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Original Article

A Study of Catheter Ablation versus Medical Management in Post-Myocardial Infarction Scar Ventricular Tachycardia Patients

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Abstract

Introduction: Sudden cardiac death accounts for approximately 50% of all cardiac deaths, representing an estimated annual incidence ranging from 250,000 to 350,000 cases in the United States.

Materials and Methods: The objective of this study is to compare patients amiodarone plus substrate-based ventricular tachycardia (VT) ablation to amiodarone (usual therapy) for all-cause mortality, including cardiac arrest and sustained VT, in patients with recurrent VT post-myocardial infarction who have survived a life-threatening VT/ventricular fibrillation event (that is, AVID/CASH/CIDS criteria) but cannot afford an implantable defibrillator.

Results: The study group was divided into RFA YES (ablated for recurrent VT and on amiodarone) and RFA NO group (only on amiodarone).

Key words: Catheter ablation, Mortality, Tachycardia

INTRODUCTION

Sudden cardiac death (SCD) accounts for approximately 50% of all cardiac deaths, representing an estimated annual incidence ranging from 250,000 to 350,000 cases in the United States. The pathophysiologic mechanism for sudden death in the majority of these patients is thought to be ventricular tachycardia (VT) related to coronary artery disease (CAD), which can then degenerate to ventricular fibrillation (VF). Patients who survive an initial episode of VT/VF are prone to an extremely high incidence of recurrent life-threatening events (~25% at 1 year). Even in patients without a history of VT/VF, the presence of CAD and left ventricular (LV) dysfunction confers a 2-year mortality rate of 22%. If VT is inducible at electrophysiological testing, the 2-year mortality is ~30%.

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MATERIALS AND METHODS

Objective

The objective of this study is to compare patients amiodarone plus substrate-based VT ablation to amiodarone (usual therapy) for all-cause mortality, including cardiac arrest and sustained VT, in patients with recurrent VT post-myocardial infarction (MI) who have survived a life-threatening VT/VF event (that is, AVID/CASH/CIDS criteria) but cannot afford an implantable defibrillator.

Endpoints

Primary endpoint

The primary endpoint of this study is freedom from all-cause mortality, sustained VT and cardiac arrest, at 24 months.

Secondary endpoints

The secondary endpoints in this study are as follows:

1. Proportion of subjects that die within 30 days or die by 24 months
2. Total number of ventricular arrhythmic events compared between the two treatments
3. Differences in LV ejection fraction (EF) between paired measurements recorded at baseline and

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6 months, 12 months for each patient will be used to test for significant differences between the two treatments.

Study Design
This was a prospective observational study.

Setting
Tertiary Cardiac Center.

Study Duration
The study was from December 2011 to December 2013 (24 months).

Number of Patients
Fifty patients with post-MI scar VT were participated in the study.

The study group is post-MI patients who have survived a recent VT/VF episode, thereby mandating implantable cardioverter-defibrillator (ICD) implantation. However, these patients are unable to afford an ICD and thus would receive medical therapy with chronic amiodarone therapy. This study will compare chronic amiodarone therapy alone and catheter ablation + chronic amiodarone therapy.

Follow-up will be conducted in regular intervals over a 24-month period.

Inclusion Criteria
Candidates will be included in the study of all of the following conditions apply.
1. ≥18 and ≤85 years of age
2. History of a remote MI (≥1 month)
3. Survival of a ventricular arrhythmic event (VT/VF) that would mandate placement of an ICD
4. Patient cannot afford an ICD and thus has been planned for treatment with amiodarone.

Exclusion Criteria
Candidates will be excluded from the study if any of the following conditions apply.
1. Patients with NYHA Class IV congestive heart failure
2. Presence of an LV thrombus
3. Contraindication to anticoagulation
4. Inability to access the endocardium due to mechanical mitral and aortic valve
5. Life expectancy <1 year for any medical condition.

Methods
Ablation procedure

- Patient anesthesia will be administered according to standard electrophysiology (EP) laboratory protocol. Arterial and venous access will be achieved through cannulation of the right and/or left femoral arteries and veins as determined by the treating electrophysiologist.
- EP study will be performed using up to triple ventricular extrastimuli from the right ventricular or LV in standard fashion. Before VT is deemed non-inducible, the following stimulation attempts must be performed: (i) Stimulation at ≥2 ventricular sites (e.g., right ventricular [RV] apex + RV outflow tract, or RV apex + LV), (ii) stimulation at ≥2 drive cycle lengths, and (iii) triple extrastimuli. Of course, if VT is inducible early in the stimulation protocol, the remaining protocol does not need to be completed if deemed inappropriate from a safety perspective.
- Twelve-lead electrocardiograms will be obtained for all inducible ventricular arrhythmias. An inducible sustained VT is defined as a monomorphic VT lasting >15 s or requiring termination with pacing or cardioversion.
- To minimize the chance of post-procedural pulmonary edema, the fluid status (I/O, left atrial pressure if a transseptal sheath is employed, etc.) must be carefully monitored. Furthermore, a Foley urinary catheter is strongly recommended for patients with an LVEF <25% or a clinical history of Class III congestive heart failure. Hemodynamic support and type of sedation are at the discretion.

RESULTS

- Over the course of 24 months, 50 patients of post-MI with scar VT enrolled.
- The study group was divided into RFA YES (ablated for recurrent VT and on amiodarone) and RFA NO group (only on amiodarone).
- All patients whose VT was scar related and consequent on a previous MI were included in the study. Patients were not enrolled within 30 days of a MI.
- Patients are followed at 3, 6, 9, 12, 18, and 24 months along with ER room presentation.
- The mean age of the patients was 53 years and 96% were male.
- MI was localized to inferior wall MI in 52% and 48% anterior wall MI.
- Of 50 patients with post-MI scar VT – 16% presented with palpitations, 14% with syncope, 14% shortness of breath, and 6% with congestive heart failure.
- The qualifying index arrhythmia was sustained monomorphic VT in 95%, inducible VT in 5%.
- About 5% of them were in NYHA Class I, 37% in NYHA Class II, and 8% in NYHA Class III at the initial presentation.
- The baseline EF was 39%.

- Patients were being treated with antiarrhythmic drug amiodarone, and most patients received antiplatelet drugs, beta-blockers, and angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers and statins.
- The two groups were well balanced with respect to baseline demographic and clinical characteristics.

Analysis

- Twenty-four underwent percutaneous and 12 surgical revascularizations before VT ablation. Following revascularization, patients were only enrolled following further documentation of spontaneous or inducible VT.
- Before radiofrequency ablation, all patients were investigated to exclude dynamic ischemic contributors to their arrhythmias including coronary angiography in 100%, echocardiogram in 100%, and functional assessments of ischemia in 20%. Twenty-two patients were enrolled under ablation group and during the ablation procedure, only one had pericardial effusion without tamponade, which was managed conservatively; one had an exacerbation of congestive heart failure requiring prolonged hospitalization and cardiac resynchronization therapy pacemaker was placed in this patient. One patient was ablated twice and presented with recurrent VT; ICD was placed for this patient. Three patients in drug group (RFA NO group) were crossover to ablation group (RFA YES group) due to recurrent episodes of VTs.
- All surviving patients completed the 2-year follow-up except the two who were in RFA NO group one lost to follow-up and other preferred ICD.
- The mean duration of follow-up was 22.5 (range, 0–26). During follow-up, all patients received antiarrhythmic drug amiodarone, and most patients received antiplatelet drugs, beta-blockers, and ACE inhibitors or angiotensin receptor blockers.
- In 2 years of follow-up, number of episodes of VT recurrences, EFs in both groups compared with baseline, mortality is compared between groups.
- At 3 months, 6 patients (22%) of those who did not undergo RFA (only on amiodarone, RFA NO group) presented with VT which was higher than those with RFA YES group and is statistically significant.
- During 6 months of follow-up, 7 patients (25.9%) in RFA NO group and 1 (4.5%) patient from RFA YES group had VT episodes ($P = 0.059$).
- During 12 months of follow-up, 5 (18.5%) patients in RFA NO group and 3 patients (13.6%) in RFA YES group had VT episodes ($P = 0.715$).
- During 24 months of follow-up, 5 (20%) patients in RFA NO group and 1 patient (4.5%) in RFA YES group had VT episodes ($P = 0.194$).

Mortality

- There were totally four deaths. One patient died of hepatic encephalopathy, one had SCD, one causes of death unknown, and one with CHF.
- There was one death in RFA YES group. Three deaths in RFA NO group ($P = 0.611$).

Ejection Fraction

- In RFA YES group, comparing baseline EF with EF at 12 months ($P = 0.05$), with EF at 24 months ($P = 0.935$), and EF at 12 months–24 months ($P = 0.004$).
- In RFA NO group, comparing baseline EF with EF at 12 months ($P = 0.229$), EF at 24 months ($P = 0.049$), EF at 12 months–24 months ($P = 0.003$).
- These results show that there is preserved EF in RFA YES group and no such preservation of EF in RFA NO group.
- Our study was initiated to objectively examine the use of substrate ablation in patients with a previous MI who were unable to afford an ICD for the secondary prevention of sudden death and chosen ablation as alternative mode of treatment which is cost effective.
- As compared with the RFA NO group, patients in the ablation group had a significant reduction in the number of VT episodes and preserved EF during the subsequent 2-year follow-up, and ablation procedure is safe.

DISCUSSION

- VT is a common complication of ischemic heart disease, with significant associated morbidity and mortality. The use of antiarrhythmic medications (AADs) to suppress the occurrence/recurrence of VT/VF in high-risk patients has been mostly disappointing. In large clinical trials, most AADs have not only proved to be inefficacious but also to actually increase mortality.[1-7]
- The one potential exception appears to be amiodarone: One study suggests some mortality benefit (GESICA), while others suggest that amiodarone provides significant antiarrhythmic benefits without a change in mortality (EMIAT, CAMIAT, and SCD-HeFT). However, even the use of amiodarone is plagued with multiple organ toxicities, ranging from pulmonary fibrosis to hepatitis, and thyroid dysfunction.[8]
- An important alternative to such questionably efficacious antiarrhythmics is the ICD, which can accurately and effectively detect and terminate VT/VF, resulting in a significant mortality benefit in both the primary and secondary prevention of SCD.[9]
- Yet, despite these beneficial results, ICD implantation cannot be considered a cure for VT. Spontaneous VT episodes are associated with increased mortality

even if arrhythmia is treated with ICD. In addition, it is common for patients to experience painful high-voltage shocks secondary to recurrent ventricular arrhythmias or to lose consciousness before the delivery of therapy. Moreover, the considerable cost of ICDs severely limits their availability in the developing world – where public and/or private health insurance systems are rudimentary at best, and where the incidence of CAD is 4 times higher than that of the developed world – highlighting the urgency of establishing an alternative therapy for post-MI patients with ventricular arrhythmias that are both accessible and effective.

- One such option may be catheter ablation of ventricular arrhythmias.
- Catheter ablation of VT currently has an important role in the treatment of incessant VT and reduction of the number of episodes of recurrent VT.
- Conventional mapping techniques require ongoing tachycardia and hemodynamic stability during the procedure. However, in many patients with scar-related VT, non-inducibility of clinical tachycardia, poor induction reproducibility, hemodynamic instability, and multiple VTs with frequent spontaneous changes of morphology preclude tachycardia mapping.
- To overcome these limitations, new strategies for mapping and ablation in sinus rhythm (SR) – substrate mapping strategies – have been developed and are currently used by many centers. The previous studies of catheter ablation performed using a single catheter approach based on conventional activation mapping and pacing techniques, frequently associated with concomitant administration of antiarrhythmic drugs can offer a reasonable rate of success over the long term in patients presenting with recurrent hemodynamically tolerated VT following an MI. It has been shown that the overall sudden death and cardiac death rates reported are comparable to those achieved in patients treated exclusively by an ICD.
- A study was done by O'Donnell *et al.* radiofrequency ablation for post-infarction VT, report of a single-center experience of 112 cases largest consecutive series to date of radiofrequency ablation in the treatment of post-infarction VT patients were studied the mean follow-up period was 61 months.
- During follow-up, VT recurred in 25 patients: 22 after a failed procedure, two following a modified result, and one following a complete success. Twenty-five patients died: 13 of progressive cardiac failure and four of presumed arrhythmic causes, three after a failed procedure, and one following a modified result. There were no procedure-related deaths. Procedural complications occurred in seven patients.
- The results of our study are comparable to Donell's series in reducing VT recurrences, but our study has less procedural complications and less overall mortality. About 81% of the cases were performed using only conventional catheters and mapping techniques. In 11% the "CARTO" electroanatomical (Biosense Webster, Diamond Bar, CA, U.S.A.) and in 5% the "Ensite 3000" non-contact and our study with substrate modification technique by CARTO and Navix Thermocool catheter this is the limitation to compare the results.
- The catheter approach to substrate modification relies on electroanatomical mapping systems that create a high fidelity representation of the endocardium, allowing for the reconstruction and electronic manipulation of an endocardial cast of the ventricular chamber that carefully delineates the normal and abnormal tissues.
- This is based on the observation that during normal SR, there are distinguishing characteristics of the endocardial electrogram (EGM) of normal and abnormal tissue: Abnormal tissue manifests a lower voltage amplitude, prolonged EGM duration, and the presence of late and fractionated potentials.
- Marchlinski *et al.* reported in a seminal study that using a substrate-mapping strategy, catheter-based RF ablation lesions directed in a linear fashion were effective in controlling scar-related drug-refractory unstable VT. Marchlinski was acutely successful in eradicating or modifying VT in seven of nine patients with a recurrence in <20%.
- Furthermore, using this high-density electroanatomical mapping, (1) this strategy can be utilized to localize the arrhythmogenic substrate in the majority of patients with a history of MI and sustained ventricular tachyarrhythmias and (2) RF ablation using an irrigated tip ablation catheter can be effectively and safely used to modify the arrhythmogenic substrate to render VT non-inducible even in the presence of multiple VT morphologies.
- Further study of Irrigated Radiofrequency Catheter Ablation Guided by Electroanatomic Mapping for Recurrent VT after MI, the multicenter Thermocool VT Ablation Trial by Stevenson *et al.* showed that catheter ablation is a reasonable option to reduce episodes of recurrent VT in patients with prior MI, even when multiple and/or unmappable VTs are present.
- Catheter ablation of stable VT before defibrillator implantation in patients with coronary heart disease (VTACH): A multicenter randomized controlled trial by Prof Karl Heinz Kuck (VTACH) study was a prospective, open, and randomized controlled trial, undertaken in 16 centers in four European countries. Patients aged 18—80 years. One hundred and ten patients were randomly allocated in a 1:1 ratio to receive catheter ablation and an ICD (ablation group, n = 54) or ICD alone (control group, n = 56 was

followed up for at least 1 year. The primary endpoint was the time to the first recurrence of VT or VF.

- Mean follow-up was 22.5 months. Time to recurrence of VT or VF was longer in the ablation group (median 18.6 months [lower quartile 2.4 and upper quartile not determinable]) than in the control group (5.9 months [IQR 0.8–26.7]). At 2 years, estimates for survival free from VT or VF were 47% in the ablation group and 29% in the control group.
- Complications related to the ablation procedure occurred in two patients; no deaths occurred within 30 days after ablation. Fifteen device-related complications requiring surgical intervention occurred in 13 patients (ablation group, four; control group, nine). Nine patients died during the study (ablation group, five; control group, four).
- VTACH interpreted that prophylactic VT ablation before defibrillator implantation seemed to prolong time to recurrence of VT in patients with stable VT, previous MI, and reduced LVEF.
- The favorable results of Stevenson *et al.* studies prompted the initiation of substrate mapping and ablation in SR to halt VT trial (SMASH-VT), a prospective randomized clinical trial to objectively assess the clinical utility of substrate ablation of scar-related VT.
- This trial was a randomized-controlled trial examining the role of substrate mapping and RF ablation in the primary prevention of ICD shocks in patients presenting with clinically life-threatening VT/VF. That is, patients with a history of MI, who survive an episode of VT/VF are at high-risk for recurrent VT and thus treated with ICDs (in essence, these patients meet AVID/CIDS/CASH criteria). In normal clinical practice, these patients are not routinely treated with adjuvant medications due to their proarrhythmic potential and side effects. In addition to an ICD and routine clinical care, these patients were additionally randomized in SMASH-VT to substrate-based catheter ablation. This catheter ablation group underwent electroanatomic mapping to delineate the endocardial infarct margins (CARTO, Biosense Webster, Inc.). Substrate modification was then performed targeting the exit sites of induced VTs and/or late potentials within the scar using standard or irrigated radiofrequency ablation catheters.
- As published in late 2007 (Reddy *et al.,* NEJM, 357:2657), the 30-day post-ablation mortality was zero, and there was no significant change in ventricular function or functional class during follow-up. During an average follow-up of 22.5 ± 5.5 months, appropriate defibrillator therapy (anti-tachycardia pacing and shocks) occurred in 21 control (33%) and 8 ablation (12%) patients (P = 0.007 by the log-rank test). Of these, appropriate defibrillator shocks alone occurred in 20 control (31%) and 6 ablation (9%) patients (P = 0.003). Mortality was not increased in the ablation arm (control 17%, ablation 9%; P = 0.29); indeed, there was a trend to decreased mortality in the ablation arm.
- Thus, the SMASH-VT study revealed that adjuvant substrate-based catheter ablation is feasible and use of a saline-irrigated RF ablation catheter for this ablation strategy is safe, and this strategy decreases subsequent ICD therapies in post-MI patients receiving defibrillators for the secondary prevention of sudden death.
- The favorable results of SMASH-VT and VTACH, Stevenson *et al.* combined with considerable technical and scientific improvements in catheter ablation of scar-related VT, also raise the possibility that the therapeutic benefit of ablation, in post-MI patients who have survived a ventricular arrhythmic event but are unable to afford an ICD.
- Our study intended to evaluate the efficacy of catheter ablation in post-MI patients who have survived a ventricular arrhythmic event and would be initiated on chronic amiodarone therapy due to an inability to afford ICD therapy.
- In our study, the 30-day post-ablation mortality was zero, and there was a significant preservation in ventricular function during follow-up in ablated patients.
- During an average follow-up of 22.5 ± 5.5 months, at 3 months, 6 patients (22%) of those who did not undergo RFA (only on amiodarone RFA NO group) presented with VT which was higher than those with RFA YES group and is statistically significant.
- During 6 months of follow-up, 7 patients (25.9%) in RFA NO group and 1 (4.5%) patient from RFA YES group had VT episodes (P = 0.059). During 12 months of follow-up, 5 (18.5%) patients in RFA NO group and 3 patients (13.6%) in RFA YES group had VT episodes (P = 0.715). During 24 months of follow-up, 5 (20%) patients in RFA NO group and 1 patient (4.5%) in RFA YES group had VT episodes (P = 0.194).
- Mortality was not increased in the ablation group; indeed, there was a trend to decreased mortality in the ablation group (P = 0.611).
- Our results are comparable with SMASH-VT and VTACH, and Stevensons *et al.* in reducing the VT recurrences and mortality.

CONCLUSIONS

- At present, radiofrequency ablation for ischemic VT is considered by many only as an adjunct to an ICD in patients with intractable or highly symptomatic VT.
- Our study has shown radiofrequency catheter ablation of patients with highly symptomatic, sustained, monomorphic post-infarction VT which can be

performed with high success rate and low procedural complication rate. The procedure can be successfully applied to a wide spectrum of patients including multiple morphologies of VT and hemodynamically unstable VT.

- With the results demonstrated in this study, procedural success of ablation could obviate the need for ICD implantation.
- These findings may expand the role of radiofrequency ablation, making it the therapy of first choice in a growing proportion of patients who cannot afford ICD, with ICDs reserved as the treatment for failed ablation procedures or for prophylactic indications.
- A definite statement of whether catheter ablation and antiarrhythmic drug (amiodarone) treatment can be used as an alternative to ICD in this subgroup of patients and, however, cannot be made until firmly proven by a dedicated study.

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