

Protecting the Esophagus During Catheter Ablation: Evaluation of a Novel Vacuum Suction-Based Retractor

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Abstract

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Catheter ablation is the current standard of care for the management of symptomatic atrial fibrillation (AFib) refractory to pharmacological therapy. One of the complications of this procedure is thermal injury to the esophagus due to its anatomical proximity to the posterior wall of the left atrium (1). Rarely (<1%), an atrioesophageal fistula can form connecting the lumen of damaged esophagus to the atrial chamber (2). This complication is almost always fatal and can result in exsanguination, air embolism, and sepsis (3, 4). With a growing number of catheter ablations being performed each year, the rate of atrioesophageal fistulas is only expected to rise (5). Other more frequent complications include esophageal wall erosions and ulcers (47%), and thermal injury to the vagus nerve plexus leading to esophageal dysmotility and gastroparesis (17%) (6, 7). Therefore, protecting the esophagus from thermal injuries is paramount in ablative procedures and several strategies have been devised to help mitigate this risk. Many physicians monitor the luminal esophageal temperature (LET) [as a surrogate for intramural esophageal tissue temperature] with a single sensor or multisensor temperature probe and interrupt energy delivery when LET reaches 38°C or 39°C during radiofrequency ablation. However, this technique significantly impacts the procedural workflow due to the waiting periods for LET to return to baseline. Alternative strategies involve cooling of the esophagus with ice water or reducing the ablation lesion power, contact force and/or duration but this strategy may increase the chances for pulmonary vein reconnection (8). To that end, there has been a growing interest in mechanical devices capable of deflecting the esophagus away from the atrium protecting it from thermal injury.

In the current issue of the Journal of Cardiovascular Electrophysiology, Houmsse et al. introduce a novel device capable of mobilizing the esophagus laterally to protect it from injury when performing catheter ablation for AFib. Although other devices have been developed and/or used for this purpose (such as the transesophageal echocardiography probe, endotracheal stylet, Esosure stylet and DV8 shaped balloon retractor), this is the only one to operate using vacuum suction allowing it to latch onto the esophageal wall. The device consists of four main components: outer extrusion, inner stacking plates, deflecting arm and control handle. The outer extrusion is inserted via a trochanter or a bougie into the esophagus and is the only portion of the retractor that comes in contact with the surrounding tissues. Small perforations at the distal end allow for vacuum suction to adhere to the esophagus and for a radiocontrast agent to be delivered to delineate the esophageal contour. The inner stacking plates are then introduced through the outer extrusion and are designed to allow movement of the deflecting arm in the medio-lateral plane only. The deflecting arm is connected to the distal end of the stacking plates through a pivot point and can be steered using the

control handle. The authors have evaluated the effectiveness and safety of the device on canine and swine animal models by measuring the distance and direction of displacement of the esophagus, examining the cellular architecture after prolonged suction, measuring the LET, and assessing compatibility of device with electroanatomical mapping systems. A total of 68 deviations were performed on four canine models. The average rightward deflection was equal to $26.6 \pm 2.5\text{mm}$ compared to $18.7 \pm 2.3\text{mm}$ for the direct leftward deflection ($p < 0.001$), and 96% of deviations did not have an esophageal trailing edge. With the exception of one study, the average distance displaced using the suction retractor was superior to other devices (9-13). The substantial distance of deflection and the minimal esophageal trailing edge significantly decreased the rise in LET from baseline (mean increase of 0.2°C vs 2.5°C without deflection). Examination of the esophageal tissue integrity following one hour of continuous suctioning revealed no change in the esophageal cellular architecture, and only minimal circular areas of hyperemia in mucosa due to the suction ports without injury to the muscularis layer. Finally, the retractor did not interfere with the electroanatomical mapping systems used (CARTO and EnSite).

Despite its interesting findings, this study has several limitations that should be acknowledged. First, the study was performed on swine and canine animal models, which are known to have an anatomy close to humans; however, the safety profile of the device and its effectiveness in displacing the esophagus may not translate in humans. Second, subjects may exhibit symptoms secondary to extreme deviation of the esophagus in the absence of distortion of the cellular architecture. Clinical studies are needed to assess the safety profile and side effects of this esophageal retractor. Third, it is unclear whether these results would be reproducible under monitored anesthesia care. Finally, the fluoroscopic equipment tools lacked electronic caliper capabilities, and the measurements were performed using radiopaque rulers.

Overall, the authors should be commended on their efforts to introduce and evaluate an inexpensive and innovative tool for esophageal protection during AFib ablation. This retractor addresses the limitations of other products that serve a similar purpose. In fact, the suctioning power of the product minimizes the trailing edge of the esophagus that could not be managed with other devices which left esophageal tissue in the ablation field (10, 13). In addition, the control handle offers significant flexibility in device manipulation allowing physicians to choose the site of angulation and the angle of deflection depending on the patient's anatomy. Future studies should focus on evaluating the safety and effectiveness of this device in humans. Given the growing number of esophageal retracting devices, studies should also aim to determine the device that produces the best esophageal protection and most desirable outcomes of ablation.

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