Esophagus Deviation during Radiofrequency Ablation of Atrial Fibrillation

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For the EASY AF Study Investigators
Funding provided by S4 Medical

Conflict of Interest / Disclosures

- Jose Osorio, MD – Study Investigator
- S4 Medical Corp - Sponsor
- Ohio State University Equity ownership
- Emile Daoud, MD - Chief Medical Officer S4; Equity

Esophageal Injury during AF Ablation

- No FDA approved device indicated for esophageal protection
- EASY AF Study is the only prospective, multicenter, randomized trial

- Numerous techniques/devices to minimize esophageal injury
  - Temperature (LET) monitoring including multi-sensor devices
  - Esophageal retractors with nitinol stylet or balloon
  - Alteration of esophageal temperature
  - Cooling/warming
  - Energy dosage and duration (e.g., High Power/ Short Duration)

EASY AF Study

- International, multicenter, prospective, double-blinded, randomized, controlled trial
  - FDA IDE trial: clinicaltrials.gov NCT04659213
- Inclusion criteria:
  - Index Radiofrequency AF ablation (any lesion set/technique); General Anesthesia; Uninterrupted anticoagulation
- Exclusion criteria:
  - Previous ablation
  - History of Esophagus or Upper GI pathology (other than GERD)

Study Protocol

- **Efficacy Endpoint**: Esophageal lesions attributable to RF ablation
- **Primary Safety Endpoint**: Esophageal lesions attributable to use of esolution device AND all complications within 30 days
- **Gastroenterologist**: blinded to randomization; image ALL esophageal abnormalities

Control Group (no device)

- Temp probe only
- Endoscopy post ablation

Treatment Group (esolution device)

- Deviation device plus temp probe
- Endoscopy post ablation

EASY AF – Study Committees

Esophageal Adjudication Committee

- 3 blinded GIs
- Reviewed images of all esophageal pathologies – adjudicated etiology

Clinical Events Committee

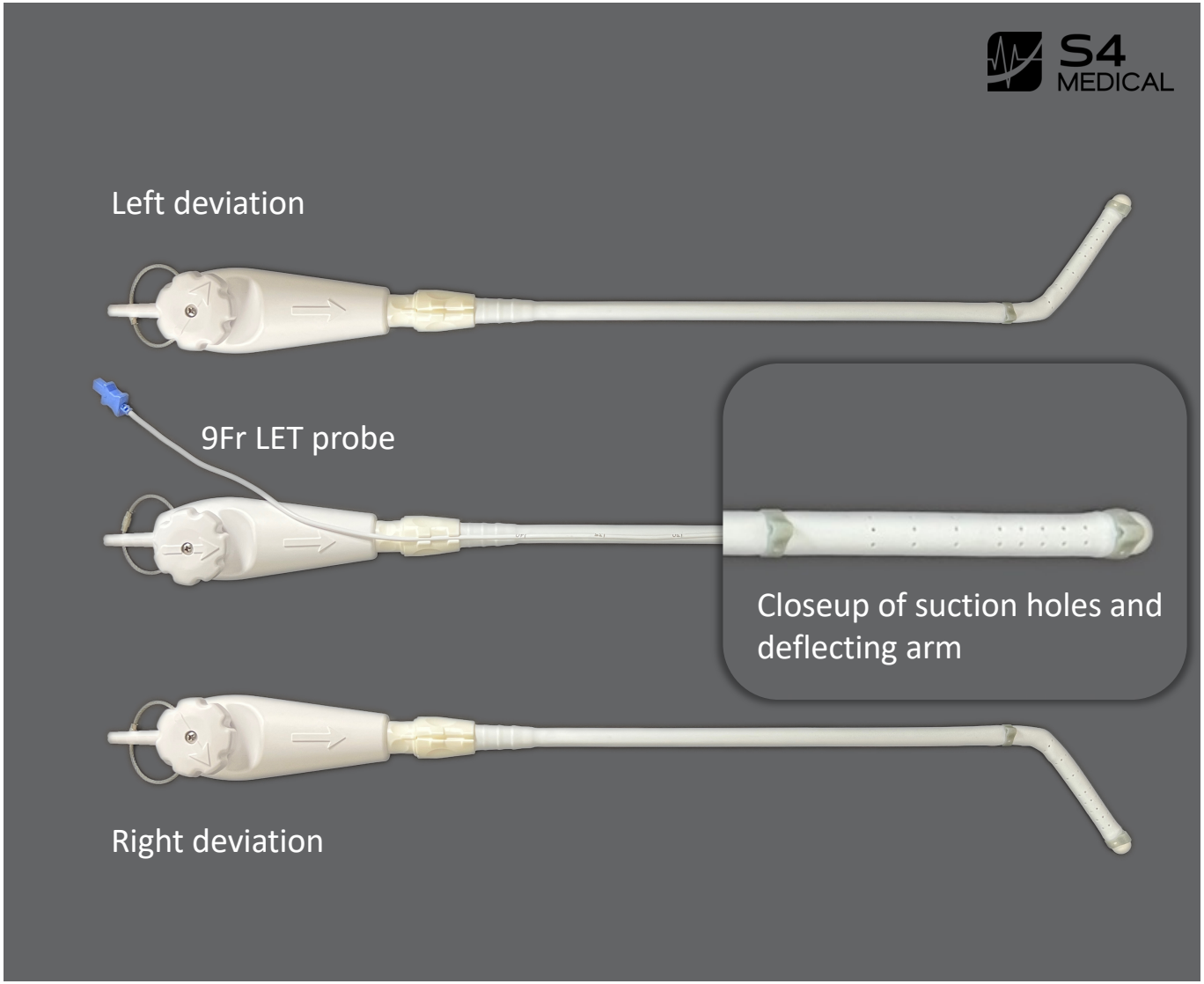
- 2 blinded EPs + 1 blinded GI
- Reviewed all adverse events and adjudicated etiology

Data Safety Monitoring Board

- Completed first interim analysis at predefined time of randomization of 120 patients

esolution Device

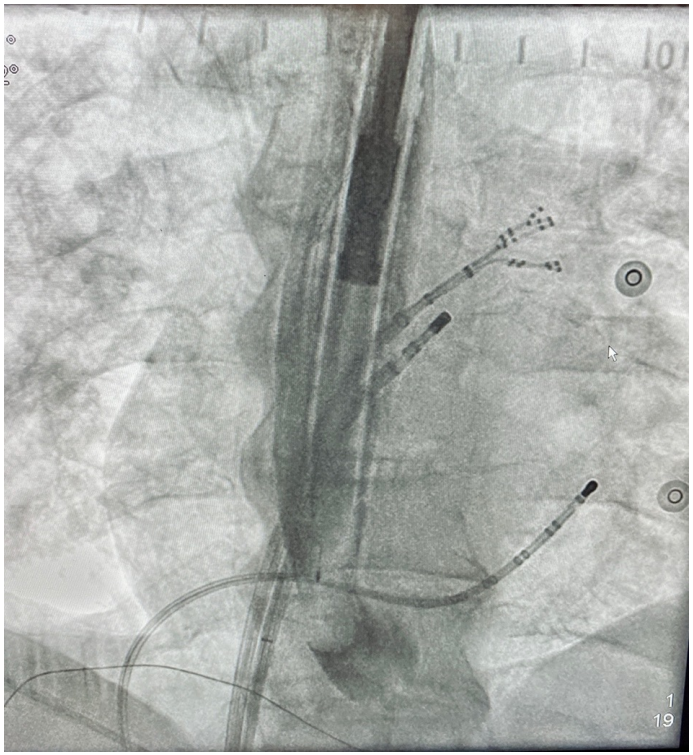
Vacuum force manages
trailing edge
+
mechanical deviation



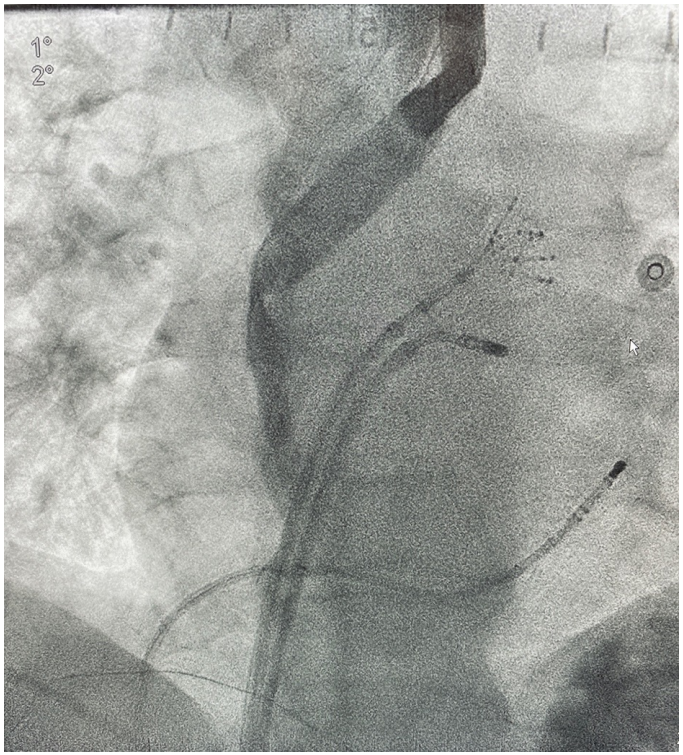
Study Population

Patient Demographics (n=120)	Control	Treatment	P value
Age (p=0.041)	65.3	61.6	0.041
Gender (female)	36%	24%	0.145
BMI	30.4	34.5	0.003
CHADS-Vasc	2.6	2.2	0.945
AF Type (PAF/PersAfib)	64% / 36%	59% / 41%	0.628
GERD (no)	66%	85%	0.021
Hypertension (% yes)	76%	77%	1.000

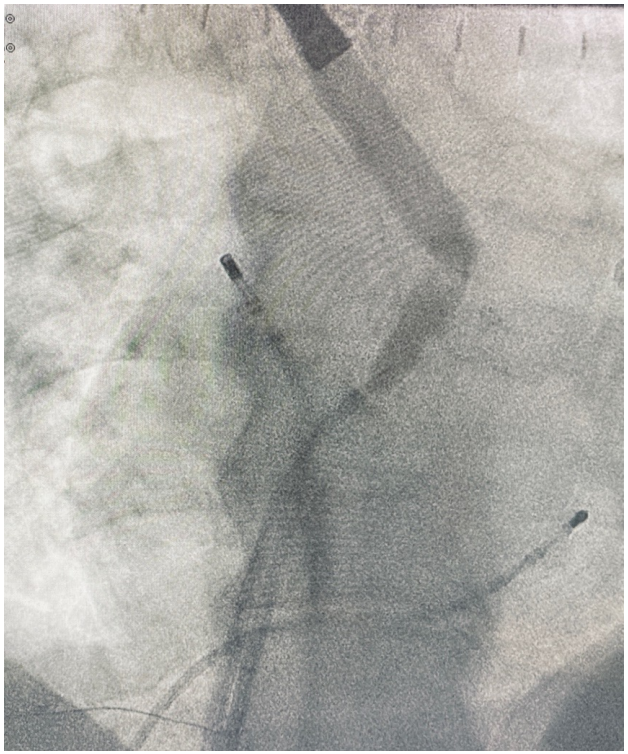
Suction + Deviation



Undeviated - Suction OFF

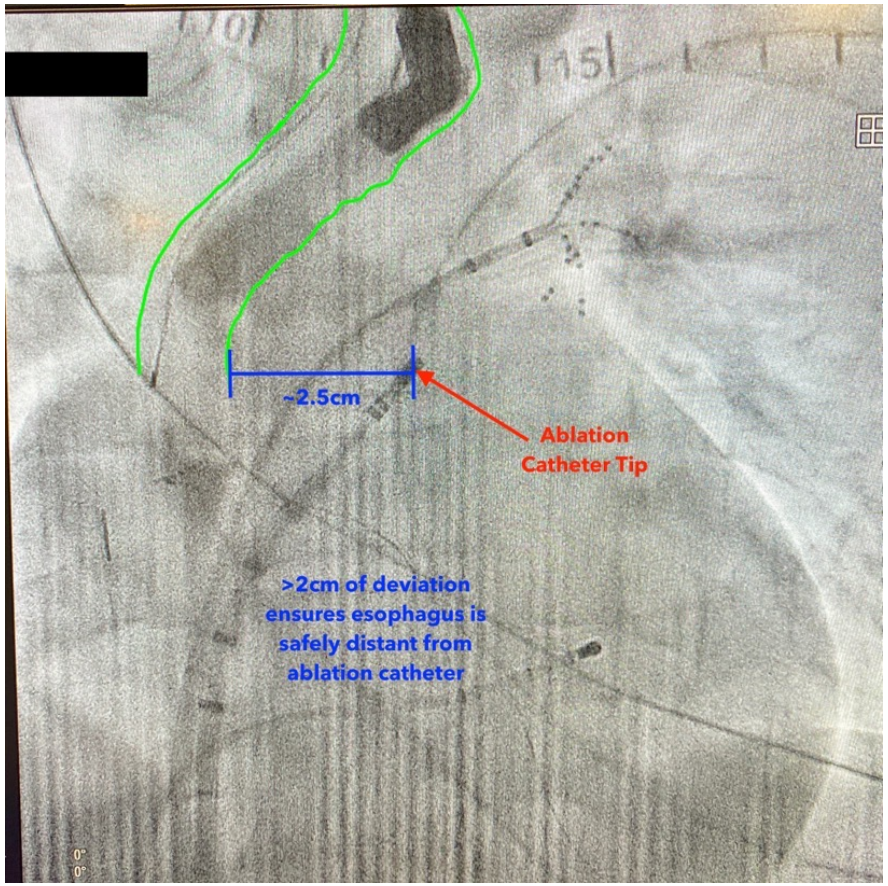


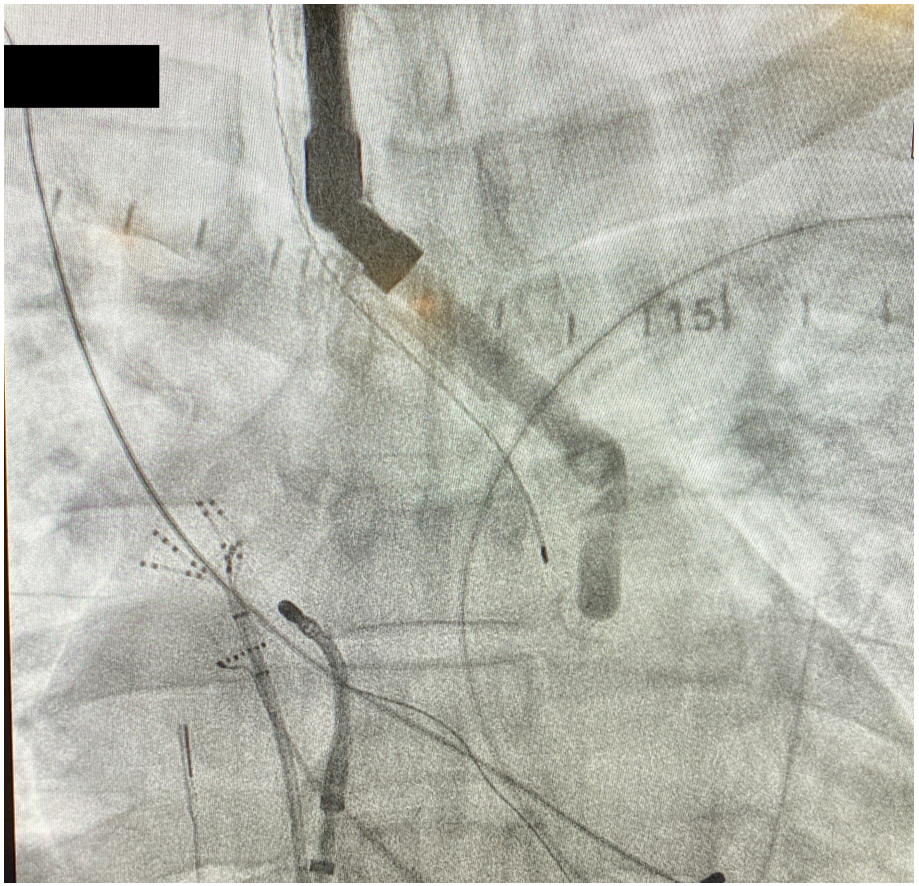
Right deviation - Suction ON



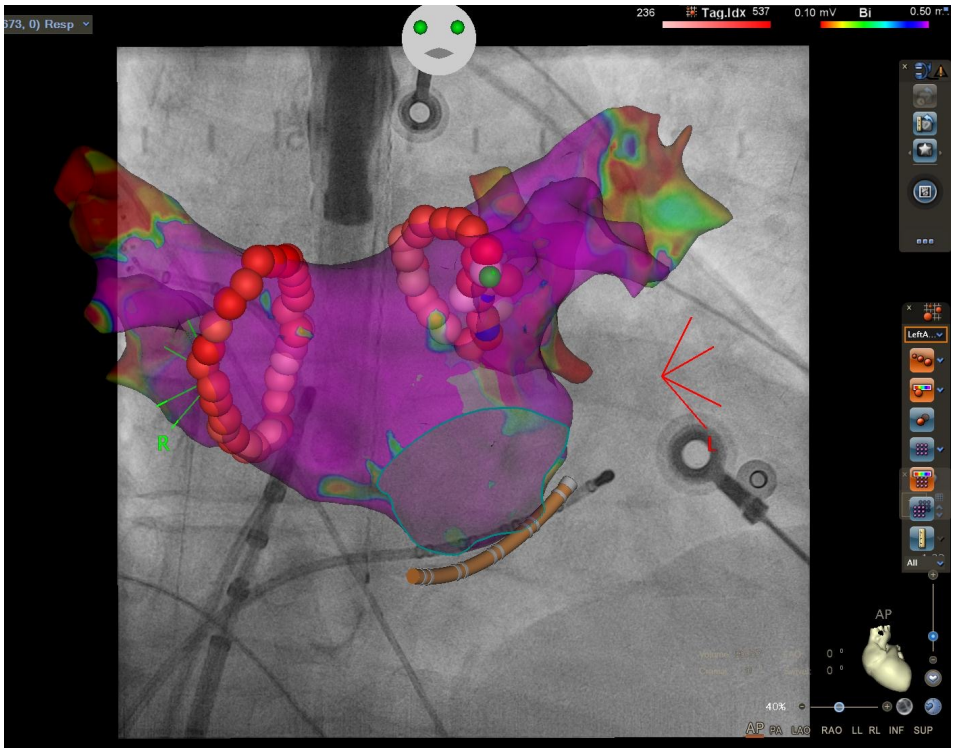
Left deviation - Suction ON

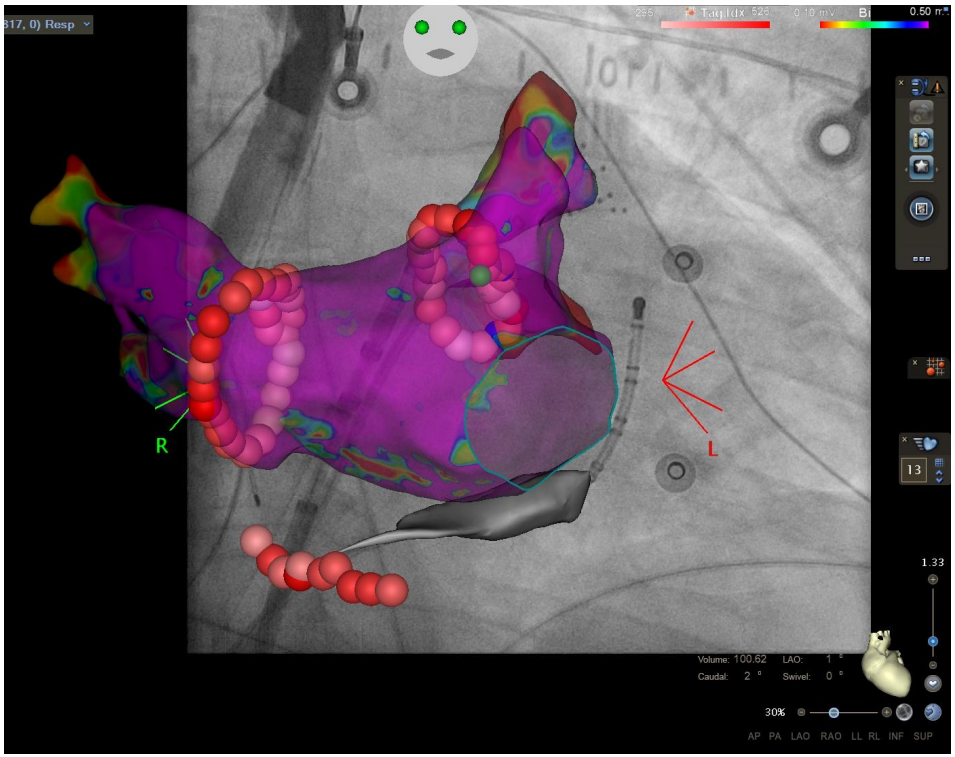
Right and Left Deviation



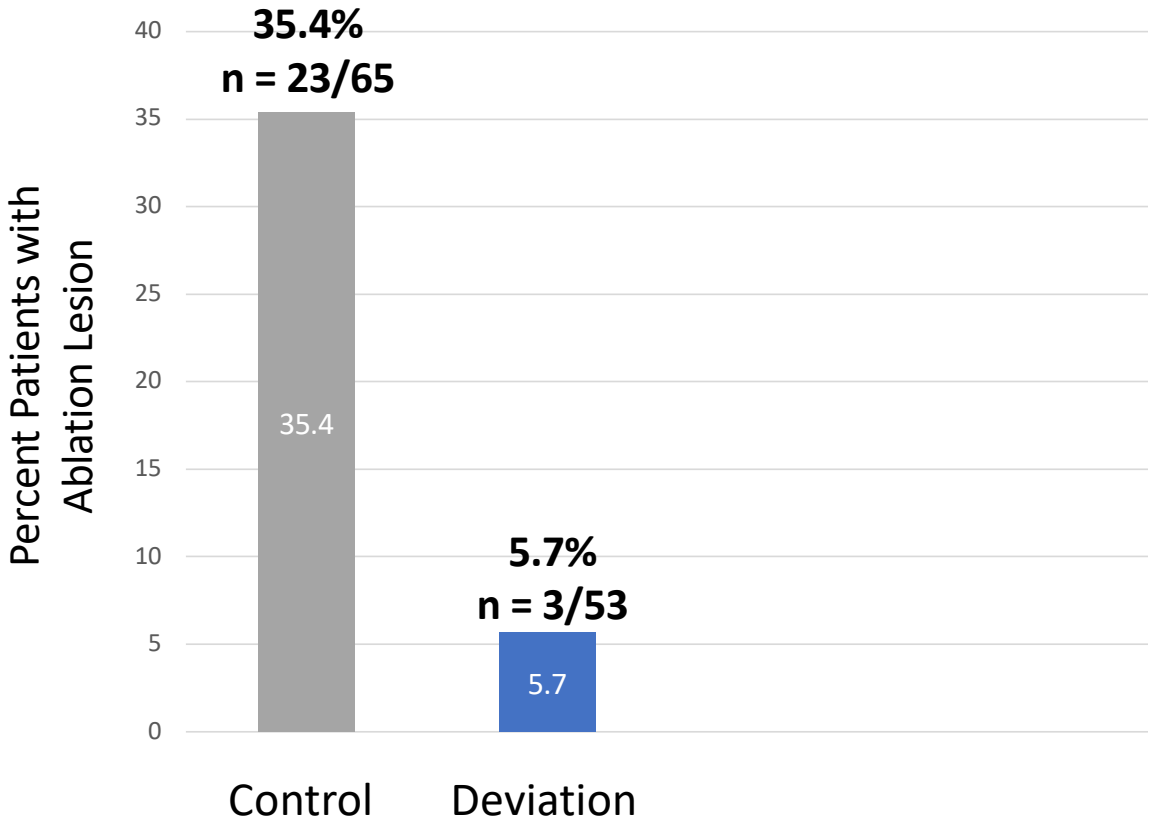


EASY AF Carto Images





DSMB Interim Analysis – Early stoppage due to Efficacy and Safety of Deviation Device, n = 120*



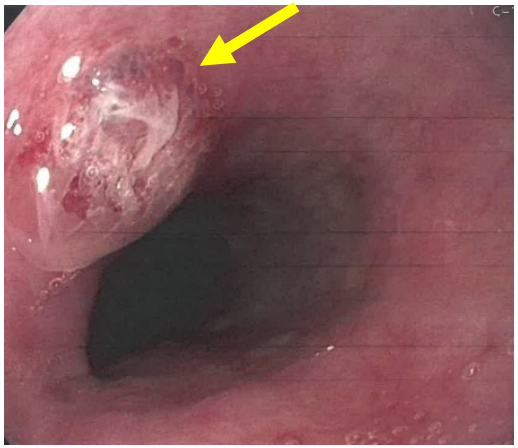
Primary efficacy endpoint:

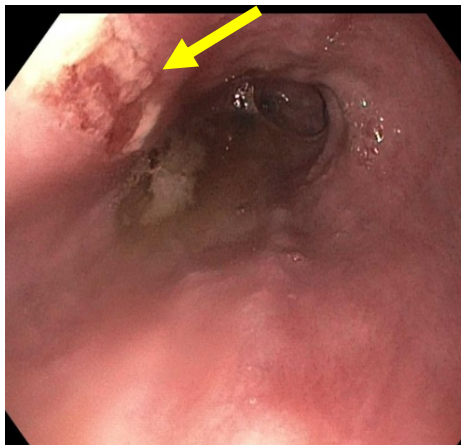
- Significantly fewer number of patients with esophageal ablation lesions
- Significantly fewer number of lesions per patient

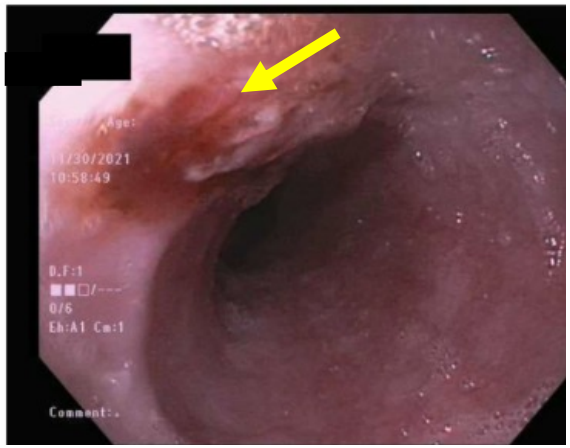
p-value < 0.0001

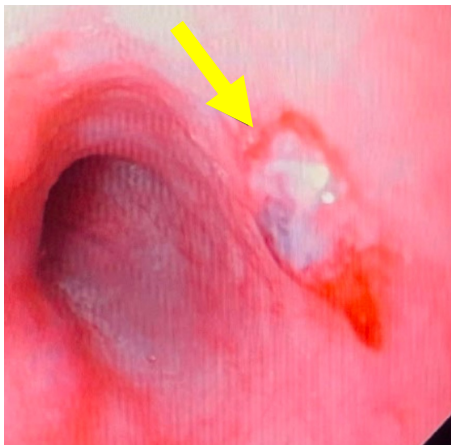
*** 2 patients did not receive EGD (one in each group)**

Images of Esophageal Ablation Injury in Control Patients

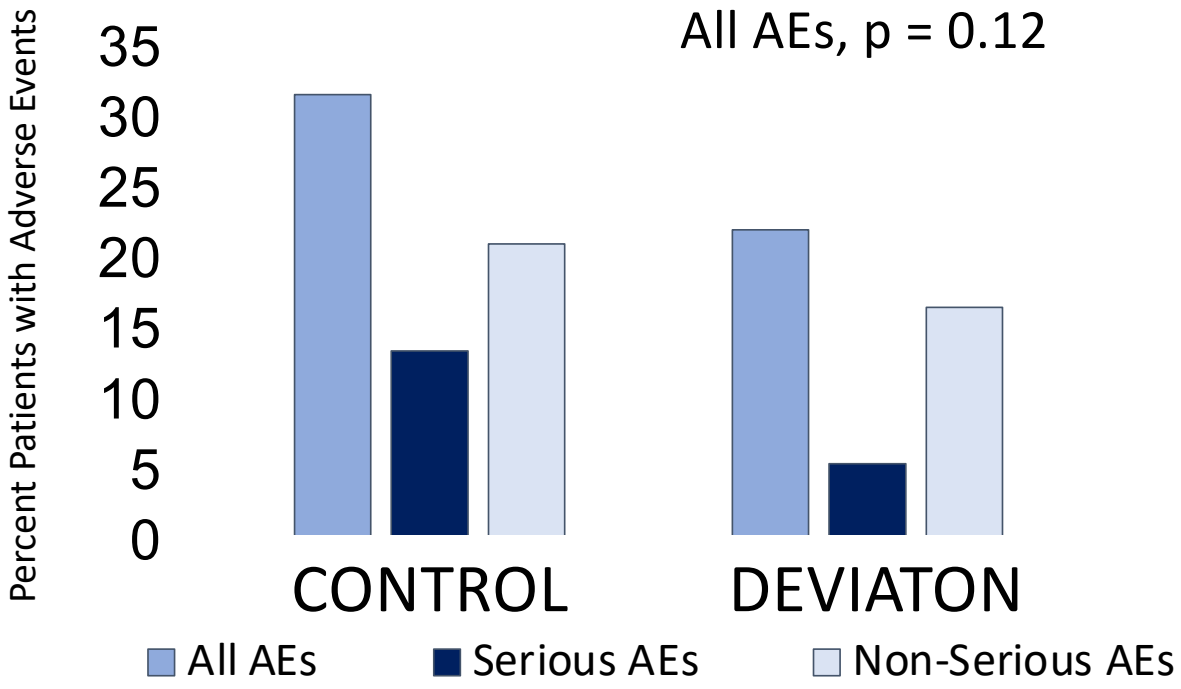






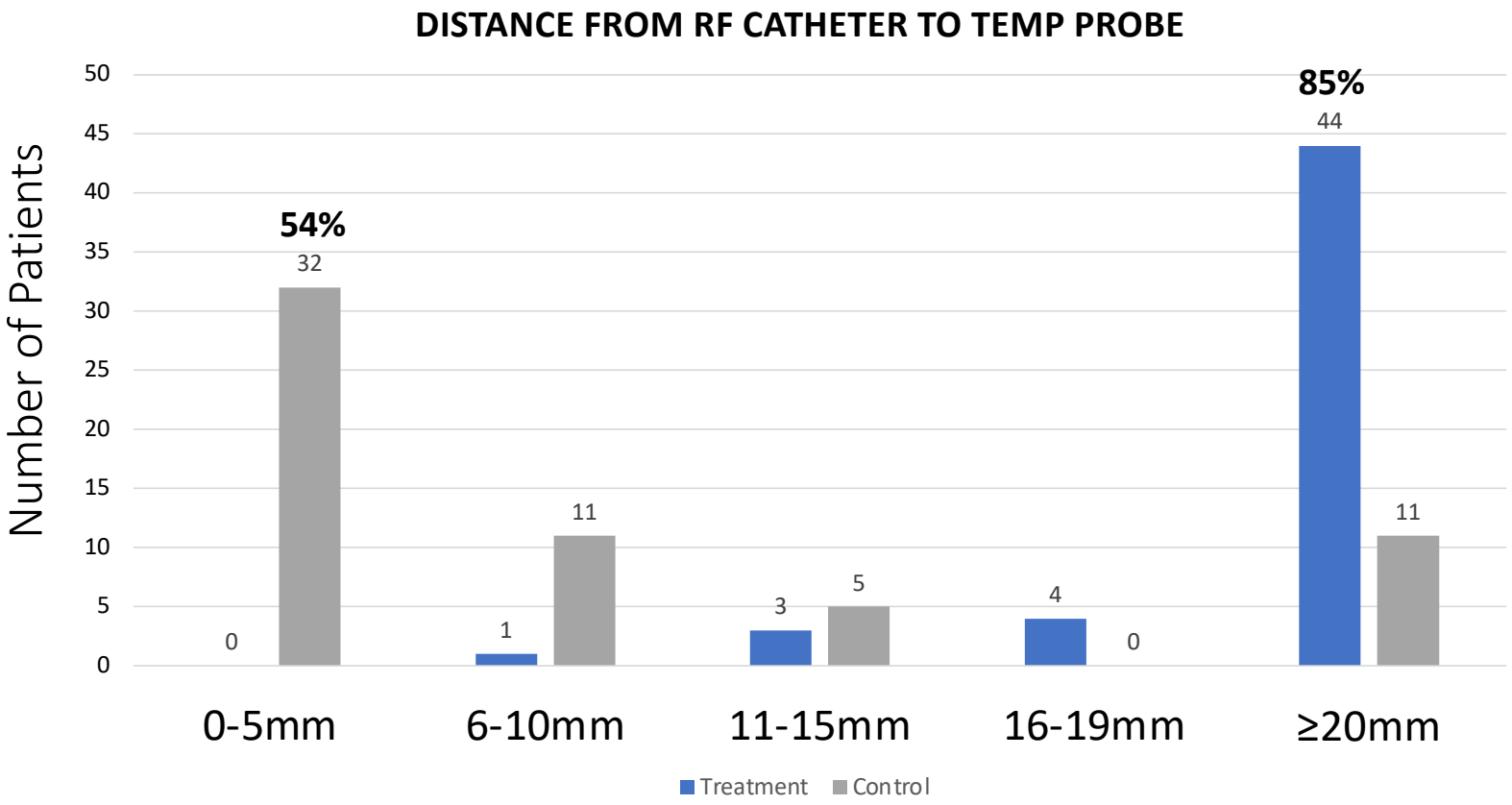


Adverse Events – No difference



No adverse events or esophageal injury were attributable to the treatment device

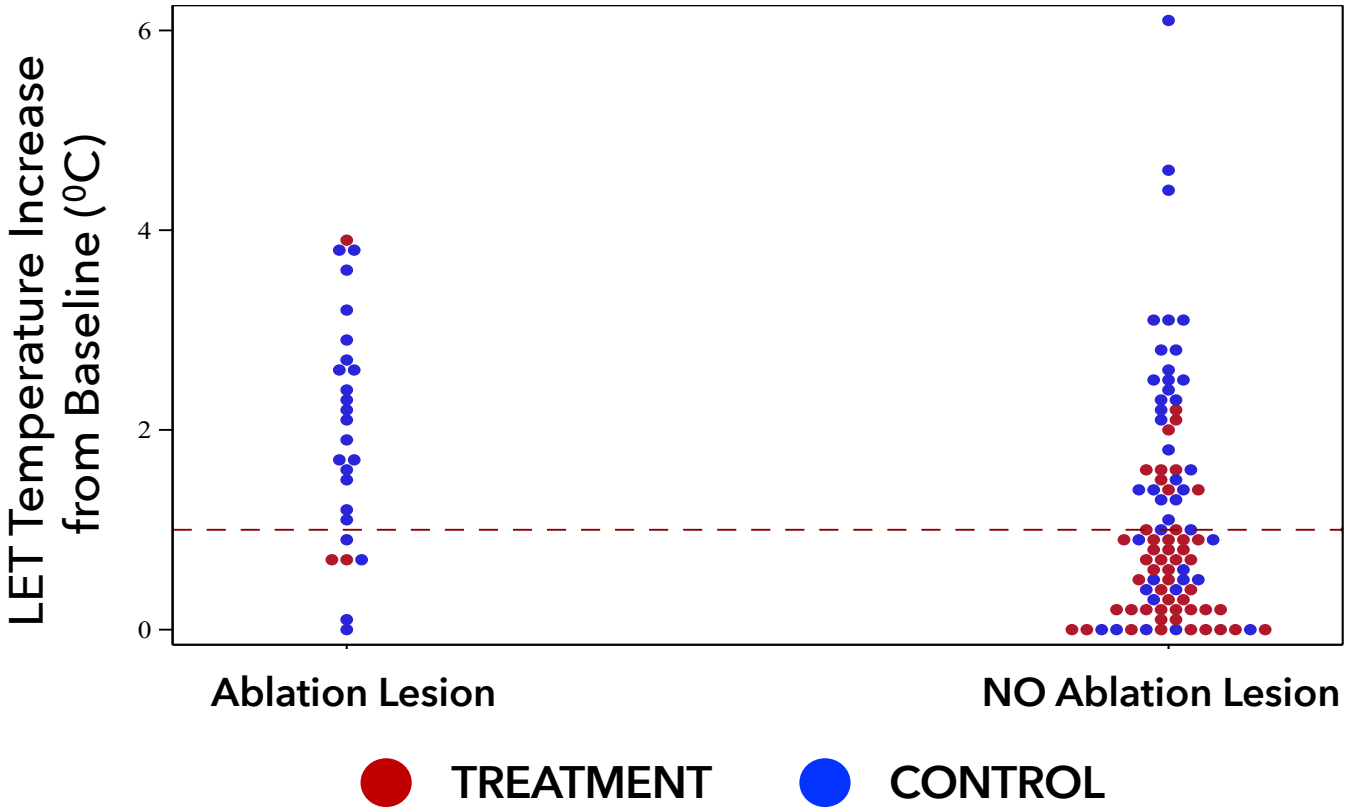
Distance from RF Catheter



92% of TREATMENT patients achieved ≥16mm deviation from ablation area

54% of CONTROL patients had an esophagus 0-5mm from ablation area

LET Temperature Increases



Weak correlation between temp and ablation injury

Lesions were found with even NO increase in temp

Conversely NO lesions found in a wide variety of temp ranges

Multivariate Analysis

- **Only variable associated with reduced esophageal ablation lesions is deviation**
- Odds ratio 0.13; 95% CI 0.04 – 0.46; p = 0.001
- Use of HPSD was not beneficial

Conclusions EASY AF

- First FDA IDE trial seeking FDA labeling
- Significant reduction of esophageal ablation lesions with use of the deviating device without any adverse event assigned to device
- A reliable technique that enhances workflow and safety without increased risk will add significant benefit to patient