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Clinical summary

The following is a synopsis of a published clinical study.

Title	Radiofrequency Ablation vs Endoscopic Surveillance for Patients with Barrett Esophagus and Low-Grade Dysplasia. A Randomized Clinical Trial.
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Journal	Journal of the American Medical Association
Pub date	Marh 26, 2014
DOI	10.1001/jama.2014.2511

BACKGROUND

Barrett's Esophagus (BE) with low-grade dysplasia is associated with the development of adenocarcinoma. The Surveillance vs Radiofrequency Ablation (SURF) randomized controlled trial compared the rate of progression to high grade dysplasia and adenocarcinoma following radiofrequency ablation (RFA) or endoscopic surveillance in patients with BE and confirmed low grade dysplasia.

STUDY DESIGN

A total of 136 patients were randomized to receive either radiofrequency ablation (RFA group, n=68) or endoscopic surveillance (Control group, n=68). RFA patients were treated with either a circumferential (HALO 360) or focal (HALO 90) device. Ablation sessions occurred every 3 months until complete endoscopic and histological eradication of BE or a maximum of 2 circumferential and 3 focal sessions were completed. Control group patients underwent high resolution endoscopy at 6 and 12 months after qualifying visit and annually thereafter until 3 years. The primary study outcome was occurrence of high-grade dysplasia or adenocarcinoma at any point during the 3-year assessment period. Secondary study outcomes included complete eradication of dysplasia, intestinal metaplasia (IM), and adverse events.

KEY RESULTS

Primary and secondary trial outcomes are summarized in the table below.

Primary and secondary efficacy outcomes				
Efficacy Outcome	RFA Group (n=68)	Control Group (n=68)	Risk Difference (% (95% CI))	P value
Progression to high-grade dysplasia or cancer (#, %)	1 (1.5)	18 (26.5)	25.0 (14.1-35.9)	<0.001
Progression to cancer (#, %)	1 (1.5)	6 (8.8)	7.4 (0.0-14.7)	0.03
Complete eradication of dysplasia at the end of endoscopic treatment (#, %)	63/68 (92.6)	--	--	NA
Complete eradication of IM at the end of endoscopic treatment (#, %)	60/68 (88.2)	--	--	NA

Complete eradication of dysplasia during follow-up (# of events/total patients %)	62/63 (98.4)	19/68 (27.9)	70.5 (59.4-81.6)	<0.001
Complete eradication of IM during follow-up (# of events/total patients %)	54/60 (90.0)	0/68 (0.0)	90.0 (82.4 – 97.6)	<0.001

There were 3 serious adverse events in 2 RFA patients:

- Hospitalization for abdominal pain 4 days after ablation in 1 patient, treated to resolution with analgesics.
- Bleeding 7 days after endoscopic resection for low-grade dysplasia prior to first ablation in 1 patient. Later dilated for stricture and development of fever and chills. No perforation noted.

There were 12 adverse events in 12 RFA patients:

- Small mucosal lacerations noted in 3 patients, no intervention required, procedure completed.
- Retrosternal pain 3 weeks after focal ablation in 1 patient, endoscopy findings were normal and pain resolved with analgesics.
- 8 patients (11.8%) developed esophageal stricture requiring dilation.

In total 13 RFA patients experienced an adverse event (1 patient had both a serious adverse and an adverse event); no control patients experienced an adverse event (risk difference 19,1% [95% CI, 9.7%-28.4%], p<0.001).

The SURF trial was terminated early at the recommendation of the Data Safety and Monitoring Board due to the superiority of ablation for primary outcome and potential for safety issues if the study continued.

CONCLUSIONS

Results suggest that RFA substantially reduces the rate of neoplastic progression to high-grade dysplasia and adenocarcinoma over 3 year follow-up. Therefore, patients with a confirmed diagnosis of low-grade dysplasia should be considered for ablation therapy.