences in means of wound surface area and wound volume (P value < 0.05). Wound surface area and wound volume were decreased significantly in groups A and B than in group C. When group A was compared to group B, group A had a more significant decrease in wound surface area and wound volume (p value < 0.05).

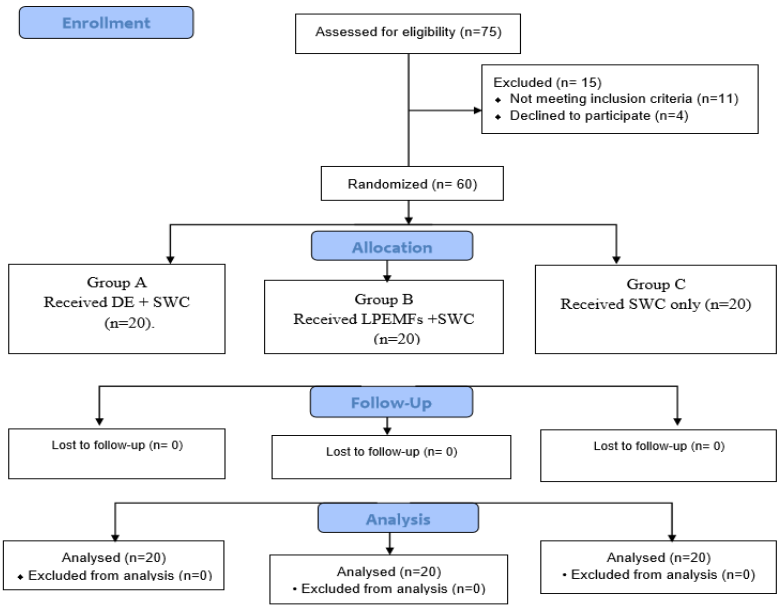

Figure1. CONSORT 2010 Flow Diagram

Table 1. Demographic characteristics of the participants.

	Group A (20)	Group B (20)	Group C (20)	P-value
Age (Year)	54.55 ±6.00	55.30±4.79	56.55±5.93	0.526*
Weight (Kg)	65.25±9.28	62.40±9.59	61.35±9.38	0.405*
Height (m)	1.57±0.06	1.60±0.056	1.59±0.048	0.231*
BMI (Kg /m2)	26.53±4.23	24.36±4.04	24.40±4.08	0.173*
Ulcer duration (month)	7.10±2.02	8.05±2.28	7.70±2.45	0.410
Gender N (%)				
Female	13 (65%)	11 (55%)	14 (70%)	0.610*
Male	7 (35%)	9 (45%)	6 (30%)	

Values are mean ± SD, SD=Standard deviation, m=meter, BMI = body mass index, * P ≥ 0.05 compared between groups (non-significant differences)

Table 2. comparison of mean differences in wound surface area and wound volume between three groups before and after intervention.

	Group A (20)	Group B (20)	Group C (20)	P-value
WSA (pre) mm2	**80.80±8.78**	**78.65±9.83**	**75.30±10.24**	**0.200***
WSA (post)mm2	**46.95±11.70**	**57.70±8.57**	**69.45±10.58**	**0.001†**
% of change	**41.89%**	**26.64%**	**7.77%**	
UV (pre) mm3	**74.55±16.28**	**70.15±11.12**	**67.85±13.71**	**0.307***
UV (post) mm3	**30.40±8.30**	**39.05±9.47**	**49.85±13.43**	**0.001†**
% of change	**59.22%**	**44.33%**	**26.53%**	
Rate of change of UV (% /week)	**9.87**	**7.39**	**4.42**	

Values are mean ± SD; SD=standard deviation; WSA= wound surface area; mm=millimeter; WU= wound volume; * P ≥ 0.05 compared between groups (non-significant differences); † P < 0.05 compared between groups (highly significant differences).

Discussion:

Pressure ulcer (PU) is a critical healthcare problem around the world. Both the quality of life and the financial impact of PUs are affected by their severity **(9).** This trial was designed to compare between DE and LPEMF in PUs management, the results recorded statistical reduction in both wound volume and size as the percentage of reduction of WSA in DE, LPEMF and control groups was 41.89%, 26.64%, 7.77% respectively. As regards wound volume, the percentage of reduction was 59.22%, 44.33%, 26.53% respectively.

Based on our knowledge, this is the first trial that evaluate DE and compare it with PEMF in ulcer healing, considering the outcomes of this study, both intervention modalities demonstrated significant improvement in all outcome measures and during the trial, no adverse effects were observed, however higher improvement was seen within the DE group. The effects of electrical stimulation on the migratory, proliferative, and synthetic functions of fibroblasts could explain this increase in function, rising the production of growth factors, as ES influences all four phases of the healing process, it had been assumed that ES improves blood circulation to the area of injury. This may boost oxygenation in the tissues and minimize edema by increasing the migration of cells essential for the inflammatory and proliferative phases. It may also have an effect on the development of epidermal growth factors and their receptors, as well. ES also has an antibacterial activity, assisting in infection prevention and healing improvement **(24).**

Moreover, one of the prominent advantages of DE is providing LEDs which also can be considered one of the contributor factors in accelerating the healing process, as LED has been shown to have favorable physiological benefits in a variety of injury classifications. Photo biomodulation has been reported to boost the metabolism of mitochondria, accelerate wound healing, and enhance angiogenesis in the skin, bone, nerves, and skeletal muscles. LEDs benefit cells by "kick-starting" their process of rapidly synthesizing additional adenosine triphosphate (ATP) and enhancing DNA and RNA activity **(25).**

Trials in vitro and in vivo on the impact of ES on the overall processes of healing revealed enhanced epithelial growth fibroblast migration, and blood supply near wounds. Six in vitro trials concluded that alternating and pulsing current had bactericidal effects. The beneficial impact of pulsed current on chronic wound healing was studied in twelve randomized controlled trials (RCTs), as compared to control groups, all of the RCTs showed a greater decrease in wound size and a faster healing rate. According to the review, ES therapy can promote chronic wound healing and possibly decrease the cost that comes with wound care **(26).**

Furthermore, Chen et al. (2022) conducted a meta-analysis and systematic review in order to update the scientific literature and assess the safety and efficacy of ES for PU healing, with no restrictions on care setting, variables, duration (of both ulcers and intervention duration), or patient types. This analysis included 17 RCTs with a total of 740 participants. A meta-analysis of eight RCTs revealed that ES reduced ulcer surface substantially greater than routine wound treatment alone or pulsed sham electrical stimulation. Nine studies found that ES enhanced the likelihood of PU being totally healed when compared to the control group. According to three investigations, adverse effects were uncommon. The meta-analysis findings revealed that ES had a statistically significant impact on the overall percent of wound surface area (WSA) reduction ($p = 0.001$), ulcer size reduction ($p = 0.02$), and the number of healed PUs ($p = 0.04$). **(27).**

When combined with the descriptive data from this systematic review, ES improves PUs by healing and minimizes absolute WSA and volume, as confirmed and reported in our study. Although there has been insufficient data in the current research that supports the application of electromagnetic therapy for treating chronic wounds and ulcers, it differs from electrotherapy.

This trial's data demonstrated improvements in both ulcer size and volume, that could be related to the influence of PEMF on tissue formation and proliferation of cells in wound healing. PEMF was proposed to promote the migration of electrically charged cells that contribute to wound repair, regaining the metabolic state of the healing cells. It has been suggested as well that PEMF produces a small electrical impulse on the wounded cell membrane, triggering an array of physiological responses such as a rise in the quantity of macrophages and fibroblasts in the wound, a decrease in inflammatory processes, and a raise in collagen and fibrin deposition, all of which assist in the process of healing. According to some hypotheses, PEMF is linked to the formation of free radicals in cells, that regulate intracellular communication **(28).**

In opposition to our findings, **Smith et al., 2013 (29)** performed a review of the literature evaluating the efficacy and safety of treatments for adults with PUs. The evaluation included four randomized trials and 112 comparative observational studies testing EMT. In terms of wound healing results, the researchers concluded that the use of electromagnetic therapy was indistinguishable from sham intervention or conventional care. **Aziz et al., 2010 (30)** also examined the effects of EMT on the healing process of PUs in a Cochrane study. The review comprised two randomized controlled trials (RCTs) that had an undefined risk of bias with 60 individuals. The two studies investigated the application of EMT versus sham EMT, while one

trial added a third arm that merely used routine care. Neither study discovered a statistically significant difference in full recovery between patients treated with EMT compared to those in the control group. According to the investigators, the findings show no clear benefit from utilizing EMT to treat PU. Yet, since there were only two of the reported trials, both with methodological flaws and small sample size, the potential of a beneficial or negative effect cannot be ruled out. According to the authors, more research is needed. A 2012 update and a 2015 update found no new trials that would affect the previous conclusions **(31,32).**

Distant electrotherapy has shown efficacy in PUs healing, the worth noting is the contactless of DE in the application, which is similar to PEMS and so decrease the risk of contamination, nevertheless to the trial's small sample size and the shortage of patients' quality of life examinations, that could have provided better statistical analysis, additional research with larger sample sizes is advised to assess and confirm the effective use of DE in PUs and to investigate various intensity levels and frequency ranges in an attempt to determine the most effective doses in ulcer management, as there are no definite guidelines for ES standardized parameters in wound healing. Further investigations are additionally needed to demonstrate the long-term impacts.

Conclusion:

Distance Electro Therapy is a new intervention of contactless electrotherapy that achieved superior results in ulcer closure.

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Data Availability Statement: The datasets generated and analyzed during the current study can be made available from the corresponding author upon reasonable request and after obtaining necessary ethical approvals 6 months after publication.

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