# Antireflux Surgery Declining, but Still an Option

***Increased access to proton pump inhibitors and new endoscopic therapies may have reduced use of surgery.***

BY DIANA MAHONEY
*New England Bureau*

DALLAS — The steep decline in antireflux surgery since the 1990s may be caused by skepticism following publication of a study suggesting that most patients who undergo surgery eventually resume taking antireflux medication, said Dr. Jonathan F. Finks at the annual meeting of the Society of American Gastrointestinal and Endoscopic Surgeons.

"Antireflux surgery took off in the 1990s, in large part because of the introduction of the laparoscopic Nissen fundoplication procedure," said Dr. Finks of the division of gastrointestinal surgery at the University of Michigan in Ann Arbor.

Based on data obtained from the Nationwide Inpatient Sample, the number of patients older than age 18 who underwent antireflux surgery in the United States reached a peak at 32,907 in the year 2000. By 2003, the number undergoing surgery fell 27% to 23,998 patients.

"The rate of decline was approximately three times greater for patients in the 30- to 50-year-old age range than it was for patients older than 60," Dr. Finks reported.

The discrepancy between the two age groups may be explained by an increased likelihood on the part of gastroenterologists to recommend surgery for patients who have had problems for a longer time and who have not attained sufficient relief from medication.

On the heels of the antireflux surgery boom, results of a 2-year randomized controlled trial comparing surgical and medical management of gastroesophageal reflux disease (GERD) were published (JAMA 2001;285:2331-8). The study showed that although patients in the surgical treatment group were less likely to regularly use antireflux medications than were patients in the medical antireflux therapy group, the use of antireflux medication in the surgical group was still substantial.

In addition, there were no differences between the treatment groups in esophagitis grade, incidence of esophageal cancer, frequency of treatment of esophageal stricture, subsequent antireflux operations, or satisfaction with antireflux therapy.

The findings did not question the efficacy of antireflux surgery—which continues to be performed primarily via laparoscopic techniques, according to the data—but rather the supremacy of surgery over other management options, said Dr. Finks.

"Surgery is considered effective, with stable and low mortality and splenectomy rates, and it is associated with good patient satisfaction, but the study findings gave cause to gastroenterologists to reconsider the indications for surgery," he said.

Surgical intervention may have declined in recent years in part because of the availability of several new endoscopic therapies and increased access to proton pump inhibiting medications, which are inexpensive and available over the counter, he noted.

Reliance on Nationwide Inpatient Sample data might not provide an accurate accounting of the surgical intervention rates, noted Dr. Finks.

"It only represents inpatient procedures, but the trends have been observed in other investigations," Dr. Finks said.

The bottom line, he said, is that both surgical and medical management of gastrointestinal reflux are reasonable options, but the decision on which approach to use should be based on an assessment of the risks and benefits for individual patients.

The findings do suggest "the need for prospective randomized clinical trials assessing the short- and long-term effectiveness of the range of current therapies," Dr. Finks concluded.

Dr. Finks reported no conflicts of interest with respect to his presentation. ■

# Rifabutin-Based Therapy Tackles *H. pylori*

BY PATRICE WENDLING
*Chicago Bureau*

NICE, FRANCE — Two different rifabutin-based, triple-therapy approaches proved to be safe and effective rescue therapies in two European trials involving patients with treatment-resistant *Helicobacter pylori*.

In primary care, first-line triple therapy has been shown to fail in up to 27% of patients. These failures are frequently due to metronidazole or clarithromycin resistance. Further, up to 75% of these infections are resistant to both drugs, Dr. Stephan Miehlke said at the 16th European Congress of Clinical Microbiology and Infectious Diseases.

**The 1-week, once-daily therapy is safe, is at least as effective as quadruple therapy, and may be particularly useful for patients who can't tolerate penicillin.**

Triple therapy with a proton pump inhibitor, rifabutin, and either amoxicillin or levofloxacin has been proven effective as salvage therapy. More recently, some physicians have undertaken first-line therapy with a proton pump inhibitor, moxifloxacin, and either clarithromycin or amoxicillin.

To assess this type of therapy, Dr. Miehlke and his associates treated 104 consecutive patients with *H. pylori* infections who were resistant to both metronidazole and clarithromycin by giving them esomeprazole 40 mg, moxifloxacin 400 mg, and rifabutin 300 mg orally once each morning for 7 days.

Indications for treatment included peptic ulcers (30%), functional dyspepsia/nonulcer dyspepsia (59%), and other diagnoses (11%). Two-thirds of the patients had a history of two or more previous treatment failures, and 25% had a known history of penicillin intolerance.

Follow-up endoscopy, including histology and *H. pylori* culture, was performed 6-8 weeks after treatment. Clinical failure was defined as at least one positive biopsy-based test or a positive urea breath test.

Four patients discontinued treatment prematurely because of adverse events, and two were lost to follow-up. Successful eradication of *H. pylori* infection was confirmed in 70 of the 86 patients (81%) for whom follow-up endoscopy was available.

In the 16 patients who were deemed treatment failures, posttreatment resistance to rifampicin was detected in 5 patients, and resistance to ciprofloxacin in 3. Minor adverse events occurred in 57% of patients and commonly included nausea, headache, and muscle pain.

Although secondary resistance can occur, the 1-week, once-daily therapy is safe, is at least as effective as quadruple therapy, and may be particularly useful for patients with an intolerance to penicillin, concluded Dr. Miehlke of the Technical University Hospital in Dresden, Germany.

Results from a second study he presented demonstrated that rifabutin-based triple therapy was comparable to high-dose dual therapy for treatment-resistant *H. pylori*, and that sequential therapy is both possible and effective.

In that study, 145 patients with *H. pylori* infection who were resistant to both metronidazole and clarithromycin were prospectively randomized to receive one of two regimens: either twice-daily therapy for 7 days with esomeprazole 20 mg, rifabutin 150 mg, and amoxicillin 1,000 mg; or thrice-daily therapy for 14 days with omeprazole 40 mg and amoxicillin 1,000 mg.

Indications for treatment included peptic ulcer disease (37%), nonulcer dyspepsia (46.6%), gastroesophageal reflux disease (2.7%), and other diagnoses (13.7%). Two-thirds of the patients (68%) had failed two or more previous treatment regimens.

Six patients discontinued treatment prematurely due to side effects, and three were lost to follow-up.

Eradication of *H. pylori* infection was achieved in 78% of triple-therapy patients (54/69) and 75% of high-dose, dual-therapy patients (50/67), according to the per protocol analysis. By the intent-to-treat analysis, the figures were 74% vs. 70%. The difference between the two groups was not statistically significant, Dr. Miehlke said.

Seven of 10 patients who failed high-dose dual therapy were cured by crossover to triple therapy.

Eight of 10 patients who failed triple therapy were cured by crossover to high-dose dual therapy.

Posttreatment resistance to amoxicillin or rifabutin was not detected. There were more adverse events reported by patients who were given triple therapy (35%) than by those who received dual therapy (20%). The most common events reported were nausea, diarrhea, headache, and erythema. ■

# *PillCam Detected Varices As Well as Endoscopy*

Camera-in-a-capsule technology may be as effective as the more invasive conventional upper endoscopy at detecting esophageal varices, according to tandem studies.

In a pilot trial, American, Israeli, and French investigators compared conventional esophagogastroduodenoscopy (EGD) with the commercially available PillCam ESO.

The targets were esophageal varices, which affect a large majority of patients with cirrhosis and portal hypertension, according to Dr. Glenn M. Eisen and colleagues at Oregon Health and Science University, Portland (Endoscopy 2006;38:31-5).

The study involved 32 patients with cirrhosis who were undergoing clinically indicated EGD for screening or surveillance for esophageal varices. All underwent a PillCam ESO study followed by an EGD within 48 hours. Capsule videos were assessed by an investigator who was blinded to the patients' medical histories and EGD findings. The median esophageal transit time for the PillCam capsule was 134.5 seconds.

Both methods detected esophageal varices in 23 patients, with the PillCam detecting small varices in one patient that were missed by EGD. In addition, both detected hypertensive gastropathy in 19 patients.

While a larger trial is needed to confirm these findings, the authors said, "this is the first pilot study showing that the esophageal capsule can be used to screen patients with liver cirrhosis for the presence of varices."

In the second study, conducted by French scientists, unsedated EGD and capsule endoscopy examinations were conducted on the same day in 21 cirrhotic patients (Endoscopy 2006;38:36-41). The PillCam ESO, which transmits 14 color images per second as it moves through the esophagus, had 81% sensitivity for the diagnosis of esophageal varices, compared with EGD, and had 100% sensitivity for the diagnosis of large varices and/or red signs.

The study, conducted at Edouard Herriot Hospital in Lyon, France, also showed that all 20 patients who swallowed a PillCam (one was unable to do so) preferred it over EGD.

**—Bruce Dixon**