

Comparison of Warm-Needling and Acupuncture for Knee Osteoarthritis: A Randomized Controlled Trial

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퇴행성 슬관절염에서의 온침과 침의 효능 비교 연구

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Objectives : The aim of this study was to investigate whether warm-needling is more effective than acupuncture in relieving the pain and improving the symptoms of knee osteoarthritis(OA). **Methods :** 76 volunteers with knee OA participated in the study. The subjects were randomly assigned to one of two groups. One group received warm-needling(n=38), while the other group received acupuncture(n=38). Sixteen sessions of warm-needling or acupuncture were conducted on the pain region of each problematic knee over a period of 8 weeks. The Western Ontario and McMaster Universities Osteoarthritis Index(WOMAC) scores, physical health score based on the 36-Item Short-Form Health Survey(SF-36) and the Global Assessment(PGA) was measured. **Results :** Compared to the acupuncture group, the warm-needling group showed a significant decrease in pain, function, and total WOMAC scores according to the Mann-Whitney U-test. The PGA scores of the warm-needling group also showed a significant improvement compared to the acupuncture group. **Conclusions :** Warm-needling showed a greater pain relief effect on knee OA compared to the acupuncture group. These findings suggest that warm-needling may be a promising alternative therapy for treating knee OA.

Key words : warm-needling, acupuncture, arthritis, WOMAC, SF-36, patient global assessment

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Introduction

Knee osteoarthritis(OA) is a chronic progressive disease that is difficult to manage and control, discouraging both patients and medical doctors. Once knee OA develops, it results in a progressive deterioration of the pathological region of the knee, often accompanied by inflammation. Curative therapies for knee OA are only partially successful. Therefore, both pharmacological and non pharmacological interventions are used in order to reduce the pain and functional limitations¹.

One of the most important causes of knee OA, from an Eastern medical point of view, is external wind-cold-dampness(風寒濕)². An external wind-cold-dampness syndrome results in pain, edema, numbness, deformation, and difficulty in bending and stretching the knee joint. The knee OA treatment used in Korean medicine includes acupuncture, moxibustion, cupping, warm needling, and herbal medication. Warm needling therapy(Fig. 1) is described in the Zhenjiuzishengjing(鍼灸資生經)³ as combining the effects of acupuncture and moxibustion in a single treatment. In this technique, dried and pounded Folium Artemisiae Argyi(Ai Ye, or mugwort) is attached to the handle of the acupuncture needle after it has been inserted into an acupuncture point². The mugwort is then lit and allowed to burn. Typically, there is about an inch between the surface of the skin and the ball

of burning mugwort so that the warmth is conducted from the handle of the needle to the needle itself and then to the surrounding tissue². This method is primarily appropriate for vacuity cold diseases and wind-damp impediment conditions. Therefore, it is used mainly for diseases characterized by an external wind-cold-dampness and chronic deficiency pattern. Examples of these include arthritis with soft tissue inflammation and musculoskeletal diseases such as ligament sprain, traumatic inflammation, and lumbago^{4,5}.

In previous reports, warm needling has been used to treat knee OA⁶, lumbar intervertebral disc herniation^{7,8}, sciatica⁹, and myasthenia gravis¹⁰. It has been suggested that warm needling could be a useful therapeutic approach for pain relief. In order to assess the efficacy of warm needling, acupuncture was selected as a positive control group. Acupuncture efficacy and safety issues associated with knee OA patients have been addressed in several clinical trials¹¹⁻¹⁴. In addition, one recent systematic review of seven randomized controlled trials with a total of 393 patients found acupuncture effective in reducing pain; yet the results were inconclusive regarding its efficiency in improving joint function¹⁵. This report by Berman et al.¹² was based on small sample sizes, local acupuncture points, and a randomized controlled trial. The significant differences in the total the Western Ontario and McMaster Universities Osteoarthritis Index(WOMAC) scores at 4 and 8 weeks indicated acupuncture's ability to ameliorate the patients' symptoms. In choosing the acupoints, we followed the method used by Berman et al.¹¹ and Li et al.⁶ Additional acupoints were selected based on the occurrence of tenderness and pain along involved meridians.

The goals of this investigation were to determine whether warm needling is a clinically effective method for relieving pain in patients with knee OA and to compare the therapeutic effects of warm needling with those of acupuncture.

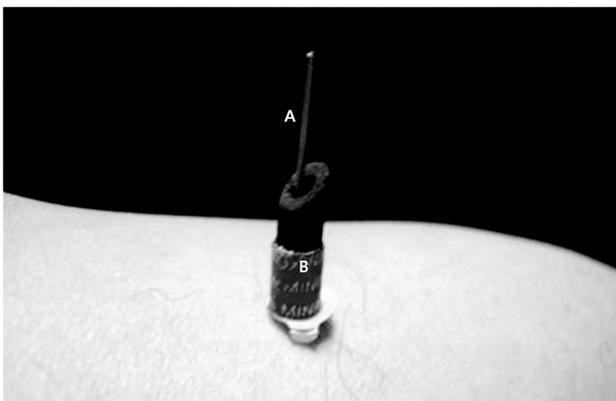


Fig. 1. Features of warm needling.

At first, an acupuncture needle was inserted in the acupoint(A). Then, the moxa stick(B) was attached on top of the inserted needle by sliding it onto the needle, using the previously prepared hole in the stick.

Materials and Methods

1. Target population

Male and female volunteers were recruited through advertisements. After all patients provided their informed consent, this study was carried out under the supervision of an ethics committee of Eastern medical doctors and a religious scholar(Kyungwon Gil Oriental Medical Hospital). All subjects were screened through the following set of inclusion and exclusion criteria:

Inclusion criteria:

- Female or male over the age of 50.
- Diagnosis of knee OA(American College of Rheumatology criteria applied).
- Knee OA duration of over 6 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 the four-week period immediately preceding the beginning of the trial.
- 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 anti-coagulants.
- Allergy to metal.
- Blood test: Rheumatoid Factor \geq 1 : 40, Erythrocyte Sedimentation Rate \geq 40 mm/hour.
- Previous treatment with acupuncture within four weeks of entry into the study.
- Taking hormone medications.
- Fears related to moxibustion or warm sensations.

The subjects that met both the inclusion and exclusion criteria were selected(the subject flowchart is shown in Fig. 2). In total, 76 volunteers with knee OA participated in the study. The subjects were randomly divided into a warm

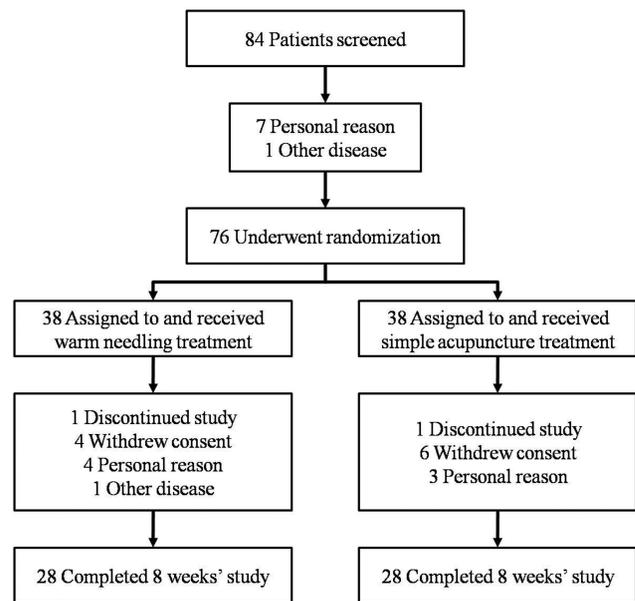


Fig. 2. The flowchart of participants.

needling and an acupuncture group; the demographic and baseline characteristics for both groups are shown in Table 1. The subjects were not acupuncture naïve since acupuncture treatment is common in South Korea. Both groups exhibited similar characteristics in their general features and baseline outcomes, showing that the randomized assignment of the subjects was appropriate for this clinical study. During the trial, the warm needling and acupuncture groups each had 10 dropouts as can be seen in Fig. 2. In the warm needling group the dropouts were classified as follows: 4 by withdrawal of consent(denial of participation and further treatment), 1 because of other diseases, 1 discontinued study, and 4 for personal reasons. In the acupuncture group, the dropouts were classified as follows: 6 by withdrawal of consent(denial of participation and further treatment), 1 discontinued study, and 3 for personal reasons.

2. Study design

1) **Randomization:** The subjects in inclusion criteria were divided into a warm needling and an acupuncture group through a random table generated by SPSS 12.0. Two practitioners licensed in Korean medicine, each with over seven years of experience in clinical treatment, performed the acupuncture and warm needling¹⁶⁾. The subjects of both

Table 1. Subject Demographic and Baseline Characteristics*

Characteristic	Warm needling (n=38)	Simple acupuncture (n=38)	Total(n=76)
Age(yr)	60.24 [†]	60.05	60.14
Gender			
Female	37(97.4%)	32(84.2%)	64(81.6%)
Male	1(2.6%)	6(15.8%)	14(18.4%)
Total	38(100%)	38(100%)	76(100%)
Weight(kg)	60.52	59.44	59.98
Height(cm)	157.42	159.32	158.37
BMI(kg/m ²)	24.42	23.41	23.92
Smoking	0(0%)	3(7.8%)	3(3.9%)
Drinking	7(18.4%)	16(42.1%)	23(30.2%)
Medication	5(13.1%)	7(18.4%)	12(15.7%)
K-L grade			
1	21(63.2%)	24(63.3%)	45(59.4%)
2	13(26.3%)	12(31.5%)	25(32.8%)
3	4(10.5%)	2(5.2%)	6(7.8%)
Total	38(100%)	38(100%)	76(100%)
Meridian			
Spleen(脾經)	22(40.7%)	27(49.1%)	49(44.9%)
Stomach(胃經)	22(40.7%)	23(41.8%)	45(41.2%)
Gall bladder(膽經)	7(12.9%)	2(3.7%)	9(8.2%)
Urinary bladder(膀胱經)	3(5.7%)	3(5.4%)	6(5.7%)
Total	38(100%)	38(100%)	76(100%)
Target knee			
Right	22(57.8%)	19(50%)	41(53.9%)
Left	16(42.2%)	19(50%)	35(46.1%)
Total	38(100%)	38(100%)	76(100%)
Outcomes			
KWOMAC pain score	8.28±2.62	7.02±4.09	
KWOMAC stiffness score	3.36±1.72	2.57±1.63	
KWOMAC function score	32.63±10.8	24.26±13.91	
KWOMAC total score	44.28±13.96	33.86±18.86	
SF-36 physical score	39.2±13.12	45.71±11.49	
SF-36 mental score	50.4±12.75	57.96±17.70	
SF-36 total score	44.8±11.37	51.83±12.93	

*There were no statistical differences between the warm needling group and the simple acupuncture group at baseline. [†]The mean scores are given.

KWOMAC : Korean Westernand McMaster Universities Osteoarthritis Index, SF-36 : 36-Item Short-Form Health Survey. The values presented with a plus/minus sign are means's.

groups were randomly assigned to the two practitioners.

2) Blinding and materials: Because it was impossible to blind the practitioners, all the subjects and the analyzers of the data were blinded.

3. Acupoint

We based the selection of acupuncture points on the Eastern Traditional Medicine meridian theory for treating knee joint pain, known as "Bi(痺)" syndrome caused by external wind-cold-dampness, which uses local points on

channels that transverse the area of pain. The selected acupoints are listed in Table 2. The acupoints consisted of common and additional acupoints. The common acupoints were the 4 local points used most commonly on knee OA. Additional acupoints were those found by using meridian diagnosis. On average, 1~2 local points were added for each subject. These additional acupoints were selected after the practitioners pressed acupoints along one or two involved meridians. The points that were eventually selected were those at which this process induced pain. The total number

Table 2. List of the Acupoints that Were Used in This Study

Classification of the acupoints	Criterion of the selection(Meridian Characteristics)	Name of acupoint
Common acupoints	The acupoints to use for all subjects(Stomach meridian)	Ex-LE4(Xiyan) ST35(Dubi) ST36(Zusanli) Ex-LE2(Heding)
Additional acupoints	Pain above and dorsal to the medial condyle of the tibia(Spleen meridian)	SP9(Yinlingquan) SP10(Xuehai)
	Pain at the medial end of the popliteal crease, dorsal to the medial condyle of the tibia(Liver meridian)	LR8(Ququan)
	Pain ventral and distal to the head of the fibula(Gallbladder meridian)	GB34(Yanglingquan) GB33(Xiyangguan)
	Pain in the middle of the popliteal fibula crease(Bladder meridian)	BL40(Weizhong)
	Pain at the lower edge of the patella, lateral to the patella ligament (Stomach meridian)	ST34(Liangqiu)
	Pain in the medial part of the popliteal fossa between the tendons of the semi-tendinosus and semi-membranosus muscles(Kidney meridian)	KI10(Yingu)

of acupoints used for each subject was 5~6 points.

4. Procedure

The warm needling group's treatment was performed at the selected acupoints(see Table 2). Patients received warm needling treatments twice a week over an eight-week period. The depth of acupuncture was about 2~10 mm, and treatment duration was about 20 minutes. As can be seen in Fig. 1, a moxa stick with a hole in the middle was attached to the handle of the needle. The burning time for a stick was around 7~8 minutes and each stick was used only one time. Twirling reinforcement-reduction methods were not used. Acupoint, frequency, and duration of the operation on the acupuncture group were the same as those applied to the warm needling group with the exception of moxibustion.

5. Measurement of the pain relief effects of warm needling

To estimate the pain relief effects of warm needling on knee OA, the Western Ontario and McMaster Universities Osteoarthritis Index(WOMAC) was used to measure the primary outcomes following eight weeks of treatment¹⁷⁾. To measure secondary outcomes, the Korean version of the 36-Items Short-Form Health Survey(SF-36)¹⁸⁾ was used to estimate the patients' quality of life at the pre-trial, 4week, and 8week periods. In addition, the Patient Global Assess-

ment was used to assess the improvement of symptoms after eight weeks of treatment. The measurements were carried out with the evaluator groups thoroughly blinded. Finally, in both groups, there were no side effects in any of the subjects.

6. Statistical analysis

The differences in the demographic and baseline characteristics of the subjects were assessed using a Chi square test and the changes of the mean scores between pre-trial baselines and post-trial outcomes between the warm needling and the acupuncture groups were assessed using ANCOVA. Patient Global Assessment was assessed using Mann-Whitney U-test(SPSS 12.0).

Results

1. Based on the WOMAC index scores, both the 8-week warm needling treatment and the acupuncture treatment were effective in treating knee OA(Table 3)

The WOMAC total score for the warm needling group was 45.43±19.50 in the pre-trial and 20.61±12.19 after the 8 weeks of treatment. Thus, the change in the WOMAC total score in the warm needling group was -24.82±13.96, showing significance with a paired t-test($p < 0.000$). The

paired t-test showed a significant change of the WOMAC total score(-17.21±18.86) in the acupuncture group as well($p < 0.000$).

2. Based on the WOMAC index scores, the 8- week warm needling treatment was more effective than acupuncture in the treatment of knee OA(Table 4)

The change in the WOMAC total score in the warm needling group was -24.82±13.96. The change of the WOMAC total score in the acupuncture group was -17.21±18.86. The change of the WOMAC pain score was -5.07±2.62 in the warm needling group and -3.89±4.09 in the acupuncture group, showing significance($p=0.038$). The change of the WOMAC function score was -17.86±10.87 in the warm needling group and -11.96±13.91 in the acupuncture group, also showing significance($p=0.012$). These results indicate that the changes in the warm needling group reveal a significant amelioration compared to the acupuncture group($p=0.010$). There was no significant change in

either group with respect to the WOMAC stiffness scores. Overall, the results of the WOMAC scores indicate that warm needling for 8 weeks has a therapeutic effect on OA of the knee.

3. According to the SF-36 results, neither warm needling nor acupuncture was effective in enhancing health related life quality(Table 4)

The pre-trial SF-36 total score was 45.54±16.65 in the warm needling group and was 59.95±13.63 after the 8-week trial. In the acupuncture group, the pre-trial SF-36 total score was 52.09±17.93 and its total score after the 8 week trial was 65.53±16.21. The change of the SF-36 total score was 14.41±11.37 in the warm needling group and 13.43±12.93 in the acupuncture group, showing no significance($p=0.321$). In addition, the SF-36 physical and mental health scores did not show statistical significance between the two groups

Table 3. Changes of the KWOMAC Total Scores in the Warm Needling Group and the Simple Acupuncture Group

	Pre-trial (n=28)	Post-trial (n=28)	p-value
Warm needling	45.43±19.50*	20.61±12.19	$p < 0.000$ †
Simple acupuncture	33.67±25.77	16.36±17.96	$p < 0.000$

*The means and standard deviations are given. †Indicates that the paired t-test showed a significant difference between the pre-trial and post-trial($p < 0.05$).

Table 5. Patient Global Assessment at the End of the 8 Weeks' Trial

	Poor	Fair	Good	Excellent	p value
Warm needling group (n=28)	0*	7	9	12	0.044†
Simple acupuncture group(n=28)	1	11	9	7	

*The numbers indicate how many subjects rated the improvement of the disease as either; poor, fair, good, or excellent. †Indicates that the Mann-Whitney U-test showed a significant difference between the warmneedling group and the simple acupuncture group($p < 0.05$).

Table 4. The Changes of the Mean Score Between Pre-trial Baselines and Post-trial Outcomes

	Warm needling group (n=28)	Acupuncture group (n=28)	p value
KWOMAC			
KWOMAC total(n=28)	-24.82±13.96	-17.21±18.86	0.010*
KWOMAC pain(n=28)	-5.07±2.62	-3.89±4.09	0.038*
KWOMAC stiffness(n=28)	-1.89±1.72	-1.35±1.63	0.188
KWOMAC function(n=28)	-17.86±10.87	-11.96±13.91	0.012*
SF-36			
SF-36 total(n=28)	14.41±11.37	13.43±12.93	0.321
SF-36 physical health(n=28)	15.68±13.12	13.65±11.49	0.539
SF-36 mental health(n=28)	13.13±12.75	13.21±17.70	0.394

The result and p value from ANCOVA with the changes from baselines. The values presented with a plus/minus sign are means's. *Indicates that the ANCOVA showed a significant difference between the pre-trial and post-trial($p < 0.05$). KWOMAC : Western Ontario and McMaster Universities Osteoarthritis Index translated into Korean language, SF-36 : 36-Items Short-Form Health Survey.

(Table 4)(The mean scores of SF-36 after 4 weeks treatment show in supplementary table).

4. According to the Patient Global Assessment, the 8 weeks of warm needling were more effective than acupuncture for knee OA(Table 5)

A Patient Global Assessment was carried out by the subjects themselves at the end of the 8 week trial in order to evaluate the condition of their knee OA. Among the 28 subjects in the warm needling group, the distribution of the Patient Global Assessment was 42.9% in "Excellent", 32.1% in "Good", 25.0% in "Fair" and 0% in "Poor". The distribution among the 28 subjects in the acupuncture group was 25.0% in "Excellent", 32.1% in "Good", 39.3% in "Fair" and 3.6% in "Poor". These results strongly suggest a significant improvement in the knee OA conditions of the subjects in the warm needling group relative to those receiving acupuncture ($p=0.044$).

Discussion

Warm needling is a therapy combining the practices of acupuncture and moxibustion. The effects of acupuncture stimulation are known to be augmented by the burning moxibustion, which conducts heat through the needle. It is further believed that this heat can facilitate blood circulation and thus relieve pain, the feeling of chilliness, and paralysis⁴. To maximize the treatment efficiency of warm needling at the early and middle stages of knee OA, it is recommended to use therapeutic strategies that promote blood circulation, eliminate hemostasis, and reduce edema and pain. At a later stage, other strategies that promote blood synthesis and warm meridians to reduce the pain are recommended⁵.

We evaluated the therapeutic efficacy and safety of warm needling and compared them to those of traditional acupuncture treatment. The results of our study indicate that patients with knee OA showed significant improvement after 8 weeks of either acupuncture or warm needling therapy. However, the warm needling group showed a more signi-

ficant pain relief effect on knee OA than the acupuncture group according to the pain, function, and total scores of WOMAC at the 4-week and 8-week points and the Patient Global Assessment. In addition, no patients reported adverse effects from either the warm needling or acupuncture therapy, which required 16 sessions per patient.

Previous studies have led to the general opinion that acupuncture is effective in relieving pain and dysfunction of the knee in elderly patients with knee OA compared to non-acupuncture treated control groups^{12,15}. Some additional reports^{11,12,19-22} showed significant pain relief in patients treated with acupuncture compared to those treated with sham acupuncture or exercise and education. Other studies^{23,24} showed no significant difference in pain reduction between patients treated with acupuncture and those in a control group or those treated with sham acupuncture. Due to methodological problems in comparing the studies that were done so far, the general consensus is that the results are promising but that more research is needed(see also: <http://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v%3Aproject=medlineplus&query=acupuncture>). To investigate the effectiveness of warm needling for knee OA, we designated the acupuncture group as the positive control group.

Among the outcome measurements used to estimate the effectiveness of warm needling on knee OA, the SF-36 did not show a significant improvement. Although the SF-36 results for warm needling might have been expected to differ from those of simple acupuncture, our findings for warm needling are consistent with those of the previous literature on acupuncture^{11,12,23}.

There were several limitations in this study. First, due to coincidence, all smokers were included in the control group. However, although previous studies reported that smoking could worsen knee OA symptoms^{25,26}, the results of the control group still showed an improvement. It is thought that control group also received acupuncture treatment, so their symptoms were improved because acupuncture treatment has effect on knee OA²⁷. A second limitation of this study was that the ratio of drop-outs was somewhat high. This can be a reason of statistical error. We selected acupuncture as

a positive control group so could not compare efficacy with negative control group like non-treatment group. Finally, we could not blind the practitioners in current study, which may affect the results. For the correct data collecting, we need to find out methods to blind practitioners in acupuncture research.

In our study, warm needling evoked relief of the pain and inflexibility²⁸⁾ caused by knee OA and was found to have improved therapeutic efficacy compared to simple acupuncture. These findings indicate the possibility that warm needling may be a promising alternative acupuncture therapy for knee OA.

Conclusion

In our study, we found that both warm needling and acupuncture provided a pain relief effect in knee OA according to the WOMAC index scores. In addition, the warm needling group showed greater improvement than the acupuncture group according to the WOMAC index scores and the Patient Global Assessment.

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국문초록

목적: 본 연구는 퇴행성 슬관절염 환자의 통증을 줄이고 증상을 개선하는데 있어 현재 침구임상에서 활용되고 있는 온침이 침보다 더욱 유효한지를 알아보기 위하여 임상연구로 시행되었다. **방법:** 총 76명의 퇴행성 슬관절염 지원자가 연구에 참가하였으며, 이들 모두는 선정기준과 제외기준에 의하여 선발되었고 최종적으로 임상연구를 마친 지원자는 66명이었다. 지원자들은 무작위로 온침군과 침군 중에 할당이 되었다. 실험군(온침)에 속한 38명은 온침시술을, 대조군(침)에 속한 38명은 침시술을 받았으며, 8주 동안 총 16회의 시술을 환측의 무릎에 시행하였다. 주된 평가척도는 Western Ontario and McMaster Universities Osteoarthritis Index(WOMAC)이었고, 부수적 평가척도는 physical health score based on the 36-Item Short-Form Health Survey(SF-36), Patient Global Assessment이었다. **결과:** 실험군이 대조군에 비해서 WOMAC의 pain, function, total score와 Patient Global Assessment에서 월등한 감소를 나타내었으나 SF-36에서는 유의한 변화가 없었다. **결론:** 이번 연구의 결과를 통해 온침이 침에 비하여 퇴행성 슬관절염 환자의 통증 감소와 기능개선에 유의성있게 효과가 있음을 확인하였다.