Summaries of recent papers

CLINICAL TRIALS OF EFFECTIVENESS

Radiation-induced xerostomia (1) pilot

Methods
Adult patients with nasopharyngeal carcinoma were randomised to receive either real or sham acupuncture for 3 days a week for 6 weeks, each session on the same day but prior to scheduled radiation treatment.

The real acupuncture group had needles inserted to standard recommended depths or achievement of de qi. The following points were included: body points CV24, LU7 and K16; ear points Shenmen, point zero, salivary gland 2-prime and larynx. All bilateral acupuncture points were treated for 20 min. Interestingly, those patients receiving real acupuncture also had a sham needle inserted at GB32 in order to maintain participant blinding.

The sham acupuncture group had treatment using a Park non-penetrating needle device at sites near but not over known acupuncture points CV24, TE6 and ST36. In addition, four real acupuncture needles were inserted on the helix of each ear, as well as GB32 at which point de qi sensation was elicited.

Patients were assessed using the Xerostomia Questionnaire (XQ) to measure degree of xerostomia; the MD Anderson Symptom Inventory-Head and Neck (MDASI-HN) to assess severity of symptoms and interference with daily activities; and stimulated and unstimulated salivary flow rates. Assessments were taken at baseline, weekly during the course of radiotherapy and then after 1 month.

Results
XQ scores were found to be significantly higher in the sham acupuncture group starting at week 3 and remaining through to week 11. The difference between the groups increased over time and reached its maximum at week 11. In addition, there were significantly fewer patients in the real acupuncture group who had clinically significant XQ scores >30 by week 6 and this continued until week 11. Group differences in the MDASI-HN scores were significant between week 3 and 6 only, and no group differences were demonstrated in either stimulated or unstimulated salivary flow rates. Results were very similar to those of the main study, shown in figure 1 below.

Radiation-induced xerostomia (2) main study

Methods
Adult patients with nasopharyngeal carcinoma were randomised to receive acupuncture or standard care. The acupuncture group received acupuncture 3 days a week on the same day but prior to radiation for a total of 7 weeks. The acupuncture points used were: body points CV24, LU7, K16; and ear points Shenmen, point zero, Salivary gland 2 and Larynx. Bilateral points were used and needles inserted for 20 min to the recommended depth and stimulated to elicit de qi. The control group did not receive acupuncture or any special education to prevent xerostomia except standard oral hygiene.

The Food and Drug Administration uses subjective outcomes as the standard for drug treatment approval for xerostomia treatment. Therefore, the primary outcome measure was the Xerostomia Questionnaire (XQ) at the end of radiotherapy and 1 month later. XQ scores >30 signify clinically significant levels of xerostomia. Secondary outcomes were the MD Anderson Symptom Inventory-Head and Neck (MDASI-HN) and changes in salivary flow, stimulated and unstimulated. Data were collected again after 6 months (figure 1).

Results
The control group had significantly higher XQ scores starting in week 3 and persisting until week 11 as well as the 6-month follow-up, with the greatest difference from the acupuncture group at week 7. However, numbers with significant scores (>30), showed no difference between the two groups after week 7. By week 11 and the 6-month follow-up, the acupuncture group had significantly fewer patients with scores >30. Similar results were seen for the MDASI-HN questionnaire indicating greater quality of life for the acupuncture group after weeks 3–4. Stimulated but not unstimulated salivary flow rates were significantly improved in the acupuncture group at week 4 and maintained until the 6-month follow-up.

Comment
These studies add to the accumulating evidence of the effect of acupuncture in control of xerostomia during radiotherapy. There was clear statistical significance even in the small pilot study, though the clinical impact was not marked in the short term.

Although a sham needling device was used in the control group, real needles were also inserted into the ears, and at GB 32 at which site de qi was elicited. This was performed to maintain participant blinding but also assumes that real needling at these sites did not have any clinical effect on the condition under study. In reality, the effect of needling on xerostomia may at least partly be a generalised effect of acupuncture, and what this second study actually compared was the effect of two doses of real acupuncture with the control group receiving the smaller dose. Although numbers of participants were small, this may be the reason why clinically significant differences were not seen for MDASI-HN scores and salivary flow
rates as were seen in the previous study where real acupuncture was compared to standard care.

**Functional dyspepsia**


Multicentre RCT (n=712) comparing four different traditional needling approaches to ‘sham’ acupuncture and pharmacological treatment.

**Methods**

Patients aged 18–65 years were randomly assigned to treatment with specific points on the stomach meridian (group A: ST42, ST40, ST36, ST34), non-specific points on the stomach meridian (group B: ST38, ST35, ST33, ST32), specific points on different meridians (group C: BL21, CV12), specific points on the gallbladder meridian (group D: GB40, GB37, GB36, GB34), needling on non-acupuncture points (group E: all on upper limb) and itopride (group F), a prokinetic agent not licensed in the UK.

All acupuncture treatments were given for 30 min, five times a week, for a total of 4 weeks. All points except CV12 were needled unilaterally and alternately on the left and right, with manual stimulation to achieve *de qi* sensation. Then points on the proximal limbs were stimulated electrically (2/100 Hz, 0.5–1.5 mA) via an auxiliary needle inserted 2 mm lateral to the stimulated point.

Primary outcome was change against baseline on the Symptom Index of Dyspepsia. Secondary outcome was change in the combined Nepean Dyspepsia Index (NDI) and Symptom Index of Dyspepsia scores; the NDI scores for quality of life, as well as dyspepsia symptoms, with a change of at least 10 points considered clinically significant. Both were measured at 4 weeks (end of treatment) and at 12 weeks.

**Results**

At 4 weeks, statistically significant improvements on the NDI score were seen in all four acupuncture groups, compared to sham (all p<0.05), but only changes seen in groups A and C were considered also clinically significant. On the Symptom Index of Dyspepsia, all four acupuncture treatments were significantly superior to sham (all p<0.05), with no significant differences between groups B, C and D. Only group A treatment was considered significantly better than group F; itopride (p=0.005). The observed improvements were still observed at 12 weeks (figure 2).

**Comment**

This large trial tested four acupuncture approaches described well enough for a practitioner to replicate the treatments. Strangely, the power calculation was based on the secondary, rather than the primary, outcome measure. A no-treatment group would have been helpful; the sham treatment was skin-penetrating needling, with electric stimulation. The difference was that the points were non-traditional, and all located on the arms, whereas groups A, B and D were all treated on the legs; this may be a factor why this worked less well. Finally, since the acupuncture was time consuming for practitioner and patient alike, I would have liked to see another assessment 6 or 12 months after randomisation to judge how long the effect lasted.

**Major depressive disorder**


Single centre, RCT (n=57) comparing verum scalp electroacupuncture with sham non-channel scalp acupuncture.

**Methods**

A total of 57 patients with mild or moderate major depressive disorder (MDD) that were recruited through advertisements or referral entered into the treatment phase of the study. All patients were tapered off psychotropic medications before staring treatment. The patients were randomly assigned to needling of either verum or control-sham groups. The verum group used a two-point (GV20 and Yintang) electroacupuncture protocol (EA) and the control sham group involved needling two points distant from any meridian or extraordinary points without electrostimulation. Both groups were treated for 12 sessions (2 sessions/week) for 30 min.

The primary outcome was the absolute change in the Hamilton Depression Rating Scale (HDRS) score. The secondary outcome measures were UKU Side Effect Rating Scale to assess tolerability, and the Medical Outcomes Study 36-Item Short Form Health Survey and Global Assessment of Function to assess functional improvement. In addition to the primary and secondary outcomes, analyses of two HDRS subscales were performed to evaluate sleep and anxiety symptoms.

**Results**

In all, 53 patients were available for the final analysis; 4 patients were removed from the control group due to not receiving the correct control treatment. Demographic and primary and secondary outcomes were comparable at the start of the study. As can be seen from figure 3, the patients in the EA and control group showed improvements in HDRS scores. However, no statistically significant differences between the groups were observed in the HDRS score.
Acupuncture research update

EA – 7.4±6.2 vs sham – 7.9±7.4; mean±SD; p=0.81), any of the secondary outcomes or the in the analysis of the HDRS. No significant side effects were reported in either group.

Comments
This study failed to show any difference between EA and control acupuncture treatment. A limitation of the study is that it attempts to evaluate two treatment variables, electroacupuncture and point location, in only two groups. This makes it difficult to make any clear conclusions. It is hard to know if the reductions in HDRS scores during the study were due to acupuncture (either EA or specific point needling) or would have occurred in this population with no treatment at all. It is known the majority of patients with mild to moderate MDD improve with time and hence HDRS scores decrease with time also. Therefore a control non-acupuncture group would have been useful.

Knee osteoarthritis


RCT (n=46) comparing laser treatment with placebo.

Methods
A total of 46 adults aged 50–75 years with osteoarthritis of the knee associated with pain and disability for at least 3 months were randomised into 2 groups. Following assessment, one group received low level laser treatment three times a week for 3 weeks while the other group received placebo treatment using an identical non-functioning laser pen. Both groups then performed identical exercises three times a week for a period of 8 weeks.

The laser pen used a gallium arsenide semiconductor and emitted a beam of 904 nm, frequency 700 Hz, average power of 60 mW, peak power of 20 W, pulse duration 4.3 ms, 50 s per point (area 0.5 cm). In the laser group, five points were irradiated over the synovium of the medial side of the knee and four points on the lateral side. An energy value of 3 J per point was used making a total of 27 J per knee for each treatment.

Assessments of pain (visual analogue scale (VAS)), function (Lequesne questionnaire), range of motion (universal goniometer) and muscular strength (maximal isometric force for the quadriceps using a portable dynamometer) were made at baseline (T1), at the end of the laser treatment after 3 weeks (T2) and at the end of the exercise period after a total of 11 weeks (T3). In addition, activity was assessed using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).

Results
Between-group analysis showed that the laser group had significant improvements compared to placebo in WOMAC scores of pain (p=0.033), function (p=0.002) and total score (p=0.008) at T2 compared to T1. These improvements remained significant at T3 compared to T1 in terms of pain (p=0.001), function (p=0.002) and total score (p=0.003). No other significant differences were found between groups.

As well as significant improvements in WOMAC scores, the intragroup analysis showed significant improvements in pain assessed by VAS (p<0.05) and activity (p<0.001) between T1 and T2 and between T2 and T3 (p<0.001). There were also improvements in range of motion (p<0.01) and functionality (p<0.001) between T2 and T3. No such improvements were seen in the placebo group (figure 4).

Comment
Blinding of subjects and the use of inactive controls are two of the main challenges in conducting controlled trials using physical modalities such as physiotherapy or acupuncture. The beauty of trials using low level laser treatment, or ‘cold’ lasers as they are known, is that subjects remain unaware of whether or not the devices are working since active treatment produces no sensation.

Postoperative analgesia (1) humans


Randomised sham-controlled trial (n=50) comparing verum acupuncture, sham acupuncture and conventional analgesia, performed at a single institution.

Method
Adult patients who were undergoing stapled haemorrhoidopexy were included if there was a clinical diagnosis of third or fourth degree haemorrhoids. Patients were randomised to either conventional analgesia alone (n=17), verum acupuncture (n=17) or sham acupuncture (n=16). All patients then underwent the same anaesthetic induction and surgery. Blinding was effective. Postoperatively, all patients received the same conventional analgesia given by blinded staff.

Patients in the verum acupuncture group received five sessions of acupuncture over their hospital stay of 3 days at points GV2, GV20, BL50 right side, ST44 left foot and PC6. Points were selected accurately using a device to measure electrical skin resistance. Patients in the sham acupuncture group were given the same number of sessions, at the same time intervals, with the same number of needles. Needles were placed in the same regions as those in the verum group, but were placed well away from true meridians. The same device was used to suggest points were being selected, to assist blinding of the patients. Acupuncture was performed by the same practitioner, and di qi sensation was aimed for.

Primary outcome measures were pain intensity on postoperative days 0 to 2 measured twice daily on a Numerical Rating Scale.

Results
Postoperative pain tended to be less in the verum acupuncture group compared to conventional analgesia alone, but not significantly (p=0.057) The verum acupuncture group had a significant reduction in pain compared to the sham acupuncture group, but this analysis should be considered exploratory due to the non-significance of the primary hypothesis. The verum and sham acupuncture groups were both able to achieve significant immediate pain relief after acupuncture treatment (figure 5).

Comment
Sample size calculation indicated 90 patients were necessary to detect a difference in pain score of 1, considered to be the minimal
clinically relevant difference. The study was terminated at 50 patients due to one of the investigators leaving. It seems unlikely, then, that statistically significant results could be achieved. The results obtained were essentially positive and it may be worthwhile to consider a larger scale trial. That said, it may have limited use as most haemorrhoid surgery is performed as a day case, which the authors acknowledge.

The problem of sham needling remains an issue, as despite using non-acupuncture points, there are still physiological analgesic effects by descending inhibitory pain pathways and diffuse noxious inhibitory controls.

Postoperative analgesia (2) dogs

- Randomised controlled trials (RCTs) of electroacupuncture (EA) for postoperative pain in dogs (n=18).

Methods

This study aimed to evaluate the analgesic effects of electroacupuncture (EA) on postoperative pain in dogs undergoing ovariohysterectomy (the routine method for neutering female dogs).

A total of 18 healthy female dogs were randomly divided into 3 groups of 6 and sedated with acepromazine. The EA group received bilateral stimulation at acupuncture points ST36, SP6 and GB34 (0.2 ms dense dispersed at 5–200 Hz, achieving muscle contraction); the Dermatome group received the same stimulation via longitudinally placed needles in the dermatomes corresponding to the site of abdominal incision in a 4 cm area to the right and left of the linea alba; and the ‘EA plus Dermatome’ group received the same stimulation at the skin sites and the acupuncture points. Treatment was for 45 min prior to surgery in all groups. The dogs then had anaesthesia induced with propofol, were intubated and had surgery.

Assessment of pain (which was blinded) was via a pain scoring system that assessed physiological data such as heart rate, blood pressure etc and behaviour, such as agitation and body posture. If the pain score exceeded 6/20 (less than 6 was judged as ‘mild’ pain), the dogs received morphine.

Results

The median pain scores were significantly lower in the EA and EA plus Dermatome groups than in the Dermatome group. Two of the dogs in the electroacupuncture and EA plus Dermatome groups required rescue analgesia compared with five of the dogs in the Dermatome group (figure 6).

Comment

The primary outcome measure of this study relies on the accuracy of the pain scoring system and, although this has been used in other studies, there is no evidence for its validation (there are few validated acute pain scales for animals). There appears to be at least one error in the scale, which rates ‘severe agitation’ in an animal as 0, that is, indicating no pain. All dogs had, according to the scale, mild to moderate pain postoperatively, regardless of the needling technique, and all still had ‘mild’ pain 24 h later. The authors conclude that, because rescue analgesia was required in fewer dogs in the two groups receiving EA into acupuncture points, that this implies that both of these regimens provide adequate analgesia. A failure in analgesia in one-third of patients is not adequate analgesia. Current perioperative multimodal analgesia can achieve better results than this, so this cannot be an alternative to usual analgesia, although it would clearly be better than nothing. This study does demonstrate what the authors intended: that electroacupuncture into acupuncture points in muscle appears to be superior to electrical stimulation into the skin. This is not surprising, especially as the points chosen in this study would be segmental for the pelvic structures and relevant abdominal musculature.

SAFETY

Bilateral pneumothorax


A 60-year-old man with mental retardation, chronic obstructive lung disease and dilated cardiomyopathy, was admitted to hospital after sudden pains in the chest. In the emergency room the patient was found to have severe respiratory distress with a respiratory frequency of 40 breaths/min, bluish colour on most parts of the body and sweating. He had a tachycardia rate of 100 beats/min and blood pressure of 170/100 with peripheral oxygen saturation of 88%.

The patient was initially treated with intravenous steroid and tertbutaline inhalation, but without any improvement. An electrocardiogram (ECG) was normal. An acid-base level showed 7.1 and arterial pressure for CO₂ of 10 kPa and for O₂ of 9.8 kPa. On suspicion of a dissecting aortic aneurysm, a computerised tomography on the thorax and abdomen was performed. A double pneumothorax was diagnosed. A pleural drain was inserted on both sides and the patient recovered almost immediately.

The patient was then able to explain that the chest pains started after he had received acupuncture from his own GP for back pain. Needles had been inserted in each site of the thorax. A follow-up x-ray film showed normal lung picture. After 3 days the patient was discharged without any symptoms.

Translation kindly provided by Palle Rosted.
Acupuncture research update

SYSTEMATIC REVIEW
Low back pain and neck pain


Systematic review of complementary therapies. Only acupuncture is reported here (though manipulation, mobilisation and massage were also included).

Methods
Studies in all languages up February 2010 included. Outcomes of interest were pain intensity and disability. The degree of clinical importance for the observed differences in visual analogue scale (VAS) pain scores between the treatment groups was classified as: small (weighted mean difference (WMD) <10%), medium (10%≤WMD<20%), or large (WMD ≥20%). This is a Cochrane standard procedure.

Results
For low back pain, there were 33 studies in total, including 1 in Chinese and 4 in Japanese. Compared with usual care, in three studies acupuncture was superior for pain at the end of treatment (VAS−1.19, 95% CI −2.17 to −0.21). For chronic pain, there were 10 trials with 1727 participants, figure 7. These showed an effect on pain at the end of treatment (VAS: −0.59, 95% CI −0.93 to −0.25). Only four studies were available that had any follow up period (short, intermediate or long), and they showed no effect of acupuncture; however, trends were strong (three short term −1.11 (−2.33 to 0.11); three medium term −0.18 (−0.85 to 0.49); and four long term −0.21 (−0.64 to 0.22)). Two studies measured disability and showed no effect.

Compared with medication, four trials found acupuncture no different; two studies (n=116) found manipulation superior to acupuncture. Two trials found acupuncture significantly better than usual care.

For neck pain, there were 24 trials. One trial found acupuncture superior to no treatment. Compared with sham acupuncture, there were no significant differences in chronic specific pain (two trials; VAS score: 0.27, 95% CI −0.60 to 1.13) or chronic non-specific pain (three trials; VAS score: −0.24, 95% CI −1.20 to 0.73). There were eight trials comparing acupuncture with other active treatments, three of which were positive.

Economic evaluation was included in two studies of back pain and one of neck pain, all showing small extra cost achieving small health gains (neck pain US$1565 vs US$1496).

Comment
There is little new information here, except that the positive result of the current Cochrane review of acupuncture versus sham for back pain was not reversed by including the subsequent (negative) study of Cherkin et al.

The reviewer was reminded forcefully of one weakness of systematic reviews. Although their great strength is to combine the results of studies and effectively generate a sample size that will be definitive, in practice by the time the studies have been placed into categories by comparison group, type of outcome (eg, pain or function), time point and those without usable data excluded, there is rarely enough data to be definitive.

BASIC RESEARCH
Exercise recovery in elite basketball players


A randomised experimental study to assess if auricular acupuncture (AA) can enhance the athletes’ recovery abilities after aggressive exercise.

Methods
A total of 24 elite basketball athletes were randomised into an AA group (n=12) and a control group (n=12). Seven auricular acupuncture points were chosen based on findings from previous studies, and magnetic stud patches were applied to these points bilaterally. The control group consisted of tape being applied to the same locations of the ears but without the studs. The variables measured were heart rate (HR), VO₂ and blood lactic acid level.

The exercise test consisted of two phases. The first phase involved all participants cycling on the bike to warm up their muscles until a set respiratory quotient was reached. In the second phase of the experiment the treatment studs and control tapes onto the relevant participants 30 min prior to the exercise test. Next the participants were asked to ride the bike until they were completely exhausted. The HR, VO₂ and blood lactic acid level were measured during the rest period before the exercise and then 5, 30 and 60 min post exercise.

Results
HR and blood lactate levels were lower in the AA group than control at 50 and 60 min post exercise (all p=0.05). The blood lactate data are shown in figure 8. Furthermore VO₂ was lower in the AA group at the 30 and 60 min post exercise but was only statistically significant at 30 min post exercise (p=0.05).

Figure 7 Acupuncture vs sham for low back pain. Based on Furlan et al. eCAM 2012;953139.

Figure 8 Blood lactate levels after exercise. Based on Am J Chin Med 2011;39:1131–8.
Comment
This is an interesting study that builds on the author’s previous work. The authors concluded that AA could expedite recovery in athletes post-exercise with regard to heart rate, oxygen consumption and blood lactic acid. They then suggested this may lead to an improvement in performance. While statistical significance difference in HR, VO2 and blood lactate the differences were present they are not large. Whether these differences translate into a clinically meaningful result is debatable. Possibly some rating scales that have used in non-acupuncture studies of post exercise recovery such as perceived muscle soreness or recovery may have been useful. The inclusion of a sham-treatment or non-specific point group would have strengthened the study.

Itch in atopic dermatitis


Methods
Adult patients with atopic dermatitis were randomised to each of the study arms of this trial in which they served as their own controls. The seven study arms were (1) verum acupuncture performed prior to itch induction (ie, preventive, VAp), (2) verum acupuncture performed during itch induction (ie, abortive, VAs), (3) placebo acupuncture, preventive (PAp), (4) placebo acupuncture, abortive, (5) verum cetirizine, ingested preventively (VC), (6) placebo cetirizine tablet (PC) and (7) no-intervention control.

Verum acupuncture consisted of electroacupuncture (100 Hz, 0.2 ms pulse width) applied to needles (0.25×40 mm) inserted to a depth of 2–3 cm. Acupuncture points were used on the dominant upper and lower limb including LI 11, HT 3, ST 34 and SP 10 for the VAp study arm; and LI 11 and HT 3 for the VAs study arm. Placebo acupuncture was also performed on the dominant side, but at non-acupuncture points on the forearm and shoulder. In the two drug arms, patients were given either cetirizine 5 mg or a similar looking placebo tablet, 45 min prior to itch provocation.

Itch was induced by the injection of allergen solution in the volar aspect of the non-dominant forearm and using a temperature modulation device.

Outcomes were weal and flare size at 10 min as well as quantitative (VAS) and qualitative (Eppendorf Itch Questionnaire) assessment of itch intensity. A standard test of attention and concentration in clinical and applied settings, the d2 test, was also completed.

Results
Mean itch intensity was significantly lower following VAs compared to all other groups (p<0.05). There was no significant difference between the two verum groups; VAp and VC (p=0.1). Both of these treatments were in turn more effective than their respective placebo interventions (p<0.05). Flare size following VAp was significantly smaller than that following PAp. The d2 attention test score was significantly lower following VC compared to all other groups (p<0.001) (figure 9).
Summaries of recent papers

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