CHRONIC ULCERS: TREATMENT WITH UNFOCUSSED EXTRACORPOREAL SHOCK WAVES

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Received July 31, 2012 – Accepted April 22, 2013

The aim of this study was to evaluate the efficacy of the treatment of chronic ulcers with unfocused shock waves. Between March 2009 and February 2012 we studied a group of 124 patients, aged between 28 and 80 years, with serious wounds arisen over three months and who met the inclusion criteria for treatment. The patients were randomly divided into groups A and B, both treated with unfocused ESWT but with an average energy density for each impulse equal to 0.10 mJ/mm² in group A (total energy equal to 1.7 mJ for each shot) and an average energy density for each impulse equal to 0.04 mJ/mm² in group B (total energy equal to 3.3 mJ for each shot). The pulses were administered at a frequency of 4 Hz in both groups. Wounds were classified according to: location, width, length, percentage of granulation tissue, necrotic tissue, fibrous tissue, presence of bacterial exudation and pain (assessed by VAS). Their evolution was monitored by photo capture. The patients were treated with a frequency of 1 session every 7 days for 7 weeks. During the treatment period, the possible occurrence of side effects was monitored. Before treatment the wounds in group A had an average area equal to 3.85 cm² and the average value of the VAS pain scale was equal to 5.8 (range 2-9); the wounds in group B had an average area equal to 3.4 cm² and the average value of the VAS pain scale was equal to 5.7 (range 3-9). At the end of the treatment protocol the mean area in group A decreased by 80% (final mean area 0.93 cm²), and the average pain on VAS scale dropped by 79%; the mean area in group B decreased by 67% (final mean area 1.2 cm²) and the average score on VAS scale dropped by 48%. None of the treated patients experienced adverse reactions to treatment. None of the treated wounds developed infection during treatment. In conclusion, shock waves can act on difficult wounds, stimulating the reparative physiological process; therefore it represents an effective and safe procedure to accelerate the healing process, reducing the operating costs and avoiding more complex interventions.

Chronic ulcers are complex wounds that do not heal spontaneously and are usually associated with local and systemic predisposing factors (1).

Wound healing is a dynamic process influenced by homeostatic balance, inflammatory and matrix-synthesis process, and by an appropriate process

Key words: chronic ulcers, unfocused shock waves, wound healing

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of tissue remodelling. From a histological point of view, the healing process is divided into three main stages: inflammatory stage, proliferative stage, and maturation or remodelling stage (2-4).

Inflammation occurs in the tissue as the first immediate response to injury. In the inflammatory phase, vasodilation causes an increased permeability of blood vessels, vasocongestion and loss of serous fluids into the surrounding tissue. When the acute responses of homeostasis and inflammation are over, the wound healing begins (5).

During the proliferative phase, the recovery processes consist of: angiogenesis, fibroplasia and epithelisation. This second stage is defined by the production of granulation tissue composed of capillary bed, fibroblasts, macrophages and a loose arrangement of collagen, fibronectin, hyaluronic acid and bacteria. The proliferative stage results in the wound filling up with connective tissue and covered with epithelium.

In the maturation stage the wound contracts through the internal moving of the surrounding tissue and skin and is reduced in size. The alteration of one of these physiological steps leads to the chronic wound.

A chronic wound is histologically determined by lack of organization in endothelial proliferation, presence of parakeratotic keratinocytes, connective tissue disorganization, increasing in keratinocytes and granulocytes, disorders of proteins, electrolytes and cytokines (1-6).

The main causes affecting the physiological healing process are: pressure, slipping and shearing forces, reduced mobility, sensory-motor function impairment, poor nutrition, advanced age, changes in hematopoiesis and external factors such as psychosocial problems, prolonged immobilization and infections (5). Many studies have shown that the predisposing bacteriological factor has a direct correlation between high levels of bacteria in pressure ulcers and lack of tissue repair (7, 8).

Previous studies showed that shock waves are effective in stimulating several endogenous growth factors such as EGF, IGF1, VEGF and nitric oxide production, inducing angiogenesis and promoting the healing of fractures, ulcers and complex lesions (1, 9-16). In their 2005 studies Gerdesmeyer et al. showed the antibacterial effect of shock waves mediated by cavitation (17); in 2009 Kuo et al. also showed that when administered properly extra corporeal shock wave therapy (ESWT) is able to: reduce the inflammatory response with subsequent reduction in the number of circulating leukocytes and of oxygen free radicals; promote the production of fibroblasts and the vascularization of the compromised skin, thus reducing the number of apoptotic cells (18). That study assessed whether ESW treatment rescues the compromised flap tissue by suppressing the apoptosis of ischemic tissue and stimulating tissue regeneration. A random-pattern extended dorsal-skin-flap (10 x 3 cm) rodent model was used: skin grafts distal to the treated area were applied on 36 rats randomly divided into 3 groups (each consisting of 12 rats): the first group did not receive treatment with ESWT, the second group was treated with a single session of ESWT immediately after surgery, and the third group was treated with 2 sessions of ESWT, one immediately after surgery, the other the next day. The assay of the above-mentioned elements showed positive results in the groups treated with shock waves compared to the untreated one and a most significant advantage in the group treated with a single session of shock waves compared to the one treated with two consecutive sessions.

Human ulcer histological analysis also showed a statistically significant increase of von Willebrand factor (vWF), vascular endothelial growth factor (VEGF), endothelial nitric oxide synthase (e-NOS), antigen nuclear proliferation (PCNA) and the expression of epidermal growth factor (EGF) with reduction of the expression of TUNEL, which is a signal of the cellular apoptotic cascade (19, 20).

These results allow to develop patterns of treatment in order to reduce the inflammatory process and the excessive protease activity and, at the same time, promote angiogenesis, and fibroblast proliferation as well as keratinocytes migration, inducing a correct biological process of wound healing.

MATERIALS AND METHODS

The study was approved by the local ethics committee, and was performed in accordance with the 1964 Declaration of Helsinki. Subjects were informed about...
the procedures and purposes of the research and gave their written informed consent before participating.

A randomized blind assessment controlled trial was designed to study the efficacy of shock wave treatment produced by the unfocused probe through the analysis of the percentage of wound healing (calculated as the reduction in wound area divided for the initial area percentage).

The study was carried out by the Department of Physical Medicine and Rehabilitation of "G. D'Annunzio" University in Chieti, and the Department of Plastic and Reconstructive Surgery of "Sapienza" University in Rome.

The secondary outcome of the study was to assess the antibacterial effect through the evaluation of specific buffers and the search for possible occurrence of infection during therapy. Inclusion criteria were as follows: vascular (blood-based and/or venous), diabetic, pressure, burn, iatrogenic, post-traumatic ulcer or ulcer in autoimmune disease. No wound healing progression or loss of substance for at least 3 months; age over 18 years; informed consent signature.

Exclusion criteria were: arrhythmias; pacemaker; severe bleeding disorders; cancer close to the treatment area; pregnancy; presence of growing cartilage; local acute inflammation; bone exposure; wound area less than 1 cm² or greater than 10x20 cm.

One hundred and twenty-four patients (67 men, 57 women), aged between 28 and 80 years, meeting the inclusion criteria were treated between March 2009 and February 2012. The selected patients had chronic ulcers for at least 3 to 24 months before the beginning of therapy (mean 10 months). They were randomly divided into 2 treatment groups A and B; all patients received unfocused ESWT treatment; patients in group A were treated with Dermagold unfocused probe (MTS Europe GmbH, Constance, Germany), patients in group B were treated with Evotron unfocused probe (HMT, Lengwil, Switzerland). All patients were treated with a frequency of 1 session every 7 days for 7 weeks. A medical record with personal data, main disease (responsible for ulcer), secondary diseases, time of onset, previous treatments and their costs, and previous medications was completed for each patient.

Before and after the treatment period the ulcers were classified according to: localization, width (in cm), length (in cm), percentage of granulation tissue, necrotic tissue, fibrous tissue, presence of bacterial exudate (classified as absent, minimal, moderate, high) and pain, which were assessed by Visual Analogic Scale (VAS). The morphological evolution was monitored, taking photos before each session using digital cameras with resolution

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**Fig. 1. Flow chart of patients enrolled in the study.**
higher than 5 megapixels and macros function; all pictures were taken at the shortest distance necessary to frame the lesion and the standardized squared.

After each session dressing with povidone-iodine and application of fat gauze, Connettivina (Fidia Farmaceutici S.p.A, Italy) and semipermeable occlusive patches was carried out. During the treatment period, the possible occurrence of side effects such as pain, petechiae and cutaneous adverse reactions related to therapy was monitored (21-22) (Fig. 1).

Sixty-two subjects (39 men and 23 women) aged between 28 and 80 years (mean age 62 years), were included in Group A, two of whom dropped out of the study because of personal problems. Of the remaining patients, 23 had diabetic ulcers, 10 pressure ulcers, 10 traumatic ulcers, 19 vascular ulcers. All subjects were always treated with ESWT unfocused probe with Dermagold electrohydraulic system (MTS Europe GmbH, Constance, Germany); the mean energy density applied for each pulse in Group A was equal to 0.1 mJ/mm² (0.09/0.11 mJ/mm²), with a total energy equal to 1.7 mJ for each shot.

Sixty-two subjects (28 men and 34 women) aged between 30 and 80 years, were included in Group B, 22 of whom dropped out of the study after the first treatment session and were not included in the final evaluation. Of the remaining 40 patients (16 men and 24 women), aged between 33 and 77 years (mean age 61 years), 9 had diabetic wounds, 11 post-trauma wounds, 1 patient pressure ulcer, 16 vascular wounds and 3 wounds in cryoglobulinemia. All subjects were always treated with ESWT unfocused probe with Evotron electrohydraulic system (HMT, Lengwil, Switzerland); the mean energy density applied in Group B was equal to 0.04 mJ/mm², with a total energy equal to 3.3 mJ for each shot.

In both Groups A and B, 300 to 600 shots were administered per session relating to the wound area, as shown in Table I, at a frequency of 4 Hz or 240 pulses per minute.

All data are given as means ± SDs. Differences between mean values before and after the treatment period were tested for significance using Student’s t-test for paired observations. ANOVA with an interaction test was used to compare the responses to the treatment in the two groups. Fisher’s PLSD test for post hoc analysis was employed. The minimum level of statistical significance was set at P<0.05. GraphPad Prism (version 5) software (Abacus Concepts GraphPad Software, San Diego, CA, USA) for statistical analysis was used.

**RESULTS**

Before treatment the average area of the 62 wounds in Group A was equal to 3.85 cm² As for the location of ulcers, 21 patients had lesions on the lower limbs, 31 on the foot-ankle complex, 10 in the pelvic region.

At first, lesions were made of 56% granulation tissue, 37% fibrous tissue, and 7% necrotic tissue; 29 subjects showed complete autonomy in the ordinary daily activities, 23 showed reduced autonomy, 10 showed autonomy with wheelchair; pain assessment in the early phase showed a mean VAS of 5.8, range 2-9.

Before treatment, the mean wound area in Group B was equal to 3.4 cm²; as for the location of ulcers, 28 were on the foot-ankle complex, 14 on lower limbs, in particular 2 patients had lesions on both lower limbs.

At first lesions were represented by an average of 55% of granulation tissue; 35% of fibrous tissue and 10% of necrotic tissue; among the 40 selected patients, 25 had complete autonomy, 14 reduced autonomy, 1 patient had autonomy with a wheelchair, pain assessment in the initial phase in this Group showed a mean VAS of 5.7, range 3-9. No patient in any group underwent antibiotic therapy during the whole treatment period.

Improvement in vascularization is quantitatively difficult to assess, therefore the surrounding skin, being a valid indicator of tissue distress, was monitored to determine the successful closure or reduction in size of the lesions in both groups during

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**Table 1. Relation between wound area and number of shots administered for each session.**

<table>
<thead>
<tr>
<th>Wound area (cm²)</th>
<th>Number of shots</th>
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</thead>
<tbody>
<tr>
<td>&lt;3</td>
<td>300</td>
</tr>
<tr>
<td>&lt;6</td>
<td>400</td>
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</tr>
<tr>
<td>&lt;20</td>
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</table>
the treatment. The mean area in Group A, equal to 3.85 cm² at the beginning, decreased by 80%, with a final average value of 0.93 cm² (p < 0.001) (Fig. 2).

The 23 diabetic wounds in this group showed an 85% mean decrease of the row surface area from a mean surface area of 1.45 cm² to a final average surface area of 0.2 cm². The 10 pressure wounds showed a 68% mean decrease of the row surface area rising from a mean surface area equal to 9.8 cm² to a final surface area of 3.1 cm². The 10 traumatic wounds showed an 87% decrease of the row surface area rising from a mean surface area of 1.2 cm² to a mean surface area of 0.15 cm². The 19 vascular wounds showed a 76% decrease of the row surface area rising from a mean surface area of 2.75 cm² to a mean surface area of 0.65 cm² (Fig. 3).

None of the patients in Group A experienced adverse reactions to therapy during the treatment. After 7 weeks of treatment 44 patients showed a complete wound healing while the other 18 had a partial recovery. As for pain, there was a 79% mean VAS reduction (p < 0.001) (4.5 points decrease compared to the initial value) with a final average value equal to 1.3 (range 0-4), as shown in Fig. 4.

No wound in Group A developed infection during therapy; such evidence may be related to the bactericidal effect of this system because negativization of culture swabs was found in 3 subjects with positive S. aureus. Each patient from Group A showed improvement in perilesional skin trophism.

As for the approval of treatment, 2 patients in group A abandoned the treatment after the fifth session for personal reasons (Table I).

The mean surface area in Group B, equal to 3.4 cm² at the beginning, decreased by 67%, with a final average value of 1.2 cm² (p < 0.001). Diabetic wounds in this group achieved a 60% mean decrease of the row surface area rising from a mean surface area of 1.2 cm² to a final average surface area of 0.48 cm²; traumatic wounds obtained an 85% decrease of the row surface area rising from a mean surface area of 1.2 cm² to a mean surface area of 0.18 cm²; pressure wounds demonstrated a 72% mean decrease of the row surface area rising from a mean surface area equal to 8.8 cm² to a final surface area of 2.5 cm²; vascular wounds demonstrated a 61% decrease of the row surface area rising from a mean surface area of 3.5 cm² to a mean surface area of 1.37 cm²; as for wounds in patients with cryoglobulinemia we
Table II. Compliance to therapy in group A where 2 patients abandoned the protocol.

<table>
<thead>
<tr>
<th>GROUP A</th>
<th>AGE</th>
<th>WOUND AREA 1st session</th>
<th>WOUND AREA 5th session</th>
<th>VAS 1st session</th>
<th>VAS 5th session</th>
<th>REASON FOR WITHDRAWAL</th>
</tr>
</thead>
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<td>7</td>
<td>4.5</td>
<td>4</td>
<td>3</td>
<td>CHANGE OF RESIDENCE</td>
</tr>
</tbody>
</table>

Fig. 5. Mean wound area in Group B before treatment and after the 7th session.

Fig. 6. Mean wound area for each disease at the first session and after the 7th week of treatment in Group B.

Fig. 7. Pain level assessed by VAS at the 1st and after the 7th session in Group B.

found a 33% decrease of the row surface area (Figs. 5 and 6).

None of patients in Group B experienced adverse reactions to treatment (bleeding, petechiae) apart from 15 patients who withdrew from the study because of pain.

At the end of therapy, 16 patients achieved complete healing, 15 obtained partial recovery, 9 wounds (5 from vascular insufficiency, 2 in diabetic microangiopathy, 2 in cryoglobulinemia) showed no improvement. As for pain, in Group B, there was a 48% mean VAS reduction (2.7 reduction points compared to the initial value) with a final mean value equal to 3 (range 1-6) (Fig. 7).

As for the approval of treatment, 22 patients withdrew from the study after the first session for personal reasons as described in Table III.

No wound in Group B developed infection during therapy; such evidence may be related to the bactericidal effect of this system because dejection of Staphylococcus aureus in culture swabs was found. Each patient from Group B showed improvement in perilesional skin trophism.

Both groups A and B showed a good response to treatment with a significant reduction in wound areas after 7 weeks and a peak of increase in terms of wound size reduction, between the third and the fourth week of treatment. During the last evaluation Group A showed a greater area reduction than Group B (Fig. 8 and 9).
Table III. Compliance to therapy in group B where 22 patients abandoned the protocol.

<table>
<thead>
<tr>
<th>GROUP B</th>
<th>AGE</th>
<th>WOUND AREA 1st session</th>
<th>WOUND AREA 2nd session</th>
<th>VAS 1st session</th>
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DISCUSSION

Chronic wound treatment is becoming an important economic and social issue related to the increase in the average population age because of the necessary costs for management, not only in financial terms but also in human resources (1, 23), patients quality of life and psychological impact on them (24).

Therefore, it would be interesting to find therapeutic solutions able to aid the healing process by reducing, at the same time, the amount of dressings applied, the need for assistance in wound care and the need for surgery.

Nowadays, chronic wound treatment is based on mechanical debridement, use of flaps or skin grafts, advanced dressings and, in an experimental way, application of a particular type of acoustic wave, defined shock wave. ESWT basically represents a cellular activator because of its ability to induce angiogenesis, to stimulate the increase in growth factors and promote cell differentiation (25-26).

The results showed that in both groups there was a significant decrease in the percentage (p <0.001) of the row surface area with a greater value in Group A compared to Group B, respectively equal to 80% and 67%. Moreover, pain reduction, assessed by VAS, was statistically significant (p <0.001) in both groups, but with a larger value in group A (4.5).
versus group B (2.7).

Application of low energy unfocused shock waves for difficult wounds was confirmed by histological studies of animal skin models (10, 12, 16, 27, 28) and a pilot study on humans carried out by Saggini et al. 2008 (1). In our study, clinical trials on humans agree in terms of efficacy, with histological data in animal models found by Kuo in 2009.

Pain reduction obtained in both groups confirmed the effectiveness of ESWT in stimulating analgesia through modulation of pain chemical mediators such as blocking of pain signal transmission induced by substance P (29-35).

Dividing the analysis of results according to wound ethiology, there was a significant response in diabetic and traumatic wounds compared to the vascular and ischemic ones, data is shown for both groups A and B. These results are probably to be related, according to other studies (1), to systemic compromise which leads to greater disability in patients with ischemic and vascular lesions. The great importance of effectiveness of shock waves in pressure-ischemia wounds should be considered because of their ability to decrease the number of interventions for clutches or skin flaps as evidenced by Larking et al. 2010; this also intersects with the bactericidal effect by induction of implosion of bubbles which exert a mechanical stress on bacterial cell membrane, promoting death, as supported by Gerdesmeyer et al. 2005 (17).

Improvement of perilesional skin trophism in both groups is significant, but the results of group A are certainly better as they are related to a higher total density of energy transferred from the probe in each therapeutic session. Moreover, the temporal sequence of therapeutic applications, a session of shock waves every 7 days in both groups showed a peak of the largest increase in terms of size reparative space between the third and fourth week of treatment. Our hypothesis is that this can be attributable to the mechanisms of energy transfer that the summation of ESWT, as activator and promoter of cell growth factors, is able to manifest through a summation of energy transfer in a specific time. This time is not characterized by a single application or a double repeated application at a distance of 24 hours: in our opinion, an expression of more energy transfers after 7 days of rest is required in order to express a better quality in tissue response. ESWT can therefore be compared with other therapies, for example hyperbaric, which require one or two sessions per week for several months (18-20, 27).

REFERENCES


