Electrical Stimulation Aids Chronic Gastroparesis

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LAKE TAHOE, CALIF. — An implanted device that delivers gastric electrical stimulation can relieve chronic gastroparesis in patients who do not respond to drug therapy, Dr. Amar Al-Juburi said at a meeting on gastroenterology and hepatology sponsored by the University of California, Davis.

Called Enterra therapy, the device is approved for humanitarian use in fewer than 4,000 patients per year who have intractable nausea and vomiting from idiopathic or diabetic gastroparesis and whose symptoms cannot be controlled by medications.

Gastric electrical stimulation is "a new tool that has really changed the management of gastroparesis," said Dr. Al-Juburi, of the division of gastroenterology at the university.

He has no relationship with Medtronic Inc., the company that makes the device.

Although institutional review board approval is required before a hospital begins using the device, many medical centers in the United States now offer Enterra therapy, and more than 1,000 of these electrical stimulators have been implanted, he estimated.

A randomized, double-blind, placebo-controlled, crossover trial involving 33 patients helped win approval of the device for humanitarian use. The Worldwide Anti-Vomiting Electrical Stimulation Study began with the device turned on in one group of patients and turned off in a second group.

One month later, the groups switched device status, and were followed for another month. Then all patients were followed with the device turned on for another 10 months for a total of 12 months.

In the first 2 months, gastric electrical stimulation significantly decreased nausea and vomiting, compared with no stimulation; and most patients preferred the time span when the device was turned on (Gastroenterology 2003;125:421-8).

Among the 23 patients followed for 12 months—with the device turned on during 11 of those months—52% showed a greater than 80% reduction in the frequency of vomiting, and 79% had at least a 50% reduction in vomiting.

The mean number of days spent in the hospital by 24 patients decreased from 49 in the year before Enterra therapy to 28 days in the year after implantation.

A summary of scores for nausea, vomiting, anorexia, abdominal pain, and distention in each patient improved significantly at 6 and 12 months, compared with baseline.

Hospitalizations dropped significantly. "That's very important," Dr. Al-Juburi noted. Patients with moderate to severe gastroparesis often show up in emergency rooms and get admitted, and it can be difficult to improve symptoms enough to discharge them.

In the study, the mean number of days spent in the hospital by 24 patients decreased from 49 in the year before Enterra therapy to 28 days in the year after implantation of the device.

"For drug-refractory gastroparesis, this is the way to go," said Dr. Al-Juburi, whose institution just started using the device.

The treatment works through high-frequency stimulation of the autonomic nervous system via a neurostimulator device that's about 2 inches in length by 1 inch in width and 0.5 inch thick.

Surgeons create three or four abdominal 5-mm ports laparoscopically to implant the device; the upper right port is used as a subcutaneous pocket to house the stimulator near the stomach's greater curvature.

Leads from the device are sutured 10 cm from the stomach's pylorus, in the area thought to be responsible for gastric pacing, Dr. Al-Juburi said. An external programmer that's turned on after stimulator implantation can be adjusted to the stimulation parameter that produces the best response.

Implantation of the device takes about 1 hour to perform. In the current study, patients spent a mean of 6 days in the hospital related to the implantation surgery.

"Gastric stimulation is, so far, really a good option for drug-refractory gastroparesis," he said. ■