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ORIGINAL RESEARCH

The efficacy of PC6 acupressure with Sea-Band[®] on reducing postoperative nausea and vomiting in patients after hysterectomy: A randomized controlled trial

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ABSTRACT

Aims and objectives: To assess whether bilateral stimulation of the PC6 acupuncture point with Sea-Band[®] could reduce patients' experience of postoperative nausea and vomiting (PONV) after hysterectomy. PONV has high prevalence among gynecological patients. Acupressure bands have been suggested to lessen PONV, however; the antiemetic effectiveness of using acupressure band is still not clarified.

Methods: Design: Randomized, non-blinded, single centre trial in a teaching hospital in Denmark. Seventy-two women scheduled for vaginal or laparoscopic hysterectomy of benign indication, were enrolled in this randomized trial. The women were allocated either to the PC6 group or to the control group. The PC6 group wore Sea-Band[®] wristbands bilaterally for 24 h. The main outcome was complete response *i.e.*, no PONV and rescue antiemetic.

Results: Sixty-two participants (PC6 n = 32; control n = 30) were analyzed. There was no statistically significant difference in complete response between the groups (PC6 group, 50% versus control group 43%) or the incidence of PONV within the first 24 h postoperatively (PC6 group, 47% versus control group 60%) or in need of rescue antiemetic (PC6 group 38% versus control group 33%).

Conclusions: At the same time as this study started, a new antiemetic was introduced to the clinic and hence interfered with the calculation of sample size and influenced the results. The study did not support the study hypotheses. PC6 acupressure bilaterally for 24 h did not result in significant preventive effects in reducing PONV nor did it result in reduced length of postoperative hospital stay.

Key Words: Acupressure, Alternative therapy, Postoperative nausea and vomiting, Hysterectomy

1. INTRODUCTION

Postoperative nausea and vomiting (PONV) is a common complication after surgery and anesthesia and is experienced by 30%–80% of the patients.^[1–6] The incidence of PONV is related to patients' nausea risk score^[1] and the nature of

the surgery.^[2–5,7] Experiencing PONV has a negative impact on perceived well-being and thus a lower degree of patient satisfaction.^[8] In addition, PONV may increase per operative costs, postoperative morbidity, post anesthesia care unit stay, prolong hospital stays, delay the time before the patient can

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go back to work, and lead to readmissions.^[5] Bearing this in mind, healthcare professionals need to handle PONV as equally important as preventing postoperative pain.

1.1 Background

Although several strategies are available for prevention of PONV, there are fewer effective treatment options after the onset of postoperative nausea PON.^[9] Even though antiemetic is widely used in clinical practice in established PONV, optimal management is unsupported by scientific evidence^[6] and the choice of rescue medication for PONV is left to the clinician.

Seen from the patient's point of view, evidence exist that patients across ages and diagnoses have experiences from hospital treatment or lack of care that threatened their well-being.^[10] Thus, it is also important to prevent unpleasant patient symptoms which are side effects of the treatment. This study is testing a preventive cross professional intervention during and after surgery.

Even though the anesthetic techniques and drugs have been optimized and modern antiemetic implemented, it has not been sufficient in preventing PONV implying alternative methods to be more common practice.^[11] Acupuncture and acupressure have been used for centuries in traditional Chinese medicine to prevent PONV.^[12] The acupuncture point "Neiguan" or PC6 is a well known acupuncture point for reducing PONV.^[12] A Cochrane Systematic Review (CSR), which included 40 trials totalling 4,858 participants, reported a clear positive effect of PC6 acupuncture point stimulation on: nausea (RR 0.71, 95% CI 0.61-0.83); vomiting (RR 0.70, 95% CI 0.59-0.83); and need for rescue antiemetics (RR 0.69, 95% CI 0.57-0.83). However, the quality of the studies was poor due to small sample size, problems with allocation sequence generation and the moderate heterogeneity of the studies.^[13]

1.2 Problem statement and hypothesis

Even though invasive and noninvasive stimulation of PC6 is known to significantly reduce PONV,^[2, 13-15] and in addition have very few side effects,^[16] there are conflicting results in terms of efficiency.^[12, 17-21] Also, there are different opinions regarding when and for how long to administer the stimulation, how long the effect lasts, and whether to use unilateral or bilateral stimulation. Some studies indicate that the higher Apfel's risk score, the better postoperative effect of stimulation of PC6.^[14, 17, 22-25] In the current study, we tested the hypothesis that acupressure of the PC6 acupuncture point would reduce moderate and severe PONV and reduce length of postoperative stay after hysterectomy. Sea-Band[®] is a popular and easy method for noninvasive stimulation

of PC6,^[12] so the primary aim of this study was to assess whether bilateral stimulation of PC6 with Sea-Band[®] could reduce patients' experiences of PONV after hysterectomy. Secondary aims were to assess intraoperative and postoperative use of antiemetic, vomiting, pain, oral intake, activity and length of postoperative hospital stay.

2. METHODS

2.1 Study design

The patients were randomized on the day of the surgery by using a block size of 8 with a ratio of 1:1 according to a computer generated sequence (www.randomization.com). The random number list was prepared by an investigator without clinical involvement in the study. The same investigator packed the appropriate numbered envelope with a card inside with information about which group the patient was allocated to; the intervention group (PC6 group) or the control group. Each patient was assigned by opening a sealed, opaque envelope to either wear a Sea-Band (PC6 group) or to receive standard treatment (control group). The envelope was opened by the first author in the presence of the patient. The first author responsible for collecting data was not blind to the treatments administered to the patients. We decided not to use a placebo group because to our knowledge, acupressure on a sham point has no effect on PONV during the first 24 hour after surgery.^[2, 13]

2.2 Ethical approval

For this single center, prospective, randomized non-blinded study, we obtained approval from the Ethics Committee of Central Denmark Region (Ref: M-2013-264-13). The study fulfilled the requirements of the Helsinki Declaration, and was conducted in accordance with GCP-ICH guidelines. The trial was registered at Controlled-trials.com (ISRCTN40965795) and at the Danish Data Protection Agency.

2.3 Setting and participants

The study took place at a public teaching Hospital in Denmark. The participants were enrolled from November 2013 to July 2014.

Calculation of sample size was based on an expected difference of 40% in the number of patients with moderate to severe postoperative nausea during the first 24 hours postoperatively.^[2] Moderate to severe nausea corresponds to a score > 4 on a Visual Analogue Scale (VAS).^[26] With 80% power ($\alpha = 0.05$, $\beta = 0.20$), a sample size of 29 patients per group was necessary. A conservative sample size of 72 was chosen to allow for incomplete data collection.

Women > 18 years of age scheduled for elective hysterectomy on benign indication were identified as potential participants

and screened for eligibility. Exclusion criteria were women with carpal tunnel syndrome, diabetes, nausea and vomiting preoperatively, lymph edema, skin diseases or wounds on the wrist, inability to communicate in Danish, severe obesity body mass index (BMI) > 35.

Eligible patients were given verbal and written information, and written informed consent was obtained before any study related procedure.

2.4 Procedure

On the evening before the surgery and before leaving home on the day of the surgery, all participants were asked to take paracetamol 1 g. Standard regimen for premedication was dexamethasone 8 mg, a synthetic adrenocortical steroid, and ibuprofen 600 mg which were given orally on the day of the surgery. The participants received one of 3 different kinds of anesthesia depending on type of surgery; general anesthesia (GA), spinal anesthesia or a combination of epidural and GA. General anesthesia was induced with propofol (1.5-2.5 mg/kg iv), and fentanyl (0.7-1.4 µg/kg iv) and was maintained with propofol or sevoflurane according to standard regimens. Epidural anesthesia was induced at the T9-T11 level with a test dose of 2 ml lidocain 2% and maintained with 6 ml bupivacaine 0.5% and epimorphine 2 mg. Spinal anesthesia was induced at the L2-L3 levels by using a 27-gauge spinal needle with a dose of 5 mg bupivacaine.

Standard treatment for postoperative nausea and vomiting were rescue doses of ondansetron, a 5-hydroxytryptamine 3 receptor antagonist and metoclopramide, a dopamine-receptor antagonist. Participants with an Apfel's risk score > 2 were given ondansetron 4 mg intravenous at the end of the surgery.

2.5 Intervention

Acupressure was provided by a single sized elastic wristband with a plastic button, the Sea-Band®. The Sea-Band® wristband was applied bilaterally 30 to 60 minutes before walking to the operating room so the plastic button was applying acupressure on the PC6 acupuncture point (located 3 of the patient's finger widths proximal to the distal crease on the plantar surface of the wrist between the palmaris longus and flexor carpi radialis tendons). The PC6 acupuncture point was marked by first author with a permanent marker before the acupressure wristband was applied to make sure the same acupuncture point was used if the Sea-Band® had to come off and on. The patients were instructed to leave the Sea-Band® in place for the next 24 hours, unless they had any side effects (redness, swelling, tenderness or paraesthesia). If there were any side effects, the patient was instructed to remove the acupressure wristband for 15 minutes and then replace it and note the time and cause in a diary.

If two patients were randomized on the same day, it was ensured that they got separate rooms in order to avoid contamination between the groups.

2.6 Data collection

The actual requirements for rescue antiemetic and morphine during the first 24 hours postoperative were documented in the patient's medical journal. Intensity of nausea and pain was measured (2, 6 and 24 h after surgery) on two separate 0-100 mm VAS (where 0 = no nausea or pain, 100 = worst imaginable nausea or pain). The cut-off points for measuring nausea on VAS are as follows: 0-1 (no nausea), > 1-4 (mild), > 4-7 (moderate) and > 7-10 (severe).^[12] Assessment of nausea and pain were made by the women themselves as well as the first time of oral intake, activity and vomiting and noted in a diary. If the women were discharged before 24 h follow-up, they got a stamped envelope to return the diary.

The primary endpoints with respect to efficacy on PONV, was any occurrence of nausea, vomiting and rescue antiemetic medication. Secondary endpoints were level of nausea, level of pain, time to oral intake, vomiting and postoperative length of stay.

2.7 Statistical analysis

Data were analyzed using Mann-Whitney test, Pearson's chi-squared test, or Fisher's exact test. Results are reported as mean. Categorical and quantitative variables were dichotomized, grouped and presented as percentage or frequency. A *p*-value < .05 was considered to be statistically significant. EpiData version 3.1 (Epi Data Association, Odense, Denmark) was used for data entry and STATA 10 (StataCorp Texas, USA) was used for statistical analysis. The statistical analysis was carried out by the first author under the guidance of an external statistician.

3. RESULTS

Seventy-two patients scheduled for vaginal or laparoscopic hysterectomy of benign indication, were allocated either to the PC6 group or to the control group (see Figure 1). The proportion of participants completing the study as planned was 89% in the PC6 group and 83% in the control group and with an overall average of 86%.

Some participants had some missing values due to extra workload so the nurses forgot to remind them to fill in the diary.

Demographic characteristics, including body mass index, age and Apfel score were not significantly different in the two study groups (see Table 1). In addition, there were no significant differences in the type of surgery, anaesthetic technique or in duration of surgery. Importantly, there were

no differences in the use of intraoperative and postoperative opioid analgesic medications in the two study groups (see Table 1). The active acupressure with Sea-Band[®] remained in place over the PC6 acupuncture point for the 24 h in 29 cases which corresponds to 91%. Approximately 9% of the women in the PC6 group reported side effects such as minor discomfort for example redness, tenderness, paraesthesia or

swelling of the wrist. 9 women were discharged on the day of surgery; 4 in the PC6 group and 5 in the control group. Only one woman forgot to return the diary, but after a reminder, she sent the diary. A great deal of the participants in this study (approximately 80%) had an Apfel score > 2 and was thus high risk patients.

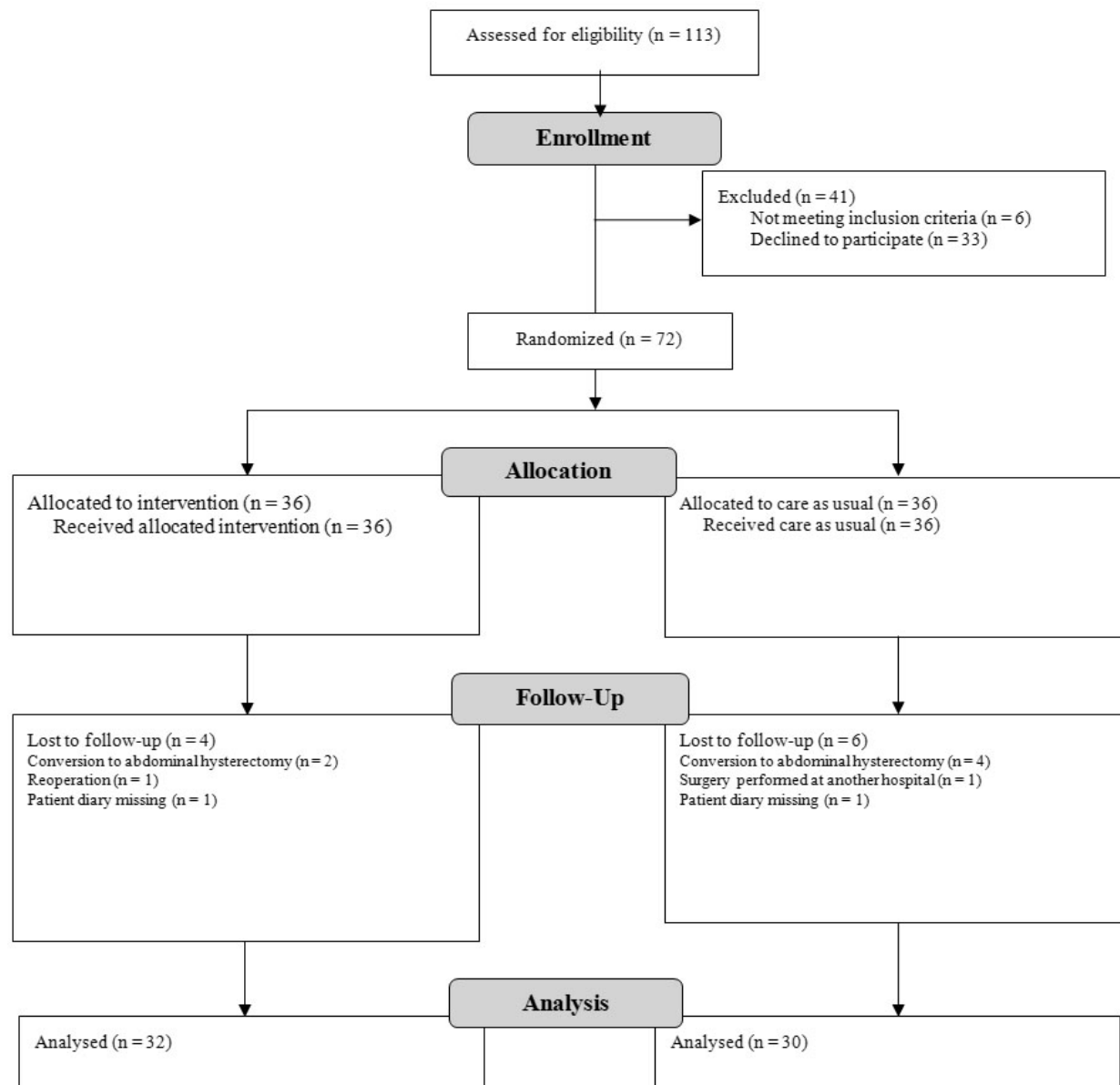


Figure 1. Participants' flow through the study

Despite the fact that in the PC6 group only 72% received dexamethasone compared to 93% in the control group, the VAS score on nausea at 2, 6 and 24 h by chance was lower at all times in the PC6 group, however; it was not statistically significant (see Table 2). At 2 and 6 h, the mean VAS score was within the cut-off point for mild nausea for both groups.

At 24 h, we saw that the PC6 group had mild nausea while the control group had moderate nausea. The proportion of patients with moderate to severe nausea was the same for both groups at 6 and 24 h, however, at 2 h, it was 3% and 13% in the PC6 group and the control group respectively.

Table 1. Baseline demographic and clinical characteristic

	PC6 (n = 32)	Control (n = 30)
Age, years	50 (\pm 9)	49 (\pm 10)
Body mass index	26.6 (\pm 4.7)	25.3 (\pm 3.1)
ASA status		
I	19 (59)	13 (43)
II	12 (38)	17 (57)
III	1 (3)	0 (0)
Charlson Comorbidity Index	0.6 (\pm 0.8)	0.6 (\pm 0.9)
Apfel-score*		
1	1 (3)	0 (0)
2	6 (19)	6 (20)
3	14 (44)	14 (47)
4	11 (34)	10 (33)
Preoperative Dexamethason	23 (72)	28 (93)
Type of surgery		
Vaginal	13 (41)	16 (53)
Laparoscopic	19 (59)	14 (47)
Anaesthetic technique		
General anaesthesia (GA)	20 (63)	18 (60)
Spinal	10 (31)	9 (30)
Epidural and GA	2 (6)	3 (10)
Intraoperative Fentanyl given (μg)	130 (\pm 164)	173 (\pm 135)
Intraoperative antiemetic given		
Ondansetron (mg)	1.9 (\pm 2.0)	2.4 (\pm 2.0)
Droperidol (mg)	0.08 (\pm 0.21)	0.13 (\pm 0.25)
Postoperative antiemetic given		
Metoclopramide (mg)	1.9 (\pm 7.8)	1.0 (\pm 4.0)
Ondansetron (mg)	2.3 (\pm 5.9)	1.3 (\pm 2.3)
Duration of operation (min)	103 (\pm 96)	94 (\pm 32)
Morphine postop (mg)	10.1 (\pm 12.4)	12.5 (\pm 16.7)

Note. Data are means (\pm SD) or numbers (%); *Risk score for PONV.

Table 2. Nausea intensity score (PON) (VAS, 0-100 mm)

	PC6	Control	P-value
Nausea, 2 h	2.2 (0.8-3.5) n = 32	3.5 (1.1-5.8) n = 30	.15
Nausea, 6 h	4.6 (2.7-6.6) n = 31	6.8 (3.8-9.8) n = 28	.22
Nausea, 24 h	2.4 (1.5-3.2) n = 31	4.2 (1.7-6.6) n = 30	.49

Note. Because of missing values, n varies slightly between the individual parameters. Data are means (95% confidence interval). Mann Whitney U-test for comparing means for continuous variables.

There were no significant differences in the incidence of vomiting between the two groups: 31% and 38% in the PC6 and the control group respectively, or in time to oral intake, mobilization, first vomiting and length of postoperative stay (see Table 3).

When looking upon the complete response *i.e.*, no PONV and rescue antiemetic during the follow-up period, the percentages for the PC6 group were 50% and for the control

group 43% (see Table 4).

In the PC6 group, the incidence of PONV during the follow-up period was 47% compared to 60% in the control group (see Table 4).

We found no significant difference between the two groups in need of rescue antiemetic, respectively, 38% and 33% in the PC6 group and the control group (see Table 4).

Table 3. Time to oral intake, mobilization, first vomiting and length of postoperative stay

	PC6	Control	P-value
Oral intake (min)	146 (116-175) n = 32	284 (132-436) n = 29	.38
Mobilisation (min)	398 (294-502) n = 29	380 (288-472) n = 28	.97
First vomiting (min)	260 (144-376) n = 9	349 (241-456) n = 11	.03
Discharge (hour)	21 (19-23) n = 32	20 (18-23) n = 30	.98

Note. Because of missing values, n varies slightly between the individual parameters. Data are means (95% confidence interval). Mann Whitney U-test for comparing means for continuous variables.

Table 4. Effect on PONV after PC6 acupressure and control group. Percent of women having complete response, nausea, vomiting and rescue antiemetic (0-24 h)

	PC6 n = (32)	Control n = (30)	P-value
Complete response PONV†	50% (32-68)	43% (24-63)	.74
Complete response on PON ‡	53% (35-71)	43% (25-63)	.44
PONV	47% (29-65)	60% (41-77)	.62
Nausea (only)	44% (26-62)	47% (28-66)	.92
Vomiting (only)	31% (16-50)	38% (21-58)	.58
Rescue antiemetic	38% (21-56)	33% (17-53)	.73

Note. Data are percentages (95% confidence interval); † No nausea, no vomiting, no rescue antiemetic; ‡ No nausea, no rescue antiemetic.

4. DISCUSSION

In this study comparing bilateral PC6 acupressure with standard treatment, we found no significant difference in complete response, nor did the groups differ in their need for rescue antiemetic. The complete response rate for the PC6 group was 50% compared with 43% in the control group.

The lack of a significant reduction in PONV with PC6 acupressure in the current study is supported by other studies. In a study very similar to this study with regards to preventive antiemetic medication in combination with the use of bilateral acupressure in patients undergoing laparoscopic surgery, the outcome failed to demonstrate any significant reduction in PONV.^[25] Another study used Vital-Band unilaterally before induction in women undergoing breast surgery. In this study, the patients did not get any prophylactic antiemetic. This study also failed to find any reduction in PONV.^[25] A Canadian study in patients undergoing cardiac surgery which used acupressure bands bilaterally before induction also failed to find any reduction in PONV.^[18]

On the other hand, other studies have found a significant reduction in PONV by applying acupressure on the PC6 acupuncture point and that the method in addition has very few side effects.^[13,16] The current study also proved that using the Sea-Band to apply acupressure was safe and well tolerated with no serious side effects.

In a Cochrane review, the authors concluded that PC6 acupressure reduces PONV.^[13] One study, which also used the Sea-Band[®] bilaterally before induction, found a significant reduction of PONV up to 24 h in women undergoing gynaecological surgery.^[20]

Thus, there has been conflicting results regarding the effectiveness of PC6 acupressure; the lack of homogeneity has been the subject of debates.^[21] The debate has been about why PC6 acupressure has not been implemented on an equal basis with medical treatment since it is known that PC6 acupressure is equated with antiemetic.^[21] Debate has also been about the reason for the failure to implement PC6 acupressure. Lack of knowledge and clear recommendations and the fact that the evidence of PC6 acupressure has failed to convince are some of the reasons that are mentioned in the debate.^[21]

Recent studies have demonstrated that despite multimodal antiemetic drug prophylaxis, patients at risk of developing PONV continue to experience an unacceptably high incidence of PONV that interfere with their recovery after surgery.^[13,25]

There are indications that PC6 acupressure is more effective in gynaecological patients and in patients with a high Apfel score.^[13,14] In this study, there was an indication that PC6 acupressure would be beneficial to these patients, however; the result was not significant.

PONV has a negative influence on patient's well-being and is one of the main reasons for delayed postoperative recovery. Healthcare professionals need to be aware of the importance of preventing PONV after surgery and consider this as equally important as preventing pain.^[27]

There were some limitations of this study. The study was not

blinded, which means that the participants knew if they were in the intervention group or in the control group and this may have caused bias in the assessment of nausea since it is a subjective endpoint. It is most likely that the sample size for this study was too small and that this may be due to changes in clinical practice. The inadequate sample size may be due to the introduction of an efficient drug (dexamethasone) to prevent PONV in the clinic and this may be the reason that we failed to demonstrate a statistically significant effect on PONV. The implementation of dexamethasone took place just before the randomization of the first patient.

Another reason that we failed to demonstrate a statistically significant effect on PONV may be due to the difference in the proportion of patients between the groups who got dexamethasone. In the PC6 group, the proportion of patients who got dexamethasone was 21% lower than in the control group. A standardized pre-operative protocol could have prevented this difference in pre-medication and increased the strength of the study.

Another limitation of this study is that the gold standard, intention to treat (ITT) analysis, was not performed. However, it was not possible since an ITT analysis requires a full set of data and as demonstrated in the flow chart, it was not possible to perform a follow-up on 4 patients from the PC6 group and 6 patients from the control group respectively.

PONV remains a concern in clinical practice as “the big little problem” which is not life threatening, is more unpleasant than postoperative pain and a contributing factor to prolonged hospitalization.^[12] In the future, hospitalization will be shorter as more inpatient settings will be reorganized to day-case surgery. As the number of ambulatory and day-case surgery continue to grow, so will the number of patients experiencing “the big little problem” after discharge. In order to provide clinicians and patients with evidence based

guidelines in treating established PONV, further research is needed.

Most trials today have focused on comparing PC6 acupressure with sham or medication unlike the current study which focused on PC6 acupressure in addition to standard treatment which consisted of prophylactic and rescue antiemetic. So in the future, there may be a need for trials with greater numbers of patients investigating PC6 acupressure along with medication.

5. CONCLUSION

At the same time as this study started, a new antiemetic was introduced to the clinic and hence interfered with the calculation of sample size and influenced the results. The study did not support the study hypotheses. PC6 acupressure bilaterally for 24 hours did not result in significant preventive effects in reducing PONV nor did it result in reduced length of postoperative hospital stay.

6. RELEVANCE TO CLINICAL PRACTICE

In this study, there was an indication that PC6 acupressure would be beneficial to patient undergoing hysterectomy, however; the result was not significant. Further and bigger studies are needed to determine the efficacy of PC6 acupressure in combination with an antiemetic.

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CONFLICTS OF INTEREST DISCLOSURE

All authors declare no conflict of interest.

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