



MEDICAL DEVICE DAILY

Digestive Disease Week Notebook May 25, 2006

Barrx Medical (Sunnyvale, California) said nine studies involving its **HALO360 and HALO90 systems** were presented at DDW. The company said the studies demonstrate the benefits of the systems for treating Barrett's esophagus, a precancerous condition caused by chronic acid reflux disease, or GERD. Left untreated, Barrett's esophagus can lead to a dangerous form of cancer called esophageal adenocarcinoma.

David Fleischer, MD, of the Mayo Clinic (Scottsdale, Arizona), shared the results of the study titled, "Circumferential RF Ablation for Non-Dysplastic Barrett's Esophagus (NDBE) using the HALO360 Ablation System (AIM Trial): One-Year Follow-up of 100 patients." The study was conducted in two phases at eight centers to assess dose response, safety, tolerability and effectiveness of the HALO360 system.

The data concludes that the circumferential ablation of non-dysplastic Barrett's esophagus can be preformed without strictures or buried glands. "The initial results are encouraging. It is critical that these patients be followed over years to assess the long-term results," said Fleischer. Virender Sharma, MD, also of Mayo Clinic in Scottsdale, presented data from the one-year results of the AIM-I (Ablation of Intestinal Metaplasia) LGD pilot trial, which is aimed at assessing the safety, tolerability and effectiveness of circumferential ablation using the HALO360 system to treat patients with Barrett's esophagus and low-grade dysplasia (LGD).

In this study of 10 patients, ablation was delivered twice to the entire length of Barrett's esophagus. Results demonstrated that the circumferential ablation using the HALO360 System safely and effectively eliminated dysplasia in 90% of patients and left no strictures or buried glands. As with the AIM trial, this trial was extended to a two-year follow-up in order to collect longer-term data. Kenneth Chang, MD, professor of clinical medicine at the University of California, Irvine, presented data from a study titled, "Focal Ablation of Barrett's Esophagus Using a Novel Endoscopic Device," which assessed the HALO90 system. This study found that when used either to complement the HALO360 system or as a stand-alone treatment, the HALO90 system will "significantly improve" the cure rates of Barrett's esophagus.