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#### 4.26. Endoscopic ablation of intestinal metaplasia containing high-grade dysplasia in esophagectomy patients using a balloon-based ablation system

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**Background:** This study aimed to determine the optimal treatment parameters for the ablation of intestinal metaplasia (IM) containing high-grade dysplasia (HGD) using a balloon-based ablation system for patients undergoing esophagectomy.

**Methods:** Immediately before esophagectomy, patients underwent ablation of circumferential segments of the esophagus containing IM-HGD using the HALO360 system. The treatment settings were randomized to 10, 12, or 14 J/cm<sup>2</sup> for two, three, or four applications. After esophagectomy, multiple sections from ablation zones were microscopically evaluated. Histologic end points included maximum ablation depth (histologic layer) and complete ablation of all IM-HGD (yes/no).

**Results:** Eight men with a mean age of 57 years (range, 45–71 years) were treated, and 10 treatment zones were created. There were no device-related adverse events. At resection, there was no evidence of a transmural thermal effect. Grossly, ablation zones were clearly demarcated sections of ablated epithelium. The maximum ablation depth was the lamina propria or muscularis mucosae. The highest energy (14 J/cm<sup>2</sup>, 4 applications) incurred edema in the superficial submucosa, but no submucosa ablation. Complete ablation of IM and HGD occurred in 9 of 10 ablation zones (90%), defined as complete removal of the epithelium with only small foci of “ghost cells” representing nonviable, ablated IM-HGD and demonstrating loss of nuclei and cytoarchitectural derangement. One focal area of viable IM-HGD remained at the margin of one ablation zone (12 J/cm<sup>2</sup>, 2 applications) because of incomplete overlap.

**Conclusion:** Complete ablation of IM-HGD without ablation of submucosa is possible using the HALO360 system. Ablation depth is dose related and limited to the muscularis mucosae. In one patient, small residual foci of IM-HGD at the edge of the ablation zone were attributable to incomplete overlap, which can be avoided. This study, together with non-esophagectomy IM-HGD trials currently underway, will identify the optimal treatment parameters for IM-HGD patients who would otherwise undergo esophagectomy or photodynamic therapy.