<table>
<tr><th>Study</th><th>Population</th><th>Intervention</th><th>Results</th><th>Validity/Conclusion</th></tr>
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<td>Abell et al, 2011
<u>S</u>tudy type:
Crossover RCT. (EndoStim study).

Objective:
To measure the effects of 72 hours of temporary gastric electrical stimulation on gastroparesis symptoms.

Primary outcomes:
Symptoms measured daily; gastric emptying, electrogastrography, and quality of life.

N of patients:
N=58.

Blinding:
Double-blind.

Follow-up:
No patients were lost to follow-up, 13 discontinued the intervention and 45 (77.6%) were included in the analysis.</td>
<td>Inclusion criteria:
Men and women 18-70 years old, <u>></u>1 year history of symptomatic gastroparesis of DM, postsurgical or idiopathic etiology. Patients refractory or intolerant to antiemetic drug classes and experiencing >7 episodes of chronic vomiting or nausea per week irrespective of gastric emptying time.
Exclusion criteria:
Acute infection of any kind, enrollment in another study, pregnancy, not a candidate for endoscopy, unwillingness or inability to provide informed consent and to return for follow-up visits.
Patient Characteristics:
Mean age 46 years (range 23-77), 81% females, 22% DM, 72% had vomiting symptoms, 98% nausea. Baseline vomiting score was significantly higher in group B (2.68) vs. 1.82 vs. in group A (p=0.04).</td>
<td>All subjects underwent an endoscopic implantation of lead/electrode. The lead was then attached to an external stimulator. The study participants were then randomized to one of two study groups;
<u>Group A N=28):</u>
The stimulators were activated (ON) continuously for days 1-3. (session 1). No stimulation (OFF) for a 24-hours washout period (day 4) and deactivated (OFF) for days 5-8 (session 2).

<u>Group B (n=30):</u>
The stimulators were not activated (OFF) for days 1-3 (session 1). No activation (OFF) for a 24-hours washout period (day 4) and then activated (ON) for days 5-8 (session 2).

Symptoms were measured daily (days 0-8). Gastric emptying, electrogastrography, and health related quality of life were assessed at baseline (day 0) and at days 4 and 8.</td>
<td>Treatment results
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<tr><th></th><th></th><th>Vomiting score (95% CI)</th><th>Nausea</th><th>Total symptom score</th></tr>
<tr><td>Session 1</td><td>Group A Stim (ON) Daily change</td><td>-0.40 (-0.51,-0.29) P <.001</td><td>-0.33 (-0.45,-0.22) P <.001</td><td>-1.30 (-1.76,-0.85) P <.001</td></tr>
<tr><td></td><td>Group B Stim (OFF) Daily change</td><td>-0.28 (-0.40,-0.17) P <.001</td><td>-0.40 (-0.51, -0.28) P <.001</td><td>-1.63 (-2.10,-1.16) P <.001</td></tr>
<tr><td>Session 2</td><td>Group A Stim OFF) Daily change</td><td>0.08 (-0.08,0.23) P <.329</td><td>-0.02 (-0.18, 0.14) P <.841</td><td>-0.20 (-0.83,0.42) P <.516</td></tr>
<tr><td></td><td>Group B Stim (ON) Daily change</td><td>-0.04 (-0.19,0.11) P =.606</td><td>0.04 (-0.12,0.21) P <.585</td><td>0.12 (-0.51,0.75) P <.700</td></tr>
<tr><td colspan="2">Total Treatment effect pooled across periods</td><td>-0.12 (-0.26, 0.03) P <.116</td><td>-0.06 (-0.21,1.09) P <.431</td><td>-0.33 (-0.92,0.27) P <.277</td></tr>
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Scores did not return to baseline at day 4 (washout period)

There was no significant improvement in gastric emptying.

Subgroup analysis showed that patients with diabetes mellitus (N=13) had stronger treatment effects on vomiting scores (-0.13 units /day with stimulation) but the difference was not statistically significant (p=0.069)

The electrodes were dislodged for 13 patients during days 4-7.</td>
<td>The study was randomized and controlled but had several limitations. The crossover design is not the ideal design for evaluating such a device as it does not allow examining the placebo effect of the device. In addition it was relatively small, included older patients than that allowed by the protocol, there were significant baseline differences between he two groups in their baseline vomiting score, the leads were dislodged in 13 patients, and the washout period was too short. In addition, only less than one fourth of the participants had a DM etiology for the gastroparesis. Overall, the results of the study show significant improvement in the two groups irrespective of stimulation which may be due to a placebo effect. There was also no significant difference in symptoms across the periods.</td>
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