

Ventricular Tachycardia Ablation as First Line Therapy: Are We There Yet?

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Editorial Comment

Coronary disease is the most common cause of sudden cardiac arrest in Western countries^{1,2} and scar-related reentry is the most important mechanism leading to sustained ventricular tachycardia (VT).³

Several randomized trials have shown the efficacy of implantable cardioverter-defibrillators (ICD) in reducing mortality both in primary and secondary prevention in patients with coronary artery disease and high risk of sudden cardiac death.⁴

Approximately 20% of patients in primary prevention and 45% of patients in secondary prevention receive an appropriate ICD intervention within the 2 years following ICD implantation.⁵⁻⁷

In addition, VT storm, defined as 3 or more appropriate ICD therapies within a 24-hour period, may affect 4% and 20% of the patients in the primary and secondary prevention, respectively.^{8,9}

However, ICD shocks decrease quality of life, increase patient's anxiety and increase the risk of nonarrhythmic mortality.^{5,10-12}

The therapeutic options to reduce ICD shocks and increase survival rates are represented by antiarrhythmic drugs (AADs) and VT catheter ablation.

AADs have shown unsatisfactory results on survival and little effects on ICD shocks reduction.^{2,13-15}

Radiofrequency catheter ablation for the treatment of drug-refractory recurrent VT in patients with ischemic cardiomyopathy has shown satisfactory results^{8,16-26} especially in the setting of VT storm.^{3,26,27}

Over the years, advances in technologies and techniques for VT ablation, such as the use of open irrigated catheters,²⁶

3D mapping systems,³ and the use of percutaneous epicardial ablation^{28,29} have expanded the referrals to VT ablation and improved procedural outcomes. The majority of data on VT ablation in the setting of coronary artery disease are restricted to patients experiencing VT refractory to AADs (secondary VT ablation).^{3,15,19,24,26,30}

As of today, only 3 studies have evaluated the role of catheter ablation as first line therapy.^{17,18,20} The VTACH study¹⁷ is the only available study that enrolled patients who were implanted with a primary prevention indication and had a subsequent appropriate ICD therapy for sustained hemodynamically stable VT. Each of these studies is exposed to different criticisms.

Schreieck *et al.*²⁰ in a small (39 pts) pilot study randomized patients undergoing secondary prevention ICD implantation for postinfarct sustained VT to early VT ablation with ICD implantation (19 pts) versus ICD alone. After a relatively short follow-up, no statistically significant difference in regards to VT recurrence was shown (47% recurrence in the ablation arm and 60% in the ICD arm). The study (published in an abstract format only) does not allow us to draw any conclusion because important information were lacking or not provided. The full manuscript once published might clarify several lacking points.

The Substrate Mapping and Ablation in Sinus Rhythm to Halt Ventricular Tachycardia trial (SMASH-VT) was a multicenter prospective, unblinded, randomized trial that sought to determine whether early catheter ablation of VT could reduce the recurrence of sustained VT in patients undergoing ICD implantation for secondary prevention.¹⁸ The authors claimed to perform "prophylactic VT catheter ablation," although enrolled patients had already experienced an episode of life-threatening sustained VT. The study initially enrolled patients undergoing secondary prevention ICD implantation without distinction of the VAs responsible for the implantation (which could include ventricular fibrillation, unstable VT and syncope with inducible VT at EP study). Subsequently, patients undergoing ICD implantation for primary prevention and/or with an appropriate ICD intervention were enrolled. It is fair to say that the outcome of patients with VF is different from the one with spontaneous VT. Of note, patients were excluded if they were being treated with antiarrhythmic drugs (class I or class III), and if they were experiencing VT storm. Patients were randomized in a 1:1 fashion to catheter ablation or medical therapy without AADs. The primary study endpoint was freedom from appropriate ICD therapy whereas overall mortality and VT storm represented

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the secondary endpoints. A very important limitation in the study is the lack of data on ICD programming that could influence the outcome among the groups.

A total of 64 patients per group were enrolled without any significant baseline clinical characteristics but left ventricular ejection fraction $\leq 20\%$ that was more common in the ablation group (25% vs 11%, $P = 0.06$). After 2-year follow-up a significant reduction of ICD shock was shown in the ablation group (9% vs 31%, $HR = 0.27$, 95% CI 0.11 to 0.67, $P = 0.003$). The number of patients that needed to be treated with ablation (NNT) to avoid 1 appropriate ICD intervention was 5, resulting in a total of 200 appropriate ICD interventions prevented every 1,000 patients treated with catheter ablation.

The absence of a control group with AADs such as amiodarone limits the relevance of the study and the benefit of the ablation treatment. Although a reduction in mortality was reported in the ablation group, the study was not powered to address this issue. The Cox proportional hazard model showed that the number of VTs induced at the EP study was the only variable associated with appropriate ICD intervention at follow-up, whereas inducibility after ablation did not influence the long-term clinical success.³¹

The VTACH trial (Multicenter Catheter Ablation of Stable Ventricular Tachycardia Before Defibrillator Implantation in Patients With Coronary Artery Disease) was a prospective, unblinded, randomized controlled trial (utilizing an intention to treat analysis) testing the hypothesis that early intervention with catheter ablation in patients with previous myocardial infarction, reduced left ventricular ejection fraction (i.e., $\leq 50\%$), and documented first episode of hemodynamically tolerated sustained VT undergoing secondary prevention ICD implantation would reduce the rate of recurrent VT or ventricular fibrillation compared with standard medical therapy plus ICD implantation.¹⁷

In this study differently from SMASH VT,¹⁸ AADs use was allowed, although only 35% of patients in both groups were treated with amiodarone at baseline and no data were reported on the use of antiarrhythmic drugs at follow-up. Patients with VT storm were excluded also from this trial. The primary endpoint was the time from ICD implantation to recurrence of any sustained VT or ventricular fibrillation; the rates of total mortality, syncope, hospitalization for cardiovascular causes, VT storm, and number of appropriate ICD intervention at follow-up were among the secondary endpoints analyzed.

Importantly, in this trial detailed information on ICD programming modes were reported.

After a mean follow-up of 22.5 ± 9 months, the 52 patients allocated to ablation had significantly longer time to arrhythmia recurrence compared with the 57 assigned to the ICD only arm (median 18.6 months vs 5.9 months), and lower 2-year arrhythmia recurrence rates (53% vs 71%, $HR = 0.61$, 95% CI 0.37 to 0.99, $P = 0.045$). In this study, the NNT to prevent 1 episode of recurrent ventricular arrhythmia was 6, which accounted for a total of 180 malignant ventricular arrhythmias prevented every 1,000 patients treated. The use of AADs at follow up was underreported, thus affecting the quality of the results.

Interestingly, the overall mortality was not different between groups (8.5% vs 8.6%, $P = 0.68$) and especially in the ICD-only group mortality was extremely low when compared with AVID (Antiarrhythmics vs Implantable Defibrillators trial), where it was 18.4%.⁷

This study as well as the others was not powered to address differences in mortality. Due to ethical issues and to the fact that ventricular arrhythmia recurrence at 2 years was present in more than half of the patients undergoing ablation in the VTACH study, the use of ablation as a stand-alone procedure cannot be recommended and ICD should be implanted in these patients.

In this issue of the *Journal*, Delacretaz et al.³² analyzed the data of the VTACH STUDY not utilizing the intention to treat analysis but the actual on-treatment analysis. The difference in time to the first occurrence of VT or VF between treatments groups was more pronounced reaching a mean of 19.5 months in the ablation group. In addition, the relative risk for VT or VF was reduced by 49% (39% in the intention-to-treat analysis). Moreover, when utilizing the on-treatment analysis, VT ablation further reduced the number of appropriate interventions per patient and year. Freedom from VT and VF after 24 months follow-up increased from 29.2% to 48.3% with VT ablation in this study.

Although the authors should be congratulated for the additive information given to the readers by this analysis, it is still important to say that the recurrence rate in the ablation group was still high and not completely satisfactory to propose VT ablation as first line therapy.

Can the ablation technique modify the above-mentioned considerations?

In the VTACH study,¹⁷ although ablation was guided by a combination of substrate mapping, activation mapping, entrainment mapping, and pace mapping, the ablation target was only the clinical monomorphic VT and no effort was taken against other VTs. The SMASH VT study accounts for the same limitation.¹⁸ Both studies do not provide information on the type of VT recurrence experienced by the patients.

These studies report on a limited substrate ablation and especially in light of recent studies showing that a more extensive substrate ablation (LAVA,³³ HOMOGENEIZATION,³⁴ LATE POTENTIALS³⁵) and more often than what previously believed epicardial VT ablation are associated with a very favorable outcome approaching around 85% freedom from any VT at 2 years follow-up and with a more limited use of AADs.³³⁻³⁵

Epicardial ablation was not utilized in any of the 3 previously described trials.^{17,18,20}

In the SMASH-VT trial,¹⁸ no correlation was found between persistence of VT inducibility after ablation and long-term outcome, but the predictive value of the number of induced VTs at the EP study in our opinion supports the rationale for an extensive substrate-based ablation approach targeting all the "abnormal potentials" within the scar. In the VTACH study,¹⁷ all enrolled patients had history of hemodynamically stable VT, and those with hemodynamically unstable VTs were excluded. Accordingly, a monomorphic stable VT was induced in 88% of the patients matching the clinical VT in 83% of cases. With this limited ablation approach, more than a half of the patients randomized to catheter ablation had ventricular arrhythmia recurrence after 2 years of follow-up.

The limited long-term success rate with limited ablation further supports the concept that extensive endo-epicardial substrate based approaches targeting all the potential VT circuits within the scar are important to increase the procedural success in contemporary patients with infarct-related VT.

Once the results of more extensive ablation are confirmed in a multicenter randomized trial, a new study on VT ablation as first line therapy with the newer ablative technique will become necessary potentially questioning the role of ICD implantation.

In the MADIT-II trial,⁶ the rate of appropriate ICD intervention for sustained ventricular arrhythmias at follow-up was about 23%. Primary VT ablation studies have demonstrated that such risk can be reduced by 32%. The systematic adoption of recently described substrate-based ablation strategies, such as endo-epicardial scar homogenization, would further reduce the risk of VT recurrence by an additional 60%. Overall, this would result in an expected drop of appropriate ICD interventions in patients similar to those enrolled in the MADIT-II to 6%. These results are remarkable, and might even question whether ICD implant is a cost-effective strategy in these patients after catheter ablation.

Conclusions

In conclusion, we believe there is evidence to support the early use of catheter ablation of VT (i.e., primary VT ablation) to decrease arrhythmia recurrence and ICD intervention in patients with coronary artery disease and malignant VAs, especially if novel and extended ablation techniques are utilized. Unfortunately, although the NNT is low, “we are not there yet” and ICD implantation cannot be deferred in these patients but potentially questioned. Available data do not allow conclusion on the impact of primary VT ablation on mortality and further studies are warranted.

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