

# Research Snapshots

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## RELATIONSHIPS BETWEEN CONSTITUTIONAL TYPES OF TRADITIONAL CHINESE MEDICINE AND HYPERTENSION

**OBJECTIVES:** This study investigated the relationship between constitutional types of Chinese medicine and primary hypertension.

**METHODS/DESIGN:** A standardised Constitution in Chinese Medicine Questionnaire (CCMQ) was used in this cross-sectional survey of a total 21 984 people from the general public of nine cities and provinces in China. The questionnaire had nine subtypes of constitutions, including: qi deficiency type, yang deficiency, yin deficiency, phlegm-dampness, damp-heat, blood stasis, qi stagnation and special constitution. Data from 7782 subjects including healthy population and those with primary hypertension were analysed in this paper. Discriminatory analysis was used to identify individual constitutional type. The influential constitutional factors for hypertension were calculated with a multiple stepwise logistic regression analysis.

**RESULTS:** Three subtypes were identified to have a stronger relationship with primary hypertension. Those factors included phlegm-dampness constitution, yin deficiency constitution and qi deficiency constitution with the odds ratio (OR) and 95% confidence interval (CI) being 2.00 [1.58, 2.55], 1.66 [1.33, 2.08] and 1.37 [1.13, 1.66],

respectively. Furthermore, the females suffering from primary hypertension (2.80 [1.79, 4.39]) had a higher ratio in phlegm-dampness type than the males did (1.61 [1.22, 2.14]).

**CONCLUSIONS:** TCM constitution types of phlegm-dampness, yin deficiency and qi deficiency could contribute to the development of primary hypertension. This study could contribute to the constitutional theory of individual disposition to diseases.

**COMMENTS:** The study conforms to Chinese medicine understanding of aetiology of diseases. There is, however, little description of how data from mixed population (normal subjects and those with primary hypertension) were analysed. Furthermore, the subtypes presented in the study could reflect the differential syndromes of primary hypertension rather than the types of constitutions. A prospective-cohort study would be a better choice for the purpose of this study.

*Zhu YB, Wang Q, Deng QW, Cai J, Song XH, Yan X. [Relationships between constitutional types of traditional Chinese medicine and hypertension]. Zhong Xi Yi Jie He Xue Bao [J Chin Integr Med] 2010;8(1):40–45.*

*Alan Xinyu Hao*

## BUSHEN HUOXUE GRANULE IMPROVES MOTOR FUNCTION OF PARKINSON'S DISEASE PATIENTS

**OBJECTIVE:** A multicenter, randomised, double-blind and placebo-controlled clinical trial aimed at evaluating the safety and efficacy of Bushen Huoxue Granule (BSHXG) on motor function improvements in patients with Parkinson's disease (PD). BSHXG is a Chinese compound herbal formula for reinforcing kidney and activating blood circulation, including herbs such as Shanzhuyu (10 g), Heshouwu (15 g), Danggui (10 g) and other unspecified herbs.

**METHODS:** A total of 120 PD patients were randomly allocated to receive BSHXG (1 pack per day) or placebo intervention (control granules 1 pack per day) in addition to an oral intake of madopar 373–1000 mg/day. Both groups were treated for three months and followed up for one month. Drop outs and adverse events were recorded.

**OUTCOME MEASURES:** The Unified Parkinson's Disease Rating Scale (UPDRS), movement scale, exercise testing and muscle tension (musculus quadriceps femoris, musculus biceps brachii) were assessed at the baseline and at weeks 4, 8 and 12 after the treatment.

**RESULTS:** At weeks 4, 8 and 12, the UPDRS scores in the BSHXG group were statistically better than the baseline

measurement ( $F = 15$ ,  $P = 0.016$ ), and than those in the placebo group ( $P < 0.05$ ). No significant changes in UPDRS scores were observed in the placebo group before and after treatment. The rise time of BSHXG in the 10-metre back and forth movement was significantly shortened in comparison to the placebo group. Before and after treatment changes in the resting state of muscle tension of biceps brachii ( $P < 0.01$ ) and quadriceps femoris ( $P < 0.01$ ) were statistically significant in the BSHXG, whilst no significant changes were observed in the placebo group. However, in both groups, no significant improvement was observed in walking time and turn around time in the 10-metre back and forth movement, or maximal voluntary contraction of biceps brachii and quadriceps femoris. Overall, the BSHXG group showed significant improvement in motor function, shortened rise time of 10-metre back and forth test and relief of muscle tension. No adverse events were recorded.

**CONCLUSION:** Results from this trial suggest that BSHXG in addition to madopar is effective and safe in improving motor functions and quality of life for PD patients. This is a well-designed clinical trial with promising results. However, a sample size of 120 PD patients is not enough to draw on meaningful clinical conclusions; secondly, comparison of results should be made not only before and after treatments within the same group, but also between two groups. Therefore, further high-quality studies with larger sample size and better statistical analysis are warranted to test the efficacy of BSHXG on Parkinson's disease.

*Yang MH, Li M, Dou YQ, Liu Y, Luo XD, Chen JZ et al. Effects of Bushen Huoxue Granule on motor function in patients with Parkinson's disease: a multicenter, randomised, double-blind and placebo-controlled trial. J Chin Integr Med 2010;8(3):231-7.*

*Yuan Ming Di*

#### ACUPUNCTURE AND HERBAL MEDICINE PACKAGE FOR UNEXPLAINED FEMALE INFERTILITY: SAFE, BUT IS IT EFFECTIVE?

**OBJECTIVE:** The aim of this study was to determine the safety and effectiveness of a standard herbal and acupuncture therapeutic package for unexplained infertility in women who sought treatment in an integrative hospital in Korea.

**METHODS:** This was a prospective observational study of the treatment offered in an integrative care unit (Conmaul Hospital, Seoul, Korea) of 'unexplained female infertility'. The study evaluates the outcome for 104 women receiving a standard care 'package' over six menstrual cycles. The inclusion criteria of regular menstrual cycle, normal hormonal cycle, no male infertility factors, excluded all women who had a physiological basis (confirmed by laparoscopy and ultrasound) to their fertility problems, except those with mild endometriosis, who were included. Women who were planning to use other artificial reproductive technologies during the six months study period were also excluded. The standard therapeutic package included Korean herbal medicine, acupuncture and moxibustion. The women received both a decoction (administered three times a day), which was prescribed based on individual diagnosis and a standard patent pill called Song Keum Dan (a formula similar to Ba zhen tang with additions to warm yang and strengthen qi); daily moxa on CV 8 (umbilicus), except during menstruation; and herbal injection (of lu rong and zi he che) acupuncture to CV 4, BL 19 and BL 22.

**RESULTS:** Fourteen women achieved pregnancy (22.1%) resulting in ten live births and four miscarriages. When successful pregnancy is analysed in the women who completed the six month course of the study (23 in total) the

pregnancy rate of 60.9% looks more successful. Only 6% of the women reported adverse events and these were minor and responded to ceasing the herbs. The dropout rate in this study reached 80%. Most women stated 'personal reasons' for their withdrawal, which the authors suggest may have been a polite way of expressing difficulty affording the payment. The study was an observational study with participants paying for their own treatments and the authors considered this expense as a key factor in the high dropout rate. No analysis was offered of outcomes related to the differential diagnoses which guided the herbal treatments.

**COMMENTS:** The 'standard package' for unexplained female infertility was predominantly herbal. Mention of acupuncture is to some degree misleading as three points were used and only for herbal injections. The low adherence to the study protocol is a problem as it is usual to find women in this cohort keen to comply unless they were offered what they considered superior treatment elsewhere. Only a very small percentage of those who withdrew gave their reason as pursuing other treatment. The authors raise questions as to possible reasons but these are not explored in this article. The conclusion that the 'true' success rate is 60.9% for those who completed the full course is not supported by the evidence which indicated that 10 of the 14 pregnancies occurred by the fourth month of treatment. This study could be a stimulus for practitioners to undertake an observational study in their own clinics, and it raises questions for those researching female fertility problems. However, it offers little evidence for this particular treatment other than its safety.

*Park JJ, Kang M, Shin S, Choi E, Kwon S, Wee H, Nam B, Kaptchuk TJ. Unexplained infertility treated with acupuncture and herbal medicine in Korea. J Altern Complement Med 2010;16(2):193-8.*

*Suzanne Cochrane*

### ACUPUNCTURE FOR DEPRESSION DURING PREGNANCY

**OBJECTIVE:** The aim of this randomised control trial was to evaluate the efficacy of acupuncture for pregnant women diagnosed with major depressive disorder.

**METHOD:** 150 women between 12 and 30 weeks gestation were recruited from local clinics and through advertising in parent and baby publications. After meeting the criteria for a diagnosis of major depressive disorder, women were randomised to receive either: specifically individualised acupuncture treatment, control acupuncture treatment (not specifically designed to treat depression) or massage treatment. Treatment was administered twice a week for four weeks then weekly for four weeks. An attempt was made to blind the acupuncturists providing the treatment. To achieve this, for each woman a specifically individualised treatment for depression as well as a control acupuncture treatment was designed by one group of acupuncturists; another group of acupuncturists then provided the prescribed treatment, without evaluating any presenting signs and symptoms. Acupuncture needles were inserted to depth to obtain deqi and retained for 20 minutes with 7–12 points selected for each session. The massage treatment was provided by massage therapists. Instructions were also given to the treatment providers to minimise verbal communication and refrain from offering any counselling, dietary or lifestyle advice. The primary outcome was the Hamilton Rating Score for Depression, administered on entry into the study and at four and eight weeks of treatment.

**RESULTS:** 141 women completed treatment, with similar depression severity and history on entering the study for all groups. Women receiving acupuncture treatment specifically designed to treat depression experienced

a significantly greater reduction in the Hamilton Rating Score for Depression and demonstrated a significantly greater response rate than those women assigned to the control acupuncture group alone or the control acupuncture and massage group combined. Minimal acupuncture-related side effects were reported and consisted of discomfort and bleeding at the site of insertion. Ten adverse pregnancy related events occurred, including that of a premature delivery, a pregnancy loss and hospitalisation for pregnancy related events; these were found to be unrelated to treatment and were not significantly different for the three treatment groups. The attempt to blind acupuncture treatment providers through separating clinical diagnosis from acupuncture treatment was not successful, with the treatment expectations for the treating acupuncturists found to be significantly lower in the treatment not specifically designed for depression.

**CONCLUSION:** The acupuncture protocol specifically designed for depression in this study demonstrated a response rate that was clinically meaningful and comparable to that of standard care within a similar timeframe.

**COMMENT:** The attempt made by the authors of this study to blind the acupuncturists delivering treatment was an interesting approach. It is possible that acupuncture diagnosis, with its focus on patient observation, limits any attempts to create a control group in this way.

*Manber R, Schnyer R, Lyell D, Chambers A, Caughey A, Druzin M, et al. Acupuncture for depression during pregnancy: a randomized controlled trial. Obstet Gynecol 2010;115:511–20.*

*Debra Betts*

### AURICULAR ACUPRESSURE IS BENEFICIAL FOR MENSTRUAL SYMPTOMS FOR WOMEN WITH PRIMARY DYSMENORRHOEA

**OBJECTIVES:** The aim of this study was to evaluate the effects of auricular acupressure on relieving menstrual symptoms and changes in serum nitric oxide (NO) for women with primary dysmenorrhoea.

**STUDY DESIGN:** 74 female college students aged between 18 and 28 without prior internal/gynaecologic diseases or secondary dysmenorrhoea, and who had menstrual pain at least three times in the past 6 months were randomly allocated to either real auricular acupressure group (RG,  $n = 37$ ) receiving seed-pressure method on liver (CO12), kidney (CO10), and endocrine (CO18) auricular acupoints, or control group (CG,  $n = 37$ ) receiving a plain adhesive patch placed on the same acupoints without seed attached. The treatment was applied about two days before the menstrual period. Acupressure protocol included massaging 15 times on each point, three times a day, for a total of 20 days. The adhesive patches with or without seeds were renewed and reapplied every five days by the researcher. Short-form Menstrual Distress Questionnaires (MDQs) were completed and Serum NO level was assessed prior to treatment and within the first two days of their next menses after completion of 20 days of acupressure.

**RESULTS:** 71 participants completed the trial (RG  $n = 36$ , CG  $n = 35$ ). Among the four categories in MDQs (pain, water retention, autonomic reactions and negative affect), pain ( $p = 0.01$ ) and negative affect ( $p = 0.04$ ) of the RG decreased significantly after treatment when compared with those in CG. The overall menstrual symptoms in the RG improved significantly more than the CG did ( $p = 0.01$ ). No significant

difference was observed in serum NO when comparing the two groups.

**CONCLUSION:** The authors concluded that auricular acupressure by seed-pressure method effectively improved menstrual symptoms of women. It remains uncertain whether the NO pathway is involved in the action of auricular acupressure.

**COMMENTS:** The design of the control intervention could not ensure successful blinding of the subjects, and the researchers did not test the credibility of blinding. Better designed sham auricular acupressure should be developed and validated in further studies.

*Wang MC, Hsu MC, Chien LW, Kao CH, Liu CF. Effects of auricular acupressure on menstrual symptoms and nitric oxide for women with primary dysmenorrhea. J Altern Complement Med 2009;15(3):235–42.*

*Claire Shuiqing Zhang*

#### ELECTROACUPUNCTURE MAY HELP PATIENTS WITH PRIMARY INSOMNIA

**OBJECTIVES:** The objective of this study was to evaluate the short-term efficacy and safety of electroacupuncture for the treatment of primary insomnia.

**STUDY DESIGN:** 60 Chinese adult volunteers who reported having poor sleep three or more nights per week with an Insomnia Severity Index (ISI) total score at least 15 out of 28 and for at least three months were randomly allocated to receive either real electroacupuncture with a constant current, 0.45 ms, square-wave, brief-pulse stimulation of 4 Hz frequency at Yintang (Ex-HN 3), Baihui (GV 20), bilateral ear Shenmen, Sishencong (Ex-HN 1), and Anmian (EX) three times per week for three weeks, or placebo electroacupuncture at the same points using non-penetrating needles connected to the same electric

stimulator but without any electrical current being delivered.

**RESULTS:** Both groups showed statistically significant improvements compared with the baseline measurements. There were significantly greater improvements in sleep efficiency as assessed with sleep diary and actigraphy in the electroacupuncture group. The proportion of subjects having less than 30 minutes of Wake-time After Sleep Onset (WASO) and a sleep efficiency of at least 85% at the post-treatment visit was significantly higher in the electroacupuncture group when compared with the placebo group. No significant between-group differences were observed in the ISI total score and other outcome measures. All adverse events were mild.

**CONCLUSION:** The authors concluded that electroacupuncture may be effective and safe in the short-term treatment of primary insomnia. Further studies with more objective measures such as polysomnography and larger sample size are necessary to verify the effectiveness of electroacupuncture for insomnia.

*Yeung WF, Chung KF, Zhang SP, Yap TG, Law AC. Electroacupuncture for primary insomnia: a randomized controlled trial. Sleep 2009;32(8):1039–47.*

*Claire Shuiqing Zhang*

#### ACUPUNCTURE AND BREAST CANCER THERAPY

**OBJECTIVE:** The aim of study was to undertake a systematic review of acupoint stimulation for therapy-related adverse events in patients with breast cancer.

**METHODS:** A comprehensive search of eight English and Chinese databases to identify clinical trials to examine the efficacy of acupressure, acupuncture or acupoint stimulation for adverse events resulting from treatment for breast

cancer was undertaken. General terms involving acupoint stimulation (APS) and cancer treatment were included in the search, as well as six separate conditions related to anticancer therapies, including vasomotor syndrome, chemotherapy-induced nausea and vomiting, lymphoedema, post-operation pain, aromatase inhibitors-related joint pain and leucopenia. The terms searched for on APS included traditional acupuncture, acupressure, electroacupuncture, and the use of magnetic devices on acupuncture points. Inclusion criteria included: randomised controlled trials (RCTs), controlled clinical trials, or single-group studies; adults diagnosed with breast cancer at any stage and undergoing treatments such as surgery, radiotherapy, chemotherapy, hormonal therapy and experiencing treatment-induced adverse events, and the inclusion of at least one clinically related outcome. 843 titles were identified up until October 2008 and data extraction was undertaken for 26 studies. Eleven trials examined chemotherapy-induced nausea and vomiting (CINV); seven evaluated vasomotor syndrome; three, post-operational pain; two, radiotherapy or chemotherapy-induced leucopenia; one, aromatase inhibitors-related arthralgia; and one, breast cancer-related lymphoedema.

**RESULTS:** CINV (ten trials) reported APS could significantly improve emesis. All eleven trials utilised the points PC 6 and ST 36. In relation to vasomotor syndrome, four RCTs found no difference between the intervention and the control group. Three trials demonstrated an association between acupoint stimulation and lower frequency of daily hot flush. The majority of the trials used six or more points. For post-mastectomy pain, results were inconsistent: two trials showed benefit but one high quality RCT showed no significant difference. Point LI 4 was used in all three trials. For joint symptoms, only one study was included and positive

results were found for joint pain and functional ability. For lymphoedema, one study demonstrated that traditional acupuncture was effective in managing post-mastectomy oedema using a single-group design. For leucopenia, two trials found that dexamethasone injected into ST 36 was effective in preventing bone marrow suppression-related leucopenia in patients undergoing chemotherapy or radiotherapy.

**CONCLUSION:** The authors conclude that three high quality studies looking at acupoint stimulation for CINV showed benefit. The authors would

not recommend ASP for other adverse events as the quality of the trials were poor, even though many showed benefit. The major recommendation was that further high quality RCTs are needed.

**COMMENT:** Although the evidence is not strong enough for the authors to recommend acupuncture to help treat therapy-related adverse events in patients with breast cancer in a western medicine journal, I believe there is still enough evidence to treat these conditions in your clinic, saying to the patient that research has shown some benefit. I personally have treated nausea and

vomiting, fatigue, post-mastectomy pain, vasomotor symptoms and lymphoedema in cancer patients with positive results to varying degrees.

*Chao L-F, Zhang A, Liu H-E, Cheng M-H, Lam H-B, Lo S. The efficacy of acupoint stimulation for the management of therapy-related adverse events in patients with breast cancer: a systematic review. Breast Cancer Research and Treatment 2009;118:255-67.*

*Chris McKeon*