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Long-Term Outcome After ICD and CRT Implantation and Influence of Remote Device Follow-Up
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Background—Outcome data for patients receiving implantable cardioverter-defibrillator (ICD) and cardiac resynchronization therapy–defibrillator (CRT-D) devices treated outside of clinical trials are lacking. No clinical trial has evaluated mortality after device implantation or after shock therapy in large numbers of patients with implanted devices that regularly transmit device data over a network.

Methods and Results—Survival status in patients implanted with ICD and CRT devices across the United States from a single manufacturer was assessed. Outcomes were compared between patients followed in device clinic settings and those who regularly transmit remote data collected from the device an average of 4 times monthly. Shock delivery and electrogram analysis could be ascertained from patients followed on the network, enabling survival after ICD shock to be evaluated. One- and 5-year survival rates in 185 778 patients after ICD implantation were 92% and 68% and were 88% and 54% for CRT-D device recipients. In 8228 patients implanted with CRT-only devices, survival was 82% and 48% at 1 and 5 years, respectively. For the 69 556 ICD and CRT-D patients receiving remote follow-up on the network, 1- and 5-year survival rates were higher compared with those in the 116 222 patients who received device follow-up in device clinics only (50% reduction; *P*<0.0001). There were no differences between patients followed on or off the remote network for the characteristics of age, gender, implanted device year or type, and economic or educational status. Shock therapy was associated with subsequent mortality risk for both ICD and CRT-D recipients.

Conclusions—Survival after ICD and CRT-D implantation in patients treated in naturalistic practice compares favorably with survival rates observed in clinical trials. Remote follow-up of device data is associated with excellent survival, but arrhythmias that result in device therapy in this population are associated with a higher mortality risk compared with patients who do not require shock therapy. (*Circulation*. 2010;122:2359-2367.)

Key Words: follow-up studies ■ shock ■ survival

Pivotal randomized clinical trials demonstrate that primary prevention with implantable cardioverter-defibrillator (ICD) and cardiac resynchronization therapy–defibrillator (CRT-D) devices improves survival in patients with heart failure due to systolic dysfunction.[1–3] In those trials, >7000 patients were randomized to appropriate heart failure medical therapy or medical therapy plus device therapy. The results of these trials provide the most contemporary data used to calculate the therapeutic and economic value of the devices.[4–6] In the United States, nearly 400 000 devices have been implanted since approval was granted by the Food and Drug Administration and since the coverage decision by the Centers for Medi-

care and Medicaid Services for primary prevention indications.[7,8] Recently updated national treatment guidelines strongly recommend ICD and CRT-D device implantation for primary prevention of sudden death and heart failure therapy in select patients.[9,10] After device implantation, there is a paucity of data on shock therapy, mortality incidence, and the interaction between these outcomes in the hundreds of thousands of recipients implanted under expanded guideline indications. This limits the ability to assess the therapeutic value of the device over long time frames and is a major limitation to our understanding of the true benefits or risks associated with this costly therapy.[11–13]

Technology advances, in recent years, enable remote real-time transmission of data, collected and stored in devices, to a protected network. Current estimates are that, in the United States, 13 000 newly implanted ICD and CRT device patients are added monthly to a remote monitoring network, and >350 000 patients are transmitting data that are accessible to their physician.[14,15] The ability of the physician and device follow-up clinic personnel to review data regularly or on demand has expanded and has challenged the traditional model of patient care after device implantation. Before the availability of remote follow-up, the standard of care after ICD or CRT-D implantation was quarterly patient clinic visits for device interrogation.[15] In this scenario, events like shock therapies or data related to device component function occurring in the interval between clinic visits are stored in the device and downloaded manually at the subsequent clinic visit. A distinctive feature of remote transmission is that devices are programmed to relay data daily from the device if a shock therapy is delivered or if a device safety issue due to a component malfunction is detected. This leads to a continuous stream of data and an increase in the amount of data available to the physician. This reduces the time to physician notification of events detected by the device or ancillary features of the system, such as networked weight and blood pressure monitors. There is also active patient involvement in the networked transmissions because the system regularly prompts patients to answer questions on status of symptoms.[14]

We sought to assess long-term survival and incidence of shock therapies in a large population of ICD and CRT device recipients implanted across the United States and engaged in remote monitoring of the device. To understand the manner in which networked device follow-up influences outcome, we compared survival between ICD and CRT-D patients followed on the remote network with those followed in the clinic setting only.

Methods

Study Design and Subject Participation

The ALTITUDE project is an independent clinical science initiative that launched in 2008 and was formed to prospectively analyze data from implanted ICD and CRT devices manufactured by Boston Scientific Corporation (Natick, Mass) that regularly communicate information over a network from patients' homes. The remote monitoring system, known as LATITUDE, gained Food and Drug Administration approval in 2005 and was market released in 2006 for CRT-D and then ICD devices. CRT-only devices do not yet have networked capability. ICD and CRT-D devices that were implanted dating back to 2004 and were capable of remote transmission were also approved for addition to the LATITUDE system. After 2006, all patients receiving new Boston Scientific ICD and CRT-D devices were eligible for enrollment in the LATITUDE remote follow-up network after implantation.

The ALTITUDE study group consists of an independent physician leadership panel. The panel prospectively identifies key clinical questions on a yearly basis for analysis and subsequent publication. A charter governs the conduct and relationship of the ALTITUDE leadership panel and Boston Scientific personnel.
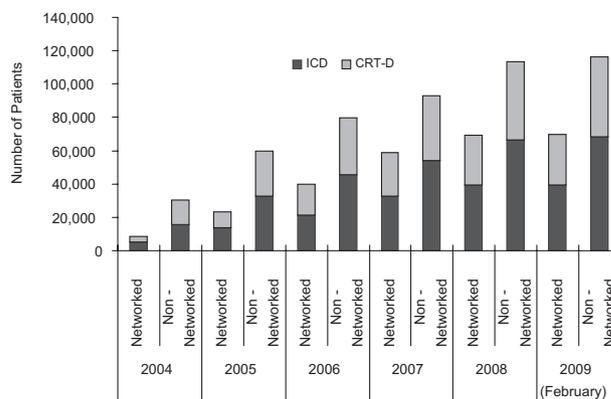

Figure 1. Cumulative patient numbers by implantation year, device type, and network follow-up.

For the network survival analysis, in the ALTITUDE survival study, a total of 69 556 patients followed at 2096 US centers were evaluated. Each was implanted with a Boston Scientific LATITUDE-compatible device. All patients transmitted remote data until the follow-up interval was closed for data analysis on February 5, 2009. Remote transmissions occurred an average of 4 ± 2 and 3 ± 2 times monthly for CRT-D and ICD devices, respectively. Additional in-clinic visits occurred an average of 2 times yearly for both device types. The remote system consists of a communicator in the home who interrogates the device. A patient may initiate a transmission on demand. The data are transferred over the telephone line and are downloaded daily to designated device implantation follow-up clinics from a secure Web site managed by Boston Scientific. Because the system was market released in 2006, there was a delay from implantation to first remote interrogation of 23.6 months for devices implanted from 2004 to 2006. For devices that were implanted after 2006, the first remote interrogation occurred at a mean of 3.5 months after implantation.

Participating follow-up centers elected to engage in a data use agreement that allows for the use of the data for research purposes in accordance with Health Insurance Portability and Accountability Act regulations. Of all centers participating in the LATITUDE network, 6% (145 clinics) did not contribute patients to this analysis because they elected not to share deidentified patient data.

The decision to place a patient in the remote follow-up system is made by the implanting physician at the time of device implantation or at the postimplantation follow-up clinic visit. After 2006 market release of LATITUDE, it was also at the discretion of the device-following physician to add to the network a patient with an existing device that was capable of networked transmission. Figure 1 depicts the cumulative number of patients, according to implant year, who were followed on or off the remote network, according to device type. A total of 124 450 patients were not enrolled in the remote follow-up program and were followed in the clinic setting only. This includes 116 222 ICD and CRT-D patients and 8228 CRT-only recipients whose devices were not capable of networked transmission.

To assess for possible physician referral bias that may influence the decision to refer a patient for networked versus traditional device follow-up, patients followed on and off the network were further compared by analysis of residential postal zip code. United States census data were then accessed to determine and compare economic, racial, and educational status.[16,17]

Survival Status and Shock Adjudication

Survival status was obtained by cross-reference to the Social Security Death Index provided to Boston Scientific for implanted patients on a quarterly schedule. Follow-up for vital status data was continued for 10 months after collection of study data was closed to

allow for lag time in reporting. Patients without Social Security numbers were excluded from the analysis and totaled 8% of the total population. These patients were younger than those included in the analysis (mean age, 65 versus 67 years) and more likely to have an ICD versus CRT device (60% versus 55%) but did not differ according to gender (74% male).

Stored atrial and ventricular electrograms collected before, during, and after the shock episodes were available in patients followed on the network. The incidence of shock therapies and appropriateness of the therapy were analyzed. An independent physician panel of 7 board-certified cardiac electrophysiologists dedicated to the classification and adjudication of shock episodes performed the electrogram review. If the device delivered the first shock therapy for a sustained ventricular rhythm according to programmed settings, it was considered appropriate therapy. Inappropriate therapy was defined as a shock delivery for a supraventricular arrhythmia or for an episode of oversensing resulting in a shock therapy.

Statistical Methods

Kaplan-Meier curves and multivariate Cox proportional hazard models adjusting for baseline covariates of age, gender, implantation year, and device type were used to calculate cumulative mortality and to assess the relationship between mortality risk and the following: network participation, transmission of additional physiological (weight, blood pressure) or symptom data via the network, and the occurrence of shock therapy. Appropriate and inappropriate shocks, as well as the initial transmission of physiological data, were treated as time-dependent covariates for Cox model analysis.[18–20] To correct for possible imbalances in the on/off network survival comparison, a subgroup analysis was additionally performed that identified patients after 1:1 matching for the characteristics of age, gender, implantation year, device model, implantation center, and patient mortality status at the time of network follow-up. A sensitivity analysis was also performed to determine whether significant baseline differences between the networked patients and those followed in traditional clinic settings may affect mortality findings.[21] This analysis included characteristics known to increase risk in ICD recipients with ischemic left ventricular dysfunction (New York Heart Association functional class, atrial fibrillation, age >70 years, left ventricular ejection fraction <20%, QRS duration >120 ms, and blood urea nitrogen >26 mg/dL).

For shock adjudication, a prespecified level of agreement was used to determine the number of stored electrograms that required repetitive review. Agreement was measured with the use of Light's κ.[22] A total of 5279 shock episodes were reviewed in 2000 patients. For all episodes, adjudication agreement for appropriateness of shock was 94% ($\kappa=0.8$). More repetitive reviews were required for single-chamber compared with dual-chamber devices because of the lower level of agreement with single-chamber devices (89% versus 96% for dual-chamber devices). All analyses were performed with the use of SAS version 9.1 and R version 2.11. Leslie A. Saxon, MD, had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Results

Study Population

A total of 194 006 patients were included in the survival analysis; 69 556 were followed on the network, and 124 450 were followed in clinic only (116 222 ICD and CRT-D devices and 8228 CRT-only devices). Demographic characteristics are shown in Table 1. The mean age of the entire ICD and CRT-D population was 67 ± 13 years, and 74% of patients were male. Device implantation duration was similar for patients followed both on and off the network and averaged 28 ± 17 months (range, 27 ± 19 to 29 ± 15 months). For matched patients, mean age was

Table 1. Patient Demographics

Group	Device Type	Patients	% Male	Age at Implant, Mean±SD, y	Implant Duration, Mean±SD, mo
Networked	ICD	39 546	75	65±13	29±16
	CRT-D	30 010	73	69±11	29±15
Total networked		69 556	74	67±12	29±15
Nonnetworked	ICD	68 481	76	66±14	27±18
	CRT-D	47 741	74	69±12	26±19
	CRT-P	8228	57	76±11	25±19
Total nonnetworked		124 450	74	68±13	27±19
Total		194 006	74	67±13	28±18

CRT-P indicates CRT-pacing.

69 ± 10 years, 87% were male, and device implantation follow-up duration was 33 ± 16 months. There were 8228 CRT-only patients, and mean age was 76 ± 11 years; 57% of patients were men, and mean implantation duration was 25 ± 19 months.

Figure 2 depicts the distribution of ICD and CRT-D patients across the United States in aggregate and according to whether or not they were followed on and off the networked system. For the entire population, patients on the network live in areas that are less urban (73% versus 79%) and more likely to be white (77% versus 70%). There were no differences in median income or educational level within geographic areas between patients on and off the network ($44 000; 49% college educated).

Survival

Figure 3A depicts annual survival for the entire population of 194 006 patients with ICD, CRT-D, and CRT-only devices implanted from 2004 onward, whether or not they were followed on or off the network. Survival at 1 year was 92% for ICD and 88% for CRT-D patients. One-year survival was lower, at 82%, for CRT-only recipients.

Survival comparisons for patients followed on or off the network by device type and adjusted for age, gender, device type, and implantation year are shown in Figure 3B. For both ICD and CRT-D recipients, annual and total survival was significantly better if patients were transmitting device information to the network. Figure 3C provides comparative survival data for 10 272 matched patients implanted with ICD and CRT-D devices on and off the network (59% for ICD, 41% for CRT-D recipients). Similar to the entire cohort, follow-up on the network was associated with a 50% relative reduction in the risk of death (ICD hazard ratio [HR], 0.56; CRT-D HR, 0.45; $P<0.0001$). Table 2 presents the sensitivity analysis for ICD recipients. Scenarios of proportionate risk demonstrate that only if the risk factor burden in the nonnetworked population were 5 times that of the networked patients would imbalance in these baseline factors reproduce the mortality difference observed (scenario 7; HR, 0.57).
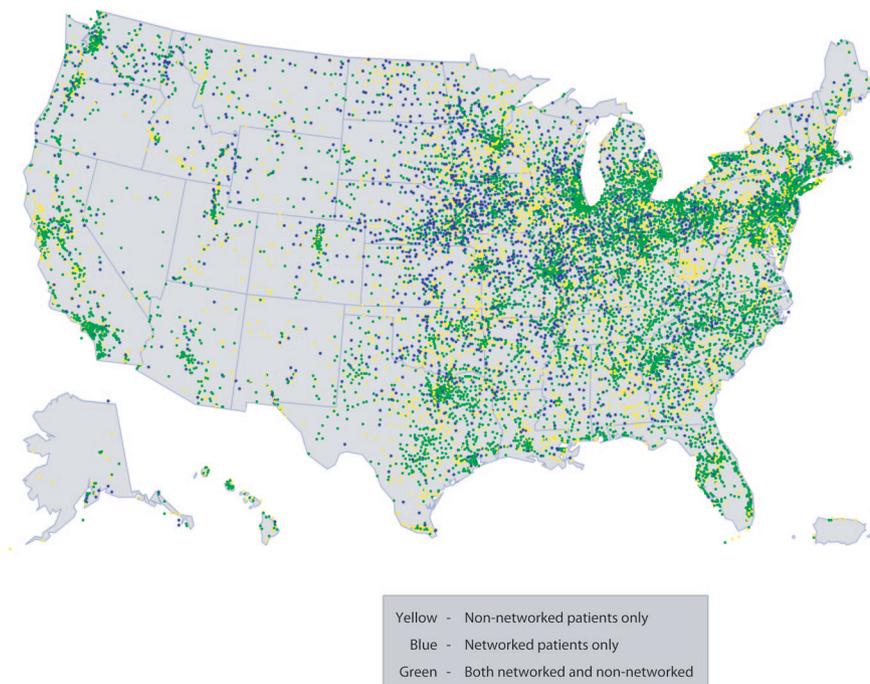
Figure 2. Geographic distribution of patients on and off the network.

Yellow - Non-networked patients only
Blue - Networked patients only
Green - Both networked and non-networked

A total of 3018 networked patients (4%) (2815 CRT-D [9.4%] and 203 ICD [0.5%]) also transmitted weight and blood pressure data with device transmissions. Patients transmitted weight and blood pressure data an average of 2.5 times per week. These CRT-D subjects transmitting weight and blood pressure data had the lowest mortality risk (HR, 0.9; $P < 0.01$) compared with other networked CRT-D patients.

Shock Therapies and Programming in Patients Followed Up on the Network

There was no difference in the incidence of shock therapy between ICD and CRT-D devices. At 1 year after implantation, a first shock was experienced by 14% of ICD and CRT-D recipients. One-year incidence of appropriate and inappropriate shock was 8% and 6%, respectively. The incidence of shock increased to 38% and 33% in ICD and CRT-D patients at 5 years, respectively. Appropriate shock incidence at 5 years increased to 23% for ICD and CRT-D patients, and inappropriate shock incidence was 16% and 17%, respectively. Figure 4 illustrates the annual shock incidence by device type.

The mean detection rate triggering shock therapies was 222 beats per minute. The majority of ICD and CRT-D devices were programmed to 2- or 3-zone therapies (77% and 78%) versus 1-zone therapies. Patients programmed to 2- or 3-zone therapies include those with a monitor-only zone. A total of 68% of all patients had antitachycardia therapies programmed. Of these, 6% of antitachycardia therapy episodes were followed by a shock.

Shock therapy adjudication results for all shocks and for shocks grouped by year are shown in Table 3. A total of 70% of shock episodes were classified as appropriate, and 30% were considered inappropriate. Sustained monomorphic ventricular tachycardia (VT) was the most common

arrhythmia resulting in appropriate device therapy, followed by ventricular fibrillation or polymorphic VT. For inappropriate episodes, the 2 most common reasons for shock were atrial flutter/atrial fibrillation and sinus tachycardia or supraventricular arrhythmia. Inappropriate shock was due to noise, artifact, or oversensing in 3% of shock episodes or 101 patients. Shocks for noise and oversensing were not associated with increased risk of death, although the sample size is small (HR, 1.3; range, 0.7 to 2.4; $P = 0.4$).

Figure 5 illustrates the multivariate model HRs for risk of death after shock therapy for all shocks and for appropriate versus inappropriate shocks. For both ICD and CRT-D devices, receipt of a shock therapy was associated with an increase in the risk of death. The greatest risk was associated with receiving both appropriate and inappropriate shocks for ICD recipients (HR, 2.62; confidence interval, 1.52 to 4.53) and appropriate shock therapies for CRT recipients (HR, 2.09, confidence interval, 1.21 to 3.60). There was not an increased risk associated with receiving a shock for polymorphic VT or ventricular fibrillation compared with monomorphic VT (HR, 1.1; confidence interval, 0.7 to 1.6).

Discussion

This study provides long-term survival data for the largest number of ICD and CRT-D recipients reported to date. The data complement previous clinical trial results enrolling highly selective patient populations. Survival over a mean follow-up of 45 months in the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) that evaluated the ICD for primary prevention of sudden death was 82%.[1] In our entire cohort of networked and nonnetworked ICD recipients, survival is slightly lower. The ICD recipients in this study would be expected to fare worse than those enrolled
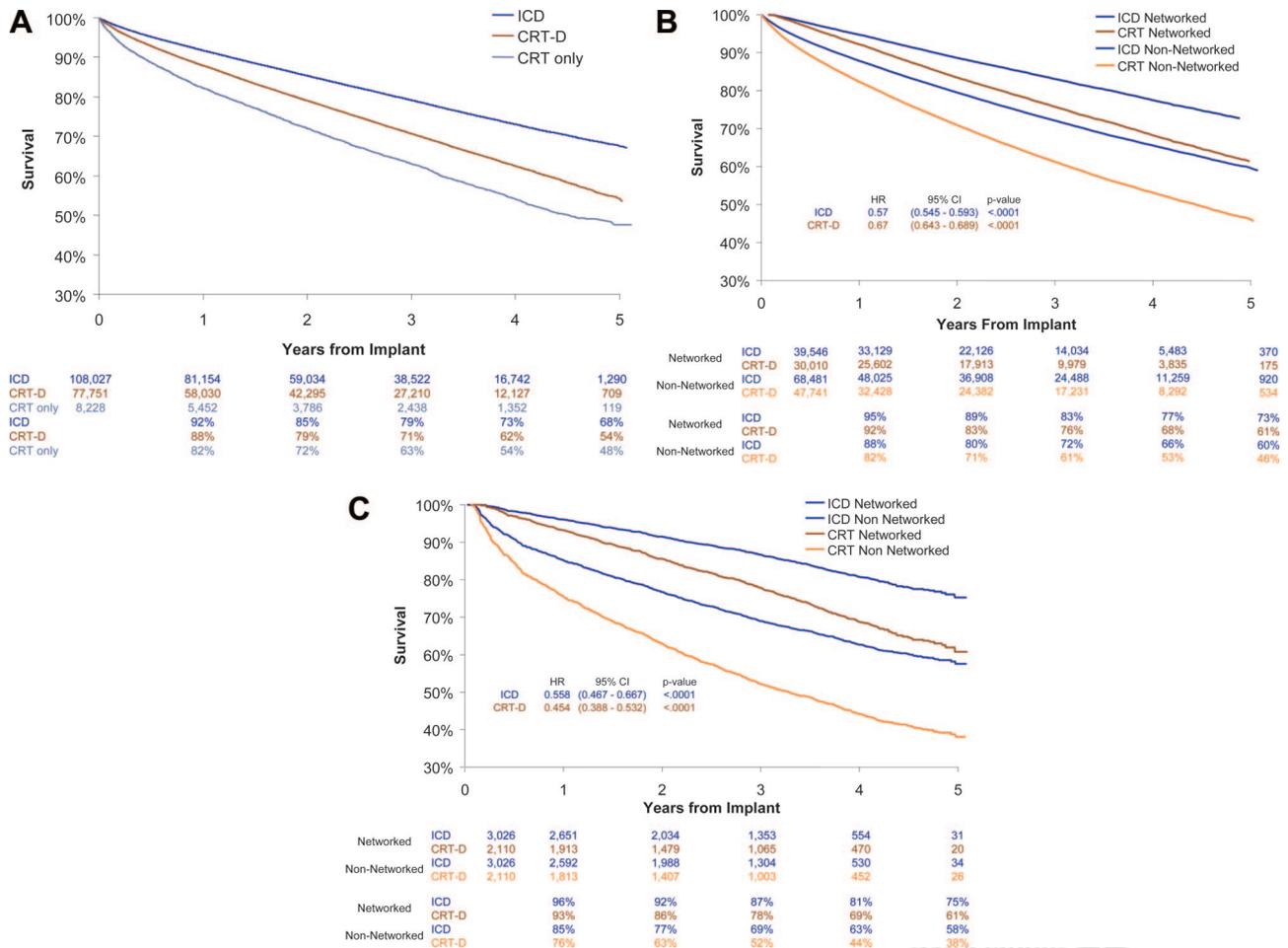
Figure 3. A, Overall survival by device type. B, Survival comparison on and off the network by device type. C, Survival comparison on and off the network-matched cohort. CI indicates confidence interval.

in primary prevention ICD clinical trials because they include patients with ICD indications for primary as well as secondary prevention of sudden death. Although we do not know the indications for ICD therapy in this cohort, contemporary data collected in both the National ICD Registry, which includes >380 000 implanted patients, and other registries find that 20% of ICD recipients are implanted for secondary prevention indications.[8–10,19]

Table 2.   Sensitivity Analysis for ICD Cohort

Proportionate Risk Scenarios	Percentage of Networked Patients With ≥1 Risk Factor*	Percentage of Nonnetworked Patients With ≥1 Risk Factor*	Estimated HR From Cox Model
1	64	75	0.92
2	57	79	0.85
3	50	83	0.79
4	43	87	0.73
5	36	92	0.67
6	28	96	0.62
7	21	100	0.57

*Risk factors: New York Heart Association functional class, atrial fibrillation, age >70 years, left ventricular ejection fraction <20%, QRS >120 ms, blood urea nitrogen >26 mg/dL.

These patients are known to confront a higher overall risk of death and need for shock therapy compared with patients implanted for primary prevention indications.[19] Nonetheless, survival in our cohort is very comparable to survivals observed in the Multicenter Automatic Defibrillator Implantation Trial (MADIT-II) of primary prevention ICD for postinfarction patients. Although it is well recognized that postinfarction patients with heart failure face a greater mortality risk than those with a nonischemic pathogenesis of heart failure, our findings are reassuring.[23] These are the first data to find that survival outcomes in tens of thousands of unselected primary and secondary prevention ICD patients implanted across the United States with contemporary devices do very well over time. For CRT-D recipients, 1-year survival is comparable to that observed in the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) trial at 88%.[3] It is gratifying to observe 3-year survival rates of >70% for the entire cohort of nearly 83 000 CRT-D recipients. These survival data are superior to the 3-year survival rate of 62% reported in the 404 patients who were randomized to medical therapy in the Cardiac Resynchronization–Heart Failure (CARE-HF) trial that evaluated the CRT pacemaker.[24] Three-year survival in the CRT-only patients in our study was similar to that in CARE-HF. The

Figure 4. Annual incidence of shock by device type.

ICD	39,396	27,890	17,177	10,035	3,651	233
CRT-D	29,904	21,814	14,055	7,497	2,686	303

Kaplan Meier Incidence

ICD		14%	22%	28%	33%	38%
CRT-D		13%	19%	25%	30%	33%

reasons that 1-year CRT-only survival in this study was below that reported in CARE-HF may be due to selection bias because physicians elected to implant a CRT-only device in only 10% of our study subjects. These subjects were older and presumably sicker than patients selected for CRT-D.[3,25] These are the first data to suggest that there is continued benefit from the CRT-D device over time in this high-risk patient group.

A significant limitation of the data set that hinders comparison to clinical trial data is the lack of randomization to remote versus nonremote follow-up as well as the paucity of clinical characteristics that would provide a more accurate comparison to clinical trial subjects. In the future, collaborative efforts with other large databases such as the National ICD registry, now in its third year, may be formed that contain detailed clinical profiles of patients undergoing ICD and CRT-D implantation.[8]

Similarly, the lack of clinical profile data and specific knowledge of comorbid conditions limits interpretation and assignation of clinical significance to the novel observation resulting from this study that frequent remote follow-up of both ICD and CRT-D devices is associated with better survival compared with traditional in-clinic follow-up. Additionally, excluded patient data from clinics that declined to participate in the data-sharing agreement and patients who did not have Social Security numbers may have contributed to bias in the data set if these patients differed significantly from the study population.

Nonetheless, it is interesting to speculate about the reasons for the improved outcomes in patients who continuously transmit remote device data. These include the fact that remotely collected data may provide earlier notification of events that result in a diagnosis or therapy that reduces subsequent risk. Remote follow-up may also encourage patients to be more aware and in touch with their health status. The presence of the remote communicator in the home, enabling the patient to initiate a transmission as well as engaging the patient by frequent queries related to heart failure symptoms, can serve to involve the patient more fully in his or her healthcare. The subgroup of CRT-D recipients in this study who appeared to face the lowest mortality risk were also those who transmitted weight and blood pressure data weekly. These data suggest motivation and engagement by both the physician referring the patient for weight and blood pressure equipment at the time of referral to the remote system as well as the patient who frequently transmits these data. It may be that this partnership influences care and mortality outcomes positively. A recent meta-analysis including >6000 patients provides complementary new data indicating that remote monitoring of both symptoms and measures of heart failure status such as weight and blood pressure results in improved survival in heart failure patients.[26] In this study, the receipt of remotely collected device and symptom status data may provide the treating

Table 3.   Shock Adjudication Results

Shocked Rhythm	0 to 12 mo	12 to 24 mo	>24 mo	Total
Appropriate shock				
Monomorphic VT	981 (41)	509 (44)	866 (51)	2356 (45)
Ventricular fibrillation/ polymorphic VT	411 (17)	174 (15)	235 (14)	820 (16)
Polymorphic and monomorphic VT	225 (9)	100 (9)	177 (10)	502 (10)
Appropriate total	1617 (68)	783 (68)	1278 (75)	3678 (70)
Inappropriate shock				
Sinus tachycardia or supraventricular tachycardia	335 (14)	179 (15)	167 (10)	681 (13)
Atrial fibrillation/ atrial flutter	321 (13)	154 (13)	220 (13)	695 (13)
Noise/artifacts/ oversensing	84 (4)	26 (2)	23 (1)	133 (3)
Nonsustained arrhythmia	33 (1)	14 (1)	14 (1)	61 (1)
Inappropriate total	773 (32)	373 (32)	424 (25)	1570 (30)
Total	2390 (100)	1156 (100)	1702 (100)	5248 (100)

Values in parentheses are percentages.

ICD devices

Any Shock	2.03 (1.66-2.50)
One or more Appropriate Shock	2.05 (1.55-2.71)
One or more Inappropriate Shock	1.84 (1.30-2.61)
Both Appropriate and Inappropriate	2.62 (1.52-4.53)

CRT-D devices

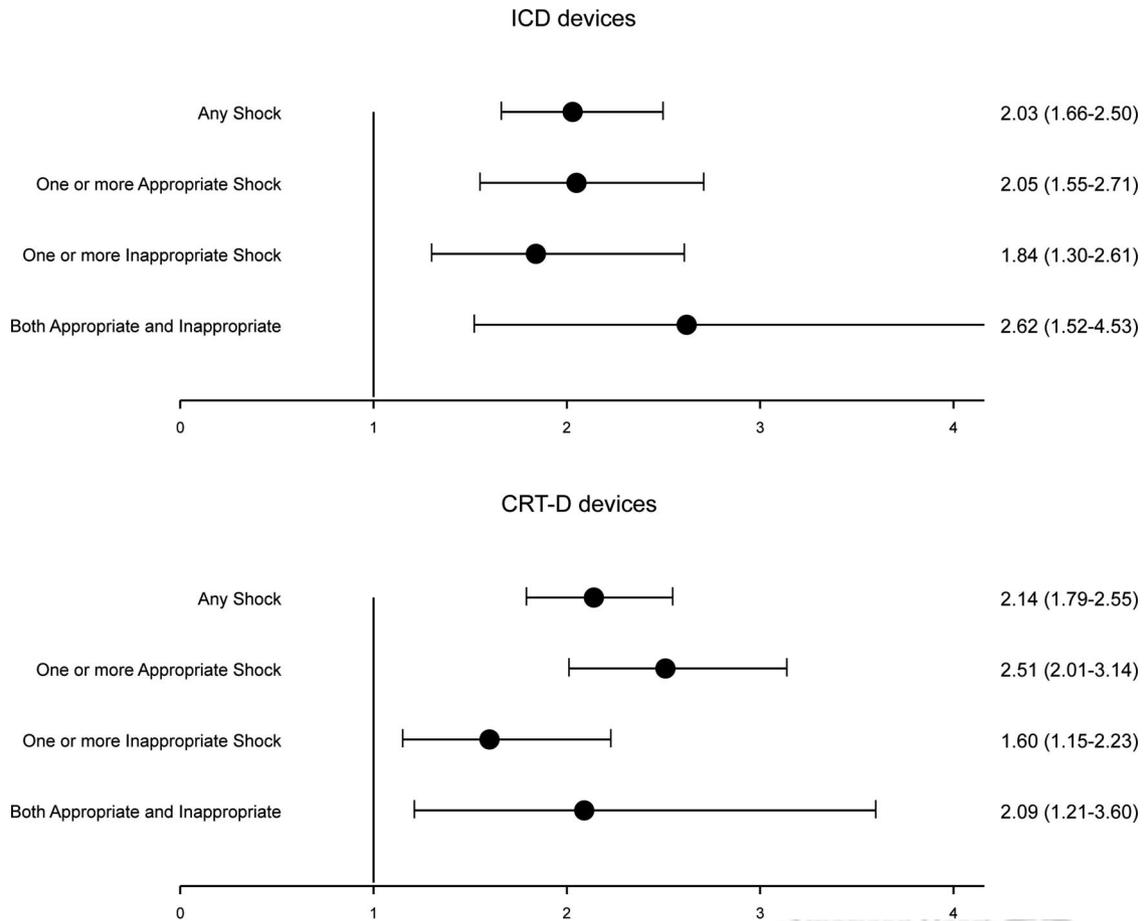|	
Any Shock	2.14 (1.79-2.55)
One or more Appropriate Shock	2.51 (2.01-3.14)
One or more Inappropriate Shock	1.60 (1.15-2.23)
Both Appropriate and Inappropriate	2.09 (1.21-3.60)

Figure 5. Multivariate model of HRs for risk of death: with and without a shock.

physician with a more comprehensive assessment of arrhythmia and heart failure status for each individual patient. Our data also support the observation that physicians are participating in the care of patients who transmit remotely because both ICD and CRT-D remote patients were still seen in the clinic an average of 2 times yearly. Despite the fact that patients transmitting remotely were more likely to live in more rural areas, remote transmissions were not used solely in lieu of a clinic visit.

Finally, the study data also provide additional insights into the manner in which device shock therapies are utilized and affect outcomes. The finding that the majority of appropriate shocks are due to sustained monomorphic VT is corroborated by the MADIT-II and SCD- HeFT studies and suggests that reentry is an important mechanism of VT in heart failure patients.[18,23] These patients experience the same mortality risk after shock as those shocked for polymorphic VT or ventricular fibrillation. However, a large percentage of patients get shocks for both monomorphic and polymorphic VT or ventricular fibrillation. Both ICD and prior CRT-D studies have observed worse outcomes after shock, with risk of death from both sudden and heart failure modes of death increased after shock.[18,19,25] We cannot draw firm conclusions from our finding that shocks due to oversensing are not associated with increased mortality risk because the patient number was small and the confidence interval crossed unity. It

remains unclear whether it is the shock therapy alone that introduces increased risk for patients or if the underlying sustained VT or atrial tachycardia resulting in shock therapy is a marker of worsening heart failure and increased mortality risk. It is intriguing to speculate about the manner in which networked device arrhythmia data, with the addition of heart failure diagnostics, will provide insight into the relationship between the risks for malignant arrhythmias and heart failure status. Remote follow-up provides the opportunity to review thousands of spontaneous episodes of ventricular as well as atrial arrhythmias and holds great promise to yield important insights into how to better program devices and treat sustained arrhythmias.

Device therapy has become a mainstay of therapy for patients with symptomatic heart failure due to systolic dysfunction who are on appropriate medical therapy. The ability to track outcomes, device therapy utilization, and patient participation is enabled by remote device follow-up capability. Networked device data transmission provides unique opportunities for clinicians and patients. Observations can be made earlier and continuously in individual patients, and these observations may influence outcomes.

Sources of Funding

members listed as authors in the byline are compensated for ALTITUDE Study Group activities as determined by a consulting agreement with Boston Scientific. There were no agreements between the authors or affiliated institutions and Boston Scientific on confidentiality relative to the content of the manuscript.

Disclosures

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CLINICAL PERSPECTIVE

Transvenous implantable defibrillators and cardiac resynchronization devices placed for primary prevention of sudden death and as a heart failure therapy for advanced systolic dysfunction in association with bundle branch block are now common therapies. Outside of clinical trials, long-term mortality outcomes are unknown. Additionally, newer-generation devices are enabled to transmit data daily from patients' homes with the use of a remote communicator, and these data are available to physicians on the Internet. This study provides 1- and 5-year survival outcome data in >194 000 device recipients with devices implanted from a single manufacturer and demonstrates that survival is equivalent to those patients studied in the pivotal randomized trials. One- and 5-year implantable cardioverter-defibrillator survival rates are 92% and 68%, respectively, and are 88% and 54% for cardiac resynchronization therapy defibrillators. Patients transmitting data remotely had the best survival, and shock therapies were associated with worsened survival in both implantable defibrillator and cardiac resynchronization device recipients. The 1- and 5-year risks of shock were 14% and 38% for implantable cardioverter-defibrillator recipients and were 13% and 33% for cardiac resynchronization therapy defibrillator subjects. Sensitivity analysis did not detect a significant imbalance between patients followed in traditional clinic settings compared with those transmitting data remotely as well as in the clinic. This is the largest report to date on survival after device implantation and finds that survival benefits observed over shorter follow-up intervals in clinical trials are maintained. This information is particularly important because there are upfront risks and costs associated with device implantation.