Large Capacity LiMnO₂ Batteries Extended CRT-D Longevity in Clinical Use Compared to Smaller Capacity LiSVO Batteries Over 6 Years

An independent poster presented at Heart Rhythm Society’s (HRS) 2015 Annual Meeting comparing contemporary CRT-D longevity

DESCRIPTION

Large Capacity LiMnO₂ Batteries Extended CRT-D Longevity in Clinical Use Compared to Smaller Capacity LiSVO Batteries Over 6 Years 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 2008 through 2009 at Royal Victoria Hospital in Belfast, Northern Ireland.¹

IMPORTANT OUTCOMES

• High-capacity LiMnO₂-powered CRT-Ds outlasted smaller-capacity LiSVO-powered CRT-Ds in clinical use
  – 2 Ah LiMnO₂ battery CRT-Ds showed 100% survival after 6 years (Boston Scientific, Group 1)
  – 1.4 Ah LiSVO battery CRT-Ds began to reach ERI after 2.5 years
    - No devices remained in service by 7 years (Medtronic, Group 2)
  – 1.875 Ah LiSVO battery CRT-Ds began to reach ERI after 2.8 years
    - None were in service after 6 years (St. Jude Medical, Group 3)
• Both battery chemistry and capacity appear to effect device longevity
• With the same budget, 64% more patients can be treated using the longest lasting devices studied compared to the shortest
• Selecting longer-lasting devices reduces healthcare resource under-utilization through device decommissioning from patient death

Get the facts and cut the risk.

Boston Scientific 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.⁷ Better defibrillator longevity could mean a reduced risk of exposure to complications and infections for your patients.⁸, ⁹, ¹⁰

For more information, visit www.devicelongevity.com.
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**PATIENT COHORT**
All patients implanted (N=155) with a CRT-D at Royal Victorian Hospital in Belfast, Northern Ireland from 2008 through 2009. Medtronic = 62 patients, St. Jude = 66 patients, Boston Scientific = 27 patients.

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

**PRINCIPAL INVESTIGATOR**
Ernest Lau, M.D., Consultant Electrophysiologist at Royal Victoria Hospital, Belfast.
CRT-D Systems 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 post-mortem 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 dethrmy. Do not use atrial tracking modes in patients with chronic refractory atrial tachycardias. Do not use atrial only modes in patients with heart failure. LV lead distalization to a position near the antra 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.

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 access wire 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.

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; 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.

Precautions

Do not enter 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 dethrmy. Do not use atrial tracking modes in patients with chronic refractory atrial tachycardias. Do not use atrial only modes in patients with heart failure. LV lead distalization to a position near the antra 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.

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Rhythm Management

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Patients and Families: 1.886.484.3288

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