Transcutaneous Acupoint Electrical Stimulation with the ReliefBand® for the Prevention of Nausea and Vomiting During and After Cesarean Delivery Under Spinal Anesthesia

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We randomized 94 patients undergoing cesarean delivery with spinal anesthesia to receive transcutaneous acupoint electrical stimulation using the ReliefBand® at the P6 point (active group) or an active ReliefBand® applied to the dorsum of the wrist (sham control group). The ReliefBand® was applied 30–60 min preoperatively and left in place for 24 h. There was no statistically significant difference between the active and sham control groups in the incidence of intraoperative/postoperative nausea (30% versus 43%/23% versus 41%), vomiting (13% versus 9%/26 versus 37%), need for rescue antiemetics (23% versus 18%/34% versus 39%), or complete response (55% versus 57%/51% versus 34%). There was also no difference between the two groups in nausea scores, number of vomiting episodes, or patient satisfaction with postoperative nausea and vomiting management.

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Intraoperative and postoperative nausea and vomiting (PONV) have been reported in up to 80% (1) and 67% (2), respectively, of women undergoing cesarean section delivery (CS) under regional anesthesia. Transcutaneous acupoint electrical stimulation (TAES) at the Neiguan (P6) acupuncture point proved effective for PONV prophylaxis after outpatient gynecologic laparoscopy (3), plastic surgery (4), and breast surgery (5) under general anesthesia. The use of TAES during and after CS has not been previously reported. This study was designed to test the hypothesis that TAES at the P6 point is effective in reducing intraoperative nausea and vomiting and PONV in patients undergoing CS using spinal anesthesia (SA) compared with sham control stimulation.

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Methods

After IRB approval, and written informed patient consent, 94 women scheduled for elective CS using SA were randomly allocated to receive an active ReliefBand® at the P6 point (active group), or the dorsum of the wrist (sham control group) of the dominant hand.

Patients who had previous experience of acupuncture or acustimulation, had experienced vomiting or retching within 24 h before surgery, had taken an antiemetic or a glucocorticoid within 24 h before surgery, or had an implanted pacemaker or defibrillator device were excluded from the study.

Before application of the ReliefBand®, a baseline verbal rating scale (VRS) for nausea was obtained, ranging from 0 (no nausea) to 10 (worst imaginable nausea). Thirty to 60 min before surgery, the ReliefBand® was applied using an adjustable strap by a nurse trained in the proper positioning of the ReliefBand®. The stimulation was applied at the lowest comfortable level felt by the patient. For blinding, the ReliefBand® was covered with opaque gauze that was taped to the wrist. All patients were requested to wear the ReliefBand® for 24 h after surgery.

The anesthetic technique was standardized. SA was performed in the sitting position using 1.4–1.6 mL of spinal bupivacaine 0.75% plus dextrose 8.25% with 20 μg fentanyl and 200 μg preservative-free morphine. Oxygen was administered by facemask. Any decrease

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Table 1. Patients' Demographics, Risk Factors for PONV, Intraoperative Data, Postoperative Analgesia, Treatment for Pruritus, and Data on the Use of the ReliefBand®

	Active ReliefBand® (n = 47)	Sham Control ReliefBand® (n = 44)
Age (yr)	30 ± 6	30 ± 6
Weight (kg)	90 ± 19	90 ± 20
Height (cm)	165 ± 8	164 ± 6
A/AA/H/W	1/16/2/28	1/17/1/25
Parity	1.5 ± 1.2	1.7 ± 1.2
History of PONV	17 (36%)	17 (39%)
History of motion sickness	11 (23%)	8 (18%)
Nonsmoker	40 (85%)	38 (87%)
Risk for PONV according to Apfel's simplified risk score (40/60/80%) (18)	6/22/19	5/21/18
Baseline nausea score	0 (0–5)	0 (0–4)
CS duration (min)	65 ± 28	68 ± 24
Estimated blood loss (mL)	780 ± 347	763 ± 265
Fluids (LR) given intraoperatively (mL)	2716 ± 740	2453 ± 565
Need for ephedrine	25 (53%)	25 (57%)
Dose of ephedrine (mg)	26 ± 18	27 ± 15
Need for IV fentanyl	6 (13%)	7 (16%)
Dose of IV fentanyl (μg)	40 ± 23	77 ± 82
Treatment for pruritus	28 (60%)	23 (52%)
Oxycodone/Acetaminophen tablets/24 h	4.3 ± 2.9	3.8 ± 2.7
ReliefBand® maintained for the 24-h duration of the study	41 (87%)	38 (86%)
Stimulation felt at all times	30 (64%)	25 (57%)
Stimulation level used on the ReliefBand® 1/2/3	11/21/15	5/21/18

A = Asian; AA = African-American; H = Hispanic; W = White; PONV = postoperative nausea and vomiting; CS = cesarean delivery; LR = lactated Ringer's solution. Data are n (%), mean ± SD, or median (range).

in systolic blood pressure >20% from baseline or to <100 mm Hg was treated with IV ephedrine. The incidence of nausea and vomiting was recorded and severity of nausea was assessed using a VRS (0–10) before skin incision, after exteriorization of the uterus, and after repositioning of the uterus into the peritoneal cavity. Any episodes of nausea or vomiting occurring at other times were recorded on a similar scale. Ondansetron 4 mg IV was given if the nausea score was ≥6 or at the patient's request. Intraoperative pain was treated with IV fentanyl. Postoperative analgesia was provided using naproxen 500 mg every 12 h and oxycodone 5 mg/acetaminophen 325 mg tablets as needed. PONV was treated with IV ondansetron 4 mg.

A separate researcher who was unaware of the patient's randomization collected the data in the postanesthesia care unit (time 0) and at 6 and 24 h postoperatively. Nausea, pain, and pruritus were assessed using a VRS (0–10) to indicate the patient's worst score since the last assessment. Data were also collected regarding the number of vomiting episodes and the need for rescue treatment for PONV, pain, and pruritus. At 24 h, women were asked to rate their satisfaction with PONV control and with the ReliefBand® using a 100-mm visual analog scale.

Previous studies demonstrated an incidence of PONV of 67% in this population (2). A sample size of 43 patients per group was determined to be adequate to demonstrate a 30% absolute reduction in the incidence of PONV with $\alpha = 0.05$ and $\beta = 0.8$. Descriptive statistics were used to summarize the demographic characteristics of patients. Fisher's exact test and χ^2 procedures for categorical data, and Wilcoxon's ranked sum test and the Kruskal-Wallis test for continuous variables were performed for comparisons among the groups. $P < 0.05$ was accepted as statistically significant.

Results

Three patients were excluded for protocol violations. The two groups were similar with respect to demographics, parity, history of PONV or motion sickness, smoking status, duration of surgery, blood loss, intraoperative fluids, intraoperative IV fentanyl, intraoperative IV ephedrine, treatment for pruritus, and consumption of oxycodone/acetaminophen tablets (Table 1).

A thoracic dermatomal level of T4-5 block was achieved and the uterus was exteriorized in all the patients. There was no statistically significant difference between the groups in the incidence of nausea, vomiting, need for rescue antiemetics, or complete response (no nausea, vomiting, or rescue) in either the intraoperative or postoperative period (Table 2). There was also no statistically significant difference between the two groups in the number of vomiting episodes, nausea, pain, itching, or sedation scores or in patients' satisfaction with PONV control (median [interquartile

Table 2. Intraoperative and Postoperative Nausea, Vomiting, Need for Rescue, and Complete Response.

	Active ReliefBand® (n = 47)	Sham Control ReliefBand® (n = 44)	Risk Ratio (95 % confidence interval)	P value
Intraoperative nausea	14 (30%)	19 (43%)	0.69 (0.39–1.20)	0.18
Intraoperative vomiting	6 (13%)	4 (9%)	1.43 (0.43–4.73)	0.55
Intraoperative antiemetic	11 (23%)	8 (18%)	1.29 (0.57–2.09)	0.54
Intraoperative complete response	26 (55%)	25 (57%)	0.97 (0.86–1.40)	0.89
Postoperative nausea	11 (23%)	18 (41%)	0.57 (0.30–1.07)	0.79
Postoperative vomiting	12 (26%)	16 (37%)	0.70 (0.37–1.31)	0.26
Postoperative antiemetic	16 (34%)	17 (39%)	0.88 (0.51–1.52)	0.65
Postoperative complete response	24 (51%)	15 (34%)	1.50 (0.91–2.46)	0.1
Intraoperative and Postoperative complete response	16 (34%)	10 (23%)	1.50 (0.76–2.94)	0.23

Values are n (%).

range], 9 [7–10] in the active group and 10 [8–10] in the sham control group). When asked to rate how they liked the ReliefBand®, the median (interquartile range) score was 6 (3–8) in the active group and 8 (5–10) in the sham control group (P = 0.03).

Discussion

Previous studies have reported the efficacy of TAES at the P6 point for PONV prophylaxis after general anesthesia (3–5). Acupressure at the P6 point was also found to be effective in preventing intraoperative and PONV after CS with SA in some studies (6,7) but was of no benefit in other studies (8).

The lack of efficacy of the ReliefBand® in reducing nausea and vomiting in this study could be explained by displacement of the Band from the acupoint site, thereby reducing its antiemetic efficacy. This concern was raised in a previous study (3) and may be more relevant in this group of mothers while they were attempting to breastfeed. In fact, many women expressed that their dissatisfaction with the active band was because of its interference with breastfeeding. Alternatively, application of the active device on the dorsum of the wrist could have had an antiemetic effect, thereby reducing the incidence of PONV in the sham control group. It had been suggested that such application of the ReliefBand® could transmit electrical impulses through the wrist to the P6 acupoint (3). Electrical stimulation does not, however, have an antiemetic effect by itself (9,10). Although some argue that stimulation at nonacupuncture sites may itself have a specific effect (11,12), others have demonstrated that nonacupoint stimulation was significantly less effective than acupoint stimulation (13–17).

Stimulation of the acupuncture point can be produced by different methods, including the application of pressure to the P6 point (acupressure), needling of the P6 point (acupuncture), and by TAES. Although some studies used bilateral P6 point stimulation (5,7,18), others used unilateral stimulation and reported a beneficial antiemetic effect from these modalities compared with sham or placebo (3,4,6). Although it is possible that bilateral stimulation could have been more effective, no studies have compared the efficacy of unilateral versus bilateral P6 point stimulation. There are also no data comparing the antiemetic efficacy of different levels of electrical stimulation with TAES. Although we could have found different results if higher levels of stimulation were used, this would have been uncomfortable to the patients and would have decreased their compliance with wearing the ReliefBand®.

In this study, there was a trend towards less nausea and a higher complete response rate in the active group, but these differences did not achieve statistical significance. We observed less PONV in the sham control group in our study than we anticipated in our power calculation. This discrepancy could have resulted in our inability to detect statistically significant differences, as our sample size calculation was based on an expected decrease of 30%. Given the actual observed rates of PONV in the two groups, a study with 106 patients per group would have 80% power to detect a significant group difference in PONV.

In summary, although the incidence of intraoperative and postoperative nausea was less frequent in patients receiving the active ReliefBand® at the P6 point, there was no statistically significant difference in the incidence of intraoperative nausea and/or vomiting and PONV compared with patients who had the ReliefBand® applied to the dorsum of the wrist during and after CS using SA. Further larger studies are warranted to establish if there is a role for TAES in this patient population.

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