

Effect and placebo effect of acupressure (P6) on nausea and vomiting after outpatient gynaecological surgery

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Background: Acupuncture and acupressure have previously been reported to possess antiemetic effect. We wanted to investigate the “true” and placebo effect of acupressure in prevention of postoperative nausea and vomiting (PONV).

Patients and methods: Sixty women undergoing outpatient minor gynaecological surgery were entered into a double-blind and randomised study. One group received acupressure with bilateral stimulation of P6 (A), a second group received bilateral placebo stimulation (P) and a third group received no acupressure wrist band and served as a reference group (R). PONV was evaluated as number of patients with complete response (no PONV), nausea only or vomiting. In addition, the need for rescue antiemetic medication and nausea after 24 h was registered.

Results: Complete response was obtained in 11, 11 and 9 patients in groups, A, P and R, respectively. Nine, 7 and 6 patients had nausea before discharge home, and 1, 1 and 8 patients were nauseated (8 vs 1 patient: $P < 0.05$) 24 h after operation in A, P and R groups, respectively. When compared to placebo acupres-

sure (2 patients vomited and 5 needed rescue), significantly ($P < 0.05$) fewer needed rescue antiemetic medication after acupressure at P6 (no vomiting or rescue medication). When compared to the observation group (5 vomited and 4 needed rescue antiemetics), significantly fewer vomited after acupressure ($P < 0.05$).

Conclusion: In patients undergoing brief gynaecological surgery, placebo effect of acupressure decreased nausea after 24 h but vomiting and need of rescue antiemetics was reduced only by acupressure with the correct P6 point stimulation.

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POSTOPERATIVE nausea and vomiting (PONV) are common after gynaecological surgery (1) and are the main symptoms which delay discharge after day-care surgery (2, 3).

Even though the most efficient pharmacological prophylactic treatments decrease the incidence of major PONV events by about 50% (3, 4), the cost-benefit of prophylactic pharmacological treatments could be questioned (5). Acupuncture towards the P6 (Neiguan) point, which is located three fingers' breadth proximal to the proximal flexor palmar crease between the tendons of flexor carpi radialis and palmaris longus (6), has been shown to decrease the incidence of nausea and vomiting to about the same extent as pharmacological treatments (7). Acupressure is a method where pressure is applied to acupuncture points. A finger, a round stick or a pea-size pearl is used. Acupressure towards P6 has been shown to be effective in several recent studies (8–12), including studies from Great Britain in the 1990s (13, 14). No adverse effects have been reported. Acupressure has

not reached widespread use and is not even mentioned in recent reviews of the subject (3, 4).

Because the placebo effect of a treatment like acupressure is probably considerable (15), we used a design in which true effect and placebo effect could be measured. For placebo stimulation we used a sensory stimulation of a non-acupressure point of similar intensity as the active acupressure stimulation (12), and a control group to measure the placebo effect. Our aim was to investigate the effect and placebo effect of acupressure on the incidence of nausea and vomiting after minor day-care gynaecological surgery.

Patients and method

Sixty women scheduled for minor gynaecological surgery on a day-care basis were included after written and verbal informed consent. Demographic data are given in Table 1. Type of surgery, as well as operating time are given in Table 2. The investigation was

Table 1

Demographic data. Values given as median (range) and for PONV prognostic factors in number of patients with a risk factor.

	Reference group n=20	Acupressure n=20	Placebo n=20
Weight (kg)	65 (49–93)	62 (54–85)	65 (50–86)
Height (cm)	168 (154–181)	167 (158–177)	162 (152–177)
Time to fluid per os (min)	90 (40–185)	85 (40–190)	105 (30–270)
Age (year)	29 (19–62)	27 (21–62)	35 (18–59)
Previous PONV or motion sickness (n)	7	8	6
Pregnant (n)	11	5	10
In the first 8 days of menstrual cycle (n)	3	5	2
Intraoperative alfentanil (mg)	0.5 (0.25–0.5)	0.5 (0.25–0.75)	0.5 (0.25–1.0)
Patients complaining of pain (n)	12	9	10
Patients given morphine on the postoperative ward	8	7	7
Morphine (mg) given on the postoperative ward	0 (0–4)	0 (0–8)	0 (0–5)
Discharge time (min)	120 (45–255)	105 (50–270)	120 (60–330)

approved by the Ethics Committee at the Faculty of Health Sciences, University of Linköping.

Design. The study was double blind and the patients were randomised after accepting entry into the study. One group received active treatment (n=20), one placebo treatment (n=20) and one group was used as a control group (n=20) (16, 17).

Anaesthesia. Premedication consisted of paracetamol 1 g given as a suppository. An intravenous line was inserted and an infusion of a balanced solution of glucose 2.5% and sodium, 1000 ml (Rehydrex®, Pharmacia & UpJohn, Stockholm, Sweden) was started. Thiopentone was used for induction, 3–5 mg/kg body weight. Alfentanil (Rapifen®, Janssen-Cilag, Beerse, Belgium) was used to achieve intraoperative analgesia, and almost all patients had an intraoperative dose of 0.5 mg (Table 1). Tracheal intubation was aided by succinylcholine. For maintenance, 66% N₂O in oxygen and isoflurane was used.

Treatment: acupressure. The P6 (Neiguan), a point located on the pericardial meridian, which is found three fingers' breadth (approximately 5 cm) proximal to the proximal flexor palmar crease, about 1 cm deep, between the tendons of flexor carpi radialis and palmaris longus, is supposed to have an effect on post-

operative nausea and vomiting (6). A Sea-Band® (Sea-Band UK Ltd., Leicestershire, England) carries a plastic pearl which is fastened to apply pressure on P6. Both forearms were used. These points were marked with water-resistant ink so that the bands could be properly replaced if removed. The areas were draped with a dressing during the stay in the hospital. The nurses giving anaesthesia and the nurses on the postoperative ward, although aware that stimulation was being performed, were not aware of the location of P6.

Placebo acupressure. A point on the dorsal side of both forearms, four fingers' breadth proximal to the proximal flexor palmar crease was used for placebo stimulation. These points were marked in the same way as with the active acupressure. Sea-Band was used for stimulation, and the same precautions were taken to keep the stimulation blinded (see above).

Reference group. These patients were informed and anaesthetised in the same way as the acupressure and placebo groups. Instructions for postoperative care and assessment were the same, as were the registrations of nausea and vomiting at home.

Nausea and vomiting. Nausea was estimated by the patients on a horizontal visual analogue scale (VAS), 100 mm. The endpoints were assigned "no nausea" to the left and "worst possible nausea" to the right. The patients were asked to assess their degree of nausea 30, 60 and 120 min after arriving at the postoperative ward.

Metoclopramide 10 mg was administered i.v. at the patient's request. If this antiemetic was not effective, droperidol 1.25 mg i.v. was given. Vomiting was noted by the nurses, as was the need for antiemetics. After discharge, at home, the patients were asked to assess the degree of nausea at 6 pm, when going to bed, at

Table 2

Type of surgery (number of patients in each group), and operating time, median (range) in minutes.

	Reference n=20	Acupressure n=20	Placebo n=20
Dilatation and curettage (n)	3	6	6
Abortion (n)	11	5	10
Conization (n)	6	9	4
Operation time (min)	20 (10–40)	30 (15–55)	25 (10–55)

Table 3

Results in complete response, nausea (only), vomiting, rescue medication and nausea after 24 h. Values given as number of patients.

	Reference group n=20	Acupressure n=20	Placebo acupressure n=20
Complete response	9	11	11
Nausea (only)	6	9	7
Vomiting	5	0**	2
Rescue medication	4	0*	5
Nausea 24 hour after operation	8	1**	1**

*= $P<0.05$ vs placebo acupressure; **= $P<0.05$ vs reference group.

breakfast time and at noon the day after surgery. They were also asked to note vomiting. A scoring on the VAS over 10 mm was classified as nausea and scoring below 10 mm was classified as no nausea. Nausea score 24 h after surgery (18), at home, was used as the patients' evaluation of the treatment.

Pain and analgesia. Pain was assessed by the patient on a horizontal VAS, 100 mm. The endpoints assigned were "no pain" to the left and "worst possible pain" to the right. All patients were premedicated with paracetamol 1 g, and this was the first analgetic option if the patient complained of pain postoperatively. Morphine was used on the postoperative ward in doses of 2 mg i.v. if additional analgesic was needed (see Table 1). The patients received paracetamol to take for pain relief up to 4 times/24 h after discharge.

Procedure. The patients were informed of the study in the morning on the day of surgery by author AA or MS. After consent, the patients were randomised to one of the three study groups. The Sea-Band was applied just before surgery by one of the authors AA or MS, and neither of them was later involved in the assessment of treatment effect. The nurses who asked the patients about nausea and administered antiemetics on the postoperative ward were not aware of which treatment the patient received or where the P6 point is located. An assessment form was sent home with the patient and was later returned together with the Sea-Band by mail to the hospital. The control group was observed in the same way as the two treatment groups.

Drop outs. There were two kinds of drop outs: patients who were scheduled for surgery under anaesthesia but for whom the surgeon changed his mind and performed the surgery under local anaesthesia, and those in whom the study protocol was violated by administration of prophylactic antiemetic during anaesthesia. The number of drop outs was 10 and they were replaced by randomising another 10 patients at the end of the study. The drop-outs were evenly distributed between the groups. All patients returned

their own assessment either spontaneously or after a reminder.

Statistics. Demographic data are given as median (range). Kruskal-Wallis test was used to test for differences between demographic data. Comparison of treatment effects was performed with Fisher's exact test, using the Ciba-Geigy table. The outcome was number of patients experiencing complete response, nausea (only), vomiting, need for rescue medication, and nausea after 24 h. A P -value of <0.05 was considered to be significant.

Results

Demographic data and factors prognostic for PONV are given in Table 1. Complete response was similar between the groups, as was the incidence of nausea (only) (see Table 3). No patient in the acupressure group vomited, but 2 patients in the placebo acupressure and 5 in the reference group ($P<0.05$, vs acupressure) vomited. No patient in the acupressure group requested rescue medication, but 5 patients in the placebo group ($P<0.05$, vs acupressure) and 4 in the reference group did. There were no differences in time to first oral fluid, the postoperative need for morphine or discharge time between the groups (Table 1).

Twenty-four hours after surgery, one patient in the acupressure group and one in the placebo group reported nausea. The corresponding number in the reference group was 8. There was a statistically significant difference between the reference group as compared to the placebo group ($P<0.05$) and acupressure group ($P<0.05$).

Discussion

We noted reduced vomiting and decreased need of antiemetics using acupressure. An effect of acupressure (8, 9, 11) as well as of acupuncture (7) on nausea and vomiting after gynaecological surgery has been reported before. Acupressure seems to be an alterna-

tive to acupuncture if hygienic aspects and costs are considered. As a major part of PONV discomfort starts at home (19), a treatment that could be continued or re-established at home seems favourable.

We expected a major placebo response. This was found in the patient's own assessment after 24 h but not during the time on the postoperative ward. The time course of placebo effects is variable and may be quite prolonged, and time of onset can also be prolonged (20).

The mechanism of action of acupuncture and acupressure on nausea and vomiting has not been established, and a placebo-type mechanism has been suggested (12). Autonomic dysfunction seems to have a correlation to nausea (21). Considering the multifactorial aetiology of PONV, it is unlikely that a single drug or treatment could counteract all causative factors (22). Different types of surgery could have different profiles with reference to aetiology factors. Most studies on acupuncture and acupressure have investigated gynaecological patients.

Methodological considerations that have to be evaluated are whether a bilateral stimulation is superior to a unilateral stimulation and whether the timing is important. An effect of timing on acupressure has been suggested by two studies, one reporting no effect of acupressure with start of stimulation after opioid medication (23) and one reporting an effect when stimulation was started before opioid medication (14).

How to measure nausea and vomiting has been debated during the last decade, as nausea and vomiting have been identified as a major quality factor from the patient's point of view. Nausea can be assessed by the nurse or the patient. A poor correlation between the assessments has been demonstrated (16). The assessment can be performed by using a nausea questionnaire, verbal categorical scales or visual analogue scale. Similar results have been obtained with these three methods (24). We have used complete response, nausea (only), vomiting, need for antiemetic, and nausea after 24 h as outcome measures. That is, part of the outcome measurement is dependent on nurse assessment, and part on the patient's assessment with a visual analogue scale.

To further clarify the usefulness of acupressure on PONV, we propose a study group with a higher incidence of PONV but a similar design as in this study so that the placebo effect could be measured. If the patients were not only randomised but also stratified according to age, sex, history of postoperative nausea or vomiting or motion sickness, additional strength would be added (25). It should also be studied

whether acupressure will decrease PONV after propofol anaesthesia.

Nausea after 24 h might well be reduced by a placebo effect, whereas correct stimulation of P6 seems to be needed to decrease demand for rescue medication and vomiting.

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