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Prevalence of Guideline Directed Medical Therapy Among Patients Receiving Cardiac Resynchronization Therapy Defibrillator Implantation in the NCDR® during the years 2006 to 2008

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Abstract

Cardiac resynchronization therapy (CRT) reduces morbidity and mortality among selected patients with left ventricular systolic dysfunction and severe heart failure symptoms despite guideline directed medical therapy (GDMT). Contemporaneous guidelines provided clear recommendations regarding selection of patients for CRT, including that all patients should first receive GDMT with beta-blockers and renin-angiotensin axis antagonists. Prevalence of GDMT among real-world patients receiving CRT defibrillators (CRT-D) has not been well studied. We identified 45,392 patients in the National Cardiovascular Data Registry Implantable Cardioverter-Defibrillator Registry who underwent first CRT-D implantation for primary prevention of sudden death between January 2006 and June 2008. We calculated the proportion of patients with contemporaneous Class I guideline indications for CRT-D, the proportion receiving GDMT for heart failure, and the proportions receiving GDMT who had Class I guideline indications for CRT-

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D. Among patients without contraindications, 87% were prescribed beta-blockers, 78% an angiotensin converting enzyme inhibitors (ACE-I) or an angiotensin II receptor inhibitors (ARB), and 70% both a beta-blocker and an ACE-I or ARB at discharge. Finally, 50% of patients met Class I guideline indications and were prescribed GDMT at discharge; 9% neither met Class I indications nor were prescribed GDMT at discharge. The major limitation of this study is the lack of dosage information in the ICD Registry and lack of prescribing information at times other than discharge. In conclusion, many patients receiving CRT-D are not receiving GDMT at discharge. Ensuring that all patients receiving CRT-D are also receiving GDMT appears to be a quality improvement target.

Keywords

Cardiac Resynchronization Therapy; Defibrillator; Guideline Directed Medical Therapy

Introduction

There is a large body of evidence from randomized controlled trials that show mortality benefit with the use of beta-blocker therapy¹⁻⁴ and angiotensin converting enzyme inhibitor (ACE-I) therapy⁵⁻⁷ in patients with systolic heart failure. Though the mortality benefit is less clear for angiotensin II receptor inhibitors (ARB)⁸⁻¹⁰, ARB agents are considered an acceptable substitute when ACE-I agents are not tolerated¹¹. Current guidelines for management of heart failure in adults recommend beta-blockers in combination with either an ACE-I or ARB as part of guideline directed medical therapy (GDMT)¹¹. The emphasis on optimal GDMT as a prerequisite prior to device implantation is in large part due to the proven mortality benefit in patients with left ventricular systolic dysfunction¹¹⁻¹³. Fein and colleagues demonstrated that nearly one in four patients undergoing cardiac resynchronization therapy (CRT) implantation did not meet contemporaneous guideline recommendations¹⁴. However, the extent to which patients are receiving GDMT in the setting of CRT implantation is less well known. Therefore, our aim was to determine the percentage of patients enrolled in the National Cardiovascular Data Registry Implantable Cardioverter-Defibrillator (ICD) Registry who received CRT devices with defibrillator capability (CRT-D) who were receiving GDMT.

Methods

Analyses in this study are based on data contained in the ICD Registry, a Centers for Medicare and Medicaid Services mandated national database developed in collaboration with American College of Cardiology Foundation and the Heart Rhythm Society. Detailed data are collected on each implantation. Selected heart failure specific elements are shown in Table 1, with a full list of elements available at <http://www.ncdr.com/WebNCDR/ICD/home/datacollection>.

The population of interest was ICD Registry patients who received CRT-D implantations between January 2006 and June 2008. The study period was chosen to be after publication of the 2005 ACC/AHA guideline update and before adoption of the 2008 ACC/AHA/HRS Device Based Therapy Guideline^{11,12}. This represents a time period when there were no

major updates in the guidelines or evidence base for CRT. The stability in the medical literature provided a time window in which indications for CRT implantation were stable and should have led to consistent characteristics in patients receiving CRT devices.

Baseline characteristics of the study population were examined. Simple proportions were calculated to determine prevalence of categorical variables, while mean and standard deviation were calculated for continuous variables. Simple proportions were also calculated to determine the proportion of patients which were receiving specific medical therapies and the proportion which had specific clinical characteristics.

Results

We identified 105,543 CRT-D implantations in 104,648 patients between January 2006 and June 2008 in 1300 facilities. After excluding indications that were not primary prevention, patients with previous ICD or pacemaker, clinical criteria which warranted implantation for secondary prevention (syncope, sustained VT, cardiac arrest, or transvenous pacing), and patients with missing data, our analysis cohort consisted of 45,392 patients (Figure 1). Baseline characteristics in the study cohort were examined and are presented in Table 2.

Clinical characteristics related to CRT-D indications and characteristics of medical therapy were also examined (Table 3). Only 71.5% of patients met all 3 clinical criteria (LVEF 35%, QRS duration > 120 ms, and NYHA Class III or IV symptoms) which represent contemporaneous guideline based Class I indications for CRT. We found 70.3% of those without contraindication were prescribed GDMT consisting of both a beta-blocker and an ACE-I or ARB at discharge. Additionally, 50.3% met contemporaneous guideline based Class I indications and were prescribed GDMT at discharge, but 8.7% neither met contemporaneous guideline based Class I indications nor received GDMT at discharge (Table 4).

Discussion

Examining the application of CRT-D device implantation in clinical practice using a cohort of over 45,000 patients from a national device registry has led us to three major conclusions. First, though the majority of patients who received CRT-D devices received GDMT at discharge, there is substantial room for improvement in prescription rates of GDMT. Second, just over half of the patients in this cohort were prescribed GDMT and met contemporaneous guideline based Class I indications for implantation. Third, 9% of patients neither met contemporaneous guideline based Class I indications for implantation nor were prescribed GDMT at discharge.

There has been a preponderance of evidence showing that in properly selected patients on GDMT, CRT improves ventricular function and symptoms while reducing heart failure hospitalizations and mortality¹⁵⁻²². We found that a significant minority of patients undergoing CRT implantation did not receive GDMT at discharge. We considered contraindications in our analysis, but due to the ICD Registry data being derived from chart abstraction there are likely clinically apparent contraindications that were not captured.

However, this is unlikely to account for all patients who were not prescribed GDMT at discharge.

As compared with major randomized clinical trials, this study provides mixed news regarding GDMT. We found 86% of patients were receiving beta blocker therapy at discharge, which compares favorably to the 72% and 68% reported in CARE-HF and COMPANION respectively^{18,23}. Unfortunately, the rate of ACE-I or ARB usage was 78%, which is considerably less than the 89% in COMPANION and the 95% in CARE-HF^{18,23}. While our analysis shows room for improvement in the use of GDMT it remains better than what was reported in COMPANION (70% vs 61%)²³.

By including GDMT data, we extended the analysis of Fein, *et al*¹⁴ to gain better insight into real world clinical practice. We demonstrate approximately half of our cohort both met contemporaneous Class I guideline based indications for CRT-D and were prescribed GDMT at discharge. While this appears low, this is likely partially an overestimate of patients not meeting guideline based indications as patients who had Class IIa indications for CRT-D could not be identified in the ICD Registry. However, even among those with Class I indications, about 30% were not prescribed GDMT at discharge. It is this group of patients that represent a missed opportunity to provide maximal benefit from CRT.

We tried to exclude implantations of CRT-D devices for secondary prevention, repeat procedures, documented GDMT contraindications, and other possibilities to account for implantations where deviations from recommendations regarding GDMT and clinical characteristics are clinically justified. Our study is also limited because the ICD Registry does not capture prescriptions at times other than discharge and does not contain dosage information. The lack of dosage information in the ICD Registry means we have likely given credit for some patients being on GDMT when they are on inadequate doses. However, this is likely counterbalanced by patients erroneously assigned as not receiving GDMT due to lack of prescription data from times other than discharge and from inadequate documentation of contraindications. While correlation of discharge medications with admission medications is likely high, the medical regimens at admission and discharge are unlikely to exactly parallel each other. However, in other cardiac conditions with a Joint Commission accountability measure for discharge prescriptions, adherence to accountability measures has been associated with improved outcomes^{24,25}. Accountability measure adherence has been reported as upward of 95% since 2008²⁶, which is far higher than the GDMT rate we report. Finally, discordance between source and ICD Registry data has been shown to be low²⁷, but it is unclear what influence this small amount of discordance had on our results.

We argue that whether our GDMT results represent deficient prescribing or deficient documentation, that both are problems to be addressed. Whether to approach this with a Joint Commission accountability measure, an extension of the ICD Registry to capture outpatient prescription information, re-alignment of financial incentives, or combinations of these are interventions that deserve further study. Given current recommendations regarding GDMT prior to and after CRT-D implantation, data collected in the ICD Registry indicate

that more attention should be paid to ensuring patients are receiving GDMT after CRT-D implantation.

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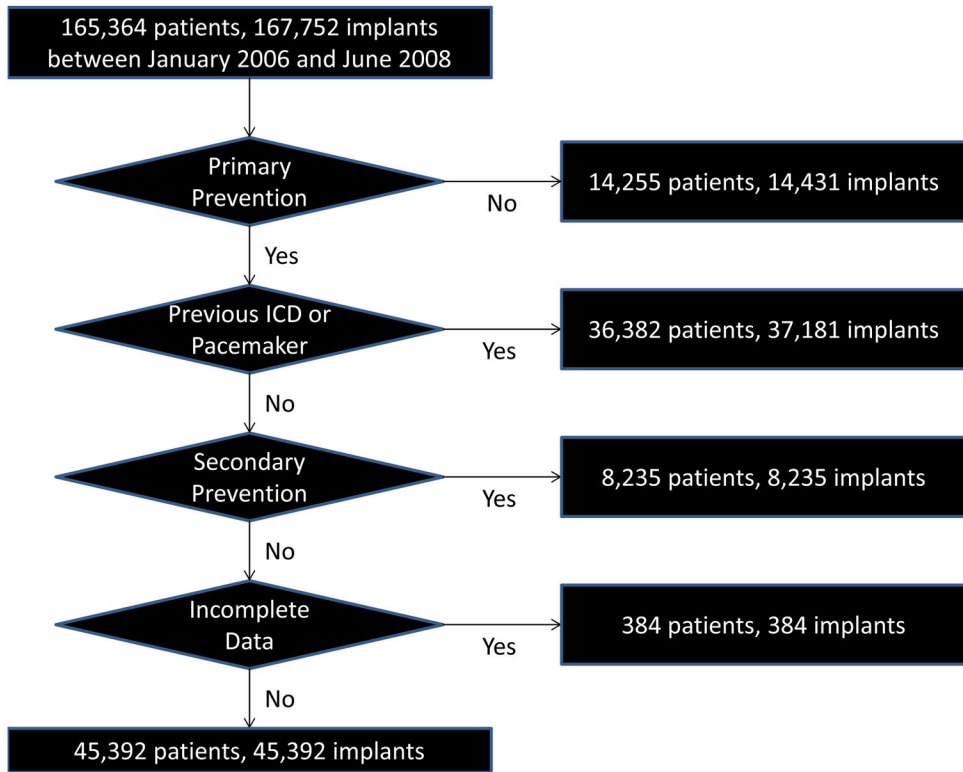


Figure 1.
Cohort Derivation

Table 1

Selected Heart Failure Specific Data Elements Collected in the Implantable Cardioverter-Defibrillator Registry

Data Element	Response Type
Clinical Characteristics and History:	
Heart Failure	Yes/No
New York Heart Association Functional Class	I – IV
Non-ischemic Dilated Cardiomyopathy	Yes/No
Prior Heart Failure Hospitalization	Yes/No
Prior Heart Transplant	Yes/No
On Heart Transplant Waiting List	Yes/No
Ischemic Heart Disease	Yes/No
Left Ventricular Ejection Fraction	%
QRS Duration	in milliseconds
Discharge Medications:	
Angiotensin Converting Enzyme Inhibitor	Yes/No
Angiotensin II Receptor Inhibitor	Yes/No
Beta-Blocker	Yes/No
Diuretic	Yes/No
Digoxin	Yes/No
Hydralazine	Yes/No
Long Acting Nitrate	Yes/No

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Table 2

Baseline Characteristics for Patients Receiving Cardiac Resynchronization Therapy with Defibrillator
(N=45,392)

Variable	Number (%) or Mean \pm SD
Admission Characteristics	
Age: Mean \pm SD (Years)	69.34 \pm 11.52
Female	14279 (31.46%)
White	37472 (82.55%)
Black	5511 (12.14%)
Other	2409 (5.31%)
Hispanic Ethnicity	2555 (5.63%)
Insurance Payor	
Government: Medicare	32773 (72.20%)
Government: Medicaid	1722 (3.79%)
Government: Other	387 (0.85%)
Commercial	6762 (14.90%)
Managed Care	2847 (6.27%)
Other	901 (1.98%)
Reason for Hospitalization	
Admitted for this Procedure	31154 (68.63%)
Hospitalized-Cardiac	8532 (18.80%)
Hospitalized-Non-Cardiac	4750 (10.46%)
Missing or Unknown	956 (2.11%)
Congestive Heart Failure	43413 (95.64%)
Current New York Heart Association Class	
Class I	678 (1.49%)
Class II	5281 (11.63%)
Class III	35968 (79.24%)
Class IV	3465 (7.63%)
Atrial Fibrillation/Atrial Flutter	13837 (30.48%)
Ventricular Tachycardia	8159 (17.97%)
Sinus Node Dysfunction	10306 (22.70%)
Cardiac transplantation	77 (0.17%)
Non-Ischemic Dilated Cardiomyopathy	18720 (41.24%)
Ischemic Heart Disease	27541 (60.67%)

Variable	Number (%) or Mean \pm SD
Prior Myocardial Infarction	21497 (47.36%)
Prior Coronary Bypass	15560 (34.28%)
Prior Percutaneous Coronary Intervention	12818 (28.24%)
Previous Valvular Surgery	3609 (7.95%)
Cerebrovascular Disease	6308 (13.90%)
Chronic Lung Disease	11254 (24.79%)
Diabetes Mellitus	18364 (40.46%)
Hypertension	34344 (75.66%)
Renal Failure/Dialysis	1693 (3.73%)

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Table 3

Clinical Criteria and Medical Therapy in Patients Receiving Cardiac Resynchronization Therapy with Defibrillator

Description	
Cardiac Resynchronization Therapy with Defibrillator Clinical Criteria for Guideline Concordance	
Left Ventricular Ejection Fraction \leq 35%	44810 (98.72%)
QRS Duration > 120 ms	37421 (82.44%)
New York Heart Association Class III or IV	39433 (86.87%)
Class III	35968 (79.24%)
Class IV	3465 (7.63%)
All of above	32458 (71.51%)
Guideline Directed Medical Therapy - Among Those Without Contraindications	
Beta-blocker	39190 (87.38%)
Angiotension Converting Enzyme Inhibitor	28029 (64.15%)
Angiotension II Receptor Inhibitor	8270 (18.56%)
Beta-blocker and Angiotension Converting Enzyme Inhibitor or Angiotension II Receptor Inhibitor	31090 (70.26%)
All Criteria for Cardiac Resynchronization Therapy with Defibrillator Clinical Guideline Concordance and Receiving Guideline Directed Medical Therapy	22276 (50.34%)

Table 4

Breakdown of Cardiac Resynchronization Therapy with Defibrillator Patients by Guideline Directed Medical Therapy^a and Clinical Guideline Concordance^b – Number (%)

	On Guideline Directed Medical Therapy ^a	Not on Guideline Directed Medical Therapy ^a	% on Guideline Directed Medical Therapy ^a
Guideline Concordant^b	22276 (50.34%)	9334 (21.09%)	70.47%
Not Guideline Concordant^b	8814 (19.92%)	3826 (8.65%)	69.73%

^a **Guideline Directed Medical Therapy** defined as receiving a beta-blocker agent and either an Angiotension Converting Enzyme Inhibitor or Angiotension II Receptor Inhibitor agent

^b **Concordance** defined as Left Ventricular Ejection Fraction \leq 35%, QRS Duration $>$ 120 ms, and New York Heart Association Class III or IV