Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart Association.

Editorial

Routine Pressure Wire Assessment at Time of Diagnostic Angiography

Is It Ready for Prime Time?

Eric Van Belle, MD, PhD; Gilles Rioufol, MD, PhD; Patrick Dupouy, MD

Van Belle et al. Circ Cardiovasc Interv 2014

Frequency of Stress Testing to Document Ischemia Prior to Elective Percutaneous Coronary Intervention

Grace A. Lin, MD, MAS
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Context Guidelines call for documenting ischemia in patients with stable coronary artery disease prior to elective percutaneous coronary intervention (PCI).

Objective To determine the frequency and predictors of stress testing prior to elective PCI in a Medicare population.

Design, Setting, and Patients Retrospective, observational cohort study using claims data from a 20% random sample of 2004 Medicare fee-for-service beneficiaries aged 65 years or older who had an elective PCI (N=23 887).

Main Outcome Measures Percentage of patients who underwent stress testing within 90 days prior to elective PCI; variation in stress testing prior to PCI across 306 hospital referral regions; patient, physician, and hospital characteristics that predicted the appropriate use of stress testing prior to elective PCI.

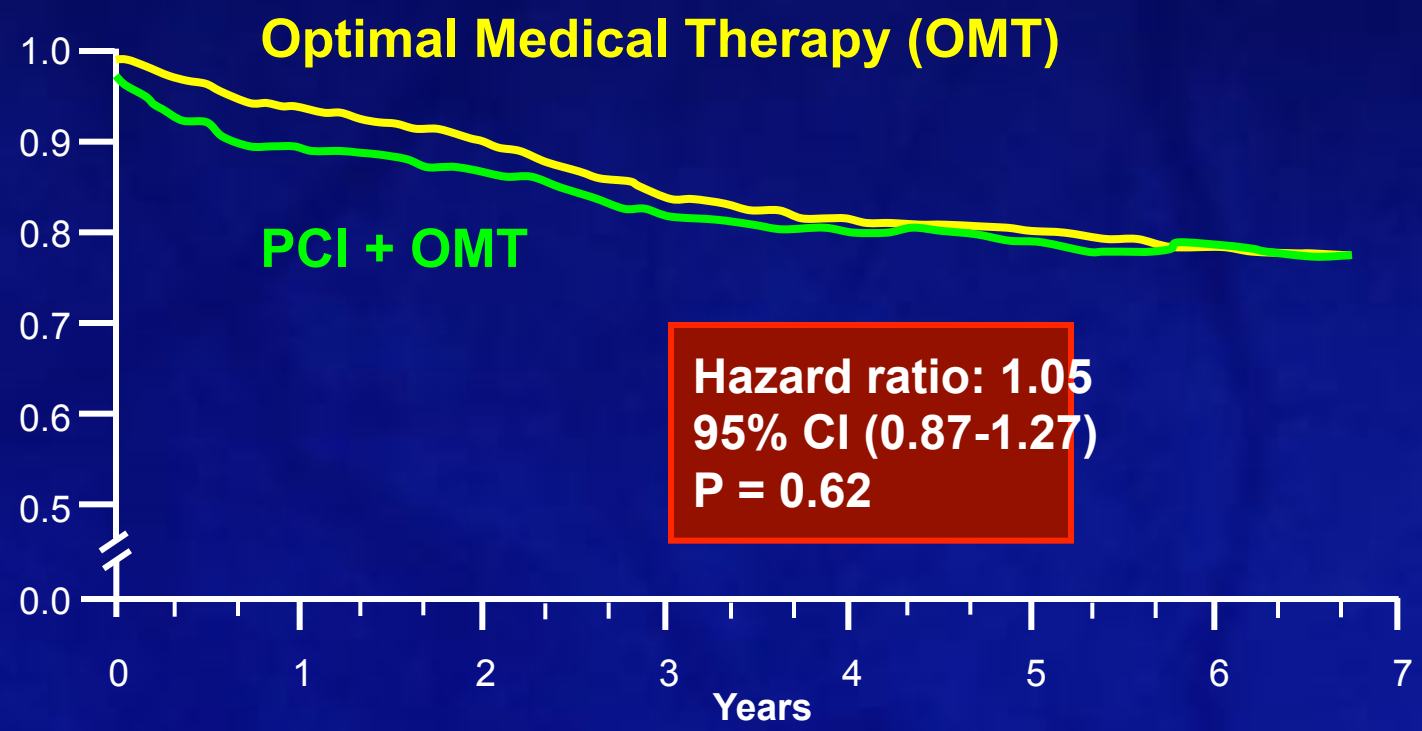
Results In the United States, 44.5% (n=10 629) of patients underwent stress testing within the 90 days prior to elective PCI. There was wide regional variation among the hospital referral regions with stress test rates ranging from 22.1% to 70.6% (national mean, 44.5%; interquartile range, 39.0%-50.9%). Female sex (adjusted odds ratio [AOR], 0.91; 95% confidence interval [CI], 0.86-0.97), age of 85 years or older (AOR, 0.83; 95% CI, 0.72-0.95), a history of congestive heart failure (AOR, 0.85; 95% CI, 0.79-0.92), and prior cardiac catheterization (AOR, 0.45; 95% CI, 0.38-0.54) were associated with a decreased likelihood of prior stress testing. A history of chest pain (AOR, 1.28; 95% CI, 1.09-1.54) and black race (AOR, 1.26; 95% CI, 1.09-1.46) increased the likelihood of stress testing prior to PCI. Patients treated by physicians performing 150 or more PCIs per year were less likely to have stress testing prior to PCI (AOR, 0.84; 95% CI, 0.77-0.93). No hospital characteristics were associated with receipt of stress testing.

Conclusion The majority of Medicare patients with stable coronary artery disease do not have documentation of ischemia by noninvasive testing prior to elective PCI.

JAMA. 2008;300(15):1765-1773 www.jama.com

IN THE UNITED STATES, PERCUTANEOUS coronary intervention (PCI) has become a common treatment strategy for patients with stable coronary artery disease (CAD) and such patients now account for the majority of PCIs performed.[1,2] However, multiple studies have established that some important outcomes for patients with stable CAD (death and risk of future myocardial infarction) do not differ between patients treated with PCI plus optimal medical therapy and patients treated with optimal medical therapy alone.[3-10] The addition of PCI does offer quicker relief of angina than medical therapy alone but also carries an increased risk of repeat revascularization, late-stent thrombosis, and a decreased

Survival Free of Death from Any Cause and Myocardial Infarction



Number at Risk

Medical Therapy	1138		1017		959	834	638	408	192		30	
PCI	1149	1013		952	833	637	417	200		35		

Baseline Clinical and Angiographic Characteristics

Characteristic	PCI + OMT (N=1149)	OMT (N=1138)	P Value
CLINICAL			
Stress test			0.84
Total patients - %	85 %	86 %	
Treadmill test	57 %	57 %	0.84
Pharmacologic stress	43 %	43 %	
Nuclear imaging - %	70 %	72 %	0.59
Single reversible defect	22 %	23 %	0.09
Multiple reversible defects	65 %	68 %	0.09
ANGIOGRAPHIC			
Vessels with disease – %			0.72
1, 2, 3	31, 39, 30 %	30, 39, 31 %	
Disease in graft	62 %	69 %	0.36
Proximal LAD disease	31 %	37 %	0.01

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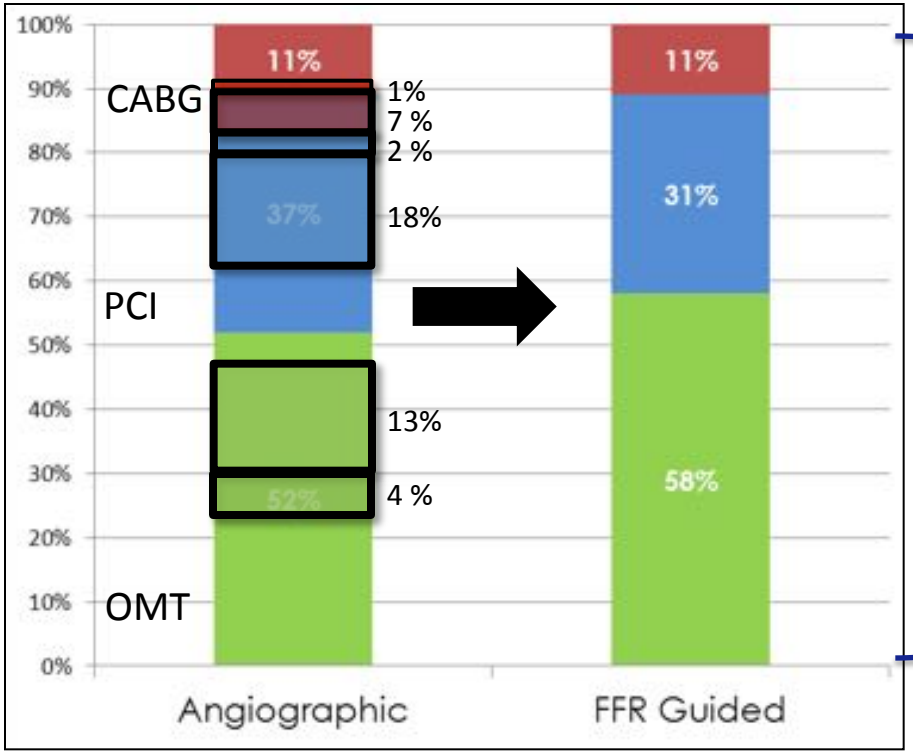
Outcome Impact of Coronary Revascularization Strategy Reclassification With Fractional Flow Reserve at Time of Diagnostic Angiography

Insights From a Large French Multicenter Fractional Flow Reserve Registry

Eric Van Belle, MD, PhD; Gilles Rioufol, MD, PhD; Christophe Pouillot, MD;



43% of patients changed therapy with FFR guidance

Van Belle et al. Circulation 2014

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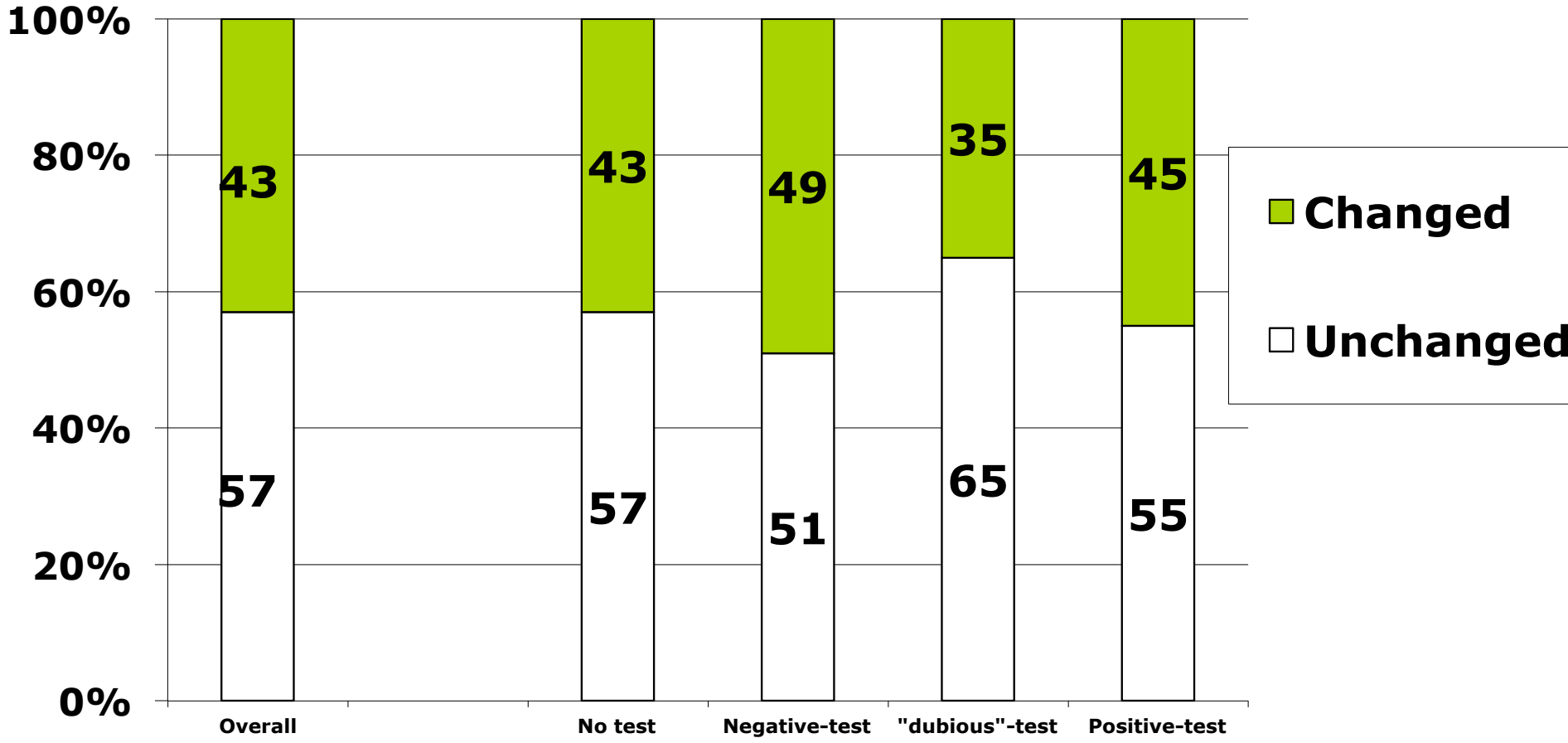
Change of the Revascularization strategy according to the results of non-invasive tests



E. Van Belle et al. Circulation 2014

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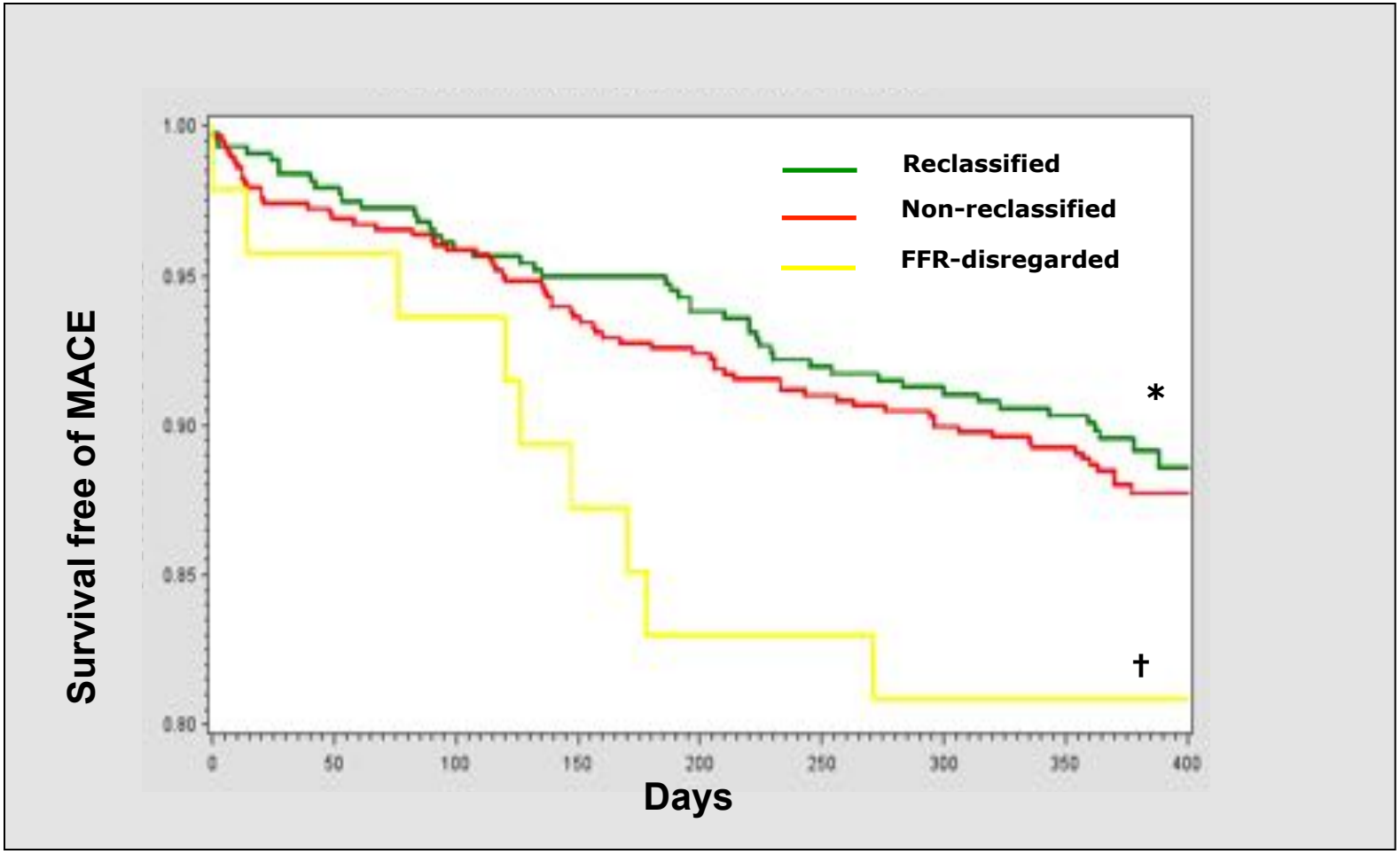
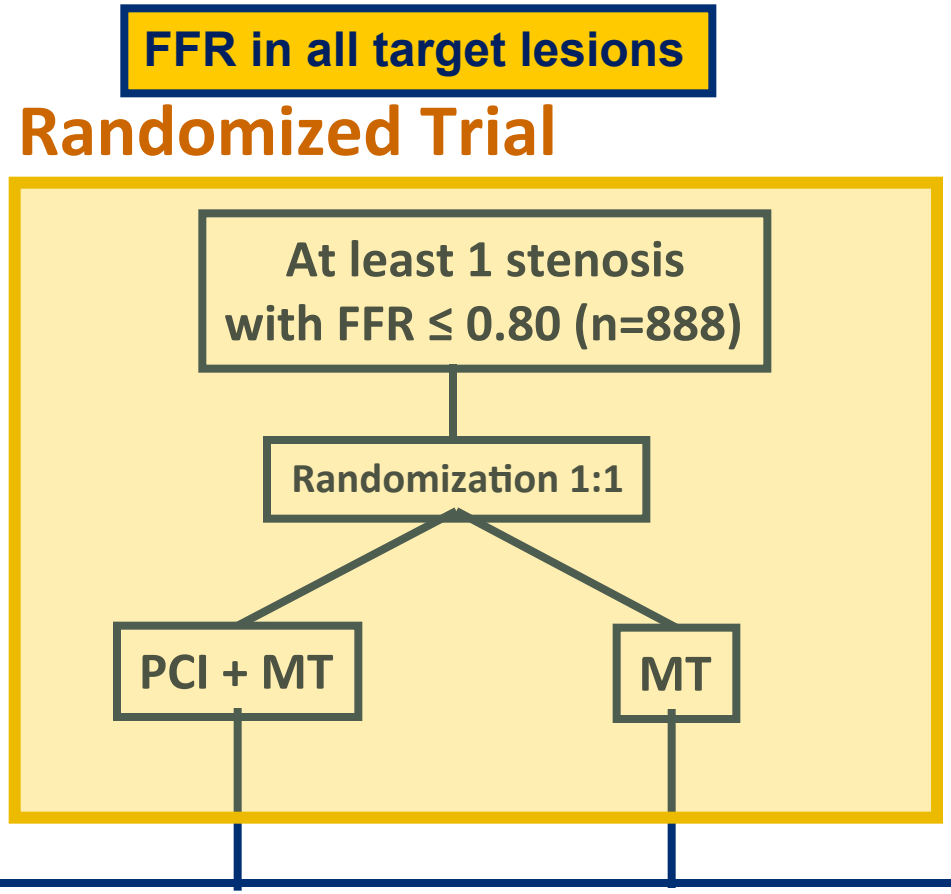
Survival free of MACE according to Reclassification by FFR (« per-use » analysis)



E. Van Belle et al. Circulation 2014

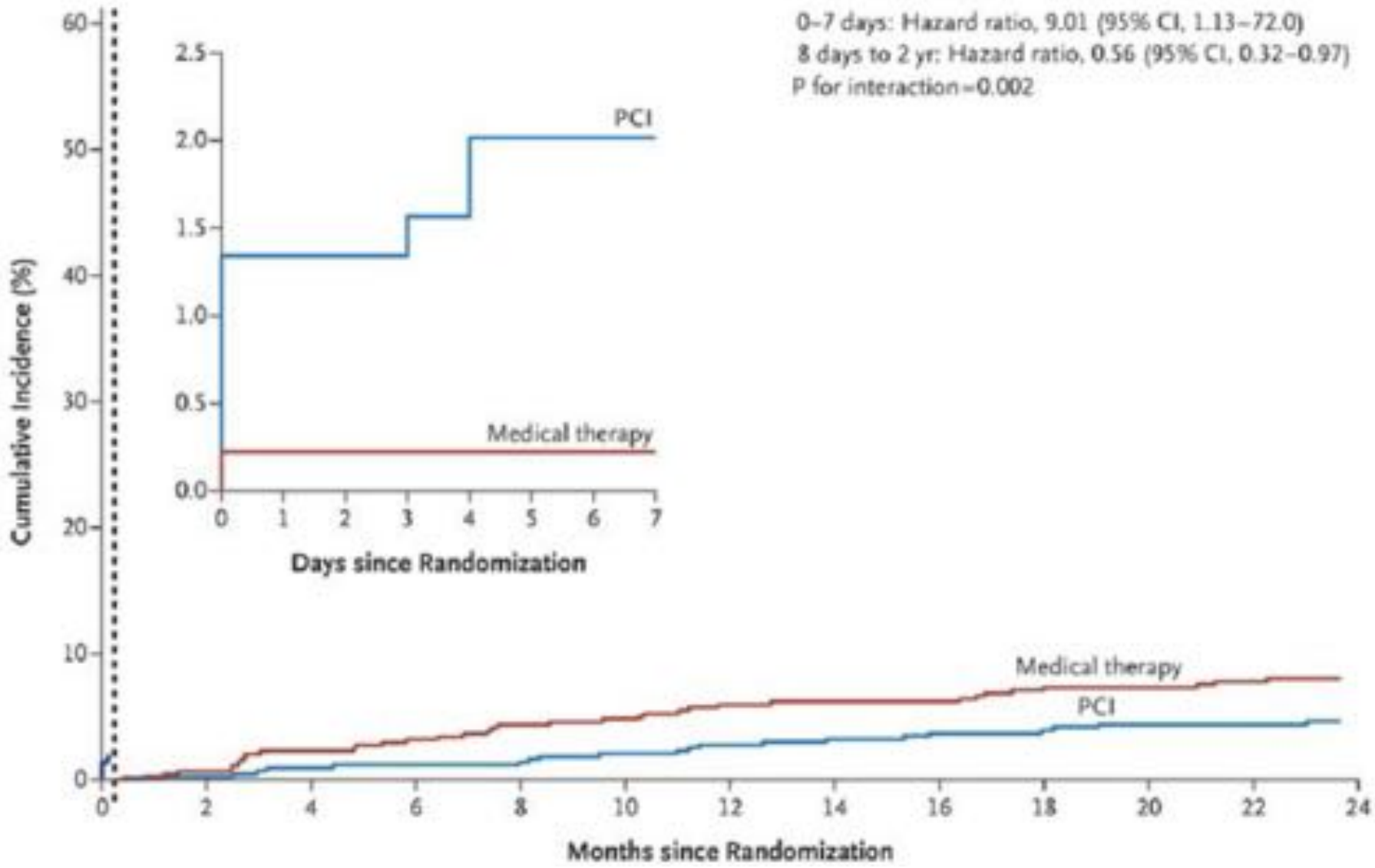
Flow Chart

Stable CAD patients scheduled for 1, 2 or 3 vessel DES-PCI
N = 1220



Follow-up after 1, 6 months, 1, 2, 3, 4, and 5 years

Death or MI at 2 years



What about ACS?

Impact of routine Fractional Flow Reserve on management decision and 1-year clinical outcome of ACS patients: Insights from the POST-IT and R3F Integrated Multicenter registriEs - Implementation of FFR in Routine Practice (**PRIME-FFR**)

Eric Van Belle, Sergio-Bravo Baptista, **Luís Raposo**, John Henderson, Patrick Dupouy and others.

On behalf of the PRIME-FFR study group

Hotline EuroPCR 2016

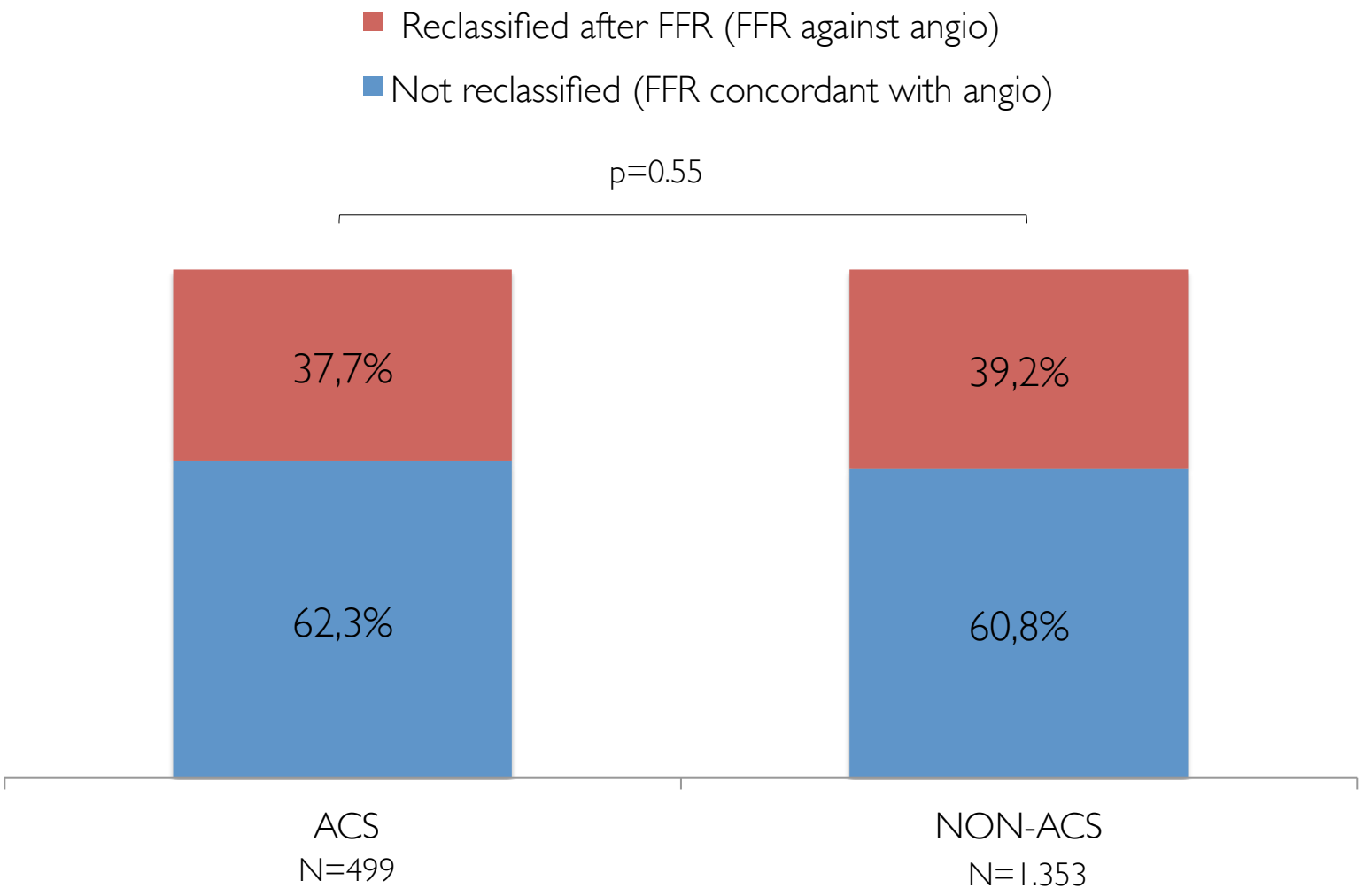
Van Belle et al. Circ Cardiovasc Interv 2017

Baseline Characteristics

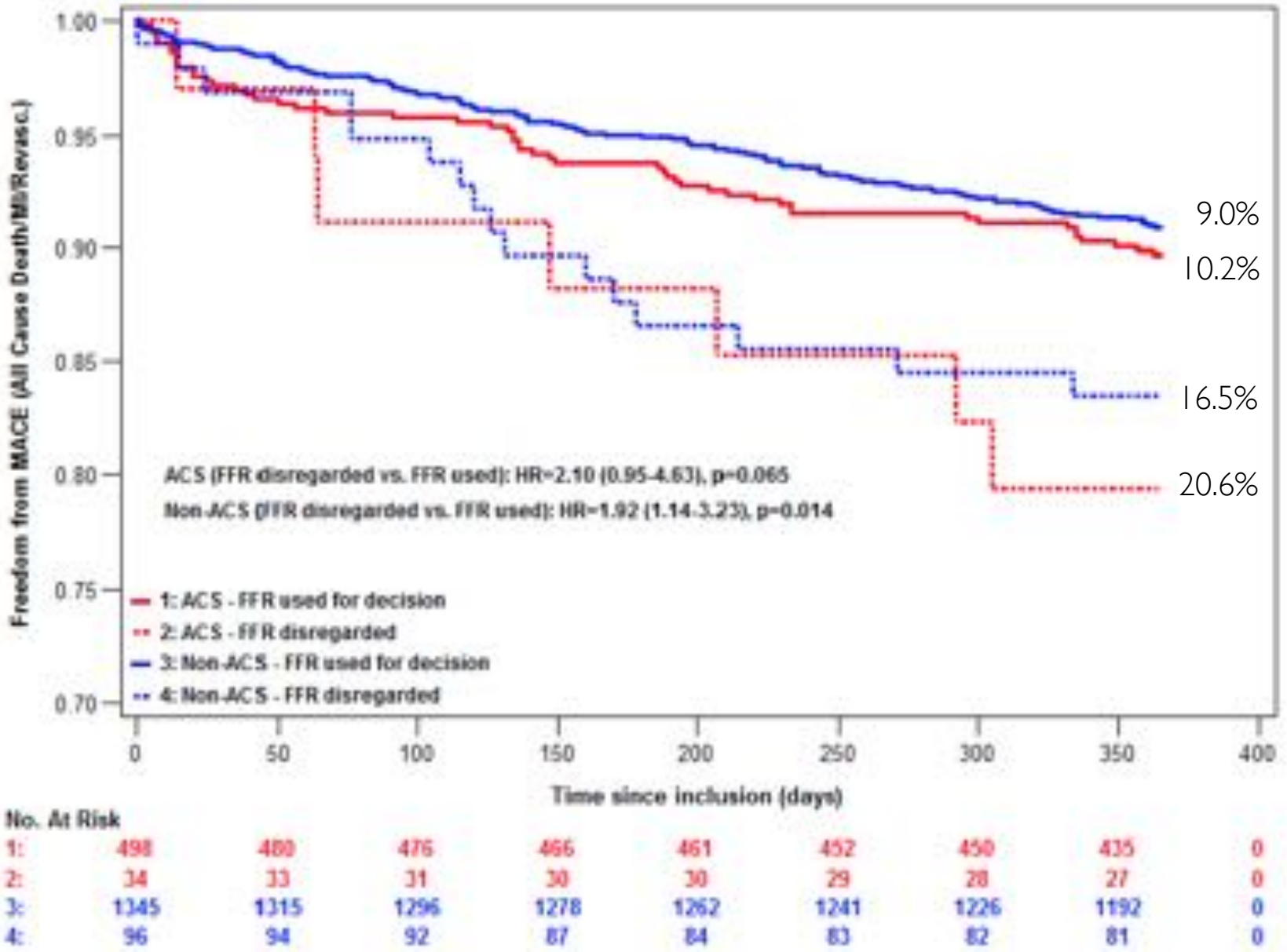
Variable (n;%)	ACS Population	Non-ACS population	*p* value
Age (years) [mean±SD]	64.0±11.5	65.3±10.1	0.019
Male Gender	401 (75.2%)	1102 (76.0%)	0.724
Diabetes mellitus	160 (30.8%)	541 (38.2%)	0.003
Hypertension	365 (70.3%)	1073 (75.7%)	0.016
Smoking (current/former<1year)	234 (43.9%)	558 (38.5%)	0.091
High Cholesterol	335 (64.9%)	1044 (73.8%)	<0.001
Myocardial infarction	187 (44.3%)	360 (31.0%)	<0.001
PCI	199 (47.2%)	538 (46.1%)	0.720
CABG	11 (2.6%)	56 (4.8%)	0.054
Left Ventricular EF ≤50%	84 (15.8%)	249 (17.2%)	0.757
Dual Antiplatelet therapy	314 (60.2%)	742 (51.6%)	<0.001
Statin	398 (76.2%)	1119 (78.0%)	0.402
ACEI/ARB	319 (62.3%)	839 (58.9%)	0.175
Beta-Blockers	318 (61.6%)	880 (61.6%)	0.999
Typical Angina Syndrome	-	562 (38.8%)	<0.001
On-going ACS	229 (43.0%)	-	
Recent ACS STEMI	91 (17.1%)	-	
Recent ACS NSTEMI/UA	213 (40.0%)	-	

Reclassification of Treatment strategy by FFR

Overall management change in patients in whom FFR was used for decision



Safety of integrating FFR on management



What about MVD patients?

2016 euroPCR

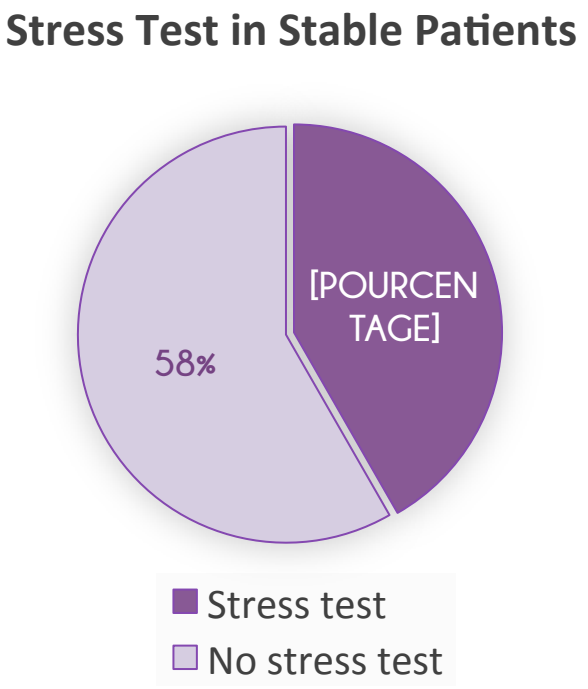
A prospective, observational, European, multi-center registry, collecting REAL-life information on the utilization of instantaneous wave-free ratio™ (iFR®) in the multi-vessel disease patients population

Prof. Eric Van Belle on behalf of the DEFINE REAL Investigators

DEFINE REAL

Patient Demographics

Patient Demographics	n = 484
Gender (male)	80%
Age (mean)	66.7 yr
Previous MI	36%
ACS	17.8%
Diabetes	26.7%
Normal LVEF	62.8.%



2016 euro PCR

ANGIOGRAPHY | PHYSIOLOGY

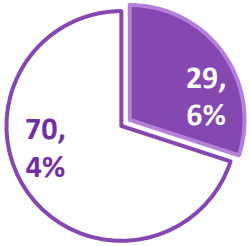
RECLASSIFICATION OF TREATMENT ?

2A

VESSEL LEVEL

Change:
PCI → CABG

Vessel Management
At Vessel Level



Vessel management change in **29.6%** of vessels

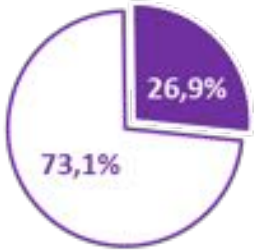
2B

PATIENT LEVEL

Change:
PCI → CABG

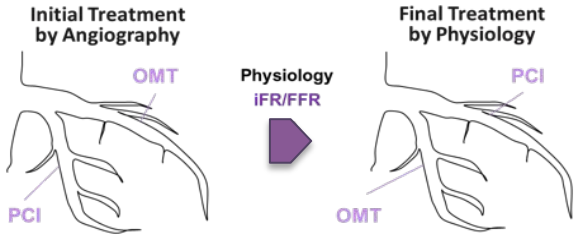
No Change:
PCI → PCI

Patient Management
At Patient Level
Patient Point of View



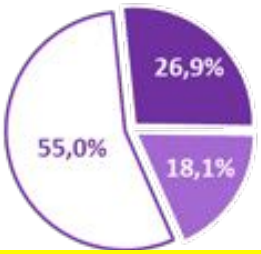
Patient management change in **26.9%** of patients

2C



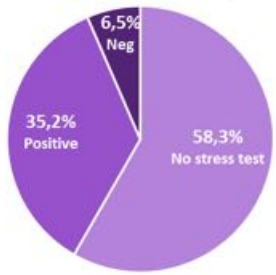
Change:
PCI → PCI of other vessel

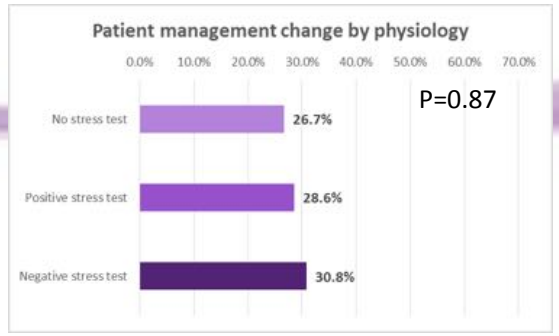
Procedural Management
At Patient Level
Physician Point of View

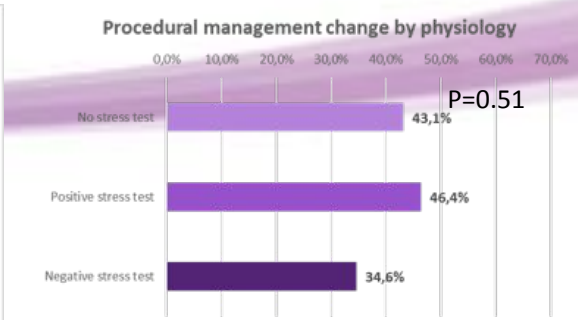


Management change in **45.0%** of patients

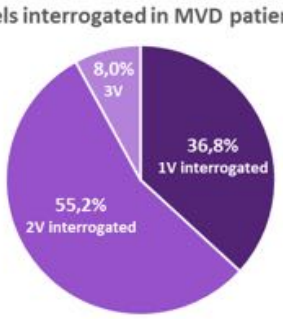
A

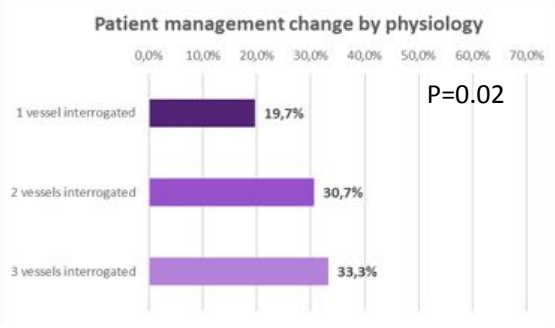


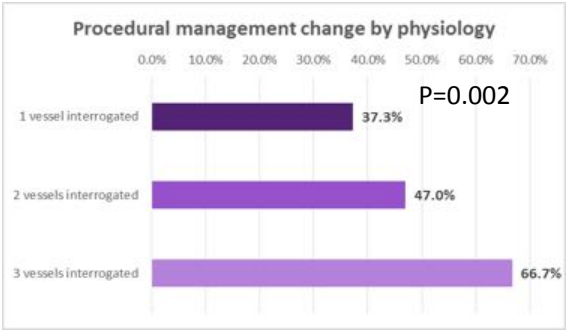




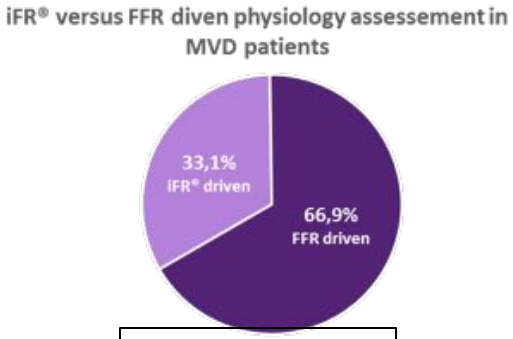
B



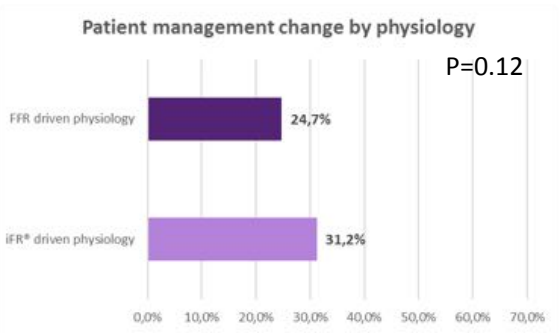


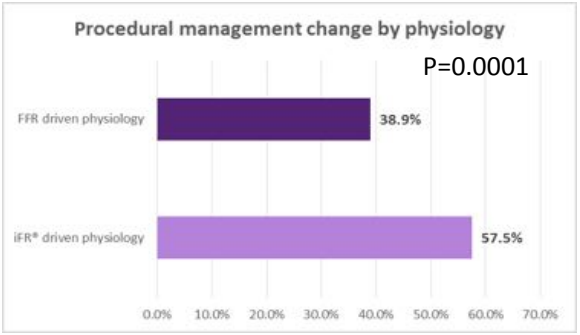


C



iFR : 1.8 vessels
FFR: 1.6 vessels





The NEW ENGLAND JOURNAL of MEDICINE

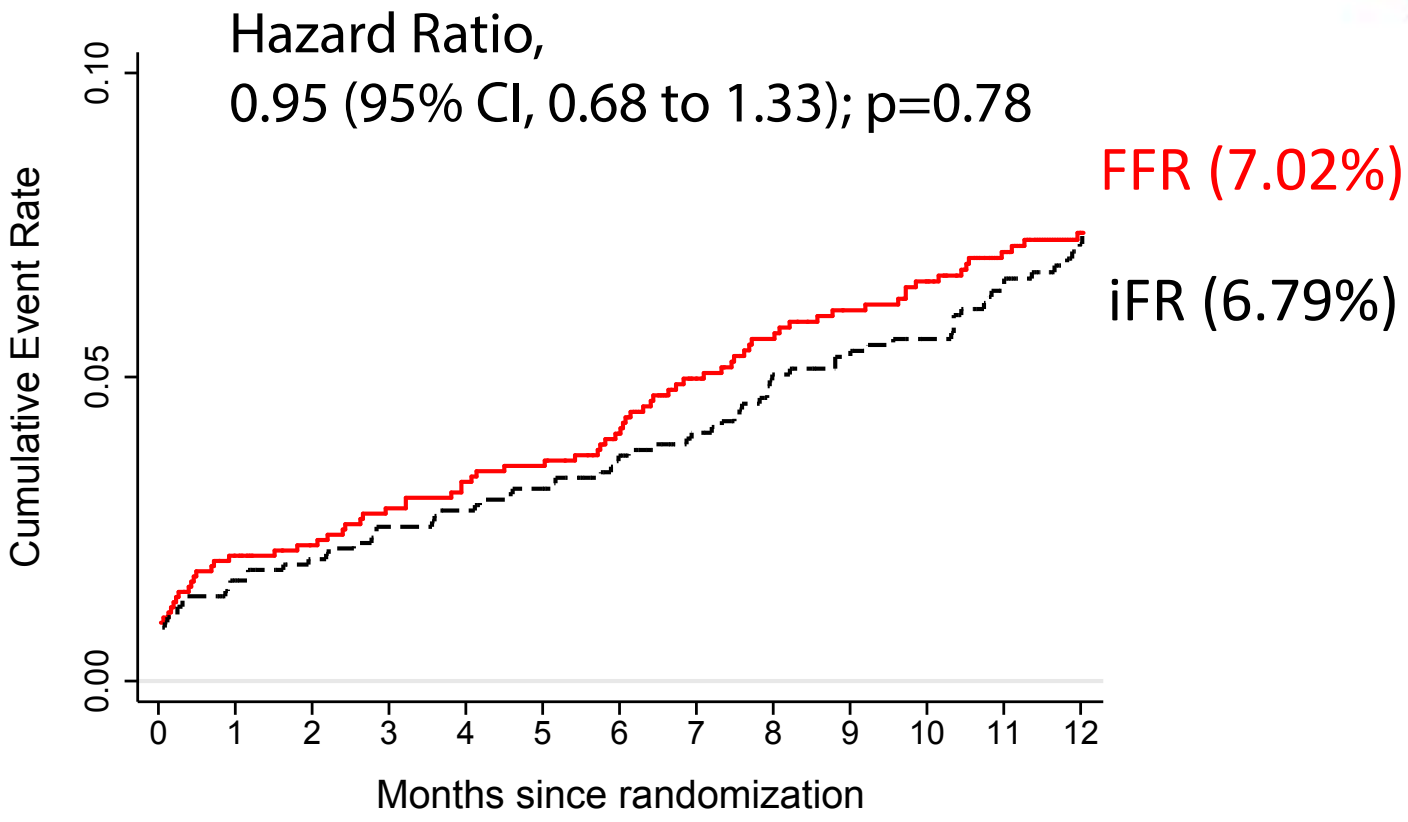
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Use of the Instantaneous Wave-free Ratio or Fractional Flow Reserve in PCI

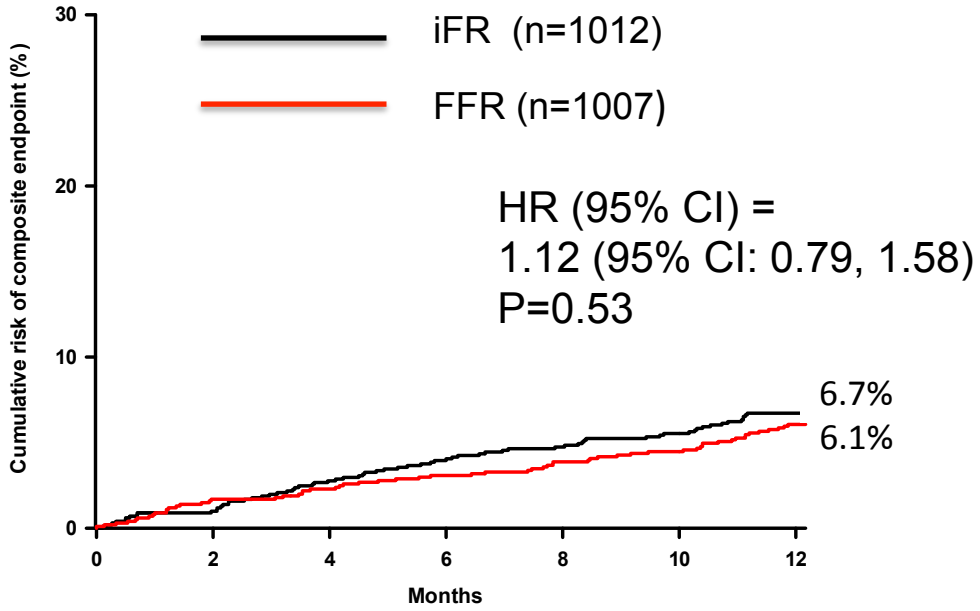
J.E. Davies, S. Sen, H.-M. Dehbi, R. Al-Lamee, R. Petraco, S.S. Nijjer, R. Bhindi, S.J. Lehman, D. Walters, J. Sapontis, L. Janssens, C.J. Vrints, A. Khashaba, M. Laine, E. Van Belle, F. Krackhardt, W. Bojara, O. Going, T. Härle, C. Indolfi, G. Niccoli, F. Ribichini, N. Tanaka, H. Yokoi, H. Takashima, Y. Kikuta, A. Erglis, H. Vinhas, P. Canas Silva, S.B. Baptista, A. Alghamdi, F. Hellig, B.-K. Koo, C.-W. Nam, E.-S. Shin, J.-H. Doh, S. Brugaletta, E. Alegria-Barrero, M. Meuwissen, J.J. Piek, N. van Royen, M. Sezer, C. Di Mario, R.T. Gerber, I.S. Malik, A.S.P. Sharp, S. Talwar, K. Tang, H. Samady, J. Altman, A.H. Seto, J. Singh, A. Jeremias, H. Matsuo, R.K. Kharbanda, M.R. Patel, P. Serruys, and J. Escaned

Primary endpoint – iFR equivalent to FFR



DEFINE FLAIR

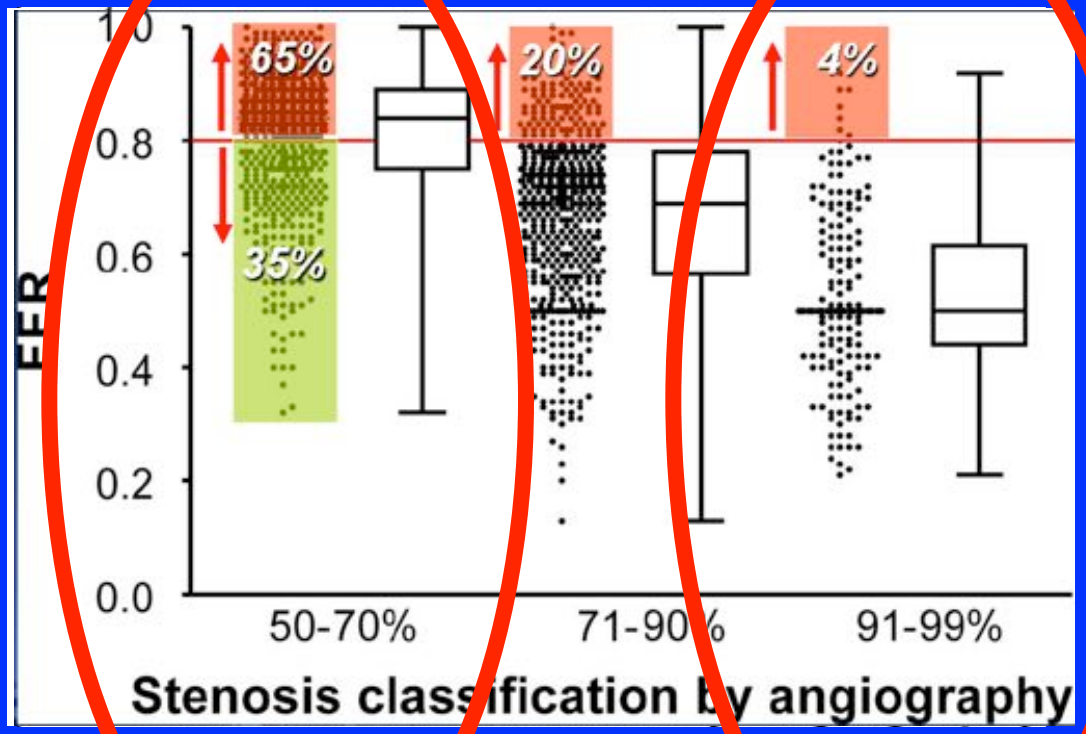
Primary Endpoint at 12 months
(Death, MI, Unplanned revascularization)



No. at Risk

iFR	1012	1002	984	971	963	956	944
FFR	1007	990	984	976	968	961	946

Angiography and functional significance

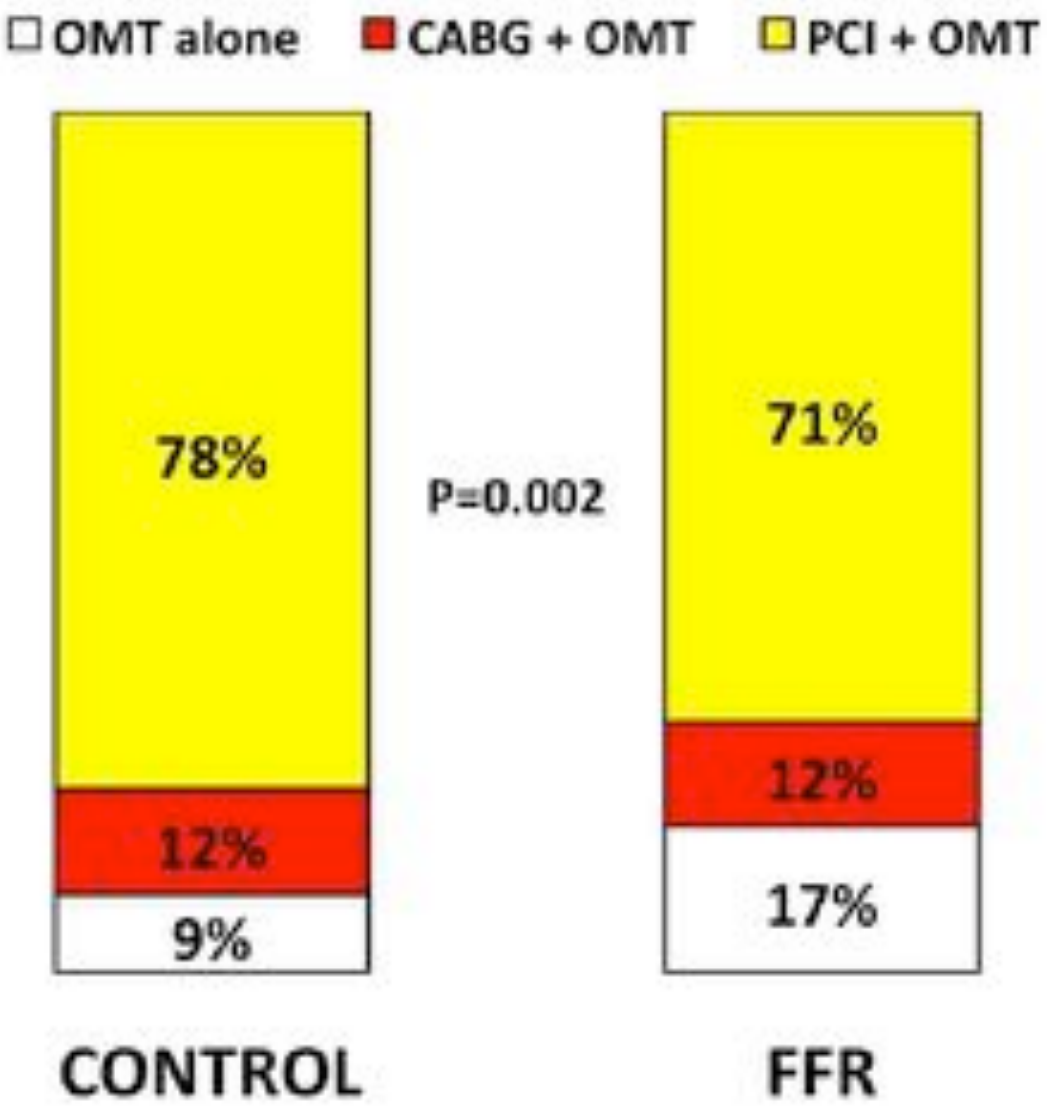


1329 lesions

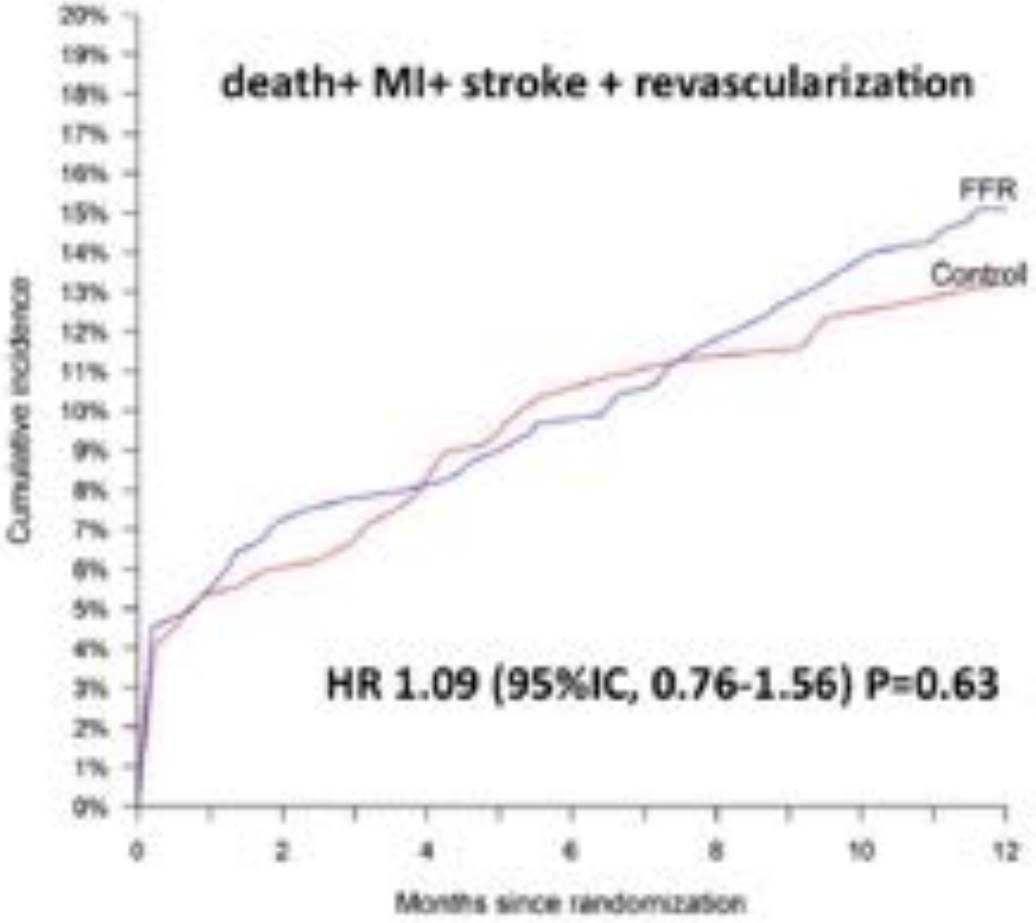
Bech et al. Circulation 2001

Tonino et al. TCT 2009

Therapeutic management (2)



Primary Endpoint at One Year*



***only for 797 patients having reached the one-year follow-up (85% of the population)**

1 patient lost of FU

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Editorial

Routine Fractional Flow Reserve Combined to Diagnostic Coronary Angiography as a One-Stop Procedure

Episode 3

Eric Van Belle, MD, PhD; Patrick Dupouy, MD; Gilles Rioufol, MD, PhD

Van Belle et al. Circ Cardiovasc Interv 2016

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Jorge Guardado, MD (Leiria)
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Maria João Sousa, MD (Porto)
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Renato Fernandes, MD (Évora)

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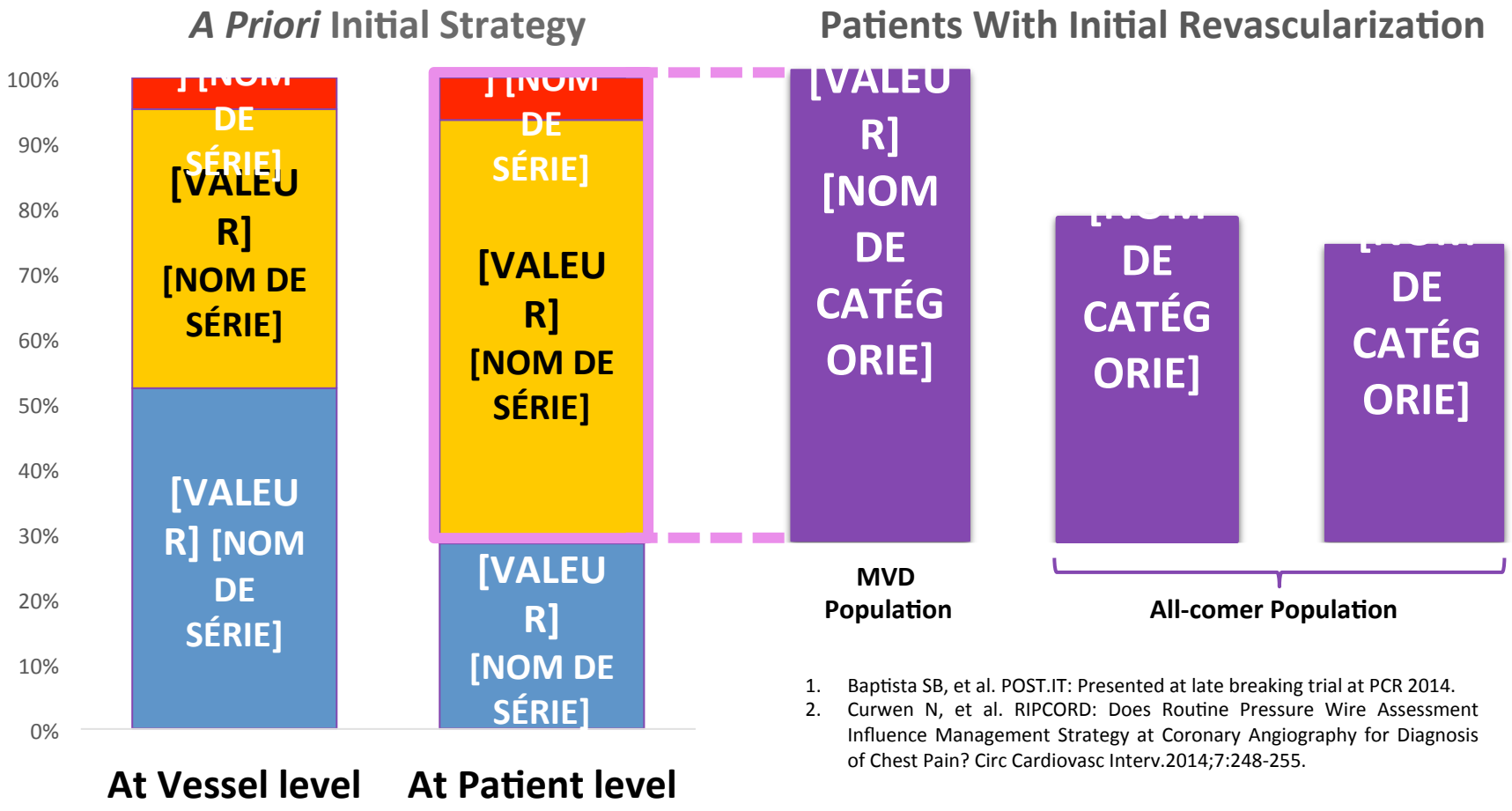
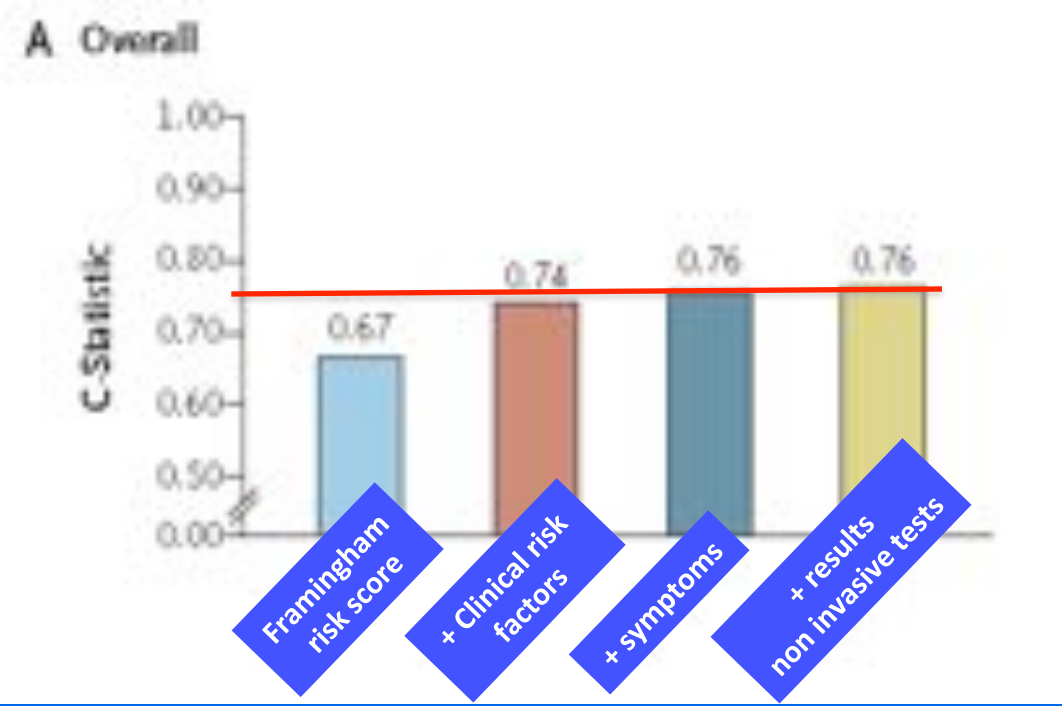
Laurent Leborgne, MD, PhD (Amiens)
Flavien Vincent (Lille)

Initial Treatment Strategy By Angiography



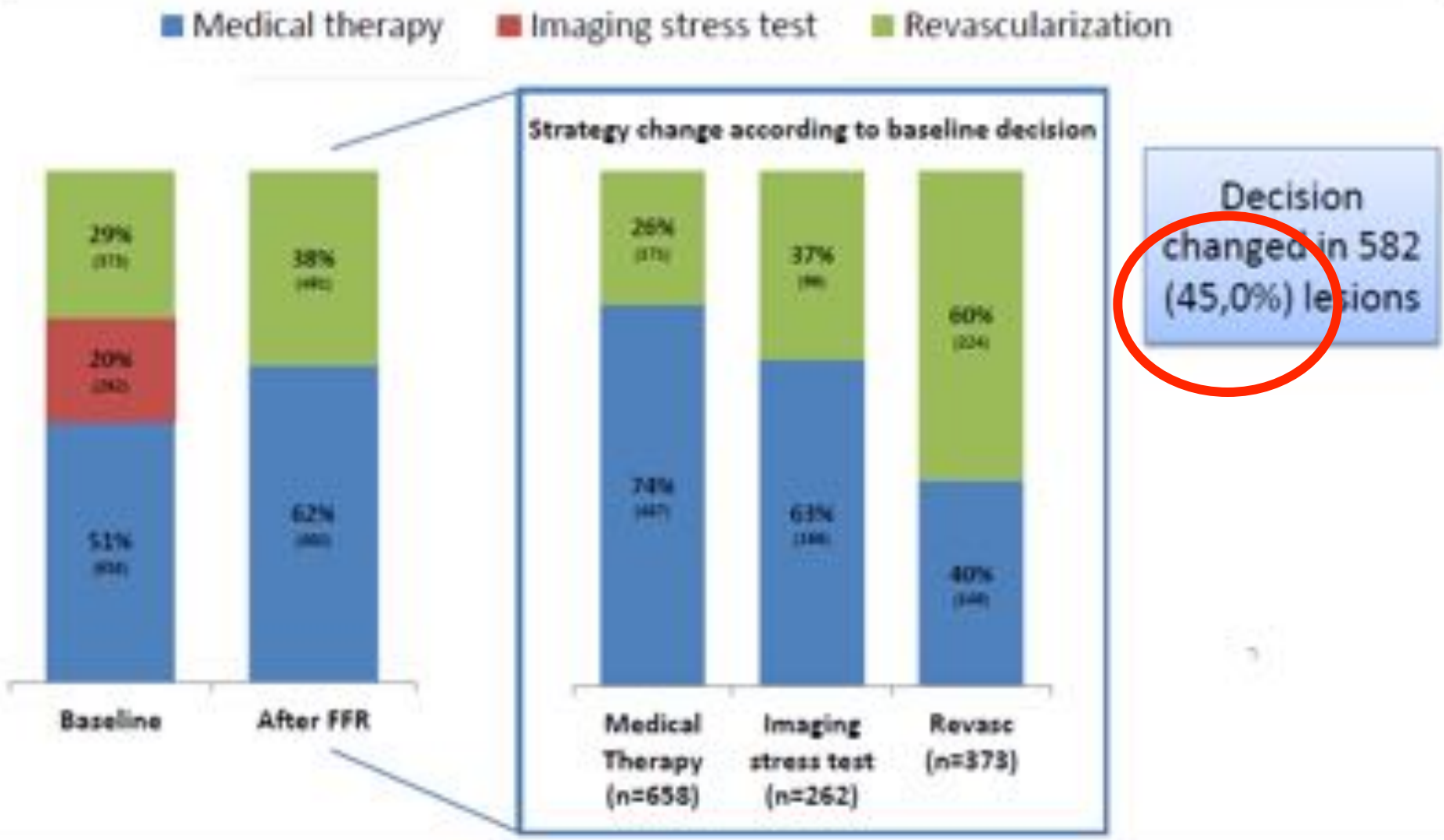
1. Baptista SB, et al. POST.IT: Presented at late breaking trial at PCR 2014.
2. Curwen N, et al. RIPCORD: Does Routine Pressure Wire Assessment Influence Management Strategy at Coronary Angiography for Diagnosis of Chest Pain? Circ Cardiovasc Interv.2014;7:248-255.

Value of non-invasive test
To predict CAD by angiography



Patel et al. NEJM 2010; 362:886

Results: strategy change *per lesion*



Baptista. Circ Cardiovasc Interv 2016
Van Belle et al. Circ Cardiovasc Interv 2016

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Editorial

Routine Pressure Wire Assessment at Time of Diagnostic Angiography

Is It Ready for Prime Time?

Eric Van Belle, MD, PhD; Gilles Rioufol, MD, PhD; Patrick Dupouy, MD

	Post–FFR Decision				
Post–Angiogram Decision	Medical	PCI	CABG	Further Info	Total
Medical	63	6	3	0	72
PCI	24	64	2	0	90
CABG	1	3	19	0	23
Further info	1	7	6	1	15
Total	89	80	30	1	200

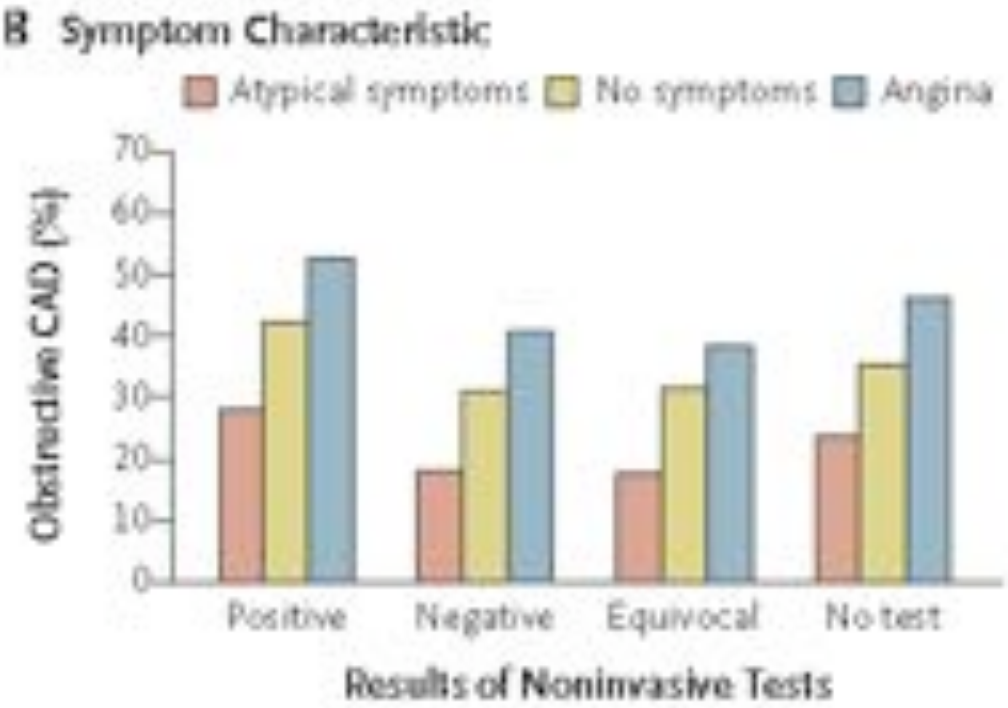
$P<0.001$ by McNemar test. CABG indicates coronary artery bypass grafting; FFR, fractional flow reserve; and PCI, percutaneous coronary intervention.

26% of patients changed therapy with FFR guidance

Curzen et al. Circ Cardiovasc Interv 2014
Van Belle et al. Circ Cardiovasc Interv 2014

Inclusion Criteria

Non-invasive test does not help to predict the risk of CAD



Patel et al. NEJM 2010; 362:886

Question 1

- **What is the value of non-invasive tests to select patient for coronary revascularization ?**

Analysis of Coronary Angioplasty Practice in the United States With an Insurance-Claims Data Base

Eric J. Topol, MD; Stephen G. Ellis, MD; Delos M. Cosgrove, MD; Eric R. Bates, MD;
David W.M. Muller, MBBS; Nicholas J. Schork, MA;
M. Anthony Schork, PhD; and Floyd D. Loop, MD

Background. Coronary angioplasty is frequently performed in the United States, with more than 300,000 procedures in 1990. Despite the high rate of use of the procedure, there have been few studies addressing practice patterns.

Methods and Results. From a private insurance claims data base of 5.4 million individuals, a total of 2,101 patients who underwent coronary angioplasty during 1988–1989 were identified. Using their 4,578 hospital admission records and 87,578 outpatient claim records, with an average follow-up of 332±182 days, we compared patients' outcomes and charges according to whether they had an exercise stress test before the procedure, by sex, by region of the country, and by whether the angioplasty was performed in an institution with a training program. Only 29% of the study cohort had exercise testing before angioplasty; patients in the West ($p=0.001$), those undergoing multivessel angioplasty ($p=0.00001$), and those whose procedures were performed at sites with training programs ($p=0.04$) were more likely to have a screening test, whereas women ($p=0.008$) and those with a recent myocardial infarction ($p=0.00001$) were less likely to have a screening test. The average length of stay for patients without myocardial infarction as a primary diagnosis was 5.6 days, with a total hospital charge of $15,027. In follow-up, 15.1% had coronary artery bypass surgery and 15% had at least one additional angioplasty procedure; the average follow-up charges were $4,879. Charges varied according to sex, region of the country, and academic status of the angioplasty institution. Certain outcomes showed variation by region of the country and academic status of the angioplasty institution.

Conclusions. The relative lack of an objective definition of myocardial ischemia and the marked variability of use of procedures according to geographic region suggest the need for further implementation of established guidelines. (*Circulation* 1993;87:1489–1497)

Conclusions

- ✓ Routine use of invasive physiology in patients with MVD, on-going UA/ NSTEMI or recent ACS is associated with a high rate of reclassification of management strategy (>30%).

- ✓ In ACS, Integrating FFR on clinical decision making and pursuing a treatment strategy divergent from angiography (including revascularization deferral) was as safe as in stable CAD patients.

- ✓ In MVD patient, implementation of iFR is safe and allows evaluation of more vessels which in turn leasd to a higher of reclassification.

Perspective

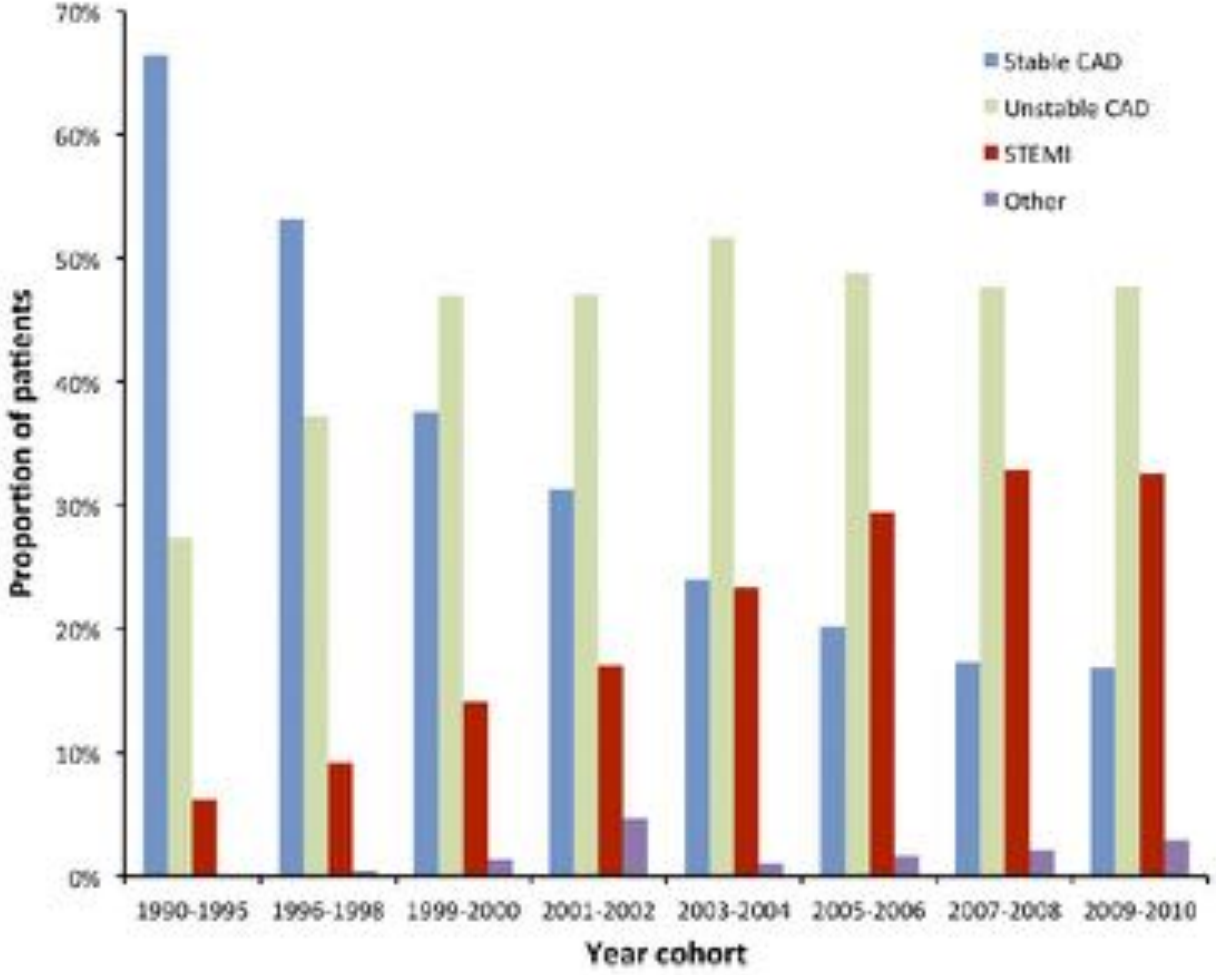
- PRIME-FFR and DEFINE REAL reinforces the observation made in previous national prospective physiology studies;
- They extends those previous findings to ACS and MVD patients and also to iFR® use;
- DEFINE FLAIR, Swedeheart, and Syntax II will provide clinical outcome data of the use of routine physiology in MVD patients.

Baseline Characteristics

Variable (n;%)	ACS Population	Non-ACS population	*p* value
Number of diseased vessels (>50%)			
0-1	284 (53.3%)	846 (58.4%)	0.055
2	156 (29.3%)	384 (26.5%)	
3	93 (17.4%)	220 (15.2%)	
Number of lesions evaluated			
1	391 (73.4%)	1049 (72.3%)	0.921
2	103 (19.3%)	300 (20.7%)	
3	31 (5.8%)	81 (5.6%)	
>3	8 (1.5%)	20 (1.4%)	
Lesion Characteristics			
Left Anterior Descending	414 (57.7%)	1146 (57.9%)	0.511
Left Main	32 (4.5%)	117 (5.9%)	0.121
Proximal LAD	125 (17.4%)	389 (19.7%)	0.187
Any proximal lesion	239 (33.3%)	687 (34.7%)	0.485
Lesion - % stenosis [mean±SD]	57.6±12.4	55.4±13.9	<0.001
ACC/AHA Classification B2/C	310 (43.2%)	757 (38.3%)	0.020
Lesions with FFR $\leq$0.80	288 (40.0%)	786 (39.7%)	0.902

Increasing Prevalence of ACS

144,039 Swedish patients (SCAAR Registry) undergoing PCI between 1990-2010



Fokkema, et al. J Am Coll Cardiol 2013;61:1222-30

Acute Microvascular Damage and FFR

STEMI

Variable Degree of Reversible Microvascular Stunning

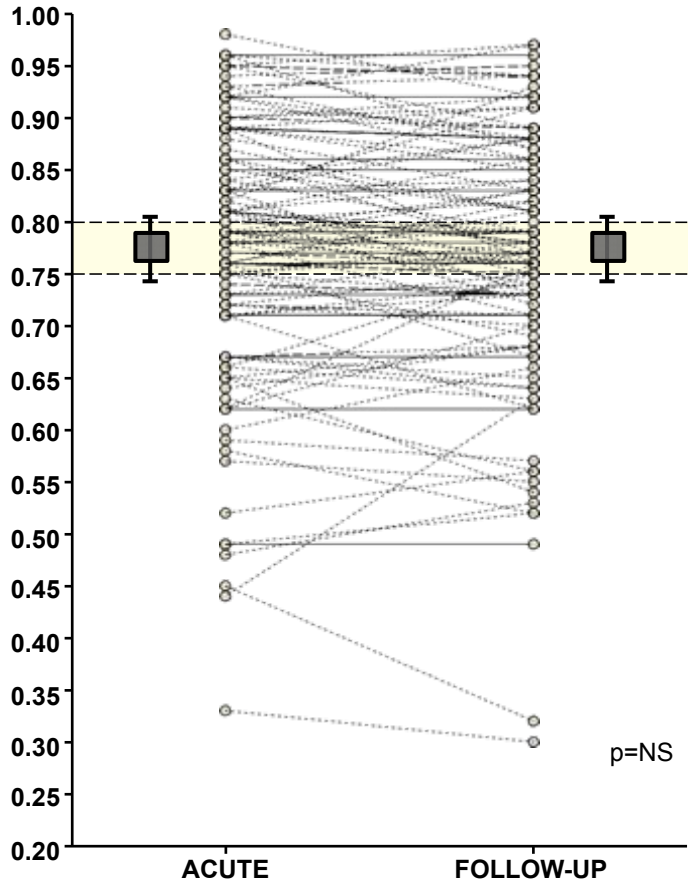
Maximum Achievable Flow is Less

Smaller Gradient and Higher FFR across Any Given Stenosis

With time, the microvasculature may recover, maximum achievable flow may increase, and a larger gradient with a lower FFR may be measured

FFR STEMI (Non-Culprit Vessels)

101 patients with an acute coronary syndrome (75 STEMI, 26 NSTEMI)
112 non culprit stenoses FFR measured acutely and 35±24 days later



In only 2/112 stenoses was the FFR >0.80 during the ACS and <0.75 at follow-up.

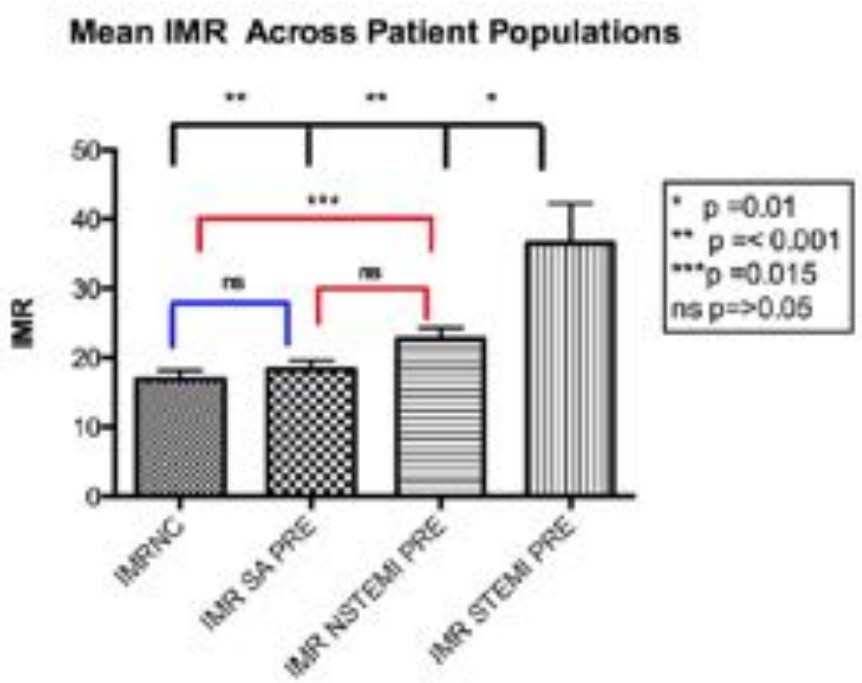
Ntalianis, et al. J Am Coll Cardiol Intv 2010;3:1274

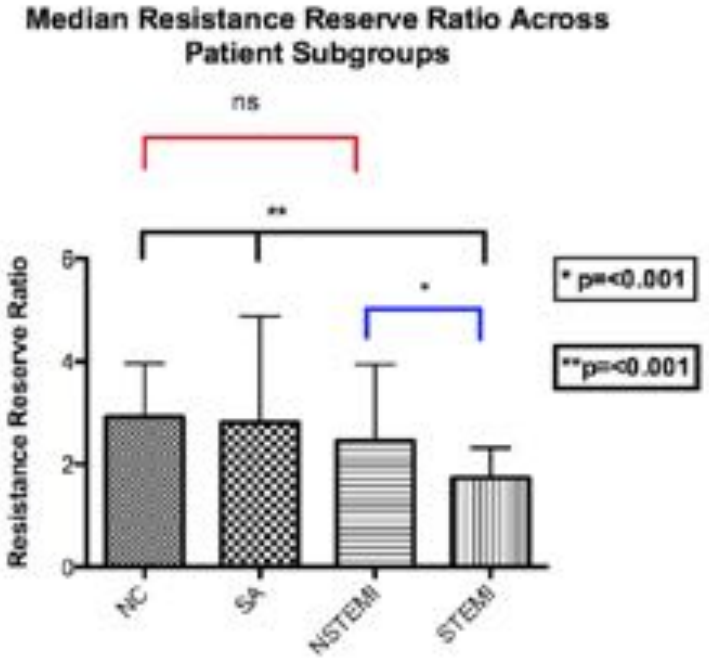
FFR during NSTEMI

- Can we measure FFR in non ST elevation acute myocardial infarction?
  - In the culprit vessel?
  - In the non-culprit vessel?
  - When we don’t know whether it the culprit or not?

Vasodilatory Capacity of the Coronary Microcirculation is Preserved in Selected Patients With Non–ST-Segment–Elevation Myocardial Infarction

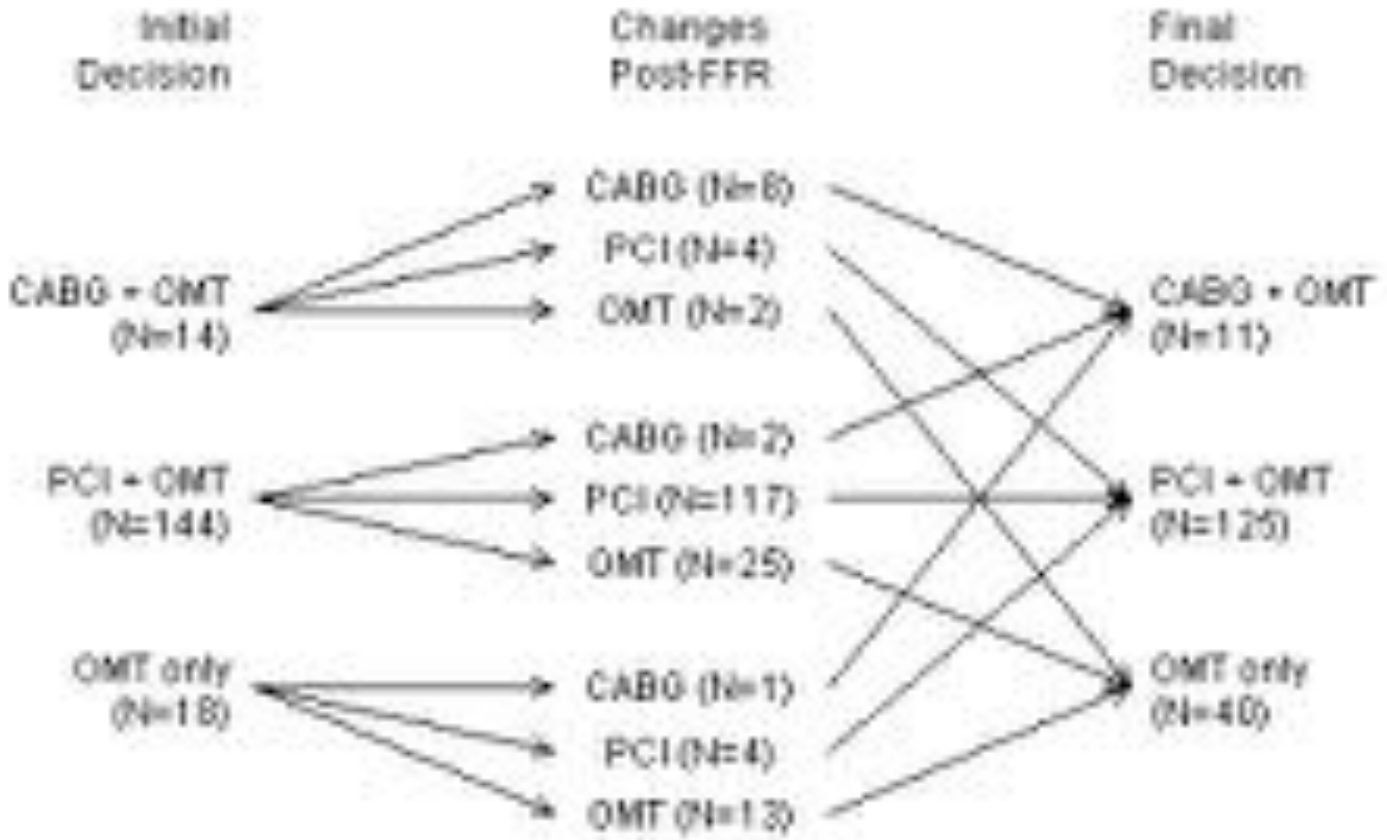
Jamie Layland, MBChB; David Carrick, MBChB; Margaret McEntegart, MBChB, PhD; Nadeem Ahmed, BSc; Alex Payne, MBChB; John McClure, PhD; Arvind Sood, MBChB, MD; Ross McGeoch, MBChB, MD; Andrew MacIsaac, MBBS, MD; Robert Whitbourn, MBBS, Bsc; Andrew Wilson, MBBS, PhD; Keith Oldroyd, MBChB, MD; Colin Berry, MBChB, PhD





Layland, et al. Circ Cardiovasc Interv 2013

FAMOUS-NSTEMI trial

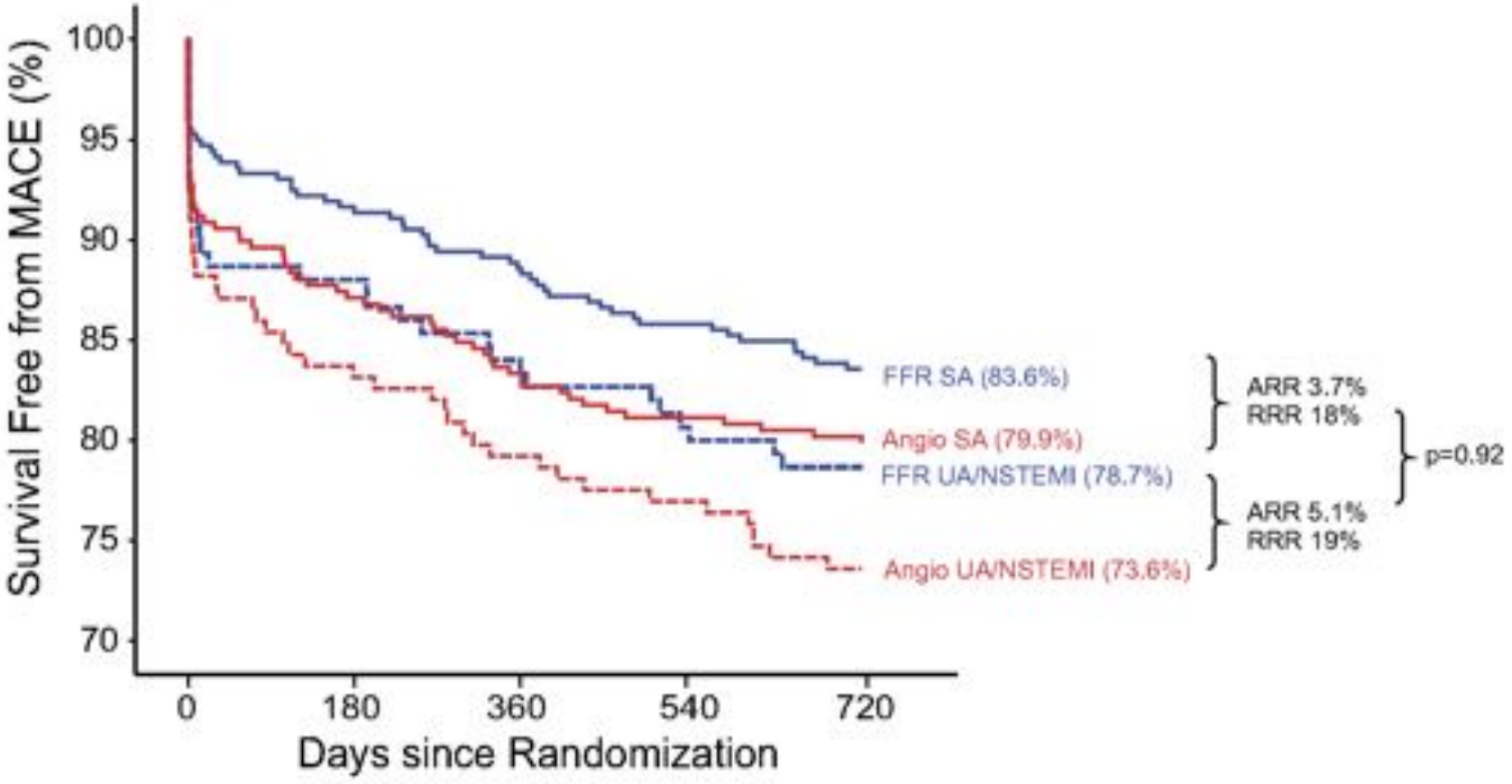


FFR treatment change ~ 22% of patients

ESC Hotline 1 Sep 2014

FFR NSTE ACS (Mixed Culprit + Non Culprit Vessel)

Benefit of FFR-guided PCI in patients with ACS (n=328) –FAME



Tonino, et al. J Am Coll Cardiol Intv 2011;4:1182-9.

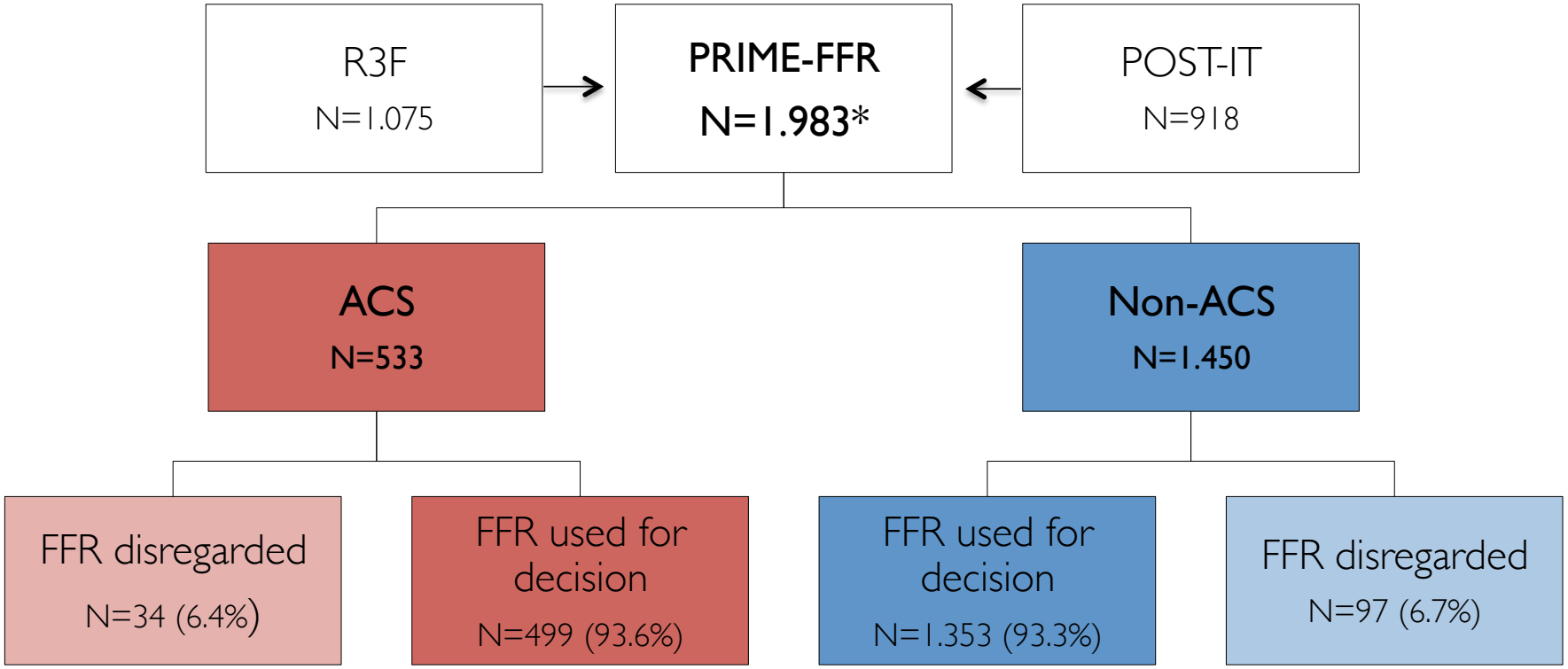
PRIME-FFR

POST-IT and R3F Integrated Multicenter registriEs - Implementation of FFR in Routine Practice

Why this study is important ?

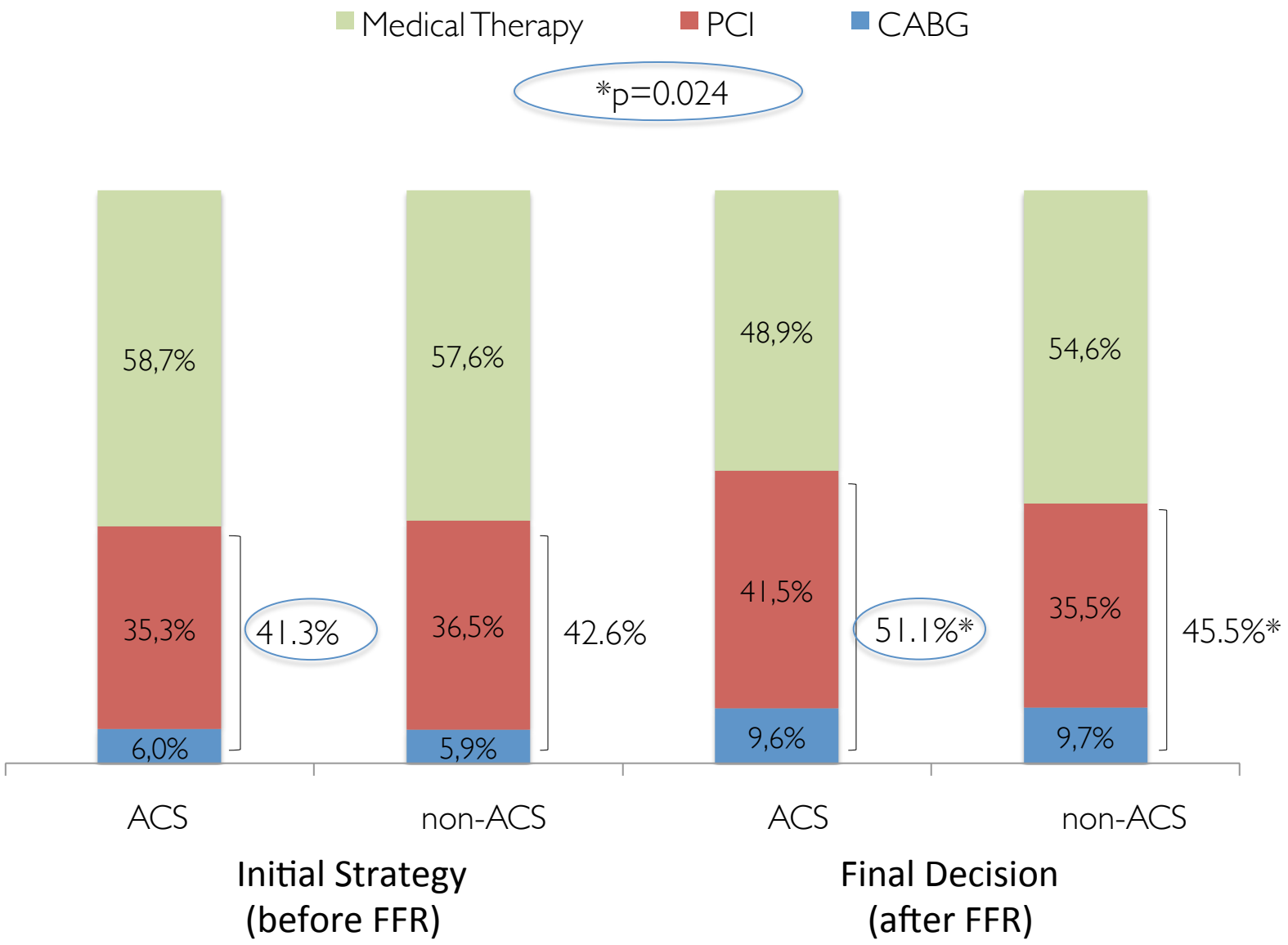
- In ACS, what is rate of reclassification of the management strategy (medical, PCI, CABG) with routine FFR usage?
- How does the rate of reclassification compare with non-ACS patients?
- Is FFR–based reclassification of the management strategy; i.e. against strategy suggested by angiography; safe in ACS patients?
- Is FFR-based deferral to medical treatment able to identify a population at low risk?

Study Design & Endpoints

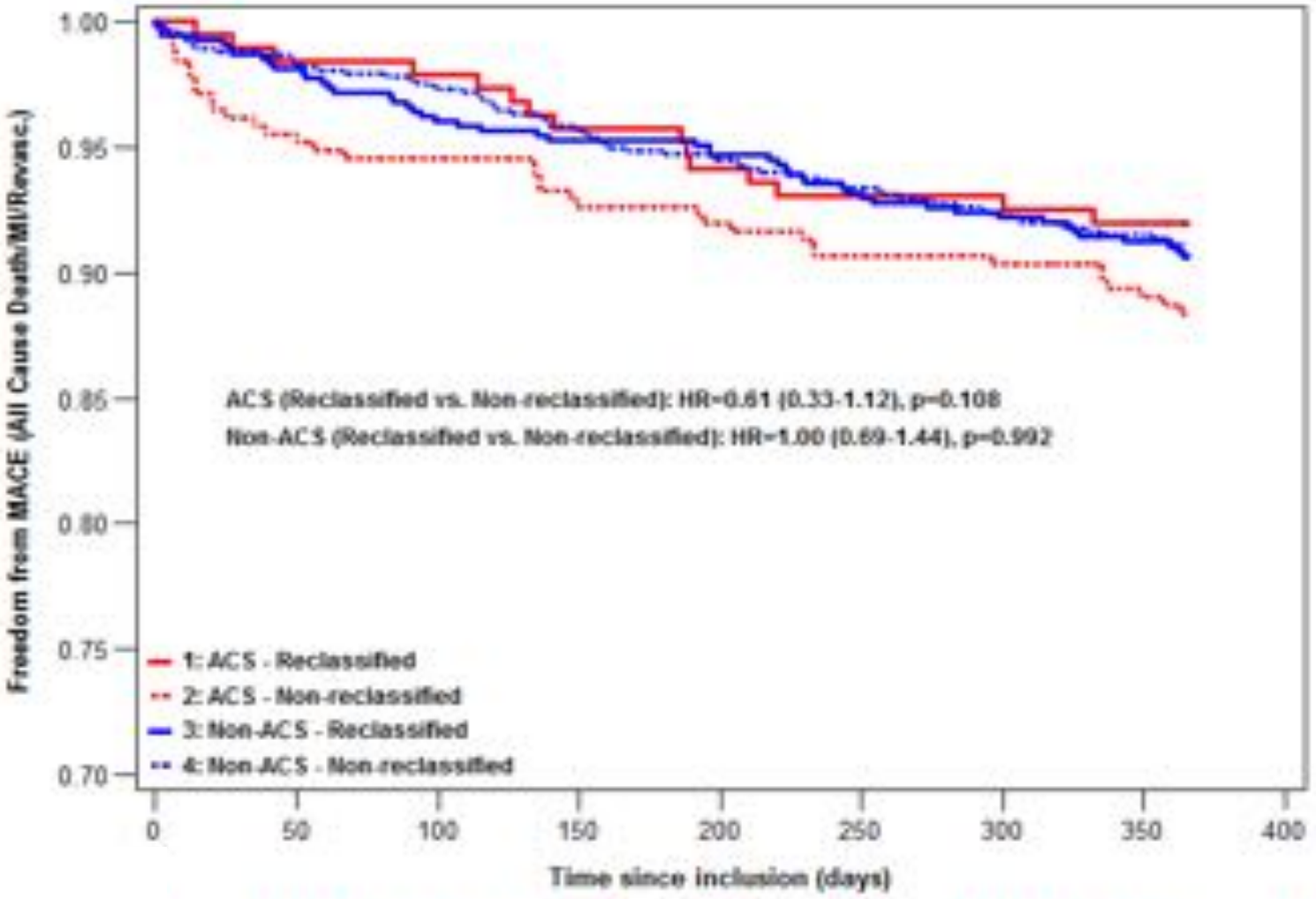


*FFR result unavailable in 10 patients

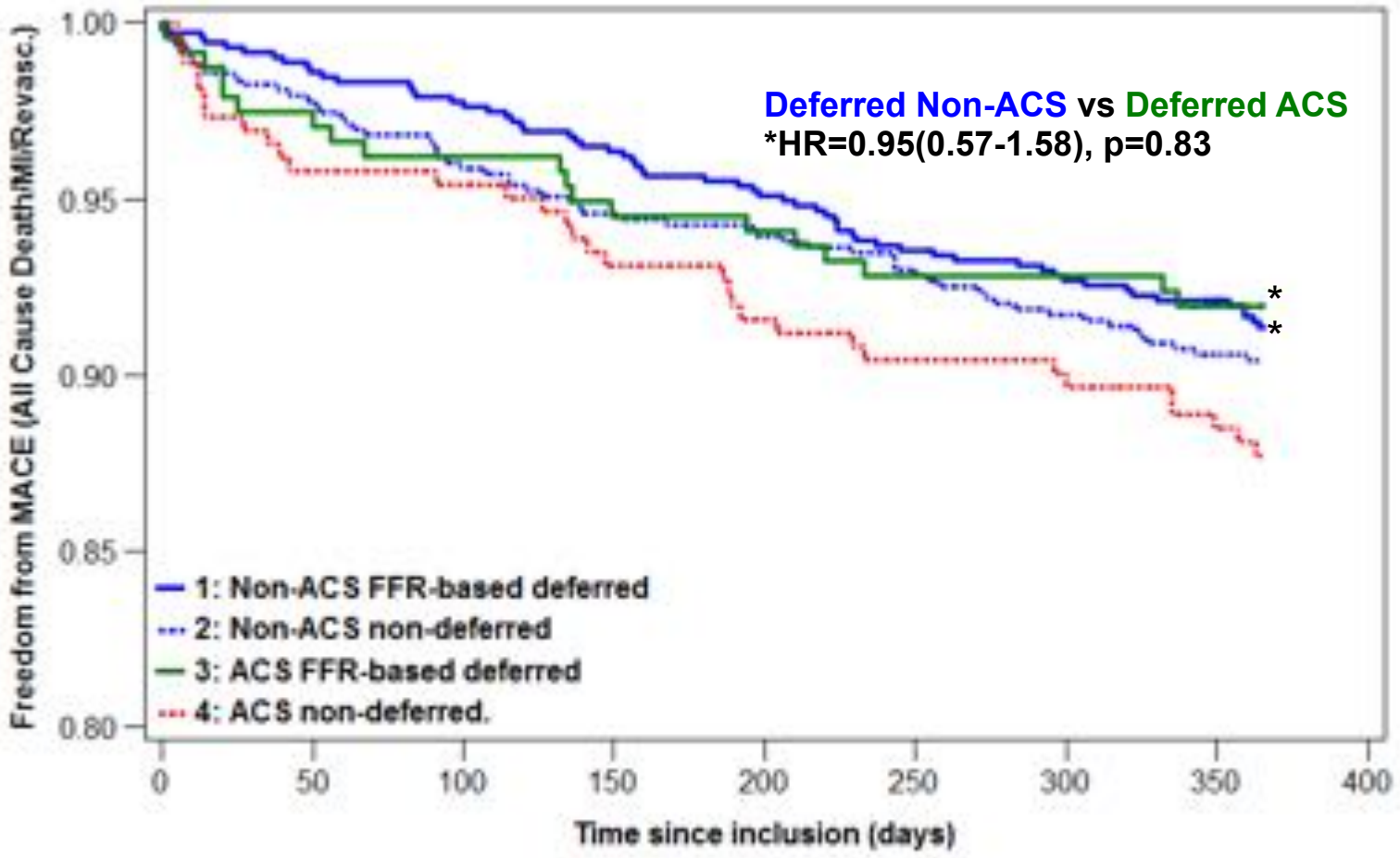
FFR & Treatment strategy change



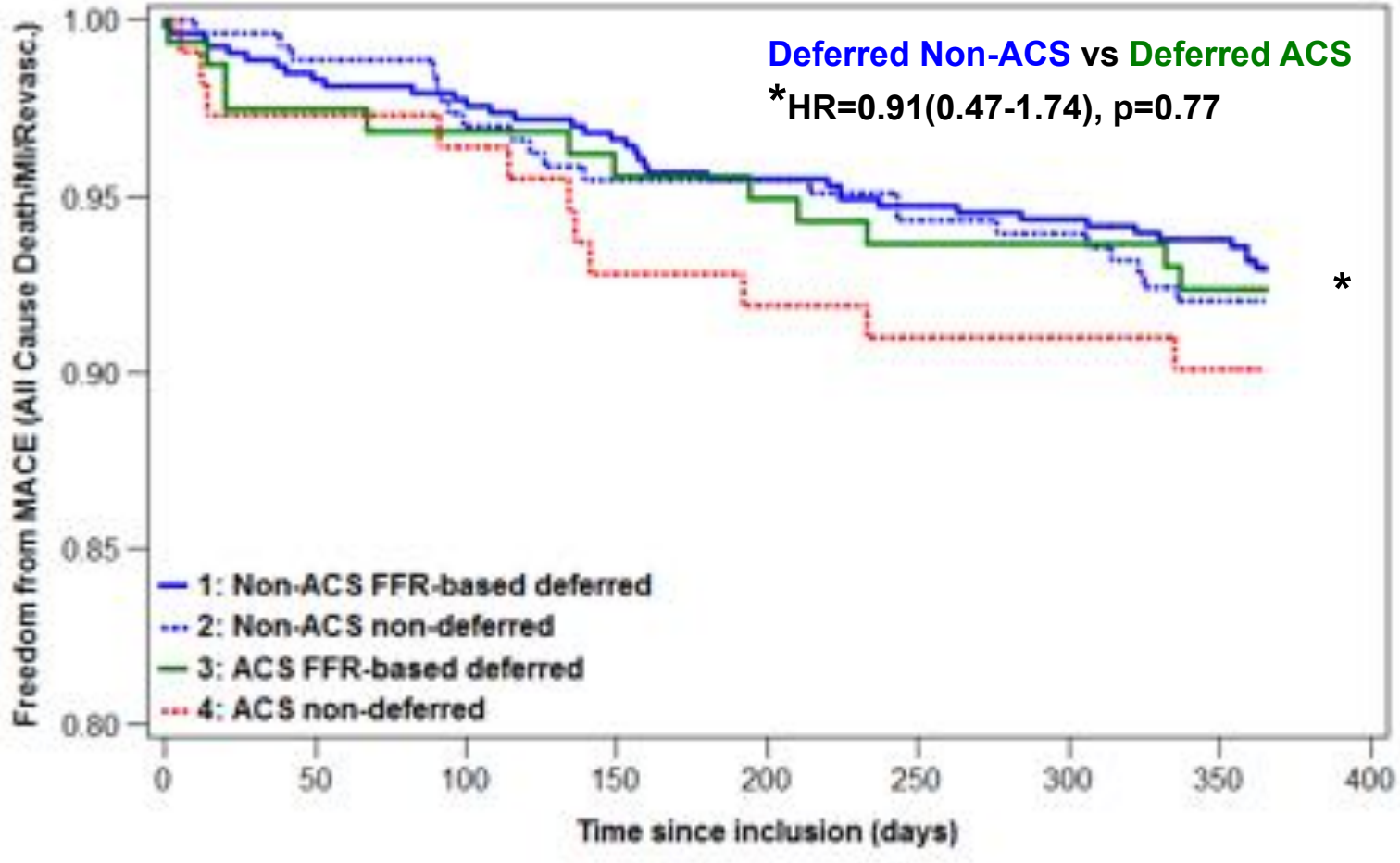
Safety of FFR-based reclassification in ACS



Safety of FFR deferral in ACS

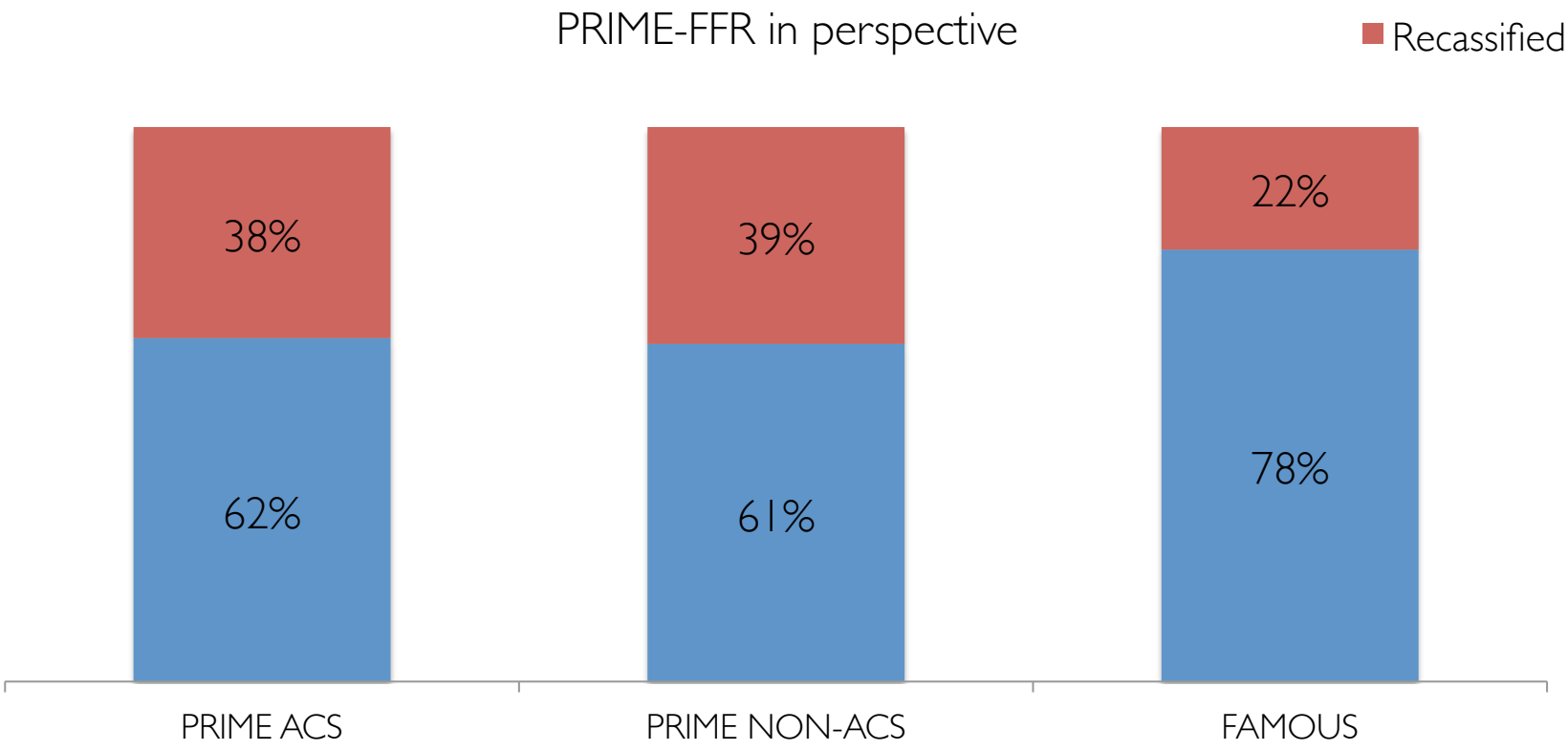


Safety of FFR-deferral in ACS investigated at culprit lesion (single vessel CAD)



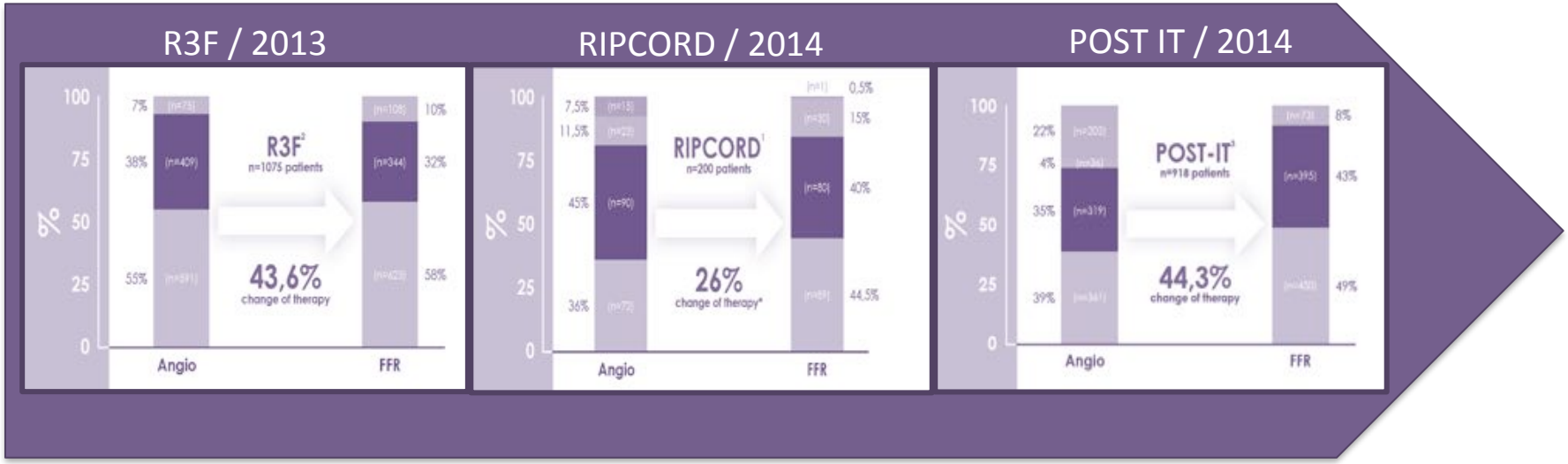
No. At Risk									
1:	532	522	518	513	504	498	494	480	0
2:	265	261	256	251	251	248	247	239	0
3:	158	154	152	150	149	146	146	141	0
4:	111	108	107	103	102	101	101	98	0

Conclusions



Background

- Results from national studies have shown that FFR evaluation during diagnostic angiography impacts the coronary revascularization strategy on a range of 26 to 44% of patients.
- There is limited data on utilization of coronary physiology and reclassification in Multi-Vessel Disease (MVD) population



Van Belle E, et al. Outcome impact of coronary revascularization strategy reclassification with FFR at time of diagnostic angiography: insights from a large French multicenter FFR registry. Circulation. Published online 19 Nov 2013

Curzen N, et al. RIPCORD: Does Routine Pressure Wire Assessment Influence Management Strategy at Coronary Angiography for Diagnosis of Chest Pain? Circ Cardiovasc Interv. 2014;7:248-255.

Baptista SB, et al. POST.IT: Presented at late breaking trial at PCR 2014.
Market Model data on file at Volcano Corporation.

Objectives

As systematic FFR multi-vessel assessment is time consuming and therefore rarely performed in routine practice, the iFR® index may help to simplify the physiology assessment of MVD patient population.

The DEFINE REAL objectives are:

- To assess prospectively the impact of physiology on revascularization strategy of MVD patients compared to diagnostic angiogram only.
- To analyze how FFR and iFR® are used in routine practice during physiology evaluation of MVD patients.

Methodology

ANGIOGRAPHY

PHYSIOLOGY

CHANGE(S) ?

Patient with Lesion DS% >40 in 2 or 3 different major vessels

Patient Eligible should be for Physiology Evaluation

Initial Treatment Strategy based on **Angiography (and clinical information)**

➔ CABG, PCI or OMT

Final treatment strategy based on **Physiology**

➔ CABG, PCI or OMT

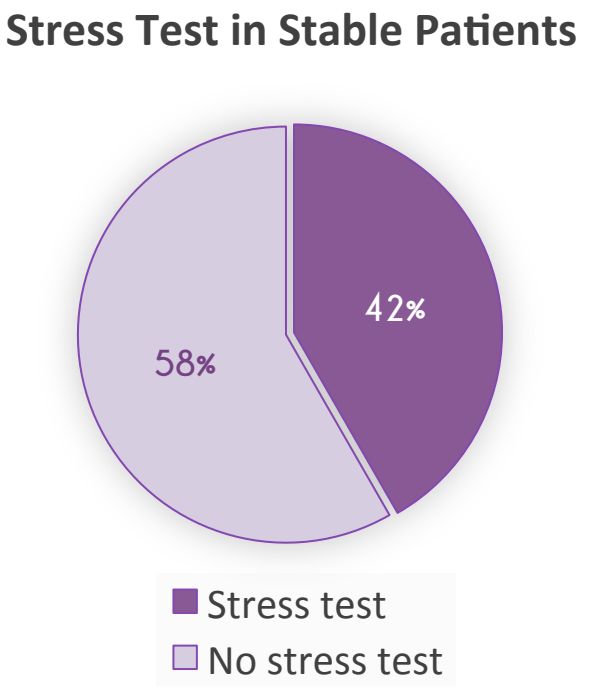
Change of Treatment Strategy based on the Difference between Initial and Final Treatment:

➔ At Vessel level

➔ At Patient level

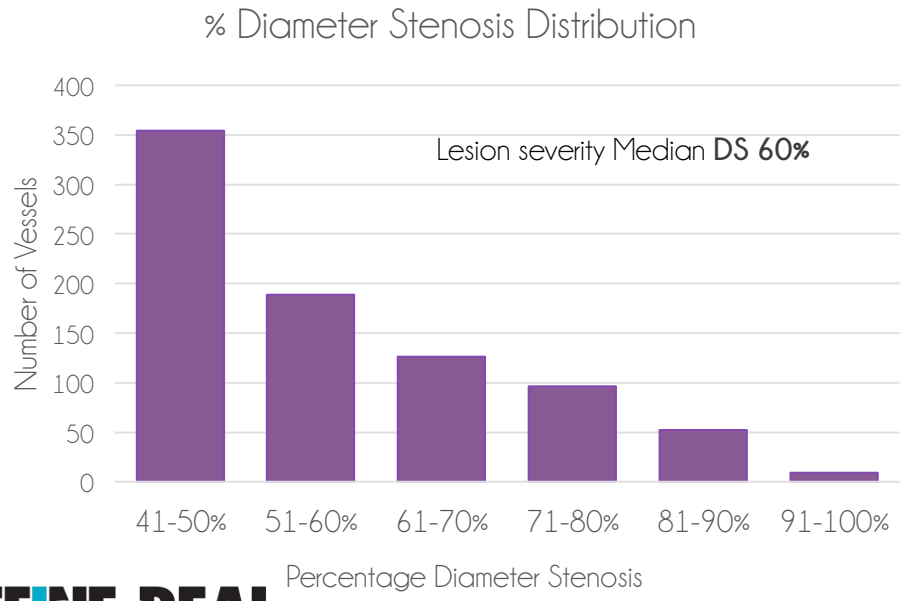
Patient Demographics

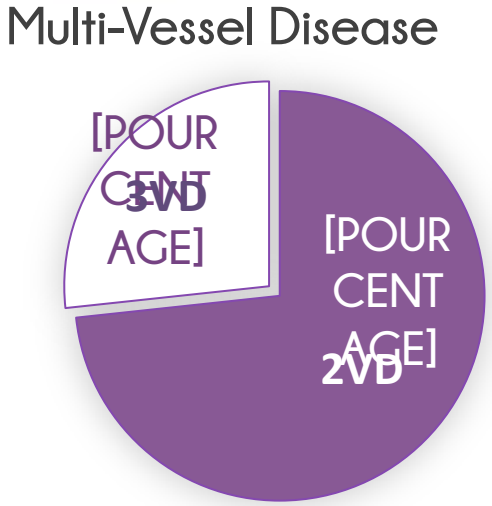
Patient Demographics	n = 484
Gender (male)	80%
Age (mean)	66.7 yr
Previous MI	36%
ACS	17.8%
Diabetes	26.7%
Normal LVEF	62.8.%
Non-invasive stress test	26.7%

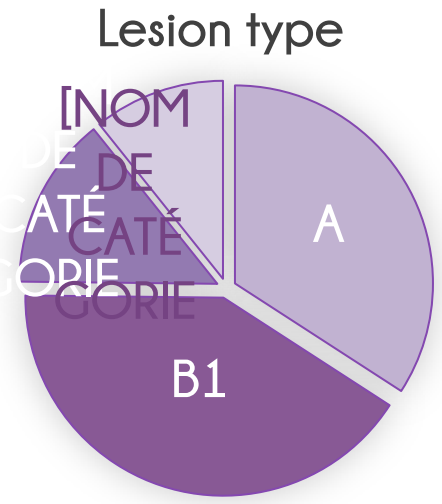


Baseline Characteristics

Patients population	**484**
• Patient with LM involved	9.1%
Vessels diseased	**1107**
• Average per patient	**2.29**
Vessels assessed by physiology	**830 (75%)**
• Average per patient	**1.71**

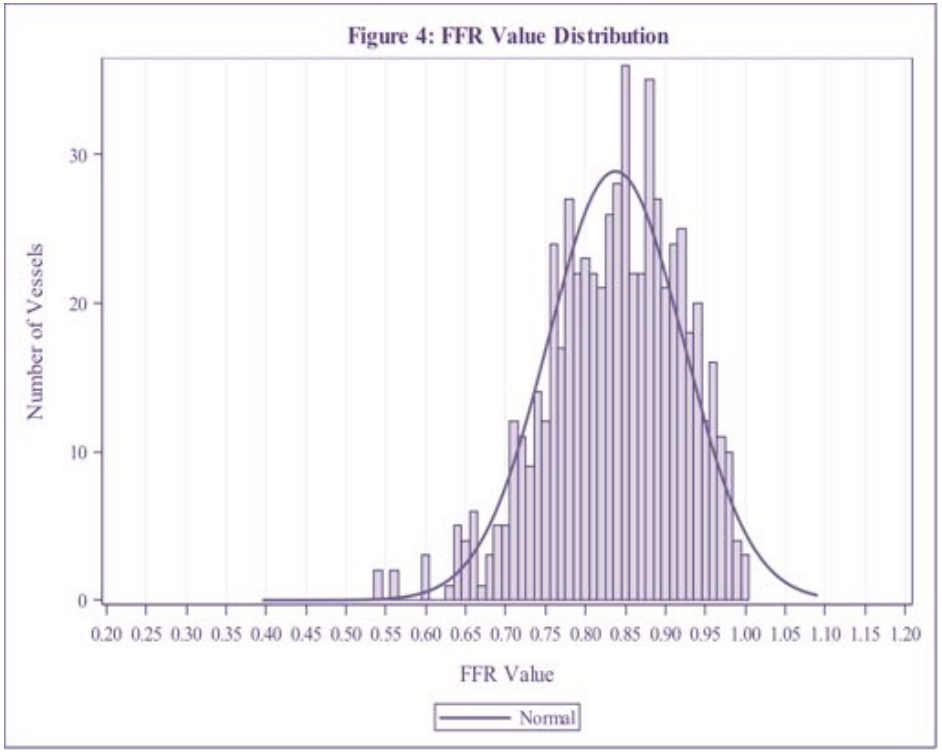






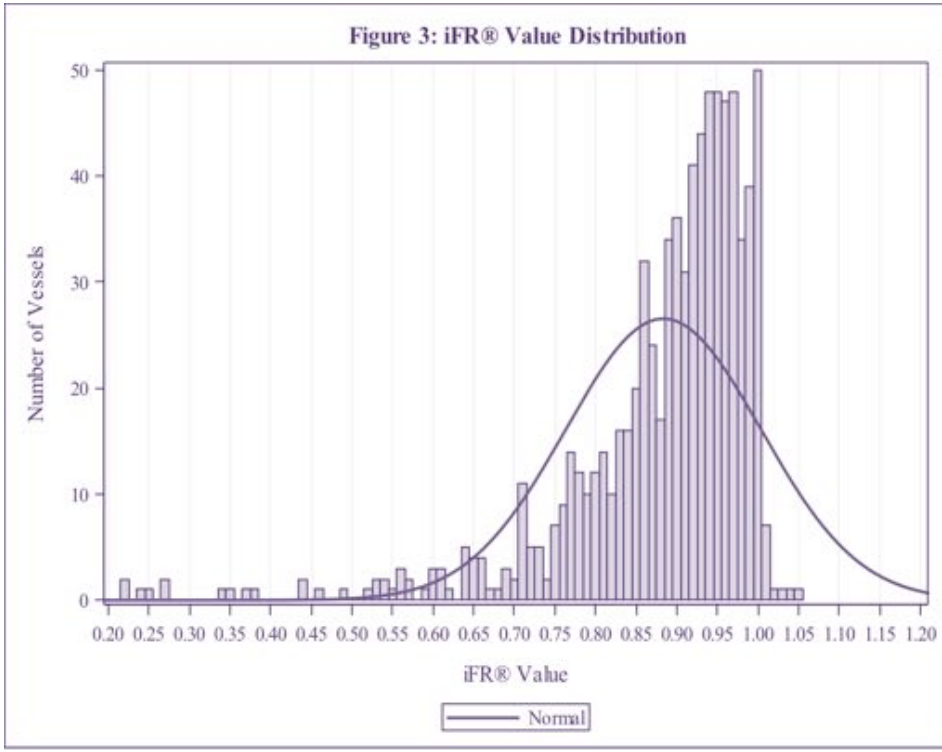
DEFINE REAL

Results of FFR/iFR®



Median FFR Value: 0,85

n = 608

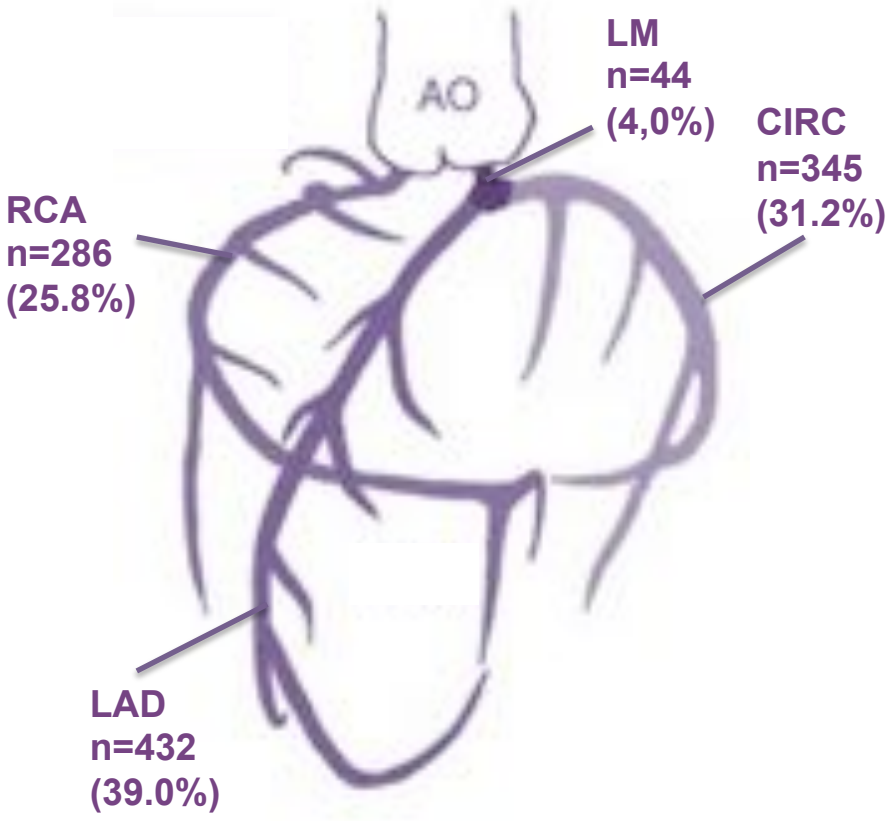


Median iFR® Value: 0,92

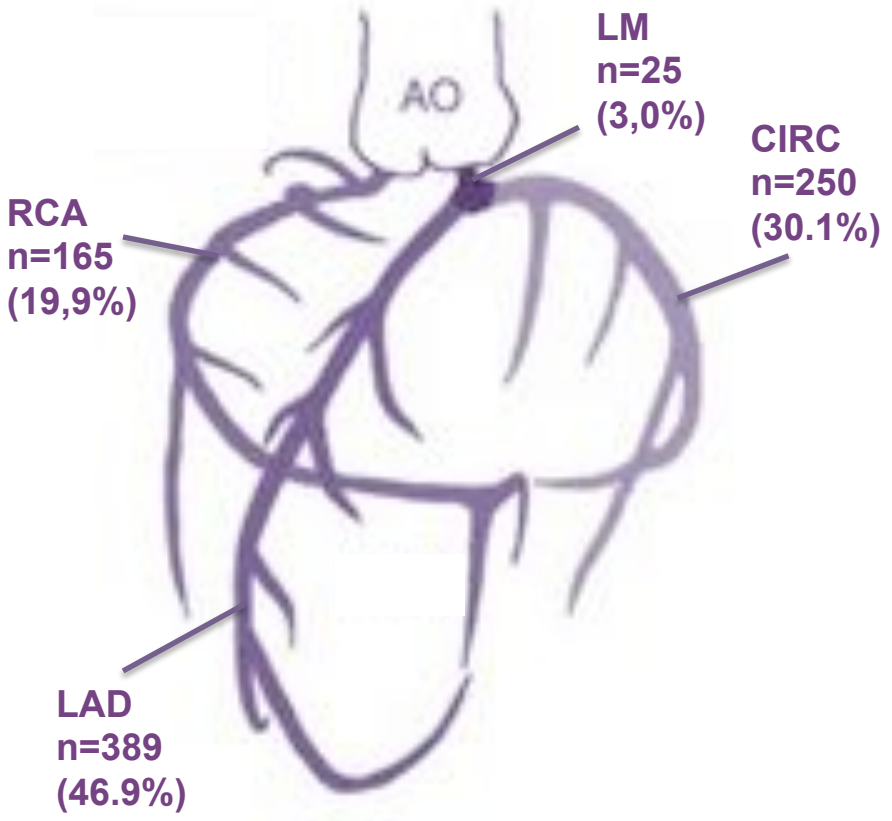
n = 793

Baseline Characteristics

Diseased Vessels by Angiography [n=1107]

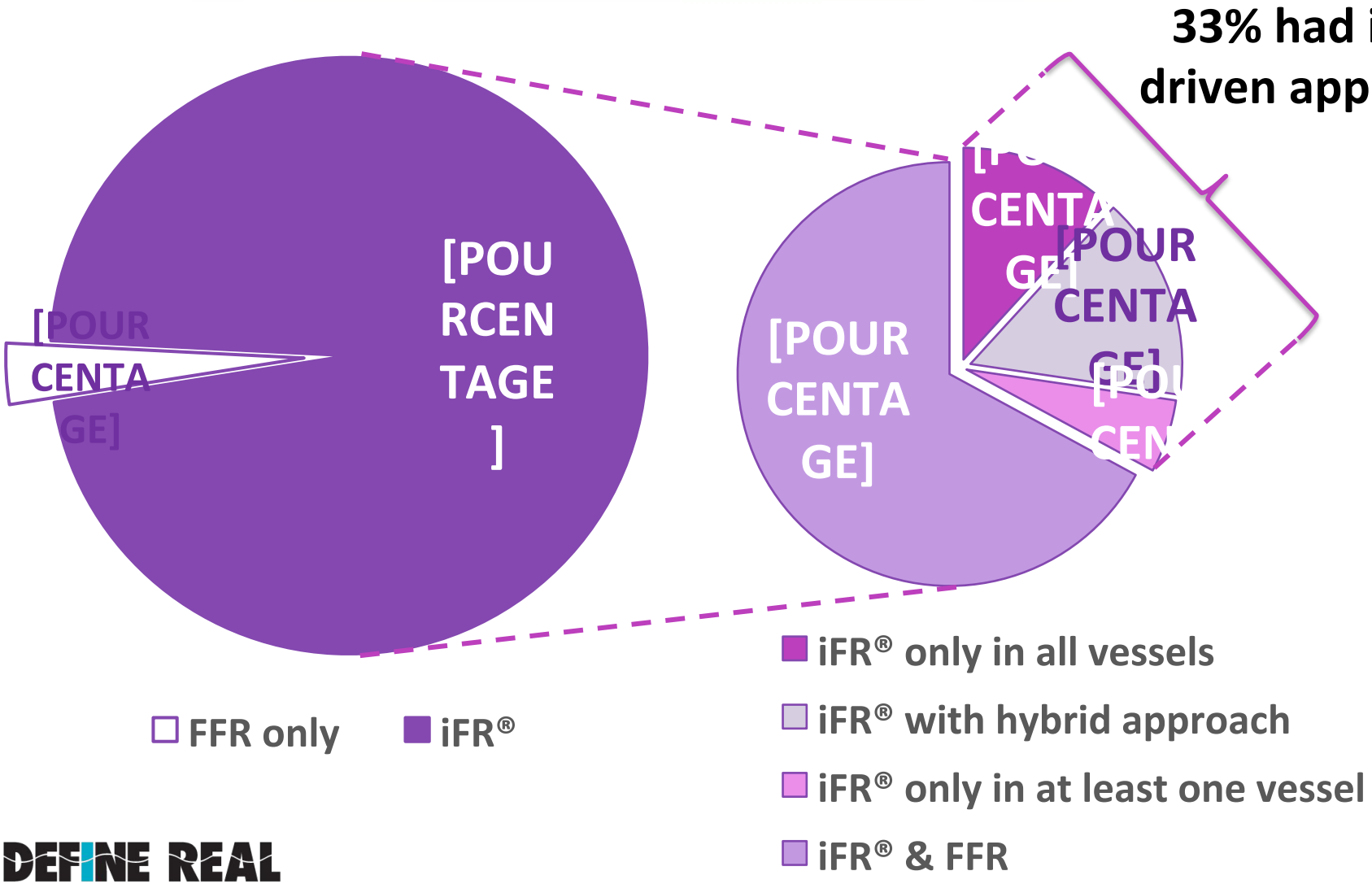


Vessels Interrogated with Physiology [n=830]



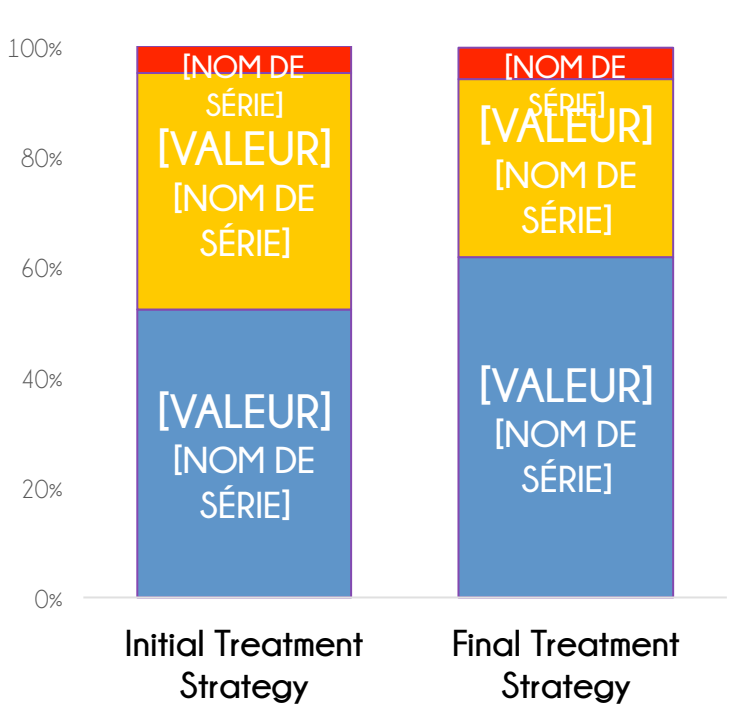
In this MVD population, 75% of diseased vessels were interrogated by Physiology

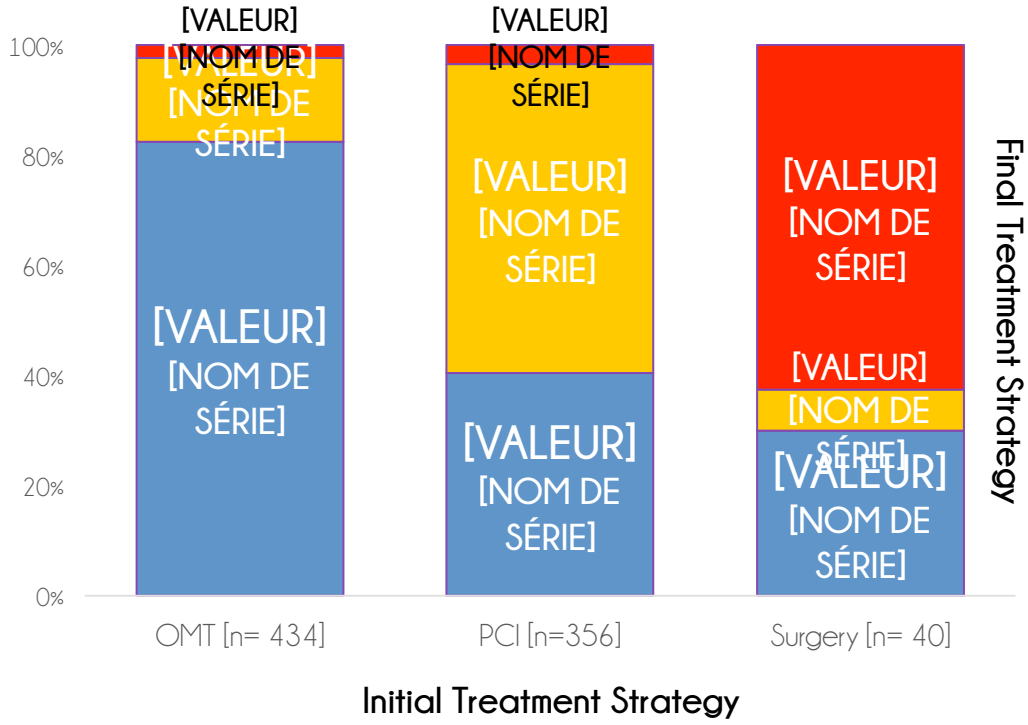
Physiology Approaches



Changes of Treatment Strategy

At Vessel Level, treatment decision was changed after physiology assessment for **30.0% of Vessels**

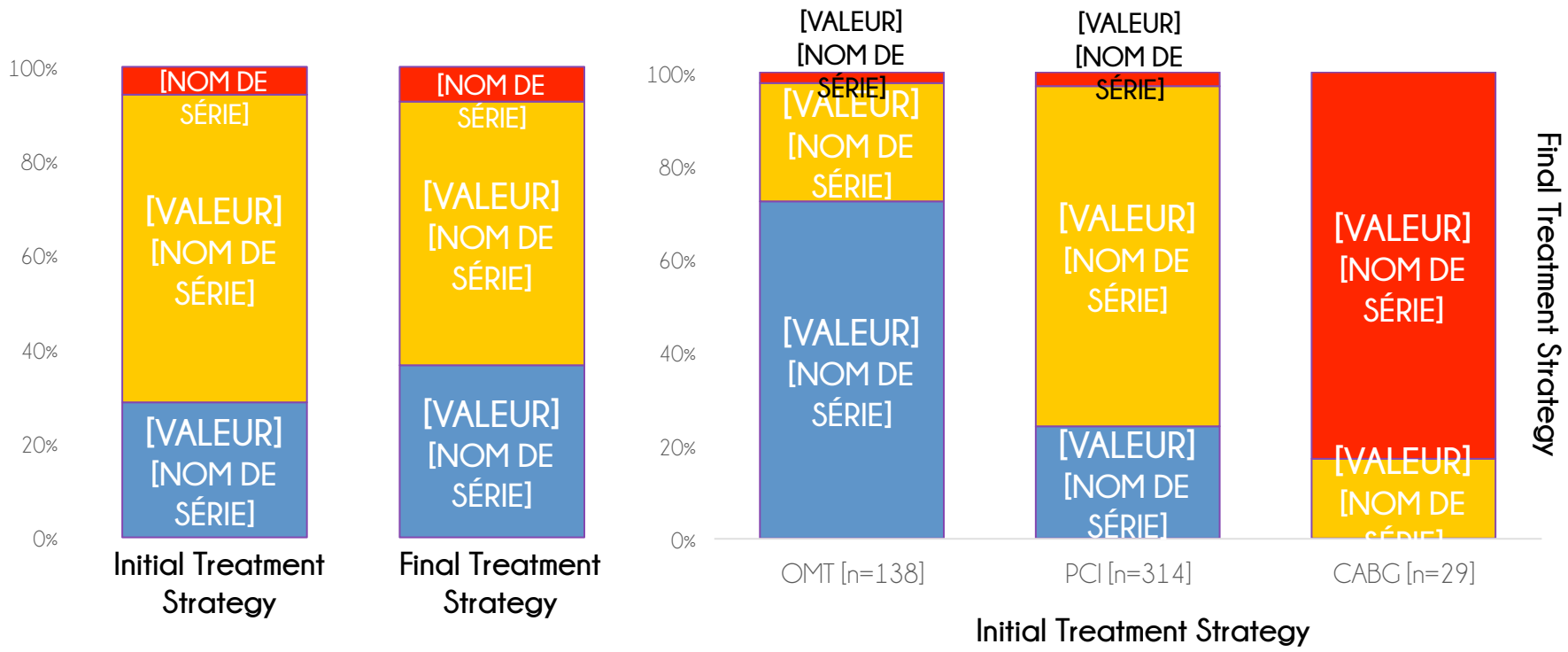




DEFINE REAL

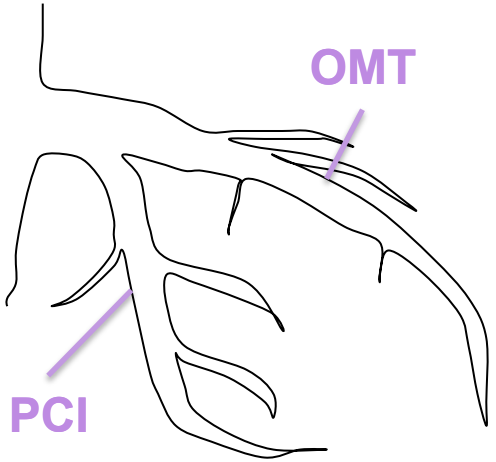
Changes of Treatment Strategy

At Patient Level (Macro Strategy), treatment decision changed after physiology assessment **for 27%** of Patients



Changes of Treatment Strategy

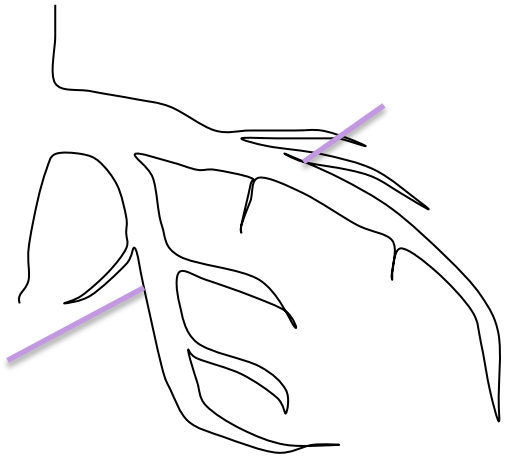
Initial Treatment by Angiography



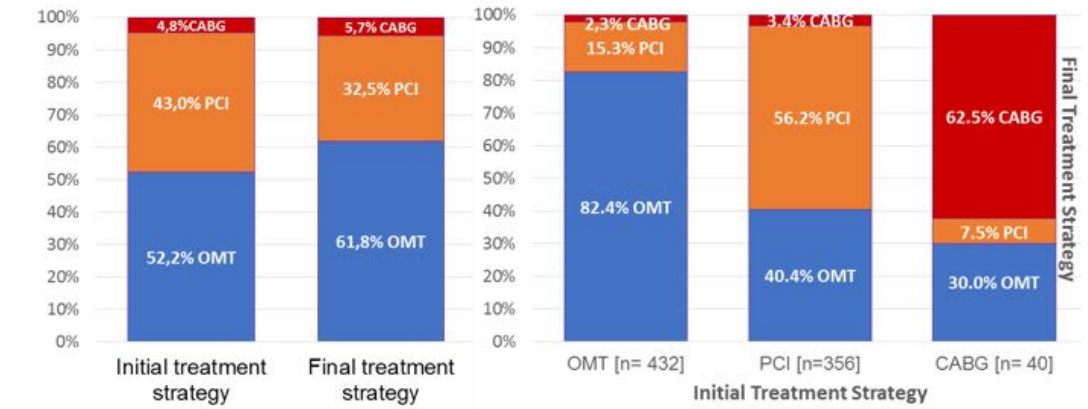
Physiology

iFR/FFR

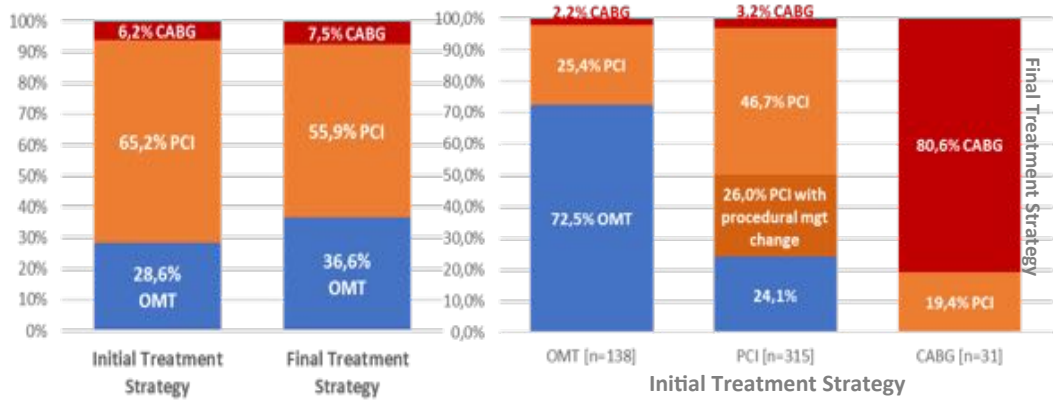
Final Treatment by Physiology



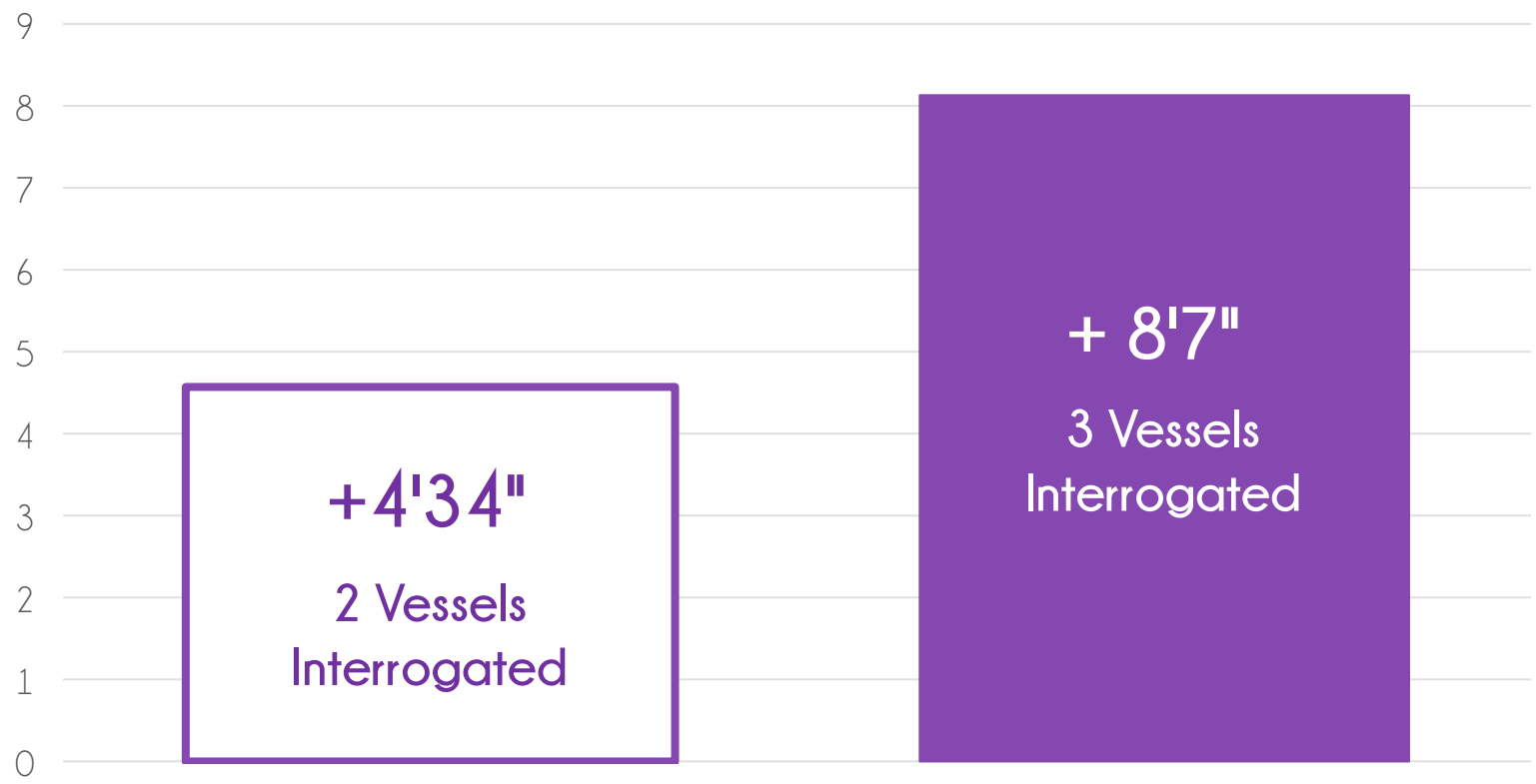
Reclassification of the revascularization strategy at vessel level (n=828) is 29.6%



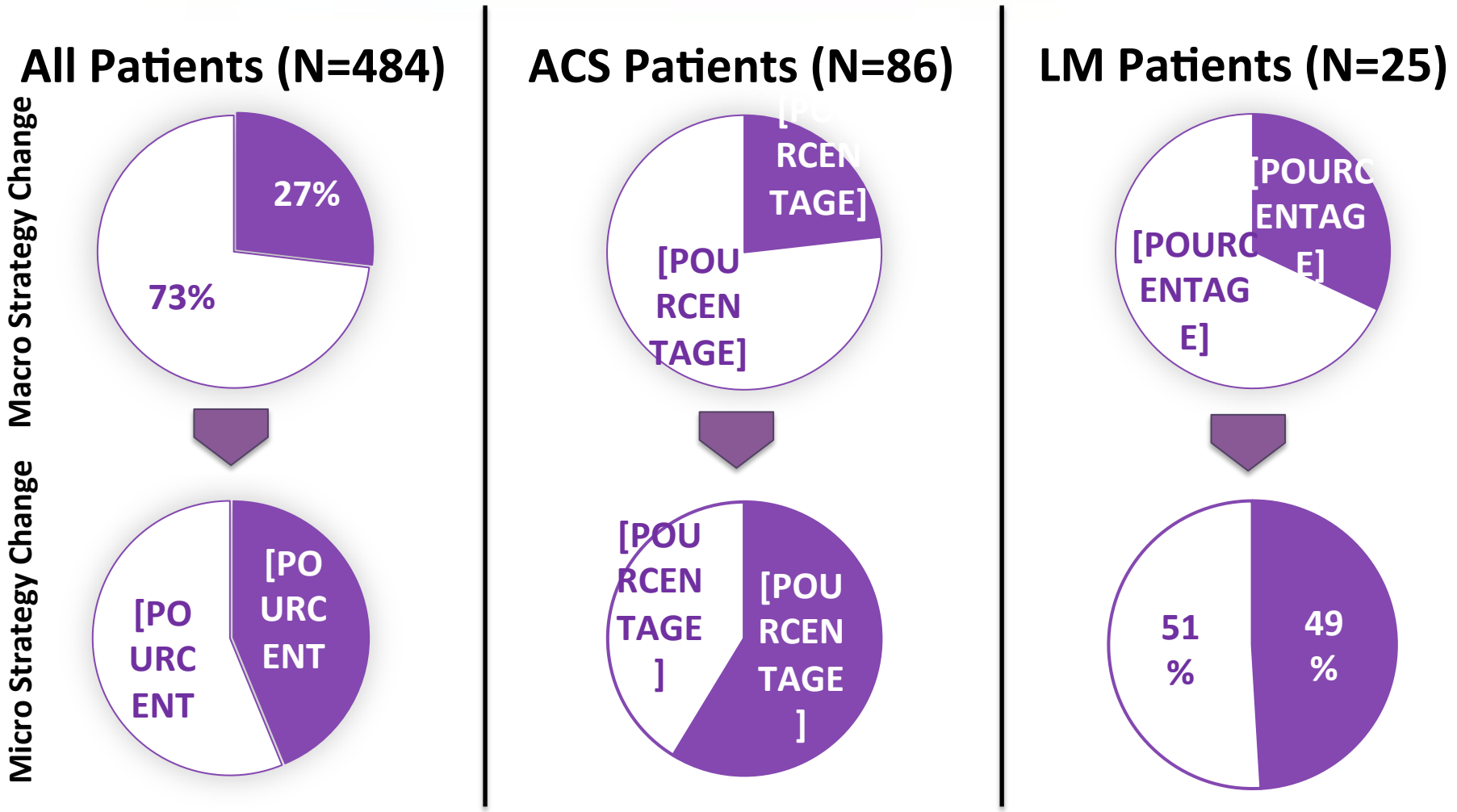
Reclassification of the revascularization strategy at patient level (n=484) is 26,9%



Extra time for Physiology in >1 vessel

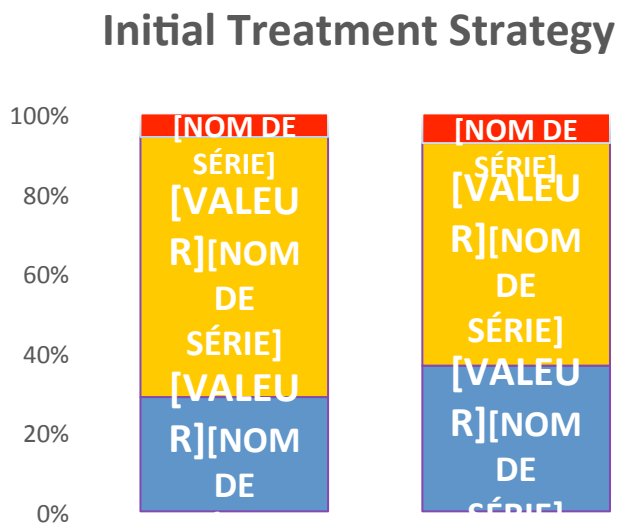


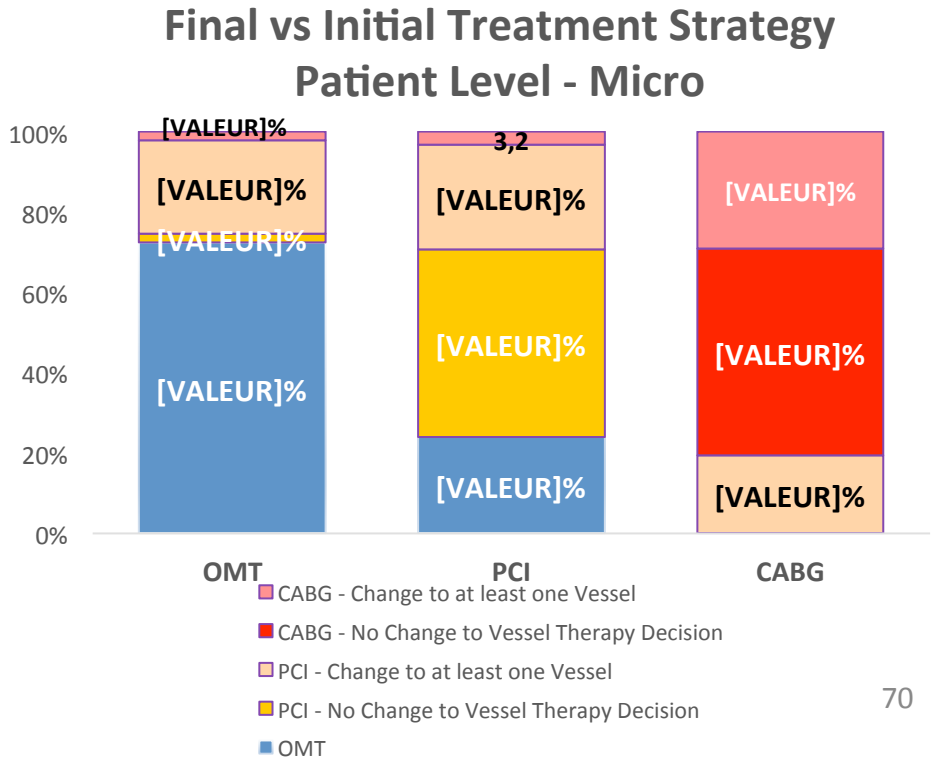
Changes of Treatment Strategy
Patient Level - Subgroup Analyses



Changes of Treatment Strategy

At Patient Level (Micro Strategy), treatment decision of at least one vessel changed after physiology assessment in **44%** of Patients





DEFINE REAL