

Endoluminal Devices to Treat GERD Are Lacking

BY BETSY BATES

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LAS VEGAS — Not long ago, Dr. C. Daniel Smith showed a slide at an American College of Surgeons meeting that proclaimed endoluminal approaches to gastroesophageal reflux disease were “here to stay.”

A mere 2 years later, he’s not so sure. “We’re already reading obits for several of these procedures,” said Dr. Smith, chairman of surgery at the Mayo Clinic in Jacksonville, Fla., at the spring meeting of the ACS.

The curtain closed rapidly on several of the new stars in endoluminal GERD technology, sharply reducing the number of devices and procedures available for use in the United States.

Back in 2005, four devices had been approved and were being marketed for U.S. use and one—the Gatekeeper—appeared to be nearing Food and Drug Administration approval.

But in the interim between then and

now, there have been several new developments:

► Medtronic Inc. withdrew its application for the Gatekeeper device because of concerns over efficacy.

► Boston Scientific Inc. voluntarily recalled the Enteryx liquid chemical polymer augmentation system in response to reports of serious adverse events, including deaths.

► Curon Medical Inc., maker of the Stretta device, declared bankruptcy, ending

sales of that radiofrequency system, at least for now.

The endoluminal GERD device market now includes only the EndoCinch suturing system and the Plicator device, which uses jaws to create a “pleat” of tissue at the gastroesophageal junction.

For reasons that are both economic and practical, it would make sense to have a safe, predictable, and efficacious minimally invasive procedure for GERD, said Dr. Smith. Each year, 700,000 GERD-

related endoscopies are performed and 200,000 patients are evaluated for possible antireflux surgery (although only about 70,000 patients undergo such a procedure).

But any endoluminal approach involves challenges, including the question of whether it would be reimbursed as an endoscopic procedure or as a more lucrative surgical procedure, which specialists would perform it, and whether it would prove truly efficacious in the long term.

Insurer Starts Paying for OTC Omeprazole

Blue Cross Blue Shield of Michigan now is covering Prilosec OTC for heartburn and acid reflux disease, reflecting increasing attention from insurers to over-the-counter drugs as vehicles for savings.

Patients who switch from prescription proton pump inhibitor Nexium (esomeprazole) to Prilosec OTC or generic omeprazole will receive their first prescription or supply for free and will pay their normal generic drug copay on subsequent refills, the insurer announced.

Officials at Blue Cross Blue Shield of Michigan (BCBSM) estimate that members of the plan will save \$9 million in out-of-pocket costs because of the switch; 1.5 million patients are insured by BCBSM, whose customer groups have agreed to the program.


Some patients may save about \$130 a year using Prilosec OTC instead of Nexium, according to the company, which added that employers could save nearly \$20 million in the first year.

“The majority of our members will find that over-the-counter or generic Prilosec will provide the same benefit as the brand name,” said James Lang, vice president for pharmacy services. “We encourage them to discuss making this change with their doctor.”

The coverage decision builds on previous strategies employed by BCBSM and other insurers to drive patients toward lower-cost drug options such as generics and OTCs.

—Christopher Walker, “The Tan Sheet”

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High expectations

for lowering

very high triglycerides (≥ 500 mg/dL)

Important Safety Information:

1. LOVAZA is contraindicated in patients who exhibit hypersensitivity to any component of this medication.
2. Before instituting LOVAZA therapy, it should be confirmed that TG levels are consistently abnormal.
3. LOVAZA should be used with caution in patients with known sensitivity or allergy to fish.
4. The patient's TG, LDL-C and ALT levels should be monitored periodically during LOVAZA therapy. In some patients, LOVAZA increased LDL-C. LOVAZA therapy should be withdrawn in patients who do not have an adequate response after 2 months of treatment.
5. Some studies with omega-3-acids demonstrated prolongation of bleeding time, which did not exceed normal limits and did not produce clinically significant bleeding episodes. Patients receiving treatment with both LOVAZA and anticoagulants should be monitored periodically.
6. There are no adequate and well-controlled studies in pregnant women. Use LOVAZA during pregnancy only if the potential benefit justifies the potential risk to the fetus; and use with caution when administering LOVAZA to breastfeeding women.
7. LOVAZA was well-tolerated in controlled studies. The most common adverse events reported were: eructation, infection, flu syndrome, dyspepsia, rash, taste perversion, and back pain.
8. Please see full prescribing information.

References: 1. Lovaza Prescribing Information. Liberty Corner, NJ: Reliant Pharmaceuticals, Inc; 2007. 2. Data on file, Reliant Pharmaceuticals, Inc. 3. Ginsberg HN. Insulin resistance and cardiovascular disease. *J Clin Invest*. 2000;106:453-458. 4. Stalenhoef AFH, de Graaf JD, Wittekoek ME, Bredie SJH, Demacker PNM, Kastelein JJP. The effect of concentrated n-3 fatty acids versus gemfibrozil on plasma lipoproteins, low density lipoprotein heterogeneity and oxidizability in patients with hypertriglyceridemia. *Atherosclerosis*. 2000;153:129-138. 5. Garg R, Vasamreddy CR, Blumenthal RS. Non-high-density lipoprotein cholesterol: why lower is better. *Prev Cardiol*. 2005;8:173-177.

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The current state-of-the-art surgical alternative, laparoscopic Nissen fundoplication, “is a pretty good operation,” Dr. Smith said. “The gold standard ... is going to have to be unseated before any of the endoluminal therapies gain acceptance.”

The EndoCinch suturing system by Bard Medical Inc., which cinches the lower esophageal sphincter, is not highly efficacious, according to Dr. Smith. Results of using the EndoCinch system at the Mayo Clinic parallel those of published studies, revealing that just 25%-38% of GERD patients are able to discontinue proton pump inhibitor (PPI)

medications following the procedure.

The Plicator device from NDO Surgical Inc. has had better outcomes, with studies showing that more than half of patients can stop taking PPIs and experience significant improvements in their health-related quality of life after they have been treated with the jawlike device.

Results of Stretta trials were promising; although results were not seen after 6 months, outcomes were better at 12-month follow-up evaluations. This may be because, following the radiofrequency ablation to the deep submucosal space at the lower esophageal sphincter, colla-

gen deposition needed time to mature.

Dr. Smith disclosed that he is on the scientific advisory committee for Endogastric Solutions Inc., manufacturer of the EsophyX device, currently available only in Europe. This device allows the operator to isolate the distal esophagus with suction.

The EsophyX then is advanced into the stomach, where it partially retroflexes to allow placement of fasteners around the circumference of the esophagus.

In one study of 84 patients treated using the EsophyX, 77 were no longer taking PPI medications 3 months after the procedure, he said. ■

IBD Information Resource Available

The Crohn's and Colitis Foundation has a new information resource center that is designed to give support and information about those diseases to patients and physicians. It is staffed by public health educators with advanced degrees.

Interpretation services are offered for 170 languages. To get more information, call 888-MY-GUT-PAIN (888-694-8872) or visit the Web site at www.cdfa.org. The information center can also be contacted by sending an e-mail to info@cdfa.org. ■

In the treatment of very high triglycerides (≥ 500 mg/dL)

- **LOVAZA** dramatically lowered triglycerides by 45%¹
 - Treatment resulted in a median increase of 45% in LDL-C; treatment with **LOVAZA** resulted in an overall reduction of atherogenic cholesterol, as reflected by a 14% reduction in non-HDL-C ($P=0.0013$)¹⁻⁵
- **LOVAZA** demonstrates an excellent safety profile and proven tolerability¹
 - The most common adverse events reported were: eructation, infection, flu syndrome, dyspepsia, rash, taste perversion, and back pain

Indication:

LOVAZA™ (omega-3-acid ethyl esters) is indicated as an adjunct to diet to reduce very high (≥ 500 mg/dL) triglyceride (TG) levels in adult patients.

Usage Considerations:

In individuals with hypertriglyceridemia (HTG), address excess body weight and alcohol intake before initiating any drug therapy. Diet and exercise can be important ancillary measures. Look for and treat diseases contributory to hyperlipidemia, such as hypothyroidism or diabetes mellitus. Certain treatments (e.g., estrogen therapy, thiazide diuretics and beta blockers) are sometimes associated with very significant rises in serum triglyceride (TG) levels. Discontinuation of the specific agent may obviate the need for specific drug therapy for HTG.

Consider lipid-regulating agent use only when reasonable attempts have been made to obtain satisfactory results with non-drug methods. Advise patients that lipid-regulating agent use does not reduce the importance of adhering to diet. (See PRECAUTIONS section of full prescribing information.)

In patients with very high TG levels the effect of LOVAZA on the risk of pancreatitis has not been evaluated, nor has its effect on cardiovascular mortality and morbidity been determined.

Please see brief summary of full prescribing information on the adjacent page.

VISIT OUR WEB SITE AT www.LOVAZA.com

The US Food and Drug Administration (FDA) has granted approval for the addition of new clinical data in the **LOVAZA** label. Please read our updated prescribing information for more details.

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LOVAZA™
 omega-3-acid ethyl esters