GERD Implant Technique Shown to Last 3 Years

BY TIMOTHY F. KIRN
Sacramento Bureau

CHICAGO — The polymer injection treatment for gastroesophageal reflux disease, known as Enteryx, outperformed sham surgery and lasted up to 3 years, investigators said in presenting two separate studies at the annual Digestive Disease Week.

Enteryx, a liquid that solidifies into a spongy implant, is injected into the deep muscle layer at or below the esophagogastric junction to increase the competence of the lower esophageal sphincter.

In one of the two studies, investigators led by Jacques Deviere, M.D., compared Enteryx treatment with sham surgery; all patients were dependent on proton-pump inhibitor (PPI) therapy prior to the start of the study.

At 3 months, 68% of 32 patients given the polymer injection treatment were completely off PPI drugs, and another 13% had reduced their use by at least 50%.

In contrast, in the sham surgery group of 32 patients, 41% discontinued PPI use and another 12% reduced PPI use by at least 50%, said Dr. Deviere, chief of the department of gastroenterology at Erasme Hospital of the Free University of Brussels.

In the second uncontrolled study, which involved a 3-year follow-up of 60 patients, the percentage of patients who benefited peaked at 1 year, when 71% were completely off PPI therapy, and another 13% had reduced their PPI use by 50%.

At 3 years, 48% were off PPIs, and another 17% had reduced PPI use by 50%, said Glen A. Lehman, M.D., professor of medicine at Indiana University, Indianapolis.

These two studies are major steps forward toward the adoption of Enteryx treatment—approved by the Food and Drug Administration in 2003—into routine practice, commented Gary W. Falk, M.D., a professor of medicine at the Cleveland Clinic Foundation.

But the specific indications for this treatment are still not clear, because the patients in the trials conducted to date have not been defined except that they have been chronic, PPI-dependent patients.

Quality-of-life heartburn scores in one study improved by a median of 76% relative to baseline when the patients were withdrawn from PPI treatment.

Moreover, caution needs to be exercised in evaluating the treatment because the material that is implanted appears to be permanent, and head-to-head trials with other therapies still need to be performed, Dr. Falk added.

At least 3,000 patients have received Enteryx treatment so far, according to available estimates.

But it is also not exactly clear how the treatment works, Dr. Falk noted.

In all the trials reported so far, including the two new trials, the treatment has not appreciably changed the esophageal pH of most patients it has helped, he added.

It may be that the pH is not changed, but the treatment is reducing the amount of acid escaping from the stomach into the esophagus, Dr. Falk suggested.

Regarding the fall-off in efficacy over time seen in the 3-year follow-up, Dr. Lehman said he could not predict whether that trend would continue.

The study measured esophageal pH at 12 months, but there were no pH measurements taken after that. Moreover, none of the patients were examined endoscopically at 3 years to see if the implant was still present and how it was faring.

Dr. Lehman suggested that the fall-off could be due to patients' becoming unwilling to tolerate discomfort that they initially considered an improvement.

In his study, quality-of-life heartburn scores improved by a median of 76% relative to scores at baseline during a washout period when patients were withdrawn from PPI treatment.

That percentage improvement continued throughout the 3 years, Dr. Lehman noted.

The majority of patients treated with Enteryx experience a transient retrosternal, burning chest pain, and/or dysphagia at first, the investigators noted. However, there were no serious, device-related adverse events in Dr. Lehman's follow-up trial.

In the controlled trial, one patient treated with Enteryx needed an esophageal dilatation procedure because of continuing dysphagia.

The two trials were sponsored by Boston Scientific Corp., Natick, Mass., maker of the Enteryx procedure kit. ■

GERD Surgery Shows Negligible Benefit in Two New Studies

BY TIMOTHY F. KIRN
Sacramento Bureau

CHICAGO — Two new studies cast doubt on the utility of one of the hottest new treatments for gastroesophageal reflux disease: the endoluminal gastric plication procedure known as EndoCinch.

Both studies were sham-surgery studies presented at the annual Digestive Disease Week.

Until now, there have mostly been highly positive reports from uncontrolled case series on the procedure, approved in 2000. One positive, small clinical trial was reported at Digestive Disease Week last year.

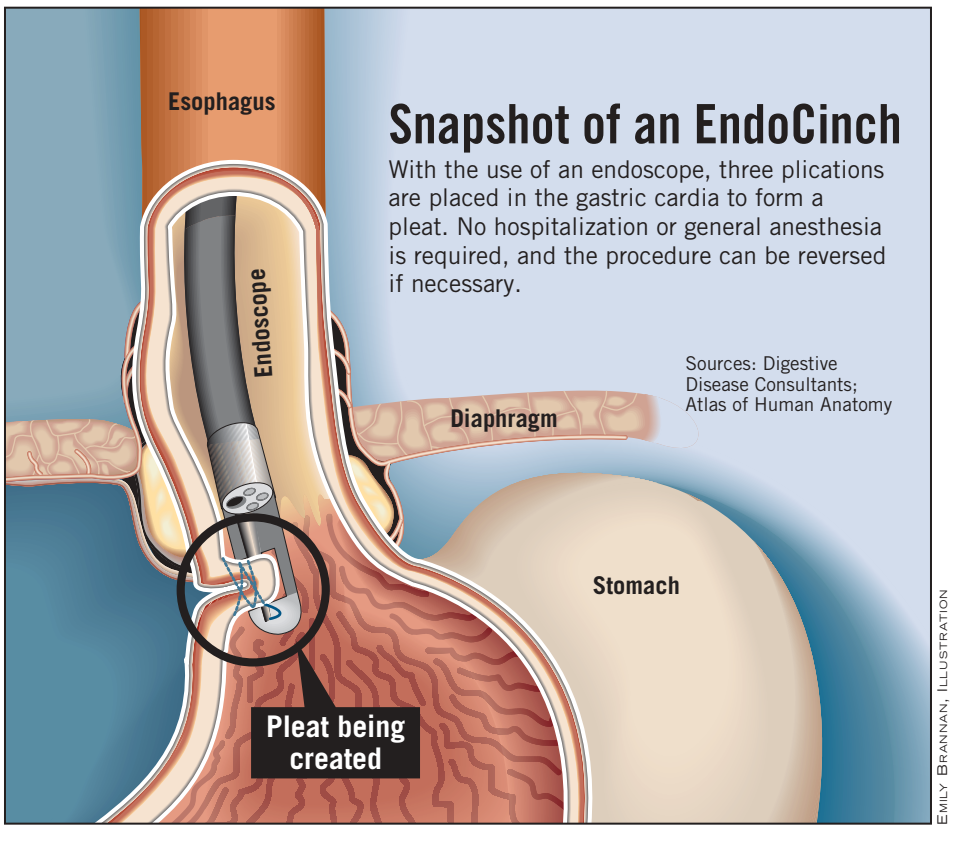
"It's quite amazing that thousands of these procedures have already been done," said one of the study investigators, Matthijs Schwartz, M.D., at a press briefing.

"Probably, we should stop doing this procedure and wait for it to be improved," Dr. Schwartz added.

The main investigator for the other study, Per-Ola Park, M.D., was similarly blunt. "Our conclusion from our study is that the EndoCinch procedure should not be used," he said.

In Dr. Park's study, 47 patients with symptomatic gastroesophageal reflux for at least 1 year were randomized to receive either the EndoCinch procedure or a sham endoscopy. The patients were followed for 1 year.

All but 3 of the 22 patients who had the EndoCinch procedure experienced disease relapse, and almost all of those had relapse within 1 month of the procedure. In fact, there was no significant difference in time to relapse between the two groups, with about 80% of the patients in both groups experiencing relapse within a month.



EMILY BRANNAN, ILLUSTRATION

The remainder of the sham-endoscopy patients had relapse after 1 month, said Dr. Park of Sahlgrenska University Hospital, Gothenburg, Sweden.

Relapse was defined as the need for proton pump inhibitor relief for heartburn, more than 1 day of severe heartburn, 2 consecutive days of moderate heartburn symptoms, or 3 days of mild symptoms.

At 12 months, there was no difference in ambulatory 24-hour pH monitoring, drug use, or health-related quality of life.

Dr. Schwartz's study found that patients who received the real procedure had a reduced need to use a proton pump inhibitor for the first 3 months after the procedure, relative to the sham-treated patients.

But there was no improvement in regurgitation frequency or severity or in esophageal acid exposure, relative to the sham group.

The study included 15 patients who underwent the procedure, 17 patients who had a sham endoscopy, and 13 patients who served as a second control group. It is well known that sham-treated patients in such studies often do quite well, noted Dr. Schwartz, director of endoscopy at the University Medical Center, Utrecht, the Netherlands.

Even though his study found a reduction in proton pump inhibitor use—the study's main outcome—Dr. Schwartz said he was skeptical of that result because it was only for 3 months. "I've seen many of these patients after 3 months, and many do relapse," he said.

Although both investigators urged caution about continued clinical use of the procedure, both also said they were fairly sure that the procedure could be improved.

Dr. Schwartz noted that in his study, the investigators used three plications to create pleats in the gastric cardia, as has become common clinical practice. But previous studies have used four or five, and in his practice, he has gone back to add plications in patients who have not had a good initial result.

Dr. Park said he would still like to see the EndoCinch procedure be made to work because it is reversible, unlike some of the other gastroesophageal reflux procedures, such as the Stretta procedure, which uses microwaves to create scar tissue.

"Perhaps if we come back with more sutures, it will work," he said during the briefing.

Dr. Park's study was sponsored by C.R. Bard Inc., maker of the EndoCinch kit. ■