



Effective Health Care

Catheter Ablation for Ventricular Tachycardia

Results of Topic Selection Process & Next Steps

The nominator, Heart Rhythm Society (HRS), is interested in a new evidence review on the effectiveness and harms of catheter ablation for ventricular tachycardia. They want to use the results of an evidence review to develop a “how-to” set of guidelines on catheter ablation for ventricular arrhythmias.

Because there is limited original research addressing the nomination, a new evidence review is not feasible at this time. No further activity on this nomination will be undertaken by the Effective Health Care (EHC) Program.

Topic Brief

Topic Name: Catheter Ablation for Ventricular Tachycardia

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Authors

Stephanie Veazie
Rose Relevo
Mark Helfand
Christine Chang

Conflict of Interest: None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

Summary

- This nomination meets the selection criteria of appropriateness, importance, duplication and impact.
- A new evidence review is not feasible at this time. We only identified 5 completed studies addressing KQ1 and KQ2 published in the past 5 years. We identified 4 in-process studies addressing KQ1 and KQ3 that are scheduled to be completed in the next 3 years.

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Background

Ventricular tachycardia (VT) is a heart rhythm disorder where abnormal electrical signals cause the lower chambers of the heart to beat faster than normal.¹ Patients with VT may experience dizziness, palpitations or loss of consciousness, and are at risk of sudden cardiac death.² VT is caused by a number of conditions including ischemic cardiomyopathy (weakened heart tissue due to coronary artery disease), non-ischemic cardiomyopathy (weakened heart tissue due to other causes), inflammatory conditions such as cardiac sarcoidosis and myocarditis, and genetic disorders such as Brugada syndrome. Other, related conditions include ventricular fibrillation (life-threatening, rapid, inadequate heartbeat) and premature ventricular contractions (isolated extra, abnormal heartbeats). Implantable cardioverter-defibrillators (ICDs) and antiarrhythmic drugs (AADs) have been used to reduce VT episodes and improve survival among those with sustained VT and related conditions, but they can impair quality of life and cause serious, sometimes fatal side effects. Catheter ablation, a procedure that uses energy to create scars in heart tissue to prevent abnormal electrical signals from moving through the heart, has been proposed as an alternative therapy³, but it is a complex procedure requiring significant resource utilization and risk of major complications.

The nominator submitted this topic because of the need for an updated review to include the VANISH trial, the largest randomized controlled trial on this topic to date.

Nominator and Stakeholder Engagement: We worked with the nominator to scope the topic and clarify the specific key questions and population, interventions, comparators, outcomes, and timing (PICOTs) of interest. We also asked the nominator what an AHRQ review would contribute given the 2017 American Heart Association/American College of Cardiology/Heart Rhythm Society guidelines, and presented our duplication and feasibility results to see if our search missed anything important. This communication resulted in identifying 2 additional studies published since 2012, 2 additional studies published prior to 2012, and removing 1 in-process study that was terminated due to low enrollment.

The key questions for this nomination are:

1. In adults with history of sustained ventricular tachycardia and ischemic cardiomyopathy what is the effectiveness and harms of catheter ablation compared to other interventions?
2. In adults with history of ventricular arrhythmia without structural heart abnormalities or inherited arrhythmia syndromes what is the effectiveness and harms of catheter ablation compared to other interventions?
3. In adults with history of sustained ventricular tachycardia and other cardiomyopathy subtypes what is the effectiveness and harms of catheter ablation compared to other interventions?

To define the inclusion criteria for the key questions we specify the population, interventions, comparators, outcomes, and timing (PICOTs) of interest (Table 1).

Table 1. Key Questions and PICOTS

Key Questions	1. In adults with history of sustained ventricular tachycardia and ischemic cardiomyopathy, what is the effectiveness and harms of catheter ablation compared to other interventions?	2. In adults with history of ventricular arrhythmia without structural heart abnormalities or inherited arrhythmia syndromes, what is the effectiveness and harms of catheter ablation compared to other interventions?	3. In adults with history of sustained ventricular tachycardia and other cardiomyopathy subtypes what is the effectiveness and harms of catheter ablation compared to other interventions?
Population	Adults with history of sustained ventricular tachycardia and ischemic cardiomyopathy	Adults with history of ventricular arrhythmia without structural heart abnormalities or inherited arrhythmia syndromes	Adults with history of sustained ventricular tachycardia and other types of cardiomyopathy <ul style="list-style-type: none"> • Nonischemic cardiomyopathy • Hypertrophic cardiomyopathy • Cardiac sarcoidosis • Arrhythmogenic right ventricular cardiomyopathy • Brugada syndrome • Myocarditis • Idiopathic VF
Intervention	Catheter ablation	Catheter ablation	Catheter ablation
Comparators	Control (no therapy or AAD)	Class 1-4 AAD	Control (no therapy or AAD)
Outcomes	Mortality, sustained ventricular tachycardia recurrence, ICD therapies, progression of heart disease, quality of life, and adverse events	Mortality, ventricular arrhythmia recurrence, ICD therapies, emergence of heart disease, quality of life, and adverse events	Mortality, sustained ventricular tachycardia recurrence, ICD therapies, progression of heart disease, quality of life, and adverse events
Timing	All	All	All

Abbreviations: AAD=Antiarrhythmic Drugs; ICD= Implantable Cardioverter-Defibrillators; VF=Ventricular Fibrillation

Methods

We assessed nomination 0747 *Catheter ablation for ventricular tachycardia* for priority for a systematic review or other AHRQ EHC report with a hierarchical process using established selection criteria (Appendix A). Assessment of each criteria determined the need for evaluation of the next one.

1. Determine the *appropriateness* of the nominated topic for inclusion in the EHC program.
2. Establish the overall *importance* of a potential topic as representing a health or healthcare issue in the United States.
3. Determine the *desirability of new evidence review* by examining whether a new systematic review or other AHRQ product would be duplicative.
4. Assess the *potential impact* a new systematic review or other AHRQ product.
5. Assess whether the *current state of the evidence* allows for a systematic review or other AHRQ product (feasibility).
6. Determine the *potential value* of a new systematic review or other AHRQ product.

Appropriateness and Importance

We assessed the nomination for appropriateness and importance.

Desirability of New Review/Duplication

We searched for high-quality, completed or in-process evidence reviews published in the last five years on the key questions of the nomination. We also contacted the nominator with our duplication results to see if we missed any important reviews. See Appendix B for sources searched.

Impact of a New Evidence Review

The impact of a new evidence review was qualitatively assessed by analyzing the current standard of care, the existence of potential knowledge gaps, and practice variation. We considered whether it was possible for this review to influence the current state of practice through various dissemination pathways (practice recommendation, clinical guidelines, etc.).

Feasibility of New Evidence Review

We conducted a literature search in PubMed from December 2012 to December 2017.

We reviewed all identified titles and abstracts (n=95) for inclusion and classified identified studies by study design, to assess the size and scope of a potential evidence review. We also contacted the nominator with our feasibility results to see if we missed any important studies.

See Appendix C for the PubMed search strategy and links to the ClinicalTrials.gov search.

Compilation of Findings

We constructed a table with the selection criteria and our assessments (Appendix A).

Results

Appropriateness and Importance

This is an appropriate and important topic. Sudden cardiac death is a major public health problem that accounts for 15-20% of all deaths.⁴ VT due to coronary artery disease and cardiomyopathies are the most common causes of sudden cardiac death in people 35 years and older. ⁴ ICD shocks and AADs are used to prevent death in patients with VT; however, they impair quality of life and are associated with serious, sometimes fatal, side effects.^{5,6} Catheter ablation is increasingly used to treat VT arrhythmias, but it is unclear whether it is superior to other strategies at improving patient outcomes such as quality of life, hospital admissions, and mortality.

Desirability of New Review/Duplication

A new evidence review would not be duplicative of an existing product. We identified two systematic reviews^{7,8} addressing KQ1. One review⁷ indirectly compared catheter ablation to AADs for people with recurrent VT on mortality and ICD intervention outcomes, and the other review⁸ directly compared antiarrhythmic drugs to non-ablative procedures (beta blockers with or without AADs) for people with recurrent VT on mortality and VT recurrence. Neither of these reviews include the 2016 VANISH trial, which presents the most up-to-date data on catheter ablation versus AADs.

See Table 2, Duplication column.

Impact of a New Evidence Review

A new systematic review on catheter ablation for ventricular tachycardia may have high impact.

In October 2017, the American Heart Association (AHA), American College of Cardiology (ACC) and Heart Rhythm Society (HRS) released joint guidelines that covered catheter ablation for a variety of ventricular arrhythmias.⁹ With some exceptions, ICDs and AADs were recommended as first-line therapy, with catheter ablation recommended as second-line therapy if medications

were not well tolerated or due to patient preferences. However, none of the recommendations on catheter ablation were based on an independently conducted systematic review. Therefore, a new AHRQ review may fill an information gap that could be used to develop guidelines.

Feasibility of a New Evidence Review

A new evidence review is not feasible at this time. We only identified 5 completed studies¹⁰⁻¹⁴ addressing KQ1 and KQ2 published in the past 5 years. We identified 4 in-process studies¹⁵⁻¹⁸ addressing KQ1 and KQ3 that are scheduled to be completed in the next 3 years.

Completed studies (last 5 years): We identified 3 completed studies addressing KQ1, including 1 randomized controlled trial (RCT)¹⁰ testing early catheter ablation versus AADs in people with ischemic heart disease, 1 RCT¹² testing early catheter ablation with ICDs versus ICDs alone in people with coronary artery disease, and the 2016 VANISH RCT¹¹ testing catheter ablation to escalation of AADs in people with ischemic cardiomyopathy. For KQ2, we identified 1 RCT¹³ and 1 retrospective cohort study¹⁴ examining catheter ablation versus AADs in people with PVCs. We identified no completed studies addressing KQ3.

Of note, the nominator mentioned 2 important studies: SMASH-VT¹⁹ and VTACH²⁰- both RCTs that compared catheter ablation with ICDs versus ICDs alone in people with prior myocardial infarction. However these were published more than five years ago, and are not formally included in our assessment of feasibility (Table 2).

In-process studies (next 3 years): We identified 1 RCT¹⁵ comparing catheter ablation to AADs in people with ischemic heart disease (KQ1; expected completion June 2018), 1 RCT¹⁶ (VANISH-2) comparing catheter ablation to AADs in people with prior myocardial infarction and VT (KQ3; expected completion Oct 2020), and two RCTs^{17,18} comparing ablation to control in people with Brugada Syndrome (KQ3; expected completion Oct 2021 and July 2021).

See Table 2, Feasibility column.

Table 2. Key questions and Results for Duplication and Feasibility

Key Question	Duplication (Completed and In-Process Evidence Reviews)	Feasibility (Published and ongoing)
KQ 1: Catheter ablation for sustained VT and ischemic cardiomyopathy	Total number of completed or in-progress systematic reviews - • Other – 2 ^{7,8}	<u>Size/scope of review</u> Relevant Studies Identified: 3 • RCT – 3 ¹⁰⁻¹² <u>ClinicalTrials.gov</u> Relevant Trials: 1 • Recruiting – 1 ¹⁵
KQ 2: Catheter ablation for ventricular arrhythmia without structural heart abnormalities or inherited arrhythmia syndromes	Total number of completed or in-progress systematic reviews – 0	<u>Size/scope of review</u> Relevant Studies Identified: 2 • RCT- 1 ¹³ • Retrospective cohort – 1 ¹⁴ <u>ClinicalTrials.gov</u> Relevant Trials: 0
KQ 3: Catheter ablation for sustained VT and other cardiomyopathy subtypes	Total number of completed or in-progress systematic reviews – 0	<u>Size/scope of review</u> Relevant Studies Identified: 0 <u>ClinicalTrials.gov</u> Relevant Trials: 4 • Recruiting – 3 ¹⁶⁻¹⁸

Abbreviations: RCT=Randomized controlled trial; VT=Ventricular tachycardia

Summary of Findings

- Appropriateness and importance: The topic is both appropriate and important.
- Duplication: A new review would not be duplicative of an existing product. We identified 2 systematic reviews for KQ1 but none for KQ2 or KQ3. One review compared catheter ablation to AADs for those with recurrent VT on mortality and ICD intervention outcomes, and the other compared antiarrhythmic drugs to non-ablative procedures on recurrence of VT and mortality. Neither of these reviews include the 2016 VANISH trial, which presents the most up-to-date data on catheter ablation versus AADs.
- Impact: A recently published guideline (Oct 2017) is available, but the recommendations on catheter ablation in patients with ventricular arrhythmia were not based on a systematic review, indicating a new AHRQ review may have high impact.
- Feasibility: A new evidence review is not feasible at this time. We only identified 5 completed studies addressing KQ1 and KQ2 published in the past 5 years. We identified 4 in-process studies addressing KQ1 and KQ3 that are scheduled to be completed in the next 3 years.

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Appendix A. Selection Criteria Summary

Selection Criteria	Assessment
1. Appropriateness	
1a. Does the nomination represent a health care drug, intervention, device, technology, or health care system/setting available (or soon to be available) in the U.S.?	Yes, this topic represents a health care intervention available in the U.S.
1b. Is the nomination a request for a systematic review?	Yes, this topic is a request for a systematic review.
1c. Is the focus on effectiveness or comparative effectiveness?	The focus of this review is on effectiveness.
1d. Is the nomination focus supported by a logic model or biologic plausibility? Is it consistent or coherent with what is known about the topic?	Yes, it is biologically plausible. Yes, it is consistent with what is known about the topic.
2. Importance	
2a. Represents a significant disease burden; large proportion of the population	Sudden cardiac death is a major public health problem that accounts for 15-20% of all deaths. ⁴ VT due to coronary artery disease and cardiomyopathies are the most common causes of sudden cardiac death in people 35 years and older. ⁴
2b. Is of high public interest; affects health care decision making, outcomes, or costs for a large proportion of the US population or for a vulnerable population	Yes, the growing prevalence of cardiovascular disease (CVD) in the U.S. has led to increased interest in new approaches for treating CVD and preventing deaths.
2c. Represents important uncertainty for decision makers	Although use of catheter ablation for VT has been increasing, it is unclear whether it's superior to other strategies (ICDs and AADs), particularly for mortality.
2d. Incorporates issues around both clinical benefits and potential clinical harms	The nomination focuses on benefits and harms of catheter ablation.
2e. Represents high costs due to common use, high unit costs, or high associated costs to consumers, to patients, to health care systems, or to payers	Catheter ablation is an expensive procedure, but could potentially decrease ER visits, all-cause hospitalizations, and annual cardiac rhythm-related medical expenditures. ²¹
3. Desirability of a New Evidence Review/Duplication	
3. Would not be redundant (i.e., the proposed topic is not already covered by available or soon-to-be available high-quality systematic review by AHRQ or others)	A new evidence review would not be duplicative of an existing product. We identified two systematic reviews ^{7,8} for KQ1. One review ⁷ indirectly compared catheter ablation to AADs for those with recurrent VT on mortality and ICD intervention outcomes, and the other review directly compared antiarrhythmic drugs to non-ablative procedures (beta blockers with or without AADs) on recurrence of VT and mortality. ⁸ Neither of these reviews include the 2016 VANISH trial, which presents the most up-to-date data on catheter ablation versus AADs.
4. Impact of a New Evidence Review	
4a. Is the standard of care unclear (guidelines not available or guidelines inconsistent, indicating an information gap that may be addressed by a new evidence review)?	In October 2017, the American Heart Association (AHA), American College of Cardiology (ACC) and Heart Rhythm Society (HRS) released joint guidelines that covered catheter ablation for a variety of ventricular arrhythmias. ⁹ With some exceptions, ICDs and AADs were recommended as first-line therapy, with catheter ablation recommended as second-line therapy if medications were not well tolerated or due to patient preferences. None of the recommendations on catheter ablation were based on an independently conducted systematic review. Therefore, a new AHRQ review may fill an information gap.

Selection Criteria	Assessment
4b. Is there practice variation (guideline inconsistent with current practice, indicating a potential implementation gap and not best addressed by a new evidence review)?	Practice is consistent with recent guidelines. The 2015 CALYPSO pilot trial found that most patients were referred to catheter ablation after failing one or more AADs. ²²
5. Primary Research	
<p>5. Effectively utilizes existing research and knowledge by considering:</p> <ul style="list-style-type: none"> - Adequacy (type and volume) of research for conducting a systematic review - Newly available evidence (particularly for updates or new technologies) 	<p><u>PubMed</u>: We identified 3 completed studies addressing KQ1, including 1 randomized controlled trial (RCT)¹⁰ testing early catheter ablation versus AADs in people with ischemic heart disease, 1 RCT¹² testing early catheter ablation with ICDs versus ICDs alone in people with coronary artery disease, and the 2016 VANISH RCT¹¹ testing catheter ablation to escalation of AADs in people with ischemic cardiomyopathy. For KQ2, we identified 1 RCT¹³ and 1 retrospective cohort study¹⁴ examining catheter ablation versus AADs in people with PVCs. We identified no completed studies addressing KQ3.</p> <p>*Of note, the nominator mentioned that 2 important studies were published more than 5 years ago: SMASH-VT¹⁹ and VTACH²⁰- both RCTs that compared catheter ablation with ICDs versus ICDs alone in people with prior myocardial infarction.</p> <p><u>Clinicaltrials.gov</u>: We identified 1 RCT¹⁵ comparing catheter ablation to AADs in people with ischemic heart disease (KQ1; expected completion June 2018), 1 RCT¹⁶ (VANISH-2) comparing catheter ablation to AADs in people with prior myocardial infarction and VT (KQ3; expected completion Oct 2020), and two RCTs^{17,18} comparing ablation to control in people with Brugada Syndrome (KQ3; expected completion Oct 2021 and July 2021).</p>

Abbreviations: AADs= antiarrhythmic drugs; AHRQ=Agency for Healthcare Research and Quality; CVD=Cardiovascular Disease; KQ=Key Question; ICD= Implantable cardioverter-defibrillators; PVCs= Premature Ventricular Contractions; RCT=Randomized Controlled Trial; VT=Ventricular Tachycardia

Appendix B. Search for Evidence Reviews (Duplication)

Listed are the sources searched.

Search date: December 2012 to December 2017

AHRQ: Evidence reports and technology assessments, USPSTF recommendations
VA Products: PBM, and HSR&D (ESP) publications, and VA/DoD EBCPG Program
Cochrane Systematic Reviews and Protocols <http://www.cochranelibrary.com/>
PubMed
PubMed Health <http://www.ncbi.nlm.nih.gov/pubmedhealth/>
HTA (CRD database): Health Technology Assessments <http://www.crd.york.ac.uk/crdweb/>
PROSPERO Database (international prospective register of systematic reviews and protocols)
<http://www.crd.york.ac.uk/prospero/>
CADTH (Canadian Agency for Drugs and Technologies in Health) <https://www.cadth.ca/>
DoPHER (Database of promoting health effectiveness reviews)
<http://eppi.ioe.ac.uk/webdatabases4/Intro.aspx?ID=9>
ECRI institute <https://www.ecri.org/Pages/default.aspx>

Appendix C. Search Strategy & Results (Feasibility)

Topic: catheter ablation

Date: December 20, 2017

Database Searched: MEDLINE (PubMed)

Concept	Search String
ventricular tachycardia and ischemic cardiomyopathy OR sustained ventricular arrhythmia OR sustained ventricular arrhythmia	(((((("Tachycardia, Ventricular"[Mesh] OR "ventricular tachycardia"[Title/Abstract])) AND "ischemic cardiomyopathy"[tiab])) OR "ventricular arrhythmia"[tiab]) OR ((("Tachycardia, Ventricular"[Mesh] OR "ventricular tachycardia"[Title/Abstract]))
AND	
Catheter Ablation	"Catheter Ablation"[Mesh] OR "catheter ablation"[tiab]
AND	
Antiarrhythmic drugs OR Control	((("Anti-Arrhythmia Agents"[Mesh] OR "Anti-Arrhythmia Agents"[Pharmacological Action])) OR "Antiarrhythmic drugs"[Title/Abstract])) OR ("Control Groups"[Mesh]) OR "Placebos"[Mesh])
NOT	
Letters, editorials, etc.	(((((("Letter"[Publication Type] OR "News"[Publication Type]) OR "Patient Education Handout"[Publication Type]) OR "Comment"[Publication Type]) OR "Editorial"[Publication Type])) OR "Newspaper Article"[Publication Type]
Limit to last 5 years ; human ; English	Filters activated: published in the last 5 years, Humans, English
N=96	
Systematic Review N=4	PubMed subsection: Systematic [sb]
Randomized Controlled Trials N=25	Cochrane Sensitive Search Strategy for RCT's: (((((((groups[tiab])) OR (trial[tiab])) OR (randomly[tiab])) OR (drug therapy[sh])) OR (placebo[tiab])) OR (randomized[tiab])) OR (controlled clinical trial[pt])) OR (randomized controlled trial[pt])
Other N=67	