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Letter to the Editor: Vagal Blocking (vBloc) Therapy; A New Era of Clinical Therapy for Extreme Obesity

Shannon K. Boi, MS^{1,2,*}, Justin X. Moore, MPH^{1,3}, Kendra J. Royston, BS^{1,4}, and Wendy Demark-Wahnefried, PhD, RN^{1,5}

¹University of Alabama at Birmingham (UAB) Comprehensive Cancer Center, University of Alabama at Birmingham, Birmingham, AL

²Graduate Biomedical Sciences – Immunology Theme, University of Alabama at Birmingham, Birmingham, AL

³Department of Epidemiology, University of Alabama at Birmingham, Birmingham AL

⁴Department of Biology, University of Alabama at Birmingham, Birmingham, AL

⁵Webb Endowed Chair of Nutrition Sciences, Department of Nutrition Sciences, University of Alabama at Birmingham, Birmingham, AL

Obesity is associated with increased risks of multiple health conditions, such as cardiovascular disease, type II diabetes and cancer [1–5]. Alarming, roughly 67% of American adults are obese or overweight [6, 7], and obese or overweight adults comprise approximately 40% of the population more globally [8]. Subsequently, effective intervention strategies for reducing excess weight are needed to combat the rising epidemic of obesity. Therefore, we are encouraged by the recent article by Apovian et al. (2016) who presented 2-year outcomes of the ReCharge trial – a trial testing the efficacy and safety of a surgically-implanted device (Maestro Rechargeable System, EnteroMedics, St. Paul, MN) that provides patients with electrical blocking signals to both trunks of the intra-abdominal vagus nerve (vagal blocking device [vBloc] therapy) [9]. The primary goal of the device is to provide meaningful, sustained weight loss in individuals with obesity as a less invasive alternative to bariatric surgery by potentially reducing hunger sensations. Participants were limited to subjects who had a body mass index (BMI) of 35–40 kg/m² with one or more obesity-related comorbidities, or individuals who had a BMI of 40–45 kg/m², regardless of comorbidity status. Subjects were enrolled at eight sites in the United States and two sites in Australia. The current report evaluated the weight loss efficacy, safety, effects on obesity-related comorbid conditions, and overall quality of life at 2-year follow-up of the planned five-year study. Apovian et al. (2016) concluded that participants reduced excess weight by 21% (8% total weight loss), and reported accompanying improvements in quality of life and

*Corresponding Author: Shannon K. Boi, MS, University of Alabama at Birmingham, 1824 6th Avenue South, WTI 301C, Birmingham, AL 35233, sboi@uab.edu, Phone: (205) 996-0166.

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cardiovascular/metabolic parameters. Moreover, the prevalence of adverse events was minimal (4%) among vBloc therapy participants, with a majority of events classified as mild or moderate in severity [9]. These results provide valuable clinical evidence on vBloc therapy that could be critical to the reduction of obesity worldwide.

Our primary interest in ReCharge relates to the possible effects that vBloc therapy has on inflammation. Emerging evidence suggests that cross-talk between the nervous system and the immune system is essential for fine-tuning and controlling inflammatory processes (termed the ‘inflammatory reflex’) [10]. Pavlov and Tracey (2012) suggest that the vagus nerve is involved in obesity pathogenesis through altered immune and metabolic regulation; of particular note, vagus nerve activity has been shown to be decreased in obesity [10]. Therefore, we are hopeful that Apovian et al. have plans to investigate potential alterations of immune parameters within the ReCharge cohort, as this study presents a unique opportunity to add to the growing body of literature on this subject.

Our interest in the long-term management of obesity and its potential impact on inflammation stems from the fact that both factors are increasingly associated with the incidence and progression of cancer [11–13]; however, inflammation alone obviously contributes to a host of different diseases. Though the sample size of ReCharge precludes an analysis of direct cancer outcomes, an analysis of intermediate inflammatory biomarkers could nonetheless add substantially to extant literature if stored samples exist and could be analyzed. Therefore in summary, we appreciate the contribution that ReCharge makes to the sparse amount of literature that currently exists regarding effective long-term weight management strategies; however, we urge the investigators to consider additional analyses of immune markers that could make broad cross-cutting contributions to several different fields.

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