Circumferential balloon-based radiofrequency ablation for ultralong and extensive flat esophageal squamous neoplasia

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Esophageal cancer is highly lethal and causes more than 400,000 deaths per year worldwide.[1] In the Asia-Pacific region, esophageal squamous cell carcinoma is the major form of the disease, and its incidence is increasing.[1] Recent advances in image-enhanced endoscopy have led to earlier diagnosis of esophageal squamous mucosal cancer or precancerous lesions.[2,3] Endoscopic submucosal dissection (ESD) enables large en bloc resection of these superficial esophageal cancers, but the technique is complicated and requires considerable expertise.[4] In particular, when there are large lesions or lesions that occupy more than three-fourths of the circumference of the esophagus, patients will have esophageal stenosis.[5-7] Stenosis can decrease quality of life, and treatment requires multiple sessions of endoscopic balloon dilation.[5] Therefore, it is important to have an alternative and more convenient method to treat these large and extensive esophageal squamous neoplasias.

Radiofrequency ablation (RFA) is a rapidly evolving therapeutic modality, and recent studies have shown its efficacy and safety for eradicating high-grade dysplasia in cases of Barrett's esophagus.[8-10] RFA also has theoretical potential for treating squamous epithelial neoplasias. However, only a few studies have demonstrated the potential efficacy for squamous neoplasia,[11-14] and no studies have reported its use for extensive and ultralong-segment (>10 cm) neoplasias. Therefore, the aim of this prospective pilot series was to assess the efficacy and safety of eradicating ultralong, extensive, flat esophageal squamous neoplasia using RFA.

Abbreviations: APC, argon plasma coagulation; ESD, endoscopic submucosal dissection; RFA, radiofrequency ablation.

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METHODS

Patient selection

We consecutively recruited adults with newly diagnosed esophageal squamous neoplasias at E-Da Hospital in Taiwan, who underwent meticulous endoscopic screening of the upper aerodigestive tract with image-enhanced endoscopy, including narrow-band imaging and Lugol chromoendoscopy.[3] In July 2011, an RFA system became available at our institution; thus, patients were eligible for the study when they met all of the 5 following criteria. (1) Results of Lugol chromoendoscopy showed unstained or mosaic-like lesions that occupied more than 50% of the circumference of the esophagus and that extended more than 10 cm longitudinally (Fig. 1A). (2) Histologic results revealed squamous high-grade dysplasia or mucosal squamous cell carcinoma. (3) The esophageal lesion was completely flat (type 0-IIb), according to the Paris classification of the endoscopic appearance of early GI neoplasia. (4) EUS showed no submucosal invasion or lymphadenopathy. (5) The patient provided informed consent.

Patients were excluded if any of the following exclusion criteria were met: (1) having a stricture that prevented passage of a therapeutic endoscope; (2) having a history of endoscopic resection, surgery, or radiation of the esophagus; (3) having uncontrolled coagulopathy with an international normalized ratio greater than 2 or platelet count less than 75,000/μL; (4) decompensated cirrhosis (Child-Pugh score ≥7); (5) having large varices or small varices with red wale marks or a history of variceal bleeding; and (6) being pregnant. The institutional review board approved the study protocol.

Radiofrequency ablation

All primary ablations were performed circumferentially using the HALO360 System (Covidien GI Solutions,

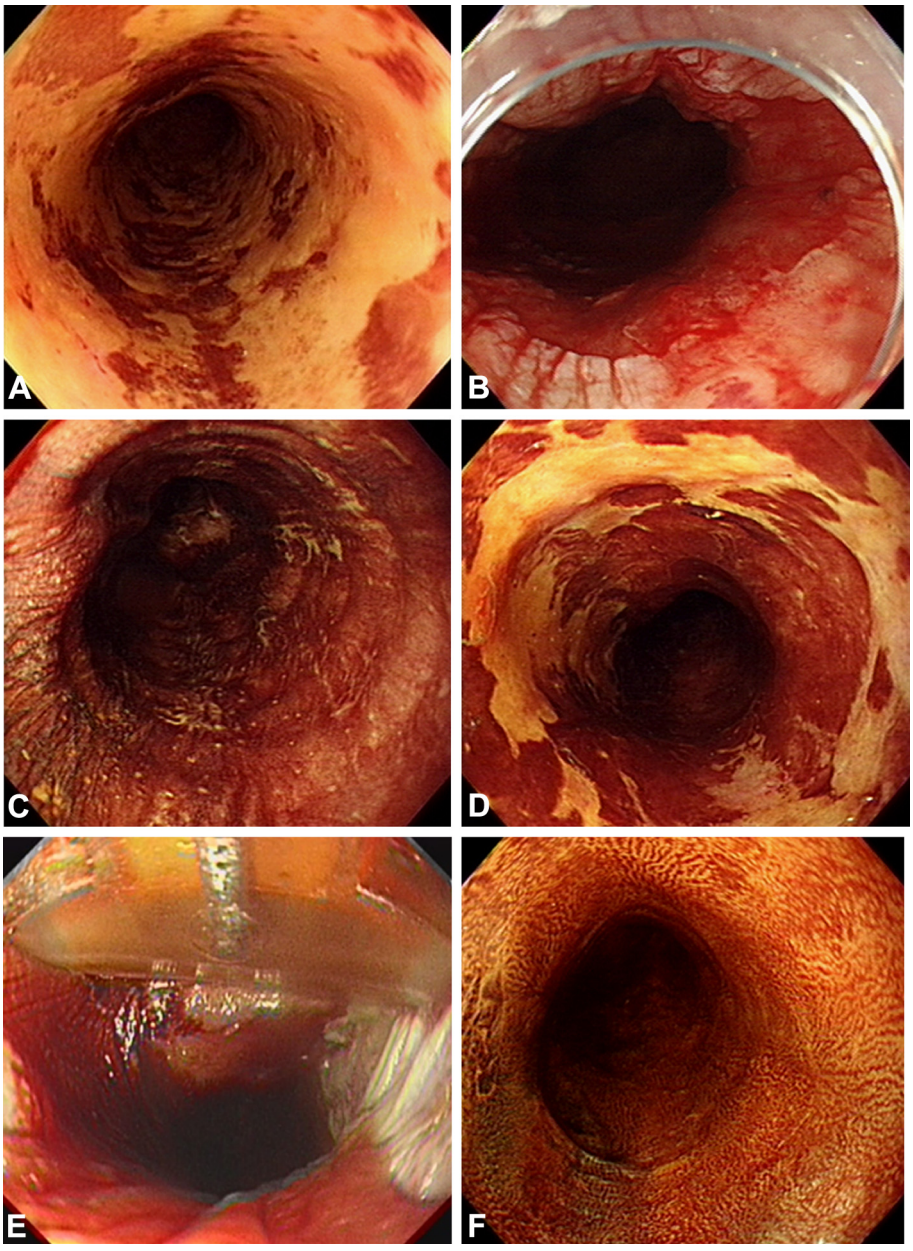

Figure 1. Circumferential balloon base radiofrequency ablation of a 12-cm long flat circumferential early squamous neoplasia (patient 1). **A**, Pretreatment Lugol staining showed circumferential extensive unstained lesions. **B**, Appearance of the mucosa after the first circumferential ablation pass and after cleaning the ablation zone. **C**, One month after ablation, Lugol staining showed good eradication. **D**, A residual unstained lesion was found at the upper portion of the esophagus. **E**, Focal ablation by using the HALO90 system was performed for the residual unstained lesion. The ablation catheter can be seen at the top of the image. **F**, Three months after primary circumferential RFA, Lugol staining showed no evidence of residual squamous neoplasia. A biopsy also confirmed the complete response.

Sunnyvale, Calif), which has been approved by the U.S. Food and Drug Administration and is approved for use in Europe (CE mark) and Taiwan (Ministry of Health and Welfare). The HALO360 system consists of an ablation catheter, an energy generator, and a sizing balloon. The ablation catheter balloon is encircled by a 3-cm long bipolar array that delivers short-duration (1 second) RFA at 40 W/cm^2 and 10 to 12 J/cm^2. We used a 12 J/cm^2 – clean – 12 J/cm^2 regimen for all of the procedures.[13] Endoscopic procedures were performed by using conscious sedation or anesthesia with appropriate doses of midazolam, fentanyl, and/or propofol. Before performing RFA, Lugol staining was performed to determine the location and size of the Lugol-voiding lesions. The area from 1 cm proximal to 1 cm distal to the Lugol-voiding lesion–bearing segment of the esophagus was defined as the treatment area, and marked by taking 2 biopsy specimens. In patients with synchronous cancers, the definitive treatment of head