

Preventive versus deferred catheter ablation of myocardial infarct-associated ventricular tachycardia: A meta-analysis



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BACKGROUND The optimal timing of catheter ablation for the treatment of ventricular tachycardia (VT) in patients with ischemic cardiomyopathy remains unclear. Studies examining the impact of early preventive ablation of VT on rates of implantable cardioverter-defibrillator (ICD) therapies and mortality have been limited by small sample size.

OBJECTIVES To conduct a meta-analysis of randomized controlled trials (RCTs) comparing initial catheter ablation and ICD implantation (preventive ablation arm) vs ICD implantation alone (deferred ablation arm) in patients with ischemic cardiomyopathy and VT.

METHODS The primary endpoint was the incidence of appropriate ICD therapy during follow-up. Secondary endpoints included appropriate ICD shock, VT storm, procedural complications, and mortality. Sensitivity analysis, meta-regression, and evaluation of bias were performed.

RESULTS Four RCTs (n = 505) fulfilled inclusion criteria. During follow-up (mean >22 months for all RCTs), preventive ablation was associated with a significant reduction in ICD therapies (odds ratio [95% confidence interval]: 0.53 [0.36–0.78]). The occurrence

of ICD shocks and VT storm were also significantly reduced in the preventive ablation group. Among patients with left ventricular ejection fraction (LVEF) >30%, preventive ablation was associated with marked reduction in ICD therapy when compared to deferred ablation (odds ratio [95% confidence interval]: 0.37 [0.19–0.72]). Overall, there was no difference in mortality between treatment groups.

CONCLUSIONS Preventive catheter ablation in patients with ischemic cardiomyopathy decreases ICD therapies, ICD shocks, and VT storm without increasing complications, particularly in patients with LVEF >30%. However, early preventive ablation is not associated with any benefit in mortality.

KEYWORDS Catheter ablation; Implantable cardioverter-defibrillator; Mortality; Myocardial infarction; Preventive ablation; Ventricular tachycardia

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Introduction

Ventricular tachycardia (VT) is associated with significant risks of mortality in patients with prior myocardial infarction and these risks have been shown to be reduced with implantable cardioverter-defibrillator (ICD) implantation.^{1,2} However, while ICDs are often effective in terminating VT, the occurrence of ICD shocks can lead to significant impairment in quality of life.³ Furthermore, recurrent VT has been associated with increased heart failure, hospitalization, and mortality.⁴ Currently, catheter ablation of VT is a mainstay

therapy for the treatment of VT storm and drug-refractory VT.⁵

However, because success rates for VT ablation may be diminished for patients with progressive heart failure and high arrhythmia burden, the optimal timing for VT ablation remains unclear.⁶ An early preventive VT ablation approach may increase long-term freedom from VT, which, in turn, may lead to reduced mortality. Prior meta-analyses comparing preventive vs deferred approaches to VT ablation identified a significant reduction in ICD therapies associated with an early VT ablation strategy but found no difference in mortality.^{7,8} However, these meta-analyses were limited by small sample sizes and did not incorporate the findings of the recently published Preventive Ablation of Ventricular Tachycardia in Patients with Myocardial Infarction

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KEY FINDINGS

- In a meta-analysis of 4 randomized clinical trials comparing a preventive ventricular tachycardia (VT) ablation strategy to a deferred ablation strategy for the treatment of myocardial infarct-associated VT, preventive ablation was associated with significant reductions in implantable cardioverter-defibrillator (ICD) therapy and VT storm.
- The impact of preventive VT ablation on reducing ICD therapies was particularly significant in the subgroup of patients with left ventricular ejection fraction >30%.
- However, reduction in ICD therapies and VT storm associated with preventive ablation did not lead to improvement in survival when compared to a deferred ablation strategy.

(BERLIN VT) trial.⁹ We sought to perform an updated systematic review and meta-analysis of randomized controlled trials (RCTs) comparing preventive vs deferred approaches to VT ablation in patients with ischemic cardiomyopathy. In addition, we examine differences in outcomes in patients assigned to these 2 treatment approaches when stratified according to left ventricular ejection fraction (LVEF).

Methods

Search strategy and eligibility criteria

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and with the protocol agreed by all authors.¹⁰ The PRISMA checklist is reported in [Supplemental Table 1](#). Medline (PubMed), Embase, and the Cochrane Library databases were searched for primary research papers, published in any language from their dates of inception until April 15, 2020. The search was performed by 2 independent reviewers (A.T., I.P.D.) using the following search algorithm: catheter ablation[title/abstract] AND (implantable defibrillator[title/abstract] OR (implantable cardioverter defibrillator[title/abstract] AND (ventricular fibrillation[title/abstract] OR (ventricular tachycardia[title/abstract])). Reference lists of all studies previously identified as having met the inclusion criteria were also manually reviewed for additional relevant publications. Disagreements were resolved by consensus with the addition of a third reviewer (P.N.K.).

Eligible studies met the following PICOS criteria: (1) Population: adult human patients who underwent treatment of VT; (2) Intervention: ICD implantation with early catheter ablation; (3) Comparative intervention: ICD implantation alone as initial strategy; (4) Outcome: any outcome of the present meta-analysis (reported below); (5) Study design: RCT. The following studies were excluded: (1) non-RCT trials; (2) secondary research papers (eg, reviews, meta-

analyses); (3) experimental studies in animals or basic science studies; (4) case reports and case series; (5) studies including duplicate populations.

Outcomes and data extraction

All data were extracted by 2 independent researchers (A.T., I.P.D.) and consensus was reached after further adjudication of a third investigator (P.N.K.). The primary outcome of interest was the incidence of appropriate ICD therapy (either shock or antitachycardia pacing). Secondary outcomes were appropriate ICD shock, incidence of VT storm, procedural complications, and mortality. Other pertinent clinical data were also extracted.

Quality assessment

The quality of all eligible studies was critically appraised and rated by 2 reviewers. Studies were assessed by the Cochrane Collaboration's tool for assessing risk of bias.¹¹ Each trial was judged to be of low, unclear, or high risk of bias. Owing to the nature of the interventions, we considered blinding not crucial for the outcome. The quality of the evidence for each outcome was summarized with Grading of Recommendations Assessment, Development, and Evaluation method (GRADE)¹² using the GRADEpro GDT software (McMaster University, 2015 [developed by Evidence Prime, Inc]). The protocol for this systematic review was registered on PROSPERO (ID181549, approval pending).

Statistical analysis

The preventive ablation arm was defined as the group of patients that underwent early ablation in addition to ICD implantation. The deferred ablation arm was defined as the group of patients that underwent ICD implantation only as initial treatment. Categorical variables were reported as proportions, whereas continuous variables were reported as mean and standard deviation. For each study, the number of events in the control and intervention arms was used to calculate a study-specific odds ratio (OR) for the outcome of interest. OR <1 denoted an outcome less frequently present in the preventive ablation arm. Next, pooled ORs and corresponding 95% confidence intervals (CI) were calculated with the random-effects model estimated by DerSimonian-Laird models. Statistical heterogeneity between studies was assessed with Cochrane Q statistic and the I² statistic; $P < .10$ for the χ^2 test or I² greater than 50% indicated significant heterogeneity. Publication bias evaluation using Egger's test for small study effect was performed for all primary outcomes. Meta-regression was used to assess the effect of patients' clinical characteristics as moderators for the primary outcomes. A predefined sensitivity analysis was performed removing 1 trial at a time (leave-one-out analysis). A 2-tailed P value <.05 was considered statistically significant. Statistical analysis was performed using STATA/SE version 16 (Stata Corp, College Station, TX).

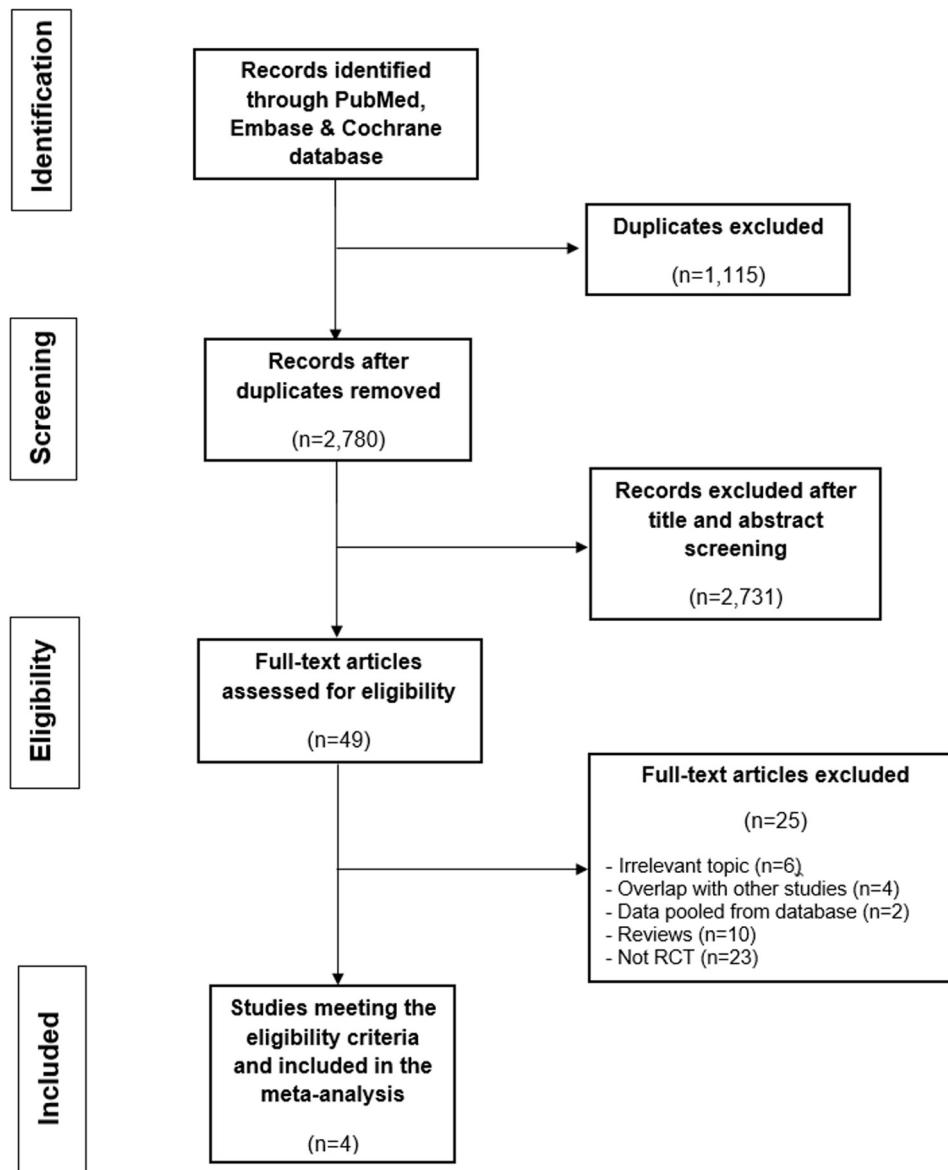


Figure 1 PRISMA flow chart for systematic review and meta-analysis of preventive vs deferred approaches to ventricular tachycardia ablation. RCT = randomized controlled trial.

Results

Study and clinical characteristics

A total of 2780 articles were identified after duplicates were removed and 2731 studies were excluded based on their title and abstract. Next, screening of the full texts of the remaining 49 articles identified 4 studies that met all eligibility criteria, as summarized in the PRISMA chart (Figure 1). These studies were all RCTs comparing the outcomes of preventive VT ablation and ICD implantation vs initial ICD implantation alone.^{9,13–15} Study characteristics and design are summarized in Table 1. Baseline clinical characteristics of the patients are detailed in Table 2. Three studies were performed in Europe and 1 in the United States. All studies included patients for whom ICD was implanted for secondary prevention of sudden cardiac death. However, in order to increase enrollment, the SMASH-VT trial also added patients

who underwent primary prevention ICD implantation and received appropriate ICD therapy for a single VT event. There was variation between the studies with respect to the subtypes of VT which fulfilled inclusion criteria for secondary prevention ICD implantation. Two studies, SMASH-VT and SMS trials, included only patients who had hemodynamically unstable arrhythmia, as defined by hemodynamically unstable VT, cardiac arrest, or syncope with inducible VT on electrophysiological study. In contrast, the VTACH trial only included patients with stable VT. Finally, the BERLIN VT trial included all patients who underwent secondary prevention ICD implantation, regardless of VT subtype. With respect to primary endpoint definition, time to first recurrent of VT/ventricular fibrillation or time to appropriate ICD therapy was used in 3 studies, whereas BERLIN VT used a composite clinical endpoint of all-cause death or rehospitalization.

Table 1 Study design and characteristics

Study	Year and region	Inclusion criteria	Study arms	Arrhythmia criteria	Mapping and ablation strategy	Endpoint for successful ablation	Primary endpoint
SMASH-VT ¹⁴	2007 US	Prior MI; secondary prevention ICD; primary prevention ICD with single VT event leading to appropriate ICD therapy	Ablation + ICD vs ICD only [†]	Hemodynamically unstable VT/VF, syncope with inducible VT or first appropriate ICD therapy	Voltage mapping, pacemap-guided linear ablation, late and fractionated potential ablation	Not described	Survival from any appropriate ICD therapy
VTACH ¹³	2010 Europe	Prior MI; secondary prevention ICD; LVEF <50%	Ablation + ICD vs ICD only [‡]	Stable VT	“Standard criteria” for ablation of stable VT and substrate modification	Noninducibility of VT	Time to recurrence of sustained VT/VF
SMS ¹⁵	2017 Europe	CAD; secondary prevention ICD; LVEF <40%	Ablation + ICD vs ICD only [§]	Hemodynamically unstable VT, VF or syncope with inducible VT	“Standard criteria” for ablation of stable VT and substrate modification	Noninducibility of VT	Time to recurrence of VT/VF
BERLIN VT ⁹	2020 Europe	Prior MI; LVEF 30%–50%; secondary prevention ICD	Ablation + ICD vs initial ICD only	Any sustained VT	Voltage mapping, late potential ablation	Elimination of late potentials and noninducibility of VT	Composite of all-cause death and unplanned hospitalization (>1 d)

CAD = coronary artery disease; ICD = implantable cardioverter-defibrillator; MI = myocardial infarction; US = United States; VF = ventricular fibrillation; VT = ventricular tachycardia.

[†]ICD implant was either planned prior to study enrollment or performed within 6 months of study enrollment.

[‡]ICD implant performed median 3 days after electrophysiology study or ablation.

[§]ICD implant performed median 2 days after ablation for the preventive ablation arm

^{||}ICD implant performed within 2 weeks after ablation for the preventive ablation arm or after enrollment for the deferred ablation arm; also per protocol, ablation was to be performed after third appropriate ICD therapy in patients in the initial ICD only arm.

A total of 246 and 259 patients were included in the preventive ablation and initial ICD arms, respectively (Table 2). Weighted mean age was 67.1 and 65.6 years for the intervention and control arms, respectively (male patients represented 91% and 86%). Weighted mean LVEF was 34.9% for the intervention and 35.2% for the control arm. One study (SMASH-VT) did not include any patients on a class I or III antiarrhythmic, whereas amiodarone was allowed in the rest of the studies. About a fourth of the pooled patients in

each arm (26% and 24%, respectively) received amiodarone, whereas more than 80% of all patients were on a beta-blocker (84% and 83%, respectively). For all studies, the mean follow-up duration was greater than 22 months. There was variability between the studies with respect to the amount of crossover between treatment arms. The percentage of patients randomized to the deferred ablation arm who subsequently underwent VT ablation during follow-up ranged from 0% to 22%.

Table 2 Study patient clinical characteristics

Study	Group	No. of patients	Age (y)	Male sex	LVEF (%)	LVEF >30%	Amiodarone	β-blocker	Ablation performed [†]	Follow-up (mo)
SMASH-VT ¹⁴	Ablation + ICD	64	67±9	59 (92)	30.7±9.5	37 (58)	0 (0)	60 (94)	61 (95)	22.5
	ICD only	64	66±10	52 (81)	32.9±8.5	30 (47)	0 (0)	63 (98)	0 (0)	
VTACH ¹³	Ablation + ICD	52	67.7±8.3	50 (96)	34.0±9.6	20 (38)	18 (35)	39 (75)	45 (87)	22.5
	ICD only	55	64.4±8.2	50 (91)	34.1±8.8	23 (42)	19 (35)	41 (75)	12 (22)	
SMS ¹⁵	Ablation + ICD	54	68.4±7.7	47 (87)	32.0±6.9	22 (42)	16 (30)	49 (91)	54 (100)	27
	ICD only	57	65.9±8.4	46 (81)	30.4±7.3	27 (47)	20 (35)	52 (91)	1 (2)	
BERLIN VT ⁹	Ablation + ICD	76	66±10	67 (88)	41±6	76 (100)	31 (41)	58 (76)	69 (91)	24
	ICD only	83	66±9	76 (92)	41±6	83 (100)	22 (27)	59 (71)	10 (12)	
Total	Ablation + ICD	246	67.1	223 (91)	34.9	156 (63)	65 (26)	206 (84)	229 (93)	
	ICD only	259	65.6	224 (86)	35.2	163 (63)	61 (24)	215 (83)	23 (9)	

ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction.

[†]Ablation performed as per protocol or as crossover during follow-up.

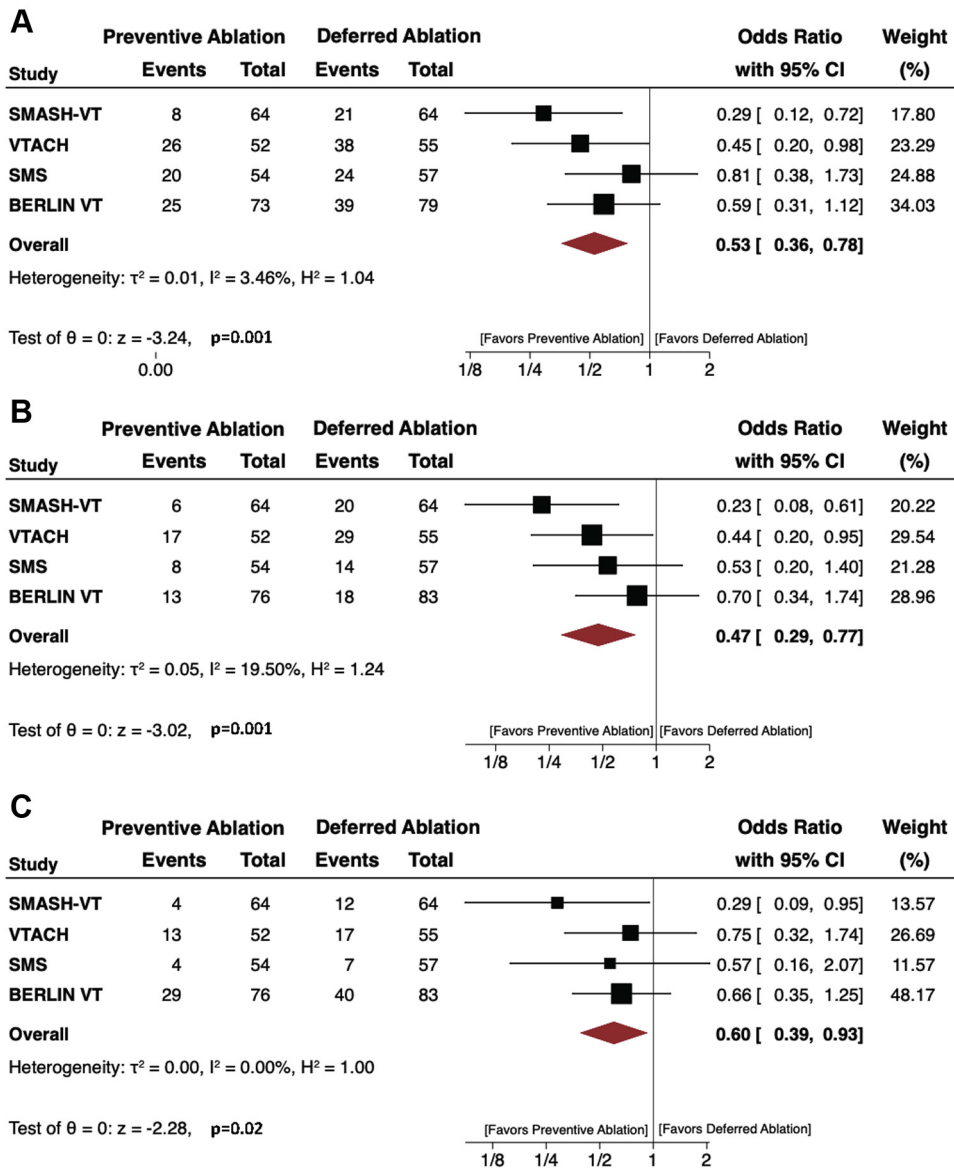


Figure 2 Forest plots of randomized controlled trials comparing the effect of preventive ablation vs deferred ventricular tachycardia (VT) ablation on (A) implantable cardioverter defibrillator therapy, (B) shock, and (C) incidence of VT storm. CI = confidence intervals.

Study outcomes

At the end of follow-up, 32.0% of patients in the preventive ablation arm received appropriate ICD therapy compared to 47.1% of patients in the deferred ablation arm. Overall, early preventive ablation was associated with a significantly lower risk of ICD therapy (OR [95% CI]: 0.53 [0.36–0.78], Figure 2). Furthermore, compared to deferred ablation, the preventive approach was associated with significantly less occurrence of ICD shock and VT storm (OR [95% CI]: 0.47 [0.29–0.77] and OR [95% CI]: 0.60 [0.39–0.93], respectively). Heterogeneity was found to be low (I^2 of 19.5% or lower) for all of these outcomes, but not zero for the primary outcome (Figure 2). Overall, all-cause mortality occurred in 10.6% of patients in the preventive ablation arm vs 10.8% in the deferred ablation arm (OR [95% CI]: 0.99 [0.49–2.02]). Heterogeneity was low ($I^2 = 27.9\%$). Finally,

complication rates did not differ significantly between the preventive and deferred ablation arms (7.7% vs 10%, OR [95% CI]: 1.02 [0.34–3.09], $I^2 = 58.3\%$) (Figure 3). However, there was significant variation in the types of complications reported in each trial, ranging from pericardial effusion and tamponade to ICD dislodgement and deep vein thrombosis (Supplemental Table 2). Using a “leave-one-out” approach, a sensitivity analysis was performed for all outcomes by excluding the study with the highest weight each time (Supplemental Figures 1 and 2). Results were similar for all outcomes, with the exception of the endpoint of VT. Exclusion of the BERLIN VT trial rendered the decreased likelihood of VT storm associated with the preventive ablation strategy a nonsignificant trend (OR [95% CI]: 0.55 [0.30–1.01]) without heterogeneity ($I^2 = 0\%$).

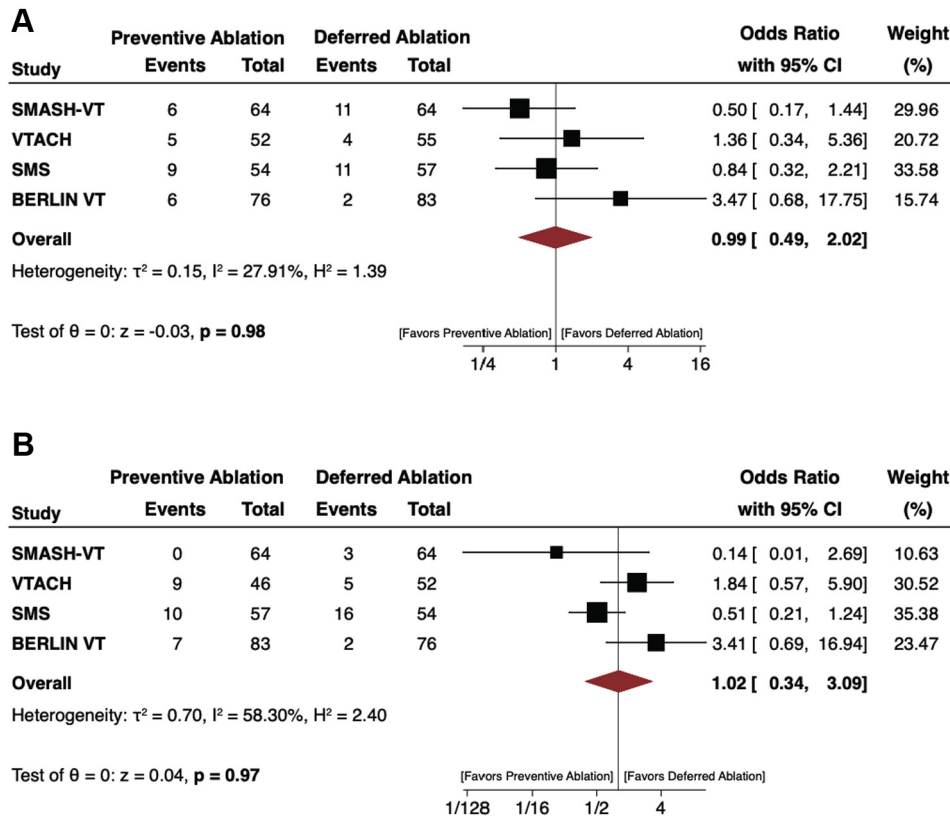


Figure 3 Forest plots of randomized controlled trials comparing the effect of preventive ablation vs deferred ablation for ventricular tachycardia on (A) mortality and (B) complication rates. CI = confidence intervals.

Subgroup analysis for LVEF >30% and meta-regression

A subgroup analysis of patients with LVEF >30% revealed that preventive ablation was associated with a significantly decreased risk of appropriate ICD therapy when compared to deferred ablation (hazard ratio [95% CI]: 0.37 [0.19–0.72]) (Figure 4). Owing to insufficient data available at the individual study level, a subgroup analysis of patients with LVEF <30% could not be performed. Given the presence of heterogeneity in the meta-analysis, a meta-regression examining the impact of key clinical variables on effect size for all outcomes was performed. With the exception of beta-blocker use with respect to procedural complications ($P = .039$), no impact on effect size was found (Supplemental Table 3).

Quality and risk of bias assessment

All studies included in our systematic review and meta-analysis were found to be of low risk of bias with respect to the domains of randomization, missing outcome data, and measurement of the outcomes. Most of them were also at low risk with respect to selection of reported results. However, all studies were found to have an unclear bias for the domain of deviation from intended intervention (Supplemental Figure 3). The quality of evidence for each outcome is summarized in a GRADE format in Supplemental Table 4. Certainty was deemed high and

importance critical for all analyzed outcomes. Finally, Egger’s test for small study effect showed the absence of significant publication bias for all outcomes examined (Supplemental Figure 4).

Discussion

Our systematic review and meta-analysis of RCTs comparing early VT ablation with ICD implantation to ICD implantation alone demonstrated a clear reduction in ICD therapies, ICD shocks, and VT storm with a preventive ablation approach. In particular, the preventive ablation strategy yielded highly significant reductions in appropriate ICD therapies among patients with LVEF >30%, which was a patient subgroup that the present study specifically explored. However, despite the absence of differences in complications between the 2 treatment arms, there was no mortality benefit favoring the preventive ablation approach. The present study is the largest meta-analysis to date to compare the efficacy and safety of preventive vs deferred ablation of patients with ischemic cardiomyopathy with documented or presumed VT.

Catheter ablation has been shown to reduce recurrent arrhythmias in patients with scar-related VT presenting with ICD shocks and VT storm.^{16–18} The current basis for catheter ablation of myocardial infarct-associated scar VT rests on the principles of targeting critical isthmuses that permit reentry circuits to sustain monomorphic VT.¹⁹ Recent advances in VT ablation that include the introduction of

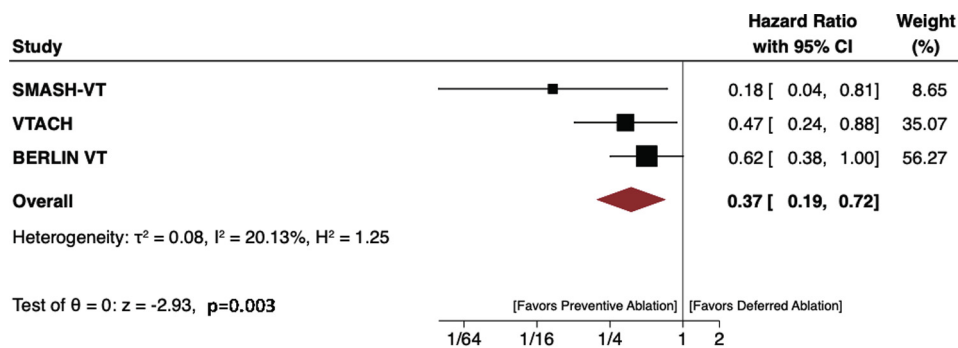


Figure 4 Subgroup analysis forest plot for patients with left ventricular ejection fraction $>30\%$ comparing the effect of preventive ablation vs deferred ablation on appropriate implantable cardioverter-defibrillator (ICD) therapy. For the VTACH study, the endpoint of sustained ventricular tachycardia was used instead of appropriate ICD therapy owing to lack of hazard ratio reporting for the latter. CI = confidence intervals.

irrigated ablation technology,¹⁷ the use of epicardial mapping and ablation,²⁰ and the adoption of improved substrate mapping and targeting techniques^{20–22} have likely led to improved VT ablation efficacy, particular for patients with ischemic cardiomyopathy. Therefore, given the well-established association between recurrent ICD shocks and mortality, a preventive VT ablation strategy as an adjunct to ICD implantation may provide additional benefit of not only reducing ICD therapies, but also decreasing mortality.

However, in our comprehensive meta-analysis of 505 patients, which included contemporary data from the BERLIN VT study, a preventive VT ablation approach was not associated with reduced mortality. This absence of mortality benefit associated with early preventive VT ablation was seen despite an overall 47% reduction in ICD therapy and 53% reduction in ICD shocks. There are several possible reasons for the lack of mortality benefit with a preventive VT ablation strategy. First, despite a statistically significant reduction in ICD therapies associated with preventive ablation, the overall degree of VT burden reduction may have been insufficient to translate to mortality benefit. Furthermore, the overall rate of VT ablation in the deferred ablation arm was almost 10%, which might have further tempered differences in outcomes. Notably, in the BERLIN VT trial, VT ablation was performed in a significant number of patients in the deferred ablation arm who did not reach a protocol-defined third ICD therapy before undergoing the procedure.⁹ Second, it is possible that much of the reduction in VT recurrence associated with preventive ablation occurs among patients with more preserved LVEF. Therefore, if much of the VT reduction benefit is occurring among patients at lower risk of mortality from heart failure, an overall mortality benefit from a preventive ablation strategy is less likely to be seen. Unfortunately, while we were able to perform a subgroup analysis of patients with LVEF $>30\%$, there was insufficient data available at the individual study level to permit a subgroup analysis of patients with LVEF $\leq 30\%$ for our meta-analysis. Finally, it is possible that in a substantial number of patients with ICDs, VT recurrence is a mortality risk marker, whereby reduction in arrhythmia burden does not reduce the mortality associated with incipient heart failure.

The results of our meta-analysis, together with those of prior smaller analyses,^{7,8} suggest that there is likely little role for preventive VT ablation for patients with ischemic cardiomyopathy for the goal of prolonging survival. However, our study does underscore the safety of a preventive ablation strategy, as there were no significant differences in complication rates among patients in the 2 treatment arms. Therefore, a preventive ablation strategy may have an important role for appropriately selected patients. Patients who present with slow VT may benefit from preventive ablation, given the concerns of drug-induced VT slowing that may complicate ICD programming. For patients with slow VT, high ICD VT rate cut-offs may result in untreated persistent VT that can lead to progressive heart failure and hemodynamic collapse. On the other hand, low ICD VT rate cut-offs may increase the risks of inappropriate shocks due to sinus tachycardia and supraventricular tachycardia. Furthermore, for patients in whom long-term treatment with antiarrhythmic drugs such as amiodarone would not be tolerated, early preventive ablation may be considered. Finally, while reduced recurrent VT in the preventive ablation arm may not lead to increased survival, it may lead to improved quality of life and reduced hospitalization and healthcare utilization and costs,²³ which may be an important consideration for patients at high risk of recurrent VT.

Study limitations

There are several limitations to our study. First, there were differences between the studies included in our meta-analysis that could not be accounted for by the statistical measurement of heterogeneity (I^2). This heterogeneity originates from different subgroups of patients enrolled in the included trials in terms of primary/secondary prevention and hemodynamic instability. In addition, different VT algorithms were used and there was variation in VT mapping approach as well as ablation endpoint definition among the studies. There were differences in the proportion of patients who were on baseline amiodarone therapy and of patients who were randomized to the deferred ablation arm but went on to undergo ablation during follow-up. This degree of nonquantified heterogeneity limits the results of the meta-analysis. A

meta-regression was performed in our study to partially address this issue. Next, there was an insufficient number of patients to permit a subgroup analysis of patients with LVEF <30%. Finally, there was unclear bias risk across all studies, which included deviations from intended interventions.

Conclusion

Preventive VT ablation in patients with ischemic cardiomyopathy leads to significant reductions in ICD therapies, shock, and VT storm without increasing complications when compared to standard ICD-only therapy. In particular, early ablation significantly decreases appropriate ICD therapies among patients with LVEF >30%. However, a preventive VT ablation approach does not lead to reduced all-cause mortality.

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Appendix Supplementary data

Supplementary data associated with this article can be found in the online version at <https://doi.org/10.1016/j.hroo.2020.08.001>.

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