Extended Abstract
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Euro Heart Failure 2020: Heart Failure Outcomes in Patients with Ischemic Cardiomyopathy after Ventricular Tachycardia Ablation

Himanayani Mamillapalli

University of Connecticut, United States

Abstract

Background:
Patients with congestive heart failure (CHF) are at an increased risk of developing ventricular tachycardia (VT). It is unclear how VT ablation affects CHF outcomes.

Objective:
The goal of this study is to evaluate CHF exacerbations and echocardiogram findings based on location of myocardial scar in patients with Ischemic Cardiomyopathy (ICM) who have undergone VT ablation.

Methods:
This was a selected cohort of consecutive patients with ICM who underwent VT ablation at Minneapolis Veterans Affairs Health Care System between July 2008 and September 2019. HF outcomes and echocardiogram variables were assessed.

Results:
Seventy-five patients with ICM underwent VT ablation, average age was 67.6 ± 7 years old and 100% male. Inferior wall scar (IWS) was the most prevalent (Figure, Table 1A). On pre-ablation echocardiogram, anterior wall scar (AWS) group overall had a lower mean ejection fraction (EF) of 26%, compared to IWS group of 32% (Table 1B). On post-ablation echocardiogram, patients with AWS had statistically significant ($p < 0.03$, two-tailed test) lower mean EF of 23% compared to IWS group of 30% (Table 1C). Twenty-five patients had admissions for CHF exacerbation post-ablation, 17 were in the first year after ablation (12 IWS and 5 AWS). Average time from ablation to CHF exacerbation was 2.1 years. Patients with IWS presented earlier with CHF exacerbation compared to AWS group (1.6 vs 1.8 years).

Conclusion:
Patients with ICM and AWS scar had a statistically significant mean lower EF post VT ablation compared to IWS scar group. However, patients with IWS scar had higher rates of admission for CHF exacerbation. Ablation of ventricular tachycardia in patients with ICM has been associated with a lower risk of cardiovascular hospitalization, VT storms and ICD shocks compared to medical management and no ablation. Mortality and ablation-related stroke rates were very low. Mortality remained identical in both categories, however.

Introduction:
Sustained ventricular tachyarrhythmia continues to be a significant cause of morbidity and mortality in patients with ischemic cardiomyopathy (ICM) [1]. The placement of implantable cardioverter defibrillator (ICD) is proven to reduce the rates of sudden death and mortality in patients with ICM and reduced ejection fraction. However, the ICD has no effect on the incidence or recurrence of the events. Recurrent ventricular tachyarrhythmias can lead to recurrent shocks and re-hospitalizations, and were proven to be associated with worse overall outcomes.

Catheter removal plans to forestall repeat of ventricular tachycardia (VT), in this way in principle, diminishing repetitive ICD stuns and along these lines the requirement for long haul utilization of conceivably harmful antiarrhythmic specialists. Be that as it may, critical debate keeps on existing in regards to its adequacy in patients with ICM. We played out a meta-examination of the accessible randomized clinical preliminaries (RCTs) to think about the job of catheter removal versus customary administration for VT in patients with ICM and ICD implantation.

Figure:

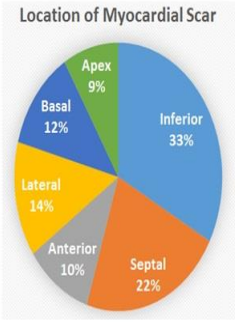

Table 1A:

Location of Scar	Number of Patients (n)
Inferior	57
Septal	38
Anterior	18
Lateral	24
Basal	21
Apex	15

Table 1B: Pre-Ablation Echocardiogram

	Inferior Scar	Anterior Scar
LViDd (cm)	6.48	6.68
LViDs (cm)	5.33	5.72
LVEF	32%	26%
LA Diameter (cm)	4.92	4.99
E/A Ratio	1.29	1.47
E/e Prime	15.01	17.92

Table 1C: Post-Ablation Echocardiogram

	Inferior Scar	Anterior Scar
LViDd (cm)	6.45	6.62
LViDs (cm)	5.55	5.65
LVEF	30%	23%
LA Diameter (cm)	4.93	5.35
E/A Ratio	1.43	2.09
E/e Prime	16.3	15.7

Figure: Location of myocardial scar in Ischemic Cardiomyopathy patients who underwent ventricular tachycardia ablation.

Table 1A: Number of patients with specific scar region involvement.

Table 1B: Mean pre-ablation echocardiogram variables.

Table 1C: Mean post-ablation echocardiogram variables.

1. Introduction

Sustained ventricular tachyarrhythmia continues to be a significant cause of morbidity and mortality in patients with ischemic cardiomyopathy (ICM) [1]. The placement of implantable cardioverter defibrillator (ICD) is proven to reduce the rates of sudden death and mortality in patients with ICM and reduced ejection fraction [2]. However, the ICD has no effect on the incidence or recurrence of the events. Recurrent ventricular tachyarrhythmias can lead to recurrent shocks and re-hospitalizations, and were proven to be associated with worse overall outcomes [3, 4, 5, 6].

Catheter removal plans to forestall repeat of ventricular tachycardia (VT), in this way in principle, diminishing repetitive ICD stuns and along these lines the requirement for long haul utilization of conceivably harmful antiarrhythmic specialists. Be that as it may, critical debate keeps on existing in regards to its adequacy in patients with ICM. We played out a meta-examination of the accessible randomized clinical preliminaries (RCTs) to think about the job of catheter removal versus customary administration for VT in patients with ICM and ICD implantation.

2. Methods

2.1 Search strategy and study selection

An efficient audit of PubMed, MEDLINE, and Cochrane Central Register of Controlled Trials was performed from January 1990 until to December 2016, with no language limitation, as indicated by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) rules [7]. We utilized the watchwords "ventricular tachycardia"; "ischemic"; "cardiomyopathy"; and "removal" independently and in mix. After qualified examinations were recovered, we screened their lists of sources for any potential missed investigations through the underlying inquiry. Besides, earlier meta-examinations were audited to guarantee the consideration of every single qualified investigation. Studies qualified for consideration were randomized controlled preliminaries contrasting catheter removal versus regular administration (control gathering) for VT in patients with ICM and ICD.

2.2 Data extraction

Two autonomous creators (A.A. furthermore, R.N.) removed complete information on study attributes, patients' socioeconomics, and quality appraisal information. The quantities of occasions for results of enthusiasm for the 2 arms were arranged. The removed information were overhauled by a third creator (M.S.) to guarantee precision. Inconsistencies were settled by agreement among all the creators.

2.3 Assessment of quality and bias

The nature of the included preliminaries and the danger of inclination were evaluated by 2 autonomous analysts (W.M. also, M.S.) utilizing the segments suggested by the Cochrane Collaboration [8], including irregular arrangement age, allotment covering, blinding of members and work force, blinding of result appraisal, deficient result information, specific detailing and different wellsprings of predisposition. Preliminaries were viewed as low potential for inclination if having <2 high-chance parts, and high potential for predisposition if having >4 high-chance segments. The general nature of proof for every result was additionally surveyed utilizing the GRADE (Grades of Recommendation, Assessment, Development and Evaluation) instrument suggested by the Cochrane Handbook for Systematic Reviews of Interventions [8].

2.4 Outcomes

The fundamental result of intrigue surveyed by the present examination was all-cause mortality. Different results of intrigue were cardiovascular mortality; cardiovascular-related hospitalization; VT storm (characterized as at least 3 ICD stuns in a 24 hours period in SMASH-VT and at least 3 in VT scenes in a 24 hours period in VTACH and VANISH); and ICD stuns. Results were accounted for at the longest development.

2.5 Statistical analysis

This meta-investigation was performed with a goal to-treat approach. Spellbinding investigations were performed utilizing weighted methods with standard deviations (SD) for consistent factors, and weighted frequencies for straight out factors. The weighted mean follow-up span of every result was determined, utilizing the example size of every preliminary as its weight. We determined the evaluated chance proportions (RR) for the whole result utilizing irregular impact DerSimonian and Laird's model [9]. We likewise played out an affectability investigation fixed-impacts rundown chances proportions (OR) utilizing Peto model [10]. Higgins I2 test [11] was utilized to survey for heterogeneity; where low heterogeneity characterized as $I2 < 25\%$, and high heterogeneity as $I2 > 50\%$. All the p-values were 2-followed with factual essentialness at 0.05. Distribution inclination was determined utilizing the Egger technique [12]. Irregular impact converse difference weighted frequency with 95% certainty stretches (CI) was determined for every result utilizing STATA Metaprop programming. Every single measurable examination were led utilizing STATA 14 (STATA Corporation; College Station, Texas).

3. Results

There were 370 papers in our initial online database scan. Five RCTs met our eligibility requirements for further

screening. On a thorough analysis, one RCT [13] was omitted as only an abstract was published and the key outcome of our concern was not stated. Therefore, 4 RCTs [14 , 15, 16, 17] with a total of 521 patients (VT ablation group n = 261; and control group n = 260) were included in the study (Fig.1). A total of 24 patients (9%) were confirmed to have progressed from control to ablation at the end of the follow-up period. The weighted mean age was 66.4 ± 1.7 years in the ablation group , compared to 66.4 ± 2.7 years in the control group, 31.7 ± 10.3 vs 31.9 ± 9.9 for the ejection fraction, and 90.4 per cent vs 91.5 per cent for the beta blocker category. The majority of the included populations were male (95.3 ± 3.6 per cent in the ablation group versus 87.7 ± 5.3 per cent in the control group; p = 0.06). The weighted mean hypertension rate was 70.6 ± 2.1 per cent in the ablation group versus 66.1 ± 21.7 per cent in the control group, while 37.3 ± 9.01 per cent for diabetes mellitus vs 42.2 ± 14.8 per cent in the control group. There were no major variations between the variables listed above. (Details on the features of the trials and baseline profiles of patients are summarized in Table 1.)

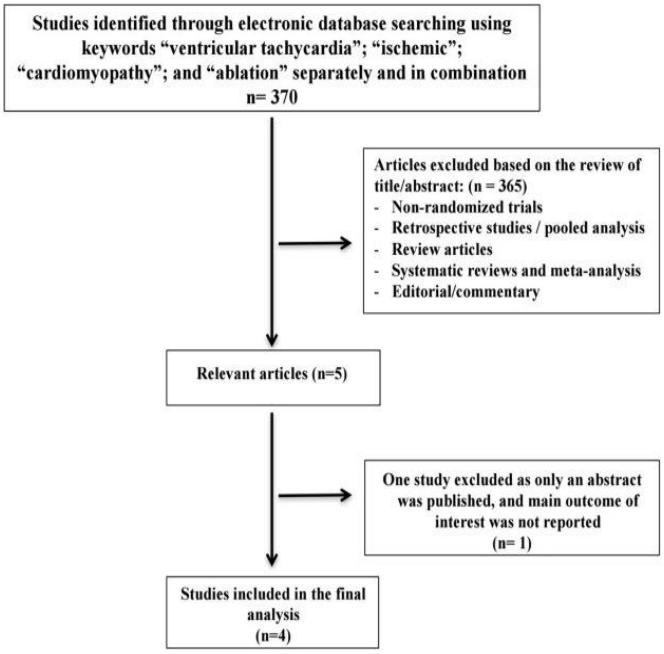

Fig. 1A flow diagram of the search strategy conducted.

3.1 Quality and risk of bias of the included trials

According to the Cochrane Collaboration method, both trials were found to be at low risk of bias. The consistency of the evidence for results was further assessed using the GRADE evaluation method and the level of high quality of evidence for all outcomes was achieved. The standard of the included trials is summarized in Supplementary Tables 1 and 2. No reporting bias was found in all outcomes (p = 0.88, 0.68, 0.96, 0.45; and 0.08 for all-cause mortality, cardiovascular mortality, cardiovascular hospitalization, VT earthquake, and ICD shocks, respectively).

3.2 Outcomes

The weighted incidence of mortality was 15 percent (95 percent CI 5–25) in the VT ablation group compared to 17 percent (95 percent CI 6–27) in the control group. At a weighted mean follow-up period of 17.5 ± 8.4 months, VT ablation was correlated with a comparable risk of all-cause mortality (RR 0.94, 95 percent CI, 0.66–1.32, p = 0.70; I2 = 0 percent); and cardiovascular mortality (RR 0.82, 95 % CI, 0.52–1.29, p = 0.39; I2 = 0 per cent) relative to the non-ablation (medical treatment only) category (Fig . 2). However, patients with VT catheter ablation reported less cardiovascular hospitalization (RR 0.72, 95 per cent CI, 0.54–0.96, p = 0.02; I2 = 0 per cent), less VT storm (RR 0.71, 95 per cent CI, 0.52–0.97, p = 0.03; I2 = 0 per cent) and a decreased chance of ICD shock (RR 0.59, 95 per cent CI, 0.34–1.05, p = 0.07; I2 = 72 per cent) compared to the control group (Fig . 3). The mortality rate for the first 30 days after ablation or as specifically linked to the ablation procedure was 0 per cent. Nevertheless, if we consider the two deaths recorded in the ablation arm in the first 6 months of the CALYPSO analysis but not defined as a direct risk of the ablation procedure, this would be 0.8%. No stroke and only one transient ischemic attack (0.4%) was identified as a complication of the ablation procedure.

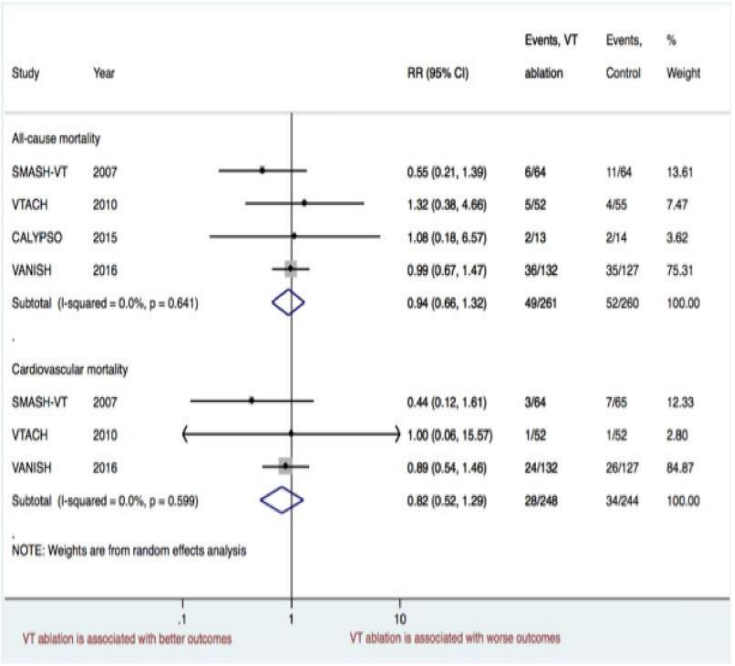

Fig. 2 Summary forest plot of all-cause mortality and cardiovascular mortality.

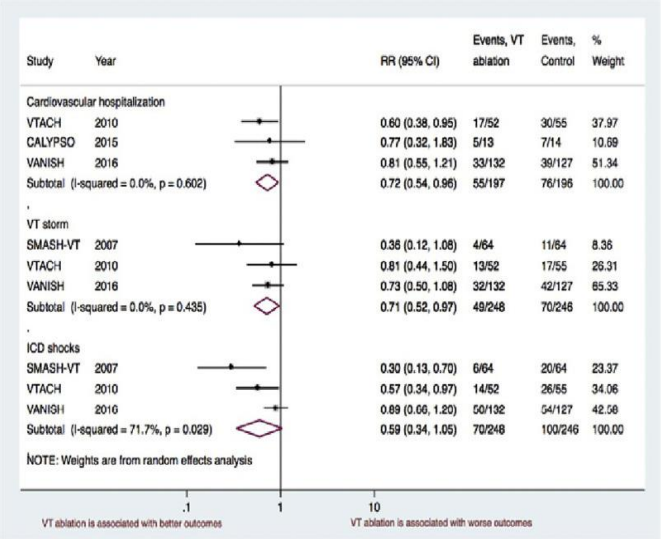

Fig. 3 Summary forest plot of cardiovascular hospitalization, VT storms, and ICD shocks.

Sensitivity analysis using the Fixed Effects Description OR was further conducted. VT ablation appeared to be associated with a higher risk of all-cause mortality (RR 0.90, 95 per cent CI, 0.58–1.41, p = 0.65; I2 = 0 per cent); and cardiovascular mortality (RR 0.77, 95 per cent CI, 0.44–1.32, p = 0.34; I2 = 0 per cent) relative to the medical management community. VT catheter ablation also remained associated with less cardiovascular-related hospitalization (RR 0.62, 95 per cent CI, 0.40–0.94, p = 0.03; I2 = 0 per cent) and less VT (RR 0.61, 95 per cent CI, 0.40–0.93, p = 0.02; I2 = 0 per cent). ICD shocks were substantially lower in the fixed-effect study of the VT catheter ablation arm (RR 0.57, 95 per cent CI, 0.39–0.83, p = 0.003; I2 = 66 per cent) relative to the control group.

4. Discussion

In the latest meta-analysis of 4 RCTs with a total of 521 participants, it has been shown that VT catheter ablation in participants with ICM and ICD is associated with a reduced risk of cardiovascular hospitalization, induced by a substantial reduction in VT storm and ICD shock relative to traditional medical care. There was no evidence of superiority in all-cause or cardiovascular mortality between the two groups. It is very important to note that the enrolment criteria in the four studies may not be representative of actual word practice where patients usually have VT ablation for a VT storm or frequent ICD shock and have failed to tolerate the maximum dose of antiarrhythmic drugs.

Ventricular tachycardia is a potentially fatal tachyarrhythmia that occurs mainly in patients with ICM due to re-entry of partly scarred ventricular myocardium. After the implementation of ICD in 1980[18], multiple studies have shown the mortality advantage of ICD implantation in patients with a history of ICM for primary prevention. It is also one of the recommended treatments for such populations according to the existing guidelines[19]. After ICD placement, recurrences of VT treated with ICD shocks are not uncommon and approximately one of every three patients will receive sufficient shocks for ventricular arrhythmia within 5 years of implantation[20]. Previous studies have shown that ICD shocks are linked to increased risk of hospitalization, heart failure, death and poor quality of life[3,4,21,22]. As a consequence, monitoring of repeated VT storms and ICD shocks after ICD implantation has gained attention over the years through either medical treatment and escalating antiarrhythmic drugs or catheter ablation. Both approaches have been correlated with a positive reduction in VT recurrence in multiple studies and mortality in a few others[15,17,23, 24, 25 , 26]. However, current guidelines recommend catheter ablation of VT in patients with recurrent arrhythmia despite appropriate conventional therapy [27, 28, 29]; data supporting these guidelines were mainly derived from observational studies. In the current meta-analysis, the aim was to analyze the available evidence to compare all approaches, using only RCTs, in order to reduce the possibility of bias associated with observational studies. Only 4 RCTs were identified which compared the two strategies as detailed in Fig. 1 and no clinical trials comparing the two treatments in patients with ischemic cardiomyopathy.

It is worth noting that there were low overall serious complications in the ablation arm.

The 30-day mortality rate directly associated with the VT ablation procedure was zero. Two deaths were reported in the ablation arm of the CALYPSO study in the first 6 months post-ablation, but were not identified as a direct risk of the ablation procedure. Including this yields a mortality rate of 0.8 per cent, far lower than the recorded 5 per cent early mortality rate (within 30 days) in the latest retrospective analysis of 2061 patients with systemic heart disease who underwent VT ablation trial [31]. In such trials, this disparity may be due to the sicker patient population. No symptomatic stroke and only one symptomatic transient ischemic attack (0.4 per cent) have been identified. Post-procedural procedures for anticoagulation were somewhat different between research involving the use of aspirin vs. warfarin and different durations for use of aspirin or warfarin, which typically represent recommendations for anticoagulation after VT ablation in patients of structural heart disease[27].

In the Ventricular Tachycardia Ablation in Coronary Heart Disease (VTACH) research, after 2 years of follow-up,

survival free from VT or ventricular fibrillation (VF) was 47% in the ablation community, significantly higher than the control group of 29% (p=0.045), whereas in the SMASH-VT trial, patients in the ablation arm had substantially lower ICD shocks and anti-tachycardia rate relative to the control group (12 % vs 33 %).

The latest Ventricular Tachycardia Ablation versus Escalation of Antiarrhythmic Drugs "VANISH" trial, the largest on the subject to date, was a multicenter study that randomized 259 patients to either ablation versus escalating antiarrhythmic drugs and observed a substantial reduction in the primary composite outcome of death, VT storm and ICD shocks (59.1% in the ablation group vs 68.5% in the escalated therapy group) [14]. Although benefits were seen in the ablation group, the event rate was high in both groups reflecting this high-risk population with an overall well-guarded prognosis. This study did not demonstrate a substantial decrease in hospital admission for cardiac conditions with ablation compared to antiarrhythmic drug therapy (p = 0.25). However, our study has shown that the reduction of VT storm and ICD shocks in the pooled population has resulted in a reduction in cardiovascular hospitalization, indicating a potential benefit in improving quality of life as well as lower health care costs. However, additional studies are needed to address these issues, as potential savings from reduced hospitalizations may be offset by procedural costs. In the VANISH trial, two subgroups tended to benefit more from ablation than the majority of the randomized population in terms of primary outcome: patients on baseline amiodarone relative to non-amiodarone, and patients with dual-chamber ICD compared to single-chamber ICD, with p values for interaction 0.03 and 0.10, respectively. Due to data limitations, we were unable to conduct subgroup analyzes to validate the advantages of these subgroups. Only the SMASH-VT trial reported subgroup analysis by type of ICD and did not show any difference in outcome between single and dual chamber ICDs. It is also important to note that in the VANISH study, all-cause mortality remained high in both groups at a mean follow-up of 27.9 months, with little disparity between ablation and medical treatment groups (27.3 per cent vs. 27.6 per cent). Compared to Patel et al.'s meta-analysis, the reduction in VT storms, ICD shocks and cardiovascular hospitalization that we reported in this study is new [32]. That being said, we were also unable to demonstrate a mortality benefit between the ablation and conventional therapy groups, despite having nearly double the patient number from the previous meta-analysis. It illustrates the lack of adequate care to date for this high-risk patient population. Neither cardiac mortality nor all-cause mortality was different between groups in our current study. VT ablation may have decreased cardiac mortality due to ventricular arrhythmia but did not affect overall cardiac mortality due to heart failure in these high-risk patients. It is also possible that studies conducted to date are undervalued in order to demonstrate a mortality benefit with ablation therapy. As a result, larger randomized trials capable of showing differences in hard clinical outcomes are needed to shed more light on the relative benefits of ablation therapy versus medical management in patients with ICM. Furthermore, whether or not VT ablation in real-life experience can minimize mortality can not be inferred from the VT ablation studies.

5. Limitations

This study was not based on patient-level data, which precludes more robust analysis. Although only randomized trials of the highly selected population were included in this analysis, they had different protocols and inclusion criteria as indicated in the Results section. Operator experience and success rates may have played a role that is not taken into account. The majority of patients were male. The total small number of patients comparing antiarrhythmic drugs to initial VT ablation therapy with short duration of follow-up was included in the analysis. Various approaches have been used for VT ablation between clinical VT ablation studies and mapping VT only versus substrate modification (Table 1) which may lead to different success rates[33]. Current studies did not address the quality of life of patients after VT ablation compared to medical therapy alone.

6. Conclusions:

Ablation of ventricular tachycardia in patients with ICM has been associated with a lower risk of cardiovascular hospitalization, VT storms and ICD shocks compared to medical management and no ablation. Mortality and ablation-related stroke rates were very low. Mortality remained identical in both categories, however.

This work is partly presenting at 31st European Heart and Heart Failure Congress on June 18-19, 2020