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Clinical guidelines PACEMAKER	Original Date: February, 2013 Page 1 of 12
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INTRODUCTION

(Epstein 2013; Hayes 2018)

- Pacemaker implantation generally serves to address bradycardias, with the intention of ameliorating related symptoms, preventing complications of syncope, and/or reducing mortality risk.
- Guidelines for the pediatric and congenital heart disease population are provided in the latter portion of this guideline.
- This guideline is not intended to cover the type of bradycardia pacing device. CRT (cardiac resynchronization therapy or biventricular pacing) and ICD (implantable cardioverter defibrillator) implantation are covered in separate guidelines.
- Elective generator replacement indicators support generator change.

ADULT INDICATIONS FOR PACEMAKERS

(Epstein 2013; Hayes 2018)

(Excludes transient causes, such as unnecessary medication, temporary metabolic and inflammatory conditions, etc.)

Sinus Node Dysfunction

- Documented symptomatic sinus bradycardia, including frequent sinus pauses that produce symptoms
- Symptomatic chronotropic incompetence, documented by stress test or electrocardiography (ECG) recording data
- Symptomatic sinus bradycardia that results from required medication
- Heart rate less than 40, in the waking state, when a clear association between significant symptoms consistent with bradycardia and the actual presence of bradycardia has not been documented.
- Syncope of unexplained origin when clinically significant abnormalities of sinus node function are discovered (e.g. an asymptomatic ventricular pause > 6 s) or

provoked by electrophysiologic study (EPS), such as a prolonged sinus node recovery time (Brignole 2013).

- Symptomatic sinus bradycardia (< 60 bpm), which includes syncope, near-syncope, dizziness, lethargy, congestive heart failure (CHF), fatigue, or dyspnea, whether spontaneous or as a result of clinically required medications or procedures (e.g. medical or catheter treatment for atrial fibrillation) that slow the heart rate, when symptoms can clearly be attributed to bradycardia (Brignole 2013).
- Ischemia-related life threatening bradyarrhythmias, when coronary spasm presents a poor or uncertain response to medical therapy (Montalescot 2013).

NOT Indicated for Sinus Node Dysfunction:

- Asymptomatic.
- Symptoms in the absence of bradycardia.
- Bradycardia resulting from nonessential drug therapy.

Acquired Third-Degree and Advanced Second-Degree Atrioventricular (AV) Block: (See definition of advanced atrioventricular (AV) Block in Additional Information section.)

- Persistent third-degree (complete) AV block, with or without symptoms
- 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
- Persistent third degree AV block or advanced second degree AV block that is due to clinically necessary medication
- In atrial fibrillation, while awake, pauses in heartbeat ≥ 5 seconds with or without symptoms
- In sinus rhythm (with AV block) and while awake, pauses in heartbeat ≥ 3 seconds or heart rates less than 40 beats per minute or an escape rhythm below the AV node, with or without symptoms
- Following catheter ablation of the AV junction
- Associated with neuromuscular diseases such as myotonic muscular dystrophy, Erb dystrophy (limb-girdle muscular dystrophy), Kearns-Sayre syndrome, and peroneal muscular atrophy
- Exercise-induced third degree AV block without myocardial ischemia

NOT Indicated for Acquired Third-Degree and Advanced Second-Degree Atrioventricular Block:

- AV block 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) and without symptoms
- AV block secondary to nonessential drug therapy

First- and Second-Degree AV Block

- Symptomatic bradycardia associated with second-degree AV block at any level of conduction, either Mobitz I or II, including patients on required medication

- Mobitz Type II second-degree AV block, with or without symptoms
- Second-degree AV block associated with a wide QRS, including isolated right bundle branch block, or if due to EP-documented intra- or infra-His conduction prolongation
- First- or second-degree AV block with “pacemaker syndrome” symptoms or hemodynamic compromise (i.e. hypotension, syncope, or pulmonary edema, particularly if PR > 0.30 s) (Brignole 2013)
- First or second degree AV block in neuromuscular diseases such as myotonic muscular dystrophy, Erb dystrophy (limb-girdle muscular dystrophy), Kearns-Sayre syndrome, and peroneal muscular atrophy
- AV block due to drug use and/or drug toxicity AND block is expected to recur after drug withdrawal
- Exercise-induced second degree heart block without myocardial ischemia

NOT Indicated for Other Presentations of First- and Second-Degree AV Block:

- AV block 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) and without symptoms
- AV Block secondary to nonessential drug therapy

Chronic Bifascicular Block

- Type II second-degree AV block, advanced second-degree AV block (see definitions section) or intermittent third-degree AV block
- Alternating bundle-branch block
- Syncope and bifascicular block when other likely causes have been excluded, specifically ventricular tachycardia
- Electrophysiologic study (EPS) documentation of an H-V interval ≥ 100 milliseconds, even in asymptomatic patients
- Electrophysiologic study (EPS) documentation of non-physiological, pacing-induced infra-His block
- In neuromuscular diseases such as myotonic muscular dystrophy, Erb dystrophy (limb-girdle muscular dystrophy), and peroneal muscular atrophy with bifascicular block or any fascicular block
- In bundle branch block with syncope and documentation of an HV interval ≥ 70 ms (Brignole 2013)

NOT Indicated for Permanent Pacing for Chronic Bifascicular Block:

- Asymptomatic fascicular block without AV block
- Asymptomatic fascicular block with first-degree AV block

After the Acute Phase of Myocardial Infarction
(UM usually not required due to inpatient status)

- Persistent second- or third-degree AV block after ST-elevation myocardial infarction (STEMI).

- Transient second- or third-degree AV block below the AV node after STEMI. If the site of block is uncertain, electrophysiologic study (EPS) may be necessary.

NOT Indicated for Permanent Pacing After the Acute Phase of Myocardial Infarction:

- Bradycardia secondary to nonessential drug therapy.
- Transient AV block without intraventricular conduction defects.
- Transient AV block with isolated left anterior fascicular block.
- New bundle-branch block or fascicular block without AV block.
- Asymptomatic first-degree AV block with bundle-branch or fascicular block.

Hypersensitive Carotid Sinus Syndrome and Neurocardiogenic Syncope

- Recurrent syncope due to spontaneously occurring carotid sinus stimulation AND carotid sinus pressure induces ventricular asystole ≥ 3 seconds.
- Syncope without clear, provocative events and with a hypersensitive cardioinhibitory response (asystole) of 3 seconds or longer.
- Neurocardiogenic syncope associated with bradycardia occurring spontaneously or at the time of tilt-table testing.

NOT Indicated for Permanent Pacing in Hypersensitive Carotid Sinus Syndrome and Neurocardiogenic Syncope:

- Hypersensitive cardioinhibitory response to carotid sinus stimulation without symptoms or with vague symptoms.
- Situational neurocardiogenic syncope in which avoidance behavior is effective and preferred.

Following Cardiac Transplantation, Cardiac Surgery and Transcatheter Intervention
(UM usually not required due to inpatient status.)

- Persistent inappropriate or symptomatic bradycardia not expected to resolve, such as one of the following (Brignole 2013):
 - Third degree AV block with low escape rate > 48 hours postoperative
 - All other AV Block, after a 5-7 day wait for improvement
 - 5 days - 3 weeks wait for inus node dysfunction (SND) to improve after surgery and transplantation.
- Prolonged bradycardia limiting rehabilitation or discharge post transplantation.
- Syncope after transplantation even when bradyarrhythmia has not been documented.

NOT Indicated for Pacing following Cardiac Transplantation:

- Bradycardia secondary to nonessential drug therapy.

Antitachycardia Pacing
(Pacing to Terminate Tachycardia)

- Symptomatic recurrent supraventricular tachycardia documented to be pacing terminated in the setting of failed catheter ablation and/or drug treatment (intolerance included).

NOT Indicated for Permanent Pacemakers That Automatically Detect and Pace to Terminate Tachycardia:

- Presence of an accessory pathway with capacity for rapid anterograde conduction.

Tachycardia Prevention

- Sustained pause-dependent ventricular tachycardia (VT), with or without QT prolongation.
- Type 3 congenital long-QT syndrome (ICD frequently preferred) (Zimetbaum 2018)
- For management of paroxysmal atrial fibrillation only when **other indications** for pacing are present (Passman 2018, January 2014)

NOT Indicated for Pacing to Prevent Tachycardia:

- Ventricular ectopy without sustained VT in the absence of the long-QT syndrome.
- Reversible, e.g., drug-related, Torsade de Pointes VT.

Hypertrophic Cardiomyopathy

- Symptomatic hypertrophic cardiomyopathy and hemodynamically significant resting (peak > 30 mm Hg) or provoked (peak > 50 mm Hg) LV outflow tract gradient, refractory to medical therapy, and suboptimal candidates for septal reduction therapy (including high risk for developing heart block post procedure) (Marin 2018).

NOT Indicated for Pacing in Patients with Hypertrophic Cardiomyopathy:

- Asymptomatic OR symptoms controlled on medical therapy.
- Without significant LV outflow tract obstruction.

Cardiac Sarcoidosis & Giant Cell Myocarditis

- Transient or permanent high degree or complete AV block (with additional recommendation to include ICD) (Blankstein 2018, Priori 2015)

Pediatric and Congenital Heart Disease Pacing Indications

(Epstein 2013; Brignole 2013; Brugada 2013, Silva 2018)

;

Children, Adolescents (<19 years), and Patients with Congenital Heart Disease

Sinus Bradycardia

- SND with symptomatic age- and activity-inappropriate bradycardia. The definition of bradycardia varies with the patient's age and expected heart rate. For normal heart rates by age, please see the table in the Additional information section. (Correlation does not need to be completely conclusive) (Hernandez-Madrid 2018).
- Sinus bradycardia with complex congenital heart disease AND a resting heart rate < 40 bpm OR pauses in ventricular rate >3 seconds.
- Congenital heart disease and impaired hemodynamics due to sinus bradycardia or loss of AV synchrony (e.g. PR interval \geq 0.30s)
- Asymptomatic sinus bradycardia following biventricular repair of congenital heart disease with an awake resting heart rate < 40 bpm or pauses in ventricular rate > 3 seconds.

Bradycardia-Tachycardia

- Bradycardia-tachycardia syndrome, when symptoms and bradycardia correlate (correlation does not need to be completely conclusive) (Brignole 2013; Hernandez-Madrid 2018).
- Congenital heart disease (CHD) and sinus node dysfunction (SND) or junctional bradycardia, for the prevention of *recurrent* episodes of intra-atrial reentrant tachycardia (IART), with SND or junctional bradycardia either intrinsic or secondary to necessary anti-arrhythmic treatment, when catheter ablation is not possible. Devices with atrial antitachycardia pacing are preferred. (Brugada 2013; Brignole 2013; Khairy 2014)
- Permanent pacing is reasonable in adults with complex CHD and an awake resting heart rate (sinus or junctional) <40 bpm or ventricular pauses >3 seconds. A device with antitachycardia pacing may be considered if the underlying anatomic substrate carries a *high likelihood* of developing IART (Khairy 2014)

AV Block

- Second- or third-degree AV block with symptomatic bradycardia, ventricular dysfunction, or low cardiac output.
- Advanced second degree AV block ((inadequate literature on asymptomatic Mobitz type II or prolonged HV interval in children, but it would appear reasonable when condition is permanent) (Brignole 2013; Silva 2018).
- Postoperative advanced second- or third-degree AV block that is expected to be permanent or that persists \geq 7 days after cardiac surgery.
- Congenital third-degree AV block with a wide QRS escape rhythm, complex ventricular ectopy, prolonged QT interval, low cardiac output, or ventricular dysfunction (Hernandez-Madrid 2018).
- Congenital third-degree AV block in the infant with a ventricular rate <55 bpm or with congenital heart disease and a ventricular rate <70 bpm.
- Congenital third-degree AV block after age 1 year with an average heart rate <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.

- Unexplained syncope after prior congenital heart surgery complicated by transient complete heart block, with residual fascicular block after a careful evaluation to exclude other causes of syncope.
- 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 is reasonable in adults with congenital complete AV block and an average daytime resting heart rate < 50 bpm (Khairy 2014).
- Any degree AV block in neuromuscular diseases such as myotonic muscular dystrophy, Erb dystrophy (limb-girdle muscular dystrophy), Kearns-Sayre syndrome, and peroneal muscular atrophy. (Epstein 2013; Brugada 2013)

Ventricular Tachyarrhythmia-Related

- Sustained, pause-dependent Ventricular tachycardia (VT), with QT prolongation, if ICD is not indicated (Epstein 2013; Hernandez-Madrid 2018).
- Type 3 congenital long-QT syndrome (ICD frequently preferred) (Zimetbaum 2018).

NOT Indicated for Pacing in Children, Adolescents, and Patients with Congenital Heart Disease

- Asymptomatic transient postoperative AV block with return of normal AV conduction.
- Asymptomatic bifascicular block +/-first-degree AV block after surgery for congenital heart disease in the absence of prior transient complete AV block.
- Asymptomatic Mobitz type I second-degree AV block.
- Asymptomatic sinus bradycardia with the longest RR interval < 3 seconds and a minimum heart rate > 40 bpm.
- Asymptomatic sinus bradycardia in a healthy child (Silva 2018)
- Bradycardia secondary to nonessential drug therapy.

ADDITIONAL INFORMATION

General

A pacemaker system is composed of a pulse generator and one or more leads. The pulse generator is implanted under the skin, usually below one of the collarbones (clavicles). It contains a battery, a microprocessor that governs timing and function, and a radio antenna to allow for noninvasive interrogation and reprogramming. The leads are insulated cables that conduct electricity from the pulse generator to the heart. Leads are most commonly inserted into a vein and then advanced under fluoroscopy (X-ray guidance) to within one or more heart chambers. The leads are fastened within the chambers to the heart muscle using either hooks or retractable/extendable screws, which are built into their tips. Timed electrical impulses are delivered from the pulse generator via the leads to the heart, where stimulation results in heart muscle contraction.

The most recent guidelines stress that asymptomatic bradycardia rarely qualifies as an indication for pacemaker insertion. However, there are some asymptomatic bradycardic rhythms for which pacemaker insertion is indicated because they present a risk of injury or death. Thus, there are also a small number of situations in which the ECG or an invasive EPS can reveal evidence of specific disease in the cardiac electrical system that warrants pacemaker insertion in the absence of symptoms. Guidelines are fairly specific and technical in these instances.

In the case of dilated cardiomyopathy, near-simultaneous stimulation of both ventricles, referred to as cardiac resynchronization therapy (CRT) has been demonstrated to improve cardiac performance and quality of life and to decrease cardiac event rates and mortality, usually among symptomatic patients with systolic heart failure and a wide QRS complex. Device implantation requires the insertion of leads that pace both the right and left ventricles, most commonly with a coronary sinus lead for the LV pacing. The majority of these patients have a CRT device with ICD function as well (CRT-D). (See separate guidelines for ICD and CRT.)

Heart Block Definitions

(Epstein 2013)

- First Degree: All sinus or atrial beats are conducted to the ventricles, but with a delay (PR interval of > 200ms).
- Second Degree: Intermittent failure of conduction of single beats from atrium to ventricles.
 - (Mobitz) Type I: Conducted beats have variable conduction times from atrium to ventricles.
 - (Mobitz) Type II: Conducted beats have uniform conduction times from atrium to ventricles.
 - Advanced or high degree: Two or more consecutive non-conducted sinus or (non-premature) atrial beats.
- Third Degree: No atrial beats are conducted from atrium to ventricle

Pediatric respiratory rate and heart rate by age*

Age group	Respiratory rate	Heart rate
	Median (1st-99th percentile)	Median (1st-99th percentile)
0 to 3 months	43 (25-66)	143 (107-181); term newborn at birth: 127 (90-164)
3 to 6 months	41 (24-64)	140 (104-175)

6 to 9 months	39 (23-61)	134 (98-168)
9 to 12 months	37 (22-58)	128 (93-161)
12 to 18 months	35 (21-53)	123 (88-156)
18 to 24 months	31 (19-46)	116 (82-149)
2 to 3 years	28 (18-38)	110 (76-142)
3 to 4 years	25 (17-33)	104 (70-136)
4 to 6 years	23 (17-29)	98 (65-131)
6 to 8 years	21 (16-27)	91 (59-123)
8 to 12 years	19 (14-25)	84 (52-115)
12 to 15 years	18 (12-23)	78 (47-108)
15 to 18 years	16 (11-22)	73 (43-104)

* The respiratory and heart rates provided are based upon measurements in awake, healthy infants and children at rest. Many clinical findings besides the actual vital sign measurement must be taken into account when determining whether a specific vital sign is normal in an individual patient. Values for heart rate or respiratory rate that fall within normal limits for age may still represent abnormal findings that are caused by underlying disease in a particular infant or child. (Fleming 2011; Fleegler, 2018)

Abbreviations

AV	Atrioventricular
CHF	Congestive heart failure
CRT	Cardiac resynchronization therapy (same as biventricular pacing)
ECG	Electrocardiogram
EPS	Electrophysiologic Study
GDMT	Guideline-Directed Medical Therapy
HRS	Heart Rhythm Society
HV	His-ventricular
ICD	Implantable cardioverter-defibrillator
LBBB	Left bundle-branch block
LV	Left ventricular/left ventricle
LVEF	Left ventricular ejection fraction
MI	Myocardial infarction
ms	Milliseconds
s	Seconds
STEMI	ST-elevation Myocardial Infarction
SND	Sinus node dysfunction
VT	Ventricular tachycardia

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