

Risk of atrioesophageal fistula formation with contact force–sensing catheters



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BACKGROUND Atrioesophageal fistula formation is a rare but life-threatening complication of atrial fibrillation ablation. Contact force (CF)–sensing catheters improve procedural effectiveness. However, the impact of the implementation of CF-sensing technology on the risk of atrioesophageal fistula formation has not been explored.

OBJECTIVE The purpose of this study was to determine the association between the use of CF-sensing catheters and atrioesophageal fistula development.

METHODS We searched the Manufacturer and User Facility Device Experience database for adverse event reports involving Food and Drug Administration–approved ablation catheters.

RESULTS Among 2689 device reports, we identified 78 atrioesophageal fistula cases, 65 of which involved CF-sensing catheters and 13 non-CF-sensing catheters. The percentage of total reports involving atrioesophageal fistula was 5.4% for CF-sensing catheters (65 of 1202) and 0.9% for non-CF-sensing catheters (13 of 1487)

($P < .0001$). Procedural details (CF and power settings) were not consistently reported. Esophageal temperature increases were detected in only 2.5% of cases (2 of 78). The mean time to presentation was 16 ± 9 days. Overall mortality was at least 56%, with patients who underwent surgical repair more likely to survive than those treated with stenting or no intervention.

CONCLUSION Atrioesophageal fistula formation accounted for a much higher proportion of reported adverse events with CF-sensing catheters compared with non-CF-sensing catheters. Improved understanding of the relationship between power/force delivery and esophageal damage is needed to minimize the risk of atrioesophageal fistula formation.

KEYWORDS Catheter ablation; Atrial fibrillation; Pulmonary vein isolation; Contact force; Radiofrequency ablation; Atrioesophageal fistula

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Introduction

Catheter ablation of atrial fibrillation (AF) is a common procedure with low overall complication rates. Atrioesophageal fistula formation is a rare event, with an estimated incidence of less than 0.25% after traditional radiofrequency (RF) ablation.^{1–3} However, atrioesophageal fistula represents a feared complication of AF ablation, with mortality exceeding 60%.^{1–3} Pulmonary vein (PV) reconnection due to

incomplete lesion formation is the most common cause of arrhythmia recurrence after AF ablation.⁴ Catheters equipped with contact force (CF)–sensing technology have been widely adopted with the goal of enhanced lesion formation and safety via detection of excessive force transmission.^{5,6} Optimal force delivery helps operators obtain adequate lesion depth, but the impact of this practice on damage to collateral structures is unknown. The purpose of this study was to determine the association between the use of CF-sensing catheters and atrioesophageal fistula development by analyzing reports of atrioesophageal fistula formation in the Manufacturer and User Facility Device Experience (MAUDE) database.

Methods

The Food and Drug Administration (FDA) MAUDE database is a searchable online database containing medical device reports submitted by device manufacturers and physicians. We queried MAUDE for adverse event medical device

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Table 1 Ablation catheters with manufacturer, Food and Drug Administration (FDA) approval, and contact force (CF)–sensing characteristics

Catheter	Manufacturer	FDA approval date	CF sensing?	MAUDE reports
TactiCath Quartz contact force	St. Jude Medical	October 24, 2014	Yes	214
ThermoCool SmartTouch	Biosense Webster	February 11, 2014	Yes	988
FlexAbility	St. Jude Medical	January 23, 2015	No	69
Therapy Cool Path Duo and Safire BLU Duo	St. Jude Medical	January 25, 2012	No	160
NaviStar and EZ Steer ThermoCool	Biosense Webster	February 6, 2009	No	1258

reports involving CF-sensing and non-CF-sensing irrigated catheters used for the treatment of AF or atrial flutter (Table 1). We performed a search of all adverse events classified as “Death” or “Injury” for each specific catheter. An additional supplemental search was also performed for “atrioesophageal fistula.” CF-sensing catheters included the ThermoCool SmartTouch catheter (Biosense Webster Inc., Diamond Bar, CA), which received FDA approval for use in AF on February 11, 2014, and the TactiCath Quartz catheter (St. Jude Medical Inc., St. Paul, MN), which was approved by the FDA on October 24, 2014. Non-CF-sensing catheters included the ThermoCool NaviStar and EZ Steer catheters (Biosense Webster; FDA approved on February 6, 2009), Therapy Cool Path Duo and Safire BLU Duo ablation catheters (St. Jude Medical, FDA approved on January 25, 2012), and the steerable FlexAbility ablation catheter (St. Jude Medical, FDA approved on January 23, 2015).

Medical device reports were manually reviewed, and cases involving atrioesophageal fistula formation were selected for inclusion. These reports were then reviewed for patient characteristics, report date, event date, symptoms on presentation, ablation procedural details (including the use of esophageal temperature monitoring), fistula repair or esophageal stenting, and ultimate outcome. In cases where explicit statements about the timing of atrioesophageal fistula presentation were not present, this variable was not reported. The percentage of adverse events that were due to atrioesophageal fistulas were compared between CF and non-CF using the Fisher exact test.

Results

A total of 2689 MAUDE database medical device reports were identified, including 1202 for CF-sensing catheters and 1487 for non-CF-sensing catheters (Table 1). Reports spanned from October 4, 2010, to December 1, 2016. Manual review of these reports revealed 78 cases of atrioesophageal fistula formation. Sixty-five of the reports involved the use of CF-sensing catheters and 13 non-CF-sensing catheters (Figure 1). The percentage of total reports of injury or death identified for atrioesophageal fistula was 5.4% for CF-sensing catheters (65 of 1202) and 0.9% for non-CF-sensing catheters (13 of 1487) ($P < .0001$) (Figure 1). MAUDE database entries of adverse events with CF-sensing catheters involved the use of ThermoCool SmartTouch in 988 reports and TactiCath in 214 reports. The overall proportion of adverse event reports representing atrioesophageal fistula was similar among the 2 types of

CF-sensing catheters (6.1% of the total reports for TactiCath and 5.3% for ThermoCool SmartTouch; $P = .6$).

Procedural details for cases resulting in atrioesophageal fistula formation involving the use of CF-sensing and non-CF-sensing catheters are listed in Supplemental Tables S1 and S2, respectively. Esophageal temperature monitoring was reported in 42% of overall cases ($n = 33$), with a rise in esophageal temperature above 37°C noted in only 2.5% of reports ($n = 2$). The majority of cases did not provide information about device settings such as power or impedance changes. Among the minority of cases (19 of 65 [29%]) with CF-sensing catheters that reported power settings on the posterior wall, the average maximal power delivered was 30 ± 7.8 W, with a range of 20–40 W. Among the atrioesophageal fistula cases reported with CF-sensing catheters, esophageal temperature monitoring was reported in 49% of cases ($n = 32$). In cases where recorded temperatures were reported (11 of 32 [34%]), 7 reported no temperature rise above 37°C and 4 reported no rise above 38.5°C. There was a broad range in time to presentation, ranging from immediately to 1 month after index ablation. The mean time to presentation was 16 ± 9 days. Figure 2 illustrates the presenting signs and symptoms among the CF-sensing catheter cases. The most common presenting symptoms were chest pain, neurological/stroke-like symptoms, and dysphagia/odynophagia.

Esophageal surgical repair was reported in 42% of patients ($n = 33$), while 14% underwent esophageal stenting ($n = 11$). No intervention was reported in the remaining 44% of patients ($n = 34$). Mortality was high, with death occurring in 56% ($n = 44$), stable condition at last follow-up reported in 31% ($n = 24$), and no outcome reported in 13% ($n = 10$). Compared with those in which no intervention was reported, patients who underwent surgical fistula repair were more likely to survive (Figure 3).

Discussion

In our analysis of atrioesophageal fistula formation after catheter ablation with CF-sensing and non-CF-sensing catheters, there are several major findings. First, the occurrence of atrioesophageal fistula formation accounted for a 5-fold higher proportion of all MAUDE medical device reports of injury or death with CF-sensing catheters compared with non-CF-sensing catheters. Second, the proportion of injury or death due to reported atrioesophageal fistula was similar in spring-based (ThermoCool SmartTouch) and fiberoptic sensor-based (TactiCath) CF-sensing catheters. Third, the fatality rate in reported cases of atrioesophageal fistula is

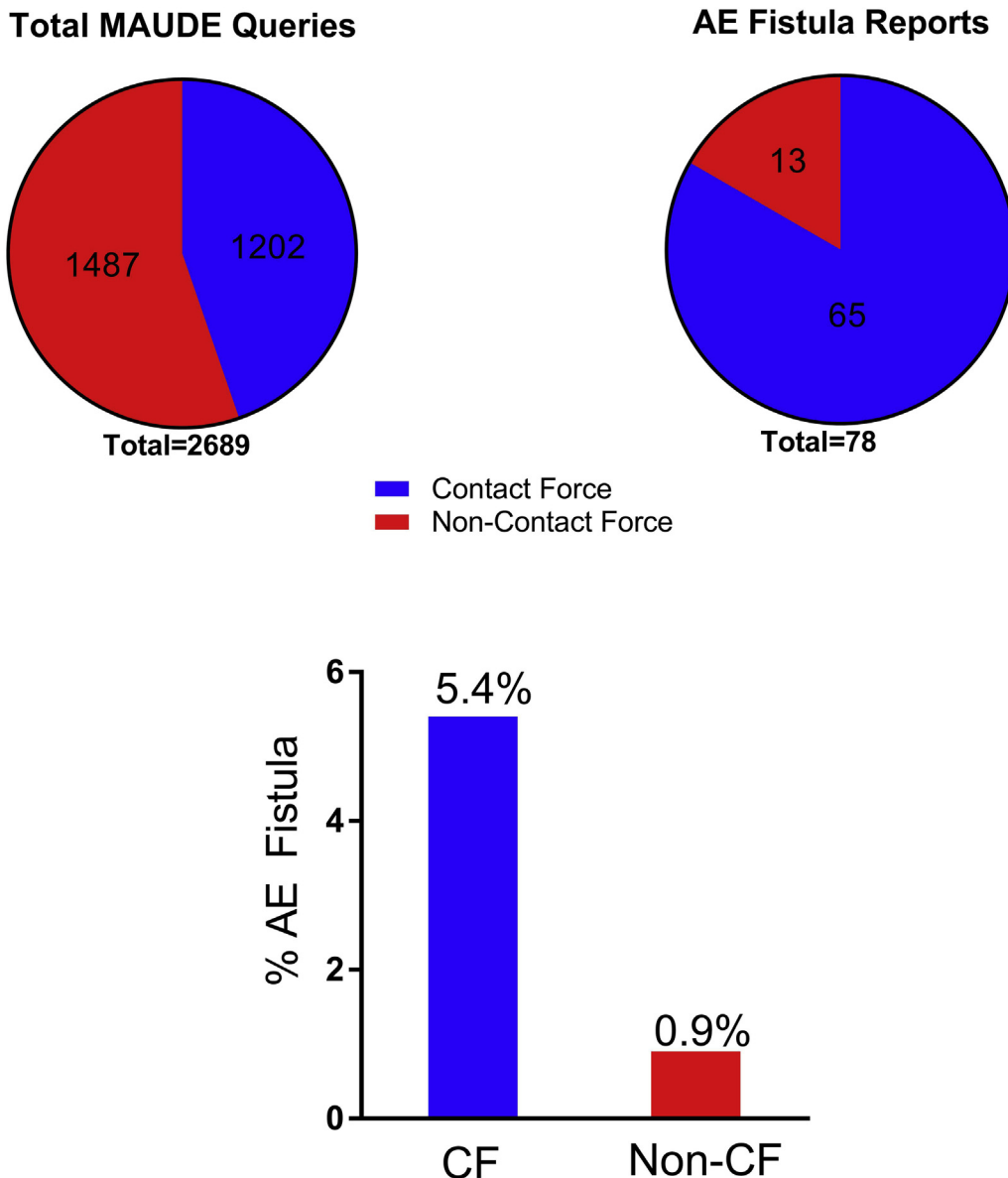


Figure 1 Atrioesophageal fistula cases: contact force vs non-contact force. AE = atrioesophageal; CF = contact force-sensing catheter; MAUDE = Manufacturer and User Facility Device Experience. Non-CF = non-contact force-sensing catheter.

greater than 50% and surgical repair appears to be associated with a higher rate of survival.

CF-sensing catheters have been evaluated in prospective clinical trials, and they appear to be safe and effective.^{5,6} Overall, CF-sensing technology has been shown to result in more durable PV isolation and reduce AF recurrence rates.⁷ Furthermore, a relationship between optimal CF and ablation outcomes has emerged.^{8,9} In the prospective randomized TOCCASTAR trial, operators who delivered consistently “optimal” CF (defined as >90% ablation procedures of >10 g force) had significantly fewer AF recurrences at follow-up.⁶ Mean force delivery in the optimal CF group was significantly higher (26.5 g vs 19.2 g; $P < .001$).⁶ Overall, these data support the concept that adequate CF results in more durable PV isolation and procedural efficacy.

While the relatively small clinical trials have not suggested any major or large differences in procedural safety with CF-sensing catheters, we found that reports of atrioesophageal fistula were much more likely to involve the use of CF-sensing catheters than of traditional RF ablation catheters. No such trend has been previously noted in the literature. In 2015, a meta-analysis including 552 patients treated with CF-sensing catheters reported no cases of atrioesophageal fistula and found a similar overall major complication rate (1.3% vs 1.9%; $P = .45$) between non-CF and CF cases.¹⁰ Operators using CF-sensing technology to target optimal CF may ablate longer and with greater force than those using traditional catheters. Considering that formation of atrioesophageal fistula presumably involves thermal injury to the esophageal mucosa,¹¹ increased energy delivery with CF-sensing-guided ablation might increase the risk of

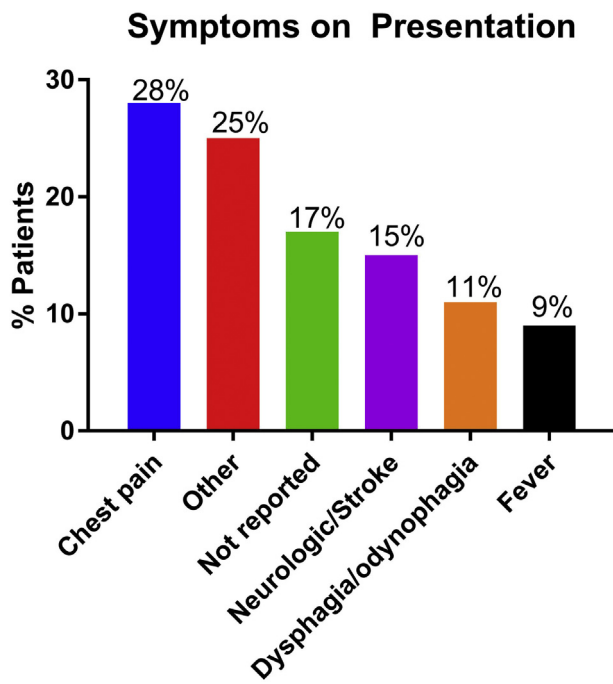


Figure 2 Major presenting symptoms of atrioesophageal fistula.

atrioesophageal fistula. While device manufacturers recommend a maximum CF of 30 g on the basis of data from animal models, this safety threshold has not been validated in humans.^{12,13} Operators currently attempt to reduce the risk of atrioesophageal fistula formation by minimizing ablation power on the posterior atrial wall. However, other ablation characteristics such as the duration of energy application may represent equally important parameters with respect to atrioesophageal fistula formation. Bhaskaran et al¹⁴ found that high power, shorter duration (50–80 W for 5 seconds) ablation procedures achieved equivalent lesion depth with fewer complications than did low power, longer duration lesion sets (40 W for 30 seconds). Overall, our findings highlight a need for an improved understanding of optimal power delivery in ablation using CF-sensing catheters on

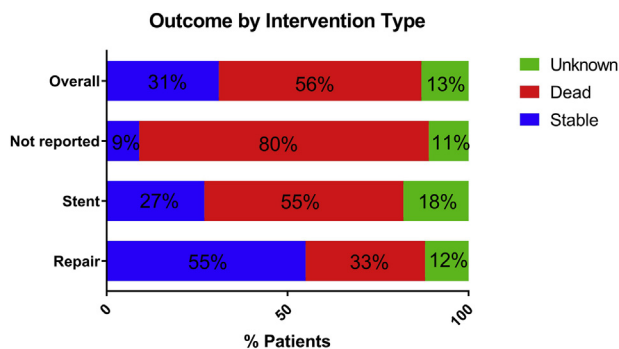


Figure 3 Outcome by intervention type. Patients designated as having received a stent underwent esophageal stenting. Repair indicates patients who underwent surgical repair. Dead = patient was reported to have died of a complication of their fistula; Stable = patient reported alive or clinically stable at last follow-up.

the posterior wall, particularly as posterior wall isolation becomes more common in ablation of persistent AF.

Currently available CF-sensing catheters use spring-coupled (SmartTouch) and fiberoptic mediated (TactiCath) sensing technology. Overall, the relative percentage of atrioesophageal fistula reports with each catheter was similar. The major adverse event rate in SMART-AF did not differ between spring-coupled (SmartTouch) and traditional catheters, with no cases of atrioesophageal fistula.⁵ However, all 4 cases of pericardial tamponade in SMART-AF involved the use of CF in excess of 40 g.⁵ TOCCASTAR also reported no significant difference in the major adverse event rate between fiberoptic mediated CF-sensing (TactiCath) and traditional RF ablation technology, with no cases of atrioesophageal fistula in either group.⁶ Consistent with our findings, there are no data to suggest that 1 particular form of CF-sensing technology poses a higher risk of atrioesophageal fistula formation.

Presentation of atrioesophageal fistula tended to be delayed with a mean presentation of 16 days after ablation, similar to prior published reports.³ Patients who underwent surgical atrioesophageal fistula repair were more likely to survive than those who underwent esophageal stenting or no repair. Although these findings are likely confounded by significant selection bias, previous studies have also suggested that surgical repair may be superior to stenting.^{15,16} In a case series of 9 patients undergoing intervention for atrioesophageal fistula, Mohanty et al¹⁵ found that 100% of patients (5 of 5) managed with esophageal stenting expired within 1 week while 100% patients (4 of 4) who underwent surgical repair were alive at a mean follow-up of 2.1 years. Another retrospective analysis of 29 patients treated for atrioesophageal fistula reported 41% mortality in patients undergoing surgical repair and 100% with esophageal stenting.¹⁶ In a systematic review of 53 case reports, Chavez et al¹⁷ also found significantly better survival with surgical repair compared with nonoperative management (83% vs 34%; $P < .05$). Therefore, our findings provide further evidence in favor of esophageal repair over stenting in patients stable enough to undergo surgery.

Atrioesophageal fistula formation occurred in the absence of changes in luminal esophageal temperature (LET) in the majority of patients in which temperature monitoring was reported (31 of 33). It is important to note that there is no way of knowing whether the esophageal probe electrodes were positioned appropriately across the vein being ablated in these MAUDE reported cases. The literature on the impact of LET monitoring on esophageal thermal damage is controversial. In a study that demonstrated decreased esophageal ulceration with LET, there was no relationship between maximal LET and esophageal lesion formation in the monitored group.¹⁸ Furthermore, the analysis was confounded by greater use of general anesthesia in the non-LET group (43% vs 13%), which is of particular significance considering the strong association between general anesthesia and endoscopically detected mucosal lesions.^{18,19} Standard temperature probes significantly underestimate esophageal

wall temperature,²⁰ and there is substantial variation in sensitivity by device (eg, esophageal probe vs stethoscope and multisensor vs single sensor).²¹ Muller et al²² recently found endoscopically detected esophageal lesion formation to be more common after ablation in patients who underwent LET monitoring (30% vs 2.5%; $P < 0.01$). These surprising findings may be mechanistically explained by heat transfer from the RF ablation catheter tip to uninsulated metal temperature probes, increasing temperatures in adjacent esophageal tissue.²³ Alternatively, a lack of temperature rise in patients who undergo LET monitoring may give the operator a false sense of safety to increase power delivery or ablation duration on the posterior wall. Further studies are clearly needed to critically appraise the role of esophageal temperature monitoring in AF ablation.

Our study findings highlight the strengths and limitations of the MAUDE database and highlight the need for more granular and systematic monitoring of adverse events related to catheter ablation. Additional postmarketing surveillance tools are on the horizon to help answer important questions about rare complications. The development of the Global Unique Device Identification Database and standardization of Unique Device Identifiers will allow more convenient adverse event reporting.²⁴ The American Heart Association's Get With the Guidelines-AFIB registry ablation module and National Cardiovascular Data Registry AFib Ablation Registry will provide additional data to facilitate monitoring and analysis of rare adverse events such as atrioesophageal fistula formation. These registries will likely facilitate additional comparisons between CF and non-CF ablation catheters with respect to outcomes and adverse events.

Study limitations

As noted in the already published analyses of the MAUDE data, there are several limitations that should be kept in mind when considering these data.^{25,26} Adverse events in clinical practice are not routinely reported to MAUDE despite FDA recommendations. In addition, these data can only provide relative proportions of frequencies, as the denominator for the use of these catheters is unknown. For example, an overall decrease in the adverse event rate secondary to CF-sensing technology could misleadingly create an increase in the proportion of atrioesophageal event reports. Finally, reports in MAUDE are not independently verified. However, atrioesophageal fistula formation is a rare event and so systematic nationwide assessment is challenging. Thus, the MAUDE data present a unique opportunity to assess rare adverse events encountered with devices.

Conclusion

Atrioesophageal fistula formation is a rare complication of catheter ablation with high mortality. CF-sensing catheters enhance procedural efficacy, but their use may be associated with increased rates of atrioesophageal fistula formation. The role of esophageal temperature monitoring in preventing atrioesophageal fistula appears limited. Overall mortality is

high, with surgical repair offering the best chance of survival. Further studies are needed to define ablation approaches that minimize esophageal injury.

Appendix Supplementary data

Supplementary data associated with this article can be found in the online version at <http://dx.doi.org/10.1016/j.hrthm.2017.04.024>.

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