Summaries and commentaries by editor Adrian White on a selection of recent acupuncture research articles

Clinical studies

Acupuncture for labour pain


This study from Aarhus in Denmark, included 607 healthy women with normal singleton pregnancy. They were randomly allocated to acupuncture with transcutaneous electric nerve stimulation (TENS) and traditional analgesics, at a ratio of 2:1:1. The analgesics that are “traditional” for Denmark were a choice of sterile water papules, nitrous oxide, warm tub bath, pethidine, and epidural analgesia. For acupuncture, 34 specified acupuncture points (on back, arms, legs and ear) could be used, and points could only be stimulated manually not electrically. Duration of needing was 30 minutes to 2 h, and could be repeated. The TENS at 100 Hz was given through two to four pads on the lumbar region.

Additional analgesia of various sorts was given on demand, and the amount given was measured and was the main outcome. Significantly fewer women in the acupuncture group were treated with nitrous oxide, pethidine, or sterile water papules compared with the traditional analgesia group, and fewer chose sterile water papules compared with the TENS group. Significantly fewer women in the acupuncture group received pharmacological or invasive pain relief, or both, compared with the other groups (acupuncture versus traditional, p<0.001; acupuncture versus TENS, p=0.051). A non-significant trend was observed towards fewer women having epidural analgesia in the acupuncture and TENS groups, respectively, compared with the traditional group. Pain scores were no different between the groups.

Acupuncture did not influence the duration of labour or the use of oxytocin. Mean Apgar score at 5 minutes and umbilical cord pH value were significantly higher among infants in the acupuncture group compared with infants in the other groups.

Birth experience and satisfaction with delivery were evaluated at 2 months postpartum. In the acupuncture group, 59 per cent of the women thought that acupuncture gave some or substantial pain relief, 55 per cent thought it had a somewhat or very calming effect, and 86 per cent thought it had no side effects. Asked if they would want to use acupuncture again for a future delivery, 53 per cent answered positively. In the TENS group, 54 per cent of the women reported that TENS gave some or substantial pain relief, 23 per cent that it had a somewhat or very calming effect. Asked if they would want to use TENS again for future delivery, 18 per cent answered positively. No signs of serious or prolonged side effects were found, neither by using acupuncture nor TENS. These responses were not significantly different between the groups.

The authors concluded that acupuncture reduced the need for pharmacological and invasive methods during delivery, and could be introduced more generally to supplement existing pain relief methods.

Expectation and the outcome of acupuncture


Readers may remember the first report of this study, which reported the run-in phase of a study, which just compared two “placebos”. The 119 participants had persistent distal upper arm pain due to repetitive stress injury. The results showed that needling with a blunt, non-penetrating acupuncture device produced greater pain relief than placebo pills did. Since we know that expectation is one of the most important components of the placebo effect, we might therefore anticipate that the participants’ expectation of the effects of the sham device would be greater than the expectation of the effects of the placebo pill.

So the authors explored this question, as well as to what extent psychological other factors such as depression, anxiety and belief in alternative medicine impact placebo response and differential responses to separate placebo interventions.

The data actually showed that none of these psychological factors were associated with pain levels at the end of treatment. The only characteristics that predicted a smaller effect were higher baseline pain score and pain for longer than 1 year’s duration. In the sham acupuncture arm (only) the baseline depression score was also correlated with the outcome.

So they concluded that, in this trial and with the exception of depression, neither expectation nor psychological states were associated with response to placebo.

Another RCT of acupuncture for OA knee


In this study from Tel Aviv, acupuncture in addition to standard care was tested in 55 elderly patients with osteoarthritis (OA) of the knee. Manual acupuncture was given at the following points, using a traditional approach to treatment: contralateral GB34 and LI11; ipsilateral SP5, Heding (Extra 31, midpoint of upper border of patella), ST35, and Xiyan (Extra 32, either side of the patellar ligament). Also, two points were added according to the meridian where the pain was perceived, either ST34 and ST43, or KI10 and KI3. Sham acupuncture consisted of pressure with the guide tube to the same points, followed by placing the needle in adhesive foam taped over the point. Treatments were twice weekly for 8 weeks, in addition to standard therapy, for example, non-steroidal anti-inflammatory inhibitors, cyclooxygenase-2 inhibitors, paracetamol, intra-articular hyaluronic acid and steroid injections.

The primary outcomes measure was the Knee Society Score (KSS) which involves some objective testing such as range of movement and stability, as well as rating of symptoms. The KSS was measured at baseline, 8 weeks (end of treatment) and at 12 weeks (follow-up). At 8 weeks both groups had improved but there were no significant differences between them. At 12 weeks acupuncture was superior (p=0.036). Patient satisfaction on a 5-point Likert scale was significantly better after acupuncture than after sham. Blinding was reported to be successful but no details were given.

It is interesting to note what the authors describe as a delayed effect of acupuncture after stopping treatment, which does not seem to have been recorded in previous studies in OA knee, and is certainly something to take account of in planning future studies. It is conceivable that the acupuncture had an initial analgesic effect which was too small to be measurable, but large enough to enable participants to increase their activity, which is clearly an important help in relieving symptoms of OA of the knee.

Acupuncture analgesia for paediatric surgery


This uncontrolled trial was conducted in a tertiary referral paediatric intensive care unit in California. A total of 20 patients were treated, aged 7 months to 18 years. Eleven of the patients had posterior spinal fusion surgery and the remaining nine patients had other surgical diagnoses.

Two 10- to 15-minute sessions of acupuncture were given 24--48 h apart. The treatment was well accepted (27 patients were...
approached: 4 patients refused, and 20 patients completed the study).

Acupuncture was well tolerated and there were no adverse events related to treatment. In follow-up interviews, 70% of both parents and patients believed acupuncture helped the child’s pain. Eighty-five per cent of the parents said they would pay out of pocket for acupuncture if it were not covered by insurance.

The pain scores, vital signs, and narcotic usage were recorded before and at several times during the session. In posterior spinal fusion patients, the mean pain scores (0–10) immediately before acupuncture and 4 and 24 h after acupuncture were: 3.7, 1.7, and 3.1, respectively for the acupuncture session, and 3.7, 2.2, and 3.1 for the second session. In the other cohort, who received surgery at other sites, the mean pain scores immediately before the first session of acupuncture and 4 and 24 h after acupuncture were 2.5, 0.3, and 1.6.

The authors concluded that acupuncture is highly accepted and feasible in critically ill, postoperative paediatric patients with acute pain. “Our findings suggest that acupuncture may be a potentially useful adjunctive tool for acute paediatric postoperative pain management. A randomized, controlled clinical trial is warranted to confirm these findings.”

### Systematic reviews of acupuncture

#### Acupuncture for neck pain


In clinical practice patients with neck pain seem to respond to acupuncture rather well, but it has proved difficult to separate out the effects of time, natural resolution, and expectation. The Cochrane review (2006) included 10 papers and summarised the evidence in favour of acupuncture compared with sham as “moderate” (meaning findings in a single, high-quality randomised controlled trial (RCT) or consistent findings in multiple low-quality trials). The evidence that acupuncture was superior to massage was “limited” (meaning a single low-quality RCT).

This new review has included 14 trials, and conducted a total of nine meta-analyses of subgroups addressing different clinical issues. The overall outcome of this review is positive, as the “headline” summary is that seven out of nine meta-analyses yielded positive results. The reviewers concluded that the quantitative meta-analysis confirmed the short-term effectiveness and efficacy of acupuncture in the treatment of neck pain; and that further studies that address the long-term efficacy of acupuncture for neck pain are warranted.

However, on looking into the paper’s text in more detail, a major flaw was discovered that seriously undermined confidence in the conduct of this review. The reviewers wanted to assess the effect of acupuncture on radicular symptoms: there was only one included study that did this. The authors then state: “literature search found two other RCTs that examined the effectiveness of acupuncture … but these two studies were not included in the present systematic review because their full reports in English were not available”.

Nonetheless, the reviewers then used data from the abstracts of these two studies and arrived at qualitative conclusions. This methodology is not “systematic”: once a paper is excluded, it must remain excluded. These results (however desirable they may be for the authors and the acupuncture profession) should therefore remain in some doubt. Acupuncture research must use the same rules as the rest of medical science.

#### Moxibustion for correcting breech presentation


Moxibustion at the point BL57 (on the little toe) has long been carried out among pregnant women in China with the purpose of correcting breech presentation. It seems difficult to imagine a possible mechanism, other than that it is something to do with the position that the pregnant woman adopts during the session of moxibustion, potentially raising the breech out of the pelvis. This review and meta-analysis included 10 RCTs and seven controlled clinical trials on moxibustion, acupuncture or any other acupoint-stimulating methods for breech presentation.

There were three good-quality RCTs, all comparing moxibustion with no treatment, and producing overall evidence of an effect. These three RCTs showed no difference between moxibustion and the knee-chest position. A controlled trial found ear acupuncture to be superior to the knee-chest position, and similarly for laser. Moxibustion in combination with another intervention — combined in one RCT with knee-chest position, and another with elevation of the pelvis — was more successful than the other intervention alone, in both cases.

The evidence from RCTs needs to be somewhat stronger before it justifies a rethink on the use of BL57 for breech presentation.

#### Acupuncture for xerostomia


More than 70 per cent of seriously ill patients with cancer suffer from xerostomia and the associated problems of swallowing, chewing and speaking which seriously interferes with their wellbeing. There are many different causes of xerostomia in these patients: previous acupuncture studies have shown a useful and lasting effect in patients with Sjögren’s syndrome and those with salivary glands injured by radiation therapy.

These authors conducted a pilot study in Sweden, mainly to see whether treatment with acupuncture was a viable option in a hospice setting among patients at the last stage of their lives, with the intention of planning a subsequent 5-week study.

During a 2-year period, 117 patients were assessed for xerostomia. Eighty-two patients were found to have moderate xerostomia (grade 1 on Visual Analogue Scale (VAS) of 0–10). Sixty-seven fulfilled the criteria for inclusion. Of these, 24 accepted the offer of acupuncture, but 10 deteriorated rapidly and could not be included. Fourteen were included but only eight were well enough to complete the study. Ten acupuncture treatments, using individualised points ST4, ST5, ST6, ST7, LI3, SP6 were given during a 5-week period. The effect of acupuncture was measured using a VAS to assess “discomfort” from xerostomia, and by measuring the saliva production before and after the series of treatments.

The results show that all the patients experienced alleviation of dryness of the mouth from 7.7 (interquartile range 7.0–8.2) before treatment to 3.3 (3.0–3.9) at the end. The associated symptoms also improved significantly. The measured amount of saliva produced on stimulation increased, but not significantly so. The patients also recorded their benefit from and appreciation of the acupuncture treatment in interviews.

The authors concluded that acupuncture was valuable for these patients, but that it would not be feasible to conduct a 5-week acupuncture intervention study at an inpatient hospice due to the patients being too close to death.

#### Acupuncture in an accident and emergency department


This was a pilot study to assess the feasibility and efficacy of providing acupuncture as the primary analgesia in patients presenting to the emergency department (ED) after minor acute trauma to the extremities. They chose a convenience sample of patients with acute, non-penetrating extremity injury. The acupuncture was given “based on their oriental medicine working diagnosis”.

Efficacy was measured using a pain VAS before and immediately after acupuncture (time 0), then every 30 minutes. A telephone call was made to patients within 72 h to ascertain pain levels using a 0 to 10 numerical rating scale. Markers of feasibility included average time patients spent in the fast track area of the...
ED versus average time in the department (TID) for all fast track patients with similar injury.

Of 47 patients approached, 20 (43%) consented to participate. The mean age of those who consented was 33 years, and 70% (n = 14) were male. Three patients, with a median VAS score of 73 mm, requested conventional analgesic drugs immediately after the acupuncture, and so were withdrawn from the study. For the remainder, the median baseline pain VAS score was 57 mm (range 14–100) which fell to 37 (range 0–94) immediately after acupuncture. Most patients ticked the box “satisfied beyond expectations” at 72 h follow-up.

This study suggests that acupuncture can be an effective analgesic intervention for patients with acute injury to the extremities. Acupuncture did not increase patients’ time in the department significantly. Several complications were reported, including four cases of light-headedness, but all were minor.

Acupuncture research methods
Sham acupuncture is not a placebo (1)

The lack of true placebo control for acupuncture becomes more plain the more we know about the neurophysiology of needling. What could be regarded as a suitable “placebo” according to the traditional approach, the blunt needle, is not inactive, which affects the interpretation of many acupuncture clinical trials. This latest paper by this well-known group of authors summarises the arguments about the various modes of action of acupuncture that have been presented in a series of papers in Acupuncture in Medicine. The accent of the paper is slightly different and expressed in a different way, and anyone interested would gain from reading this paper, which is freely available.

Placebo control of acupuncture is used to evaluate and distinguish between the specific effects and the non-specific ones. During “true” acupuncture treatment in general, the needles are inserted into acupoints and stimulated until *de qi* is evoked. In contrast, during placebo acupuncture, the needles are inserted into non-acupoints and/or superficially (so-called minimal acupuncture). A sham acupuncture needle with a blunt tip may be used in placebo acupuncture. Both minimal acupuncture and the placebo acupuncture with the sham acupuncture needle touching the skin would evoke activity in cutaneous afferent nerves. This afferent nerve activity has pronounced effects on the functional connectivity in the brain resulting in a “limbic touch response”.

Clinical studies showed that both acupuncture and minimal acupuncture procedures induced significant relief from migraine and that both procedures were effective. In other conditions such as low back pain and knee OA, acupuncture was found to be more potent than minimal acupuncture and conventional non-acupuncture treatment. It is probable that the responses to “true” acupuncture and minimal acupuncture are dependent on the aetiology of the pain. Furthermore, patients and healthy individuals may have different responses.

It is important to emphasise that acupuncture is not a simple needling intervention. There are at least three other processes, apart from needling, that characterise the acupuncture procedure, namely (1) building a treatment relationship; (2) individualising care; and (3) facilitating active engagement of patients in their own recovery.

The authors conclude that minimal acupuncture is not valid as an inert placebo control “despite its conceptual brilliance”.

Sham acupuncture is not a placebo (2)


This paper’s author believes in the neurophysiological approach to acupuncture. He tried to show that sham acupuncture, consisting of needles inserted into the “wrong” site or into non-points, is as efficacious as true acupuncture (as defined by traditional acupuncture theories) in a systematic review.

He conducted a review of the 38 studies available to him that compared true and sham acupuncture. The majority of studies (22/38 = 58%) found no statistically significant difference in outcomes. Most of the studies (15/22 = 59%) found that patients improved from baseline, so that “both treatments could be considered efficacious”, especially when superficial needling was applied to non-points.

Much as this reviewer agrees with the basic viewpoint of the author, this particular evidence does not amount to much. Patients improve from baseline for all sorts of reasons, not just because the needle has a physiological effect. There was a difference between acupuncture and sham acupuncture in 16/38 studies, which is not a minority result that can be dismissed just because it does not fit the hypothesis.

It seems to be at least arguable that, with the current evidence, there is only circumstantial evidence that needling the “wrong” site is an active treatment.

Basic research
Acupuncture and serum cortisol and prolactin


The debate about the role of acupuncture in infertility is not resolved, with positive and negative studies. These US authors recruited 67 reproductive-age infertile women undergoing in vitro fertilisation (IVF). Blood samples were obtained from all consenting new infertility patients and serum cortisol and serum prolactin were obtained prospectively. Patients either served as controls without acupuncture, or were treated according to acupuncture protocols derived from RCTs. Serum levels of cortisol and prolactin were measured and synchronised with medication stimulation days of the IVF cycle (eg, day 2 of stimulation, day 3, etc).

Cortisol levels in the acupuncture group were significantly higher on IVF medication days 7, 8, 9, 11, 12, and 13 compared with controls. Prolactin levels in the acupuncture group were significantly lower on IVF medication days 5, 6, 7, and 8 compared with controls. The authors concluded that there appears to be a beneficial regulation of cortisol and prolactin in the acupuncture group during the medication phase of the IVF treatment with a trend toward more normal fertile cycle dynamics.

However, the patients were not allocated at random, so the differences between groups could in theory be due to something other than the acupuncture.

fMRI responses to 30 minutes of acupuncture


Imaging studies have not yet provided good understanding of the response of the human brainstem to acupuncture. Two of the reasons are that the brainstem is plagued by artefacts in neuroimaging experiments, and that most previous studies have used only short (<15 minutes) periods of stimulation. These obviously miss any delayed responses that could be seen following longer duration stimulation. These authors used a special technique to diminish the artefacts (brainstem-focused cardiac-gated functional magnetic resonance imaging (fMRI)) and a stimulation period of over 30 minutes. They compared electrostimulation at acupuncture point ST36 with sham point (electrostimulation at a non-acupoint).

They found clear evidence that acupuncture modulates the brainstem nuclei that are known to be relevant to endogenous monoaminergic and opioidergic systems (including the substantia nigra).
nigra, nucleus raphe magnus, locus ceruleus, nucleus cuneiformis, and periaqueductal grey).

They also found a difference in the response to real and sham acupuncture in the ventrolateral periaqueductal grey.

And finally they found that, while some responses decayed over time suggesting classical habituation, the response of some of the limbic regions (amygdala, hippocampus, and substantia nigra), was of a bimodal pattern and not likely to be due to habituation.

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