DBT Guideline Slide Set

2012 ACCF/AHA/HRS Focused Update Incorporated Into the 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities

Developed in Collaboration With the American Association for Thoracic Surgery, Heart Failure Society of America, and Society of Thoracic Surgeons

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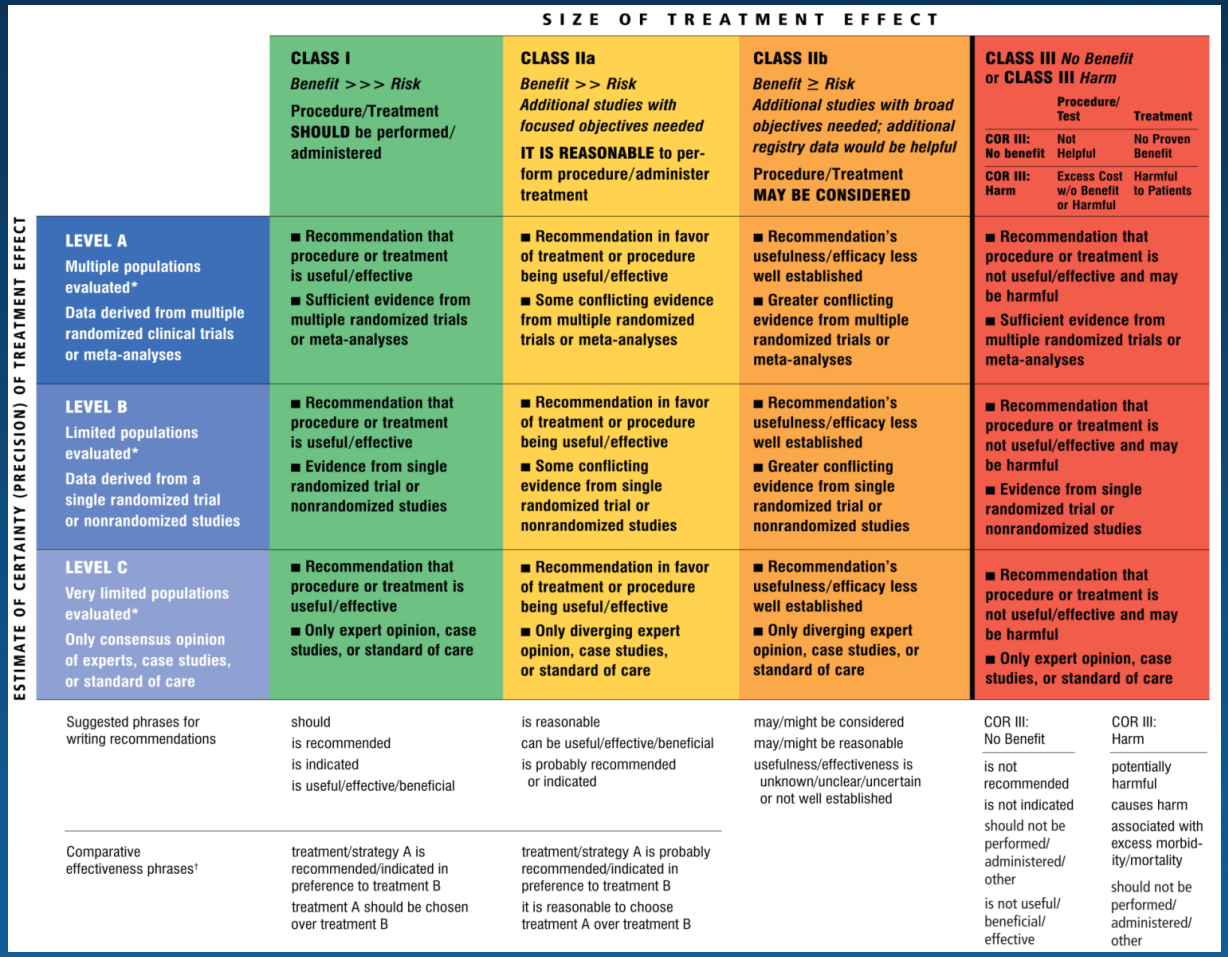
Applying Classification of Recommendations and Level of Evidence

Modified 2012

Note: The new and modified recommendations from the 2012 DBT Focused Update were graded based on the latest version of the COR/LOE table. All of the unmodified recommendations were graded on the previous COR/LOE table, listed below.



ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	SIZE OF TREATMENT EFFECT			
	CLASS I *Benefit >>> Risk* Procedure/Treatment **SHOULD** be performed/ administered	**CLASS IIa** *Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	**CLASS IIb** *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	**CLASS III** *No Benefit* or **CLASS III** *Harm* Procedure/ Test / Treatment COR III: No benefit — Not Helpful — No Proven Benefit COR III: Harm — Excess Cost w/o Benefit or Harmful — Harmful to Patients
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care
Suggested phrases for writing recommendations	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR III: No Benefit: is not recommended; is not indicated; should not be performed/ administered/ other; is not useful/ beneficial/ effective COR III: Harm: potentially harmful; causes harm; associated with excess morbidity/mortality; should not be performed/ administered/ other
Comparative effectiveness phrases†	treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B		

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

*Data available from clinical trials or registries about the usefulness/ efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

†For comparative effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

Applying Classification of Recommendations and Level of Evidence

Class I	Class IIa	Class IIb	Class III
Benefit >>> Risk Procedure/ Treatment **SHOULD** be performed/ administered	*Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	*Benefit ≥ Risk* *Additional studies with broad objectives needed; Additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	*Risk ≥ Benefit* *No additional studies needed* Procedure/Treatment should **NOT** be performed/administered **SINCE IT IS NOT HELPFUL AND MAY BE HARMFUL**

Alternative Phrasing:

should is recommended is indicated is useful/effective/ beneficial	is reasonable can be useful/effective/ beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown /unclear/uncertain or not well established	is not recommended is not indicated should not is not useful/effective/beneficial may be harmful

Applying Classification of Recommendations and Level of Evidence

Class I	Class IIa	Class IIb	Class III
Benefit >>> Risk Procedure/ Treatment **SHOULD** be performed/ administered	*Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	*Benefit ≥ Risk* *Additional studies with broad objectives needed; Additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	*Risk ≥ Benefit* *No additional studies needed* Procedure/Treatment should **NOT** be performed/administered **SINCE IT IS NOT HELPFUL AND MAY BE HARMFUL**

Level of Evidence:

Level A:	Data derived from multiple randomized clinical trials or meta-analyses Multiple populations evaluated;
Level B:	Data derived from a single randomized trial or nonrandomized studies Limited populations evaluated
Level C:	Only consensus of experts opinion, case studies, or standard of care Very limited populations evaluated

Implantable Cardioverter-Defibrillators

All primary sudden cardiac death (SCD) prevention implantable cardioverter-defibrillator (ICD) recommendations apply only to patients who are receiving optimal medical therapy and have reasonable expectation of survival with good functional capacity for more than 1 year.

Indications for Pacing

Permanent Pacing in Sinus Node Dysfunction

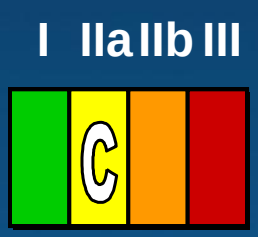
Permanent pacemaker implantation is indicated for sinus node dysfunction (SND) with documented symptomatic bradycardia, including frequent sinus pauses that produce symptoms.

Permanent pacemaker implantation is indicated for symptomatic chronotropic incompetence.

Permanent pacemaker implantation is indicated for symptomatic sinus bradycardia that results from required drug therapy for medical conditions.

Permanent Pacing in Sinus Node Dysfunction

Permanent pacemaker implantation is reasonable for SND with heart rate less than 40 bpm when a clear association between significant symptoms consistent with bradycardia and the actual presence of bradycardia has not been documented.



Permanent pacemaker implantation is reasonable for syncope of unexplained origin when clinically significant abnormalities of sinus node function are discovered or provoked in electrophysiological studies.

Permanent pacemaker implantation may be considered in minimally symptomatic patients with chronic heart rate less than 40 bpm while awake.

Permanent Pacing in Sinus Node Dysfunction

Permanent pacemaker implantation is not indicated for SND in asymptomatic patients.

Permanent pacemaker implantation is not indicated for SND in patients for whom the symptoms suggestive of bradycardia have been clearly documented to occur in the absence of bradycardia.

Permanent pacemaker implantation is not indicated for SND with symptomatic bradycardia due to nonessential drug therapy.

Acquired Atrioventricular Blocks in Adults

Permanent pacemaker implantation is indicated for third-degree and advanced second-degree atrioventricular (AV) block at any anatomic level associated with bradycardia with symptoms (including heart failure) or ventricular arrhythmias presumed to be due to AV block.

Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level associated with arrhythmias and other medical conditions that require drug therapy that results in symptomatic bradycardia.

Acquired Atrioventricular Blocks in Adults

Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level in awake, symptom-free patients in sinus rhythm, with documented periods of asystole greater than or equal to 3.0 seconds or any escape rate less than 40 bpm, or with an escape rhythm that is below the AV node.

Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level in awake, symptom-free patients with atrial fibrillation (AF) and bradycardia with 1 or more pauses of at least 5 seconds or longer.

Acquired Atrioventricular Blocks in Adults

Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level after catheter ablation of the AV junction.

Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level associated with postoperative AV block that is not expected to resolve after cardiac surgery.

Acquired Atrioventricular Blocks in Adults

Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level associated with neuromuscular diseases with AV block, such as myotonic muscular dystrophy, Kearns-Sayre syndrome, Erbs dystrophy (limb-girdle muscular dystrophy), and peroneal muscular atrophy, with or without symptoms.

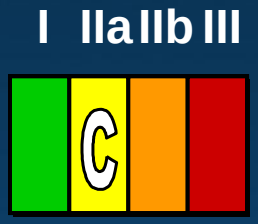
Permanent pacemaker implantation is indicated for second-degree AV block with associated symptomatic bradycardia regardless of type or site of block.

Acquired Atrioventricular Blocks in Adults

Permanent pacemaker implantation is indicated for asymptomatic persistent third-degree AV block at any anatomic site with average awake ventricular rates of 40 bpm or faster if cardiomegaly or left ventricular (LV) dysfunction is present or if the site of block is below the AV node.

Permanent pacemaker implantation is indicated for second- or third-degree AV block during exercise in the absence of myocardial ischemia.

Acquired Atrioventricular Blocks in Adults



Permanent pacemaker implantation is reasonable for persistent third-degree AV block with an escape rate greater than 40 bpm in asymptomatic adult patients without cardiomegaly.

Permanent pacemaker implantation is reasonable for asymptomatic second-degree AV block at intra- or infra-His levels found at electrophysiological study.

Permanent pacemaker implantation is reasonable for first- or second-degree AV block with symptoms similar to those of pacemaker syndrome or hemodynamic compromise.

Acquired Atrioventricular Blocks in Adults

Permanent pacemaker implantation is reasonable for asymptomatic type II second-degree AV block with a narrow QRS. When type II second-degree AV block occurs with a wide QRS, including isolated right bundle-branch block, pacing becomes a Class I recommendation. (See Section 2.1.3, “Chronic Bifascicular Block” of the full text guidelines.)

Acquired Atrioventricular Blocks in Adults

Permanent pacemaker implantation may be considered for neuromuscular diseases such as myotonic muscular dystrophy, Erb dystrophy (limb-girdle muscular dystrophy), and peroneal muscular atrophy with any degree of AV block (including first-degree AV block), with or without symptoms, because there may be unpredictable progression of AV conduction disease.

Permanent pacemaker implantation may be considered for AV block in the setting of drug use and/or drug toxicity when the block is expected to recur even after the drug is withdrawn.

Acquired Atrioventricular Blocks in Adults

Permanent pacemaker implantation is not indicated for asymptomatic first-degree AV block. (See Section 2.1.3, “Chronic Bifascicular Block” of the full-text guidelines.)

Permanent pacemaker implantation is not indicated for asymptomatic type I second-degree AV block at the supra-His (AV node) level or that which is not known to be intra- or infra-Hisian.

Permanent pacemaker implantation is not indicated for AV block that is expected to resolve and is unlikely to recur (e.g., drug toxicity, Lyme disease, or transient increases in vagal tone or during hypoxia in sleep apnea syndrome in the absence of symptoms).

Permanent Pacing in Chronic Bifascicular Block

Permanent pacemaker implantation is indicated for advanced second-degree AV block or intermittent third-degree AV block.

Permanent pacemaker implantation is indicated for type II second-degree AV block.

Permanent pacemaker implantation is indicated for alternating bundle-branch block.

Permanent Pacing in Chronic Bifascicular Block

Permanent pacemaker implantation is reasonable for syncope not demonstrated to be due to AV block when other likely causes have been excluded, specifically ventricular tachycardia (VT).

Permanent pacemaker implantation is reasonable for an incidental finding at electrophysiological study of a markedly prolonged HV interval (greater than or equal to 100 milliseconds) in asymptomatic patients.

Permanent pacemaker implantation is reasonable for an incidental finding at electrophysiological study of pacing-induced infra-His block that is not physiological.

Permanent Pacing in Chronic Bifascicular Block

Permanent pacemaker implantation may be considered in the setting of neuromuscular diseases such as myotonic muscular dystrophy, Erb dystrophy (limb-girdle muscular dystrophy), and peroneal muscular atrophy with bifascicular block or any fascicular block, with or without symptoms.

Permanent pacemaker implantation is not indicated for fascicular block without AV block or symptoms.

Permanent pacemaker implantation is not indicated for fascicular block with first-degree AV block without symptoms.

Permanent Pacing After the Acute Phase of Myocardial Infarction*

Permanent ventricular pacing is indicated for persistent second-degree AV block in the His-Purkinje system with alternating bundle-branch block or third-degree AV block within or below the His-Purkinje system after ST-segment elevation MI.

Permanent ventricular pacing is indicated for transient advanced second- or third-degree infranodal AV block and associated bundle-branch block. If the site of block is uncertain, an electrophysiological study may be necessary.

Permanent ventricular pacing is indicated for persistent and symptomatic second- or third-degree AV block.

*These recommendations are consistent with the “ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction.”

Permanent Pacing After the Acute Phase of Myocardial Infarction*

Permanent ventricular pacing may be considered for persistent second- or third-degree AV block at the AV node level, even in the absence of symptoms.

Permanent ventricular pacing is not indicated for transient AV block in the absence of intraventricular conduction defects.

Permanent ventricular pacing is not indicated for transient AV block in the presence of isolated left anterior fascicular block.

*These recommendations are consistent with the “ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction.”

Permanent Pacing After the Acute Phase of Myocardial Infarction*

Permanent ventricular pacing is not indicated for new bundle-branch block or fascicular block in the absence of AV block.

Permanent ventricular pacing is not indicated for persistent asymptomatic first-degree AV block in the presence of bundle-branch or fascicular block.

*These recommendations are consistent with the “ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction.”

Permanent Pacing in Hypersensitive Carotid Sinus Syndrome and Neurocardiogenic Syncope

Permanent pacing is indicated for recurrent syncope caused by spontaneously occurring carotid sinus stimulation and carotid sinus pressure that induces ventricular asystole of more than 3 seconds.

Permanent pacing is reasonable for syncope without clear, provocative events and with a hypersensitive cardioinhibitory response of 3 seconds or longer.

Permanent pacing may be considered for significantly symptomatic neurocardiogenic syncope associated with bradycardia documented spontaneously or at the time of tilt-table testing.

Permanent Pacing in Hypersensitive Carotid Sinus Syndrome and Neurocardiogenic Syncope

Permanent pacing is not indicated for a hypersensitive cardioinhibitory response to carotid sinus stimulation without symptoms or with vague symptoms.

Permanent pacing is not indicated for situational vasovagal syncope in which avoidance behavior is effective and preferred.

Pacing After Cardiac Transplantation

Permanent pacing is indicated for persistent inappropriate or symptomatic bradycardia not expected to resolve and for other Class I indications for permanent pacing.

Permanent pacing may be considered when relative bradycardia is prolonged or recurrent, which limits rehabilitation or discharge after postoperative recovery from cardiac transplantation.

Permanent pacing may be considered for syncope after cardiac transplantation even when bradyarrhythmia has not been documented.

Permanent Pacemakers That Automatically Detect and Pace to Terminate Tachycardias

Permanent pacing is reasonable for symptomatic recurrent SVT that is reproducibly terminated by pacing when catheter ablation and/or drugs fail to control the arrhythmia or produce intolerable side effects.

Permanent pacing is not indicated in the presence of an accessory pathway that has the capacity for rapid anterograde conduction.

Pacing to Prevent Tachycardia

Permanent pacing is indicated for sustained pause-dependent VT, with or without QT prolongation.

Permanent pacing is reasonable for high-risk patients with congenital long-QT syndrome.

Permanent pacing may be considered for prevention of symptomatic, drug-refractory, recurrent AF in patients with coexisting SND.

Pacing to Prevent Tachycardia

Permanent pacing is not indicated for frequent or complex ventricular ectopic activity without sustained VT in the absence of the long-QT syndrome.

Permanent pacing is not indicated for torsade de pointes VT due to reversible causes.

Pacing to Prevent Atrial Fibrillation

Permanent pacing is not indicated for the prevention of AF in patients without any other indication for pacemaker implantation.

Recs Modified 2012

Cardiac Resynchronization Therapy in Patients With Systolic Heart Failure

CRT is indicated for patients who have left ventricular ejection fraction (LVEF) less than or equal to 35%, sinus rhythm, LBBB with a QRS duration greater than or equal to 150 ms, and NYHA class II, III, or ambulatory IV symptoms on GDMT. *(Level of Evidence: A for NYHA class III/IV; Level of Evidence: B for NYHA class II)*.[1]

CRT can be useful for patients who have LVEF less than or equal to 35%, sinus rhythm, LBBB with a QRS duration 120 to 149 ms, and NYHA class II, III, or ambulatory IV symptoms on GDMT.[2]

CRT can be useful for patients who have LVEF less than or equal to 35%, sinus rhythm, a non-LBBB pattern with a QRS duration greater than or equal to 150 ms, and NYHA class III/ambulatory class IV symptoms on GDMT.[2]

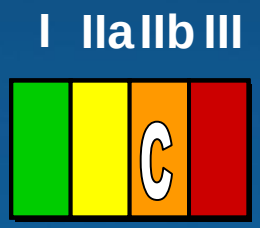
1. Modified recommendation (specifying CRT in patients with LBBB of 150 ms; expanded to include those with NYHA class II symptoms).
2. New Recommendation

Recs Modified 2012

Cardiac Resynchronization Therapy in Patients With Systolic Heart Failure

CRT can be useful in patients with atrial fibrillation and LVEF less than or equal to 35% on GDMT if a) the patient requires ventricular pacing or otherwise meets CRT criteria and b) AV nodal ablation or pharmacologic rate control will allow near 100% ventricular pacing with CRT.[1]

CRT can be useful for patients on GDMT who have LVEF less than or equal to 35% and are undergoing new or replacement device placement with anticipated requirement for significant (>40%) ventricular pacing.[2]



CRT may be considered for patients who have LVEF less than or equal to 30%, ischemic etiology of heart failure, sinus rhythm, LBBB with a QRS duration of greater than or equal to 150 ms, and NYHA class I symptoms on GDMT.[3]

1. Modified recommendation (wording changed to indicate benefit based on ejection fraction rather than NYHA class; level of evidence changed from C to B).
2. Modified recommendation (wording changed to indicate benefit based on ejection fraction and need for pacing rather than NYHA class; class changed from IIb to IIa).
3. New Recommendation

Recs Modified 2012

Cardiac Resynchronization Therapy in Patients With Systolic Heart Failure

CRT may be considered for patients who have LVEF less than or equal to 35%, sinus rhythm, a non-LBBB pattern with QRS duration 120 to 149 ms, and NYHA class III/ambulatory class IV on GDMT.[1]

CRT may be considered for patients who have LVEF less than or equal to 35%, sinus rhythm, a non-LBBB pattern with a QRS duration greater than or equal to 150 ms, and NYHA class II symptoms on GDMT.[1]

No Benefit

CRT is not recommended for patients with NYHA class I or II symptoms and non-LBBB pattern with QRS duration less than 150 ms.[1]

No Benefit

CRT is not indicated for patients whose comorbidities and/or frailty limit survival with good functional capacity to less than 1 year.[2]

1. New Recommendation
2. Modified recommendation (wording changed to include cardiac as well as noncardiac comorbidities).

Pacing in Patients With Hypertrophic Cardiomyopathy

Permanent pacing is indicated for SND or AV block in patients with hypertrophic cardiomyopathy as described previously (see Section 2.1.1, “Sinus Node Dysfunction” and Section 2.1.2, “Acquired Atrioventricular Block in Adults” in the full-text guidelines).

Permanent pacing may be considered in medically refractory symptomatic patients with HCM and significant resting or provoked LV outflow tract obstruction. As for Class I indications, when risk factors for SCD are present, consider a dual chamber (DDD) ICD (see Section 3, “Indications for Implantable Cardioverter-Defibrillator Therapy” in the full-text guidelines).

Permanent pacemaker implantation is not indicated for patients who are asymptomatic or whose symptoms are medically controlled.

Permanent pacemaker implantation is not indicated for symptomatic patients without evidence of LV outflow tract obstruction.

Permanent Pacing in Children, Adolescents, and Patients With Congenital Heart Disease

Permanent pacemaker implantation is indicated for advanced second- or third-degree AV block associated with symptomatic bradycardia, ventricular dysfunction, or low cardiac output.

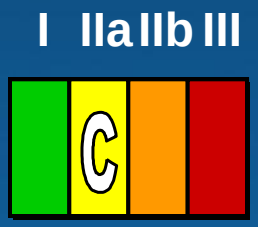
Permanent pacemaker implantation is indicated for SND with correlation of symptoms during age-inappropriate bradycardia. The definition of bradycardia varies with the patient's age and expected heart rate.

Permanent pacemaker implantation is indicated for postoperative advanced second- or third-degree AV block that is not expected to resolve or that persists at least 7 days after cardiac surgery.

Permanent Pacing in Children, Adolescents, and Patients With Congenital Heart Disease

Permanent pacemaker implantation is indicated for congenital third-degree AV block with a wide QRS escape rhythm, complex ventricular ectopy, or ventricular dysfunction.

Permanent pacemaker implantation is indicated for congenital third-degree AV block in the infant with a ventricular rate less than 55 bpm or with congenital heart disease and a ventricular rate less than 70 bpm.

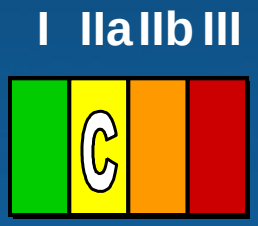


Permanent pacemaker implantation is reasonable for patients with congenital heart disease and sinus bradycardia for the prevention of recurrent episodes of intra-atrial reentrant tachycardia; SND may be intrinsic or secondary to antiarrhythmic treatment.

Permanent Pacing in Children, Adolescents, and Patients With Congenital Heart Disease

Permanent pacemaker implantation is reasonable for congenital third-degree AV block beyond the first year of life with an average heart rate less than 50 bpm, abrupt pauses in ventricular rate that are 2 or 3 times the basic cycle length, or associated with symptoms due to chronotropic incompetence.

Permanent pacemaker implantation is reasonable for sinus bradycardia with complex congenital heart disease with a resting heart rate less than 40 bpm or pauses in ventricular rate more than 3 seconds.



Permanent pacemaker implantation is reasonable for patients with congenital heart disease and impaired hemodynamics due to sinus bradycardia or loss of AV synchrony.

Permanent Pacing in Children, Adolescents, and Patients With Congenital Heart Disease

Permanent pacemaker implantation is reasonable for unexplained syncope in the patient with prior congenital heart surgery complicated by transient complete heart block with residual fascicular block after a careful evaluation to exclude other causes of syncope.

Permanent pacemaker implantation may be considered for transient postoperative third-degree AV block that reverts to sinus rhythm with residual bifascicular block.

Permanent pacemaker implantation may be considered for congenital third-degree AV block in asymptomatic children or adolescents with an acceptable rate, a narrow QRS complex, and normal ventricular function.

Permanent Pacing in Children, Adolescents, and Patients With Congenital Heart Disease

Permanent pacemaker implantation may be considered for asymptomatic sinus bradycardia after biventricular repair of congenital heart disease with a resting heart rate less than 40 bpm or pauses in ventricular rate more than 3 seconds.

Permanent pacemaker implantation is not indicated for transient postoperative AV block with return of normal AV conduction in the otherwise asymptomatic patient.

Permanent pacemaker implantation is not indicated for asymptomatic bifascicular block with or without first-degree AV block after surgery for congenital heart disease in the absence of prior transient complete AV block.

Permanent Pacing in Children, Adolescents, and Patients With Congenital Heart Disease

Permanent pacemaker implantation is not indicated for asymptomatic type I second-degree AV block.

Permanent pacemaker implantation is not indicated for asymptomatic sinus bradycardia with the longest relative risk interval less than 3 seconds and a minimum heart rate more than 40 bpm.

Guidelines for Choice of Pacemaker Generator in Selected Indications for Pacing

Pacemaker Generator	*SND*	*AV Block*	*Neurally Mediated Syncope or Carotid Sinus Hypersensitivity*
Single-chamber atrial pacemaker	• No suspected abnormality of AV conduction and not at increased risk for future AV block • Maintenance of AV synchrony during pacing desired	Not appropriate	Not appropriate
Single-chamber ventricular pacemaker	• Maintenance of AV synchrony during pacing not necessary • Rate response available if desired	• Chronic atrial fibrillation or other atrial tachyarrhythmia or maintenance of AV synchrony during pacing not necessary • Rate response available if desired	• Chronic atrial fibrillation or other atrial tachyarrhythmia • Rate response available if desired

(Table continues)

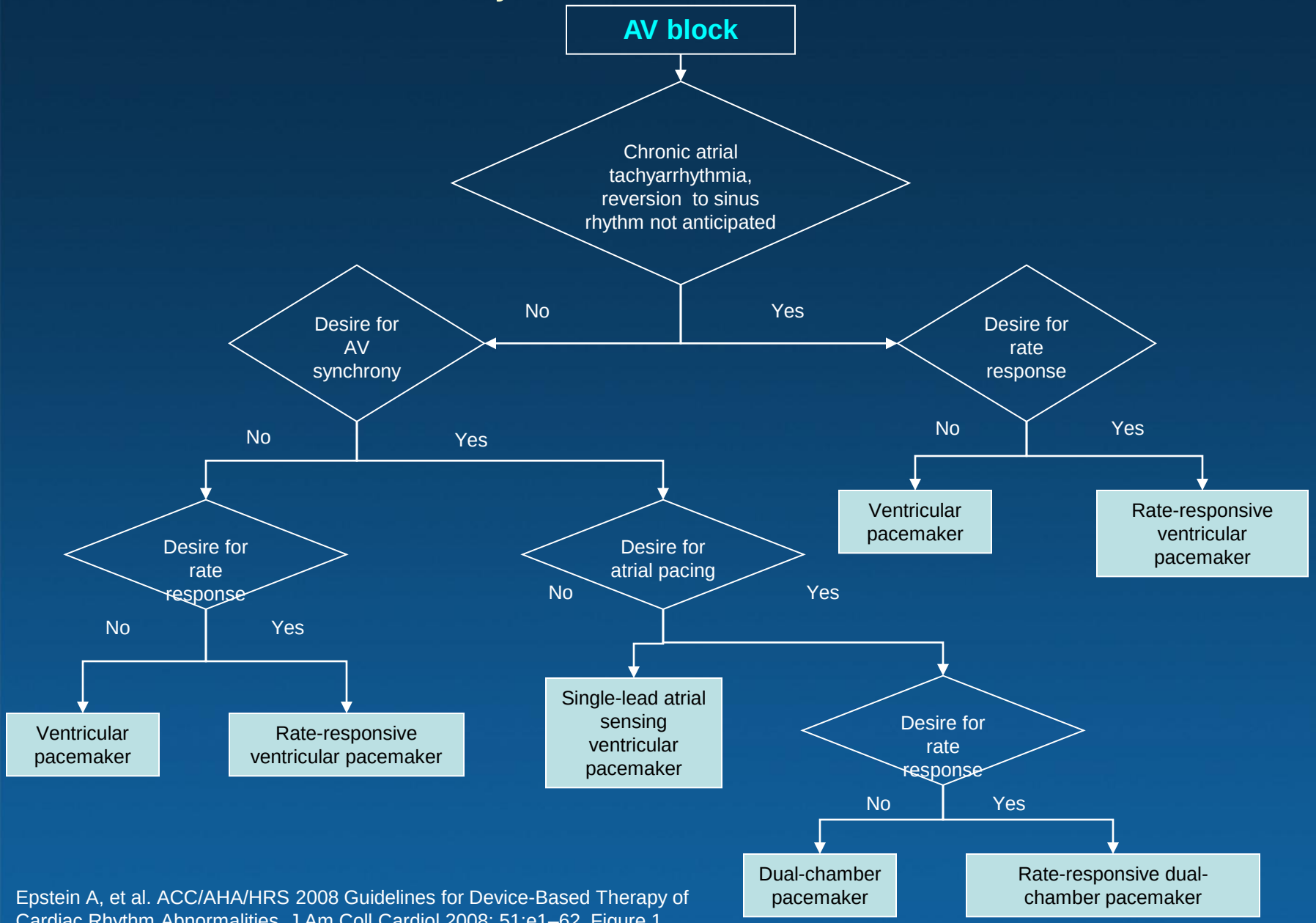
Epstein A, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. J Am Coll Cardiol 2008; 51:e1–62. Table 2.

Guidelines for Choice of Pacemaker Generator in Selected Indications for Pacing

Pacemaker Generator	*SND*	*AV Block*	*Neurally Mediated Syncope or Carotid Sinus Hypersensitivity*
Dual-chamber pacemaker	• AV synchrony during pacing desired • Suspected abnormality of AV conduction or increased risk for future AV block • Rate response available if desired	• Rate response available if desired • AV synchrony during pacing desired • Atrial pacing desired • Rate response available if desired	• Sinus mechanism present • Rate response available if desired
Single-lead, atrial-sensing ventricular pacemaker	Not appropriate	Desire to limit the number of pacemaker leads	Not appropriate

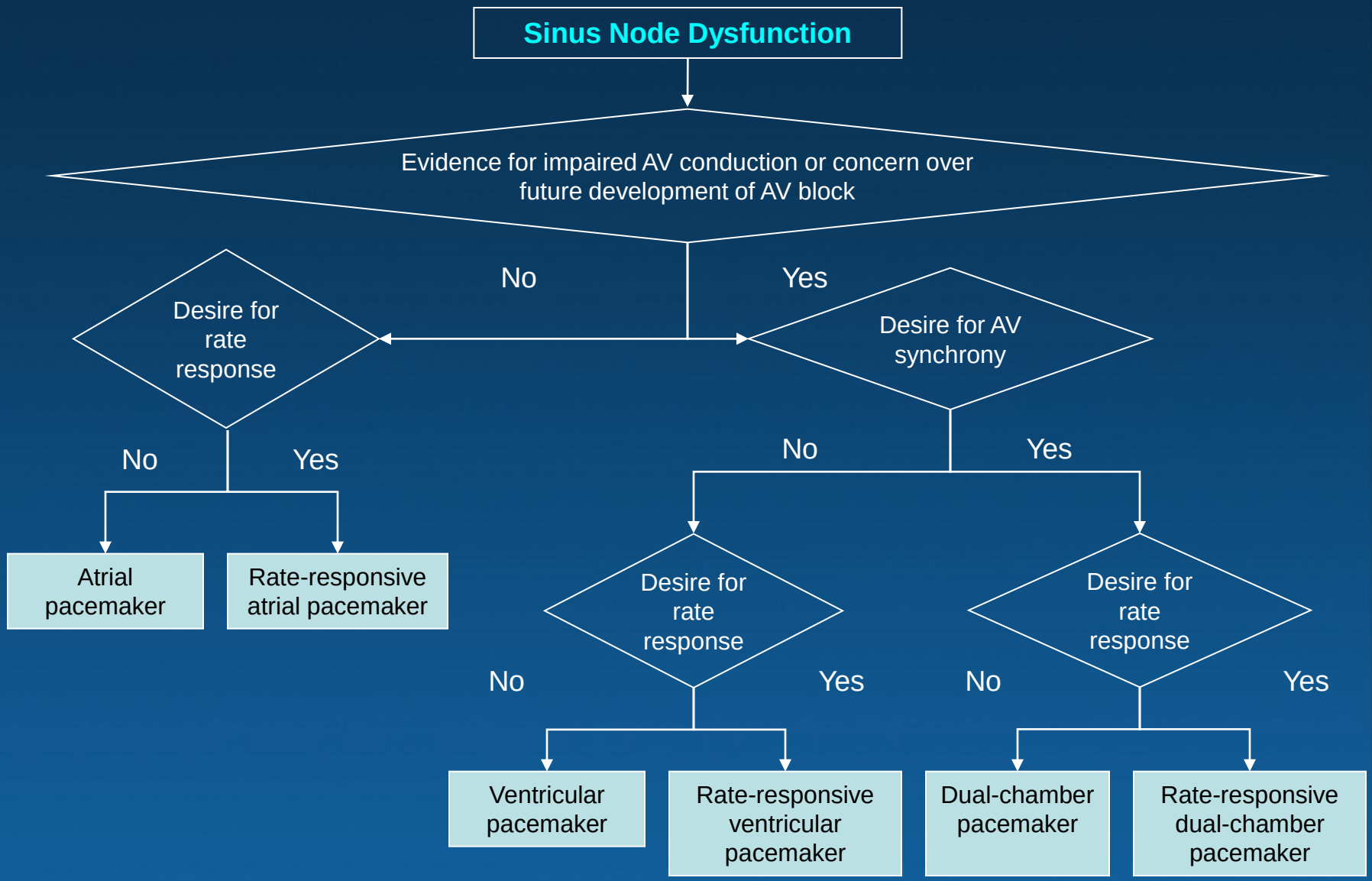
Epstein A, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. J Am Coll Cardiol 2008; 51:e1–62. Table 2.

Selection of Pacemaker Systems for Patients With Atrioventricular Block



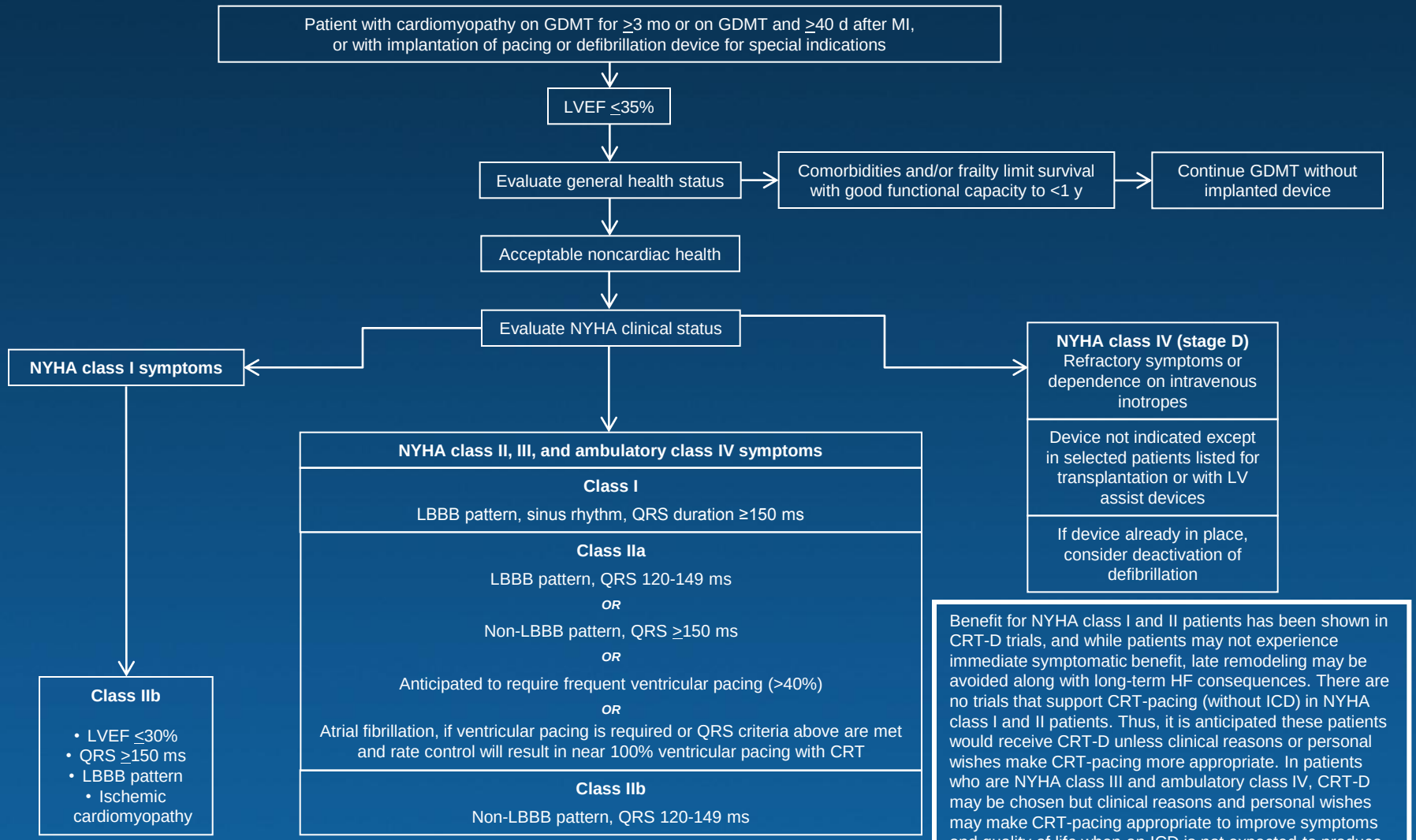
Epstein A, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. J Am Coll Cardiol 2008; 51:e1–62. Figure 1.

Selection of Pacemaker Systems for Patients With Sinus Node Dysfunction



Epstein A, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. J Am Coll Cardiol 2008; 51:e1–62. Figure 2.

Indications for CRT Therapy—Algorithm



Benefit for NYHA class I and II patients has been shown in CRT-D trials, and while patients may not experience immediate symptomatic benefit, late remodeling may be avoided along with long-term HF consequences. There are no trials that support CRT-pacing (without ICD) in NYHA class I and II patients. Thus, it is anticipated these patients would receive CRT-D unless clinical reasons or personal wishes make CRT-pacing more appropriate. In patients who are NYHA class III and ambulatory class IV, CRT-D may be chosen but clinical reasons and personal wishes may make CRT-pacing appropriate to improve symptoms and quality of life when an ICD is not expected to produce meaningful benefit in survival.

Dual Chamber and VVI Implantable Defibrillator (DAVID) Trial

- 506 patients with indications for ICD therapy
- All patients had LVEF ≤ 40%, no indication for antibradycardia pacing and no persistent atrial arrhythmias
- All patients prescribed medical rx for LV dysfunction, incl ACE inhibitors and β-blockers
- Randomized to ICD with ventricular backup pacing @ 40/min (VVI-40; n=256) or dual-chamber rate-responsive pacing @ 70/min (DDDR-70; n=250)
- ↑ Death or first hosp for HF with dual chamber pacing
  - Hazard ratio (HR) = 1.61, 95% CI 1.06 to 2.4; p ≤ 0.03

Wilkoff BL, Cook JR, Epstein AE, et al. Dual-chamber pacing or ventricular backup pacing in patients with an implantable defibrillator: the Dual Chamber and VVI Implantable Defibrillator (DAVID) Trial. JAMA 2002;288:3115-23.

Canadian Trial of Physiological Pacing (CTOPP)

- 2568 patients requiring a pacemaker for symptomatic bradycardia
- Randomized to ventricular (VVI) (n=1474) or physiological pacemaker (AAI/DDD) (n=1094)
- No difference in death/stroke @ mean 6.4 y FU
- ↓ Development of AF in AAI/DDD arm
  - RRR 20.1% (95% CI 5.4 to 32.5; p=0.009)
  - Benefit not apparent until after 2 y
- In the AAI/DDD arm only 5.2% had an atrial pacemaker
- 7% dropout in VVI arm; 25% in AAI/DDD

AAI indicates atrial demand, VVI = ventricular demand, and DDD = fully automatic.

Kerr CR, Connolly SJ, Abdollah H, et al. Canadian Trial of Physiological Pacing: Effects of physiological pacing during long-term follow-up. Circulation 2004;109:357-62.

Search AV Extension and Managed Ventricular Pacing for Promoting Atrioventricular Conduction (SAVE PACe) Trial

- 1065 patients with sinus-node disease, intact AV conduction and normal QRS interval
- Randomized to conventional dual-chamber pacing (n=535) or dual-chamber minimal ventricular pacing (n=530)
  - — study tests new pacing algorithm that avoids ventricular pacing except during periods of high-grade AV block
- With dual-chamber pacing, ↓ frequency RV pacing (9.1% vs. 99%; p<0.001) and 40% relative risk ↓ in incidence of persistent AF

Sweeney MO, Bank AJ, Nsah E, et al. Minimizing ventricular pacing to reduce atrial fibrillation in sinus-node disease. N Engl J Med 2007;357:1000-8.

Cardiac Resynchronization-Heart Failure (CARE-HF) Trial

- 813 patients with NYHA Class III or IV HF, LVSD, and cardiac dyssynchrony
- Trial limited subjects to a QRS > 150 ms (89%) or QRS 120 to 150 ms with echo evidence of dyssynchrony (11%)
- Randomized to medical rx alone or in combination with CRT
- 10% absolute and 36% relative risk ↓ in death by CRT ($p<0.002$)
- First study to show a significant ↓ in death for CRT w/o backup defibrillation compared with optimal medical rx

Cleland JG, Daubert JC, Erdmann E, et al. The effect of cardiac resynchronization on morbidity and mortality in heart failure. N Engl J Med 2005;352:1539-49. LVSD = left ventricular systolic dysfunction.

Randomized Trials Comparing Atrium-Based Pacing With Ventricular Pacing

Characteristics	Danish study	PASE	CTOPP
Pacing indication	SND	SND and AVB	SND and AVB
No. patients randomized	225	407	2568
Mean follow-up (years)	5.5	1.5	6.4
Pacing modes	AAI vs. VVI	DDDR* vs. VVIR*	DDD/AAI vs. VVI(R)
Atrium-based pacing superior with respect to:			
Quality of life or functional status	NA	SND patients: yes AVB patients: no	No
Heart failure	Yes	No	No
Atrial fibrillation	Yes	No	Yes
Stroke or thromboembolism	Yes	No	No
Mortality	Yes	No	No
Cross-over or pacing dropout	VVI to AAI/DDD: 4% AAI to DDD: 5% AAI to VVI: 10%	VVIR* to DDDR*: 26%	VVI(R) dropout: 7% DDD/AAI dropout: 25%

(table continues)

SND indicates sinus node dysfunction, AVB = atrioventricular block, AAI = atrial demand, VVI = ventricular demand, and DDD = fully automatic. R* added to pacing mode designation indicates rate-responsive pacemakers implanted in all patients.

Epstein A, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. J Am Coll Cardiol 2008; 51:e1–62. Figure 3.

Randomized Trials Comparing Atrium-Based Pacing With Ventricular Pacing

Characteristics	MOST	UK-PACE
Pacing indication	SND	AVB
No. patients randomized	2010	2021
Mean follow-up (years)	2.8	3
Pacing modes	DDDR vs. VVIR*	DDD(R) vs. VVI(R)
Atrium-based pacing superior with respect to:		
Quality of life or functional status	Yes	NA
Heart failure	Marginal	No
Atrial fibrillation	Yes	No
Stroke or thromboembolism	No	No
Mortality	No	No
Cross-over or pacing dropout	VVIR* to DDDR*: 37.6%	VVI(R) to DDD(R): 3.1% DDD(R) dropout: 8.3%

SND indicates sinus node dysfunction, AVB = atrioventricular block, AAI = atrial demand, VVI = ventricular demand, and DDD = fully automatic. R* added to pacing mode designation indicates rate-responsive pacemakers implanted in all patients.

Epstein A, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. J Am Coll Cardiol 2008; 51:e1–62. Figure 3.

Health Care Financing Administration 1984 Guidelines for Transtelephonic Monitoring

Device	Monitoring Times After Pacemaker Implantation			
Guideline I				
Single Chamber	1st Month	2nd to 36th Month	37th Month to Failure	
	Every 2 weeks	Every 8 weeks	Every 4 weeks	
Dual Chamber	1st Month	2nd to 6th Month	7th to 36th Month	37th Month to Failure
	Every 2 weeks	Every 4 weeks	Every 8 weeks	Every 4 weeks
Guideline II				
Single Chamber	1st Month	2nd to 48th Month	49th Month to Failure	
	Every 2 weeks	Every 12 weeks	Every 4 weeks	
Dual Chamber	1st Month	2nd to 30th Month	31st to 48th Month	49th Month to Failure
	Every 2 weeks	Every 12 weeks	Every 8 weeks	Every 4 weeks

Epstein A, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. *J Am Coll Cardiol* 2008; 51:e1–62. Table 4. U.S. Department of Health and Human Services.1984 Health Care Financing Administration. Available at: http://www.cms.hhs.gov/. Accessed November 2007.

Minimum Frequency of CIED In-Person or Remote Monitoring*

Type and Frequency	Method
Pacemaker/ICD/CRT	
• Within 72 h of CIED implantation	In person
• 2–12 wk postimplantation	In person
• Every 3–12 mo for pacemaker/CRT-Pacemaker	In person or remote
• Every 3–6 mo for ICD/CRT-D	In person or remote
• Annually until battery depletion	In person
• Every 1–3 mo at signs of battery depletion	In person or remote
Implantable loop recorder	
• Every 1– 6 mo depending on patient symptoms and indication	In person or remote
Implantable hemodynamic monitor	
• Every 1– 6 mo depending on indication	In person or remote
• More frequent assessment as clinically indicated	In person or remote

*More frequent in-person or remote monitoring may be required for all the above devices as clinically indicated.

CIED indicates cardiovascular implantable electronic device; CRT, cardiac resynchronization therapy; CRT-D, cardiac resynchronization therapy defibrillator; CRT-P, cardiac resynchronization therapy pacemaker; and ICD, implantable cardioverter-defibrillator.

Wilkoff BL, Auricchio A, Brugada J, et al. HRS/EHRA expert consensus on the monitoring of cardiovascular implantable electronic devices (CIEDs): description of techniques, indications, personnel, frequency and ethical considerations. Heart Rhythm. 2008;5:907–25.

Indications for ICD Therapy

Implantable Cardioverter-Defibrillators

ICD therapy is indicated in patients who are survivors of cardiac arrest due to ventricular fibrillation or hemodynamically unstable sustained VT after evaluation to define the cause of the event and to exclude any completely reversible causes.

ICD therapy is indicated in patients with structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable.

ICD therapy is indicated in patients with syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or VF induced at electrophysiological study.

All primary SCD prevention ICD recommendations apply only to patients who are receiving optimal medical therapy and have reasonable expectation of survival with good functional capacity for more than 1 year.

Implantable Cardioverter-Defibrillators

ICD therapy is indicated in patients with LVEF less than or equal to 35% due to prior MI who are at least 40 days post-MI and are in NYHA functional Class II or III.

ICD therapy is indicated in patients with nonischemic DCM who have an LVEF less than or equal to 35% and who are in NYHA functional Class II or III.

ICD therapy is indicated in patients with LV dysfunction due to prior MI who are at least 40 days post-MI, have an LVEF less than or equal to 30%, and are in NYHA functional Class I.

ICD therapy is indicated in patients with nonsustained VT due to prior MI, LVEF less than or equal to 40%, and inducible VF or sustained VT at electrophysiological study.

All primary SCD prevention ICD recommendations apply only to patients who are receiving optimal medical therapy and have reasonable expectation of survival with good functional capacity for more than 1 year.

Implantable Cardioverter-Defibrillators

ICD implantation is reasonable for patients with unexplained syncope, significant LV dysfunction, and nonischemic DCM.

ICD implantation is reasonable for patients with sustained VT and normal or near-normal ventricular function.

ICD implantation is reasonable for patients with HCM who have 1 or more major† risk factors for SCD.

ICD implantation is reasonable for the prevention of SCD in patients with arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVD/C) who have 1 or more risk factors for SCD.

ICD implantation is reasonable to reduce SCD in patients with long-QT syndrome who are experiencing syncope and/or VT while receiving beta blockers.

All primary SCD prevention ICD recommendations apply only to patients who are receiving optimal medical therapy and have reasonable expectation of survival with good functional capacity for more than 1 year.

† See Section 3.2.4, “Hypertrophic Cardiomyopathy,” in the full-text guidelines for definition of major risk factors.

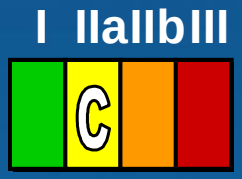
Implantable Cardioverter-Defibrillators

ICD implantation is reasonable for nonhospitalized patients awaiting transplantation.

ICD implantation is reasonable for patients with Brugada syndrome who have had syncope.

ICD implantation is reasonable for patients with Brugada syndrome who have documented VT that has not resulted in cardiac arrest.

ICD implantation is reasonable for patients with catecholaminergic polymorphic VT who have syncope and/or documented sustained VT while receiving beta blockers.



ICD implantation is reasonable for patients with cardiac sarcoidosis, giant cell myocarditis, or Chagas disease.

All primary SCD prevention ICD recommendations apply only to patients who are receiving optimal medical therapy and have reasonable expectation of survival with good functional capacity for more than 1 year.

Implantable Cardioverter-Defibrillators

ICD therapy may be considered in patients with nonischemic heart disease who have an LVEF of less than or equal to 35% and who are in NYHA functional Class I.

ICD therapy may be considered for patients with long-QT syndrome and risk factors for SCD.

ICD therapy may be considered in patients with syncope and advanced structural heart disease in whom thorough invasive and noninvasive investigations have failed to define a cause.

ICD therapy may be considered in patients with a familial cardiomyopathy associated with sudden death.

ICD therapy may be considered in patients with LV noncompaction.

All primary SCD prevention ICD recommendations apply only to patients who are receiving optimal medical therapy and have reasonable expectation of survival with good functional capacity for more than 1 year.

Implantable Cardioverter-Defibrillators

ICD therapy is not indicated for patients who do not have a reasonable expectation of survival with an acceptable functional status for at least 1 year, even if they meet ICD implantation criteria specified in the Class I, IIa, and IIb recommendations above.

ICD therapy is not indicated for patients with incessant VT or VF.

ICD therapy is not indicated in patients with significant psychiatric illnesses that may be aggravated by device implantation or that may preclude systematic follow-up.

ICD therapy is not indicated for NYHA Class IV patients with drug-refractory congestive heart failure who are not candidates for cardiac transplantation or cardiac resynchronization therapy defibrillators (CRT-D).

All primary SCD prevention ICD recommendations apply only to patients who are receiving optimal medical therapy and have reasonable expectation of survival with good functional capacity for more than 1 year.

Implantable Cardioverter-Defibrillators

ICD therapy is not indicated for syncope of undetermined cause in a patient without inducible ventricular tachyarrhythmias and without structural heart disease.

ICD therapy is not indicated when VF or VT is amenable to surgical or catheter ablation (e.g., atrial arrhythmias associated with the Wolff-Parkinson-White syndrome, RV or LV outflow tract VT, idiopathic VT, or fascicular VT in the absence of structural heart disease).

ICD therapy is not indicated for patients with ventricular tachyarrhythmias due to a completely reversible disorder in the absence of structural heart disease (e.g., electrolyte imbalance, drugs, or trauma).

All primary SCD prevention ICD recommendations apply only to patients who are receiving optimal medical therapy and have reasonable expectation of survival with good functional capacity for more than 1 year.

ICDs in Pediatric Patients and Patients With Congenital Heart Disease

ICD implantation is indicated in the survivor of cardiac arrest after evaluation to define the cause of the event and exclusion of any reversible causes.

ICD implantation is indicated for patients with symptomatic sustained VT in association with congenital heart disease who have undergone hemodynamic and electrophysiological evaluation. Catheter ablation or surgical repair may offer possible alternatives in carefully selected patients.

All primary SCD prevention ICD recommendations apply only to patients who are receiving optimal medical therapy and have reasonable expectation of survival with good functional capacity for more than 1 year.

ICDs in Pediatric Patients and Patients With Congenital Heart Disease

ICD implantation is reasonable for patients with congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias at electrophysiological study.

ICD implantation may be considered for patients with recurrent syncope associated with complex congenital heart disease and advanced systemic ventricular dysfunction when thorough invasive and noninvasive investigations have failed to define a cause.

All Class III recommendations found in Section 3 of the full-text guidelines, “Indications for Implantable Cardioverter-Defibrillator Therapy,” apply to pediatric patients and patients with congenital heart disease, and ICD implantation is not indicated in these patient populations.

All primary SCD prevention ICD recommendations apply only to patients who are receiving optimal medical therapy and have reasonable expectation of survival with good functional capacity for more than 1 year.

Major Implantable Cardioverter-Defibrillator Trials for Prevention of Sudden Cardiac Death

Trial	Year	Patients (n)	Inclusion Criterion: LVEF	Additional Study Features	Hazard Ratio*	95% CI	p
MADIT I	1996	196	≤ 35%	NSVT and EP+	0.46	(0.26-0.82)	p=0.009
MADIT II	2002	1232	≤ 30%	Prior MI	0.69	(0.51-0.93)	p=0.016
CABG-Patch	1997	900	< 36%	+SAECG and CABG	1.07	(0.81-1.42)	p=0.64
DEFINITE	2004	485	< 36%	NICM, PVCs or NSVT	0.65	(0.40-1.06)	p=0.08
DINAMIT	2004	674	≤ 35%	6-40 days post-MI and Impaired HRV	1.08	(0.76-1.55)	p=0.66
SCD-HeFT	2006	1676	≤ 35%	Prior MI or NICM	0.77	(0.62-0.96)	p=0.007
AVID	1997	1016	≤ 40%	Prior cardiac Arrest, or Unstable VT	0.62	(0.43-0.82)	p<0.02
CASH†	2000	191	Mean ≤ 45% ±18 at baseline	Prior cardiac arrest	0.766	‡	1-sided p=0.081
CIDS	2000	659	≤ 35%	Prior cardiac Arrest, Unstable VT, or Syncope	0.82	(0.60-1.1)	NS

* Hazard ratios for death from any cause in the ICD group compared with the non-ICD group. Includes only ICD and amiodarone patients from CASH.
‡CI Upper Bound 1.112. CI indicates Confidence Interval, EP+ = positive electrophysiologic study, HRV = heart rate variability, LVEF = left ventricular ejection fraction, MI = myocardial infarction, NICM = nonischemic cardiomyopathy, NS = Not statistically significant, NSVT = nonsustained ventricular tachycardia, PVCs = premature ventricular contractions, SAECG = signal-averaged electrocardiogram, VT = ventricular tachycardia.

Epstein A, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. J Am Coll Cardiol 2008; 51:e1–62. Table 5.

Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) Trial

- 1520 patients with NYHA Class III or IV HF, ischemic cardiomyopathy (ICM) or nonischemic cardiomyopathy (NICM) and QRS of at least 120 ms
- Randomized 1:2:2 to optimal pharmacological therapy (OPT) alone or in combination with cardiac resynchronization therapy with either a pacemaker (CRT-P) or pacemaker-defibrillator (CRT-D)
- Both device arms significantly ↓ combined risk of all-cause hospitalization and all-cause mortality by ~20% compared with OPT
- CRT-D ↓ mortality by 36% compared with OPT (p=0.003)
- Insufficient evidence to conclude that CRT-P inferior to CRT-D

Bristow MR, Saxon LA, Boehmer J, et al. Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. N Engl J Med 2004;350:2140-50.

Implantable Cardioverter-Defibrillators and Prevention of Sudden Cardiac Death in Hypertrophic Cardiomyopathy

- Multicenter registry study of implanted ICDs in 506 unrelated patients with HCM @ high risk for SCD (family hx of SCD, [septal thickness ≥ 30 mm], NSVT, syncope)
- Mean patient age 42 years (SD=17) and 87% had no or only mildly limiting symptoms
- Appropriate ICD discharge rates were 11% per year for 2º prevention and 4% per year for 1º prevention
- For 1º prevention, 35% of patients with appropriate ICD interventions had undergone implantation for only 1 risk factor

Maron BJ, Spirito P, Shen WK, et al. Implantable cardioverter-defibrillators and prevention of sudden cardiac death in hypertrophic cardiomyopathy. JAMA 2007;298:405-12.

Multicenter Automatic Defibrillator Implantation Trial II (MADIT II)

- 1232 patients ≥ 1 month post-MI and LVEF ≤ 30%
- Randomized to ICD (n=742) or medical therapy (n=490)
- No spontaneous or induced arrhythmia required for enrollment
- 6% absolute and 31% relative risk ↓ in all-cause mortality with ICD therapy (p=0.016)

Moss AJ, Zareba W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. N Engl J Med 2002;346:877-83.

Sudden Death in Heart Failure (SCD-HeFT) Trial

- 2521 patients with NYHA Class II or III HF, ICM, or NICM and LVEF ≤ 35%
- Randomized to
  1) conventional rx for HF + placebo;
  2) conventional rx + amiodarone; or
  3) conventional rx + conservatively programmed shock-only single lead ICD
- No survival benefit for amiodarone
- 23% ↓ in overall mortality with ICD therapy
- Absolute ↓ in mortality of 7.2% after 5 y in the overall population

Bardy GH, Lee KL, Mark DB, et al. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. N Engl J Med 2005;352:225-37.

Defibrillator in Acute Myocardial Infarction (DINAMIT) Trial

- 674 patients 6 to 40 days post-MI with LVEF ≤ 35% and impaired cardiac autonomic function
- Randomized to ICD therapy (n=332) or no ICD therapy (n=342)
- Arrhythmic death ↓ in ICD group, but ↑ in nonarrhythmic death (6.1% per year vs. 3.5% per year, HR 1.75 (95% CI 1.11 to 2.76; p=0.016)
- No difference in total mortality

Hohnloser SH, Kuck KH, Dorian P, et al. Prophylactic use of an implantable cardioverter-defibrillator after acute myocardial infarction. N Engl J Med 2004;351:2481-8.

Defibrillators in Nonischemic Cardiomyopathy Treatment Evaluation (DEFINITE) Trial

- 458 patients with NYHA Class I to III, NICM, LVEF ≤ 36% and premature ventricular contractions (> 10/h) or NSVT
- Randomized to standard medical rx alone or in combination with single-chamber ICD
- Strong trend toward ↓ all-cause mortality with ICD therapy, although not statistically significant (p=0.08)

Kadish A, Dyer A, Daubert JP, et al. Prophylactic defibrillator implantation in patients with nonischemic dilated cardiomyopathy. N Engl J Med 2004;350:2151-8.

Notable Changes in 2008 ACC/AHA/HRS Guidelines

1. ICD recommendations are combined into a single list because of overlap between primary and secondary indications.
2. Primary prevention ICD indications in nonischemic cardiomyopathy are clarified using data from SCD-HeFT (i.e., ischemic and nonischemic cardiomyopathies and LVEF ≤35%, NYHA II-III) for support.
3. Indications for ICD therapy in inherited arrhythmia syndromes and selected nonischemic cardiomyopathies are listed.
4. MADIT II indication (i.e., ischemic cardiomyopathy and LVEF ≤30%, NYHA I) is now Class I, elevated from Class IIa.
5. EF criteria for primary prevention ICD indications are based on entry criteria for trials on which the recommendations are based.
6. Emphasized primary SCD prevention ICD recommendations apply only to patients receiving optimal medical therapy and reasonable expectation of survival with good functional capacity for >1 year.
7. Independent risk assessment preceding ICD implantation is emphasized, including consideration of patient preference.
8. Optimization of pacemaker programming to minimize unneeded RV pacing is encouraged.
9. Pacemaker insertion is discouraged for asymptomatic bradycardia, particularly at night.
10. A section has been added that addresses ICD and pacemaker programming at end of life.

Notable Recommendation Changes in 2012 ACCF/AHA/HRS Focused Update

2012 DBT Focused Update Recommendations	Comments
Class I 1. CRT is indicated for patients who have LVEF less than or equal to 35%, sinus rhythm, LBBB with a QRS duration greater than or equal to 150 ms, and NYHA class II, III, or ambulatory IV symptoms on GDMT. *(Level of Evidence: A for NYHA class III/IV; Level of Evidence: B for NYHA class II)*	Modified recommendation (specifying CRT in patients with LBBB of 150 ms; expanded to include those with NYHA class II symptoms).
Class IIa 1. CRT can be useful for patients who have LVEF less than or equal to 35%, sinus rhythm, LBBB with a QRS duration 120 to 149 ms, and NYHA class II, III, or ambulatory IV symptoms on GDMT. *(Level of Evidence: B)*	New recommendation
2. CRT can be useful for patients who have LVEF less than or equal to 35%, sinus rhythm, a non-LBBB pattern with a QRS duration greater than or equal to 150 ms, and NYHA class III/ambulatory class IV symptoms on GDMT. *(Level of Evidence: A)*	New recommendation
3. CRT can be useful in patients with atrial fibrillation and LVEF less than or equal to 35% on GDMT if a) the patient requires ventricular pacing or otherwise meets CRT criteria and b) AV nodal ablation or pharmacologic rate control will allow near 100% ventricular pacing with CRT. *(Level of Evidence: B)*	Modified recommendation (wording changed to indicate benefit based on ejection fraction rather than NYHA class; level of evidence changed from C to B).
4. CRT can be useful for patients on GDMT who have LVEF less than or equal to 35% and are undergoing new or replacement device placement with anticipated requirement for significant (40%) ventricular pacing. *(Level of Evidence: C)*	Modified recommendation (wording changed to indicate benefit based on ejection fraction and need for pacing rather than NYHA class; class changed from IIb to IIa).

Notable Recommendation Changes in 2012 ACCF/AHA/HRS Focused Update

2012 DBT Focused Update Recommendations	Comments
Class IIb 1. CRT may be considered for patients who have LVEF less than or equal to 30%, ischemic etiology of heart failure, sinus rhythm, LBBB with a QRS duration of greater than or equal to 150 ms, and NYHA class I symptoms on GDMT. *(Level of Evidence: C)*	New recommendation
2. CRT may be considered for patients who have LVEF less than or equal to 35%, sinus rhythm, a non-LBBB pattern with QRS duration 120 to 149 ms, and NYHA class III/ambulatory class IV on GDMT. *(Level of Evidence: B)*	New recommendation
3. CRT may be considered for patients who have LVEF less than or equal to 35%, sinus rhythm, a non-LBBB pattern with a QRS duration greater than or equal to 150 ms, and NYHA class II symptoms on GDMT. *(Level of Evidence: B)*	New recommendation
Class III: No Benefit 1. CRT is not recommended for patients with NYHA class I or II symptoms and non-LBBB pattern with QRS duration less than 150 ms. *(Level of Evidence: B)*	New recommendation
2. CRT is not indicated for patients whose comorbidities and/or frailty limit survival with good functional capacity to less than 1 year. *(Level of Evidence: C)*	Modified recommendation (wording changed to include cardiac as well as noncardiac comorbidities).

Comparison of Trials Prompting DBT Focused Update

Trial	Patients (n)	Inclusion Criterion: LVEF	Endpoint	Endpoint p (95% CI)	Endpoint Hazard Ratio*
RAFT (2010)	1798; ICD alone group – 904 ICD-CRT group – 894	30% or less	Death from any cause or hospitalization for HF	p=0.003 (0.62-0.91)	0.75
MADIT-CRT (2009)	1820; CRT-ICD group – 1089 ICD group – 731	30% or less	Death from any cause or a non-fatal HF	p=0.001 (0.52-0.84)	0.66
REVERSE (2008)	610; CRT on – 419 CRT off – 191	40% or less	HF clinical composite response (scored as improved, unchanged or worsened)	p=0.10 (N/A)	N/A

* Hazard ratios for death from any cause in the ICD-CRT group compared with the ICD group.
CI indicates confidence interval; CRT, cardiac resynchronization therapy; HF, heart failure; ICD, implantable cardioverter-defibrillator; LVEF, left ventricular ejection fraction; MADIT-CRT, Multicenter automatic defibrillator implantation trial-cardiac resynchronization therapy; N/A, not available; RAFT, Resynchronization-defibrillation for ambulatory heart failure trial; and REVERSE, Resynchronization reverses remodeling in systolic left ventricular dysfunction.

- Tang ASL, Wells GA, Talajic M, et al. Cardiac-resynchronization therapy for mild-to-moderate heart failure. N Engl J Med. 2010;363:2385–95.
- Moss AJ, Hall WJ, Cannom DS, et al. Cardiac-resynchronization therapy for the prevention of heart-failure events. N Engl J Med. 2009;361:1329–38.
- Linde C, Abraham WT, Gold MR, et al. Randomized trial of cardiac resynchronization in mildly symptomatic heart failure patients and in asymptomatic patients with left ventricular dysfunction and previous heart failure symptoms. J Am Coll Cardiol. 2008;52:1834–43.

RAFT

Trail Name and Year	N (total)	Inclusion and Exclusion criteria	Primary Endpoints	Results
RAFT (2010)	1798 patients with NYHA class II or III, wide QRS complex, and left ventricular systolic dysfunction; ICD alone group - 904 ICD-CRT group - 894.	Inclusion: NHYA class II or III, with a LVEF of 30% or less, an intrinsic QRS duration of 120 msec or more or a paced QRS duration of 200 msec or more, sinus rhythm or permanent atrial fibrillation or flutter with a controlled ventricular rate (≤60 bpm at rest and ≤90 bpm during a 6-minute walk test) or planned atrioventricular-junction ablation after device implantation), and planned ICD implantation for indicated primary or secondary prevention of sudden cardiac death. Protocol revised in 2006 to include NYHA class II only. Exclusion: Patients with a major coexisting illness or a recent cardiovascular event.	Death from any cause or hospitalization for HF.	Primary endpoint: 297 of 894 (33.2%) ICD–CRT group and 364 of 904 (40.3%) group (ICD–CRT group HR: 0.75; 95% CI: 0.64 to 0.87; p<0.001). Death: 186 ICD–CRT group, and 236 ICD group (HR: 0.75; 95% CI: 0.62 to 0.91; p=0.003). Hospitalizations: 174 ICD–CRT group and 236 ICD group (HR: 0.68; 95% CI: 0.56 to 0.83; p<0.001).

* Hazard ratios for death from any cause in the ICD-CRT group compared with the ICD group.
CI indicates confidence interval; CRT, cardiac resynchronization therapy; HF, heart failure; HR, hazard ratio, ICD, implantable cardioverter-defibrillator; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; and RAFT, Resynchronization-defibrillation for ambulatory heart failure trial.

Tang ASL, Wells GA, Talajic M, et al. Cardiac-resynchronization therapy for mild-to-moderate heart failure. N Engl J Med. 2010;363:2385–95.

MADIT CRT

Trail Name and Year	N (total)	Inclusion and Exclusion criteria	Primary Endpoints	Results
MADIT-CRT (2009)	1820 patients with ischemic or nonischemic cardiomyopathy, an ejection fraction of 30% or less, a QRS duration of 130 msec or more, and NYHA class I or II symptoms CRT–ICD group 1089 patients and ICD group 731 patients.	Inclusion criteria: 21 years of age or older with ischemic cardiomyopathy (NYHA class I or II) or nonischemic cardiomyopathy (NYHA class II only), sinus rhythm, an ejection fraction of 30% or less, and prolonged intraventricular conduction with a QRS duration of 130 msec or more. Exclusion criteria included an existing indication for CRT; implanted pacemaker, ICD, or resynchronization device; NYHA class III or IV symptoms, previous coronary-artery bypass grafting, percutaneous coronary intervention, or an enzyme-positive myocardial infarction within 3 months before enrollment; and atrial fibrillation within 1 month before enrollment.	Death from any cause or a nonfatal HF event.	Primary end point: CRT–ICD group 187 of 1089 (17.2%) patients and in the ICD-only group (25.3%) 185 of 731 patients. In the CRT–ICD group HR: 0.66; 95% CI: 0.52 to 0.84; p=0.001.

CI indicates confidence interval; CRT, cardiac resynchronization therapy; HF, heart failure; HR, hazard ratio, ICD, implantable cardioverter-defibrillator; LVEF, left ventricular ejection fraction; MADIT-CRT, Multicenter automatic defibrillator implantation trial-cardiac resynchronization therapy; and NYHA, New York Heart Association.

Moss AJ, Hall WJ, Cannom DS, et al. Cardiac-resynchronization therapy for the prevention of heart-failure events. N Engl J Med. 2009;361:1329–38

REVERSE

Trail Name and Year	N (total)	Inclusion and Exclusion criteria	Primary Endpoints	Results
REVERSE (2008)	610 patients with NYHA functional class I or II heart failure with a QRS ≥120 ms and a LV ejection fraction ≤40% received a CRT device (+defibrillator) ; 419 CRT-ON and 191 CRT-OFF.	Inclusion criteria: Stable NYHA I with current ACC/AHA stage C or NYHA II, ability to receive a pectoral implant, QRS duration ≥120 ms at baseline or within the 30 d before enrollment, LVEF ≤0.40 confirmed at the baseline echocardiography, LVEDD ≥55 mm or LVEDD index ≥2.8 cm/m2 confirmed by baseline echocardiography, stable optimal medical regimen including ACE-inhibition and beta blockers, and patients with an indication for an ICD. Exclusion criteria: ≤18 y of age, pregnancy, NYHA class III or IV ≤3 m before enrollment, chronic or persistent atrial arrhythmias ≤1 mo before enrollment, enrollment in concurrent study, life expectancy ≤12 mo, indication for permanent cardiac pacing or previous pacemaker, previous ICD unless lifetime counters indicate <5% ventricular and atrial pacing, mechanical right heart valve, unstable angina, acute MI, CABG, or PTCA ≤3 m before enrollment, primary valvular disease and indication for valve repair or replacement, previous heart transplant, serum creatinine level ≥3.0 mg/dL, significant hepatic dysfunction, and or chronic or treatment resistant anemia (hemoglobin level ≤10.0 g/dL).	HF clinical composite response, which scores patients as improved, unchanged, or worsened.	In CRT-ON 16% worsened compared with 21% in CRT-OFF (p=0.10).

ACE-inhibition indicates angiotensin-converting-enzyme inhibition; CABG, coronary-artery bypass grafting; CRT, cardiac resynchronization therapy; HF, heart failure; HR, hazard ratio, ICD, implantable cardioverter-defibrillator; LVEDD- left-ventricular end-diastolic diameter; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NYHA, New York Heart Association; PCTA, percutaneous transluminal coronary angioplasty; and REVERSE, Resynchronization reverses remodeling in systolic left ventricular dysfunction.

Linde C, Abraham WT, Gold MR, et al. Randomized trial of cardiac resynchronization in mildly symptomatic heart failure patients and in asymptomatic patients with left ventricular dysfunction and previous heart failure symptoms. J Am Coll Cardiol. 2008;52:1834–43.