

Comparative Efficacy of Acustimulation (ReliefBand[®]) versus Ondansetron (Zofran[®]) in Combination with Droperidol for Preventing Nausea and Vomiting

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Background: Antiemetic drugs are costly, are associated with variable efficacy, and can produce unwanted side effects when used for prophylaxis against postoperative nausea and vomiting. This clinical study was designed to compare the efficacy of transcutaneous electrical acupoint stimulation using a ReliefBand[®] to ondansetron (Zofran[®]) when utilized alone or in combination for preventing postoperative nausea and vomiting after plastic surgery.

Methods: A single-center, randomized, double-blind, placebo- and sham-controlled study design was conducted to compare three prophylactic antiemetic treatment regimens in 120 outpatients undergoing plastic surgery procedures with routine low-dose droperidol prophylaxis: (1) ondansetron (n = 40), 4 mg intravenous ondansetron and a sham ReliefBand[®]; (2) acustimulation (n = 40), 2 ml intravenous saline and an active ReliefBand[®]; and (3) combination (n = 40), 4 mg intravenous ondansetron and an active ReliefBand[®]. The incidences of postoperative nausea and vomiting, as well as the need for "rescue" antiemetics, were determined at specific time intervals for up to 72 h after surgery. The outcome variables assessed included recovery times, quality of recovery score, time to resumption of normal diet, and patient satisfaction with the prophylactic antiemetic therapy.

Results: Use of the ReliefBand[®] in combination with ondansetron significantly reduced nausea (20 vs. 50%), vomiting (0 vs. 20%), and the need for rescue antiemetics (10 vs. 37%) compared with ondansetron alone at 24 h after surgery. Furthermore, the ability to resume a normal diet (74 vs. 35%) within 24 h after surgery was significantly improved when the ReliefBand[®] was used to supplement ondansetron (vs. ondansetron alone). Finally, the quality of recovery (90 ± 10 vs. 70 ± 20) and patient satisfaction (94 ± 10 vs. 75 ± 22) scores were significantly higher in the combination group versus the ondansetron group. There were no significant differences between the ReliefBand[®] and ondansetron when administered as adjuvants to droperidol for antiemetic prophylaxis.

Conclusions: The ReliefBand[®] compared favorably to ondansetron (4 mg intravenously) when used for prophylaxis against postoperative nausea and vomiting. Furthermore, the acustimulation device enhanced the antiemetic efficacy of ondansetron after plastic surgery.

CONTROVERSY continues to surround the optimal approach to preventing postoperative nausea and vomiting (PONV).¹ Recent studies suggest that the benefits of antiemetic prophylaxis are not limited to overall cost savings but include improved patient satisfaction compared to treatment of established symptoms.²⁻⁴ Although low-dose droperidol is a highly cost-effective antiemetic for routine prophylaxis,^{4,5} concerns exist regarding the side effects (e.g., dysphoria, restlessness, arrhythmias**) associated with higher doses of droperidol.^{6,7} While ondansetron has become a popular alternative to droperidol for antiemetic prophylaxis, it is costly and also has side effects.^{7,8} Ondansetron has been reported to be less effective in the management of nausea than vomiting (or retching).⁸

In their meta-analysis, Lee and Done⁹ suggested that nonpharmacologic techniques may be effective in preventing PONV. Recently, a transcutaneous acustimulation device known as the ReliefBand[®] (Woodside Biomedical Systems, Carlsbad, CA) was found to reduce nausea, but not vomiting, when applied at the P6 acupoint after laparoscopic surgery.¹⁰ However, the efficacy of nonpharmacologic techniques (e.g., acustimulation) has been questioned when compared to that of conventional antiemetic drugs (e.g., ondansetron).¹¹

Therefore, we designed a placebo- and sham-controlled study to test the hypothesis that acustimulation with the ReliefBand[®] is an effective alternative to ondansetron (Zofran[®]; GlaxoSmithKline, Research Triangle Park, NC) for antiemetic prophylaxis. A secondary objective was to determine whether the ReliefBand[®] could enhance the antiemetic efficacy of ondansetron in a high-risk plastic surgery population.

Materials and Methods

After Institutional Review Board approval and written informed consent had been obtained, 120 healthy adults scheduled for elective plastic surgery procedures during general anesthesia were enrolled in this clinical study. Patients were randomly assigned to one of three treatment groups using a computer-generated random number table: (1) the ondansetron group, which received ondansetron and a sham ReliefBand[®]; (2) the acustimu-

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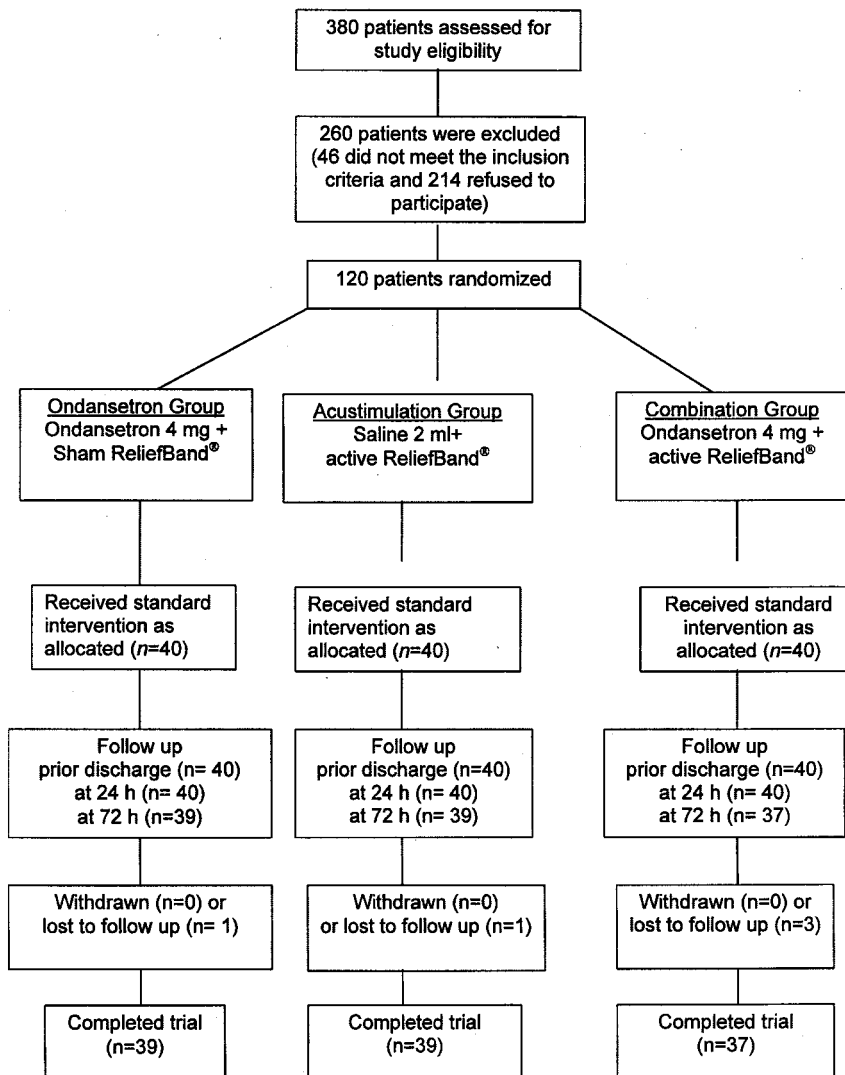


Fig. 1. Consort flow diagram illustrating the progress of patients through the clinical trial.

lation group, which received saline and an active ReliefBand®; and (3) the combination group, which received ondansetron and an active ReliefBand®. A flow diagram illustrating the progress of patients through the clinical trial is shown in figure 1.

Patients who had taken any antiemetic medication within 24 h prior to the operation, were pregnant, were experiencing menstrual symptoms, were using a permanent cardiac pacemaker, had previous experience with acustimulation therapies, or had experienced vomiting or retching within 24 h before surgery were excluded. Detailed medical history and demographic information, including age, height, weight, American Society of Anesthesiologists physical status, as well as a history of previous PONV, motion sickness, or smoking, were obtained from each patient. In the day surgery unit, the patients completed a preoperative verbal rating scale (VRS) for nausea, ranging from 0 (no nausea) to 10 (worst imaginable nausea).

All patients underwent a standardized general anesthetic technique consisting of propofol for induction and sevoflu-

rane in combination with remifentanyl for maintenance of anesthesia. Perioperative opioid analgesics were also standardized in all patients. All patients received antiemetic prophylaxis with droperidol, 0.625 mg intravenously, after induction of anesthesia. On arrival in the postanesthesia care unit, the patients received either 4 mg intravenous ondansetron (ondansetron and combination groups) or an equal volume of intravenous saline (acustimulation group) from identical-appearing syringes. A nurse specifically trained in the proper positioning of the ReliefBand® placed an active (acustimulation and combination groups) or sham (ondansetron group) device at the P6 acupoint of the dominant upper extremity (fig. 2).¹⁰ Prior to applying the device, the placement area was cleaned with an alcohol swab followed by the application of a hypoallergenic conductivity gel. All patients were requested to wear the ReliefBand® (or sham) device for 72 h after surgery, except when bathing. Although the acustimulation devices used in all three groups were identical, the sham devices were electronically altered by the manufacturer to simulate an

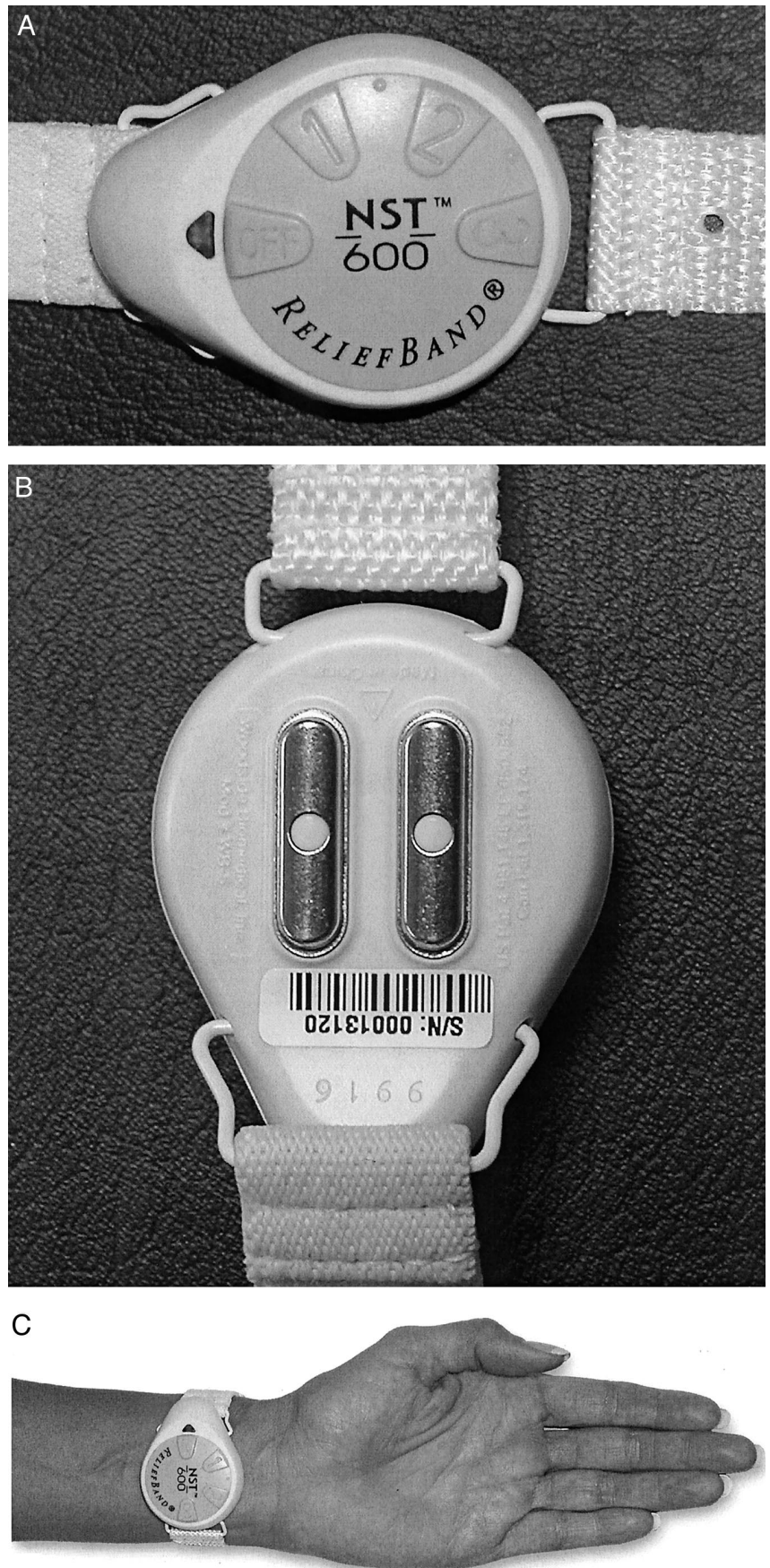


Fig. 2. (A) Top view of the ReliefBand[®] acustimulation device. (B) Bottom view of the ReliefBand[®] acustimulation device. (C) Position of the ReliefBand[®] device at the P6 acupoint on the median aspect of the wrist of the dominant upper extremity (approximately 2 to 3 cm proximal to the distal wrist crease between the tendons of the flexicarpri radials and the palmaris longus). Published with permission from Woodside Biomedical Systems.

active unit without generating electrical impulses. In order to minimize bias resulting from the presence or absence of electrical stimulation, all patients were told that the acustimulation device produces a tingling sensation that they might or might not feel. An antiemetic "rescue" drug (metoclopramide, 10 mg intravenously) was administered if the patient reported persistent nausea (with a nausea VRS ≥ 3) or vomiting or retching lasting longer than 10 min.

The durations of surgery and anesthesia, as well as the lengths of stay in the postanesthesia care unit and day surgery unit, were recorded. Postoperatively, nausea was assessed using the 11-point VRS on admission to the postanesthesia care unit, at 15 and 30 min after initiating the study treatments, and subsequently at 30 min intervals until the patient was discharged to home. All episodes of vomiting and retching, as well as the need for rescue antiemetic and analgesic medications, were recorded in a patient diary during the 72-h postoperative study period.

The home discharge criteria required that the patient be fully awake and oriented, with stable vital signs while standing; be able to walk without assistance; and not be experiencing active side effects. Prior to discharge, the patients were asked whether they felt a tingling sensation at the site of the ReliefBand[®]. Follow-up telephone calls at 24 and 72 h postoperatively were used to inquire about postdischarge emetic symptoms and to evaluate the patient's satisfaction with their quality of recovery from anesthesia and their antiemetic management using a VRS from 0 (poor recovery) to 100 (excellent recovery) and from 0 (very dissatisfied) to 100 (highly satisfied), respectively. At the time of the 24 h follow-up evaluation, the patients were also asked whether they had

resumed a normal diet, normal daily activities, and a regular sleep pattern.

Statistical Analysis

Assuming that in 50% of these patients nausea and/or vomiting would develop after plastic surgery with general anesthesia and low-dose droperidol prophylaxis alone,¹ a sample size of 40 patients was determined by *a priori* power analysis to provide an 80% power of detecting an absolute difference of 25% between treatment groups (*i.e.*, a reduction from 50% to 25%), with an $\alpha = 0.05$. Nonparametric analysis was utilized to compare nausea VRS scores, number of emetic episodes, and antiemetic usage among the three treatment groups. The chi-square test was used to compare the proportion of patients reporting nausea, having one or more emetic episodes, and receiving rescue antiemetic medication. In cases in which the expected frequencies were small, the Fisher exact test was utilized. The times to the first emetic event and to the administration of rescue medications were analyzed using log-rank test statistics. The times to when 25% of the patients in each group were judged to have failed to respond to the prophylactic antiemetic therapy (*i.e.*, required a rescue antiemetic drug for persistent nausea or emesis) were determined by the Kaplan-Meier method. Data analysis was performed using the Number Statistical System Software, version 6.0 (NCSS, Kaysville, UT). Data are presented as the mean (\pm SD), the median, numbers, or percentages, and a *P* value < 0.05 was considered significant.

Results

The three treatment groups were comparable with respect to demographic characteristics, preexisting risk

Table 1. Demographic Characteristics, Preoperative Nausea Scores, and Anesthesia and Surgery Times in the Three Treatment Groups

	Ondansetron (n = 40)	Acustimulation (n = 40)	Combination (n = 40)
Age (yr)	46 \pm 11	43 \pm 13	45 \pm 11
Gender (F/M; n)	37/3	35/5	34/6
ASA physical status (I–II–III; n)	18–22–0	13–26–1	19–19–2
Height (cm)	170 \pm 11	170 \pm 14	172 \pm 20
Weight (kg)	70 \pm 12	74 \pm 17	75 \pm 15
History of PONV [n (%)]	12 (30)	17 (42)	16 (40)
History of motion sickness [n (%)]	6 (15)	14 (35)	14 (35)
Smoker [n (%)]	1 (2)	4 (10)	4 (10)
Type of plastic surgery (n)			
Head and neck	10	8	11
Breast	16	18	17
Abdominal	10	11	7
Extremities	4	3	5
Median nausea score (0–10)	0	0	0
Anesthesia time (min)	192 \pm 95	177 \pm 96	212 \pm 123
Surgery time (min)	157 \pm 93	146 \pm 91	178 \pm 118

Values are means \pm SD, medians (ranges), numbers (n), or percentages (%). No significant differences between groups.

ASA = American Society of Anesthesiologists; PONV = postoperative nausea and vomiting.

Table 2. Recovery Times and Incidences of Postoperative Nausea, Vomiting, and Need for Rescue Antiemetic Medication in the Three Prophylactic Treatment Groups

	Ondansetron (n = 40)	Acustimulation (n = 40)	Combination (n = 40)
Recovery times			
PACU (min)	88 ± 48	79 ± 39	72 ± 45
DSU stay (min)	105 ± 50	101 ± 48	96 ± 37
During predischARGE period			
Nausea scores on arrival in PACU (0–10)			
At 15 min	0 (0–6)	0 (0–5)	0 (0–8)
At 30 min	0 (0–6)	0 (0–2)	0 (0–2)
At 60 min	0 (0–7)	0 (0–2)	0 (0–2)
At 90 min	0 (0–7)	0 (0–3)	0 (0–2)
At 120 min	0 (0–4)	0 (0–1)	0 (0–2)
Nausea [n (%)]	16 (40)	13 (33)	13 (33)
Vomiting [n (%)]	5 (12)	1 (2)	0
Antiemetic rescue [n (%)]	12 (30)	8 (20)	9 (22)
Analgesic rescue [n (%)]	10 (25)	14 (35)	13 (32)
Felt tingling sensation at wrist [n (%)]	11 (27)	29 (73)*	28 (70)*
Headaches [n (%)]	5 (12)	2 (5)	4 (10)
Erythema or swelling at wrist	0	0	0
At 24 h follow-up evaluation			
Nausea [n (%)]	20 (50)	14 (35)	8 (20)*
Vomiting [n (%)]	8 (20)	4 (10)	0*
Median nausea score (0–10)	5 (0–10)	2 (0–7)*	0 (0–6)*
Antiemetic rescue [n (%)]	15 (37)	7 (17)	4 (10)*
Resume diet [n (%)]	14 (35)	23 (59)	29 (74)*
Resume normal activities [n (%)]	2 (5)	7 (17)	4 (10)
Normal sleep pattern [n (%)]	18 (45)	15 (37)	25 (62)
Quality of recovery (0–100)	70 ± 20	80 ± 12	90 ± 10*
At 72 h follow-up evaluation			
Nausea [n (%)]	5 (12)	3 (8)	0
Vomiting [n (%)]	1 (2)	0	0
Median nausea score (0–10)	0 (0–5)	0 (0–3)	0 (0–3)
Rescue [n (%)]	0	0	0
Complete responses (%)	52	62	65
Satisfaction with antiemetic (0–100)	75 ± 22	89 ± 18	94 ± 10*

Values are means ± SD, medians (ranges), numbers (n), or percentages (%).

*Significantly different from the ondansetron group, $P < 0.05$.

PACU = postanesthesia care unit; DSU = day surgery unit.

factors for development of PONV, and preoperative nausea scores (table 1). During the predischARGE period, the incidences of PONV and recovery times were similar in the ondansetron and acustimulation groups (table 2). However, the median nausea VRS scores were significantly lower in the acustimulation and combination (*vs.* ondansetron) groups at the 24 h follow-up evaluation (table 2). Furthermore, the incidences of nausea (20 *vs.* 50%), vomiting (0 *vs.* 20%), and the need for rescue antiemetic medication (10 *vs.* 37%) within 24 h after surgery were all significantly reduced in the combination (*vs.* ondansetron) group. In addition, a higher percentage of patients in the combination (*vs.* ondansetron) group were able to resume a normal diet (74 *vs.* 35%) and sleep pattern (62 *vs.* 45%) on the first postoperative day. Finally, the use of combined therapy with ondansetron and the ReliefBand[®] improved the patients' quality of recovery (90 ± 10 *vs.* 70 ± 20) and satisfaction with their antiemetic therapy (94 ± 10 *vs.* 75 ± 22) compared to ondansetron alone.

The Kaplan–Meier estimates (fig. 3) suggested that the median time intervals for episodes requiring antiemetic rescue therapy to develop in 25% of the patients were 90 min, 140 min, and > 72 h for the ondansetron, acustimulation, and combination groups, respectively. However, the complete response rates were similar in all three treatment groups. No clinically significant local side effects were reported at the acustimulation site in any of the treatment groups (table 2). The cost of the disposable ReliefBand[®] device used in this study was US \$30, and the acquisition cost of ondansetron (4 mg) at our institution was US \$16.

Discussion

Recent studies have documented the benefits of routine antiemetic prophylaxis for high-risk surgical patients.^{2–4,12} The benefits of more effective antiemetic prophylaxis are not limited to cost savings but include

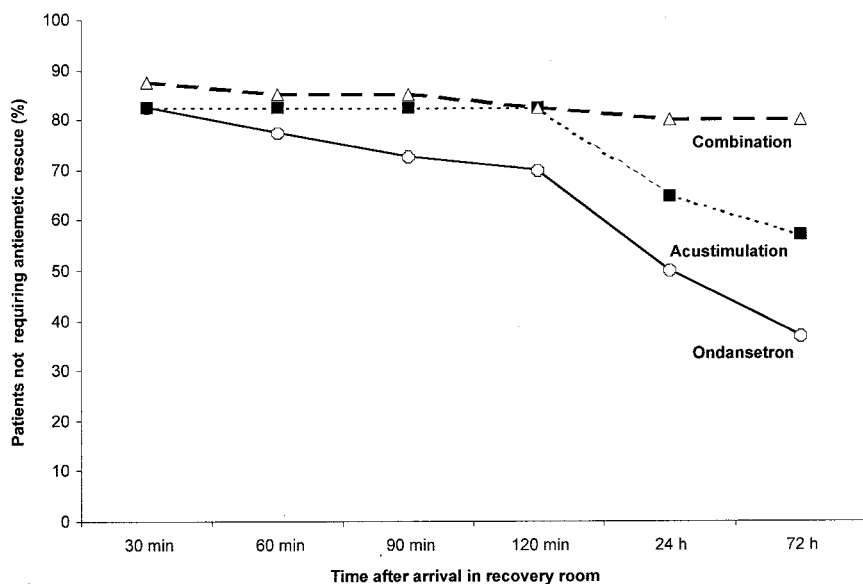


Fig. 3. Kaplan-Meier estimates demonstrating the time to rescue medication for either nausea or vomiting after arrival in the recovery room in the ondansetron (circle; $n = 40$), acustimulation (square; $n = 40$), and combination (triangle; $n = 40$) groups. The combination therapy was significantly more effective than either ondansetron or acustimulation (ReliefBand[®]) alone ($P < 0.05$).

improved patient satisfaction compared with treatment of established symptoms.¹² Although a two- or even three-drug antiemetic regimen may be justified in high-risk patient populations,^{1,12} the possibility of adverse drug interactions increases as a function of the number of drugs administered.⁷ The current study suggests that the efficacy of ondansetron can be enhanced by combining it with nonpharmacologic acustimulation therapy using the ReliefBand[®] device in plastic surgery patients receiving low-dose droperidol for routine prophylaxis. The enhanced overall antiemetic efficacy in the combination group may be related to the fact that acustimulation possesses relatively more antinausea activity than ondansetron.^{8,10,13}

The antiemetic effectiveness of stimulation at the P6 acupuncture point remains controversial because of the difficulty in designing properly controlled studies using nonpharmacologic methods.¹¹ However, in a sham-controlled study, Kotani *et al.*¹⁴ reported that preoperative intradermal acupuncture reduced nausea and vomiting after abdominal surgery. Moreover, two systematic literature reviews^{9,15} have concluded that P6 acupoint stimulation decreases emetic symptoms in adults. A recent sham-controlled prophylaxis study involving the ReliefBand[®] acustimulation device demonstrated an antinausea effect after laparoscopic cholecystectomy procedures.¹⁰ However, in the preliminary multicenter study by Zarate *et al.*,¹⁰ we failed to demonstrate a significant decrease in the incidence of vomiting or the need for rescue antiemetic drugs, analogous to the recent findings of Rusy *et al.*¹³ using electroacupuncture in children.

In this follow-up study with the ReliefBand[®], all patients were enrolled at one hospital, and the anesthetic and analgesic techniques, as well as the types of surgery and postoperative nursing care, were more tightly controlled. In addition, a commercial (*vs.* prototype) model of the ReliefBand[®] was utilized in this study. Compared

to the prototype ReliefBand[®] used in the preliminary study, the newer model has an expanded electrode contact area with the skin surface (111 *vs.* 74 mm²). The current data would suggest that the newer ReliefBand[®] device provides effective prophylaxis against both nausea and vomiting.

The common methodologic problems with many of the earlier studies involving the use of nonpharmacologic antiemetic therapies have included inadequate power to detect intragroup differences, failure to include placebo- and/or sham-controlled groups, use of nonstandardized anesthetic and analgesic techniques, and the absence of clinically relevant comparator drugs. Although the aforementioned concerns were all addressed in the present study, most of the patients (70–73%) receiving the active ReliefBand[®] device were able to detect the tingling sensation produced at the P6 acupoint, and this may have biased the patients in favor of the active (*vs.* sham) acustimulation.

Ethical concerns raised by the surgical and anesthesia staff precluded us from including a study group receiving no antiemetic prophylaxis or low-dose droperidol alone. As a result of the high incidence of PONV in plastic surgery patients, a minimally effective dose of droperidol (0.625 mg intravenously) was administered to all patients.^{1,12} Droperidol was selected for routine prophylaxis because it has been found to be a highly cost-effective prophylactic antiemetic.^{4,5} However, our surgical and anesthesia staff have insisted on the use of a combination of antiemetic drugs in the plastic surgery patient population. The choice of ondansetron as a comparator was based on the fact that it is the most commonly used antiemetic in the perioperative period and appears to have additional benefit when used in patients who have also received droperidol.^{4,16}

Analogous to recent P6 acupoint stimulation studies in children,^{13,17} this clinical investigation suggests that the

ReliefBand[®] is an elective alternative to antiemetic drugs for preventing symptoms related to PONV in adults. Although neither the ReliefBand[®] nor ondansetron was completely effective in preventing emetic symptoms in this high-risk outpatient population, these data suggest that using an acustimulation device in combination with antiemetic drugs (namely droperidol and ondansetron) leads to further improvement in patient outcome with respect to postoperative emetic symptoms. Future studies are needed to assess the optimal timing of acustimulation (*i.e.*, pre- *vs.* postoperative) with respect to its efficacy in preventing PONV. In addition, studies are needed to determine whether bilateral stimulation at the P6 acupoint is more effective than unilateral stimulation with the ReliefBand[®].

In conclusion, the ReliefBand[®] acustimulation device appeared to be an effective alternative to ondansetron for preventing PONV after plastic surgery. In addition, the ReliefBand[®] enhanced the antiemetic efficacy of ondansetron (4 mg intravenously) in this surgical population.

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