WVU Heart & Vascular Institute

Surgical vs. Percutaneous Revascularization in Patients with Diabetes and Acute Coronary Syndrome

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No Disclosures

Objectives

- Identify the impact of DM on CAD
- Review the historical comparisons of PCI and CABG in diabetics
- Review the outcomes of PCI and CABG in diabetics with ACS

Impact of DM

- DM prevalence expected to reach 642M worldwide by 2040
- Total deaths from DM expected to increase more than 50% in next 10 years
- Diabetics are prone to diffuse and rapidly progressive forms of atherosclerosis and multivessel CAD

Impact of DM

- 700,000 pts with DM undergo intervention for MV-CAD in the US each year
- CABG and PCI for MV-CAD in diabetics account for about 25% of revascularization procedures

PCI vs CABG

- 40 year debate
- With every iteration of PCI (POBA, BMS, and DES), randomized trials and observational registries have attempted to answer this question

CABG compared to PCI over long term

- Reduced risk of repeat revascularization (most trials)
- Reduced risk of MI (some trials)
- Reduced risk of death (in a few trials)

CABG over short term (30 days)

- CABG has an increased risk of periprocedural events (e.g., death, MI, stroke, renal failure, bleeding or need for transfusion, infection, prolonged intubation, prolonged recovery)

This comparison has been a moving target over the years

PCI has improved

- POBA
- 1st gen DES
- 2nd gen DES
- Edging closer to more complete revascularization
  - Now good success with Chronic Total Occlusions (CTO)
  - Left main stenting (+/- mechanical support) has expanded

But CABG has also improved

- CABG mortality rates have declined
- OPCAB
- MIDCAB
- Offers benefit of LIMA to LAD
  - Greatest survival benefit of ANY coronary intervention
- Total arterial reconstruction: BIMA, Radial artery

Comparisons are difficult

- CABG has improved
- PCI has improved
- Medical therapy has improved with novel agents introduced for many conditions
  - Lipid lowering
  - Antiplatelet
  - Antidiabetic

Comparison of Coronary Bypass Surgery with Angioplasty in Patients with Multivessel Disease

The Bypass Angioplasty Revascularization Investigation (BARI) Investigators

- Patients with multivessel disease were randomly assigned to an initial treatment strategy of CABG (n = 914) or PTCA (n = 915) and were followed for an average of 5.4 years.
- Analysis of outcome events was performed according to the intention to treat.

N Engl J Med 1996; 335:217-225

Comparison of Coronary Bypass Surgery with Angioplasty in Patients with Multivessel Disease

The Bypass Angioplasty Revascularization Investigation (BARI) Investigators

- The five-year survival rate was 89.3 percent for those assigned to CABG and 86.3 percent for those assigned to PTCA (P = 0.19; 95 percent confidence interval of the difference in survival, -0.2 percent to 6.0 percent).
- By five years after study entry, 8 percent of the patients assigned to CABG had undergone additional revascularization procedures, as compared with 54 percent of those assigned to PTCA

N Engl J Med 1996; 335:217-225

Comparison of Coronary Bypass Surgery with Angioplasty in Patients with Multivessel Disease

The Bypass Angioplasty Revascularization Investigation (BARI) Investigators

- Among diabetic patients who were being treated with insulin or oral hypoglycemic agents at base line, a subgroup not specified by the protocol, five-year survival was 80.6 percent for the CABG group as compared with 65.5 percent for the PTCA group (P = 0.003)
- Conclusions: As compared with CABG, an initial strategy of PTCA did not significantly compromise five-year survival in patients with multivessel disease, although subsequent revascularization was required more often with this strategy.
- For diabetics, five-year survival was significantly better after CABG than after PTCA

N Engl J Med 1996; 335:217-225

Comparison of coronary artery bypass surgery and percutaneous coronary intervention in patients with diabetes: a meta-analysis of randomised controlled trials

Subodh Verma, Michael E Farkouh, Bobby Yanagawa, David H Fitchett, Muhammad R Ahsan, Marc Ruel, Sachin Sud, Milan Gupta, Shantanu Singh, Nandini Gupta, Asim N Cheema, Lawrence A Leiter, Paul W M Fedak, Hwee Teoh, David A Latter, Valentin Fuster, Jan O Friedrich

- Medline, Embase, and the Cochrane Central Register of Controlled Trials from Jan 1, 1980, to March 12, 2013, for studies reported in English
- Eligible studies were those in which investigators enrolled adult patients with diabetes and multivessel coronary artery disease, randomised them to CABG (with arterial conduits in at least 80% of participants) or PCI (with stents in at least 80% of participants), and reported outcomes separately in patients with diabetes, with a minimum of 12 months of follow-up

Lancet Diabetes & Endocrinology, The, 2013-12-01,
Volume 1, Issue 4, Pages 317-328

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- The primary outcome was all-cause mortality in patients with diabetes who had CABG compared with those who had PCI at 5-year (or longest) follow-up
- 8 eligible trials: 7468 participants, 3612 with DM
- 4 of the RCTs used bare metal stents (BMS; ERACI II, ARTS, SoS, MASS II)
- 4 used drug-eluting stents (DES; FREEDOM, SYNTAX, VA CARDS, CARDia)

Lancet Diabetes & Endocrinology, The, 2013-12-01, Volume 1, Issue 4, Pages 317-328

Findings

- At mean or median 5-year (or longest) follow-up, individuals with diabetes allocated to CABG had lower all-cause mortality than did those allocated to PCI (RR 0.67, 95% CI 0.52–0.86; p=0.002)
- Treatment effects in individuals without diabetes showed no mortality benefit (1.03, 0.77–1.37; p=0.78)
- No differences in outcome whether PCI was done with BMS or DES

Conclusion

- In the modern era of stenting and optimum medical therapy, revascularization of patients with diabetes and MV-CAD by CABG decreases long-term mortality by about 1/3 compared with PCI using either BMS or DES

- CABG should be strongly considered for these patients

Treatment of complex coronary artery disease in patients with diabetes: 5-year results comparing outcomes of bypass surgery and percutaneous coronary intervention in the SYNTAX trial.

Kappetein AP[1], Head SJ, Morice MC, Banning AP, Serruys PW, Mohr FW, Dawkins KD, Mack MJ; SYNTAX Investigators.

- This prespecified subgroup analysis examined the effect of diabetes on left main coronary disease (LM) and/or three-vessel disease (3VD) in patients treated with percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG) in the SYNTAX trial

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Eur J Cardiothorac Surg. 2013 May;43(5):1006-13.

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- Patients (*n* = 1800) with LM and/or 3VD were randomized to receive either PCI with TAXUS Express paclitaxel-eluting stents or CABG
- Five-year outcomes in subgroups with (*n* = 452) or without (*n* = 1348) diabetes were examined; major adverse cardiac or cerebrovascular events (MACCE), the composite safety end-point of all-cause death/stroke/myocardial infarction (MI) and individual MACCE components death, stroke, MI and repeat revascularization

Eur J Cardiothorac Surg. 2013 May;43(5):1006-13.

Results

- In diabetic patients, 5-year rates were significantly higher for PCI vs CABG for MACCE (PCI: 46.5% vs CABG: 29.0%; P < 0.001) and repeat revascularization (PCI: 35.3% vs CABG: 14.6%; P < 0.001)
- There was no difference in the composite of all-cause death/stroke/MI (PCI: 23.9% vs CABG: 19.1%; P = 0.26) or individual components all-cause death (PCI: 19.5% vs CABG: 12.9%; P = 0.065), stroke (PCI: 3.0% vs CABG: 4.7%; P = 0.34) or MI (PCI: 9.0% vs CABG: 5.4%; P = 0.20)

Conclusions

- In both diabetic and non-diabetic patients, PCI resulted in higher rates of MACCE and repeat revascularization at 5 years.
- Although PCI is a potential treatment option in patients with less-complex lesions, CABG should be the revascularization option of choice for patients with more-complex anatomic disease, especially with concurrent diabetes

Strategies for Multivessel Revascularization in Patients with Diabetes

Michael E. Farkouh, M.D., Michael Domanski, M.D., Lynn A. Sleeper, Sc.D., Flora S. Siami, M.P.H., George Dangas, M.D., Ph.D., Michael Mack, M.D., May Yang, M.P.H., David J. Cohen, M.D., Yves Rosenberg, M.D., M.P.H., Scott D. Solomon, M.D., Akshay S. Desai, M.D., M.P.H., Bernard J. Gersh, M.B., Ch.B., D.Phil., et al., for the FREEDOM Trial Investigators*

- FREEDOM (Future REvascularization Evaluation in Patients With Diabetes Mellitus: Optimal Management of Multi-vessel Disease) trial
- 2005-10, 1900 pts, 140 international centers
- Randomized DM pts with MV CAD to CABG vs PCI
- Primary outcome: composite death from any cause, nonfatal MI, nonfatal stroke

N Engl J Med 2012; 367:2375-2384

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- The patients' mean age was 63.1±9.1 years, 29% were women, and 83% had three-vessel disease.
- The primary outcome occurred more frequently in the PCI group (P=0.005), with 5-year rates of 26.6% in the PCI group and 18.7% in the CABG group.
- The benefit of CABG was driven by differences in rates of both myocardial infarction (P<0.001) and death from any cause (P=0.049).
- Stroke was more frequent in the CABG group, with 5-year rates of 2.4% in the PCI group and 5.2% in the CABG group (P=0.03).

N Engl J Med 2012; 367:2375-2384

These studies reflect differences in CABG and PCI in diabetics with stable ischemic CAD

Do these findings hold true in ACS?

Surgical Versus Percutaneous Coronary Revascularization in Patients With Diabetes and Acute Coronary Syndromes

Krishnan Ramanathan, MB, ChB,[a] James G. Abel, MD,[a] Julie E. Park, MMath,[b] Anthony Fung, MBBS,[a]
Verghese Mathew, MD,[c] Carolyn M. Taylor, MD,[a] G.B. John Mancini, MD,[a] Min Gao, MD, PhD,[b] Lillian Ding, MSc,[d]
Subodh Verma, MD, PhD,[e] Karin H. Humphries, DSc,[a,b] Michael E. Farkouh, MD, MSc[f]

- In a large population-based database from British Columbia, this study evaluated major cardiovascular outcomes in all diabetic patients who underwent coronary revascularization between 2007 and 2014 (n = 4,661, 2,947 patients with ACS).
- The primary endpoint (major adverse cardiac or cerebrovascular events [MACCE]) was a composite ofall-cause death, nonfatal myocardial infarction, and nonfatal stroke

J Am Coll Cardiol 2017;70:2995–3006

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- The risk of MACCE with CABG or PCI was compared using multivariable adjustment and a propensity score model.

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J Am Coll Cardiol 2017;70:2995–3006

Results

- At 30-days post-revascularization, for ACS patients the odds ratio for MACCE favored CABG 0.49(95% confidence interval [CI]: 0.34 to 0.71)
- However, among SIHD patients MACCE was not affected by revascularization strategy (odds ratio: 1.46; 95% CI: 0.71 to 3.01; $p<0.01$).
- With a median follow-up of 3.3 years, the late (31-day to 5-year) benefit of CABG over PCI no longer varied by acuity of presentation, with a hazard ratio for MACCE in ACS patients of 0.67 (95% CI: 0.55 to 0.81) and the hazard ratio for SIHD patients of 0.55 (95% CI: 0.40 to 0.74; $p = 0.28$).

Early Event Rates

TABLE 3 Early (30-Day) Crude Counts and Event Rates

	Overall			ACS			SIHD		
	PCI (n = 2,888)	CABG (n = 1,931)	p Value	PCI (n = 1,966)	CABG (n = 1,051)	p Value	PCI (n = 922)	CABG (n = 880)	p Value
MACCE	176 (6.1)	64 (3.3)	<0.01	162 (8.2)	45 (4.3)	<0.01	14 (1.5)	19 (2.2)	0.31
Death	47 (1.6)	20 (1.0)	0.10	45 (2.3)	13 (1.2)	0.05	2 (0.2)	7 (0.8)	0.10
MI	130 (4.5)	22 (1.1)	<0.01	119 (6.1)	19 (1.8)	<0.01	11 (1.2)	3 (0.3)	0.06
Stroke	16 (0.6)	27 (1.4)	<0.01	15 (0.8)	17 (1.6)	0.04	1 (0.1)	10 (1.1)	<0.01

Values are n (%).

MACCE = major adverse cardiac or cerebrovascular event(s); MI = myocardial infarction; other abbreviations as in Table 1.

Late Event Rates

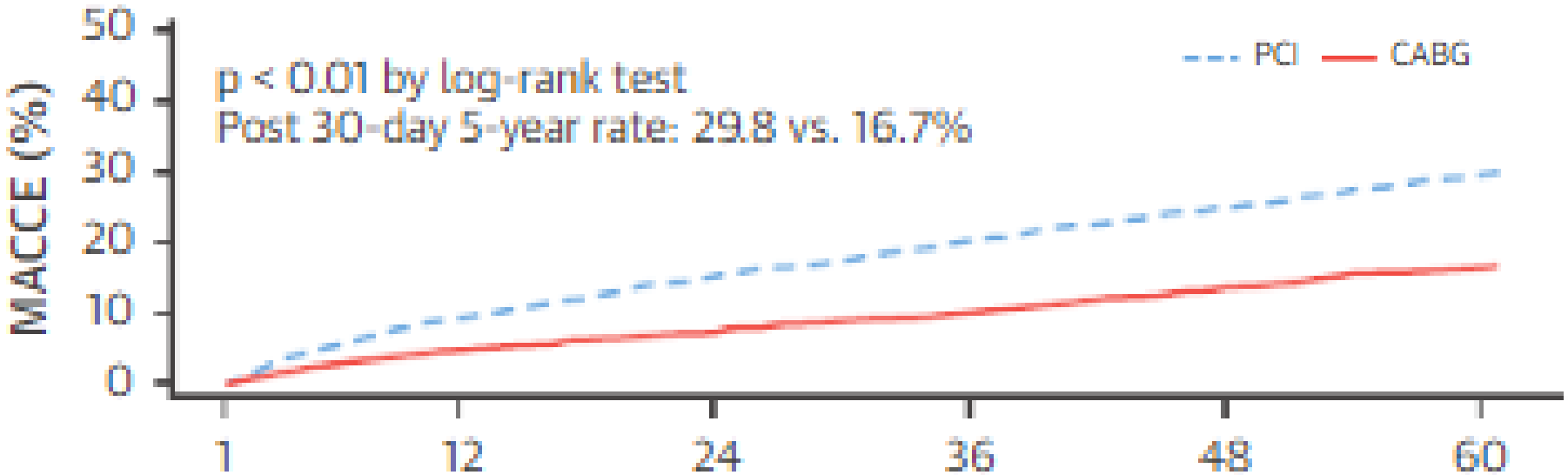
TABLE 4 Late (31-Day to 5-Year) Kaplan-Meier Event Rates

	Overall			ACS			SIHD		
	PCI (n = 2,710)	CABG (n = 1,865)	p Value	PCI (n = 1,802)	CABG (n = 1,005)	p Value	PCI (n = 908)	CABG (n = 860)	p Value
MACCE	29.8	16.7	<0.01	33.4	20.8	<0.01	22.8	12.0	<0.01
MACCE(r)	42.7	20.4	<0.01	43.6	24.2	<0.01	40.9	16.1	<0.01
Death	19.0	10.3	<0.01	22.3	12.4	<0.01	12.2	7.8	<0.01
MI	15.5	6.8	<0.01	17.6	9.9	<0.01	11.7	3.3	<0.01
Stroke	5.1	4.1	0.23	5.8	6.2	0.97	3.8	1.7	0.18
RR	24.4	7.8	<0.01	22.6	8.2	<0.01	27.7	7.4	<0.01

Values are %.

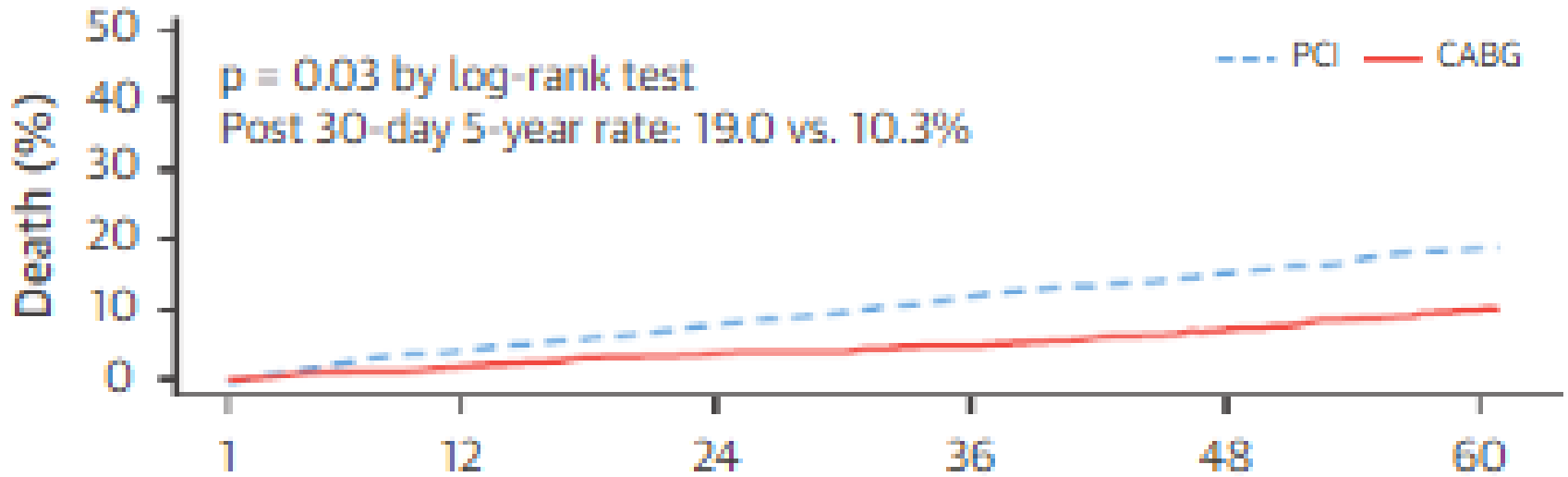
MACCE(r) = composite of major adverse cardiac or cerebrovascular event and repeat revascularization; RR = repeat revascularization; other abbreviations as in Tables 1 and 3.

Cumulative Incidence Function Curves for MACCE by Revascularization Strategy



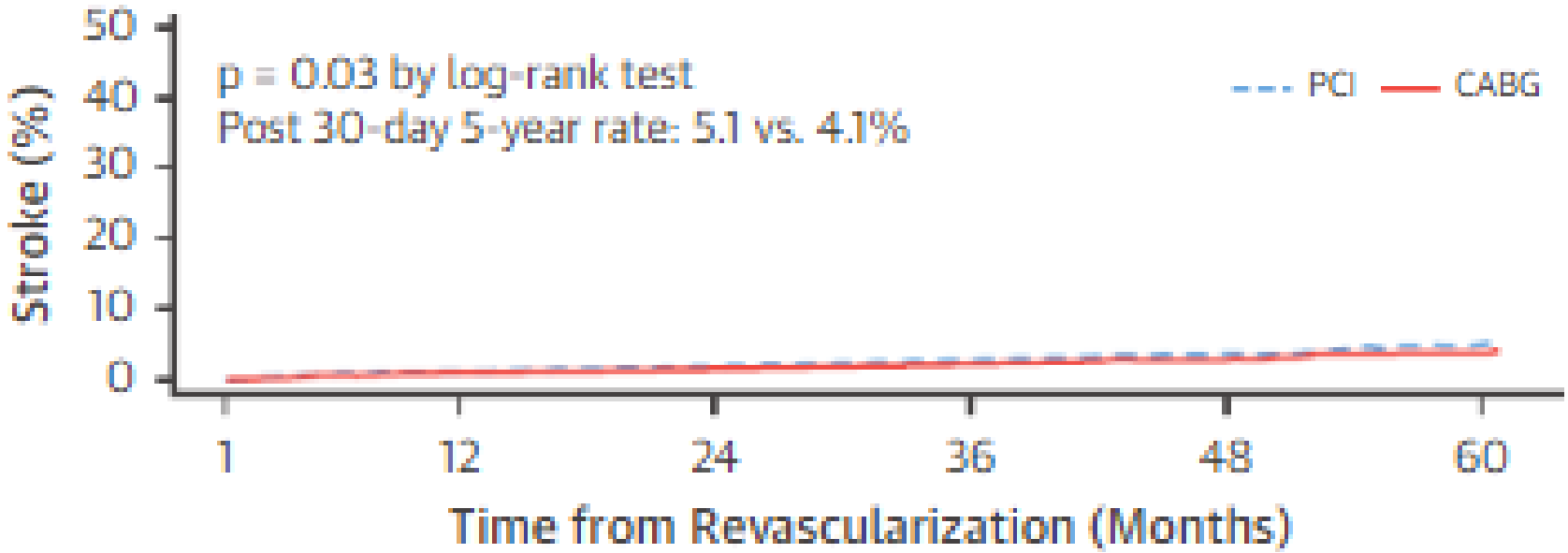
N. at risk						
PCI	2712	2193	1735	1248	798	428
CABG	1867	1488	1174	906	634	365

Cumulative Incidence Function Curves for Death by Revascularization Strategy



N. at risk						
PCI	2841	2404	1943	1417	926	510
CABG	1911	1568	1249	972	691	395

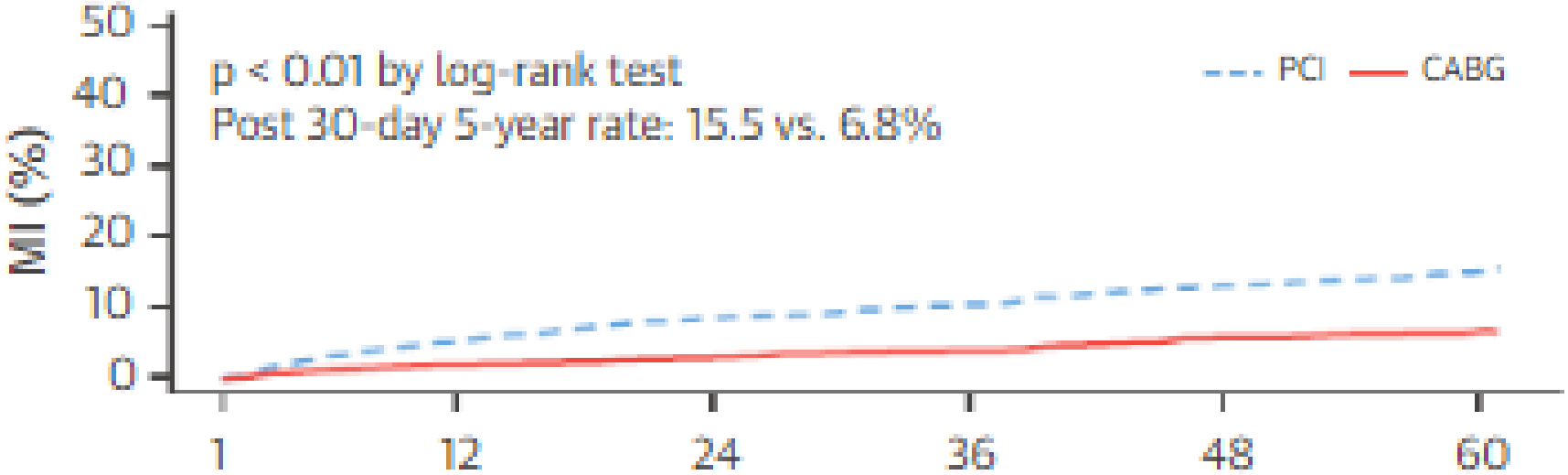
Cumulative Incidence Function Curves for Stroke by Revascularization Strategy



N. at risk

PCI	2827	2368	1904	1381	895	487
CABG	1887	1532	1217	942	664	379

Cumulative Incidence Function Curves for MI by Revascularization Strategy



N. at risk						
PCI	2722	2226	1770	1282	827	449
CABG	1890	1521	1203	930	655	379

Conclusions

- In diabetic patients with MV-CAD, CABG was associated with a lower rate of long-term MACCE relative to PCI for both ACS and SIHD.
- A well-powered randomized trial of CABG versus PCI in the ACS population is warranted because these patients have been largely excluded from prior trials

Everolimus Eluting Stents Versus Coronary Artery Bypass Graft Surgery for Patients With Diabetes Mellitus and Multivessel Disease

Sripal Bangalore, Yu Guo, Zaza Samadashvili, Saul Blecker, Jinfeng Xu, and Edward L. Hannan

Originally published 8 Jul 2015 | Circulation: Cardiovascular Interventions. 2015;8:e002626

- Patients included in the New York State registries who had diabetes mellitus and underwent isolated coronary artery bypass graft surgery or percutaneous coronary intervention with everolimus eluting stent (EES) for multivessel disease were included
- The primary outcome was all-cause mortality
- Secondary outcomes were myocardial infarction (MI), stroke, and repeat revascularization

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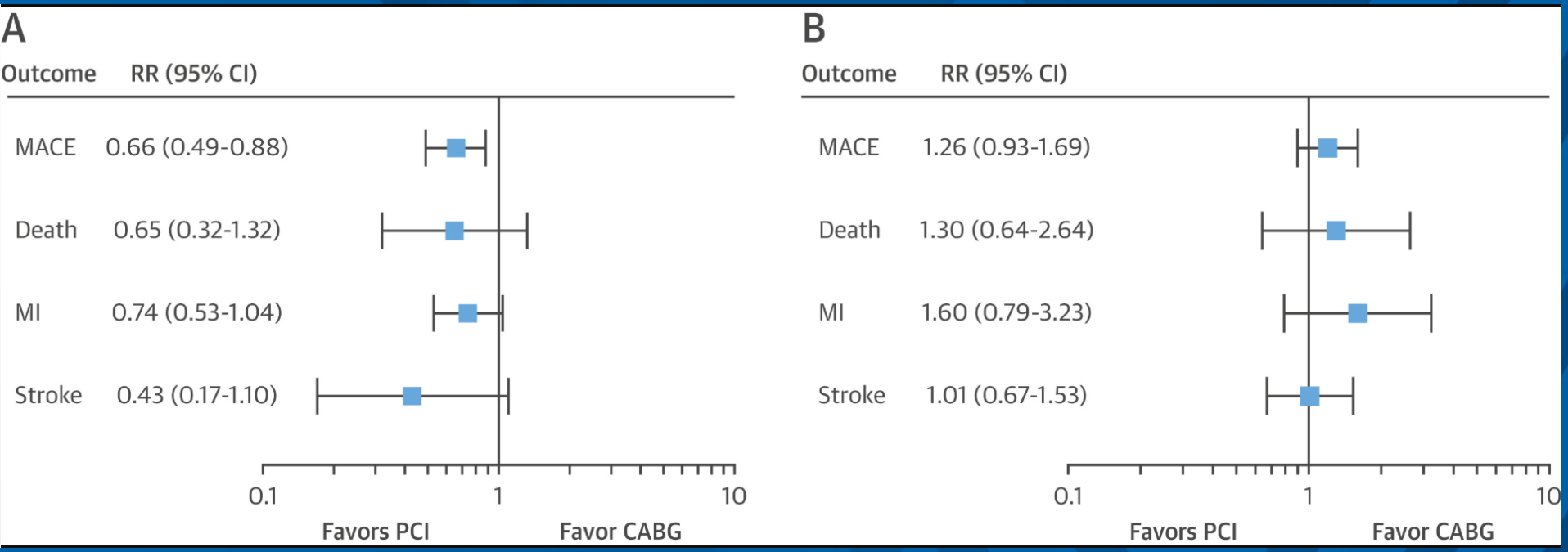
- At short-term, EES was associated with a lower risk of death and stroke but higher risk of MI
- At long-term, EES was associated with a similar risk of death and stroke, but a higher risk of MI
- ACS patients were included if > 24 hours from time of PCI

Additional Trials of PCI with second generation DES compared to CABG

- BEST [Randomized Comparison of Coronary Artery Bypass Surgery and Everolimus-Eluting Stent Implantation in the Treatment of Patients with Multivessel Coronary Artery Disease
- EXCEL [Evaluation of XIENCE versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization trial]
- NOBLE [Nordic-Baltic-British left main revascularisation study]

BEST, EXCEL, and NOBLE

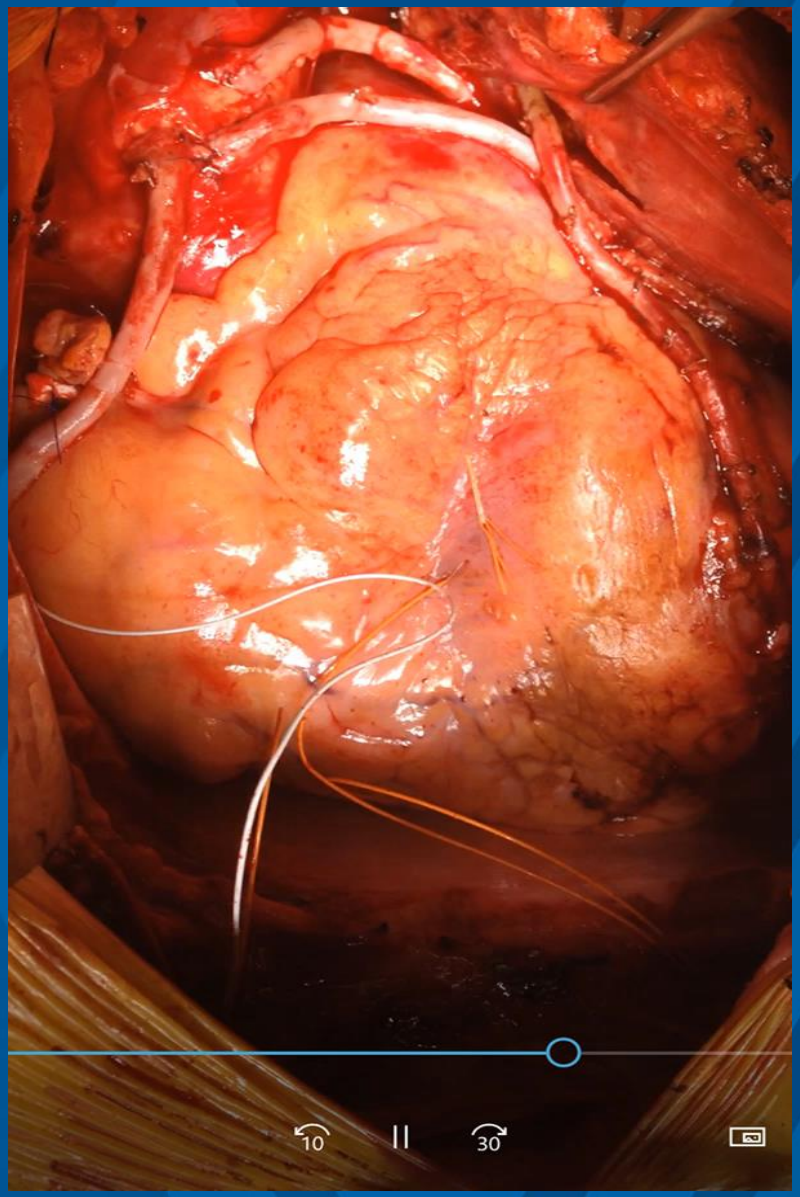
- Included ACS patients: 15-53%
- A meta-analysis of these 3 trials showed that PCI with second-generation DES was associated with significant reduction in MACE due to numerically lower death, MI, and stroke at short-term follow up (30-day outcome)
- Over the long-term (follow-up 3 to 5 years), the results from the meta-analysis of randomized trials showed outcomes that are similar between PCI and CABG
- Diabetes was not an effect modifier in analyses for any of the outcomes



- **(A)** Short-term risk and **(B)** long-term risk results from a meta-analysis of 3 randomized trials of PCI with second-generation drug eluting stents (DES) versus coronary artery bypass grafting (CABG) (BEST [Randomized Comparison of Coronary Artery Bypass Surgery and Everolimus-Eluting Stent Implantation in the Treatment of Patients with Multivessel Coronary Artery Disease], EXCEL [Evaluation of XIENCE versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization], and NOBLE [Nordic-Baltic-British left main revascularisation] trials). CI = confidence interval; MACE = major adverse cardiac event(s); MI = myocardial infarction; RR = relative risk

Old School

- Really old school: CABG with all SVG
- 2 decades: CABG with increase use of IMA
- Last 15 years: increasing evidence of benefits of multiple arterial grafts



CABG Today

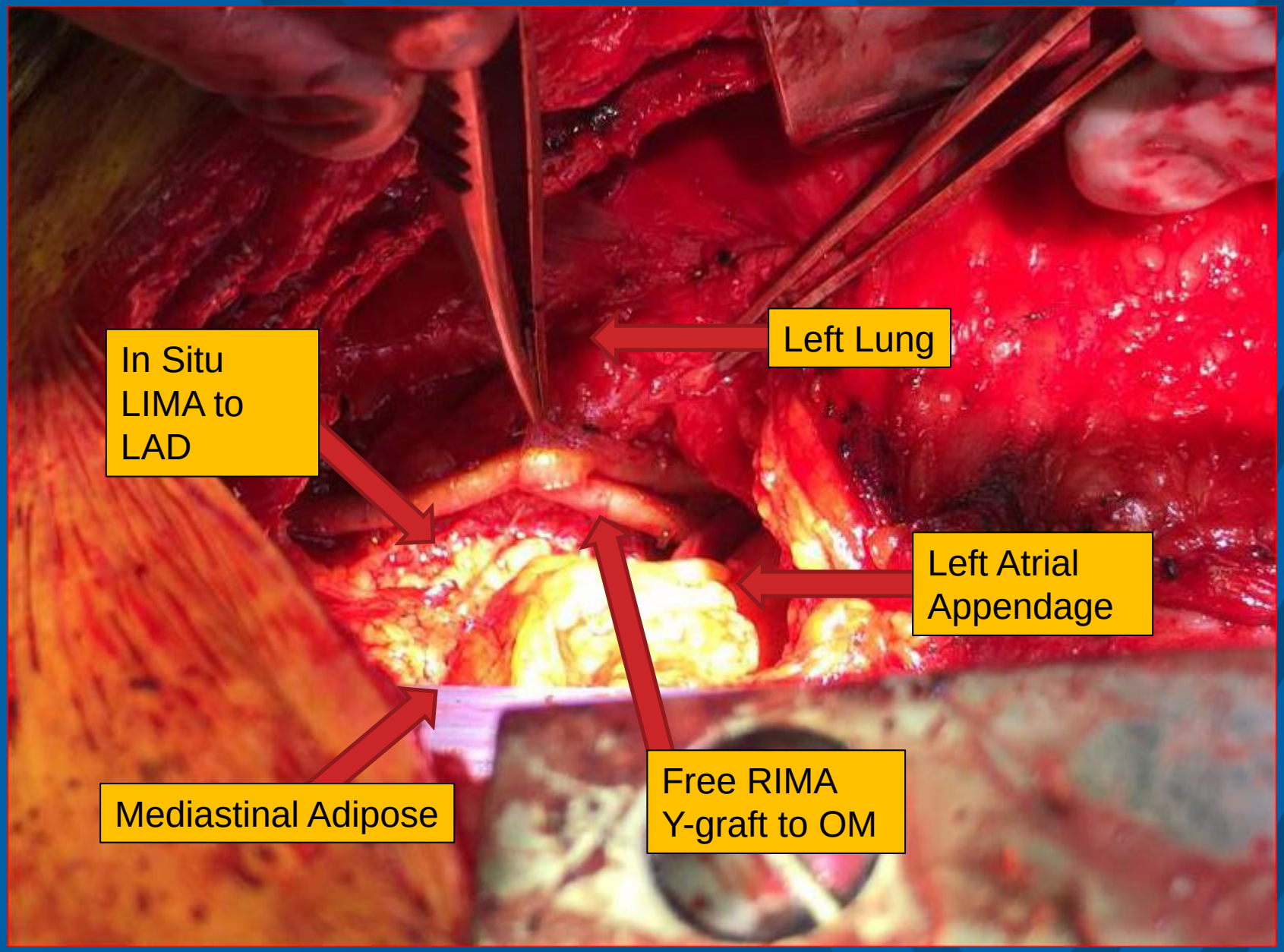
- On vs Off pump CABG debate has never been conclusively settled
- Use of multiple arterial grafts
  - BIMA
  - Radial artery
  - Use of sequenced and Y-grafts
  - Arterial conduits: accustomed to high pressures, vasoactive, better size matching

What about BIMA in DM?

Author, year, ref.	No. of patients	SIMA	BIMA	Duration of follow-up	Survival	
					SIMA	BIMA
Stevens et al., 2005, [29]	633	419	214	11 ± 3 years	73%	79%*
Calafiore et al., 2005, [30]	558	217	341	6 ± 2 years	79.5 ± 4.1%	86.7 ± 3.2%**
Puskas et al., 2012, [31]	1445	1213	232	8 years	60.6%	87.4%***
Toumpoulis et al., 2006, [32]	980	490	490	5 years	75.7%	79.9%****
Dorman et al., 2012, [33]	1107	646	461	8.9 years	9.8 years	13.1 years*****
Lev-Ran et al., 2004, [34]	285	57	228	7 years	75%	59%******

*$P < 0.0001$; **$P = 0.0274$; ***$P < 0.001$; ****$P = 0.252$; *****$P < 0.001$; ******$P = 0.006$.

SIMA = single internal mammary artery; BIMA = bilateral internal mammary arteries.

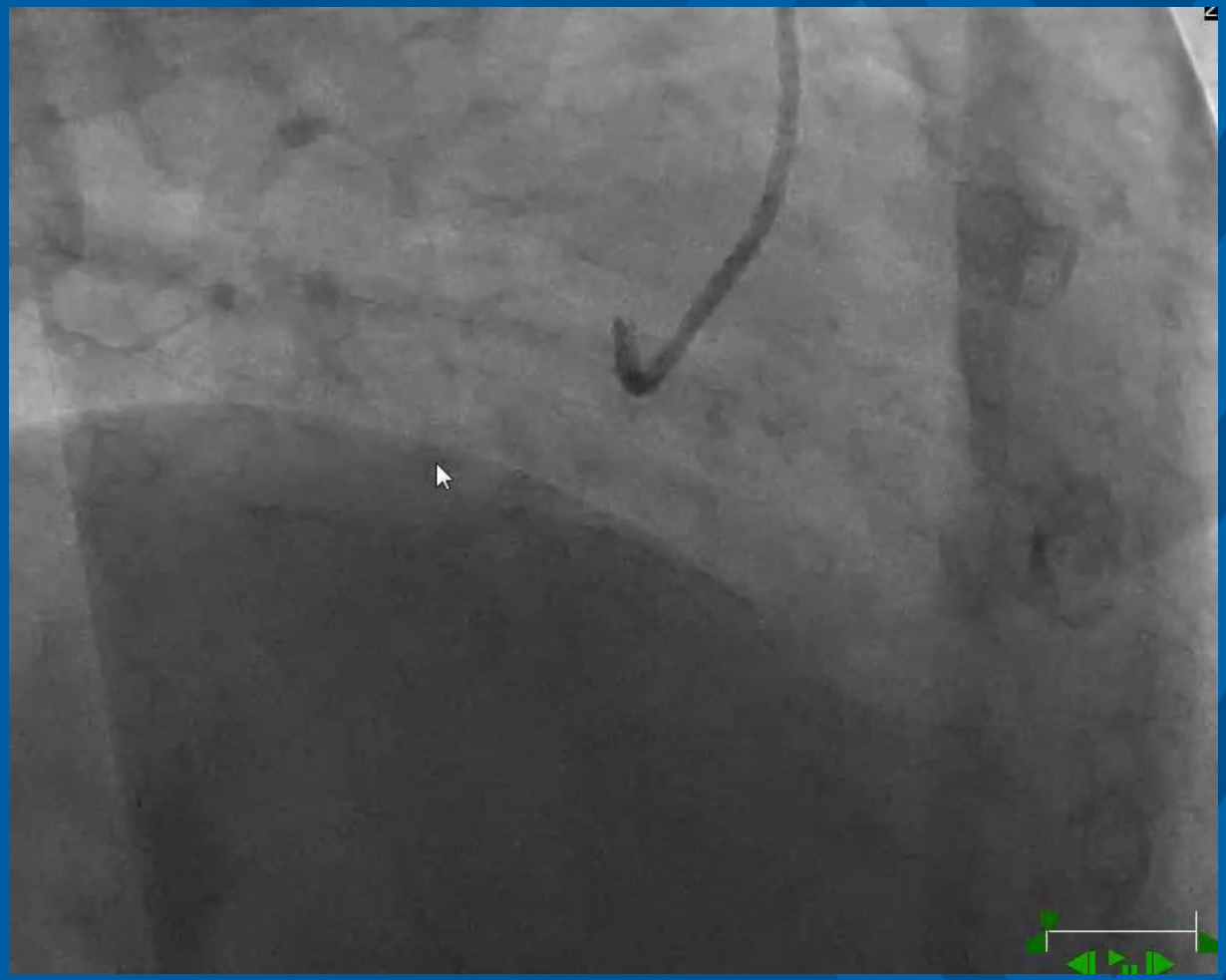

In Situ
LIMA to
LAD
Left Lung
Left Atrial
Appendage
Mediastinal Adipose
Free RIMA
Y-graft to OM

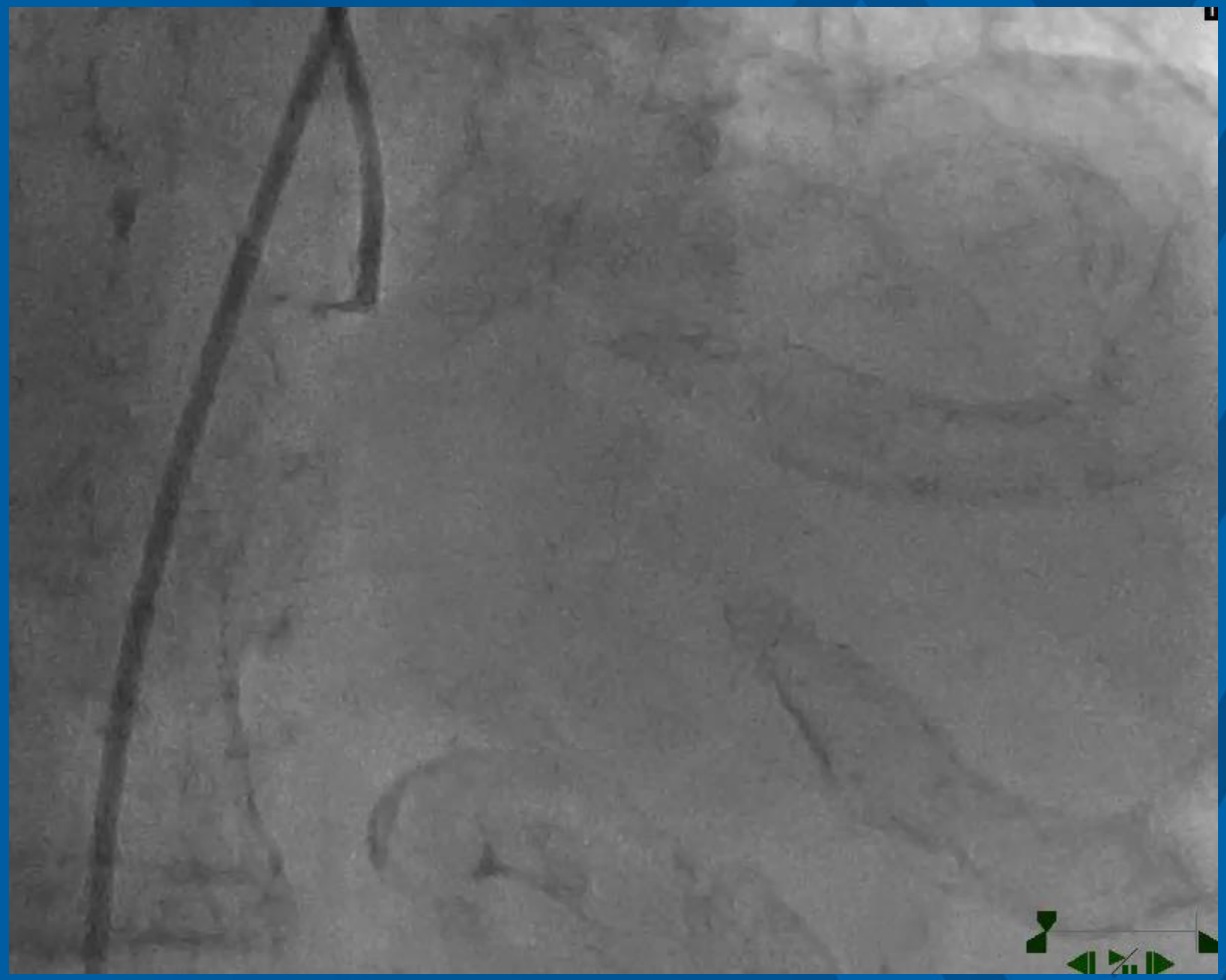
CABG vs PCI in ACS

- ACS
  - Unstable angina
  - NSTEMI: myocardial damage due to progression of a critical lesion
  - STEMI: acute vessel occlusion
- Most MI's are treated with urgent cath and PCI to the culprit vessel
- CABG is done:
  - Urgently for PCI complication
  - Semi-electively for residual CAD in remaining vessels

CASE 1

- 88 yo female (nondiabetic) with NSTEMI 2 months ago. NSTEMI was treated medically without cath due to advanced age and myocardial perfusion scan that was weakly positive for apical defect, EF 68%
- PMH: HTN, HLD, GERD, disc herniation
- Active lady, lives alone and independent with ADL's
- Represents 2months later with another NSTEMI
  - Echo: normal EF 65%, no valvular abnormalities
  - Cath: 3 vessel CAD





88 yo female 3 vessel CAD

- STS risk of M&M: 1.6%/6.9%
- Reviewed films with cardiology: PCI suboptimal given aneurysm and vessel tortuosity

What do we do?

A. Treat medically given her advanced age
B. PCI to as many lesions as feasible and treat residual disease medically
C. Minimally invasive robotic assisted LIMA to the LAD and PCI to the RCA and Circumflex
D. Off pump CABG
E. On pump CABG

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E. On pump CABG

On Pump CABG

- LIMA to LAD
- SVG to OM and PDA
- Transferred from ICU on POD 1
- Discharged to SNF on POD 4
- F/U visit: doing well, stable, chest pain free

CASE 2

- 64 yo diabetic female presents to ER with progressive chest heaviness and dyspnea
- PMH: HTN, DM
- EKG: NSR and no ST changes
- CXR clear
- Troponin positive at 8.4 (NSTEMI)


6
Quality:100%
W:254
C:127
Zoom:0.8
RAO: 29.0°
CAU: 31.0°
L: Unknown
Tilt: 0.0
200.0mm/200.0mm


1
Quality:100%
W:254
C:127
Zoom:0.8
LAO: 27.0°
CRA: 28.0°
L: Unknown
Tilt: 0.0
200.0mm/200.0mm


69
Quality:100%
W:254
C:127
Zoom:0.8
LAO: 28.0°
CRA: 0.0°
L: Unknown
Tilt: 0.0
200.0mm/200.0mm

What to do now?

A. PCI to the chronically occluded RCA and treat other coronary lesions medically
B. PCI to the LAD and begin aggressive medical therapy for CAD
C. Emergent CABG
D. Admit, treat for NSTEMI, obtain echo, plan for CABG this admission once enzymes are normalizing

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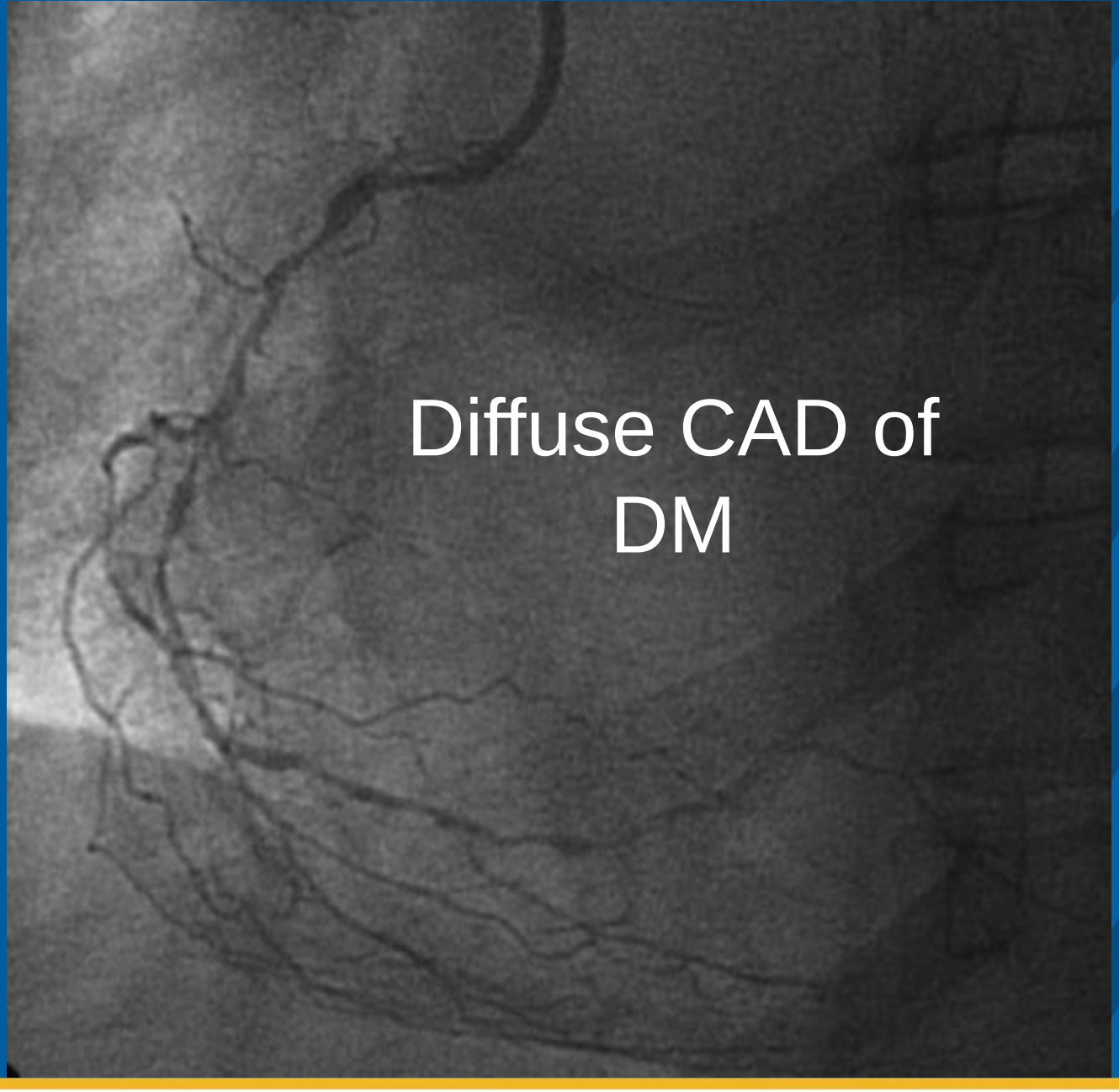
C. Emergent CABG
D. Admit, treat for NSTEMI, obtain echo, plan for CABG this admission once enzymes are normalizing


Diffuse CAD of
DM

Case 3

- 55 yo diabetic female presents with substernal chest pain and diaphoresis
- EKG with anterior ST elevation
- Troponin 55
- Emergent cath:
  - 95% proximal, focal LAD stenosis
  - RCA occluded proximally with collateral flow from the LAD and circumflex to the distal RCA
  - Circumflex has minimal luminal irregularities

What to do?

A. PCI to the LAD and RCA
B. PCI to the LAD only
C. Urgent CABG
D. Admit, treat medically for STEMI, 2 vessel CABG with all arterial reconstruction this admission once troponins have normalized

What to do?

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The obvious advantage of PCI in any ACS

TIME

Early studies showed survival advantage for CABG over PCI in DM

A. True
B. False

Diabetics tend to have more diffusely diseased vessels that provide challenges for both PCI and CABG

A. True
B. False

The best treatment for ACS in diabetics

A. Thrombolytics
B. Urgent CABG
C. PCI to the culprit lesion
D. Thrombolytics and diagnostic cath with plan for semi-elective CABG during that admission

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THANK YOU

QUESTIONS?