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Service Life of Implantable Cardioverter-Defibrillators for CRT: An Analysis of Determinants in Current Clinical Practice

An independent study comparing contemporary CRT-D longevity

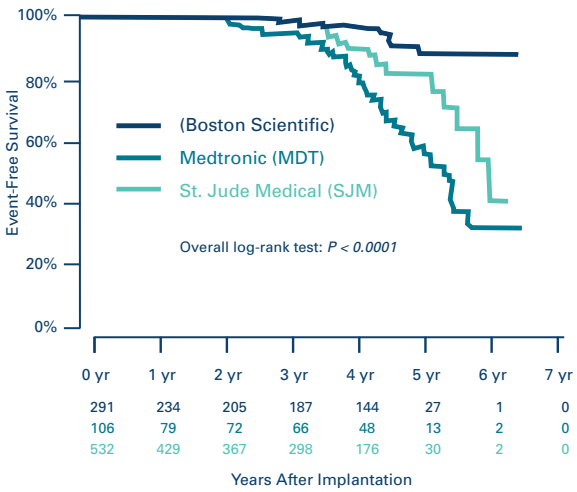
DESCRIPTION

Service Life of Implantable Cardioverter-Defibrillators for CRT: An Analysis of Determinants in Current Clinical Practice was an independent, retrospective observational study comparing battery longevity of cardiac resynchronization therapy defibrillators (CRT-Ds) of all patients implanted with CRT-ICDs from January 2008 to March 2010 at 9 Italian implanting centers. This study is unique in that it explored the comparison between generations of technology within each manufacturer as well.[1]

IMPORTANT OUTCOMES

- Battery depletion was independent of the % bi-v pacing and the burden of shocks
- LV lead output and Unipolar LV leads were associated with early battery depletion
- Modern-generation device, Li/MnO_2 or Li/CFX-SVO batteries, and Boston Scientific were deemed "protective factors" against early battery depletion

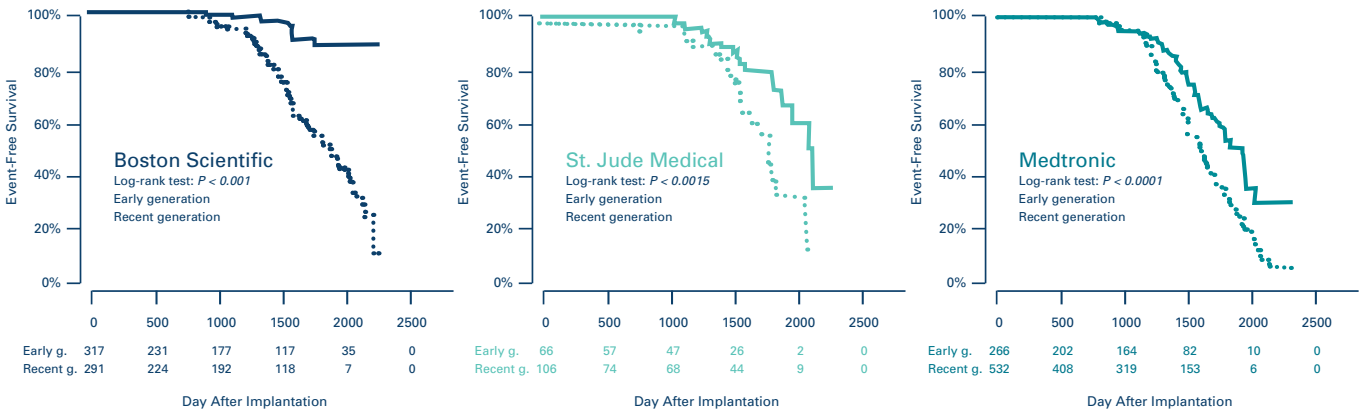
Life of Contemporary Device Service (Device Survival Function for ERI)



- Boston Scientific's modern CRT-Ds had the lowest risk of replacement at 5 years, with 88% CRT-D survival for Boston Scientific, 75% for St. Jude Medical and 52% for Medtronic

This study agreed with the results of studies from Drs. Saba[2], Johansen[3], Williams[4] and Ellis[5] – Boston Scientific CRT-Ds are lasting significantly longer than Medtronic CRT-Ds.

Life of Device Service by Generation (Device Survival Function for ERI)



- All manufacturers have markedly improved battery longevity when comparing devices CE marked before 2007 ("old generations") to those CE marked during or after 2007 ("modern generations")

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PATIENT COHORT

All patients implanted (N = 1726) with a CRT-D between January 2008 to March 2010 at 9 Italian implanting centers. Medtronic = 798 patients, St. Jude = 172 patients, Boston Scientific = 608 patients, Biotronik = 49, Sorin = 99.

METHODS

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.

PRIMARY ENDPOINTS

Device replacement for the battery reaching the elective replacement indicator (ERI).

PRINCIPAL INVESTIGATOR

Maurizio Landolina, M.D., Cardiology Department A.O. Ospedale Maggiore di Crema in Crema, Italy.

Get the facts and cut the risk.

ICDs and CRT-Ds with ENDURALIFE™ Battery technology are designed to be the world's longest lasting — with up to 80% more battery capacity than other available models.[6] Better defibrillator longevity could mean a reduced risk of exposure to complications and infections for your patients.[7, 8, 9]

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

1. Landolina M, Curnis A, Morani G, Vado A, Ammendola E, D'onofrio A, Stabile G, Crosato M, Petracci B, Ceriotti C, Bontempi L, Morosato M, Ballari GP, Gasparini M. Longevity of implant Cardioverter-defibrillators for cardiac resynchronization therapy in current clinical practice: an analysis according to influencing factors, device generation, and manufacturer. Europace (2015) doi: 10.1093/eurospace/euv109. First published online: May 14, 2015. Medtronic = 798 patients, Boston Scientific = 608 patients, St. Jude Medical = 172 patients, Biotronik = 49 patients, Sorin = 99. Five-year survival rate calculated using device replacements for battery depletion as indicated by ERI.
2. Alam MB, Munir MB, Rattan R, Flanigan S, Adelstein E, Jain S, Saba S. Battery longevity in cardiac resynchronization therapy implantable cardioverter defibrillators. Europace (2014) 16, 246-251. Kaplan Meier curves depicting survival of CRT devices free from battery depletion by device manufacturer. Battery Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators is an independent, single-center, retrospective observational study comparing battery longevity of contemporary cardiac resynchronization therapy defibrillators (CRT-Ds) of all patients implanted with CRT-ICDs from January 1, 2008 to December 31, 2010 at University of Pittsburgh Medical Center hospitals. The initial study population included 746 patients: 94 were excluded at the onset because they were lost to follow-up within a month of implant, 6 others were excluded because they had a Biotronik CRT-D and that number of devices precludes meaningful comparison. Medtronic = 416 patients, Boston Scientific = 173 patients, St. Jude = 57 patients. Survival rate calculated using device replacements for battery depletion as indicated by ERI.
3. J, Hjortshoj S, Johansen J, Jorgensen O, Nielsen J, Petersen H. Device Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators Differs Between Manufacturers: Data from the Danish ICD Registry. Presented at HRS 2014. http://ondemand.hrsonline.org/common/presentation-detail.aspx/15/35/1241/9000. Device Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators Differs Between Manufacturers was an independent, retrospective observational study comparing battery longevity of contemporary cardiac resynchronization therapy defibrillators (CRT-Ds) of all patients implanted with CRT-ICDs from January 1, 2007 to October 31, 2013 in Denmark. The initial study population included 2,793 patients: battery depletion or device failure was identified in 43 Medtronic, 4 Biotronik, 1 Boston Scientific and 33 St. Jude devices. Medtronic = 651 patients, Boston Scientific = 136 patients, St. Jude = 1,587 patients, Biotronik = 369. Time to exchange of the device because of battery depletion or device failure recorded in the Danish ICD Registry was the endpoint. Survival rate calculated using device replacements for battery depletion as indicated by ERI.
4. J. Williams, R. Stevenson. Contemporary Cardiac Resynchronization Implantable Cardioverter Defibrillator Battery Longevity in a Community Hospital Heart Failure Cohort. Presented at HFSA 2014. http://www.onlinejcf.com/article/S1071-9164(14)00389-3/fulltext Contemporary Cardiac Resynchronization Implantable Cardioverter Defibrillator Battery Longevity in a Community Hospital Heart Failure Cohort was an independent, retrospective observational study comparing battery longevity of contemporary cardiac resynchronization therapy defibrillators (CRT-Ds) of all patients implanted with CRT-ICDs from July 1, 2008, to October 31, 2010, at The Good Samaritan Hospital in Lebanon, PA. Medtronic = 28 patients, St. Jude = 10 patients, Boston Scientific = 53 patients.
5. C. Ellis, T. Markus, D. Dickerman, J. Orton, S. Hassan, E. Good, T. Okabe, A. Greenspon. 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. Medtronic = 587 patients, St. Jude = 153 patients, Boston Scientific = 273 patients. Survival rate calculated using device replacements for battery depletion as indicated by ERI.
6. Boston Scientific ICDs and CRT-Ds with EnduraLife Battery Technology have 1.8 Ah. Medtronic ICDs and CRT-Ds both have 1.0 Ah.
7. de Bie, MK. et al. Cardiac Device Infections are Associated with a Significant Mortality Risk. Heart Rhythm 2012; 9:494-498.
8. Pfenninger Khan D. The Advisory Board Company, Re-focusing 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.
9. 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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