Safe, Successful Nausea Suppression in Early Pregnancy with P-6 Acustimulation

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OBJECTIVE: To evaluate the safety and effectiveness of P-6 acustimulation for the relief of nausea and vomiting associated with early pregnancy.

STUDY DESIGN: Forty-one patients were treated with a P-6 acustimulation device at the Division of Maternal-Fetal Medicine, Eastern Virginia Medical School. Pretreatment nausea severity, posttreatment nausea relief and device effectiveness were patient rated using a 1–5 scale. All neonates were evaluated for congenital abnormalities.

RESULTS: Pretreatment nausea severity scores for treated patients averaged 4.2, with most severe and debilitating nausea rated 5. Posttreatment device effectiveness averaged 4.2, with significant or complete relief rated 5. Device ease of use averaged 4.3, with very easy to use rated 5. No congenital abnormalities were found.

CONCLUSION: Because current pharmacologic treatments for nausea in early pregnancy are not consistent, efficacious or without unwanted side effects or increased teratogenic risks, acustimulation of P-6 in pregnancy may prove to be a significant therapeutic alternative. (J Reprod Med 2001;46:811–814)

Keywords: nausea, pregnancy complications, acustimulation.

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Introduction

Nausea and vomiting (n/v) have been associated with early pregnancy since the beginning of recorded history. Pregnancy related nausea and vomiting were discussed as early as 200 AD.[1] Morning sickness with associated nausea and vomiting is common; 50–90% of patients in the first trimester of pregnancy suffer from moderate to significant nausea.[2] Vomiting has been reported by 56% of pregnant women.[2]

Morning sickness and the more severe hyperemesis gravidarum begin between the fourth and sixth weeks of pregnancy. Most women affected have numerous episodes of vomiting during the day, many without symptom-free periods. This may lead to weight loss, dehydration, electrolyte disturbances, ketosis and acetonuria, frequently requiring hospitalization. Laboratory findings may show increased ketonuria and urine specific gravity, with elevated blood urea nitrogen and hemat-

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ocrit, indicating contracted blood volume. Electrolyte imbalances may be present, with decreases noted in serum Na+, K+, Cl− and Mg− levels. In many cases there may be an increase in liver function test abnormalities, such as serum aminotransferase or serum bilirubin.

Despite counseling and discussion of the risks and benefits of pharmacologic therapy and the often profound discomfort associated with the nausea and vomiting of early pregnancy, many women, quite reasonably, refuse to use medication for fear of affecting the development of the fetus. Acupuncture and acupressure have been employed in nontraditional medicine for years to treat nausea from many causes.[3] Transcutaneous electrical nerve stimulation over the P-6 Neiguan point is an effective remedy in the suppression of nausea and vomiting from pregnancy and gynecologic surgery.[4-9] Evans et al, in a placebo-controlled, crossover study, showed an 87% efficacy rate with minimal side effects.[5] A placebo effect was identified comparable to that seen in other pharmacologic studies.[1,5]

[The device] appears to provide a high level of efficacy in suppression of nausea and emesis, appears safe for the developing fetus and is well tolerated.

Koch et al confirmed that the use of P-6 acustimulation alters gastric myoelectric activity, restoring normal three-cycle-per-minute frequency.[10] Hu and Koch demonstrated that vection-induced motion sickness' tachygastria and gastroparetic bradygastria can be resolved with acustimulation. Current therapy addressing pregnancy-induced nausea and vomiting often attempt to reestablish the physiologic activity of the gastric myoelectric pacesetter disrupted by early pregnancy (Koch, personal communication).

Materials and Methods

A five-year trial of an acustimulation device, the Relief Band™ (Woodside BioMedical, Inc., Carlsbad, California) was conducted. The device is a transcutaneus electrical nerve stimulator applied to the P-6 acupuncture point on the volar aspect of the wrists of severely nauseated pregnant women. The device is a class II medical device designed for use in motion sickness (sea sickness, etc.), chemotherapy, postoperative nausea (as an adjunct to antiemetic medications) and pregnancy. It is worn like a wristwatch on the volar aspect of the arm at the P-6 acustimulation point. It emits an electrical stimulus, similar to a transcutaneous nerve stimulation device and adjustable for pulse frequency and intensity.

Patients were recruited who complained of significant nausea and/or vomiting in the early first trimester. Candidates for inclusion were asked to rate their nausea on a 1–5 scale, where 1 was minimal nausea and 5 was significant or overwhelming nausea. Patients were excluded from the study if they were >11 weeks from their last menstrual period, were sonographically noted to have a multiple gestation, reported bleeding or cramping, had been previously diagnosed with significant metabolic disease (i.e., pregestational diabetes, gastroparesis or thyroid dysfunction) or reported having nausea self-scaled as ≤3.

Patients were also excluded if their infants were unavailable for dysmorphology evaluation after birth.

Patients included in the study were instructed in the use of the device, its placement and how to vary the electrical stimulus applied. The patients returned the device, generally in the mid second trimester, after a 48-hour trial without acustimulation showed minimal or tolerable nausea. At that time the patient was asked to rate the effectiveness of the device and its ease of use. A 1–5 scale was used for both evaluations: minimal or zero effectiveness was rated 1, and great or complete resolution of nausea was rated 5. After delivery the neonate was evaluated for birth defects by a board-certified medical geneticist. Pregnancy and delivery data were gathered from chart review.

Results

Forty-one patients agreed to participate in this P-6 acustimulation trial. These 41 patients rated their pretreatment nausea discomfort as 4.2±0.51 on a 1–5 scale. The average gestational age at initiation of device use was 6.4±1.6 weeks from the last menstrual period. The device was used, on average, 8.3±1.7 weeks. Three patients reported minimal effectiveness and had the therapy supplemented with standard pharmacologic modalities (diphenhydramine or trimethobenzamide). Although en-

rolled patients discontinued use of the device at an average of 14.1 weeks' gestation, three patients elected to continue its use into the third trimester and one to delivery, citing the device's effectiveness and concern about the return of nausea. For the majority of patients, nausea control was immediate and continuous during use of the device.

Of the 41 patients enrolled, 2 miscarried or were identified as having a missed abortion at 7–11 weeks of pregnancy. Both were treated with dilatation and curettage procedures.

Patients were asked to rate the effectiveness of the device in eliminating or significantly reducing their nausea. The average score for effectiveness was 4.2 ± 0.99 on a 1–5 scale, with 5 representing significant or complete relief. Although three patients required pharmacologic supplementation, none required other outpatient management or hospitalization for control of nausea or vomiting.

Subsequent pregnancy complications included preterm labor diagnosed at 31⁴/₇ weeks of pregnancy. The patient's preterm labor was managed with standard tocolytic therapy, and she was discharged after a 72-hour hospitalization. She delivered at 38 weeks. Mild pregnancy-induced hypertension was diagnosed in another patient, who delivered at 39¹/₇ weeks. The average weight gain documented for the 39 patients with ongoing pregnancies was 6 kg as measured from their first office visit. The average birth weight was 3,520 g.

Neonatal assessment involved a complete physical evaluation of the infant, including cranium, face, palate, chest, abdomen, back, genitals and limbs. One neonate had a unilateral simian crease, a normal population variant. No other abnormalities were identified in the 39 neonates evaluated.

Patients were asked to evaluate the device's ease of use. A 1–5 scale was used, with 1 representing "difficult" and 5 "easy." The average "ease of use" score was 4.5 ± 0.7. Comments included, "Precise placement can be difficult at first," and "Eats lots of batteries." Forty of the 41 patients (97.6%) claimed that they would use the device in another pregnancy or recommend its use to others.

Discussion

The pathophysiology of pregnancy-related nausea is poorly understood. "Morning sickness" many times is described as the "disease of theories" and is probably multifactorial in origin. Pathophysiologic theories include endocrine, psychological and autonomic nervous system dysfunction, and gastric dysrhythmia.[10] Maternal nutritional and psychological abnormalities have also been implicated. A darwinian argument proposes, "Morning sickness serves an adaptive, prophylactic function."[9]

Throughout history, psychogenic reasons have been thought to contribute to morning sickness as a somatic expression of psychological conflict or psychiatric illness exacerbated by pregnancy.[11] Singer et al cited a number of studies that support this theory and indicate that up to 70% of hyperemetic women respond to some degree of placebo.[1]

Researchers have found serum hCG levels to be elevated in hyperemetic women when compared to normal controls.[3] Elevated estrogen may play a role since many women who experience n/v while taking oral contraceptives earlier are more likely to have n/v when pregnant.[12] Elevated progesterone levels have been implicated in this nausea since hyperprogesteronemia has been associated with prolonged gastric emptying time and decreased smooth muscle motility.[3,12] Transient elevations in serum thyroxine levels, particularly serum free thyroxine, have been documented in as many as 70% of pregnancies complicated by hyperemesis gravidarum.[13] A dysfunctional gastric "pacesetter" with associated gastric dysrythmia has been suggested: retrograde gastric contractions resulting in reflux of gastric contents into the esophagus even in the absence of food are seen in the gastric dysrhythmia patient.[10,14]

Deficiencies of certain dietary nutrients may play a role. Low pyridoxine and zinc serum levels have been found in hyperemetic patients. Sahakisn et al, in a double-blind, placebo-controlled study of 59 hyperemetic pregnant women, showed that orally administered pyridoxine (25 mg administered for eight hours) significantly reduced nausea and emesis.[7]

Current recommended treatments for the nausea and vomiting of early pregnancy are scaled in their application. Initial therapy includes dietary modification and psychological support. Suggested changes in diet, including avoiding spicy, fried, hot and cold foods, and discontinuation of tobacco, caffeine and alcohol have met with limited success. Caregiver psychological support efforts have limited effectiveness and are often viewed by the patient as patronizing (Magee, personal communication).

Antiemetic pharmacologic treatments are of different types. Over-the-counter medications include vitamin B_6 and doxylamine, currently unavailable in the United States as a combined dose. Prescrip-

tion medications include metoclorpromide, trimethobenzamide, ondansetron, prochorperazine and promethazine. In the 3–12 per 1,000 pregnant women with significant hyperemesis, methscopolomine, chlorpromazine or droperidol is often added to inpatient intravenous therapy protocols. Occasionally patients require weeks of total parenteral nutrition support with attendant risks of infection, hyperglycemia, hepatic dysfunction and addiction.[17]

Although pharmacologic therapy for nausea relief are ubiquitous, the safety of the medications routinely used remains to be established. Even the seemingly benign vitamin B_6, when taken at dosages recommended for nausea suppression, is listed as a category C medication, with teratogenic risks in humans and animals largely undefined. At doses recommended for nausea control, all antiemetic medications used in pregnancy[8] are category C. (Animal studies suggest adverse effects or no controlled studies on humans or animals are available. "Drugs should be given only if the potential benefit justifies the potential risk to the fetus."[19]) Acupressure and acustimulation have been used in pregnancy without obvious risks, although the literature is scant.[20]

The use of acustimulation over P-6 allows many patients to maintain a better-quality lifestyle and work status within the home or away than otherwise. It appears to ameliorate medical complications and adverse effects when antinausea medications are used. Relief Band™ appears to provide a high level of efficacy in suppression of nausea and emesis, appears safe for the developing fetus and is well tolerated.

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