

Special Contribution

Report on the 2nd Japan-Korea Workshop on Acupuncture and EBM -Recent development of clinical trial on musculoskeletal disease-

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Abstract

The second Japan-Korea workshop on acupuncture and evidence-based medicine (EBM) was held on 22 October, 2005 at Daegu, Korea in the 13th International Congress of Oriental Medicine (ICOM). The objective of this workshop was to exchange the experiences of clinical researches on acupuncture and moxibustion treatments, and to figure out the issues and solutions for the advanced good clinical research to establish rigorous evidence.

Drs. Kawakita (JSAM) and Jang (KAMS) chaired the workshop. Two speakers from Japan (Drs. Kawakita and Itoh) and two Korean speakers (Drs. Lee and Kim) presented their data on the clinical researches of acupuncture and moxibustion. After their slide presentations, various issues were discussed in terms of their research methodology for the establishment of stronger evidence on acupuncture and moxibustion. We had new interesting findings and understood various issues and their solutions for performing clinical researches.

The most crucial product of this workshop was that we could figure out each other more than ever and we agreed the necessity of the future collaborative clinical studies on acupuncture and moxibustion. This workshop was very fruitful as the step for the future Japan-Korea collaborative clinical research. We expect an excellent discussion in this meeting to contribute to the development of clinical research on acupuncture in the future.

Key words: Japan-Korea Workshop, acupuncture, moxibustion, RCT (randomized controlled trial), EBM (evidence-based medicine)

I. Background of this workshop

Acupuncture therapy has been highly recognized by the WHO for its effectiveness, and many profound researches have been conducted on it in the United States and European countries since several decades ago. The interest towards Oriental Medicine is growing all over

the world. Particularly acupuncture is receiving more spotlights because it is the most leading field of Oriental Medicine at the present.

Now we face a new task of "Evidence Based Medicine". The world science society requires us to show not only classical prescriptions and experiences but also scientific evidences. More and more scientists are inter-

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ested in investigating the mechanism of acupuncture and moxibustion.

Korea and Japan share a long history and abundant experiences concerning acupuncture. We have been exchanging updated information through various meetings, formal and informal. Oriental Medical doctors in Korea and Japan have reserved the knowledge about the unique acupoints and remarkable skills, and recently put their efforts on the clinical research.

II. Purpose of this workshop

As the second step of the Japan-Korea collaboration of clinical trials in the future, the first purpose of this workshop was to exchange the experiences of clinical researches on acupuncture and moxibustion therapies, and secondly to find out the issues and their solutions for developing the excellent clinical research to establish strong evidence.

III. The contents of workshop: presentation of papers from Japan and Korea

The second Japan-Korea workshop on acupuncture and EBM was held at Daegu EXCO, Korea on 22 October, 2005. Over 30 members of the JSAM, KAMS and KOMS joined to the workshop. The slides for the presentation were prepared in English. List of speakers and titles are summarized in Table 1.

Topics of the 1st paper and raised issues

Dr. Itoh reported trigger-point acupuncture treatment of chronic low back pain (n=18) and neck pain (n=20) in elderly patients. The patients (age range: 65-81 years), with non-radiating back or neck pain for at least six months, were allocated into one of two groups over 12 weeks. Each group received two phases of acupuncture with an interval between them and outcome measures were pain intensity by Visual Analogue Scale (VAS) and Roland Morris Questionnaire. The standard acupuncture group received treatment at traditional acupuncture points, while the other groups received treatments on trigger-points. The trigger point acupuncture therapy was more effective than standard acupuncture therapy on chronic low back pain and neck pain in the aged patients as shown in Figure 1 and 2. He suggested that trigger-points might be more effective in the treatment of low back and neck pain. But there was not sufficient statistical data so we could not fully support this. In addition, deep or superficial needling to trigger-points was required to be studied.

Topics of the 2nd paper and raised issues solved

Dr. Kawakita reported the effect of indirect moxibustion on the elderly patients of osteoarthritis of the knee by sham controlled clinical trial (real=16, sham=14). Firstly he invented a new sham moxibustion and implemented the physical characteristics between warm (real)

Tale 1. List of speakers and titles of their presentations

Speaker	Organization	Title of Paper
1 Itoh K	JSAM	Trigger-point acupuncture treatment of chronic low back pain in elderly patients
2 Kawakita K	JSAM	Effect of indirect moxibustion on the elderly patients of osteoarthritis of the knee-sham controlled clinical trial.
3 Lee S-D	KAMS	Comparison of superficial and deep acupuncture in the treatment of ankle sprain : A randomized controlled trial
4 Kim S-C	KAMS	A pilot study of acupuncture treatment for the degenerative knee arthritis on the Evidence Based Medicine.

and sham moxibustion (Figure 3). Moxibustion treatments were done two times per week for three weeks. Acupuncture points around the knee joint bilaterally (ST34, SP9, SP10, GB33, LV8) were used. Both VAS and Western Ontario and McMaster Universities osteoarthritis index (WOMAC) scores showed improvement in both groups, but a significant reduction was found only in real group (Figure 4). No change was observed in physical examination in both groups. These data demonstrated the real moxibustion is more effective

than sham intervention for the pain relief of osteoarthritis of the knee. But the importance of heat-sensitive afferent inputs in both acupuncture and moxibustion treatment was suggested.

Topics of the 3rd paper and raised issues solved

Dr. Lee reported the comparison of superficial and deep acupuncture in the treatment of ankle sprain by a prospective randomized single-blind study in 23 ankle

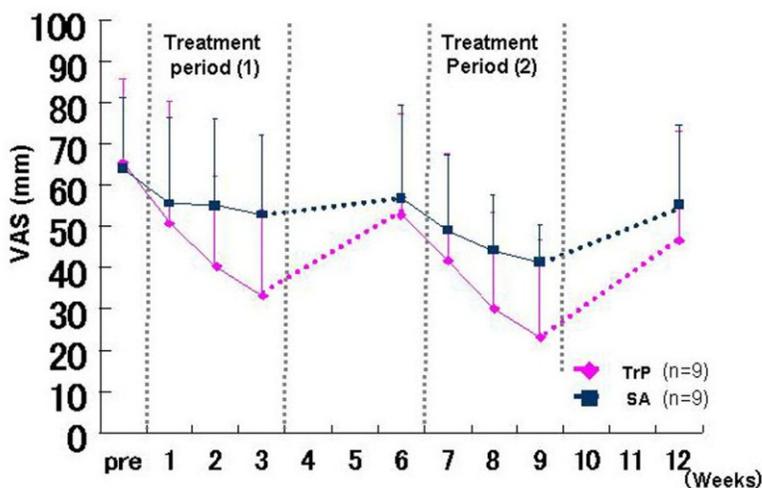


Figure 1. Effect of standard acupuncture and trigger-points treatments on low back pain
Trp : Trigger point acupuncture therapy
SA : Standard acupuncture therapy

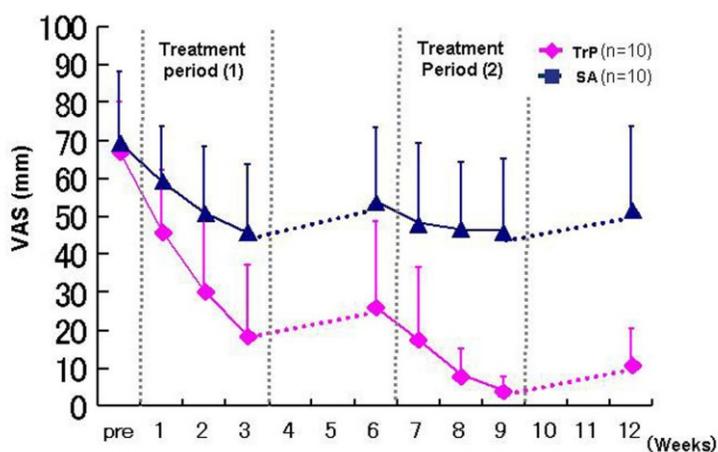


Figure 2. Effect of standard acupuncture and trigger-points treatments on neck pain

sprain patients. In superficial acupuncture group, the needle was introduced in the skin at a depth of 2 mm, whereas in deep group the needle was placed deeply into muscular tissue or the articular capsule at a depth more than 15mm. The treatment was planned for duration of 1 week, 3 times. Although at the end of the treatment there was no evidence of significant statistical differences between the two different groups, pain reduction (VAS) was greater in the group treated with deep acupuncture (Table 2, 3). He suggested that deep stimulation has a

better analgesic effect when compared with superficial stimulation in pain reduction, but the other outcome measures such as bearing weight, pressure threshold do not support his suggestion.

Topics of the 4th paper and raised issues solved

Dr. Kim reported a pilot study of acupuncture treatment for the degenerative knee arthritis on the evidence based medicine. In pragmatic acupuncture treatment

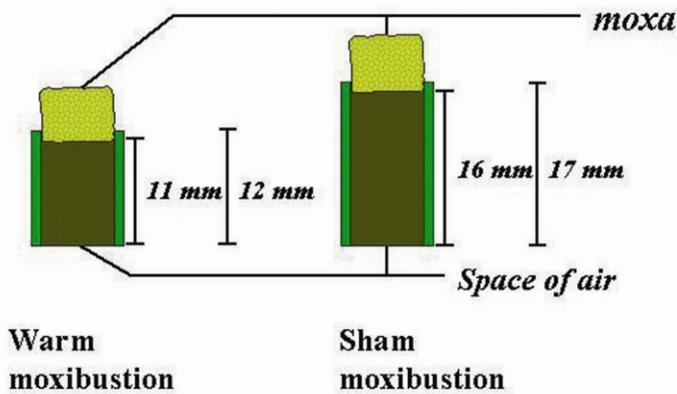


Figure 3 Warm and sham moxibustion devices

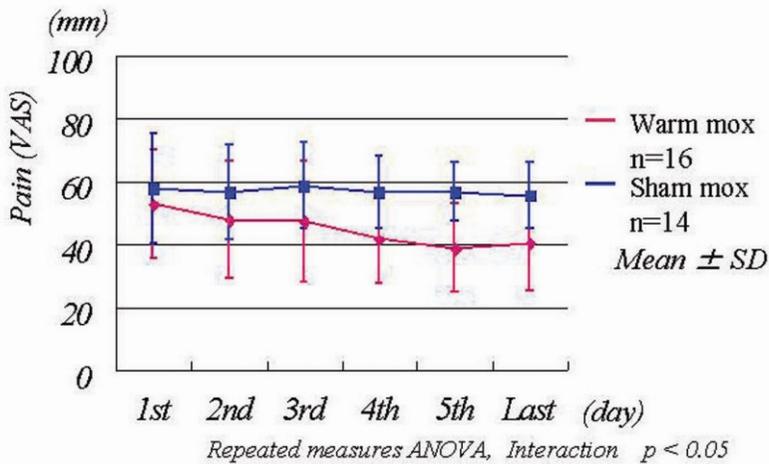


Figure 4 Time course of pain magnitude between Warm and sham moxibustion

Table 2. Comparison of visual analogue scale of deep vs superficial acupuncture in the treatment of ankle sprain

	Deep A. Group (n=10)	Superficial A. Group (n=13)	P - value
1 trial	7.36 ± 0.78	6.94 ± 1.09	ns
2 trial	3.83 ± 1.05	5.22 ± 0.82	0.0047
3 trial	1.97 ± 0.79	4.53 ± 0.99	0.0001

Table 3. Comparison of pressure algometer of deep vs superficial acupuncture in the treatment of ankle sprain.

	Deep A. Group (n=10)	Superficial A. Group (n=13)	P - value
1 trial	1.41 ± 0.57	1.86 ± 0.69	ns
2 trial	2.24 ± 0.50	2.26 ± 0.68	ns
3 trial	2.81 ± 0.55	2.53 ± 0.47	ns

group (n=20) we used 3 liver meridian points (LI 3, 4, 7) for the patients with medial knee joint pain, 2 stomach meridian points (ST 35, 36) for the patients with middle knee joint pain, and 3 gall bladder meridian points (GB 33, 34, 43) for the patients with lateral knee joint pain, we added to LI 2 point using reduction method if patients have knee edema. We used the acupuncture points of BL34, SP9, ST35, S36, BL60, GB39, SP6, and KI3 using the reinforcement-reduction method in standardization acupuncture treatment group (n=17). Primary outcomes were WOMAC pain and function scores at 4, 8, and 14 weeks. Secondary ones were consisted of 100mm VAS, ROM (Range of Motion) using Goniometer, and pain threshold using pressure algometer. In comparison of outcomes there were no significant statistical differences between the pragmatic and standardization acupuncture treatment group (Table 4, 5). He aimed to investigate whether the pragmatic acupuncture treatment provides more effective pain relief than treatment using the same acupuncture point to the all patients, but it was pointed out that there were two many study arms.

IV. General discussion

After slide presentations, various issues were discussed on their research methodology for the establishment of stronger evidence on acupuncture and moxibustion. To clarify the purpose of the study is a very important issue especially in collaborative research. Therefore, in 2nd Japan-Korea workshop on acupuncture and EBM, we decided musculoskeletal disease as an adequate target disease for the clinical research.

Dr. Itoh reported the trigger point acupuncture therapy was more effective than standard acupuncture therapy on chronic low back pain and neck pain in the aged patients. But it was pointed out that it unfair to select fixed acupuncture points only in standard acupuncture therapy group. Some researchers insisted if individualized acupuncture points were selected in acupuncture therapy group or fixed points were selected in trigger point acupuncture therapy, the results would be different.

In the research area of Oriental Medicine, moxibustion research is not so much, especially clinical trial of

Table 4. Comparison of pain on degenerative knee arthritis between the pragmatic and standardization acupuncture treatment group. Two treatment groups did not have any differences in the change of a pain threshold ($t=0.046$, $p=0.964$).

	Pragmatic acupuncture treatment group (n=20)	Standardization acupuncture treatment group (n=17)	t(p)
	$\bar{x} \pm S.D.$	$\bar{x} \pm S.D.$	
The change of pain threshold	$- .45 \pm .395$	$- .46 \pm .711$.046 (.964)

Table 5. Comparison of ROM (extension) on degenerative knee arthritis between the pragmatic and standardization acupuncture treatment group. Two treatment group did not have any differences in the change of ROM of the knee extension ($t=1.321$, $p=0.195$).

	Pragmatic acupuncture treatment group (n=20)	Standardization acupuncture treatment group (n=17)	t(p)
Variable	$\bar{x} \pm S.D.$	$\bar{x} \pm S.D.$	
The change of ROM(Extension)	4.50 ± 5.826	2.06 ± 5.321	1.321 (.195)

moxibustion is rare. Participants applauded Dr. Kawakita's sham moxibustion as a creative sham device in moxibustion research. Dr. Kawakita reported an analgesic effect of warm moxibustion and he suggested that temperature of warm moxibustion is essential for the analgesic effect. But no apparent difference between the warm and sham moxibustion on the results of physical examination (excursion of knee joints, heat and ballottement of patella). We could not make a conclusion from the present data because the experimental period might be too short and the assessment in categorical scales (improve, no change and worse) was not so sensitive. Therefore, quantitative evaluation will be required.

In Japan superficial stimulation acupuncture is prevalently used in clinics with good results. Dr. Lee suggested that deep stimulation has a better analgesic effect when compared with superficial stimulation in pain reduction, however, the other outcome measures such as bearing weight, pressure threshold do not support his suggestion. Dr. Lee's findings are controversial in this aspect and need to be discussed.

Recently numerous clinical researches of acupuncture have published in western countries, and we need to find unique acupuncture method for the clinical research to strengthen our originality. Dr. Kim's report was based on this consideration of pragmatic design. In comparison of outcomes there were no significant statistical differences between the pragmatic and standardization acupuncture treatment group. However, it was pointed out that results without comparison of baseline are unmeaning. One of the most noteworthy aspects in this workshop is growing interesting in the individualized clinical trial than n of 1 trial that has been indicated a few problems yet to be clarified.

We need to discuss how to get rid of disadvantage of n of 1 and individualized trial method and how to develop better method capable of answering the question in the clinical research with less defect based on established research method.

We also discussed and resolved following issues; validity of RCT for future study, methods of random allocation, selection of control intervention, necessity of

placebo or sham interventions, selection of outcome (subjective, objective), calculation of sample size, likelihood of multi-center RCT in Japan and Korea, difference of medical system between Japan and Korea, and financial support.

V. Future issues of the workshop

During this workshop we could not make up a common protocol for the collaborative clinical research. But we had new interesting findings and understood various issues and their solutions for performing clinical researches. The most important product of this workshop was that we could figure out each other more than ever and we agreed the necessity of the future collaborative clinical studies on acupuncture and moxibustion. This workshop was very fruitful as the step for the future Japan-Korea collaborative clinical research and the participants might agree that it was the meaningful first step for it.

We still have many issues to be discussed and solved. Safety and ethics are two topics often not perfectly considered by researcher during the clinical research on acupuncture. We are going to discuss these issues more deeply at next workshop, when we will also be talking about selection of acupuncture for the clinical research that was based on results of survey in Korea. After the workshop we agreed to have a meeting again at 54th annual scientific meeting of the JSAM which will be held in Japan in June, 2006.

We are sure that our efforts will be historically meaningful in developing traditional acupuncture into an evidence based future medicine. We are expecting that this meeting will play an important role in improving the quality of clinical research on acupuncture and the globalization of the Oriental Medicine. We sincerely hope the participants and readers of this report send their frank opinions for the next Korea-Japan Workshop to our mail addresses.

Acknowledgements

We sincerely thank to the organizing committee of ICOM meeting for setting this workshop, and to Dr. Dong-Suk Park, president of Korean Oriental Medical Society and Choi Do-Young, president of Korean Acupuncture & Moxibustion Society, for their arrangement since last year, and to the members of JSAM, KAMS

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A part of the clinical trials conducted in Japan were supported by the AHAKI foundation (Foundation for Training and Licensure Examination in Anma-Massage-Acupressure, Acupuncture and Moxibustion). A part of the clinical trials conducted in Korea were supported by the KIOM (Korea Institute of Oriental Medicine).

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Appendix

All four speakers kindly agreed to exhibit their slides to the members of the JSAM, KAMS and KOMS for promoting the clinical research in both countries. It is allowed for the personal use only, so please do not use for other purposes. You can see these slides at the homepages of the JSAM, KAMS and KOMS soon.