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ORIGINAL ARTICLE

Effect of acupuncture on nausea and/or vomiting during and after cesarean section in comparison with ondansetron

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Abstract
Purpose Acupuncture has been used for the management of postoperative nausea and vomiting (PONV). This study compared the effect of electrical acustimulation with ondansetron for preventing intraoperative and postoperative emetic symptoms and improving patient satisfaction.
Methods After gaining ethical approval, 450 parturients scheduled for elective cesarean delivery were randomly allocated to receive either electrical stimulation using P6 acupoint (pericardium 6) bilaterally for 30 min before spinal anesthesia (group III; $n = 150$), or 4 mg ondansetron 30 min before spinal anesthesia (group II; $n = 150$), or placebo (group II; $n = 150$). Nausea and vomiting were evaluated and recorded intraoperatively and postoperative for 24 h by an independent anesthetist.
Results The three groups were not significantly different with respect to intraoperative ephedrine dose and duration of surgery. Nausea and vomiting occurred statistically significantly less often in the active treatment groups (II, III) during operation and for 6 h postoperatively. There was no statistically significant difference between the groups in the incidence of nausea and vomiting from 6 to 24 h postoperatively. Patient satisfaction with PONV control was higher with the active treatment groups compared with group I.
Conclusion Electrical acustimulation is comparable to ondansetron in prevention of PONV during and after cesarean delivery under spinal anesthesia and in improving patient satisfaction.

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Introduction

Among the most common complications of either general anesthesia (GA) or neuroaxial anesthesia are postoperative nausea and vomiting (PONV). This complication delays recovery from anesthesia [1, 2]. So far, no therapy has been completely effective to eliminate PONV [3].

The limited efficacy of the available antiemetic medicines and their side effects generated an interest in new, effective techniques for the management of PONV. Acupuncture and related therapies are steadily increasing in use nowadays in different medical practices, especially as the number of patients favoring these alternative therapies increases. One of the commonly investigated uses of acupuncture is the management of PONV [4].

According to Chinese tradition, the practice of acupuncture is based on philosophy of balance and unity between the universe, living beings, and energy flow. The main idea of acupuncture is the recovery of a harmonized, balanced state of the body [5]. There are various techniques for acupoint stimulation in the treatment of PONV; e.g., manual, electrical, laser, and transcutaneous electrical stimulation [6–9]. Although the optimal method of stimulation has not been determined, the noninvasive methods are preferred because such are easier, painless, and better tolerated. On the other hand, these methods are less effective [10].

The evidence base for acupuncture at the traditional Chinese P6 point for the prevention of PONV has been reviewed on the *Cochrane Database of Systematic Reviews*, showing its effectiveness in the prevention of PONV [11].

Because many trials were done for the efficacy of acupuncture for prevention of nausea rather than vomiting, the occasional drawbacks of some antiemetic drugs such as extrapyramidal manifestation with metoclopromide, and for economic reasons, this study was designed to compare electrical stimulation of P6 and intravenous (IV) ondansetron for the prevention of nausea and vomiting during and after elective cesarean section under spinal anesthesia.

Patient and methods

This prospective double-blinded study was conducted on 450 parturients, American Society of Anesthesiologists (ASA) physical status 1 and II, subjects for elective cesarean section (CS) using spinal anesthesia. Patients were 25–35 years of age. An informed consent was signed by all parturients after being admitted to the obstetric department in the main Mansoura University Hospital. The protocol of this study was approved by the ethical and scientific committee of our department. Exclusion criteria from this study included acupuncture treatment during the previous 6 months, nausea or vomiting during 24 h preoperatively, diabetes, hypertension, cardiovascular disease, and any other serious systemic disease.

The included parturients were randomly enrolled (by sealed envelope) in three equal groups (150 parturients each) according to the antiemetic therapy used: the control group (I), the ondansetron group (II), and the electro-acupuncture group (III).

All parturients received 1,000 ml lactated Ringer's solution IV over 30 min before spinal injection. After IV fluid administration, patients of the ondansetron group (II) received 4 mg ondansetron IV 30 min before spinal anesthesia, and sham (false) points bilaterally were electrically stimulated by needle. Patients of the acupuncture group (III) were electrically stimulated by needle using the P6 acupoint (pericardium 6) bilaterally for 30 min before spinal anesthesia; 2 ml normal saline was injected intravenously. Those patients included in the control group (I) received 2 ml normal saline intravenously, and sham points were stimulated bilaterally.

Standard, disposable acupuncture needles (Tai Chic 0.25 × 30 mm; China) were used. The first needle was at the P6 point (Fig. 1), which is an acupoint located on the pericardial meridian, which is 2 cuns (a cun is equivalent to the width of the interphalangeal joint of the patient's middle finger) proximal to the proximal flexor palmar crease, about 1 cm deep, between the tendons of flexor carpi radialis and palmaris longus. A point on the dorsal side of the forearm, four fingerbreadths proximal to the proximal flexor palmar crease, was used as a sham point for

Fig. 1 *Neiguan*, the P6 point, is located 2 cun or approximately 5 cm above the transverse crease of the wrist between the tendons of m. palmaris longus and m. flexor carpi radialis [5]

Fig. 2 The KWD-808 electro-stimulator equipped with built-in timer can produce five different waveforms

placebo stimulation. A second needle, inserted at the most medial point at the antecubital crease, acted as an earthing to allow electrical current through P6.

Acupuncture needles at P6 and the sham point were placed, and low-frequency electrical stimulation was applied by KWD-8081 serial impulse electrotherapy (Fig. 2 to these points for 30 min at the lowest comfortable efficient frequency felt by the patient. The device automatically shuts off at the end of each 30-min treatment interval. Different frequencies at the acupuncture points were used to avoid tolerance. Also, strong electrical stimulation was avoided as it elicits insufferable pain through excitation of C fibers [12].

After placement of standard monitors, spinal anesthesia with 0.5% hyperbaric bupivacaine (12–14 mg) was administered. After induction of spinal anesthesia, the parturient was placed supine with left uterine displacement and head up with a slight Trendelenberg tilt of the table to achieve adequate surgical block (T4 sensory level), which was confirmed by analgesia to pinprick with a fine dental needle. Supplementary oxygen was administered. Ringer's lactate was administered by IV infusion (4 ml/kg) for replacement of any fluid deficit or blood loss more than 1,000 ml.

Maternal hypotension after spinal anesthesia was treated aggressively with additional IV fluid, more uterine tilt, and increments of IV ephedrine (4–8 mg). Hypotension was defined as a decrease in systolic blood pressure greater than 20% from baseline or pressure less than 90 mmHg. After delivery of the baby, routine use of 10 U IV oxytocin was given to all parturients to enhance uterine contractions. In addition, patients who complained of shivering were given meperidine in 5-mg increments, which was repeated every 5 min if shivering persist.

Nausea and vomiting were evaluated and recorded every 10 min intraoperatively and at 2, 4, 6, 12, and 24 h postoperatively by an independent anesthetist who was blinded to group assignment. Nausea was assessed using visual analogue score (VAS: 0, no nausea; 10, worst imaginable nausea). An antiemetic "rescue" drug (4 mg ondansetron IV) was administered for severe nausea (nausea VAS 4 or worse) or vomiting within the study period.

Data were also collected regarding time to first emetic event, the duration of surgery, amount of ephedrine consumed, and complications (residual redness on the acupuncture site, drowsiness, blurred vision, allergic reactions, fever). Patient satisfaction was evaluated and recorded based upon the whole patient experience during the study period (satisfied or not).

Statistical analysis

Sample size was determined by using Epicalc program 2000 at power 80% and confidence interval 95%. This determination based on the following assumptions: (a) more than 50% of the patients not receiving a prophylactic antiemetic would experience PONV, and prophylactic electric acupuncture may show a reduction of PONV by 25% [13]; (b) prophylactic ondansetron may show a reduction of PONV by 35% [14]. The sample size was 137 for each group. Extra numbers of patients were included to avoid defaulters, so each group comprised 150 subjects. Statistical analysis of the data was done using the Excel program and the SPSS program Statistical Package for Social Sciences, version 10 (SPSS, Chicago, IL, USA).

Normality of data distribution was analyzed by the Kolmogorov–Smirnov (K-S) test. Normally distributed data were subjected to parametric tests.

Data are presented as mean (±) SD for quantitative data. The data were tested for statistical significant difference between groups by one-way analysis of variance (ANOVA) followed by post hoc LSD (least significant difference) test for intergroup comparisons. For quantitative data, Student's t test was used to compare between two groups; the chi square test was used for qualitative data. P was significant at <0.05 at the 95% confidence interval.

Results

The three groups were not significantly different with respect to demographic characteristics, intraoperative ephedrine dose, gestational age, and duration of surgery (Table 1).

Table 1 Patients characteristics, duration of surgery, and ephedrine dose

	I	II	III
Age (years)	25.9 ± 4.6	26.4 ± 3.1	25.5 ± 3.7
Weight (kg)	75 ± 4.3	77 ± 5.1	75 ± 5.1
Height (cm)	168.1 ± 5.4	166.4 ± 3.4	168.4 ± 2.5
Gestational age (weeks)	38.9 ± 1.6	38.6 ± 1.7	38.8 ± 1.9
Surgery duration (min)	70.1 ± 4.8	69.3 ± 3.2	71.3 ± 3.2
Ephedrine dose (mg)	22 ± 3.4	21 ± 5.2	22 ± 4.3

Data are presented as mean ± standard deviation

I control group, *II* ondansetron group, *III* electro-acupuncture group

$P < 0.05$ is significant; this table shows no significant differences

Table 2 Incidence of nausea and vomiting

Variable	Group I, *n* (%)	Group II, *n* (%)	Group III, *n* (%)	*P* value
Intraoperative nausea (0)	69 (46)	33 (22)*	36 (24)*	0.001
Nausea (0–6 h postoperative)	51 (34)	12 (8)*	13 (9)*	0.003
Nausea (6–24 h postoperative)	13 (95)	9 (6)	12 (8)	0.34
Intraoperative vomiting (0)	57 (38)	25 (17)*	24 (16)*	0.001
Vomiting (0–6 h postoperative)	42 (28)	9 (6)*	11 (7)*	0.003
Vomiting (6–24 h postoperative)	11 (7)	8 (5)	9 (6)	0.45

Values are presented as number of patients and percentage of study group

* Significant when compared to group I

$P < 0.05$ is significant

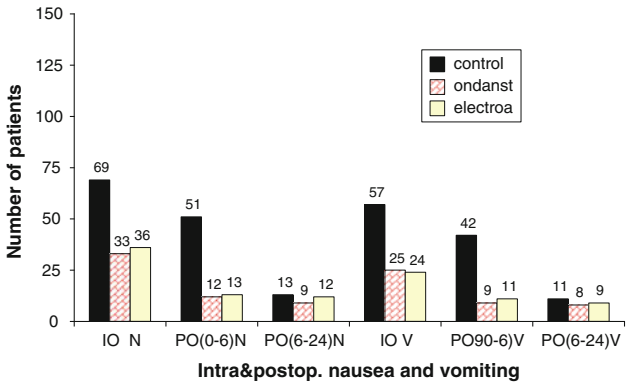

Fig. 3 Incidence of intraoperative and postoperative nausea and vomiting. *ION* intraoperative nausea, *PO(0–6)N* postoperative nausea up to 6 h, *PO(6–24)N* postoperative nausea from 6 to 24 h after operation, *IOV* intraoperative vomiting, *PO(0–6)V* postoperative vomiting up to 6 h after operation, *PO(6–24)V* postoperative vomiting from 6 to 24 h after operation

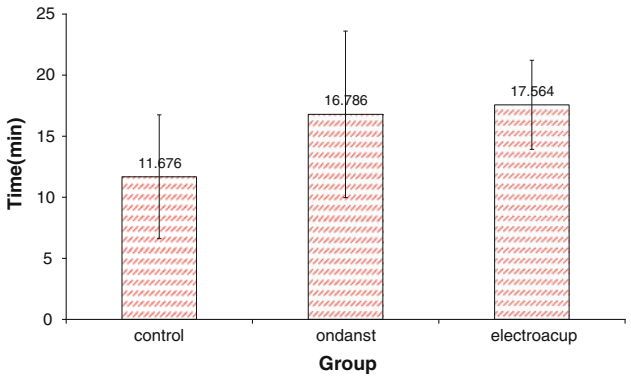

Fig. 4 Time to first emetic symptom. *odanst* ondansetron, *electroacup* electro-acupuncture

Table 3 Patient satisfaction and antiemetic rescue number (%)

	I	II	III	*P* value
Patient satisfied	14 (9)	106 (71)*	103 (69)*	0.001
Intraoperative antiemetic rescue	78 (52)	31 (20)*	29 (19)*	0.002
Antiemetic rescue (0–6 h postoperative)	51 (34)	12 (8)*	13 (8)*	0.003
Antiemetic rescue (6–24 h postoperative)	14 (9)	12 (8)	11 (7)	0.38

Values are presented as number of patients, *n* (percentage of study group in parentheses)

* Significant when compared to group I

$P < 0.05$ is significant

Nausea and vomiting occurred statistically significantly less often in the active treatment groups (II, III) during the operation and for 6 h postoperatively. There was no statistically significant difference between the groups in incidence of nausea and vomiting from 6 to 24 h postoperatively (Table 2; Fig. 3). Also, there was no statistically significant difference between group II and group III in incidence of nausea and vomiting intraoperatively and postoperatively during the study period. Antiemetic rescue was comparable in the active treatment groups (II, III) during the operation and postoperatively (Table 3).

Patient satisfaction with PONV control was higher in the active treatment groups compared with group I. Also, patients in the active treatment groups felt emesis later than those in the placebo group (Fig. 4). No local (cutaneous) side effects were reported at the acustimulation site by any patient in the treatment groups during the 24-h study period. No complications, apart from emesis, were noted.

Discussion

The clinical benefits of routine antiemetic prophylaxis for high-risk surgical patients were not limited to cost savings for treatment of emetic episodes but also included improved patient satisfaction compared with simply treating established symptoms [15]. Despite positive results obtained from studies of the effect of reducing nausea and vomiting by modern antiemetic drugs, the need for additional relief has led to an interest in nonpharmacological treatments [16].

This study compared the effect of electrical acustimulation with ondansetron for preventing intra- and postoperative emetic symptoms and improving patient satisfaction. The current study confirms that the primary benefit of electro-acustimulation was reducing nausea and improving patient satisfaction during the postoperative period.

In this study, there was a trend toward less nausea in the active groups. Although the incidence of intraoperative and early postoperative nausea or vomiting was less frequent in patients receiving electrical acustimulation at the P6 point, there was no statistically significant difference in the incidence of late postoperative nausea or vomiting compared with placebo.

The most probable mechanism of action of acustimulation is attributed to the release of endogenous opioids and modulation of other neurotransmitters in the body [17]. Acupuncture stimulates type I and type II afferent nerves, which subsequently stimulate the spinal cord. These signals innervate the midbrain, the periaqueductal gray matter, and the raphe nucleus. The signals are shown to influence the chemoreceptor trigger zone (CTZ) and subsequently innervate the nausea centers [5]. Another mechanism was proposed by Zou et al. [18], who assumed that P6 works through a somatovisceral reflex. Electro-stimulation at P6 has inhibited the rate of transient lower esophageal

sphincter relaxations triggered by gastric distension in healthy volunteers.

Because the occurrence of nausea and vomiting after spinal anesthesia for cesarean delivery is mainly intraoperative [19], the timing of acupoint stimulation is important. Acupuncture should be performed before emetic stimulation by anesthesia and surgery [20]. Preoperative electrical acustimulation of P6 does not interfere with operative maneuvers or postoperative rest and does not cause complications. Functional magnetic resonance imaging has demonstrated that an acupoint stimulated for 20 min produced identifiable effects in the human brain [21]. In our study, all parturients received electrical acustimulation at least 30 min before induction of spinal anesthesia. We believe that times of onset and peak effect of acupressure were compatible with the occurrence of emesis in our clinical setting. We believe that the only difference between groups I and III was whether they received electrical acustimulation as prophylaxis.

In contrast to our results, Ho et al. [22] found that P6 acupressure did not prevent nausea and vomiting intraoperatively with cesarean delivery under spinal anesthesia. Ho et al. used elastic wristbands that have a button on the inner surface which exerts constant pressure on the P6 acupoint. This button was blunted in the placebo group; however, the weight of the bands may be a conflicting factor. This method differs from our study as we provided needling of the P6 acupoint and electrical stimulation of that point in the acupuncture group. It is possible that different techniques of P6 acupoint stimulation show different efficacy [17]. Further studies are needed to compare noninvasive acupressure with invasive electrical acustimulation.

Stein et al. [23] compared the antiemetic effect of acupressure bands with metoclopramide before spinal anesthesia for cesarean section. Harmon et al. [24] investigated the efficacy of acupressure at the P6 point in the prevention of nausea and vomiting during and after cesarean section compared with placebo. Both studies found that P6 acupressure was effective for prevention of nausea and vomiting.

Our study suggests that the use of acupoint stimulation is as effective as administering a single dose of ondansetron 4 mg, with a similar side effects profile. It is also cost effective compared with ondansetron. Four acupuncture needles cost 2 Egyptian bounds whereas ondansetron costs 26 Egyptian bounds per 4 mg ampule. 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. However, ondansetron may be associated with side effects that include headache, fever, dizziness, abdominal cramps, and transient elevation in plasma aminotransferase and bilirubin levels [1]. Anaphylactic or anaphylactoid reactions have been reported after the administration of ondansetron given with chemotherapy [25].

Our results are in agreement with a study that showed similar efficacy between electro-acupoint stimulation and ondansetron when used as prophylaxis for patients undergoing major breast surgery [14]. Also, Dundee et al. [20] reported a 50% reduction of PONV by invasive acupuncture at the P6 point.

The parturients in the control group (I) had an incidence of PONV of 34% immediately postoperatively and 28% at 6 h after the surgery; this was reduced to 9% and 7%, respectively, by prophylaxis with acustimulation and to 8% and 6%, respectively, by ondansetron (see Table 2). The time to first emetic symptom was significantly reduced by ondansetron and acustimulation (see Fig. 2). All these changes were statistically significant and suggest a comparable efficacy of both methods. When the incidence of PONV was compared at 24 h after surgery, none of the groups showed any significant change (see Table 2).

In conclusion, prevention of PONV by electrical acustimulation is a cheap, simple technique and is comparable to ondansetron during and after cesarean delivery under spinal anesthesia.

Further studies are needed to define the efficacy and safety of electrical acustimulation plus ondansetron as prophylaxis for nausea and/or vomiting during and after cesarean delivery.

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