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Catheter-related complications and mortality of atrial fibrillation ablation following introduction of contact force-sensing technology

Joseph G Akar,[1] James P Hummel,[2] Xiaoxi Yao,[3] Lindsey Sangaralingham,[4] Sanket Dhruva,[5] Jun Dong,[6] Rebecca Ward,[6] Nilay D Shah,[4] Joseph Ross,[7] Peter A Noseworthy [4]

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For numbered affiliations see end of article.

Correspondence to
Dr Peter A Noseworthy; noseworthy.peter@mayo.edu

ABSTRACT

Objectives Contact force-sensing catheters allow real-time catheter-tissue contact force monitoring during atrial fibrillation. These catheters were rapidly adopted into clinical practice following market introduction in 2014, but concerns have been raised regarding collateral damage such as esophageal injury. We sought to examine whether the introduction of force-sensing catheters was associated with a change in short-term and intermediate-term acute care use, complications and mortality following atrial fibrillation ablation.

Design Retrospective cohort analysis. We used inverse probability treatment weight matching to account for the differences in baseline characteristics between groups.

Setting We examined patients included in the OptumLabs Data Warehouse who underwent ablation for atrial fibrillation before (2011–2013) and after (2015–2017) the market introduction of contact force-sensing catheters.

Main outcome measures We examined 30-day and 90-day rates of all-cause acute care use, including hospitalizations and emergency department visits, as well as death and hospitalization for catheter-related complications, including atrioesophageal fistula, pericarditis, cardiac tamponade/perforation and stroke/transient ischemic attack.

Results Our sample included 3470 and 5772 patients who underwent atrial fibrillation (AF) ablation before and after market introduction of contact force-sensing catheters, respectively. Complication rates were low and did not differ between the two periods (p>0.10 for each outcome). The 30-day and 90-day mortality was 0.1% and 0.3%, respectively after market introduction and unchanged from prior to 2014. The 90-day rates of all-cause acute care use decreased, from 27.0% in 2011–2013 to 23.9% in 2015–2017 (p<0.001).

Conclusions AF ablation-related catheter complications and mortality are low and there has been no significant change following the introduction of force-sensing catheters.

Key messages

What is already known about this subject?

- Previous studies examining complications following atrial fibrillation (AF) ablation are limited in their application to contemporary practice.
- Force-sensing catheter technology was rapidly and widely adopted for AF ablation procedures, however there are limited data on complications related to the use of these catheters.
- Force-sensing catheters produce more extensive ablation lesions that could predispose to complications related to cardiac perforation and collateral damage to the esophagus.

What are the new findings?

- We performed a retrospective cohort analysis using OptumLabs Data Warehouse to compare rates of adverse outcomes among patients undergoing ablation before (n=3470) and after (n=5772) the market introduction of contact force-sensing catheters.
- Complication rates were low and did not differ between the two periods (p>0.10 for each outcome).
- The 30-day and 90-day mortality was 0.1% and 0.3%, respectively and did not change after introduction of force sensing technology.
- The 90-day rates of all-cause acute care use decreased from 27.0% to 23.9% after introduction of force sensing technology (p<0.001).

How might these results affect future research or surgical practice?

- The introduction of contact-force catheter technology was not associated with increasing rates of 30-day or 90-day mortality, or serious peri-procedural complications such as atrial perforation.
- The real-world use of these catheters does not appear to be associated with increased rates of hospitalization or emergency visits.

INTRODUCTION

The incidence of short-term and intermediate-term safety outcomes following catheter ablation of atrial fibrillation (AF) requires continual reappraisal. Not only has the AF ablation technique evolved from segmental pulmonary vein ablation to wide area circumferential isolation with possible

substrate modification, but there have also been significant advances in mapping and ablation catheter technology to improve procedural safety and effectiveness. Previous studies examining complications following AF ablation are limited in their application to contemporary practice because they preceded the introduction of currently used catheters capable of force-sensing and increased power delivery to the posterior left atrial wall.[1–5] Furthermore, there are limited data on specific procedure-related complications that occur in the short-term and intermediate-term such as pericarditis and atrioesophageal fistula (AEF) in a contemporary cohort.[6]

The most significant recent advance in catheter technology has been the ability to measure contact force. Contact force-sensing catheters were introduced to the US market in early 2014 and have been rapidly and widely adopted. Contact force-sensing catheters are not dependent on tactile sensation and allow titration of contact force resulting in more consistent transmural ablation lesions.[7–9] While this is generally desirable for procedural success, the deeper ablation lesions could predispose to procedural complications, especially those related to cardiac perforation and collateral damage to adjacent structures. A recent analysis of the Food and Drug Administration's Manufacturer and User Facility Device Experience database suggested that use of contact force-sensing catheters may be associated with increased risk for AEF formation.[10]

To evaluate these concerns and provide contemporary safety data, we examined real-world outcomes following AF ablation using data from a large, national contemporary population of commercially insured patients and Medicare Advantage beneficiaries. Specifically, we examined whether the introduction of force-sensing catheters was associated with an increase in short-term and intermediate-term acute care use (hospitalization and emergency department (ED) visits), death, and complications, particularly those related to cardiac perforation including AEF.

METHODS

Data source

We conducted a retrospective cohort analysis using OptumLabs Data Warehouse, a large US database with de-identified administrative claims data for individuals enrolled in private and Medicare Advantage health plans.[11] All ages, ethnicities, and racial groups are represented in the database spanning all 50 states. Medical claims include information on physician, hospital, and outpatient prescription services.[12]

Study population

The study population included adult patients (≥18 years) with AF who underwent AF ablation between January 1, 2011 and September 30, 2017. The patients were identified using International Classification of Diseases (ICD)-9 and ICD-10 diagnostic codes for AF, combined with Current Procedural Terminology (CPT) procedural codes for AF ablation. If a patient received multiple ablations, the date of the first ablation was defined as the index date. All patients were required to have continuous medical enrollment for at least 12 months prior to the index procedure and 90 days post the index procedure or death. The Mayo Clinic Institutional Review Board exempted this study from review because the study used pre-existing, deidentified data.

Because contact force-sensing technology was introduced in 2014, we excluded patients who underwent AF ablation during this time. Essentially, we used this as a wash-out period, recognizing that while there was widespread adoption, time was needed for cardiac electrophysiology labs to use already purchased catheters and replace existing stock, exchanging contact force-sensing catheters for traditional catheters.

Covariates

Independent variables of interest at baseline were demographics: age, gender, and race (white, black, Hispanic, Asian, or unknown), region (Midwest, Northeast, South, or West) and baseline clinical characteristics: anemia, vascular disease, chronic obstructive pulmonary disease, obesity, hypertension, diabetes, renal disease, congestive heart failure, history of cardioversion, or stroke. These factors included all components of the HAS-BLED (a bleeding risk score) and CHA_2DS_2-VASc (a stroke risk score) scores. We also included baseline prescriptions for amiodarone. Comorbidities were captured by ICD-9 and ICD-10 codes in any position on claims in the 12 months prior to the index ablation procedure. Use of amiodarone in the 90 days prior to index ablation date was determined based on pharmacy claims.

Primary and secondary outcomes

Our primary outcome was all-cause acute care use, including the immediate peri-procedural period (index hospitalization for ablation), as well as subsequent ED visits and hospitalizations, within 30 days and 90 days of AF ablation. Secondary outcomes were all-cause mortality and ablation-specific complications within 30 days and 90 days of ablation. Ablation-specific complications encountered during the index hospitalization included cardiac perforation resulting in tamponade or need for urgent intervention, pericarditis, stroke or transient ischemic attack (TIA), and AEF (see online supplemental appendix table 1 for pertinent ICD-9, ICD-10, and CPT codes). Catheter-related complications were identified using primary and secondary discharge diagnosis codes (see online supplemental appendix table 2 for pertinent ICD-9, ICD-10, and CPT codes). The codes and algorithms used herein have been commonly used and validated in many previous studies.[13 14]

Mortality was identified based on the Social Security Death Master File and patient discharge status.

Since AEF is difficult to assess with a single diagnosis code, we used a hierarchical method incorporating

multiple codes as outlined in online supplemental appendix table 3. In brief, AEF was assessed as either definite or probable based on diagnosis codes occurring within 90 days of ablation. Definite AEF was defined as: (1) a diagnosis code for AEF *or* esophageal injury associated with death; or (2) an esophageal intervention associated with a diagnosis of either AEF, esophageal injury, mediastinal infection, air embolism, or hematemesis. Probable AEF was defined when: (1) patients underwent an esophageal intervention *and* had other possible signs of AEF including stroke, multi-organ failure, infection/sepsis, altered mental status, fever chest pain, or dysphagia; or (2) codes for mediastinal infection, air embolism, or hematemesis were associated with death; or (3) codes for both stroke *and* infection/sepsis were associated with death.

In order to reflect the known clinical difficulty in establishing a diagnosis of AEF, we performed a sensitivity analysis in which AEF was defined as *any two* of the diagnosis codes occurring within 90 days of ablation: mediastinal infection, air embolism, hematemesis, stroke/TIA, multi-organ failure, infection/sepsis, altered mental status, fever, chest pain, or dysphagia.

Statistical analyses

To examine the association of the contact force-sensing technology introduced in 2014 on the risk of several outcomes, we created a balanced cohort (before 2011–2013 vs after 2015–2017). We used inverse probability of treatment weighting (IPTW) to balance covariates between the two time periods. The underlying propensity model included the demographics, comorbidities, and baseline medication use shown in table 1. We evaluated the balance among the two time periods by comparing standardized mean differences of baseline covariates. A baseline characteristic was considered balanced if the standardized mean difference was <10%. We used a logistic regression to compare treatments in the weighted population. All analyses were conducted using SAS software V.9.4 and Stata V.15.1.

Table 1 Patient characteristics before and after IPTW.

	Before IPTW			After IPTW		
	2011–2013 (N=3470)	2015–2017 (N=5772)	Std. Diff. (%)	2011–2013 (N=3470)	2015–2017 (N=5772)	Std. Diff. (%)
Age, mean	61	64.2	31.60	62.83	62.9	0.90
Gender						
Female	28.60%	33.90%	11.30	31.60%	31.80%	0.50
Male	71.40%	66.10%	11.30	68.40%	68.20%	0.50
Race						
White	82.20%	82.30%	4.00	82.40%	82.30%	0.20
Black	8.80%	7.70%	4.30	8.10%	8.10%	0.00
Hispanic	4.30%	5.10%	3.70	4.80%	4.80%	0.40
Asian	1.70%	1.60%	1.00	1.60%	1.60%	0.10
Unknown	3.00%	3.30%	2.10	3.20%	3.20%	0.10
Baseline characteristics						
Amiodarone use	9.00%	12.00%	12.60	11.00%	11.00%	0.80
Anemia	21.00%	19.00%	4.40	20.00%	20.00%	0.20
Vascular disease	24.00%	27.00%	5.90	26.00%	26.00%	0.20
COPD	6.00%	5.00%	3.00	6.00%	6.00%	0.10
Obesity	31.00%	43.00%	23.80	38.00%	38.00%	0.30
Hypertension	78.00%	81.00%	7.40	80.00%	80.00%	0.30
Diabetes	19.00%	23.00%	10.40	22.00%	21.00%	0.90
Renal disease	7.00%	12.00%	16.20	10.00%	10.00%	0.80
CHF	24.00%	28.00%	8.60	27.00%	27.00%	0.90
Cardioversion	41.00%	43.00%	3.90	42.00%	42.00%	0.20
Stroke	7.00%	3.00%	18.90	5.00%	5.00%	0.30
HAS-BLED, mean*	1.7	1.9	14.40	1.8	1.9	2.70
CHA_2DS_2-VASc, mean*	2.4	2.7	23.10	2.6	2.6	4.70

*Not included in IPTW.
CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; IPTW, inverse probability of treatment weighting.

Table 2 Clinical events before (2011-2013) and after (2015-2017) introduction of force-sensing catheters.

	Before (2011–2013) n=3470 (%)	After (2015–2017) n=5772 (%)	P value
30-day events			
AEF	0.0	0.01	–
Definite	0.0	0.01	–
Probable	0.0	0.01	–
Sensitivity	1.1	0.9	0.247
Death	0.2	0.1	0.309
Tamponade or intervention	0.2	0.3	0.321
Pericarditis	1.4	1.5	0.735
Stroke/TIA	0.1	0.1	0.630
Hospitalization or ED visit	18.1	16.8	0.134
90-day events			
AEF	0.04	0.09	0.379
Definite	0.04	0.04	0.942
Probable	0.04	0.07	0.580
Sensitivity	2.2	1.6	0.039
Death	0.5	0.3	0.226
Tamponade or intervention	0.4	0.5	0.494
Pericarditis	1.7	1.8	0.675
Stroke/TIA	0.2	0.2	0.960
Hospitalization or ED visit	27.0	23.9	0.001

AEF, atrioesophageal fistula; ED, emergency department; TIA, transient ischemic attack.

RESULTS

Patient characteristics

Table 1 shows the baseline characteristics of patients undergoing AF ablation before and after introduction of contact force-sensing catheters, including 3470 patients who underwent ablation between 2011 and 2013 and 5722 patients who underwent ablation between 2015 and 2017. Patients undergoing ablation after 2014 were older, more obese, more likely females and with lower history of stroke. As demonstrated in the right panel of table 1, the groups were well-balanced following inverse probability weight matching, with all standardized mean differences <1%. There was no significant difference in age, gender, race, or comorbidities. The majority of patients included in our sample were men and white, and most had a history of hypertension. The mean CHA_2DS_2-VASc score was 2.6 in both groups between 2011–2013 and 2015–2017, respectively. The mean HAS-BLED score was 1.8 and 1.9, respectively.

Outcomes

The overall adjusted rates of short-term and intermediate-term all-cause emergency visits and hospitalizations are reported in table 2. There was a statistically significant reduction in the 90-day rates of all-cause acute care use, including ED visits and hospitalizations, in the years following market introduction of the contact-sensing catheters, from 27.0% to 23.9% (p<0.001). Prior to the introduction of contact force-sensing catheters, 18.1% of patients had at least one hospitalization or emergency visit within 30 days of undergoing AF ablation, compared with 16.8% in the years following the introduction of contact force-sensing catheters (p=0.134).

Adjusted rates of short-term and intermediate-term risk of mortality and procedural complications are also reported in table 2. We found no difference in the secondary outcomes of mortality and procedural complications before and after the market introduction of contact force-sensing catheters. The 30-day and 90-day mortality rates were not significantly changed after market introduction of force-sensing catheters (0.2% and 0.5% before vs 0.1% and 0.3% after, respectively; p values >0.10). Specifically, there was no difference in 30-day and 90-day risk of AEF (0.0% and 0.04% before vs 0.01% and 0.09% after; p>0.10), tamponade or intervention (0.2% and 0.4% before vs 0.3% and 0.5% after; p>0.3) and stroke (0.1% and 0.2% before vs 0.1% and 0.2% after; p>0.6).

DISCUSSION

We examined short-term and intermediate-term safety outcomes of patients undergoing AF ablation following the introduction and widespread adoption of contact-force sensing catheters in 2014, compared with outcomes observed among patients for whom previously available standard catheters were used. The main findings of analysis include: (1) the introduction of contact-force catheter technology did not appear to be associated with increasing rates of death and serious peri-procedural complications, including short-term and intermediate-term adverse events; (2) specifically, the introduction of contact-force catheter technology did not appear to be associated with increased risk of AEF or cardiac perforation; (3) the introduction of contact-force catheter technology did not appear to be associated with increased rates of hospitalization or emergency visits and may have been associated with a reduction in overall healthcare utilization at 90 days.

This study compares real-world, modern-era outcomes in a large, national adjusted cohort. Contrary to previous unadjusted reports, we found that AF ablation as practiced in the modern era following introduction of force-sensing catheters does not carry an increased risk of AEF or cardiac perforation. Our study suggests that the use of contact force-sensing catheters carries a small, approximately 0.1%, risk of AEF as well as low rate of mortality and morbidity due to serious adverse events related to stroke, cardiac perforation, hospitalizations, and emergency room visits. While this study did not examine the effectiveness of AF ablation following the introduction of force-sensing catheters, the low rates of adverse outcomes of AF ablation as practiced in the real world is highly encouraging and consistent with recent reports examining short-term events.[6] A recent analysis of AF ablation

trends using the Nationwide Readmissions Database from 2010 to 2015 reported a 30-day inpatient mortality rate of 0.46%, which is higher than our study despite not capturing out-of-hospital deaths, readmissions across different states, or long-term complications that can occur after 30 days (eg, AEF). It is worth noting that the Nationwide Readmissions Database contains only AF ablations performed among hospitalized patients, which likely represents a higher risk patient population given that the majority of contemporary AF ablation procedures are performed in the ambulatory setting. Another recent analysis of demonstrated that both contact force and non-contact force ablation catheters have similarly low incidence of AEF, however this analysis was derived only from ablation device manufacturer's complaint database.[15] Thus, in comparison to other studies, our analysis has the advantage of being both contemporaneous and representative of broad populations of patients undergoing AF ablation in routine practice.

AEF is one of the most morbid and lethal complications of catheter ablation of AF. While initially thought to be exceedingly rare, the incidence of AEF is now being revised and is thought to be higher than originally expected, with current estimates ranging from 0.02% to 0.11%.[16–20] Given the increase in AF ablation procedures in recent years, AEF continues to be among the most feared complications. However, the actual incidence of AEF has likely been underestimated due to the difficulty in establishing the diagnosis and its association with the AF ablation procedure. Patients with AEF usually present 2–4 weeks following the index ablation procedure with variable symptoms of fever, sepsis, hematemesis, or stroke.[16 21] Given the acuity and non-specificity of the symptoms, the patient may not be referred back to the institution where the index ablation is performed, and an association with the AF ablation procedure may be overlooked. Thus, the diagnosis of AEF may be missed and/or under-reported in single-center studies. Furthermore, given the temporal delay in the formation and clinical presentation of AEF, studies that examine acute or short-term peri-procedural complications are likely to miss or under-report this complication. Our study examined multiple algorithms as sensitivity analyses and did not find an increase in AEF over time.

Previous reports examining the period between 2000 and 2010 have demonstrated similarly low rates of serious complications with AF ablation, but these studies generally examined acute peri-procedural complications and did not examine potential adverse outcomes that may occur in the intermediate term following AF ablation, such as AEF or late-presenting tamponade. These studies also preceded the use of contact force-sensing technology and thus are not representative of modern practice. More recent studies examining AF ablation from single tertiary referral centers probably underestimated the true incidence of procedure-related death, AEF and other major complications, both because these centers tend to be more specialized and perform a larger number of procedures, but also because the centers tend to have greater experience, having used the novel technologies for a longer period of time. Our study is the first claims-based examination of AF ablation in the modern era to focus on intermediate-term complications and mortality, thereby capturing all hospitalizations regardless of institution or geography.

Limitations

There are several limitations that should be considered. First, using claims-based data, we are unable to identify the exact catheters used for ablation, as this information is not available. Therefore, our finding of no increasing rates of mortality and complications following the introduction of contact-force ablation catheters does not lead to a firm conclusion of no increased risks associated with this technology because it might have been confounded by other factors such as the increasing adoption of cryoballoon catheters in recent years. Given the rapid adoption of contact force-sensing catheters, it is reasonable to assume that these catheters were increasingly used after the 12-month blanking period following their introduction in 2014. Nevertheless, this limitation emphasizes the importance of integrating the Unique Device Identifier into claims,[22] which would enable future studies to explicitly compare outcomes among patients for whom different catheters are used. Second, while we found no trends of increased risk of safety outcomes after the introduction of contact-force catheters, we cannot rule out residual confounding despite propensity risk adjustment. In addition, we emphasize that the ascertainment of outcomes and covariates in this study relied on administrative data/claims which are subject to misclassification. No manual chart review to validate individual codes was feasible given the de-identified nature of the database. However, there would be no systematic ascertainment differences between the two treatment groups, and any potential misclassification should be non-differential and should not influence estimated treatment effects. In addition, the diagnosis and procedure codes used in this study have demonstrated good performance in validation studies with positive predictive values around 90%.[14 23–29]

CONCLUSIONS

The introduction of contact-force catheter technology in the modern era was not associated with increasing rates of 30-day or 90-day mortality, or serious peri-procedural complications, including short-term and intermediate-term serious adverse events and, importantly, AEFs. Furthermore, real-world use of these catheters does not appear to be associated with increased rates of hospitalization or emergency visits. Continued efforts are needed to monitor contemporary use of novel technologies to ensure that patients are achieving higher-quality care outcomes.

Author affiliations
[1]Department of Internal Medicine, Cardiovascular Medicine, Yale University School of Medicine, New Haven, Connecticut, USA
[2]Department of Medicine, University of Wisconsin-Madison School of Medicine and Public Health, Madison, Wisconsin, USA

[3]Division of Health Care Policy and Research, Mayo Clinic, Rochester, Minnesota, USA
[4]Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery, Mayo Clinic, Rochester, Minnesota, USA
[5]University of California San Francisco School of Medicine, San Francisco, California, USA
[6]Center for Devices and Radiological Health, US Food and Drug Administration, Silver Spring, Maryland, USA
[7]Internal Medicine, Yale University School of Medicine, New Haven, Connecticut, USA

Contributors Concept and design: JGA, JPH, JR, PN, NDS. Acquisition, analysis, or interpretation of data: JGA, JPH, XY, LS, SD, JD, RW, NDS, JR, PN. Drafting of the manuscript: JGA, PN, SD. Critical revision of the manuscript for important intellectual content: JGA, JPH, XY, LS, SD, JD, RW, NDS, JR, PN. Statistical analysis: LS, XY. Obtained funding: JR, NDS. Supervision: n/a.

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ORCID iD
Peter A Noseworthy http://orcid.org/0000-0002-4308-0456

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