

P6 Acupoint Injections Are as Effective as Droperidol in Controlling Early Postoperative Nausea and Vomiting in Children

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Background: P6 acupuncture in adults is reported to be an effective preventive treatment for postoperative nausea and vomiting (PONV). It is not clear, however, whether this technique is effective as a preventive treatment for PONV in children.

Methods: Children undergoing anesthesia and surgery were randomized to four groups: (a) intravenous saline + bilateral P6 acupoint injections (n = 50); (b) intravenous droperidol + bilateral P6 sham acupuncture (n = 49); (c) intravenous saline + bilateral sham point injections (n = 43); (d) intravenous saline + bilateral P6 sham acupuncture (n = 45). The perioperative anesthetic technique was standardized in all subjects. The incidence of postoperative nausea and vomiting (PONV) was evaluated in postanesthesia care unit (PACU) and 24 h after surgery.

Results: Incidence of nausea in the PACU was significantly lower in the acupoint group as compared with the sham point group (32% vs. 56%, $P = 0.029$) and P6 sham group (32% vs. 64%, $P = 0.002$) but not as compared with the droperidol group (32% vs. 46%, $P = \text{ns}$). Similarly, subjects in the acupoint group had a significantly lower incidence of vomiting in the PACU as compared with the sham point group (12% vs. 33%, $P = 0.026$) and P6 sham group (12% vs. 31%, $P = 0.029$) but not as compared with the droperidol group (12% vs. 18%, $P = \text{ns}$). The combined incidence of early PONV was also lower in the acupoint group as compared with the sham point group ($P = 0.045$) and P6 sham group ($P = 0.004$) but not as compared with the droperidol group (42% vs. 51%, $P = \text{ns}$). Finally, significantly fewer subjects in the acupoint group required intravenous ondansetron as an initial rescue therapy ($P = 0.024$). At 24 h after surgery, however, the incidence of late PONV was similar among the four study groups ($P = \text{ns}$).

Conclusion: In children, P6 acupoint injections are as effective as droperidol in controlling early postoperative nausea and vomiting.

POSTOPERATIVE nausea and vomiting (PONV) is a common problem in patients undergoing general anesthesia and surgery.¹⁻⁵ Despite dramatic changes in anesthesia practice and development of new antiemetic agents, the incidence of PONV has remained constant for the past

30 yr.⁶ The high cost and associated side effects of newer antiemetic drugs have prompted researchers to search for cost-effective alternatives.

Acupuncture is a medical technique that has been used in China for at least 2,000 yr.⁷ More recently, acupuncture has been used by millions of Americans for the management of various medical conditions such as headache, chronic back pain, and PONV.⁸ In November 1997, the National Institutes of Health (NIH) issued a statement that "acupuncture may be useful as an adjunct treatment or an acceptable alternative or included in a comprehensive management program for many medical conditions." A recent meta-analysis that evaluated the effectiveness of acupuncture as a preventive treatment for PONV in adults indicated that P6 acupuncture and related techniques are effective in decreasing the incidence of nausea and vomiting related to surgery.⁹

In children, however, there are few data regarding the effectiveness of acupuncture as a preventive modality for PONV.¹⁰⁻¹⁵ Although some studies indicate that acupuncture is not an effective preventive modality for PONV in children,¹⁰⁻¹⁴ a recent report contradicted these findings and suggested that P6 laser acupuncture may be an effective preventive modality in children undergoing surgery.¹⁵ At the onset of this investigation, we identified several methodologic issues, such as timing of the acupuncture intervention, sample size, perioperative anesthetic techniques, and appropriate control groups, that may explain these contradictory findings.

The aims of this study were to use this more controlled methodology to determine the effects of P6 acupoint injection on the incidence of PONV in children undergoing general anesthesia and surgery and to examine whether P6 acupoint injection is as effective as intravenous droperidol for the prevention of PONV.

Materials and Methods

Study Design and Interventions

The study population of this randomized, double blinded, sham placebo-controlled trial consisted of children, aged 7-16 yr, undergoing general anesthesia and outpatient surgical procedures. To avoid potential confounding variables, patients with American Society of Anesthesiology (ASA) physical status higher than II and subjects with a history of developmental delay or prematurity were not invited to participate in this study. The institutional review board approved the study pro-

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tolol, and written informed parental consent/assent was obtained from all subjects.

All subjects were randomly assigned to the following four groups:

- Group I (acupoint): intravenous saline + bilateral P6 acupoint injections. P6 is located at the forearm, between tendons of palmaris longus and flexor carpi radialis, one sixth of the distance between the distal wrist crease and the cubital crease.
- Group II (droperidol): 10 $\mu\text{g}/\text{kg}$ intravenous droperidol + bilateral P6 sham acupuncture. P6 sham acupuncture is defined as superficial skin prick at the exact location of P6.
- Group III (sham point): intravenous saline + bilateral sham point injections. The sham point is located at the dorsum of the arm about 5 cm distal to the shoulder in the midline. To the best of our knowledge, this sham point is not a documented acupuncture point in the Chinese acupuncture literature.
- Group IV (P6 sham point): intravenous saline + bilateral P6 sham acupuncture.

All acupuncture procedures were performed by the first author (S-M.W.), who is a certified acupuncturist.

We used a yoking randomization strategy that considered gender, age, and type of surgery of the four study groups. For example, the first 8-yr-old boy undergoing herniorrhaphy was randomized (based on a computer generated list) to one of the four study groups. The second 8-yr-old boy undergoing herniorrhaphy was randomized to one of the remaining three study groups. The third 8-yr-old boy undergoing herniorrhaphy was randomized to one of the remaining two study groups. The fourth 8-yr-old boy undergoing herniorrhaphy was automatically allocated to the remaining study group. This assured equal distribution of variables that are known to affect the outcome in the four study groups. In addition, this technique of yoking randomization assured good external validity of the results of this study.

Assessment Instruments

Incidence of Postoperative Nausea and Vomiting.

The primary outcome of this study was the incidence of PONV in the postanesthesia care unit (PACU) and during the first 24 h postoperatively. This outcome was assessed by the PACU nursing staff and a research assistant. It is important to note that although the acupuncturist (S-M.W.) could not be blinded to group assignment, she did **not** participate in the assessment of any of the outcome variables. Children, parents, surgeons, anesthesiologists, PACU nursing staff, and the research assistant, however, were all blinded to group assignment.

Demographic and Background Information Questionnaire. This brief questionnaire is designed to gather demographic information about the child such as age, ethnicity, and so on.

State Trait Anxiety Inventory–Children. The State Trait Anxiety Inventory–Children (STAI-C) is a 40-item questionnaire that provides measures of trait (20 items) and state (20 items) anxiety, where higher scores indicate greater anxiety levels.¹⁶

Bieri Faces Scale. This pain assessment scale uses seven line drawings of faces and is designed to measure pain intensity in children aged more than 3 yr.¹⁷ This scale has excellent test-retest reliability.

Postoperative Nausea and Vomiting Assessment

Nausea. Based on existing literature, we *a priori* defined nausea as an unpleasant sensation associated with awareness of an urge to vomit.¹⁸ The presence of nausea symptoms was determined either by spontaneous patient reporting or by a direct inquiry made by the investigative team every 15 min throughout the PACU stay. Also, a visual analog scale (VAS) was used to assess the need for nausea rescue therapy. The VAS used in this study ranged from “not nauseated” (score of 0) to “extremely nauseated” (score of 100).¹⁹ If a patient complained about nausea with a VAS nausea score higher than 20, rescue medication was administered immediately. If a patient complained about nausea with a VAS nausea score lower than 20, the patient’s complaint was reassessed after 5 min, and medication was administered only if symptoms persisted.

During the early postoperative period, severity of nausea was defined as the number of episodes that occurred throughout the PACU stays, controlling for length of stay in the PACU. To calculate this, we divided the number of episodes that occurred by the number of hours the patients stayed in the PACU. This resulted in a time-corrected nausea index. At 24 h postoperatively, a blinded research assistant called the parents of all children and inquired about the presence or absence of nausea symptoms that occurred after discharge from the PACU.

Retching and Vomiting. We defined retching and vomiting episodes as labored, spasmodic rhythmic contraction of respiratory muscle without or with the gastric content, respectively.¹⁸ We recorded all episodes of retching or vomiting as they occurred throughout the PACU stay and calculated incidence and frequency of these episodes. Severity of vomiting was indicated by an increased number of vomiting episodes. At 24 h postoperatively, a blinded research assistant called by telephone the parents of all children and inquired about the presence or absence of vomiting that occurred after discharge from the PACU.

We defined the incidence of PONV as the combined frequency of first-onset nausea or vomiting. We further defined early PONV as that occurring throughout the PACU stay and late PONV as that occurring after discharge from the PACU.

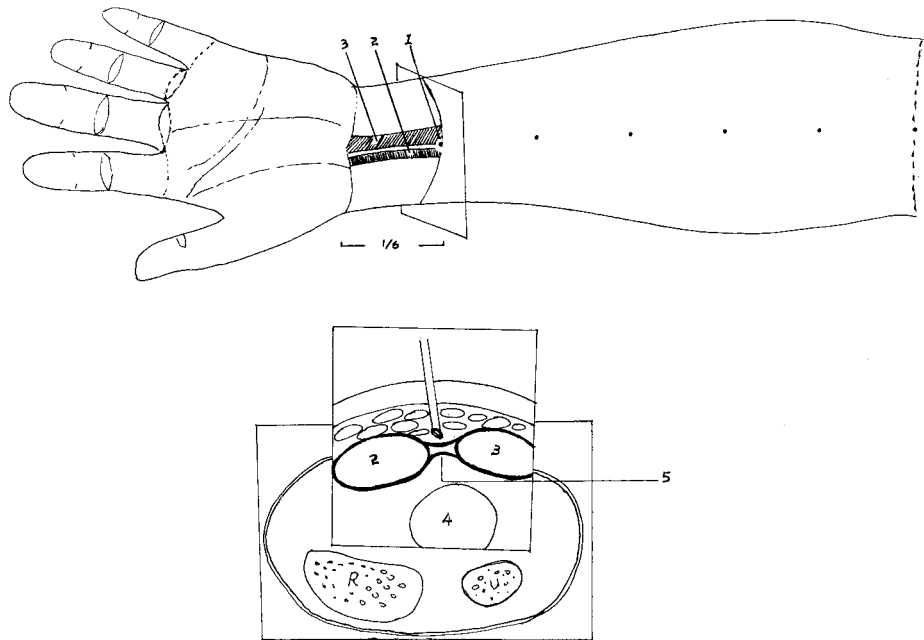


Fig. 1. This figure demonstrates the location of P6 acupuncture point and its relation to the various anatomic structures of the hand. (1) P6 acupuncture point; (2) tendon of palmaris longus; (3) tendon of flexor carpi radialis; (4) median nerve; (5) palmar aponeurosis.

Study Protocol

Recruitment of Subjects. All subjects were contacted by telephone 1 to 2 weeks before surgery, and the possibility of participating in the study was discussed. During a preoperative visit, subjects were formally recruited to the study. The study protocol was verbally explained, questions were answered, and the consent/assent form was read and signed.

Day of Surgery, Preoperative Period. After recruitment, parents completed the demographic questionnaire. No sedative premedication was offered to any children participating in this study. If a child exhibited extreme anxiety (as assessed by the parent or anesthesiologist) at the point of separation to the operating room (OR), rescue therapy in the form of parental presence during induction of anesthesia was available. The attending anesthesiologist managing the case was the only one to decide about the need for rescue therapy.

Induction and Maintenance of Anesthesia. Subjects were brought into the OR. A SpO_2 probe was placed on the child's hand, and anesthesia was induced using $\text{O}_2/\text{N}_2\text{O}/\text{sevoflurane}$ technique *via* a scented anesthesia mask. Once induction was accomplished, an intravenous catheter was inserted, and 0.1 mg/kg intravenous vecuronium and 2–4 $\mu\text{g}/\text{kg}$ of fentanyl were administered to facilitate intubation of the trachea. Next, a prefilled pharmacy-prepared syringe that contained 0.25 ml of a solution was administered intravenously to the patient. The syringe contained either saline (groups I, III, and IV) or 10 $\mu\text{g}/\text{kg}$ of droperidol (up to 0.625 mg; group II). The anesthesia personnel managing the case were thus blinded to group assignment. No additional antiemetic agents were administered, and anesthesia was main-

tained using $\text{O}_2/\text{air}/\text{isoflurane}$. Regional anesthetic techniques were not part of this study protocol.

Conclusion of Surgery. Before the conclusion of surgery, the anesthesia personnel managing the case were asked to leave the OR, and the acupuncturist administered the appropriate intervention. Subjects in groups I and III received bilateral injections of 0.2 ml of 50% dextrose solution at bilateral P6 and sham locations. P6 is located at the forearm, between tendons of palmaris longus and flexor carpi radialis, one sixth of the distance between the distal wrist crease and the cubital crease. See figure 1 for the exact location of this point. These P6 injections were performed using a B-D 1-ml tuberculin syringe with a 25-gauge needle that was inserted vertically to a depth of approximately 5–7 mm until a resistance was met, and 0.2 ml of 50% dextrose was deposited. The point of resistance indicated the needle approaching the palmar aponeurosis (fig. 1). To further assure the anesthesiologists, surgeons, patients, parents, and nurses were blinded, subjects in groups II and IV also received bilateral subcutaneous needle stick at the P6 location (sham acupuncture). After the procedure, two small adhesive bandages were applied to P6 points at the wrists of all subjects. All patients received intravenous lactated Ringer's solution based on calculated preoperative deficits, surgical procedure, and estimated intraoperative blood loss. At the conclusion of surgery, muscle relaxant effects were reversed in all patients using 50 $\mu\text{g}/\text{kg}$ of neostigmine and 10 $\mu\text{g}/\text{kg}$ of glycopyrrolate. After extubation, subjects were transported to PACU with oxygen flow through a mask-attached Jackson-Reed circuit.

Early Postoperative Period (PACU). Severity of pain was assessed using the Bieri face scale every 15 min and on patient complaint throughout PACU stay. If the severity of pain was greater than 2, intravenous fentanyl, 0.5 $\mu\text{g}/\text{kg}$, was administered to the patient.

Occurrence of retching or vomiting episodes that occurred throughout the PACU stay was recorded as well. The presence and severity of nausea were assessed every 15 min or on patient complaint throughout the PACU stay. As rescue therapy, intravenous ondansetron, 0.1–4 mg/kg, was administered if subjects had two episodes of retching and vomiting or nausea with a nausea VAS score greater than 20. Patients reporting nausea with a VAS nausea score lower than 20 were reassessed after 5 min, and medication was administered only if symptoms persisted. It is important to note that parents were present during their children's recovery period, and all study subjects were offered clear liquids during their stay in the PACU.

Late Postoperative Period (Home). Parents were instructed to give analgesic agents every 4–6 h around the clock for the first 24 h postoperatively. The analgesic drugs used in this study were limited to acetaminophen and acetaminophen with codeine mixture and were prescribed based on the surgical procedure and the child's weight. At 24 h postoperatively, a research assistant who was blinded to group assignment contacted parents by telephone and inquired about symptoms and the frequency of late nausea and vomiting that occurred since the patient was discharged from the PACU. The parents were also questioned about the type of analgesic agents used and asked to rate their child's average pain since discharge from the PACU on a scale of 0 (no pain) to 10 (extreme pain).

Statistical Analyses

As Yang *et al.*²⁰ used a similar acupuncture technique to the one used in this study, we calculated the sample size based on their data. Yang *et al.* have reported that the incidence of vomiting in adult patients was significantly higher in the control group (52%) as compared with the droperidol (17%) and P6 acupoint injection groups (12%). Based on a two-sided α level of 0.05 and a power of 0.80, we calculated that 40 subjects were needed for every study group. Because we planned to perform multiple logistic regression analysis, we increased our total projected sample size to 190 subjects.

Normally distributed data are presented as mean \pm SD; skewed data as median and interquartile range (25%–75%). Baseline characteristics of the groups were examined using analysis of variance (ANOVA) for continuous variables and chi-square analysis for categorical variables. Chi-square test was used to assess outcomes such as incidence of vomiting in the PACU and 24 h postoperatively. $P < 0.05$ is considered significant. Continuous skewed data were analyzed using the Kruskal-Wallis

test. The primary outcomes (incidence of nausea, vomiting, PONV) were also analyzed using two multivariable logistic regression models in which the dependent variable was the presence or absence of PONV and the independent variables were group assignment, gender, body weight, surgical procedure, postoperative pain as perioperative narcotic consumption, and PACU duration. We did not use pain and narcotic consumption in the same model because these two variables may be highly dependent on each other.

Results

One hundred ninety children were recruited for this study. Three children were found to have major protocol violations and were excluded from the study (two patients received intravenous morphine, and one patient received intravenous propofol). Thus, data from 187 subjects were analyzed and are presented in this article. None of the study subjects required rescue therapy in the form of parental presence during induction of anesthesia. There were no differences among the various study groups in regard to baseline demographic characteristics such as age and history of PONV (table 1). Also, there were no significant differences between the four study groups in regard to perioperative variables such as surgical procedures, episodes of pain, total narcotic usage, surgery time, time to clear liquid intake, and time to discharge (table 2). Similarly, trait and state anxiety did not differ significantly between the study groups ($P = \text{ns}$).

Early Postoperative Period

The incidence of nausea that occurred throughout the PACU stay differed significantly among the four study groups ($P = 0.012$) (table 3). *Post hoc* analyses demonstrated that the incidence of early nausea was significantly lower in the acupoint group as compared with the sham point group ($P = 0.029$) and P6 sham group ($P = 0.002$). The incidence of early nausea in the acupoint group, however, did not differ significantly compared with the droperidol group ($P = 0.18$). Nausea index differed significantly among the four study groups ($P = 0.007$) (table 3). *Post hoc* analysis demonstrated that the nausea index was significantly lower in the acupoint group as compared with the sham point group ($P = 0.001$) and P6 sham group ($P = 0.022$) but not as compared with the droperidol group ($P = \text{ns}$) (table 3).

The incidence of early vomiting differed significantly among the four study groups ($P = 0.048$) (table 3). *Post hoc* analyses demonstrated that the incidence of early vomiting was significantly lower in the acupoint group as compared with the sham point group ($P = 0.026$) and P6 sham group ($P = 0.029$). The incidence of early vomiting in the acupoint group, however, did not differ significantly from the droperidol group ($P = 0.57$). Also,

Table 1. Baseline Demographic Characteristics

	Acupoint Group (N = 50)	Droperidol Group (N = 49)	Sham Point Group (N = 43)	Sham P6 Group (N = 45)	P Value
Age (yr)					
Mean ± SD	11 ± 3	11 ± 3	11 ± 3	11 ± 3	<i>P</i> = ns
Gender (%)					
Female	36	40	53	49	<i>P</i> = ns
Male	64	60	47	51	
Body Weight (kg)					
Mean ± SD	48 ± 19	47 ± 14	48 ± 15	50 ± 18	<i>P</i> = ns
Previous surgery(%)					
Yes	35	58	42	49	<i>P</i> = ns
No	65	42	58	51	
Previous PONV*(%)					
Yes	18	21	16	18	<i>P</i> = ns
No	82	80	84	83	
Anxiety (mean ± SD)					
STAIS-C†	33 ± 6	32 ± 6	33 ± 8	34 ± 7	<i>P</i> = ns
STAIT-C‡	32 ± 6	33 ± 6	33 ± 6	34 ± 8	

* PONV = postoperative nausea and vomiting; † STAIS-C = state trait anxiety inventory, state subscale, children; ‡ STAIT-C = state trait anxiety inventory, trait subscale, children; ns = not significant.

the incidence of PONV was significantly lower in the acupoint group as compared with the sham point group (*P* = 0.045) and P6 sham group (*P* = 0.004) but not as compared with the droperidol group (*P* = ns) (table 3).

To control for potentially confounding variables, three multivariable logistic regression models were developed. In these models, the independent variables included group assignment, gender, body weight, procedure, perioperative narcotic consumption, and PACU duration. In the first model, where the presence or absence of early nausea was the dependent variable, group assignment remained a significant predictor (*P* = 0.037) for the occurrence of post-

operative nausea in the presence of all other variables. No other variables were identified as significant predictors in this model. Similarly, a second multivariable logistic regression model demonstrated that group assignment remained a significant predictor (*P* = 0.032) for the occurrence of postoperative vomiting in the presence of all the predictive variables above. No other variables were identified as significant predictors in this model. A third multivariable logistic regression model demonstrated that group assignment remained a significant predictor (*P* = 0.034) for the occurrence of PONV in the presence of all the predictive variables above.

Table 2. Perioperative Parameters

	Acupoint Group (N = 50)	Droperidol Group (N = 49)	Sham Point Group (N = 43)	Sham P6 Group (N = 45)	P Value
Surgical procedures (%)					<i>P</i> = ns
Plastics*	22	23	28	31	
ENT†	42	43	41	42	
Abdominal‡	28	26	23	20	
Orthopedics	8	8	8	7	
Surgical time (min)					
Median (range)	50 (33–73)	50 (25–75)	45 (30–76)	46 (31–91)	<i>P</i> = ns
Anesthesia time (min)					
Median (range)	55 (35–75)	54 (30–78)	46 (39–84)	50 (34–96)	<i>P</i> = ns
PACU§ duration (min)					
Median (range)	118 (94–155)	135 (90–168)	140 (108–185)	128 (98–171)	<i>P</i> = ns
Pain episodes					
Median (range)	2 (0–3)	2 (0–3)	2 (0–4)	1 (0–2)	<i>P</i> = ns
Fentanyl requirement (µg/kg)					
Operating room requirement					
Mean ± SD	3.0 ± 1.2	3.0 ± 1.1	3.5 ± 1.0	2.8 ± 1.0	<i>P</i> = ns
PACU requirement					
Mean ± SD	0.5 ± 0.5	0.5 ± 0.5	0.6 ± 0.4	0.4 ± 0.5	<i>P</i> = ns
Total requirement					
Mean ± SD	3.5 ± 1.3	3.4 ± 1.3	3.3 ± 1.2	3.2 ± 1.3	<i>P</i> = ns

* Congenital Nevi removal; † ENT = ear, nose, and throat - tonsillectomy and adenoidectomy, tympanoplasty; ‡ Hernia repair and hydrocelelectomy; § PACU = post anesthesia care unit; || = a pain episode with a Bieri score > 2; ns = not significant.

Table 3. Early Postoperative Outcomes

	Acupoint Group (N = 50)	Droperidol Group (N = 49)	Sham Point Group (N = 43)	Sham P6 Group (N = 45)	P Value*
Nausea, Incidence (n, %)	16 (32%)	23 (47%)	24 (56%)	29 (64%)	$P = 0.012$
Nasuea index** mean \pm SD	0.17 ± 0.26	0.25 ± 0.32	0.42 ± 0.44	0.34 ± 0.4	$P = 0.007$
Vomiting, Incidence (n, %)	6 (12%)	9 (18%)	14 (33%)	14 (31%)	$P = 0.048$
Vomiting, Episodes					
Median (range)	0 (0–1)	0 (0–1)	1 (0–1.7)	1 (0–1.75)	$P = 0.07$
(No. episodes, No. patients)	9/6	9/9	15/14	18/14	
PONV, Incidence (n, %)	21 (42%)	25 (51%)	27 (63%)	32 (72%)	$P = 0.024$
Ondansetron rescue (n, %)					
First	21 (42%)	25 (51%)	27 (63%)	32 (72%)	$P = 0.024$
Second	4 (8%)	5 (10%)	9 (21%)	12 (28%)	$P = 0.048$

* P Value represents chi-square analysis that included of all four groups. Please refer to text for *post hoc* analysis.

Nasuea index**=number of nasuea episodes/PACU time (hr).

Finally, significantly fewer subjects in the acupoint group required intravenous ondansetron as an initial rescue therapy ($P = 0.024$). *Post hoc* analyses demonstrated that the incidence of initial rescue therapy was significantly lower in the acupoint group as compared with the P6 sham group ($P = 0.006$) but not as compared with the other study groups ($P = ns$). Also, significantly fewer subjects in the acupoint group required a second dose of intravenous ondansetron ($P = 0.048$) (table 3). One patient from the sham point group and one patient from the sham P6 group required one dose of droperidol as a third line rescue therapy. The episodes of vomiting per patient (if occurred) did not differ significantly between the four study groups (table 3).

We also examined whether history of PONV had an effect on the incidence of early nausea or vomiting in this current investigation. We found that the incidence of vomiting in the PACU was 35.1% among subjects with a history of PONV as compared with an incidence of 20% among patients who did not have a history of PONV ($P = 0.047$). Also, the incidence of early nausea in the PACU was 61.8% among subjects with a history of PONV as compared with an incidence of 47.1% among patients who did not have a history of PONV ($P = 0.09$). In this investigation, gender was not associated with the incidence of PONV in PACU or 24 h after surgery ($P = ns$).

Fentanyl requirements did not differ between the various study groups (table 2), and there were no significant differences in the time for clear liquid intake in the PACU (49 ± 41 min *vs.* 40 ± 29 min *vs.* 60 ± 52 min *vs.*

57 ± 46 min, $P = ns$). Finally, duration of stay in the PACU did not differ between the four study groups ($P = ns$) (table 2). One patient in the droperidol group experienced an episode of restlessness and complained of blurry vision on arrival to PACU. These symptoms improved with an additional dose of fentanyl, 0.5 μ g/kg, and reassurance by the PACU staff.

Late Postoperative Period

As can be seen from table 4, the incidence of late nausea or vomiting was not significantly different among the four study groups ($P = ns$). Also, the number of episodes of nausea or vomiting per patient (if it occurred) did not differ significantly between the four study groups (table 4). Finally, PONV incidence did not differ between the four groups (table 4).

There were no differences in severity of pain at 24 h postoperatively (table 4). It is important to note that there was no adverse reactions such as puncture site redness or irritation associated with this study.

Discussion

With the conditions of this study, bilateral P6 acupoint injections are as effective as droperidol in controlling early PONV. These findings were confirmed using multivariable logistic regression models that considered various potential confounding variables. Thus, we believe that clinicians should consider adding P6 acupoint injection

Table 4. Late Postoperative Outcomes

	Acupoint Group (N = 50)	Droperidol Group (N = 49)	Sham Point Group (N = 43)	Sham P6 Group (N = 45)	P Value
Nausea, Incidence (n, %)	12 (24%)	18 (37%)	16 (37%)	15 (33%)	$P = ns$
Vomiting, Incidence (n, %)	9 (18%)	9 (19%)	10 (23%)	11 (24%)	$P = ns$
Vomiting, Episodes median (range)	0 (0–0)	0 (0–0)	0 (0–0.25)	0 (0.75)	$P = ns$
PONV†, Incidence (n, %)	16 (32%)	20 (41%)	21 (45%)	18 (40%)	$P = ns$
Pain VAS* ratings, mean \pm SD	4.7 ± 2.6	4.3 ± 2.4	4.8 ± 2.8	3.9 ± 2.6	$P = ns$

* Visual analogue scale; † Postoperative nausea and vomiting. Defined as the combined frequency of first-onset nausea or vomiting.

tions to the arsenal of interventions available for the prevention of PONV in children. We also found that the incidence of vomiting in the PACU was higher among subjects with a history of PONV as compared with patients who did not have a history of PONV. These data are in agreement with previous investigations that have addressed this issue.²¹⁻²³

Our interest in acupuncture is partially triggered by the low cost and the low incidence of adverse effects related to this modality. It should be noted, however, that administration of acupuncture requires special training that may involve significant time and monetary commitments. This may be the reason that even though acupuncture and related techniques were found to be effective for the management of PONV in multiple studies,^{8,9,15} many physicians remain skeptical and are reluctant to incorporate these techniques into their practice.

Based on our experience with residents, we would like to indicate that anesthesiologists who were trained by a certified acupuncturist could successfully perform the particular technique used in this study. Thus, we suggest that P6-related techniques should be incorporated into the curriculum of anesthesia residency programs in the United States.

In our study, there were no complaints of local irritation, pain, or damage of median nerve. P6 acupoint injection can impose minimal risk of median nerve damage because the median nerve lies just inferior to palmar aponeurosis (fig. 1). As P6 acupoint injection does **not** involve penetration of this fascia, however, damage to the median nerve is unlikely with appropriate knowledge of the technique and the involved anatomy (fig. 1). We are not aware of any case reports in the literature that involve P6 acupoint injection and median nerve damage. Three recent reports that included 99,482 treatments and 33,932 acupuncturists and physicians have addressed the issue of adverse effects and acupuncture.²⁴⁻²⁶ These reports indicate that the rate of complication related to acupuncture is remarkably low (0.13-0.14%) and that most complications are transient, lasting 2 weeks at most. The most commonly reported complications include failure to remove the needle, pain, dizziness, nausea and vomiting, bleeding, fever, and contact dermatitis. Of interest is that rates of adverse drug reactions or prescribing errors in primary care have varied from 0.5% to 6% at community pharmacies. Thus, in trained hands, acupuncture is a very safe technique.²⁷

A major problem of acupuncture in children is the unwillingness of children to accept acupuncture interventions while they are awake and conscious. Currently, there is a debate among acupuncturists regarding the level of consciousness that is essential to achieve the desired effects of acupuncture. Several previous studies have demonstrated that P6 needle acupuncture was not effective as a preventive treatment for PONV when administered with general anesthesia.¹¹⁻¹³ In contrast, two

studies involving adult patients showed that P6 acupoint injection given with general anesthesia is effective as a preventive treatment for PONV.^{20,28} The positive findings related to acupoint injection are likely to be related to the fluid deposit at the P6 acupuncture point. This fluid deposit likely creates significant pressure and stimulation effects at the site that persist after the patient has returned to the conscious state. Thus, P6 acupoint injection can be performed with the patient during general anesthesia because it has an effect after the patient is awake and conscious. It is important to note that saline solution²⁸ and glucose solution²⁰ have been used as part of this technique. As the amount of saline solution that is needed (3 ml) is larger than the amount of glucose solution needed (0.2 ml), we have opted to use glucose solution. We suggest that acupoint injection techniques are particularly useful in the treatment of children undergoing surgery.

Many existing clinical studies suffer from methodologic problems such as lack of a true control group (e.g., no sham acupuncture), inability to ensure the patient was blinded, lack of direct comparison with the recommended prophylactic intravenous antiemetic agents, and no standardization of anesthetic techniques.²⁹⁻³¹ Also, previous studies suffer from no standardization of analgesic type and quantity used and from no assessment of nausea as a separate entity from vomiting.^{10-15,29-34} Existing studies involving acupuncture and PONV in children suffer from similar methodologic issues. Our study design considered many of the above factors. We standardized the anesthesia technique and used only intravenous fentanyl as an analgesic agent. In addition, we standardized the rescue treatment for pain and PONV.

We included in this study two placebo-controlled groups, a P6 sham acupuncture and a sham point injection. The first control group involved a superficial needle stick that was demonstrated in the past not to evoke any activity in the central nervous system.³⁴ Thus, it served as a sham control group. The second control group was designed to ensure that an intramuscularly deposition of 0.2 ml of 50% glucose solution does not have any antiemetic effect and that location (P6) of injection is of importance. We did not include a no-treatment or no sham acupuncture group in our study design because of issues related to blinding and potential bias. That is, we wanted to assure the anesthesiologist and surgeon were blinded during the intraoperative period and that the patient, parent, and nursing staff were blinded during the postoperative period. The absence of a needle mark and a bandage would have indicated the group assignment of the patient to the aforementioned persons. Because of similar reasons, we chose to administer sham acupuncture to the droperidol group (group II).

We used a yoking strategy that considers gender, age, and type of surgery of the four study groups. This as-

sured equal distribution of variables that are known to affect the outcome in the four study groups. Most importantly, this technique of yoking randomization assured excellent external validity of the results of this study. That is, one can be assured that the results of this study are applicable to a variety of age groups and surgical procedures. Limiting the study to one surgical procedure may have the advantage of controlling for that variable but has the disadvantage of limiting external validity.

We report that at 24 h postoperatively there were no differences between the droperidol and control groups. It is our opinion that this is not an issue of lack of statistical power but rather an issue of study design and the use of rescue medication. That is, as a rescue therapy, intravenous ondansetron was administered if subjects had two episodes of retching or vomiting in the PACU or nausea with a VAS score greater than 20 in the PACU. Thus, the 24-h assessment was "contaminated" by the use rescue medication in the PACU. We believe that this may account for the lack of difference between groups at 24 h postoperatively.

In conclusion, we have demonstrated that with the conditions of this study, bilateral P6 acupoint injections are as effective as droperidol for the prevention of PONV in children during the PACU stay. Significantly fewer subjects in the acupoint group required intravenous ondansetron as an initial rescue therapy. These findings were confirmed using multivariable logistic regression models that considered various potential confounding variables. Thus, we believe that clinicians should consider adding P6 acupoint injections to the arsenal of interventions available for the management of PONV in children. Further, we propose that residency training programs in anesthesiology should consider the addition of P6 acupoint injections to the present curriculum.

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