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Commentary

# Do We Need ICDs for Prevention of SCD in Patients with Monomorphic Ventricular Tachycardia? – Only Time Will Tell!

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## Catheter Ablation as First-line Therapy of Ventricular Tachycardia

While the concept of catheter ablation (CA) as first-line therapy of ventricular tachycardia (VT) is not new, its widespread adoption has been hindered by the lack of supporting data. The ever-present risk of sudden cardiac death (SCD) associated with VT and proven efficacy of implantable cardioverter defibrillators (ICD) have made it difficult to justify withholding an ICD implantation even after effective CA [1–3] in patients with structural heart disease. We aimed to explore the current evidence in favor of this approach and its clinical applicability in different patient populations, with a focus on identifying key limitations and future directions.

## Key Considerations—Conceptual Differences between ICD and CA

On one hand, ICDs are made to terminate life-threatening ventricular arrhythmias but not to prevent their occurrence. Explicitly, the underlying heart disease and death from progressive heart failure are not affected by ICDs. In addition, recent progress in optimal medical therapy for heart failure have reduced death rates in general patient cohorts, diminishing the absolute survival benefit associated with ICD implantations in structural heart disease patients over time. Today, ICDs are indicated mostly for ischemic cardiomyopathy (ICM) patients with reduced left ventricular (LV) function and subgroups of non-ischemic cardiomyopathy patients in primary prevention. In secondary prevention, ICDs are the generally accepted first-line treatment in patients who survived sudden arrhythmic cardiac death or sustained ventricular arrhythmia.

On the other hand, CA of VT presents a more complex landscape. The underlying cardiomyopathy is one of the key factors determining the outcome of CA [4]. The characteristics of the arrhythmic substrate and its development over time are likely to affect the mid- and long-term outcomes of ablation-based approaches. Hence, these therapies exhibit a temporal mismatch: catheter ablation addresses the existing arrhythmogenic substrate, whereas ICDs protect against its future and even unpredictable evolution. Then again, VT is treated using different methods for targeting the ablation areas and several endpoints have been used in assessing efficacy of CA.

## Clinical Guidelines and Existing Evidence

In patients with LVEF ≥ 40% and hemodynamically tolerated sustained monomorphic VT, current guidelines present ICDs and CA as equivalent alternatives, with the same class of recommendation and level of evidence [5,6].

Indeed, these guidelines acknowledge substantial gaps in the available evidence. The decades-old AVID trial, in which ICDs were shown to improve survival in patients with a LVEF <40%, resuscitated ventricular fibrillation or sustained VT with syncope, laid foundation for the current indications for ICD in patients with structural heart disease and VT [3]. However, patients with well-tolerated VT were excluded from secondary prevention trials.

In addition to little or no advancement in evidence behind current indications for secondary prevention ICDs for decades, there is evidence that patients with hemodynamically tolerated VT and an LVEF >35% fail to derive mortality benefit from an ICD [7]. On the other hand, the current guidelines indicate that ICD should be generally considered for secondary prevention in patients with structural heart disease and sustained VT.

Hemodynamic tolerance during episodes of VT therefore becomes a matter of interpretation and debate too. Data indicates that hemodynamic effects of VTs does not depend purely on VT rate and patient LV function but may be affected by multiple factors that relate to neuro-hormonal response and intra-arterial pressures during VT [8]. Therefore, the same VT may be tolerated over longer periods of time in one situation while it may lead to collapse in a different situation. Hemodynamic tolerance remains an elusive criterion and therefore appears insufficient to inform risk stratification or guide ICD deferral.

Further research on ICDs pointed out some limitations. ICDs can terminate VT and prevent SCD, but recurrences with therapy delivery reduce quality of life [9,10] and shocks are associated with increased mortality rates [11]. This holds true particularly for appropriate shocks for ventricular fibrillation (VF) and fast VT. Evidence indicates that more important determinant of mortality is the arrhythmic substrate rather than the ICD therapy itself [12]. The implementation of ICD does not entirely prevent the occurrence of SCD. A meta-analysis of included secondary prevention trials revealed an SCD rate of 10% after 5 years [7]. Also, there is a potential complication risk associated with implantation of ICDs—even though on a low level. A meta-analysis of RCTs demonstrated a pooled complication rate of 9.1% [13]. Even the subcutaneous ICDs do not necessarily lower this burden—recent registries report early complications in the range of 10–15% [14,15].

In contrast to the ICDs for secondary prevention, there is growing evidence in favor of CA as a potent approach for structural monomorphic VTs.

Several studies have shown that successful ablation is associated with better outcomes in patients with VT [16,17]. The VTACH study demonstrated that catheter ablation may improve the survival rate of patients with LVEF > 30% who are free from VT. However, no significant difference was observed between the two groups of patients with LVEF ≤ 30% [18]. These findings are in line with the study of Tung *et al.*, a multicenter registry analyzing more than 2000 ablated patients, CA success was independently associated with lower mortality in patients after ablation of a scar-related VT [19]. In patients with LVEF ≤ 30%, higher rates of VT recurrences and mortality were indicated. According to Della Bella *et al.*, ischemic patients with tolerated VT who had a mean LVEF of 34%—majority of whom were not implanted with devices until after ablation failure (11%)—exhibited a low rate of SCD of 2.5% over a period of 3.3 years [20].

A meta-analysis encompassing 7 publications and 920 patients studied a heterogeneous VT population with structural heart disease (defined as ischemic and non-ischemic cardiomyopathy arrhythmogenic right ventricular cardiomyopathy, congenital heart disease, and hypertrophic cardiomyopathy) and preserved LVEF [21]. Only studies that evaluated SCD as one of their objectives were included in the analysis. The participants had no prior ICD implantation. Despite a VT recurrence rate of 23.2%, the incidence of SCD after CA as the first-line treatment (primary outcome) was fairly low (3.1%). The meta-analysis showed a prevalence of all-cause mortality of 5.0% in this population. Overall pooled ablation success rate was 84.6% with only 13.9% of patients requiring ICD implantation after ablation. Complications linked to CA occurred in 6.4% of patients.

The VANISH2-trial delivers insights into the efficacy of CA compared to antiarrhythmic drugs (sotalol or amiodarone) in patients with ICM [22]. 416 patients with prior myocardial infarction (MI) and monomorphic VT events have been randomized in a 1:1 fashion to receive CA or arrhythmic drugs and followed for a median of 4.3 years. However, the trial included also patients with reduced LVEF, and an ICD has been implanted prior to discharge in all patients (if not already present). Initial strategy of catheter ablation led to a lower risk of primary composite endpoint but was mainly driven by significantly lower recurrence of slow VTs (under the ICD detection rate). Whereas antiarrhythmic medication may slow VTs, CA appears to significantly reduce the re-occurrence of all VTs.

Li *et al*. studied efficacy of CA in patients with sustained VT and ICM without an ICD backup [23]. The cohort comprised of 114 patients with mean LVEF of 34% who declined ICD implantation after CA for VT for various reasons. 31.6% of these patients had a history of syncope, attributable to incidents hemodynamically poorly tolerated VT and 65% had a LVEF <40%, hinting at a higher-risk group for SCD with indications for ICD implantation. Most patients (85.1%) were not inducible for any VTs after the procedure, indicating complete ablation success, whereas 4 patients (3.5%) remained inducible for clinical VT, consistent with ablation failure. With a median follow-up of 4.5 years, VT recurred in 39.5% of the patients, and 6 patients (5.3%) died, including 2 SCDs (1.8%). Of the 12 patients (10.5%) who underwent additional epicardial ablation, only 1 experienced VT recurrence during follow-up.

The same group concluded the follow-up outcomes of CA for sustained VT in myocarditis patients to be similar to that in ICM [24]—hypothesizing that CA might even be effective in a cohort with a different underlying arrhythmic substrate.

**Table 1.** Notable observational studies on efficacy of CA of VT including their key findings.

| Study | Sample Size (patients) | Study Design | Intervention | Outcomes | Median Follow-up (months) | Key Findings |
|---|---|---|---|---|---|---|
| Della Bella P, *et al.* (2002) | 124 | Prospective | CA in ICM, ICD following procedure failure | VT recurrence, all-cause mortality, need for repeat ablation | 41.5 | Very low sudden death and cardiac mortality rates over the long-term |
| Yao Y, *et al.* (2007) | 32 | Prospective, single-center | CA in ARVC | Acute success rate, VT recurrence | 28.6 | CA of VT in ARVC showed high success rates and reduced VT recurrence |
| Kuck KH, *et al.* (2010) | 107 | Randomized controlled trial | CA + ICD or ICD alone in ICM, LVEF < 50% | Time to first VT recurrence | 22.5 | Preemptive CA before ICD implantation significantly reduced the need for ICD interventions in ICM |
| Maury P, *et al.* (2014) | 166 | Prospective observational cohort, multicenter | CA in structural heart disease (ICM, NICM, ARVC) without ICD, LVEF > 30% | All-cause mortality | 32 | Very low rate of arrhythmic death, recurrences generally non-fatal, no significant mortality benefit |
| Clemens M, *et al.* (2015) | 31 | Prospective observational cohort | CA as first-line therapy in ICM, ICD following procedure failure, LVEF >40% | Acute success rate, all-cause mortality, VT recurrence | 45.6 | Survival with or without the ICD not significantly different, no SCD in patients without ICD |
| Al-Khatib SM, *et al.* (2015) | 27 | Pilot randomized trial | CA in ICM, previously implanted ICD | VT recurrence, time to first VT recurrence, all-cause mortality | 6 | High VT recurrence rates and death after failed antiarrhythmic medication |
| Tung R, *et al.* (2015) | 2061 | Retrospective multicenter cohort | CA in structural heart disease (ICM, NICM, ARVC, HCM), LVEF <50% | VT recurrence, survival without heart transplant or all-cause death | 12 | Freedom from VT recurrence post-ablation associated with improved long-term survival |
| Wei W, *et al.* (2017) | 48 | Retrospective observational cohort, single-center | CA in ARVC | Acute success rate, all-cause mortality, long-term VT recurrence | 71.4 | Combined epicardial and endocardial approach achieved better acute success and better long-term outcomes than endocardial approach alone, rate of SCD in patients without acute success was higher |
| Santangeli P, *et al.* (2019) | 32 | Retrospective observational registry, multicenter | CA without ICD in ARVC | VT recurrence, all-cause mortality | 46 | High efficacy of CA in achieving long-term VT freedom in the absence of ICD, no deaths observed |
| Gandjbakhch E, *et al.* (2021) | 65 | Retrospective observational cohort, multicenter | CA without ICD in ARVC, LVEF > 50% | VT recurrence, all-cause mortality, survival without ICD | 52.4 | No SCD despite VT recurrences in some patients |
| Cardelli LS, *et al.* (2022) | 62 | Retrospective observational cohort | CA in structural heart disease (ICM, NICM, ARVC, ...) without subsequent ICD, LVEF>30% | Composite of all-cause death and VT recurrence | 38.8 | Low mortality rate, no SCD |

ARVC: Arrhythmogenic Right Ventricular Cardiomyopathy; NICM: Non-Ischemic Cardiomyopathy; HCM: Hypertrophic Cardiomyopathy

In cases, where the substrate cannot be effectively ablated from the endocardial surface due to its three-dimensional nature, an epicardial ablation approach may lead to successful suppression of VT. Mohanty *et al*. recently observed in a study of 361 patients with ICM VT that those receiving combined endo-epicardial ablation had significantly lower 5-year VT recurrence rates (45.6%) than those with solely endocardial ablation (89.1%) [25]. After adjustment, epicardial ablation significantly reduced VT recurrence risk (HR 0.48).

Promising results have been presented by Rademaker and colleagues [26]. The single center cohort included 51 patients who presented with hemodynamically tolerated VT with an LVEF > 35% undergoing CA as first-line therapy (without prior ICD). Of these, 37 (73%) were rendered non-inducible. Only 5 of these patients had an ICD implanted. Of the 14 patients who still had an inducible VT after the ablation, 11 had an ICD implant. During a median follow-up of 3.3 years, the overall mortality was 27%, including 1 sudden death in a patient with an ICD. Among the 37 non-inducible patients, no SCD or VT recurrence occurred. Six (16%) of these 37 patients were using either amiodarone or sotalol for the treatment of atrial arrhythmias. In patients with inducibility after ablation and VT recurrence rate of 29%, no SCD occurred. A total of 8 patients died during follow-up (4 events were due to heart failure and 4 to noncardiac causes), none of those would have benefited from an ICD.

### Several aspects of this study must be noted

Firstly, aggressive programmed electrical stimulation (PES) with 3 to 4 different basic paced cycle lengths as short as 350 ms, up to 4 extra stimuli down to 200 ms or ventricular refractoriness from 2 right ventricular and ≥ 1 left ventricular site has been used to assess inducibility. In a mixed cohort of patients with ischemic and nonischemic cardiomyopathy, patients with inducible rapid VTs with a cycle length close to refractory period after ablation—rarely had recurrence of VT [27]. Further data support the good negative predictive value of a negative PES in post-MI patients with mildly reduced LVEF and the association of inducible fast VT with spontaneous VT [28,29]. The ideal timing of PES to predict VT recurrences remains unclear, data points to non-invasive PES in ICD groups weeks after CA being more predictive of the long-term outcome.

Secondly, for most of the study duration, a systematic pacing protocol with evoked delayed potential mapping was used to identify substrates. The role of evoked delayed potential mapping for substrate identification is not yet entirely clear and is the subject of ongoing randomized trials.

Lastly, all patients who were discharged without an ICD had undergone a coronary angiogram and, when deemed necessary, coronary angioplasty before discharge. Significant residual coronary artery disease could explain severe VT symptoms and SCD. As no exclusive approach can be implemented with definitive effectiveness, a combination of therapies is necessary in order to obtain successful control of ventricular arrhythmias [30]. Current strategies of early and complete revascularization and recent advances in heart failure treatment are likely to decrease the risk of SCD in contemporary post-MI cohorts [31,32].

Substrate imaging—particularly late gadolinium enhancement cardiovascular magnetic resonance—guides procedural planning for CA and may predict post-ablation substrate evolution, with positive LV remodeling and abolition of conducting channels indicating long-term freedom from VT recurrence [33].

## Summarizing the Current Data

### Patients who may not benefit from ICDs after an effective VT ablation

CA can effectively eliminate VT in a large proportion of patients with structural heart disease. The incidence of SCD and mortality of patients with ICM, preserved LVEF and no inducible VT after CA has been shown to remain low despite later VT recurrence. It may be reasonable to offer these patients CA as first-line therapy and defer ICD implantation as a part of individualized approach with shared decision-making.

### Patients in whom this is unclear

The relationship between a successful CA of VT and SCD risk in patients with reduced LVEF seems to be less clear. CA (even if deemed successful immediately after the procedure) was not associated with higher VT free survival in post-MI patients with reduced LVEF. Moreover, other competing risk factors should be considered.

### Patients in whom data is clearly missing and therefore we definitely need ICDs after VT ablation

Patients with VT of non-ischemic etiology present rather heterogenous group with complex arrhythmic substrates. Apart from specific cohorts, like patients with repaired tetralogy of Fallot, evidence supporting CA as an alternative to ICD in this group is lacking. The evolving nature of the substrate makes recurrences likely.

### Is timing of VT ablation relevant?

It seems reasonable to consider early CA for patients with VT and structural heart disease to reduce recurrences. This benefit was even greater in ICM patients with LVEF > 30%. However, the mortality benefit of performing CA early has not been proven yet [34]. As can be concluded from VANISH-2, CA may be favored over antiarrhythmic medication in ICM patients with monomorphic VTs and implanted ICDs [22].

Recent studies have even shown that CA performed prophylactically before a first episode of VT may reduce arrhythmia occurrence by modifying the underlying substrate in certain high-risk patient cohorts (e.g. like ICM patients with chronic total occlusion [35]; patients eligible for heart transplantation due to end-stage heart failure [36]).

### Which endpoints should be reached?

Non-inducibility of the clinical VT, which has been associated with lower VT recurrence-rates, is considered the minimum endpoint of a VT ablation procedure. It is often difficult to define a clinical VT when there is no 12-lead ECG available. Moreover, up to 24% of the patients are not inducible for any VT before CA is performed. Also, inducibility may differ during a procedure and different induction protocols may show variable results. Substrate modification showed increased value over ablation of slow VTs in terms of VT-recurrence-free survival [37]. However, different strategies produce endpoints which have to be studied separately.

### Which studies do we need?

ICDs remain the only therapy with robust randomized evidence demonstrating reduction in SCD. As randomized data supporting CA as first-line therapy of VT without an implanted ICD is still lacking, this should prompt further data collection and efforts to standardize patient selection and ablation strategies. Randomized clinical trials powered to assess mortality are essential in order confirm the beneficial effects of an early CA. The optimal strategy of substrate mapping, modification and its effect on mortality rates is yet to be determined.

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