5.3. Endoscopic radiofrequency ablation of Barrett's esophagus: Safety and efficacy outcomes in 429 patients treated in a multi-center community practice registry

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Background: Radiofrequency ablation (RFA) for dysplastic and non-dysplastic Barrett's esophagus (BE) has shown favorable outcomes in several cohort studies, a randomized sham-controlled trial, and a multicenter registry; all predominantly conducted at tertiary centers under controlled circumstances. Less is known about the outcomes of RFA when performed in expert community practices.

Aim: Determine the safety and efficacy of RFA for dysplastic and non-dysplastic BE in a community practice setting.

Methods: Subjects had BE with biopsy confirming non-dysplastic intestinal metaplasia (IM), low-grade (LGD) or high-grade dysplasia (HGD). RFA was performed every 2-4 months with follow-up biopsy at each endoscopy after RFA and/or upon achieving complete endoscopic eradiation of BE. The primary endpoint is histology-based: complete response for dysplasia (CR-D) and IM (CR-IM), defined as no biopsy showing each respective finding. Three cohorts were considered: Safety (all subjects); Efficacy-A (subjects with any post-RFA biopsy despite some not having completed therapy); 3) Efficacy B (subjects with post-RFA biopsy >1 year post-RFA).

Results: In the Safety cohort (429 patients, 788 RFA procedures), there were no serious adverse events. By procedure, there were 9 strictures (1.1%), 4 mild bleeding during RFA (0.5%), 1 mucosal injury during RFA (0.1%), 1 fever (0.1%), 1 hematemesis, no intervention (0.1%). Efficacy-A achieved a CR-D and CR-IM in 89% and 72% of subjects, respectively; median BE 3 cm (IQR 2-4), median follow-up 9 mos (IQR 4-18). Efficacy-B achieved a CR-D and CR-IM in 100% and 77% of subjects, respectively; median BE 3 cm (IQR 2-4), median follow-up 20 mos (IQR 17-26).

Conclusion: Published clinical trial data reporting on RFA for BE comes from expert tertiary centers conducting the trials under tightly controlled circumstances. We sought to add to this body of evidence by evaluating the outcomes of RFA in the hands of expert community practitioners. In this large series of patients (n=429), we demonstrated a very favorable safety profile, as well as histology-based efficacy outcomes that are comparable to those from published studies.