

Shikora 2015

International Federation for The Surgery of Obesity and Metabolic Disorders 2015, 26-29th August 2015, Vienna, Austria, Oral presentation 0.201.

Reversible Vagal Nerve Blocking (VBLOC) in Patients with Moderate Obesity and an Obesity Related Co-morbid Condition: The ReCharge Study

DESCRIPTION

Twelve month results from the randomized, controlled ReCharge Clinical Trial	<i>n=46 active subjects</i> <i>n=27 sham subjects</i>
Moderately obese subjects (BMI 35–40)	

RESULTS & SUMMARY

vBloc therapy resulted in medically meaningful weight loss. Improvements in blood pressure, heart rate and lipids were shown in vBloc group. Improvements were observed in the sham group commensurate with weight loss.

+ Mean EWL at 12 months in the per-protocol group was 34±26% (95% CI, 26 to 41) in vBloc group and 19±18% (95% CI, 12 to 27) in sham group

Parameter	Baseline	12 Months	Change	95% CI
SBP (mmHg)	130±11	124±13	-5.6±13	[-9.5, -1.6]
DBP (mmHg)	80±9	78±8	-2.7±9	[-5.4, 0.1]
Fasting Glucose (mg/dL)	101±20	93±14	-7.3±15	[-12.1, -2.5]
HR (bpm)	76±10	70±8	-6.4±10	[-9.3, -3.6]
Total Cholesterol (mg/dL)	216±36	202±37	-13.2±34	[-23.6, -2.9]
HDL (mg/dL)	55±16	55±13	0.2±9	[-2.6, 3.0]
LDL (mg/dL)	131±35	123±34	-6.6±33	[-16.7, 3.4]
TG (mg/dL)	150±62	117±53	-34.0±57	[-51.3, -16.6]

Mean±S.D.

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.