Hybrid Coronary Revascularization: is it prime time?

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[redacted]

Case Presentation (1)

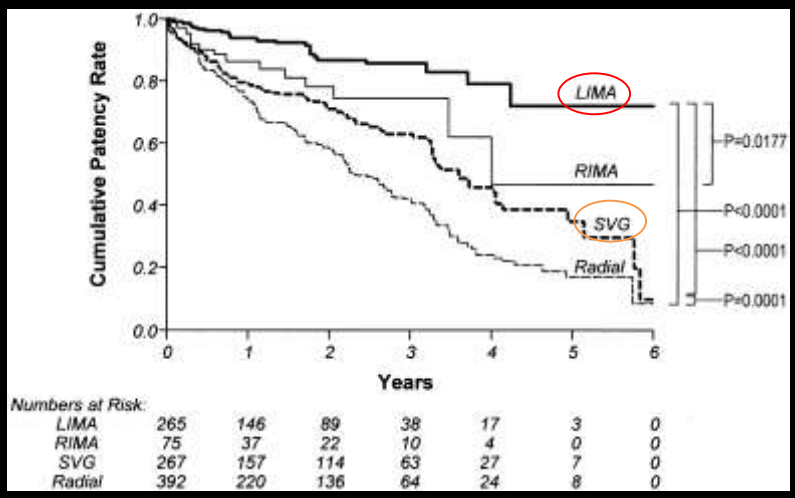
- Mr. TF, 78 yo, male, presented with two month H/O progressive exertional chest pain, radiated to left arm. He denies SOB, DOE, palpitation, or syncope.
- Stress nuclear study showed TID and mild anterior wall reversible defect. Stress EKG developed diffuse ST depression in anterior and lateral leads 3 min into stress test.
- PMH: HTN, DM, Hypothyroidism, remote H/O colon Ca

Case Presentation (2)

- Cath showed:
  - 90% stenosis in proximal LAD
  - 90% stenosis in proximal LCX leads to two large OMs
  - 70% proximal RCA and 90% mid PDA
  - SYNTAX Score: 27
  - EF 55%. Wall motion is normal
  - LVEDP 16 mmHg

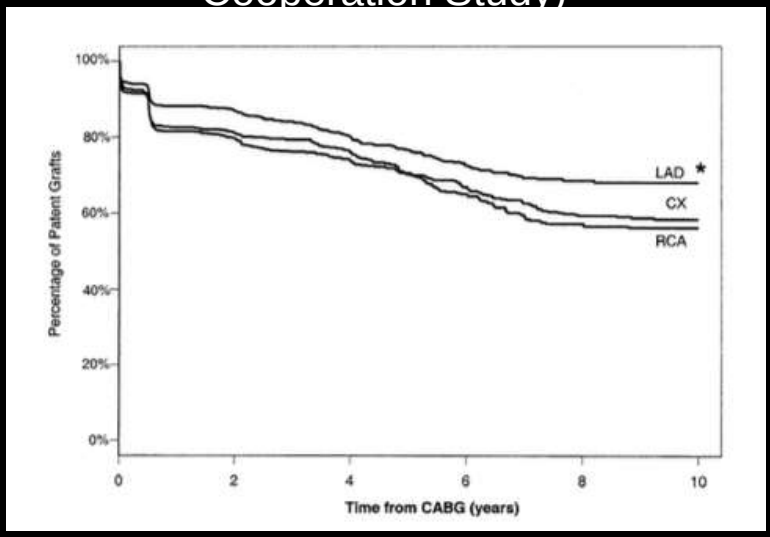
Kaplan-Meier curves of cumulative rates according to type of bypass graft

CABG: Long Term Graft Patency



Khot, U. N. et al. Circulation 2004;109:2086-2091

Long Term Patency of SVG by Vessels (VA Cooperation Study)



JACC 2004;44:101(

Can We Improve Revascularization Outcomes Beyond CABG and PCI: Hybrid Revascularization

LIMA Best → **DES Better** → **SVG Good**

LIMA Best

SVG Good

Uncoupling LIMA from SVG

Better

nventional

BARI
SYNTAX
CARDIA

LIMA Best

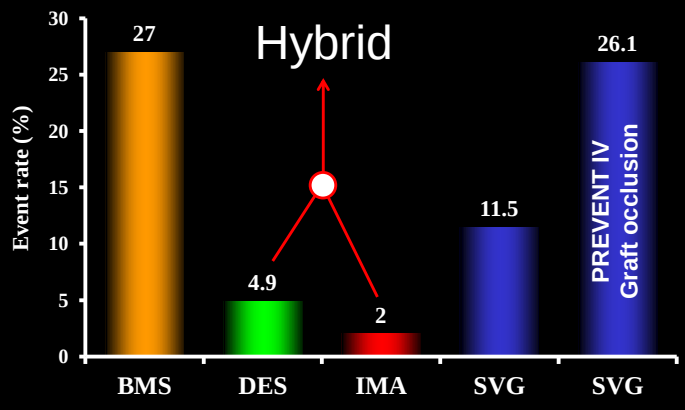
DES Better

SVG Good

Hybrid

RCT?

CABG versus PCI in DES Era



BARI, SIRIUS, TAXUS, ENDEVOR, SPIRIT, & PREVENT IV T

Hybrid Coronary Revascularization

EDITORIAL

Standardizing definitions for hybrid coronary revascularization

Ralf E. Harskamp, MD,[a,e] Johannes O. Bonatti, MD,[b] David X. Zhao, MD, PhD,[c] John D. Puskas, MD,[d] Robbert J. de Winter, MD, PhD,[e] John H. Alexander, MD, MHS,[a] and Michael E. Halkos, MD[f]

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TABLE I. Currently used definitions for hybrid coronary revascularization

Guideline/registry	Definition
2011 ACCF/AHA/SCAI Guidelines for PCI, 2011 ACCF/AHA Guidelines for CABG[11,12]	The planned combination of LITA-LAD artery grafting and PCI of ≥1 non-LAD coronary arteries. Hybrid coronary revascularization may be performed in a hybrid suite in a single operative setting or as a staged procedure (PCI and CABG performed in 2 different operative suites, separated by hours to 2 d, but typically during the same hospital stay).
2010 ESC/EACTS Guidelines on Myocardial Revascularization[10]	Planned, intentional combination of CABG, with a catheter-based intervention to other coronary arteries during the same hospital stay. Procedures can be performed consecutively on a hybrid operating room or sequentially on separate occasions in the conventional surgical and PCI environments.
STS Adult Cardiac Registry National Database (version 2.73)[9]	*A hybrid procedure* is defined as a procedure that combines surgical and transcatheter interventional approaches: (1) planned, concurrent is performed in same setting; (2) planned, staged is performed in the same hospital admission; (3) unplanned is performed after incomplete revascularization or graft closure during the same hospital admission.
NCDR CathPCI Registry (version 4.4)[13]	Hybrid therapy occurs when both surgical and percutaneous coronary revascularization are planned, with different lesions treated with the different techniques.
Clinicaltrials.gov (definitions by registered studies)	Minimal invasive LITA-to-LAD and PCI of non-LAD lesions. Procedures can be performed either in the same operating suite or during the same hospitalization

Definition of HCR

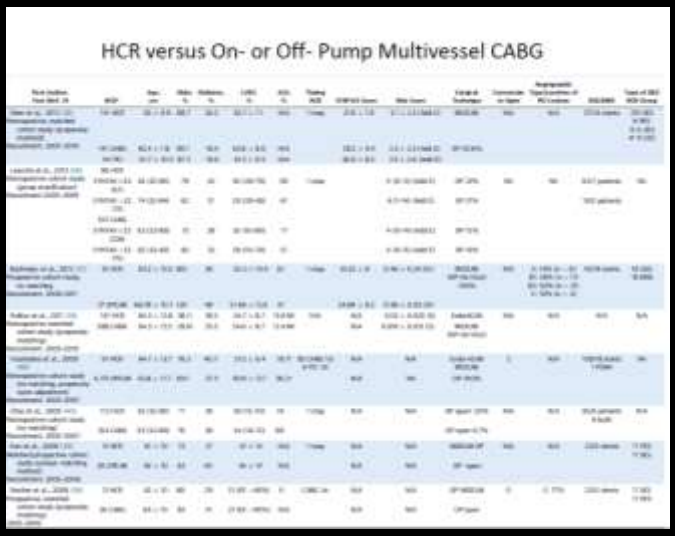
Hybrid Coronary Revascularization:

Planned combination of surgical and percutaneous techniques in two different coronary territories, both scheduled and performed within a predefined time period in a patient with multi-vessel coronary artery disease

Hybrid CV Procedures
Multiple Potential Achilles' Heels

- Bleeding
  - –P2Y12 inhibitors
- Stent thrombosis
  - –Protamine reversal
- Catheter related complication
  - –Retroperitoneal hematomas, strokes, etc
- Infectious complications
  - –Multiple moving parts and more traffic
- Renal complications
  - –Nephrotoxic contrast
- Added time and cost
  - –Is it worth it?

Current Data on HCR



Since 1996 multiple single centers' experience for a total of >3000 patients treated with HCR. CABG was performed before PCI in one half of HCR procedures, PCI was performed first in 26% and one stop/combined procedure was the least popular choice (22.8%).

Ann Thorac Surg 2011;92:215

Single vs Two Stage of HCR

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

JACC 2015;65:85-9

CABG versus "One Stage" Hybrid Post-Op Clinical Outcomes

Variables	CABG N=254	Hybrid N=112	P value
New Stroke	3 (1.1%)	2 (1.7%)	0.48
New atrial fibrillation	61 (24%)	22 (19%)	0.21
New intra-aortic balloon pump	7 (3%)	6 (5%)	0.17
Intra-stent thrombosis	N/A	1 (1%)	N/A
New low cardiac output syndrome	5 (1.9%)	5 (4.5%)	0.15
Deep sternal wound infection	3 (1%)	2 (1.8%)	0.48
Operative mortality	4 (1.5%)	3 (2.6%)	0.33

Zhao et al, JACC 2009;53:232-24.

CABG versus "One Stage" Hybrid Post-Op Renal Function

Variables	CABG N=254	Hybrid N=112	P value
Median Creatinine @ 24 hours (mg/dL)	0.9 (0.3-12.1)	0.9 (0.4-5)	0.90
Median Creatinine @ 48 hours (mg/dL)	1 (0.4-12.3)	1 (0.3-5.9)	0.78
Median Creatinine @ 72 hours (mg/dL)	1 (0.3-13.2)	1 (0.4-4)	0.58
New acute renal failure*	10 (3.9%)	3 (2.6%)	0.39
25% increase in creatinine@72 hours	89 (35%)	37 (33%)	0.40
New renal failure requiring hemodialysis	3 (1%)	0 (0%)	0.33

Zhao et al, JACC 2009;53:232-24.

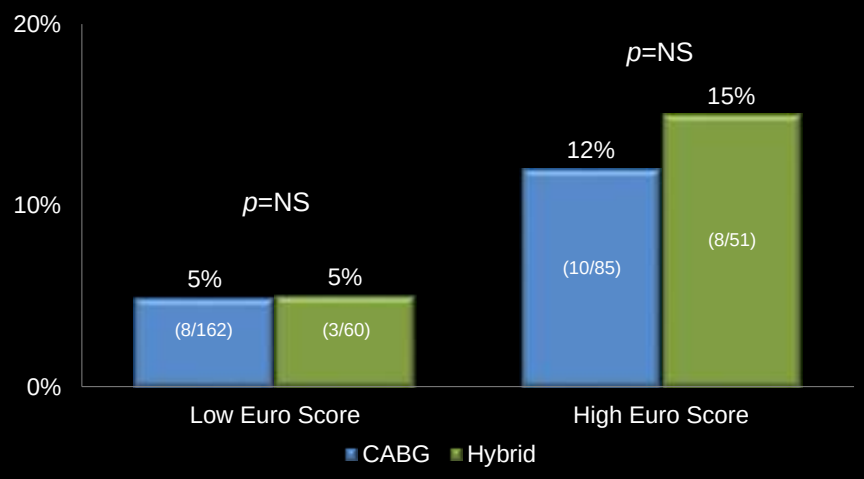
CABG versus "One Stage" Hybrid Post-Op Bleeding Complication

Variables	CABG N=254	Hybrid N=112	P value
Median chest tube drainage (L)	1.3±1.8	1.5±2.1	0.18
Reoperation for bleeding	7 (3%)	3 (3%)	0.63
Median PRBC transfusions (units) @ 48h	1 (0-20)	1 (0-10)	0.13

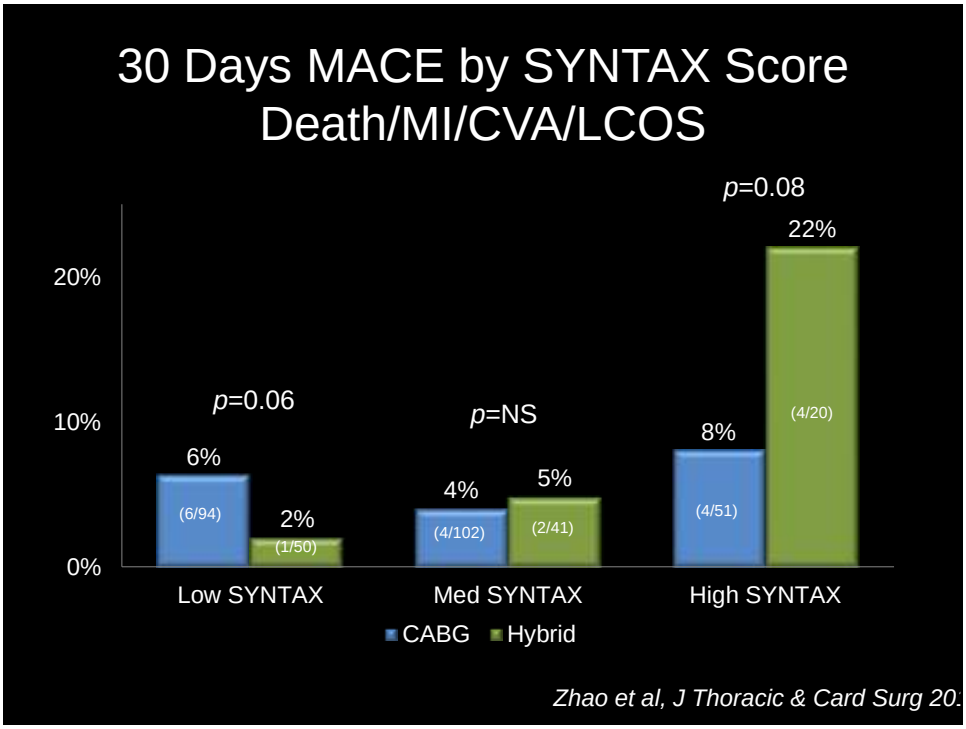
- ASA 81mg
- Plavix 300mg loading before induction
- Heparin 70U/Kg with ACT ~250 for PCI (PCI before CABG in 96% cases)
- Additional Heparin to reach ACT 400 when CABG starts
- Protamine to reverse ACT to ~150

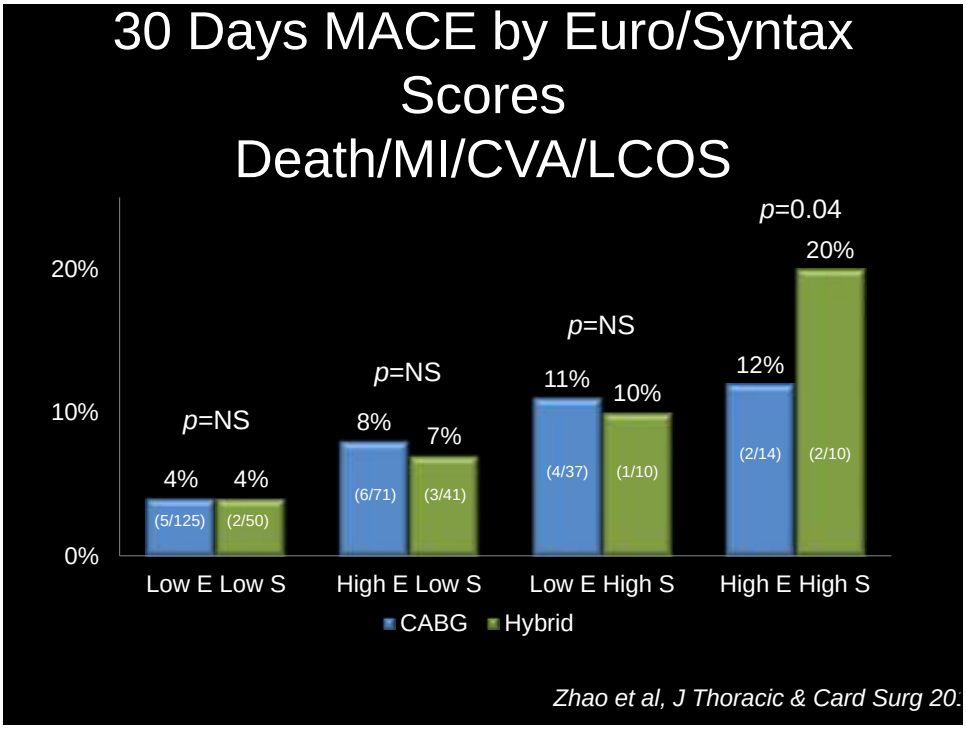
Zhao et al, JACC 2009;53:232-24

30 Days MACE by Euro Score Death/MI/CVA/LCOS

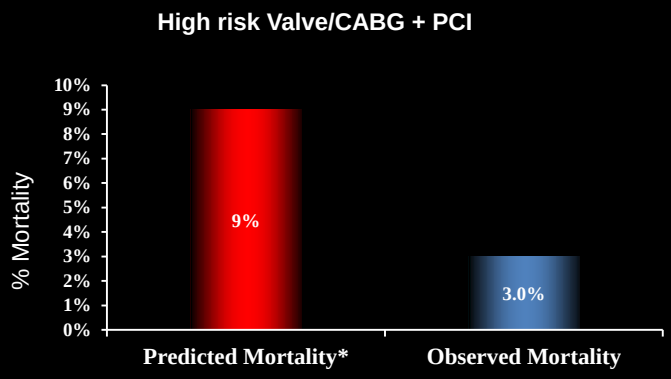


Zhao et al, J Thoracic & Card Surg 20:


30 Days MACE by SYNTAX Score
Death/MI/CVA/LCOS
20%
10%
0%
p=0.06
6%
(6/94)
2%
(1/50)
p=NS
4%
(4/102)
5%
(2/41)
p=0.08
8%
(4/51)
22%
(4/20)
Low SYNTAX
Med SYNTAX
High SYNTAX
CABG
Hybrid
Zhao et al, J Thoracic & Card Surg 20


30 Days MACE by Euro/Syntax Scores
Death/MI/CVA/LCOS
20%
10%
0%
p=NS
4%
(5/125)
4%
(2/50)
p=NS
8%
(6/71)
7%
(3/41)
p=NS
11%
(4/37)
10%
(1/10)
p=0.04
12%
(2/14)
20%
(2/10)
Low E Low S
High E Low S
Low E High S
High E High S
CABG
Hybrid
Zhao et al, J Thoracic & Card Surg 20

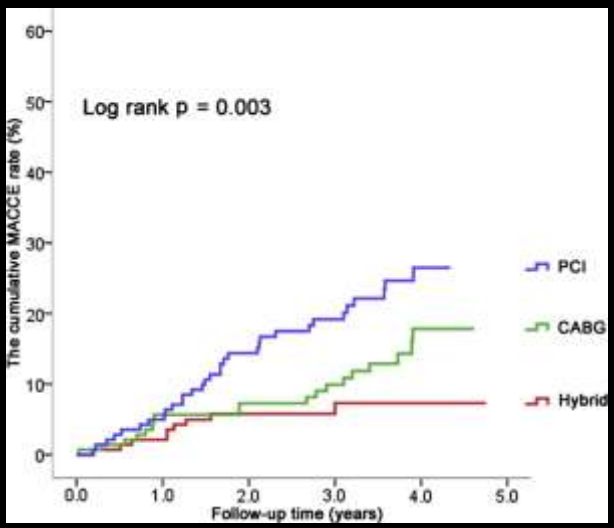
Hybrid Cardiac Intervention Improves Clinical Outcomes in High Risk Patients



* STS algorithm for preop risk assessment for valve/CABG at time of PCI

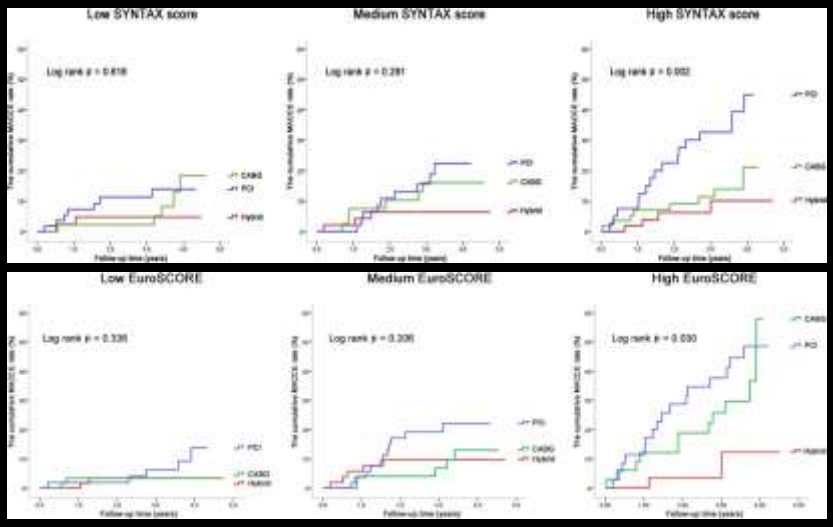
Curr Treat Options Cardiovasc Med. 2009 Dec;11(6):492-8
J Am Coll Cardiol. 2005 Jan 4;45(1):14-8

Consecutive HCR vs. CABG vs. PCI Propensity Matched/Single Center



Liuzhong Shen et al. JACC 2013;61:2525-2533

Consecutive HCR vs. CABG vs. PCI Propensity Matched/Single Center



Liuzhong Shen et al. JACC 2013;61:2525-2533

HCR vs OPCAB in Patients with DM

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Variable	HCR (n = 120)	OPCAB (n = 240)	P value
Chest tube drainage within 24 hours, mL, median (IQR)	875 (520-835)	700 (530-950)	<.001
Total chest tube drainage, mL, median (IQR)	740 (540-1080)	990 (730-1250)	<.001
Transfusion of packed RBCs, n (%)	22 (18.3)	71 (29.6)	.032
Transfusion of plasma, n (%)	23 (19.2)	53 (22.1)	.525
Transfusion of any blood products, n (%)	35 (29.2)	95 (39.6)	.076
Reoperation for controlling bleeding, n (%)	1 (0.8)	6 (2.5)	.307
Mechanical ventilation time, hour, median (IQR)	13.7 (10.5-16.9)	16.8 (13.0-19.6)	<.001
Length of ICU stay, hour, median (IQR)	21.7 (19.0-44.3)	46.5 (24.3-72.7)	<.001
Length of hospital stay, day, median (IQR)	7 (7-9)	7 (7-9)	.627

DM patients who underwent one-stop HCR from June 2007 to September 2014. (n = 120)

Propensity score matching. (One-stop HCR : OPCAB = 1 : 2)

DM patients who underwent OPCAB. (n = 1658)

HCR vs CABG: Comparative Effectiveness

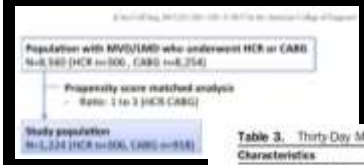
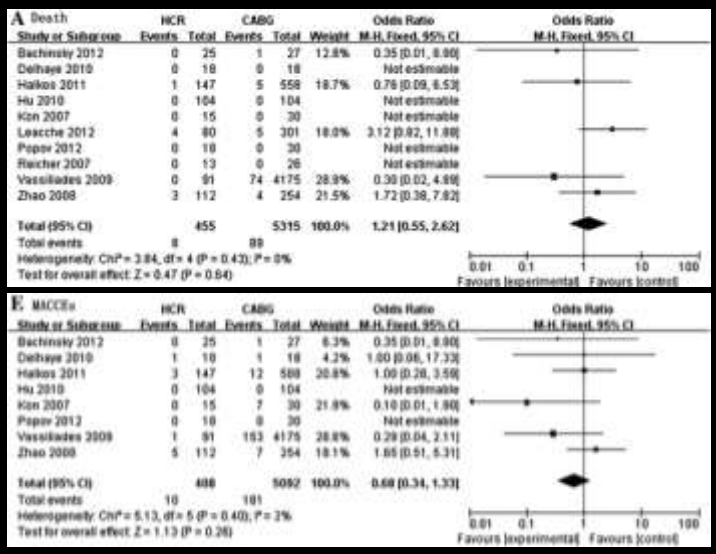


Table 3. Thirty-Day Major Adverse Cerebrovascular and Cardiovascular Events and In-Hospital Outcomes

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)	0.51 (0.36–0.83)	0.005
Reoperation	13 (4.2)	53 (5.8)	0.74 (0.40–1.39)	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)	0.45 (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)	β = −1.58, z = −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

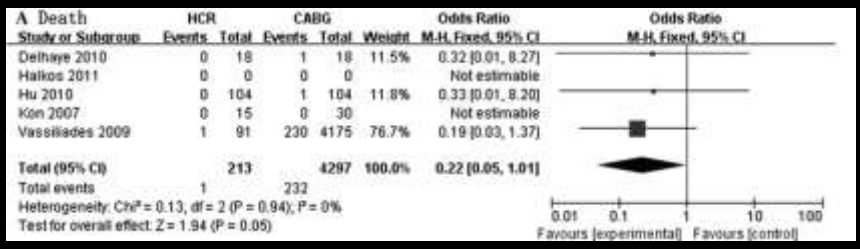
*Linear regression models were used.
HCR, hybrid coronary revascularization; OR, odds ratio; PLOS, postoperative length of stay.

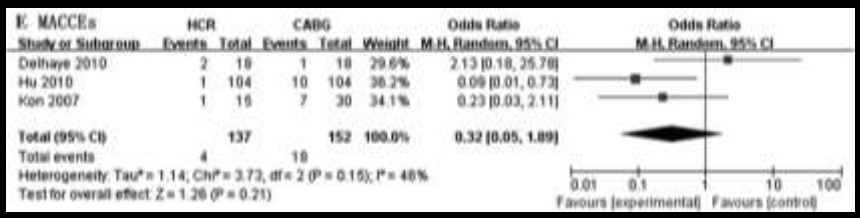
HCR versus CABG 30 days: Meta-Analysis



J Cardiothorac Surg 2015;10:(

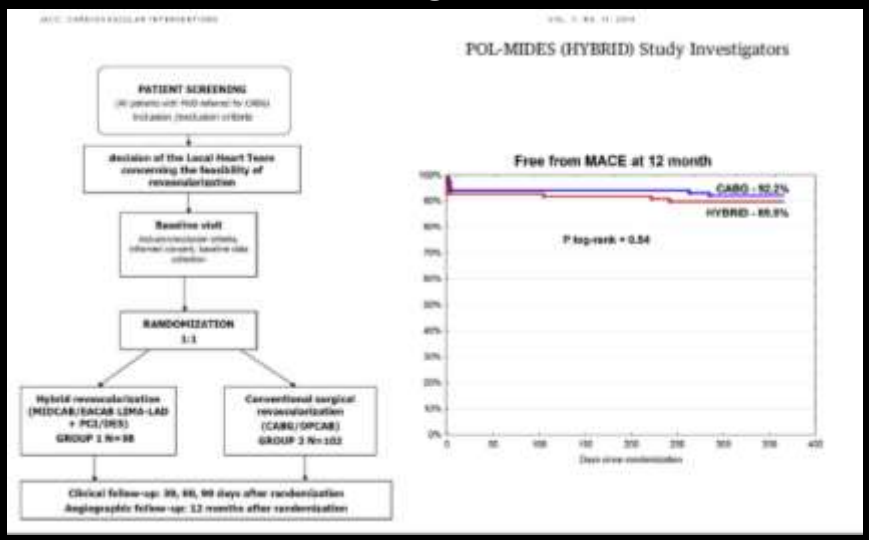
HCR versus CABG at One-year of Follow-up: Meta-Analysis





J Cardiothorac Surg 2015;10:

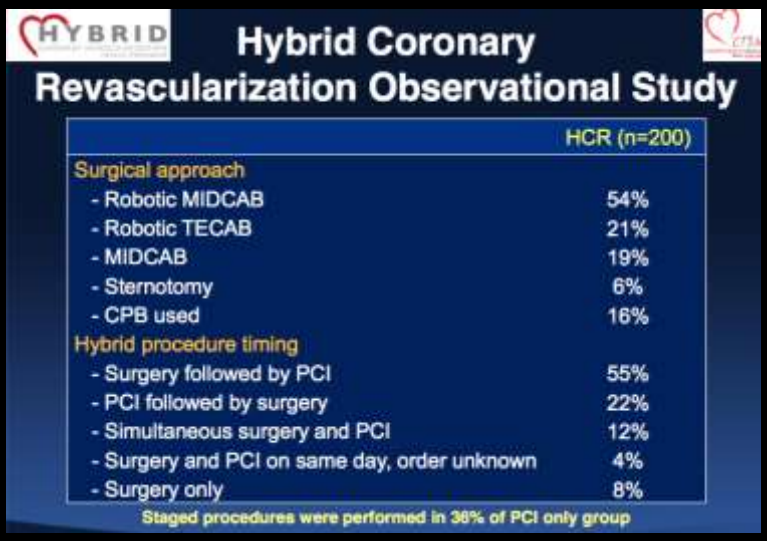
HCR vs CABG for Multivessel CAD RCT



NIH Hybrid Observational Study

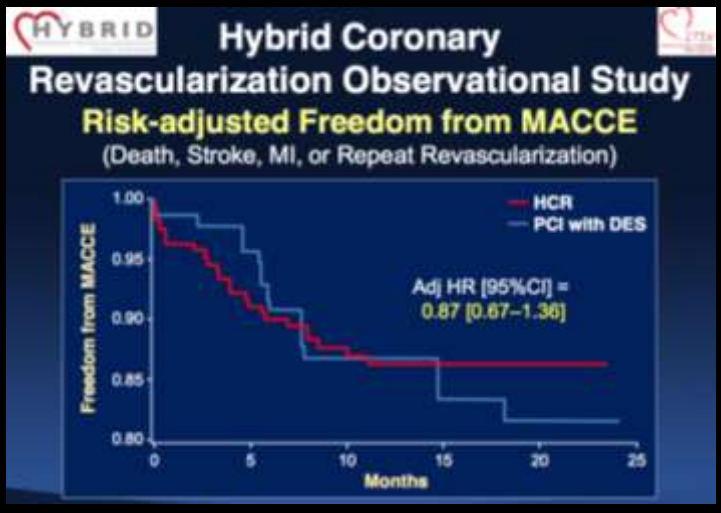
- Prospective cohort observational study
- 11 US sites
- To inform design of an RCT of HCR vs. multi-vessel PCI

NIH Hybrid Observational Study



JACC 2016;68:356

NIH Hybrid Observational Study

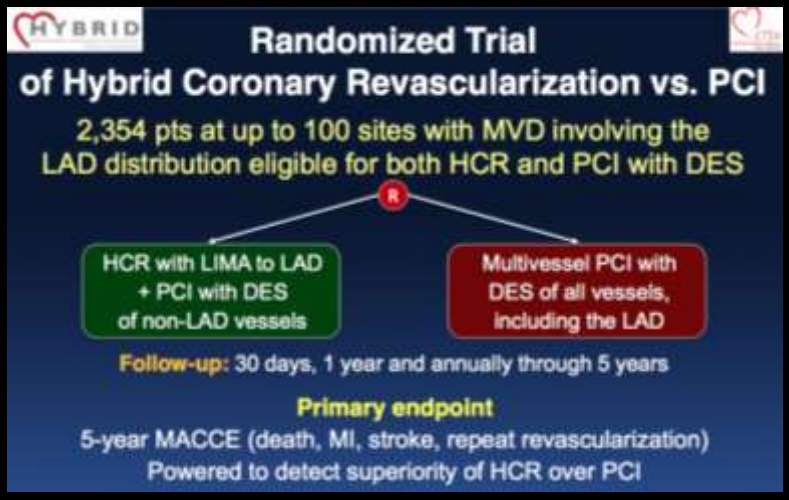


NIH Hybrid Coronary Revascularization RCT

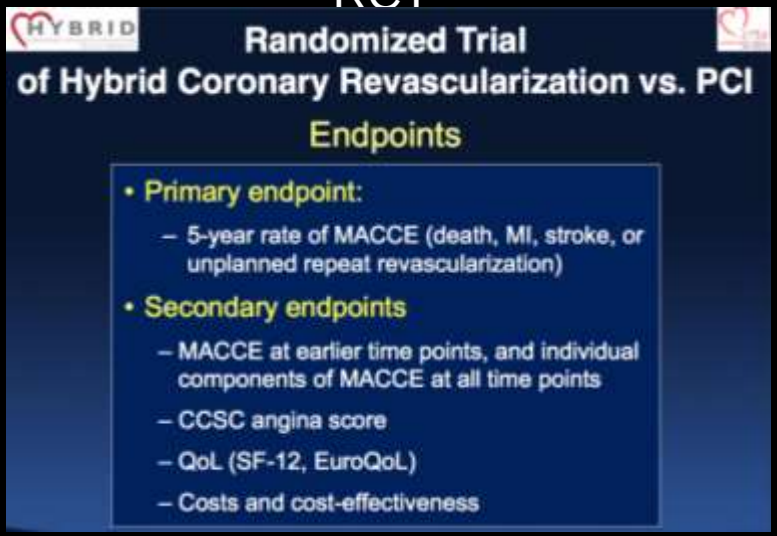
Rationale for Hybrid Revascularization

- The LIMA to the LAD graft has a 20-year patency rate as high as 90%; LIMA to LAD has been associated with reduced angina and revascularization compared to PCI in pts with isolated proximal LAD ds., and a survival benefit compared to PCI in pts with multivessel ds.
  - Caveat – no studies with contemporary DES
- For non-LAD vessels, the SVG is the still most common graft, despite a high failure rate
  - Pan-arterial revascularization is rare, even by excellent operators in non-complex ds. (eg 24.8% in EXCEL)
- Contemporary DES are believed to have substantially improved long-term event-free survival than SVGs (no RCTs)

NIH Hybrid Coronary Revascularization RCT



NIH Hybrid Coronary Revascularization RCT



NIH Hybrid Coronary Revascularization RCT

Major inclusion criteria

- Coronary anatomy requiring revascularization with:
  - MV CAD involving the LAD *and/or*
  - Distal LM *and/or*
  - Ostial or mid-shaft LM *and* disease in at least 1 other epicardial coronary artery *and/or*
  - LAD disease *and* involvement of a major diagonal artery, both of which require revascularization

NIH Hybrid Coronary Revascularization RCT

HYBRID

Randomized Trial of Hybrid Coronary Revascularization vs. PCI

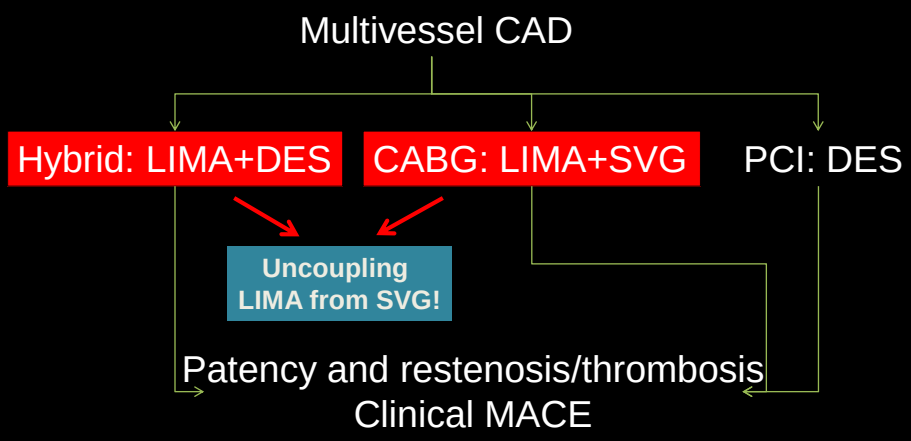
HCR procedures (at operator discretion)

- Minimally invasive LMIA-LAD surgery may be performed before, during or after PCI
  - Must be off-pump (without planned cardiopulmonary support), either sternal sparing or non-sternal sparing
  - Mid-CAB (limited anterior or lateral thoracotomy)
  - Robotic Mid-CAB or TECAB (totally endoscopic) is allowed at experienced sites
  - Anastomotic patency should be confirmed with intra-operative transit time Doppler flow prior to closure

HCR: Conclusion

- Equipoise is present as to how to best revascularize patients with multivessel disease involving the LAD
- HCR combines the best attributes of minimally invasive surgery with a LIMA-LAD + PCI with DES to non-LAD vessels, thereby eliminating use of SVGs
- Whether HCR improves long-term event-free survival in appropriate patients and is a cost-effective approach compared to multivessel PCI with DES is unknown
- The large-scale, randomized NHLBI-sponsored HYBRID trial will examine the effectiveness of HCR in pts with multivessel disease involving the LAD: Enrollment starting in 2017!

Ideal Hybrid Revascularization RCT



Surgery versus Catheter: The Times, They Are a Changin'

- CABG carries excellent long term outcomes but invasive. Benefits appear to be limited to mammary graft
- Stent technologies have advanced substantially.
  - ✓The 10X changes.
  - ✓The disruptive technologies.
  - ✓More to come.

Heart Team The Power of Alignment

The Power of Alignment

- A culture and business model where
  - Cardiology
  - Cardiac Surgery
  - Cardiac Anesthesia
  - Cardiac Imaging
  - Hospital Administration
- Work as a team
  - Requires financial, programmatic, strategic, geographic ALIGNMENT