5.9. Predictors and quantitative assessment of incomplete response after radiofrequency ablation for dysplastic Barrett's esophagus: Analysis of randomized sham-controlled clinical trial (The AIM Dysplasia Trial)

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Background: Radiofrequency ablation (RFA) has been shown to completely eradicate dysplastic intestinal metaplasia (IM) in most patients, yet residual IM may persist in some.

Aims: The primary endpoint for RFA therapy is complete response-IM (CR-IM, no histological evidence of IM). We sought to describe pt characteristics related to incomplete response-IM (IR-IM, any residual IM). We also assessed dysplasia grade, and extent/location of any residual IM. Methods: We enrolled 127 pts with dysplastic BE (63 HGD, 64 LGD) in a multi-center trial of RFA. Pts were randomized 2:1 (RFA vs. sham) then biopsied q 3 or 6 mo, with centralized path review. RFA was performed until CR-IM or max 4 sessions.

Results: 52 pts (35 RFA, 17 sham) have evaluable 12 mo histology. This sub-analysis of the RF group compares CR-IM to IR-IM at 12 mo. The groups had similar hiatal hernia size. IR-IM had a longer pre-treatment period with dysplasia ($p < 0.05$). They were also older and had higher BMI, more years with BE, longer BE cm, and more multi-focal dysplasia, but given the small sample size of IR-IM, none of these was significant (table). All IR-IM pts had downgrading of dysplasia. For the 3 IR-IM pts with baseline HGD, the worst grade of residual IM was non-dysplastic (1), indefinite (1), or LGD (1). For the 3 IR-IM pts with baseline LGD, all were downgraded to non-dysplastic IM. Of the 6 IR-IM pts at 12 mo, 4 had a single-level IM focus, while 2 had multi-level disease. Five of 6 IR-IM pts had IM only within 1 cm of the top of gastric folds (TGF), while 1 pt had more proximal IM (4-5 cm from the TGF). One IR-IM pt had persistent GERD esophagitis, 1 had ibuprofen-induced ulceration, and 1 had a baseline stricture preventing focal balloon contact.

Conclusions: All IR-IM had downgrading of dysplasia and substantial reduction of IM burden. IR-IM pts had a longer pre-treatment period with dysplasia than CR-IM. IR-IM also had insignificant increases in age, baseline BE length, BMI and % multi-focal. Follow-up RFA is planned for these pts, with the goal to eliminate residual disease.