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Luminal Esophageal Temperature Monitoring With a Deflectable Esophageal Temperature Probe and Intracardiac Echocardiography May Reduce Esophageal Injury During Atrial Fibrillation Ablation Procedures

Results of a Pilot Study

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Background—Luminal esophageal temperature (LET) monitoring is one strategy to minimize esophageal injury during atrial fibrillation ablation procedures. However, esophageal ulceration and fistulas have been reported despite adequate LET monitoring. The objective of this study was to assess a novel approach to LET monitoring with a deflectable LET probe on the rate of esophageal injury in patients undergoing atrial fibrillation ablation.

Methods and Results—Forty-five consecutive patients undergoing an atrial fibrillation ablation procedure followed by esophageal endoscopy were included in this prospective observational pilot study. LET monitoring was performed with a 7F deflectable ablation catheter that was positioned as close as possible to the site of left atrial ablation using the deflectable component of the catheter guided by visualization of its position on intracardiac echocardiography. Ablation in the posterior left atrial was limited to 25 W and terminated when the LET increased 2°C from baseline. Endoscopy was performed 1 to 2 days after the procedure. All patients had at least 1 LET elevation necessitating cessation of ablation. Deflection of the LET probe was needed to accurately measure LET in 5% of patients when ablating near the left pulmonary veins, whereas deflection of the LET probe was necessary in 88% of patients when ablating near the right pulmonary veins. The average maximum increase in LET was 2.5°C. No patients had esophageal thermal injury on follow-up endoscopy.

Conclusions—A strategy of optimal LET probe placement using a deflectable LET probe and intracardiac echocardiography guidance, combined with cessation of radiofrequency ablation with a 2°C rise in LET, may reduce esophageal thermal injury during left atrial ablation procedures. (Circ Arrhythm Electrophysiol. 2011;4:149-156.)

Key Words: catheter ablation ■ atrial fibrillation ■ complications ■ esophageal injury ■ temperature monitoring

Clinical Perspective on p 156

Luminal esophageal temperature (LET) monitoring has also been suggested as one method of assessing the risk of esophageal thermal injury with a strategy of cessation of radiofrequency ablation once a prespecified LET is obtained.
possibly minimizing this risk.4 Despite the use of LET monitoring, esophageal ulcerations have been reported to occur in 6% to 26%2-4,5 of patients undergoing AF ablation. Additionally, and somewhat more worrisome, at least 2 cases of LA-esophageal fistula have been reported in patients undergoing AF ablation procedures with LET monitoring.6-7

The ongoing high rate of esophageal thermal injury despite LET monitoring probably is related to the limitations of the current technique used for LET monitoring. Specifically, suboptimal orientation and positioning of the LET probe in relationship to the site of radiofrequency application may result in an underestimation of the true LET at the site closest to the area of radiofrequency application. It is possible that this limitation may be overcome with the use of imaging to position the LET probe in as close proximity as possible to the location of the radiofrequency catheter during ablation, thereby improving the accuracy of the LET value obtained, and allowing one to better estimate the risk of local esophageal thermal injury. Thus, the aim of this pilot study was to assess the impact of LET monitoring using intracardiac echocardiography (ICE) guidance to visualize and position the LET probe in as close proximity to the radiofrequency ablation catheter as possible, on the prevalence of esophageal injury in patients undergoing AF ablation procedures.

Methods

Patient Population

Forty-five consecutive patients with symptomatic drug refractory AF planned to undergo a first-ever AF ablation procedure, were included in this prospective observational pilot study. All patients were identified and all procedures performed at the Instituto Brasilia de Arritmia, Brasília, Brazil, between December 2008 and April 2009. All patients provided verbal and written informed consent as per the local institutional guidelines. The study was approved by the Ethics Committee of the Instituto Brasilia de Arritmia, Brasília, Brazil.

Patient demographics (age, sex, and body mass index) and disease characteristics (paroxysmal AF, LA volume, and left ventricular ejection fraction) were obtained from all patients in this cohort.

Ablation Procedure

Coumadin therapy was discontinued 3 days before the ablation procedure, and all patients bridged with low-molecular-weight heparin. Conscious sedation (n = 2) or general anesthesia (n = 43) was available for all cases and used according to patient’s preference and physician discretion. Internal jugular venous access was obtained in all patients and used to place a decapolar catheter within the coronary sinus. Additionally, an ICE catheter (10F; 5.5 to 10 MHz phased array, AcuNav Ultrasound Catheter, Biosense Webster, Diamond Bar, CA) was placed in the right atrium in all patients and used to guide transseptal puncture as well as position the LET probe (see description below). Double transseptal punctures were performed in all patients, and a 20-mm circular mapping catheter and 3.5-mm open irrigated tip ablation catheter (Navistar Thermocool or Celsius Thermocool, Biosense Webster) were placed within the LA via each transseptal sheath.

Preprocedural imaging with CT or MRI was not performed in any patient. The ablation procedure was performed with fluoroscopy, and ICE guided movements of the circular mapping catheter in 25 patients, whereas an electroanatomic mapping system (CARTO XP and CARTOSOUND, Biosense Webster) was used in the remaining patients. LA geometry was created in a point-by-point fashion using the ablation catheter and fluoroscopic and ICE guidance when the CARTO XP (Biosense Webster) electroanatomic mapping system was used (n = 9). LA geometry was created with the CARTOSOUND module by tracing the LA contours obtained with ICE imaging (n = 11).

Ablation was performed in the antral region of all pulmonary veins (PV) guided by the presence of PV potentials on the circular mapping catheter with the aim of achieving pulmonary vein isolation. Additional LA substrate modification was performed at the discretion of the operator.

The radiofrequency generator (Stockert, Biosense Webster) was set to deliver a maximum of 30 W and 42°C. Power was limited to 25 W and radiofrequency applications approximately 30 seconds in duration when abating on the posterior wall. Further reductions in radiofrequency power were undertaken with rises in LET (see below). The flow rate was 17 mL/min during radiofrequency ablation. Ablation lesions were delivered by “dragging” the catheter.

LET Monitoring

LET monitoring was achieved with a standard curve, 7F steerable symmetrical bidirectional 5-mm-tip ablation catheter (EPT Blazer II, Boston Scientific, Natick, MA). The thermistor of the ablation catheter is located at its tip. A cable adapter from the ablation catheter was plugged directly into the electrophysiology recording system (EP-Tracker, Cardiotek, Maastricht, The Netherlands), and the changes in LET from baseline were displayed on the recording system and also documented. Any rise in LET of 2°C from the baseline LET resulted in a red flashing light to be displayed on the recording system, thereby alerting the operator to an absolute 2°C rise in LET during the current radiofrequency application. Radiofrequency applications were discontinued when an absolute rise in LET >2°C above the baseline occurred—this value (2°C) was selected based on our prior experiences (selecting a rise of only 1°C resulted in frequent premature termination of radiofrequency applications), desire to account for variations in baseline LET among patients, and recognition that an elevation in LET of >2°C would correspond to a greater rise in intramural esophageal temperature that may be detrimental. In general a LET rise >2°C usually occurs before achieving an absolute LET of 39°C. Additional ablation was permitted at a reduced power output (15 to 20 W) once the LET had returned to baseline.

Use of ICE to Aid LET Probe Positioning

At the start of the ablation procedure, the deflectable ablation catheter (ie, the LET probe) was inserted into the lumen of esophagus in an undeflected manner (Figure 1). The ICE catheter was placed within the right atrium (RA) and manipulated to visualize the esophagus (Figure 1). ICE manipulation was performed by 1 of 2 operators with extensive experience in cardiac ultrasound imaging. The echocardiographic relationship between the esophagus and PVS was also documented. Occasionally, when the CARTOSOUND module was used, the esophagus was traced and displayed on the electroanatomic map to illustrate its relationship to the LA.

If the esophagus was visualized with ICE at a targeted site of ablation, then the LET probe was manipulated such that it was also visualized on ICE at a site as close as possible to the targeted ablation site (hereafter called the optimal site) (Figure 2 and online-only Supplement Video 1 and Video 2). To achieve this, the LET probe was frequently advanced or retracted in a cranio-caudal fashion, or, using the deflectable feature of the LET probe, deflected to the right or the left (Figure 2), or, turned in a clockwise or counterclockwise fashion to be positioned more anterior or posterior in the esophagus (Figure 3). LET probe manipulation was performed exclusively by a circulating nurse in the electrophysiology laboratory. Any distension in the esophagus during LET probe manipulation (Figure 4, online-only Supplement Video 1) was annotated.

Esophageal Evaluation

All patients underwent a non–symptom-driven esophageal endoscopy within 2 days of the AF ablation procedure. All procedures were performed by a single gastroenterologist. Particular attention was made to visualizing the region of the midesophagus adjacent to
the pulsating heart where ablation related thermal injury would be expected to occur.

Follow-Up
All patients were discharged after the endoscopy procedure. A therapeutic international normalized ratio was maintained for at least 4 months after the ablation procedure. Antiarrhythmic agents were initiated or continued at the discretion of the patient’s physician. All patients were prescribed the proton-pump inhibitor pantoprazole for 1 week after the procedure. During the first year of follow-up, ECGs were recorded monthly, Holter monitoring performed at the 3rd, 6th, and 12th months, and exercise testing performed during the 6th month of follow-up. Recurrence was defined as any AF recorded by ECG, Holter monitoring, or exercise testing.

Statistical Analysis
Continuous variables were reported as mean ± standard deviation and discrete variables reported in percentages. Two-by-two contingency tables were created for discrete variables and frequencies compared with the χ² test. The proportion of patients in this series with esophageal ulceration was reported, and the Zar method was used to determine the confidence interval associated with this proportion. Probability values (probability values) <0.05 were considered significant. All statistical analysis was performed with SPSS 15 for Windows (SPSS Inc, Chicago, IL).

Results
Patient and Procedural Characteristics
The Table summarizes the patient and procedural characteristics of the study cohort. No patient had a history of esophageal disease. All patients had an international normalized ratio <2.0 on the day of the procedure. General anesthesia was used in all but 2 patients (n=43, 96%). Orogastric or nasogastric tubes were not placed in any patient. The average procedure time for the entire cohort was 255±67 minutes.

Esophageal Visualization
The course of the esophagus in relation to the LA was visualized with ICE in 98% (n=44) of patients in this cohort. The esophagus was not visualized in one patient with a severely dilated LA (LA volume=240 mL/m²). This patient was excluded from the current analysis.

Using ICE, the esophagus was visualized solely in proximity to the left PVs in 41% (n=18) of patients, solely in proximity to the right PVs in 9% (n=4) of patients, and in proximity to both the right and left veins in 50% (n=22) patients. There was no change in the esophageal location during the ablation procedure with either ICE or fluoroscopic visualization.

Positioning of the LET Probe
When the esophagus was in contact with the left PVs (n=40), the optimal LET probe position was achieved with the LET probe undeflected in 95% (n=38) of patients. That is, simply advancing or retracting the LET probe in a craniocaudal fashion guided by fluoroscopy was sufficient to position the LET probe as close as possible to the radiofrequency ablation catheter in 95% of the patients in this cohort. In the remaining 2 patients, the optimal LET probe position could not simply be achieved with manipulating the LET probe in a craniocaudal direction. In these 2 patients, deflection of the LET probe to the left guided by ICE allowed it to be in a position nearest to the radiofrequency ablation catheter, which resulted in further rises in LET during radiofrequency application.

When the esophagus was in contact with the right PVs (n=26), an optimal LET probe positioning was achieved with the LET probe undeflected in 12% (n=3) of patients. That is, simply advancing or retracting the LET probe in a craniocaudal fashion guided by fluoroscopy alone was sufficient to position the LET probe as close to the radiofrequency ablation catheter in only 12% of patients. Deflection of the LET probe guided by ICE was necessary to position the LET probe as close as possible to the radiofrequency ablation catheter in the remaining 88% of cases (Figure 2). Deflection of the LET probe to achieve an optimal position was more necessary when the esophagus was near the right than left sided PVs (P<0.001).

In addition to optimizing the position of the LET probe in a lateral direction (that is, right to left), ICE aided optimiza-
tion of the LET probe position in an anteroposterior direction in 5 patients (Figure 3). For example, occasionally the LET probe would be located adjacent to the posterior wall of the esophagus; such an orientation may result in underestimation of LET due to the inability to accurately detect anterior esophageal wall heating during posterior LA ablation. In addition, distension of the anterior esophageal wall into the posterior LA by the LET probe (Figure 4 and online-only Supplement Video 1) was noted with ICE at some point during 27% of the procedures. In these situations, the LET probe was repositioned as this orientation may facilitate esophageal heating (Figure 4 and online-only Supplement Video 2).

**LET Monitoring**

The average baseline LET in this cohort was 35.8±0.7°C. All patients had at least 1 LET elevation >2°C during radiofrequency ablation that necessitated termination of radiofrequency ablation (Figure 5). Radiofrequency lesions that were terminated achieved, on average, a maximum LET rise of 2.5±1.5°C from the baseline LET with the maximum LET occurring approximately 11±8 seconds after termination of...
radiofrequency ablation. The LET returned to the baseline preablation temperature approximately 18±9 seconds after the maximum LET was achieved.

During ablation of the left PVs, deflection of the LET probe resulted in detection of at least 1 significant LET rise in 2 of 40 patients. However, during ablation of the right PVs, deflection of the LET resulted in detection of at least 1 significant LET rise in 23 of 26 patients. An association between deflection of the LET probe and LET rises was observed when ablation was performed near the right compared with the left PVs (P<0.001).

Of note, compared with prior experiences, we did not observe any unusual change in impedance during ablation when the deflectable LET probe was used with the average impedance during ablation being 113±10 ohms.

Endoscopy
All patients underwent esophageal endoscopy within 2 days after ablation procedure (68% on day 1). No esophageal mucosal abnormalities (ie, erythema or ulceration) were noted in any patient. No evidence of trauma related to the use of the LET probe was noted. The 95% confidence interval for the observed event proportion was 0% to 8%.

Follow-Up
Patients were followed up for an average of 13±3 months. No patients had esophageal symptoms (dysphagia) or LA-esophageal fistula during the follow-up period. AF recurrence was 25% after a single procedure during the follow-up period (14.3% for paroxysmal and 35% for nonparoxysmal AF), with 14% of patients free of AF still on an antiarrhythmic agent for the duration of the follow-up period.

Discussion
The results of this pilot study suggest that a strategy of optimal LET probe placement guided by real-time esophageal imaging, combined with the cessation of radiofrequency ablation after a 2°C rise in LET, may be considered another tool to reduce esophageal thermal injury during AF ablation procedures.

Efficacy of Current Methods of LET Monitoring
As esophageal thermal injury may be the precursor to the rare but devastating complication of LA-esophageal fistula, it is imperative that strategies minimizing esophageal heating during AF ablation be developed. LET monitoring during AF ablation has been proposed as one such strategy. Singh et al demonstrated that LET monitoring during AF ablation procedures (with cessation of radiofrequency at LET >38.5°C) was associated with an 83% relative risk reduction in esophageal ulcer formation compared to performing AF ablation without LET monitoring. Despite this, 6% of patients in this series had esophageal ulceration. Di Biase et al reported on a series of patients undergoing AF ablation with cessation of radiofrequency ablation with any increase in LET >39°C—esophageal ulceration was noted in 26% of patients. Rillig et al performed AF ablation with a remote robotic navigation system. Esophageal ulceration was present in 14.3% of patients despite termination of radiofrequency ablation with LET rises >39°C. Additionally, we are aware of at least 2 cases of LA-esophageal fistula formation after AF ablation performed with LET monitoring. Thus, current methods of LET monitoring during AF ablation procedures may reduce but not eliminate the risk of esophageal injury.
Role of Real-Time Esophageal Imaging
Given the complex anatomy and dynamic nature of the esophagus, it is no surprise that current methods of LET monitoring with LET probe placement guided solely by fluoroscopy are unable to eliminate esophageal injury. The ability to visualize the location of the LET probe with ICE and subsequently deflect the probe to optimize its placement probably improves the accuracy of local LET measurements. In our series of patients, adjusting the LET probe in a craniocaudal manner, similar to what is currently performed with fluoroscopy, resulted in optimal LET probe positioning in less than half of all patients, with this approach being particularly suboptimal for patients with an esophagus adjacent to the right PVs. One may speculate that should optimal LET probe positioning not be achieved then a falsely low LET or slow rise in LET may occur during radiofrequency ablation placing the patient at risk for esophageal injury. The approach we describe stresses the importance of adequate LET probe placement. The ability to visualize the entire extent of the esophageal-posterior LA wall relationship and both visualize and manipulate the LET probe in real-time in 3 dimensions is a significant improvement compared to current methods of simply advancing and retracting the LET probe with the aid of fluoroscopy. These improvements will allow for more accurate LET measurements to be obtained. Additionally, the use of ICE allowed for visualization of anterior displacement of the esophagus into the posterior wall of the LA with the LET probe—a situation that may increase thermal conduction to the esophagus and esophageal injury.

It is important to recognize that simply visualizing the esophagus alone is necessary but unlikely sufficient to avoid esophageal thermal injury deflection of the LET probe to optimize its position also necessary. This latter point is best illustrated in the report by Vijayraman, where LA-esophageal fistula occurred despite appropriate LET monitoring with a nondeflectable LET probe as well as the use of ICE and barium to visualize the esophagus. Thus, a combination of visualization of the esophagus and deflection of the LET probe to optimize its position is vital.

Choice of LET Guiding Radiofrequency Termination
Rather than terminate radiofrequency applications after an absolute LET was achieved as described in previous studies, radiofrequency applications were terminated after an increase in LET of 2°C, based on our prior experiences, desire to account for variations in baseline LET among patients, and recognition than a rise in LET >2°C would be associated with a greater rise in intramural esophageal temperature that may be detrimental. Because the average baseline LET of patients in this study was 35.8°C, radiofrequency applications were generally terminated at a lower LET than in previous studies (38.5°C to 39°C). Additionally, this approach resulted in only a small rise in LET above the actual LET temperature at which radiofrequency was terminated, and required a short time for the LET to return to baseline—the latter more indicative of less esophageal heating. These parameters compare quite favorably to a previously reported subseries of patients undergoing AF ablation with general anesthesia and conventional LET monitoring. In their series, Di Biase’s et al terminated radiofrequency ablation after a LET of 39°C was achieved. On average, the maximum LET continued to rise approximately 1.6°C above the cutoff LET (compared with 0.5°C in our cohort) with the LET returning to baseline after approximately 29 seconds (compared with 18 seconds in our cohort). These differences probably contributed to the dramatic difference in the rate of esophageal injury between Di Biase’s and our cohort (48% versus 0%). We speculate that discontinuation of radiofrequency after a change in LET of 2°C rather than after an absolute temperature is achieved will account for variability in baseline LET and thermal conduction among patients thereby minimizing esophageal heating.

![Figure 5](https://example.com/figure5.png)
Theoretical Hazards of LET Monitoring

Care must be exercised during esophageal instrumentation. For example, manipulation of the LET probe may result in traumatic injury to the esophagus. Distortion of the esophagus may facilitate heating. Finally, esophageal probes may alter the current density during ablation facilitating heating. The latter concern is not unfounded—for example, Martinek described a high rate of esophageal ulceration in patients undergoing ablation procedures with nasogastric tubes, and Mohr reported atrio-esophageal fistulas in 3 patients undergoing surgical ablation procedures with concomitantly placed transesophageal echocardiogram probes. However, the safety of LET monitoring in this study, the increasing support for the relationship between LET and esophageal injury, and the fact that an atrio-esophageal fistula has been reported in a patient without esophageal instrumentation, suggests that the benefits of LET monitoring outweigh its theoretical risks.

Limitations

Limitations of our work must be acknowledged. First, our sample size was small and may underestimate the frequency of esophageal thermal injury. Additionally, given the rarity of LA-esophageal fistula, we cannot definitely conclude that this strategy will prevent this complication. Although true, our sample size is similar to that of other series assessing esophageal protection strategies, and the finding of no ulceration in a series of consecutive patients undergoing AF ablation, the majority of whom had the procedure performed with general anesthesia—a known high risk for esophageal injury, is compelling, and has not been reported with other strategies. Second, luminal esophageal temperature may not be representative of intramural esophageal temperature. However, there are currently no clinically available methods of determining intramural esophageal temperature. Third, only the presence of esophageal mucosal injury was assessed. Injury to adjacent structures, which may be detected with more sophisticated imaging modalities such as MRI or esophageal endosonography, may be underestimated. We believe that the presence of esophageal mucosal injury is critical to report as this is the presumed precursor to the development of the LA-esophageal fistula. Fourth, we did not document whether there was a specific duration of time after radiofrequency was applied when LET rises occurred. Although one may argue for limiting radiofrequency duration below a certain time to avoid temperature rises and hence the need for LET monitoring, this approach is unlikely to be applicable to all patients as some patient may have LET rise almost immediately after radiofrequency was applied. Fifth, premature termination of radiofrequency energy may prevent adequate LA lesion formation thereby increasing the likelihood of PV reconnection. Although theoretically possible, this was not noted in our cohort where rates of freedom from AF were similar to that reported by others. Sixth, this strategy may not be widely adopted by all electrophysiologists, given the cost of using an ablation catheter as a LET probe and ICE catheter to visualize the esophagus, and comfort with using ICE. Although true, should this strategy be proven to be reproducible then efforts must be made to ensure that a cost-effective alternative is available given the potential benefits associated with elimination of esophageal thermal injury. Finally, there was no control group in our series of patients which may prevent one from commenting on the true efficacy of this approach. Although true, the rate of esophageal ulceration in our cohort was lower than that historically reported by others.

Further work is necessary to determine (1) the optimal LET rise from baseline at which radiofrequency should be terminated, (2) whether other methods of real-time visualization of the esophagus (for example barium ingestion) are an acceptable alternative to the use of ICE imaging and useful in situations in which the esophagus is unable to be visualized on ICE (such as the case of our patient with severe LA dilation), (3) whether this approach will be tolerated in patients undergoing AF ablation procedures with conscious sedation, and (4) whether there is additional merit to physically deflecting the esophagus away from the LA with the deflectable LET probe during ablation at sites associated with LET rises. It is important to note that we did not intend to actively deflect the esophagus when the deflecting the LET probe—the fact that the esophagus was visualized on ICE before positioning or deflecting the LET probe (Figure 2) is consistent with simply placing the LET probe in position rather than deflecting the esophagus to that location. Finally, given the importance of this topic, confounders relating to patient and ablation strategies, we strongly encourage conducting a large multicenter, randomized study to adequately assess the merits of LET on reducing esophageal injury.

In conclusion, a strategy of optimal LET probe placement using a deflectable LET probe and ICE guidance, combined with cessation of radiofrequency ablation with a 2°C rise in LET, is another tool which may reduce esophageal thermal injury during AF ablation procedures.

Disclosures

None.

References


CLINICAL PERSPECTIVE

The close proximity of the esophagus to the left atrium places it at risk for thermal injury during atrial fibrillation ablation procedures. Luminal esophageal temperature monitoring has been proposed as one method of reducing esophageal thermal injury. However, esophageal ulceration and atrio-esophageal fistula have been reported with the current methods used to monitor luminal esophageal temperature. In these situations, the esophageal probe can only be manipulated in a craniocaudal direction. The inability to laterally deflect current esophageal temperature probes limits their ability to detect the “hot test” spots within the esophagus. In this pilot study, we report a novel method of esophageal temperature monitoring with the use of a deflectable esophageal temperature probe, which, using intracardiac echocardiography guidance, was positioned in the esophageal lumen at the site closest to that where left atrial catheter ablation was performed. This approach, combined with cessation of radiofrequency catheter ablation with any 2°C rise in esophageal temperature, was used in a series of 45 patients, all of whom underwent non–symptom-driven esophageal endoscopy within 48 hours of the catheter ablation procedure. No patient had esophageal injury in this series. These results suggest that accurate esophageal temperature monitoring with the use of a deflectable esophageal temperature probe positioned with intracardiac echocardiography guidance, combined with cessation of radiofrequency ablation with a rise in luminal esophageal temperature of 2°C, may prevent esophageal thermal injury.
SUPPLEMENTAL MATERIAL

Supplemental Online Video 1: Distortion of the esophagus by the LET probe.

Supplemental Online Video 2: Repositioning of the LET probe which no longer distorts the esophagus.