8th CHALLENGES in CARDIOLOGY

July 2018
06th, 07th
Palace Hotel Monte Real

Coronary physiology reappraised by an Interventional Cardiologist

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Serviço de Cardiologia – Hospital Prof. Doutor Fernando Fonseca, Amadora

Potential conflicts of interest

8th CHALLENGES in CARDIOLOGY

Speaker's name: Sergio Bravo Baptista

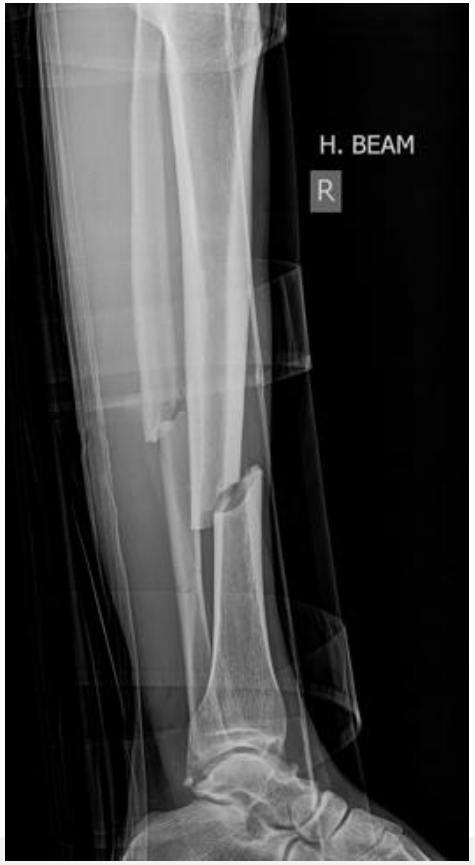
I have the following potential conflicts of interest to report:

Receipt of grants or research supports:	Abbott (St. Jude Medical) Cordis Medtronic Phillips (Volcano Corp)
Receipt of honoraria or consultation fees:	Boston Scientific Abbott (St. Jude Medical) Opsens Medical

Just try to imagine that I'm an Orthopaedic Surgeon…

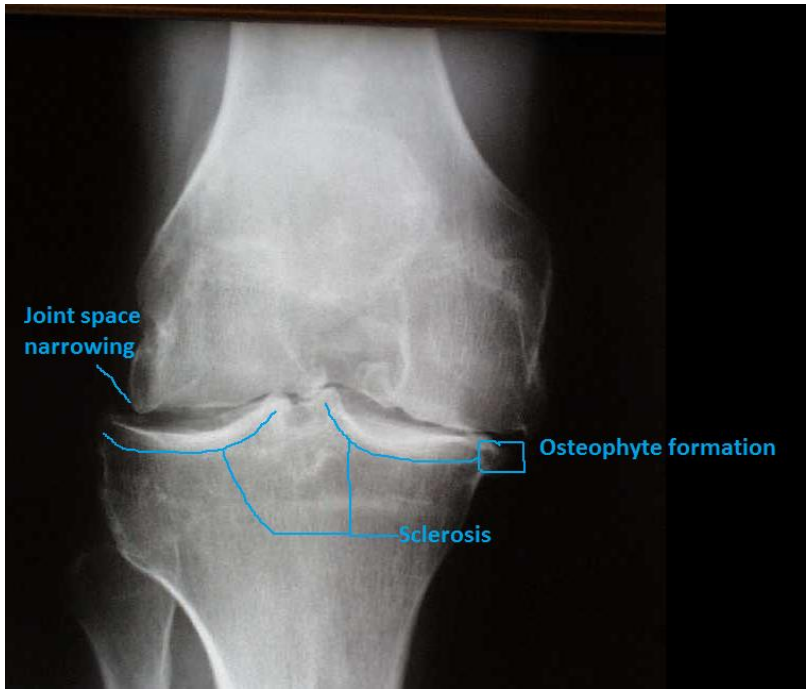
Patient: You
Event: Ski accident

Right limb: fracture



Surgery

Left limb: Moderate knee arthritis

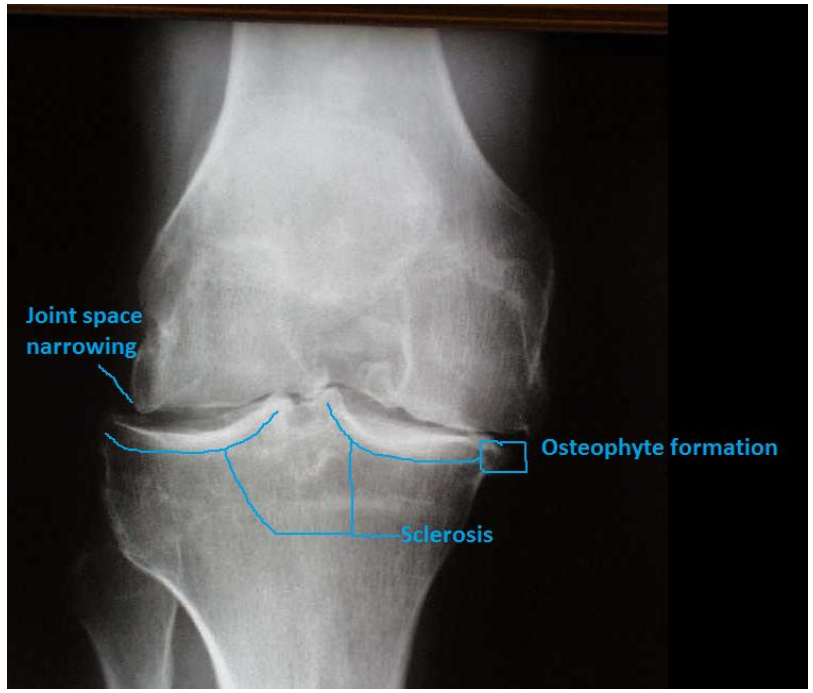


You **NEVER** had complaints on this joint!

Just try to imagine that I'm an Orthopaedic Surgeon…

Patient: You
Event: Ski accident

Left limb: Moderate knee arthritis



You **NEVER** had complaints on this joint!

You: Is there a risk in doing the knee surgery?

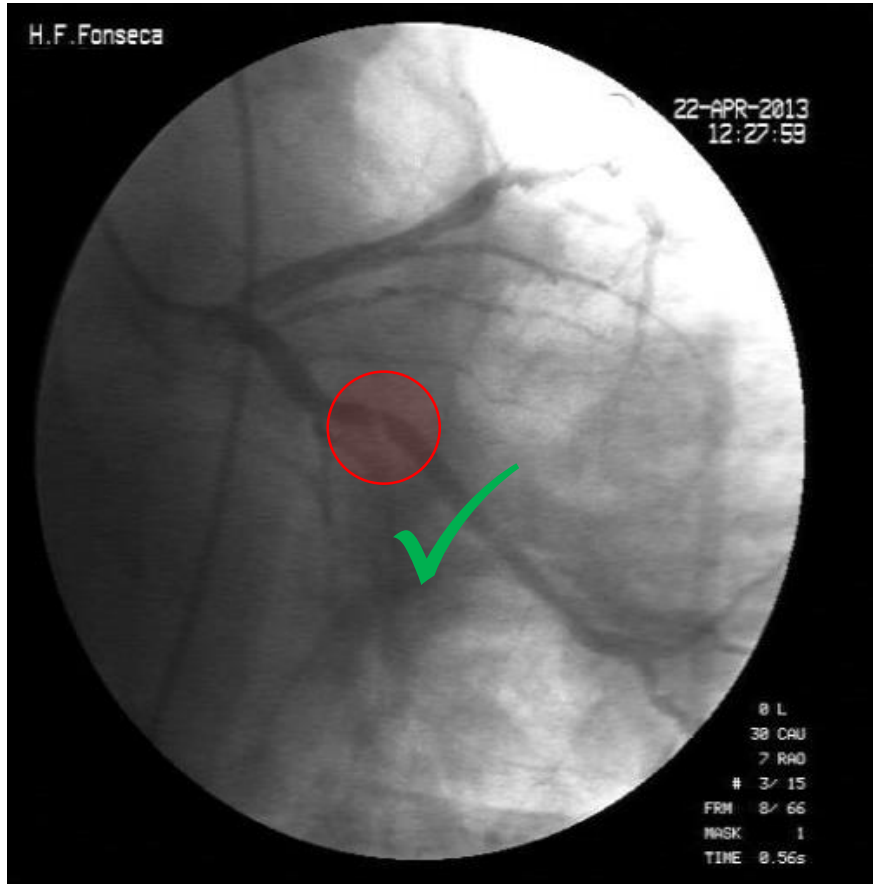
You: If I decide not to go for surgery, is there a risk of a severe event (like a fracture)?

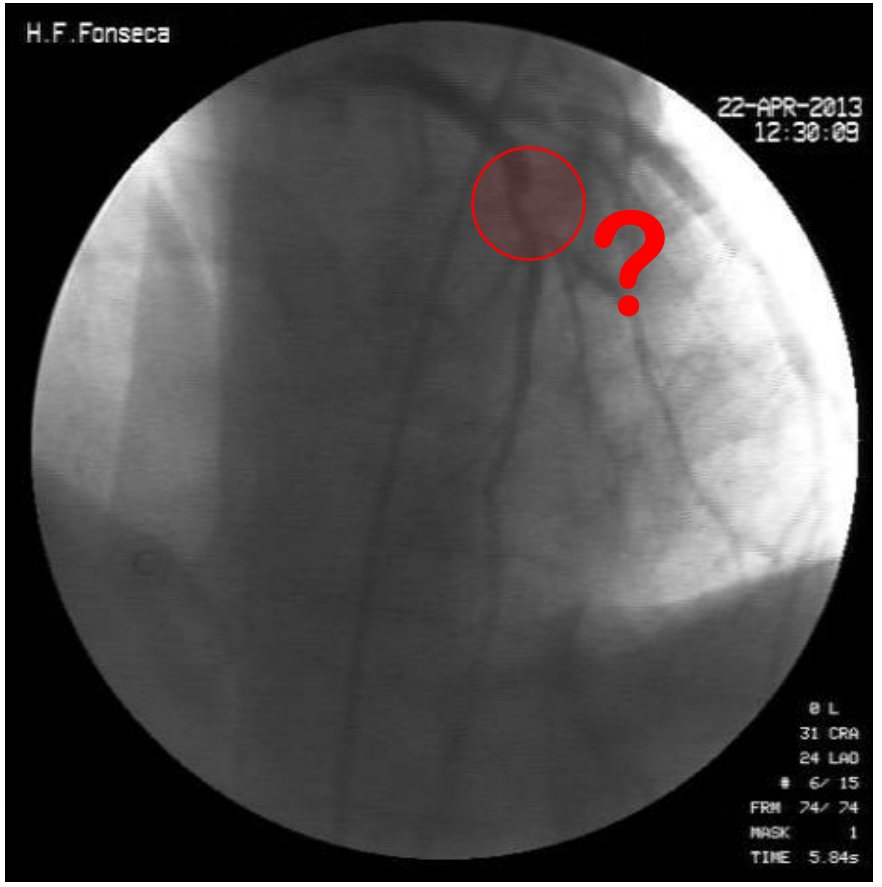
You: If I decide not to go for surgery, will the disease progress?

You: Will the surgery definitively solve my problem?

Revascularization of “stable” lesions

52y male
Smoker, Hypertension, Dislipidemia, Type 2 Diabetes
NSTEMI (TnI max 16 ng/dl) ; Echo: LVEF 50%, lateral hipoquinesia





Revascularization of “stable” lesions

8th CHALLENGES in CARDIOLOGY

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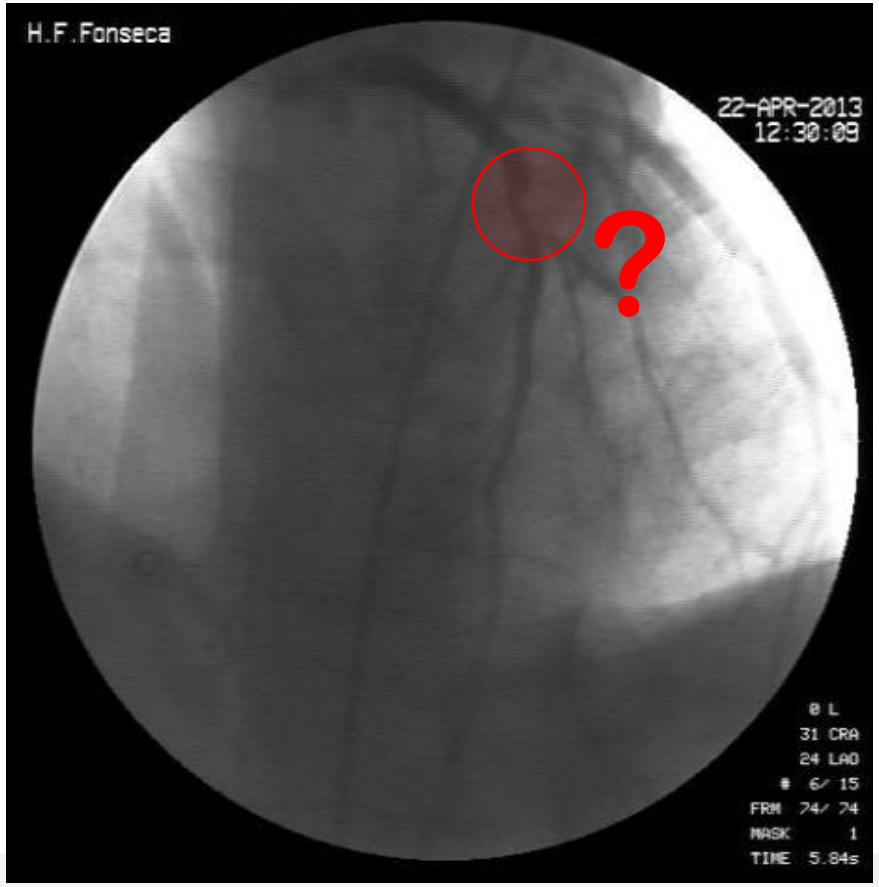


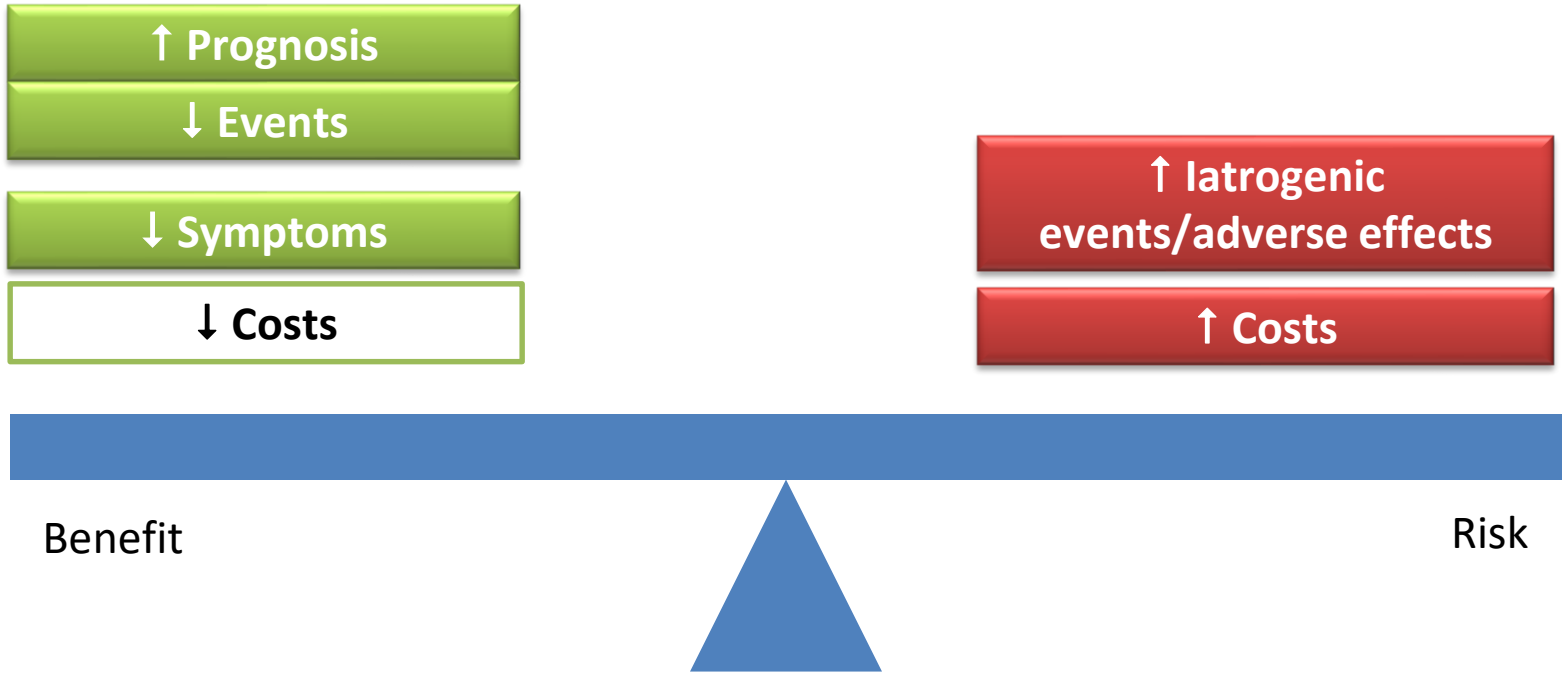
Q: Is there a risk in doing the PCI?

Q: If patient (…) decides not to go for PCI, is there a risk of a severe event (like a MI)?

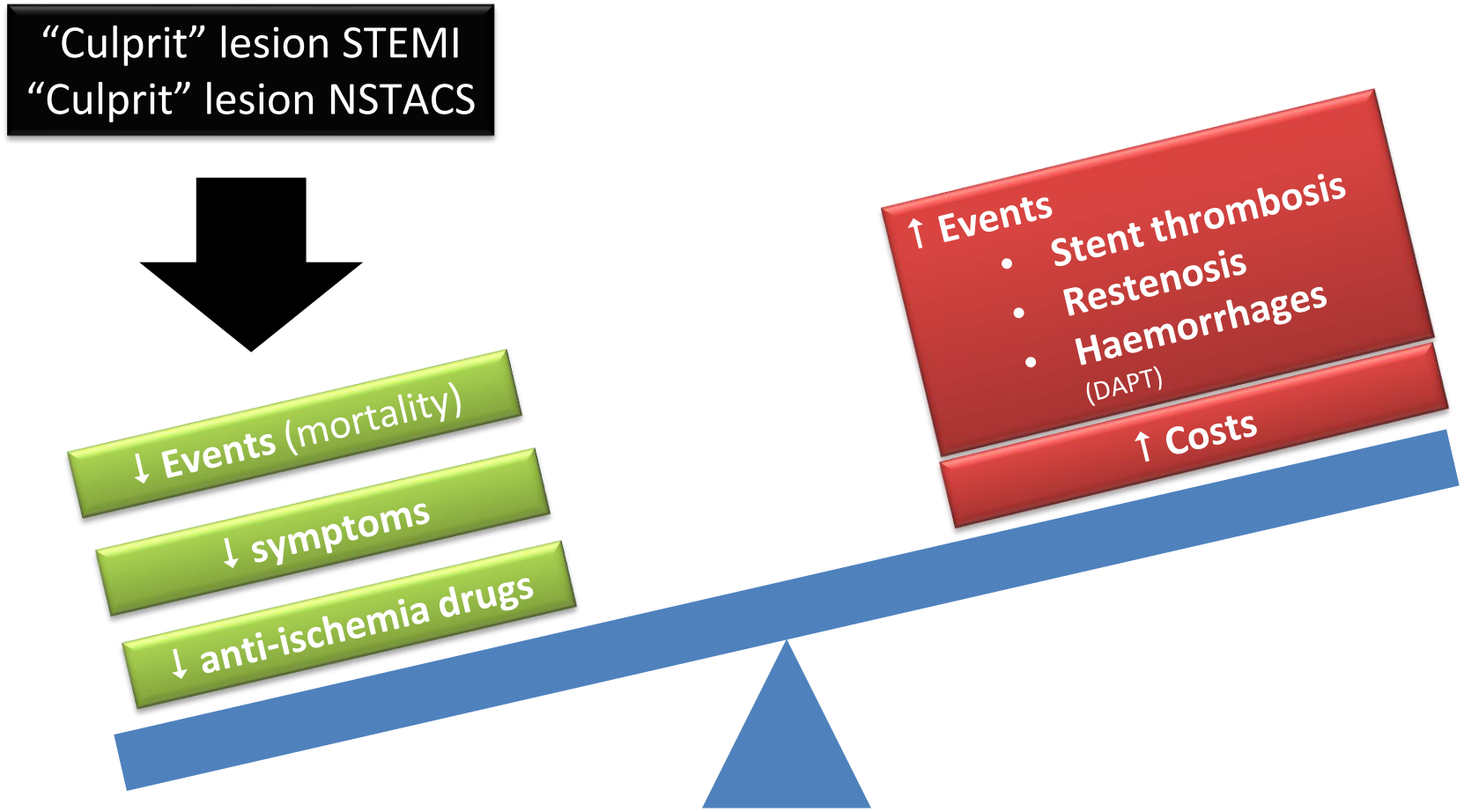
Q: If patient (…) decides not to go for PCI, will the disease progress?

Q: Will the PCI definitively solve the patient’s problem?

Risk-benefit ratio in medical procedures



Risk-benefit ratio: coronary revascularization



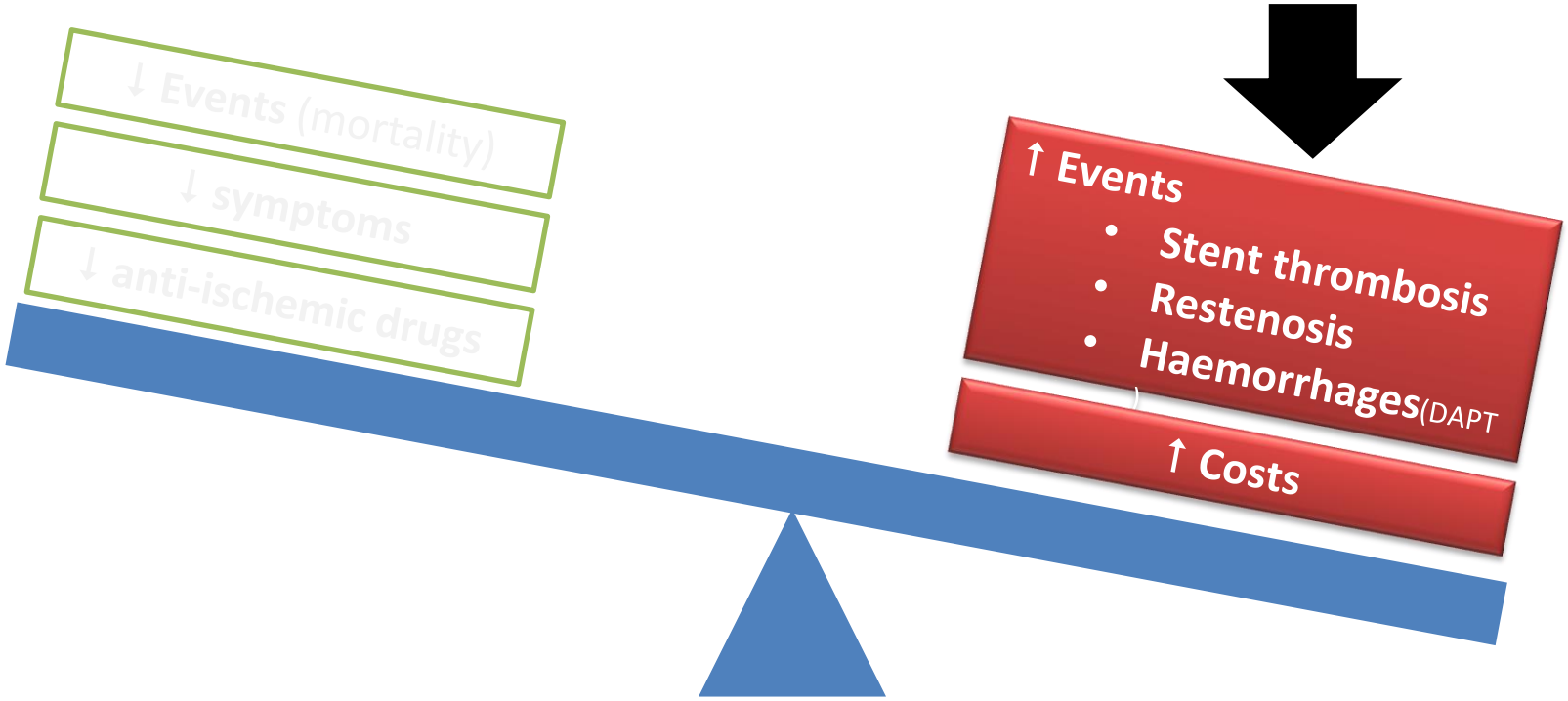
Risk-benefit ratio: coronary revascularization

"non-culprit" lesions in ACS patients (STEMI or NSTACS)
Lesions in patients with stable angina
WITH DOCUMENTED ISCHEMIA

Risk-benefit ratio: coronary revascularization

"non-culprit" lesions in ACS patients (STEMI or NSTACS)
Lesions in patients with stable angina

WITHOUT DOCUMENTED ISCHEMIA



Indications for Revascularization
European Guidelines 2014

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Prognostic and symptoms indications for coronary revascularization (PCI or CABG)

	Subset of CAD by anatomy	Class	Level
For prognosis	Left main > 50%*	I	A
	Any proximal LAD > 50%*	I	A
	2VD or 3VD with impaired LV function*	I	B
	Proven large area of ischaemia (> 10% LV)	I	B
	Single remaining patent vessel > 50% stenosis*	I	C
	1VD without proximal LAD and without > 10% ischaemia	III	A

	Subset of CAD by anatomy	Class	Level
For symptoms	Any stenosis > 50% with limiting angina or angina equivalent, unresponsive to OMT	I	A
	Dyspnoea/CHF and > 10% LV ischaemia/viability supplied by > 50% stenotic artery	IIa	B
	No limiting symptoms with OMT	III	C

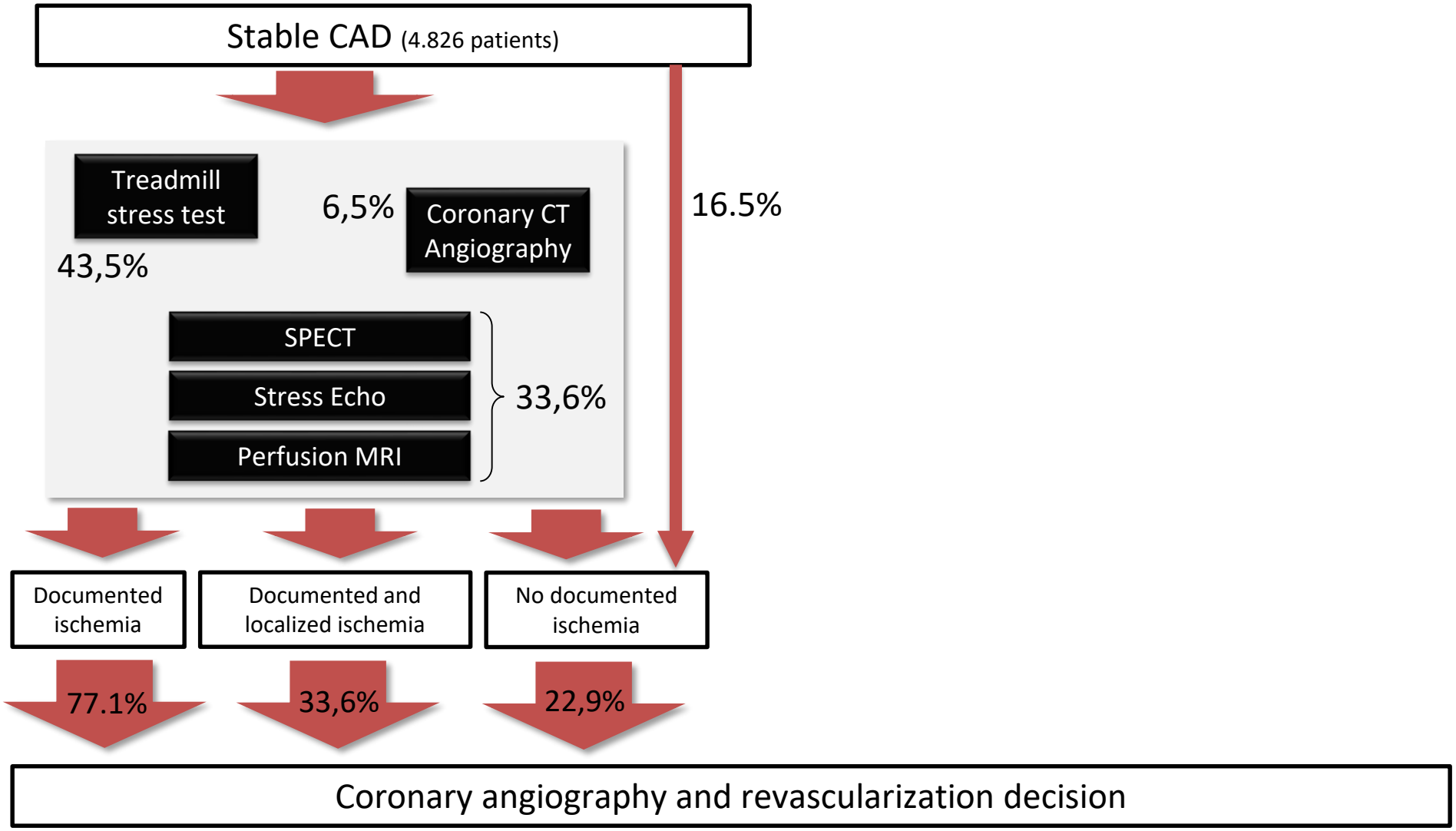
* With documented ischemia or FFR ≤0.80 for lesions 50–90%.

EUROPEAN SOCIETY OF CARDIOLOGY®

EACTS European Association For Cardio-Thoracic Surgery

ESC/EACTS 2014 Guidelines on myocardial revascularization

Diagnostic path of patients submitted to invasive coronary angiography for suspicion of CAD



Faustino M, Baptista S et al. Oral Presentation ESC 2014, Barcelona (joint collaboration H.Gaia, H.S.Cruz, Hosp. Fernando Fonseca)

Diagnostic path of patients submitted to invasive coronary angiography for suspicion of CAD

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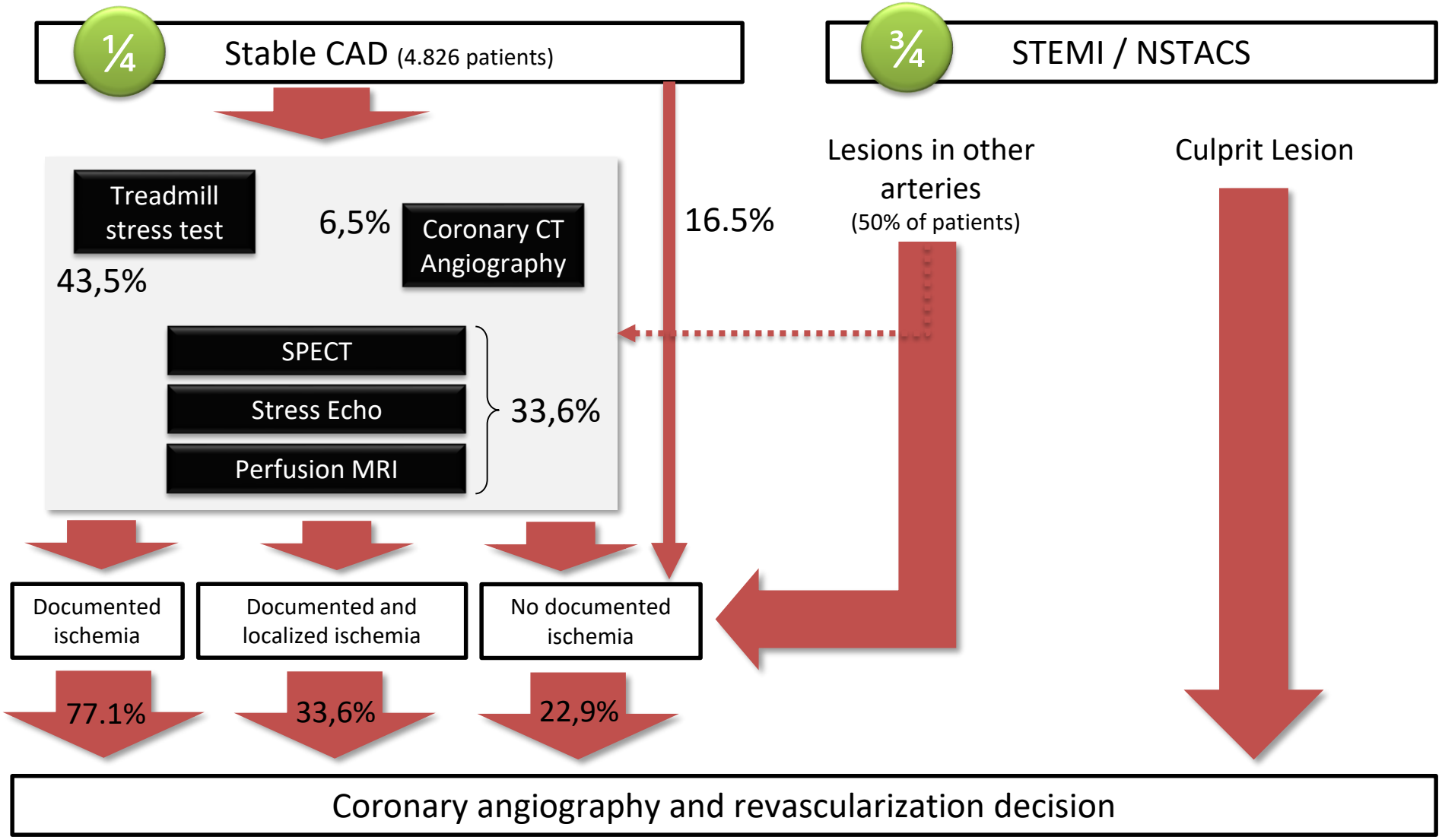

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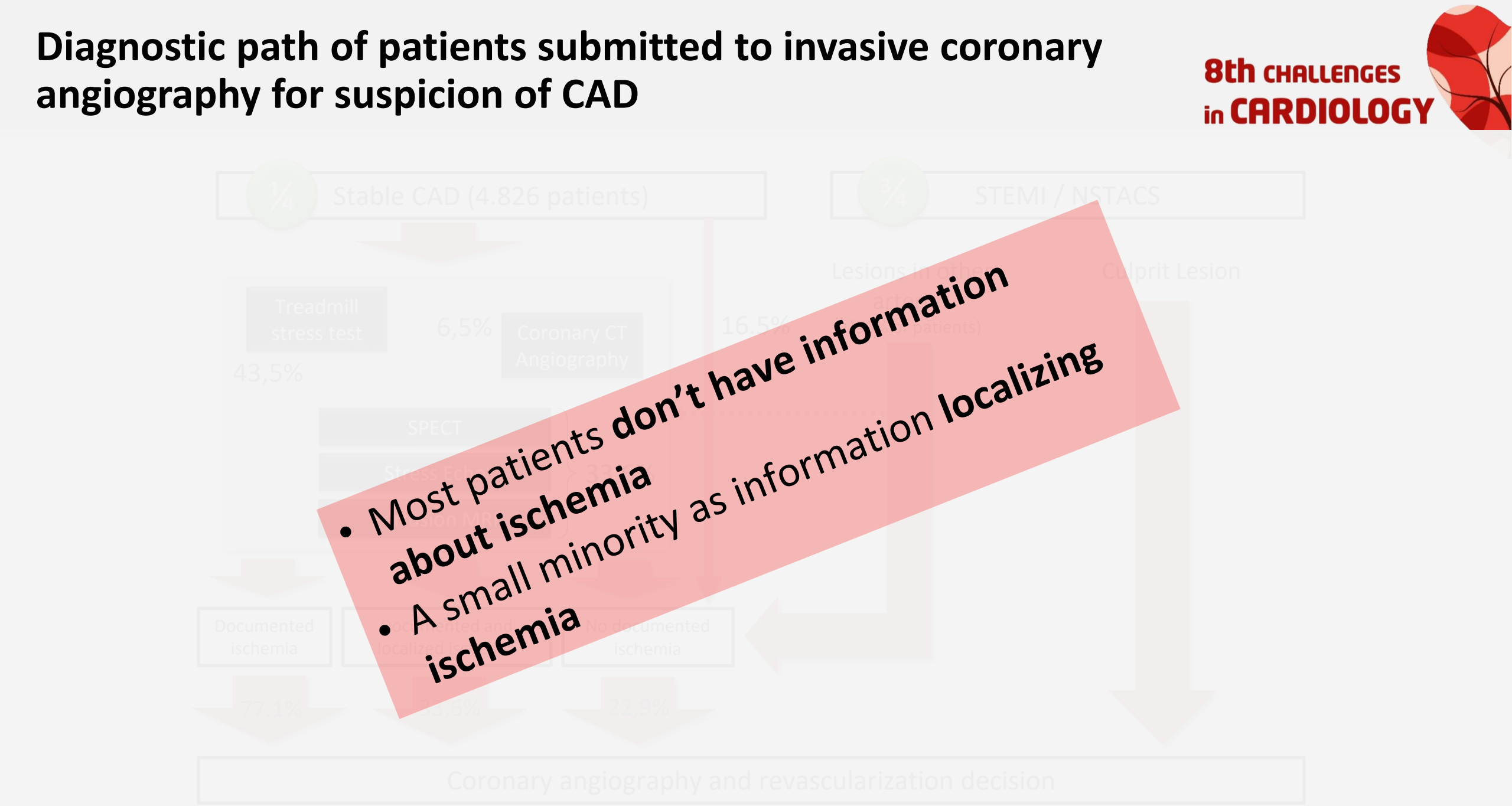

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Take-Home messages

1. **Most patients don’t have information about (localizing) ischemia at the time of the angiography**

Why do we Stent?

Increase coronary flow

↓

Reduce ischemia

↓

Relieve angina

(reduce events?)

Coronary physiology in identifying ischemic lesions

Increase coronary flow

↓

Reduce ischemia

↓

Relieve angina

(reduce events?)

→ Controlled variable in the coronary circulation

↓

Main determinant of myocardial ischemia

↓

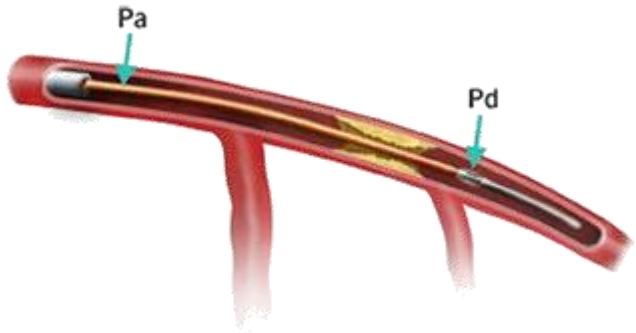
Hard to measure

Pressure = Flow x Resistance

BUT, if resistance is stable (constant)

Pressure ≈ Flow

→



Coronary physiology in identifying ischemic lesions

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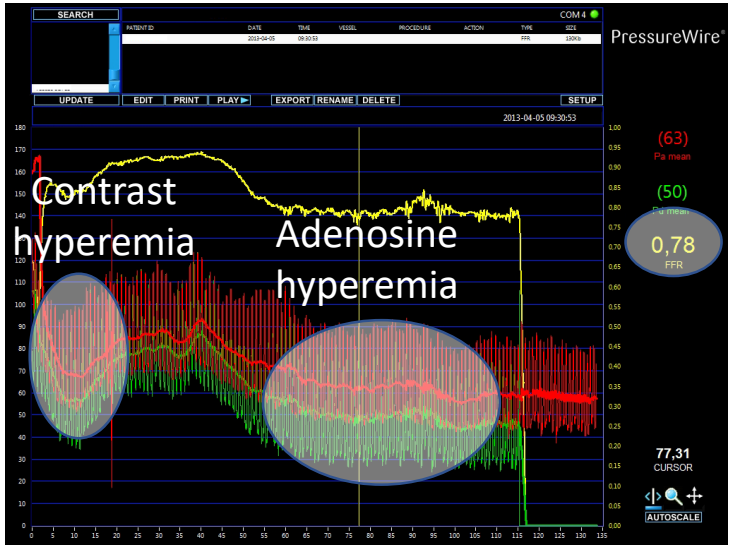
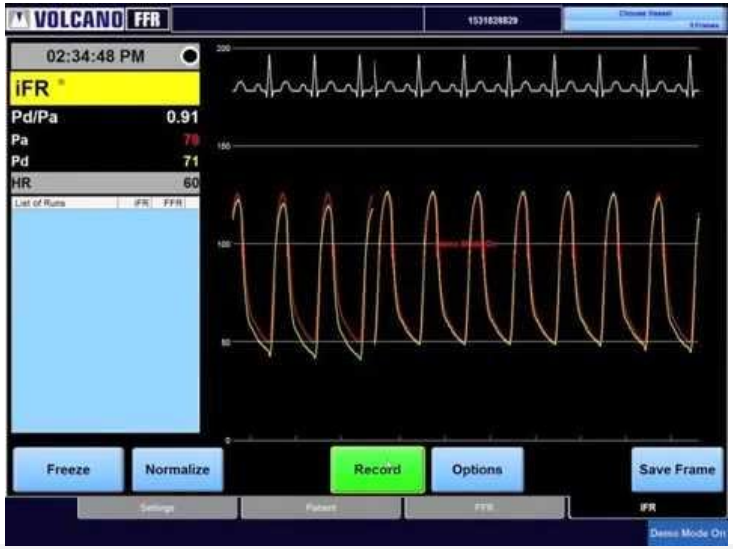
Hyperemic Indexes

- **Fractional Flow Reserve (FFR)**
  % of flow reduction across a lesion under maximal hyperemia
  Pressure=Flow x Resistance (hyperemia needed to stability resistance)
- **Contrast FFR (cFFR)**
  FFR under contrast hyperemia



Resting Indexes

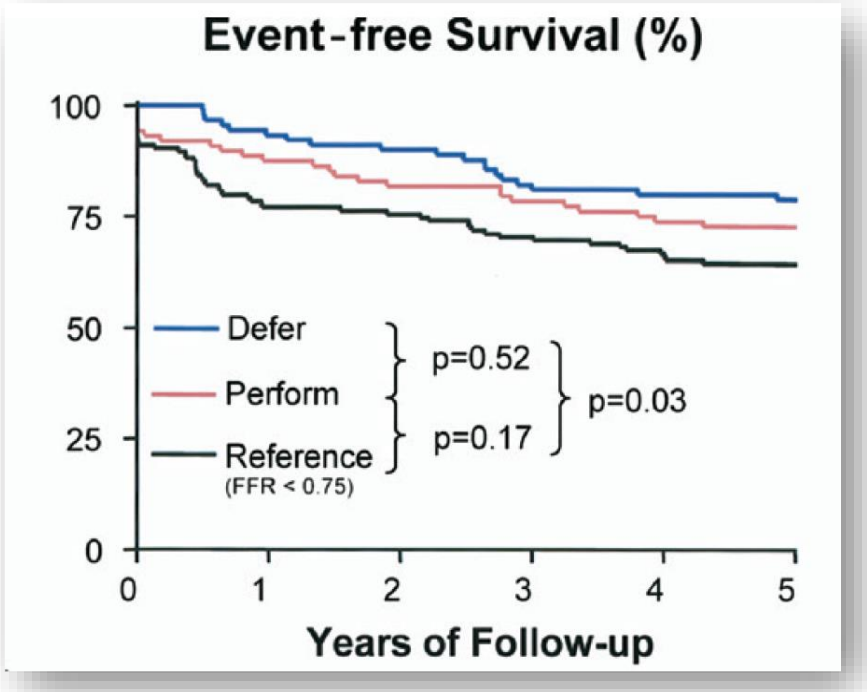
- **Instantaneous wave-free ratio (iFR)**
  Pressure gradient across the lesion measured in the diastolic wave-free period (stable resistance)
- **Resting Pd/Pa**
  Resting pressure gradient across the lesion (all cycle)

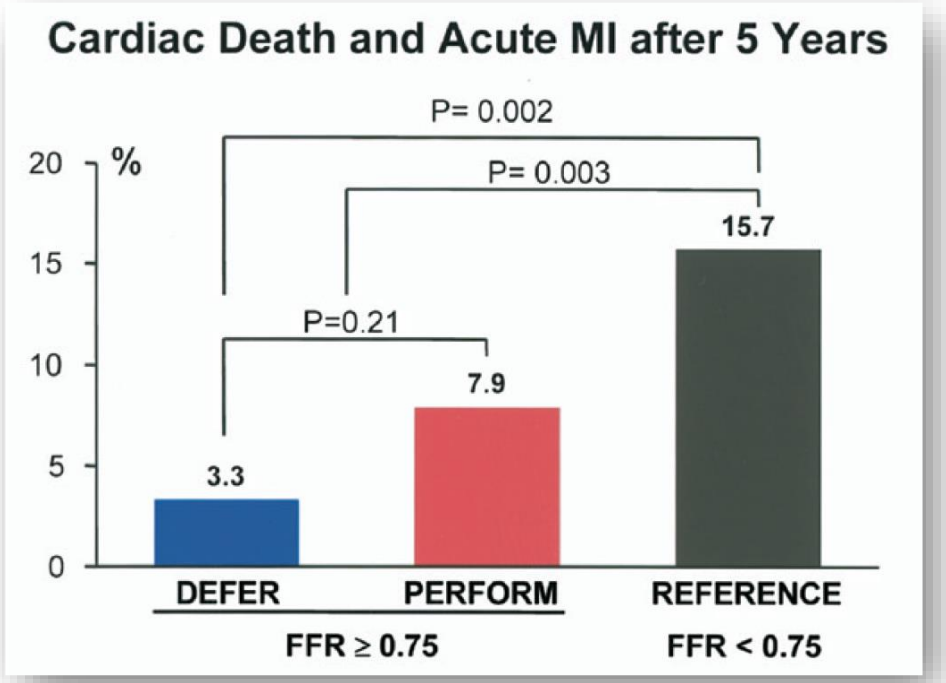


Clinical evidence with physiology indexes

- **Is it safe to use FFR to defer PCI in stable non-ischemic lesions?**

DEFER Trial
(FFR ≤ 0,75)





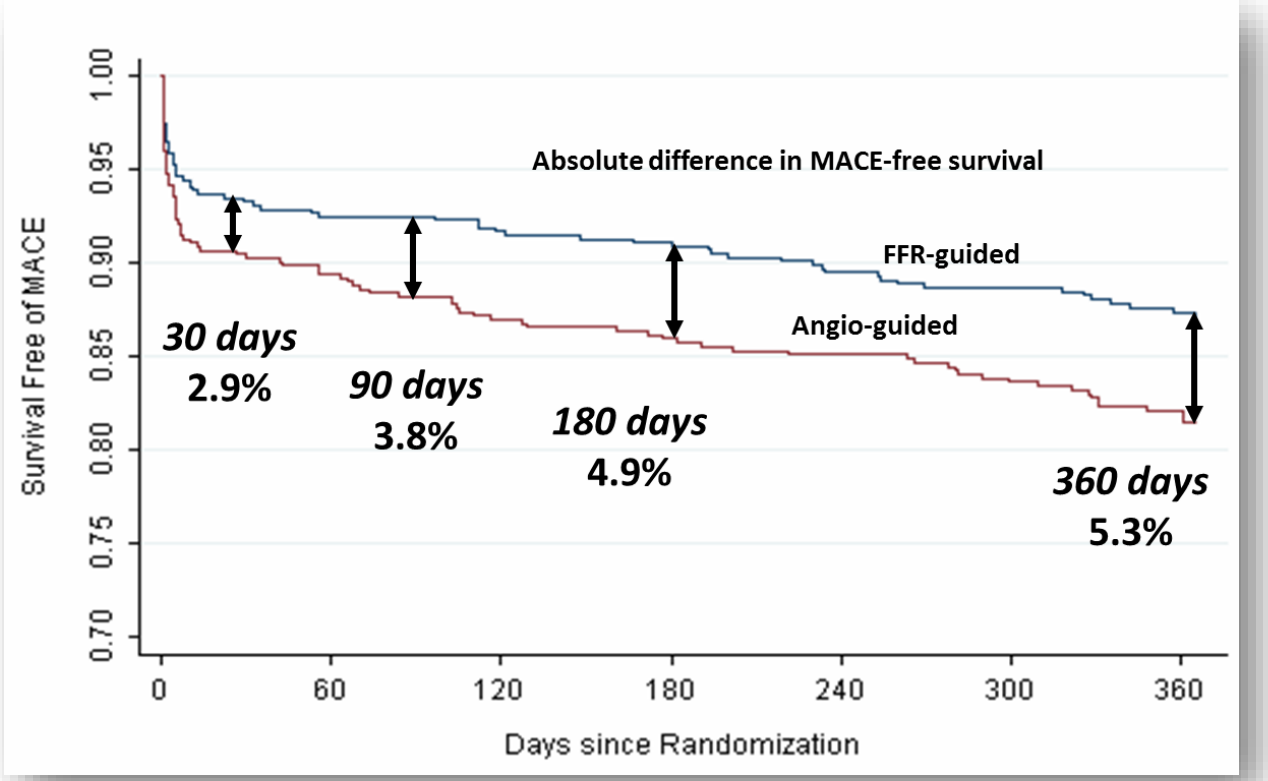
J Am Coll Cardiol 2007;49:2105–11

Clinical evidence with physiology indexes

✓ **Is it safe to use FFR to defer PCI in stable non-ischemic lesions?**

- **Is it better to guide revascularization based on FFR/iFR, as compared to Angio?**

FAME Trial
(FFR ≤ 0,80)

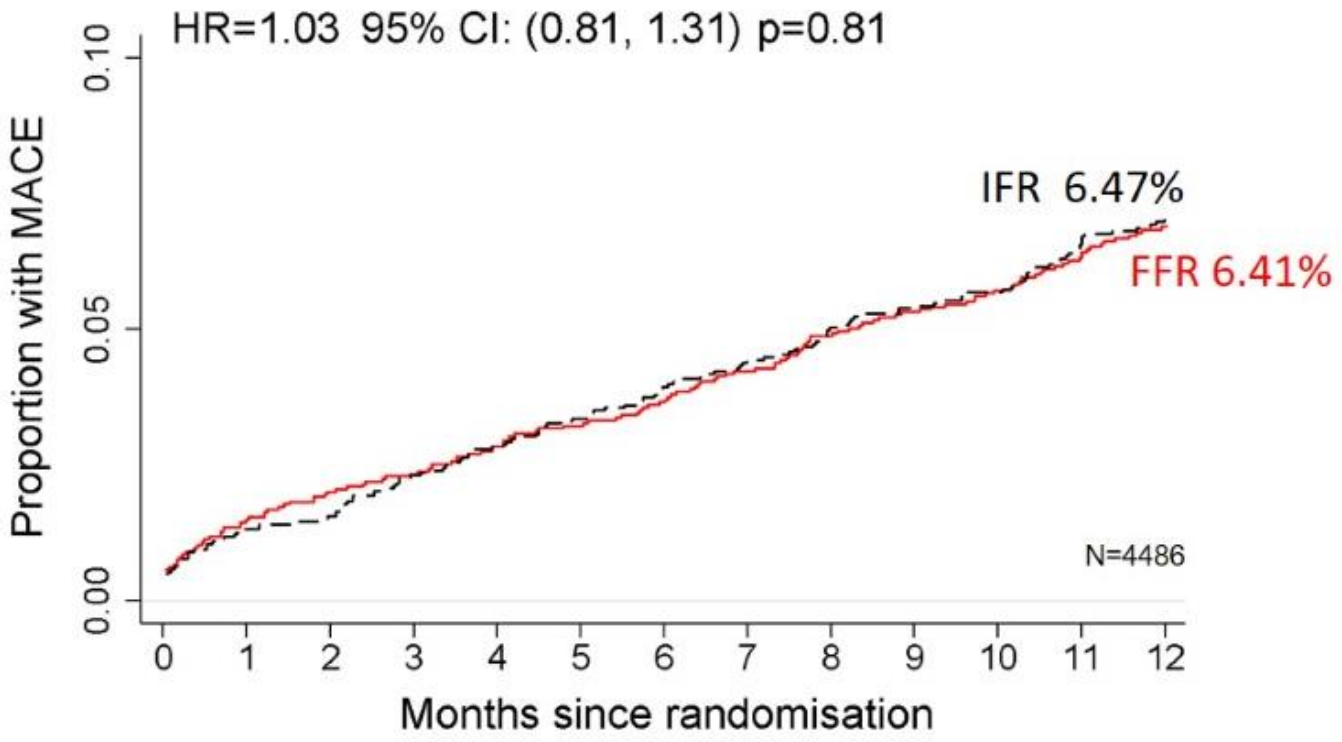


N Engl J Med 2009;360:213-24

Clinical evidence with physiology indexes

- ✓ **Is it safe to use FFR to defer PCI in stable non-ischemic lesions?**
- **Is it better to guide revascularization based on FFR/iFR, as compared to Angio?**

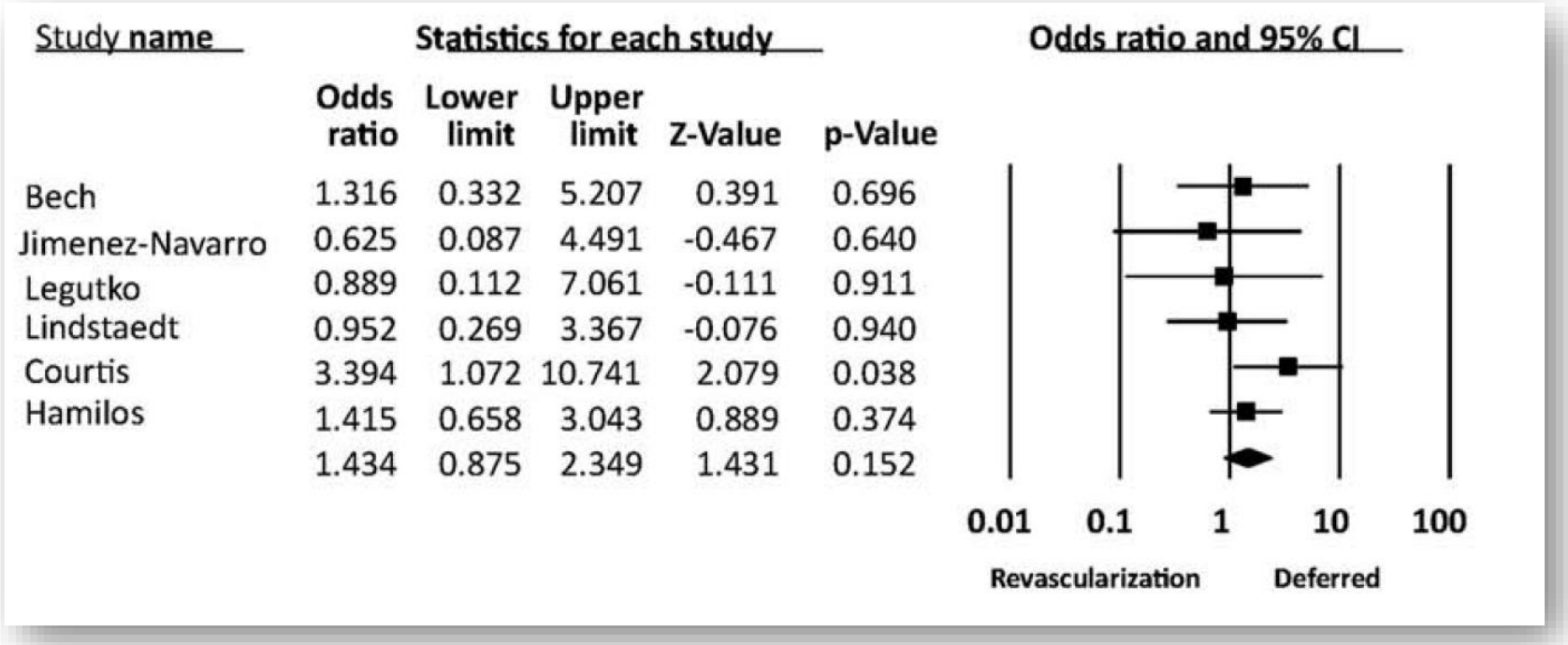
DEFINE-FLAIR Trial
SwedeHEART Trial



N Engl J Med 2017; 376:1824-1834; N Engl J Med 2017; 376:1813-1823

Clinical evidence with physiology indexes

- ✓ Is it safe to use FFR to defer PCI in stable non-ischemic lesions?
- ✓ Is it better to guide revascularization based on FFR/iFR, as compared to Angio?
- Can FFR be used in angiographic sub-sets?
  - Left Main?



Study name	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Bech	1.316	0.332	5.207	0.391	0.696
Jimenez-Navarro	0.625	0.087	4.491	-0.467	0.640
Legutko	0.889	0.112	7.061	-0.111	0.911
Lindstaedt	0.952	0.269	3.367	-0.076	0.940
Courtis	3.394	1.072	10.741	2.079	0.038
Hamilos	1.415	0.658	3.043	0.889	0.374
	1.434	0.875	2.349	1.431	0.152

Catheterization and Cardiovascular Interventions 86:12–18 (2015)

Clinical evidence with physiology indexes

- ✓ Is it safe to use FFR to defer PCI in st
- ✓ Is it better to guide revascularizatio
- Can FFR be used in angiographic su
  - ✓ Left Main?
  - Bifurcation lesions?

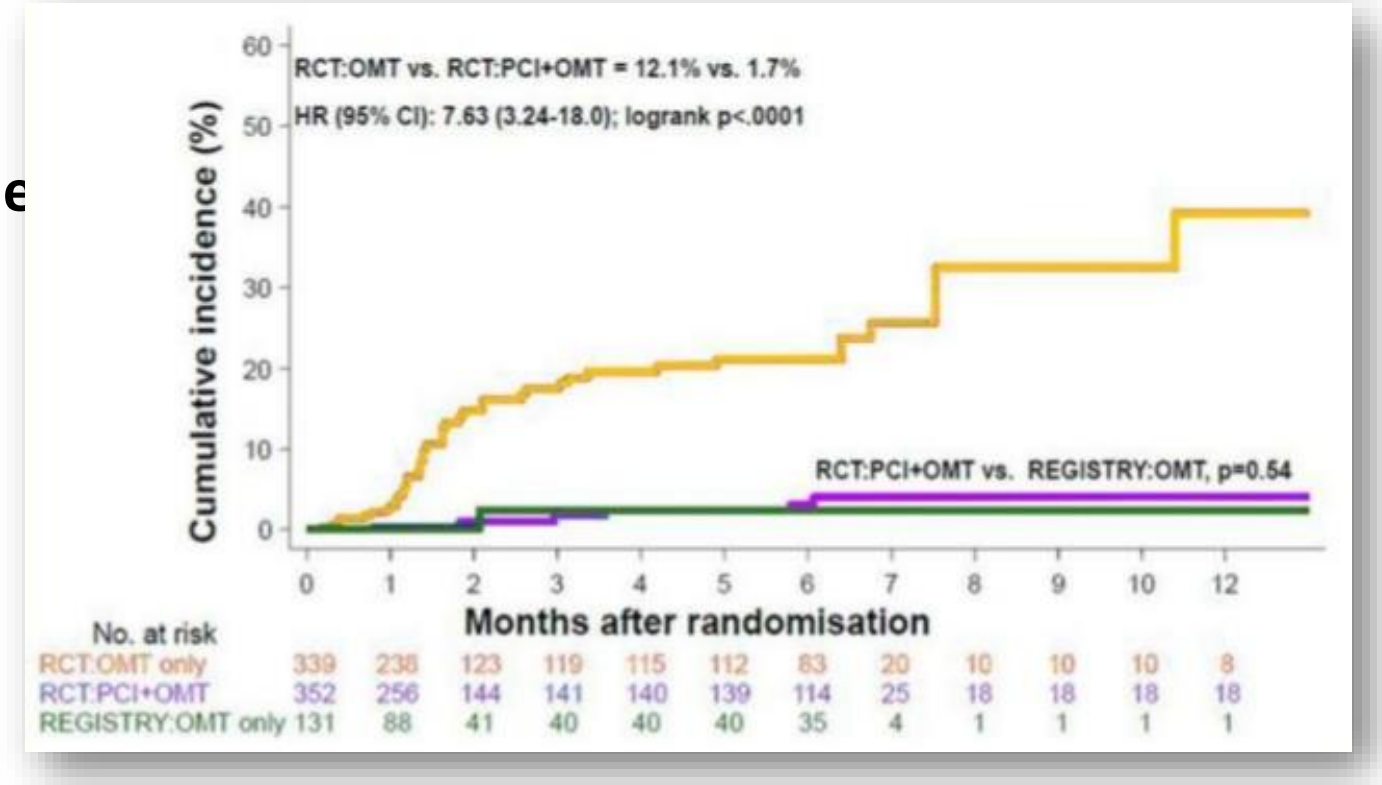
Author and year	Study population	Main results
Discrepancy between angiographic and functional severity in side branch lesions		
Koo BK et al 2005	94 jailed SB QCA vs. FFR	1. Negative correlation between %DS and FFR (r=-0.41, p<0.001). 2. No lesion with <75% stenosis had FFR <0.75. 3. Among 73 lesions with ≥75% stenosis, 20 lesions (27%) had FFR <0.75.
Bellenger et al 2007	14 jailed SB QCA vs. FFR	1. No correlation between %DS and FFR (r=-0.54, p=0.053). 2. Among 9/14 (64%) lesions with %DS >50%, 3 lesions (21%) were FFR <0.75.
Koo BK et al 2010	77 bifurcation lesions MB IVUS and SB FFR	1. Plaque volume index was decreased in the proximal MB after stenting (suggested "plaque shift"), but not in distal MB (suggested "carina shift"). 2. Pre-intervention %DS and MLD of downstream main vessel stenosis were independent predictors for functionally significant jailed SB.
Koh JS et al 2012	55 SB ostial lesions QCA, IVUS and FFR	1. In SB ostial lesions, there was no correlation between %DS and FFR (r=-0.190, p=0.164). 2. Negative remodelling was more frequent in SB ostial lesions than in MB ostial lesions (72.7% vs. 52.6%, p=0.046). 3. AUC of SB %DS for FFR ≤0.8 was 0.60. The PPV of %DS for FFR ≤0.8 was 38%, but NPV was 82%. 4. The PPV and NPV of IVUS MLA (1.8 mm²) or percent plaque burden (56%) to predict FFR ≤0.80 were only 50% and 44%.
Ahn JM et al 2012	230 jailed SB Dedicated bifurcation QCA vs. FFR	1. Negative correlation between %DS and FFR (r=-0.21, p=0.002). 2. Among 163 lesions with ≤50% stenosis, 22 lesions (13.5%) had FFR ≤0.80. Among 67 lesions with >50% stenosis, 19 lesions (28.4%) were functionally significant (FFR ≤0.80). 3. Pre-interventional %DS was an independent predictor for functionally significant jailed SB.
Nordic-Baltic Bifurcation III 2012	75 jailed SB Dedicated bifurcation QCA vs. FFR	1. Negative correlation between %DS and side branch FFR after PCI and at 8-month follow-up (r=−0.37, p=0.001; r=−0.57, p<0.001, respectively). 2. 24/75 patients (32%) showed >50% stenosis, while FFR <0.75 was found in only 6 patients (8%).
Ha J et al 2014	82 jailed SB MB 3D OCT vs. FFR	1. Best cut-off value of SB MLA was 2.05 mm² (AUC 0.81). 2. Diagnostic performance of MLA 2.05 mm² versus FFR <0.80: sensitivity 71.0%, specificity 75.0%, PPV 54.5%, NPV 91.5%.
Serial FFR measurement in jailed side branch		
Koo BK et al 2008	100 patients with provisional strategy Repeated SB FFR at 6-month follow-up (n=65).	1. At 6-month follow-up, there were no changes in FFR in lesions with (0.86±0.06 to 0.84±0.01, p=0.4) and without SB balloon angioplasty (0.87±0.06 to 0.89±0.07, p=0.1). 2. Binary restenosis rate was 48%; however, functional restenosis (FFR <0.75) rate was 8% (5/65). There were no changes in SB FFR during the 8-month follow-up period (0.92 to 0.91, p=0.80 in KBI group and 0.87 to 0.87, p=0.91 in no KBI group).
Nordic-Baltic Bifurcation III 2012	75 patients with provisional strategy Repeated SB FFR at 8-month follow-up (n=46)	There were no changes in SB FFR during the 8-month follow-up period (0.92 to 0.91, p=0.80 in final KBI group and 0.87 to 0.87, p=0.91 in no final KBI group)
FFR-guided PCI vs. Angio-guided PCI for jailed side branch		
Koo BK et al 2008	110 patients with provisional strategy, SB intervention when FFR <0.75. Control group: 110 patients without FFR measurements.	1. The FFR-guided group showed significantly less frequent SB intervention (30% in FFR-guided vs. 45% in angiography-guided group, p=0.03). 2. There was no difference in 9-month TVR (4.6% vs. 3.7%, p=0.7).
DKCRUSH-VI 2014	320 patients with Medina 1,1,1 or 0,1,1 bifurcation lesions. Randomly assigned to FFR-guided (FFR <0.80) or angiography-guided SB treatment.	1. Treatment of SB was less in FFR-guided group than in angiography-guided group (SB stenting: 25.9% vs. 38.1%, p=-0.01). 2. MACE (cardiac death, MI, TVR) rate at 1 year was comparable (18.1% vs. 18.1%, p=1.00). Restenosis at distal MB was more frequent in angiography-guided group than in FFR-guided group (9.2% vs. 1.2%, p=0.01).

EuroIntervention 2015;11:V59-V63

Clinical evidence with physiology indexes

- ✓ Is it safe to use FFR to defer PCI in stable non-ischemic lesions?
- ✓ Is it better to guide revascularization based on FFR/iFR, as compared to Angio?
- Can FFR be used in angiographic sub-sets?
  - ✓ Left Main?
  - ✓ Bifurcation lesions?
- Is FFR useful to treat ischemic le

FAME 2 Trial
(FFR ≤ 0,80)



N Engl J Med 2012;367:991-1001

Clinical evidence with physiology indexes

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- ✓ Is it better to guide revascularization ba
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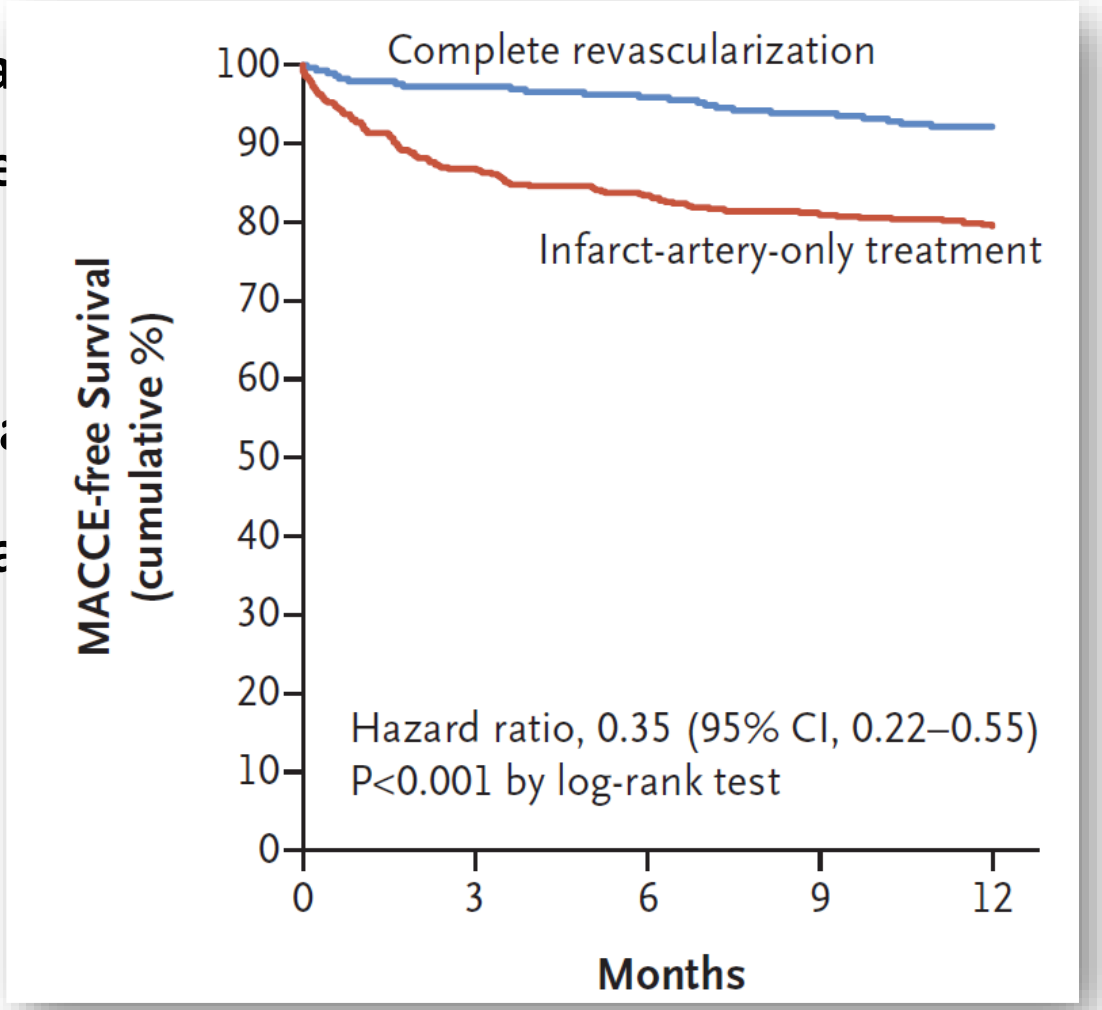
  - ✓ Left Main?
  - ✓ Bifurcation lesions?
- ✓ Is FFR useful to treat ischemic lesions ba
- Can FFR be used to guide complete reva

COMPARE-ACUTE Trial
(FFR ≤ 0,80)



Smits *et al. N Engl J Med 2017; 376:1234*

Clinical evidence with physiology indexes

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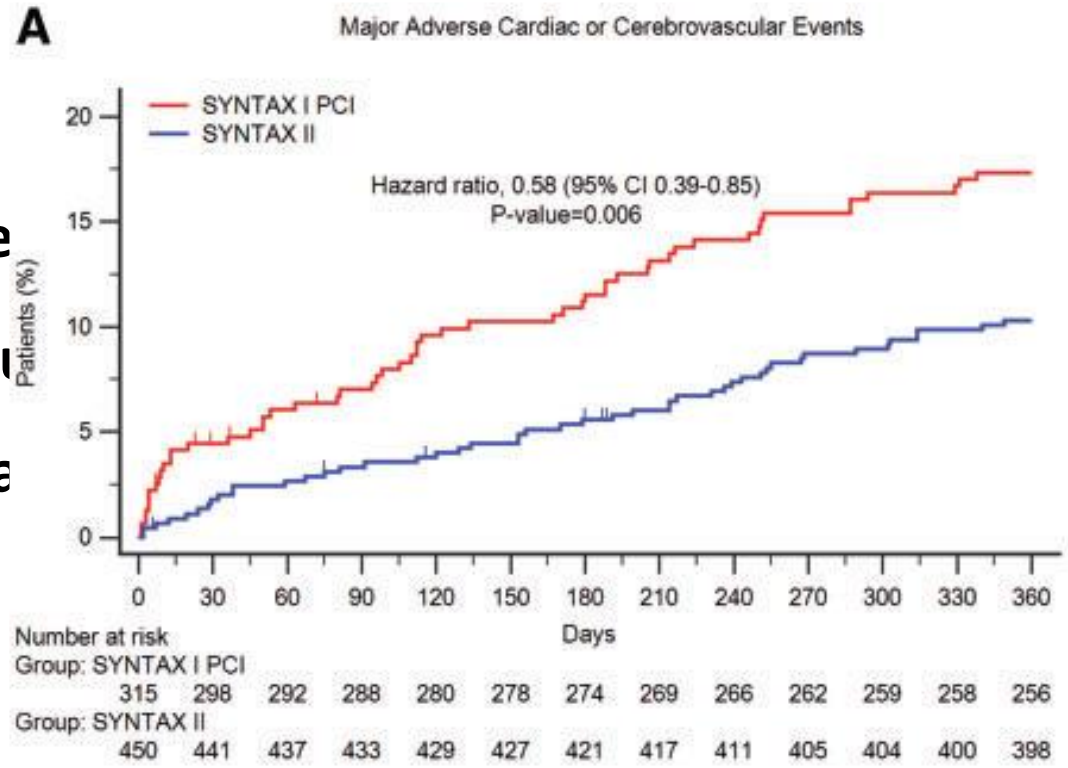

SYNTAX II Trial

Escaned J. European Heart Journal (2017) 38, 3124–3134

Clinical evidence with physiology indexes

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- Can FFR be used in angiographic sub-sets?
  - ✓ Left Main?
  - ✓ Bifurcation lesions?
- ✓ Is FFR useful to treat ischemic lesions based on FFR?
- ✓ Can FFR be used to guide complete revascularization in acute STEMI patients?
- ✓ Can FFR/iFR be used to guide revascularization in multivessel disease?

Take-Home messages

1. **Most patients don’t have information about (localizing) ischemia at the time of the angiography**

2. **There is a large body of clinical evidence about the use of coronary physiology in guiding coronary revascularization, in several clinical settings**

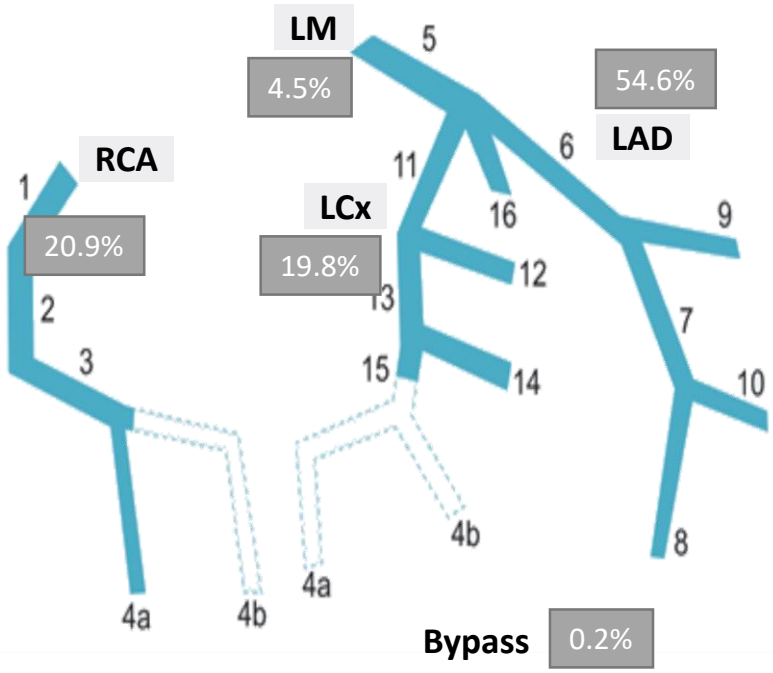
Does clinical evidence from trials apply in “real life”?

8th CHALLENGES in CARDIOLOGY

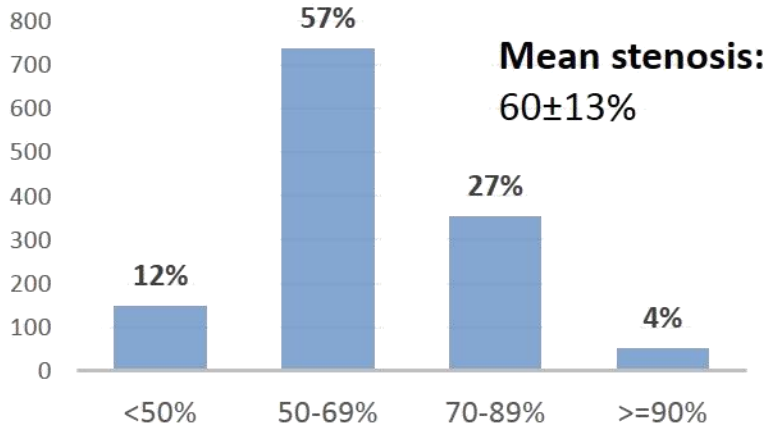
POST-IT

- **1.293 lesions** (1.4/patient)

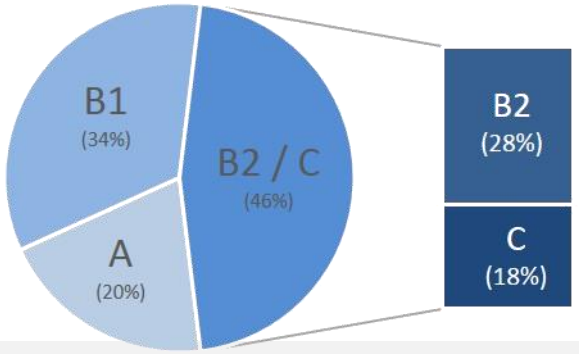
- **Lesion localization**



- **Stenosis severity:**



- **ACC/AHA lesion classification:**

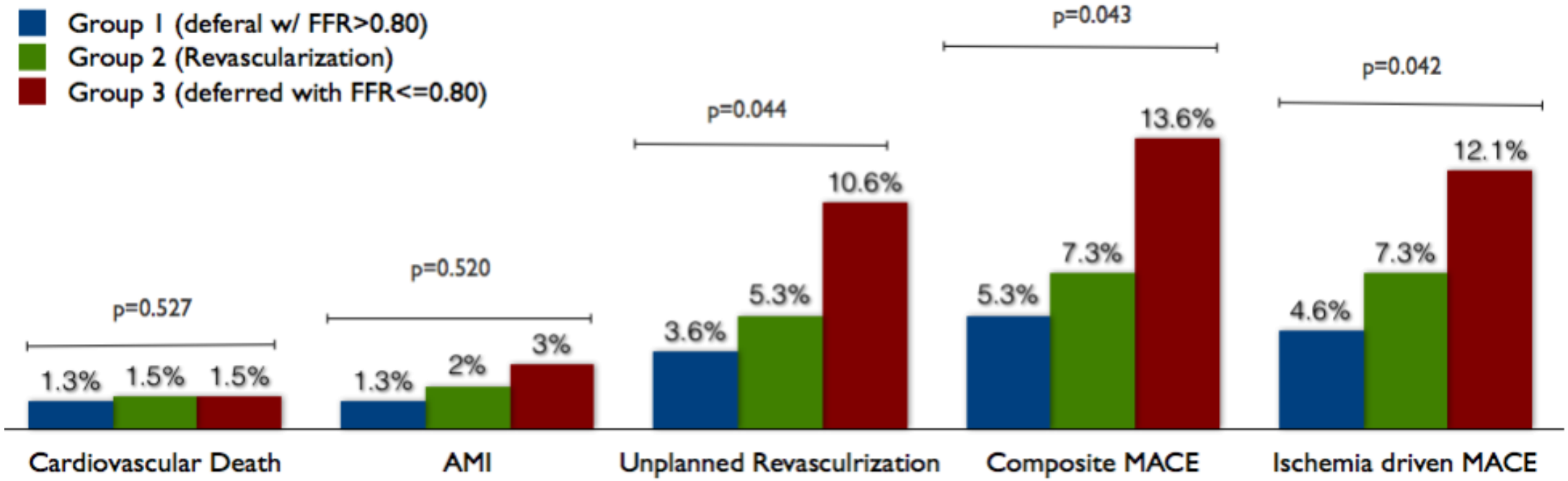


Baptista SB et al. Circ Cardiovasc Interv. 2016;9:e003288

Does clinical evidence from trials apply in “real life”?

POST-IT

MACE at 12 months (*per patient* analysis)

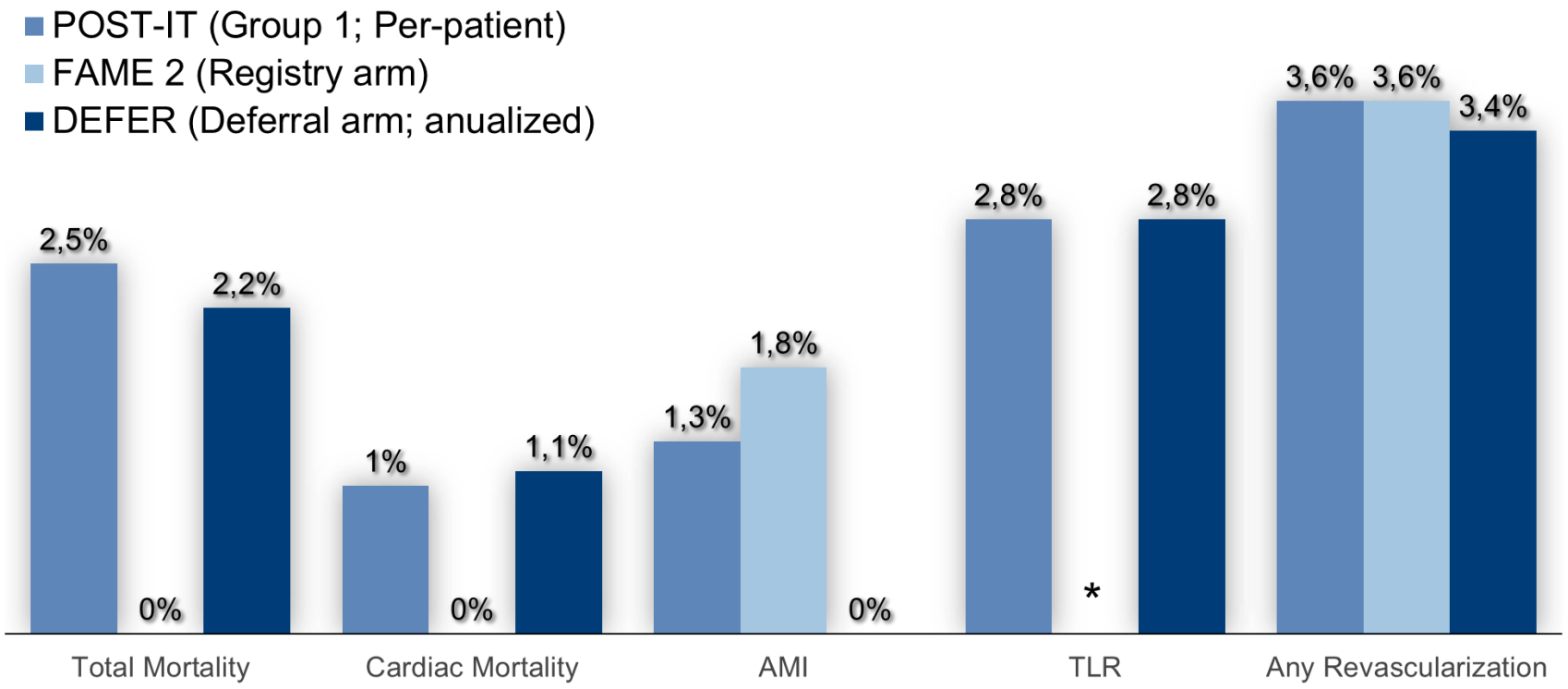


Baptista SB et al. Circ Cardiovasc Interv. 2016;9:e003288

Does clinical evidence from trials apply in “real life”?

POST-IT

MACE at 12 months – Comparison to RCTs



* Not reported in FAME 2

Baptista SB et al. Circ Cardiovasc Interv. 2016;9:e003288

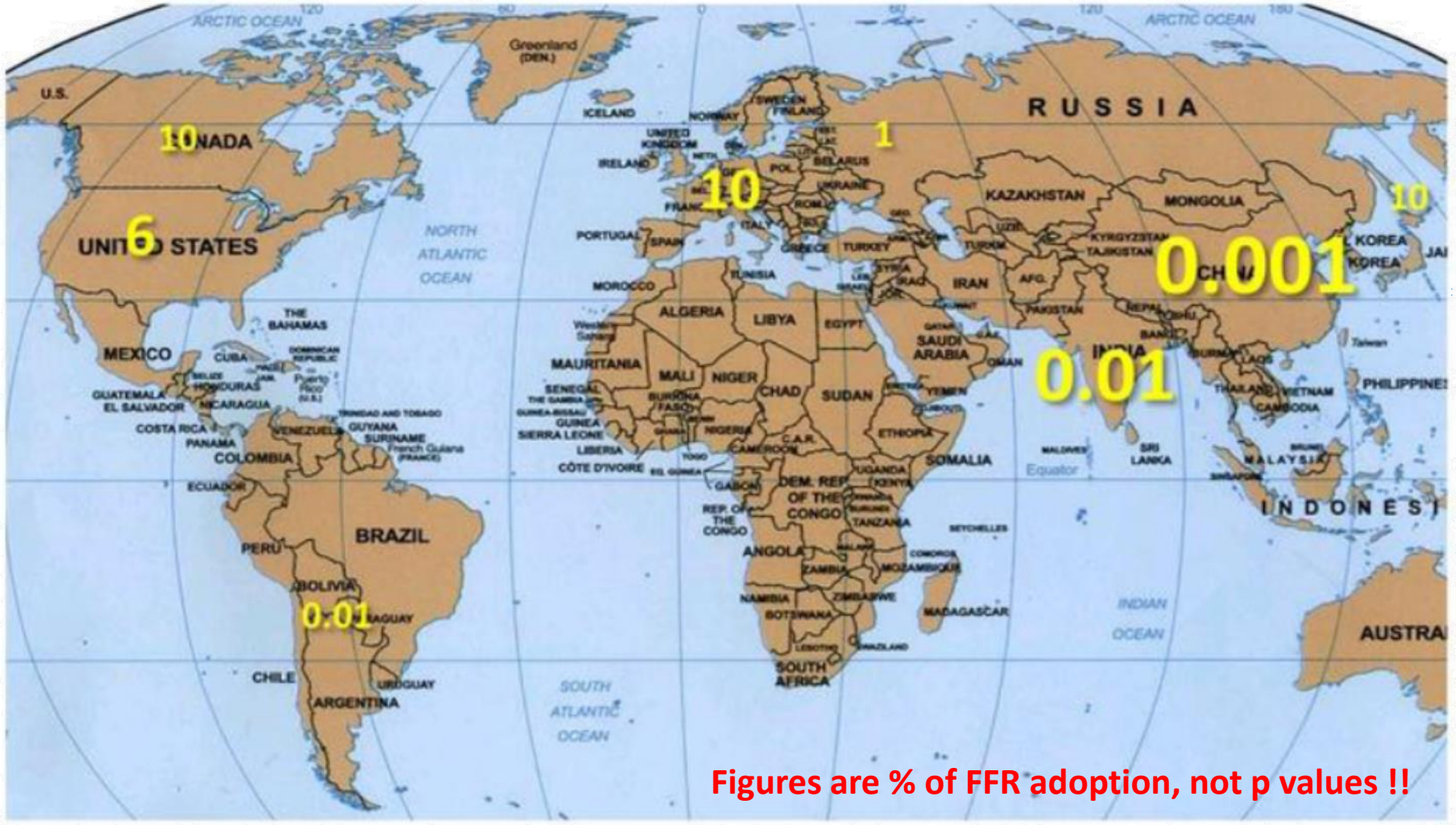
Take-Home messages

1. **Most patients don’t have information about (localizing) ischemia at the time of the angiography**

2. **There is a large body of clinical evidence about the use of coronary physiology in guiding coronary revascularization, in several clinical settings**

3. **Results of large RCTs are reproduced in “real-life” registries**

Coronary physiology: Very large body of evidence…
But very low usage…



Courtesy of J. Escaned, EuroPCR 2013

Revascularization of “stable” lesions

Reimbursement issues

Old habits (anatomy rules)

Incentives to perform PCI

Need to use adenosine (FFR)

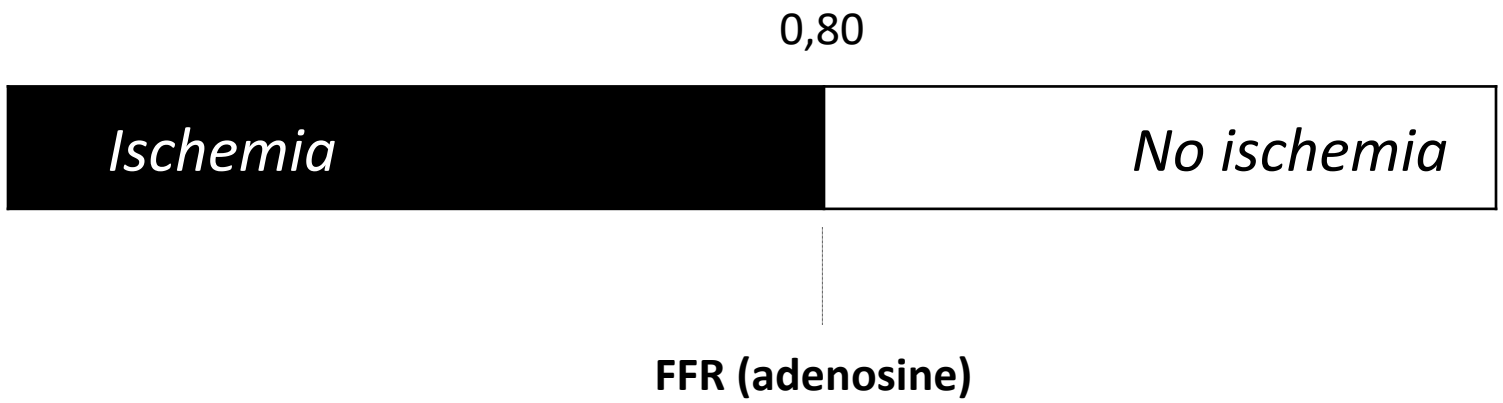
- Potential severe side effects
- Contra-indications
- Complicated procedure
- Doubts on maximal hyperemia

Discordant results

- FFR vs. iFR
- Pd/Pa vs. FFR

Is there such a thing as a “gold standard” in coronary physiology evaluation?

Black & Whyte paradigm…



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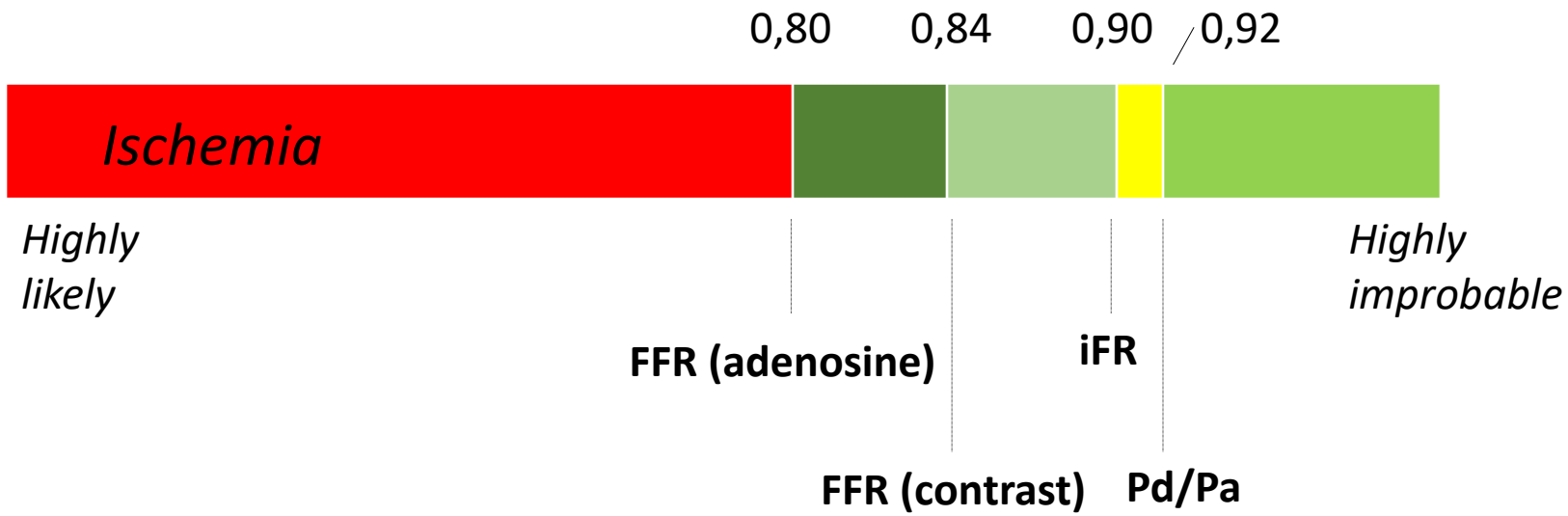
Integrating all techniques, with different diagnostic yields



Revascularization of “stable” lesions

8th CHALLENGES in CARDIOLOGY

52y male
Smoker, Hypertension, Dislipidemia, Type 2 Diabetes
NSTEMI (TnI max 16 ng/dl) ; Echo: LVEF 50%, lateral hipoquinesia

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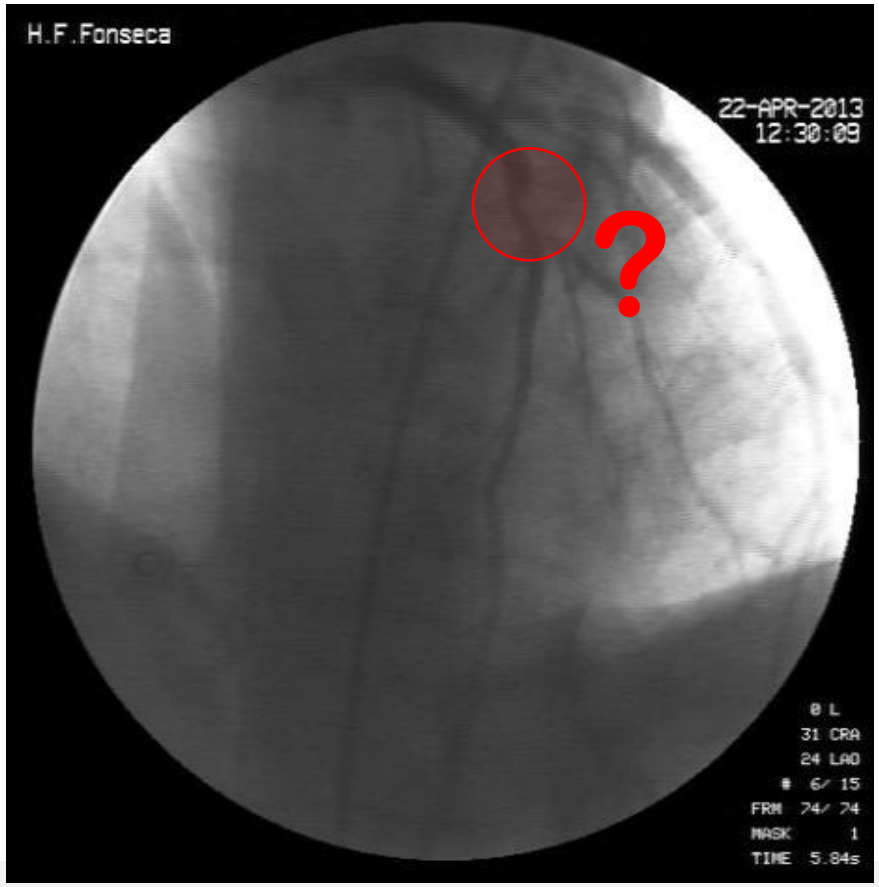


Operators accuracy in evaluating lesion severity

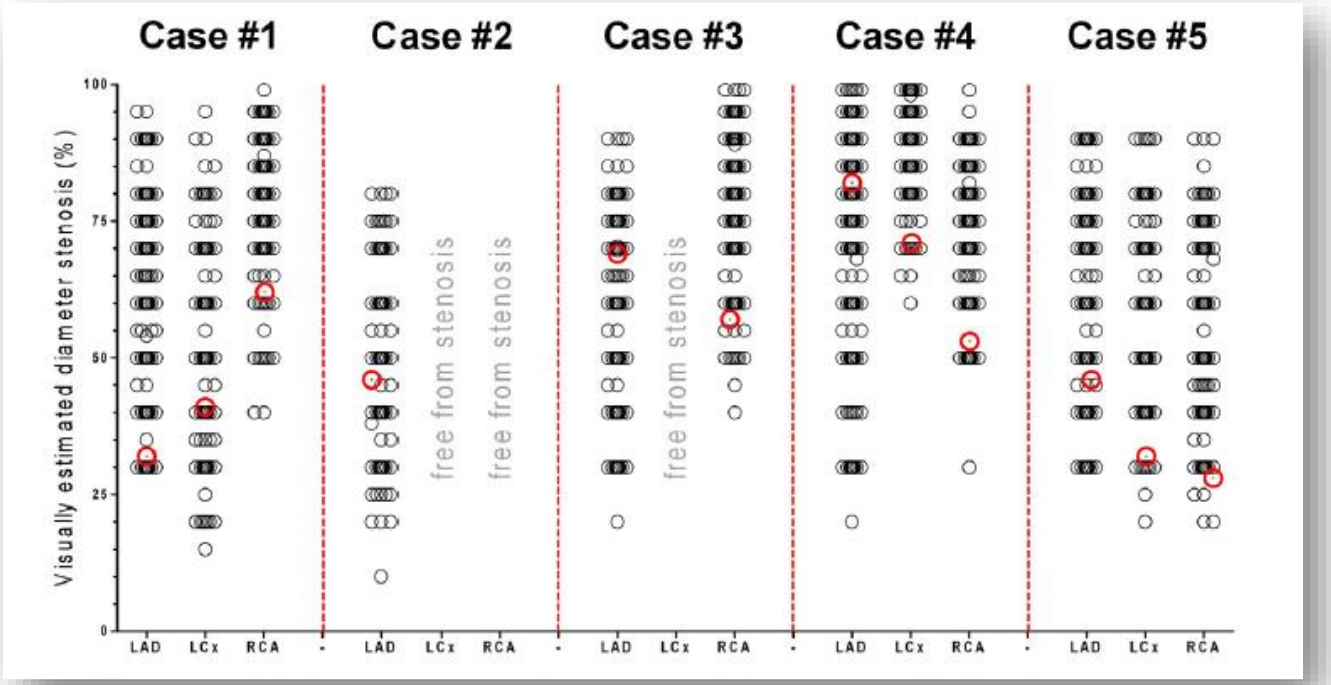
International Survey on Interventional Strategy

5 cases
12 lesions
495 Interv. Cardiologists

Purpose:

- Evaluate the lesion
- Make a decision on the indication for PCI
- (FFR value available on request)

Visually estimated percent diameter stenosis and decision patterns for the 5 cases and 12 stenoses



Circ Cardiovasc Interv. 2014;7:00-00

Take-Home messages

1. **Most patients don't have information about (localizing) ischemia at the time of the angiography**

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3. **Results of large RCTs are reproduced in "real-life" registries**

4. **Despite all the evidence, global usage of physiology to guide coronary revascularization is low (probably for several reasons). It has increased in all countries in which it has become mandatory**

5. **Interventional cardiologists are lousy in estimating lesion severity (and even lousier in admitting so…)**

POST-IT: Treatment decision is affected by FFR in half of the patients

POST-IT

Diagnostic angiography

Patient eligible for FFR
(according to operator decision)

INITIAL TREATMENT STRATEGY
(Announced before knowing FFR value)

- Medical Therapy
- Revascularization (PCI /CABG)
- Non-invasive stress test

per lesion and *per patient*

FFR evaluation in all eligible lesions
(operator's decision)

FINAL TREATMENT DECISION

- Medical Therapy
- Revascularization (PCI /CABG)
- Non-invasive stress test

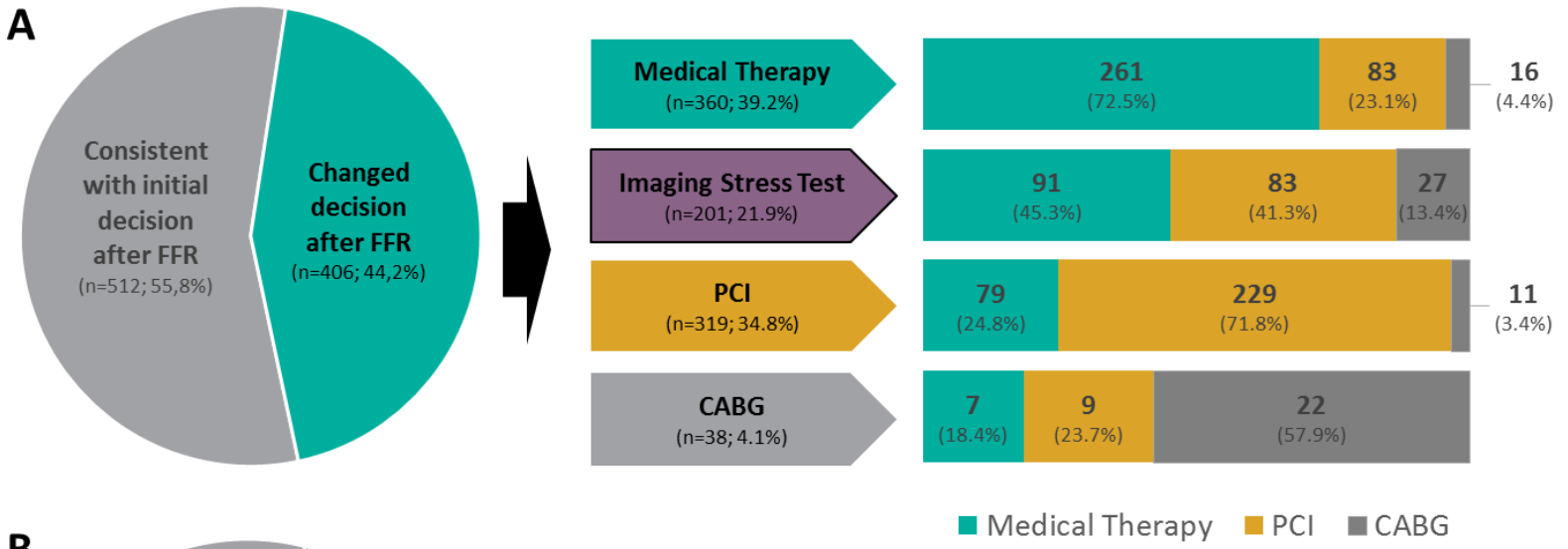
per lesion and *per patient*

Baptista SB et al. Circ Cardiovasc Interv. 2016;9:e003288

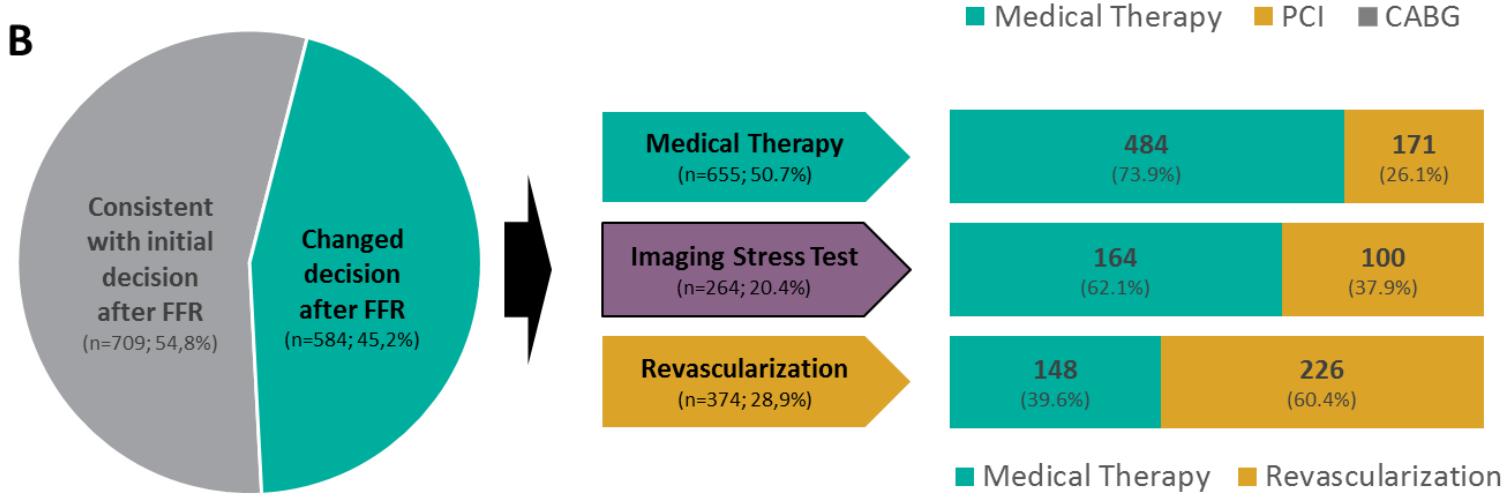
POST-IT: Treatment decision is affected by FFR in half of the patients

POST-IT

Decision change *per patient*



Decision change *per lesion*



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Revascularization of “stable” lesions

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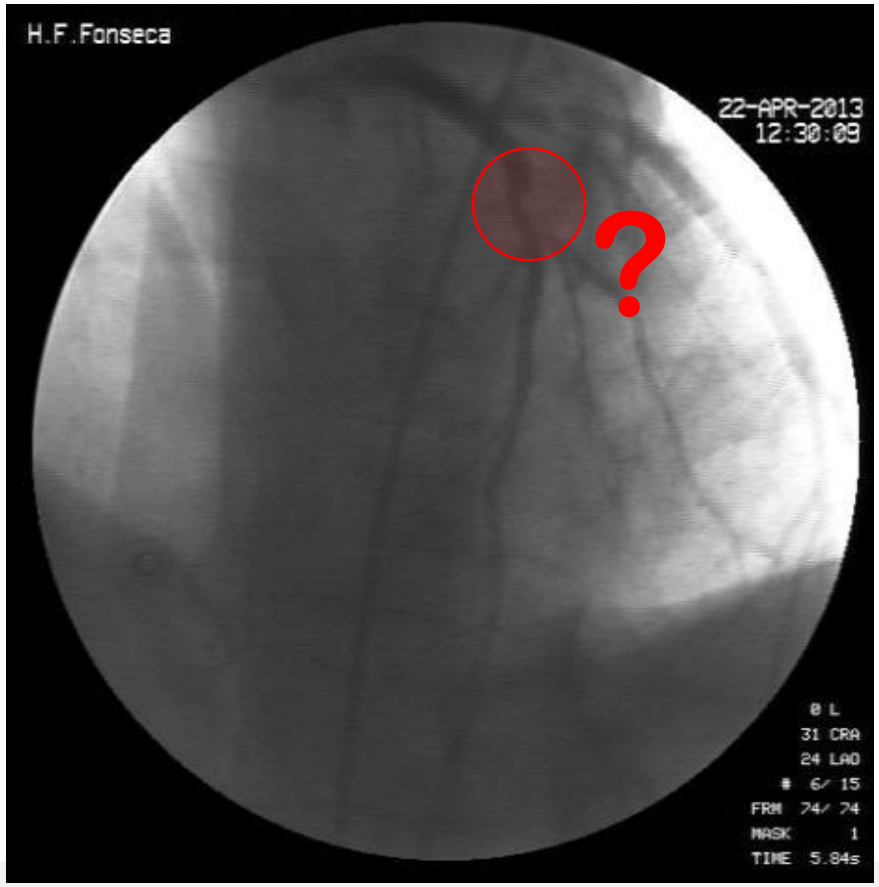

Events in intermediate deferred lesions are very rare

POST-IT study – 12 month *Follow-up (per lesion* results)

Variable (n;%)	Total Population (n=1,276)	Deferral Group (n=716)	Revasc. Group (n=490)	Deferred FFR<0.80 (n=70)	p value*
Clinical events with definite/possible relation to a study lesion					
Death from Cardiovascular Cause	10 (0.8)	3 (0.4)	6 (1.2)	1 (1.4)	0.465
Myocardial Infarction (AMI)	10 (0.8)	2 (0.3)	7 (1.4)	1 (1.4)	0.165
Death from Cardiovascular cause or AMI	18 (1.4)	5 (0.7)	11 (2.2)	2 (2.9)	0.117
Revascularization Related Events					
TLR (total events)	38 (3.0)	19 (2.7)	12 (2.4)	7 (10.0)	0.002
TLR (evidence driven)	32 (2.5)	14 (2.0)	12 (2.4)	6 (8.6)	0.003
Combined clinical and Revascularization Related Events with definite/possible relation to a study lesion					
CV Death or AMI or TLR (total events)	50 (3.9)	23 (3.2)	19 (3.9)	8 (11.4)	0.003
CV Death or AMI or TLR (evidence driven)	44 (3.4)	18 (2.5)	19 (3.9)	7 (10.0)	0.004

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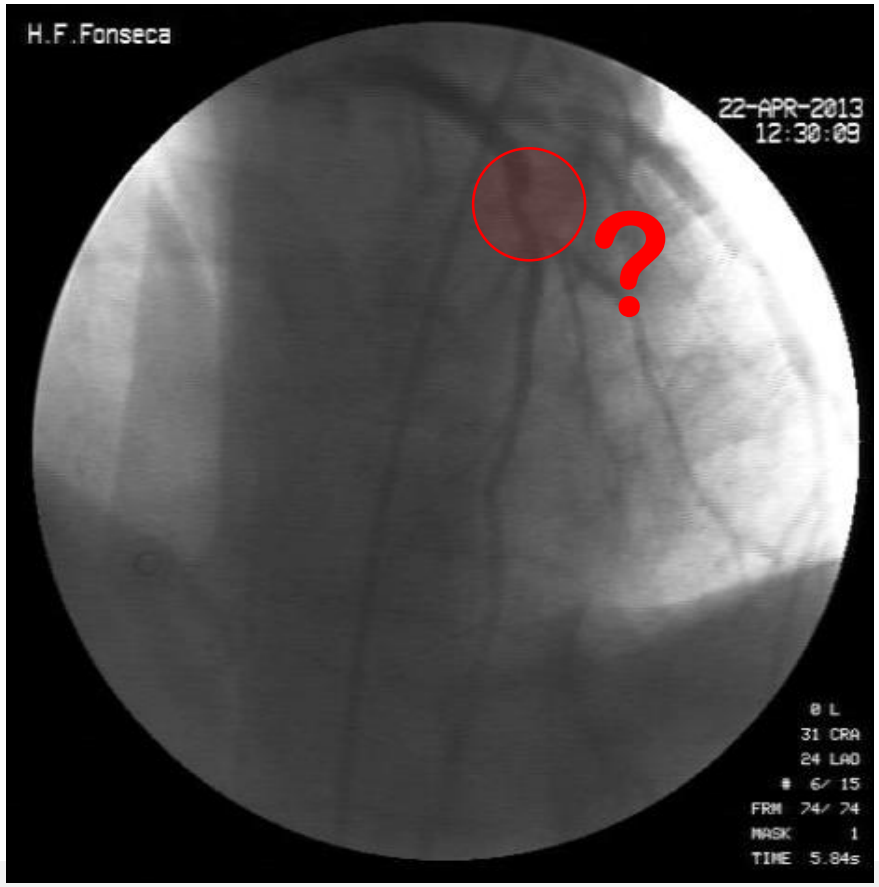

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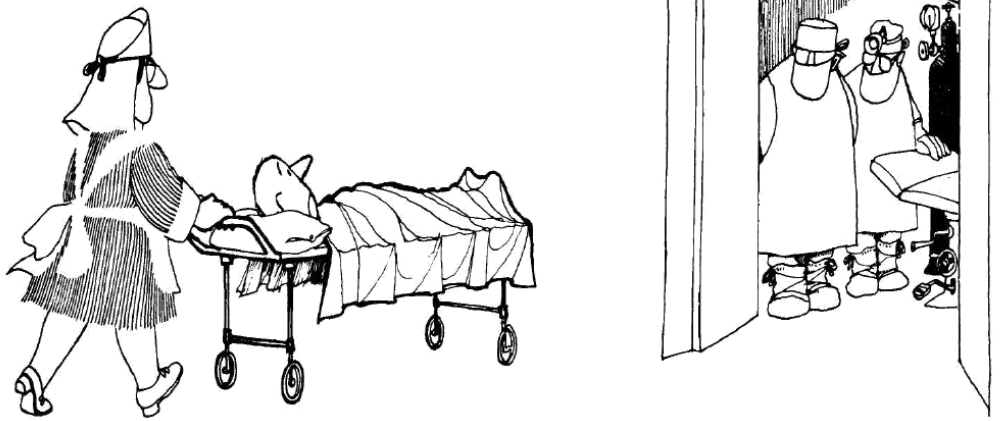
6. **Interventional cardiologists are (also) lousy in identifying ischemic lesions**
7. **Deferring PCI based on physiology is very safe**

Is now the time we should be using a pressure wire assessment during routine coronary angiography?

8th CHALLENGES in CARDIOLOGY

Knowing we don't have any information on ischemia for most of the lesions we assess on our daily routine patients, we must ask ourselves 3 questions:

- … If our ability to anticipate if a lesion is significant is not better than flipping a coin…
- … If we don't' have any stents with an event rate lower than the risk of deferring a non significant lesion…
- … If there's a risk that a significant lesion is left untreated because we fail to recognized it…



How can we live without a pressure wire evaluation in guiding coronary revascularization ??

A glimpse into the future on coronary physiology

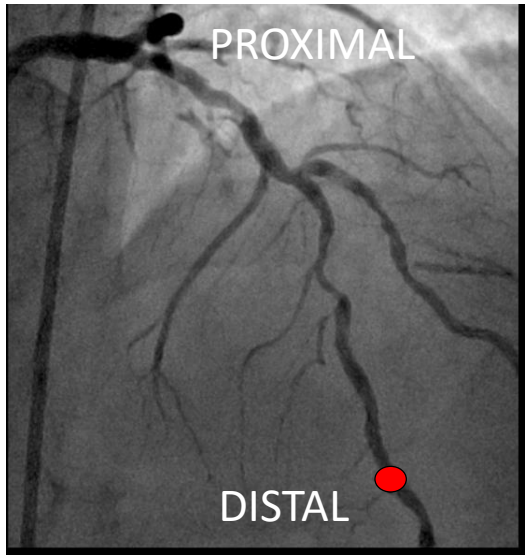
- **Pressure wire as an adjunctive tool for planning PCI**
  - ✓ iFR / Angio co-registration
- **New non-hyperemic indexes**
  - ✓ Pd/Pa min / RFR
  - ✓ dFR
  - ✓ …

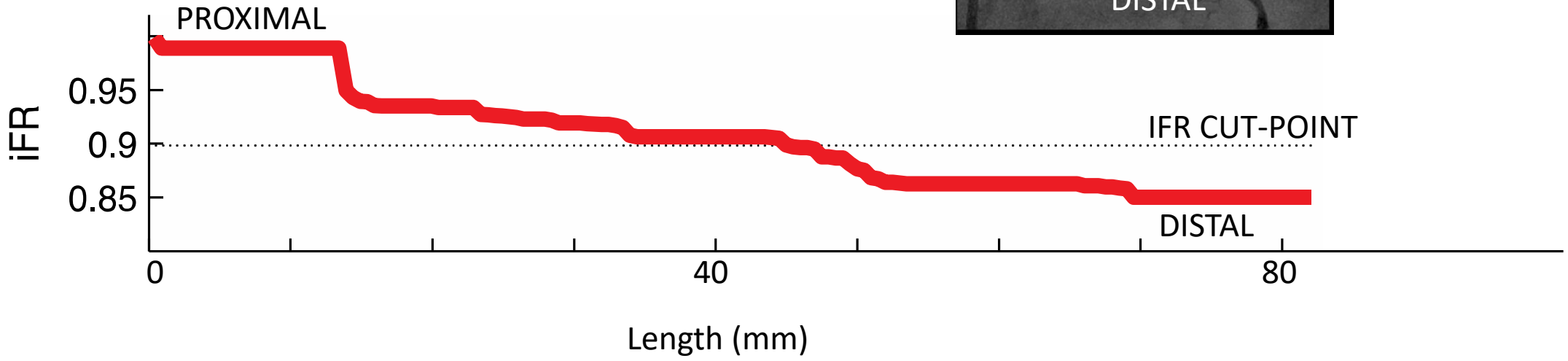
Resting iFR Pullback

Pullback – motorised controlled withdrawal of pressure wire

Continuous live iFR calculation on a beat-to-beat basis

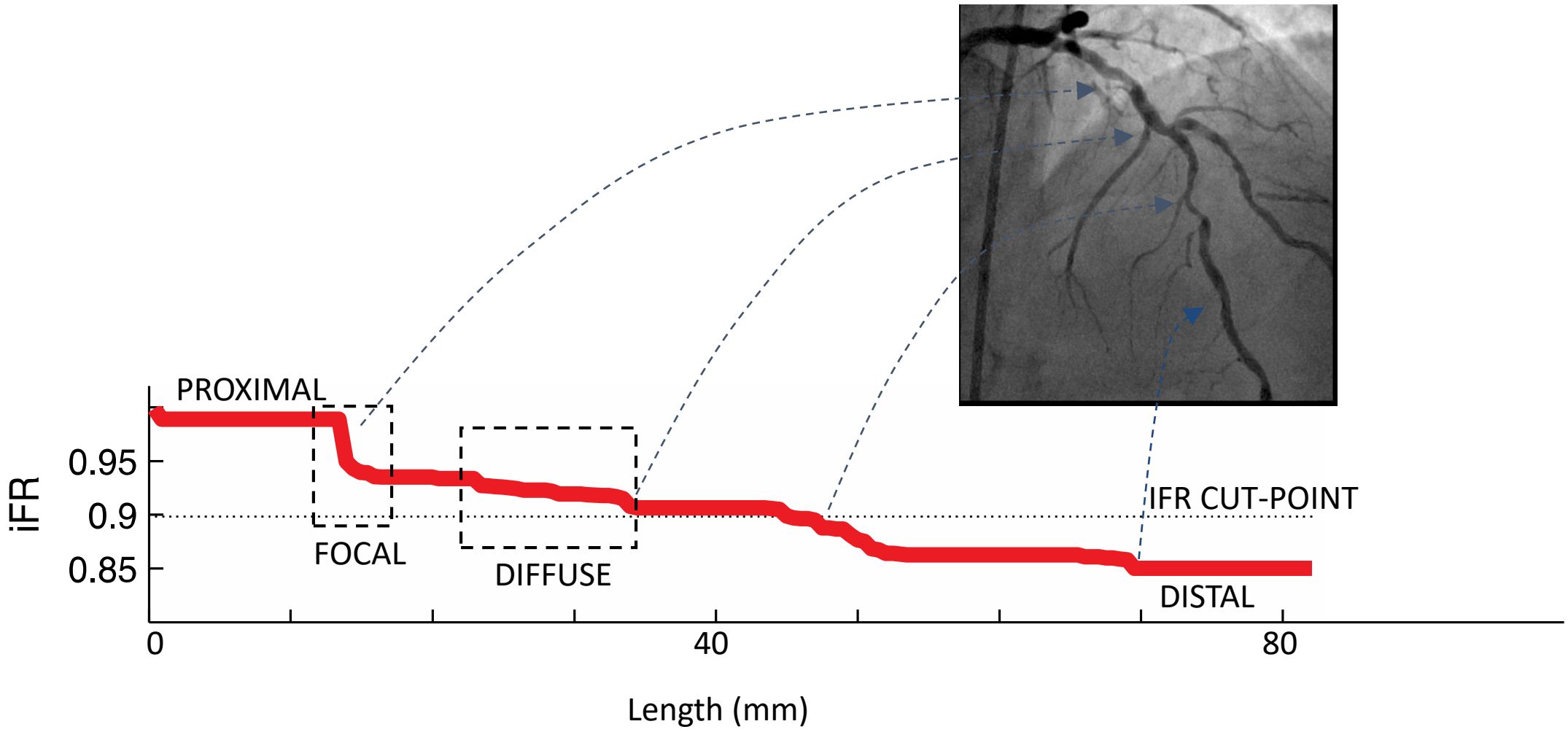
Wire moves at fixed speed → calculate Length (mm)





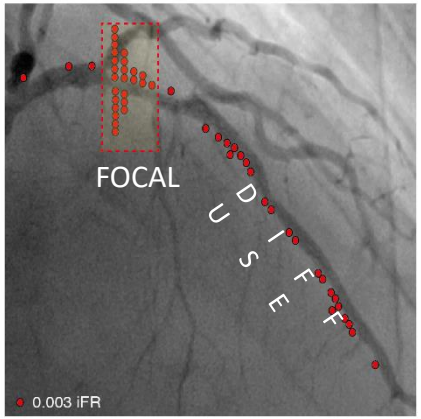
Courtesy of Dr. Justin Davies, Imperial College, London

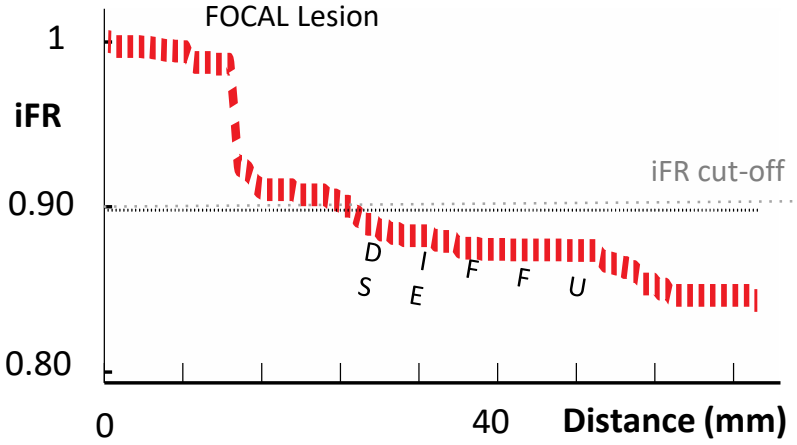
Resting iFR Pullback

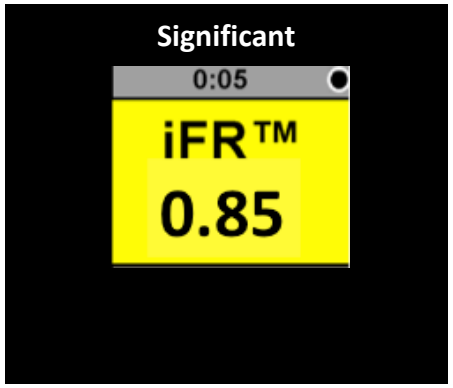


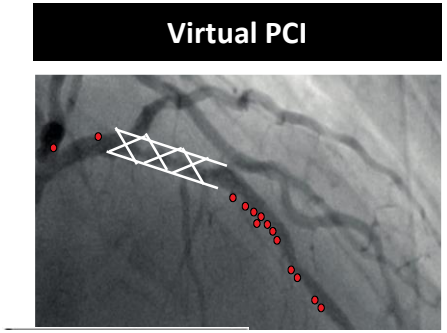
Courtesy of Dr. Justin Davies, Imperial College, London

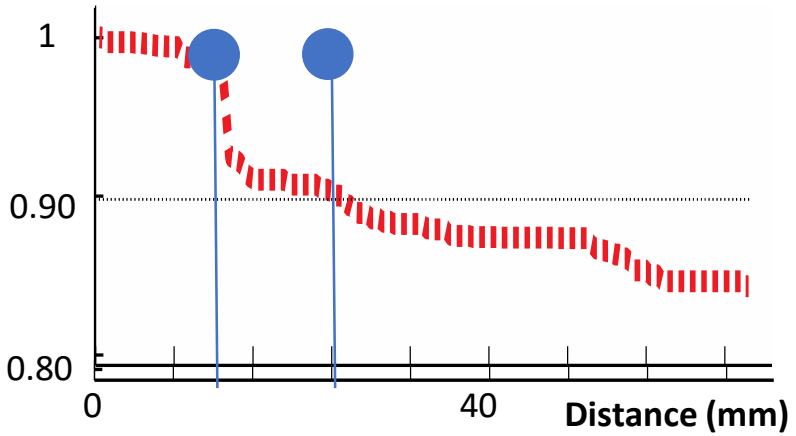
iFR: Perform a Virtual PCI











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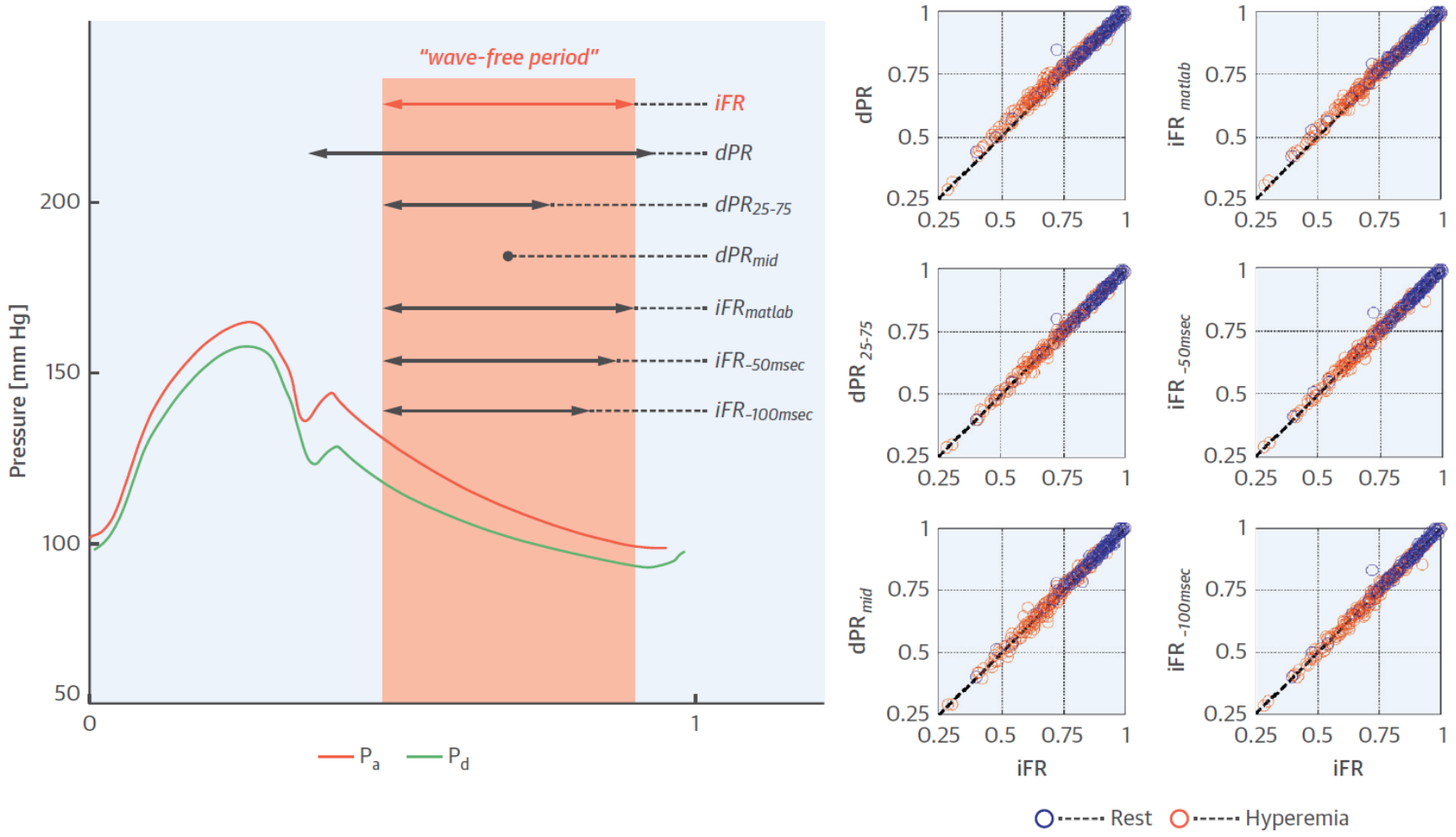
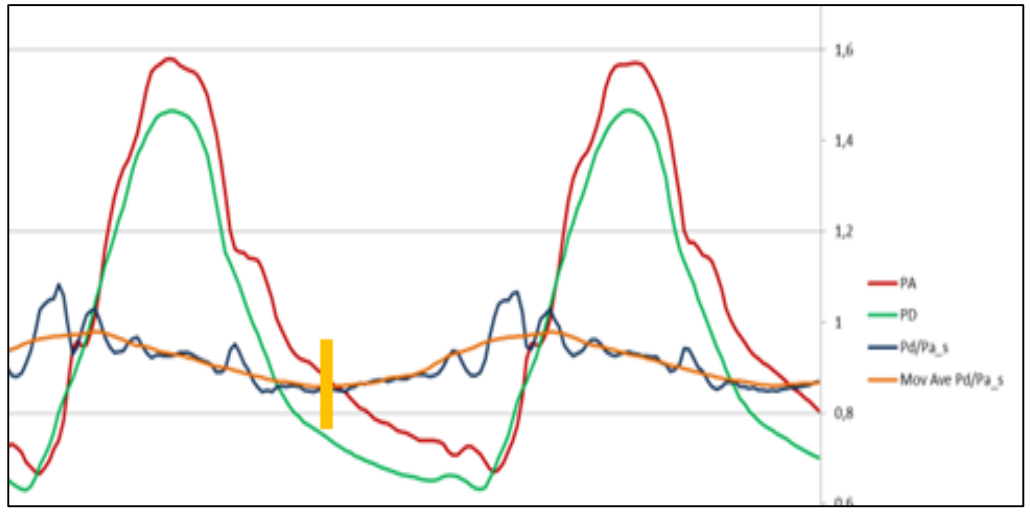
Diastolic Pressure Ratio (dPR) and other diastolic indexes compared with iFR

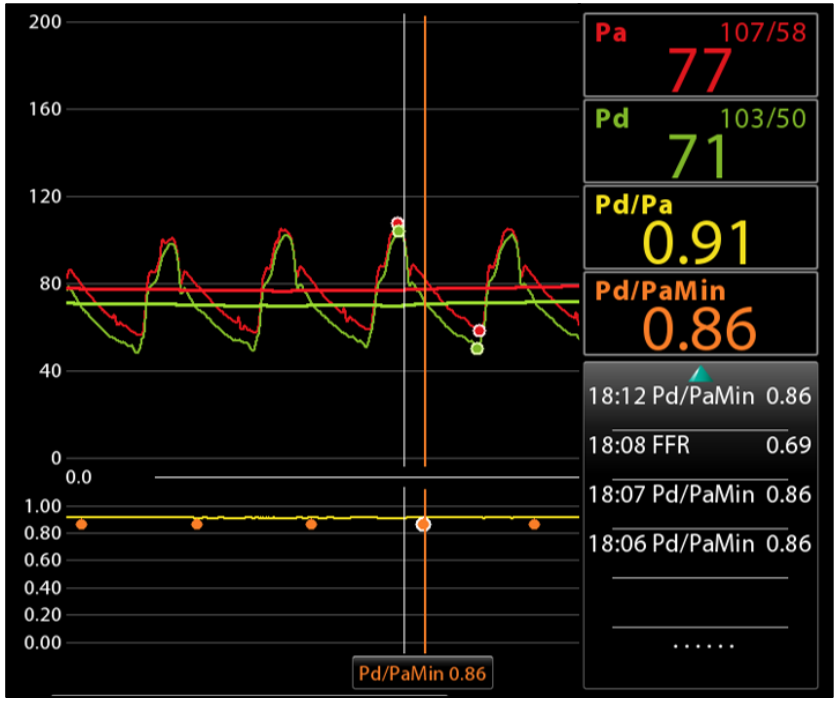


van't Veer, M. et al. J Am Coll Cardiol. 2017;70(25):3088–96.

Pd/Pa min / Resting Full-Cycle Ratio



Defined as the lowest distal (Pd) to aortic (Pa) pressure ratio at rest, regardless of its location during the cardiac cycle.



8th CHALLENGES in CARDIOLOGY

July 2018
06th, 07th

Palace Hotel Monte Real

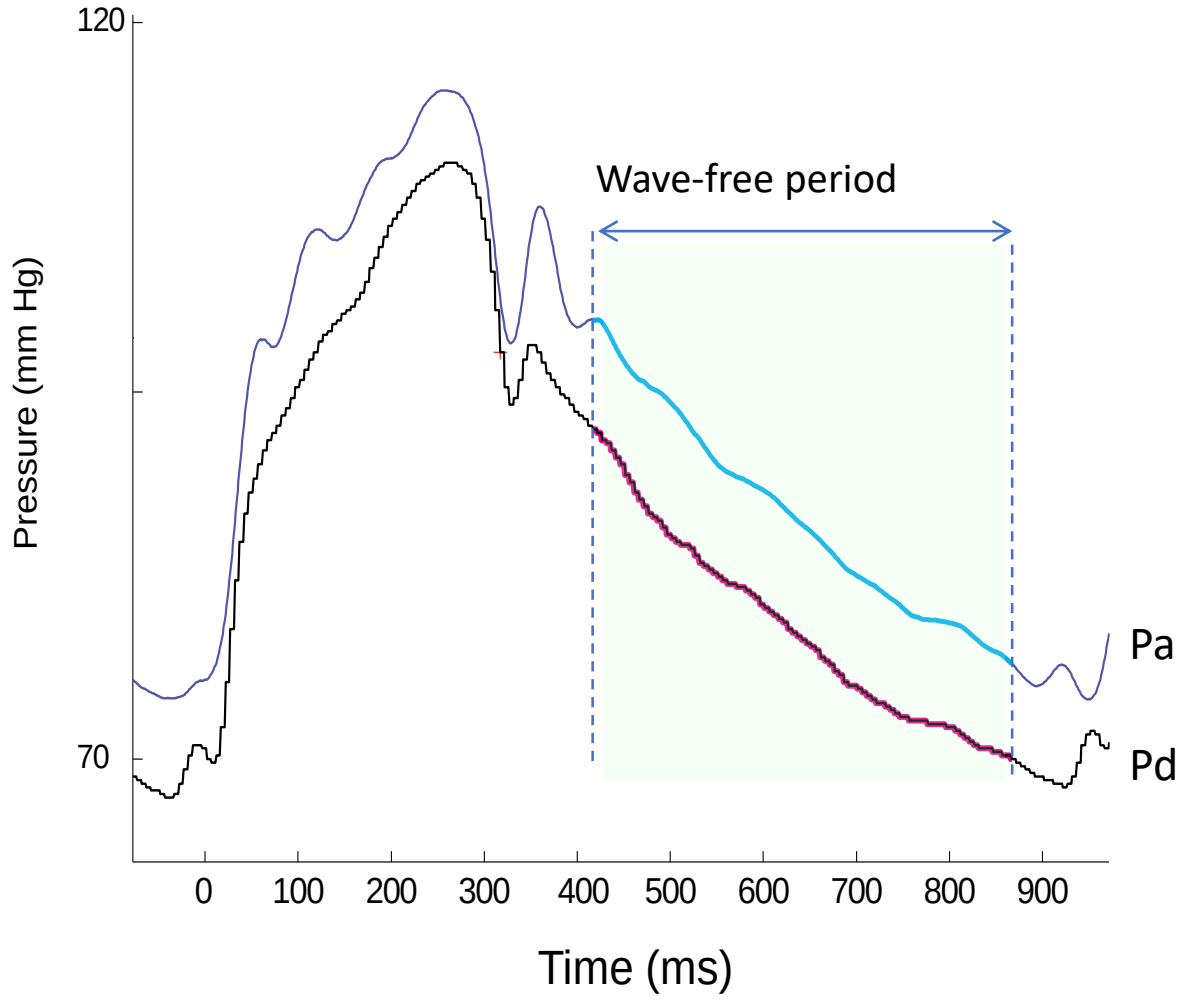
Muito obrigado!

Sérgio Bravo Baptista, MD, PhD, FESC
Serviço de Cardiologia – Hospital Prof. Doutor Fernando Fonseca, Amadora

iFR (instantaneous wave-free ratio)

The concept of iFR

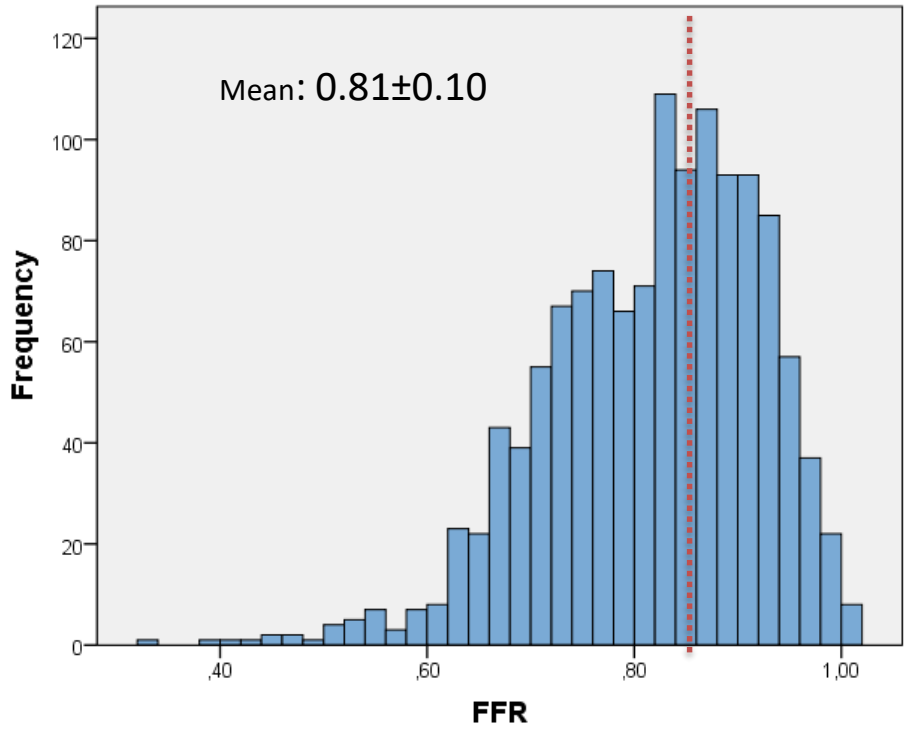
- There is a wave-free period in the cardiac cycle, when resistance is constant and minimised
- Pressure measured during this period will correlate with flow, without the need of inducing hyperaemia.



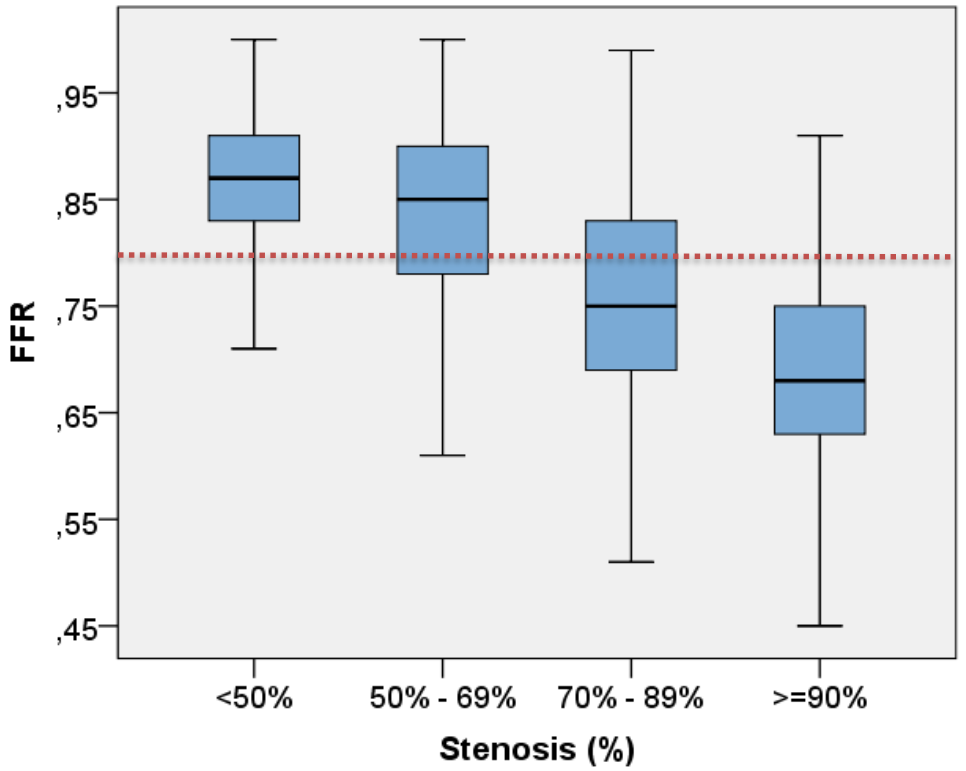
Does clinical evidence from trials apply in “real life”?

POST-IT

Distribution of FFR values (N=1.285)



FFR according to angiographical stenosis severity



Baptista SB et al. Circ Cardiovasc Interv. 2016;9:e003288

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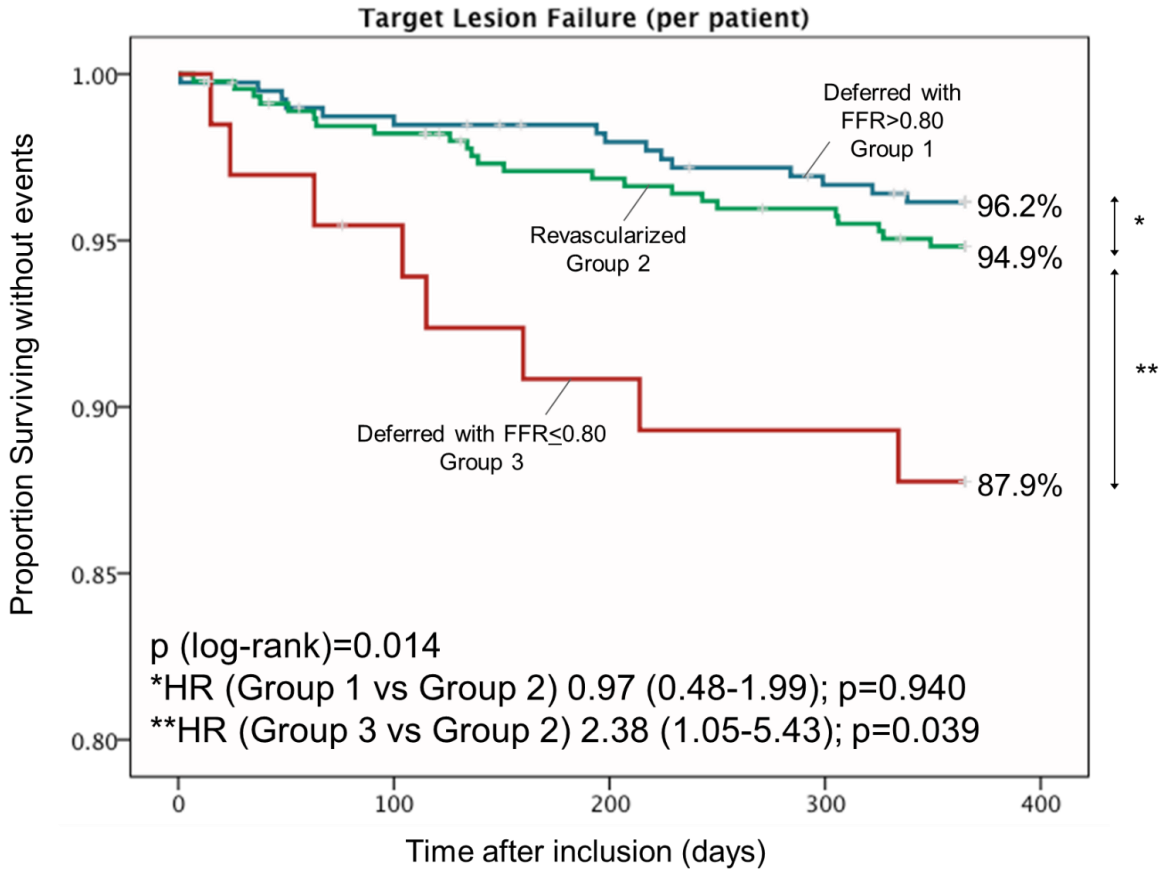
8th CHALLENGES in CARDIOLOGY

POST-IT

MACE at 12 months (*per patient* analysis)

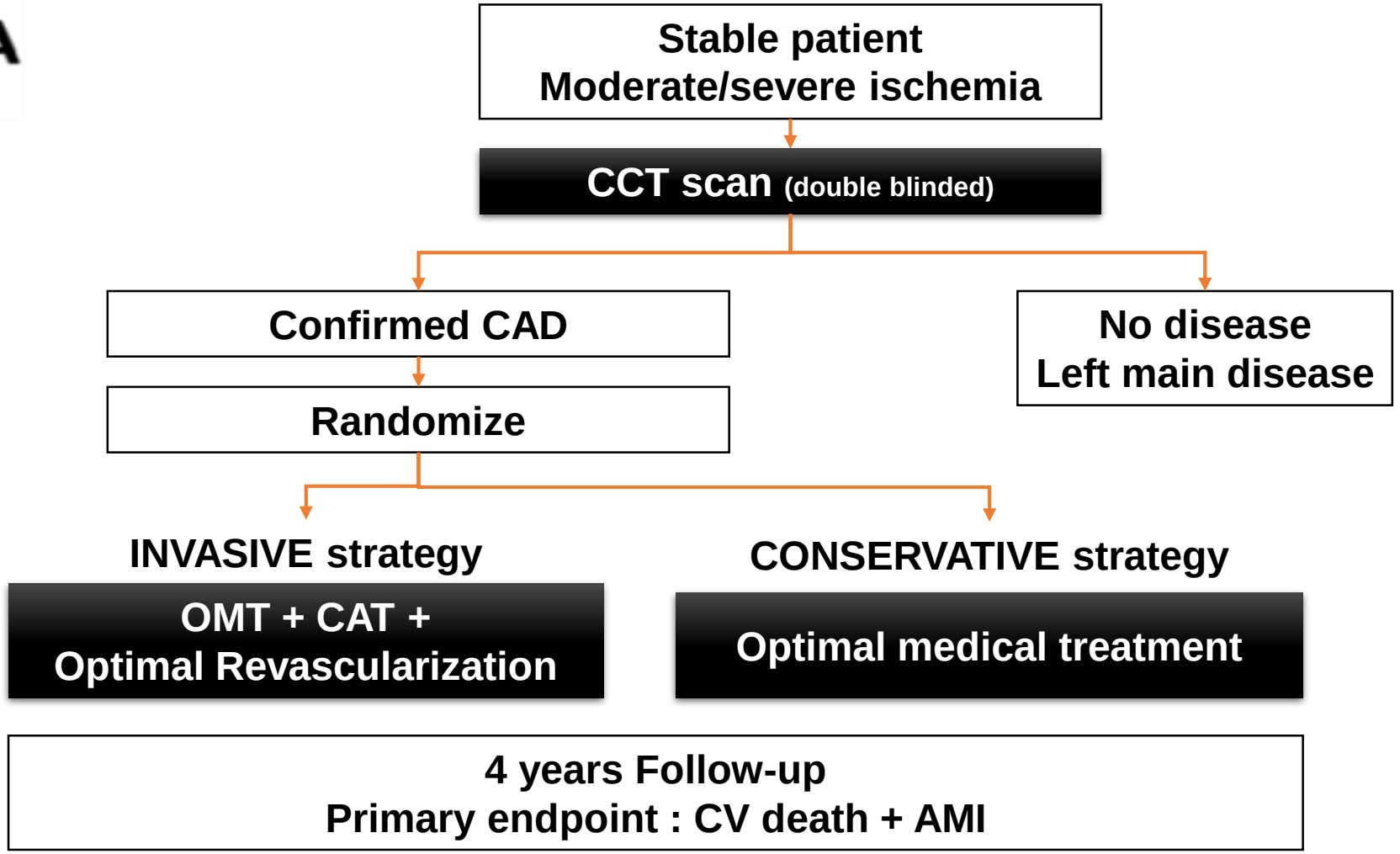


HRs adjusted for age, gender, diabetic status, hypertension, ACS at presentation and the extent of coronary artery disease

Baptista SB et al. Circ Cardiovasc Interv. 2016;9:e003288

Is it useful to treat ischemic lesions?

ISCHEMIA



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