Endoscopic Radiofrequency Ablation for Barrett's Esophagus:Five-Year Durability Outcomes From a Prospective Multi-Center Trial

David E. Fleischer, Bergein F. Overholt, Virender K. Sharma, Alvaro Reymunde, Michael B. Kimmey, Ram Chuttani,Kenneth J. Chang, V. Raman Muthusamy, Charles J. Lightdale, Nilda Santiago,
Douglas K. Pleskow, Patrick J. Dean, Kenneth K. Wang

Background: In 2004, we enrolled patients with up to 6 cm of Barrett's esophagus (BE) without dysplasia into the AIM-II Trial and assessed the efficacy of circumferential and focal radiofrequency ablation (RFA) for achieving complete eradication of intestinal metaplasia (CR-IM). We previously reported 2.5-year outcomes for this cohort, in which 98% of patients achieved CR-IM with no strictures and no subsquamous IM (SSIM).

Aims: Assess 5-year durability of CR-IM achieved after RFA.

Methods: This is a prospective, multicenter trial (NCT00489268) conducted May 2004 to Nov 2009 and approved by each site's IRB. Eligible patients were those with CR-IM at 2.5-years. At 5-years, we performed endoscopy and obtained 4 quadrant biopsies from each 1 cm of the entire original extent of BE using large-jaw forceps. Additional targeted biopsies were obtained from any BE island or tongue. All specimens were processed by a centralized laboratory and reviewed by the expert gastrointestinal pathologist for the study. CR-IM was defined as "all biopsies negative for IM." Patients with IM detected at 5-years underwent focal RFA, followed 2 months later by repeat endoscopy with biopsy.

Results: Sites attempted to contact all eligible patients and offer opportunity for participate in 5-year follow-up. Of the 60 eligible patients, 50 signed informed consent and were enrolled (37 men, mean age 59.3 10.8 yrs, mean BE 3.1 1.3 cm). Ten did not participate (3 moved, 5 declined, 1 deceased from non-BE cause, 1 had varices from alcohol).At the 5-year endoscopy (mean 5.0 /-0.1 years), there were no strictures or mucosal lesions. Mean number of biopsies obtained per patient was 31 14 (total 1,547 biopsies, lamina propria was present in 86% of specimens). In 46 of 50 patients (92%) had CR-IM, while 4 (8%) had IM (6 out of 126 specimens). The 4 patients with IM had focal RFA (12 J/cm2) followed 2 mos later by endoscopy and biopsy to assess response to salvage. Mean number of biopsies obtained per patient was 28 17 (total 112 biopsies, lamina propria present in 88% of specimens). All 4 patients reestablished CR-IM on repeat biopsy.

Conclusion: Complete eradication of IM (CR-IM) after RFA is durable. In patients with documented CR-IM at 2.5-years, 92% remained CR-IM at 5-years. For those patients with recurrence of IM noted at 5-years, CR-IM was reestablished after a single focal RFA session.