5.12. Focal ablation for treatment of dysplastic and non-dysplastic Barrett's esophagus: Safety profile and initial experience with the HALO^{90} device in 508 cases

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Introduction: Several modalities have been evaluated for focal treatment of Barrett esophagus (APC, MPEC, laser, EMR) and for wide-field ablation of BE (PDT, balloon-based circumferential RF ablation or HALO^{360}).

Aims: Assess the initial safety experience associated with the HALO^{90} focal ablation device for secondary ablation of residual BE after primary wide-field ablation, as well as primary ablation of short segment BE.

Methods: The HALO^{90} focal ablation device (BÂRRX Medical, Sunnyvale, CA) fits on the distal tip of a standard gastroscope, preserving visualization. The upper surface is a 20x15 mm articulated platform covered by a bipolar electrode array. The device uses high power RF (40 W/cm^2) and a pre-set energy density (12 J/cm^2) to control ablation depth. Using the endoscope, the electrode is positioned at the target, deflected upward, and energy delivered.

In 2006, 508 focal ablation procedures were performed in the U.S. and the Netherlands with this device for BE, with182 of these cases performed under one of several IRB-approved clinical trials for non-dysplastic BE, LGD-BE and HGD-BE. For trial cases in this series, treatment data (procedure time and medication use) were collected and post-ablation symptoms were assessed (chest, throat, abdominal pain; odynophagia; dysphagia) using a standardized 14-day diary (visual analog scale, 0-100). For all cases, a monitoring system was used to detect adverse events.

Results: Of 182 trial cases, median procedure time was 20 min (IQR 14-32). Sedation included midazolam 7 mg (IQR 5-8), and either meperidine 75 mg (IQR 50-100) or fentanyl 100 mcg (75-175). One site used propofol as a single agent (median 410 mg, IQR 337-521.)

Post-ablation Symptom Queri	Day 1 Median VAS* (IQR) (n=156)	Day Median VAS Returned to Zero
Chest Pain	9 (0-20)	Day 4
Dysphagia	2 (0-40)	Day 2
Odynophagia	10 (0-45)	Day 4
Throat Pain	10 (0-36)	Day 3
Abdominal Pain	0 (0-0)	Day 1

* VAS (visual analog scale) is out of 100 possible points

There were no perforations, mucosal lacerations, bleeds, stricture formation, or other adverse events. One patient (0.5% of trial cases) reported symptoms of esophageal spasm on day 1 and was admitted for pain control.

Conclusions: This represents the first report of the safety profile of this focal ablation device. Its use appears to be very well-tolerated by the patient with post-ablative symptoms that were minor and short-lived, and an adverse event incidence in this review of 0.5%. This technique may significantly complement wide-field ablative therapy for achieving the goal of complete BE ablation. Future studies are evaluating this device as primary therapy of short segment BE.