

Sometimes, there are simple solutions to complex problems...



How Did We Get From Indicated to Not Medically Necessary and/or Rarely Appropriate?

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40 Years Ago

- Forty years ago, Andreas Grüntzig introduced a transformational procedure:
- Dedicated to the proposition that man can “work therapeutically within the coronary arteries themselves in the face of an alert comfortable patient.”



Amazing Procedure

- In these subsequent forty years, the device has saved countless lives and helped millions of patients return to normal lifestyle free of the scourges of obstructive coronary artery disease.
- The success of this procedure led to its refinement in the form of concatenations of new technology that widened the scope of patients who could be treated.

Two Classes of Cardiologists

- In the twenty years following the introduction of the Grüntzig procedure there arose two classes of cardiologists:
 - **THOSE WHO DID the procedure (😊).**
 - **THOSE WHO DID NOT (😞).**

Those Who Did Not



- Instead of fixing the underlying problem,  gave their patients magic potions.
 - nitrates which made their patients' heads throb.
 - beta blockers which made them sleepy and ruined their sex life.
 - new miracle drugs like ranolazine, which made them constipated and sometimes neurologically disturbed.
- **With headaches, fatigue, decreased libido and constipation patients no longer worried about their angina.**

In the meantime, patients knew the difference

- Everyone (nearly everyone) wanted to be fixed.
- They flocked to 😊 and away from 😞.

ESC 2006 🙄 fought back:

- First with “studies” suggesting excessive stent thrombosis with DES.
- Turned out to be “fake news.”

Summary of Thrombosis at 3 Years of Follow-up Using Expanded Definition

Thrombosis	CYPHER® (n=878)	BMS (n=870)	Difference [95% CI]	p-value*
Thrombosis (0-30)	0.5% (4)	0.1% (1)	0.3% [-0.2%, 0.8%]	0.3743
LST (31-360)	0.2% (2)	1.2% (10)	-0.9% [-1.7%, -0.1%]	0.0215
VLST (361-1080)	0.9% (8)	0.3% (3)	0.6% [-0.2%, 1.3%]	0.2251
<u>Summary Rates</u>				
LST + VLST (31-1080)	1.1% (10)	1.4% (13)	-0.4% [-1.4%, 0.7%]	0.5369
All Thrombosis (0-1080)	1.6% (14)	1.6% (14)	0.01% [-1.2%, 1.2%]	1.0000

* Fisher's Exact Test p-value

Adjudication performed by a physician independent of Cordis

Internal Data, Cordis Corporation.

Next Came the COURAGE STUDY (April 2007)



- Study with inappropriate endpoints and a crossover rate of >30%.
- Failed to show a difference in mortality between stent group and medically managed patients, one third of whom crossed over to PCI.
- 😞 embraced this study, and declared to the world that the Grüntzig procedure was unnecessary in stable patients.
- More fake news.

What Andreas Grüntzig would say:

- PCI is a treatment for angina.
- Although we demonstrated that it was safe and effective, we never claimed that it saved lives.
- Definitive studies to this end have never been done, except in the case of acute MI.
- Failure to show a decrease in MACE in the COURAGE study in no way negates the value of PCI for management of angina.

Next Came the FAME Study (January 2009)

- This well-done study asked the question in patients with unstable angina, who had PCI of the culprit vessel, was it necessary to treat other vessels?
- FFR separated patients with subsequent events from those without.
- 🙄 embraced this study declaring to the world that PCI was unnecessary for patients with normal FFR.
- They did not mention the fact that FAME only studied whether or not to do a second vessel after a culprit vessel already had PCI.
- More fake news.

The Last Straw: Appropriateness Criteria

- Published in February 2009 by a group of mostly 🙄
- How they got the authority to tell us what is and is not appropriate is unclear.
- According to the manuscript:

The publication of appropriateness criteria reflects one of several ongoing efforts by the ACCF and its partners to assist clinicians caring for patients with cardiovascular diseases to deliver high-quality cardiovascular care. [REDACTED]

The (Hated) Rubik's Cubes

Low Risk Findings on Noninvasive Study						Asymptomatic					
Symptoms						Stress Test					
Med. Rx						Med. Rx					
Class III or IV Max Rx	U	A	A	A	A	High Risk Max Rx	U	A	A	A	A
Class I or II Max Rx	U	U	A	A	A	High Risk No/min Rx	U	U	A	A	A
Asymptomatic Max Rx	I	I	U	U	U	Int. Risk Max Rx	U	U	U	U	A
Class III or IV No/min Rx	I	U	A	A	A	Int. Risk No/min Rx	I	I	U	U	A
Class I or II No/min Rx	I	I	U	U	U	Low Risk Max Rx	I	I	U	U	U
Asymptomatic No/min Rx	I	I	U	U	U	Low Risk No/min Rx	I	I	U	U	U
Coronary Anatomy	CTO of 1 vz.; no other disease	1-2 vz. disease; no Prox. LAD	1 vz. disease of Prox. LAD	2 vz. disease with Prox. LAD	3 vz. disease; no Left Main	Coronary Anatomy	CTO of 1 vz.; no other disease	1-2 vz. disease; no Prox. LAD	1 vz. disease of Prox. LAD	2 vz. disease with Prox. LAD	3 vz. disease; no Left Main

Pouring Water on a drowning man

APPROPRIATE USE CRITERIA

ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/ STS 2017 Appropriate Use Criteria for Coronary Revascularization in Patients With Stable Ischemic Heart Disease



A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society of Thoracic Surgeons

TABLE 1.2 Two-Vessel Disease

Appropriate Use Score (1-9)								
Two-Vessel Disease								
Indication	Asymptomatic				Ischemic Symptoms			
	Not on AA Therapy or With AA Therapy		Not on AA Therapy		On 1 AA Drug (BB Preferred)		On ≥2 AA Drugs	
	PCI	CABG	PCI	CABG	PCI	CABG	PCI	CABG
No Proximal LAD Involvement								
7. ■ Low-risk findings on noninvasive testing	R (3)	R (2)	M (4)	R (3)	M (5)	M (4)	A (7)	M (6)
8. ■ Intermediate- or high-risk findings on noninvasive testing	M (5)	M (4)	M (6)	M (5)	A (7)	M (6)	A (8)	A (7)
9. ■ No stress test performed or, if performed, results are indeterminate ■ FFR ≤0.80* in both vessels	M (5)	M (4)	M (6)	M (4)	A (7)	M (5)	A (8)	A (7)
Proximal LAD Involvement and No Diabetes Present								
10. ■ Low-risk findings on noninvasive testing	M (4)	M (4)	M (5)	M (5)	M (6)	M (6)	A (7)	A (7)
11. ■ Intermediate- or high-risk findings on noninvasive testing	M (6)	M (6)	A (7)	A (7)	A (7)	A (7)	A (8)	A (8)
12. ■ No stress test performed or, if performed, results are indeterminate ■ FFR ≤0.80 in both vessels	M (6)	M (6)	M (6)	M (6)	A (7)	A (7)	A (8)	A (8)
Proximal LAD Involvement With Diabetes Present								
13. ■ Low-risk findings on noninvasive testing	M (4)	M (5)	M (4)	M (6)	M (6)	A (7)	A (7)	A (8)
14. ■ Intermediate- or high-risk findings on noninvasive testing	M (5)	A (7)	M (6)	A (7)	A (7)	A (8)	A (8)	A (9)
15. ■ No stress test performed or, if performed, results are indeterminate ■ FFR ≤0.80 in both vessels*	M (5)	M (6)	M (6)	A (7)	A (7)	A (8)	A (7)	A (8)

The number in parentheses next to the rating reflects the median score for that indication. *FFR measurements with appropriate normal ranges may be substituted for FFR. A indicates appropriate; AA, antianginal; BB, beta blockers; CABG, coronary artery bypass graft; FFR, fractional flow reserve; IFR, instant wave-free ratio; LAD, left anterior descending coronary artery; M, may be appropriate; PCI, percutaneous coronary intervention; and R, rarely appropriate.

TABLE 2.2 IMA to LAD Not Patent

Appropriate Use Score (1-9)								
Indication	Asymptomatic				Ischemic Symptoms			
	Not on AA Therapy or With AA Therapy		Not on AA Therapy		On 1 AA Drug (BB Preferred)		On ≥2 AA Drugs	
	PCI	CABG	PCI	CABG	PCI	CABG	PCI	CABG
Stenosis Supplying 1-Territory Disease (Bypass Graft or Native Artery)-Anterior (LAD) Territory								
35. ■ Low-risk findings on noninvasive testing	M (4)	R (3)	M (5)	R (3)	M (6)	M (4)	A (7)	M (5)
36. ■ Intermediate- or high-risk findings on noninvasive testing	M (6)	M (4)	M (6)	M (4)	A (7)	M (5)	A (8)	M (6)
37. ■ No stress test performed or, if performed, the results are indeterminate ■ FFR of stenosis ≤0.80*	M (5)	M (4)	M (6)	M (4)	A (7)	M (5)	A (8)	M (6)
Stenoses Supplying 2 Territories (Bypass Graft or Native Artery, Either 2 Separate Vessels or Sequential Graft Supplying 2 Territories) LAD Plus Other Territory								
38. ■ Low-risk findings on noninvasive testing	M (5)	M (4)	M (6)	M (4)	A (7)	M (5)	A (7)	M (6)
39. ■ Intermediate- or high-risk findings on noninvasive testing	M (6)	M (5)	A (7)	M (6)	A (7)	A (7)	A (8)	A (8)
Stenoses Supplying 3 Territories (Bypass Graft or Native Arteries, Separate Vessels, Sequential Grafts, or Combination Thereof) LAD Plus 2 Other Territories								
40. ■ Low-risk findings on noninvasive testing	M (5)	M (5)	M (6)	M (5)	M (6)	M (6)	A (7)	A (7)
41. ■ Intermediate- or high-risk findings on noninvasive testing	A (7)	A (7)	A (7)	A (7)	A (7)	A (7)	A (8)	A (8)

The number in parentheses next to the rating reflects the median score for that indication. *FFR measurements with appropriate normal ranges may be substituted for FFR. A indicates appropriate; AA, antianginal; BB, beta blockers; CABG, coronary artery bypass graft; FFR, fractional flow reserve; IFR, instant wave-free ratio; IMA, internal mammary artery; LAD, left anterior descending coronary artery; M, may be appropriate; PCI, percutaneous coronary intervention; and R, rarely appropriate.

Table 3.1

TABLE 3.1 Stable Ischemic Heart Disease Undergoing Procedures for Which Coronary Revascularization May Be Considered

Indication		Asymptomatic Not on AA Therapy or With AA Therapy				Ischemic Symptoms			
		PCI		CABG		On 1 AA Drug (BB Preferred)		On ≥2 AA Drugs	
		PCI	CABG	PCI	CABG	PCI	CABG	PCI	CABG
Patients Undergoing Renal Transplantation, No Diabetes									
42.	One- or two-vessel CAD, no proximal LAD involvement, with low-risk noninvasive findings	M (2)	M (2)	M (4)	M (2)	M (0)	M (4)	A (7)	M (5)
43.	One- or two-vessel CAD, no proximal LAD involvement, with intermediate- or high-risk noninvasive findings	M (5)	M (4)	M (6)	M (6)	A (7)	M (5)	A (8)	M (6)
44.	One- or two-vessel CAD, including proximal LAD, with low-risk noninvasive findings	M (3)	M (4)	M (6)	M (3)	M (0)	M (6)	A (8)	A (7)
45.	One- or two-vessel CAD, including proximal LAD, with intermediate- or high-risk noninvasive findings	M (5)	M (6)	A (7)	A (7)	A (7)	A (7)	A (8)	A (8)
46.	Left main and/or three-vessel disease, with intermediate- or high-risk noninvasive findings (e.g., SYNTAX ≤22)	M (6)	A (7)	A (7)	A (7)	A (7)	A (7)	A (8)	A (8)
47.	Left main and/or three-vessel disease, with intermediate- or high-risk noninvasive findings (e.g., SYNTAX >22)	M (3)	A (7)	M (6)	A (8)	M (0)	A (8)	M (6)	A (8)
Patients Undergoing Renal Transplantation, Diabetes Present									
48.	One- or two-vessel CAD, no proximal LAD involvement, with low-risk noninvasive findings	M (3)	M (3)	M (4)	M (3)	M (3)	M (4)	A (7)	M (5)
49.	One- or two-vessel CAD, no proximal LAD involvement, with intermediate- or high-risk noninvasive findings	M (5)	M (4)	M (5)	M (4)	M (6)	M (3)	A (7)	A (7)
50.	One- or two-vessel CAD, including proximal LAD, with low-risk noninvasive findings	M (5)	M (5)	M (6)	M (6)	M (3)	A (7)	A (7)	A (7)
51.	One- or two-vessel CAD, including proximal LAD, with intermediate- or high-risk noninvasive findings	M (6)	M (6)	M (6)	A (7)	M (6)	A (7)	A (7)	A (8)
52.	Left main and/or three-vessel disease, with intermediate- or high-risk noninvasive findings (e.g., SYNTAX ≤22)	M (6)	A (8)	M (6)	A (8)	M (6)	A (8)	A (7)	A (8)
53.	Left main and/or three-vessel disease, with intermediate- or high-risk noninvasive findings (e.g., SYNTAX >22)	M (3)	A (8)	M (5)	A (8)	M (3)	A (8)	M (5)	A (8)
Patients Who Will Undergo a Pericardial Valve Procedure (TAVR, MitraClip, Others)									
54.	One- or two-vessel CAD, no proximal LAD involvement, with low-risk noninvasive findings	M (4)		M (4)		M (4)		A (8)	
55.	One- or two-vessel CAD, no proximal LAD involvement, with intermediate- or high-risk noninvasive findings	A (7)		A (7)		A (7)		A (8)	
56.	One- or two-vessel CAD, including proximal LAD, with low-risk noninvasive findings	M (3)		M (5)		A (7)		A (8)	
57.	One- or two-vessel CAD, including proximal LAD, with intermediate- or high-risk noninvasive findings	A (7)		A (7)		A (8)		A (8)	
58.	Left main and/or three-vessel disease, with intermediate- or high-risk noninvasive findings (e.g., SYNTAX ≤22)	A (8)		A (8)		A (8)		A (8)	
59.	Left main and/or three-vessel disease, with intermediate- or high-risk noninvasive findings (e.g., SYNTAX >22)	A (7)		A (7)		A (8)		A (8)	

The number in parentheses next to the letter reflects the median score for that indication.
 A indicates appropriate; M, inappropriate; M, likely beneficial; EMS, coronary artery bypass graft; CAD, coronary artery disease; LAD, left anterior descending coronary artery; M, may be appropriate; PCI, percutaneous coronary intervention; R, rarely appropriate; SYNTAX, Syntax between PCI with Taxis and Coronary Surgery trial, and TAVR, transcatheter aortic valve replacement.

“It is expected that services performed for “appropriate” or “may be appropriate” indications will receive reimbursement.”

Patel et al:JACC 69:2212-41, 2017

Consequences

1. Arteries that need stenting are not done.
2. Doctors are unfairly accused of unnecessary stenting

Consequences of All This Nonsense

- Patients with obvious culprit lesions are not treated.
- FFRs of .81 in patients with typical symptoms are not treated.
- Optimal medical treatment condemns patients to a lifetime of poly-pharmacy along with poly side effects.
- Reimbursement will be tied to AUC.
- Peer review, credentialing and medical legal implications (In USA)
 - Whereas, only complicated cases came to peer review in the past,
 - Now the majority of peer reviews are done for questions of appropriateness.
 - As in Salem* of old envious 😏 start peer review inquiries by suggesting that a 😊 is doing inappropriate cases.

*Refers to 18th century witch trials in Salem
Massachusetts WORTH GOOGLEING

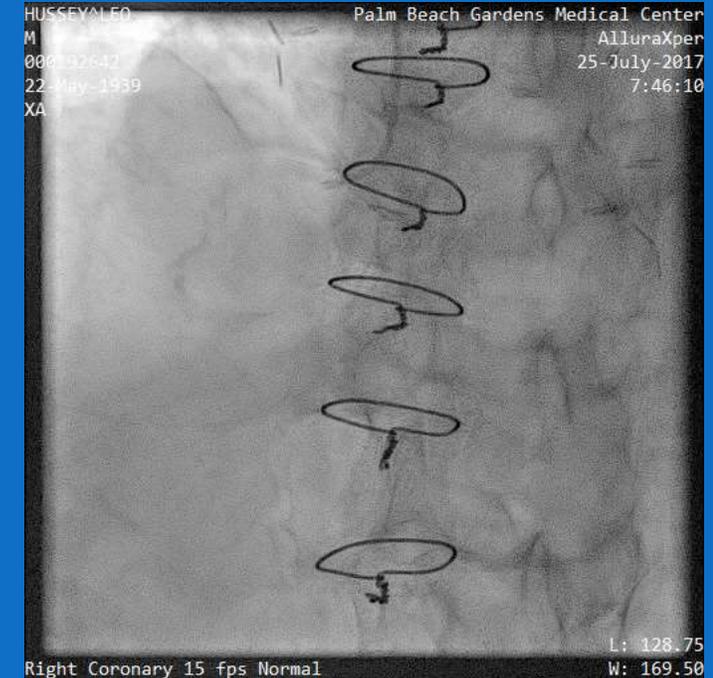
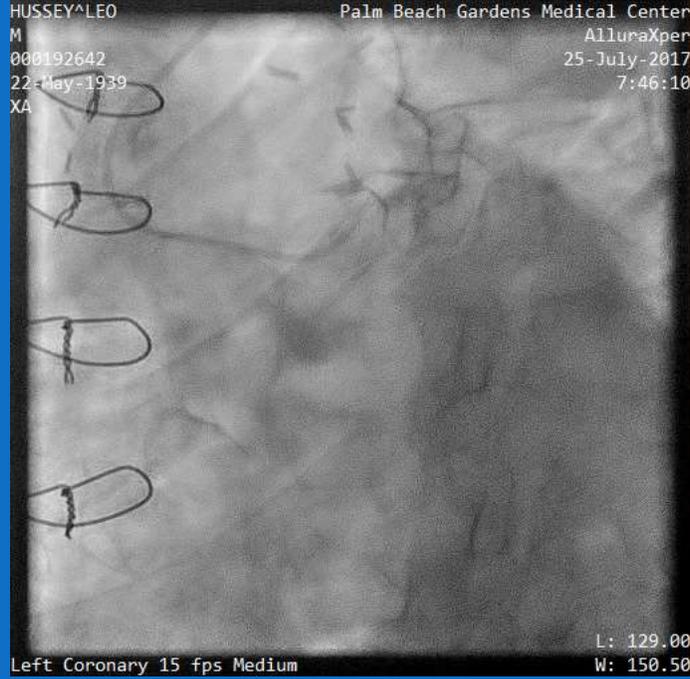
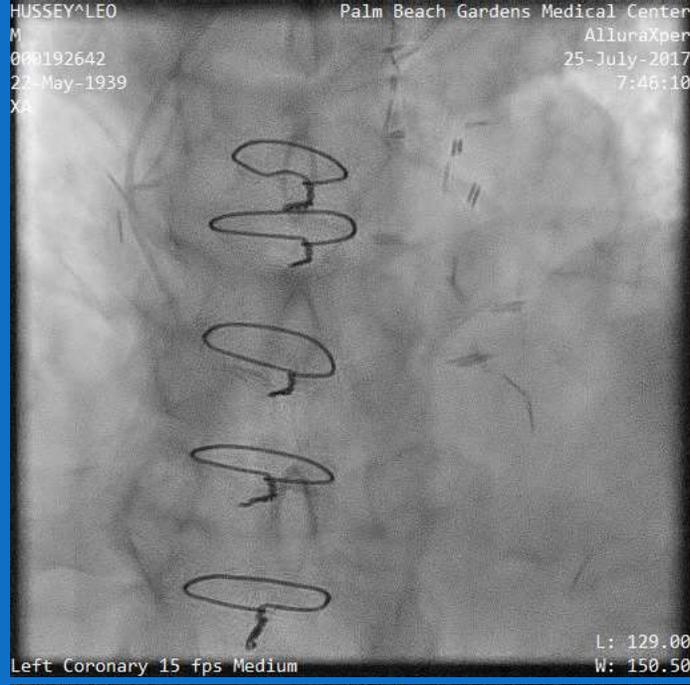
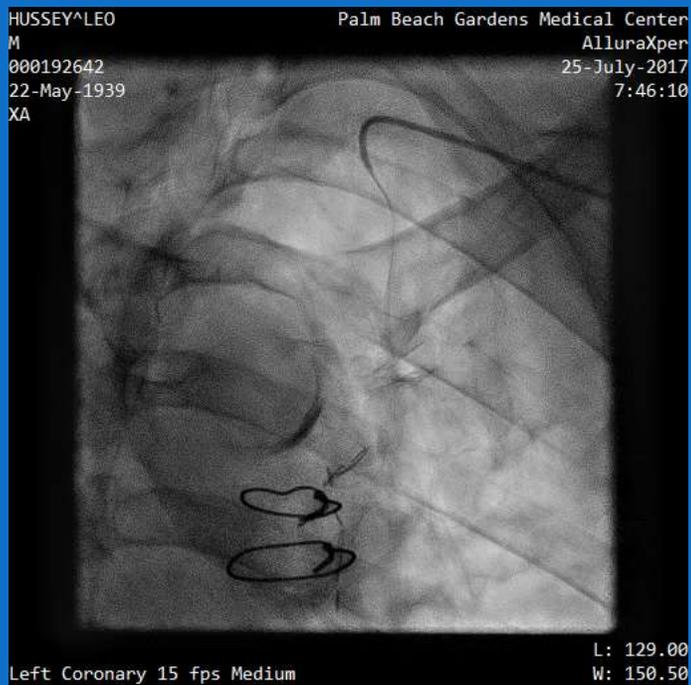
Mark Midei Can't Get a Job Taking Blood Pressure At A Walmart - Forbes

I reviewed a sampling of his cases in conjunction with one of the lawsuits. They looked a lot like a sampling of my cases including some intermediate lesions that five doctors would grade five different ways.

I assure you that every one of us do “inappropriate” cases on a regular basis. They may appear to be inappropriate by angio, but are very much appropriate in the clinical setting.

LH 79 Y.O. MAN with Previous CABG

- New onset typical AP
- Cardiac Cath
 - 100% prox LAD
 - 75+% prox OMB
 - Normal RCA
 - Normal LV
 - Patent SVG to diagonal and prox LAD
 - Patent LIMA to LAD
 - Occluded SVT to OMB
 - Managed medically
- Drove 200 miles for a second opinion.



Angios

- I recommended PCI of LCX.
- Performed successfully by referring MD
- Patient is asymptomatic

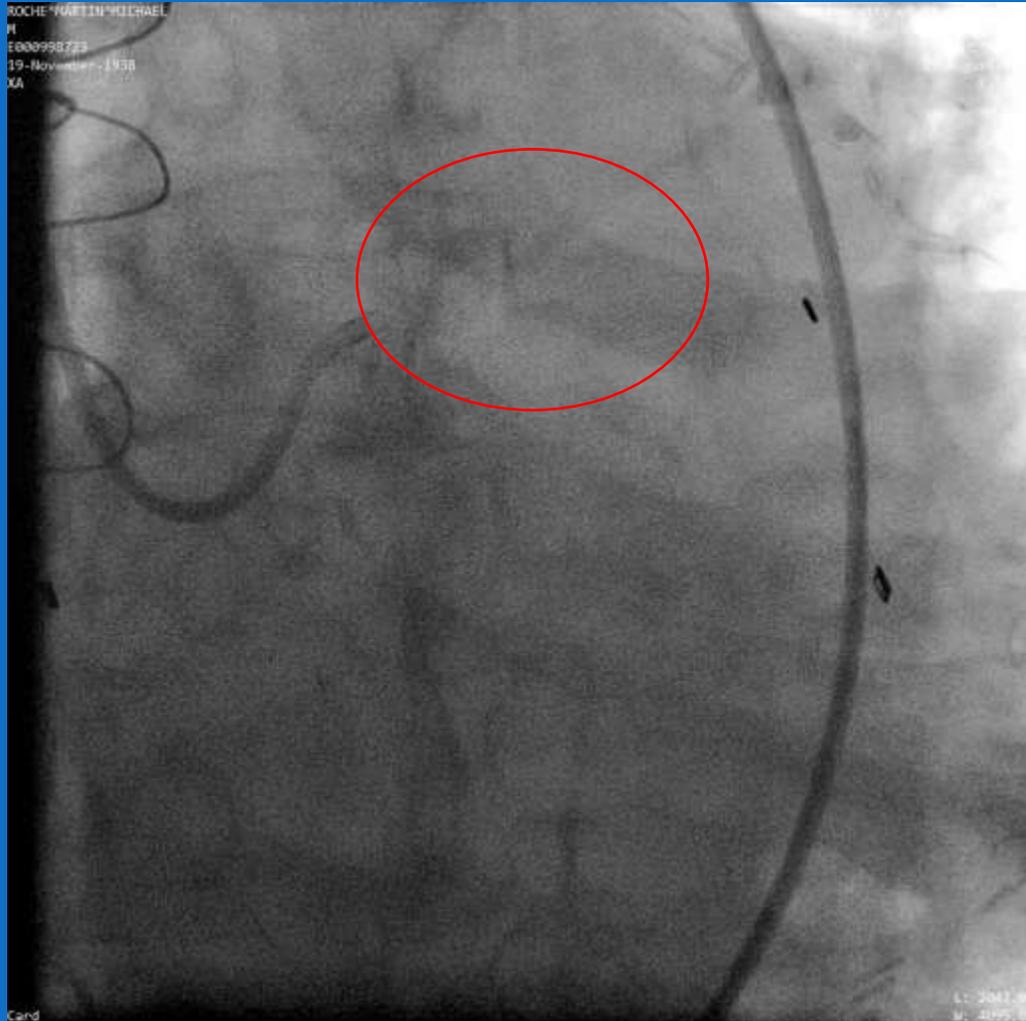
79 Y.O. MD S/P CABG X 2, PCI X3

- Recurrent AP class 3 one year post PCI of LCX.
- Strongly positive nuclear stress test with reversible abnormality of entire lateral and posterolateral segments.
- Ejection fraction ca 35%
- Calcific Aortic Stenosis with AVA 0.7cm²
- 50-75% stenosis of distal LMT, prox LCX and origin LAD.
- Patent LIMA to LAD and RIMA to RPDA
- Occluded SVG to OMB
- **On treadmill, patient could walk only two minutes at 1.5mph on level. Stopped due to angina.**

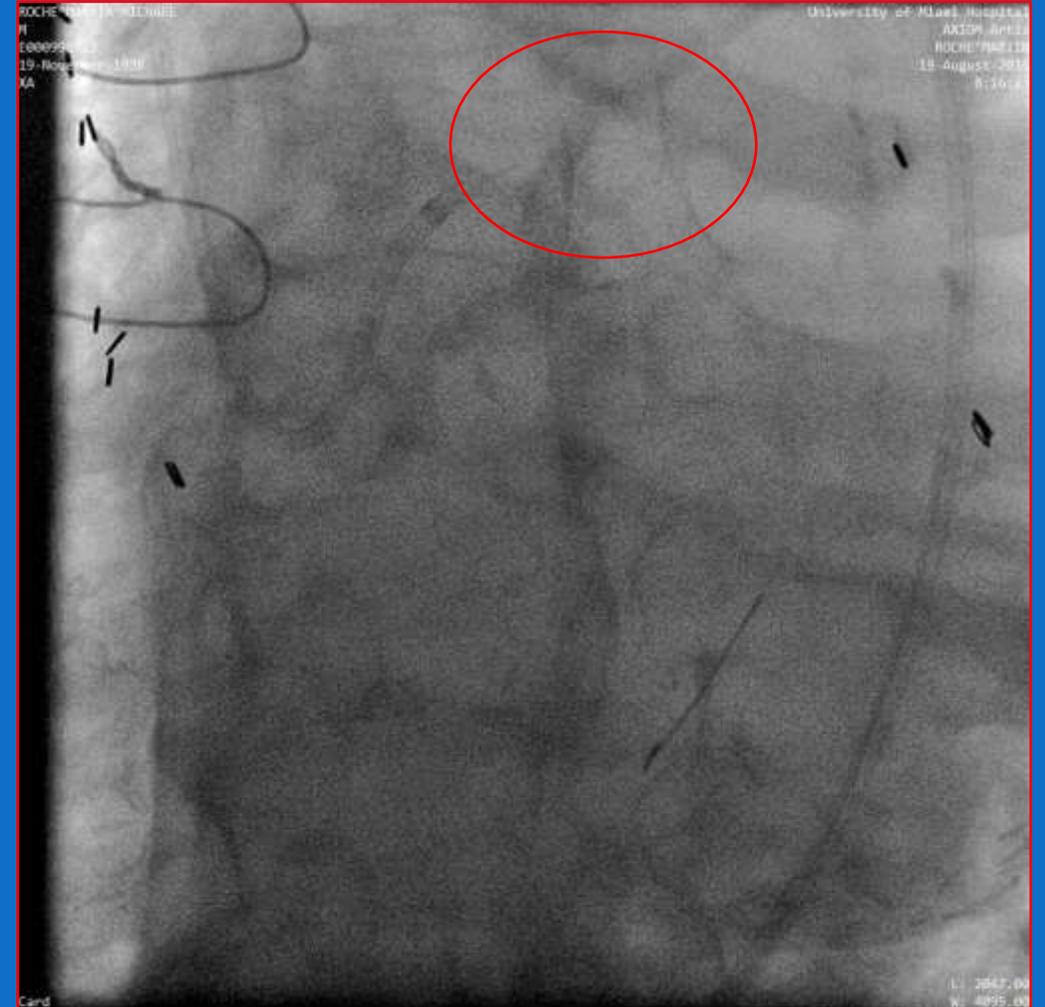
LCX PCI 8/19/2016 - LMT NOT TREATED

Symptoms class 3 pre-PCI; class 1-2 post PCI

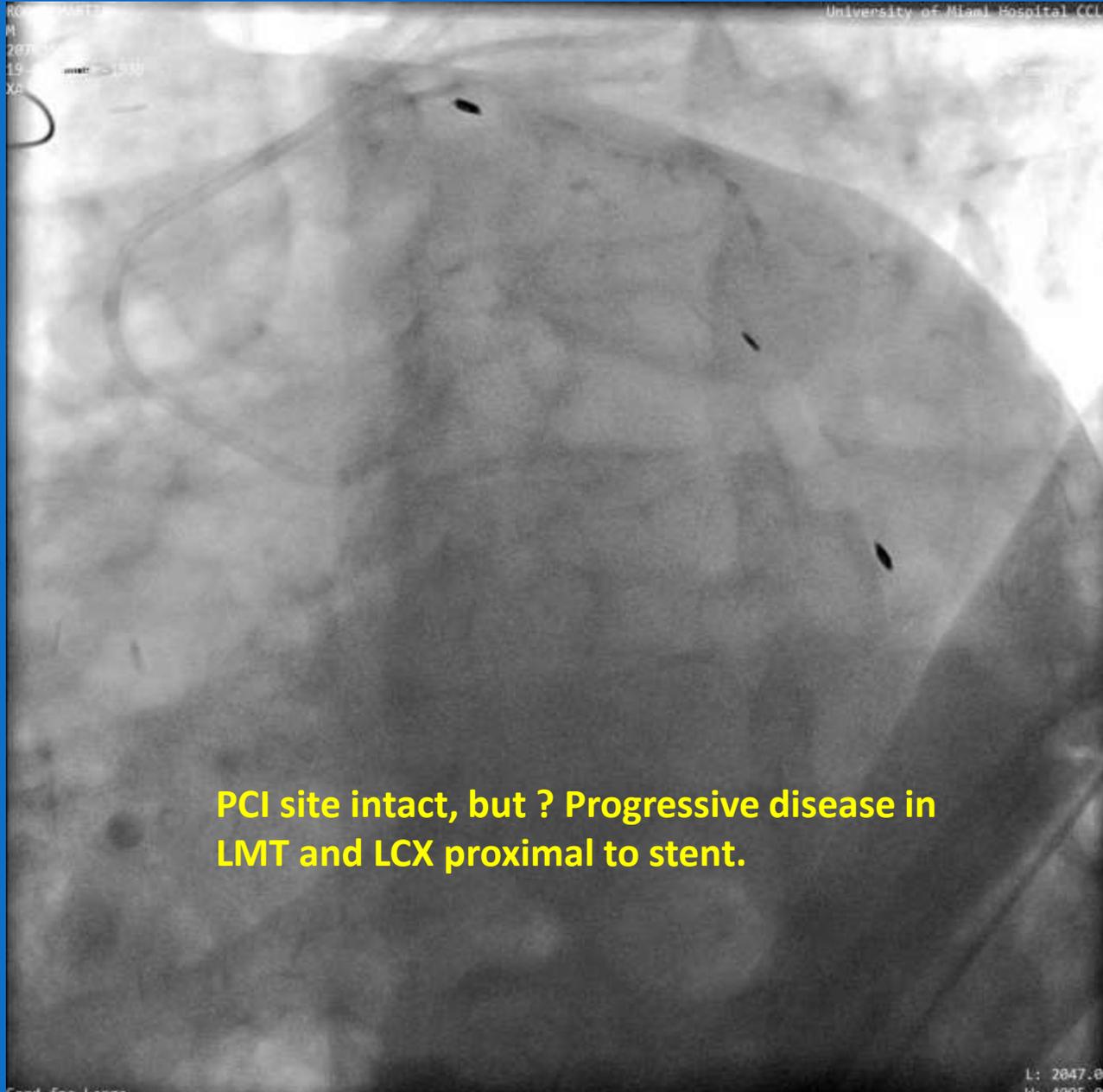
Pre PCI



Post PCI



Sixteen Months Later – Recurrent Angina



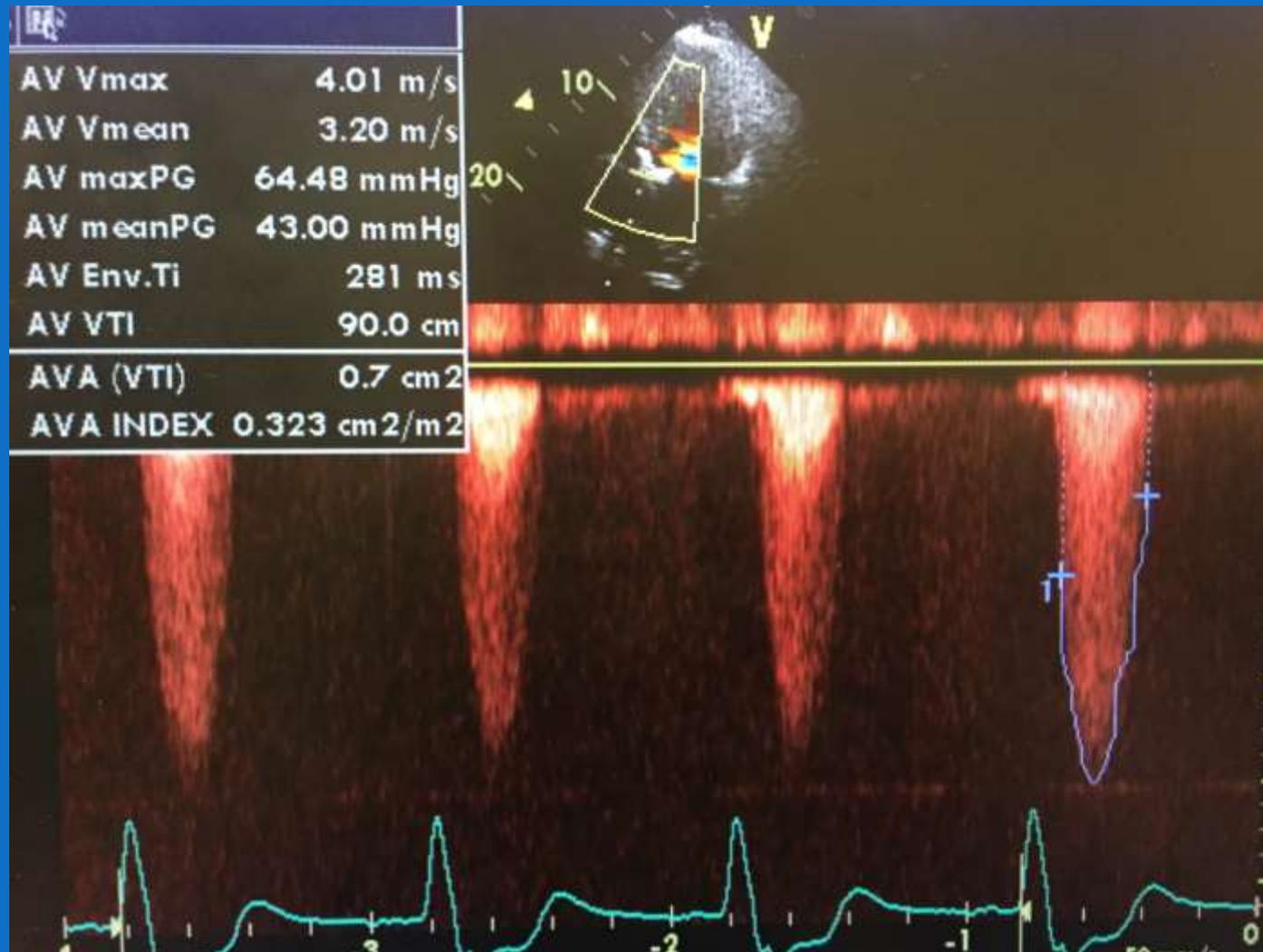
PCI site intact, but ? Progressive disease in LMT and LCX proximal to stent.



Ao Valve Doppler

Mean Gradient
43 mm HG

AVA 0.7 cm²



Decision Time

- How severe is LMT disease?
- Has it progressed during 16 months?
- FFR is .81; should we treat LMT in face of a “normal” FFR?
- Is a reliable history of severe and disabling AP more important than a “normal” FFR?
- Should we fix Aortic valve prior to LMT PCI?



Six Months Later

- Patient continued with disabling angina.
- Finally, someone agreed to fix LMT despite a “normal” FFR.
- No more angina post PCI

Post PCI



Civil War

- As Interventional Cardiologists, we are engaged in a great civil war, testing whether PCI can endure greed, envy, bureaucracy and various other foibles of humankind.
- This year we celebrate the birth of an amazing method and to remember the amazing man who invented it.
- But in a larger sense, the amazing men – many of whom are in this room – who have perfected, simplified and disseminated the procedure have honored Andreas Grüntzig far above our poor power to add or detract.
- We can best honor the man by answering those who want to limit our work, and assuring mankind that this procedure that has helped so many of our patients, shall survive the onslaughts of 😞.



Barry D. Rutherford

A Brief History of Angioplasty: Evolution of an Art

Barry D. Rutherford MD • TCT AP 2016

A large graphic on the screen features a central, larger portrait of Barry D. Rutherford. Surrounding this central portrait is a grid of approximately 30 smaller circular portraits of other individuals, likely pioneers in the field of angioplasty. The portraits are arranged in a roughly rectangular pattern, with some overlapping.

"We Stand on the Shoulders of Giants"

spiration