

The Effect of Sa-am acupuncture on Knee Osteoarthritis

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Running head : Effect of Sa-am acupuncture on knee OA

Abstract

Objective : Acupuncture has been widely used throughout the world for the treatment of knee osteoarthritis (knee OA). This study investigated whether acupuncture, particularly Sa-am acupuncture, could be effective in relieving pain and improving the symptoms of knee OA.

Method : This study was conducted as a prospective, randomized, controlled, and patient- and investigator-blinded clinical trial. Forty volunteers with knee OA participated in the study. All participants were screened through an inclusion and exclusion criteria. Thirty four participants completed the clinical trial. In total, forty subjects were randomly selected to receive Sa-am acupuncture. Eight sessions of acupuncture were given at the contralateral side of the problematic knee for 4 weeks. Korean translation of Western Ontario and McMaster Universities Osteoarthritis Index (KWOMAC) scores were measured twice: at the beginning and end of the clinical trial period. Both the Patient Global Assessment and physical health scores based on the 36-Item Short-Form Health Survey were also used to measure the results.

Results : Compared to the pre-trial scores, the Sa-am acupuncture group (n=34) showed a significant decrease in KWOMAC total scores according to a paired *t*-test. The Sa-am acupuncture group also showed significant improvement in the Patient Global Assessment when compared to the pre-trial.

Conclusions : Sa-am acupuncture for knee OA resulted in an improved KWOMAC total score. This was mostly driven by the function component score that was greatly affected by acupuncture. However, further studies with expanded designs are needed to solidify this finding with scientific rigor.

Keywords : Acupuncture, Osteoarthritis, KWOMAC, SF-36, Patient Global Assessment

Introduction

Acupuncture been used for centuries as a treatment for a wide range of human

diseases. The points on the human body that acupuncture utilizes, called acupoints, have been established over time. In addition, new acupoints have been developed with the progress of modern oriental medicine. In recent years, Western medical circles have become increasingly

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interested in the scientifically proved therapeutic effect of acupuncture¹⁻³).

When acupoints are activated by needling, a series of responses arise from the stimulations that are known to affect the central and peripheral systems^{4,5}. To study the impact of acupuncture on the central nervous system (CNS), functional magnetic resonance imaging (fMRI) has been used^{1,2,4}. Based on these investigations, it has been reported that acupuncture might modulate the activity of the limbic system and subcortical gray structures⁶. Furthermore, electro-acupuncture has been known to exert anti-inflammatory effects mediated by peripheral opioids in inflammation models⁵. This implies that acupuncture could have a beneficial effect on both the central and peripheral systems.

Osteoarthritis (OA) is a chronic progressive disease that is difficult to manage and control, discouraging both patient and medical professional. Once OA appears in the knee, it results in a progressive deterioration of the pathological region of the knee, often accompanied by inflammation⁷. Although there is no complete cure for OA until now, a variety of treatments, including acupuncture, are available for the relief of its symptom with few side effects⁸.

Acupuncture methods are classified

according to the sites intended for needle insertion, the combination of acupoints used, and the manipulation of the needle⁹. Sa am acupuncture, categorized as an acupuncture method that selects acupoints remote from pain regions based on meridian theory of acupuncture methods, has commonly been used in clinical treatment¹⁰. It was developed by a monk Sa am about 400 years ago, and has been handed down as a unique Korean acupuncture method¹⁰. Sa am acupuncture is thought to have originated from the theory of “I Ching” and “Yin Yang Five Element Theory”, and additionally to have been influenced by medical scholars¹⁰. The method is one of several acupuncture methods to prescribe in the relation of “Five Phases” with the affected meridian¹¹. Because the method is applied to the patient by tracing the fundamental cause of disease, different acupoints can be appointed for even the most common illnesses¹¹. Sa-am acupuncture will be further explored in the discussion section.

The pathological regions and acupoints located near pain regions in OA have been selected in previous studies that investigated the therapeutic effects of Sa-am acupuncture in pain relief¹²⁻¹⁴. Therefore, the pain relief effect of Sa-am acupuncture, which selects acupoints

remote from pain regions by the classification and the analysis of symptoms through the meridian, needs to be studied in OA. This study investigated whether acupuncture, particularly Sa-am acupuncture, could be effective in relieving pain and improving the symptoms of knee OA.

Methods

1. Target Population

Male and female volunteers were recruited by advertisements to participate in this study (Fig. 1). All patients signed an informed consent. This study was carried out under the review of an ethics committee made up of oriental medical doctors and a religious scholar.

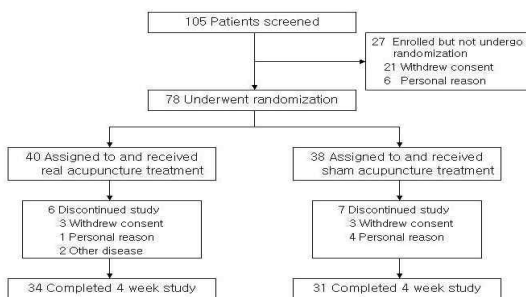


Fig. 1. Participant Flowchart.

Seventy-eight subjects were divided into each group using a random table, the Sa-am acupuncture group with 40 participants and the sham group with 38. During the trial, the number of dropouts was 6 in the Sa-am group and 7 in the sham group. The dropouts were classified as follows: in the Sa-am group, 3 by withdrawal of consent (denial of participation and treatment), 2 because of other diseases, and 1 for personal reasons; in the sham group, 3 by withdrawal of consent (denial of participation and treatment) and 4 for personal reasons.

Inclusion criteria:

- Female or male over the age of 50 (59.5 ± 5.3 years).
- Diagnosis of OA of the knee (American College of Rheumatology criteria applied).
- Duration of OA more than six months.
- Documented radiographic changes of osteoarthritis (Kellgren-Lawrence grade of 1 or more).
- Signed informed consent.

Exclusion criteria:

- Female or male over the age of 70.
- Intra articular corticosteroid injection in the knee within four weeks immediately preceding entry into the study.
- Severe chronic or uncontrolled concomitant illness.
- Diagnosis of rheumatoid arthritis of the knee.
- History or clinical indications of bleeding diathesis and cardiovascular disease, including current use of anticoagulants.
- Allergy to metal.
- Previous treatment with acupuncture within four weeks prior to entry into the study.
- Taking hormone medications.

2. Study design

Randomization:

The subjects were divided into Sa-am acupuncture and sham acupuncture groups using a random table generated by SPSS 12.0. Two operators licensed in oriental medicine, having over seven years' experience in clinical treatment, performed the acupuncture. The subjects of both groups were assigned to two operators, and each established operator throughout the trial administered both Sa am and sham acupunctures.

Blinding and materials:

Because it was impossible to blind the operators, both all subjects and the analyzers for the data were blinded. Disposable stainless steel needles were used for the Sa-am acupuncture group (DongBang Acupuncture, Korea, 0.25 × 40 mm). The patients of the sham group could not distinguish sham acupuncture from Sa-am acupuncture because Park sham needle had been used for the sham acupuncture¹⁵⁾.

3. Procedure

In the Sa-am acupuncture group, Sa-am acupuncture was performed at the selected acupoints as shown in Table 1. Patients were acupunctured two times per week over a four-week period. The depth of Sa-am acupuncture was about 1 mm - 5 mm, and the duration of the acupuncture was about 20 minutes. Twirling reinforcement reduction and nine six reinforcement reduction methods were used as a reinforcement reduction method, and the patients reported feeling deqi (needle sensation). Acupoint, frequency and duration of the operation on the sham group with Park sham needle were identical to the Sa-am group, and deqi was mimicked¹⁵⁾.

The acupoints in Sa-am acupuncture are determined from the method that has been passed down through generations by Sa-am practitioners, as shown in Table 2 and 3¹¹⁾. The acupoints appointed by "Five Phases" in the Sa-am acupuncture method is shown in Table 2. For each treatment, Sa-am acupuncture uses a set of four acupoints (two acupoints for tonifying and two acupoints for purging) selected from "Five Phases" (Table 3).

Table 1. The acupoints of Sa-am determined according to the point of pain.

The point of pain	Sa-am	Acupoints
Pain at upper and dorsal to the medial condyle of the tibia	Spleen (+)	^a Rf: HT8, SP2 ^b Rd: LR1, SP1
Pain at the medial end of the popliteal crease, dorsal to the medial condyle of the tibia	Liver (+)	^a Rf: KI10, LR8 ^b Rd: LU8, LR4
Pain at ventral and distal to the head of the fibula	Gall bladder (+)	^a Rf: BL66, GB43 ^b Rd: LI1, GB44
Pain in the middle of the popliteal fibula crease	Urinary bladder (+)	^a Rf: LI1, BL67 ^b Rd: ST36, BL40
Pain at the lower edge of the patella, lateral to the patella ligament	Stomach (+)	^a Rf: SI5, LI5 ^b Rd: GB41, ST43
Pain in the medial part of the popliteal fossa between the tendons of the semi tendinosus and semi membranous muscles	Kidney (+)	^a Rf: LU8, KI7 ^b Rd: SP3, ST41

^aRf: Reinforcement (+), needle turned right nine times.
^bRd: Reduction (-), needle turned left six times.

Table 2. The acupoints appointed by “Five Phases” in Sa-am acupuncture method^a.

Phases	Jeong	Hyoung	Su	Gyoung	Hap	
Meridian	Yin	Wood	Fire	Earth	Metal	Water
	Yang	Metal	Water	Wood	Fire	Earth
LU	LU11	LU10	LU9	LU8	LU5	LU5
LI	LI1	LI2	LI3	LI5	LI11	LI11
ST	ST45	ST44	ST43	ST41	ST36	ST36
SP	SP1	SP2	SP3	SP5	SP9	SP9
HT	HT9	HT8	HT7	HT4	HT3	HT3
SI	SI1	SI2	SI3	SI5	SI8	SI8
BL	BL67	BL66	BL65	BL60	BL40	BL40
KI	KI1	KI2	KI3	KI7	KI10	KI10
PC	PC9	PC8	PC7	PC5	PC3	PC3
TE	TE1	TE2	TE3	TE6	TE10	TE10
GB	GB44	GB43	GB41	GB38	GB34	GB34
LR	LR1	LR2	LR3	LR4	LR8	LR8

^aThis method is based on traditional Korean medicine¹⁷. The Five Phases, indicated as Jeong, Hyoung, Su, Gyoung and Hap, are all located in the extremities of the four limbs. Each of them has a type of five elemental properties, which is distinguished from the type of attached meridian.

Table 3. The acupoints distributed by ^aJeong-Gyeok and ^bSeung-Gyeok in Sa-am acupuncture method.

Meridian	^a Jeong Gyeok				^b Seung Gyeok			
	Reinforcement		Reduction		Reinforcement		Reduction	
LU	SP3	LU9	HT8	LU10	HT8	LU10	KI10	LU5
LI	ST36	LI11	SI5	LI5	SI5	LI5	BL66	LI2
ST	SI5	ST41	GB41	ST43	GB41	ST43	LI1	ST45
SP	HT8	SP2	LR1	SP1	LR1	SP1	LU8	SP5
HT	LR1	HT9	KI10	HT3	KI10	HT3	SP3	HT7
SI	GB41	SI3	BL66	SI2	BL66	SI2	ST36	SI8
BL	LI1	BL67	ST36	BL40	ST36	BL40	GB41	BL65
KI	LU8	KI7	SP3	KI3	SP3	KI3	LR1	KI1
PC	LR1	PC9	KI10	PC3	KI10	PC3	SP3	PC7
TE	GB41	TE3	BL66	TE2	BL66	TE2	ST36	TE10
GB	BL66	GB43	LI1	GB44	LI1	GB44	SI5	GB38
LR	KI10	LR8	LU8	LR4	LU8	LR4	HT8	LR2

^aJeong-Gyeok tonifies the mother organ of the deficient organ. ^bSeung-Gyeok purges the son organ of the excessive organ. There are two acupoints that use reinforcement manipulation for tonifying and two acupoints that use reduction manipulation for purging. Therefore, Sa-am acupuncture uses a set of four acupoints selected from “Five Phases”. In each of these, two tonifying and two purging, one is in its own meridian and the other is in the meridian of the mother or son.

4. Measurement of the pain relief effects of Sa-am acupuncture

To estimate the pain relief effects of Sa-am acupuncture on OA of the knee, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) translated into Korean (Korean WOMAC, KWOMAC) was used as a measurement of primary outcomes following four weeks of treatment¹⁶. As a measurement of secondary outcomes, the 36-Items Short Form Health Survey (SF-36) was used, estimating the quality

of life at pre trial and post trial. In addition, the Patient Global Assessment was used to assess the improvement of the symptoms after four weeks of treatment. The measurements were carried out with the evaluator of the subject groups blinded.

5. Statistical analysis

The number of subjects was calculated on the basis of Berman's data which showed a mean difference of -14.0 ± 20.5 (mean \pm SD) in the WOMAC score between both acupuncture groups¹⁷⁾. We estimated that 33.62 subjects would be needed in each group to give 80% power to demonstrate a statistically significant improvement in total KWOMAC score between the Sa-am and sham acupuncture groups. This statistical value was calculated by applying an intention to treat analysis. An independent *t*-test and a Mann-Whiney U-test were performed for both groups to confirm the possibility of success of randomized allocation and to compare the characteristics of the participants. Both an independent *t*-test and ANCOVA analysis were applied for the KWOMAC score, whereas only independent *t*-test for the SF-36 score. A Mann-Whiney U-test using a non-parametric system was used for the Patient Global Assessment. As the

KWOMAC total score had been repeatedly measured, the therapeutic effect by the frequency of acupuncture trial needed to be considered. Accordingly, the KWOMAC total score was analyzed by mixed effect model using an SAS mixed procedure. SPSS 12.0 was used for the Mann-Whiney U-test, and an SAS 8.2 statistical package was used for all other statistical analyses.

Results

The study's aims were to evaluate the pain relief effect of Sa-am acupuncture for degenerative OA. The subjects who had been suitable for both inclusion criteria and exclusion criteria from the recruited participants were selected. (The participant flowchart is shown in Figure 1.) With their consent, this study was initiated as double blinding for both all subjects and analyzer as a randomized controlled trial. Seventy eight subjects were divided into each group using a random table, the Sa-am acupuncture group with 40 participants and the sham group with 38. The demographic and baseline characteristics for both groups are shown in Table 4. Both groups have shown similar characteristics, with their independence verified using both general features and baseline outcomes. This

Table 4. The demographic and baseline characteristics of the participants^a.

Characteristic	Sa-am acupuncture group (n=40)	Sham acupuncture group (n=38)	Total (n=78)
Age (years)	58.9 ± 5.6	60.0 ± 5.0	59.4 ± 5.3
Gender			
Female	33 (82.5%)	31 (81.6%)	64 (82.0%)
Male	7 (17.5%)	7 (18.4%)	14 (18.0%)
Total	40 (100.0%)	38 (100.0%)	78 (100.0%)
Weight (Kg)	64.6 ± 7.2	66.1 ± 8.8	65.3 ± 8.0
Height (cm)	159.5 ± 5.4	159.2 ± 7.0	159.4 ± 6.2
BMI	25.4 ± 2.7	26.0 ± 2.5	25.7 ± 2.6
Smoking (persons)	1 (2.5%)	2 (5.3%)	3 (3.8%)
Drinking (persons)	6 (15%)	6 (15.8%)	12 (15.4%)
Medication (persons)	11 (27.5%)	7 (18.4%)	18 (23.1%)
K-L grade (persons)			
1	10 (25.0%)	12 (31.6%)	22 (28.2%)
2	12 (30.0%)	10 (26.3%)	22 (28.2%)
3	11 (27.5%)	11 (28.9%)	22 (28.2%)
4	7 (17.5%)	5 (13.2%)	12 (15.4%)
Total	40 (100.0%)	38 (100%)	78 (100.0%)
Sasang constitution (persons)			
Taeyang	0 (0%)	0 (0%)	0 (0%)
Taeum	17 (42.5%)	15 (39.5%)	32 (41.0%)
Soyang	9 (22.5%)	6 (15.8%)	15 (19.2%)
Soeum	3 (7.5%)	2 (5.3%)	5 (6.4%)
Unkown	5 (12.5%)	10 (26.3%)	15 (19.2%)
Total	34 (85%)	33 (86.8%)	67 (85.9%)
Target knee (persons)			
Right	25 (62.5%)	20 (52.6%)	45 (57.7%)
Left	15 (37.5%)	18 (47.4%)	33 (42.3%)
Total	40 (100%)	38 (100%)	78 (100%)
Acupoints (persons)			
Spleen(+)	26 (65%)	25 (65.8%)	51 (65.4%)
Liver(+)	7 (17.5%)	8 (21.0%)	15 (19.2%)
Stomach(+)	3 (7.5%)	3 (7.9%)	6 (7.7%)
Gall bladder(+)	2 (5%)	0 (0%)	2 (2.6%)
Urinary bladder(+)	2 (5%)	2 (5.3%)	4 (5.1%)
Kidney(+)	0 (0%)	0 (0%)	0 (0%)
Total	40 (100%)	38 (100%)	78 (100%)
Outcomes			
KWOMAC pain score	10.4 ± 4.6	8.6 ± 4.4	
KWOMAC stiffness score	4.6 ± 2.1	3.9 ± 2.4	
KWOMAC function score	38.1 ± 14.7	31.7 ± 15.6	
KWOMAC total score	53.0 ± 20.4	44.1 ± 21.6	
SF 36 physical score	33.4 ± 18.1	36.7 ± 17.1	
SF 36 mental score	44.7 ± 20.8	44.8 ± 18.4	
SF 36 total score	39.1 ± 18.4	40.8 ± 16.6	

^aThere were no statistical differences between the Sa-am acupuncture group and the sham group at the baseline. The values expressed with a plus/minus sign are means ± SD. KWOMAC=Western and McMaster Universities Osteoarthritis Index translated into Korean. SF-36=36-Item Short Form Health Survey.

implies that the randomized assignment of the subjects was suitable for this clinical study. During the trial, the number of dropouts was 6 in the Sa-am group and 7 in the sham group, as shown in Figure 1. The dropouts were classified as follows: in the Sa-am group, 3 by withdrawal of consent (denial of participation and treatment), 2 because of other diseases, and 1 for personal reasons; in the sham group, 3 by withdrawal of consent (denial of participation and treatment) and 4 for personal reasons.

1. 4 weeks' Sa-am acupuncture has no effect on OA through KWOMAC index scores by ANCOVA analysis.

The pre-trial KWOMAC total score was 53.0 ± 20.4 in the Sa-am acupuncture group, and its total score after the four weeks'trial was 43.4 ± 22.0 . Thus, the change in the KWOMAC total score within the Sa-am group was -9.6 ± 17.5 . The change of the KWOMAC total score in the sham group was -2.5 ± 13.5 (Table 5). The change of the KWOMAC function score was -6.8 ± 12.7 in the Sa-am group and -1.4 ± 10.9 in the sham group, showing significance ($p=0.0478$). These results reveal that the changes in the Sa am group show a significant amelioration compared to the sham group

(statistical significance $p=0.0211$). However, there was no significance in KWOMAC total and KWOMAC function scores by ANCOVA analysis. There was no significant change in either group in the cases that the changes of the KWOMAC pain and stiffness scores had been calculated, as shown in Table 5. These results on KWOMAC scores indicate that Sa-am acupuncture has a no therapeutic effect on OA of the knee.

2. 4-weeks' Sa-am acupuncture has no effect on OA through SF 36 score.

The pre-trial SF-36 total score was 39.1 ± 18.4 in the Sa am acupuncture group, and its total score after the four weeks'trial was 46.8 ± 18.6 . In the sham group, the pre trial SF-36 total score was 40.8 ± 16.6 , and its total score after the four weeks'trial was 46.5 ± 18.6 . The change of the SF-36 total score was 7.7 ± 15.3 in the Sa-am group and 5.7 ± 9.9 in the sham group, showing no significance as shown in Table 5 ($p=0.4839$). In addition, the SF-36 physical and mental health scores also did not show statistical significance between both groups (Table 5).

Table 5. The changes of the mean score between pre-trial baselines and post-trial outcomes.

	Sa-am acupuncture group	Sham acupuncture group	<i>P</i> -value
^a KWOMAC			
KWOMAC total	-9.6 ± 17.5	-2.5 ± 13.5	0.0211
KWOMAC pain	-2.0 ± 4.3	-0.9 ± 3.0	0.1735
KWOMAC stiffness	-0.8 ± 2.1	-0.2 ± 1.6	0.2004
KWOMAC function	-6.8 ± 12.7	-1.4 ± 10.9	0.0478
^b SF-36			
SF-36 total	7.7 ± 15.3	5.7 ± 9.9	0.4839
SF-36 physical health	8.5 ± 13.1	5.0 ± 13.3	0.2562
SF-36 mental health	7.0 ± 19.7	6.4 ± 12.8	0.8567

The result and *P*-value from independent *t*-tests of change from baselines. The values presented with a plus/minus sign are means ± SD. ^aKWOMAC = Western Ontario and McMaster Universities Osteoarthritis Index translated into Korean language. ^bSF-36=36-Items Short Form Health Survey.

3. 4-weeks' Sa-am acupuncture has an effect on OA through Patient Global Assessment

A Patient Global Assessment was made out by the subjects themselves at the end of the four weeks' trial in order to evaluate the condition of OA in their knee. Among the 35 subjects in the Sa-am acupuncture group, the distribution of the Patient Global Assessment was 17.1% in "Excellent", 20% in "Good", 42.9% in "Fair", and 20% in "Poor". The distribution among the 33 subjects in the sham group was 9.1% in "Excellent", 9.1% in "Good", 39.4% in "Fair", and 42.4% in "Poor". This result reveals that there is a significance between both

groups relative to KWOMAC scores and SF 36 scores as shown in Table 6 (p=0.030).

Table 6. Patient Global Assessment at 4 weeks in participant outcomes.

	Poor	Fair	Good	Excellent	<i>P</i> -value
Sa-am acupuncture group	7	15	7	6	0.030
Sham acupuncture group	14	13	3	3	

The result and *P*-value from Mann Whitney U-test at 4 weeks. Numbers indicate the number of subjects that rated each level of improvement of the disease.

4. Test by mixed effect via SAS mixed procedure

We analyzed repeatedly measured KWOMAC total scores using a mixed-model procedure of SAS. Although pre-trial measurements of the KWOMAC total scores were changed, we analyzed whether Sa-am acupuncture on OA of the knee was effective by using them as a variable. A heterogeneous general linear model was selected because it included the largest BIC (Bayesian Information Criteria) among the eight mixed model. The results show that "Group (p=0.0423)" and "Gender (0.0336)" can be a possible variable for the change of the KWOMAC total score by showing statistical significance. However, other variables did not have a significant effect on the change of the KWOMAC total score. In addition, there was no interaction among the variables, which included time, age,

and the oriental medical doctor (Table 7). This result shows that Sa-am acupuncture can have a significant effect on OA of the knee in spite of the change of variables just as estimated in independent *t*-test. However, as these results are based on KWOMAC scores, no significance of KWOMAC scores by ANCOVA analysis may have an influence on these results. The difference of change of the KWOMAC total score between both groups was estimated as low as 5.3 in the Sa-am group compared to the sham group.

Table 7. Test by Mixed Effects.

Variable	F-value	P-value
Group	4.28	0.0423
Time	1.68	0.1993
Doctor	0.95	0.339
Medication	1.22	0.2727
Age	1.11	0.2960
Gender	4.71	0.0336
^a Group Time	0.16	0.6889
^b Group Doctor	0.00	0.9464
^c Group Medication	0.50	0.4813
^d Group Age	0.51	0.4766
^e Group Gender	2.08	0.1541

^aGroup Time: the application of both group and time as variables, ^bGroup Doctor: the application of both group and doctor as variables, ^cGroup Medication: the application of both group and medication as variables, ^dGroup Age: the application of both group and age as variables, ^eGroup Gender: the application of both group and gender as variables.

Discussion

Sa-am acupuncture follows the principle of Yin and Yang¹¹⁾. Any deficiency needs to be tonified and any excess purged for

balance between Yin and Yang to be achieved, resulting in balance of the organ. This is the most important objective for treatment in the field of Korean medicine. Sa-am acupuncture is based on the theory of the “mother-son relationship”, which means that a mutual affecting relationship exists among the five elements¹¹⁾. Sa-am acupuncture puts these basic rules into practice through the reinforcement or reduction manipulation of the target organ for tonifying or purging¹¹⁾.

In Sa-am acupuncture there are two main principles, Jeong-Gyeok for reinforcing and Seung-Gyeok for reducing, applied by a set of four acupoints. The principle of Jeong-Gyeok is the tonifying mother acupoint of the mother meridian and that of its own meridian, in concurrence with the purging control acupoint of the control meridian and that of its own meridian. The principle of Seung-Gyeok is the tonifying control acupoint of the control meridian and that of its own meridian, in concurrence with the purging son acupoint of the son meridian and that of its own meridian. Ultimately, Sa-am acupuncture controls the balance among the five elements, and aims to be in harmony with the target organ during treatment¹¹⁾.

In previous studies, acupoints

surrounding a sick knee joint were largely selected for acupuncture on OA. Berman et al. selected GB34, SP9, ST36, ST35, UB60, KI3 and GB39¹²⁾. Vas et al. picked up GB34, ST40, ST36, EX LE5, SP9, LI4, SP6 and KI3¹⁸⁾. Tukmachi et al. acupunctured at LI4, BL40, BL57, GB34, SP9, ST36 and LR3¹⁹⁾. Sa-am acupuncture, which is needed at acupoints remote from sick regions following the meridian theory, has been widely adopted in Korean traditional clinical medicine. This study was designed to assess the pain relief effect of Sa-am acupuncture on OA of the knee on the basis of the KWOMAC score, SF-36, and Patient Global Assessment. The Sa-am acupuncture group showed more significant pain relief effect on OA than the sham group through the KWOMAC total score in independent t test, but not in ANCOVA analysis. This result indicates that Sa-am acupuncture treated for 4-weeks has no effect of pain relief in OA of the knee as similar to the previous study using sham needles for sham groups²⁰⁾. However, it was reported that there had been a significant difference in the studies using the WOMAC score at different acupoints from Sa-am acupuncture^{12,18,21-23)}. This presents the requirement of following study to use Sa-am acupuncture, reflecting the duration

of treatment, and the number and the baselines of patients. When the Patient Global Assessment was used, it showed that the Sa-am group experienced greater improvement than the sham group, which is similar to previous study¹²⁾. However, there was no significant effect of Sa-am acupuncture when the SF-36 was measured. This result is similar to a previous study which showed significant improvement in the WOMAC score, but not in the SF-36 physical score¹²⁾.

It is important to note how the sham control group was treated to evaluate the effect of clinical acupuncture in this study. The control group of OA subjects received either sham acupuncture or minimal acupuncture or physical therapy or waiting list or education in the previous studies^{12,17,20,21,24,25)}, and Park sham acupuncture was used for the sham control group in this study¹⁵⁾. Park sham needle was selected to blind the sham subjects, but the KWOMAC total score decreased as slight as -2.5 ± 13.5 in the sham group after the 4-weeks' trial. This indicates that the sham needle acupunctured at the same acupoints as the Sa-am group may have had a pain relief effect on the sham group. Nevertheless, the change of the KWOMAC total score in the Sa-am group decreased more than that of the sham group (Table 5).

Moreover, there has been seemed a significant pain relief effect of Sa-am acupuncture even when considering variables such as group and gender, but ultimately ANCOVA analysis for KWOMAC scores showed no significance of pain relief effect of Sa-am acupuncture treated for 4-weeks for the OA of the knee.

Conclusion

Sa-am acupuncture did not show the effect of pain relief in OA of the knee evident in the fact that the Sa-am acupuncture group did not show greater improvement in the functions of knee joint of the patients compared to the sham group by ANCOVA analysis. More studies are needed reflecting the duration of treatment, and the number and the baselines of patients.

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