

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

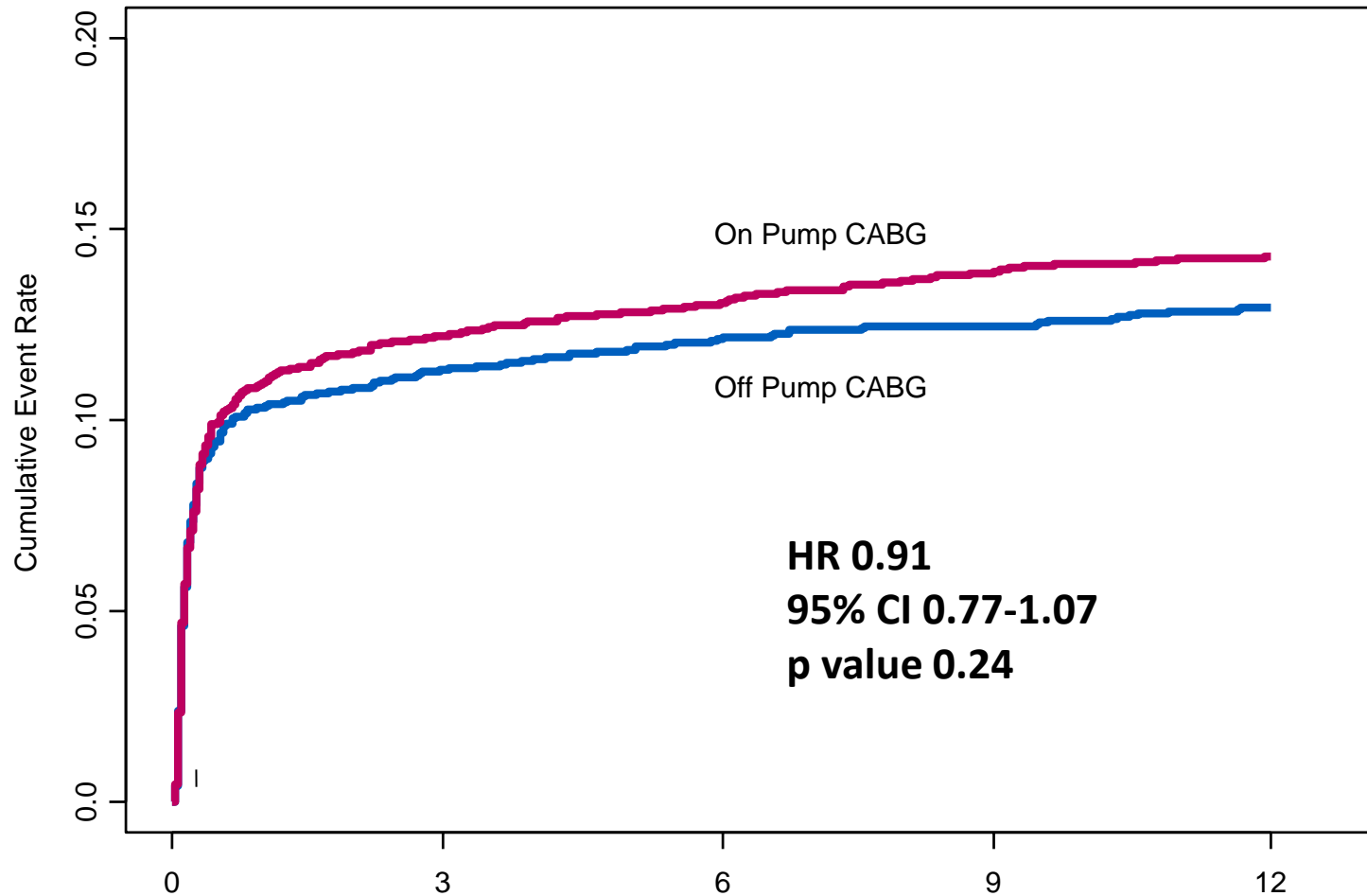
	OFF-PUMP (n = 2375) %	ON-PUMP (n = 2377) %
Left Main	22.1	20.9
Triple Vessel	56.1	60.4
Double Vessel	18.7	16.4
Single Vessel	3.0	2.1

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	

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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

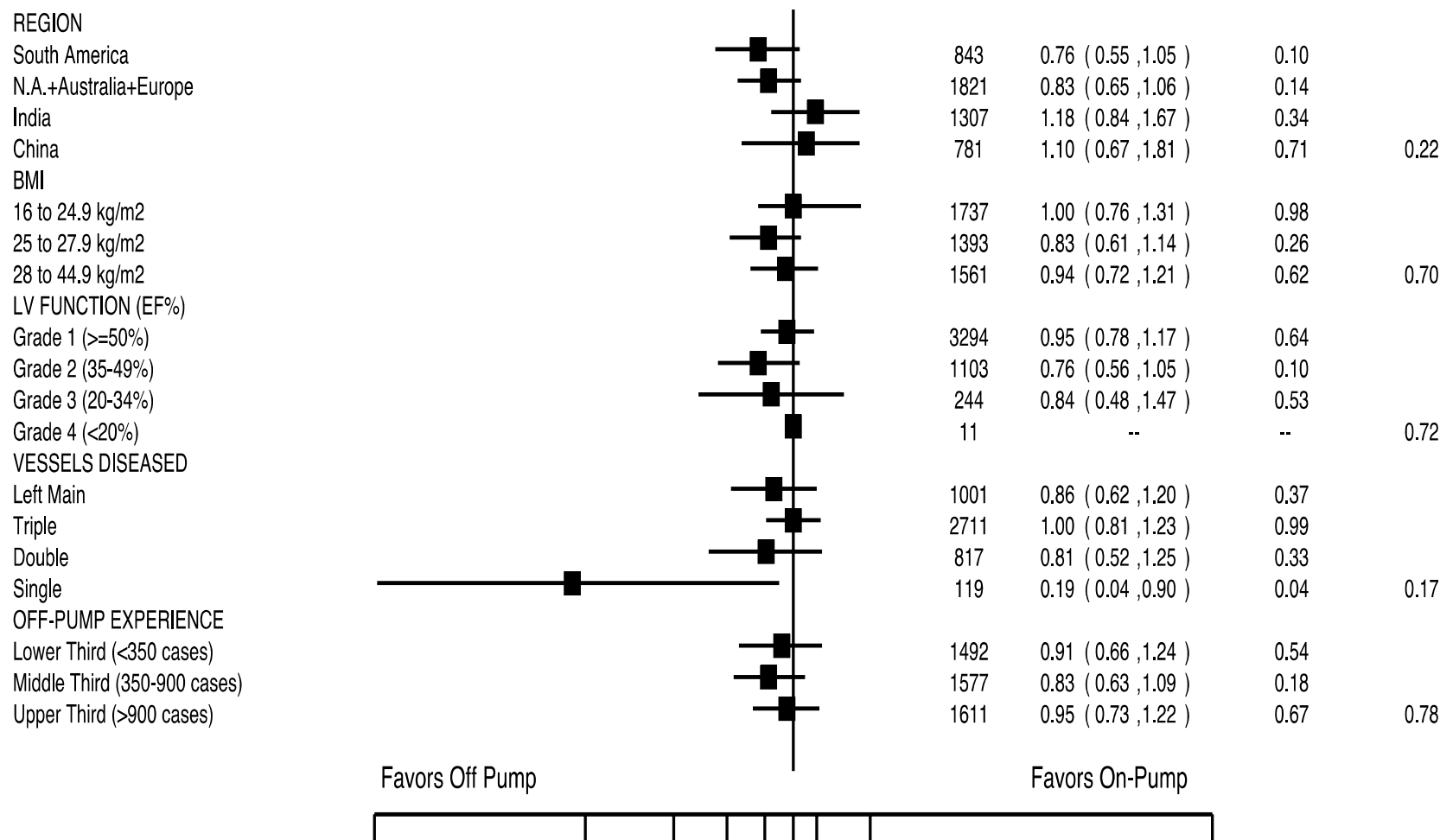
Neurocognitive Function

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

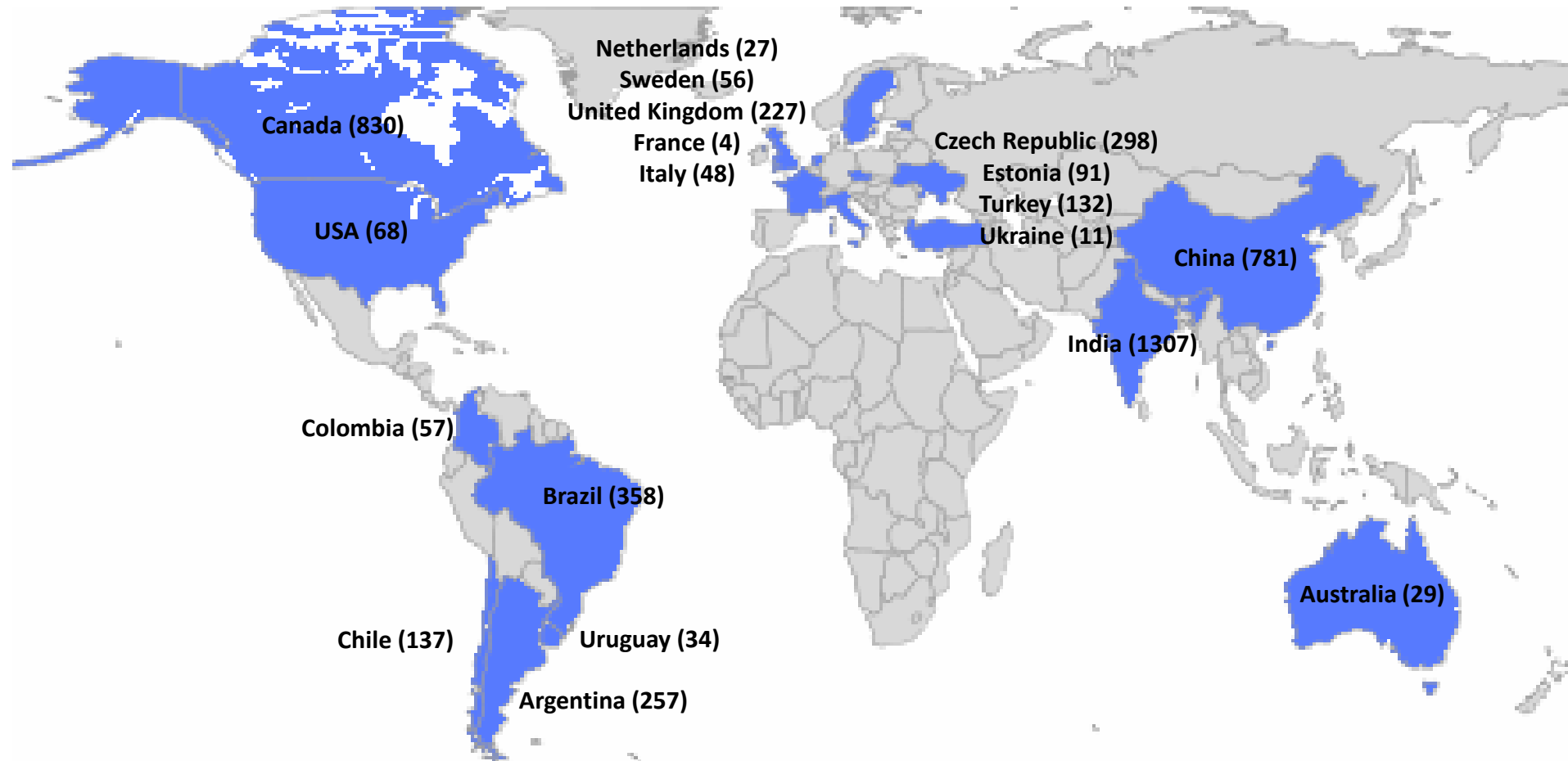
- In experienced hands, both procedures are reasonable options based on mid-term results

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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