FFR Angiográfico: ¿Simplifica el intervencionismo coronario?

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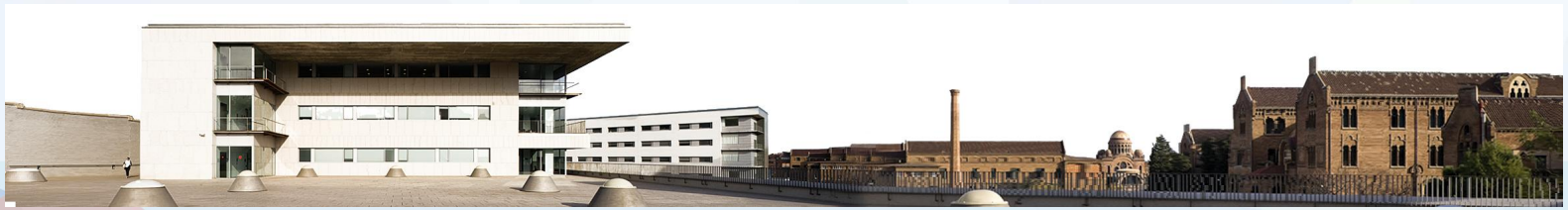
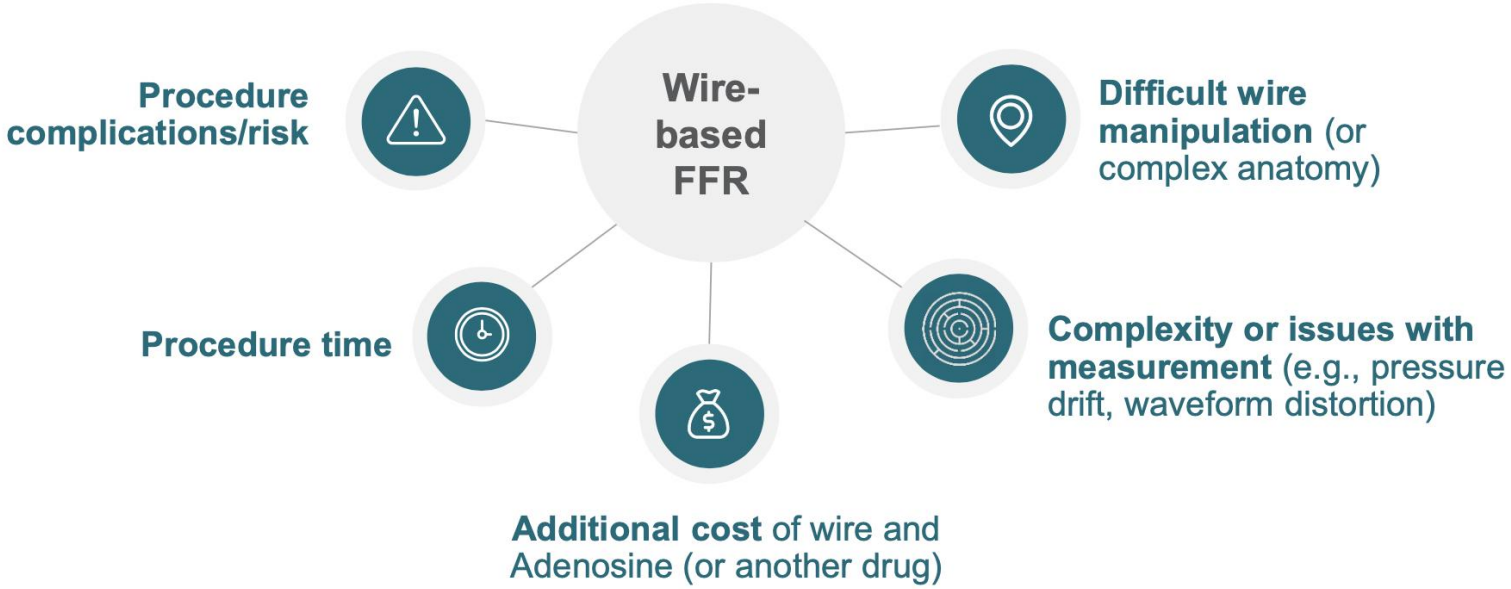


✓ FFR / iFR , RFR... : Valoración fisiológica de lesiones coronarias.

Limitations of Wire-Based FFR in the Cath Lab[1]

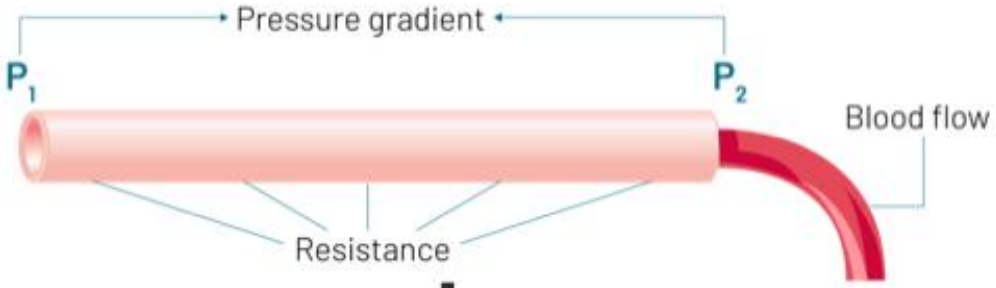


1. Kogame, et al. The Impact of Coronary Physiology on Contemporary Clinical Decision Making. JACC VOL. 13, NO. 14, 2020; 1617-1638

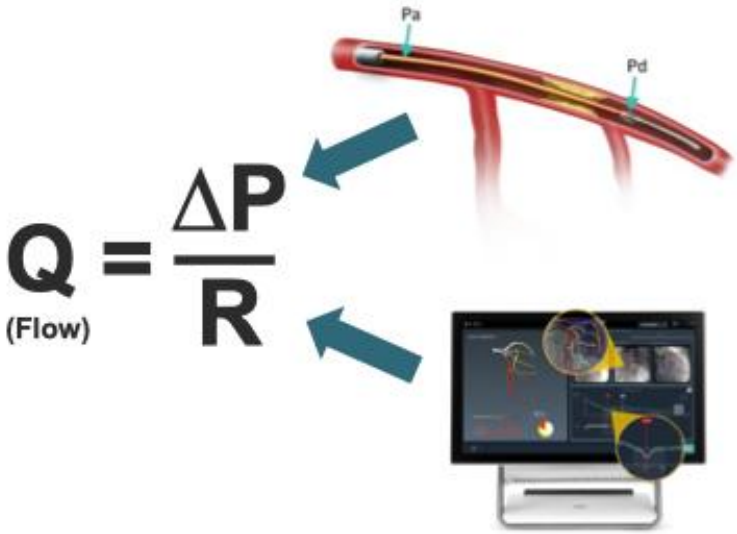
CathWorks FFRangio® System

Combina inteligencia artificial y computacional avanzada para obtener informacion fisiológica a partir de angiogramas coronarios

Blood Flow, Pressure and Resistance[1]



$$R = \frac{\rho L}{\pi r^4}$$



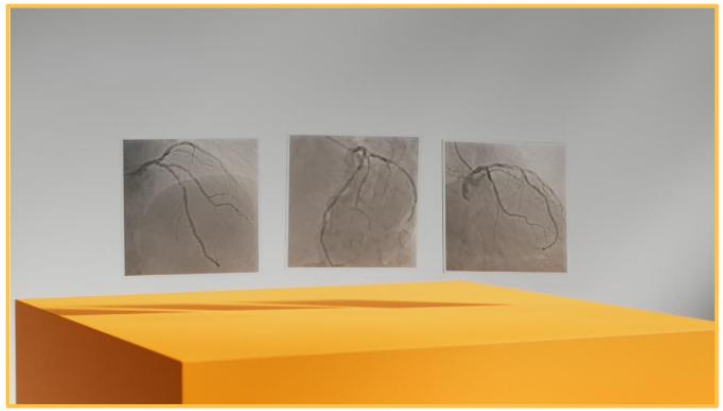
$$Q_{(Flow)} = \frac{\Delta P}{R}$$

Blood flow (Q)=ΔP/R

If blood pressure decreases, flow decreases.
If resistance increases, flow decreases.

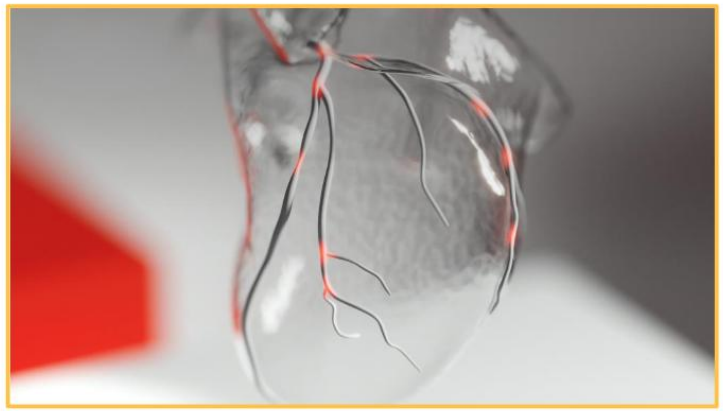
CathWorks FFRangio® System

1 Optimal 2D Angiography



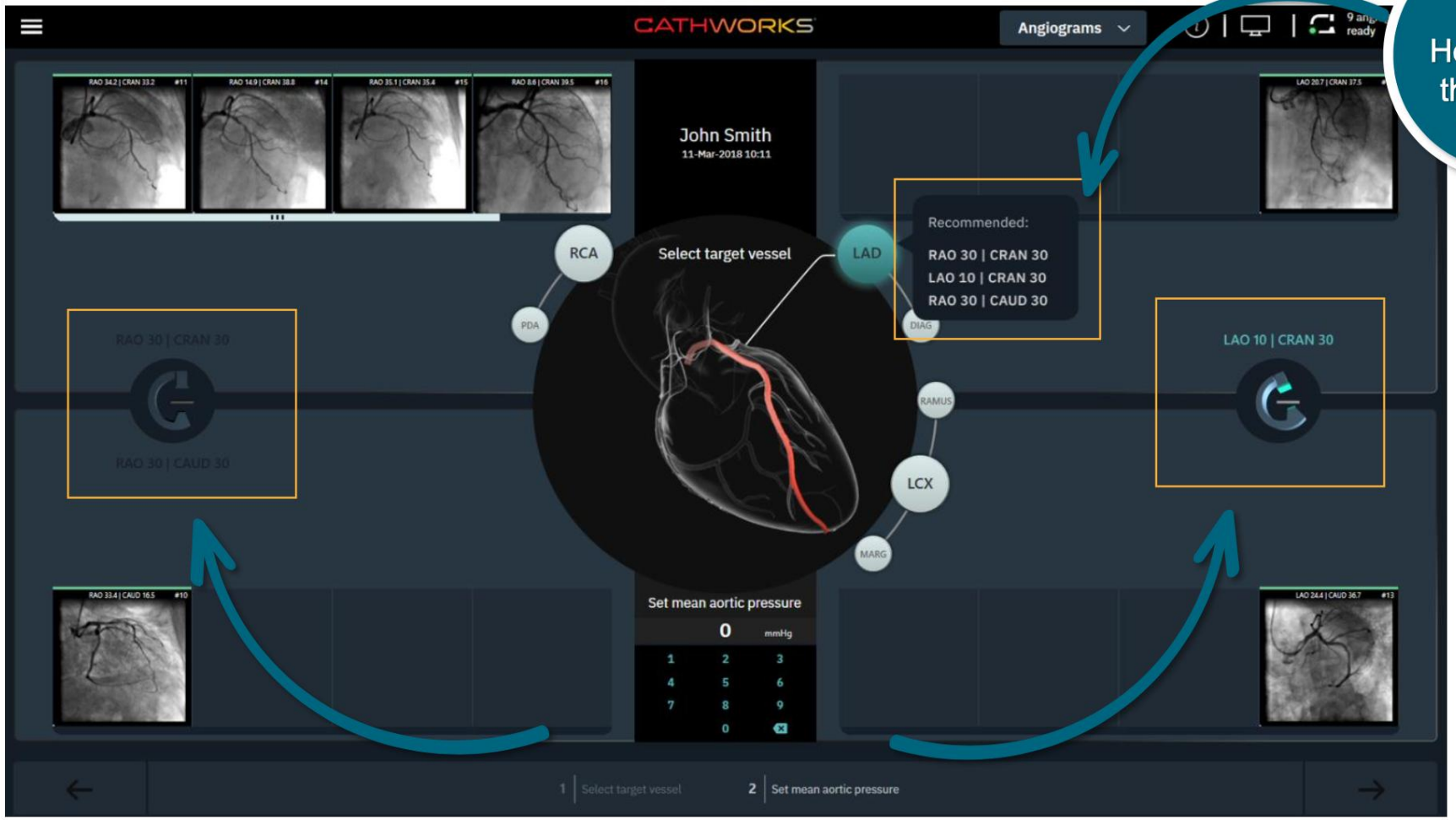
2 3D Model Reconstruction

3 Resistance Analysis

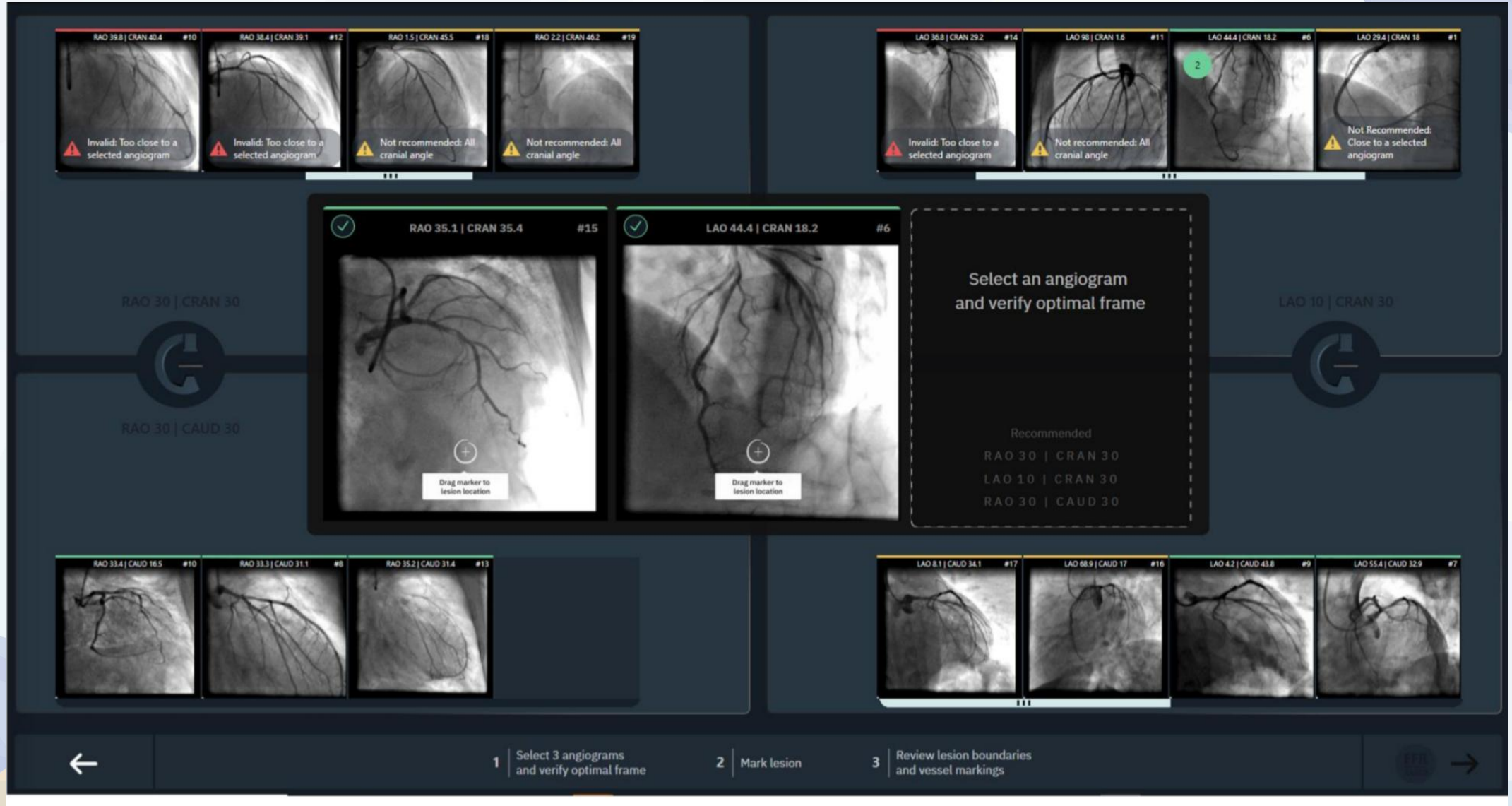


4 Comprehensive Physiological Assessment

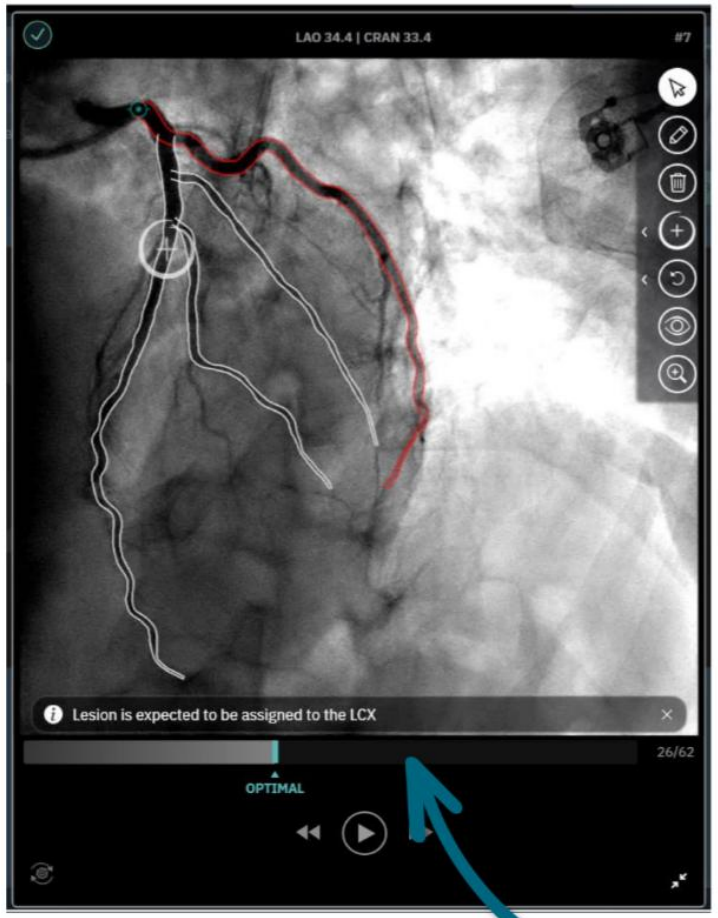
Pre-processing Angiograms and Starting an Analysis

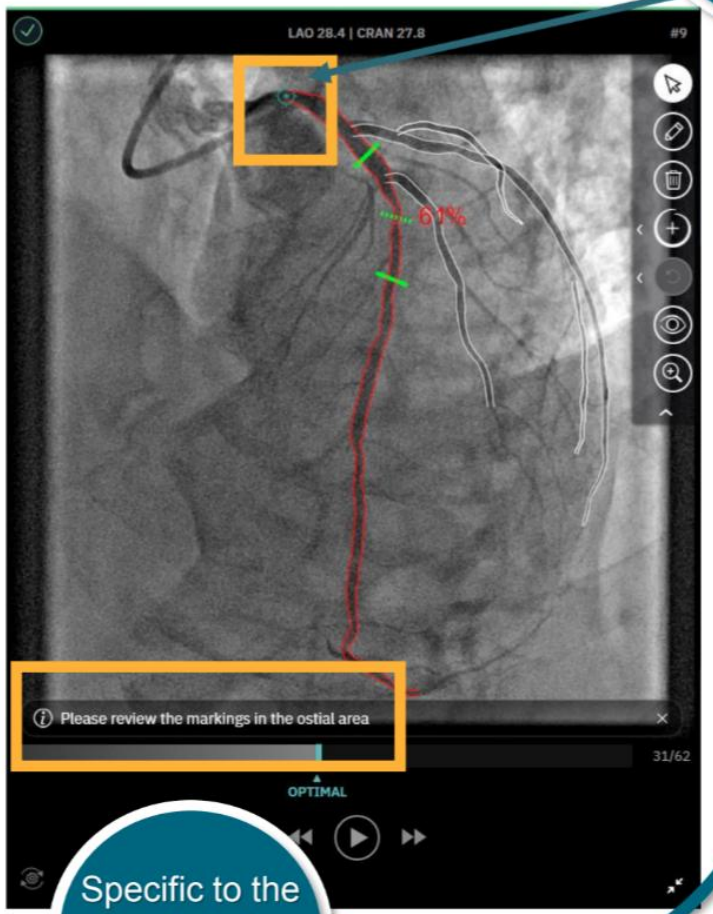


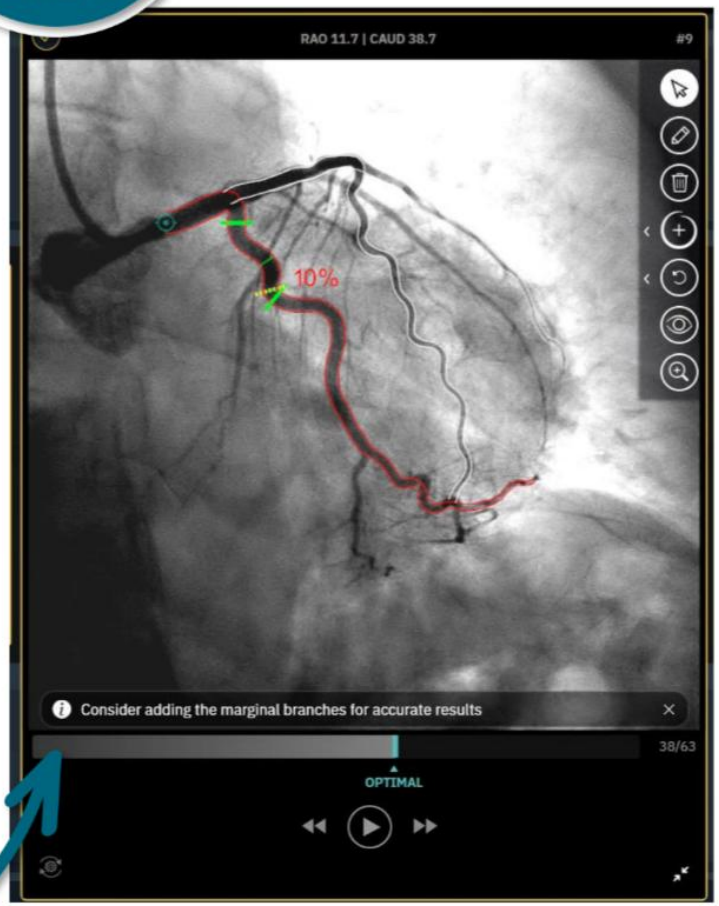
Selección de Angiografías



AI Communication and Editing Toolbar







Consider correcting radii or moving ostium location with this message

Specific to the selected target vessel

CATHWORKS

FFRangio System Major Publications

In multiple robust clinical studies, the FFRangio System has demonstrated excellent diagnostic performance compared to invasive FFR.

Publication	Study Overview	Accuracy	Sensitivity	Specificity	AUC	Conclusions
Witberg G, et al. Diagnostic Performance of Angiogram Derived Fractional Flow Reserve[1]	**Pooled analysis of five prospective studies assessing FFRangio diagnostic performance** 588 patients, 700 lesions	**93%**	91%	94%	0.95	The pooled analysis demonstrated that FFRangio had excellent diagnostic performance and a strong correlation with invasive FFR. The results were robust across a wide spectrum of patients and lesions.
Fearon W, et al. Accuracy of Fractional Flow Reserve Derived from Coronary Angiography[2]	**FAST-FFR pivotal trial assessing FFRangio diagnostic performance in 10 centers** 301 patients, 319 vessels	**92%**	94%	91%	0.94	The study demonstrated that FFRangio had excellent diagnostic performance versus invasive FFR, including in the grey zone between 0.75 and 0.85.
Omori H, et al. Angiogram Based Fractional Flow Reserve in Patients with Dual/Triple Vessel Coronary Artery Disease[3]	**Prospective study assessing FFRangio diagnostic performance in patients with multivessel disease** 50 patients, 118 lesions	**92%**	92%	92%	0.92	The study demonstrated that FFRangio had excellent diagnostic performance versus invasive FFR, with high per-vessel accuracy, sensitivity and specificity.
Skalidis I, et al. Diagnostic Performance of Angiography-derived Fractional Flow Reserve in Patients with NSTEMI[4]	**Prospective study assessing FFRangio diagnostic performance in patients with NSTEMI** 46 patients, 60 vessels	**97%**	96%	97%	0.97	The study demonstrated that FFRangio had excellent diagnostic performance in NSTEMI patients with values for sensitivity, specificity, PPV, NPV and accuracy all being greater than 95% compared to invasive FFR.

1. Witberg G, et al. Diagnostic performance of angiogram derived fractional flow reserve. J Am Coll Cardiol Intv. 2020 Feb, 13 (4)
2. Fearon W, et al. Accuracy of fractional flow reserve derived from coronary angiography. Circ. 2019; 139: 477-484
3. Omori H, et al. Angiogram based fractional flow reserve in patients with dual/triple vessel coronary artery disease. Int. J. Cardiol. 2019; 283: 17-22
4. Skalidis I, et al. Diagnostic performance of angiography-derived fractional flow reserve in patients with NSTEMI. Catheter Cardiovasc Interv. 2022; 1-8

FAST – FFR

Compara FFR Angio con FFR invasivo

FAST-FFR Pivotal Study by the Numbers[1]

The robust FAST-FFR pivotal study included data from 10 centers and 19 different FFRangio operators, across a wide range of patients and lesions.

- **301** patients in primary analysis
- **319** vessels
- **54%** LAD; **24%** RCA; **19%** LCX

- **45%** significant lesions
- **0.82** median FFR
- **31%** in grey zone[2]
- **89%** lesion class B or C

- **10** sites; **19** FFRangio users; **45+** Operators; **All 4** C-arms[2,3]
- **FFR measured on site** and qualified by independent core lab
- **FFRangio on-site** by cath lab staff; **<4% disqualified**

Main Exclusion Criteria[1,2]

- STEMI or prior STEMI on same side (right/left)
- CTO in target vessel
- Prior CABG, heart transplant, or valve surgery or prior TAVI/TAVR
- ≥ Moderate aortic stenosis
- LVEF ≤45%
- TIMI grade 2 or lower
- Left main (stenosis >50%)
- Separate ostium
- PCI with stent in target vessel in past 12 months or ISR
- Severe diffuse disease
- Ectatic or aneurysmatic target lesion
- Major collaterals

1. Fearon W, et al. Accuracy of Fractional Flow Reserve Derived From Coronary Angiography. Circulation. 2019; 139: 477-484
2. Data on fille – CathWorks - FAST-FFR FFRangio Pivotal Clinical Study Report - CLI-000184

FAST – FFR

Compara FFR Angio con FFR invasivo

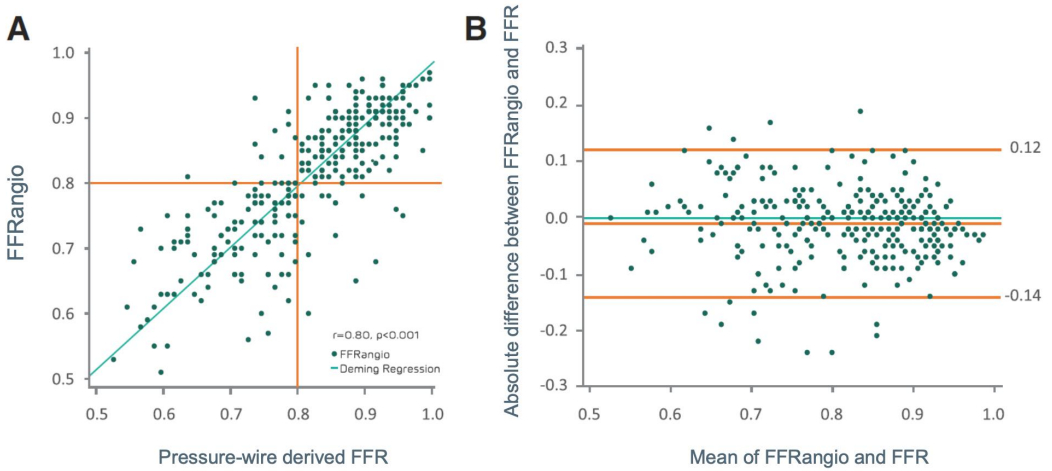
FAST-FFR Trial[1,2]

Primary Endpoint and Accuracy

Diagnostic Characteristic	
Sensitivity	**93.5%** (87.8, 96.6)
Specificity	**91.2%** (86.0, 94.6)
Diagnostic Accuracy	**92.2%** (88.7, 94.8)
Positive Predictive Value	**89.0%** (82.6, 93.2)
Negative Predictive Value	**94.8%** (90.3, 97.3)

Grey zone Accuracy (0.75-0.85)	
Sensitivity	**88.5%**
Specificity	**85.1%**
Diagnostic Accuracy	**86.9%**

Correlación entre FFR y FFR angio Bland-Altman plot



1. Fearon W, et al. Accuracy of Fractional Flow Reserve Derived From Coronary Angiography. Circulation. 2019; 139: 477-484
2. Data on fille – CathWorks - FAST-FFR FFRangio Pivotal Clinical Study Report - CLI-000184

Clinical Outcomes of FFRangio Guided Treatment for Coronary Artery Disease

1-Year Clinical Outcomes Study

Study Design

Real-world data from 7 centers in Japan and Israel.

Gifu Heart Center
Fukuoka Sano Hospital
Fukuyama Cardiology Hospital
Ichinomiya Nishi Hospital
Sakakibara Hear Institute
Saga-Kem Medical Center

Rabin Medical Center

Managed per FFRangio Guidance
1,435 patients
(1,967 lesions)

Deferred
Negative FFRangio
888 patients

Revascularized
Positive FFRangio
547 patients
100% follow-up

Baseline Characteristics

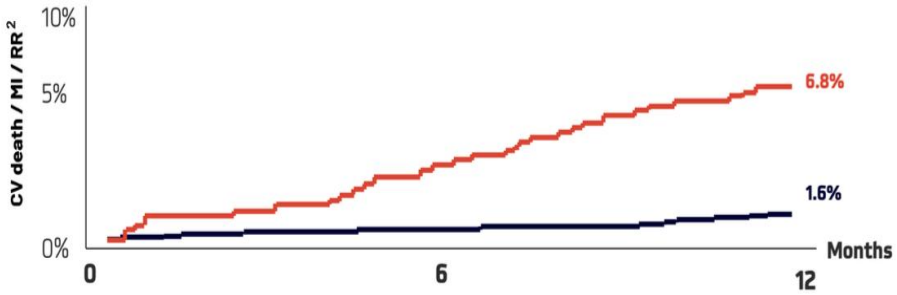
The revascularized cohort included a higher proportion of patients who suffered from diabetes, were active smokers and/or presented with acute coronary syndrome.

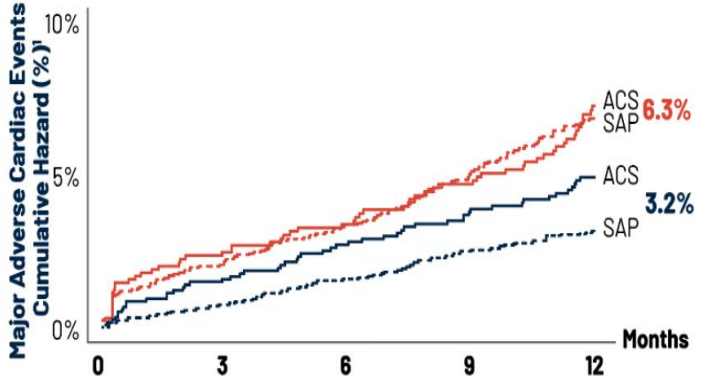
	All (n=1,435)	Deferred (n=888)	Revascularized (n=547)	P-value
Male	997 (70.4%)	579 (65.8%)	418 (77.8%)	<0.01
Diabetes mellitus	532 (37.2%)	293 (33.1%)	239 (43.9%)	<0.01
Dyslipidemia	860 (60.1%)	508 (57.3%)	352 (64.7%)	0.006
Acute coronary syndrome	381 (26.8%)	183 (12.9%)	198 (36.6%)	<0.01

1. Witberg G, et al.One-year clinical outcomes of FFR angio-guided treatment of coronary artery disease, as presented at EuroPCR 2023

1-Year Results in Perspective

In the largest wire-based FFR pooled analysis reported to date, a similar rate of events was observed between the deferred (negative FFR) and revascularized (positive FFR) cohorts as was reported in the FFRangio study.





	Deferred (n=888)	Revascularized (n=547)
CV death/MI/RR	1.6%	6.8%
CV death	0.4%	0%
Myocardial infraction	0.1%	1.0%
Repeat revascularization	1.2%	6.8%

	Deferred (n=5129)	Revascularized (n=3450)
MACE	3.2%	6.3%
Death	0.6%	0.8%
Myocardial infraction	0.6%	1.8%
Unplanned revascularization	2.3%	4.5%

Patients were safely deferred when following FFRangio guidance, demonstrated by a similar repeat revascularization rate as seen in wire-based studies.[2]

1. Cerrato E, Mejia-Renteria H, Dehbi HM et al. Revascularization deferral of nonculprit stenoses on the basis of fractional flow reserve: 1-year outcomes of 8,579 patients. JACC Cardiovasc Interv. 2020 Aug 24;13(16):1894-1903.
2. Witberg G, et al. One-year clinical outcomes of FFR angio-guided treatment of coronary artery disease, as presented at EuroPCR 2023

Comparativa con FFR invasivo

	CathWorks FFRangio				Medis QFR				Pie Medical vFFR	
Parameter	Validation[1]	FAST-FFR[2]	FFRangio MVD[3]	Pooled Analysis[4]	FAVOR[5]	FAVOR II[6]	WIFI II[7]	FAVOR CHINA[8]	FAST II Site[9]	FAST II Corelab[9]
Trial Design										
Year Published	2017	2018	2019	2020	2016	2018	2018	2017	2021	2021
N Patients	184	301	50	588	73	272	191	308	334	334
N Vessels	203	319	118	700	84	317	292	328	334	334
Diagnostic Performance Compared to FFR										
Sensitivity	88%	93.5%	92.3%	91.2%	74%	86.5%	77%	94.6%	71%	81%
Specificity	95%	91.2%	92.4%	93.5%	91%	86.9%	86%	91.7%	89%	95%
Accuracy	93%	92.2%	92.4%	92.6%	80-87%	86.8%	83%	92.7%	83%	90%
Positive Predictive Value		89.0%		91.2%					79%	90%
Negative Predictive Value		94.8%		93.5%					85%	90%

1. Pellicano M, et al. Validation study of image-based fractional flow reserve during coronary angiography. Circ Cardiovasc Interv. 2017; 10:e005259
2. Fearon W, et al. Accuracy of fractional flow reserve derived from coronary angiography. Circ. 2019; 139: 477-484
3. Omori H, et al. Angiogram based fractional flow reserve in patients with dual/triple vessel coronary artery disease. Int. J. Cardiol. 2019; 283: 17-22
4. Witberg G, et al. Diagnostic performance of angiogram derived fractional flow reserve. J Am Coll Cardiol Intv. 2020, 13 (4)
5. Tu S, et al. Diagnostic Accuracy of Fast Computational Approaches to Derive Fractional Flow Reserve From Diagnostic Coronary Angiography: The International Multicenter FAVOR Pilot Study. J Am Coll Cardiol Intv. 2016; 9: 2024-2035
6. Westra J, et al. Diagnostic Performance of In-Procedure Angiography-Derived Quantitative Flow Reserve Compared to Pressure-Derived Fractional Flow Reserve: The FAVOR II Europe-Japan Study. J Am Heart Assoc. 2018; 7: e009603. Table 3.
7. Westra J, et al. Evaluation of Coronary Artery Stenosis by Quantitative Flow Ratio During Invasive Coronary Angiography: The WIFI II Study (Wire-Free Functional Imaging II). Circ. Cardiovasc. Imaging. 2018; 11: e007107
8. Xu B, et al. Diagnostic Accuracy of Angiography-Based Quantitative Flow Ratio Measurements for Online Assessment of Coronary Stenosis. Journal of the American College of Cardiology. 2017; 70: 3077-3087
9. Masdjedi K, et al. Vessel fractional flow reserve (vFFR) for the assessment of stenosis severity: the FAST II study. EuroIntervention: journal of EuroPCR in collaboration with the Working Group on Interventional Cardiology of the European Society of Cardiology. 2022; 17: 1498-1505

CASO CLINICO

- Varón 69 años
- FRCV : HTA , DLP, DM 2. (HbA 1c 8,9% abril 2024)

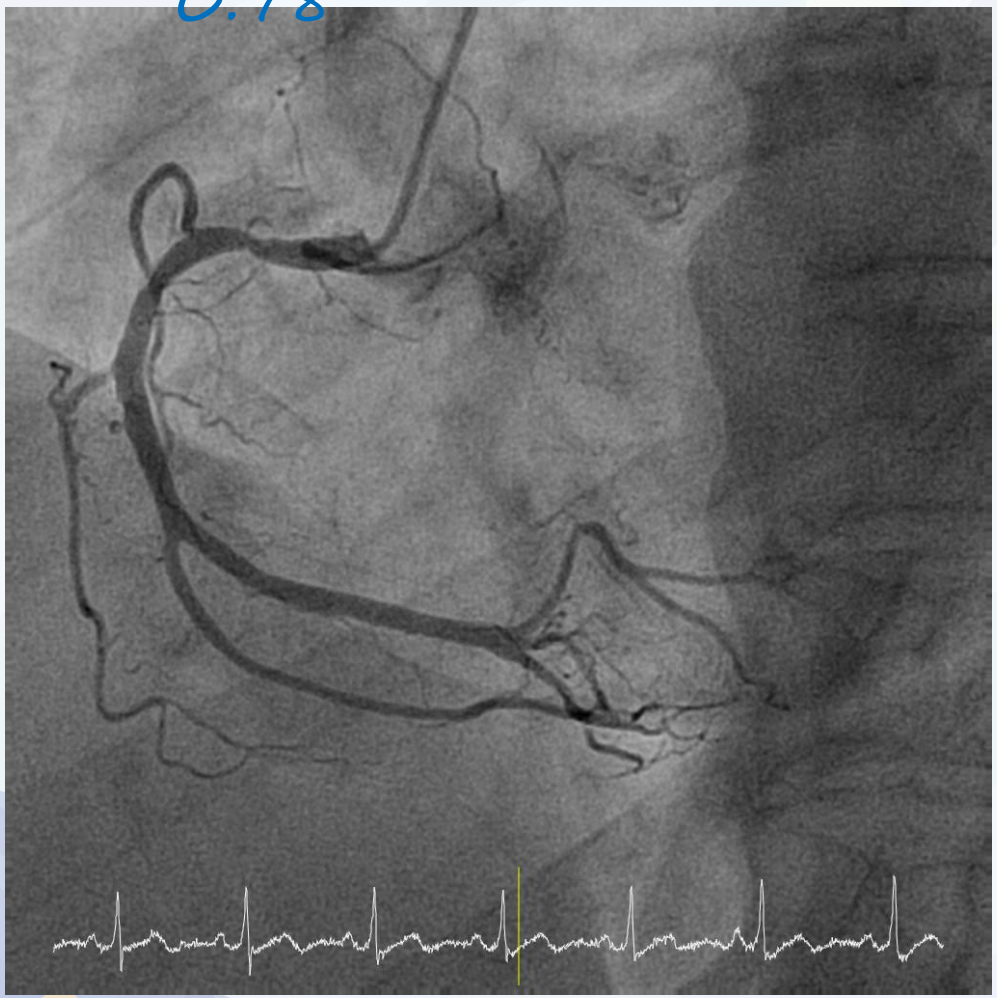
- H. Cardiológica:

- 2013: Angor estable . cRMN: Isquemia subendocárdica inferior.
- Coronariografía: CD prox. 70%. DES 3.5x12mm

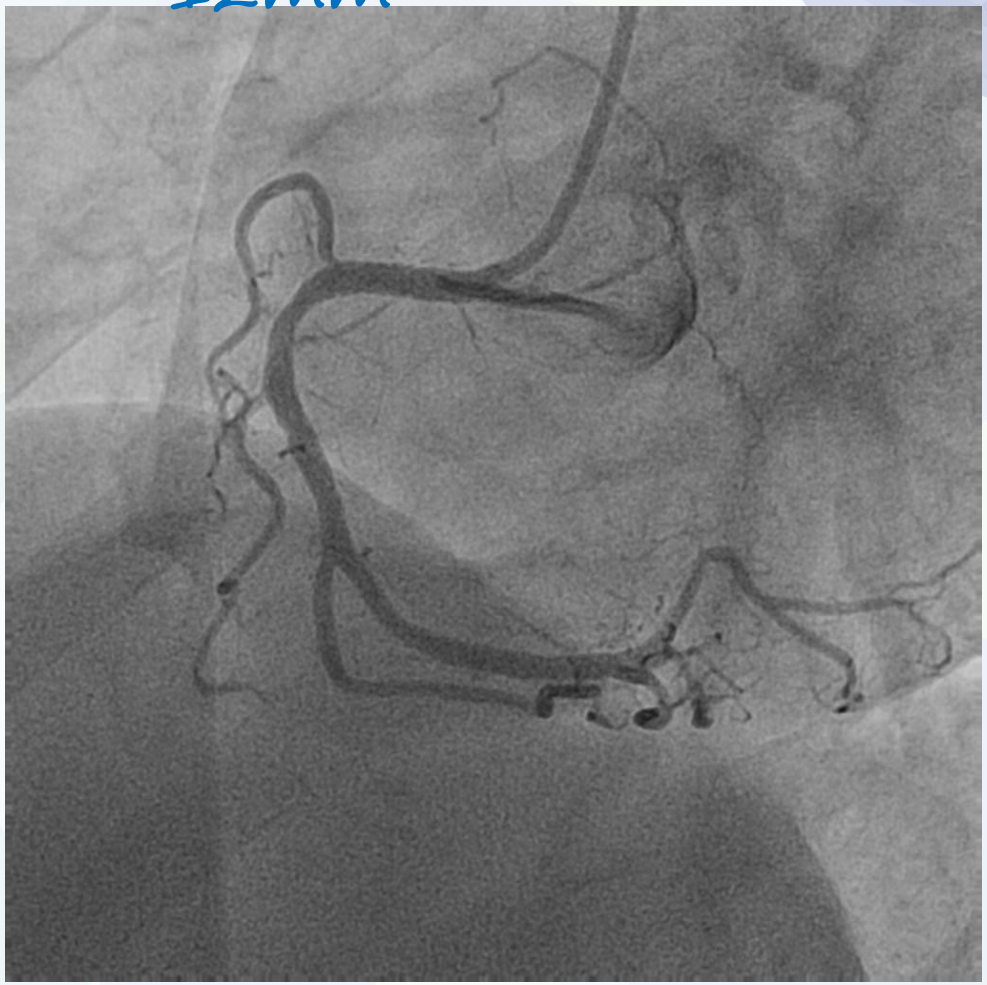
- Posterior seguimiento asintomático. PE negativa.

2013

CD prox – FFR : 0.78



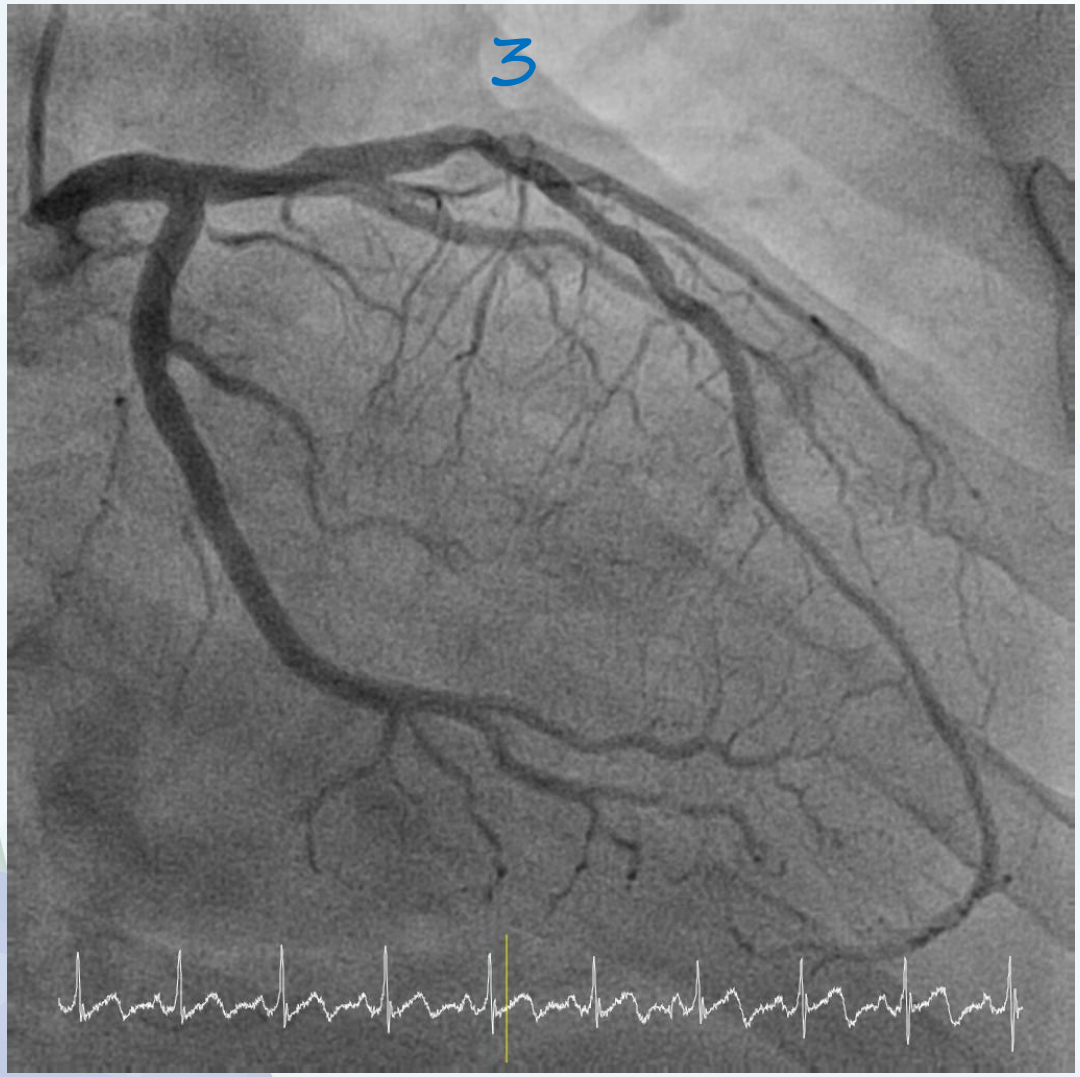
Post DES 3.5 x 12mm

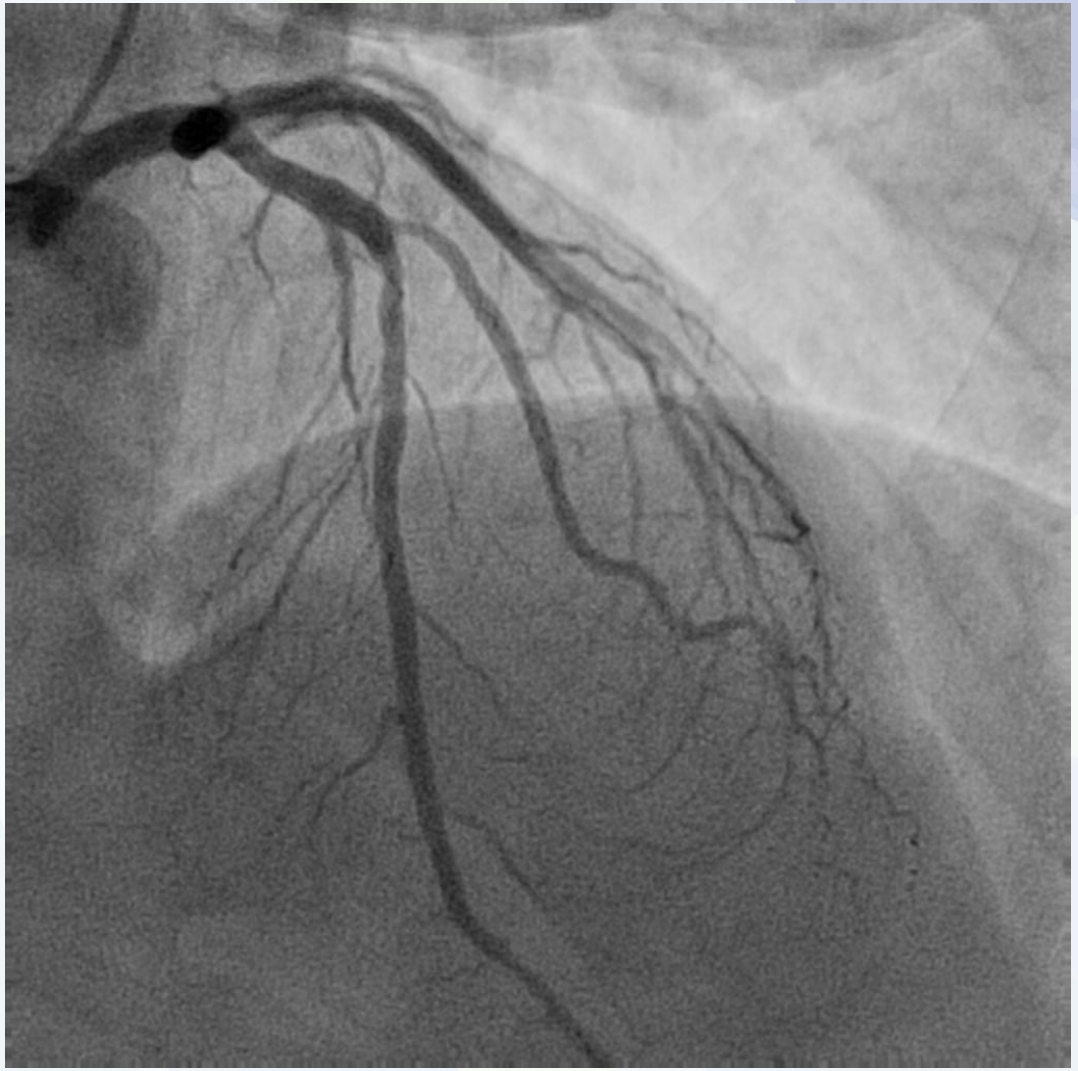


Coronaria izquierda

201

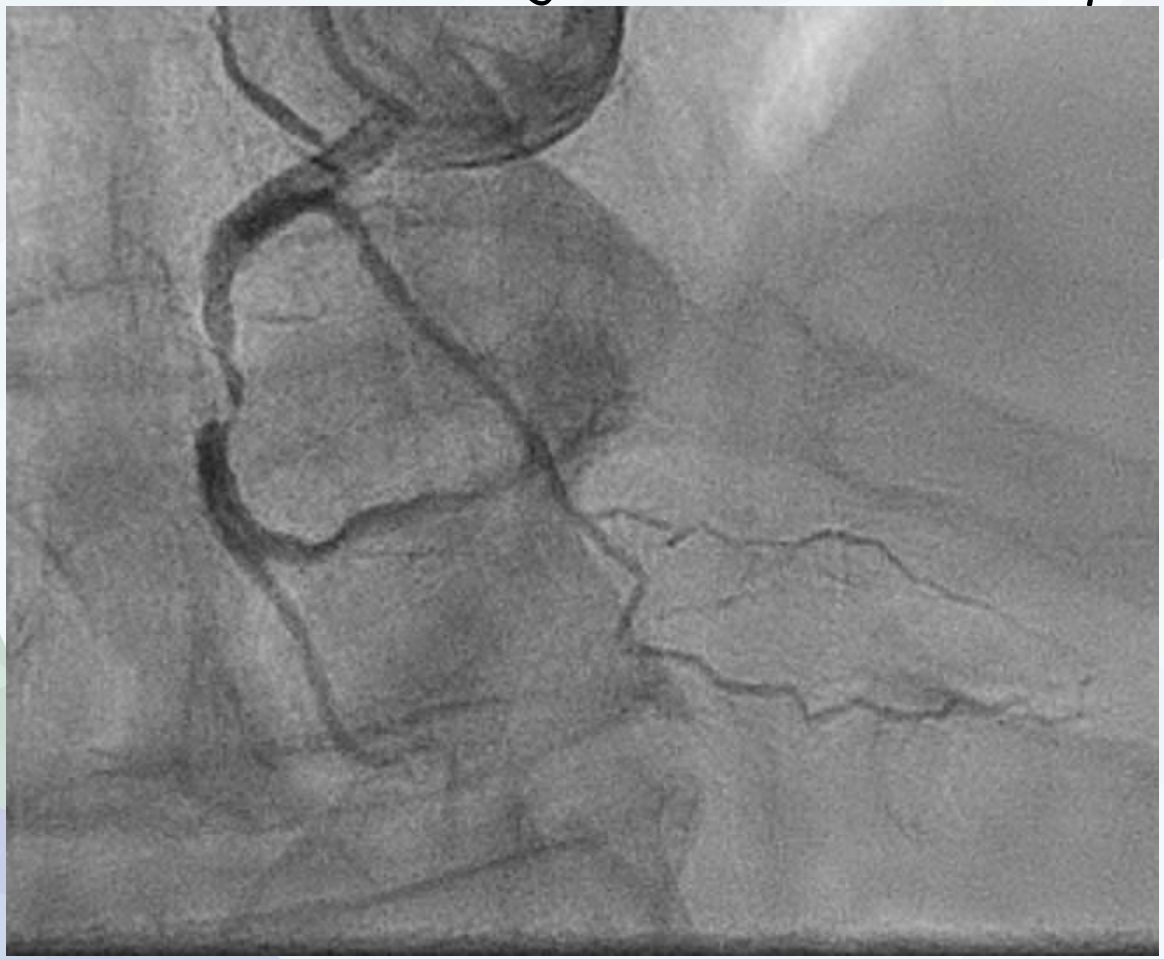
3





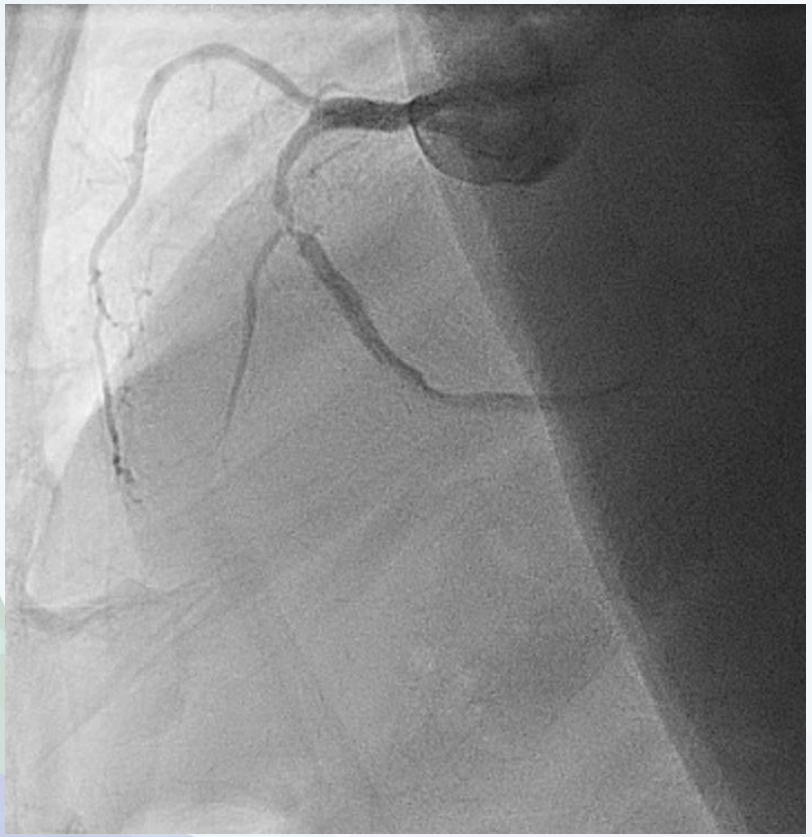
2024 : SCASEST

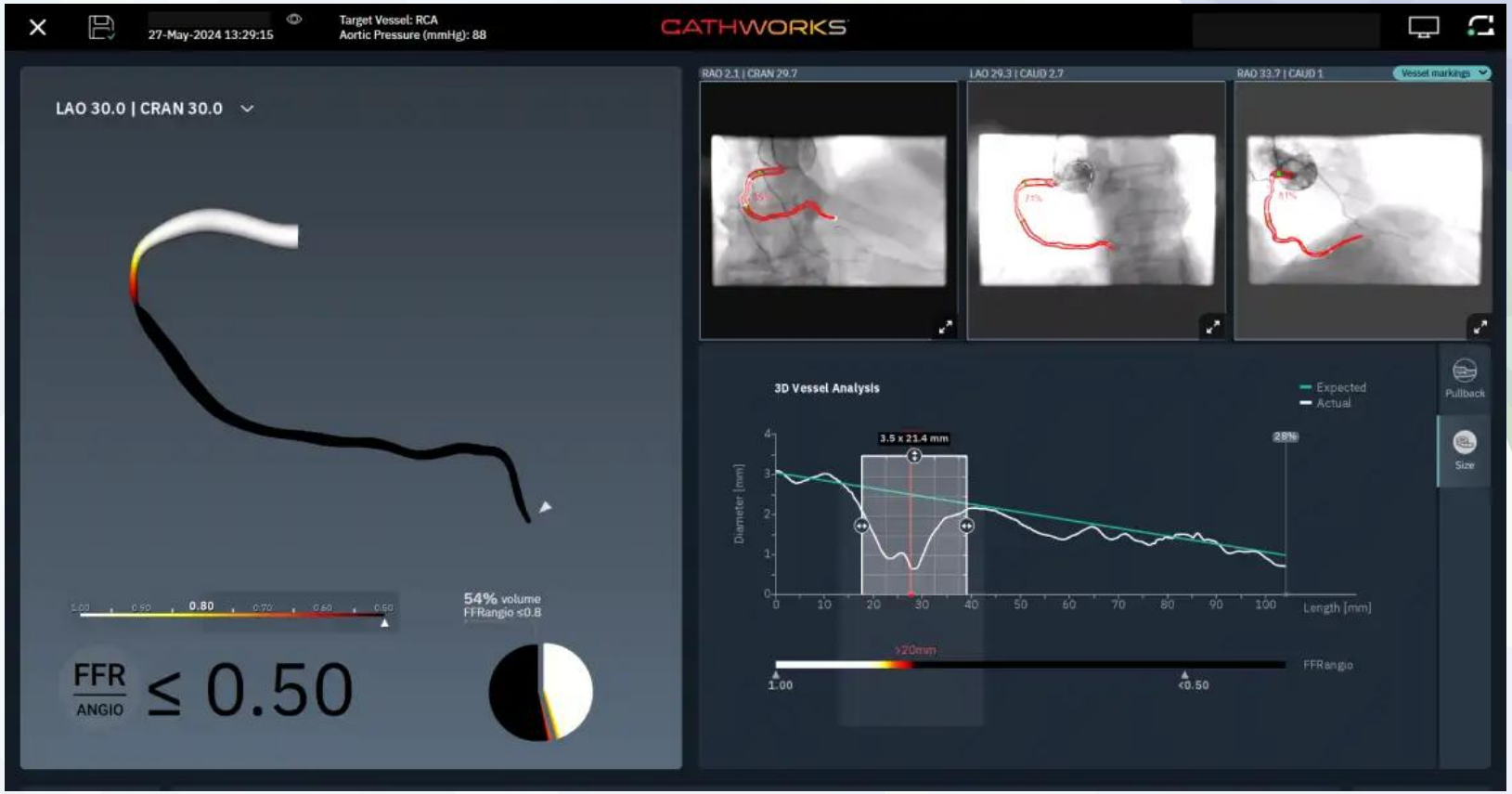
ECG sin alteraciones – ETT: FEVI normal sin segmentarismos – Trop. +



Coronariografia Izquierda

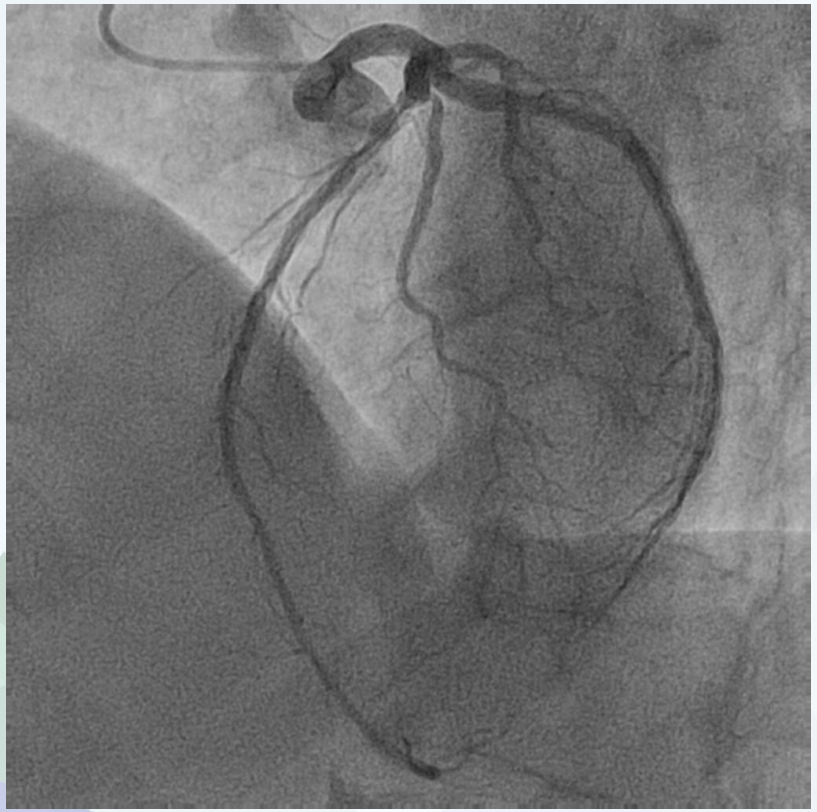
FFR angio: CD - Basal

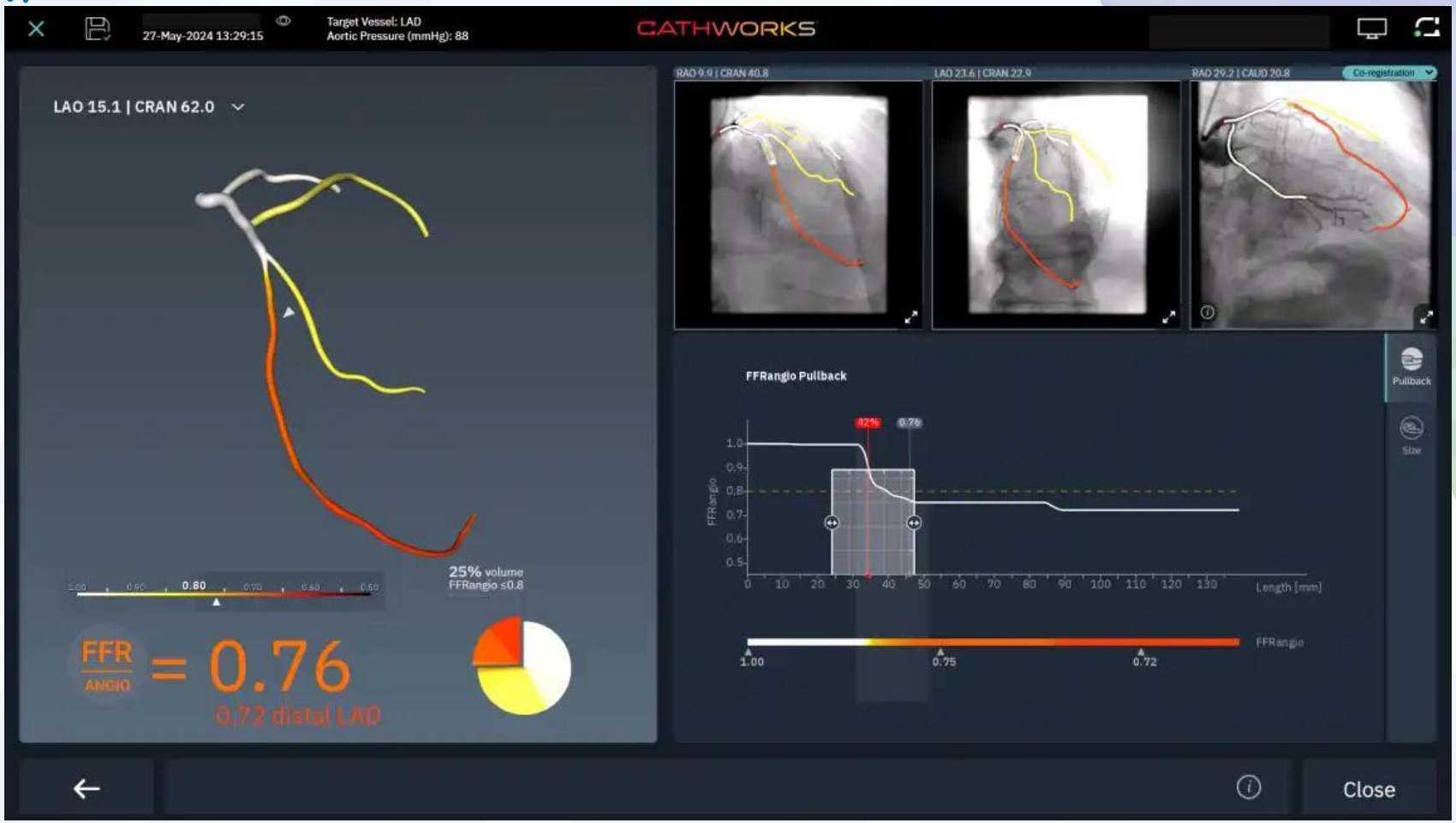




FFR angio : DA

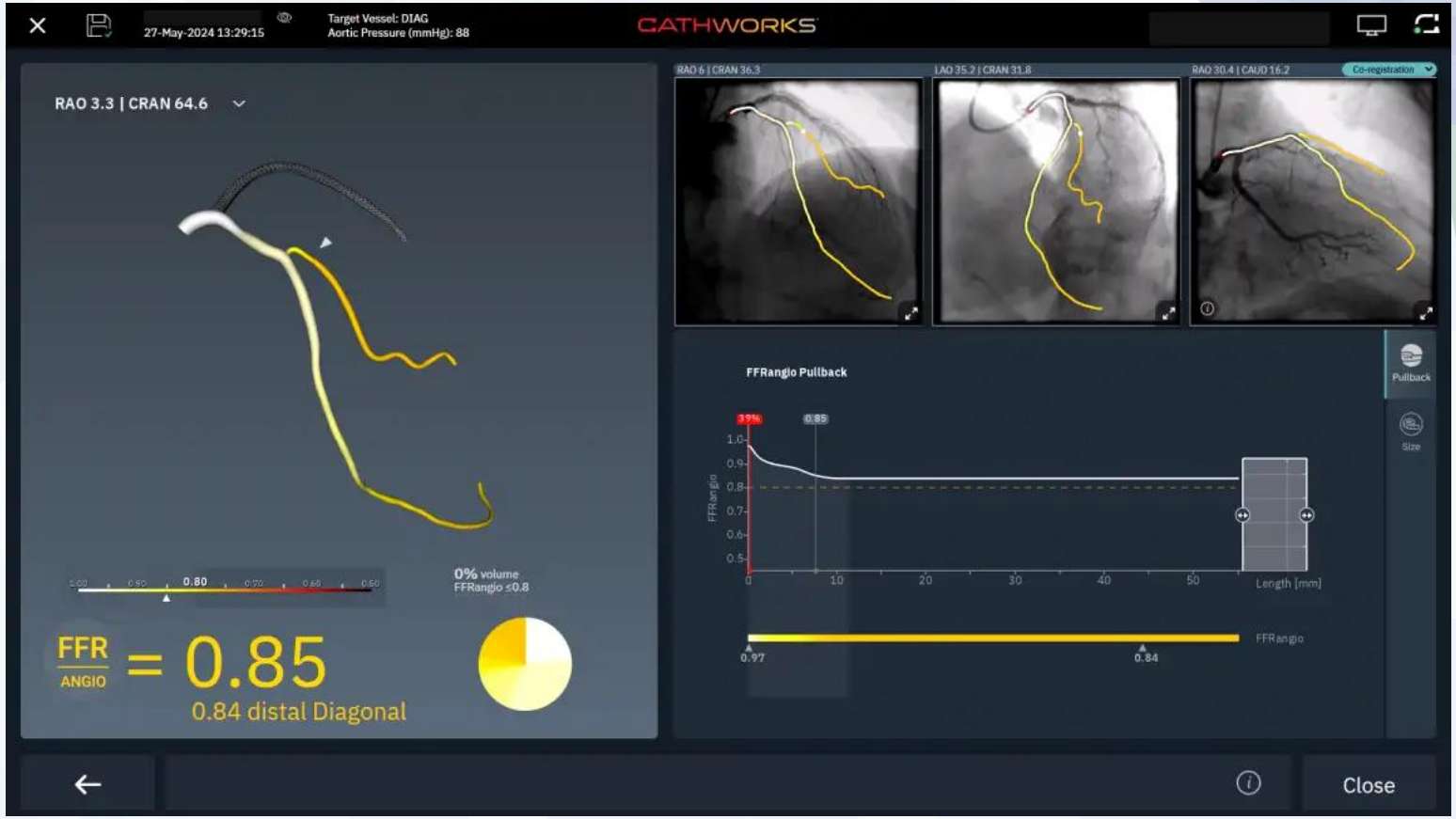
Basal



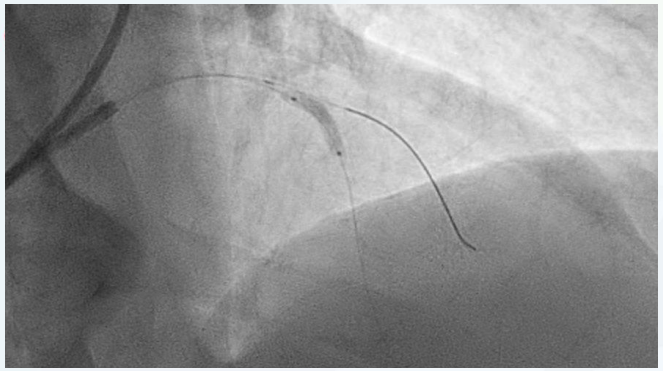


iFR: 0.88 - FFR: 0.73

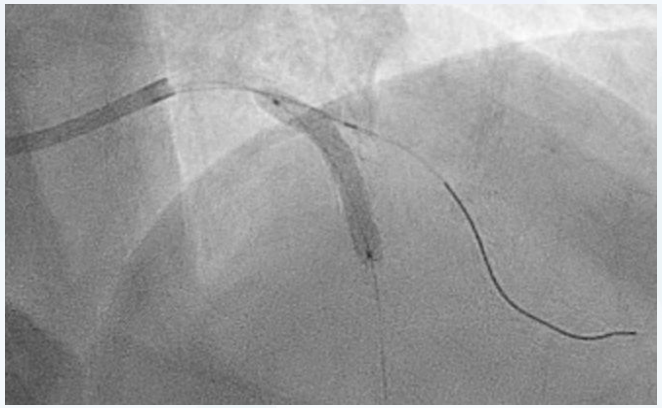
FFR angio: 1ª Diagonal - Basal



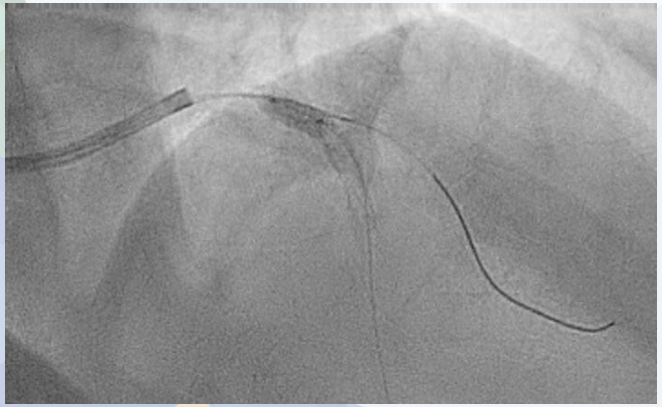
iFR: 0.96 – FFR 0.84



Balón 2.5 x 15 mm

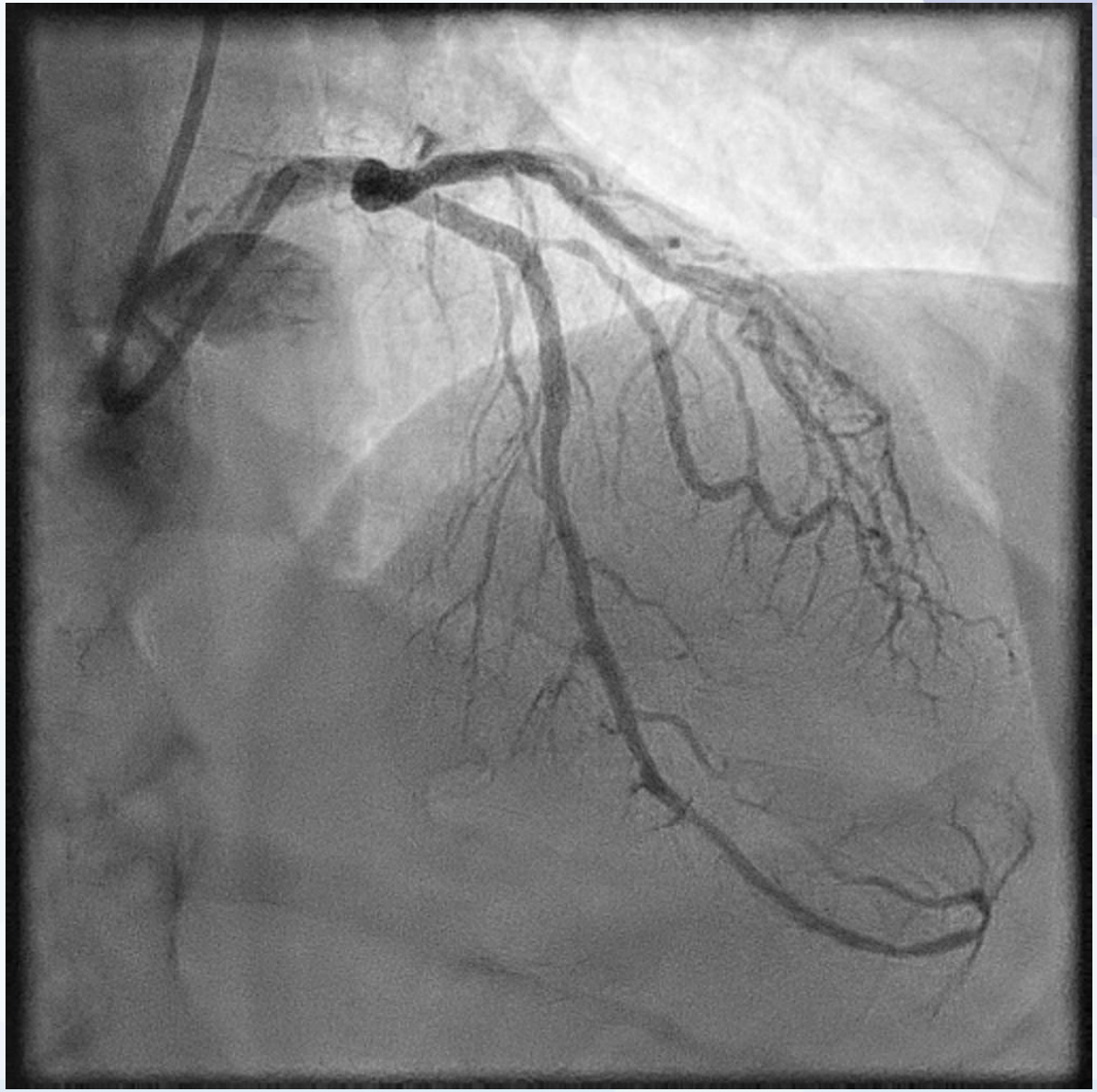


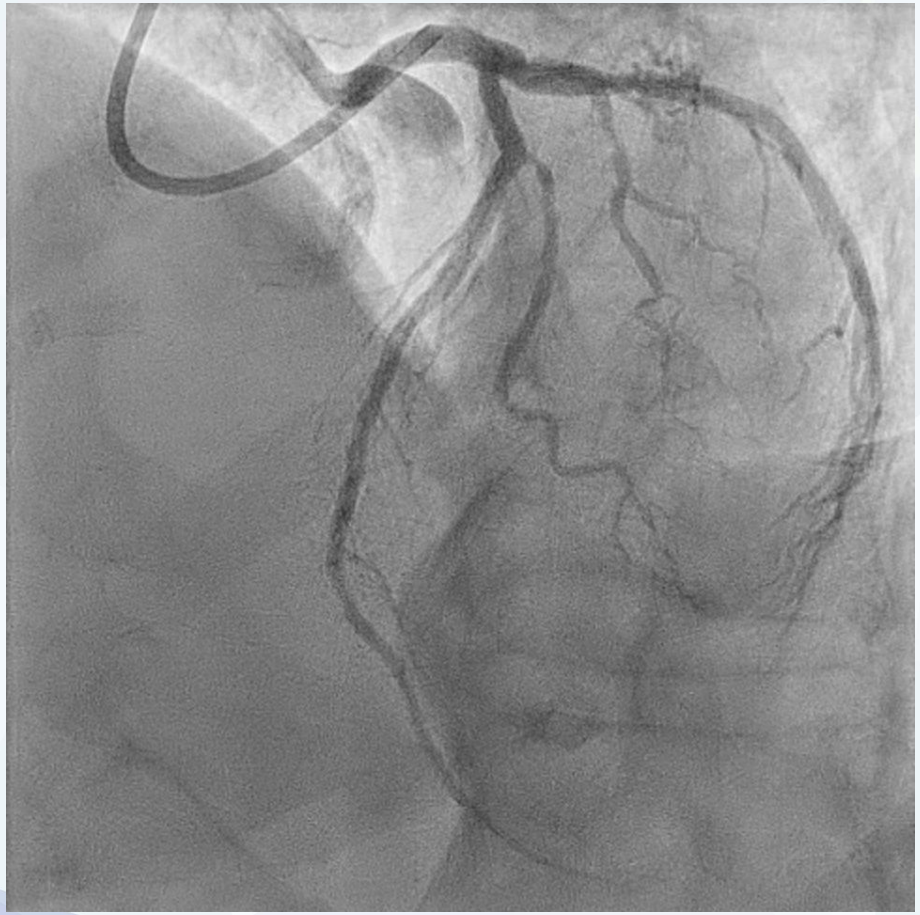
STENT ONYX 3.0 x 22mm

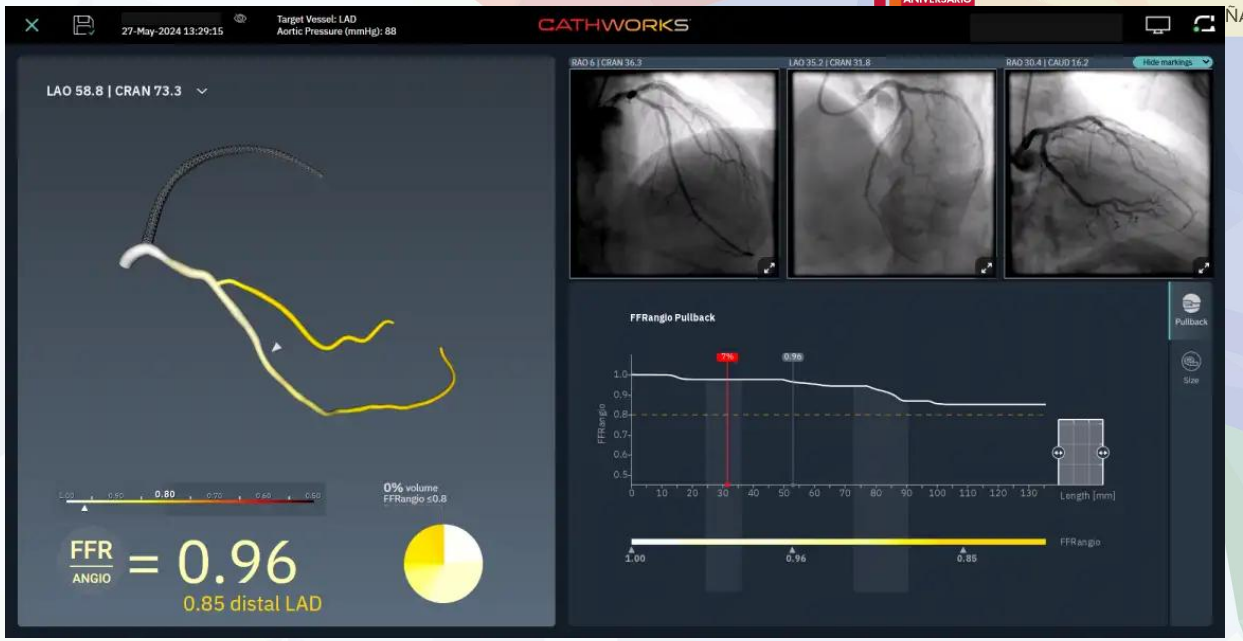


POT Balón NC 3.5 x 8 mm

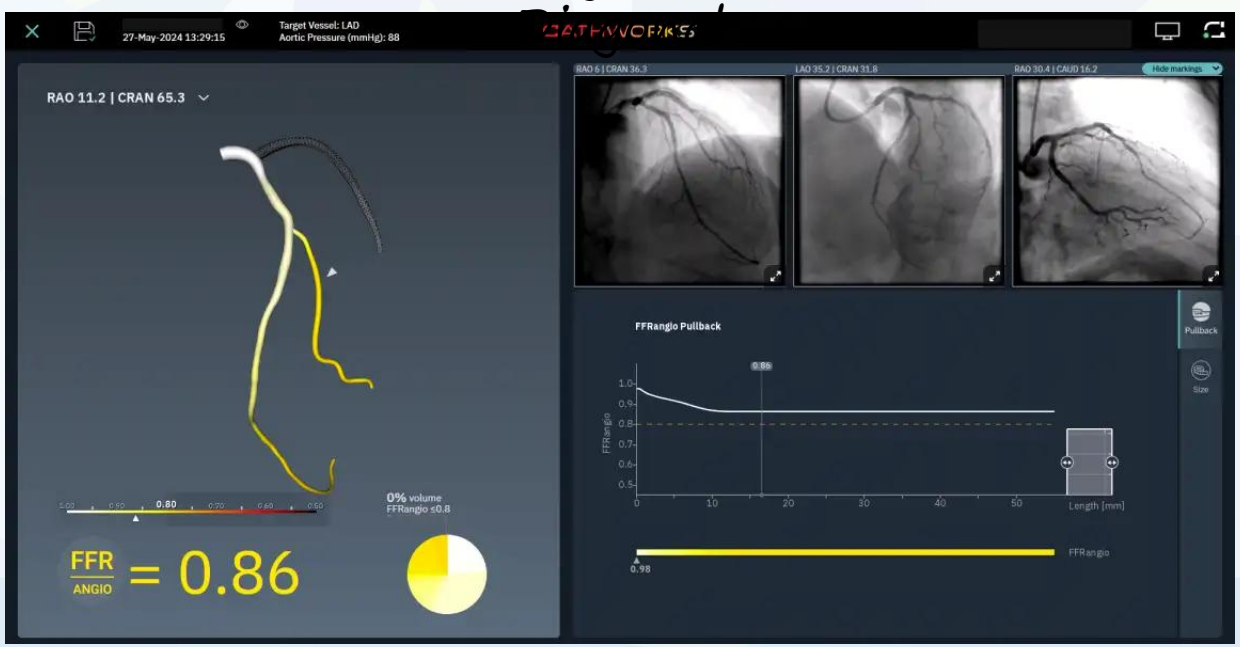
Post POT







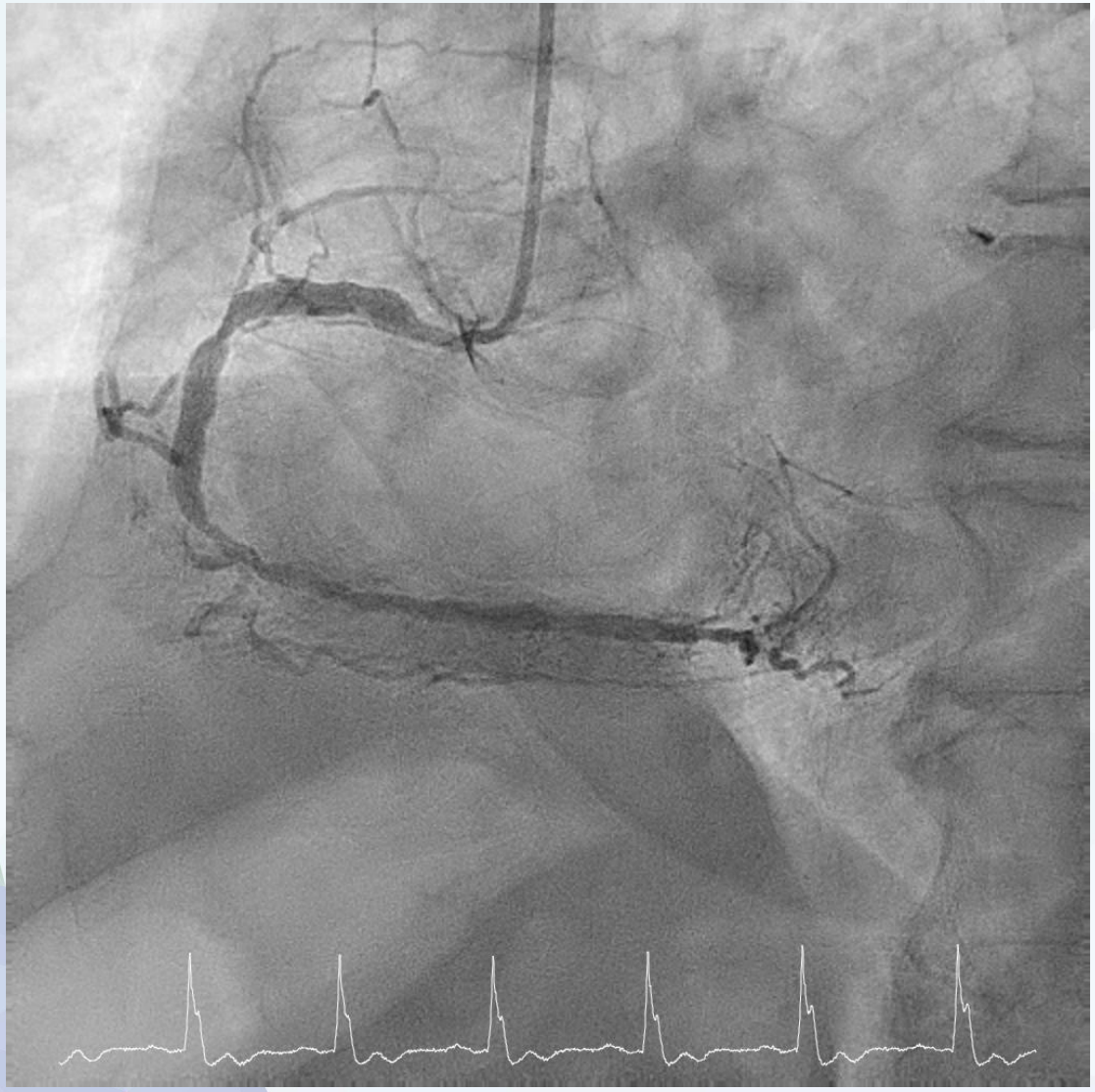
FFRangio DA -

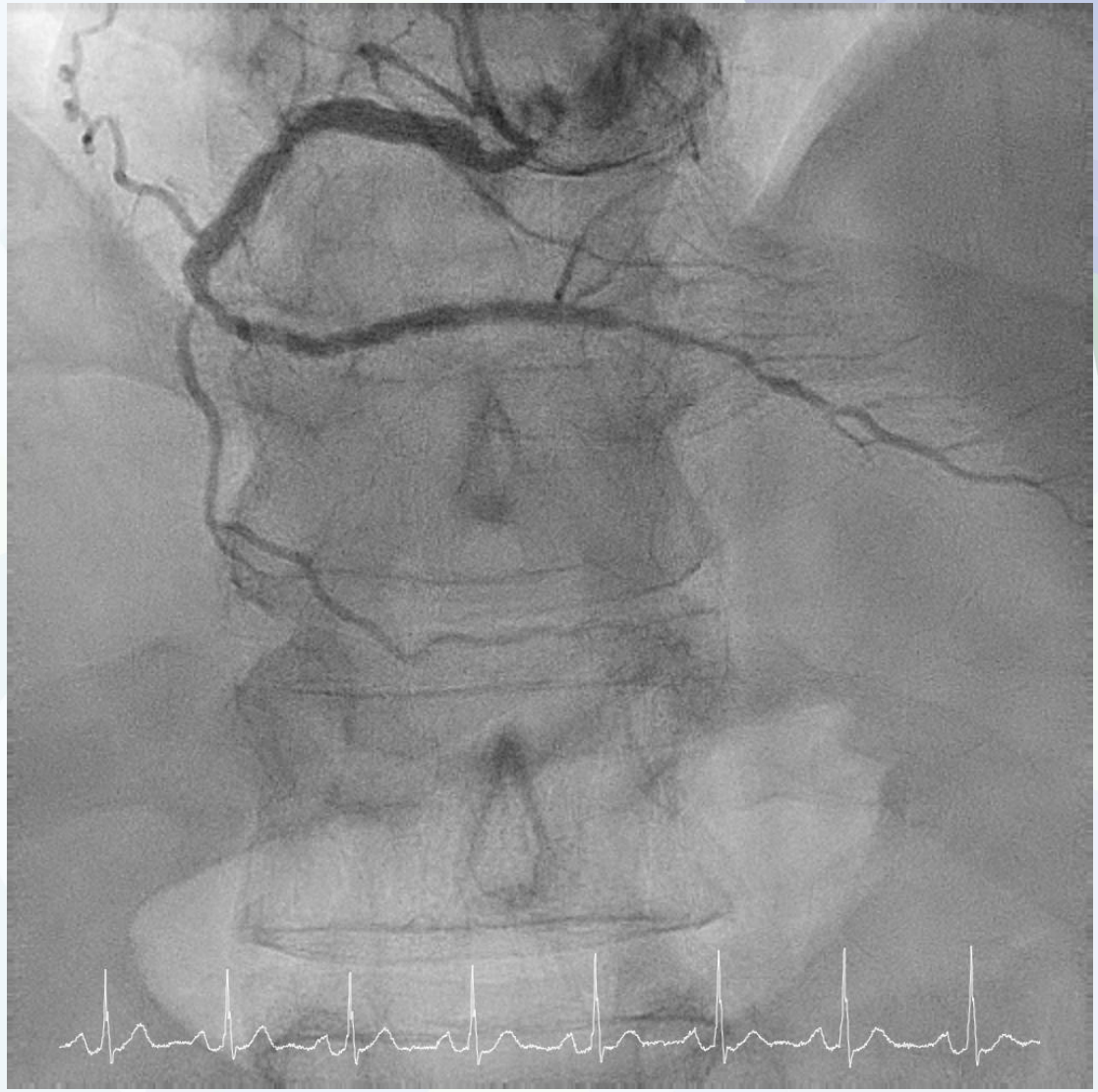


Post STENT iFR: 0.90 –
FFR: 0.85

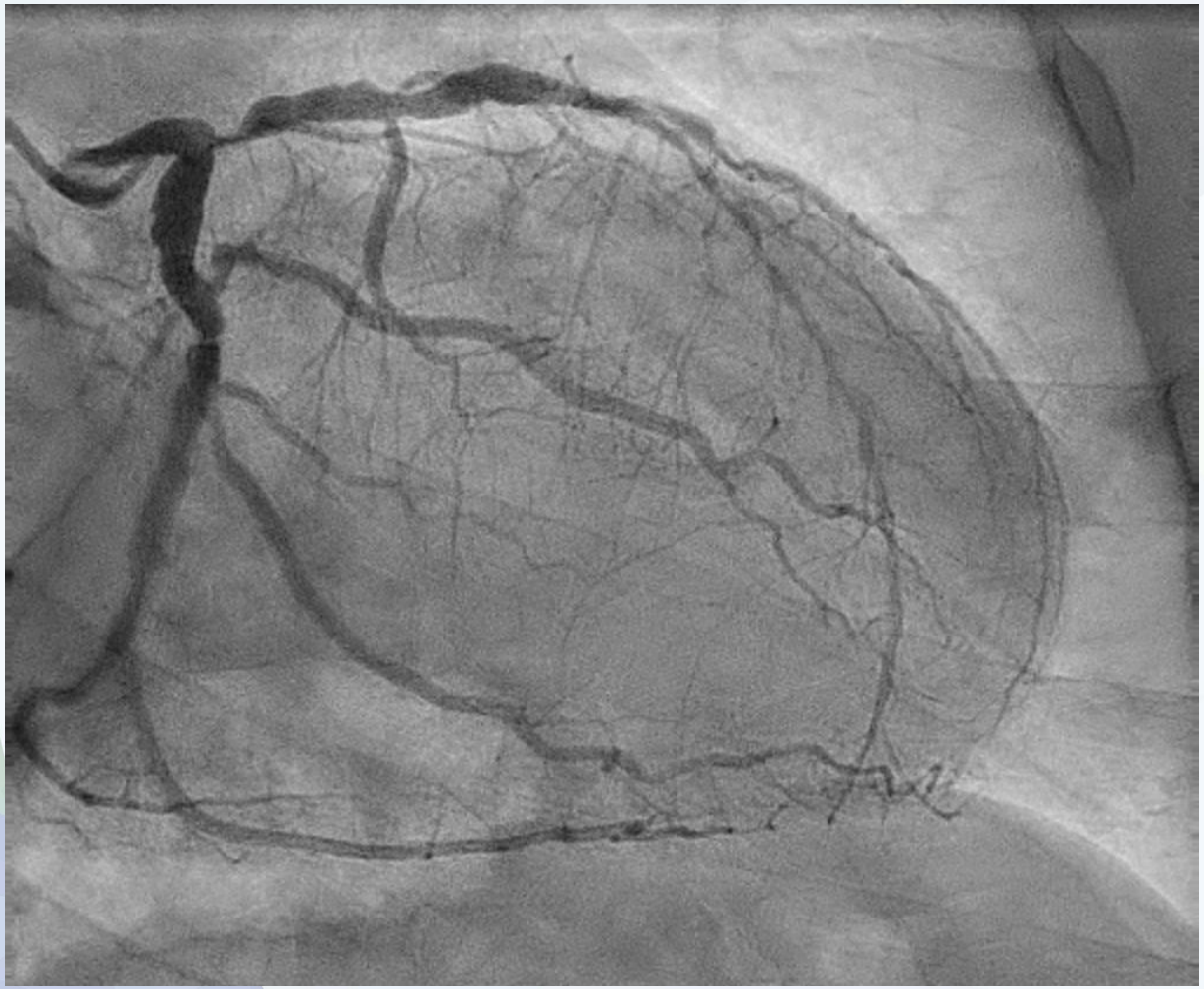
- Varón 67 años
- FRCV : HTA , DLP. Alergia contraste yodado.
- Dolor torácico atípico.
- PE: Clínicamente negativa. Eléctrica + (Infradesnivel ST V3-V6 alta carga) 98% FCMT
- TAC Coronario: Estenosis TC-DA ostial > 70% y en CD ostial > 70%. Cx ectasica estenosis moderada en tercio medio. OM2 prox. calcificación importante no descarta estenosis significativa.

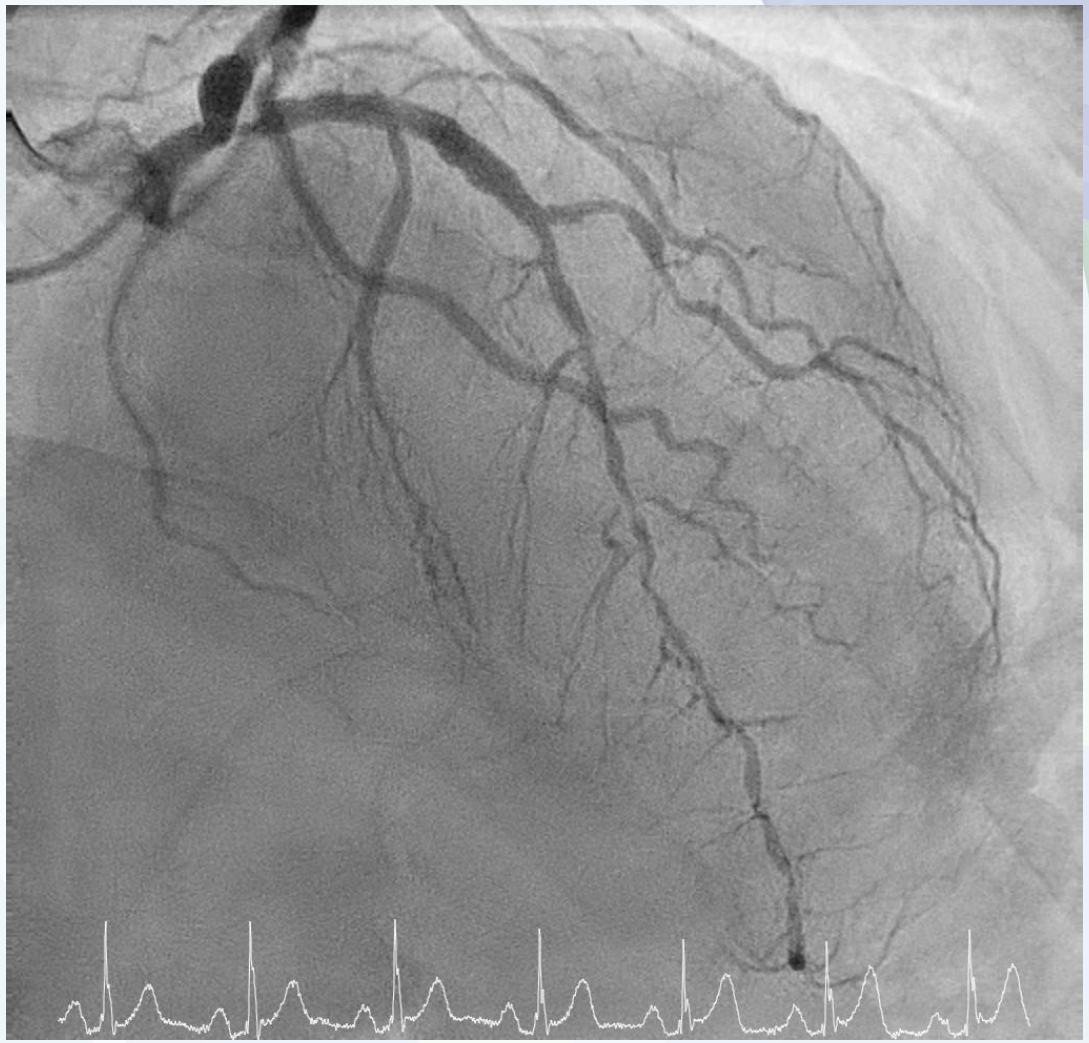
Coronariografia Derecha



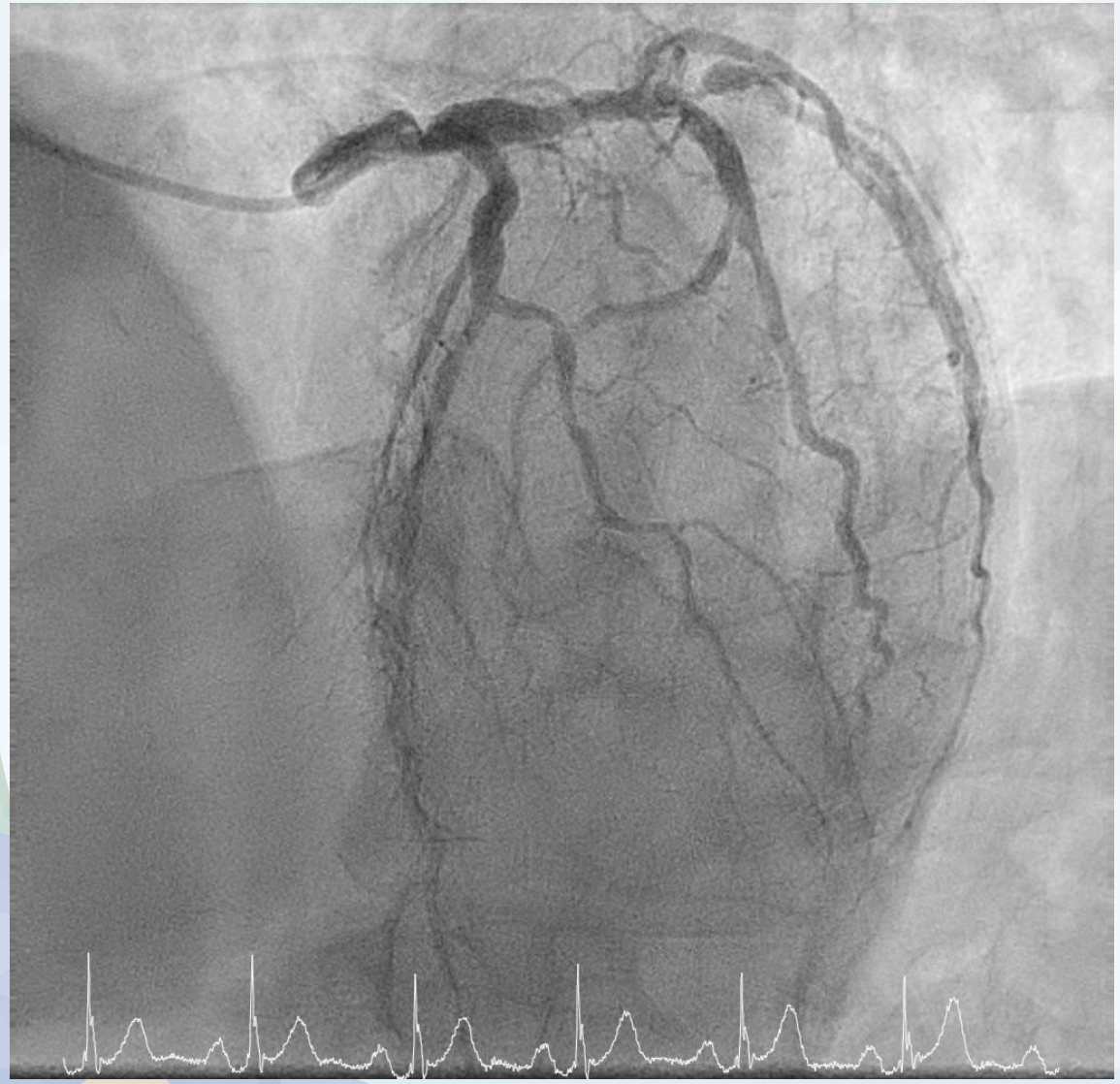


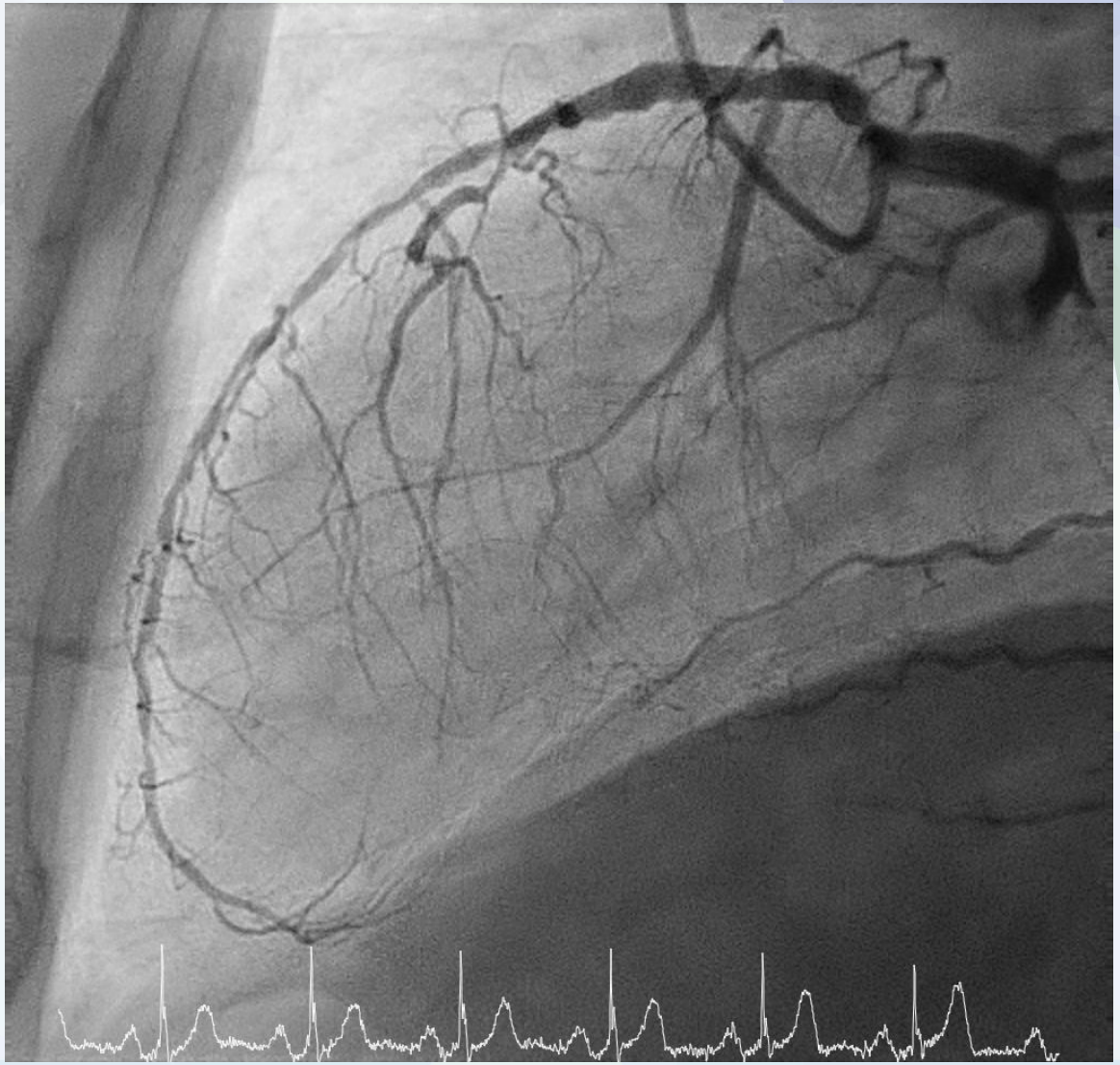
Coronariografia Izquierda





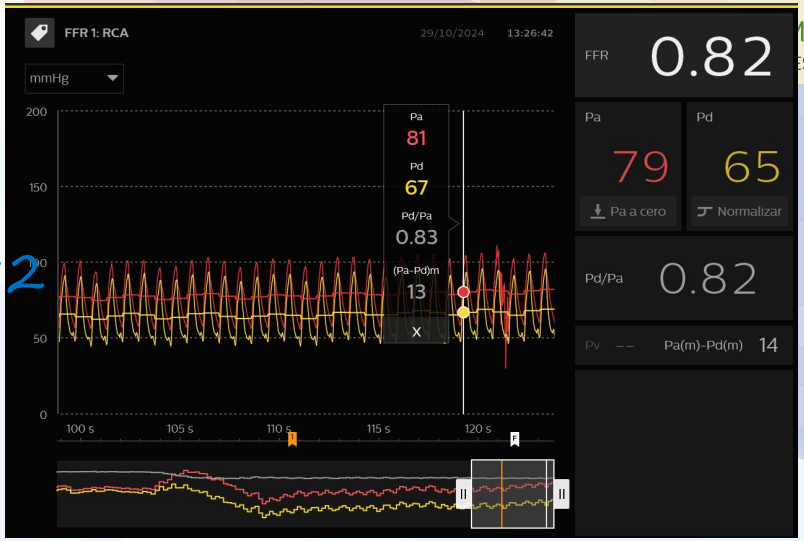
Coronariografia Izquierda



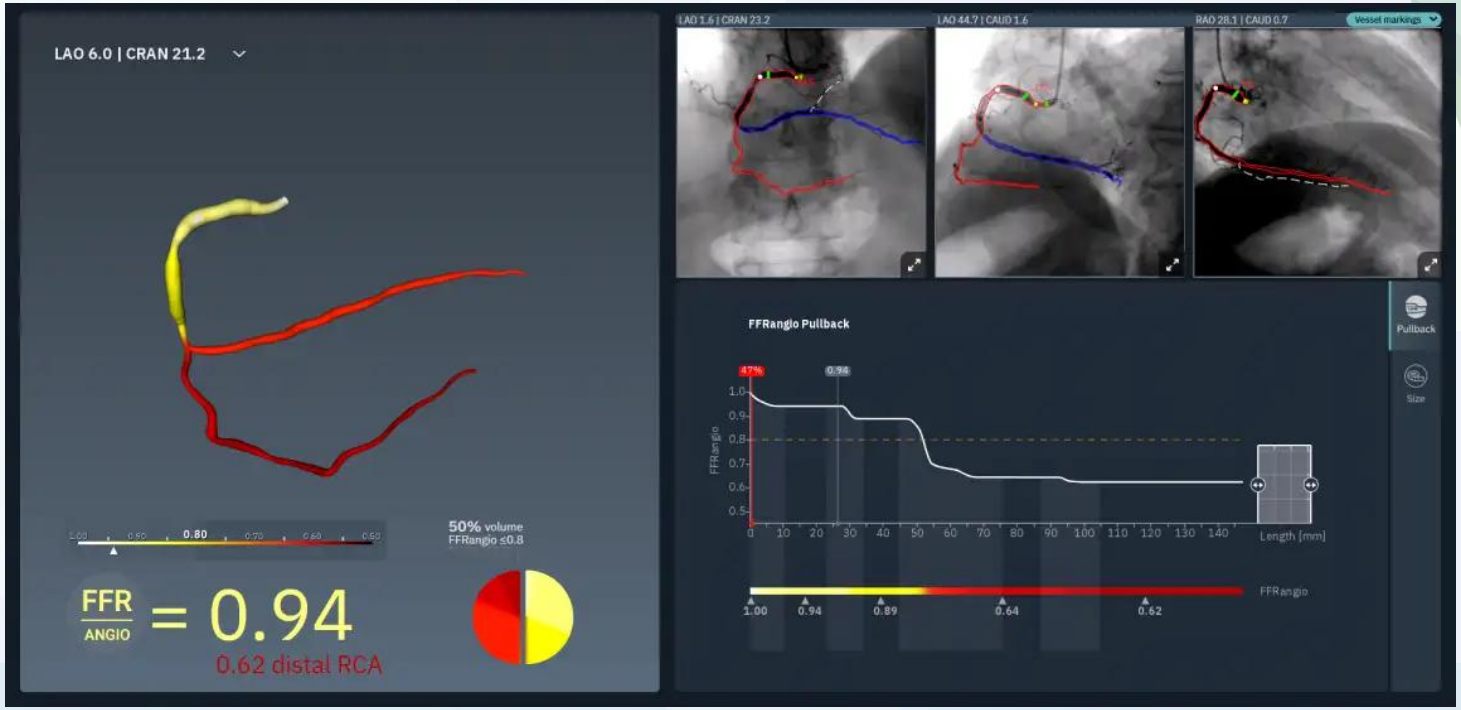


Coronaria Derecha

iFR 0.97 - FFR : 0.82

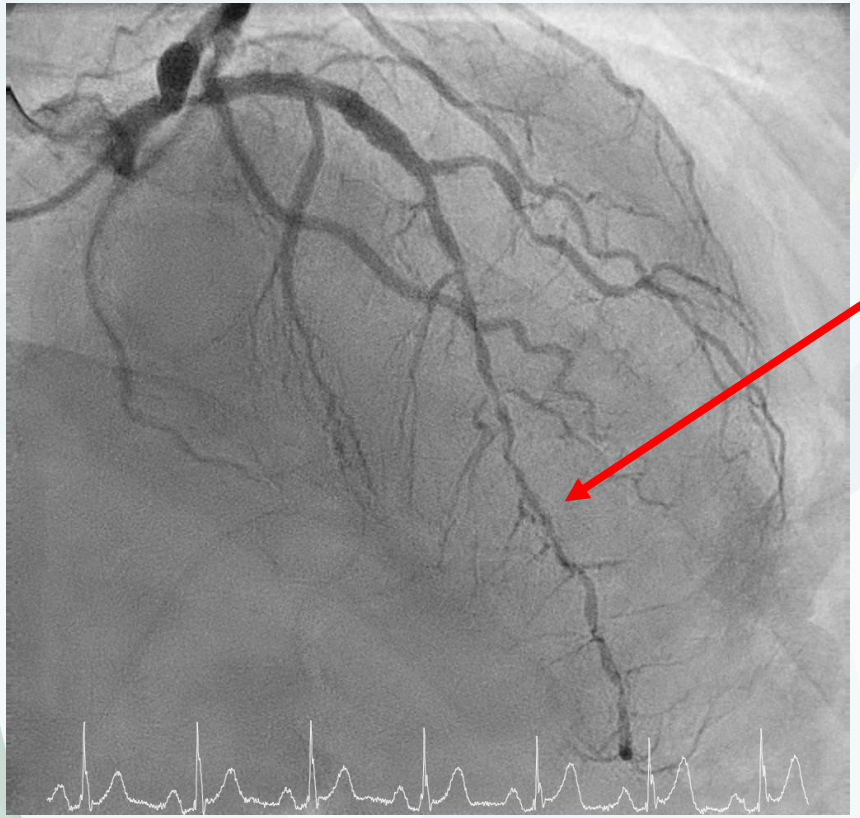


FFR angio: CD

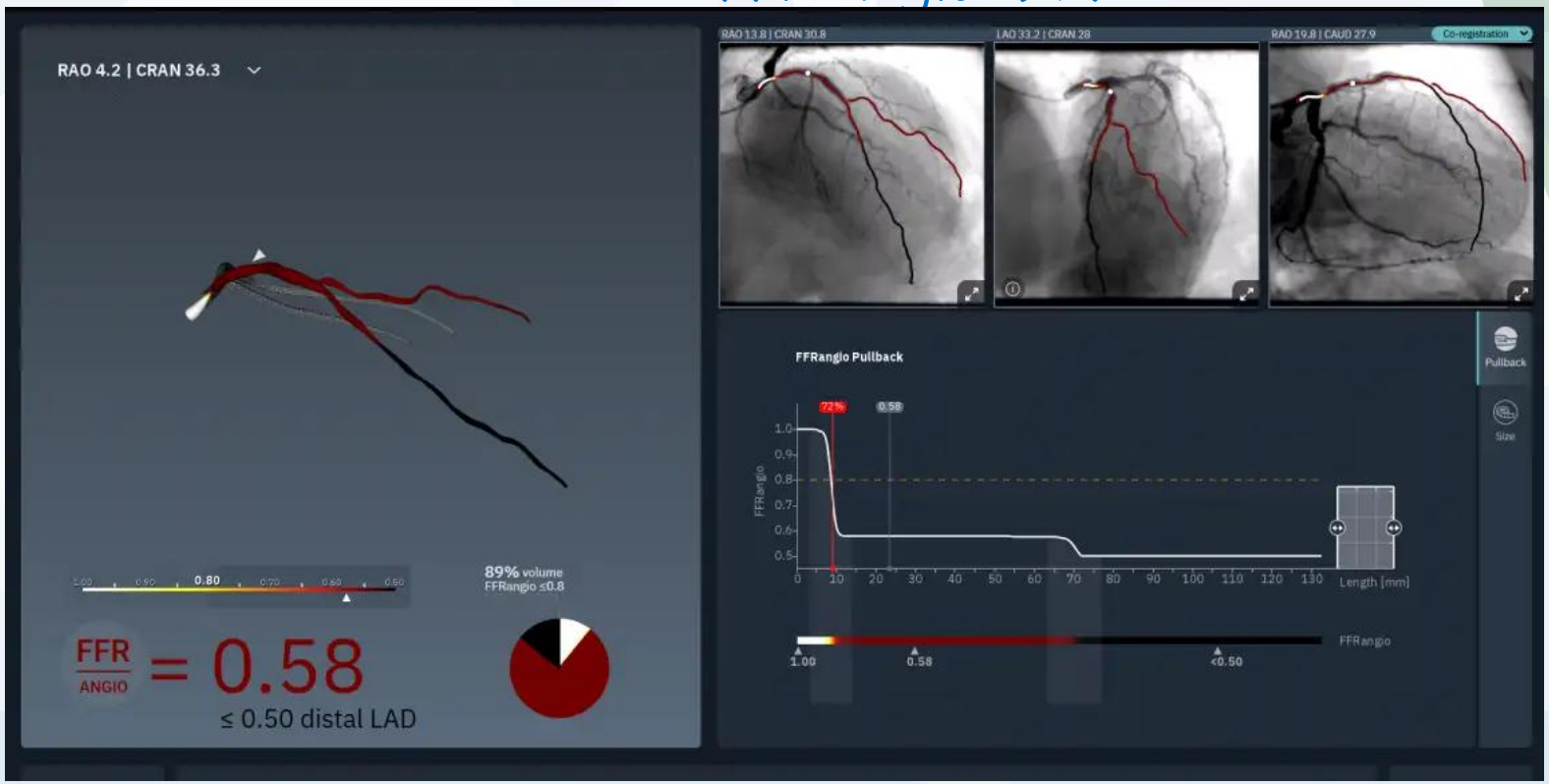


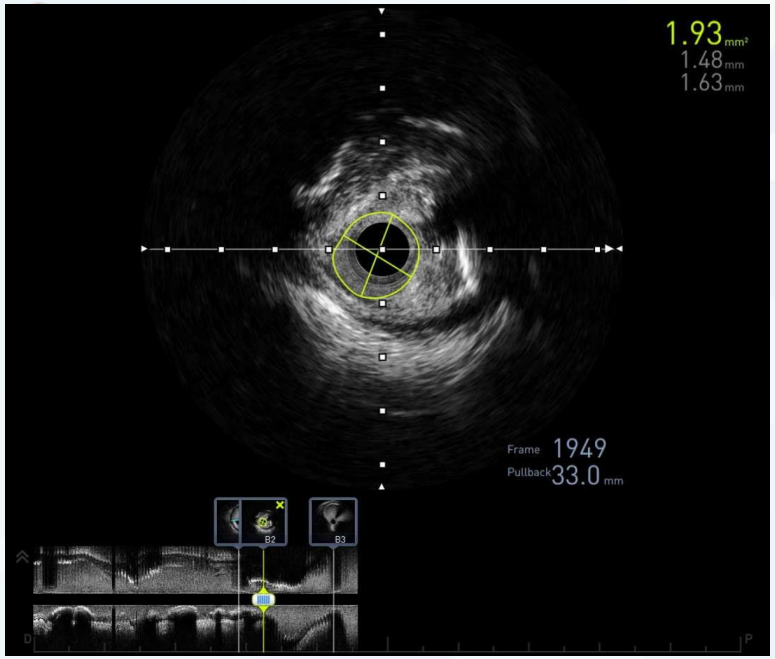
iFR : 0.66

Descendente Anterior

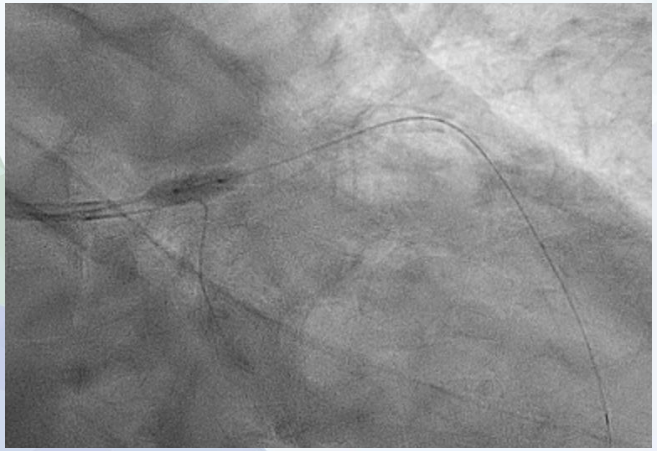


FFR angio: DA

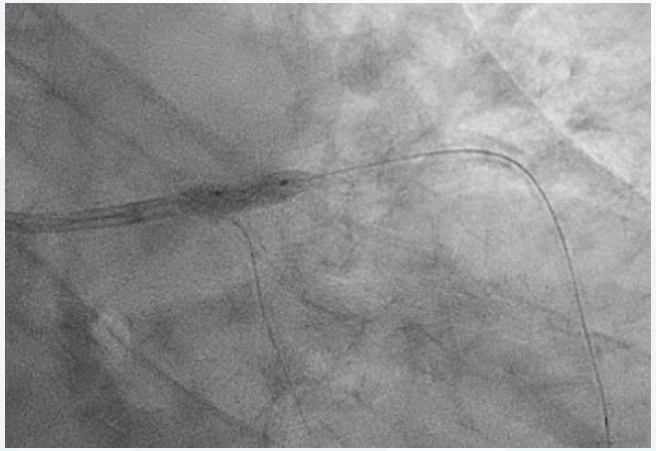




IVUS Pre ICP

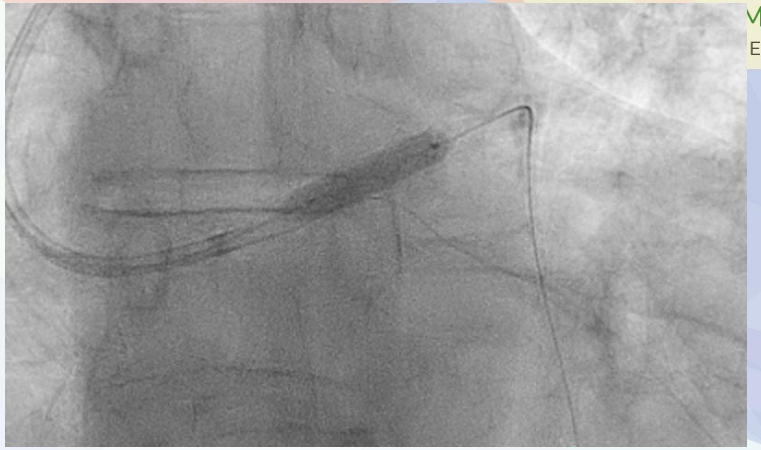


Balón corte 3,5 x 6mm

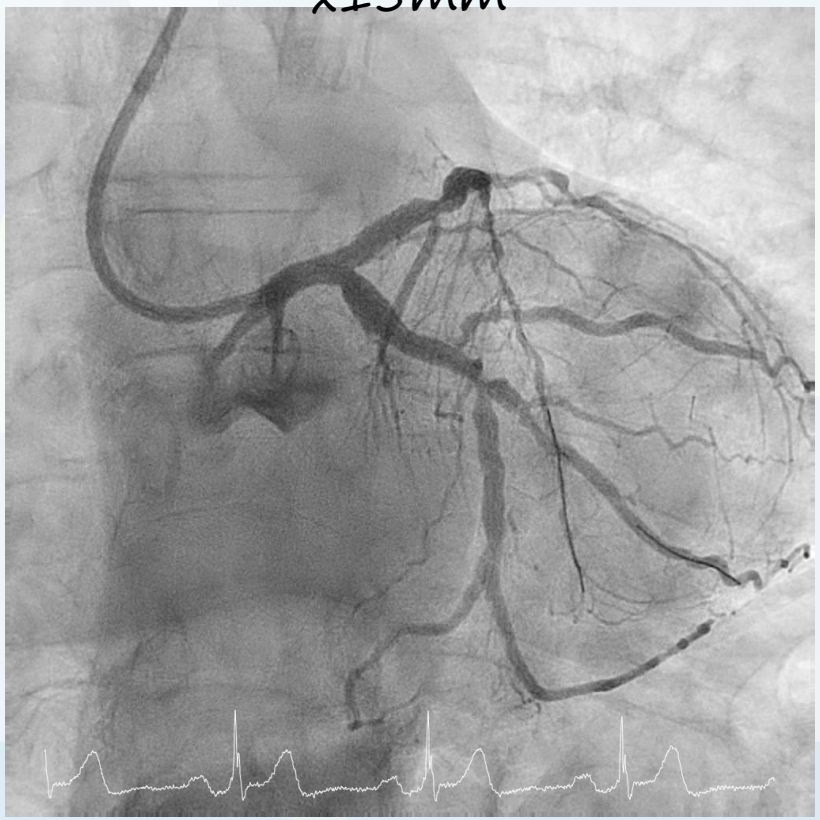


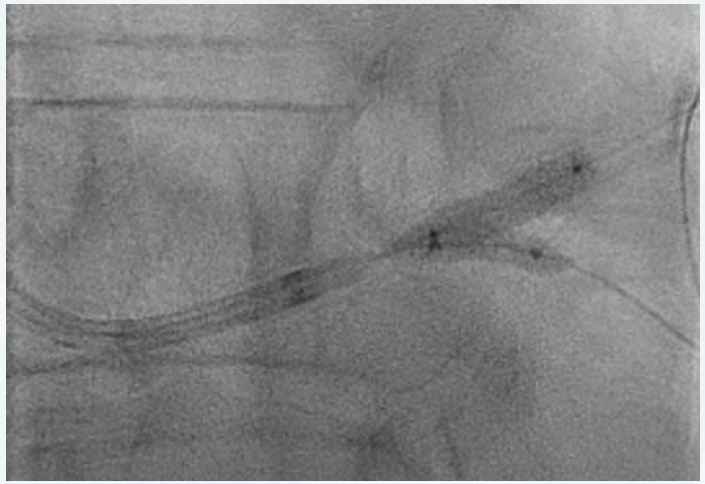
Balón NC 4.0x10mm

Post Balón TC- DA

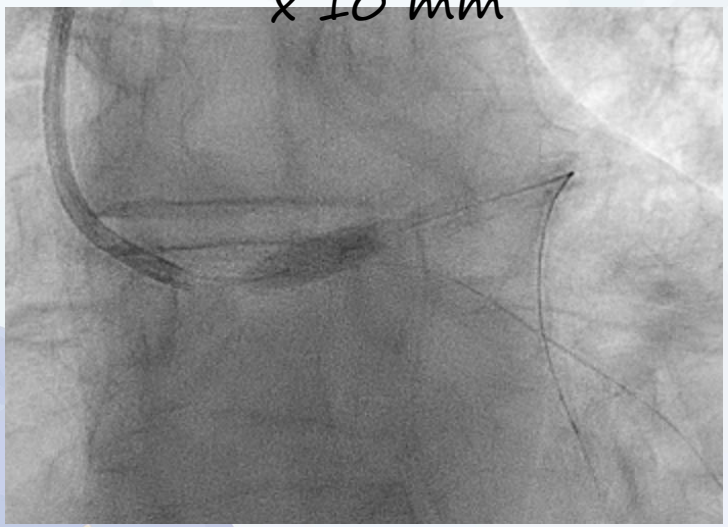


TC-DA Stent Onyx 4,5 x15mm



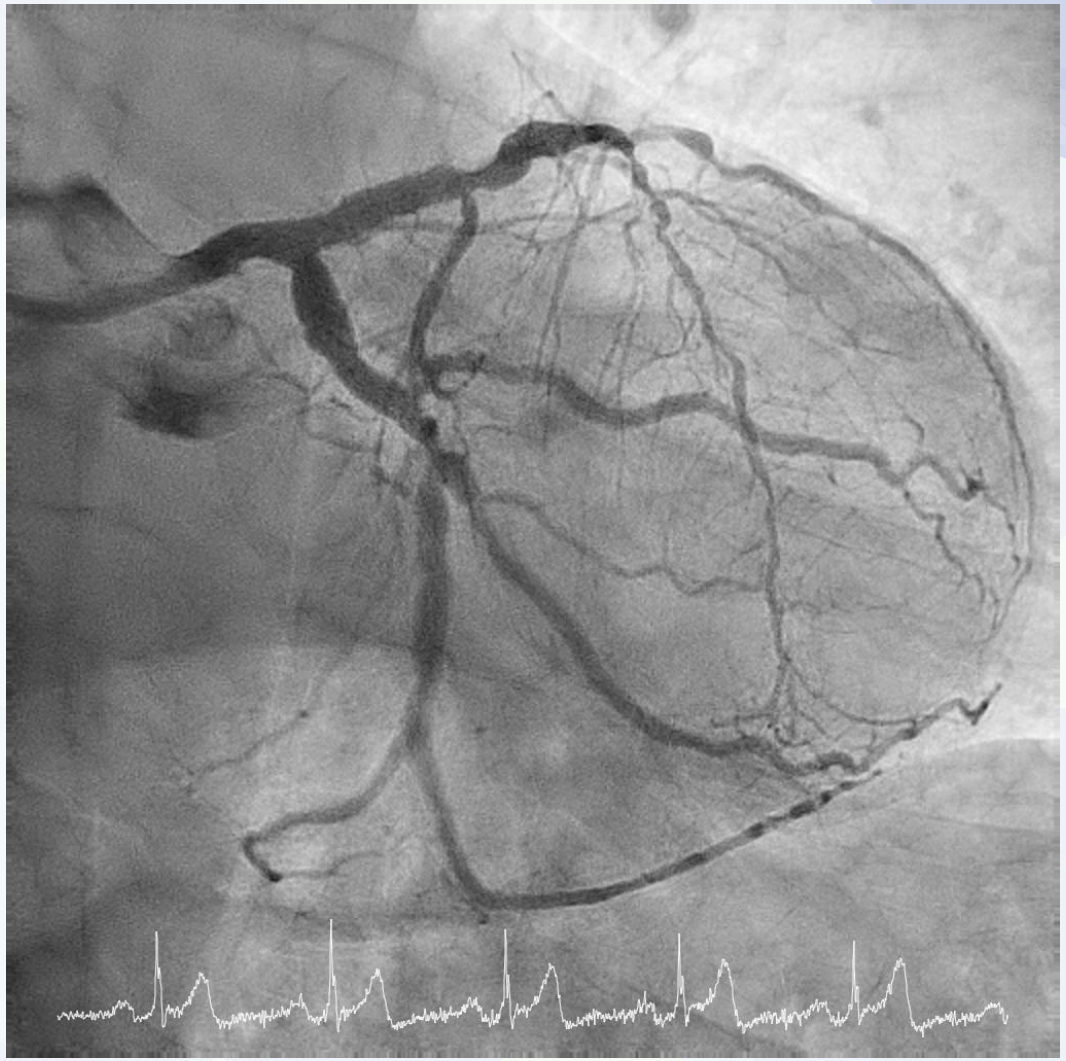


Kissing Balloon NC 4,5 x12 y 3,5 x 10 mm

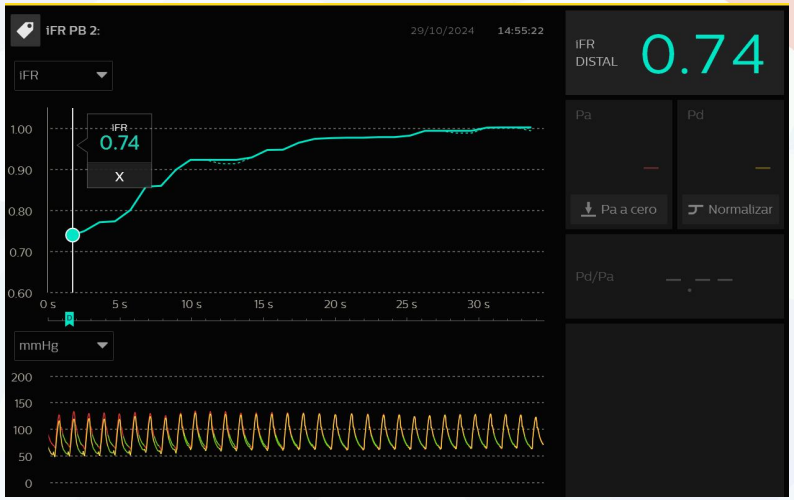


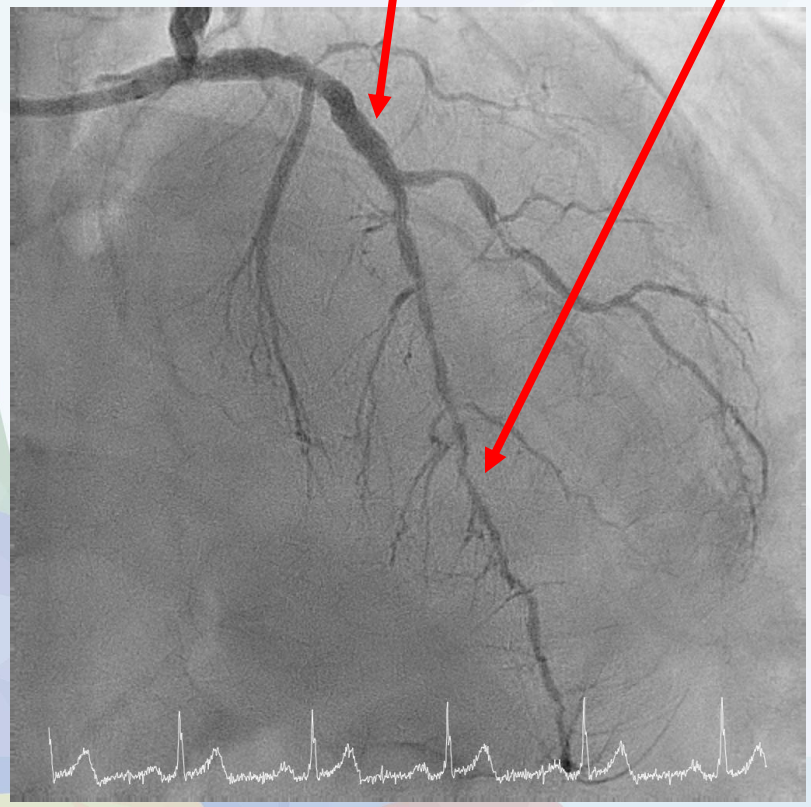
POT Balón NC 5,0 x 8

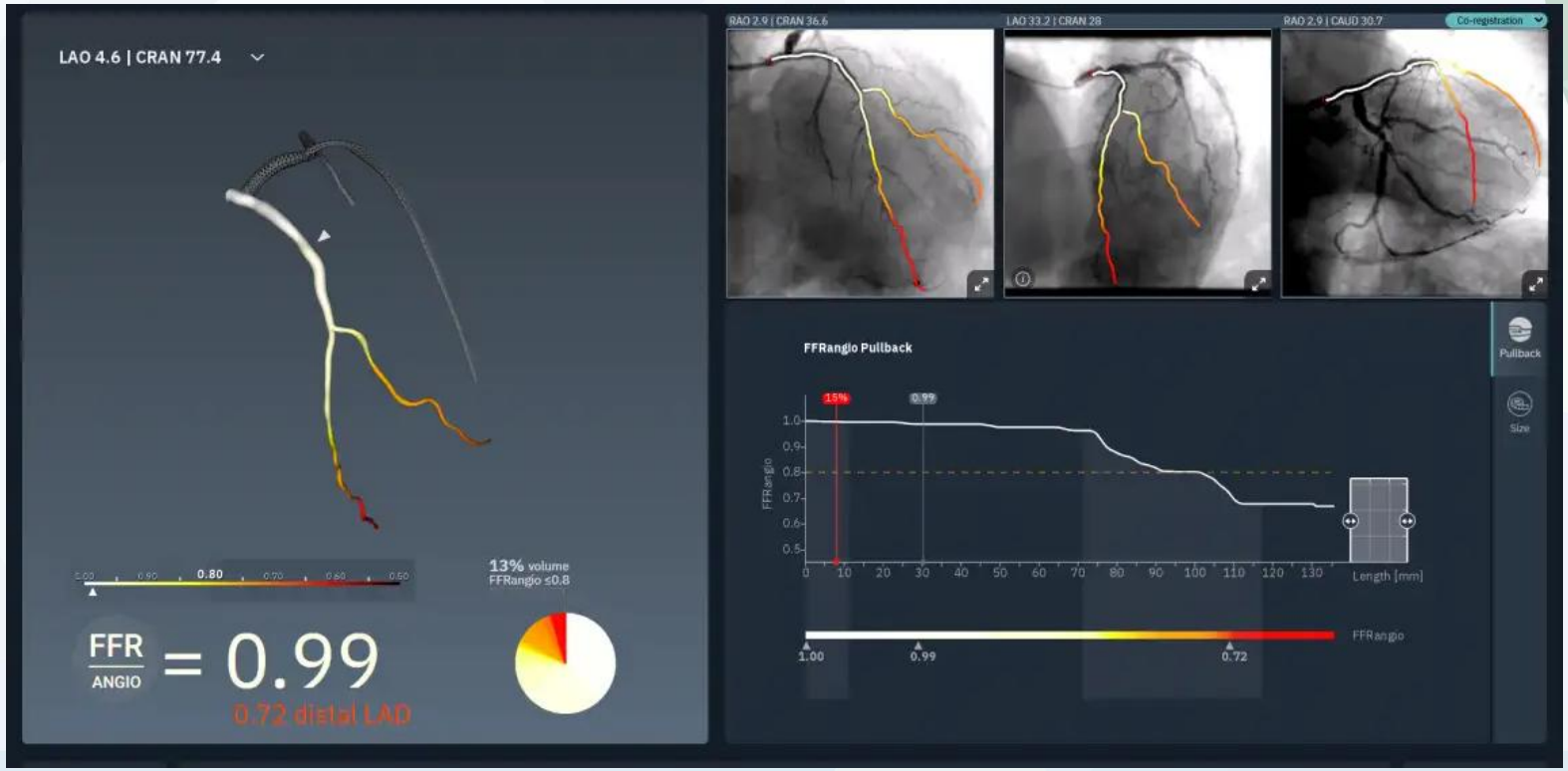
RESULTADO FINAL



FFR angio: DA post STENT







CONCLUSIONES

- CathWorks FFR Angio a demostrado una alta precision diagnóstica 92% en centros experimentados.

- FFR Angio contribuiría a simplificar el intervencionismo coronario:
  - -Evita el uso de guías invasivas
  - -Acorta tiempo de procedimiento
  - -Podría disminuir costes.

- Faltan estudios randomizados para determinar si FFR-Angio puede recomendarse como herramienta diagnóstica, no inferior a la evaluación fisiológica invasiva en tratamiento enfermedad arterial coronaria.
  (Estudio All-Rise)