

**13. Diseases of the Musculoskeletal and Connective Tissue****Reference**

Itoh K, Hirota S, Katsumi Y, et al. Trigger point acupuncture for treatment of knee osteoarthritis - a preliminary RCT for a pragmatic trial. *Acupuncture in Medicine* 2008; 26(1): 17–26. CENTRAL ID: CN-00638475

**1. Objectives**

To compare the effectiveness of trigger point acupuncture and standard point acupuncture for treating knee osteoarthritis in the elderly.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

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

**4. Participants**

Thirty outpatients clinically and radiologically diagnosed with osteoarthritis of the knee according to the American College of Rheumatology criteria and with knee osteoarthritis pain for at least six months (3 males, 27 females; age 61–82).

**5. Intervention**

Arm 1: Trigger point acupuncture group. Stainless steel needles (0.2×50 mm) were inserted into the muscle to a depth of between 10 and 30 mm. The sparrow pecking technique was used to elicit local muscle twitch, and the needles were left in place for 10 minutes (n=10).

Arm 2: Standard point acupuncture group. Stainless steel needles (0.2×40 mm, Seirin Co., Ltd.) were inserted into the muscle to a depth of 10 mm. The sparrow pecking technique was applied, and the needles were left in place for 10 minutes once the patient felt dull pain or the acupuncture sensation (de qi). The acupuncture points were 梁丘 (ST34), ST35 (犢鼻), ST36 (足三里), SP9 (陰陵泉), SP10 (血海), and GB34 (陽陵泉) (n=10).

Arm 3: Sham acupuncture group. Stainless steel needles (0.2×50 mm, with the tips cut off) were used. The treatment was applied at trigger points with the acupuncturist simulating insertion and sparrow pecking (needles were not actually inserted). Eye masks were used (n=10).

Treatment was given once a week on five occasions for Arms 1 to 3.

**6. Main outcome measures**

- Pain intensity using a visual analogue scale (VAS) was assessed before the first treatment and then 1, 2, 3, 4, 5, 10, and 20 weeks after the first treatment (eight times).
- Western Ontario and McMaster Universities Osteoarthritis (WOMAC) Index was assessed before the first treatment and then 5, 10, and 20 weeks after the first treatment (four times).

**7. Main results**

The mean VAS score was significantly lower in Arm 1 and Arm 2 than in Arm 3 ( $P<0.001$  and  $P=0.006$ , respectively). Comparison of area under the curve for the three groups showed that patients in Arm 1 had the lowest scores, confirming the significant difference in Arm 3 ( $P=0.025$ ).

The mean WOMAC index was significantly lower in Arms 1 and 2 than in Arm 3 ( $P<0.001$  and  $P<0.001$ , respectively). Comparison of area under the curve for the three groups showed that patients in Arm 1 had the lowest score, confirming the significant difference in Arm 3 ( $P=0.031$ ).

**8. Conclusions**

Trigger point acupuncture is effective for knee osteoarthritis in elderly people.

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

Trigger points appear to be due to the heightening of sensitivity of nociceptors by a variety of factors and, acupuncture stimulation of these points affect nociceptors. On the other hand, the paper mentions that stimulation of acupuncture points does not necessarily affect nociceptors that have heightened sensitivity.

**10. Safety assessment in the article**

Not mentioned.

**11. Abstractor's comments**

The study compared the effects of differing acupuncture treatments, including sham acupuncture, for elderly people with knee osteoarthritis. The measures and the outcomes are clear and coherent. The quality of this RCT is high: it included randomization and masking procedures, and reports the outcomes. However, examination of the trigger points in Arm 2 and examination of the acupuncture points in Arm 1 clearly differed. If some participants had prior experience of acupuncture, then masking might have been inadequate. The study's clinical significance is great. Further development of this research is anticipated.

**12. Abstractor and date**

Shimoichi Y, 11 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Miyamoto T, Itoh K, Ochi H, et al. The efficacy of acupuncture treatment on pain and ability with osteoarthritis of the knee. - Examination of the curative effect by the depth of an acupuncture needle -. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 2009; 59(4): 384–94 (in Japanese with English abstract). Ichushi Web ID: 2009340447

#### 1. Objectives

To evaluate the efficacy of acupuncture to different depths on motor function and pain in patients with osteoarthritis of the knee.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

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

#### 4. Participants

Twenty-six outpatients with osteoarthritis of the knee who met certain inclusion criteria such as aged 45 years or older, disease duration for at least 6 months, and not treated knee pain with acupuncture within 6 months.

#### 5. Intervention

Arm 1: Superficial acupuncture group (n=13). Acupuncture needles were inserted about 3 mm into 10 tender points of the lower limb and retained for 10 minutes, once a week for 8 weeks.

Arm 2: Deep acupuncture group (n=13). Acupuncture needles were inserted about 10–20 mm into 10 tender points of the lower limb, with the same intervention duration and frequency as Arm 1.

Three subjects dropped out of the study.

#### 6. Main outcome measures

Knee pain intensity assessed on a visual analogue scale (VAS), performance time for the Timed Up and Go (TUG) Test, 20-m walking time, time for going up and down stairs, and Western Ontario and MacMaster Universities osteoarthritis index (WOMAC).

#### 7. Main results

Treatment significantly improved knee pain intensity (assessed by VAS) compared with baseline in both arms ( $P<0.05$ ). However, treatment improved TUG score, 20 m walking time, and time of going up and down stairs only in Arm 1 ( $P<0.05$ ). No significant change in WOMAC score was observed in either arm.

#### 8. Conclusion

Both deep and superficial acupuncture decrease knee pain intensity, but only superficial acupuncture improves motor function.

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

Ten tender points (in descending order according to pain intensity) in the femoral and leg region were selected for needling. Concordance rate of the tender points and acupuncture points was over 40% in both groups. High concordance rate tended to be observed in the medial part of the knee at points such as SP9 (陰陵泉), LR8 (曲泉), and LR7 (膝關), EX-LE4 (內膝眼).

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comment

This is the first study to compare the efficacy of acupuncture at two depths of needle penetration for pain intensity and motor function, and the result is interesting. By intention to treat (ITT) analysis including patients who dropped out of the trial, superficial acupuncture improved both pain intensity and motor function, which suggests that superficial acupuncture is therapeutically as effective as deep acupuncture. A previous study demonstrated that gentle stimulation (like superficial acupuncture) is more efficient than deep acupuncture in improving motor function, which clarifies the problem with many clinical trials that use minimal acupuncture as the sham acupuncture control. However, in this trial, the evaluation of motor function might have been biased because the person who provided treatment also performed the evaluation. Since no significant inter-group difference was observed, the authors suggest that it would be unwise to conclude the greater effectiveness of superficial acupuncture than deep acupuncture. Controlling for conditions such as masking and the grade of the osteoarthritis of the knee is anticipated to improve the study. In spite of some deficiencies, this study is highly regarded for its focus and demonstration of the possible efficacy of superficial acupuncture.

#### 12. Abstractor and date

Inoue E, 23 November 2010, Furuya E, 24 November 2010, Takahashi N, 25 December 2010.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### References

Yamamoto H, Umeda T, Kibi N, et al. Clinical effects of acupuncture for osteoarthritis of the knee 3 — a randomized, controlled trial. *Kansai Iryo Daigaku Kiyo (The Bulletin of Kansai University of Health Sciences)* 2009; 3: 36–40 (in Japanese with English abstract). Ichushi Web ID: 2010044483

Yamamoto H, Umeda T, Kibi N, et al. Clinical effects of acupuncture for osteoarthritis of the knee 2 — a randomized, controlled trial. *Kansai Iryo Daigaku Kiyo (The Bulletin of Kansai University of Health Sciences)* 2008; 2: 48–52 (in Japanese). Ichushi Web ID: 2008334853

Yamamoto H, Umeda T, Kibi N, et al. Clinical effects of acupuncture for osteoarthritis of the knee — a randomized, controlled trial. *Kansai Iryo Daigaku Kiyo (The Bulletin of Kansai University of Health Sciences)* 2007; 1: 41–5 (in Japanese). Ichushi Web ID: 2008048659

#### 1. Objectives

To evaluate the clinical effects of acupuncture treatment for knee osteoarthritis (OA).

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Acupuncture Clinic, Kansai University of Health Sciences, Osaka, Japan.

#### 4. Participants

Thirty-five patients aged at least 50 years and diagnosed with knee OA between October 2005 and July 2008.

#### 5. Intervention

Arm 1: Acupuncture group. Acupuncture treatment for one month after two weeks of no treatment (n=17).

Arm 2: Placebo acupuncture group. Simulated acupuncture treatment for one month after two weeks of no treatment (n=18).

In the acupuncture group, needles were retained at the SP10 (血海), LR8 (曲泉), SP9 (陰陵泉), ST34 (梁丘), ST36 (足三里), GB34 (陽陵泉), SP6 (三陰交), KI3 (太谿), GB39 (懸鐘), BL60 (崑崙) acupuncture points for 15 minutes twice a week. In the placebo acupuncture group, insertion of needles was simulated at the same acupuncture points as Arm 1, twice a week.

One patient dropped out in Arm 2.

#### 6. Main outcome measures

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).

#### 7. Main results

The pre- to post-treatment decrease in WOMAC score was significant in Arm 1 (mean difference: -8.1, 95% CI, -3.1–13.2,  $P=0.004$ ) and in Arm 2 (mean difference: -7.9, 95% CI, -3.2–12.6,  $P=0.003$ ).

#### 8. Conclusions

Both acupuncture and placebo acupuncture are effective.

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

The acupuncture for knee osteoarthritis was performed using the Berman method (2004).

Reference: Berman BM, et al. *Ann Intern Med* 2004; 141(12): 901–10.

#### 10. Safety assessment in the article

The authors reported no adverse events.

#### 11. Abstractor's comments

The subject recruitment period and conditions of this study overlap with those in the preceding two studies (Yamamoto H, et al. 2007, Yamamoto H, et al. 2008), and the interventions and outcome measures are virtually identical, so they can be treated as a series of studies. The authors can be highly commended for using an RCT design; however, although the therapeutic effects in both groups were found to be significant, there was no significant between-group difference. This is not mentioned in the Results, but in the Discussion. It is possible that different sample size calculations may have resulted in different outcomes. Weaknesses of the study, including analysis of the success or failure of subject masking, should be improved. Future clinical studies by these authors will hopefully be larger and utilize more appropriate protocols.

#### 12. Abstractor and date

Takahashi N, 25 December 2010.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### References

Ochi H, Katsumi Y, Katayama K, et al. The effect of acupuncture with quadriceps exercise for the osteoarthritis of the knee joint — the importance of quadriceps exercise —. *Toyo Igaku to Pain Clinic (Oriental Medicine and the Pain Clinic)* 1993; 23(3): 136–42 (in Japanese with English abstract). Ichushi Web ID: 1994241815

Ochi H, Katayama K, Ikeuchi T, et al. Acupuncture with quadriceps exercise for osteoarthritis of the knee joint. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 1990; 40(3): 247–53 (in Japanese with English abstract). Ichushi Web ID: 1991224289

#### 1. Objectives

To evaluate the effectiveness of acupuncture combined with therapeutic exercise for knee osteoarthritis.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

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

#### 4. Participants

Nineteen patients diagnosed with knee osteoarthritis.

#### 5. Intervention

Arm 1: Acupuncture, silver spike point (SSP) electro-therapy, and exercise group (n=6, mean age: 59 years).

Arm 2: Acupuncture and SSP group (n=7, mean age: 51 years).

Arm 3: Therapeutic exercise group (n=6, mean age: 68 years).

Acupuncture: stainless steel disposable needles (0.18 mm×40 mm) were used to apply the sparrow pecking technique at 9 points in the thigh region and the GB31 (風市), ST36 (足三里), GB34 (陽陵泉), and SP9 (陰陵泉) acupuncture points once a week. SSP therapy: stimulation (compression wave, 10 minutes) was applied between the knee and the thigh. Therapeutic exercise: Participants did strengthening exercises at home for the muscles around the knee. The treatment period was one month.

#### 6. Main outcome measures

Score on a specially-designed evaluation (comprehensive evaluation of pain, activities of daily living, and physical findings) and muscle strength score.

#### 7. Main results

The comprehensive score increased significantly between the start of treatment and one month later ( $P<0.01$ ) in Arms 1 and 2 but not in Arm 3. The muscle strength score for knee extension increased significantly in Arms 1 and 3 ( $P<0.05$ ) but not in Arm 2.

#### 8. Conclusions

Combined use of acupuncture, SSP therapy, and therapeutic exercise is useful.

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

The paper mentions the risks of acupuncture to the joints, and uses SSP as an alternative therapy.

#### 10. Safety assessment in the article

None.

#### 11. Abstractor's comments

This valuable paper investigates the effectiveness of combining SSP therapy and therapeutic exercise with acupuncture treatment for knee OA, and it evaluates the differences between their effects. However, the authors should address issues such as the small group size (n=6 and 7), the lack of between-group comparison (only within-group comparison is reported), and the lack of analysis of any post-treatment effects. Yet, the study was designed to address real clinical issues and as such it has great significance. Hopefully, an even higher quality clinical trial that includes sample size calculations and WOMAC evaluation will be conducted. The authors' 1990 paper deals with the same matter: this abstract addresses the present paper only.

#### 12. Abstractor and date

Kawakita K, 30 January 2012.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Ochi H, Katsumi Y, Ikeuchi T, et al. A study of acupuncture for knee osteoarthritis — The importance of combined use with therapeutic exercise\*. *Meiji Shinkyu Igaku (The Bulletin of Meiji University of Oriental Medicine)* 1995; 17: 7–14 (in Japanese).

#### 1. Objectives

To evaluate the effectiveness of acupuncture combined with therapeutic exercise for knee osteoarthritis.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

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

#### 4. Participants

Forty-eight patients diagnosed with knee osteoarthritis (age range 53–77 years).

#### 5. Intervention

Arm 1: Acupuncture+silver spike point (SSP) electro-therapy group (n=18, mean age 62 years).

Arm 2: Acupuncture+SSP+therapeutic exercise group (n=20, mean age 63 years).

Arm 3: Therapeutic exercise group (n=10, mean age 67 years).

Acupuncture: stainless steel disposable needles (0.18 mm×40 mm) were used to apply the sparrow pecking technique at 9 points in the thigh region and the GB31 (風市), ST36 (足三里), GB34 (陽陵泉), and SP9 (陰陵泉) acupuncture points once or twice a week before applying SSP therapy (compression wave stimulation for 10 minutes between the knees and the thigh). Therapeutic exercise: Participants exercised mostly to strengthen the femoral quadriceps muscles, at least three times a day at home. The treatment period was one month.

Dropouts are mentioned, but the details are not reported in the original article.

#### 6. Main outcome measures

Japanese Orthopaedic Association score (JOA score) and muscle strength.

#### 7. Main results

JOA score tended to increase between the start of treatment and one month later in Arms 1 and 2 but not Arm 3. The differences between Arm 1 and Arm 3 ( $P<0.01$ ) and between Arm 2 and Arm 3 ( $P<0.05$ ) were significant. Follow up revealed a strong anesthetic effect in patients who continued to exercise. Scores for knee extension muscle strength showed significant increases in Arms 2 ( $P<0.01$ ) and 3 ( $P<0.05$ ).

#### 8. Conclusions

Combined use of acupuncture, SSP therapy, and therapeutic exercise is an effective conservative therapy for knee osteoarthritis.

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

Not mentioned.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This interesting study investigated the effects of combining acupuncture and SSP therapy with therapeutic exercise for knee OA. It revealed the significance of therapeutic exercise. SSP therapy is a form of transcutaneous electric nerve stimulation that uses spike-shaped surface electrodes. The authors have greatly improved the quality of the statistical analysis used in the present study from what it was in their previous work, but regrettably, they did not clearly describe their method of random allocation, and although dropouts are mentioned, this is not reflected in the analytical results. Further, the authors use the comprehensive JOA score as an outcome measure, yet analysis of the elements within that score, namely pain, functioning, joint range of motion, and swelling, would be worthwhile. This is a very valuable study in that it establishes a therapeutic method based on real clinical practice. Hopefully, the authors will conduct larger scale, more rigorously designed RCTs.

#### 12. Abstractor and date

Kawakita K, 3 February 2012.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Nakajima M, Inoue M, Itoi M, et al. A comparison of the effectiveness between acupuncture and local injection for neck pain: a randomized controlled trial. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 2007; 57(4): 491–500 (in Japanese with English abstract). Ichushi Web ID: 2008024979

#### 1. Objectives

To compare the effectiveness of acupuncture and local injection for neck pain.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

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

#### 4. Participants

Thirty-three outpatients from the above orthopedic surgery department.

#### 5. Intervention

Arm 1: Acupuncture group. Stainless steel needles (0.18×40 mm, Seirin Co., Ltd.) were inserted to a depth of 10–20 mm, and the sparrow pecking technique (1 Hz, 20 seconds) applied after the *de qi* (得気) sensation was achieved (n=16).

Arm 2: Local injection group. A dibucaine hydrochloride formulation and Neurotropin were injected using a 25 G needle (0.5×25 mm, Terumo Corporation), and then the needle was withdrawn (n=17).

Treatment in both groups was directed to the most painful 3–5 points weekly for 4 weeks.

#### 6. Main outcome measures

Visual analogue scale (VAS) 6-point Neck Disability Index (NDI, Japanese edition) and standardized questionnaire of cervical root disease [developed by Tanaka et al] were measured. They were evaluated before treatment, and 0, 2 and 4 weeks after the end of treatment. Evaluation was masked.

#### 7. Main results

VAS was improved significantly in Arm 1 compared to Arm 2 ( $P<0.001$ ). Both NDI and standardized questionnaire showed significant improvement within group comparison ( $P<0.001$ ).

#### 8. Conclusions

Acupuncture is more useful than local injection for neck pain.

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

The most painful points were determined to be the treatment points.

#### 10. Safety assessment in the article

No adverse events were reported.

#### 11. Abstractor's comments

This study holds great interest for acupuncture therapists because it compares a Western medical treatment to acupuncture. It is highly commendable for having attempted a randomized controlled trial. However, the objective and the results are inconsistent because the research question is unclear. The quality of the study as an RCT is problematic. It lacks prior sample-size estimates, evaluation of internal validity (random allocation and masking success), and the statistics have not been analyzed appropriately. Within-group comparison and the necessary between-group comparison were made at the same time, which has the potential to give readers a mistaken impression of the results. Accordingly, the conclusions of the study should be recognized as having limitations. The objective of this study is important to clinical acupuncture, so it is hoped that the authors will improve on the points mentioned above by repeating the trial after preparing a thorough pre-trial plan, thereby contributing to the public good.

The material in this study is similar to that in Nakajima et al. Consideration of acupuncture and local injection for neck pain — A randomized controlled trial. *Ido-no Nippon (The Japanese Journal of Acupuncture & Manual Therapies)* 2008; 67(10): 116–125. JA0817, Ichushi Web ID: 2008373095 and Nakajima et al. A study of acupuncture and local injection for neck pain — A randomized controlled trial. *Nihon Seitai Denki Butsuri Shigeki Kenkyu Kaishi (The Journal of the Japanese Bio-Electrical and Physical Stimulation Research Society)* 2008; 22: 1–6. JA0818, Ichushi Web ID: 2009099691, so they are included in this structured abstract.

#### 12. Abstractor and date

Shichido T, 5 November 2010.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Itoh K, Katsumi Y, Hirota S, et al. Randomised trial of trigger point acupuncture compared with other acupuncture for treatment of chronic neck pain. *Complementary Therapies in Medicine* 2007; 15: 172–9. Pubmed ID: 17709062

#### 1. Objectives

To evaluate the effectiveness of trigger point acupuncture for chronic neck pain.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

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

#### 4. Participants

Forty patients aged 45 years or more with neck pain for at least 6 months.

#### 5. Intervention

Arm1: Trigger point acupuncture group. Acupuncture at trigger points using disposable stainless steel needles (0.2×50 mm, Seirin Co., Ltd.) (n=10).

Arm 2: Standard acupuncture group. Disposable stainless steel needles (0.2×40 mm, Seirin Co., Ltd.) were inserted into muscle to 20 mm at the standard acupuncture points for neck pain, the GB20 (風池), GB21 (肩井), BL10 (天柱), BL11 (大杼), ST12 (缺盆), ST13 (氣戶), TE5 (外關), LI4 (合谷), and SI3 (後谿), and then the sparrow pecking technique was applied and the needles retained for 10 minutes after the *de qi* (得氣) sensation was achieved (n=10).

Arm 3: Non-trigger point acupuncture group. Disposable stainless steel needles (0.2×50 mm, Seirin Co., Ltd.) were used for acupuncture at non-tender points at least 50 mm away from trigger points in the same muscle (n=10).

Arm 4: Sham acupuncture group. Sham needles, stainless steel needles (0.2×50 mm) with the tips cut off, were used. The acupuncturist simulated insertion at trigger points, the sparrow pecking technique was applied, and then removal after 10 minutes (n=10).

Each group received two phases of acupuncture treatment, each phase comprising three treatments, one per week (3 weeks), with a 3-week period of no treatment between phases (total 13 weeks).

There were 2 dropouts each from Arms 1, 2, and 3, and 3 from Arm 4.

#### 6. Main outcome measures

Visual analogue scale (VAS) score for neck pain intensity before the first treatment, and 1, 2, 3, 6, 7, 8, 9, and 12 weeks after the first treatment (total 9 times). Neck Disability Index (NDI) score before the first treatment, and 3, 6, 9, and 12 weeks after the first treatment (total 5 times).

#### 7. Main results

VAS and NDI scores both improved significantly from baseline (pre-treatment) to 3 weeks after the first treatment in Arm 1 (both  $P<0.01$ ) and compared to the other three groups (both  $P<0.01$ ), after phase 2 treatment (9th week) in Arm 1.

#### 8. Conclusions

Trigger point acupuncture is more effective for chronic neck pain than standard acupuncture.

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

Treatment location, method, and stimulation intensity are three important factors in the effectiveness of acupuncture. Nociceptors with increased sensitivity are involved in the mechanism that makes trigger point treatment effective.

#### 10. Safety assessment in the article

Three of the participants who dropped out suffered symptom aggravation.

#### 11. Abstractor's comments

This study is highly commendable for its design and for having verified the effects of trigger point acupuncture by comparing it to standard acupuncture, non-trigger acupuncture, and sham acupuncture. The authors also report on sham acupuncture and the success of masking. Another aspect of this study is the interval between the two treatment phases and what follows. The authors touch on the time course after the interval, but this should have been described in greater detail, given that the question of whether the effects last is very important. Overall, it is a significant study based on an excellent design.

#### 12. Abstractor and date

Hosaka M, 11 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Kinoshita H, Kinoshita N. Clinical research in the use of paraneural acupuncture for sciatica. *Nihon Shinkyu Chiryō Gakkaishi (The Journal of the Japan Acupuncture and Moxibustion Society)*. 1981; 30(1): 4–13 (in Japanese with English abstract).

#### 1. Objectives

To compare the effectiveness of paraneural and with that of non-paraneural acupuncture for sciatica.

#### 2. Design

Crossover randomized controlled trial (RCT cross-over).

#### 3. Setting

Not described.

#### 4. Participants

Thirty sciatica patients (regardless of primary disease) enrolled from August 1979 to February 1980.

#### 5. Intervention

Arm 1: Paraneural acupuncture group. Stainless steel needles (0.2×50 mm) were inserted at the left and right BL23 (腎俞), healthy-side BL25 (大腸俞), affected-side Shangbaohuang (上胞育, no WHO code), Dianya (殿压, no WHO code), BL37 (殷門), Waichengjin (外承筋, no WHO code), and BL59 ([附陽], depending on the case) acupuncture points, to 2.0 cm depth (haunches) or 1.5 cm (legs). Needles were inserted then immediately removed in lumbar locations, but retained (15 minutes) in the buttocks and lower extremities. In addition, five moxa cones (large rice-grain size) were burnt at the affected-side BL25 (大腸俞), Shangbaohuang (上胞育, no WHO code), Dianya (殿压, no WHO code), and Waichengjin (外承筋, no WHO code) points. Stainless steel needles (0.25×90 mm) were also inserted at the affected-side BL25 (大腸俞) point and the trochanter to a depth of 6.0 cm and retained for 15 minutes (n=30).

Arm 2: Non-paraneural acupuncture group. Same as paraneural acupuncture group, however, needles were retained at the affected-side BL25 (大腸俞) acupuncture point and the trochanter to a depth of 2.0 cm for 15 minutes (n=30).

Thirty patients were randomly allocated to two groups (A and B). Group A received paraneural acupuncture six times, then non-paraneural acupuncture six times. The order of treatment was reversed for group B.

Thirteen participants dropped out of Arm 1, and 12 from Arm 2.

#### 6. Main outcome measures

Amount of tenderness (kg) at the Dianya (殿压) and Waichengjin (外承筋) points, Lasègue's sign (patient experiences slight pain when raising the straight leg 30–70 degrees), and subjective symptoms (four-point scale: very good=2, good=1, no change=0, and bad=-1).

#### 7. Main results

Dianya (殿压) tenderness ( $P<0.01$ ), Waichengjin (外承筋) tenderness ( $P<0.05$ ), Lasègue's sign ( $P<0.01$ ), and subjective symptoms ( $P<0.01$ ) improved after six treatments in a significantly higher percentage of patients in Arm 1 than in Arm 2.

#### 8. Conclusions

Paraneural acupuncture is the more effective treatment for sciatica.

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

Acupuncture into the muscle located beside a nerve branch may relieve symptoms completely.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This study was conducted in 1981, even before the acronym "EBM" had entered the Western medical lexicon. The authors used random allocation and crossover, which were absolutely cutting edge methods for the time, to compare the effectiveness of paraneural acupuncture to non-paraneural acupuncture for sciatica. It is truly a very important paper. The authors are to be congratulated for having conducted clinical research into acupuncture and moxibustion and achieved results using appropriate methods in that era. To their credit, they use quantitative outcome measures and classify participants according to sciatica type before allocating them randomly, which were both cutting-edge methods. The authors can also be commended for having their diagnoses checked by an orthopedic consultant.

Areas for improvement include the large participant drop-out rate, the lack of follow up of participants who dropped out, and the lack of an interval between the two interventions for washout.

#### 12. Abstractor and date

Wakayama I, 9 September 2011.



### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Yun X, Suzuki S, Urata S, et al. Therapeutic effect of the treatment of sciatica due to cold-wetness evil using an electro-warming needle. *Toho Igaku (Eastern Medicine)* 2005; 21(3): 25–7 (in Japanese with English abstract). Ichushi Web ID: 2006072612

#### 1. Objectives

To evaluate the efficacy of electrothermal acupuncture for treating sciatica due to "cold-wetness evil (寒湿)."

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Not described.

#### 4. Participants

Sixty-four patients with sciatica due to "cold-wetness evil" (45 males and 19 females, mean age, 38.4 and 35.6 years for the two groups).

#### 5. Intervention

Arm 1: Electrothermal needle group. Using DZR-1-type electrothermal acupuncture apparatus, size 6 electrothermal needles were inserted perpendicularly to a depth of 1–1.5 cun at the main acupuncture points BL54 (秩辺), BL37 (殷門) or GB31 (風市), BL40 (委中), BL57 (承山), or GB34 (陽陵泉) on the affected side, and stimulation with a current of 60–80 mA was applied. In addition, filiform needles were inserted perpendicularly at the adjunct acupuncture points BL25 (大腸兪) and BL26 (關元兪) bilaterally, and GB30 (環跳), GB31 (風市), or BL37 (殷門), GB34 (陽陵泉) or BL57 (承山), GB39 (懸鐘), GB40 (丘墟), BL60 (昆崙) on the affected side. A lifting and thrusting draining method was performed. The procedure was applied every 10 minutes. Needles were retained for 40 minutes (n=34).

Arm 2: Ordinary needle group. Filiform needles were inserted perpendicularly to a depth of 1–1.5 cun at the main acupuncture points, and a neutral supplementation and draining method was performed. Similar treatment was applied at the adjunct acupuncture points (n=30). ("Cun" used in this section is based on location of points by bone standard [骨度法] and is different from the linear measure "sun [3.03 cm]" [尺度法].)

#### 6. Main outcome measures

Therapeutic effects were determined on a 3-point scale: cure, response, and nonresponse.

#### 7. Main results

In Arm 1, cure was obtained in 23 patients and response in 9, resulting in an efficacy rate of 94.1%. In Arm 2, cure and response were obtained in 12 and 11 patients, respectively, resulting in an efficacy rate of 76.7%. When comparing the two arms, therapeutic effect was significantly superior in Arm 1 ( $P<0.05$ ).

#### 8. Conclusions

Electrothermal acupuncture is effective for treating sciatica due to "cold-wetness evil."

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

Electrothermal acupuncture was prescribed based on the traditional Chinese medical diagnosis, and administered using the traditional Chinese medical procedure. In the Discussion, fire needling was mentioned.

#### 10. Safety assessment in the article

Not described.

#### 11. Abstractor's comments

This study is highly appreciated for demonstrating the efficacy of treatment with electrothermal needles as compared with that of treatment with ordinary filiform needles. However, the treatment environment is not clear because the settings are not described. It is also unclear whether the study was an appropriate randomized controlled trial since the method for randomization was not reported. Detailed analysis of the assessment is also missing. Despite these omissions, this is a valuable study that may provide an opportunity for finding new therapies.

#### 12. Abstractor and date

Hosaka M, 11 September 2011.

## Diseases of the Musculoskeletal and Connective Tissue

### Reference

Sakai T, Tsutani K, Tsukayama H, et al. Multi-center randomized controlled trial of acupuncture with electric stimulation and acupuncture-like transcutaneous electrical nerve stimulation for lumbago. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 2001; 51(2): 175–84 (in Japanese with English abstract). Ichushi Web ID: 2001280876

#### 1. Objectives

To evaluate the efficacy and safety of low-frequency electro-acupuncture and transcutaneous electrical nerve stimulation (TENS) for low back pain.

#### 2. Design

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

#### 3. Setting

Four medical facilities in Japan (Meiji University of Oriental Medicine Hospital [current Meiji University of Integrative Medicine], Kyoto; Outpatient Clinics, Kansai College of Oriental Medicine [current Kansai University of Health Sciences], Osaka; Tsukuba College of Technology Clinic, Ibaraki; and Department of Medicine and Physical Therapy, Faculty of Medicine, University of Tokyo, Tokyo).

#### 4. Participants

A total of 70 male and female patients aged 20 years or older who had low back pain without leg pain and provided consent.

#### 5. Intervention

Arm 1: Low-frequency electro-acupuncture therapy group. Two points each for the left and right sides were selected from reactive points (taut, tender, or indurated) on the BL23(腎兪), BL25 (大腸兪), and BL52 (志室) acupuncture points, and electro-acupuncture was applied at a frequency of 1 Hz for 15 minutes using stainless steel needles (0.24×60 mm). Treatment was administered 5 times during a 2-week period (n=32).

Arm 2: TENS group. Sites, frequency, intensity, and duration of stimulation and frequency and number of treatment sessions were the same as those in Arm 1 (n=36).

There was a 1-week run-in period (patches were applied), during which 2 patients dropped out. Of the rest of 68, 4 patients dropped out of the study (1 in Arm 1, 3 in Arm 2).

#### 6. Main outcome measures

Change in pain intensity rated on a 5-point visual analogue scale (VAS) and using the Japanese Orthopaedic Association Back Pain Evaluation Questionnaire (JOA score).

#### 7. Main results

Among background factors, gender, history of acupuncture, and history of TENS were different between the two arms. There was no significant between-arm difference in pain relief and JOA score.

#### 8. Conclusions

Low-frequency electro-acupuncture and TENS have similar efficacy for low back pain.

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

None.

#### 10. Safety assessment in the article

In Arm 2, two patients complained of itching resulting from the application of electrodes.

#### 11. Abstractor's comments

In this ambitious RCT, the protocol, which is central to conducting a clinical trial, was developed over an extended period of time and the efficacy of acupuncture for low back pain, an important disorder in clinical practice of acupuncture and moxibustion, was evaluated in a multicenter setting. This study is regarded as an exploratory phase 2 trial, aiming to collect basic data for a phase 3 trial. Regrettably, TENS was used as the control treatment, but “no treatment” would have been a more desirable control. The study provides investigators who are planning RCTs with a lot of useful information, including issues concerning recruitment of subjects and selection of outcome measures.

#### 12. Abstractor and date

Takahashi N, 9 February 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Tsukayama H, Yamashita H, Amagai H, et al. Randomised controlled trial comparing the effectiveness of electroacupuncture and TENS for low back pain: a preliminary study for a pragmatic trial. *Acupuncture in Medicine* 2002; 20(4): 175–80. Pubmed ID: 12512791

#### 1. Objectives

To compare the effectiveness of electro-acupuncture with that of transcutaneous electrical nerve stimulation (TENS) in patients with low back pain in a pragmatic setting.

#### 2. Design

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

#### 3. Setting

Tsukuba College of Technology Clinic, Tsukuba, Japan.

#### 4. Participants

Twenty patients aged 20 years or older with low back pain for at least 2 weeks.

#### 5. Intervention

Arm 1: Electro-acupuncture group. Electro-acupuncture was applied at 8 acupuncture points (4 acupuncture points each in the left and right) in the lower back down through the buttocks using disposable stainless steel needles (0.20×50 mm, 0.24×60 mm) in a pragmatic manner (standard practice at the Tsukuba College of Technology Clinic). The insertion depth was 20 mm and electro-stimulation was applied at a frequency of 1 Hz for 15 minutes. At the end of electro-stimulation, press tack needles were put on 4 out of the 8 points (n=10).

Arm 2: TENS group. Using gel-type disposable electrodes (20×30 mm), electro-stimulation was applied at the same 8 points under the same conditions as in Arm 1 (n=10).

One patient in Arm 1 dropped out due to influenza.

#### 6. Main outcome measures

Pain relief rated on a visual analogue scale (VAS) before and daily for 2 weeks after the intervention.

Score for the Japanese Orthopaedic Association Back Pain Evaluation Questionnaire (JOA score) obtained before and at 3 days after the intervention.

#### 7. Main results

VAS score was significantly lower at 2 weeks after the intervention and JOA score was more improved at 3 days after the intervention in Arm 1 than in Arm 2, but it was not statistically significant ( $P=0.24$ ).

#### 8. Conclusions

Electro-acupuncture is, in the short term, the more effective of the two techniques for low back pain.

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

The authors pointed out the importance of conducting a comparative trial that employs individualized treatment, which is a part of daily clinical practice in Japan.

#### 10. Safety assessment in the article

Mild adverse reactions were reported in 3 of 10 patients in Arm 1 (transient elevation of blood pressure, discomfort due to press tack needles, and mild subcutaneous bleeding) and 2 of 9 in Arm 2 (transient aggravation of low back pain, transient fatigue, and itching).

#### 11. Abstractor's comments

This article describes a very well-designed trial comparing standard electrical therapy with electro-acupuncture and demonstrating the efficacy of acupuncture. The effort to conduct a pragmatic clinical trial is also appreciated.

However, as the authors noted in the text, sample size was small and no follow-up was carried out. Further studies are needed to establish reliability and external validity. A detailed description of how the therapy was individualized is desirable. Although the patients were randomly assigned, the trial was conducted at a clinic affiliated with a college of acupuncture and moxibustion, and therefore a concern about potential selection bias exists.

#### 12. Abstractor and date

Wakayama I, 9 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Itoh, K, Katsumi Y, Kitakoji H. Trigger point acupuncture treatment of chronic low back pain in elderly patients—a blinded RCT. *Acupuncture in Medicine* 2004; 22(4): 170–7 (in Japanese with English abstract). Pubmed ID: 15628774

#### 1. Objectives

To evaluate the effect of acupuncture on pain intensity and quality of life (QOL) in patients with chronic low back pain by comparing two types of trigger point acupuncture treatment and standard acupuncture treatment.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

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

#### 4. Participants

Thirty-five outpatients aged 65 years or older with low back pain for at least 6 months (10 males and 25 females, age range, 65–81 years).

#### 5. Intervention

Arm 1: Superficial needling to trigger points group. Stainless steel needles (0.2×50 mm) were inserted to a depth of 3 mm and the sparrow pecking technique was applied. After *de qi* (得氣) sensation was obtained, the needles were retained for 10 minutes (n=12).

Arm 2: Deep needling to trigger points group. Similar stainless steel needles were inserted to a depth of 20 mm and the sparrow pecking technique was applied. After the local muscle twitch response was observed, the needles were retained for 10 minutes (n=10).

Arm 3: Standard acupuncture group. Similar stainless steel needles were inserted to a depth of 20 mm at the BL23 (腎俞), BL25 (大腸俞), GB30 (環跳), BL40 (委中), BL60 (崑崙), and GB34 (陽陵泉) acupoints and up to 4 *ah-shi* points (阿是穴). The sparrow pecking technique was applied. After *de qi* sensation was obtained, the needles were retained for 10 minutes (n=13).

One session consisted of 3 once-weekly 30-minute acupuncture treatments and two sessions were performed with an interval between the sessions. Total treatment duration was 12 weeks.

Three patients in Arm 1, 1 in Arm 2, and 4 in Arm 3 dropped out.

#### 6. Main outcome measures

Pain intensity measured on a visual analogue scale (VAS), and QOL using the Roland Morris Disability Questionnaire (RMDQ).

#### 7. Main results

In Arm 2, VAS score after the treatment was significantly decreased compared with the pre-treatment value ( $P<0.01$ ), whereas in the other 2 arms, no significant change in the score was observed. Similar results were obtained for RMDQ scores.

#### 8. Conclusions

Deep needling to trigger points is more effective on low back pain in the elderly compared with superficial needling to trigger points or standard acupuncture.

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

None.

#### 10. Safety assessment in the article

Worsening of symptoms was observed in 1 patient in Arm 2.

#### 11. Abstractor's comments

This valuable study attempted to test the efficacy of three different acupuncture treatments. In particular, the authors' effort to demonstrate the importance of the depth of needle insertion in trigger point treatment is appreciated. It is also interesting that time series of outcome measures were observed by using the ABAB method.

The authors found significant pre- to post-treatment differences, but no difference among the three arms. Thus, although deep needling to trigger points may be superior to the other two treatments, further validation is needed. Also, sample size should be increased, and follow-up extended.

#### 12. Abstractor and date

Wakayama I, 9 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Itoh K. Effect of trigger point acupuncture treatment on chronic pain in the elderly - usefulness of acupuncture for treating chronic low back pain -\*. *Mansei Totsu (The Journal of the Japanese Society for the Study of Chronic Pain)* 2004; 23(1): 83–8 (in Japanese with English abstract). Ichushi Web ID: 2005066965

#### 1. Objectives

To compare the effect of acupuncture treatment at trigger points versus at acupuncture points in the back on chronic low back pain in the elderly.

#### 2. Design

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

#### 3. Setting

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

#### 4. Participants

Eighteen elderly patients aged 65 years or older with low back pain for at least 6 months.

#### 5. Intervention

Arm 1: Trigger point treatment group. Disposable stainless steel needles (0.16×40 mm, 0.18×50 mm) were inserted at up to 18 trigger points detected by palpation and retained for 10 minutes. One cycle consisted of 3 once-weekly treatments (3 weeks) followed by a 3-week wash out period; two cycles were administered overall (a total of 12 weeks) (n=9).

Arm 2: Acupuncture point treatment group. Disposable stainless steel needles (0.16×40 mm) were inserted at acupuncture points in the back, BL23 (腎兪), BL25 (大腸兪), GB30 (環跳), BL31 (上髎), BL33 (中髎), BL54 (秩辺), BL40 (委中), BL60 (崑崙), and GB34 (陽陵泉), and retained for 10 minutes. The frequency and duration of the treatment were the same as in Arm 1 (n=9).

#### 6. Main outcome measures

Low back and leg pain intensity rated on a visual analogue scale (VAS) at each of 9 time points: before the start of the treatment (once), one week after each treatment session (6 times), and at the end of each wash-out period (twice). Roland Morris Disability Questionnaire (RMDQ) score was recorded at each of 5 time points: before the start of the treatment (once), at the end of each treatment period (twice), and at the end of each wash-out period (twice).

#### 7. Main results

Improvement in VAS score was greater in Arm 1 than in Arm 2. In both arms, RMDQ scores were improved when compared with the pre-treatment values. The P value was not described in the original article.

#### 8. Conclusions

Trigger point acupuncture treatment reduces low back pain more effectively in the elderly compared with the standard acupuncture point treatment.

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

The author mentioned that the formation of trigger points may play a role in the development of low back and leg pain in the elderly.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This study is interesting and appreciated in that it compares the efficacy of acupuncture point treatment with that of trigger point acupuncture treatment. However, the following points should have been included or discussed: 1) P values and a discussion of the statistical analyses of results; 2) the small sample size; and 3) no flow chart. This study seems valuable as it attempted to demonstrate the need for treatment of muscles, including trigger points, in the elderly.

#### 12. Abstractor and date

Hosaka M, 11 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Katsumi Y, Itoi M, Kojima A, et al. *Ah shi* (tender) point acupuncture of chronic low back pain in aged patients\*. *Rehabiritesyon Igaku (The Japanese Journal of Rehabilitation Medicine)* 2004; 41(12): 824–9 (in Japanese). Ichushi Web ID: 2005128701.

#### 1. Objectives

Effectiveness of ah-shi (tender) point acupuncture therapy for chronic low back pain in elderly patients.

#### 2. Design

Crossover randomized controlled trial (RCT cross-over).

#### 3. Setting

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

#### 4. Participants

Nine elderly people 65 years or over with low back and leg pain persisting for at least six months.

#### 5. Intervention

Arm 1: T-S group (Tender point acupuncture, then sham acupuncture). Disposable stainless steel needles (0.18 × 50 mm) were inserted for 10 minutes at up to 18 tender points detected by palpation. Tender point acupuncture occurred once a week for 3 weeks, then after a three-week washout period, sham acupuncture commenced (3 weeks), followed by a three-week washout period. In sham acupuncture, the guide tube was placed at the tender point and after employing the same technique as real needle insertion, the participant was told that the needle had been inserted and then was allowed to rest for 10 minutes (n=4).

Arm 2: S-T group (Sham acupuncture, then tender point acupuncture). The period of treatment was the same as in Arm 1, but the order of the treatments was reversed (n=5).

#### 6. Main outcome measures

Visual analogue scale (VAS) scores for intensity of low back and leg pain were recorded nine times: once before treatment commenced, one week after each treatment (six times), and at the end of each washout period (twice). The Roland Morris Disability Questionnaire (RMDQ) was given five times: once before treatment commenced, at the end of each treatment period (twice), and at the end of each washout period (twice).

#### 7. Main results

Tender point acupuncture led to greater VAS and RMDQ improvement. The P value was not reported.

#### 8. Conclusions

Tender point acupuncture therapy is effective for chronic low back and leg pain in the elderly.

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

The importance of *ah shi* (tender) point acupuncture was mentioned.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This study seeks to validate the efficacy of tender point acupuncture for low back and leg pain in the elderly using a crossover within-group experimental design, however, no P value is mentioned in the results, and there is no statistical examination. Yet, meaningful evaluation can be made because the effects were compared with those of sham acupuncture. Further development including elaboration of the sham acupuncture method is anticipated.

#### 12. Abstractor and date

Hosaka M, 8 October 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Itoh, K, Katsumi Y, Hirota S, et al. Effects of trigger point acupuncture on chronic low back pain in elderly patients--a sham-controlled randomised trial. *Acupuncture in Medicine* 2006; 24(1): 5–12. Pubmed ID: 16618043

#### 1. Objectives

To compare the effects of trigger point acupuncture versus sham acupuncture on pain and QOL in patients with chronic low back pain.

#### 2. Design

Crossover randomized controlled trial (RCT cross-over).

#### 3. Setting

Meiji University of Oriental Medicine (current Meiji University of Integrative Medicine) Hospital, Kyoto, Japan.

#### 4. Participants

Twenty-six elderly patients aged 65 or older with chronic low back pain for at least 6 months (9 males and 17 females; age range, 65–91 years).

#### 5. Intervention

Arm 1: Group A. Trigger point acupuncture followed by sham acupuncture (n=13).

Arm 2: Group B. Sham acupuncture followed by trigger point acupuncture (n=13).

Trigger point acupuncture: Stainless steel needles (0.2×50 mm; Seirin Co., Ltd.) were inserted to a depth of 10–40 mm at trigger points, and sparrow pecking technique was applied. After the *de qi* (得氣) sensation was obtained, the needles were retained for 10 minutes. Sham acupuncture: Similar stainless steel needles (0.2×50 mm; Seirin Co., Ltd.), with blunt tips, were put on trigger points and stimulation was applied. To keep patients blinded, the acupuncturist pretended to insert the needle and to use sparrow pecking technique. After 10 minutes, needle extraction was simulated.

In both arms, one of the two acupuncture treatments (30 minutes) was administered 3 times with a frequency of once weekly (the first phase), followed by a 3-week washout period. Then the other treatment (30 minutes) was administered 3 times with a frequency of once weekly (the second phase), followed by a 3-week observation period. The overall study duration was 12 weeks.

Three patients in Arm 1 and 4 in Arm 2 dropped out.

#### 6. Main outcome measures

Visual Analogue Scale (VAS) score for pain intensity and Roland Morris Disability Questionnaire (RMDQ) score.

#### 7. Main results

Both VAS and RMDQ scores during the first phase were lower in Arm 1 ( $P<0.001$  and  $P<0.01$ , respectively). The within-group (before-and-after) comparison showed that both VAS and RMDQ scores decreased during the trigger point acupuncture phase ( $P<0.01$  for both), but remained unchanged during the sham acupuncture phase.

#### 8. Conclusions

Trigger point acupuncture is more effective than sham acupuncture on low back pain in the elderly in the short term.

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

Treatment at trigger points may be more effective than treatment at traditional acupuncture points on low back pain in the elderly.

#### 10. Safety assessment in the article

One patient experienced worsening of symptoms during the trigger point acupuncture in Arm 1.

#### 11. Abstractor's comments

This very well-designed crossover RCT demonstrated the efficacy of trigger point acupuncture, as compared with sham acupuncture, in the elderly patients with low back pain. Greater reliability and external validity of results would be obtained if the drop-out rate (one quarter in this study) is decreased and intention-to-treat (ITT) analysis is conducted.

#### 12. Abstractor and date

Wakayama I, 11 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Kawase Y, Ishigami T, Nakamura H, et al. Acupuncture treatment for lower back pain - Multi-center randomized controlled trial using sham acupuncture as a control. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 2006; 56(2): 140-9 (in Japanese with English abstract). Ichushi Web ID: 2006225874

#### 1. Objectives

To compare the efficacy of taikyoku therapy and low-frequency electro-acupuncture for low back pain.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Eleven acupuncture and moxibustion clinics, Aichi and Gifu, Japan.

#### 4. Participants

Sixty-four patients who presented to the clinic for the first time with low back pain as a main complaint (36 males and 28 females).

#### 5. Intervention

Arm 1: Taikyoku therapy+electro-acupuncture. Treatments for Arm 2 and Arm 3 were combined (n=12).

Arm 2: Taikyoku therapy alone. Using disposable stainless steel needles (0.18×30 mm), single needling technique was applied at Kurono's basic meridian points for total body conditioning, CV12 (中脘), LR14 (期門), ST25 (天枢), CV6 (氣海), BL10 (天柱), GB20 (風池), BL11 (大杼), GB21 (肩井), BL13 (肺俞), BL14 (厥陰俞), BL20 (脾俞), BL23 (腎俞), and BL25 (大腸俞) (n=13).

Arm 3: Electro-acupuncture alone. Disposable stainless steel needles (0.2×30 mm) were inserted to a depth of 5-7 mm at the BL23 (腎俞) and BL40 (委中) acupuncture points. Electro-stimulation was applied for 5 minutes with a frequency of 5 Hz and a voltage of 2 V (n=20).

Arm 4: Sham acupuncture. Without using needles, guide tubes were tapped at the BL20 (脾俞), BL23 (腎俞), and BL25 (大腸俞) acupuncture points. Eventually, electro-acupuncture for Arm 2, taikyoku therapy for Arm 3, and electro-acupuncture+taikyoku therapy for Arm 4 were additionally administered (n=19).

#### 6. Main outcome measures

Visual Analog Scale (VAS) score for pain intensity and score for the Japanese Orthopaedic Association Back Pain Evaluation Questionnaire (JOA score); both scores were measured before the treatment, after the assigned treatment, and after the final treatment.

#### 7. Main results

When comparing pre- and post-treatment values, significant improvements in both VAS and JOA scores were observed in Arm 1, Arm 2, and Arm 3 ( $P<0.05$  for all), but not in Arm 4. Between-arm comparisons revealed significant improvements in Arm 1, Arm 2, and Arm 3 compared with Arm 4 ( $P<0.05$  for all).

#### 8. Conclusions

Taikyoku therapy and low-frequency electro-acupuncture are effective for low back pain.

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

Not mentioned.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

Although there is imbalance in the number of enrolled patients at each institution as well as the number of randomized patients in each arm, this study is highly appreciated for indicating future possibilities of conducting high quality multicenter RCT. In multicenter clinical studies, lack of the standardization of therapy makes an integrated evaluation difficult. In that regard, the technical gap among institutions was minimized by measures, including frequent training, in this study; the minimized gap also made the study meaningful.

#### 12. Abstractor and date

Hosaka M, 11 September 2011.



### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Kawachi A, Kitade T, Kim M, et al. Combination of SSP therapy and far infrared irradiation for chronic low back pain. *Toyo Igaku to Pain Clinic (Oriental Medicine and the Pain Clinic)* 2006; 36(1): 35–42 (in Japanese with English abstract). Ichushi Web ID: 2007063453

#### 1. Objectives

To evaluate the efficacy of Silver Spike Point (SSP) therapy combined with far infrared irradiation for chronic low back pain.

#### 2. Design

Crossover randomized controlled trial (RCT cross-over).

#### 3. Setting

Not described.

#### 4. Participants

Sixty chronic low back pain patients.

#### 5. Intervention

Arm 1: SSP plus far infrared irradiation group. The same treatment as in Arm 1 plus far infrared ray irradiation at about 30 cm from the skin (n=30).

Arm 2: SSP group. Bilateral low frequency electrotherapy (3 Hz continuous waves for 15 minutes) at BL20 (脾俞) and BL23(腎俞) acupuncture points (n=30).

#### 6. Main outcome measures

Pain intensity after treatment (numerical scale), comfort during treatment (visual analogue scale [VAS] score).

#### 7. Main results

Intensity of chronic back pain after treatment was improved in 83% of patients in Arm 1 and 40% of patients in Arm 2. VAS scores for comfort during treatment were 8.4±0.9 mm for Arm 1, and 7.4±1.2 mm for Arm 2.

#### 8. Conclusions

The addition of far infrared irradiation to treatment with SSP further reduces pain and increases comfort in chronic back pain patients.

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

The paper mentions selection of acupuncture points from among those commonly used for chronic back pain clinically.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This trial compares SSP with SSP plus far infrared irradiation. The study measured skin temperature and deep tissue temperature, as well as tissue blood-flow volume, and investigated pain intensity and comfort in low back pain patients. It is of great interest that the study assessed both objective scores and subjective evaluations. However, temperature and blood flow were measured in one group, while clinical effects were examined in the other group, so there is a need for re-examination of the design. Acupuncture points were selected according to symptoms, but the relation between the type of low back pain and the selection of acupuncture points was not discussed. Such a discussion would improve clinical application.

#### 12. Abstractor and date

Furuhata T, Kaneko Y, 1 February 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Hirota S, Itoh K, Katsumi Y. A controlled clinical trial comparing trigger point acupuncture with tender point acupuncture treatments for chronic low back pain - a pilot study on 9 elderly patients -. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion: JJSAM)* 2006; 56(1): 68–75 (in Japanese with English abstract). Ichushi Web ID: 2006156313

#### 1. Objectives

To compare the therapeutic effects of trigger point acupuncture with those of tender point acupuncture on chronic low back pain.

#### 2. Design

Quasi-randomized controlled trial (quasi-RCT).

#### 3. Setting

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

#### 4. Participants

Twelve patients with chronic low back pain (mean age, 71.9 ±3.4 years; range, 66–77).

#### 5. Intervention

Arm 1: Trigger point acupuncture group (n=6). Needling to the trigger point of the muscle for a total of 5 times (once a week) .

Arm 2: Tender point acupuncture group (n=6). Needling to the tender point for a total of 5 times (once a week).

Three subjects dropped out during the study.

#### 6. Main outcome measures

Pain intensity (assessed using a visual analog scale: VAS) and functional disability (Roland-Morris Disability Questionnaire: RMDQ).

#### 7. Main results

At the end of the treatment course, VAS and RDQ values were significantly improved in Arm 1 ( $P<0.01$ ), whereas these values tended to be improved (but not significantly) in Arm 2. At one month follow-up, these improvements persisted and remained significant compared with baseline in Arm 1 ( $P<0.01$ ), but tended to decline and return to baseline in Arm 2.

#### 8. Conclusion

Trigger point acupuncture in contrast to tender point acupuncture appears to reduce pain intensity (VAS) and improve disability measures (RMDQ) after a few applications. The results suggest that these two techniques have different therapeutic effects.

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

Not mentioned.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comment

This study is a well-designed RCT with clear criteria for inclusion of the participants and sufficient follow-up duration. The difference in the therapeutic effects of the two acupuncture treatments, which are often confused, is of great interest. However, allocation of the patients in this study was dependent on the order of enrollment and therefore only quasi-randomized. Also as the authors mention, it is regrettable that the study design does not permit sufficient validation of masking and placebo effects. The results in this study are limited by the small number of the participants. Furthermore, the results of clinical application may vary depending on the operator's skill. Further studies concerning these issues are awaited to improve reproducibility in clinical practice.

#### 12. Abstractor and date

Matsumine R / Kaneko Y, 14 December 2010, Kawakita K / Takahashi N, 25 December 2010.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Inoue M, Kitakoji H, Ishizaki N, et al. Relief of low back pain immediately after acupuncture treatment –a randomised, placebo controlled trial. *Acupuncture in Medicine*. 2006; 24(3): 103–8. Pubmed ID: 17013356

#### 1. Objectives

To evaluate the immediate effect of tender point acupuncture on low back pain.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Center of Acupuncture Science, the Meiji University of Oriental Medicine (current Meiji University of Integrative Medicine), Kyoto, Japan.

#### 4. Participants

Thirty-one patients with low back pain who presented to the center between April 2003 and December 2004 (21 males and 10 females, mean age in the two groups: 68 and 70 years).

#### 5. Intervention

Arm 1: Acupuncture group. A stainless steel needle (Seirin Co., Ltd.; 0.18×40 mm) was inserted to a depth of 20 mm at the most tender point and sparrow pecking technique was applied for 20 seconds (n=15).

Arm 2: Sham acupuncture group. A guide tube was tapped at the most tender point, without using a needle (n=16).

#### 6. Main outcome measures

Visual Analog Scale (VAS) score for pain intensity and Schober test (a test of spinal mobility) score.

#### 7. Main results

Between-group comparison of the change from before to immediately after the treatment showed significant improvement in both VAS ( $P=0.020$ ) and Schober test ( $P<0.001$ ) scores in Arm 1.

#### 8. Conclusions

Acupuncture at the most tender point has an immediate relieving effect on low back pain.

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

The authors mentioned the descending inhibitory system or activation of spinal inhibitory system as a mechanism underlying the effect of tender point acupuncture.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This study is highly appreciated for testing the effect of acupuncture in an evaluator- and patient-masked trial. The success of the masking was also described. Because the study objective was to examine the immediate relieving effect of acupuncture, no flow chart was presented and no follow-up was carried out, but the longer-term effect is a concern. If the sham acupuncture technique is modified, further development may be expected.

#### 12. Abstractor and date

Hosaka M, 11 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Hirota S, Itoh K, Katsumi Y. Trigger point acupuncture treatment for chronic low back pain in elderly patients. *Meiji Shinkyu Igaku (The Bulletin of Meiji University of Oriental Medicine)* 2006; (38): 19–26. Ichushi Web ID: 2008088212

#### 1. Objectives

To compare the effects of acupuncture at a trigger point (TrP) and a tender point of the same muscle in elderly patients with chronic low back pain.

#### 2. Design

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

#### 3. Setting

Outpatient Clinic, Department of Orthopedic Surgery, Meiji University of Oriental Medicine Hospital, Kyoto, Japan.

#### 4. Participants

Six elderly people with low back pain for at least 6 months and no abnormal findings on neurological tests, including tests of muscle strength and deep reflex (4 males, 2 females, mean age 66.3±7.9 years).

#### 5. Intervention

Arm 1: Group A. TrP treatment then tender point treatment (n=3).

Arm 2: Group B. Tender point treatment then TrP treatment (n=3).

A TrP was defined as the point in a muscle with cord-like induration that induced pain when the low back or hip joints were moved passively. A tender point was defined simply as a point felt tender in the affected muscle identified in similar way to a TrP. Each treatment was given weekly 3 times, for 2 weeks (total 6 times). In both treatments, stainless steel needles (0.16×40 mm) were inserted into muscle, and retained for 10 minutes, regardless of de qi sensation. In both arms, 8–12 points were stimulated.

#### 6. Main outcome measures

Pain evaluated on a Visual Analogue Scale (VAS) before treatment and one week after each treatment (total 7 times). Roland-Morris Disability Questionnaire (RMDQ) before treatment, and one week after the third and the sixth treatments.

#### 7. Main results

The pre- to post-treatment decrease in VAS pain score was larger in Arm 1, but there was no clear difference between the two treatments. RMDQ scores decreased in both groups, but there was no clear quality of life improvement.

#### 8. Conclusions

TrP and tender point acupuncture are both effective for chronic back pain in the elderly, but the difference in the effectiveness of these treatments was insignificant.

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

Not mentioned.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

The significance of this study lies in its comparison of TrP treatment with tender point treatment, both common clinical treatments for low back pain, which is the most frequent complaint in acupuncture practice. The study compared two different treatments for the same muscle using a crossover design, based on the design described in a previous study, Hirota S, et al. "A controlled clinical trial comparing trigger point acupuncture with tender point acupuncture for chronic low back pain - a pilot study on 9 elderly patients -. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 2006; (56): 68–75 (in Japanese with English abstract) JA0916". Deficiencies include the lack of information about the participant recruitment period, the period and length of the study, and the washout period. In addition, sample size was small, and effectiveness was not thoroughly analyzed statistically. Further, while on one hand the authors mention in the Discussion (and they include references in the bibliography) that a certain degree of practice is required to master trigger point acupuncture therapy, the sole acupuncturist in this study had only had one year of clinical experience. It is hoped that the authors rectify these deficiencies before carrying out further research.

#### 12. Abstractor and date

Shimoichi Y, 11 September 2011.