SELECTING VAGAL BLOCKING ELECTRICAL ALGORITHMS FOR OBESITY TREATMENT

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Background
Excess weight loss (EWL) has been reported using a first generation medical device that intermittently blocks both vagi near the esophagogastric junction using laparoscopically implanted electrodes delivering high-frequency algorithms.

Aim
To compare the EWL of a second generation vagal blocking device with that of a first generation device

Methods
Retrospective analysis of data from the initial trial was used to select the best therapy algorithms. Then, in the next trial of obese patients implanted with the second generation device, vagal block was initiated using the analysis based selected therapy algorithms (STAs). Patients were followed for EWL and safety, including adverse events (AEs) up to 6 months.

Results
Parameter estimate analysis revealed greater EWL in patients with therapy algorithm durations of 90-150 seconds compared to shorter or longer durations ($p<0.01$). Twenty-seven subjects (mean BMI: 39.3±0.8) were implanted in the second trial and programmed with STAs of 120 seconds. EWL with the second generation system at 6 months was 22.7±3.1% (n=24) compared with an EWL of 14.2±2.2% (n=29) with the first generation device. For both devices, a higher number of STAs per day was associated with greater EWL ($p=0.03$). There were no deaths or unanticipated adverse device effects and no medically serious AEs associated with the second generation device.

Conclusions
Improved EWL efficacy was observed with the second generation vagal blocking device compared with the first generation device. Furthermore, greater weight loss was associated with enhanced delivery of STAs. Lastly, a good safety profile was observed with this.