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Utilization Rates of Implantable Cardioverter-Defibrillators for Primary Prevention of Sudden Cardiac Death: A 2012 Calculation for a Midwestern Health Referral Region

Allen Hoang, MD¹, Changyu Shen, PhD^{2,5}, James Zheng, PhD, MHA³, Stanley Taylor, MA², William J Groh, MD, MPH, FHR¹, Marc Rosenman, MD⁴, Alfred E. Buxton, MD⁶, and Peng-Sheng Chen, MD, FHR¹

¹Krannert Institute of Cardiology and the Division of Cardiology, Indiana University, Indianapolis, IN

²Department of Biostatistics, Indiana University, Indianapolis, IN

³The Regenstrief Institute, Indiana University, Indianapolis, IN

⁴Department of Pediatrics, Indiana University, Indianapolis, IN

⁵School of Public Health, Indiana University, Indianapolis, IN

⁶Cardiovascular Division, Department of Medicine, Beth Israel Deaconess Medical Center and Harvard Medical School, Boston, MA

Abstract

Background—Utilization rates (URs) for implantable cardioverter-defibrillators (ICDs) for primary prevention of sudden cardiac death (PPSCD) are lacking in the community.

Objective—To establish the ICD UR in central Indiana.

Methods—A query run on two hospitals in a health information exchange database in Indianapolis identified patients between 2011 and 2012 with left ventricular ejection fraction (EF) 0.35. ICD-eligibility and utilization were determined from chart review.

Results—We identified 1,863 patients with at least one low-EF study. Two cohorts were analyzed: 1,672 patients without, and 191 patients with, ICD-9-CM procedure code 37.94 for ICD placement. We manually reviewed a stratified (by hospital) random sample of 300 patients from

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Address for Correspondence: Peng-Sheng Chen, MD, 1800 N. Capitol Ave, E 475, Indianapolis, IN 46202, Phone: 317-962-0145 / Fax: 317-962-0588 / chenpp@iupui.edu.

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the no-ICD procedure code cohort and found that 48 (16%) had no ICD but had class I indications for ICD. Eight of 300 (2.7%) actually had ICD implantation for PPSCD. Review of all 191 patients in the ICD procedure code cohort identified 70 with ICD implantation for PPSCD. The ICD UR (ratio between patients with ICD for PPSCD and all with indication) was 38% overall (95% CI 28–49%). URs were 48% for males (95% CI 34–61%), 21% for females (95% CI 16–26%, $p=0.0002$ vs males), 40% for whites (95% CI 27–53%), and 37% for blacks (95% CI 28–46%, $p=0.66$ vs whites).

Conclusions—The ICD UR is 38% among patients meeting Class I indications, suggesting further opportunities to improve guideline compliance. Furthermore, this study illustrates limitations in calculating ICD UR using large electronic repositories without hands-on chart review.

Keywords

defibrillator; implantable cardioverter-defibrillator; sudden cardiac death; arrhythmia; utilization

INTRODUCTION

Multiple studies have demonstrated a mortality benefit of implantable cardioverter-defibrillators (ICDs) in the primary prevention of sudden cardiac death (PPSCD) in selected patients with left ventricular dysfunction.^{1, 2, 3, 4} This led to the adoption of ICD therapy for PPSCD and a Class IA recommendation for cardiology practice.^{5–7} However, not all eligible patients receive an ICD. Shah et al, using The Get With The Guidelines-Heart Failure (GWTG-HF) registry, described ICD utilization rates (URs) from hospitals across the United States.⁸ With rigorous methods of analyses, the GWTG-HF URs were found to be as low as 1% in the lowest tertile of hospitals to as high as 80% in the upper tertile. The region with most hospitals in the upper tertile of ICD utilization was the Midwest.⁸ The URs were not reported specifically for each geographic region, so the ICD UR in the community remains unclear. Other studies assessing (PPSCD) ICD URs confirm the low rates and high variability, as low as 28%⁹ and as high as 80%¹⁰ in the US. These URs reflect University tertiary care teaching hospitals^{11, 12} and Veterans Affairs Hospitals,^{9, 10} but none mentioned the inclusion of safety-net hospitals, where a more representative assessment of the community's adherence to guideline-based therapy can be made. Furthermore, few of these studies were derived from comprehensive chart review. Because of these limitations, the ICD UR in the community remains unclear. Other notable findings from literature review show that women are less likely than men to receive ICDs,^{13–16} that blacks are less likely than whites to receive ICDs,^{14, 17, 18} and there is great disparity in ICD implantation rates among hospital referral regions in the US.^{19, 20} We sought to establish the ICD UR in central Indiana, by collecting data from a not-for-profit, University-affiliated tertiary care teaching hospital and a county hospital and reviewing the patient charts to more accurately reflect the real-world community.

METHODS

Because chart review validation would be integral to this study, we selected two hospitals for which access to all medical records (including text reports) was readily available. These

two hospitals account for 44% of the inpatient beds among the six major hospitals in the area. All six of the major hospitals have subspecialty cardiology services.²¹ We sought to ascertain the ICD UR over a recent twelve-month period (6/1/2011–5/31/12), through database query and chart review. The study was approved by the institutional review board of Indiana University and Purdue University Indianapolis.

The UR is defined in Equation 1. The strategy to identify patients in both x and y is outlined below.

Equation 1. Utilization Rate (UR)

$$UR(\%) = \frac{x}{x+y} \times 100\% \quad (1)$$

Where x = number of patients with ICD's implanted for PPSCD during a selected period ("ICD-utilized") and y = number of patients with indication for ICD therapy but not implanted during the study period ("ICD-eligible").

Low Ejection Fraction Query

We first identified a cohort of patients with at least one left ventricular ejection fraction (EF) 0.35 by echocardiography between June 1, 2011 and May 31, 2012. Data from the health information exchange were extracted via Structured Query Language. Service codes (medical record dictionary terms) for echocardiograms were used to query EF values either directly or by calculation from left ventricular diastolic volume and systolic volume. A patient with at least one qualifying EF value obtained through either method was included in the low EF cohort. To identify low-EF patients who received an ICD during the study period, we used billing codes for ICD implantations. From the *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)*, the inpatient hospital procedure code 37.94 (Implantation or replacement of automatic cardioverter/defibrillator, total system [AICD]) was examined in our first query. We also searched for the code V45.02 (Automatic implantable cardiac defibrillator in situ) to identify patients with previous ICD implantation. Current Procedural Terminology (CPT) Code 33249 (Insertion or repositioning of electrode lead(s), for single or dual chamber pacing cardioverter defibrillator and insertion of pulse generator) was also used in an attempt to further screen for ICD implantations.

Chart Review

From the low-EF cohort generated by the automated query, those without code 37.94 were defined as Cohort A, and those with the code as Cohort B (Figure 1). Three hundred patients were randomly selected (150 from each hospital) from Cohort A for chart review, and from Cohort B, all 191 (total of 491). Patients' medical record numbers (MRNs) were randomly assigned a study number based on hospital. A standardized chart abstraction method was applied to promote consistency, recording de-identified patient data into database software (RedCapTM).

In all 491 charts reviewed, echocardiogram reports were scrutinized to find EFs recorded by physicians (as opposed to EFs extracted by the automated query, which reflect calculated values based on measurements entered by echocardiogram technicians). The reviewer used the clinician's stated EF in the official report to determine eligibility for ICD. Diagnostic reports, including echocardiograms, ventriculograms, and radionuclide imaging (including those not pre-populated by the automated low EF query) were reviewed to confirm EF.

Review for ICD Indication—Once patients with low EF were identified, defined as EF ≤ 0.35 , a review for ICD implantation was carried out as described in the sections below. Those without ICD were considered as candidates for ICD therapy by having EF ≤ 0.35 alone, without respect to ischemic disease, unless there were contraindications for ICD based on the 2008 American College of Cardiology/American Heart Association/Heart Rhythm Society (ACC/AHA/HRS) Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities,⁷ or obvious reasons why ICD would not be standard of care (Figure 1). These guidelines state that ICD is indicated in patients with LV dysfunction due to prior MI who are at least 40 days post-MI, have an EF less than 30% with NYHA functional Class I or EF less than 35% with NYHA II or III. However, because NYHA functional class and ischemic disease could not be confirmed across all charts, the primary inclusion criterion was EF ≤ 0.35 .

Verification of Utilized ICD – Cohort A—From Cohort A, ICD-implanted patients who had not been identified by code 37.94 underwent chart review to exclude implantations before the study period (6/1/2011), non-low EF, or non-primary prevention indications (Figure 1). These patients had either code V45.02 or CPT code 33249. Patients receiving cardiac resynchronization therapy (CRT) cardioverter-defibrillators (CRT-D) were treated in the same way as non-CRT ICDs by reviewing the indication for SCD prevention.

Verification of Utilized ICD – Cohort B—Among the 191 patients in Cohort B (all with code 37.94), manual chart review was performed in the same way as for those with ICD implants in Cohort A above (Figure 1). Implantations from both cohorts thus comprised the number of ICD's implanted for PPSCD during the study period.

Utilization Rate Calculation

The UR is calculated based on Equation 1, of which Equation 2 is a modification, including variables specific to the study design.

Equation 2. ICD Utilization Rate, expanded

$$UR(\%) = \frac{Cx_A + x_B}{(Cx_A + x_B) + Dy_A + y_B} \times 100\% \quad (2)$$

Where

C, D = sampling correction factors for Cohort A

x_A = patients with ICD indication and implantation in samples of Cohort A

x_B = patients with ICD indication and implantation, Cohort B

y_A = patients with ICD indication but without implantation in samples of Cohort A

y_B = patients with ICD indication but without implantation, Cohort B

Cohort A is composed of an unequal number of patients from two hospitals, from which the same number of patients were sampled (150 from each). Therefore, correction factors were used to account for the disproportional sampling rate as outlined in Equation 3. The numerator in Equation 2 estimates the number of patients with ICD among the 1,863 low EF subjects, and the denominator estimates the number of patients eligible for primary ICD, where Cx_A and Dy_A represent the estimated numbers of eligible patients with and without ICD in Cohort A of 1,672 subjects. Of note, y_B is a theoretical population and was not encountered in the present study, i.e. no patient with code 37.94 lacked an ICD and met low EF criteria for PPSCD.

Equation 3. Sampling correction for Cohort A

$$Cx_A = C_1x_{1a} + C_2x_{2a} \quad (3a)$$

$$Dy_A = D_1y_{1a} + D_2y_{2a} \quad (3b)$$

Where

C_1, D_1 = sampling correction factors for Hospital 1

C_2, D_2 = sampling correction factors for Hospital 2

x_{1A}, x_{2A} : patients with ICD indication and implantation in samples of each of the two hospitals from Cohort A

y_{1A}, y_{2A} : patients with ICD indication but without implantation in samples of each of the two hospitals from Cohort A

Because there are 1,267 and 405 patients from the two hospitals in Cohort A, a sample of 150 from each represents a sampling rate of 1 in 8.45 and 1 in 2.7, respectively. Therefore, C_1 and $D_1 = 8.45$, C_2 and $D_2 = 2.7$, and Cx_A and Dy_A hence represent the projected number of patients with and without ICD in Cohort A of 1,672 subjects. Confidence intervals of the UR are computed based on normal approximation that accounts for the sampling corrections.

RESULTS

Low-EF Query

We searched the electronic medical records of 4,352,020 patients and identified a total of 21,663 unique patients who had an EF documented between 6/1/2011 and 5/31/2012. From this pool, 1,863 patients were identified as having EF ≤ 0.35 at least once (Figure 1).

Utilized ICDs (Cx_A and x_B)

Cohort A – Calculation of Cx_A —In Cohort A, there were a total of 1,672 patients without ICD-9-CM code 37.94. Thirty-four of the sampled 300 patients had an ICD (despite absence of code 37.94) (Figure 2). Twenty-four of 34 had an ICD coded under ICD-9-CM diagnosis code V45.02, which suggests that the devices were implanted at a hospital outside the two hospitals in the study or were erroneously not assigned code 37.94. The remaining 10 of 33 carried none of the three codes 37.94, V45.02, or 33249. A query confirmed that patients with CPT code 33249 were completely accounted for by queries for 37.94 or V45.02; therefore, CPT code 33249 was not required to further identify patients with ICD devices.

By indication, 8 of the 33 were *new* implants for PPSCD associated with physician-confirmed low EF (Figure 2). The other 26 patients with an ICD had these four scenarios (multiple qualifications were assigned with descending priority, i.e. 1>2>3): (1) ICD implanted before the 12-month period [N=22] or unavailable confirmed date of original implant [N=1], (2) ICD for secondary prevention [N=1], or (3) ICD implanted despite last EF>0.35 [N=1]. The 8 patients with *new* implants for PPSCD associated with physician-confirmed low EF implies an estimated number of 50 (Cx_A) over Cohort A based on Equation 3.

Cohort B – Calculation of x_B —There were a total of 191 patients among the low-EF query whose charts contained procedure code 37.94, of which 164 had ICD implantation within the selected timeframe (Figure 3). The rest were excluded: 26 with ICD implantation before the 12-month study period and 1 incorrectly with a 37.94 code for a dual-chamber pacemaker without defibrillator function. By indication, 88 were excluded due to secondary prevention indication, 4 excluded for long QT syndrome or hypertrophic cardiomyopathy, and 2 excluded for primary prevention with EF > 0.35. The remainder, 70 (x_B), of the 191 patients in Cohort B had a new primary prevention ICD implantation during the study period and physician-confirmed low EF (Figure 3).

ICD-Eligible (Dy_A and y_B)

In the review of 300 patients from Cohort A, 137 patients without ICD were confirmed by the chart review to actually have EF \leq 0.35 (Figure 2). Excluded were patients with low EF as detected by query (based on sonographer measurements) but whose official EF as read by the cardiologist (which is not searchable by query) was >0.35. Patients were also excluded if a follow-up EF assessment showed EF >0.35. These exclusions totaled 127. One patient had an inconclusive EF, and one record was a duplicate of a patient who was confirmed as low EF (Figure 2). Of the 137 with a confirmed low EF, 48 were ICD-eligible, i.e. having no contraindications (Figure 2). According to Equation 3, there were an estimated 193 patients (Dy_A)—over 1,672 in Cohort A—who met indications for ICD implantation for PPSCD but did not have an ICD. Zero such patients from Cohort B were identified ($y_B = 0$).

Utilization Rate Calculation

Given the variables determined above — Cx_A , x_B , Cy_A , (and y_B which was zero)— for ICD-utilized and ICD-eligible without ICD during the study period, the UR could then be

calculated according to Equation 2. The ICD UR was 38% (120/313, 95% CI 28–49%). Utilization rates were 48% for males (95% CI 34–61%), 21% for females (95% CI 16–26%, $p=0.0002$ vs males), 40% for whites (95% CI 27–53%), and 37% for blacks (95% CI 28–46%, $p=0.66$ vs whites). The mean age of patients with an ICD was 55.7 years (57.0 median, interquartile range 42.4–67.8 years), and of patients without ICD, mean 60.9 years (63.3 median, interquartile range 52.7–66.5) ($p=0.11$).

Reasons for No ICD

The review of 300 patients from Cohort A revealed 137 with confirmed low EF (Table 1). Forty-eight of 137 had no contraindications to ICD and were included in the UR calculation above. Among the remaining 89, the contraindications included the following: heart failure diagnosed within 3 months of low EF (11% of Cohort A patients with low EF), death before work-up (11%), MI within 40 days or percutaneous coronary intervention/ coronary artery bypass grafting (PCI/CABG) within 3 months (11%), patient refusal (9%), do not resuscitate status (DNR) (8%), active and advanced cancer (6%), non-compliance with medical or dietary therapy (4%), dementia (4%), functional NYHA Class I non-ischemic heart failure (3%), awaiting kidney transplant (1%), primary care physician refusal (1%), pregnancy (<1%), or lost to follow-up after ICD recommendation (<1%).

For the 48 patients considered ICD-eligible but without ICD, a separate review was carried out in December 2013 to elucidate the extent to which these patients were evaluated for ICD indication. Among the 48 initially with no apparent contraindications, ICD was mentioned in inpatient or outpatient notes for 12 patients. Among these 12, ICD was discussed in greater detail in 6 cases, 3 of whom were offered ICD. Two of the 3 patients refused, while one was deferred by the cardiologist due to emaciation. For 36 patients, ICD was never mentioned at the time of the low EF study or the immediate follow-up visit. Among these, 6 patients were later found to have been awaiting revascularization or valve surgery.

DISCUSSION

Previously Calculated ICD Utilization Rates

The reported ICD UR among the eligible populations has been highly variable. At a Veterans Affairs Medical Center (VAMC) in California, the ICD UR was found to be 28% from 2002 to 2006.⁹ Atwater et al¹⁰ reported an ICD UR of 80% in 2010 at a VAMC in North Carolina. Both studies used chart review and assessed for contraindications to ICD, which would mitigate a falsely low UR. Great disparity in ICD implantation rates among hospital referral regions in the United States has been described in the literature;²² therefore, caution is advised when comparing ICD URs from those locales and from those time periods.

While we found that the ICD UR for PPSCD is low, the ICD UR for secondary prevention was also reported as low (<40%) in a database study²³ and a chart review.²⁴ The low rate of guideline compliance is not limited to device therapy, as 25% of the patients with an ICD did not receive optimal medical therapy in one study.²⁵

The most comprehensive assessment of ICD URs in the country to date was reported by Shah et al in 2009, based on data gathered from the GWTG-HF quality improvement program.⁸ ICD URs were reported to be 17% overall, with rates ranging from 1% to 80%. The present study offers a different perspective from that of GWTG-HF by focusing on the rates in the community. In addition, because our study was performed several years later than that of GWTG-HF, the time difference may in part explain the different ICD URs between our study and the GWTG-HF.

Hospital Representation of ICD UR in the Region

The hospitals included in this study comprised 44% of the Indianapolis metropolitan area's inpatient beds. Logistical reasons in designing the study prevented further involvement of the other systems. However, we feel that having representation from the region's county hospital helps to more accurately portray utilization rates in the community, when combining data with a large private hospital with university affiliation. A true ICD UR in the region is likely to be higher than that reported in this study, because the other (excluded) hospitals include one private hospital with teaching affiliation, two private not-for-profit hospitals, and a VAMC (the latter has 5% of the inpatient beds in the area). All six of these hospitals provide cardiology subspecialty services.²¹

Benefit of Chart Review

Chart review is essential for UR accuracy. Many patients who were initially identified as having a low EF were actually found to have EF >0.35 when the cardiologist's interpretation of the echocardiogram was reviewed. Another factor that could skew results without chart review is improvement of EF over time. Our initial query captured patients based on a single low EF. Chart review was required to identify those whose subsequent studies, including non-echocardiogram LV assessment methods, no longer had EF < 0.35. Furthermore, chart review is important because of the number and subjectivity of contraindications. Particularly, the contraindication "any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than 1 year" as phrased by the Centers for Medicare & Medicaid Services decision memorandum²⁶ may be inaccurately discerned if one is using diagnostic codes without chart review. Information such as DNR status, patient refusal, and advanced cancer diagnoses, etc., is not conducive to identification via queries.

Reasons for Low ICD Utilization Rate

Among the 48 ICD-eligible patients without ICD, 36 did not have mention of ICD in the records at discharge or during outpatient follow-up. This implies that physicians who ordered the imaging studies did not appreciate the importance of ICD implantation in patients with a severely reduced EF. Such lack of awareness would prevent a provider from making the appropriate referral for ICD workup. Other provider-based reasons include ineffective dissemination of current practice guidelines,²⁷ perceived marginal cost-benefit profile of ICD, and a long period of time required for medical optimization. Patient-driven reasons include not understanding the risk of sudden cardiac death, not following up with Cardiology or Electrophysiology referrals, and/or suboptimal medication adherence leading to delay in evaluation for ICD. As in previous studies, we found that the ICD UR is lower in

women than in men. However, there is no evidence that UR is different between whites and blacks. The reasons for underutilization of ICD in women remain unclear.

Proposed Interventions to Improve ICD URs

To improve patient understanding of sudden cardiac death risk, more counseling should be given when a diagnostic study reveals EF ≤ 0.35 . A discussion led by the physician with incorporation of nursing education could reinforce a patient's grasp of sudden cardiac death risk. Physician education, likewise, may help improve understanding of ICD benefit and thereby may increase referrals when appropriate. The best place for this discussion should be a clinic setting because of the complexity of indications and the nuances of living with an ICD. To get patients there, an electronic medical record prompt for patients with qualifying low EF at the time of hospital discharge would increase referral rates. Further prompts should follow the initial reminder to reduce unnecessary referrals for those likely to be poor ICD candidates. Furthermore, ongoing risk stratification studies of ICD therapy should improve the ability to identify high-risk patients and thereby increase those patients' likelihood for ICD referral.

Study Limitations

The sampling correction required to account for Cohort A was necessary because of disproportionate sampling: We reviewed 150 charts from each hospital, but the total of 1,672 patients with low EF in the initial query was not evenly distributed across the two hospitals. Ideally, chart review on all 1,672 patients from Cohort A should be done but could not be done due to resource limitations. Additionally, a likely reason for an inaccurate ICD UR is that patients are lost to follow-up. The present study allows follow-up only within the two hospitals; it misses patients who moved outside of the network during the study period. Furthermore, patients lost to follow-up but remaining in the region may be more likely to refuse ICD therapy. Because refusing ICD therapy is considered a contraindication for the purpose of this study, the presence of such a group would raise the ICD UR by reducing the denominator.

CONCLUSION

The ICD UR is 38% among patients meeting Class I indications, suggesting further opportunities to improve guideline compliance. This finding represents one of several areas in heart failure with suboptimal guideline adherence rates. This study illustrates the benefit of hands-on chart review in calculating ICD UR as compared to using only large electronic repositories. Furthermore, this study is the first to combine patients from a private and a county hospital in the same region to provide a more accurate ICD UR for the community.

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List of Abbreviations

ACC	American College of Cardiology
AHA	American Heart Association
CABG	coronary artery bypass grafting
CPT	Current Procedural Terminology
CRT	cardiac resynchronization therapy
CRT-D	cardiac resynchronization therapy cardioverter-defibrillator
DNR	do not resuscitate
EF	ejection fraction
GWTG-HF	Get With Guidelines-Heart Failure (GWTG-HF) registry
HRS	Heart Rhythm Society
ICD	implantable cardioverter-defibrillator
ICD-9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification
LV	left ventricular
MI	myocardial infarction
MRN	medical record number
NYHA	New York Heart Association
PCI	percutaneous coronary intervention
PPSCD	primary prevention of sudden cardiac death
UR	utilization rate

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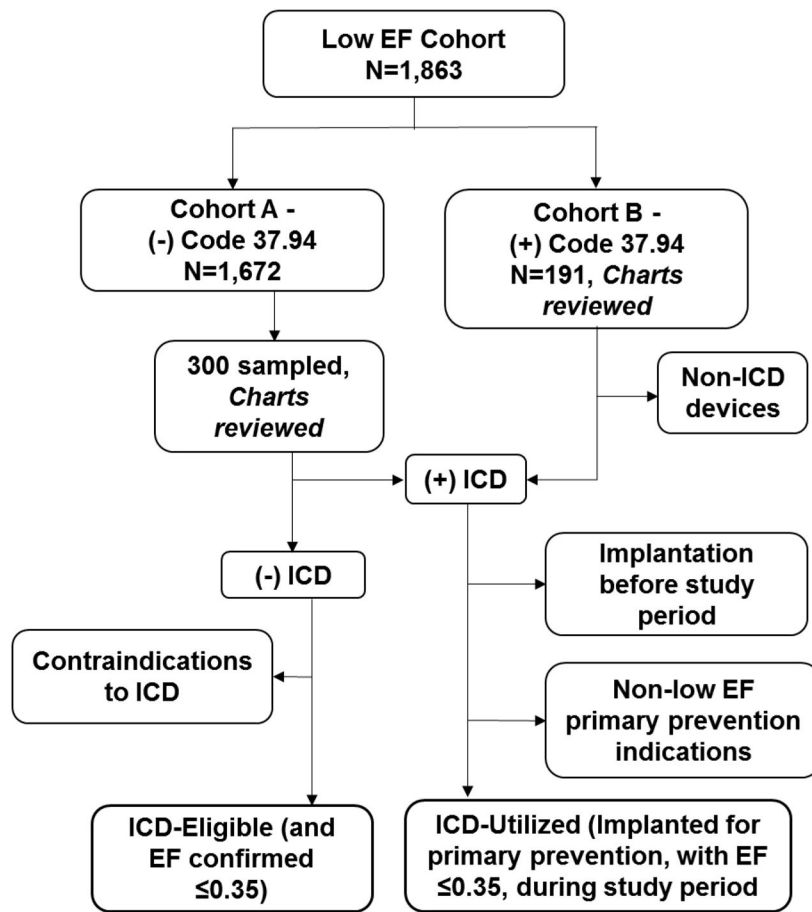


Figure 1.
Process of patient selection and review.

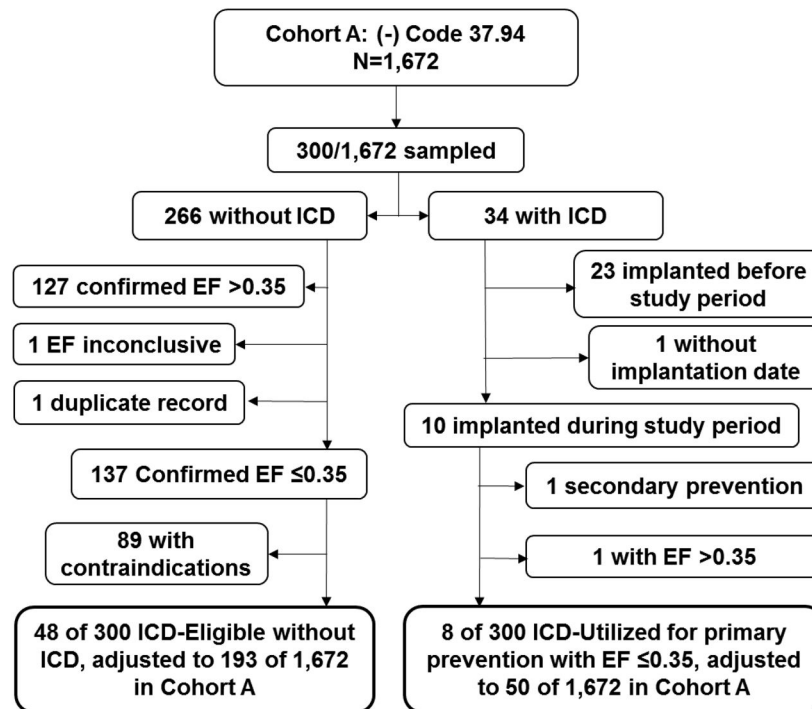


Figure 2.

Flow chart of Cohort A. Sampling correction factors of 8.45 (C_1 , D_1) for the private hospital (150 of 1,267 charts sampled) and 2.7 (C_2 , D_2) for the county hospital (150 of 405 charts sampled) were applied to estimate ICD-eligible and ICD-utilized populations over the entire cohort. For those with ICD, only those who received ICD during the study period, from June 1, 2011 to May 31, 2012, were selected.

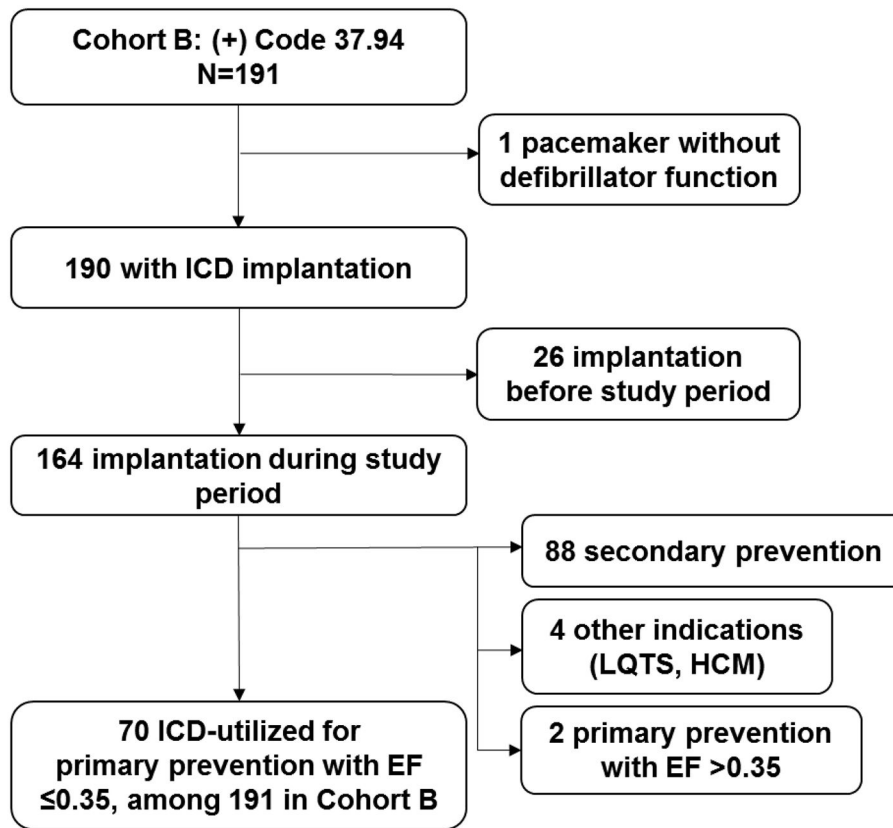


Figure 3. Flow chart of Cohort B. Those who initially received ICD before the study period were excluded as shown. Seventy patients were found to meet criteria for ICD-utilized for primary prevention with low EF.

Table 1

Contraindications for ICD in Cohort A

	Among 300 Sampled	Estimated number (percentage among low EF in Cohort A)
Total Confirmed EF 0.35	137	692 (100)
Total Contraindications	89	499 (72)
Newly diagnosed heart failure*	14	78 (11)
Died [†]	14	78 (11)
Recent MI [‡] , PCI/CABG [§]	12	78 (11)
DNR	11	58 (8)
Patient Refusal/ Reluctance	10	62 (9)
Non-compliance	8	27 (4)
Advanced cancer	6	45 (6)
Dementia	5	31 (4)
NYHA-I with non-ischemic disease	5	19 (3)
Primary Care Refusal	1	8 (1)
Awaiting kidney transplant	1	8 (1)
ICD offered but no follow-up	1	3 (<1)
Pregnancy	1	3 (<1)

* Low EF study within 3 months of chart review.

[†] Died within 3 months of low EF or chart review.

[‡] Within 40 days of encounter.

[§] Within 3 months of encounter.

ICD indicates implantable cardioverter-defibrillator; EF, left ventricular ejection fraction; MI, myocardial infarction; PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting; DNR, do not resuscitate; NYHA, New York Heart Association functional class.