

▲ Flecainide – current role in the treatment of Atrial Fibrillation

David Bennett, Marketing Centre Cardiology, MEDA



Objectives

- ▶ **The importance of treating AF**
- ▶ **Briefly present the flecainide history - what does it tell us**
- ▶ **Treatment guidelines**
- ▶ **Flecainide usage in Western Europe**
- ▶ **Summary**
- ▶ **Czech Republic experience to date**



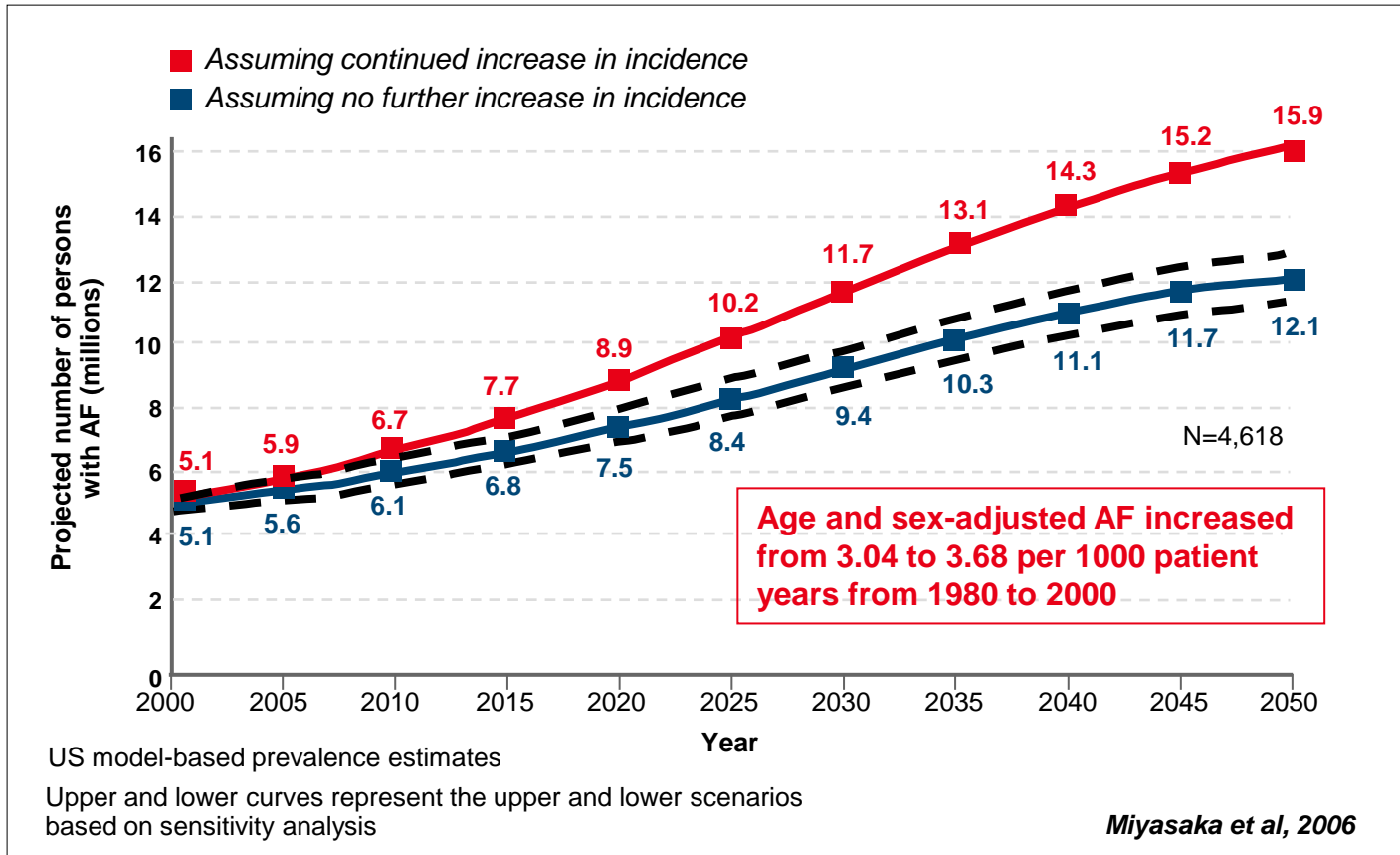


Product History

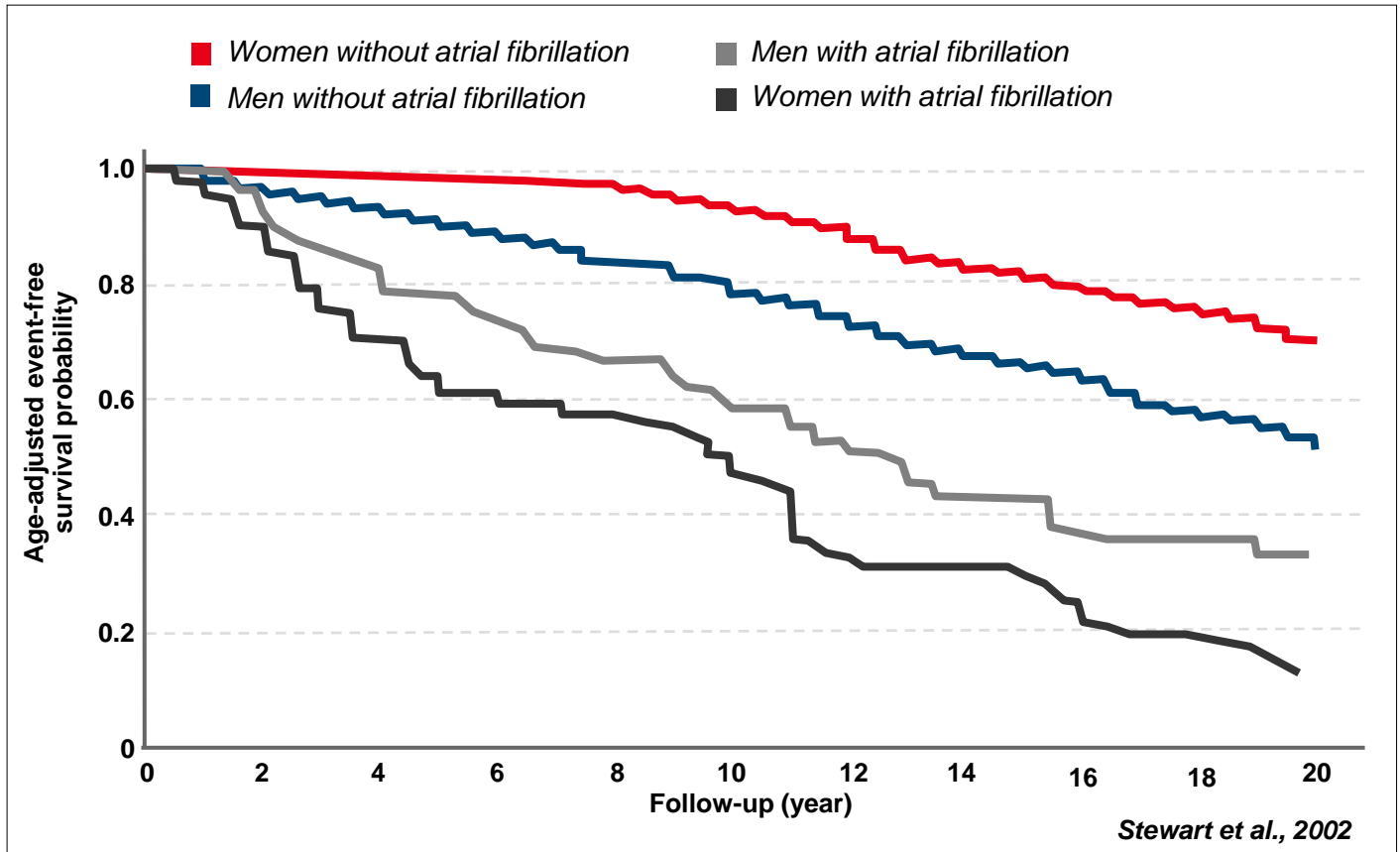
- ▶ **Tambocor™ 100 mg immediate-release tablets was first registered in Germany in June 1982**
- ▶ **The Original indication was for Ventricular Arrhythmias which was extended to Supraventricular Arrhythmias from 1986**
- ▶ **Tambocor withdrawn from CAST in April 1989**
 - ▶ Showed that the number of deaths in patients with asymptomatic or mildly symptomatic ventricular arrhythmias after myocardial infarction was greater in those receiving flecainide or encainide therapy than in those receiving placebo.
 - ▶ Subsequent to the CAST trial, a retrospective study was conducted in patients with supraventricular arrhythmias treated with flecainide or encainide. This study showed that neither drugs were shown to be associated with excess mortality.
- ▶ **Now available in over 50 countries**
- ▶ **Sold officially under a specific treatment programme in the Czech Republic since 2008**



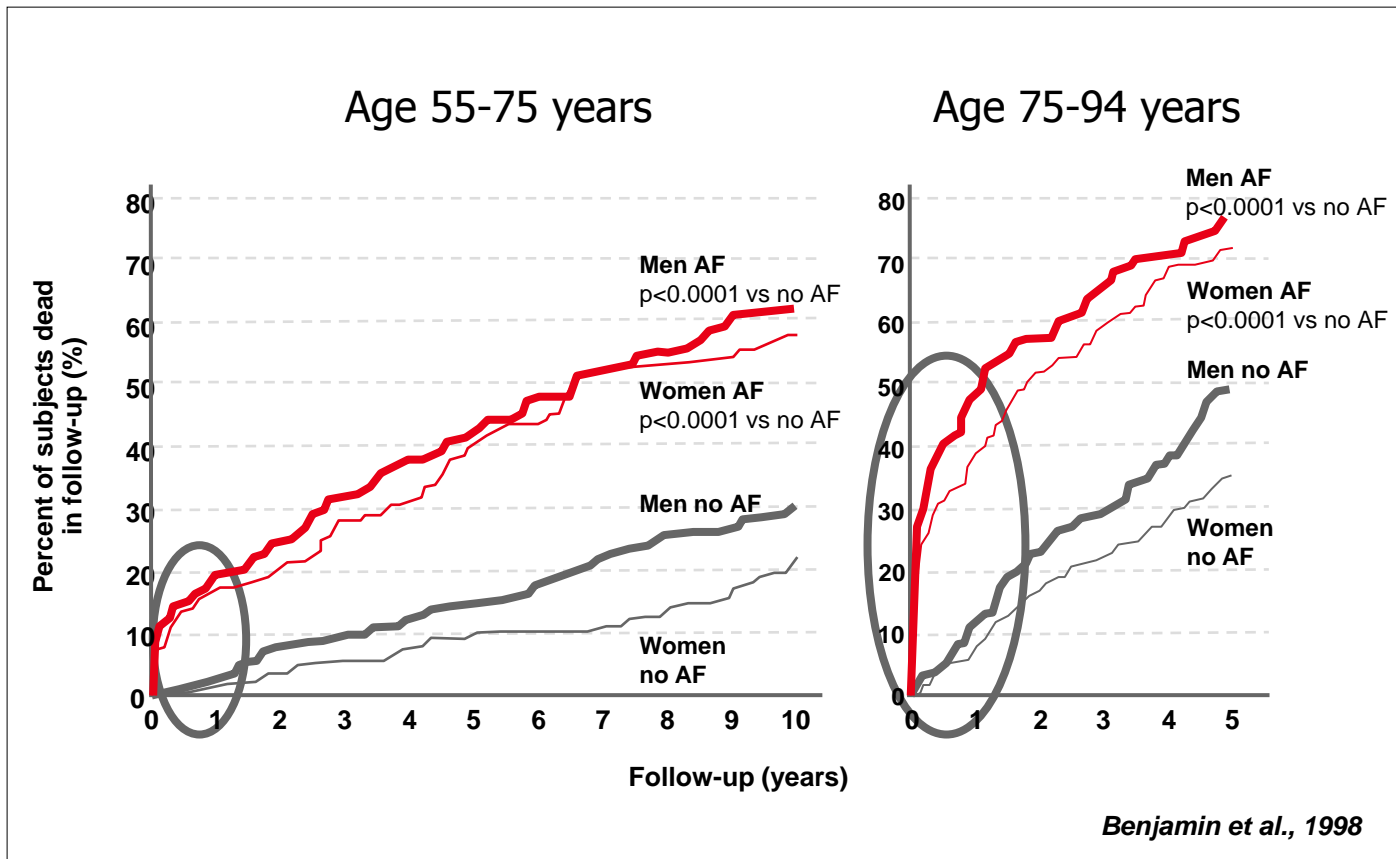
Projected number of people with AF during the next 50 years



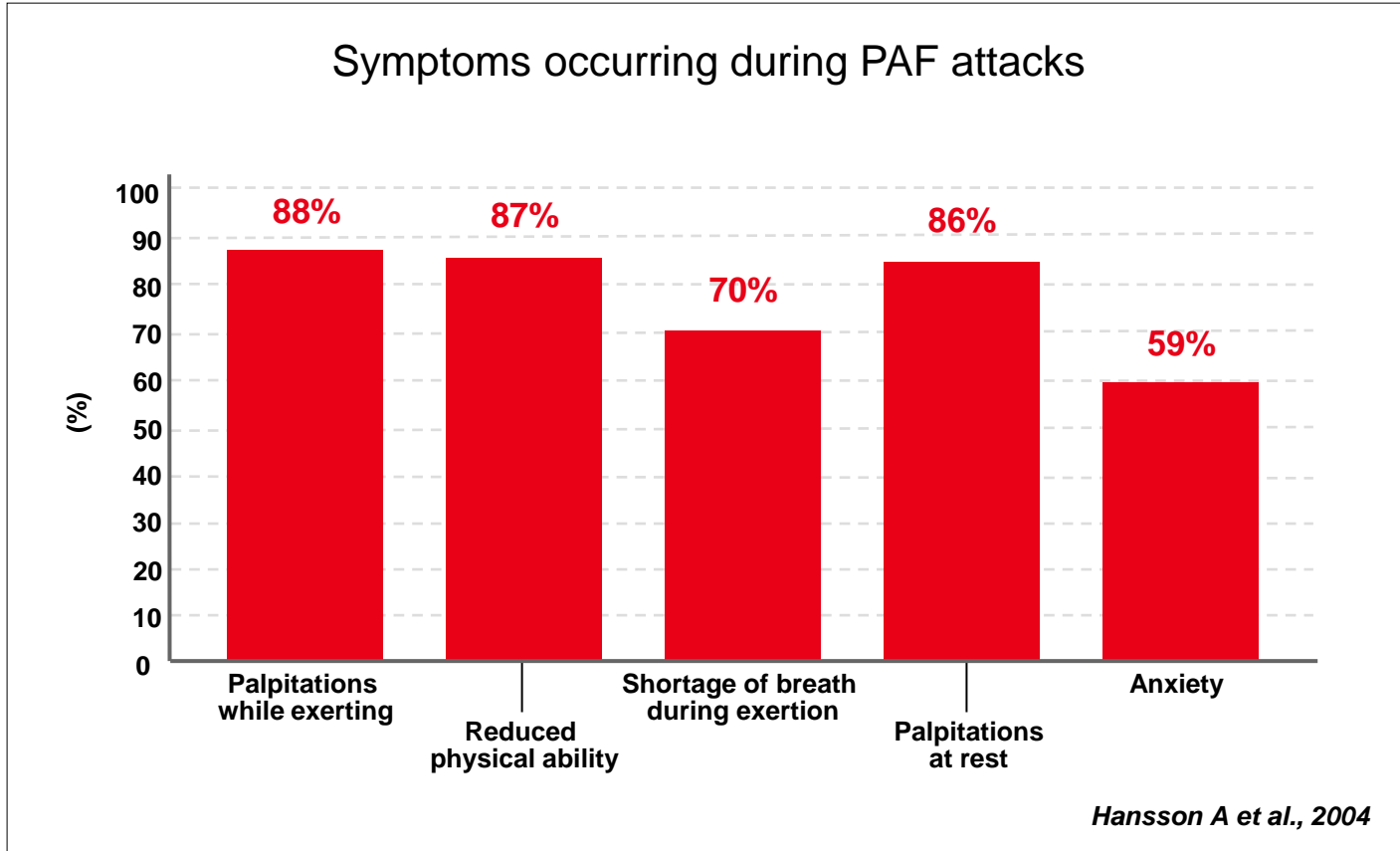
AF is associated with long-term risk of CV events



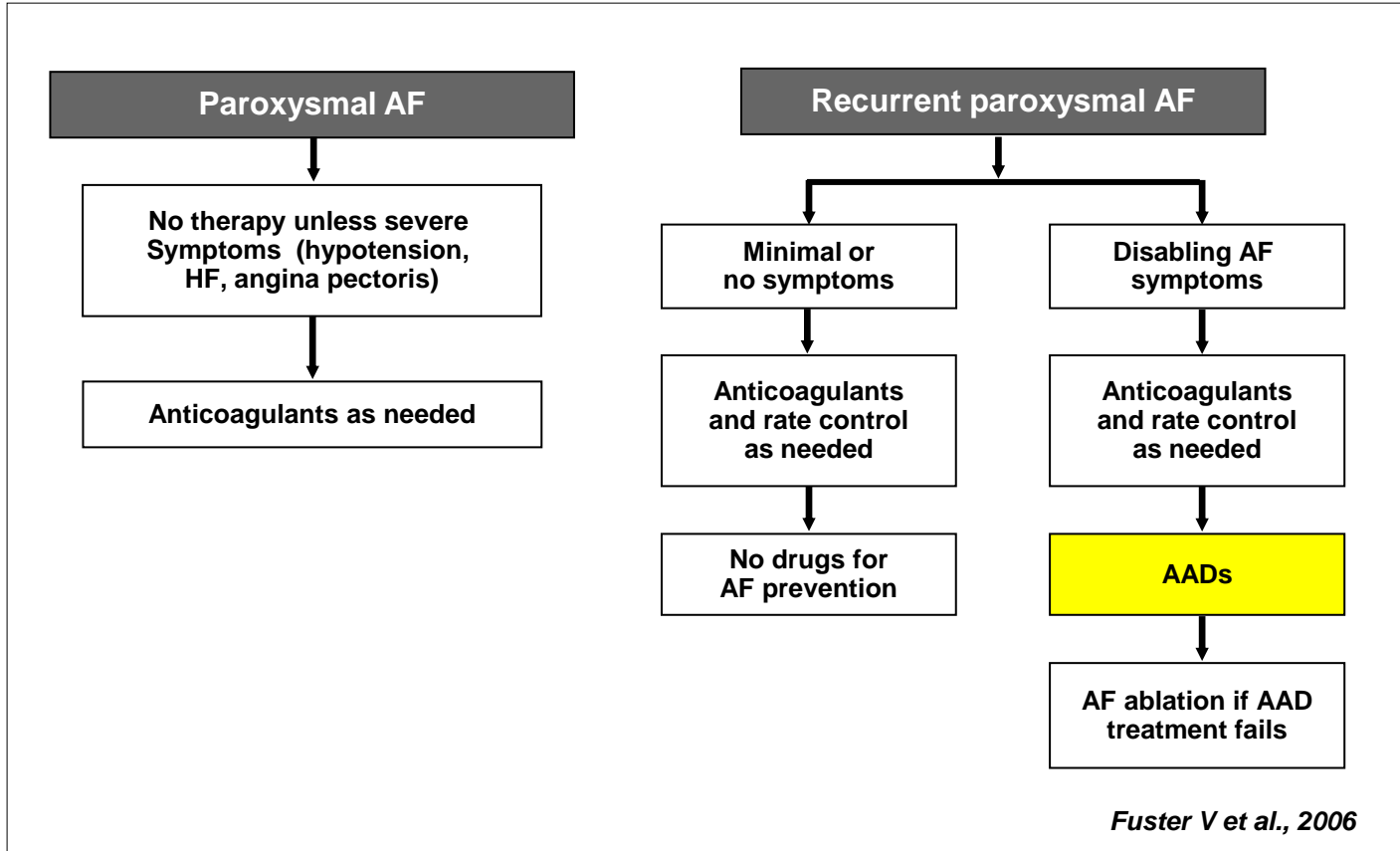
AF: an early and late killer



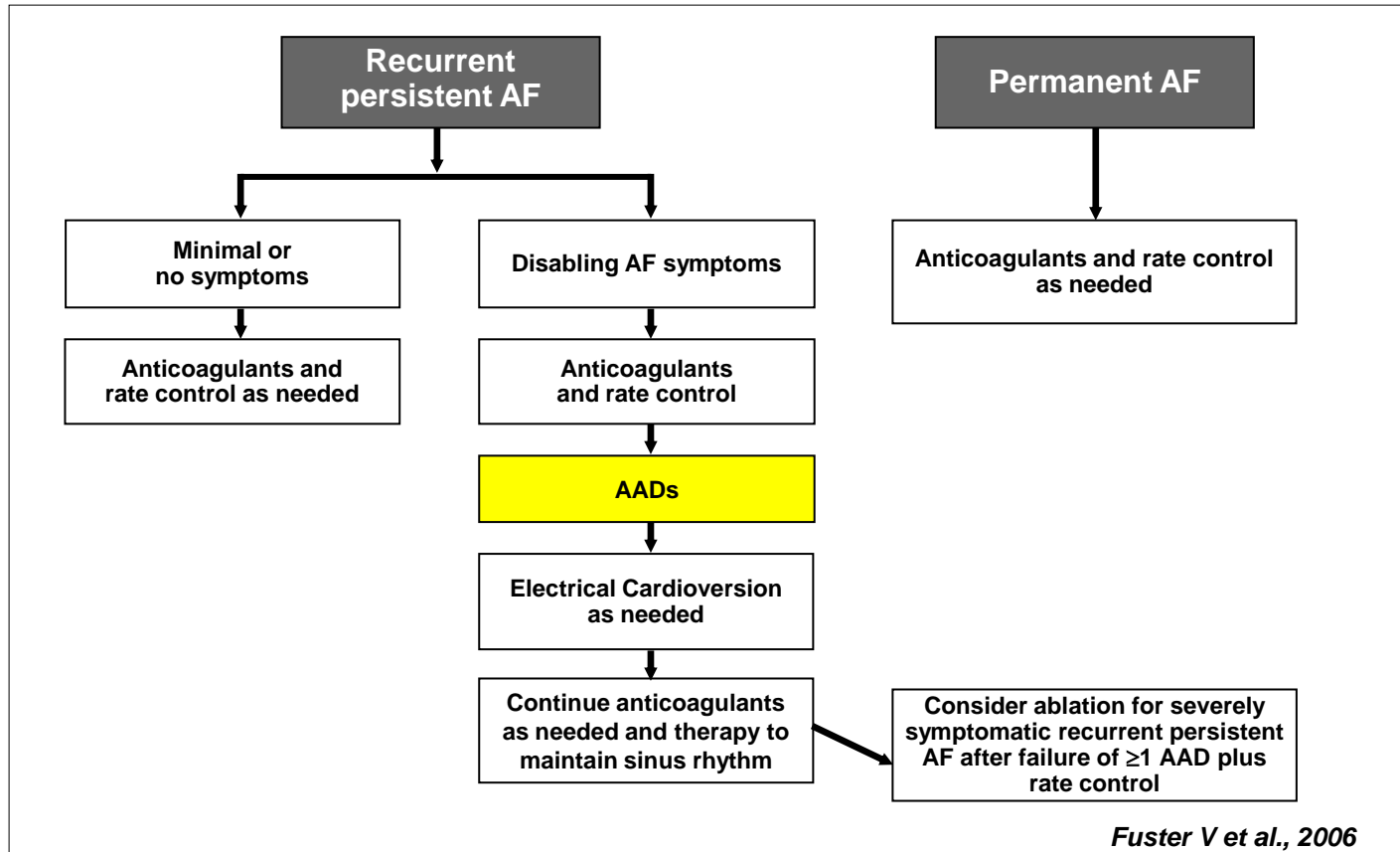
AF impairs QoL



Paroxysmal Atrial Fibrillation



Recurrent persistent AF and permanent AF



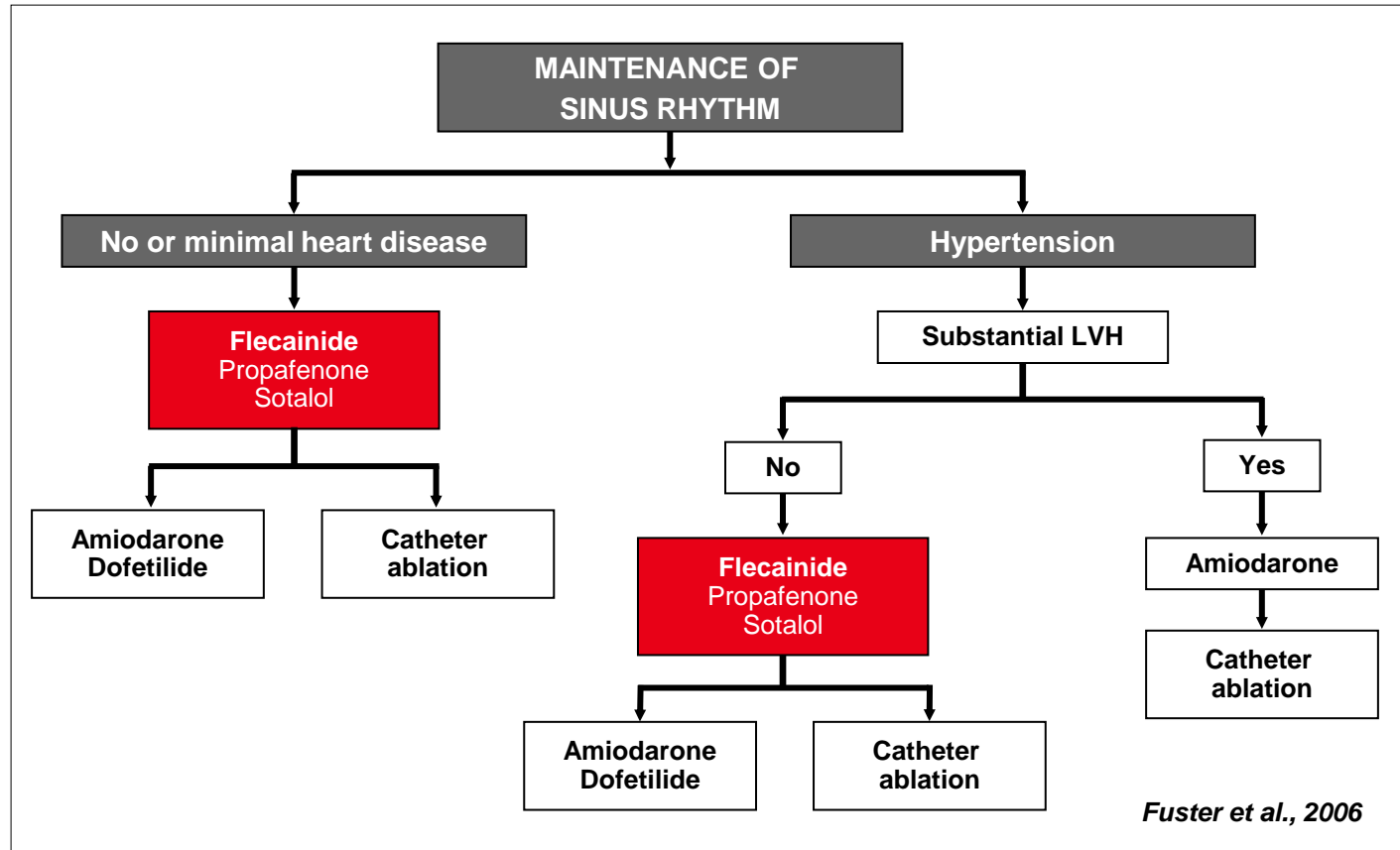


ACC/AHA/ESC guidelines

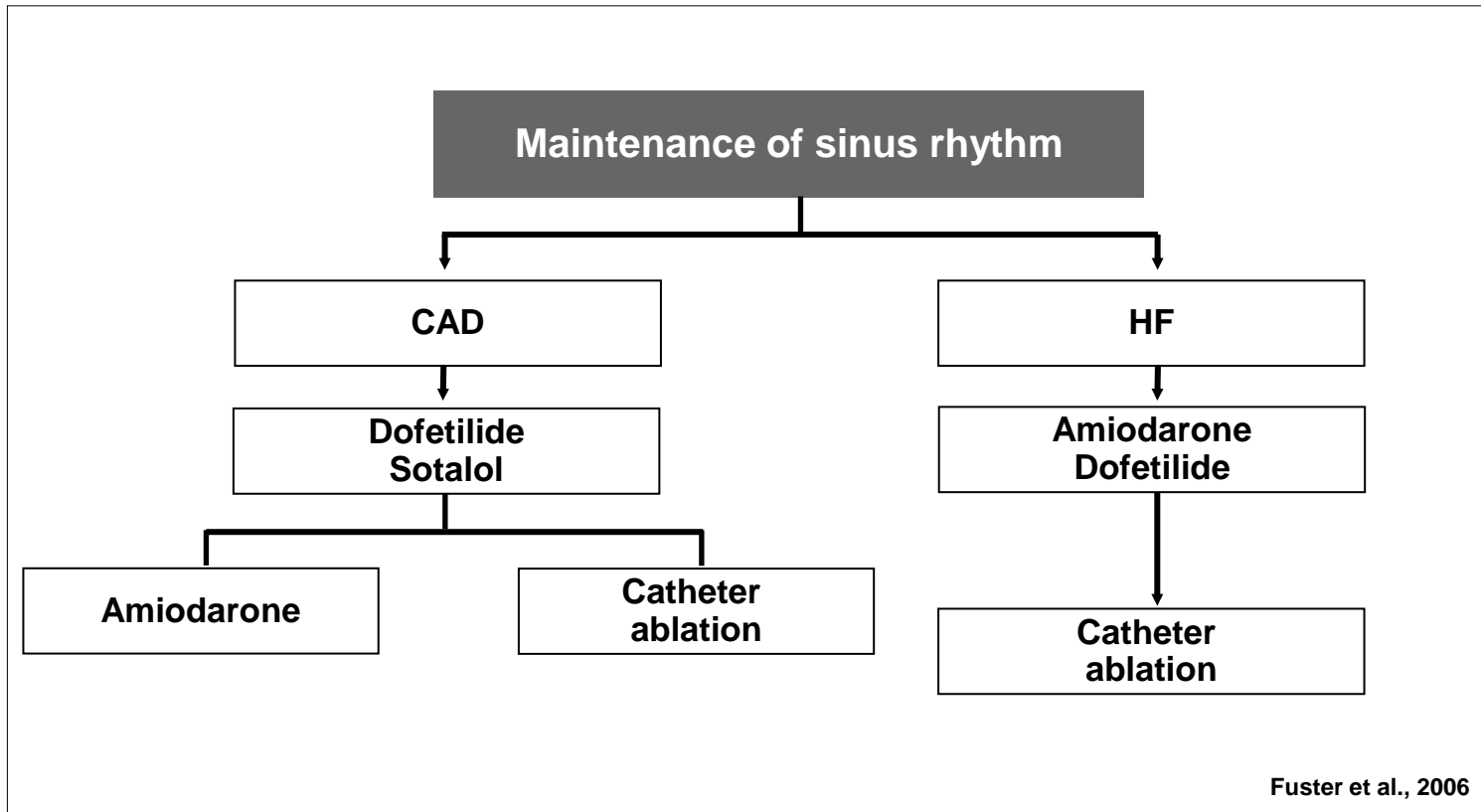
- ▶ Rate control may be a reasonable initial therapy in older patients with persistent AF who have hypertension or heart disease.
- ▶ **For younger individuals, especially those with paroxysmal lone AF, rhythm control maybe a better initial approach.**



AAD therapy to maintain SR in patients with recurrent paroxysmal or persistent AF



AAD therapy to maintain sinus rhythm in AF patients with coronary artery disease or heart failure





Flecainide is highly effective in the prevention of AF recurrence

Relapse rate for different antiarrhythmic drugs reported in the literature

	Relapse (mean, range)	Studies (n)
No drug	69% (44-85)	10
Quinidine	59% (46-89)	11
Disopyramide	51% (46-56)	3
Propafenone	61% (54-70)	3
Flecainide	38% (19-51)	3
Sotalol	58% (51-63)	3
Amiodarone	47% (17-64)	4

Minimum 6 months follow-up

Levy et al., 1998





Other Flecainide recommendations

- ▶ Flecainide has a « class I recommendation, A level of evidence » recommendation for pharmacological cardioversion of AF up to 7 days duration.
- ▶ Flecainide has a « class IIb, B level of evidence » recommendation for pharmacological cardioversion of AF longer than 7 days duration.
- ▶ Flecainide has a « class IIa, B level of evidence » Acknowledgement of Flecainide to enhance the success of direct current cardioversion and prevent recurrence of AF.

Fuster et al., 2006



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Flecainide is highly effective in the acute cardioversion of AF

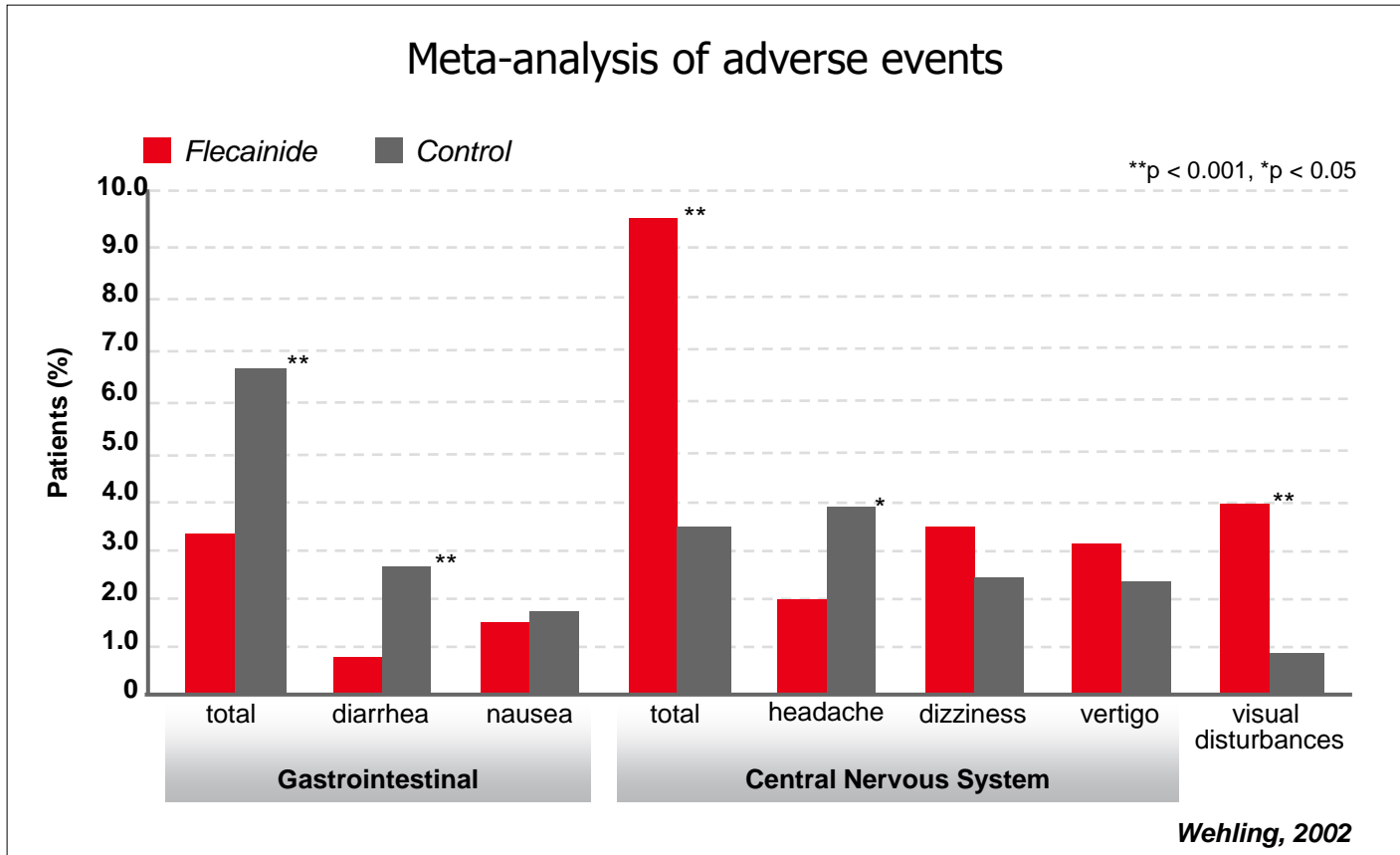
Meta-analysis of acute conversion of AF studies

	Conversion rate	No. of studies
Quinidine	11-86%	(n=6)
Procainamide	63%	(n=1)
Disopyramide	23%	(n=1)
Flecainide	52-95%	(n=8)
Propafenone	6-91%	(n=15)
Amiodarone	25-92%	(n=6)
Sotalol	8-52%	(n=3)
Ibutilide	10-49%	(n=3)
Control treatment	0-76%	(n=25)

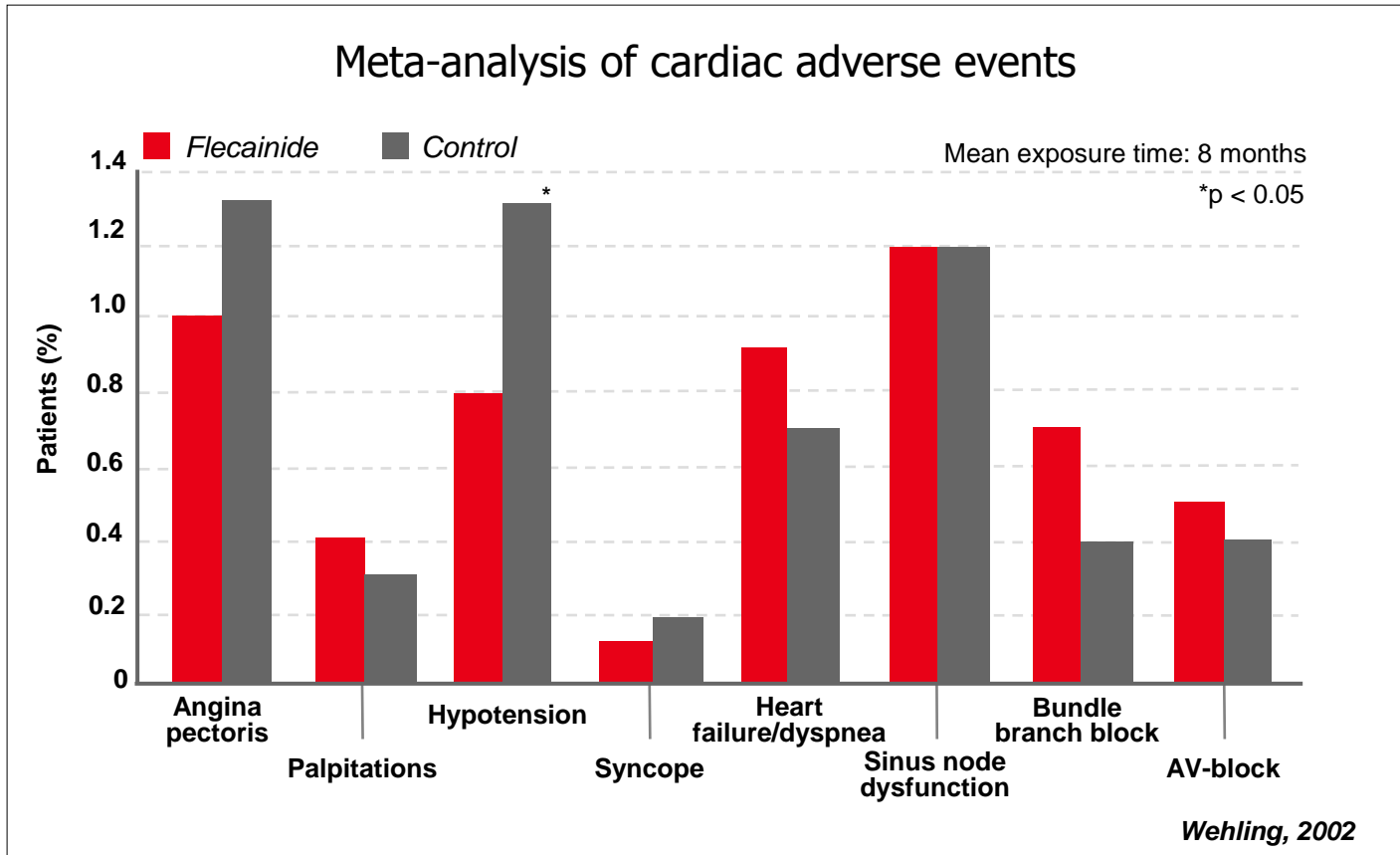
McNamara et al., 2001



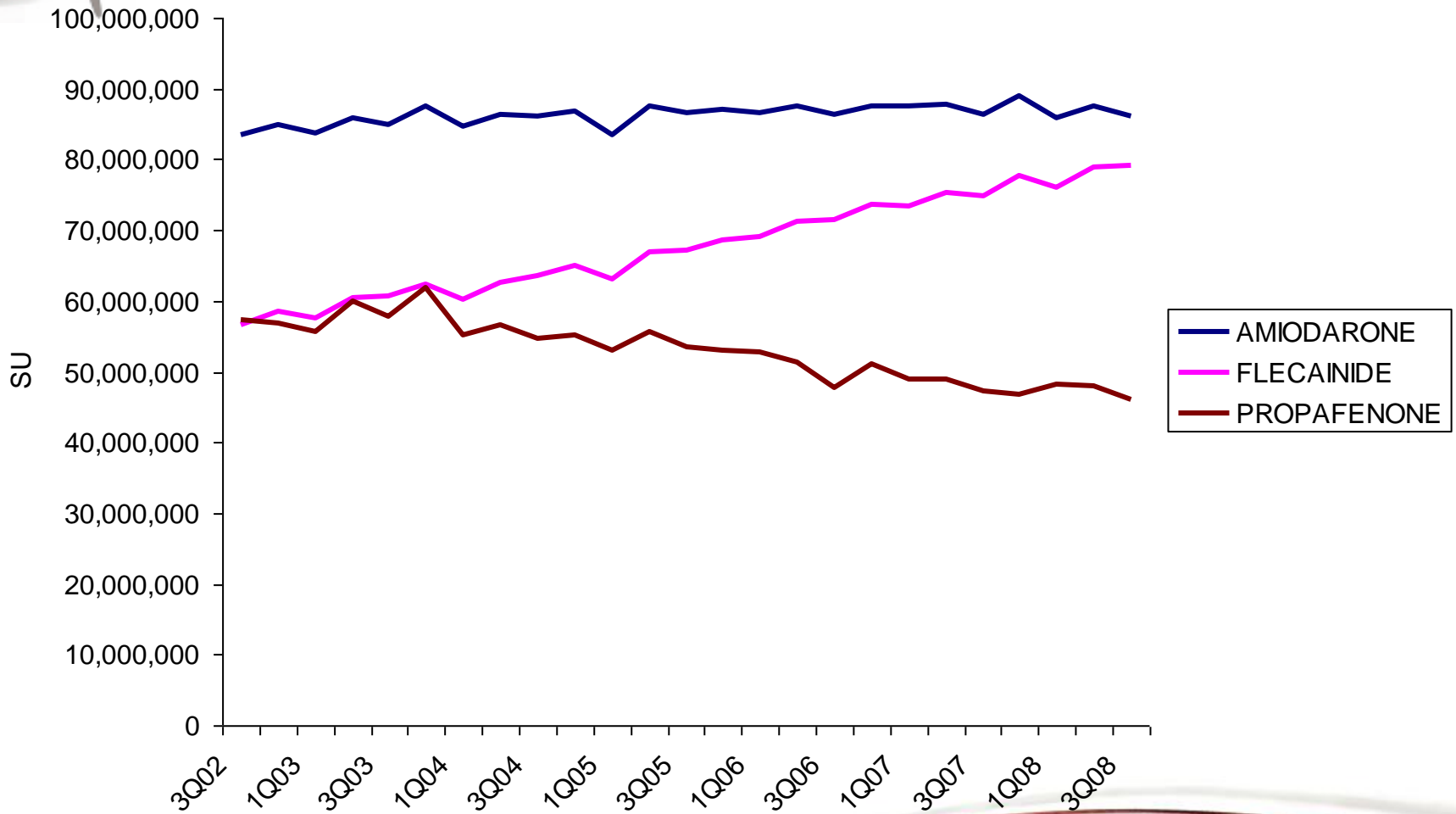
Flecainide produces a low incidence of extra-cardiac adverse events



Flecainide is safe over the long-term in patients without structural heart disease



Antiarrhythmic Drug Usage in Western Europe





11th Tambocor Periodic Safety Update Report 25 June 2007 - 24 June 2008

The estimated patient exposure for the period of this report is:

▶ **TOTAL (ESTIMATED): 194 MILLION PATIENT-DAYS**

Based on the assumption that the patients are treated continuously with Tambocor

▶ **TOTAL (ESTIMATED): 532 000 PATIENTS WERE EXPOSED TO TAMBOCOR**



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Summary

- ▶ Flecainide is a recommended first line treatment for patients without structural heart disease
- ▶ Flecainide is highly effective for acute cardioversion of AF
- ▶ Flecainide effectively reduces recurrences of AF, maintaining patients in sinus rhythm for longer
- ▶ Flecainide is a well-tolerated AAD for patients without structural heart disease inducing a low incidence of extra-cardiac adverse events
- ▶ After 25 years flecainide still remains an essential part of a physicians toolkit and with new products continuing to fail to meet expectations this looks likely to continue