Editorial

Comments on the 2013 ESC Guidelines on Cardiac Pacing and Cardiac Resynchronization Therapy

Comentarios a la guía de práctica clínica de la ESC 2013 sobre estimulación cardiaca y terapia de resincronización cardiaca

Spanish Society of Cardiology Working Group for the 2013 ESC Guidelines on Cardiac Pacing and Cardiac Resynchronization Therapy, Expert Reviewers for the 2013 ESC Guidelines on Cardiac Pacing and Cardiac Resynchronization Therapy, and the Clinical Practice Guidelines Committee of the Spanish Society of Cardiology⁶

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INTRODUCTION

Since 2007, when the previous guidelines were published,¹ numerous studies have appeared on cardiac pacing and resynchronization therapy. Consequently, the European Cardiology Society, in cooperation with the European Heart Rhythm Association, have prepared new guidelines.² In the present article, we comment on the most innovative and important issues.

INDICATIONS FOR PACING

Few randomized studies have assessed the usefulness of cardiac pacing (CP) and consequently many recommendations are based on earlier observational studies and expert consensus.

In high-degree atrioventricular (AV) block, CP reduces the incidence of syncope and improves survival. In first- and second-degree (Mobitz I) AV block, it produces symptomatic and functional improvement. In sinus node disease (SND), there is no evidence that CP improves survival but it does improve symptoms. In extrinsic (functional) bradycardia, pacemaker (PM) implantation is only justifiable as a means of preventing recurrent syncope.

Innovations and Relevant Issues

Clinical Classification of Bradyarrhythmias

Clinical classification of bradyarrhythmias with indication for CP is based on clinical severity and not on etiology. This severity-based classification is more practical. Distinction Between Persistent and Intermittent Bradycardia

The guidelines stress that, while permanent forms of bradycardia are caused by intrinsic SND or disease of the AV conduction system, the etiology of intermittent forms is difficult to identify (Figure 1). Furthermore, intermittent forms of bradycardia need to be documented to consider the need for CP (Tables 1 and 2).

Simplifying Indications for CP in Persistent Bradycardia

In SND, CP is indicated for symptomatic forms when a clear correlation exists between symptoms and bradycardia and there is no reversible cause (I B). For patients with symptoms "probably" related with bradycardia, the indication is IIb C. In acquired third- and second-degree (Mobitz II) AV block, CP is indicated independently of the symptoms (I B); in (Mobitz I) AV block, CP is indicated if symptoms exist or a Hisian or infra-Hisian site is found in the electrophysiologic study (IIa B). Cardiac pacing is never indicated if causes are reversible (Table 3).

Table 1

Diagnosis of Bradyarrhythmic Syncope After Initial Assessment: Most Useful Tests

Prolonged electrocardiographic monitoring	Provocation test
Implantable loop recorder (Holter)	Carotid sinus massage
External loop recorder	Tilt-Table Test
Home telemetry	Electrophysiology Study
Implantable loop recorder	Exercise test

Table 2

Suggested ECG Monitoring Techniques Depending on Symptom Frequency

Frequency of symptoms	Monitoring proposed
Daily	24 h Holter. In-hospital telemetry
Every 2-3 days	24-72 h Holter. In-hospital telemetry
Weekly	14-30 d external loop recorder
Less than once a month	Implantable loop recorder (Holter)

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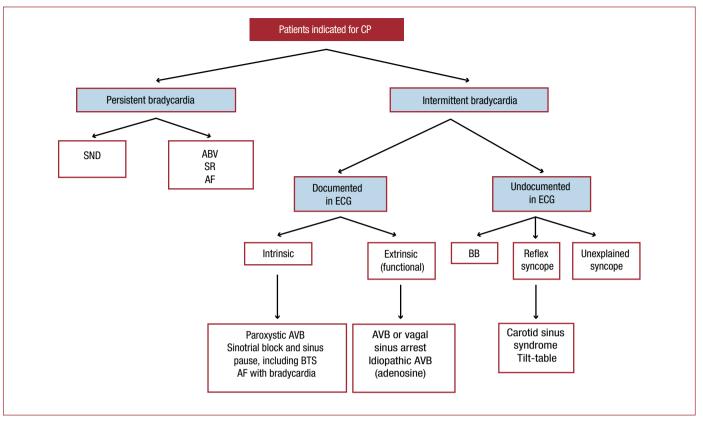


Figure 1. Classification of bradyarrhythmias based on clinical presentation. AF, atrial fibrillation; AVB, atrioventricular block; BB, branch block; BTS, bradycardia-tachycardia syndrome; CP, cardiac pacing; ECG, electrocardiogram; SND, sinus node disease; SR, sinus rhythm.

Table 3

Cardiac Pacing Indications in Persistent Bradycardia

Recommendation	Class	Level of evidence	Guideline reference
SND, with symptoms clearly attributable to bradycardia	I	В	1,6-9
SND, with symptoms probably attributable to bradycardia without conclusive evidence	IIb	С	
CP is not indicated in patients with asymptomatic SB or reversible causes	Ш	С	
Acquired third- or second-degree Mobitz II AVB, independently of symptoms	I	С	
Acquired second-degree Mobitz I AVB causing syncope or intra- or infra-Hisian location in EPS	IIa	С	
CP is not indicated in patients with AVB due to reversible causes	Ш	С	

AVB, atrioventricular block; CP, cardiac pacing; EPS, electrophysiology study; SB, sinoatrial block; SND, sinus node disease.

This exercise in simplification contrasts with the US guidelines³ which, in the section on AV block, make 16 class I, IIa and IIb recommendations. The principle difference between the 2 documents is the recommendation for asymptomatic patients with type II thirdor second-degree AV block. In the US guidelines, PM implantation is a class I recommendation only in bradycardia (> 3 second pauses, escape rhythm < 40 bpm or infra-Hisian escape), ventricular arrhythmias in the context of AV block if negative chronotropic drugs are needed, or if AV block is associated with cardiomegaly or left ventricular dysfunction. Otherwise, the guidelines establish a class IIa indication.

Selection of Pacing Mode in Persistent Bradycardia

The principle innovation is that DDD/DDDR pacing mode is preferred to AAI/AAIR mode in treating SND without permanent atrial fibrillation (AF), independently of AV conduction status. This innovation is based on the DANPACE study⁴ which, while it showed no difference in mortality after 5½ years' follow-up, did demonstrate greater risk of paroxystic AF (hazard ratio [HR] = 1.27) and reintervention (HR = 1.99) in patients with SND randomized to AAIR versus DDDR pacing. The recommendation contrasts with the US guidelines, which do not include DANPACE⁴ results, although these are included in a subsequent consensus document.

Rate-response, previously indicated in chronotropic incompetence only, is indicated in all cases, although the guidelines are not clear about the underlying cause. A further innovation are the recommendations that, in all cases of AF with AV block VVIR, pacing be used to counter the lack of atrial contribution, and programming should be to a relatively high (70 bpm) lower frequency limit.

Whenever sinus rhythm is present, DDD pacing is preferred to VVI pacing, since the former reduces the incidence of AF and stroke, improves functional capacity, and avoids PM syndrome, even though no benefits have been demonstrated in mortality or the development of heart failure (HF). The increased cost and greater incidence of complications are countered by the benefits obtained at 5 years. The

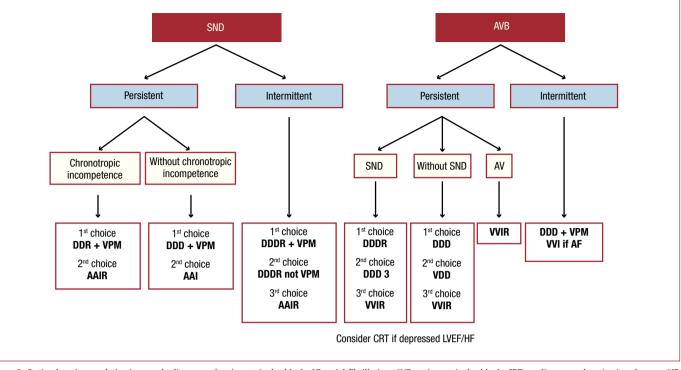


Figure 2. Optimal pacing mode in sinus node disease and atrioventricular block. AF, atrial fibrillation; AVB, atrioventricular block; CRT, cardiac resynchronization therapy; HF, heart failure; LVEF, left ventricular ejection fraction; SND, sinus node disease; VPM, ventricular pacing minimum.

guidelines also stress that DDD pacing is now preferred to VDD pacing in patients without sinus dysfunction. Furthermore, they emphasize the need to avoid unnecessary ventricular pacing in patients with SND and intermittent AV block. Whenever a high percentage of ventricular pacing is foreseeable and severe left ventricular systolic dysfunction is present, cardiac resynchronization device implantation is advised.

The pacing mode selection in SND and AV block, their different objectives, and the degree of evidence are summarized in Figure 2 and Table 4.

Indications for Cardiac Pacing in Intermittent Bradycardia

In SND, 2 indications are identified: a) symptomatic sinus arrest or sino-atrial block (SAB) documented in patients with persistent asymptomatic mild sinus bradycardia (40-50 bpm), and b) a record of long pauses after termination of tachycardia in bradycardiatachycardia syndrome.

In acquired intermittent AV block, the same recommendations are maintained for persistent bradycardia, although the correlation with symptoms is less important. In reflex syncope with bradycardia or intermittent asystole, the guidelines highlight the increasing use of prolonged monitoring devices—essentially the insertable Holter—following the publication of syncope management guidelines.⁶ The results of the ISSUE 3 trial have led to CP being recommended for patients aged \geq 40 years with recurrent reflex syncope and asymptomatic syncopal pause documented in insertable Holter \geq 3 seconds (IIa B) or \geq 6 seconds (IIa C). In patients with reflex syncope, CP is a last resort treatment and should only be used in selected patients, in whom the relation between symptoms and bradycardia must be demonstrated.

Indications for Cardiac Pacing in Patients with Suspicion of Undocumented Bradycardia

In this group of patients with branch block, reflex syncope and unexplained syncope, the approach of the guidelines is innovative and simplifies management. Indication for CP is only considered in the presence of symptoms (syncope), hence we are referred to the corresponding guidelines,⁵ except in alternating branch block, which constitutes a I C indication even in the absence of symptoms.

Table 4

Choice of Pacing Mode and Program in Patients With Persistent Bradycardia

Recommendation	Class	Level of evidence	Guideline reference
SND: DDD PM with algorithms favoring intrinsic AV conduction to reduce the risk of AF and embolisms, to reduce PM syndrome and improve quality of life	Ι	A (vs VVI)	2,3,11-13, 15-17
		B (vs AAI)	
The response in frequency should be indicated in chronotropic incompetence, above all in active, young patients	IIa	С	
In acquired AVB for patient in SR, DDD PM is preferred to VVI to avoid PM syndrome and improve quality of life	lla	A	2,11,13-15
In permanent AV and AVB, ventricular pacing is recommended with response in frequency	I	С	

AF, atrial fibrillation; AV, atrioventricular; AVB, atrioventricular block; PM, pacemaker; SND, sinus node disease; SR, sinus rhythm.

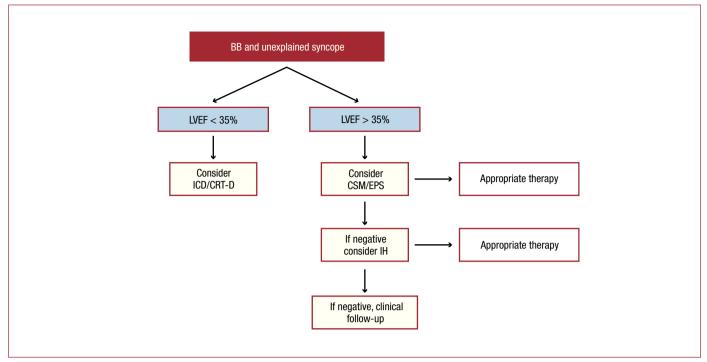


Figure 3. Therapeutic algorithm for patients with unexplained syncope and branch block. BB, branch block; CRT-D cardiac resynchronization therapy-defibrillator; CSM, carotid sinus massage; EPS, electrophysiology study; ICD, implantable cardioverter-defibrillator; IH, implantable loop recorder (Holter); LVEF, left ventricular ejection fraction.

The guidelines stress the need to determine ejection fraction (EF) in patients with branch block and syncope and recommend implantable cardioverter defibrillator (ICD) implantation/ICD-cardiac resynchronization therapy (CRT) in patients with EF < 35% and if a high percentage of ventricular pacing is foreseeable. Similarly, they emphasize the need to demonstrate the presence of bradycardia by provocation or subcutaneous Holter implantation (Figure 3).

Due to the low sensitivity but high specificity of electrophysiological study, the indication for CP in patients with syncope, branch block and positive Holter has changed from IIa C in the earlier pacing guidelines to I B in the current document. For patients with syncope of unknown cause and branch block, the indication is now IIb B (previously it was IIa C).

In carotid sinus syndrome, the indication for dual-chamber PM implantation in patients with recurrent syncope and cardioinhibitory mechanism is class I B (IIa B in syncope guidelines⁵), based on observational studies and a meta-analysis showing a 75% reduction in recurrence.

The limited value of tilt-table test results to indicate PM implantation in patients with vasovagal syncope is noteworthy. In unexplained syncope, on the basis of a small study of 80 elderly patients, CP is recommended (IIb B) in patients with unexplained syncope and a positive response (prolonged 6-10 second pause due to AV block) after intravenous injection of 20 mg adenosine triphosphate. CP is not indicated in unexplained syncope without bradycardia or recurrent falls (IIIc B).

More Controversial Issues

Chronotropic Incompetence

Neither diagnostic criteria nor therapeutic indications are defined and the guidelines propose that the usefulness of CP should be determined on a case-by-case basis, in contrast with the US guidelines, which establish a I C indication.

Pacing Mode Selection

Although the superiority of the DDD mode over VVI and AAI modes remains clear, as shown, the indication for DDD pacing as first choice in all cases of SND without permanent AF remains controversial.

Usefulness of Cardiac Pacing in Vasovagal Syncope Induced in Tilt-Table Testing With Cardioinhibitory Response

Due to the contradictory results of published randomized trials, controversy among experts continues and further research is needed.

Issues Left With No Comment

Although the guidelines insist on the need to reduce ventricular pacing in all forms of intermittent bradycardia, they do not establish an upper limit for the AV interval after which the benefits of reducing ventricular pacing could be eclipsed by the loss of AV asynchrony.

The need to monitor for the appearance of AF during follow-up is scarcely mentioned, nor do the guidelines establish criteria to confirm the presence of AF and its characteristics (duration, load, frequency, etc) in order to initiate anticoagulation treatment.

INDICATIONS FOR CARDIAC RESYNCHRONIZATION THERAPY

General Issues

The new guidelines classify the indication for CRT by the type of conduction disturbance (left branch block vs other conduction disturbances) and by QRS complex width (> 150, between 120 and 150 and < 120 ms). These new recommendations follow evidence suggesting that patients with a wider QRS complex and those with left branch block benefit more from CRT, independently of baseline functional level. This changes the previous European guidelines (which only considered QRS width > 150 ms for patients in functional

class II) and is supported by a subgroup analysis of the main clinical trials, several meta-analyses, and observational studies. The guidelines follow the philosophy of the new US document which, in 2012, had already incorporated indication restrictions for patients with QRS < 150 ms and conduction disturbances other than left branch block.

This classification aims to favor CRT use in the subgroups of patients with a greater probability of response and to restrict CRT use in those with narrower QRS or right branch block—subpopulations with a high rate of non-responders. Moreover, the best predictors of response and the only parameters accepted as an indication for resynchronization are still assumed to be those derived from the surface electrocardiogram. The panel of experts states openly and, we believe, correctly that the use of imaging techniques in selecting candidates is unclear and that currently these techniques should not be used as a criterion to indicate CRT.² The guidelines consider CRT contraindicated in patients with QRS < 120 ms (class III B) even in the presence of other criteria of mechanical asynchrony.

The guidelines equate the indication in patients in sinus rhythm and New York Heart Association (NYHA) class II with that of patients in ambulatory functional class III and IV.² This approach is supported by evidence from the REVERSE⁶, MADIT-CRT⁷ and RAFT⁸ trials and constitutes an innovation in that, although both the latest European and US guidelines already included NYHA class II as an indication for CRT, there is not the same level of evidence for patients in class II as for those in classes III and IV.

Patients in NYHA class I continue to be ruled out as candidates for CRT because few patients with these characteristics have been included in clinical trials. The panel's view is consistent with the scarce evidence on this subpopulation, given that the only recent, relevant, clinical trial (RAFT⁸) does not include patients in NYHA class I. This contrasts with the 2012 US guideline update which, for the first time, established NYHA class I as a new indication for CRT (class IIb C), albeit with the additional, highly restrictive criteria of QRS > 150 ms and EF < 30%.

Left ventricular dysfunction with $EF \le 35\%$ continues to be considered an adequate threshold to avoid the decision-making uncertainty of wider ranges.

The guidelines make proposals about standard implantation technique practice and optimization: implantation in the posterolateral region (avoiding the apex, IIa/B), programming fixed AV intervals between 100 ms and 120 ms and simultaneous biventricular pacing (VV0). No firm evidence exists for systematic optimization of AV and VV intervals.

Finally, the guidelines identify controversial issues lacking full agreement,² such as the effect of etiology, or sex, or the value of the echocardiographic study in selecting patients with narrow QRS. These issues are left open, to await new scientific evidence.

Indications for Cardiac Resynchronization Therapy in Patients in Atrial Fibrillation

The guidelines establish 2 conditions for CRT use in patients with AF: patients with a standard indication for CRT in permanent AF and those with HF or left ventricular dysfunction and suspicion of tachycardiomyopathy, who could benefit from AV node ablation and pacing system implantation. In both cases, the guidelines establish a IIa B indication. In contrast with the previous section, CRT use is not considered in patients with AF if they are in NYHA class II, given the scarcity of consistent data on this subpopulation. In contrast, the US guidelines establish a class IIa indication in AF and EF \leq 35% independently of functional class.

The document stresses that it is wise to achieve 100% left ventricular pacing in these patients. Otherwise, AV node ablation is recommended (class IIa B indication) to ensure permanent left ventricular capture. Ablation can be performed at the same time as device implantation or some weeks later to ensure that the pacing system functions correctly. This recommendation is based on data from several studies that show CRT is more efficient with left ventricular pacing percentages of > 95%.

Indications for Cardiac Resynchronization Therapy in Patients With Heart Failure and Conventional Indication for Pacing

The indication for a CRT upgrade in PM- or defibrillatordependent patients needing a high percentage of ventricular pacing is raised to class I B. This indication is similar to earlier European guideline recommendations but is assigned a higher level than that indicated in the 2012 US guidelines. The panel of experts does not specify what constitutes a "high percentage of left ventricular pacing" but does propose methodological alternatives to eliminate unnecessary right pacing. The panel only considers an upgrade in patients with severely depressed ventricular contractility (\leq 35%) and in ambulatory NYHA class III and IV, given the scarcity of data on patients in NYHA class II.

In patients indicated for pacing, with moderate to severe left ventricular depression, HF, and an expected high percentage of ventricular pacing, the panel assigns CRT a class IIa B indication for *de novo* CRT system implantation.² This distinction in class of recommendation may seem paradoxical with respect to the previous case (upgrade), particularly when upgrade procedures are usually more laborious and complex. It does not appear in the 2012 American College of Cardiology Foundation/American Heart Association/Heart Rhythm Society³ guideline update, in which both are classified as IIa indications. The authors justify the discrepancy by arguing that late upgrade results seem to provide benefits similar to those of *de novo* CRT implantation and by referring to the complexity and greater cost of CRT devices. In any case, the guidelines emphasize the lack of scientific evidence on indications for CRT in patients with HF and conventional indication for pacing, and accept an individualized focus.

Selection of Implantable Device Type for Patients Indicated for Cardiac Resynchronization Therapy

This particular problem is approached explicitly and in detail. The guidelines establish a class IA indication for cardiac resynchronization therapy-defibrillator (CRT-D) implantation when a defibrillator has been indicated and additional factors indicate CRT.²

More important are the clinical recommendations proposing the choice of CRT-D or PM-cardiac resynchronization therapy (CRT-P). Pacemaker-CRT should be chosen in very advanced HF, kidney failure or dialysis, cachexia, or fragility. Factors favoring CRT-D use are > 1 year life expectancy, NYHA class II, ischemic-origin cardiomyopathy, and absence of comorbidities. Use of CRT-P was previously limited to residual indications. In sharp contrast, the guidelines now confirm the lack of sufficient firm evidence derived from randomized clinical trials that might demonstrate CRT-D was superior to CRT-P. Hence, although the prevalent view is that CRT-D is potentially of more benefit in terms of survival, given the absence of proven superiority in clinical trials, the expert panel believes they should make no firm recommendations but, rather, simply guide selection of CRT-D or CRT-P on the basis of general clinical conditions, cost, and devicerelated complications. This approach would seem correct, especially with regard to its possible consequences in the context of cardiomyopathy of nonischemic origin. In this disease, recommendations for defibrillator use as primary prevention of sudden death are based on the results of a single study (SCD HeFT) of the period prior to resynchronization, based on an analysis of the total group (ischemic and nonischemic patients) with nonsignificant results in the nonischemic subgroup. Finally, the guidelines include the idea that patients in NYHA class II probably benefit more from CRT-D because of their improved prognosis.1

INDICATIONS FOR PACING IN SPECIFIC CONDITIONS

These guidelines cover 8 specific conditions. Most were dealt with independently in the 2007 edition, others were partially or fully discussed in one or another sections (long QT, postsurgical pacing) and the remaining conditions (pacing in pregnancy, antitachycardia algorithms, rare diseases) either did not appear or were referred to anecdotally. Finally, pacing in patients with sleep apnea and pacing in adult congenital heart disease are currently not considered specific entities.

Pacing in Acute Myocardial Infarction

The most frequent new-onset rhythm disturbances in the context of infarction are AV block and intraventricular conduction disturbances. For the first time, the guidelines indicate that risk of AV block in patients with infarction in the era of primary angioplasty is significantly lower (3.3%) by comparison with estimated risk in the era of thrombolytic agents (7%). In the current guidelines, the indication for pacing is limited to patients with AV block that persists 27 days after the infarction. In patients with intermittent AV block, in the presence of new-onset branch block, the guidelines recommend determining the usefulness of cardiac resynchronization device implantation if it is accompanied by severe ventricular dysfunction.

Pacing After Heart Surgery, Percutaneous Aortic Valve Implantation and Heart Transplantation

Pacing After Heart Surgery

The guidelines include a highly practical summary of the incidence and characteristics of rhythm disturbances requiring pacing, diseases, and most frequently associated intervention type.

If AV block develops, the previous class of recommendation (I C) is not modified nor is preimplantation waiting time. However, the guidelines do specify that if AV block develops in the first 24 hours after mitral or aortic surgery and persists beyond 48 hours, it is unlikely to be resolved and PM implantation would avoid lengthy hospitalization.

In SND, the guidelines recommend a minimum 5-day wait prior to deciding on device implantation.

Pacing After Percutaneous Aortic Valve Implantation

Based on retrospective studies and prospective registries, it is emphasized that, in patients requiring PM implantation after percutaneous aortic valve implantation, there is an association with specific factors such as preimplantation conduction disturbances, complete right bundle branch block, and CoreValve prosthesis implantation. The recommendations for implantation fulfill the same criteria as in AV block following heart surgery.

Heart Transplantation

The most frequent disturbances that can require pacing are chronotropic incompetence and SND. These guidelines establish no modifications with respect to the 2007 edition.

Pacing in Congenital Heart Disease

The guidelines consider distinctive issues such as body size, elevated activity, association with congenital heart disease, need for surgical correction of heart disease, and others that affect not only the decision on PM implantation but also the choice of the best technique (transvenous or epicardial) or most appropriate pacing mode.

Two sections specify the congenital heart diseases requiring pacing and include a special section about CRT.

Congenital AV Block

With no relevant new studies, the expert consensus view is that, faced with factors that can facilitate the appearance of syncope, HF or sudden death in the presence of AV block, PM implantation should proceed in patients both with and without symptoms (as in the previous edition). In both cases the indication is class I.

AV Block After Surgery for Congenital Heart Disease

The guidelines warn that evidence in these recommendations is moderate and that the consensus is weak. The indications are the same as in the previous guidelines, except with regard to the days needed to establish a definition of established rhythm disturbance (previously 7 days, now 10). In intermittent AV block in the presence of postsurgery branch block, indication for pacing is class IIa, whereas previously it was IIb.

Although not considered a recommendation, the guidelines advocate the usefulness of measuring HV interval in patients with branch block and postsurgical long PR to predict the appearance of late AV block.

Cardiac Resynchronization Therapy in Congenital Heart Disease

Clinical evidence in this group of patients is limited to small retrospective cross-over studies and clinical cases. In light of a recent, small European study,³ isolated left ventricular pacing for children and young people with AV block is considered an attractive therapeutic approach to ventricular dysfunction prevention.

Pacing in Hypertrophic Cardiomyopathy

Treatment of bradyarrhythmias should follow the same procedure as for patients without hypertrophic cardiomyopathy (HCM). The recommendation for pacing as a treatment for left ventricular outflow tract obstruction is not modified with respect to the previous guidelines (IIb), although the level of evidence is changed and is B or C in the current edition, depending on the factors leading to the decision for pacing. There are no relevant data on the superiority of CRT over conventional pacing, except that the patient may develop ventricular dysfunction and symptoms of refractory HF, an indication shown as useful in small studies, in both obstructive and nonobstructive HCM.

Pacing in Rare Diseases

This is a new section that covers hereditary and infrequent diseases associated with specific rhythm disturbances. In these diseases, bradyarrhythmias should be treated according to the general recommendations, with some clarifications on mode or the usefulness of pacing.

In patients with long QT syndrome, given the lack of experience with PM, the guidelines stress that ICD implantation is preferable in patients with symptoms of beta-blocker resistance or slow heart rates that affect the development of ventricular arrhythmias, as current ICD⁹ guidelines suggest. They also emphasize the probable need for early PM-ICD implantation in dilated cardiomyopathy caused by lamin mutations ("laminopathies") and for PM implantation in myotonic dystrophy.

Pacing in Pregnancy

Pacemaker implantation is recommended in pregnant patients if they develop full AV block and escape rhythm with wide QRS (indication IIa C). Risk is considered low if the fetus is at > 8 weeks' gestation. Nonetheless, it is recommended that implantation is facilitated by using techniques without radiation (echocardiography or navigation without fluoroscopy).

Pacing in First-Degree Atrioventricular Block

The 2007 recommendation (IIa C in the presence of prolonged symptomatic first-degree AV block) has been maintained in the absence of new studies that would justify changes. The guidelines only point to the need—in patients who fulfill the implantation criteria—to determine the usefulness of CRT to avoid the prejudicial effect of pacing in the right ventricle apex.

Algorithms for Prevention and Treatment of Atrial Arrhythmias With Pacing

The current guidelines do not consider these algorithms of use in preventing the development of atrial arrhythmias. However, they do not specify whether patients or specific episodes (organized and long cycles) that need pacing for bradycardia can benefit from these algorithms, as some studies have shown.

To sum up, by comparison with other indications, the number of patients in specific situations and in need of pacing is limited. In general, guideline recommendations for this type of situation are based on very few studies. Most of these studies are retrospective, registries, or clinical cases and, essentially, generate indications with C-level evidence.

MANAGEMENT CONSIDERATIONS

This section constitutes an innovation as these considerations did not appear in the previous guidelines.

Right Ventricular Pacing From Alternative Sites

Pacing from the right ventricle outflow tract is recognized as an alternative to pacing from the apex. It does not lead to a greater incidence of complications,² although hemodynamic results can depend on electrode location; para-Hisian pacing is more favorable than medioseptal pacing.

In the appendix,² the guidelines tabulate the results of a series of randomized studies that confirm differences in study design (parallel or cross-over), pacing site (outflow tract, septum, para-Hisian) and follow-up time, and that few patients are involved. The results are not uniform in terms of course of EF. These studies include the work of a Spanish group,¹⁰ with a mean 12-month follow-up, who concluded that although better asynchrony is obtained with septal pacing, there are no differences in heart function, exercise capacity, functional class, or quality of life.

Radiological criteria are not defined nor are electrocardiographic patterns for pacing, and the guidelines propose no complementary method of confirming position such as 2- and 3-dimensional echocardiography (Figure 4). It is unsurprising, therefore, that the expert committee should declare itself incapable of establishing recommendations until it has access to wider-ranging studies offering sufficient evidence, given that the studies performed to

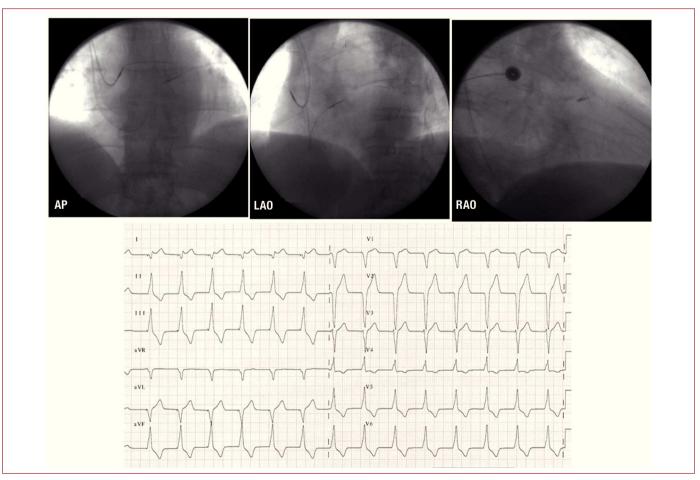


Figure 4. Right ventricle outflow tract implantation. Fluoroscopic image in anterposterior (AP) left anterior oblique (LAO) and right anterior oblique (RAO) at 45°. ECG with ventricular pacing from the aforementioned position. Note QRS morphology and duration, QRS electric axis and transition in precordial leads.

date have not demonstrated the superiority of septal over apical pacing.

Reimplantation of Pacemaker and Cardiac Resynchronization Therapy Devices After Explantation Due to Infection

This section is also new. In this situation, an indication is made about the advisability of reimplantation at a site other than the previous location (contralateral side of the thorax) or of a change to epicardial pacing, especially in patients undergoing thoracotomy or if venous access is impossible.

The guidelines distinguish between patients with no evidence of endocarditis, who can undergo reimplantation at 72 hours of negative blood cultures obtained 24 hours after explantation of the system (device and cables), and patients diagnosed with endocarditis, who cannot undergo reimplantation until at least 2 weeks after explantation, assuming they fulfill the criteria on negative blood cultures and are administered parenteral antibiotic treatment. Although not specified, explantation obviously refers to the entire pacing system (generator and cables).

In PM-dependent patients, maintenance of pacing through a temporary transvenous PM is indicated, although use of this device should be limited, given the associated complications. In such cases, definitive epicardial pacing is proposed as an alternative.

The most novel aspect is the fact that the guidelines recommend reconsidering the indication for pacing before proceeding to reimplantation—which can be avoided in between 30% and 50% of patients. This recommendation is evidently related to the firmness of the initial indication.

Magnetic Resonance Imaging in Electronic Cardiac Device-Dependent Patients

The 2007 guidelines dealt with this topic in a brief reference when discussing electromagnetic interference. The current guidelines dedicate a lengthy section exclusively to this subject, partly because of the current availability of special generators and cables.

The importance of the proximity of the zone under study to the device is highlighted. The guidelines then suggest that expert monitoring is needed during the imaging study, a period of 6 weeks should elapse between cable implantation and any study for the cables to fix effectively, patients with abandoned or epicardial cables should be excluded, PM-dependent patients should be programmed in asynchronous mode and patients without PM-dependence in inhibited mode, and that other pacing functions, especially antitachycardia therapies, should be deactivated.² All this is presented in an easily-interpreted flow-chart. In patients with magnetic resonance (MR) imaging-compatible devices, users are advised to follow the manufacturer's instructions.

In all cases, the device must be reprogrammed and pacing and detection parameters confirmed following the MR study. Finally, it is recommended that any indication for RM be carefully contrasted with the possible use of alternative imaging techniques. Furthermore, it is stressed that all of these recommendations are within the context of using RM units with a magnetostatic field of 1.5 T.¹¹

Temporary Transvenous Pacing

This is not recommended given the frequent associated complications. If used, it should be for the minimum period and PM implantation should take place as early as possible.

Notwithstanding, the guidelines advise its use in high-degree block without escape rhythm and severe bradyarrhythmias that can occur in interventional procedures, acute infarction, intoxication from drugs or systemic infections. With respect to transcutaneous pacing, the guidelines emphasize its questionable efficacy and the need for electrocardiographic and hemodynamic monitoring during pacing, and limit its use to situations in which no other pacing option is available of there is a lack of response to chronotropic drugs.

Remote Monitoring and Arrhythmias

The guidelines recognize the usefulness of remote monitoring in the follow-up of patients with CRT devices and in early diagnosis of AF episodes, especially in asymptomatic patients, since it permits early administration of anticoagulation therapy and prevention of stroke (class IIa A indication).

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CONFLICTS OF INTEREST

None declared.

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