



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

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



De quoi a t'on besoin ?

**Coordonner l'imagerie et la
physiologie**

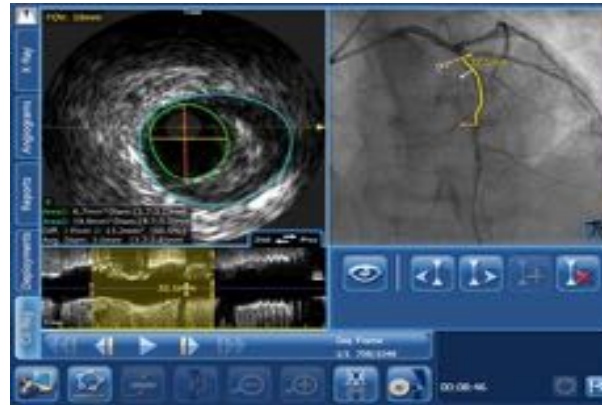
**Pour la meilleure decision
possible**

Co-registration of imaging and physiology tools

iFR Co-Registration



IVUS Co-Registration



Enhanced Angiography



OCT / OFDI Co-Registration



Dynamic Roadmap

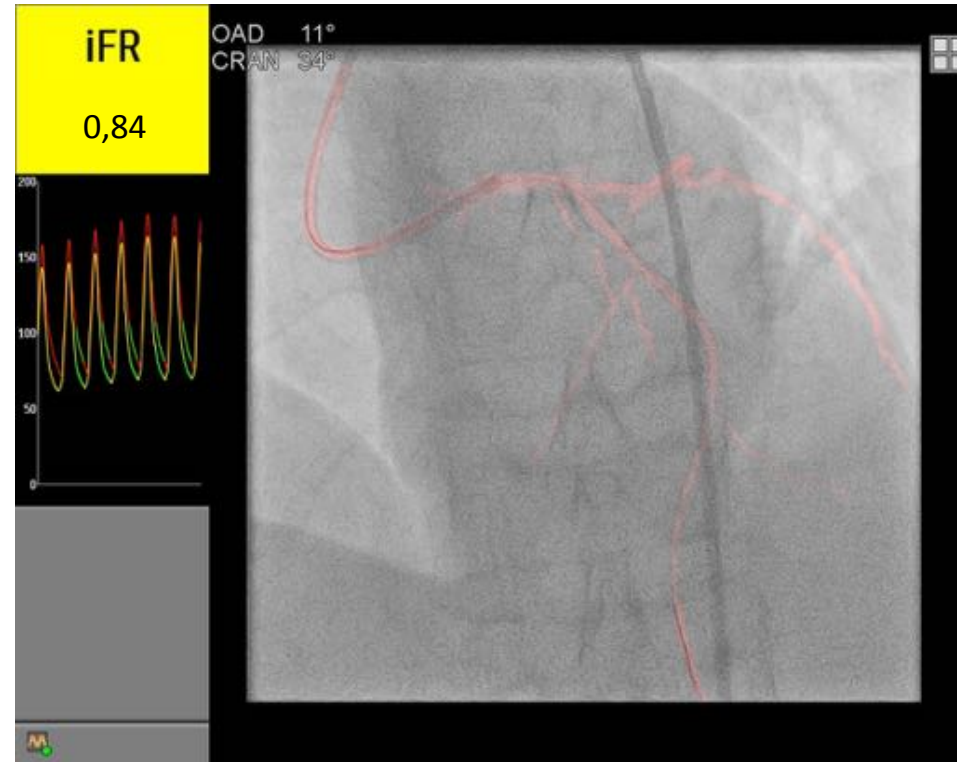


Cas clinique N°1

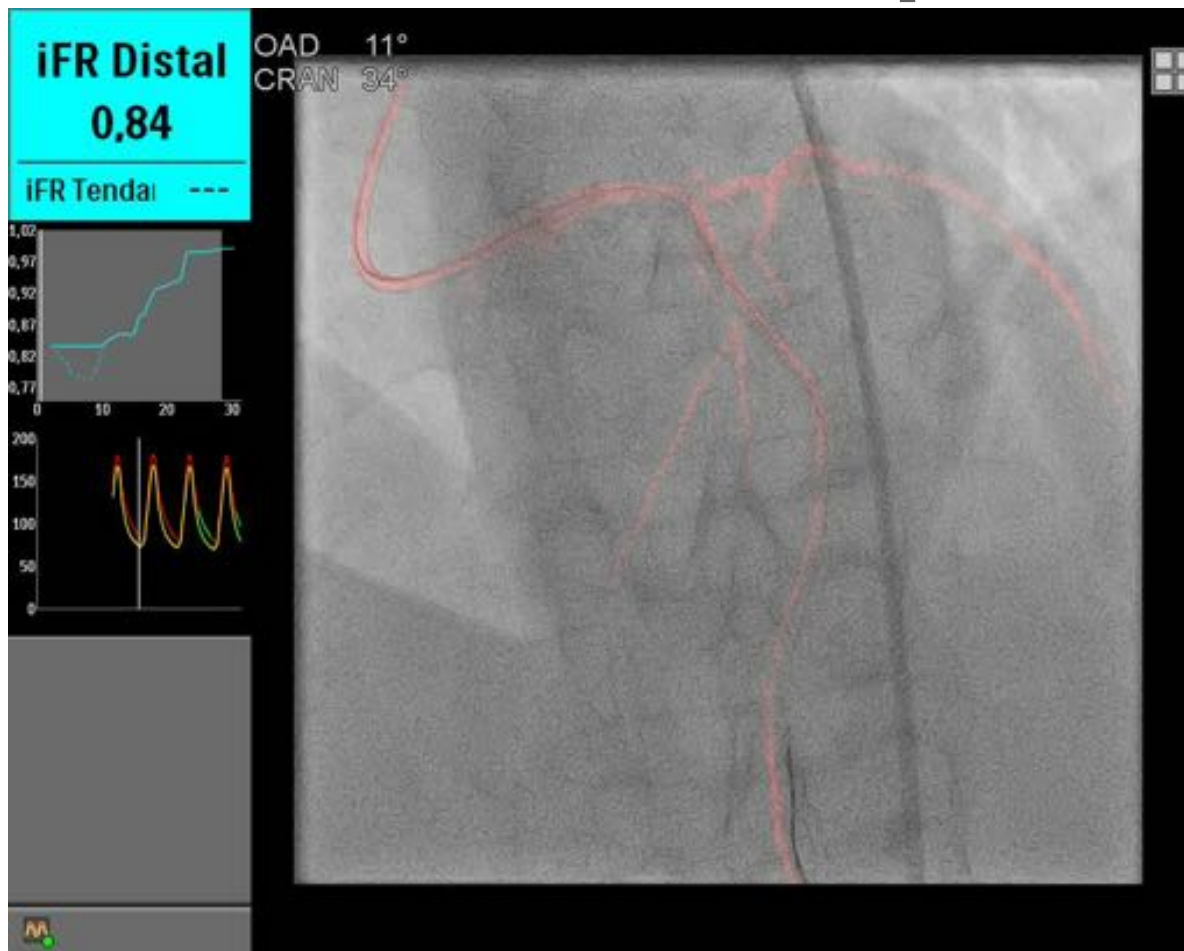
- Patiente de 76 ans.
- Antécédent de coronaropathie stentée sur l'IVA en 2011.
- Hospitalisée pour angor instable dans un Centre partenaire
- ETT : FEVG conservée
- Coronarographie : Découverte d'une sténose du TC distale
- Adressée pour angioplastie TC distale.



iFR en distalité



iFR Roadmap



Perte de charge diffuse sur TC distale et RIS IVA Moyenne :

- Prédilatation au ballon NC
- Décision angioplastie par long stent TC-IVA en overlap sur stent IVA moyenne

Stent actif Resolute ONYX 3,5*38mm TC-IVA en overlap

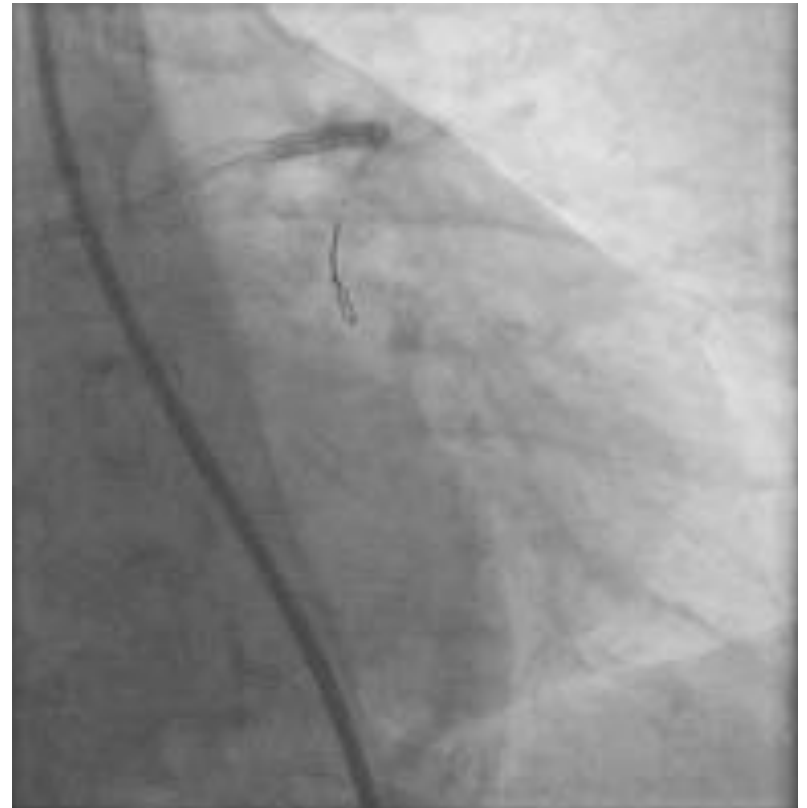
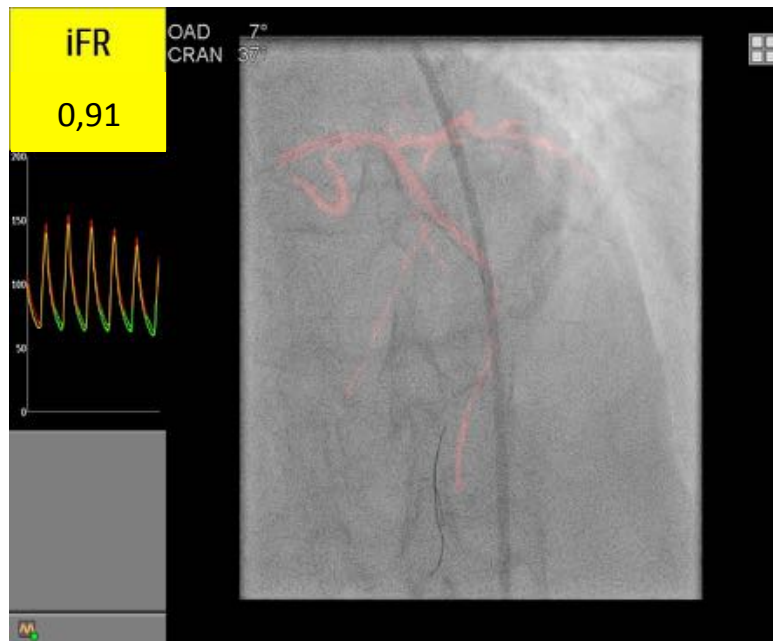
Inflaté à 12 Bar



Optimisation

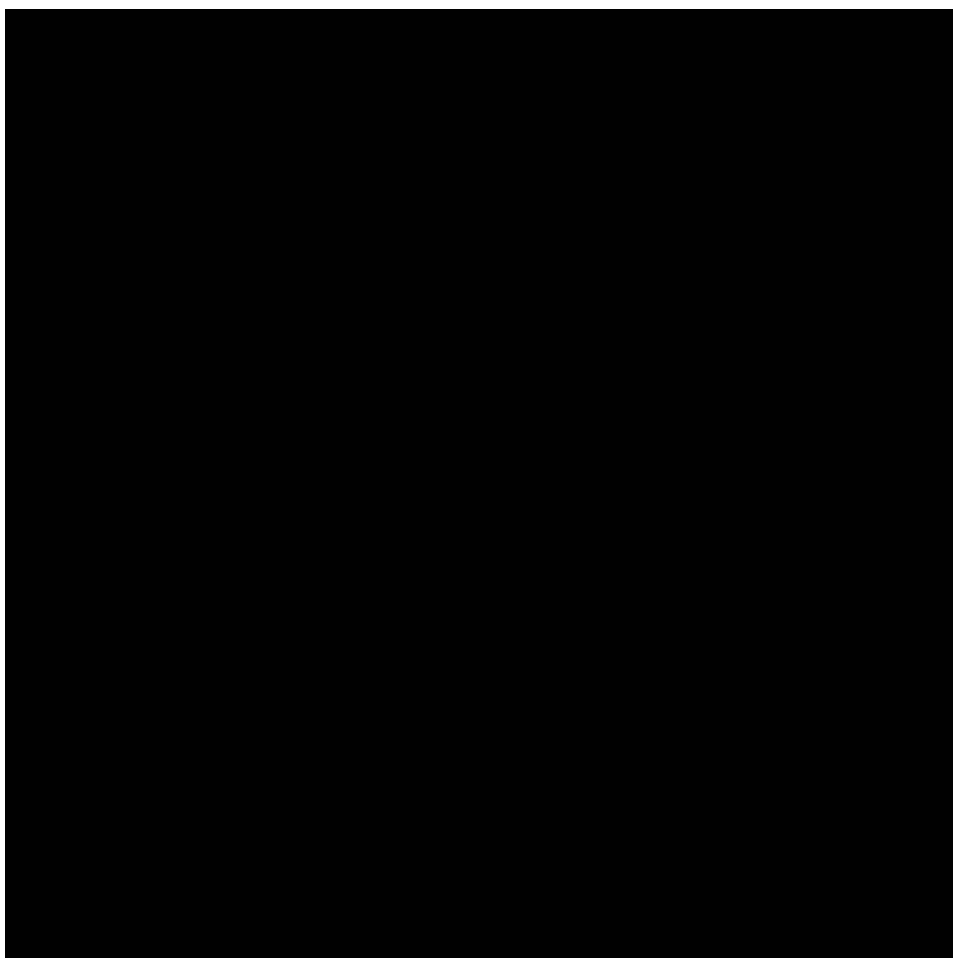


Résultat final



Cas n2



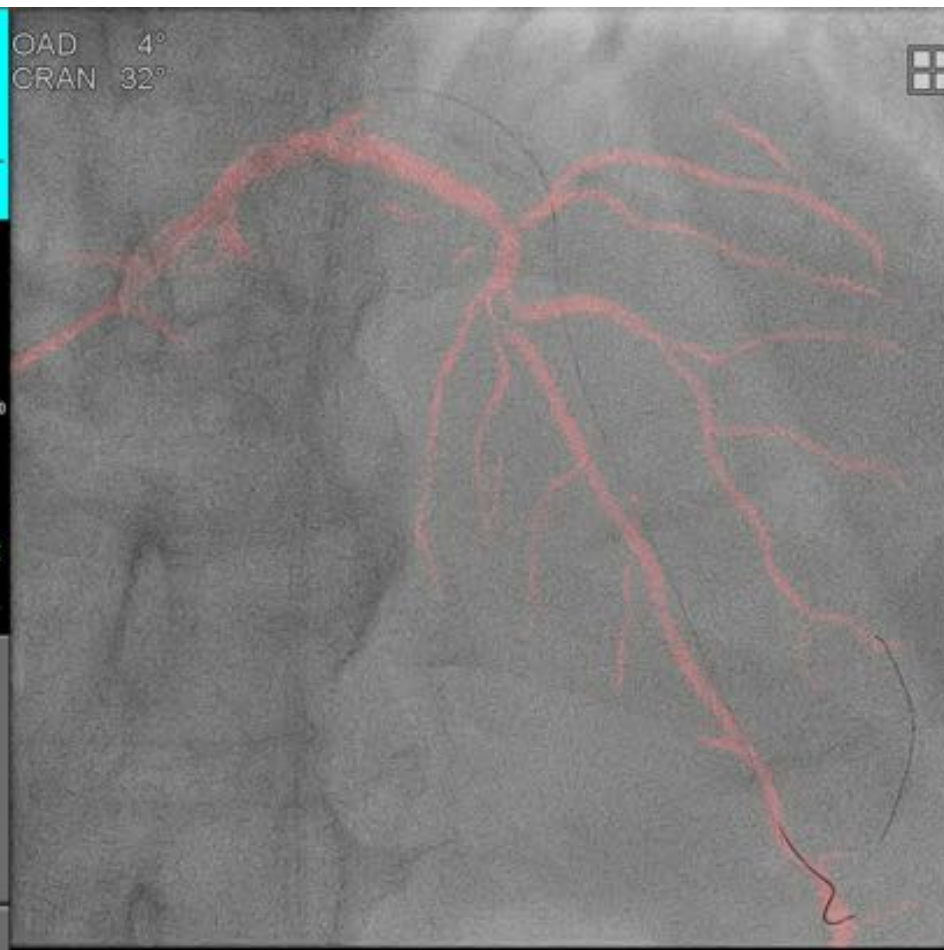
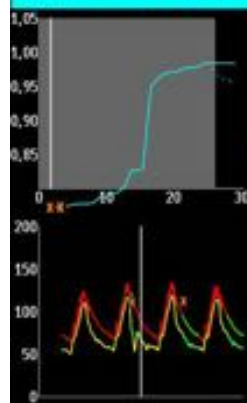


iFR Distal

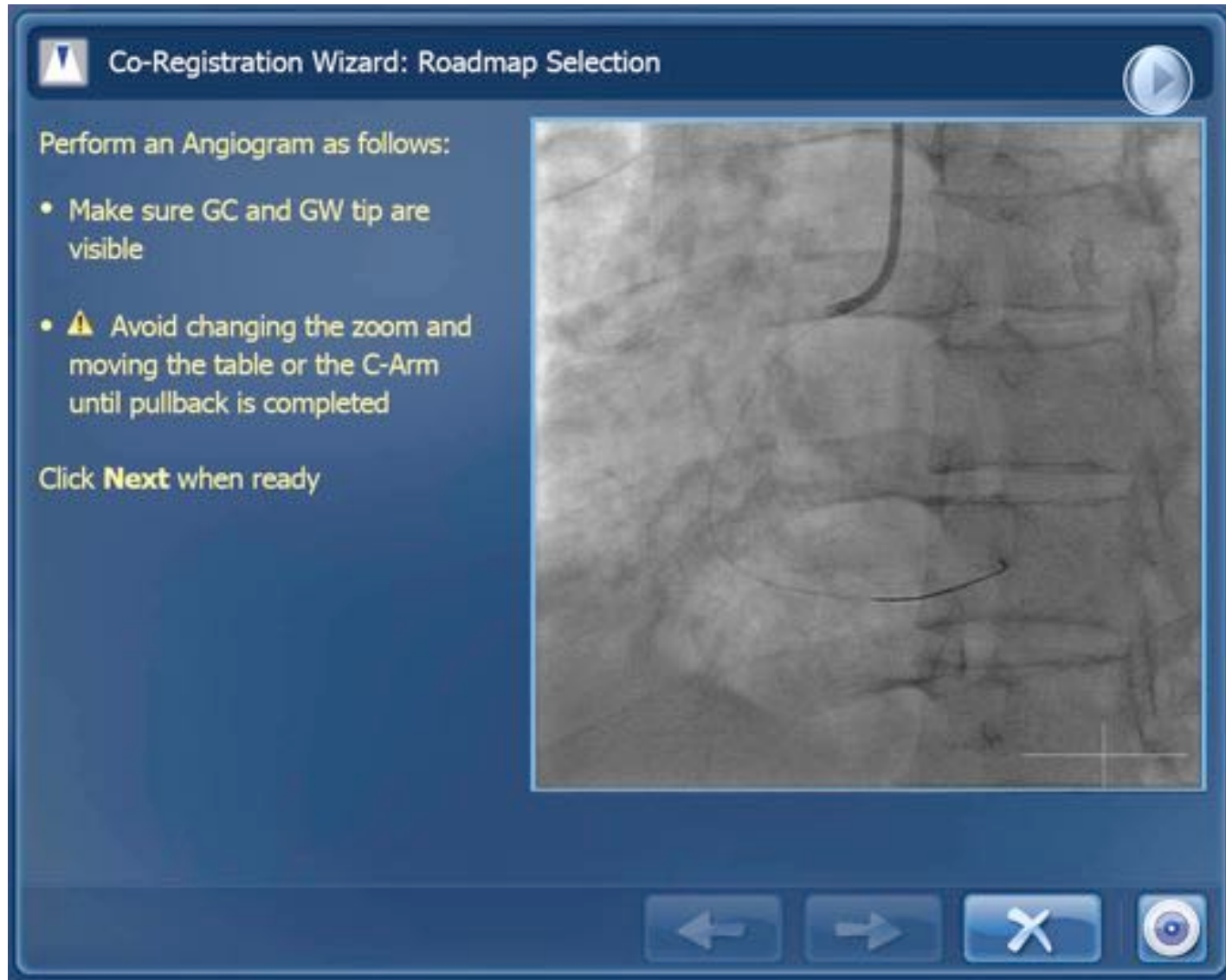
OAD 4°
CRAN 32°



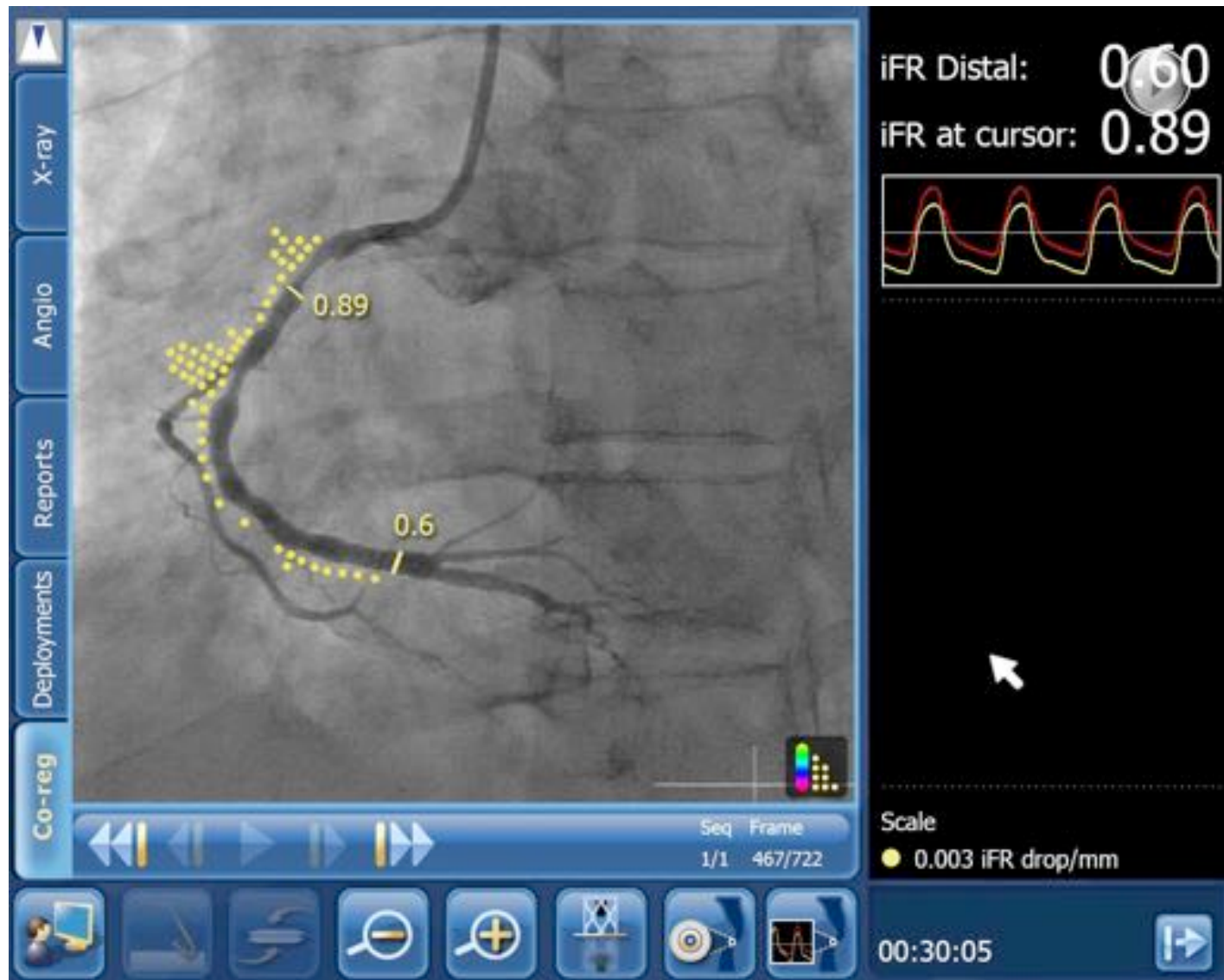
iFR Tenda: 0,77



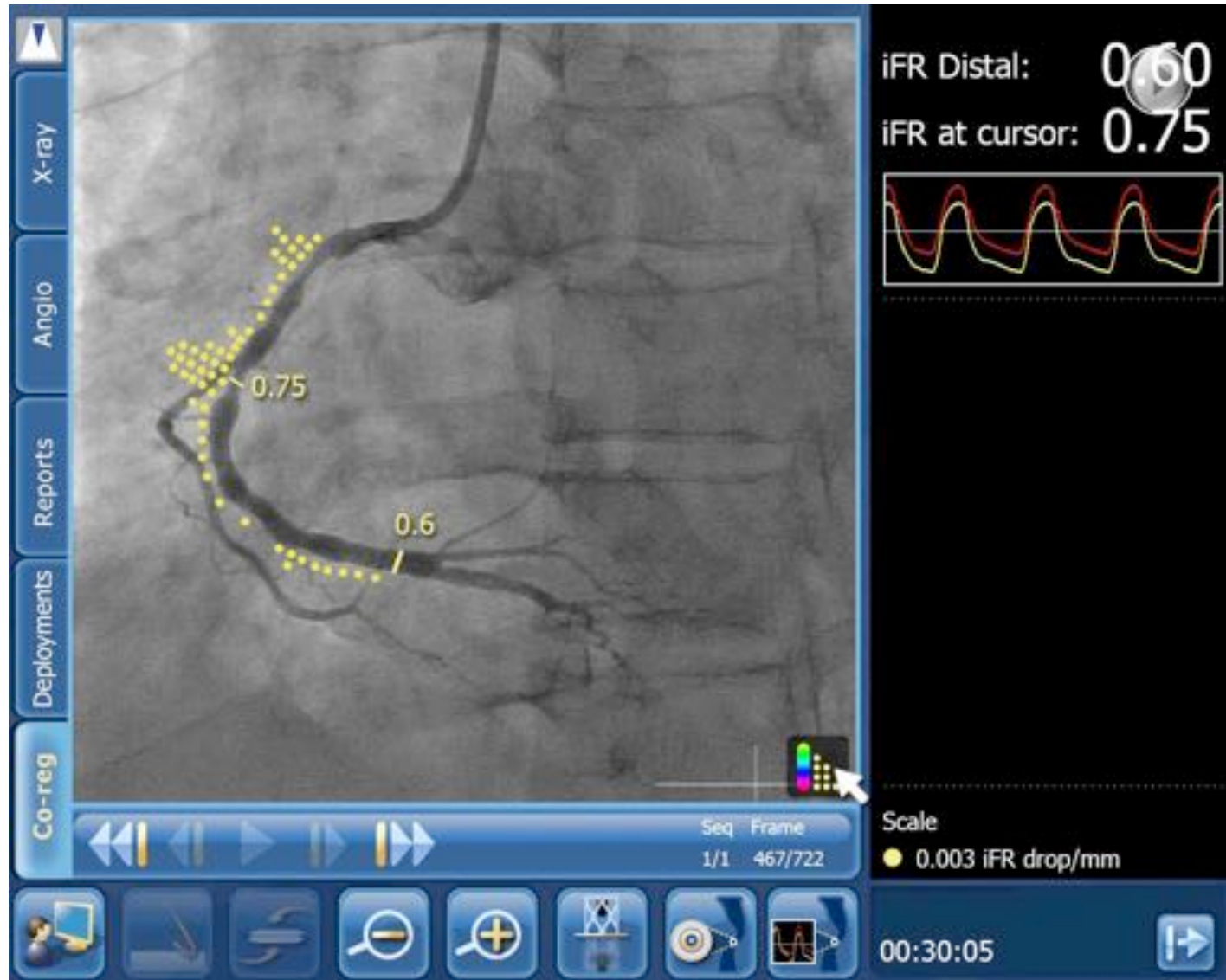
iFR Co-registration



iFR Co-registration

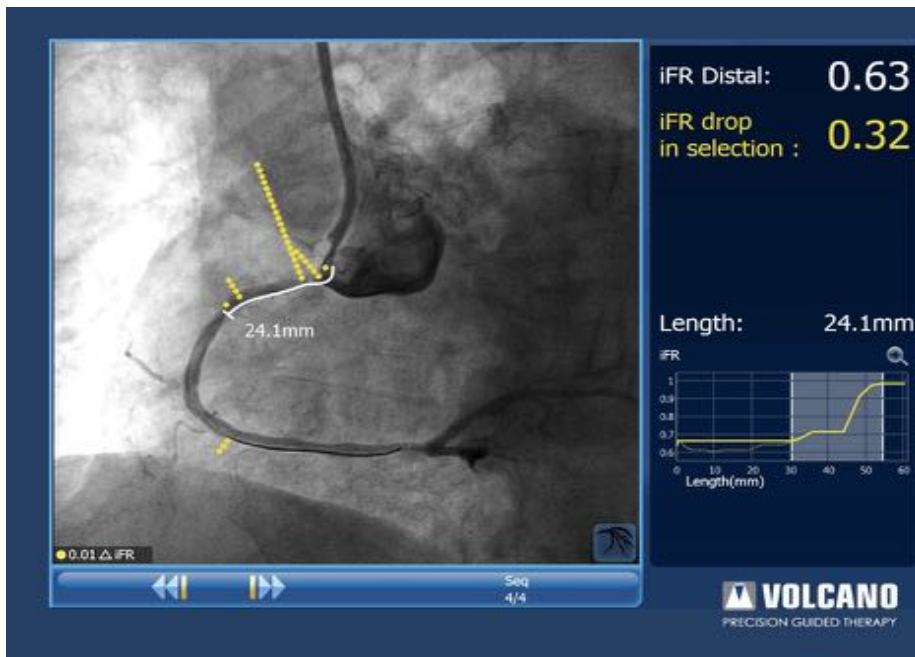


iFR Co-registration

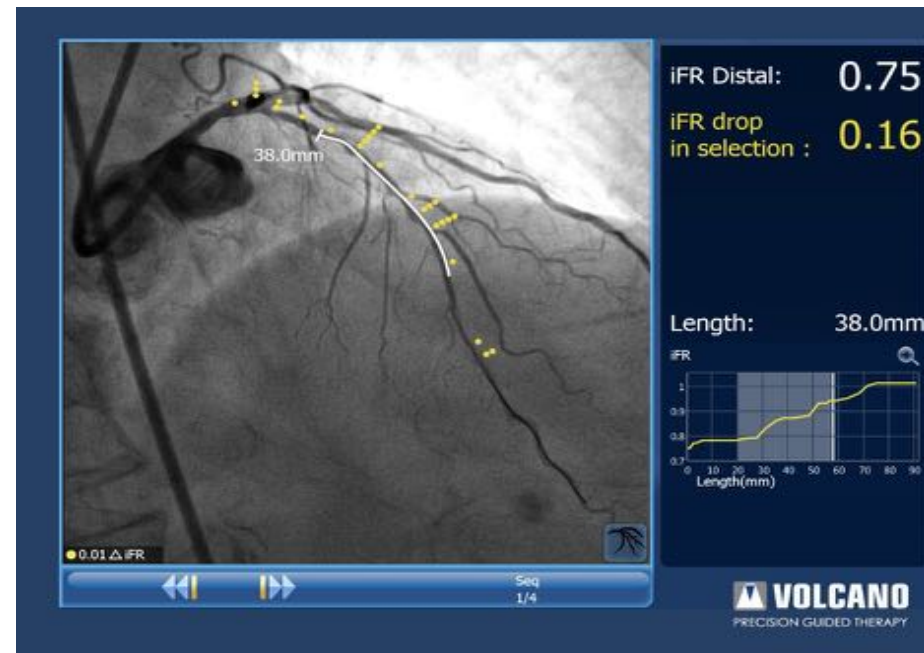


iFR Co-registration

Focal stenosis



Diffuse disease



**Coordonner l'imagerie et la
physiologie**

**Pour la meilleure decision
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Editorial

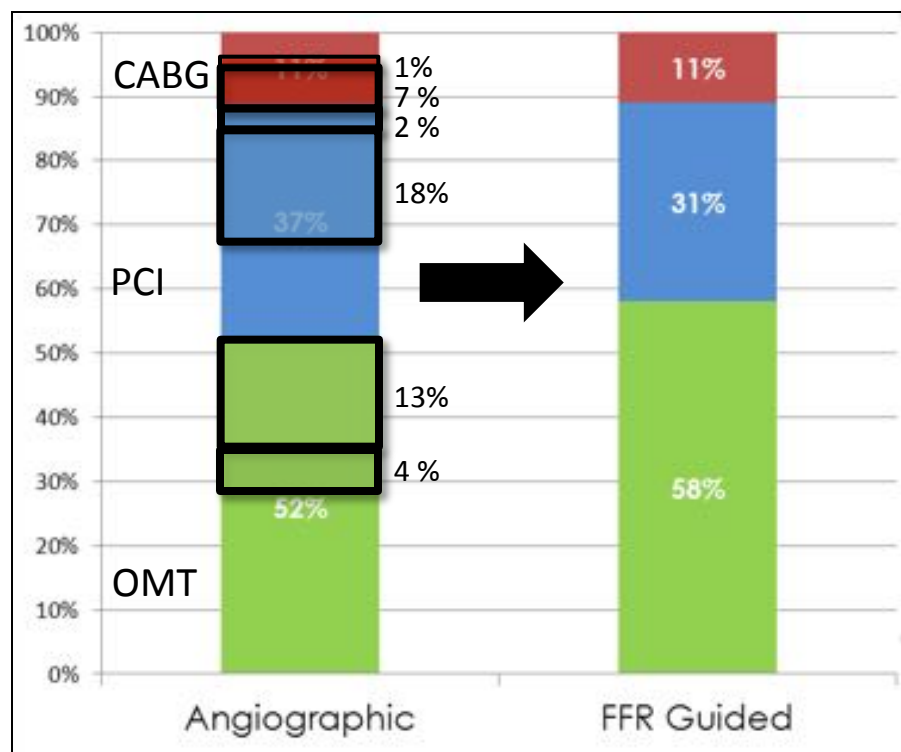
Routine Fractional Flow Reserve Combined to Diagnostic Coronary Angiography as a One-Stop Procedure Episode 3

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

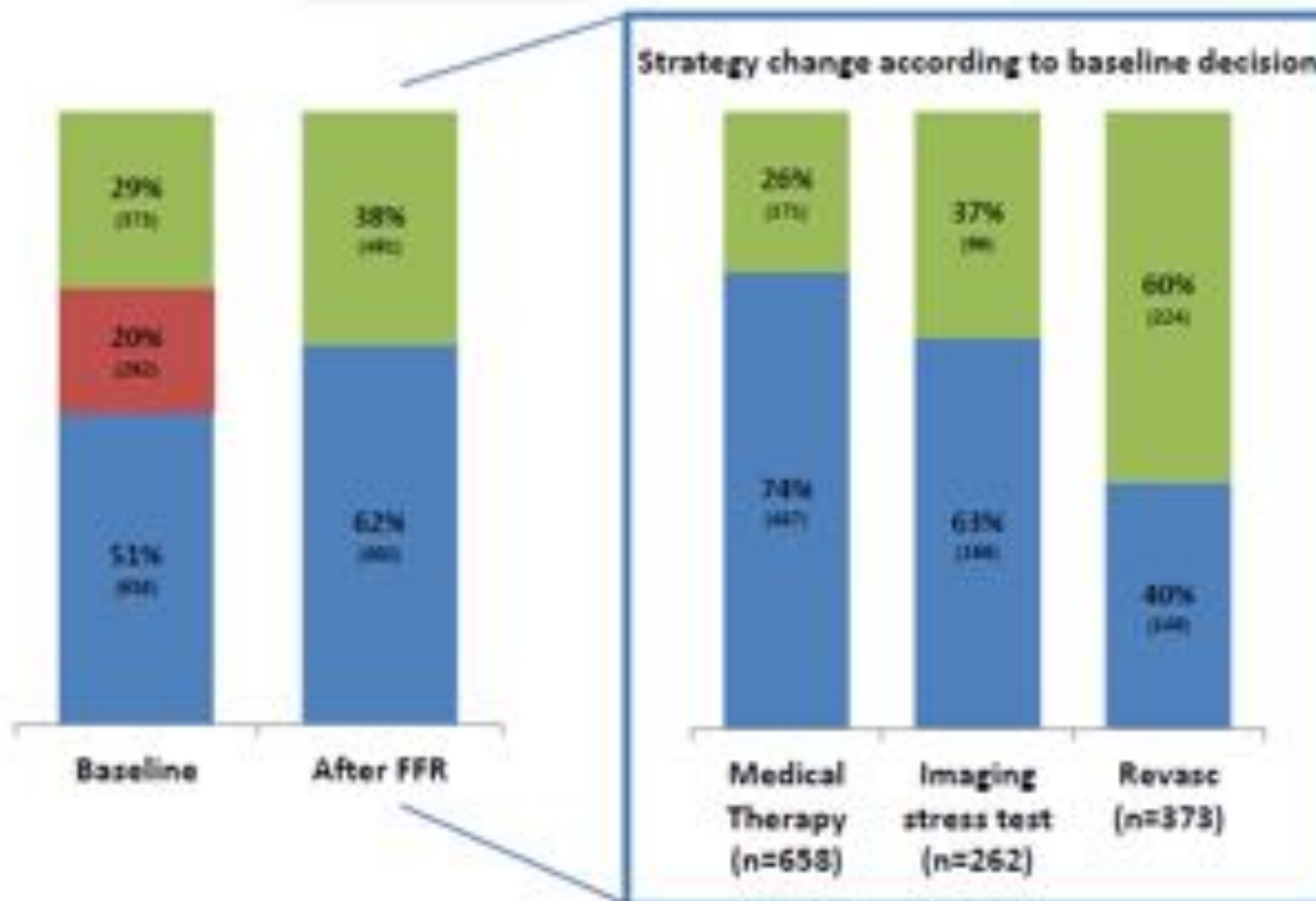
Outcome Impact of Coronary Revascularization Strategy Reclassification With Fractional Flow Reserve at Time of Diagnostic Angiography

Insights From a Large French Multicenter Fractional Flow
Reserve Registry

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



■ Medical therapy ■ Imaging stress test ■ Revascularization



Editorial

Routine Pressure Wire Assessment at Time of Diagnostic Angiography Is It Ready for Prime Time?

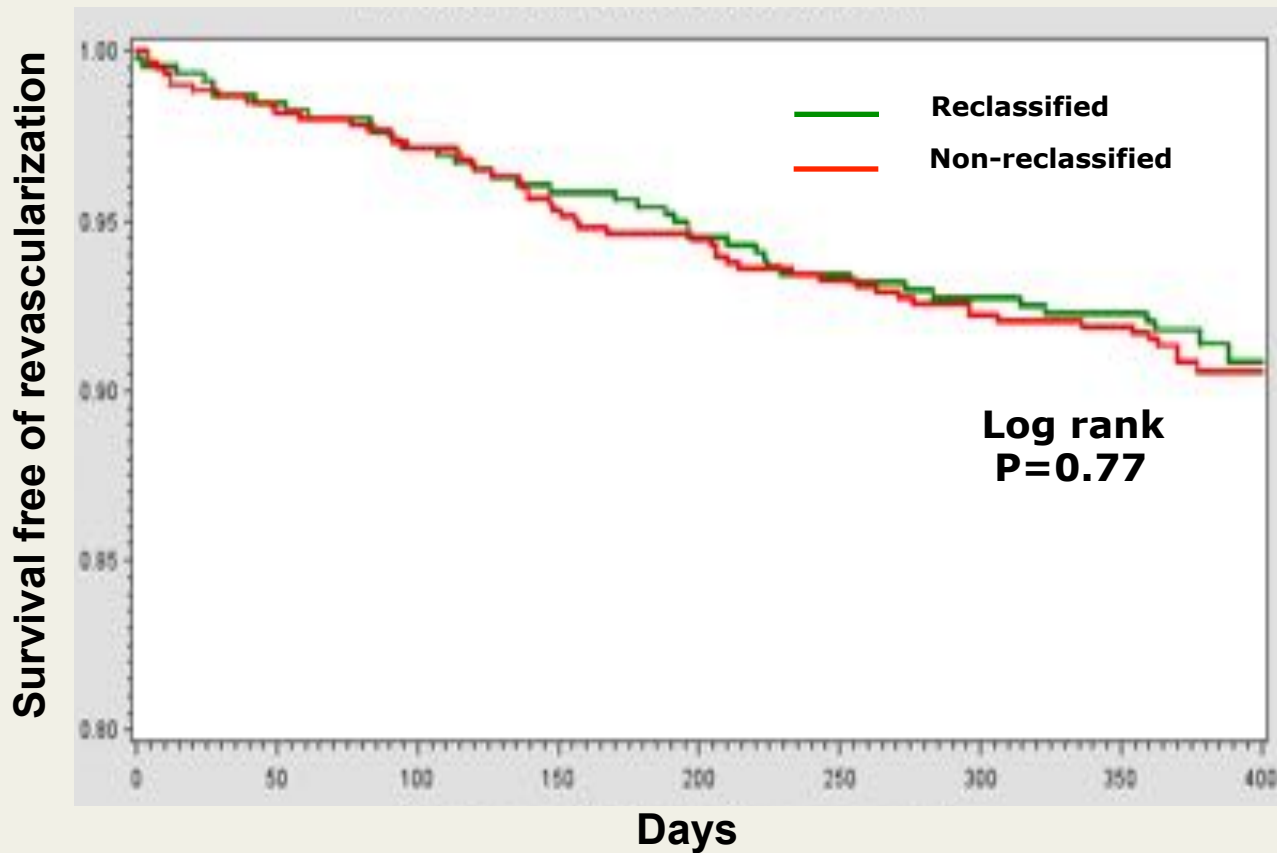
Eric Van Belle, MD, PhD; Gilles Rioufol, MD, PhD; Patrick Dupouy, MD

Post-Angiogram Decision	Post-FFR Decision				Total
	Medical	PCI	CABG	Further Info	
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

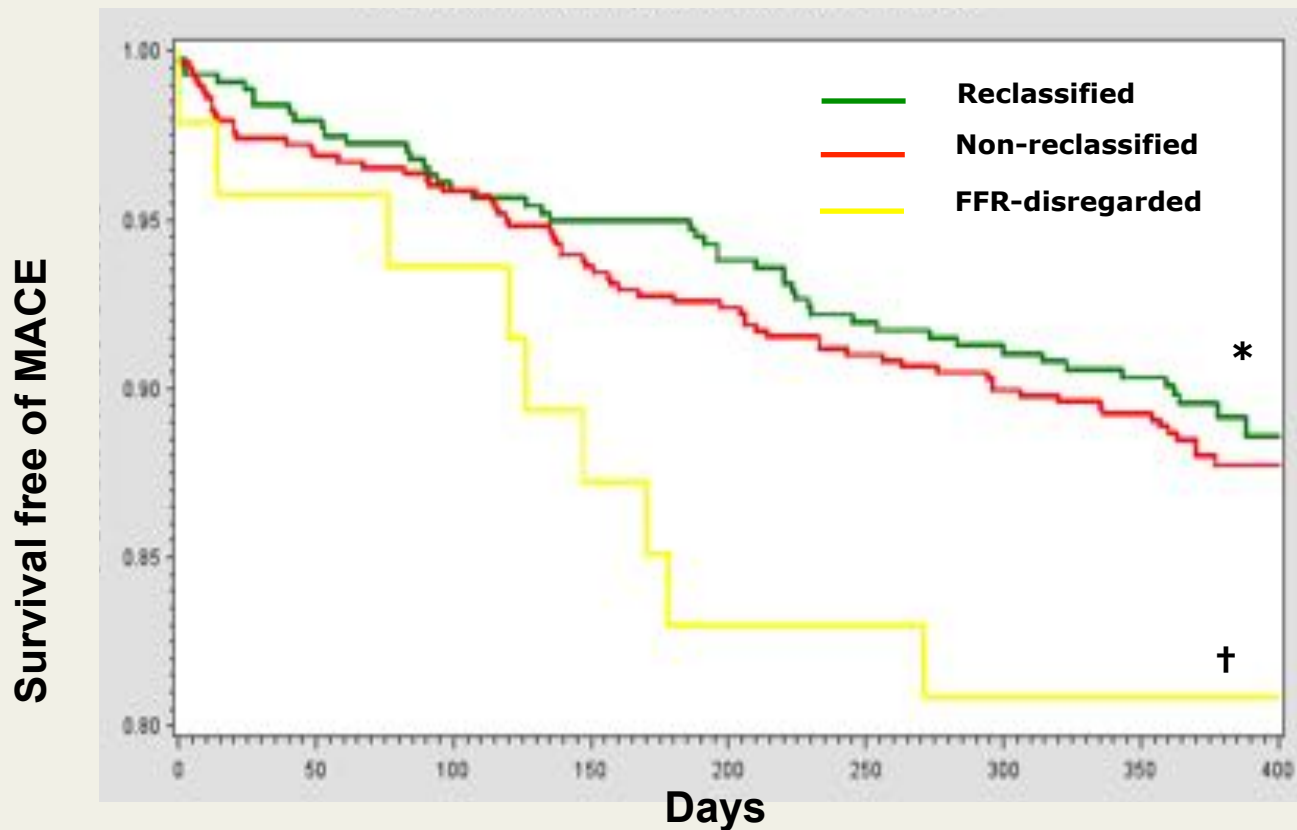
P < 0.001 by McNemar test. CABG indicates coronary artery bypass grafting; FFR, fractional flow reserve; and PCI, percutaneous coronary intervention.

26% of
patients
changed
therapy
with FFR
guidance

Survival free of unplanned revascularization and MI according to Reclassification by FFR



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



What about MVD patients?

Role of iFR in serial lesions

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



JACC

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY



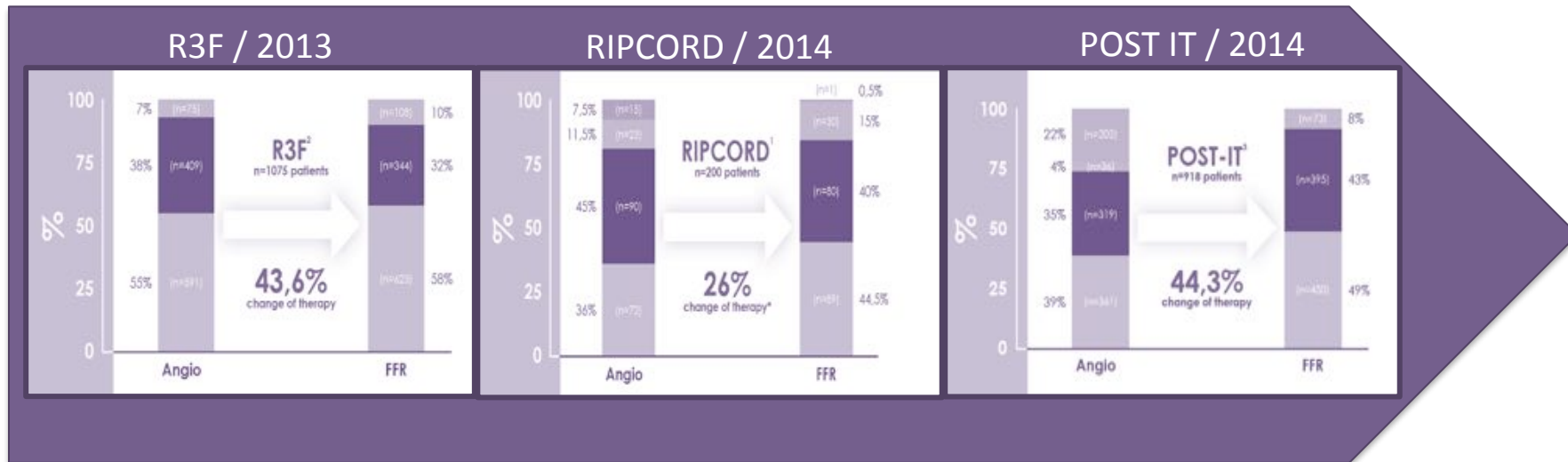
Impact of Routine Invasive Physiology at Time of Angiography in Patients With Multivessel Coronary Artery Disease on Reclassification of Revascularization Strategy

Results From the DEFINE REAL Study

Eric Van Belle, MD, PhD,^a Robert Gil, MD, PhD,^b Volker Klauss, MD,^c Mohammed Balghith, MD,^d
Martijn Meuwissen, MD, PhD,^e Jérôme Clerc, MD,^f Bernhard Witzenbichler, MD,^g Miha Cercek, MD,^h
Marios Vlachojannis, MD,ⁱ Irene Lang, MD,^j Philippe Commeau, MD,^k Flavien Vincent, MD,^l Luca Testa, MD, PhD,^l
Wojciech Wasek, MD, PhD,^m Nicolas Debry, MD,ⁿ Stephan Kische, MD, PhD,^o Gabriele Gabrielli, MD,^o
Gennaro Sardella, MD, PhD^p

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

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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.

Patient with MVD disease being investigated by angiogram



Initial Treatment Strategy based on diagnostic Angiogram:

CABG, PCI or OMT



Final treatment strategy based on Physiology (FFR or iFR):

CABG, PCI or OMT



Reclassification based upon the difference between Initial and Final Treatment:

- At **Vessel** level
- At **Patient** Management level
- At **Procedural** Management level (For those without patient management change)
 - At **overall** management (Patient + Procedural change)

ANGIOGRAPHY

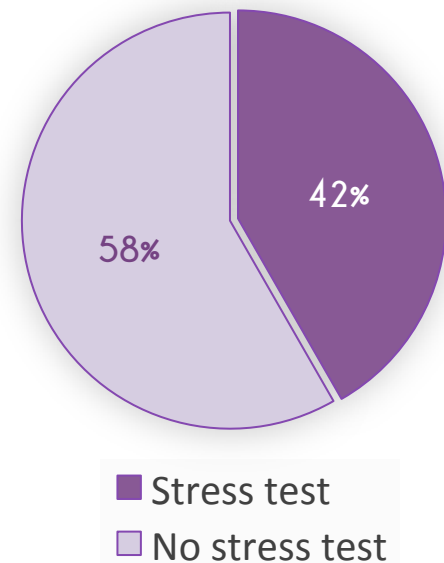
PHYSIOLOGY

RECLASSIFICATION

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 Test in Stable Patients



Tests: Stress ECG, Stress SPECT, Stress Echo, Stress MRI, CT-Scan

Baseline Characteristics

Patients population **484**

- Patient with LM involved **9.1%**

Vessels diseased **1107**

- Average per patient **2.29**

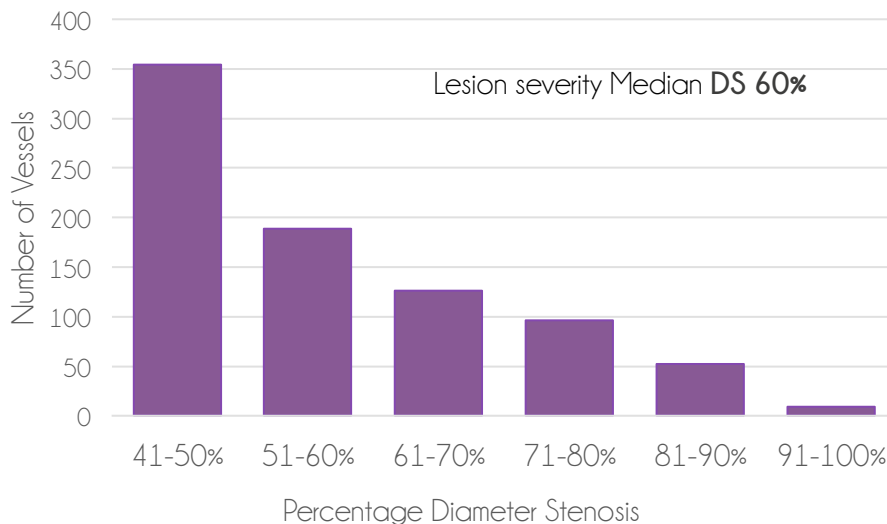
Vessels assessed by physiology **830 (75%)**

- Average per patient **1.71**

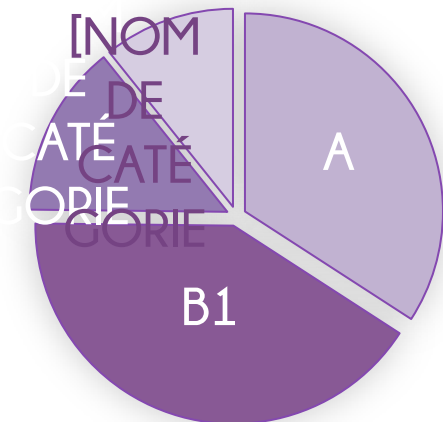
Multi-Vessel Disease



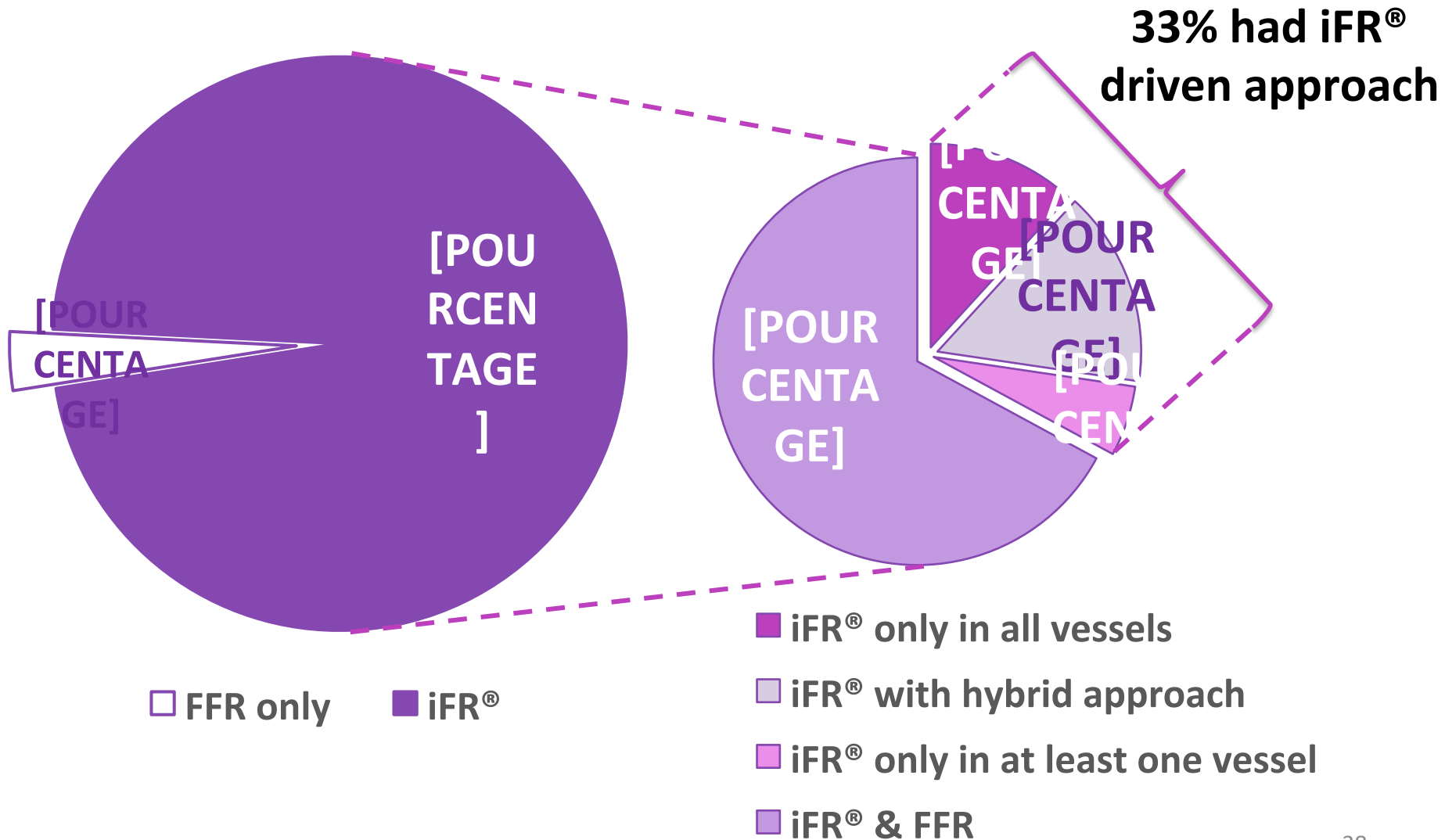
% Diameter Stenosis Distribution



Lesion type

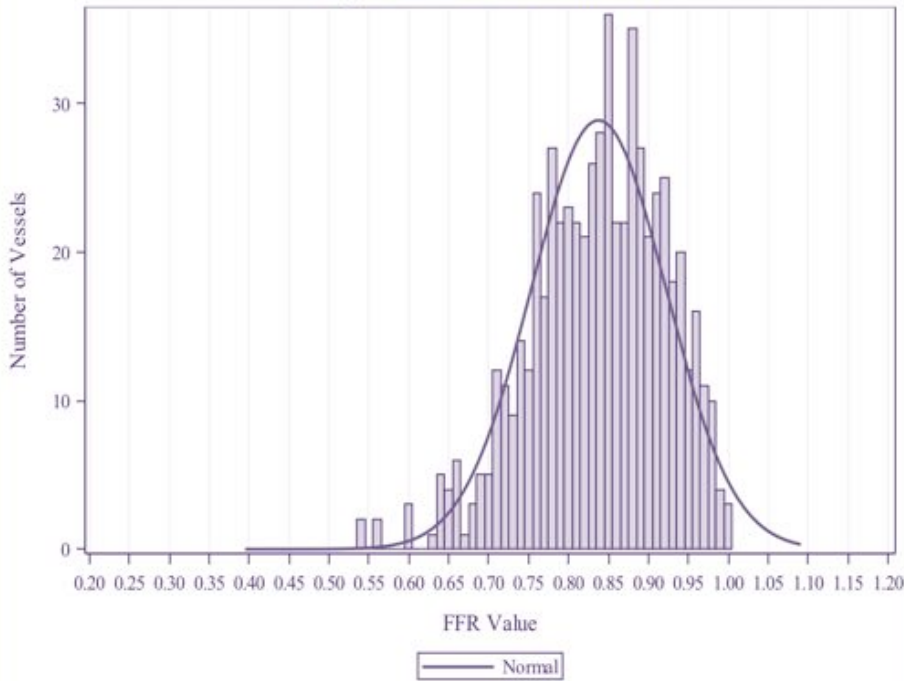


Physiology Approaches



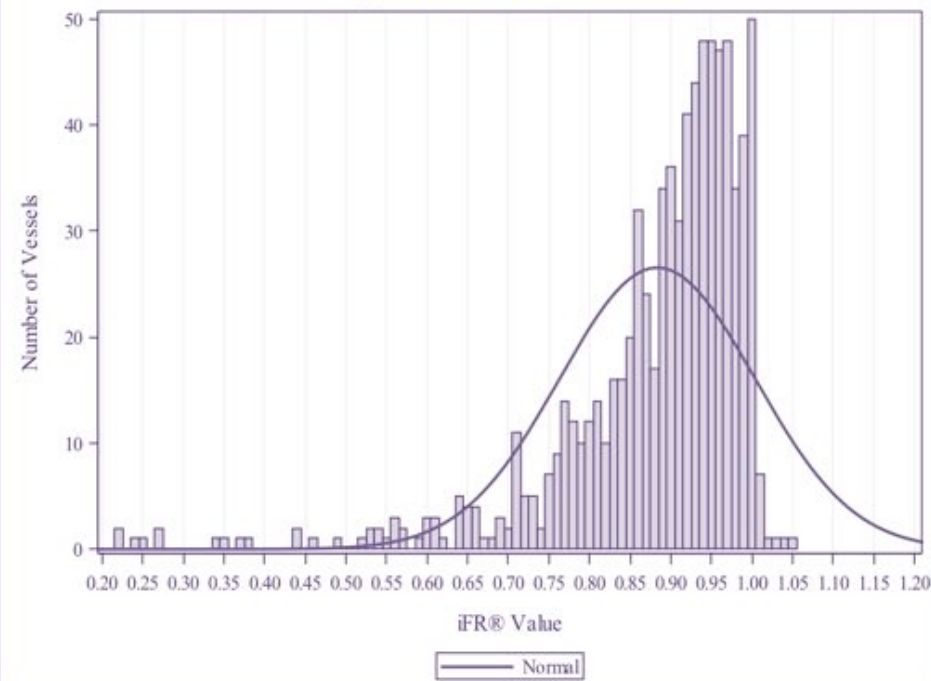
Results of FFR/iFR[®]

Figure 4: FFR Value Distribution



Median FFR Value: 0.84

Figure 3: iFR[®] Value Distribution

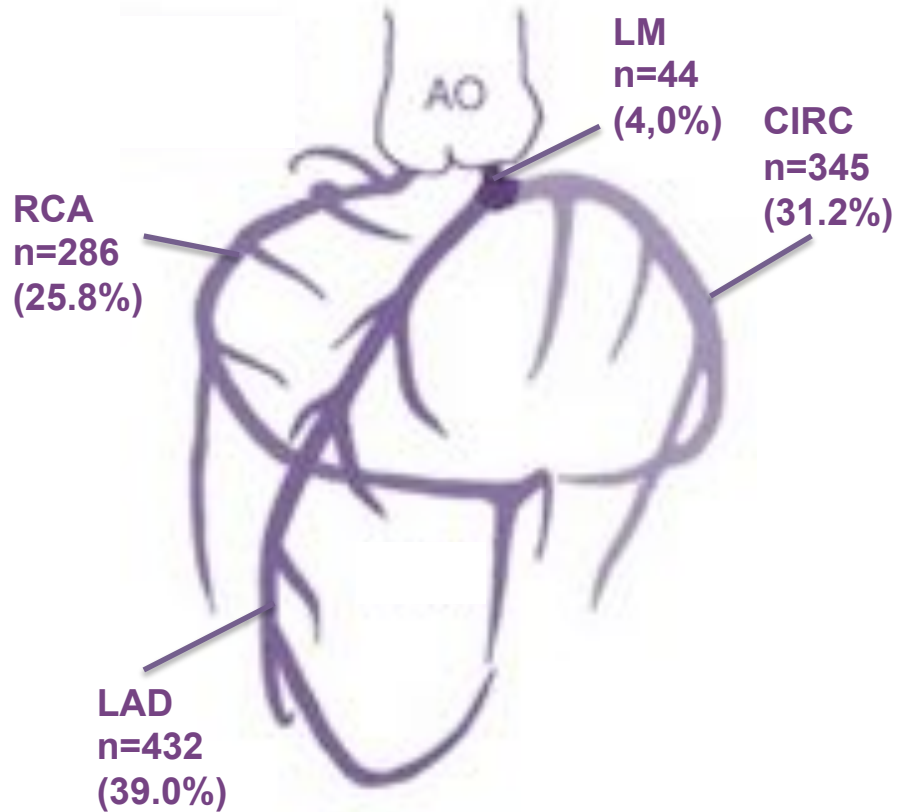


Median iFR[®] Value: 0.92

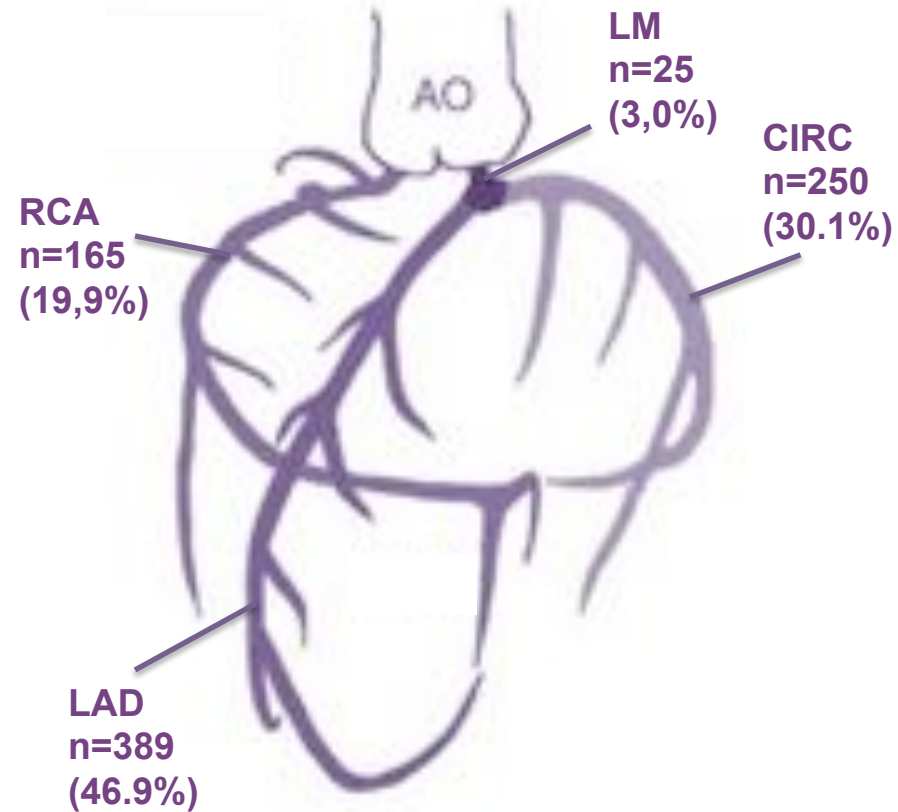
Typical intermediate lesion population

Baseline Characteristics

Diseased Vessels by
Angiography [n=1107]



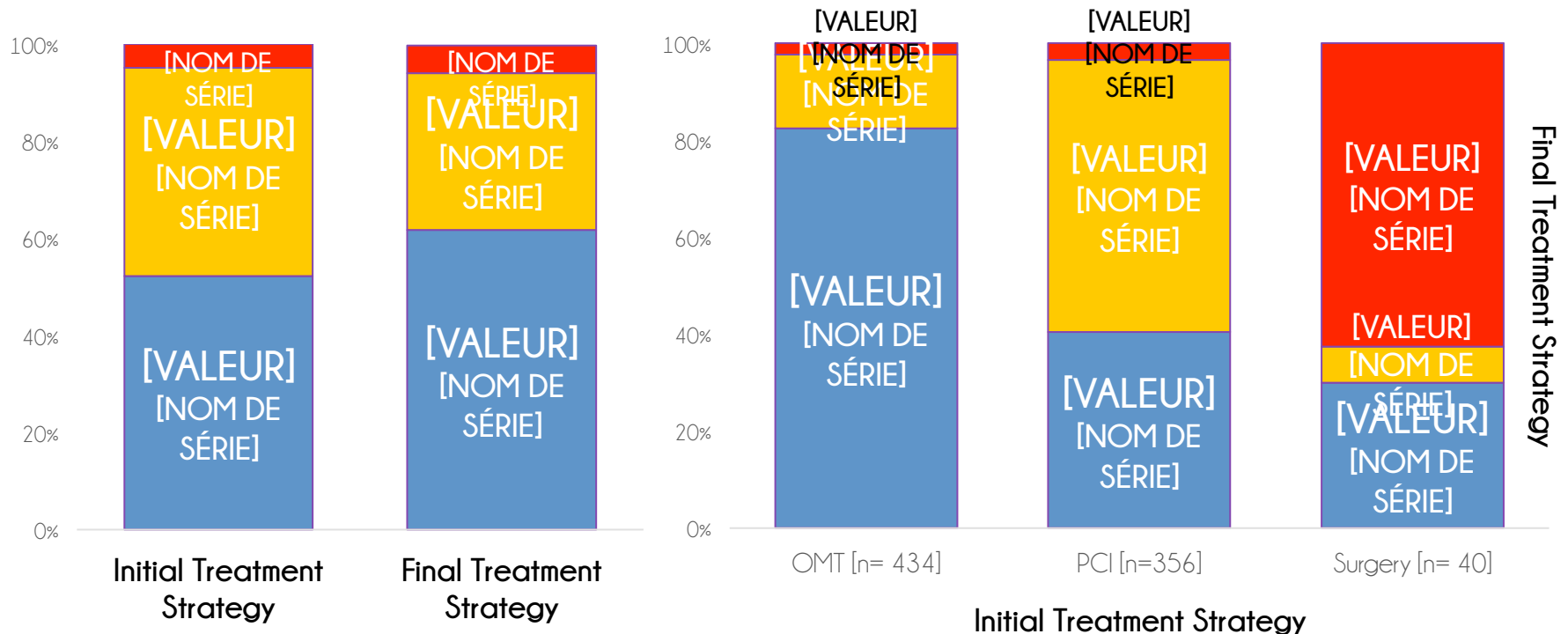
Vessels Interrogated with
Physiology [n=830]



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

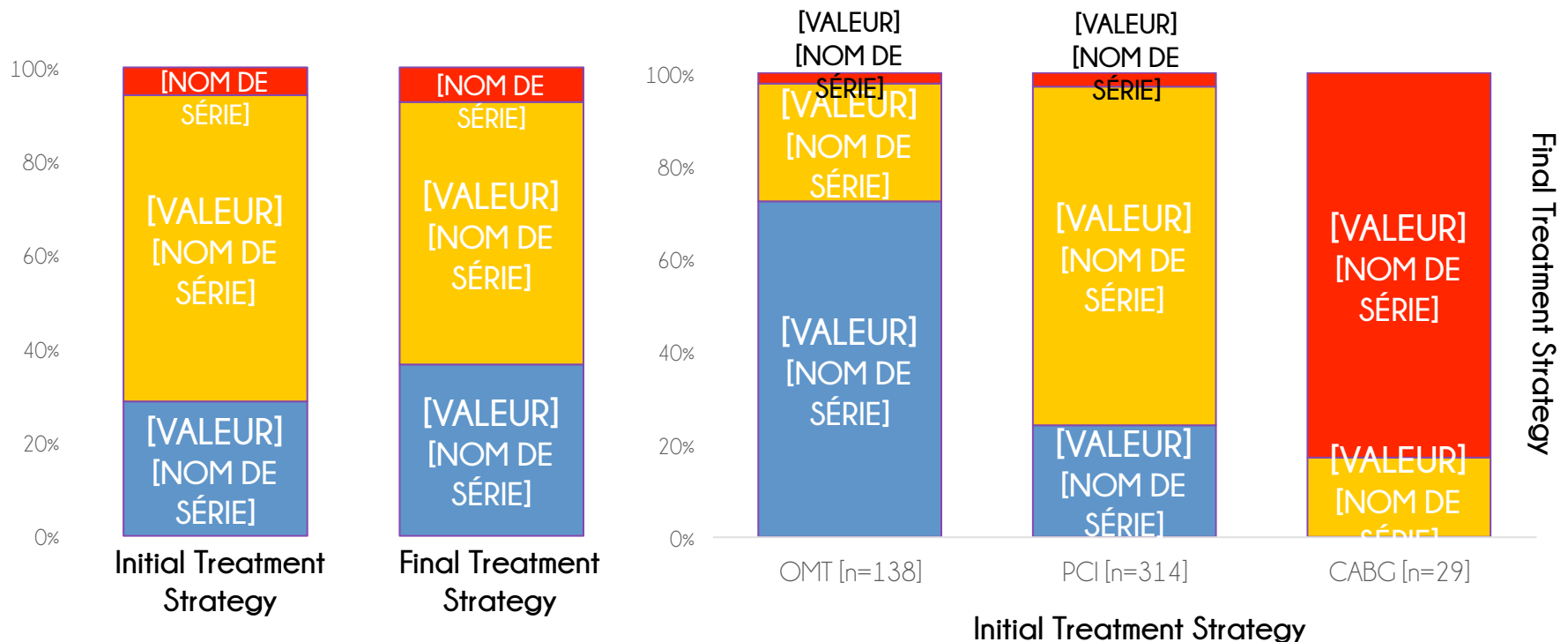
Changes of Treatment Strategy

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



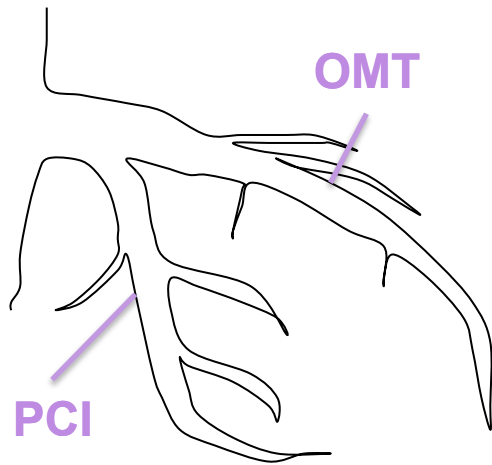
Changes of Treatment Strategy

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



Changes of Treatment Strategy (in PCI)

Initial Treatment
by Angiography

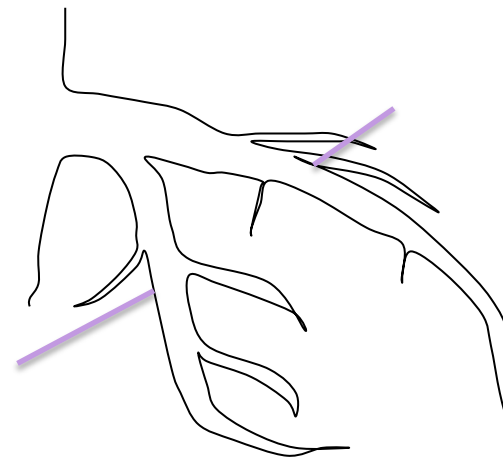


Physiology

iFR/FFR

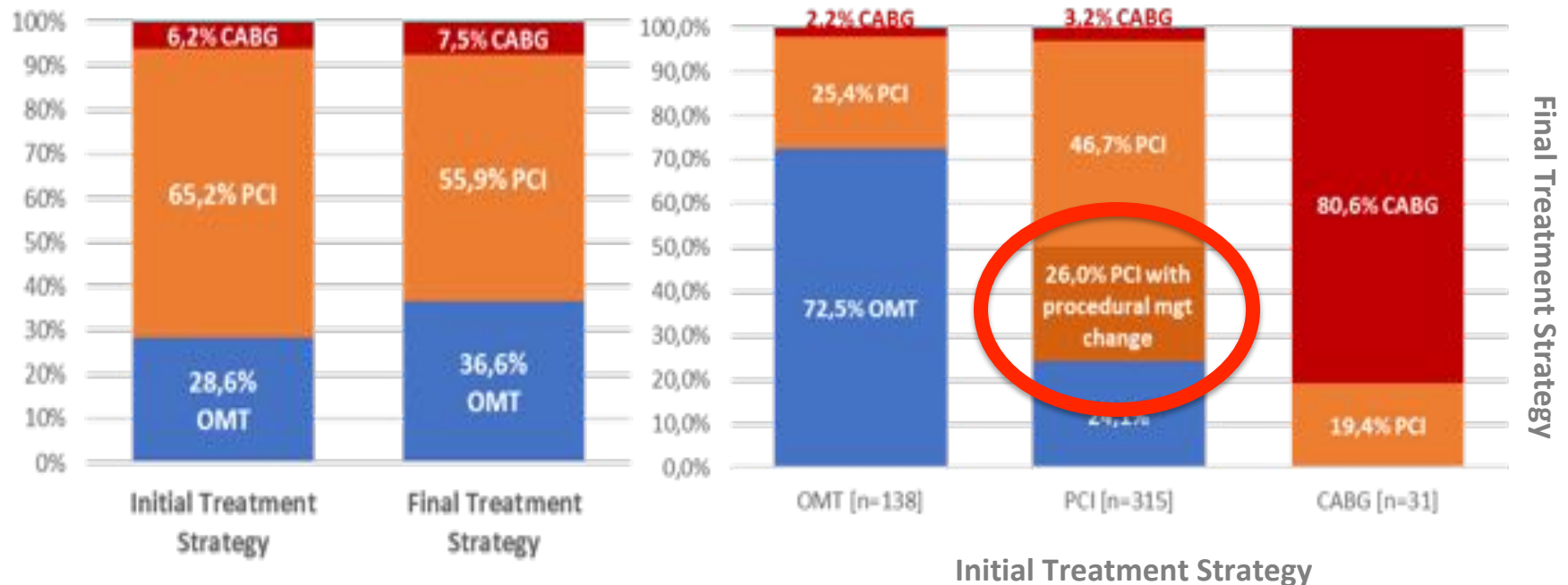


Final Treatment
by Physiology



Changes of Treatment Strategy

At Procedural Level (Micro Strategy), treatment decision changed after physiology assessment for **45%** of Patients



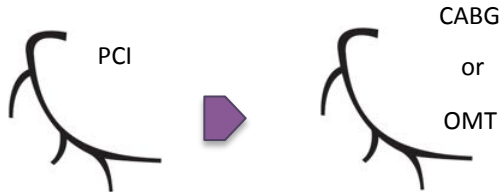
ANGIOGRAPHY

PHYSIOLOGY

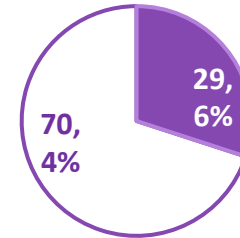
RECLASSIFICATION OF TREATMENT ?

2A

VESSEL



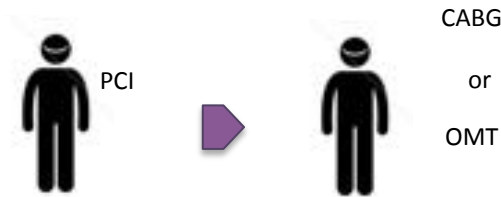
Vessel Management
At Vessel Level
(e.g PCI → CABG)



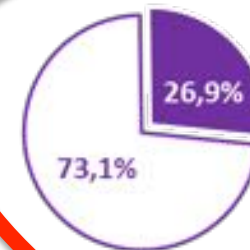
Vessel management change
in **29,6%** of vessels

2B

PATIENT



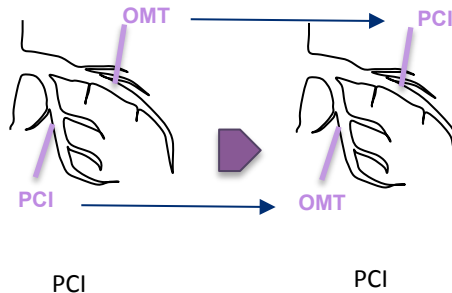
Patient Management
“visible” change for the
patient
(e.g PCI → CABG)



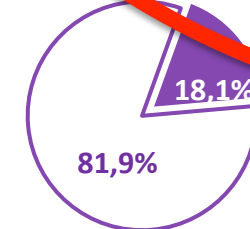
Patient management change
in **26,9%** of patients

2C

PROCEDURAL

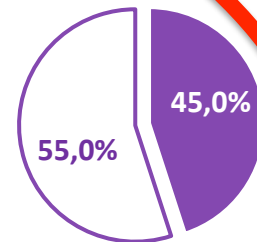


Procedural Management
Procedural change
No “visible” change for
the patient



Procedural management change
in **18,1%** of patients

2D



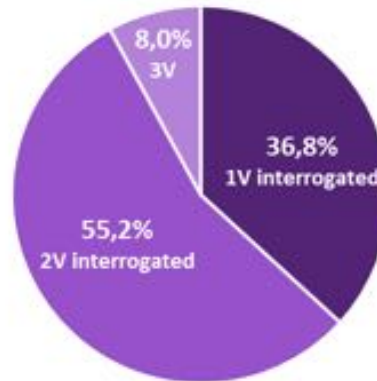
Total changes in **45,0%** of
patients

Overall Management

Patient + Procedural
change

Reclassification according to the number of vessels investigated

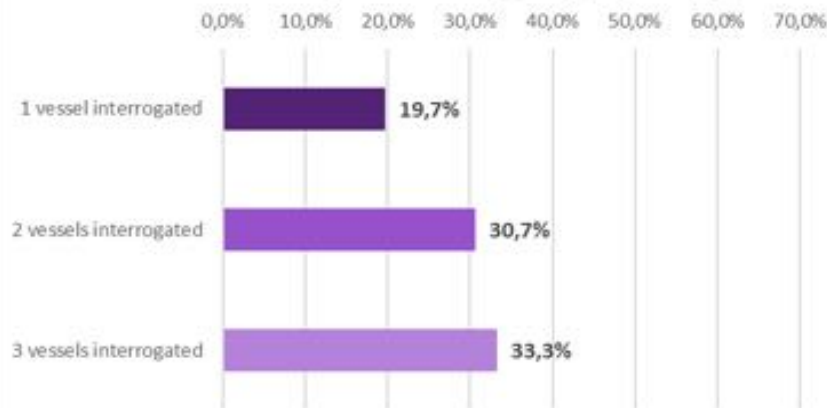
Vessels interrogated in MVD patients



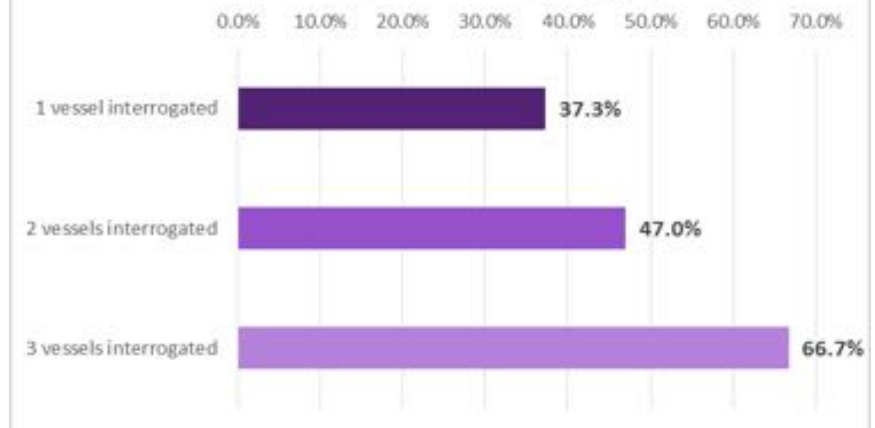
P=0.02

P=0.002

Patient management change by physiology



Procedural management change by physiology



Reclassification according to the results of non-invasive tests

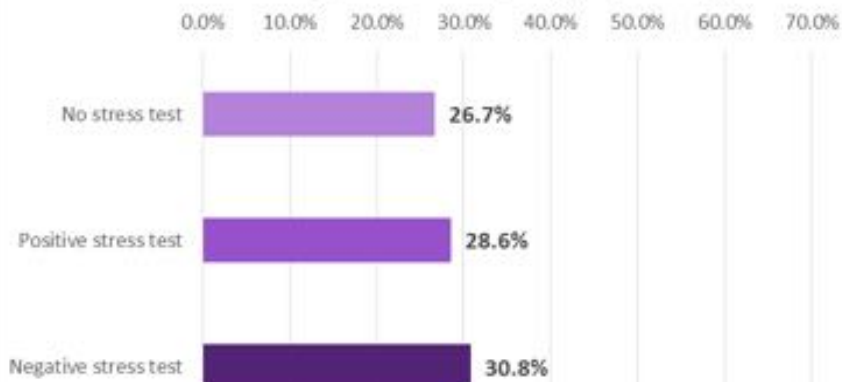
Stress test diagnosis in stable patients



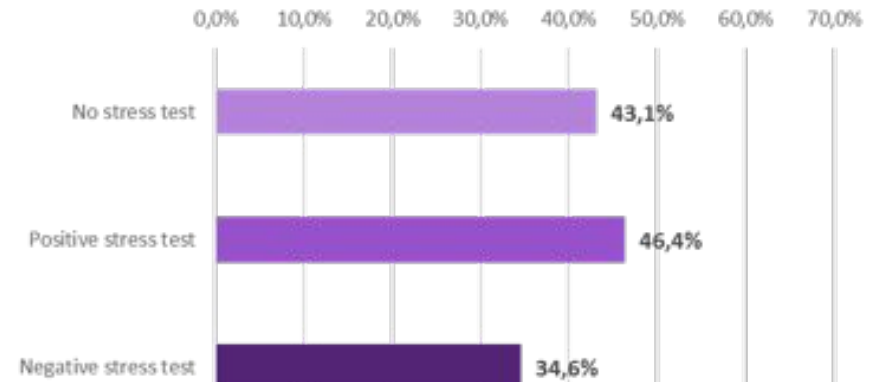
P=0.87

P=0.51

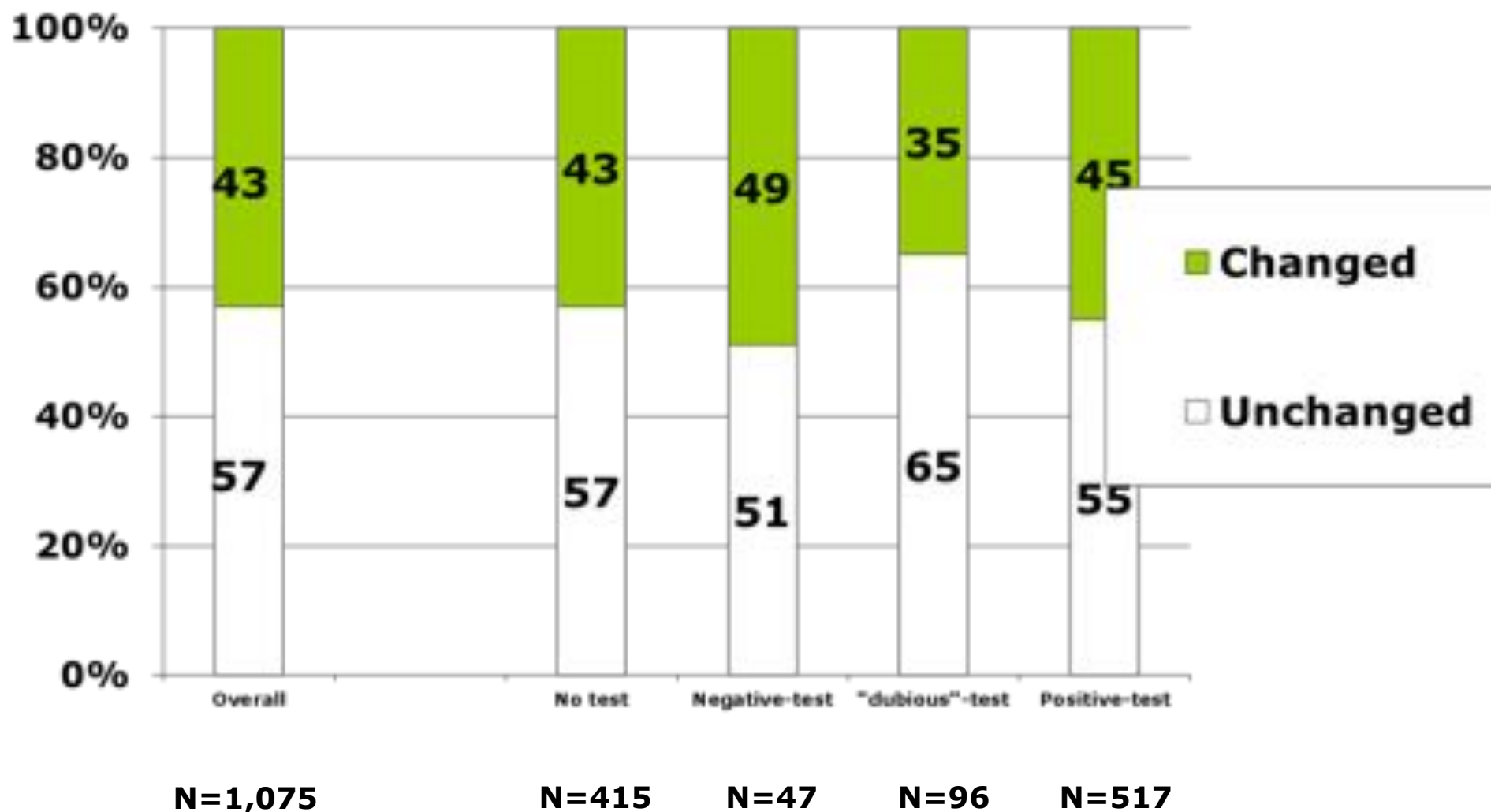
Patient management change by physiology



Procedural management change by physiology

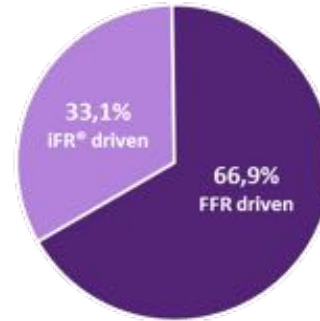


Change of the Revascularization strategy according to the results of non-invasive tests



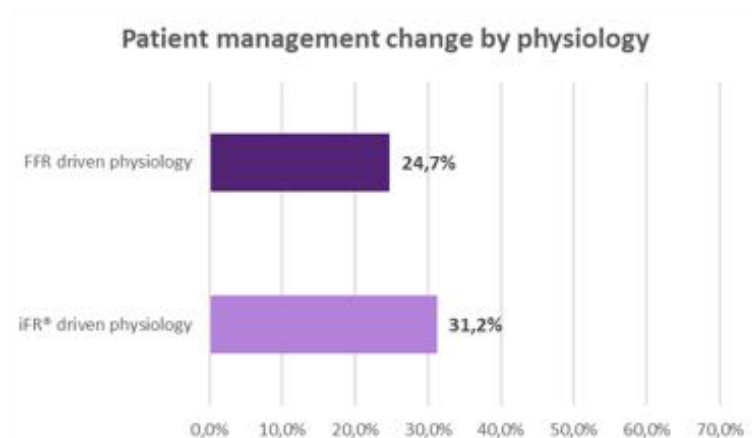
Reclassification according to the use of iFR/FFR

iFR® versus FFR driven physiology assesement in MVD patients

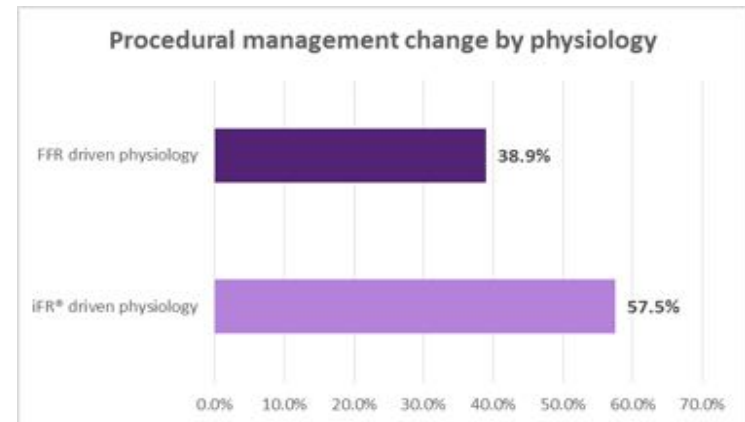


iFR : 1.9 vessels
FFR: 1.6 vessels

P=0.12



P=0.0001





Treatment Strategy Change After Routine Pressure Wire Assessment for Coronary Artery Disease

What You See Is “NOT” What You Get*

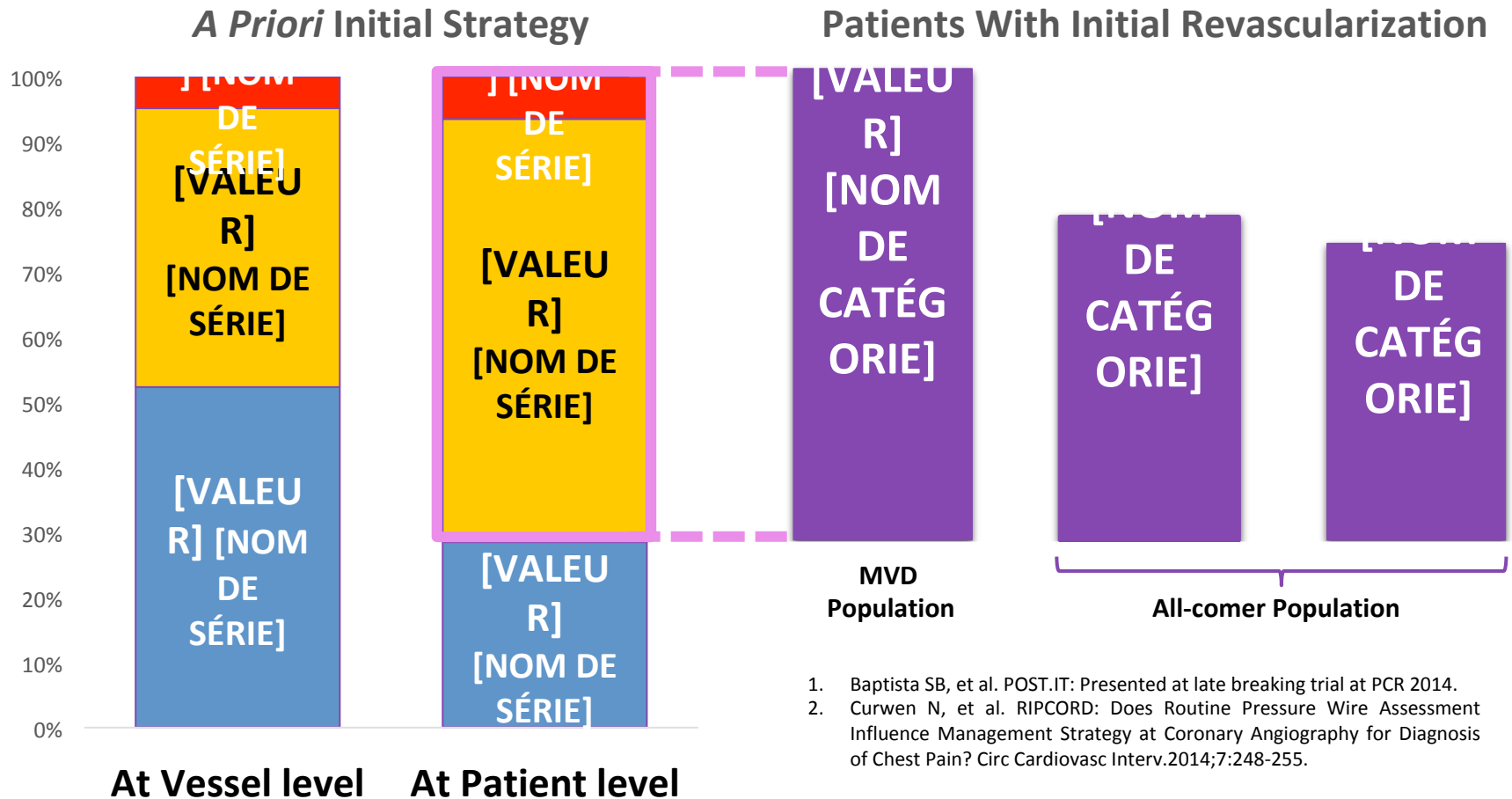
Bon-Kwon Koo, MD, PhD

TABLE 1 Summary of Previous Studies

Trial (Year) (Ref. #)	Subjects	PW Assessment	Change in Management Strategy
DEFINE REAL (2018) (6)	Multivessel disease	FFR and/or iFR Intermediate lesions	26.9% (130 of 484 patients)
POST-IT (2016) (7)	FFR in ≥ 1 vessel	FFR Operator's discretion	44.2% (406 of 918 patients)
FAMOUS-NSTEMI (2015) (8)	NSTEMI	FFR All lesions with $\geq 30\%$ stenosis	21.6% (38 of 176 patients)
R3F (2014) (9)	Ambiguous stenosis +	FFR Angiographically 35% to 65% stenosis	43.2% (464 of 1,075 patients)
RIPCORD (2014) (10)	Stable chest pain	FFR All coronary arteries ≥ 2.25 mm	26.5% (53 of 200 patients)

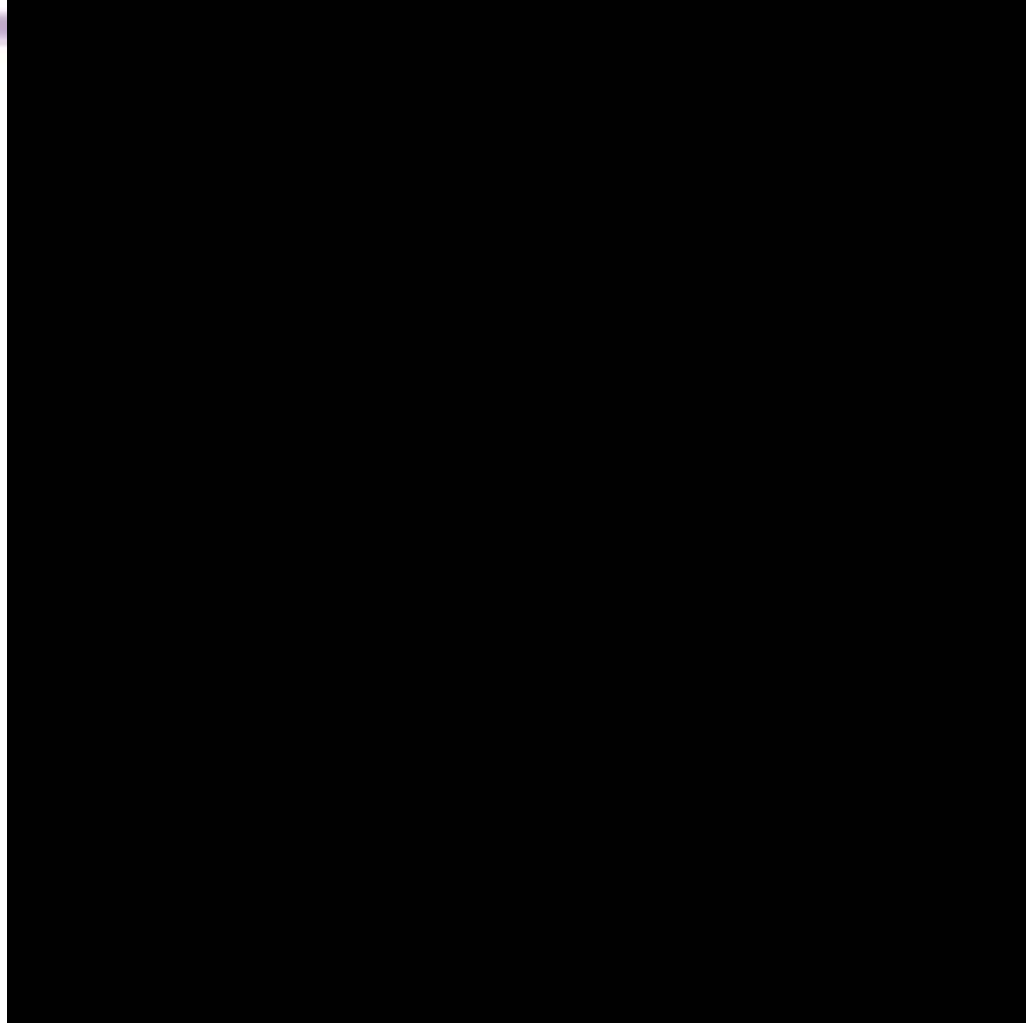
FFR = fractional flow reserve; iFR = instantaneous wave free ratio; NSTEMI = non-ST-segment elevation myocardial infarction; PW = pressure wire.

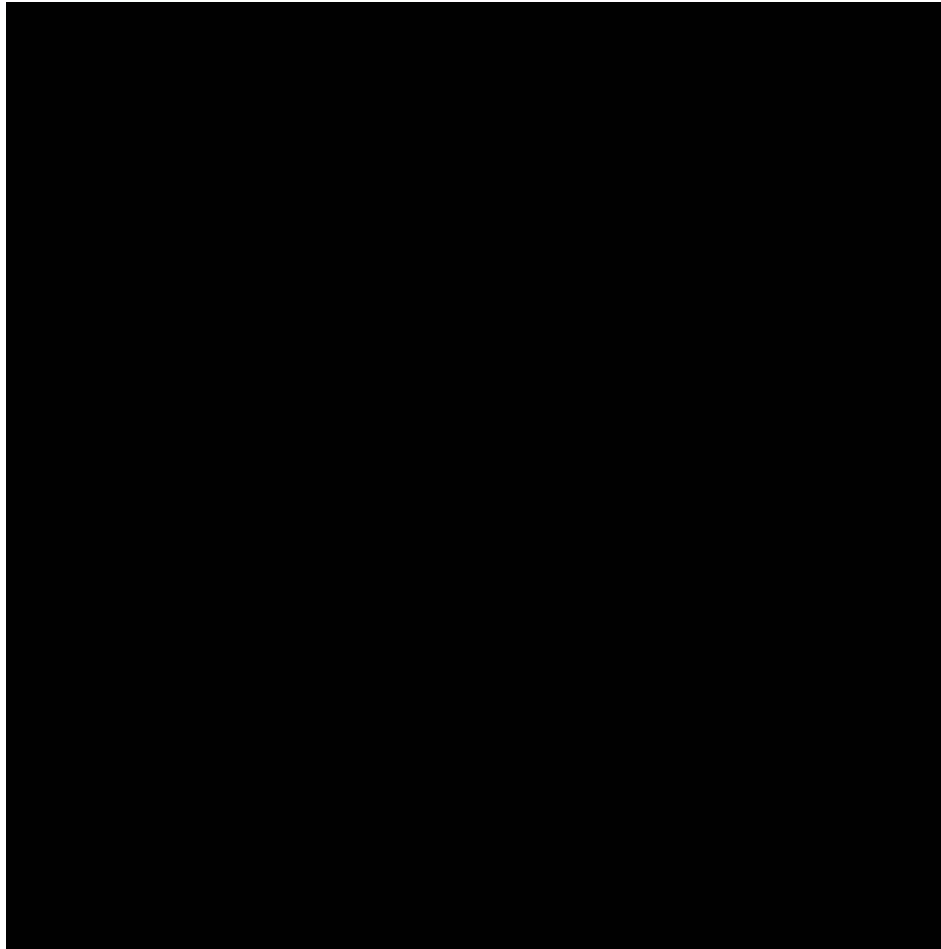
Initial Treatment Strategy By Angiography



Conclusions

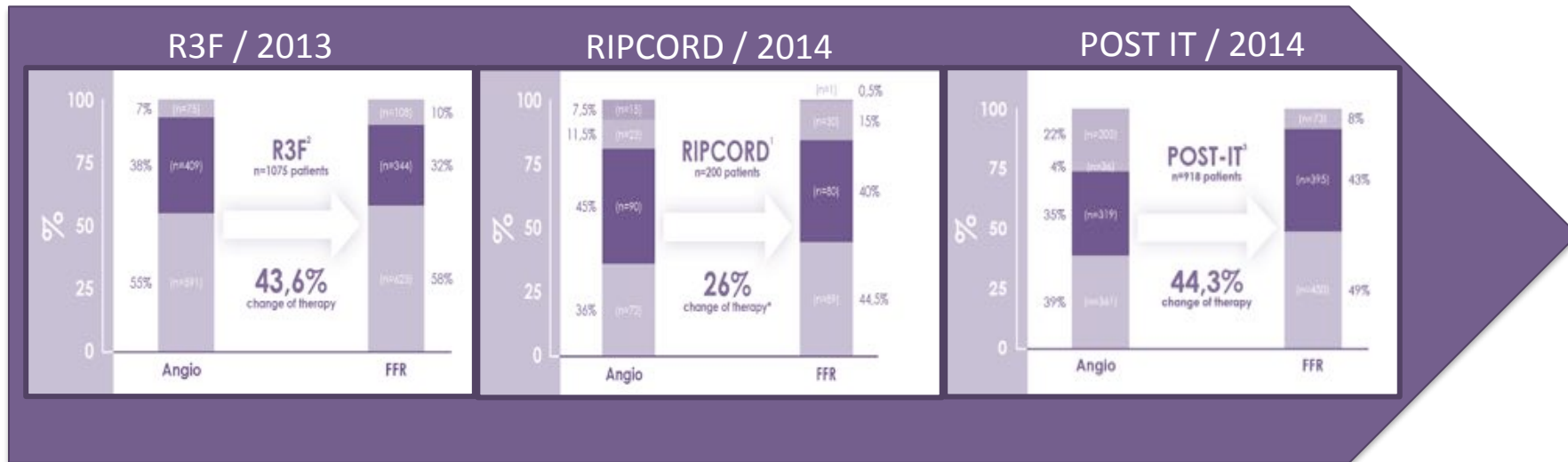
- ✓ Routine use of invasive physiology in patients with MVD is associated with a **high rate of reclassification** of management strategy (>30%).
- ✓ Reclassification rates are **independent** of the pre-angiography performance of non-invasive testing and results.
- ✓ **Interrogation of more vessels** is associated with an increased rate of reclassification.
- ✓ **Incorporating iFR® as part of the process** is associated with the investigation of more vessels, which in turn leads to a higher reclassification rate, and a decrease in the occurrence of minor safety events.





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



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- To analyze how FFR and iFR[®] are used in routine practice during physiology evaluation of MVD patients.

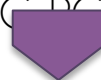
Methodology

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

ANGIOGRAPHY

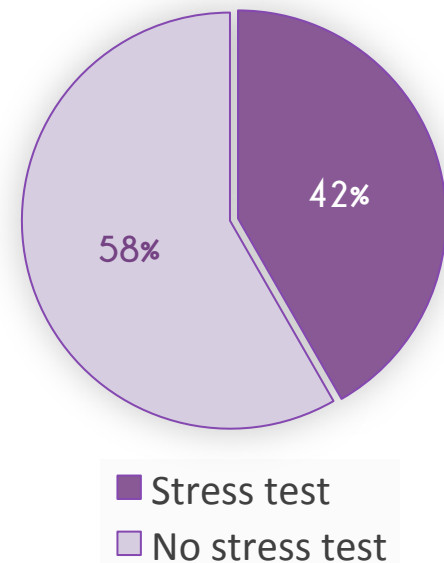
PHYSIOLOGY

CHANGE(S) ?

Patient Demographics

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

Stress Test in Stable Patients



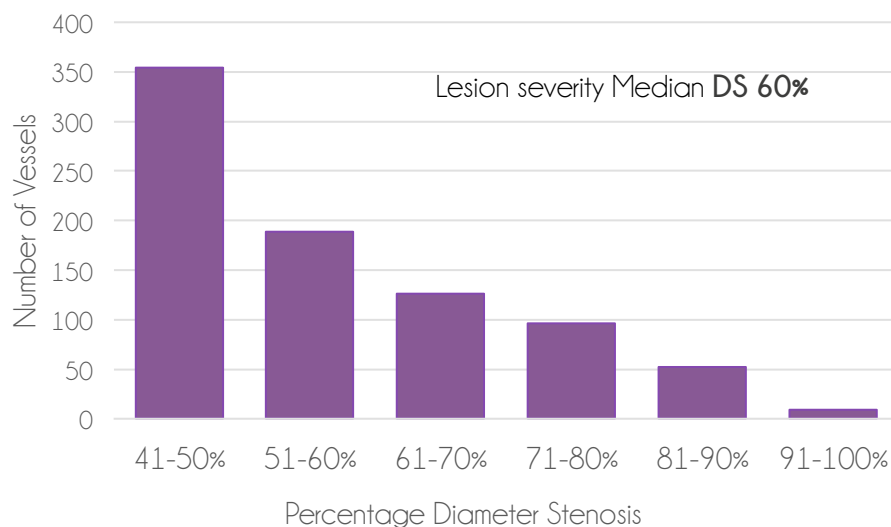
Baseline Characteristics

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

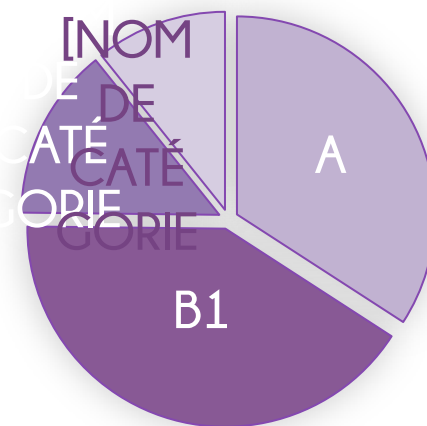
Multi-Vessel Disease



% Diameter Stenosis Distribution

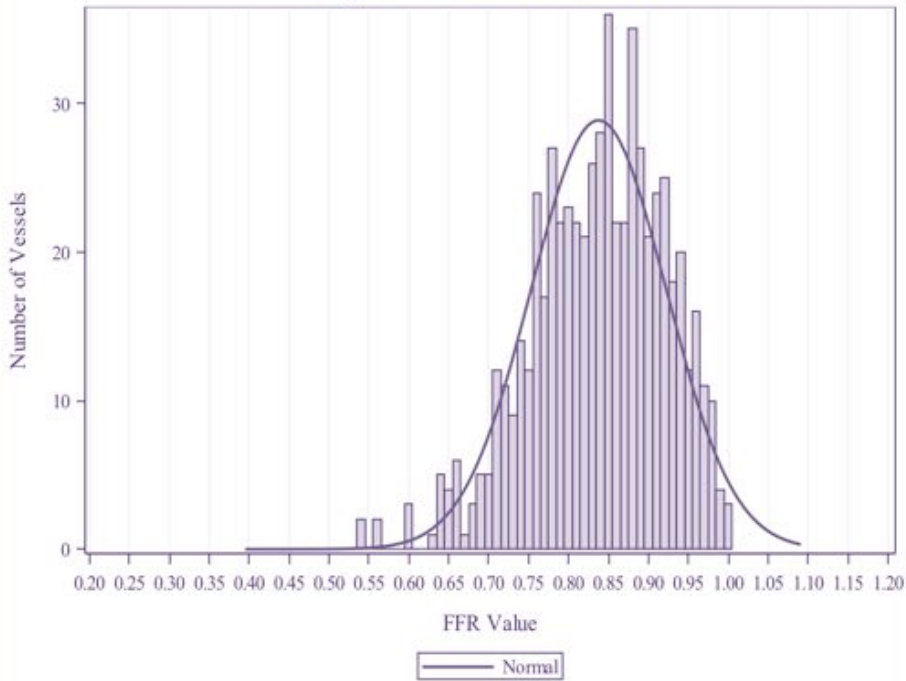


Lesion type



Results of FFR/iFR[®]

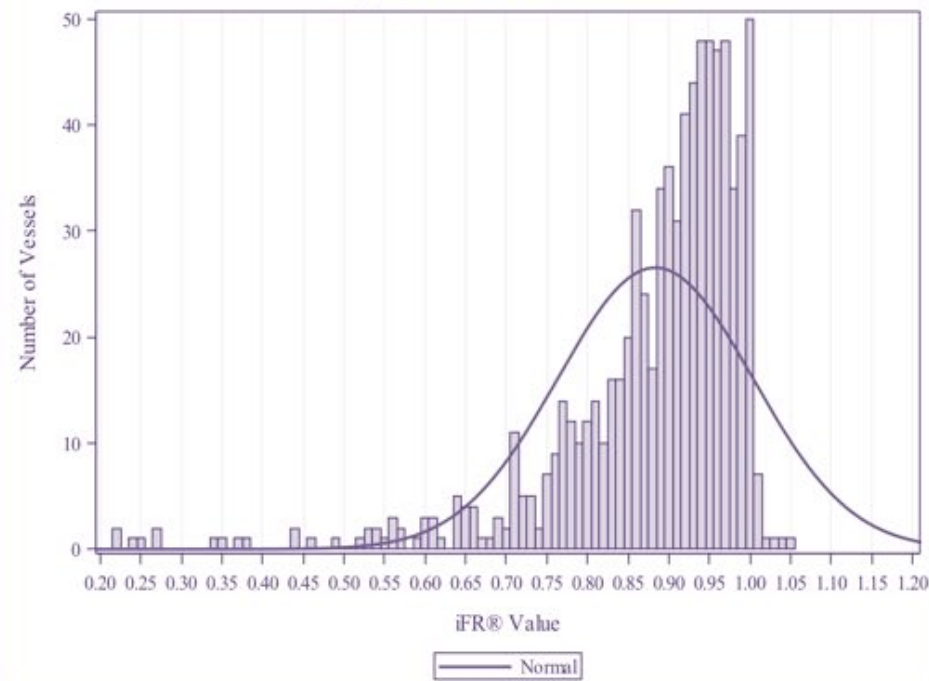
Figure 4: FFR Value Distribution



Median FFR Value: 0,85

n = 608

Figure 3: iFR[®] Value Distribution

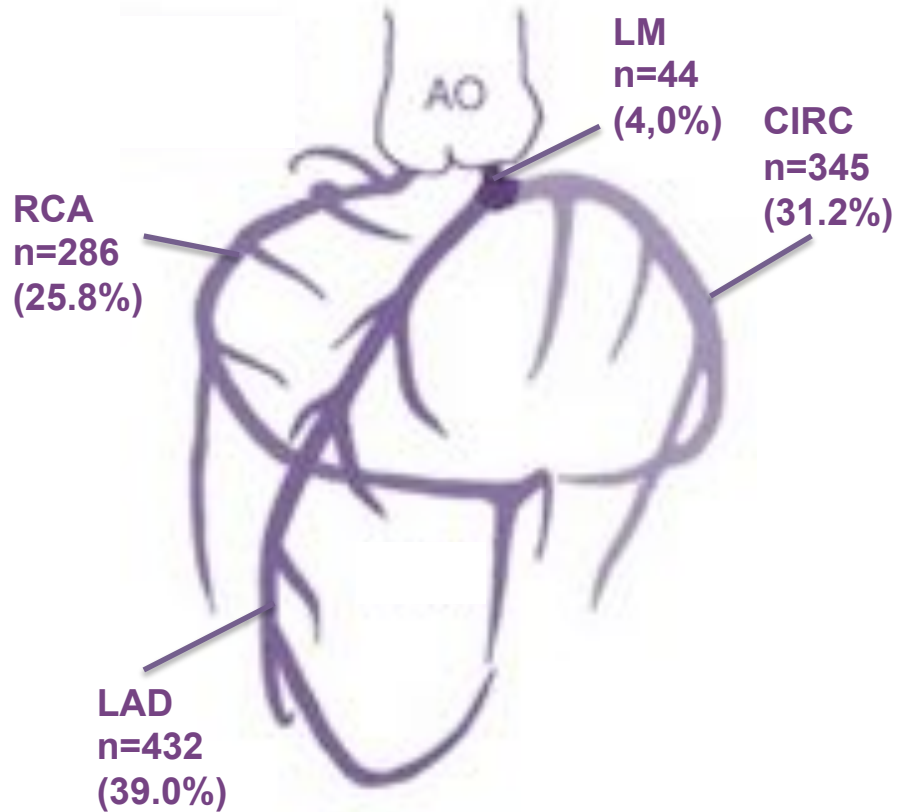


Median iFR[®] Value: 0,92

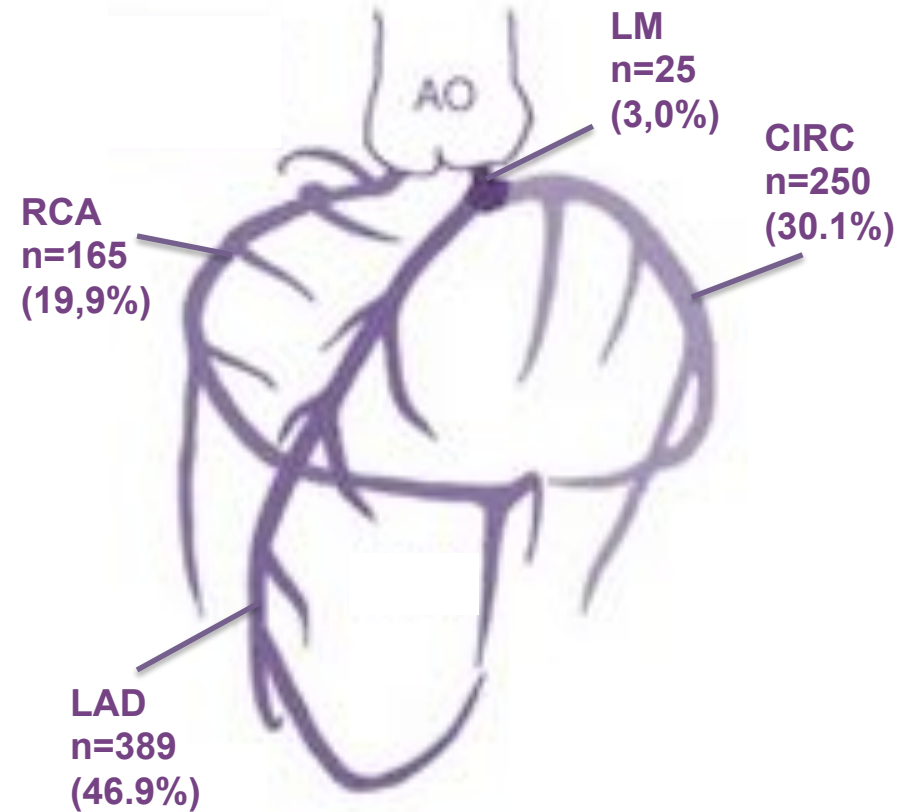
n = 793

Baseline Characteristics

Diseased Vessels by
Angiography [n=1107]

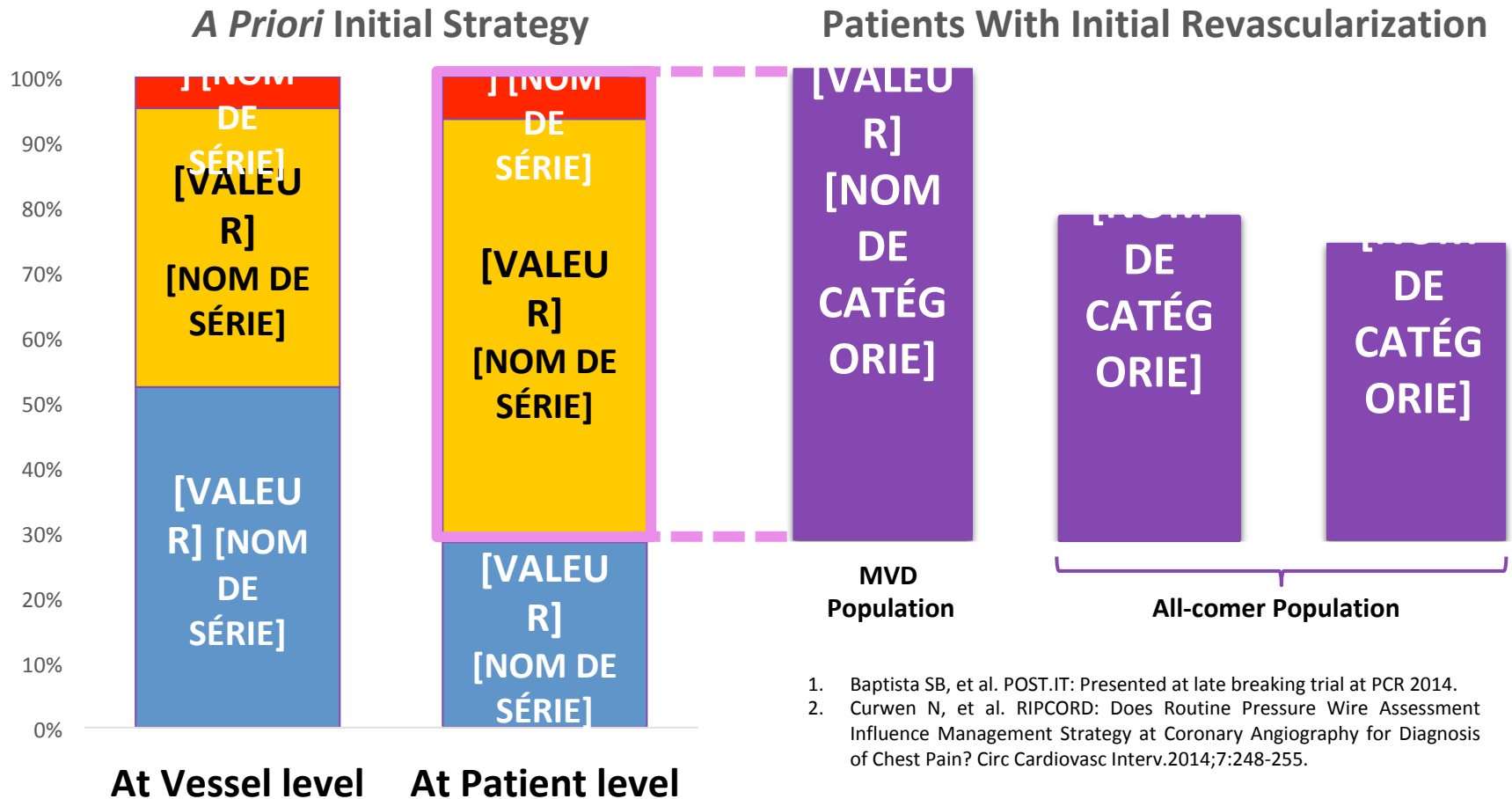


Vessels Interrogated with
Physiology [n=830]

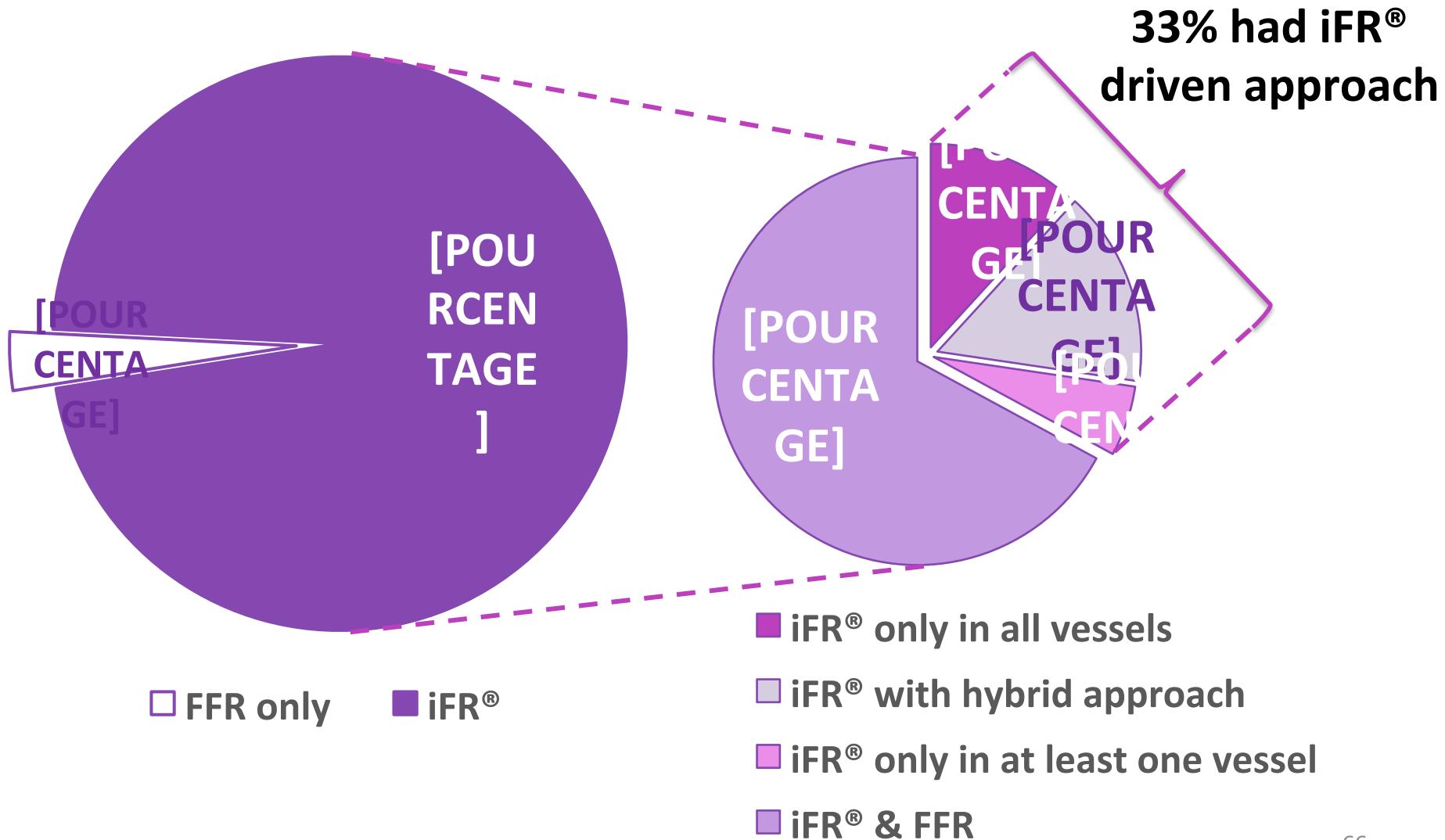


In this MVD population, 75% of diseased vessels were interrogated by Physiology

Initial Treatment Strategy By Angiography

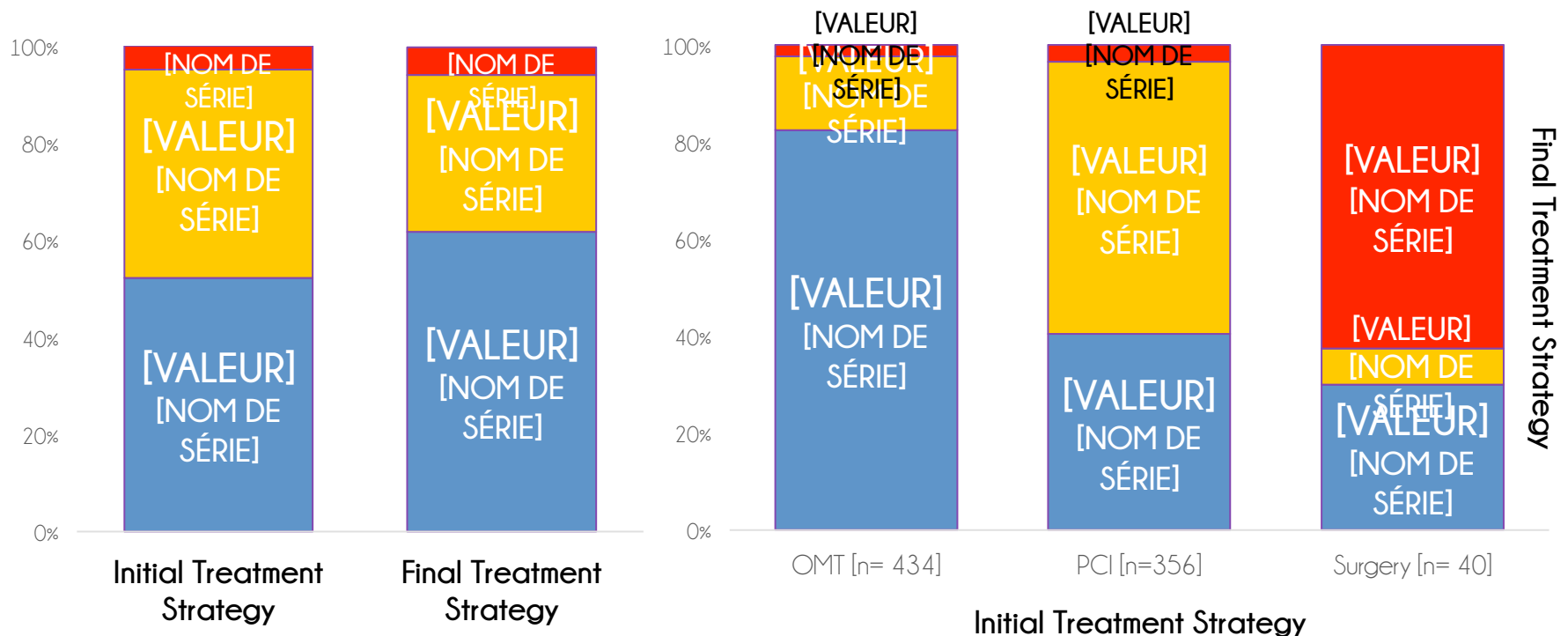


Physiology Approaches



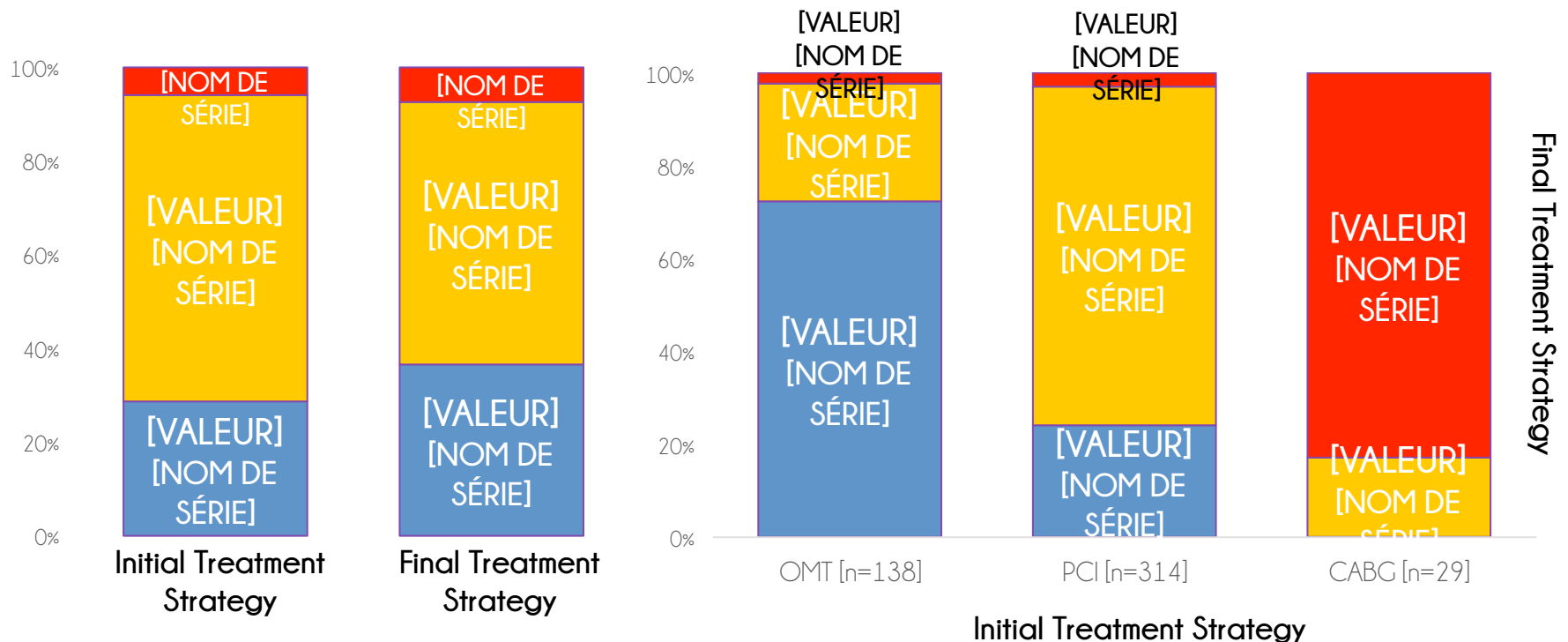
Changes of Treatment Strategy

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



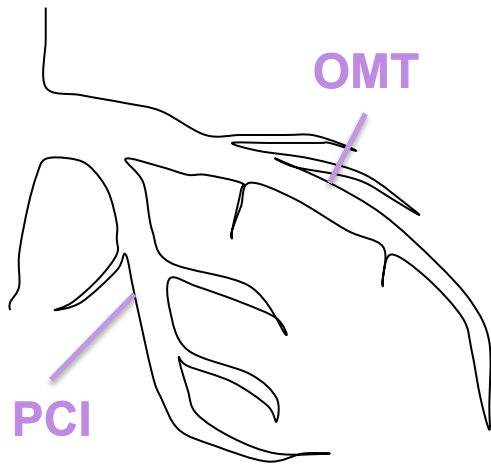
Changes of Treatment Strategy

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



Changes of Treatment Strategy

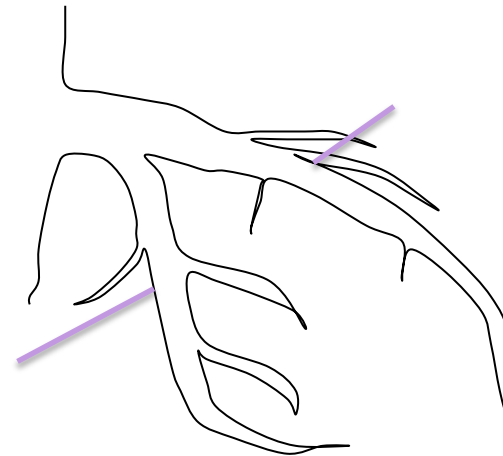
**Initial Treatment
by Angiography**



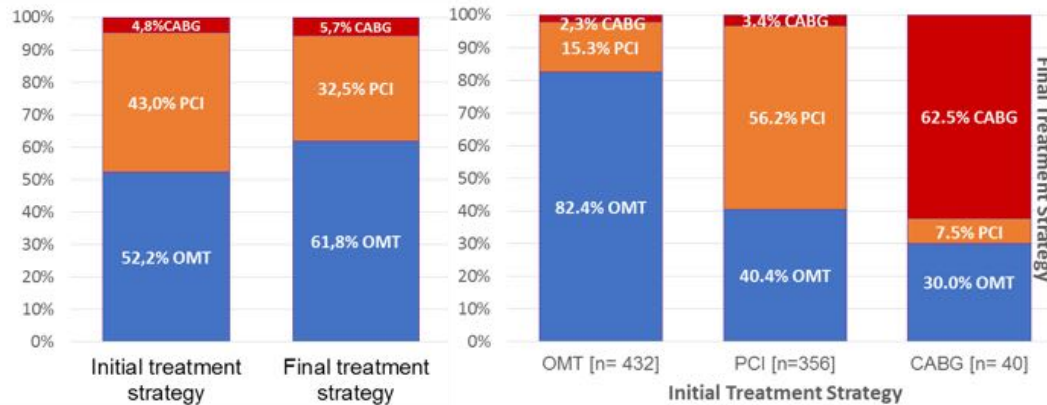
Physiology
iFR/FFR



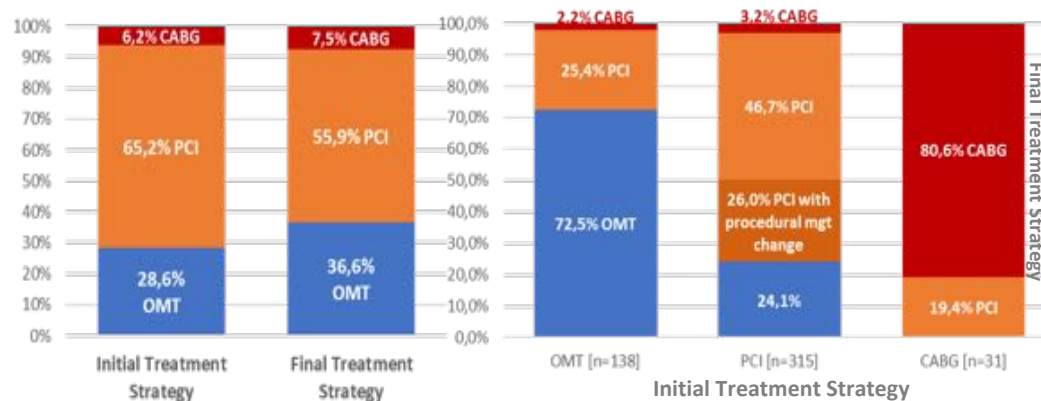
**Final Treatment
by Physiology**



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%



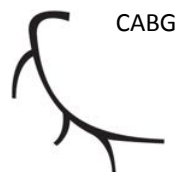
ANGIOGRAPHY

PHYSIOLOGY

RECLASSIFICATION OF TREATMENT ?

2A

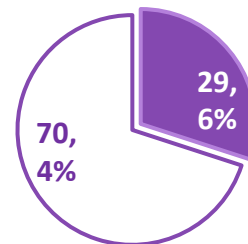
VESSEL LEVEL



Change:
PCI → CABG



Vessel Management
At Vessel Level



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

2B

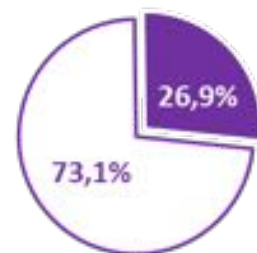
PATIENT LEVEL



Change:
PCI → CABG



Patient Management
At Patient Level
Patient Point of View



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

2C

Initial Treatment
by Angiography



Physiology
iFR/FFR



Final Treatment
by Physiology



No Change:
PCI → PCI



Patient Management
At Patient Level
Patient Point of View



Procedural management change
in **45.0%** of patients



Change:
PCI → PCI of
other vessel

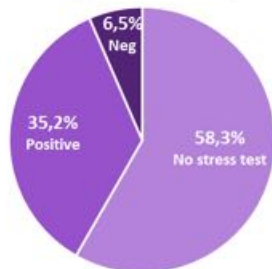


Procedural Management
At Patient Level
Physician Point of View

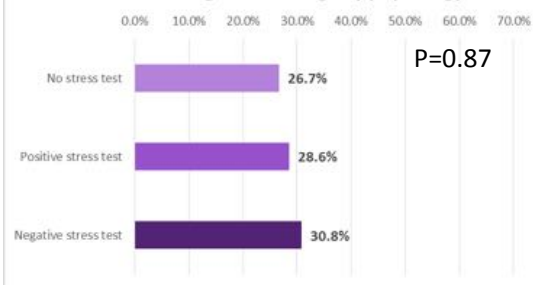


A

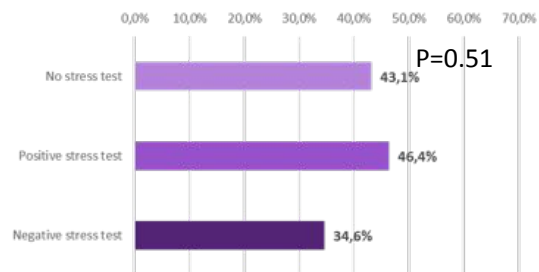
Stress test diagnosis in stable patients



Patient management change by physiology

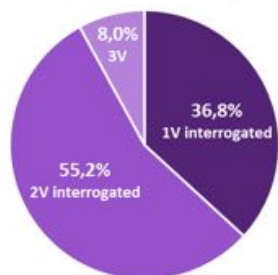


Procedural management change by physiology

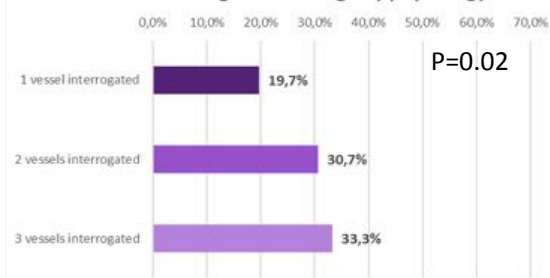


B

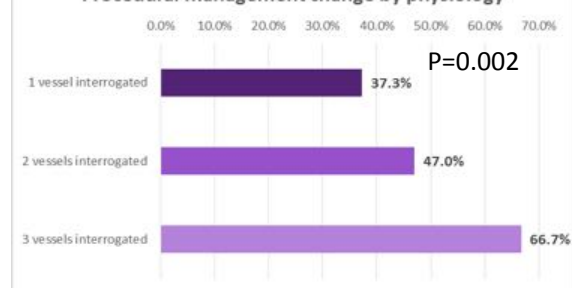
Vessels interrogated in MVD patients



Patient management change by physiology

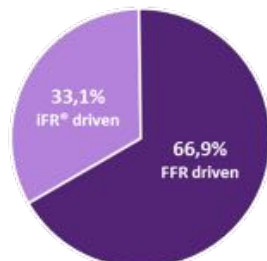


Procedural management change by physiology



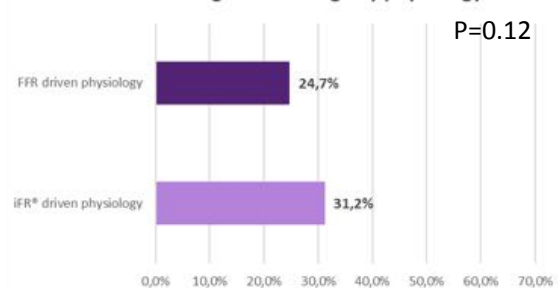
C

iFR® versus FFR driven physiology assesement in MVD patients

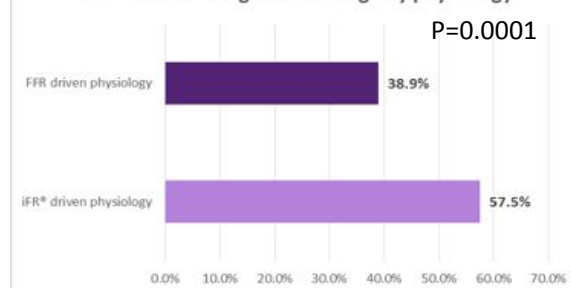


iFR : 1.8 vessels
FFR: 1.6 vessels

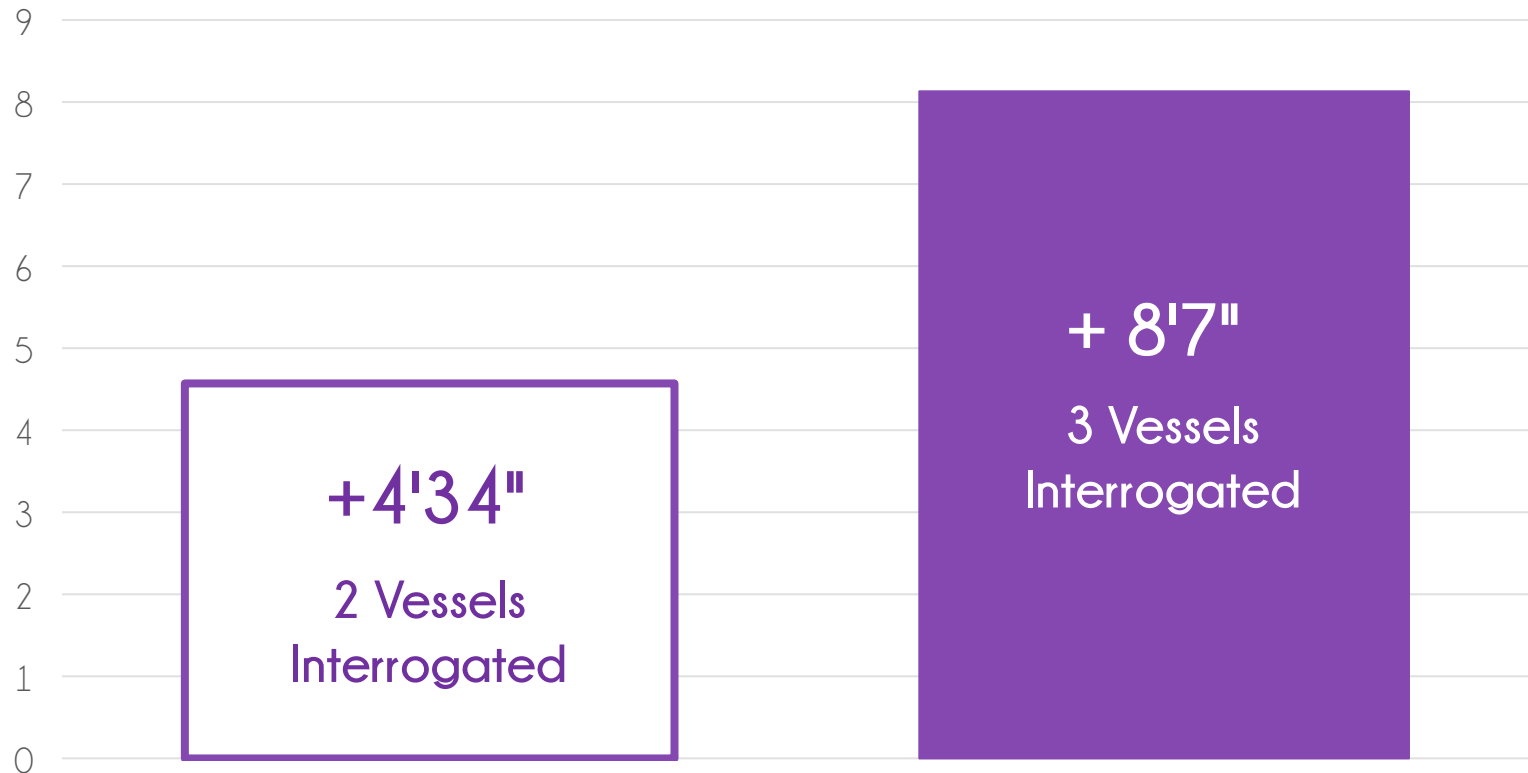
Patient management change by physiology



Procedural management change by physiology



Extra time for Physiology in >1 vessel



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 lead 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.



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

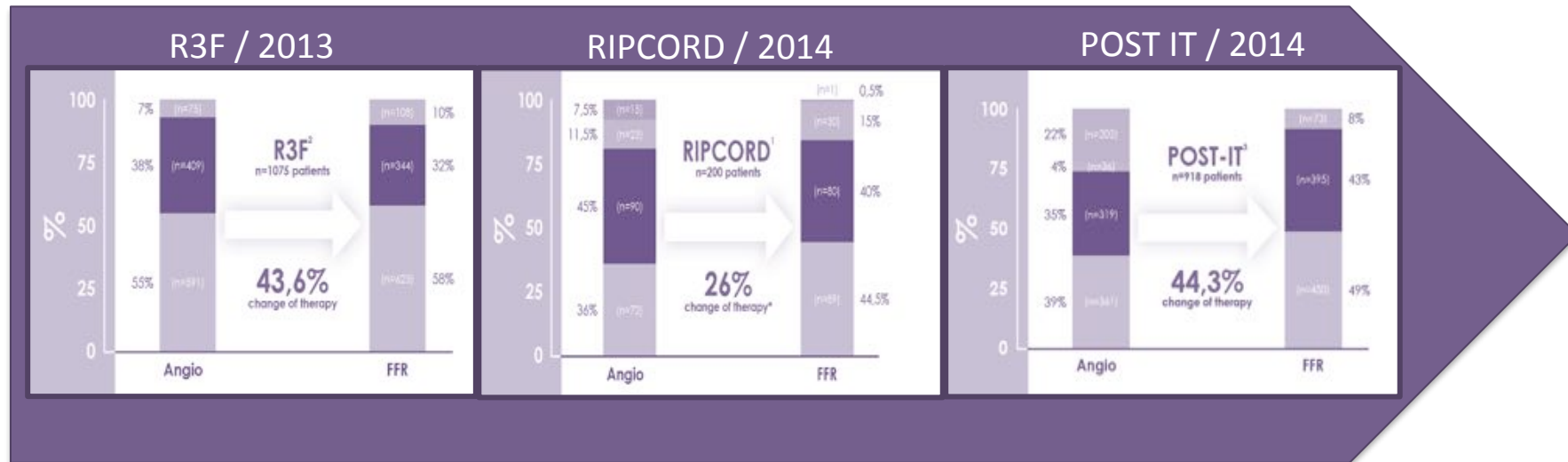
Prof. Eric Van Belle on behalf of the DEFINE REAL Investigators

DEFINE REAL



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.

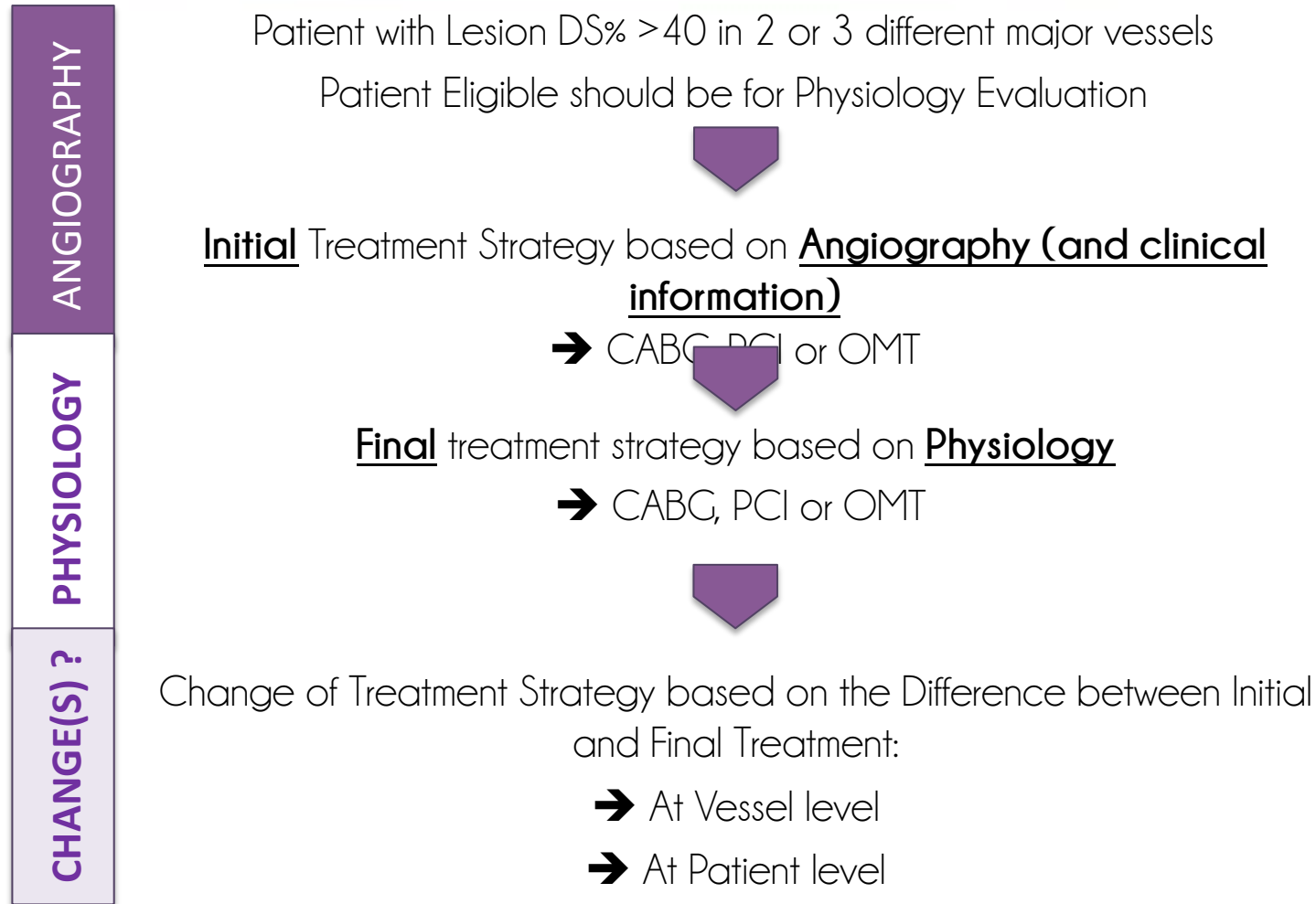
Objectives

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.

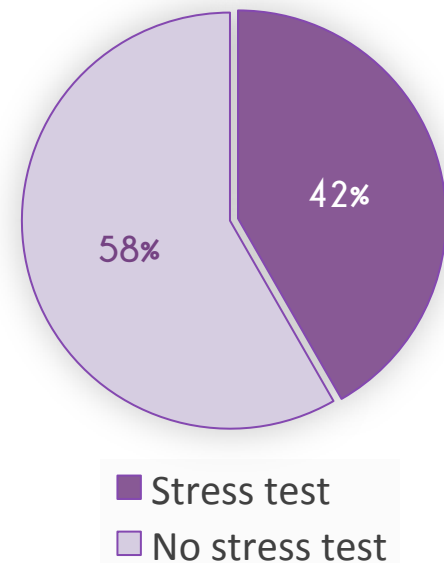
Methodology



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%

Stress Test in Stable Patients



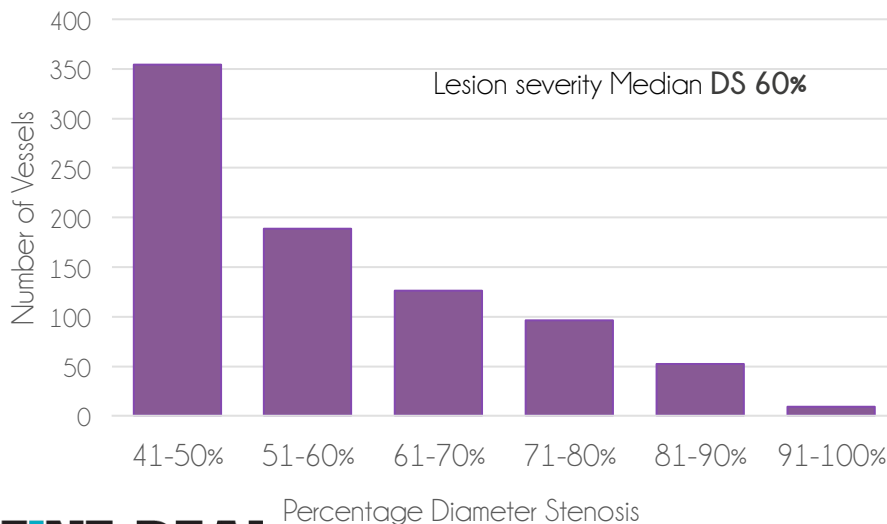
Baseline Characteristics

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

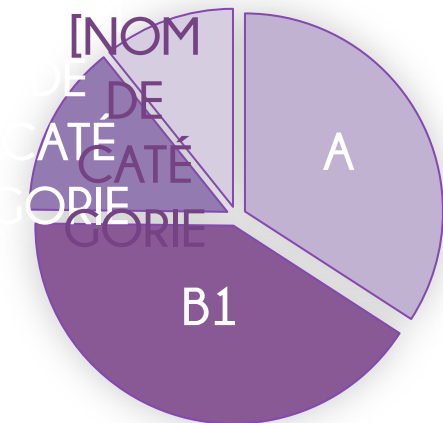
Multi-Vessel Disease



% Diameter Stenosis Distribution

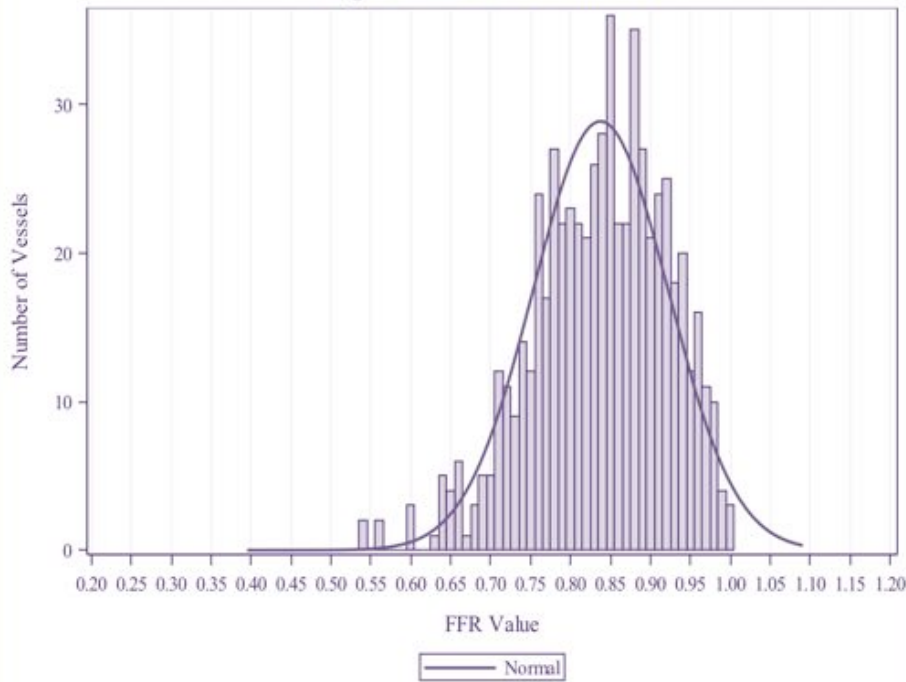


Lesion type



Results of FFR/iFR®

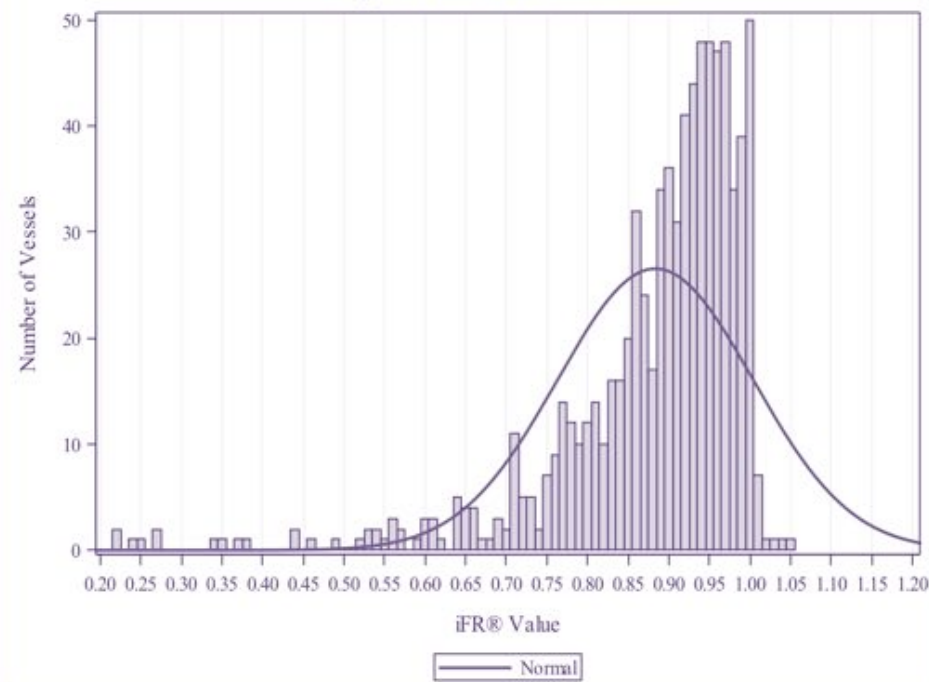
Figure 4: FFR Value Distribution



Median FFR Value: 0,85

n = 608

Figure 3: iFR® Value Distribution

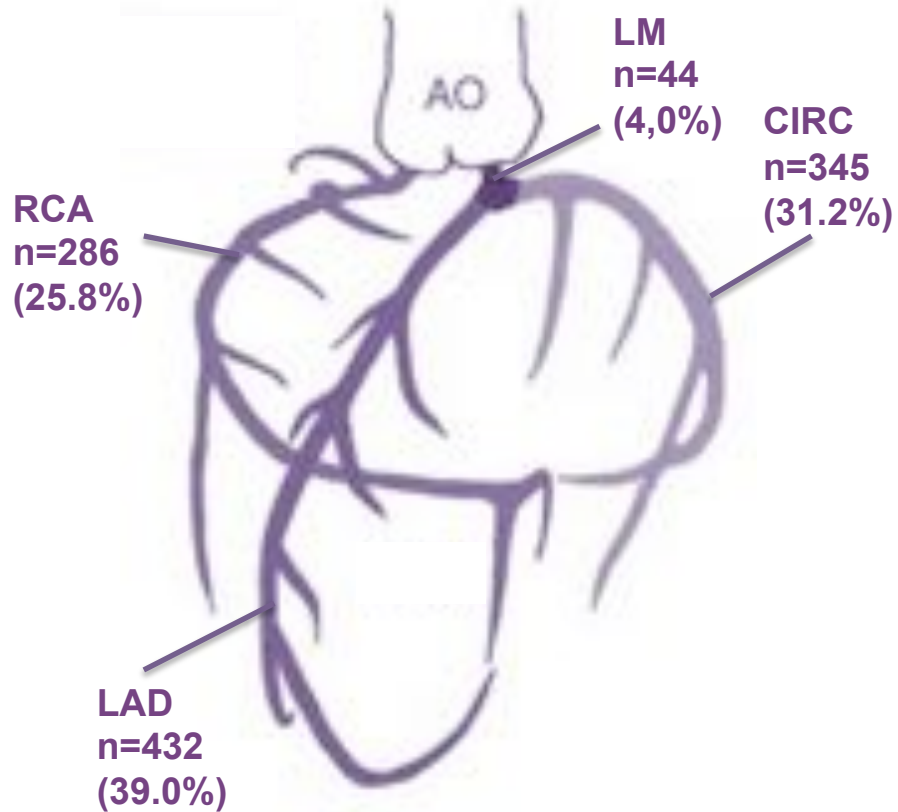


Median iFR® Value: 0,92

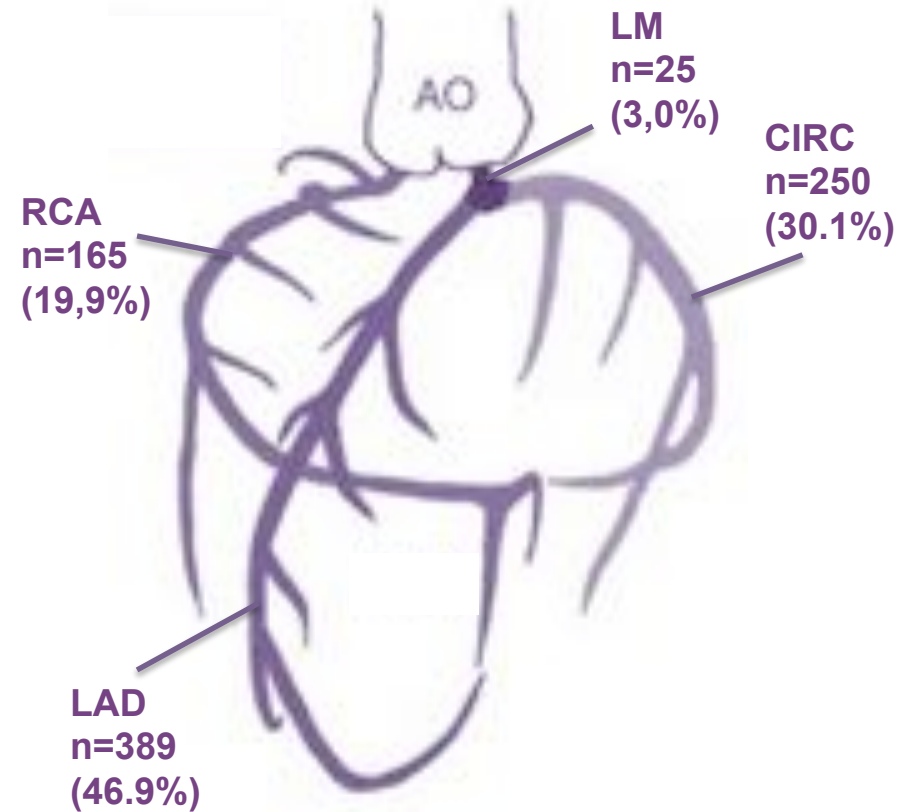
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Diseased Vessels by
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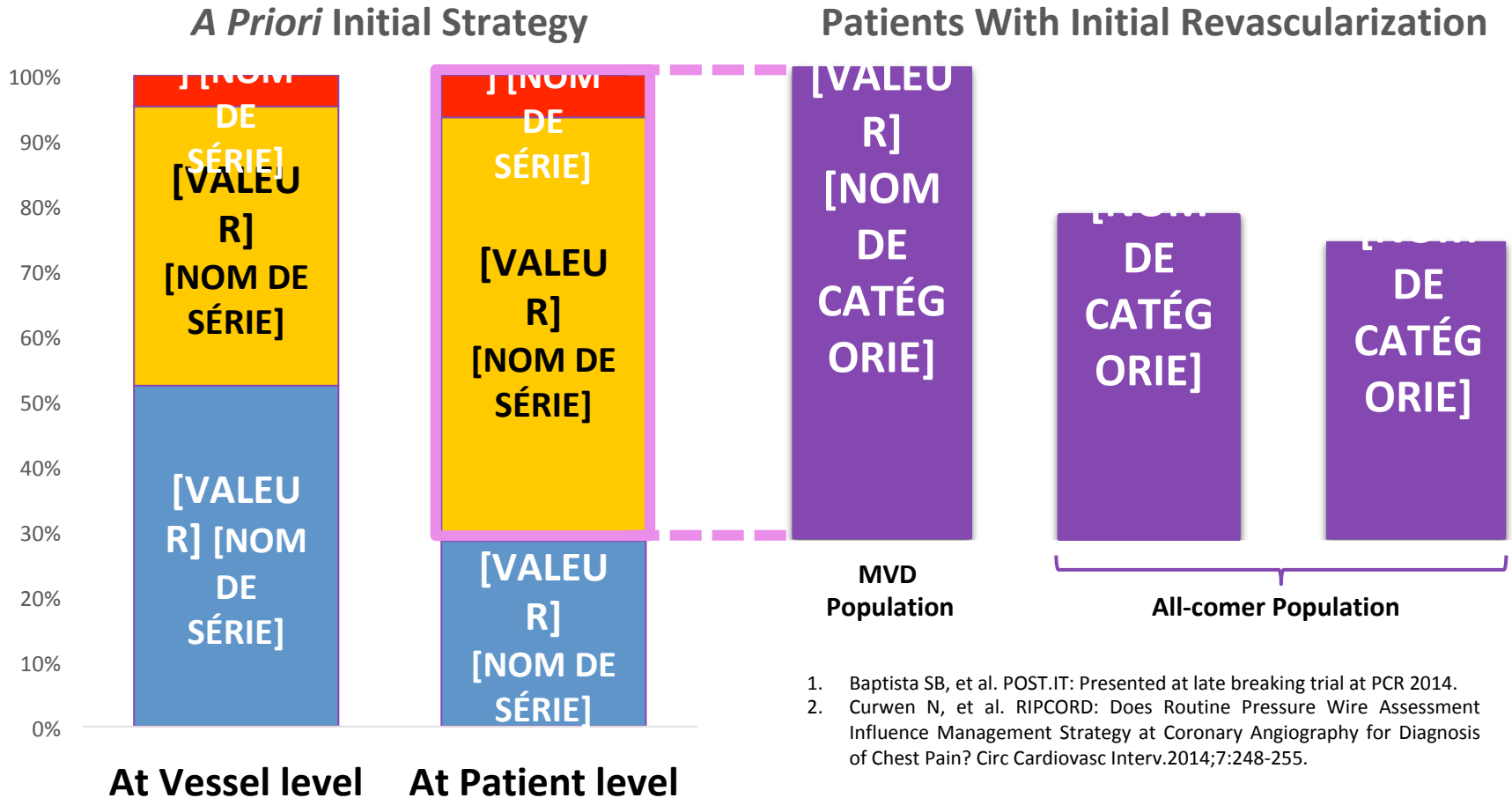


Vessels Interrogated with
Physiology [n=830]

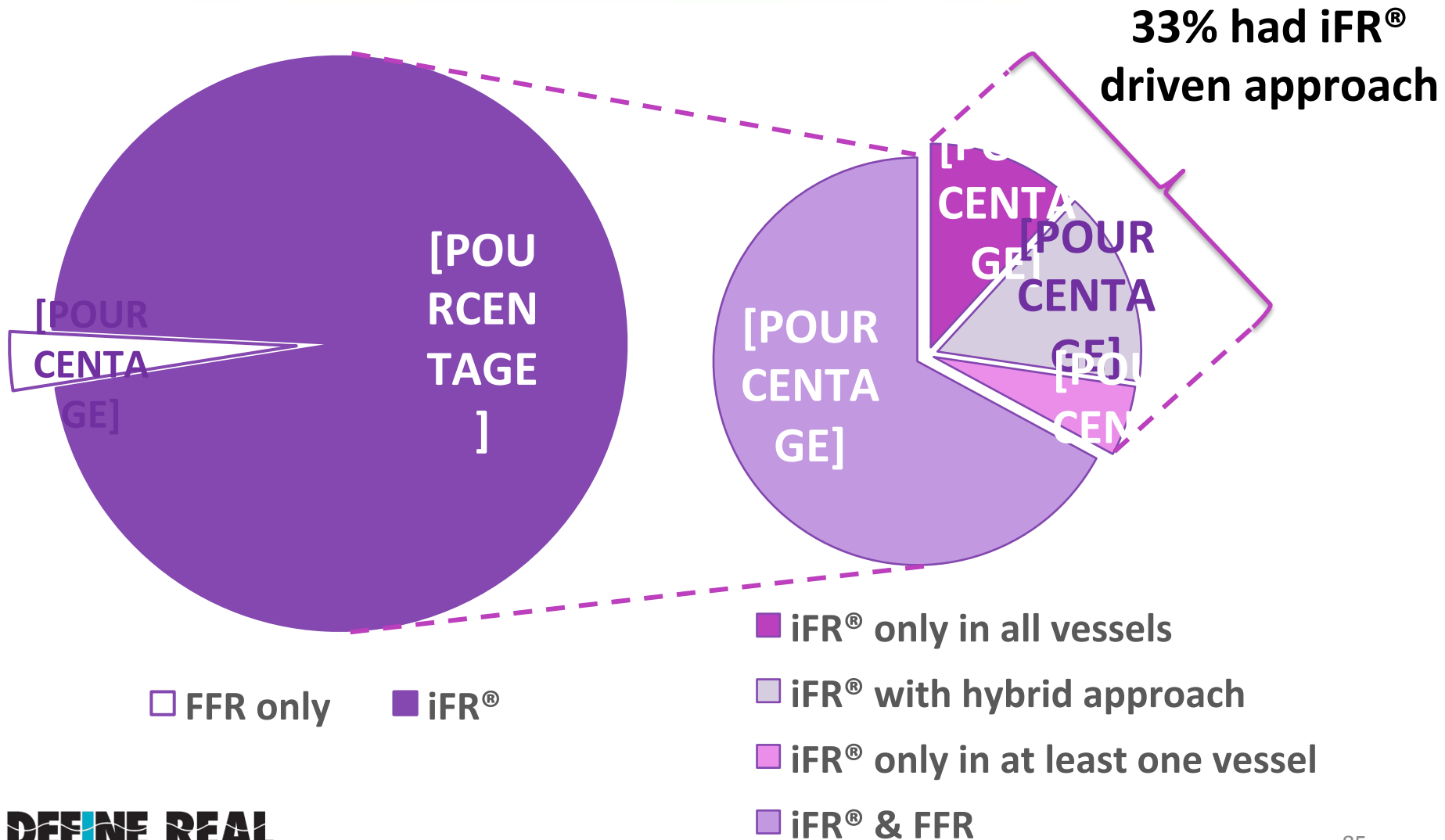


In this MVD population, 75% of diseased vessels were interrogated by Physiology

Initial Treatment Strategy By Angiography

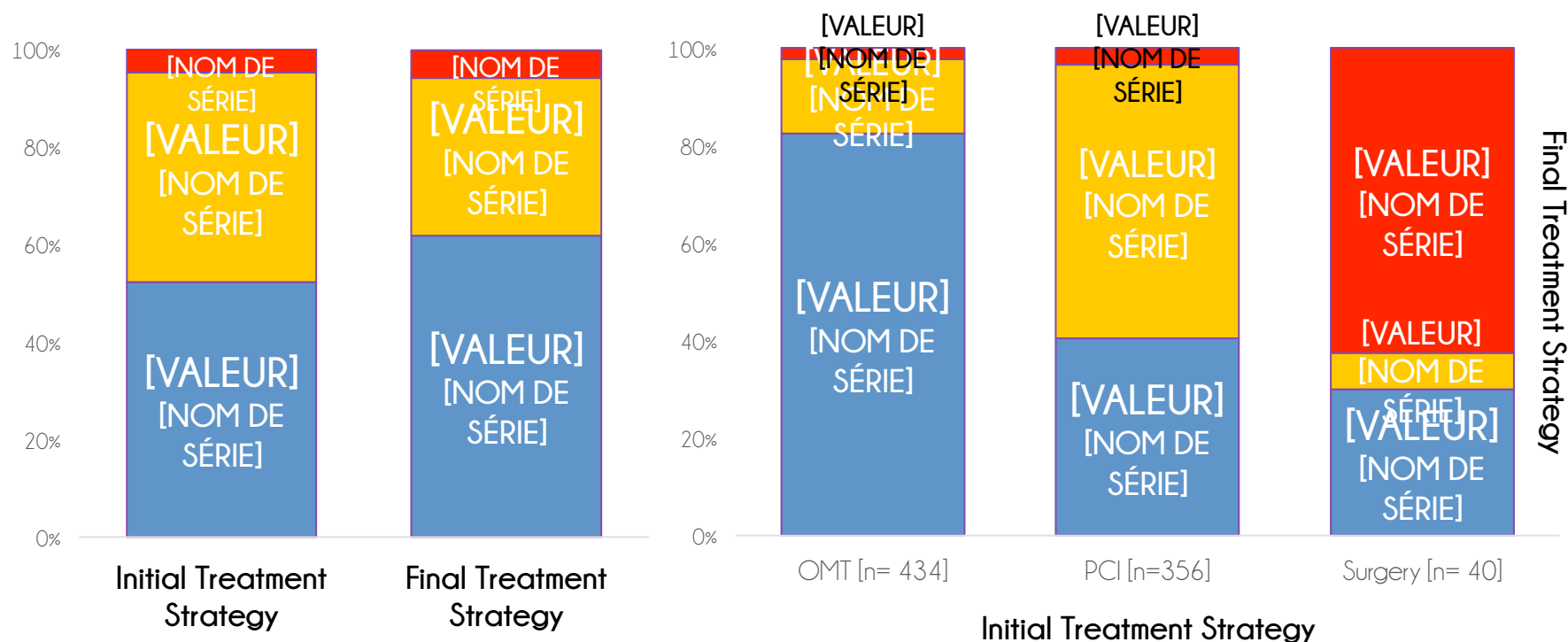


Physiology Approaches



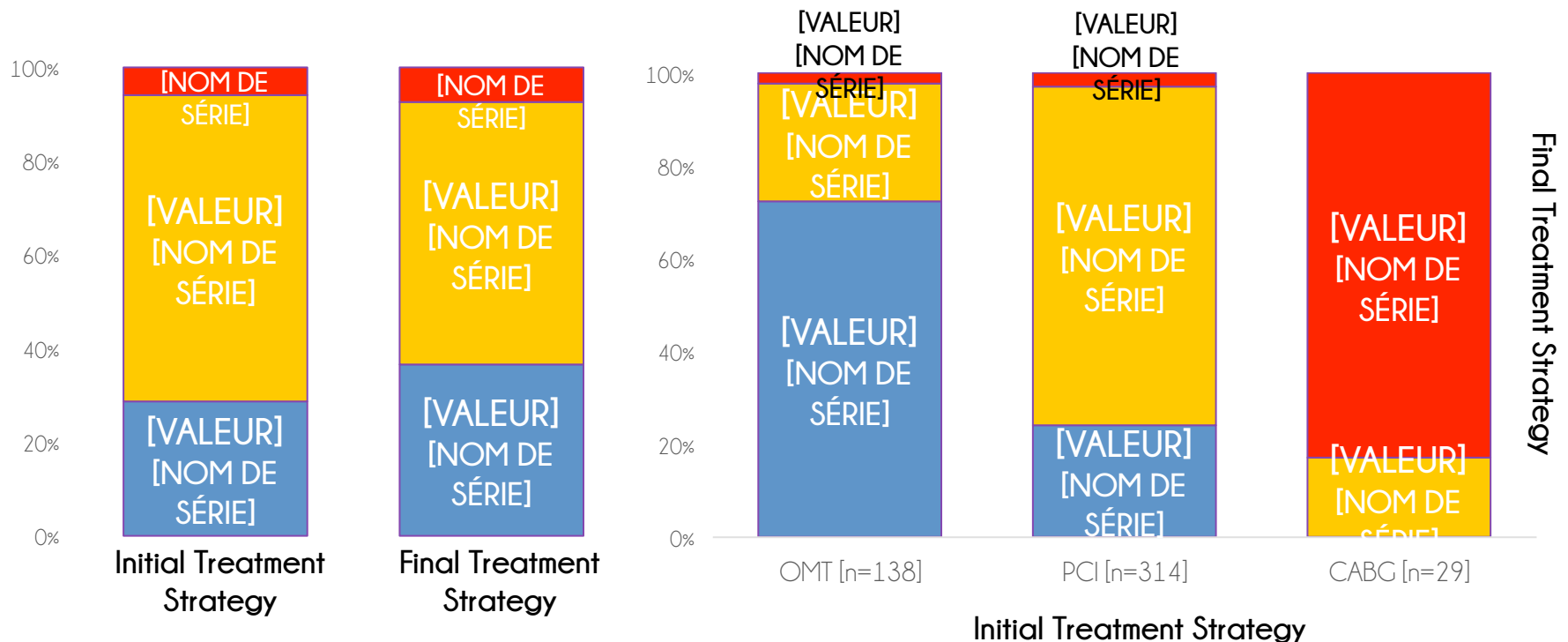
Changes of Treatment Strategy

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



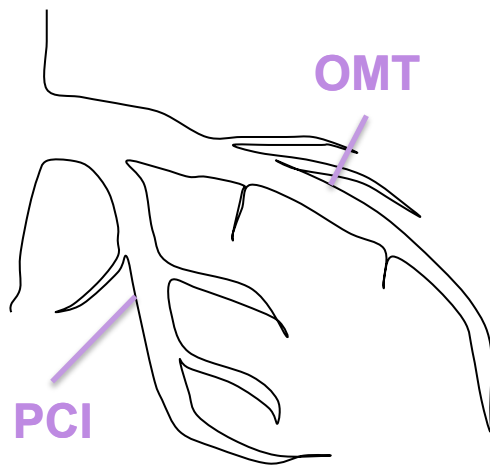
Changes of Treatment Strategy

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



Changes of Treatment Strategy

Initial Treatment
by Angiography

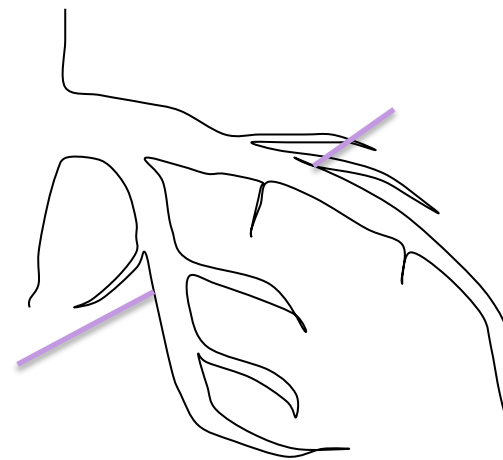


Physiology

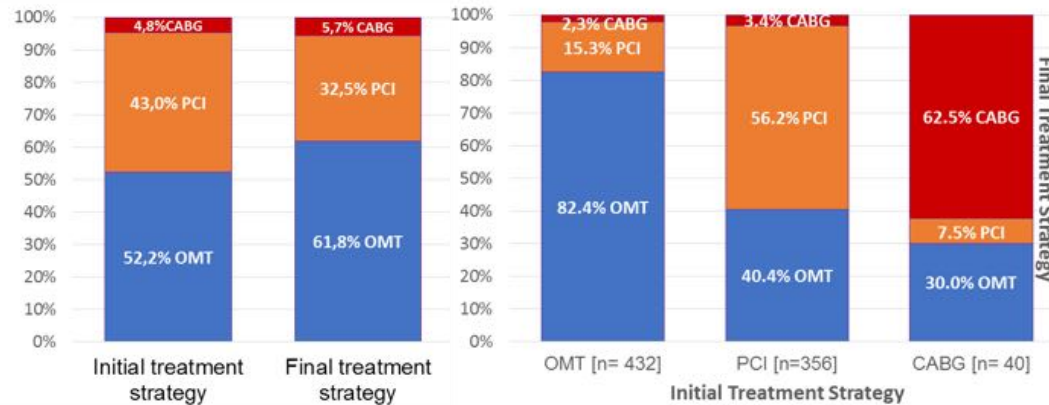
iFR/FFR



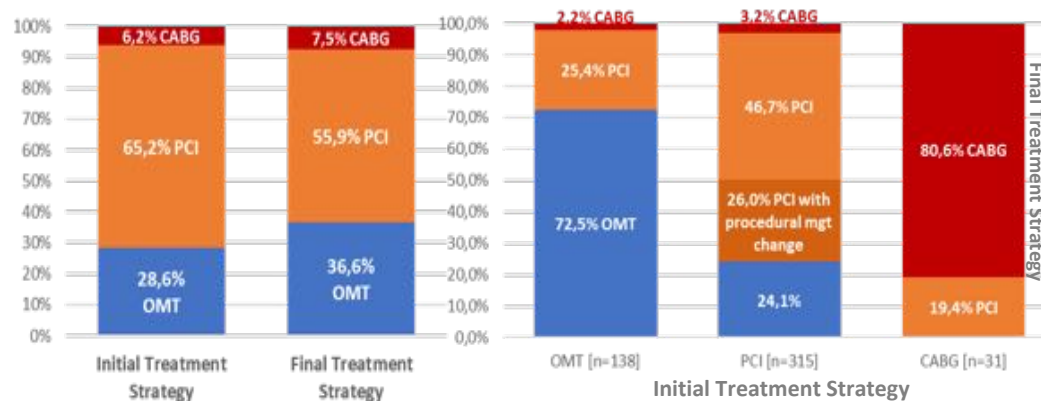
Final Treatment
by Physiology



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%



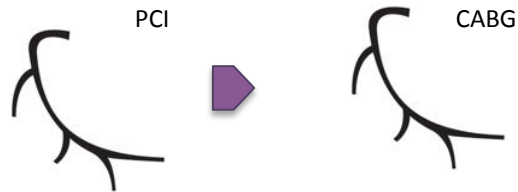
ANGIOGRAPHY

PHYSIOLOGY

RECLASSIFICATION OF TREATMENT ?

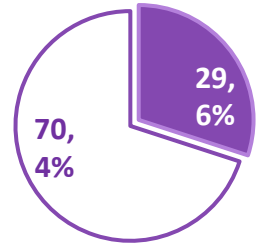
2A

VESSEL LEVEL



Change:
PCI → CABG

Vessel Management
At Vessel Level



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

2B

PATIENT LEVEL



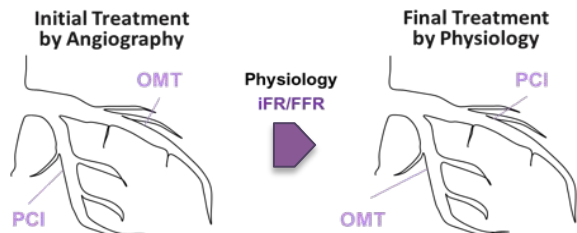
Change:
PCI → CABG

Patient Management
At Patient Level
Patient Point of View



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

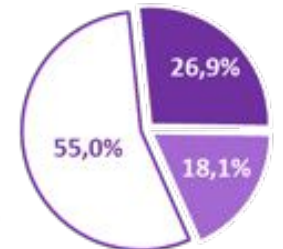
2C



No Change:
PCI → PCI

Change:
PCI → PCI of
other vessel

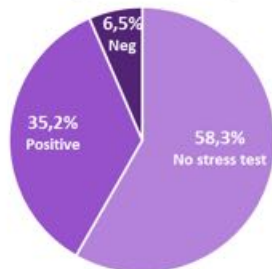
Procedural Management
At Patient Level
Physician Point of View



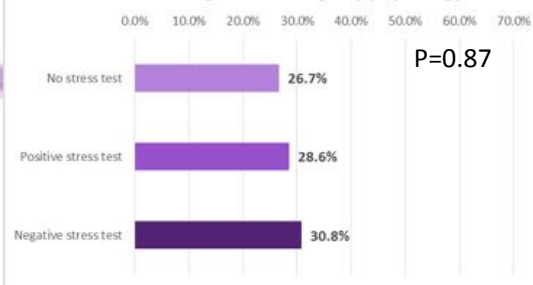
Procedural management change in **45.0%** of patients

A

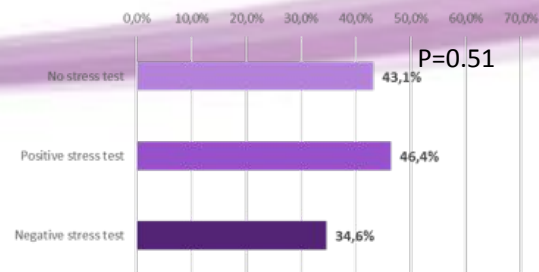
Stress test diagnosis in stable patients



Patient management change by physiology

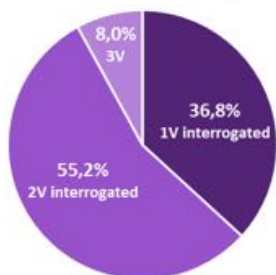


Procedural management change by physiology

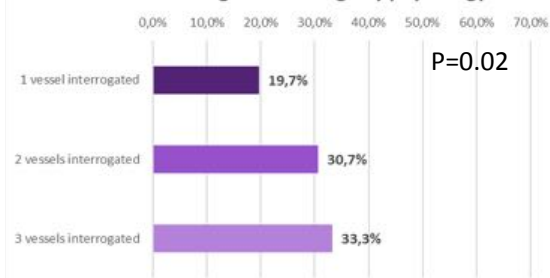


B

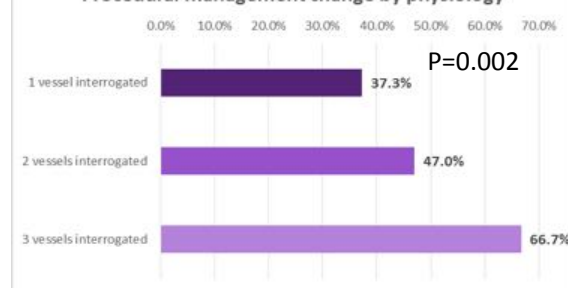
Vessels interrogated in MVD patients



Patient management change by physiology

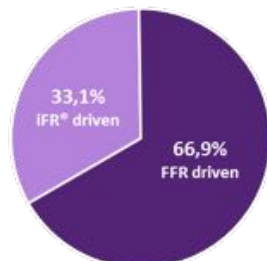


Procedural management change by physiology



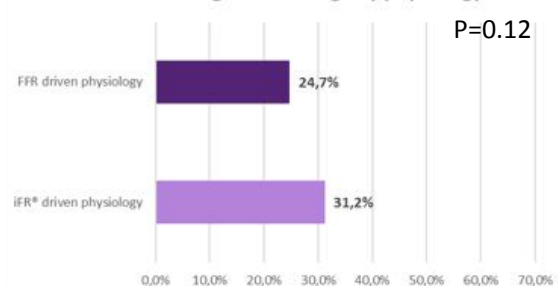
C

iFR® versus FFR driven physiology assesement in MVD patients

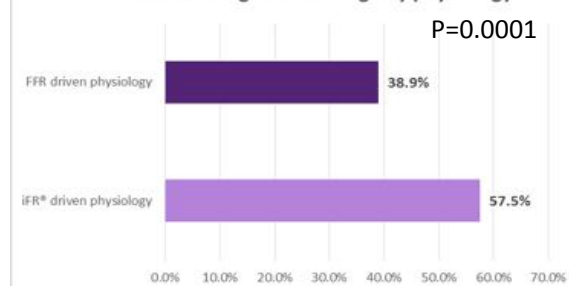


iFR : 1.8 vessels
FFR: 1.6 vessels

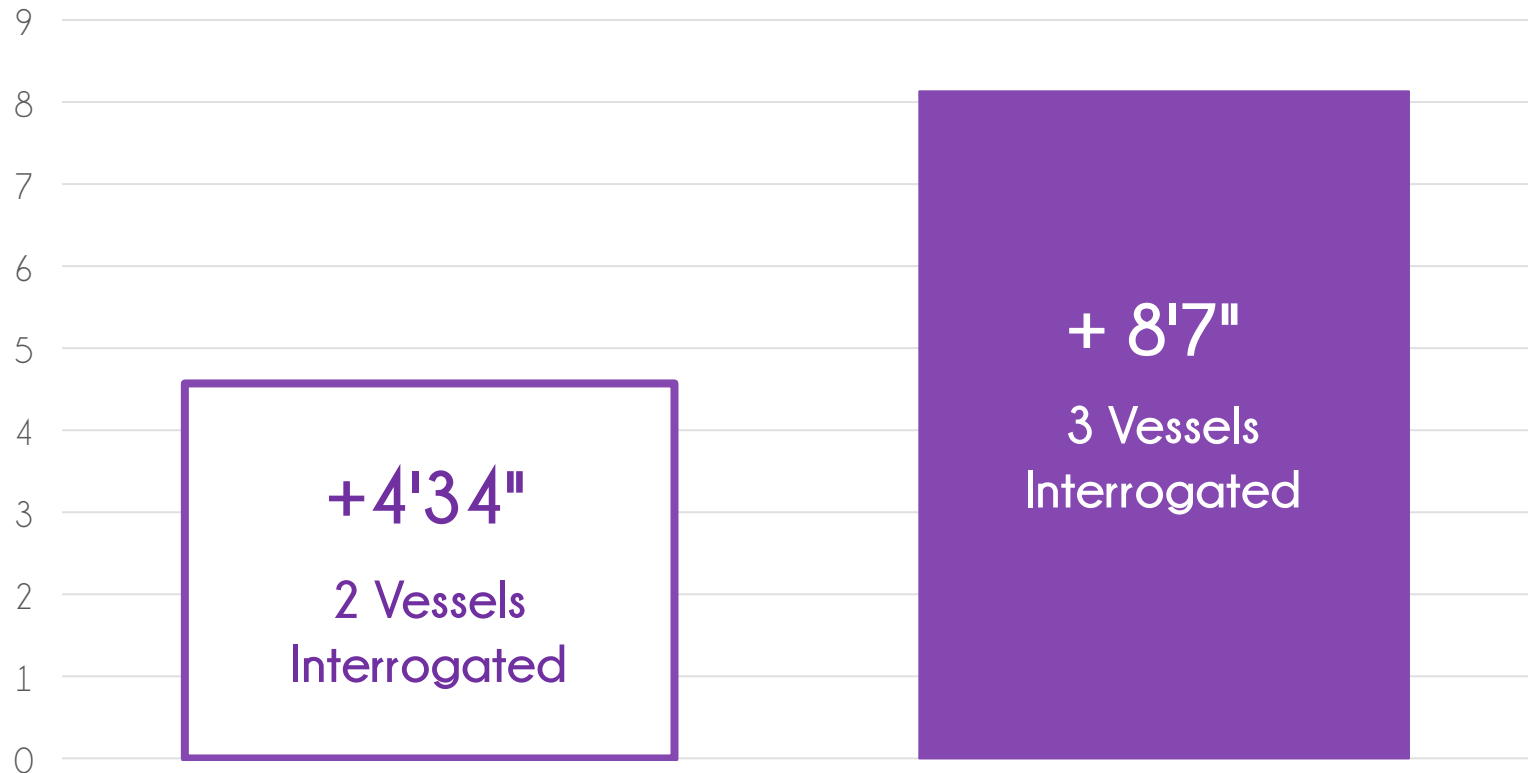
Patient management change by physiology



Procedural management change by physiology



Extra time for Physiology in >1 vessel



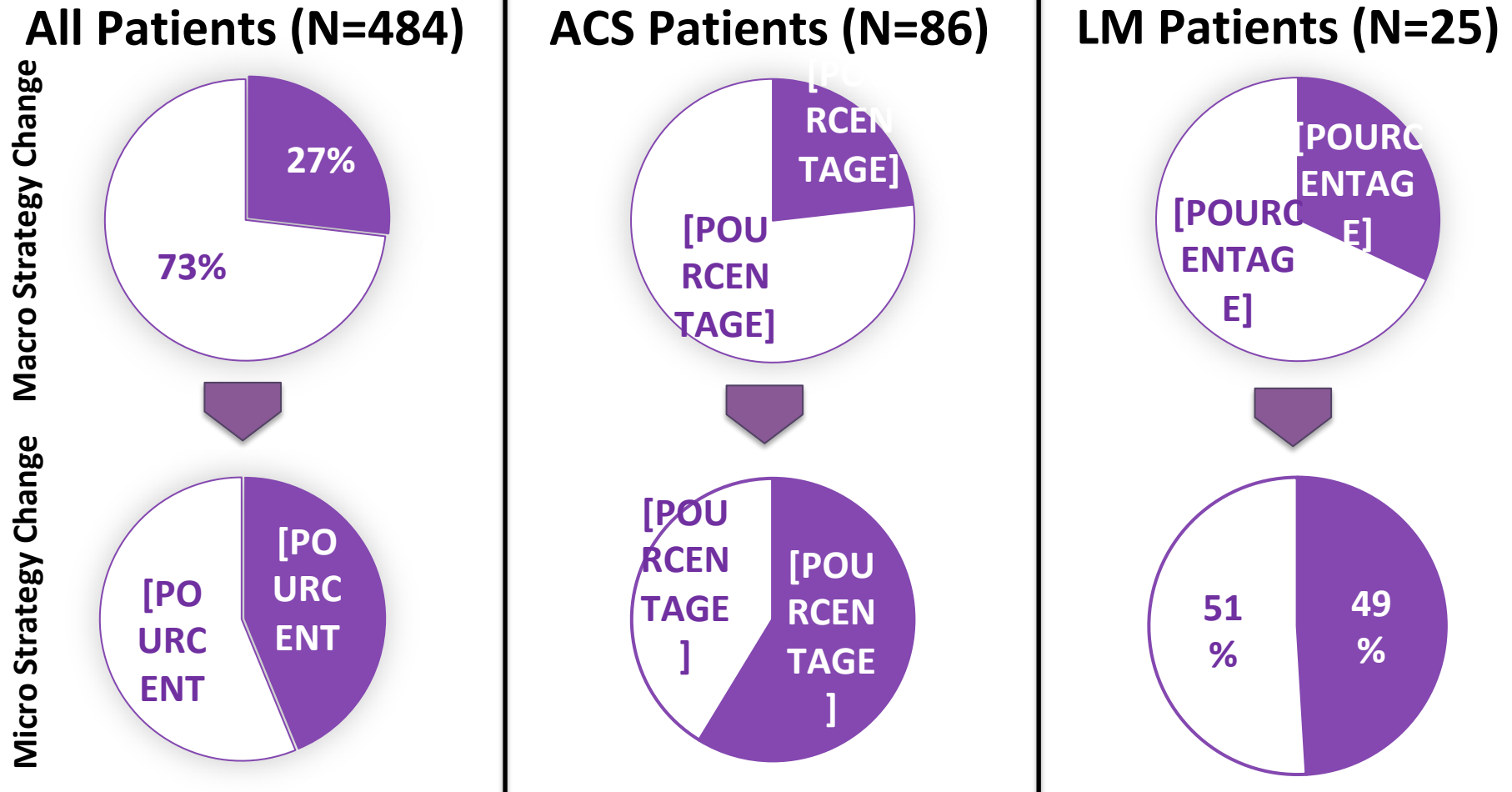
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Changes of Treatment Strategy

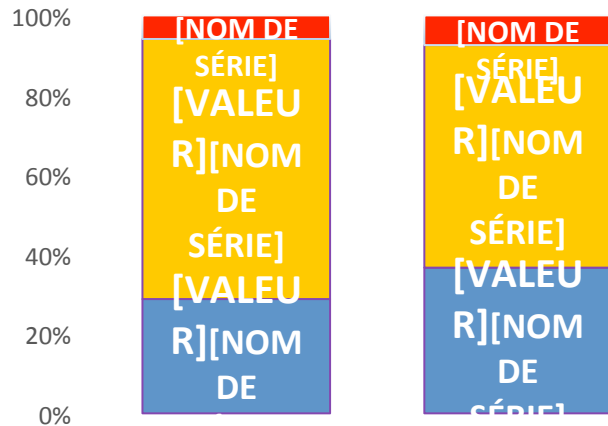
Patient Level - Subgroup Analyses



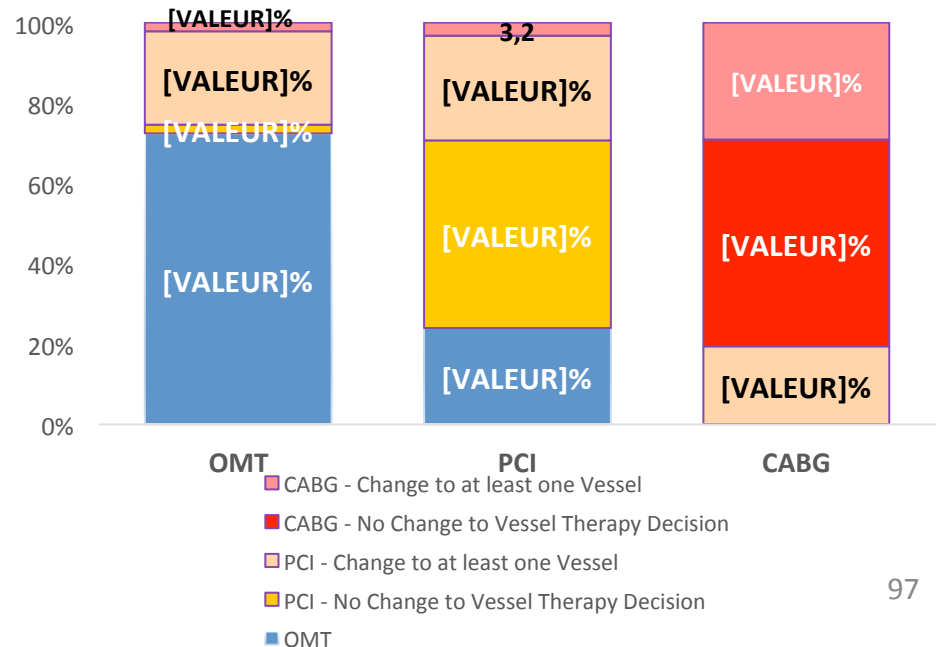
Changes of Treatment Strategy

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

Initial Treatment Strategy



Final vs Initial Treatment Strategy
Patient Level - Micro



The POST-IT & R3F Investigators

POST-IT (Portugal)

Sérgio Bravo Baptista, MD (Amadora)
Luís Raposo, MD (Lisbon)
Lino Santos, MD (V N Gaia)
Ruben Ramos, MD (Lisbon)
Rita Calé, MD (Almada)
Elisabete Jorge, MD (Coimbra)
Carina Machado, MD (Ponta Delgada)
Marco Costa, MD (Coimbra)
Eduardo Oliveira, MD (Lisbon)
João Costa, MD (Braga)
João Pipa, MD (Viseu)
Nuno Fonseca, MD (Setúbal)
Jorge Guardado, MD (Leiria)
Bruno Silva, MD (Funchal)
Maria João Sousa, MD (Porto)
João Carlos Silva, MD (Porto)
Alberto Rodrigues, MD (Penafiel)
Luís Seca, MD (Vila Real)
Renato Fernandes, MD (Évora)

R3F (France)

Eric Van Belle, MD, PhD (Lille)
Patrick Dupouy, MD (Antony)
Gilles Rioufol, MD, PhD (Lyon)
Christophe Pouillot, MD (St Denis, La Réunion)
Thomas Cuisset, MD, PhD (Marseille)
Karim Bougrini, MD (St Denis, La Réunion)
Emmanuel Teiger, MD, PhD (Créteil)
Stéphane Champagne, MD (Créteil)
Loic Belle, MD (Annecy)
Didier Barreau, MD (Toulon)
Michel Hanssen, MD (Haguenau)
Cyril Besnard, MD (Lyon)
Jean Dallongeville, MD, PhD (Lille)
Georgios Sideris, MD (Paris)
Christophe Bretelle, MD (Valence)
Nicolas Lhoest, MD (Colmar)
Pierre Barnay, MD (Avignon)
Raphael Dauphin (Lyon)
Laurent Leborgne, MD, PhD (Amiens)
Flavien Vincent (Lille)
