

# Esophageal Cooling During Radiofrequency Ablation: Can Opposite (Strategies) Attract?

Cory Tschabrunn<sup>1</sup> and Pasquale Santangeli<sup>2</sup>

<sup>1</sup>Hospital of the University of Pennsylvania

<sup>2</sup>Cleveland Clinic Foundation

October 20, 2022

## Abstract

Catheter ablation has become the standard of care for the management of antiarrhythmic drug-refractory atrial fibrillation (AF) in many patients. The cornerstone of AF ablation includes pulmonary vein isolation (PVI) and energy delivery can sometimes extend beyond the atrial myocardium and result in collateral damage to adjacent structures, include the esophagus.[1] While atrial esophageal fistula (AEF) is a generally a rare complication, there have been continued efforts aimed to reduce esophageal thermal injury during AF ablation. While emerging energy sources such as irreversible electroporation show exciting promise for selective, non-thermal targeting of myocardial tissue, safety and efficacy clinical trial evaluation is on-going.[2] Therefore, strategies that can prevent esophageal thermal injury without adversely impacting lesion formation using conventional ablation technologies are still needed.

## Esophageal Cooling During Radiofrequency Ablation: Can Opposite (Strategies) Attract?

Cory M. Tschabrunn, PhD<sup>1</sup> and Pasquale Santangeli, MD, PhD<sup>2</sup>

<sup>1</sup>Division of Cardiovascular Medicine, University of Pennsylvania Perelman School of Medicine, Philadelphia, PA

<sup>2</sup>Department of Cardiovascular Medicine, Cleveland Clinic, Cleveland, OH

## Corresponding Author:

Cory M. Tschabrunn, PhD

Hospital of the University of Pennsylvania

1 Convention Avenue – Level 2

Philadelphia, PA 19104

Phone: 267-862-0110

Email: [coryt@pennmedicine.upenn.edu](mailto:coryt@pennmedicine.upenn.edu)

## Funding Sources

Dr. Tschabrunn is supported by the Winkelman Family Fund in Cardiovascular Innovation.

## Disclosures

Dr. Tschabrunn receives research and educational grant support from Biosense Webster, Abbott, Baylis Medical, and the National Institutes of Health. Dr. Santangeli receives consulting fees from Biosense

Webster, Abbott, and Baylis Medical. Dr. Tschabrunn and Dr. Tschabrunn have also received research grant support from Attune Medical and are actively involved in leading a NIH funded clinical investigation investigating the ensoETM device.

**Word count:** 1448

Catheter ablation has become the standard of care for the management of antiarrhythmic drug-refractory atrial fibrillation (AF) in many patients. The cornerstone of AF ablation includes pulmonary vein isolation (PVI) and energy delivery can sometimes extend beyond the atrial myocardium and result in collateral damage to adjacent structures, include the esophagus.[1] While atrial esophageal fistula (AEF) is a generally a rare complication, there have been continued efforts aimed to reduce esophageal thermal injury during AF ablation. While emerging energy sources such as irreversible electroporation show exciting promise for selective, non-thermal targeting of myocardial tissue, safety and efficacy clinical trial evaluation is ongoing.[2] Therefore, strategies that can prevent esophageal thermal injury without adversely impacting lesion formation using conventional ablation technologies are still needed.

Numerous studies have investigated the utility of esophageal cooling to prevent or limit thermal injury during AF ablation. [3-8] While various devices and techniques have been proposed, several of these studies have demonstrated the feasibility and potential clinical utility of esophageal cooling for the reduction of thermal injury during RF ablation. Nonetheless the technique has not been widely adopted into clinical practice, at least partly due to the lack of multi-center randomized clinical trial data supporting the safety and efficacy of its use, particularly regarding the potential impact of esophageal cooling on left atrial lesion formation.

Towards this end, Leung and colleagues present data on acute reconnection and first-pass isolation rates from patients enrolled in their previously published prospective, randomized IMPACT study that investigated whether active esophageal cooling during AF ablation can reduce the incidence of esophageal thermal injury.[4] The authors evaluated data available from 188 patients that were randomized to undergo AF ablation with active esophageal cooling versus no cooling. Esophageal cooling was performed using the FDA-cleared ensoETM device (Attune Medical) and activated to 4°C at least 10 minutes before posterior wall ablation was started. The study included both first time and redo AF ablations. Point by point ablation lesions were guided by ablation index (AI) using a power of 40W on the anterior segment and 30W on the posterior wall. The procedural strategy included PVI or PVI combined with isolation of the posterior wall. The authors compared biophysical parameters (catheter temperature, impedance drop) during lesion delivery along with the incidence of first-pass isolation and acute reconnection rate during a 20-minute waiting period in both randomization groups. Provocation of acute reconnection with adenosine was not routinely performed in all patients. In all but 6 cases, the Thermocool Smart-Touch Surround Flow ablation catheter was used.

Impedance drop and ablation catheter tip temperature was similar across groups in the entire cohort of patients. Assessment of first-pass isolation and acute reconnection was performed in 132 patients that had underwent first time AF ablation. First pass PVI was achieved in 51/64 (80%) of patients randomized to receive activation esophageal cooling group and 51/68 (75%) patients in the control group. There was also no significant difference in acute reconnection in first time ablation patients (8% in esophageal cooling group versus 10% in control patients). Furthermore, there was no difference in posterior wall isolation success rates in patients between groups. During clinical follow-up, arrhythmia recurrence rates were also similar within the first year between cooling (21.1%) and the control group (24.1%).

The results from this study are valuable for several reasons. While active esophageal cooling has been proposed as a potential strategy to reduce esophageal thermal injury during RF ablation, it has been unclear whether esophageal cooling can adversely impact posterior RF lesion formation. This has not been systematically evaluated in a large group of patients with available data only from mathematical modeling studies and smaller clinical trials.[9] The authors' findings suggest that active esophageal cooling does not significantly impact atrial tissue lesion formation in a clinically significant way. The authors appropriately recognize that their findings are inherently limited by the single-center study design. In addition, the acute reconnection

assessment technique used was variable and it is likely that more aggressive techniques such as isoproterenol and/or adenosine infusion would likely unmask higher incidences of acute reconnection. The use of adenosine provocation was limited to only 34 (18.1%) of cases, and the criteria adopted by the investigators to use adenosine were not specified in the manuscript. In the eCool-AF pilot study that we conducted which randomized 44 first-time AF ablation patients to active cooling versus conventional temperature monitoring, we found a slightly greater, but statistically non-significant rate of acute reconnections in patients that underwent esophageal cooling when assessed with a 30-minute waiting period and additional pharmacological provocation in all patients. We also found no difference in impedance drop and catheter temperature in the eCool-AF study. However, it is important to point out that the temperatures measured from a Thermocool Smart-Touch Surround Flow catheter do not accurately reflect the actual temperature at the tissue-catheter interface, as the thermocouple temperature sensor in this catheter platform is displaced more proximally. The authors report the use of a new generation ablation catheter (Qdot Micro, Biosense Webster) with thermocouples located within the outer metal shell in a small subgroup of 6 patients (4 randomized to active cooling and 2 control patients). It would have been of interest to evaluate the recorded catheter tip temperatures in those patients to determine whether esophageal cooling truly does not affect the temperature at the LA tissue-catheter interface.

In summary, this additional analysis from Leung and colleagues investigating acute reconnection, first-pass isolation rates, and AF recurrence during follow-up is a welcomed addition to the literature and provides further evidence that esophageal cooling may not have a major impact on left atrial lesion formation. Of note, while the clinical follow-up reported is encouraging regarding similar AF recurrence rates within 1 year following ablation, AF recurrence assessment was limited to data available from standard post-ablation clinical assessment as, understandably, this was likely not part of the original study design.

While many of us remain cautiously optimistic in the promise of electroporation in mitigating AEF risk, safety and efficacy clinical investigation is on-going and it is unlikely to replace RF ablation in the immediate short-term. As such, it is prudent that we continue to investigate alternative techniques and technologies that can reduce AEF risk during RF ablation. In this context, active esophageal cooling with a dedicated device appears to provide protection from esophageal thermal injury without significantly affecting LA lesion quality, and warrants further evaluation in a multi-center clinical trial.

## References

1. Calkins, H., et al., 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation. *Heart Rhythm*, 2017. **14** (10): p. e275-e444.
2. Sugrue, A., et al., Cardiac ablation with pulsed electric fields: principles and biophysics. *Europace*, 2022. **24** (8): p. 1213-1222.
3. Leung, L.W., et al., Esophageal cooling for protection during left atrial ablation: a systematic review and meta-analysis. *Journal of Interventional Cardiac Electrophysiology*, 2019.
4. Leung, L.W.M., et al., Randomized comparison of oesophageal protection with a temperature control device: results of the IMPACT study. *Europace*, 2021. **23** (2): p. 205-215.
5. Tschabrunn, C.M., et al., Active esophageal cooling for the prevention of thermal injury during atrial fibrillation ablation: a randomized controlled pilot study. *J Interv Card Electrophysiol*, 2022. **63** (1): p. 197-205.
6. Arruda, M.S., et al., Feasibility and safety of using an esophageal protective system to eliminate esophageal thermal injury: implications on atrial-esophageal fistula following AF ablation. *J Cardiovasc Electrophysiol*, 2009. **20** (11): p. 1272-8.
7. John, J., et al., The effect of esophageal cooling on esophageal injury during radiofrequency catheter ablation of atrial fibrillation. *J Interv Card Electrophysiol*, 2020. **58** (1): p. 43-50.

8. Montoya, M.M., et al., Protecting the esophagus from thermal injury during radiofrequency ablation with an esophageal cooling device. *J Atr Fibrillation*, 2019. **11** (5): p. 2110.
9. Kulstad, E., M. Mercado-Montoya, and S. Shah, Influence of thermal conductivity on esophageal protection with a cooling device during high-power short-duration radiofrequency ablation - Abstract P1861. *European Heart Journal*, 2019. **40** (Supplement\_1).