Angiography-Based Quantitative Flow Ratio for Online Assessment of Coronary Stenosis: Italian experience in FAVOR II study

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Palermo, 25 - 26 Maggio 2018

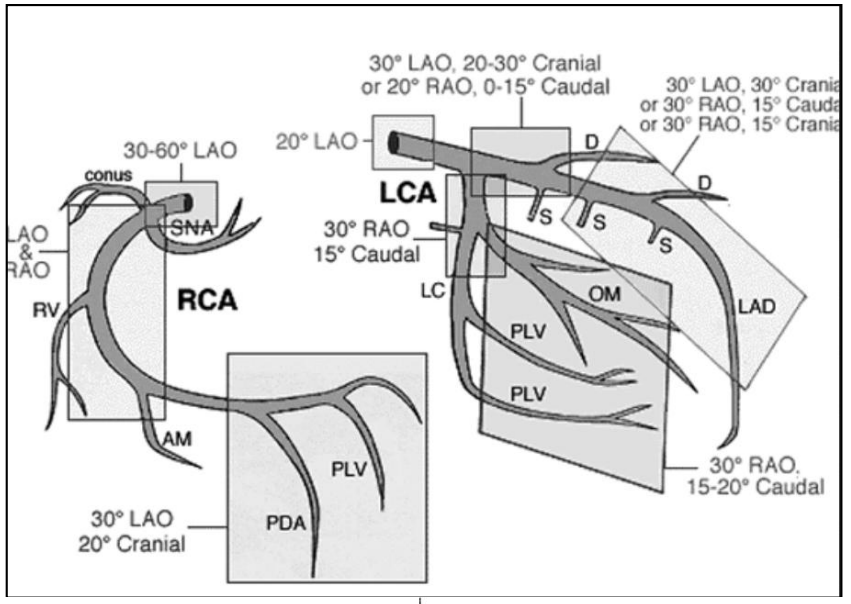
Disclosure

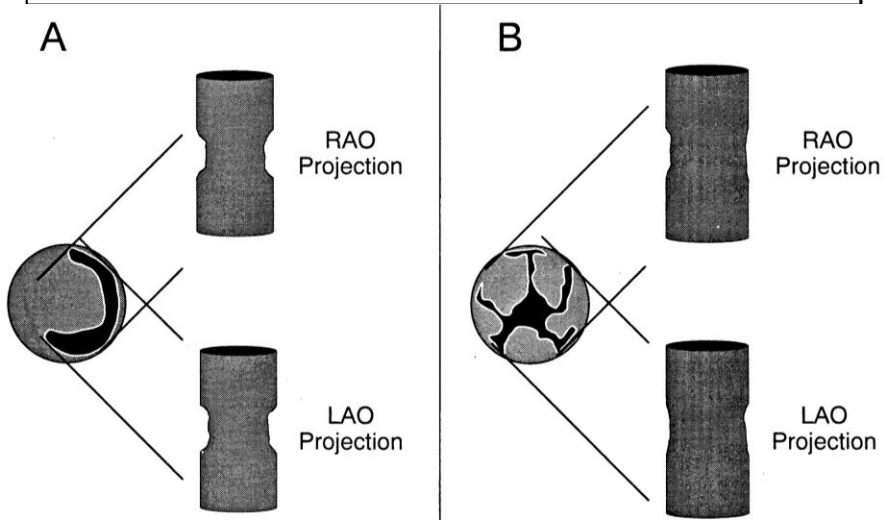
- **Speaker's name: Andrea Maschera**

☑ **Nessun conflitto di interessa da dichiarare**
I do not have any potential conflicts of interest to report

Background - Coronary angiography

- Coronary angiography (CAG) represents the gold standard for the assessment of coronary artery disease (CAD)
- For the majority of interventions, CAG is the test used for clinical decision-making
- Limitations in complex clinical settings
- QCA – IVUS – OCT available 
- **Weak ability to predict the functional impact of atheroma on myocardium**





ESC guidelines on the management of stable coronary artery disease: the Task Force on the management of stable coronary artery disease of the European Society of Cardiology. Eur. Heart J. 34(38), 2013.
Toth G, et al . Evolving concepts of angiogram: fractional flow reserve discordances in 4000 coronary stenoses. Eur Heart J 2014;35 :2831–2838

European Heart Journal
doi:10.1093/eurheartj/ehu278

2014 ESC/EACTS Guidelines on myocardial revascularization

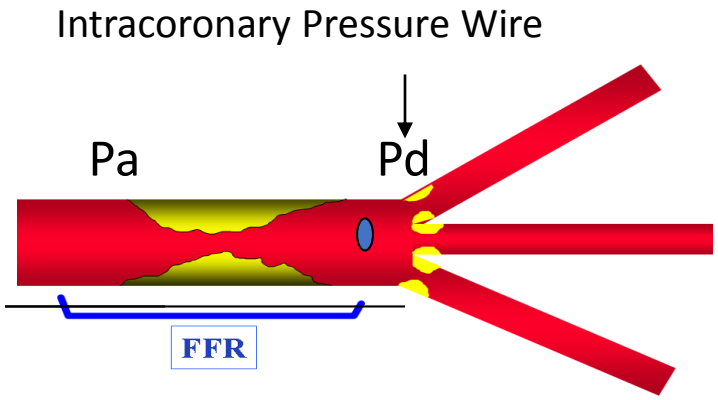
FFR --> Fractional Flow Reserve

Class IA recommendation has been granted to the use of FFR in the assessment of coronary stenosis before myocardial revascularization when previous non-invasive functional evaluation is unavailable or not conclusive

Recommendations	Class [a]	Level [b]	Ref. [c]
FFR is recommended to identify hemodynamically relevant coronary lesion(s) when evidence of ischaemia is not available.	I	A	399, 401, 405
Revascularization of stenoses with FFR <0.80 is recommended in patients with angina symptoms or a positive stress test.	I	B	400
IVUS or OCT may be considered to characterize lesions.	IIb	B	404, 406
IVUS or OCT may be ove stent	IIb	B	404
of an termediate elated ut FFR <0.80 ed.	III	B	399, 405

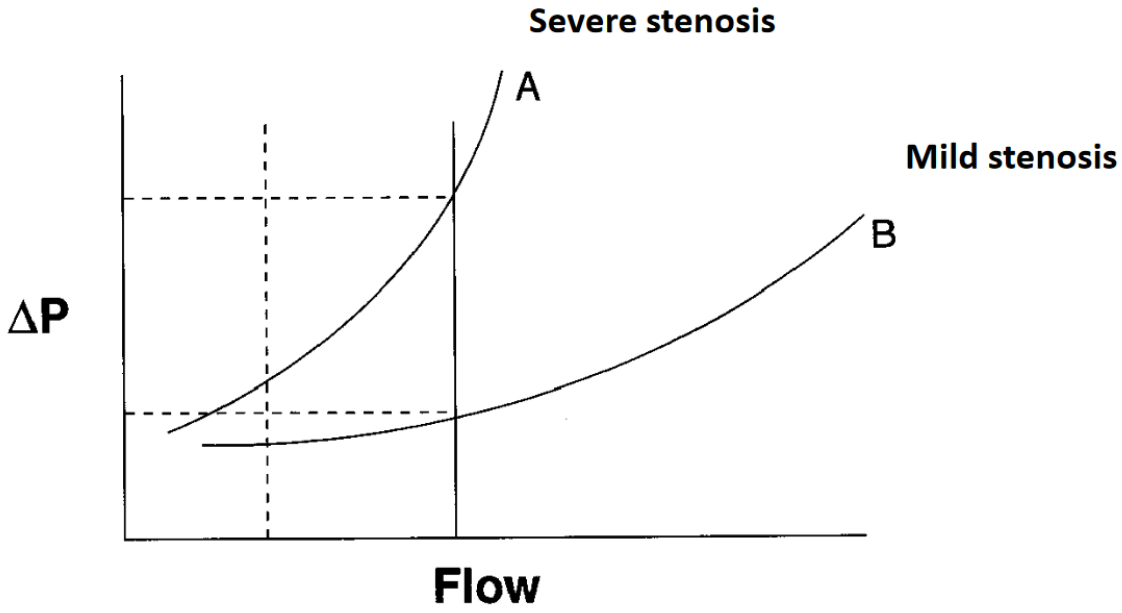
Recommendations	Class [a]	Level [b]	Ref. [c]
FFR is recommended to identify hemodynamically relevant coronary lesion(s) when evidence of ischaemia is not available.	I	A	399, 401, 405

FFR in clinical practice



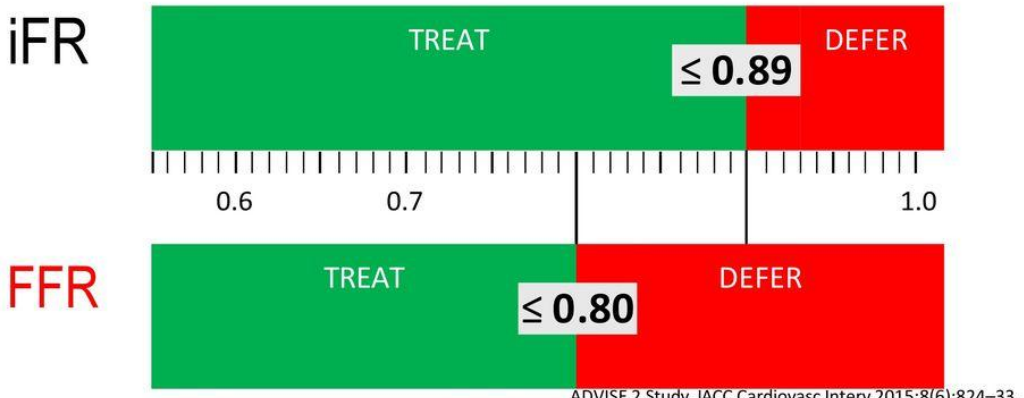
FFR = Pd / Pa

Pressure-based FFR is determined by both the stenosis geometry and the flow modulated by the downstream perfusion!



Kern MJ. Circulation 2000; 101:1344-51

Clinical iFR and FFR Cut-points



ADVISE 2 Study, JACC Cardiovasc Interv 2015;8(6):824–33.
RESOLVE Study, JACC 2014 Apr 8;63(13):1253-61

DEFINE FLAIR

- Adenosine side-effects are possible
- Evolution -> iFR® - based on ECG only

Non-invasive estimates of Fractional Flow Reserve

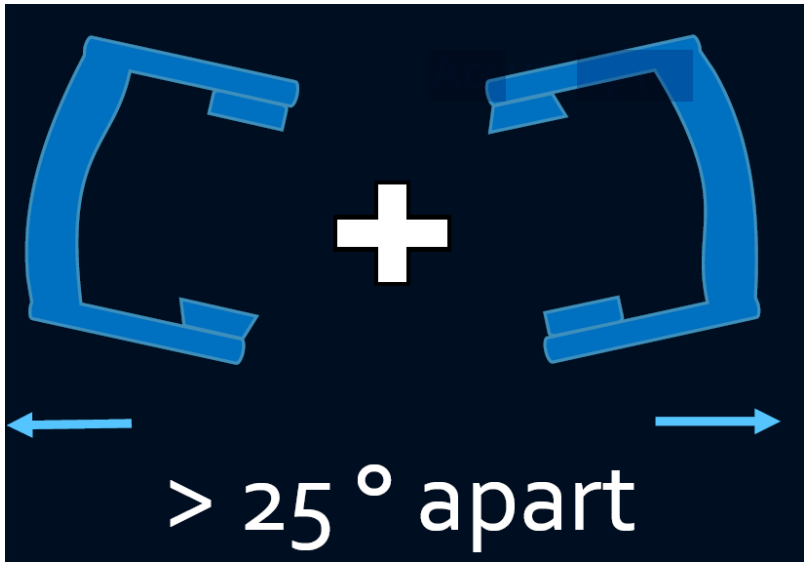
- Is current imaging good enough to evaluate flow ?
- **Computational fluid dynamics** has been applied to multislice **computed tomography** (MSCT) for the computation of FFR, showing good diagnostic performances
- Invasive **quantitative coronary angiography (QCA)-based computational FFR** was also reported with promising results
- Alternative to pressure wire based assessment

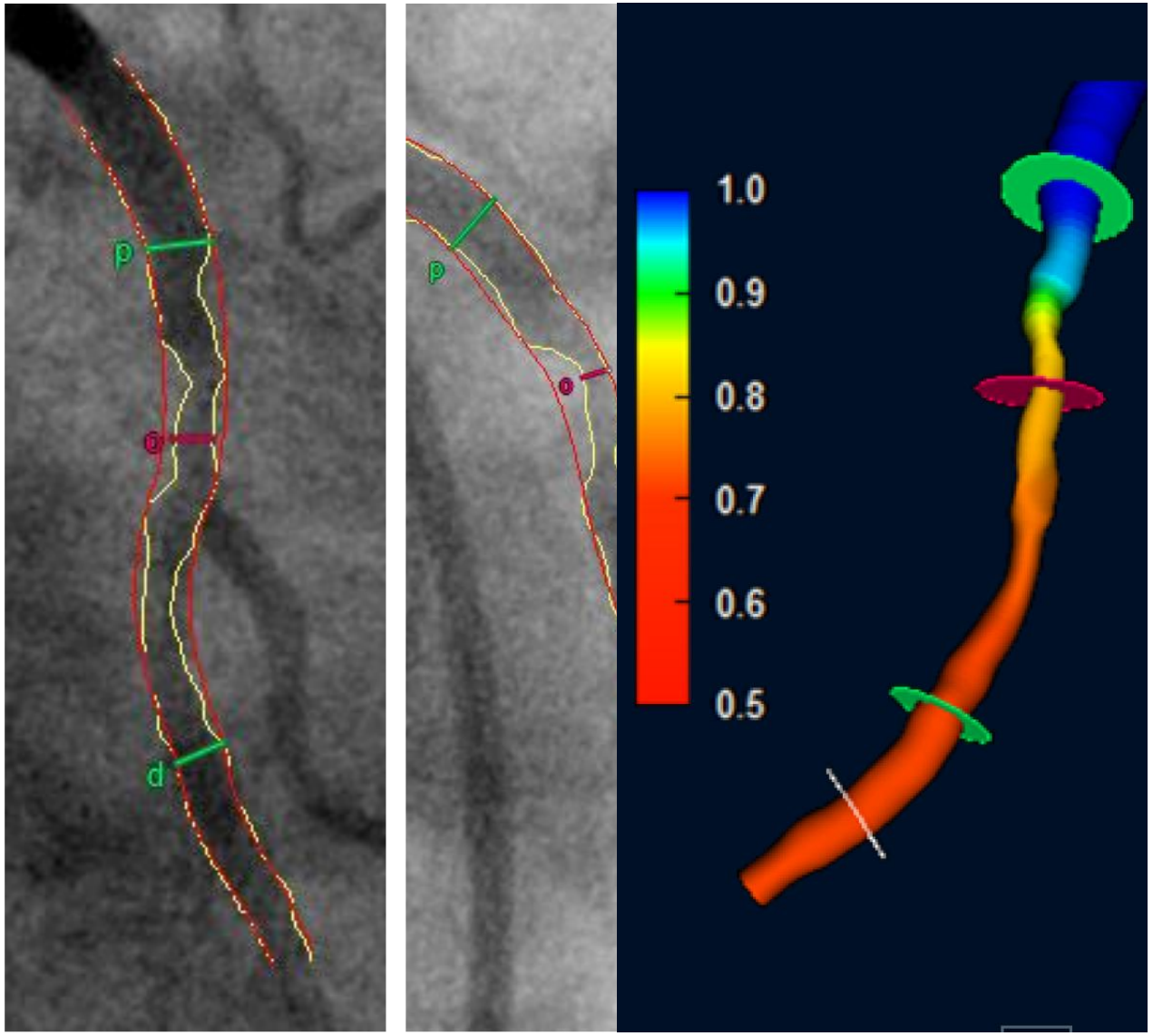
Diagnostic Accuracy of Fast Computational Approaches to Derive Fractional Flow Reserve From Diagnostic Coronary Angiography, JACC , Tu

Quantitative Flow Ratio analysis

QFR is computed from:

- lumen contours in two standard angiographic projections
- contrast flow velocity estimated by frame count during baseline conditions





QFR by MedisSuite, Medis medical imaging. CE-marked. Not approved for clinical use in the US.

The Favor II Study

Aarhus University Hospital (DK)

Observational
- Paired acquisition of FFR and computation of QFR
- Site specific protocol for effective blinding
- Strict protocol for QFR

310 patients, 11 hospitals in Europe and Japan
From March 2017 to October 2017

Procedural endpoints
Sensitivity and specificity of **QFR compared to two-dimensional QCA**
in assessing functional stenosis relevance **with FFR as reference standard**

Others : Procedural safety, Procedure time to FFR, Procedure time to QFR, ….

FAVOR II E-J

Participating sites

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3. The Department of Cardiovascular Medicine; Gifu Heart Center, Gifu City, Japan
   Dr. Hitoshi Matsuo, Dr. Toru Tanigaki
4. Department of Cardiology, Medical University of Warsaw, Warszawa, Poland
   Dr. Lukasz Koltowski, Dr. Janusz Kochman
5. Department of Cardiology, Hagaziekenhuis, The Hague, The Netherlands
   Dr. Tommy Liu, Dr. Samer Somi
6. Federico II University of Naples, Naples, Italy
   Dr. Luigi Di Serafino, Dr. Giovanni Esposito
7. Azienda Ospedaliera Sant'Anna e San Sebastiano, Caserta, Italy
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11. Cardiovascular Department, Ospedale dell'Angelo, Mestre-Venezia, Italy
    Dr. Marco Barbierato, Dr. Federico Ronco

Inclusion criteria & Angiographic inclusion criteria

Inclusion criteria

- Stable angina pectoris or secondary evaluation of stenosis after acute MI
- Age > 18 years

Exclusion criteria

- Myocardial infarction within 72 hours, Severe heart failure (NYHA≥III),
- Allergy to contrast media or adenosine, Atrial fibrillation

Angiographic inclusion criteria

- Indication for FFR in at least one stenosis:
- Diameter stenosis of 30%-90% by visual estimate
- Reference vessel size > 2 mm in stenotic segment by visual estimate

Recommended projection angles for specific lesion segments.

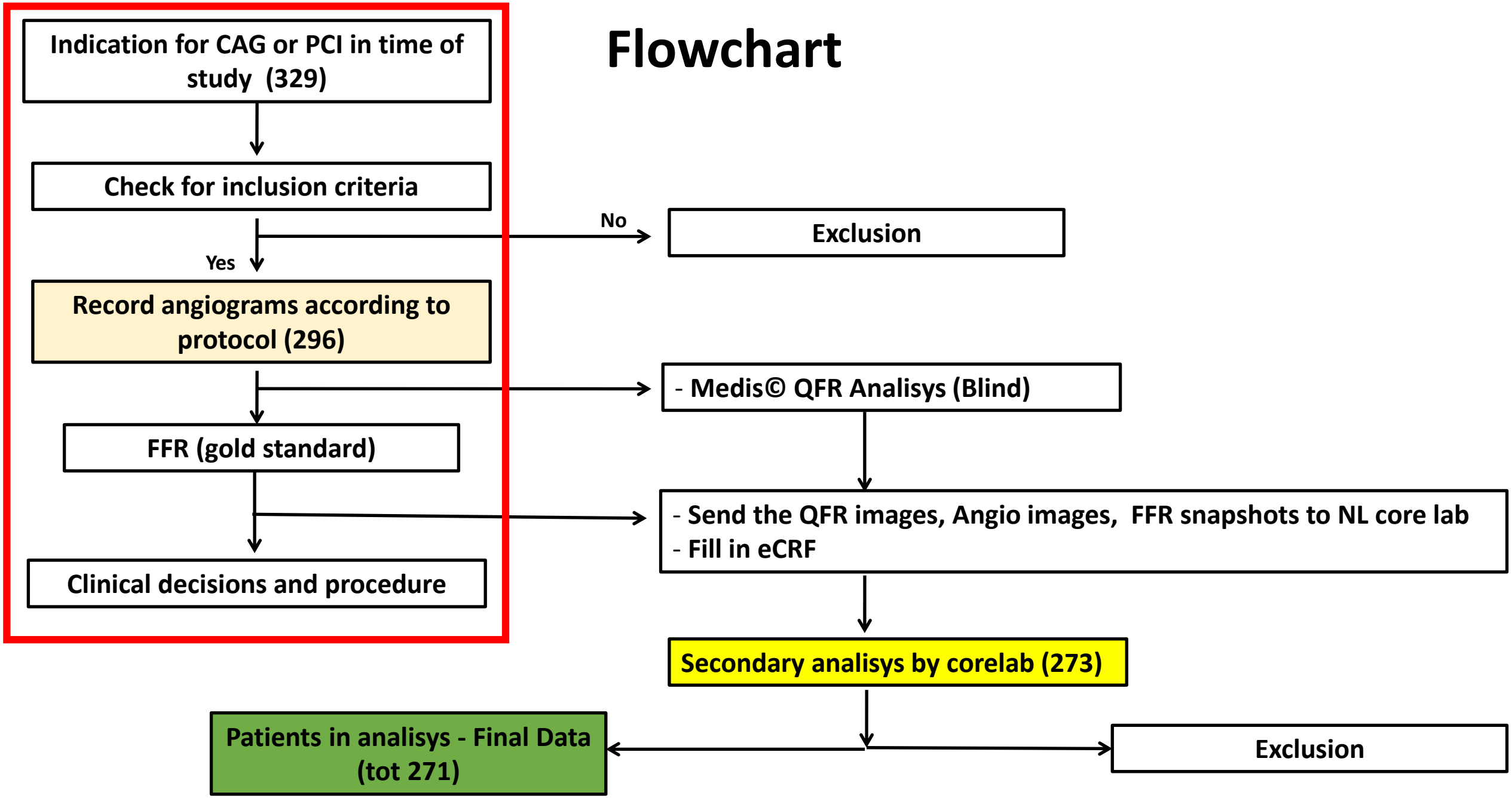
Angulation of more than 25◦ between projections is required.

Vessel /Bifurcation	1st View	2nd View
LM + LAD/LCX	RAO 20, Caudal 45	AP, Caudal 10
LAD/Diag	AP, Cranial 45	RAO 35, Cranial 20
LCX/OM	LAO 10, Caudal 25	RAO 25, Caudal 25
Proximal+Mid RCA	LAO 45, CAUD 0	AP, CAUD 0
PLA/PDA	LAO 45, CAUD 0	LAO 30, CAUD 30

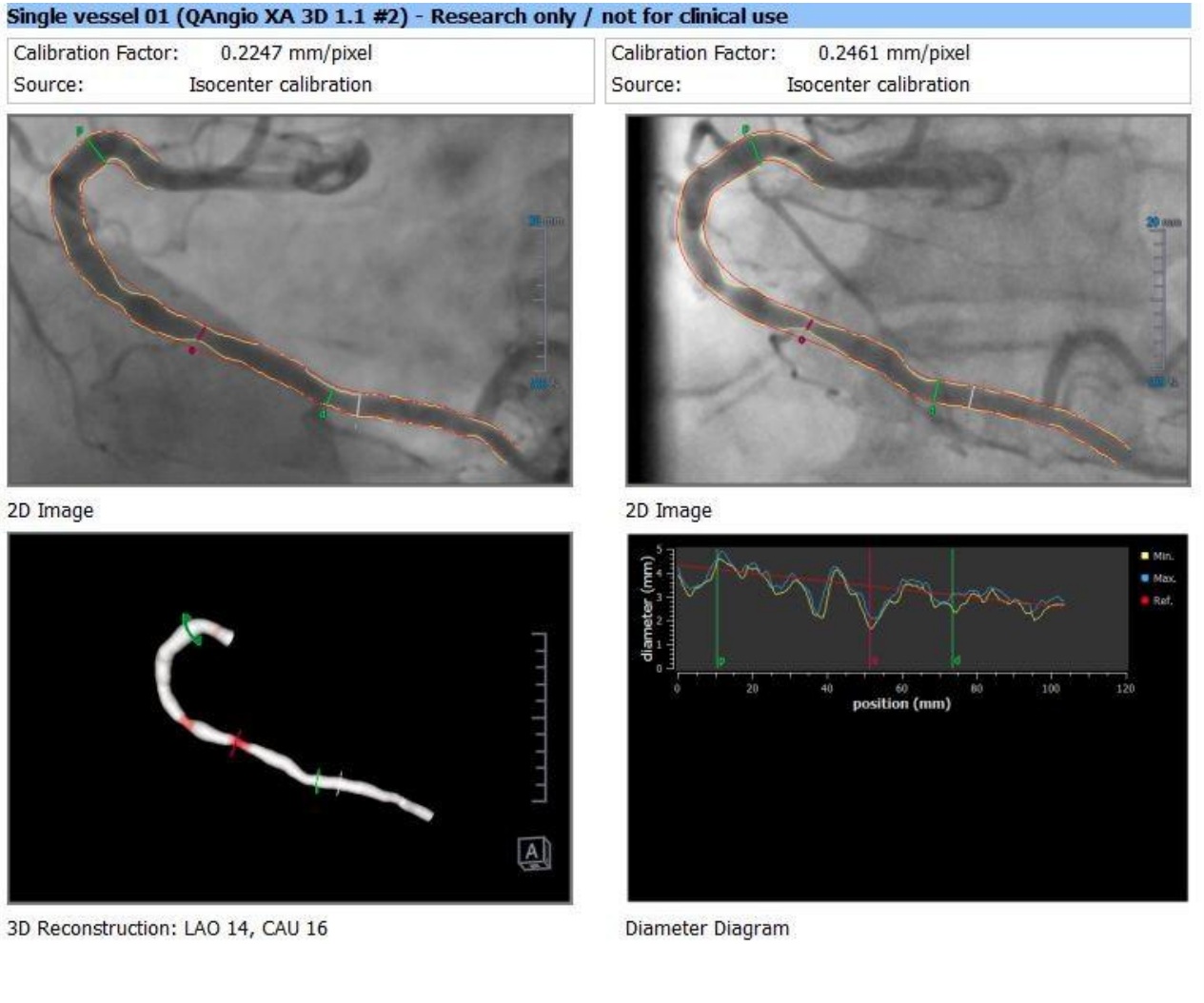
TIPS AND TRICKS (interesting for radiographers !)

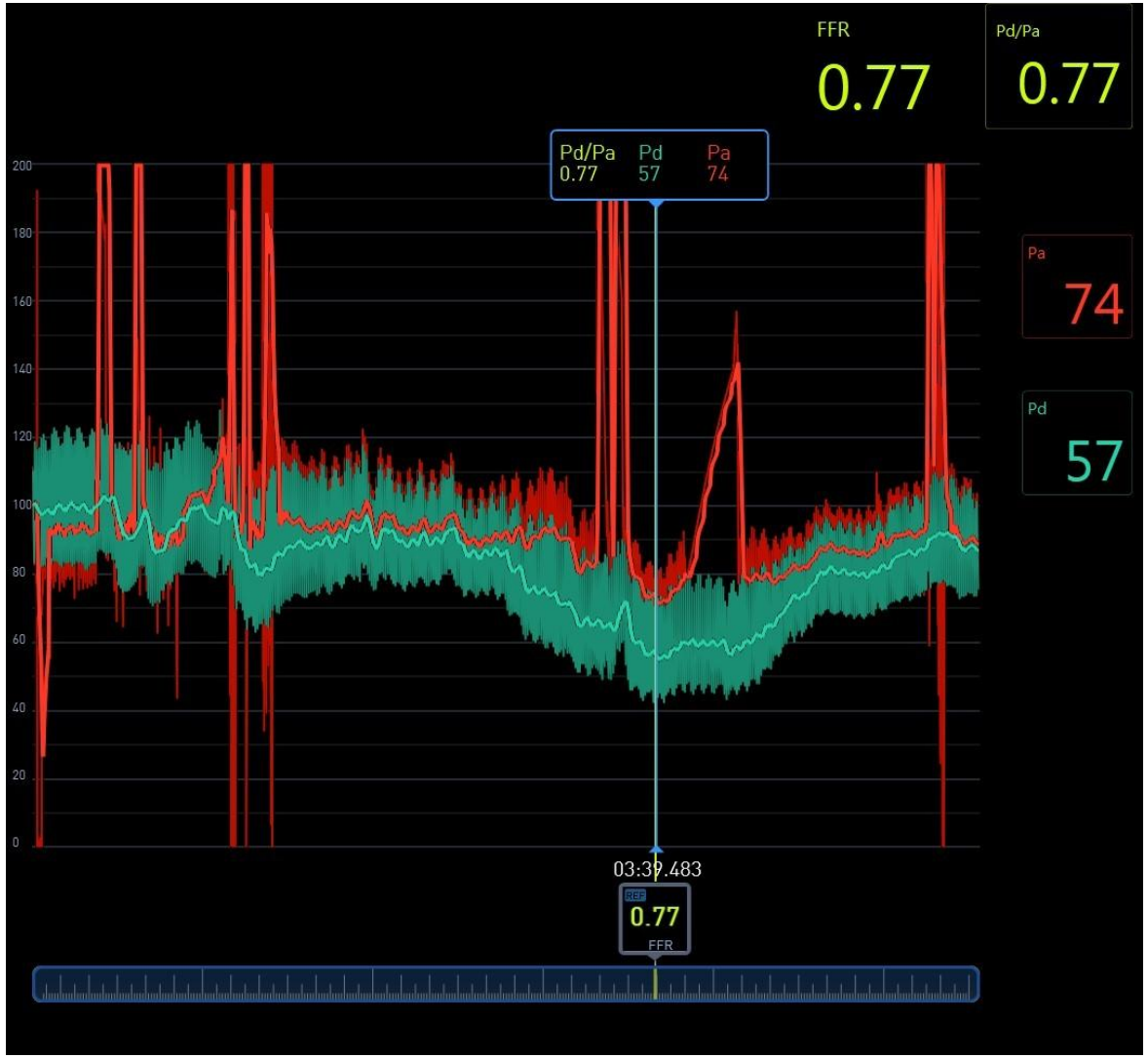
- Inject I.C. nitro-glycerine as early as possible
- Make sure that the catheter is filled with contrast before the injection
- Use continuous and fast contrast injections. Aim for full 3 cardiac cycles
- Minimize overlap of target segments
- Avoid foreshortening of the vessel
- Avoid zooming
- ***Avoid moving the table early after injection***
- Make sure that the entire vessel is visible in both projections.

Flowchart


Indication for CAG or PCI in time of study (329)
Check for inclusion criteria
No
Exclusion
Yes
Record angiograms according to protocol (296)
- Medis© QFR Analisys (Blind)
FFR (gold standard)
- Send the QFR images, Angio images, FFR snapshots to NL core lab
- Fill in eCRF
Clinical decisions and procedure
Secondary analisys by corelab (273)
Patients in analisys - Final Data (tot 271)
Exclusion

Clinical case



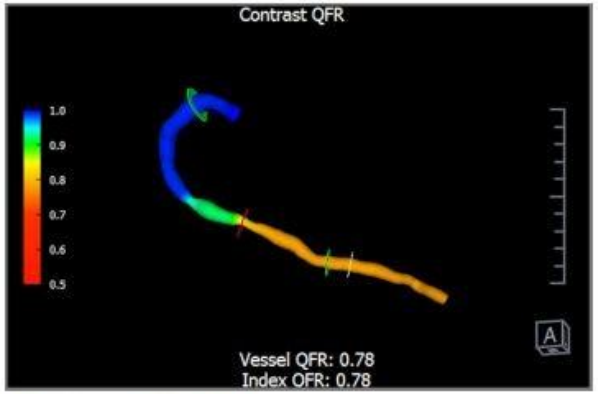


Lesion Results

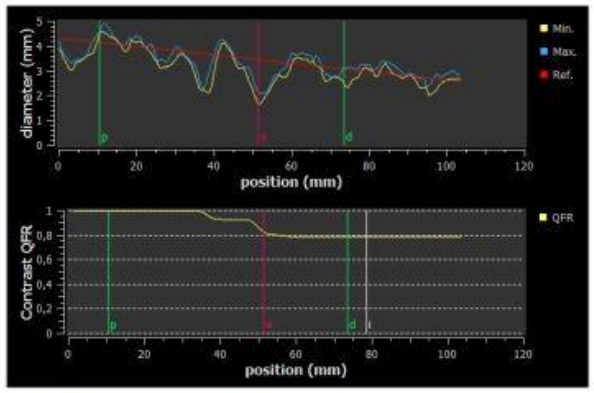
Diameter stenosis	51.7	%
Lesion length	63.0	mm
Proximal diameter	4.5 - 4.5	mm
Distal diameter	2.5 - 3.1	mm
MLD	1.7	mm
Area Stenosis	70.4	%
Bending angle	9	°
Reference volume	646.5	mm³
Plaque volume	109.9	mm³
Lumen volume	582.8	mm³

Optimal Viewing Angles

LAO 51, CRA 18	17.0	%
LAO 39, CRA 8	11.5	%
LAO 29, CAU 2	6.4	%
LAO 18, CAU 13	2.7	%
LAO 14, CAU 16	1.9	%



3D Reconstruction with QFR



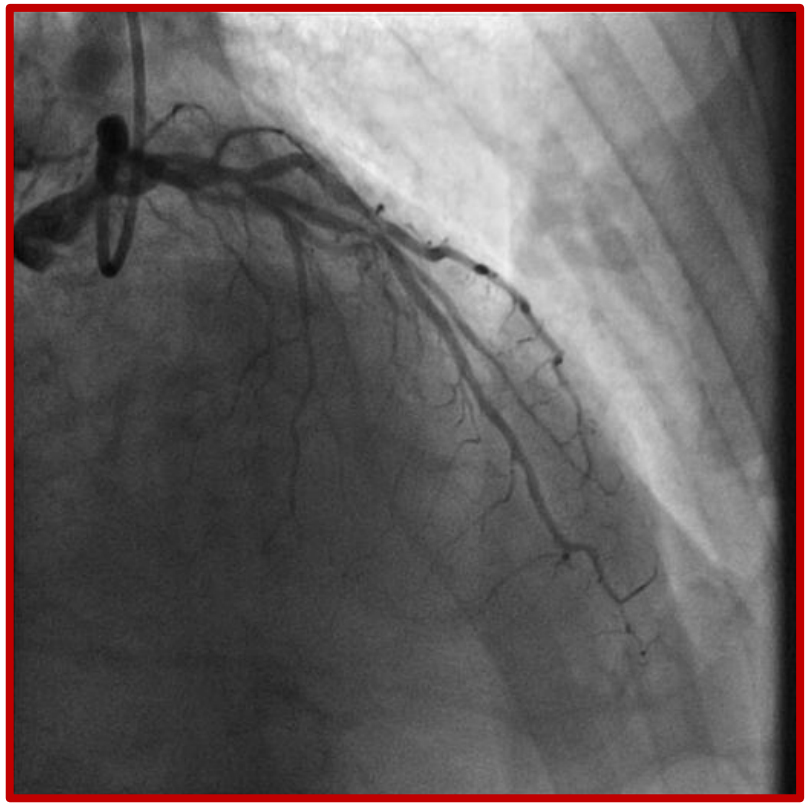
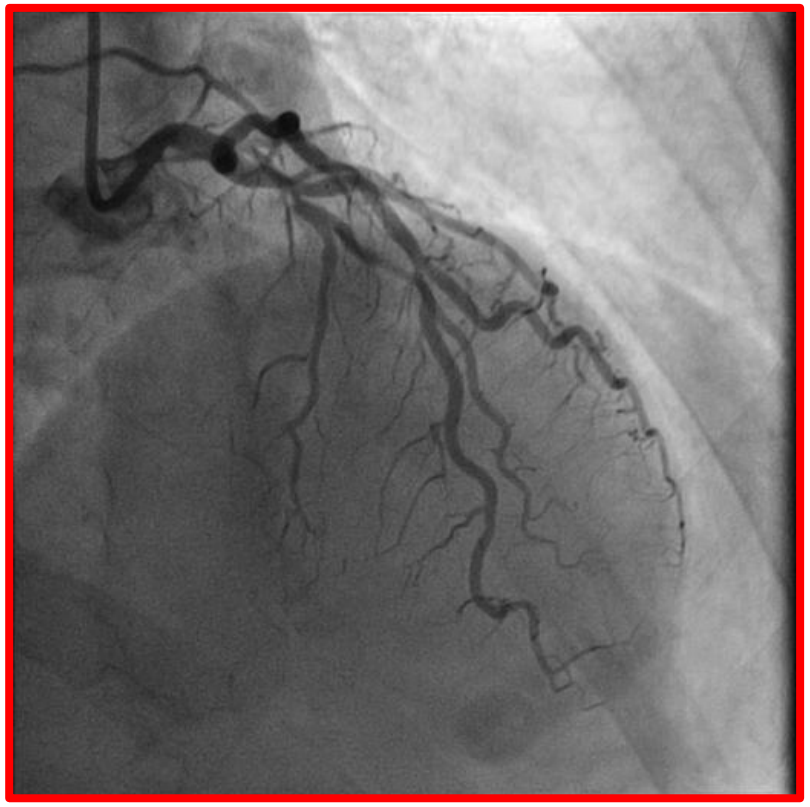
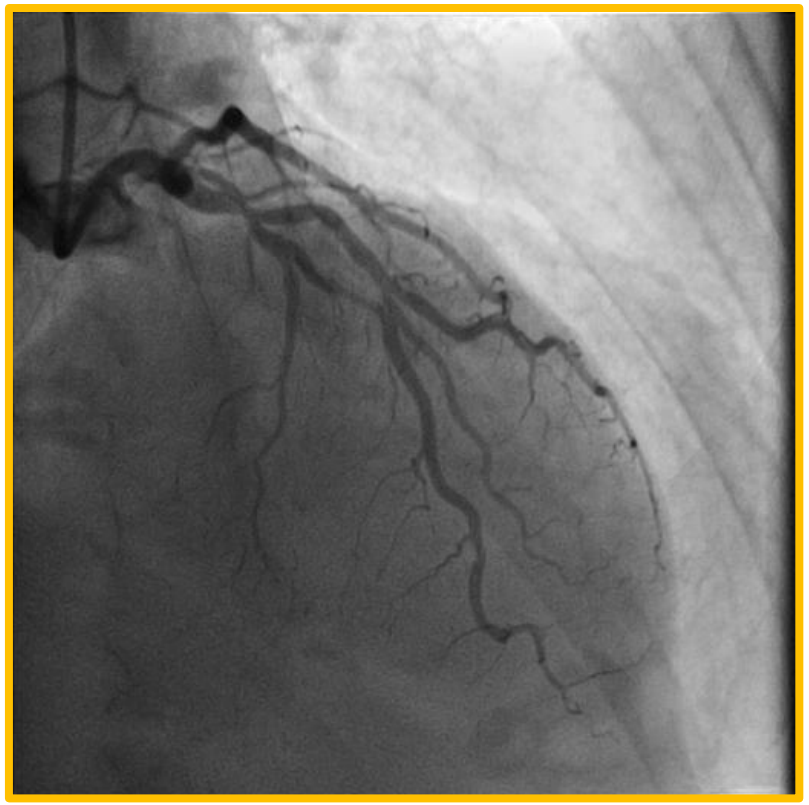
Diameter and QFR Diagrams

QFR Results

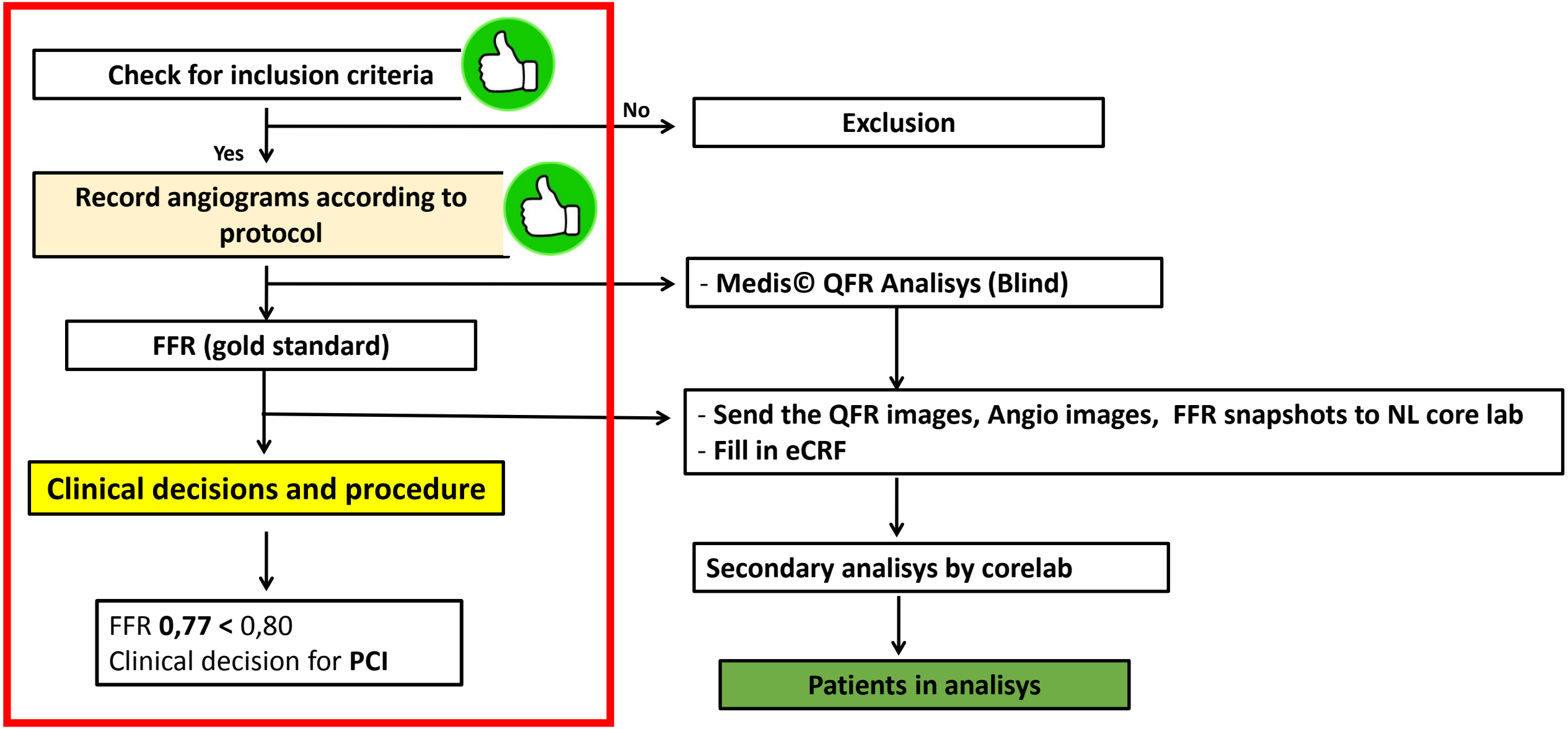
	Fixed Flow	Contrast
Vessel QFR	0.81	0.78
Lesion QFR	0.82	0.79
Index QFR	0.81	0.78

Clinical case 2

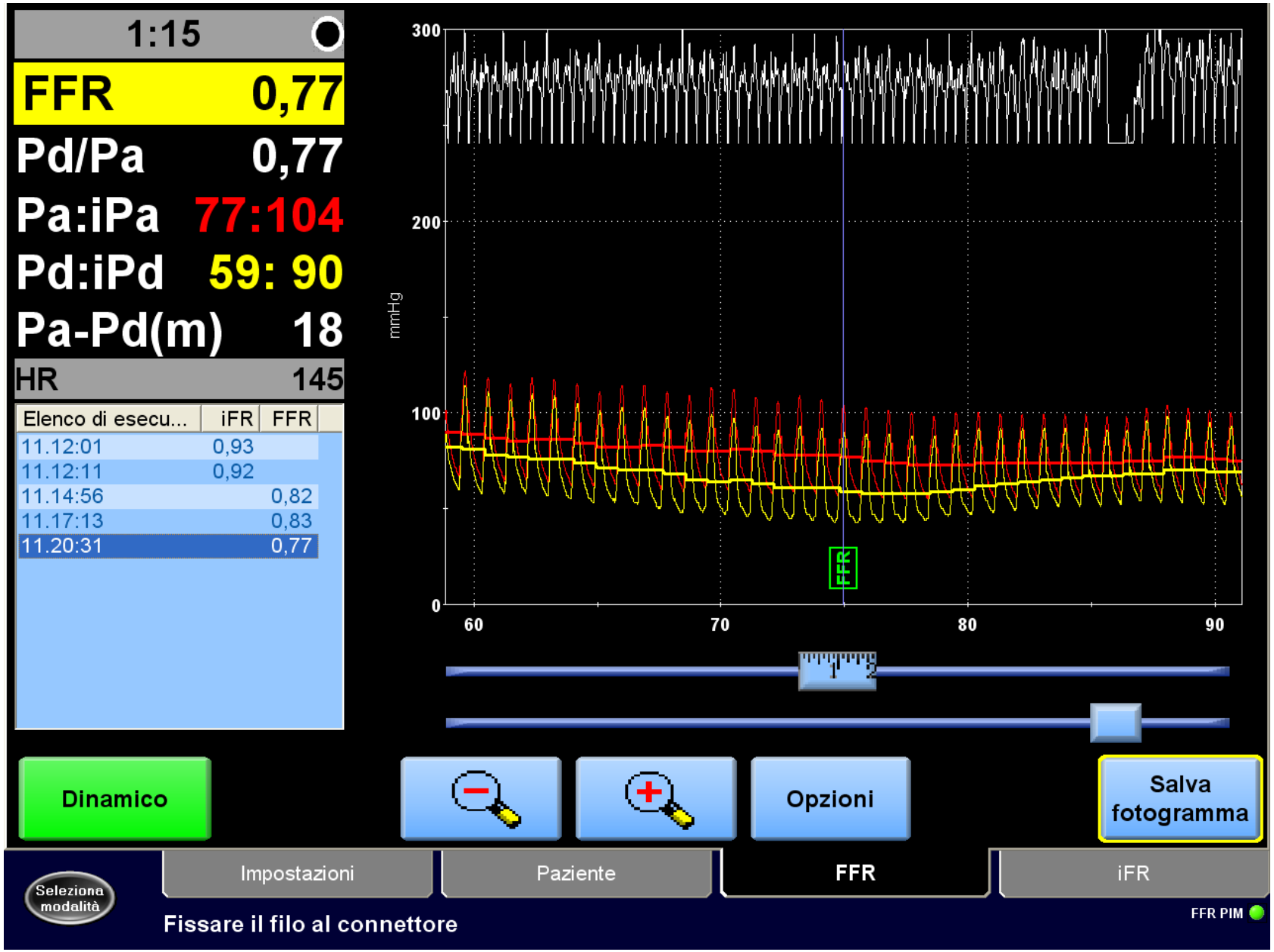
- D.D male, 53y.o RCA – STEMI 4 days ago, now candidate for LAD evaluation / revascularisation
- LAD stenosis around 60% by visual estimate -> Favour II

FAVOR II patient-adapted Flowchart

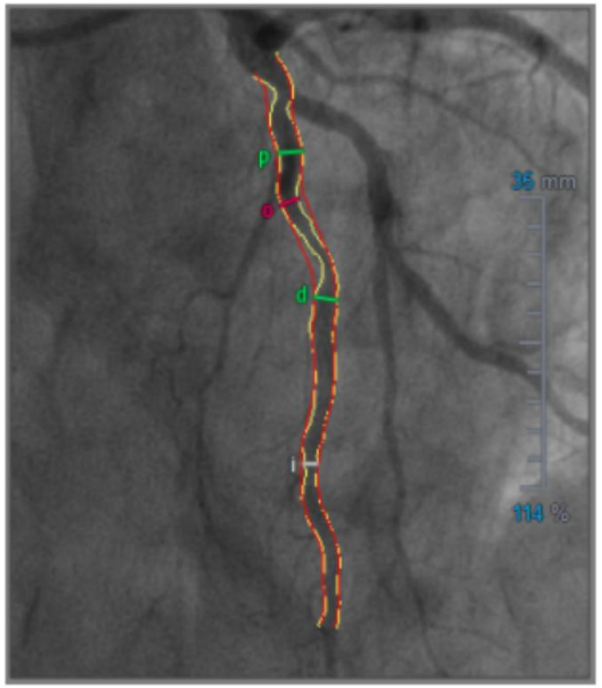


FFR


1:15
FFR 0,77
Pd/Pa 0,77
Pa:iPa 77:104
Pd:iPd 59: 90
Pa-Pd(m) 18
HR 145
Elenco di esecu... iFR FFR
11.12:01 0,93
11.12:11 0,92
11.14:56 0,82
11.17:13 0,83
11.20:31 0,77
300
200
100
0
mmHg
FFR
60
70
80
90
Dinamico
Opzioni
Salva fotogramma
Seleziona modalità
Impostazioni
Paziente
FFR
iFR
Fissare il filo al connettore
FFR PIM

QCA

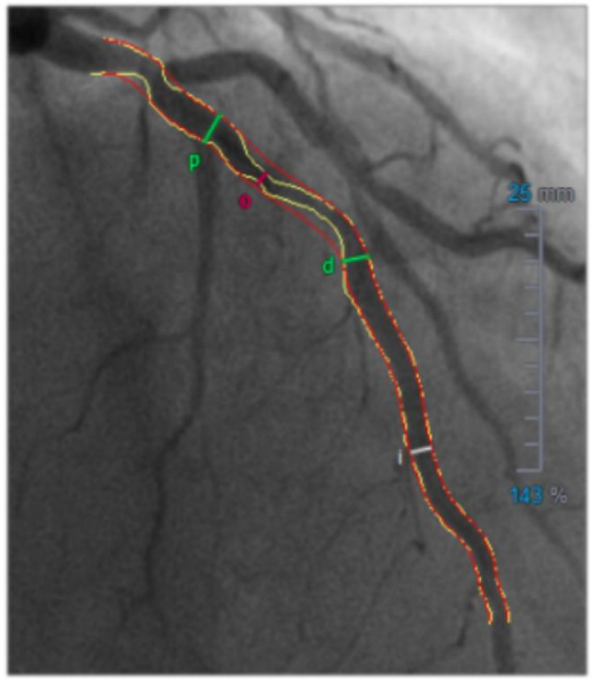
Calibration Factor: 0.2238 mm/pixel
Source: Isocenter calibration



2D Image

Calibration Factor: 0.2238 mm/pixel
Source: Isocenter calibration

Report: 25/09/2017 12:04, By: OCME Cardiologia.
Comment



2D Image

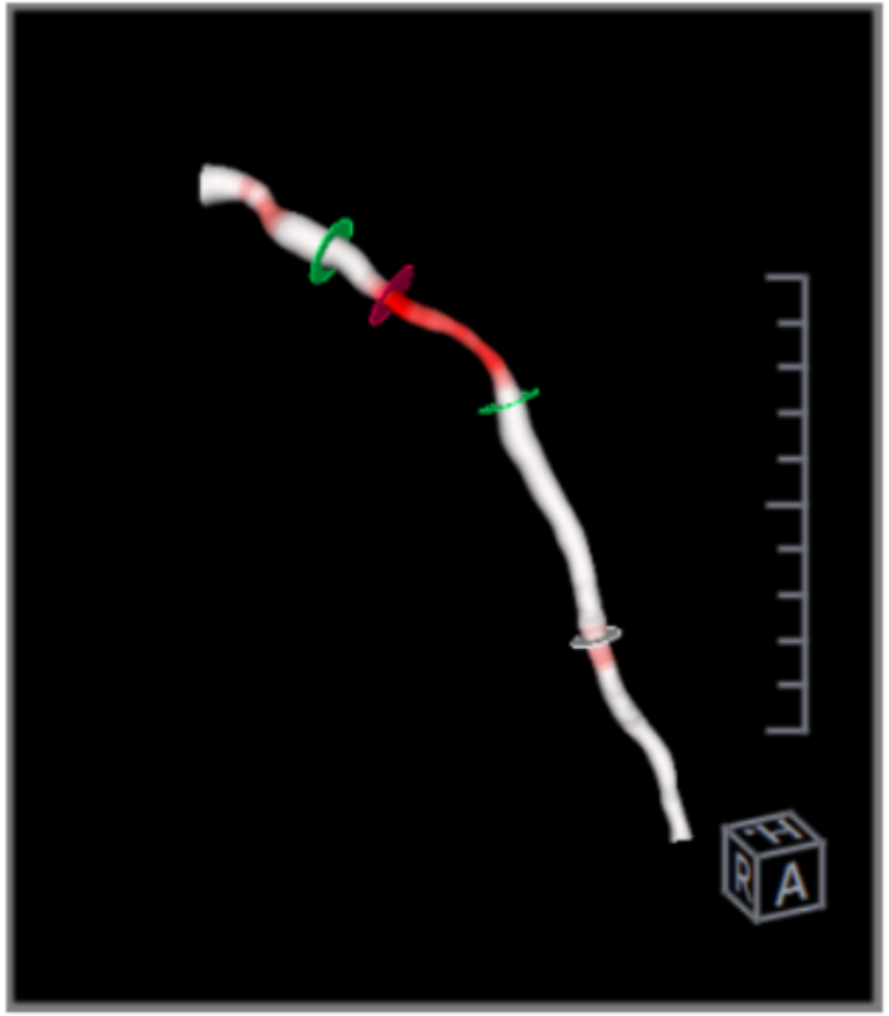
Lesion Results

Diameter stenosis	65.1 %
Lesion length	19.8 mm
Proximal diameter	2.8 - 2.8 mm
Distal diameter	2.5 - 2.7 mm
MLD	1.0 mm
Reference diameter	2.8 mm
Area Stenosis	73.7 %
Bending angle	28 °
Mean vessel bending angle	15 °
Maximum vessel bending angle	35 °
Mean lesion bending angle	22 °
Maximum lesion bending angle	35 °
Reference volume	117.2 mm^3
Plaque volume	60.2 mm^3
Lumen volume	58.9 mm^3

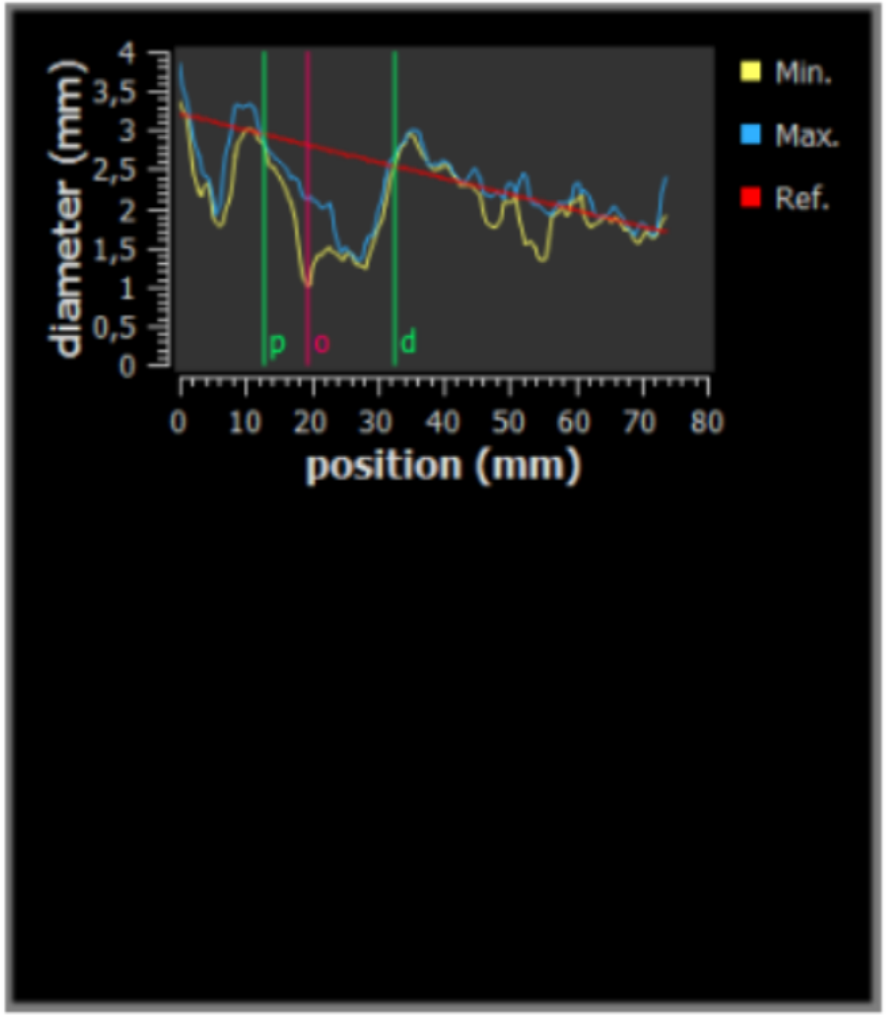
QFR

2017-09-2

Medis Suite 2.1 Report

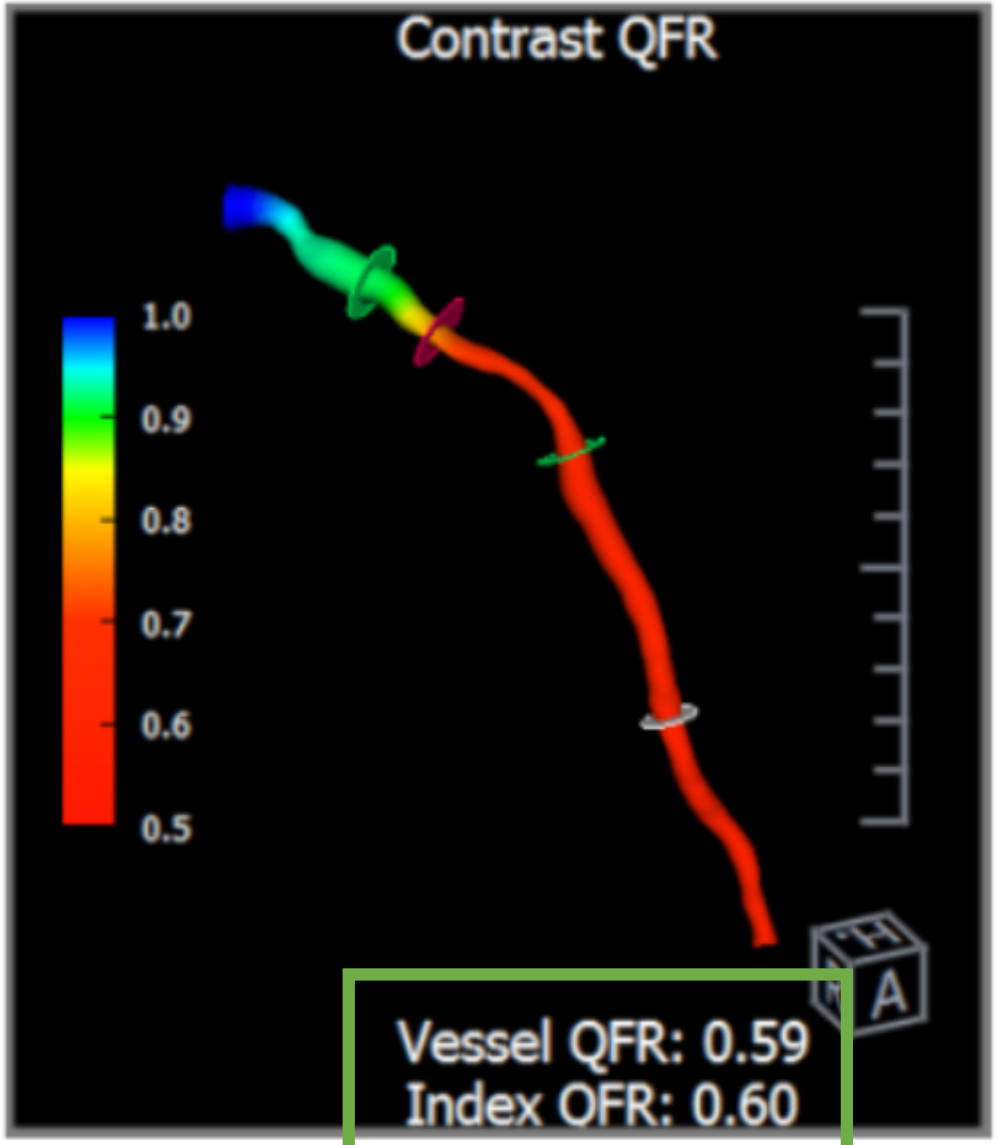


3D Reconstruction: RAO 27, CRA 27

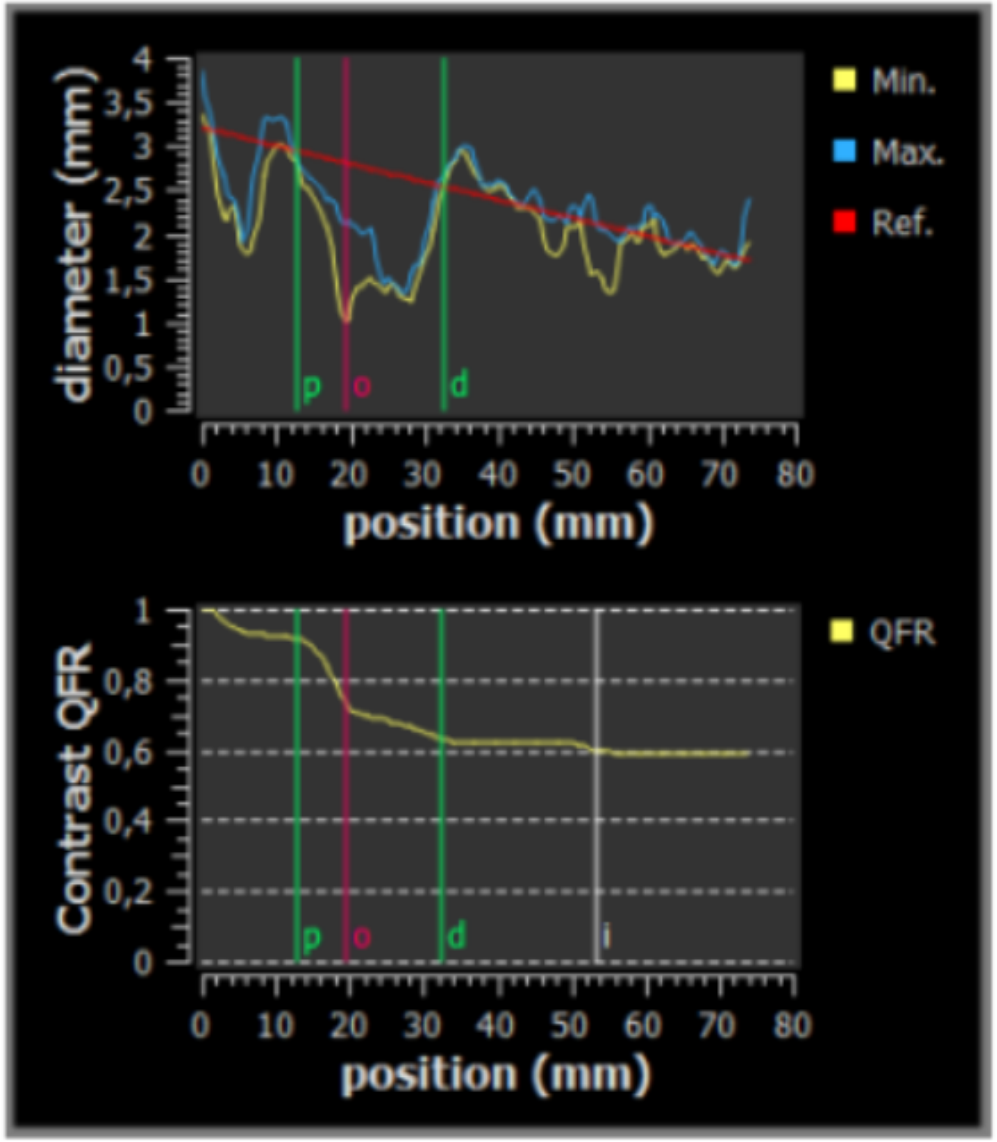


Diameter Diagram

Medis Suite 2.1 Report



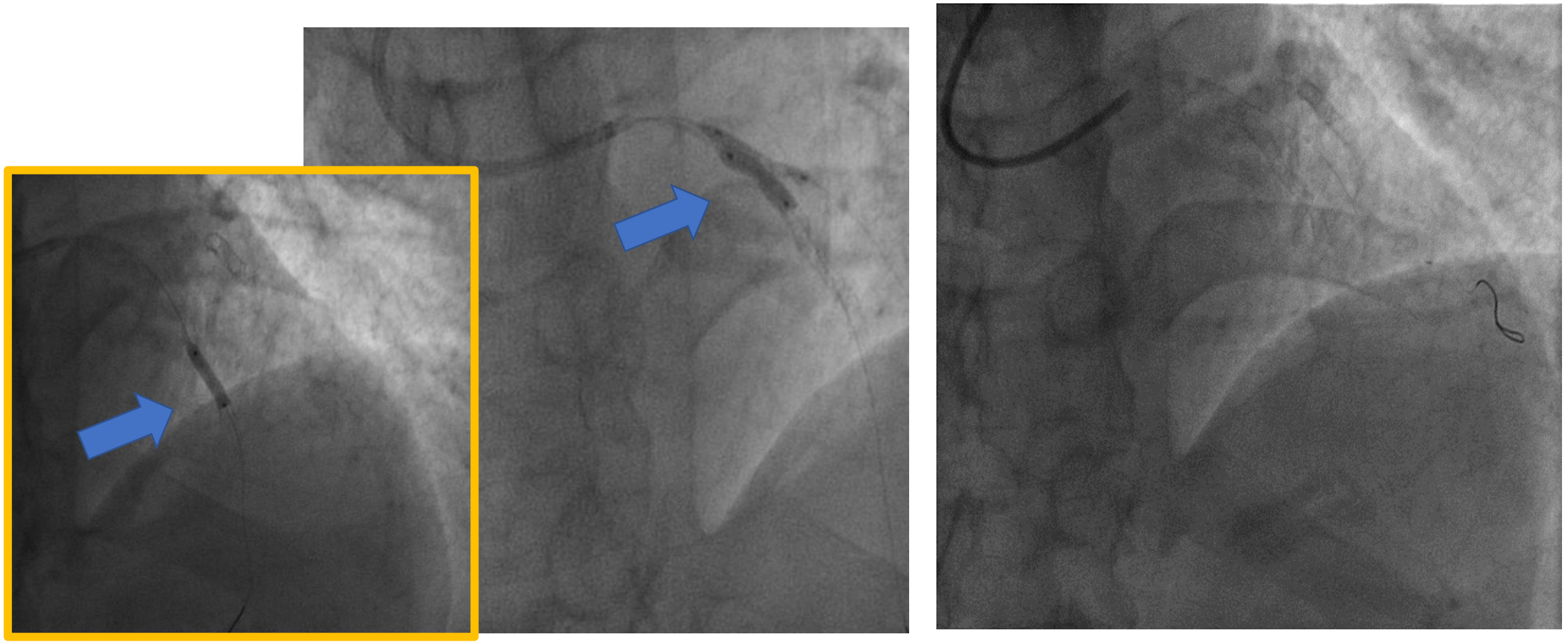
3D Reconstruction with QFR



Diameter and QFR Diagrams

PCI

Double DES placed on proximal – middle LAD, kissing baloon on LAD – D1



Study Results

QFR had **higher sensitivity** (88 percent vs. 46 percent, P<0.001) and specificity (88 percent vs. 77 percent, P<0.001) compared to 2D-QCA.

Key secondary endpoints of feasibility of QFR was 97 % (N=373)

Time to QFR was 4.8 minutes , compared to 7 minutes for FFR, P<0.001.

Randomized trials are required to determine if a QFR based diagnostic strategy provides non-inferior clinical outcome compared to pressure wire based strategies -> FAVOR III

Conclusions

- New tools for evaluating Coronary anatomy are available

- Functional evaluation is increasing in account with a lot of different features also in association with imaging
- FAVOR III → radiological data inserted
- Radiographers: a key role in cath lab
  - *Quality Imaging features*
  - *Participating in study*
  - *Patient Safety*

  - It’s a team work !

Grazie per l’attenzione!

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