R3F

Original Article

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;
Thomas Cuisset, MD, PhD; Karim Bougrini, MD; Emmanuel Teiger, MD, PhD;
Stéphane Champagne, MD; Loic Belle, MD; Didier Barreau, MD; Michel Hanssen, MD;
Cyril Besnard, MD; Raphael Dauphin, MD; Jean Dallongeville, MD, PhD;
Yassine El Hahi, PhD; Georgios Sideris, MD; Christophe Bretelle, MD; Nicolas Lhoest, MD;
Pierre Barnay, MD; Laurent Leborgne, MD, PhD; Patrick Dupouy,MD;
for the Investigators of the Registre Français de la FFR – R3F

Disclosures

**Eric Van Belle is consultant for
St. Jude Medical and Volcano**

Background

- **Recent data suggest that fractional flow reserve (FFR) is useful in guiding coronary revascularization in patients referred for a PCI procedure (DEFER, FAME, FAME2).**

- **There is however currently no large report of its impact on the decision of coronary revascularization in a broader population of patients referred for diagnostic angiography.**

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Aim of the study

The present study was designed to evaluate:

- **The rate of reclassification of the patient coronary revascularization strategy by performing FFR at the time of diagnostic angiography.**

- **The impact of reclassification on functional status and clinical outcome at 1 year.**

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Methods

- **R3F was designed to include 1,000 consecutive patients referred for diagnostic angiography with FFR measurement of at least one ambiguous coronary lesion (35-65%) in 20 centers in France (Oct. 2008 to June 2010).**

- **Clinical, non-invasive tests and angiographic data were prospectively collected in an e-CRF.**

- **Independent monitoring was performed.**

Methods

- **The investigators were asked to define and record prospectively their revascularization strategy twice:**

  - **A first time, immediately after performing the angiography but before performing the FFR. It was called the "A priori" strategy.**

  - **A second time, once the the FFR was performed. It was called the "final" strategy.**

- **This strategy could be Medical treatment, PCI or CABG.**

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Baseline characteristics (n=1,075)

Age, years	**65±10**
Males	**75%**
Family History of CAD	23%
Smokers	54%
Hypertension	66%
Hyperlipidemia	65%
Diabetes	**36%**
Previous MACE	**44%**
- Previous MI	25%
- Previous PCI	39%
- Previous CABG	4%

Baseline characteristics (n=1,075)

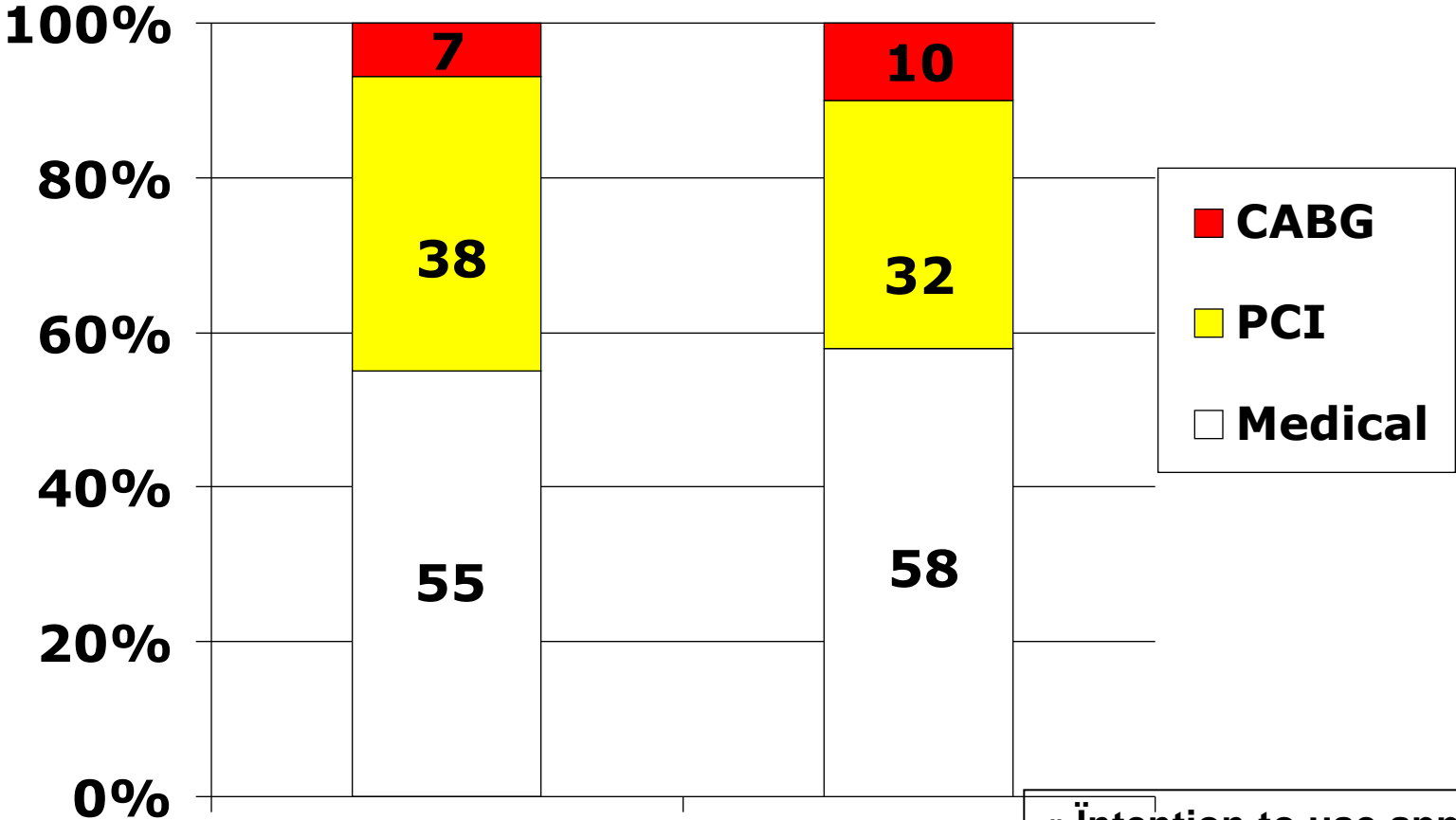|	
Stable	**80%**
- Angina	23%
- Atypical chest pain	11%
- No pain:	46%
Unstable (within 15 days)	**20%**
-Recent-STEMI	3%
-Recent-NON-STEMI	17%
Non invasive test performed	**61%**
- Positive	**48%**
- Dubious	9%
- Negative	4%
Non-invasive test not performed	**39%**

Proportion of patients receiving each treatment modality Before and After performing FFR

Legend:
- CABG (red)
- PCI (yellow)
- Medical (white)

Before:
- CABG: 7
- PCI: 38
- Medical: 55

After:
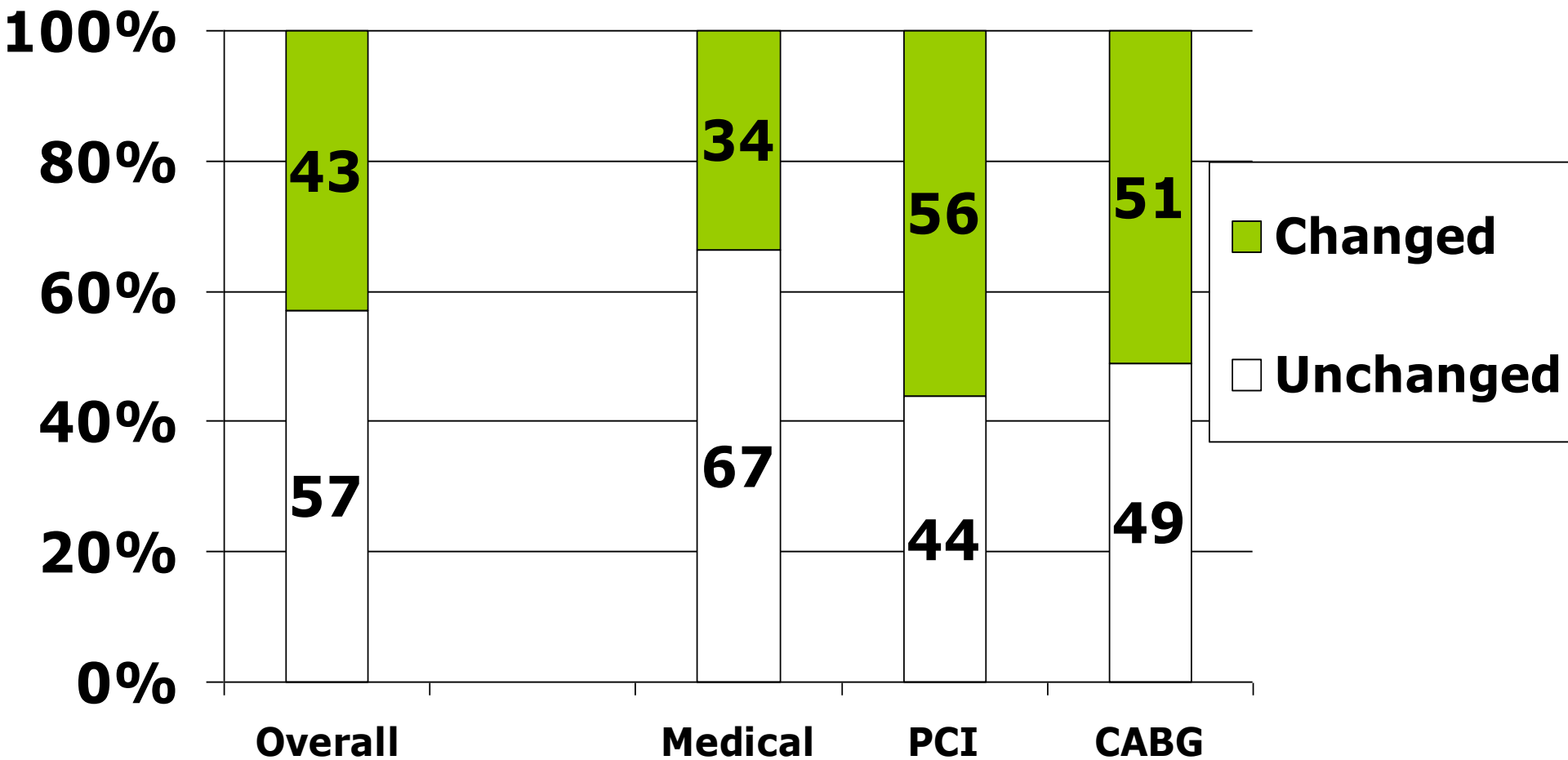- CABG: 10
- PCI: 32
- Medical: 58

« Ïntention to use approach »: in 4% of cases FFR was performed but not used for the decision of revascularization

FFR

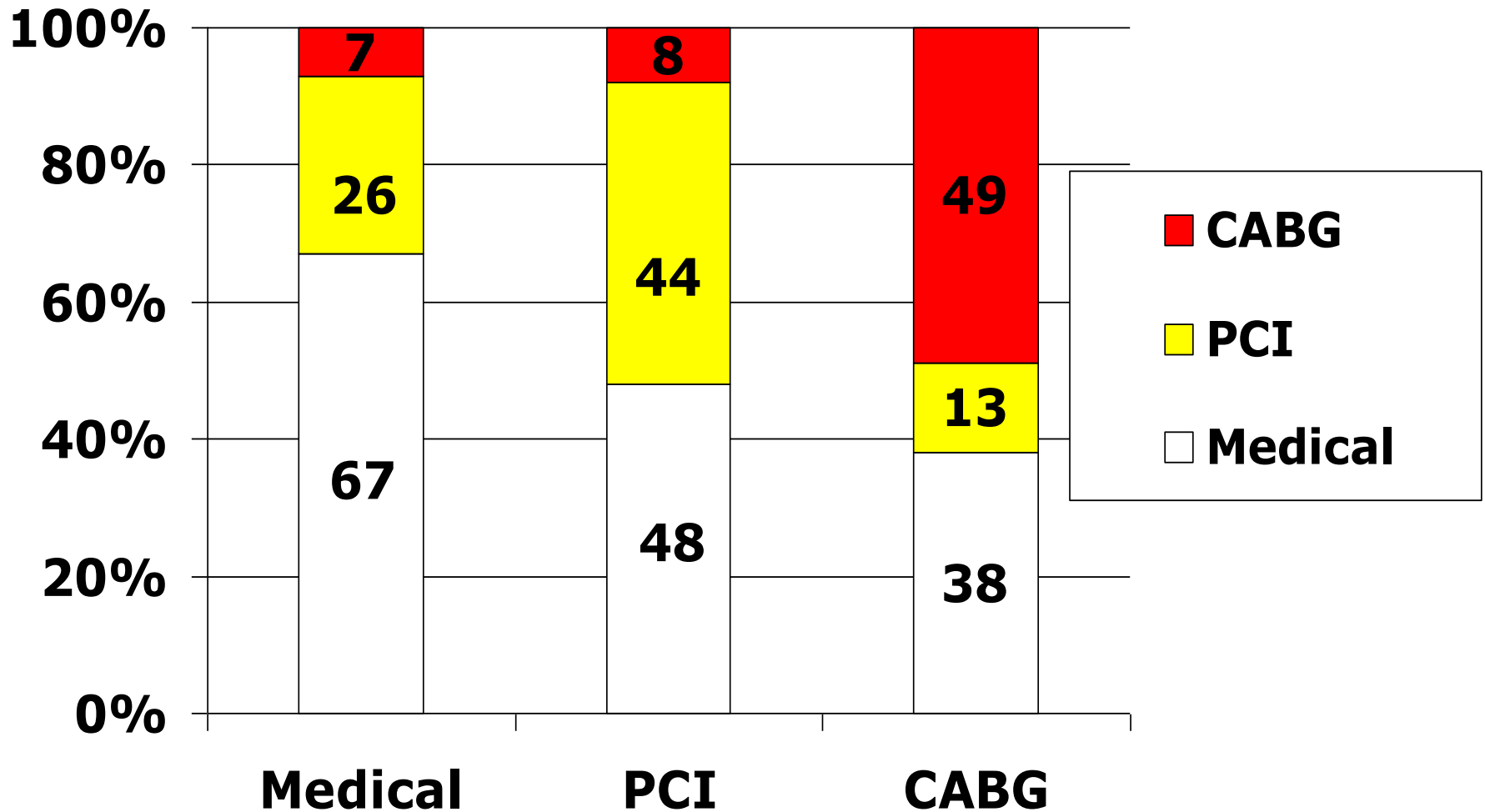# Change of treatment modality in 43% of patients after performing FFR, by initial treatment modality
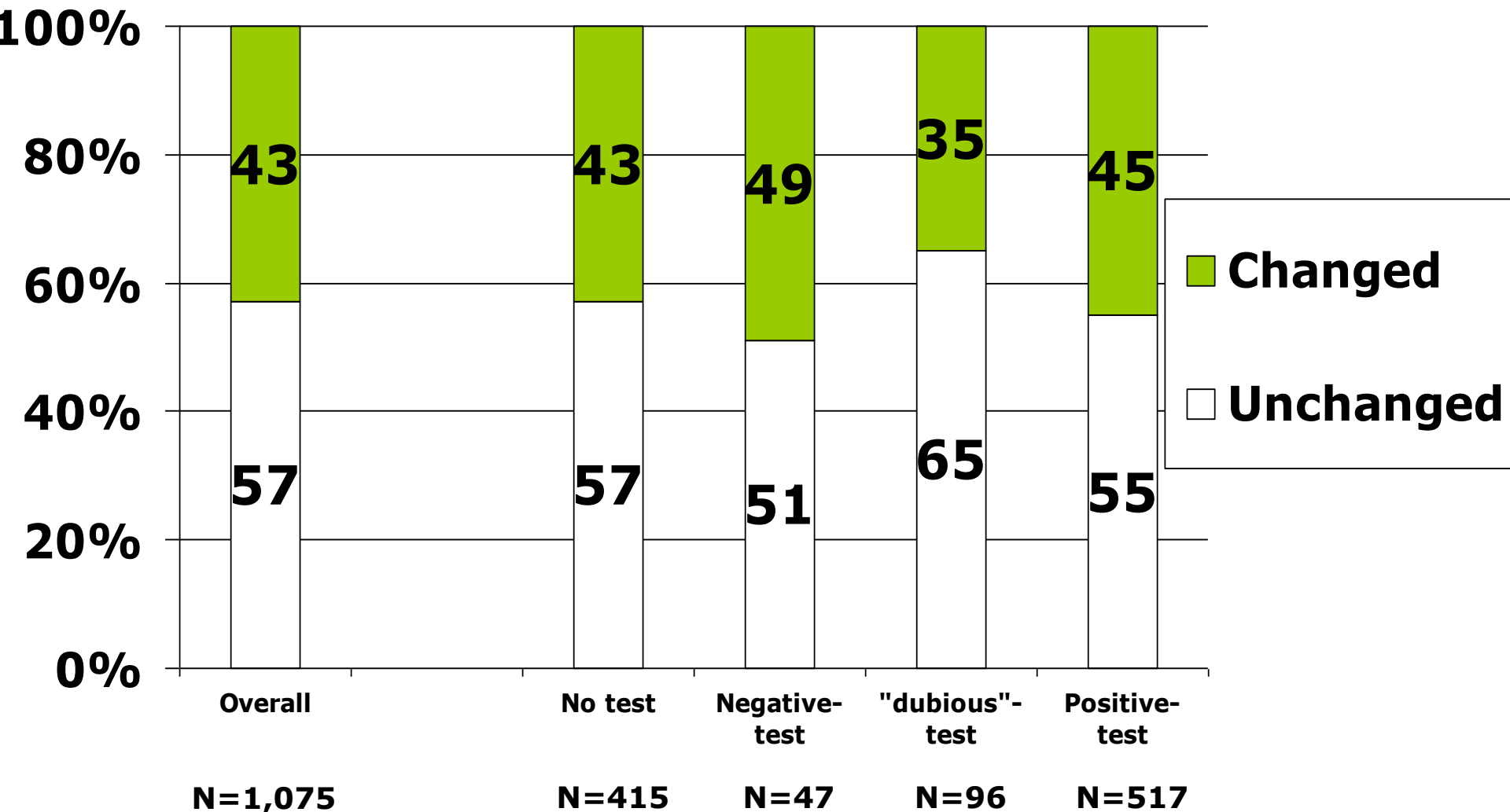

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Final treatment modality according to the initial treatment modality

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

	Overall	No test	Negative-test	"dubious"-test	Positive-test
Changed	43	43	49	35	45
Unchanged	57	57	51	65	55
	N=1,075	N=415	N=47	N=96	N=517

R3F

Decision was based on FFR in 96% of cases
(n=1022)

« Non-Reclassified »
FFR concurred with the
Decision made
by angiography
N= 611

« Reclassified »
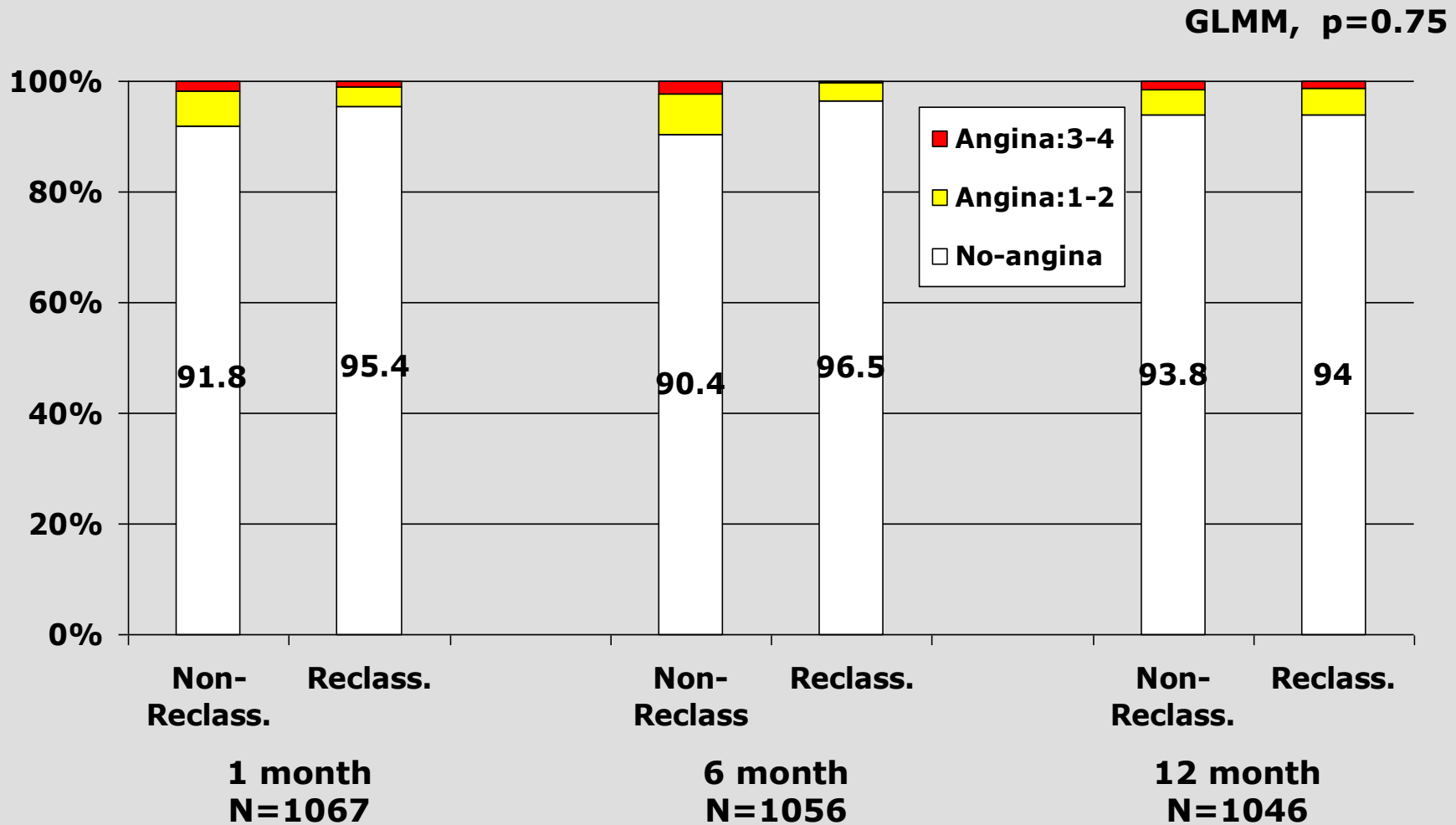FFR desagreed with the
Decision made
by angiography
N=464

Decision was not based on FFR
In 4% of cases (N=54)

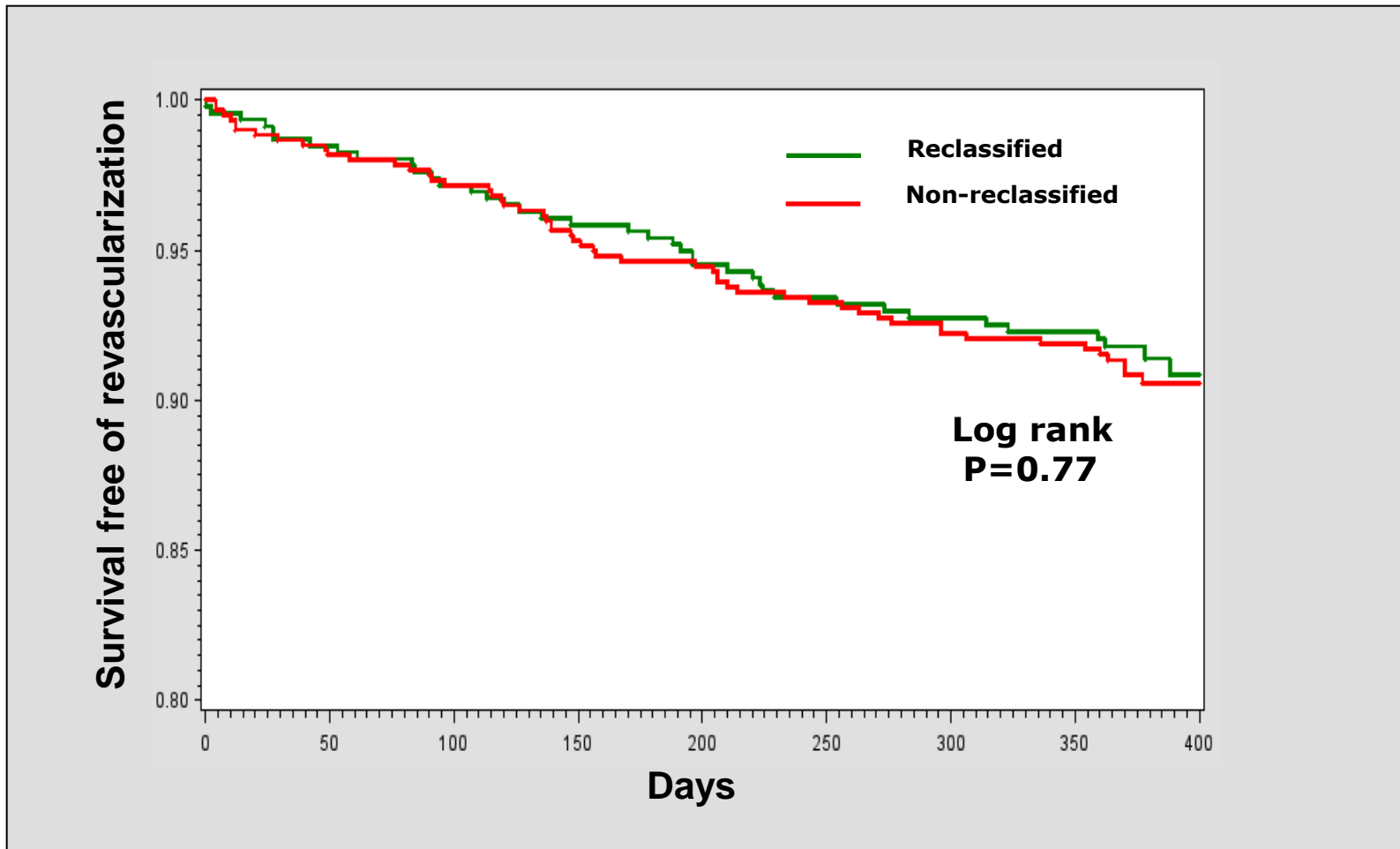Angina status
Clinical events

Angina status
Clinical events

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Angina Status during follow-up according to Reclassification by FFR

GLMM, p=0.75

Legend:
- ■ Angina:3-4 (red)
- ■ Angina:1-2 (yellow)
- □ No-angina (white)

	1 month N=1067	6 month N=1056	12 month N=1046
Non-Reclass.	91.8	90.4	93.8
Reclass.	95.4	96.5	94

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Survival free of unplanned revascularization according to Reclassification by FFR

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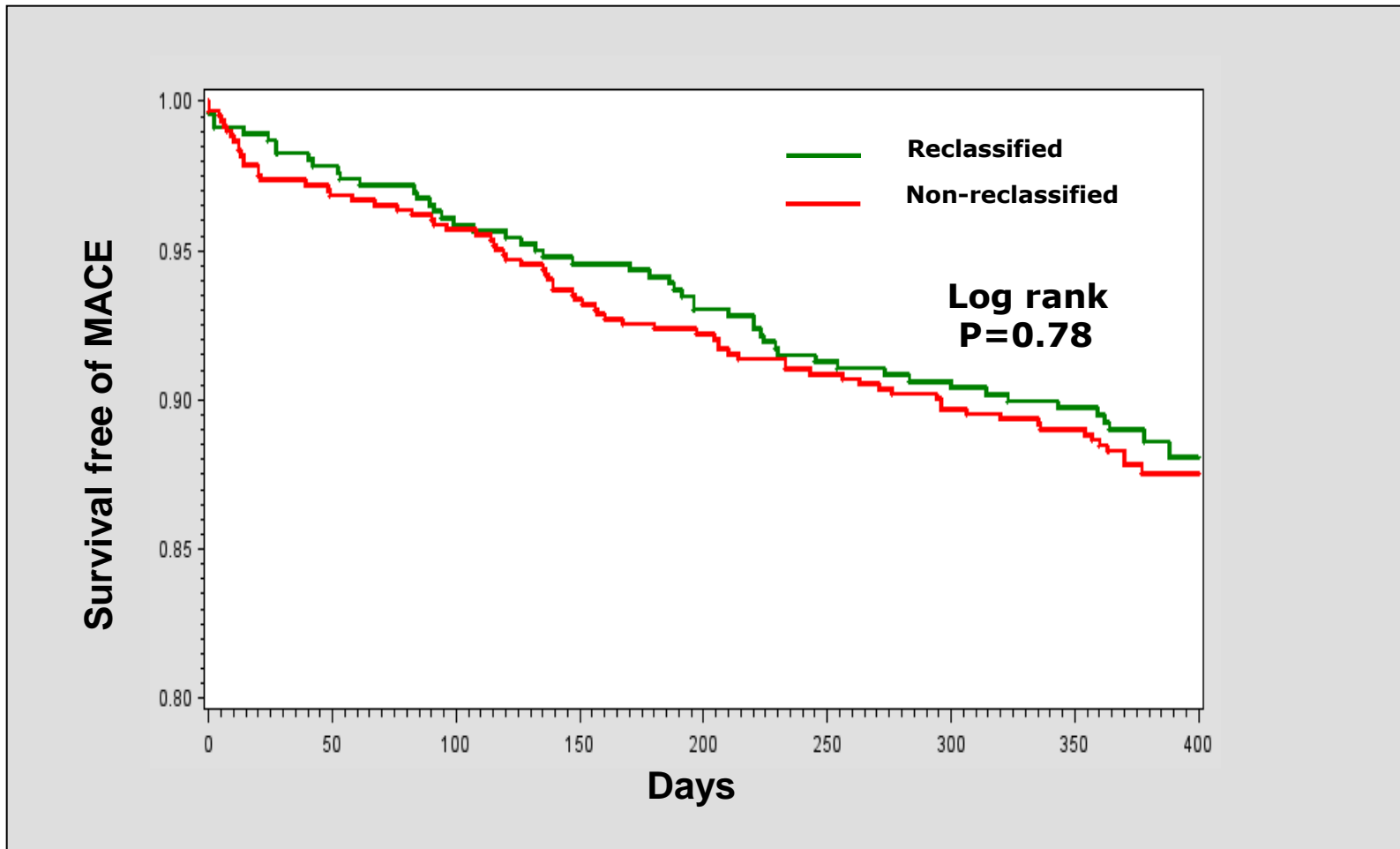# Survival free of Death or MI according to Reclassification by FFR
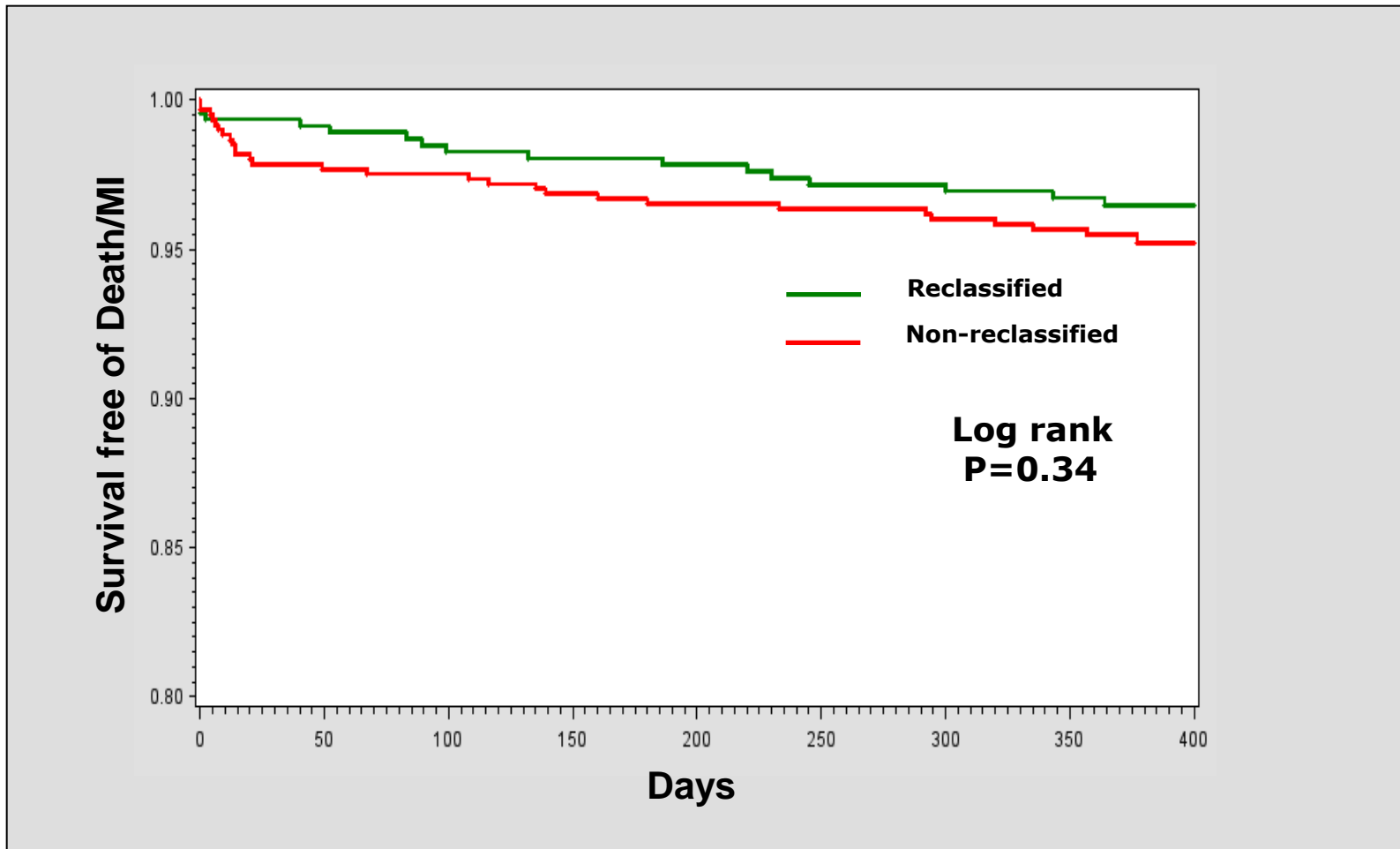
Survival free of MACE according to Reclassification by FFR

E. Van Belle et al. Circulation 2014
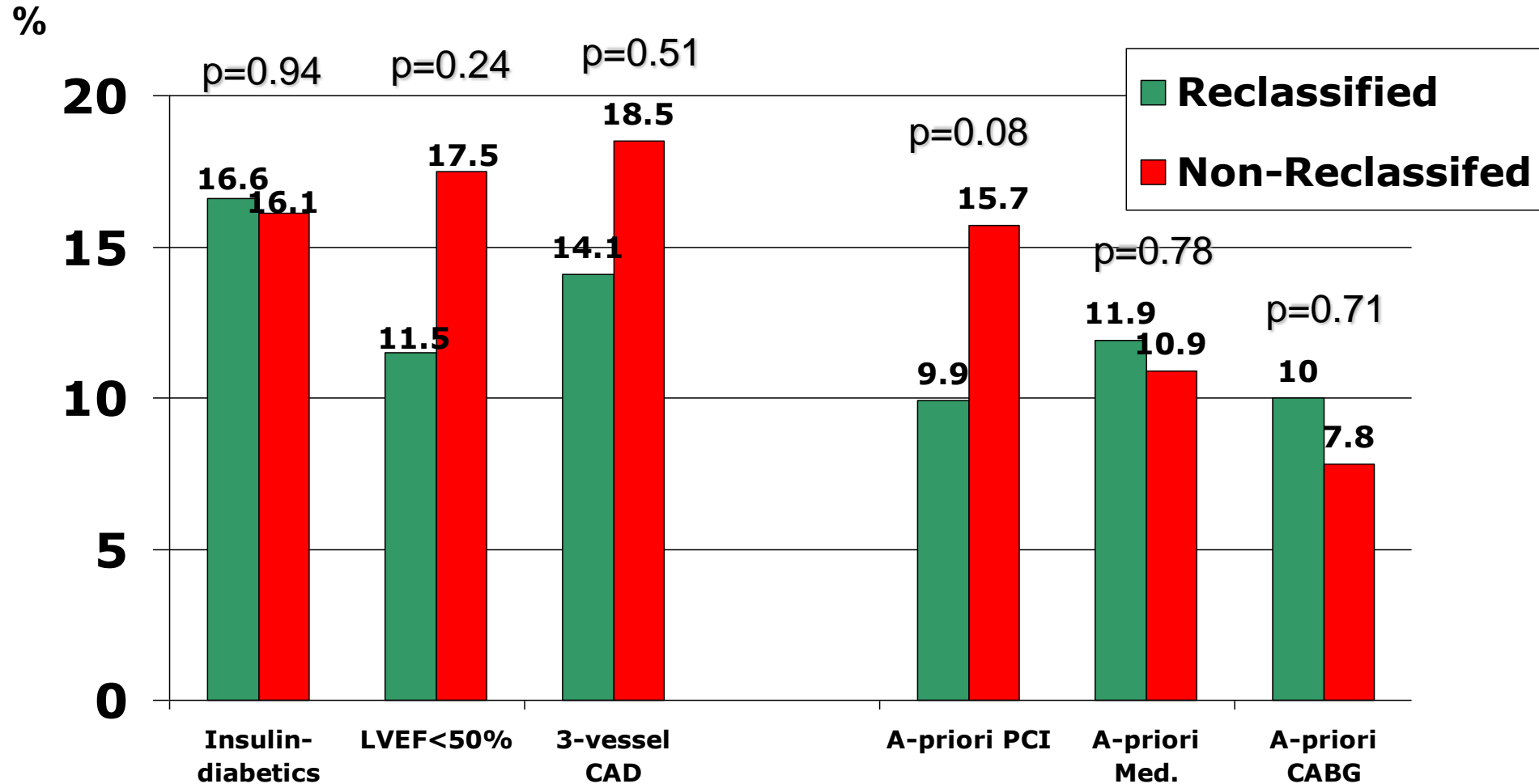
Survival free of MACE according to Reclassification by FFR (« per-use » analysis)

E. Van Belle et al. Circulation 2014
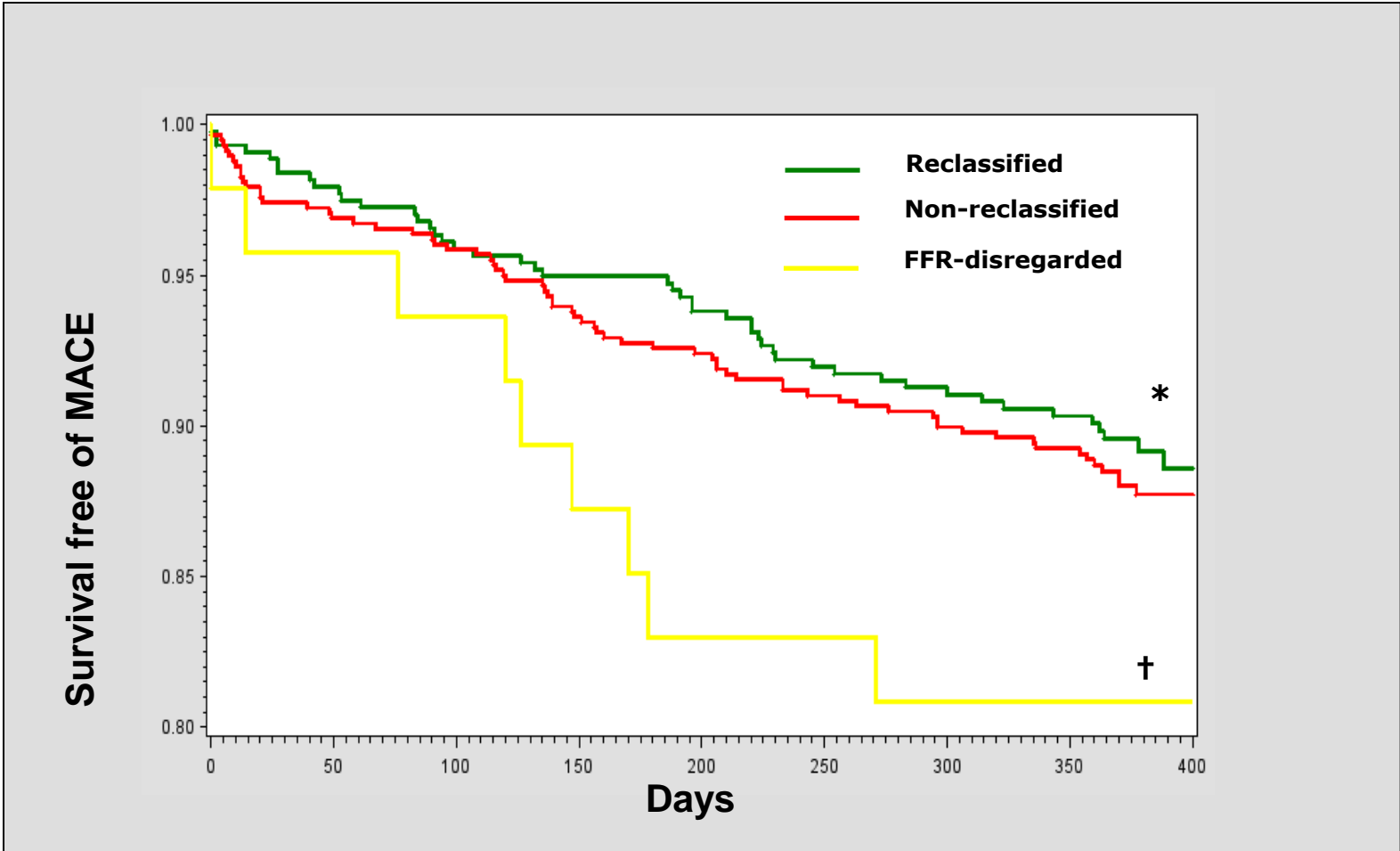
Impact of Reclassification on MACE rate at 1-year in various subgroups

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RIPCORD: Results (efficacy)

- 26% of patients had their treatment plans changed following the FFR results.

- After seeing the FFR findings, cardiologists also upgraded or downgraded their views on the seriousness of the vascular disease.

- These results have important clinical and economic implications, according to the investigators.

RIPCORD: Study results

Treatment plan	Angiography alone (patients, n)	Angiography plus FFR (patients, n)
Medical management	72	89
PCI	90	80
CABG	23	30
Additional testing	15	1

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

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

Conclusion

- **R3F and RIPCORD provide important information on the use of FFR in patients referred for diagnostic coronary angiography.**
- **They demonstrate that the use of FFR is associated with small changes in the proportion of patients referred to each treatment modality**
- **They further demonstrate that the use of FFR is associated with reclassification of the revascularization decision in one third to half of the population (26% to 43%).**
- **R3F further demonstrates that it is safe to pursue a revascularization strategy divergent to that suggested by angiography alone but guided by FFR measurements.**
- **The present data further support and extent the concept of a "physiology guided" decision of coronary revascularization.**

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Ongoing/FUTURE trial

- FUTURE trial (France): FFR at time of diagnostic angiography in patients with 2/3 vessel CAD – 1700 patients
- iFR pan-European Registry Protocol: iFr and FFR at time of diagnotic angiography in in patients with 2/3 vessel CAD – 3000 patients
- Define diagnostic (US+Europe): 2000 patients

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- Define diagnostic (US+Europe): 2000 patients

Conclusion

- Implementation of our diagnostic approach in patients with CAD is key
- Invasive physiology will play a major role to help us.
- Although additional studies are needed to help us to refine our approahc, we already have enough evidence to a broad use of phsyiology during diagnostic angiography

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Methods

- **The investigators were asked to define and record prospectively their revascularization strategy twice:**

  - **A first time, immediately after performing the angiography but before performing the FFR. It was called the "A priori" strategy.**

  - **A second time, once the the FFR was performed. It was called the "final" strategy.**

- **This strategy could be Medical treatment, PCI or CABG.**

- **Patients in whom the final strategy concurred with the strategy "a-priori" were defined as "non-Reclassified" by FFR.**

- **Patients in whom the final strategy was different from the strategy "a-priori" were defined as "Reclassified" by FFR.**

- **Functional status and clinical outcome at 1-year were compared between the "Reclassifed" and "non-reclassifed" patients.**

Methods

- **Clinical follow-up was conducted and obtained in all patients at a median of 379 days (QR=363-413 days).**

- **Follow-up visits including evaluation of angina status were performed at 1 month, 6 months and 1 year.**

- **Death, MI and revascularization were recorded and adjudicated.**

- **Revascularization decided and performed within 60 days of the index procedure were considered « planned ».**

- **All other revascularization were considered « unplanned »**

- **MACE was defined as the occurrence of death, MI or« unplanned » revascularization.**

Baseline characteristics (n=1,075)

Stable	**80%**
- Angina	23%
- Atypical chest pain	11%
- No pain:	46%
Unstable (within 15 days)	**20%**
-Recent-STEMI	3%
-Recent-NON-STEMI	17%
Non invasive test performed	**61%**
- Positive	**48%**
- Dubious	9%
- Negative	4%
Non-invasive test not performed	**39%**

Baseline characteristics (n=1,075)

Left ventricular EF, %	
- < 30%	3%
- 30-49%	14%
- > 49%	**83%**
Number of diseased vessels (>50%)	
- None	14%
- 1	38%
- 2	28%
- 3 and/or Left main	20%
Number of investigated lesions	1,422 (1.3 ± 0.7)
Index lesion (%)	
LAD	**830 (58%)**
RCA	219 (15%)
RCx	283 (20%)
LM	90 (6%)

Baseline characteristics (n=1,075)

Lesion characteristics (%)	
A/B1	941 (66%)
B2/C	476 (34%)
Reference diameter ± SD (mm)	2.9 ±0.6
MLD ± SD (mm)	1.4 ±0.7
% stenosis ± SD	**53±13**
Lesion length ± SD (mm)	12.8 ±8.1
FFR	
Mean	**0.82±0.10**
FFR <0.8	37%
FFR <0.75	22%

GLMM, P=0.55

Angina Status in patients symptomatic at baseline

Legend:
- Angina:3-4 (red)
- Angina:1-2 (yellow)
- No-angina (white)
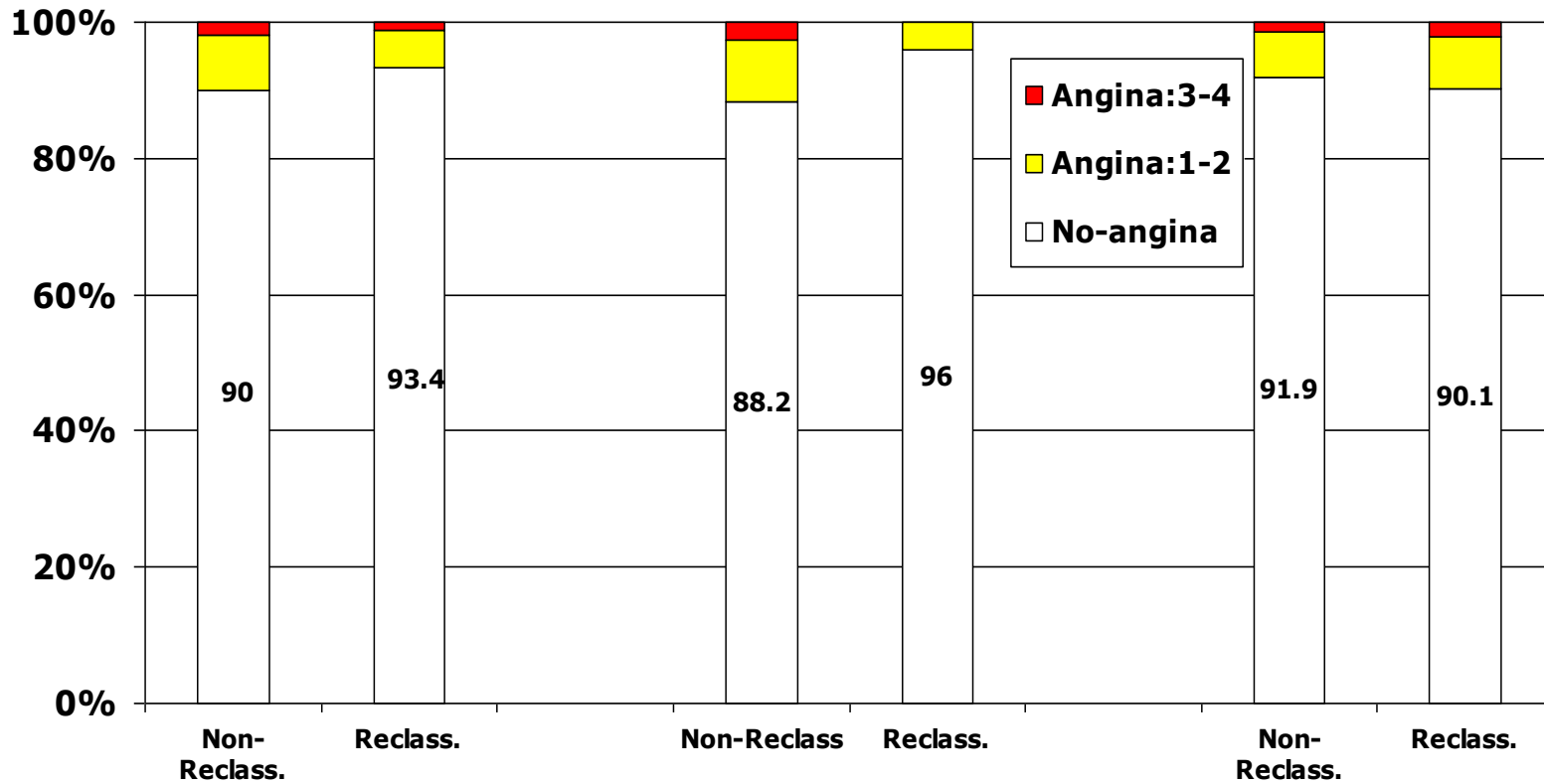
	1 month N=566	6 month N=562	12 month N=555
Non-Reclass.	90	88.2	91.9
Reclass.	93.4	96	90.1

Outcome Impact of Coronary Revascularization Strategy Reclassification With Fractional Flow Reserve (FFR) at time of diagnostic angiography:
Insights from a Large French Multicenter FFR Registry (R3F)

Eric Van Belle, Gilles Rioufol, Christophe Pouillot, Thomas Cuisset, Karim Bougrini, Emmanuel Teiger, Stéphane Champagne, Loic Belle, Didier Barreau, Michel Hanssen, Cyril Besnard, Raphael Dauphin, Jean Dallongeville, Yassine El Hahi, Georgios Sideris, Christophe Bretelle, Nicolas Lhoest, Pierre Barnay, Laurent Leborgne, and **Patrick Dupouy**, for the Investigators of the Registre Français de la FFR -"R3F".

R3F