Catheter Ablation Procedures For Supraventricular Tachyarrhythmia Including Atrial Flutter & Atrial Fibrillation

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Assessing Signals for Update

June 4, 2025

Health Technology Assessment Program (HTA)

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This report is based on research conducted by the RTI–University of North Carolina Evidence-based Practice Center through a contract between RTI International and the State of Washington Health Care Authority (HCA). The findings and conclusions in this document are those of the authors, who are responsible for its contents. The findings and conclusions do not represent the views of the Washington HCA and no statement in this report should be construed as an official position of Washington HCA.

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None of the individuals involved in producing this report reported any financial or nonfinancial conflicts of interest regarding the topic presented in this report.

Acknowledgments

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Executive Summary

Introduction

In 2013, the State of Washington's Health Technology Assessment Program published a health technology assessment (HTA) titled "Catheter Ablation Procedures For Supraventricular Tachyarrhythmia Including Atrial Flutter & Atrial Fibrillation."[1] Based on this HTA, the state's independent Health Technology Clinical Committee (HTCC) found sufficient evidence to cover cardiac catheter ablation procedures (radiofrequency or cryoablation) for adults with supraventricular tachyarrhythmias (SVTAs), including: reentrant tachycardias (e.g., Wolff-Parkinson-White syndrome, atrioventricular reentrant tachycardia [AVRT], atrioventricular nodal reentrant tachycardia [AVNRT]), symptomatic atrial flutter, and symptomatic atrial fibrillation when drug therapy is either not tolerated or ineffective. The HTCC determined no coverage for ablation with other non-reentrant supraventricular tachycardias.[2] We conducted a signal search to determine whether current evidence suggests the need for an update to the 2013 HTA.

Methods

We searched MEDLINE® (via PubMed) for relevant English-language studies published between March 25, 2012, and November 5, 2024. We limited the search to systematic reviews that included primary research studies that would meet the 2013 HTA's inclusion and exclusion criteria but expanded the eligible ablation procedures to include pulsed field ablation and laser ablation, which are new technologies developed since 2013. We abstracted brief information from relevant systematic reviews into a structured form. Using a modified Ottawa approach,[3,4] we evaluated each review for whether new evidence suggests a need for an updated HTA. Because catheter ablation was covered for reentrant SVTAs, atrial flutter, and atrial fibrillation in 2013, we focused primarily on safety outcomes, except for new technologies where we examined both efficacy and safety. We also searched for evidence that might lead to a change in coverage conditions specified by the HTCC. For indications without at least 2 relevant systematic reviews, we also reviewed clinical practice guidelines and primary studies.

Results

For atrial fibrillation (AF), 2 large systematic reviews with meta-analyses confirmed the continued safety of radiofrequency and cryoballoon ablation.[5,6] At least 4 systematic reviews with meta-analyses provided consistent evidence supporting catheter ablation as first-line therapy for appropriate patients,[7-10] suggesting the requirement for failed drug therapy may no longer be consistent with current evidence. For newer technologies, laser balloon ablation, which was United States Food and Drug Administration (FDA) approved in 2016,[11] evidence demonstrates similar effectiveness to radiofrequency ablation with comparable adverse event rates.[5] Pulsed field ablation, which was FDA approved in 2023, showed high acute procedural success (99.7%)[12] with significantly shorter procedure times[13] and was recently shown to be noninferior to cryoballoon ablation.[14] However, the coverage policy implications of the evidence for these newer technologies is unclear. Laser balloon ablation and pulsed field ablation are billed under

the same codes as radiofrequency ablation and cryoballoon ablation. Therefore, these procedures may already be covered in practice.[15]

For atrial flutter, 3 systematic reviews confirmed the safety and efficacy of both radiofrequency and cryoballoon ablation,[16-18] consistent with the 2013 HTA. Evidence for other SVTAs varied considerably by condition. Evidence for common conditions like AVNRT and AVRT confirms continued evidence of safety. There was extremely limited evidence for rare arrythmias such as inappropriate sinus tachycardia and focal junctional ectopic tachycardia. Notably, the 2013 HTA did not include any studies exclusively in patients with these rare arrythmias and coverage was determined using observational studies of mixed populations with a variety of arrhythmias; thus, the limited evidence identified in this signal search does not represent a meaningful change from the evidence reviewed in 2013 for these rare arrythmias.

Conclusion

This signal search identified evidence that was mostly consistent with conclusions from the 2013 HTA,[1] supporting the continued safety and efficacy of catheter ablation (radiofrequency and cryoablation) for AF, atrial flutter, and other SVTAs. However, new evidence from multiple systematic reviews indicates that catheter ablation could reasonably be offered as first-line therapy for appropriate patients with AF,[7-10] representing a change from the previous HTA conclusions and current coverage decision, which requires failed drug therapy before ablation. Additionally, there is new evidence since 2013 suggesting the safety and efficacy of laser balloon and pulsed field ablation for AF, though these procedures use the same billing codes as radiofrequency and cryoballoon ablation and so they may already be covered in practice. For some rare SVTAs, evidence remained very limited, but this is consistent with the state of evidence in 2013. A narrowly focused update of the HTA to evaluate the evidence for ablation as a first-line treatment in AF and the role of laser and pulsed field ablation technologies may be warranted.

1. Introduction

The State of Washington's Health Technology Assessment (HTA) Program published a health technology assessment (HTA) titled "Catheter Ablation Procedures For Supraventricular Tachyarrhythmia Including Atrial Flutter & Atrial Fibrillation."[1] The state's independent Health Technology Clinical Committee (HTCC) evaluated the findings of this HTA and made an initial coverage determination at its May 17, 2013, meeting with final adoption of the determination on September 20, 2013. The committee's coverage decision for catheter ablation procedures for supraventricular tachyarryhthmias (SVTA) is summarized in **Section 1.2** below. At the request of the state's HTA program, we conducted a signal search to determine whether new evidence is available that suggests a need to update the previous HTA. This report summarizes the findings of that signal search.

1.1 Policy Context

In 2013, the HTCC determined that there was sufficient evidence to cover with conditions cardiac catheter ablation procedures (radiofrequency or cryoablation) for reentrant tachycardias (e.g., Wolff-Parkinson-White [WPW] syndrome, atrioventricular reentrant tachycardia (AVRT), atrioventricular nodal reentrant tachycardia [AVNRT]), symptomatic atrial flutter, and symptomatic atrial fibrillation (AF) when drug therapy is either not tolerated or is ineffective.[2] The committee determined no coverage for other, non-reentrant supraventricular tachycardias.[2]

The Centers for Medicare & Medicaid Services does not currently have a national coverage determination on the use of catheter ablation for the treatment of AF or other SVTAs.[19]

1.2 Cardiac Ablation for SVTA 2013 Coverage Determination

Cardiac catheter ablation procedures (radiofrequency or cryoablation) for SVTAs including atrial flutter and AF are covered with conditions.[2] The rationale for the committee's decision was as follows:

- Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and agency and state utilization information.

- The committee concluded that the current evidence on catheter ablation procedures demonstrates that there is sufficient evidence to cover with conditions. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

- Based on these findings, the committee voted to cover with conditions catheter ablation procedures for SVTA.

    - For adults with supraventricular tachyarrhythmias, cardiac catheter ablation procedures (radiofrequency or cryoablation) **are covered with conditions**:

- Reentrant tachycardias (e.g., WPW syndrome, AVRT, AVNRT)
- Atrial flutter
  - Symptomatic atrial flutter
- Atrial fibrillation
  - Symptomatic atrial fibrillation
  - Drug therapy is either not tolerated or is ineffective
- **Noncovered indications:**
  - Other non-reentrant supraventricular tachycardias

1.3 Scope of the 2013 HTA

The key questions (KQs) from the 2013 HTA included the following:[1]

KQ1: Does catheter ablation improve patient outcomes in persons with supraventricular tachyarrhythmias compared with other treatment options: What is the evidence for comparative efficacy and effectiveness over the short term and longer term?

KQ1a: If catheter ablation is efficacious compared with other treatment options, is there differential efficacy between the different types of ablation (e.g., radiofrequency ablation vs. cryoballoon ablation)?

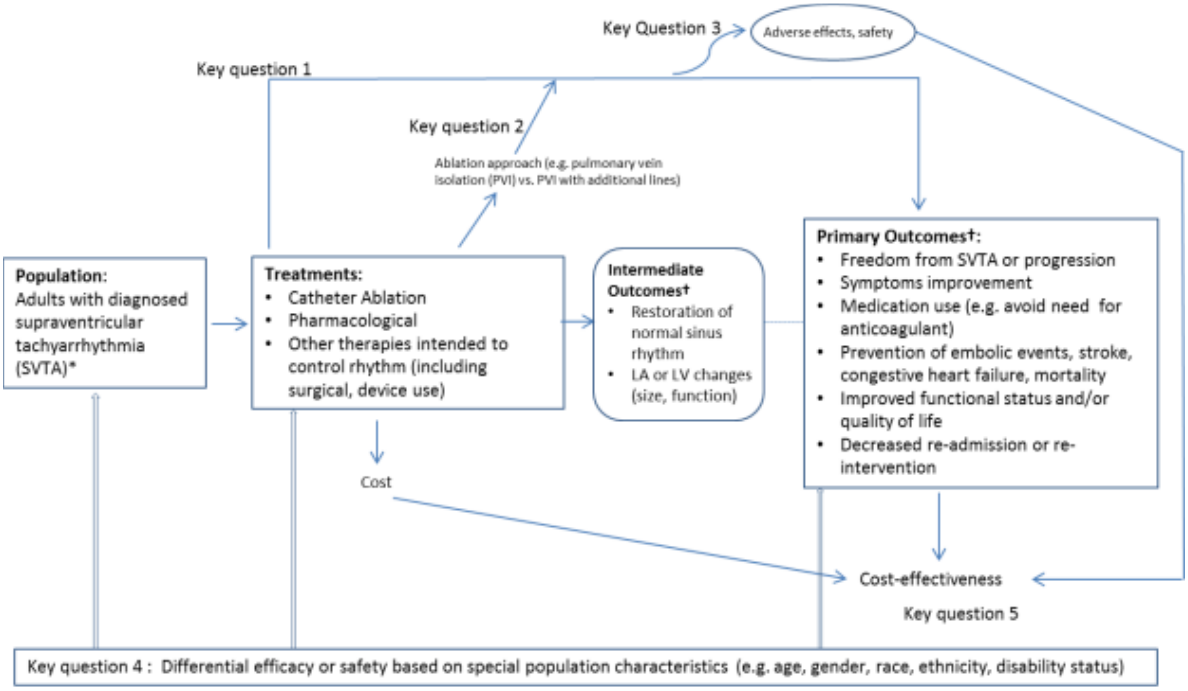
KQ2: What is the evidence regarding the comparative efficacy of various approaches to radiofrequency catheter ablation (e.g., pulmonary vein isolation [PVI] alone vs. PVI with additional ablation lines)?

KQ3: What is the evidence of the safety of catheter ablation?

KQ4: Does catheter ablation have any differential efficacy or safety compared with other treatment options in subpopulations (include consideration of age, gender, race, ethnicity, or disability)?

The following analytic framework (***Figure 1***) guided the 2013 HTA:

Figure 1. Analytic framework for cardiac ablation procedures for SVTA from the 2013 HTA



* SVTA includes supraventricular tachycardias, atrial fibrillation and atrial flutter
† General list of outcomes; not all may be relevant to a specific SVTA or all primary outcomes;
LA = left atrium, LV = left ventricle

Detailed study selection criteria from the 2013 HTA are in ***Appendix A***.[1] In brief, the authors of the previous HTA included randomized controlled trials (RCTs) and cohort studies comparing catheter ablation to medical therapy. This summary focuses on KQ1 and KQ3 as they provide the most relevant evidence regarding comparative efficacy and safety outcomes for evaluating whether updates to the existing catheter ablation coverage determination are warranted.

For KQ1 (effectiveness), the HTA included 11 RCTs and 12 cohort studies across all supraventricular tachycardia (SVT) types. For atrial fibrillation, the HTA included 8 RCTs (n = 932) and 6 cohort studies (n = 1,548) that compared radiofrequency catheter ablation with antiarrhythmic drugs. Review authors found that radio frequency ablation was superior to antiarrhythmic drugs in maintaining sinus rhythm (freedom from recurrence: 74.9% vs. 23.3% at 12 months; high strength of evidence [SoE]) and improved quality of life (Moderate SoE). Review authors found no differences in mortality (0.3% vs. 0.4%), stroke (0.3% vs. 0.6%), or heart failure (0.7% vs. 1.0%) at 12 months (low SoE).

For atrial flutter, the HTA included 1 RCT (n = 104) and 1 cohort study (n = 61) that compared radiofrequency ablation with antiarrhythmic drugs. HTA authors found radiofrequency ablation was superior to antiarrhythmic drugs for preventing recurrence at 12 to 13 months (87% vs. 29%;

moderate SoE). For SVTAs, the HTA included 2 RCTs (n = 81) and 5 cohort studies (n = 458) that showed radiofrequency ablation was more effective than medical therapy or surgery in preventing arrhythmia recurrence for WPW syndrome, AVRT, and AVNRT (low to moderate SoE). Success rates for radiofrequency ablation ranged from 93% to 100% at follow-up periods ranging from 5 months to 5 years. Overall, the evidence indicated that catheter ablation was more effective than medical therapy for maintaining normal sinus rhythm across all SVT types with no difference in mortality, stroke, or heart failure, though the strength of evidence varied by condition.[1]

For KQ3 (safety), the 2013 HTA evaluated evidence from 34 studies. For AF, the HTA included 9 RCTs, 4 cohort studies comparing radiofrequency PVI to antiarrhythmic drugs, 1 cohort study comparing radiofrequency PVI with Cox-Maze surgery, 1 RCT comparing cryoablation with antiarrhythmic drugs, and 10 case series. The HTA found low SoE for no difference in mortality, thromboembolic events (0.7% vs. 0.6%), pericardial effusion/cardiac tamponade (1.3% vs. 0.8% for radiofrequency PVI; 0.6% vs. 1% for cryoablation PVI), and pulmonary vein stenosis between ablation and antiarrhythmic drugs. For atrial flutter, the HTA included 1 RCT and 6 prospective case series. Authors reported low SoE for no difference in procedure-related mortality between radiofrequency ablation and antiarrhythmic drugs, with no treatment-related deaths reported in either group. For SVTs, the HTA included 4 cohort studies for AVNRT, 1 RCT and 1 cohort study for AVRT, 1 cohort study for mixed SVT populations, and 6 large case series. The SoE was insufficient regarding persistent AV block (higher with ablation, 22.7% vs. 4%) and pacemaker implantation (no difference, 3.1% vs. 3%) when comparing ablation to surgery for AVNRT, with no other comparative safety data available. Overall, although catheter ablation procedures had a higher complication rate compared with medical therapy, the incidence of serious complications was relatively low.[1]

1.4 Epidemiology and Burden of Disease

SVTs can be categorized by the origin of the tachyarrhythmia:[1,20]

- Atrial tachyarrhythmias initiate within the atrium and include sinus tachycardia (including inappropriate sinus tachycardia [IST] and sinus nodal reentrant tachycardia [SNRT]), atrial tachycardia [including focal and multifocal], macroreentrant atrial tachycardia [i.e., atrial flutter], and AF).

- Atrioventricular tachyarrhythmias originate within the atrioventricular (AV) node or the surrounding area and include AVNRT; AVRT, which includes WPW syndrome; focal junctional ectopic tachycardia (JET) and nonparoxysmal junctional tachycardia.[20]

1.4.1 Atrial Fibrillation (AF)

AF, which is the most common heart arrythmia, is an SVT resulting from structural or electrophysiological abnormalities that cause abnormal impulse formation and propagation.[21,22] Symptoms range from minimal to severe and include fatigue, decreased exercise tolerance, lightheadedness, difficulty breathing, and palpitations.[21] Risk factors include increasing age, hypertension, body mass index, smoking, cardiac disease, and diabetes.[23] In the United States,

prevalence of AF was 6.6 million in 2015[23,24] and is estimated to increase to 12.1 million by 2030.[25] The incidence of AF among adults aged 65 years and older is estimated to be 23.7 per 1,000 person-years (95% CI, 21.0 to 26.7).[26] In 2021, AF was the underlying cause of death in 28,037 people and was listed on 232,030 U.S. death certificates (any-mention mortality; unpublished National Heart, Lung, and Blood Institute tabulation using National Vital Statistics System 189).[23] An analysis of U.S. public and private health insurer records from 1996 to 2016 found that AF was 33rd in spending for health conditions with an estimated $28.4 billion (95% CI, $24.6 to $33.8 billion) in 2016 dollars.[23,27]

1.4.2 Atrial Flutter

Atrial flutter, or macroreentrant atrial tachycardia, is characterized by an organized atrial rhythm with a macroreentrant electrical pathway that may or may not involve the cavotricuspid isthmus (CTI).[1,28] When atrial flutter involves CTI, it is labeled CTI-dependent atrial flutter. When CTI-dependent flutter involves a circuit that rotates around the tricuspid valve in a counterclockwise direction (up the septum and down the free wall), it is called "typical"; less commonly, the CTI-dependent flutter circuit rotates in a clockwise direction (sometimes called "reverse").[29] Atrial flutter is a common atrial arrhythmia with a reported overall incidence of 88 per 100,000 person-years, and incidence increases with age.[29] Atrial flutter is 2.5 times more common in men than in women, and it is significantly more likely to occur in patients with underlying heart failure or chronic obstructive pulmonary disease.[29] Atrial flutter is associated with increased thromboembolic risk, but the exact risk is difficult to ascertain because atrial flutter often coexists with AF.[29]

1.4.3 AV Nodal Reentrant Tachycardia (AVNRT)

AVNRT is the most common SVT after AF.[30] This arrhythmia typically results from conduction down a slow AV nodal pathway and up the fast AV nodal pathway, with an almost simultaneous conduction up to the atria and down to the ventricles.[31] AVNRT is most frequently diagnosed in young adults without structural heart disease or ischemic heart disease, and more than 60% of cases are observed in women.[30] AVNRT is often not bothersome and is rarely life threatening. Symptoms often include sudden onset of palpitations, possibly with shortness of breath, dizziness, and neck pulsations.[30]

1.4.4 AV Reentrant Tachycardia (AVRT)

AVRT is characterized by the presence of accessory pathways: extra nodal pathways connecting the atria and ventricles.[30] These accessory pathways can conduct impulses in an anterograde manner, retrograde manner, or both. A type of AVRT, WPW syndrome, is characterized by pre-excitation combined with tachyarrhythmias.[1]

1.4.5 Sinus Tachyarrhythmias

Sinus tachyarrhythmias include IST and SNRT. IST is sinus tachycardia that is unexplained by physiological demands at rest, with minimal exertion, or during recovery from exercise. This definition includes the presence of associated symptoms that include weakness, fatigue, lightheadedness, and uncomfortable sensations, such as heart racing.[30] The cause of IST is unclear, and mechanisms related to dysautonomia, neurohormonal dysregulation, and intrinsic

sinus node hyperactivity have been proposed.[30] SNRT arises from reentrant circuits involving the sinus node's production of paroxysmal and often nonsustained bursts of tachycardia.[1,30]

1.4.6 Focal Atrial Tachycardias

Focal atrial tachycardias are characterized by a fast rhythm from a discrete origin, discharging at a rate that is generally regular, and conducting in a centrifugal manner throughout the atrial tissue.[30] Focal atrial tachycardias represent approximately 3% to 17% of the patients referred for SVT ablation. Symptoms may not be present, or they may be severe. Focal atrial tachycardias in adults is usually associated with a benign prognosis, although atrial tachycardia-mediated cardiomyopathy has been reported in up to 10% of patients referred for ablation of incessant SVT. Nonsustained focal atrial tachycardias are common and often do not require treatment.[30] The underlying mechanism of focal atrial tachycardias can be automatic and triggered by activity or microreentry. However, methods to distinguish the mechanism tend to have modest value because of limited sensitivity and specificity.[30]

1.4.7 Focal Junctional Ectopic Tachycardia (JET)

JET is an uncommon arrhythmia and originates from the AV node or bundle of His.[32] Enhanced normal automaticity has been suggested as the mechanism of JET, which is more common in children. Distinguishing JET and AVNRT can be challenging. Medical treatment of JET is difficult, and catheter ablation remains the mainstay of treatment in refractory cases with a high risk of atrioventricular block and recurrence.[32]

1.5 Diagnosis

The detection of SVTs, including atrial fibrillation, requires a detailed patient history and physical examination, including measurement of blood pressure, to assess for evidence of predisposing diseases and risk factors and intercurrent illness.[21] Depending on the frequency of symptoms, ambulatory ECG recording (e.g., Zio patch) may be required over weeks to months to establish the diagnosis.[21] Consumer ECG recording systems, including small handheld devices and watches, can reveal irregular rhythms, but artifact can mimic or obscure the diagnosis, and confirmatory 12-lead ECG recordings should be obtained.[21]

1.6 Treatment Options

Catheter ablation is an established therapy for SVTs based on the results of multiple RCTs and evidence from large registries.[29] Catheter ablation continues to evolve as new technologies or adaptations of existing approaches are developed to improve effectiveness or safety. Catheter ablation is considered first-line treatment for some types of arrythmias (e.g., WPW syndrome). For other arrythmias, pharmacologic therapy of arrythmias is frequently effective but can be limited by high failure rates and drug toxicity. For some arrythmias, ablation may be an option for the treatment of recurrent or persistent symptomatic arrhythmia that has been refractory to pharmacotherapy.[29] Ablation is increasingly being used as first-line therapy in AF in some types of patients (e.g., paroxysmal, young patients, heart failure) to prevent progression of disease.[33]

1.7 Technology

Catheter ablation is a procedure used to control or eliminate arrhythmias by targeting and disrupting abnormal electrical pathways in the heart. This is accomplished by ablating (i.e., destroying) cardiac tissue to leave scars that can disrupt the problematic electrical pathways or cells, helping to restore normal rhythm or prevent arrhythmias from recurring. The procedure is typically performed in an electrophysiology lab and involves guided insertion of catheters from the arm, groin, or neck through the blood vessel and into the heart. Selection of the energy source used to ablate the cardiac tissue depends on operator experience, arrhythmia target location, and patient preference.[34]

Cardiac ablation is a technology with a large, mature evidence base that reflects a well-established safety and efficacy profile across various supraventricular tachyarrhythmias.[35] For many arrythmias, such as AF, current research has shifted away from research questions about whether ablation is effective or safe to focusing instead on incremental technological advancements, refinement of techniques, and development of novel energy sources.[36] This evolution reflects the scientific community's confidence in ablation as a standard therapeutic approach, with current investigations primarily aimed at enhancing procedural efficiency, reducing collateral tissue damage, and improving long-term outcomes.[37] For many arrythmias, evidence from large multicenter trials and meta-analyses consistently demonstrates the superiority of catheter ablation over medical therapy for arrhythmia control,[38,39] with increasing emphasis now being placed on evaluating newer technologies like pulsed field ablation and other nonthermal energy sources that maintain efficacy while potentially improving the safety profile.[40,41]

1.7.1 Radiofrequency Catheter Ablation

Radiofrequency is the most commonly used energy source.[34] In radiofrequency catheter ablation, radiofrequency energy is sent through the catheter to a focal point in the heart that is believed to be the source of the arrhythmia; this thermal energy ablates small areas of the heart to disrupt abnormal electrical activity.

1.7.2 Cryoablation

Cryoablation, sometimes referred to as cryothermal ablation, uses a pressurized refrigerant in the catheter tip to ablate the source of the arrhythmia. This includes cryoballoon ablation, which involves cooling and freezing of the targeted tissue using coolant inside a balloon.[42] Cryoablation is used as an alternative to radiofrequency ablation to minimize injury to the AV node during ablation of specific arrhythmias, such as AVNRT, para-Hisian atrial tachycardias, and para-Hisian accessory pathways, particularly in children and young adults.[34]

1.7.3 Laser Ablation

Laser ablation, or laser balloon ablation, is a relatively new modality that consists of a balloon adjustable in size and a miniature endoscope allowing for visually guided segment-by-segment ablation.[43] It was first approved by the U.S. FDA in 2016,[11] and so was not included in the 2013 HTA. Like radiofrequency ablation and cryoablation, laser ablation uses thermal energy to destroy tissue. It is similar to cryoballoon ablation in that it is a single-shot technique. Laser

ablation may have favorable feasibility with less need for extensive catheter manipulations and a lower learning curve for operators.[44]

1.7.4 Pulsed Field Ablation

Pulsed field ablation is a relatively new modality that was approved by the FDA in 2023 and therefore not in use when the previous HTA was published in 2013. Pulsed field ablation involves nonthermal energy: microsecond-scale, high-voltage electrical fields to cause irreversible electroporation and destabilization of cell membranes, a process that culminates in cellular necrosis.[45,46] Experts contend that this form of energy has specificity that allows myocardial tissue to be preferentially ablated with limited effects on adjacent tissues such as the esophagus, phrenic nerve, and pulmonary vein tissue.[45]

1.8 Objectives

The primary aim of this signal search was to determine whether there is new evidence that will change the conclusions of the 2013 State of Washington HTA on cardiac catheter ablation procedures for SVTs including atrial flutter and atrial fibrillation.

2. Methods

We used a modified Ottawa approach,[3,4] relying primarily on recent systematic reviews (i.e., those published in the last 4 years). Because catheter ablation is already covered for reentrant SVTs, atrial flutter, and AF, we will focus the signal search on safety outcomes. For technologies that were not in use in 2013 and thus not explicitly included in the 2013 coverage decision (i.e., pulsed field ablation and laser ablation), we will summarize results related to both efficacy and safety.

2.1 Literature Search

We searched MEDLINE® (via PubMed) for relevant English-language studies between March 25, 2012, and November 5, 2024, allowing an overlap of 6 months with the previous search. The search strategy is described in detail in ***Appendix B***. We limited the search results to systematic reviews using filters. We searched ClinicalTrials.gov on November 5, 2024, for trials of included cardiac ablation procedures.

2.2 Study Selection

We sought to identify systematic reviews that would include primary research studies that meet the HTA's inclusion and exclusion criteria. For this signal search, the only change we made to the inclusion and exclusion criteria from the 2013 HTA was that we included pulsed field ablation and laser ablation as eligible ablation procedures. Detailed inclusion and exclusion criteria are shown in ***Appendix A***.

2.3 Data Abstraction and Signal Assessment

One reviewer evaluated titles and abstracts retrieved by our search; that same reviewer also assessed full-text systematic review articles to determine if they met selection criteria and

reported relevant findings. Newer systematic reviews were screened and abstracted first to identify the most recent evidence. Note that when systematic reviews have similar inclusion and exclusion criteria, newer systematic reviews are likely to include the same primary research studies as older systematic reviews, reducing the utility of also abstracting data from the older systematic reviews. Therefore, we stopped abstracting findings from older reviews once we identified a signal for an included indication and procedure. We also prioritized abstraction of high-impact systematic reviews (e.g., Agency for Healthcare Research and Quality, National Institute for Health and Care Excellence [NICE], or Cochrane reviews). We abstracted findings from additional systematic reviews if there were opposing or inconsistent findings or if the reviews differed in scope. For indications without 2 recent systematic reviews, we first searched for older systematic reviews, clinical practice guidelines, and then primary studies as needed to achieve a signal determination.

Because the 2013 HTA led to coverage of cardiac ablation procedures (radiofrequency and cryoablation) with conditions, we considered reviews that reported safety outcomes or provided evidence that may alter coverage conditions (i.e., coverage only after drug therapy is ineffective or not tolerated). For new ablation procedures (i.e., pulsed field ablation and laser ablation), we considered systematic reviews reporting on efficacy and safety.

3. Results

3.1 Search Yield and Overview of Studies

The PubMed search retrieved a total of 12,588 citations, including 724 systematic reviews. Given the pace and volume of published research, we screened only the 372 systematic reviews published since 2020 for this signal search and excluded 278 systematic reviews after title and abstract review. We included 94 systematic reviews at full-text and screened studies based on indication, ablation procedure, outcome, and recency of publication until a signal, defined as more than 2 systematic reviews with similar scopes reaching the same conclusion, were extracted.

3.2 Study Characteristics

For AF, we reviewed 2 systematic reviews examining radiofrequency and cryoballoon ablation safety,[5,6] 4 reviews evaluating ablation as first-line therapy,[7-10] 2 reviews reporting on laser balloon ablation,[5,8] and 3 reviews of pulsed field ablation.[12,13,47] For atrial flutter, we identified 3 systematic reviews comparing radiofrequency and cryoballoon ablation[16-18] but found no systematic reviews examining laser or pulsed field ablation. For other supraventricular tachyarrhythmias, we found 2 systematic reviews for AVNRT,[48,49] 1 for AVRT/WPW syndrome,[50], 1 for IST,[51] and limited primary studies for focal atrial tachycardias and JET.[52] For less common indications without systematic reviews, we also reviewed relevant clinical practice guidelines from the American College of Cardiology (ACC), American College of Chest Physicians (ACCP), the American Heart Association (AHA), and the Heart Rhythm Society (HRS) on the management of adult patients with SVT.[34]

3.3 Signal Findings

3.3.1 Atrial Fibrillation

Table 1 provides a summary of the signals identified from systematic reviews of AF; detailed information about these systematic reviews is provided in ***Tables C-1 to C-3*** in ***Appendix C***.

Table 1. Summary of signal search findings for AF

Ablation Procedure	Previous Coverage Decision	Signal Search Evidence	Signal
Radiofrequency and cryoballoon ablation: Safety	Covered if drug therapy is either not tolerated or is ineffective	2 large, recent systematic reviews with meta-analyses confirm safety[5,6]	No signal for update Confirms findings of 2013 HTA
Ablation as first-line therapy	Not covered as first-line therapy	4 systematic review with meta-analyses with evidence supporting first-line therapy[7-10]	Signal for update Consider updating 2013 HTA to remove or revise coverage condition
Laser balloon ablation	New technology not explicitly mentioned	2 systematic reviews with network meta-analysis suggesting safety and efficacy[5,8]	Unclear New evidence since the 2013 HTA Does not have a unique billing code from other ablation procedures (may already be covered in practice)
Pulsed field ablation	New technology not explicitly mentioned	3 systematic reviews with meta-analyses suggesting safety and efficacy[12,13,47]	Unclear New evidence since the 2013 HTA Does not have a unique billing code from other ablation procedures (may already be covered in practice)

Abbreviations: AF = atrial fibrillation; HTA = health technology assessment.
Legend
Green shading indicates new evidence that could change conclusions from the previous HTA.
Yellow shading indicates new evidence; unclear if new evidence is likely to change conclusions from the previous HTA.
No shading indicates new evidence is consistent with previous conclusions.

3.3.1.1 Atrial fibrillation: Safety

We identified 2 systematic reviews with meta-analyses with consistent findings that confirmed the safety of radiofrequency or cryoballoon ablation for AF. A 2021 evidence review by the United Kingdom's NICE based on 56 RCTs (reported in 65 papers) evaluated various ablation techniques for AF.[5] For patients with paroxysmal AF, the review found that catheter ablation techniques were the most clinically effective options. Radiofrequency point-by-point ablation was determined to be more cost-effective over a lifetime than antiarrhythmic drug treatment and other ablation strategies in patients for whom one or more antiarrhythmic drugs had failed. Cryoballoon ablation was the second most cost-effective option. The review noted that cryoballoon ablation may be more suitable for some patients because they can sometimes be performed without general anesthesia, and cryoballoon ablation may be quicker to perform, with same-day discharge more likely.[5]

Zhao et al. (2024)[6] conducted a systematic review and network meta-analysis of 22 RCTs (N = 5,073) that specifically focused on safety outcomes of different ablation techniques for AF. The review reported on outcomes including phrenic nerve palsy, pericardial effusion, infection, pseudoaneurysm, pulmonary vein stenosis, and pain. The review found no significant differences

in the incidence of major adverse events among different ablation techniques. Compared with radiofrequency ablation, cryoablation was significantly associated with a higher risk of phrenic nerve paralysis but a reduced risk of intraoperative infection.

Based on these large systematic reviews, radiofrequency ablation and cryoballoon ablation remain safe interventions to treat AF, which is consistent with the conclusions of the 2013 HTA and coverage decision.

3.3.1.2 Atrial fibrillation: Ablation as first-line therapy

We identified at least 4 systematic review with meta-analyses that evaluated catheter ablation as first-line therapy compared with antiarrhythmic drugs for AF.[7-10] Based on 5 RCTs (N = 994), Cordoso et al. (2022) found that catheter ablation significantly reduced atrial tachyarrhythmia recurrence (odds ratio [OR], 0.36; 95% CI, 0.25 to 0.52), symptomatic AF (OR, 0.32; 95% CI, 0.18 to 0.57), and hospitalizations (OR, 0.25; 95% CI, 0.15 to 0.42) compared with antiarrhythmic drugs.[7] Fong et al. (2023) reported significant reductions in AF recurrence with cryoballoon (hazard ratio [HR], 0.35; 95% CI, 0.25 to 0.48) and radiofrequency ablation (HR, 0.14; 95% CI, 0.07 to 0.30) compared with antiarrhythmic drugs based on 24 studies (N = 5,132).[8] Liu et al. (2022) focused specifically on cryoballoon ablation for persistent AF, analyzing 5 RCTs (N = 923) and 1 observational study.[9] Compared with antiarrhythmic drugs, cryoballoon ablation as first-line therapy significantly reduced the recurrence rate of atrial arrhythmia (risk ratio [RR], 0.59; 95% CI, 0.49 to 0.71), incidence of persistent AF (RR, 0.17; 95% CI, 0.06 to 0.49), and hospitalizations at 36 months (RR, 0.29; 95% CI, 0.15 to 0.58) while improving quality of life (standard mean difference on the Atrial Fibrillation Effect on Quality of Life: 0.40; 95% CI, 0.14 to 0.67).[9] Ullah et al. (2024) conducted a systematic review and meta-analysis of 6 RCTs (N = 1,120) and found that ablation reduced the risk of any AF recurrence (RR, 0.54; 95% CI, 0.39 to 0.75) compared with antiarrhythmic drugs and had comparable safety outcomes, including major adverse cardiovascular events, trial-defined composite endpoint of adverse events, stroke, and all-cause mortality, though confidence intervals for these safety outcomes were wide.[10]

Based on the consistent findings of these systematic reviews, catheter ablation could be considered as first-line therapy for appropriate patients with AF, rather than requiring a trial of antiarrhythmic drugs first. This evidence suggests a need for updating the 2013 HTA and reconsideration of the current coverage decision, which currently covers catheter ablation only after drug therapy failure or intolerance occurs. Notably, the 2023 joint ACC/AHA/ACCP/HRS Clinical Practice Guideline recommends ablation in patients with symptomatic AF when antiarrhythmic drugs have been ineffective, contraindicated, not tolerated, or not preferred.[29] However, the recommendation adds that in selected patients, generally those who are younger or who have few comorbidities, catheter ablation is useful as first-line therapy to improve symptoms and reduce progression to persistent AF.[29]

3.3.1.3 Atrial fibrillation: Laser balloon ablation efficacy and safety

Laser balloon ablation was first approved by the FDA in 2016,[11] and so was not included in the 2013 HTA. Therefore, we reviewed both efficacy and safety-related evidence. A 2021 systematic evidence review by NICE[5] included a network meta-analysis (NMA) comparing different

ablation techniques for atrial fibrillation. The NMA included only 1 RCT (Schmidt, 2017; n = 172) directly comparing laser balloon with radiofrequency point-by-point ablation.[53] This RCT found laser balloon ablation had similar effectiveness as radiofrequency ablation. Specifically, for maintenance of sinus rhythm at 12 months post-ablation, laser balloon showed no statistically significant difference compared with radiofrequency point-by-point ablation (RR, 1.01, 95% CI, 0.72 to 1.42). The rate of freedom from AF at 12 months was 63.5% for laser balloon versus 63.9% for radiofrequency ablation, indicating similar effectiveness. The NMA ranked laser balloon ablation as the third most clinically effective ablation technique for paroxysmal AF, after radiofrequency and cryoballoon ablation, though confidence intervals were wide and overlapping. This evidence review found the overall incidence of adverse events was similar between laser balloon and radiofrequency ablation (17% vs. 16.3%).[5] The NICE review concluded that laser balloon may be a suitable option for some patients because it can sometimes be performed without general anesthesia.[5]

Fong et al. (2023) examined laser balloon ablation in a NMA of 24 studies (N = 5,132) comparing different ablation modalities and antiarrhythmic drugs for paroxysmal AF.[8] In the hazard ratio-based analyses, there was no significant difference in recurrence between laser balloon ablation compared with antiarrhythmic drugs (HR, 0.43; 95% CI, 0.15 to 1.26). The authors noted that in restricted mean survival time-based analyses, laser balloon ablation was significantly favored over antiarrhythmic drugs. This finding is limited by only 2 laser balloon studies with short follow-up. The authors concluded that laser balloon ablation showed favorable short- and long-term investigation in future trials may be warranted.[8]

This evidence suggests that laser balloon ablation may be a safe and effective treatment for AF. However, the evidence base is limited compared with radiofrequency ablation and cryoballoon ablation, with only a few studies specifically examining laser balloon ablation. Because laser ablation is generally billed under the same umbrella of billing codes as radiofrequency ablation, it may already be covered under the existing coverage decision despite not being explicitly mentioned.[15] A small body of clinical evidence suggests that laser ablation's effectiveness and safety profile may be comparable to other ablation techniques that are already covered. Given the limited but promising evidence, and the fact that this technology may already be effectively covered under current billing practices, it is unclear whether an updated HTA and revaluation of the coverage decision is specifically needed for laser balloon ablation.

3.3.1.4 Atrial fibrillation: Pulsed field ablation

Pulsed field ablation is a relatively new technology, FDA approved in 2023, that was not included in the 2013 HTA. Therefore, we reviewed both efficacy and safety-related evidence.

We identified at least 3 systematic reviews with meta-analysis that assessed pulsed field ablation for AF. Evidence consistently showed that pulsed field ablation had comparable efficacy to established ablation techniques. Specifically, Qamar et al. (2024) conducted a systematic review and meta-analysis of 26 studies (N = 2,561) showing that pulsed field ablation had a high acute procedural success rate of 99.7% for ablating tissues surrounding the pulmonary veins, the most common source of AF.[12] Zhang et al. (2024) analyzed 15 trials (N = 1,880) comparing pulsed field ablation with cryoballoon ablation and found no statistically significant difference in

recurrence (OR, 0.83; 95% CI, 0.64 to 1.07), and pulsed field ablation was associated with significantly shorter procedure times (mean difference [MD], -7.17 minutes; 95% CI, -13.60 to -0.73).[47] Aldaas et al. (2024) conducted a systematic review and meta-analysis of 6 comparative studies (N = 1,012) comparing pulsed field ablation with thermal ablation methods (radiofrequency or cryoballoon) and found significantly shorter procedure times with pulsed field ablation (MD, -21.95 minutes; 95% CI, -33.77 to -10.14).[13] There was no statistically significant difference in recurrence (RR, 0.64; 95% CI, 0.31 to 1.34).[13]

We also note a recently published randomized noninferiority trial (N = 210) comparing pulsed field ablation with cryoballoon ablation that found pulsed field ablation was noninferior to cryoballoon ablation.[14] This pivotal trial found that pulsed field ablation was significantly better than cryoballoon ablation for the primary endpoint of first recurrence of atrial tachyarrhythmia between days 91 and 365 post-ablation (37.1% vs. 50.7%, between-group difference: -13.6%; 95% CI, -26.9% to -0.3%; $p<0.001$ for noninferiority, $p=0.046$ for superiority).[14]

Like laser balloon ablation, pulsed field ablation is generally billed under the same umbrella of billing codes as radiofrequency ablation;[15] it may already be covered under the existing coverage decision despite not being explicitly mentioned. Thus, it is unclear whether an updated HTA and revaluation of the coverage decision is specifically needed for pulsed field ablation.

3.3.2 Atrial Flutter

Table 2 provides a summary of the signals identified from systematic reviews of atrial flutter; detailed information about these revies is provided in ***Table C-4*** in ***Appendix C***.

Table 2. Summary of signal search findings for atrial flutter

Ablation Procedure	Previous Coverage Decision	Signal Search Evidence	Signal
Radiofrequency and cryoballoon	Covered without conditions	3 systematic reviews with meta-analyses[16-18]	No signal for update • Confirms findings of 2013 HTA
Laser balloon ablation	New technology not explicitly mentioned	No systematic reviews or other evidence; not in widespread use	No signal for update • No/limited evidence since 2013 HTA
Pulsed field ablation	New technology not explicitly mentioned	No systematic reviews other evidence; 1 case report;[54] not in widespread use	No signal for update • No/limited evidence since 2013 HTA

Abbreviations: HTA = health technology assessment.

We identified at least 3 systematic reviews with meta-analyses that evaluated cardiac ablation for atrial flutter.[16-18] Diamant et al. (2021) found radiofrequency and cryoballoon ablation, analyzed together in patients with heart failure and atrial flutter, were associated with high immediate procedural success rates (87% to 100%) with atrial flutter recurrence rates between 5% and 30% during follow-up periods extending to 2.3 years.[16] Chen et al.(2015) compared radiofrequency and cryoballoon ablation and found no statistically significant differences in acute success (RR, 0.93; *P*=0.14) or long-term success (RR, 0.94; *P*=0.08). Notably, cryoballoon ablation was associated with significantly longer procedure time (weighted mean difference [WMD], 25.95

minutes; *P*=0.01), but pain perception scores significantly favored cryoballoon ablation (standard mean difference [SMD], -2.36; *P*<0.00001).[17] Zeng et al. (2019) analyzed 8 studies comparing cryoballoon and radiofrequency ablation and reported myocardial injury based on biomarkers. The authors found cryoballoon ablation was associated with higher levels of myocardial injury biomarkers but improved pain perception compared with radiofrequency ablation.[18] The current evidence does not suggest a safety concern suggesting a need to update the 2013 HTA.

This new evidence is consistent with recent clinical practice guidelines for atrial flutter, which also indicate that catheter ablation continues to be a safe option for atrial flutter. The NICE 2021 guidelines recommended offering rate control as the first-line treatment strategy except in people with atrial flutter whose condition is considered suitable for an ablation strategy to restore sinus rhythm.[55] The 2023 joint ACC/AHA/ACCP/HRS guideline states that catheter ablation of typical atrial flutter is effective and relatively low risk. The guideline recommends catheter ablation for improving symptoms in patients with symptomatic or clinically significant atrial flutter.[29]

We did not identify any studies examining laser ablation or pulsed field ablation for atrial flutter. We did identify a case report describing pulsed field ablation used in a case of paroxysmal AF in which atrial flutter was discovered incidentally.[54] The authors of the 2024 case report note they are not aware of any studies of pulsed field ablation for conditions other than AF and suggest, based on a single case, that pulsed field ablation may have potential for treating diverse arrhythmias.[54] We also did not identify any studies of laser ablation for atrial flutter but found 2 cohort studies reporting incidence of atrial flutter as an outcome of ablation to treat AF.[56,57]

3.3.3 Other Supraventricular Tachyarryhthmias (SVTA)

Table 3 provides a summary of the evidence identified from systematic reviews, practice guidelines, and other studies of SVTAs; detailed information about this evidence is provided in ***Table C-5*** in ***Appendix C***.

Table 3. Summary of signal search findings for other SVTAs

Radiofrequency and Cryoballoon: Safety (Covered without conditions based on 2013 HTA)		
AV nodal reentrant tachycardia (AVNRT)	2 systematic reviews with meta-analysis[48,49]	No signal for update • Confirms findings of 2013 HTA
AV reentrant tachycardia (AVRT) including Wolff-Parkinson-White (WPW) syndrome	1 systematic review[50] and 1 related CPG[34]	No signal for update • Confirms findings of 2013 HTA
Sinus tachyarrhythmias (asymptomatic pre-excitation)	1 systematic review and expert panel recommendation[30]	No signal for update • Confirms findings of 2013 HTA
Inappropriate sinus tachycardia (IST)	1 systematic review.[51] and 1 related CPG[34]	No signal for update • Very limited evidence in 2013 HTA • Very limited new evidence based on signal search
Focal atrial tachycardias	1 small retrospective study (n = 15)[52]	No signal for update • Very limited evidence in 2013 HTA • Very limited new evidence based on signal search
Laser Balloon and Pulsed Field Ablation (New technology not included in 2013 HTA)		

All SVTAs listed above	No systematic reviews or CPGs; not in widespread use	No signal for update • No/limited evidence since 2013 HTA

Abbreviations: CPG = clinical practice guideline; HTA = health technology assessment; SVTA = supraventricular tachyarrythmia.

3.3.3.1 AV nodal reentrant tachycardia (AVNRT)

We identified 2 systematic reviews with meta-analysis that compared cryoballoon ablation and radiofrequency ablation in patients with AVNRT.[48,49] Siranart et al. (2024) conducted a systematic review and meta-analysis that included 27 studies (7 RCTs and 20 observational studies) with 5,110 participants.[48] Findings demonstrated overall success rates ranging from 89.78% to 100% across all ablation types, with no significant differences in success rates between different catheter types. The review found no significant difference in permanent AV block incidence between catheter types.[48] Hanninen et al. (2013) performed a systematic review and meta-analysis that included 14 trials with 5,617 participants.[49] The results showed no significant difference in acute procedural failure (RR, 1.44; 95% CI, 0.91 to 2.28) between cryoballoon and radiofrequency ablation. The review found higher long-term recurrence with cryoablation (RR, 3.66; 95% CI, 1.84 to 7.28). Notably, permanent AV block occurred in 0.75% of radiofrequency procedures compared with 0% in cryoablation procedures (n = 1,066, *P*=0.01). Similarly, the 2015 joint ACC/AHA/HRS Clinical Practice Guideline on the management of adult patients with SVTA recommended catheter ablation as first-line therapy for patients with symptomatic AVNRT.[34]

3.3.3.2 AV reentrant tachycardia (AVRT) including Wolff-Parkinson-White (WPW) syndrome

We identified 1 systematic review published in 2023 that included 11 cohort studies with 5,537 participants diagnosed with WPW syndrome who received cryoballoon or radiofrequency ablation.[50] Findings of the single-arm meta-analysis suggest a high success rate (94.1%; 95% CI, 92.4 to 95.9), a low recurrence rate (6.2%; 95% CI, 4.5 to 7.8), and a low complication rate (1%; 95% CI, 0.4 to 1.5) based on a heterogenous group of studies.[50] The 2015 joint ACC/AHA/HRS Clinical Practice Guideline recommended catheter ablation in patients with AVRT as first-line therapy.[34] This recommendation was based on studies showing a success rate of approximately 93% to 95% and a 3% risk of major complications when patients are followed up for 6 months to 8 years.[34]

3.3.3.3 Sinus tachyarrhythmias

We identified 1 systematic review published in 2015 by the ACA/AHA/HRS that informed a clinical practice guideline on the management of adult patients with SVT, specifically asymptomatic pre-excitation.[30] This review included a single RCT in 76 patients that found a lower incidence of arrhythmic events among participants who underwent ablation compared with those who did not undergo ablation (RR, 0.08; 95% CI, 0.02 to 0.33). The expert panel concluded that given a very low risk of complications, risk stratification of patients with asymptomatic pre-excitation using an electrophysiological study may be beneficial, with consideration of accessory-pathway ablation in those deemed to be at high risk of future arrhythmias.[30]

3.3.3.4 Inappropriate sinus tachycardia (IST)

We identified 1 systematic review published in 2017 on ablation to treat IST that included 9 studies with 153 participants.[51] The review found a high acute success rate (88.9%), but complications were diverse and common, with 8.5% of patients experiencing a serious complication. The authors also noted that ablation protocols varied widely across studies, sample sizes were small, and ablation was used only for severe refractory cases.[51] The 2015 joint ACC/AHA/HRS Clinical Practice Guideline for the management of adult patients with SVTA also noted that sinus node modification should only be considered for patients who are highly symptomatic and cannot be adequately treated with medication.[34] Notably, the 2013 HTA did not include any studies specifically in patients with IST and evidence considered for deliberation seems to have come largely from a cohort study of patients with a variety of SVTAs.[58] The evidence specifically for this indication remains limited but does not vary from the limited evidence reviewed in the previous HTA.

3.3.3.5 Focal atrial tachycardias

We did not identify any systematic reviews of focal atrial tachycardias in an eligible population, though we did identify 2 systematic reviews of focal atrial tachycardias in pregnant patients.[59,60] The 2015 joint ACC/AHA/HRS Clinical Practice Guideline for the management of adult patients with SVTA states that RCTs comparing treatments for focal atrial tachycardias are not available and clinical outcomes have only been reported in small observational studies. Based on nonrandomized cohort studies, the guideline recommends catheter ablation in patients with symptomatic focal atrial tachycardias as an alternative to pharmacological therapy.[34]

3.3.3.6 Focal junctional ectopic tachycardia (JET)

We did not identify any systematic reviews of focal JET, which is a rare arrhythmia.[32] We also did not identify any clinical practice guidelines on the treatment of focal JET in adults. Thus, we searched for primary studies and identified 1 multicenter, retrospective study that included 15 patients with JET.[52] This small study found a 100% acute success rate after catheter ablation but a high recurrence rated with 8 of 15 (53%) participants experiencing a recurrence and 3 of 15 (20%) experiencing a high-grade AV block requiring permanent pacemaker. The authors concluded that catheter ablation of idiopathic JET in adults is associated with a high rate of recurrence requiring multiple procedures and high risk of AV block requiring pacemaker implantation. Notably, the 2013 HTA did not include any studies specifically of focal JET.

3.3.3.7 Laser or pulsed field ablation for other SVTs

Our literature search and review of clinical practice guidelines suggests that laser and pulsed field ablation are not in wide use for the treatment of SVTs beyond AF or atrial flutter. Pulsed field ablation, in particular, is an emerging intervention for atrial arrhythmias. Only small pilot studies have been published in the literature, suggesting no need for an updated HTA of these new technologies for these less common SVTs.[61,62]

3.4 Ongoing Studies

Searches of the ClinicialTrials.gov trial registry retrieved 1,604 unique trial registrations. Trials were predominantly focused on AF. ***Table 4*** summarizes trial status by indication. We identified

189 potentially relevant trials of AF based on the inclusion and exclusion criteria of 2013 HTA. Among these, 98 trials were complete, 40 were active, and 52 were recruiting or enrolling. Ongoing studies of AF show the field has evolved beyond questions of efficacy and safety to focus primarily on technological optimization and procedural refinement. Many studies compared ablation techniques, particularly radiofrequency, cryoballoon and pulsed field ablation, or focused on procedural refinements to optimize established methods through variations in pulmonary vein isolation or modified ablation approaches. A smaller number of ongoing studies assessed safety or refinements to existing procedures to reduce specific harms (e.g., esophageal protection). At least 4 ongoing studies of AF explicitly investigate ablation as first-line treatment, suggesting research on this question may have slowed.

There were many fewer studies of atrial flutter, with 18 potentially relevant trials. Among these, 2 were not yet recruiting, 3 were recruiting, and 13 were completed. We also searched for ongoing studies of other SVTAs and only identified 2 trial entries for studies in patients with AVNRT, both of which were completed and compared ablation techniques. We conducted additional, broader searches in ClinicalTrials.gov for the less common arrhythmias (IST, focal atrial tachycardias, and JET) but found no relevant studies. For example, we identified 3 studies of IST, but none are likely to be relevant to an update: 1 study was terminated, 1 study was a single-group study without a comparator, and 1 was a registry to capture real-world data. This suggests that the body of evidence for other SVTAs is not likely to increase soon.

Table 4. Summary of clinical trials

Procedure	Recruiting or Enrolling	Active, Not Recruiting	Completed
AF	52	40	98
Atrial flutter	3	2	13
Other SVTAs[a]	0	0	2

[a] Both trials were in patients with AV nodal reentrant tachycardia.
Abbreviations: AF = atrial fibrillation; SVTA = supraventricular tachyarrhythmia.

4. Discussion and Conclusions

Catheter ablation for AF represents a topic with a large, mature evidence base, reflecting both the prevalence of this condition and the widespread adoption of catheter ablation as a standard treatment. The large volume of literature allowed identification of consistent signals across multiple systematic reviews. The signal search results confirmed the safety profile of radiofrequency and cryoballoon ablation established in the 2013 HTA, with recent, large reviews confirming safety.[5,6] Multiple systematic reviews now support catheter ablation as first-line therapy for appropriate patients,[7-10] suggesting the coverage requirement for failed or intolerable drug therapy may no longer be consistent with the latest evidence. Laser balloon ablation, which was FDA-approved in 2016 after the 2013 HTA, demonstrated similar effectiveness to radiofrequency ablation.[5] Pulsed field ablation, which was FDA approved in 2023, showed high acute procedural success,[12] significantly shorter procedure times compared with cryoballoon ablation,[13] and was recently demonstrated to be noninferior to cryoballoon ablation in an RCT.[14] There is evidence for the efficacy and safety of these newer ablation technologies, which would typically signal the need for an updated HTA. However, laser balloon and pulsed field ablation

are billed under the same codes as radiofrequency ablation or cryoablation so they may already be covered in practice under the existing HTCC coverage decision. Thus, the need for an updated HTA is unclear.

For atrial flutter, the evidence base is more limited but consistent. Three systematic reviews confirmed that both radiofrequency and cryoballoon ablation achieve high procedural success rates without raising safety concerns.[16-18] Notably, we found no systematic reviews examining laser balloon or pulsed field ablation for atrial flutter, suggesting these technologies have not been widely adopted for this indication. The existing evidence supports the findings from the 2013 HTA, suggesting no need for an update.

Evidence for other SVTAs varied considerably by condition. For more common conditions like AVNRT and AVRT, systematic reviews demonstrated high success rates and acceptable safety profiles.[48-50] However, for rarer conditions such as IST and focal JET, evidence remains extremely limited. This paucity of evidence for rare conditions reflects the challenges of conducting research in small patient populations. Notably, the 2013 HTA did not include any studies exclusively of IST, focal atrial tachycardias, or focal JET and only included observational studies in populations with a variety of arrhythmias, thus findings from our signal search do not vary from the state of evidence that existed in 2013.

4.1 Limitations

This signal search has several limitations. First, we focused on systematic reviews published since 2020 for AF. Second, many systematic reviews had broader inclusion criteria than the 2013 HTA, potentially including studies with different patient populations or comparators. Third, for rare conditions, the evidence base remains limited by small sample sizes and heterogeneous study designs, making it difficult to draw definitive conclusions about safety and efficacy. We did not conduct risk of bias assessments of included reviews or studies, and we did not evaluate certainty of evidence. Finally, we did not review all search results and relevant studies could have been missed.

4.2 Conclusion

This signal search identified evidence that was mostly consistent with conclusions from the 2013 HTA,[1] supporting the safety and efficacy of catheter ablation (radiofrequency and cryoablation) for AF, atrial flutter, and other SVTAs. However, new evidence from multiple systematic reviews indicates catheter ablation could reasonably be offered as first-line therapy for appropriate patients with AF,[7-10] representing a change from the previous HTA and current coverage decision, which requires failed drug therapy before ablation. Additionally, there is new evidence since 2013 suggesting the safety and efficacy of laser balloon and pulsed field ablation for AF, though these procedures use the same billing codes as radiofrequency and cryoballoon ablation and so may already be covered in practice. For some rare SVTAs, evidence remained very limited, but this is consistent with the state of evidence in 2013. A narrowly focused update of the HTA to evaluate the evidence for ablation as a first-line treatment in AF and the role of laser and pulsed field ablation technologies may be warranted.

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Appendix A. Inclusion and Exclusion Criteria

Detailed inclusion and exclusion criteria from the 2013 review appear below. Note that we have revised the eligible index tests to include pulsed field ablation and laser ablation, which are new technologies introduced since the prior HTA.

Table A-1. Summary of inclusion and exclusion criteria

Study Component	Inclusion	Exclusion
Population	Adults with SVT, to include: • AF • Atrial flutter • SVT: - Sinus tachycardia (inappropriate sinus tachycardia and sinus nodal reentrant tachycardia) - Atrioventricular reentrant tachycardia (AVRT) including Wolff-Parkinson-White (WPW) syndrome - Atrioventricular nodal reentrant tachycardia (AVNRT) - Atrial tachycardia (including focal and multifocal) - Focal junctional ectopic tachycardia (JET) and nonparoxysmal junctional tachycardia	• Patients < 18 years of age • Ventricular tachycardia and paroxysmal ventricular tachycardia • Any tachyarrhythmia that does not originate from the sinus node, atrial tissue, or junctional sites between the atria and ventricles • Bradycardia • Patients with prior catheter ablation
Intervention	Catheter ablation: • For atrial fibrillation, we will only consider studies evaluating targeting of the pulmonary vein or pulmonary vein antrum and use of irrigated or 8 mm catheter tips • Radiofrequency • Cryoablation • Cryoballoon • Pulsed field ablation (New) • Laser ablation (New)	• Ablation as an adjunct to surgery, intraoperative ablation • Use of non-FDA approved devices or devices not in final stages for FDA approval • For atrial fibrillation, studies in which PV electrical isolation was not the goal of ablation (e.g., stand-alone radiofrequency ablation of complex fractionated atrial electrograms and linear ablations), as well as studies of ablation of the atrioventricular junction will be excluded • Complete AV node ablation requiring pacemaker implantation
Comparator test	• Medical therapy • Maze or other surgical procedures • Therapies intended to control rhythm • For KQ2, comparison of common different ablation approaches used to treat AF will be considered (e.g., pulmonary vein isolation vs. pulmonary vein isolation with additional areas [lines])	• Comparisons of different techniques used in catheter ablation (i.e., imaging, types of catheter tips, etc.) • Cardioversion alone (i.e., in the absence of antiarrhythmic medical therapy)
Outcomes	Efficacy/effectiveness:	• Nonclinical outcomes

Study Component	Inclusion	Exclusion
	• Freedom from recurrence of SVT • Improvement of symptoms (including palpitation, tachypnea, chest stuffiness, syncope, anxiety) • Quality of life and other patient-reported outcomes • Medication use (e.g., need for anticoagulants) • Hospitalization/readmission • Repeat ablation • Intermediate outcomes (including maintenance of sinus rhythm, chamber size, ejection fraction) • Prevention of mortality, embolic events, and congestive heart failure Safety: procedure or treatment related • Mortality • Embolic complications (including stroke or ischemic attack) • Congestive heart failure • Other reported complications including pericardial effusion or cardiac tamponade, pulmonary vein stenosis, atrioesophageal fistula, deep vein thrombosis, peripheral vascular complication (including pseudoaneurysm, hematoma at catheter insertion site, vascular injury) • Radiation exposure	
Study design	• For all KQs, focus will be placed on studies with the least potential for bias • KQ1: RCTs to assess efficacy; nonrandomized studies (for atrial fibrillation only, we will require at least 100 patients and a low risk of bias) will be considered to evaluate effectiveness; if no comparative studies are available for a given condition, prospective case series with N ≥ 50 will be considered • KQ2: RCTs comparing PVI with different ablation approaches for atrial fibrillation only • KQ3 (safety), RCTs and nonrandomized studies from Key Question 1 will be included; additional comparative studies and prospective case series designed specifically to evaluate adverse events will also be considered	• Nonclinical studies, studies of technique, imaging • Studies with < 10 patients per treatment group • Studies with less than 80% of patients having first time catheter ablation will be excluded • For KQs 1, 2, and 4: studies with less than 6 months' follow-up • For KQ3, retrospective case series and prospective case series with N < 1,000 (AF), N < 100 (atrial flutter), or N < 500 (SVTs) will be excluded • For KQ3, case series that evaluated only surgical or medical approaches will be excluded

Study Component	Inclusion	Exclusion
	• KQ4 (differential efficacy): RCTs or high-quality cohort studies with low risk of bias • Formal, full economic studies will be sought for KQ5	
Publication	• Studies published in English in peer-reviewed journals, published HTAs or publicly available FDA reports • Full, formal economic analyses (e.g. cost-utility studies) published in English in HTAs or in a peer-reviewed journals published after those represented in previous HTAs	• For AF and atrial flutter, studies with a publication date prior to 2000 will be excluded on the basis that they used conventional tips that are obsolete for these diagnoses • Studies reporting only on the technical aspects of ablation (e.g., imaging, type of catheter) • Abstracts, editorials, letters • Unpublished studies • Duplicate publications of the same study that do not report on unique outcomes • Single reports from multicenter trials • White papers • Narrative reviews • Articles identified as preliminary reports when results are published in later versions • Incomplete economic evaluations such as costing studies

Abbreviations: AF = atrial fibrillation; FDA = Food and Drug Administration; HTA = health technology assessment; PV = pulmonary vein; PVI = pulmonary vein isolation; RCTs = randomized controlled trials; SVT = supraventricular tachyarrhythmia.

Appendix B. Search Strategy

Table B-1. PubMed search detailed results for atrial fibrillation

Search range: March 25, 2012, to November 5, 2025

#	Search Code	Number of Articles
1	atrial fibrillation OR Atrial Fibrillation[MeSH]	55,355
2	ablation **OR** pulmonary vein* OR Pulmonary Veins[MeSH] OR "Pulmonary vein isolation" OR "Pulmonary vein antrum isolation" OR Heart Catheterization[MeSH] OR Cryoablation OR "cryoballoon ablation" OR (Cryosurgery[MeSH] AND ablat*) OR (("atrioventricular node" OR "AV node" OR "AV nodal" OR "atrioventricular junction" OR "AV junction") AND ablat*) OR "laser ablation" OR "pulsed field ablation"	82,800
3	#1 AND #2	13,964
4	Address[Publication Type] OR Bibliography[Publication Type] OR Case Reports[Publication Type] OR Comment[Publication Type] OR Editorial[Publication Type] OR Lecture[Publication Type] OR Legal Case[Publication Type] OR Letter[Publication Type] OR News[Publication Type] OR Newspaper Article[Publication Type]	1,321,282
5	#3 NOT #4	10,670

Table B-2. PubMed search detailed results for atrial flutter

Search range: March 25, 2012, to November 5, 2025

#	Search Code	Number of Articles
1	(atrial flutter) OR Atrial Flutter[MeSH] OR (macroreentrant atrial tachycardia*) OR (typical flutter) OR (atypical flutter) OR (isthmus AND flutter)	3,403
2	ablation OR pulmonary vein* OR Pulmonary Veins[MeSH] OR "Pulmonary vein isolation" OR "Pulmonary vein antrum isolation" OR Catheter Ablation[MeSH] OR Ablation OR Cryoablation OR "cryoballoon ablation" OR (Cryosurgery[MeSH] AND ablat*) OR (microwave AND ablat*) OR "laser ablation" OR "pulsed field ablation"	67,280
3	#1 AND #2	1,512
4	Address[Publication Type] OR Bibliography[Publication Type] OR Case Reports[Publication Type] OR Comment[Publication Type] OR Editorial[Publication Type] OR Lecture[Publication Type] OR Legal Case[Publication Type] OR Letter[Publication Type] OR News[Publication Type] OR Newspaper Article[Publication Type]	1,321,282
5	#3 NOT #4	1,159

Table B-3. PubMed search detailed results for SVTAs

Search range: March 25, 2012, to November 5, 2025

#	Search Code	Number of Articles
1	(Supraventricular AND (arrhythmia* OR tachycardia*)) OR Tachycardia, Supraventricular[MeSH]	4,172
2	(sinus AND (tachycardia* OR tachyarrhythmia*)) OR Tachycardia, Sinus[MeSH]	2,666
3	((Atrioventricular OR accessory OR node OR nodal OR extranodal OR reciprocating) AND (arrhythmia* OR tachycardia*)) OR AVNRT OR AVRT OR (Wolf AND Parkinson AND White) OR Wolf-Parkinson-White Syndrome[MeSH]	4,948
4	(Junctional AND (tachycardia* OR tachyarrhythmia)) OR Tachycardia, Ectopic Junctional[MeSH]	463
5	((focal OR multifocal atrial) AND (arrhythmia* OR tachycardia*)) OR Tachycardia, Ectopic Atrial[MeSH]	3,189
6	#1 OR #2 OR #3 OR #4 OR #5	11,697
7	ablation OR pulmonary vein* OR Pulmonary Veins[MeSH] OR "Pulmonary vein isolation" OR "Pulmonary vein antrum isolation" OR Catheter Ablation[MeSH] OR Ablation OR Cryoablation OR “cryoballoon ablation” OR (Cryosurgery[MeSH] AND ablat*) OR (microwave AND ablat*) OR "laser ablation" OR "pulsed field ablation"	67,280
8	#6 AND #7	4,190
9	Address[Publication Type] OR Bibliography[Publication Type] OR Case Reports[Publication Type] OR Comment[Publication Type] OR Editorial[Publication Type] OR Lecture[Publication Type] OR Legal Case[Publication Type] OR Letter[Publication Type] OR News[Publication Type] OR Newspaper Article[Publication Type]	1,321,282
10	#8 NOT #9	3,001

Table B-4. Combined PubMed search results by publication type

Search range: March 25, 2012, to November 5, 2025

#	Search Code	Number of Articles
#1	Search #1 Results OR Search #2 Results OR Search #3 Results	12,588
#2	#1 AND ((("Review"[Publication Type] OR "Review Literature as Topic"[Mesh]) AND "systematic"[Title/Abstract]) OR "Systematic Review"[Publication Type] OR "Systematic Reviews as Topic"[Mesh] OR "systematic review"[All Fields] OR "Meta-Analysis"[Publication Type] OR "Meta-Analysis as Topic"[Mesh] OR "meta-analysis"[All Fields])	724 systematic reviews total
#3	#1 NOT #2	11,864 total without systematic reviews

Appendix C. Detailed Study Tables

Table C-1. Summary of studies evaluating safety of cryoballoon, laser balloon, or radiofrequency ablation for AF

Author Year Funder Included Conditions Included Ablation Procedures	Study Design Included Studies Search Date Range	Scope of Review	Outcomes Reported Results *Effect Estimate (95% CI)*	Review Authors' Conclusions
NICE review[5,55] UK Government Conditions: AF Procedures: Cryoballoon Laser balloon Radiofrequency	SR 56 RCTs (in 65 papers, N = NR) Inception to September 2020	Included RCTs or RCTs of RCTs in adults with AF treated with surgical ablation, hybrid catheter/surgical, radiofrequency, cryoballoon, or laser catheter ablation compared with each other, placebo, usual care, or no treatment reporting health-related QOL, stroke or systemic embolism, mortality, recurrent symptomatic AF (post-blanking period), hospitalization with a primary diagnosis of AF, repeat procedure (catheter/surgical), heart failure/ exacerbation of heart failure, serious AEs, or hospital length of stays.	For people with paroxysmal AF, catheter ablation techniques were the most clinically effective ablation options. Radiofrequency point-by-point ablation was more cost-effective over a lifetime than antiarrhythmic drug treatment and other ablation strategies in people for whom 1 or more antiarrhythmic drug had failed. Cryoballoon, radiofrequency multi-electrode, and laser ablation were the second, third, and fourth most cost-effective options, respectively. Cryoballoon and laser ablation may be more suitable for some patients because they can sometimes be carried out without general anesthesia, and cryoballoon ablation may be quicker to perform, with same-day discharge more likely. Sinus rhythm at 12 months Laser balloon vs. radiofrequency point-by-point RR: 1.01 (95: CI, 0.72 to 1.42)	Offer rate control as the first-line treatment strategy for atrial fibrillation except in people whose AF has a reversible cause, who have heart failure thought to be primarily caused by AF, with new-onset AF, with atrial flutter whose condition is considered suitable for an ablation strategy to restore sinus rhythm, or for whom a rhythm-control strategy would be more suitable based on clinical judgment. If drug treatment is unsuccessful, unsuitable, or not tolerated in people with symptomatic paroxysmal or persistent AF, consider radiofrequency point-by-point ablation or if radiofrequency point-by-point ablation is assessed as being unsuitable, consider cryoballoon ablation or laser balloon ablation.

Author Year Funder Included Conditions Included Ablation Procedures	Study Design Included Studies Search Date Range	Scope of Review	Outcomes Reported Results *Effect Estimate (95% CI)*	Review Authors' Conclusions
NICE review [5,55] (continued)			Rate of freedom from AF at 12 months Laser balloon: 63.5% Radiofrequency: 63.9% Adverse events Laser balloon: 17% Radiofrequency:16.3% NMA ranked laser balloon ablation as the third most clinically effective ablation.	
Zhao et al., 2024[6] NR Conditions: AF Procedures: Cryoballoon Laser balloon Radiofrequency	SR/NMA 22 RCTs (N = 5,073) Inception to December 1, 2023	Included RCTs of adults with AF treated with cryoballoon catheter, radiofrequency catheter, PVAC, laser balloon, or nontraditional treatment measure and reported safety outcomes, defined as complications related to surgery or drug treatment (occurring during the perioperative period or follow-up).	With outcomes were reported for Phrenic nerve palsy, pericardial effusion, infection, pseudoaneurysm, pulmonary vein stenosis, and pain, estimates were imprecise. There were relatively small sample sizes for laser balloon ablation, One study compared laser balloon and radiofrequency and found no significant differences in effectiveness between the 2 strategies. Complications and AEs were similar in both groups.	There were no significant differences in the incidence of major AEs among different ablation t radiofrequency, CA is significantly associated with the high risk of phrenic nerve paralysis, though CA can reduce the risk of intraoperative infection. Based on a single RCT, laser balloon was similar to radiofrequency in efficacy and safety.

Abbreviations: AE = adverse event; AF = atrial fibrillation; CA = cryoballoon ablation; NICE = National Institute for Health and Care Excellence; NMA = network meta-analysis; NR = not reported; PVAC = pulmonary vein ablation catheter; QOL = quality of life; RCT = randomized controlled trial; RR = risk ratio; SR = systematic review; UK = United Kingdom.

Table C-2. Summary of studies evaluating safety of cryoballoon, laser, or radiofrequency ablation for AF as first-line therapy

Author Year Funder Included Conditions Included Ablation Procedures	**Study Design Included Studies Search Date Range**	**Scope of Review**	**Outcomes Reported Results *Effect Estimate (95% CI)***	**Review Authors' Conclusions**
Cardoso, 2022[7] No external funding sources Conditions: AF Procedures: Cryoballoon Radiofrequency	SR/MA 5 RCTs (N = 994) Inception to December 2020	Included RCTs comparing catheter ablation (radiofrequency or cryoablation) with antiarrhythmic drugs in patients with symptomatic AF reporting recurrence of atrial tachyarrhythmias, recurrence of symptomatic AF, hospitalizations, symptomatic bradycardia, and QOL	Ablation vs. antiarrhythmic drugs Recurrences of AT OR: 0.36 (95% CI, 0.25 to 0.52) Symptomatic AF OR: 0.32 (95% CI, 0.18 to 0.57) Hospitalizations OR: 0.25 (95% CI, 0.15 to 0.42) Symptomatic bradycardia OR: 0.55 (95% CI, 0.18 to -1.65) Pericardial effusions or tamponade Ablation: 8 of 464 (1.7%)	Catheter ablation significantly reduces the recurrence of atrial tachyarrhythmias, and symptomatic AF compared with antiarrhythmic drugs therapy in patients who are naïve to prior attempts of rhythm control. This study provides evidence supporting catheter ablation as a Class I indication for rhythm control in patients with paroxysmal AF.
Fong, 2023[8] Funding: NR Conditions: AF Procedures: Cryoballoon Laser balloon Radiofrequency	SR/NMA 24 studies (N = 5,132) Including 2 studies of laser balloon vs. cryoballoon Inception to October 2021	Included RCTs or propensity score-matched studies among adults with paroxysmal AF comparing any combination of ablation modality or antiarrhythmic drug reporting atrial tachyarrhythmia recurrence	Frequentist NMA-derived HRs AF recurrence Cryoballoon vs. antiarrhythmic drugs HR: 0.35 (95% CI, 0.25 to 0.48) Radiofrequency vs. antiarrhythmic drugs HR: 0.14 (95% CI, 0.07 to 0.30) Laser balloon vs. antiarrhythmic drugs HR: 0.43 (95% CI, 0.15 to 1.26)	This NMA found a consistent advantage of ablation over antiarrhythmic drugs in preventing atrial tachyarrhythmia recurrence. Ablation represents a suitable first-line alternative to antiarrhythmic drug for paroxysmal AF in patients who are fit for the procedure. Laser balloon ablation showed favorable short-term efficacy that may warrant a long-term investigation in future trials.

Author Year Funder Included Conditions Included Ablation Procedures	**Study Design Included Studies Search Date Range**	**Scope of Review**	**Outcomes Reported Results *Effect Estimate (95% CI)***	**Review Authors' Conclusions**
Fong, 2023[8] (continued)			Laser balloon was significantly favored over antiarrhythmic drugs in the RMST-based analyses but not the HR-based analysis, which may be attributed to the presence of only 2 laser balloon studies and its short follow-up.	
Liu, 2022[9] Funding: NR (authors declared no conflicts of interest) Procedures: Cryoballoon ablation	SR/MA 5 RCTs (N = 923) and 1 observational study Inception to March 22, 2023	Included RCTs and observational studies of adults with persistent AF comparing cryoballoon and antiarrhythmic drugs with at least 12 months of follow-up that reported efficacy, safety, recurrence rate, QOL, and/or the incidence of persistent AF	Cryoballoon vs. antiarrhythmic drugs Recurrence rate RR: 0.59 (95% CI, 0.49 to 0.71) Incidence of persistent AF RR: 0.17 (95% CI, 0.06 to 0.49) QOL SMD): 0.40 (95% CI, 0.14 to 0.67) Hospitalization rate at 36 months RR: 0.29 (95% CI, 0.15 to 0.58).	Compared with antiarrhythmic drugs, cryoballoon ablation as first-line therapy significantly reduced the recurrence rate of atrial arrhythmia and incidence of persistent AF and improved QOL in persistent AF patients with lower incidences of hospitalization.
Ullah, 2024[10] No external funding reported Conditions: AF Procedures: Cryoballoon Radiofrequency	SR/MA 6 RCTs (N = 1,120) Inception to September 2022	Included RCTs comparing ablation with AAD therapy for adult patients with treatment-naive AF that reported recurrent AF, major bleeding, MACE, or procedure failure	Ablation vs. AADs Risk of any AF recurrence RR: 0.54 (95% CI, 0.39 to 0.75) Major adverse cardiovascular events RR: 2.65 (95% CI, 0.61 to 11.46) Trial-defined composite end point of adverse events RR: 0.71 (95% CI, 0.28 to 1.80)	Ablation may be preferred over AADs as the first-line therapy for treatment-naive AF because of its lower risk of AF recurrence; the need for subsequent ablation; and need for repeat hospitalization, along with comparable mortality, bleeding, and incidence of net adverse events.

Author Year Funder Included Conditions Included Ablation Procedures	Study Design Included Studies Search Date Range	Scope of Review	Outcomes Reported Results *Effect Estimate (95% CI)*	Review Authors' Conclusions
Ullah, 2024[10] (continued)			Stroke RR: 2.42 (95% CI, 0.22 to 26.51) All-cause mortality RR: 1.98 (95% CI, 0.28 to 13.90) Procedure/medication failure RR: 2.65 (95% CI, 0.61 to 11.46)	

Abbreviations: AAD = antiarrhythmic drug; AF = atrial fibrillation; HR = hazard ratio; MA = meta-analysis; MACE = major adverse cardiovascular event; NMA = network meta-analysis; NR = not reported; OR = odds ratio; QOL = quality of life; RCT = randomized controlled trial; RMST = restricted mean survival time; RR = risk ratio; SMD = standardized mean difference; SR = systematic review.

Table C-3. Summary of studies evaluating pulsed field ablation for AF

Author Year Funder Included Conditions Included Ablation Procedures	**Study Design Included Studies Search Date Range**	**Scope of Review**	**Outcomes Reported Results *Effect Estimate (95% CI)***	**Review Authors' Conclusions**
Aldaas, 2024[13] Marouf Family and the Butler and Gratt Family Conditions: AF Procedures: Pulsed field ablation Cryoballoon ablation Radiofrequency ablation	SR/MA 6 comparative studies (N = 1,012) Inception to September 2023	Included studies among adults with AF that compared pulsed field ablation with thermal ablation (radiofrequency ablation and cryoballoon ablation)	There were significantly shorter procedures times with PFA despite a protocolized 20-minute dwell time (MD -21.95; 95% CI, -33.77, -10.14; *p*=0.0003) but with significantly longer fluroscopy time (MD 5.71; 95% CI, 1.13 to 10.30; *p*=0.01). There were no statistically significant differences in periprocedural complications (RR 1.20; 95% CI, 0.59 to 2.44) or recurrence of atrial tachyarrhythmias (RR 0.64; 95% CI, 0.31 to 1.34) between the PFA and thermal ablation cohorts.	PFA was associated with shorter procedural times and longer fluoroscopy times, but there was no difference in periprocedural complications or rates of recurrent AF when compared to ablation with thermal energy sources. However, larger RCTs are needed.
Qamar, 2024[12] No external funding Conditions: AF Procedures: Pulsed field ablation	SR/MA 26 studies (13 observational studies, 12 nonrandomized clinical trials, and 1 RCT; N = 2,561) Inception to October 2023	Included clinical trials and observational studies in adults with AF that included PFA and reported success of pulmonary vein isolation, mean total procedure time, mean fluoroscopy time, recurrence of atrial arrhythmias (atrial fibrillation, atrial flutter, or atrial tachycardia) at any time after the ablation procedure, and procedural complication rates at the latest follow-up	The acute procedural success in isolating all pulmonary veins was 99.7%. The overall rate of recurrent atrial arrhythmias within the blanking period was 10.3%, and after the blanking period was 17.3%. The overall complication rate was only 2.8%, with only 1 case of death and no atrio-esophageal fistula reported.	This systematic review and meta-analysis of 26 studies shows that PFA has a high procedural success rate with a low risk of procedural complications. Further prospective RCTs are needed to compare its long-term efficacy and safety with conventional ablation techniques.

Author Year **Funder** **Included Conditions** **Included Ablation Procedures**	**Study Design** **Included Studies** **Search Date Range**	**Scope of Review**	**Outcomes Reported Results** ***Effect Estimate (95% CI)***	**Review Authors' Conclusions**
Zhang, 2024[47] Funding: NR Conditions: AF Procedures: Pulsed field ablation Cryoballoon ablation	SR/MA 15 trials (N = 1,880) Inception until December 2023	Included studies in adults with AF that compared PFA and cryoballoon ablation that reported recurrence rate of atrial arrhythmia, periprocedural complications, individual complications, and procedural and fluoroscopy durations	Pulsed field vs. cryoballoon ablation Recurrent atrial arrhythmia OR: 0.83 (95% CI, 0.64 to 1.07) Periprocedural complications OR: 0.78 (95% CI, 0.46 to 1.30) Procedure time MD: -7.17 (95% CI, -13.60 to -0.73) Significantly shorter with pulsed field Fluoroscopy time MD: 2.53 (95% CI, 0.87 to 4.19) Significantly longer with pulsed field Phrenic nerve palsy OR: 0.20 (95% CI, 0.07 to 0.59) Decreased incidence with pulsed field Cardiac tamponade OR: 4.07 (95% CI, 1.15 to 14.39) Increased incidence with pulsed field	The utilization of PFA provides a safer, time-saving, and tissue-specific procedure compared to CBA while maintaining comparable success rates. This has the potential to enhance procedural efficiency and optimize resource utilization in clinical practice. These findings underscore the feasibility and promise of PFA as an alternative technique for PVI in patients with AF.

Author Year **Funder** **Included Conditions** **Included Ablation Procedures**	**Study Design** **Included Studies** **Search Date Range**	**Scope of Review**	**Outcomes Reported Results** ***Effect Estimate (95% CI)***	**Review Authors' Conclusions**
Reichlin, 2025[14] NCT05534581 Funding: Inselspital Conditions: AF Procedures: Pulsed field ablation Cryoballoon ablation	Randomized noninferiority trial (N = 210) Patients with AF randomized 1:1 to undergo pulsed field or cryoballoon ablation	All patients received an implantable cardiac monitor to detect atrial tachyarrhythmias; the primary end point was the first recurrence of an atrial tachyarrhythmia between day 91 and day 365 after ablation; safety end point was a composite of procedure-related complications	Recurrence between day 91 and day 365, N (%) Pulsed field: 39 (37.1) Cryoballoon:53 (50.7) Between-group difference: -13.6 (95% CI, -26.9 to -0.3) *P*<0.001 for noninferiority *P*=0.046 for superiority Composite safety end, N (%) Pulsed field: 1 (1.0) Cryoballoon: 2 (1.9)	Among patients with symptomatic paroxysmal AF, PFA was noninferior to cryoballoon ablation with respect to the incidence of a first recurrence of atrial tachyarrhythmia, as assessed by continuous rhythm monitoring.

Abbreviations: AF = atrial fibrillation; CBA = cryoballoon ablation; MA = meta-analysis; MD = mean difference; NR = not reported; OR = odds ratio; PFA = pulsed field ablation; PVI = pulmonary vein isolation; RCT = randomized controlled trial; RR = risk ratio; SR = systematic review.

Table C-4. Summary of studies evaluating cardiac ablation for atrial flutter

Author Year Funder Included Conditions Included Ablation Procedures	Study Design Included Studies Search Date Range	Scope of Review	Outcomes Reported Results *Effect Estimate (95% CI)*	Review Authors' Conclusions
Diamant, 2021[16] Conditions: Atrial flutter Procedures: Ablation (not specific)	SR 65 studies (10 studies exclusively of atrial flutter patients, 55 studies of AF and atrial flutter patients)	Included studies reporting the incidence, prevalence, and predictors of heart failure in atrial flutter and evidence for treatments of atrial flutter in heart failure	In 10 catheter ablation studies, immediate procedural success ranged from 87% to 100%, with atrial flutter recurrence of 5% to 30% up to 2.3 years.	There is limited evidence in all aspects of the intersection between atrial flutter and heart failure. Ablation has mainly been studied in selected cohorts with tachycardia-induced cardiomyopathy, so the effectiveness in patients with atrial flutter and heart failure due to other etiologies is unknown. In those with multiple arrhythmias amenable to ablation, personalized ablation strategies chosen from a combination of presenting arrhythmias, clinical and treatment history, imaging, and mapping may ultimately yield the best clinical outcomes.

Author Year Funder Included Conditions Included Ablation Procedures	**Study Design Included Studies Search Date Range**	**Scope of Review**	**Outcomes Reported Results *Effect Estimate (95% CI)***	**Review Authors' Conclusions**
Zeng, 2019[18] Conditions: Atrial flutter Procedures: Cryoballoon Radiofrequency	SR/MA 6 RCTs and 2 non-RCTs (N = 644) Inception to October 2018	Included RCTs and quasi-RCTs in patients with atrial flutter that compared cryoballoon and radiofrequency ablation and reported myocardial injury	Cryoballoon vs. radiofrequency Serum CK levels 4 to 6 hours after ablation MD: 179.54 (95% CI, 10.09 to 348.98); *P*=0.04 Significant increase in cryoballoon group Serum CK-MB levels 4 to 6 hours after ablation MD: 10.08 (95% CI, 3.14 to 17.02); *P*=0.004 Significant increase in cryoballoon group Serum TnI levels MD: 0.12 (95% CI, -0.02 to 0.26); *P*=0.08 Significant increase in cryoballoon group Serum TnT levels MD: 0.19 (95% CI, 0.07 to 0.32); I=0.002 Significant increase in cryoballoon group Pain perception MD: 0.05 (95% CI, 0.00 to 0.84); *P*=0.04) Significantly reduced in cryoballoon group	There was substantial heterogeneity in myocardial injury measures and several concerns regarding clinical environment under which the cardiac necrosis biomarkers were used and then compared across different studies Cryoballoon significantly reduces pain perception and lowers discomfort during ablation. Cryoballoon was associated a higher occurrence of myocardial injury in comparison with radiofrequency.

Author Year Funder Included Conditions Included Ablation Procedures	Study Design Included Studies Search Date Range	Scope of Review	Outcomes Reported Results *Effect Estimate (95% CI)*	Review Authors' Conclusions
Chen, 2015[17] Conditions: Cavotricuspid valve isthmus (CVI) dependent atrial flutter Procedures: Cryoballoon Radiofrequency Funding: NR	SR/MA 7 RCTs (N = NR) March 1986 to September 2014	Included RCTs of patients with CVI-dependent atrial flutter without prior history of ablation that compared cryoballoon vs. radiofrequency and reported acute success of bidirectional conduction block, recurrence, procedure time and fluoroscopy time	Cryoballoon vs. radiofrequency Acute success rate RR: 0.93; *P*=0.14 Long-term success rate RR: 0.94; *P*=0.08 Fluoroscopy time WMD: -2.83; *P*=0.29 Procedure time WMD: 25.95; *P*=0.01 Significantly longer in cryoballoon group Pain perception SMD: -2.36; *P*<0.00001 Significantly favored cryoballoon group	Cryoablation and radiofrequency ablation produce comparable acute and long-term success rate for patients with CVI-dependent atrial flutter. Meanwhile, cryoablation ablation tends to reduce the fluoroscopy time and significantly reduce pain perception in cost of significantly prolonged procedure time.

Abbreviations: AF = atrial fibrillation; CK = creatine kinase; CK-MB = creatine kinase-MB; CVI = cavotricuspid valve isthmus; MA = meta-analysis; MD = mean difference; NR = not reported; RCT = randomized controlled trial; RR = risk ratio; SMD = standardized mean difference; SR = systematic review; TnI = Troponin I; TnT = troponin T; WMD = weighted mean difference.

Table C-5. Summary of studies evaluating cardiac ablation for other SVTAs

Author Year Funder Included Conditions Included Ablation Procedures	Study Design Included Studies Search Date Range	Scope of Review	Outcomes Reported Results Effect Estimate (95% CI)	Review Authors' Conclusions
Siranart, 2024[48] Conditions: AV nodal reentrant tachycardia (AVNRT) Procedures: Cryoballoon Radiofrequency Funding: NR	SR/MA 27 studies, including 7 RCTs and 20 observational studies (N = 5,110) Inception to May 2023	Included RCTs, cross-sectional studies, case-control studies, or cohort studies in patients with AVNRT that assessed the efficacy and safety outcomes of radiofrequency ablation and cryoablation	Overall success rate Range: 89.78% to 100% 4-mm cryoablation vs. nonirrigated radiofrequency OR: 0.649 (95% CI, 0.202 to 2.087) 6-mm cryoablation vs. nonirrigated radiofrequency OR: 0.944 (95% CI, 0.307 to 2.905) 8-mm cryoablation vs. nonirrigated radiofrequency OR: 0.424 (95% CI, 0.058 to 3.121)	No significant difference in the incidence of permanent AV block between the types of catheters. The success rates were consistently high across all groups. These findings emphasize the potential of both radiofrequency ablation and cryoablation as viable options for the treatment of AVNRT, with a similar safety and efficacy profile.
Hanninen, 2013[49] Conditions: AV nodal reentrant tachycardia (AVNRT) Procedures: Cryoballoon Radiofrequency Funding: NR	SR/MA 14 trials (N = 5,617) Inception to August 2012	Included comparative studies (cohort and RCTs) in patients with AVNRT comparing cryoballoon ablation and radiofrequency ablation reporting long-term AVNRT recurrence, acute procedural failure	Cryoablation vs. radiofrequency ablation Acute procedural failure RR: 1.44 (95% CI, 0.91 to 2.28) Long-term recurrence RR: 3.66 (95% CI, 1.84 to 7.28) Higher with cryoablation Permanent AV block Radiofrequency: 0.75% Cryoablation: Not reported in any patients treated with cryoablation (n = 1,066, *P*=0.01)	Cryoablation is a safe and effective treatment for AVNRT. Although late recurrence is more common with cryoablation than with radiofrequency ablation, avoidance of permanent AV block makes it an attractive option in patients where the avoidance of AV block assumes higher priority.

Author Year Funder Included Conditions Included Ablation Procedures	Study Design Included Studies Search Date Range	Scope of Review	Outcomes Reported Results Effect Estimate (95% CI)	Review Authors' Conclusions
Rodríguez-Mañero, 2017[51] Condition: Inappropriate sinus tachycardia Procedures: Sinus node ablation or modification via radiofrequency	SR 9 studies (N = 153) January 1995 to December 2015	Included systematic reviews, meta-analyses, RCTs, case-control, and cohort studies that included at least 2 inappropriate sinus tachycardia ablation cases and reporting acute success, complication rates, maneuvers to avoid PN injury, and long-term follow-up	Acute success rate: 88.9% Severe procedural complication, N (%) 13 (8.5) Required implantation of pacemaker 15 (9.8) Long-term success, mean (SD) follow-up 28.1 (12.6) months: 86.4% Symptomatic recurrence rate: 19.6% Continued use of antiarrhythmic drug therapy: 29.8%	Inappropriate sinus tachycardia ablation/modification achieves acute success in most patients. Complications are common and diverse. However, symptomatic relief decreases substantially over longer follow-up periods, with a corresponding high recurrence rate. The authors note a wide variety of ablation protocols across studies and small sample sizes. Procedural intervention was reserved for severe refractory cases of inappropriate sinus tachycardia.

Author Year Funder Included Conditions Included Ablation Procedures	Study Design Included Studies Search Date Range	Scope of Review	Outcomes Reported Results Effect Estimate (95% CI)	Review Authors' Conclusions
Al-Khatib, 2016[30] Conditions: Supraventricular tachycardia (asymptomatic pre-excitation) Procedure: Ablation (not specified) Funding: American College of Cardiology, American College of Cardiology/American Heart Association, American Heart Association	SR 9 studies including: 1 RCT (N = 76) 8 uncontrolled cohort studies (N = 1,594) January 1970 to August 2014	Included RCTs and nonrandomized comparative studies in patients with asymptomatic pre-excitation that compared invasive electrophysiological study with noninvasive testing, including resting ECG, stress testing, electrocardiographic monitoring, and esophageal pacing for predicting or preventing arrhythmic events in adults Also included uncontrolled observational studies with a minimum of 20 patients and follow-up of at least 80% Note: Excluded studies that enrolled patients with WPW syndrome	RCT Incidence of arrhythmic events, 5-year Kaplan-Meier estimates Ablation: 7% Did not undergo ablation: 77% RR: 0.08 (95% CI, 0.02 to 0.33) Observational cohorts Asymptomatic patients who did not undergo catheter ablation N = 883 Follow-up: 8 to 96 months Regular supraventricular tachycardia or benign atrial fibrillation: 0% to 16% Malignant atrial fibrillation: 0% to 9% Ventricular fibrillation in 0% to 2% (most cases were children)	Little evidence was found from RCTs regarding the best management strategy for patients with asymptomatic pre-excitation. Data from observational studies on 883 patients who did not undergo ablation showed that up to 9% of patients developed malignant arrhythmias. These observations, coupled with the very low risk of complications resulting from an electrophysiological study, suggest that risk stratification of patients with asymptomatic pre-excitation using an electrophysiological study may be beneficial, with consideration of accessory-pathway ablation in those deemed to be at high risk of future arrhythmias.

Author Year Funder Included Conditions Included Ablation Procedures	Study Design Included Studies Search Date Range	Scope of Review	Outcomes Reported Results Effect Estimate (95% CI)	Review Authors' Conclusions
Ibrahim Ali Sherdia, 2023[50] Conditions: AV reentrant tachycardia (AVRT), WPW syndrome Procedures: Cryoballoon Radiofrequency Funding: NR	SR/MA 11 cohort studies (N = 5,537) Inception to January 2022	Included any interventional or observational study in patients with WPW receiving cryoballoon or radiofrequency ablation that reported success rate, recurrence rate, and rate of complications	Single-arm meta-analysis Success rate: 94.1% (95% CI, 92.4 to 95.9); I^2 = 38.52% Recurrence rate: 6.2% (95% CI, 4.5 to 7.8); I^2 = 69.34% Complication rate: 1% (95% CI, 0.4 to 1.5); I^2 = 55.16% Procedure time, minutes: 92.83 (95% CI, 35.08 to 150.59); I^2 = 99.86%	Cryoballoon and radiofrequency showed a high success rate, low recurrence rate and low rate of complications in WPW patients based on heterogeneous studies.
Alasti, 2020[32] Conditions: Junctional ectopic tachycardia (JET) Procedures: Ablation (not specific) Funding: NR	Clinical review Included studies: NR Search date: NR		Although postoperative JET is not common in adults, it can occur as a result of myocardial ischemia, metabolic, or autonomic disturbance or drug toxicity (e.g., digoxin toxicity)	JET is a rare arrhythmia and its diagnosis and management remain challenging. Catheter ablation remains the mainstay of treatment in refractory JET unresponsive to medical therapy and it can be aided by using an electroanatomic mapping system.

Author Year Funder Included Conditions Included Ablation Procedures	Study Design Included Studies Search Date Range	Scope of Review	Outcomes Reported Results Effect Estimate (95% CI)	Review Authors' Conclusions
Dar, 2021[52] Conditions: Junctional ectopic tachycardia (JET) Procedure: Cryoballoon Radiofrequency Funding: NR	Retrospective study N = 15 adult patients with idiopathic JET Patients treated between January 2007 and October 2016	Review of patient and procedural characteristics including clinical outcomes among adult patients who underwent catheter ablation for idiopathic JET	Acute success rate, N (%) 15 (100) Arrhythmia recurrence, N (%) 8 (53) All underwent repeat ablation High-grade AV block requiring permanent pacemaker, N (%) 3 (20) Arrhythmia recurrence after repeat ablation 3 of 8 (37.5%)	Catheter ablation of idiopathic JET in adults is associated with a high rate of recurrence requiring multiple procedures and high risk of AV block requiring pacemaker implantation. Mapping and ablation of the noncoronary cusp can be considered as the arrhythmia was controlled in 3 patients with no inadvertent AV block.

Abbreviations: AV = atrioventricular; AVNRT = atrioventricular nodal reentrant tachycardia; AVRT = atrioventricular reentrant tachycardia; ECG = electrocardiogram; JET = junctional ectopic tachycardia; MA = meta-analysis; NR = not reported; OR = odds ratio; PN = phrenic nerve; RCT = randomized controlled trial; RR = risk ratio; SR = systematic review; SVTA = supraventricular tachyarrythmia; WPW = Wolff-Parkinson-White.