

# **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**

**Disclosures: CORONARY was funded by a grant from the Canadian Institutes  
of Health Research (CIHR).**

# 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  $\geq 70$  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

- **1<sup>st</sup> 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**

- **2<sup>nd</sup> Co-Primary Outcome**

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

# Baseline Characteristics

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

# Baseline Disease – Pre-op Angiogram

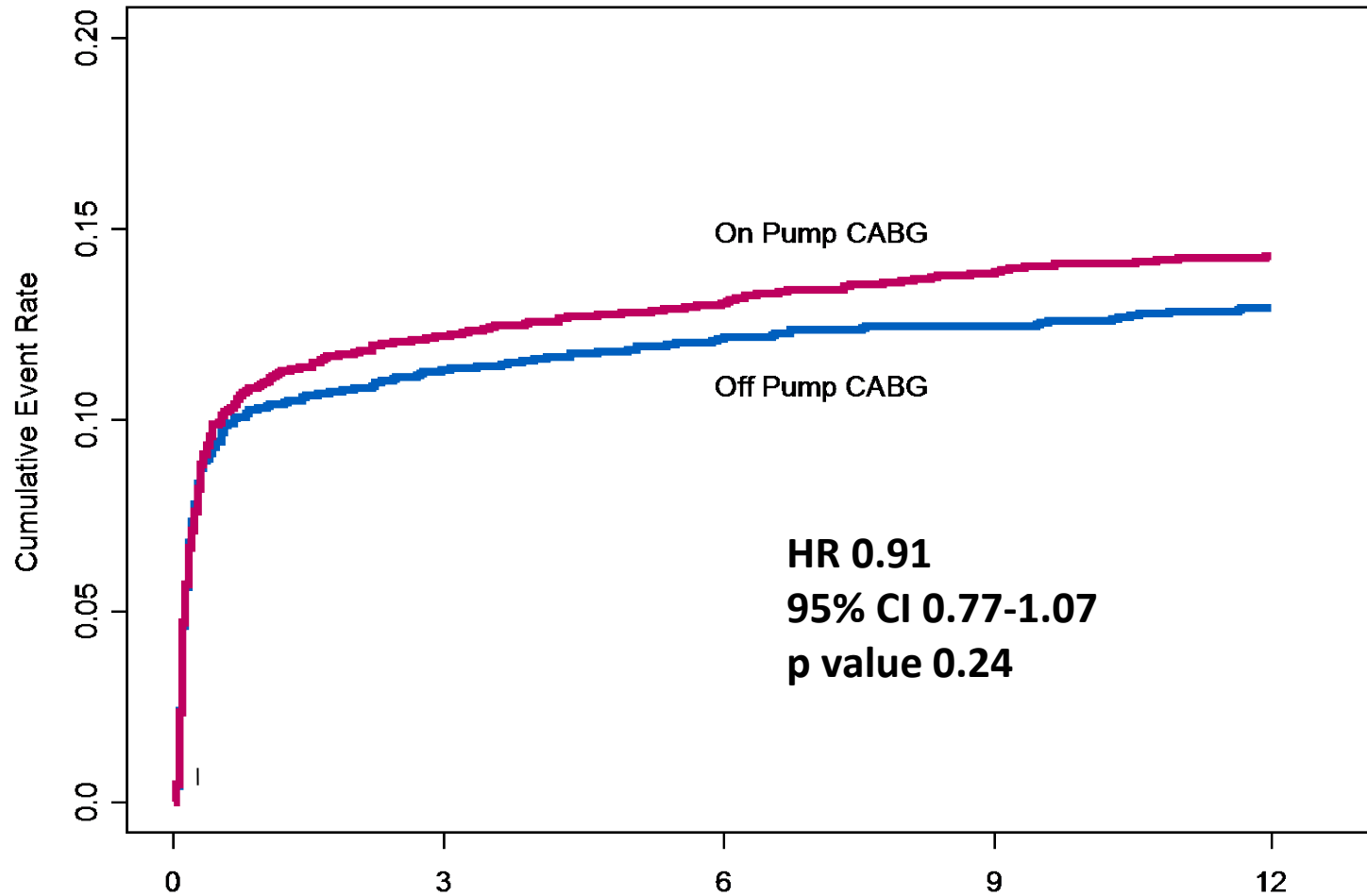
|               | OFF-PUMP<br>(n = 2375)<br>% | ON-PUMP<br>(n = 2377)<br>% |
|---------------|-----------------------------|----------------------------|
| Left Main     | 22.1                        | 20.9                       |
| Triple Vessel | 56.1                        | 60.4                 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



# 1<sup>st</sup> Co-Primary Outcome (1 Year)

|  | Off Pump % | On Pump % | Hazard Ratio | 95% CI    | p value |
|--|------------|-----------|--------------|-----------|---------|
| <b>Primary Outcome</b><br>Death, Stroke, MI, Renal Failure | 12.1       | 13.3      | 0.91         | 0.77-1.07 | 0.24    |
| <b>Components</b>  |            |           |              |           |         |
| 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 |
|-------------------------------------|------------|-----------|--------------|-----------|---------|
| <b>Cardiovascular Mortality</b>     | 4.2        | 4.0       | 1.03         | 0.78-1.37 | 0.83    |
| <b>Angina</b>                       | 1.0        | 0.9       | 1.05         | 0.58-1.88 | 0.87    |
| <b>PCI</b>                          | 1.1        | 0.8       | 1.43         | 0.79-2.57 | 0.23    |
| <b>Re-do CABG</b>                   | 0.3        | 0.04      | 7.00         | 0.86-57.0 | 0.07    |
| <b>PCI/Re-do CABG</b>               | 1.4        | 0.8       | 1.66         | 0.95-2.89 | 0.07    |
| <b>Primary Outcome per Protocol</b> | 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 |
|---|------------|-----------|--------------|-----------|---------|
| <b>Primary Outcome</b><br>Death/MI/Stroke/Renal Failure | 2.6        | 3.2       | 0.79         | 0.55-1.13 | 0.19    |
| <b>Components</b>                                       |            |           |              |           |         |
| 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<br>% | On Pump<br>% | Hazard<br>Ratio | 95% CI    | p value |
|---------------------------------|---------------|--------------|-----------------|-----------|---------|
| <b>Cardiovascular Mortality</b> | 1.5           | 1.5          | 1.06            | 0.65-1.73 | 0.82    |
| <b>Angina</b>                   | 0.8           | 0.7          | 1.13            | 0.56-2.26 | 0.74    |
| <b>PCI</b>                      | 0.7           | 0.6          | 1.15            | 0.55-2.41 | 0.72    |
| <b>Re-do CABG</b>               | <0.1          | 0            |                 |           | 0.99    |
| <b>PCI/Re-do CABG</b>           | 0.7           | 0.6          | 1.22            | 0.59-2.54 | 0.59    |













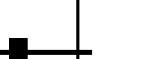




# Quality of Life

| 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> |         |
| <b>EQ-5D<sup>†</sup></b>                       |                        |              |                        |              |         |
| 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    |
| <b>EQ-5D visual-analogue scale<sup>‡</sup></b> |                        |              |                        |              |         |
| 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

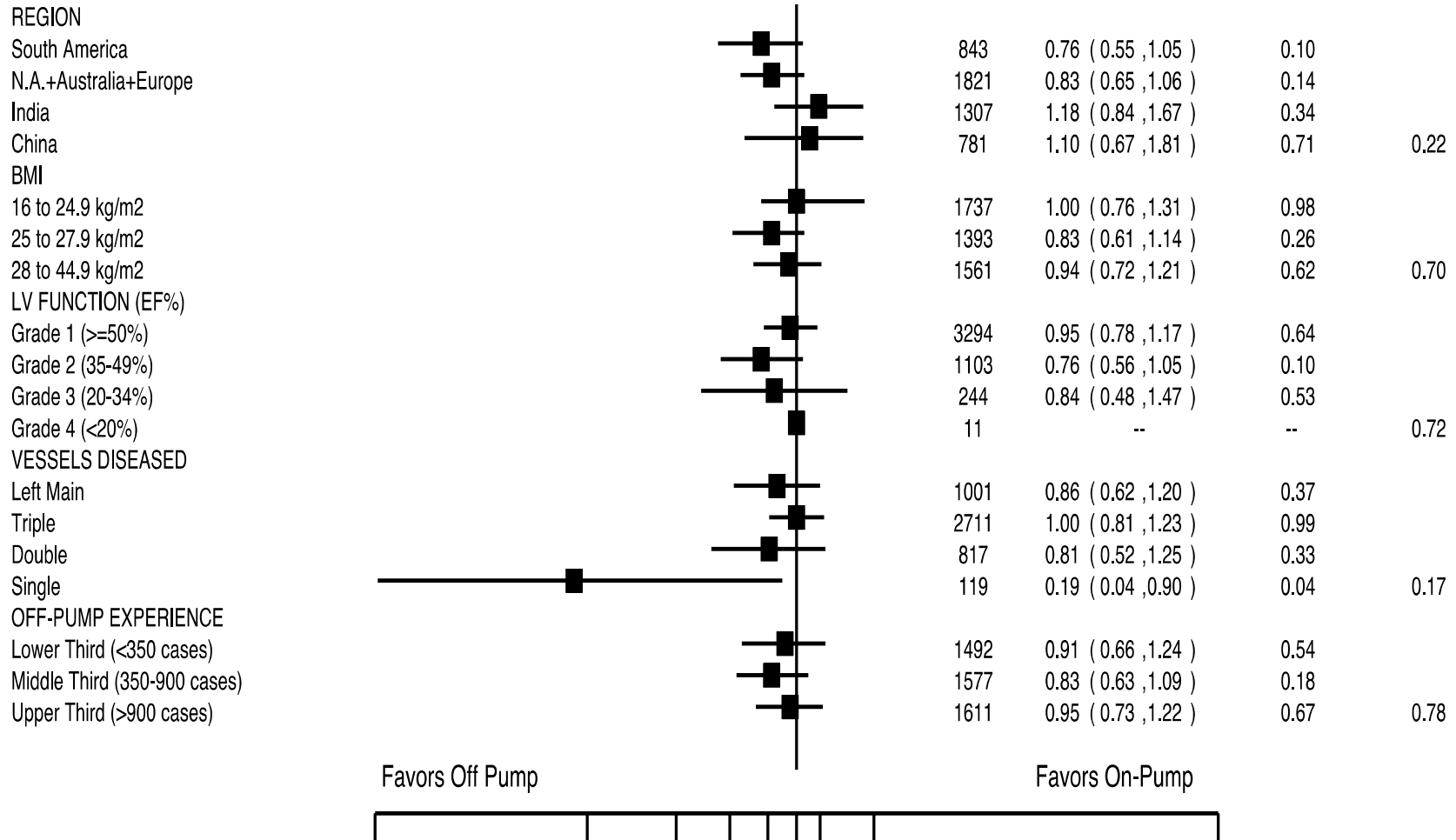
| Measure   | Off-Pump CABG          |              | On-Pump CABG           |              | P Value |
|---|------------------------|--------------|------------------------|--------------|---------|
|   | <i>no. of patients</i> | <i>score</i> | <i>no. of patients</i> | <i>score</i> |         |
| <b>Montreal Cognitive Assessment<sup>f</sup></b>  |                        |              |                        |              |         |
| 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    |
| <b>Digit Symbol Substitution Test<sup>g</sup></b> |                        |              |                        |              |         |
| 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    |
| <b>Trail Making Test Part B<sup>h</sup></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

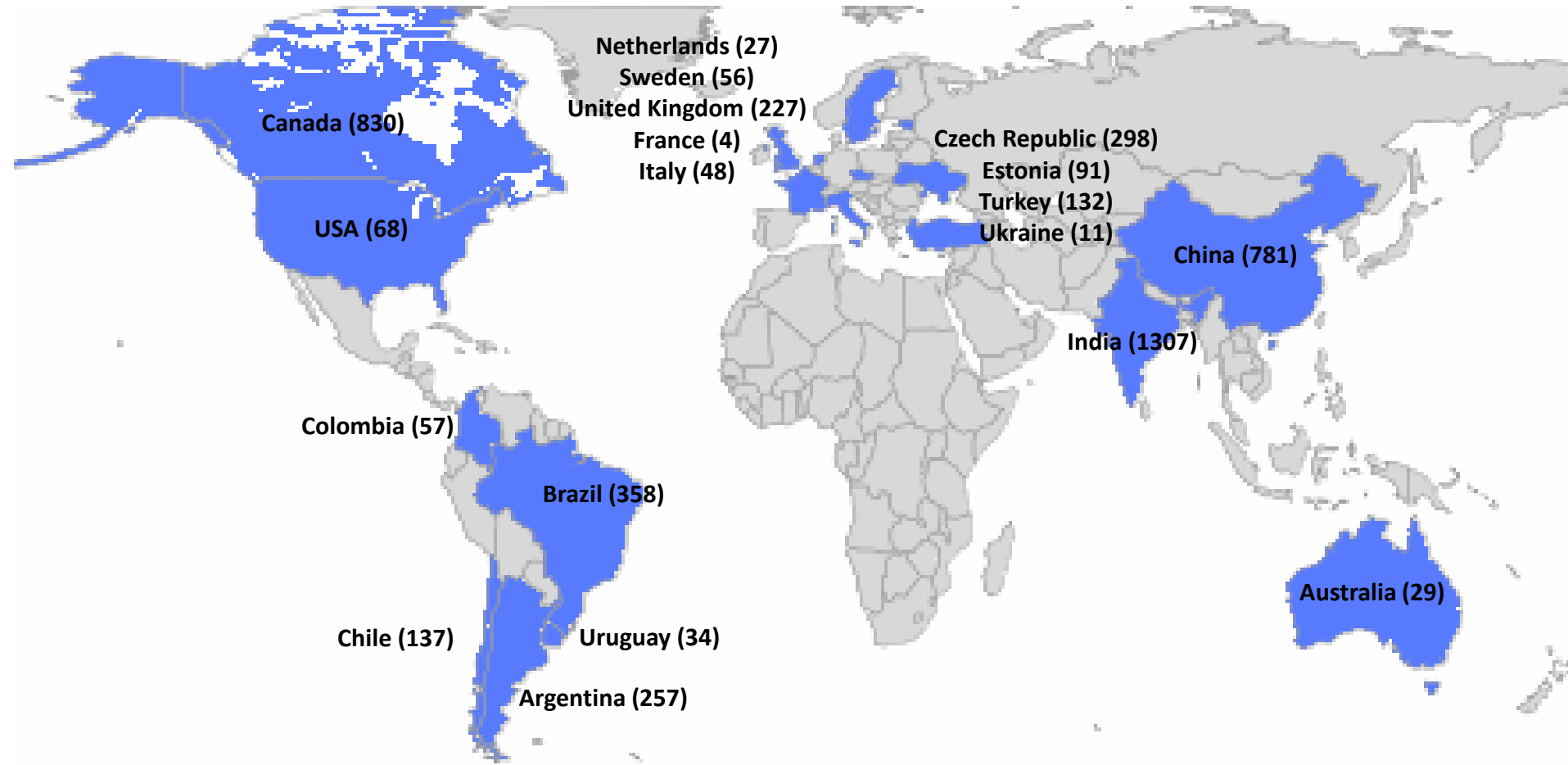
- In experienced hands, both procedures are reasonable options based on mid-term results

# Steering Committees

|                 |                |                  |
|-----------------|----------------|------------------|
| A. Lamy (Co-PI) | P.J. Devereaux | J. Murkin        |
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| A.R. Akar       | S.E. Fremes    | E. Paolasso      |
| A. Avezum       | S. Hu          | L. Piegas        |
| R. Cartier      | F. Lanas       | Z. Straka        |
| S. Chocron      | P.J. Lopez     | S. Yusuf (co-PI) |

# 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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