Hybrid Revascularization: The Future?

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• **Consultin/Speaker Fees**	Abbott Vascular, Edwards Life science; Cardiovascular System Inc.,

Agenda

- 1) The Concept
- 2) Clinical data
- 3) Upcoming large Randomized Trial (CTSN)
- 4) Remaining Issues
  - Timing/Setting
  - Antiplatelet therapy

HYBRID Revascularization: The Concept

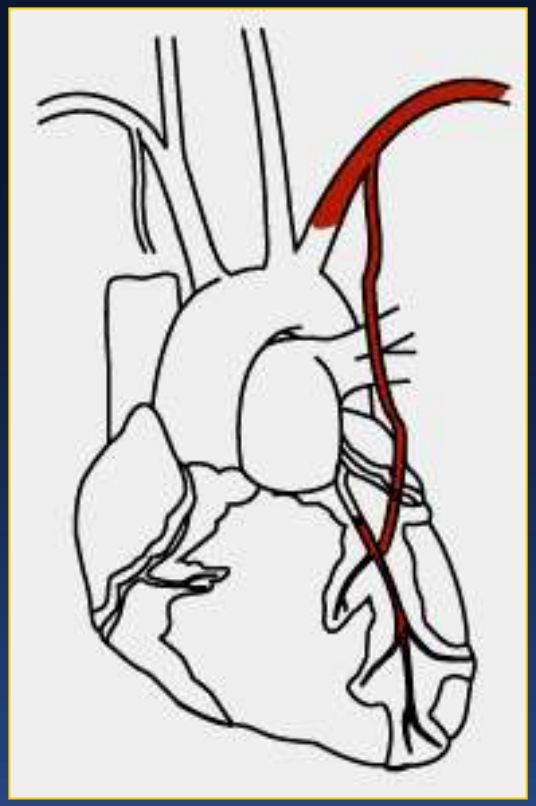
- **Minimally invasive LIMA-LAD**

+

- **PCI (with DES) to non-LAD coronary targets**

Avoid the bad and ugly of both worlds, and focus on the good of both techniques!

Hybrid Revascularization:
LIMA to LAD + PCI to other Vessels



90% LIMA patency at 10 years

Non-Invasive, Fast recovery, Less Bleeding, Less stroke

Guidelines

Practice Guideline

2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the Diagnosis and Management of Patients With Stable Ischemic Heart Disease

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons

5.11. Hybrid Coronary Revascularization: Recommendations

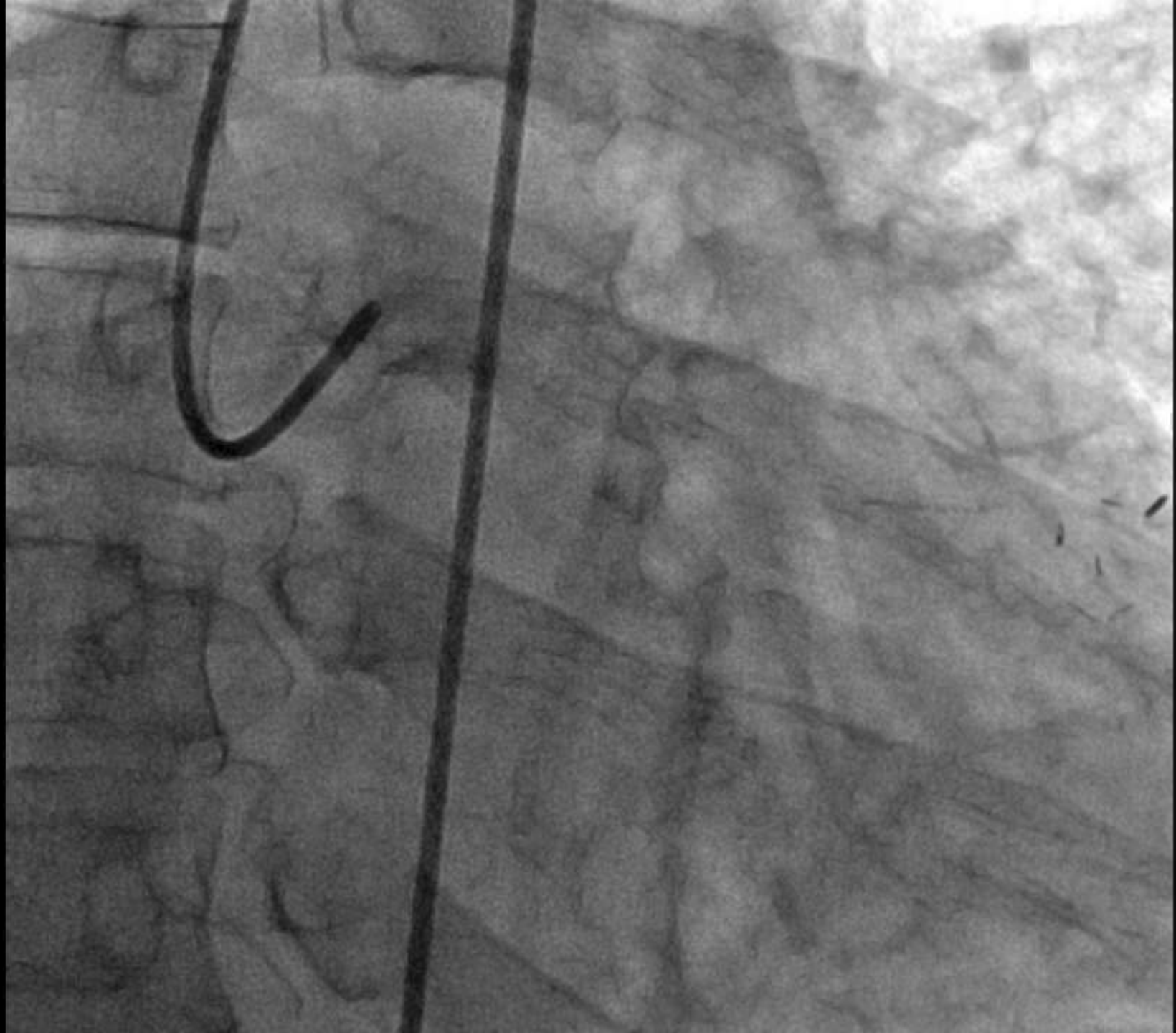
Class IIa

1. Hybrid coronary revascularization (defined as the planned combination of LIMA-to-LAD artery grafting and PCI of ≥1 non-LAD coronary arteries) is reasonable in patients with 1 or more of the following[1116–1122] (*Level of Evidence: B*):
   a. Limitations to traditional CABG, such as heavily calcified proximal aorta or poor target vessels for CABG (but amenable to PCI);
   b. Lack of suitable graft conduits;
   c. Unfavorable LAD artery for PCI (ie, excessive vessel tortuosity or chronic total occlusion).

Class IIb

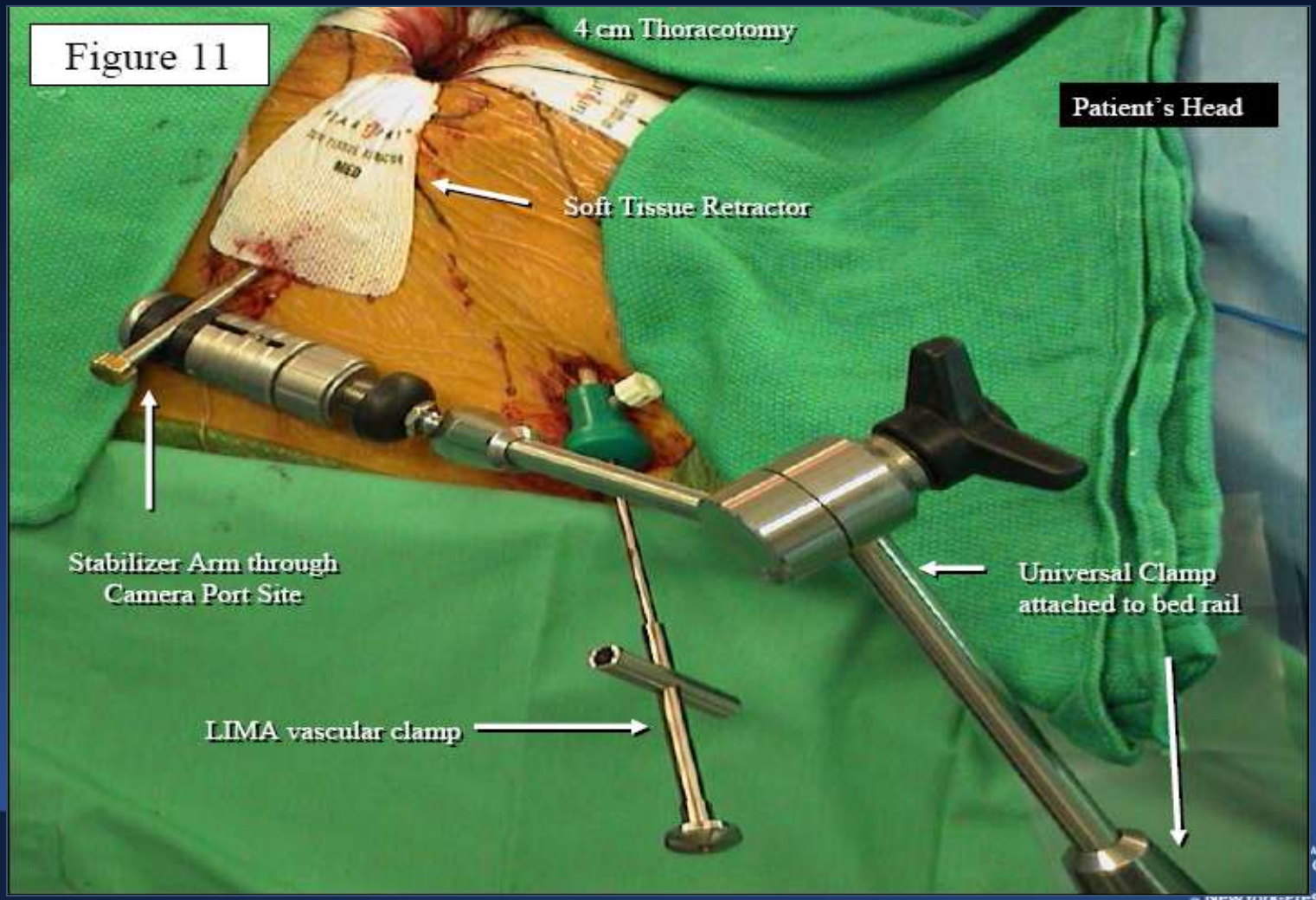
1. Hybrid coronary revascularization (defined as the planned combination of LIMA-to-LAD artery grafting and PCI of ≥1 non-LAD coronary arteries) may be reasonable as an alternative to multivessel PCI or CABG in an attempt to improve the overall risk–benefit ratio of the procedures. (*Level of Evidence: C*)

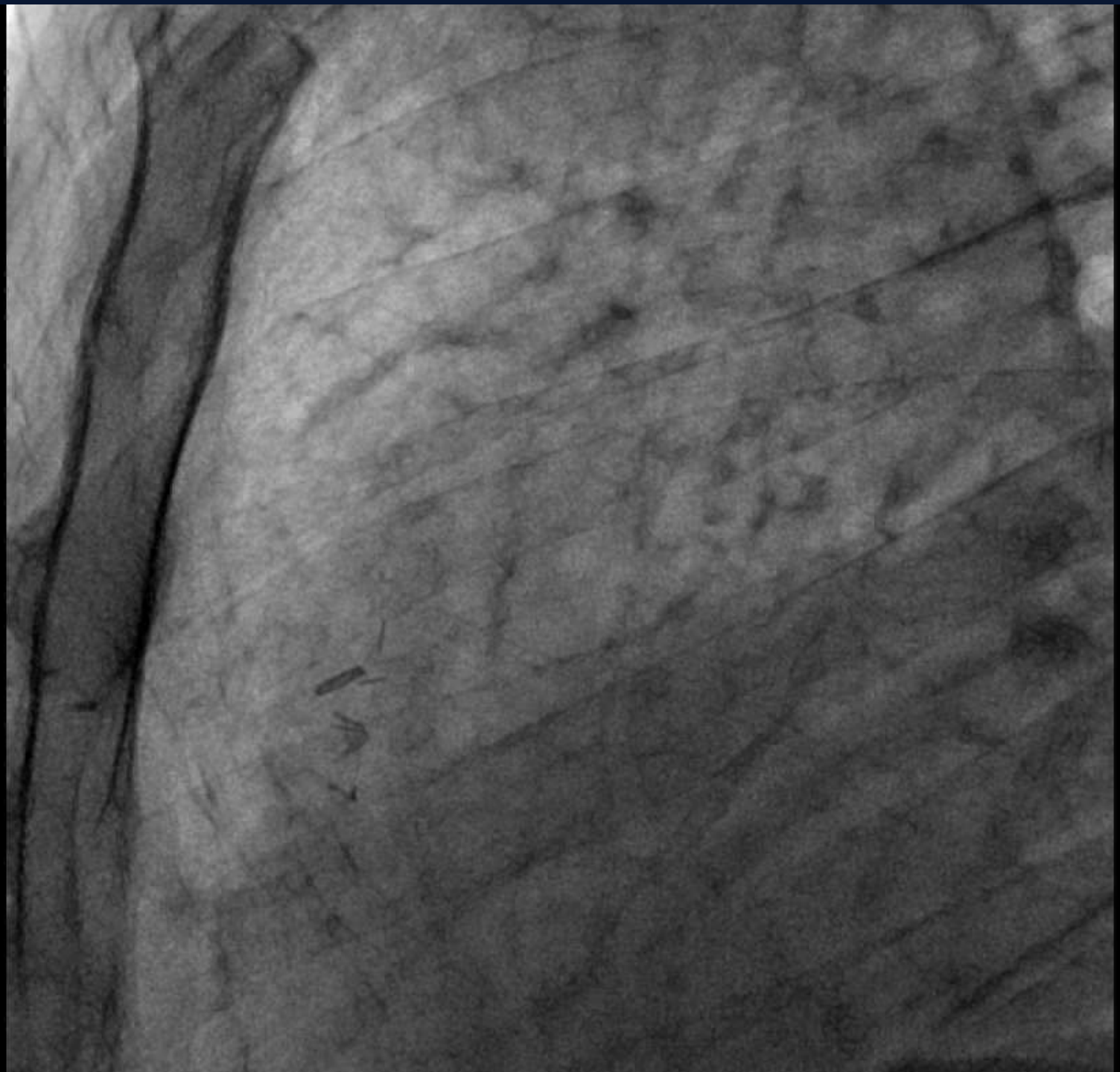
Fihn, SD et al. *Circulation* 2012



Robotic EndoACAB

LIMA to LAD Anastomosis: 3-4 cm Micro-Thoracotomy





2 Weeks After Surgery

2. Current Data

2. Current Data

Comparative Effectiveness of Hybrid Coronary Revascularization vs Coronary Artery Bypass Grafting

Ralf E Harskamp, MD, Thomas A Vassiliades, MD, FACS, Rajendra H Mehta, MD, MS, Robbert J de Winter, MD, PhD, Renato D Lopes, MD, PhD, Ying Xian, MD, PhD, Eric D Peterson, MD, MPH, John D Puskas, MD, MS, FACS, Michael E Halkos, MD, MS, FACS

Single Center Retrospective 1:3 Propensity Score Matching; n=1,224

306 Hybrid vs. 918 CABG

Median Follow-up 3.7 years

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From 2003 to 2013 Emory Hospital USA

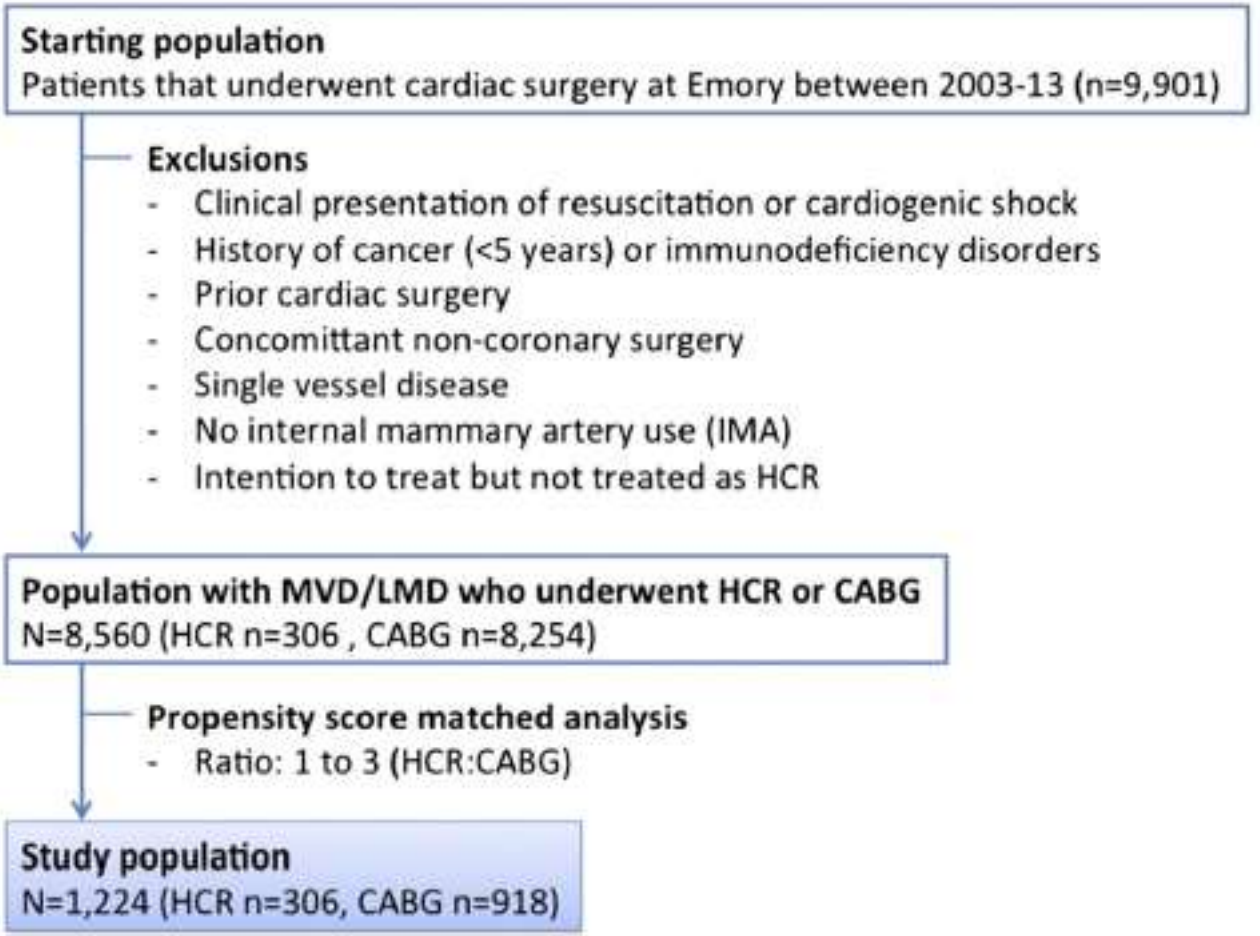

Figure 1. Flow diagram of the study population. Steps that led from the starting population to the propensity score–matched study population. These patients were included in a sensitivity analysis of intention-to-treat for hybrid coronary revascularization (HCR). LMD, left main coronary artery disease; MVD, multivessel coronary artery disease.

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Methods

- **Heart team discussion:**
- ***1) LIMA LAD first*, then staged PCI (Default)**
  - **Clopidogrel 150 mg post LIMA LAD *(72.5%)***
- ***2) PCI first* than LIMA LAD on DAPT *(20.0%)***
- ***3) One setting (7.5%)*:**
  - **LIMA LAD first then 600mg Clopidogrel at the time of the PCI (after confirmation of LIMA to LAD patency)**
- **Median time of 3 days [2-7 days] between staged procedures**
- **CABG: 83% Off Pump / 11% BIMA used**

Table 1. Baseline Characteristics Before and after Propensity Score Matching

Characteristics	Unadjusted			After PS matching		
	HCR (n = 306)	CABG (n = 8,254)	SD	HCR (n = 306)	CABG (n = 918)	SD
Age, y, mean ± SD	64.6 ± 11.6	63.3 ± 10.7	11.6	64.6 ± 11.6	64.8 ± 10.4	1.5
Sex, %						
Male	70.3	72.7	5.4	70.3	67.4	6.4
White	78.8	76.6	5.3	78.8	78.5	0.5
BMI, kg/m^2, mean ± SD	28.4 ± 5.3	29.3 ± 6.0	17.1	28.4 ± 5.3	28.3 ± 5.5	1.4
Current smoker, %	20.6	28.4	19.3	20.6	19.2	3.5
Diabetes, %	36.9	42.1	10.7	36.9	39.0	4.3
Chronic lung disease, %	3.6	5.8	11.8	3.6	4.4	4.1
Hypertension, %	91.5	87.8	13.1	91.5	92.4	3.1
Cerebrovascular disease, %	17.3	18.1	1.9	17.3	18.7	3.6
Peripheral artery disease, %	11.1	15.8	14.9	11.1	12.3	3.8
eGFR, mean ± SD	75.0 ± 27.0	71.8 ± 25.3	12.1	75.0 ± 27.0	74.3 ± 25.6	2.7
Earlier MI, %	47.4	52.8	10.7	47.4	48.4	2.0
Heart failure <14 d, %	12.4	22.8	31.5	12.4	13.4	3.0
LVEF, mean ± SD	54.7 ± 9.4	51.7 ± 12.5	31.8	54.7 ± 9.4	54.5 ± 11.2	1.9
Ht <0.35, %	27.1	27.1	0.0	27.1	26.9	0.5
Anemia, %	39.9	39.9	0.0	39.9	38.6	2.6
Isolated LMD, %	11.1	8.2	27.5	11.1	10.1	3.1
2-VD, %	45.8	18.0	38.5	45.8	46.0	0.4
3-VD, %	34.0	50.5	50.0	34.0	33.4	1,1
LM and VD, %	9.2	23.2	42.2	9.2	10.5	4.5
Elective, %	65.0	53.2	49.9	65.0	65.5	0.9
STS score, mean ± SD	1.6 ± 2.2	2.0 ± 2.7	2.7	1.6 ± 2.2	1.7 ± 2.0	3.3

eGFR, estimated glomerular filtration rate; Ht, hematocrit; LM and VD, left main coronary artery disease and also significant disease in another coronary artery; LMD, left main coronary artery disease; LVEF, left ventricular ejection fraction; PS, propensity score; STS, Society of Thoracic Surgeons; 2-VD, two-vessel coronary artery disease; 3-VD, three-vessel coronary artery disease.

Procedural Characteristics

Table 2. Procedural Characteristics of Patients in the Propensity-Score Matched Cohort

Characteristics	HCR (n = 306)	CABG (n = 918)	p Value
Total operating time, min, mean ± SD	295 ± 80	324 ± 78	<0.001
Cardiopulmonary bypass use, %	0.0	16.8	<0.001
Bilateral IMA use, %	0.7	11.0	<0.001
IMA anastomosis, mean ± SD	1.04 ± 0.21	1.17 ± 0.44	<0.001
Vein grafts, mean ± SD		1.79 ± 1.01	
Total grafts, mean ± SD		3.10 ± 0.93	
Drug-eluting stent use, n (%)	256 (83.7)		

Reduction in Cardiopulmonary bypass use and Operating time

In-hospital and 30-Day MACCE

Table 3. Thirty-Day Major Adverse Cerebrovascular and Cardiovascular Events and In-Hospital Outcomes

Characteristics	HCR (n = 306)	CABG (n = 918)	OR (95% CI)	p Value
Composite of 30-d death, MI, stroke, n (%)	10 (3.3)	28 (3.1)	1.07 (0.52–2.21)	0.85
Death	5 (1.6)	10 (1.1)	1.50 (0.51–4.39)	0.46
MI	2 (0.7)	8 (0.9)	0.75 (0.16–3.53)	0.72
Stroke	3 (1.0)	16 (1.7)	0.56 (0.16–1.93)	0.36
In-hospital major morbidity, n (%)	26 (8.5)	142 (15.5)	0.55 (0.36–0.83)	0.005
Reoperation	13 (4.2)	53 (5.8)	0.74 (0.40–1.35)	0.32
Renal failure	5 (1.7)	21 (2.3)	0.71 (0.27–1.89)	0.50
Prolonged ventilation, >24 h	16 (5.3)	102 (11.1)	0.48 (0.28–0.81)	0.006
Access site infection	0 (0.0)	11 (1.2)	—	—
Bleeding outcomes				
CABG-related bleeding, n (%)	22 (7.2)	85 (9.3)	0.78 (0.49–1.24)	0.29
Need for blood transfusion, n (%)	66 (21.6)	428 (46.6)	0.46 (0.36–0.60)	<0.001
Chest tube drainage, mL/24 h	690 (485–1,050)	920 (710–1,230)	$\beta = -1.58$, $t = -5.57$*	<0.001
Recovery parameters, n (%)				
Short PLOS, <5 d	161 (52.6)	350 (38.1)	1.38 (1.15–1.66)	0.001
Long PLOS, >14 d	7 (2.3)	46 (5.0)	0.46 (0.21–1.01)	0.053

*Linear regression models were used.
HCR, hybrid coronary revascularization; OR, odds ratio; PLOS, postoperative length of stay.

Long term Follow-up

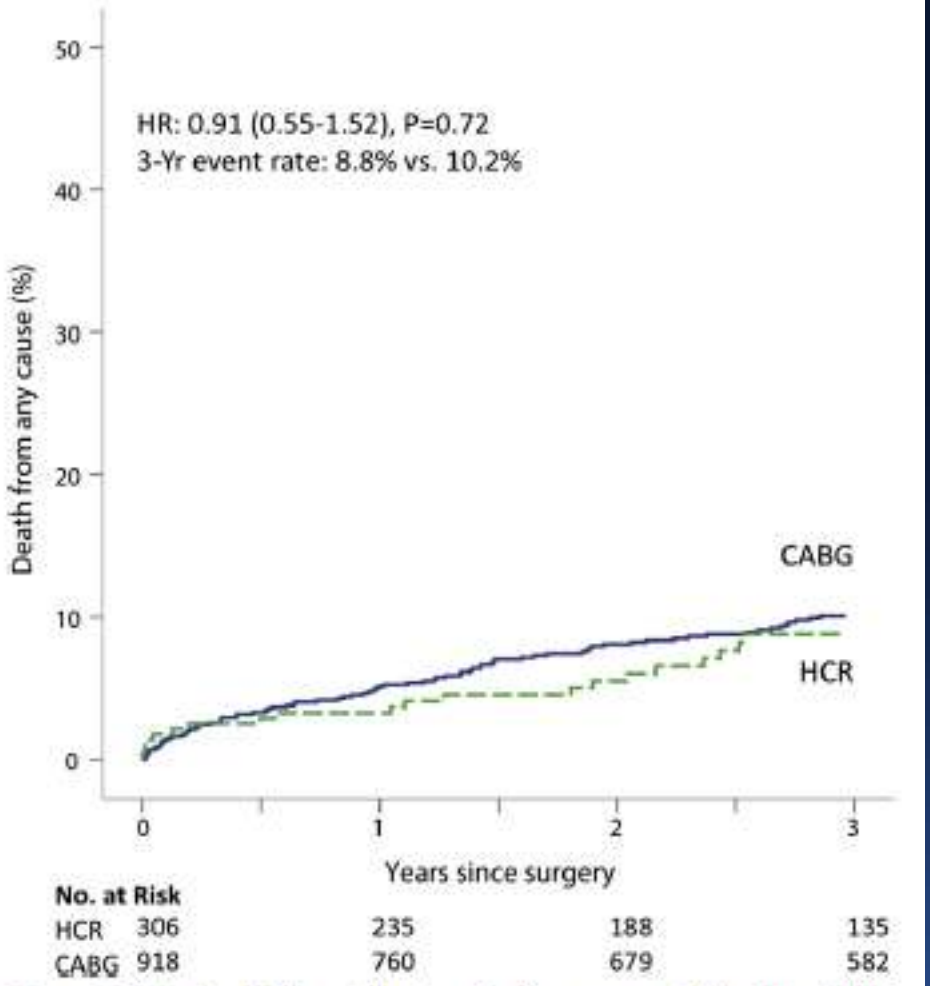

Figure 2. Kaplan-Meier estimates of all-cause mortality after hybrid coronary revascularization (HCR) vs CABG. Rates of death from any cause are truncated at 3 years after surgery. The hazard ratio was calculated using Cox modeling stratified on matched pairs. HR, hazard ratio.

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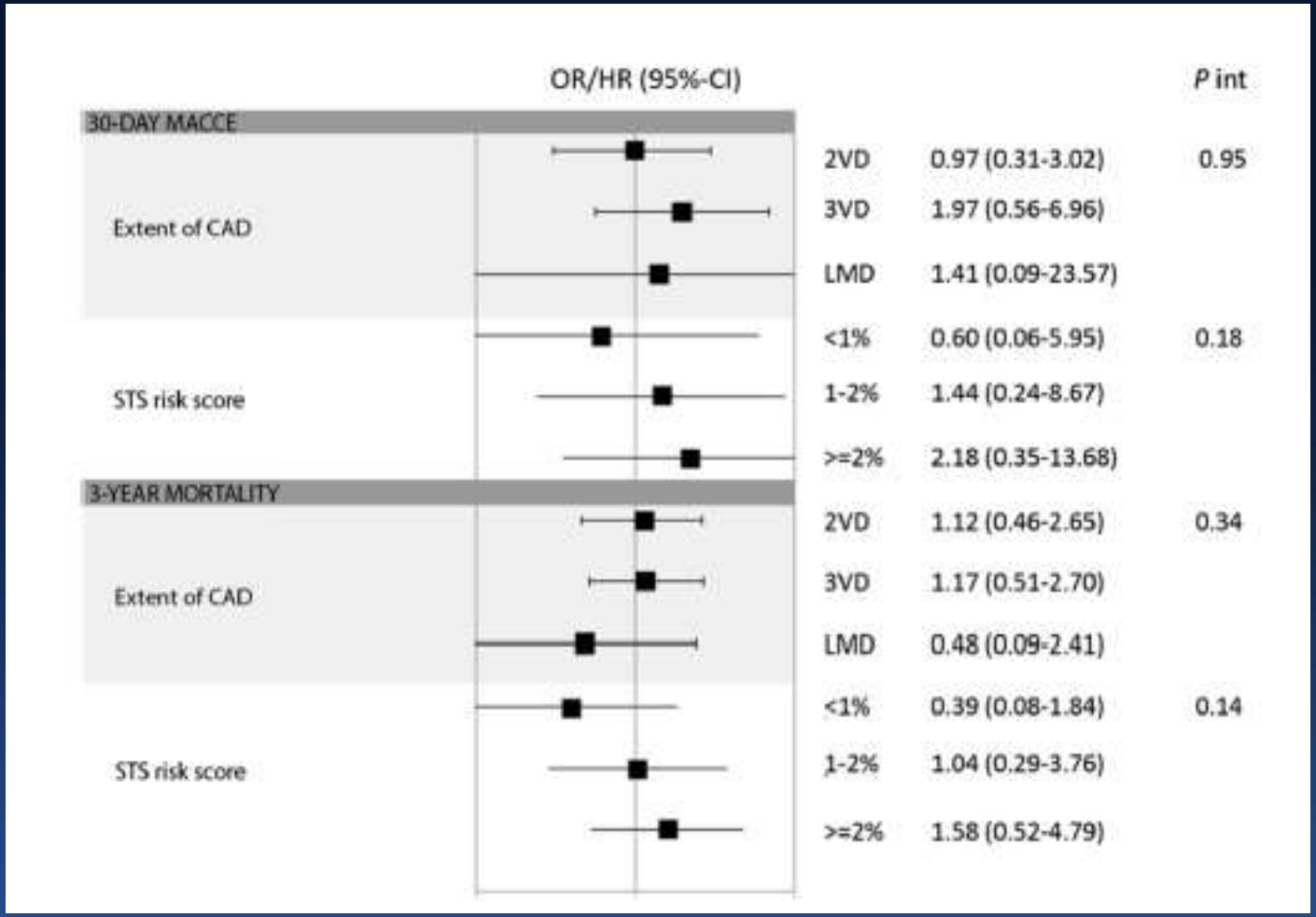
No Interaction with STS and # of diseased vessel



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Limitations

- Retrospective; Nonrandomized
- No data of lesions complexity (SxScore)
- Death attribution difficult (Hybrid; death in between staged procedure)
- No data on completeness of revascularization
- No data on stroke beyond 30 days

Conclusion

- **HYBRID revascularization can be safely performed in a selected patient population of patients with multivessel CAD**

Meta-Analysis…

Clinical outcomes after hybrid coronary revascularization versus coronary artery bypass surgery: a meta-analysis of 1,190 patients

Ralf E. Harskamp, MD,[a,b] Akshay Bagai, MD, MHS,[c] Michael E. Halkos, MD, MSc,[d] Sunil V. Rao, MD, MHS,[a] William B. Bachinsky, MD,[e] Manesh R. Patel, MD,[a] Robbert J. de Winter, MD, PhD,[b] Eric D. Peterson, MD, MPH,[a] John H. Alexander, MD, MHS,[a] and Renato D. Lopes, MD, PhD, MHS[a] *Durham, NC; Amsterdam, The Netherlands; Ontario, Canada; Atlanta, GA; and Harrisburg, PA*

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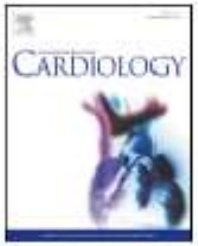


Letter to the Editor

Hybrid coronary revascularization versus coronary artery bypass surgery: Systematic review and meta-analysis☆

Kevin Phan[a,b], Sophia Wong[c], Nelson Wang[a], Steven Phan[a], Tristan D. Yan[a,b,*]

Harskamp et al. Am Heart J 2014; 167; 585-92

Phan et al. Int J Caridol 2015; 179; 484-488

8 studies, 1,664 pts

Table 1
Baseline characteristics of included studies.

First author	Year of study	Country	Study period	Number of hybrid patients	Number of CABG patients	Study design	Staging strategy
Zhou	2014	China	2007–2011	141	141	R, OS	One-stage
Bachinsky	2012	USA	2009–2011	25	27	P, OS	One-stage
Halkos[a]	2011	USA	2003–2010	147	588	R, OS	Staged: CABG first
Halkos2[b]	2011	USA	2003–2010	27	81	R, OS	Staged: CABG first
Delhaye	2010	France	2006–2008	18	18	P, OS	staged: CABG first
Zhao	2009	USA	2005–2007	112	254	R, OS	One-stage
Kon	2008	USA	2005–2006	15	30	P, OS	One-stage
de Canniere	2001	Belgium, USA	1997	20	20	R, OS	Staged: PCI first

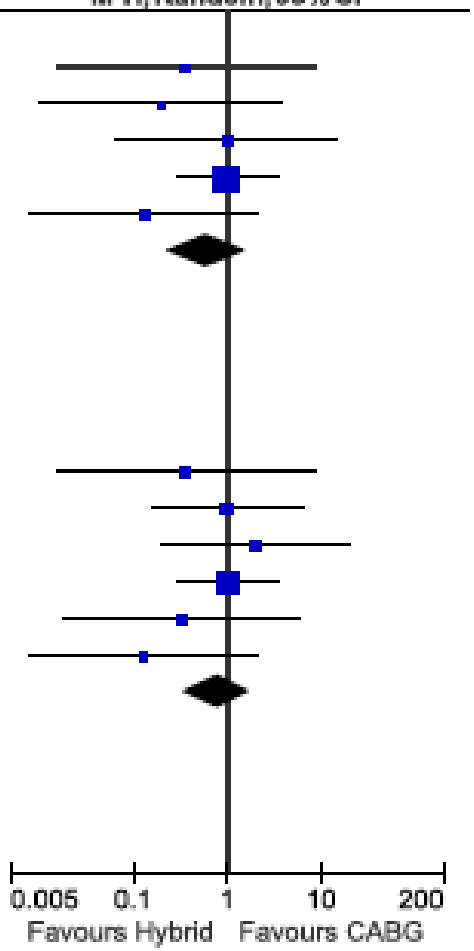
CABG, coronary artery bypass grafting; ACS, acute coronary syndrome; LVEF, left ventricular ejection fraction; R, retrospective; P, prospecti

[a] Multivessel disease only.
[b] Left main disease only.
[c] Range.

Phan et al. Int J Caridol 2015; 179; 484-488

In-Hospital and Post-op MACE; No difference

Study or Subgroup	Hybrid Events	Hybrid Total	CABG Events	CABG Total	Weight	Risk Ratio M-H, Random, 95% CI
(a) In-hospital MACCE						
Bachinsky	0	25	1	27	9.0%	0.36 [0.02, 8.43]
de Canniere	0	20	2	20	10.1%	0.20 [0.01, 3.92]
Delhaye	1	18	1	18	12.3%	1.00 [0.07, 14.79]
Halkos	3	147	12	588	57.1%	1.00 [0.29, 3.50]
Kon	0	15	7	30	11.4%	0.13 [0.01, 2.12]
Subtotal (95% CI)		**225**		**683**	**100.0%**	**0.61 [0.24, 1.58]**
Total events	4		23			
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 2.72$, df = 4 (P = 0.60); $I^2 = 0\%$						
Test for overall effect: Z = 1.01 (P = 0.31)						
(b) Postoperative MACCE						
Bachinsky	0	25	1	27	6.9%	0.36 [0.02, 8.43]
de Canniere	2	20	2	20	19.8%	1.00 [0.16, 6.42]
Delhaye	2	18	1	18	12.8%	2.00 [0.20, 20.15]
Halkos	3	147	12	588	43.6%	1.00 [0.29, 3.50]
Halkos2	0	27	4	81	8.2%	0.33 [0.02, 5.86]
Kon	0	15	7	30	8.7%	0.13 [0.01, 2.12]
Subtotal (95% CI)		**252**		**764**	**100.0%**	**0.78 [0.34, 1.78]**
Total events	7		27			
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 3.23$, df = 5 (P = 0.67); $I^2 = 0\%$						
Test for overall effect: Z = 0.60 (P = 0.55)						



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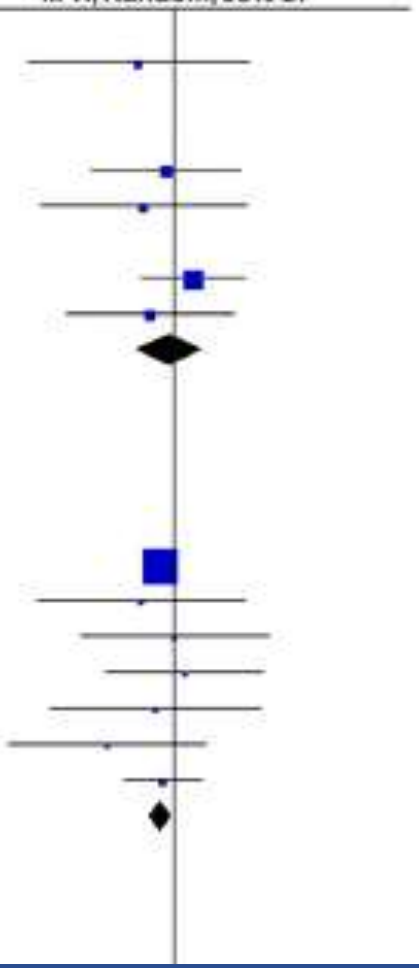
30-day Adverse Events; Hybrid Reduced MI

Study or Subgroup	Hybrid Events	Hybrid Total	CABG Events	CABG Total	Weight	Risk Ratio M-H, Random, 95% CI
(a) 30-day mortality						
Bachinsky	0	25	1	27	9.4%	0.36 [0.02, 8.43]
de Canniere	0	20	0	20		Not estimable
Delhaye	0	18	0	18		Not estimable
Halkos	1	147	5	588	20.5%	0.80 [0.09, 6.80]
Halkos2	0	27	3	81	10.9%	0.42 [0.02, 7.85]
Kon	0	15	0	30		Not estimable
Zhao	3	112	4	254	42.8%	1.70 [0.39, 7.47]
Zhou	1	141	2	141	16.4%	0.50 [0.05, 5.45]
Subtotal (95% CI)		505		1159	100.0%	0.88 [0.34, 2.33]
Total events	5		15			
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 1.56$, df = 4 (P = 0.82); $I^2 = 0\%$						
Test for overall effect: Z = 0.25 (P = 0.80)						
(b) Myocardial infarctions						
Bachinsky	15	25	24	27	84.9%	0.68 [0.48, 0.95]
de Canniere	0	15	2	30	1.2%	0.39 [0.02, 7.60]
Delhaye	1	18	1	18	1.4%	1.00 [0.07, 14.79]
Halkos	1	147	3	588	2.0%	1.33 [0.14, 12.73]
Halkos2	0	27	2	81	1.1%	0.59 [0.03, 11.83]
Kon	0	15	6	30	1.3%	0.15 [0.01, 2.48]
Zhou	5	141	7	141	8.1%	0.71 [0.23, 2.20]
Subtotal (95% CI)		388		915	100.0%	0.67 [0.49, 0.93]
Total events	22		45			
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 1.81$, df = 6 (P = 0.94); $I^2 = 0\%$						
Test for overall effect: Z = 2.43 (P = 0.01)						



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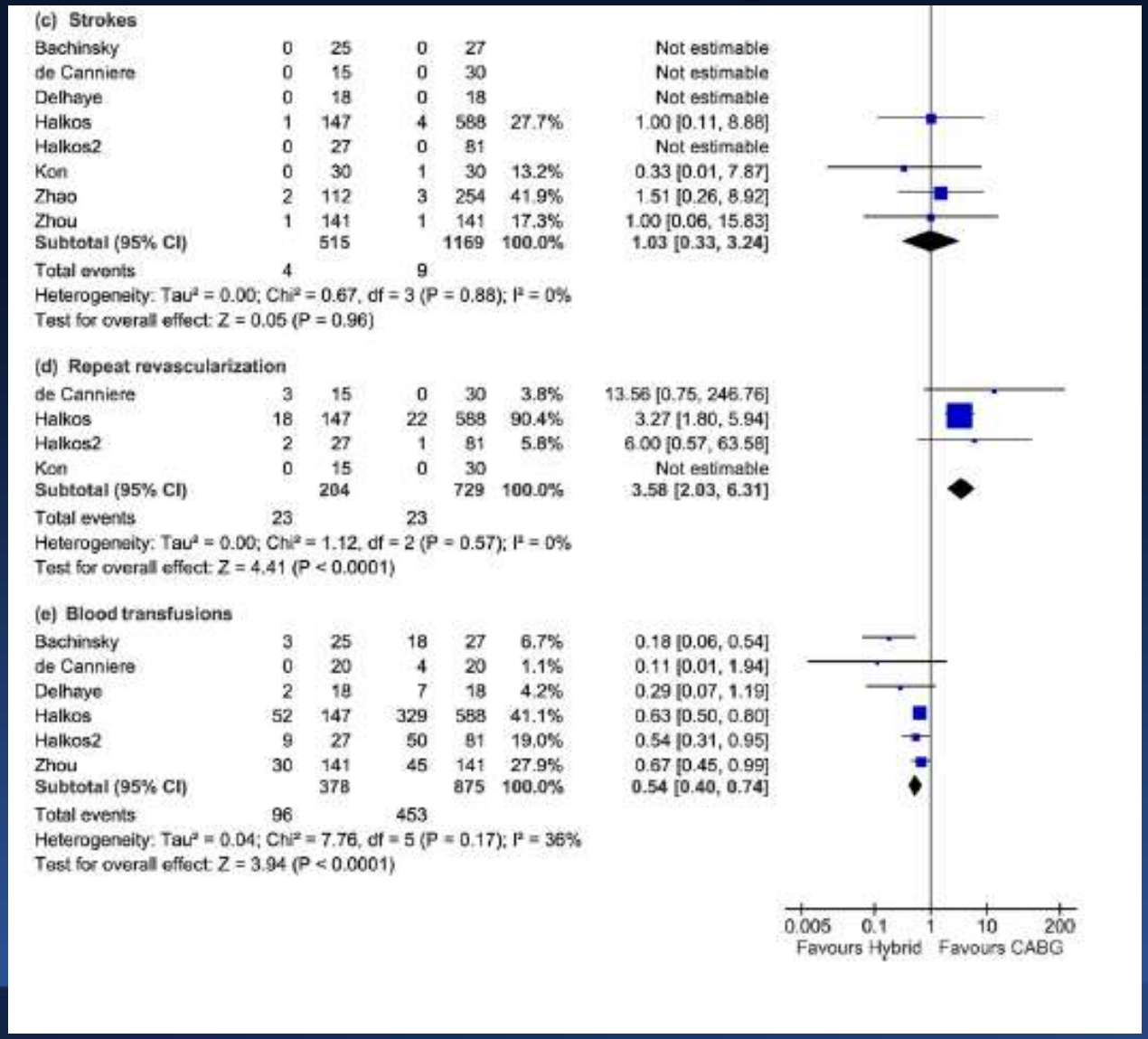
30-day Adverse Events; Hybrid: more revasc but less bleeding

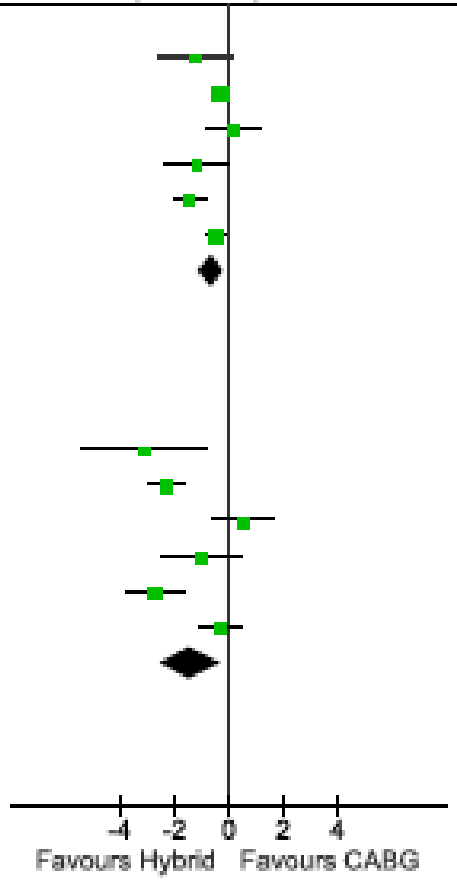


(c) Strokes						
Bachinsky	0	25	0	27		Not estimable
de Canniere	0	15	0	30		Not estimable
Delhaye	0	18	0	18		Not estimable
Halkos	1	147	4	588	27.7%	1.00 [0.11, 8.88]
Halkos2	0	27	0	81		Not estimable
Kon	0	30	1	30	13.2%	0.33 [0.01, 7.87]
Zhao	2	112	3	254	41.9%	1.51 [0.26, 8.92]
Zhou	1	141	1	141	17.3%	1.00 [0.06, 15.83]
Subtotal (95% CI)		515		1169	100.0%	1.03 [0.33, 3.24]
Total events	4		9			
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.67$, df = 3 (P = 0.88); $I^2 = 0\%$						
Test for overall effect: Z = 0.05 (P = 0.96)						
(d) Repeat revascularization						
de Canniere	3	15	0	30	3.8%	13.56 [0.75, 246.76]
Halkos	18	147	22	588	90.4%	3.27 [1.80, 5.94]
Halkos2	2	27	1	81	5.8%	6.00 [0.57, 63.58]
Kon	0	15	0	30		Not estimable
Subtotal (95% CI)		204		729	100.0%	3.58 [2.03, 6.31]
Total events	23		23			
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 1.12$, df = 2 (P = 0.57); $I^2 = 0\%$						
Test for overall effect: Z = 4.41 (P < 0.0001)						
(e) Blood transfusions						
Bachinsky	3	25	18	27	6.7%	0.18 [0.06, 0.54]
de Canniere	0	20	4	20	1.1%	0.11 [0.01, 1.94]
Delhaye	2	18	7	18	4.2%	0.29 [0.07, 1.19]
Halkos	52	147	329	588	41.1%	0.63 [0.50, 0.80]
Halkos2	9	27	50	81	19.0%	0.54 [0.31, 0.95]
Zhou	30	141	45	141	27.9%	0.67 [0.45, 0.99]
Subtotal (95% CI)		378		875	100.0%	0.54 [0.40, 0.74]
Total events	96		453			
Heterogeneity: $Tau^2 = 0.04$; $Chi^2 = 7.76$, df = 5 (P = 0.17); $I^2 = 36\%$						
Test for overall effect: Z = 3.94 (P < 0.0001)						

Phan et al. Int J Caridol 2015; 179; 484-488

Length of Stay; Benefit with Hybrid

Study or Subgroup	Hybrid Mean	Hybrid SD	Hybrid Total	CABG Mean	CABG SD	CABG Total	Weight	Mean Difference IV, Random, 95% CI
(a) ICU stay								
Bachinsky	1.19	0.58	25	2.41	3.53	27	7.6%	-1.22 [-2.57, 0.13]
de Canniere	0.84	0.075	20	1.11	0.47	20	28.0%	-0.27 [-0.48, -0.06]
Halkos	2.39	6.04	147	2.2	3.66	588	11.2%	0.19 [-0.83, 1.21]
Halkos2	1.52	1.24	27	2.68	5.01	81	9.2%	-1.16 [-2.35, 0.03]
Kon	0.98	0.42	15	2.42	1.57	30	18.9%	-1.44 [-2.04, -0.84]
Zhou	1.45	1.38	141	1.9	1.55	141	25.2%	-0.45 [-0.79, -0.11]
Subtotal (95% CI)			375			887	100.0%	-0.64 [-1.07, -0.21]
Heterogeneity: $Tau^2 = 0.16$; $Chi^2 = 17.31$, df = 5 (P = 0.004); $I^2 = 71\%$								
Test for overall effect: Z = 2.90 (P = 0.004)								
(b) Hospital stay								
Bachinsky	5.1	2.8	25	8.19	5.4	27	11.0%	-3.09 [-5.40, -0.78]
de Canniere	6.7	0.7	20	9	1.2	20	19.6%	-2.30 [-2.91, -1.69]
Halkos	6.6	6.7	147	6.1	4.7	588	17.0%	0.50 [-0.65, 1.65]
Halkos2	5.6	2	27	6.6	5.6	81	15.5%	-1.00 [-2.43, 0.43]
Kon	3.7	1.4	15	6.4	2	30	17.8%	-2.70 [-3.71, -1.69]
Zhou	8.19	2.54	141	8.49	3.53	141	19.1%	-0.30 [-1.02, 0.42]
Subtotal (95% CI)			375			887	100.0%	-1.40 [-2.52, -0.28]
Heterogeneity: $Tau^2 = 1.57$; $Chi^2 = 36.66$, df = 5 (P < 0.00001); $I^2 = 86\%$								
Test for overall effect: Z = 2.44 (P = 0.01)								



Phan et al. Int J Caridol 2015; 179; 484-488

Conclusion

- ***Hybrid*** **revascularization appears to have acceptable** ***short term mortality and complication rates similar to that of CABG, with:***
  - **Fewer myocardial infarctions**
  - **Fewer blood transfusions**
  - **Shorter hospitalization**
  - **More repeat revascularizations**

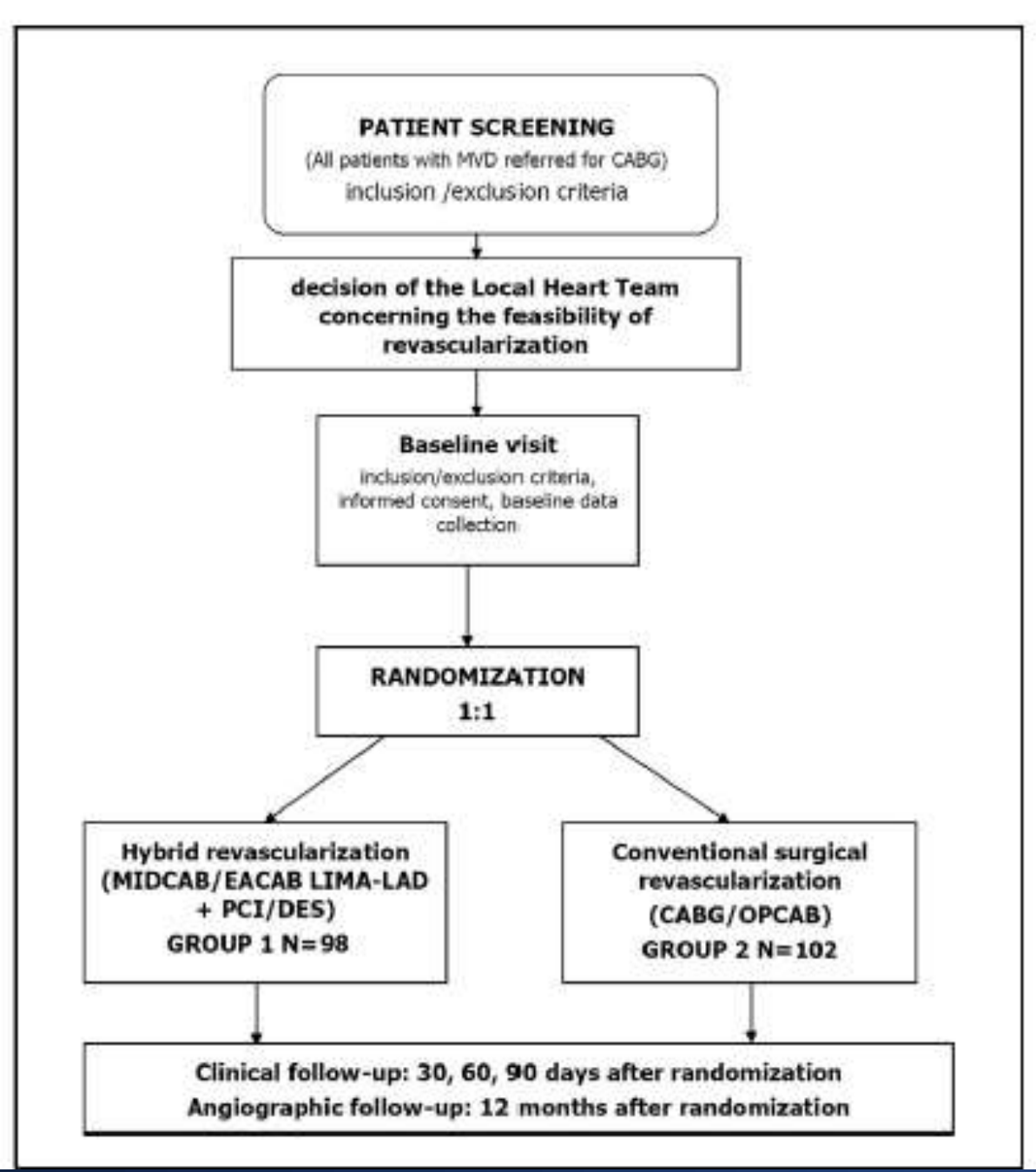
Phan et al. Int J Caridol 2015; 179; 484-488

First Pilot Randomized trial

Hybrid Revascularization for Multivessel Coronary Artery Disease

Mariusz Gąsior, MD,* Michael Oscar Zembala, MD, PhD,† Mateusz Tajstra, MD, PhD,* Krzysztof Filipiak, MD, PhD,† Marek Gierlotka, MD,* Tomasz Hrapkowicz, MD, PhD,† Michał Hawranek, MD, PhD,* Lech Poloński, MD,* Marian Zembala, MD,† on behalf of the POL-MIDES (HYBRID) Study Investigators

Gasior et al JACC Interv. 2014 2014;7:1277–83



Gasior et al JACC Interv. 2014 2014;7:1277–83

STUDY DESIGN

Hybrid revascularization – timing of the procedures and medications

- Pre-procedure
  - Aspirin 75mg/d starting at least 12h before procedure

1 stage – MIDCAB LIMA - LAD

Assessment of:
- Drainage ≤ 25ml/h within last 2 hours
- HCT > 25%; Plt >80.000

< 36 hours

- Pre-Procedure
  - Clopidogrel 600mg <2h before PCI
  - Clopidogrel 300mg <6h before PCI
- Procedural
  - Heparin initial bolus 100IU/kg i.v., ACT > 250s
- Post-procedure
  - Aspirin 75mg indefinitely
  - Clopidogrel 75 mg for 12 months

2 stage – PCI with DES

- Co-Cr everolimus eluting stents

RESULTS

ANGIOGRAPHIC CHARACTERISTICS

Variable	CABG group (n=102)	Hybrid (n=98)	P value
2 – VD (%)	46.1	45.9	0.98
3 – VD (%)	53.9	54.1	0.98
No. of lesions (mean ± SD)	3.7 ± 1.2	4.0 ± 1.4	0.16
LAD occlusion (%)	29.4	22.4	0.44
No. CTO (%)			
- RCA	6.9	6.1	0.83
- Cx	10.8	8.2	0.28
Syntax Score (mean ± SD)	***22.8 ± 5.3***	***23.4 ± 6.3***	***0.48***

Variable	CABG (n=102)	Hybrid (n=98)	P
CABG			
Total grafts (mean ± SD)	2.6 ± 0.7	1.2 ± 0.7	N/A
Arterial grafts (mean ± SD)	1.6 ± 0.9	1.1 ± 0.1	N/A
Complete arterial revascularization (%)	24.5	-	N/A
Postprocedure LIMA patency (%)		***97.8***	***N/A***
PCI			
No. treated lesions (mean ± SD)	-	2.0 ± 0.9	N/A
No. stents used (mean ± SD)	-	2.3 ± 1	N/A
Successful PCI (%)	-	92*	N/A
Overall			
Complete revascularization (%)	***78.4***	***78.6***	***0.84***
Total drainage (ml)	1168 ± 486	1018 ± 730	0.1
Time MIDCAB to PCI, h	-	21 ± 5.7	N/A
Surgery diuration, h (mean ± SD)	3.68 ± 0.9	2.5 ± 1	0.001

TABLE 2 Clinical Endpoints Occurring in the Hospital or After Discharge According to Study Group*

	CABG	HCR	p Value
In-hospital outcomes, %			
Blood transfusion	26.5	19.4	0.23
Perioperative myocardial infarction	3.9	5.1	0.69
Renal failure	0	1.0	0.98
Stroke	0	0	NA
Death	0	0	NA
Primary endpoint			
Feasibility			
Patients with complete hybrid procedure, %	—	93.9	NA
Conversion to standard CABG, %†	—	6.1	NA
Safety			
Major adverse cardiac events at 12 mo after randomization			
Death, %	2.9	2.0	0.1
Myocardial infarction, %‡	3.9	6.1	NS
Stroke, %	0	0	NA
Target vessel revascularization, %	0	2.0	NS
Major bleeding, %	2.0	2.0	NS

Gasior et al JACC Interv. 2014 2014;7:1277–83

12-Months Angiographic FU

TABLE 3 Secondary Endpoint: 12-Month Follow-Up Angiographic Measurements as Patency of Grafts and Restenosis in Revascularized Segments*

	CABG	HCR	p Value
LAD arterial graft patency, %	93†	94‡	0.74
LAD arterial graft stenosis ≥70%, %	5	1	0.36
Other grafts patency, %§	79	—	NA
Other grafts stenosis, %	2	—	NA
In-stent occlusions, %	—	5.1	NA
In-stent restenosis ≥50%, %		7.5	NA
HYBRID patency score, %‖	81	90	0.01

SVG are terrible conduits!

Gasior et al JACC Interv. 2014 2014;7:1277–83

Conclusion

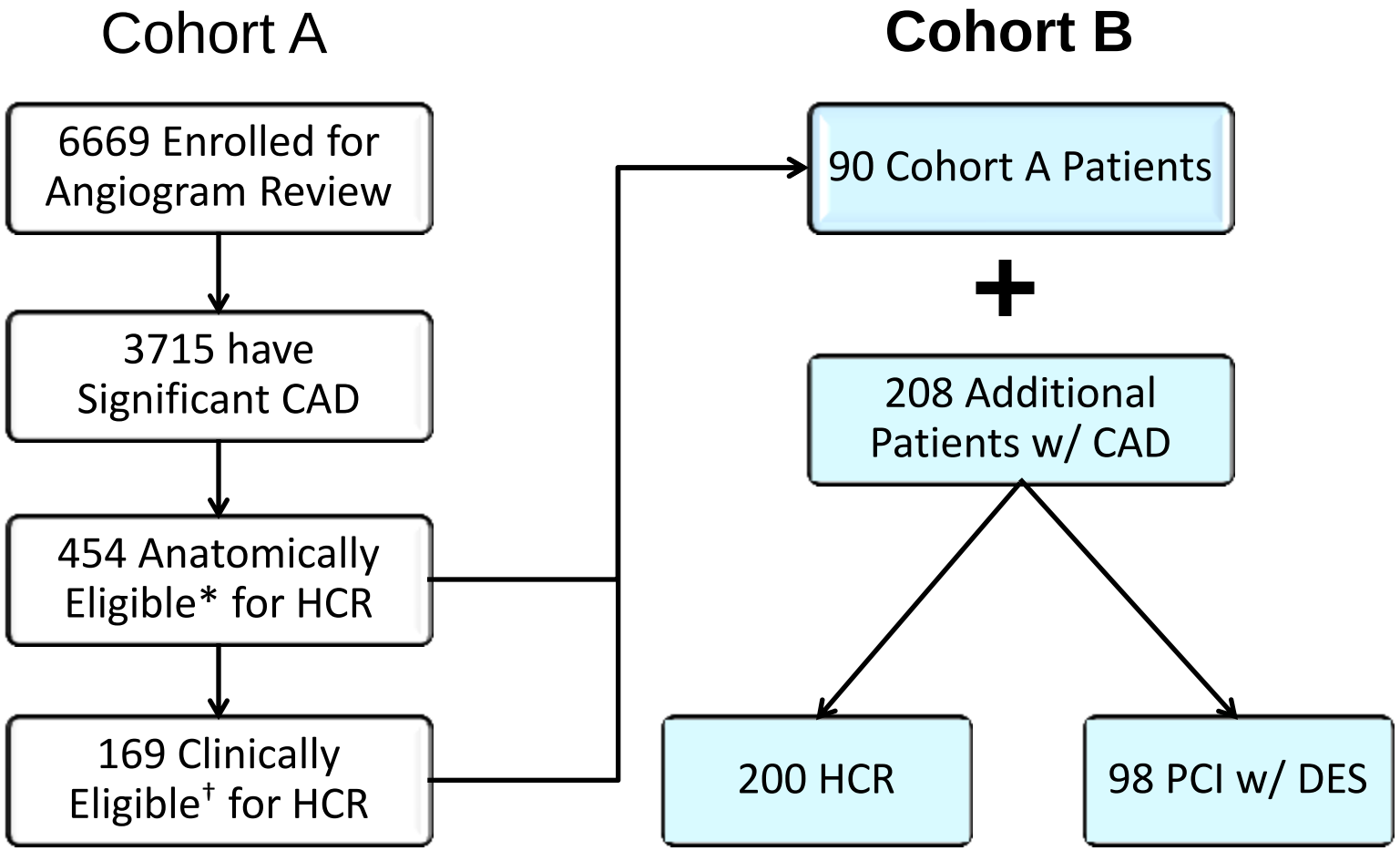
- Hybrid coronary revascularization is feasible and safe in selected population of patients with MVD
- MIDCAB as a first stage procedure in patients with MVD considered for hybrid revascularization was not associated with more adverse events
- This first randomized pilot study on hybrid coronary revascularization shows promising results supporting the idea of hybrid coronary revascularization in patients with MVD

3. Upcoming Trial

Study Background

- Prospective cohort observational study
- 11 US clinical sites
- To inform design of an RCT of HCR vs. multivessel PCI (DES)
  - Feasibility of recruitment (# anatomically eligible pts)
  - More precise characterization of population undergoing HCR
  - Variability of treatment approaches
  - Event rates (MACCE)

Study Population



*anatomical eligibility determined following angiogram review by both a surgeon and cardiologist

†clinical eligibility determined by preliminary (draft) trial inclusion/exclusion criteria

Management of HCR-Eligible Patients Across Sites

Clinical Site	HCR	PCI*
Brigham and Women's Hospital	0	1
Columbia University	3	23
Duke University Medical Center	3	5
Emory University	79	4
Lankenau Hospital	31	7
Montefiore Medical Center	26	14
Ohio State University	9	6
University of Maryland Medical Center	36	6
University of Pennsylvania	9	26
University of Virginia Health System	2	4
Vanderbilt University Medical Center	2	2
Total	**200**	**98**

- Median follow-up post-revasc 17.6 ± 6.5 months
- Analysis included 339.8 person-years at risk

*All anatomically & clinically eligible for HCR

Coronary Anatomy

	HCR n=200	PCI n=98
CAD		
Single Vessel	13.2	11.1
Double Vessel	58.8	54.3
Triple Vessel	27.5	34.0
Diseased Vessels		
LM	18.7	6.8
Proximal LAD	69.9	52.0
Mid/distal LAD	43.3	72.0
Circumflex Distribution	51.0	50.6
Ramus	9.1	8.2
RCA distribution	61.2	67.7
SYNTAX Score	18.4 (9.0)	17.2 (9.6)

*Missing data: HCR pts = 17, PCI pts = 9

Procedure Staging

	HCR n=200 N (%)	PCI n=98 N (%)
Hybrid Procedures: Staging of Surgery and Initial PCI		
Surgery followed by PCI	110 (55.0)	2 (2.0)
PCI followed by surgery	43 (21.5)	0 (0.0)
Simultaneous surgery and PCI	24 (12.0)	0 (0.0)
Surgery only	16 (8.0)	0 (0.0)
Surgery and PCI completed on same day (order unknown)	7 (3.5)	0 (0.0)
PCI-Only Procedures Staging		
Single PCI Procedure	0 (0.0)	63 (64.3)
Two PCI Procedures	0 (0.0)	30 (30.6)
Three PCI Procedures	0 (0.0)	3 (3.1)

HCR: Type of Surgical Procedure

	N	% of Total
Endo-ACAB	108	54.0
Mid-CAB	38	19.0
TECAB	42	21.0
Sternotomy (planned)	12	6.0
Total	200	100.0

MACCE Rate at 12 months

	HCR (n=200)		PCI (n=98)		**Risk-adjusted Hazard Ratio (95% CI)**
	N	Observed Rate Per Person Yr	N	Observed Rate Per Person Yr	
Any MACCE	23	0.143	10	0.119	1.063 (0.666,1.697)
Death	3	0.017	1	0.011	
Myocardial Infarction	4	0.024	3	0.034	
Stroke	5*	0.03	0	0	
Revascularization	14	0.085	8	0.094	

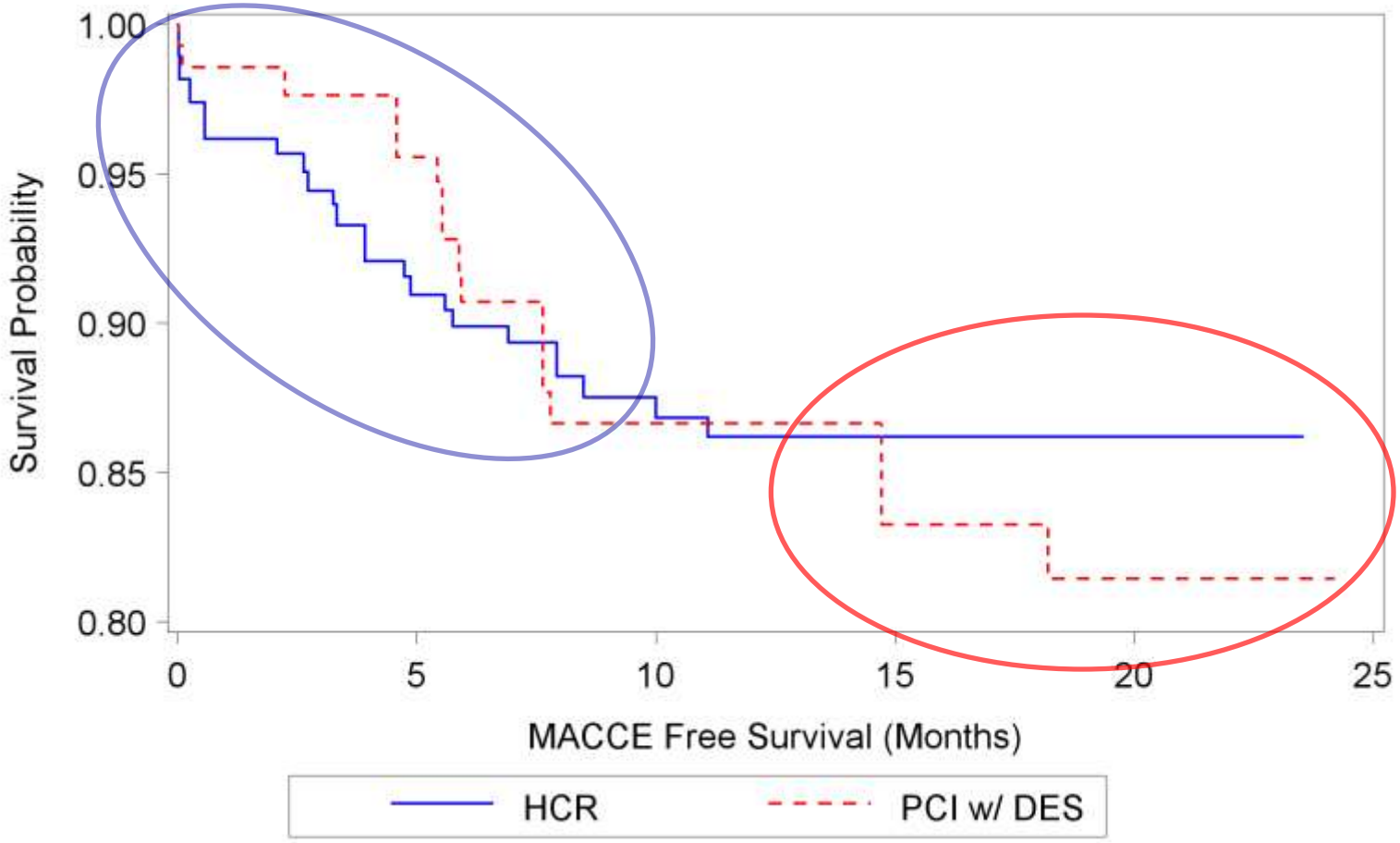
*Strokes occurred 2.0, 2.5, 4.6, 6.0 and 6.9 (mean 4.4) months after last stage of HCR.

MACCE Over Total Study Period

(17.6 ± 6.5 months mean follow-up)

	HCR (n=200)		PCI (n=98)		**Risk-adjusted Hazard Ratio (95% CI)**
	N	Observed Rate Per Person Yr	N	Observed Rate Per Person Yr	
Any MACCE	23	0.103	12	0.103	0.868 (0.556,1.355)
Death	3	0.012	2	0.016	
Myocardial Infarction	4	0.017	3	0.024	
Stroke	5	0.021	0	0	
Revascularization	14	0.061	10	0.084	

Risk-Adjusted MACCE-Free Survival Analysis



Conclusions

- MACCE rates
  - 12 months: Similar
  - Over approx 18 months total f/u: Risk-adjusted MACCE rates diverging

- Equipoise exists for rigorous comparative effectiveness trial

4. Remaining Issues

REVIEW TOPIC OF THE WEEK

Panoulas et al. JACC 2015; 65; 85-97

Hybrid Coronary Revascularization

Promising, But Yet to Take Off

Vasileios F. Panoulas, MD, PhD,*†‡ Antonio Colombo, MD,*† Alberto Margonato, MD,* Francesco Maisano, MD§

Current evidence suggests that HCR is feasible and safe for a particular target group (just over 60 years of age; mainly stable, CAD favorable anatomy; intermediate risk and SYNTAX scores; and preserved or mildly impaired left ventricular ejection fraction) with acceptable midterm outcomes that are noninferior to conventional CABG. However, data for higher-risk groups, who would theoretically benefit the most from HCR, are weak or lacking; hence, no inferences or generalizations can be made regarding the role of HCR in these patients. It is now in the hands of the scientific community and health managers to identify patients who would benefit the most and find ways to make HCR a cost-effective procedure for both hospitals and societies. If these goals are not achieved, HCR will remain a very reasonable, yet rarely implemented, revascularization option.

One-Stop Hybrid Coronary Revascularization Versus Coronary Artery Bypass Grafting and Percutaneous Coronary Intervention for the Treatment of Multivessel Coronary Artery Disease

3-Year Follow-Up Results From a Single Institution

Liuzhong Shen, MD,*† Shengshou Hu, MD,*† Haoran Wang, MD,*† Hui Xiong, MD,*† Zhe Zheng, MD,*† Lihuan Li, MD,‡ Bo Xu, MD,§ Hongbing Yan, MD,§ Runlin Gao, MD§

Beijing, China

Mean Sx Score ~27; EuroSCORE ~3.2

CABG (n=141) vs. PCI (n=141) vs. Hybrid (n=141)

Stratified by Sx score and EuroSCORE

Shen et al. J Am Coll Cardiol 2013;61:2525–33

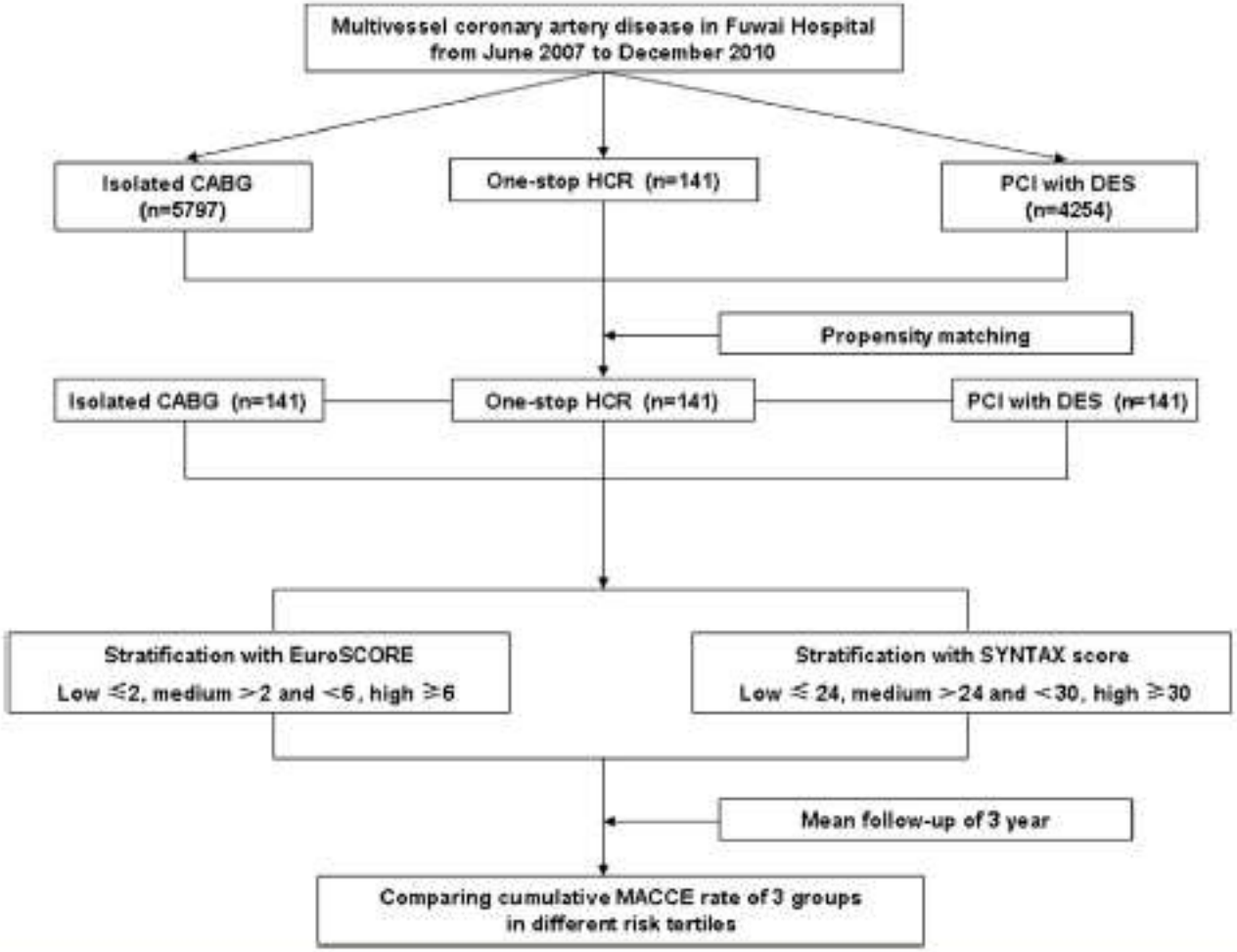


Figure 1 **Flowchart of the Study Design**

CABG = coronary artery bypass grafting; DES = drug-eluting stent(s); EuroSCORE = European System for Cardiac Operative Risk Evaluation score; HCR = hybrid coronary revascularization; MACCE = major adverse cardiac or cerebrovascular event(s); PCI = percutaneous coronary intervention; SYNTAX = Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery.

~3-Year MACCE

Table 5 MACCE in the Hybrid, CABG, and PCI Groups

	Hybrid	CABG	PCI	p Value
Death	1	4	5	0.344
Myocardial infarction	0	3	6	0.062
Neurologic event	2	9	3	0.083
Repeat revascularization	6	3	18	<0.001
Any MACCE	9	19	32	0.003
Follow-up time, mean, yrs	2.9	3.2	3.0	

Shen et al. J Am Coll Cardiol 2013;61:2525–33

Cumulative MACCE

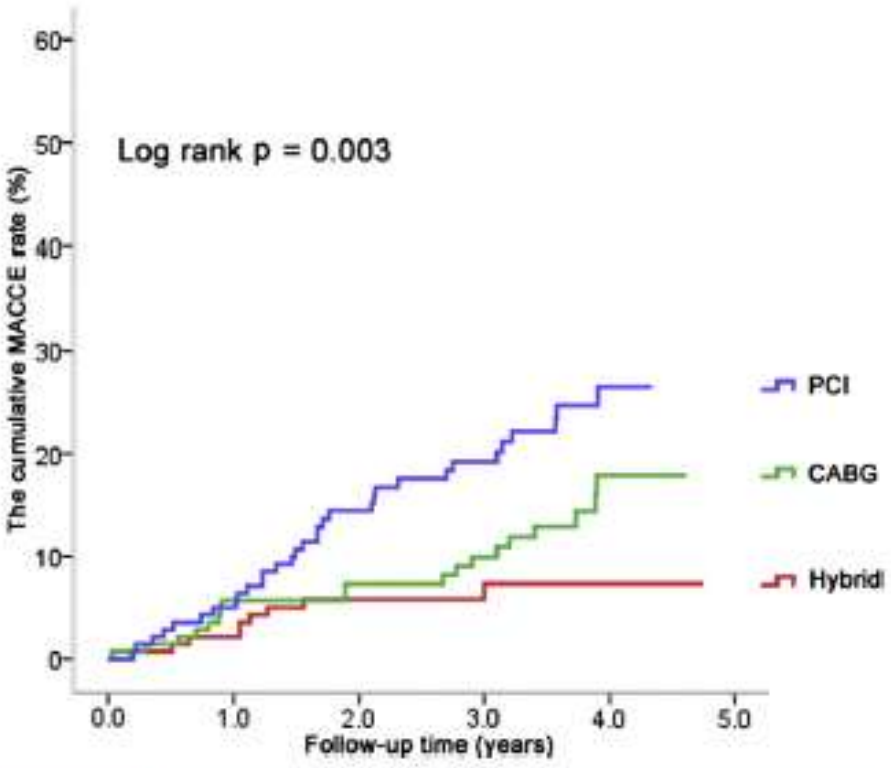


Figure 2 **The Cumulative MACCE Rate in Hybrid, CABG, and PCI Groups**

The cumulative MACCE rate in the hybrid group (6.4%) was significantly lower than that in the PCI group (22.7%; $p < 0.001$), but similar to that in the CABG group (13.5%; $p = 0.140$). Abbreviations as in Figure 1.

Shen et al. J Am Coll Cardiol 2013;61:2525–33

Hybrid performed well in all EuroSCORE groups

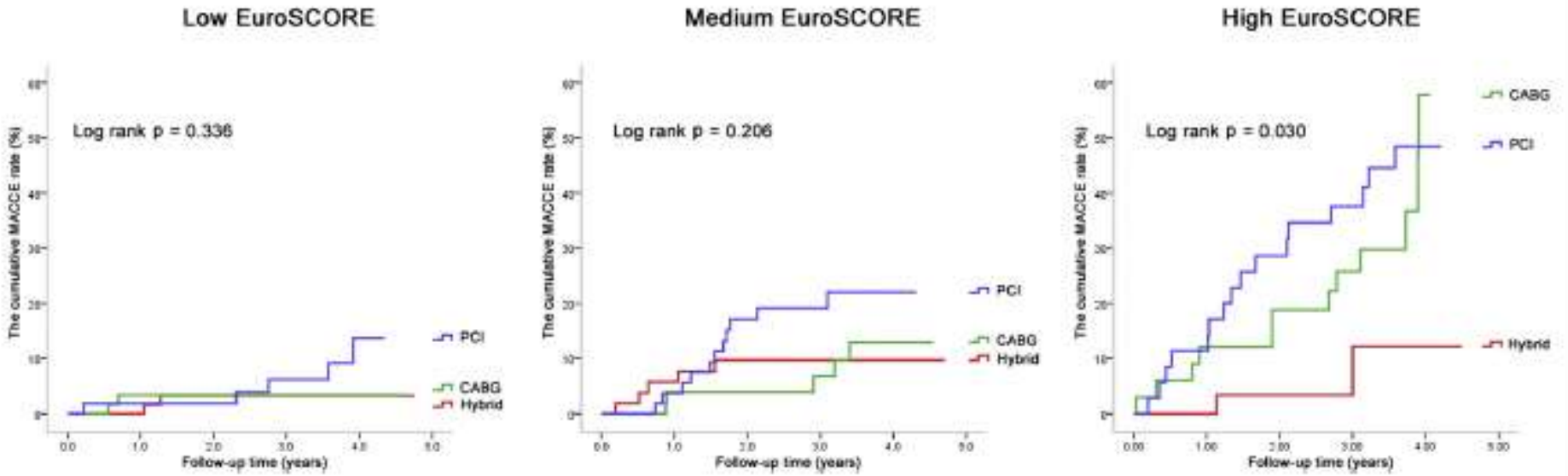


Figure 3 **The Cumulative MACCE Rate in the Hybrid, CABG, and PCI Groups From Low to High EuroSCORE Tertile**

In the low and medium European System for Cardiac Operative Risk Evaluation score (EuroSCORE) tertiles, the 1-stop HCR group had a MACCE rate similar to those in the CABG ($p = 0.959$ and $p = 0.914$, respectively) and PCI groups ($p = 0.352$ and $p = 0.172$, respectively). In the high EuroSCORE tertile, the MACCE rate in the hybrid group was significantly lower than those in the CABG ($p = 0.030$) and PCI groups ($p = 0.006$). Abbreviations as in Figure 1.

Shen et al. J Am Coll Cardiol 2013;61:2525–33

Benefit of Hybrid in High SYNTAX?

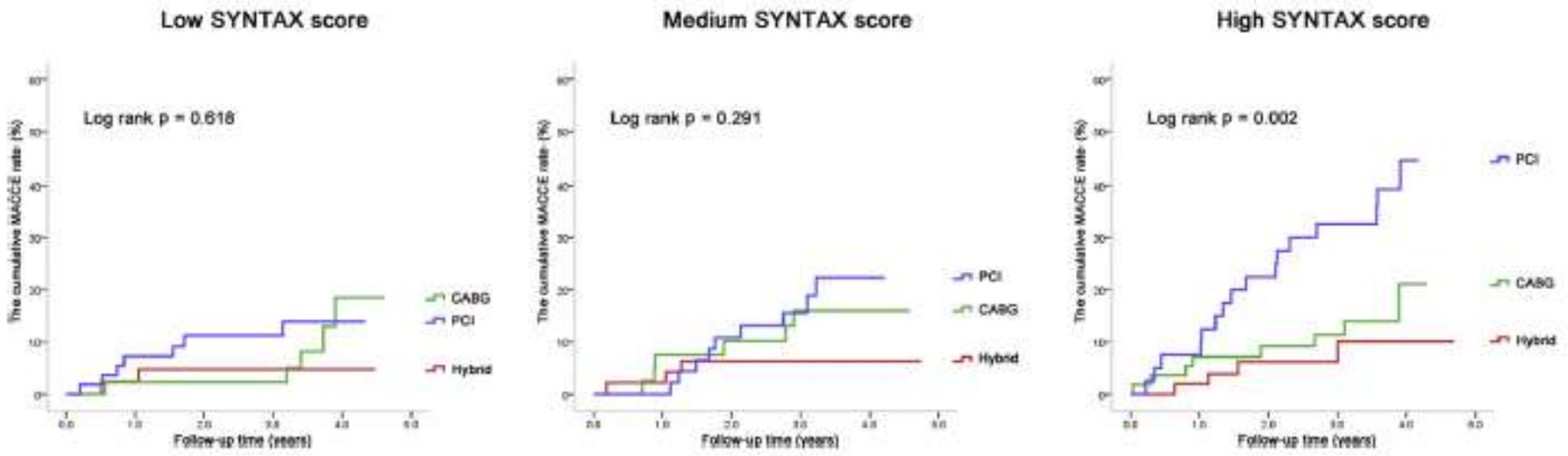


Figure 4 **The Cumulative MACCE Rate in Hybrid, CABG, and PCI Groups From Low to High SYNTAX Score Tertile**

In the low and medium SYNTAX score tertiles, the MACCE rate in hybrid group was similar to those in the CABG ($p = 0.703$ and $p = 0.254$, respectively) and PCI groups ($p = 0.224$ and $p = 0.114$, respectively). In the high SYNTAX tertile, 1-stop HCR had lower MACCE rate than that with PCI ($p = 0.002$), but similar to that with CABG ($p = 0.362$). Abbreviations as in Figure 1.

Shen et al. J Am Coll Cardiol 2013;61:2525–33

Remaining Issues:

Timing and Setting

CENTRAL ILLUSTRATION **Advantages and Disadvantages of Simultaneous and Staged HCR Procedures**

ONE STAGE (SIMULTANEOUS)	TWO-STAGE HCR	
MID-CAB followed by PCI within minutes	MID-CAB 1st, then PCI	PCI 1st, then MID-CAB
Advantages • LIMA-LAD graft can be studied by the interventional cardiologist before PCI stent implantation • PCI to high-risk non-LAD lesions can be performed with a protected LAD area • In cases of unsuccessful stent implantation, conventional CABG remains an option • Cost effective, as it reduces hospital length of stay (single-step complete revascularization) • Patient satisfaction: condenses revascularization therapy in one patient encounter	**Advantages** • Allows angiographic validation of the LIMA-LAD graft • Full antiplatelet inhibition following CABG with no perioperative bleeding risk • Protected anterior wall, lowering procedural risks during PCI of non-LAD vessels • On some occasions, after minimally invasive LIMA to LAD, patients become asymptomatic in the immediate post-operative period	**Advantages** • Allows angiographic evaluation of the size of LIMA • Lower risk of ischemia during the MID-CAB in a partially revascularized heart • Useful in the setting of acute myocardial infarction when culprit is a non-LAD lesion • In cases of unsuccessful stent implantation, suboptimal CABG can be performed
Disadvantages • Only feasible in hybrid suites, featuring state-of-the-art surgical and interventional equipment • Inflammatory response to surgery offers a risk for stent thrombosis • Dual antiplatelet therapy increases the risk of bleeding • Chronic kidney disease patients are exposed to the dual nephrotoxic insult of surgery and contrast media utilization	**Disadvantages** • Risk of ischemia of non-LAD territories during the LIMA-LAD grafting (although this is very unlikely in stable patients) • Risk of a high-risk surgical reintervention in case of an unsuccessful PCI	**Disadvantages** • No angiographic control of LIMA-LAD graft • Higher risk of stent thrombosis during surgery (due to inflammatory response to surgery/discontinuation of dual antiplatelet therapy/platelet transfusion) • Increased perioperative bleeding risk due to dual antiplatelet therapy during surgery • Risk of adverse events in the LAD territory during the between-stages interval

Panoulas et al. JACC 2015; 65; 85-97

Conclusion

- Hybrid Revascularization has been shown to be ***feasible and safe*** in highly selected patients; decreased bleeding, reduced LOS, decreased stroke compared to CABG
- Whether the use of ***routine Hybrid Revascularization*** when facing multivessel disease will improve outcomes compared to ***routine CABG or PCI*** (specially 2nd or next generations DES) remains to be demonstrated
- Hybrid Revascularization may been an interesting strategy in specific patients with high-risk anatomy

Conclusion

- The most appropriate timing, setting, and pharmacology remains to be established
- Cost-effectiveness remains to be established (Robot, hybrid room, vs. LOS) compared to both PCI and CABG