ORIGINAL ARTICLE

Prognostic impact of inappropriate defibrillator shocks in a population cohort

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ABSTRACT

Background There is a relative paucity of data linking inappropriate implantable cardioverter-defibrillator (ICD) shocks to adverse clinical outcomes.

Objective To examine the association between inappropriate ICD shocks and mortality or heart transplantation in a large population cohort.

Design, setting, patients A cohort study which included all subjects who underwent ICD implantation between 1998 and 2008 and were followed up at our institution.

Main outcome measures Multivariable Cox regression analyses were conducted to investigate the effect of inappropriate shocks on the risk of death and heart transplantation. Appropriate and inappropriate ICD therapies were modelled as time-dependent covariates.

Results A total of 1698 patients were included. During a median follow-up of 30 months, there were 246 (14.5%) deaths and 42 (2.5%) heart transplants. The incidence of inappropriate shocks was 10% at 1 year and 14% at 2 years. In the adjusted model, inappropriate shocks were not associated with death or transplantation (HR=0.97, 95% CI 0.70 to 1.36, p value=0.873). In contrast, appropriate shocks were associated with adverse outcomes (HR=3.11, 95% CI 2.41 to 4.02, p value<0.001). The lack of association between inappropriate shocks and outcomes persisted for those with severely impaired left ventricular function (ejection fraction <30%) and for those receiving multiple inappropriate treatments.

Conclusions In this study, we observed no association between inappropriate ICD shocks and increased mortality or heart transplantation, even among those with severely impaired cardiac function. These findings question whether inappropriate ICD shocks lead to adverse outcomes.

INTRODUCTION

Implantable cardioverter-defibrillators (ICDs) provide rapid identification and effective treatment of lethal ventricular arrhythmias, and also reduce arrhythmic death and all-cause mortality.[1–6] The success of ICD therapy for prevention of arrhythmic death has, nonetheless anticipated risks. After implantation, a significant proportion of patients experience inappropriate shocks for a variety of conditions such as sinus tachycardia, other supraventricular arrhythmias, physiological oversensing or lead failure.

Although improved device software and programming can prevent a significant proportion of inappropriate shocks,[7] they continue to be a significant complication of ICD therapy. ICD shocks, whether appropriate or inappropriate, result in significant psychosocial morbidity.[8–10] Furthermore, there is an established and growing body of experimental reports of the immediate adverse cardiac effects of high-voltage shocks.[11–14]

However, it is not clear whether the adverse effects of inappropriate shocks result in worse clinical outcomes. Therefore, the purpose of this study was to examine the association between inappropriate shocks and death or heart transplantation in a large population cohort.

METHODS

Study population

All patients who received any ICD device at St Paul's Hospital (University of British Columbia) from 1998 to 2008 and who received ongoing follow-up at our institution were eligible. All ICD implantation was performed, after evaluation by an electrophysiologist, in accordance with Canadian and North American guidelines available at the time.[15–17] The study protocol was approved by the research ethics board of our institution.

ICD programming

Programming of detection intervals and treatment for ventricular tachycardia (VT) and fibrillation (VF) were at the discretion of the treating electrophysiologist. Although prespecified standard ICD programming was not used, VF detection intervals were typically set at cycle length ≤320 ms in the early years and ≤250 ms in later years (2005 onwards) of the study. In addition, anti-tachycardia pacing (ATP) was applied as the initial treatment for VT in the majority of patients. To reduce inappropriate shocks due to supraventricular tachycardia or atrial fibrillation, device algorithm-based discriminators were also used in the majority. Device reprogramming was performed after inappropriate shocks to minimise recurrence.

Data sources, follow-up and ICD events

Patients' baseline demographic and clinical characteristics together with ICD specifications were collected prospectively at the time of implant. Outcome measures were also collected prospectively. This information was supplemented by a retrospective review to ascertain the timing and nature of ICD therapy.

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After implant, follow-up and management were directed by the primary responsible electrophysiologist. All subjects were evaluated 4–6 weeks after implant then followed up every 3–6 months. Routine visits included device interrogation and retrieval of stored intracardiac electrograms. Subjects were censored at the time of loss to follow-up, the occurrence of an outcome or termination of the study (31 December 2010).

The adjudication of appropriate therapy from inappropriate shocks was made by the responsible electrophysiologist. Appropriate ICD therapy included ATP and/or shock delivery triggered by sustained VT or VF. An event where both appropriate ATP and shock(s) were delivered during the same episode was classified as an ICD shock. An inappropriate shock was defined as any shock which was delivered for a cause other than VT/VF. The causes of inappropriate shocks were classified as (1) sinus/other 1:1 supraventricular tachycardia, (2) atrial flutter/fibrillation, (3) oversensing, (4) lead failure and (5) others. Inappropriate ATP was not analysed in this study. Separate ICD therapy episodes of the same type occurring within 5 min or multiple shocks during the same episode were classified as a single episode.

Outcomes

The adjudicated outcomes were all-cause mortality or heart transplantation. Death was ascertained through contact with the patient's family and confirmed using a linkage with the Medical Services Plan (the government-provided universal health plan) for British Columbia. Cardiac transplantation data were available from our institutional records, being the only cardiac transplant centre in British Columbia. Ventricular assist devices are only used as a bridge to transplantation in British Columbia and therefore they were not included as a separate outcome.

Statistical analysis

Patient baseline characteristics were expressed as mean±SD or count and percentage. Cumulative event rates were estimated by the Kaplan–Meier method. Risk factors for inappropriate shocks were evaluated using multivariable Cox regression analysis.

The effects of the type of ICD therapies on the outcome were evaluated using multivariable Cox proportional hazards regression. The predefined confounding variables of interest were age, gender, aetiology of heart disease, resynchronisation device, primary versus secondary prevention, diabetes, renal failure, atrial fibrillation, functional class, left ventricular ejection fraction (LVEF), β blocker usage and antiarrhythmic usage. In the primary analysis, a regression model was created with separate time-dependent variables for inappropriate shock and appropriate therapy.

We also carried out a number of prespecified secondary analyses. A sensitivity analysis was performed using a second model in which a single time-dependent variable of ICD therapy was created that contained four levels: (1) no therapy, (2) appropriate therapy, (3) inappropriate shock and (4) both appropriate therapy and inappropriate shock. As the presence of severe left ventricular dysfunction may influence the impact of inappropriate shocks, a stratified analysis was also performed by baseline LVEF (>30% and ≤30%). In order to examine a potential dose–response relationship, a further analysis was undertaken comparing outcomes among those receiving multiple or one/no inappropriate shocks.

All statistical analyses were carried out using SAS 9.1 (Cary, North Carolina, USA) and R 2.12.

RESULTS

Patient population

A total of 1845 patients underwent new ICD implantation at our institution between 1998 and 2008. Of these, 147 (8.0%) received their follow-up at other centres and were hence excluded owing to inability to ascertain outcome. The remaining 1698 patients comprised the study population.

The baseline characteristics of the entire study population are presented in table 1. The mean age was 61.5 years with a male preponderance (81.8%). The most common underlying cardiac condition was ischaemic cardiomyopathy (58.2%) and just over half of the devices (50.8%) were implanted for primary prevention. The mean LVEF for the overall population was 34.7%.

The median duration of follow-up was 30.0 months (range 0.13–145). During follow-up, there were 246 deaths (14.5%) and 42 subjects underwent heart transplantation (2.5%).

ICD therapy

Over the study period, 10 444 episodes of appropriate therapy occurred in 585 patients (34.5% of the total patient population). There were 714 episodes of inappropriate shocks that occurred in 281 patients (16.5% of total patient population).

Seven hundred and forty-six patients received ICD therapy, with 465 (27.4% of total patient population) receiving appropriate therapy alone, 161 (9.5%) receiving inappropriate shock (s) alone and 120 (7.1%) receiving both types of treatment.

The cumulative incidence of inappropriate shocks was 10% at 1 year and 14% at 2 years. Two or more inappropriate shocks occurred in 151/281 patients (53.7%). The incidence of a second inappropriate shock was 27% at 1 year and 37% at 2 years, from the time of the first inappropriate shock.

The most common causes for inappropriate shocks were sinus/other 1:1 tachycardia (45.2%) and atrial flutter/fibrillation (42.7%). Inappropriate shocks due to P or T wave oversensing occurred in 23/281 patients (8.2%) and lead failure was found in 24 (8.5%). Other rare causes (eg, electromagnetic interference, loose set screw) occurred in four patients (1.4%).

Risk factors for inappropriate shock

The characteristics of patients with inappropriate shocks, in comparison with those without, are shown in table 1. The former were significantly younger, more likely to have non-structural heart disease, more likely to have had a prior history of atrial flutter/fibrillation, less likely to be taking β blockers and more likely to be taking class III antiarrhythmic agents.

Multivariable Cox proportional hazards regression was performed to identify independent risk factors for inappropriate shocks. In the multivariate model, younger age (HR=0.82, 95% CI 0.75 to 0.90, p<0.001), prior atrial flutter/fibrillation (HR=1.83, 95% CI 1.39 to 2.42, p<0.001) and higher functional class (class 1–2 vs 3–4; HR=1.66, 95% CI 1.05 to 2.64, p=0.031) were independent predictors of inappropriate shocks. The indication for ICD implantation (primary vs secondary prevention) was a borderline significant independent predictor (p=0.052), with a trend towards increased inappropriate shocks in secondary-prevention patients. The type of device (single chamber vs dual/CRT) did not influence the risk of inappropriate shocks in the multivariate analysis.

Prognostic implications of inappropriate shocks

During the median follow-up period of 30.0 months, there were 246 deaths (14.5%) and 42 patients (2.4%) underwent heart transplantation.

Table 1 Baseline characteristics of patients by inappropriate shocks

Characteristics	Overall population (N=1698)	Patients receiving ≥1 inappropriate shock (N=281)	Patients without inappropriate shock (N=1417)	p Value*
Demographic				
Male, N (%)	1389 (81.8)	220 (78.3)	1169 (82.5)	0.095
Age (years), mean±SD	61.5±13.5	57.5±15.1	62.3±13.0	≤0.001
Cardiac condition, N (%)				
Non-structural heart disease	110 (6.5)	23 (8.2)	87 (6.1)	0.002
Ischaemic cardiomyopathy	988 (58.2)	137 (48.8)	851 (60.1)	
Non-ischaemic cardiomyopathy	600 (35.3)	121 (43.1)	479 (33.8)	
ICD indication, N (%)				
Primary prevention	863 (50.8)	112 (39.9)	751 (53.0)	≤0.001
Secondary prevention	835 (49.2)	169 (60.1)	666 (47.0)	
Clinical parameters, N (%)				
Hypertension	634 (37.3)	96 (34.2)	538 (38.0)	0.228
Diabetes	367 (21.6)	45 (16.0)	322 (22.7)	0.013
Atrial flutter/fibrillation	419 (24.7)	85 (30.2)	334 (23.6)	0.018
Renal failure	315 (18.6)	42 (14.9)	273 (19.3)	0.089
Prior revascularisation	733 (43.2)	91 (32.4)	642 (45.3)	≤0.001
NYHA class 3–4	289 (17.0)	22 (7.8)	267 (18.8)	≤0.001
LVEF (%), mean±SD	34.7±14.8	39.3±15.5	33.8±14.4	0.002
Drugs, N (%)				
β Blocker	1252 (73.7)	178 (63.3)	1074 (75.8)	≤0.001
Class I antiarrhythmic	47 (2.8)	10 (3.6)	37 (2.6)	0.376
Class III antiarrhythmic	601 (35.4)	114 (40.6)	487 (34.4)	0.047
ICD type, N (%)				
Single chamber	354 (20.8)	67 (23.8)	287 (20.3)	0.009
Dual chamber	1067 (62.8)	185 (65.8)	882 (62.2)	
CRT-D	277 (16.3)	29 (10.3)	248 (17.5)	

*For comparison between patients with and without inappropriate shock(s).
CRT-D, cardiac resynchronisation (with or without an atrial lead); ICD, implantable cardioverter-defibrillator; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association.

In the first multivariable Cox regression model, inappropriate shocks and appropriate therapy were modelled as separate, time-dependent variables (table 2). Notably, in the model, inappropriate therapy was not an independent predictor of death or heart transplantation, with an adjusted HR of 0.97 (95% CI 0.70 to 1.36, p=0.873). Conversely, any appropriate therapy, as compared with no appropriate therapy, was associated with increased risk of death or transplantation with an

Table 2 Multivariable Cox regression for outcomes

	Adjusted HR* (95% CI)	p Value
Primary analysis		
Inappropriate shocks (vs no inappropriate shocks)	0.97 (0.70 to 1.36)	0.873
Appropriate therapy (vs no appropriate therapy)	3.11 (2.41 to 4.02)	<0.001
Both therapy types (vs no therapy)	2.98 (1.95 to 4.56)	<0.001
Secondary analysis		
Inappropriate shocks (vs no therapy)	1.05 (0.58 to 1.90)	0.874
Appropriate therapy (vs no therapy)	3.16 (2.40 to 4.16)	<0.001
Both therapy types (vs no therapy)	2.98 (1.95 to 4.56)	<0.001
Stratified analysis		
LVEF ≤30%		
Inappropriate shocks (vs no inappropriate shocks)	0.79 (0.51 to 1.20)	0.270
Appropriate therapy (vs no appropriate therapy)	2.93 (2.18 to 3.94)	<0.001
LVEF >30%		
Inappropriate shocks (vs no inappropriate shocks)	1.56 (0.88 to 2.78)	0.130
Appropriate therapy (vs no appropriate therapy)	3.55 (2.08 to 6.06)	<0.001

*Adjusted for age, gender, resynchronisation device, renal failure, atrial fibrillation, NYHA functional class, ejection fraction and β blocker usage.
LVEF, left ventricular ejection fraction (except in the stratified analysis); NYHA, New York Heart Association.

adjusted HR of 3.11 (95% CI 2.41 to 4.02, p<0.001). Subjects who received both types of ICD therapy had a similar risk to those receiving appropriate therapy only (HR=2.98, 95% CI 1.95 to 4.56, p<0.001).

The other independent predictors of outcome were increasing age, functional class 3/4, LVEF, the presence of renal failure, atrial fibrillation and lack of β blocker use at baseline. These, and the other non-significant predictors of outcomes included in the model, are summarised in figure 1. The type of heart disease (no structural heart disease, non-ischaemic cardiomyopathy or ischaemic heart disease) did not influence the lack of association between inappropriate shocks and outcome.

Secondary analyses

To assess the robustness of our findings, ICD therapy was then modelled in a secondary analysis as a single, time-dependent variable with four levels (no therapy, inappropriate shocks only, appropriate therapy only and both types of therapy). The results of this model were congruent with our primary analysis (table 2). Inappropriate shocks were not associated with adverse outcomes (HR=1.05, 95% CI 0.58 to 1.90, p=0.874). Patients who experienced both types of ICD therapy also had an increased risk of death or transplantation (HR=2.98, 95% CI 1.95 to 4.56, p<0.001), comparable to that of patients receiving appropriate therapy only.

In the analysis stratified by baseline LVEF (table 2), inappropriate shocks were not associated with adverse outcomes in either the preserved or impaired LV function groups. Among those with an LVEF of ≤30%, the adjusted HR for death or transplantation was 0.79 (95% CI 0.51 to 1.20, p=0.27). Finally, there was no significant difference in outcomes among patients receiving multiple inappropriate shocks (more than one inappropriate shock episode) in comparison with those receiving one or no inappropriate shocks (HR=1.04, 95% CI 0.69 to 1.56).

DISCUSSION

In this cohort study we found no association between inappropriate ICD shock(s) and increased mortality or heart transplantation. This lack of association persisted for those patients with severely impaired LV function (expected to be the most vulnerable) and those receiving multiple inappropriate shocks (no dose–response relationship was seen).

Prognostic impact of inappropriate shocks

The lack of association between inappropriate shocks and adverse outcome in this study, at first glance, differs from the results of prior studies, especially the recently published Multicenter Automatic Defibrillator Implantation Trial—Reduce Inappropriate Therapy (MADIT-RIT).[18]

The purpose of the MADIT-RIT was to evaluate different programming strategies in order to minimise inappropriate therapy. It did not specifically deal with the question of whether inappropriate shocks lead to worse outcomes (although valuable information about those will have been obtained from the trial). The observed increase in mortality in the standard programming arm cannot be extrapolated to mean that inappropriate shocks caused the increase mortality. There was only a modest increase in inappropriate shocks in the conventional programming arm; most of the reduction in ICD events was due to a reduction in inappropriate ATP. Methodological concerns, such as the high rate of loss to follow-up and programming deviations, should give pause. Further information from the MADIT-RIT population with respect to the relationship between inappropriate shocks and mortality (incidence, frequency and temporal relationship) is necessary to explore the underlying reasons for the reduction in all-cause mortality.

The association between inappropriate shocks and adverse outcomes was explored in subgroup analyses of two primary prevention randomised controlled trial populations (the Multicenter Automatic Defibrillator Implantation Trial II (MADIT II) and the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT)).[19 20] When similar methodology to this study was used, inappropriate shocks were found to be independently associated with increased overall mortality. The HRs for death in these studies ranged from 1.98 to 2.29. A subsequent cohort study involving a mixed ICD population also found a borderline association between inappropriate shocks and mortality (HR=1.4, p=0.07).[21]

The reason for these discordant results is not entirely clear but important differences in patient characteristics between our study and previous studies should be noted. The patient populations in the two primary prevention randomised trial subgroup analyses had a significantly worse functional status (66% New York Heart Association (NYHA) 2–4 in MADIT II and 30.5% NYHA 3 in SCD-HeFT) than our population (7.8%

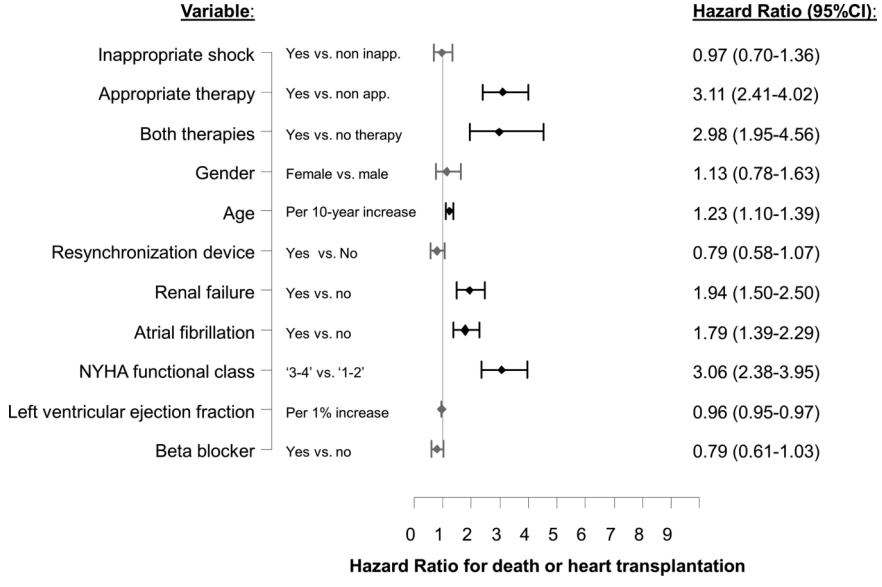

Figure 1 The HRs for death or heart transplantation are plotted for clinical characteristics of interest, including the type of implantable cardioverter-defibrillator therapy received. The HRs were derived from multivariate Cox regression and were adjusted for the other variables presented. app, appropriate; inapp, inappropriate; NYHA, New York Heart Association.

were NYHA 3–4).[19 20] This suggests that these populations might have had a higher risk of heart failure. It might be postulated that inappropriate shocks are only deleterious when patients are vulnerable. However, we found no indication of increased mortality in the subgroup of patients with LVEF ≤30% in this study (akin to the primary prevention trial populations). Furthermore, we found no indication of an interaction between functional status and the relationship between inappropriate shocks and outcome.

β-Blocker usage was surprisingly underused in both of the primary prevention studies (65% in MADIT II and 69% at enrolment in SCD-HeFT) and was lower than in our study (74%). This is despite a higher mean LVEF and greater proportion of secondary prevention patients in this study. β Blocker usage was low (51%) in the study of van Rees *et al*[21] despite a similar patient population to our own.

Lack of β blockade is associated with both an increased risk of inappropriate shocks (in this and prior studies) as well as increased mortality in patients with heart failure and may therefore confound the association between inappropriate shocks and mortality. Statistical adjustment for baseline β blocker use may only partially account for confounding as dose (those achieving target doses) and time-dependent use (compliance and initiation) were not tracked in this or previous studies.

The potential for the lack of β blockade to have been a confounding variable in previous studies is further supported by the remarkably consistent HRs for risk of mortality with appropriate therapy across this and three previous studies. The HR for mortality with appropriate therapy ranged from 2.5 to 3.98 in the three previous studies and was 3.11 in this study.[19–21]

Incidence of inappropriate shocks in ICD recipients

The cumulative incidence of inappropriate shocks in this study (9.6% and 13.7% at 1 year and 2 years, respectively) was similar to that of previous studies. In the MADIT II trial in ischaemic cardiomyopathy, the incidence was 10% and 13% at 1 year and 2 years, respectively.[22] In the only other cohort study examining inappropriate shocks in a diverse population, the cumulative incidence was 7% at 1 year and 13% at 3 years.[21]

Thus the lack of adverse outcomes with inappropriate shocks seen in this study in this study cannot be accounted for by differences in the rate of inappropriate shocks. Nonetheless, our study confirms that inappropriate shocks are common in ICD recipients.

Limitations

This is the largest study to date examining the relationship between inappropriate shocks and outcomes in the ICD population. Despite this, our study had some limitations. Over the period of this study, ICD programming was not standardised and inevitably changed over time. Reassuringly, the overall rate of inappropriate shocks in this study was comparable to that seen in other studies, including those with prespecified programming.

The ICD therapy events were adjudicated only by the treating electrophysiologist and were not independently reviewed. This might have introduced misclassification bias into the results. We also did not systematically track inappropriate ATP events and therefore could not assess their impact on outcomes, though inappropriate ATP had no impact on outcomes in the MADIT II population.[19]

Furthermore, while we attempted to collect all pertinent baseline data, statistical modelling cannot fully account for all potential confounders. We were also not able to account for changes in drug use, arrhythmia diagnoses and heart failure status over time. One cannot ethically randomise patients to receive inappropriate shocks, which is the only means of definitively balancing confounders. Nonetheless, even restriction of our cohort (another method to minimise confounding) in the subgroup analysis of patients with an LVEF≤30% failed to provide a signal of increased risk with inappropriate shocks.

CONCLUSION

In contrast to previous studies, we found no association between inappropriate ICD shocks and increased mortality or heart transplantation, even among those with severely impaired LV function. The findings of this study should not detract from the ongoing clinical effort to minimise inappropriate shocks among ICD recipients. However, these findings do question whether inappropriate ICD shocks are associated with adverse clinical outcomes.

Contributors AQ and CRK conceived the study. MWD, AQ and HQ analysed and interpreted the data. SC, JA-FY-L-W, ST, CK and MTB critically reviewed the manuscript. MWD is the guarantor and accepts responsibility for the overall content.

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