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## Treating Obesity: Vagal Blocking Therapy

In the past, bilateral truncal vagotomy had been used to treat patients with peptic ulcer disease. Astute clinicians noted that these patients had a loss of appetite following the procedure. How did this eventually lead to the development of a new treatment for obesity?

Welcome to the Clinician's Roundtable. I am Dr. Leslie Lundt, your host, and with me today is Dr. Michael Camilleri. Dr. Camilleri is a gastroenterologist and professor of medicine and physiology at the Mayo Clinic College of medicine where he received the Mayo Clinic Department of Internal Medicine Research Career Achievement Award and the Distinguished Investigator Award. He is currently the editor of the AGA Perspective.

### DR. LESLIE LUNDT:

Dr. Camilleri, how does interfering with the vagus nerve produce appetite changes?

### DR. MICHAEL CAMILLERI:

Well, there are several functions that are supported by the function of the vagus nerve. The vagus nerve is a connection between the vagal nerve centers and the brainstem and the stomach, but it also sends connecting messages to areas that control appetite such as the hypothalamus. Essentially, the vagus nerve sends messages in 2 directions, one is between the brainstem and the stomach and the others between the stomach and the brainstem and so sensations of fullness of appetite are mediated through the presence of food and content within the upper gastrointestinal tract. So that's the sense of

the side of the vagus nerve, but at the same time the vagus nerve also serves to convey messages that induce digestive function in the upper gastrointestinal tract. So, for example, the vagus nerve is responsible for stimulating acid and enzyme production by the stomach of making the stomach contract to break down food to a small size, to induce gastric emptying and also ultimately to induce contraction of the gallbladder and secretion from the pancreas that are essential for the chemical digestion of food. So as one can see the vagus is almost like a superhighway that conveys information in both directions and it's critically important for sensation of food, appetites, and also digestion.

**DR. LESLIE LUNDT:**

How did the vagal blocking therapy come about?

**DR. MICHAEL CAMILLERI:**

There has been a lot of work that has been done with using electrical signalling to change functions of different organs and the classical example for that would be the use of a pacemaker in the heart. For many years, research that was done in the 1960s to 1980s, some of which was done here at Mayo Clinic, had demonstrated the critical importance of the vagus nerve to the functions that we mentioned earlier, particularly the digestion of food, the breakdown of solid food in the stomach and its emptying. Also some of the observations were made by clinicians in the 1950s, who as you mentioned earlier, had demonstrated that people who had had vagal injury or vagotomy for peptic ulceration often lost weight and they had poor appetite and so putting all of this together and understanding the function of the vagus nerve in gastric motility, emptying, and digestion, it lends itself to posing the question if you block the function of the vagus nerve in humans, can you induce the same changes that were either produced by cutting the vagus nerve in gastric surgery or inhibiting the function of the vagus nerve by pharmacological approaches in experimental animals. So there was a lot of background information that comes from clinical observation, from studies of physiology in humans and in animals that resulted in proposing this vagal blocking therapy.

**DR. LESLIE LUNDT:**

Tell us about the procedure, how do you do it?

**DR. MICHAEL CAMILLERI:**

Essentially, it's like inserting a pacemaker in the heart, but there is a slight difference, obviously. The pacemaking wires are embedded into the muscle of the heart whereas the pacemaker wires that are used in this V-blocking therapy involves putting the wires on the anterior and posterior vagus nerves at the level of the diaphragm. Now the operation has been devised in such a way that it is done

laparoscopically and that is advantageous to many patients, of course. After pacing the wires on the anterior and posterior vagus nerves, the wires are connected to a small computer and battery that is placed under the skin and this internal computer is then managed by an external controller that is placed over the area of that internal device and therefore it can be programmed as required by the physician, so there are ways in which, for instance, one can change the parameters of the electrical stimulation of the nerve, and that brings me to the point that the way in which this device works is that it delivers high frequency, low energy electrical impulses which have been shown in experiments done in animals to block signals that are conveyed to the vagal nerves. So the blocking, in fact, is conducted by an electrical stimulus which is perhaps paradoxical.

**DR. LESLIE LUNDT:**

Who does the procedure, does a GI physician do it or surgeons.

**DR. MICHAEL CAMILLERI:**

The procedure is done by surgeons because it requires laparoscopic placement at least in the current version of these procedures and the devices, they are made in such a way that they require laparoscopic placement, but it's an interesting question you posed because there are now approaches that are being developed such that a gastroenterologist or a gastroenterological surgeon who is an expert in endoscopy may eventually be able to perform an operation through the esophagus or the top of the stomach and with the endoscope find these vagus nerves, which as we know, are outside the esophagus and stomach and implant the electrodes on to the vagus nerves in that manner. You might ask how are you going to get from inside the esophagus or inside the stomach to get to the vagus nerves that are on the wall outside the stomach; that's where the research is currently going on, but there are approaches that are still experimental that are being developed which will possibly in the future allow the endoscopist to make a tiny hole in the wall of the distal esophagus or proximal stomach in order to place these pacing wires on to the vagus nerves and then closing the hole with an endoscopic clip and then coming out. Now, of course, that's still probably several years away, but it is conceivable that this might be an approach that might be applicable in the future.

**If you are just joining us, you are listening to the clinician's round table on ReachMD, The Channel for Medical Professionals. I am Dr. Leslie Lundt, your host, and with me today is Dr. Michael Camilleri. We are discussing VBLOC, vagal blocking therapy for obesity.**

**DR. LESLIE LUNDT:**

How safe is the procedure?

**DR. MICHAEL CAMILLERI:**

Well, the experience we have up to now is in the first 30 or 31 patients that have been studied in the first clinical trial. In that study, the procedure was extremely safe, rarely patients had slow recovery of bowel function like a postoperative ileus, but there was no need for any further operations or any complications like hemorrhage or infection that required a second operation. We have also got very good data on monitoring of pulse and blood pressure which remains normal. That's important because as we all remember the vagus nerve also supplies impulses to the heart and it was conceivable that applying an electrical stimulus to the vagus nerve in the abdomen may have somehow reflexed the induced changes in heart rhythm or heart rate. However, nothing like that was seen, and if anything, the blood pressure recordings that we have over a 3 or 6-month period of time, suggest that there is a normalization of blood pressure in patients who had high blood pressure. This, of course, may be part of the benefit of losing weight, but it is also possible that the signal may have a specific effect on blood pressure control.

**DR. LESLIE LUNDT:**

How many centers are currently performing the procedure?

**DR. MICHAEL CAMILLERI:**

In the first study which had about 30 patients, there were 3 centers and they were in Adelaide, Australia; Mexico City; and Trondheim, Norway. However, there has recently been a United States multi-center study and there were 13 centers throughout the country involved in this study. I am told that the recruitment for that study has now been completed, so regrettably anybody who is interested in having this procedure done may have to wait for the next study to open.

**DR. LESLIE LUNDT:**

So it is still experimental, we can't send our patients yet.

**DR. MICHAEL CAMILLERI:**

That is correct.

**DR. LESLIE LUNDT:**

Who might be the ideal patient for this procedure?

**DR. MICHAEL CAMILLERI:**

Well, I think at the present time the ideal patient would be a male or female between ages of 18 and 65

who have a body mass index of between 35 and 45. So just to put that in perspective, we know that people are regarded as being overweight if their body mass index is between 25 and 30 and they have class I obesity between 30 and 35. It turns out that even from natural history studies that have been published, we are still not sure that a body mass index of between 30 and 35 on its own without obesity complications has any negative impact on people's lives and that's why I think at the present time I would not consider patients who have a body mass index of less than 35 unless there is a complication. For instance, if they have type 2 diabetes or they have obstructive sleep apnea or hypertension or degenerative joint disease, for example, that requires them to protect all of those body functions. So presently I would regard patients between 35 and 45 as the ideal candidates. I am also thinking not to suggest patients over body mass index of 45 because we know that those patients do indeed have those risks to bodily functions and to life because of complications like diabetes, stroke, and heart attack and those I think require a more definitive and a currently approved treatment to bring their risks from obesity down.

**DR. LESLIE LUNDT:**

So what do you see as the future for this vagal blocking therapy, when might it be available clinically?

**DR. MICHAEL CAMILLERI:**

Obviously one has to see the progress from the current study, the current multi-center study will be analyzed sometime in the middle of 2009 and I suspect that that will lead to a subsequent and perhaps final study that will be also coordinated with the help of food and drug administration in order to make sure that the appropriate regulatory considerations are included in the study, so I don't think that this is going to be available for clinical use before 2010.

**DR. LESLIE LUNDT:**

Well, thank you for giving us a preview.

**DR. MICHAEL CAMILLERI:**

You are welcome.

**We have been discussing VBLOC, vagal blocking therapy, as a potential treatment for obesity. Our guest today has been Mayo Clinic gastroenterologist, Dr. Michael Camilleri. I am Dr. Leslie Lundt. You have been listening to the Clinician's Roundtable on ReachMD, The Channel for Medical Professionals. Thank you for listening.**