



Medical Coverage Policy

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Cardiac Electrophysiological (EP) Studies and Cardiac Ablation of Abnormal Electrical Rhythms

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Overview

This Coverage Policy addresses invasive cardiac electrophysiological (EP) studies and catheter- and surgery-based treatments used in the diagnosis, risk stratification, and management of cardiac arrhythmias, including supraventricular tachycardias, ventricular arrhythmias, and atrial fibrillation.

Definitions:

- **Moderate complexity congenital heart disease (CHD):** CHD requiring intracardiac surgical repair, other than isolated atrial and ventricular septal defects (e.g., TOF, aortic stenosis, coarctation of aorta, Ebstein anomaly of the tricuspid valve)
- **Severe complexity CHD:** cyanotic CHD requiring intracardiac repair in infancy, often with staging procedures (e.g., transposition of the great arteries, truncus arteriosus, single ventricle anatomy)

Coverage Policy

Diagnostic Cardiac Electrophysiological (EP) Study

1. A diagnostic cardiac electrophysiological (EP) study (CPT® Codes 93619 & 93620) is considered **medically necessary** when **ANY** of the following criteria are met (a through m):
 - a. Primary Prevention of Sudden Cardiac Death (SCD) for **EITHER** of the following indications:
 - i. in an individual with ischemic heart disease
 1. to determine eligibility for an implantable cardioverter defibrillator (ICD), in an individual with non-sustained ventricular tachycardia (NSVT) due to prior myocardial infarction (MI) >40 days and LVEF between 36% and 40%
 - ii. in an individual with coronary artery disease (CAD) and after acute MI
 1. to determine eligibility for an ICD with NSVT and 4-40 days out from MI with **EITHER** of the following:
 - a. Revascularization performed at time of event AND LVEF $\leq$ 40%
 - b. Obstructive CAD not re-vascularized and with coronary anatomy not amenable to revascularization
 - b. Secondary Prevention of SCD for **ANY** of the following indications (i through iii):
 - i. for risk stratification for SCD in an individual with non-ischemic cardiomyopathy (NICM), who experiences syncope presumed to be due to VA and who does not meet indications for a primary prevention ICD

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- ii. to determine eligibility for an ICD after a ventricular fibrillation (VF) or hemodynamically unstable ventricular tachycardia (VT) episode during an acute MI (i.e., <48 hours), with non-sustained ventricular tachycardia (NSVT) ≥ 4 days after revascularization
 - iii. to determine eligibility for an ICD in an individual with ischemic heart disease and unexplained syncope who does not otherwise meet criteria for ICD placement by ejection fraction despite treatment with a beta blocker and an ACE inhibitor, ARB, or ARNI, unless contraindicated or not tolerated.
- c. Evaluation of ventricular arrhythmias (VA) to assess the risk of sustained VT in an individual with ischemic cardiomyopathy, NICM, or adult congenital heart disease who has syncope or other VA symptoms and who do not meet indications for a primary prevention ICD.
- d. Adult Congenital Heart Disease for **EITHER** of the following indications:
 - i. to evaluate the risk of sustained VT/VF in an adult with repaired Tetralogy of Fallot physiology with high-risk characteristics and frequent VA
 - ii. to risk stratify an individual with repaired moderate or severe complexity adult congenital heart disease and unexplained syncope when additional evaluation is needed to determine candidacy for ICD implantation
- e. Cardiac Sarcoidosis to determine eligibility for an ICD, if sustained VA is inducible, in an individual with cardiac sarcoidosis and LVEF ≥ 35
- f. Evaluation of an individual with syncope of suspected arrhythmic etiology
- g. Diagnosis and potential treatment of supraventricular tachycardia (SVT) of unknown mechanism
- h. Symptomatic individuals with manifest accessory pathways to risk-stratify for life-threatening arrhythmic events
- i. Individual with asymptomatic pre-excitation to risk-stratify for life-threatening arrhythmic events
- j. Initial clinical evaluation in patients with Atrial Fibrillation (AF) for **ANY** of the following indications (i through iii):
 - i. to clarify the mechanism of wide-QRS-complex tachycardia
 - ii. to identify a predisposing arrhythmia such as atrial flutter or paroxysmal supraventricular tachycardia
 - iii. to seek sites for curative AF ablation or atrioventricular (AV) conduction block/modification
- k. Asymptomatic individual with clinical evidence of arrhythmogenic right ventricular cardiomyopathy
- l. Asymptomatic Brugada syndrome and a spontaneous type 1 Brugada electrocardiographic pattern
- m. The following procedures are considered **medically necessary** when performed as part of a medically necessary diagnostic electrophysiologic study (CPT® Code 93619 or 93620) and supported by the clinical documentation:

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- i. Left atrial pacing and recording from the coronary sinus or left atrium (CPT® Code 93621)
- ii. Left ventricular pacing and recording (CPT® Code 93622)

All Other Indications

2. An EP study (CPT® Codes 93619, 93620, 93621, and 93622) is considered **not medically necessary** for **ALL** other indications including the following (a through c):
 - a. hypertrophic cardiomyopathy (HCM) for risk stratification
 - b. for the sole reason of inducing VA for risk stratification in an individual who meets criteria for ICD implantation
 - c. for risk stratification for VA in the setting of long QT syndrome, catecholaminergic polymorphic ventricular tachycardia, short QT syndrome, or early repolarization syndromes

Catheter Ablation

Atrial Fibrillation

3. Cardiac catheter ablation with pulmonary vein isolation (CPT® Code 93656) is considered **medically necessary** for **ANY** of the following indications (a through d):
 - a. Symptomatic atrial fibrillation (paroxysmal or persistent) **AND** antiarrhythmic drugs have been ineffective, contraindicated, not tolerated or not preferred
 - b. Symptomatic atrial fibrillation (e.g., palpitations, chest pain, dyspnea) associated with heart failure and reduced ejection fraction (HFrEF) of $\leq 40\%$
 - c. An athlete* who develops atrial fibrillation with or without symptoms
 - d. An individual with atrial fibrillation, with or without symptoms, and pulmonary hypertension (PH) with pulmonary vascular disease (PH_{PVD}) (i.e., PH with increased pulmonary vascular resistance and normal left heart filling pressures)

**Note: high-volume endurance athleticism, defined as exercise of >45 metabolic equivalent-hours per week*

4. Repeat cardiac catheter ablation is considered **medically necessary** for an individual with recurrent symptomatic atrial fibrillation.
5. An **additional** catheter ablation of a separate and distinct arrhythmogenic mechanism (CPT® Code 93655, 93657) performed during a **medically necessary** ablation procedure for the treatment of atrial fibrillation (CPT® Code 93656) is considered **medically necessary** when a **new** (i.e., not previously diagnosed) second spontaneous or induced arrhythmia requiring ablation is identified.

Supraventricular Tachycardia (SVT)

6. Transcatheter ablation (CPT® Code 93653) for the treatment of SVT is considered medically necessary as a treatment for **EITHER** of the following:
 - a. in an adult ≥ 18 years of age with **ANY** of the following (i through vii):
 - i. accessory pathway ablation in individuals with atrioventricular reentrant tachycardia (AVRT), preexcited atrial fibrillation (AF), or high-risk findings on an electrophysiological study
 - ii. cavotricuspid isthmus (CTI) dependent atrial flutter
 - iii. junctional tachycardia when medical therapy is not effective or contraindicated

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- iv. recurrent symptomatic non-CTI-dependent atrial flutter
 - v. symptomatic atrioventricular nodal reentrant tachycardia (AVNRT)
 - vi. symptomatic focal atrial tachycardia (AT) as an alternative to pharmacological therapy
 - b. in a child < 18 years of age
7. An **additional** catheter ablation of a separate and distinct arrhythmogenic mechanism (CPT® Code 93655) performed during a **medically necessary** supraventricular tachycardia ablation procedure (CPT® Code 93653) is considered **medically necessary** when a **new** (i.e., not previously diagnosed) second spontaneous or induced arrhythmia requiring ablation is identified (e.g., cavotricuspid isthmus [CTI]-dependent atrial flutter induced at the time of atrial fibrillation ablation).

Abnormal Ventricular Electrical Rhythms

8. Transcatheter ablation of abnormal ventricular electrical rhythms (CPT 93654) is considered **medically necessary** as a treatment for **EITHER** of the following arrhythmias in an adult ≥18 years of age:
- a. premature ventricular contractions (PVCs) when **EITHER** of the following are met:
 - i. PVC burden is >15% of total beats
 - ii. PVCs are symptomatic and medical or pharmacologic management is not effective, is contraindicated, is not tolerated, or is not preferred by the individual
 - b. ventricular arrhythmias (i.e., ventricular tachycardia, ventricular fibrillation) when medical or pharmacologic management is not effective, is contraindicated, is not tolerated, or is not preferred by the individual
9. An **additional** catheter ablation of a separate and distinct arrhythmogenic mechanism (CPT® Code 93655) performed during a **medically necessary** abnormal ventricular electrical rhythm ablation procedure (CPT® Code 93654) is considered **medically necessary** when a **new** (i.e., not previously diagnosed) second spontaneous or induced arrhythmia requiring ablation is identified.

Any Other Indication

10. Transcatheter ablation is considered **not medically necessary** for **ANY** other indication including the following conditions (a through c):
- a. Inappropriate sinus tachycardia (IST)
 - b. Premature atrial contraction (PAC)
 - c. asymptomatic atrial fibrillation (except athletes and individuals with pulmonary hypertension and pulmonary vascular disease [PH_{PVD}] as discussed above)
11. An **additional** catheter ablation of a separate and distinct arrhythmogenic mechanism (CPT® Code 93655, 93657) performed during an ablation procedure for the treatment of supraventricular tachycardia, abnormal ventricular electrical rhythm, or atrial fibrillation (CPT® Codes 93653, 93654, and 93656) is considered **not medically necessary** when a **new** second spontaneous or induced arrhythmia requiring ablation is **not** identified during the procedure.
12. Vein of Marshall alcohol ablation (VOM ethanol infusion) (CPT® Code 93799) for the treatment of paroxysmal/persistent atrial fibrillation is considered **not medically necessary**.

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13. **EITHER** of the following are considered **experimental, investigational or unproven** for **ANY** indication:
- Cardio-neuroablation (CNA)
 - Use of an active esophageal cooling device during cardiac catheter ablation

Surgical Ablation

14. Surgical Maze or modified Maze procedure (CPT® code 33258) performed concomitantly with cardiac surgery (e.g., valve surgery, coronary artery bypass grafting [CABG]), is considered **medically necessary** for the treatment of atrial fibrillation.
15. Standalone surgical Maze or modified Maze procedure, including endoscopic Maze as a part of a hybrid convergent procedure, when concomitant cardiac surgery is not performed (CPT® codes 33254, 33255, 33265, 33266) is considered **not medically necessary** for the treatment of atrial fibrillation.
16. Thoracoscopic epicardial ablation, including when performed as part of a hybrid convergent approach to ablation (CPT® Code 93799) is considered **experimental, investigational or unproven** for the treatment of **ANY** condition.

Coding Information

Notes:

- This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates.
- Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Diagnostic Cardiac Electrophysiological (EP) Study

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
93619	Comprehensive electrophysiologic evaluation with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording, including insertion and repositioning of multiple electrode catheters, without induction or attempted induction of arrhythmia
93620	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording
93621	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with left atrial pacing and recording from coronary sinus or left atrium (List separately in addition to code for primary procedure)
93622	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with left ventricular pacing and recording (List separately in addition to code for primary procedure)

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Catheter Ablation

Atrial Fibrillation

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (List separately in addition to code for primary procedure)
93656	Comprehensive electrophysiologic evaluation with transseptal catheterizations, insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia including left or right atrial pacing/recording, and intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation, including intracardiac electrophysiologic 3-dimensional mapping, intracardiac echocardiography with imaging supervision and interpretation, right ventricular pacing/recording, and His bundle recording, when performed
93657	Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (List separately in addition to code for primary procedure)

Catheter Ablation

Supraventricular Tachycardia (SVT)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
93653	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry
93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (List separately in addition to code for primary procedure)

Catheter Ablation

Abnormal Ventricular Electrical Rhythms

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Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
93654	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; with treatment of ventricular tachycardia or focus of ventricular ectopy including left ventricular pacing and recording, when performed
93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (List separately in addition to code for primary procedure)

Catheter Ablation

Considered Not Medically Necessary when used to report an additional catheter ablation of a separate and distinct arrhythmogenic mechanism (CPT® Codes 93655, 93657) performed during an ablation procedure for the treatment of supraventricular tachycardia, abnormal ventricular electrical rhythm, or atrial fibrillation when a new second spontaneous or induced arrhythmia requiring ablation is not identified during the procedure:

CPT®* Codes	Description
93653	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry
93654	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; with treatment of ventricular tachycardia or focus of ventricular ectopy including left ventricular pacing and recording, when performed
93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (List separately in addition to code for primary procedure)

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CPT®* Codes	Description
93656	Comprehensive electrophysiologic evaluation with transseptal catheterizations, insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia including left or right atrial pacing/recording, and intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation, including intracardiac electrophysiologic 3-dimensional mapping, intracardiac echocardiography with imaging supervision and interpretation, right ventricular pacing/recording, and His bundle recording, when performed
93657	Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (List separately in addition to code for primary procedure)

Considered Not Medically Necessary when used to report Vein of Marshall alcohol ablation (VOM ethanol infusion) for the treatment of paroxysmal/persistent atrial fibrillation:

CPT®* Codes	Description
93799	Unlisted cardiovascular service or procedure

Considered Experimental/Investigational/Unproven when used to report Cardio-neuroablation (CNA) and/or the use of an active esophageal cooling device during cardiac catheter ablation:

CPT®* Codes	Description
93799	Unlisted cardiovascular service or procedure

HCPCS Codes	Description
C1889	Implantable/insertable device, not otherwise classified

Surgical Ablation

Surgical Maze or Modified Maze Procedure

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
33258	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (eg, maze procedure), without cardiopulmonary bypass (List separately in addition to code for primary procedure)

Standalone Surgical Maze or Modified Maze Procedure

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Considered Not Medically Necessary when used to report a standalone Surgical Maze or modified Maze procedure, including endoscopic Maze as part of a hybrid convergent procedure, when concomitant cardiac surgery is not performed:

CPT®* Codes	Description
33254	Operative tissue ablation and reconstruction of atria, limited (eg, modified maze procedure)
33255	Operative tissue ablation and reconstruction of atria, extensive (eg, maze procedure); without cardiopulmonary bypass
33265	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, limited (eg, modified maze procedure), without cardiopulmonary bypass
33266	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, extensive (eg, maze procedure), without cardiopulmonary bypass

Considered Experimental/Investigational/Unproven when used to report a thoracoscopic epicardial ablation (including when performed as part of a hybrid convergent approach to ablation) for the treatment of ANY condition:

CPT®* Codes	Description
93799	Unlisted cardiovascular service or procedure

***Current Procedural Terminology (CPT®) ©2025 American Medical Association: Chicago, IL.**

General Background

Diagnostic Cardiac Electrophysiological (EP) Study

The heart produces electrical signals that spread through the heart muscle to make the muscle contract. The signals are small but can be picked up on an electrocardiograph machine. The electrocardiogram (ECG) can be helpful but often the signals are so small that they cannot be seen or are hidden on an ECG. Even tests that stretch over a longer period of time, such as a Holter monitor, may not capture an event. A cardiac electrophysiology (EP) study permits a detailed analysis of the mechanism(s) underlying the cardiac arrhythmia, precise location of the site of origin, and, if applicable, definitive treatment via catheter-based ablation techniques.

The indications for an invasive cardiac electrophysiology study can be broken down to two categories: diagnostic and risk stratification. An EP study can accomplish the following goals (Homoud, 2024):

- definitive diagnosis of an arrhythmia
- establish an etiology for syncope
- risk stratification for sudden cardiac death
- evaluate the feasibility or outcome of nonpharmacologic therapy

Absolute contraindications to EP study include (Homoud, 2024):

- unstable angina
- bacteremia or septicemia
- acute decompensated congestive heart failure not caused by the arrhythmia

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- major bleeding diathesis
- acute lower extremity venous thrombosis if femoral vein cannulation is desired

An invasive EP study is generally performed in a dedicated EP laboratory. In addition to the cardiac electrophysiologist, several other staff members are required. Intravenous conscious sedation is typically used, although in some situations (i.e., prolonged catheter ablation procedures) general anesthesia can be used (Homoud, 2024).

The pre-procedure evaluation for an invasive EP study includes a thorough history and physical examination and review of available ECGs, at baseline and, if available, during arrhythmia. In select patients additional evaluation prior to the procedure may include (Homoud, 2024):

- Event monitoring for up to four weeks to document the tachycardia.
- Transthoracic echocardiography to assess for structural heart disease. Cardiac magnetic resonance imaging may be considered for special situations (e.g., suspicion of arrhythmogenic right ventricular cardiomyopathy, hypertrophic cardiomyopathy).
- Exercise testing, if there is a history of exercise-induced arrhythmia.
- Cardiac catheterization and coronary angiography, if indicated by the individual's clinical presentation and symptoms suggesting coronary heart disease.

In most individuals, all atrioventricular (AV) nodal blocking agents, including calcium and beta blockers, digoxin, and class I and III antiarrhythmic drugs are discontinued several days prior to the scheduled procedure. In nearly all EP studies, venous vascular access is required, often from multiple sites. The femoral approach is most common; but the subclavian, internal jugular, or brachial approach may be used, most often for placement of a catheter in the coronary sinus. Multipolar electrode catheters are positioned in the heart (Homoud, 2024).

Complications of an invasive cardiac EP study are rare but potentially life threatening. The risks associated with undergoing an EP study by itself are small. Myocardial perforation with cardiac tamponade, pseudoaneurysms at arterial access sites, and provocation of nonclinical arrhythmias can occur, each with less than a 1/500 incidence. The addition of therapeutic maneuvers (e.g., ablation) to the procedure increases the incidence of complications. Because an EP study carries a relatively small but finite risk of major as well as minor complications and routinely involve the purposeful induction of serious arrhythmias, it is important that their clinical usefulness for diagnosis and therapy of cardiac arrhythmias be carefully considered (Miller, et al., 2019; Homoud, 2024).

U.S. Food and Drug Administration (FDA): A diagnostic cardiac electrophysiologic study is a procedure and, therefore, not subject to FDA regulation. Any medical devices, drugs, biologics, or tests used as a part of this procedure may be subject to FDA regulation.

Professional Societies/Organizations: The American Heart Association (AHA)/ American College of Cardiology (ACC)/ Health Rhythm Society (HRS) have numerous guidelines that address recommendations for an EP study. The recommendations listed in the clinical practice guidelines are, whenever possible, evidence-based. The Class of Recommendation (COR) indicates the strength of the recommendation, encompassing the estimated magnitude and certainty of benefit in proportion to risk. The Level of Evidence (LOE) rates the quality of scientific evidence that supports the intervention on the basis of the type, quantity, and consistency of data from clinical trials and other sources.

Guideline Class of Recommendation (COR) and Level of Evidence (LOE) are described as follows:

Class (Strength) of Recommendation:

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Class I (Strong) Benefit >>>Risk
 Class IIa (Moderate) Benefit>>Risk
 Class IIb (Weak) Benefit ≥ Risk
 Class III No Benefit (Moderate) Benefit=Risk
 Class III Harm (Strong) Risk>Benefit

Level (Quality) of Evidence:

Level A if the data were derived from high-quality evidence from more than one randomized clinical trial (RCT), meta-analyses of high-quality RCTs, or one or more RCTs corroborated by high-quality registry.

Level B-R when data were derived from moderate quality evidence from one or more RCTs, or meta-analyses of moderate-quality RCTs.

Level B-NR was used to denote moderate-quality evidence from one or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies. This designation was also used to denote moderate-quality evidence from meta-analyses of such studies.

Level C-LD when the primary source of the recommendation was randomized or nonrandomized observational or registry studies with limitations of design or execution, meta-analyses of such studies, or physiological or mechanistic studies of human subjects.

Level C-EO was defined as expert opinion based on the clinical experience of the writing group.

American Heart Association (AHA)/American College of Cardiology (ACC)/Health Rhythm Society (HRS) Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (Al-Khatib, et al., 2017)		
Indication	Recommendation for EP Study	COR/LOE
Primary Prevention of SCD in Patients With Ischemic Heart Disease	In patients with NSVT due to prior MI, LVEF of 40% or less and inducible sustained VT or VF at electrophysiological study, an ICD is recommended if meaningful survival of greater than 1 year is expected	I/B-R
Secondary Prevention of SCD in Patients with Ischemic Heart Disease	In patients with ischemic heart disease and unexplained syncope who have inducible sustained monomorphic VT on electrophysiological study, an ICD is recommended if meaningful survival of greater than 1 year is expected.	I/B-NR
Secondary Prevention of SCD in Patients With Nonischemic Cardiomyopathy (NICM)	In patients with NICM who experience syncope presumed to be due to VA and who do not meet indications for a primary prevention ICD, an ICD or an electrophysiological study for risk stratification for SCD can be beneficial if meaningful survival greater than 1 year is expected	IIa/B-NR
Ventricular Arrhythmias (VA)	In patients with ischemic cardiomyopathy, nonischemic cardiomyopathy (NICM), or adult congenital heart disease who have syncope or other VA symptoms and who do not meet indications for a primary prevention ICD, an electrophysiological study can be useful for assessing the risk of sustained VT	IIa/B-R
Adult Congenital Heart Disease	In adults with repaired tetralogy of Fallot physiology with high-risk characteristics and frequent VA, an electrophysiological study can be useful to evaluate the risk of sustained VT/VF	IIa/B-NR

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	In patients with repaired moderate or severe complexity adult congenital heart disease with unexplained syncope and at least moderate ventricular dysfunction or marked hypertrophy, either ICD implantation or an electrophysiological study with ICD implantation for inducible sustained VA is reasonable if meaningful survival of greater than 1 year is expected	IIa/B-NR
Cardiac Sarcoidosis	In patients with cardiac sarcoidosis and LVEF greater than 35%, it is reasonable to perform an electrophysiological study and to implant an ICD, if sustained VA is inducible, provided that meaningful survival of greater than 1 year is expected	IIa/C-LD
Arrhythmogenic Right Ventricular Cardiomyopathy	In asymptomatic patients with clinical evidence of arrhythmogenic right ventricular cardiomyopathy, an electrophysiological study may be considered for risk stratification	IIb/B-NR
Brugada Syndrome	In patients with asymptomatic Brugada syndrome and a spontaneous type 1 Brugada electrocardiographic pattern, an electrophysiological study with programmed ventricular stimulation using single and double extra stimuli may be considered for further risk stratification	IIb/B-NR
Hypertrophic Cardiomyopathy (HCM)	In patients with HCM, an invasive electrophysiological study with programmed ventricular stimulation should not be performed for risk stratification	III/B-NR
Ventricular Arrhythmias (VA)	In patients who meet criteria for ICD implantation, an electrophysiological study for the sole reason of inducing VA is not indicated for risk stratification	III/B-R
	An electrophysiological study is not recommended for risk stratification for VA in the setting of long QT syndrome, catecholaminergic polymorphic ventricular tachycardia, short QT syndrome, or early repolarization syndromes	III/B-NR

The 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure identifies renin-angiotensin system inhibition (ARNI, ACE inhibitor, or ARB) and evidence-based beta blocker therapy as foundational components of guideline-directed medical therapy (GDMT) for patients with heart failure with reduced ejection fraction (HFrEF). Because these therapies may improve left ventricular function, evaluation of ICD eligibility based on ejection fraction should occur in the context of appropriate heart failure medical therapy when tolerated and not contraindicated (Heidenreich, et al., 2022).

Al-Khatib, et al. (2017) defines moderate and severe complexity congenital heart disease (CHD) as follows:

- Moderate complexity CHD: CHD requiring intracardiac surgical repair, other than isolated atrial and ventricular septal defects (e.g., TOF, aortic stenosis, coarctation of aorta, Ebstein anomaly of the tricuspid valve)
- Severe complexity CHD: cyanotic CHD requiring intracardiac repair in infancy, often with staging procedures (e.g., transposition of the great arteries, truncus arteriosus, single ventricle anatomy)

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American Heart Association (AHA)/American College of Cardiology (ACC)/Health Rhythm Society (HRS) Guideline for the Evaluation and Management of Patients With Syncope (Shen, et al., 2017)		
Indication	Recommendation for EP Study	COR/LOE
Syncope	EP study can be useful for evaluation of selected patients with syncope of suspected arrhythmic etiology	IIa/B-NR

American Heart Association (AHA)/American College of Cardiology (ACC)/Health Rhythm Society (HRS) Guideline for the Management of Adult Patients With Supraventricular Tachycardia (Page, et al., 2016)		
Indication	Recommendation for EP Study	COR/LOE
SVT of Unknown Mechanism	EP study with the option of ablation is useful for the diagnosis and potential treatment of SVT	I/B-NR
Symptomatic Patients With Manifest Accessory Pathways	An EP study is useful in symptomatic patients with pre-excitation to risk-stratify for life-threatening arrhythmic events	I/B-NR
Asymptomatic Patients With Asymptomatic Pre-Excitation	An EP study is reasonable in asymptomatic patients with pre-excitation to risk-stratify for arrhythmic events	IIa/B-NR

American Heart Association (AHA)/American College of Cardiology (ACC)/Health Rhythm Society (HRS) Guideline for the Management of Patients with Atrial Fibrillation

Class I

- Electrocardiographic documentation is recommended to establish the diagnosis of atrial fibrillation (AF) (Level of Evidence: C).

The guideline states that the diagnosis of AF in a patient is based on the patient's clinical history and physical examination and is confirmed by ECG, ambulatory rhythm monitoring (e.g., telemetry, Holter monitor, event recorders), implanted loop recorders, pacemakers or defibrillators, or, in rare cases, by electrophysiological study. An electrophysiological study can be helpful when initiation of AF is due to a supraventricular tachycardia, such as atrioventricular node (AV) node reentrant tachycardia, AV reentry involving an accessory pathway, or ectopic atrial tachycardia. Electrophysiological study is often warranted in patients with a delta wave on the surface ECG indicating pre-excitation. Some patients with AF also have atrial flutter that may benefit from treatment with radiofrequency catheter ablation. AF associated with rapid ventricular rates and a wide-complex QRS (aberrant conduction) may sometimes be mislabeled as ventricular tachycardia, and an electrophysiological study can help establish the correct diagnosis (January, et al., 2014). Electrophysiological studies were not addressed in the 2019 focused update to the 2014 guideline (January, et al., 2019).

American Heart Association (AHA)/American College of Cardiology (ACC) Guideline for the Diagnosis and Management of Atrial Fibrillation

Class IIb

- In patients with an onset of unexplained AF before 30 years of age, electrophysiological study to evaluate and treat reentrant supraventricular tachyarrhythmias with a targeted ablation may be reasonable because of the high prevalence of reentrant arrhythmias in this group (Level of Evidence B-NR).

Effective 1/15/2027

The guideline states that patients are being diagnosed with AF at a younger age due to the use of consumer driven wearable devices and that reentrant SVTs are found in 25% of individuals diagnosed at <30 years of age (Joglar, et al., 2024).

American College of Cardiology Foundation (ACCF)/Heart Rhythm Society (HRS)/American Heart Association (AHA)/American Society of Echocardiography (ASE)/Heart Failure Society of America (HFSA)/Society for Cardiovascular Angiography and Interventions (SCAI)/Society of Cardiovascular Computed Tomography (SCCT)/Society for Cardiovascular Magnetic Resonance (SCMR): The 2013 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy described the appropriate use of these devices for selected patient populations (Russo, et al., 2013) and likewise, the appropriateness of the tests used to determine the need for an ICD (e.g., cardiac electrophysiological study).

Recommendations are provided based on the following scoring method:

- Median score 7–9: Appropriate care: An appropriate option for management of patients in this population due to benefits generally outweighing risks; effective option for individual care plans, although not always necessary, depending on physician judgment and patient-specific preferences (i.e., procedure is generally acceptable and is generally reasonable for the indication).
- Median score 4–6: May be appropriate for care: At times an appropriate option for management of patients in this population due to variable evidence or agreement regarding the benefit/risk ratio, potential benefit based on practice experience in the absence of evidence, and/or variability in the population; effectiveness for individual care must be determined by a patient's physician in consultation with the patient based on additional clinical variables and judgment along with patient preferences (i.e., procedure may be acceptable and may be reasonable for the indication).
- Median score 1–3: Rarely appropriate care: Rarely an appropriate option for management of patients in this population due to the lack of a clear benefit/risk advantage; rarely an effective option for individual care plans; exceptions should have documentation of the clinical reasons for proceeding with this care option (i.e., procedure is not generally acceptable and is not generally reasonable for the indication).

Generally, criteria that have been deemed Appropriate or May Be Appropriate in these scenarios often meet Class I, IIa, or IIb criteria in guideline documents, are supported by a critical mass of existing data, or were deemed by the technical panel to meet sufficient clinical judgment to be reasonable and appropriate.

ICD implantation is rated as May Be Appropriate (median score 4-6) for the following indications:

Secondary Prevention

Coronary artery disease (CAD): ventricular fibrillation (VF) or hemodynamically unstable ventricular tachycardia (VT) associated with acute (< 48 hours) myocardial infarction (MI) (newly diagnosed, no prior assessment of left ventricular ejection fraction (LVEF):

- Total Revascularization Completed After Cardiac Arrest
 - Single episode VF or polymorphic VT during acute (< 48 hours) MI (4)
 - Recurrent VF or polymorphic VT during acute (< 48 hours) MI (5)
 - VF or polymorphic VT during acute (< 48 hours) MI, NSVT 4 days post MI, Inducible VT/VF at EPS ≥ 4 days after revascularization (5)
- No Revascularization Indicated (No Significant CAD)

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- Single episode VF or polymorphic VT during acute (< 48 hours) MI, LVEF ≤ 35% (4)
- Recurrent VF or polymorphic VT during acute (< 48 hours) MI LVEF ≤ 35% (5)
- Obstructive CAD with coronary anatomy not amenable to revascularization
 - VF or polymorphic VT during acute (< 48 hours) MI, no EPS done. EF ≥ 36% (5)

Pediatric and Congenital Electrophysiology Society (PACES)/HRS Expert Consensus Statement on the Management of the Asymptomatic Young Patient with a Wolff-Parkinson-White (WPW, Ventricular Preexcitation) Electrocardiographic Pattern: The guideline discusses rationale, definition, and techniques for an invasive EP study stating that in the absence of a clear understanding of the accessory pathway anterograde characteristics by noninvasive testing, invasive testing should be considered. The purpose of such an invasive EP study in asymptomatic patients with a WPW ECG pattern is to identify a potential subgroup of patients who may be at increased risk for lethal cardiac arrhythmias and in whom the risk-to-benefit ratio favors ablation (PACES, 2012).

ACC/AHA Guidelines for Clinical Intracardiac Electrophysiological and Catheter Ablation Procedures: Recent textbook literature reports that the basic themes of the 1995 ACC/AHA Guidelines for Clinical Intracardiac Electrophysiological and Catheter Ablation Procedures remain valid (Miller, et al., 2019).

Guideline recommendations for an electrophysiological study are classified as Class I, Class II, and Class III described as follows:

Class I: Conditions for which there is general agreement that the electrophysiological study provides information that is useful and important for patient treatment. Experts agree that patients with these conditions are likely to benefit from electrophysiological studies.

Class II: Conditions for which electrophysiological studies are frequently performed, but there is less certainty about the usefulness of the information that is obtained. Experts are divided in their opinion as to whether patients with these conditions are likely to benefit from electrophysiological study.

Class III: Conditions for which there is general agreement that electrophysiological studies do not provide useful information. Experts agree that electrophysiological studies are not warranted in patients with these conditions. This classification is assigned to patients with a variety of arrhythmias and clinical syndromes resulting from cardiac electrical abnormalities. Because use of electrophysiological studies in children on occasion differs from that in adults, it is discussed in another section.

1995 ACC/AHA Task Force Report. Guidelines for Clinical Intracardiac Electrophysiological and Catheter Ablation Procedures			
Evaluation of Specific Electrocardiographic Abnormalities			
Indication	Class I	Class II	Class III
Evaluation of sinus node function	Symptomatic patients in whom sinus node dysfunction is suspected as the cause of symptoms, but a causal relationship between an arrhythmia and the symptoms has not	Patients with documented sinus node dysfunction in whom evaluation of AV or ventriculoatrial conduction or susceptibility to arrhythmias may aid in selection of the most appropriate pacing modality	Symptomatic patients in whom an association between symptoms and a documented bradyarrhythmia has been established and the choice of therapy would not be affected by EP study results

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	been established after appropriate evaluation	Patients with electrocardiographically documented sinus bradyarrhythmias to determine whether abnormalities are caused by intrinsic disease, autonomic nervous system dysfunction, or effects of drugs to help select therapeutic options Symptomatic patients with known sinus bradyarrhythmias to evaluate potential for other arrhythmias as the cause of symptoms	Asymptomatic patients with sinus bradyarrhythmias or sinus pauses observed only during sleep, including sleep apnea
Acquired AV block	Symptomatic patients in whom His-Purkinje block, suspected as a cause of symptoms, has not been established Patients with second- or third-degree AV block treated with a pacemaker who remain symptomatic and in whom another arrhythmia is suspected as a cause of the symptoms	Patients with second- or third-degree AV block in whom knowledge of the site of block or its mechanism or response to pharmacologic or other temporary intervention may help in directing therapy or assessing prognosis Patients with premature, concealed junctional depolarizations suspected as the cause of a second- or third-degree AV block pattern (e.g., pseudo-AV block)	Symptomatic patients in whom the symptoms and presence of AV block are correlated by ECG findings Asymptomatic patients with transient AV block associated with sinus slowing (e.g., nocturnal type I second-degree AV block)
Chronic intraventricular conduction delay	Symptomatic patients in whom the cause of symptoms is not known	Asymptomatic patients with bundle branch block in whom pharmacologic therapy that could increase conduction delay or produce heart block is contemplated	Asymptomatic patients with intraventricular conduction delay Symptomatic patients whose symptoms can be correlated with or excluded by ECG events
Narrow-QRS tachycardia (QRS complex <0.12 sec)	Patients with frequent or poorly tolerated episodes of tachycardia who do not adequately respond to drug therapy and for whom information about the site of origin,	Patients with frequent episodes of tachycardia requiring drug treatment for whom there is concern about proarrhythmia or effects of the antiarrhythmic drug on the sinus node or AV conduction	Patients with tachycardias easily controlled by vagal maneuvers and/or well-tolerated drug therapy who are not candidates for nonpharmacologic therapy

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	mechanism, and electrophysiologic properties of pathways of the tachycardia is essential for choosing appropriate therapy (e.g., drugs, catheter ablation, pacing, or surgery) Patients who prefer ablative therapy to pharmacologic treatment		
Wide-complex tachycardias	Patients with wide-QRS complex tachycardia in whom the correct diagnosis is unclear after analysis of available ECG tracings and for whom knowledge of the correct diagnosis is necessary for care	None	Patients with VT or supraventricular tachycardia with aberrant conduction or preexcitation syndromes diagnosed with certainty by ECG criteria and for whom invasive electrophysiologic data would not influence therapy; however, data obtained at baseline EP study in these patients might be appropriate as a guide for subsequent therapy
Prolonged-QT interval syndrome	None	Identification of proarrhythmic effect of a drug in patients experiencing sustained VT or cardiac arrest while receiving the drug Patients who have equivocal abnormalities in QT interval duration or T-U wave configuration, along with syncope or symptomatic arrhythmias, in whom the effects of catecholamine may unmask a distinct QT abnormality	Patients with clinically manifest congenital QT prolongation, with or without symptomatic arrhythmias Patients with acquired prolonged-QT syndrome with symptoms closely related to an identifiable cause or mechanism
Wolff-Parkinson-White syndrome	Patients being evaluated for catheter ablation or surgical	Asymptomatic patients with a family history of sudden cardiac death or with ventricular	Asymptomatic patients with ventricular preexcitation, except those in class II

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	ablation of an accessory pathway Patients with ventricular preexcitation who have survived cardiac arrest or who have unexplained syncope Symptomatic patients in whom determination of the mechanism of arrhythmia or knowledge of the electrophysiologic properties of the accessory pathway and normal conduction system would help in determining appropriate therapy	preexcitation but no spontaneous arrhythmia who engage in high-risk occupations or activities and in whom knowledge of the electrophysiologic properties of the accessory pathway or inducible tachycardia may help determine recommendations for further activities or therapy Patients with ventricular preexcitation who are undergoing cardiac surgery for other reasons	
Premature ventricular complexes (PVCs), couplets, and nonsustained VT	None	Patients with other risk factors for future arrhythmic events, such as a low ejection fraction, positive signal-averaged electrocardiogram, and nonsustained VT on ambulatory ECG recordings in whom EP study will be used for further risk assessment and for guiding therapy in patients with inducible VT Patients with highly symptomatic, uniform morphology PVCs, couplets, and nonsustained VT who are considered potential candidates for catheter ablation	Asymptomatic or mildly symptomatic patients with PVCs, couplets, and nonsustained VT without other risk factors for sustained arrhythmias
Evaluation of Clinical Syndromes			
Unexplained syncope	Patients with suspected structural heart disease and syncope that remain unexplained after appropriate evaluation	Patients with recurrent unexplained syncope but without structural heart disease and a negative head-up tilt test result	Patients with a known cause of syncope for whom treatment will not be guided by electrophysiologic testing

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Survivors of cardiac arrest	Patients surviving cardiac arrest without evidence of acute Q wave MI Patients surviving cardiac arrest occurring more than 48 hours after acute phase of MI in the absence of recurrent ischemic events	Patients surviving cardiac arrest caused by bradyarrhythmia Patients surviving cardiac arrest thought to be associated with a congenital repolarization abnormality (long-QT syndrome) in whom the results of noninvasive diagnostic testing are equivocal	Patients surviving a cardiac arrest that occurred during acute phase (<48 hr) of MI Patients with cardiac arrest resulting from clearly definable specific causes, such as reversible ischemia, severe valvular aortic stenosis, or noninvasively defined congenital or acquired long-QT syndrome
Unexplained palpitations	Patients with palpitations who have their pulse rate documented by medical personnel as inappropriately rapid and in whom ECG recordings fail to document the cause of the palpitations Patients with palpitations preceding a syncopal episode	Patients with clinically significant palpitations, suspected to be of cardiac origin in whom the symptoms are sporadic and cannot be documented; studies performed to determine mechanisms of arrhythmias, direct or provide therapy, or assess prognosis	Patients with palpitations documented to result from extracardiac causes (e.g., hyperthyroidism)
Therapeutic Intervention			
Guidance of drug therapy	Patients with sustained VT or cardiac arrest, especially those with prior MI Patients with AVNRT, AV reentrant tachycardia using an accessory pathway, or AF associated with an accessory pathway for whom chronic drug therapy is planned	Patients with sinus node reentrant tachycardia, atrial tachycardia, AF, or atrial flutter without ventricular preexcitation syndrome for whom chronic drug therapy is planned Patients with arrhythmias not inducible during controlled EP study for whom drug therapy is planned	Patients with isolated atrial or ventricular premature complexes Patients with ventricular fibrillation with a clearly identified reversible cause
Patients who are candidates for or who have implantable electrical devices	Patients with tachyarrhythmias before and during implantation and final (predischage) programming of an electrical device to	Patients with previously documented indications for pacemaker implantation to test for the most appropriate long-term pacing mode and sites to optimize symptomatic	Patients who are not candidates for device therapy

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	confirm its ability to perform as anticipated Patients with an implanted electrical antitachyarrhythmia device in whom changes in status or therapy may have influenced the continued safety and efficacy of the device Patients who have a pacemaker to treat a bradyarrhythmia and receive an ICD to test for device interactions	improvement and hemodynamics	
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Use Outside of the US

The European Heart Rhythm Association (EHRA) and the European Society of Cardiology (ESC) have guidelines that address recommendations for an electrophysiological (EP) study.

Guideline recommendations are classified as Class I, Class IIa, Class IIb, and Class III. The classification system is described as follows:

- Class I: Benefit >>>Risk; Procedure/Treatment should be performed/administered
- Class IIa: Benefit >> Risk; Additional studies with focused objectives needed. It is reasonable to perform procedure/administer treatment
- Class IIb: Benefit ≥ Risk; Additional studies with broad objectives needed; additional registry data would be helpful. Procedure/treatment may be considered.
- Class III: No Benefit. Procedure/Test not helpful/Treatment: no proven benefit
- Class III Harm. Procedure/Test: Excess cost without benefit, or harmful. Treatment: harmful to patients

The weight of evidence supporting each recommendation is classified as follows:

- Level A: Multiple populations evaluated. Data derived from multiple randomized clinical trials or meta-analyses.
- Level B: Limited populations evaluated. Data derived from a single randomized trial or nonrandomized studies.
- Level C: Very limited populations evaluated. Only consensus opinion of experts, case studies, or standard of care.

European Heart Rhythm Association (EHRA)/HRS/Asia Pacific Heart Rhythm Society (APHRS) Expert Consensus on Ventricular Arrhythmias (Pedersen, et al., 2014)		
Indication	Recommendation for electrophysiological (EP) Study	COR/LOE
Non-sustained ventricular arrhythmia (VA)	An invasive EP study should be considered in patients with significant structural heart disease (SHD) and non-sustained VAs especially if accompanied by unexplained symptoms such as syncope, near-syncope, or sustained palpitations	IIa/C

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Sustained monomorphic ventricular tachycardia (SMVT)	For patients with a wide QRS complex tachycardia in whom the diagnosis is uncertain, an invasive EP study should be considered to identify the tachycardia mechanism	IIa/C
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European Society of Cardiology (ESC) Guidelines for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (Priori, et al., 2015)		
Indication	Recommendation for EP Study	COR/LOE
Suspected or known ventricular arrhythmias	In patients with coronary artery disease (CAD) for diagnostic evaluation of patients with remote myocardial infarction with symptoms suggestive of ventricular tachyarrhythmias, including palpitations, presyncope and syncope	I/B
	In patients with syncope when bradyarrhythmias or tachyarrhythmias are suspected, based on symptoms (e.g. palpitations) or the results of non-invasive assessment, especially in patients with structural heart disease	I/C
	For the differential diagnosis of arrhythmogenic right ventricular cardiomyopathy (ARVC) and benign right ventricular outflow tract (RVOT) tachycardia or sarcoidosis	IIb/B
Risk stratification and management of patients with dilated cardiomyopathy	Invasive EP study with programmed ventricular stimulation (PVS) may be considered for risk stratification of sudden cardiac death (SCD)	IIb/B
Prevention of sudden cardiac death (SCD) in patients with hypertrophic cardiomyopathy	Invasive EP study with PVS is not recommended for stratification of SCD risk	III/C
Indication	Recommendation for EP Study	COR/LOE
Risk stratification and management of patients with arrhythmogenic right ventricular cardiomyopathy	Invasive EP study with PVS may be considered for stratification of SCD risk	IIb/C
Risk stratification and management in Long QT Syndrome	Invasive EP study with PVS is not recommended for SCD risk stratification	III/C
Risk stratification and management in Short QT Syndrome	Invasive EP study with PVS is not recommended for SCD risk stratification	III/C
Risk stratification and management in Catecholaminergic Polymorphic Ventricular Tachycardia	Invasive EP study with PVS is not recommended for stratification of SCD risk	III/C

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Management of ventricular arrhythmias in valvular heart disease	An EP study with standby catheter ablation should be considered in patients who develop VT following valvular surgery in order to identify and cure bundle branch re-entry VT	IIa/C
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European Society of Cardiology (ESC) Guidelines for the Diagnosis and Management of Syncope (Brignole, et al., 2018)		
Indication	Recommendation for EP Study	COR/LOE
Syncope	In patients with syncope and previous myocardial infarction, or other scar-related conditions, EP study is indicated when syncope remains unexplained after non-invasive evaluation	I/B
	In patients with syncope and bifascicular bundle branch block (BBB), EP study should be considered when syncope remains unexplained after non-invasive evaluation	IIa/B
	In patients with syncope and asymptomatic sinus bradycardia, EP study may be considered in a few instances when non-invasive tests (e.g. ECG monitoring) have failed to show a correlation between syncope and bradycardia	IIb/B
	In patients with syncope preceded by sudden and brief palpitations, EP study may be considered when syncope remains unexplained after non-invasive evaluation	IIb/C

A section of the guideline addresses additional advice and clinical perspectives stating:

- In general, whereas a positive EP study predicts the cause of syncope, a negative study is unable to exclude an arrhythmic syncope and further evaluation is warranted.
- The induction of polymorphic VT or VF in patients with ischemic cardiomyopathy or DCM cannot be considered a diagnostic finding of the cause of syncope.
- EP study is generally not useful in patients with syncope, normal ECG, no heart disease, and no palpitations.

Catheter Ablation

Atrial Fibrillation

Atrial fibrillation (AF) is a cardiac arrhythmia (abnormal heart rhythm) characterized by rapid (350–500/min), irregular, disorganized atrial impulses, and ineffective atrial contractions. AF develops through a complex interaction of abnormal electrical signals and structural changes within the atria that promote the initiation and maintenance of the arrhythmia. Risk factors include advancing age, obesity, systemic and pulmonary hypertension, diabetes mellitus, obstructive sleep apnea, ischemic heart disease, valvular heart disease, cardiomyopathy, chronic obstructive pulmonary disease (COPD), thyroid disease, alcohol abuse, and genetic predisposition. AF prevalence in the United States was estimated at 5.2 million individuals in 2010 and is projected to increase to 12.1 million by 2030. AF is associated with substantial morbidity and mortality, including increased risks of stroke, heart failure, cognitive impairment, myocardial infarction, chronic kidney disease, hospitalization, and death (Ad, 2026; Calkins et al., 2026; Joglar et al., 2024).

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Clinical manifestations range from asymptomatic disease to symptoms such as palpitations, fatigue, dyspnea (shortness of breath), dizziness, and exercise intolerance. Diagnosis is typically established by electrocardiography (ECG), with ambulatory rhythm monitoring often used to identify AF when symptomatic episodes are intermittent. AF is classified according to the duration and pattern of the arrhythmia:

- Paroxysmal AF: intermittent episodes of AF that terminate within ≤ 7 days of onset.
- Persistent AF: continuous AF that lasts longer than seven days and requires intervention.
- Long-standing persistent AF: continuous AF that lasts longer than 12 months.
- Permanent AF: AF in which the patient and clinician make a joint decision to stop further attempts to restore and/or maintain sinus rhythm. Acceptance of AF represents a therapeutic decision and does not represent an inherent pathophysiological attribute of AF.

AF may progress over time, and individuals may transition among the different substages of AF. Treatment outcomes differ according to AF pattern, symptom burden, structural changes within the atria, and the presence of underlying heart disease (Ad, 2026; Calkins et al., 2026; Joglar et al., 2024).

Management of AF may include risk factor modification, pharmacologic therapy, and nonpharmacological interventions. Major treatment goals include maintenance or restoration of sinus rhythm (normal heart rhythm), symptom improvement, and prevention of blood clots and thromboembolic complications such as stroke. Nonpharmacological treatment options include catheter-based and surgical ablation procedures intended to reduce AF burden and maintain sinus rhythm. Potential risks of these procedures vary by technique and may include bleeding, vascular injury, cardiac perforation, or esophageal injury including atrioesophageal fistula. Treatment selection is individualized based on AF characteristics, other medical conditions, stroke risk, and prior treatment response (Ad, 2026; Calkins et al., 2026; Joglar et al., 2024).

Ablation is a rhythm-control strategy that creates controlled areas of scar tissue within the heart to block or isolate abnormal electrical signals that initiate or sustain AF. Cardiac catheter ablation is a minimally invasive rhythm-control procedure performed using specialized catheters advanced through the vascular system into the heart, often with electroanatomic mapping to guide lesion placement. Because abnormal electrical signals that initiate AF commonly originate from the pulmonary veins, pulmonary vein isolation (PVI), which electrically isolates the pulmonary veins from the left atrium, has become the foundation of most contemporary AF ablation procedures. The primary goals of ablation are to reduce AF recurrence, improve symptoms, maintain sinus rhythm, and improve quality of life (Ad, 2026; Calkins et al., 2026).

U.S. Food and Drug Administration (FDA): Catheter ablation is a procedure and, therefore, not subject to FDA regulation. Any medical devices, drugs, biologics, or tests used as a part of the procedure may be subject to FDA regulation. Numerous ablation catheters have received FDA approval through the premarket application (PMA) process for treatment of arrhythmias.

Literature Review: Evidence from randomized controlled trials, systematic reviews, and meta-analyses supports catheter ablation, particularly pulmonary vein isolation (PVI)-based strategies, for reducing atrial fibrillation (AF) recurrence and improving rhythm-control outcomes in individuals with symptomatic paroxysmal or persistent AF. In the CABANA trial, catheter ablation was associated with lower rates of AF recurrence (49.9% vs. 69.5%) and the composite outcome of death or cardiovascular hospitalization (51.7% vs. 58.1%) compared with drug therapy during a median follow-up of 48.5 months (Packer et al., 2019). Subsequent analyses demonstrated reductions in AF recurrence across paroxysmal, persistent, and long-standing persistent AF populations, accompanied by improvements in AF-related symptoms and quality of life (Monahan

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et al., 2022). Additional randomized evidence supports catheter ablation for delaying progression of paroxysmal AF to persistent AF or atrial tachycardia compared with antiarrhythmic drug therapy (2.4% vs. 17.5%) and demonstrates improved long-term rhythm-control outcomes with both radiofrequency- and cryoballoon-based PVI approaches (Kuck et al., 2021; Wazni et al., 2021; Nielsen et al., 2017). Systematic review evidence has similarly reported superior maintenance of sinus rhythm with catheter ablation compared with antiarrhythmic drug therapy in non-paroxysmal AF, while studies evaluating ablation strategies consistently identify PVI as the foundation of contemporary AF ablation, with lower AF recurrence observed in approaches incorporating PVI (Sau et al., 2019; Nyong et al., 2016). Among individuals with symptomatic AF and heart failure with reduced ejection fraction, catheter ablation was associated with lower rates of death or hospitalization for worsening heart failure compared with medical therapy (28.5% vs. 44.6%; HR 0.62) (Marrouche et al., 2018). Similarly, evidence in individuals with hypertrophic cardiomyopathy (HCM) and AF demonstrates lower rates of heart failure hospitalization following catheter ablation compared with medical therapy alone (RR 0.37; 95% CI, 0.16-0.87) (Stabile et al., 2025). Additional evidence in athletic populations has demonstrated favorable rhythm-control outcomes, recurrence rates comparable to nonathletes, and preservation of exercise capacity following PVI (Mandsager et al., 2020). Overall, the literature demonstrates consistent reductions in AF recurrence and AF burden, with associated improvements in rhythm-control outcomes, symptom burden, and quality of life.

Repeat Cardiac Catheter Ablation of Atrial Fibrillation: Atrial fibrillation is a chronic, progressive disease, and recurrence after catheter ablation is common. Although catheter ablation is an established rhythm-control treatment, with approximately 60%-90% of individuals with symptomatic, drug-refractory AF experiencing improvement in arrhythmia burden, symptoms, or quality of life, it is not considered curative. Contemporary clinical trials have reported AF recurrence in approximately 22%-40% of individuals, with higher rates observed in those with persistent or long-standing persistent AF. Recurrent AF may contribute to persistent symptoms, reduced functional capacity, impaired quality of life, progression of atrial remodeling, and worsening heart failure. Risk of recurrence is higher among individuals with persistent AF, older age, structural heart disease, larger left atrial size, and more advanced atrial remodeling. Additional risk factors include obesity, obstructive sleep apnea, hypertension, diabetes mellitus, heart failure, and alcohol use (Brahier et al., 2024; Issa et al., 2024).

The mechanisms of recurrence vary according to timing following ablation. Early recurrence, generally occurring within the first three months after ablation (the post-ablation "blanking period"), may result from transient inflammatory changes, autonomic imbalance, or temporary recovery of electrical conduction across previously isolated pulmonary veins. In contrast, late recurrence is more commonly associated with durable pulmonary vein reconnection, progression of atrial cardiomyopathy, atrial fibrosis and remodeling, or development of new non-pulmonary vein triggers. Most recurrences occur within the first year after ablation and become less common several years after an initially successful procedure (Brahier et al., 2024; Issa et al., 2024).

Management of recurrent AF includes reassessment of modifiable risk factors, optimization of medical therapy, and consideration of repeat catheter ablation for individuals with recurrent symptomatic AF. Repeat procedures are generally considered safe but may increase cumulative exposure to procedural risks, including vascular complications, cardiac perforation, cardiac tamponade, pulmonary vein stenosis, and stiff left atrial syndrome. Current evidence suggests repeat catheter ablation may improve arrhythmia suppression, symptom control, and quality of life compared with antiarrhythmic drug therapy alone in some populations. However, uncertainty remains regarding patient selection, timing of repeat intervention, and the optimal lesion sets and procedural strategies beyond repeat pulmonary vein isolation. Additional randomized controlled trials with long-term follow-up are needed to better define the role of repeat catheter ablation and identify the individuals most likely to benefit (Brahier et al., 2024; Issa et al., 2024).

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Literature Review: Evidence evaluating repeat catheter ablation for recurrent atrial fibrillation (AF) includes systematic reviews and meta-analyses, randomized controlled trial follow-up analyses, and observational cohort studies. Available studies have examined freedom from recurrent atrial arrhythmias, pulmonary vein (PV) reconnection patterns, repeat intervention rates, hospitalizations, procedural complications, and long-term rhythm outcomes following repeat ablation. Comparisons have primarily focused on outcomes according to index ablation modality, PV reconnection status, and repeat-ablation strategy rather than direct comparisons with antiarrhythmic drug therapy alone. Overall, the available evidence supports repeat catheter ablation as an established treatment option for recurrent symptomatic AF, with studies demonstrating acceptable safety profiles and clinically meaningful rates of long-term rhythm control following repeat intervention (Hoevelmann et al., 2025; Müller et al., 2023; Kuck et al., 2019; Kuck et al., 2016).

Hoevelmann et al. (2025) conducted a systematic review and meta-analysis evaluating procedural findings and outcomes following first redo catheter ablation for recurrent atrial fibrillation (AF) and/or other atrial arrhythmias after prior AF ablation. Eligible studies included randomized controlled trials and cohort studies evaluating individuals undergoing a first redo ablation for recurrent AF and/or atrial arrhythmias after a prior AF ablation. Studies were required to report arrhythmia recurrence within 3-12 months following redo ablation and could also report outcomes including heart failure hospitalization, stroke/transient ischemic attack (TIA), and all-cause mortality. Studies were excluded if participants had not undergone a prior AF ablation, underwent repeat ablation within four weeks of the index pulmonary vein isolation (PVI) procedure, or if the redo ablation strategy was not reported. Letters, commentaries, editorials, narrative reviews, conference abstracts, case series, and case reports were also excluded. The analysis included 57 studies comprising 8243 participants, including 32 studies (n=4710) evaluating redo ablation for AF only and 25 studies (n=3533) evaluating redo ablation for AF with atrial flutter and/or atrial tachycardia. Median participant age was 61.1 years and 31.1% were female. Hypertension was the most common comorbidity (49.4%), followed by heart failure (12.0%), diabetes mellitus (11.1%), coronary artery disease (11.1%), and prior stroke/TIA (8.1%). More than two-thirds of participants underwent index ablation for paroxysmal AF (69.9%), and radiofrequency ablation (RFA) was used more commonly than cryoballoon ablation (CBA) during the initial procedure (61.4% vs. 36.2%). The median interval between the index and redo procedures was 5.6 months. Among studies evaluating AF recurrence after redo ablation, 66.7% of participants presented with paroxysmal AF and 31.7% with persistent AF at the time of repeat intervention. Pulmonary vein reconnection was identified in 81.9% of individuals undergoing redo ablation, with the right inferior pulmonary vein (43.9%) and left superior pulmonary vein (43.3%) demonstrating the highest reconnection rates. Pulmonary vein reconnection was less common among individuals who underwent initial CBA compared with initial RFA (72.3% vs. 85.9%). Redo procedures were performed using RFA in 95.4% of cases. The primary outcome was pooled prevalence of AF recurrence following first redo ablation. At a median follow-up of 11.5 months, AF recurrence occurred in 34.0% of participants among studies restricted to AF-only populations. Studies with a median interval of ≤12 months between the index and redo procedures reported lower AF recurrence rates than studies with longer intervals (25.5% vs. 33.9%). The pooled complication rate following redo ablation was 2.3%. Study limitations included substantial heterogeneity across studies, lack of participant-level data, variable rhythm-monitoring methods, limited head-to-head comparisons of redo strategies, inability to determine optimal management when pulmonary veins remained isolated, and predominance of participants with paroxysmal AF.

Müller et al. (2023) conducted a retrospective single-center cohort study evaluating pulmonary vein (PV) reconnection patterns, redo-ablation strategies, and long-term outcomes among individuals undergoing a first repeat catheter ablation for recurrent atrial fibrillation (AF) after an initially successful pulmonary vein isolation (PVI). 389 individuals undergoing a first redo ablation

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were included in the analysis. The mean age was 68 years, 57% were male, and 39% had paroxysmal AF. The median interval between the initial and repeat procedures was 40 ± 39 months. Prior ablation approaches included radiofrequency (RF) ablation using low-power long-duration ($n=178$), high-power short-duration ($n=96$), or very-high-power very-short-duration techniques ($n=4$), cryoballoon ablation using first-generation ($n=31$), second-generation ($n=17$), or third-generation systems ($n=37$), and surgical AF ablation ($n=26$). The primary endpoint was recurrence of any atrial tachyarrhythmia after a three-month blanking period. Follow-up consisted of serial 24-72 hour Holter monitoring and clinical evaluation, with a mean follow-up duration of 25 ± 20 months. At the time of repeat ablation, 325 of 389 individuals (84%) demonstrated reconnection of at least one pulmonary vein, with a mean of 2.0 ± 1.3 reconnected veins per individual. Reconnection rates differed according to the index ablation modality ($p=0.001$). Among individuals undergoing repeat ablation, cryoballoon-based approaches demonstrated a higher mean number of reconnected pulmonary veins compared with RF-based approaches ($p=0.002$). Reconnection was most frequently observed in the right inferior pulmonary vein (61%) and right superior pulmonary vein (59%). Additional left atrial low-voltage zones were identified in 58% of individuals. Following repeat ablation, 87% of individuals remained in sinus rhythm at three months, 73% remained in sinus rhythm at 12 months, and 67% remained in sinus rhythm after a mean follow-up of 25 ± 20 months. Long-term rhythm outcomes did not differ between individuals with and without pulmonary vein reconnection identified during the repeat procedure, with 67% of both groups remaining in sinus rhythm at the end of follow-up. Overall, the six repeat-ablation strategies evaluated were not significantly different with respect to AF recurrence during follow-up. Major complications occurred in 2.3% of individuals and included one pericardial tamponade, two strokes, two air emboli, one pacemaker lead dislodgement, and three vascular complications requiring surgery. Minor complications occurred in an additional 2.1% of individuals. In multivariable analysis, female sex ($p=0.007$) and higher CHA₂DS₂-VASc score ($p=0.028$) were independently associated with recurrent atrial tachyarrhythmia during follow-up. Study limitations include the retrospective observational design, single-center setting, heterogeneous study population, non-randomized selection of repeat-ablation strategies, and inclusion of individuals referred from multiple centers with varying initial ablation techniques.

Professional Societies/Organizations:

American College of Cardiology (ACC)/American Heart Association (AHA)/American College of Chest Physicians (ACCP)/Heart Rhythm Society (HRS) Guideline for the Diagnosis and Management of Atrial Fibrillation (Joglar et al., 2024)		
Recommendation	COR	LOE
8.1. Goals of Therapy With Rhythm Control		
In patients with reduced LV function and persistent (or high burden) AF, a trial of rhythm control should be recommended to evaluate whether AF is contributing to the reduced LV function.	I	B-R
In patients with symptomatic AF, rhythm control can be useful to improve symptoms.	IIa	B-R
In patients with a recent diagnosis of AF (<1 year), rhythm control can be useful to reduce hospitalizations, stroke, and mortality.	IIa	B-R
In patients with AF and HF, rhythm control can be useful for improving symptoms and improving outcomes, such as mortality and hospitalizations for HF and ischemia.	IIa	B-R
In patients with AF, rhythm-control strategies can be useful to reduce the likelihood of AF progression.	IIa	B-NR

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American College of Cardiology (ACC)/American Heart Association (AHA)/American College of Chest Physicians (ACCP)/Heart Rhythm Society (HRS) Guideline for the Diagnosis and Management of Atrial Fibrillation (Joglar et al., 2024)		
Recommendation	COR	LOE
In patients with AF where symptoms associated with AF are uncertain, a trial of rhythm control (eg, cardioversion or pharmacological therapy) may be useful to determine what if any symptoms are attributable to AF.	I Ib	C-LD
In patients with AF, rhythm-control strategies may be useful to reduce the likelihood of development of dementia or worsening cardiac structural abnormalities.	I Ib	B-NR
8.4. AF Catheter Ablation		
In patients with symptomatic AF in whom antiarrhythmic drugs have been ineffective, contraindicated, not tolerated or not preferred, and continued rhythm control is desired, catheter ablation is useful to improve symptoms.	I	A
In selected patients (generally younger with few comorbidities) with symptomatic paroxysmal AF in whom rhythm control is desired, catheter ablation is useful as first-line therapy to improve symptoms and reduce progression to persistent AF.	I	A
In patients with symptomatic or clinically significant atrial flutter (AFL), catheter ablation is useful for improving symptoms.	I	A
In patients who are undergoing ablation for AF, ablation of additional clinically significant supraventricular arrhythmias can be useful to reduce the likelihood of future arrhythmia.	IIa	B-NR
In patients (other than younger with few comorbidities) with symptomatic paroxysmal or persistent AF who are being managed with a rhythm-control strategy, catheter ablation as first-line therapy can be useful to improve symptoms.	IIa	B-R
In selected* patients with asymptomatic or minimally symptomatic AF, catheter ablation may be useful for reducing progression of AF and its associated complications. *Younger patients with few comorbidities and a moderate to high burden of AF or persistent AF and AFL.	I Ib	B-NR
8.4.2. Techniques and Technologies for AF Catheter Ablation		
In patients undergoing ablation for AF, pulmonary vein isolation (PVI) is recommended as the primary lesion set for all patients unless a different specific trigger is identified.	I	A
In patients undergoing ablation for AF, the value of other endpoints beyond PVI such as non-inducibility and ablation of additional anatomic ablation targets (eg, posterior wall sites, low voltage areas, complex fractionated electrograms, rotors) is uncertain.	I Ib	B-R
8.4.3. Management of Recurrent AF After Catheter Ablation		
In patients with recurrent symptomatic AF after catheter ablation, repeat catheter ablation or antiarrhythmic drug therapy is useful to improve symptoms and freedom from AF.	I	B-NR
9.2. Management of AF in Patients With HF		

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American College of Cardiology (ACC)/American Heart Association (AHA)/American College of Chest Physicians (ACCP)/Heart Rhythm Society (HRS) Guideline for the Diagnosis and Management of Atrial Fibrillation (Joglar et al., 2024)		
Recommendation	COR	LOE
In patients who present with a new diagnosis of HFrEF and AF, arrhythmia-induced cardiomyopathy should be suspected, and an early and aggressive approach to AF rhythm control is recommended.	I	B-NR
In appropriate patients with AF and HFrEF who are on guideline-directed management and therapy (GDMT), and with reasonable expectation of procedural benefit, catheter ablation is beneficial to improve symptoms, quality of life (QOL), ventricular function, and cardiovascular outcomes.	I	A
In appropriate patients with symptomatic AF and heart failure with preserved ejection fraction (HFpEF) with reasonable expectation of benefit, catheter ablation can be useful to improve symptoms and improve QOL.	IIa	B-NR
In patients with suspected AF-induced cardiomyopathy or refractory HF symptoms undergoing pharmacological rate-control therapy for AF, a stricter rate-control strategy (target heart rate <80 bpm at rest and <110 bpm during moderate exercise) may be reasonable.	IIb	B-NR
10.1. Management of Early Onset AF, Including Genetic Testing		
In patients with an onset of unexplained AF before 30 years of age, electrophysiological study to evaluate and treat reentrant supraventricular tachyarrhythmias with a targeted ablation may be reasonable because of the high prevalence of reentrant arrhythmias in this group.	IIb	B-NR
10.2. Athletes		
In athletes who develop AF, catheter ablation with pulmonary vein isolation (PVI) is a reasonable strategy for rhythm control because of its effectiveness and low risk of detrimental effect on exercise capacity.	IIa	B-NR
10.6. Wolff-Parkinson-White (WPW) and Preexcitation Syndromes		
For patients with AF with rapid anterograde conduction (preexcited AF), catheter ablation of accessory pathways (APs) is recommended.	I	B-NR
10.8. Adult Congenital Heart Disease (ACHD)		
In adults with congenital heart disease and symptomatic or hemodynamically significant paroxysmal or persistent AF, an initial strategy of rhythm control is recommended regardless of lesion severity as AF in this population is often poorly tolerated.	I	C-LD
In symptomatic patients with simple congenital heart disease with antiarrhythmic drug-refractory AF, it is reasonable to choose ablation over long-term antiarrhythmic therapies.	IIa	B-NR
In adults with congenital heart disease with AF undergoing pulmonary vein isolation (PVI), it may be reasonable to include an ablative strategy in the right atrium directed at reentrant arrhythmia secondary to atriotomy scars and the cavotricuspid isthmus (CTI).	IIb	C-LD
10.12. Pulmonary Disease		

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American College of Cardiology (ACC)/American Heart Association (AHA)/American College of Chest Physicians (ACCP)/Heart Rhythm Society (HRS) Guideline for the Diagnosis and Management of Atrial Fibrillation (Joglar et al., 2024)		
Recommendation	COR	LOE
In patients with pulmonary hypertension (PH) with pulmonary vascular disease and AF or atrial flutter (AFL), a rhythm control strategy is reasonable to improve functional status and potentially prolong survival.	IIa	B-NR
10.15. CKD and Kidney Failure		
Data on the management of AF in patients with CKD is limited because the major trials of rate control, rhythm control, and catheter ablation have generally not reported eGFR or CKD as a baseline variable or excluded such patients. Antiarrhythmic drug doses are adjusted based on pharmacokinetic data and clinical experience, with amiodarone being the only drug that does not require dose adjustment in patients with CKD or those receiving dialysis. Catheter ablation is feasible, although particular attention must be paid to fluid balance when using irrigated radiofrequency catheters.	n/a	n/a
Future Research Needs		
Standardization of ablation procedures: Great practice variation exists on how AF ablation procedures are performed, either as first or repeat procedures. Large registries and more data are required to better define standards of care in this field. Candidates for ablation: We must better identify clinical markers to better identify when catheter ablation is unlikely to benefit patients and define specific criteria for candidacy for first time and repeat procedures	n/a	n/a

American Heart Association (AHA)/American College of Cardiology (ACC)/American Medical Society for Sports Medicine (AMSSM)/Heart Rhythm Society (HRS)/Pediatric and Congenital Electrophysiology Society (PACES)/Society for Cardiovascular Magnetic Resonance (SCMR) Guideline for the Management of Hypertrophic Cardiomyopathy (Ommen et al., 2024)		
Recommendation	COR*	LOE*
Recommendations on AF 8.4 Management of Patients With HCM and AF		
6. In patients with HCM and symptomatic AF, as part of a AF rhythm control strategy, catheter ablation for AF can be effective when drug therapy is ineffective, contraindicated, or not the patient's preference	IIa	B-NR
7. In patients with HCM and AF who require surgical myectomy, concomitant surgical AF ablation procedure can be beneficial for AF rhythm control	IIa	B-NR

In 2022, the **AHA/ACC/Heart Failure Society of America (HFSA)** updated the Guideline for the Management of Heart Failure recommended that for patients with HF and symptoms caused by AF, AF ablation is reasonable to improve symptoms and QOL (Heidenreich et al. 2022).

Supraventricular Tachycardia (SVT)

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SVT is any tachycardia with atrial rates more than 100 beats/minute at rest and whose origin involves tissue from the His bundle or above. These SVTs include inappropriate sinus tachycardia, atrial tachycardia (AT) including focal and multifocal AT, macroreentrant AT (including typical atrial flutter), junctional tachycardia, atrioventricular nodal reentrant tachycardia (AVNRT), and various forms of accessory pathway-mediated reentrant tachycardias. These SVTs exclude atrial fibrillation (AF).

The etiology of SVT is usually nonspecific. However, precipitating factors (e.g., exercise, caffeine, cigarette consumption, relation to emotional upsets, and alcohol intake) should always be considered. The most common symptoms of SVT include heart palpitations, chest pain, lightheadedness, shortness of breath, and fainting. These symptoms are similar to those of panic and anxiety disorders, which can lead to misdiagnosis. Tests like electrocardiograms (ECG) and ambulatory heart monitors which measure the electrical impulses of the heart can help diagnose SVT. These tests can also help determine the type of SVT a patient has which is critical for determining a treatment plan. What makes diagnosing SVT difficult is that it usually occurs only in short periods of time and often an ECG of these periods is not available. Once an ECG is obtained, there are many types of SVT to consider.

Treatment for SVT varies from patient to patient. Treatment depends on several factors such as the type of SVT, the frequency and duration of SVT episodes, and the severity of symptoms. Treatment also depends on patient preferences. Treatment may include a "watch and wait" approach, vagal maneuvers, intermittent "pill-in-the-pocket" drug therapy, prolonged drug therapy, or procedures like catheter ablation. The goal of SVT treatment is to prevent abnormal heartbeats, minimize symptoms and reduce the risk of complications. It's important that patients are a part of the decision-making process when it comes to treatment.

An invasive electrophysiological (EP) study permits the precise diagnosis of the underlying arrhythmia mechanism, localization of the site of origin and provides definitive treatment if coupled with catheter ablation. Radiofrequency current is the most used energy source for SVT ablation. Cryoablation is used as an alternative to radiofrequency ablation to minimize injury to the AV node during ablation of specific arrhythmias. Selection of the energy source depends on operator experience, arrhythmia target location, and patient preference.

U.S. Food and Drug Administration (FDA): Catheter ablation is a procedure and, therefore, not subject to FDA regulation. Any medical devices, drugs, biologics, or tests used as a part of this procedure may be subject to FDA regulation.

Numerous radiofrequency ablation and cryoablation catheters have received FDA approval through the premarket application (PMA) process for treatment of arrhythmias.

Literature Review: The published evidence supporting transcatheter (radiofrequency) catheter ablation for supraventricular tachycardia (SVT) is substantial and spans more than three decades, including large multicenter registries, observational studies, and contemporary systematic reviews. Across both adult and pediatric populations, the literature consistently demonstrates high acute procedural success rates, generally exceeding 90% to 95%, with low rates of major complications for common SVT substrates including atrioventricular nodal reentrant tachycardia (AVNRT) and atrioventricular reentrant tachycardia (AVRT)/Wolff-Parkinson-White syndrome. Foundational pediatric registry data demonstrated acute success rates approaching 96%, with recurrence rates generally remaining low and varying by arrhythmia substrate and pathway location (Van Hare et al., 2004). More recent evidence continues to confirm these favorable outcomes, including a meta-analysis of over 6,000 pediatric patients reporting success rates of 98% for AVRT and 99% for AVNRT, with recurrence rates of 4% to 5% and complication rates of

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only 1% to 2% (Zhang and Yuan, 2025). Similarly, contemporary adult observational data demonstrate acute success rates exceeding 99% with complication rates below 1%, including among elderly patients (Chua et al., 2026). Collectively, the evidence consistently supports transcatheter ablation as a safe, highly effective, and durable treatment option for symptomatic SVT in both adults and children.

Professional Societies/Organizations: Professional society recommendations consistently support transcatheter catheter ablation as an established, effective, and often preferred treatment option for supraventricular tachycardia (SVT) across both adult and pediatric populations. The 2015 ACC/AHA/HRS guideline provides multiple Class I recommendations for catheter ablation as definitive therapy for symptomatic focal atrial tachycardia, atrioventricular nodal reentrant tachycardia (AVNRT), atrioventricular reentrant tachycardia (AVRT)/Wolff-Parkinson-White syndrome, and typical atrial flutter, citing large registry and observational data demonstrating acute success rates generally exceeding 90% to 95% with low complication rates. The guideline further identifies catheter ablation as a potentially curative therapy and, for many common SVT substrates, a first-line treatment that may eliminate the need for long-term antiarrhythmic drug therapy. Pediatric and congenital electrophysiology society guidance similarly supports catheter ablation for recurrent, drug-refractory, or symptomatic SVT, and as a definitive treatment option in appropriately selected children and adolescents. These recommendations are supported by extensive pediatric registry and observational data demonstrating high acute success rates, including reported success rates of approximately 94% for accessory pathways, 99% for AVNRT, and 93% for atrial tachycardia, with serious complications occurring infrequently. Additional consensus statements support catheter ablation for selected patients with congenital heart disease, asymptomatic but high-risk Wolff-Parkinson-White syndrome, and clinically significant supraventricular arrhythmias identified during other electrophysiologic procedures. Collectively, professional society guidance recognizes transcatheter ablation as a safe, highly effective, and frequently definitive treatment for SVT, with recommendations spanning a broad range of arrhythmia substrates and patient populations, including both adults and children.

American College of Cardiology/American Heart Association/Heart Rhythm Society: In 2015, the ACC/AHA/HRS updated the guideline for the management of adult patients with supraventricular tachycardia (Page, et al., 2016). The guideline is aimed at the adult population, ≥18 years of age, and offers no specific recommendations for pediatric patients. The guideline states that the recommendations for ongoing management, along with other recommendations and algorithms for specific SVTs, are meant to include consideration of patient preferences and clinical judgment; this may include consideration of consultation with a cardiologist or clinical cardiac electrophysiologist, as well as patient comfort with possible invasive diagnostic and therapeutic intervention. Recommendations for treatment options (including drug therapy, ablation, or observation) must be considered in the context of frequency and duration of the SVT, along with clinical manifestations, such as symptoms or adverse consequences (e.g., development of cardiomyopathy).

The guideline addresses the following evidence-based recommendations for catheter ablation:

Ongoing Management of Suspected Focal Atrial Tachycardia (AT)

- Catheter ablation is recommended in patients with symptomatic focal AT as an alternative to pharmacological therapy (Class I recommendation; Level of Evidence B-NR).

The guideline states that a large number of nonrandomized cohort studies on focal AT ablation have accumulated in the past two decades. In a 2012 ablation registry provided by 74 voluntary medical centers in Spain, AT was found in 333 of 11,042 of the ablation procedures performed. In

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experienced centers, when the AT can be induced in the laboratory, acute success rates above 90% to 95% have consistently been reported, with a complication rate of <1% to 2%.

Ongoing Management of Atrioventricular Nodal Reentrant Tachycardia (AVNRT)

- Catheter ablation of the slow pathway is recommended in patients with AVNRT (Class I recommendation; Level of Evidence B-NR).

The guideline states that catheter ablation of AVNRT is regarded as first-line therapy for treatment of symptomatic AVNRT. It is potentially curative and chronic pharmacological therapy is usually not needed after the procedure. Slow-pathway ablation, also called modification, is the preferred target during ablation of AVNRT. Large registry studies report the success rates of slow-pathway ablation to be >95%, with a <1% risk of AV block. Cryoablation of AVNRT is an alternative to radiofrequency ablation. Recent systematic reviews and trials randomizing patients to radiofrequency ablation versus cryoablation suggest an equivalent acute success rate, with a lower rate of AV block with cryoablation but a higher rate of recurrence during long-term follow-up with cryoablation.

- Oral verapamil or diltiazem is recommended for ongoing management in patients with AVNRT who are not candidates for, or prefer not to undergo, catheter ablation (Class I recommendation; Level of Evidence B-R).
- Oral beta blockers are recommended for ongoing management in patients with AVNRT who are not candidates for, or prefer not to undergo, catheter ablation (Class I recommendation; Level of Evidence B-R).
- Flecainide or propafenone is reasonable for ongoing management in patients without structural heart disease or ischemic heart disease who have AVNRT and are not candidates for, or prefer not to undergo, catheter ablation and in whom beta blockers, diltiazem, or verapamil are ineffective or contraindicated (Class IIa recommendation, Level of Evidence B-R).
- Clinical follow-up without pharmacological therapy or ablation is reasonable for ongoing management in minimally symptomatic patients with AVNRT (Class IIa recommendation, Level of Evidence B-NR).
- Oral sotalol or dofetilide may be reasonable for ongoing management in patients with AVNRT who are not candidates for, or prefer not to undergo, catheter ablation (Class IIa recommendation, Level of Evidence B-NR).
- Oral digoxin or amiodarone may be reasonable for ongoing treatment of AVNRT in patients who are not candidates for, or prefer not to undergo, catheter ablation (Class IIb recommendation, Level of Evidence B-R).
- Self-administered ("pill-in-the-pocket") acute doses of oral beta blockers, diltiazem, or verapamil may be reasonable for ongoing management in patients with infrequent, well-tolerated episodes of AVNRT (Class IIb recommendation, Level of Evidence C-D).

Ongoing Management of Orthodromic Atrioventricular Reentrant Tachycardia (AVRT)

- Catheter ablation of the accessory pathway is recommended in patients with AVRT and/or preexcited AF (Class I recommendation; Level of Evidence B-NR).

The guideline states that several large series support the use of catheter ablation of the accessory pathway as first-line therapy in patients who have had AF and/or AVRT. These series report a success rate of approximately 93% to 95% and a 3% risk of major complications when patients are followed up for six months to eight years. AF in younger patients is usually associated with the accessory pathway and is unlikely to occur after ablation; in contrast, older patients may have recurrence of AF from causes unrelated to the accessory pathway. Catheter ablation is also

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effective for treating permanent form of junctional reciprocating tachycardia (PJRT) by ablating the concealed accessory pathway with a success rate of approximately 90%. Catheter ablation of an atriofascicular (Mahaim) pathway is successful in preventing reentrant tachycardia in approximately 70% to 100% of patients.

- Oral beta blockers, diltiazem, or verapamil are indicated for ongoing management of AVRT in patients without pre-excitation on their resting ECG (Class I recommendation; Level of Evidence C-D).
- Oral flecainide or propafenone is reasonable for ongoing management in patients without structural heart disease or ischemic heart disease who have AVRT and/or pre-excited AF and are not candidates for, or prefer not to undergo, catheter ablation (Class IIa recommendation; Level of Evidence B-R).
- Oral dofetilide or sotalol may be reasonable for ongoing management in patients with AVRT and/or pre-excited AF who are not candidates for, or prefer not to undergo, catheter ablation (Class IIb recommendation; Level of Evidence B-R).
- Oral amiodarone may be considered for ongoing management in patients with AVRT and/or pre-excited AF who are not candidates for, or prefer not to undergo, catheter ablation and in whom beta blockers, diltiazem, flecainide, propafenone, and verapamil are ineffective or contraindicated (Class IIb recommendation; Level of Evidence B-R).
- Oral beta blockers, diltiazem, or verapamil may be reasonable for ongoing management of orthodromic AVRT in patients with pre-excitation on their resting ECG who are not candidates for, or prefer not to undergo, catheter ablation (Class IIb recommendation; Level of Evidence C-LD).
- Oral digoxin may be reasonable for ongoing management of orthodromic AVRT in patients without pre-excitation on their resting ECG who are not candidates for, or prefer not to undergo, catheter ablation (Class IIb recommendation; Level of Evidence C-LD).

Ongoing Management of Atrial Flutter

- Catheter ablation of the cavotricuspid isthmus (CTI) is useful in patients with atrial flutter that is either symptomatic or refractory to pharmacological rate control (Class I recommendation; Level of Evidence B-R).

The guideline states that rate control can be difficult to achieve in atrial flutter, and a rhythm control strategy is often chosen. Catheter ablation of CTI-dependent atrial flutter is often preferred to long-term pharmacological therapy; in this rhythm, the CTI represents the optimal target for ablation because a line of ablation between the tricuspid valve annulus and inferior vena cava can effectively interrupt the circuit.

- Catheter ablation is useful in patients with recurrent symptomatic non-CTI-dependent flutter after failure of at least 1 antiarrhythmic agent (Class I recommendation; Level of Evidence C-LD).

The guideline states that no prospective randomized controlled trials (RCTs) have compared the efficacy or safety of antiarrhythmic drugs with that of catheter ablation for non-CTI-dependent atrial flutter. In general, catheter ablation of non-CTI-dependent atrial flutter is more difficult than ablation of CTI-dependent flutter because the anatomic circuits are complex, are often not anatomically defined, and can be difficult to locate. Observational data support the relative effectiveness and safety of catheter ablation in experienced centers. Many of the atrial flutters that are observed during the first three months after catheter ablation or cardiac surgery will not persist beyond the periprocedural period, so attempts at ablation can be deferred unless pharmacological therapy and/or cardioversion are unsuccessful.

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- Catheter ablation is reasonable in patients with CTI-dependent atrial flutter that occurs as the result of flecainide, propafenone, or amiodarone used for treatment of AF (Class IIa recommendation, Level of Evidence B-R).

The guideline states that some patients with AF treated with propafenone, flecainide, or amiodarone will develop atrial flutter. In this circumstance, if flutter becomes the dominant arrhythmia, ablation of the CTI and continued use of the antiarrhythmic drug can decrease the incidence of atrial flutter and facilitate the pharmacological management of AF.

- Catheter ablation of the CTI is reasonable in patients undergoing catheter ablation of AF who also have a history of documented clinical or induced CTI-dependent atrial flutter (Class IIa recommendation, Level of Evidence C-LD).

The guideline states that when AF and atrial flutter coexist, one randomized study demonstrated that at one-year follow-up, greater success in terms of arrhythmia suppression and quality-of-life score resulted from AF ablation (with or without atrial flutter ablation) than from atrial flutter ablation alone. Possibly AF ablation alone is sufficient to control both arrhythmias, although CTI ablation reduced the early postablation arrhythmia recurrence rate

- Catheter ablation is reasonable in patients with recurrent symptomatic non-CTI-dependent flutter as primary therapy, before therapeutic trials of antiarrhythmic drugs, after carefully weighing potential risks and benefits of treatment options (Class IIa recommendation, Level of Evidence C-LD).

The guideline states that no prospective RCTs have compared the efficacy or safety of antiarrhythmic drugs with that of catheter ablation for non-CTI-dependent atrial flutter. Observational data, however, support the relative effectiveness and safety of catheter ablation in experienced centers. Many of the atrial flutters that are observed during the first three months after ablation or cardiac surgery will not persist beyond the periprocedural period, so attempts at ablation can be deferred unless attempts at pharmacological therapy or cardioversion are unsuccessful.

- Catheter ablation may be reasonable for asymptomatic patients with recurrent atrial flutter (Class IIb recommendation, Level of Evidence C-LD).

The guideline states that catheter ablation of atrial flutter is highly effective, with single-procedure success rates >90% and an excellent safety profile. In patients with recurrent atrial flutter, long-term maintenance of sinus rhythm is more likely with ablation than with pharmacological therapy. Also, ablation may avoid potential development of tachycardia-mediated cardiomyopathy.

Management of Asymptomatic Patients with Asymptomatic Pre-Excitation

- Catheter ablation of the accessory pathway is reasonable in asymptomatic patients with preexcitation if an EP study identifies a high risk of arrhythmic events, including rapidly conducting preexcited AF (Class IIa recommendation, Level of Evidence B-R^{SR}).

The guideline states that in a large prospective cohort study of 756 asymptomatic patients with close to eight years of follow-up, 9% of patients developed malignant AF (shortest R-R interval ≤ 250 ms), and 2% developed ventricular fibrillation. Malignant arrhythmias correlated more with high-risk EP properties of the accessory pathway than with the presence or absence of symptoms. Ablation of the accessory pathway(s) in high-risk patients was also examined in one RCT that enrolled 76 patients, showing that arrhythmic events (defined as symptomatic SVT, AF, and ventricular fibrillation in this study) occurred in 7% of patients who underwent ablation versus

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77% who did not undergo ablation. Another study that examined patients on the basis of whether an ablation was performed reported that none of the asymptomatic patients who had undergone ablation of the accessory pathway developed a malignant arrhythmia during eight years of follow-up. The risk of complications with ablation ranged from 0.1% (complete heart block) to 0.9% (ablation-induced right bundle-branch block). It is recommended that the risks and benefits of proceeding with ablation of pathways found not to have high-risk characteristics be discussed thoroughly with patients in advance of the EP procedure.

- Catheter ablation of the accessory pathway is reasonable in asymptomatic patients if the presence of pre-excitation precludes specific employment (such as with pilots) (Class IIa recommendation, Level of Evidence B-R^{SR}).

The guideline states that patients with asymptomatic pre-excitation whose job activities would place them or others at risk if a hemodynamically significant arrhythmia occurred (such as airline pilots) are potential candidates for catheter ablation. Catheter ablation is associated with a success rate of approximately 95% and a 3% risk of major complications when patients are followed up for six months to eight years. Other documents advise EP study in asymptomatic athletes who engage in moderate- or high-level competitive sports.

Ongoing Management of Junctional Tachycardia

- Catheter ablation may be reasonable in patients with junctional tachycardia when medical therapy is not effective or contraindicated (Class IIb recommendation, Level of Evidence C-LD).

The guideline states that radiofrequency ablation has been performed as a potentially curative therapy for junctional tachycardia since the early 1990s. However, in view of the reported 5% to 10% risk of AV block, catheter ablation is generally reserved for highly symptomatic patients in whom drug therapy has been ineffective or not tolerated. Many practitioners use cryoablation as an alternative to radiofrequency ablation. Given that it is often difficult to distinguish junctional tachycardia from AVNRT on the ECG, EP study with the goal of ablation may be a helpful diagnostic and potentially therapeutic intervention. Junctional tachycardia may be observed during and after slow pathway ablation of AVNRT, because of irritation of the compact AV node. This iatrogenic junctional tachycardia is transient and generally benign and can be distinguished from AVNRT through pacing maneuvers at EP study. It is crucial to recognize this phenomenon at the time of EP study because attempts to ablate the junctional tachycardia are unnecessary and could result in AV block.

Ongoing Management of SVT in Adult Congenital Heart Disease (ACHD) Patients

- Preoperative catheter ablation or intraoperative surgical ablation of accessory pathways or AT is reasonable in patients with SVT who are undergoing surgical repair of Ebstein anomaly (Class IIa recommendation, Level of Evidence B-R).

The guideline states that the prevalence of SVT among patients with Ebstein anomaly was 33% in one large series, the highest noted among ACHD patients, and increased with age. AT, atrial flutter, or AF develops in ≥50% of patients with Ebstein anomaly and significant tricuspid regurgitation. Right-sided accessory pathways are present in 15% to 30% of patients with Ebstein anomaly and may be multiple in up to ≥29% of those patients. Catheter ablation of accessory pathways in patients with Ebstein anomaly is associated with lower success rates than for other populations, acute success rate of 75% to 89% of procedures, with acute recurrence in 25% to 30%. In a series of 83 adults undergoing arrhythmia surgery at the time of surgical repair of Ebstein anomaly, accessory pathways were present in 32%, and atrial flutter/fibrillation was noted

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in 54% (483), with no recurrence of AP after surgery. Successful surgical ablation of accessory pathways has been reported in 92% to 100%. In a series of patients undergoing right atrial maze procedures or isthmus ablation for atrial flutter/fibrillation in association with repair of Ebstein anomaly, freedom from recurrent flutter/fibrillation was 75% during 34 months of follow-up. In a comparison study of combined operative arrhythmia surgery with repair, versus catheter ablation followed by surgical repair, the combined approach was effective in 94% of cases versus 76% of patients treated with the catheter approach alone. In a series of patients undergoing repair of Ebstein anomaly, patients who underwent preoperative EP study with intraoperative ablation of arrhythmia substrate had lower risk of SCD than patients without arrhythmia intervention. In patients with Ebstein anomaly undergoing planned surgical intervention, an integrated approach of arrhythmia intervention has been demonstrated to be safe and effective.

- Catheter ablation is reasonable for treatment of recurrent symptomatic SVT in ACHD patients (Class IIa recommendation, Level of Evidence B-NR).

The guideline states that multiple observational and multicenter studies have demonstrated acute success rates between 65% and 100% for treatment of SVT associated with ACHD. Acute success rates vary by tachycardia mechanism and type of congenital heart disease and repair. Success rates are highest for SVT associated with AVNRT (>80%), accessory pathways (75% to 89% among patients with Ebstein anomaly), or focal AT (80% to 100%). Success rates for catheter ablation of AT or atrial flutter are significantly lower than that reported in patients without ACHD, with overall 65% to 82% acute success in mixed anatomic substrates, but success rates have improved with advanced mapping and ablation techniques. Acute success rates in ablation of AT or atrial flutter varies significantly by type of congenital heart disease, ranging from 93% to 100% in patients with repaired ASD, 85% to 100% in atrial baffle repairs of transposition of the great arteries, and 54% to 75% of univentricular heart or Fontan repairs. Older age and presence of univentricular heart physiology was associated with decreased acute success rates in a series of 193 ablations of AT. Recurrent AT has been reported in 20% to 85% of patients during short-term follow-up, with development of AF reported in 7% to 30% of patients. Recurrent SVT may represent the same or a new reentrant circuit, and arrhythmia burden may be decreased by ablation procedures. Ablation procedures in patients with complex congenital heart disease are best performed in centers with advanced mapping techniques and expertise in congenital heart disease.

Ongoing Management of SVT in Pregnant Patients

- Catheter ablation may be reasonable in pregnant patients with highly symptomatic, recurrent, drug refractory SVT with efforts toward minimizing radiation exposure (Class IIb recommendation, Level of Evidence C-LD).

The guideline states that the risk of radiation exposure to the fetus is a concern with catheter ablation in pregnant patients, because high-dose ionizing radiation has been linked to excess malignancy and congenital malformations. The fetal radiation dose for most common cardiovascular interventions is not likely to exceed the 50-mGy negligible-risk threshold dose for excess malignancy. One study that used phantoms to simulate pregnancy estimated a low lifetime risk of malignancies from radiation exposure to the conceptus during a typical ablation procedure. With current technologies such as electro-anatomic mapping systems, catheter ablation procedures using minimal or even zero fluoroscopy have been described in pregnant women. It is recommended that if a catheter ablation procedure is required in a pregnant woman, radiation-reduction technologies should be used, and the procedure should be avoided in the first trimester when the teratogenic risk is greatest. Shielding the fetus by covering the mother with a lead apron does not eliminate radiation to the fetus because most of the radiation to the fetus comes from scatter.

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The guideline addresses the following evidence-based recommendations for acute treatment of SVT of unknown mechanism:

- Vagal maneuvers are recommended for acute treatment in patients with regular SVT (Class I recommendation, Level of Evidence B-R).
- Adenosine is recommended for acute treatment in patients with regular SVT (Class I recommendation, Level of Evidence B-R).
- Synchronized cardioversion is recommended for acute treatment in patients with hemodynamically unstable SVT when vagal maneuvers or adenosine are ineffective or not feasible (Class I recommendation, Level of Evidence B-NR).
- Synchronized cardioversion is recommended for acute treatment in patients with hemodynamically stable SVT when pharmacological therapy is ineffective or contraindicated (Class I recommendation, Level of Evidence B-NR).
- Intravenous diltiazem or verapamil can be effective for acute treatment in patients with hemodynamically stable SVT (Class IIa recommendation, Level of Evidence B-R).
- Intravenous beta blockers are reasonable for acute treatment in patients with hemodynamically stable SVT (Class IIa recommendation, Level of Evidence C-LD).

The guideline addresses the following evidence-based recommendations for ongoing management of SVT of unknown mechanism:

- Oral beta blockers, diltiazem, or verapamil is useful for ongoing management in patients with symptomatic SVT who do not have ventricular pre-excitation during sinus rhythm (Class I recommendation, Level of Evidence B-R).
- EP study with the option of ablation is useful for the diagnosis and potential treatment of SVT (Class I recommendation, Level of Evidence B-NR).
- Patients with SVT should be educated on how to perform vagal maneuvers for ongoing management of SVT (Class I recommendation, Level of Evidence C-LD).
- Flecainide or propafenone is reasonable for ongoing management in patients without structural heart disease or ischemic heart disease who have symptomatic SVT and are not candidates for, or prefer not to undergo, catheter ablation (Class IIa recommendation, Level of Evidence B-R).
- Sotalol may be reasonable for ongoing management in patients with symptomatic SVT who are not candidates for, or prefer not to undergo, catheter ablation (Class IIb recommendation, Level of Evidence B-R).
- Dofetilide may be reasonable for ongoing management in patients with symptomatic SVT who are not candidates for, or prefer not to undergo, catheter ablation and in whom beta blockers, diltiazem, flecainide, propafenone, or verapamil are ineffective or contraindicated (Class IIb recommendation, Level of Evidence B-R).
- Oral amiodarone may be considered for ongoing management in patients with symptomatic SVT who are not candidates for, or prefer not to undergo, catheter ablation and in whom beta blockers, diltiazem, dofetilide, flecainide, propafenone, sotalol, or verapamil are ineffective or contraindicated (Class IIb recommendation, Level of Evidence C-LD).
- Oral digoxin may be reasonable for ongoing management in patients with symptomatic SVT without preexcitation who are not candidates for, or prefer not to undergo, catheter ablation (Class IIb recommendation, Level of Evidence C-LD).

Class (Strength) of Recommendation:

- Class I (Strong) Benefit >>>>Risk
- Class IIa (Moderate) Benefit>>Risk
- Class IIb (Weak) Benefit > Risk
- Class III No Benefit (Moderate) Benefit=Risk

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- Class III Harm (Strong) Benefit>Risk

Level (Quality) of Evidence:

- Level A if the data were derived from high-quality evidence from more than one randomized clinical trial, meta-analyses of high-quality randomized clinical trials, or one or more randomized clinical trials corroborated by high-quality registry.
- Level B-R (Randomized) when data were derived from moderate quality evidence from one or more randomized clinical trials, or meta-analyses of moderate-quality randomized clinical trials.
- Level B-NR (Nonrandomized) was used to denote moderate-quality evidence from one or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies. This designation was also used to denote moderate-quality evidence from meta-analyses of such studies.
- Level C-LD (Limited Data) when the primary source of the recommendation was randomized or nonrandomized observational or registry studies with limitations of design or execution, meta-analyses of such studies, or physiological or mechanistic studies of human subjects.
- Level C-EO (Expert Opinion) was defined as expert opinion based on the clinical experience of the writing group.

Heart Rhythm Society (HRS); European Heart Rhythm Association (EHRA); European Cardiac Arrhythmia Society (ECAS) Asia Pacific Heart Rhythm Society (APHRS); Sociedad Latinoamericana de Estimulación Cardíaca y Electrofisiología (SOLAECE): The 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation addresses cavotricuspid isthmus ablation (Calkins, et al., 2017). The writing group recommendations state:

- If a patient has a history of typical atrial flutter or typical atrial flutter is induced at the time of AF ablation, delivery of a cavotricuspid isthmus linear lesion is recommended, (Class I, Level of Evidence B-R).
- the usefulness of linear ablation lesions in the absence of macroreentrant atrial flutter is not well established, (Class IIb, Level of Evidence C-LD).

Recommendations for AF Catheter Ablation

- In patients who are undergoing ablation for AF, ablation of additional clinically significant supraventricular arrhythmias can be useful to reduce the likelihood of future arrhythmia (Class 2a recommendation; Level of Evidence B-NR).

The guideline states that atrial fibrillation, particularly atrial flutter (AFL), can be associated with other atrial arrhythmias and that ablation of a previously documented or inducible sustained SVT or AFL is useful to reduce the likelihood of recurrent arrhythmias during an ablation for AF (Joglar, et al., 2024).

Pediatric and Congenital Electrophysiology Society (PACES) and the Heart Rhythm Society (HRS): In a 2016 expert consensus statement on the use of catheter ablation in children and patients with congenital heart disease (Saul, et al., 2016), the Pediatric and Congenital Electrophysiology Society (PACES) and the Heart Rhythm Society (HRS) stated that catheter ablation for SVT is generally considered after failure of pharmacotherapy or when medications cause intolerable side effects. In larger children/adolescents, ablation may also be offered as a definitive therapy to avoid chronic medication, or for recurrent/persistent SVT, even if medical therapy has not failed. In infants and small children, ablation is reserved for cases where medical therapy (including combinations) has failed or is not tolerated, or for life-threatening arrhythmias. Ablation is NOT recommended if SVT is well controlled with medical therapy and there are no

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intolerable side effects, especially in smaller patients. Saul, et al. provided the following points derived from prior registries, multicenter retrospective reports and a wide spectrum of non-registry, single center reports including case reports regarding the use of catheter ablation in the pediatric population:

- "Catheter ablation for pediatric patients with structurally normal hearts has an overall high acute success rate, varying from 87%–98%, depending on the mechanism and target site.
- Death is rare, and in most recent reports the rate appears to have decreased.
- Using RF energy, the risk of AV block for AVNRT ablation is approximately 1%, and for anterior and mid-septal pathways the risk is approximately 1%–3%.
- With cryoablation, permanent complete AV block has not been reported in the literature regarding children and adults.
- Serious complications continue to occur at a low rate (approximately 1%).
- There are no long-term outcome studies examining patients in adulthood after pediatric ablation; thus, concerns remain regarding scarring, late AV block development, latent coronary injury, and a small risk of malignancy secondary to radiation exposure.
- Recurrence continues to be a problem that might not have changed over time despite data showing improvements in acute procedural success rates over time."
- SVT success rates:
 - Accessory pathway: 94%
 - AVNRT: 99%
 - Atrial ectopic focus: 93%
 - Junctional ectopic tachycardia: 100%.

Pediatric and Congenital Electrophysiology Society (PACES)/ Heart Rhythm Society

(HRS): In 2012, the PACES and the HRS published an expert consensus statement on the management of the asymptomatic young patient with a Wolff-Parkinson-White (WPW, ventricular preexcitation) electrocardiogram pattern, which has been endorsed by the American College of Cardiology Foundation (ACCF), the American Heart Association (AHA), the American Academy of Pediatrics (AAP), and the Canadian Heart Rhythm Society (CHRS). For the specific purpose of this statement, the young patient is defined as being between 8 and 21 years of age, an age span routinely cared for by pediatricians and pediatric cardiologists and generally considered old enough to undergo exercise testing and catheter ablation if indicated.

Statements relevant to the use of catheter ablation include the following:

- Young patients with a shortest excited R-R interval (SPERRI) ≤ 250 ms in atrial fibrillation are at increased risk for SCD. It is reasonable to consider catheter ablation in this group, taking into account the procedural risk factors based on the anatomical location of the pathway (Class IIA, Levels of Evidence B/C).
- Young patients with a SPERRI ≥ 250 ms in atrial fibrillation are at lower risk for SCD, and it is reasonable to defer ablation (Class IIA, Level of Evidence C). Ablation may be considered in these patients at the time of diagnostic study if the location of the pathway and/or patient characteristics do not suggest that ablation may incur any increased risk of adverse events, such as AV block or coronary artery injury (Class IIB, Level of Evidence C).
- Young patients deemed to be at low risk might subsequently develop cardiovascular symptoms such as syncope or palpitations. These patients should then be considered symptomatic and may be eligible for catheter ablation procedures regardless of the prior assessment.
- Asymptomatic patients with a WPW ECG pattern and structural heart disease are at risk for both atrial tachycardia and AV reciprocating tachycardia, which may result in unfavorable hemodynamics. Ablation may be considered regardless of the anterograde characteristics of the accessory pathway (Class IIB, Level of Evidence C).

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- Asymptomatic patients with a WPW ECG pattern and ventricular dysfunction secondary to dyssynchronous contractions may be considered for ablation, regardless of anterograde characteristics of the bypass tract (Class IIB, Level of Evidence C).

Classification of Recommendations:

- Class I: Conditions for which there is evidence and/or general agreement that a given procedure or treatment plan is beneficial, useful, and effective
- Class II: Conditions for which there is conflicting evidence and/or divergence of opinion about the usefulness/efficacy of a procedure or treatment
- Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy
- Class IIb: Usefulness/efficacy is less well established by evidence/opinion
- Class III: Conditions for which there is conflicting evidence and/or general agreement that a procedure or treatment is not useful/effective and in some cases may be harmful

Level of Evidence:

- Level of Evidence A: Data derived from multiple randomized clinical trials or meta-analyses
- Level of Evidence B: Data derived from a single randomized trial or nonrandomized studies
- Level of Evidence C: Only consensus opinion of experts, case studies, or standard of care
- Level of Evidence D: Expert opinion without studies

Abnormal Ventricular Electrical Rhythms

As opposed to supraventricular tachycardias, ventricular arrhythmias arise in the ventricular myocardium or in the His-Purkinje tissue and produce wide complex tachycardias on an electrocardiogram. These ectopic, or non-sinus, depolarizations can produce premature ventricular complexes (PVCs), ventricular tachycardia (VT), or ventricular fibrillation (VF) the latter of which leads to immediate cardiac arrest. Ventricular arrhythmias are associated with caffeine, alcohol, nicotine, poor sleep, psychological stress, increased age, heart disease, genetic mutation, and myocardial infarction. They can present as palpitations, dizziness, syncope, shortness of breath, or sudden cardiac arrest. Advanced cardiac life support guidelines should be utilized for unstable episodes of VT and VF with an emphasis on prompt defibrillation and identifying and reversing any precipitating causes. Treatment options for stable VAs include antiarrhythmic drug therapy, catheter mapping and ablation, and implantable cardioverter-defibrillator (Garan, 2024; Goldberger, 2024).

U.S. Food and Drug Administration (FDA): Catheter ablation is a procedure and, therefore, not subject to FDA regulation. Any medical devices, drugs, biologics, or tests used as a part of this procedure may be subject to FDA regulation.

Numerous radiofrequency ablation and cryoablation catheters have received FDA approval through the premarket application (PMA) process for the treatment of arrhythmias.

Literature Review: There is a paucity of current, well-designed, peer-reviewed evidence evaluating the use of catheter ablation for the treatment of VAs.

Professional Societies/Organizations: Professional society guidance consistently recognizes transcatheter cardiac ablation as an established and important treatment option for the management of ventricular arrhythmias in adults, particularly for patients with symptomatic arrhythmias, arrhythmias refractory to medical therapy, or arrhythmias contributing to adverse clinical outcomes. The 2017 ACC/AHA/HRS guideline for the management of ventricular arrhythmias and prevention of sudden cardiac death states that catheter ablation is an important therapeutic option when antiarrhythmic medications are ineffective, not tolerated, or not desired by the patient and provides a Class I recommendation for catheter ablation in patients with

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frequent premature ventricular complexes (PVCs) associated with symptoms or declining ventricular function. The guideline also recognizes the association between high PVC burden and reversible PVC-induced cardiomyopathy. Similarly, the 2019 HRS/EHRA/APHRS/LAHRS expert consensus statement supports catheter ablation across a broad range of ventricular arrhythmias, particularly in patients with structural heart disease, symptomatic arrhythmias, or those with recurrent ventricular arrhythmias despite medical therapy. Collectively, contemporary professional society recommendations support transcatheter catheter ablation as an effective treatment strategy for reducing ventricular arrhythmia burden, improving symptoms, preventing arrhythmia-related deterioration in ventricular function, and reducing recurrent arrhythmic events in appropriately selected adult patients.

American College of Cardiology (ACC), American Heart Association (AHA), and Heart Rhythm Society (HRS): In a 2017 (reaffirmed 2023) guideline for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death (Al-Khatib, et al., 2017), the AHA, ACC, and HRS stated that “catheter ablation is an important treatment option for patients with VA when antiarrhythmic medications are ineffective, not tolerated, or not desired by the patient”. The authors also reported that “very frequent PVCs, 10,000 to 20,000 a day, can be associated with depressed LV function in some patients that is reversible with control of the PVCs, and has been referred to as PVC induced cardiomyopathy”. As a result, the following PVC specific recommendation was given:

- “For patients who require arrhythmia suppression for symptoms or declining ventricular function suspected to be due to frequent PVCs (generally 15% of beats and predominately of 1 morphology) and for whom antiarrhythmic medications are ineffective, not tolerated, or not the patient’s preference, catheter ablation is useful” (Class I recommendation; Level of Evidence: B-NR).

Heart Rhythm Society (HRS), European Heart Rhythm Association (EHRA), the Asia Pacific Heart Rhythm Society (APHRS), and the Latin American Heart Rhythm Society (LAHRS): A 2019 expert consensus statement on catheter ablation of ventricular arrhythmias from the HRS, EHRA, APHRS, and the LAHRS emphasized the importance of catheter ablation of VAs, particularly for those with structural heart disease and high-risk arrhythmias. The statement contains numerous condition specific recommendations supporting the use of catheter ablation for the treatment of VAs particularly when the VA has failed pharmacologic or medical therapy, is symptomatic, and/or to reduce the burden of arrhythmias and decrease the need for ICD shocks in individuals who are receiving ICD therapy. Specific to cardiomyopathy and PVCs, the authors stated that when the PVC burden is >15–25% of total beats and a comprehensive cardiac evaluation fails to identify alternate etiologies, PVC-induced cardiomyopathy should be suspected. Therefore, the following recommendation was given:

- “In patients with cardiomyopathy suspected to be caused by frequent and predominantly monomorphic PVCs and for whom AADs [antiarrhythmic drug] are ineffective, not tolerated, or not preferred for long-term therapy, catheter ablation is recommended” (Class I recommendation; LOE B-NR).

All of the recommendations are based on expert opinions, clinical experience, and data from peer-reviewed studies including randomized controlled trials, observational studies, and registries (Cronin, et al., 2020).

Any Other Indication

Inappropriate sinus tachycardia (IST)

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Inappropriate sinus tachycardia (IST) is a syndrome characterized by an abnormally elevated sinus heart rate, typically greater than 100 beats/min at rest or with minimal exertion and a mean 24-hour heart rate exceeding 90 beats/min, that is disproportionate to physiologic demands. Diagnosis occurs after exclusion of secondary causes such as anemia, thyrotoxicosis, fever, infection, volume depletion, pulmonary embolism, heart failure, stimulant use, anxiety, or drug withdrawal. The underlying pathophysiology remains incompletely understood, with proposed mechanisms including intrinsic sinus node hyperactivity and extrinsic autonomic or neurohormonal dysregulation. Patients commonly experience palpitations, breathlessness with minor activity, lightheadedness, chest pain, and fatigue, with heart rate increases often occurring gradually over seconds to minutes and triggered by minimal activity or positional changes. Although IST is not generally associated with adverse long-term prognosis and tachycardia-induced cardiomyopathy is exceedingly rare, the condition can have a substantial impact on quality of life and is frequently accompanied by significant psychosocial distress, particularly among the predominantly young female population in whom it occurs. Management focuses on patient education, reassurance, and supportive care, with lifestyle interventions such as exercise training and volume expansion often recommended. Pharmacologic therapy may include ivabradine, which has demonstrated safety and efficacy in reducing symptoms, either alone or in combination with beta-blockers; beta-blockers may also be used alone but can worsen fatigue and postural dizziness (Kalman and Sanders, 2026).

Literature Review: Rodríguez-Mañero et al. (2017) conducted a systematic review of nine studies involving 153 patients with drug-refractory inappropriate sinus tachycardia (IST) who underwent sinus node ablation or modification. While acute procedural success was reported in 88.9% of patients, symptomatic recurrence occurred in 19.6%, 29.8% of patients remained on antiarrhythmic drug therapy, and successful long-term outcomes were reported in 86.36% of patients at a mean follow-up of 28.14 ± 12.64 months. Procedure-related morbidity was notable, with severe complications reported in 8.5% of patients, including pericarditis, phrenic nerve paralysis, superior vena cava syndrome, cardiac tamponade, retroperitoneal bleeding, arteriovenous fistula, and right ventricular puncture. Permanent pacemaker implantation was required in 9.8% of patients. The authors highlighted important limitations of the evidence base, including small study populations, heterogeneous techniques and outcome measures, variable follow-up durations, and reliance on subjective symptom improvement. The available literature consisted primarily of small observational studies without randomized controlled trials. Overall, the review suggests that although transcatheter ablation may achieve short-term heart rate reduction in selected patients with IST, recurrence remains common and clinically significant complications may occur. The evidence base is limited by an overall paucity of well-designed, high-quality studies, making it difficult to establish the long-term safety, effectiveness, and net health benefit of transcatheter ablation for the treatment of IST (Rodríguez-Mañero, et al., 2016).

Professional Societies: The 2015 Heart Rhythm Society Expert Consensus Statement does not support transcatheter ablation as routine treatment for inappropriate sinus tachycardia (IST). The guideline assigns sinus node modification, surgical ablation, and sympathetic denervation a Class III recommendation (not recommended) for routine care of patients with IST, reflecting a determination that risks outweigh potential benefits or that there is no established net benefit. The expert panel noted that there are no long-term, prospective, placebo-controlled clinical trials demonstrating substantial improvement in outcomes for any therapeutic intervention in IST, and that symptoms may persist despite control of heart rate. Available data evaluating sinus node modification or ablation demonstrate that although initial procedural success can be achieved, there is a high rate of symptom recurrence, significant procedural complications, and no evidence of sustained symptomatic improvement over several years. Reported complications include permanent pacemaker requirement, transient or permanent phrenic nerve paralysis, and superior vena cava syndrome. The consensus statement further highlights uncertainty regarding the optimal ablation approach and emphasizes the young age of many affected patients and the

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invasive nature of the procedure. As a result, the authors conclude that transcatheter ablation should not be part of routine care for IST and should be considered only in highly selected circumstances or within research protocols. Overall, the guideline reflects a lack of robust, high-quality evidence supporting the long-term safety, effectiveness, and net health benefit of transcatheter ablation for the treatment of IST (Sheldon, et al., 2015).

Premature Atrial Contraction (PAC)

According to Zimetbaum and Goldman, atrial premature beats (APBs), also referred to as premature atrial contractions (PACs), are early atrial depolarizations that may originate from the right atrium, left atrium, or pulmonary veins. The ectopic atrial impulse produces a premature P wave that differs from the sinus P-wave morphology unless it arises near the sinus node and typically precedes the QRS complex. PACs represent supraventricular ectopy and may occur as isolated events or in association with other atrial arrhythmias. PACs are most commonly asymptomatic, although some individuals experience palpitations. Diagnosis is typically established using an electrocardiogram (ECG), ambulatory Holter monitoring, or an event recorder. While generally considered a benign finding, very frequent PACs have been associated with an increased risk of atrial fibrillation and other serious atrial arrhythmias and are also associated with an increased long-term risk of stroke and cardiovascular disease. Management of PACs is generally conservative. Treatment is not typically required unless PACs are associated with significant symptoms. When therapy is warranted for symptom relief, treatment consists primarily of beta blockers or calcium-channel blockers (Zimetbaum and Goldman, 2024).

Literature Review: There is insufficient evidence in the published peer-reviewed medical literature to assess the safety and efficacy of transcatheter ablation for the treatment of PACs. The available evidence is primarily limited to a small, single-center observational study without a control group, including a study of 43 patients with structurally normal hearts, limiting generalizability and increasing the potential for selection bias. In addition, the current evidence base lacks randomized controlled trials, comparative studies, and long-term outcome data, and it remains unclear whether ablation of PACs improves clinically meaningful outcomes beyond symptom relief or prevents progression to sustained atrial arrhythmias (He, et al., 2022).

He et al. (2022) conducted an observational study evaluating the feasibility, safety, and efficacy of electrophysiological mapping and radiofrequency catheter ablation (RFCA) for isolated frequent symptomatic premature atrial contractions (PACs) in patients with structurally normal hearts. Forty-three consecutive patients with frequent, symptomatic, and drug-refractory PACs were enrolled. Patients with atrial tachycardia (≥ 5 atrial beats), atrial flutter, atrial fibrillation, or structural heart disease were excluded. Indications for RFCA included suspected PAC-induced cardiomyopathy, ineffective or intolerable antiarrhythmic drug therapy, or a PAC burden exceeding 10,000 PACs per 24 hours. All patients underwent successful electrophysiological mapping and RFCA without reported complications. The primary outcomes included procedural success, recurrence of PACs, and reduction in PAC burden, while quality of life assessed by the SF-36 questionnaire was evaluated as a secondary outcome. During a follow-up period of 15 ± 8 months, PAC recurrence was observed in 2 patients. At 3 months following ablation, the mean PAC number was 396 per 24 hours and the mean PAC burden was 0.5%, both significantly reduced compared with baseline ($p < 0.05$). Quality-of-life scores also improved significantly across all measured domains (all $p < 0.05$). Author noted study limitations included the observational design, lack of comparison with alternative mapping approaches, exclusion of patients with sustained atrial tachyarrhythmias, limited sample size, and potential effects of isoproterenol on arrhythmia induction and patient selection. The authors concluded that RFCA was feasible, safe, and effective for eliminating isolated frequent symptomatic drug-refractory PACs and significantly improved symptoms and quality of life.

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Professional Societies: There is a lack of professional society guidance addressing transcatheter cardiac ablation for the treatment of PACs.

Asymptomatic Atrial Fibrillation

Asymptomatic atrial fibrillation (AF) presents unique considerations when evaluating the role of catheter ablation because the established benefits of rhythm-control therapy are primarily related to improvements in symptoms, AF burden, and quality of life. While restoration and maintenance of sinus rhythm may theoretically reduce the risks of AF progression, heart failure, stroke, and mortality, evidence more consistently demonstrates improvements in rhythm-control outcomes and quality of life than reductions in major clinical outcomes. Consequently, the primary justification for catheter ablation in contemporary clinical practice remains the treatment of symptomatic AF (Issa et al., 2024). Nevertheless, the optimal management of asymptomatic AF remains an area of ongoing debate. Emerging data suggest that some individuals with asymptomatic AF may experience rates of disease progression and adverse cardiovascular outcomes comparable to those observed in symptomatic populations, raising questions regarding whether symptom status alone should determine candidacy for rhythm-control interventions. At present, the potential benefits, risks, and long-term clinical impact of catheter ablation in asymptomatic AF continue to be evaluated (Schiavone and Di Biase, 2026).

Literature Review: Willems et al. (2022) conducted an analysis of the randomized, multicenter EAST-AFNET 4 trial evaluating whether the effect of early rhythm-control therapy differed between asymptomatic and symptomatic individuals with recently diagnosed atrial fibrillation (AF) and concomitant cardiovascular conditions. Participants were categorized by baseline European Heart Rhythm Association (EHRA) score, with EHRA I defined as asymptomatic and EHRA II-IV defined as symptomatic. The analysis included 2633 participants; 801 (30.4%) were asymptomatic and 1832 (69.6%) were symptomatic. Among asymptomatic participants, 395 were randomized to early rhythm control and 406 to usual care. Early rhythm control included antiarrhythmic drug therapy or AF ablation, while usual care included rhythm-control therapy directed at AF-related symptoms. The primary outcome was a composite of cardiovascular death, stroke, or hospitalization for worsening heart failure or acute coronary syndrome, analyzed as a time-to-event outcome. Secondary outcomes included nights spent in the hospital, rhythm status, change in symptoms, left ventricular function, quality of life, and safety outcomes. At baseline, asymptomatic participants had a mean age of 71.3 years, 37.5% were women, mean CHA₂DS₂-VASc score was 3.4, and 21.1% had heart failure. Rhythm-control therapy was initiated in 95.7% of asymptomatic participants randomized to early rhythm control, with AF ablation performed in 75 of 395 (19.0%) asymptomatic participants by 24 months. Among asymptomatic participants, the treatment effect of early rhythm control was similar to that observed in symptomatic participants, with a lower rate of the primary outcomes of cardiovascular death, stroke, or hospitalization for worsening heart failure or acute coronary syndrome compared with usual care (HR 0.76; 95% CI, 0.57-1.03). At 24 months, sinus rhythm was present in 78.9% of asymptomatic participants assigned to early rhythm control compared with 52.3% assigned to usual care. Safety outcomes were similar between asymptomatic and symptomatic participants, although serious adverse events related to rhythm-control therapy were more common in the early rhythm-control group than in the usual-care group. Study limitations include that the analysis was not powered to independently evaluate asymptomatic participants and that early rhythm-control therapy primarily consisted of antiarrhythmic drug treatment, with catheter ablation performed in a minority of participants.

Kawaji et al. (2022) conducted a post hoc subgroup analysis of a previously reported risk-matched cohort study comparing catheter ablation with conservative management in individuals with atrial fibrillation (AF). Among 4398 individuals with AF, 537 matched pairs were identified based on age, sex, date of first AF diagnosis, AF type, European Heart Rhythm Association (EHRA) symptom

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grade, and history of heart failure. Participants were stratified according to symptom status and the presence or absence of prior AF-related complications, defined as ischemic stroke or heart failure hospitalization. The primary outcome was a composite of cardiovascular death, heart failure hospitalization, ischemic stroke, or major bleeding. Of 1074 matched individuals, 414 (38.5%) were asymptomatic and 660 were symptomatic. Among asymptomatic individuals, 207 underwent catheter ablation and 207 received conservative management. Median follow-up was 5.3 years. Catheter ablation was associated with a lower incidence of major adverse cardiovascular outcomes, including cardiovascular death, heart failure hospitalization, ischemic stroke, and major bleeding, compared with conservative management among asymptomatic individuals overall ($p=0.009$). In subgroup analysis, this association remained significant among asymptomatic individuals with prior AF-related complications (e.g., previous ischemic stroke or heart failure hospitalization) ($p=0.03$) but not among those without prior AF-related complications ($p=0.11$). Rates of recurrent atrial tachyarrhythmia after the first ablation procedure were similar between asymptomatic and symptomatic individuals, although long-term arrhythmia-free survival after the final ablation procedure was lower among asymptomatic individuals ($p=0.002$). Study limitations include the post hoc subgroup design, residual differences between treatment groups despite matching, differences in follow-up between treatment groups, and limited sample size.

There is insufficient evidence in the published medical literature to demonstrate the safety and effectiveness of catheter ablation for the treatment of asymptomatic atrial fibrillation.

Additional Ablation of a Separate and Distinct Arrhythmogenic Mechanism

Additional ablation of a separate and distinct arrhythmogenic mechanism is intended to treat a newly identified spontaneous or inducible arrhythmia discovered during an electrophysiology study or ablation procedure. When a second arrhythmia requiring treatment is not identified, the clinical basis for performing an additional ablation is not established. Therefore, ablation of an additional arrhythmogenic mechanism in the absence of a documented second arrhythmia is considered not medically necessary.

Vein of Marshall alcohol ablation (VOM ethanol infusion)

Although pulmonary vein isolation (PVI) remains the cornerstone of catheter ablation for atrial fibrillation (AF), additional sources of abnormal electrical activity outside the pulmonary veins may contribute to AF recurrence in some individuals. The Vein of Marshall, a small vein located along the outer surface of the left atrium near the left-sided pulmonary veins and coronary sinus, has been identified as a potential source of electrical triggers and autonomic nerve signals that may contribute to the development and maintenance of AF. These observations have led to investigation of ethanol infusion into the Vein of Marshall (EIVOM), an adjunctive catheter-based technique in which alcohol is delivered into the vein to create a controlled area of tissue injury (chemical ablation) and interrupt abnormal electrical pathways that may not be fully addressed by conventional catheter ablation alone. EIVOM has been studied primarily in individuals with persistent AF and recurrent atrial arrhythmias. Rare but potentially life-threatening adverse events have been reported, including pericardial effusion, cardiac tamponade, stroke or transient ischemic attack (TIA), atrioventricular block, sinus node dysfunction, coronary vasospasm, hemodynamic collapse, and procedure-related death (Mendonça et al., 2026; De Becker et al., 2025).

U.S. Food and Drug Administration (FDA): Ethanol used during Vein of Marshall alcohol ablation is supplied as dehydrated alcohol, a drug regulated by the FDA and approved through the New Drug Application (NDA) pathway. ABLYSINOL® (dehydrated alcohol; NDA 207987) was approved on June 21, 2018, as an ablative agent to induce a controlled cardiac septal infarction and improve exercise capacity in adults with symptomatic hypertrophic obstructive

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cardiomyopathy who are not candidates for surgical myectomy. Additional dehydrated alcohol products have subsequently been approved as therapeutic equivalents (NDAs 217845, 219400, 219444, and 219569). FDA-approved labeling for these products does not include treatment of atrial fibrillation or ethanol infusion into the Vein of Marshall (EIVOM) (FDA, 2025).

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

Literature Review: Published evidence evaluating vein of Marshall ethanol infusion (EIVOM) as an adjunct to catheter ablation for persistent atrial fibrillation consists of systematic reviews and meta-analyses, randomized controlled trials (RCTs), retrospective comparative studies, cohort studies, and review articles. Most studies compare pulmonary vein isolation (PVI) combined with EIVOM to conventional catheter ablation strategies, including PVI alone or PVI with additional ablation lesion sets. Systematic reviews and meta-analyses have reported improved freedom from atrial fibrillation recurrence, higher rates of mitral isthmus block, and fewer repeat ablation procedures with EIVOM-based strategies compared with conventional ablation approaches. However, available evidence remains limited by procedural heterogeneity, variable rhythm-monitoring protocols, relatively short follow-up durations, and inclusion of observational data. Further high-quality studies with longer-term follow-up and standardized procedural approaches are needed to better define the safety, effectiveness, and clinical role of EIVOM for the treatment of persistent atrial fibrillation (Bola et al., 2026; Mendonça et al., 2026; Valderrábano et al., 2020).

Bola et al. (2026) conducted a systematic review and meta-analysis of five randomized controlled trials (RCTs) evaluating ethanol infusion of the vein of Marshall (EIVOM)-based strategies compared with non-EIVOM pulmonary vein isolation (PVI)-based ablation strategies in individuals with symptomatic persistent atrial fibrillation (AF). Eligible studies included adults with symptomatic persistent AF. Studies limited to paroxysmal AF, pediatric populations, preclinical or animal studies, surgical or hybrid thoracoscopic ablation, observational studies, case series, editorials, narrative reviews, and in vitro studies were excluded. The intervention was catheter-based PVI with adjunctive EIVOM during the index ablation procedure; additional linear lesion sets were permitted. The comparator was PVI alone using radiofrequency or cryothermal energy, with empirical linear lesions permitted if EIVOM was not performed. The primary efficacy outcomes were freedom from any atrial arrhythmia, freedom from AF recurrence, and freedom from atrial tachycardia/atrial flutter (AT/AFL) at 12 months. Secondary procedural outcomes included procedure time, fluoroscopy time, radiofrequency ablation time, acute bidirectional MI block, and repeat ablation. Safety outcomes included any procedure-related complication, major complications, pericardial effusion or pericarditis, and cardiac tamponade. Five RCTs with 1179 participants were included; 602 received EIVOM-based ablation and 577 received PVI-based control ablation. The overall mean age was 63.2 years, 74.1% were male, mean left atrial diameter was 44.2 mm, and average known AF duration before the procedure was 16.4 months. EIVOM-based strategies were associated with greater freedom from any atrial arrhythmia at 12 months compared with control ablation ($p < 0.001$). EIVOM-based strategies were also associated with greater freedom from AF recurrence ($p < 0.001$). Time-to-event analysis also favored EIVOM-based strategies for reduction in any atrial arrhythmia recurrence over 12 months ($p = 0.003$). EIVOM-based strategies reduced repeat ablation procedures compared with control ablation (7.13% vs 13.50%; $p = 0.009$). Any complication was numerically higher with EIVOM but was not statistically significant, and major complications were not statistically different between groups. Limitations included the small number of RCTs, procedural heterogeneity, nonuniform rhythm monitoring, open-label study designs, and follow-up limited to 12 months.

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In addition to the RCT-only review by Bola et al., Mendonça et al. (2026) conducted a broader systematic review and meta-analysis of 15 studies (four randomized controlled trials [RCTs] and 11 cohort studies) comparing ethanol infusion in the vein of Marshall (EIVOM) plus catheter ablation with catheter ablation alone for atrial fibrillation (AF). Excluded studies comprised qualitative studies, conference abstracts, reviews, editorials, expert opinions, case reports, case series, reflective articles, and studies lacking a comparator group. 3507 participants (n=69–560 per study; mean age 64.07 ± 9.57 years; 73.25% male) were included in the analysis with 1971 participants undergoing radiofrequency (RF) ablation alone, and 1536 participants treated with EIVOM. Most participants had persistent AF, preserved left ventricular ejection fraction (mean $>50\%$), and moderately enlarged left atrium (mean diameter between 42 and 49 mm). Hypertension and diabetes mellitus were the most common comorbidities, while coronary artery disease and prior stroke were less frequent. The mean CHA₂DS₂-VASc score ranged from 1.3 to 3.0. Outcomes included MI block rates, recurrence of AF and AT, fluoroscopy time, complication rates, total procedure time, MI reconnection, and unsuccessful vein of Marshall cannulations. Additional procedural factors included the volume of ethanol administered ($\leq 5\text{mL}$ vs $>5\text{mL}$) and the sequence of intervention (ethanol infusion followed by ablation vs ablation followed by ethanol infusion). Follow-up was most often 12 months, with some studies reporting longer follow-up up to approximately 3 to 4 years. EIVOM plus catheter ablation was associated with higher mitral isthmus (MI) block rates than ablation alone ($p<0.001$) and lower AF/atrial tachycardia (AT) recurrence ($p<0.001$). In a time-to-event analysis from five studies, the pooled hazard ratio for AF/AT recurrence was not statistically significant. In subgroup analyses, individuals who received a $\geq 5\text{ mL}$ of ethanol had more apparent benefit for MI block and AF/AT recurrence, and EIVOM before RF was associated with higher MI block rates; however, procedural sequence did not significantly affect AF/AT recurrence. MI reconnection was numerically lower with EIVOM but was not statistically different. Complication rates were not statistically different between groups. Study limitations include heterogeneity in participant populations, variation in procedural protocols, inclusion of observational and nonrandomized studies, and limited long-term durability data.

Valderrábano et al. (2020) conducted a randomized controlled trial that assessed if adding vein of Marshall ethanol infusion to the catheter ablation procedure reduced the recurrence of atrial fibrillation in individuals with persistent atrial fibrillation (VENUS trial). Adults aged 18–85 years with symptomatic persistent AF (sustained AF lasting $> 7\text{days}$) refractory to at least one antiarrhythmic agent were included in the study. No health disparities were identified by the investigators. Participants (n=343) were randomly assigned in a 1:1.15 ratio to accommodate for 15% technical vein of Marshall ethanol infusion failures to catheter ablation alone (n=158) or catheter ablation combined with vein of Marshall ethanol infusion (n=185). The primary outcome was freedom from AF or atrial tachycardia for longer than 30 seconds after a single procedure, without antiarrhythmic drugs, at both six and 12 months. There were 12 secondary outcomes included that measured AF burden, freedom from AF after multiple procedures, perimitral block, and others. Clinical assessments and 12-lead electrocardiograms were obtained at baseline and at one, three, six, nine and 12 months after the initial ablation. Additionally, participants underwent continuous one month monitoring (MediLynx) at six and 12 months after ablation. Of the 343 randomized participants, 316 (92.1%) completed the trial and adherence to the 30-day event monitor at six and 12 months was 85.1% and 83.3%, respectively. Catheter ablation with vein of Marshall ethanol infusion, compared with catheter ablation alone, resulted in freedom from atrial fibrillation or prolonged atrial tachycardia in 49% vs 38% at both six and 12 months, a difference that was statistically significant ($p=0.04$). Of the 12 secondary outcomes, nine were not significantly different, but AF burden ($p=0.01$), freedom from AF after multiple procedures ($p=0.04$), and success achieving perimitral block ($p<0.001$) were significantly improved in vein of Marshall-treated patients. Adverse events were similar between groups. The authors noted several limitations which include potential investigator bias in the catheter ablation group, the vein of Marshall ethanol infusion procedure was not completed in all participants randomized to it, adherence to monitoring was incomplete and the primary outcome could not be ascertained in 27

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participants because of lacking monitoring data and ten participants had repeat procedures performed during the blanking period. Additional limitations include the small participant population, short term follow-up and included over 90% of white individuals and the results may not be applicable to other races or ethnic groups. Authors concluded that among individuals with persistent AF, addition of vein of Marshall ethanol infusion to catheter ablation, compared with catheter ablation alone, increased the likelihood of remaining free of AF or atrial tachycardia at six and 12 months. However, further research is needed to assess longer-term efficacy.

Professional Societies/Organizations: Current professional society recommendations regarding Vein of Marshall (VoM) ethanol infusion for the treatment of persistent atrial fibrillation are limited. Available guidance consists primarily of clinical practice guidelines and expert consensus statements that evaluate contemporary evidence from randomized controlled trials, observational studies, and expert consensus regarding adjunctive ablation strategies. Professional societies recognize VoM ethanol infusion as an emerging adjunctive technique that may facilitate mitral isthmus block and improve selected rhythm-control outcomes in some individuals with persistent atrial fibrillation. However, professional societies generally note that the available evidence remains limited, procedural approaches are heterogeneous, and the incremental benefit of VoM ethanol infusion beyond standard pulmonary vein isolation (PVI) has not been clearly established (Joglar et al., 2024; Tzeis et al., 2024).

American College of Cardiology (ACC)/American Heart Association (AHA)/American College of Chest Physicians (ACCP)/Heart Rhythm Society (HRS): In section 8.4.2, Techniques and Technologies for AF Catheter Ablation, the 2024 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation recommends pulmonary vein isolation (PVI) as the primary lesion set for atrial fibrillation catheter ablation. The guideline states that the value of additional anatomic ablation targets beyond PVI remains uncertain and notes that multiple adjunctive targets, including the ligament of Marshall, have been evaluated in randomized controlled trials and observational studies with mixed results. No broadly applicable adjunctive ablation strategy is recommended, and the guideline does not provide a specific recommendation supporting routine use of Vein of Marshall ethanol infusion during atrial fibrillation ablation (Joglar et al., 2024).

European Heart Rhythm Association (EHRA)/Heart Rhythm Society (HRS)/Asia Pacific Heart Rhythm Society (APHRS)/Latin American Heart Rhythm Society (LAHRS): The 2024 EHRA/HRS/APHRS/LAHRS expert consensus statement on catheter and surgical ablation of atrial fibrillation discusses vein of Marshall (VoM) ethanol infusion as an adjunctive ablation strategy for persistent atrial fibrillation that may facilitate achievement of mitral isthmus block during catheter ablation. The consensus statement summarizes evidence from the VENUS randomized controlled trial, which demonstrated improved arrhythmia-free survival with adjunctive VoM ethanol infusion, but notes that the study incorporated multiple additional lesion sets and a nonstandardized ablation approach, making it difficult to determine the independent effect of VoM ethanol infusion. The document also references observational data supporting the Marshall-PLAN approach. The writing group concludes that, although available data are encouraging, the benefit of VoM ethanol infusion when added to pulmonary vein isolation (PVI) alone has not yet been established (Tzeis et al., 2024).

There is insufficient evidence in the published medical literature to demonstrate the safety and effectiveness of Vein of Marshall alcohol ablation (VOM ethanol infusion) for the treatment of atrial fibrillation.

Cardio-neuroablation (CNA)

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Cardioneuroablation is a transcatheter electrophysiologic procedure that targets autonomic ganglionated plexi within the atria to reduce excessive parasympathetic (vagal) input to the heart. The procedure is intended to treat selected patients with cardioinhibitory reflex syncope or functional bradyarrhythmias by modifying autonomic regulation of the sinus and/or atrioventricular nodes (Aksu, et al., 2024).

Literature Review: There is insufficient evidence in the published peer-reviewed scientific literature to support the safety and efficacy of CNA for any indication. Studies primarily include retrospective, open label, patient cohorts, and a single RCT with short-term follow-ups, small patient populations, and heterogenous patient populations and treatment parameters (Pachon, et al., 2023; Piotrowski, et al., 2023; Aksu, et al., 2021; Gorev, et al., 2021; Hu and Yao, 2020; Debruyne, et al., 2018; Aksu, et al., 2016; Pachon, et al., 2011).

Professional Societies/Organizations

European Heart Rhythm Association (EHRA), the Heart Rhythm Society (HRS), the Asia Pacific Heart Rhythm Society (APHRS) and the Latin American Heart Rhythm Society (LAHRS): In a 2024 scientific statement on CNA for the treatment of reflex syncope and functional bradyarrhythmias, the EHRA, HRS, APHRS and LAHRS stated that strong recommendations on the use of CNA cannot be made because there is a lack of well-designed randomized and sham-controlled clinical trials evaluating the safety and efficacy of this technology (Aksu, et al., 2024).

Active Esophageal Cooling Device

Thermal injury to the esophagus is a recognized complication of catheter ablation for atrial fibrillation because the posterior wall of the left atrium lies in close proximity to the esophagus. Severe injury may result in atrioesophageal fistula, a rare but potentially fatal complication. Multiple strategies have been explored to reduce esophageal injury during ablation, including modification of ablation energy delivery, intraluminal esophageal temperature monitoring, mechanical esophageal deviation, and active esophageal cooling. Active esophageal cooling uses a temperature-control device placed within the esophagus to lower luminal temperature during radiofrequency ablation and has been proposed as a method to reduce thermal injury while maintaining ablation effectiveness (Calkins et al., 2026; Sharkoski et al., 2025; Leung et al., 2021).

U.S. Food and Drug Administration (FDA): Temperature regulation devices for esophageal protection during cardiac ablation procedures are Class II medical devices that were classified by the FDA through the De Novo process. These devices are indicated to reduce the likelihood of ablation-related esophageal injury during radiofrequency cardiac ablation procedures and provide gastric decompression and suctioning (FDA, 2026).

Device or Product	Identifier	Manufacturer
ensoETM®	DEN230021	Advanced cooling therapy, Inc. Attune Medical

*FDA product code: QXV

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

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Literature Review: Active esophageal cooling during radiofrequency catheter ablation for atrial fibrillation has been evaluated in systematic reviews and meta-analyses, randomized controlled trials (RCTs), and observational studies. These studies primarily compare active esophageal cooling using a temperature regulation device with standard intraluminal esophageal temperature monitoring. Outcomes include endoscopically detected esophageal injury, gastroparesis, procedural performance, arrhythmia recurrence, and atrioesophageal fistula. Available evidence suggests active esophageal cooling may reduce the incidence or severity of endoscopically detected esophageal thermal injury without adversely affecting procedural success or 12-month arrhythmia outcomes. However, the available evidence remains limited by small sample sizes, heterogeneity in cooling methods and injury assessment, and limited long-term follow-up (Hamed et al., 2023; Sanchez et al., 2023; Leung et al., 2022; Leung et al., 2021). Therefore, the effect of active esophageal cooling on clinically meaningful outcomes remains uncertain, and the evidence is insufficient to establish safety and effectiveness for routine use during cardiac catheter ablation.

Hamed et al. (2023) conducted a systematic review and meta-analysis of four randomized controlled trials evaluating the role of esophageal cooling in preventing esophageal injury during radiofrequency catheter ablation for atrial fibrillation. Eligible studies enrolled individuals undergoing AF catheter ablation and required post-procedural endoscopic assessment of esophageal injury. Studies evaluating esophageal cooling methods including the ensoETM device, cold saline balloon irrigation, and ice-water cooling were compared with standard luminal esophageal temperature monitoring. Among the 4 RCTs there were a total of 294 participants (n=147 cooling; n=147 control). The primary outcome was the incidence of any esophageal injury; secondary outcomes included severe esophageal injury, mild-to-moderate esophageal injury, acute pulmonary vein reconnection, and ablation index. Endoscopic follow-up ranged from one to seven days following ablation. There was no significant difference in the incidence of any esophageal injury between esophageal cooling and control groups (15% vs. 19%; relative risk [RR] 0.86; 95% confidence interval [CI] 0.31–2.41). However, esophageal cooling was associated with a lower risk of severe esophageal injury (1.5% vs. 9%; RR 0.21; 95% CI 0.05–0.80). No significant differences were observed in mild-to-moderate esophageal injury (13.6% vs. 12.1%; RR 1.09; 95% CI 0.28–4.23), acute reconnection incidence (RR 0.93; 95% CI 0.02–36.34), or ablation index (SMD 0.16; 95% CI –0.33–0.66). Study limitations included a small pooled sample size, heterogeneity in cooling methods, temperature monitoring techniques, timing of endoscopic assessment, and definitions of esophageal injury severity, as well as the absence of long-term clinical outcome data.

Sanchez et al. (2023) analyzed retrospective data from 30 hospitals to determine the atrioesophageal fistula (AEF) rate with use of the ensoETM esophageal cooling device. Patients undergoing RF catheter ablation for the treatment of AF were included. The number of patients treated with active esophageal cooling at each hospital system ranged from 212 to 1700. In total, 14,224 individuals used the ensoETM esophageal cooling device.

- The authors reported they looked at a cohort of patients treated across the 25 systems before the adoption of active esophageal cooling device and found a total of 16 AEFs occurred, yielding an AEF rate of 0.146%. In the cohort of patients treated after adoption of active esophageal cooling device, no AEFs were identified, representing an AEF rate of 0% ($P < 0.0001$).
- The authors noted the following study limitations:
 - Study design included retrospectively gathered data
 - Data collection at each site was not standardized
 - Different methods of determining event rates at different hospitals

Leung et al. (2021) conducted a single-center, randomized trial ('IMPACT' study) to investigate the ability of the ensoETM® device to protect the esophagus from thermal injury. A total of 188 participants were recruited of whom 120 (60 protected and 60 control) underwent catheter

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ablation. Endoscopic examination was performed at 7 days post-ablation and esophageal injury was scored.

- The protected group received the ensoETM probe. After using transesophageal echocardiography to guide transseptal puncture, the probe was withdrawn and an ensoETM probe was introduced in its place, connected to a mobile console. The position was confirmed radiographically, aiming to place the distal end of the device below the diaphragm. Before beginning ablation on the posterior part of the left atrium, the probe was set to cooling mode at 4 degrees Celsius for at least 10 min. Cooling continued until ablation was complete.
- The control group received no cooling method. A single-sensor temperature probe was placed in the esophagus by the attending anesthetist and adjusted approximately to the site of ablation. Adjustment of the position of the probe during ablation was performed by the anesthetist under the direction of the operating electrophysiologist with the objective of keeping the tip of the probe as close as possible to the site of ablation whenever the site was within 1 cm of the esophagus. RF delivery was suspended if the temperature indicated by the probe exceeded 38 degrees Celsius and RF was not resumed at that location until the temperature fell below 37 degrees Celsius. To avoid delay, operators often moved to a location distant from the esophagus to continue work while waiting for the temperature to fall.
- Thermal injury to the mucosa was significantly more common in the control group than in those receiving esophageal protection (12/60 vs. 2/60; $P = 0.008$), with a trend toward reduction in gastroparesis (6/60 vs. 2/60, $P = 0.27$). There was no difference between groups in the duration of RF or in the force applied (P value range = 0.2–0.9). Procedure duration and fluoroscopy duration were similar ($P = 0.97$, $P = 0.91$, respectively).
- Authors note these limitations:
 - A larger trial would be required to answer the question whether the use of the ensoETM device eliminates the possibility of atrio-esophageal fistula formation
 - Operators participating in the study were not and could not have been blinded to the randomization.
 - A single sensor probe was used in the control group. Results found in the control group may not be generalizable to temperature measurement using other measurement devices.

A subsequent analysis of the IMPACT study by Leung et al. in 2022 evaluated whether active esophageal cooling affected lesion formation, procedural success, or longer-term outcomes in all 188 randomized participants. No significant differences were observed between active esophageal cooling and standard temperature monitoring with respect to lesion formation characteristics, pulmonary vein isolation success, or 12-month arrhythmia recurrence.

Professional Societies/Organizations: Current professional society recommendations regarding active esophageal cooling during catheter ablation for atrial fibrillation are limited. Available guidance consists primarily of clinical practice guidelines and expert consensus statements addressing prevention of ablation-related esophageal injury and atrioesophageal fistula. Professional societies recognize active esophageal cooling as one of several proposed strategies to reduce esophageal thermal injury; however, no major guideline currently recommends routine use of active esophageal cooling devices, and the effect of these devices on clinically meaningful outcomes such as atrioesophageal fistula remains uncertain (Joglar et al., 2024; Tzeis et al., 2024).

American College of Cardiology (ACC)/American Heart Association (AHA)/American College of Chest Physicians (ACCP)/Heart Rhythm Society (HRS): In Section 8.4.2, Techniques and Technologies for AF Catheter Ablation, the 2024 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation recommends pulmonary vein isolation (PVI) as

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the primary lesion set for atrial fibrillation catheter ablation. The guideline identifies atrioesophageal fistula as the most serious complication associated with catheter ablation but does not discuss active esophageal cooling devices or provide a recommendation regarding their use (Joglar et al., 2024).

European Heart Rhythm Association (EHRA)/Heart Rhythm Society (HRS)/Asia Pacific Heart Rhythm Society (APHRS)/Latin American Heart Rhythm Society (LAHRS): The 2024 EHRA/HRS/APHRS/LAHRS expert consensus statement on catheter and surgical ablation of atrial fibrillation discusses several strategies intended to reduce esophageal injury during catheter ablation, including esophageal temperature monitoring, mechanical esophageal deviation, and active esophageal cooling. The writing group notes that randomized controlled trials and a systematic review have demonstrated reductions in esophageal thermal injury with active esophageal cooling and references observational data suggesting lower rates of atrioesophageal fistula. However, the consensus statement concludes that the impact of esophageal cooling on prevention of atrioesophageal fistula has not been clearly established and that conclusive evidence is difficult to obtain because of the rarity of this complication (Tzeis et al., 2024).

There is insufficient evidence in the published medical literature to demonstrate the safety and effectiveness of using active esophageal cooling devices during cardiac catheter ablation.

Surgical Ablation

Surgical ablation is a rhythm-control treatment for atrial fibrillation (AF) that creates lines of scar tissue within the atria to interrupt abnormal electrical pathways and reduce recurrent atrial arrhythmias. The Cox-Maze procedure, first introduced in the 1980s, used a series of surgical incisions ("cut-and-sew" lesions) to interrupt atrial reentry circuits responsible for maintaining AF. Current Maze and modified Maze procedures typically use radiofrequency or cryothermal energy sources to create lesion patterns based on the principles of the original procedure while avoiding many of the surgical incisions required by earlier techniques, with the Cox-Maze IV procedure generally considered the gold standard surgical approach for AF ablation (Ad, 2026; Calkins et al., 2026; Lee, 2026).

Surgical ablation is most commonly performed concomitantly (during the same operation) with another cardiac surgical procedure, such as mitral valve surgery, aortic valve surgery, coronary artery bypass grafting (CABG), or surgery for congenital heart disease. In this setting, AF ablation is performed in conjunction with the primary cardiac operation rather than as a separate indication for surgery. (Lee, 2026; Chandra et al., 2024). More recently, surgical ablation has been proposed as a stand-alone treatment option for individuals with persistent AF after failure of antiarrhythmic drug therapy. This approach is based on the premise that surgical procedures often involve more extensive lesion sets than catheter ablation and may therefore provide improved rhythm-control outcomes. To reduce procedural invasiveness, several minimally invasive approaches have been developed, including thoracoscopic and hybrid techniques. In a hybrid approach (e.g., Fusion technique, the bipolar clamp technique, convergent technique), a cardiac surgeon creates epicardial lesions (ablations) on the outer surface of the heart while an electrophysiologist performs endocardial mapping and catheter ablation within the heart. The catheter-based component may be performed during the same procedure or as a staged procedure performed at a later date. Hybrid approaches are intended to combine access to the epicardial (outer) surface of the heart through surgery with the detailed electrical mapping capabilities available during catheter ablation (Ad, 2026; Calkins et al., 2026; Lee, 2026; van der Heijden et al., 2024; Rosati et al., 2023).

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U.S. Food and Drug Administration (FDA): Surgical ablation techniques are procedures and therefore not subject to FDA regulation. Any medical devices, drugs, biologics, or tests used as a part of these procedures may be subject to FDA regulation.

Literature Review: Evidence evaluating concomitant surgical ablation for atrial fibrillation (AF) performed during cardiac surgery includes systematic reviews and meta-analyses, randomized controlled trials (RCTs), and large multicenter and nationwide observational studies. Comparators have primarily consisted of cardiac surgery with concomitant surgical ablation versus cardiac surgery alone in individuals with pre-existing AF undergoing mitral valve surgery, aortic valve surgery, coronary artery bypass grafting (CABG), and other cardiac procedures. Across the available literature, study populations range from several hundred participants in randomized trials to more than 42,000 participants in pooled analyses, with follow-up extending from one year to as long as 15 years. Concomitant surgical ablation is consistently associated with improved maintenance of sinus rhythm, lower rates of recurrent AF, and reductions in long-term adverse clinical outcomes including all-cause mortality, stroke, heart failure-related hospitalization, and hospital readmission compared with cardiac surgery alone. While most studies report no significant differences in major perioperative complications, increased rates of permanent pacemaker implantation have been observed across several analyses, and some studies have reported increased rates of postoperative renal dysfunction. Limitations of the available studies include heterogeneity in surgical techniques, lesion sets, energy sources, and reliance on observational data for some long-term outcomes. Overall, the available evidence demonstrates sustained improvements in rhythm control and long-term clinical outcomes when surgical ablation is performed concomitantly with cardiac surgery in individuals with atrial fibrillation (Polat et al., 2025; Sakurai et al., 2025; Kim et al., 2024; Cheng et al., 2023; Gemelli et al., 2023).

Evidence evaluating stand-alone surgical and hybrid ablation for atrial fibrillation (AF) includes systematic reviews and meta-analyses, randomized controlled trials (RCTs), prospective comparative studies, and long-term observational cohorts. Comparators have primarily consisted of catheter ablation, including repeat catheter ablation strategies, versus thoracoscopic surgical ablation, hybrid epicardial-endocardial ablation, or hybrid convergent procedures in individuals with persistent and long-standing persistent AF. Contemporary systematic reviews and randomized trials have generally demonstrated improved freedom from recurrent atrial arrhythmias following thoracoscopic surgical and hybrid ablation approaches compared with catheter ablation, particularly among individuals with persistent or long-standing persistent AF (Aerts et al., 2026; Baudo et al., 2023; Doll et al., 2023; van der Heijden et al., 2023; DeLurgio et al., 2020/2022). However, not all studies have demonstrated superiority of surgical ablation, and longer-term follow-up of the CASA-AF trial reported similar arrhythmia, arrhythmia-burden, and quality-of-life outcomes between thoracoscopic surgical ablation and catheter ablation through 36 months (Boyalla et al., 2024). Long-term observational studies have also reported durable rhythm control following stand-alone Cox-Maze procedures, although interpretation is limited by the absence of comparator groups and treatment at highly experienced centers (MacGregor et al., 2022; Ad et al., 2017). In general, the available evidence is limited by relatively small study populations, heterogeneous AF populations and procedural techniques, variable lesion sets and rhythm-monitoring methods, and predominately short-term follow-up with most comparative studies reporting outcomes at approximately 12 months. Although many studies report improved arrhythmia-free survival following thoracoscopic surgical and hybrid ablation compared with catheter ablation, uncertainty remains regarding long-term clinical outcomes and identification of the individuals most likely to benefit from treatment.

Aerts et al. (2026) conducted a systematic review and Bayesian network meta-analysis of randomized controlled trials evaluating stand-alone invasive treatments for atrial fibrillation (AF). Eligible studies included evaluation of various stages of AF ranging from paroxysmal AF (PAF) to (long-standing) persistent AF, or a combination. Studies involving concomitant cardiac surgery or

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comparing different catheter ablation (CA) procedural techniques without a surgical intervention arm were excluded. Ten randomized controlled trials with 877 participants were included; most participants had persistent or long-standing persistent AF, although some studies also enrolled individuals with paroxysmal AF. The included trials compared isolated thoracoscopic ablation with CA (n=379), hybrid thoracoscopic ablation with CA (n=195), the Convergent procedure with CA (n=203), and hybrid thoracoscopic ablation with isolated thoracoscopic ablation (n=100). The primary outcome was freedom from atrial tachyarrhythmia (ATA) at approximately 12 months. Secondary outcomes were mortality, stroke, and bleeding. Compared with catheter ablation (CA), stand-alone surgical and hybrid ablation approaches demonstrated improved freedom from recurrent atrial arrhythmias at approximately 12 months, with hybrid thoracoscopic ablation ranked as the most effective treatment strategy. Study limitations include relatively small participant populations, clinically heterogeneous AF populations, variable rhythm-monitoring methods, and short term follow up duration.

Boyalla et al. (2024) reported the 36-month follow-up results of the multicenter CASA-AF randomized controlled trial comparing catheter ablation (CA) with thoracoscopic surgical ablation (SA) in individuals with symptomatic long-standing persistent atrial fibrillation (LSPAF). Participants underwent de novo ablation and were followed using implantable loop recorders for continuous rhythm monitoring. Of the 115 randomized participants (CA n=60; SA n=55), 104 (90.4%) completed long-term rhythm follow-up. Baseline characteristics were generally comparable between groups, although AF duration was longer in the SA group (27 months versus 20 months; $p=0.03$). The primary outcome was freedom from atrial fibrillation/atrial tachycardia (AF/AT) lasting >30 seconds after a single procedure without antiarrhythmic drug therapy at 36 months. Secondary outcomes included $\geq 75\%$ reduction in AF/AT burden, repeat interventions, quality of life, cost-effectiveness, and predictors of treatment success. At 36 months, CA and SA demonstrated similar arrhythmia outcomes, with freedom from AF/AT achieved in 12% of participants in the CA group and 11% in the SA group ($p=0.41$). Similarly, regarding secondary outcomes, 58% of participants in the CA group and 55% in the SA group achieved $\geq 75\%$ reduction in AF/AT burden ($p=0.91$); rates of repeat ablation procedures were comparable between groups (25% versus 26%; $p=0.83$); both groups demonstrated sustained improvements in quality of life through 36 months, with no significant long-term differences between treatment strategies. Cost-effectiveness analyses demonstrated higher overall costs for SA compared with CA, despite similar arrhythmia, quality-of-life, and burden-reduction outcomes between treatment strategies. Multivariable analyses identified larger left atrial diameter as a predictor of failure to maintain freedom from AF/AT, while longer duration of persistent AF was associated with lower odds of achieving $\geq 75\%$ arrhythmia burden reduction. Study limitations include small sample size with study conducted solely within the United Kingdom, participant attrition with differential attrition between treatment groups (SA=33%; CA=20%), and reliance on patient-reported questionnaires with missing data related to the COVID-19 pandemic.

Baudo et al. (2023) conducted a systematic review and meta-analysis comparing minimally invasive surgical off-pump ablation (MISOA), including thoracoscopic, transdiaphragmatic, and hybrid approaches, with catheter ablation (CA) for treatment of atrial fibrillation (AF). Inclusion criteria for analysis were English language, two-armed studies comparing MISOA, including the hybrid approach (HA), and CA alone, which reported restoration to sinus rhythm (SR) as primary outcome. Studies were excluded if surgical ablation was performed with an open approach or using cardiopulmonary bypass; case reports, reviews and comments were also excluded. Twenty-one comparative studies, including nine randomized controlled trials, four propensity-matched studies, and eight observational studies, were included, comprising 2234 participants (MISOA n=1070; CA n=1164) with sample sizes ranging from 21–256 participant per study. Notably, statistically significant baseline differences were observed between treatment groups, including male sex ($p=0.010$), prior cerebrovascular accident (CVA) ($p<0.001$), non-paroxysmal AF ($p<0.001$), and hypertension ($p=0.040$). The primary outcome was freedom from AF after a 3-

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month blanking period. Secondary outcome measures included postoperative CVA, postoperative pacemaker implantation, conversion to sternotomy, postoperative total adverse events, 30-day mortality, late CVA, late PPM, late total adverse events, and late mortality. Follow up duration varied from 1 to 4 years with mean pooled follow-up of 16.8 ± 7.5 months. Freedom from AF at four years was 52.1% in the MISOA group compared with 29.1% in the CA group (log-rank $p < 0.001$). MISOA was associated with a lower risk of AF recurrence compared with CA (HR 0.60; 95% CI 0.50-0.72). Similar findings were observed in analyses limited to randomized controlled trials (HR 0.56; 95% CI 0.44-0.71). The total number of postoperative adverse events ($p < 0.001$) and late adverse events ($p = 0.014$) were significantly more common following MISOA; however, no statistically significant differences were observed specifically for postoperative stroke, permanent pacemaker implantation, 30-day mortality, late stroke, late permanent pacemaker implantation, or late mortality. Study limitations include incorporation of non-randomized studies, significant baseline differences between treatment groups, reliance on reconstructed Kaplan-Meier data rather than original patient-level datasets for long-term rhythm analyses, treatment at highly experienced surgical centers, and generally limited follow-up duration among included studies.

Doll et al. (2023) conducted a prospective, multi-center, randomized controlled trial (CEASE-AF) that evaluated if hybrid epicardial-endocardial ablation (HA) would have superior effectiveness when compared to catheter ablation (CA), including repeat (rCA), in persistent and longstanding persistent atrial fibrillation (PersAF/LSPAF). Nine hospitals in Poland, Czech Republic, Germany, United Kingdom, and the Netherlands enrolled patients aged 18–75 with symptomatic, drug refractory PersAF and left atrial diameter (LAD) > 4.0 cm or symptomatic LSPAF; and had failed at least one class I or III anti-arrhythmic drugs (AAD). The primary effectiveness outcome measured the freedom from documented AF/atrial flutter (AFL)/atrial tachycardia (AT) episodes > 30 s through the 12-months follow-up visits in the absence of Class I or III AADs except for AADs at doses not exceeding previously failed doses. The safety outcome measured the major complications that occurred during the study. Patients ($n = 154$) were randomized (2:1) to either HA ($n = 102$) or CA ($n = 52$). The HA first stage (index procedure) included endoscopic epicardial ablation where pulmonary veins (PV) and left posterior atrial wall were isolated and the left atrial appendage was excluded. Endocardial touch-up ablation was performed 91–180 days post-index procedure. Endocardial CA was performed using current RF catheter technology, PVI was mandatory during the index procedure. Additional ablation strategies were in accordance with current guidelines. Follow-up visits occurred at 3- and 6-months after the first ablation (T0), then 6- and 12-months after T0; to allow for staged endocardial ablation in the HA arm or repeat endocardial ablation in the CA arm. The freedom from documented AF/atrial flutter (AFL)/atrial tachycardia (AT) episodes > 30 s through the 12-months was statistically significant in HA when compared to CA (71.6% vs 39.2%, 95% CI 14.3%–48.0%, $p < 0.001$). Major complications through 30-days after index procedures plus 30-days after second stage/rCA were similar between groups, and not statistically significant (HA: 7.8% vs CA: 5.8%, $p = 0.75$). Procedure duration was significantly longer with HA compared to CA ($p < 0.001$). Fluoroscopy time was significantly lower with HA compared to CA ($p = 0.001$). The authors noted the following limitations: all patients in the HA arm had LAA management but the effectiveness LAA exclusion was not evaluated, the different overall number of procedures differs between HA and CA and symptom-driven ECG monitoring was performed at unscheduled visits, which could have underestimated actual failure rates in both arms. Additional limitations included that the study was conducted in specific countries limiting generalizability to other ethnicities, the small sample size and short-term follow-up. Further studies in large, diverse populations with long-term follow-up are needed to evaluate efficacy, optimize protocols and outcomes.

van der Heijden et al. (2023) conducted a randomized controlled trial (HARTCAP-AF trial) that evaluated the effectiveness and safety of hybrid ablation compared to repeat catheter ablation in patients with persistent atrial fibrillation (persAF). Participants ($n = 41$) $>$ age 18 years with symptomatic (long-standing)-persAF refractory to one or more class I or III antiarrhythmic drugs

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and no prior (catheter) ablation were included in the study. Participants were randomized to hybrid ablation (n=19) or catheter ablation (n=22). The primary effectiveness outcome measured freedom from any recurrent supraventricular tachyarrhythmia off anti-arrhythmic drugs (AADs), lasting ≥ 5 minutes at 12 months. The secondary effectiveness outcome measured freedom from any recurrent supraventricular tachyarrhythmia off AADs lasting ≥ 30 seconds at 12-month follow-up. Additional outcomes measured the freedom from AAD use, the number of arrhythmia-related re-hospitalizations, and reinterventions such as cardioversions and redo catheter ablations. Changes in quality of life (QOL) were also measured. The primary safety outcome measured major adverse events and complications that occurred within 12 months of follow-up. Secondary safety outcomes measured the total number of serious adverse events. All participants in the HA group received closure of the LAA either using AtriClip (n=17) or the Lariat closure device (n=2). In the CA group, transvenous PVI and the box lesion were created in all patients. Freedom from any recurrent supraventricular tachyarrhythmia off anti-arrhythmic drugs lasting ≥ 30 seconds or ≥ 5 minutes was significantly higher in the HA group compared with the CA group (89% vs 41%, $p=0.002$; 95% vs 41%, $p<0.001$, respectively). It was more likely for the HA group compared to the CA group to receive AADs until three months after the procedure but more patients in the HA group were off AADs after 1 year (95% vs 36%, $p=0.005$). No significant differences were reported between the groups in the number of major adverse events, minor complications, QOL and AF related symptoms. Lastly, median procedure time and length of hospital stay were significantly longer in the HA group, whereas the exposure to radiation dose and time were significantly higher in the CA group. An author noted limitation was that all procedures were conducted in a single, highly specialized center with experienced cardiac surgeons and electrophysiologists, which decreases the generalizability and external validity of the results. Additionally, the authors noted that the study was not double-blinded and the rate of patients in sinus rhythm at one year might be overrated. Limitations also included the small sample size; short-term follow-up and the study was done in the Netherlands and results may not be applicable to other races or ethnic groups. Further studies in large, diverse populations with long-term follow-up are needed to evaluate efficacy, optimize protocols and outcomes.

DeLurgio et al. (2022/2020) conducted a multicenter, randomized controlled trial (CONVERGE) that evaluated the effectiveness of the combined hybrid epicardial and endocardial ablation (Hybrid Convergent) for the treatment of persistent and long-standing persistent AF with endocardial catheter ablation. Adults 18–80 years, with symptomatic persistent AF that was refractory or intolerant to at least one class I/III antiarrhythmic drug (AAD) and had a left atrium size of ≤ 6.0 cm. There was no limitation on duration of AF. No health disparities were identified by the investigators. Patients (n=153) were randomized 2:1 to the Hybrid Convergent group (n=101) or the catheter ablation group (n=51). In-person follow-up visits were performed at seven days, one, three, six, and 12 months and included an electrogram and review of medications and adverse events. The trial also included an in-person longer-term follow-up visit at 18 months and phone follow-up at two, three, four, and five years. A total of 96% patients in the Hybrid Convergent group and 98% in the catheter ablation group completed the 12-month visit. Six- and 12-month Holter data were available for 97.1% and 96.1% patients in the Hybrid Convergent group, and 100% and 98% patients in the catheter ablation group. Hybrid Convergent had significant improvement in persistent and long-standing atrial fibrillation ($p=0.036$) and success off antiarrhythmic drugs ($p=0.0128$) when compared to catheter ablation. At 18 months using 7-day Holter, 74.0% Hybrid Convergent and 55% CA patients experienced $\geq 90\%$ AF burden reduction, which was clinically significant ($p=0.0395$) in favor of the Hybrid Convergent group. A total of 2.9% patients had primary safety events within seven days, and 4.9% between eight and 30 days postprocedure. No deaths, cardiac perforations, or atrioesophageal fistulas occurred. All but one primary safety event resolved. Author noted limitations included: the absence of empirical endocardial posterior wall ablation in the catheter ablation group; only using irrigated radiofrequency catheters for endocardial ablation in both groups; cryoablation was not

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included and electrical isolation or exclusion of LAA was not performed. Additional limitations included small patient population, unequal randomization and short-term follow-up.

In 2022 DeLurgio et al. evaluated the safety and effectiveness of HC vs CA in the longstanding persistent atrial fibrillation (LSPAF) subgroup from the CONVERGE trial, which is described in detail above. The primary outcome measured freedom from atrial arrhythmias off new or increased dose of previously failed or intolerant antiarrhythmic drugs (AADs) through 12 months. The primary safety outcome measured major adverse events through 30 days with HC. Secondary effectiveness outcomes measured (1) percent of patients achieving $\geq 90\%$ AF burden reduction vs baseline and (2) AF freedom. Sixty-five patients (42.5% of total enrollment) had LSPAF; 38 in HC and 27 in CA. Freedom from AF, AFL, or AT without a new or increased dose of previously failed AAD was significantly higher at 12 and 18 months in the HC arm compared to catheter ablation arm ($p=0.022$, $p=0.006$, respectively). Freedom from AF, AFL, or AT off class I or III AADs was significantly higher in the HC arm compared to CA arm at 12 and 18 months 12 months ($p=0.031$; $p=0.038$, respectively). In LSPAF patients, the MAE rate in the HA arm was 7.9%, which included 1 cardiac tamponade, 1 stroke, and 1 phrenic nerve injury. No MAEs occurred in the catheter ablation arm. Author noted limitations include the post hoc nature of the analysis and small population size of the subgroups. The authors noted that the data should be interpreted with caution because CIs and P values were not adjusted for multiplicity. Lastly, patients were randomized 2:1 to hybrid convergent and catheter ablation arms, but randomization was not stratified by baseline AF subtype.

Professional Societies/Organizations: Professional society guidelines and expert consensus statements generally support surgical ablation as an effective rhythm-control strategy when performed concomitantly with cardiac surgery and recognize a role for stand-alone surgical and hybrid ablation in selected individuals with symptomatic atrial fibrillation (AF). Recommendations are based on randomized controlled trials, systematic reviews, meta-analyses, observational studies, registry data, and expert consensus. Across guidelines, concomitant surgical ablation is consistently recommended or considered beneficial during cardiac surgery because of improvements in maintenance of sinus rhythm and long-term rhythm outcomes. Surgical and hybrid approaches performed as stand-alone interventions are generally considered reasonable for selected individuals with persistent AF who remain symptomatic despite antiarrhythmic drug therapy and/or prior catheter ablation, although uncertainty remains regarding optimal patient selection and procedural approaches. Professional societies also emphasize procedural considerations, including lesion-set completeness, confirmation of pulmonary vein isolation, and left atrial appendage management, when surgical ablation is performed (Joglar et al., 2024; Ommen et al., 2024; Tzeis et al., 2024; Wyler von Ballmoos et al., 2024).

American College of Cardiology (ACC)/American Heart Association (AHA)/American College of Chest Physicians (ACCP)/Heart Rhythm Society (HRS) Guideline for the Diagnosis and Management of Atrial Fibrillation (Joglar et al., 2024)		
Recommendation	COR	LOE
8.6. Surgical Ablation		
For patients with AF who are undergoing cardiac surgery, concomitant surgical ablation can be beneficial to reduce the risk of recurrent AF.	IIa	B-R
For patients with symptomatic, persistent AF refractory to antiarrhythmic drug therapy, a hybrid epicardial and endocardial ablation might be reasonable to reduce the risk of recurrent atrial arrhythmia.	IIb	B-R
The ACC goes on to note that among patients with AF or AFL, concomitant surgical ablation at the time of cardiac surgery has been shown to reduce the risk of recurrent atrial arrhythmia. However, it is	n/a	n/a

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American College of Cardiology (ACC)/American Heart Association (AHA)/American College of Chest Physicians (ACCP)/Heart Rhythm Society (HRS) Guideline for the Diagnosis and Management of Atrial Fibrillation (Joglar et al., 2024)		
Recommendation	COR	LOE
associated with an increased risk of renal dysfunction and pacemaker placement. Among patients with symptomatic, persistent AF, a hybrid procedure combining epicardial and endocardial ablation has been shown to reduce the burden of atrial arrhythmia.		

American Heart Association (AHA)/American College of Cardiology (ACC)/American Medical Society for Sports Medicine (AMSSM)/Heart Rhythm Society (HRS)/Pediatric and Congenital Electrophysiology Society (PACES)/Society for Cardiovascular Magnetic Resonance (SCMR) Guideline for the Management of Hypertrophic Cardiomyopathy (Ommen et al., 2024)		
Recommendation	COR	LOE
Recommendations on AF 8.4 Management of Patients With HCM and AF		
#6. In patients with HCM and symptomatic AF, as part of a AF rhythm control strategy, catheter ablation for AF can be effective when drug therapy is ineffective, contraindicated, or not the patient's preference	IIa	B-NR
#7. In patients with HCM and AF who require surgical myectomy, concomitant surgical AF ablation procedure can be beneficial for AF rhythm control	IIa	B-NR

The Society of Thoracic Surgeons (STS) Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation (Wyler von Ballmoos et al., 2024)		
Recommendation	COR	LOE
Recommendations for mitral valve operations:		
Surgical ablation for atrial fibrillation is recommended for first-time nonemergent concomitant mitral operations to restore sinus rhythm and improve long-term outcomes.	I	A
Recommendations for operations other than mitral valve surgery:		
Surgical ablation for atrial fibrillation is recommended for any first-time non-emergent concomitant non-mitral operation to restore sinus rhythm and improve long-term outcomes.	I	B-NR
Recommendations regarding stand-alone surgical ablation:		
Surgical ablation for symptomatic atrial fibrillation in the absence of structural heart disease refractory to class I/III antiarrhythmic drugs, catheter-based therapy, or both is <u>reasonable</u> as a primary stand-alone procedure to restore sinus rhythm	IIa	B-NR
Surgical ablation for symptomatic persistent or longstanding persistent atrial fibrillation in the absence of structural heart disease is <u>reasonable</u> as a stand-alone procedure using the Cox-Maze III/IV lesion set as the preferred procedure	IIa	B-NR
Surgical ablation for symptomatic atrial fibrillation in the setting of left	III	C

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The Society of Thoracic Surgeons (STS) Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation (Wyler von Ballmoos et al., 2024)		
Recommendation	COR	LOE
atrial enlargement (≥ 4.5 cm) or more than moderate mitral regurgitation by pulmonary vein isolation alone is not recommended.		

The STS notes that individuals with symptomatic atrial fibrillation refractory to antiarrhythmic drugs with at least one unsuccessful catheter-based ablation may be referred for stand-alone surgical ablation. An increasing number of stand-alone surgical ablation studies using cryoablation and a minimally invasive thoracoscopic or robotic-assisted approach have recently shown improved outcomes in safety and effectiveness, with $>90\%$ of patients being free from atrial fibrillation at 1 year and $>80\%$ at 5 years of follow up. Notably, these results were achieved at established, high-volume centers despite including many patients with long-standing persistent atrial fibrillation. These were not always documented by continuous electrocardiographic monitoring to support the rhythm end points.

Given stronger longitudinal evidence of efficacy and longitudinal freedom from atrial fibrillation, antiarrhythmic drugs, as well as oral anticoagulation after a full biatrial Cox maze, the field awaits more homogeneous or randomized evidence on hybrid or epicardial ablation procedures that adhere to the concept of the Cox maze lesion set. Epicardial ablation with atypical lesions remains exploratory until more robust evidence becomes available (Wyler von Ballmoos et al., 2024).

*Classes of Recommendation (COR) and Levels of Evidence (LOE)

Classification of strength of recommendation

Class I (strong; benefit $\gg$ risk): procedure is useful, effective, and beneficial. Recommendation: procedure should be performed.

Class IIA (moderate; benefit $\gg$ risk): procedure can be useful, effective, and beneficial. Recommendation: procedure is reasonable.

Class IIB (weak; benefit equal to or greater than risk): effectiveness is unknown, unclear, or uncertain. Recommendation: procedure might be reasonable.

Class III, no benefit (moderate; benefit equals risk): procedure is not useful, effective, or beneficial. Recommendation: procedure should not be performed.

Class III, harm (strong; benefit less than risk): Procedure potentially causes harm or excess mortality and morbidity. Recommendation: procedure should not be performed.

Level of quality of evidence

Level A: high-quality evidence from more than one randomized controlled trial (RCT); meta-analyses or high-quality RCTs; or one or more RCTs corroborated by high-quality registry studies.

Level B randomized: moderate quality evidence from one or more RCTs or meta-analyses of moderate quality.

Level B nonrandomized: moderate quality of evidence from one or more well-designed, well-executed nonrandomized studies, registries, or observational analyses; meta-analyses of such studies.

Level C limited data: randomized or nonrandomized observational or registry studies with limitations of design or execution; meta-analyses of such studies; mechanistic or physiologic investigation in human subjects.

Level C expert opinion: consensus of expert opinion based on clinical experience (Society of Thoracic Surgeons, (Wyler von Ballmoos et al., 2024/ Badhwar et al., 2017)

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Outside of the US:

European Heart Rhythm Association (EHRA)/Heart Rhythm Society (HRS)/Asia Pacific Heart Rhythm Society (APHRS)/Latin American Heart Rhythm Society (LAHRS) Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation (Tzeis et al., 2024)		
Surgical and hybrid AF ablation	Category of advice	Type of evidence
Concomitant surgical AF ablation is beneficial in patients with paroxysmal or persistent AF undergoing left atrial open cardiac surgery regardless of prior antiarrhythmic drug failure or intolerance	Advice TO DO	META
Concomitant surgical AF ablation is beneficial in patients with paroxysmal or persistent AF intolerant or refractory to previous antiarrhythmic drug therapy, undergoing closed (non-left atrial open) cardiac surgery	Advice TO DO	META
Biatrial Cox maze procedure or a minimum of PVI plus left atrial posterior wall isolation is beneficial in patients undergoing surgical AF ablation concomitant to left atrial open cardiac surgery	Advice TO DO	RAND
Documentation of exit and/or entrance block across pulmonary veins and completeness of deployed lines is beneficial during surgical AF ablation	Advice TO DO	OPN
Concomitant surgical AF ablation is reasonable in patients with paroxysmal or persistent AF prior to initiation of Class I or III antiarrhythmic therapy, undergoing closed (non-left atrial open) cardiac surgery	May be appropriate to do	META
Stand-alone surgical or hybrid ablation is reasonable in symptomatic patients with persistent AF with prior unsuccessful catheter ablation and also in those who are intolerant or refractory to antiarrhythmic drug therapy and prefer a surgical/hybrid approach, after careful consideration of relative safety and efficacy of treatment options	May be appropriate to do	META
Stand-alone surgical or hybrid ablation may be reasonable in symptomatic patients with paroxysmal AF with prior unsuccessful catheter ablations who prefer a surgical/hybrid approach, after careful consideration of relative safety and efficacy of treatment options	Area of uncertainty	RAND

Category of advice

- Advice TO DO = Evidence or general agreement that a given measure is clinically useful and appropriate
- May be appropriate TO DO = Evidence or general agreement that a given measure may be clinically useful and appropriate
- Area of uncertainty = No strong advice can be given, lack of data, inconsistency of data
- Advice NOT to do = Evidence or general agreement that a given measure is not appropriate or harmful

Classification of different types of evidence and respective criteria

- META = Evidence from >1 high-quality RCT; Metaanalyses of high-quality RCTs
- RAND = Evidence from 1 high-quality RCT; Evidence from >1 moderate-quality RCT; Metaanalyses of moderate-quality RCTs
- OBS = Observational studies or registries; Metaanalyses of such studies

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- OPN = Randomized, non-randomized, observational or registry studies with limitations of design or execution, case series; Metaanalyses of such studies; Physiological or mechanistic studies in human subjects; Consensus of expert opinion based on clinical experience (European Heart Rhythm Association/Heart Rhythm Society/Tzeis, et al., 2024)

Thoracoscopic Epicardial Ablation

Epicardial ablation, including thoracoscopic or minimally invasive surgical techniques, has been proposed for the treatment of various cardiac arrhythmias. These approaches may be performed as stand-alone procedures or in combination with endocardial catheter ablation as part of a hybrid convergent strategy. The hybrid convergent procedure involves epicardial ablation typically followed by endocardial mapping and ablation to complete lesion sets. This procedure may be performed as part of a two staged approach or less commonly a single stage approach.

U.S. Food and Drug Administration (FDA): Cardiac ablation is a procedure and, therefore, not subject to FDA regulation. Any medical devices, drugs, biologics, or tests used as a part of this procedure may be subject to FDA regulation.

Literature Review: There is insufficient evidence in the published peer-reviewed medical literature to assess the safety, efficacy, and long-term outcomes of epicardial ablation techniques, including hybrid convergent procedures, for the treatment of arrhythmias. Additionally, randomized controlled trials evaluating these approaches for IST, POTS, or atrial flutter are lacking. The existing published, peer-reviewed literature consists of a single retrospective study and a protocol study for which final outcome data are not yet available in published form (de Asmundis, et al., 2023; de Asmundis, et al., 2022).

De Asmundis et al. (2022) conducted a multicenter retrospective study to evaluate the feasibility, safety, and efficacy of a novel sinus node (SN)-sparing hybrid ablation approach for the treatment of drug-resistant inappropriate sinus tachycardia (IST) and postural orthostatic tachycardia syndrome (POTS). A total of 255 consecutive patients (92% female; mean age 25.94 ± 3.84 years) were included, with 204 diagnosed with IST and 51 with POTS. The intervention involved a minimally invasive thoracoscopic epicardial ablation combined with simultaneous endocardial 3D mapping to preserve SN function, targeting the superior and inferior vena cava and crista terminalis regions. Comparators were pre-ablation baseline metrics. Inclusion criteria required symptomatic IST or POTS refractory or intolerant to pharmacologic therapy, confirmed by cardiologic and neurologic evaluation per HRS consensus guidelines. Exclusion criteria included identifiable primary causes of sinus tachycardia or supraventricular arrhythmias. Outcome measures included restoration of normal sinus rhythm, heart rate variability (HRV), and symptom resolution, with follow-up extending to a mean of 4.07 ± 1.8 years. Improvements were observed in HRV parameters (e.g., mean NN interval increased from 542.30 ± 28.60 ms to 1022.60 ± 169.01 ms), and no patients with POTS experienced syncope post-procedure. The most common complication was pericarditis (47%), which resolved with medical therapy; 1.9% required pacemaker implantation due to sinus arrest. Limitations include the retrospective design, lack of a randomized comparator group, and absence of standardized quality-of-life assessments.

Professional Societies/Organizations: Currently, no major professional society has issued formal guidelines or consensus statements addressing the use of epicardial ablation techniques, including when performed as part of a hybrid procedure—for arrhythmias other than atrial fibrillation. While organizations such as the American College of Cardiology (ACC) and the Heart Rhythm Society (HRS) have acknowledged hybrid convergent ablation for persistent atrial fibrillation, their published materials do not extend to other arrhythmias such as inappropriate sinus tachycardia (IST), postural orthostatic tachycardia syndrome (POTS), atrial flutter, or ventricular tachycardia.

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Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Research indicates that race significantly influences the lifetime risk of sudden cardiac death (SCD). Zhao, et al. (2019) conducted a prospective multi-center cohort study (n=15,069) funded by the National Heart, Lung, and Blood Institute to compare the lifetime risk of SCD between Blacks and whites and to assess racial risk factors. Participants, aged 45–64, were randomly selected from four U.S. cities between 1987–1989. The cohort included 2,366 Black women (15.7%), 5,947 white women (39.4%), 1,466 Black men (9.7%), and 5,296 white men (35.1%). Follow-up visits occurred in 1990–1992, 1993–1995, 1996–1998, and 2011–2013. Individuals self-identifying as races other than Black or White, or with missing outcome/covariate data, were excluded. SCD was defined as “death from a sudden pulseless condition occurring out of hospital or in the emergency room from a cardiac cause in a previously stable individual without a non-cardiac cause of cardiac arrest.” Data sources included death certificates, annual phone calls, next-of-kin interviews, physician questionnaires, coroner information, and hospital discharges. After a median follow-up of 27.4 years, cumulative SCD incidence was highest in Black men (8.5%), followed by Black women (5.9%), white men (5.6%), and white women (2.1%). Socioeconomic, cardiovascular, and electrocardiographic factors explained 65.3% of the excess SCD risk in Black participants. Income accounted for 50.5% of this risk, followed by education (19.1%), hypertension (22.1%), diabetes mellitus (19.6%), left ventricular hypertrophy (15.0%), alcohol intake (12.9%), physical activity (12.7%), BMI (6.4%), and smoking (4.4%). Black individuals were more likely to experience out-of-hospital SCD and had lower survival rates for in-hospital SCD. Cardiac arrests in low-income Black neighborhoods were less likely to receive bystander cardiopulmonary resuscitation compared to high-income white neighborhoods. In-hospital survival was also lower in low-income areas due to disparities in treatment quality. Study limitations included lack of data on individual resuscitation procedures and underlying arrhythmias, reliance on self-reported race, and unequal racial representation, with more white than Black participants.

Obi et al. (2026) conducted a systematic review and meta-analysis of propensity-matched studies to evaluate sex-based differences in outcomes following catheter ablation for atrial fibrillation (AF). A total of 21 studies involving 103,619 individuals undergoing AF ablation were included, approximately 32% of whom were female. The authors noted that women are frequently referred for catheter ablation at an older age, often present later in the disease course, and may have more extensive atrial remodeling and comorbidity burden at the time of treatment. Compared with men, women were more likely to experience early procedural complications, including cardiac tamponade (p=0.0004), hematoma (p=0.0063), and pericardial effusion (p=0.0069). Women also had a higher risk of atrial fibrillation/atrial tachycardia recurrence at two years (p=0.0120) and a higher incidence of follow-up heart failure (p=0.0020). Despite these findings, no significant sex-based differences were observed for one-year arrhythmia recurrence, all-cause mortality, stroke/transient ischemic attack, repeat ablation, or antiarrhythmic drug use. The authors concluded that women may experience delayed referral and treatment at more advanced stages of

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disease and emphasized the importance of equitable and timely access to catheter ablation and long-term follow-up regardless of sex. Study limitations included reliance on observational studies, and heterogeneity in ablation techniques and follow-up protocols.

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Any Other Indication

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	- Added policy statement for: - Left atrial pacing and recording - Left ventricular pacing and recording - An additional catheter ablation of separate and distinct arrhythmogenic mechanism	10/15/2026

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	- Revised the diagnostic EP studies policy statement for: - secondary prevention of SCD - adult congenital heart disease	
Annual Review	Revised the policy statement for asymptomatic pre-excitation.	10/15/2025
Annual Review	No clinical policy statement changes.	10/15/2024

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