4.28. Balloon-based, circumferential, endoscopic radiofrequency ablation of Barrett's esophagus: 1-year follow-up of 100 patients

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Objective: To assess the dose-response, safety, and efficacy of circumferential endoscopic ablation of Barrett's esophagus (BE) by using an endoscopic balloon–based ablation device (HALO360 System).

Design: This study was conducted in 2 serial phases (dosimetry phase and effectiveness phase) to evaluate a balloon-based ablation device that delivers a pre-set amount of energy density (J/cm^2) to BE tissue. The dosimetry phase evaluated the dose-response and the safety of delivering 6 to 12 J/cm2. The effectiveness phase used 10 J/cm^2 (delivered twice for all patients, followed by EGD with biopsies at 1, 3, 6, and 12 months. A second ablation procedure was performed if BE was present at 1 or 3 months. Patients received esomeprazole 40 mg twice a day for 1 month after ablation, and 40 mg every day thereafter. Postablation symptoms were quantified by using a 14-day symptom diary (scale, 0-100). A complete response (CR) was defined as all biopsy specimens negative for BE at 12 months.

Setting: Eight U.S. centers, between September 2003 and September 2005.

Patients: Patients were 18 to 75 years of age, with a diagnosis of BE (without dysplasia), with histopathology reconfirmation of the diagnosis within 6 months of enrollment.

Results: In the dosimetry phase, 32 patients (29 men; mean age, 56.8 years) were enrolled. Median symptom scores returned to a score of 0 of 100 by day 3. There were no dose-related serious adverse events, and the outcomes at 1 and 3 months permitted the selection of 10 J/cm^2 (x2) for the subsequent effectiveness phase of the study. In the effectiveness phase, 70 patients (52 men, 18 women; mean age, 55.7 years) were enrolled. Median symptom scores returned to a score of 0 of 100 by day 4. At 12 months (n = 69; mean, 1.5 sessions), a CR for BE was achieved in 70% of patients. There were no strictures and no buried glandular mucosa in either study phase (4,306 biopsy fragments evaluated).

Conclusions: Circumferential ablation of nondysplastic BE by using this balloon-based ablation device can be performed with no subsequent strictures or buried glands and with complete elimination of BE in 70% of patients at 1-year follow-up.