A Single Step Sizing and Radio Frequency Ablation (RFA) Catheter for Circumferential Ablation of Barrett’s Esophagus (BE): Results of a Pilot Study


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Background

Standard circumferential RFA (c-RFA) consists of:
- Sizing esophageal inner diameter at multiple levels and selecting an appropriate size ablation catheter.
- Ablating the entire BE segment (12J/cm² – clean – 12J/cm²).

Standard c-RFA results in:
- 83% median surface regression at 3-month follow up.
- Total procedure time 39 min.

Self Sizing RFA Catheter: 4cm long bipolar electrode wrapped around a balloon (figure 1) that adjusts to the esophageal diameter:
- No sizing procedure required.
- Optimal tissue contact.

Aim

Evaluate the efficacy and safety of the Self Sizer for c-RFA.

Methods

Inclusion:
- BE (2-10cm) with confirmed low-grade dysplasia (LGD), high-grade dysplasia (HGD), or early cancer (EC).
- Endoscopic resection (ER) of all visible lesions prior to RFA.

C-RFA treatment:
Self Sizer using the standard ablation regimen (12J/cm² – clean – 12J/cm²).

Primary outcome:
% endoscopically visual surface regression of BE at the first post-treatment endoscopy at 3 months separately graded by 2 endoscopists.

Secondary outcomes:
- Total procedure time.
- Complications.

Results

- 30 patients (24 men, median age 66 yrs, median BE C4M6).
- ER prior to RFA: 27%.
- Worst histology prior to RFA: HGD (n=6), LGD (n=22), IM (n=2).

Primary outcome:
Median 90% (IQR 77-95) BE surface regression at 3 months.

Secondary outcomes:
- Median total procedure time 31 min (IQR 28-38).
- 4 complications (superficial mucosal laceration, atrial fibrillation, dysphagia without endoscopic signs of stenosis, dysregulated diabetes mellitus).

Conclusions

- Despite no stenoses were seen in this small pilot study, theoretically, ablation at 12 J/cm² could result in deeper tissue damage due to the optimal tissue contact when using the Self Sizer. Therefore, ablation at 10 J/cm² is advised and currently studied in a prospective trial.
- C-RFA using the Self Sizer results in shorter procedure times, but maintains efficacy and safety compared to standard c-RFA.