Catheter Ablation for Cardiac Arrhythmias

Description

Catheter ablation is a technique for eliminating 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 utilized 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 have 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 as a result 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**

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<th>Policy Code</th>
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<td>Radiofrequency Catheter Ablation as Treatment for Atrial Fibrillation</td>
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**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 as a result of abnormal conduction through the AV node or through accessory conduction pathways that bypass the atrioventricular (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. (1) 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 (2) and 90% in a series of 140 children treated with radiofrequency ablation for permanent junctional reciprocating tachycardia. (3)

Several RCTs have compared radiofrequency ablation with cryoablation for PSVT due to AVNRT. For example, Deisenhofer et al. randomized 509 patients with AVNRT to cryoablation (n=251) or radiofrequency ablation (RFA) (n=258). (4) 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 six months’ follow-up, more patients in the cryoablation group reached the primary composite endpoint 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). (5) Rates of acute procedural success were again high in both groups (98% in the cryoablation group and 100% in the radiofrequency 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.

Ablation of PSVT due to accessory pathways shows similar or slightly lower success rates. Most clinical series and registries report success in the 85% to 100% range. (6) In a survey covering 6065 patients undergoing ablation during the period of 1997–2002, 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, or stroke) occurred in 0.6% of patients. (6) The 1995 NASPE survey included 5427 patients undergoing accessory pathway ablation. Serious complications occurred in 1.8% of patients (99/5,427), with a mortality rate of 0.08% (4/5427).

Atrial flutter: Atrial flutter usually arises from re-entrant 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. (1) One small RCT compared catheter ablation to medications for this arrhythmia. After a mean follow-up of 21 months, 80% of patients treated with ablation remained in sinus rhythm compared to only 36% of patients treated with medications. (1)
A survey of 7071 procedures for isthmus-associated atrial flutter reported a success rate in preventing recurrent atrial flutter of 97%. (6) 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 a RCT comparing cryoablation with RFA in 153 patients with atrial flutter associated with the cavitricuspid isthmus.(7) The acute and 6-month success rates were similar for the cryoablation and RFA groups, with less procedure-related pain in the cryoablation group.

Atrial flutter that is not associated with the cavitricuspid isthmus is less common, and there is less evidence for efficacy. In a combined analysis of 6 studies enrolling a total of 134 patients, success rates in abolishing atrial flutter were 50% to 88% after an average follow-up of 2 years. (1) Expert opinion (6) has estimated that with the current availability of 3D mapping systems, success for nonisthmus-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 reported a success rate of 86%, (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 including 112 patients, success for ablation of focal atrial tachycardia was approximately 90%, with late recurrences reported in 7% of patients. (6)

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 the total) who had catheter ablation as a primary management strategy. (8) Ablation therapy was successful in 109/134 patients (81%).

Section Summary: For patients with supraventricular arrhythmias and identifiable arrhythmogenic foci, numerous uncontrolled studies report 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 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. (9) Scar tissue can arise as a result 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. (10) 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%).

**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 (11) 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 (12) 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 antitachycardia pacing therapies for VT. (13) 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 were statistically different between the 2 arms.

Nonrandomized Comparative Studies
A non-randomized, comparative study was published in 2013 (preprint) by Jared Bunch et al. This study 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.(14) Kaplan-Meier survival curves demonstrate 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, (15) which enrolled 231 patients from 18 centers with recurrent VT and prior MI. 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 occurred in 3% of patients (7/231); 4 of these deaths occurred in the electrophysiology lab at the time of the procedure. Significant complications occurred in 7.3% of patients (27/231). The primary endpoint of freedom from recurrent incessant or intermittent ventricular tachycardia was achieved in 53% of patients (123/231). Mortality at 1 year of 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 (16) enrolled 146 patients from 18 clinical centers who had stable VT, ischemic heart disease, an implantable cardioverter-defibrillator (ICD), and who had failed at least 2 prior
antiarrhythmic medications. Acute procedural success was achieved in 75% of patients. After a mean follow-up of 243 ± 153 days, 46% of patients experienced a recurrence of any tachyarrhythmia. Major complications occurred in 8% of patients (12/146), including stroke/TIA (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 lead to death, for a periprocedural mortality rate of 2.7%.

The Euro-VT study (17) 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 ± 3 months, 49% of patients (31/63) developed a recurrence of VT. There were no deaths within 30 days of the procedure. One patient experienced a serious complication, with 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 patients (70%) had complete or partial success of the initial procedure. (18) Forty-two percent of patients remained completely free from recurrent ventricular tachycardia 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 227 164 subjects with ischemic cardiomyopathy (ICM). (19) Major procedure-related complications occurred in 11.1% of each group. Complete short-term success (noninducibility of any VT) occurred in 42 NIDCM patients (66.7%), compared with 128 ICM patients (77.4%; P=0.125). Cumulative VT-free survival was 23.0% for the NIDCM group, compared with 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, (20) time to ablation after first onset of VT, (21) ablation procedure duration, (22) the presence of acute hemodynamic decompensation during ablation, (23), and the presence of heart failure, dilated cardiomyopathy, VT storm, number of induced VTs, and acute procedural failure. (24)

**Section Summary:** There are 2 RCTs that evaluate catheter ablation versus usual care in patients with VT and an automatic ICD (AICD). Both studies reported that procedural success was high, and that catheter ablation was successful in reducing the number of VT episodes and reducing the number of AICD shocks. The rate of serious procedural adverse events was low in these trials. 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 AICD when the frequency of VT episodes and AICD shocks are not adequately controlled by medications.

**Idiopathic VT:** Idiopathic VT refers to tachycardia that occurs 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. (9) Idiopathic VT is relatively benign when 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, (25) 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) patients with left-ventricular outflow tract ventricular tachycardia. In several other small series, the success of ablation in abolishing the ventricular tachycardia focus ranged from 54% to 92%. (26-28) Recurrence rates of ventricular tachycardia at variable times of follow-up ranged from 0% to 14%.

Another series of 44 patients was reported by Pytowski et al in 2012. (29) This series included both patients with VT (n=23) and frequent premature ventricular contractions (PVCs) (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 the SF-36 questionnaire. A statistically significant improvement was reported on 6 of 8 domains. However, there were no significant improvements on the Physical or Mental Component Summary score.

Section Summary: There is a limited amount of evidence for treatment of patients with structurally normal hearts. Small case series report high success in eliminating the focus of arrhythmia, with a low rate 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 is not conclusive due to the small numbers of patients and the lack of controlled trials.

Incessant Ventricular Tachycardia (“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 a potentially life-threatening situation that 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 2012, including 39 reports with a total of 471 patients. (30) 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%). There were 3 deaths associated with the procedure (0.6%), and a recurrence of VT storm in 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 compared to patients with a successful procedure.

One of the larger series was reported by Carbucicchio et al. (31) This was a series of 95 patients with an ICD and drug-refractory VT storm, the majority of who had coronary artery disease. Catheter ablation was successful in acutely suppressing VT storm in all patients, although some patients required a second or third procedure to achieve control. All VTs were eliminated in 89% of patients. After a mean follow-up of 22 months, 92% of patients (87/95) remained free of VT storm, and 12% (11/95) patients died of cardiac causes.
Other smaller series also report similar outcome of ablation in VT storm. (32, 33) For example, Arya et al (32) reported on 30 patients with ischemic heart disease and VT storm who were treated with catheter ablation using a remote magnetic navigation system. Acute success, defined as suppression of all VT, was achieved in 80% of patients. After a mean follow-up of 7.8 months, 70% of patients (21/30) remained free of VT. No serious complications related to ablation were reported.

Deneke et al. (33) reported on 32 patients with electrical storm treated with catheter ablation as part of a 7-hospital collaborative network. There was one periprocedural death (3.1%) due to VT and mechanical dissociation that occurred 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% of patients (2/32), ablation failed to suppress all clinically relevant arrhythmias. After a mean follow-up of 15 months, recurrent VT occurred in 31% of patients (10/31), 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. (34) A total of 48 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, one fatal. During a mean follow up period of 18.7 months (range 1-64 months), 15 patients (53.5%) had no recurrence of VT based on regular ICD interrogations and clinical follow up and received no ICD therapy.

**Section Summary:** Case series report 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 a patient with VT storm who fails pharmacologic interventions.

**Ongoing Clinical Trials**

A recent search of the website ClinicalTrials.gov, identified a large number of randomized controlled trials (RCTs) evaluating catheter ablation ventricular tachycardia (VT) that are currently enrolling patients, which are summarized in Table 1.

**Table 1: Ongoing RCTs of catheter Ablation for Ventricular Tachycardia**

<table>
<thead>
<tr>
<th>Trial Name</th>
<th>Clinical Trials Number</th>
<th>Planned Enrollment</th>
<th>Estimated Study Completion Date</th>
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<td>Comparative Study Between Cryoablation and Radiofrequency Ablation in the Treatment of Supraventricular Tachycardia (CRYOABLATE)</td>
<td>NCT01584154</td>
<td>520</td>
<td>September 2014 (no published results identified)</td>
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<tr>
<td>Ventricular Tachycardia Ablation Versus Enhanced Drug Therapy (VANISH)</td>
<td>NCT00905853</td>
<td>260</td>
<td>January 2015 (with follow up through January 2018)</td>
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<tr>
<td>Trial Comparing Ablation With Medical Therapy in</td>
<td>NCT01798277</td>
<td>50</td>
<td>December 2015</td>
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Practice Guidelines and Position Statements

Supraventricular arrhythmias

The American College of Cardiology/American Heart Association/European Society for Cardiology (ACC/AHA/ESC) guidelines for the management of patients with supraventricular arrhythmias (1) includes the following recommendations for catheter ablation:

- **PSVT (AVNRT)**
  - 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)

- **PSVT (accessory pathway)**
  - Poorly tolerated supraventricular tachycardia (SVT) with no pre-excitation (Class I recommendation; level of evidence B)
  - Infrequent SVT, no pre-excitation (Class IIa recommendation; level of evidence B)
  - Poorly tolerated SVT with pre-excitation (Class I recommendation; level of evidence B)
  - Asymptomatic, with pre-excitation (Class IIa recommendation; level of evidence B)

- **Atrial flutter**
  - Poorly tolerated atrial flutter (Class I recommendation; level of evidence B)
  - Recurrent, well-tolerated atrial flutter (Class I recommendation; level of evidence B)
  - First episode atrial flutter, well-tolerated (Class IIa recommendation; level of evidence B)
  - Nonisthmus-dependent atrial flutter, symptomatic and refractory to medications (Class IIa recommendation; level of evidence B)
  - Atrial flutter associated with class IC drugs or amiodarone (Class IIa recommendation; level of evidence C)
Focal atrial tachycardia

- Recurrent, symptomatic atrial tachycardia (Class I recommendation; level of evidence B)
- Incessant atrial tachycardia (Class I recommendation; level of evidence B)
- Nonsustained, asymptomatic atrial tachycardia (Class III recommendation; level of evidence C)

Ventricular Arrhythmias

The European Heart Rhythm Association and the Heart Rhythm Society, in conjunction with the American College of Cardiology and the American Heart Association, 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. However, 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 ventricular tachycardia
- Recurrent refractory sustained ventricular tachycardia or ventricular fibrillation with a trigger amenable to ablation

The ACC/AHA/ESC 2006 guidelines on the management of patients with ventricular arrhythmias contain the following recommendations for catheter ablation (36):

**Incessant ventricular tachycardia (ventricular tachycardia storm):**

- Intravenous amiodarone or procainamide followed by ventricular tachycardia ablation can be effective in the management of patients with frequently recurring or incessant monomorphic ventricular tachycardia (Class IIa recommendation; Level of evidence B).

**Scar-related ventricular tachycardia associated with prior MI:**

- Adjunctive therapies to the ICD, including catheter ablation or surgical resection, and pharmacologic therapy with agents such as amiodarone or sotalol are reasonable to improve symptoms due to frequent episodes of sustained ventricular tachycardia or ventricular fibrillation in patients with left-ventricular dysfunction due to prior MI (Class IIa recommendation; level of evidence C).
- Curative catheter ablation or amiodarone may be considered in lieu of ICD therapy to improve symptoms in patients with left-ventricular dysfunction due to prior MI and recurrent hemodynamically stable ventricular tachycardia whose ejection fraction is greater than 40%. (Class IIb recommendations; Level of evidence B).
Idiopathic ventricular tachycardia:

- Catheter ablation is useful in patients with structurally normal hearts with symptomatic, drug-refractory ventricular tachycardia arising from the right or left ventricle or in those who are drug intolerant or who do not desire long-term drug therapy (Class I recommendation; Level of evidence C).

Catheter Ablation of Ventricular and Supraventricular Arrhythmias in Pediatric Patients

In 2013, the European Heart Rhythm Association (EHRA) and the Association for European Paediatric and Congenital Cardiology (AEPC) released a joint consensus statement on pharmacological and non-pharmacological therapies for arrhythmia in the pediatric population. These guidelines address the use of catheter ablation for both supraventricular and ventricular arrhythmias in both structurally normal hearts and in the setting of repaired and unrepaired congenital heart disease. In general, given the higher risk of radiofrequency ablations 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 recommend that radiofrequency catheter ablation in infants and young children is considered only when all antiarrhythmic therapies have failed. The consensus statement includes the following recommendations for catheter ablation for pediatric patients with structurally normal hearts:

- Wolf-Parkinson-White (WPW) syndrome (leading to PSVT via an accessory pathway)
  - WPW and an episode of aborted sudden cardiac death (Class I recommendation; level of evidence C).
  - WPW syndrome and syncope combined with preexcited R-R interval during atrial fibrillation less than 250 ms or antegrade accessory pathway effective refractory period during programmed electrical stimulation less than 250 ms (Class I recommendation; level of evidence C).
  - WPW syndrome and recurrent and/or symptomatic SVT and age greater than 5 years (Class I recommendation; level of evidence C).
  - WPW syndrome and recurrent and/or symptomatic SVT and age less than 5 years (Class IIb recommendation).
  - WPW syndrome and palpitations with inducible sustained SVT during electrophysiologic test, age greater than 5 years (Class I recommendation; level of evidence C).
  - Asymptomatic preexcitation, age greater than 5 years, no recognized tachycardia, risks and benefits of procedure and arrhythmia clearly explain (Class IIb recommendation; level of evidence C).
  - Asymptomatic preexcitation, age less than 5 years (Class III recommendation; level of evidence C).

- SVT:
  - Incessant or recurrent SVT associated with ventricular dysfunction (Class I recommendation; level of evidence C).
Single or infrequent SVT (no pre-excitation), age greater than 5 years (Class IIb recommendation)

SVT, age greater than 5 years, chronic antiarrhythmic therapy has been effective in control of the arrhythmia (Class IIa recommendation; level of evidence C).

SVT, age less than 5 years (including infants), when antiarrhythmic medications, including Classes I and III are not effective or associated with intolerable side effects (Class IIa recommendation, level of evidence C)

SVT controlled with conventional AA medications, age greater than 5 years (Class III recommendation, level of evidence C).

Ventricular arrhythmias:

- Recurrent monomorphic ventricular tachycardia with hemodynamic compromise and amenable to catheter ablation (Class I recommendation; level of evidence C).

In 2012, the Pediatric and Congenital Electrophysiology Society (PACES) and the Heart Rhythm Society (HRS) have published an expert consensus statement on the management of the asymptomatic young patient (aged 8-21 years) with a WPW electrocardiogram (ECG) pattern, which have been endorsed by the American College of Cardiology Foundation, the AHA, the AAP, and the Canadian Heart Rhythm Society. (38) Statements relevant to the use of catheter ablation include the following:

- Young patients with a shortest excited R-R interval (SPERRI) greater than or equal to 250ms in pre-excited atrial fibrillation are at increased risk for sudden cardiac death (SCD). It is reasonable to consider catheter ablation in this group, taking into account the procedural risk factors based on the anatomical location of the pathway (Class IIa recommendation; levels of evidence B/C)

- Young patients with a SPERRI greater than 250ms in pre-excited atrial fibrillation are at lower risk for SCD, and it is reasonable to defer ablation (Class IIa recommendation; 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 block or coronary artery injury (Class IIb recommendation; level of evidence C).

- Young patients deemed to be at low risk might subsequently develop cardiovascular symptoms such as syncope or palpitations. These patients should then be considered symptomatic and may be eligible for catheter ablation procedures regardless of the prior assessment.

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

- 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 recommendation; level of evidence C).
U.S. Preventive Services Task Force Recommendations
Not applicable

Summary
Catheter ablation is an established and widely used technique in the treatment of supraventricular arrhythmias. While large-scale RCTs of efficacy are lacking for the use of catheter ablation for the treatment of PSVT, numerous clinical series report very high success rates at well over 90%. Serious complications, mainly consisting of AV block requiring pacemaker insertion, occur in approximately 1% of patients. High success rates are also reported for atrial flutter and focal atrial tachycardia, although the evidence is less robust than for PSVT. High rates of success and low rates of complications are reported for both RFA and cryoablation. Therefore, these procedures offer a very favorable risk-benefit ratio for supraventricular arrhythmias and can be considered medically necessary.

For ventricular arrhythmias, the use of catheter ablation is less well-established. Two small RCTs in patients with an ICD demonstrated a reduction in the number of ICD discharges for ventricular arrhythmias following catheter ablation, and a systematic review of controlled trials reports a 31% reduction in VT recurrence associated with ablation. Clinical series demonstrate that acute success can be achieved in a high percentage of patients, in the range of 80% to 90%. Late recurrences do occur, but the majority of patients treated with ablation remain free of VT at 1- to 2- year follow-up. This evidence establishes that ablation for VT reduces the future occurrence of VT. As a result, it is reasonable to recommend ablation as a treatment for patients with VTs that are not controlled by ICD implantation and medications may be considered medically necessary for these patients.

The evidence is limited on treatment of VT “storm”. A few small case series of patients with VT storm report high acute success and favorable long-term response rates for catheter ablation. Based on this data, the lack of alternative treatments, and the infeasibility of performing clinical trials, catheter ablation may be considered medically necessary for patients with VT storm who fail to respond to pharmacologic treatment.

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

Medicare National Coverage
There is no national coverage determination.

References


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38. Pediatric, Congenital Electrophysiology S, Heart Rhythm S 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
June 2013  Update Policy  
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.

June 2014  Update Policy  
Policy updated with literature review. References 2, 3, 5, 13, 14, 26, and 27 added. Policy statements unchanged.

June 2015  Update Policy  
Policy updated with literature review. References 2-3, 8, 13, 21-24, and 34 added. Policy statements unchanged.

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 19, 2015 and is effective July 15, 2015.

Signature on File

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