ALBATROSS

Aldosterone **L**ethal effects **B**lockade in **A**cute myocardial infarction **T**reated with or without **R**eperfusion to improve **O**utcome and **S**urvival at **S**ix months follow-up

F. Beygui, G. Cayla, V. Roule, F. Roubille, N. Delarche, J. Silvain, E. Van Belle, L. Belle, M. Galinier, P. Motreff, L. Cornillet, JP Collet, A. Furber, P. Goldstein, P. Ecollan, D. Legallois, A. Lebon, H. Rousseau, J. Machecourt, F. Zannad, E. Vicaut, G. Montalescot

on behalf of the ALBATROSS investigators

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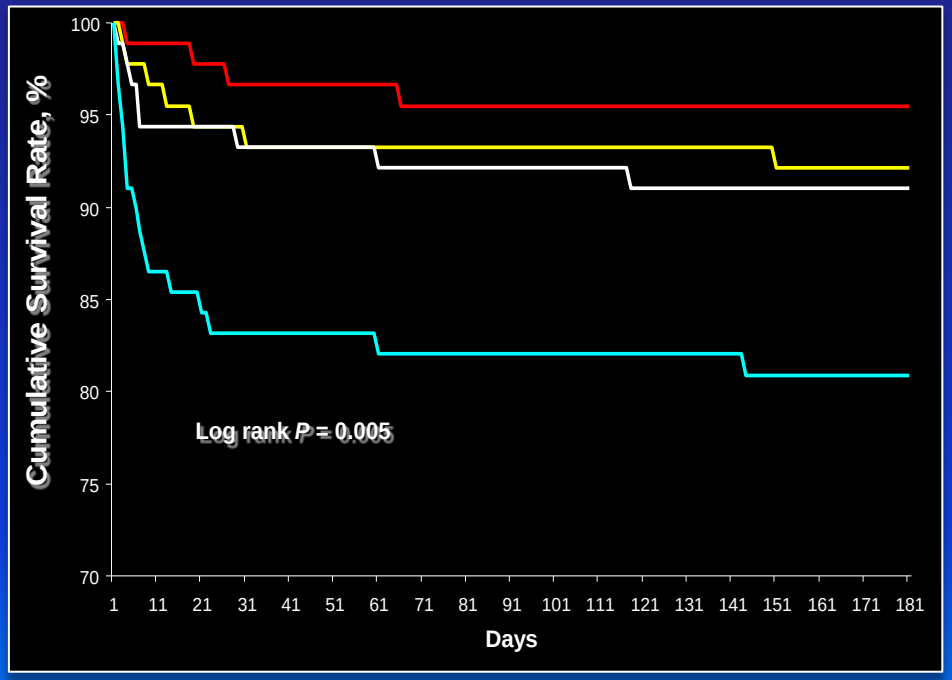
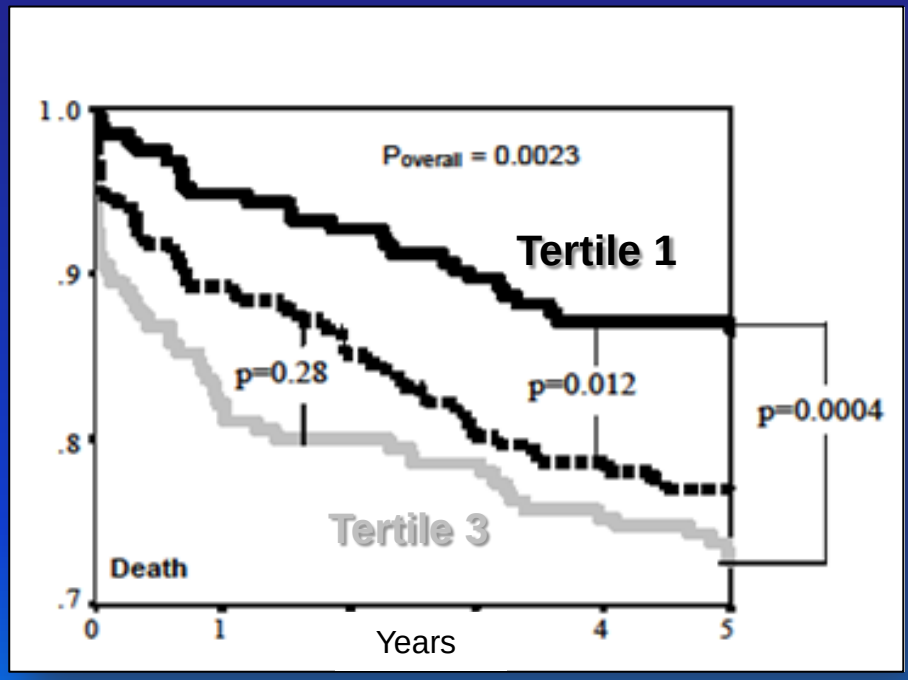
Aldosterone levels and death in AMI

Death according to quartiles of aldosterone in STEMI



Beygui F, et al. *Circulation* 2006; 114:2604-10

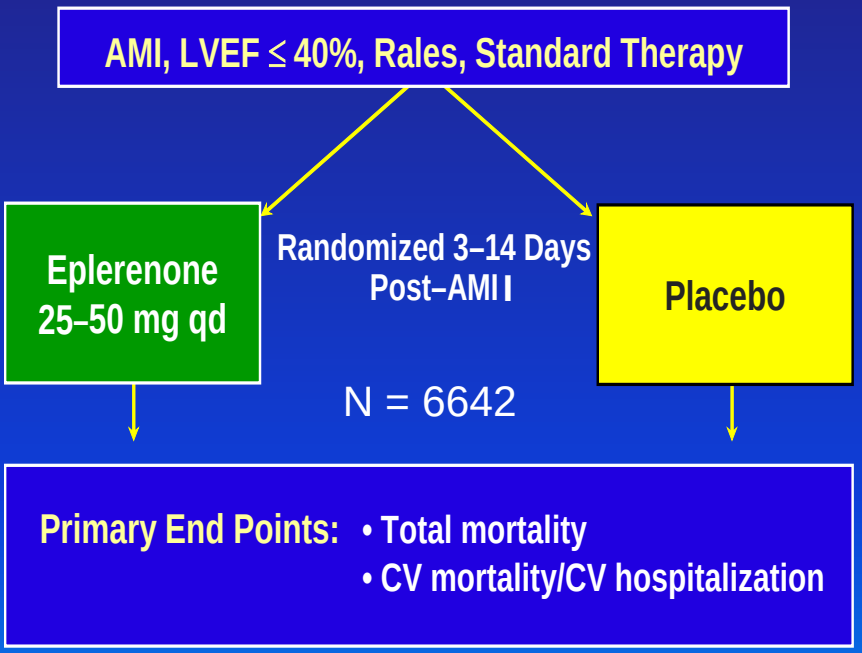
Death according to tertiles of aldosterone in MI



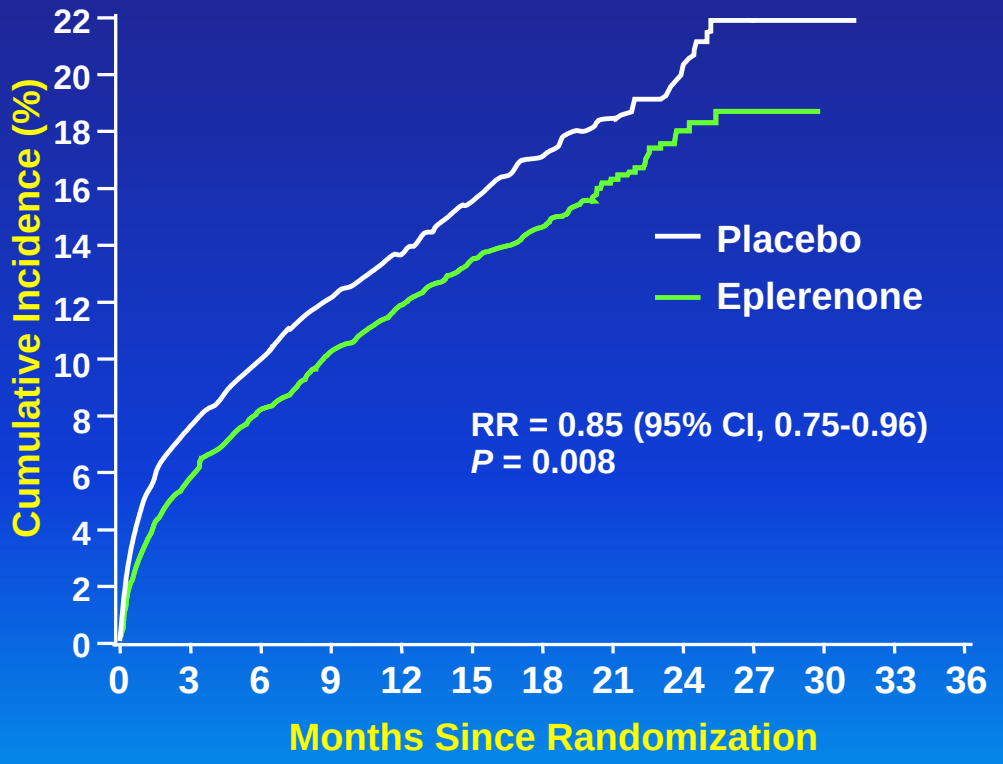
Palmer B, et al. *Eur Heart J*. 2008; 29:2489-96

EPHESUS : Post-MI heart failure

Design



Mortality



Pitt B, et al. *New Engl J Med.* 2003; 348:1309-21.

ALBATROSS study design

AMI (ST+ or ST-) in the first 72hrs

Aldosterone blockade

iv K^+ canrenoate*

* Soludactone 200mg

then

spironolactone**

** Aldactone 25mg od

Randomized
Open label

N=1600

control

1˚ End Point: death, resuscitated cardiac death, VF/VT, indication for defibrillator, heart failure
up to 6-month FU

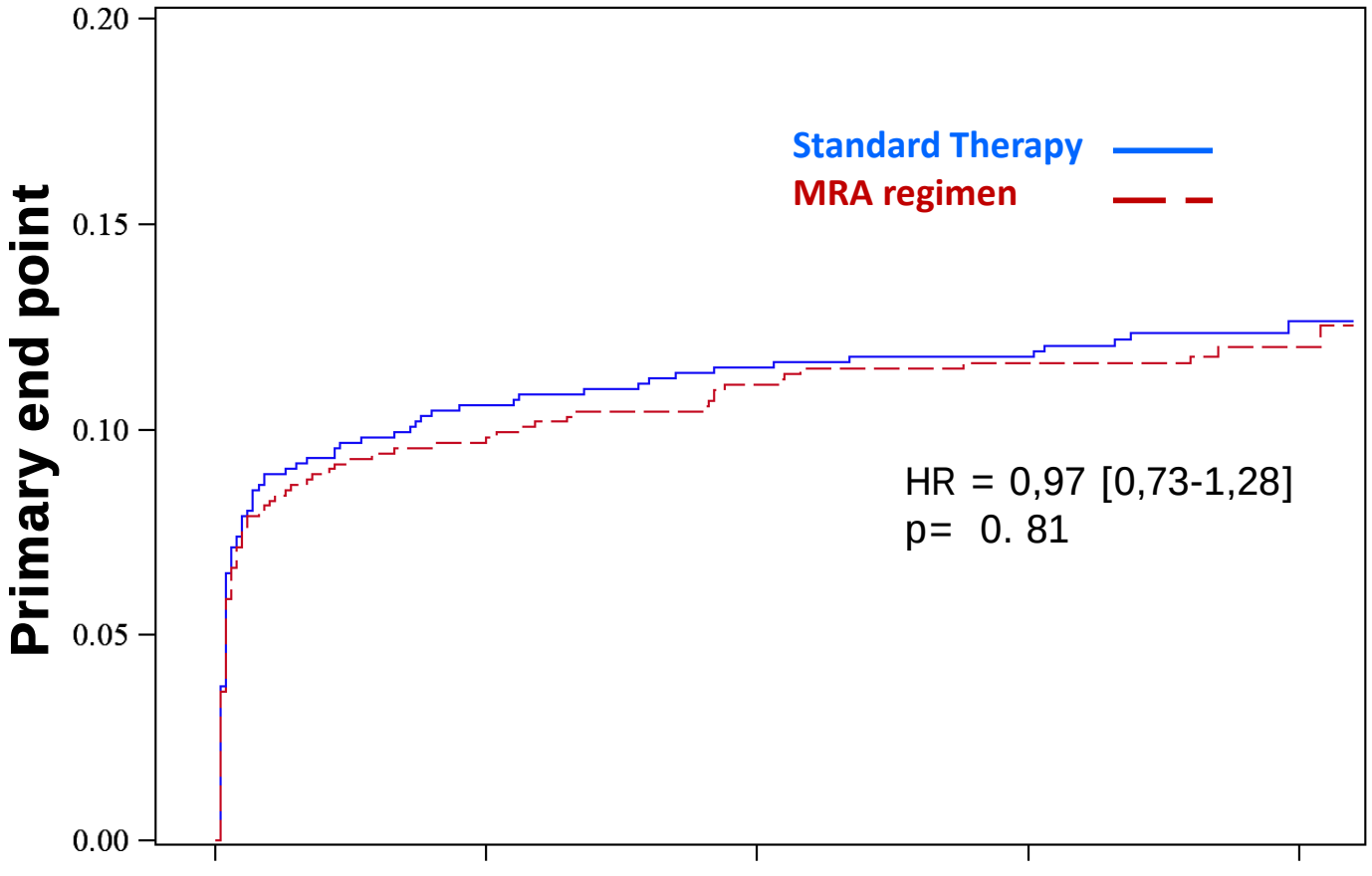
clinicaltrials.gov registration number NCT 01059136
ALBATROSS study protocol - Beygui et al. Am Heart J 2010

Baseline characteristics

	Standard treatment (N=801)	MRA regimen (N=802)
Age (median)	58	58
Current smoking (%)	52	47
Diabetes (%)	16	16
Hypertension (%)	44	42
Dyslipidemia (%)	46	47
Prior MI (%)	9	8
Prior HF (%)	1	1
STEMI (n)	617	612
NSTEMI (n)	183	186
Killip I (%)	91	93
PCI (%)	81	82
LV ejection fraction (median in %)	50	50

Primary End Point

Death, resuscitated death, VF/VT, indication for ICD *or* heart failure



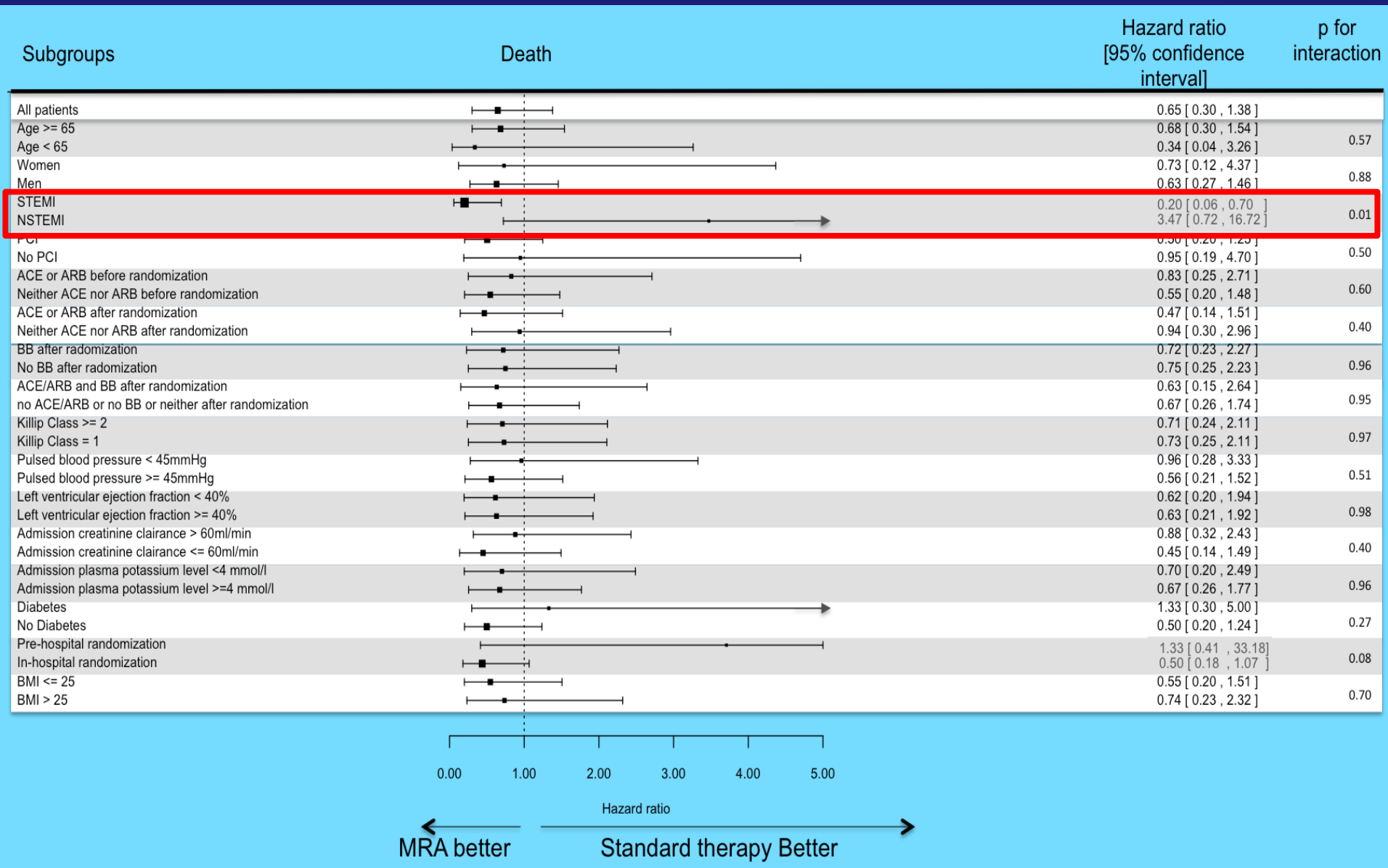
N at risks					
Standard Therapy	801	687	669	645	273
MRA Regimen	802	705	683	660	183

MRA: Mineralocorticoid Receptor Antagonist; VF: Ventricular Fibrillation; VT: Ventricular Tachycardia; ICD: Implantable Cardioverter Defibrillator

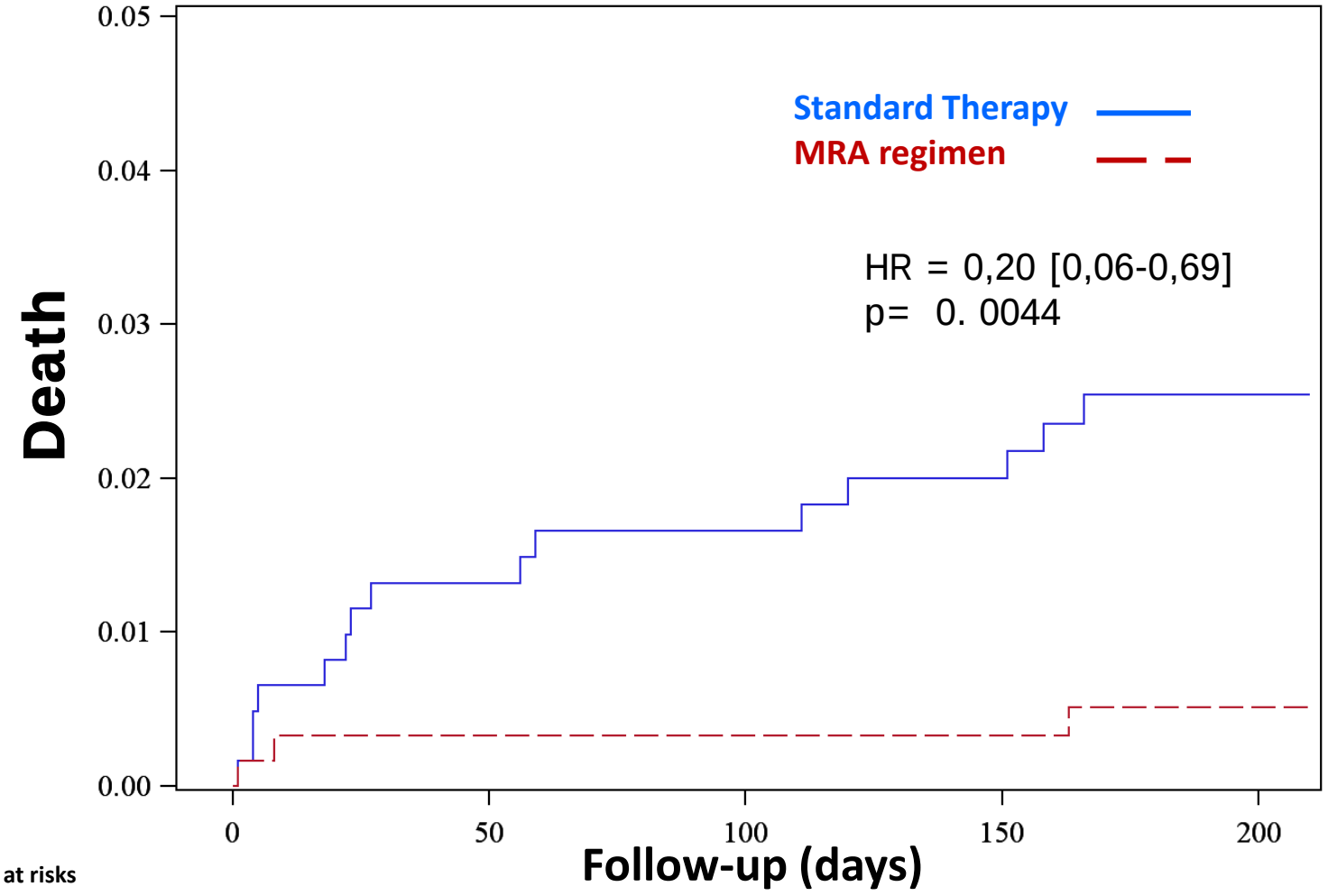
Secondary End Points

	Standard therapy (n=801)	MRA regimen (n=802)	P value
Significant ventricular arrhythmia (%)	6	5.6	0.75
New or worsening heart failure (%)	5.6	5.9	0.85
Recurrent myocardial infarction (%)	1	0.6	0.39
Death or resuscitated cardiac arrest (%)	2.4	1.6	0.28
Hyperkalemia > 5.5mmol.L^{-1} (%)	**0.2**	**3**	**<0.0001**

Death in pre-specified subgroups



Death in STEMI patients (n=1229)



N at risks					
Standard Therapy	617	587	579	556	236
MRA Regimen	612	595	587	571	162

1. Despite a strong pre-clinical rationale and favorable clinical data from registries and small randomized studies, the ALBATROSS trial failed to show a benefit of aldosterone blockade initiated early in MI, when heart failure is in general not present

2. The ALBATROSS study highlights the relative safety of the aldosterone blockade used in the study

3. Our finding of a mortality reduction associated with early aldosterone blockade in STEMI patients needs confirmation in future studies specifically dedicated to these patients

4. Meanwhile, the results of the ALBATROSS study do not warrant the extension of aldosterone blockade to MI patients without heart failure.