Clinical Evidence
Shikora 2014

Midterm Results of Reversible Vagal Nerve Blocking (VBLOC) in Obese Patients Suffering from Type 2 Diabetes Mellitus (T2DM): The DM2 Study

DESCRIPTION

Open-label, multi-center, obese subjects with T2DM

Midterm 36-month outcomes

28 subjects
n=18 subjects at 36 months

RESULTS & SUMMARY

- Medically meaningful weight loss, improvements in diabetes control; benefits sustainable to at least 36 months after implant.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>36-month follow-up</th>
<th>Change from baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg)</td>
<td>98±3</td>
<td>-8.8</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>7±0.3</td>
<td>-0.6</td>
</tr>
<tr>
<td>FPG (mg/dL)</td>
<td>132±8</td>
<td>-24.0</td>
</tr>
<tr>
<td>WC (cm)</td>
<td>114±2</td>
<td>-7.0</td>
</tr>
<tr>
<td>MAP (mmHg)</td>
<td>91±4</td>
<td>-7.3</td>
</tr>
</tbody>
</table>

EWL was 24.3% compared to baseline values

No significant complications or untoward events

FPG = fast acting plasma glucose
WC = waist circumference
MAP = mean arterial pressure

To learn more, visit www.vBloc.com

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.

vBloc and Maestro are trademarks of EnteroMedics, Inc.
© 2015 EnteroMedics, Inc. All rights reserved.