Journal of Traditional and Complementary Medicine 13 (2023) 568–574

Contents lists available at ScienceDirect

Journal of Traditional and Complementary Medicine

journal homepage: http://www.elsevier.com/locate/jtcme

Harmonic effects of sham acupuncture at Tsu San Li (St-36) in the radial pulse wave

Kuang-Chieh Hsueh [c, 1], Jenq-Haur Wang [d, 1], Chi-Ying Chen [a], Jin-Hua Chen [e, f, g], George Hsiao [a], Yu-Cheng Kuo [a, b, *]

[a] Department of Pharmacology, School of Medicine, College of Medicine, Taipei Medical University, Taipei, Taiwan
[b] School of Post-Baccalaureate Chinese Medicine, College of Chinese Medicine, China Medical University, Taichung, Taiwan
[c] Department of Family Medicine, Kaohsiung Veterans General Hospital, Kaohsiung, Taiwan
[d] Department of Computer Science and Information Engineering, National Taipei University of Technology, Taipei, Taiwan
[e] Graduate Institute of Data Science, College of Management, Taipei Medical University, Taipei, Taiwan
[f] Statistics Center/Institutional Research Center, Office of Data Science, Taipei Medical University, Taipei, Taiwan
[g] Biostatistics Center, Wan Fang Hospital, Taipei Medical University, Taipei, Taiwan

ARTICLE INFO

Article history:
Received 20 June 2021
Received in revised form
27 June 2023
Accepted 6 July 2023
Available online 15 July 2023

Keywords:
Arterial pulse
Fourier transformation
Harmonics
Meridian
Sham acupuncture

ABSTRACT

Background and aim: Acupuncture has been criticized as a theatrical placebo for the sham effect. Unfortunately, sham tests used in control groups in acupuncture studies have always ignored the underlying biophysical factors, including resonance involved in acupuncture points and meridians.
Experimental procedure: In this study, the effects of sham acupuncture at Tsu San Li (St-36) were examined by analyzing noninvasive 30-sec. recordings of the radial arterial pulses for 3 groups of patients treated with different probes (blunt, sharp, and patch) on the superficial skin of the acupuncture point. The 3 groups were then treated with the sharp probe for 3 different periods (16, 30, and 50 s). Then we compared the harmonics of the radial arterial pulse after Fourier transformation before and after the treatment.
Results: Our results indicated that different probes have effects similar to needle insertion at Tsu San Li. Meanwhile, the harmonic effect of the sharp probe strengthened as time increased.
Conclusions: This study revealed that the meridian effect of sham testing from mechanical stimulation, even from simple touch, on an acupuncture point, should not be overlooked. Thus, even simple touch can be added to electrical or laser acupuncture.

1. Introduction

Acupuncture has been criticized as a theatrical placebo[1] for its sham effect.[2] Sham acupuncture was an inert control intervention in clinical trials of acupuncture. It was supposed to be similar to placebo pills in pharmacological studies or inert-sham treatments in technique or device studies. However, these sham tests designed as the control group in acupuncture studies have always ignored the biophysical factors, resonance, in acupuncture points[3,4] and thus have led to confusing results. Our previous studies revealed that specific frequency effects are found at the acupuncture points on the Fourier components of the radial arterial pulse. The nearby non-acupuncture point also has similar but insignificant effects as the acupuncture point.[5]

Meridians are the groups of acupuncture points, and can be measured from the harmonics of the arterial pulse,[6] and thus physicians who practice traditional Chinese Medicine use the pulse to diagnose disease, to evaluate patients' physical conditions, and even to predict death. The importance of the information within arterial pulse waves has long been recognized in clinical medicine.[7] Arterial pulse wave analysis has been widely used in clinical practice, for example, in cases of hypertension, cardiac failure, and

* Corresponding author. Department of Pharmacology, School of Medicine, College of Medicine, Taipei Medical University, 2F,No. 12, St. Tongshan, Taipei, 100, Taiwan.
E-mail address: yuchengkuo@tmu.edu.tw (Y.-C. Kuo).
Peer review under responsibility of The Center for Food and Biomolecules, National Taiwan University.
[1] These first authors contributed equally to this work.

https://doi.org/10.1016/j.jtcme.2023.07.003

ageing.[8] Our previous studies revealed that the pulse spectrum of the radial arterial pulse could be highly correlated among patients with abnormal liver function.[9,10] The specific Fourier components in the pulse provide more physiologic information than do systolic and diastolic blood pressure measurements during the process of dying.[11,12] In addition, pulse spectrum analysis can be used to differentiate atopic dermatitis with the third harmonic of the radial pulse,[13] and the fourth harmonic of the radial pulse wave has been shown to predict adverse cardiac events in asymptomatic patients with type 2 diabetes.[14] Recently, pulse spectrum analysis has facilitated the diagnosis of coronary artery disease.[15] We can qualitatively and quantitatively gain physiologic or pathologic information by measuring the harmonics of blood pressure because the resonance in the cardiovascular system is highly efficient for hemodynamic evolution design.[16] Each organ and its related meridian are in resonance with a specific Fourier component of pressure waves.[17]

Meridians present in harmonics are the biophysical design for resonance, showing that the heart drives the cardiovascular system with less than 2 W. This tiny factor, including acupuncture, moxibustion, massage, bian stone, and acupressure, which change resonance, will redistribute the hemodynamics of the cardiovascular system and then appear in the harmonics of the arterial pulse. If we do not consider resonance, meridian, and acupuncture, we will miss the effect when designing a sham test.

Sham acupuncture is a control intervention used in acupuncture clinical trials.[18,19] It is similar to placebo pills in pharmacological studies or inert-sham treatments in technique or device studies.[18] The concept behind sham acupuncture is that it appears identical to acupuncture but lacks any physiological effects. However, there is controversy regarding its validity as a control intervention.[20] Some evidence suggests that sham acupuncture might have physiological effects,[21] adding to the debate on its adequacy as a control intervention.[18,22] To avoid these concerns, many studies used non-traditional acupuncture methods such as without puncturing the skin as the control group. Our primary hypothesis of this study is also based on the experiment of laser acupuncture, and the laser pointer without laser dose was as a control group of sham acupuncture in this study to represent the sham test.

In this study, we used laser acupuncture as a test group, placing three different standard probes on the Zu-San-Li acupoint and comparing the effects before and after sham acupuncture. This approach allows us to examine the effectiveness of sham acupuncture, and the results showed that the sham effect cannot be ignored. Thus, we examined the effect of sham acupuncture at Tsu San Li (St-36) by noninvasively recording the radial arterial pulses for patients treated with different types of probes (blunt, sharp, and patch) and no laser-dose-power on the superficial skin of the acupuncture point for 30 s. A second group of patients was tested with a sharp probe for differing amounts of time (16, 30, and 50 s). We then compared the harmonics of the radial arterial pulse after the Fourier transformation before and after the treatment. We hypothesized that harmonics could be physiologic indicators corresponding with the resonance on the tiny change of acupuncture point, and could explain the sham effect found in clinical studies.

2. Material and methods

For the subjects, data from 199 patients (male 82 and female 117) who visited the outpatient department (OPD) were recorded during two years study. Patients with irregular heart rhythms, arterial catheters placed on the left wrist, or patients with sensitive skin were excluded. They were not allowed to have any alcoholic and caffeinated beverages, and they were food restricted at least 1 h before experiment. A half hour rest was routinely required before the test. Room temperature was kept between 24 °C to 26 °C. All patients gave written permission to participate in the study, and we also had approval from the responsible ethical committee (CMUH107-REC2-145).

For experimental procedure, noninvasive pulse pressures of the left radical arteries were obtained at each OPD visit with a pressure transducer (PSL-200GL, Kyowa Electronic Instrument Co., Ltd., Japan). The device was attached to the patient's skin with Scotch™ brand tape, along with an adjustable belt with a small button to give suitable pressure on the transducer. To ensure accurate measurements, we aimed to identify the position near the Guan point of wrist with the highest pulse amplitude. We attached the sensor at this position to obtain reliable measurements. Our criterion for a successful measurement was to capture the pulse with the highest amplitude.[3,17] Most studies[23–25] have explored the meridian effect on human blood pressure harmonics by focusing on the left hand. The left-hand radial artery is often chosen due to its proximity to the heart and the larger waveform it produces, which facilitates data acquisition and analysis. We examined the effect of sham acupuncture at Tsu San Li (St-36) for 30 s in a group of patients (blunt, n = 37; sharp, n = 38; and patch, n = 38) treated with different-diameter probes (blunt, 4 mm; sharp, 2 mm; and patch, 8 mm; (RJ-LASER (LASERPEN®; Reimers & Janssen, Germany), which are frequently used in laser acupuncture on the superficial skin of the acupuncture point Tsu San Li (St-36) in the left side. We performed the same procedure in a second group of patients, using the sharp probe for different periods (take at 16 s, n = 42; 30 s, n = 38; and 50 s, n = 44). The pressure transducer was not removed during the entire measuring process. Because of the comparison of the meridian effects before and after the placement of the standard probe, the measurement before placement was taken as a physiological baseline. We then compared the harmonics of the radial arterial pulse after Fourier transformation before and after treatment.

For data analyzing of the radial arterial pulse, the output of the pressure transducer was connected to an IBM PC for analysis via an A/D converter with a sampling rate of 500 data points/sec. We measured the radial arterial pulse data 30 s before the probe was placed. After the specific treatment duration, we collected data again starting at 0 s while the probe was just removed. We then compared the harmonics of the radial arterial pulse by taking Fourier transformation. Here the pulse spectrum was analyzed with the Fourier transformation using T (period) = 1 pulse time.[16] All the analysis codes were developed using Matlab (MathWorks, 2022b, USA). After Fourier transformation, we analyzed the first 10 harmonic magnitudes and phases. Each measurement contained 4 to 15 pulses delivered within 6 s. The mean value of the magnitude and phase of each harmonic was then calculated. Finally, we compared the magnitude and phase of the first 10 harmonics within each group. The percent difference[5] of the harmonic proportions of harmonic n between the test period T_i and the control period T_0, by defining $[H_n(T_i) - H_n(T_0)]/H_n(T_0)$, where $H_n(T_0) = A_n(T_0)/A_0(T_0)$ is the harmonic proportion of the nth harmonic at the control period, $H_n(T_i) = A_n(T_i)/A_0(T_i)$ is the harmonic proportion of the nth harmonic at the test period, and $A_n(T)$ is the amplitude of the nth harmonic; $A_0(T)$ is the direct-current value of the pulse spectrum. Descriptive and statistical analyses of the harmonic magnitudes and phase data were performed using the SigmaPlot™ 14.0 software package (Systat, San Jose CA, USA). In order to obtain a comprehensive understanding of the potential dose-dependent relationship effects, we employed linear regression analysis. This statistical method allowed us to examine the quantitative relationship and enabled us to investigate the potential impact of different treatment durations on the measured harmonic outcomes. Then the paired *t*-test was used for statistical

verification. The baseline wave before stimulation was established by measuring the harmonics of the radial artery pulse 30 s before placing the standard probe.

3. Results

During the study, we recorded the pulse pressure of the left hands of the 199 patients. The paired *t*-test was employed for statistical analysis. The baseline for comparison before stimulation was established by measuring the pulse 30 s prior to placing the standard probe. This approach allowed for the evaluation of any changes or effects resulting from the subsequent stimulation. The result of the sham acupuncture at Tsu San Li (St-36) for the 3 groups of patients treated with different probes that are commonly used in laser acupuncture (blunt, n = 37; sharp, n = 38; and patch, n = 38) on the superficial skin of the acupuncture point for 30 s can be seen in Figs. 1 and 2.

Measuring magnitude, we found that the sharp probes were significantly decreased in the first harmonics (paired *t*-test, $P < 0.01$; Fig. 1a), and significantly increased in the ninth harmonics (paired *t*-test, $P < 0.05$; Fig. 1b). However, the blunt and patch probes were significantly increased in the third, fifth, sixth, and ninth harmonics. Meanwhile, the blunt probe produced increases in the fourth, seventh, eighth and tenth harmonics. After paired *t*-tests were performed, all these differences were significant (paired *t*-test, $P < 0.05$; Fig. 1a and b).

For the phase, we found that the sharp probes were significantly increased in the tenth harmonics (paired *t*-test, $P < 0.05$; Fig. 2b). However, the blunt probes were significantly decreased in the second, third, and fifth harmonics (paired *t*-test, $P < 0.05$; Fig. 2a and b) and the patch probes were significantly decreased in the second, third, fourth, and fifth harmonics (paired *t*-test, $P < 0.05$; Fig. 2a and b).

When we compared the 3 groups who received the sharp probe for different periods (16 s, n = 42; 30 s, n = 38; and 50 s, n = 44), in the group receiving the probe for 16 s, the first and second harmonics were significantly decreased (paired *t*-test, $P < 0.01$; Fig. 3a), and the ninth harmonic was significantly increased (paired *t*-test, $P < 0.05$; 3B). In the group that received 30-sec. probes, the first harmonic was significantly decreased (paired *t*-test, $P < 0.01$; Fig. 3a), and the ninth harmonic was significantly increased (paired *t*-test, $P < 0.05$; Fig. 3b). In the group that received 50-sec. probes, the first harmonic was significantly decreased (paired *t*-test, $P < 0.05$; Fig. 3a), and the fifth, sixth, and seventh harmonics were significantly increased (paired *t*-test, $P < 0.05$; Fig. 3b). Please note that the amplitudes of the second to seventh harmonics exhibited increasing trends with longer stimulation periods. However, the eighth harmonic displayed a negative trend, which requires further confirmation through additional tests since the statistics were not significant. On the other hand, the ninth and tenth harmonics showed enhancement within the 30-s period.

Among the group who received the sharp probe for 16 s, the first harmonic was significantly increased (paired *t*-test, $P < 0.05$; Fig. 4a), and the fourth harmonic was significantly decreased (paired *t*-test, $P < 0.05$; Fig. 4a). In the group that received the sharp probe for 30 s, the tenth harmonic was significantly increased (paired *t*-test, $P < 0.01$; Fig. 4b), while there was no harmonic with significant change in the group that received 50 s.

When we examined the details of the magnitude in the 3 groups who received sharp probes, the effects were strengthened in the first 7 harmonics as the time was increased. To analyze the increasing trend and explore the dose-dependent relationship effects, we conducted linear regression analysis to examine the quantitative relationship between the duration of the probe placed on the acupoint and the corresponding harmonic effect. The results revealed significant increases in the second and third harmonics as shown in Fig. 5a and b. The intercept values for the second and third harmonics were −1.709 and −1.935, with slopes of 0.703 and 0.636, respectively (*t*-test, P < 0.05; Table 1). In particular, the first harmonic showed significance in the harmonic analysis, but its trend was not evident in Fig. 3a. To further investigate, we converted the first harmonic back to absolute values by multiplying it with the direct-current value of the pulse. The results revealed a decreased trend, as shown in Fig. 6. The linear regression analysis showed an intercept of 32.868 and a slope of −21.809 for the first harmonic (*t*-test, P < 0.05; Table 2).

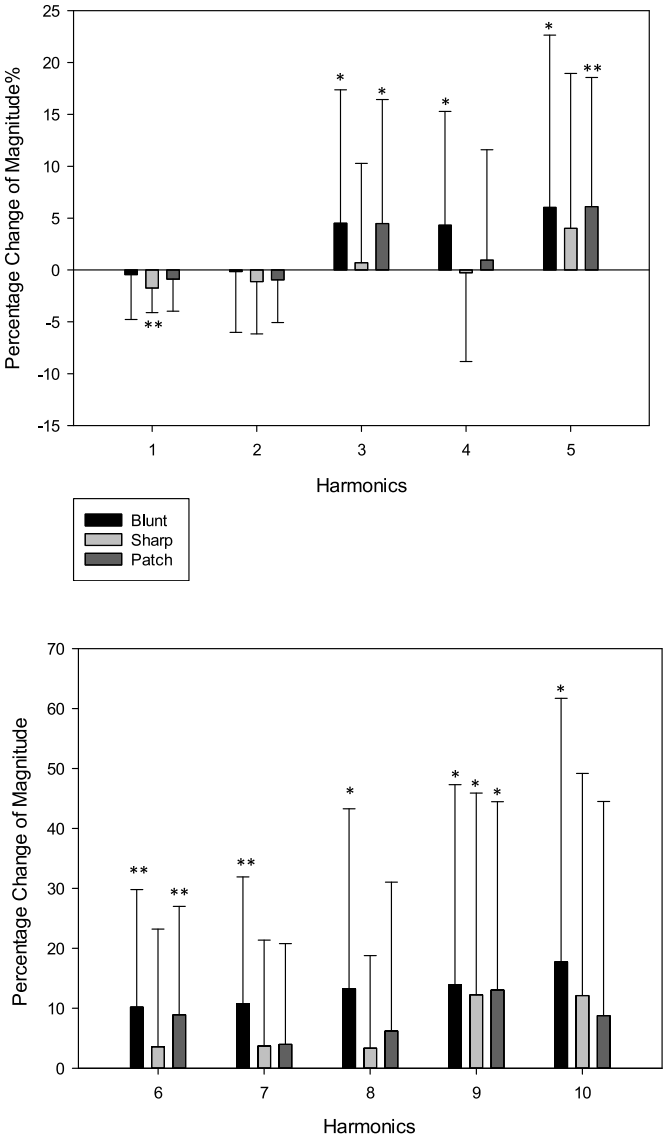

Fig. 1. a. Low (first to fifth) harmonic magnitude difference after the treatment with 3 different probes in the pulse pressure wave of the left radial artery. Fig. 1b. High (sixth to tenth) harmonic magnitude difference after the treatment with 3 different probes in the pulse pressure wave of the left radial artery.
Key: Values are mean ± SE. The black bars represent the blunt probe (n = 37); the white bars represent the sharp probe (n = 38); and the gray bars represent the patch probe (n = 38). The x-axis represents the harmonic numbers and the y-axis represents the magnitude of harmonics (*$P < 0.05$ vs. before treatment; **$P < 0.01$ vs. before treatment.).

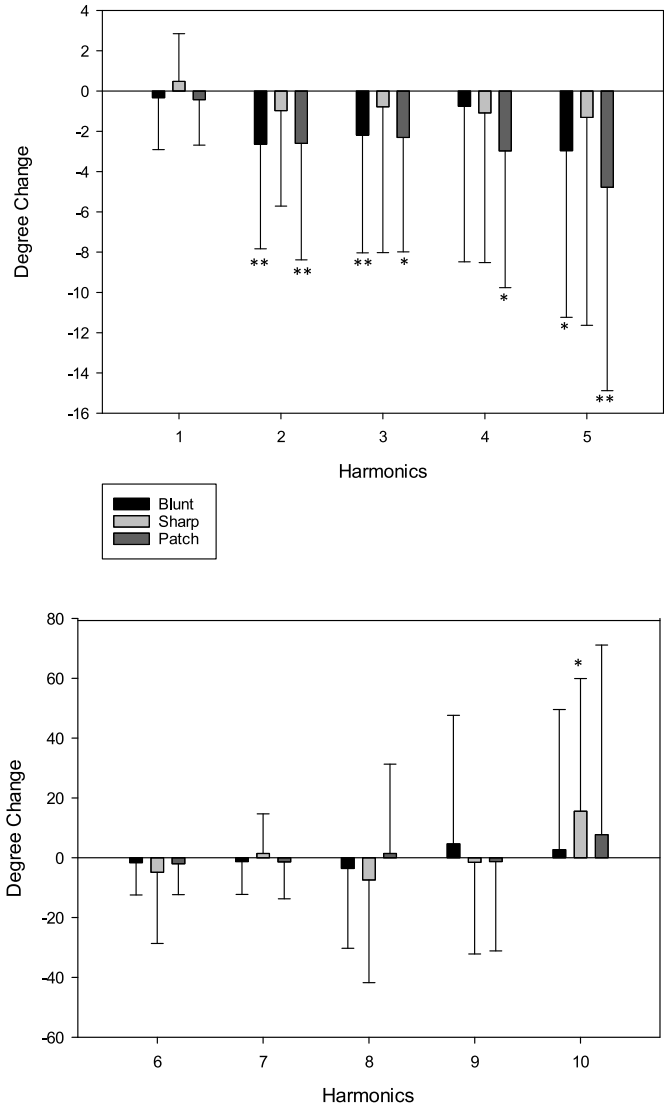

Fig. 2. a. Low (first to fifth) harmonic phase difference after the treatment of 3 different probes in the pulse pressure wave of the left radial artery. Fig. 2b. High (sixth to tenth) harmonic phase difference after the treatment with 3 different probes in the pulse pressure wave of the left radial artery.
Key: Values are means ± SE. The black bars represent the blunt probe (n = 37), the white bars represent the sharp probe (n = 38), and the gray bars represent the patch probe (n = 38). The x-axis represents the harmonic numbers and the y-axis represents the magnitude of harmonic (*P < 0.05 vs before treatment; **P < 0.01 vs. before treatment).

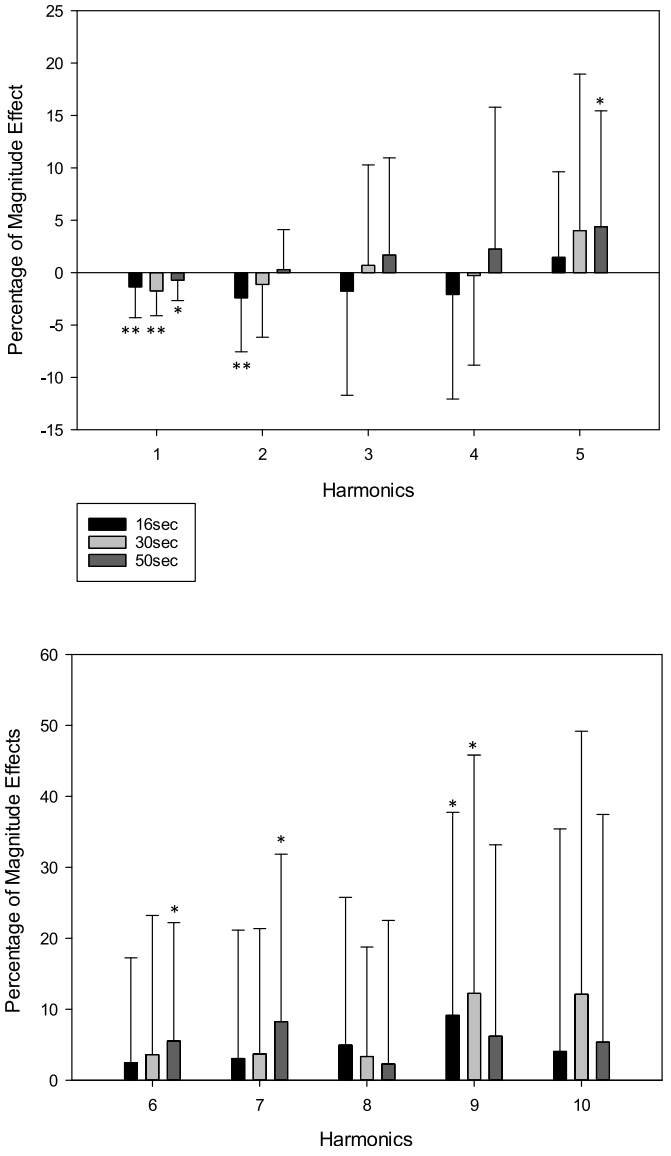

Fig. 3. a. Low (first to fifth) harmonic magnitude difference after the treatment with the sharp probe for 3 different time periods in the pulse pressure wave of the left radial artery. Fig. 3b. High (sixth to tenth) harmonic magnitude difference after the treatment of the sharp probe for 3 different time periods in the pulse pressure wave of the left radial artery. **Key:** Values are means ± SE. The black bars represent the sharp probe for 16 s (n = 42) and the white bars represent the sharp probe for 30 s (n = 38), and the gray bars represent the sharp probe for 50 s (n = 44). The x-axis represents the harmonic numbers and the y-axis represents the magnitude of harmonic. (*P < 0.05 vs before treatment; **P < 0.01 vs. before treatment).

4. Discussion

In the long history of Chinese Medicine, the use of acupuncture points has been widely applied. This method is easy to perform with massage, acupressure, bian stone, and needling on the acupuncture points, to induce the similar effect for easing patients' pain and discomfort.

For the Zu San Li acupoint as the sham acupuncture in our study, it was based on a previous paper.[5] The paper compared the effects of acupuncture at the Zu San Li point with a control group located next to the point. It was found that acupuncture at the Zu San Li point had a statistically significant effect on blood pressure harmonics, while acupuncture on the side of the Zu San Li point in the control group had no significant effect. Using the same blood pressure harmonic analysis method, our experiment explores the effect of laser acupuncture. We placed a standard probe without a laser dose on the Zu San Li acupoint as the sham acupuncture or control group. The redistribution of harmonic proportions and the decrease in the phase angle of harmonic waves were observed. These specific frequency effects were not found when acupuncture needles were applied to non-acupuncture points. These results can be explained by the resonance theory, which provides a scientific explanation of the acupuncture effect from a hemodynamic perspective.

In this study, the harmonic effects of all-group sham acupuncture were similar to that seen in acupuncture at Tsu San Li (St-36), which decreased in the first and second harmonic magnitudes, increased in other harmonics magnitudes, and decreased in almost

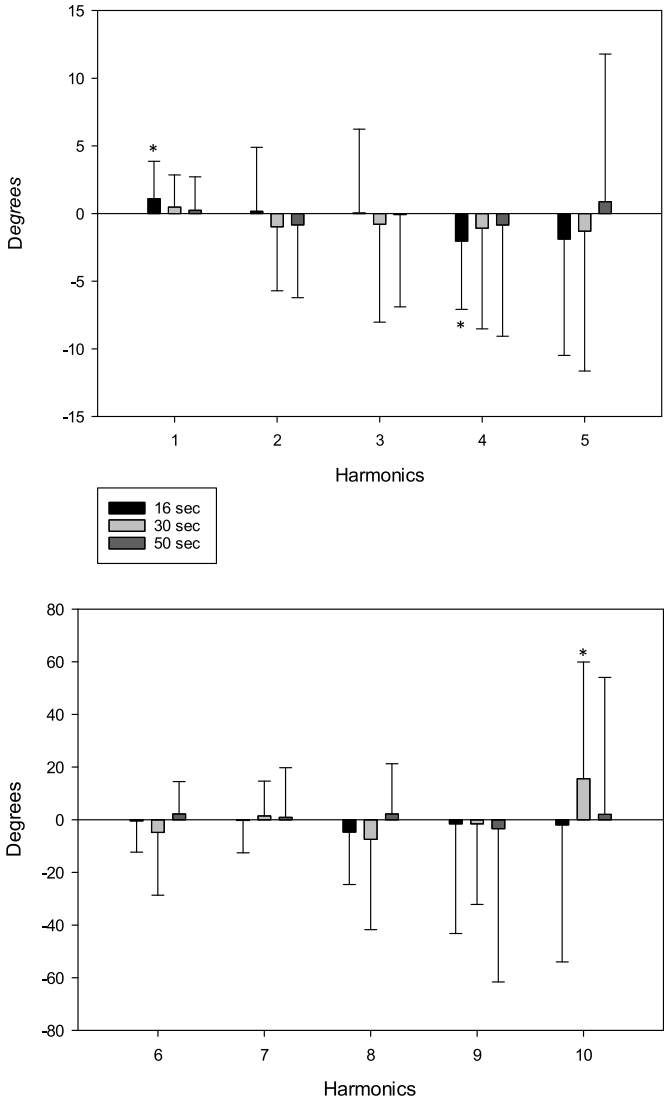

Fig. 4. a. Low (first to fifth) harmonic phase difference after treatment with the sharp probe for 3 different time periods in the pulse pressure wave of the left radial artery. Fig. 4b. High (sixth to tenth) harmonic phase difference after the treatment with the sharp probe for 3 different time periods in the pulse pressure wave of the left radial artery. **Key**: Values are means ± SE. The black bars represent the sharp probe for 16 s (n = 42), the white bars represent the sharp probe for 30 s (n = 38), and the gray bars represent the sharp probe for 50 s (n = 44). The x-axis represents the harmonic numbers and the y-axis represents the magnitude of harmonic (*P < 0.05 vs before treatment; **P < 0.01 vs. before treatment).

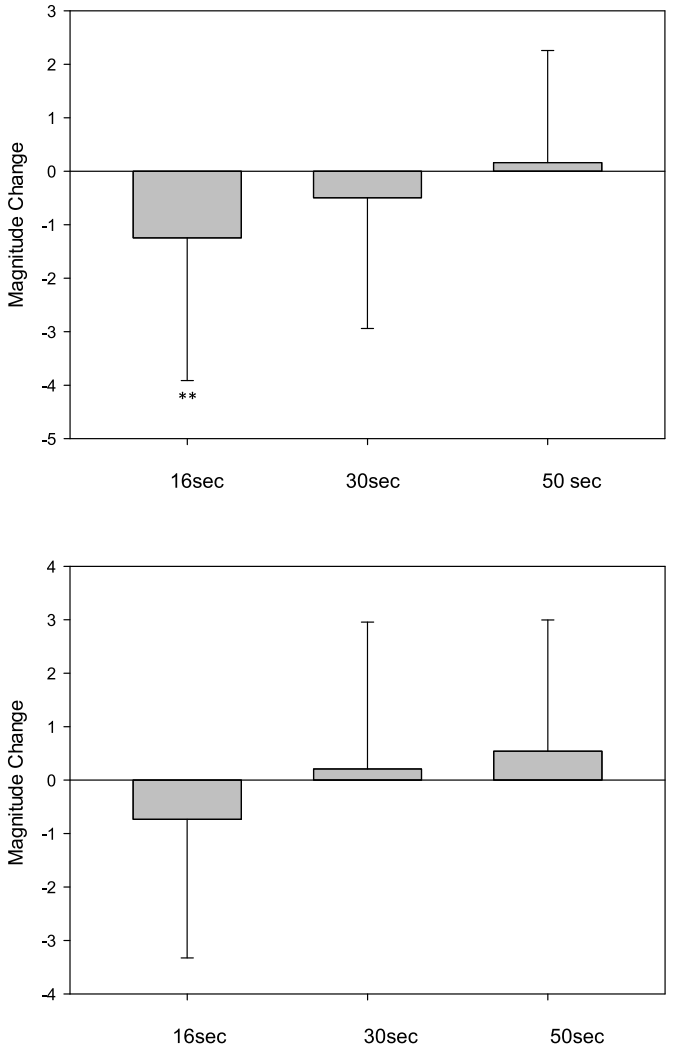

Fig. 5. a. The second harmonic magnitude difference after the treatment with the sharp probe for 3 different time periods in the pulse pressure wave of the left radial artery. Fig. 5b. The third harmonic magnitude difference after the treatment of the sharp probe for 3 different times in the pulse pressure wave of the left radial artery. **Key:** Values are means ± SE. The black bars represent the sharp probe for 16 s (n = 42) and the white bars represent the sharp probe for 30 s (n = 38), and the gray bars represent the sharp probe for 50 s (n = 44). The x-axis represents the harmonic numbers and the y-axis represents the magnitude of harmonic. (*P < 0.05 vs. before treatment; **P < 0.01 vs. before treatment).

every harmonic phase.[5] These effects are also similar to acupuncture at Hsien-Ku (St-43) in the same Stomach Meridian, but totally different from the harmonic effect at the Tai-Tsih (K-3) in the Renal Meridian.[3] Moreover, the statistical significance confirms that the harmonic effects observed when placing standard probes in ST-36 are consistent with physiological effects, regardless of gender, age, or disease status. This evidence establishes a connection between acupuncture points within the same meridian, as they exhibit similar harmonic effects. Whether stimulated by acupuncture or different sham techniques, the resulting changes in the harmonics of the arterial pulse can be attributed to the redistribution of hemodynamics within the cardiovascular system. This redistribution is assumed to be the key mechanism in traditional Chinese Medicine for treating diseases and rebalancing the patient's physical condition. According to our results, disregarding these harmonic resonances within the meridian might undermine the fundamental effects of acupuncture and could lead to a misinterpretation of the resonance effect in sham tests, potentially influenced by the placebo effect.

The 3 different probes induced similar harmonic effects with some tiny differences; that is, the 3 probes produced similar stimulation of resonance at the same acupuncture point. All three probes induced increases in the ninth harmonic, the triple warmer, or triple burner meridian, which is the superficial meridian beneath the skin of the interstitium. The interstitium contains three-fourths of the body's extracellular fluids. Recent studies remind us of the importance and true histology of the interstitium, the structure that lies beneath the skin, mucosa, and fascia. The interstitium is not merely a dense structure of collagen fibers and fibroblasts, but a source of abundant extracellular fluid used to balance loss during tissue excision and fixation. This spongy, fluid-filled structure also corresponds to the immune system and cancer spread.[26] As stated

Table 1
Analysis variances of the first three harmonics.

				Analysis Variance: Amplitude dif					
				Difference of Before and After				Slop, Linear Test	
Harmonic	Group (sharp time)	Group	Subjects	mean	st Err	Median	IQR	Intercept slop	p value
H01	Shame (sharp 16 s)	1	42	−1.226	2.656	−1.100	2.580	−1.709	0.0013
	Shame (sharp 30 s)	2	38	−1.583	2.133	−1.560	2.660	0.283	0.2380
	Shame (sharp 50 s)	3	44	−0.669	1.736	−0.540	1.535	–	–
H02	Shame (sharp 16 s)	1	42	−1.246	2.667	−0.595	2.400	−1.935	0.0008
	Shame (sharp 30 s)	2	38	−0.497	2.442	−0.590	2.880	0.703	0.0075
	Shame (sharp 50 s)	3	44	0.162	2.096	0.110	2.905	–	–
H03	Shame (sharp 16 s)	1	42	−0.734	2.593	−1.035	3.690	−1.275	0.0382
	Shame (sharp 30 s)	2	38	0.209	2.746	−0.040	3.450	0.636	0.0243
	Shame (sharp 50 s)	3	44	0.543	2.453	−0.070	3.250	–	–

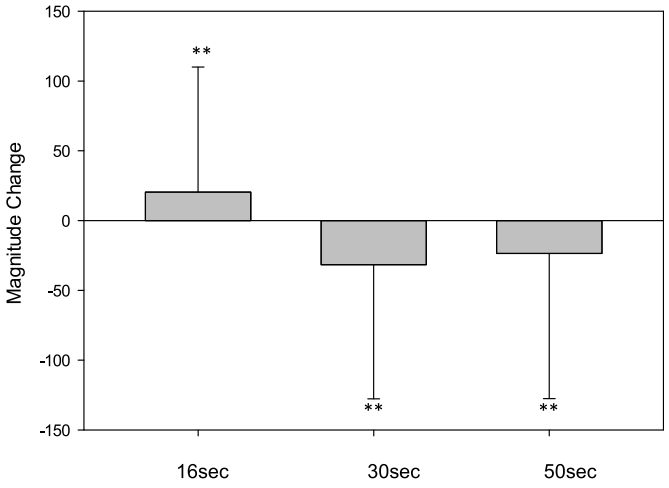

Fig. 6. The first harmonic magnitude difference after the treatment with the sharp probe for 3 different time periods in the pulse pressure wave of the left radial artery. **Key:** Values are means ± SE. The black bars represent the sharp probe for 16 s (n = 42) and the white bars represent the sharp probe for 30 s (N = 38). The gray bars represent the sharp probe for 50 s (n = 44). The x-axis represents the harmonic numbers and y-axis represents magnitude of harmonic (*$P < 0.05$ vs. before treatment; **$P < 0.01$ vs. before treatment.).

in the Huang-Ti-Nei-Ching,[27] "The Triple Burner meridian dominates the *Chi*." In addition, the (Huang-Ti-Nei-Ching)[27] states, "The Triple Burner is the organ similar to an official in charge of dredging, and is responsible for regulating water passage." All three probes and the needle acupuncture stimulated the Tsu San Li (St-36) and induced the increase in the ninth harmonic, confirming the classic descriptions and the clinical function of the Tsu San Li (St-36) for reinforcing the energy.[28]

Compared with the effect in the sharp probe on the first harmonic, which decreased at 16, 30, and 50 s, the sharp probe at the Tsu San Li (St-36) expressed a similar effect as needle acupuncture increases in the high harmonics (fifth, sixth, and seventh harmonic) until 50 s.

We conducted linear regression analysis to examine the quantitative relationship between the duration of the probe placed on the acupoint and the corresponding harmonic effect. The effects in the 3 groups of sharp probes were strengthened with a significant linear relationship as the time increased in the first 7 harmonics and the first 3 harmonics. It seems that the dose-dependent effect exists in the acupuncture point and determines its specific physiological function. This result indicates that the instant effect at the acupuncture point might be overlooked, and thus could lead to misunderstandings about the placebo effect in the sham test. Furthermore, the results of the linear regression test provide evidence that harmonic analysis can serve as a valuable quantitative research method.

5. Conclusions

The meridian effect of a sham test from the mechanical stimulation on an acupuncture point cannot be ignored. Even simple touch might be combined with electric or laser acupuncture, both of which need further study. The linear regression test results support the relationship between probe duration on the acupoint and the resulting harmonic effect. This finding confirms the effectiveness of harmonic analysis as a valuable quantitative research method in studying acupuncture.

All the subjects who received the therapy on the acupuncture points should have felt differences from placebo treatment. Just like surgical therapy, it is difficult to design a blind controlled study to distinguish the placebo effect. Thus, we should be careful when developing a sham test, especially when studying the resonance mechanism behind the acupuncture points and meridians. Without realizing the similarities and differences between acupuncture and sham acupuncture, we cannot judge the sham test as a placebo effect. If results are based on incomplete information in an effort to declare that acupuncture is "dead" or merely a theatrical placebo, too much information will be missed or overlooked.

Establishing the meridian effect through the harmonics of blood pressure waves could be a powerful tool to qualitatively and quantitatively evaluate physiologic and pharmacologic factors, even with a sham test.

Table 2
The analysis variance of the first harmonic through modifying the direct-current value.

				Analysis Variance: Amplitude DC2_dif					
				Difference of Before and After				Slop, Linear Test	
Harmonic	Group (sharp time)	Group	Subjects	mean	st Err	Median	IQR	Intercept slop	p value
H01	Shame (sharp 16 s)	1	42	20.528	89.464	14.258	104.817	32.868	0.1542
	Shame (sharp 30 s)	2	38	−31.683	96.022	−37.617	126.189	−21.809	0.0401
	Shame (sharp 50 s)	3	44	−23.520	103.985	−19.407	153.641	–	–

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

We would like to thank Convergence CT for assistance with English editing during development of the manuscript.

Abbreviations

OPD outpatient department

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