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

Rochelle Bernier, MSc, Jessica Ng, BSc, Dat T. Tran, PhD, Evan Lockwood, MD, Lucy Reyes, MN, Karen Cowan, RN, Nowell M. Fine, MD, SM, Justin Ezekowitz, MBCh, MSc, Derek V. Exner, MD, Satish R. Raj, MD, MSC, and Roopinder K. Sandhu, MD, MPH

A retrospective study was performed of patients seen at heart function clinics 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 guidelines. 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 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 guidelines. 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. However, data regarding the number of patients these guideline recommendations apply to and use of ICD therapy in clinical practice are sparse. These data would be important to benchmark care and to identify potential strategies for improvement where gaps exist.

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. 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. However, data regarding the number of patients these guideline recommendations apply to and use of ICD therapy in clinical practice are sparse. These data would be important to benchmark care and to identify potential strategies for improvement where gaps exist.

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

Corresponding author: Dr Sandhu, 8440-112 St, 2C2 WMC, Edmonton, Alberta T6G 2B7, Canada. Tel.: +1-780-407-6827; fax: +1-780-407-6452.
E-mail: rsandhu2@ualberta.ca
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 an ICD and that documentation for nonimplantation. We found that one-third of patients who met guideline criteria received an ICD and that documentation for nonimplantation was poor.

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.

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. Patients met guideline criteria for an ICD if they met the following criteria: (1) ischemic cardiomyopathy; (2) LVEF ≤ 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 ≥ 3 months of determined device eligibility; or (1) nonischemic cardiomyopathy; (2) LVEF ≤ 0.35; (3) NYHA class II to III; CRT: (1) sinus rhythm, (2) LVEF
variable selection was used to determine the
using Kruskal
recipients. Device recipients and nonrecipients were compared
the univariable association had a
logistic regression to explore patient factors associated with
device nonimplantation. We included candidate variables if
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.

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
(stdandard 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 ≤ 0.25. Stepwise
variable selection was used to determine the final model, and
variables were considered significant with a P value of
< 0.05.10 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 non-
implantation 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 non-
recipients who lacked a documented reason for nonim-
plant. 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 non-
recipients; however, half of nonrecipients lacked a docu-
mented reason for nonimplantation. At 3 years follow-up,
approximately one-quarter of nonrecipients were deceased.
Previous studies 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 and similar patient cohorts. The retrospective study by Lyons et al. 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. 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%. 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 have also demonstrated significant underuse of ICD therapy with rates as low as 13%. 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.

Table 1. ICD eligibility criteria

| ICD CRT | CRT  |
|----------|------------------|
| Cardiomyopathy | Sinus rhythm |
| Ischemic | Nonischemic |
| NYHA I-III | NYHA II-III |
| LVEF ≤ 0.35 | LVEF ≤ 0.35 |

| QRS ≥ 150 ms and non-LBBB | QRS ≥ 150 ms and LBBB |
|---------------------------|-----------------------|

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

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   |
| LVEF, mean (SD) | 40.5 (0.28-0.53) | 26.9 (8.0) | 51.5 (8.5) | < 0.001 |
| 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) | 0.765   |
| 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 (52.3) | 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)   | 0.198   |
| Peripheral vascular disease | 41 (3.3) | 19 (3.4) | 22 (3.2) |         |
| 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.
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\textsuperscript{10,13,18} 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\textsuperscript{10,14,15} 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\textsuperscript{22} 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.\textsuperscript{23} 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.

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**Figure 1.** Patient flow diagram. LVEF, left ventricular ejection fraction; HF, heart failure; NYHA, New York Heart Association.
There are several initiatives known to improve adherence to device-based therapy. 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%. 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. 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. 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                                               |
| Age > 75 y                        | 1.93 (1.32-2.83) 0.001  | 1.92 (1.31-2.82) 0.001                                    | 1.48 (1.03-2.12) 0.033  | 1.48 (1.03-2.12) 0.033                                    |
| 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 II                     | 1.06 (0.67-1.66) 0.814  |                                                          | 0.97 (0.61-1.53) 0.892  |                                                          |
| NYHA class III                    | 0.72 (0.44-1.19) 0.200  |                                                          | 0.75 (0.44-1.28) 0.291  |                                                          |
| NYHA class IV                     | 0.98 (0.23-4.10) 0.974  |                                                          | 1.71 (0.54-5.42) 0.359  |                                                          |
| NYHA class 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                            | 2.47 (1.18-5.18) 0.017  | 2.26 (1.07-4.78) 0.033                                    | 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.
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

To access the supplementary material accompanying this article, visit CJC Open at https://www.cjcopen.ca/ and at https://doi.org/10.1016/j.cjco.2019.05.002.