Efficacy of Microcurrent Stimulation versus Negative Pressure Wound Therapy on Healing of Chronic Pressure Ulcers

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ABSTRACT

Background: *A pressure ulcer is defined as a maceration of skin and/or deeper tissues due to unrelieved pressure, shear force, and/or frictional force. The development of pressure ulcers is a problem that threatens people's everyday activities. Objective: The purpose of this study was to evaluate the effectiveness microcurrent stimulation therapy (MST) versus negative pressure wound therapy (NPWT) in treatment of pressure ulcer.* ***Methodology:*** *Forty patients had pressure ulcer participated and completed the study. The patients were randomized into two groups of equal number. Group (1): received Microcurrent Stimulation Therapy, 3 times per week for 6 weeks while Group (2) received Negative Pressure Wound Therapy, also 3 times per week for 6 weeks.* ***Results:*** *revealed a highly significant differences pre and post treatment in MST and NPWT group as regard to wound volume and wound surface area (P values < 0.05). Also the results of the study revealed a highly significant differences between both groups post treatment (P values < 0.05).* ***Conclusion:*** *Our study concluded that negative pressure wound therapy was effective than microcurrent stimulation therapy in the treatment of pressure ulcer.*

Key words: *Pressure ulcer- Wound healing- Negative Pressure Wound Therapy - Microcurrent Stimulation Therapy – Wound volume-Wound surface area.*

INTRODUCTION

Wound healing, the result of a complex tissue repairing process, is a continuing challenge in rehabilitation medicine. Despite some recent advances in understanding its basic principles, problems in wound healing continue to cause significant morbidity and mortality[8,18,20]. Ulceration healing and its effects on elongation of hospitalization period is a major economical problem that faces the physical therapists and other team members of ulcers rehabilitation[3].

A pressure ulcer (PU) is a debilitating, chronic wound. PUs are a significant problem in all health settings, affecting approximately 10% of hospitalized and 5% of community-living patients. PUs represent a major burden to patients, including negative psychological, physical, and social consequences affecting health, well-being, and health-related quality of life. PU is damage that occurs on the skin and underlying tissue[26]. A pressure ulcer is an area of skin that breaks down when something keeps rubbing or pressing against the skin. PUs are caused by three main things: (1) pressure; the weight of the body pressing down on the skin (2) shear; the layers of the skin are forced to slide over one another or over deeper tissues (3) friction; rubbing the skin[1,27].

Some specific physiotherapy modalities are used to enhance and control wound healing process such as LASER therapy, therapeutic ultrasound waves, electrical stimulation and ultraviolet rays. Other adjunct therapeutic modalities include the use of hyperbaric oxygen therapy and Ozone therapy[15].

Recognition of bioelectricity's role in tissue healing provides a rationale for the therapeutic application of electrical stimulation, particularly in cases where natural repair processes have broken down[19]. Microcurrent therapy (MCT) is an example of this. Uniquely amongst the various electrotherapeutic modalities, MCT involves application of voltages and currents of similar magnitude to those generated endogenously during normal tissue healing. MCT has been shown to be of benefit in several types of tissue healing and it may be effective in others. It appears to stimulate healing generally, and not just one element of the process. It has very few side effects[4,17,22].

Negative pressure wound therapy (NPWT) also known as treatment with topical negative pressure (TNP) is a vacuum assisted method for ulcer care using a negative pressure of 60-125 mm Hg on wound bed. The method has been used since 1995 as one method for treating surgical wounds, acute wounds and more scarcely for hard-to- heal ulcers[2]. Negative pressure wound therapy has emerged as a non-pharmacological treatment for acute and chronic wounds, including Pressure ulcers, diabetic wounds, abdominal wounds, and traumatic wounds. It is primarily used for more complex chronic wounds[5]. It has been suggested that NPWT is best suited for the management of large, stage 3 and stage 4 ulcers with inadequate or poor granulation tissue and heavy exudates[28].

The purpose of this study was to compare between the efficacy of microcurrent therapy versus negative pressure wound therapy in the treatment of patients with pressure ulcer.

PATIENTS AND METHODS

Subjects

Forty five patients (20 female, 25 male) were recruited from vascular and general surgeries departments of Helmaet EL-Ziaton Hospital, Cairo, Egypt, between June 2011 and July 2012. Diagnosis was made clinically by physician. Signed informed consent was obtained from each participant before enrollment in the study. The history & clinical examination were done for all patients. Subjects who fulfilled the following criteria were eligible for enrollment in the study; (1) age between 50-70 years, (2) second and third stage of pressure ulcer (3) elapsed time since the beginning of ulcer was more than 6 months (4) affected area was ischiam or heel.

Patients were excluded if they had (1) cardiac pacemaker or metal implants, (2) Cancer patients and lower motor neuron damage individuals (3) diabetic patient (4) skin malignancy (5) infection (6) acute tuberculosis (7) mental disorders.

After exclusion of the subjects who not fulfilled the inclusion criteria, the patients were randomized into two groups. Group (1): received microcurrent stimulation plus local wound care. Group (2); received Topical negative wound pressure therapy plus local wound care.

A randomized sequence was generated by Excel to ensure random allocation of subjects. The sequence was concealed from consent-design through using an electronic password-protected document. Assessment was done before, and after 6 weeks of treatment for all patients by wound surface area and wound volume measurement.

Ethical consideration

At the time of this study, Human Research Ethics Committee had not been established in the faculty of physical therapy, but the study was approved by the department council of physical therapy for surgery.

Measurements

Assessment of wound surface area

It was calculated according to planimeter method by placing a piece of sterilized transparency film over the wound and tracing the wound perimeter on the film with fine tipped transparency marker. A separate transparency was used for each wound. The traced transparency film placed over carbon paper with a white paper in between and transcribed the tracing into metric graph paper and the numbers of square millimeters on the graph paper within the ulcer surface area was counted (only full 1 millimetre squares inside the perimeter was counted) and the area was converted to square centimeters. The tracing process was repeated three times to establish measurement reliability. The mean of the three trials calculated and considered as the ulcer surface area .This assessment was done before and after 6 weeks of treatment[30].

Assessment of wound volume

Assessment of wound volume was done by saline injection tool. A syringe of 20 cubic centimeters filled with normal saline was used. The patient was positioned in a comfortable position that allows the wound to be filled with the saline solution maximally. The saline is injected into each wound until its filling. The amount of saline injected was detected in cubic centimeters. These measurements were conducted for each patient before and after 6 weeks of the treatment for the three[9].

Treatment protocol

Before starting the first treatment session, each patient in three groups was instructed carefully about the efficacy of treatment procedure as well as, its safety, and values to gain her confidence and cooperation during the treatment sessions. Furthermore, each patient was advised to assumed a relaxed comfortable position.

Group (1) included twenty patients who were received traditional local wound care plus microcurrent stimulation therapy. Microcurrent stimulation therapy was delivered by Microcurrent 850 unit device (manufactured in Taiwan for Chattanooga Group inks; 2003) with constant current of 50% of duty cycle, at 0.3 Hz with modified square biphasic pulsed waveform and intensity of 600 microampers[21]. Sterile, disposable electrodes (negative polarity; 2 x 4 cm) were placed over each wound after being soaked in sterile 0.9% NaCl, and then carefully wrapped around the affected area. All patients were received the treatment for 45 minutes three session per week for 6 weeks. The patients were instructed to remain in the same position for the treatment period[12].

Group (2) included twenty patients who were received traditional local wound care plus topical negative pressure wound therapy. Negative pressure device; VAC system (Vacuum Assisted Closure, Advanced Therapy System, KCI Whitney, Oxon, UK; Smith_&_Nephew equipment) that consist of non adherent sponge dressing, a draining tube placed in the dressing, a transparent film to seal the wound, the drainage tube is connected into a source of negative pressure and a suction force is then applied by a VAC machine across the wound surface. The parameters of NPWT device should be suited with negative pressure of 125 mmHg, with duration of five minutes on and two minutes off and the dressing applied away from the boundaries of wound about 2-3 mm. The treatment applied three session per week for 6 weeks[6].

Traditional local wound care as the following; (1) Debridement, for removal of microorganisms, necrotic tissues and foreign bodies when needed. (2) Irrigation of the wound with normal saline. (3) Apply antimicrobial agent (betadin) then the wound was dressed. All the dressings were changed once daily for 6 weeks[10,24].

Statistical Analysis

Data were expressed as mean ± standard deviation (SD). Student t test was used to assess the difference in the studied parameters (Age, duration of ulcer, wound surface area and wound volume) between the two groups. Paired t test was used to analyze these parameters within the group. Mann-Whitney U test was used to assess (sex, affected area, stage of ulcer) between both groups. Analysis was performed using SPSS/PC software (SPSS Inc., Chicago, IL, USA). All p values less than 0.05 were considered to be statistically significant.

RESULTS

Figure (1); presents the flow chart for patients throughout each stage of the study. A total of 45 patients was screened for eligibility, and 42 subjects fulfilled the inclusion criteria. Two subjects of 42 reported poor adherence to the treatment. A participant with poor adherence to the program (defined as missing more than three consecutive sessions or more than 20% of all sessions) were excluded from the study, and their data were not used in the statistical analysis. A total of 40 subjects completed the study and were initially randomized into two groups of equal number. Group (1) Microcurrent Stimulation Therapy (MST group; n=20), and Group (2) Topical Negative Wound Pressure Therapy (TNWPT; n=20). Table (1) presents the characteristics of the patients completing the study. Both groups were comparable at the baseline regarding to the demographic and clinical characteristics.

Table (1): Demographic and clinical characteristics.

Variables	MST group		TNWPT group		P values
Age (years) (mean ±SD)	58.00±6.57		56.200±4.96		0.334*
Duration of disease (month) (mean±SD)	13.65±5.27		12.60±4.48		0.501*
Stage of ulcer (second –third)	Second	10(50%)	Second	13(65%)	0.343*
	Third	10(50%)	Third	7(35%)	
Affected Areas (Ischeal – Heel)	Ischeal	14(70%)	Ischeal	15(75%)	0.727*
	Heel	6(30%)	Heel	5(25%)	
Sex (Female –Male)	Female	10(50%)	Female	7(35%)	0.343*
	Male	10(50%)	Male	13(65%)	
Initial wound volume (cm^3) (mean±SD)	3.32±0.486		3.27 ±0.413		0.754*
Initial wound surface area(cm^2) (mean±SD)	3.62 ±0.311		3.49 ±0.651		0.661*

* No significant differences between two groups pre treatment SD: standard deviation

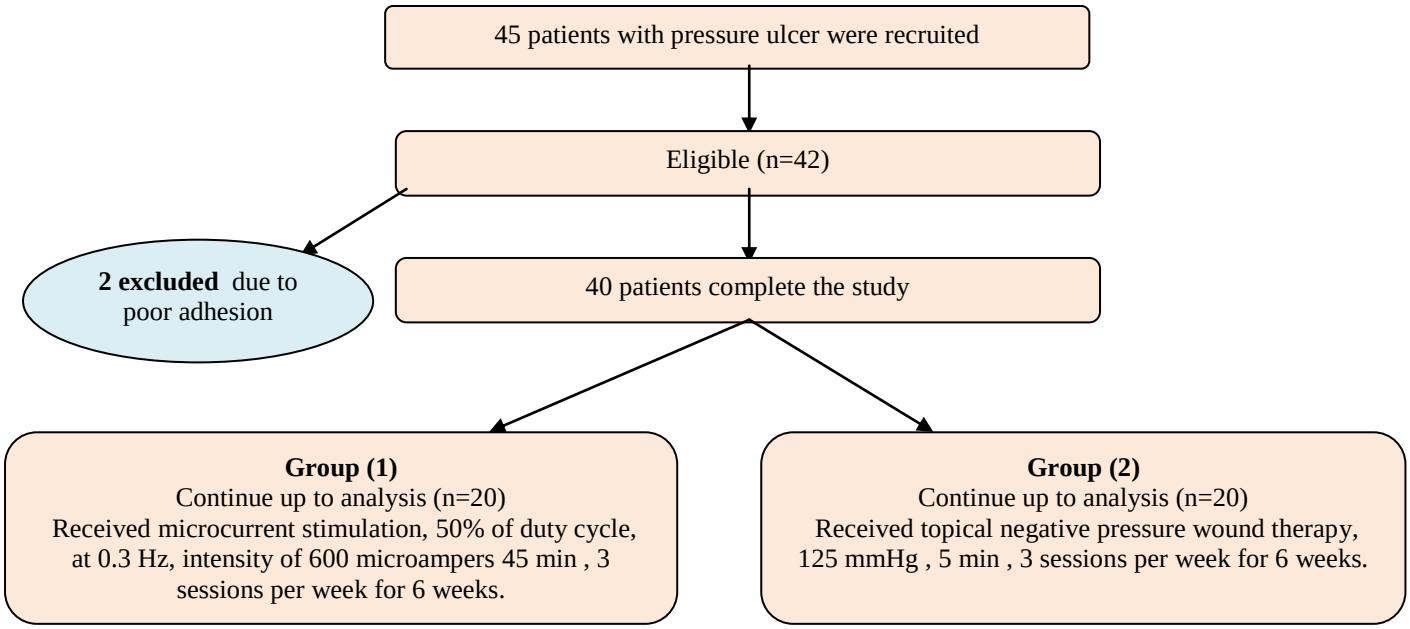

Fig. (1): Flow of participants through the study.

Wound volume Measurements:

Wound volume measurements were summarized in Table 2, The results show significant reduction in wound volume in MST and TNWPT groups pre and post treatment as P value <0.05. Also the results showed highly significant difference when comparing both groups post treatment as P value <0.05. figure (2).

Table (2): Wound volume Measurement.

Variables	MST group Group (1)	TNWPT group Group (2)	P value between groups post
Wound volume Pre (mean ±SD)	3.32±0.49	3.27±0.41	0.000*
Wound volume Post (mean ±SD)	1.49±0.28	0.79±0.38	
P value pre & post within group	0.000*	0.000*	
Percentage of improvement	55%	85%	

* highly significant difference

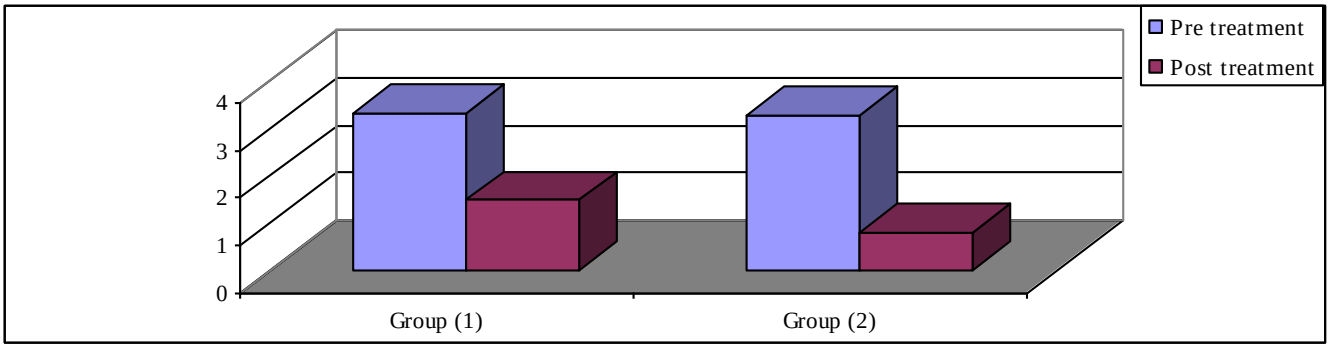

Fig. (2): Wound volume measurements pre and post treatment in both groups.

Wound surface area measurements:

Wound surface area measurements were summarized in Table 3, The results show significant reduction in wound surface area in MST and TNWPT groups pre and post treatment as P value <0.05. Also the results showed highly significant difference when comparing both groups post treatment as P value <0.05. figure (3).

Table (3): Wound surface area measurements.

Variables	MST group Group (1)	TNWPT group Group (2)	P value between groups post
Surface area Pre (mean ±SD)	3.62±0.31	3.49±0.65	0.000*
Surface area Post (mean ±SD)	1.79±0.54	0.92±0.39	
P value pre & post within group	0.000*	0.000*	
Percentage of improvement	51%	73%	

* highly significant difference

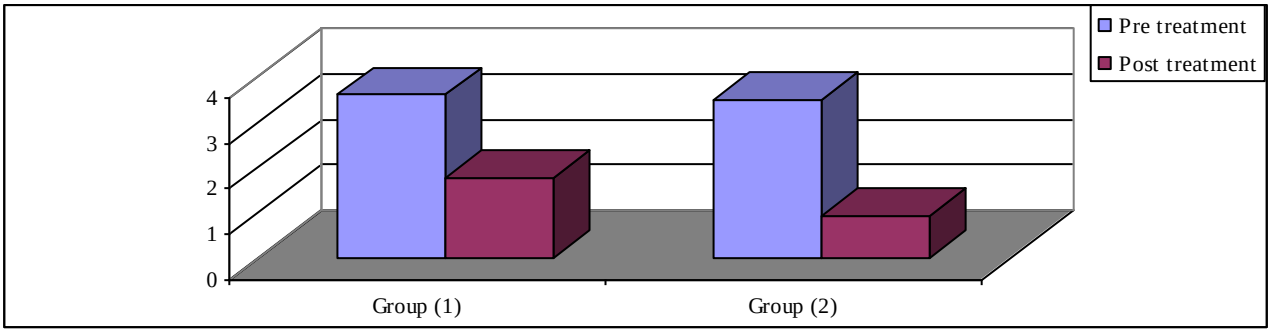

Fig. (3): Wound surface area measurements pre and post treatment in both groups.

DISCUSSION

The mechanism of tissue healing is a complex biological process that involves a perfect and coordinated cascade of cellular and molecular events promoting tissue reconstitution. This process arises as a response of the tissue to injuries induced by trauma or by surgical procedures. The process of wound healing is characterized by three phases that overlap and present a characteristic profile: inflammatory phase, proliferative phase and remodeling phase[16]. Despite some recent advances in the understanding of these basic processes, wound healing disorders continue to cause diseases and even death. A wide variety of therapies has arisen with the advances in technological applications[7].

This study compared the efficacy of microcurrent stimulation therapy versus negative pressure wound therapy in the treatment of pressure ulcer. In the present study, all variables including sex, age, location and duration of ulcer and all other factors affecting healing process were matched in all patients in both groups.

The results of this study revealed that there were significant differences as regard to wound volume and wound surface area pre and post treatment in MST group and this

confirm the efficacy of microcurrent stimulation therapy on healing of pressure ulcer that may be due to stimulation of fibroblast proliferation and collagen biosynthesis, increase number of fibroblasts and hydroxyproline levels, stimulate secretion of growth factor, and ATP synthesis, increase wound epithelialization and therefore accelerate wound healing. These findings were agreed with several studies[7,23] that investigated cellular responses to electrical currents of different amplitudes and frequencies and concluded that electrical stimulation, including (microcurrent therapy) MCT, can indeed promote healing in various types of human skin wounds, particularly ulcers.

Also these results supported by Huckfeldt,et al.,[17] who concluded that the application of Silver nylon used in conjunction with MET can be very beneficial for wound healing. These silver ions have strong germicidal effects through the blocking of cell respiration pathways which helps add to the antimicrobial affect of microcurrent therapy.

The results of the present study showed that there were significant differences as regard to wound volume and wound surface area between MCT and NPWT groups post treatment. The percentage of improvement in wound volume for MCT and NPWT group were 55% and 85% respectively and the percentage of improvement in wound surface area for MCT and NPWT group were 51% and 73% respectively. This significant efficacy of NPWT in healing of pressure ulcer may be related to the main reported mechanisms of action for NPWT which are; provision of a moist wound healing environment, removal of fluids and infectious materials, assisted profusion, decreased bacterial colonization and enhanced formation of granulation tissue[13].

Haimowitz JE et al.,[14] reported that the V.A.C. Therapy System creates a moist wound-healing environment. Advantages of a moist wound bed include promotion of granulation tissue formation in acute and chronic wounds, reduced pain, and reduced exposure to infection . The simplest outcome of this is that moisture in the wound bed prevents the formation of eschar that would delay epithelial migration. In the moist wound bed, the epithelium has a smoother pathway to re-epithelize the wound surface. Additionally, in this more aqueous milieu, growth factors are more active, more available, and more easily synthesized than in a desiccated environment.

Also Fleck et al.,[11] stated that NPWT mechanism based on the idea of turning an open wound into a controlled, closed wound while removing excess fluid from the wound bed. As mentioned earlier, circulation is enhanced when interstitial fluid is removed. Any increase in circulation and oxygenation to compromised tissue improve the area's resistance to infection, allowing wound to heal.

To the best of our knowledge, there is no study tested the effect of the MCT versus NPWT in the treatment of pressure ulcer but there were previous studies confirm the efficacy of NPWT on healing of pressure ulcer for example; Vuerstaek et al.,[29] suggested that NPWT (topical negative pressure) technology should be considered the treatment choice for chronic (hard-to-heal) ulcers due to its significant advantages concerning time for wound healing and wound bed preparation compared with conventional therapy.

Peter et al.,[25] suggested that NPWT is as safe as and mere efficacious than traditional medical wound treatment in the treatment of diabetic foot ulcers. Where a significantly greater number of NPWT patients achieve complete ulcer closure and granulation tissue formation than traditional medical treatment.

Conclusion

Our study concluded that negative pressure wound therapy was effective more than microcurrent stimulation therapy on healing of pressure ulcer.

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