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Protection of the Esophagus During Catheter Ablation of Atrial Fibrillation

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Abstract

Esophageal injury still occurs with high frequency during ablation of atrial fibrillation (AF). The purpose of this study is to provide a review of methods to protect the esophagus from injury during AF ablation. Despite advances in imaging and ablation, the potential risk of esophageal injury during AF ablation remains an important concern with a high occurrence of esophageal injury ([?]15%). There have been numerous studies evaluating varied techniques for esophageal protection including active cooling and displacement of the esophagus. These techniques are reviewed in this manuscript as well as the role of esophageal protection in managing patients undergoing AF ablation procedure.

Introduction

Catheter ablation is an important and widely used strategy to treat atrial fibrillation (AF). Given the proximity of the esophagus to the left atrium, less than 5mm in autopsy studies[1], delivery of ablation energy can radiate from the catheter resulting in esophageal injury/ulcerations and, the most serious complication, atrio-esophageal fistula (AEF). The purpose of this manuscript is to review esophageal injury related to ablation energy and the techniques used to protect the esophagus.

Scope of the Problem – Meta-Analysis

The first description of AEF with radiofrequency ablation (RFA) of AF was in 2004[2], with subsequent publications reporting upon the variable presentation, delayed recognition, and high mortality owing to air embolism, sepsis, endocarditis and gastroesophageal exsanguination[3-10]. Although this complication occurs at a low frequency of 0.1-0.2%[11,12] considering the large number of AF ablations being performed worldwide (˜180,000 annually), this would translate to AEF occurrence of 180-360 patients annually.

In contrast to the low incidence of life-threatening AEF, the incidence of esophageal injury and ulcerations, believed to be precursors to AEF, has been reported as high as 47% of patients who undergo ablation[9]. The appendix presents a meta-analysis of 42 studies (and the reference list) that assess the incidence of ablation-related esophageal injury confirmed by endoscopy. The total number of patients included is 5206 and the occurrence of endoscopy detected esophageal lesions was 758 patients, thus a rate of 14.5%. It is important to note that esophageal injury has been reported with use of the full spectrum of ablation methodologies: percutaneous RFA using 8mm and irrigated-tip single electrode, cryo-balloon energy, high-intensity focused ultrasound ablation, irrigated circular RFA, duty-cycled phased RFA, hot balloon ablation, minimally-invasive surgical ablation and robotic navigation[3-12]. Furthermore, with the introduction of contact force catheters, the incidence of AEF has been reported to be increasing[13].

Mechanism of Injury

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The exact mechanism of ablation injury to the esophagus is unclear and may be multifactorial. A common explanation is the direct effect of ablation energy resulting in injury to the esophagus – either with RF or cryo-ablation energy. Another potential mechanism is focal ischemia overlapping the site of ablation. Esophageal blood supply consists of arborizing arterial system over the surface of the esophagus. Ablation energy can result in ischemia due to occlusion of arteriole supply. Also, ablation energy can impact the vagal plexi over the esophagus resulting in gastroparesis with subsequent acid reflux.

Standard of Care

Currently, the standard of care is to place a temperature probe in the esophagus to provide luminal esophageal temperature (LET) monitoring. Studies have shown that ablation energy delivered within the left atrium near the esophagus significantly increase the LET[23-27]. Esophageal lesions have been shown to correlate with LET exceeding 41° C[16,18]. However, LET monitoring has several limitations[26,27]. Often times, the LET is surrounded by air, which acts as an insulator and reduces prompt transmission of temperature change to the LET probe. In part, this explains why an increase in LET is associated with latency (the measured temperature rise lags behind the actual peak temperature), inaccuracy, and underestimation of the esophagus temperature at the outer layers closer to the ablation source (adventitia, muscularis, and submucosa, which is the site of esophageal blood supply). In addition, rises in LET mandate interruption in energy delivery that interrupt workflow and potentially decrease procedural efficacy; and, most troublesome, esophageal injury/fistulas have been reported even with careful LET monitoring demonstrating no temperature rise[1,15,23]. Thus LET monitoring is an inadequate method to guide ablation therapy to avoid esophageal injury.

Protection of the Esophagus

Methods to protect the esophagus, beyond monitoring LET, include 2 categories, active cooling and mechanical displacement. No esophageal protection device is approved for use by the US FDA.

Active Cooling

Use of active cooling of the esophagus with ice water was unsuccessful[28]. In a more recent study, IMPACT, patients were randomized to either LET monitoring or to active cooling using the ensoETM device, which is used in critical care to alter body temperature[29]. The device is a silicone tube that is inserted into the esophagus, increased to an outer diameter of 12mm with 14.9 pounds per square inch, and has a closed loop system that pumps distilled water at 4^0C (Figure 1). Additionally, a heated air blanket was used to maintain a body temperature $>35^0$C. Endoscopy was performed at 7 days post ablation. Esophageal thermal injury was significantly greater in the control group in comparison to the protected group (12/60 vs 2/60, $p < 0.01$). There was no difference in duration of RF, procedure and fluoroscopy. This is the only randomized study assessing esophageal protection utilizing endoscopy results of esophageal injury as the primary endpoint.

Mechanical Displacement

- Transesophageal Echocardiography

Mechanical displacement of the esophagus has been utilized with varied results. In a single center prospective nonrandomized study, a transesophageal echocardiogram (TEE) probe was used in 704 patients with remarkable findings: successful deployment and deviation of the esophagus in 680/704 patients (96%) with a mean displacement of 59 millimeters and complications of minor superficial bleeding in only 2/704 (0.3%)[30]. However, a subsequent study assessing displacement of the esophagus with a TEE probe reported contrary findings of being able to move the esophagus only 9.3 millimeters and the authors comment that the device tented the esophagus rather than displaced the entire segment[31], meaning that the device did not move the trailing edge. Neither study utilized endoscopy post ablation.

- Gastroenterology Endoscope

Movement with use of a gastroenterology endoscope has been more successful[32], with deviation of about 23 millimeters, but success was in only 10/12 patients (80%) and was performed by a physician with advanced training (endoscopist), thus interrupting workflow and requiring additional resources. However, because

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the results were modest, the need for subspecialist physician to perform the procedure simultaneous with performing an ablation procedure, and without movement of the trailing edge, this technique is not routinely utilized.

- Endotracheal Stylet

Another method used to deflect the esophagus has been reported using endotracheal stylets in 114 patients[33]. The stylet was easily placed and the mean distance of deflection was 14.6 millimeters, with rise in LET when the deflection was <5mm. Furthermore, one of the major limitations is that the trailing edge was not displaced leaving this section of the esophagus vulnerable to injury. This technique, however, has not been widely embraced since results are variable and use of stylets is a crude method that has not been validated in a multicenter study.

- Balloon Deviation

Another reported technique to deviate the esophagus is balloon deviation using the DV8 device[34], which is a polyurethane device wrapped in silicone (Manual Surgical Sciences). Although the device is commercially available, it is not FDA approved.

As the device is inflated with air, the preshaped balloons result in increased esophageal pressure to a mean of 5 atmospheres (73 pounds per square inch, psi) and a maximum of 16 atmospheres (235 psi). The preshaped balloons deviate the esophagus in a predefined fashion according to the direction of the balloons, with a diameter of 17mm (Figure 2). The device is deflated, reinserted and re-inflated to move the esophagus in the opposite direction.

The device was tested in 200 patients undergoing AF ablation[34]. The study introduced the concept of measuring the mechanical esophageal deviation ($\text{MED}_{\text{Effective}}$), defined as the distance from the trailing edge of the esophagus to the ablation catheter, and correlated the $\text{MED}_{\text{Effective}}$ to the change in LET. The $\text{MED}_{\text{Effective}}$ was 18.4mm. Esophageal temperature increases occurred as $\text{MED}_{\text{Effective}}$ decreased: 100% for $\text{MED}_{\text{Effective}}$ [?] 5mm, 43% for 5.1-10mm; 26% for 10.1-15mm; 23% 15.1-20; and 2% with >20mm. There were 2 complications of oropharyngeal bleeding.

Important limitations of the DV8 device is that the ideal deviation of >20mm was achieved in only 36% of patients, that balloon inflation within the esophagus is not easily adopted by electrophysiologists or anesthesiologists, the device does not provide varied degrees of deflection and the efficacy of deviation was not confirmed by post ablation endoscopy.

-Nitinol Retractor

Another device used for esophageal deviation during AF ablation that is commercially available but not FDA approved is the *EsoSure*pre-shaped nitinol retractor used in 209 patients[35]. This stylet is introduced through an 18Fr orogastric tube that is placed in the esophagus. At body temperature, the EsoSure device takes an "S" shaped curve and hence deviates the esophagus (Figure 3). The study reported a significantly reduced occurrence of LET increase of $>1^0$C in patients with use of the stylet (3%), compared to a propensity matched control group (79%). The mean deviation was 25 millimeters. However, the presence of a trailing edge has been noted, there is no directional control and endoscopy has not been used to assess for post ablation lesions.

-Vacuum Suction

Another recently developed product for esophageal deviation that is not FDA approved is called Esolution. This device moves the esophagus using two techniques[36]. Through a central lumen of the device, a vacuum force is applied to the esophageal walls so the walls collapse upon the central core of the device. The central core consists of a mechanical arm which then can be deviated to the varied degree of control to the right or to the left. The vacuum suction applies a circumferential force that holds all walls of the esophagus so when the deflecting arm is used, the entire segment of the esophagus is deviated and the vacuum force eliminates the trailing edge (Figure 4). The device outer diameter is 11.6mm.

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The first in man study was completed in 7 patients undergoing cryoballoon ablation[37]. The suction force was 200mmHg. The mean distance of deviation was 32mm to the right and 28mm to the left, and there was no trailing edge. Each patient was discharged the same day as the procedure and endoscopy was completed at a mean of 4 days post ablation. There was no esophageal lesion related to the device or to ablation energy. This device will undergo further evaluation with an upcoming FDA-approved trial comparing the occurrence of endoscopy-confirmed esophageal lesions post RFA in patients randomized to use of Esolution vs no deviation (EASY AF Study).

Other Methods to Avoid Esophageal Injury

- High Power / Short Duration

High-power/short duration (HPSD) RFA has been increasingly utilized during left atrial posterior wall ablation since its biophysics relatively depends on resistive heating rather than conductive heating. Therefore, esophageal injury is presumably less likely compared to conventional RFA[38]. Nevertheless, a recent study showed significant increase in LET if HPSD RFA lesions performed less than 20mm from the temperature sensor[39]. There was no endoscopy performed to confirm safety of HPSD ablation. However, additionally, a recent meta-analysis reported no difference in esophageal injury with HPSD compared to conventional RFA[40]. To date, therefore, there is no data to suggest that HPSD offers an ablation strategy to reduce esophageal injury.

- Pulse-Field Ablation

Pulse-field ablation (PFA) has been applied in AF ablation. The advantage of PFA is that it creates myocardial tissue-specific death by forming micropores in the cell membrane, without risk of injury to collateral structures, including esophageal tissue. PFA efficacy and safety was evaluated in 81 patients who underwent successful pulmonary vein isolation. There was no esophageal injury in 25 patients who underwent post PFA endoscopy[41].

Conclusion

Although the occurrence of AEF is low likelihood, the occurrence of esophageal injury related to AF ablation is quite frequent (about 15%). The concern for esophageal injury during AF ablation is a focus for electrophysiologists and has resulted in numerous steps to try to prevent injury: varied modalities used to identify the location/course of esophagus, continuous monitoring of esophageal luminal temperature with a variety of temperature monitoring systems, alteration of ablation techniques and energy delivery, and empiric use of proton pump inhibitors. Furthermore, the concern for AEF persists for a few weeks post ablation, resulting in the costly and worrisome clinical scenario of emergently excluding the presence of AEF in patients who present with symptoms post ablation.

Certainly a reliable method to protect the esophagus is of clinical value, but the ancillary value of reducing physician concern during AF ablation, reducing interruption to ablation work flow, perhaps enhancing AF ablation results[34] and simplifying post procedure management of patient symptoms are also of high importance. Considering the ease of use, minimal side effects, and low costs associated with esophageal protection devices, these features offer compelling evidence for use of esophageal protection as routine care for AF ablation.

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Figure 1

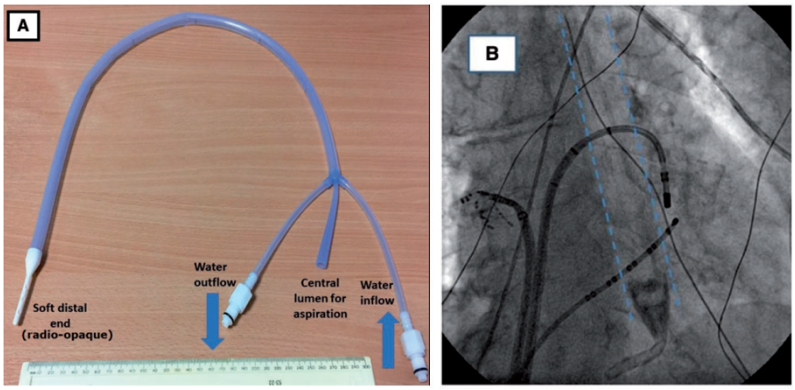

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Figure 2

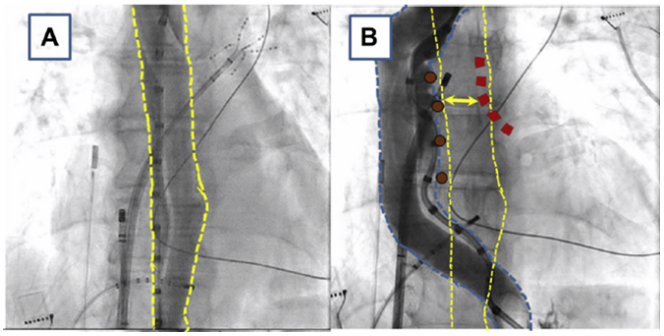

Figure 3

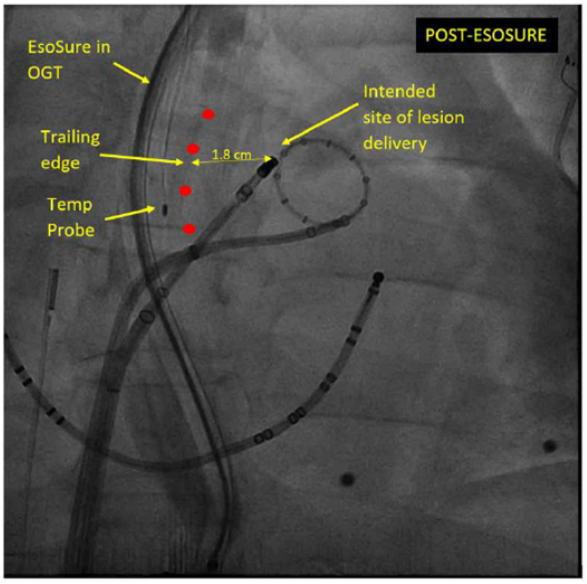

Figure 4