Intra-abdominal Vagal Blocking (VBLOC Therapy): Clinical Results with a New Implantable Medical Device

DESCRIPTION

Prospective, open-label, baseline-controlled, multi-center trial

31 subjects

3 centers

6-month follow-up

RESULTS & SUMMARY

vBloc was associated with both a significant weight loss and a desirable safety profile.

+ Calorie reduction was accompanied by earlier satiation and reduced hunger

+ 25% of patients lost >25% EWL at 6 months

+ Plasma pancreatic polypeptide (PP) responses were suppressed. Average % EWL in patients with PP response <25 pg/mL was double that with PP response >25 pg/mL (p=0.02). Greater PP response resulted in greater weight loss

+ 3 SAEs, none were device or therapy related

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<thead>
<tr>
<th>Parameters</th>
<th>Wk 4</th>
<th>Wk 12</th>
<th>Mo 6</th>
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<tbody>
<tr>
<td>EWL (%)</td>
<td>7.5</td>
<td>11.6</td>
<td>14.2</td>
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<tr>
<td>Calorie Intake</td>
<td></td>
<td>Decreased &gt;30%</td>
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Camilleri 2008


The Maestro® Rechargeable System is indicated for use in weight reduction in patients aged 18 years through adulthood who have a Body Mass Index (BMI) of 40 to 45 kg/m², or a BMI of 35 to 39.9 kg/m² with one or more obesity related co-morbid conditions, and have failed at least one supervised weight management program within the past five years. The device should not be implanted in patients with cirrhosis, portal hypertension, esophageal varices or a significant hiatal hernia; patients for whom magnetic resonance imaging (MRI) or diathermy is planned; patients with an implanted electrical medical device or gastrointestinal device or prosthesis.

The most common related adverse events include pain, heartburn, nausea, dysphagia, eructation, and abdominal cramping.

Carefully read the product instruction manuals for complete safety information.

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