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## 5. SELECT PEER-REVIEWED ABSTRACTS OF RFA FOR BE

### 5.1. **A multi-center randomized trial comparing stepwise radical endoscopic resection versus radiofrequency ablation for Barrett esophagus containing high-grade dysplasia and/or early cancer**

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**Background:** After endoscopic resection (ER) of high-grade dysplasia (HGD) and early cancer (EC) in Barrett esophagus (BE), the residual BE remains at risk for neoplasia. Complete eradication of all BE is therefore a preferred approach. One method is stepwise radical ER (SRER), which is highly effective and provides a pathology specimen, yet is technically challenging and has a moderate complication risk. By comparison, radiofrequency ablation (RFA) is highly effective with a low complication risk, yet yields no pathology specimen.

**Aim:** Compare the safety and efficacy of SRER vs. RFA for treatment of BE-HGD/EC.

**Methods:** Under an IRB approved protocol, 3 centers enrolled patients BE  $\leq$  5 cm containing HGD and/or EC (max T1sm1). Patients were stratified for visible lesions at baseline (yes/no) then randomized 1:1 to SRER or RFA. SRER patients underwent piecemeal ER of 50% of BE (including visible lesions if present) followed by ER sessions every 2 mos. RFA patients (after focal ER of visible lesions if present) underwent RFA every 2 mos. Treatment was continued until a complete response for intestinal metaplasia (CR-IM, no IM on biopsy) was achieved. After CR-IM, biopsy (4Q/2cm) was performed at 2, 6, and 12 mo.

**Results:** 47 patients were randomized (25 SRER, 22 RFA). By Dec '08, data is available for 43 (22 SRER, 21 RFA). Age, gender, BE length (median C2M4 in both), entry histology (SRER: 10 HGD/12 EC vs. RFA: 7 HGD/14 EC), and the proportion of patients with visible lesions at entry were similar between SRER and RFA. A CR-HGD/EC was achieved in 22 (100%) SRER and 20 (95%) RFA, and CR-IM in 21 (96%) SRER and 20 (95%) RFA. The total number of therapeutic sessions to achieve CR was similar (median SRER 2, RFA 3). SRER, however, required more sessions when dilations were included (6 vs. 3;  $p < 0.001$ ). Acute SRER-related complications: 1 perforation (5%), 5 bleeds (23%). There was one RFA-related delayed bleeding (5%). Prior RFA, 3 of 18 bled (17%) after entry ER. The incidence of stenosis was higher in SRER (86%) vs. RFA (14%) ( $p < 0.001$ ). All RFA stenoses had an entry ER. All stenoses resolved with dilation. Median follow-up is 13 mo in both groups. Once CR-IM was achieved, no patient in either group had recurrence of dysplasia or visible BE.

**Conclusion:** In patients with BE  $\leq$  5 cm containing HGD/EC, SRER and RFA achieved comparably high rates of CR for both IM and neoplasia. However, SRER carried a higher risk of complications and had more procedures per patient. Based on these results, we recommend a combined approach of focal ER for visible lesions followed by RFA for complete eradication of remaining BE.