



Original Article

# A Population-Based Study of Device Eligibility, Use, and Reasons for Nonimplantation in Patients at Heart Function Clinics

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## ABSTRACT

**Background:** Implantable cardioverter defibrillator (ICD) therapy is lifesaving; however, real-world data regarding the proportion of patients eligible for a primary prevention ICD and subsequent use remain sparse. This study evaluated rates of primary prevention ICD eligibility and use among patients in heart function clinics (HFCs) and to identify reasons for nonimplantation.

**Methods:** A retrospective study was performed of patients seen at HFCs in Alberta, Canada, from 2013 to 2015. Demographics, comorbidities, clinical indications, and reasons for nonimplantation were abstracted. Eligibility was defined according to the 2008 American College of Cardiology/American Heart Association/Heart Rhythm Society ICD, 2012 American College of Cardiology/American Heart Association/Heart Rhythm Society Focused Update, and 2013 Canadian

## RÉSUMÉ

**Contexte :** Le défibrillateur cardiovertreur implantable (DCI) sauve des vies. Or, les données recueillies dans la pratique réelle concernant le pourcentage de patients admissibles à l'implantation d'un tel dispositif en prévention primaire et l'utilisation subséquente de ce dispositif sont très limitées. Cette étude a évalué le taux de patients admissibles à la pose d'un DCI en prévention primaire et le taux d'utilisation de ce dispositif chez des patients traités en clinique de cardiologie. Elle a également recensé les motifs de non-implantation.

**Méthodologie :** Une étude rétrospective a été réalisée chez des patients traités de 2013 à 2015 dans plusieurs cliniques de cardiologie de l'Alberta, au Canada. Les données relatives aux caractéristiques démographiques, aux comorbidités, aux indications cliniques et aux motifs de la non-implantation ont été extraites. L'admissibilité était

Several randomized clinical trials have shown that implantable cardioverter defibrillator (ICD) therapy reduces morbidity and mortality in patients with heart failure and an impaired ejection fraction at risk for sudden cardiac death.<sup>1-5</sup> The results of these primary prevention ICD trials form the basis of guideline recommendations that help physicians identify patients who would benefit from this lifesaving therapy.<sup>6-9</sup> However, data regarding the number of patients these guideline recommendations apply to and use of ICD therapy in clinical practice are sparse.<sup>10-17</sup> These data would be

important to benchmark care and to identify potential strategies for improvement where gaps exist.

Prior observational studies from both inpatient and outpatient cohorts have found approximately half of patients with heart failure were eligible for a primary prevention ICD.<sup>10,11,17</sup> Among eligible patients, use of ICD therapy has ranged from 13%<sup>14</sup> to as high as 87%.<sup>15</sup> The low rates of ICD use were reported from large databases,<sup>12,14</sup> in which contraindications or reasons for nonimplantation were not available for abstraction. Although the higher rates of ICD use<sup>10,15,16</sup> were reviewed by using chart-level data, these studies were limited by small sample sizes,<sup>11,17</sup> single-center studies,<sup>10-12</sup> or eligibility criteria mainly focused on a reduced ejection fraction without capturing all eligible patients.<sup>10</sup> Even among large randomized clinical trials for heart failure therapy, ICD use is low, ranging from 5% to 15%.<sup>18,19</sup> Given the growing population with heart failure<sup>20-22</sup> and the higher proportion of patients eligible for device therapy, a better understanding of device eligibility and use is needed.

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**Ethics Statement:** This research was approved by the Health Research Ethics Board at the University of Alberta (Pro00063905).

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See page 180 for disclosure information.

Cardiovascular Society Cardiac Resynchronization Therapy guidelines. Logistic regression was used to calculate an odds ratio (OR) and 95% confidence interval (CI) for predictors of nonimplantation.

**Results:** Among 1239 patients in HFCs, the median age was 70 years (interquartile range, 59-80), 67% were male, and the median left ventricular ejection fraction was 0.40 (interquartile range, 0.28-0.53). Overall, 45% of patients ( $n = 553$ ) met guideline criteria for an ICD, and of those, 36% ( $n = 198$ ) received a device. Among device nonrecipients, 52% ( $n = 185$ ) had no documented reason for nonimplantation. The most common reason for nonimplantation among nonrecipients was patient preference (48%). Predictors associated with nonimplantation were age more than 75 years (OR, 1.92; 95% CI, 1.31-2.82) and history of cancer (OR, 2.26; 95% CI, 1.07-4.78). At 3 years follow-up, 27% of nonrecipients were deceased.

**Conclusions:** We found that one-third of patients who met guideline criteria received an ICD and that documentation for nonimplantation was poor.

Therefore, we aimed to determine rates of ICD eligibility and use among patients seen in heart function clinics (HFCs) using chart-level data based on relevant ICD guidelines. We also aimed to determine reasons for nonimplantation, to identify significant predictors for device nonimplantation among eligible patients, and to determine outcomes among device nonrecipients at 3 years follow-up.

## Methods

### Study population

As part of a quality-improvement initiative, the Arrhythmia Expert Working Group of the Alberta Health Services Cardiovascular and Stroke Strategic Clinical Network performed a retrospective review of all consecutive patients at 2 tertiary HFCs in Alberta, Canada, from 2013 to 2015. We chose this study period to allow adequate time for implementation of the 2012 American College of Cardiology Foundation/American Heart Association/Heart Rhythm Society Focused Update and to take advantage of electronic medical records, which were widely used in HFCs. HFCs are defined as clinics where various cardiac pathologies are treated, including both preserved and reduced ejection fractions, and cater toward the optimization of heart failure therapy among all patients. Patient inclusion criteria included all of the following: age > 18 years, history of heart failure, etiology of cardiomyopathy, and New York Heart Association (NYHA) functional class and left ventricular ejection fraction (LVEF) documented within 2 years of enrolment into the study. Patients were excluded if they had an ICD before the study period.

définie en fonction des lignes directrices de 2008 de l'American College of Cardiology, de l'American Heart Association et de la Heart Rhythm Society sur le DCI, de leur mise à jour ciblée en 2012 et des lignes directrices de 2013 de la Société canadienne de cardiologie sur la thérapie de resynchronisation cardiaque. Une régression logistique a été utilisée pour calculer le risque relatif approché (RRA) et l'intervalle de confiance (IC) à 95 % associés aux facteurs de prédiction de la non-implantation.

**Résultats :** L'âge médian des 1 239 patients traités en clinique de cardiologie était de 70 ans (plage interquartile : 59 – 80 ans); 67 % d'entre eux étaient des hommes, et la fraction d'éjection ventriculaire gauche médiane était de 0,40 (plage interquartile : 0,28 – 0,53). D'une manière générale, 45 % des patients ( $n = 553$ ) répondaient aux critères énoncés dans les lignes directrices pour la pose d'un DCI, et 36 % d'entre eux ( $n = 198$ ) ont reçu un dispositif. Parmi les patients qui n'ont pas reçu de dispositif, aucun motif justifiant la non-implantation n'a été documenté chez 52 % des patients ( $n = 185$ ); chez les 48 % des patients restants, le motif le plus courant pour justifier la non-implantation a été la préférence du patient. Les facteurs de prédiction associés à la non-implantation ont été l'âge (plus de 75 ans; RRA : 1,92; IC à 95 % : 1,31 – 2,82) et les antécédents de cancer (RRA : 2,26; IC à 95 % : 1,07 – 4,78). Après 3 ans de suivi, 27 % des patients qui n'avaient pas reçu de dispositif étaient décédés.

**Conclusions :** Nous avons constaté que le tiers des patients qui répondaient aux critères énoncés dans les lignes directrices ont reçu un DCI et que les motifs justifiant la non-implantation étaient mal documentés.

Patients active as of January 1 of each year (2013-2015) were screened, and baseline demographics, clinical indications, and comorbid disease were abstracted from the chart. Assessments of LVEF were taken closest to the most recent clinic visit. LVEF measurement modalities included magnetic resonance imaging, echocardiogram, and multigated acquisition scan. If more than 1 modality was used, the hierarchy of magnetic resonance imaging, multigated acquisition, echocardiography, myocardial perfusion imaging test, or other was followed. Chart reviewers were independent of the HFC physicians. At 3 years follow-up, device nonrecipients were identified as alive or deceased, and a cause of death was identified using hospital discharge summaries for those deceased in hospital.

### ICD eligibility

Eligibility criteria were based on the Canadian Cardiovascular Society/Canadian Heart Rhythm Society position paper on ICD use in Canada, the 2008 American College of Cardiology/American Heart Association/Heart Rhythm Society ICD and Cardiac Resynchronization Therapy (CRT) Guidelines, the 2012 American College of Cardiology Foundation/American Heart Association/Heart Rhythm Society Focused Update, and the 2013 Canadian Cardiovascular Society Guidelines for CRT.<sup>6-9</sup> Patients met guideline criteria for an ICD if they met the following criteria: (1) ischemic cardiomyopathy; (2) LVEF  $\leq 0.35$ ; (3) NYHA class I to III and an absence of revascularization within 3 months or acute myocardial infarction within 40 days and on adequate medical therapy for  $\geq 3$  months of determined device eligibility; or (1) nonischemic cardiomyopathy; (2) LVEF  $\leq 0.35$ ; (3) NYHA class II to III; CRT: (1) sinus rhythm, (2) LVEF

$\leq 0.35$ , (3) NYHA class II to IV, (4) QRS duration  $\geq 130$  ms and left bundle branch block, or (5) QRS duration  $\geq 150$  ms and non-left bundle branch block (Table 1).

### Reasons for nonimplantation

Among device nonrecipients, reasons for nonimplantation were collected on a yearly basis and determined by reviewing physician letters who attended an HFC, electrophysiology consults, and nurses' notes. Reasons for nonimplantation included patient preference, medical reason (life expectancy  $< 1$  year, poor quality of life, severe chronic kidney disease [glomerular filtration rate  $< 30$  mL/min], or significant comorbidities) and technical reason (not medically optimized or LVEF improved on subsequent tests). When a patient was eligible during multiple years of the study period, only 1 reason was collected per year.

### Outcomes

The primary outcome for this study was to determine rates of ICD eligibility and use. Secondary outcomes were to identify reasons for nonimplantation, to determine predictors for device nonimplantation in eligible patients, and to determine outcomes among device nonrecipients at 3 years follow-up.

### Statistical analysis

Baseline demographics were presented as a count, mean (standard deviation), or median (interquartile range [IQR]). Characteristics were stratified into "never eligible" patients and patients who "met guideline criteria" and then were further stratified into device recipients and device nonrecipients. Device recipients and nonrecipients were compared using Kruskal–Wallis tests for continuous variables and chi-square tests for categorical variables. We used multivariable logistic regression to explore patient factors associated with device nonimplantation. We included candidate variables if the univariable association had a  $P$  value of  $\leq 0.25$ . Stepwise variable selection was used to determine the final model, and variables were considered significant with a  $P$  value of  $< 0.05$ .<sup>10</sup> We used Stata version 14 (StataCorp LP, College Station, TX) to conduct our analysis.

This study was approved by the Health Research Ethics Board of the University of Alberta (Pro00063905) and the Conjoint Human Research Ethics Board Calgary, Alberta (REB 15-1176).

## Results

### Baseline demographics

Baseline demographics are shown in Table 2. The median age was 70 years (IQR, 59–80), the majority were male (67%), 35% of patients had ischemic cardiomyopathy, and the mean LVEF was 0.40 (IQR, 0.28–0.53). Compared with patients who received an ICD, device nonrecipients were more likely to be aged more than 75 years (39% vs 24%,  $P < 0.001$ ), to have a lower LVEF (median 26.1 vs 27.7,  $P = 0.036$ ), and to be more likely to have a history of kidney disease (20.1% vs 13.1%,  $P = 0.037$ ) and cancer (10% vs 5%,  $P = 0.013$ ) (Supplemental Table S1).

### Device eligibility and use

A total of 1935 patients in HFCs were identified over the study period (Fig. 1). Of these, 696 were excluded because of missing information, such as no NYHA class or LVEF documented within 2 years of study enrolment or a prior ICD implant, leaving 1239 patients for our analysis. Of the final cohort, 45% of patients ( $n = 553$ ) met guideline criteria for an ICD, and of those, 36% ( $n = 198$ ) received a device. Among device nonrecipients, 52% ( $n = 185$ ) had no documented reason for nonimplantation. Yearly rates of device nonrecipients having no documented reason for nonimplant were 33% (2013), 32% (2014), and 19% (2015).

Yearly rates of patients meeting guideline criteria ranged from 32% to 37% (Fig. 2), and yearly rates of device use among those meeting guideline criteria ranged from 19% to 36% (Fig. 2).

### Reasons for nonimplantation

Documented reasons for nonimplantation among those meeting guideline criteria included patient preference (48%), technical reason (35%), and medical reason (17%) (Fig. 3). Patient factors significantly associated with nonimplantation among those meeting guideline criteria were age  $> 75$  years (odds ratio [OR], 1.91; 95% confidence interval [CI], 1.31–2.82;  $P = 0.001$ ) and a history of cancer (OR, 2.26; 95% CI, 1.07–4.78;  $P = 0.033$ ) (Table 3). After adjustment, age  $> 75$  years (OR, 1.48; 95% CI, 1.03–2.12;  $P = 0.033$ ) was the only factor significantly associated with nonimplantation among nonrecipients who lacked a documented reason for nonimplant. Among nonrecipients aged  $> 75$  years, the most commonly documented reason for nonimplantation was patient preference (56%), followed by a medical reason (25%) and a technical reason (19%).

### Outcomes

At 3 years follow-up, all patients meeting guideline criteria had follow-up data available. A total of 27% (96/355) of device nonrecipients were deceased. Among the nonrecipients who lacked a documented reasons for nonimplant, 32% (60/185) were deceased. Some 45% of patients (43/96) died in hospital, and the remaining 55% (53/96) died out of hospital and a cause of death could not be identified. A cardiac cause of death was identified in 26% (25/96), 9% (8/96) died of cancer, 7% (7/96) died of renal failure, and 3% (3/96) died of complications from an infection. Among nonrecipients aged  $> 75$  years, 39% ( $n = 55$ ) were deceased. A cardiac cause of death was identified in 25% ( $n = 14$ ).

## Discussion

In this large, population-based study of ICD eligibility and use, we found that half of patients seen in the HFC met guideline criteria for a primary prevention device, and among those, one-third received an ICD. Patient preference was the most common reason for nonimplantation among nonrecipients; however, half of nonrecipients lacked a documented reason for nonimplantation. At 3 years follow-up, approximately one-quarter of nonrecipients were deceased.

**Table 1. ICD eligibility criteria**

ICD		CRT	
Cardiomyopathy		Sinus rhythm	
Ischemic	Nonischemic	LVEF $\leq$ 0.35	
NYHA I-III	NYHA II-III	NYHA II-IV	
LVEF $\leq$ 0.35	LVEF $\leq$ 0.35	QRS $\geq$ 130 ms and LBBB	QRS $\geq$ 150 ms and non-LBBB

CRT, cardiac resynchronization therapy; ICD, implantable cardioverter defibrillator; LBBB, left bundle branch block; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association.

Previous studies<sup>10-17</sup> assessing ICD eligibility have shown that 45% to 51% of patients were eligible for a primary prevention device. Our study demonstrated similar eligibility rates (45%) for primary prevention ICD therapy, and this is most likely explained by the use of comparable guideline eligibility criteria<sup>17</sup> and similar patient cohorts.<sup>10</sup> The retrospective study by Lyons et al.<sup>10</sup> was performed in an HFC included in our study and may be a factor contributing to similarities between the 2 studies. We showed that rates did not differ when including a larger population who was representative of patients in HFCs across the province.

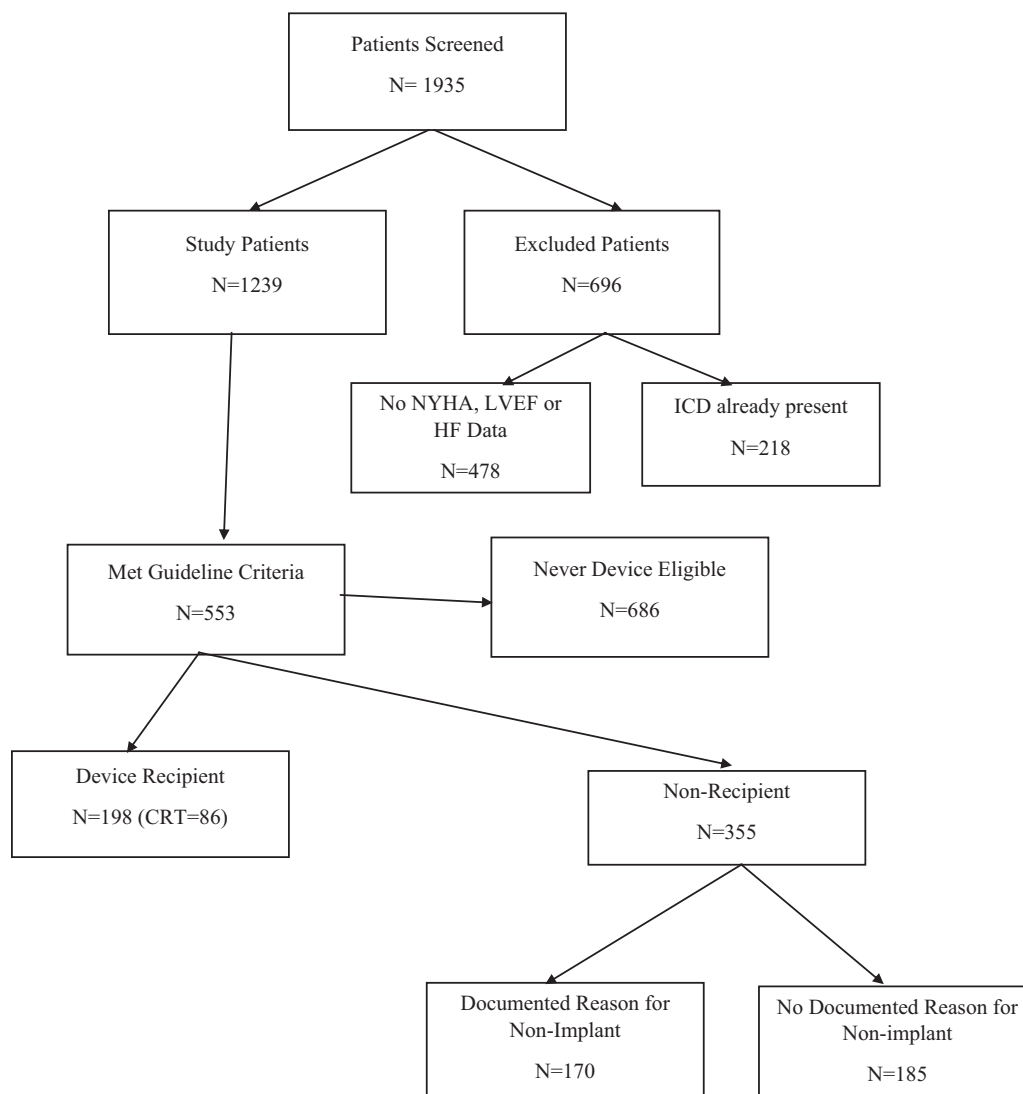
Studies investigating ICD use have demonstrated variable results.<sup>10-17</sup> A single-center retrospective review found use rates among “truly eligible” patients (those who met guideline criteria and lacked a reasons for nonimplantation) ranged from 76% to 86%.<sup>10</sup> Our study showed rates of ICD use that were lower at approximately 36%, even though the 2 studies had similar patient cohorts. A possible explanation for the difference in rates may be the study methodology. We excluded implants occurring before the study period, which provided a more accurate estimation of device use at that time, and we also used an LVEF cutoff of 0.35, which was reflective of the guideline recommendations used during our study period. Other studies<sup>11,13</sup> have also demonstrated significant underuse of ICD therapy with rates as low as 13%.<sup>14</sup> Regardless, there is a clear need to better understand potential system and physician barriers, and to develop strategies to improve the use of primary prevention ICD therapy for appropriate patients in HFCs.

Our study reports that half of device nonrecipients were missing a documented reason for nonimplantation. This is similar to another single-center, retrospective study of patients in HFCs, which found that 42% of the time, a documented reason for nonimplantation was missing among device nonrecipients.<sup>10</sup> This highlights the need to implement quality

**Table 2. Baseline demographics**

Characteristic	All patients	Patients meeting guideline criteria	Never device eligible	P value
Patients, N	1239	553	686	
Age (y), median (IQR)	70 (59-80)	69 (59-78)	71 (59-81)	0.454
Age > 75 y, n (%)	456 (36)	204 (36.8)	252 (36.7)	0.971
Sex: male, n (%)	858 (69.2)	451 (81.5)	407 (59.3)	< 0.001
Heart failure cause, ischemic, n (%)	587 (47.3)	250 (45.2)	337 (49.1)	0.172
				< 0.001
LVEF, mean (SD)	40.5 (0.28-0.53)	26.9 (8.0)	51.5 (8.5)	
NYHA class, n, (%)				
I	352 (28.4)	115 (20.8)	237 (34.5)	< 0.001
II	500 (40.4)	242 (43.8)	258 (37.6)	
III	241 (19.5)	129 (23.4)	112 (16.4)	
IV	11 (0.8)	8 (1.4)	3 (0.4)	
Not reported	135 (10.9)	59 (10.6)	76 (11.1)	
Cardiovascular comorbidities, n (%)				
Atrial fibrillation	508 (41.0)	205 (37.0)	303 (44.2)	0.010
Paroxysmal	139 (11.2)	54 (9.7)	85 (12.4)	0.763
Persistent	285 (23.0)	119 (21.5)	166 (24.2)	
Not reported	84 (6.7)	32 (5.7)	52 (7.5)	
Atrial flutter	39 (3.2)	17 (3.1)	22 (3.2)	0.920
Hypertension	628 (50.6)	268 (48.5)	360 (52.5)	0.162
Hyperlipidemia	113 (9.1)	54 (9.7)	59 (8.6)	0.503
Myocardial infarction	272 (21.9)	161 (29.1)	111 (16.2)	< 0.001
Cerebrovascular disease	130 (10.4)	59 (10.6)	71 (10.3)	0.864
Diabetes	393 (31.7)	185 (33.4)	208 (40.8)	0.008
Complicated	23 (1.8)	8 (1.4)	15 (2.2)	0.214
Uncomplicated	284 (22.9)	141 (25.4)	143 (20.8)	
Not reported	86 (6.9)	36 (6.5)	50 (7.2)	
Peripheral vascular disease	41 (3.3)	19 (3.4)	22 (3.2)	0.198
Other comorbidities, n (%)				
Kidney disease	227 (18.3)	106 (19.1)	121 (17.6)	0.497
Mild	115 (9.2)	51 (9.2)	64 (9.3)	0.765
Moderate-severe	72 (5.8)	35 (6.3)	37 (5.3)	
Not reported	40 (3.2)	20 (3.6)	20 (2.9)	
Liver disease	3 (0.2)	2 (0.2)	1 (0.1)	0.729
Cancer	128 (10.3)	51 (9.2)	77 (11.2)	0.250
Active	16 (1.2)	4 (0.7)	12 (1.7)	0.387
Remission	95 (7.6)	39 (7.0)	56 (8.1)	
Not reported	17 (1.3)	8 (1.4)	9 (1.3)	
Dementia	13 (1.1)	8 (1.4)	5 (0.7)	0.221

IQR, interquartile range; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; SD, standard deviation.

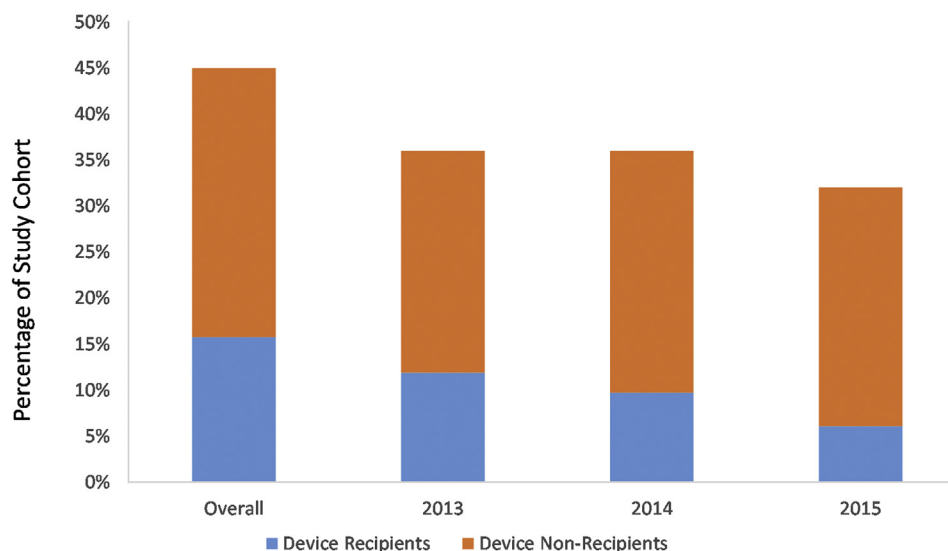


**Figure 1.** Patient flow diagram. LVEF, left ventricular ejection fraction; HF, heart failure; NYHA, New York Heart Association.

improvement initiatives geared toward emphasizing complete and clearly documented medical records consisting of patient preferences, risks, and contraindications. Patient preference was also the most commonly documented reason for non-implantation among patients meeting guideline criteria and accounted for 48% of reasons for nonadherence in our study. Prior work<sup>10,13,18</sup> has also demonstrated high rates of patient preference as a reason for nonimplantation. It is important to address patient barriers for ICD use because they are a vital part of the implant process; however, patients also may be influenced by physician discussion around the device indication, procedure, and follow-up care. Retrospective reviews have provided some insight into patient reason for refusal, that is, older age and the presence of comorbidities<sup>10,14,15</sup> were associated with device nonadherence. These were also found to be significant predictors associated with device nonadherence in our analysis. We also found similar predictors of nonimplantation with older age, a lower ejection fraction, and a history of kidney disease being significantly associated with nonimplantation. One

possible explanation for a lower ejection fraction being associated with nonimplantation is that this group is perceived as too sick for device therapy; however, further investigation is needed. In long-term follow-up, we found approximately one-third of device nonrecipients were deceased. Among deaths in the hospital, more than one-quarter were identified as cardiac, and it is possible some of these patients may have benefited from ICD therapy.

Of note, the latest Canadian ICD guidelines have been published<sup>22</sup> and are relatively consistent with the guidelines used in this study. The new guidelines focus on persistent reduced ejection fraction, optimal medical therapy, and time postrevascularization and myocardial infarction. A significant change is noted in the exclusion of NYHA as an eligibility criterion. Another important study is the **Defibrillator Implantation in Patients With Nonischemic Systolic Heart Failure (DANISH)** trial.<sup>23</sup> This large randomized clinical trial in patients with nonischemic systolic heart failure demonstrated that ICD therapy was not associated with a lower mortality when compared with medical therapy.



**Figure 2.** Eligibility and use rates according to the year.

There are several initiatives known to improve adherence to device-based therapy.<sup>24-28</sup> The IMPROVE HF registry is a quality-improvement registry designed to evaluate the outpatient management of systolic heart failure and to assess the effect of various improvement interventions, such as education initiatives, reminder systems, and quality reports. With use of the IMPROVE HF registry, ICD use increased dramatically from 50.1% to 77.5%.<sup>25</sup> The Get With The Guidelines Heart Failure initiative is another effective prospective quality improvement registry that has shown improvement in the use of CRT implants among patients with heart failure.<sup>28</sup> In addition, several patients are never referred to a specialist or appropriately

followed up. The use of electronic screening tools has significantly improved appropriate ICD referrals.<sup>29</sup> Initiatives such as these could be implemented at device implanting centers to improve use among patients meeting guideline criteria.

### Study limitations

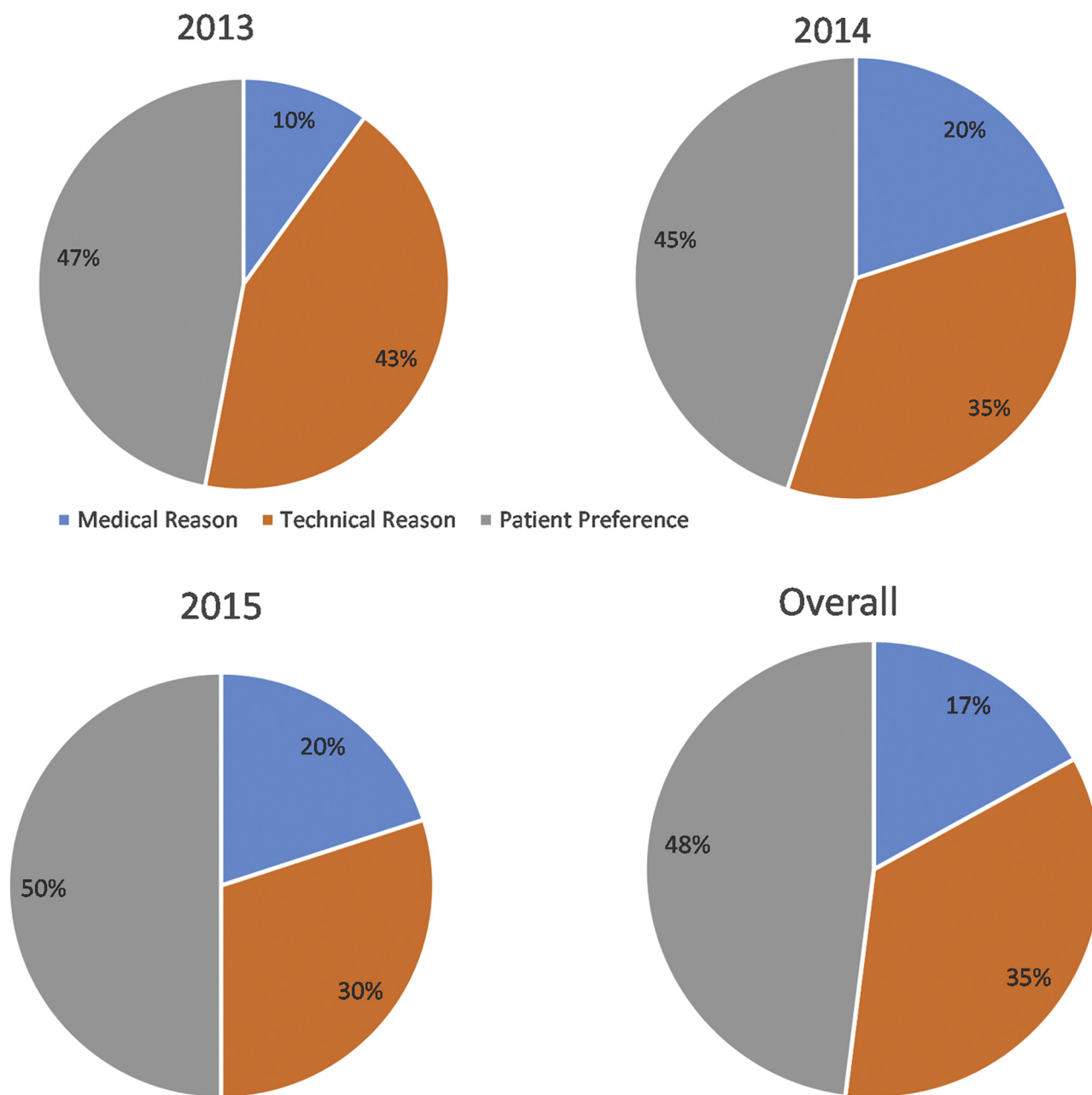
There are limitations to our study that warrant discussion. First, this was a retrospective study in which abstraction errors and variability in medical chart completeness pose a risk. However, to minimize this, each site adhered to strict definitions of device eligibility. Second, approximately one-quarter of patients were excluded because of missing heart

**Table 3.** Factors associated with nonimplantation in patients meeting guideline criteria and nonrecipients lacking a documented reason for nonimplant

Associated factor	Met guideline criteria				Nonrecipients lacking a documented reason for nonimplant			
	Univariate analysis		Final model		Univariate analysis		Final model	
	OR (95% CI)	P	OR (95% CI)	P	OR (95% CI)	P	OR (95% CI)	P
Age > 75 y	<b>1.93 (1.32-2.83)</b>	<b>0.001</b>	<b>1.92 (1.31-2.82)</b>	<b>0.001</b>	<b>1.48 (1.03-2.12)</b>	<b>0.033</b>	<b>1.48 (1.03-2.12)</b>	<b>0.033</b>
Male	0.98 (0.66-1.46)	0.932			1.01 (0.67-1.52)	0.965		
LVEF < 30%	1.12 (0.79-1.59)	0.507			0.90 (0.63-1.29)	0.576		
Ischemic	0.83 (0.59-1.17)	0.284			0.87 (0.60-1.24)	0.432		
NYHA class								
I (ref)	1.0				1.0			
II	1.06 (0.67-1.66)	0.814			0.97 (0.61-1.53)	0.892		
III	0.72 (0.44-1.19)	0.200			0.75 (0.44-1.28)	0.291		
IV	0.98 (0.23-4.10)	0.974			1.71 (0.54-5.42)	0.359		
Not reported	1.69 (0.82-3.47)	0.152			1.32 (0.72-2.43)	0.377		
Atrial fibrillation	1.27 (0.88-1.83)	0.201			1.38 (0.96-1.96)	0.078		
Hypertension	0.83 (0.59-1.17)	0.285			0.94 (0.66-1.34)	0.745		
Hyperlipidemia	0.59 (0.33-1.04)	0.067	0.55 (0.31-0.98)	0.043	0.68 (0.35-1.35)	0.274		
Myocardial Infarction	0.81 (0.55-1.18)	0.273			0.91 (0.61-1.35)	0.630		
Diabetes	0.91 (0.63-1.31)	0.619			0.85 (0.57-1.26)	0.418		
Peripheral vascular disease	1.08 (0.40-2.88)	0.881			0.93 (0.32-2.72)	0.897		
Cerebrovascular disease	0.96 (0.55-1.70)	0.900			0.82 (0.42-1.61)	0.566		
Kidney disease	1.66 (1.03-2.68)	0.039			1.32 (0.85-2.05)	0.222		
Cancer	<b>2.47 (1.18-5.18)</b>	<b>0.017</b>	<b>2.26 (1.07-4.78)</b>	<b>0.033</b>	1.65 (0.98-2.80)	0.061		
Dementia	3.52 (0.43-28.79)	0.241			1.66 (0.44-6.24)	0.456		

Bold values indicate significant values.

CI, confidence interval; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; OR, odds ratio.



**Figure 3.** Reasons for nonimplant according to the year.

failure data, NYHA class, or LVEF, which could have affected our findings. Third, survival of device nonrecipients was not compared with the device recipients. Fourth, there was no documented reason for nonadherence in approximately one-half of device nonrecipients. Fifth, more than one-half of deaths were out of hospital, and determining cause of death was not possible. Even among hospitalized deaths, the cause of death was dependent on the detail provided in the discharge summary. Sixth, the study was performed in one province, and the results may not be generalizable to other countries with different healthcare systems. Seventh, reasons for nonimplantation was not collected. This information could be useful when counseling

patients on the advantages and disadvantages of primary prevention device therapy.

**Conclusion**

In this population-based study of complex device eligibility and use, we found that one-third of patients meeting guideline criteria for ICD therapy receive a device. Among those who did not receive a device, a documented reason for nonimplantation was missing in more than one-half of patients. To develop initiatives to improve use, a better understanding of patient, physician, and system barriers to device implantation is needed. Documenting reasons for ineligibility should be encouraged.

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### **Supplementary Material**

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