Evidence Table

Clinical Area: Relief Band (post-operative)
Keywords: Nerve stimulation, post-operative nausea and vomiting, laparoscopic surgery

Study Type: Randomized controlled trial
Study Aim: To evaluate the efficacy of the Relief Band for reducing the incidence of post-operative nausea and vomiting (PONV) after outpatient laparoscopic cholecystectomy.

Outcomes
- **Primary:** Incidence of PONV
- **Secondary:** Need for rescue medication

Design
- **Number of subjects:** n=250 (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= 42 ± 16 years; 91 female/19 male; Sham group: mean age=39 ± 14 years; 48 female/8 male; Placebo group: mean age=43 ± 16 years; 41 female/8 male.
- **Inclusion criteria:** Healthy adults scheduled for laparoscopic cholecystectomy.
- **Exclusion criteria:** Use of antiemetic, glucocorticosteroid or psychoactive medication within 24 hours of the operation; pregnancy; implanted cardiac pacemaker or defibrillator device.
- **Power:** Assuming a 60% PONV rate, 80% power to detect a 20% reduction in the incidence of PONV with 100 patients in the Relief Band group and 50 patients each in the sham and placebo groups.
- **Method of randomization:** Computer-generated random number table.
- **Intervention:** Before surgery, patients were randomly assigned to one of the following three groups: 1) Active Relief Band applied at the P6 acupoint; 2) Sham Relief Band: inactive device placed at the P6 acupoint; 3) Placebo Relief Band: inactive device placed on the dorsal side of the wrist (opposite the P6 acupoint). All devices had a similar appearance, but only the active device produced electrical signals. Patients were familiarized with the positioning of the Relief Bands prior to surgery. Approximately 5-10 minutes before the end of surgery (after completing electrocautery use), the bands were secured in place and worn continuously for 9 hours after surgery. To minimize bias, all patients were told that they might or might not feel a tingling sensation.
- **Blinding:** Double-blind.
- **Source of outcome data (e.g. patient self-report, doctor report, lab results):** Patient self-report; assessments were done in the postanesthesia care unit or by telephone if patients went home before the end of the 9 hour observation period.
- **Length of follow-up:** 9 hours after surgery.
- **Completeness of follow-up:** 221/250 (88%) completed the study (29 were excluded for protocol violations).

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?** Demographic characteristics of the randomized groups were not reported. Among study completers, characteristics appeared to be similar.
- **Was the intervention compared to placebo and/or best accepted intervention?** Yes, but it is unclear why both a sham device and a placebo were used.
- **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 if patients guessed whether they had an active or sham Relief Band.
- **Intention to treat analysis?** No.

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Conclusions regarding validity of methods:
The authors appropriately defined the primary outcome as incidence of PONV, the precise definition of this measure was not specified—multiple assessments of PONV were taken during the 9 hour observation period. There was no intention to treat analysis; the study had a 88% follow-up rate, so it is possible that there could be some bias in the analysis. It is unclear why the authors chose to include both an inactive device placed on the P6 acupoint (sham) and an inactive device placed on the opposite side of the wrist (placebo). The corresponding author was a paid consultant to Woodside Biomedical which may have introduced bias.

Results
Assessments of PONV and rescue medication use at various time intervals

<table>
<thead>
<tr>
<th>Time</th>
<th>Relief Band (n=110)</th>
<th>Sham (n=56)</th>
<th>Placebo (n=55)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arrival in PACU</td>
<td>FLIE score</td>
<td>1.8 ± 1.7 1.6 ± 1.4 1.7 ± 1.5</td>
<td>Nausea (%) 25 17 28</td>
</tr>
<tr>
<td>45 min</td>
<td>FLIE score</td>
<td>1.8 ± 1.3 2.7 ± 2.0 2.0 ± 1.8</td>
<td>Nausea (%) 36 51 32</td>
</tr>
<tr>
<td>90 min</td>
<td>FLIE score</td>
<td>1.6 ± 1.2 2.7 ± 2.0 1.9 ± 1.5</td>
<td>Nausea (%) 27 51 33</td>
</tr>
<tr>
<td>120 min</td>
<td>FLIE score</td>
<td>1.6 ± 1.4 2.0 ± 1.5 2.0 ± 1.6</td>
<td>Nausea (%) 27 40 41</td>
</tr>
<tr>
<td>4 h</td>
<td>FLIE score</td>
<td>1.6 ± 1.3 2.3 ± 1.6 2.1± 1.9</td>
<td>Nausea (%) 26 52 35</td>
</tr>
<tr>
<td>6 h</td>
<td>FLIE score</td>
<td>1.6 ± 1.5 2.2 ± 1.7 2.4 ± 1.9</td>
<td>Nausea (%) 22 47 43</td>
</tr>
<tr>
<td>9h</td>
<td>FLIE score</td>
<td>1.5 ± 1.3 2.0 ± 1.6 2.4 ± 1.9</td>
<td>Nausea (%) 18 42 47</td>
</tr>
</tbody>
</table>

PACU=postanesthesia care unit
FLIE score= Functional Living Index-Emesis Scale (1=none to 7=worse imaginable). Reported as mean ± SD
1Significantly different from sham group, p<.05
2Significantly different from placebo group, p<.05
The only side effect noted was mild cutaneous irritation with erythema in two patients which resolved spontaneously within 24 ours after removing the Relief Band.

Authors’ Conclusions
“We conclude that the TAES with the ReliefBand at the P6 acupoint reduces nausea, but not vomiting, after laparoscopic cholecystectomy.”

Reviewer’s Conclusions
According to the multi-item FLIE scale and the proportion of patients with nausea, there was a significantly lower incidence of PONV 90 minutes and 4,6 and 9 hours after laparoscopic cholecystectomy with Relief Band use compared to use of an inactive device. There was no reduction in PONV incidence 45 or 120 minutes post-operative. The mean FLIE score was relatively low and the clinical significance of the degree of reduction in PONV with Relief Band use is unclear. There was no significant difference among groups in use of rescue medication or in the proportion of patients experiencing vomiting.