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Abstract

Objective) Shigeru Kinoshita published an article about decreasing heart rate through needle stimulation on the supraorbital foramen in 1975. Kinoshita used the qualitative analysis method to analyze the data. We repeated his test and sought the amount of variation from quantitative analysis of the data collected.

Methods) We chose the acupuncture point BL-2 for the examination because we considered that stimulating the supraorbital foramen corresponded to stimulating BL-2. The subjects of this study were students in our school. They were allocated randomly into two groups between a needle stimulation group and a non-stimulation group by the envelope method. For the needle stimulation group, a needle was left inserted for 10 seconds. The heart rate of all subjects in each group was measured before and after each procedure. The Cohen's effect size was calculated by Pilot RCT, and a sample size was pre-designed for the following full-scale trial using this effect size.

Results) The Cohen's Effect size was d=1.05, the correlation coefficient of effect size was r=.46 and the p-value used in the Welch test was p=.0016. Those results showed that the comparison of groups was effective, and a decrease in heart rate clearly occurred through needle stimulation.

Conclusions) The results showed that stimulation by needles was effective, and the results achieved by Shigeru Kinoshita[1)] in his study were reproducible. However, the subjects in this study were healthy people. The effect of decreasing heart rate through needle stimulation may not be generalized to patients of tachycardia. We expect that clinical trials will be performed on patients for clinical applications.

Introduction

Shigeru Kinoshita published the article "Changes in Heartbeat from a Supraorbital Foramen Stick" in 1975. The article concluded that: 1) The heart rate was decreased through stimulation of the Supraorbital Foramen; 2) No significant difference was detected between the needle stimulation groups and the non-stimulation groups.

The article reported only the qualitative data about how many subjects had a change in heart rate out of the total number of subjects. The quantitative data, the substantial data concerning degrees of heart rate change, were not reported.

The purpose of this study is to examine the repeatability of the results of Kinoshita's study using the quantitative analysis method.

The procedures were the following: 1) A small size pilot trial was performed for determining the effect size; 2) The sample size was pre-designed using the effect size; 3) A full scale trial was performed with sufficient power, as calculated by the pre-design, and the effect size was calculated again.

1. The Pilot Trial

(1) Date of Implementation

October 23rd, 2012

(2) Subjects

The subjects were 15 students from the Teacher-Training Course for Oriental Medicine Program at the Osaka College of Medical Technology.　The subjects included 8 males and 7 females ranging in age from their twenties to their thirties.

(3) Objective

This pilot trial was to calculate the effect size for the pre-design of a sample size for a full trial.

(4) Random allocation Method

The subjects were randomly allocated between a needle stimulation group and a non-stimulation group by the envelope method(Chart 1).

(5) Heart Rate Measurement Method

The pulse rate, which is synonymous with the heart rate, was measured.

(6) Procedure

The acupuncture point used was BL-2 (Figure 1).

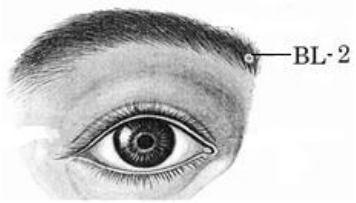

Fig.1　Used acupuncture point BL-2

For the needle stimulation group, the pulse rate of the radial artery on the wrist was measured by finger for one minute.　Then a needle was inserted into BL-2 and left for one minute.

After taking out the needle, the pulse rate was measured for one minute again.　The pulse rate before and after the procedure were compared.

The needle used was a 30mm - No.1 made by SEIRIN Co., Ltd.

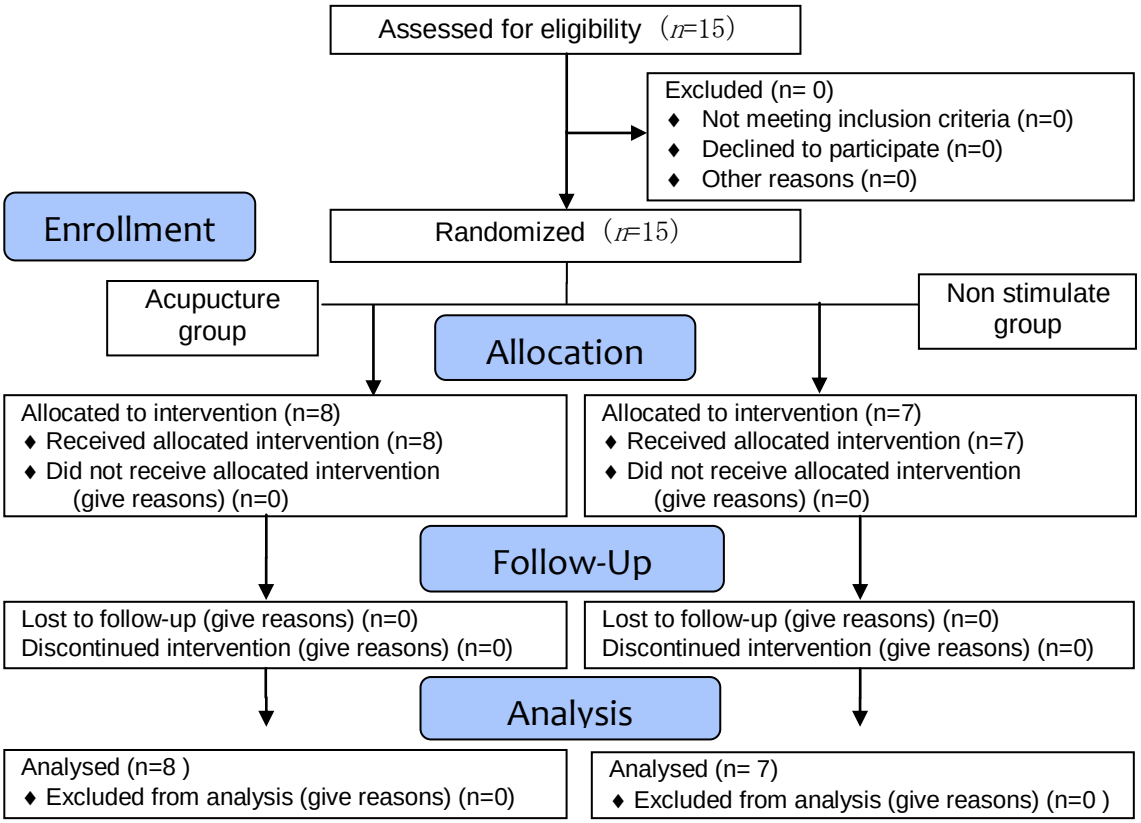

Chart 1. CONSORT 2010 Flow Diagram

For the non-stimulation group, the pulse rate of the radial artery on the wrist was measured by finger for one minute.　Then, the subject lay on the bed for one minute, and the pulse rate was measured for one minute again after that.

The pulse rates before and after the procedure were compared.

(7)Subject Backgrounds

The backgrounds of the subjects are given below in Table 1.

Table 1 .background factor

	Acupuncture Group	Control Group
Cases	8	7
Sex	male(6), female(2)	male(2), female(5)
Age; twenties	male(4), female(1)	male(2), female(4)
thirties	male(2), female(1)	male(0), female(1)
Age(m±SD)	28±11	26±11
Initial Values; VAS (m±SD)	70.1±20.33	67.9±5.37

m±SD: mean ± standard deviation

(8) Analysis Results

The results of the Randomized Controlled Trial are given in Table 2 below.

The test and the effect size for the quantitative data, excluding the analysis by Kinoshita, were calculated.

The average pulse rate of the eight subjects in the needle stimulation group was 6.38.　The average pulse rate of the seven subjects in the non-stimulation group was .00.　The effect size between groups was 0.98.

Table 2. Pulse rate in pilot trial

Acupuncture Gp.	Pre stimulate	Post stimulate	difference (Pre-post)
1	108	90	18
2	96	72	24
3	62	60	2
4	60	60	0
5	54	54	0
6	66	65	1
7	54	51	3
8	61	58	3
Control Gp.	Pre stimulate	Post stimulate	difference (Pre-post)
C1	78	78	0
C2	66	66	0
C3	72	72	0
C4	66	66	0
C5	65	65	0
C6	66	66	0
C7	62	62	0

Calculation of Sample Size for a Full-scale Trial

The sample size necessary for conducting a full-size trial was calculated using the results of the pilot trial.

The sample size which we needed for a full-size trial was 20 subjects in each group (d=.98, power=80%, level of significance=5% and two-sided test).[6)]

Since it was possible to recruit this many subjects, we went on to conduct a full-size trial.

2. Full-size Trial

(1) Date of Implementation

December 5th, 2013

(2) Participants

The trial was conducted on 43 students from the Acupuncture & Moxibustion Therapist Daytime Section, the Acupuncture & Moxibustion for Health & Beauty Therapist Program, and the Teacher-Training Course for Oriental Medicine Program at the Osaka College of Medical Technology.

(3) Methods of Random Allocation

The subjects were randomly allocated to a needle stimulation group or a non-stimulation group by the central registration method(Chart 2).

(4) Procedure

The procedure was the same as the pilot trial.　The point examined was BL-2.

For the needle stimulation group, the pulse rate of the radial artery on the wrist was measured by finger for one minute.　Then a needle was inserted into BL-2 and left for one minute.

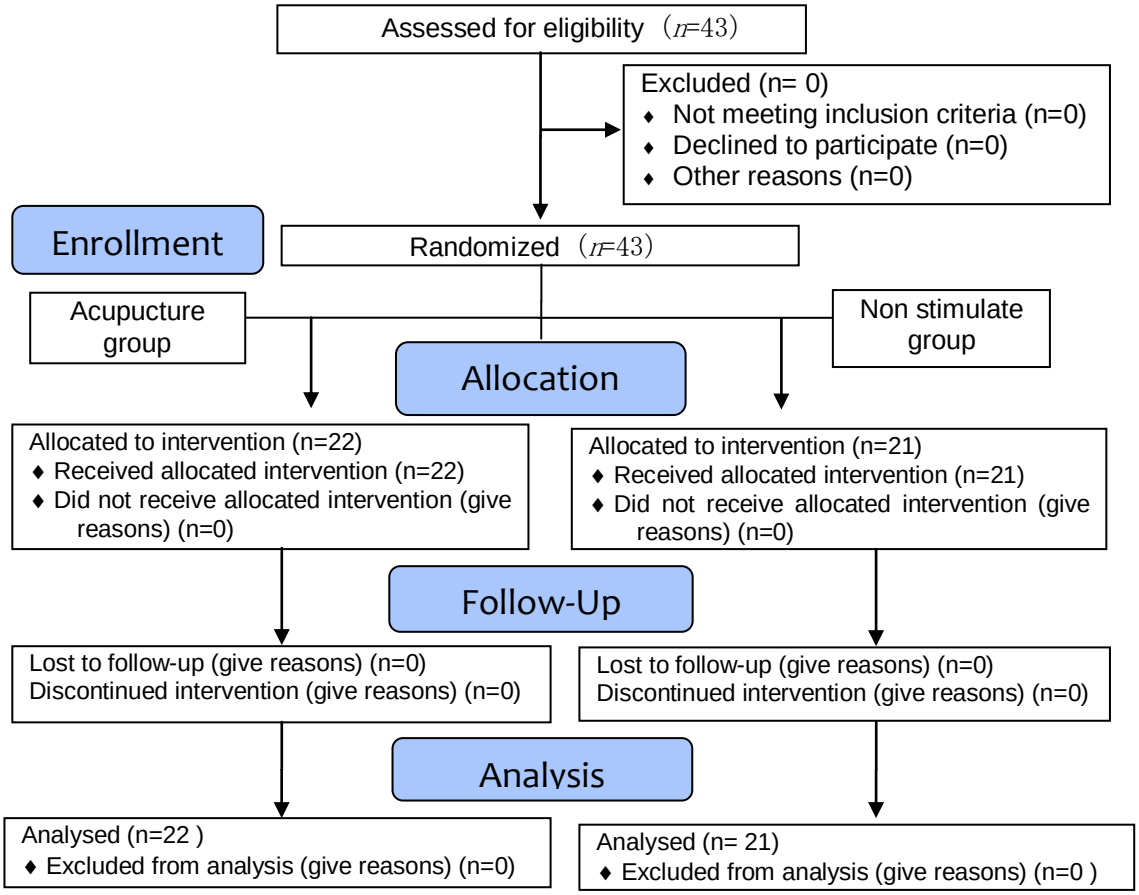

Chart 2. CONSORT 2010 Flow Diagram

After taking out the needle, the pulse rate was measured for one minute again.　The pulse rates before and after the procedure were compared.
The needle used was a 30mm - No.1 made by SEIRIN Co., Ltd.

For the non-stimulation group, the pulse rate of the radial artery on the wrist was measured by finger for one minute.　Then, the subject lay on the bed for one minute, and the pulse rate was measured for one minute again after that.
The pulse rates before and after the procedure were compared.

(7) Subject Backgrounds

The backgrounds of the subjects are given below in Table 3.

Table 3 .background factor

	Acupuncture Group	Control Group
cases	22	21
sex	male(11), female (11)	male(9), female(12)
Age; twenties	male(7), female(8)	male(6), female(9)
thirties	male(3), female(3)	male(2), female(2)
forties	male(1), female(0)	male(1), female(1)
age (m ± SD)	26.60±6.90	27.00±8.14
Initial Values; VAS (m ± SD)	71.4±10.84	70.8±10.8

m ± SD: mean ± standard deviation

(8) Results

Table 4. Pulse rate in Full-size Trial

Acupuncture Gp.	Pre stimulate	Post stimulate	Difference (Pre-post)
No.1	102	98	4
No.2	78	70	8
No.3	79	76	3
No.4	69	68	1
No.5	73	73	0
No.6	60	54	6
No.7	84	80	4
No.8	58	59	-1
No.9	65	60	5
No.10	60	57	3
No.11	69	64	5
No.12	71	63	8
No.13	72	72	0
No.14	76	63	13
No.15	83	82	1
No.16	64	58	6
No.17	80	75	5
No.18	76	77	-1
No.19	62	53	9

No.20	61	54	7
No.21	74	61	13
No.22	55	52	3
Control Gp.	Pre stimulate	Post stimulate	difference (Pre-post)
No.1	88	84	4
No.2	94	92	2
No.3	76	76	0
No.4	62	62	0
No.5	71	71	0
No.6	82	81	1
No.7	79	78	1
No.8	80	78	2
No.9	58	56	2
No.10	62	61	1
No.11	66	64	2
No.12	71	68	3
No.13	58	57	1
No.14	80	74	6
No.15	80	81	−1
No.16	64	64	0
No.17	60	59	1
No.18	68	67	1
No.19	65	62	3
No.20	69	66	3
No.21	53	58	−5

The mean (m) ± standard deviation (SD) of the heart rate in the acupuncture stimulation group was 4.64±3.98.

The mean (m) ± standard deviation (SD) of the heart rate in the non-stimulation group was 1.29±2.15.

Cohen's d of the effect size between the two groups was d=1.05. The point-biserial correlation coefficient was r=.46.

Based on the judgment standard of the general effect size, if 1.10≧d≧.75 in this test, then, it constitutes "a large effect size".

It is also said to be "a large effect size" when the point-biserial correlation coefficient r is more than .37.

Before the t-test, the F-test was used for examining whether the variability between the two groups is equal or not.

The result showed there was a significant difference with F=.0038 (F＜.01). It meant that the t-test could not be used because of the heteroscadasticity.

We used the Welch test, which is used when the variance is hypothesized to be unequal, to determine the difference between the averages of the two samples.

The result of the test was that there was a significant difference, with p=.0016 (p<.5), that it was difficult to assume the result was coincidental, and that, therefore, the strength of the evidence was assured.

Comprehensive Results

The results of the pilot trial and the full-size trial showed that the needle stimulation group had the larger effect size and was more effective in reducing heart rate than the non-stimulation group.
In addition, the result from the Kinoshita article was reproduced in the quantitative data analysis.

Discussion

Mr. Kinoshita reported only the result calculated by the qualitative data analysis method (x^2 test), i.e., how many subjects out of how many subjects had a reduced or unchanged heart rate.
For that reason, the amount of variation and the substantive heart rate changes were not indicated in the article.

Therefore, in this study we analyzed the effect size and conducted the t-test in order to make clear the amount of variation in the change of heart rate itself.
The result showed "a large effect size" that greatly exceeded the standard effect size of d=.60. This meant that there was a significant difference.

The standards for ES in medical science are that less than .2 constitutes a small effect size, .4 is medium, and more than .6 is a large effect size.[5)]
The r of the ES, the point-biserial correlation coefficient (R_{bis}: nominal and quantitative), is one of the indexes used to show an association between the nominal scale and the quantitative scale.
In other words, the point-biserial correlation coefficient demonstrates the degree of association between a result and an effect of an intervention (acupuncture) as determined by the correlation between two groups (two data: the qualitative scale) and the value of measurement (the continuous variable: the quantitative scale).

The standards for the r of the ES in medical science are that less than .05 is a small effect size, around .2 is a medium effect size, and more than .37 is a large effect size.

In this study, Cohen's d=1.05 and the point-biserial correlation coefficient is r=.46. The Welch test was also calculated, and is significant with p=.0016. The results demonstrated clearly that acupuncture was effective in decreasing heart rate.
The first branch of the trigeminal nerve (the ophthalmic nerve) has a branch to the frontal nerve. Then the frontal nerve branches to the supraorbital nerve and the supratrochlear nerve, and are then distributed over the skin.
It could be thought that the supratrochlear nerve innervates at the area of BL-2.
There is the Aschner reflex (the oculocardiac reflex), which is a decrease in pulse rate associated with compression of both eyeballs with the eyes closed. The trigeminal nerve is the afferent pathway of the reflex.
Based on the result of this study, stimulating BL-2, located on the area of the trigeminal nerve, can be inferred to be effective for controlling the pulse rate through the same mechanism as the Aschner reflex.

Mr. Kinoshita concluded that there was no significant difference between compressions of the supraorbital foramen and the bed rest group, and there was significant difference between compressions of the eyeballs and the bed rest group.

Based on the results of Mr. Kinoshita and this study, it can be said "compression of the supraorbital foramen < stimulating BL-2 < compression of the eyeballs". It may be thought that stimulating BL-2 can be expected to have an effect similar to compression of the eyeballs.

Even though the data collected are from healthy people, because the effect of decreasing heart rate through acupuncture was distinct, it is conceivable that this could be applied clinically for treatment of tachycardia.

However, one consideration is that clinical trials need to be conducted to examine the durability of the effect on patients.

Used software

standard deviation(SD):**Vassarstats** <http://vassarstats.net/basic.html> (2014/2/4　access)
Effect Size (ES):Effect Size Calculators <http://www.uccs.edu/~lbecker/> (2014/2/4 access)
Test of homogeneity:Vassarstats <http://vassarstats.net/> (2014/2/4 access)
Welch test:GraphPad Software <http://graphpad.com/quickcalcs/ttest1/> (2014/2/4 access)

Acknowledgement

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We also express our respect for Mr. Shigeru Kinoshita, who has done the original study and gave comments to our final writing.

This article was translated from Japanese into English by Ms. Ai Okamura and Mr. Gillam Matthew.

References

1) Shigeru Kinoshita: Changes in Heartbeat from a Supraorbital Foramen Stick. The Journal of The Japan Acupuncture & Moxibustion Society 1975; 24(1): 22-26

2) Nobuo Nara: The clinical medicine general remarks 2nd edit. pp.119.　Ishiyaku Publishers, Inc. Jan 10th 2010

3) Yuko Sato, Akio Saito: Physiology 2nd edit. pp.194 - 210. Ishiyaku Puclishers, Inc. Jan 1st 2009

4) Textbook writing subcommittee: New edition An Outline of Meridian and Acupuncture Point. pp.122, 123. Ido No Nippon Sha

5) Reed JF 3rd, Slaichert W.: Statistical proof in inconclusive 'negative' trials. Arch Intern Med. 1981 Sep;141(10):1307-10.

6) R. Barker Bausell , Yu-Fang Li: Power Analysis for Experimental Research, Cambridge University Press, 55, 2002