The importance of standardization in surgical ablation for atrial fibrillation

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The cut-and-sew Cox maze procedure for atrial fibrillation (AF) was first performed in 1987; despite its success, however, it was considered too complex and thus never gained a great deal of popularity.¹ The field of surgical ablation for AF was therefore developed around various ablation devices and operative schemes. Although significant improvements have been made in such approaches, the Cox maze III or IV procedure, performed according to the original design and with only those ablation devices that can produce consistent transmural lesions, remains the recognized gold standard for the surgical ablation of AF. In the vast majority of cases, inferior results reflect incomplete application of the lesions or technical errors.²⁻⁴

In contrast to the relatively limited use that initially characterized AF surgical ablation procedures, today these procedures are being much more widely performed by surgeons with a much wider variety of training, experience, skill, and education. As a result, standardization is lacking in the selection of ablation devices and appropriate lesion sets, as well as in the procedures used for follow-up and outcome reporting. This lack of standardization in education, experience, and training translates to a unique and challenging situation in surgical practice. Recognizing the need for more uniformity in reporting the results of surgical ablation, several large national and international professional societies and organizations, including the Heart Rhythm Society (HRS), the European Heart Rhythm Association, and the European Cardiac Arrhythmia Society, have established consensus-based recommendations for reporting outcomes of clinical trials of ablation techniques.⁵⁻⁹

Not only reported success rates but also definitions of success for surgical ablation vary widely. As a result, success rates reported in the literature range from 64%¹⁰ to 98%,¹¹ a phenomenon that is unique in medicine. The reason for this variability is clear, but more work should be done to improve excellence in the field. Improved standardization in outcome prediction and improved consistency in reporting

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Central Message

The article by Shah and colleagues reflects the lack of standardization in the surgical ablation of atrial fibrillation.

See Article page 391.

See Editorial page 298.

according to clearly established clinical indicators for success or failure are of highest priority. Failure in this regard complicates efforts to identify those patients who are most likely to benefit from surgical ablation procedures. We need to establish a reliable clinical process that includes appropriate training, as well as longitudinal indicators for outcome predictors for surgical ablation that can be used throughout clinical practice.

The study by Shah and colleagues¹² in this issue of the *Journal* has explored the potential sex differences in outcomes of surgical ablation for AF. The research question posed by Shah and colleagues¹² has been previously addressed in all aspects of treatments for AF, both medical and nonmedical.^{13,14} Recently, our group conducted a uniform analysis of patients undergoing a Cox maze III or IV procedure in which only those devices with proven consistency for transmural lesions were used (cryothermia either alone or in combination with bipolar radiofrequency; N = 540).¹³ We found that, despite the fact that female patients were at higher operative risk and came to surgery with higher rates of congestive heart failure and concomitant mitral valve surgeries than male patients, their outcomes were comparable to those of male patients. The rate at which female patients returned to sinus rhythm without being given antiarrhythmic

drugs was the same, as were the 2-year survival rate and cardiac-related mortality. In addition, significant improvements in quality of life and in AF-related symptoms were documented for female patients.¹³

Shah and colleagues¹² from Northwestern are to be congratulated for performing AF surgical ablation procedures in such high numbers, which exceed the national average.¹⁵ The article reflects their extensive experience with surgical ablation procedures that include many different ablation devices, some of which have been discontinued as a result of their inefficacy (laser and high-intensity focused ultrasound), as well as a wide variety of lesion sets. The latter were most often applied in the study on the basis of a single surgeon's discretion. Thus these decisions were often made not according to the disease process but rather on the basis of the concomitant procedure being performed. Shah and colleagues¹² make it clear in the article's Discussion section that no sex differences in outcomes were found and that they believe the Cox maze procedure to be an inappropriate procedure in many cases.

The question that should be asked is whether Shah and colleagues¹² have brought enough supporting evidence to their claim that the Cox maze procedure is overly aggressive. Their supporting reference for this claim is a recent *New England Journal of Medicine* study by Gillinov and colleagues¹⁶ that is characterized by some significant limitations, including inconsistent use of lesion sets and ablation technologies. The latter include unipolar radiofrequency, which is known to deliver inconsistent lesions. In addition, the study results of Gillinov and colleagues¹⁶ are not reported according to HRS guidelines, and most important, the study is greatly underpowered for a comparison of lesion sets, although Gillinov and colleagues¹⁶ correctly define the question of lesion set as a secondary end point. The *New England Journal of Medicine* article of Gillinov and colleagues¹⁶ is an important one, but in comparison with drug studies, multicenter, prospective, randomized cardiac surgery studies should be looked at very carefully, especially when such variability among centers and techniques is allowed within the study design.

Shah and colleagues¹² report rhythm results at last follow-up, a practice that is not in accordance with HRS guidelines but is nevertheless often allowed and tolerated in the reporting of surgical ablation results. (Can you imagine a report on the patency rate of vein grafts in which the results of cardiac catheterization are compiled at 3 months in some patients and 10 years in others, and the patency rates are constructed from those recorded at last follow-up?) The HRS guidelines mandate that rhythm results should be presented at specific time points with clear definitions of success in the absence of class I or III antiarrhythmic drugs.⁹ Reporting freedom from AF at last follow-up does not provide reliable information about rhythm status, because there is likely to be vast variability in the time points at which patients had their last follow-up. In contrast, providing rhythm status at defined

time points (eg, 6 months, 1 year, 2 years) provides clearer information to allow an adequate comparison between sexes. Shah and colleagues¹² could perhaps maximize their follow-up data by also reporting on time to first AF recurrence. This approach, although clearly not able to adequately illustrate how patients move in and out of rhythm status, might indicate a pattern of earlier initial AF recurrence for one sex relative to the other, if such a pattern exists. Equally important is the unclear method with which patients who had catheter ablation for recurrence of atrial arrhythmia were defined in the study. The HRS guidelines clearly suggest that subsequent ablation procedures should be considered to have failed in such cases.⁹

Shah and colleagues¹² astutely point out the very important challenge of working with cardiologists to standardize approaches during follow-up. Good communication and program development would address these issues. It is exceedingly difficult, however, to draw valid conclusions when using differing follow-up time points, lesion sets, and ablation devices, some of which are not consistent with reliable transmural ablation and were not selected according to an established protocol. Our group has faced the same challenges in a nonacademic environment (we are now following up more than 1000 patients operated on since 2005), but we have been able to establish the foundations for a protocol-based patient selection and follow-up process.¹⁷

It is also important to be aware of the fact that, in this study as in others, Shah and colleagues¹² used different tools to define "success." The use of long-term monitoring systems is important, but how can electrocardiography be compared with long-term monitoring, which is significantly more sensitive in identifying atrial arrhythmias? Reported results should be clear about the methodology and devices used. The HRS guidelines suggest 24-hour Holter monitoring.⁹ Readers should be aware that in this case more is not necessarily better when it comes to monitoring, because data must be reviewed by an expert to rule out false-positive and false-negative results.

Shah and colleagues¹² point out that, in light of the large numbers of surgical ablation procedures being performed today, it is important for these procedures to be done safely and effectively. In their Discussion section, Shah and colleagues¹² clearly state that the type of concomitant procedure performed, rather than the variables associated with AF, was used to guide decisions about which lesion set to use. This would seem to suggest that it is perfectly fine to perform pulmonary vein isolation in cases where the left or the right atrium is not being opened (eg, coronary artery bypass graft or aortic valve replacement). Such an approach is not based on clinical data; to the contrary, recent studies found that the concomitant Cox maze procedure was not associated with increased risk for complications across different risk groups and procedures^{18,19} and that

pulmonary vein isolation was associated with poor success rates only when performed concomitantly with aortic valve replacement, subjecting 50% of patients to postprocedural atrial arrhythmias.²⁰ As surgeons, our goal should be to apply the correct lesion set in the appropriate cases, using only with those ablation tools that have been shown to produce consistent and reliable transmural lesions. The decision of which surgical ablation approach to use should be based only on the clinical variables associated with AF and other clinical justifications.

Shah and colleagues¹² claim that one of the strengths of their study is the wide variety of lesion sets and devices used throughout the study period. I would be very careful before agreeing with this assertion. Clinical judgment and experience are extremely important, and although the Northwestern group has certainly mastered these, this study is a retrospective one in which a wide variety of approaches were allowed on the basis of surgeon discretion and a wide variety of methods were used during follow-up.

The results of the study show that sex is probably not associated with higher rates of failure of surgical ablation of AF. This conclusion fits well with what we know about the mechanism of AF and the predictors of surgical ablation failure. There is no reason to think that these differ by sex. It is important, however, to recognize that female patients are getting treated later in the course of their disease and as a result may have more risk factors that are predictive of failure.¹³ Numerous studies have determined that the most important variables associated with success of surgical ablation are age, size of the left atrium, type of AF, and, perhaps most important, duration of the arrhythmia.

It is essential to establish and adhere to a process for the different schemes of surgical ablation to improve patient selection and success rates. We must strive for excellence in surgical ablation by educating and training surgeons and cardiologists in the procedure. To that end, it is of utmost importance that we understand and standardize procedures for patient selection, ablation tools, and follow-up protocols for postprocedural treatment and reporting.

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