A Clinical Therapeutic Assessment for the Administration of Different Modes of Ultrasounds to Stimulate the Zusanli Acupuncture Point of Hypertension Patients

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Abstract

A clinical trial to assess the therapeutic effect of ultrasonic stimulations on the acupuncture point was carried out. Specifically, ultrasound frequencies of 1 and 3 MHz associated with different duty cycles of the tone burst wave at different acoustic power were employed to stimulate the Zusanli acupuncture point of a subject's right leg. The Ryodoraku values were measured from the 12 primary meridians of both hands to monitor the change of the meridian impedance following the stimulation. Totally 67 healthy volunteers and 60 hypertension patients were evaluated, in which these subjects were administered ultrasonic stimulations for 10 minutes. In addition to measurement of the Ryodoraku value, physiological quantities including blood pressure and pulse rate were also recorded.

Results demonstrated that after ultrasound stimulations on the Zusanli acupoint, the Ryodoraku values measured from both the hypertension patients and healthy subjects were significantly decreased ($p<0.01$). The percentage change of the Ryodoraku value associated with stimulations using a 3 MHz is 8% larger than that of a 1 MHz. The application of a 770 mW ultrasound has an approximately 6% percentage change larger than that of a 380 mW. Moreover, ultrasonic stimulation of a 100% duty cycle developed an approximately 7% percentage change more than that of a 10% duty cycle. In additional, the systolic pressure, diastolic pressure, and pulse of hypertension patients were obviously reduced ($p<0.05$) after the ultrasonic stimulation. The average decrease of these physiological quantities was from 3 to 7%. Therefore, this study verified that the therapeutic effect of ultrasonic stimulations on the acupuncture point, which could be taking into account for further development of an ultrasonic acupuncture system.

***Keywords*:** Ultrasound, Ryodoraku value, Acupuncture, Hypertension

Introduction

The acupuncture, which integrates the concepts of qi (or chi), blood, meridian, and acupuncture points (acupoints), is a commonly applied medical procedure in traditional Chinese medicine (TCM). The practice of acupuncture procedures was performed for more than twenty-five hundreds years ago. The text related to acupuncture was originally written in the Yellow Emperor's Classic of Internal Medicine (Huang Di Nei-jing) in which the practice of the acupuncture is made by manually inserting a needle through the skin into tissues at strategic acupoints on the body and at different depths. When an appropriate treatment of the acupuncture is administered at a specific acupoint, it will bring the therapeutic effects to improve the circulation of qi in the meridian and to balance five elements and the ying-yang quantities of the body [1]. Therefore, following a proper administration of the acupuncture, the body might be able to create its self-regulation and protective capability of resisting diseases. The therapeutic effects of the acupuncture are highly accepted in many Asian nations for quite a long time and however were recognized by the Western societies until 1970s [2], in which the therapeutic effects of the acupuncture are proved to be effective in the treatment of pain and other acute syndromes. Consequently, the procedure and effects of the acupuncture on different organs were discussed [3]. Many researchers began to explore the mechanisms behind the therapeutic effects of the acupuncture, which included Neurohumoral theory, morphogenetic singularity theory, and etc. [4].

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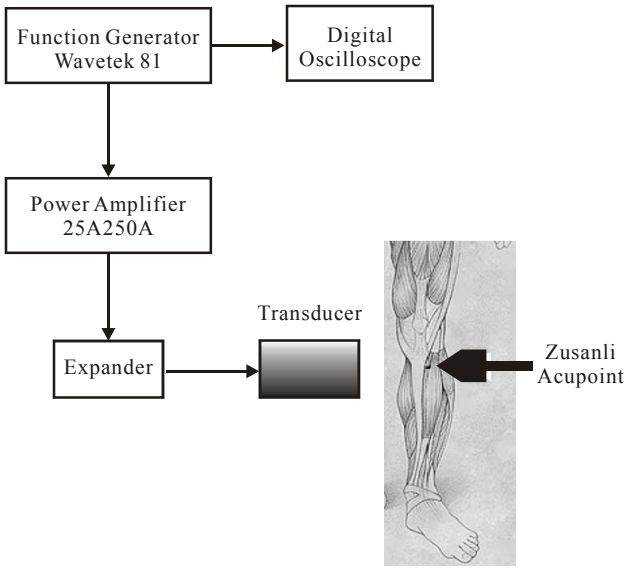

Figure 1. Experimental arrangement for the pilot study.

To date, many researchers are still highly interested in exploring the therapeutic effects of the acupuncture to reduce the pain. A 60 to 75% of patients had relieved their chronic pain after received the acupuncture treatment [5]. It also found that the acupuncture may improve reducing from those headache patients effectively [6]. Moreover, the acupuncture was effective to reduce other pain syndromes in the body [7]. It was further found that the endogenous opioid was secreted during the treatment of the needle acupuncture [8]. Other acupuncture treatments using the electrical stimulation on mice also demonstrated that it is the release of endogenous opioids into the central nervous system to inhibit the perception of the pain [9]. In addition to the relief of pain, the treatment of the acupuncture was commonly applied to be an alternative medicine that is used in almost all departments in a hospital.

The needle acupuncture is a typical and effective modality in TCM. However, the insertion of the needle to a specific meridian point at a certain depth required many training and experiences. Though the needle acupuncture is considered to be only a little invasive procedure, many patients are still fear of pain during the insertion of the needle and worry about the infection possibility. For these reasons, many modalities including those applied electrical, optical, and mechanical pressure means to disturb the acupuncture points, were developed [10]. The transcutaneous electro-nerve stimulator (TENS) applying a short electrical impulse is a device commonly to be applied to relieve pain. Furthermore, ultrasound is a mechanical wave that is free of irradiation. As a proper energy of the ultrasonic wave was propagated in the biological tissues, the ultrasound only produces compression and relaxation pressures for a molecule or a particle in the medium. Therefore, the relaxation process of a particle at its original location might cause a friction interacted with the surrounding tissues to generate the thermal effect [11]. Depending on the ultrasonic pressure, the propagation of ultrasound in the tissues could also generate other non-thermal effects, including cavitation, acoustic radiation force, and acoustic streaming [11]. Nevertheless, the power, modes of operation, and related electrical techniques for an ultrasound system could be well designed and developed to date. Therefore, the ultrasound stimulation was attempted to be directly administered into the acupuncture points, that led to promising therapeutic results to many disease [12,13]. Another study compared the therapeutic effects of using alternative modalities included ultrasonic, impulse electricity, laser, and microwave acupunctures to treat 126 mice, they found that all of these modalities were effective to the pain relief [14]. Especially, the ultrasonic acupuncture obtained best therapeutic effect among others, which was postulated due to that ultrasound has better capability of penetrating energy into the body than laser or electrical impulse. Moreover, the ultrasonic transducer could be fabricated to allow acoustic energy focusing at a certain length. Results of these studies shed a light on that ultrasound could be an appropriate alternative modality to the traditional needle acupuncture.

To extensively explore the therapeutic effects of ultrasonic stimulations on acupuncture points, we have arranged clinical trials on hypertension patients using different modes of ultrasonic stimulations including frequency, power, and duty cycle. The therapeutic effect was assessed from results of measurements including the Ryodoraku value from the 12 primary meridians in patients' hands, blood pressure, and the pulse rate. Apparently, changes of those measured quantities from patients between prior and posterior treatment of ultrasonic stimulations were observed. These results demonstrate the feasibility for further development of ultrasonic acupuncture systems.

Materials and method

The pilot studies to explore the therapeutic effect of the ultrasonic acupuncture was arranged using a stimulation system, given in Figure 1 which includes a pulse function generator (Wavetek Model 81), a power amplifier (Amplifier Research 25A250A), and transducers (Parametrics). The 1 and 5 MHz tone bursts of both 10 and 60% duty cycles within 1 ms pulse repetition period were adjusted using the pulse function generator. Different electrical power of tone bursts were raised by the power amplifier before they were applied to excite the transducers to produce the average ultrasonic power of 250 mW measured by an ultrasonic power meter (UPM-DT-1, Ohmic instruments). Totally, 48 healthy volunteers, aged between 20 and 25, were evaluated by administering different ultrasonic stimulations at the Zusanli (ST36) acupoint of their right legs. The response associated with the ultrasonic stimulation was then quantified by the Ryodoraku values of acupoints, measured by a Ryodoraku Health Monitor (SD802L, Skylark Device & Systems Co.), from the 12 primary meridians in both hands, which including the acupuncture points of Taiyuan (LU09), Dalin (PC07), Shenmen (HT07), Yanggu (SI05), Yangchi (TH04), and Yangxi (LI05). To reduce effect accounting for those environmental and psychological factors, the volunteers were asked to keep relaxing and take a rest for 15 minutes before the following testing and

Table 1. Grouping for the pilot study from healthy volunteers

Frequency / duty cycle / power	Numbers of subjects
Control group (False stimulation)	8
1MHz/60%/250mW	10
1MHz/10%/250mW	10
5MHz/60%/250mW	10
5MHz/10%/250mW	10

Table 2. Grouping for clinical trials from healthy volunteers

Frequency / duty cycle / power	Numbers of subjects
Control group (False stimulation)	8
1MHz/10%/380mW	11
1MHz/100%/380mW	12
1MHz/100%/770mW	12
3MHz/10%/380mW	12
3MHz/10%/770mW	12

Table 3. Grouping for clinical trials from hypertension patients

Frequency / duty cycle / power	Numbers of subjects
Control group (False stimulation)	8
1MHz/10%/380mW	8
1MHz/100%/380mW	8
1MHz/100%/770mW	10
3MHz/10%/380mW	11
3MHz/10%/770mW	15

measurements. Subsequently, Ryodoraku values of the acupoints associated with both hands from each volunteer were measured before the administration of ultrasonic exposure. To better investigate the effects of acupuncture points associated with different modes of ultrasonic stimulations, 48 volunteers were grouped into five categories, listed in Table 1, in which volunteers in the controlled group were given by the false stimulations. Consequently, the Zusanli acupoint in the right leg of each volunteer was administered by ultrasonic stimulation for 10 minutes in which the period of stimulation is in accordance with results of our previous works [15]. After the stimulation, the Ryodoraku values of the acupoints from volunteers were measured. The variation of Ryodoraku values corresponding to different modes of ultrasound stimulation is then assessed to investigate the therapeutic effects of the ultrasonic stimulation. To evaluate the baseline Ryodoraku values of the volunteers, the false stimulation was arranged following the same stimulating procedure as other experimental groups except that the ultrasonic energy was turned off without noticing the volunteers to be tested.

Clinical therapeutic assessment for the administration of different ultrasounds to acupuncture points was explored from hypertension patients in the department of Acupuncture at Taipei City Hospital of Traditional Chinese Medicine (TCHTCM). Due to the arrangement of ultrasonic stimulation system used in the pilot study is not appropriate for clinical applications, a commercial available ultrasonic therapy device (SD-956, Skylark Device & Systems Co.), which is portable and was modified to be able to flexibly adjust the energy and modes of operation, was applied in the following clinical studies. The ultrasonic therapy device equipped with two 1 and 3 MHz transducers with the size of 4 cm^2. The power, 380 and 770 mW, of the ultrasonic therapy device associated with different frequencies and duty cycles were measured by the ultrasonic power meter. Consequently, the therapeutic effect associated with different ultrasonic stimulations, including dependency on ultrasonic frequency, duty cycle, and power, was evaluated from 67 healthy volunteers, age between 20 and 25 years old, and 60 hypertension patients, age between 38 and 78 years old, screened by the TCHTCM. Those healthy volunteers and hypertension patients without taking any drugs or receiving other treatments before administration of ultrasound stimulations were grouped into six categories, arranged in Table 2 and 3, respectively, associated different modes of treatments. The protocol for the clinical trials is the same as that of the pilot study. Moreover, to better evaluate the therapeutic effects of ultrasonic stimulations on the Zusanli acupoint, the blood pressure and pulse rate in addition to the Ryodoraku value were also measured before and after the treatments. To better compare those values of measurement, the percentage change, given in equation (1), of the Ryodoraku value, blood pressure, and pulse rate were obtained by normalizing the measured value associated with posterior treatments to that of prior treatments.

$$\frac{(value)_{posterior-treatment}}{(value)_{prior-treatment}} \times 100\% \quad (1)$$

Results and Discussion

Results obtained from the pilot study using the arranged system in Figure 1 were given in Table 4. It demonstrated that after administration of low power ultrasounds at 1 and 5 MHz of different duty cycles to the Zusanli acupuncture points in the right leg, percentage changes of the Ryodoraku value measured from 12 primary meridians in both hands tend to be decreased significantly with $P<0.01$. However, the Ryodoraku values associated with those without administration of ultrasound stimulations in the control group did not vary much. It showed that the psychological influence due to the false stimulation of ultrasound did not apparently affect the circulation of qi in the meridian largely. It can be further validated that it is the administration of ultrasound on the acupuncture points that leads to the change of the Ryodoraku value before and after the treatments.

By applying the ultrasonic stimulations emitted from the

Table 4. Percentage changes of the Ryodoraku values from the 12 primary meridians of both hands for the pilot study from healthy volunteers

Stimulation condition \ Acupoint		Taiyuan	Dalin	Shenmen	Yanggu	Yangchi	Yangxi
Control group (False stimulation)	Left hand	98±6	99±8	100±3	100±9	104±11	102±7
	Right hand	100±8	96±7	95±7	98±6	100±6	99±10
1MHz/60%/250mW	Left hand	73±11	73±8	70±9	66±18	75±11	76±10
	Right hand	66±17	67±15	69±9	73±10	80±9	70±11
1MHz/10%/250mW	Left hand	85±8	79±11	87±9	81±9	84±6	76±16
	Right hand	86±9	86±8	84±10	84±8	84±9	83±11
5MHz/60%/250mW	Left hand	64±19	67±19	65±16	68±12	68±17	65±15
	Right hand	70±15	71±18	63±14	56±17	67±12	63±11
5MHz/10%/250mW	Left hand	70±20	72±18	70±14	75±13	75±13	81±8
	Right hand	78±14	80±11	73±20	84±10	81±10	81±18

Table 5. Percentage changes of the Ryodoraku values from the 12 primary meridians of both hands for clinical trials from healthy volunteers

Stimulation condition \ Acupoint		Taiyuan	Dalin	Shenmen	Yanggu	Yangchi	Yangxi
Control group (False stimulation)	Left hand	98±6	99±8	100±3	100±9	104±11	102±7
	Right hand	100±8	96±7	95±7	98±6	100±6	99±10
1MHz/10%/380mW	Left hand	84±7	78±9	75±8	76±8	86±10	84±9
	Right hand	81±9	79±7	74±9	85±11	89±8	80±9
1MHz/100%/380mW	Left hand	79±8	77±6	76±8	72±8	81±4	74±9
	Right hand	74±8	72±10	80±7	77±10	74±7	75±6
1MHz/100%/770mW	Left hand	69±10	67±7	70±9	71±8	67±7	74±11
	Right hand	72±8	66±7	74±10	70±9	67±7	70±10
3MHz/10%/380mW	Left hand	75±7	75±6	74±6	76±6	75±8	77±5
	Right hand	76±10	76±9	78±8	74±6	72±6	76±5
3MHz/10%/770mW	Left hand	70±7	71±7	71±7	73±8	70±8	69±7
	Right hand	69±10	73±8	73±8	72±8	69±6	66±9

ultrasound therapy device, the percentage changes of the Ryodoraku values of the 12 primary meridians in both hands from the healthy volunteers, given in Table 5, and the hypertension patients, shown in Table 6, are all decreasing significantly with $P<0.01$. On the other hand, the changes from those subjects received false stimulations were not apparent. The variation tendency of results obtained from these clinical trials agrees well with those in the pilot study. The degree of percentage changes according to Tables 5 and 6 indicated that it decreases largely corresponding to the administration of ultrasound of higher frequency, more duty cycle, and larger power. Furthermore, the average percentage change of the Ryodoraku value measured from the 12 primary meridians of both healthy volunteers and hypertension patients in Figures 2 and 3, respectively, clearly showed that administration of larger ultrasonic power tends to decrease largely the Ryodoraku value. Furthermore, the decrease of the Ryodoraku value corresponds to the decrease of both the blood pressure and pulse rate, indicated in Table 7. The statistical analysis by the Paired t-test moreover demonstrated that the percentage change of the systolic pressure tends to decrease significantly ($P<0.05$) corresponding to all different modes of ultrasonic stimulations. The decrease of the diastolic pressure followed by the stimulation conditions of 1MHz/100%/380mW, 1MHz/100%/770mW, and 3MHz/10%/770mW, in which P value is smaller than 0.01. Furthermore, administration of the ultrasounds of 1MHz/10%/380mW, 1MHz/100%/380mW, 3MHz/10%/380mW, and 3MHz/10%/770mW may decrease the pulse rate in which P value is smaller than 0.05. The therapeutic effects to lower the Ryodoraku, blood pressure, and

Table 6. Percentage changes of the Ryodoraku values from the 12 primary meridians of both hands for clinical trials study from hypertension patients

Stimulation condition \ Acupoint		Taiyuan	Dalin	Shenmen	Yanggu	Yangchi	Yangxi
Control group (False stimulation)	Left hand	100±4	100±4	96±5	103±7	100±4	99±5
	Right hand	97±3	96±4	99±6	97±9	102±7	101±6
1MHz/10%/380mW	Left hand	71±8	70±5	71±5	70±16	77±15	76±14
	Right hand	74±4	72±7	71±5	87±11	87±5	75±5
1MHz/100%/380mW	Left hand	70±7	61±12	68±11	63±18	69±18	65±18
	Right hand	73±7	65±17	70±11	60±15	81±6	72±13
1MHz/100%/770mW	Left hand	61±12	59±15	60±11	64±11	66±9	58±12
	Right hand	60±12	55±12	66±11	63±7	65±9	67±6
3MHz/10%/380mW	Left hand	69±9	67±10	67±6	66±8	64±11	67±10
	Right hand	69±8	68±14	67±12	67±6	68±10	68±7
3MHz/10%/770mW	Left hand	62±7	64±6	63±8	63±7	61±7	64±8
	Right hand	62±8	61±9	64±8	61±9	64±6	63±8

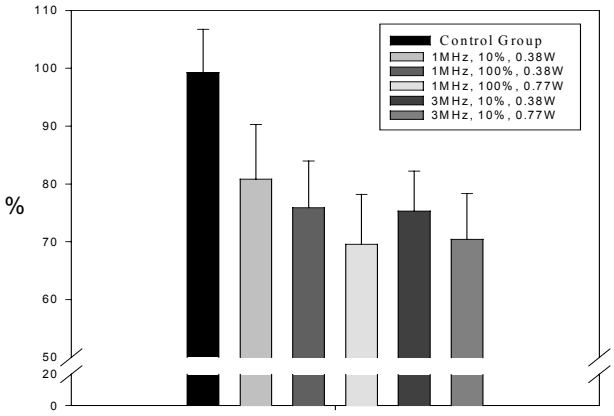

Figure 2. Percentage changes of the Ryodoraku values for healthy volunteers prior and posterior to ultrasound stimulations of different frequencies, duty cycles, and power.

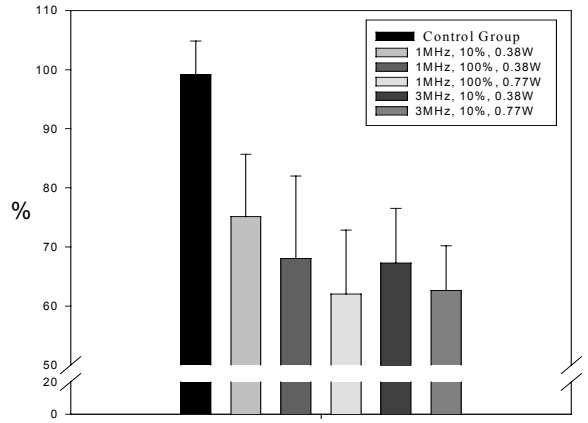

Figure 3. Percentage changes of the Ryodoraku values for hypertension patients prior and posterior to ultrasound stimulations of different frequencies, duty cycles, and power.

Table 7. Percentage changes of the blood pressure and pulse rate for clinical trials study from hypertension patients, in which * denotes $P<0.05$ and ** is for $P<0.01$.

Stimulation condition	Systolic Pressure	Diastolic Pressure	Pulse Rate
Control group (False stimulation)	100±1	101±7	103±3*
1MHz/10%/380mW	95±5*	96±7	95±4**
1MHz/100%/380mW	93±5**	96±2**	94±7*
1MHz/100%/770mW	94±5**	93±5**	96±7
3MHz/10%/380mW	94±3**	97±6	95±6*
3MHz/10%/770mW	94±2**	95±2**	94±2**

pulse rate of the hypertension patients can be easily comprehended in Figure 4. Again, there is no apparent percentage change of all measured quantities found in the control group.

The therapeutic effect is further assessed from results after different modes of ultrasonic stimulations at the Zusanli acupoint. Table 8 listed a comparison of percentage changes of measured quantities between the healthy volunteers and hypertension patients following different frequencies of ultrasonic stimulations, includes 1MHz/10%/ 380mW and 3MHz/10%/380mW. The stimulation by higher frequency ultrasound tends to reduce those measured physiological quantities largely. Table 9 is a list to compare the therapeutic effect by ultrasonic stimulations at different duty cycles, includes 1MHz/10%/380mW and 3MHz/100%/380mW. Apparently, larger duty cycle corresponding to more

Table 8. Percentage changes of the Ryodoraku value, blood pressure, and pulse rate between healthy volunteers and hypertension patients dependent on 1 and 3 MHz ultrasound, in which * denotes P<0.05 and ** is for P<0.01.

Subjects	Healthy volunteers	Hypertension patients			
Stimulation condition	Average Ryodoraku value	Average Ryodoraku value	Systolic Pressure	Diastolic Pressure	Pulse Rate
1MHz/10%/380mW	81±9**	75±11**	95±5*	96±7	95±4**
3MHz/10%/380mW	75±7**	67±9**	94±3**	97±6	95±6*

Table 9. Percentage changes of the Ryodoraku value, blood pressure, and pulse rate between healthy volunteers and hypertension patients dependent on different duty cycles, in which * denotes P<0.05 and ** is for P<0.01.

Subjects	Healthy volunteers	Hypertension patients			
Stimulation condition	Average Ryodoraku value	Average Ryodoraku value	Systolic Pressure	Diastolic Pressure	Pulse Rate
1MHz/10%/380mW	81±9**	75±11**	95±5*	96±7	95±4**
3MHz/10%/380mW	80±8**	68±14**	93±5**	96±2**	94±7*

Table 10. Percentage changes of the Ryodoraku value, blood pressure, and pulse rate between healthy volunteers and hypertension patients dependent on different ultrasonic power, in which * denotes P<0.05 and ** is for P<0.01.

Subjects	Healthy volunteers	Hypertension patients			
Stimulation condition	Average Ryodoraku value	Average Ryodoraku value	Systolic Pressure	Diastolic Pressure	Pulse Rate
1MHz/100%/380mW	80±8**	68±14**	93±5**	96±2**	94±7*
1MHz/100%/770mW	70±9**	62±11**	94±5**	93±5**	96±7
3MHz/10%/380mW	75±7**	67±9**	94±3**	97±6	95±6*
3MHz/10%/770mW	71±8**	63±8**	94±2**	95±2**	94±2**

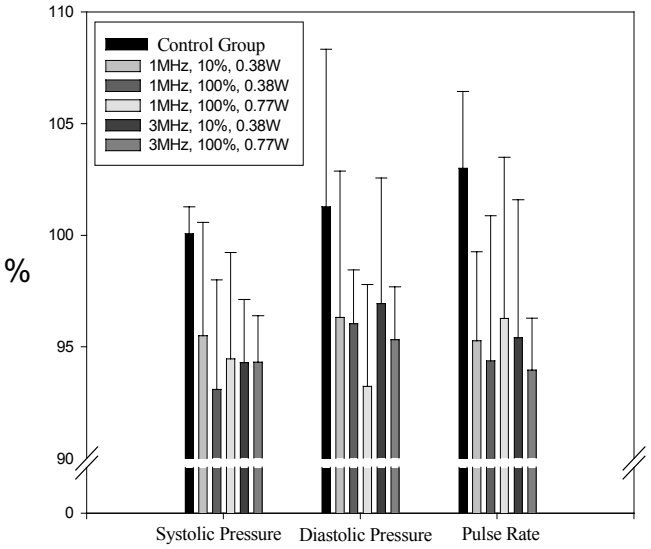

Figure 4. Percentage changes of blood pressure and pulse rate for hypertension patients prior and posterior to ultrasound stimulations of different frequencies, duty cycles, and power.

stimulations produce higher percentage changes of the physiological quantities. The change due to ultrasonic stimulations of different powers can be comprehended in Table 10, which include 1MHz/100%/380mW, 1MHz/100%/770mW, 3MHz/10%/380mW, and 3MHz/10%/ 770mW. It demonstrated the ultrasonic stimulation of a higher power of 770mW affects the percentage change of the physiological quantities larger than that of 380mW. Results of these studies suggest that the increase of duty cycle, frequency, and ultrasonic power has better therapeutic effects on the decrease the blood pressure of hypertension patients.

Previous studies showed that the variations of the skin impedance and the cardiovascular conditions are regulated by the auto-regulation nervous system [16]. The blood pressure and pulse rate are decreased accordingly. According to the neurophysiological points of view, the expansion of blood vessels, reduction of blood pressure, and decrease of the heart beat are all attributed by the inhibition of the symphonic nerve system. Thus, the decrease of the Ryodoraku value corresponding to the increase of the skin impedance posterior the administration of ultrasonic stimulations is assumed to be associated with the inhibition of the symphonic nerve. It is

then postulated that the ultrasonic stimulation on the acupuncture points might indirectly inhibit the symphonic nerve system.

Conclusions

Both results obtained from the pilot studies and clinical trials indicated that the Ryodoraku value, blood pressure, and pulse rate tend to be reduced after the administration of ultrasonic stimulations at the Zusanli acupoint. For both healthy volunteers and hypertension patients, the tendency of the decrease of the Ryodoraku values measured from the 12 primary meridians of both hands is significantly, with P value smaller than 0.01. After administration of ultrasonic stimulations, the decrease of the Ryodoraku value, blood pressure, and pulse rate for hypertension patients was found to be larger than those of healthy volunteers, with P value smaller than 0.05. In comparison with the therapeutic effects associated with different modes of ultrasonic stimulations, results demonstrated that the degree of decrease of those physiological quantities depends on the frequency, duty cycle, and acoustic power of the ultrasonic stimulations. It concludes that higher frequency, more duty cycle, and larger acoustic power of ultrasonic stimulation would result a larger change for the physiological quantities. However, the optimal results of ultrasonic stimulations associated with the combination of different ultrasonic modes remain unclear. This study verifies that the administration of ultrasonic stimulation on the acupuncture point may be another alternative ways to affect the circulation of qi in the meridian, in which these results furthermore provide a basis for the future development of the ultrasonic acupuncture system.

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