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Ampere Hour (Ah) as a Predictor of CRT ICD Pulse Generator Battery Longevity: A Multi-Center Study

A poster presented at Heart Failure Society of America's (HFSA) 2014 Annual Meeting comparing contemporary CRT-D longevity

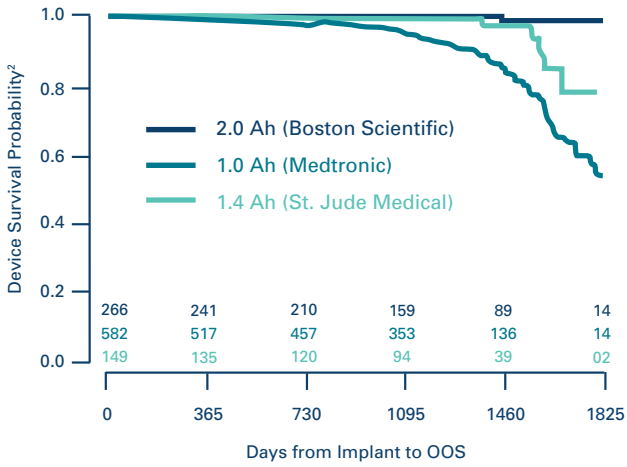
DESCRIPTION

Ampere hour (Ah) as a Predictor of CRT ICD Pulse Generator Battery Longevity is a multi-center, retrospective observational study that analyzed the relationship between the residual PG battery capacity (Ampere hour or Ah) in contemporary cardiac resynchronization therapy defibrillators (CRT-Ds) and device longevity in all patients implanted with CRT-ICDs from August 1, 2008, to December 31, 2010, at Vanderbilt University, Eastside Cardiovascular Medicine, University of Michigan, Thomas Jefferson University, Robert Wood Johnson University Hospital, Cooper Health System, and North Ohio Research.[1]

IMPORTANT OUTCOMES

- Ampere hour (Ah) is a useful predictor of survival to ERI for modern CRT-D generators
- CRT-D replacement (ERI) occurred in 12.4% of 1 Ah systems (72/582), versus 4.05 in 1.4 Ah (6/149) and 0.45 in 2 Ah devices (1/266) over mean follow-up of 3.1 years
- Patients with 1 Ah CRT-D had lower AF burden (32.9% vs 46.1% (2 Ah), and 53.4% (1.4 Ah), *P*=0.0006). 1 Ah devices were more likely to have >75% atrial pacing (20.4%, vs 8.6% (2 Ah), 16.7% (1.4 Ah), *P*=0.005)

Life of Device Service (Device Survival Function for ERI)



Data collected from 710 patients showed that battery capacity (Ah) is a useful predictor of device longevity and Boston Scientific devices, with a battery capacity of 2.0 Ah, last significantly longer than Medtronic or St. Jude Medical devices.[1]

Log-rank *P*-values (Comparing Survival Curves)

Any Difference *<0.001* 2.0 Ah vs 1.4 Ah *0.0013* 1.0 Ah vs 1.4 Ah *0.0036*

Get the facts and cut the risk.

Boston Scientific offers ICDs and CRT-Ds designed to be the world's longest lasting — with up to 80% more battery capacity than other available models.[3] Better CRT-D longevity could mean a reduced risk of exposure to complications and infections for your patients.[4,5,6]

For more information, visit **www.devicelongevity.com.**

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PATIENT COHORT

710 patients from multiple sites (Vanderbilt University, Eastside Cardiovascular Medicine, University of Michigan, Thomas Jefferson University, Robert Wood Johnson University Hospital, Cooper Health System, and North Ohio Research). Average age at implant: 67.1 ± 11.8 years. Mean LVEF: 25.3 ± 12.8%. Mean QRS duration: 152.4 ± 25.0 ms. NYHA class III: 71.0%. Medtronic = 587 patients, St. Jude = 153 patients, Boston Scientific = 273 patients.

METHODS

- The multi-center retrospective study included all CRT-Ds implanted from August 1, 2008, to December 31, 2010, at the sites listed above
- Patients were followed over an average of 3.1 ± 1.3 years (582 1Ah Medtronic, 266 2Ah Boston Scientific, and 149 1.4Ah St. Jude Medical)
- Baseline demographics, device, and lead data were obtained from the electronic medical record
- Covariates that can affect time to battery depletion were included in a multivariate Cox proportional hazard model
- Analysis was performed between 1.0 Ah, 1.4 Ah, and 2.0 Ah devices as defined by manufacturer specifications
- Comparison was made between devices for the presence of atrial fibrillation high LV lead >3 ICD shocks in the lifetime of the device, and % atrial pacing by quartile

PRIMARY ENDPOINTS

PG survival was calculated from implant date to time of PG replacement, heart transplant, device infection, or patient death.

PRINCIPAL INVESTIGATOR

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1. Ellis C, Markus T, Dickerman D, Orton J, Hassan S, Good E, Okabe T, Greenspon A. Ampere Hour as a Predictor of CRT ICD Pulse Generator Longevity: A Multi-Center Study. Presented at HFSA 2014. http://www.onlinejcf.com/article/S1071-9164(14)00337-6/fulltext. Ampere Hour (Ah) as a Predictor of CRT ICD Pulse Generator Battery Longevity is a multi-center, retrospective observational study comparing battery longevity of contemporary cardiac resynchronization therapy defibrillators (CRT-Ds) of all patients implanted with CRT-ICDs from August 1, 2008, to December 31, 2010, at Vanderbilt University, Eastside Cardiovascular Medicine, University of Michigan, Thomas Jefferson University, Robert Wood Johnson University Hospital, Cooper Health System, and North Ohio Research.
2. PG survival was calculated from implant date to time of PG replacement, heart transplant, device infection, or patient death.
3. Boston Scientific PUNCTUA™ ICD, ENERGEN™ ICD, INCEPTA™ CRT-D Physician's Technical Manual. Page 40. Part Number: 358362-001 EN US 2012-05. Boston Scientific ICD batteries have 1.7 Ah. Boston Scientific PUNCTUA™ CRT-D, ENERGEN™ CRT-D, INCEPTA™ CRT-D Physician's Technical Manual. Page 41. Part Number: 358373-008 EN US 2012-05. Boston Scientific CRT-D batteries have 1.8 Ah. Medtronic Evera™ XT DR ICD DDBB2D1 Device Manual. Page 27. Part Number: M946305A001. Medtronic VIVA™ XT CRT-D DTBA2D4 Device Manual. Page 28. Part Number: M943142A001.
4. de Bie MK, et al. Cardiac Device Infections Are Associated with a Significant Mortality Risk. *Heart Rhythm* 2012; 9:494-498.
5. Pfenninger Khan D. The Advisory Board Company, Refocusing Technology Investments on Cost Effectiveness, Long-term Outcomes, Nov 2011. http://www.advisory.com/Research/Cardiovascular-Roundtable/Cardiovascular-Rounds/2011/11/Refocusing-technology-investments-on-cost-effectiveness-long-term-outcomes.
6. Ramachandra. Impact of ICD Battery Longevity on Need for Device Replacements. *PACE* 2010; 33:314–319.

CRT-D System from Boston Scientific — COGNIS™

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 ≤ 35% and QRS duration ≥ 120 ms
• Left bundle branch block (LBBB) with QRS ≥ 130 ms, EF ≤ 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. For single patient use only. Do not reuse, reprocess, or resterilize. Program the pulse generator Tachy Mode to Off during implant, explant or postmortem procedures. Always have sterile external and internal defibrillator protection available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing. 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 scanning. Do not subject a patient with an implanted pulse generator to diathermy. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. 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. Do not kink, twist or braid the lead with other leads. Do not use defibrillation patch leads with the CRT-D system. Do not use this pulse generator with another pulse generator. For Patient Triggered Monitor (PTM) feature, make sure the feature is enabled prior to sending the patient home with a magnet. Once the PTM feature has been triggered and the magnet response programming is set to inhibit therapy, the patient should not reapply the magnet.

Precautions
For specific 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. S)

CRT-D Systems from Boston Scientific – PUNCTUA™, ENERGEN™, and INCEPTA™

Indications and Usage
The PUNCTUA™, ENERGEN™, and INCEPTA™ 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 ≤ 35% and QRS duration ≥ 120 ms
- Left bundle branch block (LBBB) with QRS ≥ 130 ms, EF ≤ 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. For single patient use only. Do not reuse, reprocess, or resterilize. Program the pulse generator Tachy Mode to Off during implant, explant or postmortem procedures. Always have external defibrillator protection available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing. 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 scanning. Do not subject a patient with an implanted pulse generator to diathermy. Do not use atrial-tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. 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. Do not kink, twist or braid the lead with other leads. Do not use defibrillation patch leads with the CRT-D system. Do not use this pulse generator with another pulse generator. For Patient Triggered Monitor (PTM) feature, make sure the feature is enabled prior to sending the patient home with a magnet. Once the PTM feature has been triggered and the magnet response programming is set to inhibit therapy, the patient should not reapply the magnet. For DF4-LLHH or DF4-LLHO leads, use caution handling the lead terminal when the Connector Tool is not present on the lead and do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4-LLHH or DF4-LLHO lead terminal, other than the terminal pin even when the lead cap is in place.

Precautions
For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; follow-up testing; explant and disposal; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments; and supplemental precautionary information. 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. C)

ICD Systems from Boston Scientific – PUNCTUA™, ENERGEN™, and INCEPTA™

ICD Indications and Usage
PUNCTUA™, ENERGEN™, and INCEPTA™ ICDs are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

Contraindications
Use of these 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. For single patient use only. Do not reuse, reprocess, or resterilize. Program the pulse generator ventricular Tachy Mode to Off during implant, explant or post-mortem procedures. Always have external defibrillator protection available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing. 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 scanning. Do not subject a patient with an implanted pulse generator to diathermy. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use this pulse generator with another pulse generator. Do not kink, twist or braid lead with other leads. For Patient Triggered Monitor (PTM) feature, make sure the feature is enabled prior to sending the patient home with a magnet.Once the PTM feature has been triggered and the magnet response programming is set to inhibit therapy, the patient should not reapply the magnet. For DF4-LLHH or DF4-LLHO leads, use caution handling the lead terminal when the Connector Tool is not present on the lead and do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4-LLHH or DF4-LLHO lead terminal, other than the terminal pin even when the lead cap is in place.

Precautions
For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments follow-up testing; explant and disposal; supplemental precautionary information. Advise patients to avoid sources of electromagnetic interference (EMI).

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. C)

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