

The background image shows a large, modern hospital building with multiple stories and many windows. The building has a light-colored facade. On the upper part of the building, there are signs in Greek. One sign says 'μαιευτικό' (Gynecology) and another says 'παιδιατρικό' (Pediatrics). The building is surrounded by greenery, including bushes and a lawn in the foreground. A red-bordered box is overlaid on the image, containing the main title and the speaker's name.

# ***Off vs. on pump surgery***

***in view of the recent trials***

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# guidelines for the treatment of CAD

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- Current guidance in the UK (NICE guidelines) and the US recommends the use of CABG in the treatment of anatomically complex triple vessel disease.
- The UK also prefers CABG for the treatment of coronary artery disease in those  $>65$  and those with diabetes, whilst the US recommends a heart team approach.

# attraction of off pump CABG

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1. reduction in the inflammatory response
  2. minimal aortic manipulation
  3. avoidance of aortic cannulation
- (2) - (3) may reduce the risk of stroke

# attraction of on pump CABG

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many surgeons would argue that **cardioplegic arrest** provides the best conditions for optimal revascularisation

# Cochrane review published in 2012



- all-cause mortality was significantly increased in the off pump group
- no differences in the incidence of myocardial infarction, stroke, renal insufficiency and coronary re-intervention

since 2012 more RCTs and meta-analysis

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1.Kowalewski *et al.* showed that there was a significant 28% reduction in the incidence of stroke in the off pump group, which was related to patient risk profile

J Thorac Cardiovasc Surg 2016;151:60-77

2.Deppe *et al.* also found a reduced incidence of stroke in the off pump group, whilst this group also had an increased need for revascularisation

Eur J Cardiothorac Surg 2016;49:1031-41

3.Dieberg *et al.* reported a P value of 0.05 for the stroke comparison and only found a significant difference in the incidence of atrial fibrillation

Int J Cardiol 2016;223:201-11

*Two limitations that affect each of these studies are the small size of many of the included RCTs and a concentration on short term (30 days) outcomes*

## four largest trials

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- **CORONARY** (n=2,375 off vs. 2,377 on) 2006 - 2011, 4752 patients were enrolled at 79 hospitals in 19 countries on four continents follow-up data 98.8% complete
- **DOORS** (n=450 off vs. 450 on) (900 patients from Denmark)
- **GOPCABE** (n=1,271 off vs. 1,268 on) (2539 patients from Germany)
- **ROOBY** (n=1,104 off vs. 1,099) from the Veterans Affairs medical system

# 30 day results

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- None of these studies showed a significant difference in the occurrence of death or stroke at or within 30 days of surgery
- The same was true for the incidence of myocardial infarction in CORONARY, DOORS and GOPCABE
- A significantly higher early need for repeat revascularisation in the off pump group was measured in CORONARY and GOPCABE
- ROOBY measured no difference in the rate of repeat revascularization

*In short none of these major studies showed a difference in hard clinical outcomes between the off and on pump groups at 30 days.*

# completeness of revascularization

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In each of the four largest trials a significantly greater number of grafts were placed in the on pump group, although the difference in the number of grafts placed in each group was only 0.1–0.2 grafts

The CORONARY trial also reported the completeness of revascularisation where 278 patients were incompletely revascularised in the off pump group compared to 236 in the on pump group ( $P=0.05$ )

In spite of this mortality in the CORONARY study was not significantly different between the off and on pump groups at 30 days and 1 year

# mid-term (6 months to one year) results

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*based on reported outcomes from*

*1)CORONARY,*

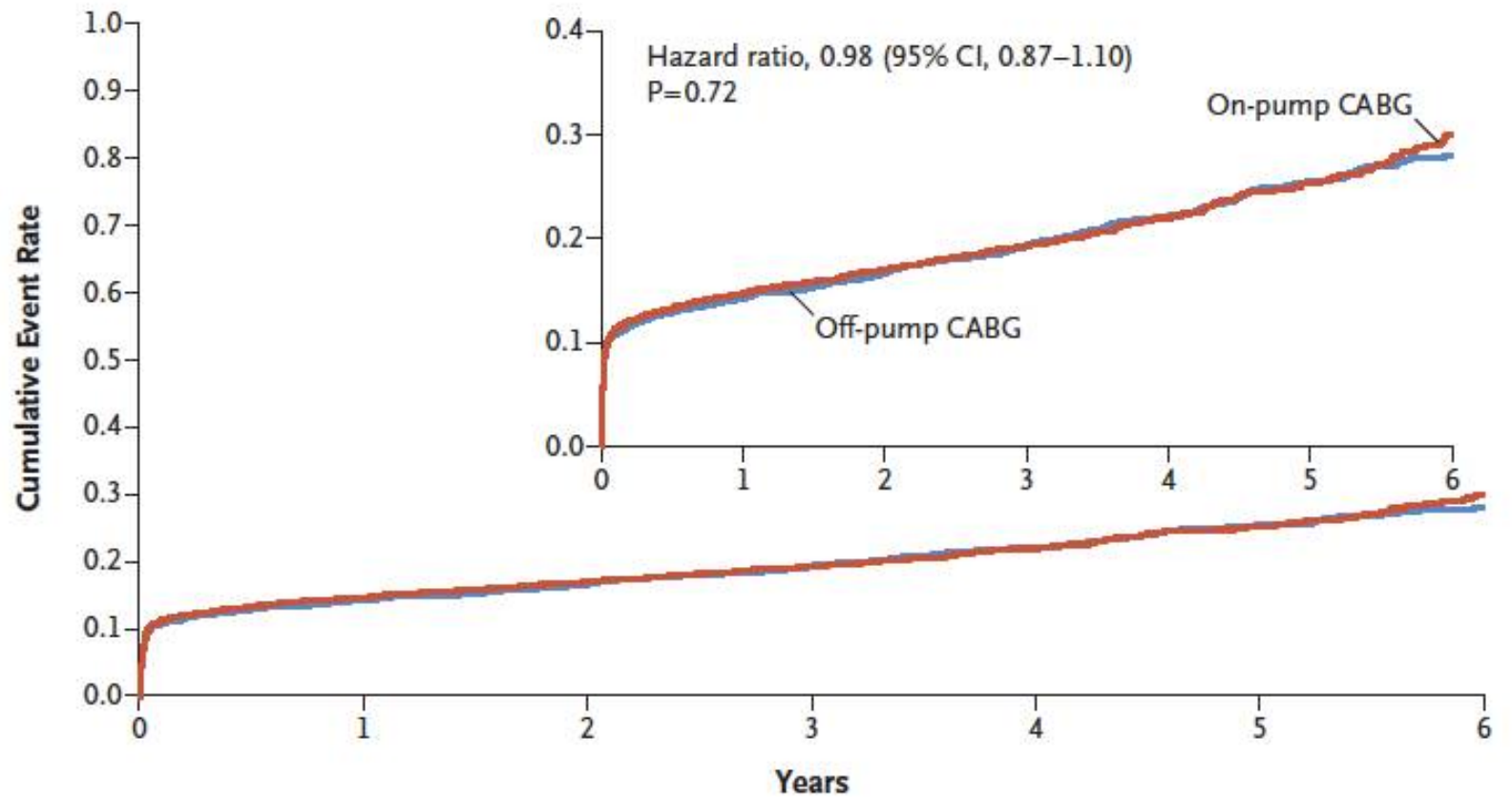
*2)DOORS and*

*3)GOPCABE :*

*no difference in the incidence of mortality, myocardial infarction and stroke between the two groups; however, there was a significantly higher rate of revascularisation in the off pump group*

# 5-year outcomes of the CORONARY trial

*The NEW ENGLAND JOURNAL of MEDICINE*



## No. at Risk

On-pump CABG	2377	2048	1989	1937	1746	973	433
Off-pump CABG	2375	2057	1996	1937	1744	969	440

**Figure 1. Kaplan–Meier Curves for the Second Coprimary Outcome at 5 Years.**

The second coprimary outcome was a composite of death, nonfatal stroke, nonfatal myocardial infarction, nonfatal new renal failure requiring dialysis, or repeat coronary revascularization (percutaneous coronary intervention or coronary-artery bypass grafting [CABG]). The inset shows the same data on an enlarged y axis.

# 5-year outcomes of the CORONARY trial

**Table 1. Outcomes at 5 Years.**

Outcome	Off-Pump Group (N= 2375)	On-Pump Group (N= 2377)	Hazard Ratio (95% CI)	P Value
Second coprimary outcome — no. (%) <sup>*</sup>	548 (23.1)	560 (23.6)	0.98 (0.87–1.10)	0.72
Death	346 (14.6)	322 (13.5)	1.08 (0.93–1.26)	0.30
Myocardial infarction	178 (7.5)	194 (8.2)	0.92 (0.75–1.13)	0.41
Stroke	55 (2.3)	66 (2.8)	0.83 (0.58–1.19)	0.32
New renal failure requiring dialysis	40 (1.7)	45 (1.9)	0.89 (0.58–1.37)	0.60
Repeat revascularization <sup>†</sup>	66 (2.8)	55 (2.3)	1.21 (0.85–1.73)	0.29
PCI	59 (2.5)	52 (2.2)	1.15 (0.79–1.66)	0.48
CABG	9 (0.4)	4 (0.2)	2.27 (0.70–7.38)	0.17
Nonprespecified outcomes — no. (%)				
Cardiovascular death <sup>‡</sup>	237 (10.0)	230 (9.7)	1.04 (0.87–1.24)	0.69
Repeat coronary angiography	125 (5.3)	114 (4.8)	1.11 (0.86–1.43)	0.43
Recurrent angina	41 (1.7)	39 (1.6)	1.05 (0.68–1.63)	0.81
Primary outcome in per-protocol population — no./total no. (%) <sup>§</sup>	487/2148 (22.7)	499/2182 (22.9)	0.99 (0.87–1.12)	0.86

<sup>\*</sup> The second coprimary outcome was a composite of death, nonfatal stroke, nonfatal myocardial infarction, new renal failure requiring dialysis, and repeat revascularization (percutaneous coronary intervention [PCI] or coronary-artery bypass grafting [CABG]).

<sup>†</sup> Some patients had CABG and a PCI.

<sup>‡</sup> All deaths in the first 30 days were considered to be cardiovascular deaths.

<sup>§</sup> The per-protocol population included patients who underwent the randomly assigned procedure (i.e., without crossing

# 5-year outcomes of the CORONARY trial

**Table 2. Mean Costs per Patient.**

Type of Cost	Off-Pump Group	On-Pump Group	Between-Group Difference
	mean cost in U.S. dollars*		
Initial hospitalization			
Total cost (95% CI)	9,959 (9,925 to 10,612)	9,914 (9,581 to 10,329)	45 (−596 to 685)
Cost of procedures	1,978	1,934	44
Cost of ICU stay	5,000	5,060	−60
Cost of ward stay	2,981	2,920	61
Discharge to year 1 follow-up			
Total cost (95% CI)	1,322 (1,153 to 1,554)	1,206 (1,067 to 1,398)	115 (−143 to 374)
Cost of procedures	110	81	29
Cost of events	482	417	65
Cost of medication	730	708	22
Year 1 follow-up to end of trial			
Total cost (95% CI)	3,826 (3,563 to 4,151)	3,871 (3,591 to 4,198)	−45 (−463 to 373)
Cost of procedures	209	252	−43
Cost of events	886	937	−51
Cost of medication	2,731	2,682	49
Total cost (95% CI)	15,107 (14,554 to 15,844)	14,992 (14,504 to 15,530)	115 (−697 to 927)
Total discounted cost (95% CI)	13,286 (12,805 to 13,897)	13,190 (12,764 to 13,660)	96 (−607 to 799)

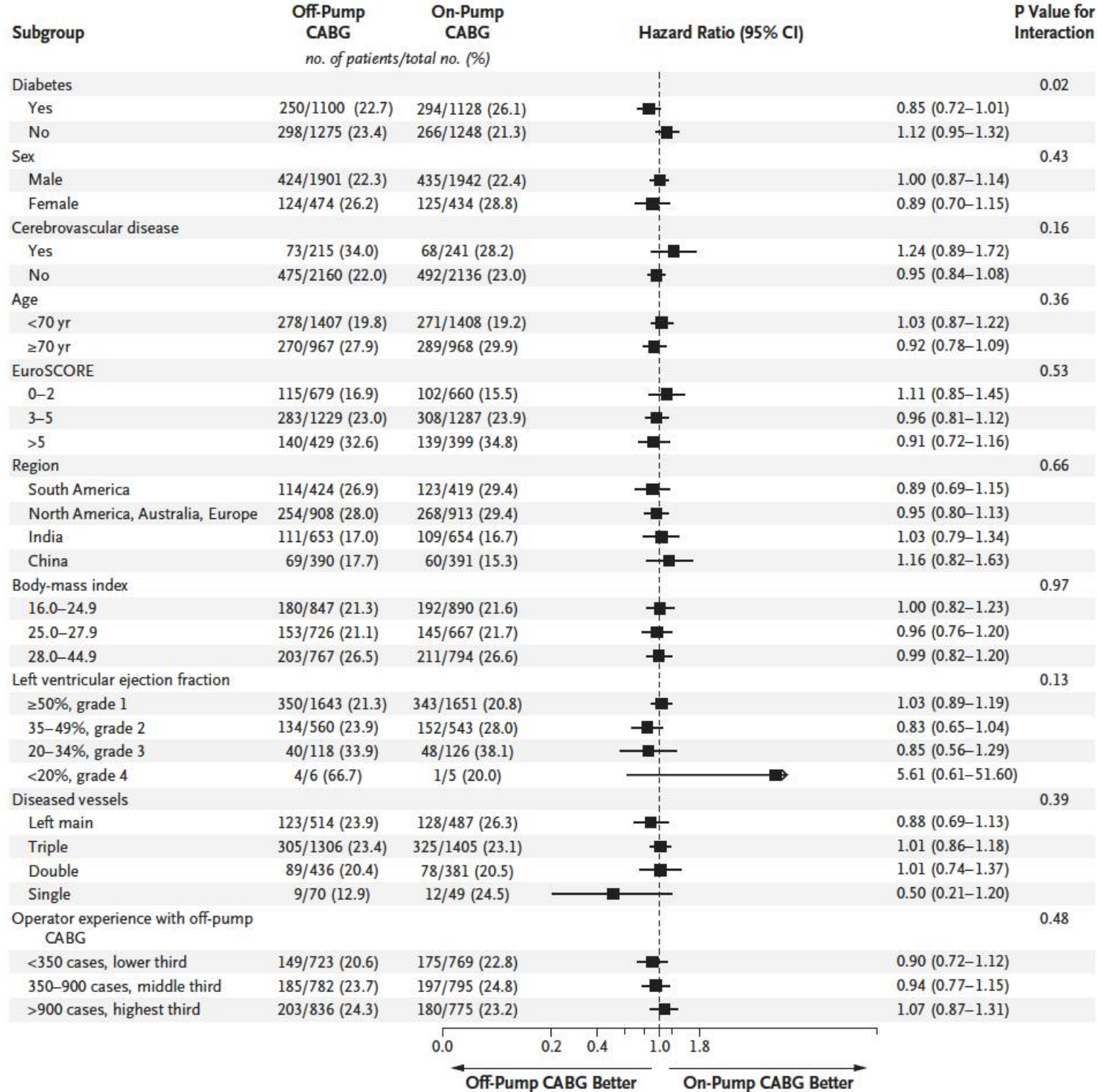
# 5-year outcomes of the CORONARY trial

**Table 3. Quality-of-Life Results.\***

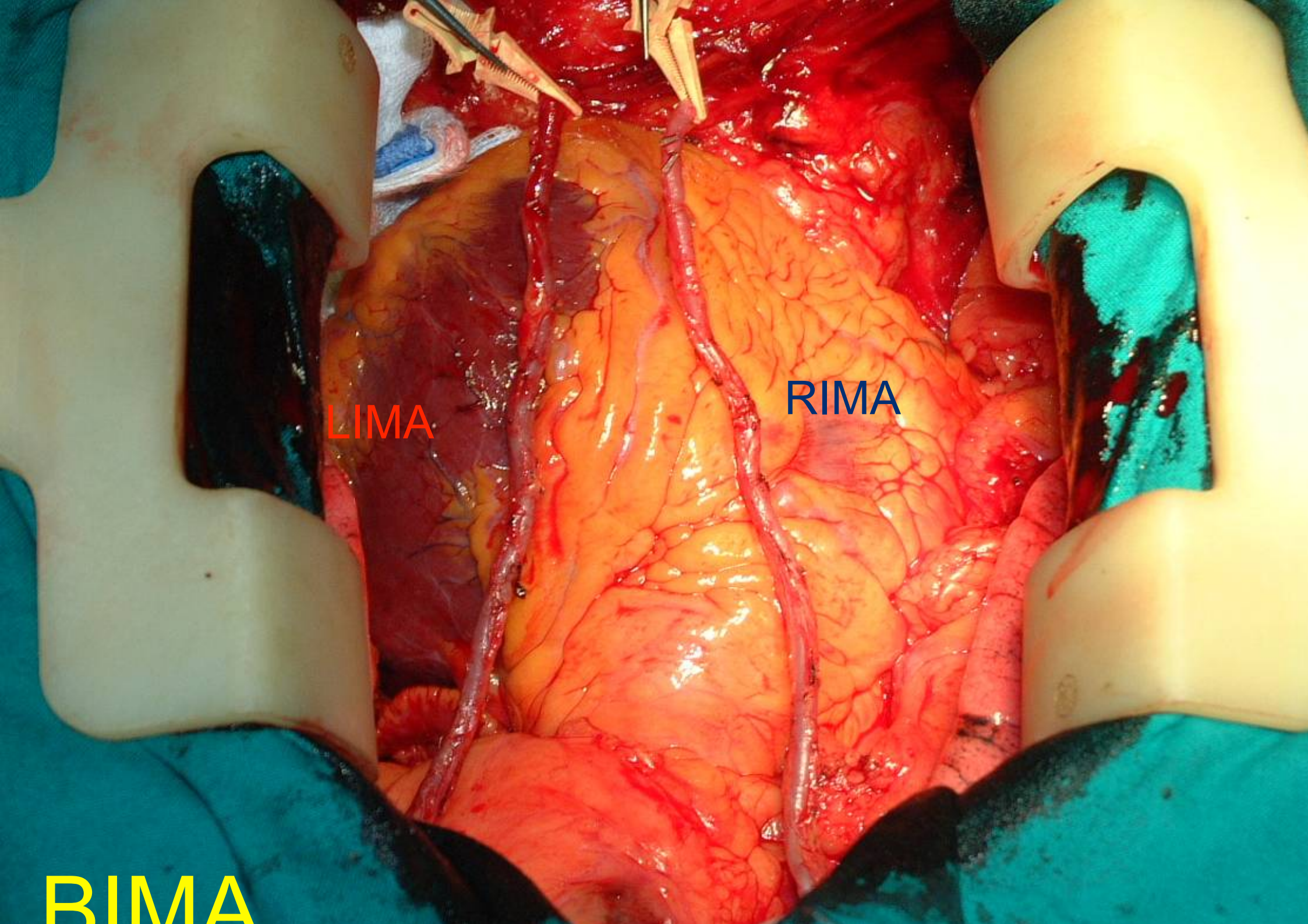
Measure	Off-Pump Group		On-Pump Group		P Value
	No. of Patients	Score	No. of Patients	Score	
EQ-5D†					
Baseline	1424	0.77±0.22	1421	0.77±0.22	0.97
Change from baseline					
To discharge	1265	−0.03±0.28	1251	−0.03±0.26	0.75
To 30 days	1154	0.07±0.26	1161	0.08±0.25	0.25
To 1 yr	1045	0.13±0.25	1055	0.15±0.24	0.26
To end of trial	1059	0.12±0.25	1071	0.13±0.26	0.28
EQ-5D visual-analogue scale‡					
Baseline	1423	65.8±17.6	1422	66.6±17.8	0.24
Change from baseline					
To discharge	1264	1.8±18.2	1250	1.0±17.8	0.27
To 30 days	1154	8.5±17.6	1159	8.0±17.6	0.44
To 1 year	1044	11.3±17.9	1055	11.5±17.6	0.86
To end of trial	1055	10.4±20.4	1069	10.4±20.9	0.99

\* Plus-minus values are means ±SD. The number of patients at baseline is the number of patients who performed the baseline test. The number of patients at each subsequent time is the number of patients who performed the test both at baseline and at that specific time.

† The European Quality of Life–5 Dimensions questionnaire (EQ-5D) assesses five dimensions of quality of life. The total score ranges from 0 to 1, with higher scores indicating better quality-of-life status.



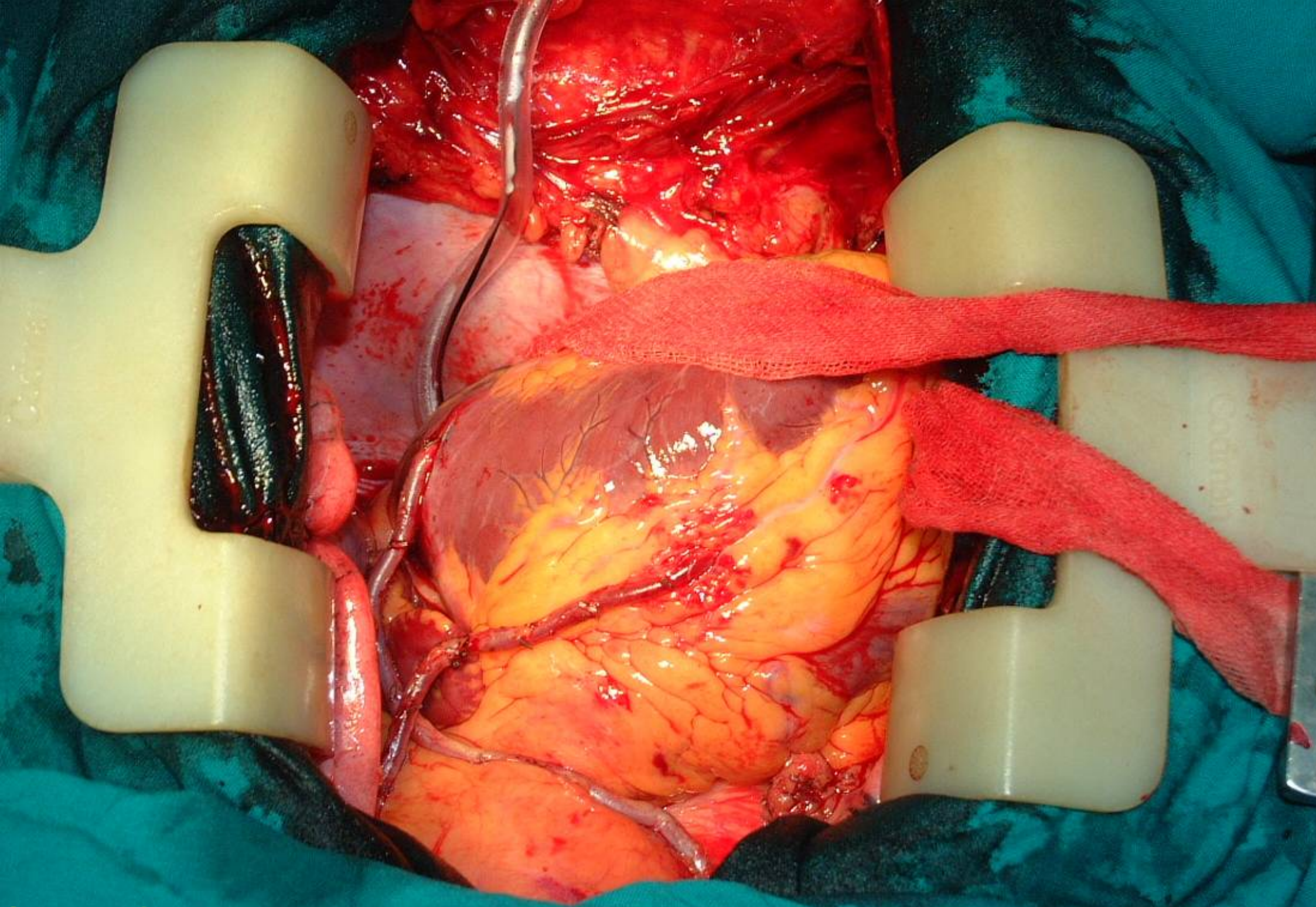
**Figure 2** Hazard Ratios for the Second Conprimary Outcome in Prespecified Subgroups



LIMA

RIMA

RIMA



ORCAD

ality  
control



# Conclusions:

At 5 years, no significant difference between the two groups in the rate of :

- death,
- nonfatal stroke,
- nonfatal myocardial infarction,
- nonfatal new renal failure requiring dialysis
- rate of subsequent revascularization procedures

no significant difference in **cost** or **quality of life**

the results indicate that *both procedures are equally effective and safe*

