

Device blocking stomach nerve signals shows promise in obesity

A new implantable medical device, developed in collaboration with Mayo Clinic researchers, shows promise as a reversible and less extreme alternative to existing bariatric surgeries, according to findings published in the current issue of the journal *Surgery*.

In a six-month open label trial involving three medical centers in Australia, Mexico and Norway, the 31 obese participants who received the vagal nerve blocking device, also called VBLOCTM vagal blocking therapy, lost an average of nearly 15 percent of their excess weight. A quarter of the participants lost more than 25 percent, and three patients lost more than 30 percent.

Michael Camilleri, M.D., is a gastroenterologist who helped design the study and one of the Mayo Clinic researchers whose previous work and know-how contributed to development of the device in collaboration with EnteroMedics, Inc. Dr. Camilleri says the goal is to find a less drastic alternative to bariatric surgery that will still yield significant weight loss. Bariatric surgery techniques include "banding" -- placement of a band around the top part of the stomach to reduce its capacity -- or bypass procedures which reroute food and remove part of the stomach.

"For this study, we wanted to get an initial assessment of whether blocking the vagus nerve electrically could cause obese patients to feel full after a normal-sized meal," Dr. Camilleri explains. "Patients were not put on any restricted diets or given counseling that typically accompanies gastric banding or bypass. We wanted to determine how much weight loss could be attributed to the device alone."

Dr. Camilleri says VBLOC therapy is similar to a heart pacemaker, but instead of stimulating a normal, regular heartbeat, it uses high-frequency electricity to block the nerve impulses between the brain and the stomach and pancreas. A pacemaker continuously monitors the heart and regulates its beating. But the patient flips a switch to activate the VBLOC device when the system is worn during the daytime hours so that the blocking signal can influence how the stomach functions and food is digested following a meal.

The lead wires are implanted in the abdomen laparoscopically, with electrodes attached to the vagal nerves and the neuroregulator, a pacemaker-sized device, is implanted just under the skin. While gastric bypass involves removing portions of the digestive tract and rerouting the flow of food and, therefore, is not reversible, the VBLOC delivery system can be removed if desired, and previous studies in animals have indicated that it does not damage or permanently affect the vagal nerves. With VBLOC, there is no distortion of digestive system anatomy as is the case with both gastric bypass and gastric banding, and to date there have been no significant issues related to food intolerance, nausea or vomiting as is common with both bypass and banding.

Dr. Camilleri was involved in designing the study, but because Mayo Clinic physicians and scientists participated in the development and preclinical testing of the device, the initial clinical research was conducted elsewhere to avoid having results affected by a conflict of interest. The participating centers for the initial study were Flinders Medical Centre, Adelaide, Australia; Instituto Nacional de la Nutricion (INNSZ), Mexico City; and St. Olav's University Hospital, Trondheim, Norway. James Toouli, M.D., Ph.D., of Flinders, is the co-lead author with Dr. Camilleri of the study findings published in *Surgery*.

Dr. Camilleri says a follow-up double-blinded study, which will involve up to 300 patients at multiple medical centers including a limited number from Mayo Clinic, will be important for gauging the device's

true effectiveness.

"In an open label study such as the one being published this month, there is always potential for the device to 'work' because patients believe it will," he explains. "In the next study, which has already begun, all patients will have the device implanted, but one-third will not have it turned on during the first year of the study, so that after meals, it won't be blocking the nerve signals; this is called 'sham' treatment. Neither the patients nor their doctors will know whether the blocking signals are going through or not. This "pivotal" study will tell us whether a placebo effect is responsible for some of the weight loss.

"After the pivotal study is completed, those who had the 'sham' treatment will have their devices turned on so they can experience the benefits," Dr. Camilleri says. "And unlike the first study, participants also will have access to behavioral counseling and dietary modifications, which will lead to a more realistic comparison of the magnitude of weight loss through vagal blockade as compared with bariatric surgery. The findings published this month are promising, but the next study will tell us whether VBLOC therapy is a viable alternative to gastric bypass or gastric banding, and for which patients."

Source: Mayo Clinic

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