Meta-analysis comparing outcomes of catheter ablation for ventricular arrhythmia in ischemic versus nonischemic cardiomyopathy

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Abstract

**Background:** Catheter ablation is an effective treatment for ventricular arrhythmia (VA) in ischemic cardiomyopathy (ICM). However, results in non-ICM (NICM) patients are not satisfactory, and studies comparing differences between NICM and ICM are limited. We conducted a meta-analysis of procedural characteristics and long-term outcomes of catheter ablation for VA, comparing results between ICM and NICM.

**Methods:** Studies in the PubMed, EMBASE, and Cochrane databases were systematically reviewed. Four studies reporting comparison of catheter ablation of VA between ICM and NICM were examined. The Newcastle-Ottawa Scale was used to appraise study quality. A random-effects model with inverse variance method was used for comparisons.

**Results:** Epicardial approach was significantly more undertaken for the NICM group than in the ICM group (odds ratio [OR]: 0.13; 95% confidence interval [CI]: 0.09-0.18; \( P < .00001 \)). Mean ablation time (\( P = .54 \)), fluoroscopy time (\( P = .55 \)), and procedural time (\( P = .18 \)) did not differ significantly between the ICM and NICM groups. Procedural failure rates (OR: 0.46; 95% CI: 0.24-0.89; \( P = .02 \)) and VA recurrence rates (risk ratio [RR]: 0.68; 95% CI: 0.46-1.01; \( P = .06 \)) were significantly higher in the NICM group than in the ICM group. However, all-cause mortality (RR: 1.37; 95% CI: 0.75-2.49; \( P = .31 \)) did not differ significantly between groups.

**Conclusions:** Procedural failure and VA recurrence rates were significantly higher in the NICM group, despite significantly more frequent epicardial access. These highlight the limitations of catheter ablation for VA in NICM, given our current knowledge.

**Abbreviations:** AAD, antiarrhythmic drug; AR, attributable risk; CI, confidence interval; CRT, cardiac resynchronization therapy; ICD, implantable cardiac defibrillator; ICM, ischemic cardiomyopathy; NICM, nonischemic cardiomyopathy; OR, odds ratio; RR, risk ratio; VA, ventricular arrhythmia; VT, ventricular tachycardia.

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1 INTRODUCTION

Ventricular arrhythmia (VA) in patients with cardiomyopathy has traditionally been managed with antiarrhythmic drugs (AADs). However, effectiveness of AADs can be limited by patient noncompliance in response to side effects and drug-drug interactions. Implantable cardiac defibrillators (ICDs) are another treatment option for patients with ischemic cardiomyopathy (ICM). Multiple randomized controlled trials have shown improved survival rates in ICM patients who received ICDs for inducible ventricular tachycardia (VT). Recently, catheter ablation has become a viable treatment alternative for VAs in patients with ICM in contemporary electrophysiological practices worldwide, thanks to advances in ablation catheter tools, mapping technologies, and ablation strategies. Studies have suggested that catheter ablation lowers the risk for VA recurrences, prolongs survival rates, and reduces long-term healthcare costs, compared to AAD therapy.

VAs in ICM commonly originate from the relatively fixed, well-defined left ventricular endocardial substrate. Conversely, VAs in non-ICM (NICM) are more likely to originate from the epicardial region or from the right ventricle. ICM patients with VA are more likely than NICM patients with VA to be considered appropriate candidates for catheter-based treatment after ICD shock, given that the evidence supporting ICD therapy in NICM is sparse, compared with that for ICM. This, along with the limited effectiveness of AADs in NICM patients with VA, makes catheter ablation an option worth exploring.

Nonetheless, the success of catheter ablation of VA in NICM patients is limited by the heterogeneous nature of the epicardial substrate, which could lead to higher VA recurrence rates. Because of this ambiguity, long-term outcomes for catheter ablation in patients with NICM need further exploration.

Comparing catheter ablation safety and effectiveness outcomes in ICM patients with VA versus NICM patients with VA would undoubtedly shed more light on the effectiveness of the intervention. However, few studies have attempted such comparisons; existing studies are cross-sectional and compromised by relatively small sample sizes, short follow-up periods, various ablation strategies, few reported event outcomes, and conflicting results. To address this issue and to systematically assess and synthesize the results of previous studies, we conducted this first meta-analysis comparing outcomes of catheter ablation for VA in ischemic versus NICM.

2 METHODS

2.1 Search strategy

We performed a systematic review for literature published till March 2020. Physician-reviewers Dibbendhu Khanra and Sumit K. Shah searched PubMed, EMBASE, and the Cochrane Central Register of Controlled Trials (CENTRAL) databases for relevant literature using “VT,” “VA,” “catheter ablation,” “radiofrequency ablation,” “structural heart disease,” “ICM,” “NICM,” and combinations of these as the search keywords. References of selected articles were searched for additional literature. Discrepancies were resolved by a third reviewer (Indranill Basu-Ray).

2.2 Study selection

For the meta-analysis, we selected studies that directly compared periprocedural or long-term effectiveness outcomes data for catheter ablation of VA in ICM versus NICM. Studies that involved catheter ablation of VA in structurally abnormal hearts but that did not separately report outcomes data for each cardiomyopathy type were excluded. Single-arm studies, case reports, case series, and cohort studies that had fewer than 10 patients or that did not present adequate safety or effectiveness outcomes data were also excluded (Figure 1).

2.3 Data extraction

The data isolated from the studies included sample size (numbers of patients in the ICM and NICM groups); baseline demographics such as age and sex; and clinical data such as left ventricular ejection fraction, presence of ICD or cardiac resynchronization therapy (CRT) devices, New York Heart Association functional status, and mean number of failed AADs. Procedural data included ablation details, procedural failures, and complications; clinical outcomes data included VA recurrence and mortality.

2.4 Primary outcomes

The primary outcomes were long-term results, such as all-cause mortality and VA recurrence, by cardiomyopathy type (ICM versus NICM).
2.5 | Quality assessment

The Newcastle-Ottawa Scale was used to assess the quality of studies included in the meta-analysis. Good quality is indicated by 3-4 points in the selection domain, 1-2 points in the comparability domain, and 2-3 points in the outcome domain (for an overall rating of 6-9 points). Quality scaling paired with star ratings helps ensure the representative character of the studies as well as the comparability of any nonrandomized studies included in the meta-analysis.

For this study, we used a version of the scale that was customized for assessing comparability in cohort studies. Three benchmark norms were included in the analysis: (a) selection criteria (representativeness of the exposed cohort, selection of the nonexposed cohort, ascertainment of the exposure, demonstration that the outcome of interest was not present at start of study); (b) cohort comparability; and (c) outcomes criteria (assessment of outcome, length and adequacy of follow-up).

2.6 | Data analysis and synthesis

Statistical analyses were performed using Review Manager (RevMan version 5.3, the Cochrane Collaboration, London, United Kingdom, 2014). Odds ratios (ORs) or risk ratios (RRs), as appropriate, were used
to pool differences in binary events, and mean differences with standard deviations were used to pool differences in continuous outcomes. The random effects model of DerSimonian and Laird was used. To minimize imprecision of the estimate of pooled effects, inverse variance methods were used to calculate effect sizes for both continuous and dichotomous data.24,25

Heterogeneity was assessed by $I^2$ statistics. Funnel plots were drawn to determine publication bias.26,27 Sensitivity analyses were conducted for variables with high heterogeneity. Bivariate analysis and meta-regression modeling were conducted using R Software (version 3.5.1, package “metabin”) to explain the heterogeneity of the primary outcome variable with statistical significance and to construct a bubble plot.28

### 3 | RESULTS

Of the six studies that reported outcomes of catheter ablation for VA in ICM and NICM groups, four cohort studies meeting the inclusion criteria and comprising 769 ICM patients and 410 NICM patients were selected for the meta-analysis (Figure 1).14–19 Two studies by Tilz et al and Tung et al did not separately report data on ICM and NICM and were therefore excluded.18,19 The four included studies scored at least 6 points on the customized Newcastle-Ottawa Scale (Table S1), indicating good quality.

### 3.1 | Comparisons of study parameters, demographic data, and clinical data

Comparisons of the study parameters, demographic data, and clinical data from the four studies are summarized in Table 1. The median follow-up duration of the studies ranged from 20 months to 72 months. The ICM cohort was significantly older than the NICM cohort (67.9 years vs 57.7 years, respectively, $P < .001$) and trended toward lower mean left ventricular ejection fraction (mean difference [95% CI] −4.52, where CI is confidence interval, $[−10.64−1.59\%]$, $P = .15$). Despite the higher mean ejection fraction in the NICM group, a greater proportion of these patients had advanced heart failure (New York Heart Association stage III or IV) (190 vs 111, respectively, $P = .26$) and an existing ICD with or without CRT (455 vs 220, respectively, $P = .06$). In both cohorts, most patients had at least two failed attempts of VA management with AADs before catheter ablation was undertaken. The clinical VT cycle length was similar for both the ICM and the NICM cohorts (mean difference [95% CI] 4.16 milliseconds $[−39.40−47.71$ milliseconds], $P = .85$).

### 3.2 | Comparisons of procedural data and long-term outcomes

Comparisons of the procedural parameters and long-term outcome data are presented in Table 2 and Figure 2.
Because of the variable length of follow-up and a high chi-square value (28.2), we constructed a bubble plot of VA recurrences with respect to maximum duration of follow-up (Figure S2). Follow-up duration did not affect the VA recurrence rate in the meta-regression model.

### 3.3 | Study heterogeneity

Outcomes of epicardial approach and VA recurrences had high heterogeneity, as evidenced by $I^2 > 50\%$. We therefore prepared funnel plots for these outcomes to examine publication bias (Figure S1). However, because fewer than 10 studies were included in the meta-analysis, the test’s power may have been too low to detect true asymmetry from chance, and thus no definitive inference can be drawn. Although a random effects model was used, and sensitivity analyses were performed for these two outcome variables, none of the studies included in the analyses contributed to major heterogeneity.

For VA recurrence, heterogeneity was denoted by $I^2 > 90\%$. However, tau^2, which is a direct estimation of inconsistency, was low (0.14). Because of the variable length of follow-up and a high chi-square value (28.2), we constructed a bubble plot of VA recurrences with respect to maximum duration of follow-up (Figure S2).

### 4 | DISCUSSION

To our knowledge, this is the first meta-analysis comparing procedural characteristics and long-term outcomes of catheter ablation for
VA in both ICM and NICM patients. The main findings of the analysis are that NICM had lower acute and long-term success rates compared with ICM. In addition, procedural aspects of catheter ablation vary by substrate, with epicardial access more commonly employed in NICM patients and substrate mapping more commonly performed in ICM patients.

4.1 Baseline characteristics

Critical baseline characteristics at the time of catheter ablation differed by cardiomyopathy type. Patients with NICM had worse functional status, despite being younger and having better left ventricular systolic function, compared with the ICM group. Higher rates of ICD with or without CRT in the NICM group may reflect more advanced disease and worse functional status. All of these factors influence presentation, referral patterns for move advanced therapies, and as a consequence response to both AADs and catheter ablation.

NICM patients commonly have less cardiovascular comorbidity. This was shown in the study by Muser et al, in which patients with NICM had significantly less hypertension, diabetes, hyperlipidemia, and atrial fibrillation or flutter. Patients with VA included in our analysis had already been on two or more AADs before catheter ablation was performed. In a study by Frankel et al, approximately two-thirds of NICM patients were referred late for catheter ablation, after amiodarone escalation and multiple VA episodes. In the present study, NICM patients were younger than ICM patients, and this may reflect a need for earlier referral due to cardiomyopathy progression and decline in functional status.

4.2 Procedural characteristics

Most studies have used standard programmed electrical stimulation of the left ventricle from the right ventricle to induce faster VT, with up to triple extra stimuli having at least two drive cycle lengths for arrhythmia induction. In our analysis, we observed some variance in induction approaches: Goya et al used just two extra stimuli; in the study by Muser et al, 52% of patients underwent a repeat noninvasive programmed stimulation 2-4 days after catheter ablation to induce residual VA. Goya et al also mapped and ablated stable VA during arrhythmia; unstable VA was
mapped during sinus rhythm or by substrate modification. Muser et al did voltage-based substrate mapping in their sample of patients with electrical storm, due to the instability of arrhythmia-based mapping. Similar substrate mapping was also used by Kumar et al, but key data were not presented in that manuscript. Ablation strategies based on substrate delineation, late-potential ablation, and scar modification are not always applicable in NICM, given the heterogeneity of the disease and the lack of endocardial substrate. Kumar et al reported that 25% (91/358) of ICM patients and 27% (78/289) of NICM patients underwent more than one VA ablation procedure.

Procedural time was longer for the NICM group than for the ICM group, but the difference was not statistically significant. Overall, the longer procedure times in the NICM group might be explained by more frequent utilization of an epicardial approach and the presence of heterogeneous substrate. Mean procedure time in Muser et al was greater than that in Dinov et al, probably because all patients of Muser et al underwent substrate mapping as a consequence of having presented in electrical storm. General anesthesia was used in one-third of those patients, and ablation time was longer.

The standard access to the left ventricle was retrograde across the aortic valve in the study by Goya et al and antegrade via a transseptal puncture in Dinov et al. Fluoroscopy time was significantly higher in the NICM group than in the ICM group in Dinov et al. However, overall fluoroscopy time was not significantly different among both the groups in our meta-analysis, with a mean difference of −2.76 minutes.

Ablation time was significantly longer in the ICM group than the NICM group in the study by Kumar et al, as radiofrequency applications were repeated in target areas until they were rendered electrically unexcitable, with unipolar pacing at 10 milliamps and a 2-millisecond pulse width. Ablation time was longer in the study by Muser et al, as all patients presented with electrical storm, and ablation time was increased to >3 minutes at sites associated with transient VT suppression.

In a recent meta-analysis by Romero et al, a combination approach comprising endocardial and epicardial mapping and ablation was associated with a lower risk for VA recurrence, compared with endocardial approaches alone. In that meta-analysis, sensitivity analysis suggested a lower risk when a combination approach was used in patients with ICM (RR: 0.43) and in patients with arrhythmogenic right ventricular cardiomyopathy (RR: 0.59), compared with NICM patients (RR: 0.87). The combination approach also significantly increased procedural risk (RR: 2.62). However, our current aggregate data did not show that a combination approach improved outcomes in NICM patients to the degree that they would be similar to ICM patients. Although the complication rate did not increase, procedural time was lengthened.

Kumar et al related procedural failure to long-term VA recurrence risk and all-cause mortality in the ICM and NICM groups. In the study by Goya et al, acute success was achieved in all NICM patients. Muser et al reported that at least one VT with cycle length >250 milliseconds was inducible in 26% of patients with ICM and in 32% of patients with NICM. In multivariable analysis, inducibility of any VT with a cycle length >250 milliseconds at the end of the procedure was the only variable independently associated with VT recurrence during follow-up. In Dinov et al, procedural failure or partial success was associated with VA recurrence in both the ICM and NICM groups. Overall, procedural failures were significantly more frequent in NICM patients than in ICM patients and were consistent with unhealthier long-term outcomes. Tau² and I² were 0, and chi-square was 0.90, which was relatively low given the large sample size (769 NICM patients and 410 ICM patients). Thus, the heterogeneity factor is likely not of importance.

The HELP VT trial found no significant differences in procedure-related complications between the two groups. In ICM subjects the most common major complication was access-related (4.8%), followed by worsening of heart failure (1.8%), third degree atrio-ventricular block (1.2%) and pneumonia or acute respiratory distress syndrome (3.2%). Muser et al reported pericardial effusion (2.6%) as the commonest complication among ICM subjects and coronary artery occlusion (2.8%) as the most frequent complication in NICM group. Kumar et al also did not find any significant difference in complications between the two groups. Overall, our meta-analysis also did not report any significant difference in complications between the two groups.

### 4.3 Long-term outcomes

Mortality data were extracted either from reported study results or from Kaplan-Meier survival curves. Overall, mortality trended higher in the ICM group compared with the NICM group but did not reach statistical significance. Although the 1.37 relative risk indicates a 37% greater risk in the ICM group, this needs to be considered cautiously, as the P-value for the overall effect was .31. This may be explained in part by the relatively older age and the more-severe left ventricular dysfunction in the ICM cohort and the higher use of ICD with or without CRT in the NICM group. Other factors that may provide insight into the higher ICM mortality rate are race or ethnic composition, economic status, genetic make-up, and lifestyle, which at times may be factored into Kaplan-Meier estimations of survival. Further, the morphological substrate for ICM is often fixed, whereas in NICM there are multiple factors that lead to the progression and modification of the arrhythmia substrate over time. Although VT ablation can successfully modify the existing substrate at the time of the procedure, it generally will not impede disease progression or the formation of new substrates or new triggers.

Calculating the attributable risk (AR) is another approach to evaluating mortality rates. AR is the difference in the probabilities of mortality between two groups. The RR of 1.37 for all-cause mortality takes into account the weights attached to each one of the four studies. If RR were computed using the raw data for all-cause mortality, the probability of mortality would be .3524 in ICM and .2295 in NICM. The difference between these two probabilities is .1229; the other variables were considered to be equal, and factors modifying arrhythmia substrates were ignored. This means that 12.29% of the reduction in mortality could be attributed to the intervention factor in the NICM group.

AR can also be measured by the etiological fraction, according to the following formula: etiological fraction = (MortalityICM − MortalityNICM) / (MortalityICM − MortalityNo intervention)
Study limitations

In this analysis, amiodarone was prescribed similarly after catheter ablation of VA in both the ICM and NICM groups, such that the arrhythmia-related outcomes are comparable. To improve catheter ablation approaches for those with NICM, patients will need to be further categorized by specific type of NICM, because the underlying mechanisms vary greatly; analysis results can then be compared. Of note, exercised abundant caution in interpreting the outcomes data is presented in Table 2, so as to avoid Type I (α) or Type II (β) errors.

4.4 Study limitations

This study should be interpreted in light of certain methodological limitations. The number of studies is small, and the study of Kumar et al contributed the lion share of patients. This is particularly problematic since it seems that ablation was the primary treatment strategy in Kumar et al, because most of the patients in that series did not have an ICD. This issue is particularly important since, in majority of cases, ablation is not pursued as a primary treatment strategy except in patients with VT and otherwise normal hearts. Baseline characteristics of the ICM and NICM cohorts were not similar in the meta-analysis. No uniform mapping or ablation protocol was followed across the studies, and follow-up periods were variable. The $I^2$ value was 90% in the analysis of VA recurrence data. Subgroup analysis or meta-regression analysis could not be completed due to lack of data; similarly, funnel plots could not be interpreted formally due to the small number of studies.

5 CONCLUSIONS

Despite significantly longer procedural times for catheter ablation in NICM, procedural failures and VA recurrences were significantly more common in that group which may be attributed to heterogeneous substrate, unpredictable disease progression, and widely varying underlying mechanisms. These aggregate procedural characteristics and their associated outcomes highlight the limitations of catheter ablation for NICM, given our current knowledge and tools. The mortality trend we observed in ICM patients probably reflected their older age, more-advanced left ventricular systolic dysfunction, and less-frequent use of ICD or CRT. Prospective studies are needed to address short- and long-term outcomes of catheter ablation of VA in NICM patients, with further definition of their cardiomyopathy subtype and adequate follow-up duration.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest that could be perceived as prejudicing the impartiality of the research reported.

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SUPPORTING INFORMATION
Additional supporting information may be found online in the Supporting Information section at the end of the article.

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