ELSEVIER

Surgery for Obesity and Related Diseases ▮ (2016) 00–00

SURGERY FOR OBESITY AND RELATED DISEASES

Position statement

American Society for Metabolic and Bariatric Surgery position statement on vagal blocking therapy for obesity

Pavlos Papasavas, M.D.[a], Maher El Chaar, M.D.[b], Shanu N. Kothari, M.D.[c,*], on behalf of the American Society for Metabolic and Bariatric Surgery Clinical Issues Committee

[a]*Department of Surgery, Hartford Hospital, Hartford, Connecticut*
[b]*The Medical School of Temple University/St Luke's University Hospital and Health Network, Allentown, Pennsylvania*
[c]*Department of General Surgery, Gundersen Health System, La Crosse, Wisconsin*

Received December 2, 2015; accepted December 3, 2015

The following statement is issued by the American Society for Metabolic and Bariatric Surgery in response to a recent approval by the US Food and Drug Administration (FDA) of a new device for weight loss called vagal blocking therapy for obesity (VBLOC) in patients with a body mass index (BMI) 35 to 45 kg/m^2. The recommendation is based on current clinical knowledge and published peer-reviewed scientific evidence available at this time. The statement is not intended as, and should not be construed as, stating or establishing a local, regional, or national standard of care.

The vagus nerve plays a significant role in the regulation of stomach functions (meal-evoked fundic relaxation, antral contractions, and gastric emptying), secretion of ghrelin, pancreatic endocrine and exocrine secretion, and glycemic control. Truncal vagotomy can result in weight loss. In a study by Kral, 21 obese patients underwent truncal vagotomy and lost 20 ± 4 kg (range 0–51) at 12 to 40 months postoperatively; however, longer follow-up showed limited efficacy [1,2]. Truncal vagotomy may be accompanied by transient and chronic side effects, such as diarrhea, vomiting, and weight regain through compensatory mechanisms.

VBLOC, a new therapy for obesity, induces intermittent intra-abdominal vagal blocking with the use of high-frequency electrical energy. The development of this technology was based on short-term animal studies, which proved the concept that intermittent vagal blocking leads to weight loss without permanent damage to the vagus nerves [3,4]. The long-term effect of intermittent blocking of the human vagus nerve is unknown. Two C-shaped electrodes are positioned laparoscopically on the anterior and posterior vagal trunks near the gastroesophageal junction and are connected to a rechargeable neuroregulator placed in a subcutaneous pocket on the lateral aspect of the thoracic wall. VBLOC may adjustably deliver signals for 12 or more hours daily at a frequency of 5000 Hz, amplitude between 3 and 8 mA, and a duty cycle, 5 minutes blocked and 5 minutes unblocked. The intermittent block of the vagus nerve may allow for nerve recovery, potentially preventing tachyphylaxis. Patients are required to charge the device for 60 to 90 minutes twice a week with the use of an external transmit coil.

Three open label [5–7] and 2 randomized double-blind, sham-controlled clinical trials [8,9] with a follow-up extending to 18 months have been published [10]. In the first randomized trial (EMPOWER trial), a double-blind, prospective, multicenter trial, 294 patients were implanted with the device and randomized into treated (n = 192, device was activated) or control (n = 102, device remained deactivated) groups [8]. The mean preoperative BMI was 41 ± 1 kg/m^2 for both the treated and control groups. At 12 months, the excess weight loss (EWL) was similar between the treated and control groups (17 ± 2% for the treated group and 16 ± 2% for the control group). The adverse event rate was 3%. In the second randomized trial (ReCharge trial), the mean preoperative BMI was 41 ± 3 kg/m^2 in the treated (n = 162) and sham (n = 77) groups [9]. The sham group underwent implantation of a neuroregulator without implantation of the leads. Participants and follow-up staff were blinded for a minimum of 12 months. The mean difference in EWL between the treatment group and the sham group was statistically significant at 8.5% (24.4% in the treatment group versus 15.9% in the sham group); however, it did not meet the 10% target of the

*Correspondence: Shanu N. Kothari, MD, FACS, Department of General Surgery, Gundersen Health System, 1900 South Avenue C05-001, La Crosse, WI 54601, USA.
E-mail: snkothar@gundersenhealth.org

http://dx.doi.org/10.1016/j.soard.2015.12.004

study. The device-related adverse event rate was 3.7%. A study update [10] with 18-month follow-up showed an EWL of 23.5% (8.8 % total weight loss) in the treatment group versus 10.2% in the sham group (3.8% total weight loss). At 18 months, 54% of the treatment group patients achieved more than 20% EWL, and 41% achieved more than 25%. Patients in the sham group regained over 40% of their EWL by 18 months, and most of this weight gain took place before the unblinding of the patients. Overall, the most commonly reported related adverse events were heartburn, dyspepsia, abdominal pain, belching, and dysphagia. Most of these adverse events were transient and resolved spontaneously. There was one case of gastric perforation at the gastroesophageal junction during removal of the device. The revisional surgery rate at 18 months was 6.8%.

In another small prospective study of 26 patients with type 2 diabetes followed up for 12 months, VBLOC resulted in 25% EWL, improvement in HbA1C and reduction of blood pressure in patients with hypertension [7].

The quantity of the data available at this time (6 published studies [5–10]; approximately 600 implanted devices) and the length of follow-up indicate adequate safety and efficacy in the short term. More prospective studies with longer follow-up are required to establish the clinically significant efficacy and patient tolerance of this device. The Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program is an ideal venue to track the data on this procedure beyond the reported 18 months to monitor durability of weight loss, adverse events, and long-term efficacy. The American Society for Metabolic and Bariatric Surgery currently supports the following regarding VBLOC for the treatment of obesity and encourages members to participate in post-FDA approval studies:

1. Reversible vagal nerve blockade has been shown to result in statistically significant EWL at 1 year compared with a control group in one of 2 prospective randomized trials.
2. Reversible vagal nerve blockage has been shown to have a reasonable safety profile with a low incidence of severe adverse events and a low revisional rate in the short term. More studies are needed to determine long-term reoperation and explantation rates.
3. The prospective collection of VBLOC outcomes as part of the national center of excellence databases is encouraged to establish the long-term efficacy of this new technology.

Disclosures

The authors have no relevant conflicts of interest to disclose.

References

[1] Kral JG, Görtz L. Truncal vagotomy in morbid obesity. Int J Obes 1981;5(4):431–5.
[2] Kral JG. Surgical treatment of obesity. Med Clin North Am 1989;73 (1):251–64.
[3] Tweden KS, Toouli J, Herrera MF, et al. Vagal blocking for obesity control (VBLOC): studies of pancreatic function and safety in a porcine model. Obes Surg 2006;16(8):988.
[4] Tweden KS, Saar MG, Camilleri M, et al. Vagal blocking for obesity control (VBLOC): studies of pancreatic and gastric function and safety in a porcine model. Surg Obes Relat Dis 2006;2(3):301–2.
[5] Camilleri M, Toouli J, Herrera MF, et al. Selection of electrical algorithms to treat obesity with intermittent vagal block using an implantable medical device. Surg Obes Relat Dis 2009;5(2):224–9.
[6] Camilleri M, Toouli J, Herrera MF, et al. Intra-abdominal vagal blocking (VBLOC therapy): clinical results with a new implantable medical device. Surgery 2008;143(6):723–31.
[7] Shikora S, Toouli J, Herrera MF, et al. Vagal blocking improves glycemic control and elevated blood pressure in obese subjects with type 2 diabetes mellitus. J Obes 2013;2013:245683.
[8] Sarr MG, Billington CJ, Brancatisano R, et al. EMPOWER Study Group. The EMPOWER study: randomized, prospective, double-blind, multicenter trial of vagal blockade to induce weight loss in morbid obesity. Obes Surg 2012;22(11):1771–82.
[9] Ikramuddin S, Blackstone RP, Brancatisano A, et al. Effect of reversible intermittent intra-abdominal vagal nerve blockade on morbid obesity: the ReCharge randomized clinical trial. JAMA 2014;312(9):915–22.
[10] Shikora SA, Wolfe BM, Apovian CM, et al. Sustained weight loss with vagal nerve blockade but not with sham: 18-month results of the ReCharge trial. J Obes 2015 2015:365604.