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

Psychological effects of acupuncture

Some recent studies have given new insights into the ‘placebo’ affects associated with acupuncture. These are reviewed as a group.

Expectation did not influence the outcome (1)


This paper is an analysis of further data from an earlier RCT (n = 552). The study itself found that the effect of advice and exercise on knee pain and function in osteoarthritis was not further increased by the addition of either acupuncture or sham acupuncture.1 This analysis investigated the relationship between the clinical outcomes for patients and their preferences and expectations, as well as those of the therapist.

Methods

Patients (n = 552) in 37 centres were randomised to advice and exercise, or advice and exercise plus true or non-penetrating acupuncture. Before randomisation, patients recorded their general expectations of the outcome and any preferences they had for a specific treatment, and scored, on an 11 point scale, the strength of their expectations that their knee problem would be improved by either advice and exercise or acupuncture. In addition, the 67 physiotherapists, after assessing each patient, recorded their own preferences for them and their treatment expectations.

The clinical outcome was (a) change scores on the Western Ontario and McMaster Osteoarthritis Index (WOMAC) and (b) treatment response according to the OMERACT-OARSI criteria.

Results

Ten per cent of patients had a preference for advice and exercise, 13% for acupuncture and 44% would choose either. Mean scores for the expectation of benefit was 5.9 (SD 2.3) for advice and exercise and 6.5 (SD 2.2) for acupuncture. At 6 and 12 months, there was no significant relationship between patients’ clinical outcomes and their treatment preferences; nor between patients’ expectations and pain (WOMAC) at 6 or 12 months. Overall, 202 patients happened to receive the treatment for which they had a preference—but they did not show any greater improvement than the remainder. However, in the analysis with a secondary outcome (OMERACT-OARSI), those who received the treatment for which they had high expectations of benefit were almost twice as likely to be classified as a treatment responder at 6 months (OR 1.7, 95% CI 1.06, 2.79) and 12 months (OR 1.9, 95% CI 1.13, 3.13).

The physiotherapists expressed a preference for treatment for 45% of their patients, their expectations of benefit were the same for advice and exercise, and for acupuncture. However, their expectations for individual patients did not correlate with their outcome. Even when high expectations of the patients themselves matched high expectations of the physiotherapists, the outcome was not better.

Conclusion

This study only found a weak link between patients’ expectations and the outcome of treatment in this trial. Other studies have found a relationship, and it is not yet clear what governs the effect of expectation.

Expectation did not influence the outcome (2)


This study searched for the ‘response predictors’ in the earlier large (n = 658) study of acupuncture for chronic back pain. The original study showed no difference between individualised, standardised or simulated acupuncture treatments, all of which were superior to usual care for function at 8 weeks and 52 weeks, and for pain at 8 weeks.2

Methods

The authors first identified which factors predicted improvements in patients’ back pain and function. Then we tested for an interaction between the prognostic factors and acupuncture treatment in four models: functional outcomes (measured by the Roland-Morris Disability Scale) at 8 and 52 weeks post-randomisation, and symptom outcomes (measured with a numerical rating scale) at 8 and 52 weeks.

Results

Overall, the strongest predictors of improvement in back function and symptoms were higher baseline levels of these measures, receipt of an acupuncture treatment, and non-use of narcotic analgesics. Benefit from acupuncture compared to usual care was greater with worse pre-treatment levels of back dysfunction (interaction p < 0.004 for the functional outcome, Roland Morris Disability Scale at 8 weeks). No other consistent interactions were observed.

Comment

Expectation of benefit from acupuncture was one of the factors included in this analysis: expectation made no difference to the outcome of treatment.

Outcome influenced by patient and practitioner characteristics


This is another output from the recent study (n = 289) of placebo acupuncture for irritable bowel syndrome. The first results published in BMJ showed that an ‘augmented’ or empathic consultation had significantly larger effect than a ‘limited’ consultation, which in turn showed a greater effect than a waiting list (time, regression to the mean and Hawthorne effect).3

This analysis examined whether the characteristics of the patient, the practitioner, or their interpersonal interaction had any effect on the outcome. Patients were assessed for five personality characteristics: extraversion, neuroticism, agreeableness, conscientiousness and openness to experience. The patient-practitioner interaction was assessed by blinded scoring of videos of their consultations for items such as aloofness, tact and empathy.

Methods

Patients with irritable bowel syndrome who were treated with (non-penetrating) placebo acupuncture in either a warm empathic interaction (Augmented, n = 96), a neutral interaction (Limited, n = 97), or a waitlist control (Waitlist, n = 96). The researchers examined the relationships between the placebo response and: (a) patient personality and demographics; (b) treating practitioner; (c) the patient-practitioner interaction. Four different outcome measures were combined into a single score which was standardised to a mean score across all patients of 50 (SD 10).

Results

Patient extraversion, agreeableness and openness to experience were associated with placebo response, but only in the augmented group. In the augmented group, women (55.8 SD 10.3) had significantly better outcomes than men (50.5 SD 8.8)—in fact, the men had approximately the same average outcome as the patients in the limited consultation group. Regression analyses controlling for all
other independent variables suggest that only extraversion is an independent predictor of placebo response.

There were significant differences between the four practitioners and their patients’ outcomes; this difference was twice as large (6 points) as the effect attributable to treatment group assignment (3 points). Videotape analysis indicated that the augmented group fostered a treatment relationship similar to a prototype of an ideal healthcare interaction. This difference between practitioners has already been observed in psychotherapy research.

Conclusions

Personality and gender influenced the placebo response, but only in the warm, empathic, augmented group. This suggests that, to the degree a placebo effect is evoked by the patient-practitioner relationship, personality characteristics of the patient will be associated with the placebo response. In addition, practitioners differed markedly in effectiveness, despite standardised interactions. The authors propose that the quality of the patient-practitioner interaction accounts for the significant difference between the groups in placebo response.

It’s not ‘expectation’ anyway!


This paper reports the qualitative interviews of 12 patients who received placebo in the same trial (n = 289) as the preceding report. It makes fascinating reading and anyone interested in current ideas of placebo responses is urged to read the original. The introduction alone is a master-class. Patients in the placebo arms of randomised controlled trials (RCT) often experience positive changes from baseline. While multiple theories concerning such ‘placebo effects’ exist, peculiarly, none has been informed by actual interviews of patients undergoing placebo treatment. Patients received an additional set of interviews at the beginning, midpoint and end of the trial.

Box 1 Fred summarises this sense of neutral expectations by saying: “I really have no expectations whatsoever, you know”. Kate said: “I can’t say I’m expecting that much, but I think if something did happen, it’d be a pleasant surprise…. It is worth a shot because otherwise, if nothing else, I’m no worse off than I am today, you know…. I haven’t anything to lose”.

And Alan passively states: “Not really. I don’t have any particular [expectations], no. I just want to come for the experience and see what happens”.

We found that patients: (1) were persistently concerned with whether they were receiving placebo or genuine treatment; (2) almost never endorsed ‘expectation’ of improvement but spoke of ‘hope’ instead and frequently reported despair; (3) almost all reported improvement ranging from dramatic psychosocial changes to unambiguous, progressive symptom improvement to tentative impressions of benefit; and (4) often worried whether their improvement was due to normal fluctuations or placebo effects.

The placebo effect involved a spectrum of factors and any single theory of placebo—for example, expectancy, hope, conditioning, anxiety reduction, report bias, symbolic work, narrative and embodiment—provides an inadequate model to explain its salubrious benefits.

Clinical trials of effectiveness

Hot flushes in breast cancer patients


This RCT compared acupuncture with needle control in women (n = 59) with breast cancer suffering from hot flashes as a result of anti-oestrogen medication.

Methods

Women enrolled in the study had completed breast cancer surgery and radiotherapy and were experiencing hot flashes from adjuvant oestrogen-antagonist treatment (Tamoxifen) which they had been taking for at least 3 months. Women were randomised to weeks of either traditional Chinese acupuncture with eight needles in LR3, GB20, LU7, KI3, SP6, CV4, PC7 and LR8 on the side opposite the operation site; needles were stimulated to elicit de qi at the beginning and end of the session; or a control group with sham acupuncture consisting in superficial insertion of needles to four non-points bilaterally. They were given 15 treatments over 10 weeks, ie, twice weekly for the first 5 weeks. The physiotherapist administering the acupuncture used standardised interaction to minimise the bias as much as possible.

The outcome was the mean number of hot flashes at day and night up to 12 weeks following treatment, as well as the Kupperman index, a quality of life scale in this condition.

Results

During the treatment period, the mean number of hot flashes at day and night was significantly reduced by 50% and almost 60%, respectively from baseline in the acupuncture group, and was further reduced by 30% both at day and night during the next 12 weeks (figure 2). In the sham acupuncture group, a significant reduction of 25% in hot flashes at day was seen during treatment, but was reversed during the following 12 weeks, and no reduction was seen in hot flashes at night. The difference between groups was highly significant (p<0.001) both during and after treatment. The Kupperman index was reduced by 44% from baseline to the end of the treatment period in the acupuncture group, and largely maintained 12 weeks after treatment ended. No corresponding changes were seen in the sham acupuncture group.

Comment

As survival from breast cancer increases there is a corresponding rise in the number of women living with long term consequences of treatment, including hot flashes. In women with natural menopause, acupuncture clearly has a large effect but it is not possible to be sure if this is a true needle effect since the majority of needle-controlled trials have had too small samples to be definitive. One previous study in cancer patients showed no effect compared with non-penetrating

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needles, though only gave eight treatments over 4 weeks. Maybe the long course of treatments in this study contributed importantly to the significant effect that was seen. Thus two studies in this highly important area have opposite results and more research is urgently needed.

Male infertility


This RCT compared acupuncture and blunt needle in infertile males (n = 57).

Method

In this study, males from infertile couples were recruited if they had sperm counts of <1 million sperm/ml. The acupuncture group received acupuncture at points ST36, SP6, KI3, LR3, BL32, BL52, ST29, SP10 bilaterally and CV4, GV20 in the midline. In the control group, non-penetrating needles were used at the same points (omitting GV20 because of difficulty fixing the device). Treatments lasted for 45 minutes, and were given twice weekly for 6 weeks.

The outcome was sperm motility (World Health Organization categories A–C), supported by sperm concentration and semen volume. Semen examination was done twice before and after treatment, at approximately monthly intervals.

Results

A significantly higher percentage of motile sperm was found after acupuncture, which was not seen after blunt needle. (The report does not contain a clear statistical comparison between groups, only needles, though only gave eight treatments over 4 weeks. Maybe the long course of treatments in this study contributed importantly to the significant effect that was seen. Thus two studies in this highly important area have opposite results and more research is urgently needed.

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Comment

The abstract gives the impression that this study showed a positive finding; however, the difference between groups was not (apparently) verified statistically and was contradicted by other supporting outcomes.

Induction of labour


This RCT (n = 89) evaluated the efficacy of acupuncture for inducing labour. Acupuncture is routinely used for this purpose in some societies and recommended by the Shanghai College of Traditional Medicine. The current Cochrane Review of the evidence concluded that women given acupuncture are less likely to need induction than those given standard care.

Methods

Nulliparous women at 38 weeks or greater were randomised to (traditional Chinese medicine) acupuncture, sham acupuncture or usual care only groups. For the genuine acupuncture group, up to five sessions of manual acupuncture were given over two weeks using points LI4, SP6, BL32 and BL54 bilaterally. (The location of BL54 is 3 cun lateral to the fourth sacral foramen.) The sham acupuncture group received needling in non-points: two on the outer side of the hip, and one each on the lateral surface of forearms and lower legs. All needles were retained for 30 min.

The primary outcome was time from enrolment to delivery, recorded retrospectively by a blinded observer from the medical records or by telephoning the woman. Secondary outcomes included rates of spontaneous labour and caesarean delivery. Medical records were abstracted for maternal demographic, medical and delivery outcome data. ANOVA, Student t test, χ² and Kaplan-Meier statistics were used to compare groups.

Results

Eighty-nine women were enrolled and randomised. The groups were similar for all baseline characteristics such as maternal age, gestational age, prior acupuncture experience, tobacco, alcohol and drug use. There were no statistically significant differences among groups for time from enrolment to delivery (p = 0.20), rates of spontaneous labour (p = 0.66), or rates of caesarean delivery (p = 0.37). Rates of maternal and neonatal outcomes were not significantly different.

Comment

Neither traditional Chinese medicine acupuncture nor sham acupuncture (in similar spinal segments) were effective in initiating spontaneous labour or reducing the rate of caesarean delivery compared with usual medical care. This result conflicts with the current state of the evidence, so which is right? There are three points to consider, the first two suggested by the authors in their excellent discussion section.

Firstly, were the women likely to be less responsive to acupuncture? In this study women were recruited once they had reached 38 weeks—which might be too early to respond. This could be important and needs to be pursued: acupuncturists are anxious about early pregnancy for fear of inducing spontaneous uterine contractions (abortion). If uterine contractions can only be induced very late in pregnancy, that would support the safe use of these points in early pregnancy.

Secondly, was this study large enough to avoid type II error (i.e., not identifying a difference that really exists)? The sample size was calculated based on being able to identify a 3 day difference. One
could argue that a smaller difference might be clinically relevant. However, the results showed no trends towards any meaningful differences between the groups.

Thirdly, this study did not use electroacupuncture (EA), because of the perceived difficulties in blinding patients. Maybe electrical stimulation is necessary for the effect? More and probably larger studies are needed.

Systematic reviews
Two reviews on moxibustion for breech


The first review, from the Chinese Centre for Evidence Based Medicine, found 10 RCTs with 2090 participants, and also included evidence from seven non-randomised studies 2090 participants. The second included six RCTs with 1087 participants, and commented on the high degree of heterogeneity.

They agree in the main meta-analysis, which showed significant differences between moxibustion and no treatment (relative risk 1.35, 95% CI 1.20 to 1.51). The actual rate of cephalic version among the moxibustion group was 72.5% and 53.2% in the control group. The number needed to treat was 5 (95% CI 4 to 7).

The Chinese study went on to compare moxibustion and the knee-chest position: there were no significant differences (RR 1.30, 95% CI 0.95 to 1.79; 3 RCTs). Laser stimulation was more effective than assuming the knee-chest position plus pelvis rotating.

Comment
This reviewer remains highly sceptical of any specific effect of moxibustion to the little toe, in the absence of a plausible physiological mechanism, and is reassured that the evidence is compatible with the concept that the reported effects may actually be achieved through the knees-up position that the patient has to adopt to apply the treatment to her little toes.

Basic research
Sympathetic activity in polycystic ovary syndrome


This is the first demonstration that low-frequency EA and physical exercise can reduce high sympathetic nerve activity in women with PCOS.

Glia cells


According to recent evidence, acupuncture at ST36 can regulate gastric activity, probably through the central neurons in the dorsal vagal complex. However, whether EA at ST36 regulates the glial cells of the dorsal vagal complex is unknown.

In this study, we observed the effect of EA at ST36 on regulation of gastric activity. Propentofylline (PPF), a glial metabolic inhibitor, was used to inhibit the function of glial cells. EA at ST36 increased the expression of glial fibrillary acidic protein (GFAP) and OX42 significantly compared to that of the control group, with associated changes in gastric motility, with significantly higher frequency and wave amplitude. In the rats that were pretreated with PPF, the expressions of GFAP and OX42 were decreased markedly, as was gastric motility. The results suggest that EA at ST36 could regulate gastric activity by activating glial cells in the dorsal vagal complex.

Glia cells are increasingly recognised to have important role in long-term modulation of brain functions.

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