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## 4. ABSTRACTS FROM PEER-REVIEWED PAPERS OF RFA FOR BE

### 4.1. Radiofrequency ablation in Barrett's esophagus with dysplasia

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**Background:** Barrett's esophagus, a condition of intestinal metaplasia of the esophagus, is associated with an increased risk of esophageal adenocarcinoma. The condition may progress through stages of dysplasia before cancer. We assessed whether an endoscopic intervention, radiofrequency ablation, could eradicate dysplastic Barrett's esophagus and decrease the rate of neoplastic progression.

**Methods:** In a multicenter, sham-controlled trial, we randomly assigned 127 patients with dysplastic Barrett's esophagus in a 2:1 ratio to receive either radiofrequency ablation (ablation group) or a sham procedure (control group). Randomization was stratified according to the grade of dysplasia (low-grade or high-grade) and the length of Barrett's esophagus (<4 cm or 4 to 8 cm). Primary outcomes at 12 months included the complete eradication of dysplasia and intestinal metaplasia. Secondary outcomes included progression to more severe dysplasia or cancer and adverse events.

**Results:** In the intention-to-treat analyses, among patients with low-grade dysplasia, complete eradication of dysplasia occurred in 90.5% of those in the ablation group, as compared with 22.7% of those in the control group ( $P<0.001$ ). Among patients with high grade dysplasia, complete eradication occurred in 81.0% of those in the ablation group, as compared with 19.0% of those in the control group ( $P<0.001$ ). Overall, 77.4% of patients in the ablation group had complete eradication of intestinal metaplasia, as compared with 2.3% of those in the control group ( $P<0.001$ ). Patients in the ablation group had less disease progression (3.6% vs. 16.3%,  $P = 0.03$ ) and fewer cancers (1.2% vs. 9.3%,  $P = 0.045$ ). Patients reported having more chest pain after the ablation procedure than after the sham procedure. In the ablation group, one patient had upper gastrointestinal hemorrhage, and five (6.0%) patients had esophageal stricture.

**Conclusions:** In patients with dysplastic Barrett's esophagus, radiofrequency ablation was associated with a high rate of complete eradication of both dysplasia and intestinal metaplasia and a reduced risk of disease progression. (ClinicalTrials.gov number, NCT00282672.)