Effects of combining electroacupuncture with conventional care for the treatment of pressure ulcers
– Comparison of local electroacupuncture and remote electroacupuncture–

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Abstract
[Objective] We examined the effect of varying the stimulation site for electroacupuncture (EA) treatment of pressure ulcers.
[Method] The subjects were 56 patients with pressure ulcers in their pelvic areas. The subjects were randomly assigned to three groups. The control group was 19 patients (conventional treatment and care in conformity with pressure ulcer care guidelines), local site EA group (local group) was 19 patients (local site EA combined with conventional treatment and care), and remote EA group (remote group) was 18 patients (remote site EA combined with conventional treatment and care). The local group received EA stimulation around the ulcerated area. The remote group received EA stimulation at both BL 40 (Weizhong, Ichu) and BL 57 (Chengshan, Shozan). The electrical source was a bipolar pulse wave at a frequency of 3 Hz and a stimulation time of ten minutes 5 times a week.
[Results] Compared to the control group after four weeks of treatment, the local group showed a significantly lower DESIGN-R rate of change. After six weeks, the local group showed a significantly lower level than the remote group. The local group showed a significantly smaller wound size compared to the control group after four weeks of treatment. After six weeks, the local group showed significantly smaller wound size than the remote group.
[Conclusion] These results suggest that EA to the surrounding area is the most useful method for prompt healing of pressure ulcers.

Key words: pressure ulcer, electroacupuncture, DESIGN-R, wound size

I. Introduction

Pressure ulcers are commonly known as “bedsores” and are caused by the loss of blood flow to skin tissue due to prolonged external pressure. Thus, the level of severity differs depending on the degree of loss of blood flow. The prevailing rate of pressure ulcers that are caused in the above-mentioned way is reported to be 1.9% ~ 5.5%¹. For treating pressure ulcers locally, removing pressure is most important and, in addition, externally applied medicines and wet-dressing therapy are also used in many cases². In recent years, externally applied medicines and dressing materials continue to improve, but still the number of average healing days for pressure ulcers is 13.3-233.5 days and, for some cases, the clinical course of severe pressure ulcers extends beyond a year or more³. The Japanese Society of Pressure Ulcers recommends physical therapy in its Guideline for Prevention and Management of Pressure Ulcers (hereafter, the Guideline)⁴. However, the Guideline has currently no description about acupuncture and moxibustion therapy. Furthermore, when we previously investigated publications that reported on acupuncture and moxibustion therapy

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for the treatment of pressure ulcers, there were only two reports abroad and no reports in Japan. These reports indicate that the cause of occurrence of pressure ulcers is different between European and North American countries and Japan. Although the number of reports is few, they imply the possibility that acupuncture and moxibustion are effective on pressure ulcers. Because the cause mechanism of pressure ulcers in Japan is supposed to differ from that of Europe and North America, it is necessary to obtain reports on acupuncture and moxibustion treatments on pressure ulcers. Thus far, we have reported that, for the treatment of pressure ulcers, therapy is improved by combining electroacupuncture (EA) with conventional care. However, finding the optimal stimulation conditions has been a challenge.

To cope with this, we examined the clinical effects of varying the stimulation site for EA for treating pressure ulcers in order to investigate the effects of combining EA with conventional pressure ulcer care.

II. Method

1. Subjects

Subjects were 56 patients who were suffering from chronic secondary pressure ulcers that occurred from April 2010 to March 2011. Criteria for the subjects were the following: (1) patients with hospital-acquired pressure ulcers and patients with non-hospital-acquired pressure ulcers that occurred not longer than three months before being found, (2) patients with ischemic stroke or intractable neurological diseases that required lying in bed most of the time, (3) patients whose family’s consent could be obtained, (4) when starting the examination, the severity of pressure ulcers is classified into stage II (the epidermis and part of the dermis is damaged), stage III (damage extends into the subcutaneous tissue) or stage IV (damage extends beyond the subcutaneous tissue), and (5) pressure ulcers are limited to the sacrum, greater trochanter and buttocks. The exclusion criteria were the following: (1) patients who are suffering from pneumonia or infectious disease (excluding infected pressure ulcers), or suffering from severe cardiac disease, or when doctors decide that providing acupuncture treatment is difficult, (2) patient’s or family’s consent has not been obtained, (3) classification of pressure ulcers when found is type I (an area of redness does not fade or blanch), type V (damage reaches articu lar cavity or body cavity) or DU (depth undetermined), (4) deep tissue injury is suspected, (5) skin diseases such as scabies and mycosis are recognized, and (6) patients who are using a cardiac pacemaker.

2. Ethical considerations

Researchers or nurses explained to patients with pressure ulcers or to their families about the following points: (1) the purpose and method of the present study, and anticipated effects and risks, (2) patients who do not participate or discontinue participation will not suffer a penalty, (3) protection of privacy, and (4) patients will be compensated if their pressure ulcers are judged to have gotten worse. After explanation, we obtained consent for participation, if agreed.

Upon approval by the Ethics Committee, the present study was conducted.

3. Subject allocation method

When getting a first notification about the occurrence of the pressure ulcer cases, the nurses, who were members of the Pressure Ulcer Countermeasure Committee, visually judged and classified the severity of pressure ulcers of the subjects. Subjects were randomly allocated to three groups using the envelope method (three types of 50 envelopes per type were prepared. These three types of envelopes contained three kinds of notation, i.e., “control group,” “local EA group,” or “remote EA group,” one of which was printed on each paper sheet. The notations were not visible from the outer side of the envelope. These envelopes were opened by a third party immediately before starting the examination). Consequently, the control group consisted of 19 cases that were to receive conventional treatment and care, the local EA group consisted of 19 cases that were to receive conventional treatment and care combined with local-site electroacupuncture, and the remote EA group consisted of 18 cases that were to receive remote-site electroacupuncture.

4. Study design

The present study used a quasi-randomized controlled trial combined with the envelope method. Intention-to-treat analysis (ITT analysis) was performed to cope with subjects who dropped out because of transferring to another hospital, worsening of their physical state and so on during the study period. The ITT analysis allows for assigning the immediate previous value (the value at the last rating before dropping out).

Pressure ulcers were rated by a DESIGN-R total score and wound size by raters who were unaware of the subjects groupings.

(1) Conventional treatment and care method

Pressure ulcers with dermis damage were protected with dressing materials to keep a moist environment. For pressure ulcers with damage into subcutaneous tissue or beyond, positive treatment was undertaken to heal the ulcers by keeping a moist environment and removing aggravating factors that might lead to tissue necrosis and wound infection. In addition, patients were cared for every 2 or 4 hours by changing lying position and using positioning aids such as mattresses with body-pressure balancing functions (the time interval was determined depending on the physical condition of patients and the effectiveness of the pressure balancing mattress), and washing the wound using weak acid soap and lukewarm water.

Externally applied medicines and dressing materials were appropriately selected by doctors, nurses, and
pharmacists according to the status of the wound. The medicines and dressing materials specifically used for this present study were selected by doctors, members of the Pressure Ulcer Committee and floor nurses, and actual treatment was performed by floor nurses. When chemical debridement was applied to necrotic tissues (if they were recognized), and, if it did not work effectively, surgical debridement was used. Nutrition consumption was planned by a hospital nutrition manager taking into account the nutritional needs of each case.

(2) EA method (Fig. 1)

For the present study, 40-mm No. 20 stainless steel needles were used. Electrical stimulation was made by Ohm Pulser LFP-4000 A (manufactured by Zen Iryoki Co. Ltd.). Stimulation was applied to patients five days a week. The stimulation waveform was a bipolar pulse, stimulation frequency of 3 Hz, current supply time of 10 min and stimulation intensity below the muscle contraction threshold (about 10 percent decrease from the intensity where muscle contraction appears without pain).

For the local site EA group, needles were inserted to a depth of about 10-30 mm at four points on the normal skin 0.5-1.0 cm apart around the ulcerated area. Electrical stimulation was made using a bipolar pulse wave as described above.

For the remote EA group, needles were inserted to a depth of about 10 mm at BL 40 (Weizhong, Ichu) and BL 57 (Chengshan, Shozan) of both lower extremities, and electrodes were placed on these needle points. Current was made to flow between BL 40 and BL 57 of each lower extremity. Electrical stimulation was performed in the same way as for the local EA group. In selecting acupuncture points for electrical stimulation, it was intended to stimulate such lower extremity points that are controlled by the same motor nerve system that controls the site of the wound. That is, these stimulation points were selected among the sites of the Bladder Meridian of Foot-Taiyang (Zutaiyang Pangguangjingxue) and the Gallbladder Meridian of Foot-Shaoyang (Zushaoyang Danjingxue) in oriental medicine.

5. Rating method

Clinical effects were rated using the DESIGN-R total score and wound size by nurses at the bedside of the subjects. These nurses had clinical experience of seven years or more, were unaware of the subjects groupings, and were not in charge of the hospital wards where the subjects were staying.

The DESIGN-R total score was derived based on six items, i.e., exudates, size, inflammation/infection, granulation tissue, necrotic tissue and skin pockets, which were rated four times in total, i.e., before starting the examination, and two weeks, four week and six weeks after starting it (rating was finished when completely healed). The wound size (cm$^2$) was calculated by measuring the longest length of the wound and the widest width at a line perpendicular to the length axis.

Statistical considerations used Stat View Ver.5.0 (SAS Institute Inc.). The background comparison of the patients was performed using Mann-Whitney's U-test. Changes of the Design-R score and the wound size over time were analyzed by using a one-way factorial analysis of variance, which was followed by using the Bonferroni method. Comparison of differences among the three groups was performed by using a two-way factorial analysis of variance without replication. As a result, no
interaction was found in either the Design-R (P = 0.64) or the wound size (P = 0.90). Finally, the three groups were analyzed at each rating period by using the Bonferroni method. In each case, the level of statistical significance was set at 5%.

III. Results

1. Background of subjects (Table 1)

Among the control group, the local EA group and the remote EA group, no statistical significance was found in gender, body status (age, height, weight, and BMI), Braden’s scale (a risk assessment tool for pressure ulcer development), total protein (TP), serum albumin (Alb), blood C-reactive protein (CRP) and comprehensive severity of sickness.

2. Change of the DESIGN-R over time and its comparison among the three groups (Fig. 2)

The results of the changes of DESIGN-R total score over time are as follows:

With the control group, the total score was 19.0 ± 11.3

Table 1 Background of three subject groups

<table>
<thead>
<tr>
<th></th>
<th>Control group (n=19)</th>
<th>Local EA group (n=19)</th>
<th>Remote EA group (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Man : Woman (people)</td>
<td>10:9</td>
<td>8:11</td>
<td>9:9</td>
</tr>
<tr>
<td>Age (years)</td>
<td>78.0±10.7</td>
<td>77.0±10.8</td>
<td>78.4±9.4</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>152.3±11.0</td>
<td>155.2±11.2</td>
<td>158.2±9.7</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>45.6±9.7</td>
<td>46.1±7.9</td>
<td>50.1±10.5</td>
</tr>
<tr>
<td>BMI</td>
<td>19.3±2.9</td>
<td>19.0±3.1</td>
<td>19.5±4.2</td>
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<tr>
<td>Braden’s scale (score)</td>
<td>11.3±2.7</td>
<td>10.4±3.5</td>
<td>11.0±2.1</td>
</tr>
<tr>
<td>TP (g/dl)</td>
<td>6.1±0.6</td>
<td>6.1±0.7</td>
<td>6.0±0.8</td>
</tr>
<tr>
<td>Alb (g/dl)</td>
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<td>3.0±0.5</td>
<td>3.1±0.4</td>
</tr>
<tr>
<td>CRP (mg/dl)</td>
<td>5.1±0.8</td>
<td>3.1±0.8</td>
<td>2.7±0.4</td>
</tr>
<tr>
<td>Severity (people)</td>
<td>II 7, III 9, IV 3</td>
<td>II 6, III 11, IV 2</td>
<td>II 8, III 8, IV 2</td>
</tr>
</tbody>
</table>

Fig. 2 Change of the DESIGN-R over time and its comparison among the three groups
The DESIGN-R total score were no significant differences in three groups.
N.S= no significant
at the beginning of the examination, and it changed to 18.8 ± 11.8 after two weeks, 15.0 ± 13.3 after four weeks, and 13.5 ± 13.1 after six weeks. Compared to the score at the beginning, the score after six weeks was significantly lower (P < 0.05).

With the local EA group, the total score was 24.3 ± 15.0 at the beginning of the examination, and it changed to 18.0 ± 13.6 after two weeks, 12.7 ± 13.0 after four score at the beginning, the scores after two weeks and later were significantly lower (P < 0.05).

With the remote EA group, the total score was 19.1 ± 12.7 at the beginning of the examination, and it changed to 16.5 ± 10.5 after two weeks, 15.4 ± 12.1 after four weeks, and 12.7 ± 9.3 after six weeks. Compared to the score at the beginning, the score after six weeks was significantly lower (P < 0.05).

The results of the comparison among the three groups indicated no significance over the whole examination duration.

3. Change of the wound size over time and its comparison among the three groups (Fig. 3)

The results of the changes of the wound size over time are as follows:

With the control group, the total score was 10.3 ± 13.1 at the beginning of the examination, and it changed to 9.0 ± 9.4 after two weeks, 4.4 ± 5.6 after four weeks, and 3.4 ± 3.7 after six weeks. Compared to the score at the beginning, the score after four weeks was significantly lower (P < 0.05).

With the local EA group, the total score was 13.7 ± 17.1 at the beginning of the examination, and it changed to 9.1 ± 11.9 after two weeks, 6.7 ± 11.3 after four weeks, and 4.3 ± 8.7 after six weeks. Compared to the score at the beginning, the scores after two weeks or more were significantly lower (P < 0.05).

With the remote EA group, the total score was 9.9 ± 9.5 at the beginning of the examination, and it changed to 8.7 ± 10.4 after two weeks, 7.6 ± 11.4 after four weeks, and 6.5 ± 10.4 after six weeks. Compared to the score at the beginning, the score after six weeks was significantly lower (P < 0.05).

The results of the comparison among the three groups indicated no significance over the whole examination duration.

![Chart](chart.png)

Fig. 3. Change of the wound size over time and its comparison among the three groups
There were wound size is no significant differences in three groups.
N.S= no significant
4.5 Comparison of the rate of change of the DESIGN-R among the three groups (Fig. 4)

The rates of change of the DESIGN-R were derived with the rate at the beginning of the examination as 100%; then, the three groups were compared by the rate of change thus obtained.

The rate of change after two weeks was 100.9 ± 28.3% for the control group, 68.9 ± 25.7% for the local EA group, and 88.8 ± 23.4% for the remote EA group.

The rate of change after four weeks was 74.5 ± 35.0% for the control group, 43.5 ± 28.1% for the local EA group, and 73.9 ± 38.7% for the remote EA group. Compared to the control group, the local EA group indicated a significantly lower rate of change of DESIGN-R (P < 0.05).

The rate of change after six weeks was 66.5 ± 43.9% for the control group, 26.2 ± 22.7% for the local EA group, and 64.1 ± 44.2% for the remote EA group. Compared to the control group, the local EA group indicated a significantly lower rate of change of DESIGN-R (P < 0.01). In addition, compared to the remote EA group, the local EA group indicated a significantly lower rate of change of DESIGN-R (P < 0.01).

5. Comparison of the rate of change of the wound size among the three groups (Fig. 5)

The rates of change of the wound size were derived with the rate at the beginning of the examination as 100%; then, the three groups were compared by the rate of change thus obtained.

The rate of change after two weeks was 95.2 ± 29.9% for the control group, 73.8 ± 34.4% for the local EA group, and 71.7 ± 42.2% for the remote EA group.

The rate of change after four weeks was 65.8 ± 40.7% for the control group, 44.1 ± 32.6% for the local EA group, and 61.3 ± 42.9% for the remote EA group. Compared to the control group, the local EA group indicated a significantly lower rate of change of wound size (P < 0.05).

The rate of change after six weeks was 63.0 ± 55.8% for the control group, 21.8 ± 25.3% for the local EA group, and 56.2 ± 43.5% for the remote EA group. Compared to the control group, the local EA group indicated a significantly lower rate of change of the wound size (P < 0.01). In addition, compared to the remote EA group, the local EA group indicated a significantly lower rate of change of the wound size (P < 0.01).
IV. Consideration

It is supposed that the mechanism that causes pressure ulcers in Japan differs from that of Europe and North America. In Europe and North America, pressure ulcers develop when external pressure is exerted against the skin due to obesity caused by over-nutrition, whereas in Japan pressure ulcers usually develop when external pressure is applied where bones protrude. It is reported that incidences of pressure ulcers are tending to decrease in Japan; however, their prevalence is not noticeably decreasing at hospitals. The reason is assumed to be the large number of in-patients with intractable pressure ulcers. Conventionally, local treatment for pressure ulcers has been to encourage moist wound healing associated with using externally applied medicines and dressing materials, as well as performing wound bed preparations to accelerate spontaneous healing. However, there are few cases where either physical therapy or acupuncture/moxibustion therapy has been provided to accelerate spontaneous healing. Duan, et al reported that the treatment of 73 pressure ulcer cases with warming moxibustion was 95.9% effective. Yan, et al reported that, among 54 pressure ulcer cases, the acupuncture-treated group indicated a significant improvement compared to the not-treated group. As shown by these examples, acupuncture/moxibustion therapy should be effective. Within this background, it is necessary to also publish reports in Japan which take into consideration the difference in the causal mechanism of pressure ulcers. Thus far, we have reported that patients with sacral pressure ulcers showed significant improvement when they received conventional treatment and care combined with electroacupuncture, indicating that electroacupuncture is useful for treating pressure ulcers. However, there remain issues concerning optimal stimulation, including stimulation sites and frequency of applying stimulation. To cope with this, in this study, we investigated the clinical ratings of electroacupuncture effect depending on the difference in stimulation sites. Subjects were divided into three groups, namely, the control group (conventional treatment and care that conforms with pressure ulcer care guidelines), local site EA group (conventional treatment and care in addition to electroacupuncture around the wound), and remote EA group (conventional treatment and care in addition to

Fig. 5 Comparison of the rate of change of the wound size among the three groups

Initiation was 100%. After four weeks later, we recognized significant low level in the local EA group as compared with the control group. Six weeks later, the group more local EA than a remote EA group had significant low level.

Display it with mean±S.D
N.S= no significant
electroacupuncture at BL 40 (Weizhong, Ichu) and BL 57 (Chengshan, Shozan) on the Bladder Meridian of Foot-Taiyang. These acupuncture sites were selected from among sites located on the Bladder Meridian of Foot-Taiyang and the Gallbladder Meridian of Foot-Shaoyang that flow in pressure ulcers on the sacrum, buttocks and greater trochanter.). As a result, significant improvement was found in the local EA group compared to the control and remote EA group, whereas no significant difference was found between the control and remote EA groups.

In this study, although we did not investigate the functional mechanism, we found that local EA acupuncture stimulation on pressure ulcers causes skin temperature to increase\(^{10}\). A mechanism that causes orienting reflex, secretion of a vasodilator substance, and sympathetic nerve activity suppression is supposed\(^{13}\). However, orienting reflex and secretion of a vasodilator substance may have a greater effect than the increased blood flow caused by sympathetic nerve activity suppression, because no significant difference is found between the control and remote EA groups\(^{11}\). Jansen, et al\(^{12}\) reported from the results of performing electroacupuncture for rat muscle-skin flap that the reaction of the skin flap to increased cutaneous blood flow is associated with substance P, which is related to orienting reflex and calcitonin gene-related peptides. They also reported that the difference in the amount of tissue mass between the skin tissue and the muscle tissue to be stimulated affects cutaneous blood flow\(^{13}\). Although, in this study, we did not measure the skin and muscle tissue masses, the difference in the amount of muscle tissue mass between the buttocks and the surlar region may affect the difference in blood flow between them. In addition, the reaction of blood flow increase due to angiogenesis, inflammation suppression reaction and collagen-increasing reactions are supposed to be produced by the accumulation of electroacupuncture effects\(^{14-15}\). Although the angiogenesis function due to acupuncture stimulation has not been confirmed in humans, Oda et al\(^{14}\) reported that they confirmed the increased vascular endothelial growth factor and angiogenesis function produced by applying acupuncture to ischemia rats. In addition, Park et al\(^{15}\) reported that they confirmed the significant reduction of wound size, suppression of pro-inflammatory cytokine and a significant increase of vascular endothelial growth factor and type I collagen produced by applying acupuncture to a wounded rat model. As described above, it is supposed that not only blood flow increases but also angiogenesis function and inflammation suppression effects are produced, and they are associated in a compound manner, thus promoting early healing of pressure ulcers. However, angiogenesis function generated by acupuncture stimulation has not been confirmed in humans, and besides, the wound that occurred in the wounded rat model was an acute wound, and its pathology may be different from the pathology of a pressure ulcer that is a chronic wound. These issues will be dealt with as future tasks.

V. Conclusion

In this paper, electroacupuncture was applied to different stimulation sites and consequent effects on the DESIGN-R scores and wound sizes of pressure ulcers were studied. As a result, it is concluded that electroacupuncture stimulation to the surrounding area of the pressure ulcer, when combined with conventional treatment and care, will promote healing.

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