

# Esophageal Capsule Endoscopy After Radiofrequency Catheter Ablation for Atrial Fibrillation

## Documented Higher Risk of Luminal Esophageal Damage With General Anesthesia as Compared With Conscious Sedation

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**Background**—Left atrioesophageal fistula is a rare but devastating complication that may occur after catheter ablation of atrial fibrillation. We used capsule endoscopy to assess esophageal injury after catheter ablation for atrial fibrillation in a population randomized to undergo general anesthesia or conscious sedation.

**Methods and Results**—Fifty patients undergoing atrial fibrillation ablation for paroxysmal symptomatic atrial fibrillation refractory to antiarrhythmic drugs were enrolled and randomized, including those undergoing the procedure under general anesthesia (25 patients, group 1) and those receiving conscious sedation with fentanyl or midazolam (25 patients, group 2). All patients underwent esophageal temperature monitoring during the procedure. The day after ablation, all patients had capsule endoscopy to assess the presence of endoluminal tissue damage of the esophagus. We observed esophageal tissue damage in 12 (48%) patients of group 1 and 1 esophageal tissue damage in a single patient (4%) of group 2 ( $P < 0.001$ ). The maximal esophageal temperature was significantly higher in patients undergoing general anesthesia (group 1) versus patients undergoing conscious sedation (group 2) ( $40.6 \pm 1^\circ\text{C}$  versus  $39.6 \pm 0.8^\circ\text{C}$ ;  $P < 0.003$ ). The time to peak temperature was  $9 \pm 7$  seconds in group 1 and  $21 \pm 9$  seconds in group 2, and this difference was statistically significant ( $P < 0.001$ ). No complication occurred during or after the administration of the pill cam or during the procedures. All esophageal lesions normalized at the 2-month repeat endoscopic examination.

**Conclusion**—The use of general anesthesia increases the risk of esophageal damage detected by capsule endoscopy. (*Circ Arrhythmia Electrophysiol.* 2009;2:108-112.)

**Key Words:** catheter ablation of atrial fibrillation ■ complications ■ esophageal injury  
■ left atrioesophageal fistula ■ left atrium

Radiofrequency catheter ablation of atrial fibrillation (AF) is an established treatment for the management of symptomatic drug refractory patients.<sup>1</sup>

### Clinical Perspective see p 112

Although complications occurring during and after the procedure are infrequent, tools for the early identification of potential complication are welcome. Left atrioesophageal fistula (LAF) is a rare but devastating complication that may occur after catheter ablation of atrial fibrillation.<sup>2-4</sup> In this study, we sought to establish whether esophageal lesions identified by capsule endoscopy could be affected by different anesthesia protocols.

### Methods

#### Patients Population and Sedation Protocol

Fifty patients undergoing pulmonary vein antrum isolation (PVAI) ablation for paroxysmal symptomatic atrial fibrillation refractory to antiarrhythmic drugs (AADs) were enrolled and randomized into 2 groups: those receiving general anesthesia (25 patients, group 1) and those undergoing the procedure under conscious sedation with fentanyl or midazolam (25 patients, group 2). In group 1, induction of anesthesia was obtained with 1 mg/kg propofol followed by a maintenance dose of  $4 \text{ mg} \cdot \text{kg}^{-1} \cdot \text{h}^{-1}$  to achieve adequate relief from pain. Subsequently inhalational agents were administered through an endotracheal tube. In group 2, patients received intravenous administration of fentanyl and midazolam to achieve sedation.

All patients gave informed consent before the procedure. The study was approved by the Institutional Review Board.

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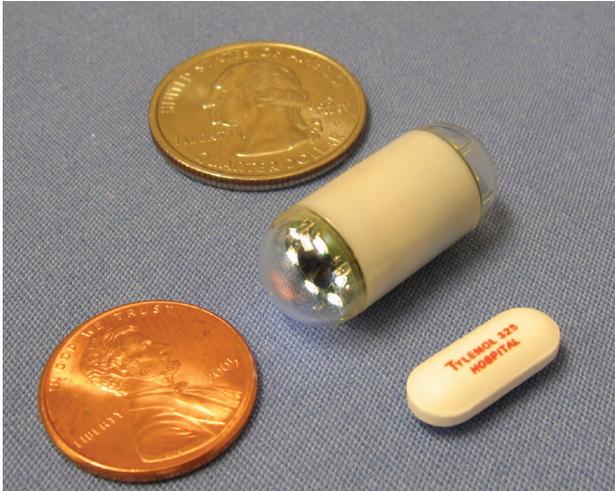
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**Figure 1.** Capsule endoscopy. The capsule has small dimensions, similar to a coin, as showed in the picture.

### Pulmonary Vein Isolation Ablation

The description of the PVAI technique has been reported extensively elsewhere.<sup>5–6</sup> Briefly, we used a circular mapping catheter (Lasso, Biosense Webster) and a 3.5-mm irrigated tip catheter (ThermoCool) to ablate the antrum of the pulmonary veins. Intracardiac echocardiogram (ICE) was used to monitor the transseptal puncture and to define the ostium of the pulmonary veins. An esophageal temperature probe (ER400-9, Smiths Medical ASD Inc) was used to detect temperature rise during power delivery with radiofrequency energy applications. The same temperature probe was used in both groups. The esophagus course was visualized by intracardiac echo and by assessing the location of the temperature probe.

ICE was not consistently incorporated as a technique used to track lesion formation. Radiofrequency (RF) energy was limited to 45 W of power, to 20-second durations at each site, and to no more than 41°C catheter tip temperature. Energy delivery was limited to 35 W over the esophagus. In addition RF energy was discontinued when the temperature of the esophageal probe reached 39°C. During ablation in areas in close proximity to the esophagus like the posterior wall and the pulmonary veins, the height of the esophageal temperature probe was adjusted depending on the actual position of the ablation catheter. Ablation was never prematurely terminated in response to pain but only in response to temperature rises.

The end point of the PVAI technique was the local elimination of all the pulmonary vein potentials with an electric disconnection between the LA and the pulmonary veins.

Further ablation of the superior vena cava (SVC) along the ostium was also performed unless the phrenic nerve was captured.<sup>7</sup>

### Follow-Up

The day after ablation, all patients had capsule endoscopy in a fasting state to assess the presence for endoluminal tissue damage of the esophagus. Esophageal capsule endoscopy was performed using PillCam ESO and the Given Imaging System. Patients were attached to the Sensor Array and Data recorder. The PillCam ESO capsule (Given Diagnostic System, Yoqneam, Israel) was then administered orally with a sip of water in a supine position. (Figure 1).

The PillCam contains an imaging device and light source at both ends of the capsule and takes up to 14 images per second or a total of 2600 color images as it passes down the esophagus. The device has been proven to provide similar information to standard endoscopy.<sup>8,9</sup> The images were collected and then reviewed by a single gastroenterologist experienced in endoscopy images and blinded to the treatment group. Follow-up of all patients was scheduled at 3, 6, 9, and 12 months after the procedure. If patients were unable to be seen, a nurse practitioner contacted them by telephone and monitoring tests were obtained.

**Table 1. Baseline Characteristics**

Clinical Characteristic	Group 1:	Group 2:	P Value
	General Anesthesia (n=25)	Conscious Sedation (n=25)	
Age, years	57±8.1	58.4±7.5	0.7
Male, %	72	76	0.38
HTN, %	32	36	0.38
AF duration, months	4.3±5.7	4.2±5	0.5
LA size, cm	4.2±2.6	4.1±3.6	0.11
LVEF, %	55±8	54.6±6	0.16
History of GERD or peptic ulcer disease, patients	2	2	—
Proton pump inhibitor or H <sub>2</sub> blocker preablation, patients	2	2	—

HTN indicates hypertension; LVEF, left ventricular ejection fraction; GERD, gastroesophageal reflux disease.

### Statistical Analysis

All continuous data are presented as mean±SD and were compared by Student *t* test. Categorical variables comparison used  $\chi^2$  analysis or Fisher exact test when appropriate. A probability value <0.05 was considered statistically significant.

### Results

The baseline characteristics of the 2 groups are reported in Table 1. There were no statistical differences regarding age, gender, hypertension, duration of AF, ejection fraction, and left atrial dimensions.

The total fluoroscopy times of group 1 was 65.2±22.8 minutes and 64.8±21.2 in group 2 ( $P=0.72$ ). The total duration of radiofrequency applications were 54±11 minutes for group 1 and 55±8 for group 2 ( $P=0.12$ ). Average power over the esophagus areas was 33.2±4 in group 1 and 32.3±4.2 in group 2 ( $P=0.8$ ). Average measured catheter tip temperature over the esophageal areas was 35.6±4 in group 1 and 34.8±5 in group 2 ( $P=0.28$ ).

The maximal esophageal temperature was significantly higher in patients undergoing general anesthesia (group 1) versus patients undergoing conscious sedation (group 2) (40.6±1°C versus 39.6±0.8°C [ $P<0.003$ ]; Table 2).

The time to peak temperature was 9±7 seconds in group 1 and 21±9 seconds in group 2, and this difference was statistically significant ( $P<0.001$ ; Table 2). In addition, the time to baseline

**Table 2. Esophageal Tissue Damage and Esophageal Temperature Measurements**

	Group 1:	Group 2:	P Value
	General Anesthesia (n=25)	Conscious Sedation (n=25)	
Maximum esophageal temperature	40.6±1°C	39.6±0.8°C	<0.003
Time to baseline temperature recovery, seconds	29±3	18±2	<0.001
Time to peak temperature, seconds	9±7	21±9	<0.001
Esophageal tissue damage, n (%)	12 (48)	1 (4)	<0.001



**Figure 2.** The arrow indicates a mucosal burn or erosion with a clean base at the level of the midesophagus.

temperature recovery was different between group 1 and group 2, respectively ( $29 \pm 3$  and  $18 \pm 2$  seconds,  $P < 0.001$ ; Table 2).

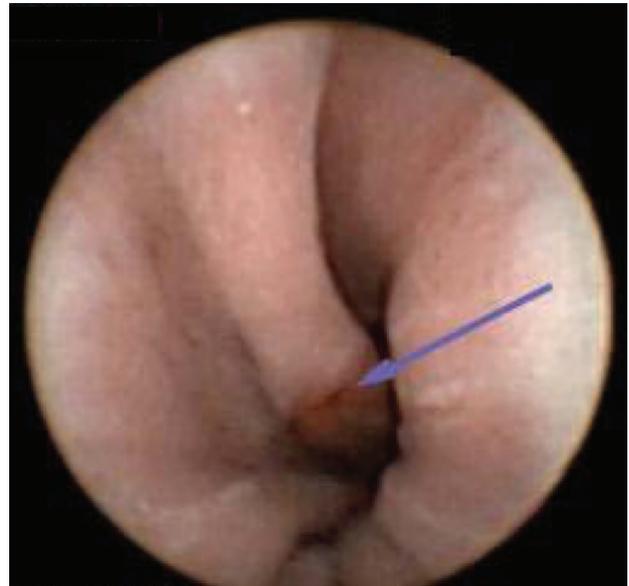
We identified 13 esophageal tissue damage located at midesophagus at the level of the ablation lesions in 13 different patients. They have been described as mucosal erosion with clean base (Figure 2) or accompanied by blood or clot (Figure 3).

We observed esophageal tissue damage at midesophagus in 12 (48%) patients of group 1 and one positive finding in a single patient (4%) of group 2 ( $P < 0.001$ ; Table 2). Moreover, 5 lesions at the distal esophagus were observed: 2 of them (8%) in group 1, and the other 3 (12%) in group 2. These lesions were small linear ulcerations most likely not related to RF energy delivery (Figure 4).

No correlation was seen between postprocedural symptoms (usually nonspecific and reported as chest pain or nausea) and



**Figure 3.** The arrow indicates a mucosal burn or erosion with blood and clot at the level of the midesophagus.



**Figure 4.** Small linear ulceration at the level of the distal esophagus, just above the pyloric sphincter. This lesion is unlikely to result from RF energy delivery.

esophageal tissue damage with the endoscopy. None of the patients were treated with  $H_2$  blocker or proton pump inhibitors because of postablation symptoms. However, 4 of these patients (2 patients per group) were treated with proton pump inhibitor for previous history of gastric ulcer or esophageal reflux (Table 1). None of the patients included in this series developed LAF.

No complication occurred during and after the administration of the pill cam and during the ablations procedures. All esophageal lesions normalized at the 2-month repeat endoscopic examination without any pharmacological treatment.

## Discussion

### Main Findings

This study is the first to identify objective evidence of damage on the luminal esophageal wall after RF catheter ablation for atrial fibrillation in relationship to the anesthesia protocol. Most of the esophageal lesions discovered by the pill cam were not correlated with the patient's symptoms. The possible explanation of the higher rate of endoluminal mid esophageal tissue damage in the general anesthesia group can be the reduced esophageal motility and the lack of patient swallowing with general anesthesia.<sup>10,11</sup>

Over the past decade, the use of catheter ablation for the treatment of AF has increased.<sup>1</sup> Extensive ablations of the LA and additional lesions at different locations have been proposed to increase the success rate of the procedures.<sup>12-18</sup> These strategies can increase the occurrence of numerous complications. Esophageal injury and LAF are considered life-threatening complications that may occur after radiofrequency is applied in the posterior wall of the LA.<sup>2-4</sup> Little information is known regarding the esophageal damage achieved by these lesions, because it is logistically difficult to assess the esophagus with standard endoscopic evaluation.

A low occurrence rate of LAF (1%) was first described during open heart surgery.<sup>19</sup> In patients undergoing RF catheter ablation of AF, the reported incidence of this complication is around 0.01%.<sup>3</sup> However, this percentage may be underestimated. Pappone et al<sup>2</sup> reported 2 cases of LAF. One of the patients died, and the other survived after surgery. Scanavacca et al<sup>20</sup> described a case of LAF after ablation with an 8-mm catheter using a maximum power of 60 W and a maximum temperature of 55°C.

Typically, the clinical presentation of the fistula occurs late after the procedure (within 2 weeks),<sup>2-4,20</sup> and the symptoms are usually nonspecific, including fever, neurological abnormalities, gastrointestinal bleeding, and sepsis. The mechanism of esophageal injury is not completely known. Thermal injury seems to be the most likely cause (with area of necrosis surrounded by inflammatory cells), although an ischemic mechanism has been considered as well.<sup>2-4,19-22</sup>

### Anatomic Considerations

The anatomic location of the esophagus may change during ablation, and therefore registration of a preacquired static picture of the esophagus might not be adequate.<sup>3,23</sup> In addition, fluoroscopic guidance may be misleading to avoid damage to the esophagus because it does not provide the border of the esophageal tube.

ICE can provide real-time localization of the esophagus but cannot eliminate the risk of thermal injury.<sup>6</sup> Computed tomography (CT) scans appear useful to understand the distance between the LA wall and the esophagus but do not allow measurements of wall thickness less than 0.5 mm.<sup>24</sup> In addition, CT scans give a static picture of the esophagus and cannot evaluate the possibility of esophageal motion during the procedure.<sup>24</sup>

Sanches-Quintana<sup>22</sup> described a nonuniform thickness of the LA posterior wall. Shorter RF applications and avoidance of overlapping lines have been suggested to minimize esophageal injury at sites in close proximity with the esophagus.

Measurements of luminal esophagus temperature during LA ablation are the most used way to avoid thermal injury.<sup>24,25</sup> However, luminal temperature does not necessarily reflect temperature within the esophageal wall.<sup>26</sup> Additionally, because parameters followed during energy delivery such as power or impedance are not predictive of temperature rises, it is difficult to predict the effects on the esophagus.

### Possible Mechanism of the Findings

Different mechanisms can explain the difference of the esophageal tissue damage discovered between the 2 different anesthesia protocols. One possible explanation is the reduced motility and the reduced deglutination of the esophagus during general anesthesia. This could result in ablation at the same esophageal location throughout the duration of the lesion. On the other hand, with conscious sedation pain caused by RF delivery could trigger active peristalsis and swallowing, resulting in cooling and inconsistent heat transfer to the esophageal wall. Of note, ablation was never prematurely terminated in response to pain but only in response to temperature rises.

In addition, the lack of swallowing during general anesthesia might also prevent physiological cooling and increase the probability that the lesions extend to the esophageal wall. Indeed, the highest peak temperature, the time to peak, and

time to baseline esophageal temperatures observed under general anesthesia seem to support this hypothesis.

We believe our results open discussion on which anesthesia protocol should be used for atrial fibrillation ablation. Larger studies are required to give guideline recommendations. However, our results suggest that it is probably safer to be more conservative in patients undergoing the procedure under general anesthesia. In this respect, a lower temperature threshold may be warranted, but this needs to be balanced with the ability to achieve effective lesions.

### Study Limitation

Many factors can influence the risk of esophageal damage, including contact pressure, maximum power, lesion duration, esophageal cooling, and others.

We only assessed the impact of each type of anesthesia using a fixed protocol of RF delivery. However, one would expect that this information could be extended to the other ablation protocols. It is possible that the pill cam might have not pictured all portions of the esophagus. However, this is unlikely considering that this device acquires 14 images per second and it has been shown to provide similar information to standard endoscopy.<sup>8,9</sup> Another possible limitation is the fact that the electrophysiologists performing the procedures were not blinded to the anesthesia protocol. Although we recognize the potential limitation regarding the blinding, we would like to point out that the images provided by the capsule have been analyzed by a gastroenterologist blinded to the procedure and to the anesthesia used. Therefore, the information provided by the pill cam contains objective data.

### Conclusion

The use of general anesthesia seems to increase the risk of esophageal tissue damage detected by capsule endoscopy. It remains to be seen whether capsule endoscopy will be a useful clinical tool, because all of these patients suffered no long-term sequelae without treatment. Esophageal tissue damage was easily seen using capsule endoscopy; thus, this minimally invasive tool may be valuable in evaluating the propensity of new technologies to damage esophageal tissue. Further studies are warranted to understand whether patients with esophageal tissue damage after ablation require a different follow-up or additional treatment.

### Disclosures

Drs Burkhardt, Saliba, Horton, Schweikert, Cummings, and Natale report receiving compensation from St Jude Medical for participation in speaker's bureaus; Drs Schweikert, Horton, Cummings, Saliba, and Natale report receiving compensation from Boston Scientific for participation in speaker's bureaus; Drs Burkhardt, Schweikert, Horton, Saliba, and Natale report receiving compensation from Biosense Webster for participation in speaker's bureaus; Drs Horton, Saliba, Cummings, Schweikert, and Natale report receiving compensation from Medtronic for participation in speaker's bureaus; Dr Horton reports receiving compensation from Hansen Medical for participation in speaker's bureaus; Dr Burkhardt reports serving as a consultant/advisory board to Stereotaxis; Dr Dodig reports receiving compensation from Given Imaging for participation in speaker's bureaus; Dr Schweikert reports serving as a consultant/advisory board to Biosense Webster; Dr Cummings reports serving as a consultant/advisory board to Siemens and Coraazon; and Dr Natale reports participation in a research grant from St Jude Medical.

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## CLINICAL PERSPECTIVE

The present study is the first to identify objective evidence of damage on the luminal esophageal wall after radiofrequency catheter ablation for atrial fibrillation in relationship to the anesthesia protocol used. A pill cam has been used to identify endoluminal esophageal lesions after ablation. We found a higher number of esophageal lesions in the arm randomized to general anesthesia versus the one undergoing conscious sedation. The possible explanation for the higher rate of endoluminal esophageal tissue damage can be the reduced esophageal motility and the absence of patient swallowing with general anesthesia. Our results open the door to discussion on which anesthesia protocol should be used for atrial fibrillation ablation. Larger studies are required to give recommendations. Our results suggest that it is probably safer to be more conservative in patients undergoing the procedure under general anesthesia. Of interest, none of the patient reporting esophageal tissue damage developed atrioesophageal fistula, and all the lesions healed over time. Whether patients demonstrating endoluminal tissue damage after the ablation procedure require a specific follow-up needs further investigation. The pill cam can be considered a useful tool to check for this life-threatening complication.

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