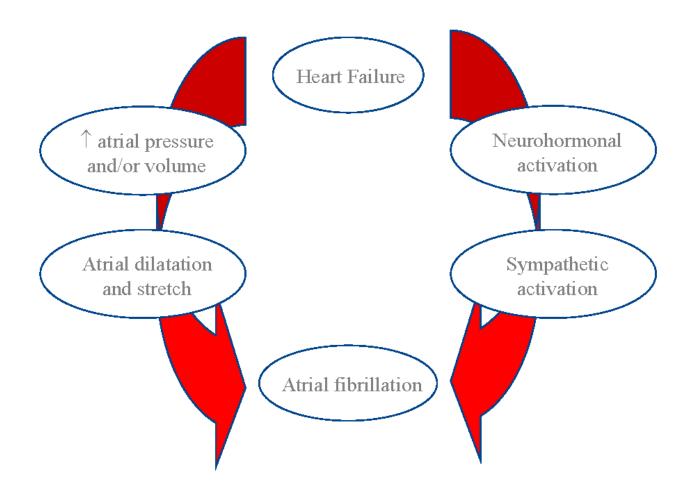
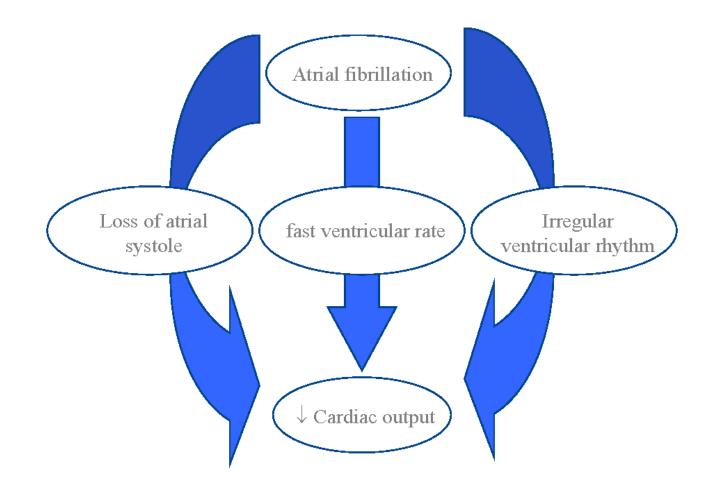


CHF promotes AF



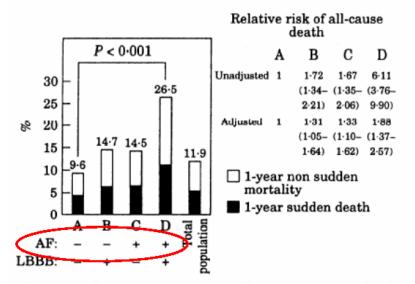


AF worsens CHF





The presence of AF in CHF patients worsens their prognosis



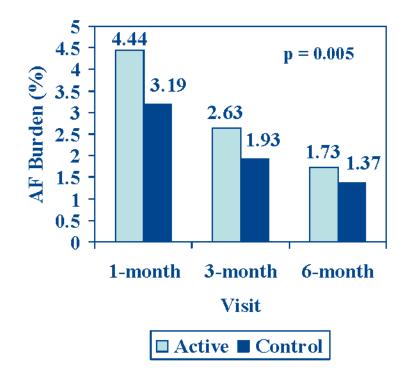
Patients with both LBBB and AF have a worse 1year mortality than other CHF patients.

Figure 1 One-year total mortality and sudden death in patients without complete left bundle-branch block (LBBB) and chronic atrial fibrillation (AF) (group A), with isolated left bundle-branch block (group B), with isolated chronic atrial fibrillation (group C) and simultaneous presence of complete left bundle-branch block and atrial fibrillation (group D).

Baldasseroni et al, EHJ 2002



AF Prevention by pacing: Background



The ADOPT-A study demonstrated that the AF Suppression[™] algorithm is safe and decreases symptomatic AF burden significantly in patients with sick sinus syndrome and AF at each follow up visit.

Carlson et al. JAm Coll Cardiol. 2003



MASCOT - Study endpoints

Primary:

• Reduction in the incidence of permanent Atrial Fibrillation at 12 and 24 months.

Secondary:

- Incidence of new-onset AF;
- Changes in LVEF, LVESD, LVEDD;
- Changes in NYHA functional class;
- Changes in quality of life;
- Mortality.



MASCOT – Baseline characteristics (2)

	TOTAL (n=409)
Heart rate (bpm)	71 ± 7
Systolic BP (mm Hg)	119 ± 18
Diastolic BP (mm Hg)	71 ± 11
LVEF (%)	25 ± 6
LVESD/DD (mm)	60 ± 10 / 70 ± 10
LVESV/DV (ml)	$164 \pm 68 \ / \ 222 \pm 81$
LA diameter (mm)	47 ± 9
Hypertension (%)	43
Diabetes (%)	29



MASCOT – AOP ON vs. OFF

	OFF (n=197)	ON (n=197)
Male (%)	80	79
Ages (years)	68 ± 9	68 ± 10
NYHA Class III (%)	88	84
Ischemic (%)	51	47
AF History (%)	17	19
QRS width (ms)	162 ± 26	166 ± 32
QoL	46 ±22	43 ± 20
LVEF (%)	25 ± 6	26 ± 7

All p-values between the 2 groups non significant



MASCOT – Response to AOP

	AOP OFF	AOP ON	
% atrial pacing	30±33	80±29	<i>P</i> <0.0001
% ventricular pacing	95±10	95±14	P=ns
Heart rate (bpm)	67±11	72±13	P=0.05

- The AOP algorithm was turned OFF in 13 patients, because of permanent AF (2 pts), atrial lead displacement (2 pts), high atrial threshold and risk of early battery depletion (4 pts), and intolerable palpitations/atrial tachyarrhythmias in (5 pts).
- It was turned ON in 1 patient suffering from paroxysmal AF.



MASCOT – Response to CRT

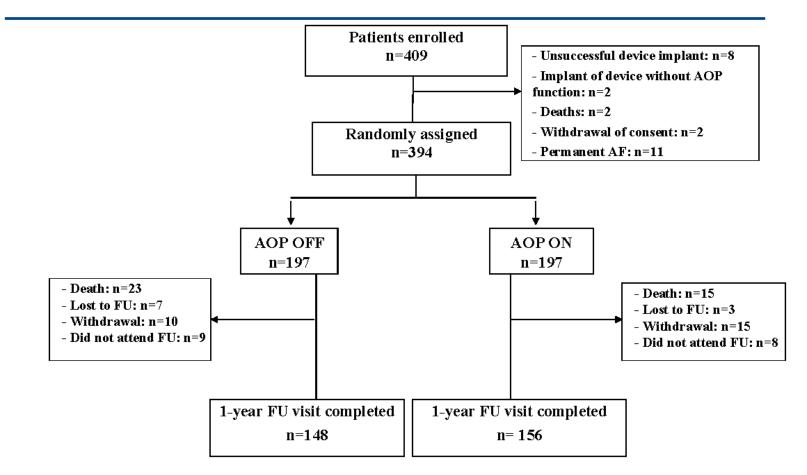
	AOP OFF		AOP ON	
	Baseline	1 year	Baseline	1 year
% of pts who improved ≥ 1 NYHA class	N/A	70	N/A	67
LVEF (%)	24.5±6.2	32.7±10.9*	25.8±6.8	33.1±12.6*
LVESD (mm)	60±10	53±13*	60±10	57±14*
QoL	46±22	24±20*	43±20	25±20*

* *p*<0.0001compared to baseline

There are no differences between groups at 1-year.

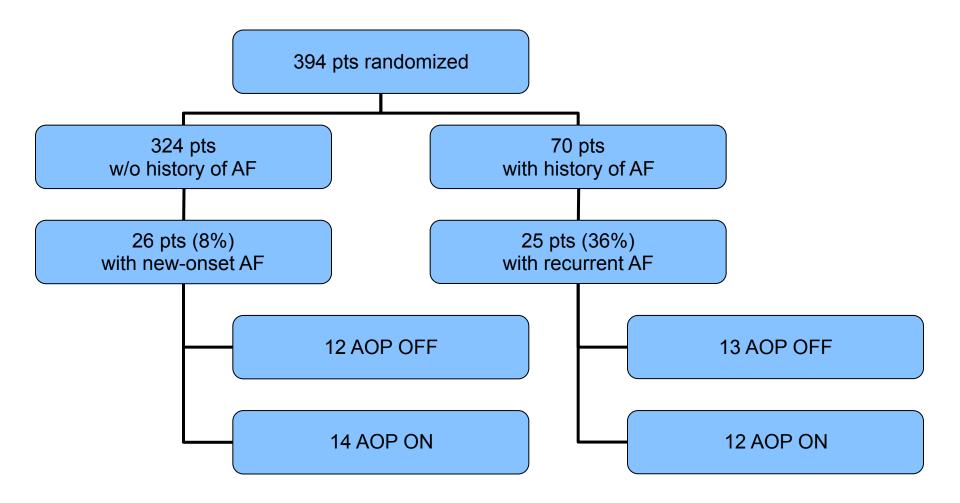


MASCOT – Patients flow

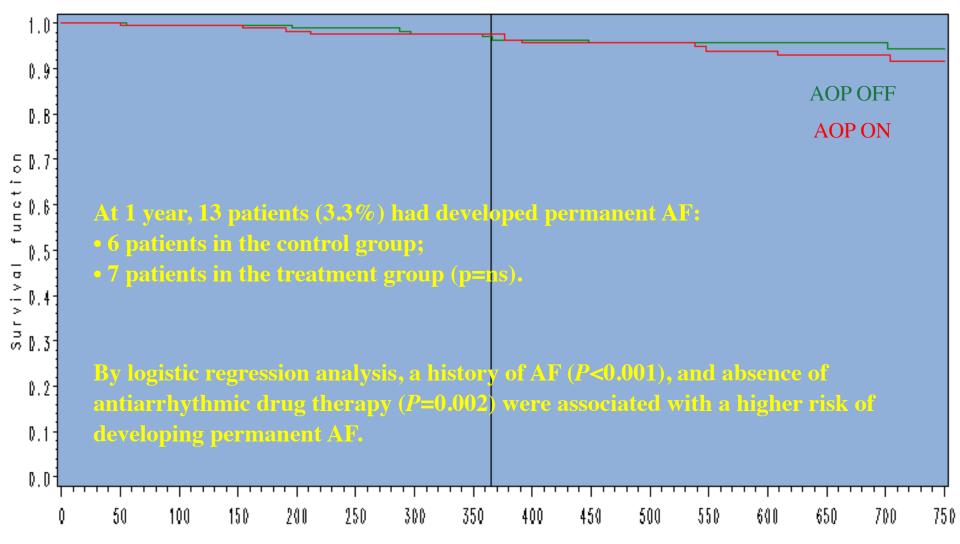


All analyses were based on the intention-to-treat principle

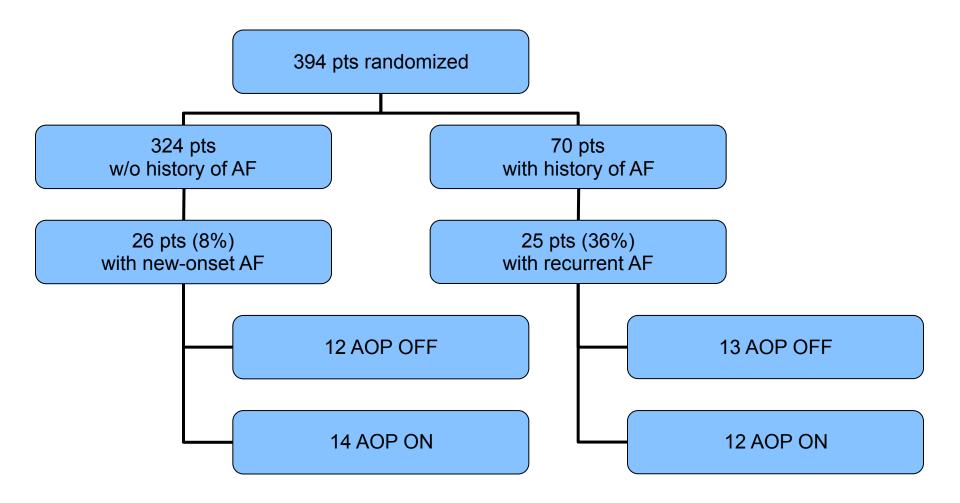
MASCOT – New onset AF



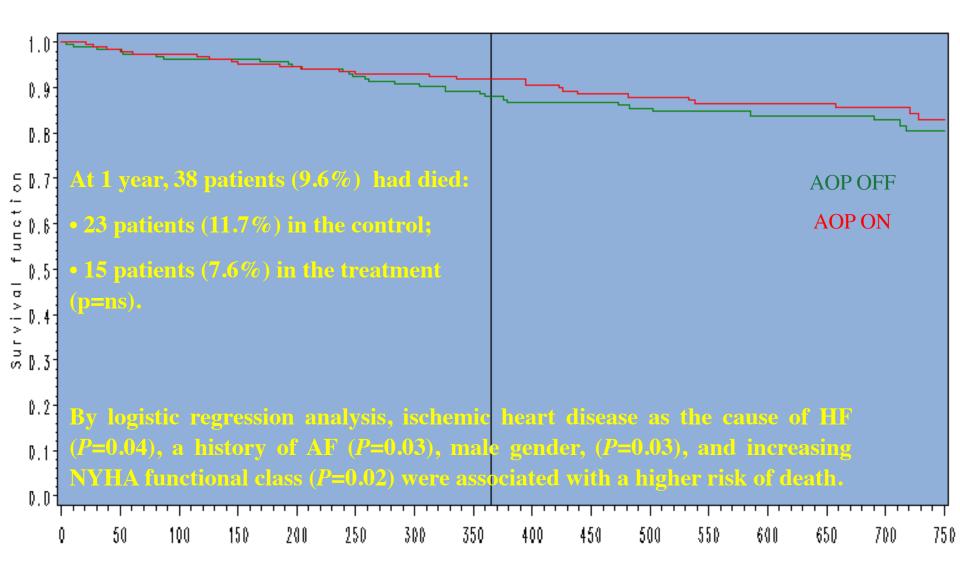
MASCOT – Incidence of permanent AF



MASCOT – New onset AF



MASCOT – Mortality





MASCOT – Conclusions

- The MASCOT study is the 1st study that investigated prospectively the development of AF in CRT patients.
- The incidence of permanent AF is much lower that expected in the CRT population (3.3%) and thus the efficacy of atrial overdrive pacing could not be assessed.
- AOP appears to be safe and well tolerated by heart failure patients and does not impair the response to CRT.
- AOP should be switched OFF to save battery energy and could be turned ON based on device diagnostics and patient symptoms in case of atrial tachyarrhythmias.