Guidelines for Reporting Data and Outcomes for the Surgical Treatment of Atrial Fibrillation

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Atrial fibrillation is the most common sustained cardiac rhythm disturbance, affecting an estimated 2.5 million people in the United States. Atrial fibrillation may occur with or without structural heart disease. The medical and surgical literature has seen an exponential growth in reports of ablation techniques and the Cox-Maze procedure to treat atrial fibrillation. There has been no agreement or standards on the proper reporting of these techniques and results. The current literature is in disarray, and this report is an attempt to provide a framework for the necessary elements to be included in reports on this subject. The Workforce on Evidence Based Surgery of the Society of Thoracic Surgeons encourages the adoption of these guidelines for reporting clinical results derived from patients undergoing surgical procedures for atrial fibrillation. Adoption of these guidelines will greatly facilitate the comparison between the reported experiences of various authors treating different cohorts of patients at different times with different techniques and energy sources. These guidelines are also appropriate for catheter-based treatment of atrial fibrillation. Thus, more reliable evaluation and comparisons of results will advance our knowledge and further the development and application of these procedures.

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Atrial fibrillation is the most common sustained cardiac rhythm disturbance and its prevalence increases with age. An estimated 2.5 million people have the condition in the United States. Atrial fibrillation may occur with or without structural heart disease. Significant morbidity, mortality, and health care costs are associated with the condition. The patient's clinical condition often deteriorates owing to the hemodynamic compromise associated with the arrhythmia, and thromboembolic events directly related to the arrhythmia can be devastating.

Medical treatment with antiarrhythmic drugs, electrical cardioversion, rate control medications, and anticoagulation follows evidence-based guidelines established by a panel of experts from the American College of Cardiology, the American Heart Association, and the European Society of Cardiology [1–7, 8, 9]. Surgical approaches to the treatment of atrial fibrillation can be traced to the Cox-Maze procedure, which was designed to interrupt all possible macroreentrant circuits in the atria, thereby precluding the ability of the atria to fibrillate [10, 11].

The 15-year success rate of the Cox-Maze procedure has been reported to be as high as 94% for stand-alone atrial fibrillation and 97% for atrial fibrillation associated with other cardiac conditions such as mitral valve disease. In addition, freedom from thromboembolic events after this procedure is 99.4% at 15 years [12, 13]. Despite these favorable results, the complexity of the original procedure, a cut-and-sew technique that required cardiopulmonary bypass and cardioplegic arrest, prevented its widespread adoption. Even with the subsequent simplification of the Cox-Maze procedure using minimally invasive techniques and cryosurgery, it remained too invasive to be applicable to large numbers of patients [14–18].

Recent electrophysiologic studies have expanded our understanding of the factors that initiate individual episodes of atrial fibrillation, although the mechanism by which those episodes, as well as permanent atrial fibrillation, are sustained remains controversial. The role of the pulmonary veins and posterior left atrium in the genesis of atrial fibrillation is well established. The importance of creating conduction block across the left atrial isthmus to preclude postoperative atrial flutter or fibrillation, or both, is suggested by results of the Cox-Maze III procedure, and this lesion is a desirable component of many new surgical approaches to atrial fibrillation [19–23].

Interventional electrophysiologists originally adopted

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the Maze concept and attempted to reproduce its lesions by using endocardial catheters and unipolar radiofrequency energy. When it was learned that "triggers" in the pulmonary veins induced most episodes of atrial fibrillation, they focused their attention on isolating the pulmonary veins, a much simpler procedure than trying to reproduce the Maze lesions [23].

Although highly successful for intermittent (paroxysmal and persistent) atrial fibrillation, pulmonary vein isolation alone has proven to be inadequate for most patients with continuous (permanent) atrial fibrillation. These latter patients are best treated with a more extensive lesion set that includes pulmonary vein isolation plus other linear lesions to interrupt established macroreentry in the atria. However, catheter-based and new surgical approaches to ablation are associated with challenges that have limited their widespread adoption; these include access problems, difficulties with catheter guidance, extended procedure times, and variable success rate [13]. In the United States, with its 2.5 million atrial fibrillation patients, only approximately 12,000 patients per year undergo catheter ablation and roughly 2,000 per year undergo any type of surgical procedure for atrial fibrillation. This represents less than 1% of all patients with atrial fibrillation [24].

The complexity and time required for the ablation procedure has been further diminished by the surgical adoption of a variety of energy sources, such as radiofrequency (both unipolar and bipolar, both "dry" and "wet"), laser, microwave, cryothermy, and high-intensity focused ultrasound. These energy sources have enabled the development of off-pump and beating-heart techniques for selected patients. Widespread adoption of these energy sources has led to a marked increase in surgical ablation, especially in association with operations performed on patients undergoing mitral valve surgery and, less frequently, in those undergoing aortic valve or coronary artery bypass graft procedures, or both.

Although a variety of new interventional and surgical approaches to atrial fibrillation are available, analysis of outcomes is problematic. Because of the current widespread use of different energy sources and different atrial lesion patterns, the general medical, cardiologic, electrophysiologic, and surgical literatures are extremely difficult—if not impossible—to interpret. This confusion is compounded by (1) a lack of uniform preoperative clinical definitions, (2) the absence of an electrophysiology-based classification system that is meaningful for interpreting and reporting results of catheter or surgical interventions, (3) a lack of consensus on methods and timing of follow-up evaluations, and (4) the absence of strict definitions of procedural success and failure.

The literature reporting the outcomes for cardiac valve replacement several decades ago suffered from similar problems. This led to the publication and subsequent adoption of specific guidelines for reporting the results of valve surgery in our major journals [25]. Agreement on how to report results clarified the outcomes of valve surgery and provided a sound basis for comparison between different prosthetic devices or surgical techniques, or both. With the current literature in disarray, it is clearly time to propose guidelines for reporting results of the interventional and surgical treatments of atrial fibrillation, such guidelines to be approved and sanctioned by the Workforce on Evidence Based Surgery of the Society of Thoracic Surgeons. We propose that all publications reporting results of any type of surgical procedure for the treatment of atrial fibrillation include:

A. Description of the type of preoperative atrial fibrillation by the American Heart Association (AHA)/American College of Cardiology (ACC) *and* Cox Classification system [10]:

AHA/ACC Classification	Cox Classification
Paroxysmal (self-terminating)	Intermittent
Persistent (not self-terminating)	Intermittent
Permanent	Continuous

Additional data to be collected includes:

a. Duration of the preoperative arrhythmia (ie, when first recognized)
b. Atrial fibrillation burden

True atrial fibrillation burden measurement requires continuous monitoring of the cardiac rhythm. This technology is not yet clinically available. However, an estimate of atrial fibrillation burden over a defined short interval can be made from Holter or event monitor recordings. For permanent cases, the burden is defined as 1.0 (ie, in atrial fibrillation 100% of the time). For paroxysmal cases, the burden is defined as the percentage of the time the patient is in atrial fibrillation. Ideally, this would be estimated from Holter monitor or event monitor if available; otherwise, estimated from the percentage of electrocardiograms (ECGs), taken at different times randomly, showing atrial fibrillation. If the patient is estimated to be in atrial fibrillation 50% of the time, the prevalence is 0.5.

c. Name of any and all drugs that have failed
d. Previous nonablation procedures to control atrial fibrillation, including attempts at medical conversion, electrical cardioversion, and rapid atrial pacing
e. Presence of permanent pacemaker
    1. A-V sequential
    2. Other
f. Anticoagulant status
    1. Sodium warfarin
    2. Aspirin
    3. Other
    4. Specific combination of above

B. Preoperative patient characteristics
    a. Age
    b. Gender
    c. Race
    d. Predominant cardiac diagnosis (coronary artery disease, cardiomyopathy, hypertension, valvular disease and type, other, no apparent heart disease)
    e. Left atrial size (maximum diameter and area)

Table 1. Atrial Fibrillation Surgery

Date:
Instructions: 1. Place an X in each box to state whether a lesion was made for the segment listed.
2. For each segment marked "Yes," place an X in the column of the ablation mode/energy that was used.
3. For segments or ablation modes that are not on this list, describe in the appropriate box.

	Application		Lesion Made?			Radiofrequency						
Segments	Endo Cardial	Epi Cardial	No	Yes	Cut and Sew	Bipolar	Unipolar	Cryothermy	Microwave	Ultrasound	Laser	New: Ablation Mode
Left atrium												
Right PV isolation												
Left PV isolation												
Individual PV isolation to each of 4 PVs												
Connection inferior PVs												
Connection superior PV												
Box around all 4 PVs												
Connection to mitral annulus												
Connection to left atrial appendage												
Lesion on atrial septum												
New segment: describe												
Right atrium												
Superior vena cava-inferior vena cava lesion												
Right atrial appendage												
Isthmus												
Caudal/T segment												
Lesion at tricuspid annulus												
Lesion at coronary sinus (right atrium)												
New segment: describe												

Note if lesions were performed on or off cardiopulmonary bypass.

PV = pulmonary vein.

f. Left ventricular ejection fraction
g. Previous procedures to control atrial fibrillation (catheter ablation, Cox Maze, "mini Maze")
h. Previous cardiac surgery
i. Previous percutaneous coronary interventions

Although the complete Cox-Maze procedure is equally effective for patients with intermittent (paroxysmal or persistent) or continuous (permanent) atrial fibrillation, no other catheter or surgical procedure thus far developed can make that claim [12]. It is therefore imperative that in any clinical report, the absolute numbers of patients with intermittent (paroxysmal or persistent) atrial fibrillation and continuous (permanent) atrial fibrillation be reported in clear terms. The term "chronic" atrial fibrillation should not be used to describe atrial fibrillation under any circumstances because it means "long-standing" to some authors and "continuous" to other authors.

A. Description of the surgical procedure
   a. Performed as a "stand-alone" therapy for atrial fibrillation

b. Performed in combination with other cardiac surgical procedures
   1. Name of concomitant surgical procedure(s)
   2. Re-do procedure or not
c. Report electrical isolation
   1. Tested
   2. Mode of testing
   3. Achieved, yes/no

B. Detailed description of the lesion set employed for each subset of patients (intermittent or continuous; for a suggested data collection sheet, see Table 1)
   a. Right atrium
      1. Excision of right atrial appendage
      2. Lesion through right atrial appendage without excision
      3. Right atrial isthmus lesion
         i. Between coronary sinus Os and tricuspid valve annulus
         ii. Between inferior vena cava orifice and tricuspid valve annulus
      4. Superior vena cava to inferior vena cava lesion
      5. Lateral free-wall lesion
         i. Complete to anterior-medial tricuspid valve annulus
         ii. Not complete to tricuspid valve annulus
         iii. With or without terminal cryolesion
      6. Medial free-wall lesion
         i. Complete to anterior-medial tricuspid valve annulus
         ii. Not complete to tricuspid valve annulus
         iii. With or without terminal cryolesion
      7. Other
   b. Left atrium
      1. Pulmonary vein isolation
         i. All four together
         ii. Right as a pair
         iii. Left as a pair
         iv. Connecting lesion between pairs
         v. Individual isolation
         vi. Right superior pulmonary vein
         vii. Right inferior pulmonary vein
         viii. Left superior pulmonary vein
         ix. Left inferior pulmonary vein
      2. Left atrial isthmus lesion
         i. Atrial lesion alone
         ii. Atrial lesion plus coronary sinus lesion
      3. Left atrial appendage
         i. Lesion from pulmonary vein(s) into appendage
         ii. Circumferential lesion around base of appendage
         iii. Excision of appendage
         iv. Closure of base of appendage without excision (specify internal versus external [device, staples, suture])
      4. Mapping and ablation of autonomic ganglia
      5. Division of the ligament of Marshall

C. Atrial septum
   a. Lesion across anterior limbus of fossa ovalis
   b. Epicardial lesion between superior vena cava/inferior vena cava right atrial lesion and the pulmonary vein encircling lesion
   c. No septal lesion

D. Technique used to create the lesion set
   a. Endocardial application of energy source
      1. Catheter
      2. Surgical
   b. Epicardial application of energy source
      1. Catheter
      2. Surgical
   c. Incisions (surgical) "cut and sew"
   d. Procedural testing (if any) to document that the lesion created conduction block

E. Energy sources used
   a. Radiofrequency
      1. Unipolar
         i. Irrigated
         ii. Nonirrigated
      2. Bipolar
         i. Irrigated
         ii. Nonirrigated
   b. High-intensity focused ultrasound
   c. Cryoablation
      1. Nitrous oxide cryosurgery
      2. Argon cryosurgery
   d. Microwave
   e. Laser
   f. "Cut and sew"
   g. The *specific* combination of any of the above

Procedure-related adverse events such as esophageal damage, pulmonary vein stenosis, and phrenic/vagal nerve damage must be reported.

F. Post procedure care protocol for *type and duration* of drug therapy (record antiarrythymic drugs and dosages and anticoagulation strategy and status)
   a. Anti-arrhythmic drug protocol
   b. Anticoagulation protocol (target international normalized ratio)
   c. Cardioversion protocol
   d. Repeat ablation (details to be documented)

G. Time points to document rhythm (eg, normal sinus rhythm, junctional, Afib, A-flutter, necessity for pacemaker etc.) and method of documentation (electrocardiogram, 24-hour recorded Holter monitor, event monitor [duration and triggers], etc

Because arrhythmias may transiently appear, there is as yet no methodology available to monitor and identify these episodes and their duration continuously throughout life. It is well recognized that merely recording symptomatic episodes importantly underestimates the occurrence of these episodes. New clinical monitoring devices are becoming clinically available that will be implantable. These devices will more accurately monitor cardiac rhythm and allow the burden of atrial fibrillation to be tracked accurately.

During the first 3 postoperative months, there is a high incidence of atrial fibrillation (35% to 40%) that is mechanistically different (inflammatory) and is not correlated with long-term success. Therefore, the data

related to atrial fibrillation during this time period needs further study but can be "locked out" in the outcome analysis.

H. Record other important outcome time-related events such as all neurologic events and their residua, mortality and circumstances surrounding the death (mode of death)
   a. Immediate preprocedure rhythm
   b. Hospital discharge rhythm (number of days postprocedure)
   c. 3-month postprocedural rhythm
   d. 6-month postprocedural rhythm
   e. 1 year postprocedural rhythm and annually hereafter

I. Outcome rhythm (must include dates for events)
   a. Document freedom from atrial fibrillation with or without antiarrhythmic therapy (ie, drug free or not)
   b. Cardioversion history
   c. Anticoagulation status at follow-up
   d. Need for repeat ablation
   e. Need for new permanent pacemaker

J. Freedom from thromboembolic events at each time point of follow-up

K. Documentation of atrial transport function by echocardiography or cardiovascular magnetic resonance, or both
   a. Left atrial size (dimensions and volume) at outcome time points (6 months, 1 year, annually)
   b. Atrial systole (acceleration of blood flow into left ventricle from the left atrium with atrial systole

L. Quality-of-life assessment should be measured to document the clinical and functional status of the patient post procedure at all intervals of follow-up

M. Mortality
   a. Perioperative (within 30 days)
   b. Late postoperative (after 30 days)
   c. Cause of death

N. Procedural detail display

   Reporting the lesion sets, mode of therapy, and energy source can best be displayed on a grid that lists on the left side anatomic locations (starting with the left atrium, not right), and indicating whether a lesion was made, whether it was catheter or surgical, whether it was epicardial or endocardial, and the energy source used (Table 1).

O. Analysis

   The post procedural rhythm must be analyzed off antiarrhythmia medication, ensuring that the cure of atrial fibrillation was due to the ablation procedure.

Most events (freedoms from death, pacemaker, stroke, repeat ablation) can be analyzed using standard Kaplan-Meier methodology. Ideally, freedom from atrial fibrillation and freedom from atrial fibrillation symptoms cannot, for several reasons. They are conditions or intermittent occurrences that are not mathematically or statistically appropriate for Kaplan-Meier analysis. When atrial fibrillation is recognized, the time of recognition rarely represents the time of its initiation. Therefore, each electrocardiogram documenting atrial fibrillation must be treated using interval censoring, because atrial fibrillation is a state and because patients may move over time between atrial fibrillation and normal sinus rhythm (and other rhythms).

One may plot instead the prevalence of atrial fibrillation in a population at a given time, or less useful, would be to choose to define ablation failure as recurrence of atrial fibrillation at some time point after ablation. The best data would include documentation of the atrial fibrillation burden in a patient—the percentage of time that a patient is in atrial fibrillation. This would require continuous monitoring of heart rhythm and is currently not feasible.

For time-related events such as stroke and death, analysis by readily available methods such as Kaplan-Meier curves should be performed. For cardioversion and strokes, repeated-events analysis is appropriate [26]. However, neither rhythm nor medications are events; thus, methods for analysis of longitudinal, repeated data are required. Interpretation of such analyses is different from that for time-related events. For rhythm, the average prevalence of a given rhythm state or use of medications for the population studied is computed. Rather than prevalence, cumulative duration of rhythm may be expressed as a time-related "burden" if continuous monitoring of rhythm and its duration become available in the future. For rhythm in the absence of continuous life-long recordings, the best compromise is to document every assessment, state the mode of assessment, and then analyze for prevalence of atrial fibrillation.

This "easy" depiction of "success" of the ablation procedure is misleading. Atrial fibrillation comes and goes: the more one monitors, the more one sees asymptomatic episodes. Currently, a compromise approach would be to analyze all of the intermittent data available in terms of time-related prevalence (burden) of atrial fibrillation with ordinary or nonlinear longitudinal (mixed) models that account for all the repeated assessments. It is important to compare prevalence before the procedure with prevalence after the procedure. Otherwise, in patients with preprocedure paroxysmal atrial fibrillation, 20% of the time placebo therapy would result in an 80% success rate.

Kaplan-Meier analysis is traditionally used, and it is clear that it will still be used in the electrophysiologic and surgical literature. It sets a high bar for success: if one episode of documented atrial fibrillation occurs, for example at 1 year and none for the next 3 years, the patient is a failure by Kaplan-Meier analysis but clearly is a success in terms of atrial fibrillation burden. Appropriate and consistent methods of reporting atrial fibrillation burden are evolving.

In summary, the Workforce on Evidence Based Surgery of the Society of Thoracic Surgeons encourages the adoption of these guidelines for reporting clinical results derived from patients undergoing surgical procedures for atrial fibrillation. Adoption of these guidelines will greatly facilitate the comparison between the reported experiences of various authors, treating different cohorts

of patients at different times with different techniques and energy sources. The analysis of the burden of atrial fibrillation will evolve as continuous monitoring becomes clinically available. These guidelines are also appropriate for catheter-based treatment of atrial fibrillation. Thus, more reliable evaluation and comparisons of surgical results will advance our knowledge and further the development and application of these procedures to the large population of patients with atrial fibrillation.

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