

# Guidelines for Cardiac Pacing and Cardiac Resynchronisation Therapy

The Task Force for Cardiac Pacing and Cardiac Resynchronisation Therapy of the European Society of Cardiology

Developed in collaboration with the European Heart Rhythm Association

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ESC Guidelines



## † Guidelines for cardiac pacing and cardiac resynchronization therapy

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# Introduction

- The guidelines for the appropriate use of pacemaker devices presented in this document, a joint ESC and EHRA initiative, aim to provide for the first time in Europe an up to date specialists' view of the field.
- The guidelines cover two main areas: the first includes permanent pacing in bradyarrhythmias, syncope, and other specific conditions, while the second refers to ventricular resynchronisation as an adjunct therapy in patients with heart failure.

# Classes of Recommendations

Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful and effective
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a given treatment or procedure
Class IIa	Weight of evidence/opinion is in favour of usefulness/efficacy
Class IIb	Usefulness/efficacy is less well established by evidence/opinion
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective and in some cases may be harmful

# Levels of Evidence

Level of Evidence A	Data derived from multiple randomized clinical trials or meta-analyses
Level of Evidence B	Data derived from a single randomized clinical trial or large non-randomized studies
Level of Evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries

\*Recommendations for ESC Guidelines Production at [www.escardio.org](http://www.escardio.org).

# 1. Pacing for Arrhythmias

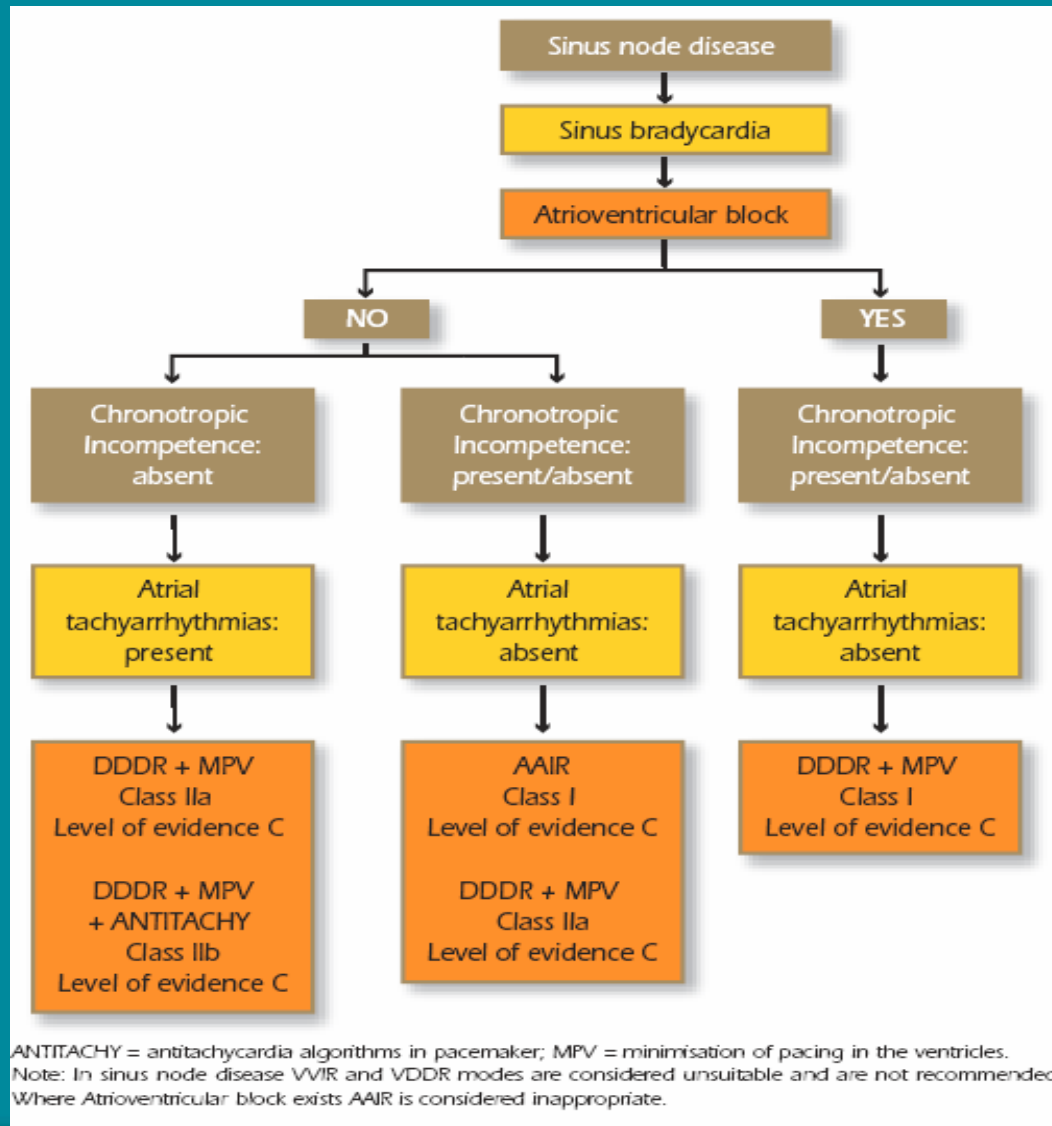
# 1.1. Sinus node disease

## Recommendations for cardiac pacing in sinus node disease

Class	Clinical Indication	Level of evidence
<b>Class I</b>	<ol style="list-style-type: none"><li>1. Sinus node disease manifests as symptomatic bradycardia with or without bradycardia-dependant tachycardia. Symptom-rhythm correlation must have been:<ul style="list-style-type: none"><li>▪ spontaneously occurring</li><li>▪ drug-induced where alternative drug therapy is lacking.</li></ul></li><li>2. Syncope with sinus node disease, either spontaneously occurring or induced at electrophysiological study.</li><li>3. Sinus node disease manifests as symptomatic chronotropic incompetence:<ul style="list-style-type: none"><li>▪ spontaneously occurring</li><li>▪ drug-induced where alternative drug therapy is lacking.</li></ul></li></ol>	<b>C</b>
<b>Class IIa</b>	<ol style="list-style-type: none"><li>1. Symptomatic sinus node disease, which is either spontaneous or induced by a drug for which there is no alternative but no symptom rhythm correlation has been documented. Heart rate at rest should be &lt; 40 bpm.</li><li>2. Syncope for which no other explanation can be made but there are abnormal electrophysiological findings (CSNRT &gt; 800 ms).</li></ol>	<b>C</b>
<b>Class IIb</b>	<ol style="list-style-type: none"><li>1. Minimally symptomatic patients with sinus node disease, resting heart rate &lt; 40 bpm while awake and no evidence of chronotropic incompetence.</li></ol>	<b>C</b>
<b>Class III</b>	<ol style="list-style-type: none"><li>1. Sinus node disease without symptoms including use of bradycardia-provoking drugs.</li><li>2. ECG findings of sinus node dysfunction with symptoms not due directly or indirectly to bradycardia.</li><li>3. Symptomatic sinus node dysfunction where symptoms can reliably be attributed to non-essential medication.</li></ol>	<b>C</b>

Note: when sinus node disease is diagnosed atrial tachyarrhythmias are likely even if not yet recorded, implying that serious consideration should be given to anticoagulant therapy.

# Pacemaker mode selection in sinus node disease



# 1.2. Atrioventricular and intraventricular conduction disturbances

## Recommendations for cardiac pacing in acquired AV block

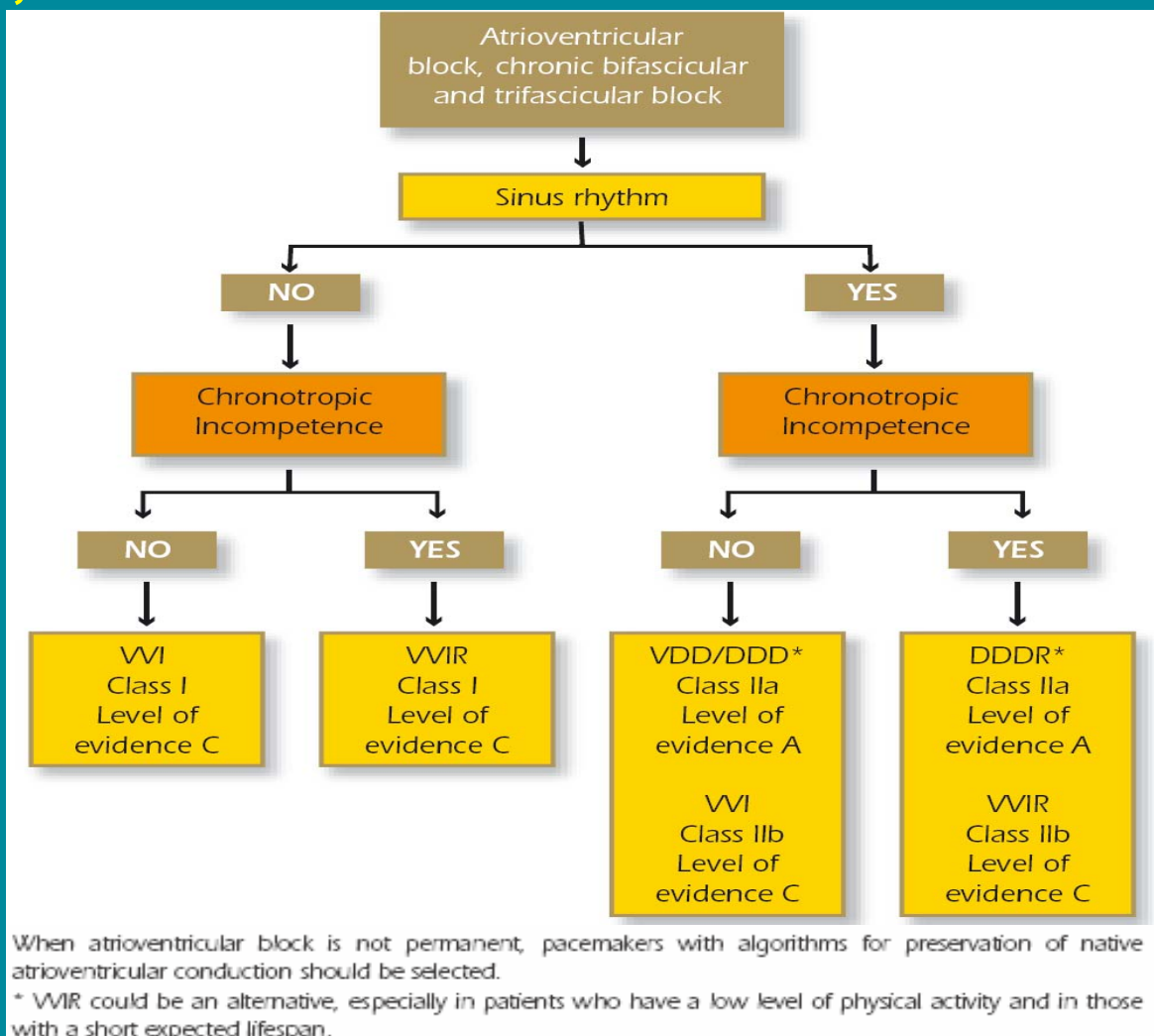
Class	Clinical Indication	Level of evidence
Class I	1. Chronic symptomatic third or second degree (Mobitz I or II) atrioventricular block.	C
	2. Neuromuscular diseases (e.g. myotonic muscular dystrophy, Keams-Sayre syndrome etc.) with third-degree or second-degree atrioventricular block.	B
	3. Third or second degree (Mobitz I or II) atrioventricular block: a) after catheter ablation of the atrioventricular junction b) after valve surgery when the block is not expected to resolve	C
Class IIa	1. Asymptomatic third or second degree (Mobitz I or II) atrioventricular block.	C
	2. Symptomatic prolonged first degree atrioventricular block.	C
Class IIb	1. Neuromuscular diseases (e.g. myotonic muscular dystrophy, Keams-Sayre syndrome, etc.) with first degree atrioventricular block.	B
Class III	1. Asymptomatic first degree atrioventricular block.	C
	2. Asymptomatic second degree Mobitz I with supra-Hisian conduction block.	C
	3. Atrioventricular block expected to resolve.	C

## 1.2. Atrioventricular and intraventricular conduction disturbances

### Recommendations for cardiac pacing in chronic bi- and tri-fascicular block

Class	Clinical Indication	Level of evidence
<b>Class I</b>	<ol style="list-style-type: none"> <li>Intermittent third degree atrioventricular block.</li> <li>Second degree Mobitz II atrioventricular block.</li> <li>Alternating bundle-branch block.</li> <li>Findings on electrophysiological study of markedly prolonged HV interval (<math>\geq 100</math> ms) or pacing- induced infra-His block in patients with symptoms.</li> </ol>	<b>C</b>
<b>Class IIa</b>	<ol style="list-style-type: none"> <li>Syncope not demonstrated to be due to atrioventricular block when other likely causes have been excluded, specifically ventricular tachycardia.</li> <li>Neuromuscular diseases (e.g. myotonic muscular dystrophy, Kearns-Sayre syndrome, etc.) with any degree of fascicular block.</li> <li>Incidental findings on electrophysiological study of markedly prolonged HV interval (<math>\geq 100</math> ms) or pacing- induced infra-His block in patients without symptoms.</li> </ol>	<b>B</b> <b>C</b> <b>C</b>
<b>Class IIb</b>	None.	
<b>Class III</b>	<ol style="list-style-type: none"> <li>Bundle branch block without atrioventricular block or symptoms.</li> <li>Bundle branch block with first-degree atrioventricular block without symptoms.</li> </ol>	<b>B</b>

# Pacemaker mode selection in acquired atrioventricular block, chronic bifascicular and trifascicular block



# 1.3. Recent myocardial infarction

## Recommendations for permanent cardiac pacing in conduction disturbances related to acute myocardial infarction

Class	Clinical Indication	Level of evidence
<b>Class I</b>	<ol style="list-style-type: none"><li>1. Persistent third degree heart block preceded or not by intraventricular conduction disturbances.</li><li>2. Persistent Mobitz type II second degree heart block associated with bundle branch block, with or without PR prolongation.</li><li>3. Transient Mobitz type II second or third degree heart block associated with new onset bundle branch block.</li></ol>	<b>B</b>
<b>Class IIa</b>	None.	
<b>Class IIb</b>	None.	
<b>Class III</b>	<ol style="list-style-type: none"><li>1. Transient second or third degree heart block without bundle branch block.</li><li>2. Left anterior hemiblock newly developed or present on admission.</li><li>3. Persistent first degree atrioventricular block.</li></ol>	<b>B</b>

# 1.4. Reflex syncope

## The main causes of reflex syncope

- Vasovagal syncope (common faint)
- Carotid sinus syncope
- Situational syncope:
  - acute haemorrhage (or acute fluid depletion)
  - cough, sneeze
  - gastrointestinal stimulation (swallowing, defecation, visceral pain)
  - micturition (post-micturition)
  - post-exercise
  - post-prandial
  - others (e.g. brass instrument playing, weightlifting)
- Glossopharyngeal neuralgia



# Recommendations for cardiac pacing in carotid sinus syndrome

Class	Clinical Indication	Level of evidence
<b>Class I</b>	1. Recurrent syncope caused by inadvertent carotid sinus pressure and reproduced by carotid sinus massage, associated with ventricular asystole of more than three seconds' duration (patient may be syncopal or presyncopal), in the absence of medication known to depress sinus node activity.	<b>C</b>
<b>Class IIa</b>	1. Recurrent unexplained syncope, without clear inadvertent carotid sinus pressure, but syncope is reproduced by carotid sinus massage, associated with a ventricular asystole of more than three seconds' duration (patient may be syncopal or presyncopal), in the absence of medication known to depress sinus node activity.	<b>B</b>
<b>Class IIb</b>	1. First syncope, with or without clear inadvertent carotid sinus pressure, but syncope (or pre-syncope) is reproduced by carotid sinus massage, associated with a ventricular asystole of more than three seconds' duration, in the absence of medication known to depress sinus node activity.	<b>C</b>
<b>Class III</b>	1. Hypersensitive carotid sinus reflex without symptoms.	<b>C</b>

## Recommendations for cardiac pacing in vasovagal syncope

Class	Clinical Indication	Level of evidence
<b>Class I</b>	None.	
<b>Class IIa</b>	1. Patients over 40 years of age with recurrent severe vasovagal syncope who show prolonged asystole during ECG recording and/or tilt testing, after failure of other therapeutic options and being informed of the conflicting results of trials.	<b>C</b>
<b>Class IIb</b>	1. Patients under 40 years of age with recurrent severe vasovagal syncope who show prolonged asystole during ECG recording and/or tilt testing, after failure of other therapeutic options and being informed of the conflicting results of trials.	<b>C</b>
<b>Class III</b>	1. Patients without demonstrable bradycardia during reflex syncope.	<b>C</b>

# 1.5. Paediatrics and congenital heart diseases

## Recommendations for cardiac pacing in paediatrics and congenital heart disease

Class	Clinical Indication	Level of evidence
<b>Class I</b>	1. Congenital third degree atrioventricular block with any of the following conditions: <ul style="list-style-type: none"><li>▪ symptoms</li><li>▪ ventricular rate less than 50-55/min in infants</li><li>▪ ventricular rate less than 70/min in congenital heart disease</li><li>▪ ventricular dysfunction</li><li>▪ wide QRS escape rhythm</li><li>▪ complex ventricular ectopy</li><li>▪ abrupt ventricular pauses &gt; 2-3x basic cycle length</li><li>▪ prolonged QTc, or</li><li>▪ presence of maternal antibodies-mediated block.</li></ul>	<b>B</b>
	2. Second or third degree atrioventricular block with <ul style="list-style-type: none"><li>▪ symptomatic bradycardia*</li><li>▪ ventricular dysfunction</li></ul>	<b>C</b>
	3. Postoperative Mobitz type II second- or third-degree block which persists at least 7 days after cardiac surgery.	<b>C</b>
	4. Sinus node dysfunction with correlation of symptoms.	<b>C</b>

# 1.5. Paediatrics and congenital heart diseases

## Recommendations for cardiac pacing in paediatrics and congenital heart disease

Class IIa	1. Asymptomatic sinus bradycardia in the child with complex congenital heart disease and <ul style="list-style-type: none"><li>▪ resting heart rate less than 40/min, or</li><li>▪ pauses in ventricular rate more than 3 s.</li></ul>	C
	2. Bradycardia-tachycardia syndrome with the need of antiarrhythmics when other therapeutical options, such as catheter ablation, are not possible.	C
	3. Long-QT syndrome with <ul style="list-style-type: none"><li>▪ 2:1 or third-degree atrioventricular block</li><li>▪ Symptomatic bradycardia* (spontaneous or due to beta-blocker)</li><li>▪ pause dependent ventricular tachycardia.</li></ul>	B
	4. Congenital heart disease and impaired haemodynamics due to sinus bradycardia* or loss of atrioventricular synchrony	C

# 1.5. Paediatrics and congenital heart diseases

## Recommendations for cardiac pacing in paediatrics and congenital heart disease

Class	Clinical Indication	Level of evidence
<b>Class IIb</b>	1. Congenital third degree atrioventricular blocks without a Class I indication for pacing.	<b>B</b>
	2. Transient postoperative third-degree atrioventricular block with residual bifascicular block.	<b>C</b>
	3. Asymptomatic sinus bradycardia in the adolescent with congenital heart disease and <ul style="list-style-type: none"> <li>▪ resting heart rate less than 40/min or</li> <li>▪ pauses in ventricular rate more than 3 s.</li> </ul>	<b>C</b>
	4. Neuromuscular diseases with any degree of atrioventricular block without symptoms.	<b>C</b>
<b>Class III</b>	1. Transient postoperative atrioventricular block with return of atrioventricular conduction within 7 days.	<b>B</b>
	2. Asymptomatic postoperative bifascicular block with and without first degree atrioventricular block.	<b>C</b>
	3. Asymptomatic type I second-degree atrioventricular block.	<b>C</b>
	4. Asymptomatic sinus bradycardia in the adolescent with minimum heart rate more than 40/min and maximum pause in ventricular rhythm less than 3 s.	<b>C</b>

\* Clinical significance of bradycardia is age dependent

## 1.6. Cardiac transplantation

### Recommendations for cardiac pacing after cardiac transplantation

Class	Clinical Indication	Level of evidence
Class I	1. Symptomatic bradyarrhythmias due to sinus node dysfunction or atrioventricular block three weeks after transplantation.	C
Class IIa	1. Chronotropic incompetence impeding the quality of life late in the post-transplant period.	C
Class IIb	1. Symptomatic bradyarrhythmias between the first and third week after transplantation.	C
Class III	1. Asymptomatic bradyarrhythmias and tolerated chronotropic incompetence. 2. Monitoring of cardiac rejection alone. 3. Bradyarrhythmias during the first week of transplantation.	C

## 2. Pacing for Specific Conditions

## 2.1. Hypertrophic cardiomyopathy

### Recommendations for cardiac pacing in hypertrophic cardiomyopathy

Class	Clinical Indication	Level of evidence
Class I	None.	
Class IIa	Symptomatic bradycardia due to beta blockade when alternative therapies are unacceptable.	C
Class IIb	Patients with drug refractory hypertrophic cardiomyopathy with significant resting or provoked LVOT gradient and contra-indications for septal ablation or myectomy.	A
Class III	1. Asymptomatic patients. 2. Symptomatic patients who do not have LVOT obstruction.	C

LVOT = left ventricular outflow tract

### 3. Cardiac Resynchronisation Therapy (CRT) in Patients with Heart Failure

#### Evidence-based clinical effects of CRT

- State-of-the-art management of congestive heart failure (CHF), besides alleviating symptoms, preventing major morbidity, and lowering mortality, increasingly strives to prevent disease progression, in particularly the transition between asymptomatic LV dysfunction and overt CHF.
- The clinical effects of long-term CRT were firstly evaluated in non-controlled studies, in which a sustained benefit conferred by biventricular pacing was measured. Randomized multi-centre trials with crossover or parallel treatment assignments were subsequently conducted to ascertain the clinical value of CRT in patients with advanced CHF and in sinus rhythm, with or without indications for an implantable cardioverter-defibrillator (ICD). Meta-analyses were also published.
- The usual study enrolment criteria were: 1) CHF in New York Heart Association (NYHA) functional Class III or IV despite optimal pharmacological treatment; 2) LV ejection fraction (EF) < 35%, LV end-diastolic diameter > 55 mm, and QRS duration  $\geq$  120 or 150 ms.

# 3. Cardiac Resynchronisation Therapy (CRT) in Patients with Heart Failure

## Recommendations

- Pacing for heart failure can be applied either by biventricular pacing or, in selected cases, by left ventricular pacing alone. The following recommendations consider cardiac pacing for heart failure delivered through biventricular pacing, since this mode is supported by the greatest body of evidence. This, however, does not preclude other pacing modes, such as LV pacing, to correct ventricular dyssynchrony.
- Ventricular conduction delay continues to be defined according to QRS duration ( $QRS \geq 120$  ms). It is recognised that ventricular conduction delay may not result in mechanical dyssynchrony. Dyssynchrony is defined as an uncoordinated regional contraction-relaxation pattern. Although from the theoretical point of view it may be more appropriate to target mechanical dyssynchrony, rather than electrical conduction delay, no large controlled study has prospectively assessed the value of mechanical dyssynchrony in heart failure patients undergoing pacing for heart failure.

### 3. Cardiac Resynchronisation Therapy (CRT) in Patients with Heart Failure

*Recommendations for the use of cardiac resynchronization therapy by biventricular pacemaker (CRT-P) or biventricular pacemaker combined with an ICD (CRT-D) in HF patients.*

Heart failure patients who remain symptomatic in NYHA Class III-IV despite optimal pharmacological treatment, with low ejection fraction (LVEF  $\leq$  35%), left ventricular dilatation\*, normal sinus rhythm and wide QRS complex ( $\geq$  120 ms)

- Class I - Level of evidence A for CRT-P to reduce morbidity and mortality.
- CRT-D is an acceptable option for patients who have expectancy of survival with a good functional status for more than 1 year, Class I - Level of evidence B.

\* Left ventricular dilatation/Different criteria have been used to define LV dilatation in controlled studies on CRT: LV end diastolic diameter > 55 mm; LV end diastolic diameter > 30 mm/m<sup>2</sup>, LV end diastolic diameter > 30 mm/m (height).

### 3. Cardiac Resynchronisation Therapy (CRT) in Patients with Heart Failure

*Recommendations for the use of biventricular pacing in HF patients with a concomitant indication for permanent pacing.*

Heart failure patients with NYHA Class III-IV symptoms, low ejection fraction (LVEF  $\leq$  35%), left ventricular dilatation\* and a concomitant indication for permanent pacing (first implant or upgrading of conventional pacemaker).

- Class IIa - Level of evidence C

*Recommendations for the use of an ICD combined with biventricular pacemaker (CRT-D) in HF patients with an indication for an ICD.*

Heart failure patients with a Class I indication for an ICD (first implant or upgrading at device change) who are symptomatic in NYHA Class III-IV despite optimal pharmacological treatment, with low ejection fraction (LVEF  $\leq$  35%), left ventricular dilatation\*, wide QRS complex ( $\geq$  120ms).

- Class I - Level of evidence B.

\* Left ventricular dilatation/Different criteria have been used to define LV dilatation in controlled studies on CRT: LV end diastolic diameter > 55 mm; LV end diastolic diameter > 30 mm/m<sup>2</sup>, LV end diastolic diameter > 30 mm/m (height).

### 3. Cardiac Resynchronisation Therapy (CRT) in Patients with Heart Failure

*Recommendations for the use of biventricular pacing in HF patients with permanent atrial fibrillation.*

Heart failure patients who remain symptomatic in NYHA Class III-IV despite optimal pharmacological treatment, with low ejection fraction (LVEF  $\leq$  35%), LV dilatation\*, permanent atrial fibrillation and indication for AV junction ablation.

- Class IIa - Level of evidence C.

\* Left ventricular dilatation/Different criteria have been used to define LV dilatation in controlled studies on CRT: LV end diastolic diameter > 55 mm; LV end diastolic diameter > 30 mm/m<sup>2</sup>, LV end diastolic diameter > 30 mm/m (height).