Characterization of health care utilization in patients receiving implantable cardioverter-defibrillator therapies: An analysis of the managed ventricular pacing trial

John Rickard, MD, MPH,* David Whellen, MD, MPH, FHRS,† Lou Sherfesee, PhD,‡ Brett J. Peterson, BS,‡ Tara Nahey, DVM, PhD,‡ Anthony S. Tang, MD, FHRS,§ Kenneth A. Ellenbogen, MD, FHRS,# Alan Cheng, MD‡

*From the *Cleveland Clinic Foundation, Cleveland Ohio, †Thomas Jefferson University, Philadelphia, Pennsylvania, ‡Medtronic, Mounds View, Minnesota, §University of British Colombia Vancouver, BC, and #Virginia Commonwealth University, Richmond, Virginia.*

BACKGROUND Implantable cardioverter-defibrillators (ICDs) are effective in terminating lethal arrhythmias, but little is known about the degree of health care utilization (HCU) after ICD therapies.

OBJECTIVE Using data from the managed ventricular pacing trial, we sought to identify the incidence and types of HCU in ICD patients after receiving ICD therapy (shocks or antitachycardia pacing [ATP]).

METHODS We analyzed HCU events (ventricular tachyarrhythmia [VTA]–related, heart failure–related, ICD implant procedure–related, ICD system–related, or other) and their association with ICD therapies (shocked ventricular tachycardia episode, ATP-terminated ventricular tachycardia episode, and inappropriately shocked episode).

RESULTS A total of 1879 HCUs occurred in 695 of 1030 subjects (80% primary prevention) and were classified as follows: 133 (7%) VTA-related, 373 (20%) heart failure–related, 97 (5%) implant procedure–related, 115 (6%) system-related, and 1160 (62%) other. Of 2113 treated VTA episodes, 1680 (80%) received ATP only and 433 (20%) received shocks. Stratifying VTA-related HCUs on the basis of the type of ICD therapy delivered, there were 25 HCUs per 100 shocked VTA episodes compared with 1 HCU per 100 ATP-terminated episodes. Inappropriate ICD shocks occurred in 8.7% of the subjects and were associated with 115 HCUs. The majority of HCUs (52%) began in the emergency department, and 66% of all HCUs resulted in hospitalization.

CONCLUSION For VTA-related HCUs, shocks are associated with a 25-fold increase in HCUs compared to VTAs treated by ATP only. Application of evidence-based strategies and automated device–based algorithms to reduce ICD shocks (higher rate cutoffs, use of ATP, and arrhythmia detection) may help reduce HCUs.

KEYWORDS Health care utilization; ICD; Shocks; ATP; Hospitalization; MVP

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Introduction

Implantable cardioverter-defibrillators (ICDs) have been shown to reduce all-cause mortality in patients with systolic heart failure (HF).[1–3] Since their introduction over 30 years ago, ICD implant procedures have increased[4] and greater use of resources have been required for routine care, especially soon after ICD therapies have been delivered. The latter events have resulted in unscheduled visits to hospitals, emergency departments (EDs), and clinics, but the extent to which these services have been used remains poorly understood. Understanding this in the present era of cost containment is critical in an effort to identify ways to improve health care efficiency. The purpose of this investigation was to characterize health care utilizations (HCUs) in patients receiving ICD therapies, specifically focusing on differences between shocks and antitachycardia pacing (ATP) as well as venues of care (ED vs outpatient clinics).

Methods

Study design and participants

This is a post hoc analysis of data collected in the randomized, multicenter managed ventricular pacing (MVP) trial.[5] Briefly, patients aged 18 years and older who underwent a primary or secondary prevention ICD implant procedure per current clinical guidelines were enrolled from 2004 to 2006 at 84 centers globally and followed for up to 3 years from device implant. Patients with a need for pacing, in

Dr Rickard has received honorarium from Medtronic and Boston Scientific. Dr Sherfesee, Mr Peterson, Dr Nahey, and Dr Cheng are employed by Medtronic. **Address reprint requests and correspondence:** Dr John Rickard, Division of Cardiology, Cleveland Clinic Foundation, 9500 Euclid Avenue, J2-2 Cleveland, OH 44195. E-mail address: rickarj2@ccf.org.

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permanent atrial fibrillation, or having a life expectancy of <12 months were excluded. Ventricular tachyarrhythmias (VTAs), device therapies, and utilization of health care services were collected. An ethics committee approved the MVP protocol at each participating center, and all subjects provided signed informed consent.

Device programming

ICD programming was standardized. Devices were programmed to detect VTAs >171 beats/min for those with known slow ventricular tachycardia and >176 beats/min otherwise, with the number of intervals to detect ventricular fibrillation set to 18/24. Arrhythmias between 171 and 200 beats/min received ATP as the first 2 therapies, followed by shocks if necessary. Arrhythmias between 200 and 250 beats/min received ATP as the first therapy, followed by shocks if necessary.

Data collection

Demographic data were obtained at the baseline visit. Adverse events, HCUs, and arrhythmias stored on subjects' devices were collected during follow-up. HCUs included unscheduled clinic and urgent care visits, ED visits, and hospitalizations. Adverse events were defined as any undesirable clinical occurrence in a subject that is related to the subject's cardiovascular, pulmonary, or renal system or events in which the subject presented with symptoms compatible with fluid retention and/or decreased exercise tolerance. All available device-recorded spontaneous arrhythmias with electrogram information were adjudicated by an episode review committee as true VTA or non-VTA (eg, sinus tachycardia, atrial fibrillation, and oversensing).

End points

The first end point evaluated was the type of HCU. HCUs were classified as (1) VTA-related, (2) HF-related, (3) ICD implant procedure–related (such as pneumothorax or hematoma), (4) ICD system–related (including HCUs related to inappropriate shocks or system modifications), or (5) other (not related to HF or device). The second end point was the type of ICD therapy–related HCUs experienced by subjects, classified as related to a (1) shocked VTA episode, (2) ATP-terminated VTA episode, or (3) shocked non-VTA episode (inappropriately shocked). HCUs related to inappropriate shocks were considered a subclassification of ICD system–related HCUs for this analysis. End points were adjudicated by an independent adverse events committee and a subset of the MVP Steering Committee.

ICD therapy–related HCUs

VTAs were classified into the following subcategories (for the second end point of ICD therapy–related HCU types):

- Shocked VTA episode
- ATP-terminated VTA episode
- Untreated VTA
- Shocked non-VTA episode (inappropriately shocked)

Table 1 Baseline demographic characteristics (N = 1030)

Characteristic	Value
Age (y)	62.2 ± 11.9
Sex: male	819 (79.5)
NYHA classification	
Class I	262 (25.4)
Class II	567 (55)
Class III	193 (18.7)
Class IV	2 (0.2)
LVEF (%)	34.8 ± 11.9
Dilated cardiomyopathy	859 (83.4)
Ischemic	644 (62.5)
Nonischemic	215 (20.9)
Sinus node dysfunction	40 (3.9)
Left bundle branch block	127 (12.3)
Right bundle branch block	84 (8.2)
Intraventricular conduction delay	32 (3.1%)
AV block (most recent)	170 (16.5)
First degree block	156 (15.1)
Second degree block	7 (0.7)
Third degree block	1 (0.1)
Supraventricular tachyarrhythmias	177 (17.2)
Paroxysmal supraventricular tachyarrhythmia	33 (3.2)
Atrial tachycardia	16 (1.6)
Atrial fibrillation, atrial flutter	141 (13.7)
Persistent	10 (1)
Paroxysmal	131 (12.7)
Ventricular tachyarrhythmias	455 (44.2)
Nonsustained VT	260 (25.2)
Sustained monomorphic VT	149 (14.5)
Sustained polymorphic VT	6 (0.6)
Unspecified sustained VT	16 (1.6)
Torsades de pointes	4 (0.4)
Ventricular fibrillation, ventricular flutter, cardiac arrest	82 (8)
ACE inhibitors or ARBs	850 (82.5)
β-Blockers	914 (88.7)
Diuretics	557 (54.1)
Amiodarone/sotalol	133 (12.9)
Reason for ICD therapy: primary indication	829 (80.5)

Values are presented as mean ± SD or as n (%).

ACE = angiotensin-converting enzyme; ARB = angiotensin receptor blocker; AV = atrioventricular; ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; VT = ventricular tachycardia.

Episodes that received both ATP and shocks were considered shocked VTA episodes. The committee reviewed all HCUs with corresponding documentation of arrhythmia or device therapy occurrence or for which the subject experienced an arrhythmia or device therapy 30 days prior. Adverse events, the 30-day history of device-detected and treated episodes, final episode adjudication from the episode review committee (VTA or non-VTA), and the HCU narrative were used to determine whether the HCU was related to device therapy.

Final classification of HCU type

The final classification of HCU relatedness for both end points were established hierarchically: (1) VTA with subclasses of (a) shocked, (b) ATP terminated, and (c) untreated; (2) HF; (3) ICD implant procedure; (4) ICD system (including inappropriate shock); or (5) other.

Table 2 Summary of VTA, shock, HF, procedure, and system relatedness of HCUs (N = 1030)

Relatedness	No. of HCUs (No. of subjects)
VTA	133 (82)
Shocked VTA	110 (74)
Nonshocked VTA*	23 (19)
Shocked non-VTA (inappropriate shocks)	72 (62)
Shocked episode (unknown if VTA)	1 (1)
Heart failure–related and not VTA-related	373 (193)
Associated with procedure-related AE only	97 (76)
Associated with system-related AE only	43 (36)
Other	1160 (511)
Total	1879 (695)

AE = adverse event; ATP = antitachycardia pacing; HCU = health care utilization; HF = heart failure; VTA = ventricular tachyarrhythmia.
*Reflects ATP-terminated VTA, untreated VTA, and VTA for which therapy relatedness was unknown.

Statistics

Descriptive statistics were used to summarize baseline demographic characteristics. Percentages were used to show the HCU types experienced by subjects. Cumulative incidence curves accounting for the competing risk of all-cause mortality were generated to compare onset of treated and, specifically, shocked VTA with HCUs related to appropriate VTA therapy. Rates at annual time points are reported along with 95% confidence intervals. Annual rates were used to summarize the prevalence of different types of HCUs (eg, HF-related and VTA-related). Subjects were censored at the time of their last device interrogation for the calculation of rates of arrhythmic episodes. The data analysis for this article was performed using SAS/STAT software version 13.1 of the SAS System for Windows. The cumulative incidence rate was obtained with S-PLUS software version 8.2 for Windows.

Results

This analysis included 1030 subjects who had complete HCU-related data, of which 824(80%) had primary prevention indication. The complete baseline characteristics are summarized in Table 1 and are similar to those of prior ICD clinical studies. During a mean follow-up of 2.4 years, 1879 HCUs occurred in 695 subjects (68%). Among them, 358 HCUs (19%) were identified for further adjudication because they were flagged as being VTA or ICD therapy–related on the clinical report form or because the patient had experienced a VTA or ICD therapy within 30 days before the HCU. Of the 358 HCUs, 206 (57.5%)were related to VTA or shocks. With respect to treated arrhythmias, there were 2113 episodes of treated VTAs in 222 subjects (22%) and 616 episodes of treated non-VTAs in 125 subjects (12%). Of all treated VTA episodes, 1680 (80%) received ATP only and 433 (20%) received shocks. There were an additional 1219 treated episodes in 51 subjects not adjudicated because of missing electrograms.

HCU incidence rate and types

The 1879 observed HCUs were classified as follows: 133 VTA-related, 373 HF-related, 97 implant procedure–related, 115 system-related, 1 related to shock of unknown origin, and 1160 other (Table 2). The vast majority of HCUs (89%) were unrelated to VTA or inappropriate shocks. Examples included HCUs for myocardial infarction, transient ischemic attack, and chronic obstructive pulmonary disease. Annual rates for each HCU type in different follow-up intervals are shown in Figure 1, which illustrates that the frequency of therapy-related HCUs are highest in the 6 months after ICD implantation and remain fairly constant thereafter.

ICD therapy–related HCUs

During follow-up, 206 VTA and/or therapy-related HCUs of the following types occurred in 139 subjects: 110 (53%) for shocked VTA episodes, 11 (5%) for ATP-terminated VTA episodes (nonshocked VTA), 12 (6%) for untreated VTA or VTA in which the therapy relatedness was unknown, 72 (35%) for inappropriately shocked episodes, and 1 for a shocked episode with unknown VTA status. ATP-related HCUs were due to dizziness/syncope, palpitations, chest

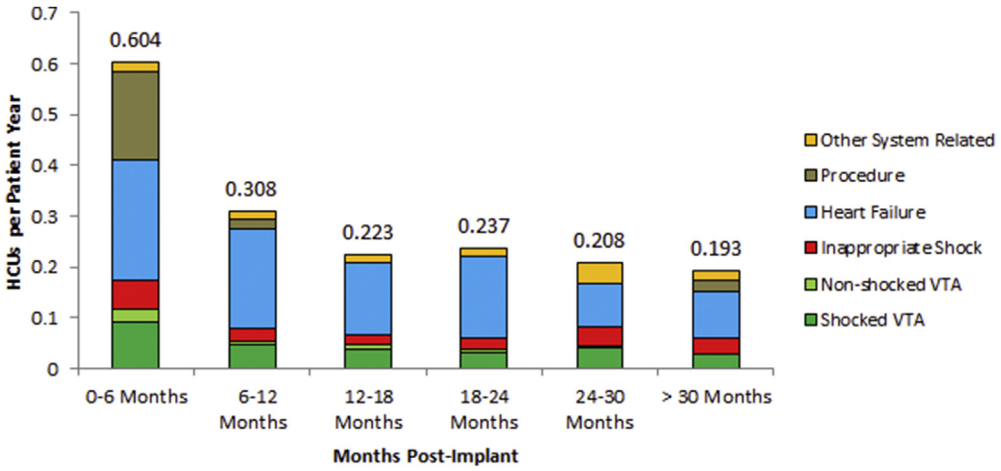

Figure 1 Annual rates for HCUs in each of the 6 periods after the implant procedure. Only HCUs relatedness to VTA, ICD therapy, heart failure, implant procedure, or the ICD system are included. HCU = health care utilization; ICD = implantable cardioverter-defibrillator; VTA = ventricular tachyarrhythmia.

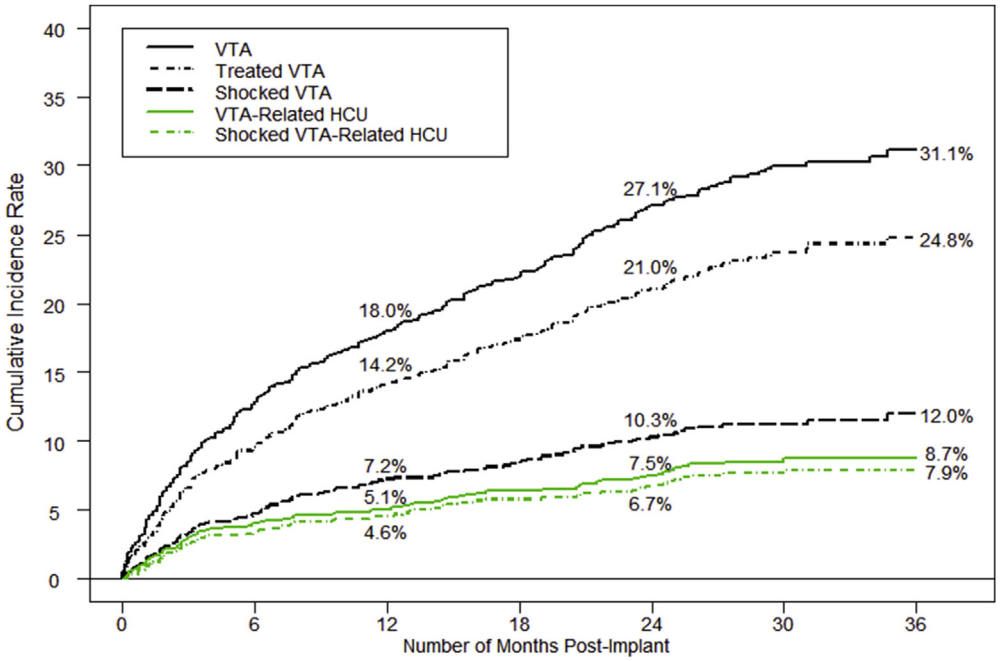

Figure 2 Cumulative incidence rate for first VTA, VTA treated with antitachycardia pacing or shock, VTA treated with shock, VTA-related HCU, and shocked VTA-related HCU accounting for competing risk of mortality. HCU = health care utilization; VTA = ventricular tachyarrhythmia.

discomfort, or, in 1 case, a phantom shock. The percentage of patients experiencing ventricular arrhythmias and ventricular arrhythmia–related HCUs is presented in Figure 2 and Table 3. During 36 months, 8.7% of subjects had a VTA-related HCU and 10.3% had an inappropriately shocked episode. Only 1.2% of the study population had an HCU related to an ATP-terminated VTA episode, whereas 7.9% were estimated to have had a shocked VTA-related HCU and 7.1% had an inappropriate shock–related HCU. HCUs from a shocked VTA resulted in a dramatic increase in HCUs compared with a VTA treated with ATP. In fact, for every 100 VTAs treated with an ICD shock, there were 25 HCUs as compared with 1 HCU event for every 100 VTAs treated with ATP. The elevated HCU rate was also observed for inappropriate shocks. For every 100 incidents of inappropriate shock, there were 30 HCUs.

Location of ICD therapy–related HCUs

The majority of ICD therapy–related HCUs started in the ED (59%), and most resulted in hospitalization (65%) (Table 4). Seven percent of shock-related HCUs started in the hospital compared with 21% of HCUs unrelated to VTA or ICD therapy. The hospital was the most frequent final location of shock-related HCUs (64%), followed by the clinic (21%) and ED (14%). Sixty-five percent of shocked VTA-related HCUs, 64% of inappropriate shock–related HCUs, and 57% of ATP-terminated or self-terminated VTA-related HCUs resulted in hospitalization (Table 4). Most (106 of 182 [58%]) shock-related HCUs occurred in >1 location (eg, presented in the ED and then hospitalized).

Discussion

This analysis has provided 3 important insights in our understanding of HCU after ICD therapies. First, 89% of HCUs in typical ICD subjects are not related to the device with 20% related to HF and 10.4% related to device therapy. Second, shocks generate significantly more HCUs compared with VTA episodes terminated by ATP only. Lastly, the majority of ICD shocks result in ED visits followed by hospitalization.

Table 3 Cumulative incidence rates for VTA and HCU end points at 12, 24, and 36 mo after the implant procedure

	Cumulative incidence rate (%) (95% confidence interval)*		
End point	12 mo	24 mo	36 mo
VTA	18.0 (15.7–20.5)	27.1 (24.5–29.9)	31.1 (27.6–35.1)
Treated VTA	14.2 (12.2–16.4)	21.0 (18.7–23.7)	24.8 (22.1–27.7)
Shocked VTA	7.2 (6.0–8.8)	10.3 (8.6–12.3)	12.0 (10.0–14.5)
VTA-related HCU	5.1 (4.0–6.4)	7.5 (6.0–9.4)	8.7 (7.1–10.8)
Shocked VTA-related HCU	4.6 (3.5–6.1)	6.7 (5.2–8.6)	7.9 (6.4–9.8)

HCU = health care utilization; ICD = implantable cardioverter-defibrillator; VTA = ventricular tachyarrhythmia.
*Cumulative incidence rates represent the estimated percentage of subjects experiencing the end point at 12, 24, and 36 mo after the ICD implant procedure. Rates were calculated using time-to-event methods accounting for mortality as a competing risk.

Table 4 Summary of VTA and device therapy relatedness of HCUs by HCU type (N = 1030)

Relatedness	No. of HCUs (No. of subjects)
Shocked VTA	110 (74)
Clinic visit only	21 (15)
ED visit only	17 (14)
Clinic and ED visit	1 (1)
Hospitalization	71 (56)
Hospitalization only	6 (5)
Clinic visit and hospitalization	10 (10)
ED visit and hospitalization	51 (41)
Clinic visit, ED visit, and hospitalization	4 (4)
Nonshocked VTA (or therapy relatedness unknown)	23 (19)
Clinic visit only	7 (6)
ED visit only	1 (1)
Clinic and ED visit	2 (1)
Hospitalization	13 (13)
Hospitalization only	2 (2)
Clinic visit and hospitalization	1 (1)
ED visit and hospitalization	9 (9)
Clinic visit, ED visit, and hospitalization	1 (1)
Shocked non-VTA (inappropriate shocks)	72 (62)
Clinic visit only	17 (16)
ED visit only	9 (9)
Clinic and ED visit	0 (0)
Hospitalization	46 (42)
Hospitalization only	6 (5)
Clinic visit and hospitalization	8 (8)
ED visit and hospitalization	31 (30)
Clinic visit, ED visit, and hospitalization	1 (1)
Shocked episode (unknown if VTA)	1 (1)
Other relatedness to VTA or shocks	4 (4)
Not related to shocks, ATP, or VTA	1669 (639)
Clinic visit only	295 (175)
ED visit only	252 (158)
Clinic and ED visit	7 (7)
Hospitalization	355 (261)
Hospitalization only	355 (261)
Clinic visit and hospitalization	126 (98)
ED visit and hospitalization	594 (324)
Clinic visit, ED visit, and hospitalization	40 (33)
Total	1879 (695)
Clinic visit only	341 (197)
ED visit only	281 (175)
Clinic and ED visit	10 (8)
Hospitalization	1247 (584)
Hospitalization only	369 (270)
Clinic visit and hospitalization	145 (113)
ED visit and hospitalization	687 (365)
Clinic visit, ED visit, and hospitalization	46 (38)

Other includes cases in which relatedness to all 3 categories (VTA, device therapy, and shocks) was unknown (n = 1), HCU was related to device therapy but shock and VTA relatedness unknown (n = 1), or HCU was related to ATP-terminated non-VTA (n = 1).

ATP = antitachycardia pacing; ED = emergency department; HCU = health care utilization; VTA = ventricular tachyarrhythmia.

There are limited data on HCU after ICD therapy. Bhavnani et al[6] showed a significant difference in health care costs associated with inappropriate shock (compared to no shocks) within a year after device implant. Taken together, appropriate and inappropriate ICD shocks frequently result in health care system utilization and subsequent costly testing. In the current study, we similarly show that a significant number of shock events ultimately lead to an HCU. A similar finding, however, was not noted for ATP events where the large majority did not lead to an HCU. ATP therapy has been shown to terminate most ventricular tachycardia episodes and potentially improve quality of life compared with ICD shocks.[7]

While reducing shocks and hence HCUs is an important goal, our study shows that the majority of HCUs in patients with ICD are not related to their device. While reducing shocks will likely result in reduced HCUs, dramatic reductions are unlikely given multiple other comorbid conditions. The potential to use device diagnostics to decrease HF-related HCUs is an appealing idea. Although still a minority of overall HCUs at 20%, HF-related HCUs remain an important target for cost reduction. Understanding ways in which to reduce these events remains paramount.

Our study also found that patients who seek care after a shock primarily present to the ED, which often leads to inpatient hospitalization. While individual practices vary, often single shock episodes can be managed by a device clinic either the same or the next day in clinic rather than necessitating ED care. Given the costly nature of ED and inpatient hospital care, our data suggest that there may be room for cost reduction via patient education in how single shock episodes are managed.

Study limitations

Our study has several limitations. First, this was a *post hoc* analysis of a randomized clinical study. Hence, all limitations associated with this type of analysis need to be considered. Second, the time period from when the MVP trial was conducted predated multiple trials where prolonged detection intervals, higher rate cutoffs, and improved detection algorithms were used. While shocks are less likely with modern-day programming,[8-11] the correlation between shocks and HCU is likely similar.

Conclusion

Overall, the majority of HCUs in the population with ICD are not related to their device. For device-related HCUs, shocks generate significantly more HCUs compared to VTAs terminated by ATP. Lastly, HCUs using the ED commonly result in hospitalization. Application of evidence-based strategies to reduce ICD shocks, such as higher rate cutoffs, use of ATP, improved patient counseling for postshock care, and detection algorithms, may help reduce therapy-related HCUs and shift them from higher to lower cost venues.

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