13. Diseases of the Musculoskeletal and Connective Tissue

Reference

Inoue M, Nakajima M, Itoi M, et al. Comparison of the effectiveness of acupuncture treatment and local injection for low back pain - A randomized controlled clinical trial - *Nihon Onsen Kikou Butsuri Igakukai Zasshi* (*The Journal of the Japanese Society of Balneology, Climatology and Physical Medicine*) 2008; 71(4): 211–20 (in Japanese with English abstract). Ichushi Web ID: 2008333712

1. Objectives

To compare the clinical effects of local injection and local acupuncture treatment for low back pain.

2. Design

Randomized controlled trial (RCT).

3. Setting

Department of Orthopedic Surgery, the Meiji University of Integrative Medicine Hospital, Kyoto, Japan

4. Participants

Twenty-six outpatients who presented with low back pain between April 2006 and December 2007, received acupuncture therapy or local anesthetic injection for low back pain, and were suspected of suffering low back pain complications due to causes other than movement disorder were included, but not patients who received other treatment for low back pain within one month before commencement of the study (14 males; 12 females; average age in the two groups 70.8 and 73.6 years).

5. Intervention

Arm 1: Acupuncture. Stainless steel needles (0.18 x 40 mm, Seirin Co., Ltd.) were inserted to a depth of 10–20 mm at the most painful points (two to five points) in each patient's lower back, then after the patient experienced *de qi* (得気) sensation, sparrow pecking stimulation was applied (1 Hz, 20 s), and the needles were removed. Patients received treatment once a week on four occasions (n=13).

Arm 2: Local injection. 25 G hypodermic needles (0.5 x 25 mm, Terumo Corporation) were inserted to a depth of 10–20 mm at the most painful points (two to five points) in each patient's lower back and were removed after drug injection (NeoVitacain®, Neurotropin®). Patients received treatment once a week on four occasions (n=13).

6. Main outcome measures

Pain was evaluated (on a visual analog scale [VAS]) before and after the initial treatment, before each subsequent treatment, and at two and four weeks after completion of the treatment. The Roland-Morris Disability Questionnaire (RMDQ) was used for evaluation before the initial treatment, at completion of treatment, and then at two and four weeks after completion of treatment. The Pain Disability Assessment Scale (PDAS) was used for evaluation before the initial treatment, at completion of treatment, and then two and four weeks after completion of treatment.

7. Main results

Significant improvement in all measures in both Arm 1 and Arm 2 occurred over time (VAS: $P<0.0001$, $P=0.0156$, respectively; RMDQ: $P<0.0001$, $P=0.0188$, respectively; PDAS: $P<0.0001$, $P=0.0196$, respectively). VAS scores improved significantly in both arms immediately after treatment ($P<0.0001$, $P=0.0428$, respectively), but the size of the VAS change was significantly greater in Arm 1 ($P=0.0348$). Continued treatment showed significantly greater change in VAS score (comparing the scores before the initial treatment and before the fourth treatment) in Arm 1 ($P=0.0076$). The change in the RMDQ and the PDAS (comparing the scores before the initial treatment and after completion of the treatment) was also significantly greater in Arm 1 ($P=0.0024$, $P=0.0039$, respectively).

8. Conclusions

Acupuncture treatment is more effective than local injection for low back pain associated with degenerative change in elderly patients.

9. From acupuncture and moxibustion medicine perspective

Acupuncture treatment uses physical stimulation alone, while local injection uses a combination of physical stimulation and anesthesia. The difference between the effects in the two groups could be due to the differences between the mechanisms of pain suppression and it is possible that physical stimulation alone is more effective, depending on the type and severity of the pain.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This study is of great interest because it compares acupuncture with local injection, a Western medical therapy for low back pain. The measures used are highly reliable and the outcomes are appropriately described. The findings of the study do not apply to low back pain in all age groups, including low back pain for reasons other than degeneration, as the subjects of the study were 70 years or older. Improving the quality of the RCT including sample size precomputation and blinding of participants to the intervention is desirable, however, low back pain is one of the most common chief complaints in acupuncture therapy, so use of a variety of approaches for clinical study design is anticipated.

"Comparison of the effectiveness of local injection and acupuncture treatment for low back pain - A randomized controlled clinical trial. *Nihon Seitai Denki Butsuri Shigeki Kenkyu Kaishi* (*The Journal of the Japanese Bio-Electrical and Physical Stimulation Research Society*) (Inoue et al., 2008; 22:1-6. JA0806)" deals with the same topic as is dealt with in this structured abstract.

12. Abstractor and date

Shichido T, Shimoichi Y, 11 September 2011.

13. Diseases of the Musculoskeletal and Connective Tissue

Reference

Itoh K, Itoh S, Katsumi Y, et al. A pilot study on using acupuncture and transcutaneous electrical nerve stimulation to treat chronic non-specific low back pain. *Complementary Therapies in Clinical Practice* 2009; 15: 22–5. CENTRAL ID: CN-00681603

1. **Objectives**

To analyze the synergistic effects of acupuncture and transcutaneous electrical nerve stimulation (TENS) on chronic low back pain (LBP).

2. **Design**

Randomized controlled trial (RCT).

3. **Setting**

The Meiji University of Oriental Medicine Hospital, Kyoto, Japan.

4. **Participants**

Thirty-two LBP patients, 60 years or older, at least six months after onset (12 males, 20 females, ages 61 to 81).

5. **Intervention**

Arm 1: Acupuncture group. Disposable stainless steel needles (0.2×40 mm, Seirin Co., Ltd.) were inserted into muscle to a depth of 10 mm using the sparrow pecking technique until the patient experienced the *de qi* (得気) sensation, then retained for at least 10 minutes. The needles were inserted at BL23 (腎俞), BL25 (大腸俞), BL32 (次髎), BL40 (委中), BL60 (崑崙), GB30 (環跳), and GB34 (陽陵泉) acupuncture points. Treatment was given once a week for five weeks (n=8).

Arm 2: TENS group. Surface disposable electrodes (small and large) were placed at and near the most tender points; the pulse rate was set to 122 Hz and intensity was set to two to three times the patient's sensory threshold for 15 minutes. Treatment was given once a week for five weeks (n=8).

Arm 3: Acupuncture + TENS group. TENS was given for 15 minutes, and acupuncture treatment for 15 minutes. The respective treatments were the same as in Arms 1 and 2. Treatment was given once a week for five weeks (n=8).

Arm 4: Control group. Though nonspecific, treatment with topical poultices containing methylsalicylic acid was given, if required (n=8).

Two, one, two and one participants were dropped from Arms 1, 2, 3, and 4, respectively.

6. **Main outcome measures**

Pain intensity (visual analogue scale [VAS]) score and Roland Morris (Roland-Morris Disability Questionnaire [RMDQ]) score for quality of life (QOL).

7. **Main results**

The 4- and 5-week VAS scores for Arm 3 and the 5-week RMDQ score for Arm 3 were significantly lower than pre-treatment scores (before-after comparison) ($P<0.008$). The mean 5-week VAS score for Arm 3 was significantly lower than the corresponding score for Arm 4 (comparison between groups). The RMDQ scores after 5 weeks of the treatment for Arm 3 decreased significantly compared to pre-treatment scores (before-after comparison) ($P<0.008$).

8. **Conclusions**

Acupuncture therapy combined with TENS alleviates pain and improves QOL in LBP patients.

9. **From acupuncture and moxibustion medicine perspective**

"Gate control" is cited as the mechanism underlying the therapeutic effects of acupuncture with TENS. Since acupuncture excites small-diameter afferent fibers and TENS excites large-diameter afferent fibers, the authors surmise that their combined use is the reason for the effectiveness of the combined treatment against pain.

10. **Safety assessment in the article**

Not mentioned.

11. **Abstractor's comments**

This is a very well designed RCT and an important study suggesting the effectiveness of the combined use of acupuncture with TENS. It is also commendable that patients were properly followed up until the fifth week. Interestingly, VAS scores improved about the same amount in the TENS group and the control group, but improved significantly more in the TENS + acupuncture group relative to the control group. This has clinical importance. However, there was no intention-to-treat (ITT) analysis and the results would have been more readily comprehensible if presented in graph form.

12. **Abstractor and date**

Wakayama I, 23 September 2011.

13. Diseases of the Musculoskeletal and Connective Tissue

Reference

Miyazaki S, Hagihara A, Kanda R, et al. Applicability of press needles to a double-blind trial. A randomized, double-blind, placebo-controlled trial. *Clinical Journal of Pain* 2009; 25(5): 438–44. CENTRAL ID: CN-00706848

1. **Objectives**

To evaluate the efficacy of press tack needle (円皮鍼) for low back pain.

2. **Design**

Double blinded randomized controlled trial (DB-RCT).

3. **Setting**

Faculty of Sports and Health Science, Fukuoka University, Fukuoka, Japan.

4. **Participants**

Ninety university students with no experience of acupuncture treatment (recruited between 18 September and 31 October 2007).

5. **Intervention**

Arm 1: Press tack needle (円皮鍼) group. Press tack needles (Pyonex, 0.2×0.6 mm, Seirin Co., Ltd.) were applied at the left BL23 (腎俞) acupuncture point (n=45).

Arm 2: Placebo group. Identical press tack needles, with only the needle element removed, were applied at the left BL23 (腎俞) acupuncture point (n=45).

Three participants dropped out of Arm 1 and six dropped out of Arm 2.

Participants were subdivided into healthy participants and low back pain participants. Low back pain participants were those with low back pain for several days, low back pain on examination before the intervention, or a six-month or greater history of low back pain. Therefore, Arm 1 (n=42) included nine low back pain participants and 33 healthy participants. Arm 2 included five low back pain participants and 34 healthy participants.

6. **Main outcome measures**

Low back pain intensity rated on a visual analogue scale (VAS).

7. **Main results**

Efficacy was greater for low back pain in Arm 1 than Arm 2 (P=0.03). The reduction in subjective symptoms was greater among low back pain participants than healthy participants in Arm 1 (P<0.001).

8. **Conclusions**

Treatment with press tack needles is effective for low back pain.

9. **From acupuncture and moxibustion medicine perspective**

While treatment at BL23 (腎俞) acupuncture point was effective for low back pain, not all treatment should be at this one acupuncture point: clinical therapists need to combine this acupuncture point with others in their treatment.

10. **Safety assessment in the article**

Only one participant in Arm 1 complained of sleepiness.

11. **Abstractor's comments**

This is a very well designed double-blind trial. The authors describe in detail how patients were successfully blinded to treatment allocation, inasmuch as the original purpose of the study was to determine whether press tack needle efficacy could be assessed in double-blind trials. It is also commendable that the sample size was calculated

However, the design was somewhat complex because of the subdivision of the two groups into healthy participants and low back pain participants. There was only one outcome measure (VAS score), so inclusion of another measure might have been beneficial. Unfortunately, as the authors mention, follow up ceased at 20 minutes after intervention, so any subsequent effects are unknown. Despite these issues, further development of this research offers promise.

12. **Abstractor and date**

Wakayama I, 23 September 2011.

13. Diseases of the Musculoskeletal and Connective Tissue

Reference

Itoh S, Itoh K, Katsumi Y. Effect of trigger point acupuncture treatment in older patients with chronic low back pain: randomized controlled trial. *Zen Nihon Shinkyu Gakkai Zasshi* (*Journal of the Japan Society of Acupuncture and Moxibustion*) 2009; 59(1): 13–21 (in Japanese with English abstract). Ichushi Web ID: 2009213798

1. **Objectives**

To evaluate the efficacy of trigger point acupuncture treatment for chronic low back pain in elderly people.

2. **Design**

Randomized controlled trial (RCT).

3. **Setting**

Department of Orthopedic Surgery, the Meiji University of Integrative Medicine Hospital, Kyoto, Japan.

4. **Participants**

Thirty-nine elderly outpatients with a six-month or greater history of chronic low back pain.

5. **Intervention**

Arm 1: Trigger point group. Needles were inserted at 9.4±2.3 (mean±SD) locations per participant into the gluteus medius, lumbar quadrate, gluteus maximus, and iliopsoas muscles, and retained for 10 minutes. *De qi* (得気) sensation and muscle contraction were not considered. Treatment was given once a week five times. Follow up continued until three months after treatment stopped (n=13).

Arm 2: Tender point group. Treatment was applied at tender points in the painful region. The examination to locate tender points took acupuncture points into account. Needles were inserted at 9.7±2.3 locations per participant at BL23 (腎俞), BL22 (三焦俞), BL25 (大腸俞), BL52 (志室), BL21 (胃俞), BL53 (胞肓), BL54 (秩辺), GB31 (風市), and EX-B7 (腰眼) acupuncture points to a depth of 10 to 20 mm and retained for 10 minutes. De qi sensation and muscle contraction were not considered. Treatment period and frequency were the same as in Arm 1 (n=13).

Arm 3: Sham group. Needles were inserted at 9.0±2.2 locations per participant at the same locations as in Arm 1. Treatment period and frequency were the same as in Arm 1 (n=13).

For a total of 5, 8, and 7 participants dropped out in Arms 1, 2, and 3, respectively.

6. **Main outcome measures**

Low back and leg pain intensity rated on a visual analogue scale (VAS) before treatment, each treatment, and then one month and three months after treatment stopped. During the treatment period, post-treatment scores were the scores obtained before the subsequent treatment. Quality of life (QOL) scores using the Roland Morris Disability Questionnaire (RMDQ) were obtained before treatment started, after each of five treatments, and then one month and three months after treatment stopped.

7. **Main results**

Low back and leg pain intensity changed significantly for Arm 1 compared to Arms 2 and 3 (Interaction, $P<0.05$). The decrease in pain intensity decreased from the first treatment (within-group comparison) ($P<0.01$) and persisted for three months after treatment stopped. Symptoms were not alleviated in either Arm 2 or 3.

No significant difference of QOL in three groups (group comparison). Scores improved greatly in Arm 1 (within-group comparison) but not in either Arm 2 or 3.

8. **Conclusions**

VAS scores show that trigger point acupuncture is more effective than tender point treatment or sham treatment for chronic low back pain in elderly people. Pain is alleviated after one treatment. Trigger point acupuncture treatment of low back pain improves QOL.

9. **From acupuncture and moxibustion medicine perspective**

Not mentioned.

10. **Safety assessment in the article**

Not mentioned.

11. **Abstractor's comments**

This study compared trigger points and tender points as locations for acupuncture stimulation. The study compared a trigger point group, a tender point group, and a sham group, but it is regrettable that all the participants could not be retained, since some participants dropped out during the follow up. There was a significant change in the trigger point group compared to the other two groups by the end of treatment period, and clear effects could be inferred from the results of the within-group comparison. It is commendable that consideration was given to locating points with a certain level of tenderness for tender point identification. However, the method used by the authors' to locate stimulation sites raises some concern. For the sham group it was locating trigger point acupuncture sites only, for the trigger point acupuncture group it entailed examining the hip joint range of motion and locating sites, while for the tender point group it was locating the tender points in the low back and legs only. It is recommended that the effectiveness of trigger point acupuncture be verified by comparing it to the sham treatment. The researchers suggest that trigger points correspond to the pain relief points, so it may be possible to further improve the results of tender point treatment taking the classical acupuncture points into account, if it is possible to use trigger points properly. Recruitment and retention of subjects is a vital element of clinical research. It is hoped that the authors resolve this problem and move ahead with further research.

12. **Abstractor and date**

Furuya E, 19 November 2010.

13. Diseases of the Musculoskeletal and Connective Tissue

Reference

Nabeta T, Furuta T, Kitakouji H, et al. Randomized controlled pilot study of acupuncture on neck stiffness. *Zen Nihon Shinkyu Gakkai Zasshi* (*Journal of the Japan Society of Acupuncture and Moxibustion*) 1997; 47(3): 173–81 (in Japanese with English abstract). Ichushi Web ID: 1998092691

1. **Objectives**

To investigate the problems associated with conducting clinical trials of acupuncture.

2. **Design**

Randomized controlled trial using sealed envelopes for allocation (RCT: envelope).

3. **Setting**

Meiji School of Oriental Medicine, Osaka, Japan.

4. **Participants**

Thirty-two student volunteers who were identified as having neck stiffness by questionnaire prior to the intervention, and who gave informed consent by signature (mean age in the two groups: 32.8 and 30.4 years).

5. **Intervention**

Arm 1: Acupuncture group. A needle (0.2×50 mm) was inserted to a depth of 20 mm at the BL10 (天柱) point and was retained for 10 minutes after the sparrow-pecking technique was repeated 5 times (n=16).

Arm 2: Control group. A needle was used to pierce the skin at the BL10 (天柱) point but was removed after simulating insertion and sparrow pecking. Subsequent needle removal was also simulated (by deliberately making a sound when replacing the needle in the needle receptacle) (n=16).

The treatment period continued for three weeks. The volunteers received a weekly-intervention (3 in total). Two participants were dropped from Arm 1 (one due to herpes, and one due to needle pain), data were unavailable for four participants.

In Arm 2, data were unavailable for two participants (reasons unknown).

6. **Main outcome measures**

Stiffness was measured on a visual analogue scale (VAS) before treatment, immediately after treatment, and 1, 3, 5, and 7 days after treatment. Participants were asked about neck stiffness in the stimulation region, and stiffness in the whole shoulder. Subjects were also asked after the trial what kind of acupuncture they received.

7. **Main results**

There was no significant between-group difference in VAS change. In response to the question after the trial "What kind of acupuncture did you feel you received?," 66.7% of participants in Arm 1 and 35.7% in Arm 2 replied "They inserted needles." The difference was significant (χ^2=7.843, P=0.02).

8. **Conclusions**

Acupuncture has no effect on neck stiffness.

9. **From acupuncture and moxibustion medicine perspective**

Not mentioned.

10. **Safety assessment in the article**

One participant complained of needle pain in Arm 1.

11. **Abstractor's comments**

This study was intended to clarify the problems associated with the conduct of clinical trials of acupuncture and moxibustion by actually conducting an RCT of acupuncture. The aim of the study was not to evaluate the effect of acupuncture on neck stiffness. The authors mention that many problems result from the clinical trial design. Specifically, they discuss interventions, control group interventions, selection of disorders, recruitment bias, masking, statistical power, and intent-to-treat analysis. For researchers intending to conduct a study, the study has greater value as a reference for study design than as an evaluation of the therapeutic effect of acupuncture on neck stiffness. There were problems with the authors' intentions and ethics, and the value of the study may have been increased by selection of a disorder and acupuncture intervention that could be applied in the clinic.

12. **Abstractor and date**

Takahashi N, 6 December 2011.

13. Diseases of the Musculoskeletal and Connective Tissue

Reference

Nabeta T, Kawakita K. Relief of chronic neck and shoulder pain by manual acupuncture to tender points - a sham-controlled randomized trial. Complement Ther Med. 2002; 10:217–22. CENTRAL ID: CN-00736622.

1. **Objectives**

To assess the relief of neck and shoulder pain and stiffness provided by treatment with real acupuncture to tender points.

2. **Design**

Randomized controlled trial (RCT).

3. **Setting**

An acupuncture and moxibustion school, Osaka, Japan.

4. **Participants**

Thirty-four staff and students from an acupuncture and moxibustion school who complained of chronic dull pain and stiffness in the neck and shoulders (20–63 years of age; average ages in the two groups: 34.2 and 30.8).

5. **Intervention**

Arm 1: Acupuncture to tender points group. The stimulation points were all tender points in the left and right neck, shoulder, and back. Disposable needles (0.2 x 40 mm, Seirin Co., Ltd.) were inserted, then sparrow pecking technique was applied five times to elicit a *de qi* (得気) sensation. Participants received treatment once a week for three weeks (n=17).

Arm 2: Control group. The stimulation points were all tender points in the left and right neck, shoulder, and back. Needles with rounded tips (sham needles) were used and insertion and sparrow pecking were simulated. Participants received the same number of treatments as in Arm 1 (n=17).

Two participants from Arm 1 and five from Arm 2 withdrew.

6. **Main outcome measures**

The intensity of the pain in the neck, shoulders, and back, as well as the intensity of the stiffness in the shoulders was rated on a visual analogue scale (VAS). Pain intensities were rated before treatment (at six, four, two days, and immediately before), after each treatment (immediately, then at one, three, and five days after), and after the third treatment (at seven and nine days). Subjects were asked a question about their sensations during real and the sham acupuncture.

7. **Main results**

VAS scores decreased significantly in Arm 1 immediately after each treatment and one day after each treatment (within the group, $P<0.01$). Scores subsequently tended to return to baseline level, but differences tended to last longer with successive treatments. Similar tendencies were observed in Arm 2, but they were not statistically significant. No significant differences were observed between the two groups at any point after treatment. Pressure pain thresholds tended to increase with real acupuncture, but not with sham acupuncture. The study managed to mask participants to the intervention.

8. **Conclusions**

Acupuncture to tender points is effective for chronic neck and shoulder pain and stiffness for a short period.

9. **From acupuncture and moxibustion medicine perspective**

There is a similarity between tender point sites and acupuncture points.

10. **Safety assessment in the article**

Not mentioned.

11. **Abstractor's comments**

The study is well designed. Worth particular mention is that the study compares the effectiveness of acupuncture therapy for neck and shoulder pain and stiffness with a sham acupuncture technique that simulates needle insertion. Also the study succeeded in blinding participants to the interventions.

A recent large-scale acupuncture clinical trial proposed 12 as the standard number of treatments, but there was no significant between-group difference in this study, which means the number of treatments was insufficient. Although the study also mentioned intention-to-treat (ITT) analysis, it is regrettable that the sample size was not designed to assure a particular power. However, using sham acupuncture as a control in clinical trials could be a model for future studies.

12. **Abstractor and date**

Takahashi N, 3 December 2011.

13. Diseases of the Musculoskeletal and Connective Tissue

Reference

Furuya E, Nayuki T, Yakame M, et al. Effect of press tack needle treatment on shoulder stiffness. *Zen Nihon Shinkyu Gakkai Zasshi* (*Journal of the Japan Society of Acupuncture and Moxibustion*) 2002; 52(5): 553–61 (in Japanese with English abstract). Ichushi Web ID: 2003144987

1. **Objectives**

To evaluate the effect of press tack needle treatment on shoulder stiffness.

2. **Design**

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

3. **Setting**

Tokyo Therapeutic Institute, Tokyo, Japan.

4. **Participants**

A total of 53 teachers and students with awareness of (subjective) shoulder stiffness (15 males and 38 females).

5. **Intervention**

Arm 1: Press tack needle group. Pyonex needles (Seirin Co., Ltd.; length 0.6 mm) were inserted at up to 4 tender points detected by palpation, and retained for 3 days (n=28).

Arm 2: Placebo press tack needle group. Needles with the same shape as Pyonex and tips removed were used. Stimulation was applied in the same manner as in Arm 1 (n=25).

6. **Main outcome measures**

Visual analogue scale (VAS) score for shoulder stiffness (evaluated before, immediately after, and 3 days after the treatment) and the number of subjects with "awareness of shoulder stiffness" (based on the Hiro Jikaku-shojo Shirabe [questionnaire on subjective fatigue symptoms], developed by the Japan Society for Occupational Health; evaluated before and 3 days after the treatment).

7. **Main results**

Comparison of pre- and post-treatment VAS scores revealed significant improvements immediately ($P<0.05$) and 3 days ($P<0.01$) after the treatment in Arm 1, but no significant change in Arm 2. The number of subjects with "awareness of shoulder stiffness" was significantly decreased in Arm 1 compared with Arm 2 ($P<0.01$).

8. **Conclusions**

Continuous retention of press tack needles improves shoulder stiffness.

9. **From acupuncture and moxibustion medicine perspective**

The authors mentioned that press tack needle retention may enhance parasympathetic function, and that self-care with press tack needles might be a successful treatment for mibyo (presymptomatic disease).

10. **Safety assessment in the article**

Adverse events occurred in 5 subjects in Arm 1 (itching in 4 and discomfort in 1) and 4 in Arm 2 (itching in 3 and discomfort in 1), but no one dropped out.

11. **Abstractor's comments**

This study is highly valued in that the effect of press tack needle treatment was evaluated in a double-masked trial. But, as all the subjects were teachers or students at the Tokyo Therapeutic Institute, who were likely able to distinguish press tack needles from placebo press tack needles, description about the success or failure of the double masking is needed. This revolutionary study attempted double masking (subject and practitioner masked), which is generally difficult in a clinical study of acupuncture. Future development of this type of study is anticipated.

12. **Abstractor and date**

Hosaka M, 11 September 2011.

13. Diseases of the Musculoskeletal and Connective Tissue

Reference

Shinohara S. Clinical effects of acupuncture (intradermal needles) based on the muscle meridians for the complaints on the joints and muscles during movements. *Meiji Shinkyu Igaku* (*The Bulletin of Meiji University of Oriental Medicine*) 2000; 26: 65–80 (in Japanese with English abstract). Ichushi Web ID: 2001218258

1. **Objectives**

To evaluate the efficacy of intradermal acupuncture based on the muscle meridians for relieving locomotor complaints (pain, stiffness, rigidity, and twitching during movement).

2. **Design**

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

3. **Setting**

Center of Acupuncture Science, the Meiji University of Oriental Medicine (current Meiji University of Integrative Medicine); Outpatient Clinic of the Department of Orthopedic Surgery, the Meiji University of Oriental Medicine Hospital, Kyoto, Japan.

4. **Participants**

Ninety patients with locomotor complaints. The mean ages for three groups were: 61.4, 63.9 and 62.4 years, respectively.

5. **Intervention**

Arm 1: Real meridian treatment group: intradermal needle was inserted (transverse insertion, 0.2–0.5 mm) at the brook point (栄穴) on the periphery of the muscle meridian passing the site related to the complaints, and fixed with bandages (n=30).

Arm 2: Sham treatment group (n=30): at the same point as in Arm 1, intradermal needle was discarded just before the insertion and bandage fixation was applied.

Arm 3: Other meridian treatment group (n=30): intradermal needle was inserted (transverse insertion, 0.2–0.5 mm) at the brook point (栄穴) on the muscle meridian adjacent to that treated in Arm 1, and fixed with bandages (n=30).

Two patients in Arm 3 dropped out.

6. **Main outcome measures**

Visual Analog Scale (VAS) score for pain during movement.

7. **Main results**

VAS score improved significantly before and after the treatment in Arms 1 and 2 ($P=0.0001$ and $P=0.0287$, respectively), whereas it did not change significantly in Arm 3. The greatest improvement in the score was seen in Arm 1. Also, reduction ("change" in the text) in VAS score was significantly greater in Arm 1 compared with Arm 2 ($P<0.01$) and Arm 3 ($P<0.001$).

8. **Conclusions**

Intradermal acupuncture based on the muscle meridians is effective for relieving locomotor complaints.

9. **From acupuncture and moxibustion medicine perspective**

The author mentioned that the muscle meridian, described in "Ling Shu (霊枢)"/Jing jin Muscle Regions Along Meridians (経筋篇) (No. 13), is a specific meridian system that controls functions of the locomotor system.

10. **Safety assessment in the article**

Not mentioned.

11. **Abstractor's comments**

This article is valuable in that the authors described the significance of using muscle meridians for locomotor system control, based on the analysis of classic literature, and then attempted, in a clinical study, to prove a working hypothesis that muscle meridian-based treatment might contribute to the improvement of locomotor complaints. The author's attempt to evaluate the original effects of intradermal acupuncture on locomotor complaints, rather than on disorders, is also appreciated. Some improvements may be needed in the following aspects: 1) the author did not mention sham needle when obtaining informed consent; 2) VAS was the only outcome measure; 3) only direct effects immediately after the treatment were evaluated and no follow-up was carried out; and 4) masking status was not evaluated. Further development of studies on the muscle meridians is anticipated.

12. **Abstractor and date**

Wakayama I, 9 September 2011.

13. Diseases of the Musculoskeletal and Connective Tissue

Reference

Ito K, Katsumi Y. Effect of acupuncture treatment on chronic low back pain with leg pain in aged patients - a controlled trial about short-term effects of trigger point acupuncture -. *Zen Nihon Shinkyu Gakkai Zasshi* (*Journal of the Japan Society of Acupuncture and Moxibustion*) 2005; 55 (4): 530–37 (in Japanese with English abstract). Ichushi Web ID: 2005296314

1. Objectives

To evaluate the efficacy of trigger point acupuncture treatment for chronic low back pain (LBP) with leg pain in aged patients.

2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

3. Setting

Department of Orthopedic Surgery, the Meiji University of Oriental Medicine (current Meiji University of Integrative Medicine) Hospital, Kyoto, Japan.

4. Participants

Forty-four outpatients (aged 65 years or older) with LBP and leg pain persisting for at least 6 months.

5. Intervention

Arm 1: Standard acupuncture group (n=11), Standard acupuncture applied to traditional acupuncture points..
Arm 2: Superficial trigger point acupuncture group (n=11).
Arm 3: Deep trigger point acupuncture group (n=11).
Arm 4: Sham trigger point acupuncture group (n=11).
The intervention performed once a week for 3 weeks. Dropped out rate was 18% (8/44).

6. Main outcome measures

The intensity of LBP with leg pain was assessed using a visual analog scale (VAS), and quality of life (QOL) was assessed using the Roland-Morris Disability Questionnaire (RDQ).

7. Main results

At the end of the treatment period, pain intensity and QOL were significantly improved in Arm 3 alone compared with Arm 4 ($P<0.01$). The effects persisted during the 3-week follow-up. Comparison of final values in Arm 2 with baseline values in each arm revealed a significant effect of superficial trigger point acupuncture.

8. Conclusion

Trigger point acupuncture can be an effective treatment for chronic low back pain with leg pain in aged patients.

9. From acupuncture and moxibustion medicine perspective

The observation that deep needling of the trigger points is more effective than standard acupuncture at traditional acupuncture points is interesting, as traditional acupuncture points and trigger points are closely related. However, this matter is not discussed.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comment

This is a well-designed clinical study with four parallel arms, and the trial and analyses were appropriately conducted. The report indicates that trigger point acupuncture treatment once a week for 3 weeks significantly improves chronic low back pain (with leg pain) in the elderly. On the other hand, the report showed that standard acupuncture at traditional acupuncture points and superficial needling of the trigger points are ineffective. Sham acupuncture (mimicked needling without insertion of the needle) was used successfully for single-masking. Pain intensity was rated on a VAS with 100 as the greatest pain ever experienced, which should have been the greatest pain imaginable. Also, methods other than the envelope method, such as assignment by a computer-generated randomization list, were attempted for appropriate randomization. Regrettably there is no description of adverse events. Anyhow, more high-quality studies like this one are indicated.

12. Abstractor and date

Kawakita K, 15 December 2010.

Symptoms and Signs

Reference

Tomita K, Kitakoji H, Honjo H, et al. Effect of moxibustion treatment for nocturia: a randomized controlled trial. *Zen Nihon Shinkyu Gakkai Zasshi* (*Journal of the Japan Society of Acupuncture and Moxibustion: JJSAM*) 2009; 59(2): 116–24 (in Japanese with English abstract). Ichushi Web ID: 2009213798

1. Objectives

To evaluate the effectiveness of moxibustion treatment for nocturia.

2. Design

Randomized controlled trial (RCT).

3. Setting

Home and the Department of Urology, the Meiji University of Oriental Medicine (current Meiji University of Integrative Medicine) Hospital, Kyoto, Japan.

4. Participants

Forty eight outpatients with nocturia refractory to drug treatment who visited a department of urology.

5. Intervention

Arm 1: Moxibustion group (n=25). Indirect moxibustion applied to the CV3 (中極) acupuncture point, self-administered three times/day for one week.

Arm 2: Sham moxibustion group (n=23). Indirect moxibustion without adequate heating. Duration and frequency of the treatment were the same as in Arm 1.

Drop-out rate was 25% (12/48).

6. Main outcome measures

The number of nocturia events.

7. Main results

Treatment significantly decreased the average number of nocturia episodes in Arm 1 ($P<0.01$), but not in Arm 2 ($P=0.551$). There was no significant between-group difference in effectiveness ($P=0.306$).

8. Conclusion

Indirect moxibustion may be able to improve nocturia.

9. From acupuncture and moxibustion medicine perspective

The CV3 (中極) acupuncture point was selected because it was 1) expected to affect bladder function regulation, and 2) be suitable for self-administration of moxibustion.

10. Safety assessment in the article

Second-degree burns were documented in 3 cases in Arm 1.

11. Abstractor's comment

Sham moxibustion (indirect moxibustion; application of insufficient heat) was used as control in this study, and validity of the sham moxibustion as control was also assessed. As there have been few RCT studies on moxibustion, this study should provide valuable information. Notably, the average number of nocturia events, the outcome measure of this trial, was significantly decreased in the treatment group. However, finding of no significant difference between arms was disappointing. The results were not assessed by ITT analysis even though some subjects withdrew from the study. Group allocation might have been biased by symptoms and underlying medical conditions. Indirect moxibustion performed at home might hamper recruitment of subjects and result in increased drop-out rate, but even so, these problems can be solved and lead to further progress in the studies.

12. Abstractor and date

Takahashi N, 10 August 2010, 21 August 2010.

18. Symptoms and Signs

Reference

Minagawa M, Ishigami T, Hori S, et al. Controlled clinical trials using the envelope method for urinary dysfunction — the effectiveness of the zhongji (cv-3). *Zen Nihon Shinkyu Gakkai Zasshi* (*Journal of the Japan Society of Acupuncture and Moxibustion*) 1999; 49(3): 383–91 (in Japanese with English abstract). Ichushi Web ID: 2000067347

1. **Objectives**

To evaluate the effects of treatment for urinary dysfunction as chief complaint, and treatment plus acupuncture at the CV3 (中極) acupuncture point.

2. **Design**

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

3. **Setting**

Nine practicing acupuncture and moxibustion clinics, Japan.

4. **Participants**

Ninety patients with urinary dysfunction symptoms identified by questionnaire (mean age in the two groups: 59.8 and 59.7 years).

5. **Intervention**

Arm 1: CV3 (中極) group. Single needle treatment (5–7 mm) at the CV3 (中極) acupuncture point, in addition to treatment for the chief complaint (n=44).

Arm 2: Control group. Treatment for the chief complaint only (n=46).

Treatment in both groups at least once a week (three times in total).

6. **Main outcome measures**

Evaluation of urinary dysfunction by questionnaire before each treatment and after the third treatment.

7. **Main results**

No significant between-group and between-gender differences were observed in the change in overall urinary dysfunction score, frequency of nighttime urination, and daytime urination interval.

8. **Conclusions**

Acupuncture stimulation at the CV3 (中極) acupuncture point has no effect on urinary dysfunction.

9. **From acupuncture and moxibustion medicine perspective**

Not mentioned.

10. **Safety assessment in the article**

Not mentioned.

11. **Abstractor's comments**

The authors should be commended for having conducted a multi-center RCT with 90 urinary dysfunction patients. It is an important paper that demonstrates a study can be conducted at acupuncture and moxibustion clinics. Regrettably, the authors do not describe how they estimated sample size and how random allocation and masking were conducted. In addition, it is possible that the outcome was negative because the intervention was the usual treatment in the control group and only the usual treatment plus CV3 (中極) acupuncture in the intervention group. We anticipate further research that addresses those problems, since the authors did manage to conduct this multi-center randomized controlled trial.

12. **Abstractor and date**

Shinohara S, 31 January 2011, Takahashi N, 11 January 2012.

18. Symptoms and Signs

Reference

Yamazaki T, Fukuda F, Ishizaki N, et al. The effect of acupuncture on chronic fatigue in healthy subjects. *Nihon Mibyou Shisutemu Gakkai Zasshi* (*The Journal of Japan Mibyou System Association*) 2009; 15(2): 186–96 (in Japanese with English abstract). Ichushi Web ID: 2010161854

1. Objectives

To evaluate the effectiveness of acupuncture for chronic fatigue (*mibyou* [未病]; fatigue with no medical explanation).

2. Design

Randomized controlled trial (RCT).

3. Setting

Not described.

4. Participants

Nineteen workers from a firm in northern Kyoto prefecture who noticed persistent fatigue over the previous 6 months but no other related medical abnormality (age range, 25–65; mean age, 50.4 and 46.2 years, respectively).

5. Intervention

Arm 1: Acupuncture group. History taking (interview) and acupuncture treatment for fatigue twice a week for a total of 16 times (eight weeks). The basic acupuncture points were the LI4 (合谷), ST36 (足三里), KI3 (太谿), and BL23 (腎俞), and additional acupuncture points were selected for use in treatment according to the complaint location. Stainless steel needles (0.14×30 mm; Seirin Co., Ltd.) were used (n=9).

Arm 2: Control group. Interview conducted once a week (n=10).

One participant dropped out of Arm 2.

6. Main outcome measures

Subjective measures

Subjective physical fatigue and mental fatigue (visual analogue scale,VAS).General Health Questionnaire-12 (GHQ-12), and accumulated fatigue (Self-Diagnostic Checklists for Accumulated Fatigue, Ministry of Health, Labour, and Welfare).

Objective measures

Blood chemistry (ACTH, dopamine, adrenalin, noradrenalin, and cortisol), sleep efficiency scores (measured by actigraphy), and level of oxidative stress (8-hydroxy-2-deoxyguanosine [8-OHdG]) and potential antioxidant [PAO]).

7. Main results

All subjective measures improved significantly in Arm 1 compared to Arm 2 (P=0.001-0.034). Differences in objective measures were not significant either before and after interventions, or between groups.

8. Conclusions

Acupuncture alleviates chronic fatigue with no medical explanation (*mibyo*).

9. From acupuncture an

10. d moxibustion medicine perspective

Fatigue is treated as a deficiency of the qi (気虚, *kikyo*) and blood (血虚, *kekkyo*). LI4 (合谷), ST36 (足三里), KI3 (太谿), and BL23 (腎俞) are considered the basic acupuncture points for treatment of those deficiencies.

11. Safety assessment in the article

No adverse event was developed.

12. Abstractor's comments

This study treats physical and mental fatigue as mibyou, and uses multiple measures to examine the effects of acupuncture in detail on this pathological condition. The authors properly present the baseline information for each group, the flowchart on allocation, and adverse event information. There were few participants (9 and 10 in the respective groups), and there was no follow up at the end of the 8-week study period. These are areas needing improvement. Focusing attention on mibyou is very significant for acupuncture and moxibustion. Expectations are great for future development in this area.

13. Abstractor and date

Haruki J, 9 September 2011.

18. Symptoms and Signs

Reference

Sakaguchi S, Kanai S, Toda S. A randomized controlled trial of the effect of acupuncture and moxibustion on sensitivity to cold*. *Kansai Iryou Daigaku Kiyou* (*The Bulletin of Kansai University of Health Sciences*) 2007; 1: 82–5 (in Japanese). Ichushi Web ID: 2008048658

1. **Objectives**
   To evaluate the effect of acupuncture and moxibustion on sensitivity to cold.
2. **Design**
   Randomized controlled trial (RCT).
3. **Setting**
   Kansai College of Oriental Medicine, Osaka, Japan.
4. **Participants**
   Nineteen volunteers with sensitivity to cold who: 1) responded to recruitment advertisements posted on the bulletin board in Kansai College of Oriental Medicine for approximately 2 weeks from the end of October 2005; and 2) provided written and oral informed consent (mean age, 20.5±3.2 years; range, 18–32 years).
5. **Intervention**
   Arm 1: Acupuncture group. In the supine position, disposable stainless steel needles (0.25×20 mm, Seirin Co., Ltd.) were inserted to a depth of 15 mm at the SP6 (三陰交) and ST36 (足三里) acupuncture points. Pre-cut moxa for heating (Hiei™, Senefa Corporation) was attached to the needle handle and burned. At the same time, warming moxibustion was applied around the CV4 (関元) acupuncture point by using 4 moxa rolls (Fukuju-koh™, Nippon Wakame Fukyu Kyokai) inserted in a guide tube for warm moxibustion (蓮台). Then, in the prone position, the moxibustion was applied around the BL32 (次髎) acupuncture point in the same manner as described above for CV4 (関元) while irradiating the lumbar area with infrared light (n=10).
   Arm 2: Control group. No treatment during the intervention period (n=9).
   One subject in Arm 1 with incomplete data was excluded from the analysis.
   Treatment was administered taking into consideration each subject's menstrual cycle; once or twice per week, a total of 5 times, between the end of the menstrual period and the beginning of the next one.
6. **Main outcome measures**
   Degree of suffering from coldness assessed on a 6-point numerical rating scale (0–5; self-administered): 0=no cold feeling, 5=maximal coldness.
   Score for static blood (瘀血, *oketsu*) measured by a masked evaluator before and after the intervention.
   Peripheral blood hematocrit, remnant-like particles-cholesterol (RLP-C) level, and viscosity.
7. **Main results**
   Degree of suffering from coldness showed no interaction with treatment arms and no significant between-arm difference. Similarly, score for static blood showed no interaction with treatment arms and no significant between-arm difference. The three hematologic variables also showed no interaction and no significant between-arm difference.
8. **Conclusions**
   Acupuncture and moxibustion has no additional effect over that of control treatment on sensitivity to cold.
9. **From acupuncture and moxibustion medicine perspective**
   The authors linked the development of sensitivity to cold with static blood.
10. **Safety assessment in the article**
    Not mentioned.
11. **Abstractor's comments**
    This valuable RCT evaluated the efficacy of acupuncture and moxibustion for reducing sensitivity to cold as compared with no treatment. Although the validity was not evaluated, the study is appreciated for seeking high-quality RCT by masking the evaluator of the static blood score. As a result, no effect of acupuncture and moxibustion was found, but it may become possible to detect a therapeutic effect on sensitivity to cold if sample size were predefined and outcome measures changed. The selection of treatment acupuncture points seems to have taken the link between sensitivity to cold and static blood into account, but the quantity and quality of the intervention should be discussed more extensively. Since sensitivity to cold is thought to occur over a wide age range, comparative trials including a wider range of age groups is desired.
12. **Abstractor and date**
    Takahashi N, 6 December 2011.

19. Post-anesthesia and Postoperative Pain

Reference

Ishimaru K, Sakita M. Effects of acupuncture analgesia on postoperative pain. *Toyo Igaku to Pain Clinic* (*Oriental Medicine and the Pain Clinic*) 2002; 32(1–4): 10–18 (in Japanese with English abstract). Ichushi WEB ID: 2004115450.

1. **Objectives**
   To evaluate the effects of acupuncture analgesia on postoperative pain.
2. **Design**
   Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).
3. **Setting**
   Department of Surgery, the Meiji University of Oriental Medicine (current Meiji University of Integrative Medicine) Hospital, Kyoto, Japan.
4. **Participants**
   Twenty-two outpatients who received abdominal surgery under general anaesthesia.
5. **Intervention**
   Arm 1: Electro-acupuncture group. Electro-acupuncture treatment (3 Hz) applied at the LI4 (合谷) and ST36 (足三里) acupuncture points was performed at three hours after surgery for three hours (n=11).
   Arm 2: Non-energization group. No needle insertion or energization (n=11).
6. **Main outcome measures**
   β-endorphin and adrenocorticotropic hormone (ACTH) levels in peripheral blood, subjective pain evaluation.
7. **Main results**
   Post-operative β-endorphin levels were higher than pre-surgery levels in Arm 1 and although they had decreased by three hours after surgery (before electro-acupuncture commenced), they increased again immediately after electro-acupuncture. In contrast, while levels were higher than pre-surgery levels in Arm 2, they continued to decrease linearly with time. There was a significant difference ($P<0.05$) between groups in the levels six hours after surgery (after completion of electro-acupuncture). The average ACTH levels in Arm 1 were 42.8±27.4 pg/mL before surgery, and 335.4±205.7 pg/mL one hour after surgery commenced. In Arm 2, the average ACTH levels were 37.6±19.2 pg/mL before surgery, and 237.1±178.0 pg/mL one hour after surgery commenced. This meant a significant increase ($P<0.01$) from pre-surgery levels in both groups. ACTH levels continued to decrease in both groups after surgery, and no significant difference between groups was found. Painkillers were required for only one of the 11 participants in Arm 1, but they were required for 10 of the 11 participants in Arm 2.
8. **Conclusions**
   Post-operative electro-acupuncture decreases painkiller usage by raising β-endorphin levels.
9. **From acupuncture and moxibustion medicine perspective**
   The trial selected the LI4 (合谷) and ST36 (足三里) acupuncture points, which, as the basic data and the results of surgery during acupuncture anesthesia suggest, offer the most pain relief.
10. **Safety assessment in the article**
    Not mentioned.
11. **Abstractor's comments**
    This interesting study compares the effects of acupuncture analgesia for post-operative pain using the time course of β-endorphin and ACTH levels in blood; it also evaluates painkiller dosage and mentions the mechanism of action of acupuncture analgesia as well as its effects. Unfortunately the envelope method was used for randomization. The control group was described as the "non-energization group," but in fact, no needles were inserted, so "no treatment group" would be a more apt description. This is an important study that suggests the clinical usefulness of acupuncture analgesia. Further examination is desirable.
12. **Abstractor and date**
    Inoue E, 27 January 2010.

21. Others

Reference

Kuge H, Hatano Y, Mori H. Influence of fireless moxibustion on QOL (SF-36®) in elderly people. *Nihon Onsen Kiko Butsuri Igakkai Zasshi* (*The Journal of the Japanese Society of Balneology, Climatology and Physical Medicine*) 2008; 71(3): 180–6 (in Japanese with English abstract). Ichushi Web ID: 2008252546

1. Objectives

To evaluate the effectiveness of fireless moxibustion at home to maintain QOL for elderly people.

2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

Setting

Subjects' homes, Japan.

3. Participants

Twenty-seven elderly people living at home (10 males, 17 females, ages 66–94).

4. Intervention

Arm 1: Fireless moxibustion group. Fireless moxibustion (Sennenkyu Taiyo®, Senefa Corporation) was used for about one hour each at the bilateral BL23 (腎俞) and ST36 (足三里) acupuncture points, every two days for a total of four treatments (n=11).

Arm 2: Sham fireless moxibustion group. Same treatment, but using Sennenkyu Taiyo® altered to give off no heat (n=16).

5. Main outcome measures

SF-36™ Ver.2 acute Japanese version, evaluation on day 7, 14, and 21.

6. Main results

Scores related to "bodily pain" in the SF-36 (questions seven and eight) improved significantly after treatment in Arm 1 ($P<0.05$).

7. Conclusions

Fireless moxibustion used at home relieves bodily pain in elderly people.

8. From acupuncture and moxibustion medicine perspective

None.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

This study is of great significance for its focus on fireless moxibustion, which can be easily used at home to maintain or improve the QOL of elderly people, whose numbers continue to grow in Japan. The study evaluated low back and leg complaints; however, there was a pretreatment difference between the two groups. Therefore, the recruitment process might have been improved by stratifying participants by complaint after recruitment, or recruiting participants with low back and leg complaints. Masking subjects was difficult and bias might have been introduced as one type of moxa heated up to 50°C and the other did not heat up. It would be preferable to describe the timing of the trial and the success or failure of masking. This therapy holds promise for elderly people trying to maintain or improve their QOL. Having a therapy that users can manage themselves, without frequent visits to a medical facility, is of great help to elderly people who live far from town or city centers. Further research is anticipated.

11. Abstractor and date

Shimoichi Y, 11 September 2011.

Appendix 4

あん摩・マッサージ・指圧
エビデンスレポート2011
－18のRCT－

(EAMS 2011)

2012.3.31

Evidence Reports of Anma-Massage-Shiatsu:
18 Randomized Controlled Trials of Japan
(EAMS 2011)
31 Mar 2012

東アジア伝統医学の有効性・安全性・経済性のシステマティック・レビュー
あマ指エビデンスレポート・タスクフォース

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目 次

CONTENTS

1. あん摩，マッサージ，指圧構造化抄録作成の背景 (background)

人口の高齢化を背景に医療費及び介護費が急騰し各保険の財政基盤が危機に直面している。この問題を契機に、2006年には治療重視型の医療から予防に軸足を移した医療に改める医療制度構造改革が行われ、介護分野でも介護予防事業に国を挙げて取り組むことになった。しかし皮肉にも、この改革以降、要介護・要支援認定率は高齢者の増加率を上回る勢いで増えており、2011年8月現在、全高齢者に占めるその割合は17%を超えた。

上の事実は、既存の医療・介護予防サービス体系の枠組みで行われた改革の限界を示唆しつつ、一方では、伝統療法を含む多様な医療資源を総動員しなければ、超高齢社会における医療・介護は立ちゆかなくなるという、差し迫った課題を投げかけている。

この観点から、あん摩・マッサージ・指圧 (以下，あマ指と略記) の特性をみると、医療免許制度及び公的教育制度が確立していること、江戸期以降、民間に根付いていること等の点で，地域における公的医療・介護資源としての高い的確性を有しており、その早期制度化 (公的医療化) が望まれる。

しかしながら、あマ指分野では、エビデンスに基づく医療 (evidence-based medicine: EBM) に係る本格的評価は行われてこなかった。このことが、あマ指療法の医療・介護資源としての価値を過小視する風潮を生む一方で、制度化の作業を困難にしてきた一因と思われる。

こうした状況の中で、玉石混交の、あマ指関連情報を網羅的に吟味し、その中から信頼できる文献をデータベース化すること、ならびに、それを誰もが検索できるシステムとして構築することは、日々、患者に有用な施術情報を希求している臨床家の便宜となるほか、あマ指療法への国民の信頼度を高める上で大きな意義を持つものと考える。

そこで、2010 年度に採択された厚生労働科学研究費補助金（地域医療基盤開発推進研究事業）による「東アジア伝統医学の有効性・安全性・経済性のシステマティック・レビュー」(研究代表者：津谷喜一郎)の分担研究の一環として、あマ指療法に関する論文のシステマティック・レビューを行い，当該療法の有効性，安全性，経済性に関するエビデンスのグレードを明らかにし，その成果を構造化抄録にまとめることとした。

2. 目的 (purpose)

あマ指療法に関する論文を網羅的に収集・吟味し、それぞれのエビデンスのグレードを明らかにした上で，エビデンスレベルの高い論文を構造化抄録にまとめ公開する。

3. 構造化抄録作成のステップ (steps for development of structured abstracts)

構造化抄録 (structured abstract) を作成するまでの工程は、候補書誌の検索 → 対象外論文のスクリーニング → 除外論文のスクリーニング → 構造化抄録の作成の手順で

実施した。

(1) 候補書誌の検索

あマ指療法に関するエビデンスレポートを作成するにあたり、今回は、日本で発行された雑誌に日本人が報告した関連研究の成果を収集することとした。そのため、候補書誌の検索には医学中央雑誌 Web Ver.4 (1983-2010) のデータベースのみを用いた。

候補書誌の選定に当たっては、まず、キーワード (統制語)を決定し、**Table 1** に示した検索式を作成した。その上で、論文のタイトルまたはアブストラクトに、あマ指と同属・同類の手技療法の用語がつけられているか、もしくは含まれているもので、かつ、対照群に関する基準 (メタアナリシス/RD or ランダム化比較試験/RD or 準ランダム化比較試験/RD) を満たす論文を候補書誌の検索条件とした。

Table 1 医中誌 Web Ver.4 によるあマ指関連の研究検索式と件数

検索日 2010 年 5 月 21 日

No.	検索式	件数
#1	あんま/AL or 按摩/AL or あん摩/AL or 指圧/TH or 指圧/AL or pointillage/AL or Shiatzu/AL or shiatsu/AL or "finger pressure"/AL or Acupressure/AL or acupressurist/AL or "Zhi Ya"/AL or "Chih Ya"/AL or manipulation/AL or manipulative/AL or マニピュレーション or マニピュレイション	4,424
#2	マッサージ/TH or マッサージ/AL or 揉み治療/AL or 揉み療治/AL or もみ治療/AL or もみ療治/AL or massage/AL or masseur/AL or masseuse/AL or massagist/AL or massotherap/AL	6,304
#3	#1 or #2	9,907
#4	リフレクソロジ/AL or reflexolog/AL or ゾーンセラピー/AL or "Zone Therap"/AL or ナプラパシー/AL or naprapath/AL or カイロプラク/AL or chiropractic/AL or chiropraxis/AL or 整体/AL	1,412
#5	#1 or #2 or #4	10,669
#6	#5 and RD=診療ガイドライン	3
#7	#5 and RD=メタアナリシス not #6	3
#8	#5 and RD=ランダム化比較試験 not #6 not #7	45
#9	#5 and RD=準ランダム化比較試験 not #6 not #7 not #8	19
#10	#5 and 臨床試験/TH not #6 not #7 not #8 not #9	35
#11	#5 and RD=比較研究 not #6 not #7 not #8 not #9 not #10	354
#12	(#6 or #7 or #8 or #9 or #10 or #11)	459