Guideline Title


Bibliographic Source(s)


Guideline Status

This is the current release of the guideline.


Recommendations

Major Recommendations

Definitions for the level of evidence (A-C) and classification of recommendations (I-III) are provided at the end of the "Major Recommendations" field.

Note from the National Guideline Clearinghouse (NGC) and the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) Task Force on Practice Guidelines: In 2012, the ACCF/AHA Task Force performed a focused update of the 2008 guidelines for device-based therapy of cardiac rhythm abnormalities to revise existing guideline recommendations that are affected by evolving data or opinion. The updated recommendations are presented below, along with the original 2008 recommendations. Sections affected by the focused
update are labeled "2012 Focused Update." All other recommendations remain current in their 2008 form.

Indications for Pacing

Recommendations for Permanent Pacing in Sinus Node Dysfunction (SND)

**Class I**

1. Permanent pacemaker implantation is indicated for SND with documented symptomatic bradycardia, including frequent sinus pauses that produce symptoms (Kay, Estioko, & Wiener, 1982; Kusumoto & Goldschlager, 1996; Rasmussen, 1981). (Level of Evidence: C)

2. Permanent pacemaker implantation is indicated for symptomatic chronotropic incompetence (Kay, Estioko, & Wiener, 1982; Kusumoto & Goldschlager, 1996; Rasmussen, 1981; Linde-Edelstam et al., 1992; Gammage et al., 1991). (Level of Evidence: C)

3. Permanent pacemaker implantation is indicated for symptomatic sinus bradycardia that results from required drug therapy for medical conditions. (Level of Evidence: C)

**Class IIa**

1. Permanent pacemaker implantation is reasonable for SND with heart rate less than 40 beats per minute (bpm) when a clear association between significant symptoms consistent with bradycardia and the actual presence of bradycardia has not been documented (Kay, Estioko, & Wiener, 1982; Rasmussen, 1981; Shaw, Holman, & Gowers, 1980; Dreifus, Michelson, & Kaplinsky, 1983; Rubenstein et al., 1972). (Level of Evidence: C)

2. 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 (Fisher, 1981; Reiffel & Kuehnert, 1994). (Level of Evidence: C)

**Class IIb**

1. Permanent pacemaker implantation may be considered in minimally symptomatic patients with chronic heart rate less than 40 bpm while awake (Kay, Estioko, & Wiener, 1982; Rasmussen, 1981; Linde-Edelstam et al., 1992; Shaw, Holman, & Gowers, 1980; Dreifus, Michelson, & Kaplinsky, 1983; Rubenstein et al., 1972). (Level of Evidence: C)

**Class III**

1. Permanent pacemaker implantation is not indicated for SND in asymptomatic patients. (Level of Evidence: C)

2. 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. (Level of Evidence: C)

3. Permanent pacemaker implantation is not indicated for SND with symptomatic bradycardia due to nonessential drug therapy. (Level of Evidence: C)

Recommendations for Acquired Atrioventricular (AV) Block in Adults

**Class I**

1. Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level associated with bradycardia with symptoms (including heart failure) or ventricular arrhythmias presumed to be due to AV block (Dreifus, Michelson, & Kaplinsky, 1983; Friedberg, Donoso, & Stein, 1964; "Recommendations for pacemaker prescription," 1991; Kastor, 1975). (Level of Evidence: C)

2. 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 (Dreifus, Michelson, & Kaplinsky, 1983; Friedberg, Donoso, & Stein, 1964; "Recommendations for pacemaker prescription," 1991; Kastor, 1975). (Level of Evidence: C)

3. 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 (Ector, Rolies, & De Geest, 1983) or any escape rate less than 40 bpm, or with an escape rhythm that is below the AV node (Kay, Estioko, & Wiener, 1982; Shaw, Holman, & Gowers, 1980). (Level of Evidence: C)

4. 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. (Level of Evidence: C)

5. 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 (Gallagher et al., 1982; Langberg et al., 1989). (Level of Evidence: C)
6. 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 (Kim et al., 2001; Kastor, 1975; Gilks et al., 1997; Kaplan et al., 2003). (Level of Evidence: C)

7. 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, Erb dystrophy (limb-girdle muscular dystrophy), and peroneal muscular atrophy, with or without symptoms (Perloff et al., 1984; Hiromasa et al., 1987; Stevenson et al., 1990; James & Fisch, 1963; Roberts, Perloff, & Kark, 1979; Charles et al., 1981; James, 1962). (Level of Evidence: B)

8. Permanent pacemaker implantation is indicated for second-degree AV block with associated symptomatic bradycardia regardless of type or site of block (Strasberg et al., 1981). (Level of Evidence: B)

9. 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 ("Recommendations for pacemaker prescription," 1981; Shaw et al., 1985). (Level of Evidence: B)

10. Permanent pacemaker implantation is indicated for second- or third-degree AV block during exercise in the absence of myocardial ischemia (Chokshi et al., 1990; Barold & Magica, 1991). (Level of Evidence: C)

Class IIa

1. 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 (Dreifus, Michelson, & Kaplinsky et al., 1983; Friedberg, Donoso, & Stein, 1964; Gadboys, Wisoff, & Litwak, 1964; "Recommendations for pacemaker prescription," 1991; Barold & Magica, 1991; Kastor, 1975). (Level of Evidence: C)

2. Permanent pacemaker implantation is reasonable for asymptomatic second-degree AV block at intra- or infra-His levels found at electrophysiological study (Strasberg et al., 1981; "Recommendations for pacemaker prescription," 1991; Shaw et al., 1985). (Level of Evidence: B)

3. Permanent pacemaker implantation is reasonable for first- or second-degree AV block with symptoms similar to those of pacemaker syndrome or hemodynamic compromise (Barold, 1996; Kim et al., 1993). (Level of Evidence: B)

4. 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," in the original guideline document) (Barold, 1996; "Recommendations for pacemaker prescription," 1991; Zipes, 1979; Kastor, 1975). (Level of Evidence: B)

Class IIb

1. 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 (Perloff et al., 1984; Hiromasa et al., 1987; Stevenson et al., 1990; James & Fisch, 1963; Roberts, Perloff, & Kark, 1979; Charles et al., 1981; James, 1962). (Level of Evidence: B)

2. 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 (Zeltser et al., 2004; Shohat-Zabarski et al., 2004). (Level of Evidence: B)

Class III

1. Permanent pacemaker implantation is not indicated for asymptomatic first-degree AV block (see Section 2.1.3, "Chronic Bifascicular Block," in the original guideline document) (Mymin et al., 1986). (Level of Evidence: B)

2. 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 (Strasberg et al., 1981). (Level of Evidence: C)

3. Permanent pacemaker implantation is not indicated for AV block that is expected to resolve and is unlikely to recur (McAlister et al., 1989) (e.g., drug toxicity, Lyme disease, or transient increases in vagal tone or during hypoxia in sleep apnea syndrome in the absence of symptoms) (Shohat-Zabarski et al., 2004; McAlister et al., 1989). (Level of Evidence: B)

Recommendations for Permanent Pacing in Chronic Bifascicular Block

Class I

2. Permanent pacemaker implantation is indicated for type II second-degree AV block (Dhingra et al., "The significance," 1974; Donoso, Adler, & Friedberg, 1964; Ranganathan et al., 1972; Dhingra et al., "Syncope," 1974). (Level of Evidence: B)

3. Permanent pacemaker implantation is indicated for alternating bundle-branch block (Josephson, 1993). (Level of Evidence: C)

Class IIa

1. 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) (Fisch, Zipes, & Fisch, 1980; McAnulty et al., 1982; Kubertus & Collignon, 1969; DePasquale & Bruno, 1973; Denes et al., 1977; McAnulty et al., 1978; Peters et al., 1979; Scheinman et al., 1982; Morady et al., 1984; Click et al., 1987; Ezi et al., 1983; Twidale et al., 1988; Englund et al., 1995; Scheinman et al., 1977; Probst et al., 1979; Dhingra et al., 1979; Cheng, 1971; Dhingra et al., "Syncope," 1974; Brignole et al., 2001). (Level of Evidence: B)

2. 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 (Scheinman et al., 1982). (Level of Evidence: B)

3. Permanent pacemaker implantation is reasonable for an incidental finding at electrophysiological study of pacing-induced infra-His block that is not physiological (Dhingra et al., 1979). (Level of Evidence: B)

Class IIb

1. 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 (Perloff et al., 1984; Hiromasa et al., 1987; Stevenson et al., 1990; James & Fisch, 1963; Roberts, Perloff, & Kark, 1979; Charles et al., 1981; James, 1962). (Level of Evidence: C)

Class III

1. Permanent pacemaker implantation is not indicated for fascicular block without AV block or symptoms (McAnulty et al., 1982; McAnulty et al., 1978; Scheinman et al., 1982; Scheinman et al., 1977). (Level of Evidence: B)

2. Permanent pacemaker implantation is not indicated for fascicular block with first-degree AV block without symptoms (McAnulty et al., 1982; McAnulty et al., 1978; Scheinman et al., 1982; Scheinman et al., 1977). (Level of Evidence: B)

Recommendations for Permanent Pacing After the Acute Phase of Myocardial Infarction (MI)*

Class I

1. 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 (Ranganathan et al., 1972; Col & Weinberg, 1972; Ritter et al., 1976; Ginks et al., 1977; Domenighetti & Perret, 1980; Lamas et al., 1986). (Level of Evidence: B)

2. 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 (Col & Weinberg, 1972; Ritter et al., 1976). (Level of Evidence: B)

3. Permanent ventricular pacing is indicated for persistent and symptomatic second- or third-degree AV block. (Level of Evidence: C)

Class IIb

1. 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 (Shaw, Holman, & Gowers, 1980). (Level of Evidence: B)

Class III

1. Permanent ventricular pacing is not indicated for transient AV block in the absence of intraventricular conduction defects (Col & Weinberg, 1972). (Level of Evidence: B)

2. Permanent ventricular pacing is not indicated for transient AV block in the presence of isolated left anterior fascicular block (Ginks et al., 1977). (Level of Evidence: B)

3. Permanent ventricular pacing is not indicated for new bundle branch block or fascicular block in the absence of AV block (Hindman et al., 1978; Col & Weinberg, 1972). (Level of Evidence: B)

4. Permanent ventricular pacing is not indicated for persistent asymptomatic first-degree AV block in the presence of bundle branch or fascicular block (Col & Weinberg, 1972). (Level of Evidence: B)

*These recommendations are consistent with the "American College of Cardiology (ACC)/AHA Guidelines for the Management of Patients with ST-Elevation Myocardial Infarction"
Antman et al., 2004.

Recommendations for Permanent Pacing in Hypersensitive Carotid Sinus Syndrome and Neurocardiogenic Syncope

Class I

1. 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 (Brignole et al., 1992; Brignole et al., 1991). (Level of Evidence: C)

Class IIa

1. Permanent pacing is reasonable for syncope without clear, provocative events and with a hypersensitive cardioinhibitory response of 3 seconds or longer (Brignole et al., 1992). (Level of Evidence: C)

Class IIb

1. Permanent pacing may be considered for significantly symptomatic neurocardiogenic syncope associated with bradycardia documented spontaneously or at the time of tilt-table testing (Sutton et al., 2000; Ammirati, Colivicchi, & Santini, 2001; Connolly et al., 2003; Sheldon et al., 1998). (Level of Evidence: B)

Class III

1. Permanent pacing is not indicated for a hypersensitive cardioinhibitory response to carotid sinus stimulation without symptoms or with vague symptoms. (Level of Evidence: C)

2. Permanent pacing is not indicated for situational vasovagal syncope in which avoidance behavior is effective and preferred. (Level of Evidence: C)

Recommendations for Pacing After Cardiac Transplantation

Class I

1. Permanent pacing is indicated for persistent inappropriate or symptomatic bradycardia not expected to resolve and for other Class I indications for permanent pacing. (Level of Evidence: C)

Class IIb

1. Permanent pacing may be considered when relative bradycardia is prolonged or recurrent, which limits rehabilitation or discharge after postoperative recovery from cardiac transplantation. (Level of Evidence: C)

2. Permanent pacing may be considered for syncope after cardiac transplantation even when bradyarrhythmia has not been documented. (Level of Evidence: C)

Recommendations for Permanent Pacemakers That Automatically Detect and Pace to Terminate Tachycardias

Class IIa

1. Permanent pacing is reasonable for symptomatic recurrent supraventricular tachycardia (SVT) that is reproducibly terminated by pacing when catheter ablation and/or drugs fail to control the arrhythmia or produce intolerable side effects (Peters et al., 1985; Fisher et al., "Long-term efficacy," 1987; Den Dulk et al., 1984; Saksena et al., 1986; Barold et al., 1987). (Level of Evidence: C)

Class III

1. Permanent pacing is not indicated in the presence of an accessory pathway that has the capacity for rapid anterograde conduction. (Level of Evidence: C)

Recommendations for Pacing to Prevent Tachycardia

Class I

1. Permanent pacing is indicated for sustained pause-dependent VT, with or without QT prolongation (Eldar et al., 1987; Eldar et al., 1992). (Level of Evidence: C)

Class IIa
1. Permanent pacing is reasonable for high-risk patients with congenital long-QT syndrome (Eldar et al., 1987; Eldar et al., 1992). (Level of Evidence: C)

**Class IIb**

1. Permanent pacing may be considered for prevention of symptomatic, drug-refractory, recurrent AF in patients with coexisting SND (Lamas et al., 2000; Saksena et al., 1996; Saksena et al., 1998). (Level of Evidence: B)

**Class III**

1. Permanent pacing is not indicated for frequent or complex ventricular ectopic activity without sustained VT in the absence of the long-QT syndrome (Fisher et al., "Antiarhythmic effects,” 1987). (Level of Evidence: C)
2. Permanent pacing is not indicated for torsade de pointes VT due to reversible causes (Moss & Robinson, 1992; Viskin et al., 1996). (Level of Evidence: A)

Recommendation for Pacing to Prevent Atrial Fibrillation

**Class III**

1. Permanent pacing is not indicated for the prevention of AF in patients without any other indication for pacemaker implantation (Knight et al., 2005). (Level of Evidence: B)

Recommendations for Cardiac Resynchronization Therapy (CRT) (Updated)

See "Indications for CRT Therapy–Algorithm" in Appendix 6 of the original guideline document.

**Class I**

1. CRT is indicated for patients who have left ventricular ejection fraction (LVEF) less than or equal to 35%, sinus rhythm, left bundle-branch block (LBBB) with a QRS duration greater than or equal to 150 ms, and New York Heart Association (NYHA) class II (Moss et al., 2009; Tang et al., 2010), III, or ambulatory IV (Abraham et al., 2002; Bristow et al., 2004; Cleland et al., 2005; Goldstein et al., 2004) symptoms on guideline-directed medical therapy (GDMT). (Level of Evidence: A for NYHA class III/IV; Level of Evidence: B for NYHA class II)

**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 (Abraham et al., 2002; Bristow et al., 2004; Cleland et al., 2005; Moss et al., 2009; Tang et al., 2010; Linde et al., 2008). (Level of Evidence: B)
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 (Abraham et al., 2002; Bristow et al., 2004; Cleland et al., 2005; Tang et al., 2010). (Level of Evidence: A)
3. CRT can be used 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 (Brignole et al., 2005; Brignole et al., 2011; Doshi et al., 2005; Gasparini et al., 2006; Wilton et al., 2011; Upadhyay et al., 2008). (Level of Evidence: 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 (Doshi et al., 2005; Wilkoff et al., 2002; Adelstein et al., 2011; Vatankulu et al., 2009). (Level of Evidence: C)

**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 (Moss et al., 2009; Tang et al., 2010). (Level of Evidence: C)
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 (Tang et al., 2010; Rickard et al., 2011). (Level of Evidence: B)
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 (Moss et al., 2009; Tang et al., 2010). (Level of Evidence: B)
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 (Moss et al., 2009; Tang et al., 2010; Rickard et al., 2011). (Level of Evidence: B)

2. CRT is not indicated for patients whose comorbidities and/or frailty limit survival with good functional capacity to less than 1 year (Goldstein et al., 2004). (Level of Evidence: C)

Recommendations for Pacing in Patients with Hypertrophic Cardiomyopathy (HCM)

Class I

1. Permanent pacing is indicated for SND or AV block in patients with HCM as described previously (see Section 2.1.1, "Sinus Node Dysfunction," and Section 2.1.2, "Acquired Atrioventricular Block in Adults" in the original guideline document). (Level of Evidence: C)

Class IIa

1. Permanent pacing may be considered in medically refractory symptomatic patients with HCM and significant resting or provoked LV outflow tract obstruction. (Level of Evidence: A) As for Class I indications, when risk factors for sudden cardiac death (SCD) are present, consider a DDD (dual-chamber pacemaker that senses/paces in the atrium/ventricle and is inhibited/triggered by intrinsic rhythm) implantable cardioverter-defibrillator (ICD) (see Section 3, "Indications for Implantable Cardioverter-Defibrillator Therapy," in the original guideline document) (Famanapazir et al., 1994; Nishimura et al., 1997; Kappenberger et al., 1997; Maron et al., 1999; Nishimura et al., "Effect," 1996; Nishimura et al., "Dual-chamber," 1996).

Class III

1. Permanent pacemaker implantation is not indicated for patients who are asymptomatic or whose symptoms are medically controlled. (Level of Evidence: C)

2. Permanent pacemaker implantation is not indicated for symptomatic patients without evidence of LV outflow tract obstruction. (Level of Evidence: C)

Recommendations for Permanent Pacing in Children, Adolescents, and Patients with Congenital Heart Disease

Class I

1. Permanent pacemaker implantation is indicated for advanced second- or third-degree AV block associated with symptomatic bradycardia, ventricular dysfunction, or low cardiac output. (Level of Evidence: C)

2. 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 (Kay, Estioko, & Wiener, 1982; Ector, Rolies, & De Geest, 1983; Beder et al., 1983; Kelly et al., 2001). (Level of Evidence: C)

3. 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 (Strasberg et al., 1981; Lillehei et al., 1963). (Level of Evidence: B)

4. Permanent pacemaker implantation is indicated for congenital third-degree AV block with a wide QRS escape rhythm, complex ventricular ectopy, or ventricular dysfunction (Michaelsson, Jonzon, & Riesenfield, 1995; Moak et al., 2001; Villain et al., 2006). (Level of Evidence: B)

5. 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 (Pinsky et al., 1982; Jaeggi et al., 2002). (Level of Evidence: C)

Class IIa

1. 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 (Silka et al., 1990; Stephenson et al., 2003; Pfammatter et al., 1995). (Level of Evidence: C)

2. 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 (Dewey, Capeless, & Levy, 1987; Sholler & Walsh, 1989). (Level of Evidence: B)

3. 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 longer than 3 seconds. (Level of Evidence: C)

4. Permanent pacemaker implantation is reasonable for patients with congenital heart disease and impaired hemodynamics due to sinus bradycardia or loss of AV synchrony (Cohen et al., 2001). (Level of Evidence: C)
5. 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 (Villain et al., 2006; Banks, Jenson, & Kugler, 2001; Gross et al., 2006; Villain et al., 2003). (Level of Evidence: B)

Class IIb

1. Permanent pacemaker implantation may be considered for transient postoperative third-degree AV block that reverts to sinus rhythm with residual bifascicular block (Krongrad, 1978). (Level of Evidence: C)

2. 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 (Sholler & Walsh, 1989; Michaelsson, Jonzon, & Riesenfeld, 1995). (Level of Evidence: B)

3. 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 longer than 3 seconds. (Level of Evidence: C)

Class III

1. Permanent pacemaker implantation is not indicated for transient postoperative AV block with return of normal AV conduction in the otherwise asymptomatic patient (Weindling et al., 1998; Krongrad, 1978). (Level of Evidence: B)

2. 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. (Level of Evidence: C)

3. Permanent pacemaker implantation is not indicated for asymptomatic type I second-degree AV block. (Level of Evidence: C)

4. 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. (Level of Evidence: C)

Indications for ICD Therapy

Recommendations for ICDs

Class I

1. ICD therapy is indicated in patients who are survivors of cardiac arrest due to ventricular fibrillation (VF) or hemodynamically unstable sustained VT after evaluation to define the cause of the event and to exclude any completely reversible causes (European Heart Rhythm Association et al., 2006; "A comparison of antiarrhythmic-drug therapy," 1997; Weyer et al., 1995; Siebels & Kuck, 1994; Connolly et al., "Canadian," 2000; Kuck et al., 2000; Connolly et al., "Meta-analysis," 2000). (Level of Evidence: A)


3. ICD therapy is indicated in patients with syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or VF induced at electrophysiological study (European Heart Rhythm Association et al., 2006; Connolly et al., "Canadian," 2000). (Level of Evidence: B)

4. ICD therapy is indicated in patients with LVEF less than 35% due to prior MI who are at least 40 days post-MI and are in NYHA functional Class II or III (European Heart Rhythm Association et al., 2006; Bardy et al., 2005). (Level of Evidence: A)

5. ICD therapy is indicated in patients with nonischemic dilated cardiomyopathy (DCM) who have an LVEF less than or equal to 35% and who are in NYHA functional Class II or III (European Heart Rhythm Association et al., 2006; Bardy et al., 2005; Kadish et al., 2004; Desai et al., 2004). (Level of Evidence: B)

6. 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 30%, and are in NYHA functional Class I (European Heart Rhythm Association et al., 2006; Moss et al., 2002). (Level of Evidence: A)

7. ICD therapy is indicated in patients with nonsustained VT due to prior myocardial infarction (MI), LVEF less than 40%, and inducible VF or sustained VT at electrophysiological study (European Heart Rhythm Association et al., 2006; Moss et al., 1996; Buxton et al., 1999). (Level of Evidence: B)

Class IIa

1. ICD implantation is reasonable for patients with unexplained syncope, significant LV dysfunction, and nonischemic DCM. (Level of Evidence: C)

2. ICD implantation is reasonable for patients with sustained VT and normal or near-normal ventricular function. (Level of Evidence: C)
3. ICD implantation is reasonable for patients with HCM who have 1 or more major risk factors for SCD (see Section 3.2.4, "Hypertrophic Cardiomyopathy," in the original guideline document for definition of major risk factors). (Level of Evidence: C)

4. ICD implantation is reasonable for the prevention of SCD in patients with ARVD/C who have 1 or more risk factors for SCD. (Level of Evidence: C)

5. ICD implantation is reasonable to reduce SCD in patients with long-QT syndrome who are experiencing syncope and/or VT while receiving beta blockers (Zareba et al., 2003; Viskin, 2003; Goel et al., 2004; Monnig et al., 2005; Goldenberg et al., 2006; Hobbs et al., 2006). (Level of Evidence: B)

6. ICD implantation is reasonable for nonhospitalized patients awaiting transplantation. (Level of Evidence: C)

7. ICD implantation is reasonable for patients with Brugada syndrome who have documented VT that has not resulted in cardiac arrest. (Level of Evidence: C)

8. ICD implantation is reasonable for patients with catecholaminergic polymorphic VT who have syncope and/or documented sustained VT while receiving beta blockers. (Level of Evidence: C)

9. ICD implantation is reasonable for patients with cardiac sarcoidosis, giant cell myocarditis, or Chagas disease. (Level of Evidence: C)

Class IIb

1. 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. (Level of Evidence: C)

2. ICD therapy may be considered for patients with long-QT syndrome and risk factors for SCD (European Heart Rhythm Association et al., 2006; Zareba et al., 2003; Viskin, 2003; Goel et al., 2004; Monnig et al., 2005; Goldenberg et al., 2006; Hobbs et al., 2006). (Level of Evidence: B)

3. 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. (Level of Evidence: C)

4. ICD therapy may be considered in patients with a familial cardiomyopathy associated with sudden death. (Level of Evidence: C)

5. ICD therapy may be considered in patients with LV noncompaction. (Level of Evidence: C)

Class III

1. 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. (Level of Evidence: C)

2. ICD therapy is not indicated for patients with incessant VT or VF. (Level of Evidence: C)

3. 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. (Level of Evidence: C)

4. ICD therapy is not indicated for NYHA Class IV patients with drug-refractory congestive heart failure who are not candidates for cardiac transplantation or CRT-D. (Level of Evidence: C)

5. ICD therapy is not indicated for syncope of undetermined cause in a patient without inducible ventricular tachyarrhythmias and without structural heart disease. (Level of Evidence: C)

6. 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). (Level of Evidence: C)

7. 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) (European Heart Rhythm Association et al., 2006). (Level of Evidence: B)

Recommendations for ICDs in Pediatric Patients and Patients with Congenital Heart Disease

Class I

1. ICD implantation is indicated in the survivor of cardiac arrest after evaluation to define the cause of the event and to exclude any reversible causes (Silka et al., 1993; Hamilton et al., 1996; Alexander et al., 2004; Choi, Porter, & Ackerman, 2004). (Level of Evidence: B)

2. 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 (Karamlou et al., 2006). (Level of Evidence: C)

Class IIa
1. 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 (Muslin et al., 1998; Khairy et al., 2004). (Level of Evidence: B)

**Class IIb**

1. 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 (Kammenaad et al., 2004; Dubin et al., 2003). (Level of Evidence: C)

**Class III**

1. All Class III recommendations found in Section 3, “Indications for Implantable Cardioverter-Defibrillator Therapy,” in the original guideline document apply to pediatric patients and patients with congenital heart disease, and ICD implantation is not indicated in these patient populations. (Level of Evidence: C)

**Definitions:**

**Applying Classification of Recommendations and Level of Evidence**

<table>
<thead>
<tr>
<th>Size of Treatment Effect</th>
<th>CLASS I</th>
<th>CLASS IIa</th>
<th>CLASS IIb</th>
<th>CLASS III No Benefit or Class III Harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure/Treatment</td>
<td>Benefit &gt;&gt; Risk</td>
<td>Procedure/Treatment</td>
<td>Benefit ≥ Risk</td>
<td>Procedure/Treatment</td>
</tr>
<tr>
<td>SHOULD be performed/</td>
<td></td>
<td>IT IS REASONABLE</td>
<td>Additional studies with focused objectives needed</td>
<td>MAY BE CONSIDERED</td>
</tr>
<tr>
<td>administered</td>
<td></td>
<td>to perform</td>
<td>or multiple randomized or meta-analyses</td>
<td>Procedure/Treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>procedure/administer treatment</td>
<td>or meta-analyses</td>
<td>or nonrandomized studies</td>
</tr>
</tbody>
</table>

**Estimate of Certainty (Precision) of Treatment Effect**

<table>
<thead>
<tr>
<th>LEVEL A</th>
<th>Recommendation that procedure or treatment is useful/effective</th>
<th>Recommendation in favor of procedure or treatment being useful/effective</th>
<th>Recommendation’s usefulness/efficacy less well established</th>
<th>Recommendation that procedure or treatment is not useful/effective and may be harmful</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple populations</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>evaluated*</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Data derived from multiple randomized clinical trials or meta-analyses</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>LEVEL B</th>
<th>Recommendation that procedure or treatment is useful/effective</th>
<th>Recommendation in favor of procedure or treatment being useful/effective</th>
<th>Recommendation’s usefulness/efficacy less well established</th>
<th>Recommendation that procedure or treatment is not useful/effective and may be harmful</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limited populations</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>evaluated*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data derived from single randomized clinical trials or nonrandomized studies</td>
<td></td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LEVEL C</th>
<th>Recommendation that procedure or treatment is useful/effective</th>
<th>Recommendation in favor of procedure or treatment being useful/effective</th>
<th>Recommendation’s usefulness/efficacy less well established</th>
<th>Recommendation that procedure or treatment is not useful/effective and may be harmful</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very limited populations</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>evaluated*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Only consensus opinion of experts, case studies, or standard of care</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 gender, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

**Clinical Algorithm(s)**

The following algorithms are provided in the original guideline document:

- Selection of Pacemaker Systems for Patients with Atrioventricular Block
- Selection of Pacemaker Systems for Patients with Sinus Node Dysfunction
- 2012 Indications for Cardiac Resynchronization Therapy (CRT) (Appendix 6)
Scope

Disease/Condition(s)
Cardiac rhythm abnormalities requiring cardiac pacemakers or implantable cardioverter-defibrillator (ICD) devices, including:

- Sinus node dysfunction
- Acquired atrioventricular (AV) block
- Chronic bifascicular block
- AV block following acute myocardial infarction
- Hypersensitive carotid sinus syndrome
- Neurocardiogenic syncope
- Bradycardia or syncope following cardiac transplantation
- Arrhythmias associated with neuromuscular diseases, sleep apnea syndrome or cardiac sarcoidosis
- Long-QT syndrome
- Tachycardias
- Atrial fibrillation
- Severe systolic heart failure
- Hypertrophic cardiomyopathy
- Congenital heart disease

Guideline Category
Management
Prevention
Treatment

Clinical Specialty
Cardiology
Geriatrics
Internal Medicine
Pediatrics
Thoracic Surgery

Intended Users
Physicians

Guideline Objective(s)
- To revise the existing guideline recommendations that are affected by evolving data or opinion
- To update the 2008 recommendations for device-based therapy of cardiac rhythm abnormalities

Target Population
Children, adolescents, and adults in need of permanent cardiac pacemaker and/or implantable cardioverter-defibrillator (ICD) insertion to restore
normal cardiac rhythm or prevent life-threatening cardiac arrhythmias

Interventions and Practices Considered

1. Permanent cardiac pacemaker insertion
2. Implantable cardioverter-defibrillator (ICD) therapy

Note: The writing committee considered the advisability of extending the scope of these guidelines to include recommendations for follow-up and device replacement but deferred this decision given other published statements and guidelines on this topic. These are addressed in the original guideline document as a matter of information; however, no endorsement is implied.

Major Outcomes Considered

Subjective and objective symptom improvement
Quality of life
Functional status
New York Heart Association functional classification
Exercise capacity
Patient adherence
Heart failure end points
Atrial fibrillation end points
Stroke or thromboembolism end points
Rates of inappropriate implantable cardioverter-defibrillator detections and therapies
Sudden cardiac death
All-cause mortality

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

2008 Guideline
An extensive literature survey was conducted that led to the incorporation of 527 references. Searches were limited to studies, reviews, and other evidence conducted in human subjects and published in English. Key search words included but were not limited to antiarrhythmic, antibradycardia, atrial fibrillation, bradyarrhythmia, cardiac, cardiac resynchronization therapy (CRT), defibrillator, device therapy, devices, dual chamber, heart, heart failure, implantable cardioverter-defibrillator (ICD), implantable defibrillator, device implantation, long-QT syndrome, medical therapy, pacemaker, pacing, quality-of-life, resynchronization, rhythm, sinus node dysfunction, sleep apnea, sudden cardiac death, syncope, tachyarrhythmia, terminal care, and transplantation. Additionally, the committee reviewed documents related to the subject matter previously published by the American College of Cardiology (ACC), American Heart Association (AHA), and Heart Rhythm Society (HRS). Searches were conducted from approximately 2005 through early 2008.

2012 Focused Update
The 2012 focused update is not intended to be based on a complete literature review from the date of the previous guideline publication but rather to include pivotal new evidence that may affect changes to current recommendations.
For the 2012 focused update, late-breaking clinical trials presented at the annual scientific meetings of the ACC, AHA, and HRS, and European Society of Cardiology (2008 through 2010), as well as other selected data reported through February 2012, were reviewed by the guideline writing group along with the Task Force and other experts to identify trials and other key data that might affect guideline recommendations. Studies relevant to the management of patients treated with device-based therapy (DBT) for cardiac rhythm abnormalities were identified and reviewed. On the basis of these data, the writing group determined that updates to the 2008 guideline were necessary for cardiac resynchronization therapy (CRT) and device follow-up. The writing group also thoroughly reviewed other sections from the 2008 DBT guideline on hypertrophic cardiomyopathy, arrhythmogenic right ventricular dysplasia/cardiomyopathy, genetic arrhythmia syndromes, congenital heart disease, primary electrical disease, and terminal care; and determined that although some new information may be available, the recommendations remain current.

An extensive literature survey was conducted that led to the incorporation of 595 references. Searches were limited to studies, reviews, and other evidence conducted in human subjects and published in English. Key search words included but were not limited to antiarrhythmic, antibradyarrhythmia, atrial fibrillation, bradyarrhythmia, cardiac, CRT, defibrillator, device therapy, devices, dual chamber, heart, heart failure, ICD, implantable defibrillator, device implantation, long-QT syndrome, medical therapy, pacemaker, pacing, quality-of-life, resynchronization, rhythm, sinus node dysfunction, sleep apnea, sudden cardiac death, syncope, tachyarrhythmia, terminal care, and transplantation. Additionally, the committee reviewed documents related to the subject matter previously published by the ACC, AHA, and HRS. References selected and published in this document are representative and not all-inclusive.

Number of Source Documents

2008 Guideline

The literature survey led to the incorporation of 527 references.

2012 Update

The literature survey led to the incorporation of 595 references.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Applying Classification of Recommendations and Level of Evidence

<table>
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<td>Benefit or Risk</td>
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<td>Recommendation in favor of treatment or procedure being useful/effective</td>
<td>Recommendation in favor of treatment or procedure being useful/effective</td>
<td>Recommendation's usefulness/effectiveness less well established</td>
</tr>
<tr>
<td></td>
<td>Sufficient evidence from multiple randomized trials or meta-analyses</td>
<td>Some conflicting evidence from multiple randomized trials or meta-analyses</td>
<td>Evidence from single randomized trial or nonrandomized studies</td>
<td>Evidence from single randomized trial or nonrandomized studies</td>
</tr>
<tr>
<td></td>
<td>Recommendation in favor of treatment or procedure being useful/effective</td>
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</tr>
</tbody>
</table>

Estimate of Certainty (Precision) of Treatment Effect

**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

**LEVEL B**

- Limited populations evaluated*
  - Data derived from single randomized clinical trials or nonrandomized studies

- Recommendation that procedure or treatment is useful/effective
- Evidence from single randomized trial or nonrandomized studies

**LEVEL C**

- Recommendation
- Recommendation in favor
- Recommendation's
- Recommendation that procedure
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 gender, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

2008 Guideline

Writing committees were specifically charged to perform a formal literature review, weigh the strength of evidence for or against a particular treatment or procedure, and include estimates of expected health outcomes where data exist. The committee reviewed and ranked evidence supporting current recommendations, with the weight of evidence ranked as Level A if the data were derived from multiple randomized clinical trials that involved a large number of individuals. The committee ranked available evidence as Level B when data were derived either from a limited number of trials that involved a comparatively small number of patients or from well-designed data analyses of nonrandomized studies or observational data registries. Evidence was ranked as Level C when the consensus of experts was the primary source of the recommendation. See the "Rating Scheme for the Strength of the Evidence" field.

2012 Focused Update

Writing committees are specifically charged to perform a literature review, weigh the strength of evidence for or against a particular treatment or procedure, and include estimates of expected health outcomes where data exist.

In analyzing the data and developing recommendations and supporting text, the focused update writing group uses evidence-based methodologies developed by the Task Force. The Class of Recommendation (COR) is an estimate of the size of the treatment effect, with consideration given to risks versus benefits, as well as evidence and/or agreement that a given treatment or procedure is or is not useful/effective and in some situations may cause harm. The Level of Evidence (LOE) is an estimate of the certainty or precision of the treatment effect. The writing group reviews and ranks evidence supporting each recommendation, with the weight of evidence ranked as LOE A, B, or C, according to specific definitions (see the "Rating Scheme for the Strength of the Evidence" field). Studies are identified as observational, retrospective, prospective, or randomized, as appropriate. For certain conditions for which inadequate data are available, recommendations are based on expert consensus and clinical experience and are ranked as LOE C. When recommendations at LOE C are supported by historical clinical data, appropriate references (including clinical reviews) are cited if available. For issues for which sparse data are available, a survey of current practice among the clinician members of the writing group is the basis for LOE C recommendations, and no references are cited. The schema for COR and LOE is summarized in the "Rating Scheme for the Strength of the Evidence" field. A new addition to this methodology for the 2012 focused update is separation of the Class III recommendations to delineate whether the recommendation is determined to be of "no benefit" or is associated with "harm" to the patient. (This version of the COR/LOE table was used for development of the 2012 Focused Update.)

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

2008 Guideline
Experts in the subject under consideration are selected from both organizations to examine subject-specific data and write guidelines. The process includes additional representatives from other medical practitioner specialty groups when appropriate. Writing committees are specifically charged to perform a literature review, weigh the strength of evidence for or against a particular treatment or procedure, and include estimates of expected health outcomes where data exist. Patient-specific modifiers, comorbidities, and issues of patient preference that may influence the choice of particular tests or therapies are considered as well as frequency of follow-up and cost-effectiveness.

In preparing this revision, the committee was guided by the following principles:

1. Changes in recommendations and levels of evidence were made either because of new randomized trials or because of the accumulation of new clinical evidence and the development of clinical consensus.
2. The committee was cognizant of the health care, logistic, and financial implications of recent trials and factored in these considerations to arrive at the classification of certain recommendations.
3. For recommendations taken from other guidelines, wording changes were made to render some of the original recommendations more precise.
4. The committee would like to reemphasize that the recommendations in this guideline apply to most patients but may require modification because of existing situations that only the primary treating physician can evaluate properly.
5. All of the listed recommendations for implantation of a device presume the absence of inciting causes that may be eliminated without detriment to the patient (e.g., nonessential drug therapy).
6. The committee endeavored to maintain consistency of recommendations in this and other previously published guidelines. In the section on atrioventricular (AV) block associated with acute myocardial infarction (AMI), the recommendations follow closely those in the "ACC/AHA Guidelines for the Management of Patients with ST-Elevation Myocardial Infarction". However, because of the rapid evolution of pacemaker/implantable cardioverter-defibrillator (ICD) science, it has not always been possible to maintain consistency with other published guidelines.

2012 Focused Update

Experts in the subject under consideration have been selected from both organizations to examine subject-specific data and write guidelines. The process includes additional representatives from other medical practitioner and specialty groups when appropriate. Writing committees are specifically charged to perform a literature review, weigh the strength of evidence for or against a particular treatment or procedure, and include estimates of expected health outcomes where data exist. Patient-specific modifiers, comorbidities, and issues of patient preference that may influence the choice of particular tests or therapies are considered as well as frequency of follow-up and cost-effectiveness. When available, information from studies on cost will be considered; however, review of data on efficacy and clinical outcomes will constitute the primary basis for preparing recommendations in these guidelines.

In an effort to respond promptly to new evidence, the Task Force has created a "focused update" process to revise the existing guideline recommendations that are affected by evolving data or opinion. New evidence is reviewed in an ongoing fashion to more efficiently respond to important science and treatment trends that could have a major impact on patient outcomes and quality of care.

Writing committees are charged with the task of performing an assessment of the evidence and acting as an independent group of authors to develop, update, or revise written recommendations for clinical practice. Experts in the subject under consideration have been selected from both organizations to examine subject-specific data and write guidelines. The process includes additional representatives from other medical practitioner and specialty groups when appropriate. Writing committees are specifically charged to perform a literature review, weigh the strength of evidence for or against a particular treatment or procedure, and include estimates of expected health outcomes where data exist. Patient-specific modifiers, comorbidities, and issues of patient preference that may influence the choice of particular tests or therapies are considered, as well as frequency of follow-up and cost-effectiveness. When available, information from studies on cost will be considered; however, review of data on efficacy and clinical outcomes will constitute the primary basis for preparing recommendations in these guidelines.

Because the ACCF/AHA practice guidelines address patient populations (and healthcare providers) residing in North America, drugs that are not currently available in North America are discussed in the text without a specific class of recommendation. For studies performed in large numbers of subjects outside North America, each writing group reviews the potential impact of different practice patterns and patient populations on the treatment effect and relevance to the ACCF/AHA target population to determine whether the findings should inform a specific recommendation.

In preparing this revision, the committee was guided by the following principles:

1. Changes in recommendations and levels of evidence were made either because of new randomized trials or because of the accumulation of new clinical evidence and the development of clinical consensus.
2. The committee was cognizant of the health care, logistic, and financial implications of recent trials and factored in these considerations to arrive at the classification of certain recommendations.

3. For recommendations taken from other guidelines, wording changes were made to render some of the original recommendations more precise.

4. The committee would like to reemphasize that the recommendations in this guideline apply to most patients but may require modification because of existing situations that only the primary treating physician can evaluate properly.

5. All of the listed recommendations for implantation of a device presume the absence of inciting causes that may be eliminated without detriment to the patient (e.g., nonessential drug therapy).

6. The committee endeavored to maintain consistency of recommendations in this and other previously published guidelines. In the section on AV block associated with AMI, the recommendations follow closely those in the "ACC/AHA Guidelines for the Management of Patients with ST-Elevation Myocardial Infarction." However, because of the rapid evolution of pacemaker/ICD science, it has not always been possible to maintain consistency with other published guidelines.

Rating Scheme for the Strength of the Recommendations

See the "Rating Scheme for the Strength of the Evidence" field above.

Cost Analysis

Optimizing Pacemaker Technology and Cost

An analysis of the Mode Selection Trial (MOST) found that the cost-effectiveness of dual-chamber pacemaker implantation compared with ventricular pacemaker implantation was approximately $53,000 per quality-adjusted year of life gained over 4 years of follow-up. Extended over the expected lifetime of a typical patient, the calculated cost-effectiveness of dual-chamber pacing improved to $6800 per quality-adjusted year of life gained.

It has been estimated that 16% to 24% of pacemaker implantations are for replacement of generators; of those, 76% are replaced because their batteries have reached their elective replacement time. Hardware and software (i.e., programming) features of pacemaker systems that prolong useful battery longevity may improve the cost-effectiveness of pacing. Leads with steroid elution and/or high pacing impedance allow for less current drain. Optimal programming of output voltages, pulse widths, and atrioventricular (AV) delays can markedly decrease battery drain; one study showed that expert programming of pacemaker generators can have a major impact on longevity, prolonging it by an average of 4.2 years compared with nominal settings. Generators that automatically determine whether a pacing impulse results in capture allow for pacing outputs closer to threshold values than conventional generators. Although these and other features arguably should prolong generator life, there are other constraints on the useful life of a pacemaker generator, including battery drain not directly related to pulse generation and the limited life expectancy of many pacemaker recipients; rigorous studies supporting the overall cost-effectiveness of these advanced pacing features are lacking.

Cost-Eff ectiveness of Implantable Cardioverter-Defibrillator (ICD) Therapy

Long-term follow-up studies have consistently demonstrated that cumulative medical costs are increased substantially among patients receiving an ICD. Several studies have attempted to weigh whether these added costs are worthwhile in light of the potential for improved survival among patients receiving ICD therapy. These studies calculate a cost-effectiveness ratio that is defined as the difference in the total cost of patients receiving an ICD and patients receiving alternative therapy, divided by the additional life-years of survival provided by an ICD compared with alternative therapy. A benchmark for comparison is provided by renal dialysis, which costs approximately $50,000 to add 1 life-year of survival. Cost-effectiveness, like other outcome measures in clinical research studies, must be interpreted in the light of the characteristics of the study populations and the length of follow-up available.

The early studies of ICD cost-effectiveness were based on mathematical models and relied on nonrandomized studies to estimate clinical efficacy and cost. These studies found cost-effectiveness ratios of $17,000, $18,100, and $29,200 per year of life saved. Another model incorporated costs of nonthoracotomy ICDs and efficacy estimates based on randomized trials and found ICD cost-effectiveness was between $27,300 and $54,000 per life-year gained, which corresponded to risk reductions of 40% and 20%, respectively.

Several randomized clinical trials have measured both cost and clinical outcomes and thus can directly estimate ICD cost-effectiveness. MADIT found a 54% reduction in total mortality and a cost-effectiveness ratio of $27,000 per life-year added. In contrast, CIDS found a 20% reduction in total mortality and a cost-effectiveness ratio of $139,000 per life-year added. The cost-effectiveness ratio from the AVID trial was $66,677 per life-year added. MADIT II found a 32% reduction in total mortality and $39,200 higher costs among ICD-assigned patients than among those...
treated with conventional therapy. The cost-effectiveness ratio in MADIT II was measured as $235,000 per year of life added at 2 years of follow-up but was projected to be between $78,600 and $114,000 per year of life added by 12 years of follow-up. The Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) reported that total mortality was reduced by 23% and costs increased by $19,000 over 5 years of follow-up in patients assigned to ICDs compared with patients assigned to placebo. SCD-HeFT estimated the lifetime cost-effectiveness ratio of the ICD strategy was $38,400 per year of life added. This range of results from randomized studies is primarily due to different estimates of the effectiveness of the ICD in reducing mortality, because all showed similar increases in the cost of care among ICD recipients. When the results of all clinical trials were used in a model that used a consistent framework to project the full gain in life expectancy and lifetime costs in each trial, the cost-effectiveness of the ICD ranged from $25,300 to $50,700 per life-year added in the randomized trials in which the ICD reduced mortality. In the Coronary Artery Bypass Graft-Patch (CABG-Patch) trial and Defibrillator in Acute Myocardial Infarction Trial (DINAMIT), however, patients assigned to an ICD had lower survival and higher costs than patients assigned to conventional therapy, and the ICD strategy was not cost-effective. The evidence suggests that proper patient selection is necessary for ICD implantation to be cost-effective; when ICD implantation is restricted to appropriately selected patients, it has a cost-effectiveness ratio similar to other accepted cardiovascular therapies and compares well to the standard benchmark of renal dialysis ($30,000 to $50,000 per year of life saved). In principle, ICD implantation will be more cost-effective when used for patients at high risk of arrhythmic death and at low risk of other causes of death. Additional risk stratification of patients with a reduced left ventricular ejection fraction (LVEF) may improve patient selection for the ICD and thereby enhance its cost-effectiveness. Cost-effectiveness of the ICD would also be improved by lowering the cost of the device itself and further improving its reliability and longevity.

The cost-effectiveness of CRT has not been evaluated extensively. A CRT device that provides pacing but not defibrillation capability (CRT-P device) reduces hospitalization for heart failure patients, and these cost savings partially offset the initial cost of device implantation. CRT-P devices are also effective in improving QOL and may improve survival. The cost-effectiveness of CRT-P devices versus medical therapy appears to be favorable. There are few data on the cost-effectiveness of a CRT device that incorporates both pacing and defibrillation capabilities (CRT-D) compared with CRT-P devices.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

2008 Guideline

The document was reviewed by 2 official reviewers nominated by each of the American College of Cardiology (ACC), American Heart Association (AHA), and Heart Rhythm Society (HRS) and by 11 additional peer reviewers. Of the total 17 peer reviewers, 10 had no significant relevant relationships with industry. In addition, this document has been reviewed and approved by the governing bodies of the ACC, AHA, and HRS, which include 19 ACC Board of Trustees members (none of whom had any significant relevant relationships with industry), 15 AHA Science Advisory Coordinating Committee members (none of whom had any significant relevant relationships with industry), and 14 HRS Board of Trustees members (6 of whom had no significant relevant relationships with industry). All guideline recommendations underwent a formal, blinded writing committee vote. Writing committee members were required to recuse themselves if they had a significant relevant relationship with industry. The guideline recommendations were unanimously approved by all members of the writing committee who were eligible to vote. The section "Pacing in Children and Adolescents" was reviewed by additional reviewers with special expertise in pediatric electrophysiology.

The guideline document was approved by the ACC Foundation Board of Trustees, the AHA Science Advisory and Coordinating Committee, and the HRS Board of Trustees in February 2008.

2012 Update

The 2012 focused update was reviewed by 2 official reviewers each nominated by the ACC, AHA, and HRS, as well as 1 reviewer each from the American Association for Thoracic Surgery, Heart Failure Society of America, and Society of Thoracic Surgeons, and 21 individual content reviewers. All information on reviewers' relationships with industry and other entities was collected and distributed to the writing group and is published in this document (see Appendix 5 of the original guideline document). The 2012 focused update was approved for publication by the governing bodies of the ACCF, AHA, and HRS and was endorsed by the American Association for Thoracic Surgery, Heart Failure Society of America, and Society of Thoracic Surgeons.

The guideline document was approved by the ACCF Board of Trustees, the AHA Science Advisory and Coordinating Committee, and the HRS
Evidence Supporting the Recommendations

References Supporting the Recommendations


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Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

The recommendations listed in this document are, whenever possible, evidence based.
Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate use of cardiac pacemakers and implantable cardioverter-defibrillators (ICDs)
- Improved effectiveness of care, optimal outcomes, and appropriate use of resources
- Decreased morbidity and mortality in patients requiring implantation of cardiac pacemakers or ICDs

Potential Harms

- Recent evidence suggests that ventricular desynchronization due to right ventricular apical (RVA) pacing may have adverse effects on left ventricular (LV) and left atrial structure and function. These adverse effects likely explain the association of RVA pacing, independent of atrioventricular synchrony, with increased risks of atrial fibrillation and heart failure in randomized clinical trials of pacemaker therapy and, additionally, ventricular arrhythmias and death during implantable cardioverter-defibrillator (ICD) therapy.
- Cardiac resynchronization therapy device defibrillation capabilities (CRT-D) was associated with a higher risk of adverse device- or implantation-related complications at 30 days after implantation (probability [p] <0.001) compared with an ICD and no cardiac resynchronization therapy (CRT).
- Studies have suggested that chronic RVA pacing in young patients, primarily those with congenital complete heart block, can lead to adverse histological changes, LV dilation, and LV dysfunction.
- Conventional ICD therapy in any form may be associated with worsening heart failure, ventricular tachycardia, ventricular fibrillation, and noncardiac death that can be related to the adverse effects of RVA pacing.
- Complications related to replacement of ICD generators under advisory have been well documented, including infection, the need for reoperation, and death. The estimated device failure rate and the likelihood of mortality resulting from device failure must be weighed against the risk of procedural morbidity and mortality associated with device replacement.
- The use of ICD therapy carries a risk for psychological consequences and may lead to a decrement on quality of life, especially among patients who have experienced shocks. Reports of significant behavioral disorders, including anxiety, device dependence, or social withdrawal, have been described with ICD implantation.
- Thoracotomy in fragile patients with heart failure has been associated with bleeding, stroke, hypotension, and arrhythmias.
- Cardiac resynchronization devices and ICDs are not infallible; failure of electronics, batteries, and leads can occur.

Contraindications

Contraindications

A prosthetic mechanical tricuspid valve represents an absolute contraindication to placement of transvenous right ventricular leads, because such leads will cross the valve and may interfere with valve function. This scenario occurs commonly in patients with tricuspid valve endocarditis and a transvenous pacemaker.

Qualifying Statements

Qualifying Statements

- It is important that the medical profession play a significant role in critically evaluating the use of diagnostic procedures and therapies as they are introduced and tested in the detection, management, or prevention of disease states. Rigorous and expert analysis of the available data documenting absolute and relative benefits and risks of those procedures and therapies can produce helpful guidelines that improve the effectiveness of care, optimize patient outcomes, and favorably affect the overall cost of care by focusing resources on the most effective strategies.
- The American College of Cardiology Foundation/American Heart Association (ACCF/AHA) practice guidelines are intended to assist healthcare providers in clinical decision making by describing a range of generally acceptable approaches to the diagnosis, management, and
prevention of specific diseases or conditions. The guidelines attempt to define practices that meet the needs of most patients in most
circumstances. The ultimate judgment about care of a particular patient must be made by the healthcare provider and patient in light of all the
circumstances presented by that patient. As a result, situations may arise in which deviations from these guidelines may be appropriate.
Clinical decision making should consider the quality and availability of expertise in the area where care is provided. When these guidelines
are used as the basis for regulatory or payer decisions, the goal should be improvement in quality of care. The Task Force recognizes that
situations arise in which additional data are needed to inform patient care more effectively; these areas will be identified within each
respective guideline when appropriate.

- Prescribed courses of treatment in accordance with these recommendations are effective only if they are followed. Because lack of patient
  understanding and adherence may adversely affect outcomes, physicians and other healthcare providers should make every effort to engage
  the patient's active participation in prescribed medical regimens and lifestyles. In addition, patients should be informed of the risks, benefits,
  and alternatives to a particular treatment and should be involved in shared decision making whenever feasible, particularly for class of
  recommendation IIa and IIb, for which the benefit-to-risk ratio may be lower.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm
Pocket Guide/Reference Cards
Slide Presentation

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need
End of Life Care
Getting Better
Living with Illness

IOM Domain
Effectiveness
Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)
Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1998 Apr (revised 2013 Jan 22)

Guideline Developer(s)

American College of Cardiology Foundation - Medical Specialty Society
American Heart Association - Professional Association
Heart Rhythm Society - Professional Association

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*The 2012 writing group members were required to recuse themselves from voting on sections to which their specific relationships with industry and other entities may apply; see Appendix 4 in the original guideline document for recusal information.

Financial Disclosures/Conflicts of Interest

The Task Force makes every effort to avoid actual, potential, or perceived conflicts of interest that may arise as a result of industry relationships or personal interests among the members of the writing group. All writing group members and peer reviewers of the guideline are required to disclose all current healthcare–related relationships, including those existing 12 months before initiation of the writing effort.

For the 2008 guidelines, all members of the writing committee, as well as peer reviewers of the document, were asked to provide disclosure statements of all such relationships that may be perceived as real or potential conflicts of interest. Writing committee members are also strongly encouraged to declare a previous relationship with industry that may be perceived as relevant to guideline development.

In December 2009, the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) implemented a new policy for relationships with industry and other entities (RWI) that requires the writing group chair plus a minimum of 50% of the writing group to have no relevant RWI (Appendix 4 of the original guideline document includes the ACCF/AHA definition of relevance). These statements are reviewed by the Task Force and all members during each conference call and/or meeting of the writing group and are updated as changes occur. All guideline recommendations require a confidential vote by the writing group and must be approved by a consensus of the voting members. Members may not draft or vote on any text or recommendations pertaining to their RWI. The 2012 members who recused themselves from voting are indicated in the list of writing group members, and specific section recusals are noted in Appendix 4 of the original guideline document. 2008 and 2012 authors' and peer reviewers' RWI pertinent to this guideline are disclosed in Appendices 1, 2, 4, and 5 of the original guideline document, respectively. Additionally, to ensure complete transparency, writing group members' comprehensive disclosure information—including RWI not pertinent to this document—is available as an online supplement. Comprehensive disclosure information for the Task Force is also available online at [http://cardiosource.org/ACC/About-ACC/Who-We-Are/Leadership/Guidelines-and-Documents-Task-Forces.aspx](http://cardiosource.org/ACC/About-ACC/Who-We-Are/Leadership/Guidelines-and-Documents-Task-Forces.aspx).

Guideline Endorser(s)

American Association of Thoracic Surgery - Medical Specialty Society
Heart Failure Society of America, Inc - Disease Specific Society
Society of Thoracic Surgeons - Medical Specialty Society

Guideline Status

This is the current release of the guideline.

Guideline Availability


Print copies: Available from the American College of Cardiology, 2400 N Street NW, Washington DC, 20037; (800) 253-4636 (US only).

Availability of Companion Documents

The following are available:


Print copies: Available from the American College of Cardiology, 2400 N Street NW, Washington DC, 20037; (800) 253-4636 (US only).

Patient Resources

None available

NGC Status

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