Clinical Evidence

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vBloc neurometabolic therapy

Intermittent Vagal Nerve Block for Improvements in Obesity, Cardiovascular Risk Factors, and Glycemic Control in Patients with Type 2 Diabetes Mellitus: 2-Year Results of the VBLOC DM2 Study

DESCRIPTION

Prospective, open-label, multicenter, obese subjects with DM2	*n=28 subjects*
24-month follow-up	

RESULTS & SUMMARY

- Improvements in obesity and glycemic control were largely sustained after 2 years of treatment with vBloc therapy with a well-tolerated risk profile.

- \+ 2 related SAEs (reposition of neuroregulator for pain at the neuroregulator site and revision of a lead following lead breakage)
- \+ Among 23 subjects with medication data, 83% were able to maintain, decrease or discontinue their diabetes medications

Parameters	Mean at baseline	Estimated mean change at 24 months (p value)
All subjects (n=28)		
EWL (%)	-	22 (p<0.0001)
TWL (%)	-	6.9 (p<0.0001)
HbA1c (%)	7.8	−0.6 (p=0.003)
FPG (mg/dL)	151	−15 (p=0.056)
SBP (mmHg)	124	−2 (p=0.62)
DBP (mmHg)	80	−2 (p=0.46)
MAP (mmHg)	95	−2 (p=0.48)
WC (cm)	120	−7 (p<0.0001)
Hypertensive subjects at baseline (n=15)		
SBP (mmHg)	131	−10 (p=0.02)
DBP (mmHg)	85	−6 (p=0.042)
MAP (mmHg)	100	−7 (p=0.014)

FPG = fasting plasma glucose
SBP = systolic blood pressure (mmHg)
DBP = diastolic blood pressure (mmHg)
MAP = mean arterial pressure
WC = waist circumference

Important Safety Information
Carefully read the vBloc® Therapy Instruction manuals for complete indications, contraindications, warnings, precautions and potential adverse events, and full instructions.

Indications: 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/m^2, or a BMI of 35 to 39.9 kg/m^2 with one or more obesity related co-morbid conditions, and have failed at least one supervised weight management program within the past five years.

Contraindications: The device should not be implanted in patients: who have cirrhosis/portal hypertension/esophageal varices/ clinically significant hiatal hernia; for whom MRI/diathermy is planned; at high risk for surgical complications; or who have an implanted electronic device or gastrointestinal device/prosthesis.

Warnings/Precautions/Adverse Events: Certain medical therapies/procedures may cause patient injury/nerve damage/burns/ heating/pain; may cause damage to/dislodgement of the implanted device; and may turn therapy off. These include lithotripsy/ radiation/mono polar electrosurgical tools/PET scans/radiofrequency ablation. Patients who attempt to move the implanted device may move/damage/disconnect the system components. The system must be kept charged to prevent damage, which may require surgery. The neuroregulator should be fully charged prior to turning it off. Lead impedance testing should only be performed using equipment approved by EnteroMedics to prevent patient injury. Continued therapy with a fractured lead may cause pain/inflammation/nerve damage. The Maestro System is MR Unsafe, including when the device is explanted and not all parts are removed. The system may interact with other implanted/body worn devices. Portable outlets/extension cords should not be connected to the AC recharger. Do not immerse external system components in fluid. Keep strong magnets at least 6 inches from the implanted device. The neuroregulator and mobile charger should be turned off in the presence of metal detectors, other security systems, strong magnetic fields and RF emitters including RFID systems to prevent activation/interference. The mobile charger should be turned off while on aircraft. The system should only be implanted by surgeons trained in its implantation. Infection at the implant site may occur and could require use of antibiotics/surgery/device explant. Do not modify system components. Interference from radio frequency transmitters in close proximity to system components may impact system function. Safety and effectiveness has not been established for use within a hyperbaric chamber/with external defibrillation/ during pregnancy/for use in patients under 18 years of age. Battery capacity will diminish over time, requiring longer/more frequent charging. Patients with impaired vision may not be able to operate the system. The most common related adverse events that were experienced during clinical study included pain/heartburn/nausea/dysphagia/eructation/abdominal cramping.

To learn more, visit www.vBloc.com

vBloc
neurometabolic therapy

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

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