Recent papers summarised by Adrian White

Clinical effectiveness

Intensive care


Randomised controlled trial (RCT) of PC6 stimulation to promote gastric emptying (n=50).

Methods

Thirty mechanically ventilated neurosurgical intensive care unit (ICU) patients who had delayed gastric emptying, defined as a gastric residual volume (GRV) >500 ml for ≥2 days, after surgery for subarachnoid haemorrhage, intracranial haemorrhage or traumatic injury. They were randomised to two groups. The ‘acupuncture stimulation’ group had bilateral transcutaneous electrical acupuncture point stimulation at PC6 at 7 Hz and 7–13 mA depending on the patient’s wrist size. This was given for one 30-min period daily then 5-min periods every 2 h. The conventional promotility drug treatment group (DTG) were given metoclopramide initially, followed, if unresponsive, with cisapride (until this drug was withdrawn from the market, after which erythromycin) over a period of 6 days. Patients in the stimulation group did not receive any conventional promotility drugs. Successful treatment (ie, tolerance of feeding) was defined as GRV <200 ml per 24 h.

Results

Demographic and haemodynamic data were similar in both groups. After 5 days of treatment, 80% of patients in the PC6 stimulation group successfully developed feeding tolerance compared with 60% in the DTG group. GRVs are shown in figure 1 and there were significant differences between the groups (eg, p = 0.005 on day 1). Overall, the feeding balance in the PC6 stimulated group improved significantly on all days of treatment in comparison with the DTG group. Patients in the DTG group did not show an increase in feeding balance until day 6.

Comment

Malnutrition remains a severe problem in the recovery of critically ill patients and leads to increased in-hospital morbidity and in-hospital stay. Even though early enteral nutrition has been shown to improve overall patient outcomes in the ICU, tubefeed administration is often complicated by delayed gastric emptying and gastrooesophageal reflux.

Acupuncture has been successfully used in the treatment and prevention of perioperative nausea and vomiting. This simple and inexpensive protocol for acupuncture administration could make a significant impact in this environment.

From the scientific point of view, one limitation of this study is that the nurses making the observations were not blinded. This would have been difficult but possible (eg, using double dummy design).

Radiation nausea and vomiting


A sham-controlled RCT compared with a historical cohort (n=267).

Methods

A standard care cohort (n=62) was created from a cross section of patients with cancer receiving radiotherapy over abdominal/pelvic regions from 1999 to 2003. Then from 2004 to 2008, consecutive patients attending one of three clinics and receiving at least 25 Gy of radiotherapy were randomised to verum (penetrating) acupuncture (n=109) in PC6 bilaterally, or sham acupuncture (n=106) with a telescopic non-penetrating Park needle at a sham point 2 inches proximal to PC6. Both interventions were given three times a week for 2 weeks, then twice a week during the whole radiotherapy period. The occurrence of emesis reported in each group was compared after a mean dose of 27 Gy.

Results

Nausea and vomiting were experienced during the preceding week by 37% and 8% (respectively) in the verum acupuncture group, 38% and 7% in the sham acupuncture group and 63% and 15% in the standard care group, as shown in figure 2. The incidence of nausea in the acupuncture cohort (combining verum and sham) was lower than that in patients receiving standard care (37% vs 63%, relative risk (RR) 0.6, 95% CI 0.5 to 0.8). This difference was still seen after adjustment for potential confounding factors for nausea (RR 0.8, CI 0.6 to 0.9). Nausea intensity was lower in the acupuncture cohort (78% no nausea, 13% a little, 8% moderate, 1% much) compared to the standard care cohort (52% no nausea, 32% a little, 15% moderate, 2% much) (p=0.002). The acupuncture cohort expected antiemetic effects from their treatment (95%).
Patients who expected nausea had an increased risk for nausea compared to patients who expected low risk for nausea (RR 1.6; CI 1.2 to 2.4).

Comment
The comparison with standard care was non-randomised, and symptoms were measured slightly differently in the two groups – because it was considered unethical to ask patients in the standard care group to keep a diary because that might increase the symptoms. Although the authors accounted for differences in their statistical analysis, there could be other factors at work. Expectations of acupuncture were measured, and were very high, and in addition the acupuncture patients received a lot of extra care compared with the standard care cohort.

Patients were randomised to acupuncture or sham acupuncture, so the lack of difference between their effects is a reliable finding. The blunt sham needle was stimulated by hand in the same way as the acupuncture needles, without the intention to elicit de qi. Thus from this study, the anti-nausea effect appears not to be dependent on the specific point or on needle penetration.

Intraoperative analgesia


RCT (n=120) of auricular acupuncture (AA) for intraoperative analgesia.

Methods
One hundred and twenty patients scheduled for total hip arthroplasty (THA) were enrolled in this patient-anaesthetist-blinded study. The patients were randomly assigned to receive needling of specific AA points – Hip, Shenmen and Lung – or a sham procedure (needling of three non-acupuncture points on the ear helix) ipsilateral to the surgery site. Fixed indwelling AA needles were placed in the evening before THA, covered with skin-coloured adhesive tape and a surgical cap, and removed on the day after surgery to ensure blinding of the anaesthetists. The acupuncturists had no other contract with the patients.

The patients received general anaesthesia with desflurane, and end-tidal concentration was kept within 3.5 volume % to 5.5 volume % to maintain the Bispectral Index within 40–55%. The anaesthetists were asked to titrate fentanyl to keep the heart rate and blood pressure within 20% of baseline values.

The primary outcome was fentanyl amount given during surgery. The secondary outcome measures were incidence of nausea and vomiting and time to first request of analgesics in the recovery room, as well as incidence of intraoperative bradycardia, which required atropine administration; the frequency of hypotensive episodes. The success of patients’ and anaesthetists’ blinding was also documented.

Results
The data of fentanyl requirement of 116 patients were available for the final analysis: two were withdrawn because of complication and two were given the wrong drug by mistake. As shown in figure 3, the patients in the AA group required 15% less fentanyl during surgery than the controls (4.6±1.1 μg/kg vs 5.2±1.3 μg/kg; mean±SD; p=0.008). Demographic data and secondary outcome measures were comparable in both groups. Eleven patients in the control group experienced nausea and vomiting compared with six in the acupuncture group – which difference did not reach statistical significance.

Comment
This 15% reduction of fentanyl requirement achieved by AA was statistically but not clinically significant. The true clinical effect could be greater if electrical stimulation was applied, and if the control group did not have the skin punctured.

The modest clinical effect, AA should be further investigated for its clinical usefulness for complementary analgesia during the surgery.
Acupuncture research update

Postoperative pain


Electrical device tested in small (n=40) RCT.

Methods

Forty female patients undergoing laparoscopy were randomised. At the end of the operation, while still under general anaesthesia, the AA group had 3 mm needles inserted at three sites (Shenmen, Thalamus and one segmental organ-specific point) and attached to a proprietary electrical stimulation device, P-Stim. This gave a constant 1 Hz stimulation at 2 mA for 3 out of every 6 h over the trial period of 72 h. The control group had electrodes applied, and attached to an inactive P-Stim unit.

Postoperatively, patients received 1000 mg paracetamol every 6 h. Additional piritramide was given on demand. A blinded observer obtained the Visual Analogue Scale (VAS) scores at 0, 2, 24, 48 and 72 h as well as the postoperatively administered doses of piritramide. Both piritramide dose and pain VAS were the main outcome measures.

Results

There was no difference in VAS scores or the consumption of piritramide (see figure 4) during the first 72 h postoperatively between groups: acupuncture versus placebo: 2.32 (CI 1.40 to 3.25) versus 2.62 (1.89 to 3.36) average pain on VAS 0–10; 15.3 (12.0 to 18.6) mg versus 13.9 (10.5 to 17.3) mg piritramide.

Comment

This study shows no opioid sparing effect postoperatively, and, since the blinding was good quality, it challenges the current evidence in favour of an effect. However, there may be type II error since the sample size here was calculated to identify a 25% treatment effect – which is large, though it has been achieved in previous, unblinded, studies. And there may be ‘floor’ effects in this group of patients since they were given large regular doses of paracetamol after laparoscopy.

Breastfeeding


RCT (n=90) comparing acupuncture with advice alone.

Methods

Ninety women who had been referred to the local breastfeeding service for advice on poor milk production were randomly divided into two groups: acupuncture treatment or observation (usual care). Acupuncture sessions were performed twice weekly for 3 weeks (total six sessions). Patients were placed into one of two diagnostic categories from their history. All were treated at SI1, ST18 and CV17. Those with one diagnosis (‘Qi and Blood deficiency’) were ST36, SP6 and BL20 were added; for those with a diagnosis of ‘Liver Qi Stagnation’, LR3 and PC6 were added. There was a specific protocol for manipulation of the needles to elicit de qi. The control group made weekly visits to the clinic and the midwife observed their breastfeeding, giving routine care. The report does not make it clear whether the acupuncture group received ‘routine care’ in addition to the acupuncture.

The evaluation was based on a semi-structured clinical assessment of quality of breastfeeding by the midwife at enrolment and after 3 weeks, plus a telephone interview conducted by the midwife at the third month of the infants’ lives.

Results

Breastfeeding rates are shown in figure 5. The differences at both 3 weeks and 3 months were significant (p<0.05). Such preliminary data suggest that 3 weeks of acupuncture treatment were more effective than observation alone in maintaining breastfeeding until the third month of the newborns’ lives.

Comment

The authors state this is the first study of acupuncture for breastfeeding in the West though apparently they found several studies already in Chinese literature. They call it ‘preliminary data’ and the study is interesting rather than impressive – it is a shame that it is scientifically limited by lack of objective measure of milk production, and they seem not to have arranged for the usual care advice to be delivered by blinded healthcare staff – which would be feasible. Since women were enthusiastic to have acupuncture (and three left the study when they were randomised to usual care), and the acupuncture group attended more

Figure 4 Postoperative pain VAS.

Figure 5 Numbers breastfeeeding.
Effect modifiers


Re-analysis of RCT data (n=9900) to identify patient characteristics that either predict the outcome or influence the effect of acupuncture.

Methods

Data from German trials on chronic low back pain, headache, neck pain or pain due to osteoarthritis of the knee or hip were pooled. The outcome was the 3-month change from baseline of the SF-36 bodily pain subscale. To identify predictors for treatment effects and effect modifiers (ie, variables that interact with the form of treatment), patients’ characteristics and their interaction with treatment were included in a mixed linear model to predict treatment outcome.

The variables tested were: sex; age; duration of schooling, university degree; family status (single household vs multi-person household); duration of pain; concomitant diseases (hypertension, circulatory disorders, heart attack, cardiac failure, stroke, asthma, diabetes, cancer, coronary heart disease, inflammatory joint diseases and other); previous treatment with CAM within 12 months before the study; reasons for choosing acupuncture (earlier successful acupuncture therapy, recommended by physician, failure of other therapies, recommended by friends/relatives, preference of holistic treatment, wish to reduce pain medication, other reasons).

Results

A total of 9990 patients treated by 2781 physicians were analysed. The outcome was markedly improved in the acupuncture group (p<0.001). Patients’ characteristics that increased the acupuncture effect (ie, acted as effect modifiers) are shown in table 1: being female, living in a multi-person household, failure of other therapies before the study and a previous positive acupuncture experience.

Comment

Choosing the patients most likely to respond to acupuncture is crucial – not only for designing clinical trials but more importantly for organising an efficient service. Most attention has focused on expectation, for which the evidence is mixed.

This project made a clear distinction between outcome predictors (patient characteristics that would influence the patient’s outcome whether they had acupuncture treatment or not) and effect modifiers (patient characteristics that are associated with a better response to acupuncture).

The authors identified nine predictors of outcome, independent of treatment: worse prognosis was found among those with lower baseline pain, previous acupuncture treatment (without considering whether the treatment was successful), and the presence of certain concomitant diseases – hypertension, asthma, diabetes and ‘other’. In contrast, better prognosis was found among patients under the age of 50 years, patients with more school education, and patients whose pain condition began less than 4 years ago. That is in line with other evidence.

This study takes our understanding forward. You could characterise a ‘likely responder’ to acupuncture as a woman living with other people, who had an earlier good result with acupuncture and whose condition has also responded previously to other therapies. However, the effects seen here are not large enough to provide a basis for deciding who should and should not have acupuncture at an individual level.

Systematic reviews

Primary dysmenorrhoea


A review of 10 RCTs.

Methods

The extensive search included Chinese databases. RCTs compared acupuncture, electroacupuncture, and acupressure with placebo control, usual care, and pharmacological treatment. Participants had to be women of reproductive age with primary dysmenorrhoea during the majority of the menstrual cycles or for three consecutive menstrual cycles, and moderate to severe symptoms.

Primary outcomes were pain relief and improved menstrual symptoms, measured by self-rating scales. Other outcomes included use of analgesics, quality of life and absence from school or work.

Results

Six trials reported on acupuncture (n = 673). Overall, there was an improvement in pain relief compared with a placebo control (OR 9.5, 95% CI 21.17 to 51.8), non-steroidal anti-inflammatory drugs (standardised mean difference, SMD −0.70, 95% CI −1.08 to −0.32) and Chinese herbs (SMD −1.34, 95% CI −1.74 to −0.95). In two trials acupuncture reduced menstrual symptoms (eg, nausea, back

Table 1 ORs of an effect

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Acupuncture</th>
<th>Usual care</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>1.1</td>
<td>0.88</td>
<td>0.028</td>
</tr>
<tr>
<td>Single person household</td>
<td>0.75</td>
<td>1.16</td>
<td>0.002</td>
</tr>
<tr>
<td>Earlier positive acupuncture experience</td>
<td>1.25</td>
<td>0.92</td>
<td>0.005</td>
</tr>
<tr>
<td>Earlier failure of other therapies</td>
<td>0.90</td>
<td>0.70</td>
<td>0.049</td>
</tr>
</tbody>
</table>
pain) compared with medication (OR 3.25, 95% CI 1.53 to 6.86); in one trial acupuncture reduced menstrual symptoms compared with Chinese herbs (OR 7.0, 95% CI 2.22 to 22.06); and in one trial acupuncture improved quality of life compared with usual care.

Four trials reported on acupressure (n = 271). There was an improvement in pain relief from acupressure compared with a placebo control (SMD −0.99, 95% CI −1.48 to −0.49), and in one trial acupressure reduced menstrual symptoms compared with a placebo control (SMD −0.58, 95% CI −1.06 to −0.10). The risk of bias was low in 50% of trials.

**Comment**
The evidence here shows that acupuncture has large effects on these symptoms. This would make a good topic for further trials.

**Smoking cessation**


Update of a previous review (33 studies including 9 new).

**Methods**

Chinese databases were included in the search for the first time. RCTs compared acupuncture, acupressure, laser therapy or electrostimulation with either no intervention, sham treatment or another intervention for smoking cessation.

Abstinence from smoking was assessed both at the earliest time-point (before 6 weeks) to detect any effect at all; and up to 1 year to detect any sustained, clinically useful effect.

**Results**

We included 33 reports of studies. Compared with sham acupuncture, the fixed-effect risk ratio for the short-term effect of acupuncture in 2206 participants was 1.18 (95% CI 1.03 to 1.34), and for the long-term effect was 1.05 (CI 0.82 to 1.35) as shown if figure 6. The studies were not judged to be free from bias. Acupuncture was less effective than nicotine replacement therapy. There was no evidence that acupuncture is superior to waiting list, nor to psychological interventions in short- or long-term. The evidence on acupressure and laser stimulation was insufficient and could not be combined. The evidence suggested that electrostimulation is not superior to sham electrostimulation.

**Comment**

One new study of ‘laser acupuncture’ produced a remarkably positive result and was double-blinded, but was contradicted by a second study.

The main analysis of needle acupuncture included body, facial (mainly from France) and auricular acupuncture (AA). It was, strictly speaking, positive in the short-term but only one study was individually positive and the majority really did not show any effect at all. After much debate, we reached a rather tortuous conclusion. ‘There is no consistent, bias-free evidence that acupuncture, acupressure, laser therapy or electrostimulation are effective for smoking cessation, but lack of evidence and methodological problems mean that no firm conclusions can be drawn.’

One particular issue with this evidence is that RCTs of AA compared ‘correct’ points with ‘incorrect’ ones: the idea that there are right and wrong points in the ear is traditional but unlikely to have any biological basis.

More research into acupuncture, acupressure and laser stimulation is justified because these are popular interventions and safe when correctly applied.

**Basic research**

**Cranial blood flow**


**Methods**

Ten healthy male subjects (mean age 25.6±0.8 years) lay relaxed while middle cerebral artery (MCA) and anterior cerebral artery (ACA) blood flow velocities were measured using a transcranial laser Doppler flowmeter. Then subjects over-breathed for 1 min in order to generate hypocapnia, and the blood flow was remeasured (CO2 reactivity). Finally, subjects were needled at GV20 to a depth of 5 mm for 20 min, with stimulation every 5 min.

Measurements were therefore taken both at rest and during hypocapnia, and were repeated four times each at different cerebral artery territories with an interval of 1 week. Blood flow velocity was corrected to 40 mm Hg of end-tidal CO2 partial pressure (PETCO2), and was expressed as CV40. CO2 reactivity was measured as percent change in mean blood flow velocity/mm Hg PETCO2.
Mean MCA and ACA blood flow velocities at rest and CO$_2$ reactivity during hypocapnia increased significantly after GV20 acupuncture treatment as shown in the figure 6 (p=0.005 for all comparisons), mean arterial blood pressure and pulse rate at rest did not change significantly.

**Comment**
This was a well thought out study designed mostly to establish the protocols for measurement and analysis. The authors excluded sham control needling because of the uncertainties over whether it has any effect or not. And they regret that they were not able to measure the flow in posterior cerebral artery because of difficulty of access. The authors argue that the changes in cerebral blood flow were due to reflex vasomotor control rather than changes in oxygen or CO$_2$ content of the blood. Other studies have shown changes in cerebral blood flow after acupuncture to body points such as PC6, ST36.

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