Clinical Trial Summary

Radiofrequency Ablation in Barrett's Esophagus with Dysplasia

Published in *The New England Journal of Medicine* – May 2009

Study Rationale

- Barrett's esophagus confers a significantly elevated risk of developing esophageal adenocarcinoma
- Dysplasia within the Barrett's epithelium is the best predictive marker for cancer risk
- Endoscopic radiofrequency ablation (RFA) with the HALO ablation system (BÂRRX Medical, Sunnyvale, CA) has demonstrated high rates of complete eradication of the Barrett's epithelium in previously published clinical trials
- A randomized, sham-controlled trial was conducted to compare RFA to a sham procedure for eradicating Barrett's with dysplasia and reducing the risk for cancer development

Study Design

- Randomized, sham-controlled trial conducted at 19 U.S. centers
- 127 patients with Barrett's with high-grade or low-grade dysplasia (up to 8 cm length)
- Expert pathology lab (Cleveland Clinic) reviewed all biopsies for study endpoints
- Random assignment to either RFA or a sham intervention (no RFA)
- Frequent biopsies of the esophagus were performed to assess outcomes
- All patients received high-dose esomeprazole

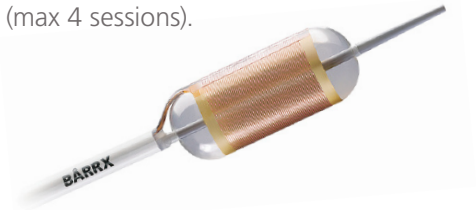
SELECTED STUDY OUTCOMES

Primary analysis was intention-to-treat (ITT)

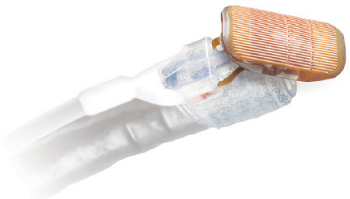
- *Complete eradication of dysplasia at 1 year*
- *Complete eradication of intestinal metaplasia at 1 year*
- *Disease progression (progression of dysplasia or development of cancer)*
- *Adverse events, including stricture occurrence*
- *Buried gland prevalence at 12 months*

Endoscopic Ablation Intervention

Patients assigned to RFA received ablation at 2-3 month intervals (max 4 sessions).

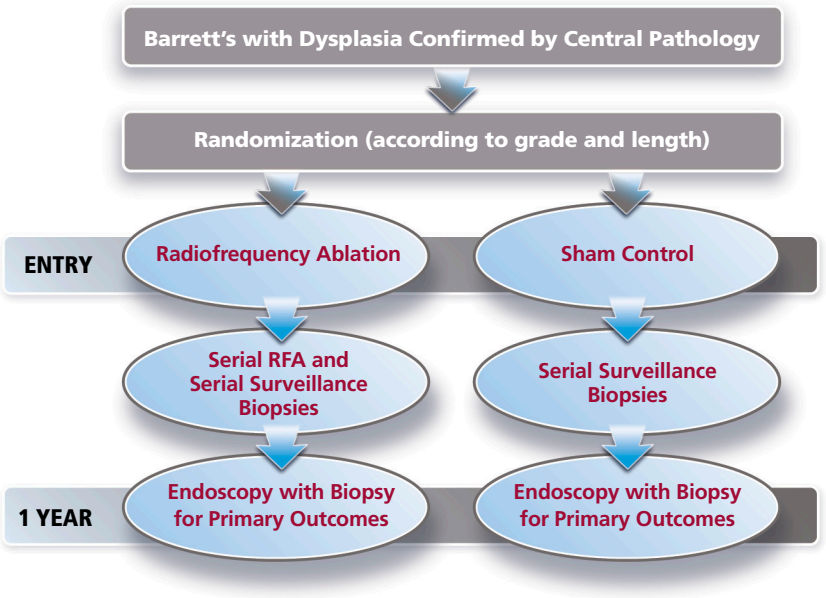


Circumferential RFA (primary) was applied with the HALO^{360+} Ablation Catheter



Focal RFA (touch-up or secondary procedure) was applied with the HALO^{90} Ablation Catheter

Patient Flow



All data derived from and charts created from data in: Shaheen NJ, Sharma P, Overholt BF, et al. Radiofrequency ablation in Barrett's esophagus with dysplasia. N Engl J Med 2009;360:2277-88

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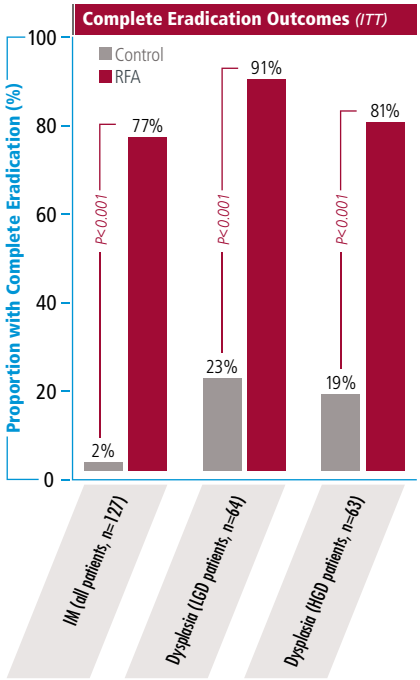
Results

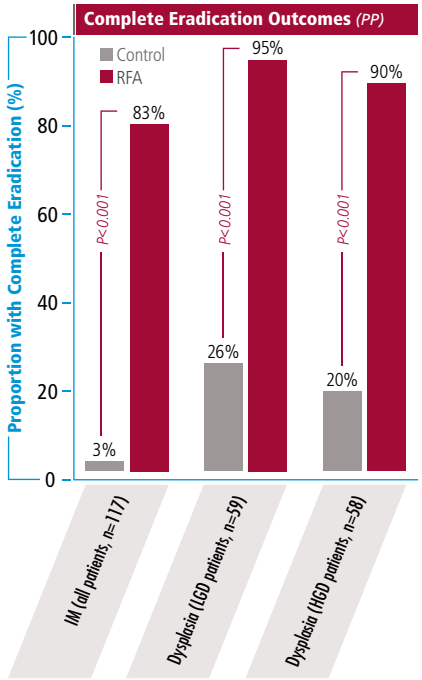
Primary Endpoints

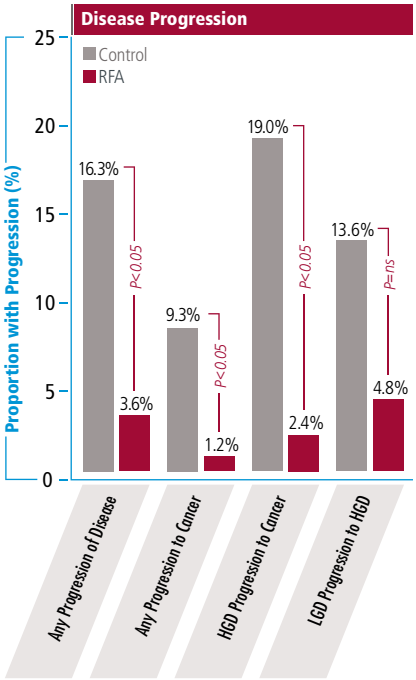
ITT = intention to treat analysis, PP = per protocol analysis	RFA Group *ITT*	RFA Group *(PP)*	Control Group *ITT*	Control Group *(PP)*	P Value
COMPLETE ERADICATION of INTESTINAL METAPLASIA *(all patients)*	77%	(83%)	2%	(3%)	<0.001
COMPLETE ERADICATION of DYSPLASIA *(LGD patients)*	91%	(95%)	23%	(26%)	<0.001
COMPLETE ERADICATION of DYSPLASIA *(HGD patients)*	81%	(90%)	19%	(20%)	<0.001

Secondary Endpoints

- 87% lower cancer incidence in RFA (1.2%) vs. control (9.3%) (p<0.05)
- 78% lower overall disease progression in RFA (3.6%) vs. control (16.3%) (p<0.05)
- At 1 year, buried glands were present in 5% of RFA vs. 40% of control (p<0.001)
- Adverse events: 2 overnight admissions for chest pain, 1 GI bleed in RFA
- Strictures: 5 patients in RFA (6% of patients, 1.7% of procedures)







Conclusion

A randomized sham-controlled trial of radiofrequency ablation was performed in patients with Barrett's esophagus with dysplasia. Patients treated with ablation had a very high rate of complete eradication of dysplasia and IM, as well as a decreased rate of disease progression (including cancer development), as compared to controls.

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