

Common Questions About Pacemakers

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Pacemakers are indicated in patients with certain symptomatic bradyarrhythmias caused by sinus node dysfunction, and in those with frequent, prolonged sinus pauses. Patients with third-degree or complete atrioventricular (AV) block benefit from pacemaker placement, as do those with type II second-degree AV block because of the risk of progression to complete AV block. The use of pacemakers in patients with type I second-degree AV block is controversial. Patients with first-degree AV block generally should not receive a pacemaker except when the PR interval is significantly prolonged and the patient is symptomatic. Although some guidelines recommend pacemaker implantation for patients with hypersensitive carotid sinus syndrome, recent evidence has not shown benefit. Some older patients with severe neurocardiogenic syncope may benefit from pacemakers, but most patients with this disorder do not. Cardiac resynchronization therapy improves mortality rates and some other disease-specific measures in patients who have a QRS duration of 150 milliseconds or greater and New York Heart Association class III or IV heart failure. Patients with class II heart failure and a QRS of 150 milliseconds or greater also appear to benefit, but there is insufficient evidence to support the use of cardiac resynchronization therapy in patients with class I heart failure. Cardiac resynchronization therapy in patients with a QRS of 120 to 150 milliseconds does not reduce rates of hospitalization or death. (*Am Fam Physician*. 2014;89(4):279-282. Copyright © 2014 American Academy of Family Physicians.)

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Deciding when a pacemaker should be placed can be a complicated decision. This article reviews some of the various indications for pacemaker placement.

When Are Pacemakers Indicated in Patients with Sinus Node Dysfunction or Atrioventricular Block?

Pacemakers are indicated for patients with certain symptomatic bradyarrhythmias caused by sinus node dysfunction. They are also indicated for those with third-degree atrioventricular (AV) block or type II second-degree AV block. The decision to implant a pacemaker in patients with type I second-degree AV block is controversial. Pacemaker therapy in patients with first-degree AV block is generally not recommended, although there are rare indications.

SUPPORTING EVIDENCE

Sinus Node Dysfunction. Sinus node dysfunction encompasses a wide range of rhythm abnormalities, from persistent sinus bradycardia to persistent sinus arrest with replacement by escape rhythms. The term also includes chronotropic incompetence, an inability of the heart to increase its rate in response to increased demand.¹ Symptomatic bradyarrhythmias are the most common

indications for pacemaker placement, with nearly one-half placed for sinus node dysfunction²; however, this practice is supported by only low-quality evidence from observational studies that show improvement in symptoms but not in mortality rates.³⁻⁶

Guidelines from the European Society of Cardiology/European Heart Rhythm Association (ESC/EHRA) and the American College of Cardiology/American Heart Association (ACC/AHA) state with a high level of certainty that the benefit of pacemakers far outweighs the risk in patients with symptomatic bradycardia or frequent sinus pauses of at least three seconds, and/or symptomatic chronotropic incompetence.^{1,7} Based on expert opinion and small studies in limited populations, the guidelines also state that pacemaker therapy would be reasonable in the following clinical scenarios: (1) in a patient who has a heart rate less than 40 beats per minute and intermittent symptoms consistent with bradycardia, but in whom bradycardia has not been documented at the time symptoms occur; (2) in a patient with syncope of unexplained origin and in whom clinically significant abnormalities of the sinus node are found or induced during an electrophysiologic study; and (3) in a patient who has a daytime heart rate less than 40 beats per minute and minimal symptoms.^{1,7}

SORT: KEY RECOMMENDATIONS FOR PRACTICE

<i>Clinical recommendation</i>	<i>Evidence rating</i>	<i>References</i>	<i>Comment</i>
Sinus node dysfunction and AV block			
Pacemakers should be placed for patients with sinus node dysfunction resulting in symptomatic bradyarrhythmias, frequent sinus pauses of at least three seconds, or chronotropic incompetence.	C	1, 3-7	Recommendation from consensus guidelines based on expert opinion
Pacemaker placement may be considered for patients who have a heart rate less than 40 beats per minute and intermittent symptoms consistent with bradycardia, but in whom bradycardia has not been documented at the time the symptoms occur.	C	1, 7	—
Pacemaker placement may be considered for patients with syncope of unexplained origin in whom clinically significant abnormalities of the sinus node are found or induced during an electrophysiologic study.	C	1, 7	—
Pacemaker placement may be considered for patients who have a daytime heart rate less than 40 beats per minute and minimal symptoms.	C	1, 7	—
There is a strong indication for pacemaker placement in patients with third-degree or type II second-degree AV block.	C	1, 7-12	Recommendation based on consensus guidelines
The decision to place a pacemaker for patients with type I second-degree AV block is controversial; the American College of Cardiology/American Heart Association recommends placement for symptomatic patients and for asymptomatic patients with an infra- or intra-Hisian block found at the time of the electrophysiologic study.	B	1, 3, 7, 13	Recommendations based on expert opinion and small cohort studies
Pacemaker placement is not indicated for patients with asymptomatic first-degree AV block.	C	1, 7, 14	—
Pacemaker placement should be considered for patients with symptomatic first-degree AV block and a PR interval greater than 0.3 seconds.	C	1, 7, 14, 15	—
Hypersensitive carotid sinus syndrome and neurocardiogenic syncope			
There is insufficient evidence to support the use of pacemakers in patients with hypersensitive carotid sinus syndrome, despite recommendations based on expert opinion.	C	16, 17	Recommendation based on a Cochrane systematic review and randomized, double-blind, controlled trial
There is insufficient evidence to support the use of pacemakers in patients with neurocardiogenic syncope, except in a limited population with severe symptoms.	C	16, 18	Recommendation based on a Cochrane systematic review and randomized controlled trial
Heart failure			
Cardiac resynchronization therapy is indicated in patients with NYHA class II to IV heart failure and a QRS duration greater than 150 milliseconds.	A	1, 7, 19-22	Consistent across meta-analyses and guidelines
There is insufficient evidence to support the use of cardiac resynchronization therapy in patients with NYHA class I heart failure and in those with a QRS of 120 to 150 milliseconds.	C	7, 20, 22	Conclusions from meta-analysis and guidelines differ regarding QRS interval indications

AV = atrioventricular; NYHA = New York Heart Association.

A = consistent, good-quality patient-oriented evidence; B = inconsistent or limited-quality patient-oriented evidence; C = consensus, disease-oriented evidence, usual practice, expert opinion, or case series. For information about the SORT evidence rating system, go to <http://www.aafp.org/afpsort>.

AV Block. Pacemakers are typically recommended for patients with acquired AV block. They are also recommended for patients with third-degree or complete AV block (i.e., complete dissociation between the P wave and the QRS complex), based on case series.⁸⁻¹⁰ Type II second-degree AV block is diagnosed in patients with constant PR intervals and an occasional missing QRS complex following a P wave. Pacemakers are recommended for patients with type II second-degree AV block because of the risk of progression to third-degree AV block, but the evidence is limited to several small case studies.^{11,12} It is unlikely that higher-quality trials will be performed because type II second-degree AV block and

third-degree AV block have high rates of morbidity and mortality, and no other therapeutic options are available.

Type I second-degree AV block (Wenckebach) refers to a gradual prolongation of PR intervals before a dropped QRS complex. The decision to implant a pacemaker in these patients is controversial, and guidelines differ on the recommended treatment. The ESC/EHRA guidelines recommend pacemakers for all patients in this category,¹ whereas the ACC/AHA guidelines recommend pacemakers for symptomatic patients and for asymptomatic patients with an infra- or intra-Hisian block found at the time of the electrophysiologic study.⁷ Evidence of benefit was noted in small cohort studies, but they did not correct

for numerous baseline clinical characteristics that differed between treatment groups.^{3,13} Given the low quality of these data, the guideline recommendations are based largely on expert opinion.

First-degree AV block is defined as a fixed PR interval of at least 0.2 seconds. There is no indication for pacemaker placement in asymptomatic patients with first-degree AV block.¹⁴ The ESC/EHRA and ACC/AHA guidelines recommend that pacemaker therapy be considered only if the patient is symptomatic and the PR interval is greater than 0.3 seconds.¹⁷ However, this recommendation is based on expert opinion and case studies.¹⁵

Should Pacemakers Be Used in Patients with Hypersensitive Carotid Sinus Syndrome or Neurocardiogenic Syncope?

Evidence is lacking to support the use of pacemakers in patients with hypersensitive carotid sinus syndrome, although select older patients with severe neurocardiogenic syncope may benefit.

SUPPORTING EVIDENCE

The ACC/AHA guideline defines hypersensitive carotid sinus syndrome as syncope or presyncope resulting from an extreme reflex response to carotid sinus stimulation.¹ Neurocardiogenic syncope is defined as a neural reflex that results in peripheral vasodilation and bradycardia; vasovagal syncope is one of the most common patterns in this category. Hypersensitive carotid sinus syndrome and neurocardiogenic syncope involve neurally mediated reflexes. Although these are not life-threatening conditions, they can adversely affect a patient's overall health and quality of life. The ACC/AHA guideline recommends pacemakers for patients with hypersensitive carotid sinus syndrome who have recurrent syncope as a result of carotid sinus stimulation and ventricular asystole of three or more seconds. It also states that pacemakers may be used in patients who have syncope with no obvious provoking event and a cardioinhibitory response of at least three seconds. Despite these recommendations, a 2011 Cochrane review found insufficient evidence to support pacemaker use in patients with carotid sinus syncope,¹⁶ and a randomized, double-blind, controlled trial comparing pacemaker and loop recorder implantation found no significant difference between the interventions in the number of falls, syncopal events, time to first fall after implantation, or quality of life.¹⁷

The 2011 Cochrane review also found insufficient evidence to support pacemaker placement in patients with vasovagal syncope, a type of neurocardiogenic syncope.¹⁶ A recent randomized, double-blind, placebo-controlled

study that was not included in the Cochrane review showed benefit in a limited population with severe neurocardiogenic syncope.¹⁸ This study found that older patients who had severe neurocardiogenic syncope (average of seven syncopal episodes in the previous two years and asystolic pauses averaging 11 seconds) had a decreased time to first syncopal event after a pacemaker was implanted. However, this study was a manufacturer-funded trial and did not report the total syncopal burden or number of falls.

When Should Pacemakers Be Used in Patients with Heart Failure?

Cardiac resynchronization therapy (CRT) is indicated in patients with New York Heart Association (NYHA) class II to IV heart failure and a QRS duration greater than 150 milliseconds. There is insufficient evidence for CRT in patients with NYHA class I heart failure. Evidence does not support CRT in patients with a QRS of 120 to 150 milliseconds. A combination of CRT and an implantable cardioverter-defibrillator (ICD) reduces overall mortality rates compared with an ICD alone in patients who have indications for both.^{1,7,19-22}

SUPPORTING EVIDENCE

Heart failure can lead to prolongation of the QRS complex and a delay in the electromechanical forces between ventricles. Studies have shown that this is associated with worsening heart failure symptoms, sudden death, and increased overall mortality.²³ CRT improves the synchronicity between ventricles. A 2007 meta-analysis that included patients with NYHA class III or IV heart failure who had a left ventricular ejection fraction of 21% to 30% and a QRS of 155 to 209 milliseconds showed a significant reduction in hospitalization and overall mortality rates (number needed to treat for mortality = 29 at six months), and an improvement of at least one NYHA class when CRT was added to optimal medical management.¹⁹

There is also evidence that patients who have less symptomatic heart failure benefit from CRT. A 2011 meta-analysis found that patients with heart failure of any NYHA class had lower mortality and heart failure hospitalization rates with CRT compared with other interventions.²⁰ All-cause mortality was reduced in patients who underwent CRT, with an absolute risk reduction of 4.7% and a number needed to treat of 24 for NYHA class I or II, and an absolute risk reduction of 2.5% and a number needed to treat of 40 for NYHA class III or IV. Although the inclusion criteria varied among the evaluated trials, patients in the most heavily weighted trial had a left ventricular ejection fraction less than 30%. Approximately

Pacemakers

80% of patients had NYHA class II heart failure, 20% had class III, and the mean QRS was 157 milliseconds.²¹ Given the limited NYHA class I population in the trials, there is insufficient evidence to support the use of CRT in these patients.^{7,20}

Although the ACC/AHA and ESC/EHRA guidelines recommend CRT in patients with a QRS greater than 120 milliseconds, a meta-analysis of patients with heart failure and a QRS of 120 to 150 milliseconds did not show a significant reduction in the composite outcome of death and hospitalization.²² The lack of benefit was consistent between heart failure classes and across trials with minimal heterogeneity. However, the meta-analysis showed a mortality benefit in those with a QRS greater than 150 milliseconds. A newer study of CRT use in patients with heart failure and a QRS duration of less than 130 milliseconds was terminated because of a hazard ratio of death of 1.81.²⁴

Because many patients have indications for both CRT and an ICD, a separate meta-analysis investigated whether a combination of these interventions improved overall mortality rates.²⁵ When comparing ICD alone with ICD plus CRT, the study found an absolute risk reduction of 4% with a number needed to treat of 25 for overall mortality when the combination is used.

Data Sources: The main sources include UM-MEDSEARCH, which includes Medline, PreMedline, EBM reviews, Cochrane, ACP Journal Club, and International Pharmaceutical Abstracts; Essential Evidence Plus; and the National Guideline Clearinghouse. Search words included: pacer, pacemaker, cardiac pacemaker, neurocardiogenic syncope, vasovagal syncope, sick sinus syndrome, sinus node dysfunction, AV block, atrioventricular block, ICD, implantable cardioverter defibrillator, heart block, bradycardia, bradyarrhythmias, heart failure, CRT, cardiac resynchronization therapy, biventricular, single chamber, dual chamber, left ventricular only. Search dates: December 2011, July 2012, and November 2013.

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