Current Perspective in Off-Pump Coronary Revascularization

2 Decades in Review

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CONSULTANT: JOHNSON & JOHNSON

What I am not going to do today

- Zealots excessively defending On-Pump or Off-Pump CABG
- Selectively picking articles supporting one or another viewpoint
- Show an endless parade of articles with data difficult to comprehend
- Spinning the data

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LONGITUDINAL ASSESSMENT OF NEUROCOGNITIVE FUNCTION AFTER CORONARY-ARTERY BYPASS SURGERY

MARK F. NEWMAN, M.D., JERRY L. KIRCHNER, B.S., BARBARA PHILLIPS-BUTE, PH.D., VINCENT GAVER, B.S., HILARY GROCOTT, M.D., ROBERT H. JONES, M.D., DANIEL B. MARK, M.D., JOSEPH G. REVES, M.D., AND JAMES A. BLUMENTHAL, PH.D., FOR THE NEUROLOGICAL OUTCOME RESEARCH GROUP AND THE CARDIOTHORACIC ANESTHESIOLOGY RESEARCH ENDEAVORS INVESTIGATORS*

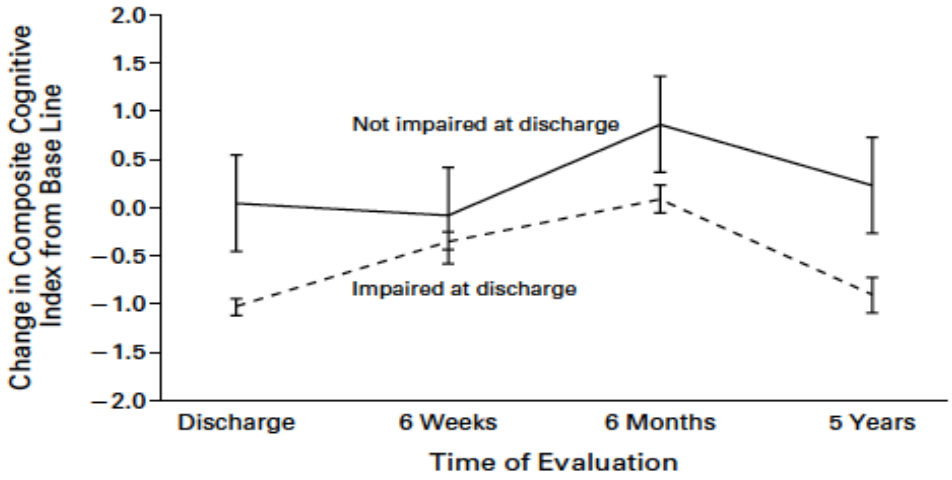

Figure 2. Composite Cognitive Index as a Function of Cognitive Impairment at Discharge.
The composite cognitive index is the sum of the scores for the four domains and includes cognitive decline as well as increases in scores as a result of learning. Positive change represents an overall improvement (learning), whereas negative values indicate overall decline. The I bars represent the standard error.

FREE

SEPT. 2002

VITALITY

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U.S. PRESCRIPTIO
DRUG USAGE EXPLO

Medicine:

STUDIES SHOW BYPASS PATIENTS LOSING MEMORY

by Lee Bowman

Two new studies published recently offer additional evidence that heart bypass surgery patients have lingering brain injury and loss of memory and concentration.

Doctors have noticed for years that patients who have coronary bypasses lose some mental sharpness in the following days and weeks - more difficulty following directions or doing mental math or planning complex actions ahead of time. Some studies show the decline continues in many patients for years after the operation.

Bypass surgery is performed on some half a million people in the United States each year, and like many major surgeries it can release microscopic blood clots, lower body temperature and expose the body to various amnesia-causing drugs.

In one study, published in the July issue of the journal Neuropsychology, researchers at the University of North Carolina-Wilmington compared before-and-after surgery mental test performances by 39 bypass patients and 49 control patients recruited from a senior wellness program who did not have surgery, but were retested in the same interval.

Julian Keith and his colleagues report that the control patients "significantly outperformed" bypass patients on two important tests of attention and memory both before and after surgery.

much the surgery itself that may be hurting memory.

The performance gap was even greater after surgery, though, and Keith said this indicates that brain systems that support attention may be particularly vulnerable to injury, because "the more machinery required to do the task, the more likely it is that a brain insult will disrupt the process."

Most researchers suspect that the use of a heart-lung bypass machine during the surgery somehow contributes to small clots entering the bloodstream and causes damage to the brain.

In the second study, published in the July issue of the Archives of Neurology, German researchers used before- and after-surgery brain imaging on 35 bypass patients. They were able to identify areas of the brain with reduced oxygen flow due to mini-clots in 9 of the patients, but they didn't match up with any scores on mental tests for those patients.

But in measures of metabolic rate in certain compounds of the brain, there were some changes that the researchers were able to correlate with tests of mental performance.

Scientists around the world are continuing to study the problem and looking at steps ranging from revised surgical techniques to giving patients drugs that might help better protect brain cells just prior to the operation.

- "Lingering brain injury"
- "Memory loss"
- "Loss of mental sharpness"
- "Doctors knew this for years"

Promoting Off-Pump CABG as Surgery for the executives

What not to do

- Demonization of the pump

- CPB has been one of our greatest allies in building our specialty
- We need to continues the refinement of CPB techniques and technology
- Other extracorporeal circulation (ECMO)

What **I am** going to do

- Share with you my insight regarding
  Off-Pump CABG
- Where it fits/for what patients
- Where it fits for the cardiac surgeon
- Where it fits in cardiac surgery programs

Potential Benefits by avoiding CPB

- Minimize
  - Renal dysfunction
  - Lung dysfunction
  - Brain dysfunction
  - Coagulopathy / bleeding
  - Inflammatory response (SIRS)
  - Micro embolism (Platelets, fibrin, small debris, etc)
- Avoids Clamping and Cannulation
  - ATE embolism/Stroke
  - Aortic dissection
- Avoids Ischemic cardioplegic arrest
  - Especially beneficial in low EF patients

Morbidities Associated With CPB

- Myocardial Necrosis
- Systemic Inflammatory Response
- Neuro-Cog effects / Brain injury
- Pump Lung (Adult Respiratory Distress Syndrome)
- Hypertension and distention of the heart
- Renal Dysfunction
- Embolization
- Coagulation Disorders
- Increased Blood Loss

Off-PUMP CABG

- Technically demanding operation
  - Surgeon
  - All the surgical team
- Requires a higher focuses/effort on the anesthesiologist
- Steep learning curve

Risk of a lesser quality revascularization

Benefit of avoiding morbidity associated with the CPB

Concerns about the quality of the revascularization

- Quality of anastomosis
  - Exposure and visualization
  - Motion
- Early graft thrombosis
  - Lower dose of heparin
  - Lack of coagulopathy
- Incomplete revascularization
  - Vessels in the lateral wall of the LV
  - Patients who become unstable when heart positioned

Trends in Off-Pump CABG

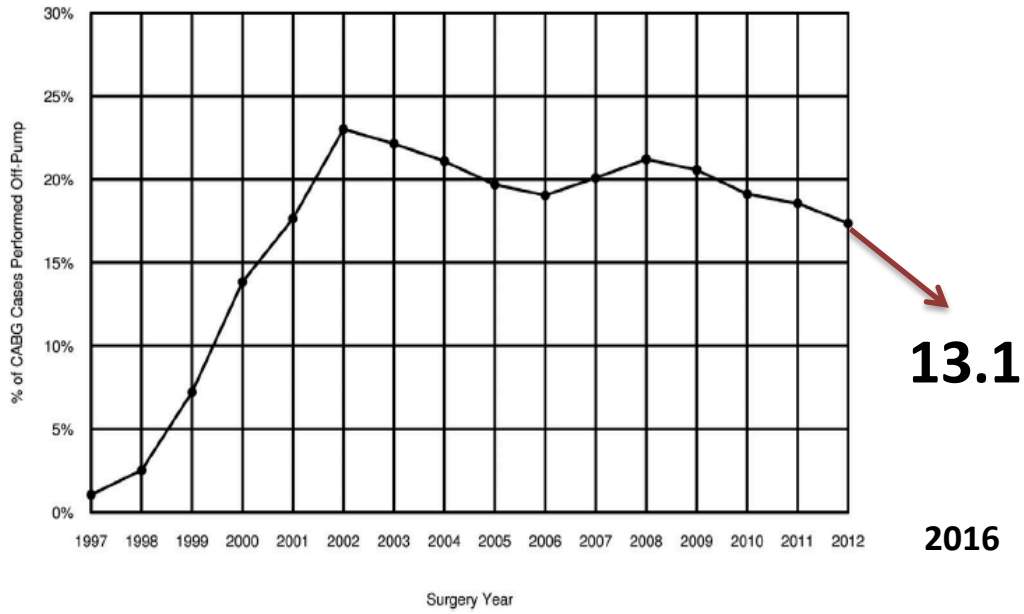
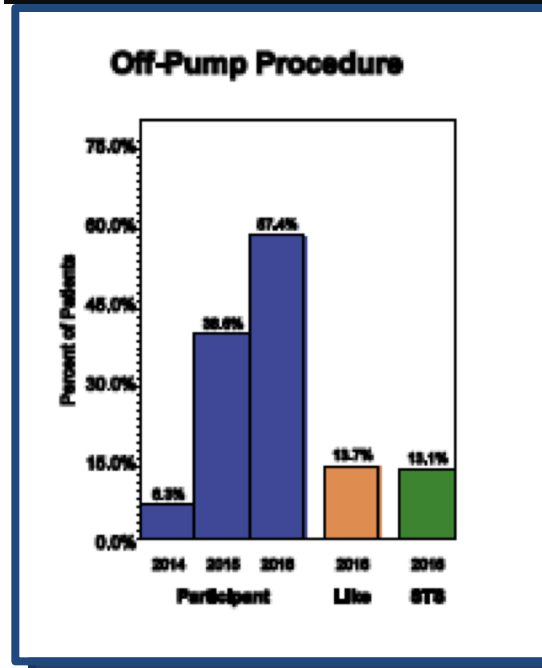


FIGURE 2. Relative use of ON versus OFF CABG for the entire cohort (1997-2012). *CABG*, Coronary artery bypass grafting.

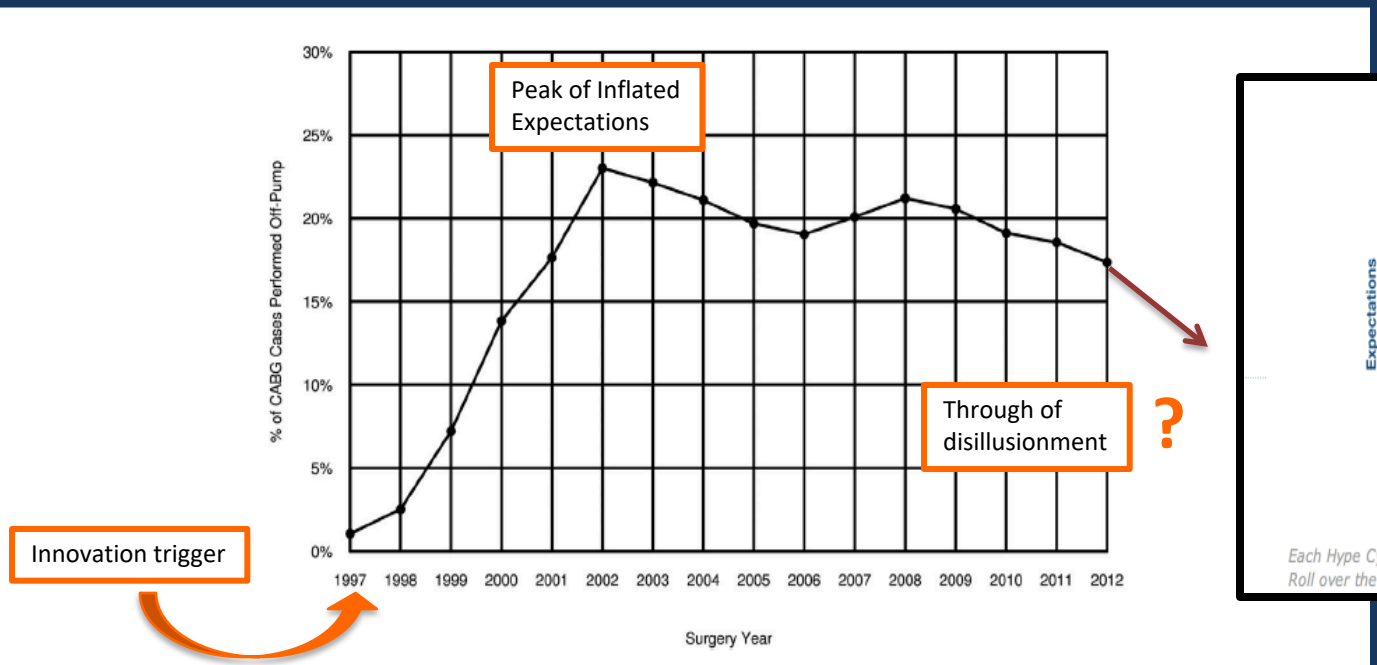
858 The Journal of Thoracic and Cardiovascular Surgery • September 2014

Rush/Copley Medical Center



Off-Pump CABG in 2016: 13.1 %. STS Database

Trends in Off-Pump CABG



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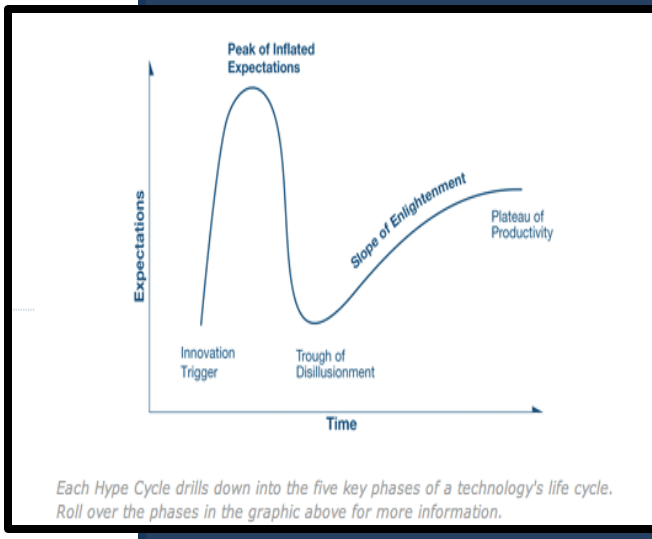


Gartner Hype Cycle

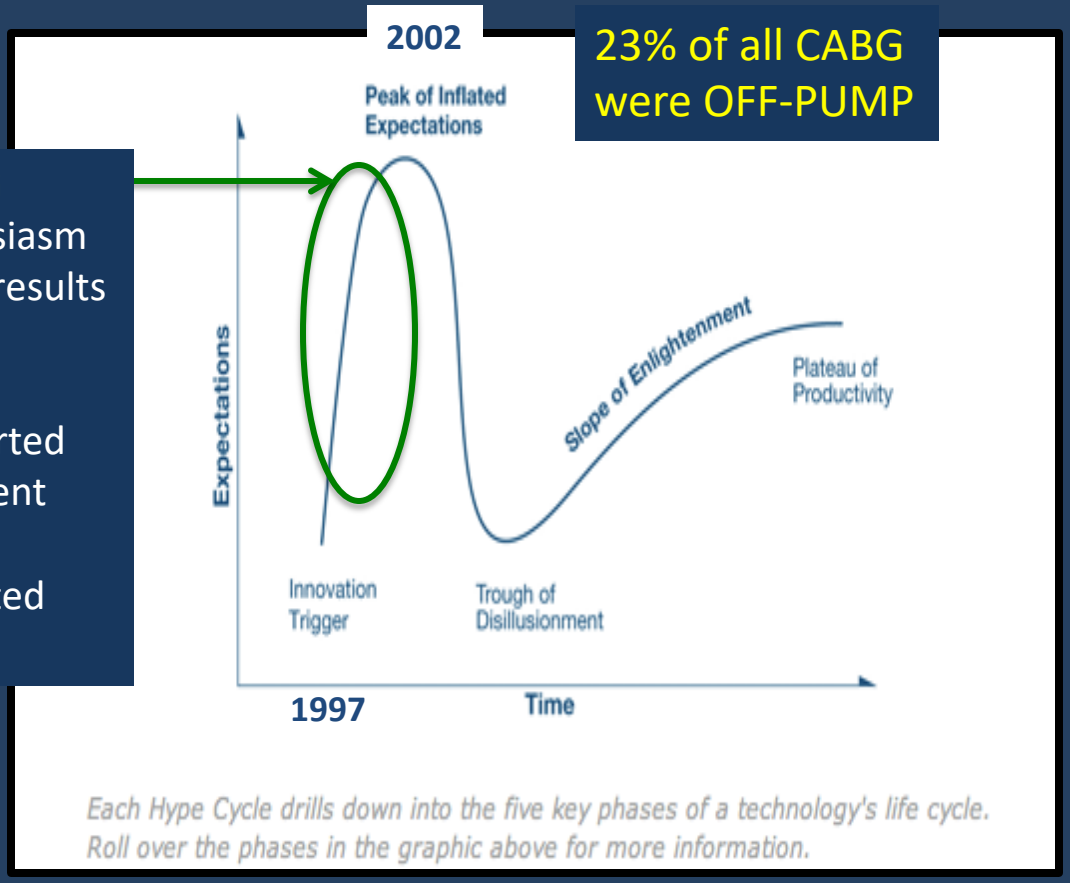
Gartner hype cycle: Graphic representation of maturation of techniques and technology and plateau of adoption

Off-Pump CABG trends along the Hype Cycle

FUEL FOR THE UPSWING

- Early adopters enthusiasm
- Reports of favorable results
  In major societies
- Videos/courses
  Many industry supported
- Evolution on equipment

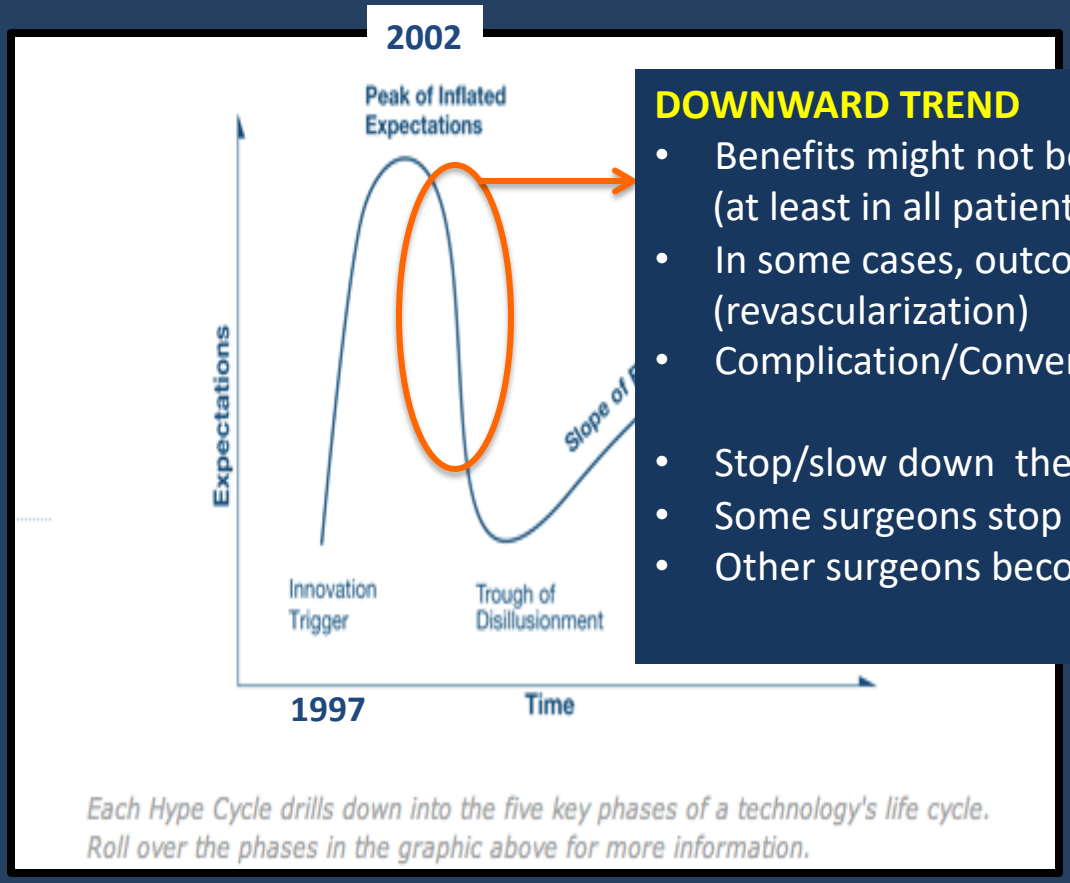
- More surgeons adopted
  Off PUMP



INNOVATION TRIGGER → **PEAK OF INFLATED EXPECTATIONS**

Single Center Studies (by experts) mostly retrospective reviews

Off-Pump CABG trends along the Hype Cycle



DOWNWARD TREND

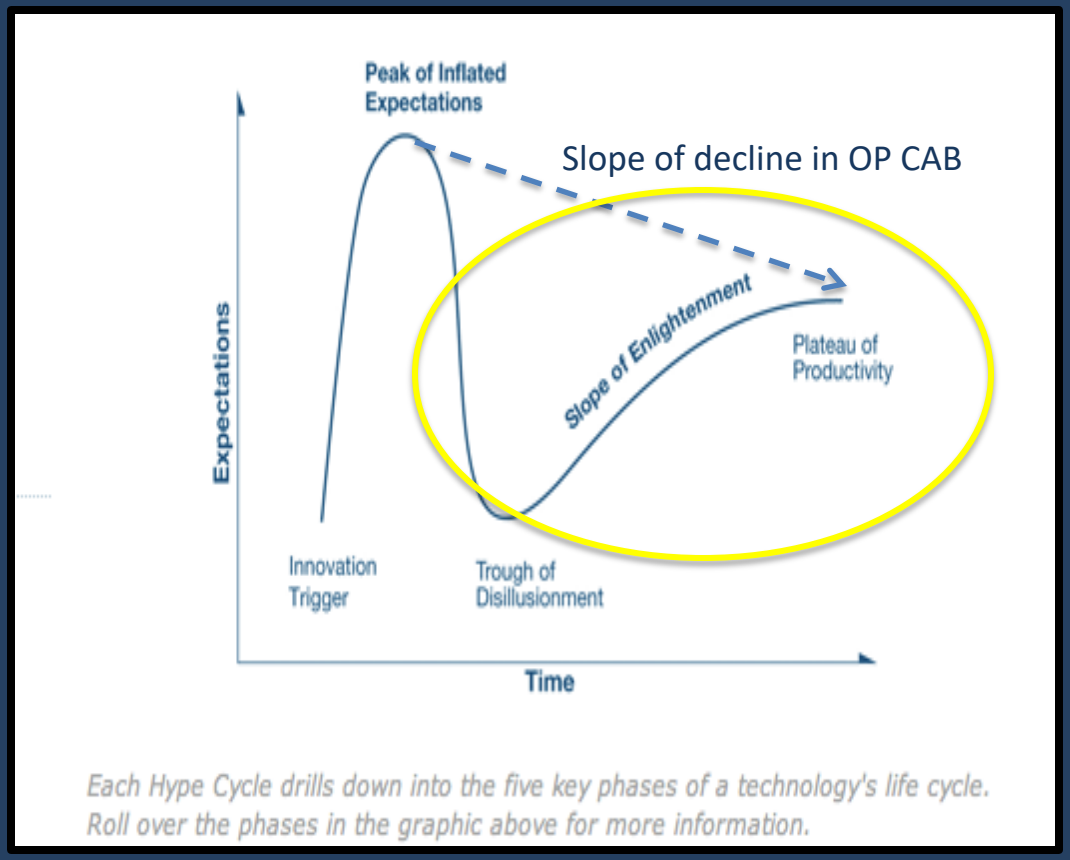
- Benefits might not be as initially expected (at least in all patients)
- In some cases, outcomes might be worse (revascularization)
- Complication/Conversions

- Stop/slow down the adoption
- Some surgeons stop doing Off Pump
- Other surgeons become more selective

Are we there yet ?

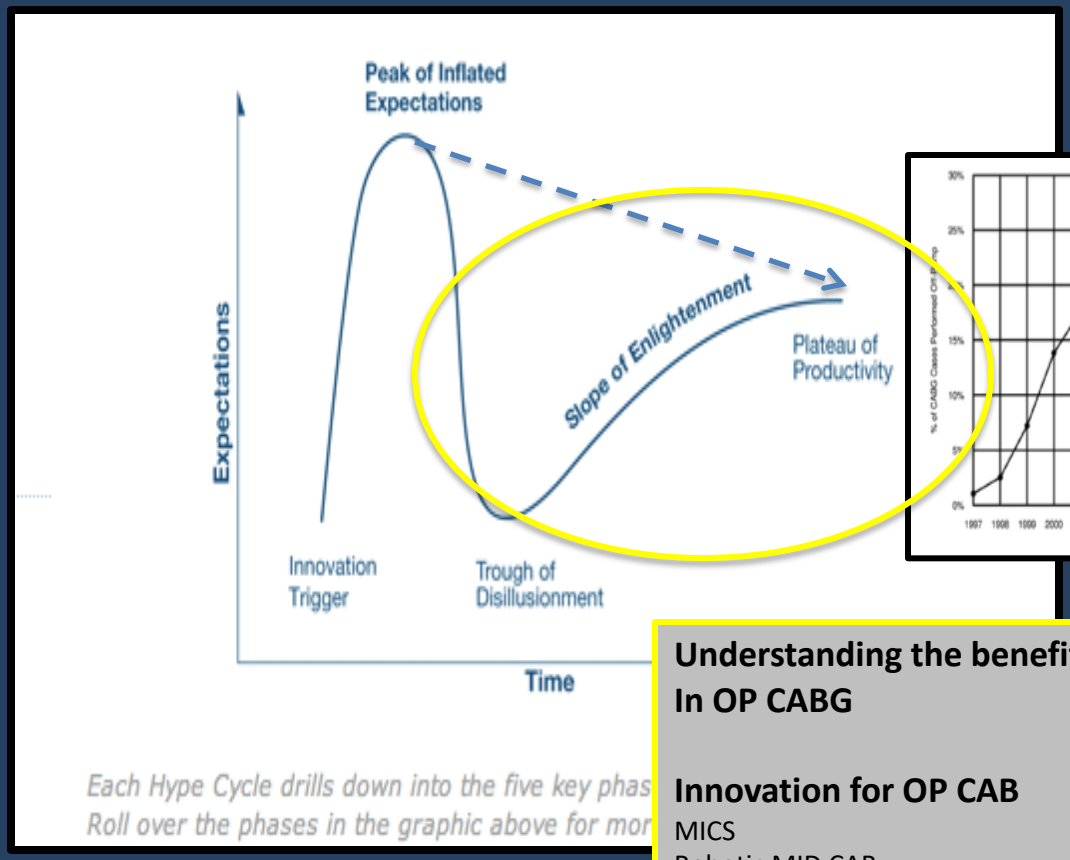
PEAK OF INFLATED EXPECTATIONS → **TROUGH OF DISILLUTIONMENT**

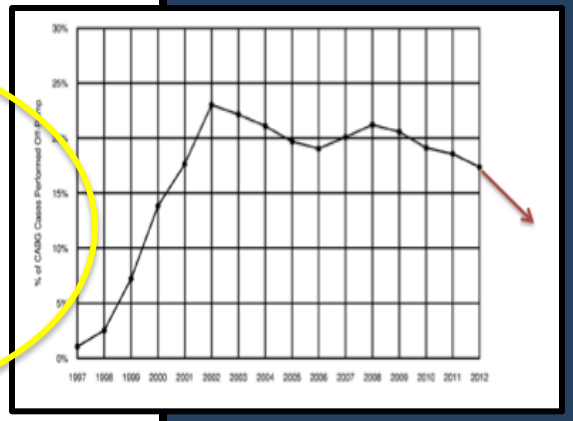
Decline in Off-Pump CABG



Much less pronounced than in the Hype-cycle.

Decline in Off-Pump CABG





Declining in OP CAB volume in US

Much less pronounced than i

Understanding the benefits In OP CABG

Innovation for OP CAB

MICS
Robotic MID CAB
TE CAB
Connectors
Regional Reop OP CAB
Hybrid Revascularization

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

OP CAB literature *(3 main groups)*

- Smaller RCT and retrospective reviews from specialized centers
  - Equivalent or superior outcomes with OP CAB
- Observational data from large databases
  - OP CAB better in high-risk groups
- Large-scale randomized trials in relatively low risk patients
  - Comparable hard outcomes
  - Better soft outcomes in OP CAB
  - Some incomplete revasc/Graft patency worse in OP CAB

Single Center Studies (by experts) mostly retrospective reviews

OFF-PUMP CABG IS BETTER

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

- Lower mortality in high risk groups
- Lower morbidity
- Better soft outcomes

- Excellent/comparable quality of revascularization

↓

- Excellent mid term results: Survival /low rate of for re-interventions

Meta-Analysis

- Selke
- Reston
- Chen
- Puskas
- Taggart
- Cochrane

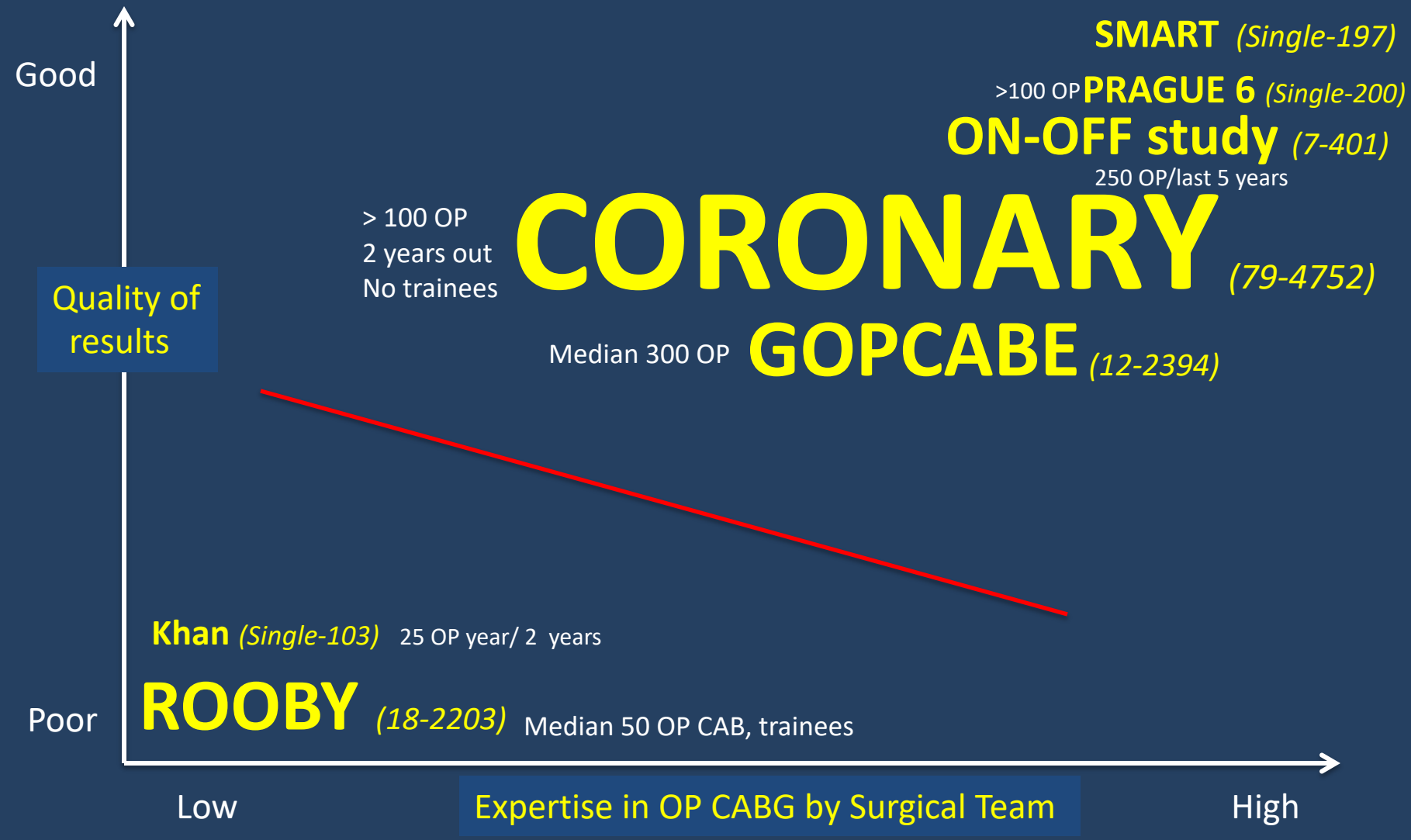
Large Database Studies

- NY Database (close to 50,000 Pts)
  - Lower surgical mortality and morbidity
  - Higher rate of repeat revascularization
- STS Database (close to 15,000 pts)
  - Lower surgical mortality in high–risk groups
- New Zealand CT Database (close to 8,000 pts)
  - No difference but strong trend for lower mortality and stroke
- Credo-Kyoto Database (close to 2,500 pts)
  - Lower risk of stroke in high risk-groups

The large number of patients in these databases allows the analysis of high-risk groups

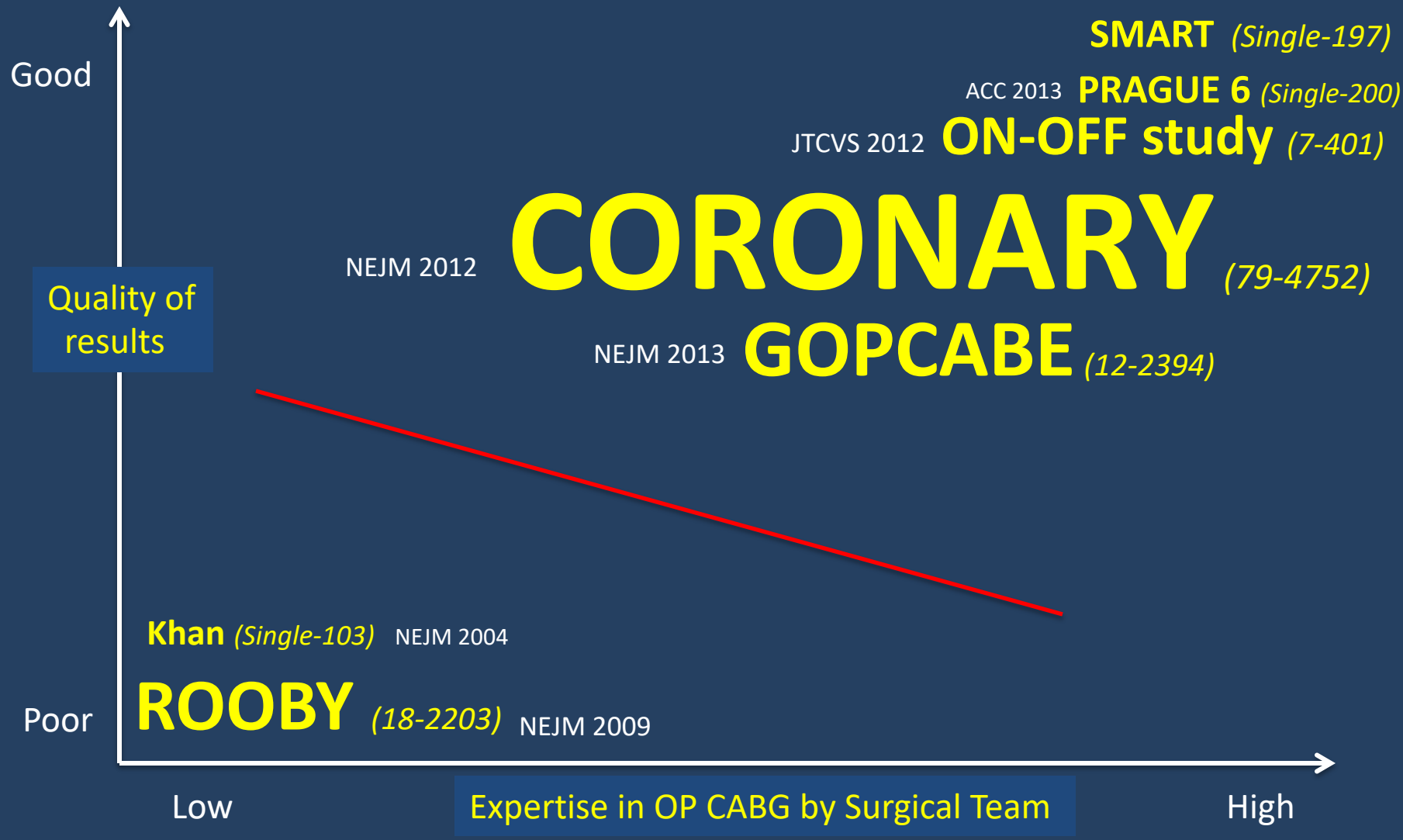
Prospective-Randomized Control Trials: Off-Pump Vs. On Pump CABG

Surgeon and Team experience



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

Maturation of techniques and technology



The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 NOVEMBER 5, 2009 VOL. 361 NO. 19

On-Pump versus Off-Pump Coronary-Artery Bypass Surgery

A. Laurie Shroyer, Ph.D., Frederick L. Grover, M.D., Brack Hattler, M.D., Joseph F. Collins, Sc.D., Gerald O. McDonald, M.D., Elizabeth Kozora, Ph.D., John C. Lucke, M.D., Janet H. Baltz, R.N., and Dimitri Novitzky, M.D., Ph.D., for the Veterans Affairs Randomized On/Off Bypass (ROOBY) Study Group

ROOBY STUDY

	Off-Pump	On-Pump			
Long-term					
1-Yr composite§	105 (9.9)	78 (7.4)	2.5 (0.1 to 4.9)	1.33 (1.01 to 1.76)	0.04
1-Yr composite with death from cardiac causes rather than from any cause	93 (8.8)	62 (5.9)	2.9 (0.6 to 5.1)	1.48 (1.09 to 2.02)	0.01
1-Yr composite with all end points from time of CABG	155 (14.6)	104 (9.9)	4.7 (1.9 to 7.5)	1.47 (1.17 to 1.86)	0.001
Nonfatal myocardial infarction between 30 days and 1 yr after surgery	21 (2.0)	23 (2.2)	−0.2 (−1.4 to 1.0)	0.90 (0.50 to 1.62)	0.76
Revascularization between 30 days and 1 yr after surgery	49 (4.6)	36 (3.4)	1.2 (−0.5 to 2.9)	1.35 (0.88 to 2.05)	0.18
Death from any cause within 1 yr	43 (4.1)	30 (2.9)	1.2 (−0.4 to 2.8)	1.41 (0.90 to 2.24)	0.15
Death from cardiac causes within 1 yr	29 (2.7)	14 (1.3)	1.4 (0.2 to 2.6)	2.05 (1.09 to 3.86)	0.03

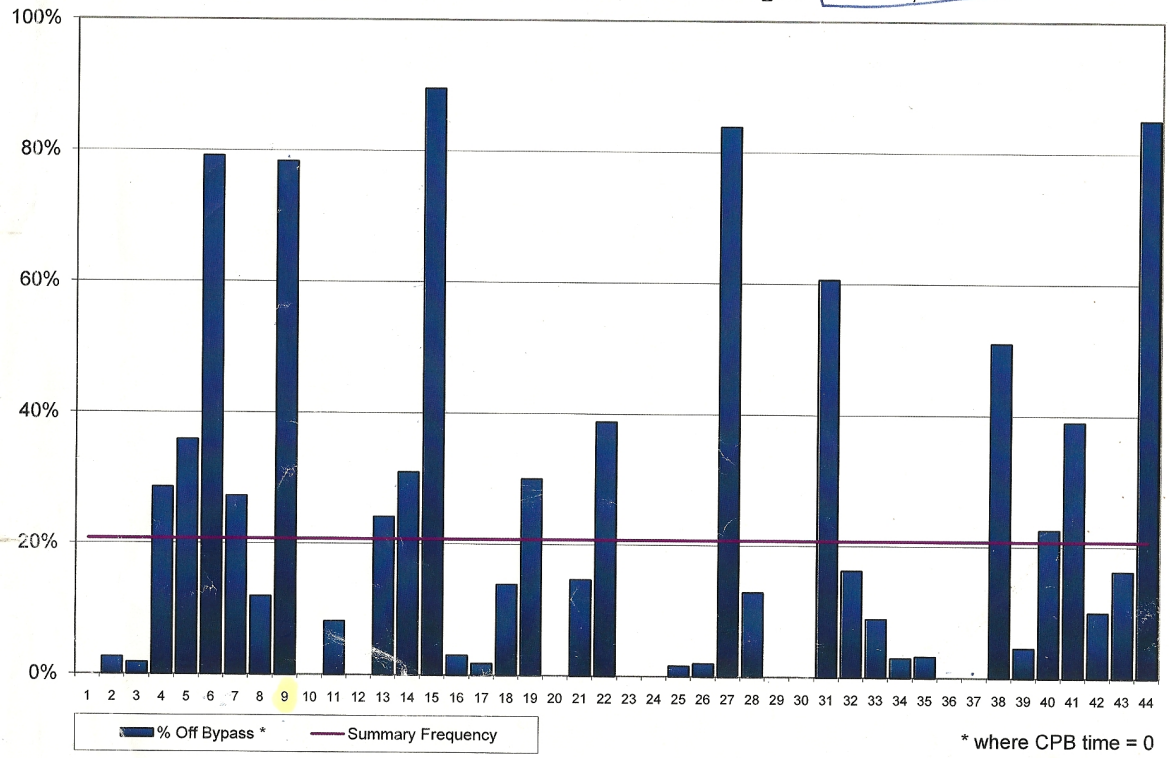
PRIMARY 1 YEAR COMPOSITE END-POINT:
Death (any cause) + Non-fatal MI + Repeat revascularization

All VA Hospitals

FIGURE R-18

% OFF BYPASS *

CABG-Only Cases: October 1, 2008 through March 31, 2009



* where CPB time = 0

Comments about ROOBY NEJM 2009

- < 1 off-pump operation/hospital/month
  - 1104 Patients on the Off Pump Group
  - Study from Feb 2002-May 2008= 75 months
  - 14 Off Pump cases per month/ 18 sites

- No Off-Pump expertise on the surgeons
  - Median 50 off Pump cases (minimum 20)
  - 12% conversion to On-Pump
  - Many cases done by residents

NUMBER OF GRAFTS

Progression of off-pump CABG program

Number of Grafts	1 - 100	101 – 230	230-500
One	21%	15%	4%
Two	55%	45%	35%
Three or more	23%	39%	61%
Average *Grafts/Patient*	**2.0**	**2.4**	**2.7**

Nashville VA Medical Center

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Three or more	23%	39%	61%
Average *Grafts/Patient*	**2.0**	**2.4**	**2.7**

- *65 grafts on the lateral wall (OM o Ramus) in the last 78 cases*

Nashville VA Medical Center

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
  - Flow evaluation

Dr. Subramanian comments

CONTROVERSIES IN CARDIOTHORACIC SURGERY

Are randomized trials the best way to judge the efficacy of surgical procedures?

Timothy J. Gardner, MD

Only if there is the surgeons and surgical teams are well equipped to perform the operation under study. The rest of the team, ICI, Step down , follow up is also comparable on both groups

JTCVS 2010

Randomized clinical trials for new surgical operations: Square peg in a round hole?

Joel D. Cooper, MD

A major limitation of RCTs in surgery is the difficulty, if not impossibility, of standardizing the procedure being evaluated. There is surgeon to surgeon variation in terms of both surgical approach and technical ability and experience. The preoperative and postoperative care may vary from center to center. Poor-quality surgery or care represents failure to deliver the intended treatment, and the trial may then measure the deliverability and not the efficacy of the treatment. Evolution in technical modification, risk, and selection criteria is likely to occur in a course of a prolonged clinical trial. Surgical procedures typically progress via such modifications that individually are unlikely to produce detectable benefits but that collectively may do so.

- Poor quality surgery or care represents failure to deliver the intended treatment
- The trial may then measure the deliverability and not the efficacy of the treatment

JTCVS 2010

Number of Grafts vs. complete revascularizacion

- Complete revascularization is the surgical mantra *(pure thought-strong believe)*
- More grafts in all On Pump cases compared to Off-Pump CABG
  - Is the revascularization in the On-Pump better or more complete by doing more grafts
- Use some numbers
- Does this difference matters?

Complete Revascularization in the BARI trial

Criteria: vessel diameter 1.5 mm-lesion-loss of 50% of the lumen

- Traditional Complete *(1 graft per system)*
- Functionally Complete *(1 graft per diseased segment)*
- A ratio according to Grafts/segments diseases
  - More
  - Equal
  - Less
- 2 or more grafts per system

Conclusions

- **About the same outcomes**
- **Worse results if 2 grafts in the Non-LAD system**,

Vander Salm TJ et al. JACC 2002

Survival according to I COR score

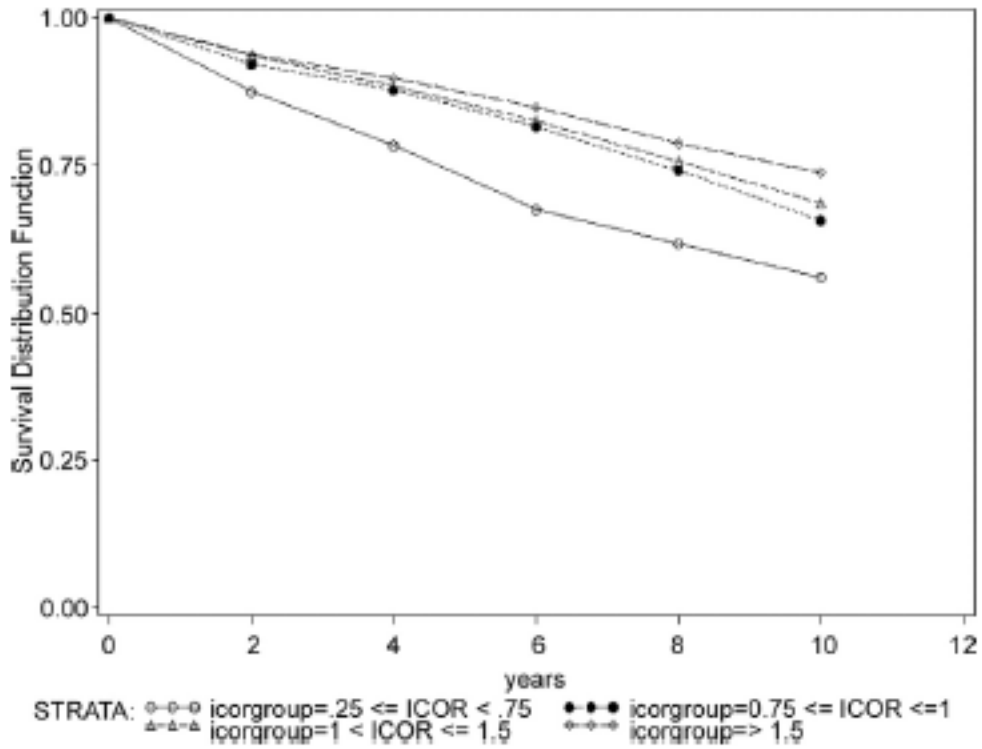


Fig 2. Life-table survival curves by number of grafts (1 to 3 or 4 to 7) and surgery type. (Open circles = index of completeness of revascularization [ICOR] group = 0.25 ≤ ICOR < 0.75; solid circles = ICOR group = 0.75 ≤ ICOR ≤ 1; triangles = ICOR group = 1 < ICOR ≤ 1.5; diamonds = ICOR group = > 1.5.)

Lattouf et al. Ann Thorac Surg 2008

Acute Graft Patency by Fitzgibbon Score
622 Grafts

	A	B	A + B	O	n
OPCAB	**96.8**	**2.2**	**99.0**	**1.0**	**315**
CPB	**95.4**	**2.0**	**97.4**	**2.6**	**307**

1 Year Graft Patency by Fitzgibbon Score
511 Grafts

	A	B	A + B	O	n
OPCAB	**90.0**	**3.6**	**93.6**	**6.4**	**251**
CPB	**94.3**	**1.5**	**95.8**	**4.2**	**260**

A Randomized Comparison of Off-Pump and On-Pump Multivessel Coronary Artery Bypass Surgery

Khan NE, et al. NEJM 2004;350:21-8

- 50 ONCAB, 54 OPCAB
- No deaths
- Similar # grafts/pt (3.4 vs 3.1)
- Post-op LOS similar (7days)
- Troponin levels higher in ONCAB (p=.02)
- 3 month graft patency lower in OPCAB (98% vs 88%, p=.002)

re

Special Report

Should Off-Pump Coronary Artery Bypass Grafting Be Abandoned?

Harold L. Lazar, MD

Circulation 2013

Special Report

Should Off-Pump Coronary Artery Bypass Grafting Be Abandoned?

Harold L. Lazar, MD

Circulation 2013

Review Article

We should ban the OPCAB approach in CABG, just as we should ban jetliners and bicycles, or maybe not!

Paul Sergeant

Department of Cardiac Surgery, Gasthuisberg University Hospital, KU Leuven, Leuven, Belgium

Correspondence to: Paul Sergeant. Reigersweide 16, 3390 Sint Joris Winge, Belgium. Email: Paulsergeant133@gmail.com.

J Thorac Disease 2016

Introduction

The hype cycle is a conceptual framework used to describe the adoption of emerging technologies. It can be used to illustrate the stages of adoption of off-pump coronary artery bypass graft (OPCAB) (*Figure 1*) (1). An initial introduction or Technology Trigger was followed by enthusiasm among early adopters and reports of single center experiences that compared favorably with on-pump surgical revascularization. Then a Peak of Inflated Expectations occurred in which OPCAB became widely adopted with continued positive results reported in retrospective and registry series. Subsequently, a Trough of Disillusionment describes the waning of interest as large-scale prospective trials failed to demonstrate mortality benefit and even reports of some inferior long term outcomes. Finally, there was a Slope of Enlightenment with maturing of this technology including the development of adjunctive tools to facilitate off-pump coronary anastomoses. Finally, we are approaching a Plateau of Productivity where we have a more refined understanding of how OPCAB procedures fit into our surgical, interventional and hybrid revascularization armamentarium.

Notes

- Complete revascularization. VanderSalm. Use it in discussing number or grafts CABG vs OP CAB. Compare to concept in syntax trials
- Incorporate the FFR guided CABG in the discussion
- Discussion about the merits of more grafts
- Bigger elaboration with the Hype –cycle
- Experience at the VA
- Reason I start OP CABG
- Value of hybrid revascularization.
- Syntax vs EUROSCORE
- Syntax as a global score-discussion
- Data without insight

Quality of Cardiovascular perfusion in each institution

- Better perfusion-less benefits in Off-Pump
- Worse perfusion-more obvious are the benefits in the Off-pump group.

Are you incline to do 2 or 3 grafts per case or 4,5 and 6.

Completeness of revascularization

VanderSalm

The Failed Promise of OPCAB

There is no heavier burden than a great potential.

Linus
—Charles Schultz

Where OP CAB fits in this era?

- Identifying the patients who benefit the most by OP CAB

Risk/benefit Ratio

Surgical Mortality

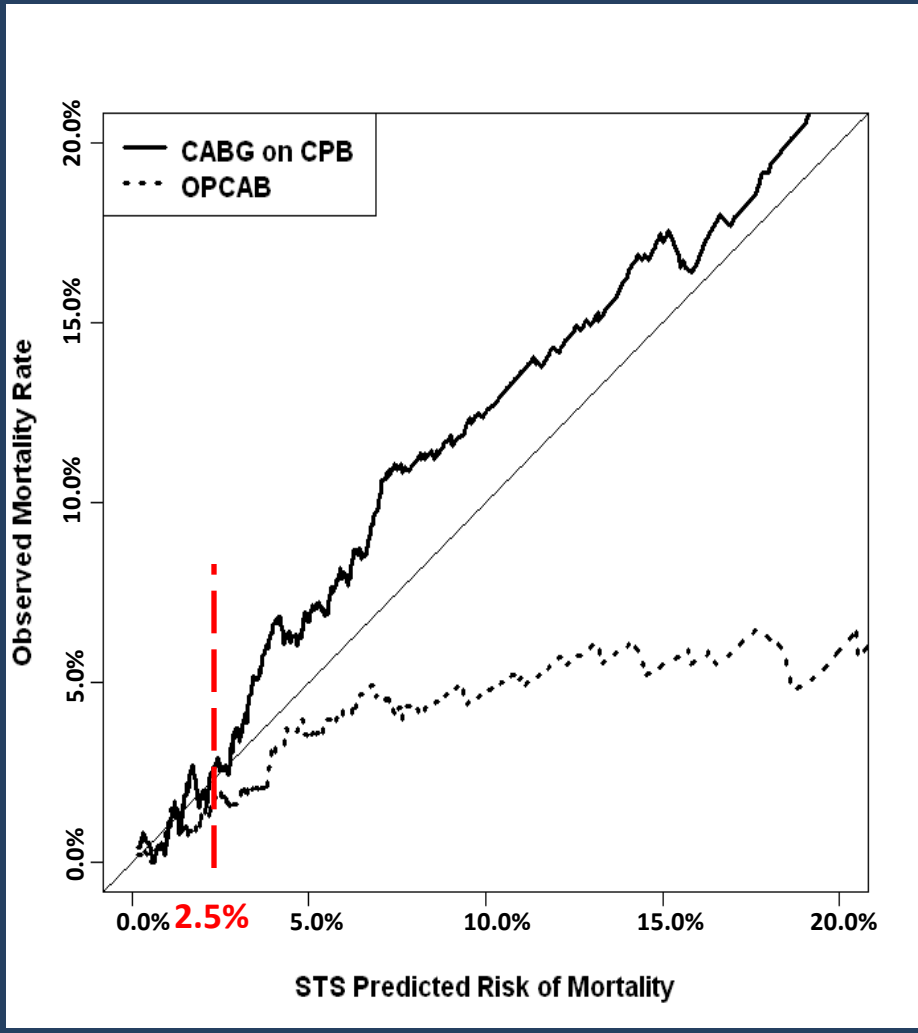
Higher Risk, higher benefit of Off-Pump

STS database *n=14,766*

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

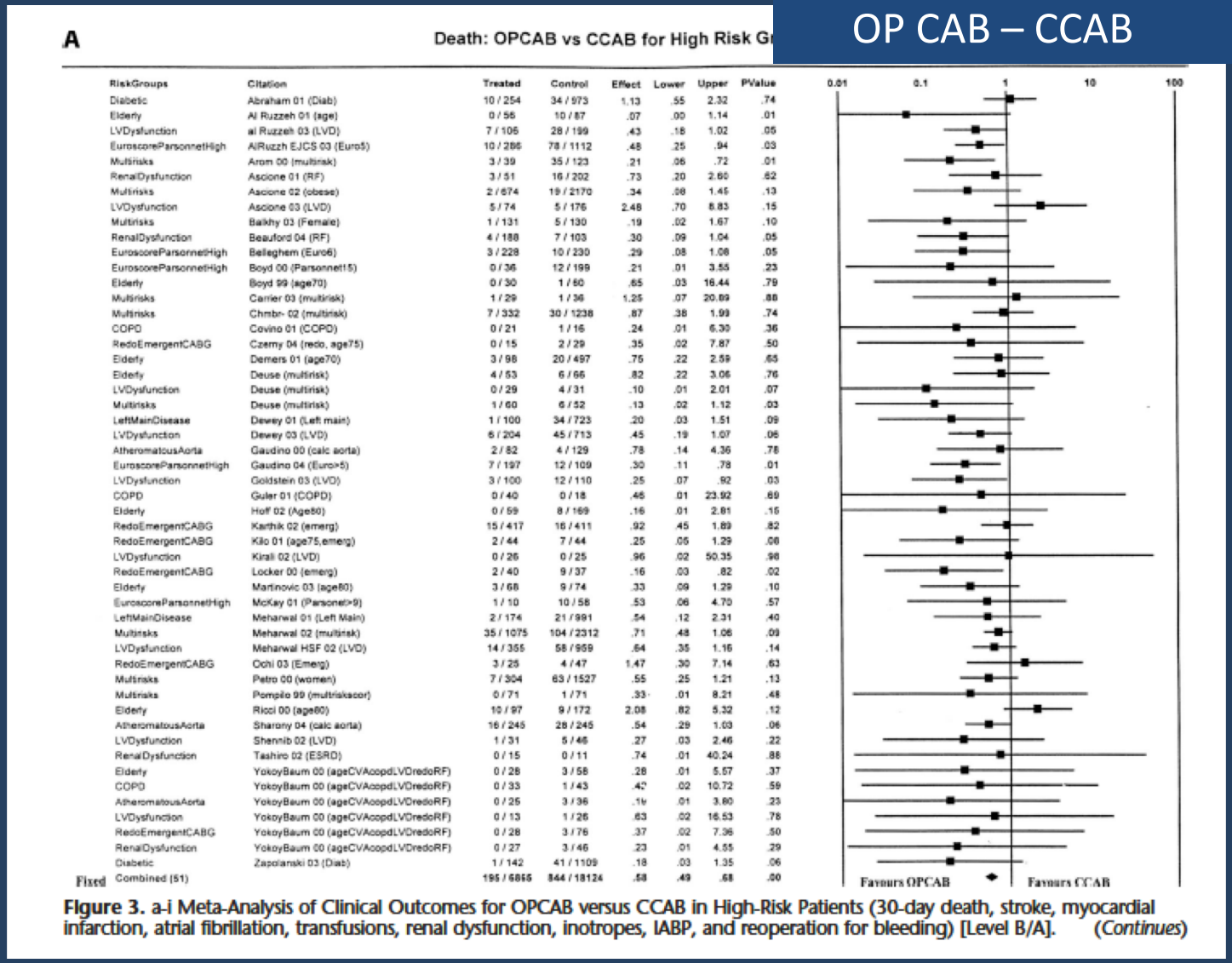


Puskas et al. Ann Thorac Surg 2009

Mortality in High-risk groups

favors

OP CAB – CCAB



A

Death: OPCAB vs CCAB for High Risk G

RiskGroups	Citation	Treated	Control	Effect	Lower	Upper	PValue
Diabetic	Abraham 01 (Diab)	10 / 254	34 / 973	1.13	.55	2.32	.74
Elderly	Al Ruzzeh 01 (age)	0 / 56	10 / 87	.07	.00	1.14	.01
LVDysfunction	al Ruzzeh 03 (LVD)	7 / 105	28 / 199	.43	.18	1.02	.05
EuroscoreParsonnetHigh	AlRuzzh EJCS 03 (Euro5)	10 / 286	78 / 1112	.48	.25	.94	.03
Multirisks	Arom 00 (multirisk)	3 / 39	35 / 123	.21	.06	.72	.01
RenalDysfunction	Ascione 01 (RF)	3 / 51	16 / 202	.73	.20	2.60	.62
Multirisks	Ascione 02 (obese)	2 / 674	19 / 2170	.34	.08	1.45	.13
LVDysfunction	Ascione 03 (LVD)	5 / 74	5 / 176	2.48	.70	8.83	.15
Multirisks	Balkhy 03 (Female)	1 / 131	5 / 130	.19	.02	1.67	.10
RenalDysfunction	Beauford 04 (RF)	4 / 188	7 / 103	.30	.09	1.04	.05
EuroscoreParsonnetHigh	Belleghem (Euro6)	3 / 228	10 / 230	.29	.08	1.08	.05
EuroscoreParsonnetHigh	Boyd 00 (Parsonnet15)	0 / 36	12 / 199	.21	.01	3.55	.23
Elderly	Boyd 99 (age70)	0 / 30	1 / 60	.65	.03	16.44	.79
Multirisks	Carrier 03 (multirisk)	1 / 29	1 / 36	1.25	.07	20.89	.88
Multirisks	Chmbr- 02 (multirisk)	7 / 332	30 / 1238	.87	.38	1.99	.74
COPD	Covino 01 (COPD)	0 / 21	1 / 16	.24	.01	6.30	.36
RedoEmergentCABG	Czerny 04 (redo, age75)	0 / 15	2 / 29	.35	.02	7.87	.50
Elderly	Demers 01 (age70)	3 / 98	20 / 497	.75	.22	2.59	.65
Elderly	Deuse (multirisk)	4 / 53	6 / 66	.82	.22	3.06	.76
LVDysfunction	Deuse (multirisk)	0 / 29	4 / 31	.10	.01	2.01	.07
Multirisks	Deuse (multirisk)	1 / 60	6 / 52	.13	.02	1.12	.03
LeftMainDisease	Dewey 01 (Left main)	1 / 100	34 / 723	.20	.03	1.51	.09
LVDysfunction	Dewey 03 (LVD)	6 / 204	45 / 713	.45	.19	1.07	.06
AtheromatousAorta	Gaudino 00 (calc aorta)	2 / 82	4 / 129	.78	.14	4.36	.78
EuroscoreParsonnetHigh	Gaudino 04 (Euro>5)	7 / 197	12 / 109	.30	.11	.78	.01
LVDysfunction	Goldstein 03 (LVD)	3 / 100	12 / 110	.25	.07	.92	.03
COPD	Guler 01 (COPD)	0 / 40	0 / 18	.46	.01	23.92	.69
Elderly	Hoff 02 (Age80)	0 / 59	8 / 169	.16	.01	2.81	.15
RedoEmergentCABG	Karthik 02 (emerg)	15 / 417	16 / 411	.92	.45	1.89	.82
RedoEmergentCABG	Kilo 01 (age75,emerg)	2 / 44	7 / 44	.25	.05	1.29	.08
LVDysfunction	Kirali 02 (LVD)	0 / 26	0 / 25	.96	.02	50.35	.98
RedoEmergentCABG	Locker 00 (emerg)	2 / 40	9 / 37	.16	.03	.82	.02
Elderly	Martinovic 03 (age80)	3 / 68	9 / 74	.33	.09	1.29	.10
EuroscoreParsonnetHigh	McKay 01 (Parsonet>9)	1 / 10	10 / 58	.53	.06	4.70	.57
LeftMainDisease	Meharwal 01 (Left Main)	2 / 174	21 / 991	.54	.12	2.31	.40
Multirisks	Meharwal 02 (multirisk)	35 / 1075	104 / 2312	.71	.48	1.06	.09
LVDysfunction	Meharwal HSF 02 (LVD)	14 / 355	58 / 959	.64	.35	1.16	.14
RedoEmergentCABG	Ochi 03 (Emerg)	3 / 25	4 / 47	1.47	.30	7.14	.63
Multirisks	Petro 00 (women)	7 / 304	63 / 1527	.55	.25	1.21	.13
Multirisks	Pompilo 99 (multriskacor)	0 / 71	1 / 71	.33	.01	8.21	.48
Elderly	Ricci 00 (age80)	10 / 97	9 / 172	2.08	.82	5.32	.12
AtheromatousAorta	Sharony 04 (calc aorta)	16 / 245	28 / 245	.54	.29	1.03	.06
LVDysfunction	Shennib 02 (LVD)	1 / 31	5 / 46	.27	.03	2.46	.22
RenalDysfunction	Tashiro 02 (ESRD)	0 / 15	0 / 11	.74	.01	40.24	.88
Elderly	YokoyBaum 00 (ageCVAcopdLVDredoRF)	0 / 28	3 / 58	.28	.01	5.57	.37
COPD	YokoyBaum 00 (ageCVAcopdLVDredoRF)	0 / 33	1 / 43	.42	.02	10.72	.59
AtheromatousAorta	YokoyBaum 00 (ageCVAcopdLVDredoRF)	0 / 25	3 / 36	.19	.01	3.80	.23
LVDysfunction	YokoyBaum 00 (ageCVAcopdLVDredoRF)	0 / 13	1 / 26	.63	.02	16.53	.78
RedoEmergentCABG	YokoyBaum 00 (ageCVAcopdLVDredoRF)	0 / 28	3 / 76	.37	.02	7.36	.50
RenalDysfunction	YokoyBaum 00 (ageCVAcopdLVDredoRF)	0 / 27	3 / 46	.23	.01	4.55	.29
Diabetic	Zapolanski 03 (Diab)	1 / 142	41 / 1109	.18	.03	1.35	.06
Fixed	Combined (51)	195 / 6865	844 / 18124	.58	.49	.68	.00

Figure 3. a-i Meta-Analysis of Clinical Outcomes for OPCAB versus CCAB in High-Risk Patients (30-day death, stroke, myocardial infarction, atrial fibrillation, transfusions, renal dysfunction, inotropes, IABP, and reoperation for bleeding) [Level B/A]. *(Continues)*

Meta-analysis
30.000 Patients
40 RCT
44 No RCT

Puskas y col. Innov CT Surg 2005

Morbidity

Meta analysis
30.000 Pacientes
40 RCT
44 No RCT

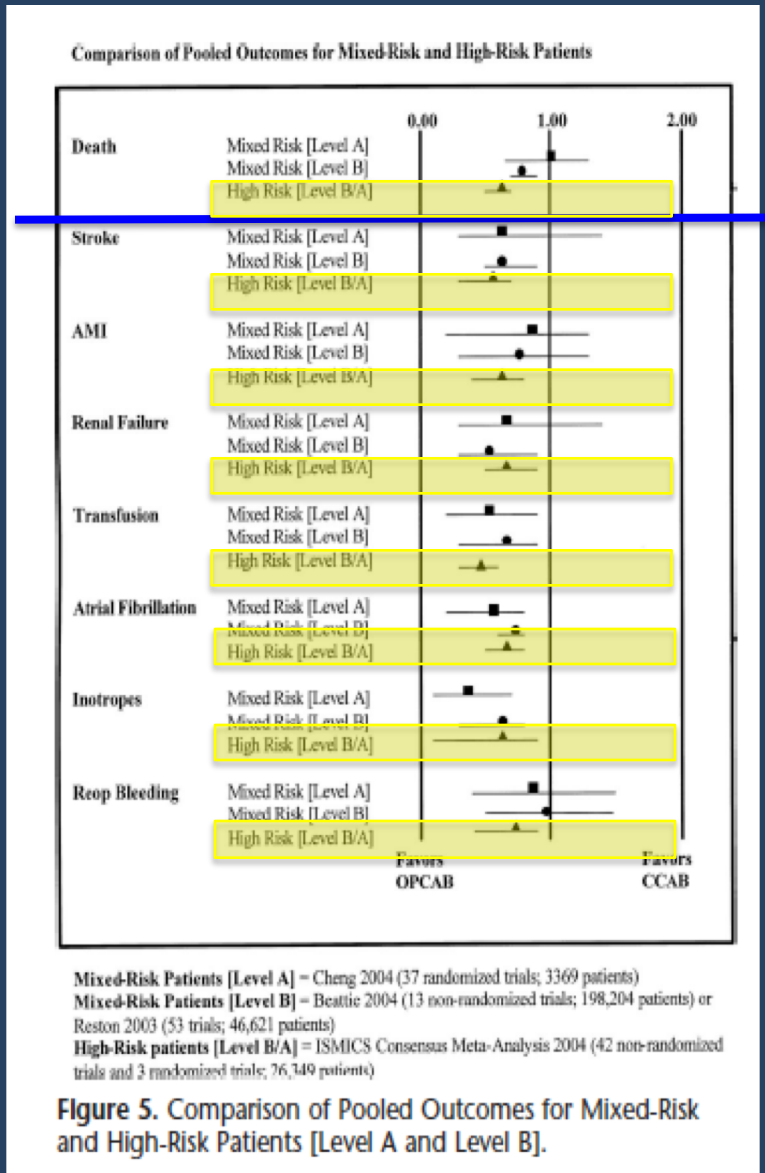


Figure 5. Comparison of Pooled Outcomes for Mixed-Risk and High-Risk Patients [Level A and Level B].

Mortality

Morbidity

Puskas y col. Innov CT Surg 2005

The Off-Pump CABG paradox

- Better for the high-risk patients
- Let's perform OP CAB only in the high-risk groups
- If OP CAB is only performed in high risk-patient, surgeons and teams will not acquire and maintain the appropriate level of expertise
- Then, these high-risk patients will be subjected to operations in the hands of a not well trained teams
- Expect worse results than in the ROOBY trial

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
  - Did not have good results/comfort zone
  - Peer or institutional pressure
  - Response to some data
- Surgeons who consistently perform OP CAB in their practice

- Performed some OP CAB and abandon it
- Performed OP CAB routinely and then abandon it

OP CAB benefits
Institutional perspective

- High-risk cases who would benefit from OP CAB
- Re-operative OP CABG (regional revascularization-Tailored approach)
- Application to a non-OP CAB practice
  - Position device (instead holding the Heart-Pulmonary Vein isolation (Surgery for Atrila Fibrillation)
  - Position/stabilization if bleeding behind the heart post CABG
- Minimally Invasive Approaches
  - MID CAB or MICS
  - Robotic Assisted MID CAB
  - TE CAB

Isolated or in the Context of Hybrid Revascularization
LIMA-LAD
Stenting to Non-LAD vessels

Conclusions

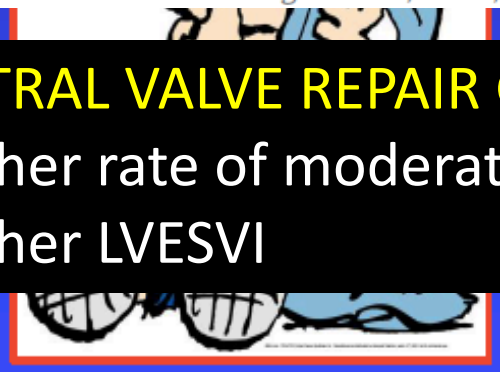
- OP CAB will continue a refinement and maturation process
- Should be strongly considered in high risk patients due its proven benefits (mortality and morbidity)
- Excellent technique to complement innovative approaches
- Should be performed by experienced/expert teams

The Failed Promise of OPCAB

The Failed Promise of Mitral Valve Repair

Mitral-Valve Repair versus Replacement for Severe Ischemic Mitral Regurgitation

Michael A. Acker, M.D., Michael K. Parides, Ph.D., Louis P. Perrault, M.D., Alan J. Moskowitz, M.D., Annetine C. Gelijns, Ph.D., Pierre Voisine, M.D., Peter K. Smith, M.D., Judy W. Hung, M.D., Eugene H. Blackstone, M.D., John D. Puskas, M.D., Michael Argenziano, M.D., James S. Gammie, M.D., Michael Mack, M.D., Deborah D. Ascheim, M.D., Emilia Bagiella, Ph.D., Ellen G. Moquete, R.N., T. Bruce Ferguson, M.D., Keith A. Horvath, M.D., Nancy L. Geller, Ph.D., Marissa A. Miller, D.V.M., Y. Joseph Woo, M.D., David A. D'Alessandro, M.D., Gorav Ailawadi, M.D., Francois Dagenais, M.D., Timothy J. Gardner, M.D., Patrick T. O'Gara, M.D., Robert E. Michler, M.D., and Irving L. Kron, M.D., for the CTSN*



MITRAL VALVE REPAIR GROUP

Higher rate of moderate/severe MR

Higher LVESVI

NEJM 2014

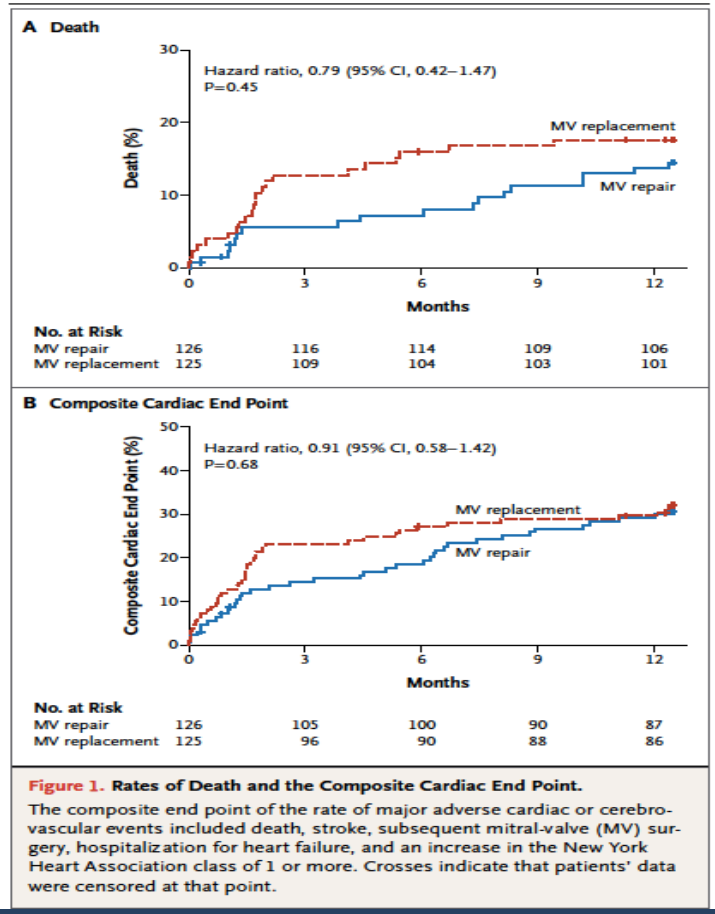


Figure 1. Rates of Death and the Composite Cardiac End Point.

The composite end point of the rate of major adverse cardiac or cerebrovascular events included death, stroke, subsequent mitral-valve (MV) surgery, hospitalization for heart failure, and an increase in the New York Heart Association class of 1 or more. Crosses indicate that patients' data were censored at that point.

Concerns about the quality of the revascularization

- Quality of anastomosis
  - Exposure and visualization
  - Motion
- Early graft thrombosis
  - Lower dose of heparin
  - Lack of coagulopathy
- Incomplete revascularization
  - Vessels in the lateral wall of the LV
  - Patients who become unstable when heart positioned

Number of Mitral Valve Repair- CABG 3,464 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

44% absolute decrease in the number of Mitral Valve Repair-CABG in the last decade

Hybrid Coronary Revascularization

Best treatment option for multivessel CAD

Jorge M. Balaguer, MD
Associate Professor of Thoracic and Cardiovascular Surgery
Rush University
Chief, Cardiac Surgery
Rush Copley Medical Center

CONSULTANT: JOHNSON & JOHNSON

Is this your practice?

- LIMA
- RIMA
- Radial Artery
- Off Pump
- No touch technique for Aorta
- Intraoperative flow evaluation
- Epi-aortic ultrasound

CABG in the United States

- LIMA
- RIMA < 5%
- Radial Artery 4%
- Off Pump 15%
- No touch technique of the Aorta (very few)
- Intraoperative flow evaluation (very few)
- Epi-aortic ultrasound (very few)

This means

- The vast majority of the CABG in the US are:
  - LIMA + 2 veins
  - On pump
  - Blind OR
  - No flow evaluations
  - No epi-aortic ultrasound

Hypothesis

- The vast majority of the CABG in the US are:
  - LIMA + 2 veins
  - On pump
  - Blind OR
  - No flow evaluations
  - No epi-aortic ultrasound

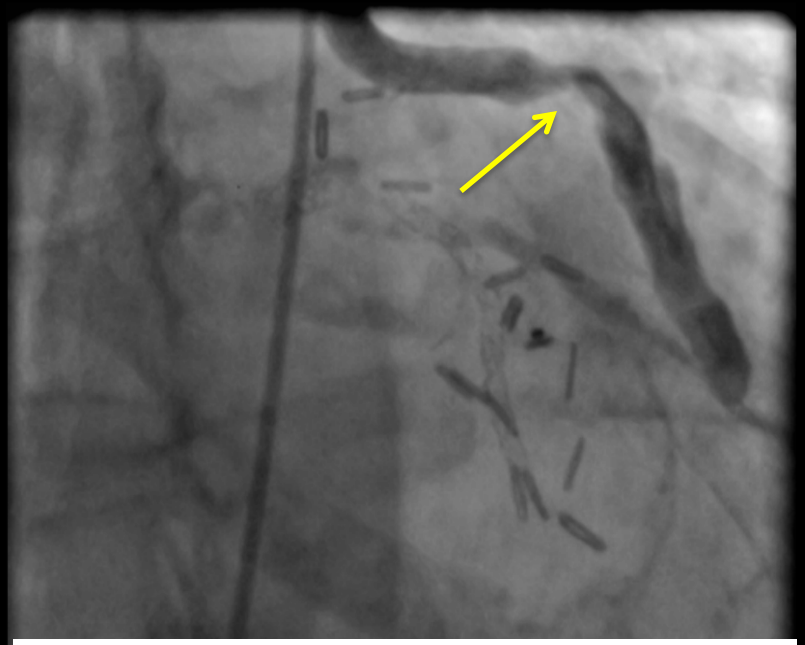
Hypothesis is that: a Hybrid CABG-PCI Revascularization, including LIMA-LAD is better that the most common surgical revascularization practice in the United States

Rationale (conduits and stents)

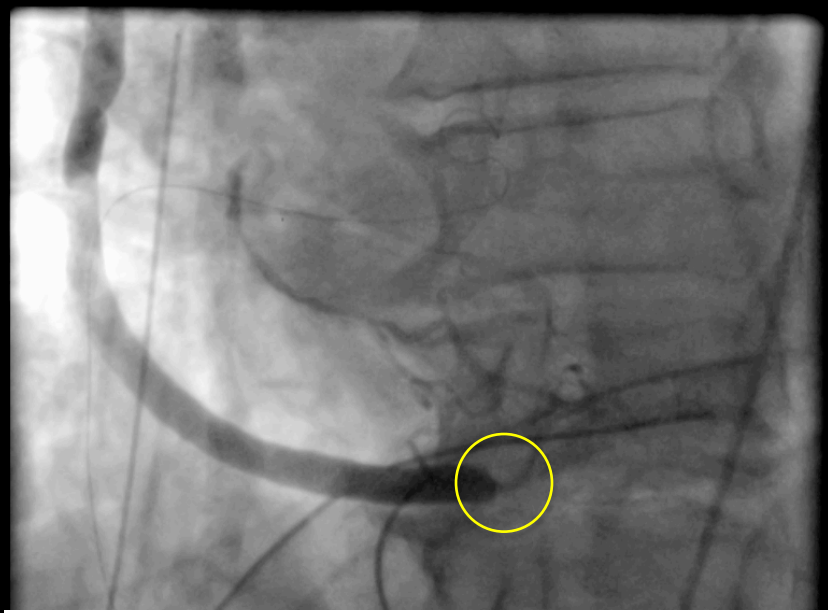
- **LIMA to LAD :** *Superior graft to most important coronary system*
  - Survival
  - Event free survival
  - Trophic benefit over the LAD system
  - Living pedicle
- **SVG = DES for non-LAD vessels**
  - DES: Syntax score and complexity of the lesions
  - Vein grafts attrition rate is variable depending of the quality of the vein and multiple other factors

Keeping complete revascularization as the Goal

Hybrid Strategy in Complex Cases

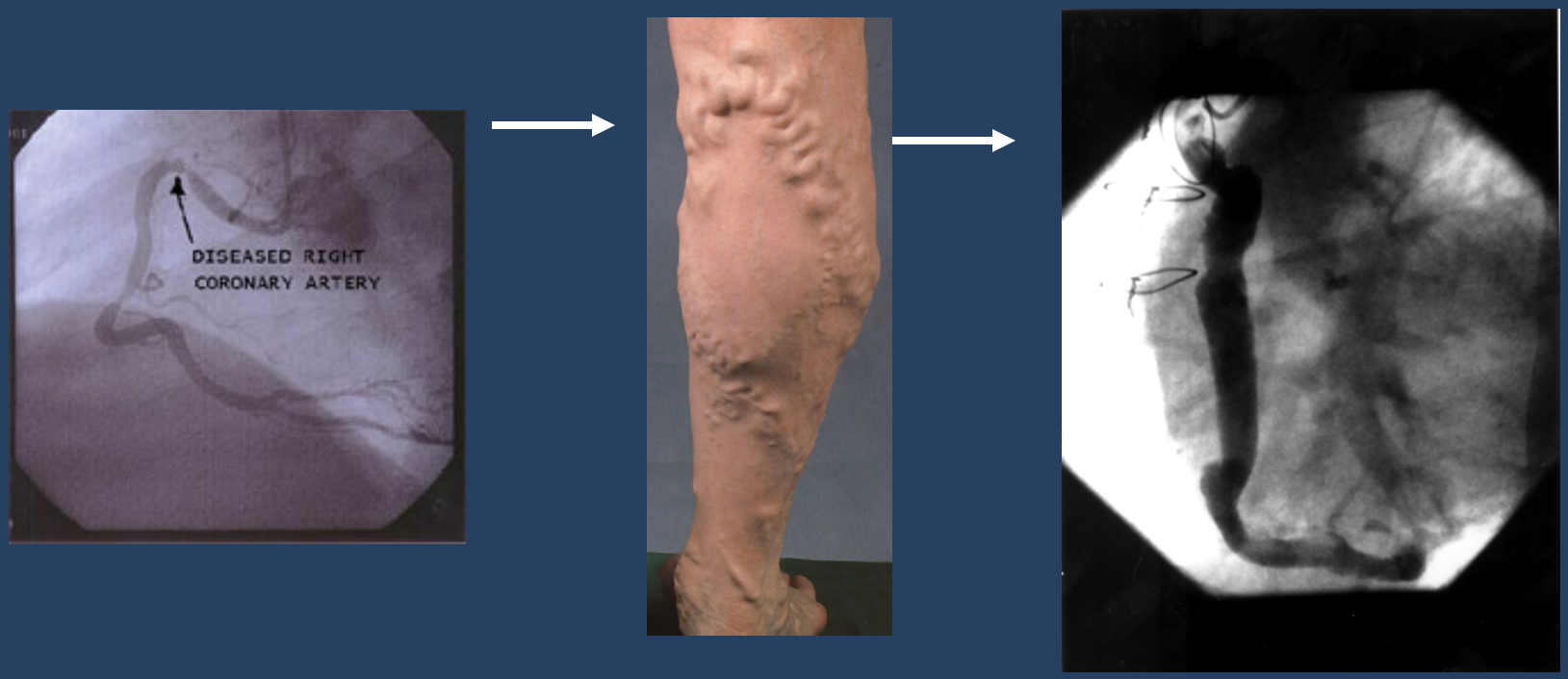


Conduit Quality



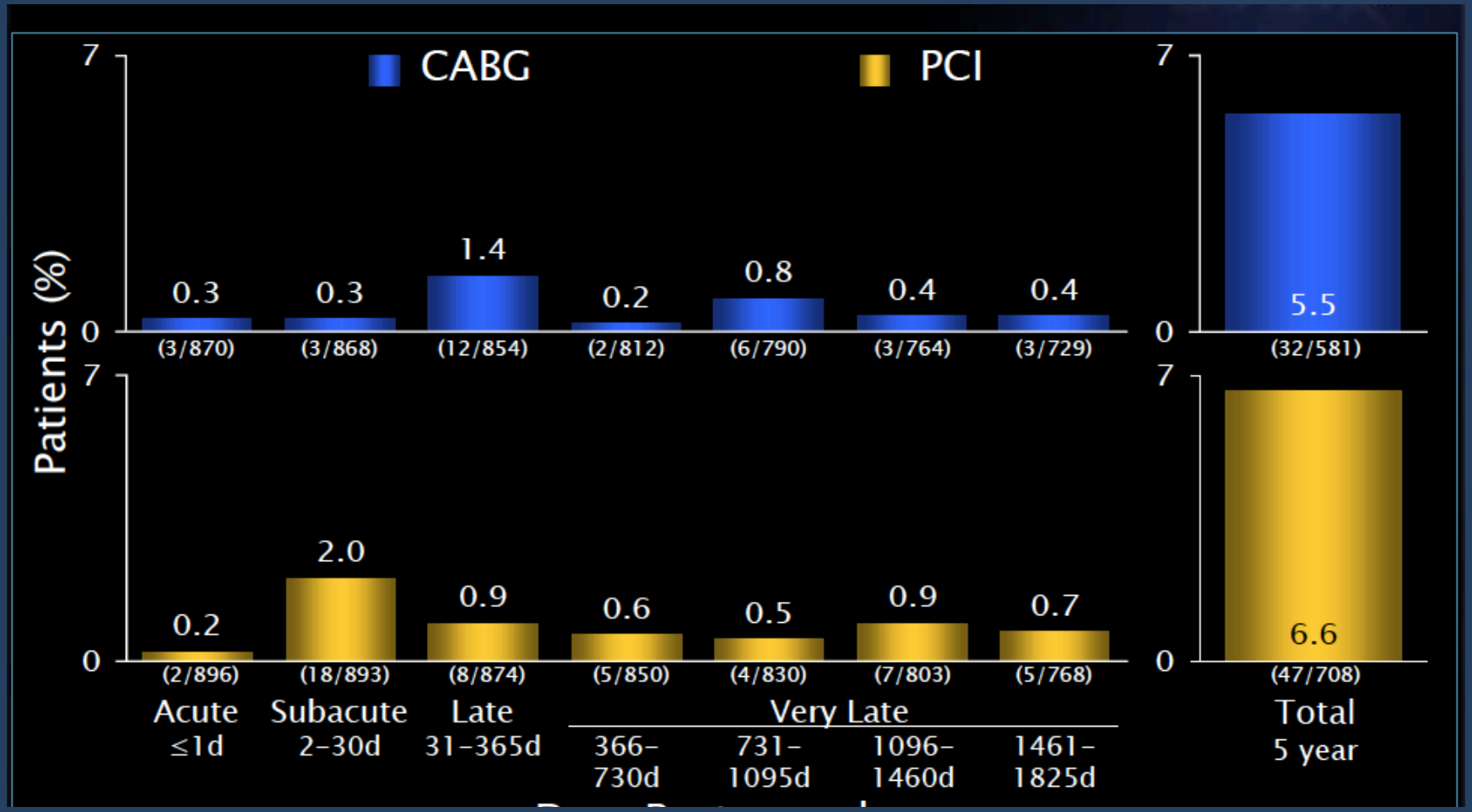
"Conduit-Target Mismatch"

Hybrid Strategy in Complex Cases



Indication: Lack of adequate conduit. Favorable lesion for PCI

Graft failure and stent thrombosis



Advantages of Hybrid Revascularization

- LIMA-LAD minimally Invasive
  - MIDCAB or MICS
  - Robotically Assisted MIDCAB
  - TE-CAB
- Off Pump
- Do not require instrumentation of the Aorta
- Complete revascularization is the goal
- Imaging *(confirm the quality of the graft)*

Advantages of Hybrid Revascularization

- LIMA-LAD minimally Invasive
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  - TE-CAB
- Off Pump
- Do not require instrumentation of the Aorta
- Complete revascularization is the goal
- Imaging *(confirm the quality of the graft)*

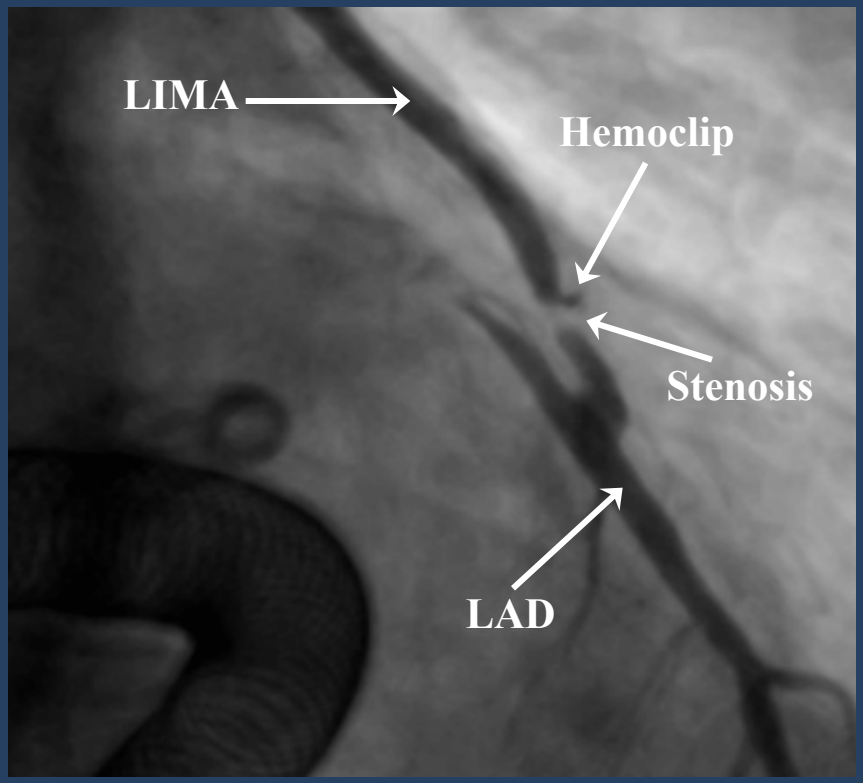
Imaging is a critical component of the Hybrid Revascularization Strategy

Hybrid Cardiovascular Operating Room

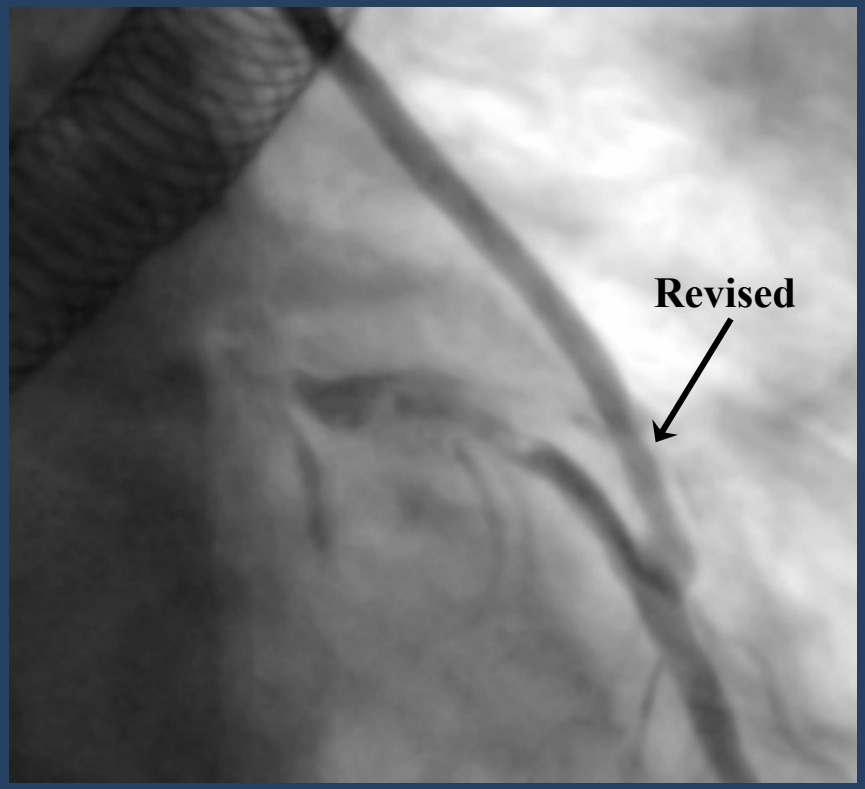
At Vanderbilt University

LIMA to LAD graft

Surgical hemoclip across the graft



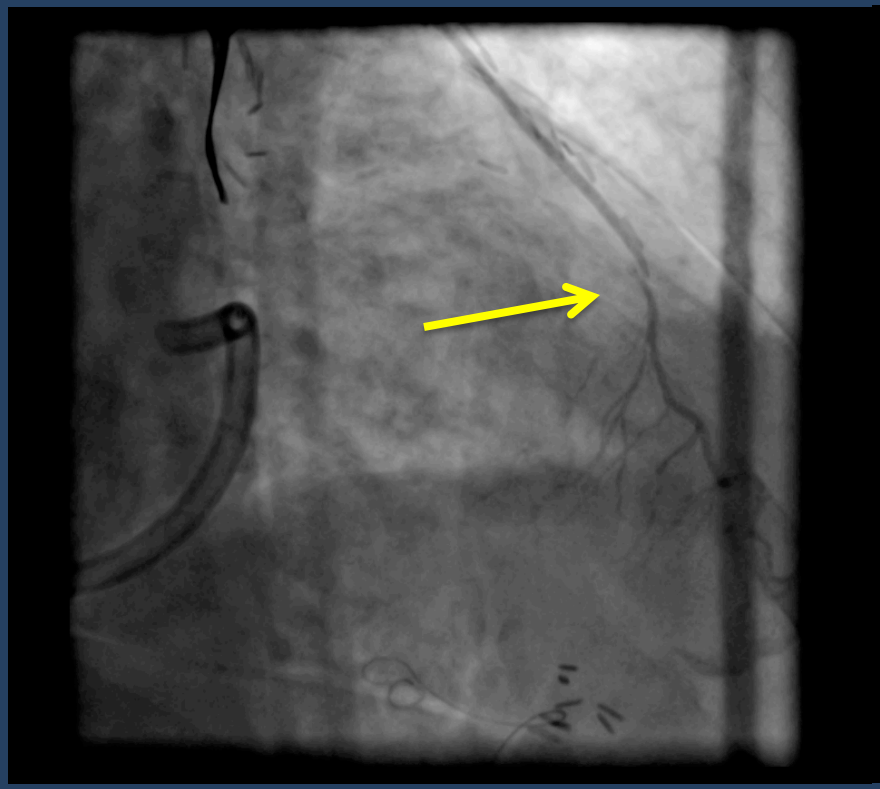
Before revision



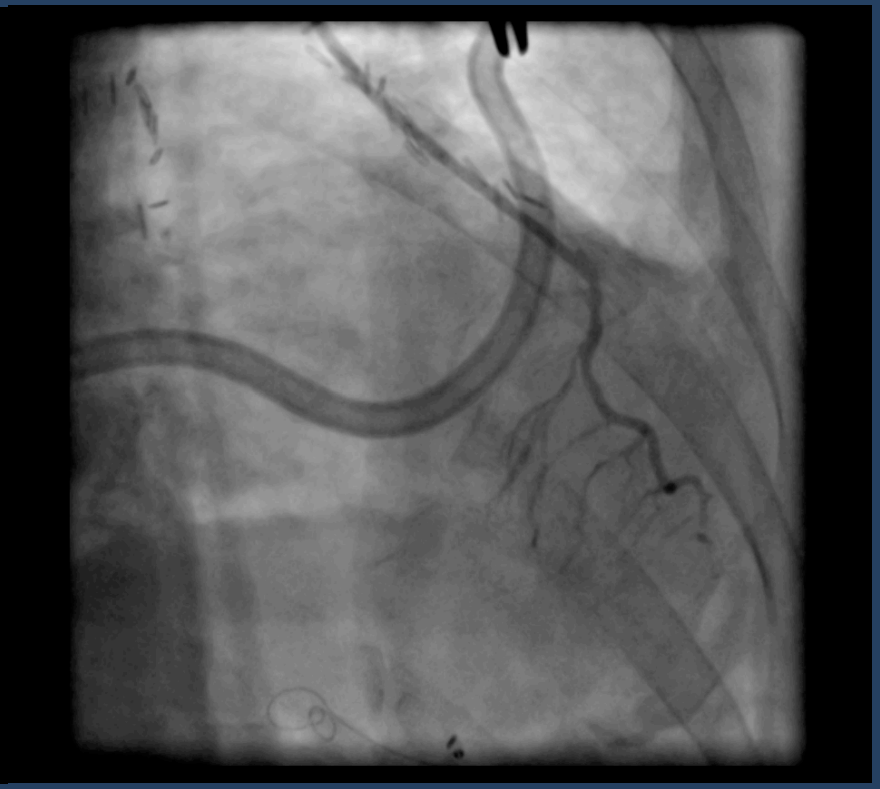
After revision

LIMA to LAD

Loss of the lumen on the distal part of the LIMA immediately before the anastomosis



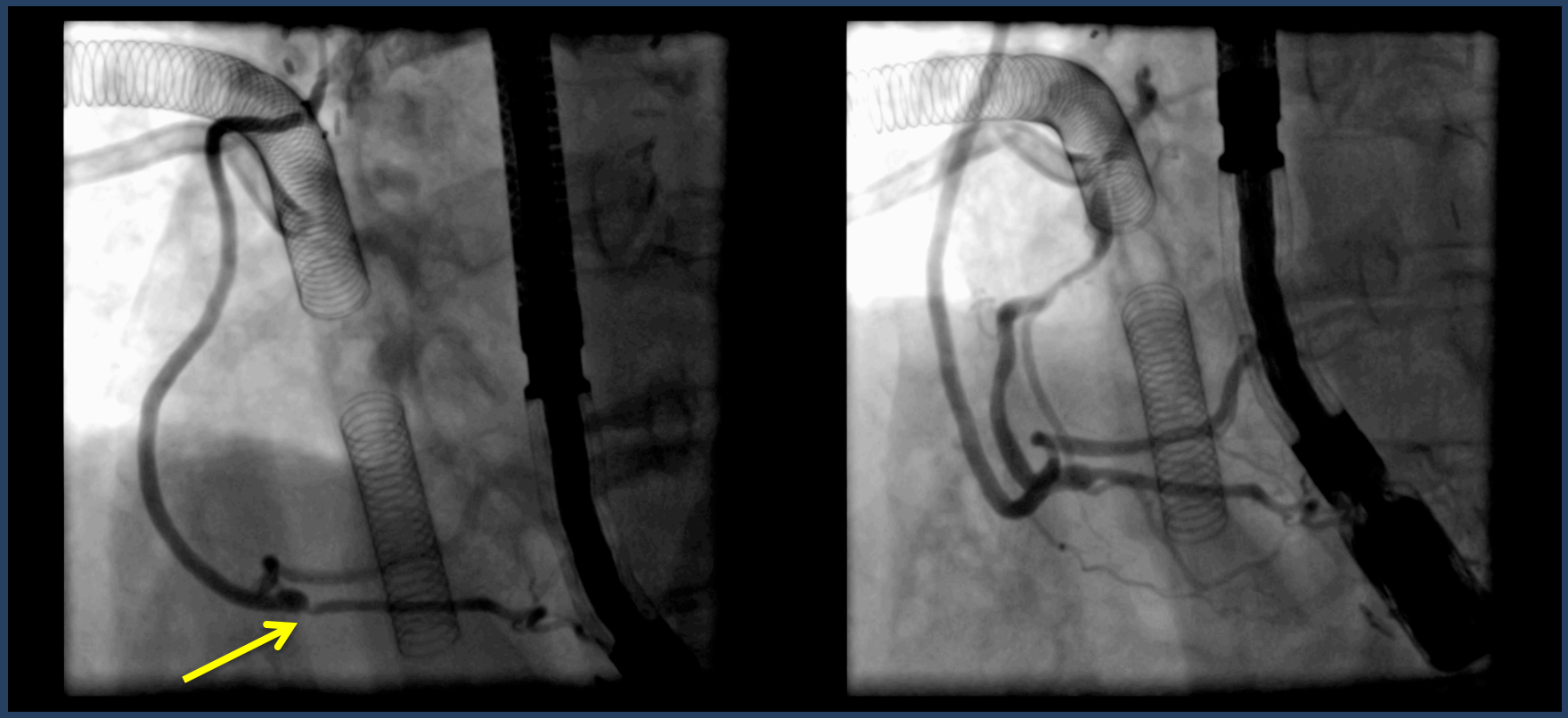
Before revision



After revision

Vein Graft to PDA (RCA)

Loss of lumen at the toe of distal anastomosis

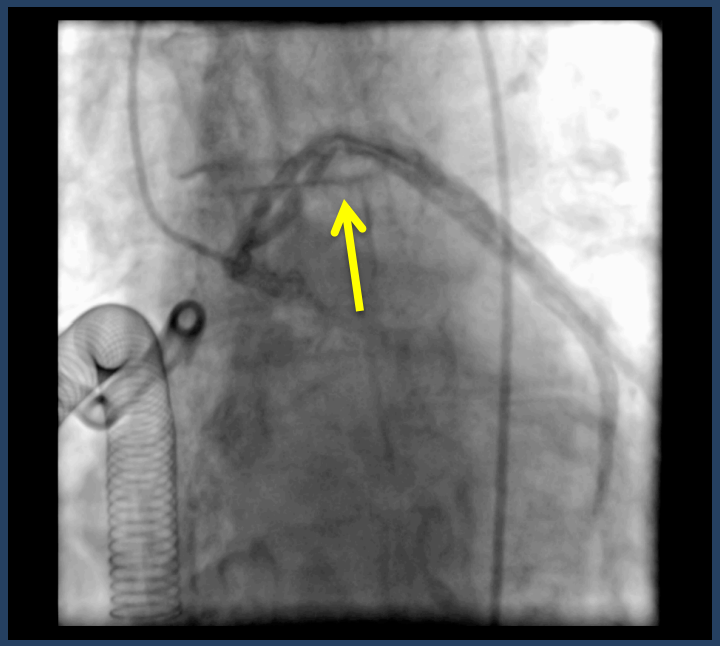


Before revision

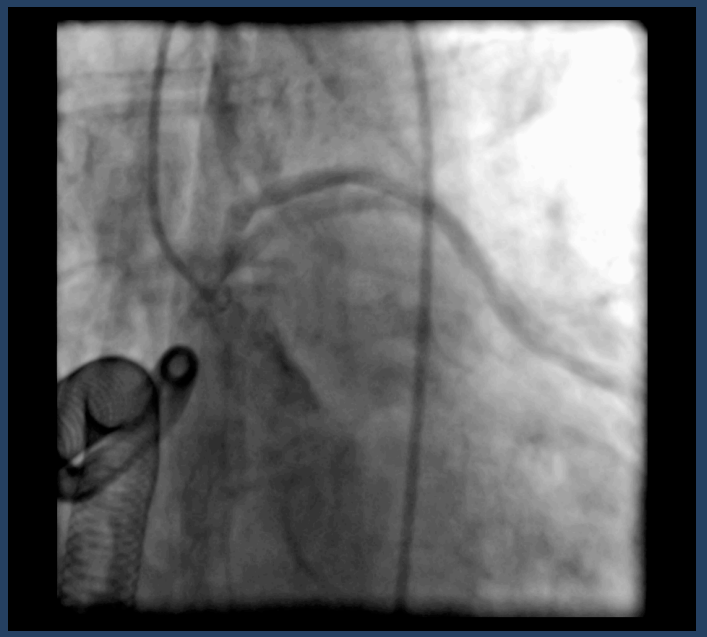
After revision

Vein Grafts to LAD and OM1

Kinking of both grafts



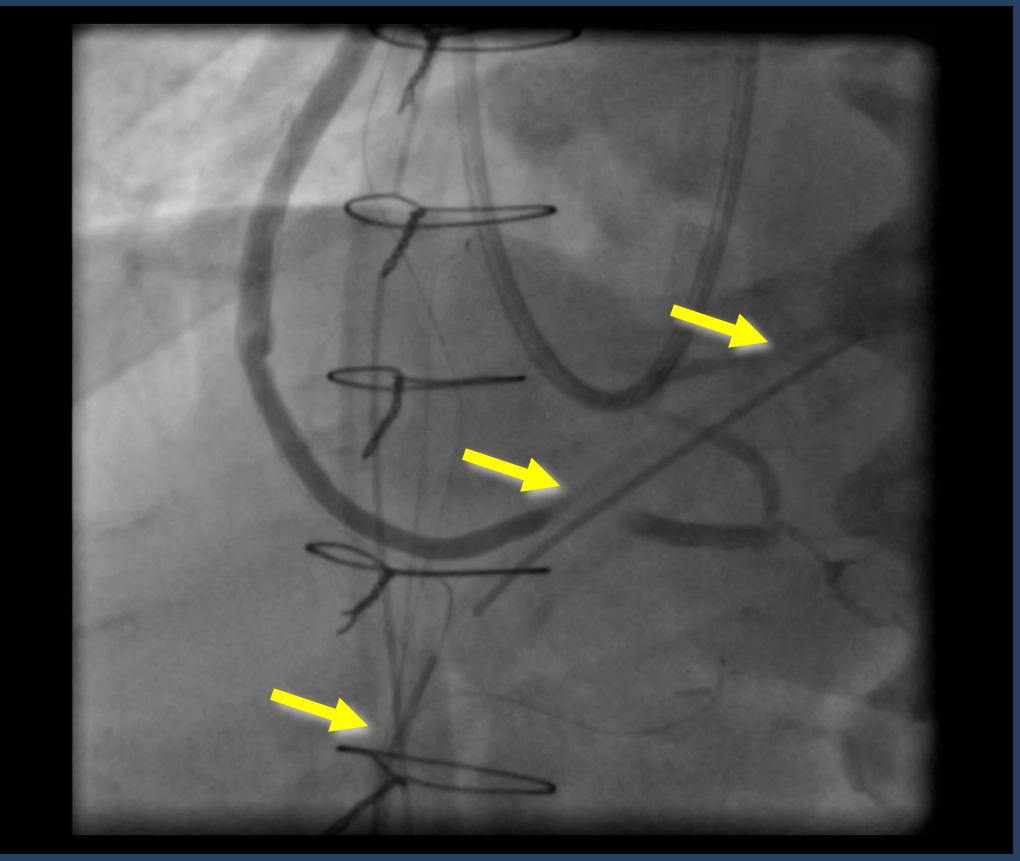
Before revision



After revision

Vein graft to PDA

Chest tube compressing the graft



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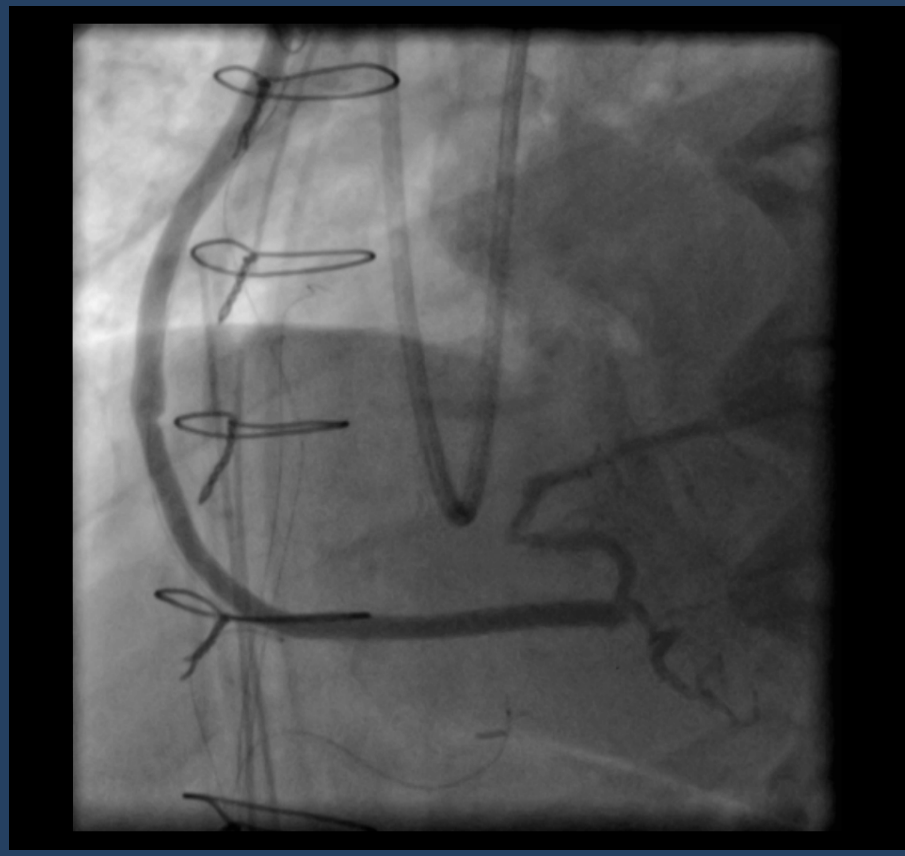
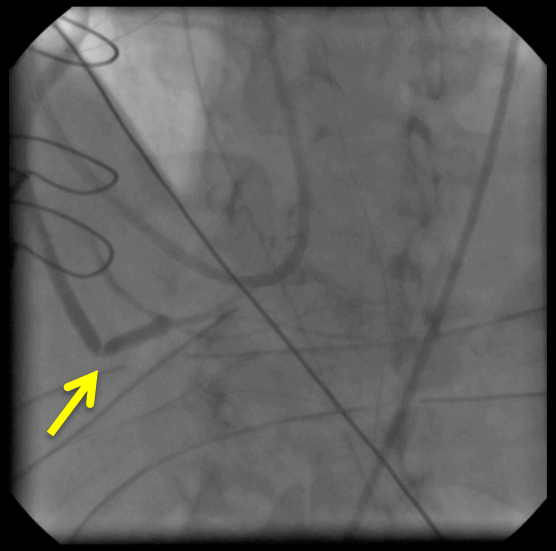


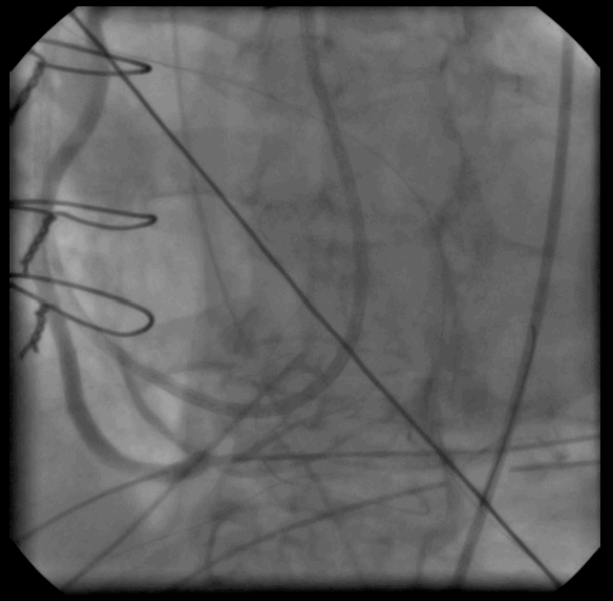
After revision

Vein graft to PDA (RCA)

Kink on the graft before distal anastomosis

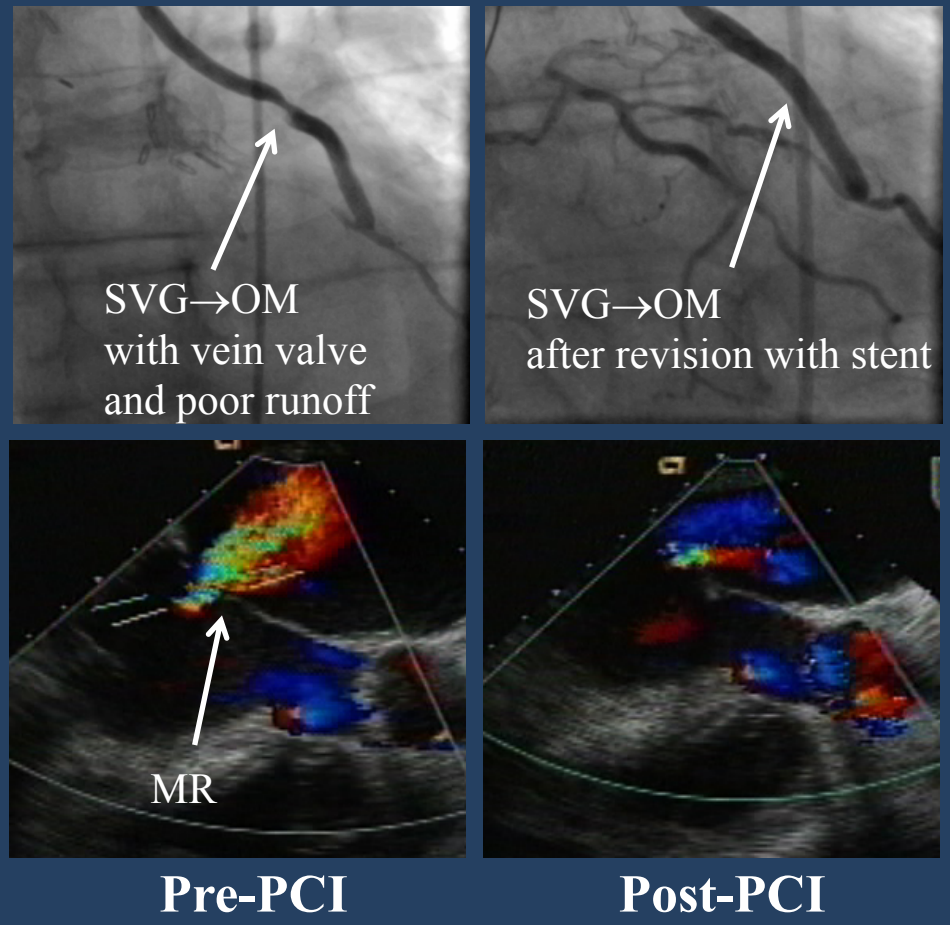


Before revision



After revision

Angiographic bypass defect associated with new onset mitral regurgitation



Greelish et al. JTCVS 2006

Angiographic graft findings (defects)

97 of 796 grafts (12%)

Table 4 Location of Angiographic Graft Finding Versus Type of Graft Intervention*

Type of Graft Intervention	Location of Angiographic Findings in Grafts: Conduit (n = 54 of 796, 6.8% of All Grafts)	Distal Anastomosis (n = 30 of 796, 3.7% of All Grafts)	Target Vessel (n = 13 of 796, 1.6% of All Grafts)
Traditional open surgical revision, n = 27 of 796, 3.4% of all grafts	12 grafts Clip damaging LIMA (n = 3) Suture damaging LIMA (n = 1) Graft kink not correctable with minor adjustment (n = 6) SVG valve impeding flow (n = 2)	12 grafts: LIMA-LAD (n = 11) SVG (n = 1)	3 grafts: Correct vessel, wrong location (n = 1) Wrong vessel (n = 2)
Open-chest PCI, n = 48 of 796, 6% of all grafts (n = 43 unplanned hybrid procedure patients†)	23 grafts: SVG valve impeding flow (n = 9) LIMA dissection (n = 6) Graft kink (n = 7) SVG–coronary size mismatch (n = 1)	15 grafts: SVG (n = 11) LIMA-LAD (n = 4)	10 grafts: Correct vessel, wrong location (n = 7) Wrong vessel (n = 1) Poor runoff, diffuse disease (n = 1) Dissection in the native coronary (n = 1)
Minor adjustment of graft not requiring traditional surgical revision or open-chest PCI, n = 22 of 796, 2.8% of all grafts	19 grafts: Adjustment of conduit lie (n = 7) Clip removal (n = 1) Stitch removal (n = 1) Chest tube removal (n = 2) Intravenous nitroglycerin for LIMA spasm (n = 4)	3 grafts: Unroofing of fascia over the anastomosis (n = 3)	N/A

Surgical: 3.4%

PCI: 6%

Minor adjustment: 2.8%

Conduit	Distal Anastomosis	Target Vessel
6.8%	3.7%	1.6%

Zhao et al. JACC 2009

1-Stop Hybrid Revascularization

CLINICAL RESEARCH Interventional Cardiology

Routine Intraoperative Completion Angiography After Coronary Artery Bypass Grafting and 1-Stop Hybrid Revascularization

Results From a Fully Integrated Hybrid Catheterization Laboratory/Operating Room

David X. Zhao, MD, FACC, Marzia Leacche, MD, Jorge M. Balaguer, MD, Konstantinos D. Boudoulas, MD, Julie A. Damp, MD, James P. Greelish, MD, John G. Byrne, MD, FACC, the Writing Group on behalf of the Cardiac Surgery, Cardiac Anesthesiology, and Interventional Cardiology Groups at the Vanderbilt Heart and Vascular Institute

Nashville, Tennessee

JACC 2009

Details of the Hybrid Procedures

Hybrid Revascularization procedures (n=112)

Median # Grafts	2
LIMA Utilization	93%
Off Pump %	20%
DES	84%
BMS	8%
DES + BMS	7%
Mean # stents	1.8 +/- 1.1
Contrast	200 cc (20-500)
Planned Hybrid	67 Pts (60%)
Unplanned Hybrid	45 Pts (40%)

Antiplatelet Therapy in Hybrid Revascularization Procedures

Planned Hybrid

Preop.

- ASA 325 mg
- Clopidogrel 300 mg

Immediately before surgery

Post Op.

- ASA 325 mg for life
- Clopidogrel 75 mg for 1 year

Unplanned Hybrid

Preop.

- ASA 325 mg

Intraop.

- Clopidogrel 300 mg

Via NGT when decision for PCI was made

Post Op

- ASA 325 mg for life
- Clopidogrel 75 mg for 1 year

30-day Results

No "Achilles Heels" for Hybrid Approach

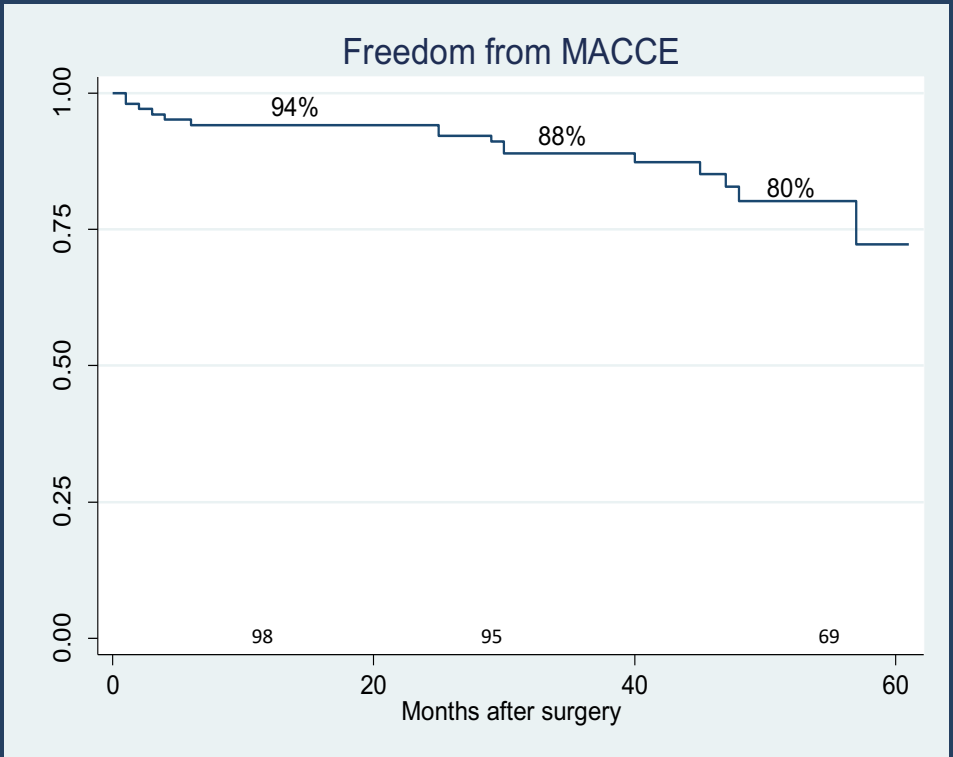
Table 5 Post-Operative Characteristics

Variables	Entire Group (n = 366)	Standard (n = 254)	Hybrid (n = 112)	p Value*
Median chest tube drainage (ml)	1,420 (110–12,700)	1,382 (170–7,240)	1,550 (110–12,700)	0.18
Reoperation for bleeding	10 (3%)	7 (3%)	3 (3%)	0.63
Median PRBC transfusions (units/patient) at 48 h	1 (0–20)	1 (0–20)	1 (0–10)	0.13
Median creatinine at 24 h (mg/dl)	0.9 (0.3–12.1)	0.9 (0.3–12.1)	0.9 (0.4–5)	0.90
Median creatinine at 48 h (mg/dl)	1 (0.3–12.3)	1 (0.4–12.3)	1 (0.3–5.9)	0.78
Median creatinine at 72 h (mg/dl)	1 (0.3–13.2)	1 (0.3–13.2)	1 (0.4–4)	0.58
Median CPK at 48 h (U/l)	906 (189–7,788)	452 (189–7,788)	1,492 (736–6,430)	0.01
Median CK-MB at 48 h (ng/ml)	16 (2–164)	10 (2–140)	28 (11–164)	0.01
Median CK-MB ratio at 48 h (%)	1.6 (0.5–8.4)	1.4 (0.5–8.4)	1.9 (0.6–2.7)	0.33
Median troponin I at 48 h (ng/ml)	0.4 (0.01–4.6)	0.3 (0.03–1.8)	1.2 (0.01–4.6)	0.42
New acute renal failure	13 (4%)	10 (3.9%)	3 (2.6%)	0.39
25% increase in creatinine at 72 h	126 (34%)	89 (35%)	37 (33%)	0.40
New stroke	5 (1.4%)	3 (1.1%)	2 (1.7%)	0.48
New renal failure requiring hemodialysis	3 (1%)	3 (1%)	0 (0%)	0.33
New atrial fibrillation	83 (23%)	61 (24%)	22 (19%)	0.21
New intra-aortic balloon pump	13 (4%)	7 (3%)	6 (5%)	0.17
Intrastent thrombosis	1 (0.3%)	N/A	1 (1%)	N/A
New low cardiac output syndrome	10 (3%)	5 (1.9%)	5 (4.5%)	0.15
Deep sternal wound infection	5 (1%)	3 (1%)	2 (1.8%)	0.48
Median length of stay (days)	5 (1–97)	5 (1–33)	6 (1–97)	0.08
Operative mortality	7 (2%)	4 (1.5%)	3 (2.6%)	0.33

Conclusions

- One-stop hybrid revascularization was
  - Reasonable
  - Safe
  - Feasible
- Hybrid OR Enhances options for the treatment of patients with complex CAD

Hybrid Group. Long-Term Outcomes
Mean follow-up: 3 years (95% complete)

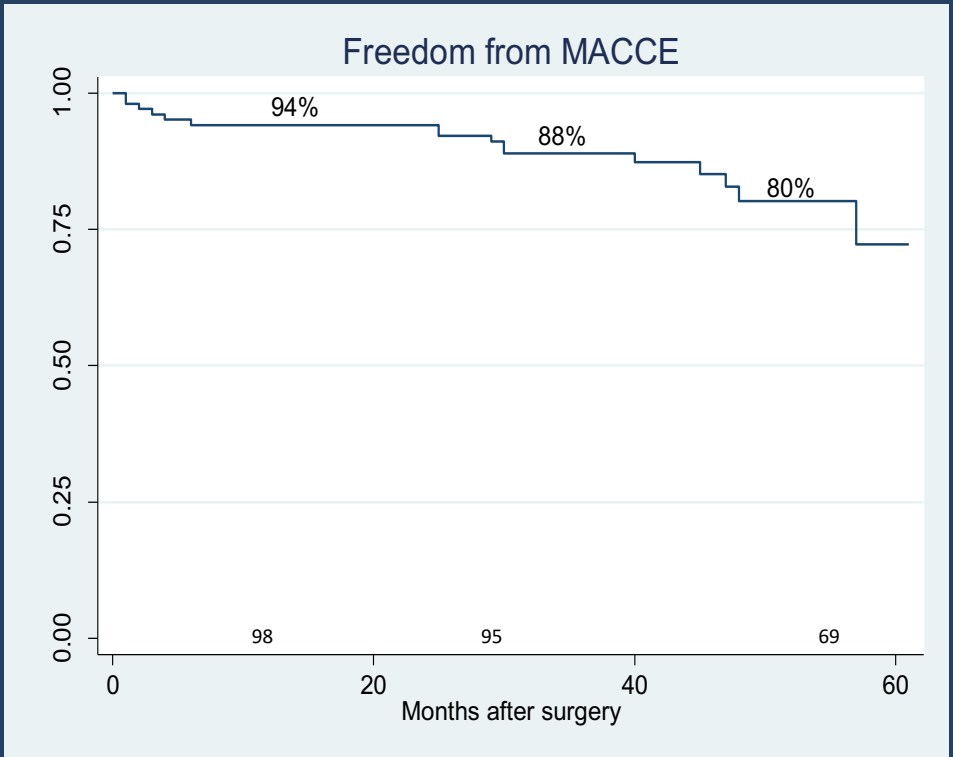


- **Hybrid Survival** **94%**
- **Repeat Revascularization** **6.5%**
  - ***For Stent restenosis*** ***5.5%***
  - ***For SVG failure*** ***1 %***
- **No re-intervention needed for LIMA-LAD grafts**

Leacche et al.

Hybrid Group. Long-Term Outcomes

Mean follow-up: 3 years (95% complete)



- **Hybrid Survival 94%**
- **Syntax CABG: 93% PCI: 91%**

- **Repeat Revascularization 6.5%**
  - ***For Stent restenosis 5.5%***
  - ***For SVG failure 1 %***

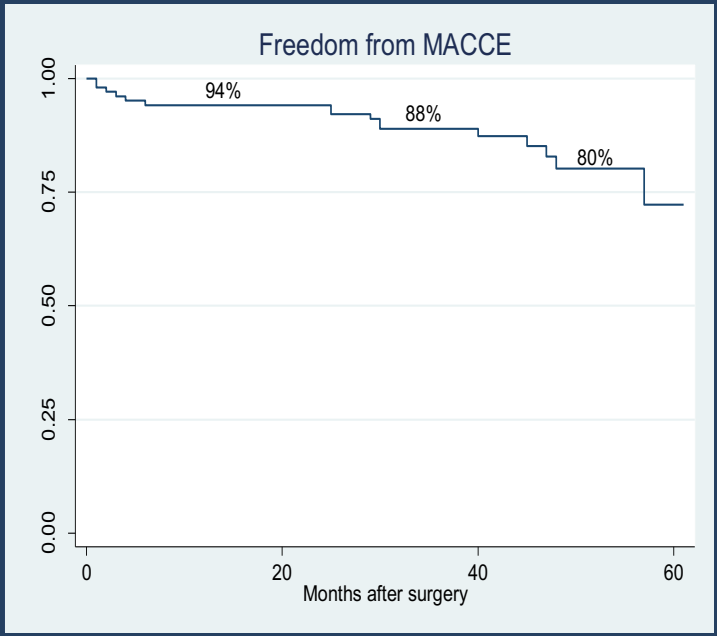
Syntax CABG: 12.2% PCI: 22.5%

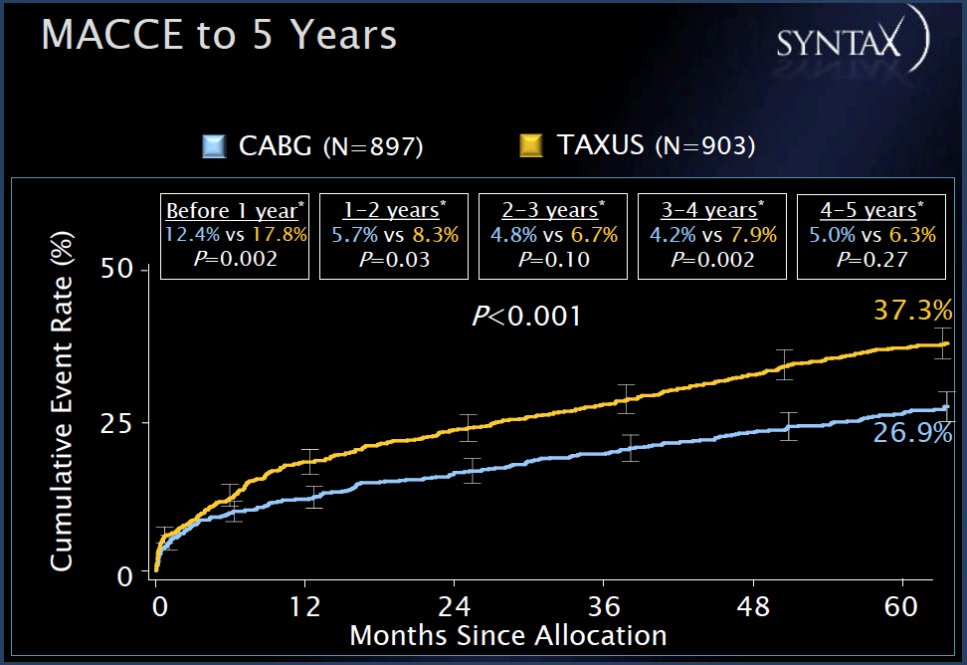
- **No re-intervention needed for LIMA-LAD grafts**

Leacche et al.

Hybrid Group. Long-Term Outcomes

Mean follow-up: 3 years (95% complete)





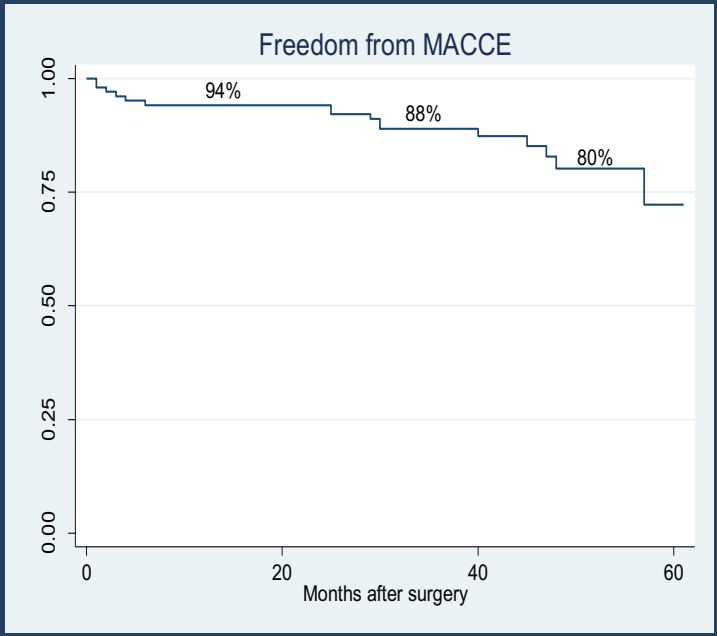
Freedom from MACCE at 3 years

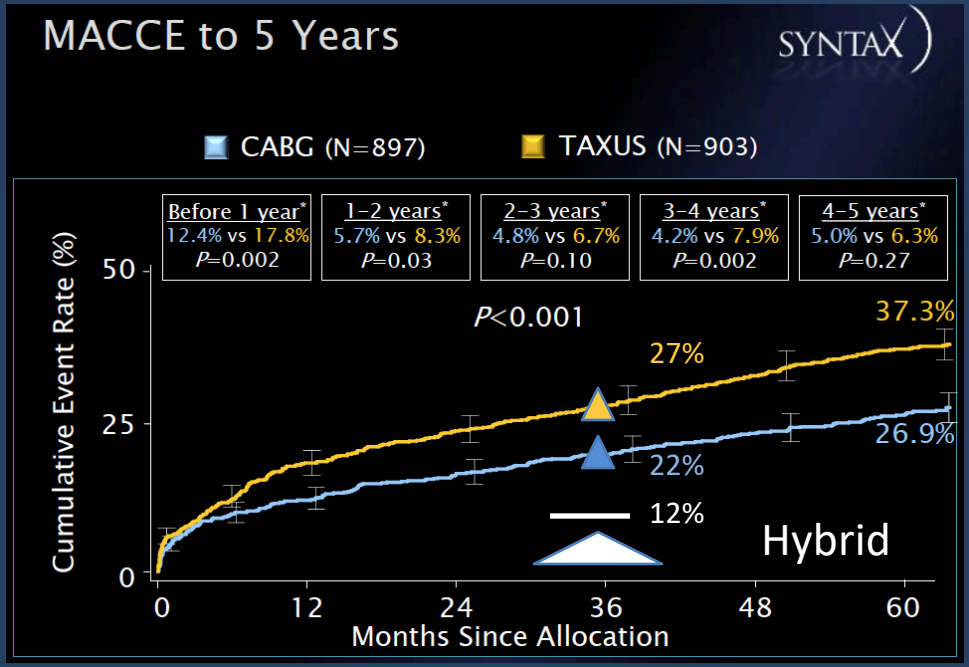
Hybrid: 88%

Leacche et al.

Hybrid Group. Long-Term Outcomes

Mean follow-up: 3 years (95% complete)





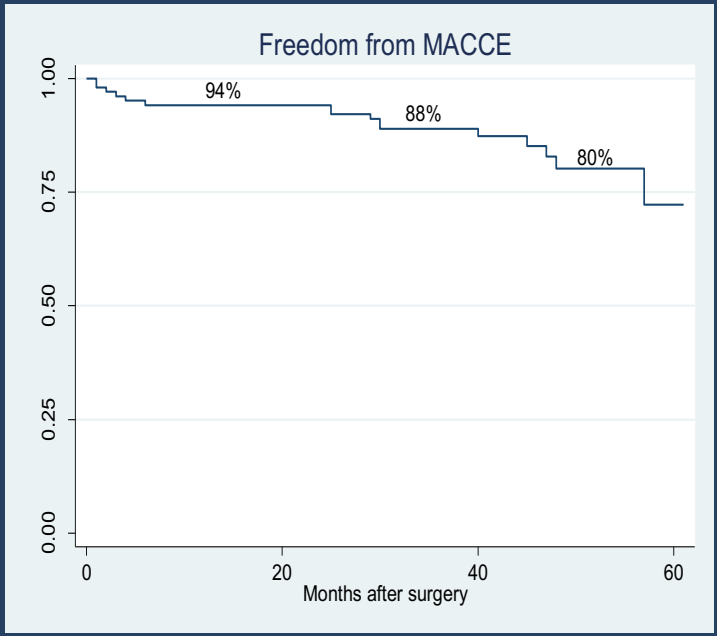
Freedom from MACCE at 3 years

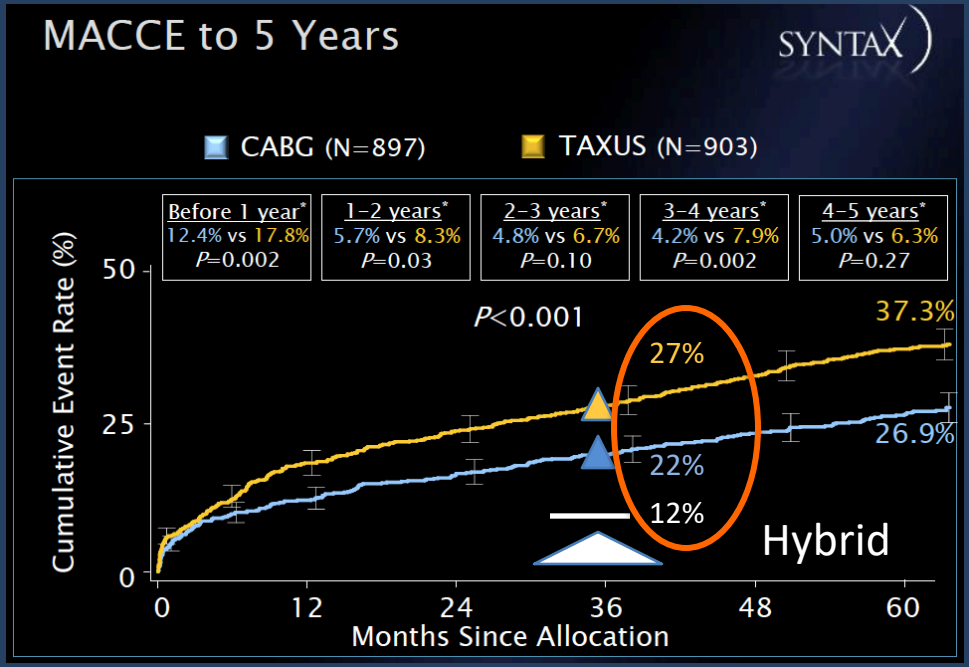
Hybrid: 88%

Leacche et al.

Hybrid Group. Long-Term Outcomes

Mean follow-up: 3 years (95% complete)





Freedom from MACCE at 3 years

Hybrid: 88%

Leacche et al.

Hybrid Coronary Revascularization

Minimally Invasive LIMA to LAD + PCI

Added value proposition

Advantages

- Faster recovery (minimally Invasive-off pump)
- Never events
  - Stroke
  - Mediastinitis

If 1-stop Hybrid revascularization approach is used

- Complete revascularization by the end of the procedure
- Imaging to confirm the quality of the LIMA-LAD graft

Integrating Coronary Anastomotic Connectors and Robotics Toward a Totally Endoscopic Beating Heart Approach: Review of 120 Cases

Husam H. Balkhy, MD, L. Samuel Wann, MD, Dorothy Krienbring, RN, and Susan E. Arnsdorf, RN

Center for Robotic and Minimally Invasive Cardiac Surgery, The Wisconsin Heart Hospital, Milwaukee, Wisconsin

Table 3. Perioperative Complications in 120 Totally Endoscopic Coronary Artery Bypass Patients

Complication	Frequency	Percentage
30-day mortality	1	0.8%
Perioperative myocardial infarction	1	0.8%
Perioperative cerebrovascular accident	1	0.8%
Return for bleeding	2	1.6 %
Wound infection	0	0.0%
Phrenic nerve palsy	1	0.8%
Prolonged hospitalization	2	1.6%
Brachial artery embolism	1	0.8%
Pericardial effusion	1	0.8%
Pleural effusion requiring intervention	2	1.6%

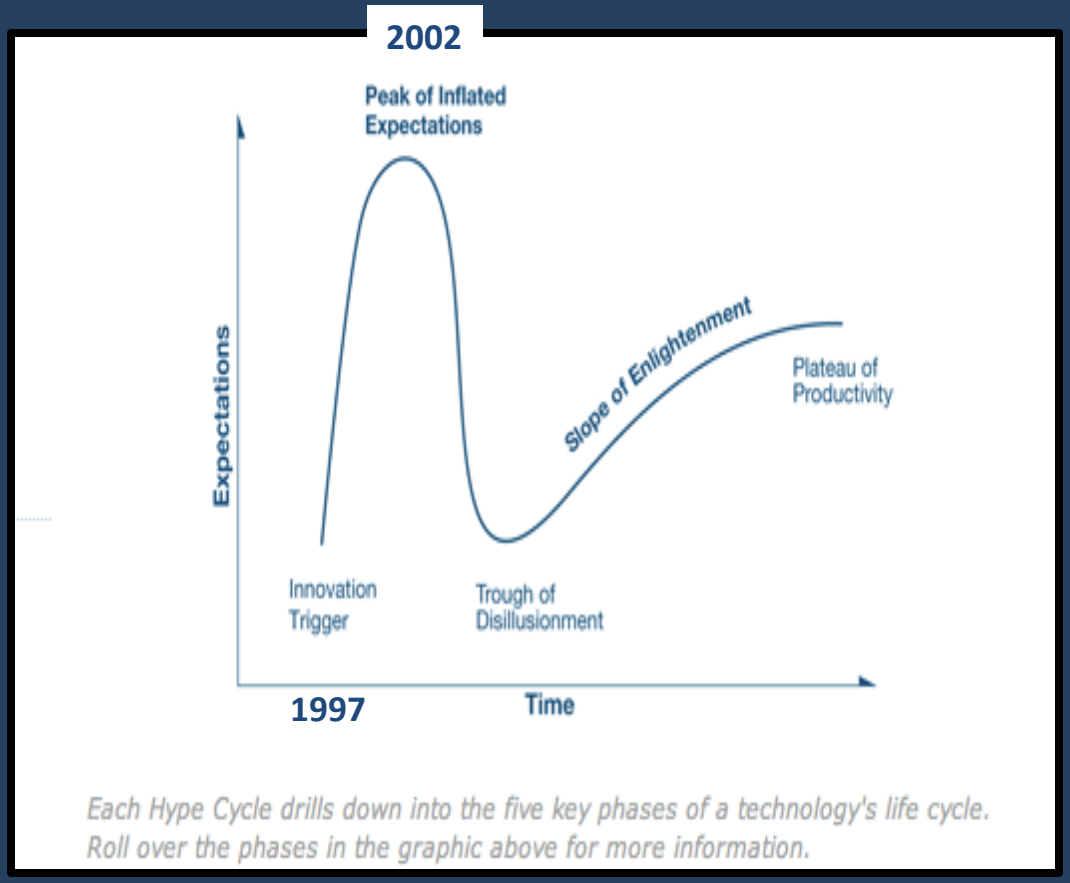
block and ligate the left atrial appendage using an endoloop technique under transesophageal echo guidance.

Mean length of hospital stay was 3.3 ± 2.4 days. There

Mean PO Hospital Stay

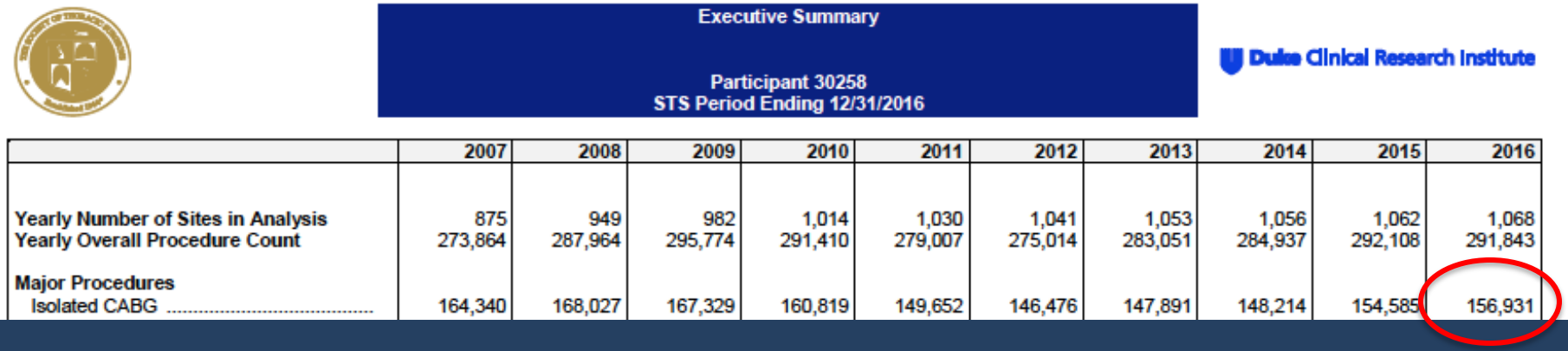
3.3 days

Off-Pump CABG trends along the Hype Cycle



Innovation Trigger

Trends in CABG in the US



Executive Summary

Participant 30258
STS Period Ending 12/31/2016

Duke Clinical Research Institute

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Yearly Number of Sites in Analysis	875	949	982	1,014	1,030	1,041	1,053	1,056	1,062	1,068
Yearly Overall Procedure Count	273,864	287,964	295,774	291,410	279,007	275,014	283,051	284,937	292,108	291,843
Major Procedures										
Isolated CABG	164,340	168,027	167,329	160,819	149,652	146,476	147,891	148,214	154,585	156,931

2016

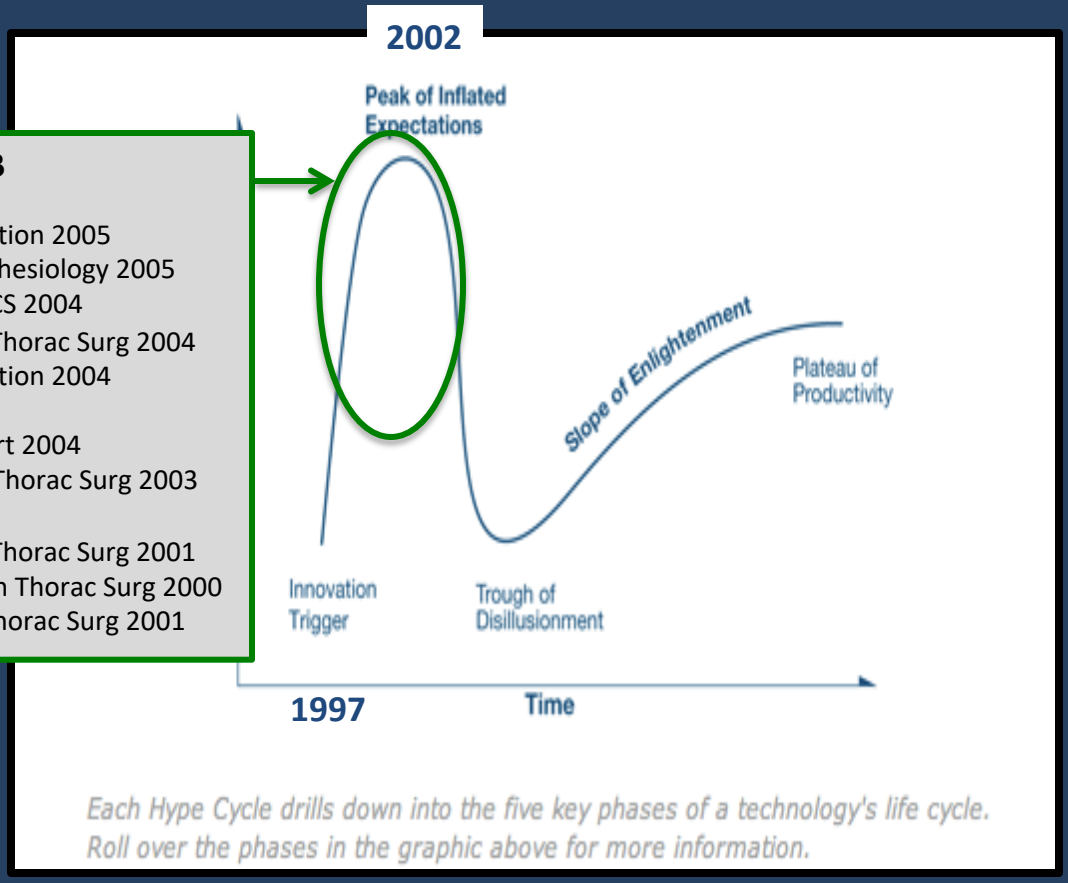
156,931 CABG in the US (STS database)

Highest number since 2010

Off-Pump CABG trends along the Hype Cycle

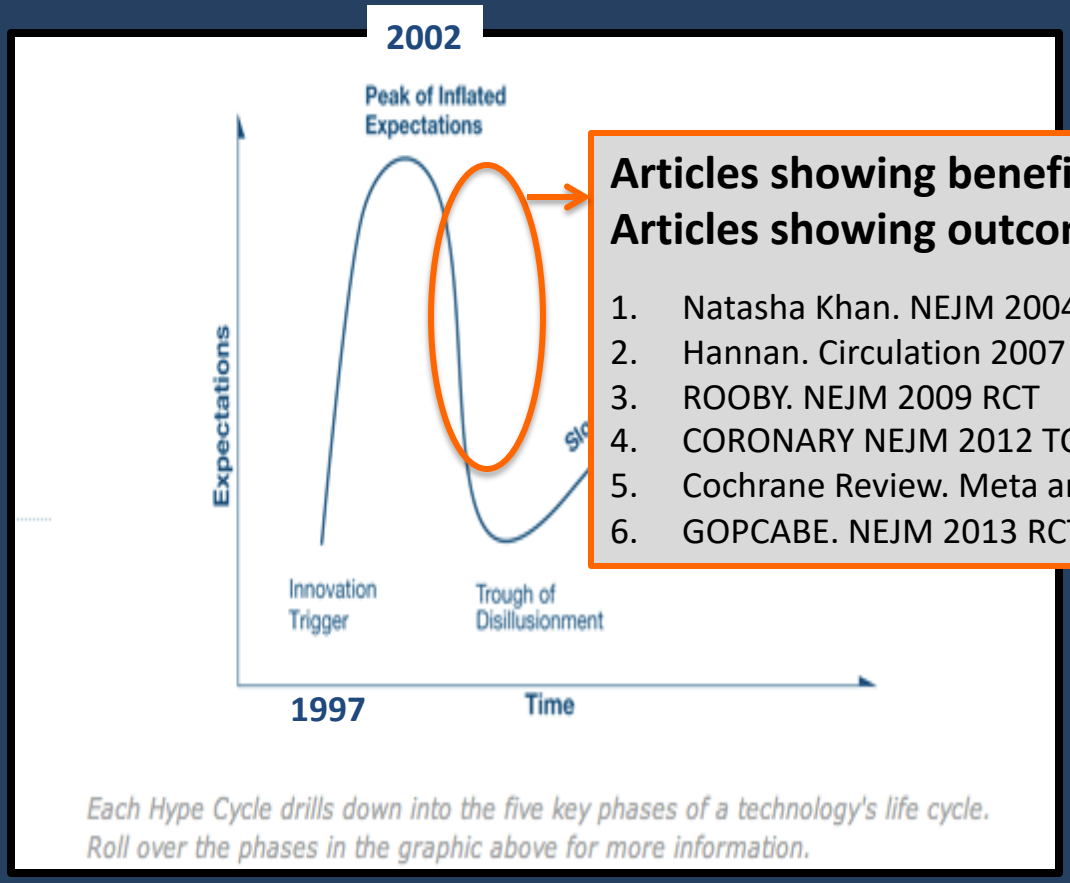
Articles supporting OP CAB

1. Selke. Meta-Analysis. Circulation 2005
2. Cheng. Meta-Analysis. Anesthesiology 2005
3. Puskas. Meta-Analysis. ISMICS 2004
4. Matsura. Angiographic Ann Thorac Surg 2004
5. Mack. HCA database. Circulation 2004
6. Puskas. RCT. JAMA 2004
7. Van Dijk. Retrospective. Heart 2004
8. Reston. Meta-Analysis. Ann Thorac Surg 2003
9. Van Dijk, RCT. JAMA 2002
10. Plomondon. Database. Ann Thorac Surg 2001
11. Omeroglu. Angiographic. Ann Thorac Surg 2000
12. Puskas. Single Center. Ann Thorac Surg 2001



Upward trend to reach the peak of inflated expectations

Off-Pump CABG trends along the Hype Cycle



Articles showing benefits were less clear
Articles showing outcomes were worse

1. Natasha Khan. NEJM 2004 RCT
2. Hannan. Circulation 2007 Database
3. ROOBY. NEJM 2009 RCT
4. CORONARY NEJM 2012 TCT
5. Cochrane Review. Meta analysis. 2012
6. GOPCABE. NEJM 2013 RCT

Downward trend towards the next landmark: Trough of disillusionment

Meta-Analysis

- Selke
- Chen
- Reston
- Puskas
- Cochrane

Meta-analisis: Cheng y col. (37 randomized studies / 3.369 patients)

REVIEW ARTICLES

David C. Warltier, M.D., Ph.D., Editor

Anesthesiology 2005; 102:188–203

Does Off-pump Coronary Artery Bypass Reduce Mortality, Morbidity, and Resource Utilization When Compared with Conventional Coronary Artery Bypass? A Meta-analysis of Randomized Trials

Davy C. Cheng, M.D., M.Sc., F.R.C.P.C.,* Daniel Bainbridge, M.D., F.R.C.P.C.,† Janet E. Martin, Pharm.D.,‡ Richard J. Novick, M.D., M.Sc., F.R.C.S.C.,§ The Evidence-based Perioperative Clinical Outcomes Research Group‖

CME This article and its accompanying editorial have been selected for the *Anesthesiology* CME Program. After reading both articles, go to http://www.asahq.org/journal-cme to take the test and apply for Category 1 credit. Complete instructions may be found in the CME section at the back of this issue.

The authors undertook a meta-analysis of 37 randomized trials (3369 patients) of off-pump coronary artery bypass surgery *versus* conventional coronary artery bypass surgery. No significant differences were found for 30-day mortality (odds ratio [OR], 1.02; 95% confidence interval [CI], 0.58–1.80), myocardial infarction (OR, 0.77; 95%CI, 0.48–1.26), stroke (OR, 0.68; 95%CI, 0.33–1.40), renal dysfunction, intraaortic balloon pump, wound infection, rethoracotomy, or reintervention. However, off-pump coronary artery bypass surgery significantly decreased atrial fibrillation (OR, 0.58; 95%CI, 0.44–0.77), transfusion (OR, 0.43; 95%CI, 0.29–0.65), inotrope requirements (OR, 0.48; 95%CI, 0.32–0.73), respiratory infections (OR, 0.41; 95%CI, 0.23–0.74), ventilation time (weighted mean difference, −3.4 h; 95%CI, −5.1 to −1.7 h), intensive care unit stay (weighted mean difference, −0.3 days; 95%CI −0.6 to −0.1 days), and hospital stay (weighted mean difference, −1.0 days; 95%CI −1.5 to −0.5 days). Patency and neurocognitive function results were inconclusive. In-hospital and 1-yr direct costs were generally higher for conventional coronary artery bypass surgery *versus* off-pump coronary artery bypass surgery. Therefore, this meta-analysis demonstrates that mortality, stroke, myocardial infarction, and renal failure were not reduced in off-pump coronary artery bypass surgery surgery; however, selected short-term and mid-term clinical and resource outcomes were improved compared with conventional coronary artery bypass surgery.

This article is accompanied by an Editorial View. Please see: Floyd T, Fleisher LA: Off-pump coronary artery bypass and the hypothesis from which it grew: Is it yet to be tested? What are the downsides of the lingering questions? ANESTHESIOLOGY 2005; 102:3–5.

Additional material related to this article can be found on the ANESTHESIOLOGY Web site. Go to http://www.anesthesiology.org, click on Enhancements Index, and then scroll down to find the appropriate article and link. Supplementary material can also be accessed on the Web by clicking on the "ArticlePlus" link either in the Table of Contents or at the top of the Abstract or HTML version of the article.

CORONARY artery disease remains the number one cause of death in the Western world and contributes significantly to health care resource utilization. In a recent ranking report from the Agency for Healthcare Research and Quality, heart disease tops the list at nearly $68 billion (1997 United States dollars).[1] In the United States alone, cardiovascular disorders result in more than 561,000 angioplasties and 519,000 surgical bypass procedures annually.[2] Consequently, the social burden of cardiovascular disease is of unmistakable relevance, and interventions to mitigate the associated economic and clinical burdens need urgent exploration.

Although it has been shown that, compared with medical management alone, conventional coronary artery bypass surgery (CCAB) prolongs life and reduces symptoms, these benefits are tempered by risks including mortality (2–5%), stroke (2%), transfusions (30–90%), atrial fibrillation (30%), and neurocognitive dysfunction (50–75%).[3–6] Adverse clinical consequences associated with CCAB have been largely attributed to the cardiopulmonary bypass circuit, hypothermic cardiac arrest, aortic cannulation, and cross-clamping.[6–8] Consequently, there has been an upsurge of interest in safer alternatives to CCAB, including percutaneous cor-

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Received from the Department of Anesthesia & Perioperative Medicine, University of Western Ontario, London, Ontario, Canada. Submitted for publication May 5, 2004. Accepted for publication July 16, 2004. Support was provided solely from institutional and/or departmental sources. Presented at the 25th Annual Meeting of the Society of Cardiovascular Anesthesiologists, Miami, Florida, April 26–30, 2003.

Address reprint requests to Dr. Cheng: Department of Anesthesia & Perioperative Medicine, London Health Sciences Centre-University Campus, 339 Windermere Road, Room 5-CA19, London, Ontario, Canada N6A 5A5. Address electronic mail to: davy.cheng@lhsc.on.ca.

Off pump better:

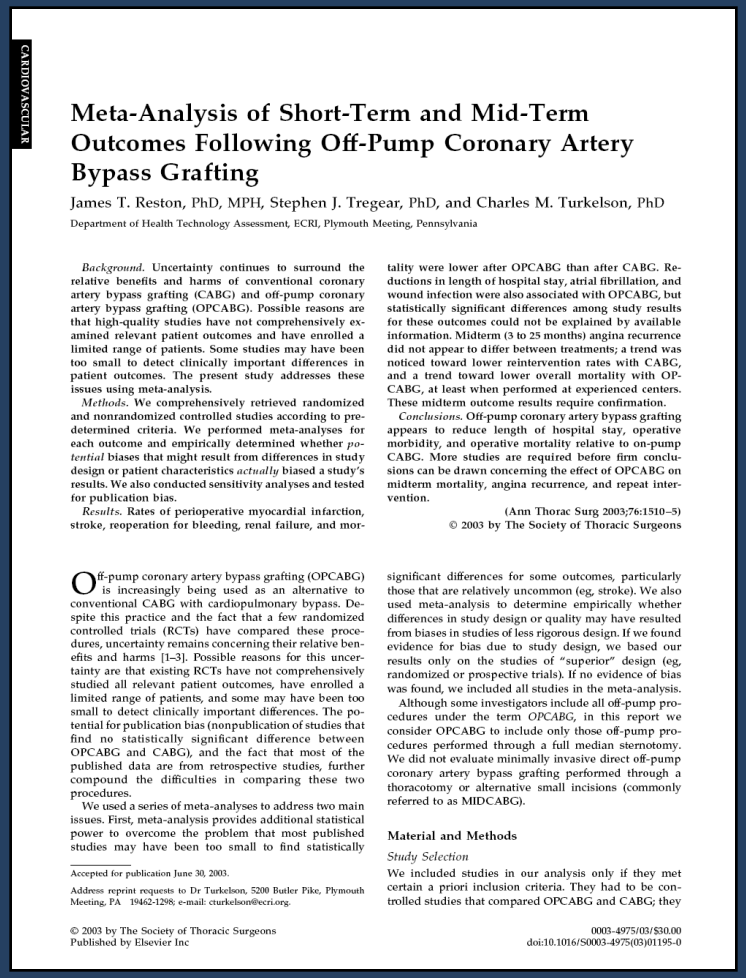
- Atrial fibrillation
- Respiratory infections
- Use of inotropic
- Blood transfusions
- Time on ventilator (3 hours)
- ICU stay (0.3 days)
- Hospital stay (1 day)

RRR entre el 35% y 60%

Anesthesiology 2005

Meta-analysis: Reston et al.

(53 studies / 46.621 patients)



CARDIOVASCULAR

Meta-Analysis of Short-Term and Mid-Term Outcomes Following Off-Pump Coronary Artery Bypass Grafting

James T. Reston, PhD, MPH, Stephen J. Tregear, PhD, and Charles M. Turkelson, PhD

Department of Health Technology Assessment, ECRI, Plymouth Meeting, Pennsylvania

Background. Uncertainty continues to surround the relative benefits and harms of conventional coronary artery bypass grafting (CABG) and off-pump coronary artery bypass grafting (OPCABG). Possible reasons are that high-quality studies have not comprehensively examined relevant patient outcomes and have enrolled a limited range of patients. Some studies may have been too small to detect clinically important differences in patient outcomes. The present study addresses these issues using meta-analysis.

Methods. We comprehensively retrieved randomized and nonrandomized controlled studies according to predetermined criteria. We performed meta-analyses for each outcome and empirically determined whether *potential* biases that might result from differences in study design or patient characteristics *actually* biased a study's results. We also conducted sensitivity analyses and tested for publication bias.

Results. Rates of perioperative myocardial infarction, stroke, reoperation for bleeding, renal failure, and mortality were lower after OPCABG than after CABG. Reductions in length of hospital stay, atrial fibrillation, and wound infection were also associated with OPCABG, but statistically significant differences among study results for these outcomes could not be explained by available information. Midterm (3 to 25 months) angina recurrence did not appear to differ between treatments; a trend was noticed toward lower reintervention rates with CABG, and a trend toward lower overall mortality with OPCABG, at least when performed at experienced centers. These midterm outcome results require confirmation.

Conclusions. Off-pump coronary artery bypass grafting appears to reduce length of hospital stay, operative morbidity, and operative mortality relative to on-pump CABG. More studies are required before firm conclusions can be drawn concerning the effect of OPCABG on midterm mortality, angina recurrence, and repeat intervention.

(Ann Thorac Surg 2003;76:1510–5)

Off-pump coronary artery bypass grafting (OPCABG) is increasingly being used as an alternative to conventional CABG with cardiopulmonary bypass. Despite this practice and the fact that a few randomized controlled trials (RCTs) have compared these procedures, uncertainty remains concerning their relative benefits and harms [1–3]. Possible reasons for this uncertainty are that existing RCTs have not comprehensively studied all relevant patient outcomes, have enrolled a limited range of patients, and some may have been too small to detect clinically important differences. The potential for publication bias (nonpublication of studies that find no statistically significant difference between OPCABG and CABG), and the fact that most of the published data are from retrospective studies, further compound the difficulties in comparing these two procedures.

We used a series of meta-analyses to address two main issues. First, meta-analysis provides additional statistical power to overcome the problem that most published studies may have been too small to find statistically significant differences for some outcomes, particularly those that are relatively uncommon (eg, stroke). We also used meta-analysis to determine empirically whether differences in study design or quality may have resulted from biases in studies of less rigorous design. If we found evidence for bias due to study design, we based our results only on the studies of "superior" design (eg, randomized or prospective trials). If no evidence of bias was found, we included all studies in the meta-analysis.

Although some investigators include all off-pump procedures under the term *OPCABG*, in this report we consider OPCABG to include only those off-pump procedures performed through a full median sternotomy. We did not evaluate minimally invasive direct off-pump coronary artery bypass grafting performed through a thoracotomy or alternative small incisions (commonly referred to as MIDCABG).

Material and Methods

Study Selection

We included studies in our analysis only if they met certain a priori inclusion criteria. They had to be controlled studies that compared OPCABG and CABG; they

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doi:10.1016/S0003-4975(03)01195-0

Off pump better:

- Lower mortality
- Lower rate of
  - *Stroke*
  - *Post op MI*
  - *A. Fib.*
  - *Reop. Bleeding*
  - *Renal failure*

RRR entre el 35% y 50%

Ann Thorac Surg 2003

Use of Bilateral Internal Thoracic Arteries in CABG Through Lateral Thoracotomy With Robotic Assistance in 150 Patients

Sudhir Srivastava, MD, Suresh Gadasalli, MD, Madhava Agusala, MD, Ram Kolluru, MD, Jayaram Naidu, MD, Manish Shroff, MD, Reyna Barrera, PAC, Shaune Quismundo, RN, and Vishwa Srivastava, BA

Departments of Cardiovascular Surgery and Cardiology, Alliance Hospital, and Cardiac Surgical Associates, Odessa, Texas

Background. Internal thoracic arteries (ITA) have been shown to offer longer graft patency. Off-pump coronary artery bypass graft surgery (CABG) through small lateral thoracotomy has been reported. The present study deals with feasibility of using bilateral ITAs (BITA) in CABG through small lateral thoracotomy facilitated by the da Vinci robotic system.

Methods. Since July 2002, 150 patients underwent CABG through small lateral thoracotomy using robotic

Results. Planned arterial revascularization was completed in 148 patients. Mean number of arterial grafts per patient was 2.6 ± 0.8. All coronary arteries could be reached with BITA as in situ or composite grafts. There was no mortality, stroke, myocardial infarction, or wound infection. Seven patients had new onset atrial fibrillation. Four patients required exploration of postoperative bleeding. Mean postoperative length of stay was 3.6 ± 2.9 days.

Mean PO Hospital Stay:

3.6 days

Morbidities Associated With CPB

- Myocardial Necrosis
- Systemic Inflammatory Response
- Neuro-Cog effects / Brain injury
- Pump Lung (Adult Respiratory Distress Syndrome)
- Hypertension and distention of the heart
- Renal Dysfunction
- Embolization
- Coagulation Disorders
- Increased Blood Loss

Early clinical and angiographic outcomes after robotic-assisted coronary artery bypass surgery

Michael E. Halkos, MD, MSc,[a] Henry A. Liberman, MD,[b] Chandan Devireddy, MD,[b] Patrick Walker, BA,[a] Aloke V. Finn, MD,[b] Wissam Jaber, MD,[b] Robert A. Guyton, MD,[a] and John D. Puskas, MD, MSc[a]

TABLE 3. Clinical outcomes of entire cohort

Outcome	N = 307
30-d mortality	4 (1.3%)
Stroke	1 (0.3%)
Myocardial infarction	5 (1.6%)
Conversion to sternotomy	16 (5.2%)
Reexploration for bleeding	7 (2.3%)
Repeat revascularization	8 (2.6%)
Postoperative atrial fibrillation	47 (15.3%)
Renal failure	6 (2.0%)
No. of patients receiving any blood product transfusion	66 (21.5%)
Superficial wound infection	6 (2.0%)
Sternal complications/mediastinitis	0
Extubated in OR	123 (40.0%)
Prolonged ventilation (>24 h)	18 (5.9%)
Median ventilation time	2.0 h (range, 0-193)
Median ICU length of stay	1.0 d (range, 0-19)
Median hospital length of stay	4.0 d (range, 2-27)

ICU, Intensive care unit, *OR*, operating room.

Median PO Hospital Stay

4 days

TE CAB and Hybrid Revascularization

Robotic Totally Endoscopic LIMA-LAD + PCI to non LAD vessels

Table 3. Postoperative Results

Variable	Total (n = 226)	Hybrid (n = 140)	Converted (n = 22)	Wait and See (n = 64)	*p* Value
Revision bleeding	8 (3.5%)	5 (3.6%)	2 (9.5%)	1 (1.5%)	0.227
IABP	2 (0.9%)	0 (0.0%)	0 (0.0%)	2 (3.1%)	0.078
AFib	39 (17.3%)	24 (17.1%)	5 (22.7%)	10 (15.6%)	0.748
Ventilation time (h)	9 (0–349)	9 (0–85)	14 (4–288)	9 (0–349)	0.003
Pneumonia	8 (3.5%)	3 (2.1%)	2 (9.1%)	3 (4.7%)	0.220
Stroke	2 (0.9%)	1 (0.7%)	0 (0.0%)	1 (1.6%)	0.749
CVVH	3 (1.3%)	0 (0.0%)	1 (4.5%)	2 (3.1%)	0.074
Mortality	3 (1.3%)	0 (0.0%)	1 (4.8%)	2 (3.1%)	0.071
ICU stay (h)	22 (13–1048)	22 (13–250)	42 (16–384)	21 (16–1048)	0.064
Hospital stay (days)	6 (3–54)	6 (3–49)	8 (6–22)	6 (3–54)	0.002
Time to walking outside (days)	7 (1–90)	7 (1–90)	14 (2–60)	7 (1–90)	0.258
Time to household work (days)	15 (2–180)	14 (3–180)	21 (10–120)	14 (2–168)	0.082
Time to all activities (days)	42 (0–720)	42 (0–720)	75 (21–359)	42 (7–360)	0.180

Bonatti et al. Ann Thorac Surg 2012

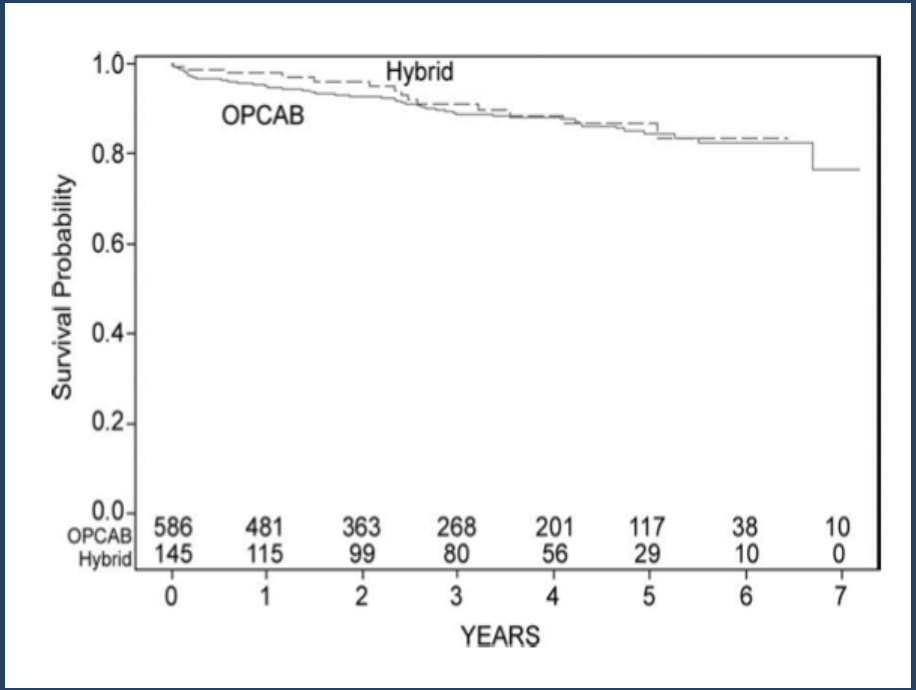
Hybrid Coronary Revascularization
(MIDCAB/PCI) vs. Op CAB for multi-vessel CAD

30 days Outcomes

- Comparable Mortality, MI, Stroke
- Comparable ICU and Hospital Stay
- Fewer Blood Tx in the Hybrid Group

At Follow-up

- Comparable survival
- Higher rate of repeat revascularization in the HCR



Halkos et al. Ann Thorac Surg 2011

The difference of having intraoperative imaging

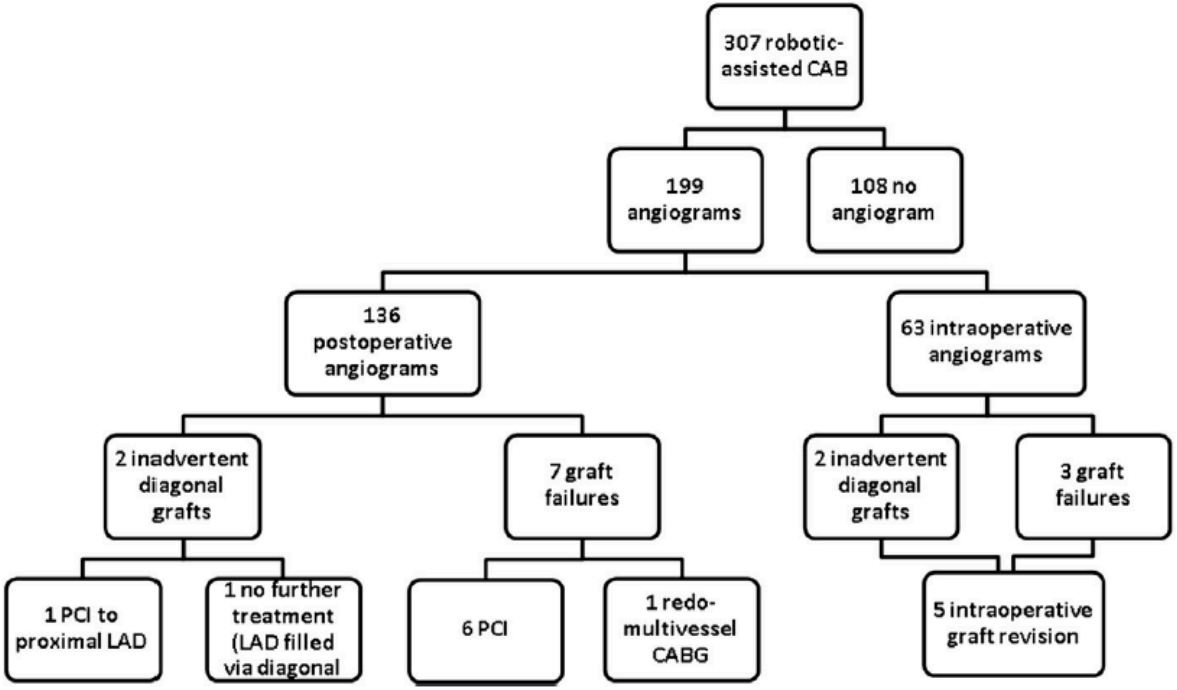


FIGURE 1. Flow diagram of patients undergoing robotic-assisted CABG categorized by angiography and graft defects. *CAB*, Coronary artery bypass; *CABG*, coronary artery bypass grafting; *LAD*, left anterior descending; *PCI*, percutaneous coronary intervention.

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Conclusion

- Hybrid Revascularization is a safe and effective approach for the treatment of patients with multi-vessel CAD
- It is at least comparable to the most common treatment CABG on pump LIMA+ veins in the blind OR
- If performed in the Hybrid OR simultaneously including imaging, in selected case the outcomes could be even superior to most CABG

Minimally Invasive Hybrid Coronary Artery Revascularization

David M. Holzhey, MD, Stephan Jacobs, MD, Michael Mochalski, MD, Denis Merk, MD, Thomas Walther, MD, PhD, Friedrich W. Mohr, MD, PhD, and Volkmar Falk, MD, PhD

Department of Cardiac Surgery, Heart Center Leipzig, Leipzig, Germany

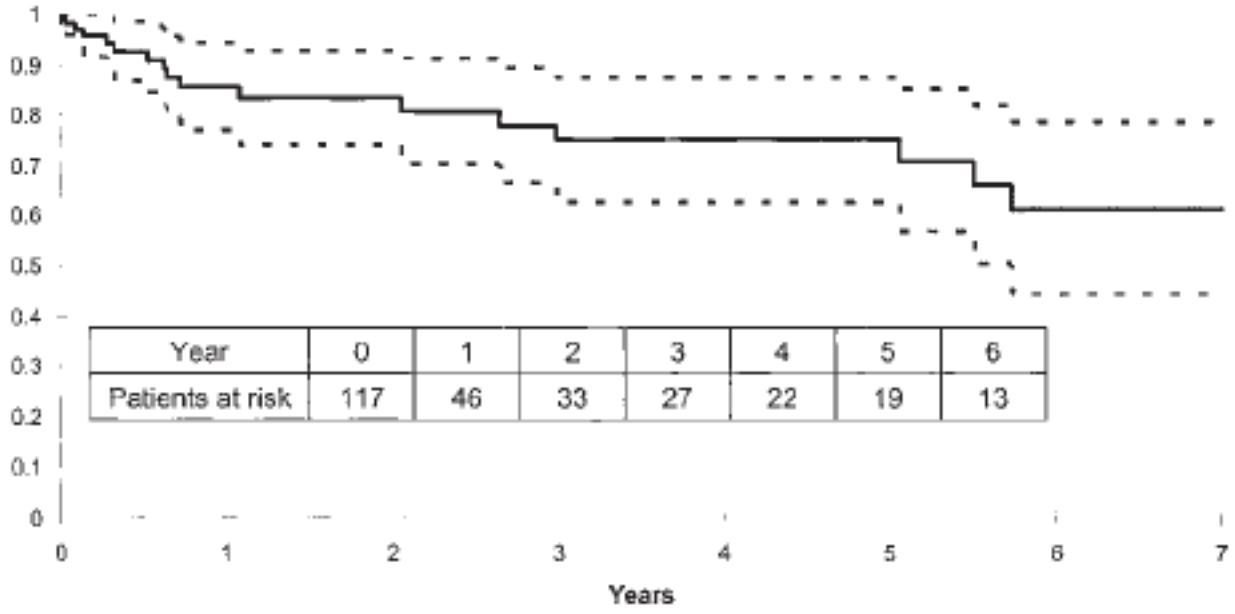


Fig 2. Freedom from major cardiac and cerebral events (death, myocardial infarction, stroke, reintervention on target vessel) and angina, with 95% confidence interval (dashed lines).

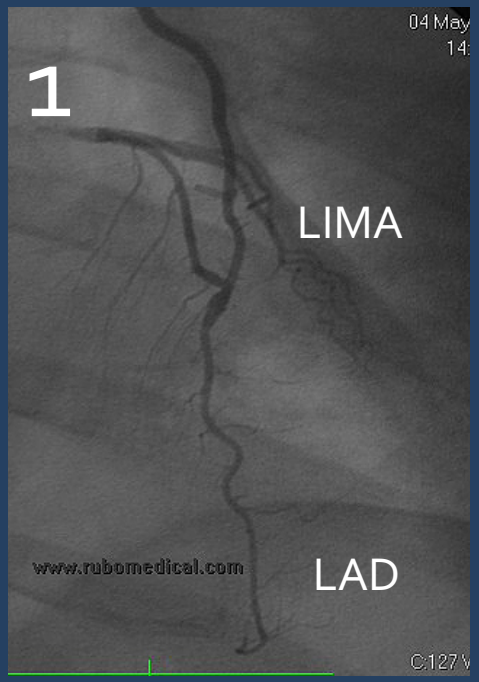
n=117

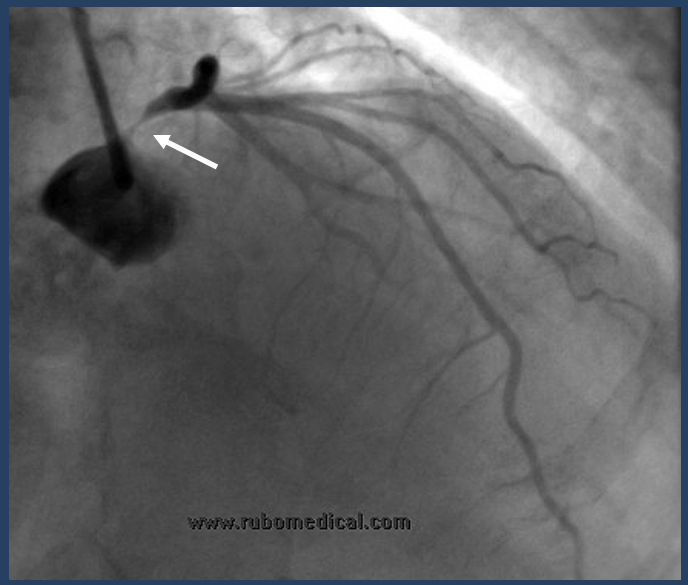
89 MIDCABG
30 TECAB

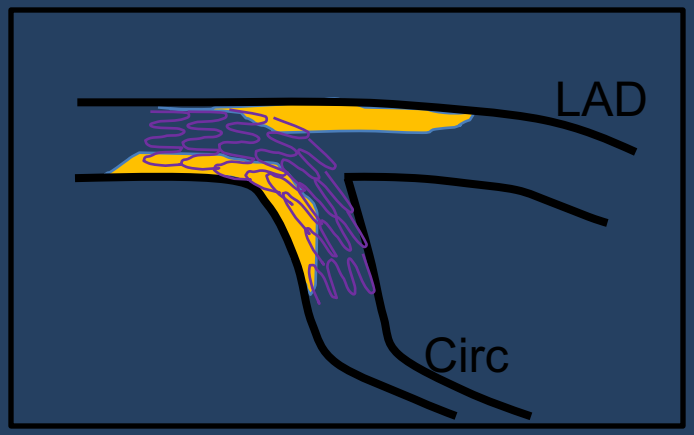
Cohort Study

Ann Thorac Surg 2008

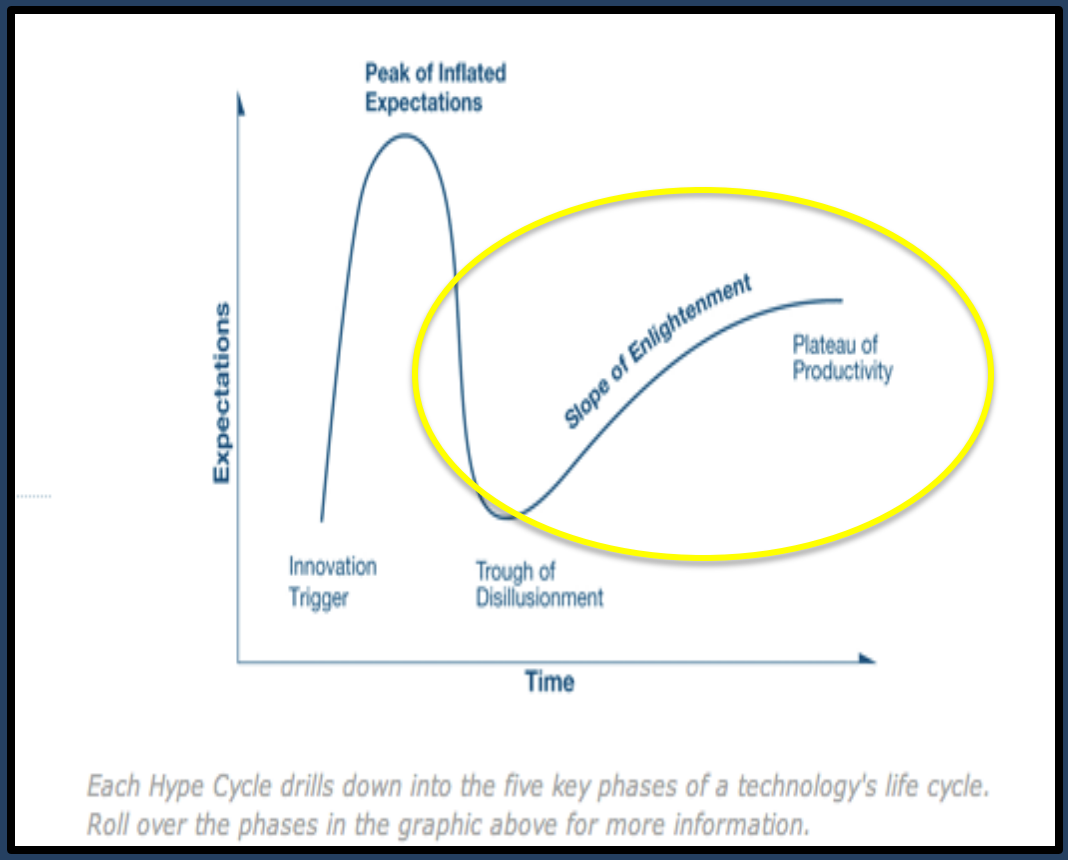
Hybrid Revascularization (MIDCAB/PCI) for Left Main for high risk CABG







Off-Pump CABG trends along the Hype Cycle



Hybrid Coronary Revascularization
(MIDCAB/PCI) vs. Op CAB for Left Main CAD

30 days Outcomes

- Comparable Mortality, MI, Stroke
- Comparable ICU and Hospital Stay
- Fewer Blood Tx in the Hybrid Group

At Follow-up

- Comparable survival

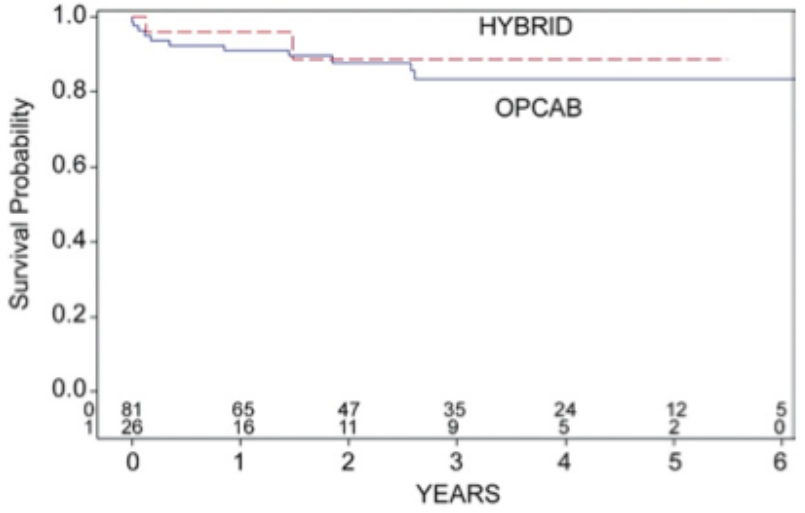


Fig 5. Estimated 5-year survival was similar after off-pump coronary artery bypass grafting (OPCAB; 83.4%) versus hybrid coronary revascularization (HYBRID; 88.6%; p = 0.55).

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Clinical Outcomes After Hybrid Coronary Revascularization Versus Off-Pump Coronary Artery Bypass

A Prospective Evaluation

Thomas A. Vassiliades, MD, MBA, Patrick D. Kilgo, MS,† John S. Douglas, MD,‡ Vasilis C. Babaliaros, MD,‡ Peter C. Block, MD,‡ Habib Samady, MD,‡ Christopher U. Cates, MD,‡ S. Tanveer Rab, MD,‡ and Douglas C. Morris, MD‡*

91 patients Hybrid Group

Thoracoscopic Harvest (Non Robotic) Then MIDCAB

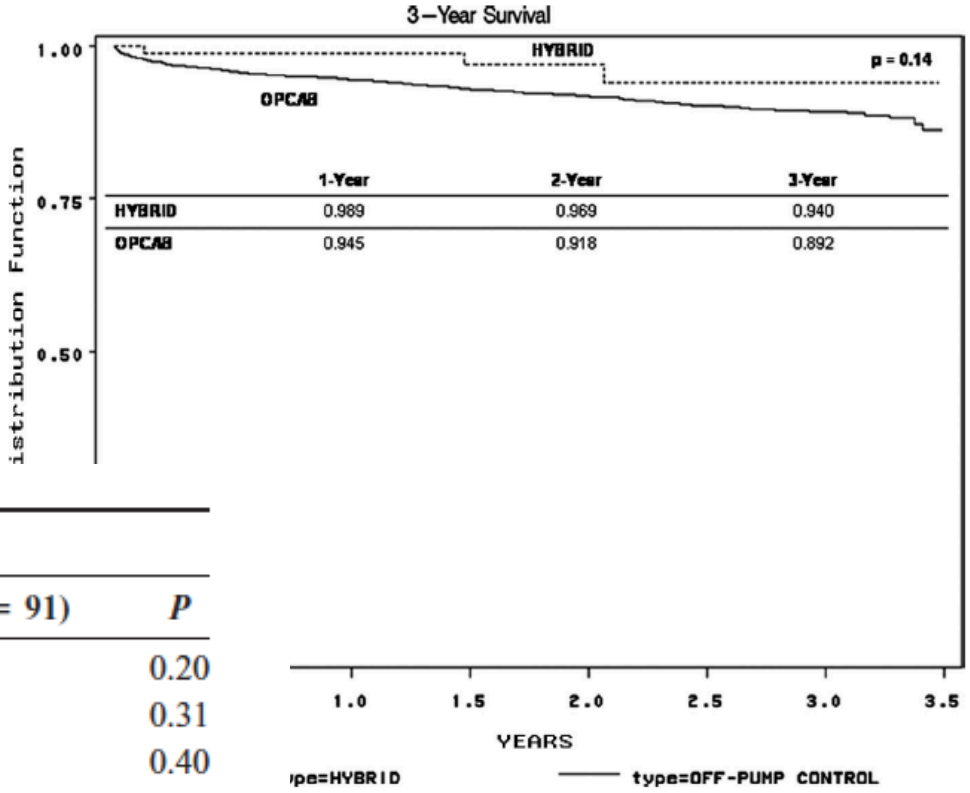

TABLE 2. Table of Raw Outcomes at 30 Days

Outcome	OPCAB (n = 4175)	HYBRID (n = 91)	*P*
Death (%)	74 (1.8)	0 (0.0)	0.20
Stroke (%)	47 (1.1)	0 (0.0)	0.31
MI (%)	20 (0.5)	1 (1.1)	0.40
MACCE (%)	126 (3.0)	1 (1.1)	0.29
TVR (%)	12 (0.3)	0 (0.0)	0.61

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Graft patency with MICS

TABLE 3. Adverse events and outcomes at 6 months follow-up

Occurrence of study adverse events over 6-mo course of study (N = 89)	
Peripheral vascular complication	0
Pleural effusion	14 (15%)
Atrial fibrillation	15 (17%)
Renal insufficiency	1 (1.1%)
Vein harvest site infection	1 (1.5%)
Superficial chest wound infection	2 (2.2%)
Deep chest wound infection	0
Primary outcome at 6 mo	
No. of patients/grafts assessed by CTA	72/165
Fitzgibbon grade A	150 (91%)
Fitzgibbon grade B*	1 (0.6%)
Fitzgibbon grade O	14 (8.5%)
Patent LITA grafts	72 (100%)
Patent SVGs	76 (85%)
Overall graft patency†	151 (92%)

Data are n (%), unless otherwise stated. *CTA*, Computed tomography angiography; *LITA*, left internal thoracic artery; *SVG*, saphenous vein graft. *In an SVG. †Three of 4 radial grafts used in the study demonstrated Fitzgibbon grade A patency. One radial graft was occluded (grade O).

Ruel, McGuinn et al. JTCVS 2014

Prospective-Randomized Control Trials comparing Off-Pump with On-Pump CABG

Randomized clinical trials for new surgical operations: Square peg in a round hole?

Joel D. Cooper, MD

" There is a surgeon to surgeon variation in terms of both surgical approach, technical ability and experience. The PO care might vary from center to center "

A major limitation of RCTs in surgery is the difficulty, if not impossibility, of standardizing the procedure being evaluated. There is surgeon to surgeon variation in terms of both surgical approach and technical ability and experience. The preoperative and postoperative care may vary from center to center. Poor-quality surgery or care represents failure to deliver the intended treatment, and the trial may then measure the deliverability and not the efficacy of the treatment. Evolution in technical modification, risk, and selection criteria is likely to occur in a course of a prolonged clinical trial. Surgical procedures typically progress via such modifications that individually are unlikely to produce detectable benefits but that collectively may do so.

- Poor quality surgery or care represents failure to deliver the intended treatment
- The trial may then measure the deliverability and not the efficacy of the treatment

Joel et al. JTCVS 2010