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EDITORIAL COMMENT

Atrial Fibrillation Ablation in the Real World*

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Atrial fibrillation (AF) ablation has offered the promise to free patients of symptoms of palpitations, dyspnea, and fatigue, as well as eliminate the need for use of chronic drug therapy with agents that sometimes have significant risks, cost, and inconvenience for the patient. The belief among many is that elimination of symptomatic AF with ablative procedures will also restore patients to the AF-free natural history curve, with reduction in stroke and mortality long term. These advantages are compelling, and they explain the wide adoption of a procedure that is technically challenging and has results that can be characterized as mediocre at best. Despite the fact that reports have claimed procedural success rates of 76% to 91% (1–4), carefully monitored clinical trials performed by experienced operators have indicated a true success rate in the range of 66% (5). In addition, procedural complication rates that are widely quoted to patients when decisions about risk versus benefit of AF ablation are being weighed are derived from publications that depend primarily upon self-reporting by single research centers or by centers participating in surveys (6,7).

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These reports most certainly underestimate the true prevalence of adverse events related to this intervention. It is therefore imperative that alternate methodologies are pursued to independently corroborate rates of arrhythmia recurrence and complications with AF ablation in the real world.

In this issue of the *Journal*, Shah et al. (8) presented data from the Healthcare Utilization Project California State Inpatient Database tracking prevalence of AF ablation procedures, acute procedure-related complications, and subsequent cause-specific readmissions for recurrent arrhythmias or procedural complications. This important study offers us insight into the outcomes from AF ablation in the real world. With this methodology, more than 4,000 patients who underwent an initial AF ablation procedure during a 4-year period were identified. The population seemed typical for patients who undergo this procedure nationally in that they were somewhat younger and had fewer comorbidities than the typical AF patient (9,10). The researchers found that complications occurred in 5% of patients and that one-half of those complications were vascular in nature. A total of 2.5% of patients had perforation or tamponade, a higher incidence than the 1.3% rate reported in the worldwide survey on AF ablation (6). The incidence of stroke and death were 0.24% and 0.02%, respectively, and were similar to published reports. The mean length of stay for patients with procedures reported as uncomplicated was 1.46 days, with hospitalization ≥3 days in 8.6% of these patients, implying that the complication rate might have been underreported. Not surprisingly, increasing age, female sex, and the comorbidities heart failure, hypertension, chronic renal disease, and lung disease were associated with procedural complications (11–14). In the multivariable analysis, the comorbidities did not reach significance, most likely because their prevalence tracked with age.

The other main independent predictor of procedural complications in the study of Shah et al. (8) was lack of procedural experience as indicated by volume of procedures performed at each center. It was striking that the mean volume of AF ablations per hospital was 15.4 per year overall. Because high-volume centers were included in the analysis, the median number of AF ablations per hospital annually (not provided) was certainly much lower. The researchers did not have data regarding the number of operators, but it is likely that the total number of operators was greater than the number of hospitals, which would result in a lower median number of procedures per operator annually. Thus, it would appear that one of the most technically challenging procedures in the field of interventional cardiac electrophysiology is commonly being performed by physicians lacking appropriate experience.

What is unknown and unknowable from the present study using their methodology is the overall recurrence rate of AF after ablation. Shah et al. (8) reported that the 1- and 2-year rates of freedom from hospital admission in California for recurrent AF were 78.3% and 70.4%, respectively. However, most patients who experience AF recurrence are managed entirely in the outpatient setting. The majority of rehospitalizations reported were readmissions for repeat catheter ablation. So, was the true rate of freedom from arrhythmia recurrence at 1 year 70%, or 50% or 30%? This cannot be determined. The rehospitalization rates are interesting data in that they emphasize the ongoing health resource utilization by these patients after attempted catheter ablation, but they should by no means be considered as surrogate data for actual arrhythmia recurrence rates.

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It has been well documented that after AF ablation with pulmonary vein isolation, pulmonary vein reconnection rates are high (15–18). It is often necessary to perform additional ablation at a follow-up procedure to achieve permanent vein isolation and procedure success. Most high-volume AF ablation centers report a repeat procedure rate of 27% to 51% (6,19–21), but only 17.4% of patients from the present study had a second procedure during the study period in California. It is possible that some patients traveled out of state for repeat procedures, but it is more likely that low-volume operators lacked the experience or confidence to go forward with additional ablation.

The present study raises many familiar concerns for the field of catheter ablation of AF. First, the real-world success rate of this procedure is unknown but is likely considerably lower than published reports from single-center studies. Second, complication rates are significant, as are late hospitalization rates. Data from many investigations in AF ablation as well as different disciplines within cardiovascular medicine have repeatedly demonstrated that operator and hospital procedure volume are inversely correlated with poor outcomes (12,14,22,23). Once again, the correlation between experience and procedural results was demonstrated in the study of Shah et al. (8). It is problematic that complex procedures continue to be performed at very low-volume centers in the U.S. medical system. As long as a hospital is able to profit from supporting interventional procedures by its physicians, there will be a tendency to set a low bar for granting privileges to any doctor who claims proficiency. Although no honest healthcare provider would ever consciously place a patient needlessly in harm's way, there are strong forces (economic, reputational, convenience) that prevent subspecialists from referring patients to other subspecialists within the same field. Concentration of expensive, highly technical procedures such as coronary artery bypass grafting in high-volume referral centers has been achieved in part with the certificate of need process (24,25) However, this course of action is cumbersome, politically charged, and unpopular in many circles. Professional societies can establish standards for training and minimal procedure volumes necessary for competency. The Heart Rhythm Society, in conjunction with other professional organizations from the United States and Europe, has developed an expert consensus statement on catheter and surgical ablation of AF (8), with the updated document scheduled for release in January 2012. Unfortunately, conforming to these standards is voluntary, and standards based upon procedural volume are usually arbitrary and controversial (26). Ultimately, the torte system is the back stop to prevent operators from working beyond the limits of their experience and training, but that punitive process is expensive and inefficient, and just addresses the most egregious cases of abuse and only after substantial harm has come to the patient.

It is imperative that any center that commits to establishing an AF ablation program initiates robust quality assurance methodology that tracks the long-term outcomes after intervention. Until this is done, it is impossible to understand whether the individual operators and the hospital team are providing acceptable service to their patients. When patients are counseled about the risks and benefits of AF ablation, real data reflecting the operator's and team's results should be quoted, not data from an unaffiliated high-volume center from a different continent. If healthcare providers do not regulate themselves, it is inevitable that outside bodies will impose regulation upon us.

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