

### 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, 肩髃) 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.