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Battery Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators:

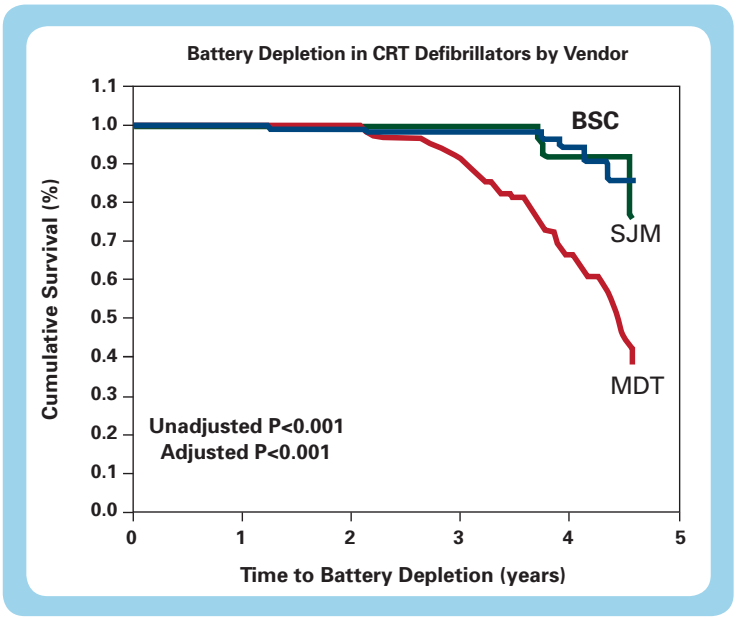
An independent study comparing contemporary CRT-D longevity

DESCRIPTION

Battery Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators is the first[1] independent, head-to-head retrospective study comparing battery longevity of contemporary cardiac resynchronization therapy defibrillators (CRT-Ds).[1] Medtronic = 416 patients, Boston Scientific = 173 patients, St. Jude = 57 patients.

IMPORTANT OUTCOMES

- During the average 2.7 year follow-up 25% of Medtronic devices reached ERI compared to 4% for BSC and 7% for St. Jude
- Additionally, the four-year battery survival rate[2] of Boston Scientific devices was 94%, compared to Medtronic's devices at 67% and St. Jude Medical's devices at 92%
- After accounting for variables such as programming and therapy, Medtronic had 6 times the risk of CRT-Ds reaching ERI over the course of the study



Real devices. *Real* settings. *Real* differences.

Boston Scientific offers CRT-Ds designed to be the world's longest lasting – with nearly double the battery capacity of other available CRT-D models. For more information, visit www.devicelongevity.com.

Boston Scientific. *www.devicelongevity.com.*

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INCLUSION CRITERIA

All patients (n=646) implanted with CRT-ICDs from January 1, 2008 to December 31, 2010 at University of Pittsburgh Medical Center hospitals were considered for the study. Ultimately the final study population consisted of the following manufacturers and their respective CRT-D patients:

- Medtronic had 416 patients
- Boston Scientific had 173 patients
- St. Jude had 57 patients

EXCLUSION CRITERIA

- Device companies with too small sample sizes that would preclude meaningful comparison
- Patients lost to follow-up within one month of implant

DESIGN

The analysis controlled for known parameters affecting battery drainage, including lead parameters and burden of pacing and tachyarrhythmia therapy.

PRIMARY ENDPOINTS

- Rate of battery depletion (reaching elective replacement indicator, or ERI)
- Time from device implantation to battery depletion

PRINCIPLE INVESTIGATOR

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[1] Alam M, Munir B, Rattan R, Flanigan S, Adelstein E, Jan S, Saba S. Battery Longevity in Cardiac Resynchronization Therapy Defibrillators. 2013; Europace (2013) doi: 10.1093/europace/eut301. First published online: October 6, 2013. 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.

[2] Survival rate calculated using device replacements for battery depletion as indicated by ERI.

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 atrialtracking 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. R)

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CRM-193506-AB MAY2016