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INDICATIONS FOR PACEMAKERS – ADULT (Excludes conditions that are expected to resolve)
(Epstein 2013; Hayes 2018, Kusumoto 2019)

Sinus Node Dysfunction (SND)

- Documented symptomatic sinus bradycardia, including frequent sinus pauses
- Symptomatic chronotropic incompetence (broadly defined as an inability to increase heart rate commensurate with activity or demand), documented by stress test or electrocardiography (ECG) recording data
- Symptomatic sinus bradycardia that results from required guideline-directed medical therapy (GDMT) for which there is no alternative treatment
- Heart rate less than 40 while awake, even without definite association with significant symptoms consistent with bradycardia
- Tachycardia-bradycardia syndrome and symptoms attributable to bradycardia (Kusumoto 2019)
- Syncope of unexplained origin with clinically significant SND, either seen or provoked in electrophysiologic study (EPS)

Acquired Atrioventricular (AV) Block

- Persistent third-degree (complete) AV block, regardless of symptoms
- Second-degree Mobitz Type II AV block and high-grade AV block, regardless of symptoms
- Atrial fibrillation while awake, with pauses ≥ 5 seconds, or symptomatic bradycardia
- In sinus rhythm (with AV block) while awake, pauses ≥ 3 seconds or heart rates less than 40 beats per minute or an escape rhythm below the AV node
- Following catheter ablation of the AV junction
- Second-degree AV block, third degree AV block, or an H-V interval ≥ 70 ms, associated with neuromuscular diseases such as myotonic muscular dystrophy, Erb dystrophy (limb-girdle muscular dystrophy), Kearns-Sayre syndrome, and peroneal muscular atrophy, regardless of symptoms
- Symptomatic AV block that results from required medical therapy for which there is no alternative treatment
- Exercise-induced second or third-degree AV block without myocardial ischemia
- Symptomatic bradycardia associated with second-degree AV block, either Mobitz I or II
- Second-degree AV block associated with a wide QRS, or EPS-documented intra- or infra-His conduction

- First- or second-degree AV block with “pacemaker syndrome” symptoms (chronic fatigue, dyspnea on exertion, symptomatic hypotension) or hemodynamic compromise
- Marked first-degree or second-degree Mobitz Type 1 AV block with symptoms clearly attributable to the AV block

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 of unexplained origin when other likely causes have been excluded, specifically ventricular tachycardia (Shen 2017)
- Syncope and bundle branch block with an HV interval ≥ 70 ms, or evidence of infranodal block at EPS (Kusomoto 2018)
- Incidental findings at EPS study of an H-V interval ≥ 100 milliseconds, or non-physiological, pacing-induced infra-His block in asymptomatic patients

Hypersensitive Carotid Sinus Syndrome and Neurocardiogenic Syncope

- Recurrent syncope due to spontaneously occurring carotid sinus stimulation AND carotid sinus pressure induced ventricular asystole ≥ 3 seconds, or AV block, or ≥ 50 mm Hg drop in systolic BP (Epstein 2008, Shen 2017)
- Syncope without clear, provocative events and with a hypersensitive cardioinhibitory response (asystole) ≥ 3 seconds
- Recurrent syncope and asystole ≥ 3 seconds with syncope or ≥ 6 seconds without symptoms or with presyncope, documented by implantable loop recorder (Brignole 2012, Varosy 2017)

Pacing to Terminate or Prevent Tachycardia

- Symptomatic recurrent supraventricular tachycardia documented to be terminated by pacing in the setting of failed catheter ablation and/or drug treatment (intolerance included)
- Sustained pause-dependent ventricular tachycardia (VT)

INDICATIONS FOR PEDIATRIC AND CONGENITAL HEART DISEASE PACING

(Brignole 2013, Brugada 2013, Epstein 2013,)

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

Sinus Node Dysfunction (SND)

- SND with symptomatic age- and activity-inappropriate bradycardia
- 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
- 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
- Congenital heart disease (CHD) and SND or junctional bradycardia, for the prevention of recurrent episodes of intra-atrial reentrant tachycardia (Brugada 2013, Brignole 2013, Khairy 2014).

AV Block

- Second- or third-degree AV block with symptomatic bradycardia, ventricular dysfunction, or low cardiac output
- Congenital third-degree AV block with a wide QRS escape rhythm, complex ventricular ectopy, or ventricular dysfunction
- 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
- Adults with congenital complete AV block with symptomatic bradycardia, wide QRS escape rhythm, mean daytime heart rate < 50 bpm, complex ventricular ectopy, or ventricular dysfunction (Kusomoto 2018)
- Adults with congenital complete AV block, regardless of symptoms (Kusomoto 2018)
- Unexplained syncope after prior congenital heart surgery complicated by transient complete heart block, with residual fascicular block after excluding other causes of syncope
- Congenital third-degree AV block in asymptomatic children or adolescents with an acceptable rate, a narrow QRS, and normal ventricular function

Scenarios in which Pacemakers are Not Indicated

- SND in patients that are asymptomatic or symptoms occur without documented bradycardia
- Asymptomatic first-degree AV block or Mobitz I second-degree AV block with a narrow QRS
- Asymptomatic fascicular block (left anterior or posterior fascicular block)
- Hypersensitive cardioinhibitory response to carotid sinus stimulation without symptoms or with vague symptoms
- Asymptomatic bifascicular block +/- first-degree AV block after surgery for congenital heart disease without prior transient complete AV block

BACKGROUND

(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.

OVERVIEW

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.

Heart Block Definitions

(Epstein 2013)

- First Degree: All sinus or atrial beats are conducted to the ventricles, but with a delay (PR interval of > 200 ms)
- 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 with some conducted beats
- Third Degree: No atrial beats are conducted from atrium to ventricle

Abbreviations

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| 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 |

POLICY HISTORY:**Review Date:** July 2019**Review Summary:**

- Added broad definition of chronotropic incompetence
- For sinus node dysfunction added indication for tachycardia-bradycardia syndrome “and symptoms attributable to bradycardia”
- Indications after the acute phase of myocardial infarction were removed
- For hypersensitive carotid sinus syndrome and neurocardiogenic syncope:
 - Added indication for recurrent syncope and asystole ≥ 3 seconds with syncope or ≥ 6 seconds without symptoms or with presyncope, documented by implantable loop recorder
 - Removed indication for neurocardiogenic syncope associated with bradycardia occurring spontaneously or at the time of tilt table testing
- For hypertrophic cardiomyopathy, removed symptomatic hypertrophic cardiomyopathy and hemodynamically significant resting (peak > 30 mmHg) or provoked (peak > 50 mmHg) LV outflow tract gradient, refractory to medical therapy, and suboptimal candidates for septal reduction therapy (including high risk for developing heart block post procedure)
- For pediatric and congenital heart disease pacing, AV block, the following indications were added:
 - Adults with congenital complete AV block with symptomatic bradycardia, wide QRS escape rhythm, mean daytime heart rate < 50 bpm, complex ventricular ectopy, or ventricular dysfunction
 - Adults with congenital complete AV block, regardless of symptoms
- For pediatric and congenital heart disease pacing, AV block, removed postoperative advanced second or third degree AV block that is expected to be permanent or that persists ≥ 7 days after cardiac surgery; and transient postoperative third degree AV block that reverts to sinus rhythm with residual bifascicular block
- For pediatric and congenital heart disease pacing, scenarios in which pacemakers are not indicated, the following were added:
 - Asymptomatic first-degree AV block or Mobitz I second-degree AV block with a narrow QRS
 - Asymptomatic fascicular block (left anterior or posterior fascicular block)
 - Hypersensitive cardioinhibitory response to carotid sinus stimulation without symptoms or with vague symptoms

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