Long-term outcomes of heart failure patients who received primary prevention implantable cardioverter-defibrillator: An observational study

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Abstract

Background: Implantable cardioverter-defibrillator (ICD) therapy is indicated for selected heart failure patients for the primary prevention of sudden cardiac death. Little is known about the outcomes in patients selected for primary prevention device therapy in the northern region of New Zealand.

Method: Heart failure patients with systolic dysfunction who underwent primary prevention ICD/cardiac resynchronization therapy-defibrillator (CRT-D) implantation between January 1, 2007, and June 1, 2015, were included. Complications, mortality, and hospitalization events were reviewed.

Results: Three hundred and eighty-five primary prevention devices were implanted (269 ICD, 116 CRT-D). Mean age at implant was 59.1 ± 11.4 years. Mean duration of follow-up was 3.64 ± 2.17 years. The commonest cause of death was heart failure (41.8%). Only 2 patients died from sudden arrhythmic death. The 5-year heart failure mortality rate was 6%, whereas the 5-year sudden arrhythmic death rate was 0.3%. Heart failure hospitalizations were commoner in those who received ICD than CRT-D (67.7% vs 25.8%, \( P < .001 \)). Maori patients have low implant rates (14%) with relatively high rates of admissions with heart failure and ventricular arrhythmia admissions.

Conclusions: Even in appropriately selected heart failure patients who received primary prevention devices, only a small percentage died as a result of sudden arrhythmic death. CRT-D should be the device of choice where appropriate in heart failure patients. Significant challenges remain to improve access to device therapy and maximize benefit to those who do get implanted.

Keywords
heart failure, implantable cardioverter-defibrillator, left ventricular ejection fraction, New York Heart Association (NYHA) class, sudden cardiac death
1 | INTRODUCTION

Randomized controlled trials have demonstrated the impact of ICD in the primary prevention of sudden cardiac death (SCD) in patients with poor left ventricular function without evidence of documented ventricular arrhythmias.1-5 Under current international guidelines, class I indications for ICD implantation for primary prevention of SCD include patients with:6

1. Left ventricular ejection fraction (LVEF) \( \leq 35\% \) due to previous myocardial infarction (MI) who are ≥40 days post-MI and are in New York Heart Association (NYHA) class II or III,
2. Nonischemic cardiomyopathy (NICM) with LVEF \( \leq 35\% \) and who are NYHA class II or III and
3. Pre-existing ischemic cardiomyopathy (ICM) with LVEF \( \leq 30\% \) and are in NYHA class I.

A number of studies in the United Kingdom estimated the required ICD implant rate to meet National Institute for Health and Clinical Excellence (NICE) recommendations for primary and secondary prevention vary between 100 and 150/million/y.7,8 New Zealand traditionally has had lower numbers of new implants/million population for ICD.9,10 In 2007, the ICD implant rate in New Zealand was 41/million population compared with Australia (145/million), the United States (577/million), and Western Europe (140/million).9-12 About 27% of implanted devices were for primary prevention indications.9 Since then, there was a steady increase in ICD implant rates. In 2013, there were 423 ICDs implanted in New Zealand.13 The number of new implant/million population was still low at 95.13

Several potential barriers to the optimal use of ICD therapy in eligible patients have been reported.14-16 Affordability and capacity are of concern.17 In New Zealand, there are approximately 12 000 hospital admissions each year; approximately 5500 patients are for heart failure (HF).18 A large number of HF patients would potentially fulfill international guidelines criteria for these devices. Considering current workforce and funding constraints, the published 2010 New Zealand guidelines have more restrictive recommendations. These guidelines currently recommend primary prevention ICD in patients with ICM of at least 1 month after acute MI or NICM present for at least 3 months, LVEF \( \leq 30\% \) measured ≥3 months after optimal HF treatment, and at least 3 months remote from any revascularization procedure.19 This is different from the international guidelines in terms of the LVEF cutoff point and was based primarily on resource concerns. Additionally, primary prevention ICD is not recommended routinely for patients ≥75 years of age. Other criteria qualifying for CRT-D implantation included LVEF ≤35% at least ≥6 weeks of optimal medical HF treatment, whose QRS duration on electrocardiogram (ECG) is >149 ms or is 120-149 ms with two additional criteria for dys-synchrony on echocardiogram (aortic pre-ejection delay >140 ms, interventricular mechanical delay >40 ms, or delayed activation of the posterolateral left ventricular wall), who are NYHA class II/III, have had no major cardiovascular event in the prior 6 weeks, and who are in sinus rhythm. In line with other guidelines, there should be no major comorbidity that would reduce survival to ≤18 months that would be a disqualification for CRT-D implantation.19

No data are currently available for CRT-D or ICD implant rates or outcomes in HF patients in the northern region of New Zealand who received primary prevention ICD/CRT-D.

2 | METHODS

This was an observational study that described the medium- to long-term outcomes of HF patients who received primary prevention ICD or CRT-D residing in the Auckland (ADHB), Counties Manukau (CMHB), Northland (NDHB), and Waitemata (WDHB) District Health Boards region (northern region). The time period of the study was from January 1, 2007, to June 1, 2015. All de novo ICD and CRT-D implants, all pacemaker upgrades to ICD and CRT-D, and epicardial lead placement with CRT-D procedures were included. Procedures involving solely ICD and CRT-D pulse generator replacement were excluded.

Patients were identified using an established device database. Data pertaining to the procedure and the postprocedure period were obtained from clinical records and that database. Data collected included patient demographic data, procedure-related data, acute (within 24 hours of implant), early (≥24 hours to 2 weeks from implant), and late (≥2 weeks after implantation) complications. Appropriate and inappropriate ICD shocks were recorded from the device database during follow-up.

Subsequent hospitalization events postimplant were identified using the administrative data of Ministry of Health (MoH) and National Minimum Datasets [NMDS] inpatient hospitalization data via National Health Index (NHI) linkage up to December 2015. HF and ventricular arrhythmia hospitalizations were defined using the International Classification of Diseases diagnosis 10 (ICD-10) codes (Appendix A). Mortality data were collected using New Zealand Mortality Collection. The cause of death data was only available up until the end of 2013. For those with no cause of death data accessible from NMDS, review of clinical records was performed to further determine the cause of death.

Mortality was classified as cardiovascular death, HF death, arrhythmic death, malignancy, and other noncardiac death.

Ethics approval of the study was obtained from the Central Health and Disability Ethics Committee (Ethics ref: 15/CEN/58/AM02).

2.1 | Statistical analysis

Baseline characteristics were summarized as either mean with standard deviation or frequency with percentage depending on the nature of the data. Comparisons between ICD and CRT-D were conducted using either the Wilcoxon rank-sum test, the chi-squared
test, or the two-sample Z test. Survival rates over time were depicted in Kaplan-Meier curves, and the differences between survival distributions were evaluated with the log-rank test. Univariate logistic regression was conducted to determine potential independent predictors of all-cause mortality, cardiovascular mortality, and HF mortality. Statistical analyses were performed using the statistical package SAS version 9.3 (SAS Institute, Cary, NC, USA). All P-values resulted from two-sided tests and a P-value of <.05 were considered statistically significant.

3 | RESULTS

A total of 404 procedures were performed in 385 HF patients. Mean age at implant was 59.1 ± 11.4 years. Majority were male (84.9%) and of European descent (61.6%). Mean follow-up was 3.64 ± 2.17 years with 282 (73.3%) patients having up to 5 years follow-up. ICD was the most common device implanted (69.9%), and the majority of the ICDs were single-chamber devices (53.3%). In the CRT-D group, a left ventricular lead was successfully placed in 104 patients (89.7%) at the initial procedure. Seven required a second procedure endovascularly. Nine patients had epicardial lead placement. Four patients did not receive CRT because of failed left ventricular lead placement.

The baseline characteristics of the patients are shown in Table 1. Compared to the CRT-D patients, ICD patients were younger (58.1 ± 11.9 years vs 61.1 ± 10.1, P = .019) and more likely to have ICM (49.1% vs 22.6%, P < .0001).

Five ICD patients were later upgraded to CRT-D. The mean time of upgrade was 3.2 ± 2.3 years. Indications for upgrade were a composition of worsening HF with deterioration in NYHA class, deterioration of LVEF, and/or widening of QRS duration on ECG.

3.1 | Complications

During the first 24 hours after implantation, there were 12 acute complications. These included lead dislodgements requiring intervention in 6 patients (5.2%) in the CRT-D group and 3 patients (1.5%) in the ICD group (P = .02) (Table 2).

There were 5 device-pocket infections (1.29%) that required removal. Mean duration to infection was 1.79 ± 1.78 months. Mean duration to infection in ICD group was 1.68 ± 2.04 months, whereas it was 2.28 months in the CRT-D group (P = N.S).

3.2 | Device therapy

During the follow-up, 76 (19.7%) patients had received antitachycardia pacing (ATP) and 66 (17.1%) had appropriate ICD shocks. There was no difference in device therapy in the ICD and CRT-D patients (P = .80 and P = .14 for ATP and appropriate ICD shocks, respectively). There was no difference in the incidence of appropriate ICD therapy in ICM and NICM patients (P = .42 and P = .47, respectively). In our study, 35 (9.1%) patients received inappropriate shocks, most commonly due to atrial fibrillation (71.4%) and regular supraventricular tachyarrhythmias (25.7%). A small number experienced inappropriate therapy because of T-wave oversensing (2.9%).

### TABLE 1 Baseline characteristics of heart failure patients who received primary prevention ICD and CRT-D

|                | ICD (n = 269) | CRT-D (n = 116) | P   |
|----------------|--------------|----------------|-----|
| Mean age (y ± SD) | 58.1 ± 11.9  | 61.1 ± 10.1    | .019|
| Gender          |              |                |     |
| Male (%)        | 234 (87)     | 92 (80)        | .079|
| Female (%)      | 35 (13)      | 23 (20)        |     |
| Ethnicity (%)   |              |                |     |
| NZ European/Other | 147 (54.7)  | 89 (77.4)      | <.0001|
| Maori           | 48 (17.8)    | 6 (5.2)        |     |
| Pacific Island  | 29 (10.8)    | 15 (13.0)      |     |
| Asian           | 40 (14.8)    | 4 (3.5)        |     |
| Unspecified     | 5 (1.9)      | 1 (0.9)        |     |
| DHBs (%)        |              |                |     |
| Auckland DHB    | 63 (23.4)    | 26 (22.4)      | .867|
| Counties Manukau DHB | 74 (27.5) | 34 (29.3)      |     |
| Northland DHB   | 25 (9.3)     | 8 (6.9)        |     |
| Waitemata DHB   | 107 (39.8)   | 48 (41.4)      |     |
| Underlying heart disease (%) |         |                |     |
| Ischemic cardiomyopathy | 132 (49.1)  | 26 (22.6)      | <.0001|
| Nonischemic cardiomyopathy | 114 (42.4)  | 77 (66.9)      | <.0001|
| Other causes    | 23 (8.6)     | 13 (11.2)      | .56 |
| NYHA class (%)  |              |                |     |
| I              | 92 (34.2)    | 12 (10.4)      | <.0001|
| II             | 145 (53.9)   | 58 (50.4)      |     |
| III            | 32 (11.9)    | 45 (39.2)      |     |
| Mean LVEF (%)  | 24.6 ± 5.2   | 23.9 ± 5.7     | .125|
| Atrial arrhythmias (%) |         |                |     |
| Paroxysmal AF  | 25 (9.3)     | 13 (11.3)      | .545|
| Chronic AF     | 55 (20.5)    | 13 (11.3)      | .031|
| AV node ablation (%) | 0        | 2 (1.7)        | .089|
| Diabetes mellitus (%) | 58 (21.6)  | 26 (22.8)      | .788|
| Hypertension (%) | 81 (30.1)   | 28 (24.6)      | .271|
| QRS morphologic type (%) |       |                |     |
| RBBB           | 28 (10.4)    | 0              | <.0001|
| LBBB           | 29 (10.8)    | 101 (87.8)     |     |
| IVC            | 23 (8.6)     | 0              |     |
| Paced          | 0            | 13 (11.3)      |     |
| QRS duration (%) |              |                |     |
| Intrinsic (RBBB + LBBB + IVC) | 153.3 ± 22.4| 175.1 ± 18.3  |     |

(Continues)
TABLE 1 (Continued)

|                      | ICD (n = 269) | CRT-D (n = 116) | P-value |
|----------------------|---------------|-----------------|---------|
| Acute                | 4 (1.5%)      | 8 (6.9%)        | .01     |
| Lead dislodgement    | 3 (1.5%)      | 6 (5.2%)        | .02     |
| Cardiac tamponade    | 1 (0.4%)      | 1 (0.9%)        | .28     |
| Coronary sinus       | -             | 1 (0.9%)        |         |
| dissection           |               |                 |         |
| Early                | 4 (1.5%)      | 1 (0.9%)        | .62     |
| Lead dislodgement    | 2 (0.7%)      | 1 (0.9%)        | .9      |
| Device-pocket        | 2 (0.7%)      | -               | -       |
| hematoma             |               |                 |         |
| Late                 | 11 (4.1%)     | 6 (5.2%)        | .64     |
| Lead issues          | 6 (2.2%)      | 4 (4.3%)        | .38     |
| Device-pocket        | 1 (0.4%)      | 1 (0.9%)        | .28     |
| revision             |               |                 |         |
| Infections           | 4 (1.5%)      | 1 (0.9%)        | .62     |

ICD, implantable cardioverter-defibrillator; CRT-D, cardiac resynchronization therapy-defibrillator; DHB, District Health Board; NYHA, New York Heart Association; LVEF, left ventricular ejection fraction; AF, atrial fibrillation; LBBB, left bundle branch block; RBBB, right bundle branch block; IVC, intraventricular conduction delay.

There was no difference between the two groups in the time to first inappropriate shocks (P = .74).

3.3 | Mortality

At the end of the follow-up, 67 (17.4%) patients had died. Of these deaths, 42 were classified as cardiovascular death, 8 deaths were due to malignancy and 8 from other noncardiac causes (P = .88). The remainder 9 were classified as unspecified cause in the community. The 5-year all-cause and 5-year cardiovascular mortality rates were 14% and 9%, respectively.

Of the 42 cardiovascular deaths, 28 were due to HF and 12 deaths were attributable to MI, or cerebrovascular accidents. Only 2 were due to sudden arrhythmic death. These 2 patients had end-stage HF for palliative care with slow ventricular arrhythmias below the detection rate programmed in their ICD for which no therapies were delivered. The 5-year HF mortality rate was 6%, whereas the 5-year sudden arrhythmic death rate was low at 0.3%.

There was no difference in cardiovascular or HF mortality rates in ICD and CRT-D patients (Figure 1A,B). For ICM and NICM patients, no difference in cardiovascular or HF survival was observed overtime (Figure 2A,B).

Using univariable logistic regression analysis, Maori ethnicity, NYHA class III symptoms, and LVEF were significant predictors in all-cause and cardiovascular mortalities (Table 3). However, only NYHA class III symptoms remained an independent predictor for HF mortality (odds ratio [OR] 4.2, 95% confidence interval [CI] 1.273-13.641, P = .018).

3.4 | Hospitalization events

Among the 385 patients, 260 patients had 1194 all-cause hospitalizations after implant. Mean duration from implant to subsequent hospitalization was 9.57 ± 10.85 months. Mean duration from implant to subsequent hospitalization for ICD patients was 10.39 ± 11.9 months and for CRT-D patients was 7.54 ± 7.26 months, respectively (P = .026).

3.4.1 | Heart failure hospitalizations

Of the 1194 hospitalizations, there were 275 HF events in 93 patients (67.7% ICD and 32.3% CRT-D patients, respectively) (P < .001) and 20.4% were Maori. Mean duration from implant to first subsequent HF event was 15.87 ± 14.8 months. For ICD and CRT-D patients, there was no difference in the mean duration to first HF hospitalization after implant (P = .40).

3.4.2 | Ventricular arrhythmia hospitalizations

There were 65 ventricular arrhythmia hospitalizations in 43 patients (76.7% ICD and 23.3% CRT-D patients, respectively) (P = .07), and 23.3% were Maori. Mean duration from implant to first ventricular arrhythmia hospitalization was 18.24 ± 16.53 months. No difference was found in the mean duration from implant to first ventricular arrhythmia hospitalization in ICD and CRT-D patients (P = .08).

4 | DISCUSSION

Our study is a “real-world” description of the medium- to long-term outcomes of HF patients who received primary prevention ICD and CRT-D. In appropriately selected patients, there was a low incidence of arrhythmic death. CRT-D patients have lower hospitalization rates for both HF and ventricular arrhythmias. We have acceptable complication rates comparable to international published reports for the time.20-21

HF is an increasing problem in both developed and developing countries. The Framingham Heart Study showed that HF is associated with increased risk of SCD.22 However, the most common mode of death in this group of patients remains progressive HF. In a subanalysis of the Comparison of Medical Therapy, Pacing and Defibrillation in Heart Failure (COMPANION) trial, pump failure (44.4%) was the most common mode of death followed by SCD (26.5%) in patients with advanced HF.23 Our findings were
concordant with published data demonstrating the most common cause of death is due to worsening HF. Only a small percentage of patients died from sudden arrhythmic death (2.9%) with a 5-year arrhythmic mortality rate of 0.3%. Thus, the commonest mode of death in HF patients, even those at risk for ventricular arrhythmias, is progressive pump failure that cannot be addressed by an ICD alone. In our study, there were 275 HF hospitalizations and 65 ventricular arrhythmia events confirming that patients with HF were at higher risk of worsening HF than ventricular arrhythmias. LVEF was a strong predictor for all-cause and cardiovascular mortality in the univariate analysis. Therefore, optimization of HF management with the aim of improving LVEF (with the used of CRT devices where appropriate) remains important. Although progressive HF remained the commonest cause of death (41.8%), a significant proportion of patients still died from malignancy (11.9%). These patients have significant comorbidities resulting in 876 other noncardiac-related hospital admissions.

Maori ethnicity was a significant predictor of all-cause and cardiovascular mortality in our study. In general, Maori are disproportionately represented in adverse health outcomes. The device implantation rates were 14% (n = 54) in Maori, and only 5.2% (n = 6) received CRT-D. They comprised of 20% and 23% of subsequent HF and ventricular arrhythmia admissions. Despite the advances in the management of HF, Maori were about 4 times as
likely as non-Maori to be hospitalized for HF (relative risk [RR] 4.01, CI 3.83-4.21). The HF mortality rate among Maori was more than twice as high as that of non-Maori (RR 2.36, CI 1.76-3.17). The reasons behind these inequalities are multifactorial including socioeconomic deprivation, cultural beliefs in health, and differences in adherence to guideline recommendation treatment. Among the 54 Maori patients who received these devices, 19 (35.2%) died during the follow-up period. HF was the cause of death in 26.3% of these patients. This suggests that more effective methods of optimizing HF therapy in Maori patients are required but the effective strategies to achieve this remain uncertain. Asians have lower incidence of HF, and this was reflected by the low number of device implantations.

Overall the perioperative risk is low for these devices, but the longer-term complications of these devices cannot be ignored. A recent meta-analysis reported a complication rate of 9.1% in 6433 patients with ICD implantation over 16 months. Similarly, the National Cardiovascular Data Registry (NCDR) ICD registry reported 6.1 (CI, 6.0-6.2) ICD-related complications per 100 patient-years that required reoperation or hospitalization. Our results suggest that while the implant rates are low, patients who had the devices implanted had slightly higher but acceptable rate of complications comparable to international published reports. Our success rate of LV lead implantation at first procedure was 89.7% compared to 97% in the RESynchronization reVErses Remodeling in Systolic Left vEntricular Dysfunction (REVERSE) trial.
Defibrillation for Ambulatory Heart Failure Trial (RAFT) study and 98.4% in Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy (MADIT-CRT) trial. However, these centers are centers with high volumes. Given the limited resources and low-volume implant rate, the acute perioperative complication rates are similar to published data and only 3.4% patients did not get CRT-D devices because of failed LV lead placement.

With the increasing number of complex device implantations, infection becomes a major challenge to face. Rates of device-related infection between 0.5% and 5.1% have been reported in retrospective and prospective studies with current estimated risk close to 1%. Our infection rate (1.4%) was similar to those published.

Data are lacking regarding the management of patients with ICD who subsequently develop indications for CRT. Clinical predictors of upgrade during the main RAFT study included NYHA class III vs II and a wider QRS duration. This was similar to the reasons of upgrade in the published 2010 New Zealand guidelines. There is the potential that a sizable group of HF patients not being referred therefore, missing out on appropriate device support. Confounders and selection bias should therefore be kept in mind when interpreting the results of our study. Our study does not represent the entire New Zealand. The 4 DHBs in northern region serve 38% of the total New Zealand population with estimated 1.76 million people in this region. The implant rate and the practice may differ in other implant hospitals in the country.

The latest available cause of mortality data from the MoH was only up until 2013 due to delays related to ongoing coronial enquires. For those with no cause of death data available after year 2013, we reviewed clinical records to determine the cause of death. There were 8 patients who died outside the hospital where no formal record of mortality cause was available. This potentially could impact on the accuracy of the subanalysis of HF and ventricular arrhythmia mortalities. The main strength of our study was the long duration of follow-up. The mean follow-up was 2.17 years, with 73.3% patients having 5 years of follow-up.

5 | LIMITATIONS

There are several limitations in our study. This is a retrospective study where all the patients were retrospectively recruited but prospectively followed up. The published 2010 New Zealand guidelines have stricter recommendations for ICD and CRT-D in patients with HF compared to the International guidelines. There is the potential that a sizable group of HF patients not being referred therefore, missing out on appropriate device support. Confounders and selection bias should therefore be kept in mind when interpreting the results of our study. Our study does not represent the entire New Zealand. The 4 DHBs in northern region serve 38% of the total New Zealand population with estimated 1.76 million people in this region. The implant rate and the practice may differ in other implant hospitals in the country.

The New Zealand Cardiac Implanted Device Registry (ANZACS-QI 15) has recently been developed to collect information on all cardiac device implantations in New Zealand, which will aid quality improvement initiatives and to allow subsequent examination of equity of access to therapy, outcomes, and complications in a "real-world" view. The first description of data on new pacemaker implants from this Registry has been recently published. We believe our study adds to the ANZACS-QI 15 data, giving a more detailed picture of current New Zealand practice with primary prevention ICD/CRT-D use in selected HF patients.
6 | CONCLUSION

Based on our observational study, effective ICD/CRT-D in appropriately selected HF patients resulted in a very low incidence of arrhythmic death. The incidence of hospitalization for both ventricular arrhythmias and HF was significantly lower in the CRT-D group suggesting that where appropriate this should be the device of choice for HF patients. Significant challenges remain in order to improve access to device therapy among these patients given the limited funding available in New Zealand.

ETHICS APPROVAL

Ethics approval of the study was obtained from the Central Health and Disability Ethics Committee (Ethics ref: 15/CEN/58/AM02).

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CONFLICTS OF INTEREST

Authors declare no Conflict of Interests for this article.

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APPENDIX A

INTERNATIONAL CLASSIFICATION OF DISEASES DIAGNOSIS 10 (ICD-10) CODES USED FOR DATA EXTRACTION

Heart failure:
- I110
- I130
- I132
- I500
- I501
- I509

Ventricular arrhythmias:
- I460
- I461
- I469
- I470
- I472
- I490