Summaries of recent papers

Migraine prophylaxis: randomised controlled trial


Multicenter, randomised control trial (n=140) comparing traditional acupuncture with medication.

Methods

Adult patients diagnosed with migraine without aura who had previously not had prophylactic treatment were recruited from five hospital outpatient departments. They were randomised to two groups in equal numbers: (1) the treatment group had verum acupuncture plus placebo medication and (2) the control group had sham acupuncture plus flunarizine, a drug recommended as a first-line preventive treatment of migraine. The study period of 20 weeks included a baseline observation period of 4 weeks, a treatment period of 4 weeks, and follow-up period of 12 weeks.

Both verum and sham acupuncture groups had three treatment sessions lasting 30 min each week for 4 weeks which were conducted by experienced acupuncture practitioners. In both groups, needles were stimulated manually to achieve a sensation of de qi. Obligatory acupuncture points used in the verum acupuncture group included scalp points GV20, GV24, GB13, GB8 and GB20. Additional acupuncture points could be chosen according to the features of the headache according to traditional Chinese medicine (TCM) headache types. Sham acupuncture points were chosen on the basis of having no known association with headache according to TCM. They were selected over the elbows and knees and were 3 mm away from the correct site of the actual acupuncture points.

The primary outcome measure was the proportion of patients with at least 50% reduction in the number of migraine days (responders). Secondary outcomes included the Visual Analogue Scale (VAS) for pain, a general health survey, acute medication use and adverse events.

Results

Significant differences were seen in the responder rates in the treatment group in comparison with the control group of 59% versus 40% after 4 weeks (p=0.043), and 56% versus 37% after 16 weeks (p=0.042). The number of patients using acute medication was also reduced significantly in the treatment group compared with the control group at weeks 4 and 16. No differences were seen between the two groups in pain intensity as assessed by VAS, or in quality-of-life scores (figure 1).

Comment

Judging by the title of the trial ‘double-dummy’, the authors have assumed that the type of sham needling used has no clinical effect on migraine and that the comparison is between verum acupuncture and the active drug only. However, acupuncture at non-acupuncture sites has been shown to have physiological analgesic effects by the mechanisms of diffuse noxious inhibitory controls and the descending inhibitory pain pathways. In reality, this trial is likely to have been a comparison of segmental acupuncture (plus placebo drug), with non-segmental, weaker acupuncture plus active drug. The assumption is that a bigger effect size could be attributed to acupuncture alone than has found is this study. This study adds to the accumulating evidence that acupuncture is effective for migraine prophylaxis.¹

REFERENCE


Infant colic 1: case series


This exploratory case series (n=913) documents changes in symptoms after acupuncture.

Methods

This study included 913 infants with normal weights and lengths at birth; data were incomplete on another 79 infants. The infants’ mean age was 5.4 weeks when the observations started. Light needling stimulation at LI4 was performed (insertion depth 1–3 mm with light stimulation until some resistance was felt) daily for 10–20 s bilaterally for a mean of 6.2 consecutive days. A questionnaire with verbal rating scales for parents to evaluate a range of symptoms was used before and after the treatment period.

Results

Before treatment the infants were assessed by the parents with phrases such as ‘often have infl ated stomachs’
(99%) and ‘seldom drool’ (76%), ‘regurgitate’ (53%) and ‘belch’ (62%). The reported frequency of defecation was 5–8 times/day (64%), with a yellowish-green colour (61%) and with a water-thin consistency (74%). After treatment, the variables inflated stomachs, drooling and regurgitating were systematically changed, and rated by the parents as occurring ‘sometimes’ while belching was rated as occurring ‘often’. The frequency of defecation was reduced to 1–4 times/day. The parents also rated their impression of the infants’ general colic symptoms, including crying behaviour, as much ameliorated in 76% of cases (figure 2).

Figure 2 Parent’s ratings of colic response to acupuncture.

Infant colic 2: randomised controlled trial


The aim was to describe the feeding and bowel actions in a blinded study (n=90) of acupuncture for infantile colic.

Methods

A prospective, randomised, controlled, blind clinical study was conducted at a private acupuncture clinic in Sweden. Ninety otherwise healthy 2–8-week-old infants fulfilling the criteria for infantile colic and not receiving dicyclomine were included. Eighty-one infants went through a structured programme consisting of six visits to the clinic, twice weekly. Infants randomised to receive acupuncture were given minimal, standardised acupuncture for 2 s at LI4 in one hand only. The control group were seen by the acupuncturist, but were not needled. Frequency and size of bowel action and duration of feeding sessions were reported by parents in a diary. The overall effect was evaluated by report on sleeping patterns.

Results

At baseline, both groups had bowel actions more frequently (4.2 times/day) than normal in infants of this age. There were no differences between groups in the frequency and duration of feeding during the intervention weeks. Furthermore, there were no significant differences between the groups in the frequency of bowel action, either at baseline or during the intervention weeks. There was an expected decrease in frequency of bowel action in both groups, reaching 2.1 (p=0.001) in the acupuncture group and 3.1 (p<0.001) in the control group. More parents in the acupuncture group than in the control group (28% and 15% respectively, p=0.006) reported the infant’s sleep to be ‘better’ or ‘much better’ (figure 3).

Comment on both studies

The clinical diagnosis of infant colic is based on the children’s crying behaviour characterised by ‘paroxysmal and inconsolable crying’ predominantly in the evening (when parents need to sit down and relax!) together with typical body language with flexed knees, clenched fists and a grimacing face, often flushed. Its pathogenesis is not well understood.

The original randomised controlled trial (RCT) of acupuncture for infantile colic found an effect with four sessions of brief acupuncture. These further, somewhat exploratory, studies aimed at throwing some light on the mechanisms of acupuncture. So they concentrated on reported changes in the various symptoms that are associated with infantile colic.

Both studies showed overall improvements in the child’s condition after acupuncture, though the blinded study shows that some of the effect is due to expectancy, as one would expect. It is noteworthy that the acupuncture dose was lower in the RCT than the case series–only unilateral and only 2 s duration.

The large case series found that drooling increased but intestinal infl ation was reduced. The blinded study only showed a trend towards greater reduction of stool frequency in the acupuncture group—both groups improved significantly, which is expected during this stage of fetal development.

These findings are consistent with the currently proposed mechanism of acupuncture in colic. During the insertion of the needle, the sympathetic tone is increased, generating a decreased gastrointestinal activity. After acupuncture, the autonomic activity may be characterised by an increased parasympathetic tone and decreased sympathetic tone, resulting in increased gastrointestinal motility.

The ‘bottom line’ remains: brief acupuncture is a safe and effective treatment for infantile colic which seems highly acceptable to parents.
REFERENCE

Primary dysmenorrhoea: RCT

Randomised control trial (n=92) comparing real acupuncture with placebo needle.

Methods
This was a community study of women aged 14–25 with moderate severity of primary dysmenorrhoea who were not responding well to analgesics.

Women underwent an initial TCM diagnosis to identify the TCM pattern causing dysmenorrhoea. Both groups received treatment for 30–40 min each week for 3 weeks, followed by a break in treatment during the week that menses was due. This sequence was repeated for three menstrual cycles, after which there was a follow-up observational period for a further 3 and 12 months with no further treatment.

Primary acupuncture points in the real acupuncture group included SP4, SP6, SP8, ST29, CV3 and BL32 with additional points used according to the individual diagnoses. Bilateral points were used with a minimum of seven points at each treatment. Acupuncture was carried out by experienced acupuncture practitioners who stimulated the acupuncture needles manually to achieve de qi after initial insertion of the needles and then half way through each 30–40 min session.

The control group received sham acupuncture using a Streitberger placebo needle placed 2–4 cm away from acupuncture points or meridians. Locations included the sacrum, lower back, lower abdomen, foot, lower leg and forearm. The placebo needle tip was blunted and the authors report that skin penetration did not occur.

Results
Women in the acupuncture group reported a significant reduction in the duration of menstrual pain and need for analgesia at 6 months. Pain intensity was lower at 3 and 6 months but the difference did not reach statistical significance. None of these improvements were sustained at the 12-month follow-up. Mood changes were reduced during the 3-month treatment phase in the acupuncture group (figure 4).

Comment
This study failed to show sufficient evidence of effective relief of menstrual pain using acupuncture but may not have had the statistical power to do so. The effectiveness of the blinding of the control is called into question since 41% of women receiving acupuncture believed they had received true acupuncture, but the figure was only 22% in those receiving the placebo needle.

Pain of photoocoagulation: controlled trial

Feasibility study (n=36) of acupuncture for pain associated with laser eye treatment.

Methods
Patients attending for panretinal photocoagulation (PRP) were offered acupuncture whenever an acupuncturist was available at the same time as the ophthalmologist. This was a prospective, comparative non-randomised study on patients with proliferative diabetic retinopathy who were receiving PRP treatment. The protocol of PRP included three sessions of treatment at 2-week intervals. Paracetamol 500 mg was given for each session. No patients had acupuncture in the first or third sessions. In the second session, acupuncture was given to one group only. Acupuncture was performed only at GB37 on one leg, just before the laser procedure. The needle was inserted to about 0.5 cm and stimulated manually to achieve de qi, then left in place until after the treatment, which took 10–15 min, or stimulated once more if the patient complained of pain. An 11-point Likert-type verbal pain score was completed by all patients after each PRP treatment.

Results
Of 34 patients with proliferative diabetic retinopathy, 18 were allocated to the acupuncture group and 16 to the
control group. Groups were similar at baseline, and there was no statistical difference in mean pain scores at the first PRP session (without acupuncture). After the second PRP treatment, the mean pain score in the acupuncture group was significantly lower than in the control group (p<0.0001). No adverse reactions or complications were noted (figure 5).

Comment
The effect looks useful clinically, but the study is open to several biases, most importantly selection bias, leading to high hope of acupuncture in all patients and therefore resentful demoralisation in the untreated controls. So it is not possible to say how much of the effect would be reproduced in another study or another clinical setting.

**Temporomandibular joint disorders: systematic review**


Systematic review of seven RCTs of acupuncture versus sham acupuncture.

**Methods**

Thirteen electronic databases were searched systematically, including seven Korean databases and a Chinese database (China Academic Journal, http://www.cnki.co.kr). Parallel or cross-over RCTs of acupuncture compared with sham acupuncture for temporomandibular joint disorder (TMD) were included.

**Results**

A total of seven RCTs met inclusion criteria, with 141 patients. Five trials showed a low risk of bias. Six used needle acupuncture, one used laser acupuncture. The points used were various combinations of LI4 most commonly, followed by SI3, ST6, SI18, SI2 and ST7. Needle acupuncture was significantly better than sham acupuncture for reducing pain, as shown in the figure. The mean reduction in pain VAS was −13.6 (95% CI −23.83 to −1.97) (figure 6).

**Comment**

This is the third systematic review of acupuncture for TMD since 2010. All three have concluded that a large trial is needed, fully justified by the evidence and important to conduct. The amount of researcher effort spent on the reviews would have gone some way towards designing that trial.

**Necrotising fasciitis: case report (safety)**


Necrotising fasciitis as a possible complication of acupuncture (n=1).

**Case report**

A 44-year-old woman with known aplastic anaemia received one session of acupuncture for pain in her right calf, four needles for 20 min. She developed pain in her calf 2 days later. Ten days later she was admitted to hospital with calf pain, swelling and redness at the needle site, limited mobility and fever. Haemoglobin was 5.7 g/100 ml, white cell count 500/μl. She was treated initially for cellulitis with intravenous antibiotics. A CT scan of her leg and ultrasound-guided aspiration of fluid in her gastrocnemius muscle confirmed a diagnosis of necrotising fasciitis due to *Staphylococcus aureus* infection. The patient declined surgical debridement and required hospitalisation for 3 weeks, on intravenous antibiotics for 18 days.

**Comment**

The authors concluded that this patient had had an iatrogenic infection, caused by acupuncture. The acupuncturist was TCM trained, experienced and had used single-use sterile needles and skin disinfectant. It was not stated whether he had asked about the patient’s aplastic anaemia, though it was stated that the patient did not inform him. They suggest due care in offering acupuncture to an immunocompromised patient, even suggesting performing treatment in a positive air pressure environment; I think, only a few acupuncturists are in a position to do so.

For a healthcare practitioner providing acupuncture, the main learning points are the need for good history taking, awareness of infective complications due to acupuncture, good technique and careful consideration when offering acupuncture to an immunocompromised patient.

**Opioid receptors in neuropathy: basic research**


The importance of this study is that there is no current effective treatment for chemotherapy-induced peripheral neuropathy, but some early reports suggest that acupuncture might have an effect. Two experiments were conducted. The first was to study the effect of electroacupuncture (EA) on peripheral neuropathy in rats induced by injecting paclitaxel, a chemotherapy agent commonly known to cause neurotoxicity. Treatment consisted of electrical stimulation of needles inserted bilaterally at GB30. Interestingly, the sham acupuncture groups also had needles inserted at GB30 but with no electrical or manual stimulation. This part of the experiment showed
The authors have hypothesised that the mechanism of action is through EA activation of μ opioid receptors which reduce the GABAergic inhibitory transmission of the dopaminergic neurons in the ventral tegmental area (VTA) and thus increase the VTA dopaminergic neuron activity by a mechanism of disinhibition. This finding should certainly stimulate further research.

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Research shorts

that EA at 10 Hz was significantly more effective in reducing mechanical hyperalgesia-like and allodynia-like behaviour than EA at 100 Hz. (figure 7).

The second experiment involved three groups of paclitaxel-treated rats which were injected respectively with μ, δ and κ opioid receptor antagonists, and a fourth group injected with saline. Each group was then subdivided into two further groups, one of which was treated with EA at 10 Hz and the other with sham acupuncture as before. The results showed that 10 Hz EA inhibited paclitaxel-induced neuropathic pain by activating all three opioid receptor subtypes μ, δ and κ. Thus acupuncture’s effect on neuropathic pain seems to use different mechanisms from its effect on inflammatory pain, which depends on μ and δ, but not κ receptors.

Reduced voluntary alcohol intake: basic research


2 Hz electroacupuncture but not 100 Hz reduces voluntary alcohol intake in rats.

Methods

Rats were trained to self-administer alcohol which led them to increase their intake considerably and become dependent. The control group were alcohol naive and a third group of rats were trained to drink 5% sucrose solution under the same conditions.

Thereafter, EA (or sham EA) was given to the rats 30 min before access to alcohol or 5% sucrose solution. EA was applied at ST36 bilaterally while sham EA was applied to the tail at a non-acupuncture point and no current stimulation applied. A subgroup of the EA treatment group were allowed to continue drinking alcohol and were then treated with high-frequency (100 Hz) EA after a 2-week recovery from the 2 Hz EA treatment.

Results

Low-frequency (2 Hz) EA but not high-frequency (100 Hz) EA significantly decreased the alcohol intake compared with sham EA treatment. In comparison, low-frequency EA applied at ST36 did not significantly alter sucrose intake. Repeated EA reduced the intake and preference for alcohol but this returned to pretreatment levels when the EA treatment was stopped (figure 8).

Comment

The authors have hypothesised that the mechanism of action is through EA activation of μ opioid receptors which reduce the GABAergic inhibitory transmission of the dopaminergic neurons in the ventral tegmental area (VTA) and thus increase the VTA dopaminergic neuron activity by a mechanism of disinhibition. This finding should certainly stimulate further research.

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Figure 7 Alloodynia scores in different groups. EA, electroacupuncture.

Figure 8 Low-frequency (2 Hz) electroacupuncture reduces alcohol consumption.
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