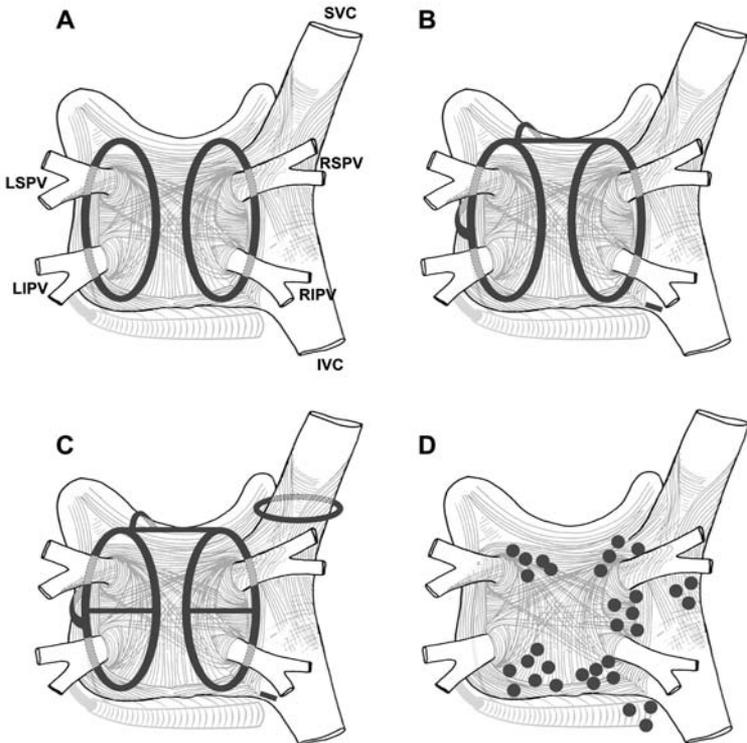


- Executive Summary -

HRS/EHRA/ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation: Recommendations for Personnel, Policy, Procedures and Follow-Up



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INTRODUCTION

Objectives

The purpose of this Expert Consensus Statement is to provide a state-of-the-art review of the field of catheter and surgical ablation of Atrial Fibrillation (AF), and to report the findings of a Task Force convened by the Heart Rhythm Society, partnered with the European Heart Rhythm Association (EHRA) and the European Cardiac Arrhythmia Society (ECAS), to define the indications, techniques, and outcomes of these procedures. The main objective of this Expert Consensus Statement is to improve patient care by providing a foundation of knowledge for those involved with catheter and surgical ablation of AF. The Task Force writing group was composed of members representing the American College of Cardiology, the American Heart Association, the European Cardiac Arrhythmia Society, the European Heart Rhythm Association, the Society of Thoracic Surgeons, and the Heart Rhythm Society. This document was approved for publication by the governing bodies of these organizations.

This Expert Consensus Statement summarizes the opinion of the Task Force members based on their experience and a review of the literature. In addition, a draft of the document was reviewed by other experts representing the participating organizations. In writing a “consensus” document, we recognize that consensus does not mean that there was complete agreement among all Task Force members. We attempted to identify those aspects of the field of catheter ablation of AF for which a true “consensus” could be identified. Anonymous surveys of the entire Task Force were used to identify these areas of consensus which are stated in Tables 1 and 2 of the Expert Consensus Statement and noted below, where appropriate. Furthermore, it is recognized that this field continues to evolve rapidly. As this document was being prepared, further clinical trials of catheter ablation of AF were underway.

DEFINITIONS AND INDICATIONS FOR CATHETER ABLATION

Definitions

We have adopted the classification system that was developed by the ACC/AHA/ESC 2006 Guidelines for the Management of Patients with Atrial Fibrillation. We recommend that this classification system be used for future studies of catheter and surgical ablation of AF.

Paroxysmal AF is defined as recurrent AF (> 2 episodes) that terminates spontaneously within seven days. Persistent AF is defined as AF which is sustained beyond seven days, or lasting less than seven days

but necessitating pharmacologic or electrical cardioversion. Included within the category of persistent AF is “longstanding persistent AF” which is defined as continuous AF of greater than one year duration. The term permanent AF is defined as AF in which cardioversion has either failed or not been attempted. The term permanent AF is not appropriate in the context of patients undergoing catheter and/or surgical ablation of AF as it refers to a group of patients where a decision has been made not to pursue restoration of sinus rhythm by any means, including catheter or surgical ablation.

Indications for Catheter Ablation

The Task Force supports the recommendations of the 2006 ACC/AHA/ESC Guidelines for the Management of Atrial Fibrillation. In particular, the Task Force agrees that catheter ablation of AF in general should not be considered as first line therapy. There is a consensus among the Task Force that the primary indication for catheter AF ablation is the presence of symptomatic AF refractory or intolerant to at least one Class 1 or Class 3 antiarrhythmic medication. The Task Force also recognizes that, in rare clinical situations, it may be appropriate to perform catheter ablation of AF as first line therapy. Catheter ablation of AF is also appropriate in selected symptomatic patients with heart failure and/or reduced ejection fraction. While some patients with asymptomatic AF seek catheter ablation as an alternative to long-term anticoagulation, this desire by itself should not be considered an appropriate selection criterion. The presence of a left atrial thrombus is a contraindication to catheter ablation of AF.

TECHNIQUES AND ENDPOINTS FOR ATRIAL FIBRILLATION ABLATION

A variety of techniques have been developed for catheter ablation of AF. These are reviewed in the Expert Consensus Statement. The Task Force reached consensus on the following recommendations concerning the techniques and endpoints of AF ablation:

- (1) Ablation strategies which target the PVs and/or PV antrum are the cornerstone for most AF ablation procedures.
- (2) If the PVs are targeted, complete electrical isolation should be the goal.
- (3) For surgical PV isolation, entrance and/or exit block should be demonstrated.
- (4) Careful identification of the PV ostia is mandatory to avoid ablation within the PVs.

- (5) If a focal trigger is identified outside a PV at the time of an AF ablation procedure, it should be targeted if possible.
- (6) If additional linear lesions are applied, line completeness should be demonstrated by mapping or pacing maneuvers.
- (7) Ablation of the cavotricuspid isthmus is recommended only in patients with a history of typical atrial flutter or inducible cavotricuspid isthmus dependent atrial flutter.
- (8) If patients with long standing persistent AF are approached, ostial PV isolation alone may not be sufficient.

Anticoagulation and Strategies to Prevent Thromboembolism

Careful attention to anticoagulation of patients before, during, and after ablation for AF is critical to avoid the occurrence of a thromboembolic event, which is recognized as one of the most serious complications of AF and also of AF ablation procedures. It is for this reason that the Task Force recommends that the anticoagulation guidelines published as part of the ACC/AHA/ESC 2006 Guidelines for the Management of Patients with Atrial Fibrillation be adhered to. In particular, the guidelines for anticoagulation, both for long-term management and also those that apply to cardioversion procedures should be followed. In addition to following these anticoagulation guidelines, there is a consensus among the Task Force that patients with persistent AF who are in AF at the time of ablation should have a TEE performed to screen for a thrombus. The lower level of anticoagulation during an ablation procedure should be maintained at an ACT of at least 300–350 seconds throughout the procedure. After catheter ablation and sheath removal, anticoagulation should be reinitiated promptly. There was a consensus among the Task Force that:

- (1) Warfarin is recommended for all patients for at least two months following an AF ablation procedure.
- (2) Decisions regarding the use of warfarin more than two months following ablation should be based on the patient's risk factors for stroke and not on the presence or type of AF.
- (3) Discontinuation of warfarin therapy post ablation is generally not recommended in patients who have a CHADS score greater than 2.

TRAINING REQUIREMENTS AND COMPETENCIES

The strategies, specific methods, and technology pertaining to ablation of AF are evolving. Accordingly, the guidelines for training to perform this procedure must be flexible in recognition of different

approaches and technologies that will change with advances in the field.

The training and competencies required for training in AF ablation differs from other ablation procedures because, in comparison, ablation of AF is more difficult, is associated with greater risks, and requires more careful follow-up. The American College of Cardiology/American Heart Association 2006 update of the clinical competence statement on invasive electrophysiology studies, catheter ablation, and cardioversion proposed a minimum of 30–50 AF ablation procedures for those who undergo fellowships in clinical cardiac electrophysiology. This number underestimates the experience required for a high degree of proficiency. Trainees who intend to perform ablation of AF independently should consider additional training after their standard fellowship is completed.

Electrophysiologists who have already completed a fellowship and choose to undergo training for ablation of AF should observe colleagues with a high degree of expertise; a period of supervision is recommended and advisable. In the absence of definitive data, numerical requirements are arbitrary, but as a guideline, it seems appropriate for experienced electrophysiologists to be supervised when they begin to perform these procedures. The exact number may depend on prior experience with trans-septal punctures and cannulation of the left atrium. Electrophysiologists should perform several ablation procedures for AF per month if they intend to remain active in this area.

FOLLOW-UP CONSIDERATIONS

Follow-up and Monitoring Guidelines

Arrhythmia monitoring is an important component of the initial evaluation of patients who are to undergo catheter ablation procedures for AF. ECG monitoring also plays an important role in the follow-up after an ablation procedure. Early recurrences of AF are common during the first one to three months following a catheter ablation procedure. For this reason, arrhythmia monitoring to assess the efficacy of catheter ablation is typically delayed for at least three months following catheter ablation. Arrhythmia monitoring may be in the form of intermittent sampling using a standard ECG or a patient activated event monitor with or without a memory loop. Various types of continuous monitoring systems are also available.

There was general agreement among the Task Force that all patients who undergo catheter ablation of AF should be seen in follow-up at a minimum of three months following the ablation procedure and then every six months for at least two years. ECGs should be obtained at

all follow-up visits and patients who complain of palpitations should be evaluated with an event monitor. Prior to hospital discharge, it is recommended that patients receive detailed follow-up instructions and be provided with contact information that will facilitate prompt evaluation of symptoms consistent with a late complication of the ablation procedure. Although there is no consensus among the Task Force on the role of routine imaging studies to screen for pulmonary vein stenosis, there was general agreement that the threshold for using imaging tools for symptom evaluation should be low.

Although early recurrence of AF carries an independent risk of treatment failure, its occurrence should not prompt immediate re-ablation attempts, as 20% to 57% of patients experiencing this event within the first months post-ablation will not have any further arrhythmias during long-term follow-up. Since the mechanism of AF post-ablation may be different from that of the patient's clinical arrhythmia and may resolve completely upon resolution of the inflammatory process, some operators choose to treat all patients with suppressive antiarrhythmic agents for the first 1 to 3 months following ablation. Repeat ablation procedures should be delayed for at least three months following the initial procedure if the patient's symptoms can be controlled with medical therapy.

COMPLICATIONS OF CATHETER ABLATION

Catheter ablation of AF is one of the most complex interventional electro-physiological procedures. It is therefore to be expected that the risk associated with AF ablation is higher than for ablation of most other cardiac arrhythmias. The complications section in the Expert Consensus Statement provides detailed discussions of the causes, diagnosis, and management of the complications of catheter ablation of AF.

OUTCOMES AND EFFICACY OF CATHETER ABLATION

Up until the writing of this document, there had been no standardization in the design of clinical trials of AF ablation. It is now well recognized that the outcomes of AF ablation differ considerably depending on whether patients have paroxysmal, persistent, or longstanding persistent AF. Similarly, variables such as age, concomitant cardiac disease, and left atrial size are important determinants of outcome. Other important considerations are: the duration of the blanking period; the frequency and intensity of arrhythmia monitoring; whether patients with atrial flutter during follow-up are classified as successes or failures; the use of AADs; and the frequency and timing of performance of

repeat ablation procedures. Each of these factors plays a role in how a particular study defined “success.”

We reviewed the results of 23 nonrandomized trials of catheter ablation of AF that included at least 50 patients. The reported single procedure efficacy of catheter ablation in these trials varied widely. Although the single procedure success of catheter ablation of patients with paroxysmal AF ranged from 38% to 78%, most series reported a single procedure efficacy of 60% or greater. In contrast, the single procedure success of catheter ablation of patients with persistent AF ranged from 22% to 45%, with most centers reporting an efficacy of 30% or less. The single procedure success of catheter ablation of patients with mixed types of AF ranged from 16% to 84%. The reported multiple procedure success of catheter ablation of patients with paroxysmal AF ranged from 54% to 80%, with most series reporting a multiple procedure efficacy of 70% or greater. The multiple procedure success of catheter ablation of patients with persistent AF ranged from 37% to 88%, with most centers reporting a multiple procedure efficacy of 50% or greater. The multiple procedure success of catheter ablation of patients with mixed types of AF ranged from 30% to 81%.

We also reviewed the results of five randomized studies. One trial randomized 70 patients with paroxysmal AF to treatment with either antiarrhythmic drug (AAD) therapy (flecainide or sotalol) or catheter ablation. At one year of follow-up, 63% of patients randomized to AAD therapy had at least one AF recurrence as compared with 13% patients treated with catheter ablation. A second study randomized 146 patients with persistent AF to treatment with catheter ablation versus cardioversion alone. The primary endpoint was freedom from AF or atrial flutter in the absence of AAD therapy one year after catheter ablation. An intention to treat analysis revealed that 74% of patients in the ablation group and 58% of those in the control group were free of recurrent AF without AAD therapy at one year of follow-up. The third study investigated the adjunctive role of catheter ablation in 137 patients with paroxysmal or persistent AF. At 12 months of follow-up, 9% of patients in the AAD arm were free of recurrent AF, as compared with 56% of patients treated with catheter ablation and AAD therapy. The fourth trial compared the outcomes of catheter ablation with AAD therapy in 199 patients with paroxysmal AF. Patients treated with catheter ablation demonstrated a higher success rate (as defined as freedom from recurrent symptomatic or asymptomatic AF). Eighty-six percent of patients treated with catheter ablation were free of recurrent AF as compared with 22% of patients treated with AAD therapy. The fifth and most recent randomized clinical trial, found that 40 of 53 ablation patients (75%) were free of recurrent AF, as compared with 7% (4 of 59) who were AF free with drug therapy. In this trial, 63% of drug-treated patients crossed over to ablative therapy.

A recent survey on the methods, efficacy, and safety of catheter ablation of AF was based on a detailed questionnaire that was completed by more than 180 centers throughout the world. The outcomes of nearly 9000 AF ablation procedures were reported by these centers, with a median of 38 AF ablation procedures per center. The success rate, as defined as freedom from symptomatic AF in the absence of antiarrhythmic therapy was 52%. An additional 24% of patients were free of asymptomatic AF in the presence of a previously ineffective antiarrhythmic drug. The mean duration of follow-up of these patients was 12 ± 8 months. The incidence of major complications was 6%.

The results of the reviewed studies and survey provide substantial evidence of the efficacy of catheter ablation for treatment of patients with AF. However, it is also clear that outcomes vary considerably. Potential factors that may impact outcome include:

- differences in technique;
- differences in follow-up and definitions of success;
- differences in the use of antiarrhythmic therapy;
- differences in experience and technical proficiency, and so forth.

SURGICAL ABLATION OF ATRIAL FIBRILLATION

The Maze procedure for the surgical treatment of AF, introduced in 1987 by Dr. James Cox, was designed to interrupt all macro-reentrant circuits that might potentially develop in the atria by creating a myriad of incisions across both the right and left atria placed so that the SA node could “direct” the propagation of the sinus impulse throughout both atria. In contrast to previous unsuccessful procedures, the Cox-Maze procedure successfully restored both atrioventricular synchrony and a regular heartbeat, and decreased the incidence of late stroke. Over the last decade, the Cox-Maze procedure has become the gold standard for the surgical treatment of AF.

Despite its proven efficacy, the Cox-Maze procedure did not gain widespread application because few cardiac surgeons were willing to add the operation to coronary revascularization or valve procedures due to its complexity and technical difficulty. In an attempt to simplify the operation and make it more accessible to the average surgeon, groups around the world replaced the incisions of the traditional “cut-and-sew” Cox-Maze procedure with linear ablation lines which have been created using a variety of energy sources including radiofrequency (RF) energy, microwave, cryoablation, laser and high-intensity focused ultrasound (HIFU). Replicating the full Cox-Maze lesion set with linear lines of ablation has been shown to be both feasible and clinically effective. At present, the majority of patients undergoing open-heart

surgery who have persistent AF are offered concomitant AF surgery at experienced centers.

Although surgery for lone AF has been performed for two decades, this field needs prospective multi-center trials to help define the most appropriate lesion sets, the proper ablation technology and the clinical indications for these procedures. Furthermore, it is critical for future studies to better document the possible survival benefits of adjunctive AF surgery. It is important to note that virtually all of the historical series reported only the recurrence of symptomatic AF and have used only intermittent ECG follow-up. The true success rates of these procedures are likely to be lower than has been reported. Even considering these shortcomings, the Cox-Maze procedure has had good long-term results in the treatment of both lone AF and AF associated with organic heart disease. The advent of ablation technology has simplified the surgical treatment of AF and expanded the indications, particularly for concomitant AF procedures in patients undergoing other cardiac surgery. Minimally invasive approaches presently in development could expand the indications for stand-alone surgery for AF in the future.

The Task Force reached the followed areas of consensus concerning the indications for surgical AF ablation:

- (1) Symptomatic AF patients undergoing other cardiac surgery;
- (2) Selected asymptomatic AF patients undergoing cardiac surgery in whom the ablation can be performed with minimal risk;
- (3) Stand-alone surgery for AF should be considered for symptomatic AF patients who prefer a surgical approach, have failed one or more attempts at catheter ablation, or are not candidates for catheter ablation.

CLINICAL TRIAL CONSIDERATIONS

The many unresolved questions and issues regarding currently available clinical trial data provide a strong incentive for conducting additional clinical studies of specific design to answer critical questions in the ablative arena. These include: sufficiently powered randomized mortality studies; multi-center outcome trials; industry-sponsored device approval studies and, carefully constructed single and multicenter registry studies.

Standards for Reporting Outcomes in Clinical Trials

In light of this need, the Task Force defined 18 specific standards (listed in the clinical trials sections of the Expert Consensus Statement)

for reporting outcomes in clinical trials of catheter ablation for AF, including the following for which there was consensus:

- A blanking period of three months should be employed after ablation when reporting outcomes.
- Freedom from AF/flutter/tachycardia of antiarrhythmic therapy is the primary endpoint of AF ablation.
- For research purposes, time to recurrence of AF following ablation is an acceptable endpoint after AF ablation, but may under represent true benefit.
- Freedom from AF at various points following ablation may be a better marker of true benefit and should be considered as a secondary endpoint of ablation.
- Atrial flutter and other atrial tachyarrhythmias should be considered as treatment failures.
- An episode of AF/flutter/tachycardia detected by monitoring should be considered a recurrence if it has a duration of 30 seconds or more.
- An AF/flutter/tachycardia episode is present if it is documented by ECG and lasts at least 30 seconds.
- Single procedure success should be reported in all trials of catheter ablation of AF.
- An event monitor should be obtained to screen for recurrent AF/flutter/tachycardia in patients who complain of palpitations during follow-up.
- Patients being evaluated as part of a clinical trial or in whom warfarin may be discontinued should have some type of continuous ECG monitoring performed to screen for asymptomatic AF/flutter/tachycardia.
- 24-hour Holter monitoring is an acceptable minimal monitoring strategy for patients enrolled in a clinical trial and is recommended at three to six months intervals for one to two years following ablation.

CONCLUSION

Catheter and surgical ablation of AF are commonly performed procedures throughout the world. The Expert Consensus Statement provides an up-to-date review of the indications, techniques, and outcomes of catheter and surgical ablation of AF. Areas for which a consensus can be reached concerning AF ablation were identified.

It is our hope that this document can improve patient care by providing a foundation for those involved with ablation of AF. Successful AF ablation programs optimally should consist of a cooperative team of

electrophysiologists and surgeons to ensure appropriate indications, procedure selection, and follow-up.

Please refer to the Expert Consensus Statement for the full Text, References, Tables and Figures.

The published document can be found in the June 2007 edition of the Heart Rhythm (Elsevier) and Europace (Oxford University Press) journals.

This document is posted at the Heart Rhythm Society on the Clinical Guidelines page:

<http://www.HRSONline.org/Policy/ClinicalGuidelines>