Are physiological changes experienced by healthy subjects during acu-TENS associated with acupuncture point sensations?

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ABSTRACT

Background Transcutaneous electrical nerve stimulation over acupuncture points (acu-TENS) has been reported to improve clinical outcomes. The objectives of the present study were to investigate whether acupuncture point sensations were experienced during acu-TENS, and whether such sensations were associated with any concomitant changes in autonomic nervous system activity.

Methods This study adopted a single-blinded, randomised, controlled trial methodology. A total of 36 healthy subjects were randomly assigned to an experimental group (acu-TENS on right LI4 and LI11 points); control group (acu-TENS to bilateral kneecaps); or placebo group (sham acu-TENS on right LI4 and LI11 points). Heart rate (HR), mean arterial blood pressure (MAP), SD of the NN interval (SDNN) and low frequency to high frequency ratio (LF/HF) were measured before, during and after intervention. The Hong Kong Chinese version of the Massachusetts General Hospital Acupuncture Sensation Scale (C-MMASS) index was used for quantifying the acupuncture point stimulation sensations.

Results The experimental group showed a significant increase in HR (mean (SD) 73.5 (6.3) to 75.9 (6.7) bpm, $p=0.027$), MAP (88.5 (4.5) to 91.0 (4.1) mm Hg, $p=0.004$), SDNN (143.36 (8.58) to 153.69 (7.64) ms, $p=0.002$) and LF/HF (1.26 (0.19) to 1.31 (0.21), $p=0.037$) during the intervention. The control group showed a significant increase in SDNN (140.21 (8.72) to 143.39 (9.47) ms, $p=0.009$) and LF/HF (1.21 (0.09) to 1.23 (0.12), $p=0.033$). There were no significant physiological changes in the placebo group. Overall C-MMASS indices for the experimental, control and placebo groups were 3.23 (0.3), 2.14 (0.6) and 0.29 (0.32), respectively. The between-group difference was statistically significant ($F=139.24$, $df=2$, $p<0.05$). However, correlation analysis did not support any

association between sensation intensity and physiological responses in any groups (γ ranged from -0.36 to 0.25).

Conclusions This study showed that 'acupuncture point sensations' were experienced during acu-TENS to LI4 and LI11, but such sensations were not associated with physiological responses induced during the stimulation.

INTRODUCTION

Complementary treatments are receiving increased attention as a choice for health maintenance. Traditional Chinese Medicine (TCM) practitioners believe acupuncture is able to modulate *qi* flow and restore the *yin-yang* balance, and hence health can be maintained.^{1–2} In Western medicine, acupuncture concepts have been explained as a regulation of the autonomic nervous system (ANS), revitalising and balancing the body's homeostasis through modulation of the sympathetic and parasympathetic systems.^{3–4} Analysis of heart rate variability (HRV), has become a common measurement parameter in many acupuncture studies.^{5–10}

While positive effects of acupuncture have been acknowledged by many studies, its associated adverse effects have also been reported.^{11–12} Thus, non-invasive techniques including acupressure^{13–14} and laser acupuncture¹⁵ have been seen as 'safer' alternatives. Transcutaneous electrical nerve stimulation (TENS) applied over acupuncture points (acu-TENS), has been reported to be effective in reducing dyspnoea in patients with chronic obstructive pulmonary disease (COPD),^{16–17} facilitate early haemodynamic recovery after open heart surgery,¹⁸ relieve labour pain^{19–20} and reduce blood pressure changes in normal healthy subjects.^{21–22} Acu-TENS is

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also associated with an increase in blood β -endorphin level,^{17 23} a decrease in airway resistance²⁴ and is possibly associated with regulation of the ANS.^{17 23 24}

Comparative investigation of the mechanism of action of acu-TENS and acupuncture continues, but a fundamental criterion for effective acupuncture, '*de qi*', has not been examined during acu-TENS. In TCM terms, *de qi* is a unique sensation that indicates an appropriate psychophysical response to acupuncture.^{1 2} In Western medicine, the *de qi* sensation is thought to indicate stimulation of the ANS via modulation of the cerebrocerebellar limbic system.^{25 26} Based on previous reports on acu-TENS,^{16 17} we hypothesise that acu-TENS can induce ANS changes similar to acupuncture; however, whether acupuncture point sensations described as *de qi* are necessary for the ANS changes elicited during acu-TENS has not been investigated. This study therefore aims to investigate acupuncture point sensations experienced during acu-TENS and whether such sensations are associated with any concomitant changes in ANS activity.

METHODS

Subjects

This study adopted a single-blinded (patient-blinded), randomised, controlled trial design. Ethics approval was obtained from the Human Subjects Review Committee of the involved university (Project ID: HSEARS20110510001) and was carried out within the ethical standards set forth in the Helsinki Declaration of 1975. Written consent was obtained from all participants. Normal healthy subjects who were naïve to TENS or acupuncture or acu-TENS and able to read Chinese were recruited. Subjects were excluded if they had a history of cardiopulmonary, neurological and psychological disorders, or if they required any medication for cardiovascular, neurological or psychological conditions within 1 week prior to the study.

Sample size calculation

Using the analysis and sample size software PASS 2008 (<http://www.ncss.com/pass.html>), and based on the results of our previous study on *de qi* measurement,²⁷ to achieve a medium effect size, power of 0.8 and produce a 2-sided 95% CI with a width equal to 0.987 and SD of 2.00, a total sample size of 36 subjects was considered appropriate for the study.

Randomisation procedure

Subjects were randomly assigned to one of the three groups using sequentially numbered, opaque sealed envelope simple randomisation method.²⁸ A total of 12 sheets of paper were marked with 'experimental group', 12 sheets with 'control group' and 12 sheets with 'placebo group', and the sheets were then put into 36 opaque envelopes (1 sheet per envelope), which were then sealed. The deck of envelopes was shuffled thoroughly by an independent assistant.

Then, the front of each envelope was marked sequentially with the numbers 1–36. These envelopes were then placed in numerical order in a plastic container. Each subject was asked to draw an envelope, which was then opened by an independent investigator.

Experimental procedure

On arrival at the laboratory, subjects were asked to rest for 30 min in a sitting position to establish a steady cardiopulmonary state. Subjects were instructed to breathe normally, to minimise any effect of respiration on HRV. All measurements were taken between 16:00 and 18:00 to minimise the circadian effect on the ANS.²⁹

Systolic and diastolic blood pressures were taken on the left arm by a digital patient monitor (Mindray PM-8000 Express Patient Monitor, Bio-Medical Electricity, Hamburg, Germany). The mean arterial pressure (MAP) was recorded. Electrocardiogram (ECG) electrodes were applied over left and right clavicles and left upper quadrant of abdomen and then connected to the digital patient monitor device. HR was continuously monitored. The ECG signals were analysed by Chart 5 Pro for Windows. The ECG signals were transferred to the PowerLab 16/30 (ADInstruments Pty Ltd., New South Wales, Australia) for data acquisition and analysis of the HRV.

MAP, HR and HRV parameters were measured at 5 min before the intervention, every 5 min for 45 min during the intervention and at the 5th minute after the stimulation. Data recorded during the 45 min intervention were averaged for analysis. Immediately after the intervention, subjects were asked to complete the Hong Kong Chinese version of the Massachusetts General Hospital Acupuncture Sensation Scale (C-MMAS)²⁷ to quantify the acupuncture point stimulation sensations.

HRV measurement

The HRV was analysed in accordance with the recommendations of the Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology.³⁰ For frequency domain analysis, power spectral analysis was performed by the Fast Fourier Transformation technique.^{29 30} Low frequency (LF), defined as the power between 0.03 and 0.15 Hz, mainly represents sympathetic modulation; high frequency (HF), defined as the power between 0.15 and 0.5 Hz, is regarded as an index of vagal (parasympathetic) modulation; the ratio LF/HF reflects the global sympathovagal balance of the body.^{30 31} For the time domain analysis, the recorded SD of the NN interval (SDNN) is referred to as the global index of the HRV.^{29 30 31}

Point location and preparation

The locations of the right LI4 and LI11 points and the apex of patella were identified by a trained physiotherapist. Isopropyl alcohol was applied for skin

preparation after locating the points. Two self-adhesive ECG electrodes (F-601 SKINTACT) were then placed over the acupuncture points and attached to a dual channel portable TENS unit (120z Dual Channel TENS, EMS Physio Ltd, Oxfordshire, UK). The pulse frequency and pulse width of the TENS were set at 2 Hz and 200 ms, respectively, with the intensity adjusted to the subject's maximum tolerable level short of muscle contraction. Total duration of stimulation was 45 min.^{17 23 24}

Intervention protocols

All interventions were conducted in the sitting position. For the experimental group, subjects received acu-TENS over the right LI4 and LI11 points; for the control group, subjects received TENS over the apex of bilateral kneecaps; for the placebo group, subjects received the same protocol as the experimental group and TENS but the points were covered with non-conducting plastics of the same size as the TENS electrodes, such that no electrical current would pass through the skin. Subjects were informed that they might or might not feel the electrical stimulation depending on the pulse frequency used.

Modified Massachusetts General Hospital Acupuncture Sensation Scale, Chinese version

The C-MMASS consists of 12 descriptors of sensation, including soreness, aching, deep pressure, heaviness, fullness/distension, tingling, numbness, dull pain, warmth, cold, throbbing, plus a blank supplementary row left for subjects to describe their own perceptions.²⁷ Each descriptor is presented on a 10-cm bar, anchored with numerical scores 0–10 and with the words 'none', 'mild', 'moderate' and 'severe' spaced evenly along the continuum. Immediately after the 45-min intervention, subjects were asked to quantify the sensations experienced by rating the intensity for each descriptor. The C-MMASS index was then calculated²⁷ and was used to quantify the overall intensity of the acupuncture sensations experienced.

Statistical analysis

All statistical analyses were conducted using the Statistical Package for Social Sciences (SPSS) V.17.0 for Windows. Demographic and baseline data were compared among the three groups using one-way analysis of variance (ANOVA). The within-group change in HR, MAP, LF/HF, SDNN and the C-MMASS index of the groups at before, during and after intervention were analysed by one-way repeated ANOVA. Between-group differences were analysed by one-way ANOVA with post hoc pairwise comparison and least significant difference (LSD) adjustment. The null hypothesis was rejected if the calculated F ratio exceeds the critical value with $p < 0.05$. An exploratory correlation analysis using Spearman's correlation was performed between the overall C-MMASS index,

mean MAP, HR, SDNN and LF/HF in each group. The level of significance was set at 0.05 for all analyses.

RESULTS

In all, 36 participants (22 men and 14 women) were recruited for this study (mean (SD): age 32.8 (2.1) years).

Blood pressure changes

The MAP increased significantly from 88.5 (4.5) mm Hg to 91.0 (4.1) mm Hg during acu-TENS in the experimental group ($p = 0.004$); at 5 min after intervention, the MAP returned to 89.3 (4.6) mm Hg and was still slightly higher than baseline but did not reach statistical significance ($p = 0.898$). There was no significant change in MAP for the control (from 88.7 (5.9) mm Hg to 89.6 (5.8) mm Hg) ($p = 0.315$) or the placebo groups (86.6 (5.7) mm Hg to 87.1 (5.4) mm Hg) ($p = 0.3$) during the stimulation (figure 1).

Heart rate changes

The HR increased significantly from 73.5 (6.3) bpm to 75.9 (6.7) bpm during acu-TENS in the experimental group ($p = 0.027$) and gradually returned to baseline (74.6 (8.4) bpm) post stimulation. There was also a slight increase in HR in the control group from 73.0 (4.5) bpm to 74.2 (3.7) bpm during the stimulation period, but this was not statistically significant ($p = 0.57$); the HR returned to baseline at 5 min after the stimulation. For the placebo group, there was no significant changes in HR (from 72.1 (6.9) bpm to

Figure 1 Changes in mean arterial pressure at various measurement timepoints in the three groups. Experimental group: transcutaneous electrical nerve stimulation over acupuncture points (acu-TENS) to right LI4 and LI11 points; control group: TENS to bilateral kneecaps; placebo group: TENS applied to non-conductive plastic films on the right LI4 and LI11 points. *Difference of mean arterial pressure between prestimulation and during stimulation in the experimental group ($p < 0.05$).

Figure 2 Heart rate changes at various measurement timepoints in the three groups. Experimental group: transcutaneous electrical nerve stimulation over acupuncture points (acu-TENS) to right LI4 and LI11 points; control group: TENS to bilateral kneecaps; placebo group: TENS applied to non-conductive plastic films on the right LI4 and LI11 points. *Difference of heart rate between prestimulation and during stimulation in the experimental group ($p < 0.05$).

71.6 (4.7) bpm) throughout the stimulation period ($p = 0.831$) (figure 2).

SDNN changes

The SDNN increased from 143.36 (8.58) ms to 153.69 (7.64) ms in the experimental group during stimulation ($p = 0.002$); at 5 min post stimulation, it remained higher than the baseline value by 6.31 ms ($p = 0.037$). For the control group, the SDNN increased from 140.21 (8.72) ms to 143.39 (9.47) ms during the stimulation ($p = 0.009$); at 5 min post stimulation, it was 2.46 ms higher than the baseline but the change was not statistically significant ($p = 0.068$). For the placebo group, there was no significant change in SDNN during or after the stimulation (144.38 (10.19) ms to 144.23 (10.23) ms), (figure 3). A significant between-group difference in the SDNN during the stimulation was found among the three groups ($F = 4.06$, $df = 2$, $p = 0.027$). Post hoc analysis with LSD adjustment showed there was a significant difference in the SDNN between the experimental and control groups ($p = 0.013$, CI 2.3 to 18.3) and between the experimental and placebo groups ($p = 0.029$, CI 0.97 to 17.0). There was also a significant main effect for acu-TENS on SDNN ($F = 19.068$, $p < 0.05$) and a significant interaction effect between acu-TENS and the period of stimulation ($F = 7.91$, $p < 0.05$).

LF/HF changes

The LF/HF increased from 1.26 (0.19) to 1.32 (0.21) during acu-TENS ($p = 0.019$) and at 5 min after the

Figure 3 SDNN and LF/HF changes at various measurement timepoints in the three groups. Experimental group: transcutaneous electrical nerve stimulation over acupuncture points (acu-TENS) to right LI4 and LI11 points; control group: TENS to bilateral kneecaps; placebo group: TENS applied non-conductive plastic films on the right LI4 and LI11 points. #Difference of SDNN between the experimental group and the control group during acu-TENS ($p < 0.05$). \$Difference of SDNN between the experimental group and the placebo group during acu-TENS ($p < 0.05$). JDifference of LF/HF between the experimental group and the control group during acu-TENS ($p < 0.05$). +Difference of LF/HF between the experimental group and the placebo group during acu-TENS ($p < 0.05$). HF, high frequency; LF, low frequency; SDNN, standard deviation of the NN interval.

stimulation (1.30 (0.17)) ($p = 0.037$). There was a small but statistically significant increase in LF/HF in the control group during the stimulation period (from 1.21 (0.09) to 1.23 (0.12)) ($p = 0.033$). This ratio returned to baseline 5 min after the stimulation. Changes in this ratio were not significant in the placebo group, where the LF/HF remained at 1.23 (0.11) throughout the intervention (figure 3). A significant between-group difference in the LF/HF was found during the stimulation period ($F = 11.25$, $df = 2$, $p = 0.03$). Post hoc analysis with LSD adjustment showed there was a significant difference in the LF/HF between the experimental and control groups ($p = 0.02$, CI 0.45 to 2.2) and between the experimental and placebo groups ($p = 0.017$, CI 0.4 to 2.3). Furthermore, there was a significant primary effect for acu-TENS on LF/HF ($F = 2.73$, $p = 0.044$) while there

was no significant interaction effect between acu-TENS and the period of stimulation ($F=0.411$, $p=0.72$).

Intensity of acupuncture point sensations perceived during intervention

There was a significant difference in the C-MMASS index among the three groups ($F=139.24$, $df=2$, $p<0.05$); with the overall C-MMASS indices of the experimental, control and placebo groups being 3.23 (0.3), 2.14 (0.6) and 0.29 (0.32), respectively. Post hoc analysis with LSD adjustment showed that there was a significant difference in the C-MMASS index between the experimental and control groups ($p<0.05$, CI 0.72 to 1.45) and between the experimental and placebo groups ($p<0.05$, CI 2.57 to 3.30). In the experimental group, the three descriptors recorded with highest ratings were throbbing, soreness and fullness/distension. For the control group, the three strongest sensations recorded were tingling, throbbing and numbness. For the placebo group, the strongest sensation recorded was tingling. No subject opted to add any new descriptors in the blank row provided (figure 4).

Association between C-MMASS score and the physiological responses

Correlation analysis between the overall C-MMASS index score and HR, MAP, SDNN and LF/HF revealed a very low association between the intensity of sensations and any of the recorded physiological responses in all groups (table 1).

DISCUSSION

This is the first study to report a relationship between acu-TENS and acupuncture point sensations, similar to *de qi* reported in the literature.^{3 32 33} The results show that acupuncture point sensations were experienced by our healthy cohort and were strongest during acu-TENS, compared to non-acupuncture point and placebo stimulations.

De qi is believed to be an indispensable component of effective acupuncture.³ Previous studies have shown that *de qi* sensation is associated with regulation of blood flow,^{34–38} changes in neuronal activity in different areas of the brain,^{39–41} changes in ANS activities^{42–48} and an increase in pain threshold.⁴⁹ A survey conducted by the British Acupuncture Council on 574 members revealed that 87% of acupuncturists would aim to attain *de qi* during acupuncture.⁵⁰ Our previous work demonstrated that needle electroacupuncture to LI4 and LI11 increases sympathetic discharge, which was strongly associated with acupuncture point sensations.⁴² Insertion of the needle into the acupuncture points, together with the needle-twirling manoeuvre, lead to muscle tension, trembling, twitching and spasm; this in turn stimulates muscle proprioceptors and gives rise to distinct needle sensations.⁵¹ Such sensory inputs modulate ANS activities by regulating the brain activity through deactivation of the cerebrocerebellar limbic systems.³⁴ TENS, however, stimulates the human body through a different mechanism. TENS induces cutaneous stimulation through burst train mode, low pulse frequency, electrical activity.^{22 52} Application of TENS to acupuncture points may induce acupuncture point sensations

Figure 4 Intensity of sensations expressed by C-MMASS index score reported by different groups. Experimental group: transcutaneous electrical nerve stimulation over acupuncture points (acu-TENS) to right LI4 and LI11 points; control group: TENS to bilateral kneecaps; placebo group: TENS applied non-conductive plastic films on the right LI4 and LI11 points. C-MMASS, Modified Massachusetts General Hospital Acupuncture Sensation Scale, Chinese version.

Table 1 Correlation between C-MMASS and the physiological responses

C-MMASS score	MAP	HR	SDNN	LF/HF
Experimental group	−0.16 (p=0.62)	0.08 (p=0.81)	−0.32 (p=0.32)	−0.06 (p=0.85)
Control group	−0.42 (p=0.17)	−0.06 (p=0.86)	−0.36 (p=0.6)	−0.07 (p=0.12)
Placebo group	−0.26 (p=0.41)	0.25 (p=0.15)	0.08 (p=0.81)	0.09 (p=0.76)

Experimental group: acu-TENS to right LI4 and LI11 points; control group: TENS to bilateral kneecaps; placebo group: TENS applied to non-conductive plastic films on the right LI4 and LI11 points.

Acu-TENS, transcutaneous electrical nerve stimulation over acupuncture points; C-MMASS, Modified Massachusetts General Hospital Acupuncture Sensation Scale, Chinese version; HF, High frequency; HR, heart rate; LF, low frequency; MAP, mean arterial blood pressure; SDNN, SD of the NN interval.

through electrical stimulation of the particular acupuncture point.

The results of this current study demonstrate that subjects in the experimental group experienced strong sensations of throbbing, soreness, fullness and distension, similar to the sensations described during needle acupuncture. The C-MMASS score was also reported to be highest in the experimental group, moderate in the control group and minimal in the placebo group. Anatomically, acupuncture points are areas with a high density of nerve endings and lower electrical impedance compared to other tissues.^{53–56} It is possible that the ‘sensation’ experienced by subjects in the experimental and control groups was due to electrical current stimulation. The lower C-MMASS score recorded in the control group may be a consequence of a lower density of nerve endings in the patella region, eliciting weaker sensations compared to stimulation of actual acupuncture points. However, the acupuncture point sensations reported in the control group were different from those reported by the acu-TENS group. The dominant sensation reported by our control group was tingling, numbness and throbbing. This could be sensation of electrical stimulation rather than *de qi*. It is therefore our postulation that the ‘acupuncture point effect’ could at least, in part, account for the high C-MMASS score recorded in our subjects in the experimental group, and not just have arisen as a consequence of current stimulation. However, this study also suggests that the acupuncture point sensations, with descriptive features similar to *de qi*, are not associated with ANS changes induced during acu-TENS.

It is interesting to note that although there should be no electrical stimulation occurring in the placebo group, some subjects still reported mild sensations of tingling, soreness, fullness/distension and throbbing during the intervention. A previous report has also shown that placebo acu-TENS over *Dingchuan* (EX-B1) could increase forced expiratory volume in 1 second (FEV₁), reduce respiratory rate and dyspnoea score in patients with COPD,¹⁷ and reduce airway resistance in healthy individuals after exercise.²⁴ Our speculation is that despite our novel placebo method of impeded electrical current to the skin, tactile sensations over the site of electrode placement were still experienced. It is possible that when one is focused

on a certain body area, one could become aware of spontaneous activity of motoneurons or peripheral sensory afferents.⁵⁷ Furthermore, there is evidence to suggest that complex medical interventions or medical devices have high placebo effects.⁵⁸ The intervention procedures in this study required complex setup and frequent subject–practitioner contacts; therefore, the subjects in the placebo group may have a high expectation that contributed to the slight distinct sensations experienced.

In contrast to other studies which showed that TENS decreased sympathetic tone by providing powerful analgesic effects through the release of opioid peptides in the central nervous system,^{23 59–61} our study demonstrated an increase in sympathetic discharge when acu-TENS was applied to LI4 and LI11. It may be possible that acu-TENS has a bidirectional effect when acupuncture points are stimulated; as our subjects were healthy individuals, they did not require modulation of the parasympathetic tone to induce a calming effect. Another explanation for the increase in sympathetic activities induced is that, as LI4 and LI11 are located in the Large Intestine meridian—believed to be the sympathetic division of the ANS,⁶² it is possible that stimulation of the acupuncture points on the *yang* meridian will increase the sympathetic discharge. Furthermore, it was previously reported that naturally occurring sympathetic action potentials occur in bursts trains.⁶² A burst mode TENS with the intensity at the maximal tolerable level was used in this current study; this may have facilitated sympathetic discharge. This may also explain why when TENS was applied to non-acupuncture points, an increase in sympathetic activities was also demonstrated although to a much lesser extent when compared with acu-TENS.

Limitations of the study

One limitation of our study is the small sample size; however, our data have produced a satisfactory medium effect size and thus we consider our findings to be valid.

If stimulation were applied to bilateral LI4 and LI11, the acupuncture point stimulation effect could be stronger. However, we were mindful to prevent occlusion of the circulation to the left forearm arm by the blood pressure cuff, especially during the inflation

phase, as it may consequently perturb the fidelity of the acu-TENS effects on the acupuncture points.

Lastly, direct measurement of sympathetic activities such as muscle sympathetic activity and evaluation of the plasma catecholamine level⁶³ could help to provide more concrete evidence to demonstrate the association between acu-TENS and sympathetic outflow.

CONCLUSIONS

This is the first study to investigate the relationship between acupuncture point sensations and acu-TENS. This study showed that acupuncture point sensations were experienced during acu-TENS to LI4 and LI11; however, as the intensity of the sensations was not correlated with the physiological responses induced, we conclude that acupuncture point sensations are not associated with the physiological responses evoked during acu-TENS.

Summary points

- ▶ When using transcutaneous electrical nerve stimulation (TENS), the relationship between sensation and physiological response is unknown.
- ▶ We compared TENS at acupuncture points with TENS at a control site and placebo TENS.
- ▶ Real TENS generated physiological responses, but these were not correlated to sensation.

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Contributors All authors were involved in the study design. TWDY and AYMJ were responsible for the conduct of the study and drafting the manuscript. TWDY performed statistical analysis.

Competing interests None.

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