Published in final edited form as:

Am Heart J. 2008 August ; 156(2): 322–328. doi:10.1016/j.ahj.2008.04.003.

Short-term mortality and cost associated with cardiac device implantation in patients hospitalized with heart failure

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Abstract

Background—The use of implantable cardiac devices in the management of heart failure has increased, but patient selection and in-hospital outcomes in clinical practice have not been critically explored. Therefore, we evaluated the in-hospital mortality and costs associated with patients with heart failure who received an implantable cardioverter defibrillator, cardiac resynchronization device, or device lead.

Methods—We analyzed admissions with *International Classification of Diseases, Ninth Revision*, procedure codes for implantation/revision of cardioverter defibrillator or cardiac resynchronization device and a primary or secondary diagnosis code for heart failure in a prospective hospital database from 2004 to 2005. Odds ratios were calculated to quantify risk for mortality. Average accumulated costs over time were calculated before and after day of first device implant procedure.

Results—Among 27,907 hospitalizations, in-hospital mortality varied based on day of device implantation and use of intravenous inotropic therapy. Mortality was 0.3% for patients who did not require inotropic drugs versus 3.3%, 6.6%, and 15.2% for patients who required initiation of drug before, on the day of, or after device implantation, respectively. Logistic regression demonstrated that the most potent risk for in-hospital mortality was the use of inotropic drugs. Similar trends were observed for any vasoactive therapy. There was a marked increase in costs associated with these admissions.

Conclusions—Implantation of cardiac devices during a hospitalization for heart failure may be associated with significant in-hospital mortality if patients require intravenous vasoactive therapy. Risk stratification methodology that incorporates ongoing/anticipated need for these drugs will likely improve clinical decision making. (Am Heart J 2008;156:322-8.)

Major improvements in heart failure (HF) care have been established with pharmacological therapy.¹⁻⁸ However, morbidity and mortality remain significant for patients with advanced symptoms.⁹⁻¹¹ Furthermore, recent literature has suggested that some standard therapies have adverse effects; for example, digoxin therapy may be associated with higher mortality in women;¹² diuretic therapy may have significant adverse consequences;^{13,14} and intravenous inotropic drugs and nesiritide may increase morbidity and mortality.¹⁵⁻¹⁷

With this background, the development and clinical adoption of electrophysiologic devices (transvenous implantable cardioverter defibrillators [ICDs]) for the prevention of sudden

cardiac death, cardiac resynchronization therapy for symptomatic HF [CRT-P], or a combination of the 2 [CRT-D]) have changed the way in which patients with HF are treated by adding a nonpharmacologic treatment paradigm. Based on a series of trials¹⁸⁻²⁴ that used parameters such as left ventricular ejection fraction, electrocardiographic findings, and symptoms to identify patients who might benefit, the devices gained favor and are currently supported by guidelines of relevant professional societies.^{25,26} At the same time, important questions have been raised about the safety and appropriateness of devices, based on recalls,²⁷ uncertainty about the magnitude of benefit in subsets of the HF cohort,^{22,28} and cost considerations.^{29,30}

Clinical decision making is made more difficult by the complexity of clinical trials data and specificity of the recommendations. As an example, although ICDs are not indicated in patients with New York Heart Association class IV HF because of an absence of survival benefit, CRT-P therapy is allowed in this population. In the United States, most implantations of CRT devices occur in conjunction with ICDs suggesting that many patients are receiving a device that may not change the natural history of the disease. Recent analyses suggest a lack of a mortality benefit with ICD therapy for primary prevention of arrhythmic death among patients with multiple clinical factors associated with adverse outcomes.³¹ Clearly, patient selection will have implications for cost-effectiveness, quality, and appropriateness of care and the experience that patients and their families have with the disease.³²

Therefore, we evaluated the practice of implantation or revision of devices in patients admitted to acute care hospitals with a HF diagnosis to understand current patterns of use. We were particularly interested in defining a cohort at high risk for in-hospital mortality after a device procedure. A potential surrogate for severity of illness and risk for mortality is the administration of intravenous vasoactive therapy, in particular inotropic drugs. Use of device therapy in this cohort has not been critically evaluated in major clinical trials.

Methods

We used PREMIER's Perspective Comparative Database for calendar years 2004 and 2005. PREMIER is a hospital performance improvement alliance created and owned by several hundred hospitals and health systems.³³ Data validation and audits are performed by PREMIER to ensure quality. The database incorporates detailed patient level data from acute care hospitals in a large national sample organized by discharge month (n = 240 hospitals).

Variables within PREMIER include patient demographic information (based on UB92 coding), admission and discharge dates by month and year, length of stay (LOS), in-hospital mortality, procedure and diagnosis codes according to the *International Classification of Diseases, Ninth Revision* (ICD-9), and hospital characteristics (size, location, and teaching status). Itemized billing records for costs associated with care, such as drug therapy and surgery, are reported to reflect actual provider expenses.

The inclusion criteria for this study population were (1) inpatient admission between January 2004 and December 2005; (2) primary or secondary ICD-9 diagnosis of HF; (3) ICD-9 procedure code for implantation or replacement of complete device, generator, or lead exclusive of standard transvenous pacemakers (00.50-00.54, 37.94-37.98); and (4) age >18 years. Hospitalizations were excluded if the procedure date was unknown (n = 540) or records could not be found in billing data that validated the ICD-9 procedure codes (n = 1,104). Excluding these subjects did not result in significant differences in patient demographics, LOS, use of intravenous vasoactive therapy, or hospital characteristics across the device groups.

Patients were organized into exclusive device groups as follows: (1) CRT-D, (2) ICD alone, (3) CRT-P, and (4) left ventricular or ICD leads only. Individuals receiving >1 procedure were

assigned to the group in the order listed above. Those patients who received both ICD and CRT-P devices in the same hospitalization but on separate days were designated to the CRT-D device group but the first day of intervention served as the day of procedure.

A separate set of groupings was created to examine the administration of inotropic drugs and secondarily any vasoactive therapy in relation to day of device procedure because this would suggest a heightened risk for adverse events as follows: (1) drug therapy initiated before day of device procedure, (2) drug therapy initiated on day of procedure, (3) drug therapy initiated after day of procedure, and (4) no drug therapy during hospitalization. Intravenous vasoactive drug therapy was defined by the use of vasodilators (nesiritide, nitroglycerin, sodium nitroprusside) or inotropes (dobutamine, dopamine, milrinone). Mortality and total costs were evaluated across device and time-relationship groups (day of admission, days 2-7, on or after day 8).

Statistical analysis

χ^2 analyses were used to determine whether there were significant differences among the device and time-relationship categories by patient characteristics and inhospital mortality. Kruskal-Wallis tests were used to determine significant differences by LOS and patient age. Given that the treatment groups had disparate days in hospital before the procedure of interest, we opted to use logistic regression with forced entry rather than Cox regression techniques to determine whether there were significant differences in inhospital mortality based on temporal relationships. Patient age (19-64, 65-74, 75-84, ≥ 85 years), race (black, other), and sex were included as covariates in the model. We did not consider age as a continuous variable because all patients ≥ 89 years (1.2%) were considered as one age group because of privacy concerns and thus would have created an unnatural ceiling effect. Goodness of fit was assessed using analysis of residuals and the Hosmer-Lemeshow test. Odds ratios were calculated to quantify risk that each characteristic posed for inhospital mortality.

Total costs were defined as the sum of all itemized costs (direct and indirect) in the billing records except professional fees. We assessed daily hospitalization expenses per beneficiary, controlling for inhospital death. For examination of daily costs, a small percentage (0.4%) of individuals was eliminated because of inadequate assignment of billing data for all hospitalization days. Removal of these subjects did not have a significant effect on mean total cost. Average accumulated costs over time were calculated for the 4 time-relationship patient groups, before and after day of first device procedure.³⁴ Kruskal-Wallis and Wilcoxon-Mann-Whitney tests were used to evaluate differences in incremental daily costs between treatment groups. All costs were converted to December 2005 dollars according to the Consumer Price Index for medical care.³⁵

Data management and analyses were performed using SAS version 9.1 (SAS Institute Inc, Cary, NC). Differences were considered statistically significant at $P < .05$. The authors had full access to the data and take responsibility for its integrity. All authors have read and agree to the manuscript as written.

Results

The number of hospitalizations with ICD-9 procedure codes for an implantable cardiac device and a primary or secondary ICD-9 diagnosis for HF was 27,907. Patients were predominantly male, white, and older (mean [SD] age 68.4 [12.0] years, median age 70.0 years) (Table I). The most common non-HF primary ICD-9 diagnosis code was paroxysmal ventricular tachycardia (427.1, 11.0%). The most common secondary ICD-9 diagnoses included hypertension (54.1%), diabetes (35.3%), and chronic obstructive lung disease (19.4%). The mean LOS was 6.3 days.

Device implantation

Most patients were designated to CRT-D and ICD generator groups (43.3% and 48.5% respectively) (Table II). Device procedures were most often performed on the first day of hospitalization (41.2%); however, a significant proportion (19.4%) received a device after hospital day 7. A small percentage (1.3%) had device procedures on >1 hospital day, including patients who received an ICD followed by a CRT device.

The CRT-P patients were more often female and older compared to all other cohorts (39.1% vs 26.5%, $P < .001$ and 70.1 vs 68.0 years, $P < .001$, respectively). Similarly, ICD patients were more often black (15.5% vs 10.3%, $P < .001$) and had a longer LOS (7.1 vs 5.6 days, $P < .001$).

Drug therapy

Slightly more than two fifths (40.3%) of patients received intravenous diuretic therapy; smaller percentages received intravenous vasoactive therapy and/or inotropic drugs (25.0 and 15.1%, respectively). Compared to the rest of the device population, patients receiving inotropic drugs were younger (66.6 vs 68.6 years, $P < .001$) and experienced longer LOS (14.7 vs 4.9 days, $P < .001$). Of patients receiving inotropic drugs, 72.7% ($n = 3,060/4,210$) had the drug initiated before the device procedure, 16.5% ($n = 696$) on the day of procedure, and 10.8% ($n = 454$) after device implantation (Table III). The corresponding percentages for intravenous vasodilator therapy were 80.0% ($n = 5,574/6,970$), 13.0% ($n = 909$), and 7.0% ($n = 487$), respectively.

Mortality by hospital day and inotropic drug use

The distributions of device implantations by hospital day and subsequent inhospital mortality are shown in Table II. Similar trends of inhospital mortality were observed across device types based on day of device implantation. Less than 1% (0.3%) of patients died if the device procedure was performed on the first day. Implantation later in the stay resulted in higher likelihood of death, most notably after the first week in CRT-P patients (6.0%).

The inhospital mortality among patients who received inotropic drugs was significantly higher than in patients who did not (5.1% vs 0.3%, $P < .001$) (Table III). Among the former, mortality was related to the timing of drug initiation relative to device implantation. Mortality rates were 3.3% (100/3,060), 6.6% (46/696), and 15.2% (69/454) based on initial administration of inotrope before, on the same day, or after device implantation, respectively. This gradient was consistent across all device types (Table IV), although the numbers of patients who received a CRT-P device or had a lead revision were small relative to the other groups.

Results were similar when evaluating the timing of any intravenous vasoactive therapy rather than inotrope alone relative to device implantation with rates of 2.5% (138/5,574), 4.4% (40/909), and 11.7% (57/487), respectively.

Logistic regression revealed significantly increased mortality risk based on first day of inotrope relative to day of device procedure: no inotrope (reference, odds ratio [OR] 1.0), inotrope before (OR 11.6, $P < .001$), inotrope on same day (OR 23.7, $P < .001$), or inotrope after (OR 58.6, $P < .001$) (Table V). Older age (≥ 85 years) also increased risk of death (OR 1.7, $P = .034$) though sex and race did not. Results were similar when considering any vasoactive therapy, though treatment group odds ratio estimates were slightly lower (OR 10.6, 18.7, and 54.1 for vasoactive therapy initiated before, during, and after device, respectively, $P < .001$).

Costs associated with device implantation

The mean total cost for a hospitalization involving device implantation was \$43,735 (median \$40,304) with higher mean costs for individuals who died during hospitalization (\$80,020, median \$60,617). At 1 and 2 weeks after device procedure, large proportions of individuals had been discharged (87.6% and 97.0%), contributing zero daily cost, whereas 0.5% and 0.8% of subjects were censored because of death. Examination of accumulated costs from day of device implantation, grouped by timing of inotropic drug initiation relative to first device procedure, demonstrates that patients receiving inotropic drugs after device procedure had the highest costs at 1 and 2 weeks (\$14,431 and \$23,059, respectively, $P < .001$ [vs no inotrope, inotrope before device, and inotrope on day of device]) (Figure 1). After device procedure, any administration of inotropic drugs during the hospitalization was an indicator for higher costs; this is demonstrated, for example, at 2 weeks among individuals initiated on inotrope after the procedure (\$49,928, $P < .001$ [vs no inotrope, inotrope before device, and inotrope on day of device]).

Discussion

A major transformation in the care of patients with HF occurred with the advent of transvenous ICDs followed by the introduction of cardiac resynchronization devices alone or in combination with ICD technology. The clinical trials that formed the basis for regulatory approval of these devices did not in general enroll patients with advanced HF; when these patients were included, they tended to be ambulatory.²⁸ Furthermore, the language used in clinical practice guidelines of major professional organizations reflects the specific indications established by the Food and Drug Administration and the Center for Medicare and Medicaid Services; many patient subgroups have not been critically evaluated.

In that context, we demonstrate, using detailed day of service data from a large hospital database, a high early mortality and significant cost associated with patients who undergo implantation or revision of a device and who require initiation of intravenous vasoactive therapy. Therefore, the clinical use of ICDs and potentially by extension CRT devices in patients who require intravenous vasoactive therapy, may be limited. Furthermore, the implantation or revision of devices in this clinical setting does not appear to be consistent with current guidelines.

From a pharmacoeconomic standpoint, the assessment of incremental cost-effectiveness of ICDs when used for primary prevention demonstrates a relationship between dollars per quality-associated life year and duration of device effectiveness. For example, data from an analysis of 7 trials demonstrates a curvilinear relationship between cost-effectiveness and duration of mortality benefit; if the ICD were effective in preventing sudden cardiac death for exactly 3 years, the incremental costs would exceed \$70,000.³⁰ The figures increase as the duration of ICD benefit achieved shortens. This is highly relevant as patients with advanced HF often do not survive 3 years^{9-11,36-39} and patients on intravenous inotropic drugs have a significantly reduced survival.⁴⁰ Indeed, in the PREMIER database, the inhospital mortality rate among patients receiving inotropic therapy, regardless of device status, was 24.1%.

Although the highest OR for inhospital mortality is associated with the initiation of inotrope after device implantation, it is possible that many of these patients can be identified in advance (ie, at the time a decision is made about device therapy), using a multitude of prognostic models that define patients at high risk for rehospitalization or death.⁴¹⁻⁴⁴ This will require prospective validation and further research. However, the comparable ORs associated with inotrope use before or on the day of device implant are also high.

In addition, we found that patients who had implantations beyond the seventh day of a HF hospitalization were at a significantly higher risk of dying in hospital. It is likely that these devices were implanted on a nonelective basis, which is relevant because neither ICD nor CRT devices have been evaluated for or were intended as “rescue therapy.” The repercussions of this practice for patients and patient families are significant, in part because of patient expectations of device efficacy⁴⁵ and the experience of death with an active device.³² Furthermore, there are implications for cost because the metric of quality-adjusted life years is highly dependent on the duration and magnitude of the survival benefit achieved. Hence, careful patient selection remains a major component of clinical judgment in the application of advanced and technically complicated treatment options in a sick and high-risk cohort.⁴⁶ This point is also emphasized in an analysis of Medicare records in which unselected patients receiving an ICD for primary prevention had a modest but not statistically significant 1 year survival benefit.⁴⁷

Limitations

We excluded device implantations if the patient were admitted for other diagnoses such as primary ventricular arrhythmia in the absence of HF; however, the role for ICDs in this patient population is generally accepted. The ICD-9 procedure coding does not allow for definitive distinction between first implant, upgrade, and revision (of lead or generator). We do not have data on preexisting device therapy; however, all patients were subjected to a new device procedure. Rather than upgrade or revise, physicians and patients can consider “passive” device deactivation by deferring a generator change.⁴⁸

It is not possible to apply published risk models that could provide additional prognostic information about the various cohorts defined in this study, largely because these models include clinical variables such as systolic blood pressure or respiratory rate on admission that are not available in the PREMIER database. We cannot determine whether a patient received prior courses of vasoactive therapy nor can we exclude that some patients were on inotropic drugs and “bridged-to-transplant” with an ICD.⁴⁹ There may be unmeasured risk factors for inhospital mortality that are not available in the database; nevertheless, we believe that our observations can serve as a foundation for future research into improved risk stratification models that can inform us about which patients with advanced HF are the best candidates for device therapy.

Finally, we are not able to evaluate mortality rates after discharge or the impact of the devices on subsequent rehospitalizations. It is likely however that the short-term mortality risk and morbidity remains elevated, especially in the ICD cohort, given the overall prognosis of patients hospitalized with advanced HF.

In summary, the implantation of cardioverter defibril-lators and cardiac resynchronization devices during a hospitalization for HF may be associated with significant inhospital mortality if patients require intravenous vasoactive therapy and in particular inotropic drugs. Risk stratification methodology that incorporates ongoing or anticipated need for vasoactive therapy will likely improve clinical decision making.

Acknowledgments

The study is supported in part by National Institutes of Health RO1-AG021515 (Dr P Hauptman).

Dr Hauptman: Grant support from the National Institutes of Health; local site coinvestigator on the SCD-HeFT trial. Mr Swindle: No relevant financial relationships. Dr Burroughs: No relevant financial relationships. Dr Schnitzler: No relevant financial relationships.

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Figure 1.
Average accumulated costs curves by treatment type.

Table I

Patient characteristics (N = 27 907)

Variables	n	%
Age (y)		
19-64	9256	33.2
65-74	8704	31.2
75-84	8530	30.6
≥85	1417	5.1
Male	20 269	72.6
Race		
White	19 200	68.8
Black	3577	12.8
Other	5130	18.4
Hospital bed count		
0-400	9177	32.9
401-600	8401	30.1
≥601	10 329	37.0
Teaching hospital	14 169	50.8
Urban hospital	26 279	94.2

Table II

Inhospital mortality by day of device procedure and type of device (N = 27 907)

Day of device	CRT-D device		ICD device		CRT-P device		LV/ICD lead	
	n	Mortality (%)	n	Mortality (%)	n	Mortality (%)	n	Mortality (%)
All	12 071	0.9	13 534	1.0	1829	2.1	473	0.6
1	5858	0.8	4522	0.3	876	0.7	251	0.0
2-7	4382	1.1	5736	0.9	685	2.5	182	1.1
8+	1831	2.6	3276	2.0	268	6.0	40	2.5

LV, Left ventricular.

Table III

Inhospital mortality by day of device procedure and time relationship between inotrope and procedure (N = 27 907)

Day of device	Device procedure alone		Inotrope before device procedure		Inotrope on day of device procedure		Inotrope after device procedure	
	n	Mortality (%)	n	Mortality (%)	n	Mortality (%)	n	Mortality (%)
All	23 697	0.3	3060	3.3	696	6.6	454	15.2
1	11 025	0.1	-	-	314	3.8	168	9.5
2-7	9465	0.3	1032	3.0	287	7.7	201	15.4
8+	3207	0.9	2028	3.4	95	12.6	85	25.9

Table IV

Mortality rates by type of procedure (N = 27 907)

Time relationship	CRT-D device		ICD device		CRT-P device		LV/ICD lead	
	n	Mortality (%)	n	Mortality (%)	n	Mortality (%)	n	Mortality (%)
Device procedure alone	10 352	0.3	11 429	0.3	1525	0.5	391	0.0
Inotrope before device procedure	1154	3.2	1692	3.0	176	6.8	38	0.0
Inotrope on day of device procedure	332	6.0	246	6.1	91	9.9	27	7.4
Inotrope after device procedure	233	10.7	167	19.2	37	29.7	17	5.9

Table V

Logistic regression results modeling inhospital death (N = 27 907)

Variables	OR (95% CI)	P
Treatment group *		
Proc alone	1.00	
Inotrope before proc	11.61 (8.54-15.78)	<.001
Inotrope on day of proc	23.69 (16.21-34.64)	<.001
Inotrope after proc	58.63 (41.42-82.98)	<.001
Sex		
Male	1.14 (0.87-1.50)	.351
Female	1.00	
Race		
Black	1.23 (0.87-1.74)	.357
Other	1.00	
Age (y)		
19-64	0.71 (0.52-0.98)	.037
65-74	0.98 (0.73-1.33)	.905
75-84	1.00	
>85	1.74 (1.10-2.74)	.018

Proc, Device procedure.

* First day of device procedure relative to first day of inotrope.