Breaking News! When It Comes To Complications of Catheter Ablation of Atrial Fibrillation: Experience Matters

Running title: Calkins; Complications of AF Ablation

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During the past decade, catheter ablation of atrial fibrillation (AF) has emerged as an important treatment option for patients with symptomatic AF refractory to antiarrhythmic drug therapy. The 2012 HRS/EHRA/ECAS Expert Consensus Document on Catheter Ablation of Atrial Fibrillation provides a Class 1 Level of Evidence A recommendation for catheter ablation of AF in patients with paroxysmal atrial fibrillation who have failed treatment with at least one antiarrhythmic medication and a Class 2 Level of Evidence B recommendation for patients with paroxysmal AF who have not failed antiarrhythmic drug therapy.

In the present issue of Circulation, Deshmukh et al. report the incidence of in-hospital complications of catheter ablation of AF among 93,801 AF ablation procedures performed in the United States between 2000 and 2010. The data was obtained from the Nationwide Inpatient Sample (NIS) data set, which is a nationally representative survey of hospitalizations conducted by the Healthcare Cost and Utilization Project. This data set includes a 20% sample of United States community hospitals. Complications were broken down into five groups: cardiac complications, vascular complications, respiratory complications, neurologic complications, and infectious complications. In-hospital mortality was also determined. Delayed complications which commonly present after hospital discharge including pulmonary vein stenosis and atrial esophageal fistula could not be evaluated. The data was analyzed to identify predictors of complications, and also to determine the relationship between operator and hospital volume with the incidence of complications. There were five main findings of this study. First, most of the AF ablation procedures (81%) were performed by operators doing less than 25 AF ablation procedures per year, and in hospitals with annual AF ablation volumes less than 50. Second, the overall complication rate was 6.3% and the overall in-hospital mortality was 0.42%. The frequency of complications increased from 5.3% in 2000 to 7.5% in 2010. Third, the incidence of complications was increased in elderly patients and AF ablation in women had a 2% higher
complication rate than in men. And fourth, annual operator volume less than 25 and annual hospital volume less than 50 were associated with a higher rate of complications.

In writing this editorial I am charged with helping to interpret the results of this study in the context of both my own experience with catheter ablation as well as the considerable body of previously published literature on AF ablation. I would like to focus my comments by addressing three questions. First, are the findings of this study valid? Second, are the findings of this study important? And third, what are the clinical implications of this study both for patients considering having the procedure performed, for operators who perform this procedure, and for hospitals that grant privileges to physicians to perform this procedure?

It is my opinion that the results of this study are valid. While it is easy to criticize the many assumptions needed to perform this analysis (including the absence of a procedure code for AF ablation), to identify the limitations inherent to data derived from administrative data bases, and to argue that these findings are outdated (> 3 years old), I believe that strength comes from numbers and that the results of this study are valid. It is striking that the overall complication rate (6.3%) is virtually identical to the 6% and 4.5% complication rates reported in Cappato’s 2005 and 2010 Worldwide Surveys\textsuperscript{3,4}. The complication rate is also very similar to the complication rates reported in recent analyses of the California State Inpatient Database and a Claims Database of Medicare Beneficiaries\textsuperscript{5,6}. It is also reassuring to me that several of the conclusions of this study, such as the increased risk of complications in women and in the elderly are well aligned with data we have published from our single center ablation registry\textsuperscript{7,8}.

I believe that the results of this study are unique, important, and sobering. The uniqueness of this study rests in its size and scope as well as the fact that these are “real world” data obtained from smaller hospitals and lower volume operators. More than 80% of the 93,801 AF ablation procedures were performed by operators with an annual AF ablation volume less
than 25. The importance of this study results from the significance of these findings. As physicians we are all bound by the phrase “Primum non nocere; first, do no harm”.

And as electrophysiologists we perform AF ablation procedures to improve quality of life. A 6.3% overall complication rate (not including serious delayed complications such as PV stenosis and atrial esophageal fistula) and one in-hospital death for every 238 patients undergoing AF ablation is not in keeping with this. The results of this study are sobering on many fronts. First, it appears that complication rates of AF ablation when viewed broadly are not falling and in fact may be increasing. This contrasts from our own tertiary care hospital experience where our complication rate has dropped from 11.1% to 1.6% over a 10 year period, with no deaths. Furthermore, in the past five years there have been no complications with a permanent sequellae. Secondly, complication rates were age related increasing to 9.4% in patients over 80 years. To the extent that advanced age is the most powerful predictor of AF, the clinical implications of this finding should be clear to all. And third, complication rates were dramatically and powerfully impacted both by operator volume and hospital AF ablation volume. While perhaps predictable, the clinical impact of this finding is enormous as more than 80% of AF ablation procedures were performed by operators performing less than 25 AF ablation procedures per year. This annual AF ablation volume is below the volume recommended in the 2012 HRS/EHRA/ECAS Expert Consensus Document which states that recommends that electrophysiologists should perform at least 50 AF ablation procedures during training and then should perform “several procedures for AF per month if they intend to remain active in this area.”

And finally, what are the implications of the results of this study for interested parties? First, the results of this study should remind electrophysiologists of the complexity of AF ablation procedures and the very significant risk associated with these procedures, especially
when performed by inexperienced low volume operators. The successful complication free performance of AF ablation procedures requires successful execution of a large series of detailed steps. These steps include proper patient selection, detailed attention to anticoagulation strategies before, during, and following the procedure, successful performance of a single or double transeptal puncture, careful sheath management to prevent thrombi and air embolization, precise catheter manipulation, and vigilant patient follow-up. At each of these steps both technical skill and clinical judgment is required. In my opinion only those operators who have a serious commitment to the field of AF ablation should perform these procedures. Even if adequately trained during an EP fellowship, it is not possible to maintain the skills and clinical judgment needed to safely carry out this procedure with case volumes less than the recommended minimum of “several per month”. Second, the results of this study should be considered by hospital committees that grant clinical privileges. While there is an inherent conflict between the desire of hospitals to perform more revenue generating procedures and the granting of clinical privileges, in the long term the public is not well served if these privileges are granted to operators who do not have the skills and commitment to perform these procedures safely. Third, the results of this study should be carefully considered by industrial partners who manufacture technology used for AF ablation. There clearly is room for both the perfection of current ablation technologies to make them more “user friendly” and the development of new ablation technologies. But it is notable that high volume operators appear to be able to employ currently available ablation technology safely and effectively. And finally, the results of this study need to be considered by patients who are making the final decision concerning who will perform their ablation procedure and where it will be performed.

At the end of the day, I think this paper is a welcome addition to the literature. Not only does it provide new and important information concerning complications of AF ablation, but it
also helps launch an important discussion among those interested in this rapidly growing field.

**Conflict of Interest Disclosures:** None.

**References:**


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