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# A Randomized Controlled Trial Comparing the Efficacy of P6 Acupuncture Plus Ondansetron versus Ondansetron or P6 Acupuncture in the Prevention of Nausea and Vomiting after Bupivacaine-Morphine Spinal Anesthesia

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### **Abstract**

Objective: To compare P6 acupuncture plus ondansetron with either ondansetron or P6 acupuncture in the prevention of postoperative nausea and vomiting (PONV) in patients submitted to spinal anesthesia. Methods: A randomized controlled trial was performed with 90 patients undergoing orthopedic surgery under spinal anesthesia with bupivacaine, 15 to 17.5 mg, and morphine, 100 μg. They were assigned to one of the three groups: Group Ondansetron (n = 30), patients were given ondansetron, 8 mg intravenously, before spinal block was performed; Group P6 acupuncture (n = 30), patients were subjected to bilateral electrical stimulation of P6 acupoint for 30 minutes before anesthesia; and Group P6 acupuncture plus ondansetron (n = 30), the exact combination of the groups Ondansetron and P6 acupuncture. Results: In the post anesthesia care unit, the incidence of nausea and vomiting ranged from 13.3% to 26.7% and from 6.7% to 13.3%, respectively, with no significant differences among groups (p > 0.05). Ondansetron group had the highest incidence of nausea (73.3%) (p < 0.001) and vomiting (43.3%) (p < 0.001) at the ward from 0 to 24 hours, followed by P6 acupuncture (33.3% and 26.7%) and P6 acupuncture plus ondansetron groups (16.0% and 0%). Conclusion: Preoperative stimulation of P6 acupoint in combination with ondansetron has higher efficacy than either P6 acupoint stimulation or the administration of

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ondansetron on the prevention of PONV in patients submitted to bupiva-caine-morphine spinal anesthesia.

# **Keywords**

Anesthesia, Nausea, Vomiting, Acupuncture, Ondansetron

### 1. Introduction

Postoperative nausea and vomiting (PONV) is one of the commonest complications after anesthesia. It has been reported that at least one in each four patients suffers from PONV [1] [2]. Then, the prevention and treatment of nausea and vomiting have become important subjects in anesthesiology [3]. Currently, even with new anesthetic techniques, which involve the use of prophylactic agents and the selection of anesthetics with lower emetic potentials, the incidence of PONV has not decreased and is still approximately 20% to 30% [4] [5] [6].

The efficacy of antiemetic drugs is limited and their administration is not free from side effects [7] [8]. No isolated intervention can completely prevent or treat PONV. Several factors may still be associated with a higher incidence of PONV, including patients under the age of 50 years, female sex, abdominal surgery, nitrous oxide administration and longer duration of anesthesia [9] [10].

Acupuncture has been used as a non-pharmacological technique for the prevention of nausea and vomiting in situations such as pregnancy [11] [12], post-chemotherapy [13] [14] and during the postoperative period [15] [16]. Nonetheless, due to the variable quality of the studies and heterogeneity, there has been inconsistency on the efficacy of acupuncture as a prophylactic or treatment therapeutic in all these clinical scenarios [17] [18] [19] [20].

Acupuncture can be used alone or combined with conventional antiemetic drugs. Evidence is inconclusive concerning the use of a combined strategy of P6 (*Neiguan*) acupoint stimulation with antiemetic drugs over pharmacological prophylaxis on the prevention of PONV [21]. The objective of this study was to evaluate the efficacy of the combination of P6 acupoint stimulation plus the administration of ondansetron compared with the administration of either ondansetron or P6 acupoint stimulation in the prevention of PONV in patients undergoing orthopedic surgeries under spinal anesthesia with bupivacaine plus morphine.

### 2. Methods

After the approval by the Research Ethics Committee of the Federal University of Amazonas, UFAM, CAAE 4679.0.000.115-09, this prospective randomized controlled trial was conducted from may 2010 to December 2011 in the *Hospital Universitário Getúlio Vargas* and in the *Fundação Hospital Adriano Jorge*, Manaus, Amazonas, Brazil. The study is in accordance with the CONSORT state-

ment, the Brazilian Standards of Good Clinical Practice and the Declaration of Helsinki. All the participants provided written informed consent before undergoing any procedure.

Ninety patients undergoing elective orthopedic surgery of the lower limbs or hips, aged 18 years or older, of both sexes, physical status 1 or 2 according to the American Society of Anesthesiologists (ASA) and capable of reporting researched symptoms were included. The exclusion criteria were fear of acupuncture needles, impossibility of using the P6 and LI11 (*Quchi*) acupoints, patients using any antiemetic drug for 48 hours previously to the surgical procedure and the need of general anesthesia at any moment after the performance of spinal anesthesia.

The groups were differentiated by the opening of a sealed envelope one hour before the surgical procedure, as follows: Group Ondansetron (n=30), patients were given ondansetron, 8 mg intravenously (IV), 5 minutes before spinal block was performed; Group P6 acupuncture (n=30), patients were subjected to bilateral electrical stimulation (10 Hz) of the P6 acupoint with LI11 as a neutral acupoint for 30 minutes before anesthesia, performed at the post anesthesia care unit; and Group P6 acupuncture plus ondansetron (n=30), the exact combination of the groups Ondansetron and P6 acupuncture. P6 acupoint is located on the anterior surface of the forearm between the tendons of the flexor carpi radialis and the palmaris longus, next to the median nerve, two Chinese inches (one Chinese inch = 1.5 to 2 cm) proximal to the distal wrist crease. LI11 acupoint is located on the lateral end of the elbow crease, in a depression between the end of the crease and the lateral epicondyle of the humerus, on the extensor carpi radialis longus muscle.

At the operating room, patients were monitored with a 3-lead electrocardiogram, noninvasive blood pressure and pulse oximetry. An intravenous line was obtained in the upper limb with a 18 G or 20 G catheter and lactated Ringer's solution was administered at 8 to 10 ml·kg<sup>-1</sup>·h<sup>-1</sup>. Additional boluses of lactated Ringer's solution were administered according to clinical judgment. The patients were sedated with midazolam, 3 to 5 mg IV, and fentanil, 30 to 50 µg IV, and received supplemental oxygen through a nasal catheter at a rate of 2 l·min<sup>-1</sup>. The administration of the spinal anesthesia followed a standard technique: with the patient seated, puncture with a 25 G Quincke needle via median access in the L<sub>3</sub> - L<sub>4</sub> or L<sub>4</sub> - L<sub>5</sub> intervertebral spaces was performed. After the visualization of the cerebrospinal fluid, 15 to 17.5 mg of hyperbaric or isobaric 0.5% bupivacaine plus morphine, 100 µg, were injected with independent syringes. The anesthetic was injected at a rate of 1 ml·10 s<sup>-1</sup>. Immediately after the administration of the drugs, the patients were placed in the supine position and thermal sensitivity and motor blockade levels were evaluated. Values of systolic blood pressure lower than 90 mmHg and values of heart rate lower than 45 beats·min<sup>-1</sup> were treated with administration of ephedrine, 5 mg IV, and atropine, 0.5 mg IV, respectively. Postoperative analgesia was provided with tramadol hydrochloride, 1 mg·kg<sup>-1</sup> IV (maximum dose: 100 mg) and with metamizole, 25 mg·kg<sup>-1</sup> IV

(maximum dose: 2 g). After the surgery, the patients were kept at least 2 hours at the post anesthesia care unit and were transferred to the ward when a score nine or 10 was achieved on the modified Aldrete-Kroulik score.

When patients presented with nausea and/or vomiting, the rescue treatment was ondansetron, 4 mg IV, in all groups.

The outcome evaluated was the incidence of nausea and/or vomiting in the post anesthesia care unit and in the surgical ward within the first 24 hours after surgery. Independent evaluators not aware of the groups being studied were invited to evaluate the patients and the outcome. PONV was considered when any episode of either nausea or vomiting, or both, occurred. The investigators recorded the presence of any other complains or observed side effects.

### **Statistical Analysis**

The sample size was calculated based on a reduction of the incidence of postoperative nausea and vomiting in 50% with the combination of antiemetic drug
and acupuncture, considering the estimated incidence to be 75% [1]. With a test
power of 80% and a significance set at 5%, a minimum of 30 patients per group
were necessary to detect differences between groups. After electronic randomization, three groups of 30 individuals were composed. Allocation concealment
was provided by opaque envelopes numbered from one to 90 and the study followed the numeric order of the envelopes. For the categorical variables, the
Fisher's exact test was performed and was followed by a post hoc pair wise comparison when any difference was detected. For the quantitative variables,
ANOVA was performed and was followed by a Tukey's test when any difference
was detected. The significance level used was 5%.

### 3. Results

The flow diagram of patients included in the study is shown on **Figure 1**. The three groups studied were homogeneous in terms of characteristics of patients and possible risk factors for postoperative nausea and vomiting (**Table 1**).

The incidence of nausea was significant different among groups in the surgical ward, with a significant reduction for P6 acupuncture plus ondansetron group in comparison to Ondansetron group (p < 0.001), and for P6 acupuncture group in comparison to Ondansetron group (p < 0.004) (Table 2).

The incidence of vomiting was significant different among groups in the surgical ward, with a significant reduction for P6 acupuncture plus ondansetron group in comparison to both Ondansetron group (p < 0.001) and P6 acupuncture group (p = 0.004) (Table 2).

No side effects were observed in relation to acupuncture or the use of ondansetron at any time.

## 4. Discussion

The main finds of our study were that the combination of P6 acupuncture with

ondansetron reduced the incidence of nausea at the postoperative period, in comparison with the use of ondansetron, and also reduced the incidence of vomiting at the postoperative period in comparison to both ondansetron and P6 acupuncture. P6 acupuncture alone was no better than ondansetron to reduce the incidence of postoperative vomiting.

P6 acupoint has been used as a strategy to prevent the occurrence of PONV. It was from the observations of the use of the manual pressure in P6 acupoint as prophylaxis against vomiting in early pregnancy at the People's Republic of China that the first clinical studies were started in anesthesiology [22]. The elec-

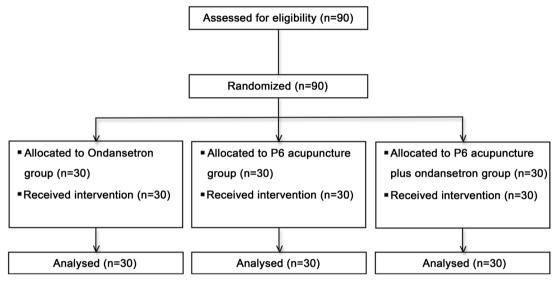


Figure 1. CONSORT flow diagram of patients included in the study.

**Table 1.** Characteristics of patients according to each group and length of surgery. Values are mean  $\pm$  standard deviation or number.

	Groups			
	Ondansetron (n = 30)	P6 acupuncture (n = 30)	P6 acupuncture plus ondansetron (n = 30)	p value
Age; years	39.7 ± 14.8	37.1 ± 12.4	34.8 ± 11.2	0.341
Sex; male/female	23/7	23/7	25/5	0.765
Weight; kg	73.2 ± 11.4	$73.4 \pm 13.4$	$78.3 \pm 19.1$	0.334
Height; cm	$167 \pm 8$	$167 \pm 6$	169 ± 9	0.572
Body mass index; kg⋅m <sup>-2</sup>	$26.3 \pm 3.6$	$26.1 \pm 4.2$	$27.2 \pm 5.2$	0.583
ASA physical status; 1/2	27/3	28/2	27/3	0.871
Systemic hypertension; yes/no	3/27	2/28	3/27	0.871
Diabetes Mellitus; yes/no	1/29	1/29	0/30	0.599
Tobacco use; yes/no	8/22	6/24	7/23	0.829
Motion sickness; yes/no	3/27	3/27	1/29	0.538
Length of surgery; min	102 ± 48	101 ± 49	96 ± 58	0.881

**Table 2.** Number (percentage) of patients presenting nausea or vomiting in the post anesthesia care unit (PACU) and at the surgical ward, according to their distribution in the groups.

	Groups			
	Ondansetron (n = 30)	P6 acupuncture (n = 30)	P6 acupuncture plus ondansetron (n = 30)	p value
Nausea				
PACU	7 (23.3)	8 (26.7)	4 (13.3)	0.519
Surgical ward (0 to 24 hours)	22 (73.3)	10 (33.3) <sup>a</sup>	5 (16.0) <sup>b</sup>	< 0.001
Vomiting				
PACU	2 (6.7)	2 (6.7)	4 (13.3)	0.724
Surgical ward (0 to 24 hours)	13 (43.3)	8 (26.7)	$0^{c,d}$	< 0.001

 $<sup>^{</sup>a}p = 0.004$  vs. Ondansetron;  $^{b}p < 0.001$  vs. Ondansetron;  $^{c}p = 0.004$  vs. P6 acupuncture;  $^{d}p < 0.001$  vs. Ondansetron.

trical stimulation of P6 acupoint is also suggested to be more practical than manual needling, even though the efficacy on the reduction of PONV may not be different [23]. Another aspect of interest is the period and time of electrical stimulation. A more prolonged stimulation seems to be more effective than a short period or just preoperative stimulation [24]. Thinking of a more feasible procedure and patients' comfort, we decided to do just a 30-minute preoperative electrical stimulation of P6.

The use of opioids during the perioperative period is strongly associated with an increased incidence of postoperative nausea and vomiting. In patients undergoing ambulatory surgery, it was found a dose-dependent incidence of PONV in the post anesthesia care unit with fentanil systemically administered [25]. Intrathecal use o morphine results in increased incidence of PONV [26] and prophylaxis is highly recommended [27].

Acupuncture has become one of the commonest sought therapies among those considered as unconventional, alternative or unorthodox, for different medical conditions [28]. Nonetheless, its theoretical background based on the metaphysical concepts of energy from the traditional Chinese medicine may not be clear and not associated with the basis of the scientific disciplines, such as biochemistry, physiology and pharmacology and, for this reason, disapproved by the scientific community [29]. Despite its metaphysics background, there are several hypotheses concerning its physiological effects for some clinical conditions, including local intramuscular effect, nerve stimulation, autonomic system stimulation and increased secretion of endorphin [29] [30] [31].

Results concerning any kind of stimulation of P6 acupoint for the treatment of postoperative nausea and vomiting after general anesthesia are conflicting, sometimes indicating a reduction in the incidence of postoperative nausea, sometimes in the incidence of postoperative vomiting and sometimes not showing any clear advantage over a pharmacological therapy. After awaking, patients

submitted to appendectomy under general anesthesia had a wristband positioned around P6 acupoint, and pressure was applied for seven hours after surgery. Control group had a sham wristband with no pressure applied on P6 acupoint. The incidence of nausea was no different between the groups but P6 acupoint pressure reduced the incidence of vomiting [32].

In gynecological patients undergoing laparoscopic surgery, considered a high-risk group of patients for PONV, the combination of electrical stimulation of P6 and the use of dexamethasone reduced the incidence of nausea during 24 hours after surgery when compared to the use of dexamethasone alone. These results were comparable to those obtained with the prophylaxis with the use of tropisetron in combination with dexamethasone, when compared to the use of dexamethasone alone. The incidence of vomiting in the first 24 hours were 18%, 15% and 24% for the combination of electrical stimulation of P6 acupoint and dexamethasone, tropisetron plus dexamethasone and dexamethasone alone, respectively, with no significant differences among groups [33].

In women undergoing gynecological or abdominal laparoscopy under sevof-lurane-fentanil anesthesia, neuromuscular blockade was monitored by a conventional nerve stimulator over the ulnar nerve, used as control group, or over the median nerve, corresponding to P6 acupoint. The incidence of nausea decreased significantly from 56% in the control group to 40% in the P6 group during the first 6 hours postoperatively but emesis was not significantly reduced in this period, from 25% to 16%. During the 24-hour analysis, overall incidence of nausea was significantly reduced from 56% to 40% by the P6 group but the incidence of emesis was not statistically different, 28% to 23%, in control and P6 groups, respectively [34].

In children undergoing tonsillectomy/adenoidectomy, blinded P6 acupoint electrical stimulation was compared to sham acupuncture (electrical stimulation of acupuncture needles in different sites other than P6) or control group (no acupuncture). Acupuncture needles were placed while patients were anesthetized, and low-frequency electrical stimulation was applied to these points for 20 minutes in the recovery room. PONV was evaluated for 24 hours. The incidence of nausea was reduced by P6 acupuncture (60%) but not by sham acupuncture (85%) compared with controls (93%). The incidence of vomiting was not significantly different with P6 acupuncture (63%) or sham acupuncture (88%) compared with controls (78%) [35].

Literature also shows conflicting results when prevention of PONV with acupuncture is studied in patients undergoing spinal anesthesia. Parturients receiving epidural morphine for post cesarean section pain relief were allocated to receive the acupressure bands or placebo bands on the P6 acupoint bilaterally before the administration of spinal anesthesia and were observed over a 48-hour period. The incidence of nausea and vomiting was significantly decreased from 43% and 27% in the control group to 3% and 0% in the acupressure group, respectively [36]. Nonetheless, in elective cesarean section under spinal anesthesia,

preoperative electrical stimulation of P6 reduced the incidence of nausea and vomiting during the first 6 hours after surgery in comparison to non-treated patients but had equivalent efficacy with 4 mg of ondansetron administered 30 minutes before anesthesia [37]. In another study with patients undergoing cesarean section under spinal anesthesia, transcutaneous preoperative P6 acupoint electrical stimulation was compared with dorsum of the wrist stimulation (sham group). The incidence of postoperative nausea was 23% and 41% and the incidence of vomiting was 26% and 37% for P6 electrical stimulation and sham groups, respectively, with no statistical difference detected [38].

Even though the majority of the studies on the prevention of PONV with acupuncture use the P6 acupoint, other acupoints have been studied showing a decrease in the incidence of PONV when compared to placebo or sham acupuncture [39] [40].

Our study has some limitations. The patients were not blinded to the treatments and due to ethical issues our study was not placebo-controlled. Nonetheless, the outcome evaluators were unaware of the groups studied.

### 5. Conclusion

We concluded that preoperative electrical stimulation of P6 acupoint in combination with intravenous administration of ondansetron has a higher efficacy than either the administration of ondansetron or P6 acupoint electrical stimulation on the prevention of the occurrence of PONV in patients submitted to bupivacaine-morphine spinal anesthesia. Despite the lack of a complete understanding of the effects and mechanism of action of acupuncture, considering the results of this study, we recommend that acupuncture be an option as an adjunct therapy to ondansetron on the prevention of PONV, a very unpleasant complication related to the surgical/anesthetic intervention.

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