Ablation Resolves Dysplasia in Barrett's Esophagus

BY ROBERT FINN
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SAN DIEGO — Interim results from a randomized, controlled trial suggest that radiofrequency ablation is more effective than frequent surveillance for Barrett's esophagus.

The study compared 84 patients who underwent ablation with 43 who underwent a sham operation. All patients received high-dose acid suppression (40 mg esomeprazole twice daily). The ablation patients with high-grade dysplasia underwent endoscopic biopsies at 3, 6, 9, and 12 months, whereas those with low-grade dysplasia underwent endoscopic biopsies at 6 and 12 months, Dr. Nicholas Shaheen reported at the annual Digestive Disease Week.

At the end of that time, 80% of the patients in the ablation group with high-grade dysplasia and 90% of those with low-grade dysplasia experienced a complete response, which the investigators defined as having all biopsies free of any histologic evidence of dysplasia, "not a single goblet cell," said Dr. Shaheen of the University of North Carolina, Chapel Hill.

In contrast, 26% of the control patients experienced a complete response. The difference between the ablation and control patients was statistically significant in the intent-to-treat analysis.

Of all the patients who underwent ablation, 77% experienced a complete response for intestinal metaplasia, compared with none of the control patients. Once again, this difference was statistically significant.

There was also a significant difference in the rate of histologic progression from low-grade dysplasia to high-grade dysplasia, and from high-grade dysplasia to cancer. Of the patients who received a sham operation, 19% experienced progression of the disease, compared with just 5% of the ablated patients.

Adverse events in the study were relatively minor. Of the ablated patients, 6% experienced strictures, but all resolved after a mean of two dilations. There were three serious adverse events among the ablated patients and none among the patients who received a sham operation. One patient experienced an upper GI bleed, and two others experienced chest pain and were admitted overnight for observation.

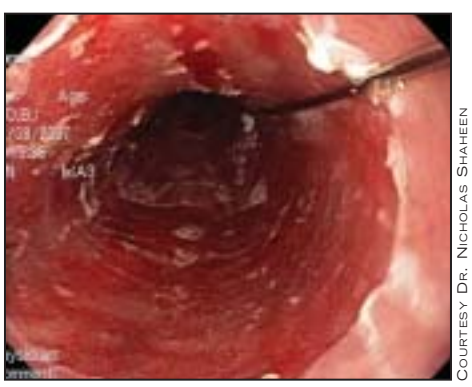
Significantly more ablation than control patients achieved a complete response of 'not a single goblet cell.'

DR. SHAHEEN

"Patients often do have chest pain after the procedure," Dr. Shaheen said in an interview. "This pain is usually mild to moderate, and was managed successfully in 295 of the 297 procedures performed in the trial with oral pain medications or no medications. Two patients did have to be admitted for chest pain. This is in contrast to our older therapies, such as PDT [photodynamic therapy], after which we hospitalized everyone for pain control."

The study, which is ongoing, is being conducted at 19 medical centers in the United States. It was funded by BÂRRX Medical Inc., which manufactures the radiofrequency ablation system used in the study.

Dr. Shaheen acknowledged receiving "other financial benefits" from that company, as well as receiving consulting fees, speaking fees, research support, and/or other financial benefits from AstraZeneca Pharmaceuticals LP, TAP Pharmaceutical Products Inc., Procter & Gamble Co., Eisai Co., Merck & Co., and Ethicon Endo-Surgery Inc. ■



COURTESY DR. NICHOLAS SHAHEEN

Dysplasia resolved after ablation in 80%-90% of Barrett's esophagus patients.