Summaries of recent papers

Chronic obstructive pulmonary disease: RCT

A three-arm study (n=60) of acupuncture as an adjunct to an intensive pulmonary rehabilitation programme.

Methods
A randomised controlled trial (RCT) in participants who fulfilled the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria for severe chronic obstructive pulmonary disease (COPD). Nineteen controls had no specific intervention; 25 underwent physical rehabilitation (PR) alone and 16 had both acupuncture and PR. Intensive PR consisted of twice weekly attendances for exercise and education over 2 h, plus inspiratory muscle training and unsupervised home exercise on 3 days each week. Additional acupuncture consisted of seven once a week sessions (immediately after a PR class), using points LI11, LI10, TE10, TE6, LU5 and LU7. Stimulation details are not reported. The control group duration was only 8 weeks, after which they started either PR alone or PR and acupuncture; they had no 3-month follow-up.

The primary outcome was a change in measures of systemic inflammation (interleukins, tumour necrosis factor α and C-reactive protein (CRP)) at the end of PR. Secondary end points were lung function, including maximum inspiratory pressure (PiMax), quality-of-life scores with the St George’s questionnaire, functional capacity (including steps taken, dyspnoea scores and exercise capacity).

Results
There were no changes in measures of systemic inflammation in any group. After PR, both groups had significantly improved quality-of-life scores, reduced dyspnoea scores, improved exercise capacity and PiMax compared with the controls. After both 7 weeks and 3 months, the acupuncture group showed greater improvement in Borg scores than PR alone (figure 1). There was also a trend towards a lower CRP in the acupuncture group. There were no other differences between the two treatment groups.

The primary outcome selected was changes in inflammatory indices—but there were no changes in either the acupuncture or rehabilitation groups, so this is not a meaningful outcome. Future studies should use clinical outcomes. It seems that acupuncture may have a clinically useful effect as the Borg score was significantly improved. There were some other trends in the data, which are likely to justify further, larger studies. There may have been a ‘ceiling’ effect of the intensive exercise.

Although the headline conclusion is ‘negative’, this study does certainly not amount to a dismissal of the role of acupuncture in this condition.

Childhood asthma: RCT

Randomised controlled trials (RCTs) (n=93) of the effects of acupuncture as part of rehabilitation.

Methods
Patients aged 12–17 years had asthma and were undergoing inpatient rehabilitation and using inhaled corticosteroids with on-demand β-agonists (National Guidelines steps 2–4). Twelve sessions of acupuncture were given in 4 weeks, at BL13, CV17 (obliquely to depth 2–3 mm), and LU7 as obligatory points: plus six optional points according to traditional Chinese medicine diagnosis—mucous symptoms: ST40, kidney qi deficiency: KI6; lung yin deficiency LI11; stomach heat: ST41, grief, worries, anxieties: BL42. The control group had a group discussion with a doctor.

The study was designed to identify a difference in peak expiratory flow rate of 10 litre/s. The severity of symptoms, lung function, illness-specific quality of life (Paediatric Asthma Quality of Life Questionnaire) and general and asthma-specific level of anxiety (State Trait Anxiety Inventory for Children) were investigated in 46 patients receiving acupuncture and 47 control patients. In addition to asthma sports, climate therapy and behavioural training, the intervention group received acupuncture treatment with a standardised needle pattern (12×30 min).

Results
The dropout rate was 27%. There was significant improvement in most parameters in both groups. The lung function tests and quality-of-life scores did not show any differences between groups. The peak expiratory flow variability differed significantly (p<0.01) between the groups (figure 2). The acupuncture group also had lower perceived anxiety scores. These differences were no longer significant at 4 months’ follow-up.
**Acupuncture research update**

**Comment**

About half of children with severe asthma receive some form of complementary medicine or another. There is little research into acupuncture for asthma in children so this is a preliminary study to observe whether there is an overall effect. It was actually a 'tough call' for acupuncture since the children were also receiving other forms of rehabilitation. The study was designed to observe a difference in peak expiratory flow rate (PEFR) but the actual PEFR results were not presented. The two positive findings (PEFR variability and anxiety) were secondary measures, so should be interpreted cautiously.

**Migraine prophylaxis: RCT**


Randomised controlled trial (RCT) n=480, with four arms.

**Methods**

Four hundred and eighty patients with migraine were randomly assigned to one of four groups, on the basis that migraine in traditional Chinese medicine diagnosis is 'Shaoyang', treated best at precise points and as second best at other points on the Shaoyang meridians, TE and GB. Therefore the treatments were (1) Shaoyang-specific acupuncture (TE5, GB34, GB40, GB20); (2) Shaoyang-nonspecific acupuncture (TE19, TE8, GB38, GB42); (3) Yangming-specific acupuncture (ST8, LI6, ST36, ST42) or (4) 'sham' acupuncture control (off-point needling at three sites in the arm and one in the leg). (My quotation marks round 'sham'). De qi was elicited in the first three groups: electroacupuncture (EA) at 2–100 Hz was used in all groups. There is confusion over whether or not shorter needles were used in the 'sham' group than the other groups.

All groups received 20 treatments over a period of 4 weeks. The primary outcome was the number of days on which a migraine was experienced during weeks 5–8 after randomisation. Secondary outcomes included the frequency of migraine attack, migraine intensity and migraine-specific quality of life.

**Results**

The primary outcome was negative, figure 3: compared with patients in the control group, patients in the acupuncture groups reported fewer days with a migraine during weeks 5–8; however, the differences between treatments were not significant (p>0.05). Other analyses were positive for acupuncture: there was a significant reduction in the number of days with a migraine during weeks 13–16 in all acupuncture groups compared with control. There was a significant, but not clinically relevant, benefit for almost all secondary outcomes in the three acupuncture groups compared with the control group. There were no relevant differences between the three acupuncture groups.

**Comment**

This trial used a larger number and frequency of treatments than many other trials of acupuncture for migraine. But it confirms the current state of the evidence—namely, that for migraine prophylaxis, point location is not important. Whether a reduction from six headaches a week to two is a placebo effect, an acupuncture effect or an effect of time cannot be decided from this study as it did not have a usual-care control group.

The authors comment that the size of the effect of acupuncture compared with 'sham' was 'clinically minor' but this is irrelevant because clinically there is no choice between sham and real acupuncture! Still tests appeared to have an effect on migraine prophylaxis compared with sham acupuncture. This is another of those studies that show an effect not at the end of treatment but at follow-up some months later. The use of EA is typical in China so was used in the control group to aid blinding. The researchers described what they intended to be 'sham' acupuncture as 'modern theory of acupuncture' in the information to participants, which raises ethical questions. Using EA in all groups makes interpretation difficult.

**Dental anxiety: RCT**


Randomised controlled trial (RCT) comparing acupuncture with sham and no intervention, n=182.

**Figure 4** True and sham points used.

**Methods**

This prospective, randomised patient-blinded study with 182 patients compared anxiety before dental treatment after auricular acupuncture at the relaxation, tranquilliser and master cerebral points (auricular acupuncture group, see figure 4) versus acupuncture at sham points (finger, shoulder and tonsil points; sham group) and a non-intervention control group. Needles were left in situ for 20 min before dental surgery. The acupuncturist had no other role in the study. Anxiety was assessed using the Spielberger State Trait Anxiety Inventory (German version) before auricular acupuncture and 20 min thereafter, immediately before dental treatment. Scores of >40 indicated a high level of anxiety and >50 very high.
Results

Twenty per cent of patients in both acupuncture groups noted warmth or strange feelings, and there was no difference in credibility, but there was a slightly higher belief in acupuncture in the true acupuncture group.

Auricular acupuncture reduced the state anxiety score more effectively than sham acupuncture (p=0.0008), figure 5. In contrast, state anxiety in the non-intervention control group increased and was statistically different from both intervention groups (p<0.001). After correcting for group differences in baseline state anxiety, the reduction in anxiety was −7.3 score points (CI −9.0 to −5.6) in the auricular acupuncture group and −3.7 score points (CI −5.4 to −1.9) in the sham group (p=0.008).

Comment

Only 14% of all screened patients could be included, mainly because anxiety levels were generally low. After the study, 98% of participants would want to use acupuncture for future dental work, regardless of its perceived benefit—which implies ‘negative placebo’ was strong in the no-intervention control group. This reviewer finds the point specificity shown in the results difficult to explain: it can hardly have a neurological basis, so one has to wonder if there might have been subconscious bias from the acupuncturist.

Preoperative anxiety: RCT


Body and auricular acupuncture were compared (n=35).

Methods

Thirty-five elective ambulatory surgery patients who scored over 50 on the Zung Self-Rating Anxiety Scale (SAS) were included. Patients receiving treatment for anxiety or with a psychiatric diagnosis were excluded. Subjects were randomly allocated in two intervention groups, each with eight sessions in 4 weeks. The body acupuncture group received acupuncture at GV20 and its four surrounding points, LR3 and Yintang between the eyebrows. The auricular acupuncture group received ear acupuncture at the Shenmen point. The SAS was completed again after acupuncture but before surgery.

Results

Three patients, all in the auricular acupuncture group, dropped out. There were significant reductions in the SAS scores in both groups (p<0.01), but no difference between them (see figure 6).

Comment

The effect of acupuncture on anxiety is an important topic, but this study provides little additional information. It has no clear hypothesis. It was conducted in 2005–6 and published in 2011. There are some deficiencies in the reporting, especially details of treatment. The authors’ claim that ‘both auricular and body acupuncture treatment methods were effective’ cannot be supported—anxiety in pre-operative patients might have been reduced owing to several factors. A different study design and analysis would be needed to show that the two treatments were ‘equivalent’.

Polycystic ovarian syndrome: RCT


Sham-controlled randomised controlled trials (RCT), n=84.

Methods

This was a randomised, double-blind, sham-controlled clinical trial (5-month protocol). Eighty-four women of reproductive age completed the intervention. Eligibility required a polycystic ovarian syndrome diagnosis and no hormonal intervention 60 days before enrolment. Intervention included 12 sessions of true electroacupuncture at BL23, BL28, SP6, SP9 and manual stimulation at PC6, TE5, GV20. Sham acupuncture consisted of the Park sham device placed on standardised, non-point locations on all four extremities. Sessions were twice a week for 4 weeks, then weekly for 4 weeks. Serum luteinising hormone (LH) and follicle-stimulating hormone (FSH) were measured at baseline, after intervention and 3 months later. Ovulation was measured with weekly urine or blood samples.

Results

Both arms demonstrated a similar mean ovulation rate over the 5 months (0.57/month among n=40 true acupuncture and 0.40/month among n=44 sham participants). As shown in figure 7, there were no differences between groups in LH or FSH, or in the LH to FSH ratio.

Figure 5  STAI scores in dental surgery.

Figure 6  Anxiety scores.

Figure 7  Levels of LH and FSH (mIU/ml).
Acupuncture research update

There were seven pregnancies (no difference by intervention, p=0.7). Lower fasting insulin and free testosterone were highly correlated with a higher ovulation rate within the true acupuncture group only (p=0.05), after controlling for prestudy menstrual frequency and body mass index.

Comment

Previous studies in this area have been positive, but small and not sham-controlled. Basically this rigorous study had a negative outcome. The only analysis that might be worth further study was that the subgroup of women with less severe metabolic disturbance tended to show a response to acupuncture.

Polycystic ovary syndrome 2: RCT secondary analysis


![Figure 8](image)

**Figure 8** Plasminogen activator inhibitor 1 (IU.ml) pre and post intervention.

Secondary analyses of a prospective, randomised controlled clinical trial (n=84).

Methods

Women with polycystic ovary syndrome (PCOS) were randomised to (1) acupuncture: 16 weeks of 2 Hz low-frequency electroacupuncture (EA) at CV3, CV6 and ST29, and manual acupuncture at SP6, SP9 and LI4/PC6 alternately (14 treatments over 16 weeks); (2) physical exercise (aerobic, at least three times a week and monitored) or (3) no intervention. Outcomes were anthropometrics, circulating coagulation and fibrinolytic markers, insulin sensitivity (euglycaemic hyperinsulinaemic clamp), haemodynamics and adipose tissue morphology/function, recorded at baseline, after 16 weeks of intervention and after a 16-week follow-up.

Results

Only one outcome was significantly different between the groups. In the low-frequency EA group, circulating plasminogen activator inhibitor 1 activity decreased by 21.8% after 16 weeks of intervention and by 31.1% at the 16-week follow-up and differed from the physical exercise and the no intervention groups, figure 8. The EA group had reductions in circulating fibrinogen and tissue plasminogen activator, sagittal diameter and diastolic blood pressure after treatment, and fibrinogen remained lower at the 16-week follow-up, but these differences were not significant. In the physical exercise group, lipoprotein lipase activity increased and diastolic blood pressure decreased after treatment, and both diastolic and systolic blood pressure were lower at follow-up. No other variables were affected.

Comment

PCOS is associated with an increased risk of thrombosis, which acupuncture may reduce. This study is only exploratory since it was not designed specifically to test this outcome. But this strongly suggests that other studies should investigate this possible effect of acupuncture.

Shoulder impingement syndrome: RCT


Multicentre randomised controlled trials (RCT) (n=91) comparing subacromial corticosteroid injection with acupuncture plus exercises.

Methods

Patients aged 30–65 presenting with shoulder pain of more than 2 months’ duration at five primary healthcare centres were offered a visit to a research physiotherapist. After confirmation of a diagnosis of shoulder impingement syndrome through a standardised process they were randomised to either a corticosteroid or acupuncture group. The corticosteroid group received a subacromial injection of methylprednisolone 40 mg in 1 ml plus 8–10 ml of 1% prilocaine. Thereafter, they were advised to return to normal activities except for the first 2 weeks during which they had to avoid heavy arm activities. The acupuncture group received twice weekly sessions of manual acupuncture over a 5-week period for a total of 10 sessions. Each 30-min session consisted of needling a standardised selection of acupuncture points: LI4, LI14, LI15, LU1 and TE14. Needles (30 mm length and 0.20 mm diameter) were stimulated manually for a few seconds three times to achieve a feeling of *de qi*. In addition, patients receiving acupuncture were taught to do home exercises which focused on restoring motion and strengthening the rotator cuff.

Results

Over the 12-month study period, both the corticosteroid and acupuncture groups reported a significant improvement in pain and shoulder function (p<0.001) compared with baseline, see figure 9. However, there was no significant difference between the two groups with respect to these primary outcomes, nor of the secondary outcome of health-related quality of life. The other secondary outcome of global impression of change was in favour of the acupuncture group at 6 months, but again there was no difference at 12 months.

Comments

The design of this study has a number of limitations. First, although both treatment groups improved, it cannot be known if this was due to the interventions or to the natural course of the disease. However, this study is only exploratory since it was not designed specifically to test this outcome. But this strongly suggests that other studies should investigate this possible effect of acupuncture.
would require a third conservative treatment group to act as a control. The study design also does not allow direct comparison of the two treatment modalities of corticosteroid injection and acupuncture since acupuncture treatment was supplemented with home exercises. Therefore, it is not possible to know how much of the improvement in the acupuncture group was due to acupuncture and how much to the home exercises, if indeed they did have an effect over and above natural resolution of the problem.

Placebo response: RCT


The aim was to quantify non-specific effects of acupuncture, examining needling, the consultation and the practitioner.

Randomised controlled trial (RCT) (n=221) in patients with hip and knee pain.

**Methods**

In a prospective randomised, single-blind, placebo-controlled, multifactorial, mixed-methods trial, 221 patients with osteoarthritis awaiting joint replacement surgery were recruited. Interventions were acupuncture, Streitberger placebo acupuncture and mock electrical stimulation via electrodes. The consultations were either empathic (normal) or non-empathic (efficient, with limited discussion). The acupuncture points were selected by the practitioner from a limited list, with an average of six needles with deep needling and de qi was elicited. Electroacupuncture was not used. The placebo acupuncture was given at the same points. Interventions involved eight 30 min treatments over 4 weeks, which were given by three practitioners. The primary outcome was pain (Visual Analogue Scale) at 1 week after treatment. Face-to-face qualitative interviews were conducted (purposive sample, 27 participants).

**Results**

Improvements occurred from baseline for all interventions, with no significant differences between real and placebo acupuncture (figure 10). Empathic consultations did not affect pain (p=0.26) but practitioner 3 achieved greater analgesia than practitioner 2 (10.9, 3.9 to 18.0; p=0.002). Qualitative analysis indicated that patients’ beliefs about treatment legitimacy and confidence in outcomes were reciprocally linked. The supportive nature of the trial attenuated differences between the different consultation styles. Improvements occurred from baseline, but acupuncture has no specific efficacy over either placebo. The individual practitioner and the patient’s belief had a significant effect on outcome.

There was no statistical difference between the effect or credibility of the different placebos, or between placebos and acupuncture. An unknown characteristic of the treating practitioner predicts outcome, as does the patient’s belief (independently). Beliefs about treatment legitimacy shape the way in which patients self-report outcome, complicating and confounding study interpretation.

**Comment**

The lack of specific effect seen for both empathy and for acupuncture cannot be explained for certain. It runs against the tide of evidence. Possibly, there was no effect in these patients (other than the effect of time), and that cannot be observed since no usual-care group was involved. However, one practitioner did have an effect. Maybe any effect was diluted in the results because hip pain seems less responsive than knee pain. Maybe there were simply too many other influences on the outcome, or too few patients.

**Muscle strength: laboratory study**


Resistance exercising of one limb is known to increase the strength of the contralateral limb. This randomised controlled trial (n=43) tested the effect of acupuncture.

**Methods**

Young men (n=43) were randomly allocated into four groups: control; manual acupuncture at two acupuncture points (ST36 and ST39) with manual stimulation for 15 s every 5 min; electroacupuncture (EA) at 40 Hz at maximum intensity tolerable at the same two points: and identical EA at two non-acupuncture points located on the tibialis anterior muscle, 3 cm lateral to the lateral anterior crest of the tibia. The participants in the experimental groups received 15 min of acupuncture or EA on the right leg in each session, initially, increasing to 30 min, for three sessions a week for 6 weeks.

The main outcome measure—the maximal strength in isometric ankle dorsiflexion of both legs—was assessed before and after the experimental period.

**Results**

Repeated-measures analysis of variance identified significant and similar strength gains (range, 55–64% in the right leg and 32–49% in the left leg; p<0.01) in all acupuncture groups, but not in the control group (−2% to 2%, p>0.05), as shown in figure 11.

**Comment**

At least for muscle strength, this is powerful evidence that the effect of acupuncture is far from point-specific and off-point acupuncture is not inactive. The authors called the EA to muscle belly ‘sham’ in...
their design, but this word seems remarkably inappropriate for such a large effect. Average gains of 46% in muscle strength with manual acupuncture, 35% with EA and 64% with EA to the muscle belly are remarkable. Changes were almost as great in the contralateral, untreated leg.

Basic science
Suppression of bladder activity


Methods

Previous studies have shown that sacral acupuncture suppresses micturition. Furthermore, this effect may be mediated by a micturition centre in the brainstem called Barrington’s nucleus. γ-Aminobutyric acid (GABA) is one of neurotransmitters involved in the micturition reflex.

This experiment was carried out on 55 anaesthetised rats which each had a catheter placed through the abdominal wall into the bladder, and an electrode positioned in the brainstem to monitor neuronal activity. The bladder catheter was bifurcated with one end connected to a syringe filled with physiological saline used to fill the bladder, and the other to a device used to measure pressure changes. A single acupuncture needle was placed on the lumbosacral periosteum just lateral to the midline between L6 and S4.

Acupuncture stimulation was applied when neuronal activity accompanied spontaneous bladder contraction. Needles (diameter 0.3 mm) were manually stimulated at a rate of 1.5–2.0 Hz. Acupuncture was judged to affect bladder contraction when the relaxation period between contractions was more than twice the average of the preceding five relaxation periods.

In an additional experiment, the involvement of the GABAergic system in the regulation of bladder activity was examined by the intraperitoneal injection of bicuculline, a GABA receptor blocker. After the experiment, the brains of the rats under study were histologically examined.

Results

In a preliminary experiment, insertion of an acupuncture needle without stimulation was not found to have any effect on bladder contractions. However, suppression of contractions was induced within a few seconds of onset of manual needle stimulation and this continued for 13 min. The most effective site for stimulation was found to be at the S2 level corresponding to BL33. After injection of bicuculline, acupuncture stimulation failed to suppress bladder contraction (figure 12), indicating that the GABAergic system has a role in mediating the acupuncture effect on the bladder. Examination of the brainstem showed that the firing profile of bladder activity-related neurons in and around Barrington’s nucleus was altered by sacral acupuncture. This indicates that acupuncture mediates its effects through the central nervous system, especially the brainstem micturition centre.

Comment

Lower urinary tract syndrome includes voiding and overactive bladder symptoms, which are a challenge to treat effectively. This study suggests that acupuncture may be a useful treatment and gives a scientific rationale as well as a guide to point selection.

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Accepted 19 January 2012

Summaries of recent papers

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*Acupunct Med* 2012 30: 63-68
doi: 10.1136/acupmed-2012-010138

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