

**Where Do We Come From? Where Are We Going?**

**Adverse Outcomes in Catheter Ablation for Atrial Fibrillation**

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“By seeking and blundering, we learn.”

– Goethe

In this issue of Circulation: Arrhythmia and Electrophysiology, Michowitz and coauthors present the incidence of cardiac tamponade with catheter ablation for atrial fibrillation (AF). Including nearly 35,000 procedures from 2000 to 2012, the authors report 2 major findings. First, women had a 1.8-fold increased risk of cardiac tamponade relative to men over this time frame. Second, the incidence of tamponade decreased inversely with procedural experience at the study’s participating centers. The present study is consistent with previous studies that have reported that women are more likely to have adverse outcomes with catheter ablation, and that experience contributes to reduced procedural complications.2-3 The investigation by Michowitz et al informs us about the ongoing challenges in studying catheter ablation and how we can understand its potential for harm as well as benefit.

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Over the past decade, advances in catheter ablation technique and approach have been significant. The early literature describing catheter ablation for AF comprised single-center studies using diverse approaches in small numbers of patients.4-5 In contrast, a 2012 international expert consensus statement on catheter ablation revised the indications for performing ablation in symptomatic patients to class I for paroxysmal AF and IIa for persistent AF after unsuccessful management with antiarrhythmic medication.6 The maturation of the technique is such that catheter ablation is now being tested as first-line therapy in clinical trials.7-8 The equipoise to perform such studies speaks to advances in the clinical use of catheter ablation and, just as importantly, its increased safety over the years. The possibility of catheter ablation comprising a first-line therapy for paroxysmal AF has not yet been explicitly endorsed but was discussed in a recent editorial.9 However, there are large challenges that remain for the literature of catheter ablation beyond showing improved success rates and decreased complications.

Like the early studies describing catheter ablation as a novel technique for treating small numbers of patients with AF, initial safety of catheter ablation was learned from isolated series. In 1998, for example, Robbins et al10 reported a high incidence of pulmonary vein stenosis that approached 10% (2 of 18) of individuals treated for symptomatic AF with catheter ablation. Interest in more comprehensive assessments of complications rates resulted in a 2005 worldwide survey by Cappato et al.11 The reported overall complication rate was 6% and, relevant to Michowitz et al, pericardial tamponade comprised only a fraction of these events (107 of 8745 procedures or 1.2%). An updated survey performed by the Cappato and colleagues12 in 2010 reported that the overall complication rate had decreased to 4.5%, with a similar rate of pericardial tamponade (213 of 16,309 procedures or 1.3%). In a comparable time frame, analyses using Medicare data 2005-200913 and California health claims data spanning 2005-200814 identified the incidence of tamponade as 1.7 to 2.5%, respectively. The data presented by Michowitz et al report an incidence of cardiac tamponade spanning 2002 to 2012 that is far less than these other studies: 289 cases overall, for an incidence of 0.8%.

Patients and clinicians may be confused by the heterogeneity in reported rates of pericardial tamponade. The differences between reports may be small but the relevance to patient safety is substantial given the elective nature of the procedure and potential severity of the complication. Pericardial tamponade in catheter ablation merits particular attention because of its associated mortality; in a large survey of procedural mortality, 1 in 4 deaths (8 of 32 events) occurred in the setting of pericardial tamponade.15 Multiple reasons may account for the differences across studies. There may be improvements in catheter choice, technique, anatomic visualization, operator experience, selection biases regarding the decision to report complications, and differences in data collection and presentation. As well, the analysis by Michowitz et al spans 2002 to 2012, years that saw enormous changes in catheter ablation technique. To provide contemporary data that are informative, analyses need to account for the secular trends in complication rates that reflect the evolution of procedural techniques.14

Like the previous surveys,11,12 the study by Michowitz et al is described as worldwide. Whereas the authors are to be congratulated for the international participation of 10 countries in 3 continents, the term is potentially misleading here and in the previous surveys given the selection biases inherent in the design of these studies. Worldwide implies that these studies are globally representative, but several continents and the vast majority of electrophysiology laboratories performing AF catheter ablation have not been included.

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In addition, in the studies of Cappato et al and the Michowitz study, many of the centers contacted did not provide data. The 2005 survey reported a response rate of 23%, and the 2010 update response rate reached 67%, but only 16% providing complete interview data.11,12 In the study performed by Michowitz et al, selection for participation was determined by a 2-step process. Centers were first identified by a Medline search capturing published reports of pericardial tamponade during catheter ablation. We have no way of knowing how complication rates differ between electrophysiology groups opting to publish reports of procedural complications and those who do not. However, we admit the selection bias in voluntary reports is considerable, stemming from the greater likelihood that complication rates are published by academic centers with higher procedural volumes and more professional prestige. More adverse events also may occur in smaller centers given the lower volume of procedures. In the second step of selection, the directors of centers that had published on pericardial tamponade had to agree to participate in the Michowitz et al study. Of 85 candidate centers with published reports of pericardial tamponade, only 19 centers chose to participate. It is unclear how they differ from the 66 centers that declined to participate.

The result is that the retrospective report by Michowitz et al represents an unknown fraction, a numerator with no known denominator, with uncertain representativeness of the worldwide use of catheter ablation and the incidence of pericardial tamponade. To their credit, Michowitz et al1 have collected a sizeable sample of catheter ablations and outcomes from selected, high caliber centers, and they caution about the limited generalizability outside of highly skilled academic institutions. Unfortunately, substantial study center selection bias in this and similar surveys preclude a broader assessment of the safety of catheter ablation today. For patients and physicians outside of these centers, these data are not adequate to inform and weigh procedural risks.

Understanding sex-specific risks for adverse outcomes are critical for anticipating and preventing complications. A key finding by Michowitz et al was that women had higher risk than men for developing pericardial tamponade during a catheter ablation for AF. Fewer women than men undergo catheter ablation, and women have been shown to have lower referral for the procedure and a suggestion of decreased procedural success than men.15 In the study by Michowitz and colleagues, there were 169 (0.7% of 25,261 ablations) cases of tamponade in men and 120 (1.2% of 9,682 ablations) in women. These data are consistent with a Medicare analysis that similarly identified that women had greater incidence of AF ablation–related pericardial tamponade than men.16 A multicenter observational study similarly reported that women had a greater incidence of bleeding complications than men.15

The reasons for increased risk of tamponade in women undergoing AF ablations are multifactorial. Women have smaller heart sizes than men, increasing the likelihood for complications during trans-septal puncture. Differences in body weight may affect procedural anticoagulation to prevent thromboembolism. Most centers, consistent with those described by Michowitz et al, perform far more catheter in ablations in men than in women. If experience is the key to success, then treating fewer women may be related to increased risk of adverse outcomes. We additionally note that the estimate of the odds ratio determining the risk of tamponade by sex was not adjusted. Other characteristics, such as body surface area or atrial size, patient age, anticoagulation strategy, procedural duration, and radiofrequency exposure time may be relevant to the development of tamponade. A large Italian registry has reported that longer procedure duration confers a 2-fold risk for complications.27 None of these characteristics were included in the report by Michowitz et al. We are impressed that Michowitz et al included nearly 35,000 procedures in the analysis, but find it challenging to appreciate how to use these data to improve clinical care and outcomes. Well-designed prospective studies are essential to understand the sex-based differences in patient selection, reasons for complications, and long-term prospective benefits.

It is not surprising that for both men and women, Michowitz et al identified that the incidence of cardiac tamponade decreased with center volume. Here is a clear message to the referring cardiologist, the electrophysiologist, and the patient: more is better. Identifying improved outcomes with experience is consistent with reports of operator experience in other cardiovascular procedures.18,19 Similar to other geographically broad surveys of AF and catheter ablation,11,12 Michowitz et al do not report on the relation of individual operator experience to adverse outcomes. Teasing out the effects of the setting versus the operator’s experience is critical for guiding patients appropriately.

The challenges for catheter ablation are multiple. For one, 2014 is the era of comparative effectiveness, a time when we have tools to quantify procedural complications prospectively. Adverse outcomes are rapidly developing as publically accessible metrics.28 Outcomes of catheter ablation may be reported as hospital- and physician-level data similar to other cardiac interventions.29 Risk-adjusted and uniform reporting on procedure details and complications would provide a more reliable avenue for learning about adversity in catheter ablation for AF than we have presently. Systematic reporting would preclude the bias of cherry picking by publication record and participation in survey-based assessments. Determining the relations of institutional and operator characteristics with adverse outcomes may become a matter of course. At present, the mechanism to implement such an approach is already in place. As indicated by the international consensus statement on ablation,4 the American College of Cardiology National Cardiovascular Data Registry (NCDR) has extensive hospital- and outpatient-based registries for evaluating outcomes and quality improvement.31 There is no compelling reason for the continued absence of an NCDR registry for catheter ablation. Similarly, jump-starting the proposed Safety of AF Ablation Registry Initiative would provide an accessible avenue for reporting longitudinal outcomes across community and academic centers.22 A fundamental premise is that more systematic and comprehensive reporting will greatly enhance our understanding of the prospective long-term benefits and potential procedural harms in using catheter ablation for treating AF.

Shared decision-making is emerging as a quality of care measure. Shared decision-making requires understanding and being able to communicate to the patient the anticipated benefits and risks of potential management strategies. All who undergo the procedure will be at risk for pericardial tamponade and other adversity; invariably, some will be harmed. Our professional mandate is to understand and communicate that
harm to benefit ratio\(^2\) when advocating an elective invasive procedure. Retrospective single-center studies or multicenter surveys provide limited assistance to patients navigating the choice to undergo catheter ablation. The most persuasive finding till date for patients is to choose the center with the most experience; not all patients have that option.

In summary, we find the survey by Michowitz et al informative. Like many studies of catheter ablation, its central limitation is generalizability attributable to selection biases. Bringing the literature and study of catheter ablation up to date requires prospective extensive reporting and granular assessments of sex-based, institution- and operator-based variation. Further examination of the clinical effectiveness will prepare catheter ablation for the growing expectations of public transparency and shared patient decision-making.

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