11. Diseases of the Digestive Syestem

Reference

Hong SH, Kwon OS, Kim SH et al. Effects of Injinoryung-San on alcoholic hepatitis. *Dongui-Saengli-Byeongli-Hakhoeji* (*Korean Journal of Oriental Physiology & Pathology*) 2008; 22(1): 204–8 (in Korean with English abstract).

1. Objectives

To evaluate the effect of Injinoryung-san (茵蔯五苓散) on alcoholic hepatitis.

2. Design

Double-blinded randomized controlled trial (DB-RCT).

3. Setting

Two Oriental hospitals (Daejeon Oriental Hospital and Oriental Medicine Hospital of Dongeui Universtiy), Republic of Korea.

4. Participants

Thirty-one male subjects who drank more than once a week and 40 g a day (age range, 20–70) with elevated serum aspartate transaminase (AST), alanine transaminase (ALT), and gamma-(γ)-glutamyl transferase (GGT) levels and no clinical findings of hepatoma, hepatic cirrhosis, viral hepatitis, drug-induced hepatitis, and metabolic disorders by abdominal ultrasonography.

5. Intervention

Arm 1: Injinoryung-san (茵蔯五苓散) treatment for 2 weeks.

Arm 2: Placebo control treatment for 2 weeks.

During the study, 4 subjects were excluded from the efficacy evaluation (2 for violation of inclusion/exclusion criteria, 1 for violation of drug intake restrictions, and 1 for insufficient adaptability). Twenty-seven subjects (15 in Arm 1, 12 in Arm 2) were finally included for analysis.

6. Main outcome measures

Abdominal ultrasonography findings, blood biochemistry including serum levels of AST, ALT and GGT, and mean cell volume (MCV) 2 , 4, and 6 weeks after treatment. Changes in body composition before and after treatment.

7. Main results

There were no between-group differences in AST, ALT, and AST/ALT. But GGT level after 2 weeks, MCV and GGT level after 4 weeks, and MCV after 6 weeks were significantly lower in Arm 1 than in Arm 2.

8. Conclusions

Injinoryung-san (茵蔯五苓散) may have a partial effect on alcoholic hepatitis.

9. Safety assessment in the article

Hangover symptoms the day after treatment and a skin rash on both thighs developed in one patient in Arm 1. The symptoms were thought to be drug-related and disappeared a week after the end of treatment. Hepatic dysfunction became worse in one patient in Arm 1, but this patient failed to attend his follow up visit. In laboratory tests, all values were within normal range.

10. Abstractor's comments

In this study, the treatment period was short and many patients dropped out before the end of the study. A search for new Oriental drug candidates for treating alcoholic hepatitis is needed.

11. Abstractor and date

Cho JH, 16 July 2010.

12. Skin Diseases

Reference

Shin SH, Kim JH, Kim MB, et al. A clinical research about the effects of Seunggaltang on patients with atopic dermatitis. *Daehan-Hanbang-AnIbiinhupibugwa-Hakhoeji* (*Journal of Korean Oriental Medical Ophthalmology Otolaryngology Dermatology*) 2007; 20(2): 199–212 (in Korean with English abstract).

1. Objectives

To evaluate the efficacy of Seunggal-tang (升葛湯) powder extract for atopic dermatitis.

2. Design

Randomized controlled trial (RCT).

3. Setting

One Oriental hospital (Oriental Medicine Hospital of Dongeui Universtiy), Republic of Korea.

4. Participants

Thirty-nine patients (age range: 14 - 65 years) diagnosed with atopic dermatitis using the criteria of Hanifin and Rajka.

5. Intervention

Arm 1: Treatment with Seunggal-tang (升葛湯) extract was oraly administered for 8 weeks, 3 times per day (n=13, male/female=8/5).

Arm 2: Treatment with placebo extract was oraly administered for 8 weeks, 3 times per day (n=10, male/female=1/9).

6. Main outcome measures

1) Skin variables– oil content, transepidermal water loss (TEWL), skin water content, erythema, and melanoderma.
2) Self-developed clinical severity Index.
3) Blood variables- IgE level and mast cell count.

7. Main results

Sixteen subjects dropped out during the study. Skin water content around the Yintang (EX-HN3, 印堂) acupuncture point was significantly increased 8 weeks after treatment (P=0.0168). Treatment in Arm 1 reduced clinical severity (itchiness and sleep problems), and neither treatment significantly affected the blood variables.

8. Conclusions

Seunggal-tang (升葛湯) improves subjective symptoms.

9. Safety assessment in the article

Safety was confirmed by comparison of the results of blood tests and urine analysis before and after treatment.

10. Abstractor's comments

This study is highly meaningful as it had a randomized, controlled design. However, as the drop-out rate was high, the reliability of the trial is decreased. Most studies on atopic dermatitis in Korea examine reactions to topical products, such as cosmetics, ointment, shampoo, etc. Therefore, this study is highly meaningful as it has a randomized, controlled design and evaluates the effect of oral herbal medicine on atopic dermatitis. I think that the high drop-out rate in this study illustrates the difficulty of conducting a clinical trial of a systemic herbal remedy. So, I think that this study is valuable not for its result but for its methods.

11. Abstractor and date

Nam HJ, 8 June 2010.

12. Skin Diseases

Reference

Kim SH, Yun DC, Kim HT, et al. A clinical research of atopic dermatitis treated by Yeongyuseungmatang (連翹升麻湯) in cosmetics. *Daehan-Hanbang-AnIbiinhupibugwa-Hakhoeji* (*Journal of Korean Oriental Medical Ophthalmology Otolaryngology Dermatology*) 2008; 21(2): 126–41 (in Korean with English abstract).

1. Objectives

To evaluate the efficacy of cosmetics containing Yeongyuseungma-tang (連翹升麻湯) on atopic dermatitis patients.

2. Design

Double-blinded randomized controlled trial (DB-RCT).

3. Setting

One Oriental hospital (Semyung University Oriental Medicine Hospital), Republic of Korea.

4. Participants

Thirty-three patients aged over 16 years old with atopic dermatitis diagnosed using the Hanifin and Rajka criteria.

5. Intervention

Arm 1: Moisturizing cream containing Yeongyuseungma-tang (連翹升麻湯) applied to skin with atopic dermatitis for 4 weeks, 2–3 times per day (n=17).

Arm 2: Atopico Skincare Cream applied to skin with atopic dermatitis for 4 weeks, 2–3 times per day (n=16).

6. Main outcome measures

1) SCORing Atopic Dermatitis (SCORAD) Index.
2) Blood variables– total IgE level, eosinophil count.
3) Skin variables– skin surface temperature, transepidermal water loss (TEWL), skin water content, skin acidity.
4) Global efficacy assessment by subjects.

7. Main results

Four-week treatment significantly decreased the SCORAD index in both groups (P=0.014 in Arm 1 and 0.021 in Arm 2), and increased skin surface temperature, skin water content, and skin acidity significantly in both groups. Changes in total IgE level was not significant. Treatment in Arm 1 singnificantly increased scores on the global efficacy assessment, while it significantly decreased eosinophil count and TEWL.

8. Conclusions

The efficacy and safety of cosmetics containing Yeongyuseungma-tang (連翹升麻湯) are greater than those of Atopico Skincare Cream.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

Insofar as this study was performed under conditions maintained by a thermo-hygrostat and using proper skin testing equipment, the results are meaningful. Moreover, since Atopico Skincare Cream is used widely by atopic dermatitis patients, the fact that cream containing Yeongyuseungma-tang has similar efficacy is very promising. However, the authors failed to account for the decrease in eosinophil count, increase in IgE level, and increase in TEWL despite the increase in skin water content in the control group.

11. Abstractor and date

Nam HJ, 8 June 2010.

12. Skin Diseases

Reference

Yun DC, Kim HT, Kim EH, et al. Clinical research of atopic dermatitis treated by Hwangryeonhaedok-Tang (黃連解毒湯) in cosmetics. *Dongui-Saengli-Byeongli-Hakhoeji* (*Korean Journal of Oriental Physiology & Pathology*) 2008: 22(6); 1611–20 (in Korean with English abstract).

1. Objectives

To evaluate the efficacy of cosmetics containing Hwangryeonhaedok-Tang (黃連解毒湯) for atopic dermatitis.

2. Design

Double-blinded randomized controlled trial (DB-RCT).

3. Setting

One Oriental hospital (Semyung University Oriental Medicine Hospital), Republic of Korea.

4. Partcipants

Thirty-one patients aged over 16 years old diagnosed with atopic dermatitis using the criteria of Hanifin and Rajka.

5. Intervention

Arm 1: A moisturizing cream containing Hwangryeonhaedok-Tang (黃連解毒湯) applied to skin with atopic dermatitis for 4 weeks, 2–3 times per day (n=15, male/7, female/8).

Arm 2: A moisturizing cream alone applied to skin with atopic dermatitis for 4 weeks, 2–3 times per day (n=16, male/3, female/13).

6. Main outcome measures

1) SCORing Atopic Dermatitis (SCORAD) Index.
2) Blood variables– total IgE level, eosinophil count.
3) Skin variables– skin surface temperature, transepidermal water loss (TEWL), skin water content, skin pH.
4) Global efficacy assessment by subjects.

7. Main results

Treatment significantly decreased the SCORAD index and increased skin water content and global efficacy in Arm 1 compared to Arm 2 (P=0.008 and 0.03, respectively).

There were no between-group differences in total IgE level, eosinophil count, skin surface temperature, TEWL, and skin acidity.

8. Conclusions

Moisturizing cream containing Hwangryeonhaedok-Tang improves atopic dermatitis.

9. Safety assessment in the article

No severe adverse events.

10. Abstractor's comments

This study comparing moisturizing creams with and without Hwangryeonhaedok-Tang has provided more meaningful results than other similar previous studies. However, it is unclear why transepidermal water loss (TEWL) was increased in both groups. As this study was performed under conditions maintained by a thermo-hygrostat and using proper skin testing equipment, this study is meaningful.

11. Abstractor and date

Nam HJ, 9 June 2010.

12. Skin Diseases

Reference

Kim CH, Hwang DS, Kim JT, et al. A randomized, double-blind, placebo-controlled study to herbal shampoo and essence about dandruff. *Daehan-Hanbang-AnIbiinhupibugwa-Hakhoeji* (*Journal of Korean Oriental Medical Ophthalmology Otolaryngology Dermatology*) 2007; 20(3): 222–35 (in Korean with English abstract).

1. Objectives

To evaluate the effect of herbal shampoo and essence on dandruff.

2. Design

Double-blinded randomized controlled trial (DB-RCT).

3. Setting

One Oriental hospital (Daejeon Orinetal Hospital), Republic of Korea.

4. Participants

Patients with dandruff and *Pityrosporum ovale*, the yeast thought to be the cause of dandruff (n=47).

5. Intervention

Arm 1: Two-week treatment with herbal shampoo and essence; hair washed once a day in the morning (n=25, male/female=14/11).

Arm 2: Two-week treatment with conventional shampoo and essence; hair washed once a day in the morning (n=22, male/female=19/3).

6. Main outcome measures

1) Cell count of the dandruff-producing organism.
2) Measurement of sebum secretion rate on upper part of forehead using a Sebumeter®.
3) Subjective symptoms score.

7. Main results

In Arm 1, treatment significantly decreased the number of *P. ovale* cells and rate of sebum secretion (P=0.0083, 0.0182 respectively). In both Arm 1 and Arm 2, subjective symptom scores were significantly improved (Arm 1, P=0.0006; Arm 2, P=0.0182), but there was no significant between-group difference.

8. Conclusions

The herbal shampoo and essence treatment reduces dandruff.

9. Safety assessment in the article

None. However, no adverse reactions occurred in a previous study using the 2-day herbal patch test in normal male volunteers (n=20).

10. Abstractor's comments

In traditional Korean medicine, dandruff is considered to be a sign of seborrheic dermatitis caused by the accumulation of dampness-heat (濕熱) in the spleen and stomach, or due to blood regulation by external wind –heat (風熱). This study confirmed the effectiveness of shampoo/essence containing extracts of five herbs (Sophora Radix, Asiasarum sieboldi, Coptis chinensis Franch, Fritillaria thunbergii Miquel, and Atractylodes lancea DC) for dandruff. Insofar as the safety of the shampoo was previously established and *P. ovale* cell count provided objective data, the results of this study are meaningful.

11. Abstractor and date

Nam HJ, 8 June 2010.

13. Diseases of the Musculo Skeletal System and Connective Tissue

Reference

Lee SH, Hong SJ, Kim SY, et al. Randomized, controlled, double blind study of bee venom therapy on rheumatoid arthritis. *Daehan-Chimgu-Hakhoeji* (*Journal of Korean Acupuncture & Moxibustion Society*) 2003; 20(6): 80–8 (in Korean with English abstract).

1. Objectives

To evaluate the effect of bee venom therapy on rheumatoid arthritis.

2. Design

Double-blinded randomized controlled trial (DB-RCT).

3. Setting

One Oriental hospital (Kyunghee University Medical Center), Republic of Korea.

4. Participants

Rheumatoid arthritis patients (n=80).

5. Intervention

Arm 1: Bee venom acupuncture treatment (n=40).
Arm 2: Saline treatment (n=40).
Treatment was twice a week, for 2 months (total 16 treatments) and was applied to local acupuncture points at the sites of inflammation. These sites with acupuncture points were the:

(1) hand including distal interphalangeal joint (DIP), proximal interphalangeal joint (PIP), metacarpophalangeal joint (MCP), and wrist joint—Yanggu (SI5, 陽谷), Yangchi (TE4, 陽池), Yangxi (LI5, 陽溪), and Daling (PC7, 大陵) acupuncture points;
(2) elbow joint—Quchi (LI11, 曲池), Tianding (LI17, 天鼎), and Xiaohai (SI8, 小海) acupuncture points;
(3) shoulder joint—Jianyu (LI15, 肩髃) and Jianliao (TE14, 肩髎) acupuncture points;
(4) knee joint—Heding (EX-LE2, 鶴頂), Xiyan (EX-LE5, 膝眼), Zusanli (ST36, 足三里), Yanglingquan (GB34, 陽陵泉), and Yinlingqun (SP9, 陰陵泉) acupuncture points;
(5) ankle joint—Qiuxu (GB40, 丘墟), Shenmai (UB62, 申脈), Shangqiu (SP5, 商丘), and Zhaohai (KI6, 照海) acupuncture points.

Prescribed medications were continued without change throughout the course of the study.
Among 80 subjects enrolled, 11 subjects dropped out during the study (8 in Arm 1, 3 in Arm 2).
Reasons for drop out included: lack of cooperation (n=5), problems with transport (n=3), adverse events (n=2), uncertainty of efficacy (n=1).

6. Main outcome measures

1) Number of tender joints, number of swollen joints, morning stiffness, pain assessed on a visual analogue scale (VAS, Health assessment questionnaire (HAQ) score.
2) Erythrocyte sedimentation rate (ESR), C-reactive protein (CRP) level.

7. Main results

1) Clinical symptom evaluation
Two-month (but not one-month) treatment significantly decreased the number of tender joints, number of swollen joints, and morning stiffness in Arm 1 *vs.* Arm 2 (2.5±1.4, 2.5±1.4, 1.4±0.8 *vs.* 3.4±2.8, 3.4±2.8, 1.9±1.2, respectively, $P<0.05$).
2) Quality of life (QOL) evaluation
Similarly, 2-month but not 1-month treatment significantly decreased HAQ score in Arm 1 *vs.* Arm 2 (0.7±0.6 *vs.* 0.4±0.3, $P<0.05$). There was a significant between-group difference in VAS score for pain after 1 month of treatment (48.5±2.3 [Arm 1] *vs.* 58.9±17.4 [Arm 2]) and 2 months of treatment (40.3±2.7 [Arm 1] *vs.* 57.2±27.8 [Arm 2]), and the decrease in VAS score was significantly greater in Arm 1 ($P<0.05$).
3) ESR and CRP evaluation
The decrease in ESR and CRP level was significantly greater in Arm 1 than in Arm 2 after 1 month of treatment (28.3±12.0, 1.1±1.3, *vs.* 30.6±19.8, 2.5±4.6 [Arm 2]) and after 2 months of treatment (18.3±10.3, 0.8±0.7 *vs.* 37.7±24.5, 2.5±2.5 [Arm 2]) ($P<0.05$).

8. Conclusions

Bee venom acupuncture improves clinical symptoms, QOL, and inflammation. Effectiveness requires more than 2 months of treatment.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

This study compares the effectiveness of bee venom acupuncture to that of saline placebo control for rheumatoid arthritis. Bee venom acupuncture elicited an objective therapeutic response from patients with rheumatoid arthritis. This study was a randomized controlled trial. The reasons for drop-out but not the randomization and blinding methods were clearly described, and the analysis was per-protocol and not by intention-to-treat. Moreover, the saline treatment had limitations as a placebo control.

11. Abstractor and date

Kim JI, 28 June 2010.

13. Diseases of the Musculo Skeletal System and Connective Tissue

Reference

Byun H, Kim SW, Ahn JH, et al. Individualized acupuncture *vs.* standardized acupuncture in symptomatic treatment of osteoarthritis of the knee—a randomized controlled trial (IS Randomized, controlled trial N 40706107). *Daehan-Chimgu-Hakhoeji* (*Journal of Korean Acupuncture & Moxibustion Society*) 2007; 24(4): 183–95 (in Korean with English abstract).

1. Objectives

To evaluate the effect of personalized acupuncture (Sa-Am acupuncture [舍岩鍼]) on osteoarthritis of the knee.

2. Design

Randomized controlled trial (RCT).

3. Setting

One Oriental hospital (Dongkuk University Ilsan Oriental Hospital), Republic of Korea.

4. Participants

Patients with knee degenerative osteoarthritis meeting American College of Rheumatology (ACR) classification criteria (n=50).

5. Intervention

Arm 1: Standard local acupuncture + personalized Sa-Am acupuncture (n=25).
Arm 2: Standard local acupuncture (n=25).
Acupuncture treatment: 2 treatments a week for 6 weeks, 12 treatments in total.
Local acupuncture (applied to 6 acupuncture points in the affected site): Yanglingquan (GB 34 陽陵泉), Yinlingqun (SP9, 陰陵泉), Dubi (ST35, 犢鼻), Xiyan (EX-LE5, 膝眼), Heding (EEX-LE2, 鶴頂), and Ashi (阿是). If pain occurred in both knees, both were treated. All patients received the same, mixed frequency stimulation (i.e. alternating low [2Hz] with high [30Hz] frequency stimulation) (applied to 4 Sa-Am acupuncture points in unaffected sites): Ganjeonggyeok (肝正格), Ganseunggyeok (肝勝格), Sinjeonggyeok (腎正格), and Sinseunggyeok (腎勝格). If pain occurred in both knees, the knee with less pain was treated.
Among 50 subjects enrolled, 3 dropped out (all in Arm 1).
Reasons for dropping out: loss to follow-up (n=1), relocation (n=1), pain during acupuncture treatment (n=1)

6. Main outcome measures

Pain self-assessed on a visual analogue scale (VAS), and scores on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), 36-Item Short-Form Health Survey (SF-36), Lequesne Functional Index (LFI), Korean Version of Health Assessment Questionnaire (KHAQ).

7. Main results

Treatment significantly decreased the pain VAS, WOMAC, LFI, and KHAQ scores, but not SF-36 score.
The effect of personalized acupuncture and standard acupuncture:
From the fitted regression line of VAS and WOMAC before and after 3, 6, and 18 weeks of treatment in Arm 1, VAS score decreased slightly as treatment progressed and returned to pretreatment level after 18 weeks of treatment.
Regarding the equilibrium box diagram of VAS, VAS scatter was much larger in Arm 1 than Arm 2 at baseline, 3 weeks, and 6 weeks, but not at 18 weeks. Regarding the change in median VAS and WOMAC scores, both scores decreased continuously in Arm 1 and Arm 2, but increased at 18 weeks in Arm 2.
There was no between-group difference in LFI and KHAQ.

8. Conclusions

Both treatments relieve symptoms and are safe. Personalized acupuncture can provide even more pain relief by 3 months after treatment.

9. Safety assessment in the article

No adverse events occurred.

10. Abstractor's comments

This randomized controlled trial compared treatment with personalized acupuncture (local acupuncture points: electroacupuncture, Distal acupuncture points: Sa-Am acupuncture) with standard acupuncture (local acupuncture points: electroacupuncture) for knee osteoarthritis. A flowchart of the trial was presented, results were recorded according to STRICTA recommendations, and the number of drop-out and excluded subjects were clearly indicated. The study was single blind, but blinding of all the subjects, investigators, and diagnosticians (but not clinicians) was possible. However, the use of per protocol analysis was a limitation of this study and the values in graphs are not clear, and so results cannot be interpreted. Moreover, the difficulty of knowing what part of the treatment effect is due to spontaneous remission is another serious limitation.

11. Abstractor and date

Kim JI, 14 June 2010.

13. Diseases of the Musculo Skeletal System and Connective Tissue

Reference

Park IS, Jung CY, Jang MK, et al. A randomized clinical trial of local acupuncture points compared with distal acupuncture points in degenerative osteoarthritis on knee. *Daehan-Chimgu-Hakhoeji* (*Journal of Korean Acupuncture & Moxibustion Society*) 2008; 25(2): 227–42 (in Korean with English abstract).

1. Objectives

To compare the effect of treatment at local acupuncture points and distal acupuncture points on knee degenerative osteoarthritis.

2. Design

Randomized controlled trial (RCT).

3. Setting

One Oriental hospital (Dongkuk University Ilsan Oriental Hospital), Republic of Korea.

4. Participants

Patients with knee degenerative osteoarthritis meeting American College of Rheumatology (ACR) classification criteria (age, 55–80; n=26).

5. Intervention

Arm 1: Washout (2 weeks) followed by acupuncture (local acupuncture points), washout, and acupuncture (distal acupuncture points) (n=13).

Arm 2: Washout (2 weeks), followed by acupuncture (distal acupuncture points), washout, and acupuncture (local acupuncture points) (n=13).

Acupuncture was performed 3 times per week for 2 weeks.

Local acupuncture points (i.e., acupuncture points at affected sites): Dubi (ST35, 犢鼻), Xiyan (EX-LE5, 膝眼), Heding (EX-LE2, 鶴頂), and Ashi (阿是).

Distal acupuncture points (i.e., acupuncture points at unaffected sites): 4 points selected from among the Ganshu (BL18, 肝俞), Shenshu (BL23, 腎俞), Kunlun (BL60, 崑崙), Xuanzhong (GB39, 懸鐘), Sanyinjiao (SP6, 三陰交), Xingjan (LR2, 行間), Jiexi (ST41, 解溪), and Taixi (KI3, 太溪) acupuncture points.

If pain was present on both sides of the body, both sides were treated (at a total of 8 acupuncture points).

Among 26 subjects, 9 dropped out.

Reasons for patient withdrawal: Pain during or after the acupuncture (n=4), relocation (n=2).

Patients with WOMAC score less than 40 (n=3) were excluded.

6. Main outcome measures

Pain assessed on a visual analogue scale (VAS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score.

7. Main results

Local acupuncture significantly decreased pain VAS score and WOMAC score, and distal acupuncture significantly decreased WOMAC pain subscore and overall WOMAC score. There was a significant between-group difference in WOMAC score (47.5±17.1 [local acupuncture] *vs.* 58.1±10.5 [distal acupuncture], P=0.036).

8. Conclusions

Both treatments significantly improve osteoarthritis symptoms. Based on overall WOMAC score, local acupuncture is more effective than distal acupuncture. Efficacy does not depend on the sequence of local and distal acupuncture treatment.

9. Safety assessment in the article

No adverse events occurred.

10. Abstractor's comments

This study compared the efficacy of local acupuncture with that of distal acupuncture as treatment. A flowchart of the trial was presented, the results were recorded according to STRICTA recommendations, and the number of drop-out and excluded subjects were clearly indicated. The study was single blind, but blinding of all the subjects, investigators, and diagnosticians (but not clinicians) was possible. The authors used per protocol analysis, and the drop-out rate was very high (34.6%, 9 of 26 subjects).

11. Abstractor and date

Kim JI, 7 June 2010.

13. Diseases of the Musculo Skeletal System and Connective Tissue

Reference

Kim HB, Lee RM, Lee MH, et al. Comparative study of effects of 'Intramuscular bee venom herbal acupuncture' and 'Intracutaneous bee venom herbal acupuncture' in knee osteoarthritis patients. *Daehan-Chimgu-Hakhoeji* (*Journal of Korean Acupuncture & Moxibustion Society*) 2008; 25(2): 151–64 (in Korean with English abstract).

1. Objectives

To compare the effect of 'intramuscular bee venom herbal acupuncture' and 'intracutaneous bee venom herbal acupuncture' in knee osteoarthritis patients.

2. Design

Randomized controlled trial (RCT).

3. Setting

One Oriental hospital (Kyunghee University Medical Center), Republic of Korea.

4. Participants

Patients with knee osteoarthritis and knee pain over 6 months (age, >40 years; n=45).

5. Intervention

Arm 1: Intramuscular bee venom herbal acupuncture (n=21), Treatment (0.5 cc/knee).

Arm 2: Intracutaneous bee venom herbal acupuncture (n=24). Treatment (0.1 cc per acupuncture point, total 0.5 cc) applied to the Heding 鶴頂 (EX-LE2), Xiyan (EX-LE5, 膝眼), Dubi (ST35, 犢鼻), Zusanli (ST36, 足三里), and Ququan (LR8, 曲泉) acupuncture points.

Twice a week for 4 weeks, total 8 times.

Oriental therapies in other Oriental hospitals was not permitted, but ambulatory care such as acupuncture and Oriental drugs, and TDP thermotherapy in the clinical trial setting were permitted. The analgesics e.g., conventional NSAIDs and other COX-2 selective inhibitors, used before the trial were permitted during and until the end of the trial.

Among 45 subjects enrolled, 13 dropped out (4 in Arm 1, 9 in Arm 2).

Reasons for withdrawal: Onset of another disease (n=3), missing information on questionnaire (n=3), unable to attend follow-up evaluation appointments (n=3), loss to follow-up (n=2), unsatisfied with treatment effect (n=2)

6. Main outcome measures

Korean Pain Assessment Card score, Korean Western Ontario and McMaster Universities Osteoarthritis Index (KWOMAC) score, pain severity scored on a visual analogue scale (VAS), 36-Item Short-Form Health Survey (SF-36) score, Overall Outcome on a nine point scale.

7. Main results

Both treatments significantly decreased KWOMAC score. There was no significant between-group difference. Treatment in Arm 1 significantly increased subscores of the SF-36 for physical function (64.1±17.6 *vs.* 73.5±16.0 after treatment, P=0.006) and bodily pain (48.7±12.4 *vs.* 60.4±19.3, P=0.006). But there was no significant between-group difference. Both treatments significantly improved overall outcome, but there was no significant between-group difference.

Improvement in knee pain evaluated on a 9-point scale was evaluated as excellent (n=1, 5.9%), good (n=11, 64.7%), fair (n=3, 17.6%), and poor (n=2, 11.8%) in Arm 1 and excellent (n=0), good (n=10, 66.7%), fair (n=4, 26.6%), and poor (n=1, 6.7%) in Arm 2. The mean score were 5.8±2.0 and 5.6±1.1 in Arm 1 and Arm 2 respectively. Both treatments significantly improved overall outcome, but there was no significant between-group difference.

8. Conclusions

Both intramuscular and intracutaneous bee venom herbal acupuncture are effective with similar efficacy in knee osteoarthritis.

9. Safety assessment in the article

Itching (n=2, 11.8%), swelling (n=1, 5.9%), pain (n=1, 5.9%) were reported to be adverse effects of intramuscular treatment, and itching (n=4, 26.7%) and swelling (n=1, 6.7%) were reported to be adverse effects of intracutaneous treatment. These events were mild (Mueller Grade 0), and occurred with similar frequency in each group.

10. Abstractor's comments

In this study, the method of randomization (computerized randomization, block size 4), criteria for inclusion and exclusion, use of concomitant drugs, and reasons for withdrawal were described in detail, and safety was assessed. The knee ultrasonography results are for future reference. The authors found no between-group difference and concluded that bee venom herbal acupuncture has efficacy, but no control treatment was included for comparison. The objectivity of the analysis could have been improved by addition of a control.

11. Abstractor and date

Kim JI, 24 June 2010.

13. Diseases of the Musculo Skeletal System and Connective Tissue

Reference

Kim SC, Na WM, Lee SY, et al. A study on pain relief effects and allergic responses for the osteoarthritis of the knee joint between sweet bee venom and bee venom pharmacopuncture. *Daehan-Yakchim-Hakhoeji* (*Journal of Pharmacopuncture*) 2008; 11(1): 31–40 (in Korean with English abstract).

1. Objectives

To compare the effect of sweet bee venom (enzyme removed) pharmacopuncture with that of bee venom pharmacopuncture on knee osteoarthritis.

2. Design

Randomized controlled trial (RCT).

3. Setting

One Oriental hospital (Oriental Medical Hospital at Gwangju, Wonkwang University), Republic of Korea.

4. Participants

Patients with degenerative knee osteoarthritis (age, >50; n=30).

5. Intervention

Arm 1: Sweet bee venom (SBV) pharmacopuncture (n=15).

Arm 2: Bee venom (BV) pharmacopuncture (n=15).

Three treatments a week for 2 weeks.

One cc (total) was applied to the Yanglingquan (GB34, 陽陵泉), Yinlingqun (SP9, 陰陵泉), Dubi (ST35, 犢鼻) Heding [EX-LE2, 鶴頂]), Xiyan (EX-LE5, 膝眼), and pressure pain point (壓痛點) acupuncture points. The side of the body with the most pain was treated.

During the clinical trial, use of any Western and Eastern drugs was restricted.

6. Main outcome measures

Pain self-assessed on a visual analogue scale (VAS).

7. Main results

Treatment in Arm 1 provided significantly more pain relief throughout the body (18.2±15.2 *vs.* 15.6±16.3, P=0.002) and pain relief at the affected site (33.3±8.3 *vs.* 25.9±15.3, P=0.000). Delayed-type hypersensitivity responses occurred at a significantly lower frequency in Arm 1.

8. Conclusions

Sweet bee venom pharmacopuncture is a better analgesic than bee venom pharmacopuncture.

9. Safety assessment in the article

No immediate-type and delayed-type hypersensitivity reactions occurred.

Site pain due to treatment began 6 hours after treatment and lasted 6 hours in Arm 1, and began 6 hours after treatment and lasted 24 hours in Arm 2. Adverse events of bee venom treatment were severe edema and flare (n=3, every treatment), moderate edema and flare (n=4, 5th and 6th treatment), moderate itching (n=3, every treatment and lasting 48 hours), itching (n=4, at 5th and 6th treatment and lasting 24 hours). Adverse events of sweet bee venom treatment were minor edema and flare (n=2, at 1st and 2nd treatments) and minor itching (n=2, at 1st and 2nd treatment and lasting 3 hours).

10. Abstractor's comments

This study evaluated the efficacy and safety of sweet bee venom pharmacopuncture. The study hypothesis was that sweet bee venom pharmacopuncture caused less hypersensitivity. The results showed that sweet bee venom pharmacopuncture was much safer. Although the results were reported according to STRICTA recommendations, the randomization method and study design were not described. Moreover, pain VAS score was the only variable. A quantitative clinical trial is needed.

11. Abstractor and date

Kim JI, 5 July 2010.

13. Diseases of the Musculo Skeletal System and Connective Tissue

Reference

Yang KR, Song HS. A comparative study of warm needling and bee venom pharmacopuncture on osteoarthritis of the knee—a randomized controlled trial. *Daehan-Yakchim-Hakhoeji* (*Journal of Pharmacopuncture*) 2008; 11 (2): 21–31 (in Korean with English abstract).

1. Objectives

To compare the effect of bee venom pharmacopuncture with that of warm needling on knee osteoarthritis.

2. Design

Randomized controlled trial (RCT).

3. Setting

One Oriental hospital (Kyungwon University Orineal Hospital), Republic of Korea.

4. Participants

Knee osteoarthritis patients (age, 50–70; n=49).

5. Intervention

Patients were assigned to two groups according to a computer-generated randomization table.

Arm 1: Bee venom pharmacopuncture (BVP; n=25, number of drop outs=7).

Arm 2: Warm needling (WN; n=24, number of drop outs=9).

Twice a week for 8 weeks (16 rounds in all).

Treatment acupuncture points: 4–6 acupuncture points were selected from among the following: Yinlingqun (SP9, 陰陵泉), Xuehai (SP10, 血海), Ququan (LR8, 曲泉), Xiyangguan (GB33, 膝陽關), Yanglingquan (GB34, 陽陵泉), Weizhong (UB40, 委中), Liangqiu (ST34, 梁丘), Yingu (KI10, 陰谷), and the 1 and 2 A-Shi and treated.

1) Sweet bee venom treatment: 0.01 ml applied to the above acupuncture points (less than 0.2 ml in total) was followed by acupuncture for 20 minutes at the same acupuncture points.
2) Warm needling treatment: Acupuncture and moxa sticks burned 7–8 minutes, followed by acupuncture for 20 minutes all at the above acupuncture points.

Among 49 subjects enrolled, 16 dropped out during the study (7 in Arm 1, 9 in Arm 2).

Reasons for withdrawal: another disease (n=1), inability to continue (n=2), personal reasons (n=3)

6. Main outcome measures

Korean Western Ontario and McMaster Universities Osteoarthritis Index (KWOMAC) score, pain self-assessed on a visual analogue scale (VAS), 36-Item Short Form Health Survey (SF-36) score.

7. Main results

1) KWOMAC, VAS

Compared with WN, BVP resulted in significantly improved VAS score (-3.4±1.5 in BVP *vs.* -3.1± 1.0 in WN), KWOMAC total score (-14.4±8.4 in BVP *vs.* -9.1±6.4 in WN) and function subscore (-11.1±5.9 in BVP *vs.* -6.3±4.4 in WN) after 8 weeks of treatment ($P<0.05$). There was no significant between-group difference in subscales other than the function subscale.

2) SF-36

After 8 weeks of treatment, there was no significant between-group difference in the SF-36 total score (-11.8±7.1 in BVP *vs.* -9.7±5.3 in WN), physical health score (-15.1±9.2 in BVP *vs.* -13.2±8.1 in WN), and mental health score (-8.4±8.6 in BVP *vs.* -7.0±8.7 in WN).

8. Conclusions

BVP is more effective than WM (i.e., provides more satisfaction and better functional improvement).

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

This study compared the efficacies of two therapies. However, these efficacies were not clear without a control group for comparison. Additional study is needed.

11. Abstractor and date

Kim JI, 1 July 2010.

13. Diseases of the Musculo Skeletal System and Connective Tissue

Reference

Seo BK, Ryu SR, Kang JW, et al. Clinical study of the efficacy and safety of Jetongdan on patients with osteoarthritis of the knee. *Daehan-Hanui-Hakhoeji* (*Journal of Korean Oriental Medical Society*) 2005; 26(2): 231–40 (in Korean with English abstract).

1. Objectives

To evaluate the effect of Jetongdan on Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) OA (an index of knee osteoarthritis severity).

2. Design

Double-blinded randomized controlled trial (DB-RCT).

3. Setting

One Oriental hospital (Kyunghee University Medical Center), Republic of Korea.

4. Participants

Knee osteoarthritis patients (n=80).

5. Intervention

Arm 1: Jetongdan treatment for 8 weeks, 3 doses per day, 3 capsules per dose (n=42).

Arm 2: Placebo treatment. Placebo capsule with same treatment regimen (n=38).

If non-steroidal inflammatory drugs were used, treatment was started after a 1-week washout period.

6. Main outcome measures

WOMAC; erythrocyte sedimentation rate (ESR).

Each index was recorded before treatment, and 4 weeks and 8 weeks after treatment.

7. Main results

Treatment significantly accelerated the decrease in composite WOMAC score and WOMAC physical function subscore in Arm 1 compared with Arm 2 ($P<0.001$), and the between-group differences were significant ($P<0.05$). Both treatments also significantly accelerated the decrease in WOMAC pain subscore ($P<0.001$) but had no effect on ESR.

8. Conclusions

Jetongdan treatment improves WOMAC score and ESR score. Failure to demonstrate improvement in pain and stiffness is attributed to between-group differences in baseline characteristics. Further study using a larger sample is recommended.

9. Safety assessment in the article

Jetongdan treatment had no adverse effect on kidney and liver function:

10. Abstractor's comments

This randomized, double-blind study evaluates the efficacy and safety of Jetongdan in patients with osteoarthritis. However, there was a significant between-group difference in pretreatment WOMAC scores (48.3±12.8 [Arm 1] *vs.* 56.3±16.7 [Arm 2], $P=0.038$) indicating bias due to inadequate randomization. The contents and formulation were not described, and the reasons for the change in number of subjects included for analysis was not provided. P-values but not the WOMAC scores and changes in ESR were presented. Jetongdan treatment was not individualized, so the result of this study is difficult to apply realistically in clinical settings.

11. Abstractor and date

Kim JI, 28 June 2010.

13. Diseases of the Musculo Skeletal System and Connective Tissue

Reference

Seo BK, Ryu SR, Kang JW, et al. Effects of Jetongdan on the quality of life in patients with osteoarthritis of knee. *Daehan-Chimgu-Hakhoeji* (*Journal of Korean Acupuncture & Moxibustion Society*) 2005; 22(6): 219–28 (in Korean with English abstract).

1. Objectives

To evaluate the effect of Jetongdan on the quality of life in patients with knee osteoarthritis.

2. Design

Double-blinded randomized controlled trial (DB-RCT).

3. Setting

One Oriental hospital (Kyunghee University Medical Center), Republic of Korea.

4. Participants

Knee osteoarthritis patients (n=80).

5. Intervention

Arm 1: Jetongdan treatment, 3 capsules per dosage, 3 doses a day for 8 weeks (n=40).

Arm 2: Placebo treatment on the same schedule as in Arm 1 (n=40).

Among 80 subjects enrolled, 28 subjects dropped out during the study (15 in Arm 1, 13 in Arm 2).

6. Main outcome measures

Scores on the Korean Health Assessment Questionnaire (KHAQ), Lequesne's Functional Index (LFI), and pain measured on a visual analogue scale (VAS).

Measurements were taken before treatment, and at 4 weeks and 8 weeks after treatment.

7. Main results

Treatment in Arm 1 resulted in a significantly greater decrease in overall KHAQ score (from 33.0±5.8 before to 27.6±4.0 after 8 weeks of treatment, $P<0.000$), hygiene subscore (from 4.7±1.3 to 3.8±0.8, $P=0.006$), and activities subscore (from 6.5±1.3 to 5.2±0.9, $P=0.001$). However, treatment had no effect on LFI and pain VAS scores.

8. Conclusions

Jetongdan improves the quality of life in patients with knee osteoarthritis.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

This study is part of the study described by abstract K050013H (Seo BK, et al. Clinical study of the efficacy and safety of Jetongdan on patients with osteoarthritis of the knee. *Daehan-Hanui-Hakhoeji* [*Journal of Korean Oriental Medical Society*] 2005; 26(2): 231–40). According to the original paper, the study enrolled 80 people, but group allocation and reasons for the withdrawal of 28 subjects are not described. The drop-out rate (35%) is very high.

11. Abstractor and date

Kim JI, 3 June 2010.

13. Diseases of the Musculo Skeletal System and Connective Tissue

Reference

Lee HJ, Park HJ, Chae YB, et al. Tai Chi Qigong for the quality of life of patients with knee osteoarthritis: a pilot, randomized, waiting list controlled trial. *Clinical Rehabilitation* 2009; 23(6): 504–11.

1. Objectives

To evaluate the effect of Tai Chi Qigong (太極氣功) on the quality of life of patients with knee osteoarthritis.

2. Design

Randomized controlled trial (RCT).

3. Setting

HwaSeong City Health Center, Republic of Korea.

4. Participants

Patients diagnosed with knee osteoarthritis defined as over grade II on the Kellgren-Lawrence Scale (n=44).

5. Intervention

Computer-generated balanced block randomization was used for a 2:1 (Arm 1:Arm 2) allocation of participants.

Arm 1: Tai Chi Qigong treatment (n=29)

Arm 2: Just observation (n=15)

Tai Chi Qigong treatment: twice a week, 18 movements per round (1 hour) for 8 weeks (total 16 rounds).

Among 44 subjects enrolled, 3 subjects dropped out (1 in Arm 1, 2 in Arm 2).

Reasons for dropping out: conflict with professional activities (n=1), move to another place (n=1), no reason (n=1).

6. Main outcome measures

Health status (Short Form 36 [SF-36] score); physical functioning (Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC] score, elapsed time to walk 6 meters). Pretreatment measures were compared to posttreatment measures.

7. Main results

Treatment significantly increased overall SF-36 score in Arm 1 compared to Arm 2 (64.4±20.9 *vs.* 55.1±17.5, P=0.010), as well as the mental (P=0.018) and physical (P=0.030) subscores, and significantly decreased the WOMAC pain subscore (–2.2±4.1 *vs.* 0.2±1.8, P=0.030) and walking time (5.9±1.0 *vs.* 6.7±1.8, P=0.005). However, there was no significant between-group difference in overall WOMAC score (20.8±18.7 *vs.* 28.5±19.6, P=0.086).

8. Conclusions

Eight weeks of Tai Chi Qigong helps relieve symptoms and improves quality of life in patients with knee osteoarthritis.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

The study process as well as the number of drop-outs and reasons for dropping out were clearly described in a flowchart. Moreover, intent-to treat analysis was used to obtain an unbiased estimate of treatment efficacy. There was no blinding in this study, which is a limitation, due to the characteristics of the Tai Chi Qigong treatment. The SF-36 scores and 6-m walking time (but not WOMAC score) provided clear evidence of improvement.

11. Abstractor and date

Kim JI, 24 June 2010.

13. Diseases of the Musculo Skeletal System and Connective Tissue

Reference

Yu SM, Lee JY, Kwon KR, et al. Comparative study of acupuncture, bee venom acupuncture, and bee venom pharmacopuncture on the treatment of herniation of nucleus pulpous. *Daehan-Chimgu-Hakhoeji* (*Journal of Korean Acupuncture & Moxibustion Society*) 2006; 23(5): 39–54 (in Korean with English abstract).

1. Objectives

To compare the efficacy of acupuncture, bee venom acupuncture, and bee venom pharmacopuncture as treatment for herniation of nucleus pulposus.

2. Design

Randomized controlled trial (RCT).

3. Setting

One Oriental hospital (Inega Oriental Hospital), Republic of Korea.

4. Participants

Patients with intervertebral disc herniation (age, 20–60; n=37).

5. Intervention

Arm 1: Standard treatment (acupuncture, drug treatment, physiotherapy) (n=15).
Arm 2: Standard treatment + bee venom pharmacopuncture (BVP; n=11).
Arm 3: Standard treatment + bee venom acupuncture (BVA; n=11).
Acupuncture was applied to the Mingmen (GV4, 命門), Yaoyangguan (GV3, 腰陽關), Shenshu (BL23, 腎俞), Qihaishu (BL24, 氣海俞), Dachangshu (BL25, 大腸俞), Guanyuanshu (BL26, 關元俞), and Huantiao (GB30, 環跳) acupuncture points twice a day (in the morning and afternoon); Houxi (SI3, 後溪), Zusanli (ST36, 足三里), Yanglingquan (GB34, 陽陵泉), and Linggu (靈骨) acupuncture points in the morning; Mingmen (GV4, 命門), Yaoyangguan (GV3, 腰陽關), Naoshu (SI10, 臑俞), Qihaishu (BL24, 氣海俞), Dachangshu (BL25, 大腸俞), Guanyuanshu (BL 26, 關元俞), and Huantiao (GB30, 環跳) acupuncture points in the afternoon. Depending on the severity of the pain, additional acupuncture would be applied to the kidney JEONGGYEOK(腎正格), liver JEONGGYEOK(幹正格), and gallbladder JEONGGYEOK(膽正格) acupuncture points.
BVP (once a day in the afternoon): Concentration of injected venom increased over time from 1:4000 in 0.1 ml to 1:2000 in 1 ml.
BVA (once a day in the afternoon): The bee venom was placed on the end of each acupuncture needle.
No details concerning other drug treatment, physiotherapy, bedside rest were given.
Two patients, who chose surgery instead, withdrew (one subject each in Arm 2 and 3).

6. Main outcome measures

Pain self-assessed on a visual analogue scale (VAS), Oswestry Disability Index (ODI) score assessed before treatment, and after 10, 20, and 30 days of treatment; degree of physical recovery (excellent, good, fair, and poor) as assessed by the Straight Leg Raising Test (SLRT) and range of motion (ROM).

7. Main results

Treatment in all groups relieved pain ($P<0.05$) and significantly improved ODI score ($P<0.05$).
Overall, recovery was either excellent (14.3%, 5 cases), fair (45.7%, 16 cases), or good (40%, 14 cases). Recovery was excellent (0), good (4), and fair (22) in the acupuncture groups, and excellent (3), good (5), and fair (2) in the bee venom acupuncture group, and excellent (2), good (5), and fair (3) in pharmacopuncture group.

8. Conclusions

Bee venom acupuncture (or bee venom pharmacopuncture) with conventional treatment is more effective than acupuncture alone for intervertebral disc herniation.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

The terms 'bee venom acupuncture' and 'bee venom pharmacopuncture' are not generally used. In this study, the method of randomization was not described. Moreover, as the control acupuncture treatment is known to be effective, it is suggested that the study lacks a placebo control.

11. Abstractor and date

Kim JI, 17 June 2010.

13. Diseases of the Musculo Skeletal System and Connective Tissue

Reference

Lee SH, Kang MW, Lee H, et al. Effectiveness of bee-venom acupuncture and Ouhyul herbal acupuncture in herniation of nucleus pulposus—comparison with acupuncture therapy only. *Daehan-Chimgu-Hakhoeji* (*Journal of Korean Acupuncture & Moxibustion Society*) 2007; 24(5): 197–205 (in Korean with English abstract).

1. Objectives

To compare the efficacy of bee venom acupuncture and Ouhyul herbal acupuncture in patients with herniation of the nucleus pulposus.

2. Design

Randomized controlled trial (RCT).

3. Setting

One Oriental hospital (Daejeon Orinetal Hospital), Republic of Korea.

4. Participants

Patients with herniation of the nucleus pulposus (n=60).

5. Intervention

Arm 1: Acupuncture (n=20).
Arm 2: Acupuncture + bee venom acupuncture (BVA; n=20).
Arm 3: Acupuncture + Ouhyul herbal acupuncture (n=20).

1) BVA: Once every 2 days, 0.1~0.6 cc was injected in the A-si acupuncture point on the lumbar torso.
2) Ouhyul herbal acupuncture: About 0.6 cc was injected in the A-si acupuncture point on the lumbar torso (frequency of injection, not mentioned). The Ouhyul herbal acupuncture mixture consisted of Gardeniae Fructus, Corydalidis Tuber, Olibanum, Myrrha, Persicae Semen, Paeoniae Radix Rubra, Salviae miltiorrhizae Radix, and Sappan Lignum.

Standard treatment:

1) Acupuncture: Twice a day. Near acupuncture point needling in the morning at the Shenshu (BL23, 腎俞), Zhishi (BL52, 志室), Qihaishu (BL24, 氣海俞), Dachangshu (BL25, 大腸俞), Guanyuanshu (BL26, 關元俞), Yaoyangguan (GV3, 腰陽關), Remote Acupuncture Point Needling in the afternoon on Zulinqi (GB41, 足臨泣), Hegu (LI4, 合谷), Waiguan (TE5, 外關), Kunlun (BL60, 崑崙), Yanglingquan (GB34, 陽陵泉), and Zusanli (ST36, 足三里) acupuncture points.
2) Drug treatment: 3 times a day. Whallak-tang (活絡湯) during the early stage, and Sanghwatang Gamibang (雙和湯 加味方) during the late stage.
3) Physiotherapy: Hot pack, Interferential Current Therapy, Transcutaneous Electrical Nerve Stimulation, and cupping therapy depending on the needs of the patients

6. Main outcome measures

Pain self-assessed on a visual analogue scale (VAS), clinical evaluation grade (excellent, good, fair, and poor), and score on the straight leg raising test (SLRT).

7. Main results

The among-group difference in pain VAS score was significant after treatment for 5 days (69.5, 76, 57, P=0.000) and 7 days (49.5, 60.5, 47.5, P=0.047) but not after treatment for 3 days (77, 80, 70.5, P =0.114) and 9 days (41.5, 28.5, 36, P=0.076). There was a significant between-group difference in the percentage decrease in pain VAS score after treatment for 5 days (30.5%, 23%, 44% in Arms 1, 2, 3, respectively; P=0.000) and during treatment between 5 and 9 days (41.9%, 62.3%, 35.6%; P=0.04). After 9 days of treatment, the condition of most patients in Arm 2 was fair and the condition of most patients in Arm 3 was good. There was no significant between-group differences in the SLRT score.

8. Conclusions

Ouhyul herbal acupuncture treatment is more effective for intervertebral disc herniation than single acupuncture treatment, but after 5–9 days of treatment, the bee venom acupuncture is the most effective treatment.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

The randomization method was not described. Moreover, no control and no safety assessment were included.

11. Abstractor and date

Kim JI, 1 July 2010.

13. Diseases of the Musculo Skeletal System and Connective Tissue

Reference

Kim KT, Song HS. A randomized controlled double blinding study of bee venom acupuncture therapy on sprain of C-spine. *Daehan-Chimgu-Hakhoeji* (*Journal of Korean Acupuncture & Moxibustion Society*) 2005; 22(4):189–95 (in Korean with English abstract).

1. Objectives

To evaluate the effect of bee venom acupuncture therapy on C-spine sprain.

2. Design

Double-blinded randomized controlled trial (DB-RCT).

3. Setting

One Oriental hospital (Kyungwon University Orineal Hospital), Republic of Korea.

4. Participants

Patients with C-spine sprain but not radicular pain or organic disease (n=26).

5. Intervention

Arm 1: Bee venom acupuncture + acupuncture (n=13).

Arm 2: Acupuncture (n=13).

Among 26 subjects enrolled, 5 dropped out during the study (3 in Arm 1, 2 in Arm 2).

6. Main outcome measures

Severity of disability self-assessed on a visual analogue scale (VAS) and Neck Disability Index (NDI) score.

7. Main results

Treatment in both groups significantly decreased VAS and NDI scores, but these decreases were greater in Arm 1 than Arm 2.

8. Conclusions

Bee venom acupuncture combined with acupuncture is more effective than acupuncture only for treating C-spine sprain.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

This study was meaningful inasmuch as bee venom acupuncture is used in treating back pain and C-spine sprain. The reasons for withdrawal were described and blinding was used. However, an evaluation of the adverse events of bee venom acupuncture and statement of the exclusion criteria would have improved this study.

11. Abstractor and date

Kim HJ, 17 August 2010.

13. Diseases of the Musculo Skeletal System and Connective Tissue

Reference

Lee KH, Youn HM, Ko WS, et al. Comparison of treatment effects and allergic responses to stiff neck between sweet bee venom and bee venom pharmacopuncture.*Daehan-Yakchim-Hakhoeji* (*Journal of Pharmacopuncture*) 2008; 11(4): 39–48 (in Korean with English abstract).

1. Objectives

To compare the efficacy and safety of sweet-bee venom and bee venom acupuncture.

2. Design

Double-blinded randomized controlled trial (DB-RCT).

3. Setting

One Oriental hospital (Oriental Medical Hospital of Dongeui Universtiy), Republic of Korea.

4. Participants

Patients with stiff neck (n=41).

5. Intervention

Arm 1: Cupping therapy (附缸療法) + bee venom (BV) acupuncture + conventional acupuncture. (n=21)

Arm 2: Cupping therapy (附缸療法) + sweet bee venom (SBV) acupuncture + conventional acupuncture. (n=20)

6. Main outcome measures

Stiff neck severity self-assessed on a visual analogue scale (VAS), Neck Disability Index (NDI) score, Clinical Evaluation Grade (CEG), allergic reaction assessed on a VAS.

7. Main results

Stiff neck severity VAS score, NDI score, and CEG decreased significantly regardless of treatment, and there were no significant between-group difference in these decreases. The severity of treatment-site edema and itching were significantly less in Arm 2 than Arm 1.

8. Conclusions

Sweet bee venom acupuncture and bee venom acupuncture both have similar efficacy for stiff neck, and both are relatively safe (i.e., trigger only weak allergic reactions).

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

This study evaluated the efficacy and safety of bee venom acupuncture for stiff neck. As the enrollment procedure was clear and blinding was satisfactory, the results of this study result could be used to guide the choice between BV and SBV for acupuncture. However, the method used to evaluate allergic reaction severity was too subjective and it remains questionable whether the effect of general acupuncture and cupping therapy was greater than the effect of SBV and BVA.

11. Abstractor and date

Kim HJ, 17 August 2010.

13. Diseases of the Musculo Skeletal System and Connective Tissue

Reference

Ryu HS, Jeon SH, Park DS, et al. Clinical study for Chuna treatment on neck pain patient with hypolordotic cervical spine. *Cheokchu-Singyeong-Chuna-Ui-Hakhoeji* (*The Journal of Korea Chuna Manual Medicine for Spine and Nerves*) 2006; 1(2): 11–20 (in Korean with English abstract).

1. Objectives

To evaluate the effect of Chuna treatment on neck pain in patients with hypolordotic cervical spine.

2. Design

Randomized controlled trial (RCT).

3. Setting

One Oriental hospital (Chuncheon Oriental Hospital), Republic of Korea.

4. Participants

Neck pain patients with hypolordotic cervical spine (n=20).

5. Intervention

Arm 1: Acupuncture + Chuna treatment (n=10).
Arm 2: Acupuncture only (n=10).

6. Main outcome measures

Pain self-assessed on a visual analogue scale (VAS), change in cervical curvature.

7. Main results

There was a statistically significant between-group difference in VAS score after 3 and 5 rounds of treatment. There was no statistically significant between-group difference in the rate of recovery from cervical lordosis after 5 rounds of treatment.

8. Conclusions

Chuna treatment combined with acupuncture is more effective than acupuncture only for neck pain in patients with hypolordotic cervical spine. However, short-term Chuna treatment does not promote the recovery of the hypolordotic cervical spine.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

This study evaluated the effectiveness of Chuna treatment for neck pain. This study was meaningful insofar as efficacy was objectively evaluated using radiological criteria. Although the hypolordotic cervical spine was not improved, treatment resulted in pain relief. However, the randomization method was improper.

11. Abstractor and date

Kim HJ, 17 August 2010.

13. Diseases of the Musculo Skeletal System and Connective Tissue

Reference

Jung EY, Na SS, Lee KN. Clinical effect of Gigong therapy by measuring ABR-2000 on neck stiffness patients. *Daehan-Uilyo-Gigong-Hakhoeji* (*Journal of Korean Academy of Medical Gigong*) 2003; 7(1): 61–76 (in Korean with English abstract).

1. Objectives

To evaluate the effect of Gigong therapy (氣功外氣療法) on neck stiffness measured by ABR-2000.

2. Design

Randomized controlled trial (RCT).

3. Setting

One Oriental hospital (Wolgol Korean Clinic), Republic of Korea.

4. Participants

Patients with neck stiffness (age= over 18 years, n=22).

5. Intervention

Arm 1: Hand acupuncture treatment followed by Gigong therapy, flaming cupping therapy, and Gigong-flaming cupping therapy, and Gigong-manual remedy therapy (n=11).

Arm 2: Hand acupuncture cupping therapy (n=11).

6. Main Outcome Measures

Stress measured by stress analyzer ABR-2000 (Meridian Co., Ltd., Seoul, Korea).

7. Main Results

Treatment eliminated chronic symptoms sooner and had a greater effect on regulation and activity subscores in Arm 1 than Arm 2.

8. Conclusions

Gigong therapy acts on the autonomic nervous system and reduces strain.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

This study showed that adding Gigong therapy to general acupuncture and cupping therapy improves their effect on neck stiffness. The effect of Gigong therapy was impressive, but use of ABR-2000 to evaluate the effect is questionable.

11. Abstractor and date

Nam HJ, 21 August 2010.