

CORONARY: The Coronary Artery Bypass Grafting Surgery Off or On Pump Revascularization Study

Results at 1 Year

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on behalf of the CORONARY Investigators

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Background

- Benefits and risks of performing CABG surgery on beating heart (off pump) not clearly established.
- Meta-analyses of 59 trials involving 8961 pts
 - No differences in major CV outcomes except strokes
- ROOBY (1 Year)
 - Primary Outcome: Off-pump is worse ($p=0.04$)
 - CV Deaths: Off-pump is worse ($p=0.03$)

CORONARY Trial Organization

- 79 centers in 19 countries
- 4,752 patients recruited between (November 2006 October 2011)
- Designed, coordinated, managed and data analysed and reported by the Population Health Research Institute, Hamilton Health Sciences and McMaster University in Hamilton, Canada
- The data was monitored by independent DSMB
- Funded by Canadian Institutes of Health Research

Inclusion/Exclusion Criteria

- **Inclusion Criteria**
 - Isolated CABG with median sternotomy
 - One of the following:
 1. Peripheral vascular disease
 2. Cerebrovascular disease
 3. Renal Insufficiency
 4. Age ≥ 70 years
 5. Age 60 -69 with at least one risk factor (diabetes, urgent revascularization, smoker, LVEF $\leq 35\%$)
 6. Age 55 -59 with at least two of the above risk factors
- **Exclusions**
 - Additional cardiac procedure planned
 - Contraindications to off-pump or on-pump CABG
 - Emergency or re-do CABG

Qualifications of Surgeons

- Surgical expertise-based randomization
 - > 2 years of experience as staff cardiac surgeon
and
 - > 100 cases of one or both techniques
 - Trainees were not allowed to be primary operators

Primary Outcomes

- **1st Co-Primary Outcome**

Composite of total mortality, stroke, non fatal myocardial infarction, new renal failure at 30 days post randomization

results presented ACC 2012



results at 1 year

- **2nd Co-Primary Outcome**

Composite of above outcomes plus repeat coronary revascularization over 5 yrs of follow-up (expected 2016)

Baseline Characteristics

	OFF-PUMP (n = 2375)	ON-PUMP (n = 2377)
Mean Age (years)	67.6	67.5
Males (%)	80.0	81.7
Prior MI	33.8	35.2
Previous Stroke	6.7	7.8
Peripheral Arterial Disease	8.0	8.2
Congestive Heart Failure	5.9	6.6
Urgent Surgery	39.5	38.1
Euroscore		
0 – 2	28.6	27.8
3 – 5	51.7	54.2
> 5	18.1	16.8

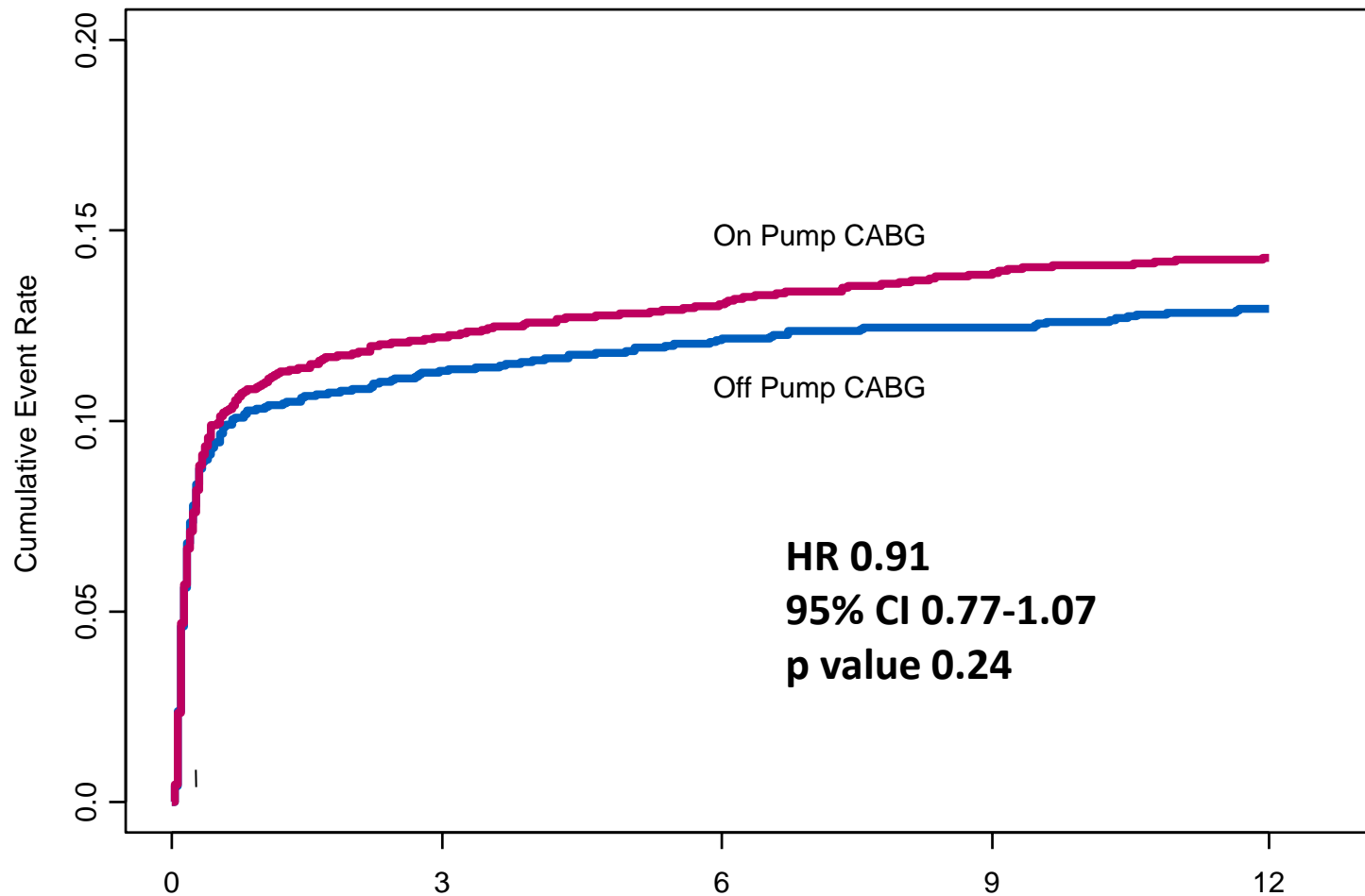
Baseline Disease – Pre-op Angiogram

	OFF-PUMP (n = 2375) %	ON-PUMP (n = 2377) %
Left Main	22.1	20.9
Triple Vessel	56.1	60.4
Double Vessel	18.7	16.4
Single Vessel	3.0	2.1

1st Co-Primary Outcome (1 Year)

	Off Pump %	On Pump %	Hazard Ratio	95% CI	p value
Primary Outcome Death, Stroke, MI, Renal Failure	12.1	13.3	0.91	0.77-1.07	0.24
Components					
Death	5.1	5.0	1.03	0.80-1.32	
Stroke	1.5	1.7	0.90	0.57-1.41	
Non Fatal MI	6.8	7.5	0.90	0.73-1.12	
New Renal Failure	1.3	1.3	0.97	0.59-1.60	

Death/MI/Stroke/New Renal Failure at 1 Year



Other Outcomes at 1 year

	Off Pump %	On Pump %	Hazard Ratio	95% CI	p value
Cardiovascular Mortality	4.2	4.0	1.03	0.78-1.37	0.83
Angina	1.0	0.9	1.05	0.58-1.88	0.87
PCI	1.1	0.8	1.43	0.79-2.57	0.23
Re-do CABG	0.3	0.04	7.00	0.86-57.0	0.07
PCI/Re-do CABG	1.4	0.8	1.66	0.95-2.89	0.07
Primary Outcome per Protocol	11.5	13.2	0.86	0.73-1.02	0.08

Primary Outcome between 31 days and 1 Year

	Off Pump %	On Pump %	Hazard Ratio	95% CI	p value
Primary Outcome Death/MI/Stroke/Renal Failure	2.6	3.2	0.79	0.55-1.13	0.19
Components					
Death	2.1	2.3	0.87	0.58-1.31	
Stroke	0.5	0.6	0.83	0.36-1.92	
Non Fatal MI	0.2	0.4	0.50	0.15-1.65	
New Renal Failure	0.1	0.2	0.50	0.09—2.71	

Other Outcomes between 31 days and 1 Year

	Off Pump %	On Pump %	Hazard Ratio	95% CI	p value
Cardiovascular Mortality	1.5	1.5	1.06	0.65-1.73	0.82
Angina	0.8	0.7	1.13	0.56-2.26	0.74
PCI	0.7	0.6	1.15	0.55-2.41	0.72
Re-do CABG	<0.1	0			0.99
PCI/Re-do CABG	0.7	0.6	1.22	0.59-2.54	0.59


















Quality of Life

Measure	Off-Pump CABG		On-Pump CABG		P Value
	<i>no. of patients</i>	<i>score</i>	<i>no. of patients</i>	<i>score</i>	
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 year	1024	0.13±0.24	1035	0.14±0.24	0.25
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	0.26
To 30 days	1154	8.5±17.6	1159	8.0±17.6	0.44
To 1 year	1023	11.3±18.1	1035	11.4±17.6	0.88

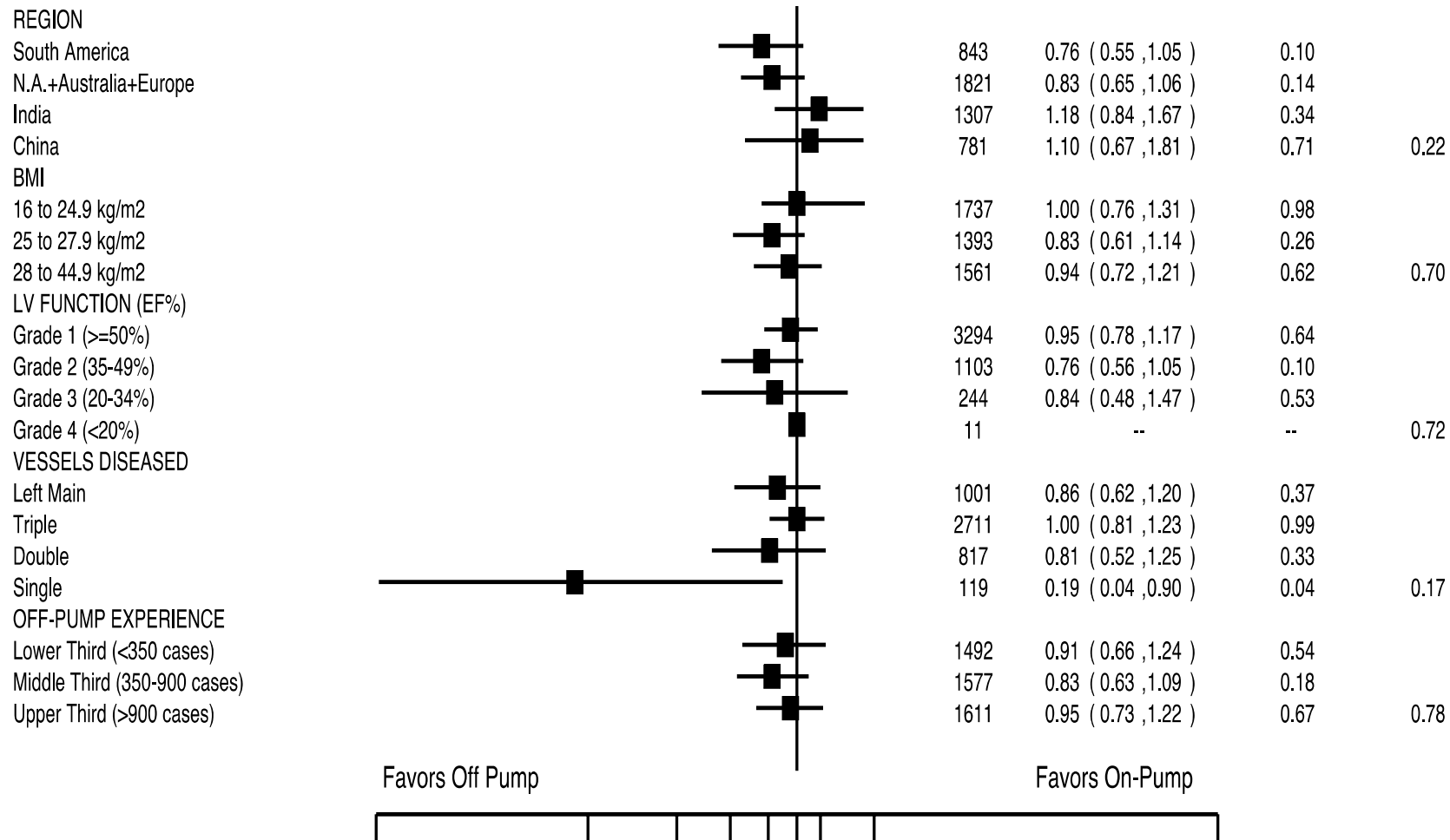
Neurocognitive Function

Measure	Off-Pump CABG		On-Pump CABG		P Value
	<i>no. of patients</i>	<i>score</i>	<i>no. of patients</i>	<i>score</i>	
Montreal Cognitive Assessment§					
Baseline	1053	23.2±4.4	1028	23.2±4.3	0.90
Change from baseline					
To discharge	896	0.2±2.9	881	0.1±2.9	0.22
To 30 days	797	1.0±3.1	784	0.8±3.1	0.26
To 1 year	645	0.4±4.0	628	0.3±4.0	0.51
Digit Symbol Substitution Test¶					
Baseline	989	33.0±17.8	986	31.9±18.0	0.15
Change from baseline					
To discharge	812	−1.6±11.4	797	−2.7±10.0	0.04
To 30 days	694	1.8±11.4	685	1.3±10.8	0.40
To 1 year	522	1.8±13.2	528	1.3±12.3	0.56
Trail Making Test Part B					
Baseline	721	158.0±88.1	711	163.7±89.5	0.22
Change from baseline					
To discharge	523	5.2±55.4	498	7.0±52.6	0.59
To 30 days	470	−10.9±58.1	487	−4.7±71.2	0.14
To 1 year	353	−6.8±64.0	340	−3.2±70.2	0.49

Subgroups (1)

		N	HR (95% CI)	P-value	Interaction
AGE					
<70 years		2815	0.97 (0.77 , 1.22)	0.77	0.46
>=70 years		1935	0.86 (0.69 , 1.07)	0.17	
SEX					
Males		3843	0.93 (0.78 , 1.12)	0.47	0.46
Females		908	0.81 (0.59 , 1.12)	0.21	
CEREBROVASCULAR DISEASE					
Yes		456	1.10 (0.69 , 1.75)	0.69	0.41
No		4296	0.89 (0.75 , 1.06)	0.18	
PERIPHERAL ARTERIAL DISEASE					
Yes		385	0.79 (0.48 , 1.28)	0.33	0.54
No		4366	0.93 (0.78 , 1.10)	0.37	
DIABETES					
Yes		2228	0.80 (0.63 , 1.01)	0.06	0.13
No		2523	1.02 (0.82 , 1.28)	0.84	
RENAL FAILURE (WITH DIALYSIS)					
Yes		66	0.63 (0.23 , 1.74)	0.37	0.51
No		4594	0.90 (0.76 , 1.06)	0.20	
CONGESTIVE HEART FAILURE					
Yes		296	0.66 (0.40 , 1.11)	0.12	0.20
No		4455	0.95 (0.80 , 1.12)	0.52	
EUROSCORE					
0 to 2		1339	1.18 (0.82 , 1.69)	0.37	0.27
3 to 5		2516	0.85 (0.68 , 1.06)	0.16	
> 5		828	0.83 (0.60 , 1.15)	0.27	

Subgroups (2)



Conclusions

- At 1 Year there was no difference between Off pump CABG and On pump CABG:
 - Primary Outcome
 - Individual components of the Primary Outcome
 - Revascularization procedures
 - Quality of Life
 - Neurocognitive functions

Implications

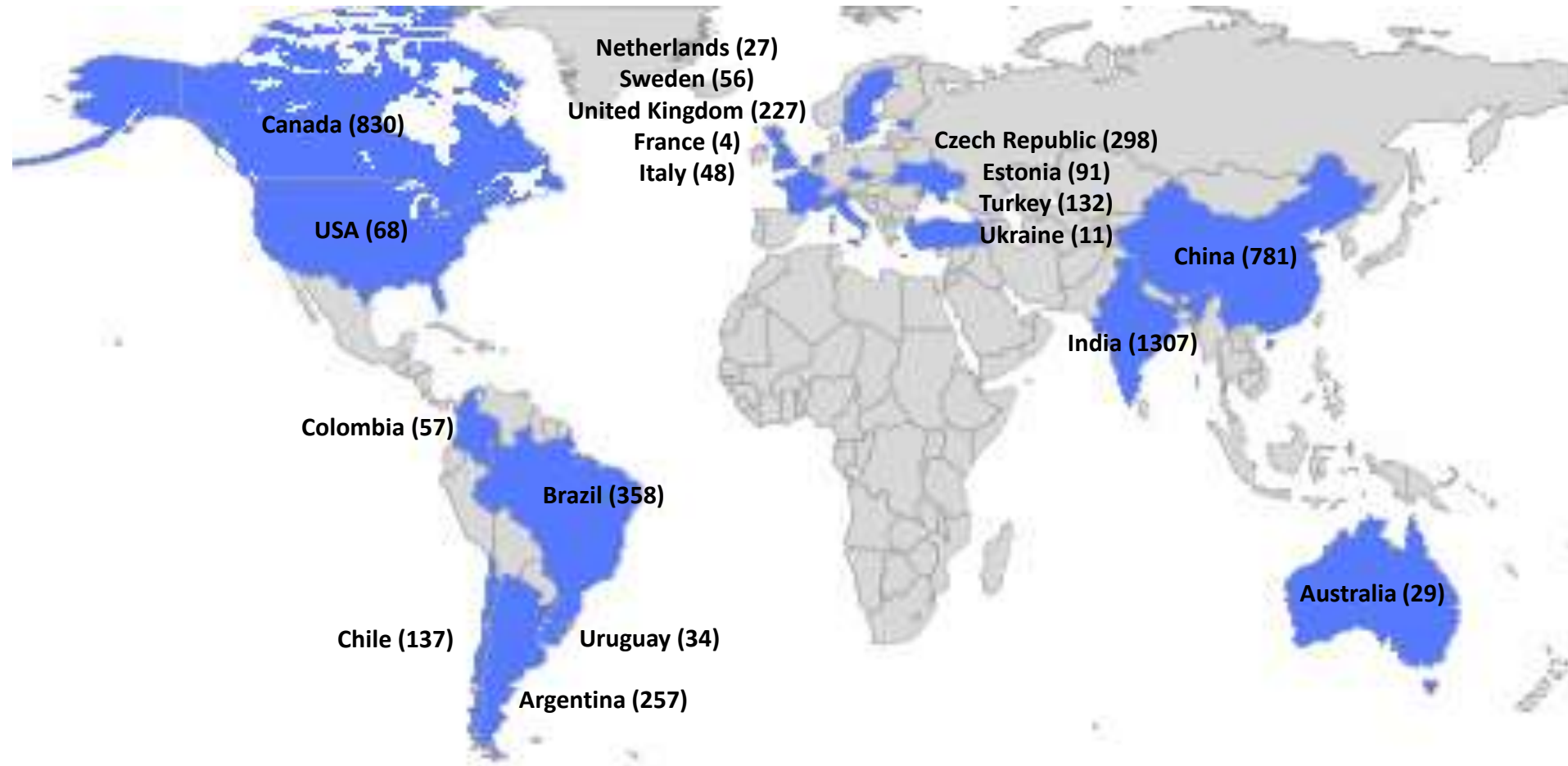
- In experienced hands, both procedures are reasonable options based on mid-term results

Steering Committees

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Final Recruitment by Country

4752 patients from 79 sites in 19 countries



ORIGINAL ARTICLE

Effects of Off-Pump and On-Pump Coronary-Artery Bypass Grafting at 1 Year

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