

18. Symptoms and Signs

Reference

Cho JH, Cho CK, Shin JW, Son JY, Kang W, Son CG. Myelophil, an extract mix of astragali radix and salviae radix, ameliorates chronic fatigue: A randomized, double-blind, controlled pilot study. *Complementary Therapies in Medicine* 2009; 17(3): 141–46.

1. Objectives

To evaluate the effect of Myelophil on patients with chronic fatigue.

2. Design

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

3. Setting

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

4. Participants

Patients with fatigue more than 6 months (n=36, male/female=13/23, average age=44 years).

5. Intervention

Arm 1: Treatment group 1. (Low dosage)-Myelophil 1.5 g per treatment, b.i.d. for 4 weeks (n=13).

Arm 2: Treatment group 2. (High dosage)-Myelophil 3 g per treatment, b.i.d. for 4 weeks (n=11).

Arm 3: Control group. Hyangsapyungwisan (香砂平胃散), 1.5 g per treatment, b.i.d. for 4 weeks (n=12).

Lyophilised Myelophil was an aqueous extract of equal quantities of Astragali Radix and Salviae Radix, according to the over-the-counter Korean monograph. The extract yield was 20.5% (w/w).

6. Main Outcome Measures

Severity of fatigue before and after the administration of Myelophil was self-rated on a numeric rating scale (NRS) and the Chalder fatigue severity questionnaire, translated into Korean.

7. Main Results

The severity of fatigue (NRS mean±standard deviation) was initially 52.5±17.2, 41.9±15.8, and 46.3±17.8 in the low-dose, high-dose, and control groups, respectively and improved over time, in all three groups. The linear mixed models showed statistically significant differences with respect to both time and group ($P<0.05$). The severity of fatigue (VAS mean±standard deviation) was initially 6.5±1.5, 5.9±1.0, and 5.9±1.6 in the low-dose, high-dose, and control groups, respectively, and decreased over time in all three groups, indicating a decrease in the severity of fatigue. However, only the low-dose group showed significant improvement in feelings of fatigue, compared with the control ($P<0.05$). To examine the effect of Myelophil on immunological status, the expression of 42 serum cytokines was analyzed using an antibody array. There was no significant difference in the expression of any cytokine after 4 weeks of Myelophil treatment, at either dose.

8. Conclusions

The NRS and VAS results are consistent and support the conclusion that Myelophil reduces chronic fatigue. The low dose of Myelophil seemed to be more effective than the high dose, as only the low-dose resulted in statistically significant differences in both the NRS and VAS scores. Serum levels of 42 cytokines before and after Myelophil treatment remained unchanged at either Myelophil dose. Myelophil acts against chronic fatigue, especially against physical manifestations of fatigue.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

This study evaluates the ameliorative effect of Myelophil on chronic fatigue. This study is meaningful in that it is a randomized, controlled trial and published in a Science Citation Index Expanded international journal. Although the effectiveness of Myelophil was demonstrated, the anti-fatigue mechanism of Myelophil was not.

11. Abstractor and date

Jang KT, 31 August 2010.

18. Symptoms and Signs

Reference

Chun SY, Lee ES. The effects of the magnetic therapy treated on acupuncture point for recovery from fatigue with before and after exercise. *Hanbang-Jaehwal-Uihakgwa-Hakhoeji (Journal of Oriental Rehabilitation Medicine)* 1998; 8(1): 158–70 (in Korean with English abstract).

1. Objectives

To evaluate the effect of treatment with magnetic field on fatigue-related physiological changes.

2. Design

Randomized controlled trial (RCT).

3. Setting

One Oriental hospital (details not mentioned), Republic of Korea.

4. Participants

Gymnastics students of K University (n=14).

5. Intervention

Arm 1: Magnetic treatment group (n=5). Magnetic treatment at the bilateral Zusanli (ST36, 足三里), Chengjin (UB56, 承筋), and Chengshan(UB57, 承山) acupuncture points.

Arm 2: Intradermal acupuncture treatment group (n=4). Intradermal acupuncture treatment at the bilateral Zusanli (ST36, 足三里), Chengjin (UB56, 承筋), and Chengshan (UB57, 承山) acupuncture points.

Arm 3: Non-magnetic treatment group (n=5). Moxa-pellet treatment at the bilateral Zusanli (ST36, 足三里), Chengjin (UB56, 承筋), and Chengshan(UB57, 承山) acupuncture points. A moxa-pellet is similar in appearance to a permanent magnet but has no magnetic field or needle.

6. Main outcome measures

Blood lactic acid concentration, change in heart rate, change in oxygen uptake, ventilation rate per minute, lactic acid concentration, and change in heart rate recovery at 15 minutes after exercise, reaction time to light stimulation before and after of maximal exercise.

7. Main results

- 1) The blood lactic acid concentration at maximal exercise was decreased in magnetic treatment group and intradermal acupuncture treatment group during convalescence, and was significantly different from that in the other group.
- 2) The heart rate at maximal exercise was decreased in magnetic treatment group and intradermal acupuncture treatment group, but remained unchanged during every period of exercise in the non-magnetic treatment group. The difference in heart rate was significant among groups.
- 3) Among the groups, the intradermal acupuncture treatment group showed higher oxygen uptake.
- 4) Lactic acid concentration and heart recovery rate at the end of 15 minutes of convalescence after maximal exercise improved in the magnetic treatment group and intradermal acupuncture treatment group but not in the non-magnetic treatment group, which showed a tendency toward less improvement.

8. Conclusions

Magnetic treatment significantly improves recovery from fatigue-related change.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

This article described how magnetic fields can be used to reduce physiological changes related to fatigue. This method could be applied in parallel with other therapies.

11. Abstractor

Cho SH, 13 July 2010.

18. Symptoms and Signs

Reference

Kim HK, Lee ES. The effect of magnetic field stimulation of ear acupoints on physical vitality before and after exercise.* *Hanbang-Jaehwal-Uihakgwa-Hakhoeji (Journal of Oriental Rehabilitation Medicine)* 1998; 8(1): 187–202 (in Korean).

1. Objectives

To evaluate the effect of magnetic field therapy on recovery from muscle fatigue.

2. Design

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

3. Setting

One Oriental hospital (details not mentioned), Republic of Korea.

4. Participants

Student gymnasts (n=14).

5. Intervention

Arm 1: Magnetic therapy at the ear acupoints related to the heart, liver, Shenmen (HT7, 神門), and endocrine system (n=5).

Arm 2: Intradermal Acupuncture (n=4).

Arm 3: Moxa-pellet Treatment (n=5).

6. Main Outcome Measures

Physiological change in blood lactate concentration, heart rate, reaction time on light stimulation, oxygen intake, minute ventilation at maximal exercise level, and rate of recovery of lactate concentration and heart rate after maximal exercise.

7. Main Results

Blood lactic acid concentration was slightly and nonsignificantly lower in Arm 1 than in Arm 2 and Arm 3. Heart rate was significantly lower in Arm 1 than in Arm 2 and Arm 3. Reaction time on light stimulation was significantly reduced and rate of lactate concentration and heart rate were significantly improved in Arm 1 and Arm 2 compared to Arm 3. Minute ventilation was significantly decreased in Arm 1 compared to Arm 2 and Arm 3. However, there was no significant between-group difference in oxygen intake.

8. Conclusions

Magnetic therapy and intradermal acupuncture are more effective than moxa-pellet treatment. Compared with magnetic therapy, intradermal acupuncture was better at reducing oxygen intake and minute ventilation and worse at reducing heart rate and other physiological measures.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

This randomized, controlled, double-blinded study evaluated the effect of the magnetic therapy at ear acupoints on muscle fatigue in comparison to intradermal acupuncture and moxa-pellet treatment. Although the study design was objective, the number of subjects was limited to 14 patients. Therefore, additional study with a large number of patients is needed.

11. Abstractor and date

Nam HJ, 21 August 2010.

19. Injury, Poisoning and Certain Other Consequences of External Causes

Reference

Lee KH, Kim JE, Youn HM, et al. Comparison of the treatment effect between Oriental medicine therapy and Oriental and Western medicine combination therapy on traffic accident patients. *Daehan-Yakchim-Hakhoeji (Journal of Pharmacopuncture)* 2007; 10(3): 91–9 (in Korean with English abstract).

1. Objectives

To compare the effect of Oriental medicine therapy with that of Oriental-Western combination therapy on recovery from injury due to traffic accidents.

2. Design

Randomized controlled trial (RCT).

3. Setting

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

4. Participants

Sixty-one patients hospitalized more than 2 weeks for neck pain, shoulder-back pain, and low back pain due to nonspecific cervical and lumbar injuries and intervertebral disc herniation suffered as a result of traffic accident trauma. Patients with injuries occurring more than 6 months earlier, age lower than 10 or higher than 70 years, anamnestic spine fracture, spinal tumor, psychiatric disorders, immune disorders, diabetes mellitus, heart diseases, kidney diseases, pregnancy (lactiferous phase), infectious skin diseases, drug dependency, and under treatment with adrenocortical steroids and non-steroidal anti-inflammatory drugs, were excluded.

5. Intervention

Arm 1: Acupuncture applied to the Fengchi (GB20, 風池), Jianjing (GB21, 肩井), Tianzhu (BL10, 天柱), Gaohuangshu (BL43, 膏肓), Tianzong (SI11, 天宗), Shenshu (BL23, 腎俞), Qihai (BL24, 氣海俞), Dachangshu (BL25, 大腸俞), Weizhong (BL40, 委中), Kunlun (BL60, 崑崙), etc. acupoints + bee venom pharmacopuncture (蜂藥鍼) + drug treatment + cupping therapy + physiotherapy (n=32).

Arm 2: Acupuncture applied to the Fengchi (GB20, 風池), Jianjing (GB21, 肩井), Tianzhu (BL10, 天柱), Gaohuangshu (BL43, 膏肓), Tianzong (SI11, 天宗), Shenshu (BL23, 腎俞), Qihai (BL24, 氣海俞), Dachangshu (BL25, 大腸俞), Weizhong (BL40, 委中), Kunlun (BL60, 崑崙), etc. acupoints + bee venom pharmacopuncture (蜂藥鍼) + drug treatment + cupping therapy + physiotherapy + Western therapies such as diclofenac beta-dimethyl aminoethanol, etc (n=29).

6. Main Outcome Measures

Pain evaluated on a visual analogue scale (VAS), Neck Disability Index (NDI), Oswestry Disability Index (ODI), and Roland Morris Disability Scale (RMDS).

7. Main Results

In Arm 1, the change in average VAS, NDI, ODI, and RMDS scores from baseline was 1.72, 1.56, 0.94, and 0.06, respectively after 1 week of treatment and 2.94, 3.44, 2.44, and 0.88 after two weeks of treatment, respectively. In Arm 2, this was 1.86, 0.83, 0.45, and 0.21 after 1 week and 2.72, 1.69, 0.59, 0 and 72 after two weeks. This change was slightly larger in Arm 1 than Arm 2, but the between-group differences at both 1 and 2 weeks were without significance.

8. Conclusions

Oriental medicine therapy and Oriental-Western medicine combination therapy have similar efficacies in patients suffering traffic accident injuries.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

This study verified the similar efficacies of Oriental medicine therapy and Oriental-Western medicine combination therapy. The diseases for which Oriental-Western medicine combination therapy is effective need to be identified.

11. Abstractor and date

Cho JH, 16 July 2010.

19. Injury, Poisoning and Certain Other Consequences of External Causes

Reference

Kwon KR. Effects of spiral taping in motor disturbance of the neck induced by cervical sprain—randomized clinical controlled trials. *Daehan-Chimgu-Hakhoeji (Journal of Korean Acupuncture & Moxibustion Society)* 2006; 23(2): 159–64 (in Korean with English abstract).

1. Objectives

To evaluate the effectiveness of spiral taping for motor disturbance of the neck induced by cervical sprain.

2. Design

Randomized controlled trial (RCT).

3. Setting

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

4. Participants

Patients with motor abnormality of the neck induced by cervical sprain (n=23).

5. Intervention

Arm 1: Spiral taping + acupuncture + Oriental medicine treatment (n=12).

Arm 2: Acupuncture + Oriental medicine treatment (n=11).

6. Main outcome measures

Range of motion (ROM).

7. Main results

The treatment effect was significant in Arm 2 after 2 rounds and in Arm 1 after 1 round. There was no significant between-group difference, but efficacy was higher in Arm 1 than Arm 2.

8. Conclusions

Spiral taping enhanced the effectiveness of treatment for motor abnormality of the neck induced by cervical sprain.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

Though spiral taping is widely used, its efficacy has rarely been studied. This study demonstrated a meaningful clinical effect. However, ROM was the only the outcome measure, and the study design would have been better if VAS and NDI were additionally evaluated. Although the spiral taping is known as safe treatment, a limitation of this study is that skin reaction and clinical adverse events were not evaluated.

11. Abstractor and date

Kim HJ, 17 August 2010.

19. Injury, Poisoning and Certain Other Consequences of External Causes

Reference

Kim HS, Kim MK, Hwang JP, et al. The clinical studies for Kinesio taping on patients with nuchal pain caused by traffic accidents. *Hanbang-Jaehwal-Uihakgwa-Hakhoeji (Journal of Oriental Rehabilitation Medicine)* 2008; 18(3): 67–80 (in Korean with English abstract).

1. Objectives

To evaluate the effect of Kinesio taping[®] on traffic accident patients with nuchal pain.

2. Design

Randomized controlled trial (RCT).

3. Setting

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

4. Participants

Patients with nuchal pain caused by injuries from traffic accident trauma, with cervical spine deformity on cervical spine X-ray, and hospitalized in Dae-Jeon Oriental Hospital, Department of Oriental Rehabilitation Medicine, between February 2007 and May 2008 (n=40, age=20–55 years).

5. Intervention

Arm1: Treatment group (n=20). Acupuncture + Physical therapy + Oriental drug + Kinesio taping[®] (for 48 hours or less, twice a week for 2 weeks, four treatments in total at the sternocleidomastoid, trapezius, and semispinal muscles) (n=20).

Arm 2: Control group. Acupuncture + Physical therapy + Oriental drug therapy (n=20).

6. Main Outcome Measures

Pain evaluated on a visual analogue scale (VAS), Pain Rating Score (PRS), Neck Disability Index (NDI).

7. Main Results

There was a significant decrease in VAS and NDI scores after 3 days of treatment and PRS score after 6 days of treatment in Arm1 ($P<0.05$). The decrease in VAS and NDI scores was significantly greater in Arm 1 than Arm 2 after 12 days of treatment ($P<0.05$) and the decrease in the PRS score was significantly greater in Arm 1 than Arm 2 after 9 days of treatment ($P<0.05$).

8. Conclusions

Kinesio taping with acupuncture provides more relief from nuchal pain caused by traffic accident trauma.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

This study verified the effectiveness of treatment with Kinesio taping for relief of nuchal pain due to traffic accident trauma. In the treatment group, patients received acupuncture, physical therapy, Oriental drug therapy, and Kinesio taping therapy, twice a week for 2 weeks (4 treatments in total). The VAS, PRS, and NDI scores were evaluated 5 times during hospitalization and showed that Kinesio taping improved the condition of traffic accident patients. In particular, pain reduction was greater later in the course of treatment. It is suggested that treatment with Kinesio taping after acupuncture can increase the treatment effect.

11. Abstractor and date

Cho SH, 13 July 2010.

19. Injury, Poisoning and Certain Other Consequences of External Causes

Reference

Jeon TD, Lee HG, Hong SY, et al. The clinical studies for muscle energy techniques on patients with nuchal pain caused by traffic accidents. *Hanbang-Jaehwal-Uihakgwa-Hakhoeji (Journal of Oriental Rehabilitation Medicine)* 2009; 19(1): 125–34 (in Korean with English abstract).

1. Objectives

To evaluate the effectiveness of muscle energy techniques for nuchal pain caused by injuries from traffic accident trauma.

2. Design

Randomized controlled trial (RCT).

3. Setting

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

4. Participants

Patients with nuchal pain due to injuries caused by traffic accident trauma, with cervical spine deformity on cervical spine X-ray, and hospitalized in Dae-Jeon Oriental Hospital, Department of Oriental Rehabilitation Medicine, between July 2008 and October 2008 (n=20).

5. Intervention

Arm 1: Treatment group (n=10). Acupuncture + Oriental physiotherapy + Oriental drug treatment (Danggwisusan (當歸鬚散) + Muscle energy technique (5 times a week, during the Ante Meridiem [AM] hours. applied to the problematic muscle after evaluating the sternocleidomastoid, trapezius, levator scapulae, and scalene muscles.

Arm 2: Control group (n=10). Acupuncture applied to the Jianjing (GB21, 肩井), Jianzhongshu (SI15, 肩中俞), Jianwaishu (SI14, 肩外俞), Shenshu (BL23, 腎俞), Qihai (BL24, 氣海俞), Dachangshu (BL25, 大腸俞), Zhishi (BL52, 志室), Taibai (SP3, 太白), Taiyuan (LU9, 太淵), and Quchi (LI11, 曲池) acupoints + Oriental physiotherapy + Oriental drug treatment (Danggwisusan, 當歸鬚散).

6. Main Outcome Measures

Scores on the McGill Pain Questionnaire-Short Form (SF-MPQ), visual analogue scale (VAS) for pain, Pain Disability Index (PDI), Neck Disability Index (NDI).

7. Main Results

The SF-MPQ sensory subscore, pain VAS, PDI, and NDI scores were significantly decreased in both groups ($P<0.05$). The decrease in VAS and PDI scores were significantly greater in Arm 1 than Arm 2 ($P<0.05$).

8. Conclusions

Treatment with the combination of muscle energy with Oriental medicine treatment is more effective than treatment with Oriental medicine alone for nuchal pain caused by injuries due to traffic accident trauma.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

This study evaluated the effectiveness of the muscle energy technique for nuchal pain after traffic accident trauma. The SF-MPQ, VAS, PDI and NDI scores were significantly improved in both groups, but treatment in Arm 1 was more effective than treatment in Arm 2 by all measures, especially VAS and PDI scores, which were significantly different between groups. Although PDI and NDI scores reflect ability to perform similar activities of daily life, they are subjective measures and the number of patients was small. An additional clinical trial with a large number of patients for a longer period is needed.

11. Abstractor and date

Cho SH, 13 July 2010.

19. Injury, Poisoning and Certain Other Consequences of External Causes

Reference

Ahn CK, Seo JW, Kim SJ. The effect of the 4 imageries of Alexander technique in traffic accident patients with whiplash injuries. *Hanbang-Jaehwal-Uihakgwa-Hakhoeji (Journal of Oriental Rehabilitation Medicine)* 2006; 16(4): 61–72 (in Korean with English abstract).

1. Objectives

To evaluate the effect of the Alexander technique on patients with whiplash injuries.

2. Design

Randomized controlled trial (RCT).

3. Setting

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

4. Participants

Patients with neck sprain due to traffic accident trauma, hospitalized in Conmaul Oriental Medical Hospital, Department of Oriental Rehabilitation Medicine, between April 2006 and August 2006 (n=23).

5. Intervention

Arm 1: Treatment group. Acupuncture applied to the A-shi, Fengchi (GB20, 風池), Jianjing (GB21, 肩井), Dazhui (GV14, 大椎), Fengfu (GV16, 風府), and Fengmen (BL12, 風門) acupoints + Oriental medicine (Whallak-Tang [Huoluotang {活絡湯}])) + Cupping therapy + hot pack + Ultrasound + Interferential Current Therapy (ICT) + Alexander technique (employing 4 images) (n=10).

Arm 2: Control group. Acupuncture applied to the A-shi, Fengchi (GB 20, 風池), Jianjing (GB 21 肩井), Dazhui (GV14, 大椎), Fengfu (GV16, 風府), and Fengmen (UB12, 風門) acupoints + Oriental medicine (Whallak-Tang (Huoluotang {活絡湯})) + Cupping therapy+ hot pack + Ultrasound + ICT (n=13).

6. Main Outcome Measures

Neck Disability Index (NDI), pain evaluated on a visual analogue scale (VAS 100 mm).

7. Main Results

Treatment significantly decreased NDI and VAS scores in Arm 1 and VAS ($P<0.05$) but not NDI score in Arm 2. There were no between-group differences in these measures.

8. Conclusions

The Alexander technique is effective.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

This study evaluated the efficacy of the Alexander technique (using 4 images) for neck pain from traffic accident trauma. During the 7-day acupuncture treatment, patients in Arm 1 but not Arm 2 were trained to perform the Alexander technique using 4 images (10 minutes/session, total of 5 sessions). Treatment significantly decreased NDI and VAS scores in Arm 1, but there was no significant between-group difference. It is hard to attribute increased pain reduction to the Alexander technique, but it is thought that the Alexander technique had some effect. In the future, more study is needed with large number of subjects to evaluate the effect of mind-body therapy on the musculoskeletal system.

11. Abstractor and date

Cho SH, 13 July 2010.

19. Injury, Poisoning and Certain Other Consequences of External Causes

Reference

Song HS. The effect of bee venom acupuncture (BVA) on acute ankle sprain: A randomized controlled trial and double blinding-pilot study. *Daehan-Yakchim-Hakhoeji (Journal of Pharmacopuncture)* 2005; 8(2): 11–6 (in Korean with English abstract).

1. Objectives

To evaluate the effect of bee venom acupuncture on acute ankle 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 acute ankle sprain (n=30).

5. Intervention

Arm 1: Bee venom acupuncture group. Bee venom acupuncture applied to the Qiuxu (GB40, 丘墟), Zhongfeng (LR4, 中封), Shangqiu (SP5, 商丘), and Jiexi (ST41, 解溪) acupoints + Acupuncture applied to the Qiuxu (GB40, 丘墟), Zhongfeng (LR4, 中封), Shangqiu (SP5, 商丘), Jiexi (ST41, 解溪), Zusanli (ST36, 足三里), and Yanglingquan (GB34, 陽陵泉) acupoints (n=13).

Arm 2: Control group. Saline acupuncture applied to the Qiuxu (GB40, 丘墟), Zhongfeng (LR4, 中封), Shangqiu (SP5, 商丘), and Jiexi (ST41, 解溪) acupoints + Acupuncture applied to the Qiuxu (GB40, 丘墟), Zhongfeng (LR4, 中封), Shangqiu (SP5, 商丘), Jiexi (ST41, 解溪), Zusanli (ST36, 足三里), and Yanglingquan (GB34, 陽陵泉) acupoints (n=17).

6. Main Outcome Measures

Scores on the Ankle-Hindfoot Scale (AHS) and visual analogue scale (VAS) for sprain severity.

7. Main Results

The decrease in VAS score was significantly greater after 3 days of treatment in Arm 1 than in Arm 2 ($P<0.05$), and the decrease in VAS score and increase in AHS score were significantly greater after 7 days of treatment in Arm 1 than Arm 2 ($P<0.05$). The decreases in VAS and AHS scores were significantly greater after 7 days than after 3 days of treatment in both groups ($P<0.05$).

8. Conclusions

Bee venom acupuncture is more effective than control treatment for acute ankle sprain. Bee venom acupuncture may help reduce the inflammatory reaction caused by soft tissue damage.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

In this study, the effect of bee venom acupuncture at 4 acupoints followed by acupuncture at 6 acupoints on the acute ankle sprain was evaluated by comparing AHS and VAS scores. The improvement in the VAS and AHS scores was more significant in the bee venom group than in the control group.

11. Abstractor and date

Cho SH, 13 July 2010.

19. Injury, Poisoning and Certain Other Consequences of External Causes

Reference

Hwang JS, Lim DJ, Hwang JH, et al. Study of the effect of blood-letting cupping treatment for acute ankle sprain: A randomized controlled trial. *Daehan-Chimgu-Hakhoeji (Journal of Korean Acupuncture & Moxibustion Society)* 2005; 22(3): 243–52 (in Korean with English abstract).

1. Objectives

To evaluate the effect of blood-letting cupping on acute ankle sprain.

2. Design

Randomized controlled trial (RCT).

3. Setting

One Oriental hospital (Bundang Oriental Hospital of Dongguk University), Republic of Korea.

4. Participants

Patients with obvious trauma, excluding fracture, who visited the hospital within 1 week and received no other treatment (n=29).

5. Intervention

Arm 1: Blood-letting cupping.

Arm 2: Control.

Out of 29 patients, 19 (11 in Arm 1, 8 in Arm 2) were finally included for analysis.

6. Main Outcome Measures

Scores on the Ankle-Hindfoot Scale (AHS) and Numerical Rating Scale (NRS).

7. Main Results

Treatment resulted in significantly greater improvement in Arm 1 than Arm 2 (AHS, NRS: $P=0.041$, 0.026).

8. Conclusions

Treatment by blood-letting cupping is effective for acute ankle sprain.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

This study was a randomized, controlled trial conducted in patients who visited the hospital with acute ankle sprain within 1 week. Patients were allocated to treatment and control groups, and sprain severity was evaluated using AHS and NRS scores. Blood-letting cupping had a significant effect on acute ankle sprain relief, but the small number of subjects is a limitation of this study.

11. Abstractor and date

Cho SH, 13 July 2010.

19. Injury, Poisoning and Certain Other Consequences of External Causes

Reference

Lee DY, Kim SJ. Clinical study on the ankle joint traction therapy for ankle sprain. *Hanbang-Jaehwal-Uihakgwa-Hakhoeji (Journal of Oriental Rehabilitation Medicine)* 2005; 15(4): 39-46 (in Korean with English abstract).

1. Objectives

To evaluate the effect of ankle joint traction therapy on ankle sprain.

2. Design

Randomized controlled trial (RCT).

3. Setting

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

4. Participants

Patients who visited Se-Myung Oriental Hospital between 1 June 2005 and 31 August 2005 with less than second degree lateral ankle sprain at onset within 48 hours (n=24).

5. Intervention

Arm 1: Treatment group. Acupuncture applied to the Qiuxu (GB40, 丘墟), Zulinqi (GB41, 足臨泣), Shenmai (BL62, 申脈), Kunlun (BL60, 崑崙), Xuanzhong (GB39, 懸鐘), Zusanli (ST36, 足三里), Yanglingquan (GB34, 陽陵泉), Shangqiu (SP5, 商丘), Zhaohai (KI6, 照海), Taixi (KI3, 太溪), Sanyinjiao (SP6, 三陰交), Yinlingquan (SP9, 陰陵泉), and Yingu (KI10, 陰谷) acupoints +Ankle joint traction (n=12).

Arm 2: Control group. Acupuncture applied to the Qiuxu (GB40, 丘墟), Zulinqi (GB41, 足臨泣), Shenmai (BL62, 申脈), Kunlun (BL60, 崑崙), Xuanzhong (GB 39 懸鐘), Zusanli (ST36, 足三里), Yanglingquan (GB34, 陽陵泉), Shangqiu (SP5, 商丘), Zhaohai (KI6, 照海), Taixi (KI3, 太溪), Sanyinjiao (SP6, 三陰交), Yinlingquan (SP9, 陰陵泉), and Yingu (KI10, 陰谷) acupoints (n=12).

6. Main Outcome Measures

Sprain severity evaluated on a visual analogue scale (VAS).

7. Main Results

The between-group difference in VAS was significant at the second and third but not the first round of treatment. The decrease in VAS was significantly greater between first and third rounds in Arm 1 than Arm 2.

8. Conclusions

Ankle joint traction therapy combined with acupuncture is more effective than acupuncture only for ankle sprain.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

In traditional Korean medicine, ankle sprain includes foot pain, foot muscle pain, ankle pain, foot distress, accompanied by ache due to swelling caused by extravasated blood and ache due to reddish swelling and bluish bruise. Ankle pain in traditional Korean medicine is treated by HaengKiWhalHyeol (行氣活血, conducting Ki and activating blood) and TongGeyungWhalRak (通經活絡, restoring menstrual flow and activating collateral flow), and SeoGeunWhalRak (舒筋活絡, relaxing muscles and activating collateral flow).

This study evaluated the effect of ankle joint traction on ankle sprain. This treatment combined with acupuncture reduced sprain severity VAS. The reduction in VAS score was significant after the second round of treatment. However, the number of subjects was small, and it is hard to conclude that only 1 week of treatment is effective. Additional study with a large number of patients for a longer term is needed. Moreover, the rehabilitation therapy and strategies for recurrence prevention should be studied.

11. Abstractor and date

Cho SH, 13 July 2010.

19. Injury, Poisoning and Certain Other Consequences of External Causes

Reference

Park JM, Yoon MS, Woo I, et al. The effect of ankle meridian tendino-musculature taping on lateral ankle sprain; Randomized controlled clinical study. *Hanbang-Jaehwal-Uihakgwa-Hakhoeji (Journal of Oriental Rehabilitation Medicine)* 2006; 16(1): 63–71 (in Korean with English abstract).

1. Objectives

To evaluate the effect of ankle meridian tendino-musculature taping on lateral ankle sprain.

2. Design

Randomized controlled trial (RCT).

3. Setting

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

4. Participants

Patients with less than second-degree lateral ankle sprain (onset within 48 hours) who visited the Jaseng Oriental Hospital between 15 November 2004 and 5 August 2005 (n=47).

5. Intervention

Arm 1: Treatment group. Acupuncture (So-jul [小節], O-Ho [五虎], Yifeng [TE17, 翳風]) + Ankle meridian tendino-musculature taping + taping therapy around ankle (n=24).

Arm 2: Control group. Acupuncture (So-jul [小節], O-Ho [五虎], Yifeng [TE17, 翳風]) + Ankle meridian tendino-musculature taping (n=23).

6. Main Outcome Measures

Severity of sprain evaluated on a visual analogue scale (VAS), ankle circumference measurement.

7. Main Results

The decrease in VAS score during the first to fourth treatments was significantly greater in Arm 1 than Arm 2.

8. Conclusions

The ankle meridian tendino-musculature taping is effective treatment for varus ankle sprain within 48 hours of onset.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

This study compares acupuncture with a combination of acupuncture and ankle meridian tendino-musculature taping as treatment for ankle sprain (n=47). VAS and ankle circumference measurement were used to evaluate these treatments. Although ankle meridian tendino-musculature taping significantly improved VAS score and ankle circumference, the number of subjects was small, which is a limitation of this study. Moreover, there were no between-group differences after the 5th treatment and it was impossible to determine the incidence of chronic ankle instability and recurrence.

11. Abstractor and date

Cho SH, 13 July 2010.

Appendix 7

漢方治療の経済評価エビデンスレポート 2011

(EREK 2011)

2012.3.31

Evidence Report of Economic Evaluation of Kampo Treatment 2011

(EREK 2011)

31 March 2012

東アジア伝統医学の有効性・安全性・効率性のシステマティック・レビュー
漢方治療の経済評価タスクフォース

研究協力者

唐 文涛

菊田健太郎

五十嵐中

東京大学大学院薬学系研究科・医薬政策学 修士課程

東京大学大学院薬学系研究科・医薬政策学 博士課程

東京大学大学院薬学系研究科・医薬政策学 特任助教

研究代表者

津谷喜一郎

東京大学大学院薬学系研究科・医薬政策学 特任教授

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1. 目的

医療費の上昇が日本の医療制度にとって大きな問題となる状況下で、広義の統合医療に関心が高まっている。その中で主要な地位を占める漢方薬を用いた漢方治療の経済評価の現状はどのようなものであろうか？

本研究は、日本における漢方治療の経済評価論文を収集し、一定の質のものを構造化抄録の形で提示し、質評価を行い、課題を明確にすることを目的とする。

2. 方法

検索するデータベースとして医中誌 Web Ver. 5 を用いた。検索日は 2012.2.8。ここには 1983 年から 2011 年 11 月まで文献が含まれる。検索語は「漢方」と「経済」とした。

検索された論文について、2 つの step のスクリーニングを行った。

1 次スクリーニングは、論文のタイトルとアブストラクトを用い、漢方薬経済評価と関係のない文献、会議録、症例報告を除外した。

2 次スクリーニングは、1 次スクリーニングによって選択された文献の本文を読んで行った。そこで漢方治療経済評価と認められ、かつ構造化抄録でまとめることが可能な文献が同定された。

財団法人 医療経済研究・社会保険福祉協会「健康食品の経済評価」調査班による「健康食品の経済的エビデンスレポート - 健康食品の経済評価のシステムティックレビューと 28 の構造化抄録- 」(2011.3)を参考にして、構造化抄録(structured abstract: SA)の形式として以下の 8 項目を用いた。

- 1) リサーチクエスション
- 2) 対照集団と介入
- 3) セッティング
- 4) 方法
- 5) 結果
- 6) 著者の結論
- 7) Abstractor のコメント
- 8) Abstractor and date

この構造化抄録を作成すると同時に、漢方治療の経済評価の論文を研究デザインにより分類した。

3. 結果

(1) 論文の検索とスクリーニング

漢方治療経済評価論文スクリーニングのフローチャートを **Fig. 1** に示す。

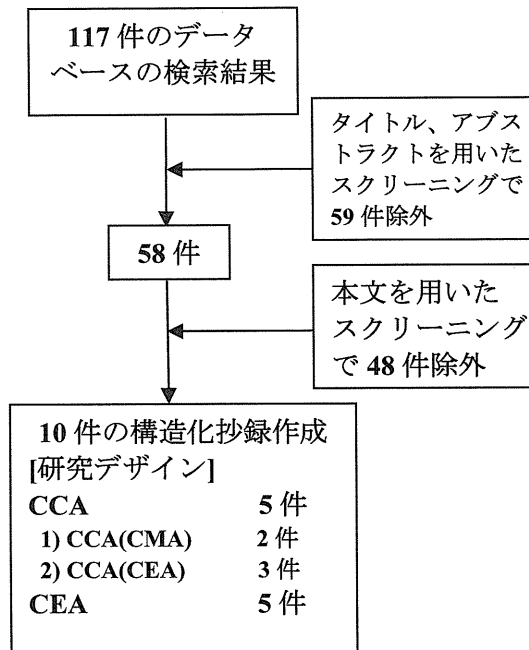


Fig. 1 漢方経済評価論文スクリーニングのフローチャート

医中誌 Web Ver.5 の検索により、総計 117 件の文献が検索された。

タイトルとアブストラクトを用いた 1 次スクリーニングにより、漢方治療の経済評価と関係のない文献、会議録、症例報告 59 件を除外し、58 件の文献を選択した。

本文を用いた 2 次スクリーニングにより、48 件の文献を除外し、漢方治療の経済評価と認められた 10 件の文献を抽出した。

除外理由は以下の 8 つに分類されるた。

- | | |
|----------------------------|--------|
| 1) 具体的なコストが報告されていない | : 11 件 |
| 2) 症例報告 | : 4 件 |
| 3) 総説・解説 | : 24 件 |
| 4) システマティック・レビュー | : 2 件 |
| 5) 同じ経済評価の結果の引用
もしくは被引用 | : 18 件 |
| 6) 評価対象が漢方薬ではない | : 1 件 |
| 7) 情報不足 | : 2 件 |
| 8) 意思決定にあまり貢献しない | : 1 件 |

1 つの文献について複数の理由で除外された場合がある。

2 次スクリーニングによって抽出された 10 件の文献リストを ICD10 の順序にしたがい **Annex 1** に示す。

これら 10 件について「漢方治療の経済評価エビデンスレポート 2011」(Evidence Report of Economic Evaluation of Kampo Treatment 2011 (EREK 2011)) を作成した。本レポート後半に示す。

除外された 48 件の文献リストを同様に **Annex 2** に示す。

(2) 研究デザインによる分類

10 件の経済評価論文を研究デザインにより以下のように分類された。

費用効果分析 (cost-effectiveness analysis: CEA): 5 件

費用結果分析 (cost-consequence analysis: CCA): 5 件

なおここでの CCA は、各医療介入の費用の構成要素とさまざまなアウトカムを列挙するのみで、列挙した費用と結果の統合を行っていない研究デザインをさす。今回同定された 5 件の CCA におけるアウトカムの測定方法から見ると、そのなかの 2 件のデザインは費用最小化分析 (cost-minimization analysis: CMA) と類似し、残りの 3 件は CEA と類似すると考えられた。

4. 考 察

(1) 漢方治療の経済評価研究の量

今回の漢方薬経済評価のレビューでは、1 次スクリーニングと 2 次スクリーニングとで漢方治療の経済評価と認められた文献はわずかに 10 件と少なかった。

日本の漢方製剤のランダム化比較試験 (RCT) のシスマティック・レビューは、日本東洋医学会によって実施され、漢方治療エビデンスレポート (EKAT) として Web 上で公開されている。

<http://www.jsom.or.jp/medical/ebm/index.html>

EKAT2010 に 345 件、また Appendix 2011 に 14 件、合計 359 件が存在する。

この数と比べて、経済評価の数はわずか 10 件である。経済評価の結果は漢方を処方するかどうかという意思決定に 1 つの重要なエビデンスであり、その数は少ないと考えられる。

2 次スクリーニングで上位 2 つの除外理由は、総説・解説 24 件 (50.0%) と、「同じ経済評価の結果の引用もしくは被引用」18 件 (37.5%) であった。

これまで日本で発表された漢方薬経済評価と関連する論文の多数は本領域の現状のシスマティック・レビューとは言えないナラティブ・レビューである「総説」と経済評価の方法論の紹介であることが明らかになった。

また、同じ経済評価の結果の引用もしくは被引用は、それが明示されておらず、引用元と引用先の編集委員会の手承を得ていない場合は、「二重投稿」(duplicate publication) とみなされる場合がある。すでに Kitagawa, Tsutani により、320 件の漢方製剤の RCT を含む EKAT2009 を用いた解析で、RCT 論文としては 384 編存在し、その内 11 編は明確な「二重投稿」とされている。

Kitagawa M, Tsutani K. Duplicate publication cases in the field of Kampo (Japanese herbal medicine) in Japan. *Journal of Chinese Integrative Medicine* 2011; 9(10): 1055-60.

経済評価についても、この二重投稿は今後、注意が望まれる。

漢方治療経済評価の数が少ない背景には、従来の臨床研究では有効性が中心として注目されており、経済性などのその他の要因を分析する意識が不足していることや、臨床研究でのコストデータの収集・推定の方法に馴染んでいない、薬剤経済学の方法を学習

する場が多くない、ことなどが原因として考えられる。これらの課題の是正が望まれる。

(2) 漢方治療の経済評価研究の質

今回、「具体的なコストが報告されていない」という理由で除外された文献も 10 件 (20.8%) と多く見つかった。それらの研究では有効性を中心として漢方薬の臨床実績を分析しており、経済性についての言及は非常に短いものにとどまる。漢方薬の導入がもたらしうる臨床経済効果を示唆しているものの、具体的なコストが報告されていないものは、本来の意味での経済評価とは呼べない。

漢方薬経済評価と認められた 10 件の文献のなかで、費用結果分析 (CCA) の研究デザインを採用したものが 5 件、同定された。先に述べたように、CCA は関連する費用とアウトカムを列挙するのみで、費用とアウトカムの統合を行わないため、各臨床介入の効率性あるいは費用対効果を相対的に評価することは困難である。意思決定者は CCA の結果を利用する時、自分で費用と結果を統合し結論を導かなければならない。CCA は意思決定者への情報提供と他のデザインの経済評価の基礎として有用であるが、意思決定のツールとしての有用性は限られていると考える。

完全な経済評価(full economic evaluation: FEE)は、臨床的アウトカムとコストと双方のデータと、対照群(control)を持つものである。これによって経済的エビデンス(economic evidence)が「つくら」れ、それによって本来の意思決定ができるものである。

なお、10 件の経済評価でアウトカムの指標として臨床検査の結果、入院日数、感染率などさまざまが用いられたが、生活の質 QOL や質調整生存年 QALY を考察する費用効用分析 (cost-utility analysis: CUA) は見つからなかった。

4. 結 論

医中誌 Web Ver. 5 を用いた検索で得られた 117 件の論文を、タイトルとアブストラクトによる 1 次スクリーニング、また本文を読むことの 2 次スクリーニングで、10 件の漢方治療の経済評価の論文が得られた。これについて 8 項目の構造化抄録からなる「漢方治療の経済評価エビデンスレポート 2011」(Evidence Report of Economic Evaluation of Kampo Treatment 11, EREK 2011)が作成された。日本では、漢方治療の経済評価はまだ 10 件と少数で、またその質も高いものが少なく、政策における意思決定や臨床の場で意思決定にはなお不十分である。漢方治療経済評価におけるより質の高い研究をより多く実施することが望まれ、そのためのインフラが整備されることが期待される。

Annex 1 日本における漢方治療の経済評価論文リスト

No.	年代	ICD-10	Research Question	漢方処方名	論文	デザイン ¹⁾
1	2001	A49.0	脳梗塞で入院した患者に対して、MRSA感染の予防また治療を目的とする漢方の補剤投与の費用対効果を、補剤投与なしを対照とした評価。	十全大補湯、 補中益気湯	坂巻弘之. 老人病院などにおける医療経済学と漢方薬. 漢方と最新治療 2001: 10(4): 338-42.	CEA
2	2008	C18.9	術後の大腸癌の患者に対する大建中湯投与による治療の費用対効果を、投与なしを対照とした評価	大建中湯	今津嘉宏, 渡辺賢治. 漢方の消化管手術における臨床成績. 臨床外科 2008: 63(4): 479-86.	CCA (CEA)
3	1996	D50	鉄欠乏性貧血と診断された女性の患者に対する当帰芍薬散の治療の費用対効果を、フェロミア錠（鉄剤）を対照とした評価	当帰芍薬散	赤瀬朋秀, 望月眞弓, 佐川賢一, 他. 疫学的手法を用いた漢方薬の薬効及び経済性の評価 鉄欠乏性貧血に対する当帰芍薬散の効果. 産婦人科漢方研究のあゆみ 1996: 13: 62-5.	CCA (CMA)
4	2000	J00	かぜ症候群の患者に対する漢方薬による治療と洋漢併用治療の費用対効果を、西洋薬による治療を対照とした評価。	麻黄湯、桂枝湯 など多種の処方	赤瀬朋秀, 秋葉哲生, 井齋偉矢, 鈴木重紀. かぜ症候群における薬剤費の薬剤疫学及び経済学的検討 漢方薬と西洋薬の経済性における比較研究. 日本東洋医学雑誌 2000: 50(4): 655-63.	CEA
5	2003	J30.1	スギ花粉症の患者に対する漢方医の治療と洋漢併用治療の費用対効果を、西洋医学の治療を対照とした評価	小青龍湯、葛根湯加川芎辛夷、 麻黄附子細辛湯 など多種の 処方	川口毅. アレルギー性鼻炎患者の全人的治療をめざして 東洋医学的治療の医療経済効果—花粉症の医療費. 日本東洋医学雑誌2003: 54(1): 136-40.	CCA (CEA)
6	1998	K74	肝硬変の患者に対する小柴胡湯の追加療法の費用対効果を、従来の治療法を対照とした評価	小柴胡湯	岡 博子. 医療経済からみた漢方治療 肝硬変からの肝癌予防. Progress in Medicine 1998: 18(4): 681-6.	CEA
7	2006	M17.9	変形性膝関節症の患者に対する防已黄耆湯による治療の費用対効果を、NSAIDs内服による治療を対照とした評価	防已黄耆湯	濃沼政美, 白神誠. 変形性膝関節症の保存的薬物療法に対する防已黄耆湯の薬剤経済分析. 医療薬学 2006: 32(8): 729-39.	CEA
8	2000	N30.0	急性膀胱炎の患者に対する猪苓湯投与による洋漢併用療法の費用対効果を、レボフロキサシン（抗菌剤）を対照とした評価	猪苓湯	井齋偉矢. 急性膀胱炎に対する洋漢併用療法による治療効果と経済効果. 日本東洋医学雑誌 2000: 50(6): 195.	CCA (CMA)
9	2003	なし	長期療養型病床群の患者に対する洋漢併用治療の費用対効果を、西洋薬による治療を対照とした評価	記載なし	針生雄吉. 杜都中央病院の高齢者医療における漢方薬治療の経済的効果及び臨床的效果について. 漢方の臨床 2003: 50(11): 1547-50.	CCA (CEA)

No.	年代-番号	ICD-10	Research Question	漢方処方名	論文	デザイン
10	2011	なし	和漢診療科に入院した患者の退院時の治療の費用対効果を、入院の時の治療を対照とした評価。	甘草瀉心湯、桂枝茯苓丸など多種の処方	大野賢二, 関矢信康, 並木隆雄, 他. 漢方治療がもたらす医療経済効果 入院治療を中心として. 日本東洋医学雑誌 2011: 62(1): 29-33.	1)

1) 研究デザイン

- CEA : 費用効果分析 (Cost-effectiveness analysis)
- CBA : 費用便益分析 (Cost-benefit analysis)
- CUA : 費用効用分析 (Cost-utility analysis)
- CMA : 費用最小化分析 (Cost-minimization analysis)
- CCA : 費用結果分析 (Cost-consequence analysis)