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Global Survey of Esophageal Injury in Atrial Fibrillation Ablation

Characteristics and Outcomes of Esophageal Perforation and Fistula

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ABSTRACT

OBJECTIVES This study sought to assess the incidence, operator demographics, clinical characteristics, procedural factors, and prognosis of esophageal perforation and fistula after atrial fibrillation ablation.

BACKGROUND Esophageal injury is a feared complication of atrial fibrillation ablation.

METHODS An Internet-based global survey soliciting anonymous information regarding esophageal perforation and fistula was emailed to 3,080 physicians. Detailed information regarding physician, patient, and procedural characteristics related to esophageal perforation with or without fistula was collected.

RESULTS The survey was completed by 405 of 3,080 physicians (13%). Responding physicians performed 191,215 atrial fibrillation ablations and esophageal perforation with or without fistula occurred in 31 patients (0.016%) with multiple ablation catheter types despite monitoring of esophageal position or temperature during ablation in 90% of patients. Among patients who present with esophageal perforation, death, or severe neurologic injury occurred more frequently in patients with greater body mass index (30.9 ± 6.8 kg/m^2 vs. 25.8 ± 3.3 kg/m^2; $p = 0.03$), and lower left ventricular ejection fraction ($55.1 \pm 9.1\%$ vs. $61.7 \pm 5.4\%$; $p = 0.04$). Among analyzed patients, atrial-esophageal fistula was seen in 72%, pericardial-esophageal fistula in 14%, and esophageal perforation without fistula in 14%. Mortality was 79% with atrial-esophageal fistula and 13% in esophageal perforation without atrial-esophageal fistula.

CONCLUSIONS Esophageal perforation is rare but continues to occur with multiple catheter types despite esophageal monitoring during ablation. The prognosis of esophageal perforation is substantially improved if diagnosed and treated before development of atrial-esophageal fistula. An early surgical approach to esophageal perforation should be strongly considered regardless of evidence of fistula. (J Am Coll Cardiol EP 2016;2:143–50) © 2016 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

AEF = atrial-esophageal fistula

AF = atrial fibrillation

LA = left atrium

RF = radiofrequency

Catheter ablation of atrial fibrillation (AF) may be complicated by injury to extracardiac structures. Ablation of the left atrial (LA) posterior wall may result in esophageal injury ranging from mild erythema to ulceration (1), and in rare, but devastating cases, esophageal perforation with (2) or without (3) fistula formation. There are limited data regarding the prevalence, circumstances, and outcomes of these complications (4-8). The aim of this study is to assess real-world prevalence and outcomes of these complications, and to assess in detail physician, patient, and procedural characteristics related to esophageal perforation with or without fistula. We have previously reported data regarding time-course of presentation and outcomes related to various degrees of gastric and esophageal injury from the present survey (9).

METHODS

The online survey was circulated to the 3,080 registered physician members of the Heart Rhythm Society in 2013 and all physicians who perform AF ablation were invited to participate in the survey. Survey responses were collected between November 1, 2013 and June 1, 2014. The survey was designed to be brief to improve response rates while collecting detailed data regarding esophageal perforation (text of survey is available in the Online Appendix). The following data were collected anonymously without identifying physician or patient data:

1. Operator characteristics: procedure volume, practice setting, geographic location, and incidence of AF ablation-related esophageal injury. Operators reporting incident complications were invited to provide additional data regarding complications.
2. Esophageal perforation:
   a. Patient characteristics including age, sex, height, weight, LA size, left ventricular ejection fraction, comorbidities, paroxysmal or persistent AF, and number of prior LA ablations.
   b. Catheter ablation procedure characteristics including type of ablation catheter, posterior LA wall radiofrequency (RF) power settings and lesion duration, esophageal monitoring used, pre-procedure imaging, lesion set, and use of prophylactic proton pump inhibitor.
   c. Clinical presentation details including post-operative date and nature of initial symptoms, post-operative date and nature of symptoms at time of admission, specialty of physician performing initial evaluation, and diagnostic studies obtained.
   d. Final diagnosis: "atrial esophageal fistula" (AEF) if there was imaging or clinical evidence of communication between LA and esophagus, "esophageal-pericardial fistula" if there was imaging or clinical evidence of communication between the LA and pericardium, and "esophageal perforation without fistula" if there was imaging or clinical evidence of esophageal perforation but no evidence of communication between esophageal lumen and pericardium or LA.
   e. Intervention performed, if any, and clinical outcomes.

STATISTICAL METHODS. Continuous variables are expressed as the mean ± SD and categorical variables as percentages. Analysis was performed using Prism version 6.0d (GraphPad Software, Inc., La Jolla, California). Continuous variables were analyzed using the Mann-Whitney test. Categorical variables were analyzed using Fisher exact test. A 2-sided p value <0.05 was considered statistically significant. Data collection and analysis was according to protocols approved by the Partners Human Subject Protection Committee.

RESULTS

PHYSICIAN CHARACTERISTICS. Among the 3,080 physicians who received the survey, 405 responded (13%), of whom 404 were cardiac electrophysiologists, and 1 was a cardiothoracic surgeon. Among responding physicians, 231 (57%) were affiliated with an academic institution and 174 (43%) were in private practice. In aggregate, 191,215 AF ablations were performed by responding physicians, and esophageal perforation with or without fistula was reported in 31 (0.016%) patients by 30 (7%) responding physicians. Characteristics of responding physicians stratified by incidence of esophageal perforation are presented in Table 1. Of note, physicians reporting esophageal perforation had performed on average a significantly greater number of AF ablations (835 ± 675 vs. 472 ± 676; $p < 0.001$) and were significantly more likely to have been performing AF ablation with more years of experience ($p = 0.01$). The incidence of esophageal perforation among 199 operators with above median procedural experience (>250 AF ablations performed) and among 130 physicians in practice for >10 years, however, was not greater than the overall incidence of esophageal perforation among all responding physicians (0.015% and 0.014%, respectively). No physicians reporting esophageal perforation had been in practice for less than 4 years, and incidence of

esophageal perforation was similar in all geographic areas.

ESOPHAGEAL PERFORATION AND FISTULA. Responding physicians provided full survey details for 28 of 31 patients who had esophageal perforation or fistula formation reported. Of these 28 patients, 16 (57%) died, 1 (4%) survived with severe neurologic injury, 2 (7%) survived with mild neurologic injury, and 9 (32%) survived and were neurologically intact. Patient characteristics, procedural data, and information regarding patient presentation and outcomes are presented for the entire cohort (n = 31), and stratified by clinical outcome: death or severe neurologic injury versus mild or no neurologic injury with p value for difference between these subgroups (Table 2).

PATIENT CHARACTERISTICS. Patients presenting with esophageal perforation had a mean age of 58.7 ± 9.9 years and were 81% male. Compared with patients who survived esophageal perforation with no or mild neurologic injury, patients with esophageal perforation that resulted in death or severe neurologic injury were shorter (67.2 ± 4.3 inches vs. 70.4 ± 3.2 inches; p = 0.04), had greater body mass index (30.9 ± 6.8 kg/m^2 vs. 25.8 ± 3.3 kg/m^2; p = 0.03), and lower left ventricular ejection fraction (55.1 ± 9.1% vs. 61.7 ± 5.4%; p = 0.04). All patients with esophageal perforation with left ventricular ejection fraction less than 55% (n = 4) died. There is a trend of greater prevalence of diabetes, hypertension, and obstructive sleep apnea in patients with esophageal perforation resulting in death or severe neurologic injury; however, these differences did not reach statistical significance. Gastroesophageal reflux disease was reported in 23% (n = 6) of patients with esophageal perforation, and hiatal hernia was reported in 10% (n = 3) of patients with esophageal perforation. Of patients who developed esophageal perforation, 48% (n = 13) underwent catheter ablation of persistent AF and 55% (n = 15) had undergone at least 1 prior LA ablation for AF.

PROCEDURAL CHARACTERISTICS. An externally irrigated RF ablation catheter was used in 21 (76%) esophageal perforation cases, of which 50% survived without severe neurologic injury. A second-generation cryoballoon was used in 2 esophageal perforation cases (7%) and a nonirrigated RF catheter was used in 2 (7%) esophageal perforation cases, all 4 of which died from esophageal perforation-related injury. Posterior wall RF ablation was performed with a power of 29.2 ± 7.7 W (range, 20 to 40 W) and lesion duration of 30.6 ± 16.4 s (range, 15 to 60 s). Esophageal perforation occurred despite esophageal monitoring in 90% (n = 25) of patients and preprocedure computed tomography scan or magnetic resonance imaging in 94% (n = 26) of patients. The most common RF ablation lesion set was ipsilateral pair-wise pulmonary vein isolation (86%), and 14% (n = 4) of patients with esophageal perforation had additional posterior wall RF ablation in conjunction with pulmonary vein isolation. There was no difference in ablation catheters used between patients with esophageal perforation who survived without severe neurologic injury and patients who died or had severe neurologic injury (p = 0.60) (Table 2).

TABLE 1 Characteristics of Responding Physicians

	% Physicians Without Incidence of Esophageal Perforation (n = 375)	% Physicians Reporting Incidence of Esophageal Perforation (n = 30)	p Value
Private practice	43	47	0.71
University based	57	53	0.71
AF ablations performed	250 (110–500)	550 (400–1,000)	<0.001
Years performing AF ablation			0.01
1–3	20	0	
4–6	19	20	
7–9	29	30	
≥10	32	50	
Practice region			0.44
North America	76	80	
South America	4	0	
Europe	10	17	
Asia	6	0	
Australia	4	3	

AF = atrial fibrillation.

PATIENT PRESENTATION AND OUTCOMES. The post-operative day of reported symptom onset in patients with esophageal perforation was 19.3 ± 12.6 days (range, 1 to 59 days), and the post-operative day of admission was 22.5 ± 11.1 days (range, 7 to 59 days). Admission on the day of symptom onset occurred in 54% of patients with esophageal perforation, of whom 46% survived without severe neurologic injury. The 13 patients with esophageal perforation who were not readmitted on the day of symptom onset were readmitted 5.8 ± 4.8 days (range, 1 to 18 days) after report of initial symptoms with significantly increased incidence of fever (92% vs. 38%; p = 0.003) and neurologic symptoms (69% vs. 15%; p = 0.02) (Figure 1). Of 15 patients with esophageal perforation or fistula with neurologic symptoms at time of readmission, 10 died, 1 survived with severe neurologic injury, 2 survived with mild neurologic injury, and 2 survived without neurologic injury.

The specialty of the physician who first evaluated patients with esophageal perforation or fistula was

TABLE 2 Patient and Procedural Characteristics for Patients With Esophageal Perforation

	Esophageal Perforation With or Without Fistula: All (N = 31)	Esophageal Perforation With or Without Fistula: Death or Severe Neurologic Injury (N = 17)	Esophageal Perforation With or Without Fistula: Mild or No Neurologic Injury (N = 11)	p Value
Age, yrs	58 (50–67)	60 (54–67)	55 (46–66)	0.29
Male, %	81	77	82	1.00
Height, inches	70 (66–72)	69 (65–72)	71 (68–72)	0.04
Weight, lbs	182.5 (160–210)	185 (160–220)	170 (160–201)	0.32
Body mass index, kg/m^2	26.8 (24.4–31.8)	28.5 (25.1–35.5)	24.4 (23.3–27.0)	0.03
Left atrial diameter, cm	4 (4–4.65)	4.2 (4–5)	4 (4–4.2)	0.67
Left ventricular ejection fraction	60 (55–65)	55 (50–60)	62 (55–65)	0.04
Diabetes, %	26	35	9	0.19
Hypertension, %	65	77	45	0.12
Coronary artery disease, %	10	6	9	1.00
Obstructive sleep apnea, %	14	18	0	0.26
Gastroesophageal reflux disease, %	23	18	27	0.65
Hiatal hernia, %	10	12	9	1.00
Persistent AF, %	48	53	36	0.46
Repeat ablation, %	55	53	45	1.00
Ablation catheters, %				0.60
RF, nonirrigated	7	12	0	
RF, external irrigation	76	65	91	
RF, internal irrigation	7	6	9	
Cryoballoon, second-generation	7	12	0	
Other	3	5	0	
Posterior wall RF power, W	30 (25–30)	30 (25–30)	30 (25–30)	0.78
Posterior wall RF lesion duration	30 (20–30)	30 (20–30)	30 (20–60)	0.87
Esophageal monitor, %				
Intracardiac echocardiography	26	18	45	0.19
Single point temp	65	59	73	0.69
Multipoint temp	10	12	9	1.00
Fluoroscopy of probe	3	18	36	0.38
3D mapping of esophagus	3	6	0	1.00
None	10	6	18	0.54
Pre-ablation imaging, %				0.55
MRI	10	6	18	
CT	84	82	64	
None	6	12	18	
RF lesion set, %				
Pair-wise ipsilateral PVI	88	94	82	0.56
Single ring PVI	12	6	18	0.56
Roof line	24	13	36	0.35
Additional posterior wall RF	14	13	18	1.00
Proton pump inhibitor post-ablation	77	65	91	0.19

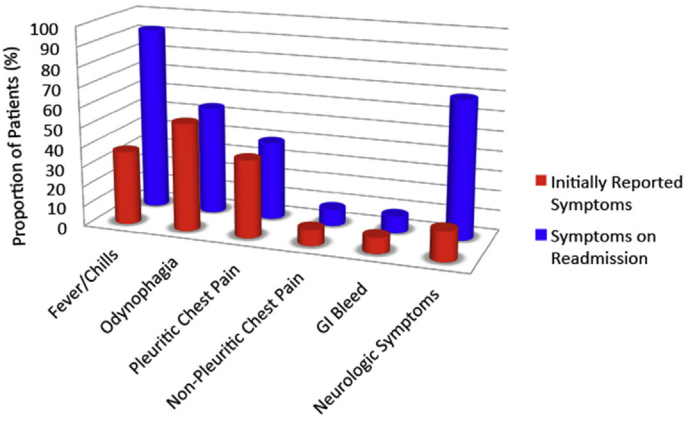
p value indicates significance between esophageal perforation with or without fistula death, and severe neurologic injury and mild or no neurologic injuries.
CT = computed tomography; MRI = magnetic resonance imaging; PVI = pulmonary vein isolation; RF = radiofrequency; other abbreviations as in Table 1.

most frequently emergency medicine (63%). An electrophysiologist performed the initial evaluation for 14% of patients and 3 of 4 (75%) of these patients survived without severe neurologic injury. Patients who survived without severe neurologic injury tended to be more likely to have had a computed tomography with intravenous contrast during initial evaluation, but the trend did not reach statistical significance (91% vs. 59%; p = 0.09). Esophageal endoscopy was performed in 6 patients with esophageal perforation. Three patients who were ultimately diagnosed with AEF underwent esophageal endoscopy and all 3 of these patients died. Three patients ultimately diagnosed with esophageal perforation without fistula formation underwent esophageal endoscopy, of whom 1 died of severe sepsis and 2 survived without severe neurologic injury.

Of the 28 patients with esophageal perforation for whom detailed information was provided, 20 (71%) were diagnosed with AEF, 4 (14%) were diagnosed with pericardial-esophageal fistula, and 4 (14%) were diagnosed with esophageal perforation without fistula formation. The final diagnosis of patients who died or had severe neurologic injury was significantly different than that of patients who survived without severe neurologic injury ($p = 0.002$) (Table 3). Among patients with esophageal perforation, a significantly greater proportion of patients who died or had severe neurologic injury were ultimately diagnosed with an AEF (94% vs. 36%). Of the 20 patients with AEF, 16 died or had severe neurologic injury, 2 had mild neurologic injury, and 2 survived without neurologic injury at time of discharge. All patients with AEF who survived without severe neurologic injury underwent thoracic surgery (Figure 2A). Three patients with esophageal perforation without fistula underwent esophageal stenting and survived without neurologic injury, and 1 patient with esophageal perforation without fistula underwent thoracic surgery and later died from sepsis (Figure 2B). All 4 patients with pericardial-esophageal fistulas survived following thoracic surgery and were neurologically intact at discharge (Figure 2C).

Esophageal stenting was performed in 6 patients. All 3 patients who were ultimately found to have AEF who underwent esophageal stenting died or had severe neurologic injury, whereas all 3 patients with esophageal perforation without fistula who underwent esophageal stenting survived without neurologic injury. One patient who was found on surgical exploration to have an esophageal perforation without fistula subsequently underwent percutaneous endoscopic gastrostomy tube insertion and esophageal rest and survived without neurologic injury. Of the 11 patients with esophageal perforations with or without fistula who survived to hospital discharge without severe neurologic injury, 10 patients remained well with a mean follow-up time of 26 ± 16 months post-discharge. One patient who underwent surgical repair of a pericardial-esophageal fistula and was discharged without neurologic injury was readmitted 1 week after discharge and died of a stroke related to an AEF at the surgical repair site.

FIGURE 1 Symptom Progression Before Admission



Reported symptoms of patients with esophageal perforation not admitted at time of initial symptom report (n = 13) on initial presentation **(red)** and on admission **(blue)**. GI = gastrointestinal.

DISCUSSION

The present survey is the largest series of systematically collected data regarding esophageal injury in AF ablation to date. No physicians with less than 4 years experience reported esophageal perforation, whereas esophageal perforation was reported most frequently by physicians with greater than 10 years' experience. Factors contributing to this difference may include greater awareness of esophageal injury among more recently trained physicians, more experienced operators performing procedures on higher risk patients, a greater willingness of experienced physicians to report complications, and greater opportunity for low-frequency events among physicians with greater experience.

Although cases of esophageal perforation without fistula, and pericardial-esophageal fistula have been previously reported (3), we are not aware of prior estimates of their relative incidence in comparison with AEF in the published data. Our data suggest that 28% of patients with esophageal perforation present without fistula or with pericardial-esophageal fistula, and the prognosis of these patients is significantly better than that of patients presenting with AEF. It is unclear if improved vigilance will allow a greater proportion of patients to be diagnosed and treated before the development of AEF.

In patients presenting with esophageal perforation, lower left ventricular ejection fraction and increased body mass index were associated with death or severe neurologic injury. The increased prevalence of comorbidities, such as diabetes, hypertension, obstructive sleep apnea, and gastroesophageal reflux disease, in patients with death or neurologic injury related to esophageal perforation was not statistically significant, but given the small sample size and retrospective nature of the data

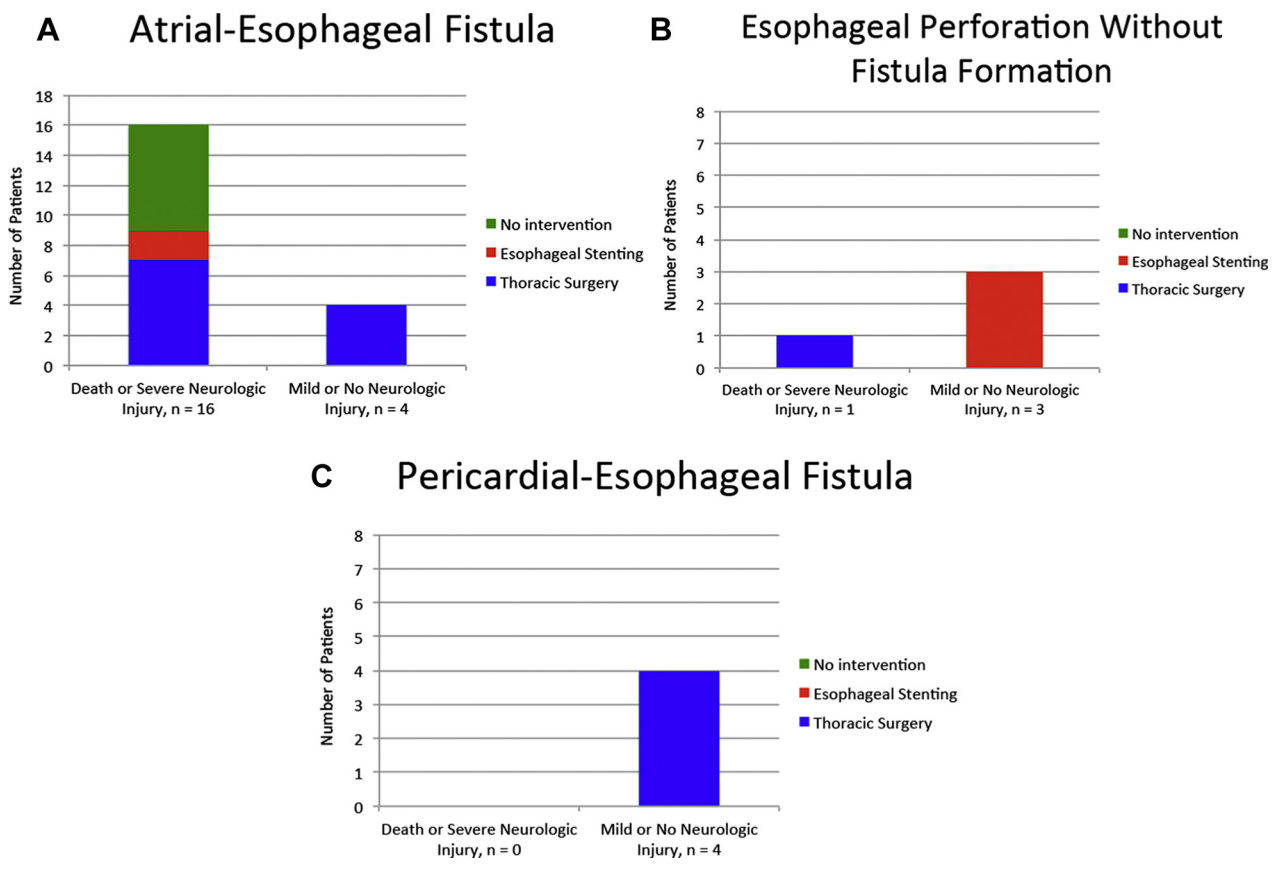
TABLE 3 Patient Presentation and Outcome Characteristics for Patients With Esophageal Perforation

	Esophageal Perforation With or Without Fistula: All (N = 31)	Esophageal Perforation With or Without Fistula: Death or Severe Neurologic Injury (N = 17)	Esophageal Perforation With or Without Fistula: Mild or No Neurologic Injury (N = 11)	p Value
POD of first symptom report	20 (8–26)	21 (10–25)	20 (7–30)	0.35
Presenting symptoms, %				
Odynophagia	29	24	36	0.67
Fever/chills	39	35	46	0.70
Pleuritic chest pain	37	24	55	0.12
Nonpleuritic chest pain	18	18	18	1.00
Neurologic symptoms	36	33	36	1.00
Hematemesis/gastrointestinal bleed	15	18	9	1.00
POD of admission	20 (13–28)	21 (13–27)	20 (14–30)	0.54
Time from symptoms to admission	2.6 ± 4.6	2.7 ± 4.6	2.6 ± 4.1	
Admitted on day of first symptom report, %	54	47	63	0.46
Specialty of evaluating, %				0.58
Emergency medicine	62	64	55	
Cardiology	14	18	9	
Electrophysiology	14	6	27	
Internal medicine	7	6	9	
Other	3	6	0	
Symptoms on admission, %				
Odynophagia	32	28	36	0.38
Fever/chills	71	76	64	0.67
Pleuritic chest pain	36	24	55	0.12
Nonpleuritic chest pain	18	18	18	1.00
Neurologic symptoms	50	59	36	0.44
Hematemesis/gastrointestinal bleed	11	18	9	1.00
Admission imaging, %				
Esophageal endoscopy	21	24	18	1.00
Noncontrast only CT	14	18	9	1.00
CT with intravenous contrast	71	59	91	0.09
CT with oral contrast	14	18	9	1.00
Final diagnosis, %				0.002
Atrial-esophageal fistula	72	94	36	
Pericardial-esophageal fistula	14	0	36	
Esophageal perforation without fistula	14	6	28	
Intervention, %				0.03
Thoracic surgery	52	47	64	
Esophageal stenting	23	12	36	
None	25	41	0	

p value indicates significance between esophageal perforation with or without fistula death, and severe neurologic injury and mild or no neurologic injuries.
POD = post-operative day; other abbreviations as in Table 2.

collected, it is unclear if these comorbidities may be associated with increased risk of esophageal perforation or with unfavorable outcome in patients that develop esophageal perforation. Incident esophageal perforation was noted with all types of ablation catheters and despite all methods of esophageal monitoring. Although externally irrigated RF was the most commonly used ablation catheter in patients with esophageal perforation, it is unclear if this was disproportionately so, and nearly all of the patients with esophageal perforation who survived without severe neurologic injury underwent RF ablation with externally irrigated RF catheters. Esophageal monitoring of some form was performed in 90% of patients with esophageal perforation, and no individual form of esophageal monitoring was associated with improved survival. These data suggest that use of esophageal monitoring alone is insufficient for esophageal perforation prevention and that additional efforts, such as intensified esophageal monitoring and empiric reduction in RF power/duration on the LA posterior wall, should be considered in combination with prescription of a proton pump inhibitor in the post-operative period.

FIGURE 2 Esophageal Perforation Outcomes Stratified by Final Diagnosis and Intervention



(A) Atrial-esophageal fistula outcomes stratified by intervention. **(B)** Esophageal perforation without fistula formation outcomes stratified by intervention. **(C)** Pericardial-esophageal fistula outcomes stratified by intervention.

Our data reinforce the importance of close post-operative follow-up and a low threshold for immediate evaluation of patients with symptoms concerning for esophageal perforation, such as fever, odynophagia, neurologic symptoms, and chest pain. Incidence of fever and neurologic injury was significantly greater on admission in patients with delay between initial symptom report and admission, and although the sample size was small, patients who initially presented to their electrophysiologist seemed to have a favorable prognosis. In addition, given poor outcomes associated with AEF without surgical correction, and poor outcomes when endoscopy or esophageal stenting is performed and the patient is ultimately found to have an AEF, we believe that an early, surgical approach to esophageal perforation should be strongly considered. Finally, the reported successful surgical repair of esophageal-pericardial fistula followed by subsequent development of AEF and death weeks after discharge demonstrates the importance of close follow-up in the post-operative period following successful surgical repair of esophageal perforation.

STUDY LIMITATIONS. Our study has several limitations common to surveys. All data were reported retrospectively by responding physicians, and inaccurate responses caused by poor recall cannot be excluded. Reported 0.016% incidence of esophageal perforation in the present analysis is lower than the 0.03% to 0.04% incidence previously reported (4,10), which might indicate low response rate or self-selection bias, which are limitations of survey-based data. The population of physicians who respond to online surveys may not be representative of all physicians who perform AF ablation. In addition, the survey solicited responses by email from physicians who performed AF ablation with the subject, "Response Requested: Esophageal Injury in AFib Ablation," thus, the overall 13% response rate may be enriched relative to the overall survey population in

incidence of esophageal injury. Despite this, the distribution of responding physicians provides a diverse sample of physicians who perform AF ablation with regards to geographic distribution, experience, and practice setting. Lastly, given the anonymous nature of the survey, it is impossible to obtain additional details regarding patients in the survey.

The analysis is descriptive in nature. Small sample size is expected because of low prevalence of esophageal injury in AF ablation, especially severe esophageal injury. Because of the small sample size, the comparisons are considered exploratory and hypothesis-generating.

CONCLUSIONS

Esophageal perforation following AF ablation continues to occur with multiple catheter types and despite multiple modalities of esophageal monitoring during ablation and post-procedure proton pump inhibitor use. Among patients who present with esophageal perforation, increased body mass index and decreased left ventricular ejection fraction may be associated with unfavorable outcomes. Because the window from symptom onset, diagnosis, and neurologic injury is often short, and the prognosis of esophageal perforation substantially improved if diagnosed before development of AEF, it is extremely important to maintain vigilance for this rare complication in the first 2 months after AF ablation, and in the post-operative period following surgical repair of esophageal perforation.

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PERSPECTIVES

COMPETENCY IN MEDICAL KNOWLEDGE: Approximately 70% of esophageal perforation following catheter ablation of atrial fibrillation results in atrial esophageal fistula. The prognosis for survival without severe neurologic injury for esophageal perforation without fistula and pericardial-esophageal fistula is more favorable than that of atrial esophageal-fistula. The window between symptom onset and neurologic injury is often short in patients with esophageal perforation following atrial fibrillation ablation. It is extremely important to maintain vigilance for this rare complication in the first 2 months after AF ablation, and in the post-operative period following surgical repair of esophageal perforation.

TRANSLATIONAL OUTLOOK: Esophageal perforation remains a rare but devastating complication of atrial fibrillation ablation despite use of various esophageal monitoring techniques. Additional research is required to develop ablation techniques with reduced risk of esophageal injury and imaging techniques that allow earlier detection.

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KEY WORDS atrial-esophageal fistula, atrial fibrillation, catheter ablation, esophageal perforation

APPENDIX For supplemental material, please see the online version of this article.