PC.6 Acupressure for Dental Nausea: A Prospective Randomised Double Blind Clinical Trial with Crossover, Part 2

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Summary

This reports the second part of a single-centre, prospective, randomised, double-blind clinical trial with crossover. It has aimed to assess whether PC.6 acupressure could reduce nausea related to maxillary dental impression taking.

The selection criterion was a self registration of nausea greater than 33% of a 100mm visual analogue scale (VAS) following an initial maxillary impression (control) in patients referred for treatment. Exclusion criteria were: current medication with a secondary emetic or anti-emetic effect, prior knowledge of PC.6 acupressure, a recent history of nausea, and the first trimester of pregnancy. Twenty three entered the trial and 18 completed.

The test involved a second and third impression with prior application of finger pressure on either PC.6 or a dummy point on the forearm The initial point was chosen by the patient, leaving the other point to be pressed subsequent to crossover. The mean level of nausea was recorded by patients after PC.6 acupressure and also after pressure at a dummy point. These recordings were then compared.

The sample consisted of 6 males and 12 females, and the mean age was 14.74 years. The mean difference in nausea between PC.6 acupressure and pressure at the dummy point was -0.39mm % of the VAS (SD 40.48mm %). The 95% Confidence Interval was -20.52 and 19.74mm %, and the difference was not significant. Three and a half minutes of PC.6 acupressure did not significantly reduce nausea experienced with a maxillary impression, compared with pressure at the dummy point, in this small sample: both showed a mean reduction of 50% on the control figure.

Key words

Acupressure, Controlled trial, Dental impressions, Nausea.

Introduction

The use of acupressure to reduce the sensation of nausea has been reviewed previously in Part 1 of this study which reported on the preliminary findings of its application to control nausea induced by tactile stimulation of the oro-pharynx *(1)*. The aim of this single-centre, prospective, randomised, double-blind clinical trial with crossover is therefore to present the final conclusions on the use of acupressure at the *Pericardium 6 (Neiguan)* acupoint, as applied to the same sample of dental patients who have completed the crossover section of the trial since the first report. The study took place in a hospital department providing secondary orthodontic care in England between 1991 and 1994, and involved the taking of an initial maxillary dental impression (control) and subsequently two similar impressions, one after PC.6 acupressure and the other after acupressure at a *dummy* point, described in Part 1, on the forearm of the patient's dominant upper limb, the patient having chosen the sequence at random and then applied pressure, both without the knowledge of the clinician or any appreciation by the patient of the significance of either point. The full experimental technique is explained, with illustrations, in the report of the first part of this trial *(1)*.

Since the difference in nausea levels between the points used had not yet been assessed in dentistry, it was not possible to perform sample size calculations prior to starting the trial; so, as this was a pilot study, a sample number was chosen that seemed practical within the circumstances of the clinic without prolonging the trial excessively.

Method

Informed consent to participate in this study was sought from the parents of 35 consecutive hospital orthodontic patients, referred for treatment from the local population, whose self registration of nausea on a 100mm visual analogue scale (VAS) was greater than 33% following an initial maxillary impression. Nine withheld their consent and a further three were excluded when the entry criteria were applied as outlined in the preliminary report. The exclusion criteria were either if the patient was currently taking medication with a secondary emetic or anti-emetic effect, had prior knowledge of PC.6 acupressure, a recent history of nausea, or was in the first trimester of pregnancy. From the initial sample of 23 patients, two subsequently withdrew their consent midway, two failed to cross over, and it was retrospectively decided to withdraw one other because she had used deep nasal respiration to supplement her finger pressure in an attempt to further reduce her nausea on one of the test occasions.

The final sample therefore comprised eighteen caucasian individuals, with a mean age of 14.74 years, a standard deviation of 3.58 years, and a range of 8.80 to 20.46 years of age. Six of them were male, and altogether four were left handed.

The impression techniques were standardised as described in Part 1. After the removal of each impression, the patients marked a 100mm VAS to record the level of nausea they had experienced and, in order to eliminate any ambiguity, each analogue had an accompanying paragraph which explained both the range of the scale to be marked *(2)*, and how the recording should be made with a 0.1mm pen.

For both test procedures, after a patient had pressed PC.6 or the dummy point under double blind conditions for one minute, each was asked to report any sensation of heaviness or tingling *(qi)* in either the arm or hand. If affirmative, this experience of *qi* was recorded, together with its delineation. After two minutes the impression was inserted, and for the remaining one and a half minutes, while the impression material was setting, the patient continued to apply finger pressure to the chosen point. Subsequent to its withdrawal, and out of sight of the clinical staff, the patient marked another visual analogue scale, recorded which point had been pressed, and then sealed these records in an envelope.

When the second test impression was taken the same method was repeated, except that the patient pressed the other, not previously chosen, point instead. A minimum time interval of 24 hours between the second and third impressions was imposed with the intention to avoid any possible carry over of antiemetic effect from the second to the third occasion. The impressions were subsequently cast in dental stone, and at the end of the trial these were measured as previously described in Part 1. The age of the patients and the lengths of the study models were recorded on the three different occasions, and the data were summarised as means and standard deviations.

The study involved each patient in a crossover, so the appropriate statistical methods were used for this design to test the null hypothesis that there was no difference in the mean registration of nausea recorded after either PC.6 acupressure or dummy-point pressure, also to test for a period effect and treatment period interaction. This involved unpaired *t* tests by order of treatment on the difference between periods one and two, the difference between PC.6 and dummy pressure, and the sum of period 1 and period 2.

Paired *t* tests were also used to test the null hypotheses that there were no differences between either the mean ages of the patients or the mean lengths of the study models on these two occasions. All statistical analyses were conducted using appropriate computer programmes by an independent statistician.

Table 1
VISUAL ANALOGUE NAUSEA RECORDINGS (mm%)

	Control	PC.6	Dummy	PC.6-Dummy difference
Mean	72.00	36.33	36.72	-0.39
SD	14.84	31.36	25.96	40.48

For 10.36 df (due to unequal SD's), t = -0.04, p is not significant.
Error of the method: 0.27mm

Table 2
AGE (decimal years)

	Control	PC.6	Dummy	PC.6-Dummy difference
Mean	14.74	15.60	15.93	-0.33
SD	3.58	3.37	3.13	0.93

For 17 df, t = -1.48, p is not significant.

Table 3
STUDY MODEL LENGTHS (mm)

	Control	PC.6	Dummy	PC.6-Dummy difference
Mean	71.43	70.94	71.41	-0.47
SD	7.06	6.49	8.36	8.59

For 16 df, t = -0.23, p is not significant.
Error of the method: 1.7mm

Results

Eight of the patients made a random mental choice to press the dummy point on the first test occasion, with PC.6 therefore being used by them on the second occasion, while the other ten patients made the reverse choice.

The mean period effect was -0.26, *i.e.* on average the nausea registrations were 2.06 percentage points lower in the first period compared to the second (*p* is not significant). There was no evidence of treatment period interaction.

Table 1 shows the means and standard deviations (SD) of the nausea VAS recordings that were made on the three occasions when impressions were taken, together with the method error of measurement (using Dahlberg's equation as explained in Part 1). Compared to the control, both PC.6 acupressure and dummy-point pressure resulted in a mean reduction of 50% in the level of nausea experienced. However, there was no statistical difference between the mean levels of nausea recorded on the two test occasions. A Shapiro-Wilk W test confirmed that the PC.6-dummy nausea differences were Normally distributed (W = 0.97, Z = -1.24, PR > Z = 0.89).

Table 2 shows the means and standard deviations of the ages of the patients at the time of the control impression, as well as the occasions when either PC.6 acupressure or dummy-point pressure had been used, irrespective of the order in which they

had been applied. There was no statistical difference between these latter two means.

Table 3 shows the means and standard deviations of the lengths of the study models that were cast from all three impressions, together with the method error of measurement. Once again, the difference between the mean lengths of the models from both test episodes was not significant.

Out of the total sample of eighteen patients, two reported experiencing a sensation of *qi* on both occasions: when pressing the PC.6 and dummy points, while two did so only on pressing PC.6, and another three only with the dummy point. Eleven had no sensation of *qi* with either point.

Discussion

Both of the comparable mean reductions in nausea for the PC.6 acupressure and dummy-point pressure episodes in this study *(Table 1)* were still consistent with the placebo effect previously reported in Part 1, when the data available for analysis at that stage did not include the results of each patient's crossover.

However, it could be argued that the absence of *qi*, the non-anatomically distributed sensation indicative of correct stimulation *(3)*, in the majority of patients on the occasions when PC.6 had been pressed suggests that inadequate finger pressure might have been applied during the test procedure, which could then explain why no difference in nausea reduction was found between the two test episodes. Yet it is curious that five patients also reported the sensation of *qi* when they pressed at the dummy point, while for *sham* acupuncture on a *placebo* point this has not been previously demonstrable *(4)*.

The point first pressed (PC.6 or dummy), and thus the sequence of points used in the trial, was chosen at random by each patient without reference to the clinic staff and without any appreciation of the significance of either point. Some may not consider this method as true randomisation since a patient's decision to choose a particular point might not be entirely a matter of chance *(5)*, although the numbers choosing each point were in fact very similar (8:10). However, as both points were used in sequence by each patient in the course of the trial, this is not likely to have influenced the result.

One report of PC.6 acupressure in children under 12 years of age showed no reduction of post-operative vomiting *(6)*, and in this study three patients (17%) were under 12 when this point had been used. It is possible that acupressure is ineffective in children, but while this could be a potential factor in this study the numbers involved were quite small.

Table 1 demonstrates that the 0.39 percentage point difference in the mean level of nausea experienced between use of the two pressure points was not significant, with the limits of the 95% confidence interval at -20.52 and 19.74mm %. That is to say, the true difference could lie somewhere between these two values, and ideally a larger sample would be required for a more accurate result. Indeed, the estimated crossover sample size required to detect a 10mm difference in the nausea scores between the two pressure points, with a standard deviation of 40, and an 80% power of achieving a statistically significant result at the 5% level (two sided) would be 126 patients.

However, to identify and recruit this number of patients with the requisite level of soft palate sensitivity to a tactile nauseogenic stimulus within a reasonable period of time by one clinician would be extremely difficult. Realistically any such future research would require a multi-centre design, and should perhaps be restricted to adults. With consent, this would then allow the subjects to be tested 24 hours apart, thereby eliminating one of the potential confounding variables imposed on this study: namely the long interval between the test episodes.

The induction of nausea by tactile stimulation of the oro-pharynx during dental impression taking is likely to have a different mechanism to the induction of nausea following anaesthesia. This may be why PC.6 acupressure appears less effective for tactile-induced nausea than pharmacologically induced, and could indirectly suggest a mechanism for the therapeutic effect of PC.6 acupressure in post-operative nausea: through influence on the chemo-receptor trigger zone rather than the vomiting centre directly. However, as the trial size has been too small to draw any firm conclusions as to efficacy, so it may be presumptive to advance any hypothesis as to mechanism based on these results.

Acupressure at both PC.6 and the dummy point showed a similar, although non-significant, improvement in mean VAS nausea recording over the control. This could indicate a similar placebo effect at both points, or alternatively that both points are active to a similar degree for nausea induced by tactile oro-pharyngeal stimulation.

Conclusion

Three and a half minutes of PC.6 acupressure did not significantly reduce the sensation of nausea, as measured by VAS, induced by tactile stimulation of the soft palate compared to that achieved by finger pressure at a dummy point in this small sample of young patients: both showed a mean reduction of 50% on the control figure.

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