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.