

**HRS Abstracts and Late Breaking Trial Results from the
ALTITUDE Clinical Science Program
as presented at the Heart Rhythm Society Conference,
May 4-7, 2011; San Francisco, CA, LA USA**

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Survival after Shock Therapy for VF in ICD and CRT-D Recipients Followed on a Remote Network: The ALTITUDE STUDY GROUP

Introduction

- ❖ Clinical trial data collected in ICD recipients indicate that receipt of a shock for ventricular fibrillation (VF) versus ventricular tachycardia (VT) predicts increased risk of heart failure hospitalization and death
- ❖ In the MADIT II study, survival for patients after receiving therapy for VF was less than 50% at 2 years¹
- ❖ We evaluated mortality after shocks for VF in a large unselected patient cohort that transmits ICD and CRT-D device data over a network

Survival after Shock Therapy for VF in ICD and CRT-D Recipients Followed on a Remote Network: The ALTITUDE STUDY GROUP

Methods

- ❖ The ALTITUDE study group was designed to analyze the LATITUDE® remote monitoring system (Boston Scientific) to evaluate patient outcomes across the United States
- ❖ The LATITUDE agreement signed by centers participating in ALTITUDE includes use of limited or de-identified data for research
- ❖ Of 81,081 patients, a sample of 5,279 shock episodes in 1,996 patients (767 CRT-D, 1,229 ICD) was adjudicated by a panel of electrophysiologists
- ❖ Adjudication categories for ventricular rhythms were VF/PVT, MVT and PVT, and MVT
- ❖ All-cause mortality was determined from the Social Security Death Index, with six months allowed for reporting of mortality information
- ❖ Kaplan Meier analysis was used to determine survival

Survival after Shock Therapy for VF in ICD and CRT-D Recipients Followed on a Remote Network: The ALTITUDE STUDY GROUP

Results

- ❖ A total of 231 ICD patients (19%) and 173 CRT-D patients (22%) had shock episodes adjudicated as a VF rhythm
- ❖ Including rhythms adjudicated as PVT, 332 (27%) of ICD patients and 257 (34%) of CRT-D patients had shock episodes for VF or PVT

Table 1. Patient Characteristics by Shock Group and Device Type

	Shock For VF		Shock for VF or PVT		Shock for VF, PVT or MVT	
	ICD	CRT	ICD	CRT	ICD	CRT
Patients	231	173	332	257	773	499
Mean age	63 ± 14	67 ± 12	64 ± 14	68 ± 11	66 ± 13	68 ± 11
Male	172 (74.5%)	135 (78%)	251 (75.6%)	203 (79%)	616 (79.7%)	416 (83.4%)

- ❖ Survival after shock, by shock group is shown in table 2

Table 2. Survival from Shock Episode by Shock Group and Device Type

	Shock For VF		Shock for VF or PVT		Shock for VF, PVT or MVT	
	ICD	CRT	ICD	CRT	ICD	CRT
1 year	0.82	0.81	0.85	0.76	0.89	0.78
2 year	0.73	0.64	0.75	0.61	0.79	0.64
3 year	0.65	0.51	0.67	0.48	0.69	0.52
4 year	0.57	0.42	0.60	0.41	0.63	0.43
5 year	0.56	0.29	0.57	0.30	0.56	0.35

Survival after Shock Therapy for VF in ICD and CRT-D Recipients Followed on a Remote Network: The ALTITUDE STUDY GROUP

Results

- ❖ Mean survival was 4.9 years after shock for VF in ICD and 3.6 years for CRT-D recipients (figure 1)
- ❖ Including shocks for PVT, mean survival was 5.2 years after shock for VF or PVT in ICD and 3.7 years for CRT-D recipients (figure 2)
- ❖ Mean survival following a shock for VF, PVT or MVT was 5.8 years for ICD and 3.9 years for CRT-D recipients (figure 3)

Survival after Shock Therapy for VF in ICD and CRT-D Recipients Followed on a Remote Network: The ALTITUDE STUDY GROUP

Figure 1. ICD and CRT-D Survival following receipt of a first shock for VF

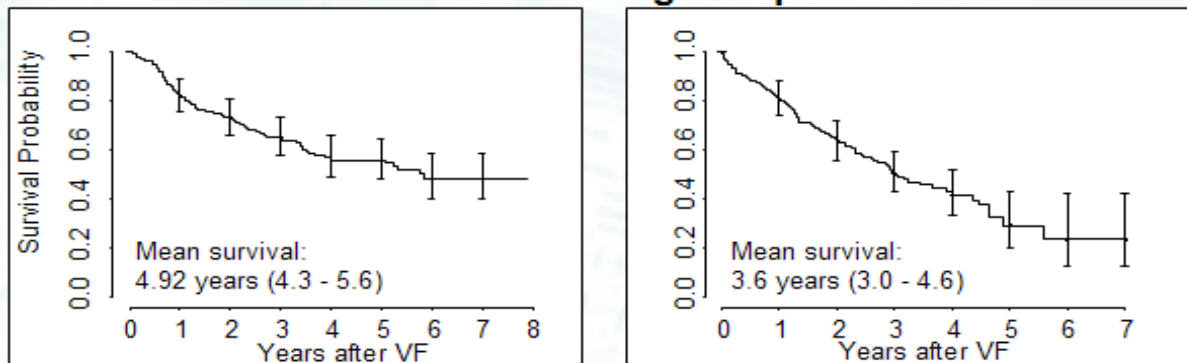


Figure 2. ICD and CRT-D Survival following receipt of a first shock for VF or PVT

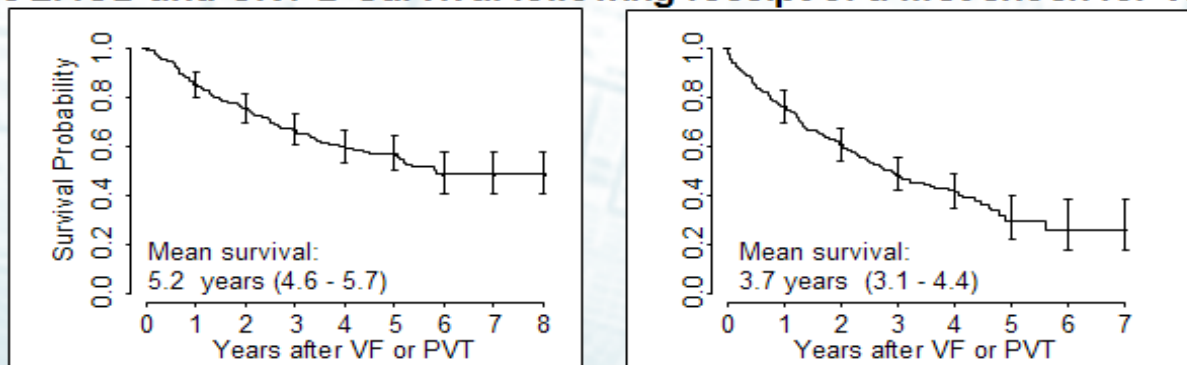
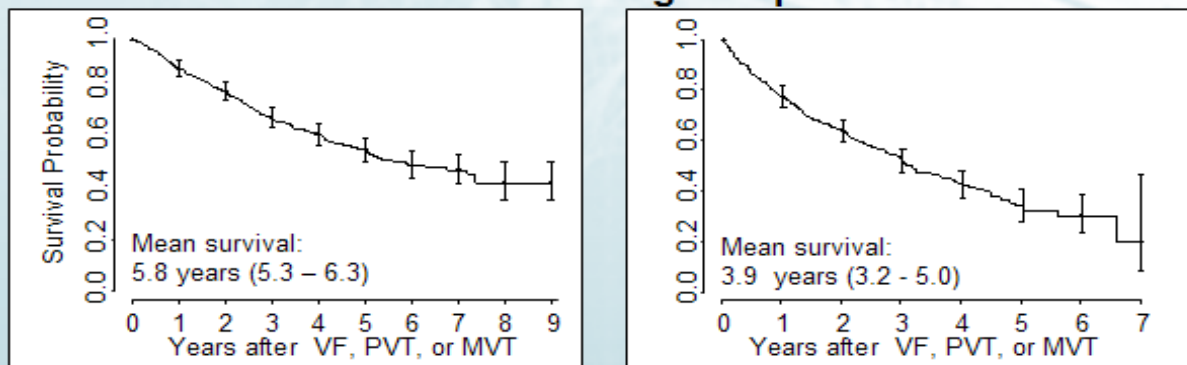


Figure 3. ICD and CRT-D Survival following receipt of a first shock for VF, PVT or MVT



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Survival after Shock Therapy for VF in ICD and CRT-D Recipients Followed on a Remote Network: The ALTITUDE STUDY GROUP

Conclusion

For ICD and CRT-D patients followed on a remote network, receipt of a shock for VF is associated with better survival than has previously been reported in the confines of clinical trials. This may be due to differences in implanted patients or more aggressive therapies directed toward contemporary patients that transmit data regularly.

Reference: Moss AJ, Greenberg H, et al. Long-term clinical course of patients after termination of ventricular 1120 Tung et al. JACC Vol. 52, No. 14, 2008

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Disclosures: Leslie A Saxon: Boston Scientific, St. Jude Medical, Medtronic. F. Roosevelt Gilliam, III, Boston Scientific. Brian D. Powell: Boston Scientific, Biotronik. Milan Seth: Boston Scientific. Paul W. Jones: Boston Scientific. David L. Hayes: Medtronic, St. Jude Medical, Biotronik, Inc., Wiley Publishing, Visible Assets, and Boston Scientific

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The Association of Atrial Fibrillation, ICD and CRT-D Shocks, and Mortality in Patients Participating in Remote Device Follow-Up

Introduction & Objectives

- ❖ There is a significant risk of atrial fibrillation (AF) in ICD and CRT-D recipients.
- ❖ The relationship between AF, shock episodes, and mortality risk is unknown.
- ❖ The ALTITUDE study group was designed to analyze comprehensive data from the LATITUDE® remote monitoring system (Boston Scientific) to evaluate patient outcomes, using a limited or de-identified data set under the terms of the LATITUDE agreement.
- ❖ This analysis evaluated the association between AF at the time of first shock and subsequent mortality.

The Association of Atrial Fibrillation, ICD and CRT-D Shocks, and Mortality in Patients Participating in Remote Device Follow-Up

Methods

- ❖ A total of 50,238 patients had data available in LATITUDE with a mean follow-up of 21.6 ± 12.3 months.
- ❖ Of these, 18.2% (9,165) received at least 1 shock.
- ❖ Sample shock episodes from 1,545 patients with dual chamber ICD or CRT-D devices were reviewed by a panel of seven electrophysiologists.
- ❖ Both atrial and ventricular episodes were adjudicated for 1,440 episodes during the first shock.
- ❖ Mortality outcomes, both unadjusted and adjusted for age, gender, time from implant to first shock, and implant year, were compared between patients with and without AF (at the time of first shock) using Cox proportional hazards regression.
- ❖ Means were computed using two-sample t-test and frequencies were compared using Fisher's exact test.

The Association of Atrial Fibrillation, ICD and CRT-D Shocks, and Mortality in Patients Participating in Remote Device Follow-Up

Results

❖ AF was present at the time of first shock in 25.0% of patients (Table 1). Overall, 12.9% of patients (11.2% of ICD recipients and 13.8% of CRT-D recipients) had both AF and VT or VF (dual tachycardias).

		AF at Shock	
Shock Type	Reason for Shock*	ICD	CRT-D
Appropriate	Ventricular Fibrillation/Polymorphic Ventricular Tachycardia	14/73 (19.2%)	27/137 (19.7%)
	Monomorphic Ventricular Tachycardia	12/163 (7.4%)	42/329 (12.8%)
	PVT and MVT	4/32 (12.5%)	3/55 (5.5%)
Inappropriate	Atrial Fibrillation	109/109 (100.0%)	147/147 (100.0%)
	Sinus Tachycardia or SVT	N/A (n=115)	N/A (n=160)
	Nonsustained Arrhythmia	N/A (n=7)	N/A (n=9)
	Noise/Artifacts/Oversensing	N/A (n=32)	N/A (n=63)

*By adjudication; 9 episodes had missing/unknown reason for shock. Values are n (percent). N/A=not applicable.

The Association of Atrial Fibrillation, ICD and CRT-D Shocks, and Mortality in Patients Participating in Remote Device Follow-Up

Results

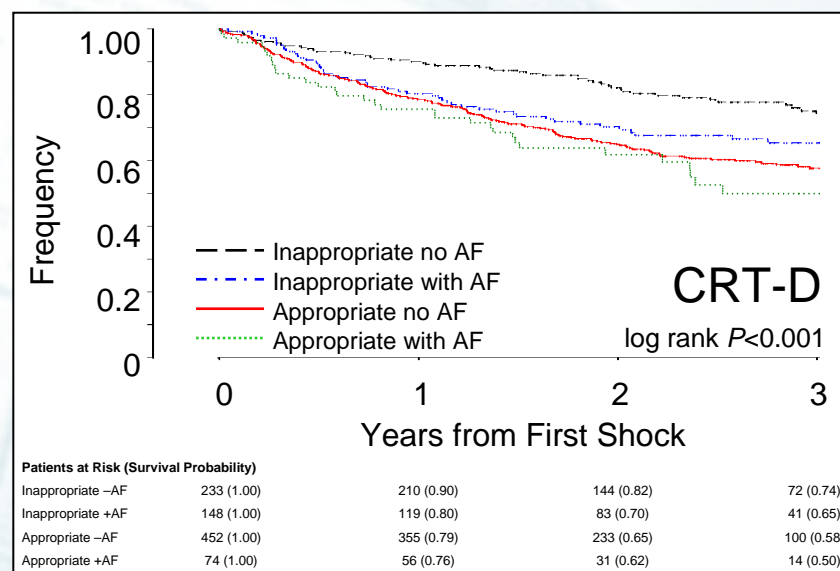
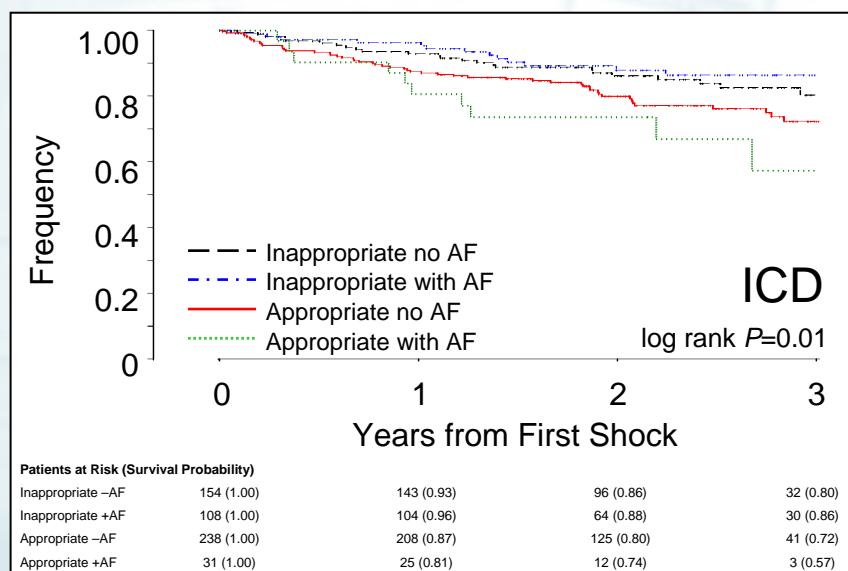
❖ Patient demographics by device and shock type are shown in Table 2.

Device	Shock type	Characteristic	AF	No AF	P value
ICD	Inappropriate	Patients, n	109	154	
		Age, years	64.0 ± 11.6	60.6 ± 16.1	0.06
		Female, n (%)	20 (18.3%)	40 (26.0%)	0.18
	Appropriate	Patients, n	31	238	
		Age, years	65.8 ± 14.3	66.5 ± 12.8	0.77
		Female, n (%)	7 (22.6%)	50 (21.0%)	0.82
CRT-D	Inappropriate	Patients, n	148	233	
		Age, years	66.3 ± 13.1	65.2 ± 13.3	0.42
		Female, n (%)	47 (31.8%)	52 (22.3%)	0.04
	Appropriate	Patients, n	74	453	
		Age, years	69.2 ± 10.6	67.7 ± 11.2	0.27
		Female, n (%)	7 (9.5%)	74 (16.3%)	0.16

Values are n (percent) or means ± standard deviation unless otherwise indicated.

The Association of Atrial Fibrillation, ICD and CRT-D Shocks, and Mortality in Patients Participating in Remote Device Follow-Up

Results



❖ In unadjusted KM analyses, survival was worst in patients with dual tachycardia (presence of AF in a patient with appropriate shock for VT/VF) (Figure).

The Association of Atrial Fibrillation, ICD and CRT-D Shocks, and Mortality in Patients Participating in Remote Device Follow-Up

Results

- ❖ Dual tachycardia has worse survival than VT/VF only, and VT/VF only had worse survival than AF only.
- ❖ Dual tachycardia has larger negative effects in ICD recipients than CRT-D recipients, although this comparison fails to reach statistical significance (interaction *P* value between device and rhythm type = 0.26).
- ❖ After adjustment for age, sex, device type, time from implant to shock, and implant year, dual tachycardia still tended to be associated with worse survival than other tachyarrhythmias (Table 3). (The lack of statistical significance in 3/4 comparisons is likely due to underpowering, given the consistent directionality of the hazard ratios.)

Device	Shock Type (Deaths/Total Patients)	HR (95% CI)	<i>P</i> value
ICD	VT/VF with AF (32.3% [10/31]) vs VT/VF only (22.3% [52/238])	1.59 (0.81, 3.14)	0.18
	VT/VF with AF (32.3% [10/31]) vs AF only (13.8% [15/109])	3.06 (1.36, 6.89)	0.007
CRT-D	VT/VF with AF (44.6% [33/74]) vs VT/VF only (40.2% [182/453])	1.21 (0.84, 1.76)	0.31
	VT/VF with AF (44.6% [33/74]) vs AF only (35.8% [53/148])	1.44 (0.93, 2.22)	0.10

Chi square test.

The Association of Atrial Fibrillation, ICD and CRT-D Shocks, and Mortality in Patients Participating in Remote Device Follow-Up

Summary & Conclusions

AF is present in 25% of dual chamber ICD and CRT-D recipients at the time of first shock. Dual tachycardias were not rare and were present in 13% of patients. Patients with dual tachycardia had poorer survival after shock than those with VT/VF alone, and patients with VT/VF had poorer survival than those with only AF.

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Clustering Pattern of Nonsustained Ventricular Arrhythmia Episodes in ICD Patients

Introduction

- The occurrence of ventricular tachycardia requiring ICD therapy can be sporadic or clustering. The temporal pattern of ventricular tachycardia has not been well characterized.
- Fractal geometry has been used to find patterns not easily detected with conventional statistics: clustering of premature ventricular contractions [1-3] and long-range correlation properties of heart rate have been analyzed in different cardiac patient populations [4-6] and have been related to outcome [7].

Objective

To better understand the temporal pattern of nonsustained ventricular tachycardia in an unselected patient population transmitting data to a remote monitoring system.

Clustering Pattern of Nonsustained Ventricular Arrhythmia Episodes in ICD Patients

Methods

Fractal Geometry: A fractal is a fragmented geometric shape that can be split into parts, each of which has the same properties as a reduced-size copy of the whole [8].

Why are episodes of NSVT considered fractal? If the statistical properties of the distribution of events are invariant to a change of time scale, then analytic techniques from fractal geometry can be used to quantify its properties.

How can fractal geometry be used to estimate clustering? The fractal dimension, D , depends on the probability of finding 2 NSVTs within a given time interval (r) and the duration of ' r ' (Figure 1 and 2). The result is a measure of clustering.

Clustering Pattern of Nonsustained Ventricular Arrhythmia Episodes in ICD Patients

Methods

Figure 1.

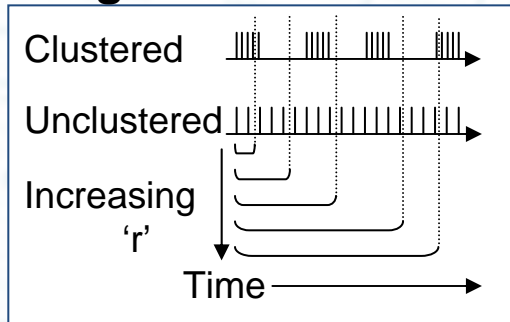
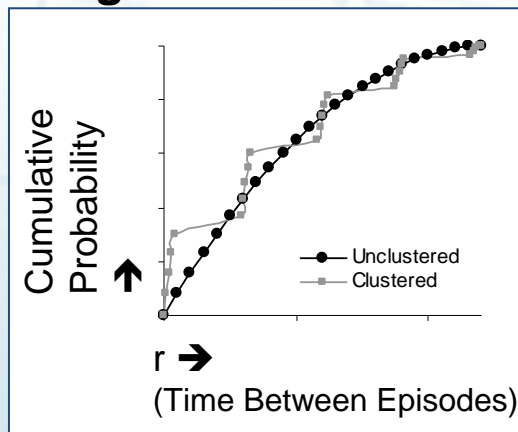


Figure 2.

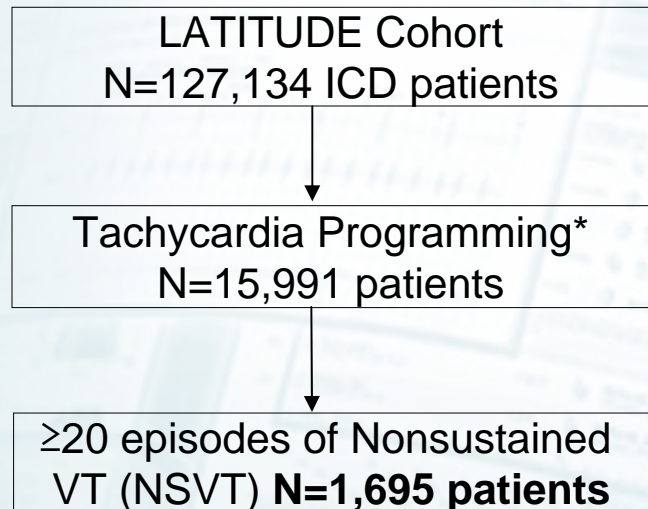


- Differences between clustered and unclustered data are shown in figure 1
 - *Clustered*: Rate of accumulation of NSVT pairs will not be proportional to 'r' (Figure 2).
- D is the slope of the log-log transformation of the cumulative probability and 'r'.
 - 'D' near 1 reflect a uniform distribution of NSVTs; lower values reflect the presence of clustering
 - 'D' calculated from real patient data was compared to simulated randomly but uniformly distributed data (same # of episodes) over the same time period
 - Wilcoxon signed rank test assessed whether the D statistic varied between the real and simulated data

Clustering Pattern of Nonsustained Ventricular Arrhythmia Episodes in ICD Patients

Results

Figure 3. Patient Flow



*Tachycardia programming information available (and consistent programming) from 30 d post implant to first shock episode or for a minimum of 6 mo without a shock

- In the patient population studied, NSVT exhibited significant clustering compared with matched, simulated, randomly distributed uniform data ($P<0.001$)
- Clustering of these NSVT episodes was associated with an increased likelihood of receiving inappropriate therapy (Table 1)

Clustering Pattern of Nonsustained Ventricular Arrhythmia Episodes in ICD Patients

Results

Table 1. Clustering of NSVT and Therapy

	N	Device NSVT episodes during follow up: (D) Median	Hazard Ratio (per 1 unit reduction in D)	P value
No Shock: Alive at study close	935	0.78	NA	NA
No Shock: Died during study	35	0.76	0.87 (0.34 - 2.23)	0.78
Any Shock	725	0.66	1.76 (1.37 - 2.26)	<.001
First shock – Appropriate	284	0.70	0.98 (0.67 - 1.43)	0.89
First shock – Inappropriate	302	0.57	3.01 (2.02 - 4.48)	<.001
First shock – EGM unavailable	139	0.69	1.17 (0.70 - 1.98)	0.56

Clustering Pattern of Nonsustained Ventricular Arrhythmia Episodes in ICD Patients

Summary & Conclusions

Frequent NSVT episodes were clustered in time. Clustering of NSVT episodes was positively associated inappropriate shock. Further study is needed to confirm the utility of these new measures of NSVT clustering.

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Brief Summary

CRT-D Systems from Boston Scientific CRM

CRT-D Systems from Boston Scientific CRM

Indications and Usage

These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications:

- Moderate to severe heart failure (NYHA Class III-IV) with EF \leq 35% and QRS duration \geq 120 ms
- Left bundle branch block (LBBB) with QRS \geq 130 ms, EF \leq 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure

Contraindications

There are no contraindications for this device.

Warnings

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient. Program the pulse generator Tachy Mode to Off during implant, explant or postmortem procedures to avoid inadvertent high voltage shocks. Always have sterile external and internal defibrillator protection available during implant. If not terminated in a timely fashion, an induced tachyarrhythmia can result in the patient's death. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient. Do not subject a patient with an implanted pulse generator to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents. Do not use atrial-tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in VT or VF. Do not use atrial-only modes in patients with heart failure because such modes do not provide CRT. LV lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Programming therapy for slow monomorphic VT may preclude CRT delivery at faster rates if these rates are in the tachyarrhythmia zones. Do not kink leads. Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture. Do not use defibrillation patch leads with the CRT-D system, or injury to the patient may occur. Do not use this pulse generator with another pulse generator. This combination could cause pulse generator interaction resulting in patient injury or lack of therapy delivery. For specific models, when using a subpectoral implantation, place the pulse generator with the serial number facing away from the ribs. Implanting the pulse generator subpectorally with the serial number facing the ribs may cause repetitive mechanical stress to a specific area of the titanium case, potentially leading to a component failure and device malfunction.

Precautions

For information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization, storage and handling; implant and device programming; follow-up testing; explant and disposal; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments. Advise patients to avoid sources of electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Potential Adverse Events

Potential adverse events from implantation of the CRT-D system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.

(Rev. N) CRV-14001-AA-Jul2011

Brief Summary

ICD Systems from Boston Scientific CRM

- ICD Indications and Usage

- ICDs are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. ICDs with atrial therapies are also intended to provide atrial antitachycardia pacing and atrial defibrillation treatment in patients who have or are at risk of developing atrial tachyarrhythmias.

- Contraindications

- Use of ICD systems are contraindicated in: Patients whose ventricular tachyarrhythmias may have reversible cause, such as 1) digitalis intoxication, 2) electrolyte imbalance, 3) hypoxia, or 4) sepsis, or whose ventricular tachyarrhythmias have a transient cause, such as 1) acute myocardial infarction, 2) electrocution, or 3) drowning. Patients who have a unipolar pacemaker.

- Warnings

- Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the ICD system. Such damage can result in patient injury or death. Program the pulse generator ventricular Tachy Mode to Off during implant, explant or post-mortem procedures to avoid inadvertent high voltage shocks. Always have sterile external and internal defibrillator protection available during implant. If not terminated in a timely fashion, an induced tachyarrhythmia can result in the patient's death. Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing should the patient require external rescue. Patients should seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient. Do not subject a patient with an implanted pulse generator to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents. Do not use atrial tracking modes (or an AVT device) in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in VT or VF. (Applies to dual-chamber devices only.) Do not use this pulse generator with another pulse generator. This combination could cause pulse generator interaction resulting in patient injury or lack of therapy delivery. Do not kink leads. Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture. For specific models, when using a subpectoral implantation, place the pulse generator with the serial number facing away from the ribs. Implanting the pulse generator subpectorally with the serial number facing the ribs may cause repetitive mechanical stress to a specific area of the titanium case, potentially leading to a component failure and device malfunction.

- Precautions

- For information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization, storage and handling; implantation and device programming; follow-up testing; explant and disposal; environmental and medical therapy hazards; home and occupational environments. Advise patients to avoid sources of electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

- Potential Adverse Events

- Potential adverse events from implantation of the ICD system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, psychologic intolerance to an ICD system - patients susceptible to frequent shocks despite antiarrhythmic medical management/imagined shocking, and component failure. In rare cases severe complications or device failures can occur.

- Refer to the product labeling for specific indications, contraindications, warnings/ precautions and adverse events. Rx only.

- (Rev. M)

Brief Summary

LATITUDE Patient Management System

- LATITUDE® Patient Management System from Boston Scientific CRM

- Intended Use

- The LATITUDE Patient Management system is intended for use to remotely communicate with a compatible pulse generator from Boston Scientific CRM and transfer data to a central database.

- Contraindications

- The LATITUDE system is contraindicated for use with any pulse generator other than a compatible pulse generator from Boston Scientific CRM. Not all Guidant or Boston Scientific pulse generators are compatible with the LATITUDE system. For contraindications for use related to the Guidant or Boston Scientific pulse generator, refer to the System Guide for the pulse generator being interrogated.

- Precautions

- The LATITUDE system is designed to notify clinicians within 24 hours if new pulse generator alert conditions are detected by the Communicator. Alert notifications are based on clinician configured alert settings. Pulse generator data will typically be available for review on the LATITUDE system within 15 minutes of a successful interrogation. However, data availability and alert notification can take up to 24 hours or the next business day. Note that data will not be available and alert notification cannot occur if:
 - The Communicator is unplugged or is not able to connect to the LATITUDE system through an active phone line.
 - The pulse generator and the Communicator cannot establish and complete a telemetry session. This session must be initiated by the patient if he or she has a pulse generator that uses inductive telemetry.
 - The Communicator becomes damaged or it malfunctions.
 - The patient is not compliant with prescribed use or is not using the LATITUDE system as described in the patient manual.
- Up to two weeks may elapse before LATITUDE first detects the conditions mentioned above and additional time may be required for clinic notification and resolution of the condition. During this time, no new patient data, device data, or alert notifications since the last successful data transmission will be available.
- Alert notifications are not intended to be used as the sole basis for making decisions about patient medical care. Alerts can be verified by reviewing supporting diagnostic information stored in the implanted device and viewing information on the LATITUDE clinician website.

- Adverse Effects

- None known.

- *Refer to the product labeling for specific instructions for use. Rx only.*

- *(Rev. J)*

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