STS/EACTS Latin America Cardiovascular Surgery Conference
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Hilton Cartagena | Cartagena, Colombia

Current Perspective in Off-Pump Coronary Revascularization

Jorge M. Balaguer, MD

Visiting Associate Professor
Division of Cardiothoracic Surgery
Stony Brook University, New York

Currently at University of Pittsburgh Medical Center
Altoona, PA

CONSULTANT: JOHNSON & JOHNSON

Morbidity Associated with CPB

- Myocardial Necrosis
- Systemic Inflammatory Response
- Neuro-Cognitive effects / Brain injury
- Pump Lung (Adult Respiratory Distress Syndrome)
- Renal Dysfunction
- Embolization
- Coagulation Disorders
- Increased Blood Loss
- *Also cannulation complications and challenges*

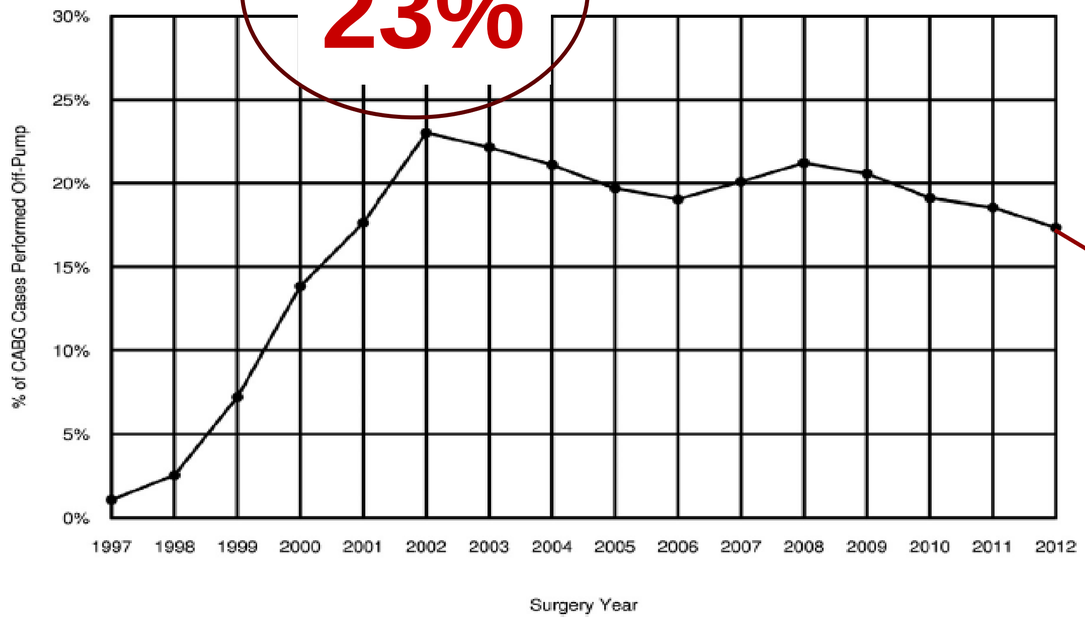
OFF-PUMP CABG Challenges

- Technically demanding operation
  - Surgeon
  - Whole the surgical team (off-pump team)
- Requires expertise on the anesthesiologist
- Years of deliberate practice to master this technique / Expert level
- Steep learning curve

Trends in Off-Pump CABG

2002

23%



13.1%

2016

12.5%

2017

FIGURE 2. Relative use of ON versus OFF CABG for the entire cohort (1997-2012). *CABG*, Coronary artery bypass grafting.

858 The Journal of Thoracic and Cardiovascular Surgery • September 2014

Off-Pump CABG in 2017: 12.5 %. STS Database

Number of Off-Pump CABGs
20,400 in 2016 (STS database)

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Major Procedures										
Isolated CABG	164,340	168,027	167,329	160,819	149,652	146,476	147,891	148,214	154,585	156,931
Isolated Aortic Valve Replacement	18,730	21,376	24,501	25,620	27,255	28,768	30,679	29,840	30,052	28,037
Isolated Mitral Valve Replacement	4,522	4,845	5,336	5,496	5,878	6,295	6,642	6,989	7,184	7,592
Aortic Valve Replacement + CABG	15,879	17,536	18,823	18,344	18,214	18,372	18,582	18,384	17,935	17,196
Mitral Valve Replacement + CABG	2,582	2,576	2,589	2,446	2,322	2,383	2,434	2,641	2,752	2,885
Aortic + Mitral Valve Replacements	1,285	1,317	1,503	1,468	1,609	1,661	1,777	1,910	1,844	1,964
Mitral Valve Repair	5,424	6,155	6,817	7,300	7,835	8,394	8,822	8,867	8,943	8,619
Mitral Valve Repair + CABG	4,854	5,177	4,898	4,759	4,596	4,708	4,797	4,293	3,957	3,464

More off-pump CABGs than AVR-CABG, MVR, MVR-CABG, MVP, MVP-CABG and AVR-MVR

Off-pump coronary artery bypass grafting: Misperceptions and misconceptions

European Heart Journal (2012) **33**, 1181–1183
doi:10.1093/eurheartj/ehr374

EDITORIAL

Off-pump vs. on-pump CABG: are we any closer to a resolution?

David P. Taggart[1]* and Douglas G. Altman[2]

Cardiovascular Surgery, University of Oxford, UK; and [2]Centre for Statistics in Medicine, University of Oxford, Oxford, UK

Review Article

"On" or "Off" pump coronary artery bypass grafting – Is the last word out?

O.P. Yadava, Anirban Kundu*

Department of Cardiac Surgery, National Heart Institute, New Delhi-110065, India

1042–1043
doi:10.1093/ejcts/ezv399 Advance Access publication 15 December 2015

EDITORIAL COMMENT

Cite this article as: Sousa Uva M, Kolh P. The on-pump/off-pump saga: an enduring conundrum. Eur J Cardiothorac Surg 2016;49:1042–3.

The on-pump/off-pump saga: an enduring conundrum

Miguel Sousa Uva[a] and Philippe Kolh[b,*]

- **Retrospective studies from specialized centers**
- **Randomized trials in relatively low risk patients**
- **Meta Analysis**
- **Observational data from large databases**

Single Center Studies (by experts)

mostly retrospective reviews

OFF-PUMP CABG IS BETTER

- Mack
- Hoff
- Taggart
- Angellini
- Di Giammarco
- Calafiore
- Navia
- Benetti
- Buffono
- Van Dijk

- Lower mortality in high risk groups
- Lower morbidity (all patients)
- Better soft outcomes

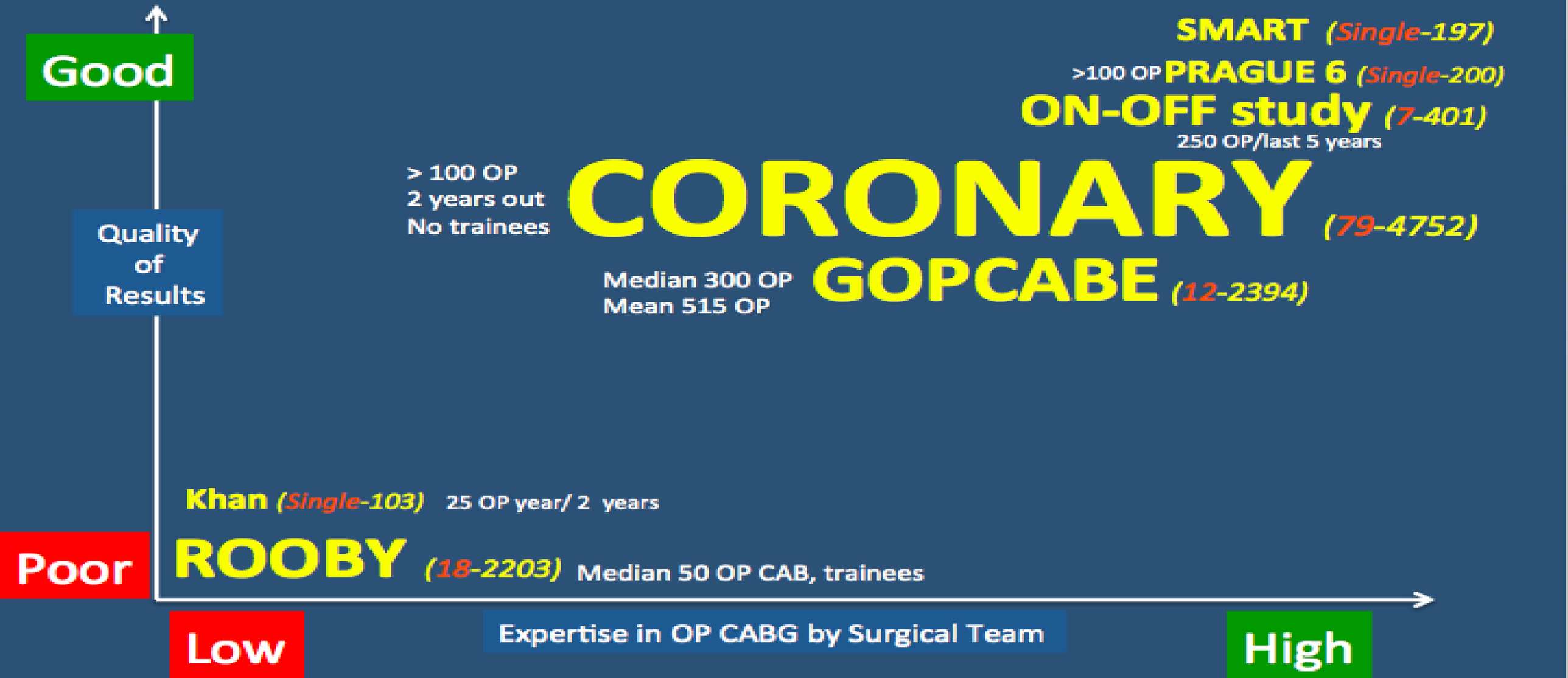
- Good quality of revascularization

↓

- Good mid and long-term results:
  - Survival
  - Low rate of re-interventions

Prospective-Randomized Control Trials: Off-Pump Vs. On Pump CABG

Surgeon and Team experience



Prospective-Randomized Control Trials: Off-Pump Vs. On Pump CABG

Surgeon and Team experience

Good

Quality of Results

Poor

Low

Expertise in OP CABG by Surgical Team

High

Graft Patency

SMART *(Single-197)*

COMPARABLE GRAFT PATENCY: OFF-PUMP and ON-PUMP CABG

> 100 OP
> 2 years out
> No trainees

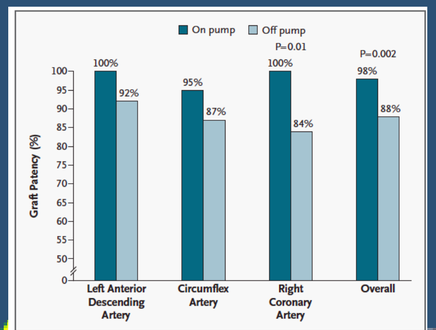
CORO

Median 300 OP
Mean 515 OP

Khan *(Single-103)*

ROOBY

50 OP CAB, trainees



KHAN Graft Patency in Each Territory in the On-Pump and Off-

Table 3. Early (Inhospital) and Late (1-Year) Arterial and Venous Graft Patency by Coronary Arterial Target

SMART TRIAL

	No. of Grafts With FitzGibbon A or B Score/Total No. of Grafts With Any FitzGibbon Score (%)*					
	Arterial Conduits (n = 250)			Venous Conduits (n = 372)		
	Off-Pump Coronary Artery Bypass	CABG With Cardiopulmonary Bypass	*P* Value†	Off-Pump Coronary Artery Bypass	CABG With Cardiopulmonary Bypass	*P* Value†
Left anterior descending coronary artery and branches (n = 273)						
Early	90/90 (100)	90/90 (100)	>.99	46/48 (95.8)	45/45 (100)	.50
1-year	69/71 (97.2)	76/77 (98.7)	>.99	34/36 (94.4)	35/35 (100)	.49
Right coronary artery and branches (n = 168)						
Early	14/14 (100)	12/13 (100)	.49	68/68 (100)	69/73 (94.5)	.12
1-year	11/13 (84.6)	10/10 (100)	.49	54/56 (96.4)	55/60 (91.7)	.44
Circumflex coronary artery and branches (n = 181)						
Early	22/22 (100)	21/21 (100)	>.99	71/72 (98.6)	64/66 (97.0)	.61
1-year	15/17 (88.2)	16/17 (94.1)	>.99	52/58 (89.7)	57/61 (93.4)	.52
All coronary arteries (n = 622)						
Early	126/126 (100)	123/124 (99.2)	>.99	185/188 (98.4)	178/184 (96.7)	.48
1-year	95/101 (94.1)	102/104 (98.1)	.26	140/150 (93.3)	147/156 (94.2)	.93

Abbreviation: CABG, coronary artery bypass graft.
*An "A" on the FitzGibbon scoring system indicates "perfectly patent"; a "B," patent, with any stenosis of less than 50% of the diameter of th an "O," totally occluded.[22]
†Pearson χ^2 test.

SMART TRIAL

Prospective-Randomized Control Trials: Off-Pump Vs. On Pump CABG

Surgeon and Team experience

30 Day Composite Outcome

SMART *(Single-197)*

>100 OP PRAGUE 6 *(Single-200)*

ON-OFF study *(7-401)*

250 OP/last 5 years

> 100 OP
2 years out
No trainees

CORONA

CA

Good

Quality of Results

Poor

Khan *(Single-103)*

ROOBY

Low

Expertise in OP CABG by Surgical Team

High

TABLE 3. Primary end point — ON-OFF STUDY

End point	ECC (n = 203)	OPCAB (n = 208)	Unadjusted *P* value	Adjusted *P* value
Composite	27 (13.3)	12 (5.8)	.009	.010*
Operative mortality	7 (3.4)	4 (1.9)	.376	.379
Myocardial infarction	6 (3.0)	4 (1.9)	.539	.514
Stroke	1 (0.5)	—	.494	.995
Renal failure	10 (4.9)	5 (2.4)	.173	.149
Reoperation for bleeding	7 (3.4)	3 (1.4)	.216	.115
ARDS	—	1 (0.5)	1.000	.995

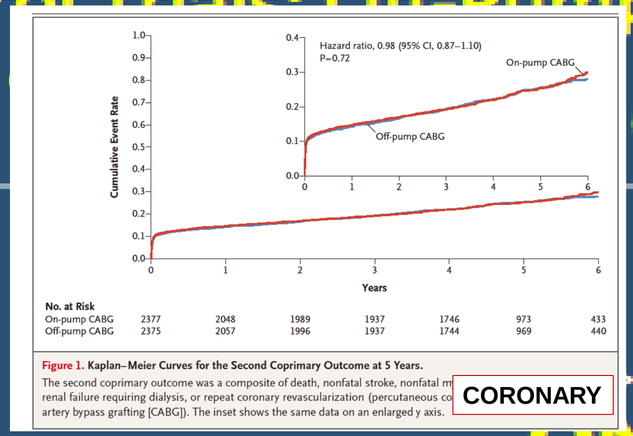
Table 2. Short-Term and Long-Term Primary End Points According to Treatment Group.* — ROOBY

Primary End Point	Off-Pump Group (N=1104)	On-Pump Group (N=1099)	Absolute Percentage-Point Difference (95% CI)	Relative Risk (95% CI)	P Value†
	no. (%)				
Short-term					
30-Day composite‡	77 (7.0)	61 (5.6)	1.4 (−0.6 to 3.5)	1.26 (0.91 to 1.74)	0.19
Death within 30 days after surgery or before discharge	18 (1.6)	13 (1.2)	0.4 (−0.5 to 1.4)	1.38 (0.68 to 2.80)	0.47
Complications within 30 days after surgery or before discharge					
Cardiac arrest	20 (1.8)	12 (1.1)	0.7 (−0.3 to 1.7)	1.66 (0.82 to 3.38)	0.21
Renal failure requiring dialysis	9 (0.8)	10 (0.9)	−0.1 (−0.9 to 0.7)	0.90 (0.37 to 2.20)	0.82
Stroke	14 (1.3)	8 (0.7)	0.5 (−0.3 to 1.4)	1.75 (0.74 to 4.14)	0.28
Coma	4 (0.4)	3 (0.3)	0.1 (−0.4 to 0.6)	1.33 (0.30 to 5.93)	1.00
Repeat cardiac surgery	8 (0.7)	8 (0.7)	−0.0 (−0.7 to 0.7)	1.00 (0.38 to 2.65)	1.00
Reoperation for bleeding	30 (2.7)	23 (2.1)	0.6 (−0.7 to 1.9)	1.30 (0.76 to 2.22)	0.40
New mechanical support	17 (1.5)	9 (0.8)	0.7 (−0.2 to 1.6)	1.88 (0.84 to 4.21)	0.17
Mediastinitis	11 (1.0)	14 (1.3)	−0.3 (−1.1 to 0.6)	0.78 (0.36 to 1.72)	0.55
Tracheostomy	5 (0.5)	7 (0.6)	−0.2 (−0.8 to 0.4)	0.71 (0.23 to 2.24)	0.58

Prospective-Randomized Control Trials: Off-Pump Vs. On Pump CABG

Surgeon and erience

5 year MACE



Good

Quality of Results

Poor

Low

Expertise in OP CABG by Surgical Team

High

SMART *(Single-197)*

>100 OP PRAGUE 6 *(Single-200)*

ON-OFF study *(7-401)*

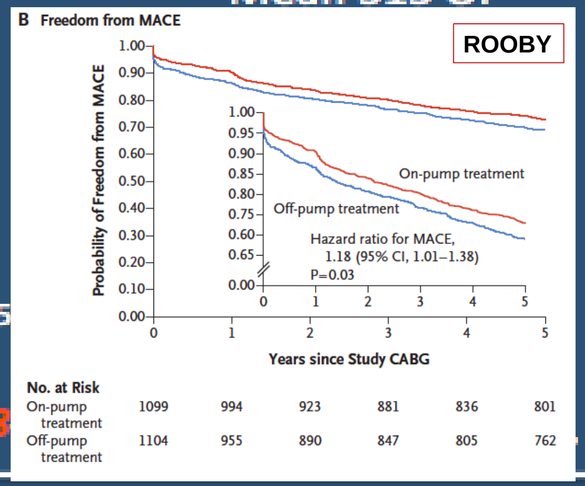
250 OP/last 5 years

> 100 OP
2 years out
No trainees

CORONARY *(79-4752)*

Median 300 OP
Mean 515 OP

GOPCABE *(12-2394)*



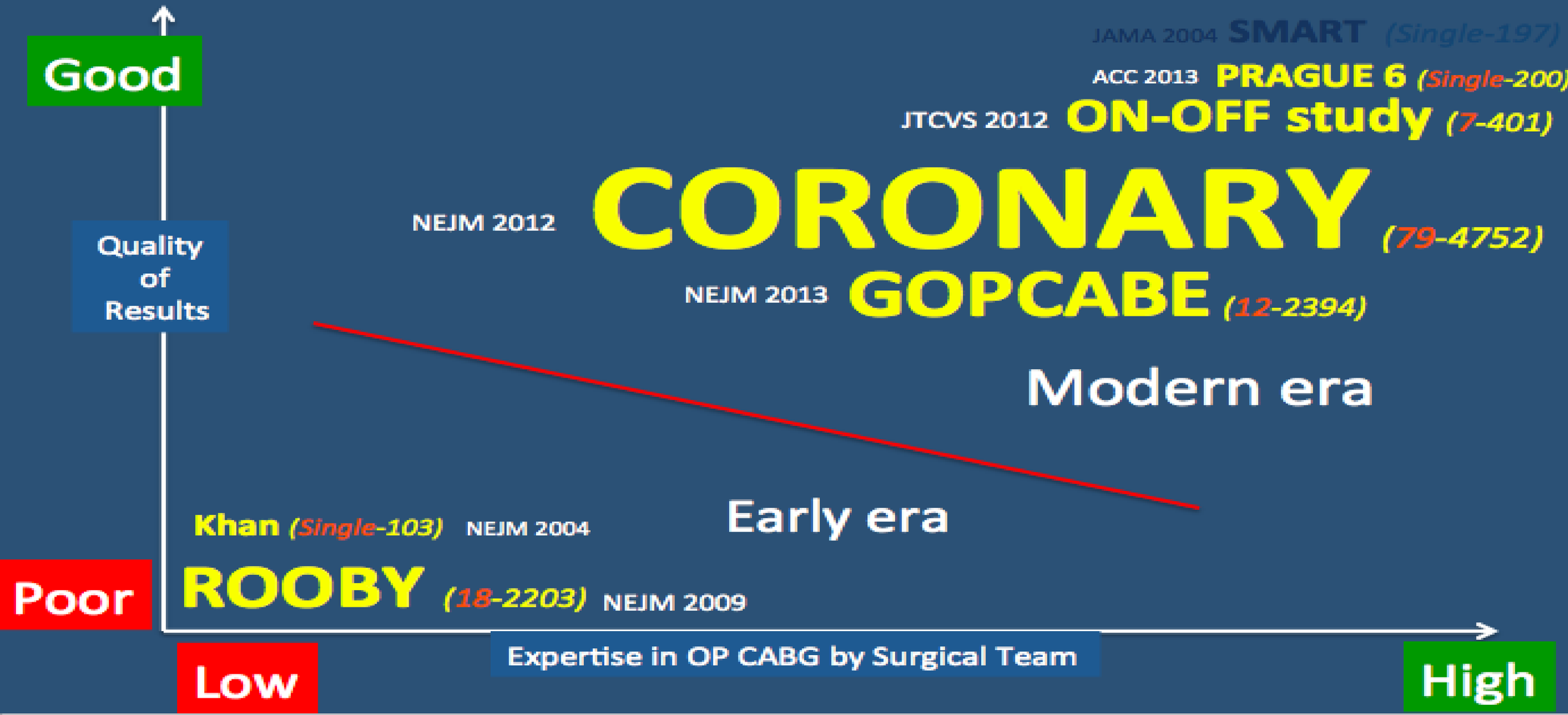
Khan *(Single-103)* 25

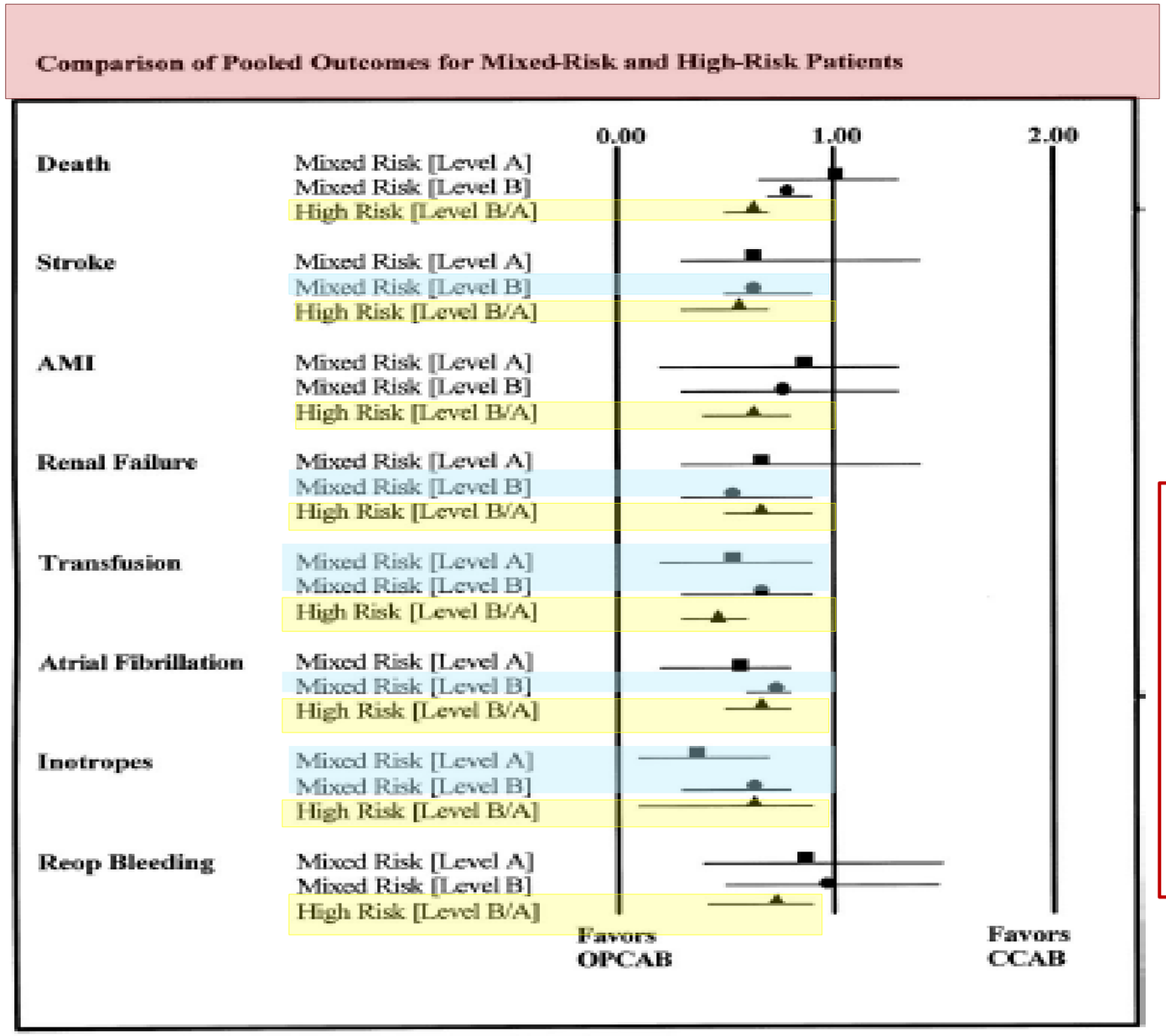
ROOBY *(18*

trainees

Prospective-Randomized Control Trials: Off-Pump Vs. On Pump CABG

Early and Modern era





Mixed-Risk Patients [Level A] = Cheng 2004 (37 randomized trials; 3369 patients)
Mixed-Risk Patients [Level B] = Beattie 2004 (13 non-randomized trials; 198,204 patients) or Reston 2003 (53 trials; 46,621 patients)
High-Risk patients [Level B/A] = ISMICS Consensus Meta-Analysis 2004 (42 non-randomized trials and 3 randomized trials; 26,349 patients)

Meta Analysis

37 RCT: 3,300 Pts
42 Non RCT: 26,349 Pts

Outcomes according to Risk On-PUMP vs. OFF-PUMP

- Lower Mortality and morbidity in high-risk groups
- Lower morbidity in all risk groups

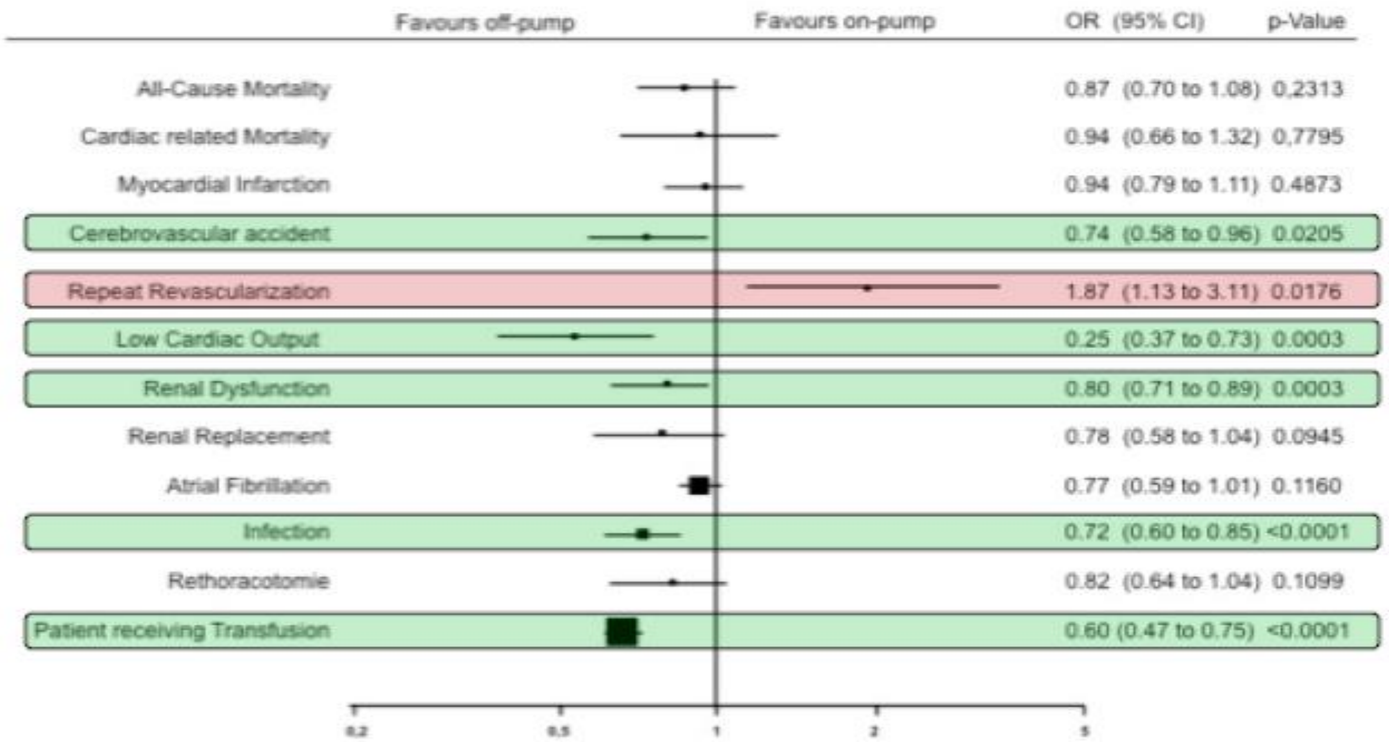
Puskas 2004

META-ANALYSIS: Reston 2003, Puskas 2004, Selke 2005, Cheng 2005, Cochrane 2012, Takagi 2013, Deppe 2015, Kowaleski (and Taggart) 2016, Zhao 2017, Filardo 2018, etc

Current evidence of coronary artery bypass grafting off-pump versus on-pump: a systematic review with meta-analysis of over 16 900 patients investigated in randomized controlled trials †

Antje-Christin Deppe ✉; Wasim Arbash; Elmar W. Kuhn; Ingo Slottosch; Maximilian Scherner; Oliver J. Liakopoulos; Yeong-Hoon Choi; Thorsten Wahlers

Eur J Cardiothorac Surg (2016) 49 (4): 1031-1041.



OPCAB reduces risk for

- *Stroke
- * Low Cardiac-Output Syndrome
- * Renal Dysfunction
- * Infection
- * Patients receiving Transfusion

OPCAB increases risk for

- * Repeat Revascularization

Large Database Studies

OFF-PUMP CABG is associated with

- **NY Database** (close to 50,000 Pts) *Hannan et al. Circulation 2007*
  - Lower surgical mortality and morbidity
  - **Higher rate of repeat revascularization**
- **NY Database** (close to 68,000 Pts.) *Racz et al. JACC 2004*
  - Lower surgical morbidity
  - Higher mid term mortality *(no in the last 2 years)*
  - **Higher mid term rate of repeat revascularization**
- **STS Database** (close to 15,000 pts) *Puskas et. Al. Ann Thorac Surg 2009*
  - Lower surgical mortality in high–risk groups
- **HCA Database** (close to 7,000 Pts-all women) *Mack et al. Circulation 2004*
  - Lower surgical mortality and morbidity
- **STS Database** (close to 120,000 Pts) *Cleveland et al. Ann of Thorac Surg 2001*
  - Lower surgical mortality and morbidity
- **California Database (CCORP)** (30,000 Pts) *Li et al. Ann Thorac Surg 2010*
  - Lower rate of stroke
- **New Jersey Dept. Health Registry** (22,000 Pts) Chikwe et al. JACC 2018
  - **Higher repeat revascularization**
  - Lower 10 year survival

- Lower Surgical Mortality and Morbidity
- Higher repeat revascularization
- Higher long term mortality

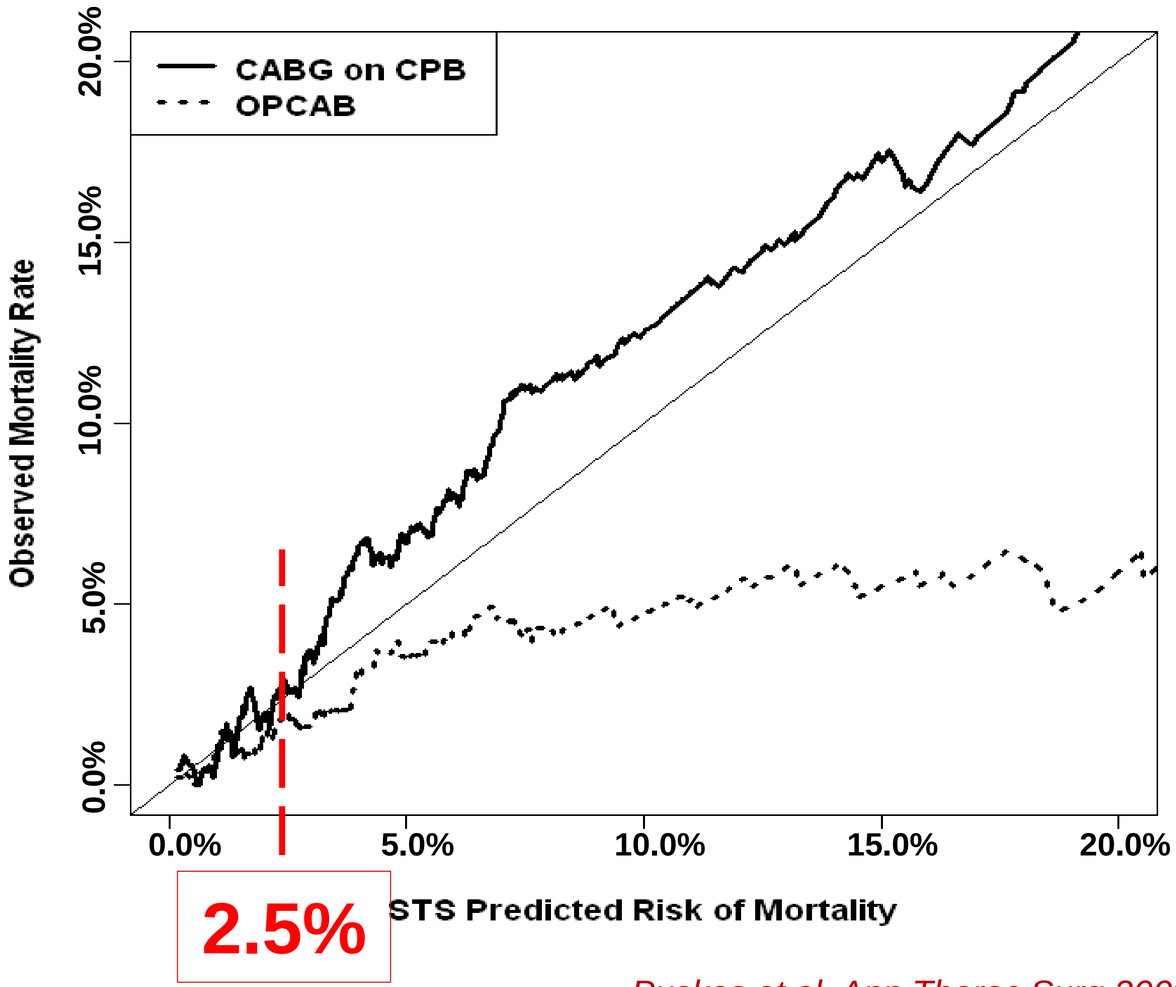
Surgical Mortality

Higher Risk, higher benefit of Off-Pump

STS 2009: Puskas y col.

- Retrospective. STS database
- 14,766 consecutive CABG patients at Emory
- 17 surgeons.
- Analyzed in 4 quartiles stratified by risk, as defined by the STS PROM equation

PROM Range	OPCAB Deaths (%)	CAB Deaths (%)	OPCAB Odds Ratio (95% CI)	p-value
0%-0.75%	5/1824 (0.3)	6/1883 (0.3)	0.86 (0.26, 2.82)	0.80
0.75%-1.3%	15/1755 (0.9)	17/1921 (0.9)	0.97 (0.48, 1.94)	0.92
1.3%-2.5%	19/1665 (1.1)	37/2025 (1.8)	0.62 (0.36, 1.08)	0.09
>2.5%	58/1839 C(3.2)	124/1854 (6.7)	0.45 (0.33, 0.63)	<0.0001



Puskas et al. Ann Thorac Surg 2009

Stroke and global neurological adverse events

Lower in the Off-PUMP population

OFF-PUMP	ON-PUMP	P value	reference
1.6%	2%	0.003	Racz et al. 68,000 patients
1.2%	1.5%	0.0006	Hannan et al. 50,000 patients
1.25%	1.5%	0.001	Cleveland et al. 118,000 patients
1.4%	2.1%	0.002	Mack et al. 7,300 patients
	OR 1.8		Marui et al. 3,700 patients (high-risk)
1.03	1.79	0.006	Mack et al. 7,376 pts (all female)

Delirium

OFF-PUMP	ON-PUMP	P value	reference
2%	8%	0.001	Bucerlus et al. 16,000 patients

Coronary Artery Bypass Grafting With and Without Manipulation of the Ascending Aorta

A Network Meta-Analysis

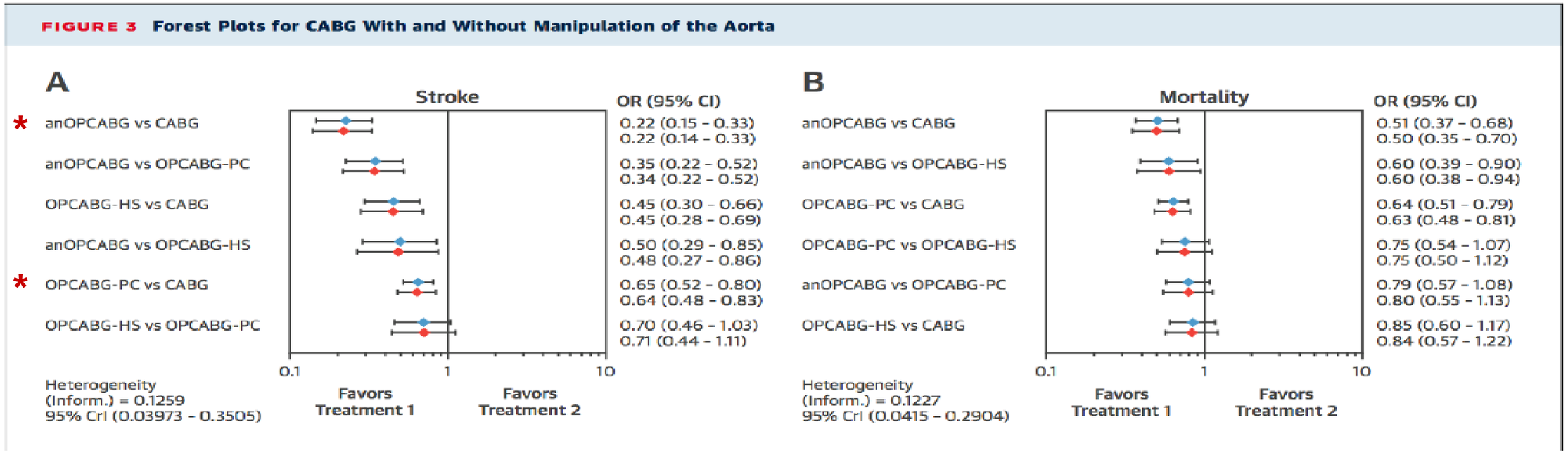
Dong Fang Zhao, BA,[a,b] J. James Edelman, PhD,[a,b,c] Michael Seco, MBBS,[a,b,c] Paul G. Bannon, PhD,[a,b,c,d,e] Michael K. Wilson, MBBS,[b,c,e] Michael J. Byrom, PhD,[a,b,c,d,e] Vinod Thourani, MD,[f] Andre Lamy, MD, MHSc,[g] David P. Taggart, PhD,[h] John D. Puskas, MD,[i] Michael P. Vallely, PhD[a,b,c,d,e]

J Am Coll Cardiol 2017;69:924–36

Stroke

- Bayesian network meta-analysis.
- 13 studies / 37,720 patients

FIGURE 3 Forest Plots for CABG With and Without Manipulation of the Aorta



An Aortic OP CAB (no touch technique)	ON-PUMP CABG
0.4%	1.8%

78% Relative Risk Reduction

OP CAB	ON-PUMP CABG
1.3%	1.8%

35% Relative Risk Reduction

OFF-PUMP CABG
Quality of revascularization

- **Off-PUMP is associated with a higher rate of repeat revascularization**
- 0.2 more grafts/patient in the ON-PUMP groups
- Better graft patency in the ON-PUMP groups
- **Driven by worse patency in vein grafts**
    - Technical (easier to perform LIMA-LAD OFF-PUMP than graft on the non LAD (often veins)
    - Run off
    - Biology (combination of relative hypercoagulable post OFF-PUMP + low endothelial cell viability in SVG)
- **Early studies (Rooby, Khan) the difference is more significant**
    - *Inexperienced OFF-PUMP teams*
    - *Off-Pump Equipment*
    - *Vessel loops around the vessels*
    - *Heparin management*
    - *Antiplatelet therapy management*

- Off-Pump CABG performed by inexperienced surgeons and teams will produce suboptimal results and will be reflected in randomized trials, database studies, meta-analysis and, more importantly, in clinical practice

- **If OFF-PUMP CABG performed at an expert level, could obtain (in addition to the short term benefits in mortality and morbidity) the graft patency and long term outcomes of ON-PUMP CABG?**

Maturation Process

- **Individual program maturation – overcoming the learning curve-acquiring expert level**

- **Maturation of the Off-Pump techniques-technology. The second decade**
  - Stabilizer
  - Position devices
  - Shunts
  - Misted blower
  - Anastomotic devices
  - Flow evaluation

Subramanian et al.

The Failed Promise of OPCAB

There is no heavier burden than a great potential.

Linus
—Charles Schultz

Where OP CAB fits in this era?

Patients who are high risk (for CPB) would benefit the most by OP CAB

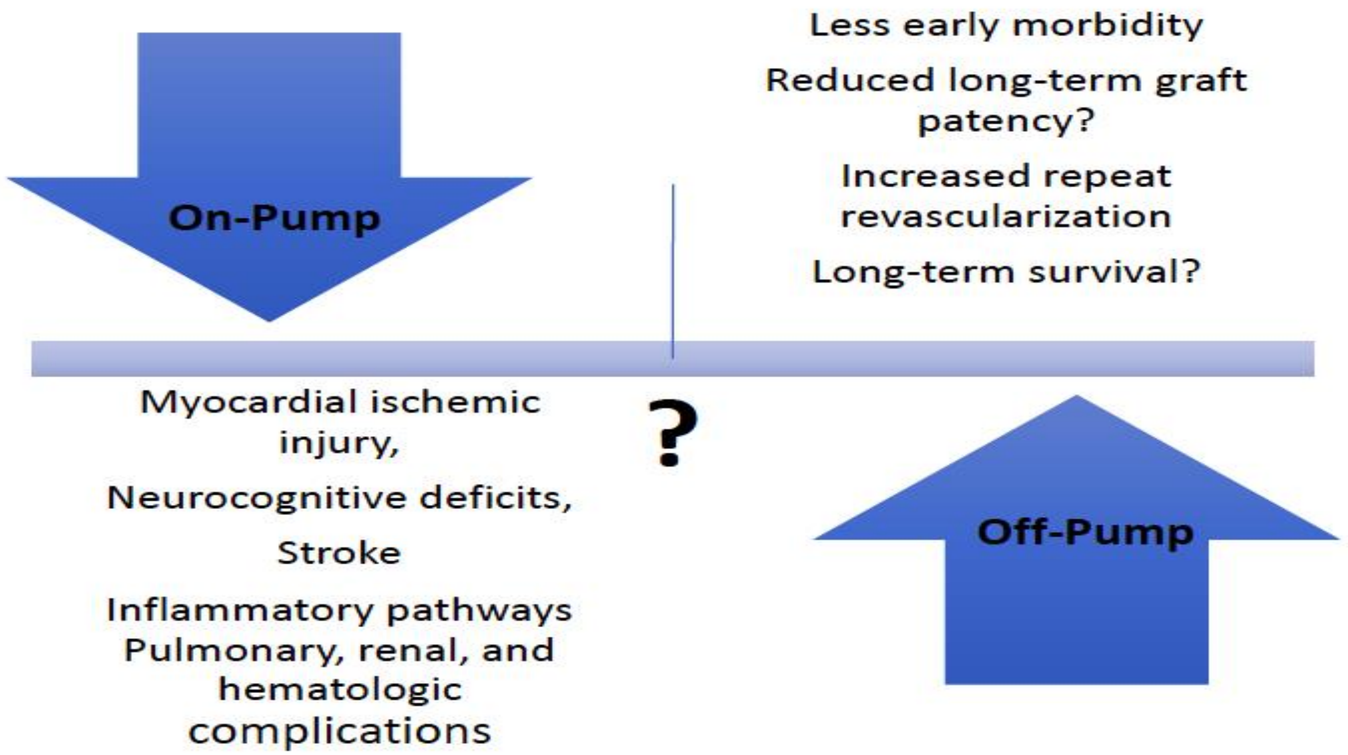
Risk / benefit Ratio

Risk associated with technical adverse events

Benefits in avoiding CPB

Expertise of OP CAB Team critical

Trade offs



Lower mortality in
The high-risk groups

Sousa Uva 2017

Cardiac Surgeons and OP CAB

- Surgeons who have never done OP CAB
- Surgeons who have done OP CAB but they don’t do it any more
    - Performed some OP CAB and abandon it
        - Poor results
        - Out of comfort zone
    - Perform OP CAB routinely and then abandon it
        - Peer or Institutional pressure
        - Response to emerging data
- Surgeons who consistently perform OP CAB in their practice

OP CAB
Institutional perspective

- High-risk cases who would benefit ***the most*** from OP CAB

- Complement Minimally Invasive Programs
  - MID CAB or MICS
  - Robotic Assisted MID CAB
  - TE CAB

- Isolated
- Hybrid Revascularization:
  - *LIMA-LAD + Stenting to Non-LAD vessels*

Final Remarks

- **OP CAB will continue a refinement and maturation process**
  - **GOALS:**
  - **Continue the process to decrease the risk of mortality and morbidity (Safer operation)**
  - **Improve on areas such as graft patency/complete revascularization**
  - **Perioperative Anticoagulation/antiplatelet management/conduit selection**
  - **Patient selection (risk/benefit ratio)**
- **Should be strongly considered for high-risk patients**
- **Excellent technique to complement innovative approaches**
- **Should be performed by experienced teams with a systematic approach**

STS/EACTS Latin America Cardiovascular Surgery Conference

November 15-17, 2018

Hilton Cartagena | Cartagena, Colombia

The Society of Thoracic Surgeons

EACTS

UPMC LIFE CHANGING MEDICINE

THANK YOU

STONY BROOK ESTABLISHED 1957 STATE UNIVERSITY OF NEW YORK