RealiseAF

An International, Observational, cross sectional survey evaluating atrial fibrillation management and the cardiovascular risk profile of AF patients

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Presenter Disclosures

- **Research grant:** Yes
- **Speaking or consulting:** Yes
- **Stockholding:** No

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Rationale

- RealiseAF provides a snapshot of AF management that could be not be generated in clinical trials which only enroll selected populations
- RealiseAF, the largest AF registry to date, was designed to assess patient characteristics, the control of atrial fibrillatiion and to investigate the quality of life of AF patients.

Methods

An international, large scale cross-sectional survey

Conducted in over 10,000 patients in 26 countries in 2009/2010

Patients

- Inclusion criteria
  - History of AF with at least one AF episode documented by ECG or by Holter monitoring, in the last 12 months.
  - Signed informed consent
- Exclusion criteria
  - Inability to provide consent
  - Post operative AF (< 3 months after surgery)
  - Participation in an AF or antithrombotic clinical trial in the previous month

Representativeness and Quality control

- Unbiased recruitment
  - Random selection of participating physicians (cardiologists and internists)
  - Ratio of Cardiologists to Internists pre-determined on a national basis.
  - Short enrollment period (< 6 weeks) to maximize consecutive recruitment
  - Enrollment target per site: min of 10, max of 30 patients per site

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Pre-Specified Aims

- **Primary:**
  - Assess "control" of AF (either SR or AF with HR ≤ 80 bpm) at the time of the visit
  - Investigate the CV risk profile of AF patients
- **Secondary:**
  - Describe AF characteristics
  - Describe AF management strategies
  - Assess Health-related-QOL associated with AF

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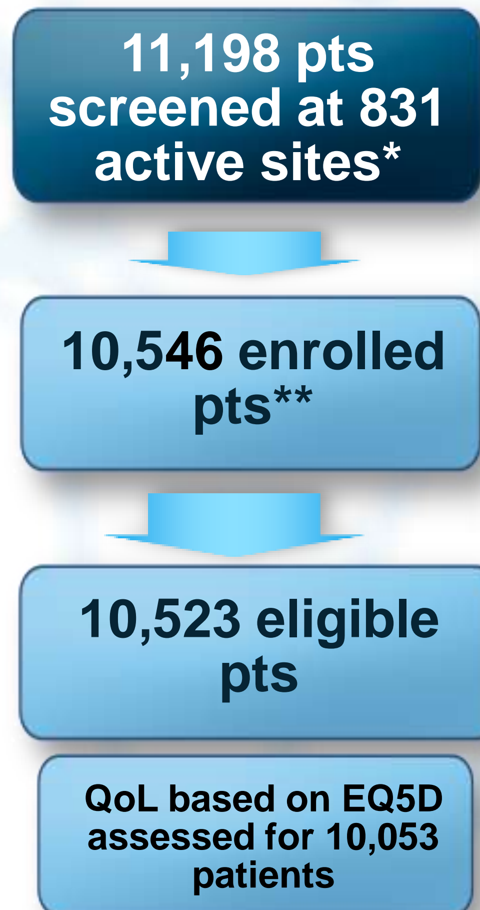
Patient flow and characteristics



	Total N=10,523
Age ≥ 60 years (%)	73.9
Age mean (SD)	67 (12.2)
Males (%)	56.4
Ethnicity(%)	
Caucasian	84.2
Black	0.1
Asian	10.1
Hispanic	3.5
Other	2.1
BMI (kg/m²) mean (SD)	28.3
SBP (mm Hg) mean (SD)	132.8
DBP (mm Hg) mean (SD)	79.8
$CHADS_2$ score ≥ 2	59.6%

*6.1% exclusions-3.0% declined consent-4.2% other
**No history of AF 6 (<0.1%) - Mentally disabled 1(<0.1%) - Post-cardiac surgery AF 1 (<0.1%) - Clinical trial in AF or antithrombotic in the previous month 3(<0.1%) - Other 14 (0.1%)

768 / 831 active sites completed the screening log

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AF characteristics

	Total (%)
Lone AF*	5.1
Time since AF diagnosis	
< 3 months	20.6
3 to 6 months	6.3
6 to 12 months	10.2
> 12 months	62.9
Type of AF	
Paroxysmal	24.8
Persistent	22.3
Permanent	46.4
Unable to assign (first episode)	6.4
Paroxysmal+Persistent	<0.1

*Patients aged under 60 years with no Coronary Artery Disease, no Heart Failure, no Valvular Heart Disease, no Chronic pulmonary disease, no VTE and no Arterial Hypertension

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High prevalence of concomitant CV risk factors in AF patients

Risk factor	%
Age > 50 for male and > 65 for female	77.8
Family history of premature cardiovascular disease	23.0
Family history of premature sudden death	6.1
Current smoker	10.2
Physical inactivity	61.1
Obesity (BMI >= 30kg/m2)	32.7
Arterial hypertension	72.2
Diabetes melittus	21.3
Dyslipidemia	46.3

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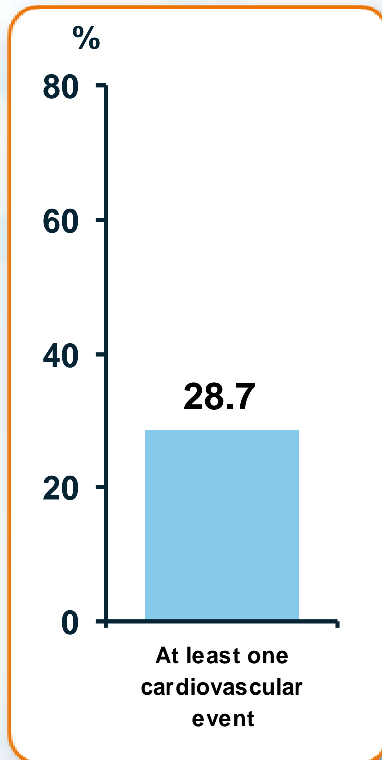
Frequent and severe CV events leading to unplanned hospitalization in AF patients

In the last 12 months



Event (%)	Value
Acute decompensation of heart failure	11.3
Acute coronary syndrome	7.8
Stroke	6.1
Transient Ischemic attack	2.8
Non CNS peripheral embolic events	0.8
Pulmonary embolism	1.0

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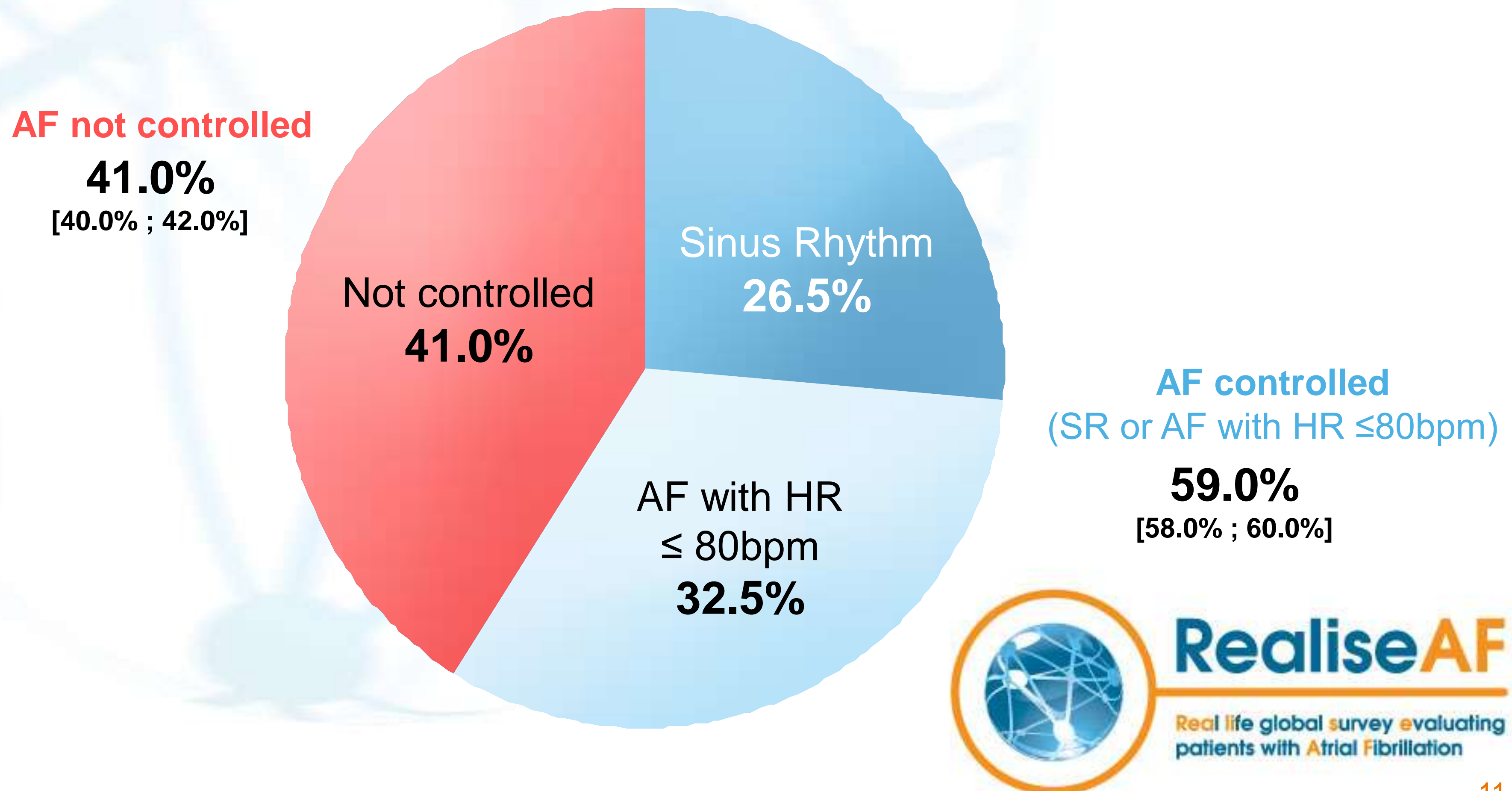
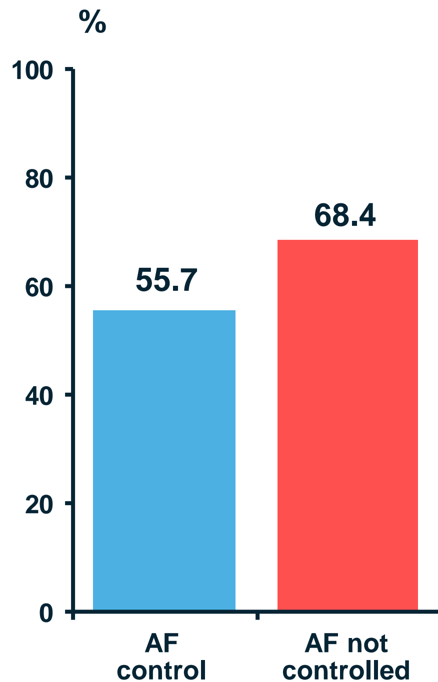
Primary outcome: control of AF

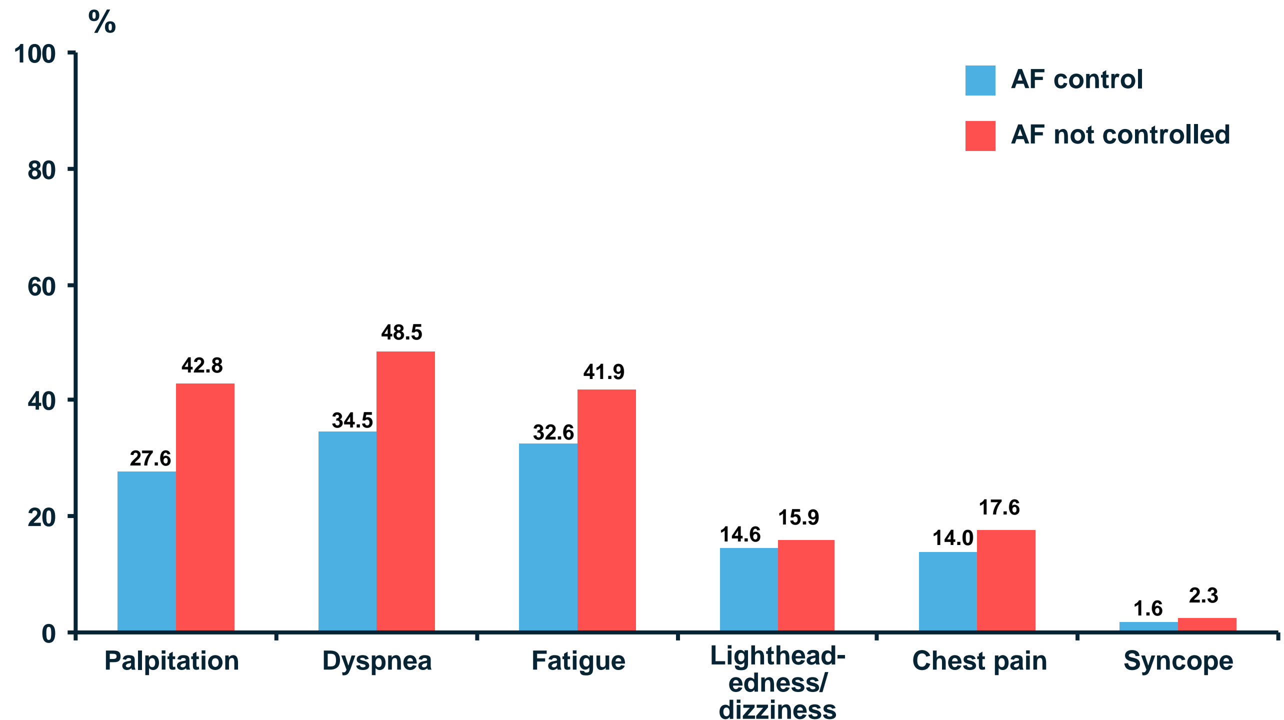
Sinus rhythm or AF with HR ≤ 80 bpm, on the ECG the day of the visit

Patients evaluable for primary criteria (n=9,665)



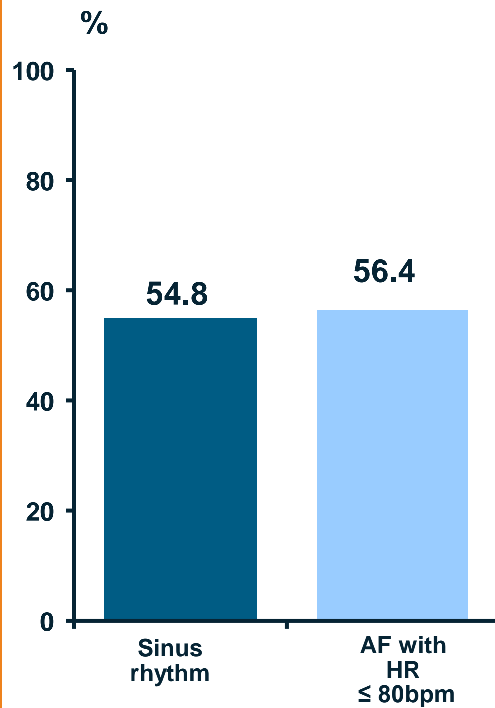
AF control was indicative of symptom control

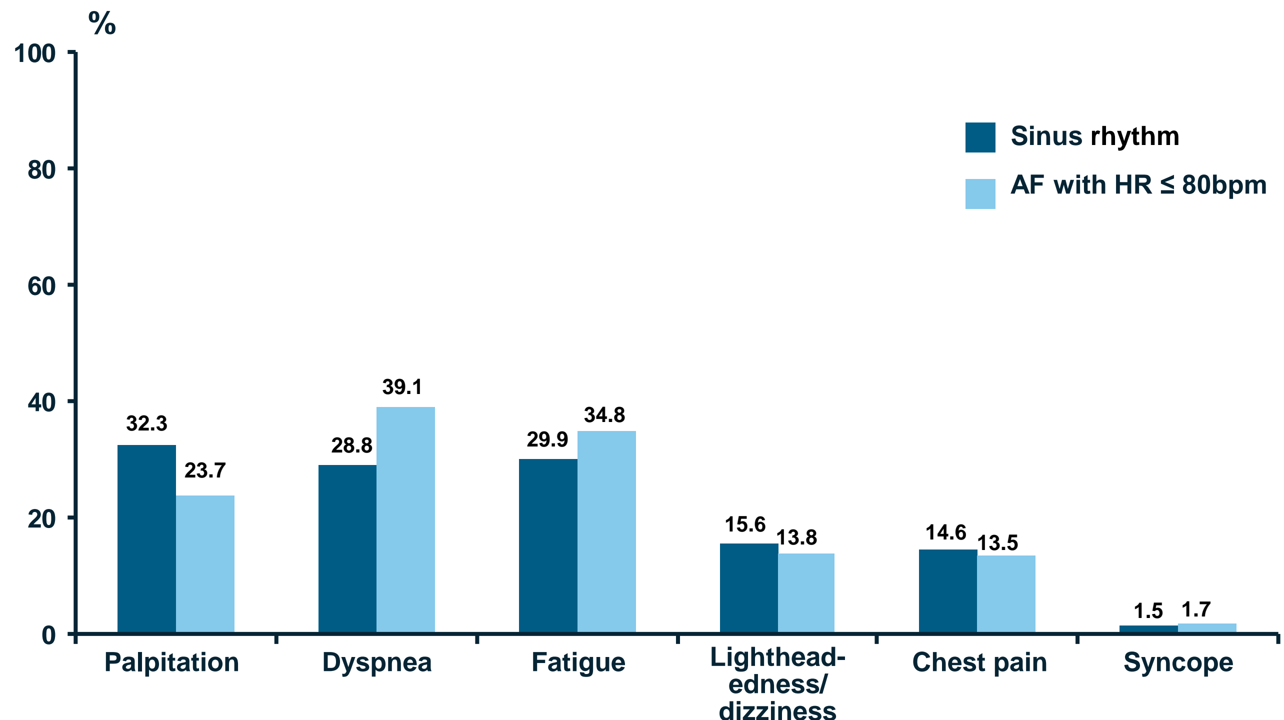




*Symptoms last week including the day of the visit according to AF control

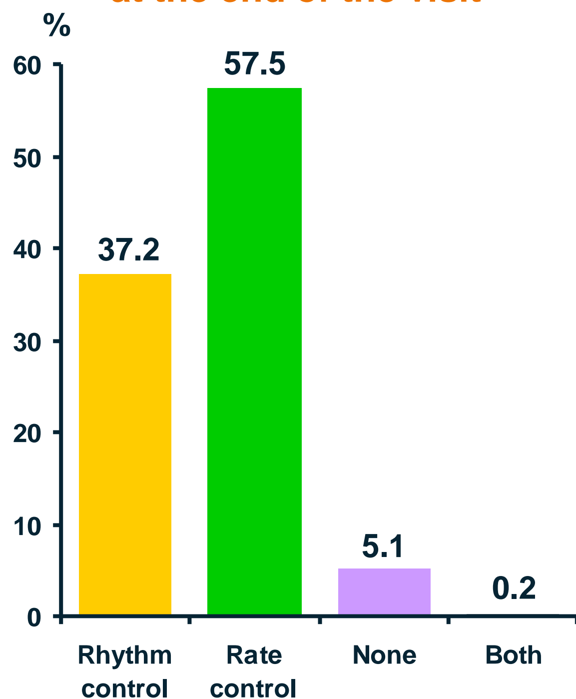
Patients in sinus rhythm or in AF with HR ≤ 80bpm are both symptomatic

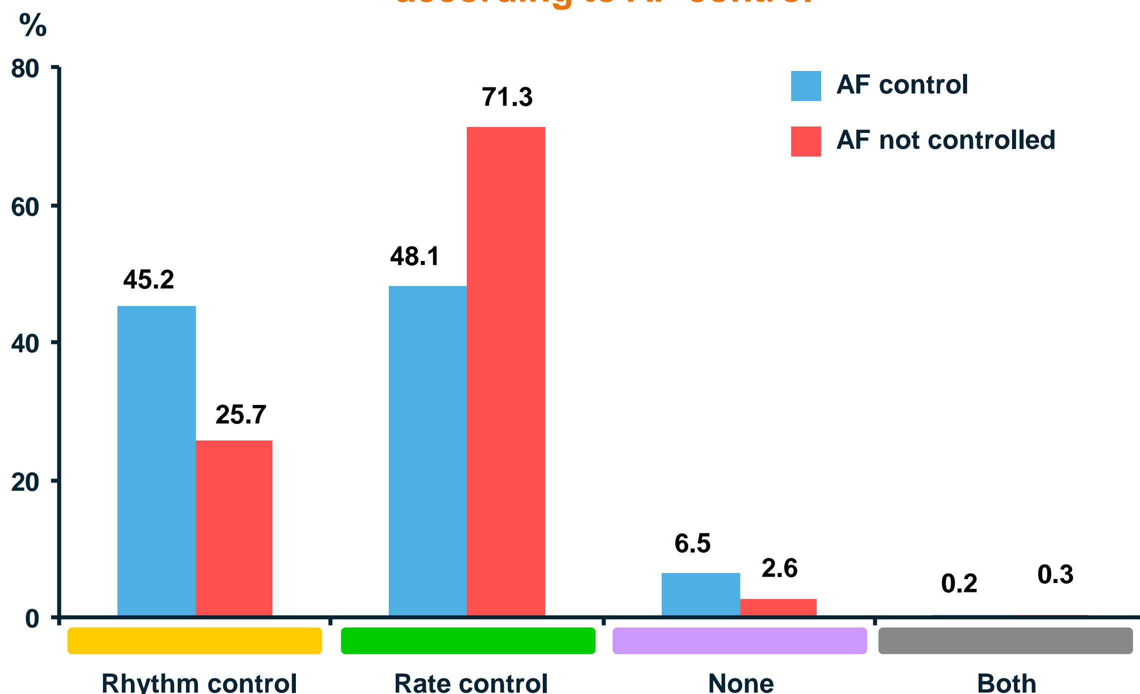




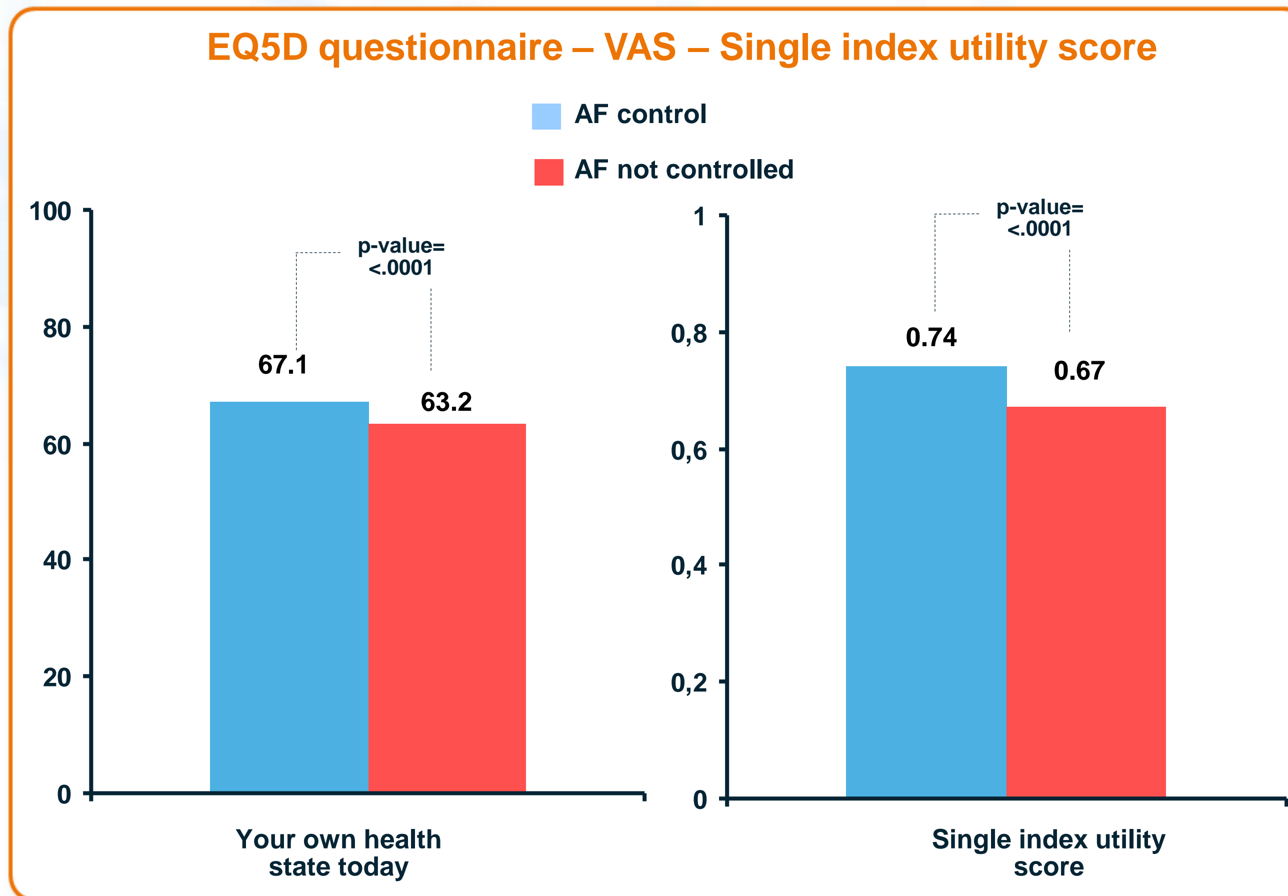
*Symptoms last week including the day of the visit

Rate control was the strategy most frequently chosen, although the least effective





AF control is associated with moderately improved quality of life (QoL)



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Rhythm status and QoL

EQ5D questionnaire – VAS – Single index utility score

- Sinus rhythm
- AF with HR ≤ 80bpm
- AF not controlled

	Sinus rhythm	AF with HR ≤ 80bpm	AF not controlled	p-value
Your own health state today	69.2	65.4	63.2	<.0001
Single index utility score	0.75	0.72	0.67	<.0001

100
80
60
40
20
0

1
0,8
0,6
0,4
0,2
0

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QoL based on EQ5D according to rhythm and control status

EQ5D questionnaire - Health profiles
According to AF control

Legend: Sinus rhythm; AF with HR ≤ 80bpm; AF not controlled

%	Sinus rhythm	AF with HR ≤ 80bpm	AF not controlled
I have no problems in walking about	63.1	50.8	47.1
I have no problems with self-care	84.6	77.2	73.0
I have no problems with performing usual activities	65.0	56.2	50.6
I have no pain or discomfort	52.4	49.3	42.9
I am not anxious or depressed	54.2	60.5	54.4

Y-axis: % (0, 20, 40, 60, 80, 100)

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Conclusion

- Control of AF was not optimal and patients remained frequently symptomatic even when AF was controlled.
- Rate control was the most commonly used strategy, however with a lower proportion of AF control.
- Control of AF was associated with a modest but consistent improvement of quality of life.
- Improvement of quality of life of AF patients is a therapeutic goal in the new 2010 ESC guidelines, Current AF management doesn't necessarily achieve this objective.

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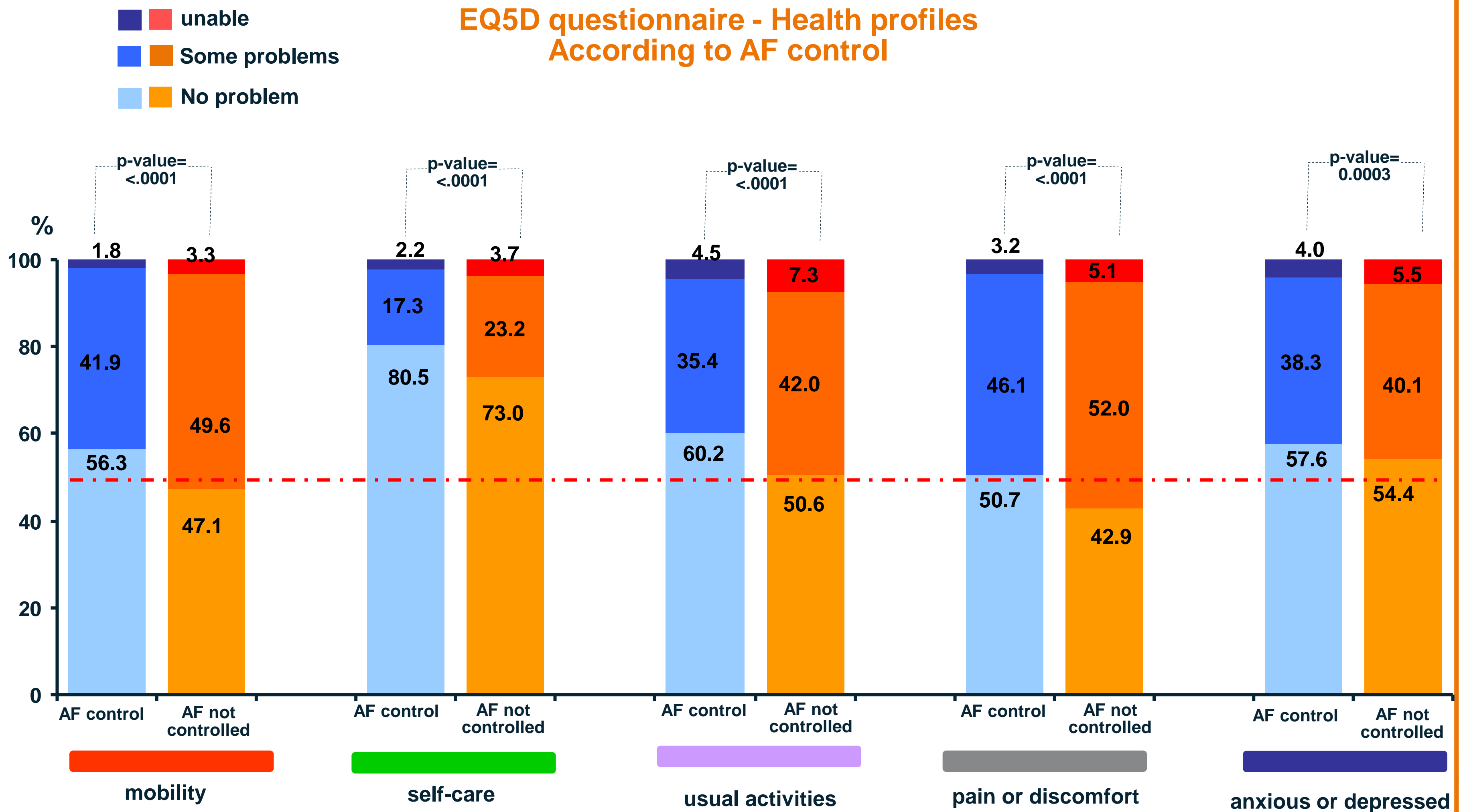
QoL based on EQ5D according to AF control



The high majority of AF patients stay on current therapeutic strategy although presence of symptom and/or absence of control

No change of AF therapeutic strategy* during the visit

	%
Symptomatic patients in sinus rhythm (N=1,401)	83.7
Symptomatic patients in AF with HR <=80 bpm (N=1,769)	85.2
Asymptomatic not controlled** patients (N=1,245)	82.6
Symptomatic not controlled** patients (N=2,691)	76.1

*Including no change of therapeutic as Rhythm to Rhythm, Rate to Rate, None to None and Rhythm+Rate to Rhythm+Rate
**in AF with HR >80 bpm and no sinus rhythm

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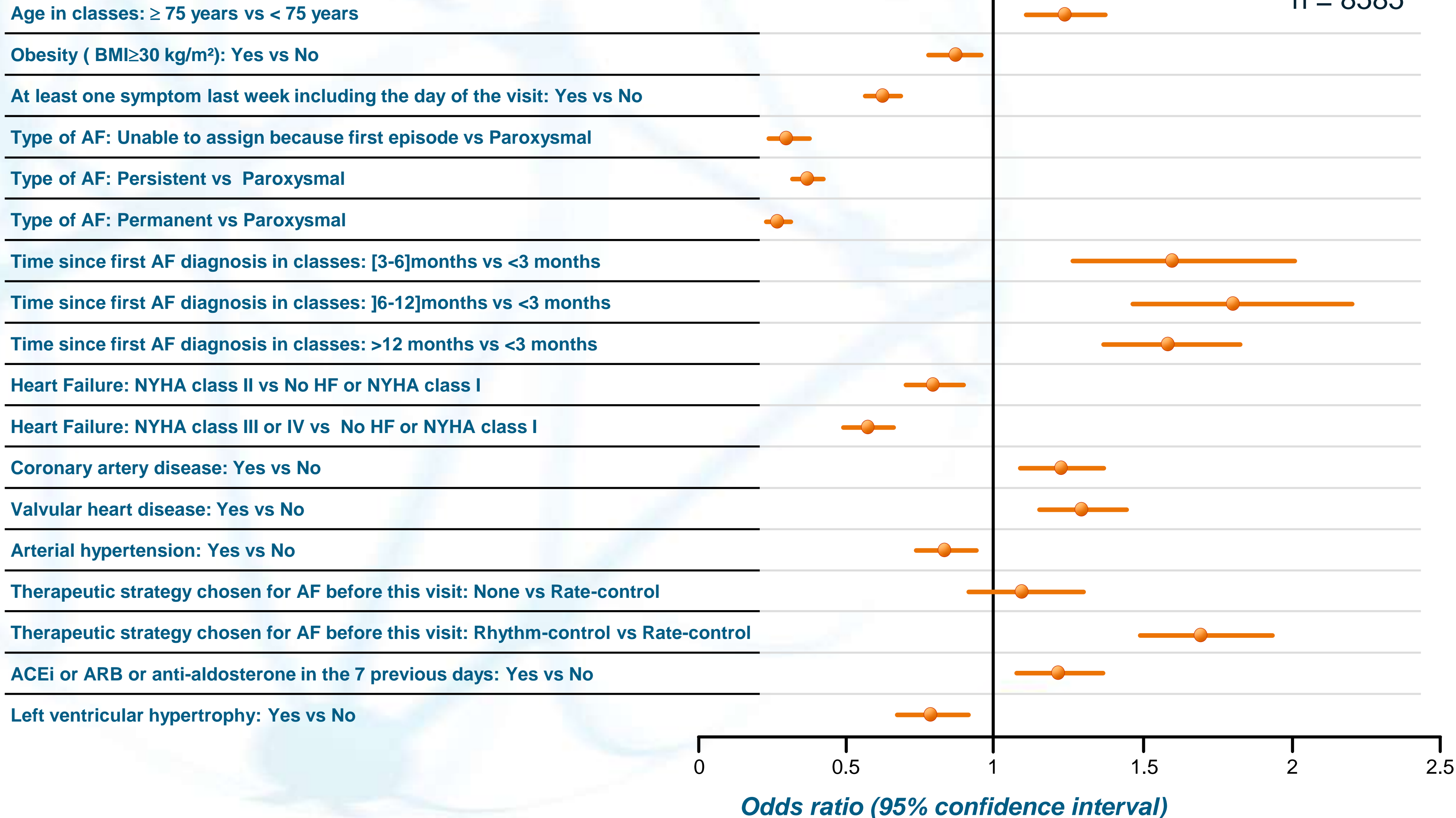
Predictors of AF control



*C-statistic=**0.732** / Hosmer-Lemeshow test, p=**0.1407***

QoL based on EQ5D according to AF therapeutic strategy