CHIP:

New Frontier OR No Man's Land?

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No Disclosures

OBJECTIVES

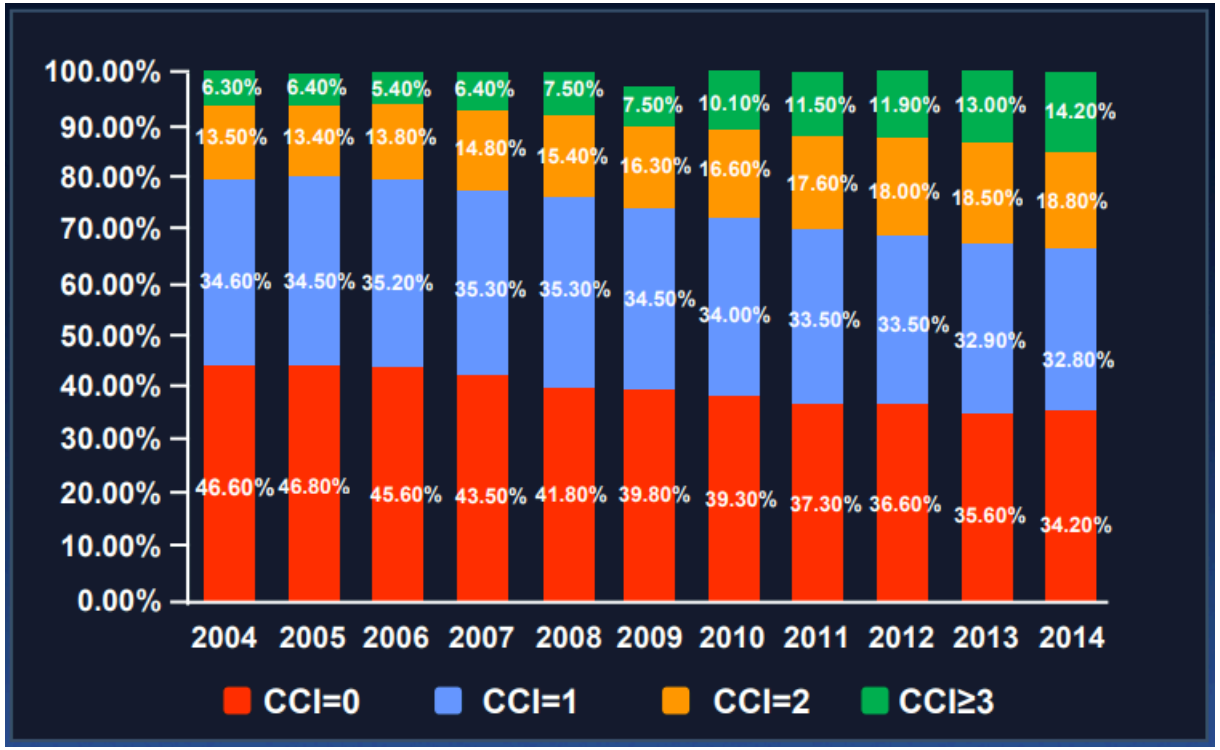
- Define CHIP
  - Complex Higher-Risk PCI in Indicated Patients
- Two View Points
  - New Frontier
  - No Man's Land
- Future Directions

DEFINE CHIP

- Complex High-Risk PCI in *Indicated* Patients
  - Potential symptom or mortality benefit of revascularization in a non-surgical patient with complex anatomic lesions
  - Acute scenario bailout

DEFINE CHIP

Co-Morbidities in CCL Trend:

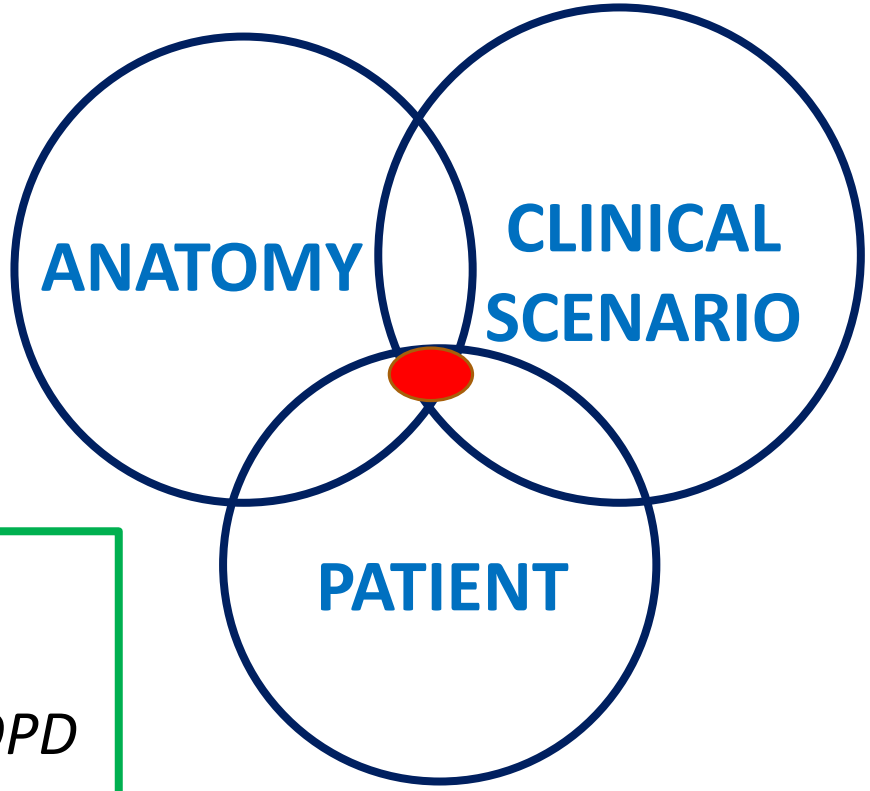


NCDR Cath PCI Registry Data

DEFINE CHIP

- Intersection of:
  - Complex Coronary Anatomy
  - Significant Co-Morbidities
  - Complex Clinical Scenario

- *Unprotected LM*
- *Bi/Tri-furcation*
- *SVG/LIMA*
- *↑ Calcium burden*
- *Long diffuse lesions*
- *CTOs*

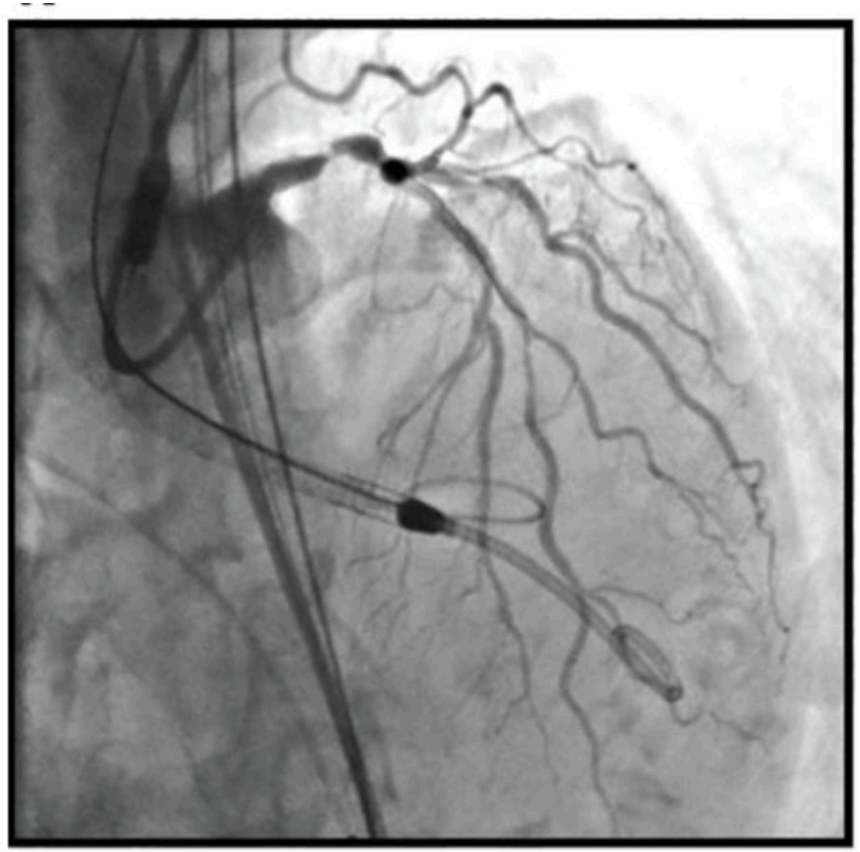


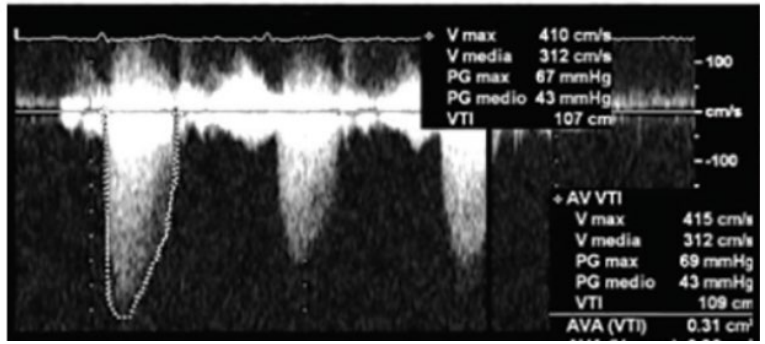
- *Hemodynamic Instability*
- *Post-Arrest*
- *Peri/Post Trauma*
- *Post-Pericardiotomy*
- *Bailout Scenario*
- *Surgical Turndown*

- *Low LVEF*
- *Significant VHD*
- *ESRD | DM | COPD*
- *Prior CABG*
- *Liver Disease*
- *PH/RV Failure*
- *Malignancy*

CHIP PATIENT

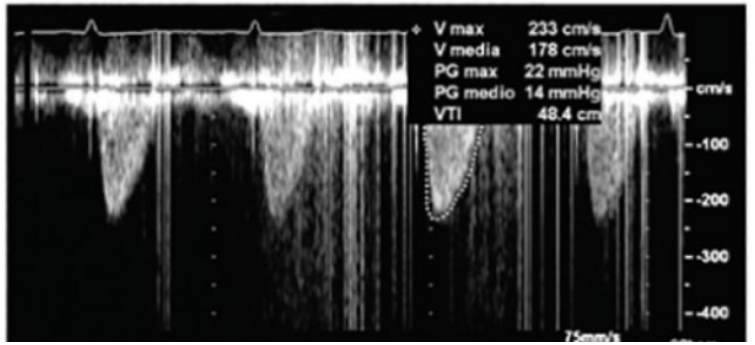
- 10 patients with severe AS
- ACS Presentation of NSTEMI
- All LM or MV Disease





CHIP PATIENT

- PCI with Impella support followed by Valvuloplasty as bridge to TAVR
- Radial access 8/10 patients
- No complications



CHIP PATIENT

71M presented to OSH with nose fracture after syncopal spell

Endorsed 3d chest pain

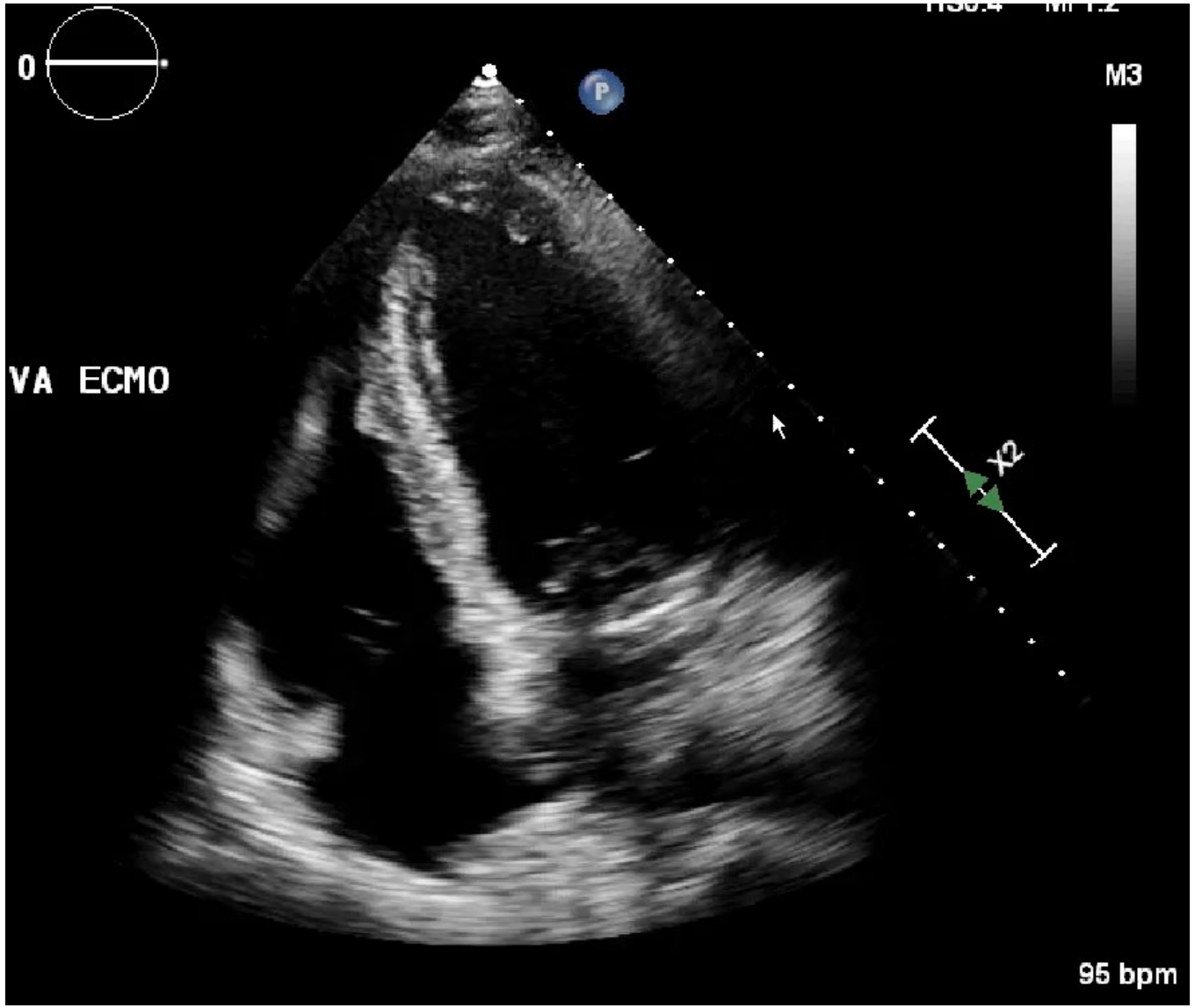
EKG: Inferior Posterior MI

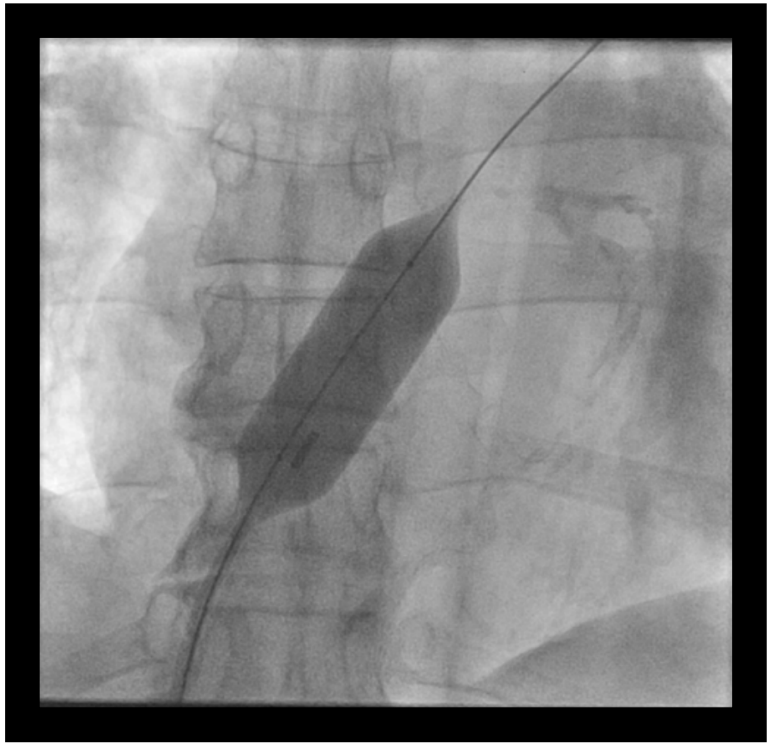
One episode of VT

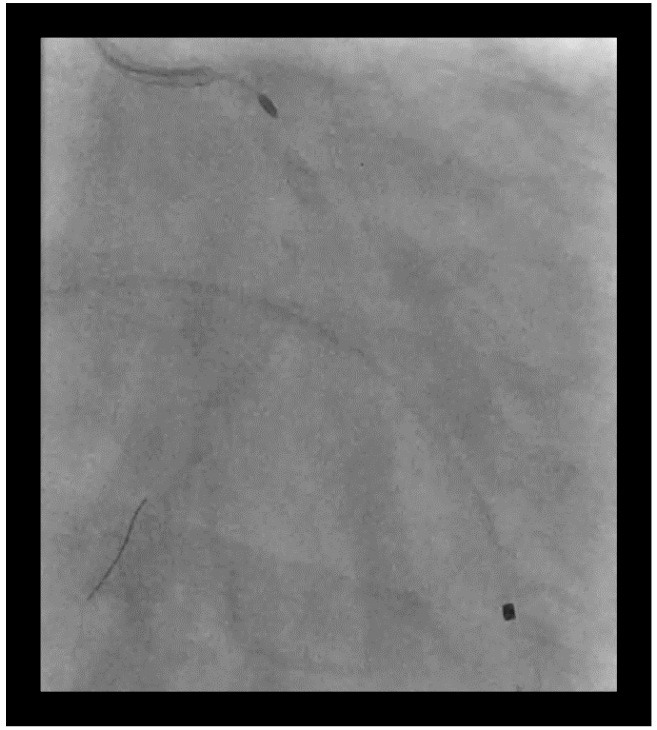
LHC showed trifucating LM disease and left dominant system

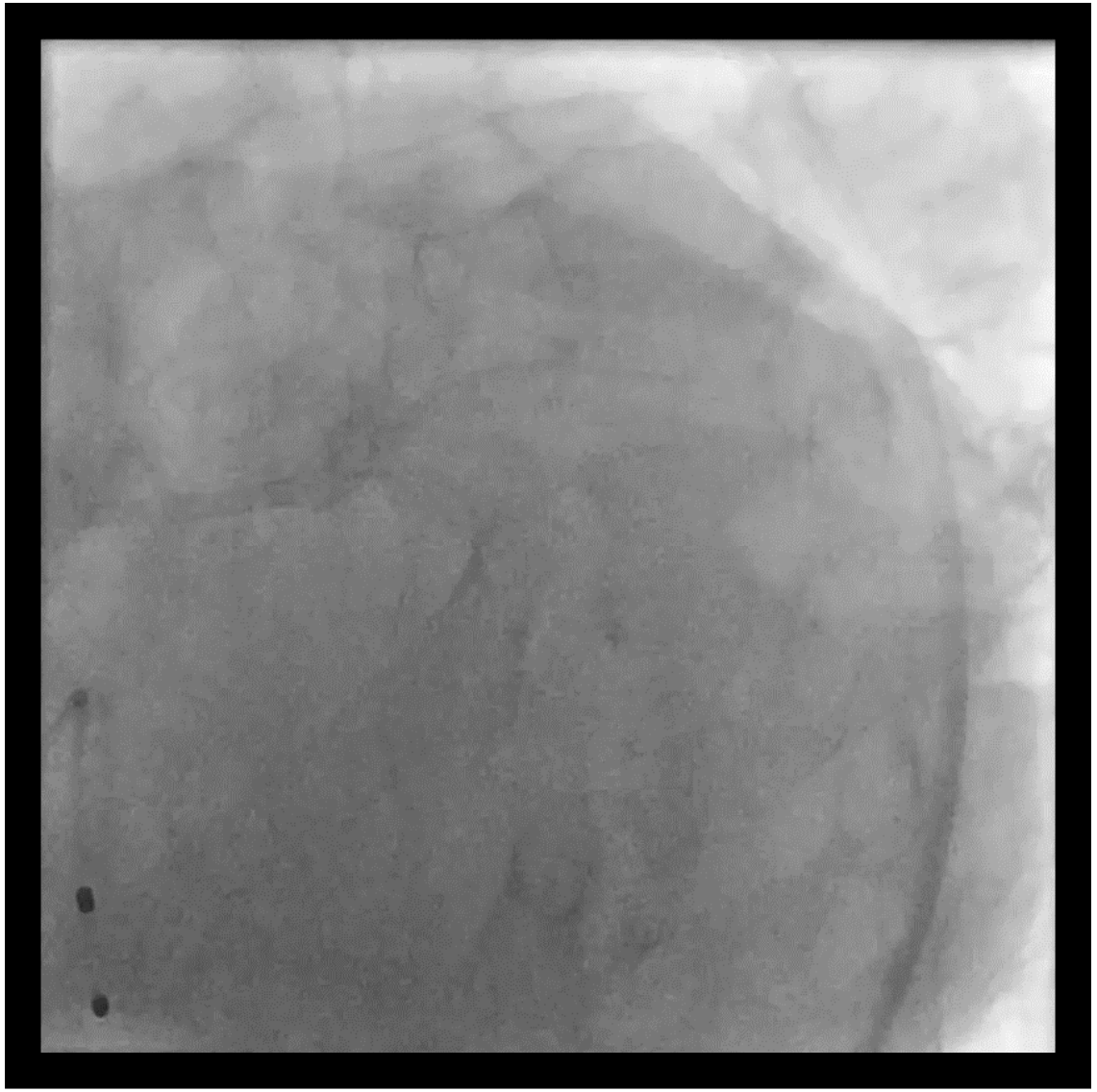
Elevated LVEDP 23

Transferred with IABP to UMD for CABG


0
M3
VA ECMO
X2
95 bpm







CHIP: New Frontier

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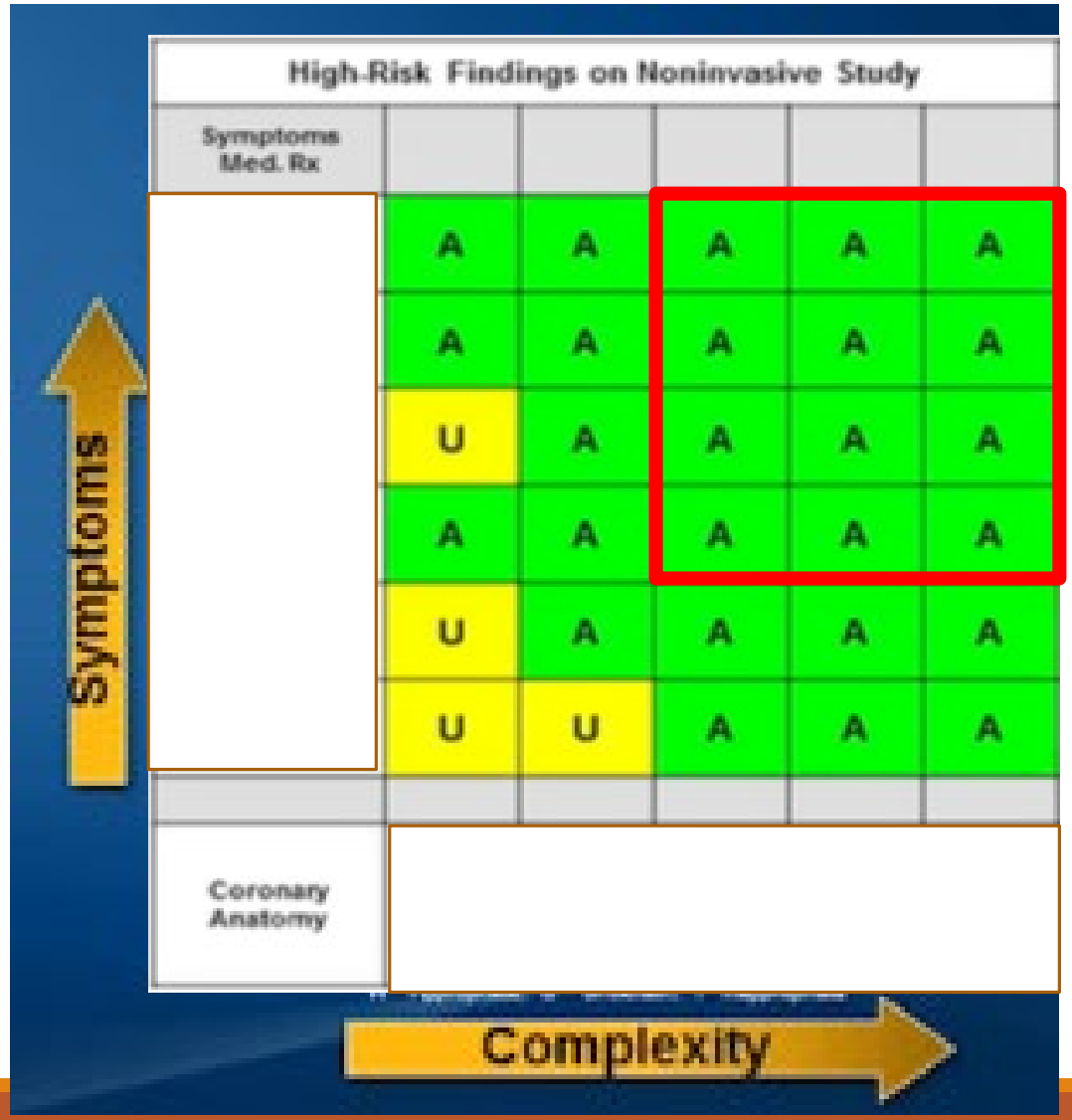
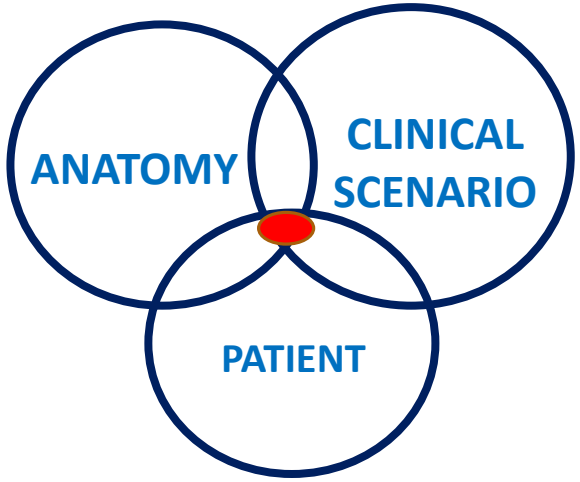


- Patients with anatomically complex disease without surgical revascularization options with prognostically or symptomatically important disease burden

CHIP: New Frontier

- **Challenges to treatment**
  - **Lack of widespread technical and cognitive expertise**
  - **Unclear mortality/morbidity benefit**
  - **Perception of lack of benefit amongst operators/referrings**



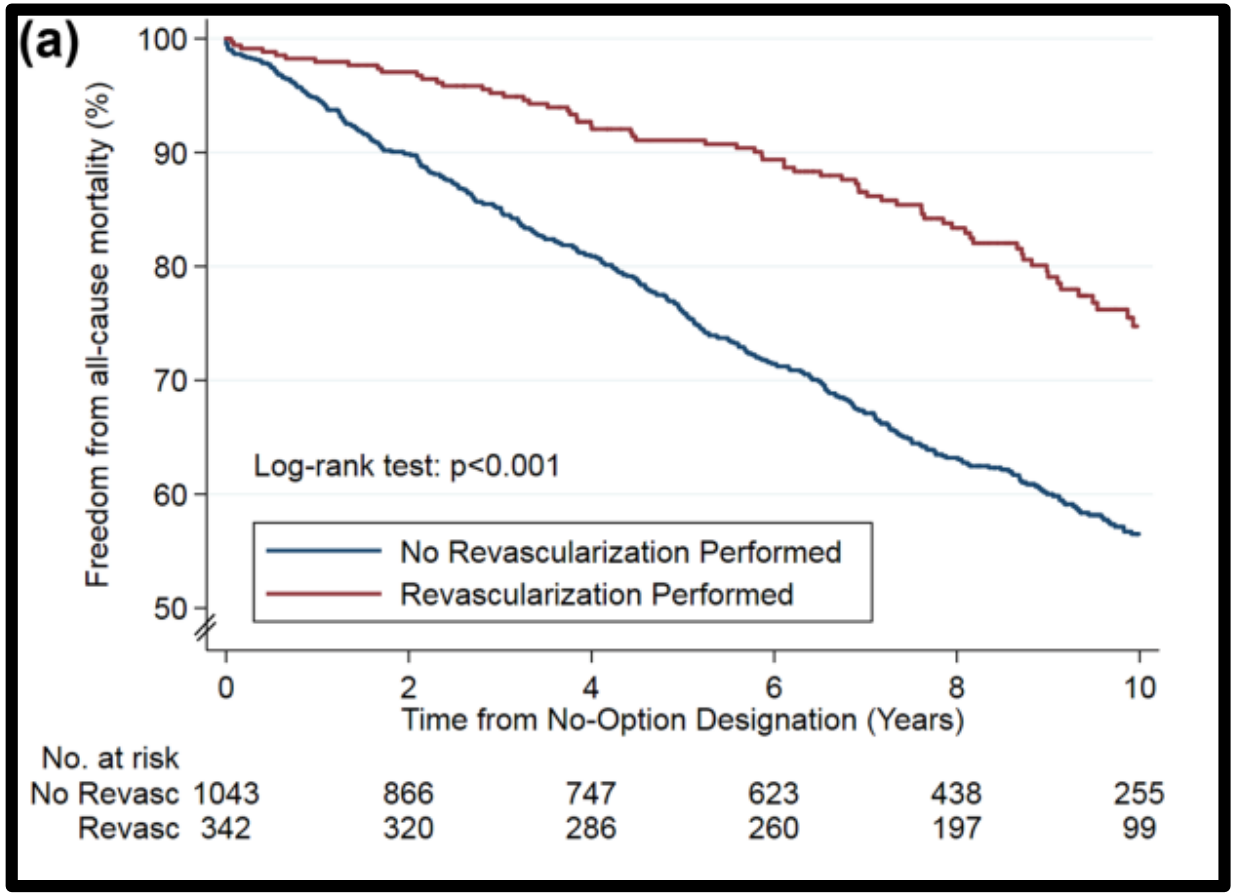
	CABG	PCI
Two-vessel CAD with proximal LAD stenosis	A	A
Three-vessel CAD with low CAD burden (i.e., three focal stenosis, low SYNTAX score)	A	A
Three-vessel CAD with intermediate to high CAD burden (i.e., multiple diffuse lesions, presence of CTO, or high SYNTAX score)	A	U
Isolated left main stenosis	A	U
Left main stenosis and additional CAD with low CAD burden (i.e., one to two vessel additional involvement, low SYNTAX score)	A	U
Left main stenosis and additional CAD with intermediate to high CAD burden (i.e., three vessel involvement, presence of CTO, or high SYNTAX score)	A	I

Circulation 2016;134:422-31; Appropriate Use Crtieria for Coronary Revascularization Focused Update 2012

CHIP: New Frontier

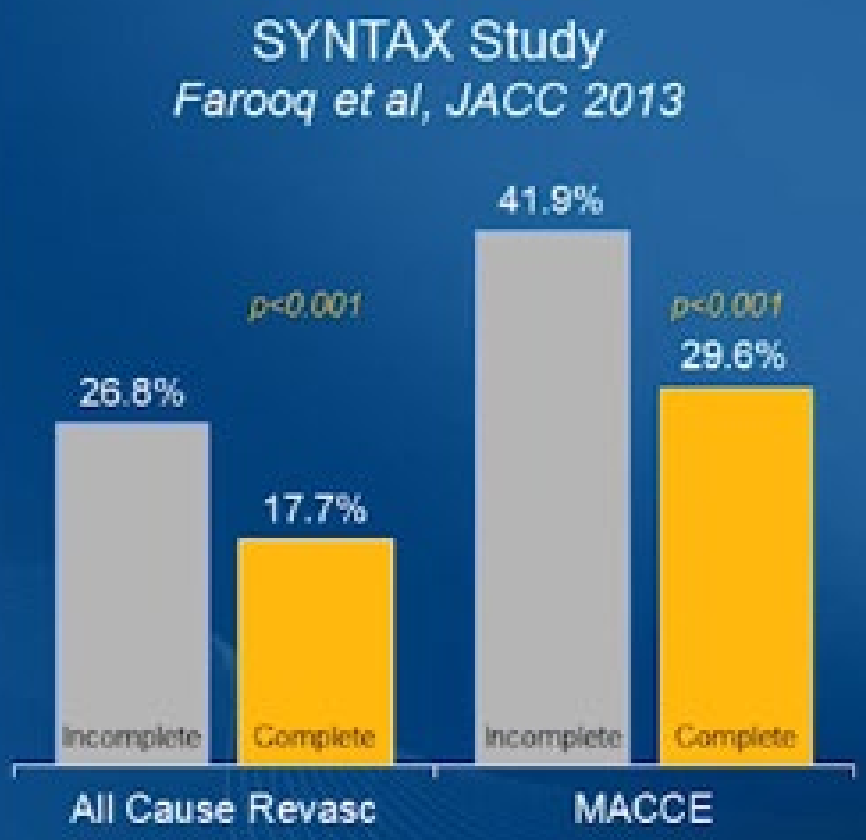
OPTIMIST Program

- 40 state database for refractory angina
- 1996-2014
- 342/1363 patients underwent revascularization within 2.2 yrs after 'no-option' diagnosis
- 2% v. 4.4% mortality at 5.1 years in revascularized



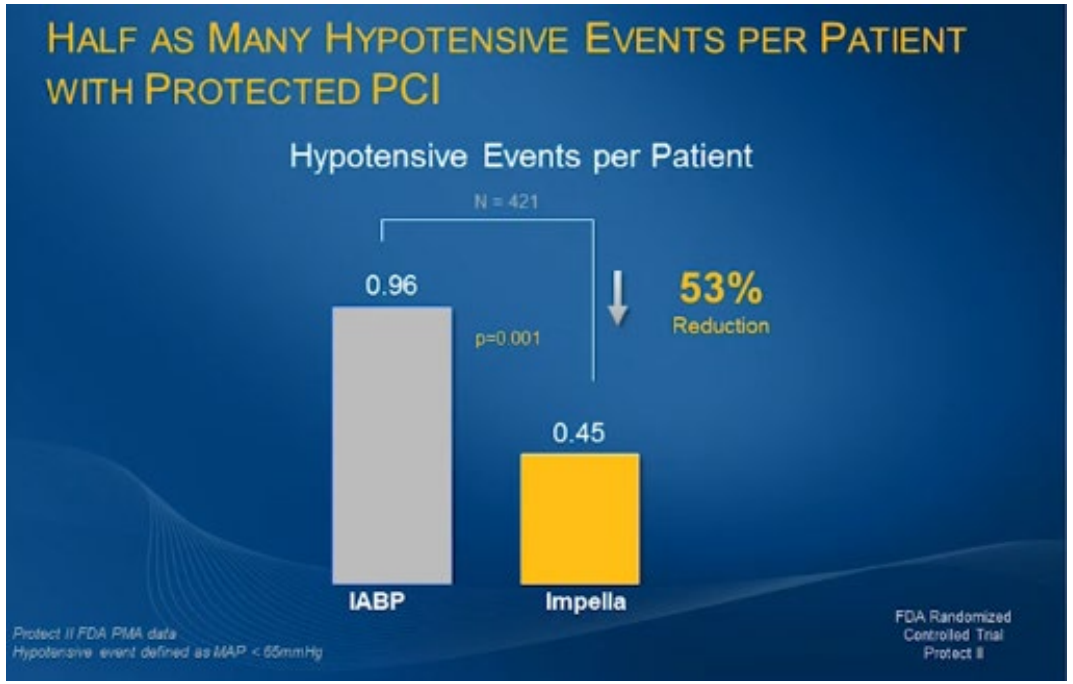
Catheter Cardiovasc Interv. 2018 Dec1:92(7):1215-1219

Complete Revascularization vs. Incomplete



CHIP: New Frontier

- Impella Device
  - PROTECT II Trial
    - RCT IABP v. Impella 2.5 in patients with LM or 3VD and low EF undergoing revascularization
    - 30d No difference/90d MAE benefit
  - USPella Registry
    - Impella in AMICS
- FDA Indication for elective and emergent high-risk PCI



SCAI-Women in Innovations Announces the Winner of the Complex and High-Risk Interventional Procedures CHIP Fellowship

100,000 Grant from ABIOMED

September 23, 2018

Kirtane et al. Circulation. 2016;143:422-32.

Roundtable Discusses Protected PCI for High-Risk Patients

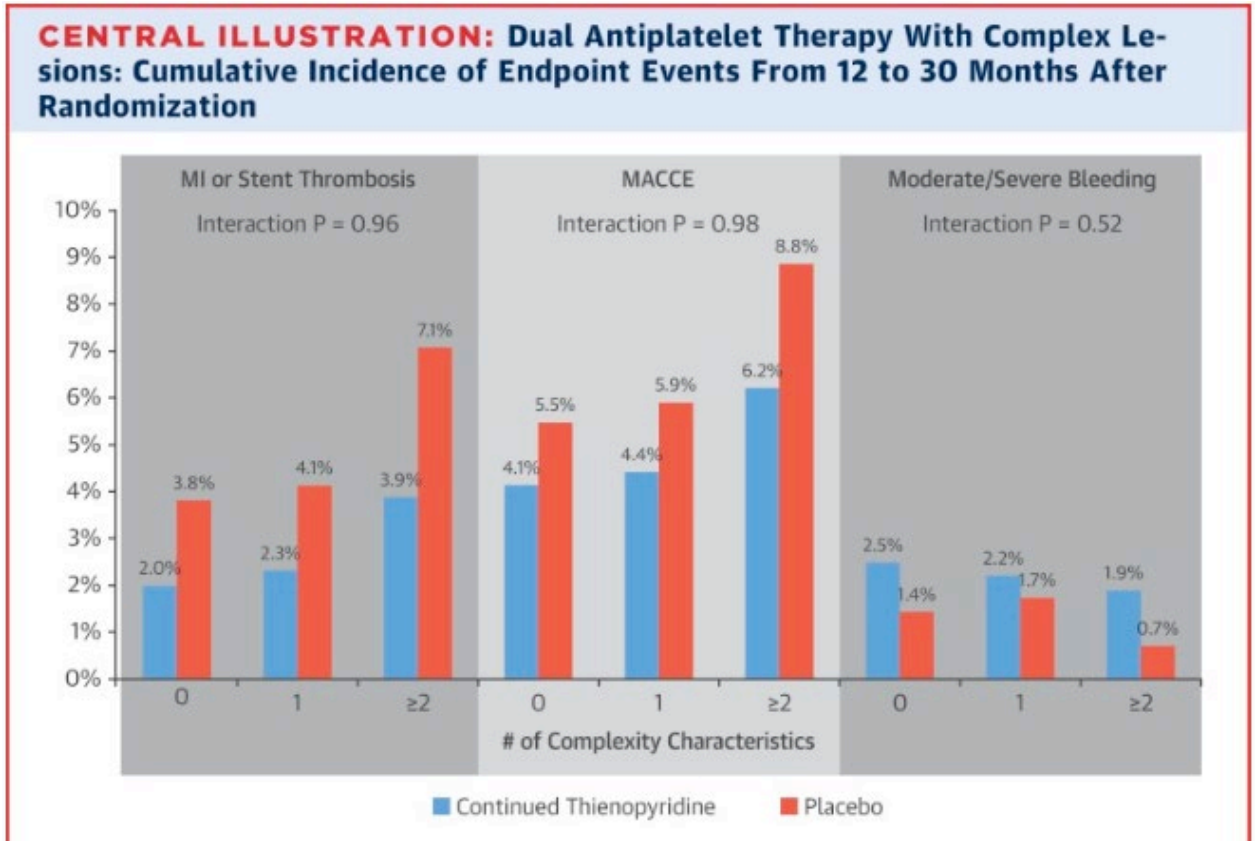
CHIP: No Man's Land

- Lack of DATA
  - Anti-platelet regimens
  - Women
  - Elderly
  - Risk stratification
- Learning Curve
- Implications for Public Reporting

CHIP: DAPT

DAPT Trial

- 11,554 patients -> 12 v. 30 months DAPT
- Randomization at 12m if no bleed/ischemic event
- Subset with complex disease (3700) reviewed
- No interaction of MI/ST/MACCE with procedural complexity
- More events in 1st year in complex patients



CHIP: WOMEN

	Percent Enrollment Male	
TRIAL	*Arm 1*	*Arm2*
CTO NCDR	78%	78%
Protect II	80.6%	82%
Excel	78%	74%

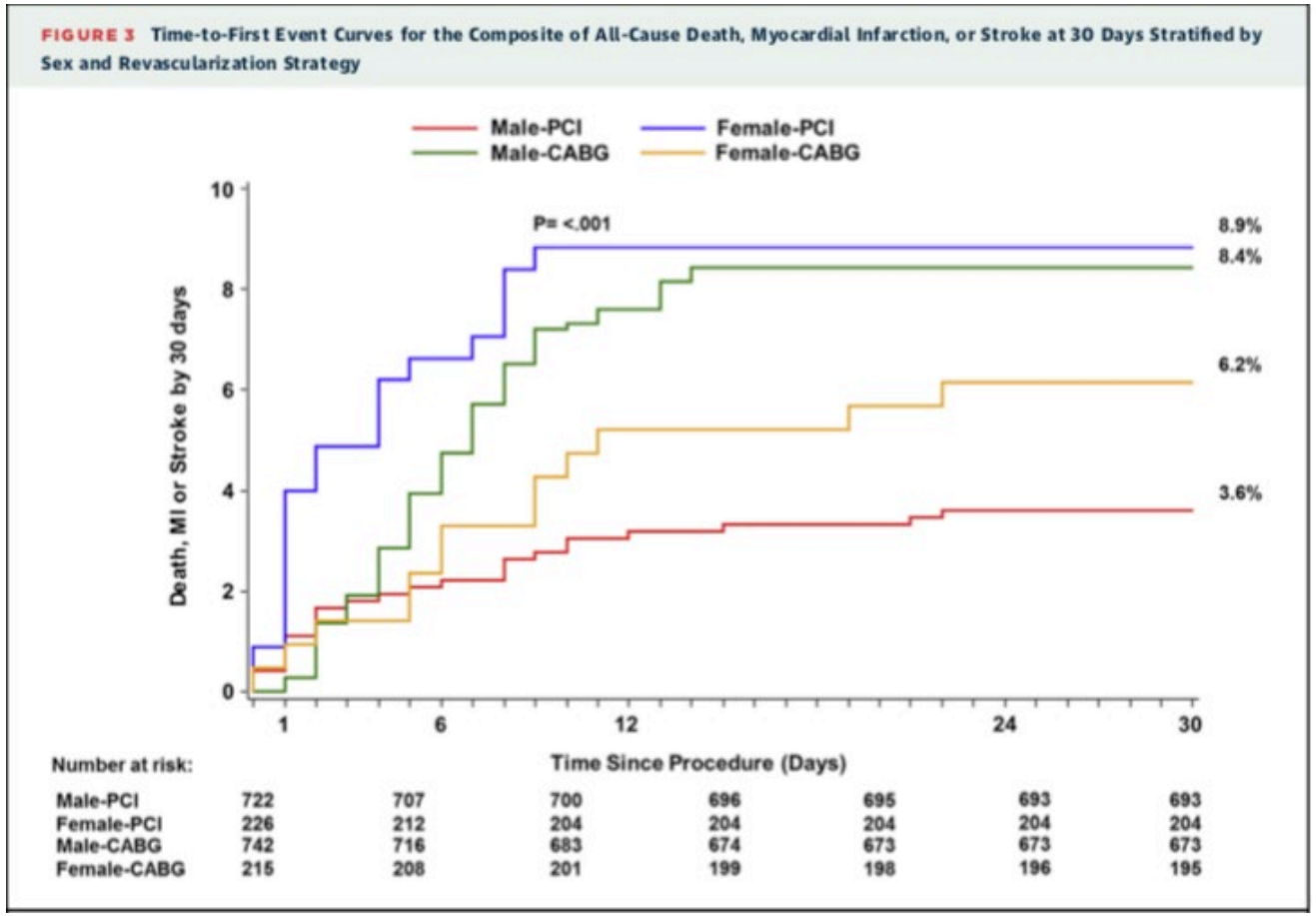
Outcomes After Coronary Stenting or Bypass Surgery for Men and Women With Unprotected Left Main Disease

The EXCEL Trial

Underpowered Sub-Group Analysis of RCT

- **1905 Patients, 441 Women (23%)**
- **Women had more co-morbidities (HTN, CHF, DM)**
- **Women had lower Syntax scores, more complete revascularization**
- **At 30d, women had more cardiac death/MI/Stroke with PCI than men and compared with CABG**

CHIP: WOMEN



No sex interaction after multi-variate analysis

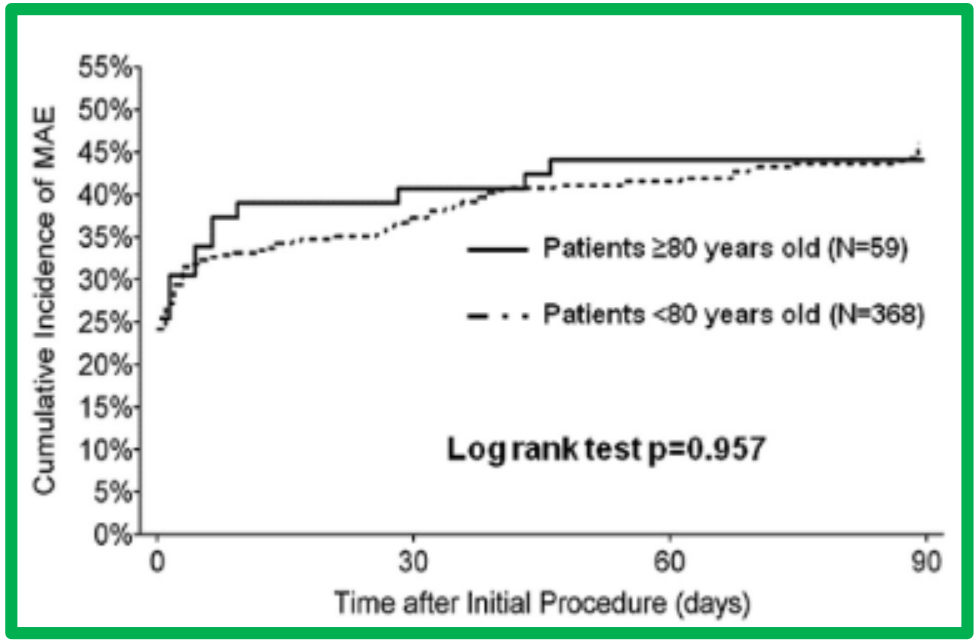
ELDERLY AND PCI

- **Higher in-hospital mortality and long-term mortality**
  - **More Vascular and Bleeding complications**
  - **More extensive, complex, calcified, tortuous CAD**
  - **Frailty**
  - **More Co-morbidities – *PAD/COPD/CKD***
  - **Physiology**
    - **Endothelial dysfunction**
    - **Diastolic dysfunction**

CHIP IN ELDERLY:

* RCT Patients with reduced LVEF undergoing elective HR-PCI with depressed LVEF randomized to Impella or IABP*

- **PROTECT II in Octegenarians:**
  - **59 pts > 80 vs. 368pts < 80**
  - **No significant difference in vascular complications (3.4% v 2.4%)**
  - **No significant difference in 90d MACCE/MACE**
  - **Lesser revascularization in >80 group (1.7% vs 10.4%)**
  - **More calcified and more LM disease in > 80**

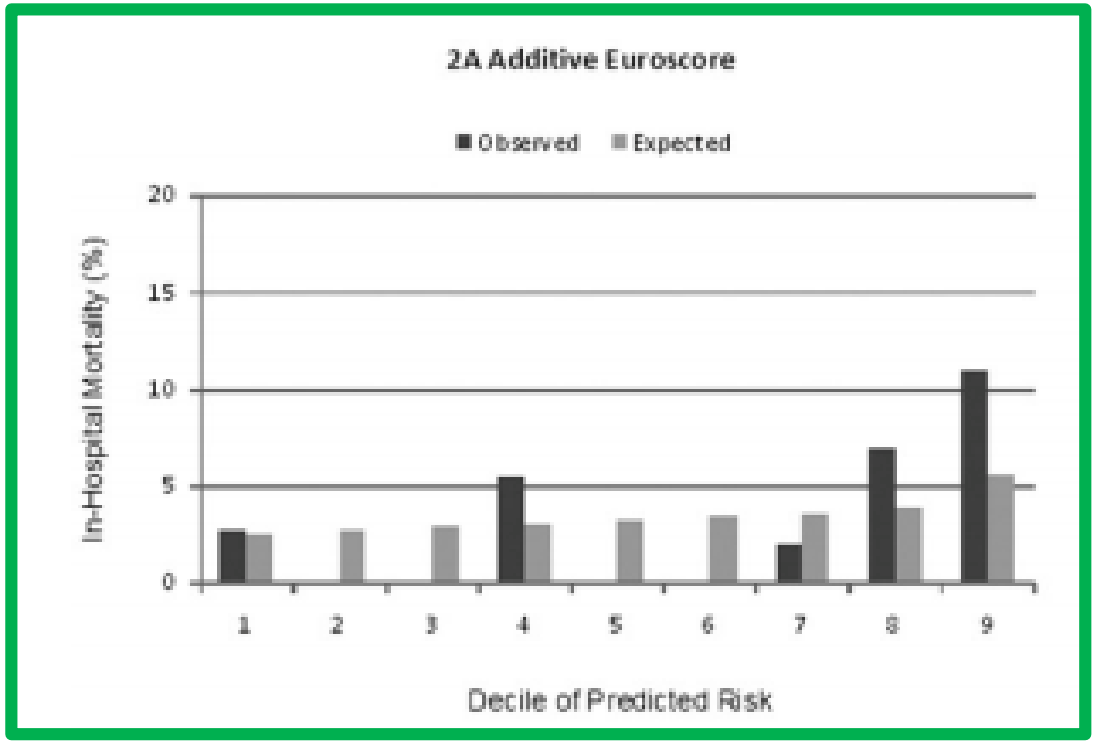


RISK ASSESSMENT

- **Unique co-morbidities and clinical features not incorporated in current risk calculators**
  - **Surgical inoperability**
  - **Malignancy**
  - **Liver Disease**
  - **Trauma**
  - **Pre-transplant status**

Farooq et al. Heart 2011;97:1902-13

RISK ASSESSMENT

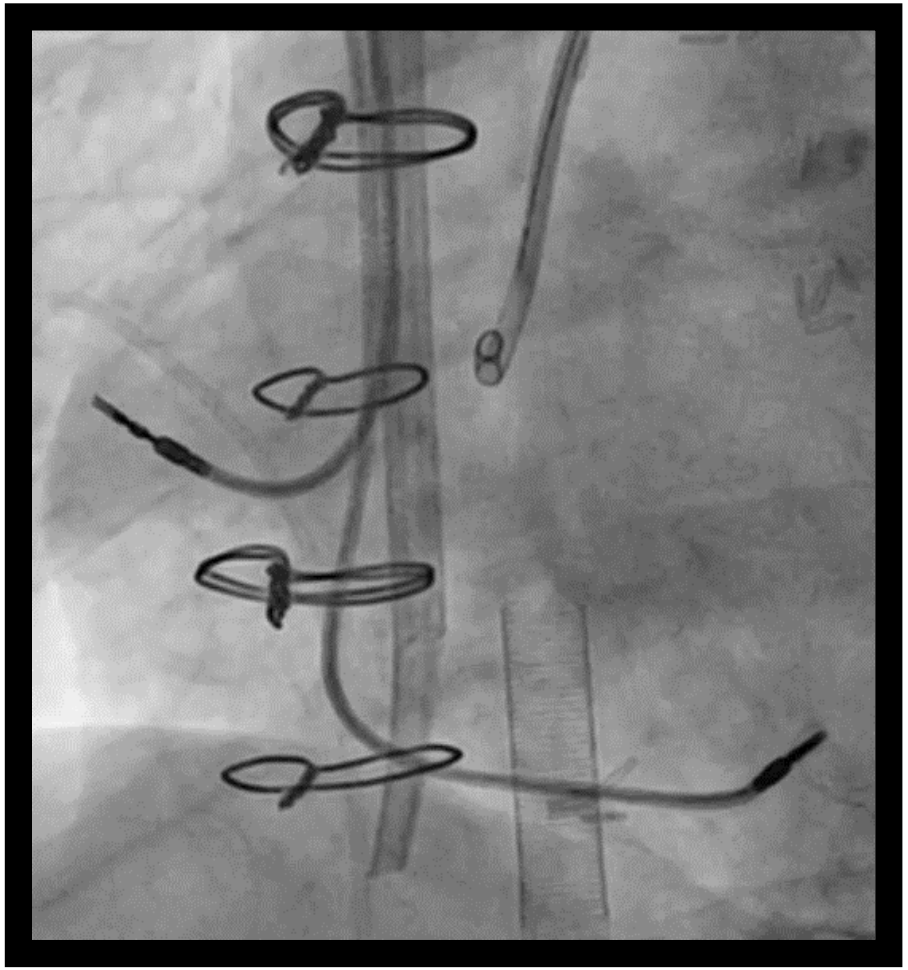


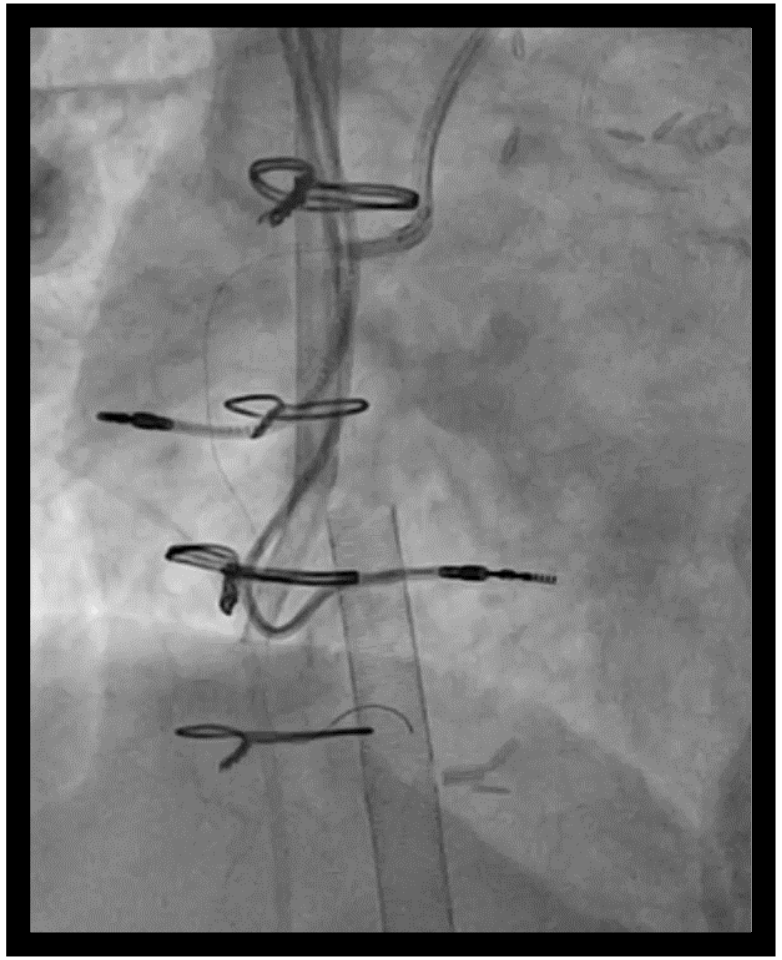
- **Combined anatomic and clinical risk calculators may hold promise**
  - **Syntax II Score**

Henriques JP et al. International Journal of Cardiology 189 (2015) 272-78

CHIP: No Man's Land

- Lack of DATA
  - Anti-platelet regimens
  - Women
  - Elderly
  - Risk stratification
- Learning Curve
- Implications for Public Reporting





> “I never attended a session titled 'Patients I Didn't Cath' at any national or local interventional cardiology conference.”

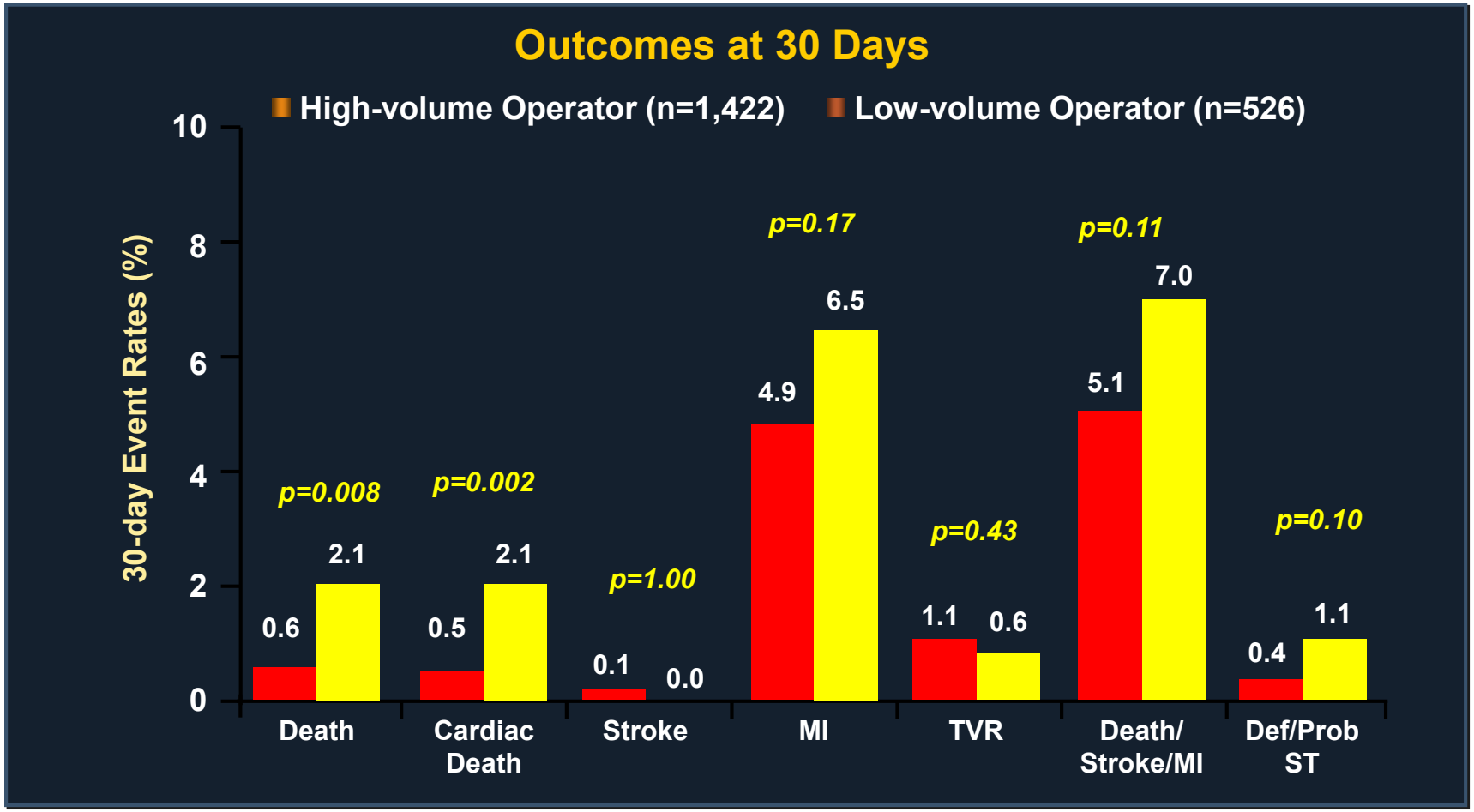
Jaya Mallidi. “The Yin and Yang of Interventional Cardiology: Physician and Proceduralist.” Medscape. Februa

LEARNING CURVES

- **Cognitive**
  - Nuances of case selection: Under-treating and Over-treating
  - Communication of risk
- **Technical**
  - CTO/Atherectomy/Bifurcation/MV PCI
  - Complication management
  - Imaging: IVUS and OCT

HEART TEAM APPROACH

Learning Curves



CHIP: No Man's Land

- Lack of DATA
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  - Women
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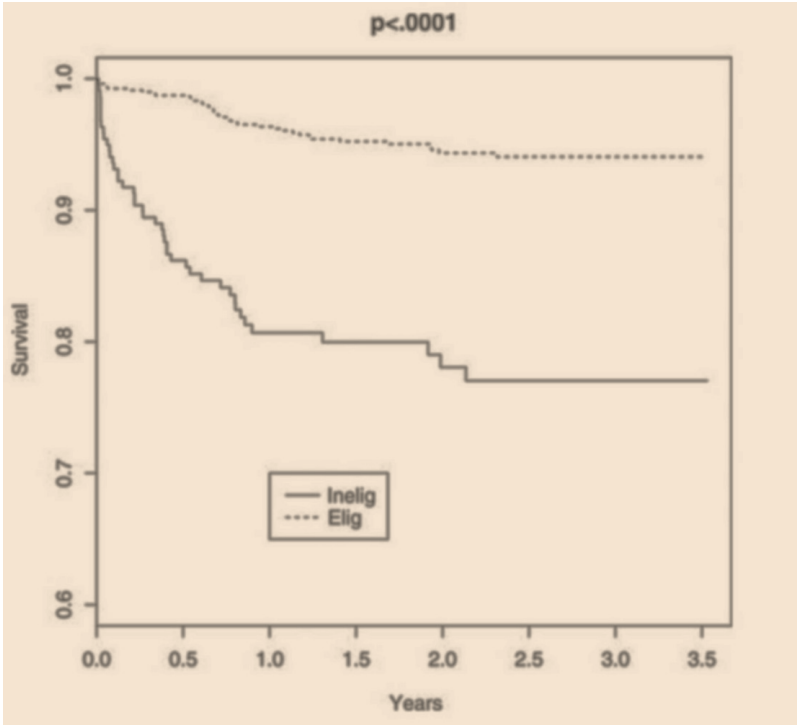
PUBLIC REPORTING

- Patients undergoing UPLM or MVD PCI at BWH/MGH
- 22% of 1013 patients documented in EMR as ineligible for surgery
- After risk-adjustment, surgical ineligibility independently predictive of in-hospital and long-term mortality
  - 7% vs. 1% In-hospital mortality
- Value – based reimbursement



CHIP: FUTRE DIRECTIONS

- Prevalence of ‘CHIP’ Population
- Outcomes
- Cost of revascularization of CHIP patients
- How widespread are adequately trained ICs to perform complete revascularization across complex lesion subsets
- What is the long-term durability of PCI in CHIP lesions
- Outcomes in male versus female CHIP patients and elderly patients

CHIP: FUTURE DIRECTIONS

CHIP CENTERS OF EXCELLENCE

- **Complex PCI Skills:**
  - **Bifurcation Disease**
  - **MVD PCI**
  - **Rotational Atherectomy**
  - **Antegrade and Retrograde CTO**

- **Hemodynamic Support Expertise**
- **Critical Care Physician/Heart Failure Physician/Shock Team**
- **Advanced Surgical Capabilities: ECMO, Tandem Heart, DT-VAD**

CHIP CENTERS

ANNUAL VOLUMES PER OPERATOR:

LEVEL 1	LEVEL 2	LEVEL 3
10+ CTO 10+ Atherectomy 12+ MCS	20-25+ CTO 10+ Atherectomy 20+ MCS	50+ CTO 15+ Atherectomy 50+ MCS

CONCLUSIONS

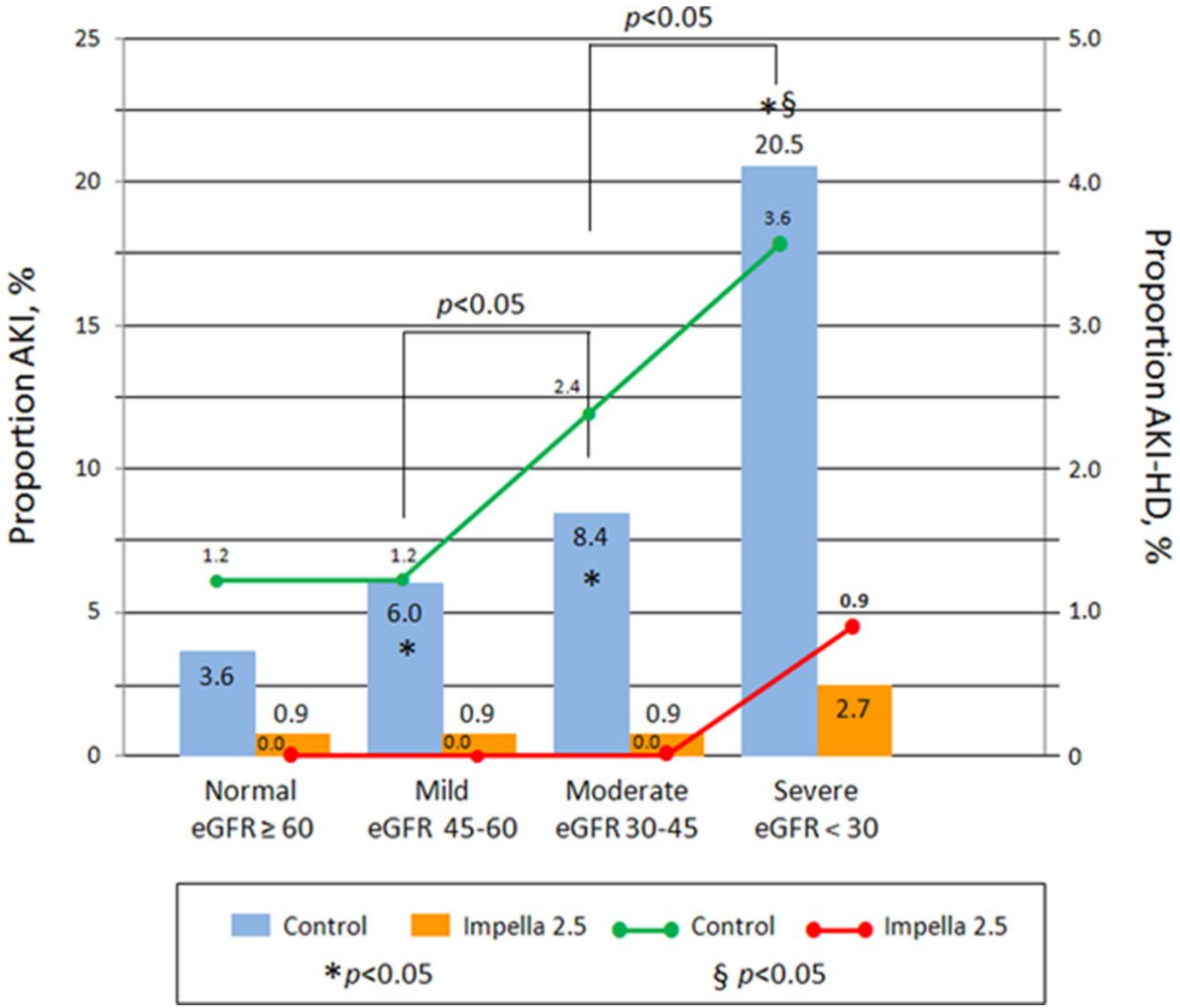
- **CHIP patients are a complex sub-set of IC patients and a growing demographic**
- **Effective management requires cognitive and technical expertise**
- **Many areas of uncertainty remain in optimal management and risk-stratification of CHIP patients**

Impella Support in PCI with Reduced AKI

Hemodynamic Support With a Microaxial Percutaneous Left Ventricular Assist Device (Impella) Protects Against Acute Kidney Injury in Patients Undergoing High-Risk Percutaneous Coronary Intervention

Michael P. Flaherty ✉, Sadip Pant, Samir V. Patel, Tyler Kilgore, Sujith Dassanayaka, John H. Loughran, Wasiq Rawasia, Buddhadeb Dawn, Allen Cheng, and Carlo R. Bartoli

Originally published 10 Jan 2017 | https://doi-org.proxy-hs.researchport.umd.edu/10.1161/CIRCRESAHA.116.309738 |
Circulation Research. 2017;120:692–700


p<0.05
*§
20.5
3.6
p<0.05
2.4
8.4
*
1.2
1.2
6.0
*
3.6
0.9
0.9
0.9
0.9
0.0
0.0
0.0
2.7
25
20
15
10
5
0
5.0
4.0
3.0
2.0
1.0
0
Proportion AKI, %
Proportion AKI-HD, %
Normal
eGFR ≥ 60
Mild
eGFR 45-60
Moderate
eGFR 30-45
Severe
eGFR < 30
Control
Impella 2.5
Control
Impella 2.5
*p<0.05
§ p<0.05

RISK DETERMINATION

The Syntax Score Algorithm

1. Arterial dominance
2. Arterial segments involved per lesion

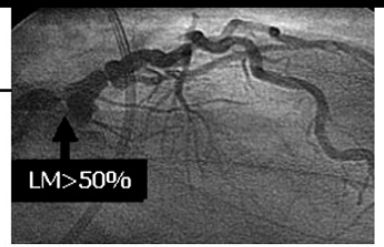
Lesion characteristics

3. Total occlusion
- i. Number of segments involved
- ii. Age of the total occlusion (>3 months)
- iii. Blunt stump
- iv. Bridging collaterals
- v. First segment beyond the occlusion visible by antegrade or retrograde filling
- vi. Side branch involvement

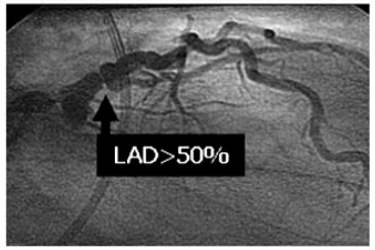
4. Trifurcation
- i. Number of segments diseased

5. Bifurcation
- i. Medina type
- ii. Angulation between the distal main vessel and the side branch <70°

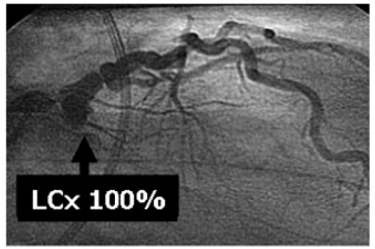
6. Aorto-ostial lesion
7. Severe tortuosity
8. Length >20 mm
9. Heavy calcification
10. Thrombus
11. Diffuse disease/small vessels
- i. Number of segments with diffuse disease/small vessels



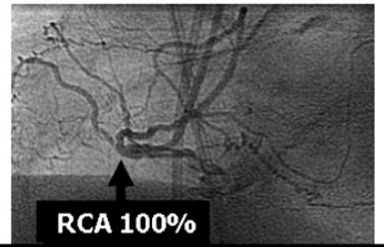
Lesion 1
Segment 5: 5x2 10
+ Bifurcation type A 1
+ Heavy calcification 2
Lesion 1 score: 13



Lesion 2
Segment 6: 3.5x2 7
+ Bifurcation type A 1
+ Angulation<70 1
+ Heavy calcification 2
Lesion 2 score: 11



Lesion 3
Segment 11: 1.5x5 7.5
Age T.O. is unknown 1
+Blunt stump 1
+Side branch 1
+ Heavy calcification 2
Lesion 3 Score: *12.5*



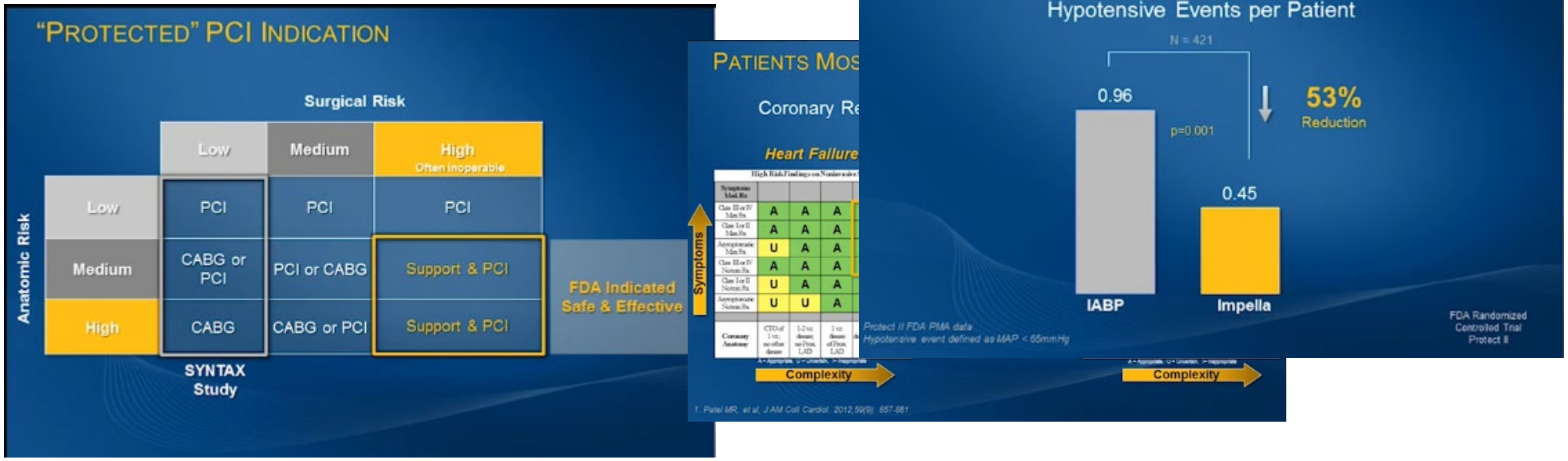
Lesion 4
Segment 1: 1x5 5
Age T.O. is unknown 1
+Blunt stump 1
+Side branch 1
First segment visualized by contrast:4
2
+ Tortuosity 2
+ Heavy calcification 2
Lesion 4 Score: *14*

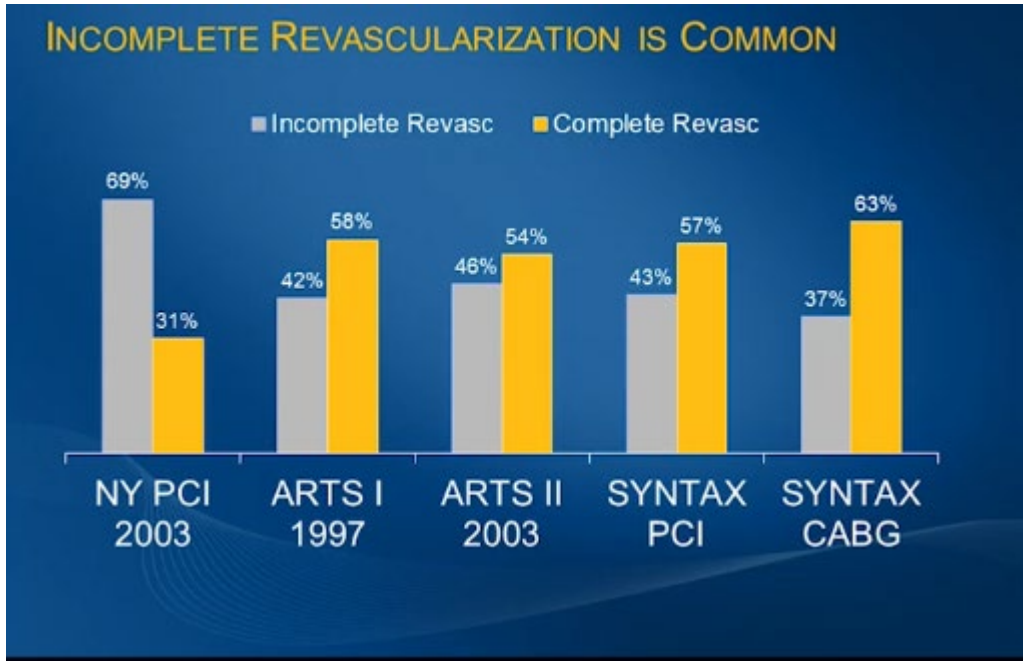
Farooq et al. Heart 2011;97:1902-13

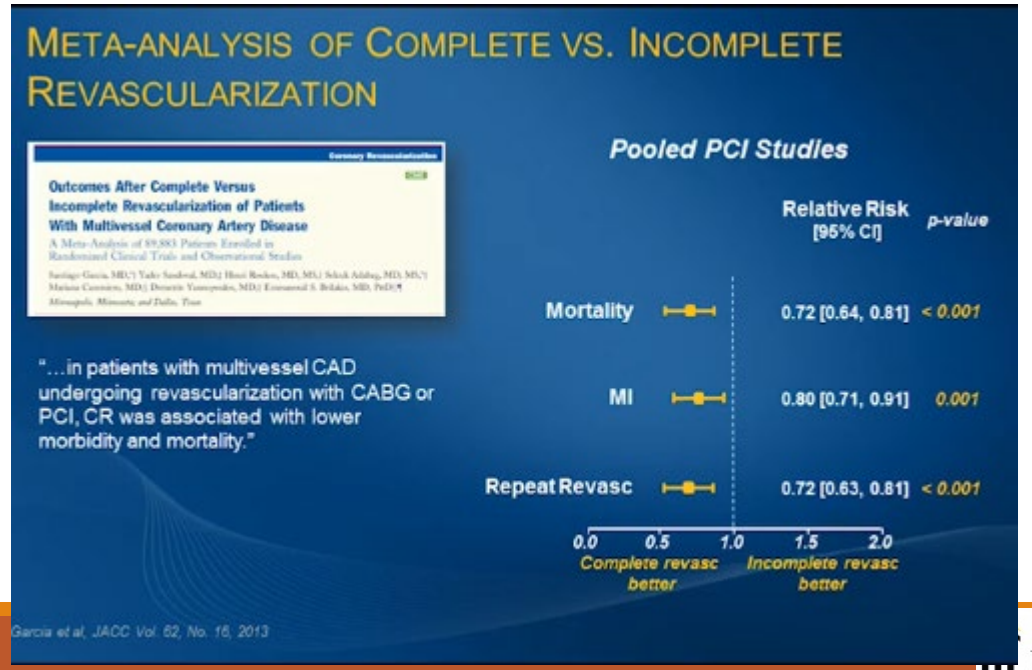
CHIP: New Frontier

Impella Device with success in supporting PCI in these patients

FDA Indication



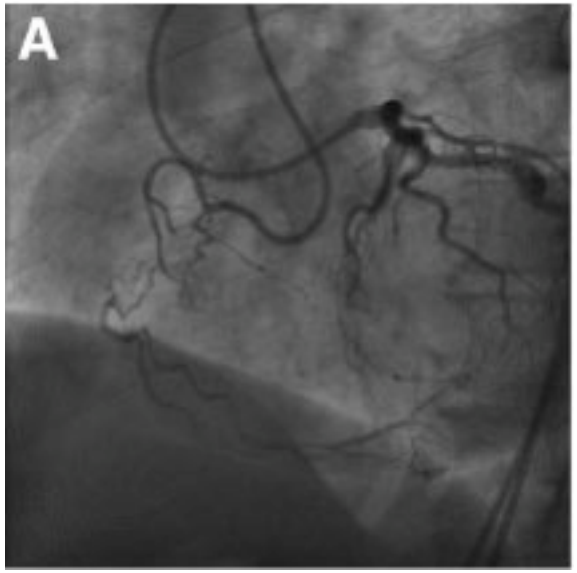

INCOMPLETE REVASCULARIZATION IS COMMON
Incomplete Revasc
Complete Revasc
69%
31%
42%
58%
46%
54%
43%
57%
37%
63%
NY PCI 2003
ARTS I 1997
ARTS II 2003
SYNTAX PCI
SYNTAX CABG

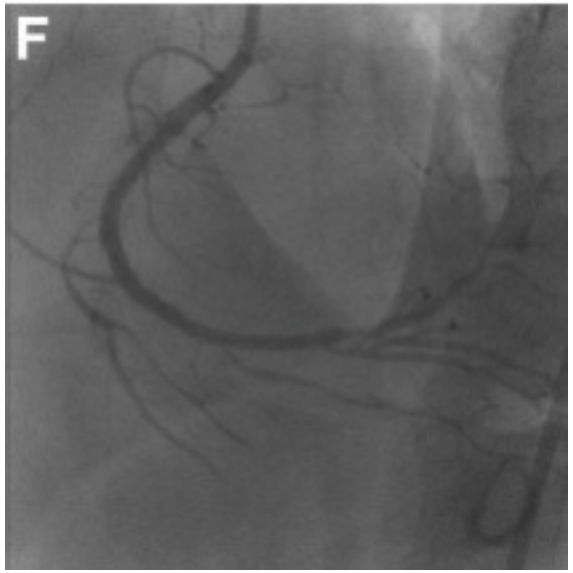

META-ANALYSIS OF COMPLETE VS. INCOMPLETE REVASCULARIZATION
Outcomes After Complete Versus Incomplete Revascularization of Patients With Multivessel Coronary Artery Disease
"…in patients with multivessel CAD undergoing revascularization with CABG or PCI, CR was associated with lower morbidity and mortality."
Pooled PCI Studies
Relative Risk [95% CI]
p-value
Mortality
0.72 [0.64, 0.81]
< 0.001
MI
0.80 [0.71, 0.91]
0.001
Repeat Revasc
0.72 [0.63, 0.81]
< 0.001
0.0
0.5
1.0
1.5
2.0
Complete revasc better
Incomplete revasc better
Garcia et al, JACC Vol. 62, No. 16, 2013

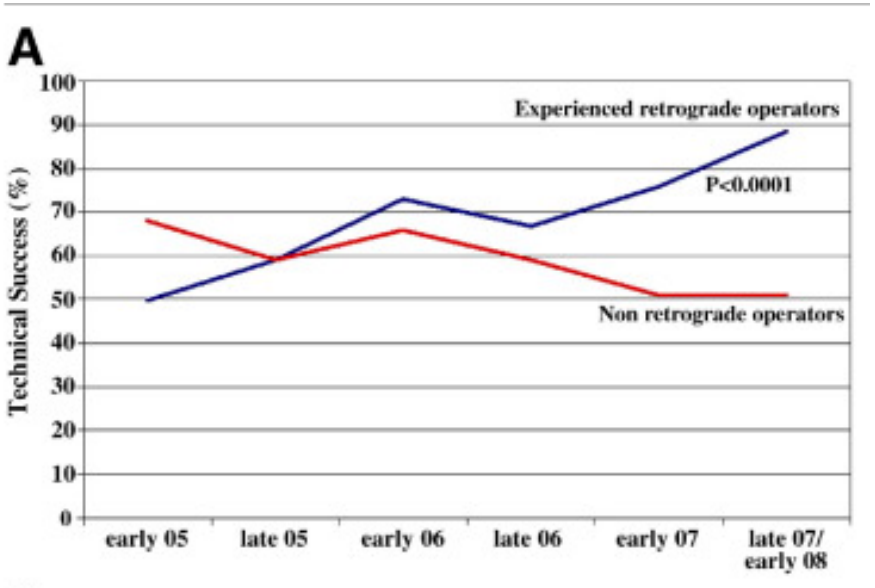
CHIP Subsection	Proposed Core Competencies
CHIP Population and Revascularization	Current trends in cath lab management, complex PCI cost effectiveness, data in support of complete revascularization, new “CHIP” population
Precision PCI (Coronary Physiology and Imaging)	Data supporting use of FFR and IFR, basic IVUS imaging interpretation, basic OCT image interpretation (lesion length, vessel size)
Hemodynamics and Ventricular Support	Right heart hemodynamic analyses, aortic and transvalvular MCS implantation, basic MCS bedside management (positioning, device flow management, waveform analysis)
Complex Anatomy, Multivessel PCI, Atherectomy	Angiogram analysis, angiographic calcification recognition, basic 2 stent bifurcation techniques, guide support management
CTO PCI	Dual catheter angiography and analysis, CTO toolbox fundamentals, comfort with antegrade wire escalation, introduction of antegrade dissection re-entry
Complication Management	Complication recognition, “call for help” algorithm, toolbox familiarity, post PCI “no-flow” management
Large Bore Access Management	Closure device management, femoral access up to 14F, radial access up to 7F, femoral cross over technique

LEARNING CURVES

- CTOs
  - 636 Patients 2005-2008
  - Procedural Outcome of 2 Group: High CTO v. Low CTO
  - Technical Success: 75% v 59%
  - Higher success, increased improvement







Circulation 2016;134:422-31; JACC:Cardiovascular Interventions Volume 2, Issue 9, 2009:834-42

WHITE PAPER

Treatment of Higher-Risk Patients With an Indication for Revascularization

Evolution Within the Field of Contemporary Percutaneous Coronary Intervention

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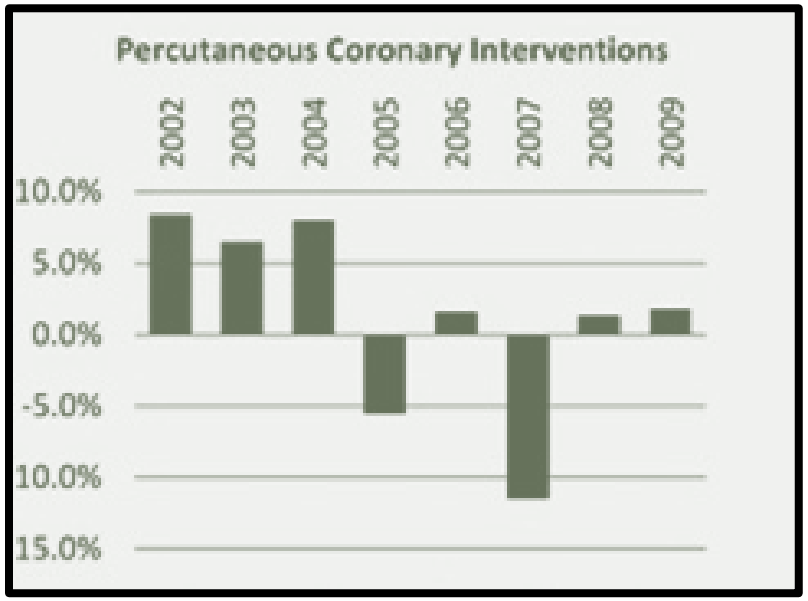
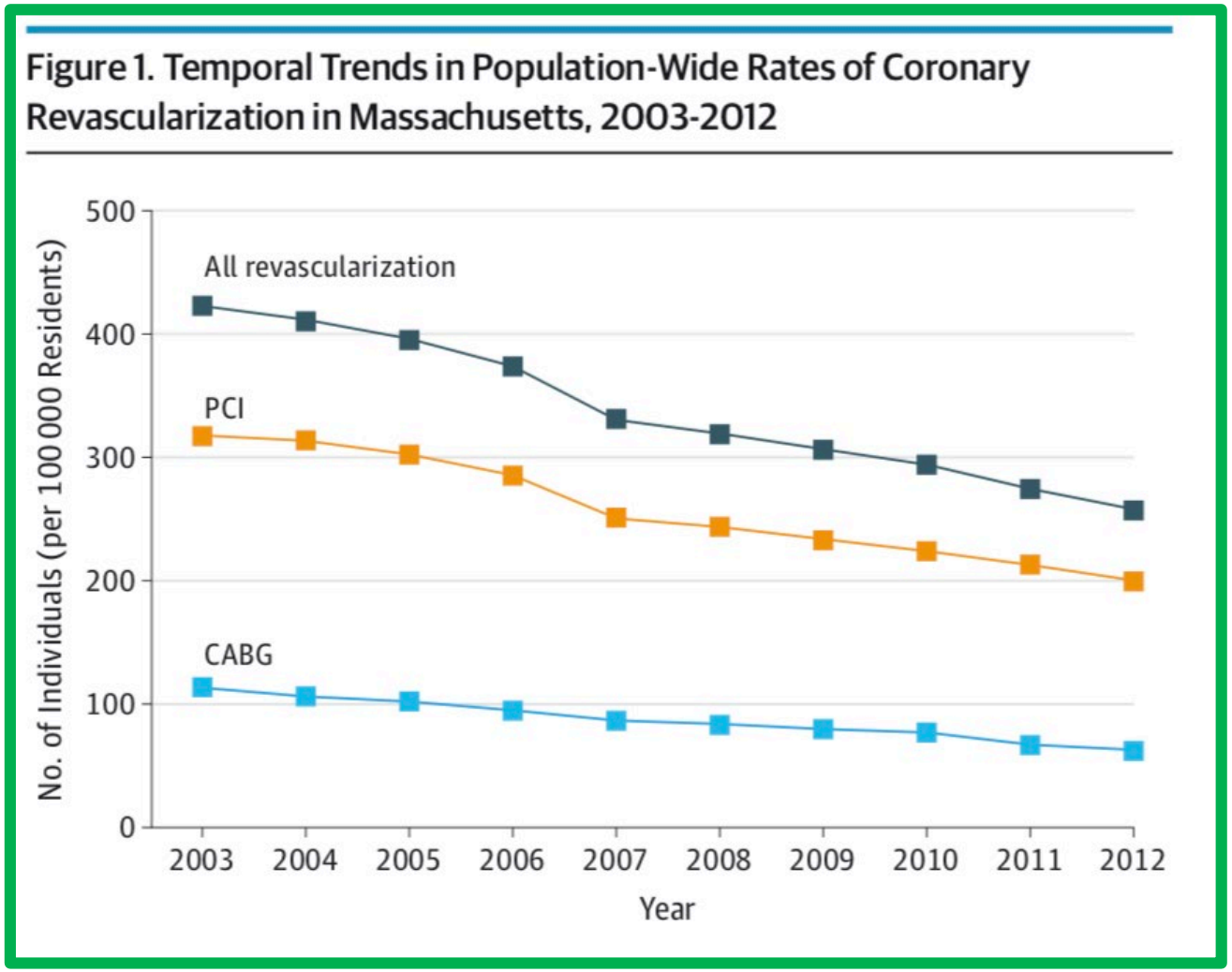
Kirtane et al. Circulation. 2016;143:422-32.

BACKDROP OF CHIP

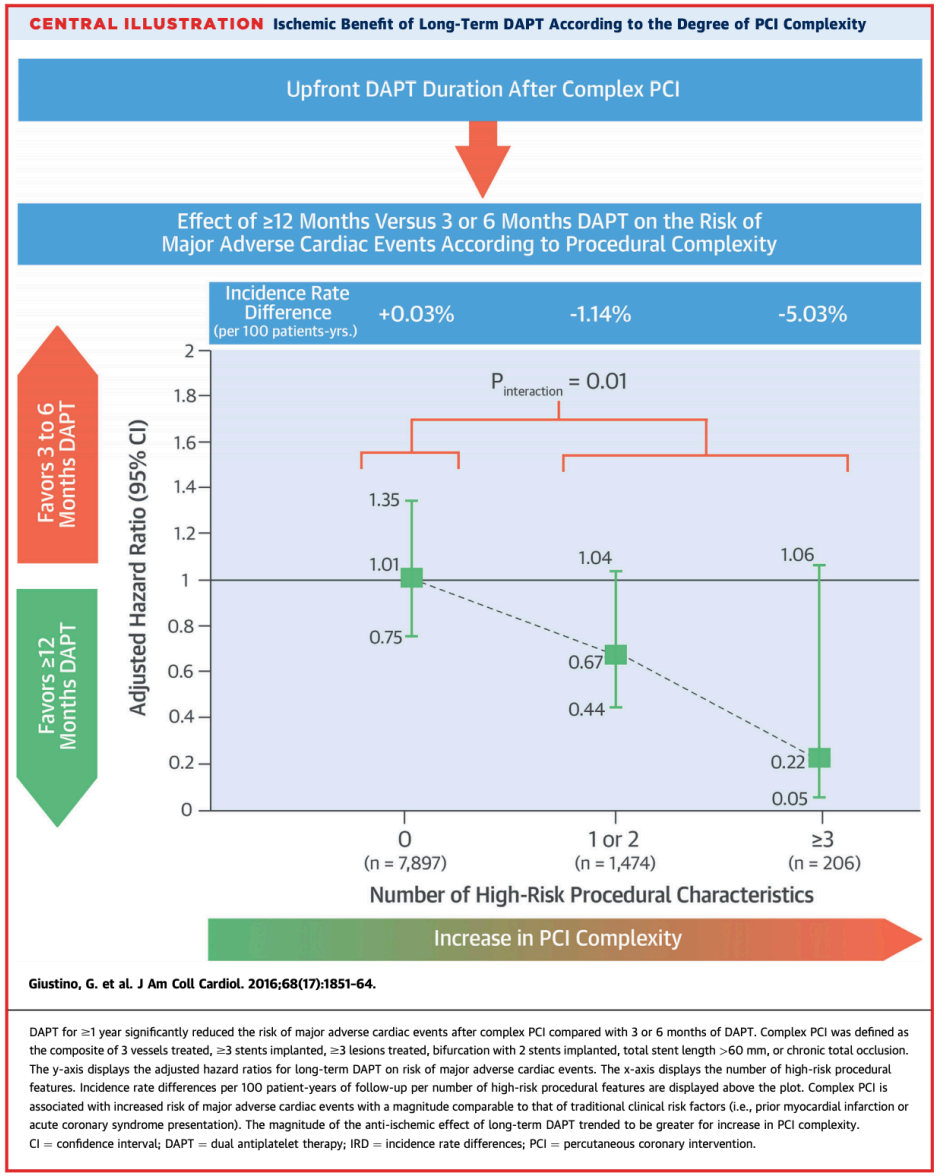




Riley et al. Circulation: Cardiovascular Quality and Outcomes. 2011;4:193-97; Yeh et al. JAMA Internal Medicine. March 2015. Volume 175

CHIP: DAPT

- Post-hoc pooled analysis of RCTs evaluating DAPT duration
- 1680/9577 underwent complex PCI
- Increase in PCI complexity favored >12m with regards of MACE



Giustino et al. J Am Coll Cardiol 2016;68:1851-64; Yeh et al. J Am Coll Cardiol 2017;70:2213-23

CHIP: WOMEN

Table 2. Hazard of PCI as Compared With CABG for 5-Y All-Cause Death in Women and Men

Trial		HR (95% CI)	*P* Value	*P* Value for Interaction
SYNTAX	Women	2.213 (1.242–3.943)	0.007	
	Men	1.001 (0.736–1.361)	0.995	
	Ratio of $HR_{women\ vsmen}$	2.192 (1.140–4.218)		0.019