Catheter Ablation for Cardiac Arrhythmias

Description

Catheter ablation is a technique to eliminate cardiac arrhythmias by selectively destroying a portion of myocardium or conduction system tissue that contains the arrhythmogenic focus. A variety of different energy sources can be used with catheter ablation, such as radiofrequency and/or cryotherapy.

Background

Catheter ablation has been used as a treatment for cardiac arrhythmias for several decades. Radiofrequency energy is the most commonly used source for ablation of cardiac arrhythmias, although other energy sources such as cryoablation have also been used. The technique treats supraventricular tachycardias by partially or fully ablating the atrioventricular (AV) node or accessory conduction pathways, thus ablating the arrhythmogenic focus. It controls idiopathic ventricular tachycardia (VT) or re-entrant VTs by eliminating the focus.

Ablation is preceded by preprocedural imaging and mapping of the focus during electrophysiologic studies. Imaging and anatomic mapping systems recreate the 3-dimensional structure of the cardiac chambers. This assists the electrophysiologist in defining the individual anatomy, locating the electroanatomic location of arrhythmogenic foci, and positioning the ablation catheter for delivery of radiofrequency energy. There are a variety of approaches to preprocedural imaging and mapping. Most commonly computed tomographic angiography (CTA) and/or magnetic resonance imaging (MRI) are used for initial imaging. Mapping can be done by an electroanatomic technique, by using multielectrode arrays, or by variations of these approaches.

Anticoagulation is indicated for some patients undergoing ablation. In general, ablations involving the right side of the heart for supraventricular arrhythmias do not require anticoagulation. Ablations in the left side of the heart are often combined with anticoagulation during and/or after the procedure. There are no standardized guidelines for which patients should receive anticoagulation or for the duration of therapy.

Catheter ablation is invasive in that a catheter is passed into the heart via an arm or leg vein. The risks of catheter ablation vary with the specific type of procedure performed and whether or not there are underlying structural abnormalities of the heart. A variety of complications has been documented; these include:
Vascular injury. Injury can occur to the peripheral vessels at the site of vascular access, with resulting hemorrhage, arteriovenous fistula, and/or pseudoaneurysm formation. Venous injury may lead to deep venous thrombosis, with the attendant risk of pulmonary embolism. Significant vascular injury has been estimated to occur in approximately 2% of ablation procedures.

Cardiac tamponade. Perforation of the myocardium can lead to bleeding into the pericardial space and cardiac tamponade. This complication is estimated to occur in approximately 1% of ablation procedures and may require pericardiocentesis for treatment.

Myocardial ischemia/infarction. Ischemia or infarction can result from damage to the coronary arteries during the procedure or from demand ischemia because of the procedure. The rate of these complications is not well characterized.

Thromboembolism. Destruction of tissue by radiofrequency energy promotes thrombus formation. Thromboembolism following ablation most commonly leads to stroke or transient ischemic attack (TIA). The estimated incidence of stroke or TIA following catheter ablation is 1.3%.

Heart failure. Heart failure can be precipitated by “stunning” of myocardium following ablation, and/or by the saline administration required during the procedure. Patients who are at risk for this complication are mostly those with pre-existing left-ventricular dysfunction. Patients undergoing large ablations of the left ventricle are at greatest risk.

Radiation exposure. In any ablation procedure using radiofrequency energy, the patient (and possibly the treating clinicians) is exposed to radiation from fluoroscopy. Systems intended to reduce radiation exposure, such as the use of electroanatomic mapping and remote navigation systems, are available.

Regulatory Status
A very large number of percutaneous cardiac ablation catheters and catheter systems have been approved through the premarket approval (PMA) process by the U.S. Food and Drug Administration (FDA) since 1994. FDA product code: LPB

In addition, various catheter-based electrosurgical cutting and coagulation accessories have been cleared for marketing via the 510(k) process. For example, the Cardioblate® system (Medtronic Inc.) has been cleared for “[ablation] of cardiac tissue during general surgery using radiofrequency energy.” FDA product code: OCL

Related Policies
2.02.19 Catheter Ablation as Treatment for Atrial Fibrillation
7.01.44 Implantable Cardioverter Defibrillator

Policy
*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Catheter ablation may be considered medically necessary for the treatment of supraventricular tachyarrhythmias, as follows:
• Treatment of paroxysmal supraventricular tachycardia due to AV nodal re-entry tachycardia
• Treatment of paroxysmal supraventricular tachycardia due to accessory pathways
• Treatment of atrial flutter
• Treatment of focal atrial tachycardia

Catheter ablation using radiofrequency energy may be considered medically necessary for the treatment of chronic, recurrent, ventricular tachycardia that is refractory to implantable cardioverter-defibrillator treatment and antiarrhythmic medications, and for which an identifiable arrhythmogenic focus can be identified.

Catheter ablation for ventricular tachycardia “storm” (see Policy Guidelines), may be considered medically necessary when pharmacologic treatment has been unsuccessful in controlling the arrhythmia.

Catheter ablation for all other ventricular arrhythmias is considered not medically necessary.

Policy Guidelines

Catheter ablation may be considered first-line therapy for treatment of the supraventricular tachyarrhythmias noted above; that is, patients do not need to have failed medical therapy to be considered for catheter ablation.

Permanent pacemaker implantation might be necessary following catheter ablation for supraventricular arrhythmias.

Ventricular tachycardia “storm”, also known as incessant ventricular tachycardia (VT), is defined as at least three episodes of sustained VT in a 24-hour period. This is considered a life-threatening situation that requires prompt attention and treatment.

This policy does not address catheter ablation for atrial fibrillation; refer to Policy 2.02.19 if atrial fibrillation is a consideration.

Rationale

The search strategy focused on identifying references and review articles on supraventricular arrhythmias and on identifying primary literature on the efficacy and risks of catheter ablation for ventricular arrhythmias.

Supraventricular Arrhythmias

Paroxysmal supraventricular tachycardia (PSVT): PSVT arises because of abnormal conduction through the AV node or through accessory conduction pathways that bypass the atroventricular (AV) node. There are several subtypes of PSVT, the most common being AV nodal re-entrant tachycardia (AVNRT). (1) Ablations for PSVT can usually be done in the right atrium, thus reducing the risk of entering the left atrium through trans-septal puncture. Because these ablations are very focused and
confined to the right side of the heart, complications are less than with other ablations. The main complication of ablation is high-grade AV block that may require placement of a pacemaker.

Evidence on the efficacy of catheter ablation for PSVT consists of numerous case series and uncontrolled trials. There are no large-scale randomized, controlled trials (RCTs) that compare ablation with placebo or alternative treatments. The available evidence establishes that catheter ablation is associated with high rates of success in abolishing PSVT with low rates of AV block. For example, the North American Society of Pacing and Electrophysiology (NASPE) prospective catheter ablation registry reported on 1197 patients undergoing ablation for AVNRT. Success in eliminating the arrhythmia was reported in 96.1% of patients, with a 1% incidence of second- or third-degree AV block. The recurrence rate was estimated to be 3% to 7%. Case series in pediatric patients have also demonstrated high rates of procedural success: for example, 91% in a series of 318 children treated with radiofrequency ablation for supraventricular arrhythmias and 90% in a series of 140 children treated with radiofrequency ablation for permanent junctional reciprocating tachycardia.

Several RCTs have compared RFA with cryoablation for PSVT due to AVNRT. For example, Deisenhofer et al randomized 509 patients with AVNRT to cryoablation (n=251) or RFA (n=258). Patients in both groups had very high rates of immediate ablation success. Immediate success rates were slightly higher in the cryoablation group (98.4% vs 96.8%), but this difference was not statistically significant. At 6-month follow-up, more patients in the cryoablation group reached the primary composite end point of immediate ablation failure, permanent AV block, and recurrent AVNRT (12.6% vs 6.3%, p=0.018); this difference in the composite outcome was primarily driven by a higher rate of recurrent AVNRT in the cryoablation group (9.4% vs 4.4%, p=0.029). Rodriguez-Entem et al reported results from an RCT that included 119 patients with AVNRT who were randomized to cryoablation (n=60) or RFA (n=59). Rates of acute procedural success were again high in both groups (98% in the cryoablation group, 100% in the RFA group). In a longer follow-up period (mean, 256.6 days), recurrent AVNRT was more common in the cryoablation group (15% vs 3.4%, p=0.03). One patient in the RFA group had permanent AV block versus no patients in the cryoablation group.

A multicenter RCT published in 2015 compared minimally fluoroscopic catheter RFA with conventional fluoroscopy-guided ablation for supraventricular tachycardias (SVTs) in 262 patients (mean age, 36 years) undergoing electrophysiology (EP) studies for SVT. Mean follow-up was 12 months. The acute success rate was 99% in both groups, with a 1.1% complication rate. The long-term success rate was 97% in the minimally fluoroscopic group and 94% in the conventional group. The minimally fluoroscopic group had with a significantly lower radiation dose (0 mSv [interquartile range (IQR)], 0.08 mSv [IQR, 0.00-0.08 mSv] vs 8.87 mSv [IQR, 3.67-22.01 mSv]; p<0.001) and total fluoroscopy time (0 seconds [IQR, 0-12] vs 859 seconds [IQR, 545-1346 seconds]; p<0.001). X-ray was not used at all in 72% of patients in the minimally fluoroscopic group.

Ablation of PSVT due to accessory pathways has shown similar or slightly lower success rates. Most clinical series and registries have reported success in the 85% to 100% range. In a survey covering 6065 patients undergoing ablation during the period of 1997 to 2002, long-term success of accessory pathway ablation was 98%. Repeat procedures were necessary in 2.2% of cases, and a serious complication (ie, tamponade, AV block, coronary artery injury, retroperitoneal hemorrhage, and stroke) occurred in 0.6% of patients. The 1995 NASPE survey included 5427 patients undergoing accessory pathway ablation. Serious complications occurred in 1.8% (99/5427) of patients, with a mortality rate of
0.08% (4/5427). As part of the evidence review for the 2015 American College of Cardiology, American Heart Association, and Heart Rhythm Society guideline on the management of adults patients with SVT, the evidence review committee conducted a systematic review to answer 4 questions, one of which is relevant to this review:

“What are the efficacy and effectiveness of invasive EP study with catheter ablation of the accessory pathway as appropriate versus noninvasive tests with treatment (including observation) or no testing/ablation as appropriate for preventing arrhythmic events (including sudden cardiac death) and improving outcomes in patients with asymptomatic pre-excitation?”

The committee found 1 dual-design RCT/observational study relevant to this question. The RCT component compared ablation to no ablation in 72 patients who were asymptomatic with ventricular pre-excitation documented by 12-lead electrocardiograph and inducible arrhythmia on EP study and 35 years of age or less. The median follow-up was 27 months during which 2 (5%) of the 37 patients in the ablation group had regular SVT compared to 21 (60%) of the 35 patients in the no-ablation group. The incidence of arrhythmic events were 7% in the ablation group compared to 77% in the no-ablation group (relative risk reduction, 0.08; 95% confidence interval [CI], 0.02 to 0.33; p<0.001).

Atrial flutter: Atrial flutter usually arises from reentrant circuits, the most common of which is associated with the cavotricuspid isthmus. Success rates following ablation have varied, partly because of the evolution of the technique and partly because of varying definitions of recurrence. In a summary of studies that used current techniques and a stringent definition of treatment success, success rates of 90% to 100% were estimated. One small RCT compared catheter ablation with medications for this arrhythmia. After a mean follow-up of 21 months, 80% of patients treated with ablation remained in sinus rhythm compared with only 36% of patients treated with medications.

A survey of 7071 procedures for isthmus-associated atrial flutter (previously discussed) reported a success rate in preventing recurrent atrial flutter of 97%. Repeat procedures were required in 4% of patients. Serious complications were reported in 0.4% of patients, the most common of which was AV block. Other reported complications included injury to the coronary arteries and ventricular arrhythmias. In 2013, Bastani et al reported results of an RCT comparing cryoablation with RFA in 153 patients with atrial flutter associated with the cavotricuspid isthmus. Acute and 6-month success rates were similar for the cryoablation and RFA groups, with less procedure-related pain in the cryoablation group. Chen et al (2015) reported results of a meta-analysis of the efficacy and safety of cryoablation versus RFA for patients with cavotricuspid valve isthmus-dependent atrial flutter. Seven RCTs (total N=496 participants) published between 1986 and 2014 were included in the review. Acute success was achieved in 85.4% in the cryotherapy group versus 92.7% in the RFA group (relative risk [RR], 0.93; 95% CI, 0.85 to 1.02; p=0.14) and long-term success was reported in 91.8% versus 96.6% (RR=0.95; 95% CI, 0.91 to 1.01; p=0.08). The fluoroscopy time was nonsignificantly shorter (weighted mean difference [WMD], -2.83 seconds; 95% CI, -8.06 to 2.40 seconds; p=0.29) in cryoablation while the procedure time was significantly longer (WMD=25.95 seconds; 95% CI, 5.91 to 45.99 seconds; p=0.01). Pain perception during ablation was considerably lower in the cryoablation group than in the RFA group (standardized mean difference, -2.36; 95% CI, -3.30 to -1.41; p<0.001).

Atrial flutter not associated with the cavotricuspid isthmus is less common, and there is less evidence for efficacy. In a combined analysis of 6 studies (total N=134 patients), success rates in abolishing
atrial flutter were 50% to 88% after an average follow-up of 2 years.\textsuperscript{1} Expert opinion\textsuperscript{7} has estimated that, with the current availability of 3-dimensional mapping systems, success for non-isthmus-dependent atrial flutter is expected to be at least 90%.

**Focal atrial tachycardia**: Focal atrial tachycardia usually arises from an abnormal automatic focus or micro-reentry circuits in the right atrium. Ablation involves identification of the abnormal trigger by mapping studies, followed by focused ablation of the abnormal area.

Atrial tachycardias are relatively uncommon; as a result, the evidence on efficacy of catheter ablation is limited. Pooled data from 514 patients undergoing ablation has reported a success rate of 86\%,\textsuperscript{1} with a recurrence rate of 8\%. Serious complications occurred in 1\% to 2\% of patients, consisting of cardiac perforation, phrenic nerve damage, and sinus node dysfunction. In another combined analysis of 7 studies (total N=112 patients), success for ablation of focal atrial tachycardia was approximately 90\%, with late recurrences reported in 7\% of patients.\textsuperscript{7}

In a retrospective multicenter study of 249 pediatric patients with focal atrial tachycardia, Kang et al reported that 134 patients underwent catheter ablation for a total of 167 procedures, including 69 (28\% of total) who had catheter ablation as a primary management strategy.\textsuperscript{3} Ablation therapy was successful in 109 (81\%) of 134 patients.

**Section Summary: Supraventricular Arrhythmias**

For patients with supraventricular arrhythmias and identifiable arrhythmogenic foci, numerous uncontrolled studies have reported high success with low rates of adverse events. Success in eliminating PSVT following catheter ablation is likely to be in the range of 95\% or higher, and success in eliminating atrial flutter is likely to be in the 90\% to 100\% range. Several RCTs have evaluated different ablation techniques, with similar rates of PSVT elimination and higher rates of recurrence for cryoablation versus RFA. There were no significant differences in the rate of permanent AV block, but rates of this complication was very low in both groups, and small differences cannot be excluded. There is less evidence on focal atrial tachycardia, with reported success rates somewhat lower. For patients who desire to avoid medications, catheter ablation is a reasonable first-line alternative treatment for these supraventricular arrhythmias.

**Ventricular Arrhythmias**

**Ventricular Tachycardia in Patients with Structural Heart Disease ("Scar-Related VT"):** Ventricular tachycardia (VT) most commonly occurs in the setting of underlying structural heart disease. VT in a patient with structural heart disease is usually precipitated by scar tissue in the left ventricle.\textsuperscript{13} Scar tissue can arise because of myocardial infarction (MI) or it can result from fibrosis of myocardium that occurs with nonischemic cardiomyopathy. Ablation in patients with structural heart disease is more difficult than for patients with idiopathic VT. This is because larger areas of ablation are typically required, there are often multiple areas that require ablation, and because patients with structural heart disease are at higher risk for complications at baseline.

Evidence on the efficacy of ablation for these patients comes largely from case series and a few controlled studies.
Systematic Reviews

Mallidi et al. performed a systematic review of all controlled studies of catheter ablation for ventricular arrhythmias. Five controlled studies with a total of 457 patients were identified. Four of these were RCTs, although 2 were unpublished, and the fifth was a small non-RCT from Japan. There was a decreased overall risk of VT recurrence for patients undergoing catheter ablation compared to treatment without ablation (odds ratio [OR], 0.62; 95% confidence interval [CI], 0.51 to 0.76). In the 2 unpublished RCTs, the absolute reduction in VT recurrence was reported to be 26% and 13%, although statistical testing for these differences was not reported. Combined analysis of complications concluded the following rates of adverse events: death (1%), stroke (1%), cardiac perforation (1%), and complete heart block (1.6%).

Santangeli et al published a systematic review of the comparative effectiveness of catheter ablation and antiarrhythmic drugs for the prevention of recurrent VT in patients with implantable cardioverter defibrillators (ICDs) in 2016. The authors searched PubMed, CENTRAL, BioMed Central, Cardiosource, ClinicalTrials.gov, and ISI Web of Science for RCTs evaluating antiarrhythmic drugs or catheter ablation versus medical management published before October 2015. They included 14 trials in the meta-analysis; 8 trials (2268 patients) evaluated antiarrhythmic drugs and 6 trials (427 patients) evaluated catheter ablation. Three catheter ablation trials included in Santangeli (2016) were also in the Mallidi (2011) review. No direct comparisons of antiarrhythmic drugs with catheter ablation were included; the search for this review occurred before the publication of the VANISH trial (described below). Both catheter ablation (OR=0.45; 95% CI, 0.28 to 0.71, p=0.001) and antiarrhythmic drugs (OR=0.66, 95% CI, 0.44 to 0.97; p=0.037) were associated with a significant reduction in inappropriate ICD interventions. An indirect comparison between catheter ablation and antiarrhythmic drugs found no significant difference between the strategies in reduction of risk of recurrent VT (ratio of OR=0.58; 95% CI, 0.26 to 1.27; p=0.174) or all-cause mortality (ratio of OR=0.58; 95% CI, 0.24 to 1.42; p=0.234).

Randomized Controlled Trials

The 2 published RCTs included in the Mallidi et al systematic review described above evaluate catheter ablation plus implantable cardioverter-defibrillator (ICD) to ICD alone for patients with ventricular tachycardia and previous MI. These studies were designed to evaluate whether catheter ablation can reduce the number of ICD discharges. The SMASH-VT study randomly assigned 128 patients with ventricular tachycardia or ventricular fibrillation and a prior MI who were not receiving antiarrhythmic medications. Mean follow-up was 22.5 ± 5.5 months. The primary endpoint was survival free from any appropriate ICD therapy (shocks or antitachycardia pacing). Major complications related to catheter ablation occurred in 4.7% (3/64) patients. One patient had a pericardial effusion that did not require intervention, 1 patient had worsening heart failure that required prolonged hospitalization, and 1 patient had a deep vein thrombosis that required anticoagulation. The primary endpoint was reached by 12% (8/64) of patients in the ablation group compared with 33% (21/64) in the defibrillator alone group (hazard ratio [HR], 0.31; 95% CI, 0.13 to 0.76; p=0.01). There were fewer deaths in the ablation group (3/64 vs 6/64, respectively), but this difference did not reach statistical significance (p=0.29). There was no difference in New York Heart Association class at the end of follow-up.

The Ventricular Tachycardia Ablation in Coronary Heart Disease (VTACH) study randomly assigned 110 patients from 16 centers in Europe with stable VT, previous MI, and left-ventricular ejection fraction less than 50% to catheter ablation plus ICD versus ICD alone. Antiarrhythmic medications
were allowed at the discretion of the treating clinician. Of 52 patients assigned to ablation, 7 did not undergo the procedure. Twelve of 55 patients in the ICD-alone group crossed over to the ablation group. All analyses were performed using intention-to-treat analysis. Patients were followed for a mean of 22.5 ± 9.0 months for the primary endpoint of first recurrence of VT or ventricular fibrillation. Time to the primary outcome was 18.6 months in the ablation group compared with 5.9 months in the ICD-alone group (p=0.045). By Kaplan Meier analysis, 59% of patients in the ablation group, compared with 40% in the ICD-alone group, were free of any VT or fibrillation event at 12 months of follow-up. Quality of life (QOL) data, measured by the Short Form (SF)-36 instrument, were available for a subset of patients (n varied between 20 and 30 in each group). There were no significant between-group differences in any of the QOL measures. There was a significant difference in the secondary outcome of hospitalizations in favor of the ablation group (HR= 0.55; 95% CI, 0.30 to 0.99; p=0.04). There were no differences in the other secondary outcomes of death, VT "storm," or syncope.

Since the publication of the Mallidi et al systematic review, Al-Khatib et al published results of pilot RCT comparing early catheter ablation with antiarrhythmic medication therapy among patients with ischemic heart disease, an ICD, and a history of at least 1 ICD shock or at least 3 antiarrhythmic pacing therapies for VT.²⁸ Twenty-seven patients were randomized to antiarrhythmic medication (n=14) or catheter ablation (n=13); enrollment was terminated prematurely after the investigators determined that the main objectives of the study (feasibility and evaluation of the effect of catheter ablation on clinical outcomes.) Two deaths occurred in each group during the 6 month follow up period. Fourteen patients had recurrent VT: 8 (62%) in the ablation arm and 6 (43%) in the antiarrhythmic medication arm. Three patients developed heart failure: 2 (15%) in the ablation arm and 1 (7%) in the antiarrhythmic medication arm. A total of 12 patients were hospitalized for VT: 5 (46%) in the ablation arm and 7 (50%) in the antiarrhythmic medication arm. Eight patients developed a serious adverse event: 3 (23%) in the ablation arm and 5 (36%) in the antiarrhythmic medication arm. Statistical comparisons between groups are not presented, although the authors state that none of the endpoints was statistically different between the 2 arms.

Results from the Ventricular Tachycardia Ablation versus Escalated Antiarrhythmic Drug Therapy in Ischemic Heart Disease (VANISH) trial were published in 2016.¹⁹ VANISH was a multicenter RCT enrolling patients with ICM and an ICD who had VT despite use of antiarrhythmic drugs. Patients were randomized to catheter ablation (ablation group; n=132) with continuation of baseline antiarrhythmic medications or escalated antiarrhythmic drug therapy (escalated-therapy group; n=127). The primary outcome was a composite of death, VT storm, or appropriate ICD shock. Analysis was intention to treat. Mean follow-up was 27.9 months. Seventy-eight (59.1%) of 132 patients in the ablation group and 87 (68.5%) of 127 in the escalated-therapy group experienced the primary outcome (HR=0.72; 95% CI, 0.53 to 0.98; p=0.04). There was no difference in mortality; 36 (27.3%) patients in the ablation group and 34 (27.6%) in the escalated therapy group died (HR=0.96; 95% CI, 0.60 to 1.53; p=0.86). The difference in the primary outcome was driven by differences in rates of appropriate shocks and episodes of VT storm. VT storm occurred in 32 (24.2%) patients in the ablation group and 42 (33.1%) patients in the escalated-therapy group (HR=0.66; 95% CI, 0.42 to 1.05; p=0.08). Appropriate ICD shocks occurred in 50 (37.9%) patients in the ablation group and 54 (42.5%) patients in the escalated-therapy group (HR=0.77; 95% CI, 0.53 to 1.14; p=0.19). Subgroup analyses indicated that the benefit of catheter ablation with respect to the primary outcome was only among patients for whom the index arrhythmia occurred despite amiodarone therapy at baseline. Treatment-related adverse events were more frequent (51 vs 22; p=0.002) in the escalated therapy group. Two cardiac perforations and 3
cases of major bleeding occurred in the ablation group; 1 patient died of cardiac arrest, 1 died of sepsis, and 1 withdrew from the trial 3 days after randomization. There were 2 deaths from pulmonary toxic effects and 1 from hepatic dysfunction in the escalated-therapy group.

Di Biase et al (2015) published results of a multicenter RCT of 259 patients with ICD, ICM, and hemodynamically tolerated VT who were randomized to clinical ablation (n=60) or substrate-based ablation targeting all abnormal electrograms in the scar (n=58). No patients were lost to follow-up and all were included in analyses. Nine (15.5%) and 29 (48.3%) patients had VT recurrence at 12-month follow-up in substrate-based and clinical VT ablation groups, respectively (HR=0.26; 95% CI, 0.11 to 0.61; p<0.001). Seven (12%) patients in the substrate ablation group and 19 (32%) in the clinical ablation group required rehospitalization related to arrhythmia (HR=0.31; 95% CI, 0.13 to 0.78; p=0.014). Twelve-month mortality was 8.6% in the substrate ablation group versus 15.0% in the clinical ablation group (HR=0.52; 95% CI, 0.17 to 1.82; p=0.21). Procedure-related complications were similar in both groups (p=0.61).

### Nonrandomized Comparative Studies

A 2014 nonrandomized, comparative study by Bunch et al evaluated outcomes for 102 patients with VT due to structural heart disease who underwent catheter ablation for recurrent ICD shocks, compared with 2088 patients with ICDs and no history of appropriate shocks and 817 patients with ICDs and a history of appropriate shocks for VT or ventricular fibrillation. Kaplan-Meier survival curves demonstrated that patients who had appropriate shocks but who did not undergo catheter ablation had consistently higher mortality rates than both other groups (p<0.001).

### Noncomparative Studies

Several prospective, multicenter case series have been published. The largest multicenter case series is the Multicentre Thermocool Ventricular Tachycardia Ablation Trial, which enrolled 231 patients with recurrent VT and prior MI from 18 centers. These patients had a high burden of VT (median, 11 episodes in the prior 6 months), and 70% had previously failed treatment with amiodarone. Mortality within 7 days of the procedure was 3% (7/231); 4 of these deaths occurred in the electrophysiology lab at the time of the procedure. Significant complications occurred in 7.3% (27/231) of patients. The primary end point (freedom from recurrent incessant or intermittent VT) was achieved in 53% (123/231) of patients. Mortality at 1-year follow-up was 18%. Approximately one-third of the deaths were attributed to arrhythmias, one-third to heart failure, and one-third to other causes.

Calkins et al enrolled 146 patients from 18 clinical centers who had stable VT, ischemic heart disease, an implantable ICD, and who had failed at least 2 prior antiarrythmic medications. Acute procedural success was achieved in 75% of patients. After a mean follow-up of 243 days, 46% of patients experienced a recurrence of any tachyarrhythmia. Major complications arose in 8% (12/146) of patients, including stroke or transient ischemic attack (2.7%), tamponade (2.7%), complete heart block (1.4%), valve injury (0.7%), MI (0.7%), and femoral artery laceration (0.7%). Four of these complications led to death (periprocedural mortality rate, 2.7%).

The Euro-VT study enrolled 63 patients from 8 centers in Europe with sustained VT and prior MI who were refractory to previous drug and/or device therapy. Two-thirds of the patients had prior ICD implantation. Procedural success was achieved in 81% of patients. Freedom from VT at 12 months was approximately 45% by Kaplan-Meier analysis. During a mean follow-up of 12 months, 49%
(31/63) of patients had VT recurrence. There were no deaths within 30 days of the procedure. One patient experienced a serious complication (VT degenerating to ventricular fibrillation during the procedure), necessitating cardiopulmonary resuscitation.

In 2014, a prospective European case series reported on 90 patients with ischemic heart disease who received catheter ablation for VT, with or without ICD placement, with an average follow-up of 33 months. Most (70%) patients had complete or partial success of the initial procedure. Forty-two percent of patients remained completely free from recurrent VT over the follow-up period. Another prospective case series published in 2014 evaluated catheter ablation outcomes for VT in 61 subjects with nonischemic dilated cardiomyopathy (NIDCM) and 164 subjects with ICM. Major procedure-related complications occurred in 11.1% of each group. Complete short-term success (noninducibility of any VT) occurred in 42 (66.7%) NIDCM patients, compared with 128 (77.4%) ICM patients (p=0.125). Cumulative VT-free survival was 23.0% for the NIDCM group and 43.0% for the ICM group (HR for VT recurrence, 1.62; 95% CI, 1.12 to 2.34; p=0.01).

Other retrospective studies have evaluated the association between outcomes after VT ablation and procedural and patient factors, including the presence of immediate post ablation noninducibility of VT, time to ablation after first onset of VT, ablation procedure duration, presence of acute hemodynamic decompensation during ablation, and the presence of heart failure, dilated cardiomyopathy, VT storm, number of induced VTs, and acute procedural failure. A large, retrospective series of 695 consecutive patients reported long-term outcomes after VT ablation in patients with no structural heart disease, ICM, and non-ICM. Median follow-up was 6 years after ablation. Acute complete success was achieved in 60% of patients with ICM and 56% of patients with non-ICM; major complications occurred in 8.3% and 6.7%, respectively. Ventricular arrhythmia free survival at 6-year follow-up was 54% and 38% in ICM and non-ICM, respectively. Overall survival was 48% and 74%.

Section Summary: Ventricular Tachycardia Due to Structural Heart Disease
Two systematic reviews have described 9 individual RCTs that evaluated catheter ablation versus usual care with medical management and 1 RCT that directly compared escalation of antiarrhythmic medications to catheter ablation in patients with VTs and an automatic ICD. Studies reported that procedural success was high and that catheter ablation was successful in reducing the number of VT episodes and the number of automatic ICD shocks. The rate of serious procedural adverse events was low in these trials. The VANISH trial found a significantly lower rate of a composite of death, VT storm, and appropriate ICD shock among patients undergoing catheter ablation versus those receiving an escalation in antiarrhythmic drug therapy in patients with ICM and an ICD who had VT despite antiarrhythmic drug therapy. An additional pilot RCT demonstrated no significant outcome differences between catheter ablation and medical management for VT, but may have been underpowered to detect a difference between groups. Observational studies have corroborated a decrease in VT following catheter ablation in similar patient populations. This evidence is sufficient to conclude that catheter ablation improves outcomes for patients with VT and an automatic ICD when the frequency of VT episodes and automatic ICD shocks are not adequately controlled by medications.

Idiopathic VT: Idiopathic VT refers to tachycardia in the absence of demonstrable heart disease. It most commonly arises from the right ventricular outflow tract, although it sometimes arises from the
left ventricular outflow tract or other cardiac structures.\textsuperscript{13} Idiopathic VT is relatively benign compared with other forms of VT; it is usually well-tolerated and sudden death is rare.

Because idiopathic VT is an uncommon disorder, there is limited evidence on the efficacy of catheter ablation, and the available evidence consists of small clinical series. In a series of 48 patients, success of catheter ablation in eliminating the focus was achieved in 83\% (29/35) of patients with right ventricular outflow tract VT and 92\% (12/13) of patients with left-ventricular outflow tract VT.\textsuperscript{32} In several other small series, the success of ablation in abolishing the VT focus ranged from 54\% to 92\%.\textsuperscript{33-35} Recurrence rates of VT at variable durations of follow-up ranged from 0\% to 14\%.

Another series of 44 patients was reported by Pytkowski et al in 2012.\textsuperscript{36} This series included patients with VT (n=23) and with frequent premature ventricular contractions (n=21) originating from the right ventricular outflow tract. All patients underwent successful ablation and were followed up at 3 months. The primary outcome was improvement in QOL, as measured by a change in SF-36 score. A statistically significant improvement was reported on 6 of 8 domains. However, there were no significant improvements on the Physical Component or the Mental Component Summary scores.

The previously described retrospective series with long-term follow-up by Kumar et al included results of VT ablation in patients without structural heart disease.\textsuperscript{31} Acute complete success was achieved in 79\% of patients with no structural heart disease, with a major complications rate of 3.7\%. With a median follow-up of 6 years, ventricular arrhythmia free survival at 6 years was 77\% and overall survival was 100\%.

\textbf{Section Summary: Idiopathic VT}

There is a limited amount of evidence for treatment of patients with structurally normal hearts. Small case series have reported high success rates in eliminating the focus of arrhythmia, with low rates of serious adverse effects and a relatively low rate of recurrence. This evidence suggests that there is a benefit to catheter ablation for this population but the evidence is not conclusive due to the small numbers of patients and the lack of controlled trials.

\textbf{Incessant VT (Storm)}

Incessant VT, or “ventricular tachycardia storm, refers to tachycardia that occurs more than 3 times in a 24-hour period, often in association with an acute cardiac event such as MI. VT storm is potentially life-threatening situation and requires rapid treatment and control. The evidence base for this indication consists of small case series describing outcomes after treatment with catheter ablation.

A systematic review of case series was published in 2013, including 39 reports (total N=471 patients).\textsuperscript{37} Successful termination of all ventricular arrhythmias was achieved in 72\% of cases (95\% CI, 71\% to 89\%), and treatment failure occurred in 9\% (95\% CI, 3\% to 10\%). Three (0.6\%) deaths were associated with the procedure, and recurrence of VT storm was 6\%. During a mean follow-up of 61 weeks, 17\% of patients died, with approximately one-quarter of all deaths attributed to arrhythmias. The risk of death was approximately 4 times higher for patients with a failed procedure than for patients with a successful procedure.

One of the larger series of patients was reported by Carbucicchio et al.\textsuperscript{38} This series included 95 patients with an ICD and drug-refractory VT storm, most of whom had coronary artery disease.
Catheter ablation was successful in acutely suppressing VT storm in all patients, although some required a second or a third procedure to achieve control. All VTs were eliminated in 89% of patients. After a mean follow-up of 22 months, 92% (87/95) of patients remained free of VT storm; 12% (11/95) patients died of cardiac causes.

Other smaller series have also reported similar outcomes of ablation in VT storm.\textsuperscript{39-41} For example, Arya et al reported on 30 patients with ischemic heart disease and VT storm who were treated with catheter ablation using a remote magnetic navigation system.\textsuperscript{39} Acute success, defined as suppression of all VT, was achieved in 80% of patients. After a mean follow-up of 7.8 months, 70% (21/30) of patients remained free of VT. No serious complications related to ablation were reported.

Deneke et al reported on 32 patients with electrical storm treated with catheter ablation as part of a 7-hospital collaborative network.\textsuperscript{40} There was 1 (3.1%) periprocedural death due to VT and mechanical dissociation during the procedure. Complete success, defined as the acute suppression of all inducible arrhythmias, was achieved in 60% (19/32) patients, and partial success was achieved in 31.3% (10/32). In 6% (2/32) of patients, ablation failed to suppress all clinically relevant arrhythmias. After a mean follow-up of 15 months, VT recurred in 31% (10/31) of patients, and VT storm recurred in 6% (2/31).

Mussigbrodt et al reported outcomes for VT storm ablation in 28 patients with arrhythmogenic right ventricular cardiomyopathy who had ICDs in place.\textsuperscript{41} Forty-eight ablation procedures, including 6 epicardial procedures, were conducted. Three major periprocedural complications occurred (6.3%), including 1 pericardial effusion due to right ventricular perforation, which required emergency surgery, and 2 massive pulmonary thromboembolisms, 1 fatal. During a mean follow-up period of 18.7 months (range, 1-64 months), 15 (53.5%) patients had no recurrence of VT based on regular ICD interrogations and clinical follow-up, and received no ICD therapy.

Section Summary: Incessant VT (Storm)
Case series have reported high procedural success rates for catheter ablation in VT storm. Serious complications occur at reasonably low rates, and mortality from the procedure was reported to be 0.6% in a meta-analysis of case series. Because of the emergency nature of this condition, RCTs are not expected to be performed. In addition, there are no other available treatment options for patients with VT storm who fail pharmacologic interventions.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

<table>
<thead>
<tr>
<th>Table 1. Summary of Key Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT No.</td>
</tr>
<tr>
<td>NCT02130765</td>
</tr>
<tr>
<td>NCT01584154</td>
</tr>
</tbody>
</table>
**Practice Guidelines and Position Statements**

**Supraventricular Arrhythmias**

**American College of Cardiology et al**
The 2015 American College of Cardiology (ACC), American Heart Association (AHA), and Heart Rhythm Society (HRS) guidelines for the management of adult patients with supraventricular arrhythmias\(^9\) included the following recommendations for catheter ablation:

- **PSVT (AVNRT [atrioventricular nodal reentrant tachycardia])**
  - Recurrent, symptomatic AVNRT (Class I recommendation; level of evidence B)
  - Infrequent AVNRT in patients who desire complete control of arrhythmia (Class I recommendation; level of evidence B).
  - Infrequent, well-tolerated AVNRT (Class I recommendation; level of evidence B)

- **SVT [supraventricular tachycardia] of unknown mechanism**
  - With pre-excitation present in sinus rhythm (Class I recommendation; level of evidence B)
  - Without pre-excitation present in sinus rhythm (Class I recommendation; level of evidence B)

- **Focal atrial tachycardia (Class I recommendation; level of evidence B)**

- **Symptomatic AVNRT; ablation of slow pathway (Class I recommendation, level of evidence B-NR)**

- **Orthodromic AVRT, ablation of accessory pathway (Class I recommendation; level of evidence B-NR)**

- **Asymptomatic pre-excitation,**
  - EP [electrophysiology] study identifies high risk of arrhythmic events (Class IIa, level of evidence B-NR)
  - Pre-excitation precludes employment (Class IIa, level of evidence B-NR)

- **Atrial flutter**
  - Symptomatic or refractory to rate control pharmacological treatment (Class I, level of evidence B-R)
  - Recurrent, symptomatic and has failed at least 1 rhythm control pharmacological treatment (Class I, level of evidence C-LD)
  - Occurs as the result of flecainide, propafenone, or amiodarone (Class IIa, level of evidence C-LD)
  - Recurrent, symptomatic non-CTI [cavotricuspid isthmus] dependent flutter as primary therapy, before therapeutic trials (Class IIa, level of evidence C-LD)
Asymptomatic with recurrent AF (Class IIb, level of evidence C-LD)

- Junctional tachycardia
  - Drug therapy options are contraindicated or ineffective (Class IIb, level of evidence C-LD)
  - Recurrent, symptomatic SVT in ACHD [adult congenital heart disease] (Class IIa, level of evidence B-NR)
  - Undergoing planned surgical repair of structural heart disease or ischemic heart disease (Class IIa, level of evidence B-NR)
  - Pregnant, with highly symptomatic, recurrent, drug-refractory SVT (Class IIb, level of evidence C-LD)

**Ventricular Arrhythmias**

**European Society for Cardiology**

In 2015, the European Society for Cardiology (ESC) published guidelines on the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. The guidelines were based on a comprehensive review of published evidence and the level of evidence and strength of recommendations were weighed and graded (see Table 2).

**Table 2: European Society for Cardiology 2015 Guidelines**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Class</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urgent catheter ablation is recommended in patients with scar-related heart disease presenting with incessant VT or electrical storm</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>Catheter ablation is recommended in patients with ischaemic heart disease and recurrent ICD shocks due to sustained VT</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>Catheter ablation should be considered after a first episode of sustained VT in patients with ischaemic heart disease and an ICD</td>
<td>IIa</td>
<td>B</td>
</tr>
<tr>
<td>Radiofrequency catheter ablation at a specialized ablation centre followed by the implantation of an ICD should be considered in patients with recurrent VT, VF or electrical storms despite complete revascularization and optimal medical treatment</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>Catheter ablation should be considered in patients with LV dysfunction associated with PVCs</td>
<td>IIa</td>
<td>B</td>
</tr>
<tr>
<td>Urgent catheter ablation in specialized or experienced centres is recommended in patients presenting with incessant VT or electrical storm resulting in ICD shocks</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>Amiodarone or catheter ablation is recommended in patients with recurrent ICD shocks due to sustained VT</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>Amiodarone or catheter ablation should be considered after a first episode of sustained VT in patients with an ICD</td>
<td>IIa</td>
<td>B</td>
</tr>
<tr>
<td>Catheter ablation as a first line therapy is recommended in patients presenting with bundle branch re-entrant tachycardia</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>Catheter ablation is recommended in patients with DCM and bundle branch re-entry ventricular tachycardia refractory to medical therapy</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>Catheter ablation may be considered in patients with DCM and VA not caused by bundle branch re-entry refractory to medical therapy</td>
<td>IIb</td>
<td>C</td>
</tr>
<tr>
<td>Catheter ablation, performed in experienced centres, should be considered in patients with frequent symptomatic PVC or VT unresponsive to medical therapy to improve symptoms and prevent ICD shocks, respectively</td>
<td>IIa</td>
<td>B</td>
</tr>
<tr>
<td>Catheter ablation may be considered in patients with a history of electrical storms or repeated appropriate ICD shocks</td>
<td>IIb</td>
<td>C</td>
</tr>
<tr>
<td>Medical therapy or catheter is recommended in children with frequent PVCs or VT thought to be causative of ventricular dysfunction</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>Catheter ablation should be considered when medical therapy is either not effective or undesired in symptomatic children with idiopathic RVOT VF/PVCs or verapamil-sensitive left fascicular VT</td>
<td>IIa</td>
<td>B</td>
</tr>
<tr>
<td>Catheter ablation by experience operators should be considered after failure of medical therapy</td>
<td>IIa</td>
<td>B</td>
</tr>
</tbody>
</table>
Catheter ablation is not recommended in children < 5 years of age except when previous medical therapy fails or when VT is not haemodynamically tolerated

Catheter ablation is recommended as additional therapy or an alternative to ICD in patients with CHD who have recurrent monomorphic VT or appropriate ICD therapies that are not manageable by device reprogramming or drug therapy

Catheter ablation should be considered as an alternative to drug therapy for symptomatic sustained monomorphic VT in patients with CHD and an ICD

Surgical ablation by electrophysiological mapping may be considered in patients with CHD undergoing cardiac surgery, with clinical sustained VT and with inducible sustained monomorphic VT with an identified critical isthmus

Catheter ablation or prophylactic anti-arrhythmic therapy is not recommended for asymptomatic infrequent PVC in patients with CHD and stable ventricular function

Catheter ablation of RVOT VT/PVC is recommended in symptomatic patients and/or in patients with a failure of anti-arrhythmic drug therapy (e.g. beta-blocker) or in patients with a decline in LV function due to RVOT-PVC burden

Catheter ablation of LVOT/aortic cusp/epicardial VT/PVC by experienced operators after failure of one or more sodium channel blockers (class IC agents) or in patients not wanting long-term anti-arrhythmic drug therapy should be considered in symptomatic patients

Catheter ablation by experienced operators is recommended as a first-line treatment in symptomatic patients with idiopathic left VTs

CHD: congenital heart disease; DCM: dilated cardiomyopathy; ICD: implantable cardioverter defibrillator; LV: left ventricular; LVOT: left ventricular outflow tract; PVC: premature ventricular complex; RVOT: right ventricular outflow tract; VA: ventricular arrhythmia; VF: ventricular fibrillation; VT: ventricular tachycardia.

European Heart Rhythm Association et al
The European Heart Rhythm Association (EHRA) and HRS, in conjunction with ACC and AHA, published an expert consensus document in 2009 on the use of catheter ablation for VTs. These recommendations were based on review of the literature and clinical experience. In most indications, high-quality evidence was lacking, and recommendations were primarily based on expert opinion.

Catheter ablation was recommended for the following indications:

- Recurrent ventricular tachycardia refractory to “antiarrhythmic medications”
- Incessant ventricular tachycardia (ventricular tachycardia storm) “that is not due to a reversible cause”
- Frequent ventricular tachycardia “that is presumed to cause ventricular dysfunction”
- Bundle “branch reentrant or interfascicular VTs”
- “Recurrent sustained polymorphic VT or VF [ventricular fibrillation] [with a] trigger [amenable to] ablation”

Catheter Ablation of Ventricular and Supraventricular Arrhythmias in Pediatric Patients

European Heart Rhythm Association et al
In 2013, EHRA and the Association for European Paediatric and Congenital Cardiology released a joint consensus statement on pharmacologic and nonpharmacologic therapies for arrhythmia in the pediatric population. These guidelines addressed the use of catheter ablation for both supraventricular and ventricular arrhythmias in both structurally normal hearts and in repaired and unrepaired congenital heart disease. In general, given the higher risk of RFAs in the pediatric age group compared with adults and the limited data on the long-term effects of radiofrequency lesions on
the immature myocardium, the authors recommended that radiofrequency catheter ablation in infants and young children is considered only when all antiarrhythmic therapies have failed. The consensus statement included the following recommendations for catheter ablation for pediatric patients with structurally normal hearts (see Table 3).

**Table 3: European Heart Rhythm Association et al 2013 Guidelines**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Class</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>WPW syndrome</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>WPW syndrome and episode of aborted SCD</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>WPW syndrome and syncope combined with preexcited RR interval during AF &lt;250 ms or antegrade APERP during PES &lt;250 ms</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>WPW syndrome and recurrent and/or symptomatic SVT and age &gt;5 years</td>
<td>IIb</td>
<td>C</td>
</tr>
<tr>
<td>WPW syndrome and recurrent and/or symptomatic SVT and age &lt;5 years</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>WPW syndrome and palpitations with inducible sustained SVT during EP test, age &gt;5 years</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>Asymptomatic preexcitation, age &gt;5 years, no recognized tachycardia, risks and benefits of procedure and arrhythmia clearly explained</td>
<td>IIb</td>
<td>C</td>
</tr>
<tr>
<td>Asymptomatic preexcitation, age &lt;5 years</td>
<td>III</td>
<td>C</td>
</tr>
<tr>
<td>Supraventricular tachycardia</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>Incessant or recurrent VT associated with ventricular dysfunction</td>
<td>III</td>
<td>C</td>
</tr>
<tr>
<td>Single or infrequent VT (no pre-excitation), age &gt;5 years</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>SVT, age &gt;5 years, chronic AA therapy has been effective in control of the arrhythmia</td>
<td>Ia</td>
<td>C</td>
</tr>
<tr>
<td>SVT, age &lt;5 years (including infants), when AA medications, including Classes I and III are not effective or associated with intolerable side effects</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>SVT controlled with conventional AA medications, age &gt;years</td>
<td>III</td>
<td>C</td>
</tr>
<tr>
<td>Ventricular arrhythmias</td>
<td>I</td>
<td>C</td>
</tr>
</tbody>
</table>


**Pediatric and Congenital Electrophysiology Society et al**

In 2012, the Pediatric and Congenital Electrophysiology Society and HRS published an expert consensus statement on the management of the asymptomatic young patient (age range, 8-21 years) with a WPW electrocardiogram pattern, which was endorsed by the American College of Cardiology Foundation, AHA, the American Academy of Pediatrics, and the Canadian Heart Rhythm Society. Statements relevant to the use of catheter ablation included the following:

4. “Young patients with a SPERRI [shortest excited R-R interval] ≤250 ms in atrial fibrillation are at increased risk for SCD [sudden cardiac death]. It is reasonable to consider catheter ablation in this group, taking into account the procedural risk factors based on the anatomical location of the pathway (Class IIA, Levels of Evidence B/C).

5. Young patients with a SPERRI >250 ms in atrial fibrillation are at lower risk for SCD, and it is reasonable to defer ablation (Class IIA, Level of Evidence C). Ablation may be considered in these patients at the time of diagnostic study if the location of the pathway and/or patient characteristics do not suggest that ablation may incur an increased risk of adverse events, such as AV [atrioventricular] block or coronary artery injury (Class IIB, Level of Evidence C).
6. Young patients deemed to be at low risk might subsequently develop cardiovascular symptoms such as syncope or palpitations. These patients should then be considered symptomatic and may be eligible for catheter ablation procedures regardless of the prior assessment.

7. Asymptomatic patients with a WPW ECG pattern and structural heart disease are at risk for both atrial tachycardia and AV reciprocating tachycardia, which may result in unfavorable hemodynamics. Ablation may be considered regardless of the anterograde characteristics of the accessory pathway (Class IIB, Level of Evidence C).

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

**U.S. Preventive Services Task Force Recommendations**

Not applicable

**Summary of Evidence**

For individuals who have supraventricular arrhythmias who receive catheter ablation, the evidence includes numerous case series and uncontrolled trials and 1 randomized controlled trial (RCT). Relevant outcomes are overall survival, symptoms, change in disease status, morbid events, medication use, and treatment-related morbidity. Clinical series of paroxysmal supraventricular tachycardia have reported very high success rates at well over 90%. Serious complications, mainly consisting of atrioventricular block requiring pacemaker insertion, occur in approximately 1% of patients. High success rates are also reported for atrial flutter and focal atrial tachycardia. There are few comparative or trial data. The RCT assessing catheter ablation of the accessory pathway confirmed that incidence of arrhythmic events is greatly reduced with catheter ablation. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals with drug- and implantable cardioverter defibrillator refractory ventricular tachycardia due to structural heart disease who receive catheter ablation, the evidence systematic reviews of RCTs. Relevant outcomes are overall survival, symptoms, change in disease-status, morbid events, medication use, and treatment-related morbidity. Across 9 individual RCTs that evaluated catheter ablation versus usual care with medical management and 1 RCT that directly compared escalation of antiarrhythmic medications to catheter ablation in patients with VTs and an automatic ICD, the evidence has shown that procedural success is 80% to 90% and that catheter ablation is successful at reducing the number of VT episodes by about 30% and associated with approximately a 50% reduction in inappropriate ICD interventions compared to usual medical management alone. The rate of serious procedural adverse events is low. Late recurrences do occur, but most patients treated with ablation remain free of VT at 1- to 2-year follow-ups and 40% to 50% remain VT free after 6 years of follow-up. The trial directly comparing catheter ablation to escalation of medication found a 28% lower rate of a composite of death, VT storm, and appropriate ICD shock among patients undergoing catheter ablation versus those receiving an escalation in antiarrhythmic drug therapy. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.
For individuals who have idiopathic VT refractory to drug therapy and ICD placement who receive catheter ablation, the evidence includes a few case series. Relevant outcomes are overall survival, symptoms, change in disease status, morbid events, medication use, and treatment-related morbidity. There are no comparative or trial data and, given the rarity of the disease, such RCTs are unlikely. Case series have reported high success and low rates of adverse events with catheter ablation. However, the body of literature is small. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have VT storm who have failed pharmacologic treatment who receive catheter ablation, the evidence includes a few case series. Relevant outcomes are overall survival, symptoms, change in disease status, morbid events, medication use, and treatment-related morbidity. Serious complications have been reported at reasonably low rates, and mortality from the procedure has been reported to be 0.6% in a meta-analysis of case series. There are no comparative or trial data. Because of the emergent nature of this condition, RCTs are not expected to be performed. However, in these situations, morbidity and mortality are expected to be extremely high in patients who have failed pharmacologic therapy; therefore, the available evidence is considered sufficient to draw conclusions about outcomes. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

**Medicare National Coverage**

There is no national coverage determination.

**References**


43. Aliot EM, Stevenson WG, Almendral-Garrote JM, et al. EHRA/HRS Expert Consensus on Catheter Ablation of Ventricular Arrhythmias: developed in a partnership with the European Heart Rhythm Association (EHRA), a Registered Branch of the European Society of Cardiology (ESC), and the Heart Rhythm Society (HRS); in collaboration with the American College of Cardiology (ACC) and the American Heart Association (AHA). Europace. Jun 2009;11(6):771-817. PMID 19443434


45. Pediatric Congenital Electrophysiology Society, Heart Rhythm Society, American College of Cardiology Foundation, et al. PACES/HRS expert consensus statement on the management of the asymptomatic young patient with a Wolff-Parkinson-White (WPW, ventricular preexcitation) electrocardiographic pattern: developed in partnership between the Pediatric and Congenital Electrophysiology Society (PACES) and the Heart Rhythm Society (HRS). Endorsed by the governing bodies of PACES, HRS, the American College of Cardiology Foundation (ACCF), the American Heart Association (AHA), the American Academy of Pediatrics (AAP), and the Canadian Heart Rhythm Society (CHRS). Heart Rhythm. Jun 2012;9(6):1006-1024. PMID 22579340

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 2011</td>
<td>New Policy</td>
<td>Policy updated with literature review, references added and reordered. Two policy statements added: Catheter ablation for ventricular tachycardia “storm” may be medically necessary when pharmacologic treatment is unsuccessful. Catheter ablation for all other ventricular arrhythmias is not medically necessary.</td>
</tr>
<tr>
<td>June 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review. References 2, 3, 5, 13, 14, 26, and 27 added. Policy statements unchanged.</td>
</tr>
<tr>
<td>June 2015</td>
<td>Update Policy</td>
<td>Policy updated with literature review; references 6, 8-9, 12, 15, 20-21, 33, and 44 were added. Policy statements unchanged.</td>
</tr>
</tbody>
</table>

Keywords

Arrhythmia, Cardiac Catheter Ablation
Cardiac Arrhythmic Foci, Catheter Ablation of Catheter Ablation of Cardiac Arrhythmic Foci Radiofrequency Catheter Ablation for Cardiac Arrhythmias

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 2, 2016 and is effective January 15, 2017.

Signature on File

Deborah M. Smith, MD, MPH