Efficacy of Modulated Microcurrent Stimulation in Pressure Ulcers Treatment: A Monocentric, Prospective, Double-Blind, Randomized Study

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Abstract

Pressure ulcers are defined as “Localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear” (NPUAP/EPUAP 2009) that generally affected people with impaired mobility. In clinical practice there are several methods to facilitate the healing of pressure ulcer. There is evidence that pressure ulcers are characterized by abnormally low electrical potentials, resulting in voltage gradients compared with the surrounding healthy tissue, for this reason electrical stimulation is used to treat pressure ulcers in medical practice.

We conducted a monocentric, double-blind, randomized, prospective clinical trial in our rehabilitation center. 33 patients with pressure ulcers at stage II and III NPUAP/EPUAP classification were enrolled. With the aim to investigate the effect of specific modulation of microcurrent wave therapy (BabytechBH®) on tissue regeneration in pressure ulcers treatment.

Our data show a reduction in ulcer initial size in treatment group to a mean of 46% (p<0.001). During the same period, pressure ulcers in the control group healed to a mean of 21% of their initial size (p=0.05). Moreover pressure ulcer related pain, evaluated with NRS for pain scale, showed a decrease from a mean value of 53% in the treatment group regard a decrease from 22% in the control group. In conclusion tissue stimulation with wave trains of microcurrents seems to be efficacy in facilitating pressure ulcers healing and can be considered an effective treatment for reducing patients’ pain.

Keywords: Pressure ulcer; Pain; Electrotherapy; Micro-currents; Wound healing

Introduction

Pressure ulcers (PU) is defined as “Localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear” (NPUAP/EPUAP 2009) [1]. People with impaired mobility (e.g. stroke or spinal cord injury patients, or unconscious patients) are at risk of developing pressure ulcers. In these patients other conditions contribute to poor tissue viability as poor nutrition, poor sensation, urinary and fecal incontinence, and poor overall physical and mental health. The sacrum and heel are the most common location of pressure ulcers, although other areas are prone to development pressure ulcers. The impact of pressure ulcers concern human and economic aspects, so that affect quality of life and lead to more frequent hospitalization. Geriatric patient who develops a pressure ulcer has a four-fold increased risk of death [2]. In economic terms, the cost of healing a pressure ulcer is likely high because it often involves a multitude of prolonged complex treatments and hospitalization [3-5]. About the prevalence of pressure ulcers, a review combined data that surveyed more than 14,000 patients from 45 health care institutions in Canada: on the average, 1-in-4 patients across Canadian health care settings suffered from a pressure ulcer [6]. According to Mawson et al study the 59% of patients admitted to the hospital following Spinal Cord Injury develops a pressure ulcer within 30 days [7].

There are different systems for classifying a pressure ulcer. The most commonly used is the North American National Pressure Ulcer Advisory Panel system and the European Pressure Ulcer Advisory Panel System (NPUAP/EPUAP: 2009) [8]. Synthetically: category I pressure ulcers are areas of a skin redness, which do not blanch under light pressure, whereas category II involve skin damage, and category III and IV pressure ulcers involve loss of fat, muscle and bone. Obviously there are other conditions of unstageable or suspected deep tissue injury that are also comprise in the classification system (NPUAP/EPUAP: 2009)[8]. To avoid the development of pressure ulcers is very important to indentifying patients at risk, by considering patient characteristics and risk factors. Pressure ulcer prevention aims to eliminate or reduce factors that predispose a person to pressure ulcer development. Strategies commonly used include other than regular risk assessment, use of special pressure relieving support surfaces, regular repositioning and turning, local skin care, and nutrition support. Many tools have been developed to assess individuals’ risks of developing a pressure ulcer [9]. The most often used tool is the Braden scale and Norton scale. Conservative treatment of pressure ulcers involves control of the causal factor as: removal of pressure, correction of nutritional deficiencies, removal of necrotic tissue, prevention of skin maceration, control of infections, and system to encourage soft tissue repair. Moreover a numerous tools exist in clinical practice to facilitate wound healing. Microcurrent electrical neuromuscular stimulator (MENS) is a device used to facilitate soft tissue healing. There is evidence that MENS may result in a...
significantly greater reduction in the surface area and more complete healing ulcers compared with sham therapy [10]. However there are no definitive data on the efficacy of electrotherapy, because of significant statistical heterogeneity, small sample sizes, and methodological flaws [10].

Thus, the aim of this study is to investigate the MANS therapy efficacy in healing of pressure ulcers treatment in patients hospitalized in rehabilitation unit. It was hypothesized that patients treated with MENS device would report higher tissue regeneration. Secondary outcome was observed de effect of this therapy in patient’s pain perception.

Materials and Methods

We conducted a monocentric, double-blind, randomized, prospective clinical trial in our rehabilitation center. 33 patients with pressure ulcers at stage II and III NPUAP/EPUAP classification were enrolled in clinical trial. All patients satisfy inclusion/exclusion criteria (Table 1). Patient or legal guardian signed an informed consensus form, after a comprehensive explanation of the study protocol. 3 patients were excluded because did not conclude the treatment (one for worsening of basic disease, two because transferred to another hospital in advance), two patients in treatment group and one in the control group.

The subjects were divided, randomly, to either group A or group B. Both groups of patients were treated identically using a conventional protocol for healing pressure ulcers and with MENS system (“BabytechBH®”, Talamonti group s.r.l., San Benedetto, Italy). The characteristic of patients enrolled in the study were shown in table 2.

The equipment used in the patients who received the sham therapy had been deactivated by the manufacturer in an not perceived manner so that neither the patients nor the researchers were aware of which group of patients were receiving treatment or sham therapy. During the initial evaluation patients were evaluated for nutritional status by a nutritionist and then nutritional status and dietary intake was monitored regularly. Wound surface area and appearance were evaluated for each patient using the Push Tool 3 scale, prepared by NPUAP. Widespread and very useful scale to monitor the evolution of the ulcers [1].

To use this scale is necessary to observe and measure the ulcer, evaluate the surface, exudate and type of tissue, and then score for each characteristics of scale and add the final score. To evaluate pain of pressure ulcers we used the Numeric Rating Scale (NRS) for pain. It is a unidimensional measure of pain intensity in adults [11-13]. It is a segmented numeric version of visual analog scale (VAS) in which patients select a whole number (0-10) that best reflects the intensity of their pain. Particurarly 0 representing one pain extreme (no pain) and 10 representing the other pain extreme (pain as the bed as you can imagine) [12,13]. All patients randomized were evaluated for their risk profile to develop pressure ulcers by Norton scale

(Norton scale in all patients was equal to or greater than 8).

Rehabilitative protocol

30 patients that satisfy inclusion/exclusion criteria were randomized in two groups: 14 patients in group A (GrTr), treated with MENS (BabytechBH®) and 16 patients in group B (GrNoTr) treated with sham therapy (control group).

During study period of 4-week all patients received also conventional wound therapy, usually utilized in our center by qualified personnel. These interventions considered: dietary intake as necessary, pressure relief and protection for patients with sensory impairment. Moreover there were used wound dressing as: hydrogels, hydrocolloids, adsorbent foam dressing. All medications were tailored to meet the needs of each patient.

Some topical agents containing metal ions and petrolatum-based products were not used, to avoid interference with MENS device. Qualified nurses, as necessary, performed sharp debriment (9 patients; 4 in GrTr and 5 in GrNoTr).

In the same periods both groups were treated with MENS device 3 times a day each session was about 35/40 minutes. In GrNoTr was a sham treatment.

The treatment was made with 4 electrodes which were applied on the area around the pressure ulcer because in this way the micro-currents passage throughout the wound bed is guaranteed. The electrodes can be used for the three daily treatments and they can be left on the skin of the patients until the last daily treatment.

All patients were evaluated for pressure ulcer evolution (Push Tool 3 scale) and for pain (NRS) at the beginning of the study (T0), after 2 weeks (T1) and at the end of the study (4wk, T2).

Table 1: Inclusion and exclusion criteria

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<tbody>
<tr>
<td>Age greater than 18</td>
<td>Age younger than 18</td>
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<tr>
<td>Pressure ulcers stage II-III NPUAP classification</td>
<td>Cardiac Pace-maker</td>
</tr>
<tr>
<td>Not included in other clinical trials</td>
<td>Superficial metal ions or metal implants near the area</td>
</tr>
<tr>
<td>Forced decubitus supine position or ortopnoic (permanent or transiet).</td>
<td>Pregnancy</td>
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<tr>
<td>Norton score greater equal to 8</td>
<td>systemic infection, renal failure, active cancer or radiotherapy-chemotherapy, steroid therapy, severe cardiac disease, cardiac arrhythmia, diabetes, severe Hypertension</td>
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Table 2: Characteristic of group’s patients

<table>
<thead>
<tr>
<th>Treatment group</th>
<th>Non treatment group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>14</td>
</tr>
<tr>
<td>Sex</td>
<td>8m (8f)</td>
</tr>
<tr>
<td>Age</td>
<td>73.9 ± 10.3</td>
</tr>
<tr>
<td>Weight</td>
<td>73.9 ± 16.8</td>
</tr>
<tr>
<td>High</td>
<td>1.62 ± 0.08</td>
</tr>
<tr>
<td>BMI</td>
<td>28.2 ± 5.9</td>
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The collected data were analyzed using Graph Pad Prism (version 5) software (Abacus Concepts Graph Pad Software, San Diego, CA). Difference between groups, before and after the rehabilitative period were calculated using The Wilcoxon Matched Pairs Test. Friedman ANOVA test was used to compare values obtained in the first and second evaluations in both groups. For all tests, statistical significance was set at P<0.05 was used for statistical analysis.

Results

The evaluation of wound surface area and appearance with the Push Tool 3 Scale, at baseline (T0) and at the end of the study (T1), showed a reduction from the initial score of 12.5 to a final score equal to 6.28 (p<0.001). Instead in the control group the mean value of the Push Tool 3 Scale was reduced from 12 to 9.5 (p<0.05) (Figure 1).

The analysis of wound numeric rating scale (NRS) values, concerning the pressure-ulcers related pain, at baseline (T0) and at the end of the study (T1) showed a reduction from initial score of 7 to a final score of 5 (p<0.001) in the treatment group. In the control group the mean value of the NRS scale was reduced from 4.5 to 3.5 (p<0.01) (Figure 2).

Discussion

In this study we investigated the efficacy of a new electrical stimulation therapy, based on electrical microcurrent and sound-waves concurrently for healing pressure ulcers at stage II and III of NPUAP classification in patients hospitalized in rehabilitation center. Pressure ulcer is defined as: “an ulceration of skin and/or deeper tissues due to unrelieved pressure, shear force(s), and/or frictional force(s)” [14]. Pathophysiological causes of pressure ulcer are not completely understood. The primary cause is mechanical load as pressure or pressure and shear applied to soft tissues, especially over a bony prominence (NPUAP 2009). Some laboratory and animal studies speculate several aetiological mechanisms to develop pressure ulcer as: localized ischaemia, reperfusion injury, impaired lymphatic drainage, and cell deformation [15].

Infact occlusion or obstruction of the blood vessels in soft tissue caused by external loading determine ischaemia, and reduces supply of nutrients to cells and reduces elimination of metabolites [16,17]. Damage, caused by ischaemia may be exacerbated by reperfusion phase [18]. As well as lymphatic vessel occlusion, caused by external loading, determine accumulation of waste products and augmentation of interstitial fluid contributing to pressure ulcer development [19,20].

Relevant risk factors for development of pressure ulcers are: paralysis and sensory loss, other than: increased age, vitamin deficiency, hypoproteinemia, skin maceration do to incontinence, soft tissue atrophy, as well as bacterial contamination can causebreaking and prolonged healing of soft tissue [14]. Management of pressure ulcer provide: control of causal factors, prevent skin maceration, correction of nutritional deficiencies, control of infection, than necrotic tissue removal, if necessary, and encouragement of tissue repair [14,21-23]. Several methods exist in medical practice to accelerating healing of chronic ulcers.

There is evidence that pressure ulcers are characterized by abnormally low electrical potentials, resulting in voltage gradients compared with the surrounding healthy tissue (Bradock et al.), for this reason electrical stimulation is used to treat pressure ulcers in medical practice.

Beneficial effects of electrical stimulation for chronic ulcers healing have been reported both for low intensity direct current (LIDC) [14,24-26], or for high voltage pulsed direct current (HPVC) [27-29]. Treatment protocols, used in several studies, for application of electrical stimulation vary widely: electrical stimulation devices can provide a direct current (monopolar or bipolar) or both direct and alternating currents. Therapeutic electric currents can be delivered into the wound and/or peri-wound tissue through electrodes applied directly to the patient’s skin [10]. Studies comparing various treatments time duration for HVPC that was reported vary from 20 minutes a day to 45 minutes or 30 minutes twice a day. Different systematic reviews examined the evidence on the effectiveness of electrical stimulation as an adjunctive therapy for chronic pressure ulcers. All studies compared electrotherapy with sham electrotherapy (placebo). Generally the studies included mostly elderly patients.

Some studies included different stage of pressure ulcers, and the duration of active treatment period varied from 20 days to 8 weeks. Griffin et al. reported significantly greater reduction in the mean area of ulcers treated with electrotherapy compared with sham therapy: (median) 80% (range 52%-100%) vs. 52% (14%-10%) [15]. Wood et al. [33] showed that significantly more ulcers treated with electrotherapy...
achieved a greater than 80% reduction in the area of the ulcer compared with sham therapy. Other three studies [14,32,33] provided information about complete ulcer closure, in a pooled analysis, each of three studies showed a higher proportion of complete healing in the electrotherapy group compared with the sham therapy group, but the difference was statistically significant only in one of the studies [32]. The Forest plot of complete healing of ulcers during treatment showed that electrotherapy was more than 4 times as effective as sham treatment in healing ulcers [RR 4.48, (95% CI, 1.91–10.51), p=.0006]; however, there was significant heterogeneity among the studies.[10]

In this study we found that after 4 weeks of treatment, pressure ulcers healing in the treatment group to a mean of 46% of their initial size (from 13.5 at T0 to 9.5 at the end of the study, p<0.05). During the same period, pressure ulcers in the control group healed to a mean of 21% of their initial size (from 12 at T0 to 9.5 at the end of the study, p<0.001). Moreover the study evaluated pressure ulcers related pain with the NRS for pain, a segmented numeric version of visual analog scale (VAS) in which patients selects a whole number (0-10) that best reflects the intensity of their pain [34-36]. The results of this study showed a decrease of NRS scale from a mean value of 53% in the treatment group (from 7 at T0 to 3.6 at the final study); regard a decrease from 22% in the control group (from 4.5 at T0 to 3.5 at the final of the study). Our rehabilitative MENS device has proven to be very efficacy in facilitating pressure ulcers healing and can be considered an effective treatment for reducing pain.

Wave trains of microcurrents can induce a cellular reactivation with increase in ATP production due to the mitochondrial stimulation [37,38]; increase in the activity of sodium-potassium pump; increase in ion exchange. All these events leads to the restoration of those functions which had been altered as a result of the disease in act [39].

Furthermore sound waves of the device used in our study determine the energetic implementation of simple and complex molecular systems, on the base of the experimented theory of activation of molecular vibration. Practically such sound waves have the ability to go in resonance with a wide set of molecules constituting the extracellular compartment liquid and the ability to activate such molecules [41,42]. This depository action concurrently with the stimulatory action towards the muscular tunic of blood vessels, that facilitates the propulsive effect and increases the peripheral flow of blood and lymph, allows to enrich issues with nutritive substances, revascularization of the treated area, making easier the cellular regeneration [43]. In this way MENS therapy with Babytech stimulation frequency seem to be able to reactivate the interstitial matrix allows reestablishing the normally existing physiological relationships between cells and tissues. Such activation is guaranteed by the increase of oxygenation, by cellular nourishment and by an effective draining and regenerating action.

Conclusion

Modulated microcurrent stimulation determines a simultaneous and coordinated stimulation on all physiological system (muscular system, veno-lymphatic system and connective tissue): the increase of regional temperature; the shift of excited molecular components along lymphatic ways; the reactivation of drainage systems into the involved compartments. It find a new equilibrium of local onco-osmotic pressures; removal of the components which are present in extra cellular space, making easier the cellular regeneration and consenting a re-establishment of the motility of vascular and venous-lymphatic walls which were previously suffering: in this way this therapy support pressure ulcer care.

Our data confirm the finding of previous studies on the use of electrical therapy for wound ulcers.

References

1. National Pressure Ulcer Advisory Panel (2007). Pressure ulcer stages revised by NPUAP