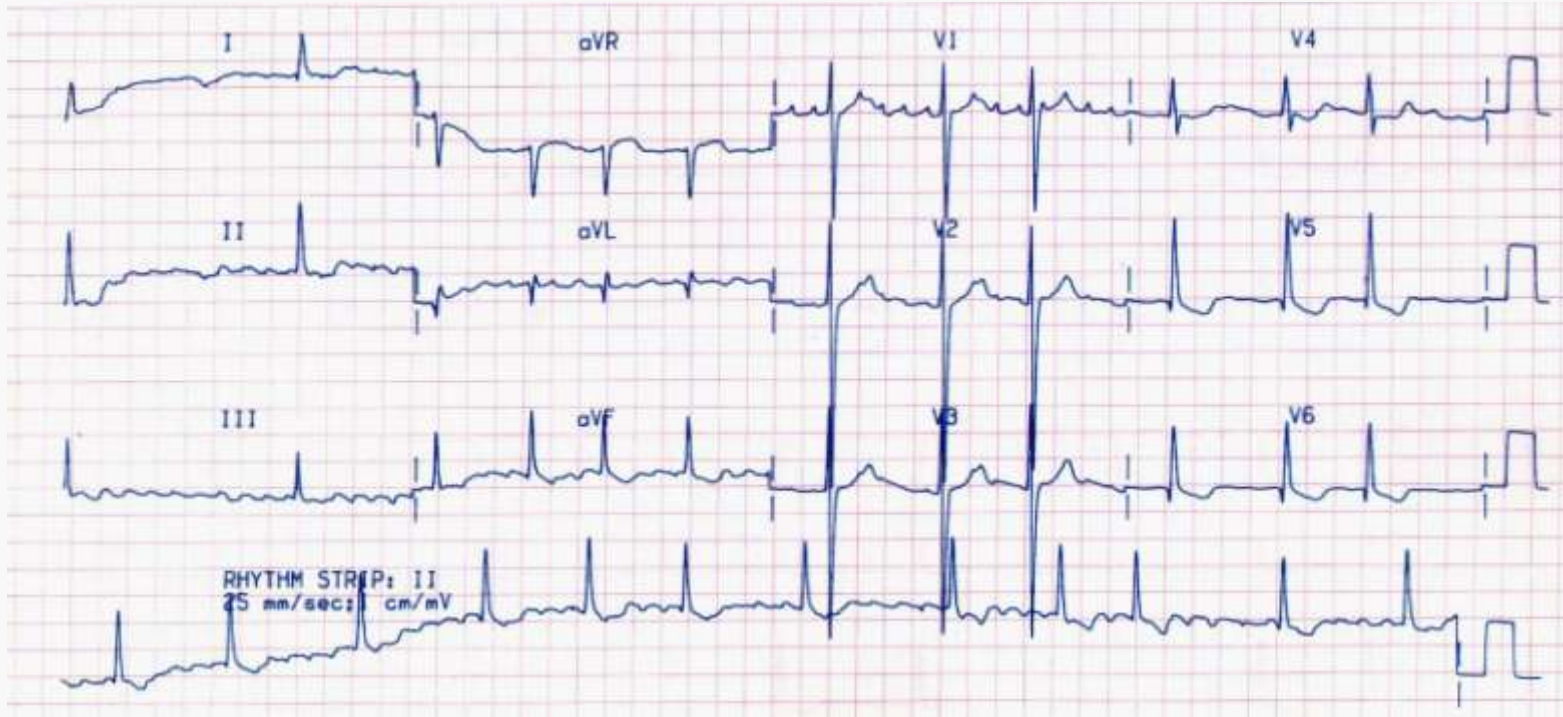


Patient paced for sinus node disease, now in persistent AF



Dr Stuart Harris

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What do we know?



ACC/AHA/ESC Guidelines

ACC/AHA/ESC 2006 guidelines for management of ventricular arrhythmias and the prevention of

A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Group to Develop the Guidelines)

the Heart

European doi:10.10



ESC Guidelines

Guidelines for the diagnosis and treatment of Heart Failure: full text (update 2005)

The Task Force for the diagnosis and treatment of CHF of the European Society of Cardiology

ACC/AHA/HRS Guidelines of Cardiac Rhythm

A Report of the American Heart Association Task Force on Practice Guidelines (Writing Group to Revise the ACC/AHA Guidelines for the Management of Cardiac Pacing and Resynchronization Therapy)

European Heart Journal Advance Access published online first

Guidelines for cardiac pacing and resynchronization therapy

The Task Force for Cardiac Pacing and Cardiac Resynchronization Therapy of the European Society of Cardiology. Developed in Collaboration with the European Heart Rhythm Association

Authors/Task Force Members: Panos E. Vardas* (Chairperson) (Greece); Angelo Auricchio (Switzerland); Jean-Jacques Blanc (France); Jean-Claude Daubert (France); Helmut Drexler (Germany); Hugo Ector (Belgium); Maurizio Gasparini (Italy); Cecilia Linde (Sweden); Francisco Bello Morgado (Portugal); Ali Oto (Turkey); Richard Sutton (UK); Maria Trusz-Gluza (Poland)

HFSA 2006 Guideline Executive Summary

Executive Summary: HFSA 2006 Comprehensive Heart Failure Practice Guideline

HEART FAILURE SOCIETY OF AMERICA

St. Paul, Minnesota

Committee Members

Kirkwood F. Adams, Jr, MD¹ (Co-Chair)

JoAnn Lindenfeld, MD² (Co-Chair)

Guideline Update for the Management of Chronic Heart Failure in the Adult

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Update the 2001 Guidelines for the Evaluation and Management of Heart Failure)

AHA/ACC/ESC

Class I (good evidence – should implant)

- 2nd / 3rd degree AV block with:
 - Symptomatic bradycardia
 - Drug induced bradycardia when drug cannot be withdrawn
 - Asymptomatic in SR with episode of rate < 40 bpm (awake) or asystole of > 3-secs
 - Asymptomatic in AF with evidence of pause > 5-secs
 - Post – AV node ablation
 - Post-op AV block not expected to resolve
 - Following MI not expected to resolve
 - Neuromuscular disease with AV block with/without symptoms
 - Asymptomatic 3rd with HR > 40 bpm if impaired LV or if infra-His
- Bi-/Trifascicular block and:
 - Intermittent 3rd degree AV block
 - Type II 2nd degree AV block
 - Alternating bundle branch block
- Symptomatic sinus node dysfunction (incl drug induced)
- Symptomatic chronotropic incompetence
- Pause dependent VT with / without prolonged QT
- Recurrent syncope caused by ventricular pause > 3 secs / carotid sinus hypersensitivity

Sick Sinus Syndrome

- Sinus node dysfunction associated with symptoms
- Associations
 - AV node disease
 - Chronotropic incompetence
 - AF
- Pacing – single/dual chamber
 - Physiological Pacing

Quick reference guide

Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block

1 Guidance

This guidance refers only to pacing for the primary indications of sick sinus syndrome and/or atrioventricular block, and does not cover more complex pacing indications.

1.1 Dual-chamber pacing is recommended for the management of symptomatic bradycardia due to sick sinus syndrome, atrioventricular block, or a combination of sick sinus syndrome and atrioventricular block, except:

- In the management of sick sinus syndrome in patients in whom, after full evaluation, there is no evidence of impaired atrioventricular conduction; in this situation, single-chamber atrial pacing is appropriate
- In the management of atrioventricular block in patients with continuous atrial fibrillation; in this situation, single-chamber ventricular pacing is appropriate
- In the management of atrioventricular block (atrioventricular block alone, or in combination with sick sinus syndrome), when patient-specific factors, such as frailty or the presence of comorbidities, influence the balance of risks and benefits in favour of single-chamber ventricular pacing.

2 Implementation

2.1 Implications for the NHS

2.1.1 About 25,000 pacemakers are implanted every year in the UK; three quarters of these are first implants, and one quarter are replacements.

2.1.2 The current hardware cost of pacemaker implantation based on the market cost and the types implanted is about £43 million per year. This may underestimate the annual cost of pacemakers because the market price represents a substantial discount on the list price of pacemakers. However, the Institute does not have access to information on the list price of pacemakers.

2.1.3 Dual-chamber pacemakers accounted for nearly 60% of the pacemakers implanted in 2003. The anticipated additional cost of implementing this guidance is dependent on the acquisition cost of dual-chamber pacemakers, the number of patients with continuous atrial fibrillation who are not eligible for dual-chamber pacing, and the likely uptake of dual-chamber pacing. The uptake is likely to vary between 70% and 90%, for which the implementation cost varies between about £8 million and £10 million per year, based on the current implantation rate. This does not take into consideration differences in the staff and theatre costs for implanting dual- and single-chamber pacemakers. The Institute was aware that dual-chamber pacing may be associated with slightly more follow-up, which may have implications for staff workload, but did not have sufficient information to estimate the national impact on human resources.

2.2 Local implementation and audit

2.2.1 Clinicians who care for people who have symptomatic bradycardia associated with sick sinus syndrome and/or atrioventricular block should review their current practice and policies to take account of the guidance set out in Section 1.

Physiological Pacing

VR in AF

VR in AF with CHB

VR in co-morbid CHB

DR in CHB

DR in SSS

AR in appropriate SSS

Technology Appraisal Guidance 88

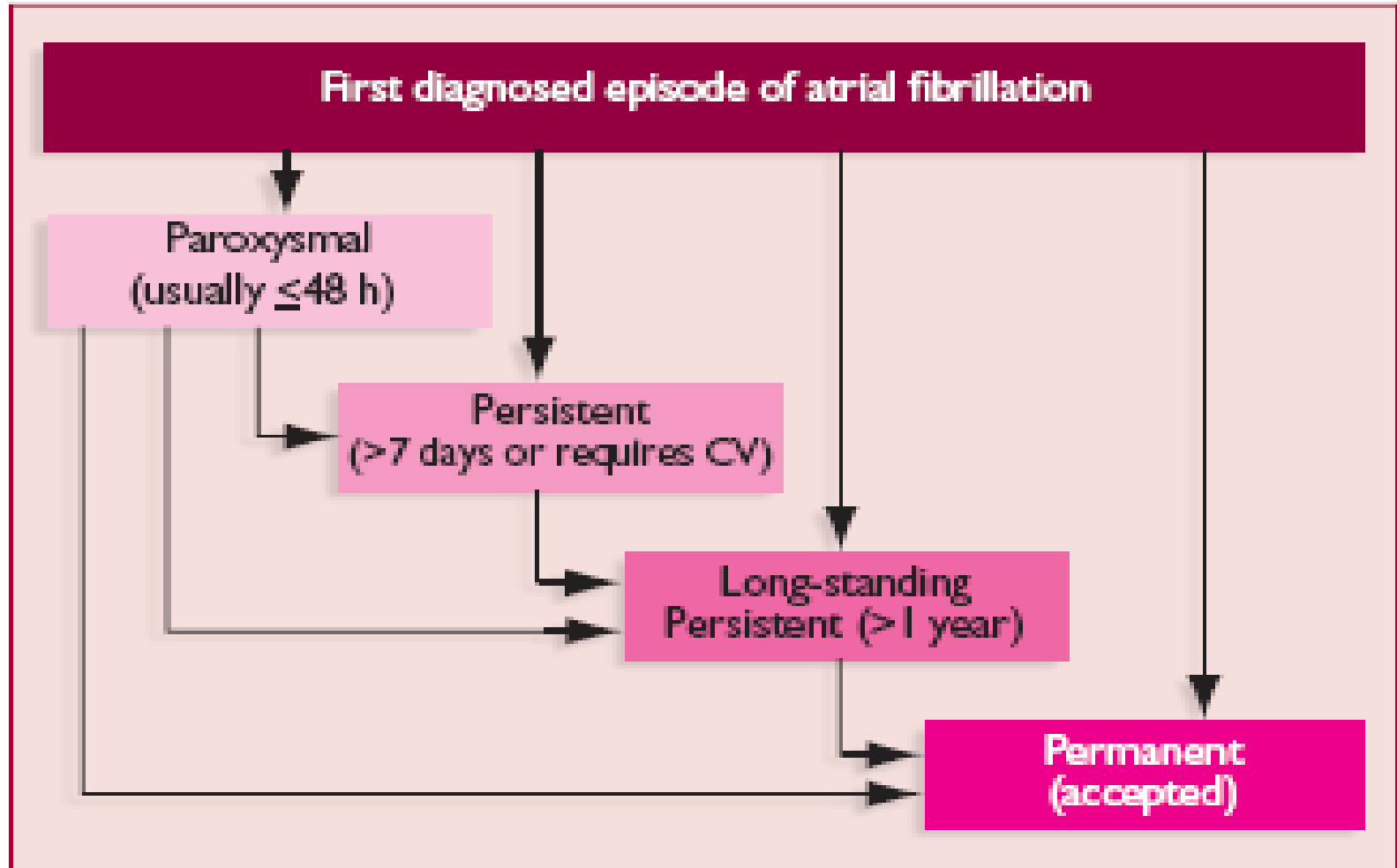
This guidance is written in the following context:

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

STUDY	BRADY	RAND	AGE	F-UP	%AF	%HF	End Point	Result	X-over
DANISH n225	SSS	DEVICE AAI/VVI	76	5.5yrs	45	7	Death AF TE events H-Failure	AAI AAI AAI VVI	14%
PASE n407	SSS/AVB >65 yr	MODE DDDR/VVIR	76	1.5yrs	28	28	QOL	SSS-DDDR	26%
CTOPP n2568	SSS/AVB >18 yr	DEVICE VVIR DDDR/AAIR	73	3yrs	14	30	Death CVA AF QOL	NS NS DDDR NS	3%
MOST n3024	SSS >21 yr	MODE DDDR VVIR	74	3yrs	44	14	Death CVA AF HF-Hosp	NS NS DDDR VVIR	31%
UK-PACE n2021	CHB >70 yr	DEVICE DDDR VVI/VVIR	80	4.6yrs	11	16	Death AF CVA HF-Hosp	NS NS NS NS	3%

What else do we know?

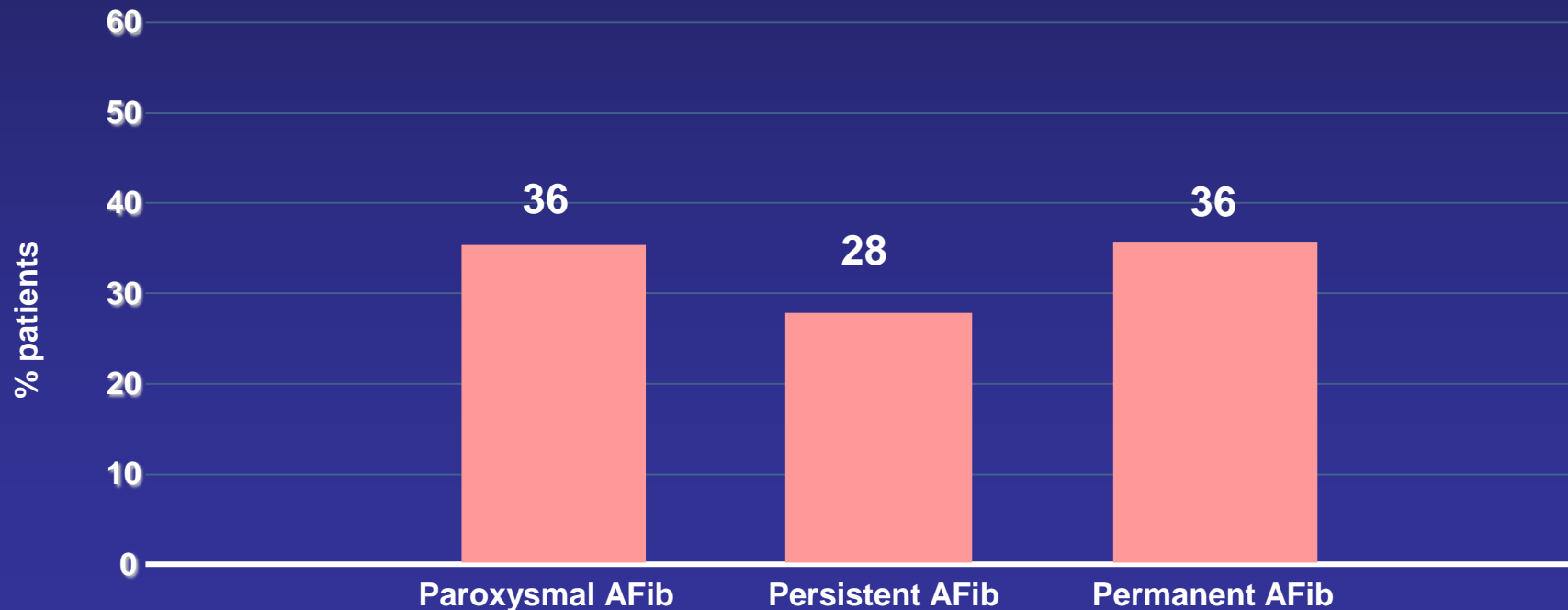
Classification of AF Subtypes



Presentation of AF in EuroHeart Survey

EuroHeart Survey 2005

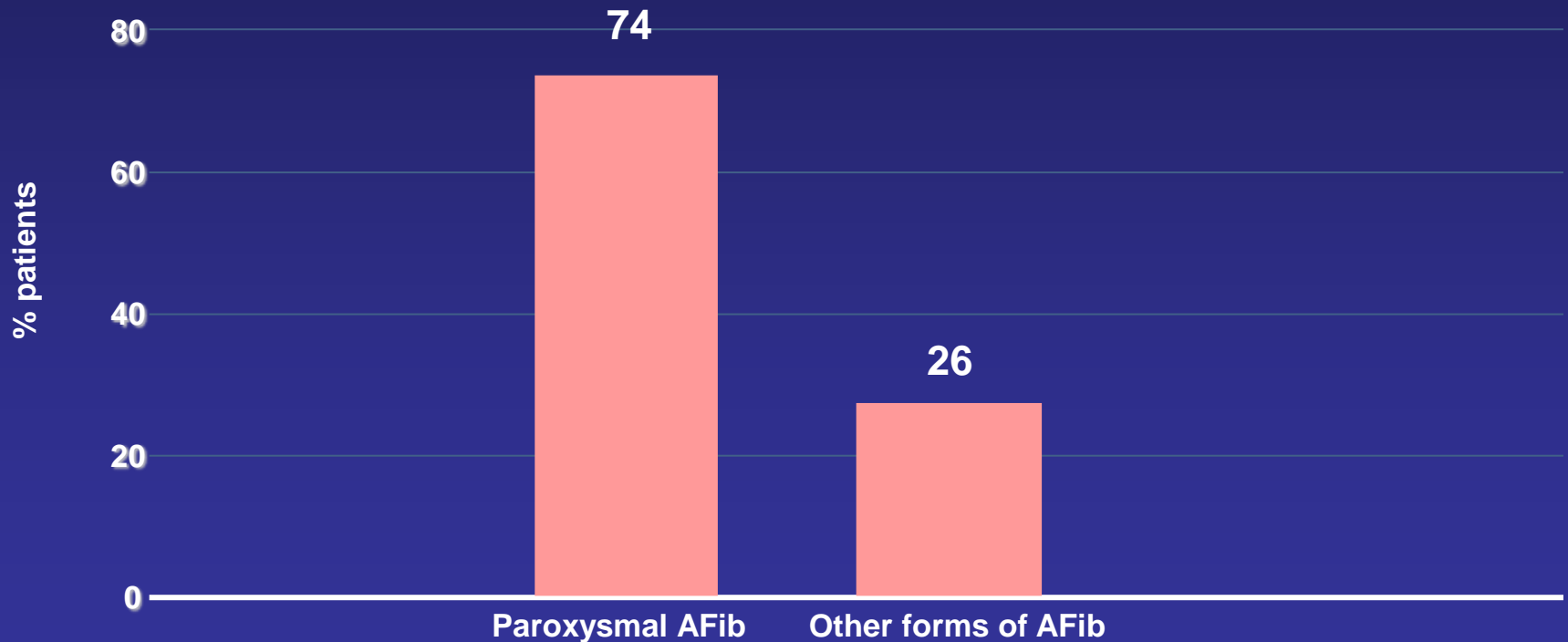
- 5,333 patients enrolled with AFib on ECG or Holter recording during the qualifying admission/consultation, or in the preceding 12 months



Presentation of AF in Olmsted County Study

Olmsted County

- 4,618 residents who had ECG-confirmed first AFib in the period 1980-2000



AF is the Most Common Cardiac Arrhythmia

- Most common sustained cardiac arrhythmia¹
 - AF affects 1 in 25 adults >60 years and 1 in 10 adults >80 years²
- 6.8 Million Patients with AF in EU and US¹
 - 2.3 million Americans and 4.5 million Europeans
- Prevalence expected to increase due to an aging population²

1. ACC/AHA/ESC 2006 guidelines J Am Coll Cardiol 2006;48:854-906.

2. Go AS. et al. JAMA 2001;285:2370-2375.

Prevalence of AF

ATRIA study

**General population-based
prevalence**

0.95%

Prevalence in Europe

UK cost analysis study 1995-2000

- UK epidemiological study used to calculate health care resource utilization in 1995 and 2000
- In 1995, approximately 534,000 people (281,000 men and 253,000 women) were treated for AFib

General population-based prevalence

0.90%

– 5% in patients aged >65

Prevalence of AF

Olmsted County study

**General population-based
prevalence**

2.5%

Incidence of AF – Lifetime Risk

Framingham study – 1 in 4 lifetime risk of developing AF

- 8725 patients free of AFib at 40 years of age followed from 1968-1999
- Lifetime risk to develop AFib at the age of 40 years:
 - **26.0% in men**
 - **23.0% in women**
- Lifetime risk high even in absence of CHF or MI (1 in 6)

Asymptomatic AF is Common

- At least 33% of AF patients could be asymptomatic¹
- Holter and transtelephonic monitoring studies have demonstrated that asymptomatic episodes of paroxysmal AF are 10-12 times more frequent than symptomatic episodes^{2,3}
- Rate-control therapies may slow the ventricular response so that even permanent AF can be asymptomatic¹

1. Savelieva I, et al. Pacing Clin Electrophysiol. 2000;23:145-148
2. Page RL, et al. Circulation. 2003;107:1141-1145
3. Defaye P, et al. Pacing Clin Electrophysiol. 1998;21:250-255

AF Confers a Significant Burden on Patients

Morbi-Mortality

- 2-fold increase in risk of mortality¹
- Near 5-fold increase in risk of stroke²
 - Stroke associated with AF is typically more severe than ischemic stroke due to other causes³
- AF promotes heart failure and HF aggravates AF to worsen a patient's overall prognosis⁴

Quality of Life

- QoL may be considerably impaired due to risk of exacerbation of symptoms⁵

1 Benjamin EJ et al. Circulation. 1998;98:946-952

2 Wolf et al. Stroke 1991;22:983-988

3 Dulli DA et al. Neuroepidemiology. 2003;22(2):118-23

4 Wang TJ et al. Circulation 2003;107: 2920-2925.

5 Hamer ME et al. Am J Cardiol 1994;74:826-9.

What we have so far

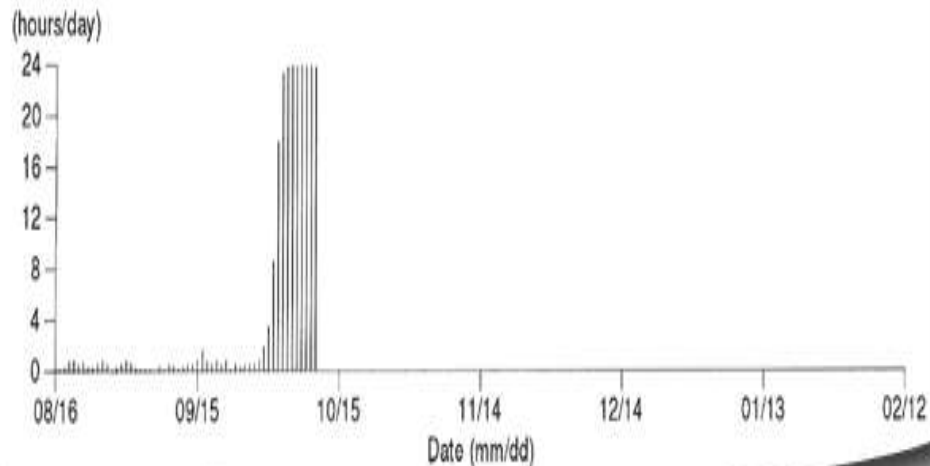
- Only really 2 indications for pacing
 - Symptomatic bradycardia
 - OR high risk for developing it
- Important to correlate with symptoms by appropriate monitoring
- PPM insertion/revision is not risk free

Pacemaker Revision carries a risk



What do pacemakers tell us?

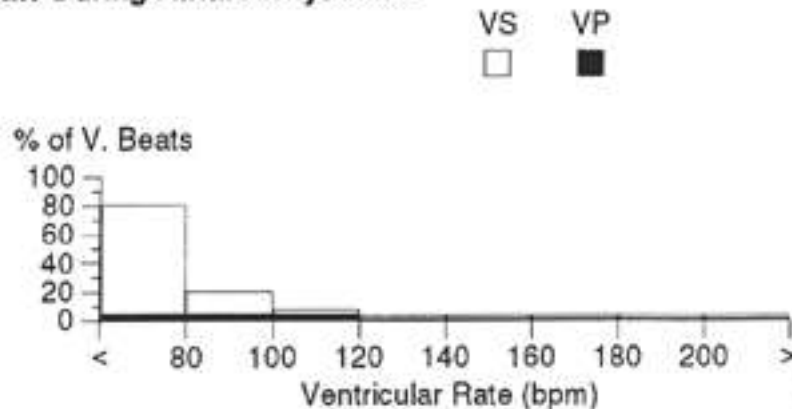
Atrial Arrhythmia Trend



V. Rate Summary: 10/10/01 9:01 PM
 VHR Episodes 0
 AHR Episodes 14 (23.8 hrs/day - 99.3%)
 Episode Trigger Mode Switch

Type	Date/Time	Duration hh:mm:ss	Rates (bpm):			Sensor	EGM	
			Max A	Max V	Avg V			
AHR	First	10/04/01 4:37 AM	:01:08	272	85	69	48	No
AHR	Fastest	10/04/01 6:44 PM	18:26:03	380	73	73	47	No
AHR	Longest	10/06/01 11:15 PM	23:38:01	380	86	73	49	No
AHR		10/08/01 1:25 PM	20:10:29	380	102	73	49	Yes
AHR		10/09/01 9:40 AM	22:11:55	346	113	73	51	Yes
AHR		10/10/01 7:56 AM	12:56:47	331	110	74	49	Yes
AHR		10/10/01 9:01 PM	11:45:47	331	120	74	53	Yes

V. Rate During Atrial Arrhythmias



331 120 74

Atrial Arrhythmias

Duration	Count
= >72hr	0
24hr - <72hr	0
12hr - <24hr	9
4hr - <12hr	1
1hr - <4hr	0
10min - <1hr	1
1min - <10min	2
<1min	1
Total	14

What we need to know?

- Does the patient have any symptoms?
- How long have they been in atrial fibrillation?
- Is this paroxysmal?
- Is SR preferable in this patient?
- Have they paced their ventricle whilst in AF?
- What do the ventricular rate histograms show?

Decision time

- If want SR then you need a DDDR generator
- If Permanent AF with evidence of V pacing then need VVIR generator
- If there are high V rates then probably VVIR generator
- If lots of RV pacing ? Upgrade to CRTD
- If no symptoms, minimal high rates, no pacing ????

Questions?