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Original Article

A Clinical Trial to Assess the Efficacy of Acupuncture on Hot Flashes in Postmenopausal Women

-Focusing on the comparison of the effects of Traditional Korean medical acupuncture (TKMA) and Minimal Acupuncture (MA)-

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Objective : In this study we wanted to confirm if proper stimulation and *de-Qi* of traditional Korean medical acupuncture could increase hot flash relief efficacy.

Design : A randomized controlled, single blind study. We used two modalities of acupuncture, one with optimal stimulation [Study group; Korean medical acupuncture (TKMA)] and one with minimal stimulation [Control group; Minimal acupuncture (MA)]. Same acupoints [PC6(內關), HT8(少府), HT7(神門), LI4(合谷), ST36(足三里), SP6(三陰交), Ren4(關元)] were used in both groups. Fifty-two patients were treated twice a week for 8 weeks, and follow-up was done after 4 weeks from the last treatment. Patients were checked hot flash VAS (visual analog scale), frequency and duration every time they visited.

Results : Hot flash relief efficacy by 100mm hot flash VAS was obvious in both groups. Hot flash VAS scores of study group were smaller than the scores of control group at the early stage (3rd, 4th and 8th visit), but there wasn't a remarkable difference between study and control group at the end of the trial. Besides, diminution of hot flash VAS was faster and more even in the study group than control group by visualization using 'Box plot'.

We compared frequency and duration of hot flash, 100mm sweating, palpitation, sleep disturbance VAS, and Kupperman Index, MENQOL, Patient's global assessment score. Both groups showed definite decrease from the baseline, but the difference was not statistically significant.

There wasn't any adverse event. Hot flash relief efficacy was kept in most patients after 4 weeks' follow-up.

Conclusion : Acupoint combination by Traditional Korean medical theory is effective on hot flashes and hot flash relief efficacy was faster and more even in optimal stimulation than minimal stimulation.

Key Words : Hot flash, postmenopausal, acupuncture, Randomized controlled trial (RCT), Complementary and alternative medicine (CAM), Hormone replacement therapy (HRT)

Introduction

Hot flash is defined as having a sudden flash of heat particularly affecting the face. Hot flashes and night sweats are the most common vasomotor symptoms in menopausal women[1,2]. These are typical early symptoms of perimeno-

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pausal period and, even for Korean women, most females experience such hot flashes at some point in their life time[3-5].

Hormone replacement therapy (HRT) is effective to reduce this symptom. Nevertheless, arecent study by WHI in the U.S. reported that the benefits of HRT shown by absence of a hot flash had been diluted by risks of side effects, such as increased incidences of breast cancer, endometrial cancer as well as cerebrovascular disease, and pulmonary thromboembolism[6,7]. Furthermore, hormonal therapy indicated for a hot flash may not be appropriate for females with a past medical history of an estrogen-dependent tumor. Thus, recently, more women hope to relieve hot flashes and other clinical symptoms of menopause with a complementary approach of acupuncture and oriental herbal medicine, Korea[4,5].

Several study results[8-11] are excellent bases which demonstrate objectively the efficacy of a properly-arranged sequential acupuncturing for the relief of menopausal hot flashes. It is believed that the efficacy of acupuncture is induced by an acupoint specific treatment effect achieved by stimulating particular acupoints and by the sensation of an arrival of *Qi* by specific stimulations applied to acupoints or bodily region. Particularly, *de-Qi* (the arrival of *Qi*) is an important method of acupuncture and is an approach to perceive peculiar sensations by applying a certain level of stimulation after insertion of needles[12]. This is recognized as an important means to improve the therapeutic effect in traditional Korean acupuncture.

In order to verify the effect of improvement of the symptoms associated with hot flashes, by first formulating an acupoint prescription in line with traditional Korean acupuncture technique per the meridian theory and endowing *de-Qi* by the manipulation method, a randomized, single-blind clinical trial was carried out.

Materials and Methods

1. Study Design and Subject

Randomized single-blinded prospective study incorporating minimal acupuncture-controlled design was conducted for postmenopausal women. This study included females who had undergone acupuncture treatment from the Clinical Research Center, Dongguk University Ilsan Korean Medicine Hospital (DUIH) from June 2006 through October 2006 for women who had hot flashes at least 14 times or more a week and a level of hot flash measured with 100mm VAS at 50 or higher. These subjects were recruited between May 2006 and August 2006 and participated in this study for 12 weeks. It included 1 week before acupuncture treatment (a baseline week), 8 weeks of acupuncture treatment and 4 weeks of follow-up observ-ations.

Subjects were provided withthe information about this investigation and asked to sign a consent form. This study was approved by the DUIH Institutional Review Board. This study included only subjects who were 40 years to 60 years in age of postmenopausal women having hot flashes atleast 14 times or more a week, had hot flashes measured with 100mm VAS by themselves with the level 50 or higher, did not have a menstrual cycle for 1 year or longer, had blood FSH level of 30mIU/mL or more, and became menopausal naturally or post-surgically after a total hysterectomy. Subjects were asked not to take new drugs or health foods during this trial and agreed not to change currently adm-

inistering drugs or health foods or their dosages. In cases of administration of drugs that could affect hot flashes, such as HRT or SSRI, this study was limited to female subjects with drugs which had passed the washout period of the drug effect. On the other hand, this study excluded females with a menopause following total hysterectomy or anticancer treatment due to malignancy. It excluded women with a past medical history of malignancy within 5 years, currently taking an anticoagulant, or having a medical history of (or currently suffering) heart disease. It also excluded females with uncontrollable hypertension, diabetes mellitus, vaginal bleeding of unknown origin within the last 6 months or having a metallic allergy to the extent that acupuncture would not be possible. With respect to the design of this study, acupoint selection and duration of acupuncture were based on the study by Wyon et al[8]. and clinical

Table 1. Acupuncture Points and Methods of Study Group (Optimal Stimulated Group)

Point	Meridian	Needling	Location	Reinforcing and reducing	Manipulation
PC 6	Pericardium	Push a needle perpendicularly into the subcutaneous tissues up to the 5-8 fen depth depending on the thickness of subcutaneous tissues.	2 cun above the transverse crease of the wrist, between the tendon of m. Palmaris longus and m. flexor radialis	reducing	Twirling-rotating and lifting-thrusting
HT 8	Heart	Depending on the extent of hypertrophy, push a needle perpendicularly into the subcutaneous tissues up to the depth of 3 fen.	Between the fourth and fifth metacarpal bones	reducing	Twirling-rotating and lifting-thrusting
HT 7	Heart	Depending on the extent of hypertrophy of the subcutaneous tissues, push a needle perpendicularly into the subcutaneous tissues up to the depth of 3 fen.	At the ulnar end of the transverse crease of the wrist	reducing	Twirling-rotating and lifting-thrusting
LI 4	Large intestine	Depending on the extent of hypertrophy of the subcutaneous tissues, push aneedle perpendicularly toward the second metacarpal bone to the depth of 5-8 fen	On the dorsum of the hand, between the first and second metacarpal bones, approximately in the middle of the second metacarpal bone on the radial side	reducing	Twirling-rotating and lifting-thrusting
ST 36	Stomach	Depending on the extent of hypertrophy of the subcutaneous tissues, push a needle perpendicularly toward of the contralateral SP 9 to the depth of 5-8 fen.	On the lateral side of the shank, one finger breadth from the anterior crest of the tibia	Reinforcing	Twirling-rotating and lifting-thrusting
SP 6	Spleen	Depending on the extent of hypertrophy of the subcutaneous tissues, push a needle perpendicularly toward of the contralateral G 39 to the depth of 5-8 fen.	3 cun above the medial malleolus, dorsal to the posterior border of the tibia	Reinforcing	Twirling-rotating and lifting-thrusting
Ren4	Ren mai	Depending on the extent of hypertrophy of the subcutaneous tissues, push a needle perpendicularly up to the depth of 1 Cun*.	On the midline 3 cun below the umbilicus	Reinforcing	Twirling-rotating and lifting-thrusting

*A cun is a relative body measure in Traditional Korean Medicine. It is the distance between the transverse creases of the interphalangeal bone of the thumb when the finger is slightly flexed.13), 1 fen = 1/10 Cun.

experiences of these authors supplemented by the results of conferences by specialists.

2. Randomization

Using a stratified randomization schedule, subjects were randomly selected into two groups: Study group (Traditional Korean medical acupuncture group, TKMA) and Control group (Minimal Traditional Korean acupuncture group, MA). Random Allocation Software (Version 1.0 Department of Anesthesia, Isfanhan University of Medical Science) was used to randomize these subjects into these two groups and a block randomization method was incorporated.

3. Study group and Control group

The same acupuncturing needle points of these two groups were set for the trial. For the

Table 2. Study Flow Chart

Period	Screening	Active treatment																F/U
Visit	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Time point			1*		2*		3*		4*		5*		6*		7*		8*	3mon±14d from the last visiting day
Informed Consent	X																	
Demographic study	X																	
Examination of symptoms and history of menopause	X																	
Exam history of drug treatment	X																	
Hot flash 3rd phase assessment	X																	
Exam of body composition	X																	
Physical exam	X																X	
Clinical pathology test	X																X	
Confirmation of change in past medical history and past drug history		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Inclusion criteria / Exclusion criteria		X																
Randomization and allocation		X																
Carry out procedure for study group/ control groups		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Hot flash VAS (100mm)		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Hot flash Frequency (number of frequency/week)		X	X		X		X		X		X		X		X		X	X
Hot flash Duration (min/attack of hot flash)		X	X		X		X		X		X		X		X		X	X
Sweating VAS (100mm)		X	X		X		X		X		X		X		X		X	X
Palpitation VAS (100mm)		X	X		X		X		X		X		X		X		X	X
Sleep disturbance VAS (100mm)		X	X		X		X		X		X		X		X		X	X
Kupperman's Index		X							X								X	X
MENQOL		X							X								X	X
Patient's global assessment		X							X								X	X
Confirmation of an adverse event		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

* : week

study group, Korean medicine doctor (KMD) assessed the physical strength of patients and the thickness of their subcutaneous tissues. They decided on a method and extent of stimulation providing an optimal approach using his or her discretion. Moreover, the lower abdomen of the subjects was irradiated with an infrared ray for 20±3 minutes. A manipulation method was carried out once after an acupuncture treatment. A single KMD licensed by the Korean Ministry of Health and Welfare with experiences of more than 3 years carried out the procedure.

For the control group, the same clinician inserted needles on the same acupoints to a minimal depth (±1mm) and a manipulation method was not applied to all subjects, allowing them to feel a minimal stimulation[13].

4. Study Results

The primary results of this study were represented by 100mm hot flash VAS scores. The secondary results were obtained by using frequency of hot flashes (incidences/week), duration of hot flash (min/attack), 100mm Sweating VAS score, 100mm Palpitation VAS, 100mm Sleep disturbance VAS, Kupperman's menopausal Index, MENQOL[14] and Patient's Global Assessment.

5. Statistical methods

T-test was used for sequential data for the comparisons of equivalence between these subject groups and Fisher Exact Test was used for categorical data. Wilcoxon test was used to examine differences between groups in hot flash VAS scores and secondary results by using frequency of treatment[15-18].

Results

1. Subject Flow

Fifty-four out of 214 women, who had inquired into this study after seeing an advertisement of this clinical test, were selected and signed a consent form. However, 6 females withdrew from this study due to the duration of this study or the distance to this hospital. Thus, 52 subjects were randomly selected and 26 were categorized into each of these two groupsstudy group and control group (Fig. 1)

2. Description of Sample

No significant baseline differences existed between study group and control group in the primary results (Hot flash VAS) and the secondary results (Hot flash frequency, Hot flash duration, Sweating VAS, Sleep disturbance VAS, Kupperman's menopausal Index, MENQOL and Patient's Global Assessment). No significant baseline group differences existed in age, BMI,

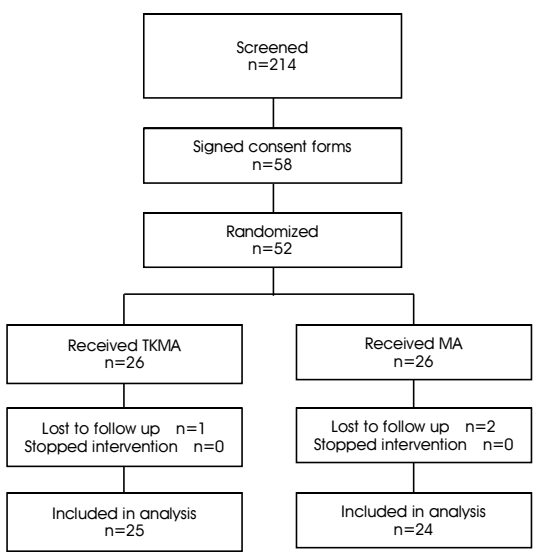

Fig. 1. Consort Diagram Representing Subject Activities in This Study.

age of menopausal onset, number of years since menopause, and history and time since HT. However, the number of cases with a history of hysterectomy of was 1 for study group and 7 for control group, showing a higher rate for control group. Also, there were no significant differences in the level of FSH, LH and E2 between these two groups.

3. Effect on the Hot flash VAS score

At the end of treatment after 8 weeks, both groups showed a significant reduction in hot flash VAS scores and severity. There was no remarkable difference between two groups in the longitudinal analysis. However, there were significant differences in the hot flash scores at 4^{th}, 5^{th}, 8^{th} and 9th hospital visits, assessed by the number of hospital visits. Wilcoxon Test was used for data analysis (Table 3).These study results might indicate that the study group relatively had an effect of reducing hot flash promptly. Figure 2 shows the effect of hot flash reduction in a box plot.

Comparisons of lowess curves to assess the trend of Hf VAS changes for each group are shown in Figure 3.

Furthermore, the follow-up observations carried out 4 weeks after treatment showed that the hot flash VAS scores of 14 out of 25 subjects (56 %) in study group decreased or were not changed, but that of 11 subjects (44 %) increased. The hot flash VAS scores of 13 out of 24 subjects (54.17 %) in the control group decreased or were not changed, but that of 11 (45.83 %) increased. In view of these results, both the optimally-stimulated group and minimally-stimulated group showed a drop in the hot flash VAS scores. This trend was also shown in the reduction rate of

Table 3. Hot flash VAS (100mm) Scores by the Number of Hospital Visits

Visit	Study	Control	p-value*
2(baseline)	70.250±2.767 (26)	76.731±2.397 (26)	0.064
3	66.154±3.047 (26)	70.808±3.485 (26)	0.194
4	57.096±3.567 (26)	71.083±3.325 (24)	0.005
5	55.192±3.453 (26)	66.900±3.851 (25)	0.022
6	53.808±4.065 (26)	62.896±4.136 (24)	0.086
7	51.423±4.032 (26)	61.560±3.982 (25)	0.085
8	47.981±3.902 (26)	63.312±3.795 (24)	0.008
9	44.731±4.552 (26)	57.417±4.691 (24)	0.033
10	42.900±4.794 (25)	54.062±5.057 (24)	0.114
11	41.788±4.143 (26)	49.479±5.190 (24)	0.252
12	36.500±4.666 (25)	47.500±5.764 (23)	0.190
13	36.020±4.584 (25)	45.130±5.050 (23)	0.212
14	37.848±4.645 (23)	45.562±5.473 (24)	0.292
15	33.062±3.944 (24)	43.543±5.322 (23)	0.198
16	29.000±3.637 (24)	42.857±6.243 (21)	0.162
17	28.340±4.222 (25)	39.667±6.111 (24)	0.250

* Hot Flash (Hf) VAS scores in the table are expressed in the mean ± standard deviation (sample size) . P-values are the results of Wilcoxon Test.

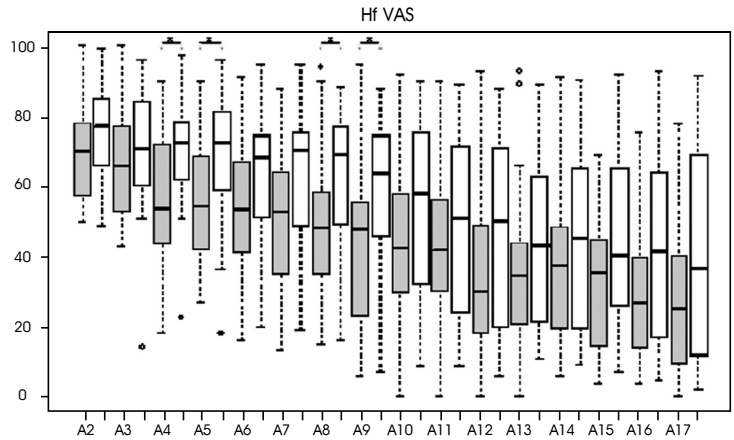

Fig. 2. Box plot of Hot fash VAS. Gray color blocks belong to study group, White color blocks denote control group, x-axis indicates frequencies of hospital visits. "*" mark indicate box plot that showed a significant difference.

VAS values. These results could be interpreted as having significant efficacy for hot flash improvement through 8 weeks of treatment regardless of a level of needling stimulation on acupoints or of a stimulation method in this study. Since a control group with no treatment, had not been established, one would say the effect of hot flash reduction could not have been due to acupuncture treatment. However, considering the fact that these subjects had hot flashes for relatively a long period (8 weeks or more) after menopause, one could not conclude that the slight change of hot flash demonstrated for 8 weeks might have been a natural remission. Rather, in consideration of previous studies on acupunctural approaches, such improvement could be understood as having an effect of an acupunctural treatment indicated for hot flashes. Also, with respect to efficacy in these two groups, the final therapeutic effects of both groups were remarkable at the end of 8 weeks treatment. However, a partial significance in

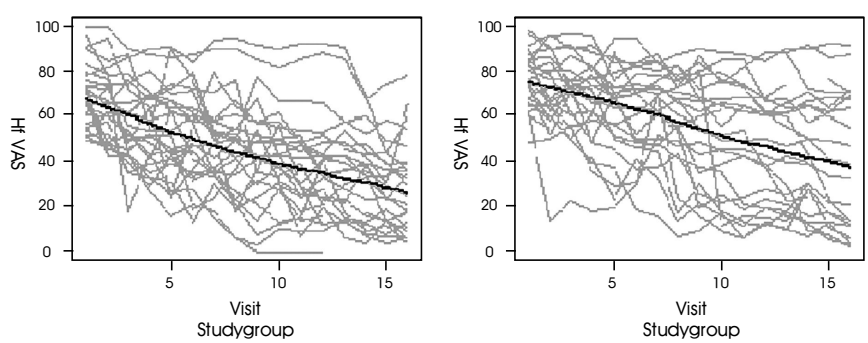

Fig. 3. Lowess curve of Hot flash VAS. Hot flash VAS plot of each patient for each group. Hot flash VAS of each patient was shown in gray lines and a solid black line is the lowess curve for each group.

Table 4. Sweating VAS Scores by Number of Hospital Visits

Visit	Study	Control	p-value*
2	70.423±3.423 (26)	67.827±5.622 (26)	0.749
3	66.058±2.927 (26)	61.500±5.561 (26)	0.927
5	50.904±3.380 (26)	63.080±4.880 (25)	0.020
7	52.038±4.212 (26)	55.440±5.024 (25)	0.528
9	47.673±4.662 (26)	53.229±5.240 (24)	0.190
11	42.442±4.839 (26)	48.062±5.091 (24)	0.404
13	39.500±5.534 (25)	43.283±5.007 (23)	0.522
15	39.333±4.608 (24)	36.804±5.232 (23)	0.758
17	32.460±4.607 (25)	40.292±5.482 (24)	0.342

* The SW VAS values in Table 5 are expressed as the mean ± standard deviation (sample size) . P-values are the results of Wilcoxon Test.

efficacy difference was statistically ascertained at a somewhat stable period going from the early phase into the middle phase of acupuncture treatment. Thus, the anticipation was that at least there could be a manipulation-specific effect although it might not be as much effect as that of the acupoint-specific effect.

4. Effects on Sweating

Although there were no significant differences in the analysis of longitudinal and baseline analysis, there was a significant difference between these two groups in SW VAS values measured on the 5th hospital visit (Table 4). This result of SW VAS could somewhat concur with that of hot flash severity.

5. Results of assessment of other components

1) Effect on Frequencies on Hot flash attack

The mean frequency of hot flashes at 1st, 4th

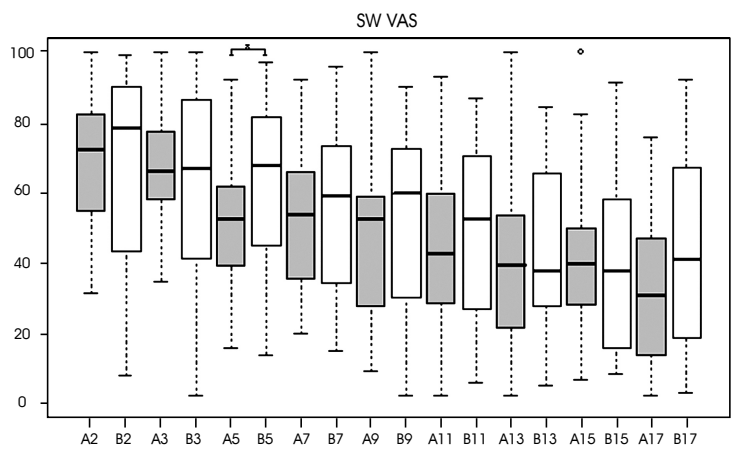

Fig. 4. Box plot of Sweating VAS. Gray color blocks belong to study group, White color blocks denote control group, x-axis indicates frequencies of hospital visits. "*" mark indicate box plot that showed a significant difference.

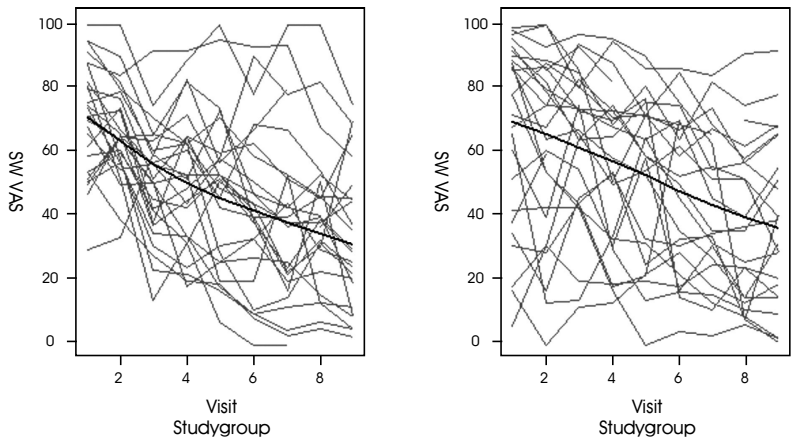

Fig. 5. Plot and lowess curve of sweating VAS. Sweating VAS plot of each patient for each group. Sweating VAS of each patient was shown in gray lines and a solid black line is the lowess curve for each group.

and 8th week was compared with that of the mean frequency per week. The results were more severe for the study group. Hot flashes were not only turned for the better continuously, frequencies of study and control group became reversed in 4 weeks enabling an inference of a relatively excellent effect. Nevertheless, there was no statistical significance in the analysis of final results after 8 weeks of treatment.

2) Effect on Hot flash Duration

The mean duration (in minute) per each attack of hot flash was compared at 1st, 4th and 8th week and both groups showed a similarly shortened duration. Nevertheless, these differences were not statistically significant.

3) Effect on Palpitation

The mean values of palpitation VAS (100 mm), often accompanied by hot flash, for each group were compared at 1st, 4th and 8th week of treatment. The results showed both groups to be similarly reduced, but the differences were not statistically significant.

4) Effects on sleep disturbance

The mean values of sleep disturbance VAS (100mm) for each group were compared at 1st, 4th and 8th week of treatment. The VAS values of TKMA group at 8th week of treatment were distinctively lower than that of the MA group and symptomatic improvement also showed an invariable phase.

5) Effect on Kupperman Index and MENQOLI

The mean scores of Kupperman Index and MENQOL for each group were compared at 1st, 4th and 8th week of treatment. The results showed significant reduction for both groups in all periods, but there were no statistically significant differences between the two groups.

6) Effect on Patient's Global Assessment

The mean values of patient's global assessment for each group were compared at 1st, 4th and 8th week of treatment. The results showed an ameliorating effect in both groups, but there were not significant differences between these two groups.

6. Success of blinding

Subjects were asked to fill the questionnaire on blinding at 4th week of follow-up. 18 out of 24 subjects (75 %) that belong to control group and 21 out of 25 (84 %) that belong to study group thought that they underwent traditional Korean medical acupuncture treatment. Almost all subjects in both groups thought they belonged to the study group (p=0.7554, Fisher exact test).

7. Adverse Events

General clinical test conducted before and after treatment showed no abnormal findings. One subject belonging to the control group had complaint of temporary skin rash and pruritis, but these symptoms disappeared the next day. No adverse events were observed in all the other subjects.

Discussion

Recent studies[8,10] have verified the effect of acupuncture on hot flashes, but definitive significance on differences between acupunctural effect and that of sham or minimal acupuncture has not been elucidated yet. In this study, there were significant improvement in hot flash VAS, which reflects a perceived level of hot flash, frequency and number of occurrence of hot flash for both the study group and control group. Furthermore, these authors could verify improvement on hot flash-accompanied sweating and Kupperman's Index and MENQOL, the menopause-related scales. However, there were statistically no significant differences between these groups in the longitudinal and baseline analysesat the end of 8 week treatment. Nevertheless, these authors observed statistical significance of differences in therapeutic effects between these two groups in each phase of treatment. From hot flash VAS values, the primary assessment index, the differences in therapeutic effect by frequencies of hot flash between these two groups were examined using Wilcoxon Test. Significant effects of TKMA were verified after 2nd (4th visit), 3rd (5th visit), 6th (8th visit), and 7th treatment (9th visit). Also, the results of making comparisons of the mean values of frequency of hot flash per week measured every week of treatment showed that study group had a higher frequency during the 1st week of treatment. However, it improved continuously making us to anticipateremarkable significance. Furthermore, the number of frequency of hot flashes for study group and control group became reversed after the 4th week of treatment. Thus, it was observed that study group had better efficacy than control group did. Also, mean duration (min) per attack of hot flash, another secondary assessment index, was compared every week of treatment. The results showed both groups had a similar decrease in duration. However, statistical significance could not be discovered.

This trial was carried out in the transitional period from late spring to very hot summer, making it difficult to verify treatment effect. The mean values of sweating VAS (100mm), a secondary assessment index, having such prospect of difficulty of therapeutic verification, were compared every week of treatment. Unlike such anxiety, both groups showed an effect of improvement. Moreover, subjects perceived slightly more severely during 1st week of treatment in this index, but sweating VAS scores remarkably improved by 8th week of treatment. Particularly, an early relatively severe condition became reversed and sweating VAS scores

continuously improved for the better. Thus, a relative superiority was observed. There were no significant results in the longitudinal and baseline analyses. However, SW VAS values after the 3rd treatment (The 5th Visit) showed significant differences between groups. It forecasted that TKMA could show faster effect than that of MA, thus forecasting more efficient possibility.

The mean values of sleep disturbance VAS (100mm), a secondary assessment index, for each group were compared every week of treatment. The results showed that the study group had remarkably low scores as opposed to the control group at the 8th week of treatment. Aspect of improvement also showed a uniform condition.

Acupoints were selected in accordance with formal traditional Korean acupuncture. These two groups have differences merely in the level and method of stimulation. The study group showed a superior effect in the period from an early treatment phase, in which therapeutic effect was minimal, to the early and middle phases, in which therapeutic effect might just begin to occur. Owing to the therapeutic effect following accumulation of minimal stimulations, as this study approached the completion of the trial, similar therapeutic effects would be observed. Besides, in cases of the study group, improvement of each index might show almost uniform aspect. However, the control group showed a decreased levelof improvement or a large reduction effect as shown in box plot. Thus, therapeutic effect of TKMA seemed favorable in quality. It concurs with the significance of *de-Qi* stimulations perceived in the clinical field. Accordingly, if continuous studies wouldbe carried out by expanding subject groups and by making improvement of an allocation method, which could increase the extent of consistency on strength, frequency and duration between the two groups, significance of study results could be further risen. Since no subjects had complaints of any serious adverse events, these authors could verify that acupunctural treatment would be quite safe.

Conclusion

A single-blinded randomized clinical test was carried out on treatment of acupuncture, through which optimally-stimulated traditional Korean acupuncture and minimally stimulating acupuncture for hot flashes and related symptoms of postmenopausal women. From the result, very effective symptomatic improvements of hot flashes and related symptoms in both groups could be ascertained. From the final results attained after 8 weeks of treatment, distinctive differences between these two groups could not be verified. Nevertheless, with respect to the extent of hot flash and sweating, the statistical significance that study group had more prompt effect in the early treatment phase could be verified. Moreover, the statistical significance on frequency and duration of hot flash could not be ascertained. However, these authors could verify subjectively a more uniform effect in the study group. Thus, through improvement in clinical test methods and expansion of study groups in the days ahead, the anticipation is that an objective verification of the efficacy of optimally-stimulated Korean traditional acupuncture indicated for hot flashes may be possible.

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