Can acupuncture have specific effects on health? A systematic review of acupuncture antiemesis trials

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SUMMARY

The effects of acupuncture on health are generally hard to assess. Stimulation of the P6 acupuncture point is used to obtain an antiemetic effect and this provides an excellent model to study the efficacy of acupuncture. Thirty-three controlled trials have been published worldwide in which the P6 acupuncture point was stimulated for treatment of nausea and/or vomiting associated with chemotherapy, pregnancy, or surgery.

P6 acupuncture was equal or inferior to control in all four trials in which it was administered under anaesthesia; in 27 of the remaining 29 trials acupuncture was statistically superior. A second analysis was restricted to 12 high-quality randomized placebo-controlled trials in which P6 acupuncture point stimulation was not administered under anaesthesia. Eleven of these trials, involving nearly 2000 patients, showed an effect of P6. The reviewed papers showed consistent results across different investigators, different groups of patients, and different forms of acupuncture point stimulation.

Except when administered under anaesthesia, P6 acupuncture point stimulation seems to be an effective antiemetic technique. Researchers are faced with a choice between deciding that acupuncture does have specific effects, and changing from 'Does acupuncture work?' to a set of more practical questions; or deciding that the evidence on P6 antiemesis does not provide sufficient proof, and specifying what would constitute acceptable evidence.

INTRODUCTION

Acupuncture is a controversial method of treatment, and one of the most contentious issues is whether it can have specific effects on health. This question is not easily answered. Though the placebo-controlled, randomized clinical trial is thought to be the most reliable method of determining whether a therapy has specific effects on health, there are difficulties in applying this methodology to acupuncture. For example, practitioners of acupuncture claim that each patient requires a special regimen such that two patients with the same diagnosis (say, rheumatoid arthritis) require needling of different sets of acupuncture points. Moreover, the various schools of acupuncture do not completely concur on the points that would be indicated for a given patient. Interestingly, there is wide agreement that non-indicated points can be of some benefit, complicating the task of a designing placebo controls.

The methodological difficulties of acupuncture research are exacerbated by traditional practitioners' use of adjunctive therapies such as herbs, massage, dietary treatment, and moxibustion (the burning of a herb over an acupuncture point). Furthermore, practitioners claim to have greatest success with chronic conditions such as back pain, arthritis, asthma, and migraine in which clinical trials are complicated by withdrawals, drop-outs, and natural remissions.

Stimulation of the P6 acupuncture point, which is located just above the wrist, is traditionally associated with the control of nausea and vomiting and provides an excellent model to study the efficacy of acupuncture. Only one acupuncture point is used, allowing for easy design of treatment and control groups. In many instances—e.g., after surgery—only a short follow-up is needed and the outcome measures, at least in the case of vomiting, are highly objective. Clinical trials of P6 antiemesis are thus easy to design and conduct and provide a useful 'test case' of the efficacy of acupuncture. In this review of published work I seek to examine whether P6 acupuncture point stimulation has specific effects in the control of nausea and vomiting associated with surgery, cancer chemotherapy, and morning sickness. The result of the review will cast light on the question: 'Can acupuncture have specific effects on health?'

SEARCH PROCEDURE

A publication search was conducted in March 1995 by means of the Research Council for Complementary Medicine's

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CISCOM database. CISCOM is thought to be the most comprehensive database of complementary medicine research in the world, and will form the basis of the registry of randomized controlled trials for the Cochrane Collaboration field in complementary medicine. Though CISCOM is not on-line, it is available for use by researchers. The keywords used were 'clinical trials' with 'acupuncture' with 'nausea' or 'vomiting' or 'hyperemesis gravidarum'. The term 'acupuncture' is a general term which searches for a number of narrower terms: 'electroacupuncture', 'moxibustion', 'acupuncture point', and 'meridians'. Searches were also made with 'transcutaneous electronic nerve stimulation' to see if reference was made to the use of the P6 acupuncture point. MEDLINE (1966 to March 1995) and EMBASE (1985 to March 1995) were re-searched with the same terms to check the comprehensiveness of CISCOM (no extra studies were located), and citation tracking was used to find further suitable references. Leading authorities were contacted and asked to check that the list of references was indeed comprehensive.

Trials were included in the review if they met three specific criteria: (1) therapy—stimulation of the P6 acupuncture point by needling, manual pressure, or electricity; (2) condition—nausea and/or vomiting resulting from surgery, cancer chemotherapy, or pregnancy; (3) methodology—the clinical outcome of a group of patients receiving P6 stimulation compared with that in patients receiving no intervention, a placebo, or a non-acupuncture intervention.

Forty-two papers were located[1–42]. Two papers were included despite containing no mention of the P6 acupuncture point. In one[29], the treatment involved electrical stimulation to the volar surface of the wrist with a device akin to a wrist watch. It is likely, therefore, that this trial involved stimulation of the P6 acupuncture point. The author was contacted and he confirmed that the device would have stimulated the P6 point and that this was the express purpose of therapy. A second paper[6] was included because the therapy was described as 'wrist acupressure' and a diagram indicated that the site of pressure was the P6 point.

Trials fitting the criteria above were reviewed systematically. One paper[16] published in German was assessed by Klaus Linde, of the Ludwig-Maximilians-Universität. Dr Linde reviewed a selection of other papers to provide a double-check of the reliability of the scoring method.

The internal validity of each paper was assessed by means of a methodological checklist as follows. The *population* from which the trial participants are drawn should be adequately described. The experimental and control groups should come from the same population. The sampling method should not introduce bias or confounding variables. A full list of eligibility and exclusion criteria should be given where appropriate. The *sample size* should be sufficient to ensure that positive results were not due to chance variation and that negative results were not due to insufficient power. There should be *random allocation* to different treatment groups. All relevant *prognostic variables* should be adequately assessed. There should be no major differences between groups at baseline. The *test intervention* should be described in full. There should be no substantial variations in the treatment received by different patients in the experimental group. A credible, inactive *placebo* should be used where possible. Where no placebo is used, control groups should receive standard care, but this should have been independently evaluated against placebo. *Outcome measures* must be appropriate to the therapy and condition. The follow-up times should also be appropriate. Patients should be *blind* to their treatment allocation, as should researchers assessing outcome. *Withdrawals* and *non-respondents* should constitute less than 20% of the initial sample. The number of observations, central tendency, and measure of dispersion should be given for the main outcome measures, and appropriate *inference statistics* should be used. The main outcome measure should be predefined: multiple testing should be avoided. Intention-to-treat analysis should be used where appropriate.

Each paper was ranked as good, fair, or poor for each criterion. 'Good' indicates that the criterion was met adequately; 'fair' indicates that though the criterion was not fully met, the results of the trial were unlikely to have been affected; and 'poor' indicates that the criterion was not met, and that this may well have affected the result of the trial. For example, the adequacy of baseline matching was scored as good if all relevant prognostic variables were assessed at baseline and there were no major differences between groups; as fair if some variables were omitted, or if there were minor differences between groups, but that these were unlikely to have affected the result of the trial; and as poor if there were substantial differences between groups, if important prognostic variables were omitted, or if no baseline matching was attempted. Note that only the internal validity (i.e. rigour) of each trial was assessed. For example, if a trial had particularly restrictive eligibility or exclusion criteria, such that the sample differed importantly from that generally found in clinical practice, this lowers its external validity (i.e., generalizability). However, internal validity would be affected only if the particular choice of criteria could influence the outcome of the trial.

Trials were classed as positive if the authors made an explicit statement to that effect in the text and, in addition, P6 was statistically superior to the control procedure for at least one outcome measure.

RESULTS

Nine papers[34–42] were excluded from the review after analysis. Paper 34 was found to be a pooling of data from

several studies that had previously been reported in brief. Two of the studies[8,9] pooled in paper 34 were randomized and these were analysed separately. There were insufficient data in the original reports to undertake a methodological analysis; however, paper 34 described a methodology in detail and stated that this methodology had been used for all trials. Studies 8 and 9 were therefore taken to have the methodology described in paper 34. Other trials reported in brief and pooled in paper 34 were excluded[36–42] on the grounds that non-randomized studies reported with little methodological detail would not add usefully to this review. Paper 35 was excluded because it was found to be a duplicate of paper 22. One trial[21] was published in Chinese; it was read in abstract form only and, though its results are presented in Table 1, it was excluded from the analysis. All excluded trials showed an effect of P6 stimulation on emesis, so this exclusion strategy is likely to have been conservative.

Tables 1–3 summarize the results of the studies and Table 4 gives methodological assessments. Some comments on the quality assessment are offered in Table 5. Agreement between reviewers was good. Most scoring differences resulted from reading errors and the remainder were resolved by discussion.

Thirty-three trials were analysed. Twenty-one[1–21] examined postoperative vomiting, five[22–26] cancer chemotherapy, and seven[27–33] morning sickness. Manual or electrical acupuncture was used in 13 studies[1–5,7–9,11–12,14,22,23], manual acupressure in seven[6,10,15,16,27,30,32], acupressure applied by a commercially available elasticated wrist band ('Sea Bands') in seven[13,19,24,25,28,31,33], transcutaneous electric nerve stimulation (TENS) in four[17,18,26,29], and acupoint injection in two studies[20,21]. Control groups included no intervention[7–9,12,18–21,26,28] or historical[10,23,25], acupuncture under general[1–4] or local[14] anaesthesia, stimulation of a 'dummy' point[5,22,27,31,32], and or the use of placebo 'Sea Bands'[16,13,30] or inactive ('mock') TENS stimulators[17,18].

In the four trials where stimulation was given under general anaesthesia P6 showed no effect; of the remaining 29 trials 27 were positive for P6 antiemesis. It was decided to conduct a further analysis including only randomized, placebo controlled trials in which P6 was not administered during anaesthesia and where not more than two methodological criteria were scored as poor. Twelve trials[5–6,13–18,22,27,30,32], involving a total of 1932 patients, were included in this analysis and 11 of these revealed statistically significant differences between P6 and placebo. The exception is Lewis *et al.*, who observed no benefit from P6 acupressure in children undergoing outpatient strabismus correction[15]. The 11 positive trials were conducted by eight different principal investigators working at seven different sites and using several different forms of P6 stimulation.

DISCUSSION

Several systematic reviews of acupuncture have already been published. Kleijnen studied 13 trials of acupuncture for asthma[44] and concluded that the generally poor methodology and contradictory results precluded definitive judgment. Ter Riet's review of acupuncture for chronic pain[45] came to a similar conclusion. Only 11 of 51 studies were considered of sufficiently high quality. Of these, five favoured acupuncture—an indeterminate result. In a meta-analysis of acupuncture for treatment for pain, Patel *et al.*[46] claimed that 'while few individual trials had statistically significant results, pooled results of many subgroups attained statistical significance in favour of acupuncture'. There are reasons to query this claim. The authors combined trials with very different methodologies, including both blinded and unblinded studies, those with different control groups (no intervention, electrical stimulation, or placebo acupuncture), and those involving different sites and aetiologies of pain. A subgroup analysis of only blinded studies found acupuncture to be only marginally superior to control. A fourth review[47] involved the unusual expedient of combining data from studies on tobacco, alcohol, and heroin addiction. The authors concluded that acupuncture is not an effective modality for substance dependence. However, the data set consisted largely of studies on smoking cessation and the application of the overall result of the review to the two subgroups where there were few data (alcohol and heroin abuse) is open to question.

The equivocal findings of previous systematic reviews may reflect the methodological difficulties of acupuncture research. However, this systematic review does suggest that P6 stimulation is an effective antiemetic technique. Two questions now arise. First, why the obvious difference between trials depending on whether or not acupuncture was administered under anaesthesia? Secondly, could the positive results be due to something other than a specific effect of P6 acupuncture point stimulation on nausea and vomiting?

There are three possible reasons why acupuncture under anaesthesia proved ineffective. One is the timing. In a non-randomized study, Dundee[11] compared 'late' acupuncture, administered during surgery, with 'early' acupuncture, given with premedication, in 89 patients undergoing minor gynaecological surgery. Just over half of the patients in the late acupuncture group experienced nausea or vomiting compared with only 22% in the early acupuncture group. This result suggests that P6 stimulation, like conventional antiemetic drugs, must be given before the emetic stimulus to be effective. Another possibility is that P6 antiemesis involves a neural mechanism and thus requires an intact nervous system. This hypothesis is supported by the finding that local anaesthesia blocks the effect of P6 acupuncture

Table 1 **P6 as an antiemetic for postoperative nausea and vomiting**

Reference No.	Sample	Interventions	Results
1	*n*=44 laparoscopy	ACP during anaesthesia versus no intervention	Symptom free 1–6 h: ACP 55%, control 50%. NS
2	*n*=90 minor gynaecological	ACP during anaesthesia versus no intervention control versus droperidol	Symptom free: ACP 70%, control 72%, droperidol 83%. NS
3	*n*=45 children tonsillectomy	ACP during anaesthesia versus no intervention	Vomiting: ACP 39%, non-acupuncture 36%. NS
4	*n*=90 children strabismus repair	ACP during anaesthesia versus droperidol versus both	Vomiting in 48 h: droperidol 41%, ACP 45% combined treatment 34%. NS
5	*n*=75 minor gynaecological surgery	ACP at P6 versus ACP at dummy point versus control	Symptom free post-operatively: control 24%, ACP 76%, dummy ACP 24%. $P<0.001$
6	*n*=500 general surgery	Acupressure versus no intervention	Patients vomiting: control 16%, P6 4.4%. $P<0.001$
7	*n*=93 minor gynaecological	ACP versus electro-ACP versus cyclizine versus no intervention	Symptom free: control 29.7%, ACP 77.4%, electroACP 83.9%, cyclizine 64.3%. ACP versus control $P<0.0005$
8	*n*=60 'Short operation'	ACP versus no intervention control	Symptom free pre/post op: ACP 80%/83%, control 56%/53%. $P<0.05$
9	*n*=155 minor gynaecological	ACP versus electro-ACP versus cyclizine versus metoclopramide versus no intervention control	Symptom free: ACP 77%, electro ACP 81%, cyclizine 19%, metoclopramide 68%, control 32%. ACP versus control $P<0.0005$
10	*n*=31 minor gynaecological	Acupressure versus historical no treatment control	Symptom free 0–1 h: ACP 87%, control 45% ($P<0.001$). 1–6 h: ACP 58%, controls 39%. NS.
11	*n*=33 minor gynaecological	ACP with premedication versus ACP during anaesthesia. Non-randomized study	Symptom free: ACP with premed 78%, ACP during operation 49%. $P<0.05$
12	*n*=100 women laparoscopy	ACP versus TENS at P6 versus prochlorperazine versus no intervention	Emesis: control 44%, ACP 12%, TENS 36%, prochlorperazine 12%. ACP versus control $P<0.05$
13	*n*=162 general surgical	'Sea Bands' acupressure versus dummy 'Sea Bands' acupressure versus prochlorperazine	Mean nausea score day 1/2: P6 1.2/0.9, dummy P6 2.4/2.2, antiemetics 3.1/2.2. P6 versus dummy $P=0.002$. Days 3–6 NS. Emesis day 1/2/3: P6 16/14/4%, dummy 21/19/8%, antiemetics 20/18/20% NS.
14	*n*=74 minor gynaecological	ACP with local anaesthetic at P6 versus ACP with saline at P6	Symptom free 0–6 h post operative saline 81.1%, lignocaine 52%. $P=0.013$
15	*n*=66 children strabismus repair	'Sea Bands' acupressure versus dummy 'Sea Bands' acupressure	Vomiting within 24 h. P6 92%, control 83%. NS.
16	*n*=90 minor gynaecological	Acupressure versus dummy acupressure versus no intervention	Nausea, emesis 0–1/1–6/0–6/6–24 h post operative: ACP 23,20/23,20/37,30/23,10%, dummy 53,33/53,30/63,43/43,30%, controls 60,20/70,33/80,37/57,37. ACP versus dummy $P=0.03$ for first two measures
17	*n*=103 hysterectomy	TENS at P6 versus dummy TENS at P6	Vomiting 2/3/6 h post operative active TENS 24/27/31%, placebo 42/50/67%. $P<0.05/0.025/0.001$. $P<0.005$ overall
18	*n*=230 major orthopaedic surgery	TENS at P6 versus sub-threshold TENS at P6 versus dummy TENS versus no intervention	Vomiting (male/female): TENS and sub-threshold TENS 47/40%. Control groups 50/67%. $P=0.007$ females only. Sickness severity $P<0.001$ females only.
19	*n*=80 major gynaecological	'Sea Bands' versus no intervention control	Differences between groups: severity $P=0.002$, no. of doses of anti-emetics $P=0.001$, others NS
20	*n*=120 minor gynaecological	Acupoint injection versus droperidol versus no intervention control	Vomiting: ACP 12.5%, droperidol 17.5%, control 52.5%. Both treatments $P<0.05$ versus control
21	*n*=64 dilatation and curettage	Acupoint injection versus no intervention control	Nausea or vomiting: ACP 6.25%, control 31.25%. $P<0.05$

ACP=Acupuncture; NS=not significant. Trials are randomized unless indicated. Some scores given in results assessed from raw data (e.g. tables) rather than given by author

Table 2 **P6 for nausea and vomiting associated with cancer chemotherapy**

Reference No.	Sample	Intervention	Results
22	$n = 10$ cisplatin for testicular cancer	Electro-ACP at P6 versus electro-ACP at dummy point	Mean score (max = 4): ACP 3.76, dummy 1.6 $P < 0.001$
23	$n = 77$ women, cisplatin	ACP versus historical control	Vomiting episodes/duration/symptom free: ACP 1.7/160 min/58%, control 3.2/249 min/49%. Nausea score/duration/symptom free: ACP 0.2/29 min/54%. Control 0.6/113 min/41.2%
24	$n = 38$ oncology ward	'Sea Bands' at P6 versus 'Sea Bands' at a dummy point	Subjective preference: P6 55%, dummy 24%. $P < 0.02$. Combined symptoms scores P6 superior, $P < 0.01$
25	$n = 18$ oncology ward	'Sea Bands' at P6 versus no intervention historical control	No outcome measures: P6 said to be effective
26	$n = 8$ cross-over, highly emetic chemotherapy	TENS at P6+ondansetron versus ondansetron only	Symptom free patient days: P6 58.8%, ondansetron only 31.3%. $P < 0.0005$.

Trials are randomized unless indicated. Some scores given in results assessed from raw data (e.g. tables) rather than given by author

antiemesis[14]. Seventy-four women scheduled for minor gynaecological operations were given P6 acupuncture at the time of premedication. Before acupuncture, the P6 site was injected with either saline or lignocaine in double-blind fashion, with random assignment to treatment. Women in the lignocaine group experienced significantly more emetic sequelae than those in the saline group ($P = 0{\cdot}01$). The third possibility is that acupuncture works by non-specific or psychological mechanisms. The lack of a placebo control such as dummy acupuncture, in which a needle is placed at an inappropriate site, is a worrying feature of many of the studies. Dundee[35] explains that his ethics committee forbade more placebo controlled trials once early studies had shown dummy acupuncture to be ineffective in controlling emesis[5,22]. One study[35] was actually stopped in mid course after clear differences were shown between active and placebo groups.

However, stimulation of a dummy point has consistently proved less effective than stimulation of P6[5,22,27,31,32]. Dummy acupuncture points have been shown to be credible to patients in trials of morning sickness[31], so differences in outcome between real and dummy points cannot be explained by different levels of patient belief. Studies with alternative forms of placebo, such as 'Sea Bands'[13,16,30] or

Table 3 **P6 for morning sickness**

Reference No.	Sample	Intervention	Results
27	$n = 450$ attending antenatal clinic	Manual pressure on P6 or dummy point versus no intervention control	Severe or troublesome sickness: P6 24.4%, dummy 36.6%, control 56.6%. P6 compared to both $P < 0.0005$.
28	$n = 16$ experiencing morning sickness	Acupressure wrist bands versus no intervention	Morning sickness relieved in 12 of 16 on active treatment ($P < 0.025$) Anxiety, depression, behaviour and nausea improved in treatment condition ($P < 0.05$)
29	$n = 23$ experiencing morning sickness	TENS at P6 versus deactivated TENS	Improvement: treatment 87%, placebo 43% ($P < 0.05$). Nausea scores: treatment 2.4. placebo 2.7 ($P < 0.05$). Maximum nausea scores NS.
30	$n = 60$ experiencing morning sickness	Acupressure wrist bands versus placebo wristbands	Symptoms reduced or absent: treatment 64–69%, placebo 29–21% ($P < 0.05$)
31	$n = 16$ experiencing morning sickness	'Sea Bands' at P6 versus 'Sea Bands' at dummy point	Nausea score: P6 32.3%, placebo 49.3% ($P < 0.019$)
32	$n = 60$ experiencing morning sickness	Manual pressure on P6 or dummy point	Change in score nausea (1–12)/vomiting (1–12)/total (3–32): P6 2.58/0.35/3.95. Placebo 0.95/0.2/1.44. $P < 0.0021$ for nausea.
33	$n = 42$ experiencing morning sickness	'Sea Bands' at P6 versus dummy 'Sea Bands' non-randomized	Change in nausea score: P6 0.232 control −0.399 ($P = 0.052$ in favour of control)

Trials are randomized unless indicated. Some scores given in results assessed from raw data (e.g. tables) rather than given by author

Table 4 **Methodological assessment of eligible trials**

Reference No.	Population	n	Treatment allocation	Match	Tnt	Placebo	Outcome assess-ment	Subject blinding	Observer blinding	Complete	Present-ation of statistics	Stats quality	Results	Anaesth?
1	0	0	+	–	+	0	+	+	+	+	+	0	–ve	Yes
2	+	+	+	+	+	0	+	+	+	+	+	0	–ve	Yes
3	+	0	+	+	+	0	+	+	+	+	+	0	–ve	Yes
4	+	+	+	+	+	0	+	+	+	+	+	+	–ve	Yes
5*	+	0	+	0	+	+	+	+	+	+	+	+	+ve	No
6	0	+	0	+	+	0*	–	+	+	+	+	+	+ve	No
7	+	+	+	0	+	–	+	–	+	+	+	0	+ve	No
8	+	+	+	0*	+	–	+	–	+	+	+	0	+ve	No
9	+	+	+	0*	+	–	+	–	+	+	+	+	+ve	No
10	0	+	–	–	+	–	+	–	–	+	+	0	+ve	No
11	0	+	–	–	+	+	+	0	–	+	–	+	+ve	No
12	+	0	+	+	+	–	+	–	–	+	+	+	+ve	No
13	+	+	+	0*	+	+	+	0*	0	+	+	0	+ve	No
14	+	+	+	+	+	+	+	0	+	+	+	0	+ve	No
15	+	+	+	+	+	+	+	0*	+	+	+	0	–ve	No
16	0	0	0	+	+	0	+	0	–	+	+	+	+ve	No
17	+	+	+	+	+	+*	+	+*	+	+	+	+	+ve	No
18	+	+	+	–	+	+*	+	+	+	+	+	+	+ve*	No
19	–	+	+	–	+	–	+	–	–	–	–	0	+ve	No
20	+	+	+	+	+	–	+	–	–	+	+	+	+ve	No
22	0	–	+	+	+	+	+	+	0	+	0	+	+ve	No
23	+	0	–	–	+	–	+	–	–	+	+	0	+ve	No
24	+	0	+	–	+	+	–	+	+	–	–	0	+ve	No
25	–	–	–	–	+	–	–	–	–	–	–	–	+ve	No
26	0	–	+	+	+	–	+	–	–	+	+	+	+ve	No
27	+	+	0*	–	+	+	+	+	+	0*	0	–	+ve	No
28	+	–	+	+	0	–	+	–	–	–	0	0	+ve	No
29	0	–	+	–	+	0	+	–	+	+	–	0	+ve	No
30	+	0	+	+	+	+	+	0	+	+	+	+	+ve	No
31	+	–	+	–	+	+	+	+	+	–	–	+	+ve	No
32	+	0	+	+	+	+	+	+	+	–	+	+	+ve	No
33	+	–	–	–	+	+	–	+	+	–	–	+	+ve	No

n: Sample size adequate; Match: baseline matching; Tnt: test intervention; Complete: completeness of data set; Stats Quality: appropriate inference statistics used; Anaesth?: acupuncture administered under anaesthetic?

inactive TENS stimulators[17,18] have also shown placebo less effective than verum treatment. One possible argument against TENS versus mock TENS is that the former produces skin sensations whereas the latter does not. However, McMillan[18] found statistically significant differences between inactive TENS and sub-threshold TENS (electrical stimulation not strong enough to be perceived). The demonstration that the antiemetic effects of acupuncture can be blocked by local anaesthesia[14] and that inappropriately high levels of P6 stimulation can exacerbate nausea and vomiting[7] provide further evidence against a purely psychological explanation of P6.

Another possible argument against a specific effect of P6 is that some of the better studies[17,18] used electrical stimulation of the acupuncture site. It may be that electrical stimulation has an inherent antiemetic effect. Warfield[43] undertook a randomized trial to examine the effects of TENS on pain, duration of stay, tolerance of physical therapy, nausea, and other outcomes in 24 patients undergoing thoracotomy. Electrical stimulation was provided at the site of incision. No statistically significant differences in nausea scores were found between active and placebo devices. This suggests that electrical stimulation is not, of itself, an effective antiemetic.

Table 5 **Notes on quality analysis**

Reference No.	Comments
5	Two trials presented in the same paper, one controlled, the other uncontrolled. This is an analysis of the control trial
6	Randomization by hospital registration number. Placebo/subject blinding. Patients were not told they were in a trial and were not told why their wrist was being squeezed
8	Short report. Full methodological description given in paper 33. Matching as described in paper 33
9	Short report. Full methodological description given in paper 33. Matching as described in paper 33
13	Matching: some minor differences between groups. Patients wore 'Sea Bands' either with or without a stud. This makes unblinding a possibility
15	Patients wore 'Sea Bands' either with or without a stud. This makes unblinding a possibility
17	Though patients may have been able to distinguish active and placebo TENS by skin sensations, paper 18 suggests this is not a major consideration as sub-threshold TENS is of value
18	Result positive for females only. Subgroup analysis was validated according to Oxman and Guyatt (Ref 49)
27	Only 50% of women in the two treatment groups returned fully completed diaries. However, differences remained even after a 'worst case analysis' which assumed that all non-respondents had suffered troublesome or severe sickness
28	No matching but a crossover trial. No explicit reference to observer blinding in the text, but abstract described trial as 'double-blind'

The methodology of this review deserves discussion. The search strategy, inclusion and exclusion criteria, and the methodological checklist used to assess each trial are conventional[44,45,47] but the use of the three criteria—good, fair and poor—without predetermined criteria is a less common approach to methodological scoring in systematic reviews of acupuncture. A decision was made not to set predetermined parameters for scoring criteria (e.g., a certain number of patients per group) simply because different aspects of a trial interrelate and individual criteria cannot be assessed in isolation. For example, the relevance of an intention-to-treat analysis depends on the number of patients who withdraw from a trial; similarly, the importance of a single main outcome measure depends on the degree of heterogeneity amongst multiple outcomes. Though the absence of predetermined criteria possibly lowers the replicability of the review it does reflect the fact that researchers can reasonably disagree about the validity of a trial.

The scoring category 'fair', where a trial has a flaw but one which the reviewer believes is unlikely to affect the results, is a novel element. It was introduced as a pragmatic measure and is best validated by the use of examples. In Fassoulaki's trial of TENS stimulation at P6 for post-operative sickness[17], outcome was measured at three separate times. None was initially designated as the primary outcome measure and the trial can be criticized on the grounds of multiple testing. However, P6 was statistically superior at all three follow-ups. Multiple testing is therefore unlikely to explain the result of this trial. Dundee's trial of morning sickness[27] was flawed because it was incomplete: almost half the patients in the treatment and placebo groups failed to return completed questionnaires. However, Dundee conducted a 'worst case' analysis in which non-respondents were assumed to have either 'severe' or 'troublesome' sickness. Statistically significant differences between active and control treatments remained. So, although the trial was incomplete, this is unlikely to have influenced its result. Similarly, in Barsoum's trial of acupressure for postoperative nausea[13] the slightly larger number of patients receiving no premedication in the P6 group is unlikely completely to explain the large difference in outcome between groups.

A possible methodological flaw of this review is that concealment of treatment allocation before randomization was not analysed. The importance of this methodological criterion became apparent as a result of empirical research[48] conducted after the protocol of this review had been completed. It has not previously been incorporated in systematic reviews of acupuncture[44–47], and most of the papers in the main analysis[5,13,15–18,27,30,32] do not state the methods used to conceal treatment allocation. Concealment was clearly adequate in one case[13] and clearly inadequate in another[6]. Further research on P6 antiemesis might start by correspondence with each author to determine whether treatment allocation had been adequately concealed. Statistical combination of data from all trials would supplement the 'vote count' method used in this review and allow a sensitivity analysis to determine whether bias caused by inadequate concealment of treatment allocation could explain the apparent effect of P6 antiemesis.

The purpose of this review was to investigate whether acupuncture can have specific effects by examining

acupuncture antiemesis as a model. It has been argued that P6 acupuncture point stimulation provides a useful 'test case' to determine whether acupuncture can be explained purely in terms of the placebo response. However, this review will not conclude with a conclusion: it is for the reader to decide whether the evidence constitutes scientifically acceptable proof that acupuncture can have specific effects. That said, it is worth spelling out the implications of a decision for or against proof of acupuncture antiemesis. If the reader does decide that P6 antiemesis is a reality, it is time to change 'Can acupuncture have specific effects on health?' to a more pragmatic set of questions. These might include consideration of the clinical value, cost-effectiveness, applicability, and acceptability of acupuncture. There would also need to be research on which patients or conditions respond to acupuncture treatment, and possibly investigation of the most effective methods of treatment. Importantly, these trials would not be tests of acupuncture as a whole, but research on particular methods and particular patients. Furthermore, even if acupuncture does have a specific effect on health, we cannot deduce that it is necessarily useful. It may, for example, be of only minor clinical value and/or appropriate for only a limited number of patients.

None of the studies included in this review is methodologically perfect and the reader may instead decide that the P6 research does not constitute acceptable proof that acupuncture has specific effects on health. If so, attention would have to be paid to the sort of research that would settle this question. In short, how could we answer 'Can acupuncture have specific effects on health?' other than by a conventional systematic review of what is, after all, conventional research? How much evidence would constitute 'enough' evidence?

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