# **DEVICE THERAPY**

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# ICD implantation for secondary prevention in patients with ventricular arrhythmia in the setting of acute cardiac ischemia and a history of myocardial infarction

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# **Abstract**

Introduction: In patients with a prior myocardial infarction (MI) but preserved left ventricular (LV) function, sustained ventricular arrhythmias (VAs) may arise in the setting of an acute coronary syndrome (ACS). It is unknown whether an implantable cardioverter-defibrillator (ICD) is mandatory in these patients as VA might be triggered by a reversible cause. The purpose of this study is to analyze the benefit of ICD therapy in this patient population.

Methods: We conducted a retrospective observational study in ICD recipients implanted from 2008 to 2011. The study group consisted of patients with sustained VA in the setting of an ACS, with a history of MI, but with left ventricular ejection fraction (LVEF) greater than 35 (group A). The two control groups consisted of patients admitted with VA with a history of MI, but without ACS at presentation, either with LVEF greater than 35% (group B) or  $\leq$ 35% (group C). The primary endpoint was the number of patients with appropriate ICD therapy (antitachycardia pacing or shock).

**Results:** A total of 291 patients were included with a mean follow-up of 5.3 years. Appropriate ICD therapy occurred in 45.6% of the patients in group A vs 51.6% and 60.4% in groups B and C (P = .11). In group A, 31.1% received an appropriate ICD shock vs 34.7% and 44.3% in control groups B and C (P = .12).

**Conclusion:** On the basis of these data, ICD implantation seems warranted in patients with history of MI presenting with VA in the setting of an ACS, despite preserved LV function and adequate revascularization. Further trials, preferably randomizes, should be performed to address these findings.

## KEYWORDS

acute coronary syndrome, ICD, secondary prevention, ventricular arrhythmia

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## 1 | INTRODUCTION

Several large-randomized trials showed that secondary prevention with an implantable cardioverter-defibrillator (ICD) is indicated for patients surviving life-threatening ventricular arrhythmia (VA) due to the high risk of recurrence. <sup>1-3</sup> A primary prevention ICD indication exists for patients with left ventricular ejection fraction (LVEF) less than 35% at high risk for future VA due to their arrhythmic substrate. VA triggered by a correctable cause such as acute cardiac ischemia is considered not a standard indication for an ICD in patients with a preserved LVEF greater than 35%. <sup>1,2,4,5</sup>

In patients with a prior myocardial infarction (MI) but an LVEF less than 35%, sustained VA may suddenly arise in the setting of acute cardiac ischemia. There is limited data available to determine whether this constitutes an indication for secondary prevention, or whether the VA should be considered to be caused by a reversible clinical situation that does not necessarily warrant ICD implantation after adequate revascularization.

In the antiarrhythmics versus implantable defibrillator (AVID) trial, the value of ICD implantation for secondary prevention of sudden cardiac death (SCD) was analyzed. A subanalysis of this trial, published in 2001, suggested that patients with a reversible cause of VA remain at high risk for recurring VAs,<sup>6</sup> but this did not lead to specific recommendations or changes in SCD prevention guidelines. There is, however, a need for more long-term follow-up data to assess the risk of recurring VA and the necessity of ICD implantation for secondary prevention purposes in this specific patient category. Patients with a secondary prevention ICD have a higher rate of appropriate ICD therapy as compared to primary prevention.<sup>7-9</sup> However, it is not known whether this also applies to patients with both a transient or correctable cause of the VA as well as a myocardial scar as a substrate.

The purpose of the present study is to retrospectively analyze the benefit and risk of ICD therapy in patients with a prior MI presenting with VA in the setting of acute cardiac ischemia despite adequate revascularization and a preserved LVEF.

# 2 | METHODS

The present study is a retrospective observational multicenter study. Patients were retrospectively included over a time period of 4 years from 1 January 2008 to 31 December 2011. All consecutive patients with ICD implantation for secondary prevention purposes were screened for eligibility. Patients in the study group (group A) were eligible if they manifested all of the following: (a) history of MI at least 6 weeks before index presentation; (b) presentation with sustained ventricular tachycardia (VT) or ventricular fibrillation (VF); (c) a diagnosis of acute coronary syndrome (ACS) at presentation based on history, electrocardiogram (ECG), laboratory values, and/or (non) invasive imaging, treated with revascularization therapy through coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI). Patients could also be included if no revascularization was performed, but the diagnosis of ACS was verified by means

of history, ECG, lab, and (non)invasive imaging; (d) preserved LVEF of greater than 35%; and (e) ICD implantation following the event at presentation. Two control groups were defined consisting of patients with ischemic heart disease and an established secondary prevention ICD indication after surviving VA in the absence of acute ischemia as a triggering event for VA; group B consisted of patients with a prior MI with an LVEF of greater than 35%, while patients in group C had a prior MI with an LVEF ≤ 35. Patients with a contraindication for ICD implantation or with a life expectancy less than 1 year were not implanted with an ICD and excluded from the current analysis.

Data were collected from the patients' hospital files and device follow-up records. The primary endpoint was the number of patients with appropriate ICD therapy (antitachycardia pacing [ATP] and shocks). Secondary endpoints were the number of patients with an appropriate ICD shock, the occurrence of inappropriate ICD therapy, and all-cause mortality.

From a pathophysiological perspective, ischemia triggered VA is more likely to present as polymorphic VT or VF than monomorphic VT. On the basis of this principle, we performed a subanalysis in patients presenting with either VT or VF.

After the ICD implant, patients were periodically followed in the outpatient clinic by the implanting hospital or by a referring hospital. ICD interrogation was performed biannually according to a fixed schedule. In the case of arrhythmias or ICD therapy, data were monitored for appropriate or inappropriate ICD therapy. ICD settings were left to the discretion of the treating physician. The study was approved by the Local Ethics Committee of the St. Antonius Hospital and in accordance with the Declaration of Helsinki.

## 2.1 | Statistical analysis

Continuous variables are presented as mean  $\pm$  one standard deviation. Comparative analysis was performed using the two-tailed t test for continuous variables and  $\chi^2$  test for discrete variables. Kaplan-Meier analysis was performed to assess time free from ICD therapy and survival; P < .05 was considered statistically significant.

# 3 | RESULTS

# 3.1 | Baseline

A total of 291 patients were included in three centers, 90 of whom (30.9%) in the study group A, 95 (32.6%) in group B, and 106 patients (36.5%) in group C. The baseline characteristics are shown in Table 1. Mean age was  $67.2 \pm 9.5$  years, and 84.9% of the patients were male. At the index event, more patients presented with VF in the study group compared to the control groups (66.7% vs 44.1% and 47.5%; P = .006). During hospitalization for the index event. 91% of the patients in the study group underwent coronary revascularization (51.5% PCI and 39.1% CABG). The mean LVEF

TABLE 1 Baseline characteristics

	Study population A N = 90 (30.9%)	Control group B LVEF > 35% N = 95 (33.7%)	Control group C LVEF < 35% N = 106 (36.4%)	P value
Male sex	81 (90.0%)	76 (80.0%)	90 (84.9%)	.17
Age at implantation ICD	67.1 ± 9.1	67.1 ± 8.7	67.5 ± 10.4	.95
History Location infarction Anterior wall Inferior wall	38 (46.3%) 31 (37.8%)	22 (25.3%) 54 (62.1%)	47 (46.1%) 43 (42.2%)	.010
Other PCI	13 (15.9%) 23 (26.7%)	11 (12.6%) 35 (37.6%)	12 (11.8%) 34 (33.3%)	.0
CABG Atrial fibrillation LVEF	18 (20.7%) 23 (26.4%) 41.5 ± 11.3	28 (30.1%) 24 (26.4%) 42.4 ± 8.8	39 (39.4%) 31 (29.8%) 30.5 ± 7.8	. <b>022</b> .83
Creatinine mean  Medication Aspirin	108 ± 65 53 (64.6%)	90 ± 19 49 (57.6%)	105 ± 43 48 (53.3%)	.32
P2Y12 inhibitor Vitamin K antagonist Beta blocker	11 (13.4%) 17 (20.7%) 46 (56.1%)	15 (17.6%) 26 (30.6%) 45 (52.9%)	7 (7.8%) 36 (40.0%) 57 (62.6%)	.15 . <b>024</b> .41
Sotalol Amiodarone Class I antiarrhythmics	5 (6.1%) 2 (2.4%) 0 (0%)	11 (12.9%) 7 (8.2%) 4 (4.7%)	4 (4.4%) 10 (11.0%) 1 (1.1%)	.084 .092 .084
Calcium channel blocker Digoxin Statin ACE inhibitor/ARB	13 (15.9%) 3 (3.7%) 64 (78.0%)	16 (18.8%) 3 (3.5%) 66 (77.6%)	12 (13.2%) 8 (8.8%) 66 (72.5%)	.59 .24 .63 .57
Diuretics Aldosterone inhibitor	51 (63.0%) 22 (26.8%) 12 (14.8%)	53 (62.4%) 18 (21.2%) 5 (6.0%)	63 (69.2%) 44 (48.4%) 18 (19.8%)	.01 .027
Index event Rhythm on presentation Ventricular fibrillation	56 (66.7%)	41 (44.1%)	48 (47.5%)	<.01
Ventricular tachycardia ACS STEMI NSTEMI Unstable angina Revascularization PCI CABG	28 (33.3%) 43 (100%) 16 (21.6%) 50 (67.6%) 8 (10.8%) 77 (85.6%) 46 (51.5%) 34 (39.1%)	52 (55.9%)	53 (52.5%)	
LVEF	40 ± 11	44 ± 7	25 ± 6	
ICD 1 Chamber 2 Chamber CRTD Subcutaneous ICD	30 (34.1%) 51 (58.0%) 2 (2.3%) 5 (5.7%)	31 (32.6%) 60 (63.2%) 2 (2.1%) 2 (2.1%)	39 (36.8%) 51 (48.1%) 14 (13.2%) 2 (1.9%)	<.01

Abbreviations: ACE, angiotensin-converting enzyme; ACS, acute coronary syndrome; ARB, angiotensin-receptor blocker; CABG, coronary artery bypass grafting; CRTD, cardiac resynchronization therapy defibrillator; ICD, implantable cardioverter-defibrillator; LVEF, left ventricular ejection fraction; NSTEMI, non-ST elevation myocardial infarction; PCI, percutaneous coronary intervention; STEMI; ST-elevation myocardial infarction.

Note: Bold values P < .05 is considered significant.

was  $40\% \pm 11\%$  in the study group,  $44\% \pm 7\%$  in group B, and  $25\% \pm 6\%$  in group C. By definition, the LVEF was higher in group A compared to group C, but the difference with group B also reached statistical significance (P = .008). Patients in group C also received cardiac resynchronization therapy defibrillators (13.2%) more often than patients in the study group A (2.2%) and control group B (2.1%).

# 3.2 | Outcome

The primary and secondary outcomes are presented in Table 2. Over a mean follow-up of  $5.3\pm1.7$  years, the primary endpoint of appropriate ICD therapy (either ATP or shock) occurred in 45.6% of the patients in the study group A vs 51.6% and 60.4% in control groups B and C, which was not statistically significant (P=.11). The number of patients

TABLE 2 Main results

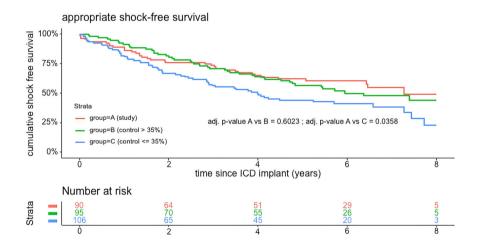
	Study group N = 90 (30.9%)	Control group LVEF > 35% N = 95 (33.7%)	Control group LVEF< 35% N = 106 (36.4%)	P value
Mean follow-up, y	$5.3 \pm 2.3$	$5.4 \pm 2.2$	5.0 ± 2.4	.43
ICD therapy	45 (50.0%)	54 (56.8%)	66 (62.3%)	.12
Appropriate ICD therapy	19 (44.2%)	28 (54.9%)	36 (69.2%)	.11
Appropriate shock	28 (31.1%)	32 (33.7%)	47 (44.3%)	.12
Inappropriate shock	9 (10.0%)	13 (13.7%)	8 (7.5%)	.36
Mortality	15 (16.7%)	19 (20.0%)	31 (29.2%)	.087

Abbreviations: ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction.

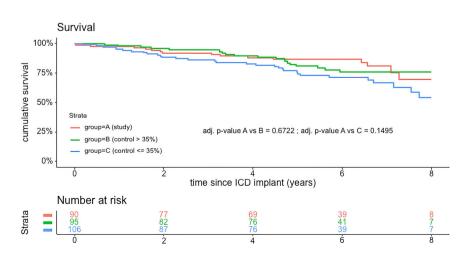
with appropriate therapy in group C was higher than in group A (P = .045). There were no statistically significant differences in the number of patients with an appropriate ICD shock, with 31.1% in the study group A vs, respectively, 33.7% and 44.3% in the control groups B and C (P = .12), although there was a trend toward more appropriate shocks in group C. In the patients who received an appropriate ICD shock, the mean time to first appropriate shock was  $2.0 \pm 1.7$ ,  $2.6 \pm 2.1$ , and  $2.0 \pm 0.7$  years for the three groups. Figure 1 shows the Kaplan-Meier curves of time free of appropriate ICD shock over the complete follow-up for the three groups.

In the study group A, 50.0% of the patients received ICD therapy (appropriate and inappropriate) vs 56.8% and 62.3% in the control groups (P = .23). Inappropriate shock rate was similar in all three groups (10.0%, 13.7%, and 7.5%, respectively; P = .36).

During follow-up, overall mortality was 16.7% in the study group A, 20.0% in group B, and 29.2% in group C (P = .087). Although mortality was almost twice as high in group C compared to group A, this did not reach statistical significance. The Kaplan-Meier curves for mortality during follow-up are shown in Figure 2. Table 2 lists the results of the primary and secondary endpoints.



**FIGURE 1** Kaplan-Meier curve for time free of appropriate ICD shock. ICD, implantable cardioverter-defibrillator



**FIGURE 2** Kaplan-Meier curve for survival. ICD, implantable cardioverter-defibrillator

**TABLE 3** Endpoints selected on VF at presentation

	Study group	Control group LVEF > 35%		
N = 56 (62.2%)	N = 41 (43.1%)	N = 48 (45.2%)	Control group LVEF < 35%	P value
ICD therapy	20 (35.7%)	18 (43.9%)	35 (72.9%)	<.01
Appropriate ICD therapy	17 (30.4%)	16 (39.0%)	33 (68.8%)	<.01
Appropriate shock	12 (21.4%)	10 (24.4%)	27 (56.2%)	<.01
Inappropriate shock	6 (10.7%)	5 (12.2%)	4 (8.3%)	.84

Abbreviations: ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; VF, ventricular fibrillation. *Note*: Bold values *P* < .05 is considered significant.

In patients with VF at presentation, patients in group A had significantly less (appropriate) ICD therapy compared to patients in control groups B and C (30.4% vs 39.0% and 69.8%; P < .01) (Table 3). No differences in inappropriate therapy were observed in patients presenting with VT (Table 4).

# 4 | DISCUSSION

The population described in our current study represents a gap in our evidence-based knowledge of secondary prevention ICD indications in patients with ischemic heart disease. Patients with VA in the setting of ACS and prior MI with preserved LV function, on the one hand, have a reversible trigger (ACS) which may cause VA, the ACS, but on the other hand, these patients also have an irreversible substrate for VA in the form of the scar of the prior MI. Given the potential complications associated with ICD implantation, there is a definite need for data supporting the indication for ICD implantation. In this study, these patients were retrospectively analyzed for appropriate and inappropriate ICD therapy and compared to patients with an acknowledged guideline ICD indication for secondary prevention without ACS (divided into two groups, either with a preserved or severely reduced ejection fraction).

The most important outcome of this analysis is that there is a considerable and similar need for ICD therapy in the study group of patients with VA triggered by an ACS as compared to both control groups without an ACS as a possible trigger. Comparing appropriate therapy (ATP and shocks), 45.6% of the patients in the study group received appropriate ICD therapy during the mean follow-up of 5.3 years, similar to secondary prevention patients with LVEF greater than 35% without ACS, and, as expected, lower than in secondary prevention patients with a severely depressed LV function. The same observation

was made for ICD shocks alone with 31.1% of patients receiving any appropriate shock. This implicates that there is a true benefit of ICD implantation in patients with VA in the setting of an ACS and a remote MI. As we do not have a control group of patients with a history of MI presenting with VA in the context of an ACS who were not implanted with an ICD, we were not able to compare the patients included in this analysis with patients in whom ICD implantation was deferred.

# 4.1 | Appropriate therapy

It is interesting to consider the differences in event rates between this population, and other primary and secondary prevention populations with an acknowledged guideline indication for ICD therapy. The incidence of appropriate ICD therapy in the study population with a documented VT/VF event is higher than in patients with a conventional primary prevention indication (17%-23% over follow-up up to 5 years). <sup>10-13</sup> In a recent analysis, Providencia et al <sup>14</sup> reported 22.2% appropriate ICD therapy in primary prevention patients during more than 3 years of follow up.

On the other hand, the LVEF of 40% is considerably higher than in the previously mentioned primary prevention trials, and the revascularization might be considered protective against future arrhythmia. In the CABG-PATCH trial, no mortality benefit was observed for concomitant ICD implant at the time of CABG in patients with a reduced LVEF. Although this was a primary prevention trial, revascularisation was considered protective for the primary endpoint mortality. However, CABG in the setting of multivessel disease is different from PCI of single-vessel disease, which was the most frequent treatment in our cohort. In our patient population, revascularization was insufficient in preventing recurrences of VA considering the rate of appropriate ICD therapy. The appropriate

TABLE 4 Endpoints selected on VT at presentation

N = 28 (31.1%)	Study group N = 52 (54.7%)	Control group LVEF > 35% N = 53 (50.0%)	Control group LVEF < 35%	P value
ICD therapy	23 (82.1%)	35 (67.3%)	31 (58.5%)	.098
Appropriate ICD therapy	22 (78.6%)	33 (63.5%)	31 (58.0%)	.19
Appropriate shock	14 (50.0%)	22 (42.3%)	20 (37.7%)	.57
Inappropriate shock	2 (7.1%)	8 (15.4%)	4 (7.5%)	.42

Abbreviations: ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; VT, ventricular tachycardia.

therapy rate was similar to that of group B, an established secondary prevention population, all with an LVEF greater than 35%, although the LVEF was significantly higher in this group. The absolute difference in therapy rate, however, was limited, while these groups were comparable with regard to most other characteristics.

Secondary prevention trials have shown a wide range of appropriate therapy rates, depending on numerous factors, most importantly LVEF and NYHA class. 10-12 A subanalysis of the AVID trial showed that patients with a transient cause of the VA remained at high risk for recurrent VAs, but did not provide exact percentages.<sup>6</sup> Welsenes et al<sup>7</sup> reported a 5-year appropriate therapy rate of 37% for primary prevention and 51% for secondary prevention in a large single-center cohort, whereas Schaer et al<sup>16</sup> report a rate of any ICD therapy of 59.2% after 5-years follow up. Stockburger et al<sup>17</sup> observed an appropriate therapy rate of 29% after over 3 years of follow-up in their secondary prevention ICD cohort. The high shock and ATP rates observed in our population despite revascularization are in line with these reports and seem to justify ICD implantation in patients with an ACS, remote MI, and VAs despite a preserved LVEF. Further trials, preferably randomized, are necessary to evaluate the ICD indication in these patients and to study the effect on mortality.

# 4.2 | Inappropriate shocks

We did not observe a difference in the inappropriate shock rate between the groups. It might be expected that the patients in group C who had a lower LVEF would have had a higher rate of inappropriate shocks (eg, for atrial fibrillation [AF] with high ventricular rate). At baseline, the prevalence of AF was similar, but we have no information on the appearance of AF or other supraventricular tachycardia during follow up. Previous trials specifically identified AF as a predictor for inappropriate therapy. <sup>18,19</sup> Nevertheless, the absolute number of inappropriate shock in this study and control groups was very low, and, therefore, interpretation of these data should be done with caution.

# 4.3 | Mortality

All-cause mortality during follow up was 16.7% in the study group A, 20.0% in the first control group B, and 29.2% in the second control group C. The all-cause mortality rate was highest in the second control group C. This may be explained by the worse LVEF at baseline and the higher prevalence of congestive heart failure. Although the mortality rate was almost twice as high in group C compared to the study group A, this did not reach statistical significance as the study was not designed or powered for this endpoint. Yearly mortality rates in other ICD studies ranged from 4.6% to 10%, comparable with the mortality rates of the second control group C.<sup>3,7,10</sup> On the basis of these observations, we can conclude that aside from the significant risk of VA during follow up, patients with ACS, remote MI, and VA in combination with a preserved LVEF have a very good prognosis.

## 4.4 Determination of ACS

All patients in the study group A were diagnosed with obstructive coronary disease, and almost all of them underwent revascularization during hospitalization. Sometimes it may be difficult to determine whether cardiac enzyme release is secondary to (resuscitated) VT/VF. or due to an ACS. Only in case of an ST-elevation myocardial infarction (STEMI), there usually is no doubt as there is pathognomonic ST elevation. In the present study, however, STEMI was present only in a minority of patients (11.6%). After a period of VA, ST segments can be dynamic due to demand ischemia, which as well can cause elevated troponin levels in the absence of significant stenosis in any main coronary artery branch. Kontos et al<sup>20</sup> describe a troponin rise of at least 10 times the upper limit of normal in 85% of patients presenting with VA, even in most patients without significant coronary artery stenosis at coronary angiogram. In this study, most patients of the study group were diagnosed with ACS non-ST-elevation myocardial infarction (NSTEMI) due to ST-segment depression on electrocardiography after resuscitation and/or elevated troponin levels, as these parameters are key in diagnozing NSTEMI.<sup>21</sup> Although most patients underwent revascularization of documented obstructive coronary disease during coronary angiography, in many cases, this was not typically preceded by functional diagnostic tests to determine ischemia.

It is assumed that VF occurs more commonly in the setting of acute cardiac ischemia and monomorphic VT more in the presence of a substrate such as previous MI.<sup>22–24</sup> This is in line with the results of this study. At the index event, 64.2% of the patients of the study group A presented with VF vs 36.5% and 45.1% in the control groups B and C. The study group with VF at presentation received less appropriate ICD therapy than the patients in the study group presenting with VT, although this group still required 22.9% adequate ICD therapy. This could signify that in the patients presenting with VF, the arrhythmia was more ischemia driven, whereas, in the patients presenting with VT, the pre-existing substrate played a more important role. The subgroups are, however, too small to ascertain these differences.

# 4.5 | Limitations

To the best of our knowledge, this study is the first analysis for secondary prevention ICD implantation in patients presenting with a VA in the setting of ACS and a history of MI, with ICD therapy (appropriate and inappropriate) and mortality as endpoints. This study provides insight in the rate of ICD therapy in this patient population and shows a similar benefit of an ICD implantation in these patients compared to patients with an established secondary prevention ICD indication. An important limitation of this trial is the relatively small sample size. The retrospective nature of this analysis has its corresponding limitations, of which the most important might be the absence of a control group without an ICD. The outcome of this analysis, however, supports the use of ICD therapy in these patients. Direct comparison of these results with previous randomized ICD trials has its limitations because of differences in patient

populations and improved accompanying medical treatment of heart failure and arrhythmias in current times.

Further studies in larger multicenter settings with similar patient populations are necessary to confirm the results of this study.

# 5 | CONCLUSION

Patients with a history of prior MI but preserved LV function presenting with VA in the setting of an ACS have a similar rate of appropriate ICD therapy compared to patients with an established secondary prevention ICD indication, which seems to warrant ICD therapy despite adequate revascularization and preserved LVEF.

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