

Consensus Statement on Pacemakers and Cardiac Resynchronization Therapy

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Table of contents

Introduction	314
Sinus node dysfunction	314
Indications for permanent pacing in sinus node dysfunction	314
Fascicular blocks	314
Recommendations for permanent pacing in fascicular blocks	315
Acquired and congenital atrioventricular blocks	315
Recommendations for permanent pacing in atrioventricular blocks	315
Indications for temporary pacing	316
General recommendations for temporary pacing	316
Recommendations for temporary pacing in the acute phase of acute myocardial infarction (AMI)	316
Permanent pacing after the acute phase of myocardial infarction	317
Indications for permanent pacing after the acute phase of myocardial infarction	317
Hypersensitive carotid sinus and neurocardiogenic syndrome	317
Recommendations for permanent pacing in neurocardiogenic syncope and hypersensitive carotid sinus ..	317
Pacing after cardiac surgery	317
Indications for permanent pacing after cardiac surgery	317
Pacing after catheter ablation of the atrioventricular junction	318
Indications for permanent pacing after catheter ablation of the AV junction	318
Unconventional indications for permanent pacing	318
Recommendations for permanent pacing in congenital long-QT syndrome	318
Recommendations for permanent pacing in hypertrophic cardiomyopathy	318
Recommendations for permanent pacing in sleep apnea	318
Recommendations for permanent pacing in atrial fibrillation	319
Pacing in children, adolescents and patients with congenital heart disease	319
Recommendations for permanent pacing in children, adolescents and patients with congenital heart disease	319
Selection of mode of cardiac pacing and sensor	319
Overview	319
Sinus node dysfunction	320
Atrioventricular block	320
Chronic bifascicular and trifascicular blocks	320
Atrial fibrillation with slow ventricular response	320
Long-QT syndrome	320
Pacemaker programming settings:	320
Hypertrophic cardiomyopathy	321
Neurocardiogenic syncope	321
Cardiac resynchronization therapy	321
QRS width and evaluation of dyssynchrony	322
Indications for cardiac resynchronization therapy	322
Pacemaker follow-up:	322
Interventions recommended during follow-up	323
Follow-up protocol	323
Criteria for replacement of the pulse generator	323
Management of pacemaker recalls	323
Infections associated with pacemakers and implantable cardioverter defibrillator devices	324
Diagnostic criteria of infective endocarditis related to PM/ICD	324
Treatment	324
General recommendations for the treatment of infections associated with PM and ICD	325
Lead removal indications	326
Risk factors to consider before lead removal	326
Surgical approach	326
Indications for transvenous removal of pacemaker and cardioverter defibrillator leads	326

INTRODUCTION

The Area of Standardizations and Consensus, the Electrophysiology Council and a prominent group of experts of the Argentine Society of Cardiology, including members of the Argentine Society of Cardiac Pacing, have worked together during the last months to deliver the Consensus Statement on Pacemakers and Cardiac Resynchronization Therapy in order to provide cardiologists, and why not electrophysiologists, with the indispensable information required at the moment of making decisions on this important subject.

In addition to the traditional sections of pacemaker indications, we have included new sections with indications in less prevalent conditions: congenital long-QT syndrome, atrial fibrillation, sleep apnea, hypertrophic cardiomyopathy and vasovagal syncope.

We have also considered suggesting recommendations in complex and widely discussed areas: indications for temporary pacing, management of device infections and recommendations for lead removal.

The advent of cardiac resynchronization therapy in heart failure also led us to propose, for the first time, the recommendations of our Society regarding this important issue for clinical practice.

The table of contents will provide the reader with guidelines to choose the best pacemaker device and with recommendations for appropriate follow-up of patients with permanent pacemakers,

The final recommendations for each item are expressed using the following classification:

- **Class I:** conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.
- **Class II:** conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.
- **Class IIa:** weight of evidence/opinion is in favor of usefulness/efficacy.
- **Class IIb:** usefulness/efficacy is less well established by evidence/opinion.
- **Class III:** conditions for which there is evidence and/or general agreement that a procedure or treatment is not useful/effective and in some cases may be harmful.

Despite the lack of sufficient bibliography supporting many conditions, recommendations are based on the level of evidence according to the following categories:

- **Level of evidence A:** consistent evidence from randomized clinical trials or meta-analyses. Multiple population risk strata evaluated. General consistency of direction and magnitude of effect.
- **Level of evidence B:** data derived from a single randomized trial, or non-randomized studies. Limited population risk strata evaluated.
- **Level of evidence C:** data derived from consensus opinion of experts, case studies, retrospective studies, registries.

We hope that this Consensus Statement really becomes a reference text for all cardiologists and a guideline for decision-making.

Dr. Carlos Labadet

SINUS NODE DYSFUNCTION

Indications for permanent pacing in sinus node dysfunction

Class I

1. Symptomatic sinus node dysfunction with documented symptomatic bradyarrhythmias, such as severe sinus bradycardia (< 40 bpm) or sinus pauses. (Level of evidence C).
2. Symptomatic sinus bradycardia or sinus pauses as a consequence of essential long-term drug therapy of a type and dose for which there are no acceptable alternatives. (Level of evidence C).
3. Symptomatic chronotropic incompetence. (Level of evidence C).

Class IIa

1. Sinus bradycardia occurring spontaneously or as a result of necessary drug therapy when a clear association between significant symptoms and the presence of bradycardia has not been documented. (Level of evidence C).
2. Syncope of unexplained origin when major abnormalities of sinus node function, such as bradycardia-tachycardia syndrome, are discovered in electrophysiologic studies. (Level of evidence C).

Class IIb

1. In minimally symptomatic patients, chronic heart rate less than 40 bpm while awake. (Level of evidence C).

Class III

1. Sinus node dysfunction in asymptomatic patients, including those in whom substantial sinus bradycardia < 40 bpm is a consequence of long-term drug treatment. (Level of evidence C).
2. Sinus node dysfunction in patients with symptoms suggestive of bradycardia (syncope, presyncope, dizziness) that are clearly documented as not associated with a slow heart rate. (Level of evidence C).
3. Sinus node dysfunction with symptomatic bradycardia due to nonessential drug therapy. (Level of evidence C).

FASCICULAR BLOCKS

Fascicular and bifascicular block refers to impaired conduction in one or two fascicles of the right and left bundles (e.g., right bundle-branch block [RBBB] associated with left anterior hemiblock [LAH], right bundle-branch block associated with left posterior hemiblock [LPH] or left bundle-branch block [LBBB]). "Trifascicular" block is defined as

bifascicular block associated with prolongation of the HV interval in the electrophysiologic study. Alternating bundle-branch block in the ECG refers to situations in which there is clear electrocardiographic evidence for block in all three fascicles.

Fascicular blocks can be manifest as:

1. Fixed block, when it is persistent with cycle lengths > 1500 ms.
2. Transient block, when the conduction abnormality temporarily disappears.
3. Intermittent block, when it coexists with normal conduction within the same ECG record. Intermittent fascicular blocks may be tachycardia-dependent (phase 3 block) or bradycardia-dependent (phase 4 block).

Fascicular blocks may be located in the Purkinje network, Purkinje-muscle junction or in the distal ventricular myocardium.

Recommendations for permanent pacing in fascicular blocks

Class I

1. Intermittent third-degree AV block. (Level of evidence B).
2. Type II second-degree AV block. (Level of evidence B).
3. Alternating bundle-branch block. (Level of evidence C).

Class IIa

1. Syncope not demonstrated to be due to AV block when other likely causes have been excluded, specifically ventricular tachycardia (VT). (Level of evidence B).
2. Incidental finding at electrophysiologic study of markedly prolonged HV interval (greater than or equal to 100 ms) in asymptomatic patients. (Level of evidence B).
3. Incidental finding at electrophysiologic study of pacing-induced infra-His block that is not physiologic. (Level of evidence B).

Class IIb

1. Neuromuscular diseases such as myotonic muscular dystrophy, Kearns-Sayre syndrome, Erb's dystrophy (limb-girdle), and peroneal muscular atrophy with any degree of fascicular block, with or without symptoms, because there may be unpredictable progression of AV conduction disease. (Level of evidence C).

Class III

1. Fascicular block without AV block or symptoms. (Level of evidence B).
2. Fascicular block with first-degree AV block without symptoms. (Level of evidence B).

ACQUIRED AND CONGENITAL ATRIOVENTRICULAR BLOCKS

Recommendations for permanent pacing in atrioventricular blocks

Class I

1. Acquired third-degree and advanced AV block. (Level of evidence B).
2. Symptomatic congenital third-degree AV block. (Level of evidence B).
3. Symptomatic second-degree AV block regardless of type (Mobitz I or II, 2:1, etc.) or site of block (supra-His, His or infra-His block). (Level of evidence B).
4. Neuromuscular diseases with AV block, such as myotonic muscular dystrophy, Kearns-Sayre syndrome, Erb's dystrophy and peroneal muscular atrophy. (Level of evidence B).

The presence of symptoms does not determine the indication for permanent pacing in third-degree or advanced AV block due to the fact that escape rhythms originated in the His-Purkinje system are unstable and are prone to generating prolonged episodes of asystole under different conditions (e.g. fever, "bursts" of ventricular premature beats).

Class IIa

1. Asymptomatic congenital third-degree AV block with average awake ventricular rates < 40 bpm or pauses > 3.0 seconds. (Level of evidence B).
2. Asymptomatic type II second-degree AV block. (Level of evidence B). In this type of AV block, progression to advanced or third-degree AV block is unexpected and has an adverse prognosis; therefore, it constitutes an indication for permanent pacing in many institutions.
3. First-degree AV block with symptoms 1 similar to those of "pacemaker syndrome" (pseudo-pacemaker syndrome), with 1ventricular rates < 40 bpm and alleviation of symptoms with temporary dual-chamber pacing with shorter AV intervals (Level of evidence B).

Class IIb

1. First-degree AV block with PR interval > 300 ms in patients with left ventricular dysfunction and symptoms of congestive heart failure in whom a shorter AV interval results in hemodynamic improvement (consider implantation of cardiac resynchronization therapy) (Level of evidence C).
2. Type-I second-degree AV block with hemodynamic impairment associated to the loss of AV synchrony even in the absence of bradycardia, as mentioned in recommendations Class I. (Level of evidence B).
3. Symptomatic neuromuscular diseases with HV interval > 70 ms. (Level of evidence C).

Class III

1. Asymptomatic congenital AV block without awake pauses > 3 seconds or ventricular rate < 40 bpm. (Level of evidence B).
2. Third-degree AV block associated with acute inflammatory diseases, ischemia, metabolic abnormalities or drug toxicity. (Level of evidence B).
3. Asymptomatic type I second-degree AV block. (Level of evidence B).
4. Asymptomatic first-degree AV block.

Congenital third-degree AV block is not as a benign condition as it was previously considered, due to the risk of sudden death, ventricular dysfunction and heart failure. The presence of concomitant complex ventricular premature beats, escape rhythms with slow ventricular rate or wide QRS and/or left ventricular dysfunction is an indication for permanent pacing. In the study by Michaelsson et al., the entire population with asymptomatic congenital third-degree AV block and QTc > 450 ms presented Adams-Stokes syndrome; in this way, long QTc interval is an indication for permanent pacing.

Certain neuromuscular diseases are associated with AV block, atrial fibrillation and sudden death. Occasionally, cardiac compromise is the only evidence of neuromuscular disease. Myotonic muscular dystrophy, Kearns-Sayre syndrome, Erb's dystrophy and peroneal muscular atrophy are associated with sinus node dysfunction, AV and intraventricular conduction abnormalities and atrial fibrillation. There may be unpredictable progression of AV conduction disease; sudden death occurs in 10% to 30% of cases. Patients with symptoms of bradycardia (dizziness, syncope or palpitations) should undergo electrophysiologic study even in the absence of significant abnormalities in the 24-hour Holter monitoring, and the presence of a HV interval > 70 ms is an indication for permanent pacing. This recommendation applies to all types of AV blocks regardless of symptoms.

In AV blocks associated with drug toxicity, it should be noted that the conduction abnormality may appear spontaneously despite drug discontinuation ("latent" AV blocks) and permanent pacing could be an indication.

INDICATIONS FOR TEMPORARY PACING

General recommendations for temporary pacing*Class I*

1. Symptomatic bradycardia (acute impaired consciousness, persistent angina, hypotension or any other sign of shock) due to reversible or not reversible causes, not responsive to atropine or isoproterenol, and secondary to sinus node disease or dysfunction, AV block or permanent pacemaker malfunction that cannot be corrected by reprogramming the device. (Level of evidence C).

2. Asymptomatic type II second-degree AV block with wide QRS in patients undergoing urgent non-cardiac surgery. (Level of evidence C).
3. Treatment of ventricular arrhythmias secondary to bradycardia-related acquired long-QT syndrome. (Level of evidence C).

Class IIa

1. Asymptomatic congenital third-degree AV block, regardless of age, in patients undergoing non-cardiac surgery. (Level of evidence C).
2. Asymptomatic type II second-degree AV block with narrow QRS in patients undergoing urgent non-cardiac surgery. (Level of evidence C).
3. During the postoperative period after cardiac surgery for maintaining hemodynamic stability. (Level of evidence C).
4. Bradycardia with heart rate < 40 bpm not responsive to drug therapy in patients undergoing non-cardiac surgery. (Level of evidence C).
5. Asymptomatic type II second-degree AV block not responsive to drug therapy in patients undergoing non-cardiac surgery. (Level of evidence C).
6. Refractory bradycardia in patients with shock. (Level of evidence C).

Class IIb

1. As adjunct therapy of the underlying cause of reversible long-QT syndrome. (Level of evidence C).
2. Overdrive suppression of supraventricular or ventricular tachyarrhythmias without hemodynamic impairment. (Level of evidence C).
3. Prevention of extreme bradycardia or asystole after electrical cardioversion of supraventricular arrhythmias in patients under pharmacological therapy. (Level of evidence C).
4. During pacemaker generator or lead replacement in pacemaker dependent patients after having confirmed its efficacy. (Level of evidence C).

Class III

1. Chronic bifascicular block (RBBB + LAH or LBBB) with or without first-degree AV block, in asymptomatic patients undergoing non-cardiac surgery. (Level of evidence B). However, transcutaneous or transvenous pacing devices should be available in the operation room.
2. Asystole during cardiac arrest. (Level of evidence C).

Recommendations for temporary pacing in the acute phase of acute myocardial infarction (AMI)*Class I*

1. Ventricular asystole. (Level of evidence C).
2. Third-degree AV block in anterior AMI. (Level of evidence C).
3. Symptomatic bradycardia secondary to sinus node dysfunction or AV block not responsive to drug therapy in inferior AMI. (Level of evidence C).
4. Asymptomatic type II second-degree AV block. (Level of evidence C).

5. Type I second-degree AV block associated with bifascicular block (RBBB + LAH or LBBB) in anterior AMI. (Level of evidence C).
6. Alternating bundle-branch block. (Level of evidence C).

Class IIa

1. Type I second-degree AV block associated with bifascicular block in inferior AMI. (Level of evidence C).
2. First degree-AV block associated with bifascicular block. (Level of evidence C).
3. First degree-AV block associated with new fascicular block. (Level of evidence C).
4. New fascicular block. (Level of evidence C).

Class IIb

1. Symptomatic third-degree AV block in inferior AMI. (Level of evidence C).
2. First degree-AV block associated with preexistent fascicular block. (Level of evidence C).
3. New right bundle-branch block. (Level of evidence C).

Class III

1. Type I second-degree AV block with or without LAH in inferior AMI. (Level of evidence C).
2. First degree-AV block with or without LAH. (Level of evidence C).
3. Preexistent fascicular block with normal PR interval. (Level of evidence C).
4. Isolated left anterior or posterior hemiblock. (Level of evidence C).

PERMANENT PACING AFTER THE ACUTE PHASE OF MYOCARDIAL INFARCTION

Unlike acquired AV blocks, indications for permanent pacing do not necessarily depend on the presence of symptoms but on the site of block which determines the prognosis. The use of temporary pacemaker is not a predictor of permanent pacing. The long-term prognosis is related primarily to the extent of myocardial injury and the character of intraventricular conduction disturbances rather than the AV block itself.

Indications for permanent pacing after the acute phase of myocardial infarction

Class I

1. Persistent second-degree AV block in the His-Purkinje system with bilateral bundle-branch block or third-degree AV block within or below the His-Purkinje system regardless of the site of AMI. (Level of evidence B).
2. Advanced second- or third-degree AV block, or infranodal third-degree AV block or at the AV node level associated with wide QRS. If the site of block is uncertain, an electrophysiologic study may be necessary. (Level of evidence B).
3. Persistent (more than 2 or 3 weeks) third-degree AV block at the AV node level. (Level of evidence B).

Class III

1. Transient AV block in the absence of intraventricular conduction defects. (Level of evidence B).

2. Transient AV block in the presence of isolated left anterior fascicular block. (Level of evidence B).
3. Acquired left anterior fascicular block in the absence of AV block. (Level of evidence B).
4. Persistent first-degree AV block in the presence of bundle-branch block that is old or age indeterminate (Level of evidence B).

HYPERSENSITIVE CAROTID SINUS AND NEUROCARDIOGENIC SYNDROME

Hypersensitive carotid sinus syndrome and neurocardiogenic syndrome are the result of inappropriate autonomous reflex that triggers inadequate vasodilatation and bradycardia.

The hypersensitive carotid sinus syndrome is defined as syncope or presyncope resulting from an extreme reflex response to carotid sinus stimulation. It is an uncommon cause of syncope. Hyperactive response to carotid sinus stimulation is defined as asystole due to either sinus arrest or AV block of more than 3 seconds, or a substantial symptomatic decrease in systolic blood pressure, or both.

Recommendations for permanent pacing in neurocardiogenic syncope and hypersensitive carotid sinus

Class I

1. Recurrent syncope caused by carotid sinus stimulation; minimal carotid sinus pressure induces ventricular asystole of more than 3 seconds' duration in the absence of any medication that depresses the sinus node or AV conduction. (Level of evidence C).

Class IIa

1. Significantly symptomatic and recurrent neurocardiogenic syncope associated with severe bradycardia documented spontaneously or at the time of tilt-table testing in case of failure of adequate pharmacological or non-pharmacological treatment. (Level of evidence B).

Class III

1. A hyperactive cardioinhibitory response to carotid sinus stimulation in the absence of symptoms or in the presence of vague symptoms such as dizziness, lightheadedness, or both. (Level of evidence C).

PACING AFTER CARDIAC SURGERY

Indications for permanent pacing after cardiac surgery

(Including heart transplantation and Cox-Maze surgery)

Class I

1. Third-degree AV block persisting 3-5 days after cardiac surgery and 3 weeks after heart transplantation. (Level of evidence B).
2. Persistent second-degree AV block at any anatomic level:

- With symptomatic bradycardia. (Level of evidence C).
 - In asymptomatic patients requiring medication that is likely to produce symptomatic bradycardia. (Level of evidence C).
 - In the presence of pauses greater than 3000 ms and/or heart rate less than 40 bpm while awake. (Level of evidence C).
3. Sinus node dysfunction with documented symptomatic bradycardia, including symptomatic sinus pauses. This indication also includes sinus node dysfunction secondary to negative chronotropic drugs which should not be discontinued. In case of heart transplantation, 3 weeks are required before implant of a permanent pacemaker. (Level of evidence C).

Class IIa

1. Asymptomatic persistent second-degree AV block at any anatomic level. (Level of evidence C).
2. First-degree AV block associated with bundle-branch block or fascicular block, with intra- or infra-His block found at electrophysiological study. (Level of evidence C).
3. Bradycardia < 40 bpm with symptoms or signs of heart failure. (Level of evidence B).
4. Symptomatic bradycardia < 60 bpm in heart transplant patients. (Level of evidence B).

Class IIb

None

Class III

1. Asymptomatic bradycardia. (Level of evidence C).
2. First-degree AV block. (Level of evidence C).
3. Transient second-degree AV block at any anatomic level. (Level of evidence C).
4. Bundle-branch and fascicular blocks. (Level of evidence C).

PACING AFTER CATHETER ABLATION OF THE ATRIOVENTRICULAR JUNCTION

Indications for permanent pacing after catheter ablation of the AV junction

Class I

1. All patients undergoing catheter ablation/modification of the AV junction. (Level of evidence C).

UNCONVENTIONAL INDICATIONS FOR PERMANENT PACING

Although permanent pacing is not the mainstay treatment of certain clinical conditions, it has been proposed as an alternative therapeutic option. The potential benefits may be either the result or the consequence of pacing on ventricular remodelling, repolarization, or changes in heart rate due to appropriate sensing of different events. Unconventional indications for permanent pacing include:

- a. Long QT syndrome.
- b. Hypertrophic cardiomyopathy.
- c. Sleep apnea.
- d. Atrial fibrillation.
- e. Vasovagal syndrome.
- f. Advanced heart failure.

The indications for permanent pacing in vasovagal syndrome and in heart failure are discussed in their corresponding sections.

Recommendations for permanent pacing in congenital long-QT syndrome

Class I

1. Symptomatic sinus bradycardia or third-degree AV block. (Level of evidence C).
2. Sustained pause-dependent ventricular tachycardia with indication of ICD therapy in combination with overdrive suppression pacing to prevent frequent ICD shocks. (Level of evidence C).

Class IIa

None

Class IIb

1. Asymptomatic long-QT syndrome without previous or family history of arrhythmia or sudden death with **advanced** or second-degree 2:1 AV block. (Level of evidence C).

Class III

1. Patients with long-QT syndrome with a history of ventricular arrhythmias or sudden death, or with a family history of arrhythmias or sudden death in young family members with indication of ICD therapy. (Level of evidence C).

Recommendations for permanent pacing in hypertrophic cardiomyopathy

Class I

1. Class I indications for sinus node dysfunction or AV block. (Level of evidence C).

Class IIb

1. Medically refractory symptomatic patients with hypertrophic cardiomyopathy and significant resting or provoked left ventricular outflow tract obstruction in whom alcohol septal ablation or myectomy are contraindicated. (Level of evidence A).

Class III

1. Asymptomatic or medically controlled patients. (Level of evidence C).
2. Symptomatic patients without evidence of left ventricular outflow tract obstruction. (Level of evidence C).

Recommendations for permanent pacing in sleep apnea

Class I

None

Class IIa

1. In patients in whom cardiac resynchronization therapy is indicated. (Level of evidence C).

Class III

1. Permanent pacemaker implant. (Level of evidence B).

Recommendations for permanent pacing in atrial fibrillation

Class I

None

Class IIa

None

Class IIb

1. Prevention of recurrent symptomatic and refractory atrial fibrillation in patients with coincidental sinus node dysfunction. (Level of evidence B).

Class III

None

PACING IN CHILDREN, ADOLESCENTS, AND PATIENTS WITH CONGENITAL HEART DISEASE

Permanent pacing in children and adolescents is unequivocally indicated in:

1. Symptomatic sinus bradycardia.
2. Symptomatic and recurrent bradycardia-tachycardia syndromes.
3. Congenital third-degree AV block.
4. Advanced second- or third-degree AV block, either surgical or acquired.

Recommendations for permanent pacing in children, adolescents and patients with congenital heart disease

Class I

1. Advanced second- or third-degree AV block, associated with symptomatic bradycardia, ventricular dysfunction or low cardiac output. (Level of evidence C).
2. Sinus node dysfunction with correlation of symptoms during age-inappropriate bradycardia. The definition of bradycardia depends on patient's age and expected heart rate. (Level of evidence B).
3. Postoperative advanced second- or third-degree AV block that persists 7-10 days after cardiac surgery. (Level of evidence B).
4. Congenital third-degree AV block with a wide QRS escape rhythm, complex ventricular ectopy, or ventricular dysfunction. (Level of evidence B).
5. Congenital third-degree AV block in the infant with an average ventricular rate less than 50 bpm or with congenital heart disease and a ventricular rate less than 70 bpm. (Level of evidence B).
6. Sustained pause-dependent VT, with or without prolonged QT, in which the efficacy of pacing is thoroughly documented. (Level of evidence B).
7. Advanced second- or third-degree AV block, associated with neuromuscular disease. (Level of evidence B).

Class IIa

1. Bradycardia-tachycardia syndrome with the need for long-term antiarrhythmic treatment other than digitalis. (Level of evidence C).
5. 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 two or three times the basic cycle length, or associated with symptoms due to chronotropic incompetence. (Level of evidence B).
3. Long-QT syndrome with 2:1 AV or third-degree AV block. (Level of evidence B).
4. Asymptomatic sinus bradycardia in the child with complex congenital heart disease with resting heart rate less than 40 bpm or pauses in ventricular rate more than 3 seconds. (Level of evidence C).
5. Patients with congenital heart disease and impaired hemodynamics due to sinus bradycardia or loss of AV synchrony. (Level of evidence C).
6. Neuromuscular diseases with first- or second-degree AV block, with or without symptoms, because there may be unpredictable progression of AV conduction disease. (Level of evidence C).

Class IIb

1. Third-degree AV block that reverts to sinus rhythm with residual bifascicular block. (Level of evidence C).
2. Third-degree AV block in the infant, child, adolescent or young adult with an acceptable rate, a narrow QRS complex, and normal ventricular function. (Level of evidence B).
3. Asymptomatic sinus bradycardia in the adolescent with congenital heart disease with resting heart rate less than 40 bpm or pauses in ventricular rate more than 3 seconds. (Level of evidence C).

Class III

1. Transient postoperative AV block with return of normal AV conduction. (Level of evidence B).
2. Asymptomatic postoperative bifascicular block with or without first-degree AV block. (Level of evidence C).
3. Type I second-degree AV block. (Level of evidence C).
4. Asymptomatic sinus bradycardia in the adolescent with longest RR interval less than 3 seconds and minimum heart rate more than 40 bpm. (Level of evidence C).

SELECTION OF MODE OF CARDIAC PACING AND SENSORS

Overview

Once the need for permanent pacing has been established, the most appropriate pacing mode for the patient must be selected. The fundamental decision is to choose between single- and dual-chamber devices; however, other factors to consider include presence and type of sensor for rate response, size, type of leads, battery capacity, local availability of technical support

and cost. Patient-related factors are also important to decide the mode of cardiac pacing: exercise capacity, age, the degree of dependence on ventricular pacing or the expected ventricular pacing percentage, ventricular function, structural cardiac conditions or anatomical variations that might pose problems in lead placement, operator experience and, finally patient's quality-of-life issues.

The following levels of recommendation are based on the different variables and on the lack of conclusive scientific evidence in favor of or against of a specific pacing mode:

- **Recommended:** there is sufficient evidence from randomized clinical trials or consensus statement criteria that the pacing mode chosen has a clear benefit for patients.
- **Accepted:** the pacing mode chosen is a reasonable alternative option, yet it is not the first-line treatment.
- **Not recommended:** the pacing mode chosen may be considered; yet its efficacy is less well established or the risk/benefit ratio is less favorable.
- **Contraindicated:** the pacing mode chosen is not helpful and may be harmful.

This Consensus Statement provides general recommendations for pacemaker implantation based on cardiac rhythm abnormalities using a revised generic classification code:

I	II	III	IV	V
Chamber paced	Chamber sensed	Response to a sensed event	Rate modulation	Multisite pacing
O = Absent	O = Absent	O = Absent	O = Absent	O = Absent
A = Atrium	A = Atrium	I = Inhibited	R = Rate	A = Atrium
V = Ventricle	V = Ventricle	T = Triggered	modulation	V = Ventricle
D = Dual (A + V)	D = Dual (A + V)	D = Dual (I + T)		D = Dual (A + V)

NASPE/BPEG

Sinus node dysfunction

This Consensus Statement considers: (Figure 1):

- *Pacing modes in patients with SND and normal AV conduction:*
- **Recommended:** AAIR or DDDR.
- **Accepted:** AAI or DDD with absence of rate modulation.
- **Not recommended:** VVI or VDD.
- *Pacing modes in patients with SND and evidence of AV conduction defects:*
- **Recommended:** DDDR.
- **Accepted:** DDD.
- **Not recommended:** VVI/R
- **Contraindicated:** AAI/R.

In high-risk patients susceptible to AF or in those with history of AF it is advisable to activate automatic switch mode. Atrial fibrillation prevention pacing algorithms may be used if available. Dual chamber devices should be programmed to minimize ventricular pacing using long AV intervals or intrinsic conduction search tools.

Atrioventricular block

This Consensus Statement considers: (Figure 2):

- *Pacing modes in patients with AV block and normal sinus node function:*
- **Recommended:** DDDR and VDD.
- **Accepted:** VVI/R.
- **Contraindicated:** AAI/R.
- *Pacing modes in patients with AV block and sinus node dysfunction:*
- **Recommended:** DDDR.
- **Accepted:** DDD.
- **Not recommended:** VVI/R and VDD.
- **Contraindicated:** AAI/R.

Chronic bifascicular and trifascicular blocks

This Consensus Statement considers: (Figure 3):

- *Pacing modes in patients with chronic bifascicular or trifascicular block and normal sinus node function:*
- **Recommended:** DDDR and VDD.
- **Accepted:** VVI/R.
- **Contraindicated:** AAI/R.
- *Pacing modes in patients with chronic bifascicular or trifascicular block and sinus node dysfunction:*
- **Recommended:** DDDR.
- **Accepted:** DDD.
- **Not recommended:** VVI/R and VDD.
- **Contraindicated:** AAI/R.

Atrial fibrillation with slow ventricular response

This Consensus Statement considers:

- *Pacing modes in patients with atrial fibrillation with slow ventricular response:*
- **Recommended:** VVIR.
- **Accepted:** VVI.
- **Contraindicated:** DDD/R, VDD, AAI/R.

Long QT Syndrome

This Consensus Statement considers:

- *Pacing modes in patients with long-QT syndrome:*
- **Recommended:** DDD/R or AAI/R.
- **Accepted:** VVI/R.
- **Not recommended:** VDD.

Pacemaker programming settings

- *Mode:* DDD.
- *Rate:* adjust lower rate limit (LRL) to prevent arrhythmias. A safe lower limit rate is 70 bpm in adults and 80 bpm in pediatric patients (≤ 21 years).
- *Rate responsiveness:* not evaluated.
- *AV delay:* not evaluated.
- *Precautions:* it is advisable to turn off the following pacemaker settings: hysteresis, sleep function, rate hysteresis-search, extended post-ventricular atrial refractory period, and mode switch.
- *Pause prevention:* rate smoothing down on when available with upper rate limit of 120-130 bpm, rate smoothing up and rate-drop on; finally, there is no experience with ventricular rate stabilization.

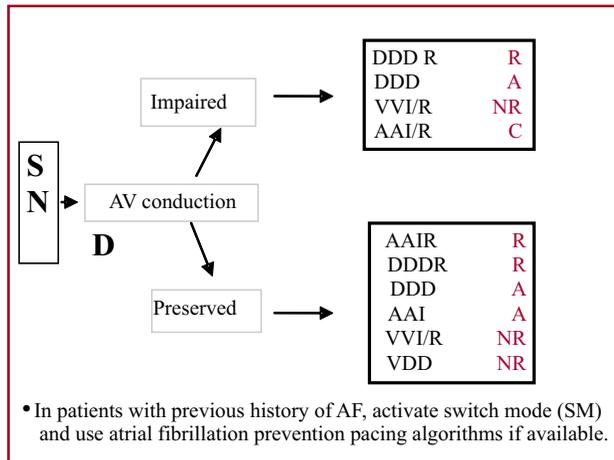


Fig. 1. Pacing modes in sinus node dysfunction. R: Recommended. A: Accepted. NR: Not recommended. C: Contraindicated.

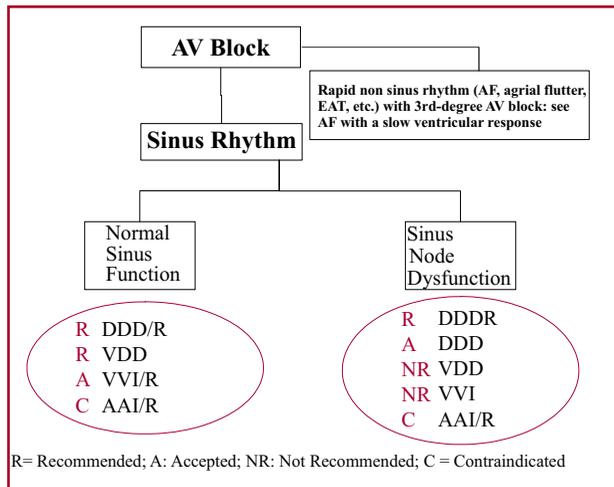


Fig. 2. Pacing modes in atrioventricular block. R: Recommended. A: Accepted. NR: Not recommended. C: Contraindicated.

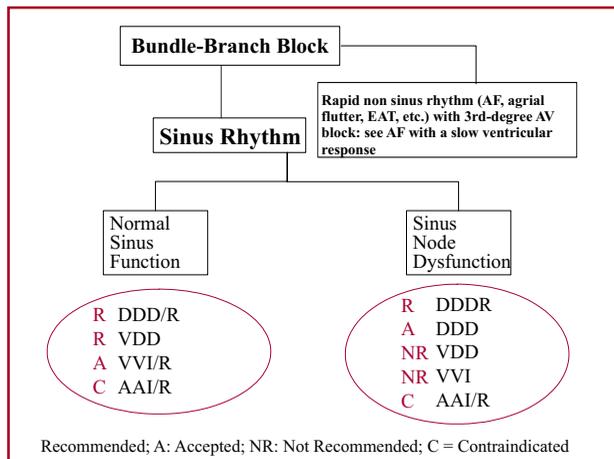


Fig. 3. Pacing modes in chronic bifascicular and trifascicular blocks. R: Recommended. A: Accepted. NR: Not recommended. C: Contraindicated.

Hypertrophic cardiomyopathy

This Consensus Statement considers: (Figure 4):

- *Pacing modes in patients with HCM and sinus rhythm:*
- **Recommended:** DDD/R.
- **Accepted:** VDD.
- **Not recommended:** VVI/R.
- **Contraindicated:** AAI/R.

- *Pacing modes in patients with HCM and permanent atrial fibrillation:*
- **Recommended:** VVI/R.
- **Contraindicated:** DDD/R, VDD, AAI/R.-VDDD.

Neurocardiogenic syncope

This Consensus Statement considers:

- *Pacing modes in patients with neurocardiogenic syncope:*
- **Recommended:** DDD/R.*
- **Accepted:** DDD-VVI/R.
- **Not recommended:** VDD.
- **Contraindicated:** AAI/R.

*Used with syncope prevention algorithms rate-drop or close loop. However, in our opinion, the evidence currently available is insufficient to decide whether DDD pacemakers without these algorithms are not efficient to treat this condition.

CARDIAC RESYNCHRONIZATION THERAPY

Many patients with advanced heart failure (HF) have atrioventricular conduction delays. In addition to global contraction impairment, about 70% of patients also present mechanical dyssynchrony between the right and the left ventricle (interventricular dyssynchrony) or between two or more segments of the left ventricle (left intraventricular dyssynchrony).

Ventricular dyssynchrony produces suboptimal ventricular filling and paradoxical septal motion, re-

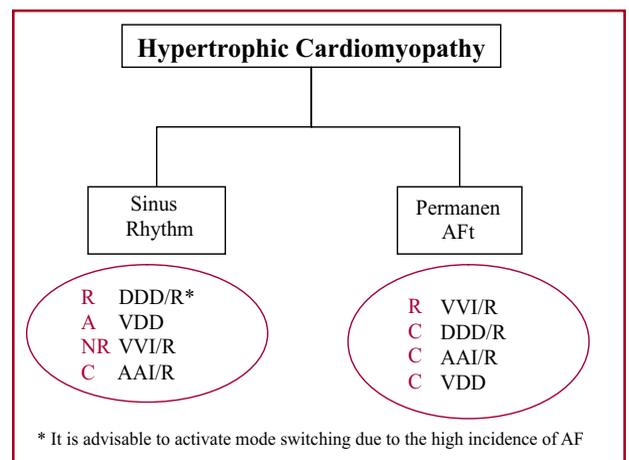


Fig. 4. Pacing modes in hypertrophic cardiomyopathy. R: Recommended. A: Accepted. NR: Not recommended. C: Contraindicated.

duces left ventricular dP/dT, increases mitral regurgitation and reduces left ventricular ejection fraction (LVEF). It has been associated with increased hospitalizations due to HF and mortality.

Cardiac resynchronization therapy (CRT) is based on the use of devices for atrial and biventricular stimulation with a pacemaker.

The ventricular lead is placed in a suitable cardiac vein via the coronary sinus; in occasions an epicardial lead is placed using a mini-thoracotomy or a thoracoscopic approach.

Cardiac resynchronization therapy reestablishes atrioventricular, interventricular and intraventricular synchrony in patients with sinus rhythm, producing adequate ventricular filling and reducing the severity of mitral regurgitation. In this way, CRT produces reverse remodeling with reduction of LV volumes and increases the EF.

Many randomized clinical trials have evaluated the efficacy of CRT in advanced HF patients with sinus rhythm and prolonged QRS complex duration (QRSd), mainly with left bundle-branch block.

QRS width and evaluation of dyssynchrony

Between 12% and 47% of patients with advanced HF have a QRSd \geq 120 ms. QRS duration is associated with more advanced heart failure, poor FC, lower EF, more severe mitral regurgitation and greater hospitalization and mortality. For these reasons, it was initially considered an indirect marker of mechanical dyssynchrony. However, mechanical dyssynchrony has also been detected in patients with QRSd $<$ 120 ms and may be absent with QRSd $>$ 120 or 150 ms. Prolonged QRSd has a better correlation with interventricular dyssynchrony compared to left intraventricular dyssynchrony. The latter is a better predictor of reverse remodeling and clinical improvement after biventricular pacing. Although echocardiography has emerged as the modality of choice for assessment of dyssynchrony, there are no standardized criteria for its detection; many echocardiographic methods have been used to evaluate patients for dyssynchrony, however, there is still no clear gold standard. In fact, despite all these patients should undergo echocardiographic evaluation, QRS duration still remains the most important criterion of dyssynchrony for the indication of CRT implantation.

Indications for cardiac resynchronization therapy

Class I

1. Patients with advanced heart failure, in NYHA FC III or ambulatory Class IV with optimal recommended medical therapy who have LV ejection fraction \geq 35%, sinus rhythm, and QRS duration \geq 120 ms. (Level of evidence A).

Class IIa

1. Patients with permanent pacing in sinus rhythm or atrial fibrillation who have frequent dependence on ventricular pacing and develop heart failure

symptoms and progressive left ventricular dysfunction (EF \leq 40%) attributed to RV pacing in the absence of correctable causes. (Level of evidence C).

2. Patients with advanced heart failure, in NYHA FC III or ambulatory Class IV with optimal recommended medical therapy and LV ejection fraction \geq 35% who have frequent dependence on right ventricular pacing. (Level of evidence C).
3. Patients with advanced heart failure, in NYHA FC III or ambulatory Class IV with optimal recommended medical therapy who have LV ejection fraction \leq 35%, atrial fibrillation and QRS duration \geq 120 ms.

The added challenge to provide clinical benefits of CRT in atrial fibrillation patients is to ensure biventricular pacing \geq 90% through adequate blockade of native conduction through the AV node either pharmacologically or by catheter ablation. (Level of evidence B).

Class IIb

1. Patients with heart failure, in NYHA FC I or II, LV ejection fraction \leq 35% despite optimal recommended medical therapy undergoing implantation of a permanent pacemaker with anticipated frequent right ventricular pacing. (Level of evidence C).

Class III

1. Patients with heart failure in functional class III-IV in the absence of optimal recommended medical therapy.
2. Patients with symptoms of advanced heart failure due to reversible causes.
3. Patients with end-stage heart failure or whose life expectancy is $<$ 1 year.

PACEMAKER FOLLOW-UP

The goals of pacemaker follow-up are:

- To optimize pacing system function in order to meet the patient's clinical requirements.
- To optimize the patient's quality of life in order to reduce fear and anxiety.
- To maximize pulse generator longevity while maintaining patient safety.
- To identify and correct abnormal pacing system behavior.
- To triage non-device related health problems and make appropriate referrals.
- To provide education to colleagues, patients and community.
- To identify pulse generators approaching end-of-life anticipating replacement of system components.
- To maintain adequate system records and data base.

Patients should be followed-up at regular intervals and for their whole life. Schedule of pacemaker system evaluation depends on each patient's characteristics.

Interventions recommended during follow-up

Patients should attend a pacemaker clinic for follow-up. Pacemaker basic parameters should be entered in each patient's medical record.

Follow-up clinics basically need:

1. Human resources

- One cardiologist-electro physiologist trained in cardiac pacing who will supervise the functional aspects of the clinic.
- One technician trained in pacing according to the volume of patients.
- Pacemaker industry support personnel.

2. Physical resources

- Continuous ECG display monitor.
- Access to 12-lead ECG.
- At least one programmer for all pacemakers implanted in the institution.
- Magnets.
- Technical information on the behavior of all implantable pulse generators and leads.
- Contact telephone numbers for all relevant manufacturers.
- Resuscitation equipment.
- Sterile equipment to manage wounds.
- Individual medical record.
- Facilities to admit patients urgently 24 hours/day.

Follow-up protocol

Follow-up schedule.

In the absence of complications, a common schedule of pacemaker system evaluation would be:

- First control, in the post-implantation period before discharge.
- Second control, 2 weeks after discharge.
- Third control, within 30-45 days post-implant to program pacemaker definite parameters.
- Patient should be evaluated every 4 -6 months thereafter depending on the complexity of the pacemaker (single- or dual-chamber device) and on the individual characteristics of each patient.

Follow-up protocol

Pacemaker control should follow a systematized methodology. For example, pacing threshold should not be measured before evaluating pacemaker dependency.

Routine pacemaker follow-up should include:

- Evaluation of symptoms.
- Exploration of pacemaker pocket (device erosion).
- Identification of the underlying rhythm.
- Assessment of magnet rate and automatic threshold if the device has automatic features incorporated.
- Inhibition of the generator to evaluate the intrinsic rhythm, especially when battery capacity is near exhaustion.
- Determination of sensing and capture thresholds in each chamber.

- Determination of myopotentials with unipolar leads or with bipolar leads programmed to the unipolar lead mode.
- Investigation of retrograde conduction.
- Analysis of telemetry data (battery status, leads, histograms, event counters, mode switching, arrhythmias histograms, ECG strips histograms, automatic capture or automatic sensing threshold graphs, intracardiac electrograms, etc.)
- Adjustments of output parameters, polarity detection, AV intervals and refractory periods.

Criteria for replacement of the pulse generator

There are three ways to identify signs of battery depletion.

- *Free running rate*: most devices have an elective replacement indicator (ERI) to alert when the pulse generator should be replaced in a short time; this indicator may take the form of a 10% decrease in free running rate from the nominal rate of pacing. When the pulse generator reaches its end of life (EOL), the free running rate decreases more and is associated with failure to sense and to capture. The minimal time interval from the beginning of battery depletion (ERI) to EOL is three months depending on the model.
- *Magnet-pacing rate*: placement of a magnet over a pulse generator causes it to pace in an asynchronous baseline pacing rate, in a range between 80 to 100 beats/min, depending on the manufacturer, and for at least three beats.
- *Bi-directional telemetry*: it allows to measure battery voltage and impedance. The initial battery voltage of 2.7 Volts gradually drops until battery exhaustion (< 2.5 Volts), while battery impedance increases from 0.1 Kohms to 4 Kohms at the EOL. Another indicator of battery depletion is the loss of the sensor function of the pacemaker (in those devices with sensors) and automatic pacing mode change (DDD or DDDR to VVI or VOO).

Management of pacemaker recalls

Recalls and advisories are issued when there is a systematic failure mode affecting a large number of devices or patients.

As pulse generator and lead failures can be attributed to various mechanisms, device failure cannot be easily predicted. Advisories or recalls can be classified as:

1. *High risk*: a reasonable probability that the device fault will cause serious adverse consequences or death.
2. *Moderate risk*: a reasonable probability that the device fault will cause temporary or medically reversible adverse health consequences, or a remote probability of serious adverse consequences.
3. *Low risk*: device fault is not likely to cause any adverse consequences.

The management of a device recall includes:

- Notification by the manufacturer.
- Classification of the recall.
- Notification to the physician and to the follow-up center.
- Receipt of the list of patients and device serial numbers.
- Verification by the center of the patient list.
- Development of management plan.
- Notification to primary physician and administration.
- Notification to patients.
- Ongoing communication with patients, institution, government agencies and news media.
- Modification of interventional and follow-up strategies as required.
- Return of explanted device to manufacturer.

In this situation, the responsibilities of the pacemaker follow-up center are to:

- Confirm implanted devices (model and serial number).
- Identify patients being followed and their individual risk (pacemaker dependency, etc.)
- Identify patients followed-up at other clinics, lost to follow-up or deceased.
- Obtain all the available information on the device recall.
- Develop and implement a management strategy (this may be based on the recommendations of the manufacturer but may be modified by local expertise or individual patient conditions).
- Notify the responsible physician and hospital administration.
- Notify and educate the patient.
- Institute a follow-up plan that is acceptable for to the patient.
- Document the steps taken to contact the patient and the management plan for that patient.
- Reevaluate and change management plans as more information becomes available.

INFECTIONS ASSOCIATED WITH PACEMAKERS AND IMPLANTABLE CARDIOVERTER DEFIBRILATOR DEVICES

The mechanisms associated with infective endocarditis related to pacemakers and ICD devices are the following:

1. Contamination of the surgical wound during implantation, which may produce a pocket abscess in the immediate postoperative period or several months or even years after surgery.
2. Cutaneous device erosion, generally in the late postoperative period.
3. Secondary infection due to bacterial colonization of the lead during the course of transient bacteremia. This mechanism is possible due to lead endothelialization.

Diagnostic criteria of infective endocarditis related to PM/ICD

The diagnosis of endocarditis on PM leads is based on the following clinical and pathological criteria:

a. Pathological criteria

- Microorganisms demonstrated by culture or histology in vegetation, in a vegetation that has embolized, or in intracardiac abscess, or by culture of the lead.

b. Clinical criteria

Clinical criteria are classified in major and minor:

1. Major criteria

- Typical microorganisms for infective endocarditis from two separate blood cultures:
 - *Streptococcus viridans*, *Streptococcus bovis*, HACEK group.
 - *Staphylococcus aureus* or enterococci, in the absence of a primary focus.
- Evidence of endocardial involvement.
- Oscillating intracardiac mass on PM leads or on the endocardial structure in contact with PM leads.
- Abscess in contact with PM leads.

2. Minor criteria

- Fever > 38 °C
- Vascular phenomena.
- Immunologic phenomena.
- Echocardiogram consistent with infective endocarditis but not meeting major criterion.
- Positive blood culture but not meeting major criterion.

Thus, the *diagnosis* of IE is defined as definite, possible or rejected.

Definite

Definite IE is defined either by pathological criteria: microorganisms demonstrated by culture or histology in vegetation, in a vegetation that has embolized, or in intracardiac abscess, or by culture of the lead.

Or by the following clinical criteria:

Two major criteria, or one major and three minor criteria, or five minor criteria.

Possible

Findings consistent with infective endocarditis that fall short of definite but not rejected.

Rejected

Firm alternate diagnosis explaining evidence of IE, or resolution of fever, with antibiotic therapy for > 4 days, or no pathological evidence of IE.

Treatment

Currently, there are no guidelines or recommendations for the diagnosis and treatment of this type of infections, and certain aspects of the adequate management are controversial even among groups of experts. The management of infections associated with PM and ICD devices has been, and still remains, the

source of frequent debate, and there are no randomized and controlled studies recommending a particular strategy for each clinical situation.

The following recommendations for the management of infections associated with PM and ICD devices are suggested by this task force.

General recommendations for the treatment of infections associated with PM and ICD

1. The organization of a “task force” that includes cardiologists, clinicians, infectious disease specialists, surgeons and microbiologists is a good clinical practice that should not be deferred as a way to get the best results in the management of these infections. These physicians represent altogether the disciplines that can provide a comprehensive approach of the problem and its best solution. (Class I - Level of evidence C).
2. Infections related to PM and ICD devices should be managed with combined medical and surgical approach. (Class I - Level of evidence C).
3. Some authors have proposed conservative strategies associated with long-term suppressive antimicrobial therapy in order to avoid invasive procedures (surgical approach). However, some of those studies were carried out when appropriate devices and equipment for percutaneous procedures were not available. This issue is currently different.
4. Cardiovascular implantable device infections may present with vague symptoms and most of the publications have reported failure of conservative treatment and also greater mortality. For this reason, **complete device and lead removal is recommended for all patients with cardiovascular implantable device infections, associated with antimicrobial therapy** against the infecting pathogen identified by blood cultures and generator-pocket tissue and lead-tip cultures. (Class I - Level of evidence B).
5. A conservative approach may be indicated in the following situations:
 - a. Duly documented infections limited to the pocket site. In these situations strict long-term follow-up is indicated (6 to 12 months). (Class IIa - Level of evidence C).
 - b. When the patient’s clinical condition does not allow complete device and lead removal (through a percutaneous approach, sternotomy or in a combined fashion). (Class IIa - Level of evidence C). The device should be removed as soon as possible once the patient has overcome his clinical condition.
 - c. If the patient in whom conservative treatment was initiated subsequently presents documented infection due to microorganisms such as *Staphylococcus aureus*, *Pseudomonas aeruginosa* or fungi, complete device and lead removal is recommended to prevent recurrences, complications and even death. (Class IIa - Level of evidence C).
6. The route of administration of antimicrobial agents depends on the site and the severity of the infection. Intravenous administration is recommended in infections with systemic involvement, documented bacteremia, high suspicion of endocardial involvement or definite endocarditis, or in device pocket infections with evidence of extensive and/or severe cellulitis. (Class I -Level of evidence C).
7. On the contrary, sequential therapy with intravenous and oral antimicrobial therapy, or an initial oral route may be attempted in localized pocket infections in the absence of documented bacteremia or evidence of endocarditis. (Class I - Level of evidence C).
8. Duration of antimicrobial therapy is not clearly defined; it should be 10 to 14 days for pocket infections after pulse generator removal and local drainage/cleaning. Long-term suppressive antimicrobial therapy should be considered for suspected or documented endocardial involvement or bacteremia (positive blood cultures) with similar schedules to those used for management of EI associated with heart valve prosthesis. We refer the reader to the SAC-SADI Consensus Statement on Infective Endocarditis. The same recommendation applies to those cases with positive lead-tip culture in the absence of bacteremia or vegetations as the goal of the treatment is to eradicate the eventual endocardial involvement (Class IIa - Level of evidence B). This is especially important if the patient needs new device placement.
9. Long-term antimicrobial suppressive therapy is used in **selected** patients with PM or ICD device infections who are not candidates for device removal, or after a failed attempt to remove the device due to technical reasons (regardless of the surgical approach), in the presence of strong suspicion of or clearly documented endocardial involvement (Class IIa - Level of evidence C).
10. In general, antimicrobial therapy should be administered intravenously; however, sequential therapy with intravenous and oral antimicrobial agents is a possibility under special circumstances according to the clinical criterion of the attending medical team (Class IIa - Level of evidence C). This strategy may be applied to those patients who do not require immediate new device placement.
11. The optimal timing of device replacement is controversial and extremely variable according to different publications: from 1 day to 2 months. Although several aspects should be considered (type of pathogen identified, patient’s clinical condition, assessment of the need for new device placement) it seems reasonable to wait for at least 5 to 7 days after initiation of antimicrobial therapy and until blood cultures become negative before a new device is placed (Class IIa - level of evidence B).
12. In patients particularly exposed to infection recurrence due to clinical and/or underlying conditions

(e.g., patients under chronic hemodialysis) in whom implantation of a new device is imperative, it is recommended to avoid a transvenous implant and use an extracardiac or epicardial approach (Class IIa - Level of evidence C).

13. Patients with cardiovascular implantable device infections should be referred to a specialized center with appropriate facilities to identify, classify and solve the problem (Class I - Level of evidence C).

LEAD REMOVAL INDICATIONS

Risk factors to consider before lead removal

- a. *Duration of the implant:* leads in place longer are more difficult to remove as they are tightly bond to the vascular system.
- b. *Younger patients:* they develop more robust fibrous tissue and thus lead removal is more difficult.
- c. *Female gender:* major complications are significantly higher in women undergoing extraction of three leads or more.
- d. *Number of leads:* major complication risk is proportional to the number of leads present.
- e. *Presence of a calcification involving the lead:* powered sheaths, laser sheaths and electrosurgical sheaths cannot be used in the presence of lead calcifications.
- f. *Lead thickness:* thicker leads (old leads, bifurcated bipolar leads and ICD leads) present more adhesions and more risk of complications.

Surgical approach

The size of the vegetation in patients with pacemaker-related infective endocarditis is a marker for extraction technique. Percutaneous lead removal is recommended for a vegetation size not greater than 10 to 15 mm. A surgical approach is indicated for greater sizes. Some experienced centers have reported percutaneous lead removal with vegetations of 40 mm, with greater risk of pulmonary thromboembolism.

If, for any reason, lead removal fails, cutting the proximal portion of the lead is *INAPPROPRIATE* and should be avoided in any situation.

Indications for transvenous removal of pacemaker and cardioverter defibrillator leads

Class I

1. Sepsis (including endocarditis) as a result of documented infection of any intravascular part of the pacing system, or as a result of a pacemaker pocket infection when the intravascular portion of the lead system cannot be aseptically separated from the pocket. (Level of evidence C).

2. Life-threatening arrhythmias secondary to a retained lead fragment. (Level of evidence C).
3. A retained lead, lead fragment, or extraction hardware that poses an immediate or imminent physical threat to the patient. (Level of evidence C).
4. Clinically significant thromboembolic events caused by a retained lead or lead fragment. (Level of evidence C).
5. Obliteration or occlusion of all usable veins, with the need to implant a new transvenous pacing system. (Level of evidence C).
6. A lead that interferes with the operation of another implanted device (e.g., pacemaker or defibrillator) (Level of evidence C).

Class IIa

1. Localized pocket infection, erosion, or chronic draining sinus that does not involve the transvenous portion of the lead system, when the lead can be cut through a clean incision that is totally separate from the infected area. (Level of evidence C).
2. An occult infection for which no source can be found, and for which the pacing system is suspected. (Level of evidence C).
3. A lead that, because of its design or failure, may pose a threat to the patient that is not immediate or imminent if left in place. (Level of evidence C).
4. Leads preventing access to the venous circulation for newly required implantable devices. (Level of evidence C).
5. Nonfunctional leads in a young patient. (Level of evidence C).

Class IIb

1. Chronic pain at the pocket or lead insertion site that causes significant discomfort for the patient, is not manageable by medical or surgical technique without lead removal, and for which there is no acceptable alternative. (Level of evidence C).
2. A lead that interferes with the treatment of a malignancy. (Level of evidence C).
3. A traumatic injury to the entry site of the lead for which the lead may interfere with reconstruction of the site. (Level of evidence C).

Class III

1. Any situation where the risk posed by removal of the lead is significantly higher than the benefit of removing the lead. (Level of evidence C).
2. A single lead in a vessel that has become nonfunctional in an older patient. (Level of evidence C).
3. A normally functioning lead that has a reliable performance history at the time of pulse generator replacement. (Level of evidence C).