**Treatment for seasonal allergic rhinitis by Chinese herbal medicine: a randomized placebo controlled trial**


**Context:** Chinese herbal medicine (CHM) is widely used to treat seasonal allergic rhinitis (SAR), however, evidence of efficacy is lacking.

**Objectives:** To evaluate the efficacy of a Chinese herbal formulation for the treatment of SAR.

**Design:** Randomized, double blind, placebo controlled trial.

**Setting:** RMIT Chinese Medicine Clinic.

**Patients:** 55 patients with seasonal allergic rhinitis (active 28, placebo 27).

**Interventions:** CHM extract capsule (containing 18 herbs) or placebo, given daily for 8 weeks.

**Main outcome measures:** The primary measure of efficacy was changes in severity of nasal and non-nasal symptoms using a Five Point Scale (FPS) measured by both patients and the practitioner. The secondary measure was the change in score for the domains measured in the Rhinoconjunctivitis and Rhinitis Quality of Life Questionnaire (RQLQ) assessed by patients.

**Results:** Forty-nine patients completed the study (active 24, placebo 25). After eight weeks, the severity of nasal symptoms and non-nasal symptoms were significantly less in the active treatment group than in the control group, both for measurements made by patients and those by the practitioner. Comparison of active and placebo treatment groups RQLQ scores also indicated significant beneficial effects of treatment (end point Section 1: p<0.05; Section 2: p<0.01). Intention-to-treat analyses of categorical items showed moderate to marked improvement rates were 60.7% and 29.6% for active and placebo respectively. Eleven patients reported mild adverse events including 1 withdrawn from the trial.

**Conclusions:** This CHM formulation appears to offer symptomatic relief and improvement of quality of life for some patients with seasonal allergic rhinitis.

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**A randomized controlled trial of a Chinese herbal remedy to increase energy, memory, sexual function, and quality of life in elderly adults in Beijing, China**


**Background:** Chinese herbal medicines are commonly used to improve general health and well-being despite limited scientific data to support their efficacy. We conducted a randomized, double-blind, placebo-controlled trial to determine whether an herbal remedy that is used widely in China was associated with changes in quality of life, energy, memory, sexual function, and qi (the Chinese concept of “vital energy” that is important in general health).

**Methods:** Residents (n = 237) of Beijing, China, who were aged > or =60 years and had self-reported decreased energy, memory, or sexual function, were randomly assigned to take four tablets of a Chinese herbal formula or of an identical placebo, three times a day for 30 days. Patients returned for one follow-up visit after 30 days for assessment of all outcomes. The main outcome measures were changes in quality of life at 30 days as measured by the 12-Item Short Form Health Survey (SF-12) Mental and Physical Component Summary scales.

Results: Use of Chinese herbs was associated with a small benefit in the Mental Component scale (difference of 1.9 points; 95% confidence interval [CI]: 0.1 to 3.6) and no benefit in the Physical Component scale (difference of -0.1 points; 95% CI: -1.7 to 1.5) as compared with placebo. A small improvement in the qi scale was no longer significant after adjusting for baseline differences in this score between
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groups. There was no improvement in physical performance, memory, or sexual function. The herbal product was well tolerated.

Conclusion: Short-term use of a mixture of Chinese herbs was associated with a small benefit in one measure of mental health that is of unclear clinical importance.

Clinical study on relationship between memory quotient, estrogen and Chinese nourishing kidney herbs in perimenopausal women

Objective: To explore the memory quotient and hormone level in women with perimenopausal syndrome and healthy women in perimenopausal period, and the effect of estrogen and Chinese nourishing Kidney herbs (CNKH) on memory.

Methods: Fifty-six women of perimenopausal syndrome were treated with estrogen (n=24) and CNKH (n=32) respectively. The changes of memory and estrogen level before and after treatment were determined and compared with those in healthy women.

Results: The memory quotient (MQ) and estrogen level increased and follicle-stimulating hormone (FSH) level decreased significantly after treatment in both groups (p<0.01), these parameters approached to those in healthy women. The difference of therapeutic effect between the two treated groups was insignificant (p>0.05).

Conclusion: The decrease of memory is related to the lowering of estrogen level. CNKH could improve the brain function and enhance memory.

Effect of yiqi bushen huoxue herbs in treating children asthma and on levels of nitric oxide, endothelin-1 and serum endothelial cells

Objective: To observe the therapeutic effect of Yiqi Bushen Huoxue herbs (YQBSHX, the Chinese herbs for supplementing Qi, replenishing Kidney and activating blood circulation) on children asthma in regard to its effect on the serum levels of nitric oxide (NO), endothelin-1 (ET-1) and circulating endothelial cells (CEC).

Methods: Two hundred children with asthma were divided into two groups, the YQBSHX and the control group, and their serum levels of NO, ET-1 and CEC were detected in acute and remission stage respectively. Twenty cases in each group were followed-up for 1 year to observe the frequency of asthma attack and the changes in ET-1, NO and CEC levels.

Results: Serum levels of ET-1, NO and CEC in patients of acute stage were obviously raised. After treatment, the above-mentioned criteria in the YQBSHX group were significantly lower than those in the control group (p<0.01). And the frequency of attack in the YQBSHX group was markedly reduced.

Conclusion: YQBSHX herbs could reduce ET-1, NO and CEC levels in children asthma, lessen the frequency of attack, therefore, to elevate the cure rate of children asthma.

Effects of acupuncture therapy on insomnia

Objective: To assess the trends across intervention studies using acupuncture for insomnia from 1975 to 2002, to examine dependent variables, and to evaluate the effects of acupuncture therapy on insomnia in older people.

Method: Data were collected from November 2001 to January 2003. A wide range of electronic databases was searched using the keywords ‘insomnia’, ‘acupuncture’ and ‘controlled’. Papers were included if they were published in the English language between 1975 and 2002 and described an experimental study using acupuncture therapy to treat insomnia. Eleven reports meet these criteria.

Findings: Most of the studies had been conducted since 1990. The findings showed that the first author was usually a Chinese medical doctor (n=9) employed in a traditional department of medicine. Most of the papers were published in two journals: International Journal of Clinical Acupuncture and Journal of Traditional Chinese Medicine. Data were limited because of the small number of studies available. Half
the studies had small samples (50 subjects or fewer), which were composed mainly of older women who had a variable duration of insomnia from 3 days to 34 years. The main method used to assess outcomes was questionnaire. All the studies reported statistically significant positive results.

**Conclusion:** The results of this review suggest that acupuncture may be an effective intervention for the relief of insomnia. Further research, using a randomized clinical trial design, are necessary to determine the effectiveness of acupuncture. More work is also needed to promote the long-term therapeutic effects of acupuncture and to compare it with other therapies for insomnia.

**Electrical stimulation of auricular acupuncture points is more effective than conventional manual auricular acupuncture in chronic cervical pain: a pilot study**


In this prospective, randomized, double-blinded, controlled study, we tested the hypothesis that auricular electroacupuncture relieves pain more effectively than conventional manual auricular acupuncture. We studied 21 chronic cervical pain patients without radicular symptoms with insufficient pain relief (visual analogue scale >5) treated with standardized analgesic therapy. All patients received disposable acupuncture needles on the dominant side on the following acupuncture points: cervical spine, shen men, and cushion. In 10 patients, needles were continuously stimulated (2-mA constant current, 1 Hz monophasic) by using the electrical point stimulation device P-STIM. In 11 control patients, no electrical stimulation was administered. All needles were withdrawn 48 h after insertion. Acupuncture was performed once a week for 6 wk. Patients had to complete a questionnaire assessing pain intensity, psychological well-being, activity, sleep, and demand for rescue medication (lornoxicam and tramadol). The reduction in pain scores was significant in the electrical acupuncture group. Similarly, psychological well-being, activity, and sleep were significantly improved in patients receiving electrical acupuncture, and consumption of rescue medication was significantly less. These results demonstrate that continuous electrical stimulation of auricular acupuncture points by using the new point stimulation device P-STIM improves the treatment of chronic cervical pain in an outpatient population.

**Implications:** Continuous electrical stimulation of auricular acupuncture points by using the new point stimulation device P-STIM significantly decreases pain intensity and significantly improves psychological well-being, activity, and sleep in chronic cervical pain patients.

**A Phase I-II study in the use of acupuncture-like transcutaneous nerve stimulation in the treatment of radiation-induced xerostomia in head-and-neck cancer patients treated with radical radiotherapy**


**Purpose:** Recent studies have suggested that acupuncture may improve radiation-induced xerostomia with an increase in the median salivary flow rate and sustained symptom relief. An acupuncture-like transcutaneous nerve stimulation method (Codetron) without invasive needles was developed to mimic acupuncture treatment. This Phase I-II study examined the effectiveness of Codetron in treating radiation-induced xerostomia.

**Methods and materials:** Patients with symptomatic xerostomia after radical radiotherapy for head-and-neck cancer but with evidence of residual salivary function were recruited into the study. Two 6-week courses of Codetron treatment
of acupuncture points preselected according to traditional Chinese medicine principles were given with a 2-week break between each course. Basal and citric acid-primed whole saliva production was measured at baseline and up to 1 year after treatment completion. Xerostomia symptoms were assessed by a five-item xerostomia symptom questionnaire with a visual analog scale and quality of life was evaluated using the Head and Neck Radiotherapy Questionnaire.

**Results:** We enrolled 46 patients in the study. All patients had received radiotherapy doses of $\geq 50$ Gy to bilateral head-and-neck fields, including the parotid glands. Of the 46 patients, 37 completed the follow-up assessments at 3 and 6 months after treatment completion. No Codetron treatment-related complications occurred. Improvement in xerostomia symptoms was noted, with a mean increase in the visual analog scale score of 86 ($p<0.0005$) and 77 ($p<0.0001$) at 3 and 6 months after treatment completion, respectively. For all patients, the increase in the mean basal and citric acid-primed whole saliva production at 3 and 6 months after treatment completion was also statistically significant ($p<0.001$ and $p<0.0001$, respectively). No statistically significant change in the quality-of-life evaluation compared with baseline was observed.

**Conclusion:** The results suggest that Codetron treatment improves whole saliva production and related symptoms in patients with radiation-induced xerostomia. The treatment effects were sustained for at least 6 months after Codetron treatment completion. A prospective randomized Phase III trial with appropriate controls is being planned.

**Treatment of rheumatoid arthritis with electromagnetic millimeter waves applied to acupuncture points - a randomized double blind clinical study**


The aim of the study was to evaluate the efficacy and safety of electromagnetic millimeter waves (MW) applied to acupuncture points in patients with rheumatoid arthritis (RA). Twelve patients with RA were exposed to MW with power 2.5 mW and band frequency 54-64 GHz. MW were applied to the acupuncture points of the affected joints in a double blind manner. At least 2 and maximum 4 points were consecutively exposed to MW during one session. Total exposure time consisted of 40 minutes. According to the study design, group I received only real millimeter wave therapy (MWT) sessions, group II only sham sessions. Group III was exposed to MW in a random cross-over manner. Pain intensity, joint stiffness and laboratory parameters were recorded before, during and immediately after the treatment. The study was discontinued because of beneficial therapeutic effects of MWT. Patients from group I ($n=4$) reported significant pain relief and reduced joint stiffness during and after the course of therapy. Patients from group II ($n=4$) revealed no improvement during the study. Patients from group III reported the changes of pain and joint stiffness only after real MW sessions. After further large-scale clinical investigations MWT may become a non-invasive adjunct in therapy of patients with RA.

**Acupuncture and responses of immunologic and endocrine markers during competition**


**Introduction:** Acupuncture is used to modulate the physical well-being of athletes in Asian countries. However, there is little information on the immediate effects of acupuncture treatment on physiological or psychological responses to exercise.

**Purpose:** The purpose of this study was to examine the effect of acupuncture treatment on the physical well-being of elite female soccer players during a competition period.

**Methods:** Subjects were divided into two groups: those who received acupuncture treatment (18.1 +/- 2.3 yr +/-SD), N = 9) and a control group (17.7 +/- 2.8 yr, N = 12). In the treatment group, acupuncture stimulus was applied at LI 4 (Goukoku), ST 36 (Ashi-sanri) for 20 min, and ST 6 (Kyosya), LU 6 (Ko-sai) points for 15 min 4 h after the game every night during the competition period. The measured parameters included salivary secretory immunoglobulin A (SIgA) level, cortisol level in saliva, subjective rating of physical well-being, and profile of mood states (POMS).

**Results:** The following were the main results: 1) Exercise-induced decrease of salivary SIgA and increase of salivary cortisol were inhibited by acupuncture. 2) Acupuncture improved subjective rating of muscle tension and fatigue. 3) The POMS score was modulated by acupuncture.

**Conclusion:** These results support the effectiveness of acupuncture for physical and mental well-being of athletes.
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Anti-phlogistic and immunocompetent effects of acupuncture treatment in women suffering from chronic pelvic inflammatory diseases


Thirty-nine women of reproductive age suffering from chronic pelvic inflammatory disease (PID) for at least two years, previously treated pharmacologically with no effect, were enrolled in a four-week therapeutic protocol consisting of 12 acupuncture treatments performed with the frequency of three per week. In each female patient at baseline and after the study, pain score and the following parameters in blood serum were evaluated: concentration of immunoglobulin M (IgM), albumins, alpha1-globulins, alpha2-globulins and gamma-globulins, erythrocyte sedimentation rate (ESR) and white blood cell (WBC) count. A significant decrease (from 4.89 +/- 0.82 to 0.63 +/- 1.05) in pain score was obtained. The other parameters remained unchanged. These results suggest that acupuncture treatment of PID exhibits a clear anti-inflammatory and immunocompetent effect.

Acupuncture to reduce nausea during chemotherapy treatment of rheumatic diseases


Objective: To study if acupuncture, combined with ondansetron treatment, reduces nausea and vomiting associated with cyclophosphamide infusion in patients with rheumatic diseases.

Methods: Thirty-nine patients were treated with acupuncture at point PC 6 and/or in the ear to decrease nausea and vomiting. The patients reported the severity of nausea and number of bouts of vomiting at the start of chemotherapy and after 4, 8, 24, 48 and 72 h.

Results: Compared with ondansetron treatment alone, the combined acupuncture-ondansetron treatment significantly decreased both the severity of nausea and the number of bouts of vomiting 24 and 48 h after the subjects had received acupuncture at the first treatment session (nausea: p<0.0001; vomiting: p<0.0035). Nearly the same results were seen 48 and 72 h after the subjects had had their last treatment of acupuncture (nausea p<0.0080). Similar results were found after 24 to 48 h, when a comparison was made between two sessions close in time (nausea: p<0.0001 after 24 h, p<0.0003 after 48 h; vomiting: p<0.0007).

Conclusions: Our results clearly indicate that combined treatment with acupuncture and ondansetron reduces the severity and the duration of chemotherapy-induced nausea as well as the number of bouts of vomiting as compared with ondansetron therapy alone, in patients with rheumatic diseases.

Acupuncture during labor can reduce the use of meperidine: a controlled clinical study


Objective: To evaluate the effectiveness of acupuncture as an analgesic during labor.

Design: A randomized, unblinded, controlled study.

Setting: A labor ward in a University Hospital.

Patients: Parturients at term.

Interventions: One group received acupuncture (n=106); another did not (n=92). A second control group (n=92), drawn from the labor ward protocol, consisted of patients who met the eligibility criteria for the study and were matched to the “no acupuncture” group by parity, but who had not been offered the opportunity to take part. Outcome measure “effectiveness of acupuncture” was measured by the requirement for use of meperidine.

Results: Meperidine was given to 11% of the acupuncture group, 37% of the no acupuncture group (p<0.0001), and 29% of the control group. The use of other analgesics was also lower in the acupuncture group. Patient satisfaction was high: 89 of 103 patients asked said they would want acupuncture during another labor.

Conclusions: Acupuncture during labor reduced the requirement for other painkillers and has high patient satisfaction in this randomized, unblinded, controlled study.

Acupoints massage in improving the quality of sleep and quality of life in patients with end-stage renal disease


Background: Traditional Chinese acupressure is a nonin-
Aims: The purpose of the present study was to test the effectiveness of acupoints massage for patients with end-stage renal disease and experiencing sleep disturbances and diminished quality of life.

Methods: The study was a randomized control trial. A total of 98 end-stage renal disease patients with sleep disturbances were randomly assigned into an acupressure group, a sham acupressure group, and a control group. Acupressure and sham acupressure group patients received acupoints or no acupoints massage three times a week during haemodialysis treatment for a total of 4 weeks. The measures included the Pittsburgh Sleep Quality Index, Sleep Log, and the Medical Outcome Study - Short Form 36.

Findings: The results indicated significant differences between the acupressure group and the control group in Pittsburgh Sleep Quality Index subscale scores of subjective sleep quality, sleep duration, habitual sleep efficiency, sleep sufficiency, and global Pittsburgh Sleep Quality Index scores. Sleep log data revealed that the acupressure group significantly decreased wake time and experienced an improved quality of sleep at night over the control group. Medical Outcome Study - Short Form 36 data also documented that acupressure group patients experienced significantly improved quality of life.

Conclusion: This study supports the effectiveness of acupoints massage in improving the quality of sleep and life quality of end-stage renal disease patients, and offers a non-invasive therapy for sleep-disturbed patients.

Acupuncture for the treatment of obesity: a review of the evidence


Although acupuncture is being utilized to treat a variety of important health problems, its usefulness in obesity management has not yet been fully evaluated. The aim of this review paper was to survey and critically evaluate the descriptive and controlled trials of acupuncture for enhancing weight loss. The underlying principles of acupoint stimulation are described, with an emphasis on auricular (ear) acupuncture, the method most often chosen for obesity studies. The difficulties of selecting suitable placebo controls are highlighted. To date, most trials have been descriptive in nature, of short duration (< or =12 weeks), and designed using non-standard treatment protocols. Despite the unique challenges involved, further careful study of acupuncture’s potential usefulness as an adjunct in weight management is recommended. An agenda for future research in this area is provided.

Electroacupuncture analgesia for colonoscopy


Objective: A study was undertaken to compare the effectiveness of acupuncture in reducing patient’s discomfort and anxiety during colonoscopy with a standard sedation protocol.

Method: 30 patients scheduled to undergo colonoscopy were randomly assigned to receive acupuncture, sham, or no acupuncture. A verbal rating scale was used to measure patient’s pain when the endoscope reached 4 scheduled positions. Midazolam was administered at baseline and again anytime patients complained of “severe” pain. The amount of midazolam was recorded. A verbal rating scale was used to assess patient’s satisfaction with the level of sedation achieved.

Results: Pain level was lower, although not significantly, in the acupuncture group. Midazolam boluses were required in 3 patients with acupuncture (30%), 8 in the sham group (80%) and 9 in the control group (90%) (p=0.01). 6 patients in the acupuncture group (60%) reported optimum acceptance of colonoscopy compared with only 1 in the sham group (10%) and 0 in the control group (p=0.016). Satisfaction scores, assessed 24-72 h after colonoscopy, were extremely high (median score 90 of 100) in the 3 groups.

Conclusion: Acupuncture may decrease the demand for sedative drugs during colonoscopy by reducing discomfort and anxiety of the patient and the well-known adverse effects of pharmacologic sedation.
Effects of the herbal medicine Inchinko-to (TJ-135) on liver function in postoperative patients with biliary atresia - a pilot study


**Purpose:** A continuation of liver fibrosis after undergoing successful Kasai operation has become the important clinical issue in the long-term follow-up of patients with biliary atresia (BA). The aim of this study is to evaluate the efficacy of the herbal medicine Inchinko-to (TJ-135) on the treatment of liver fibrosis in patients with BA without jaundice, especially from the viewpoint of the long-term effects of TJ-135.

**Methods:** Six postoperative patients with BA ranging between 3 and 13 years of age with normal serum total bilirubin levels (total bilirubin<1.0 mg/dL [17 micromol/L]) received TJ-135 from 2 to 4 years. The liver enzyme (glutamic oxaloacetic transaminase (GOT), glutamic pyruvic transaminase (GPT), gamma glutamyl transpeptidase[gamma-GTP]transpeptidase[gamma-GTP] levels and hyaluronic acid (HA) levels were compared before and after the administration of TJ-135. The monthly collected data were averaged on a 1-year basis. The record of one postoperative patient with BA and a normal serum total bilirubin level was incorporated as a control. This patient showed portal hypertension and did not receive TJ-135.

**Results:** Five of the six patients who showed abnormal values for liver enzymes, exhibited a significant decrease in serum GOT, gamma-GTP, or GPT levels after a 1 to 3-year administration of TJ-135, and the improvement in these parameters persisted thereafter. Furthermore, one patient who had an abnormally high value of HA also showed a significant decrease in the serum level of HA. In the remaining patient with normal liver enzyme values, no significant change was observed during the administration of TJ-135. The control patient exhibited a chronological decrease in the serum GOT and GPT levels by 5 years of age, but the serum gamma-GTP and HA levels remained stable throughout the postoperative period.

**Conclusions:** The long-term effectiveness of TJ-135 was only found in those patients with abnormal liver enzyme levels and HA, thereby suggesting that TJ-135 has a protective and antifibrotic effect on the liver.

Herbal medicine Inchin-ko-to (TJ-135) prevents liver fibrosis and enzyme-altered lesions in rat liver cirrhosis induced by a choline-deficient L-amino acid-defined diet


**Aims:** The herbal medicine Inchin-ko-to (TJ-135), extract power from three herbs, has recently been reported possessing anti-apoptotic activity. The aim of this study was to investigate whether TJ-135 has any influence on the development of preneoplastic lesions as well as liver fibrosis.

**Methods:** The effects of the TJ-135 were examined using the choline-deficient L-amino acid-defined diet-induced liver fibrosis model. In addition, the effect of TJ-135 on mitogen-activated protein (MAP) kinase, type III procollagen mRNA expression and the medium N-terminal procollagen III propeptide (PIIINP) concentration in a hepatic stellate cell line (L910) were examined.

**Results:** TJ-135 prevented fibrosis in a dose-dependent manner up to 1.5% (w/w). TJ-135 also reduced the expression of type III procollagen mRNA in the liver, as well as the number of activated stellate cells. Furthermore, TJ-135 reduced the area of preneoplastic lesions in the liver. With L910 cells, TJ-135 reduced MAP kinase (ERK and JNK but not P38) activities resulting in reduced type III procollagen mRNA and PIIINP concentrations in the medium in a dose-dependent manner.

**Conclusions:** These results indicate that although TJ-135 has anti-apoptotic activity, TJ-135 does not increase preneoplastic lesions but significantly reduces liver fibrosis through the inhibition of stellate cell activation without a reduction of hepatocyte cell death.
Preventive effects of oren-gedoku-to on mucositis caused by anticancer agents in patients with acute leukemia


Most anticancer agents frequently cause mucositis, such as stomatitis and gastrointestinal mucosal injury, which is closely associated with decrease in quality of life, infections and discontinuation of chemotherapy in patients with malignancy. We retrospectively evaluated the preventive effect of oral administration of oren-gedoku-to on stomatitis and diarrhea induced by cytotoxic drugs in 40 patients with acute leukemia. Incidence of stomatitis was 27.9% in the group given oren-gedoku-to, which was significantly lower compared with 71.6% in those who received a gargle consisting of allopurinol, sodium gualenate, and povidone-iodine. Drug-induced diarrhea was observed in 9.3% of the oren-gedoku-to group compared with 31.7% of the control group. These observations indicate a significant preventive effect of oren-gedoku-to on mucositis caused by anticancer agents.

Inhibitory effects of Oren-Gedoku-To (Huanglian-Jie-Du-Tang) on free radical-induced lysis of human red blood cells


Oren-gedoku-to (Huanglian-Jie-Du-Tang, OGT) has been used for the treatment of cerebrovascular disease, hypertension, gastritis and liver disease in Japan. The present study was to test our hypothesis that ingestion of Oren-gedoku-to extract (TJ-15) would protect red blood cell (RBC) membrane from free radical-induced oxidation if antioxidants in OGT could be absorbed and circulated in blood. When incubated with RBC suspension, OGT and its four constituting herbs provided strong protection for RBC membrane to hemolysis induced by 2,2-azo-bis (2-amidinopropane) dihydrochloride (AAPH), an azo free radical initiator. The inhibitory effect was in a dose-dependent manner at concentrations of 5 microgram/ml to 500 microgram/ml. Furthermore, the ingestion of 7.5 g of OGT (daily dose) was associated with a significant decrease in susceptibility of RBC to hemolysis in humans. The direct protection of RBC membrane from free-radical attack as observed in the present study could provide an important pathophysiological basis for making use of the favorable hemorheological effect of OGT.

A pilot study comparing the clinical effects of Jia-Wey Shiau-Yau San, a traditional Chinese herbal prescription, and a continuous combined hormone replacement therapy in postmenopausal women with climacteric symptoms


Objectives: Interest in use of alternative remedies for managing menopausal symptoms is increasing exponentially during these years. Jia-Wey Shiau-Yau San (JWSYS), one of the traditional Chinese herbal prescriptions, is a famous herbal remedy used for the management of various menopausal-related symptoms. A randomized, controlled pilot study was performed to evaluate the clinical effects of JWSYS compared with those of a continuous combined hormone replacement therapy, Premelle, on quality of life in non-hysterectomized postmenopausal women.

Methods: The present trial compared the effect of a 16-week treatment with JWSYS or HRT (Premelle) in postmenopausal women with climacteric symptoms. The Greene Climacteric Scale was used to assess the clinical effects at baseline and after 16 weeks’ treatment with either JWSYS or Premelle. The physiological parameters, such as follicle-stimulating hormone and estradiol levels, were also recorded at the same time points.

Results: The results showed that JWSYS had a relatively lower discontinuation rate due to adverse effects, in particular the bleeding and breast tenderness. Both JWSYS and Premelle effectively alleviated most of the menopausal symptoms with no significant differences between treatment groups, whereas the beneficial effects of JWSYS were not mediated by hormone replacement-like effects. Moreover, JWSYS showed a good compliance and safety without estrogenic effects and metabolic alterations.

Conclusions: It was suggested that JWSYS was a safe and efficacious therapy and might be an alternative choice for relief of climacteric symptoms in postmenopausal women. However, the exact efficacy and clinical roles of JWSYS have not been convincingly demonstrated in this study because of the blinding approach and some statistical concerns, and only the possibility of its efficacy has been raised. Therefore, a blinding trial with more patient numbers to evaluate the efficacy of JWSYS deserves further study.
Comparative efficacy of Keishi-bukuryo-gan and pentoxifylline on RBC deformability in patients with "oketsu" syndrome


Keishi-bukuryo-gan (Gui-Zhi-Fu-Ling-Wan) (KBG) is one of the prescriptions used in Japan for improving the "oketsu" syndrome, so-called blood stasis syndrome. "Oketsu" syndrome is an important pathological conception in Japanese traditional medicine and often accompanies cerebro-vascular disorders. Previously, we were able to reveal a deterioration of RBC (Red blood cell) deformability and viscoelasticity in patients with "oketsu" syndrome. The purpose of the present study was to evaluate whether KBG has an effect on RBC deformability in comparison with pentoxifylline (PXF).

The subjects were 30 male patients with multiple lacunar infarctions. Eighteen patients (44-79 yrs, mean +/- SD, 66.1 +/- 10.7 yrs) were treated with 12 g of KBG daily for 4 weeks (KBG group). Twelve patients (59-78 yrs, 70.7 +/- 6.4 yrs) were treated with 300 mg of PXF daily for 4 weeks (PXF group).

Based on the "oketsu" score, the patients of each group were divided into two subgroups, a non-"oketsu" group ("oketsu" score 20 points or less) and an "oketsu" group ("oketsu" score 21 points or higher). KBG had significant effects on RBC deformability as evaluated by filtration method. KBG also significantly increased intracellular ATP content, as did PXF. Moreover, KBG was more effective for patients with a more severe "oketsu" state. However, PXF was effective only in patients with "oketsu" syndrome, who might have deteriorated RBC deformability. In conclusion, the effect of KBG on RBC deformability was by no means inferior to PXF.

Menopausal hot flash and calcitonin gene-related peptide; effect of Keishi-bukuryo-gan a kampo medicine, related to plasma calcitonin gene-related peptide level

Chen JT, Shiraki M. Maturitas 2003;45:199-204

Objectives: The purpose of this study is to investigate relationship of menopausal hot flash and calcitonin gene-related peptide (CGRP). Furthermore, this study evaluated the effect of the Japanese herbal (kampo) medicine Keishi-bukuryo-gan from the aspect of CGRP regulation.

Methods: Plasma CGRP and vasoactive intestinal peptide (VIP) levels were measured during hot flash and CGRP reactivity was studied by cold load test in subjects with/without hot flashes. The effect of Keishi-bukuryo-gan (Gui-Zhi-Fu-Ling-Wan) was assessed in comparison with plasma CGRP level.

Results: Only plasma CGRP but not VIP significantly elevated at the occurrence of hot flash (p=0.002). Stress by cold load significantly enhanced the over-secretion of CGRP in subjects with flash compared with those without flash (p=0.003) 3 min after the load. Keishi-bukuryo-gan decreased plasma CGRP level in subjects with hot flash.

Conclusions: CGRP but not VIP was mainly related to the occurrence of hot flash. Keishi-bukuryo-gan improves hot flash possibly affecting plasma CGRP level.

Therapeutic usefulness of Keishi-bukuryo-gan for diabetic nephropathy


Keishi-bukuryo-gan is a traditional herbal medicine, which is used clinically as a vascular system disorder-eliminating drug. In this study, its effect on the progression of diabetic nephropathy in experimental rats was investigated. The diabetic nephropathy model used in this study shows functional and morphological changes of the kidney resembling those seen in patients with diabetic nephropathy. Increased proteinuria and serum urea nitrogen and creatinine levels and decreased creatinine clearance, which are important parameters of renal function, were observed in rats with diabetic nephropathy. Pathological examination of the kidney revealed diffuse, nodular and exudative lesions and arteriolar hyalinosis. The deterioration of renal function was ameliorated in rats treated with Keishi-bukuryo-gan for 15 weeks and these results agreed with the renal histological findings. In addition, metabolic abnormalities mediated by persistent hyperglycaemia (the glycation reaction, excessive polyol pathway activity, oxidative stress and lipid metabolic abnormalities) were also observed. However, Keishi-bukuryo-gan reduced accumulation of advanced glycation end products, determined by measuring fluorescence, and serum lipid peroxidation, triglyceride and total cholesterol levels dose-dependently.

Thus, this study indicates the potential therapeutic usefulness of Keishi-bukuryo-gan for retarding the progression of renal damage and suggests that its beneficial effects were due to its ability to improve metabolic abnormalities associated with diabetes.
Effects of the Japanese herbal medicine Keishi-bukuryo-gan and 17beta-estradiol on calcitonin gene-related peptide-induced elevation of skin temperature in ovariectomized rats


The effects of a Japanese herbal medicine, Keishi-bukuryo-gan (Gui-Zhi-Fu-Ling-Wan), and 17β-estradiol on calcitonin gene-related peptide (CGRP)-induced elevation of skin temperature were investigated in ovariectomized (OVX) rats. Ovariectomy not only potentiated CGRP-induced elevation of skin temperature and arterial vasorelaxation but also induced a lower concentration of endogenous CGRP in plasma and up-regulation of arterial CGRP receptors, suggesting that lowered CGRP in plasma due to ovarian hormone deficiency increases the number of CGRP receptors and consequently amplifies the stimulatory effects of CGRP to elevate skin temperature. Oral Keishi-bukuryo-gan (100-1000 mg/kg, once a day for 7 days) restored a series of CGRP-related responses observed in OVX rats by normalizing plasma CGRP levels in a dose-dependent manner as effectively as s.c. injection. 17β-estradiol (0.010 mg/kg, once a day for 7 days). However, Keishi-bukuryo-gan did not affect the lower concentration of plasma estradiol and the decreased uterine weight due to ovariectomy, although the hormone replacement of 17β-estradiol restored them. These results suggest that Keishi-bukuryo-gan, which does not confer estrogen activity on plasma, may be useful for the treatment of hot flashes in patients for whom estrogen replacement therapy is contraindicated, as well as menopausal women.

The stimulatory effects of nasal discharge from patients with perennial allergic rhinitis on normal human neutrophils are normalized after treatment with a new mixed formula of Chinese herbs


In our previous study, we found a new mixed formula of Chinese herbs containing Shin-yi-san (辛夷散) + Xiao-qing-long-tang (小青龙汤) + Xiang-sha-liu-jun-zi-tang (香砂六君子汤) (9 + 3 + 3 g divided in 3 doses/day) was beneficial to the patients with perennial allergic rhinitis (AR) via complicated immunomodulatory effects on both mononuclear cells (MNC) and polymorphonuclear neutrophils (PMN). In the present study, we further determined the effects of nasal fluid from AR patients on the functions of human PMN before and after treatment with the mixed formula. We found the nasal discharge, but not serum, from AR group with high serum IgE (H-IgE, serum IgE>200 KIU/l) before treatment exerted many stimulating effects on normal PMN including delayed apoptosis, enhanced production of soluble intercellular adhesion molecule 1 (sICAM-1), interleukin 8 (IL-8) and prostaglandin E2 (PGE2), increased phagocytosis, and augmented cycloxygenase 2 (COX-2) mRNA expression of PMN. However, these stimulating effects of nasal fluid on PMN were not found in low IgE group (L-IgE, serum IgE<200 KIU/l). These PMN-enhancing effects of H-IgE nasal fluid were abolished after 3-month treatment with the mixed Chinese herb formula. In conclusion, our results suggest that the new mixed herb formula treatment suppressed nasal mucosa inflammation by normalizing stimulatory effects of allergic nasal discharge of patients with H-IgE allergic rhinitis.

Effectiveness of Gorei-san (TJ-17) for treatment of SSRI-induced nausea and dyspepsia: preliminary observations


Selective serotonin reuptake inhibitors (SSRIs) are apt to cause gastrointestinal adverse events such as nausea and dyspepsia. Gorei-san (TJ-17), or Wu Ling San in Chinese, is composed of five herbs (Alismatis rhizoma, Atractylodis lanceae rhizoma, Polyporus, Hoelen, and Cinnamomi cortex) and has been used to treat nausea, dry mouth, edema, headache, and dizziness. The authors investigated the efficacy of TJ-17 for patients who experienced nausea or dyspepsia induced by SSRIs. Twenty outpatients who experienced nausea or dyspepsia induced by SSRIs were recruited for the study. Seventeen patients were female, three were male, and patient age ranged from 21 to 74 years (49.8 +/- 17.0 years). TJ-17 was added to the previous regimen. Nausea and dyspepsia disappeared completely in nine patients, decreased in four patients, decreased slightly in two patients, and did not change in five patients. No adverse events were associated with the addition of TJ-17 in any patient.