
4.33. Complete ablation of esophageal epithelium with a balloon-based bipolar electrode: A phased evaluation in the porcine and in the human esophagus

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Gastrointest Endosc 2004;60:1002-10

Background: The aim of this study was to evaluate the endoscopic and the histologic effects of a balloon-based bipolar radiofrequency electrode for ablation of porcine and human esophageal epithelium.

Methods: All procedures were performed with a balloon based, bipolar radiofrequency system that creates a circumferential, thin-layer epithelial ablation zone within the esophagus. In Phase I, multiple ablations were created in 10 farm swine, followed by acute euthanasia and histologic assessment for completeness of epithelial removal and ablation depth. In Phase II, multiple ablations were created in 19 farm swine, with varying power and energy density, followed by endoscopy at 2 and 4 weeks to assess stricture formation. In Phase III, 3 ablations were created in 12 farm swine, with varying energy density (5, 8, 10, 12, 15, or 20 J/cm²) at 350 W. Animals were euthanized at 48 hours. Histologic examination determined the percentage of epithelium removed and the ablation depth. In Phase IV, 3 patients underwent esophageal epithelial ablation before esophagectomy, creating separate lesions proximal to the tumor. Completeness of epithelial ablation and ablation depth was quantified histologically.

Results: In Phase I, complete removal of esophageal epithelium was achieved at energy density settings of 9.7 to 29.5 J/cm². In Phase II, 9.7 and 10.6 J/cm² produced no stricture, whereas more than 20 J/cm² produced a stricture in every case. In Phase III, 8-20 J/cm² resulted in 100% epithelial ablation. Five and 8 J/cm² spared the muscularis mucosae, whereas 10 J/cm² caused injury to the muscularis mucosae but preserved the submucosa. In Phase IV, histologic examination demonstrated full thickness epithelial removal in areas of electrode contact. Ablation extended only to the muscularis mucosae, without injury to submucosa.

Conclusions: In the porcine and the human esophagus, circumferential, full-thickness ablation of epithelium without direct injury to the submucosa is possible and was well tolerated. In all cases, depth of ablation was linearly related to energy density of treatment.