

Classification of Recommendations

- Class I** Conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.
- Class II** Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.
- Class IIa:** Weight of evidence/opinion is in favor of usefulness/efficacy.
- Class IIb:** Usefulness/efficacy is less well established by evidence/opinion.
- Class III** Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful.

Level of Evidence

- Level A** Data derived from multiple randomized clinical trials or meta-analyses.
- Level B** Data derived from a single randomized trial or nonrandomized studies.
- Level C** Only consensus opinion of experts, case studies, or standard-of-care.

References

- 1 Epstein AE, Dimarco JP, Ellenbogen KA, et al. ACC/AHA/HRS 2008 Guidelines for device-based therapy of cardiac rhythm abnormalities [corrections appear at <http://content.onlinejacc.org/cgi/content/full/jacc.2008.02.032/DC1>]. *J Am Coll Cardiol*. May 27, 2008;51(21):e1-62.
- 2 Fonarow GC, Yancy CW, Albert NM, et al. Heart failure care in the outpatient cardiology practice setting: findings from IMPROVE HF. *Circulation: Heart Failure*. 2008;1:98-106. Available at: circ.heartfailure.ahajournals.org. Accessed July 16, 2008.
- 3 Piccini JP, Hernandez AF, Dai D, et al. Use of cardiac resynchronization therapy in patients hospitalized with heart failure. *Circulation*. August 26, 2008;118(9):926-933.

Brief Statement: Medtronic ICDs and CRT-ICDs

Indications

Medtronic Implantable Cardioverter Defibrillators (ICDs) are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

Medtronic Cardiac Resynchronization Therapy (CRT) ICDs are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias and for the reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy and have a left ventricular ejection fraction less than or equal to 35% and a prolonged QRS duration.

Contraindications

Medtronic ICDs and CRT-ICDs are contraindicated in patients whose ventricular tachyarrhythmias may have transient or reversible causes, patients with incessant VT or VF, patients who have a unipolar pacemaker. Medtronic ICDs are also contraindicated for patients whose primary disorder is bradyarrhythmia.

Warnings and Precautions

Changes in a patient's disease and/or medications may alter the efficacy of the device's programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset, or device damage. Do not place transthoracic defibrillation paddles directly over the device. Additionally, for CRT-ICDs, certain programming and device operations may not provide cardiac resynchronization.

Potential Complications

Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate tachyarrhythmia episodes, acceleration of ventricular tachycardia, and surgical complications such as hematoma, infection, inflammation, and thrombosis.

See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1 (800) 328-2518 and/or consult Medtronic's website at www.medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

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2008 ACC/AHA/HRS Guidelines for Implantable Defibrillator and Cardiac Resynchronization Therapy for Cardiac Rhythm Abnormalities¹

Despite ICD and CRT being a Class I or IIa indication for treatment of patients, research confirms underutilization and variation of care in heart failure patients.^{2,3}

RECOMMENDATIONS FOR IMPLANTABLE CARDIOVERTER DEFIBRILLATORS

Class I Recommendations

ICD therapy is indicated in patients*:

Level of Evidence: A

- With LVEF \leq 35% due to prior MI who are at least 40 days post-MI and are in NYHA Functional Class II or III
- With LV dysfunction due to prior MI who are at least 40 days post-MI, have an LVEF \leq 30%, and are in NYHA Functional Class I
- Who are survivors of cardiac arrest due to VF or hemodynamically unstable sustained VT after evaluation to define the cause of the event and to exclude any completely reversible causes

Level of Evidence: B

- With nonischemic DCM who have an LVEF \leq 35% and who are in NYHA Functional Class II or III
- With nonsustained VT due to prior MI, LVEF $<$ 40%, and inducible VF or sustained VT at electrophysiological study
- With structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable
- With syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or VF induced at electrophysiological study

* Assuming patients are on chronic, optimal medical therapy and have a reasonable expectation of survival with good functional status for $>$ 1 year.

Class IIa Recommendations

ICD implantation is reasonable for patients*:

Level of Evidence: B

- To reduce SCD in patients with Long QT Syndrome who are experiencing syncope and/or VT while receiving beta blockers

Level of Evidence: C

- With unexplained syncope, significant LV dysfunction, and nonischemic DCM
- With sustained VT and normal or near-normal ventricular function
- With catecholaminergic polymorphic VT who have syncope and/or documented sustained VT while receiving beta blockers
- For the prevention of SCD in patients with ARVD/C who have one or more risk factors for SCD
- With HCM who have one or more major risk factors for SCD
- With Brugada syndrome who have had syncope or documented VT that has not resulted in cardiac arrest
- With cardiac sarcoidosis, giant cell myocarditis, or Chagas disease
- For nonhospitalized patients awaiting transplantation

* Assuming patients are on chronic, optimal medical therapy and have a reasonable expectation of survival with good functional status for $>$ 1 year.

RECOMMENDATIONS FOR CARDIAC RESYNCHRONIZATION THERAPY IN PATIENTS WITH SEVERE SYSTOLIC HEART FAILURE

Class I Recommendations

CRT with or without ICD therapy is indicated for the treatment of heart failure in patients with*:

- NYHA Functional Class III or ambulatory Class IV heart failure symptoms
- LVEF \leq 35%
- QRS duration \geq 120 ms
- Sinus rhythm
- Optimal recommended medical therapy
(Level of Evidence: A)

Class IIa Recommendations

CRT with or without an ICD is reasonable for treatment of heart failure in patients with*:

- NYHA Functional Class III or ambulatory Class IV heart failure symptoms
- LVEF \leq 35%
- QRS duration \geq 120 ms
- Atrial fibrillation
- Optimal recommended medical therapy
(Level of Evidence: B)

CRT with or without an ICD is reasonable for treatment of heart failure in patients with*:

- NYHA Functional Class III or ambulatory Class IV heart failure symptoms
- LVEF \leq 35%
- Frequent dependence on ventricular pacing
- Optimal recommended medical therapy
(Level of Evidence: C)

* Assuming patients are on chronic, optimal medical therapy and have a reasonable expectation of survival with good functional status for $>$ 1 year.