

# Electroacupuncture Prophylaxis of Postoperative Nausea and Vomiting following Pediatric Tonsillectomy with or without Adenoidectomy

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**Background:** Electrical stimulation of acupuncture point P6 reduces the incidence of postoperative nausea or vomiting (PONV) in adult patients. However, acupressure, laser stimulation of P6, and acupuncture during anesthesia have not been effective for reducing PONV in the pediatric population. The authors studied the effect of electrical P6 acupuncture in awake pediatric patients who had undergone surgery associated with a high incidence of PONV.

**Methods:** Patients aged 4–18 yr undergoing tonsillectomy with or without adenoidectomy were randomly assigned to acupuncture, sham acupuncture, or control groups. Acupuncture needles at P6 and a neutral point were placed while patients were anesthetized, and low-frequency electrical stimulation was applied to these points for 20 min in the recovery room while the patients were awake (P6 Acu group). This treatment was compared with sham needles along the arm at acupuncture points not associated with antiemesis (sham group) and a no-needle control group. The arms were wrapped to prevent identification of treatment group, and anesthetic, analgesic, and surgical technique were standardized. Assessed outcomes were occurrence of nausea, occurrence and number of episodes of vomiting, time to vomiting, and use of antiemetic rescue medication.

**Results:** One hundred twenty patients were enrolled in the study, 40 per group. There were no differences in age, weight, sex, or opioid administration between groups. The PONV incidence was significantly lower with P6 acupuncture (25 of 40 or 63%; odds ratio, 0.135; number needed to treat, 3.3;  $P < 0.001$ ) compared with controls (37 of 40 or 93%). Sham puncture had no effect on PONV (35 of 40 or 88%;  $P =$  not significant). Occurrence of nausea was significantly less in P6 Acu (24 of 40 or 60%; odds ratio, 0.121;  $P < 0.01$ ), but not in the sham group (34 of 40 or 85%) compared with the control group (37 of 40 or 93%). Vomiting occurred in 25 of 40 or 63% in P6 Acu; 35 of 40 or 88% in the sham group, and 31 in 40 or 78% in the control group ( $P =$  not significant). Patients receiving sham puncture vomited significantly earlier ( $P < 0.02$ ) and needed more rescue treatment (33 of 40 or 83%; odds ratio, 3.48;  $P < 0.02$ ) compared with P6 Acu (23 of 40 or 58%) and the control group (24 of 40 or 60%).

**Conclusions:** Perioperative P6 electroacupuncture in awake patients significantly reduced the occurrence of nausea com-

pared with the sham and control groups, but it did not significantly reduce the incidence or number of episodes of emesis or the use of rescue antiemetics. Sham acupuncture may exacerbate the severity but not the incidence of emesis. The efficacy of P6 acupuncture for PONV prevention is similar to commonly used pharmacotherapies. Its appropriate role in prevention and treatment of PONV requires further study.

POSTOPERATIVE nausea or vomiting (PONV) remains one of the most common and distressing side effect after outpatient surgery, occurring in 40–70% of children after tonsillectomy.<sup>1,2</sup> PONV may be associated with increased bleeding, pain, and prolonged hospital stay. Various antiemetic medications can reduce but not eliminate the problem, and complementary approaches may further improve outcome.<sup>1,3–5</sup> In 1998, the National Institutes of Health reported on the efficacy of acupuncture at P6 in adult postoperative and chemotherapeutic nausea.<sup>6</sup> P6 is the acupuncture point located 2 Chinese inches (cun units) proximal to the distal skin crease of the wrist, in the anterior antebrachial region on the ulnar side of the tendon of the flexor carpi radialis.<sup>7</sup> Stimulation of P6 in adult women undergoing gynecologic surgery has been shown to reduce the incidence of PONV markedly.<sup>8</sup>

There has been an increased use of alternative forms of medicine in all patients, including children, undergoing surgery.<sup>9–11</sup> Acupuncture has been shown to decrease the need for opioids in abdominal surgery<sup>12</sup> and to improve pulmonary function after hysterectomy.<sup>3</sup> Reports of using acupuncture to treat children with PONV have been inconclusive. Schlager *et al.*<sup>4</sup> showed laser stimulation of the P6 point in children undergoing eye muscle surgery to be effective in decreasing the incidence of vomiting, but another investigation was unable to show a decrease in PONV using acupressure and acupuncture with small auricular acupuncture needles at the same acupuncture point in tonsillectomy patients.<sup>5</sup> Similarly, acupressure was not found to be effective in reducing PONV after strabismus surgery.<sup>13</sup> Acupuncture, using needles inserted during general anesthesia, was not effective for preventing PONV after tonsillectomy<sup>14</sup> or strabismus surgery.<sup>15</sup>

In all reports of acupuncture to treat pediatric patients for PONV, the studies have been performed with patients undergoing general anesthesia, or the studies have used techniques such as laser, acupressure, or tiny needles. None of the investigators used needle techniques with electrical stimulation of the needles in the awake patient. This method of treatment has been effective in

This article is featured in "This Month in Anesthesiology."  
Please see this issue of ANESTHESIOLOGY, page 5A.

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Received from the Department of Pediatric Anesthesiology, Medical College of Wisconsin-Children's Hospital of Wisconsin, Milwaukee, Wisconsin. Submitted for publication April 19, 2001. Accepted for publication August 7, 2001. Supported by the Jane B. Pettit Pain Foundation, Children's Hospital of Wisconsin, Milwaukee, Wisconsin.

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adult patients undergoing cancer chemotherapy.<sup>16</sup> Acupuncture needles can easily be placed without pain at the conclusion of a surgical procedure before emergence from anesthesia and then be stimulated with low-frequency electrical stimulation while the patient is awake to accomplish the same treatment for PONV that has been so effective in adults. Therefore, we performed a study of P6 electrical stimulation acupuncture for reduction of PONV in awake children undergoing tonsillectomy, with or without adenoidectomy.

## Materials and Methods

### *Patient Selection and Anesthetic Technique*

The study protocol was approved by Children's Hospital of Wisconsin Research and Publications Committee/Human Rights Review Board (Milwaukee, WI). Patients with American Society of Anesthesiologists physical status I and II, older than 4 and younger than 18 yr of age, undergoing tonsillectomy with or without adenoidectomy were eligible. Exclusion criteria included presence of skin lesions near acupuncture sites, previous and severe PONV, or a chronic history of nausea and vomiting. Patients were enrolled after written informed consent was obtained from their parents. A randomized block design procedure was used to assign enrollees to one of three treatment groups: acupuncture at P6 with electrical stimulation of needles (P6 Acu), sham acupuncture with stimulation (sham group), and a nontreatment control group.

Anesthetic and surgical techniques were standardized. Solid food was held for at least 8 h before surgery, and clear liquids were permitted up until 2 h before surgery for all groups. All patients received oral midazolam (0.5 mg/kg to a maximum of 10 mg) 20 min before induction of anesthesia with halothane or sevoflurane in oxygen (30%) and nitrous oxide (70%) *via* mask. After intravenous cannulation, 0.2 mg/kg mivacurium, 0.1 mg/kg morphine sulfate, and at least 20 ml/kg lactated Ringer's solution were administered. Anesthesia was maintained with oxygen, 70% nitrous oxide, and isoflurane *via* an endotracheal tube. Ventilation was controlled at a peak inspiratory pressure of 25–30 cm H<sub>2</sub>O to maintain an end-tidal carbon dioxide tension of 35–40 mmHg, until spontaneous return of neuromuscular function. Awake tracheal extubation was performed after orogastric suction. Postoperative pain was treated with 0.05 mg/kg morphine, repeated as needed. Lactated Ringer's solution was infused at a maintenance rate until oral clear liquids were accepted without vomiting. Thereafter, oral analgesics were administered as needed every 3 h (acetaminophen with codeine, 1 mg/kg). Surgical techniques were standardized, and dexamethasone was not administered. Details of treatment in three groups follow. All active, sham, and control treatments were performed by the same acupuncturist (LR).



Fig. 1. P6 Acu treatment on the forearm of a patient.

### *P6 Acupuncture (P6 Acu)*

After removal of the second tonsil, standard, disposable acupuncture needles (Serin No. 5, 0.25 × 30 mm, Shizuoka, Japan) were inserted to a distance of approximately 10 mm at a right angle to the skin, to a depth of 1 cm at the P6 point (AKA Master of the Heart 6-MH6). P6 is on the antebrachial region, 2 cun (2 Chinese inches, equivalent to the width of the interphalangeal joint of the thumb of the patient) proximal to the anterior crease of the wrist, on the ulnar side of the tendon flexi carpi radialis. The needle was inserted between this tendon and the tendon of the palmaris longus, if it was present. A second needle was inserted at a neutral point midway up the forearm, on the same meridian but on a different dermatome (T1) (fig. 1). This second needle acted as a skin surface electrode to allow electrical current through P6, the point most commonly used for treatment of PONV<sup>13,14</sup> and chemotherapy-induced nausea and vomiting.<sup>16,17</sup> Needles were bent to lay flat against the skin, and the top end of the needle was taped to the skin. The negative lead (black) of an ITO electroacupuncture unit (LTD IC-1107; ITO-Co., Braintree, MA) was attached to

P6, and the positive (red) lead was attached to the neutral point. The arm was then covered with full-length, soft restraints so the needle positions could not be seen. After placement of needles, the patient was allowed to emerge from anesthesia. Stimulation of the needles at low frequency, 4 Hz, was continued for 20 min as soon as the patient was awake.

#### *Sham Acupuncture with Needle Stimulation (Sham)*

Two needles were inserted high on the arm, on the ventral surface in the same acupuncture meridian at acupuncture point P2 (which is located in the anterior brachial region, 2 cun distal to the end of the anterior axillary fold between the two heads of the biceps brachii muscle) and a neutral point. Both points are outside the dermatome of P6, or C5. These points, on the same meridian but outside the dermatome, do not exert the same anti-nausea effect that P6 exhibits.<sup>18</sup> The arms were covered, and stimulation occurred in the same manner.

#### *No Acupuncture (Control)*

No needles were inserted. Insulated wires were attached to the insides of the arm covers, which were applied to the arms as in the other groups. The stimulator box was activated so its indicator light was on to maintain blinding.

#### *Outcome Assessment*

The primary outcome measures were the incidence of nausea, vomiting, and need for rescue therapy in the first 24 postoperative hours. PONV was defined as the presence of nausea, vomiting, or need for rescue therapy. Outcomes were recorded on a standard form beginning at entry to the recovery room. Experienced recovery room nurses, who were blinded to the treatment group, assessed nausea and vomiting. Vomiting was defined as forceful expulsion of gastric contents from the mouth. Retching was defined as an active attempt to vomit without expulsion of gastric contents. Repeated episodes occurring within 2 min were considered the same episode.<sup>2</sup> Nausea that persisted for 15 min was treated. Rescue treatment for PONV, using ondansetron (0.15 mg/kg up to 4 mg  $\times$  1), was given if two or more episodes of vomiting occurred or if persistent nausea was reported. If PONV persisted,

half this dose was repeated in 2 h, after which droperidol (10  $\mu$ g/kg) was used. Assessment questionnaires with stamped, addressed return envelopes were given to parents when the patients were discharged to record all episodes of vomiting and all complaints of nausea over 24 h. The information on these forms was gathered by phone contact on postoperative day 1 and when the questionnaire was returned. Patients were not sent home with antiemetics.

#### *Data Analysis and Statistics*

Sample size estimation was based on a previous probability of nausea and vomiting of 65% and a reduction to 30% with acupuncture, based on literature in pediatric tonsillectomy patients and on reduction of PONV in adult patients after acupuncture. Using an  $\alpha$  of 5% and a power of 80%, the estimated sample size for binomial proportions was 37 patients per group. To maximize power, equal size groups of 40 patients per group were generated using a randomized block design selection procedure.

Summaries of demographic and outcome data were expressed as mean  $\pm$  SD for continuous variables, or as number and percent. Differences between groups were assessed by one-way analysis of variance and by chi-square tests as appropriate for data type, with Tukey correction for multiple comparisons. Mantel-Haenszel odds ratios for outcomes were computed relative to the control group, with significance assessed using the likelihood-ratio test with and without adjustment for demographic characteristics. Numbers needed to treat (NNT) for each outcome were computed from the inverse of the absolute risk reduction for P6 Acu and sham compared with controls. Differences in time to first episode of vomiting were analyzed using Kaplan-Meier survival analysis and the log-rank test for equality of the survivor functions. The cutoff for statistical significance was set at  $P < 0.05$  for all tests.

## Results

One hundred twenty-two patients were asked to participate, 121 were enrolled after 1 refused, and 1 was disqualified after enrollment when propofol was admin-

**Table 1. Patient Demographics**

	P6 Acupuncture	Sham Puncture	Control
Age (yr)	6.35 $\pm$ 2.06	7.4 $\pm$ 3.20	6.53 $\pm$ 2.49
Weight (kg)	29.95 $\pm$ 16.02	30.2 $\pm$ 15.21	26.5 $\pm$ 12.44
Gender (female)	20 (50%)	23 (58%)	15 (38%)
Surgical time (min)	34.65 $\pm$ 22.95	28.15 $\pm$ 10.61	32.28 $\pm$ 23.18
Perioperative morphine (mg/kg)	0.14 $\pm$ 0.06	0.15 $\pm$ 0.06	0.15 $\pm$ 0.06
Postoperative codeine (mg $\cdot$ kg <sup>-1</sup> $\cdot$ 12 h <sup>-1</sup> )	2.1 $\pm$ 1.4	1.8 $\pm$ 1.4	1.8 $\pm$ 1.4

Demographic characteristics of the patient groups are summarized. No significant differences were found between groups. Data are expressed as mean  $\pm$  SD or number and percent.

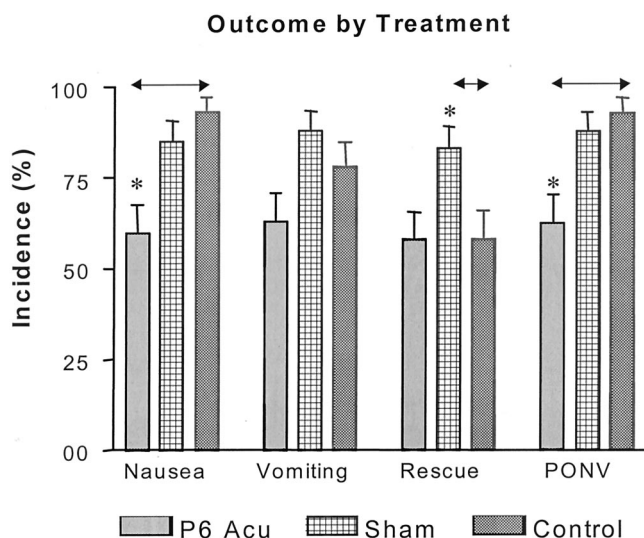


Fig. 2. The incidence of nausea (N), vomiting (V), rescue therapy (R), and any postoperative nausea or vomiting (PONV) outcome (N, V, or R) by treatment group. P6 acupuncture reduced the incidence of nausea and any PONV outcome. Sham puncture was associated with increased rescue therapy. Data shown are the mean and standard error of mean incidence of each outcome. \**P* < 0.05 compared with controls.

istered during the anesthetic, generating 120 patients eligible for analysis, with 40 patients in each group. The groups were similar for age, sex, weight, analgesics administered, and surgical time (table 1), with no differences found.

The incidence of nausea was reduced by P6 acupuncture (24 of 40 or 60%; *P* = 0.0007) but not by sham acupuncture (34 of 40 or 85%; *P* = not significant) compared with controls (37 of 40 or 93%). The incidence of vomiting was not significantly different with P6 acupuncture (25 of 40 or 63%) or sham acupuncture (35 of 40 or 88%) compared with controls (31 of 40 or 78%). The incidence of rescue therapy for nausea and vomiting was not reduced by P6 acupuncture (23 of 40 or 58%) compared with control (24 of 40 or 60%), but was significantly higher with sham acupuncture (33 of 40 or 83%; *P* = 0.0153). The composite PONV incidence was significantly lower with P6 acupuncture (25 of 40 or 63%; NNT, 3.3; *P* = 0.0007) but not with sham acupuncture (35 of 40 or 88%; *P* = not significant) compared

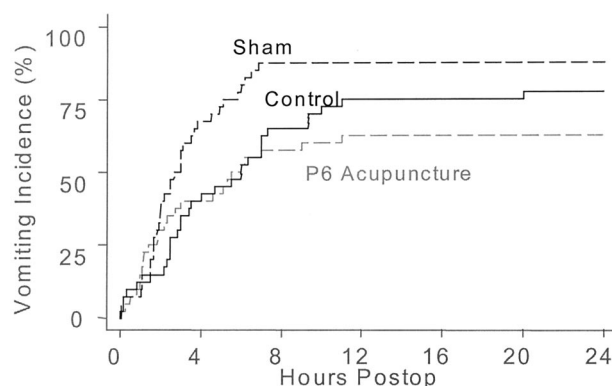


Fig. 3. The occurrence of vomiting over time by treatment group is displayed in survival-curve format. The survival functions are significantly different by the log-rank test, with vomiting occurring earlier and more frequently in the sham puncture group (*P* < 0.02).

with controls (37 of 40 or 93%; fig. 2 and table 2).

Antiemetic efficacy was also assessed by analysis of time to vomiting. The survival function for vomit-free interval was significantly unequal between groups (*P* = 0.0136), with sham acupuncture patients vomiting significantly earlier (fig. 3).

Discussion

This study provides strong evidence that P6 electroacupuncture in awake patients reduces the feeling of nausea but that the effect may not be powerful enough to reduce the incidence of vomiting after tonsillectomy, a powerfully emetogenic procedure. A previous study in adult postoperative patients using acupressure at P6 also reduced nausea but not vomiting.<sup>19</sup> Transcutaneous acupoint stimulation at P6 has been shown to reduce nausea but not vomiting after laparoscopic cholecystectomy in adults.<sup>20</sup> These are similar to our findings in children. Although we suspect that vomiting may occur without nausea as a result of pharyngeal or gastric stimulation, this study does not address this hypothesis.

The overall incidence of nausea and vomiting in these patients was high and was similar to that reported in the surgical and anesthetic literature.<sup>1,2</sup> Dexamethasone has

Table 2. Outcome Measures by Treatment Group

Outcome	Control	P6 Acupuncture		Sham Puncture	
	Incidence	Odds Ratio	NNT	Odds Ratio	NNT
Nausea	93%	0.12 (0.03, 0.52)‡	3.1 (2.0, 6.6)‡	0.46 (0.11, 2.0)	13.3 (4.7, -16.0)
Vomiting	78%	0.48 (0.17, 1.3)	6.7 (2.9, -20.1)	2.03 (0.6, 6.8)	-10.0 (15.3, -3.8)
Rescue	60%	1.0 (0.61, 1.2)	Infinite (4.6, -4.6)	3.48 (1.2, 10.2)*	-4.0 (-17.6, -2.3)*
PONV	93%	0.135 (0.03, 0.58)‡	3.3 (2.1, 7.7)†	0.57 (0.12, 2.59)	20.0 (5.5, -12.3)

Point estimates and 95% confidence intervals of odds ratios and NNT (numbers needed to treat) for outcomes are computed relative to group 3 controls. NNT = number of patients needed to be treated to eliminate undesired outcome in one patient; negative numbers for NNT indicate harmful effects of treatment. PONV = postoperative nausea, vomiting, or rescue therapy administration. \* *P* < 0.05; † *P* < 0.005; ‡ *P* < 0.001.

been shown to have antiemetic effects with an NNT of 3 or 4 patients for PONV.<sup>21-24</sup> Because of confounding antiemetic effects, dexamethasone was not used as a surgical adjunct. The incidences of nausea, vomiting, and rescue antiemetic treatment are often grouped in studies aimed at evaluation PONV<sup>25,26</sup> or at establishing a risk score for the occurrence of PONV,<sup>27</sup> and for this reason, we evaluated each variable independently and as a composite. The composite outcome was thought to be important because a higher incidence in vomiting, which did not in itself reach statistical significance, might have offset the significantly reduced incidence of nausea, or *vice versa*. However, we did not see this effect. The reduction in nausea with P6 acupuncture was robust but was not accompanied by a decrease in incidence of vomiting or need for rescue therapy compared with the control group. Therefore, active P6 acupuncture was effective in reducing PONV.

Postoperative nausea or vomiting remains difficult to treat in the pediatric patient undergoing tonsillectomy, adenoidectomy, or both. Although active acupuncture reduced the incidence of nausea and was effective in preventing PONV in 37% of recipients for an NNT of 3.3, we would not support its use in lieu of prophylactic intravenous antiemetics. White and Watcha<sup>25</sup> recommended routine antiemetic prophylaxis for these high-risk surgical patients with single or combination drug therapy having a treatment effect yielding an NNT of 2.5-4.5. Furst and Rodarte<sup>1</sup> showed that prophylactic ondansetron in this patient population reduced the incidence of vomiting from 62% to 27% for an NNT of 2.9. Welters *et al.*<sup>28</sup> showed that prophylactic antiemetic was effective (NNT of 3.3) in reducing PONV in strabismus surgery. Rose *et al.*<sup>29</sup> showed that 0.15 mg/kg ondansetron, administered before surgical manipulation of the eye muscles, was effective in reducing PONV in strabismus patients and speculated that the duration of hospital stay and costs due to PONV can be decreased with prophylactic use of this drug. Similar estimates of treatment efficacy have been found for ondansetron (NNT of 3)<sup>30</sup> and droperidol (NNT of 4)<sup>31</sup> after strabismus surgery. Therefore, the efficacy of P6 acupuncture was comparable with the most effective pharmacotherapies but was more labor intensive.

Pharmacologic therapies to manage nausea have been directed at the neurotransmitter receptors in the brain regions receptive to emetic stimuli. Ondansetron is a pure 5-hydroxytryptamine type 3 receptor antagonist, and it is this mechanism that is thought to be responsible for its antiemetic effects. Electroacupuncture has been thought to modulate serotonin, dopamine, substance P, and endogenous endorphins in the central nervous system.<sup>17</sup> However, we do not know the neurochemical basis for the effect of electroacupuncture on nausea, but intact peripheral and central nervous system processing seems to be important for the efficacy of acupuncture

because other studies in anesthetized patients<sup>14</sup> have failed to show the positive treatment effect we found with stimulation in awake patients.

Interestingly, the odds of PONV was 4.2 times higher with sham puncture than P6 acupuncture, and sham acupuncture patients vomited significantly earlier than controls or P6 acupuncture patients. The worsened outcome with sham acupuncture raises the possibility that improperly administered acupuncture may be harmful, perhaps by stimulation of other active acupuncture sites or simply by increasing nociceptive input. The potentially harmful effect of improper acupuncture technique and apparent requirements for patient awareness are barriers to the widespread use of acupuncture for primary prophylaxis of PONV, especially in the needle-phobic pediatric patient.

In summary, this study presents evidence that active awake electroacupuncture reduces the incidence of nausea but not vomiting after tonsillectomy in the pediatric patient. Reduction in nausea was significant and robust enough that the overall incidence of PONV was also significantly reduced, with a treatment effect as powerful as that of pharmacologic therapies. Whether this efficacy is additive to effective pharmacotherapy or more useful in the treatment-resistant patient warrants further study.

The authors thank Joseph Kerschner, M.D., Valerie Flanary, M.D., Thomas Kidder, M.D., Steven Conley, M.D., (all from the Department of Otolaryngology, Medical College of Wisconsin, Milwaukee, WI), Charles Harkins, M.D., David Beste, M.D. (both from Pediatric Ear, Nose and Throat Specialists, Milwaukee, WI), and Jill Potter, R.N. (Nursing Department, Children's Hospital of Wisconsin, Milwaukee, WI), for facilitating patient enrollment.

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