


# **New Guidelines of ESC**

## **Indications of Cardiac Pacing and Resynchronisation Therapy**



**World Congress of Cardiology 2006**

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Congress 2006 and the World Heart Federation's  
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**Prof. Panos Vardas**

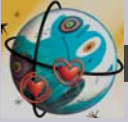
*University of Crete*

*Greece*



EBAC

# Why do we need European Guidelines?



- Scientific reasons**
- Cultural and political reasons**

# Reasons Necessitating Uniform European Guidelines



## □ Scientific reasons

- Rapid **evolution** of current knowledge in certain scientific areas
- Results of **recent published** trials concerning the indications for pacing, mode selection, cost effectiveness, follow-up
- Supplementation of the existing Guidelines in **areas that are not dealt with** (i.e. CRT in specific populations, etc.)

# Reasons Necessitating Uniform European Guidelines



## Cultural and political reasons

- Europe, as a multicultural entity, requires guidelines written by Europeans ensuring better implementation

# New ESC guidelines

## *Targets*



- ❑ **The new guidelines aim to provide an up to date specialist's view at the field**
- ❑ **The guidelines will cover:**
  - **Pacing in bradyarrhythmias, syncope and other specific conditions**
  - **Cardiac resynchronisation as an adjunct therapy in patients with Heart Failure**

# New ESC guidelines



- ❑ The recommendations will be based on an extensive review of the literature to reach evidence based conclusions**
- ❑ Where the literature is lacking, the recommendations will be based on expert consensus**

# Classifying and Ranking the Indications



Classification and ranking of the indications are the same as with the ACC/AHA guidelines

## Classification

- **Class I:**
- **Class II:**
  - **Class IIa:**
  - **Class IIb:**
- **Class III:**

## Ranking

- **Level A** Evidence derived from multiple randomized clinical trials, involving a large number of individuals.
- **Level B** Data derived from a limited number of trials, involving a small number of patients or from well-designed data analyses on non-randomized studies or observational data registries.
- **Level C** Data derived from a consensus of experts.

# Main Pacing Indications



- Sinus Node Disease**
- Atrio-Ventricular Block**
- Reflex Syncope**
- Pacing in Specific Conditions**
- Cardiac Resynchronisation Therapy**

# Sinus Node Disease

*Where indications should be based on*



**Given that cardiac pacing in patients with SND does not affect survival, the decision for pacing should be based on the existence of symptoms**

- **Syncope, near-syncope**
- **Fatigue**
- **Dyspnoea**
- **Reduced exercise capacity**

**that are related with ECG findings indicative of SND**

- **Sinus pauses**
- **Atrial tachyarrhythmias**
- **Exaggerated bradycardia**
- **Chronotropic incompetence**

# Sinus Node Disease

## *Pacemaker mode selection*



### What large randomized trials have shown

- ❑ **Atrial based pacing is superior to ventricular pacing in terms of lower incidence of AF.**
- ❑ **Concerning stroke, HF and mortality the findings are conflicting**

*Andersen et al. Lancet 1997*

*PASE trial. Pace 2003*

*CTOPP study. JACC 2001*

*MOST. N Engl J Med 2002*

- ❑ **Antitachycardia algorithms could play an important role in reducing atrial tachyarrhythmias**

# AV - Block

*What ESC guidelines should take into account*



- In high grade AV block cardiac pacing relieves symptoms, apart from prolonging survival.
- In cases with mild AV block (Mobitz I), the level of the conduction disturbance (i.e. supra-, infra- or intra- Hisian block) and age, play a significant role for decision making
- In any case, reversible causes of AV block should be excluded.

# AV - Block

## *Pacemaker mode selection*



### What large randomized trials have shown

- ❑ **AV pacing is superior to ventricular in terms of**
  - significantly lowering the incidence of AF
  - trend in lowering the risk of stroke and death from cardiovascular causes in patients younger than 74 years old
- ❑ **Ventricular pacing is related with high incidence of pacemaker syndrome**
- ❑ **The apex of the RV is not the best choice for ventricular lead placement**

# Sinus Node Disease and Heart Block

## *Decision making*



**In most cases for decision making, the indicative level of evidence is C (expert consensus) because of the lack of large randomized controlled trials.**

# Pacing in Vasovagal syncope



- ❑ Accounts for 50% of all the cases that are admitted for syncope
  
- ❑ Five randomized trials with conflicting results regarding pacing effect
  - VASIS, Circulation 2000
  - VPS, JACC 1999
  - CYDIT, Circulation 2001
  - VPS II, JAMA 2003
  - SYNPACE, EHJ 2004
  
- ❑ The key factor for the decision to implant a pacemaker is patient selection (i.e. severe symptoms related to bradycardic response)  
To this end the role of ILR is important (ISSUE2)

# Pacing in Specific Conditions.



**HOCM**

**Sleep Apnoea**

# Pacing in HOCM



- ❑ It is clearly evident (from randomized studies) that some patients derive benefit from short AV delay DDD pacing in terms of symptoms, functional capacity, and QoL

PIC study, EHJ 1997

Galter et al. EHJ 1997

- ❑ To date there is no certain way to predict the response to pacing
- ❑ The lack of large randomized trial makes the indications for pacing controversial
- ❑ Pacing can only be recommended in patients with contra-indications for septal ablation or myectomy and in elderly pts with drug refractory HOCM

# Pacing in Sleep Apnoea Syndrome

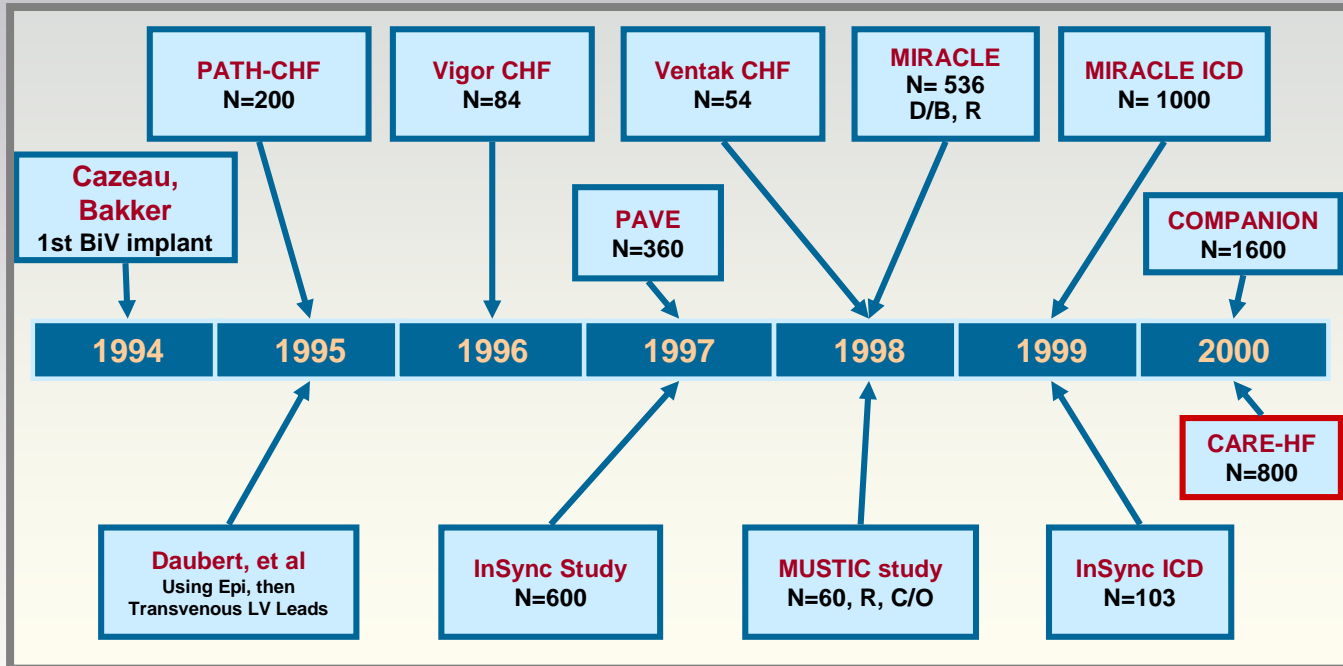


- ❑ **SAS is very common respiratory disturbance with therapy that is based on n-CPAP - although with relatively low compliance.**
- ❑ **Data from recently published studies indicated that AOP could have a role in selected patients with SAS while it is totally ineffective in patients with the pure obstructive type of the disease.**

**Garrigue et al. NEJM 2002  
Simantirakis et al. NEJM 2005**

- ❑ **However, is very early to jump into conclusions before large randomized trials become available.**

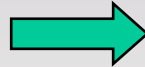
# Cardiac Resynchronisation Therapy



# Cardiac Resynchronization



- ❑ Restores AV and V synchrony
- ❑ Improves LV systolic Function and diastolic filling
- ❑ MV regurgitation reduction
- ❑ Reverses LV remodeling



- Symptomatic improvement
- Functional capacity improvement
- QoL improvement
- Disease progression delay
- Morbidity reduction

**The recently published results of large randomized trials confirmed these beneficial effects and found that CRT also improves survival.**

*COMPANION  
CARE HF*

# Resynchronization therapy in CHF



- ❑ CRT is already class I indication in the ACC/AHA and ESC 2005 guidelines for Heart Failure
- ❑ CRT using BiV pacing can be considered in patients with reduced EF and ventricular dyssynchrony (QRS width  $\geq$  120ms), who remain symptomatic (NYHA III–IV) despite optimal medical therapy to improve:

## **symptoms**

*Class of recommendation I, level of evidence A*

## **hospitalizations**

*Class of recommendation I, level of evidence A*

## **mortality**

*Class of recommendation I, level of evidence B*

# ESC CRT Guidelines



- CRT is only indicated in patients with symptoms of HF and systolic LV dysfunction as defined by the guidelines for HF of the European Society of Cardiology**
- Thus, the recommendations are exclusively applicable to this patient population**
- CRT in patients without systolic LV dysfunction and symptoms of HF is discouraged**

# ESC CRT Guidelines



- 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 HF patients undergoing CRT.**
- Thus, recommendations for CRT will be given based upon duration of the QRS complex.**
- Ventricular conduction delay is defined as QRS prolongation  $\geq 120$  ms.**

# CRT in specific populations



- Patients with an indication for PM or ICD**
- Patients with a previously implanted device**
- Patients with permanent AF**

**Level of Evidence C**

# ESC Cardiac Pacing and CRT Guidelines



- The European Guidelines on Cardiac pacing and Resynchronisation Therapy are based on the most recent published data.**
- It is true that especially for the traditional indications, classifications are based on expert consensus.**
- The cost effectiveness of the proposed sophisticated devices have to be evaluated in detail**