

Diagnostic Value of the ICD Atrial Lead in Accurate Discrimination of Supraventricular from Ventricular Arrhythmias

The ALTITUDE EGM Study

Brian D. Powell, MD, Yong-Mei Cha, MD, Paul W. Jones, MS, Milan Seth, MS, David A. Cesario, MD, PhD, Michael Cao, MD, Camille G. Frazier-Mills, MD, Soraya M. Samii, MD, Samuel J. Asirvatham, MD, F. R. Gilliam, III, MD and Leslie A. Saxon, MD

Mayo Clinic, Rochester, MN, Univ Southern California, Boston Scientific, Duke Univ, Pennsylvania State Univ, Cardiology Associates NE Arkansas

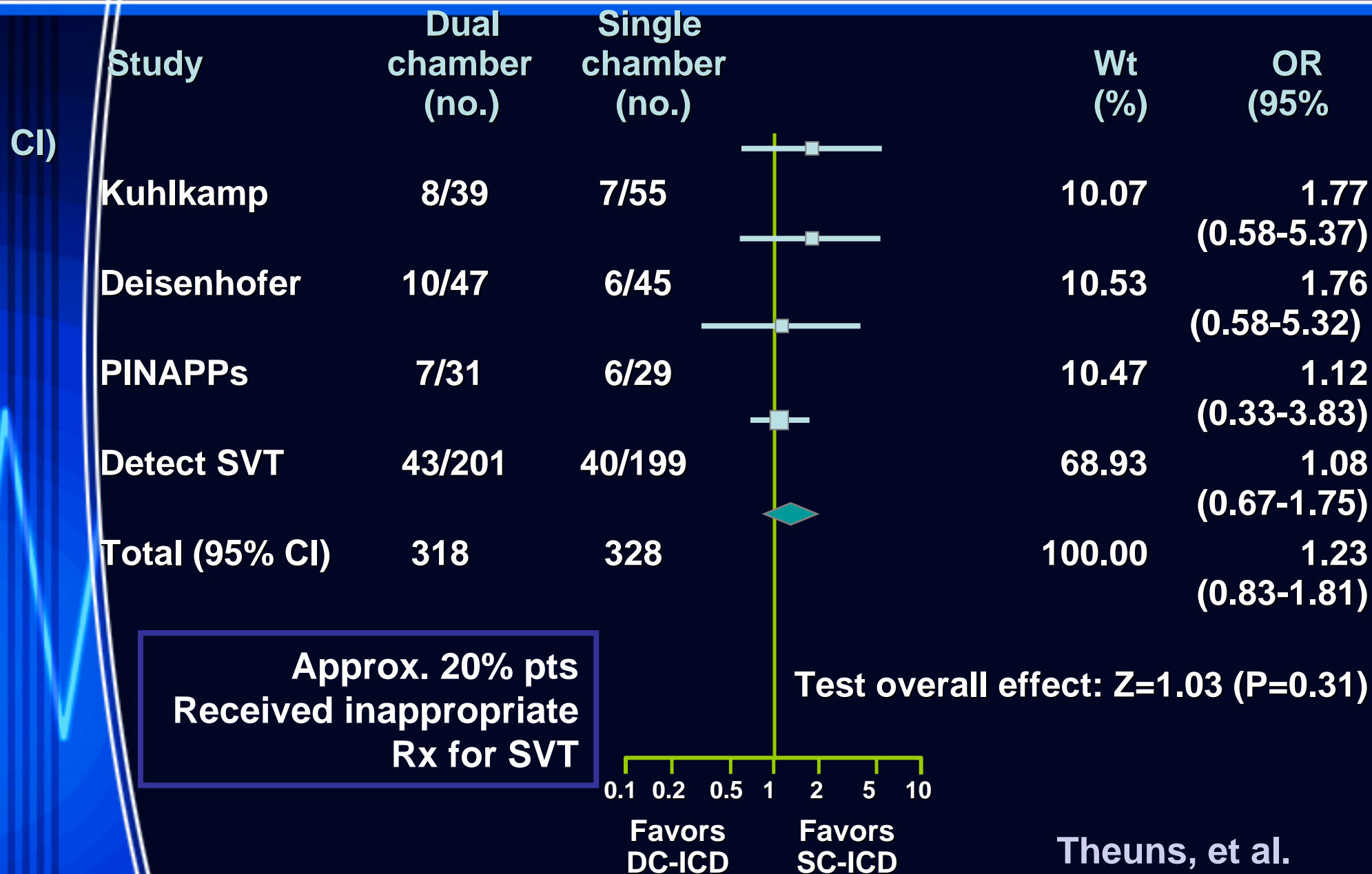
The content in this presentation was published in the Journal of Cardiovascular Electrophysiology online on May 20th, 2011. This presentation is for educational purposes only and should not be copied or presented without the permission of Boston Scientific. Like any other service, in spite of our best efforts the information in this presentation may become out of date over time. Nothing on this presentation should be construed as the giving of advice or the making of a recommendation and it should not be relied on as the basis for any decision or action. The materials on this Web Site are intended for educational purposes only. Boston Scientific accepts no liability for the accuracy or completeness or use of, nor any liability to update, the information contained on this Presentation. CRV-14001-AA-Jul2011

Background

- Interpretation of intracardiac electrogram (EGM) tracings from ICD devices may be limited in the absence of an atrial lead
- Most primary prevention ICD trials used single chamber ICDs
- Approximately 12-17% of ICD patients receive inappropriate shocks over 2-4 years

Discussion

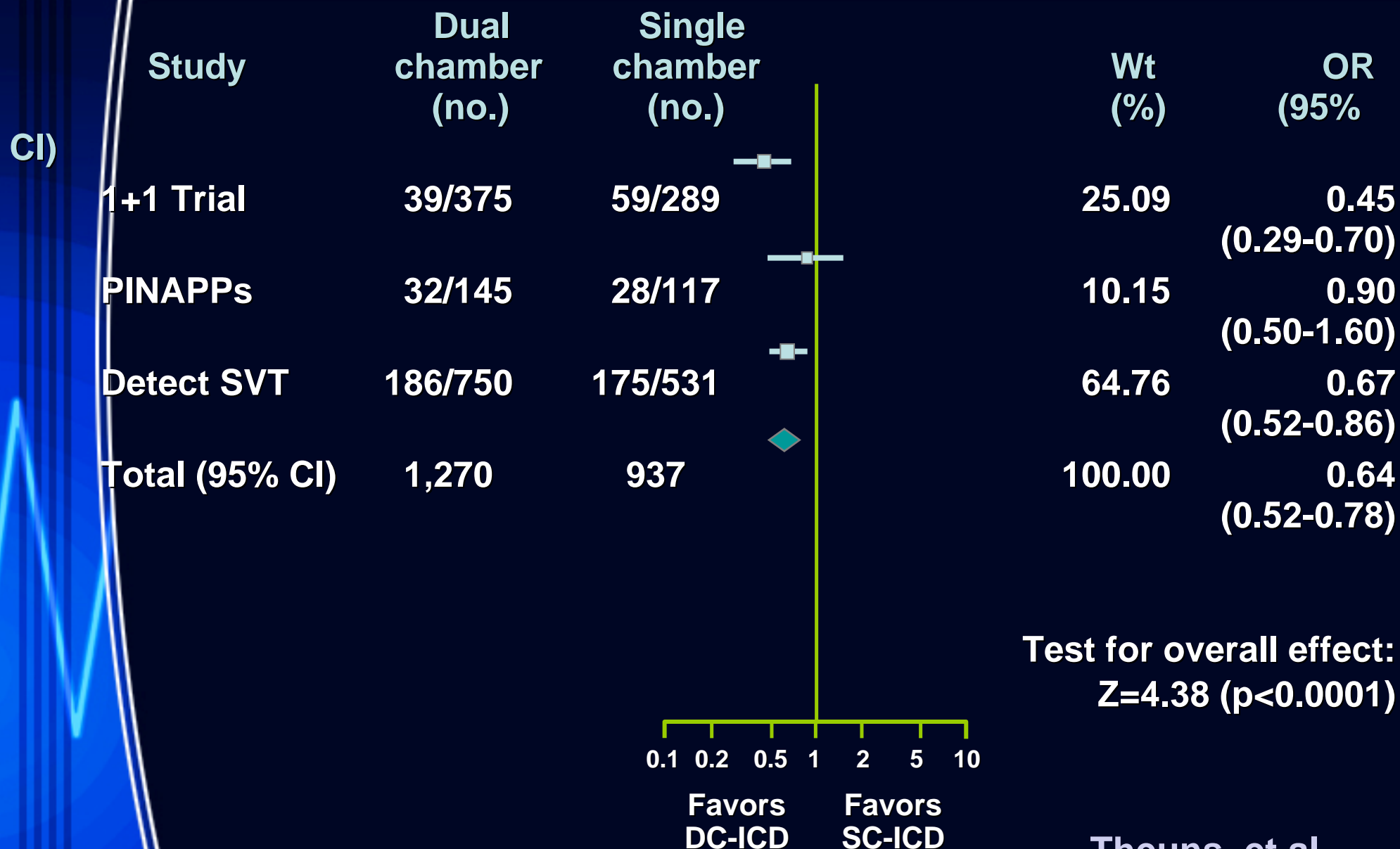
Patients Who Received Inappropriate Therapy



Theuns, et al.

Discussion

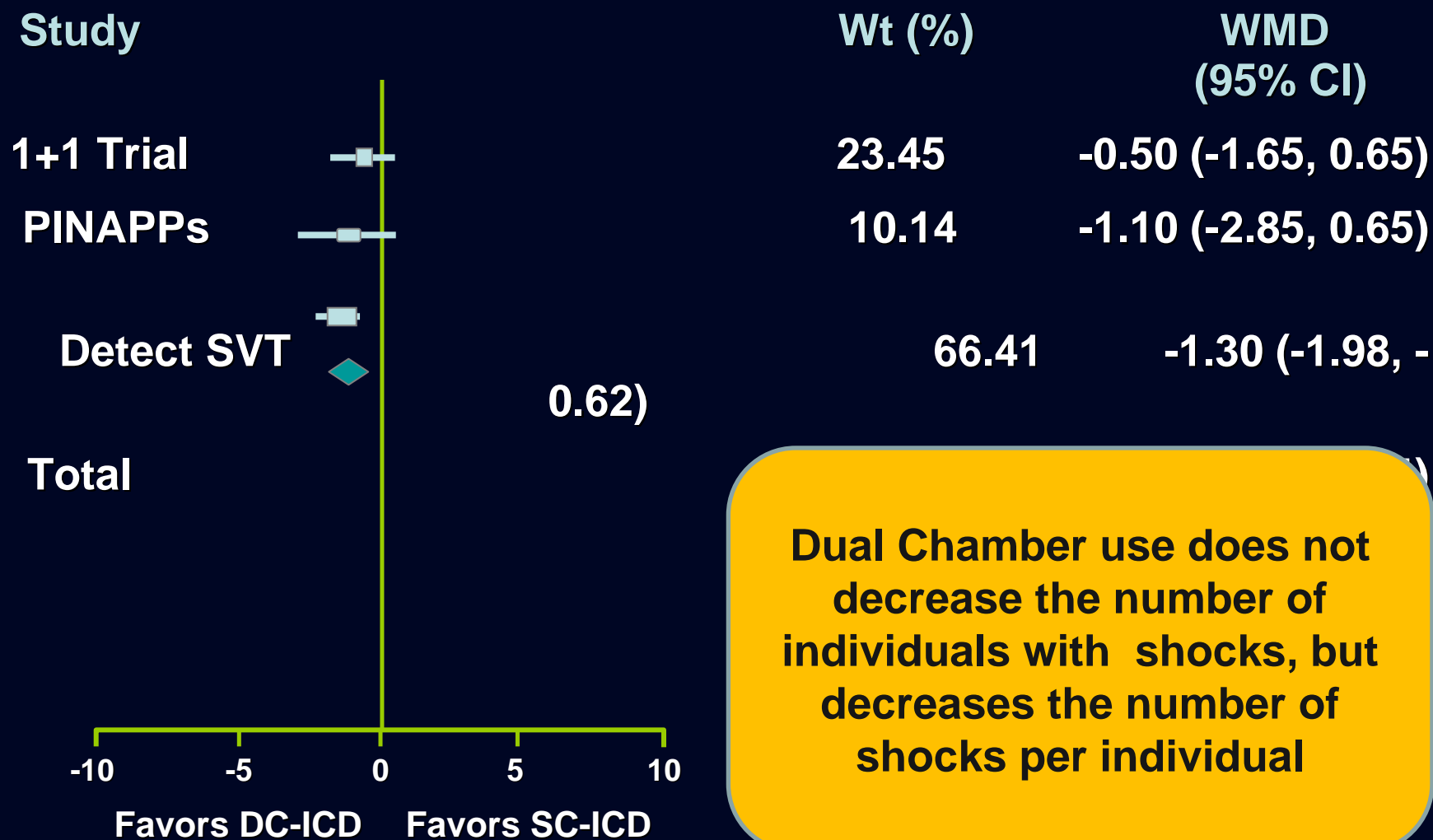
Number of Inappropriate Episodes



Theuns, et al.

Discussion

Number of Inappropriate Therapies per Patient



Dual Chamber use does not decrease the number of individuals with shocks, but decreases the number of shocks per individual

Objectives

- We sought to evaluate the diagnostic value of the atrial lead in correctly determining the type of arrhythmia leading to ICD shocks, when reviewed by physicians

Methods

- The ALTITUDE study group prospectively defined queries and study design to analyze ICD and CRT-D data transmitted through a remote monitoring system (LATITUDE[®], Boston Scientific)
- Sample of 132 shock episodes in dual chamber ICD's
- Each episode was adjudicated by 7 electrophysiologists

ALTITUDE Adjudication Committee

Leslie Saxon, MD, ALTITUDE Chair

- University of Southern California

Brian Powell, MD, EGM Panel Chair

- Mayo Clinic

Samuel Asirvatham, MD

- Mayo Clinic

Michael Cao, MD

- University of Southern California

David Cesario, MD

- University of Southern California

Yongmei Cha, MD

- Mayo Clinic

Camille Frazier-Mills, MD

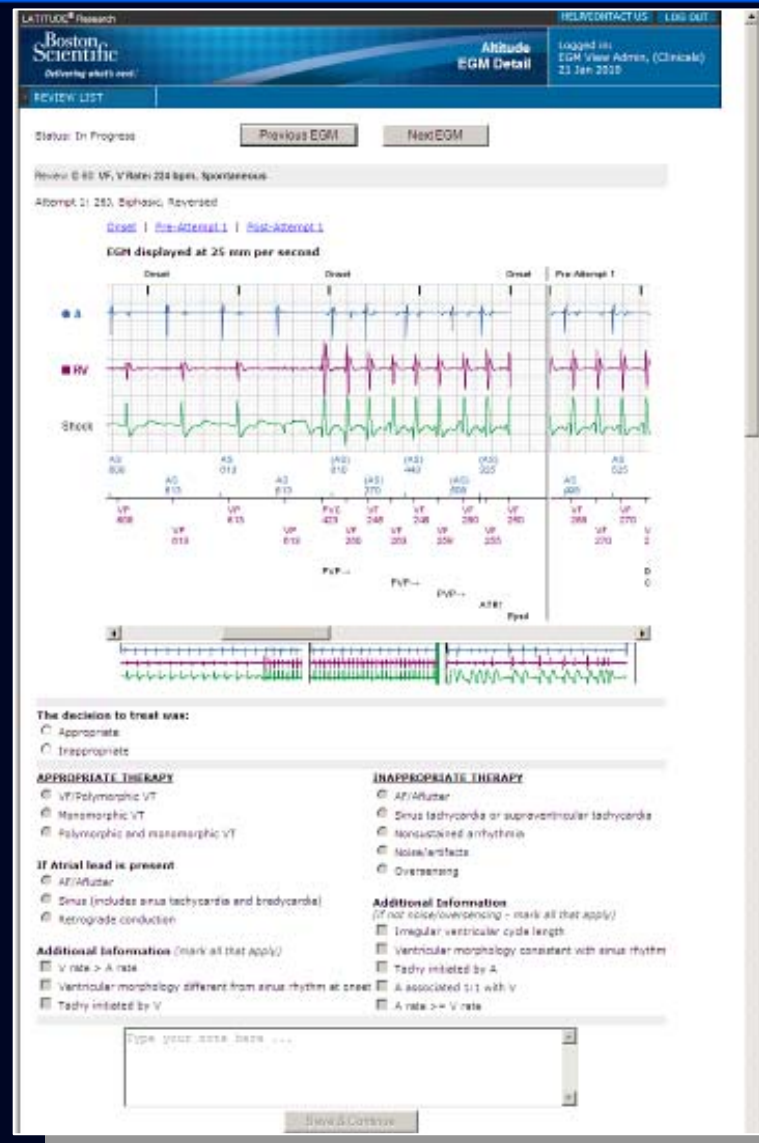
- Duke University

F. Roosevelt Gilliam, MD

- Cardiology Associates of NE Arkansas

Soraya Samii, MD

- Penn State



ALTITUDE Adjudication Committee

Leslie Saxon, MD, ALTITUDE Panel Chair

- University of Southern California

Brian Powell, MD, EGM Panel Chair



The decision to treat was:

- ☐ Appropriate
- ☐ Inappropriate

APPROPRIATE THERAPY

- ☐ VF/Polymorphic VT
- ☐ Monomorphic VT
- ☐ Polymorphic and monomorphic VT

INAPPROPRIATE THERAPY

- ☐ AF/Aflutter
- ☐ Sinus tachycardia or supraventricular tachycardia
- ☐ Nonsustained arrhythmia
- ☐ Noise/artifacts
- ☐ Oversensing

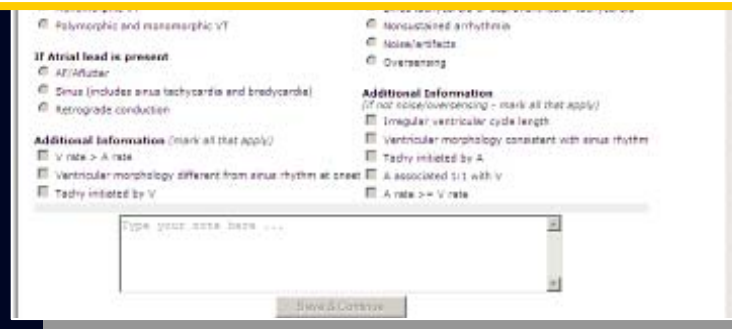
- Duke University

F. Roosevelt Gilliam, MD

- Cardiology Associates of NE Arkansas

Soraya Samii, MD

- Penn State



Methods

Implantable Cardioverter Defibrillator Electrogram Adjudication for Device Registries: Methodology and Observations from ALTITUDE

BRIAN D. POWELL, M.D.,* YONG-MEI CHA, M.D.,* SAMUEL J. ASIRVATHAM, M.D.,*
DAVID A. CESARIO, M.D.,† MICHAEL CAO, M.D.,† PAUL W. JONES, M.S.,‡
MILAN SETH, M.S.,§ LESLIE A. SAXON, M.D.,† and F. ROOSEVELT GILLIAM III, M.D.,§

Interobserver and intraobserver Kappa scores for dual-chamber ICDs were 0.84 (0.71–0.91) and 0.89 (0.82–0.95), consistent with substantial agreement. Interobserver and intraobserver Kappa scores for single-chamber ICDs were 0.61 (0.54–0.67) and 0.69 (0.59–0.79).

therapies. Adjudication of a large number of stored ICD electrograms (EGMs) presents a unique challenge. The ALTITUDE study group was designed to use the LATITUDE remote monitoring system to evaluate ICD patient outcomes across the United States.

Methods and Results: *Of 81,081 patients on remote monitoring, a random sample of 2,000 patients having 5,279 shock episodes was selected. The ALTITUDE EGM review committee was comprised of seven electrophysiologists from four institutions. An online EGM adjudication system was designed. Episodes were classified as appropriate (70% of shock episodes) or inappropriate ICD therapies (30%). Light's Kappa was used to assess agreement.*

Interobserver and intraobserver Kappa scores for dual-chamber ICDs were 0.84 (0.71–0.91) and 0.89 (0.82–0.95), consistent with substantial agreement. Interobserver and intraobserver Kappa scores for single-chamber ICDs were 0.61 (0.54–0.67) and 0.69 (0.59–0.79). The rhythm categories of “nonsustained arrhythmia” and “polymorphic and monomorphic ventricular tachycardia” resulted in the greatest degree of discordant adjudication between reviewers.

Conclusions: *This method of adjudication of a large volume of stored EGM data prior to device therapies will allow new observations in regards to device performance and has the potential to improve device programming and design. There was substantial interreviewer agreement for rhythm classification. Agreement was greater for dual-chamber compared to single-chamber devices, indicating the atrial lead adds diagnostic value in rhythm interpretation. (PACE 2011; 1–10)*

Methods

- Reference Rhythm Pre-shock (“Gold Standard”)
 - Majority consensus of rhythm classification by 7 electrophysiologists
- Subsequently, 6 electrophysiologists adjudicated the same episodes with blinding of the atrial EGM tracings and markers

Methods

- Half of episodes were randomly blinded for atrial EGM data for the first 3 reviewers, and alternate blinding was applied for the same episodes for the other 3 reviewers.

Review Group	Group A			Group B		
Reviewer	1	2	3	4	5	6
Episode 1	Un-blinded			Blinded		
Episode 2	Blinded			Un-blinded		
Episode 3	Blinded			Un-blinded		
...						
Episode 132	Un-blinded			Blinded		

Methods

- General Estimating Equations models were used to assess the impact of blinding on the likelihood of correct adjudication

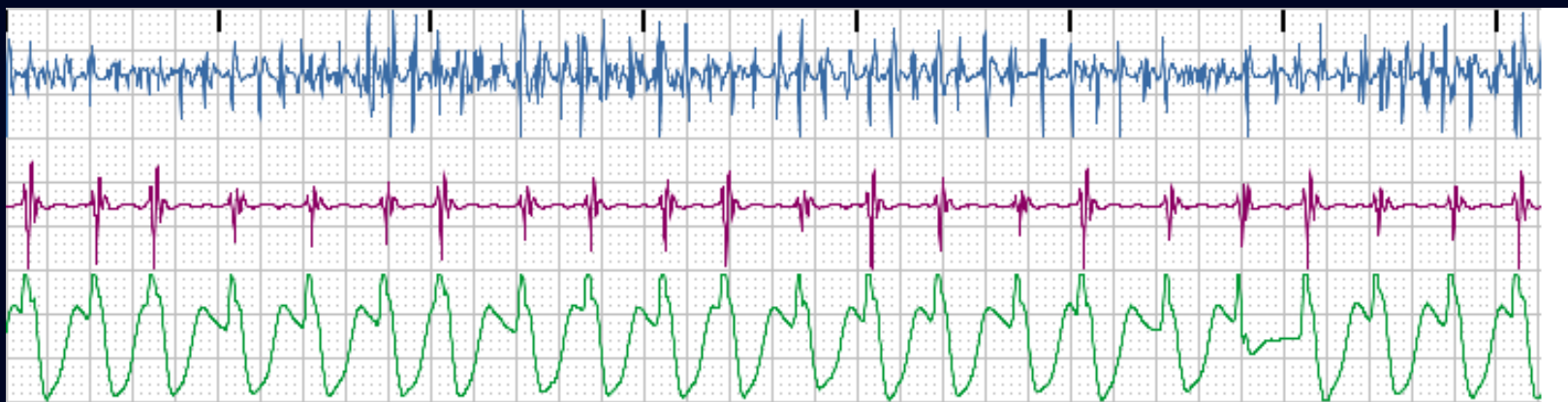
Example

Blinded and Un-blinded EGM Review

Atrial Lead EGM Blinded



Atrial Lead EGM Un-blinded



Results

Number of Episodes by Reference Category

Reference Category	Episodes	Percent of Total
Monomorphic VT	60	45.5%
AF/Aflutter	24	18.2%
VF/PMVT	20	15.2%
Supraventricular (SVT)	19	14.4%
PMVT and SMVT	5	3.8%
Noise/Oversensing	4	3.0%
Total	132	

Results

Ventricular Rhythms Classification

- Ventricular rhythms incorrectly classified as AF/SVT by atrial blinding

Rhythm	Number of total reviews	Percent Classified as AF/SVT		p-value
		Blinded	Un-blinded	
VT/VF	510	6.3%	5.1%	p=0.57

Results

Atrial Rhythms Classification

- Atrial rhythms incorrectly classified as VT/VF by atrial blinding

Reference Category	Number of total reviews	Percent Classified as VT/VF		p-value
		Blinded	Un-blinded	
AF/AFlutter	144	22.2%	5.6%	p=0.01
SVT	114	45.6%	10.5%	p<0.001
Total	228	29.8%	7.1%	p<0.001

- SVT was more likely than AF/AFlutter to be called a ventricular rhythm incorrectly (OR: 1.29, p=0.001) and more likely than AF/AFlutter to be negatively impacted by blinding (p=0.02)

Results

Consensus Appropriate / Inappropriate

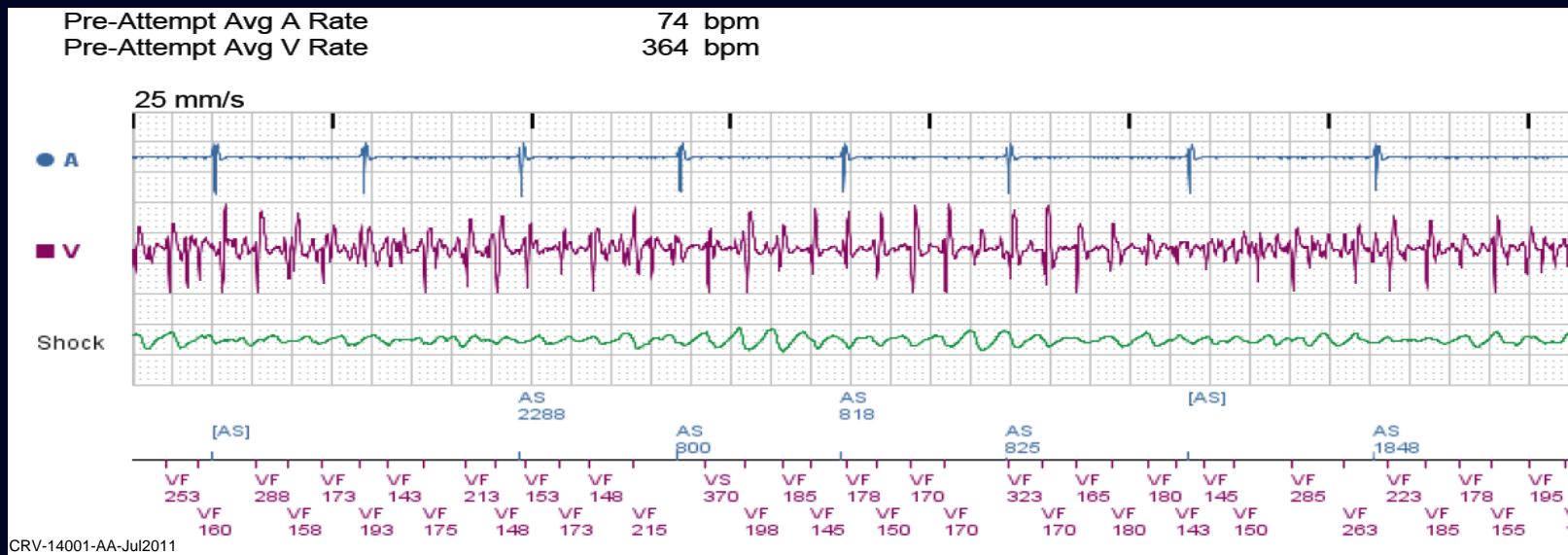
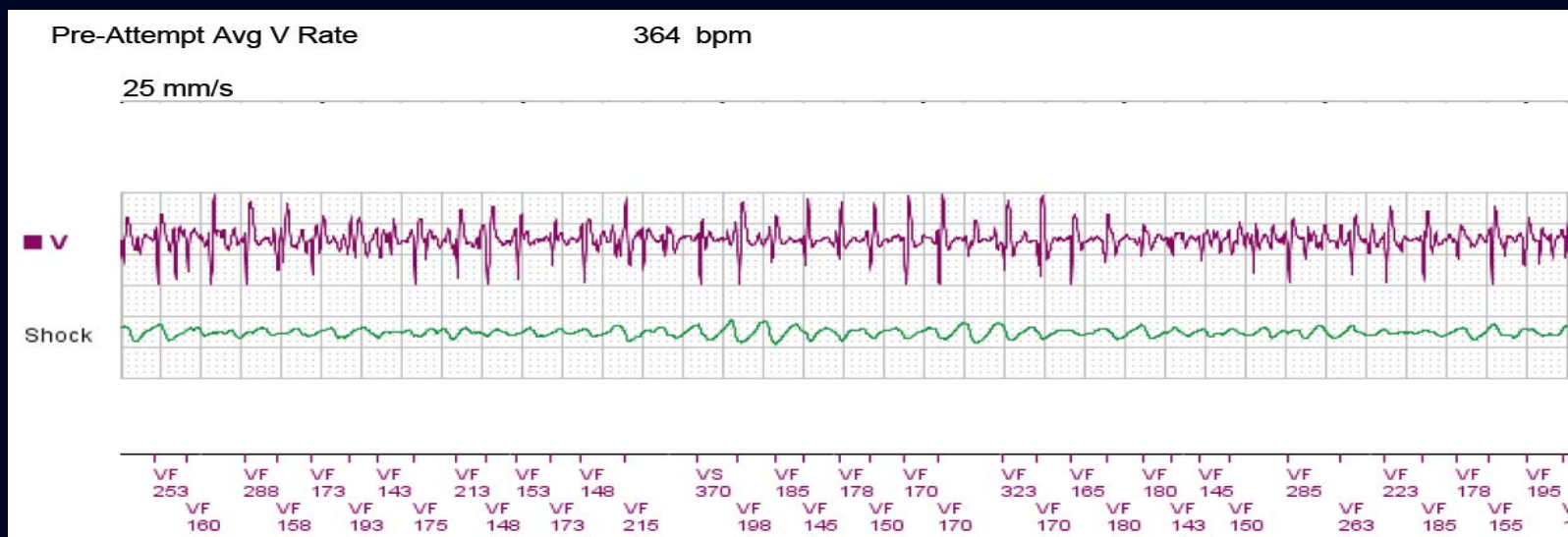
	VT/VF Rhythms (n=85) Percent Correct		Non VT/VF Rhythms (n=47) Percent Correct	
Reviewer	Blinded	Un-blinded	Blinded	Un-blinded
1	93%	97%	91%	100%
2	93%	95%	61%	92%
3	95%	86%	54%	96%
4	95%	86%	67%	87%
5	98%	100%	79%	91%
6	95%	98%	70%	92%
p-value	p = 0.57		p < 0.001	
Consensus	96%	93%	74%	94%
p-value	p = 0.174		p = 0.007	

Limitations

- Adjudication was performed by Electrophysiologists
 - An standardized automated algorithm may have resulted in different findings
- Sinus rhythm morphology reference was not used
- Patients were not included if their dual chamber ICD successfully discriminated an SVT, avoiding a shock
 - This sample may have more complex supraventricular arrhythmias for classification

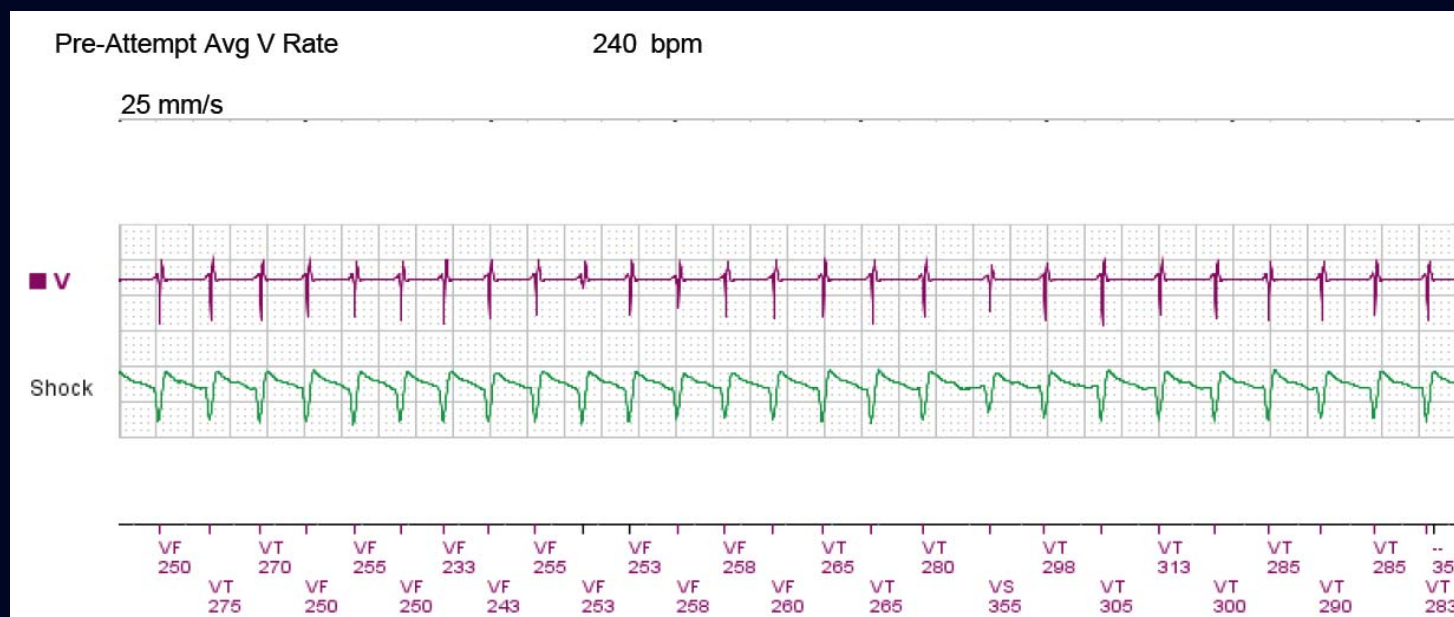
Discussion

Why VT/VF was correctly adjudicated regardless of atrial lead data

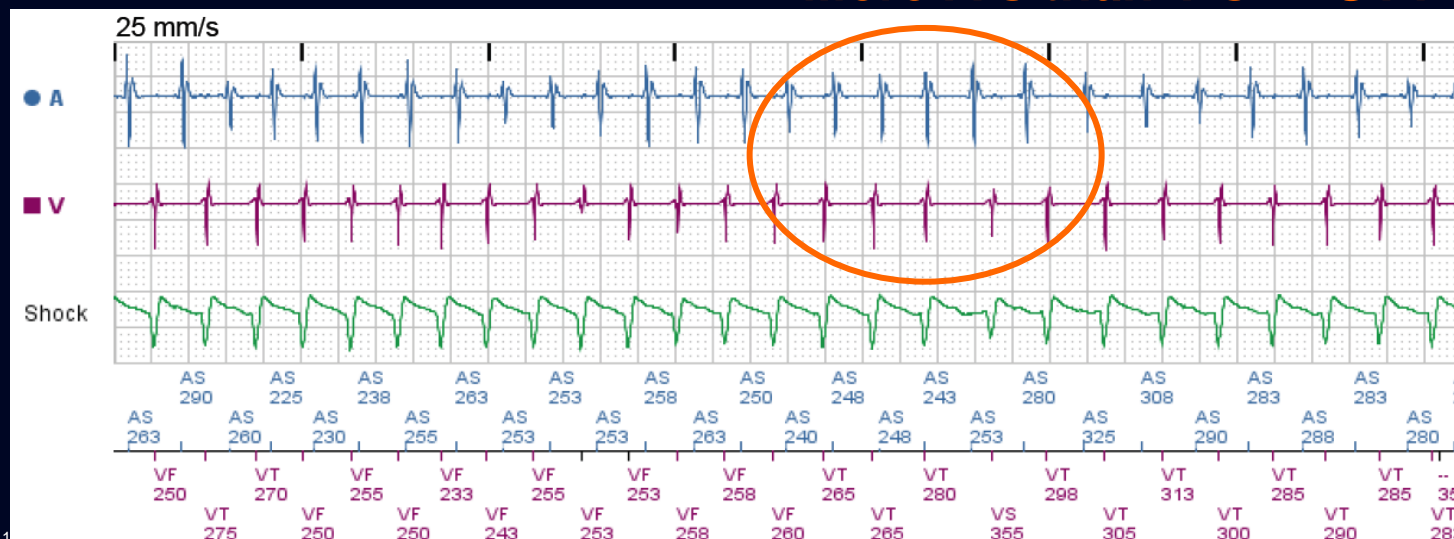


Discussion

Example of Blinded and Un-blinded EGM Review



More A's than V's SVT

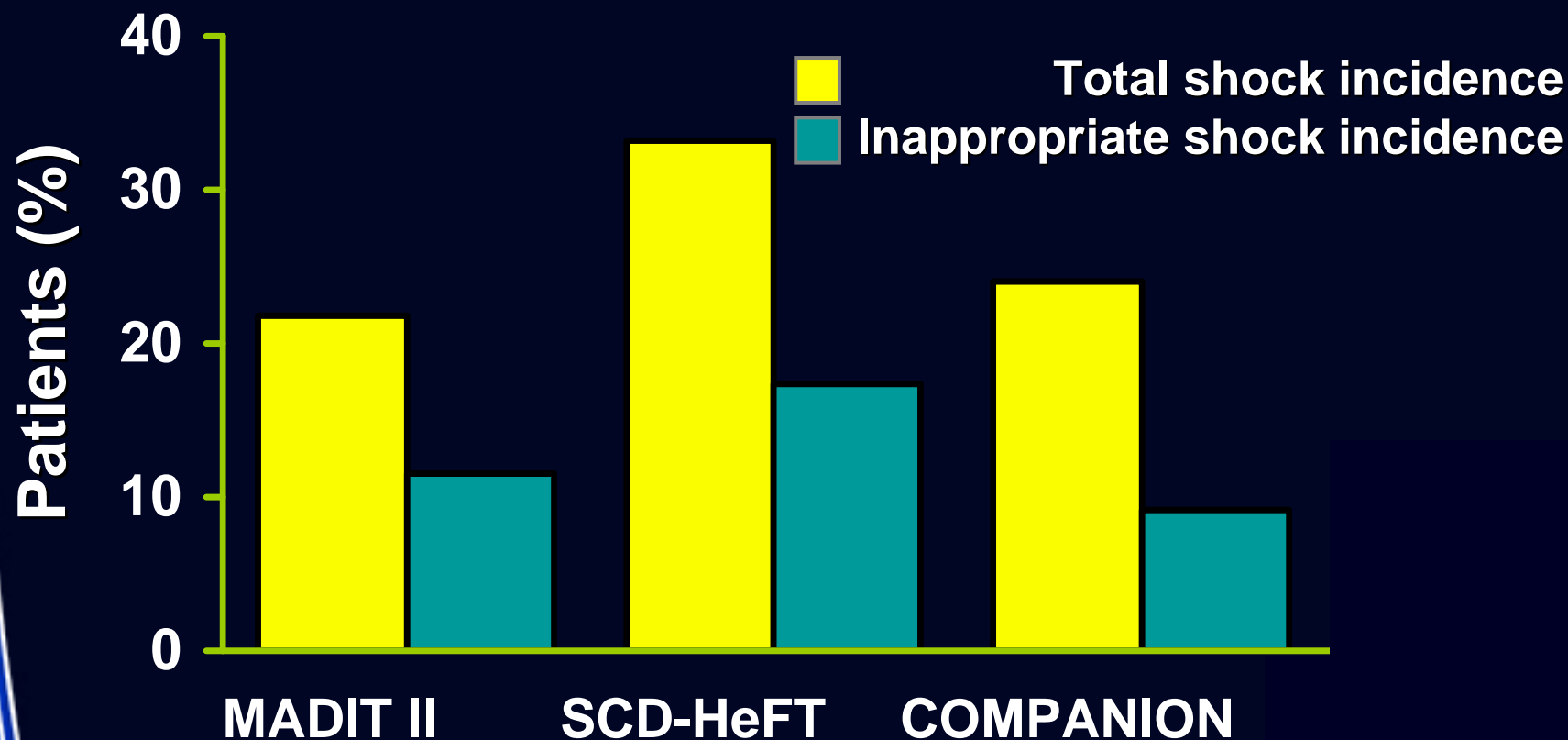


Discussion

- **Potential added value of atrial lead EGM data for SVT discrimination**
 - **Without atrial channel data, EP's tended to interpret 22-45% of AF and SVT episodes as VT**
 - **Potential for overestimating the number of appropriate shocks in single chamber ICD clinical trials**

Background

- Incidence of ICD and CRT-D shocks in primary prevention trials
 - Up to 17% patients receive inappropriate shocks over 2-4 years



¹Daubert JP et al: 51:1357, ²Bardy GH et al: NEJM 352(3):225, 2005;

³Saxon et al: Circ 114:2766, 2006; *Data are for 1st shock only

Discussion

■ Clinical implications

- This could result in a tendency toward under-diagnosis of AF in patients with single chamber ICD's
- This could potentially result in a tendency toward device overtreatment of SVT/AF in single chamber ICD's and inappropriate shocks

Conclusions

- Absence of atrial electrogram information is associated with an increased number of incorrect adjudications of inappropriate ICD shocks as appropriate therapy
- Atrial electrogram data improved the accuracy of rhythm classification by 22% for supraventricular rhythms with no difference for ventricular rhythms
- This finding suggests that adjudication of EGMs from single chamber ICDs may introduce a bias towards overstating the occurrence of appropriate therapies
- Potential for improvement in ICD discrimination by the presence of an atrial lead

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 ≥ 120 ms
- Left bundle branch block (LBBB) with QRS ≥ 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)

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)*