

P6 acupressure may relieve nausea and vomiting after gynecological surgery: an effectiveness study in 410 women

[L'acupression en P6 peut soulager les nausées et les vomissements postopératoires gynécologiques : une étude d'efficacité auprès de 410 femmes]

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Purpose: To investigate the effect of sensory stimulation of the P6 point on postoperative nausea and vomiting (PONV) after gynecological surgery in the everyday clinical setting (effectiveness study).

Methods: Four hundred and ten women undergoing general anesthesia for elective gynecological surgery were included in a prospective, consecutive, randomized, multicentre, placebo-controlled, double-blind clinical trial with a reference group. One group was given bilateral P6 acupressure ($n = 135$), a second group similar pressure on bilateral non-acupressure points ($n = 139$), and a third group ($n = 136$) served as reference group. Nausea (scale 0–6), vomiting, pain, and satisfaction with the treatment were recorded. Primary outcome was complete response, i.e., no nausea, vomiting or rescue medication for 24 hr. Results were analyzed by applying logistic regression with indicators of treatments, type of operation and risk score for PONV as explanatory variables.

Results: Complete response was more frequent in the P6 acupressure group than in the reference group ($P = 0.0194$). Conversely, the incidence of PONV was 46% in the reference group, 38% after pressure on a non-acupoint and 33% after P6 acupressure. The decrease from 46% to 33% was statistically significant. When considering vaginal cases separately, the decrease in PONV was from 36% to 20% ($P = 0.0168$). The corresponding decrease from 59% to 55% in the laparoscopic surgery group was not statistically significant.

Conclusion: P6 acupressure is a non-invasive method that may have a place as prophylactic antiemetic therapy during gynecological surgery.

Objectif: Rechercher l'effet d'une stimulation sensorielle acupressive en P6 sur les nausées et vomissements postopératoires (NVPO) à la suite d'une intervention chirurgicale gynécologique dans un cadre clinique normal (étude d'efficacité).

Méthode: Un essai clinique prospectif, randomisé, multicentrique, en double aveugle contre placebo et comportant un groupe de référence a été réalisé auprès de 410 femmes qui se sont présentées successivement pour une intervention gynécologique non urgente sous anesthésie générale. Les patientes d'un premier groupe ont reçu de l'acupression en P6 ($n = 135$), celles d'un second groupe ont reçu une pression semblable sur des points bilatéraux, non d'acupression, ($n = 139$) et un troisième groupe ($n = 136$) a servi de référence. Les nausées (échelle de 0–6), les vomissements, la douleur et la satisfaction face au traitement ont été notés. Le premier résultat était une réponse complète, donc absence de nausées, de vomissements ou de médication de secours pendant 24 h. Les résultats ont été analysés par régression logistique avec des indicateurs de traitements, le type d'intervention et le taux de risque de NVPO comme variables explicatives.

Résultats: La réponse complète a été plus fréquente avec l'acupression en P6 que chez les patientes témoins ($P = 0,0194$). Inversement, l'incidence de NVPO a été de 46 % dans le groupe de référence, 38 % après une pression de points non acupresseurs et 33 % après l'acupression en P6. La diminution de 46 % à 33 % était significative. L'examen séparé des cas d'intervention vaginale indique une baisse des NVPO de 36 % à 20 % ($P = 0,0168$). La baisse correspondante de 59 % à 55 % dans les cas d'intervention laparoscopique n'était pas significative.

Conclusion: L'acupression en P6 représente une méthode non effractive de traitement antiémétique prophylactique qui peut avoir sa place pendant une intervention gynécologique.

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P6 acupressure, a non-invasive variation of acupuncture, has been proposed as prophylaxis against postoperative nausea and vomiting (PONV). As measures of outcome and methodology differ between studies and most studies are small it remains uncertain whether there is a clinically useful effect of P6 acupressure¹⁻¹² (Table I).

Our hypothesis was that P6 stimulation increases the number of patients without symptoms of PONV after gynecological surgery in the everyday clinical setting, in contrast to similar pressure on non-acupoint and no treatment.

Patients and methods

Women ($n = 410$) scheduled for elective gynecological surgery (abortion, dilatation and curettage, conisation or laparoscopic surgery) were included in a prospective, consecutive, multicentre, placebo-controlled, double-blind clinical trial with a reference group. Demographic data are given in Table II. The investigation was approved by the Ethics Committee at our hospital.

Procedure

After consenting to the study the patients were randomized by sealed envelope to one of the three study groups. A nurse who was not involved in anesthetizing or caring for the patient postoperatively positioned the Seaband (SeaBand®, UK Ltd., Leicestershire, England) on both wrists at either the P6 point or on a non-acupoint just before the start of the anesthesia (Figure). The wrists were wrapped for blinding. Anesthetic agents were given at the anesthesiologist's discretion. Details of anesthetics and analgesics administered are listed in Table II. The patients were asked to wear the bands continuously for 24 hr. If the band caused discomfort, they could be removed for 30 min every two hours. The reference group received no prophylactic treatment and, therefore, was not blinded. An assessment form was sent to all participating patients, who were asked to record their level of nausea, vomiting, pain at different time points (8:00 p.m., 8:00 a.m. and 8:00 p.m.), and satisfaction with the treatment. Nausea was estimated using a seven-point scale (0–6). Primary outcome was complete response, i.e., no report of nausea, vomiting or rescue medication.

The probability of postoperative vomiting was predicted using the Apfel risk score which is based on patient-related factors; age, gender, non-smoking, a history of motion sickness or PONV and estimated duration of anesthesia.¹³

Statistics

In the logistic regression analysis, the Apfel risk score and the type of operation (laparoscopic or vaginal) were included as explanatory variables. Post hoc, analysis of postoperative morphine requirements was carried out.

Twenty-six patients were withdrawn either because scheduled general anesthesia was changed to local anesthesia ($n = 12$), or an antiemetic was given without the criteria for treatment of PONV being met ($n = 14$). Criteria for treatment were nausea described as intolerable (as three or more on the 0–6 scale) or the patient vomiting twice. In addition, one patient known for malignant hyperthermia, two patients who were allergic to latex and one who could not read Swedish were withdrawn. These patients were replaced by including another 30 at the end of the study period. Withdrawals were evenly distributed between the groups.

Results

Risk factors and results for PONV are given in Tables II and III. Less PONV was seen after P6 acupressure than in the reference group ($P = 0.0194$). P6 acupressure did not differ significantly from pressure on a non-acupoint ($P = 0.1659$). The incidence of PONV was 46% in the reference group, 38% after pressure on a non-acupoint and 33% after P6 acupressure.

When the effects of acupressure are evaluated for cases of laparoscopic and vaginal surgery separately in the logistic regression analysis the results are different. After laparoscopic surgery PONV is seen in 59% of patients in the reference group compared to 55% in the acupressure group ($P = 0.2319$). The corresponding figures in the vaginal surgery group were 36% and 20% ($P = 0.01685$).

A total of 61 adverse events were reported. The bands felt uncomfortable, produced a red indentation or caused itching, ($n = 15$), headache and dizziness ($n = 1$), or the wrists hurt and the tightness of the band caused swelling or deep marks or blistering at the site of the button ($n = 45$).

Most patients would have liked to receive the same treatment again (88% in the reference group, 83% in the non-acupoint pressure group and 79% in the P6 stimulation group).

Discussion

Our objective was to determine if P6 acupressure has an effect in the clinical situation. Thus, we included all patients that met inclusion criteria and did not have contraindications for pressure bands (weight over 110 kg and/or problems with the wrists) in a multicentre

TABLE I Articles from major western medical journals up to 2000 that studied acupuncture as prophylactics of postoperative nausea and vomiting (PONV)

| First author Ref no. | Allen 5 | Alhaisi 11 | Agarwal 12 | Barsoum 3 | Dandee 2 | Fan 8 | Ferrara-Love 6 | Fry 1 | Gieron 4 | Harmon 10 | Ho 7 | Stein 9 | Alhaisi present study |
|---|--|---|-------------------------------------|--|--|--|--|--|---|--|---|--|--|
| Randomized Double-blind Design | Yes No inf. Active and placebo stimulation | Yes Yes Active, placebo stimulation and no treatment | Yes Yes Active stimulation | Yes No inf. Active stimulation Placebo stimulation with and without antiemetic | No Single Active stimulation and no treatment | Yes Yes Active and placebo stimulation | Yes Yes Active, placebo stimulation and no treatment | Yes Yes Active stimulation and no treatment | Yes Yes Active, placebo stimulation and no treatment (pilot-study) | Yes Yes Active and placebo stimulation | Yes Yes Active and placebo stimulation without antiemetic | Yes Yes Active and placebo stim. with and without antiemetic | Yes Yes Active, placebo stimulation and no treatment |
| Withdrawals described | Yes | Yes | Yes | Yes | No inf. | Yes | Yes | No inf. | No inf. | No inf. | No inf. | No inf. | Yes |
| Incidence of nausea/vomiting in placebo/ control | Nausea 4.3% | Nausea 40% | Nausea 20% | 2.4 in VAS without antiemetic | Nausea 42% | Nausea and vomiting 41% | Nausea and/ or vomiting 50% | Vomiting 16% | Nausea 57% | Nausea and vomiting 42% | Nausea inf. 27% | Nausea 70% Vomiting 24% | Nausea and/or vomiting 46% |
| Number patients per group | 23 | 20 | 100 | 49 | 51 | 108 | 30 | 250 | 30 | 52 | 30 | 25 | 135, 139, 136 |
| Definition of stimulation | Yes | Yes | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Definition of PONV | Yes | Yes | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Primary outcome measures | Nausea only, retching and/or vomiting 0-24 hr | Complete response, nausea, vomiting, nausea and vomiting rescue med. 24 hr | No | Nausea Vomiting 24 hr | Nausea and vomiting 25% | Early nausea and vomiting 0-6 hr | Nausea and vomiting | Nausea and vomiting | Nausea and vomiting | Nausea, retching and vomiting | Nausea 0-48 hr, vomiting, retching 0-48 hr | Nausea and vomiting | Complete response, nausea, vomiting, rescue med. 24 hr |
| Effect on nausea | No | Yes | No | Yes | Yes | Yes | Yes (similar to placebo) | Yes | Yes | Yes | Yes | Yes | Yes |
| Effect on vomiting | No | Yes | No | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No | No |
| Reduction of antiemetics | Yes | Yes | No | No | - | - | - | - | - | No | No | No | No |
| Full response after acupuncture | - | 55% | 75% | Intensity (VAS) 1.2 | 57% | 77% | 90% | - | 77% | 81% | - | 76% | 67% |
| Full response after placebo | - | 45% | 71% | Placebo intensity 2.4 | Control 32% | 59% | Placebo 80% Control 50% | - | 47% | 58% | - | 24% | 62% |
| Adverse effect | No inf. | No inf. | Yes | Yes | Yes | Yes | No inf. | No inf. | Yes | Yes | Yes | Yes | Yes |

VAS = visual analogue scale; No info. = no information; rescue med = rescue medication.

TABLE II Risk factors for postoperative nausea and vomiting, intraoperative and postoperative drugs and time to oral intake and discharge

| | <i>P6 acupressure</i> (<i>n</i> = 135) | <i>Pressure on a non-acupoint</i> (<i>n</i> = 139) | <i>Reference</i> (<i>n</i> = 136) |
|--|--|--|---------------------------------------|
| <i>Known risk factors</i> | | | |
| Previous postoperative nausea and vomiting | 44 | 49 | 48 |
| Previous motion sickness | 56 | 43 | 42 |
| Pregnant | 25 | 19 | 25 |
| In the first eight days of menstrual cycle | 19 | 15 | 16 |
| Smoker | 42 | 46 | 35 |
| Apfel risk score | 0.7 (0.5) | 0.6 (0.4) | 0.7 (0.5) |
| <i>Intraoperative</i> | | | |
| Propofol | 133 | 135 | 125 |
| Thiopentone | 2 | 5 | 11 |
| Atropine sulphate | 21 | 29 | 25 |
| Glycopyrronium bromide | 13 | 14 | 15 |
| Alfentanil | 78 | 69 | 63 |
| Fentanyl | 54 | 62 | 70 |
| Duration of anesthesia (min) | 35 (23) | 37 (23) | 39 (26) |
| Duration of operation (min) | 24 (15) | 26 (19) | 27 (21) |
| <i>Postoperative</i> | | | |
| Pain, visual analogue scale > 3 | 85 | 84 | 86 |
| Morphine, postop (mg), median (maximum) | 0 (8) | 0 (12.5) | 0 (13.5) |
| Patients needing morphine | 21 | 27 | 29 |
| Time to oral intake (min) | 77 (46) | 79 (40) | 76 (57) |
| Time to discharge (min) | 110 (62) | 115 (59) | 111 (57) |

Figures are as number or mean (SD) unless otherwise stated.

study and the study was not stratified for PONV risk factors. We also avoided interference with prevailing hospital routines. For instance, the choice of anesthetic agent was at the anesthesiologist's discretion. To account for any difference in PONV risk between patients, and for differences in incidence of PONV due to gynecological procedures, the Apfel risk score¹³ and the type of operation (laparoscopic/vaginal) were used as explanatory variables in the analysis. We found a slightly lower incidence of PONV in the acupressure group compared to the reference group. Analyzing the results further, the prominent effect appears to be in patients having vaginal surgery.

It was reported recently that there is less pain, PONV and need for opioids when acupuncture is applied during surgery.¹⁴ Interestingly, if we add postoperative morphine requirement into our logistic regression analysis (patients having more than 2.5 mg morphine postoperatively) we find more patients needed morphine in the reference group ($P = 0.0396$). This

could indicate that patients having perioperative P6 acupressure require less analgesia. On the other hand this difference may have occurred by chance.

Lee and Done proposed criteria for a good study on acupressure: the trial should be randomized and double-blinded; the number and the reason for withdrawals should be described; and it should have sufficient power.¹⁵ They emphasized the importance of describing the operation, the type of anesthesia, and of defining stimulation and the P6 point. The method used to define and document PONV should be reported, primary outcome measures should be defined and adverse effects should be reported. We have reviewed the articles that mention acupressure in adults in journals indexed in Medline and CINAHL up to 2000¹⁻¹² in relation to the criteria suggested by Lee and Done.¹⁵ The results are summarized in Table I. We have designed our study according to these criteria and have included our results in the Table. Our study is possibly the largest containing a non-acustim-

TABLE III Effect on postoperative nausea and vomiting (PONV) after P6 acupressure, pressure on a non-acupoint and reference group. Percent of patients having complete response (no nausea, no vomiting, no rescue medication), are also divided into early and late complete response. Percent of patients having PONV, nausea (only), vomiting (only) and rescue medication are given

| | <i>P6 acupressure</i> <i>n = 135 (51/84)</i> % | <i>Pressure on a non-acupoint</i> <i>n = 139 (53/86)</i> % | <i>Reference</i> <i>n = 136 (61/75)</i> % |
|----------------------------------|--|--|---|
| Complete response | 67* (45/80*) | 62 (43/73) | 54* (41/64*) |
| Early complete response (0–3 hr) | 84 | 83 | 76 |
| Late complete response (3–24 hr) | 75* | 67 | 59* |
| PONV | 33* (55/20*) | 38 (57/27) | 46* (59/36*) |
| Nausea (only) | 24* (29/20*) | 22 (26/19) | 32* (31/32*) |
| Vomiting (only) | 1 (0/1) | 0 (0/0) | 3 (3/3) |
| Rescue medication | 5 (8/2) | 7 (11/3) | 4 (7/1) |

* $P < 0.05$ when P6 acupressure is compared to reference group. Figures for all patients and separately after categorization to (laparoscopic/vaginal surgery).

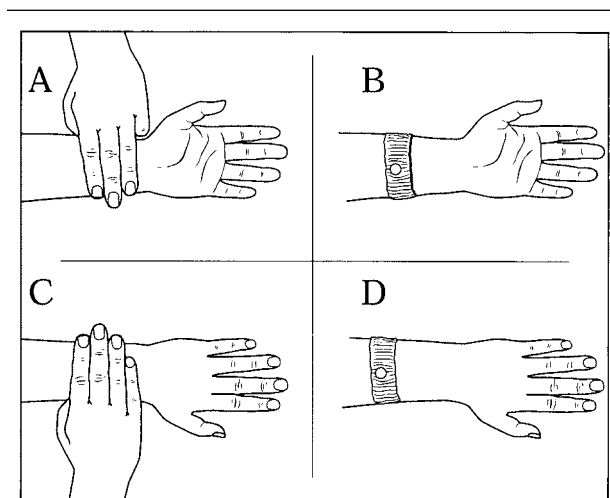


FIGURE Location of points stimulated. A) Pericardium P6 point (Neiguan). Three patient's fingers breadth (approximately 5 cm proximal to the proximal flexor palmar crease), at a depth of about 1 cm between the tendons of flexor carpi radialis and palmaris longus. B) Active acupressure. A Seaband (SeaBand®, UK Ltd., Leicestershire, England) elastic wristband with a pressure stud (a 7 mm button) was placed prior to anesthesia over both P6 points. C) Non-acupoint stimulation. A point on the dorsal side of each forearm, four fingers breadth (patient's fingers) proximal to the flexor palmar crease. D) Pressure on a non-acupoint. Seabands were placed prior to anesthesia over the points described under C.

ulation group and a control group.^{4,6,11} This design makes it possible to estimate both the placebo effect and the incidence of PONV in the study population.

We conclude that acupressure is a non-invasive method that may be used as PONV prophylaxis during gynecological surgery. Our results would suggest a relative decrease in PONV of 28% compared to no PONV prophylaxis at all. A significant decrease occurs following vaginal surgery (44%) but not after laparoscopic surgery (7%).

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