Evidence Table

Clinical Area: **Relief Band (pregnancy)**
Keywords: **Pregnancy, nerve stimulation, nausea, vomiting**
Reference: **Rosen T, deVeciana M, Miller HS et al. A randomized controlled trial of nerve stimulation for relief of nausea and vomiting in pregnancy. *Obstet Gynecol* 2003; 102: 129-135.**

Study Type: Randomized controlled trial
Study Aim: To evaluate the effectiveness of the Relief Band at treating nausea and vomiting in early pregnancy.

Outcomes
- *Primary:* Rhodes Index of Nausea, Vomiting and Retching, Total Experience Score (Rhodes Index)
- *Secondary:* Weight gain or loss, change in urinary ketones and specific gravity, medication use.

Design
- *Number of subjects:* N=230 (the authors did not report the number of patients randomized to each group)
- *Description of study population:* (Of study completers) Relief Band group: Mean age=29.7 ± 5.3 years; 72% White; mean gestational age=9.2 ± 1.7 weeks; 34% nulliparous: Sham group: Mean age=29.3 ± 5.8 years; 67% White; mean gestational age=9.0 ± 1.7 weeks; 35% nulliparous.
- *Inclusion criteria:* At least 18 years old; estimated 6-12 weeks' gestation; experienced nausea and vomiting for at least 3 days.
- *Exclusion criteria:* Other conditions associated with nausea and vomiting e.g. diabetes, malignancy treated with chemotherapy; cardiac pacemaker; previous use of acupressure.
- *Power:* 80% power to detect at least a 35% reduction in the Rhodes Index from baseline.
- *Method of randomization:* Computer-generated list of numbers; used sequentially numbered, opaque, sealed envelopes.
- *Intervention:* Patients were randomized to receive: 1) active Relief Band, a battery-powered acustimulation device worn like a wristwatch. There is a rotary dial on the device that allows users to choose between 5 intensity levels or; 2) Identically-appearing sham device. The sham device did not emit an electrical current. To preserve blinding, all women were told that they may or may not feel a "tingling" sensation from the device. Patients were instructed to adjust the intensity of the device to achieve maximum symptom relief.
- *Blinding:* Single-blind (patients).
- *Source of outcome data (e.g. patient self-report, doctor report, lab results):* Patient self-report. Patients completed questionnaires at study entry and on days 1-3, 9.11, 13, 17 and 21.
- *Length of follow-up*: 21 days.
- *Completeness of follow-up:* n=187/230 (81%) women completed the trial.

Validity
- *Is the study type appropriate for the questions being asked?* Yes.
- *Was the study population typical of patients with this disease?* Yes.
- *Were the treatment/control groups comparable at baseline?* Appeared to be. A limitation in study reporting was that the authors reported demographic information for study completers, not all study participants.
- *Was the intervention compared to placebo and/or best accepted intervention?* Yes, to a sham intervention.
- *Was there compliance with the intervention?* Yes.
- *Was there equal intensity of observation of study and control subjects?* Yes.
- *Was the process of observation likely to effect the outcome?* Possibly, because outcome assessment was non-blinded. However, outcomes were self-report patient data from self-administered questionnaires, so there was not much room for interpretation of outcomes by research personnel.
- *Intention to treat analysis?* No.

Conclusions regarding validity of methods:
Advantages were that there was adequate randomization, clear inclusion criteria and a statistical power analysis. However, approximately 20% of participants did not complete the trial and the analysis was not intention to treat. This could introduce bias if patients who dropped out were different from those who completed the trial. The authors noted that drop-outs were more likely to be multiparous and to have ketonuria at study entry; there may have also been differences on unmeasured characteristics. The trial was single-blind; outcome assessors were not blinded, but outcome measures did not require interpretation by the assessors so this was unlikely to introduce significant bias.

Results
Baseline scores (study completers)

	Relief Band group (n=95) Mean (SD)	Sham Group (n=92) Mean (SD)	p-value
Rhodes Index*	13.5 (6.0)	12.0 (5.3)	.114

* Scale can range from 0-32. Higher numbers indicate more nausea, vomiting and retching episodes and greater distress associated with these episodes.

Primary outcome (study completers)

	Relief Band group (n=95) No. (95% CI)	Sham Group (n=92) No. (95% CI)	p-value
Rhodes Index*	6.48 (5.31-7.66)	4.65 (3.67-5.63)	0.02

* Change in Rhodes Index score from baseline (larger change is a better result).
Note: Analysis of variance findings were that there was a significant effect of group assignment (Relief Band vs. sham), p=0.02 and a significant effect of time (p=0.01).

Secondary outcomes (study completers)

	Relief Band group (n=95)	Sham Group (n=92)	p-value
Weight gain, No. lb (SD)	2.9 ± 4.7	1.2 ± 5.5	0.003
Urine specific gravity, mean (SD)	1.019 (.008)	1.021 (.007)	0.158
Ketonuria, No.			
Negative-trace	83	82	0.555
Small-large	12	9	
Used additional medication, %	72	75	NS

Adverse effects
The authors reported that there was one adverse effect related to use of the device; this patient developed severe irritation at the electrode sites from an active device.

Authors' Conclusions

"Nerve stimulation therapy is effective in reducing nausea and vomiting and promoting weight gain in symptomatic women in the first trimester of pregnancy"

Reviewer's Conclusions

The authors found greater improvement in nausea and vomiting symptoms during early pregnancy in a group of women using the Relief Band for 21 days compared to a sham device. Although there was a statistically significant difference between groups, the clinical significance of a 1.83 difference in reduction in the Rhodes Index is not clear. The lack of intention to treat analysis (20% of randomized patients were not included in the analysis) may have introduced bias.