

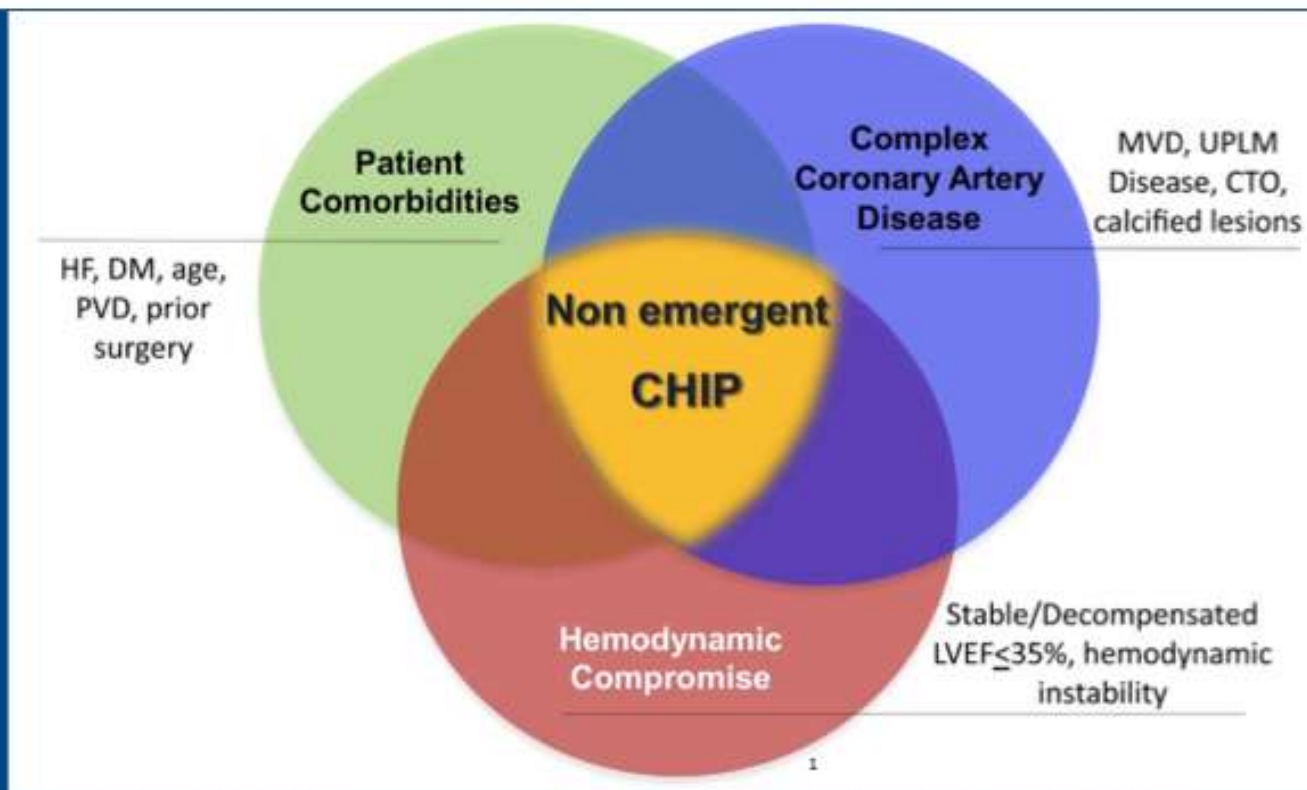


CHIP / Protected PCI



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Contilia Heart & Vascular Center
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Germany

Complex and High-risk Indicated PCI (CHIP)



CHIP patients should be assessed by a multidisciplinary team^{1-2,5}

one anatomical plus one clinical factor qualify as complex and high-risk^{1,5}

By protected CHIP high-risk patients who are not eligible for surgery can be treated and outcome improved.³⁻⁴

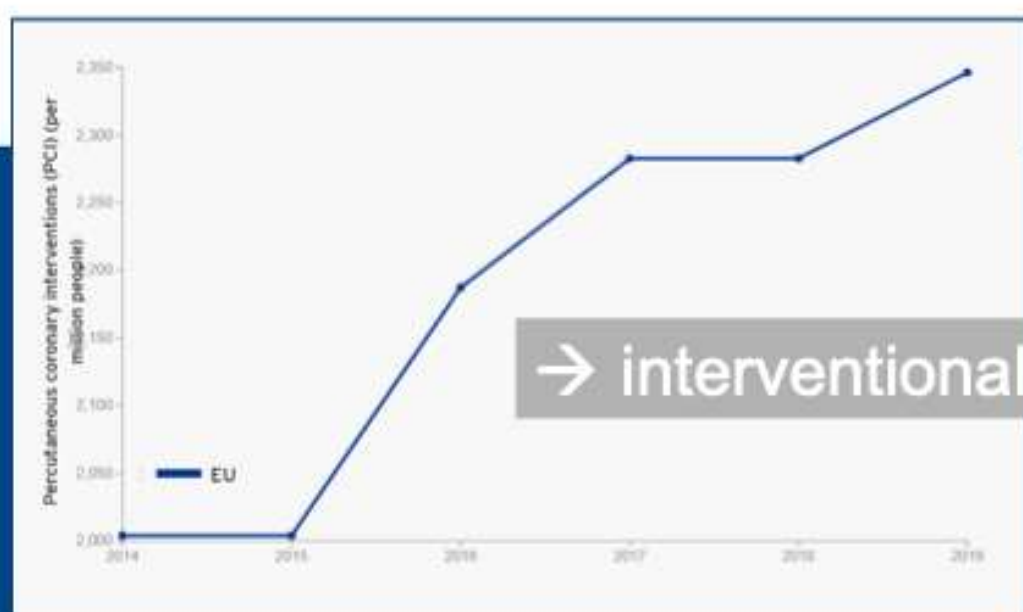
1. Chieffo AInt J Cardiol 2019; 293:84–90.

2. Leick, J. et al., Eur. Hear. J. Suppl. 24, 14–110 (2022)

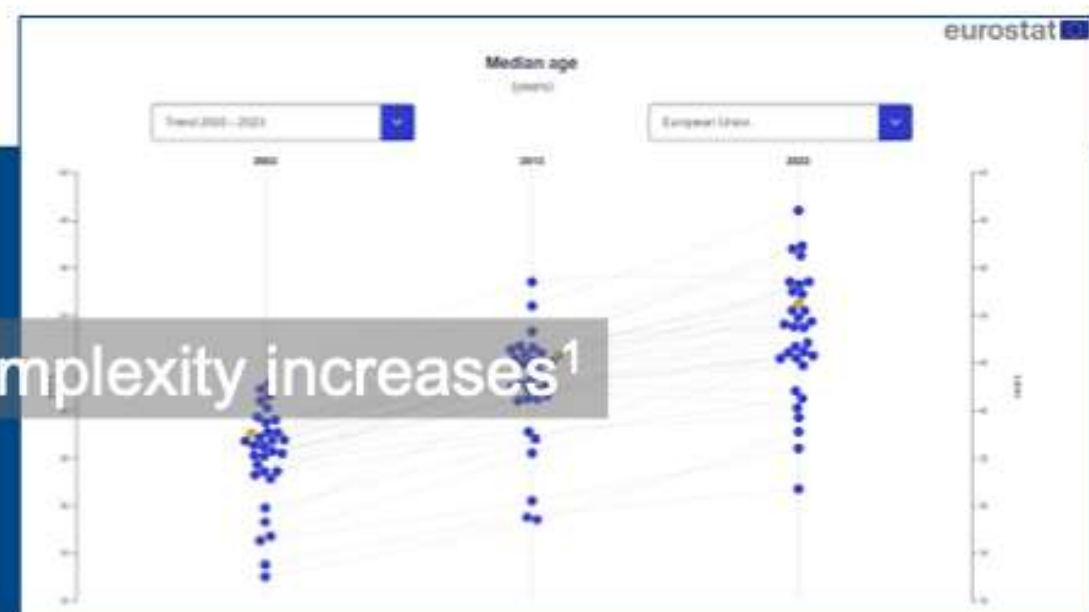
3. Wollmuth, J. et al. J. Soc. Cardiovasc. Anglogr. Interv. 1, 100350 (2022)

4. O'Neill, W. W. et al. Circulation 126, 1717–1727 (2012)

5. Kirtane et al, Circulation. 2016 Aug 2;134(5):422-31



→ interventional complexity increases¹



Cause for increasing number of interventions: ageing of the population and in connection with this the increase of the morbidity of ischemic heart disease cases¹

More complex coronary artery disease in older patients – more tortuosity, more calcification, more left main stenoses²

1. German Heart Report 2022: Deutsche Herzstiftung, Deutscher Herzbericht 2022, Frankfurt am Main, September 2023, pp. 42 and 49

2. Rajani et al., Evolving trends in percutaneous coronary intervention, Br J Cardiol 2011;18:73–6

3. https://eatlas.escardio.org/Atlas/ESC-Atlas-in-Interventional-Cardiology/Interventional-cardiology-procedures/siccp_pci_1m_r

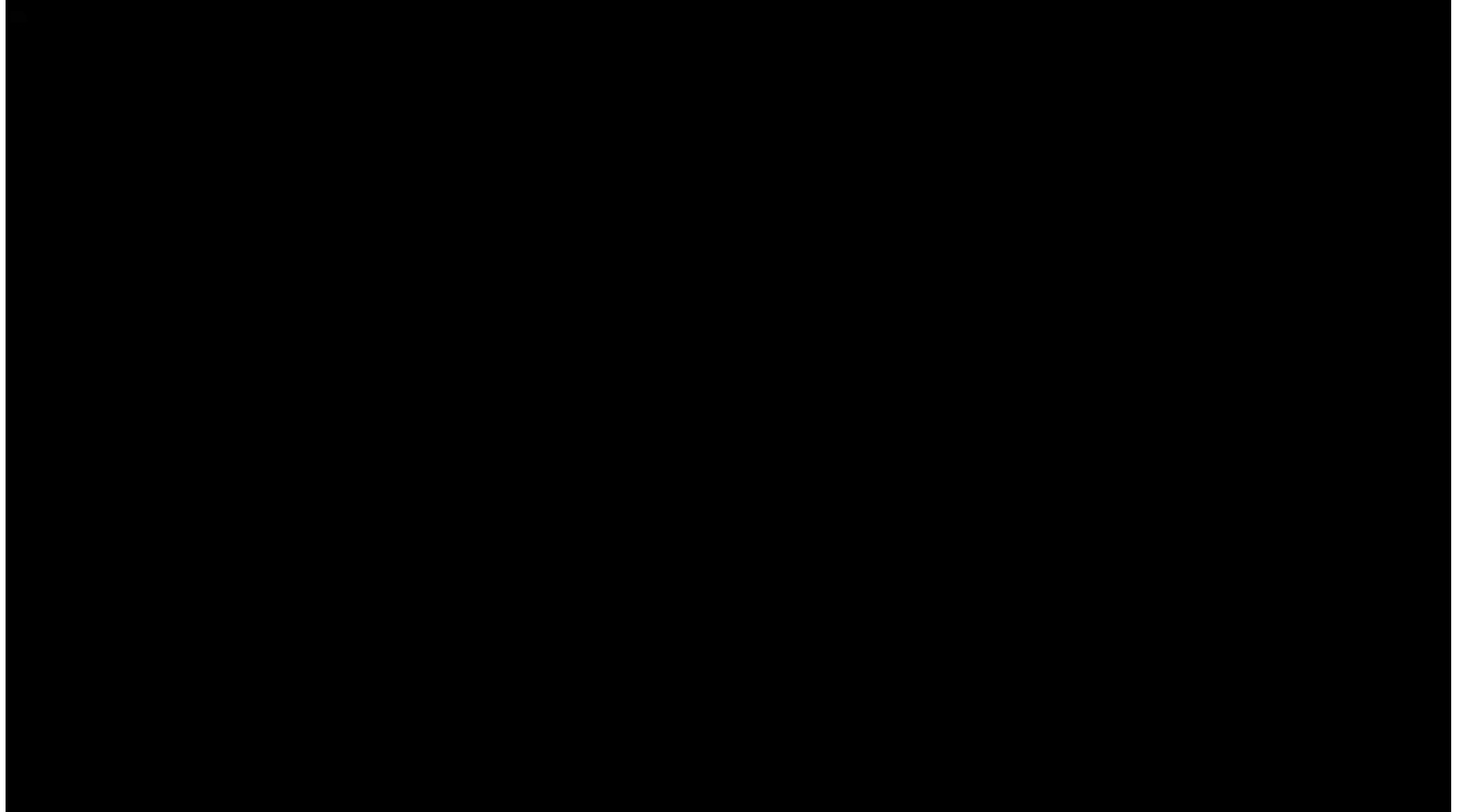
percutaneous-coronary-interventions-pci-per-million-people, 31-10-2024

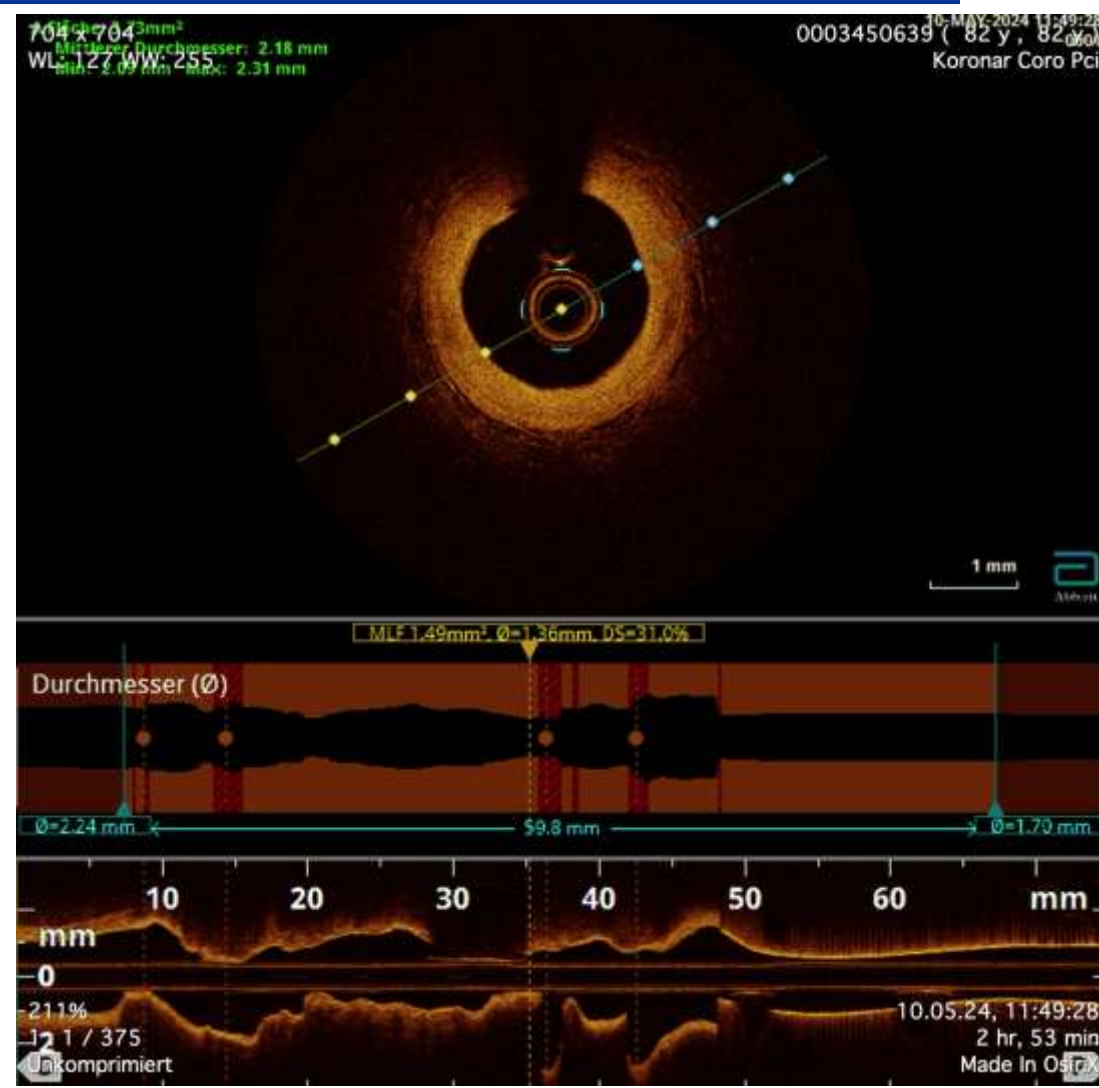
4. <https://ec.europa.eu/eurostat/web/interactive-publications/demography-2024#ageing-population>, 31-10-2024

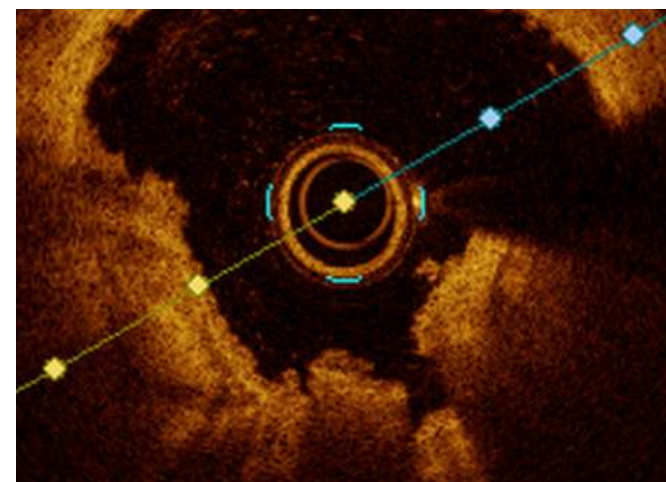
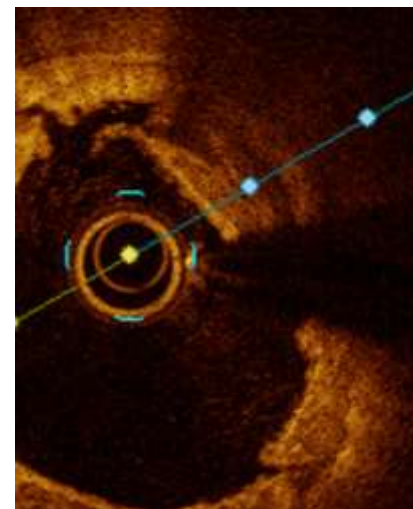
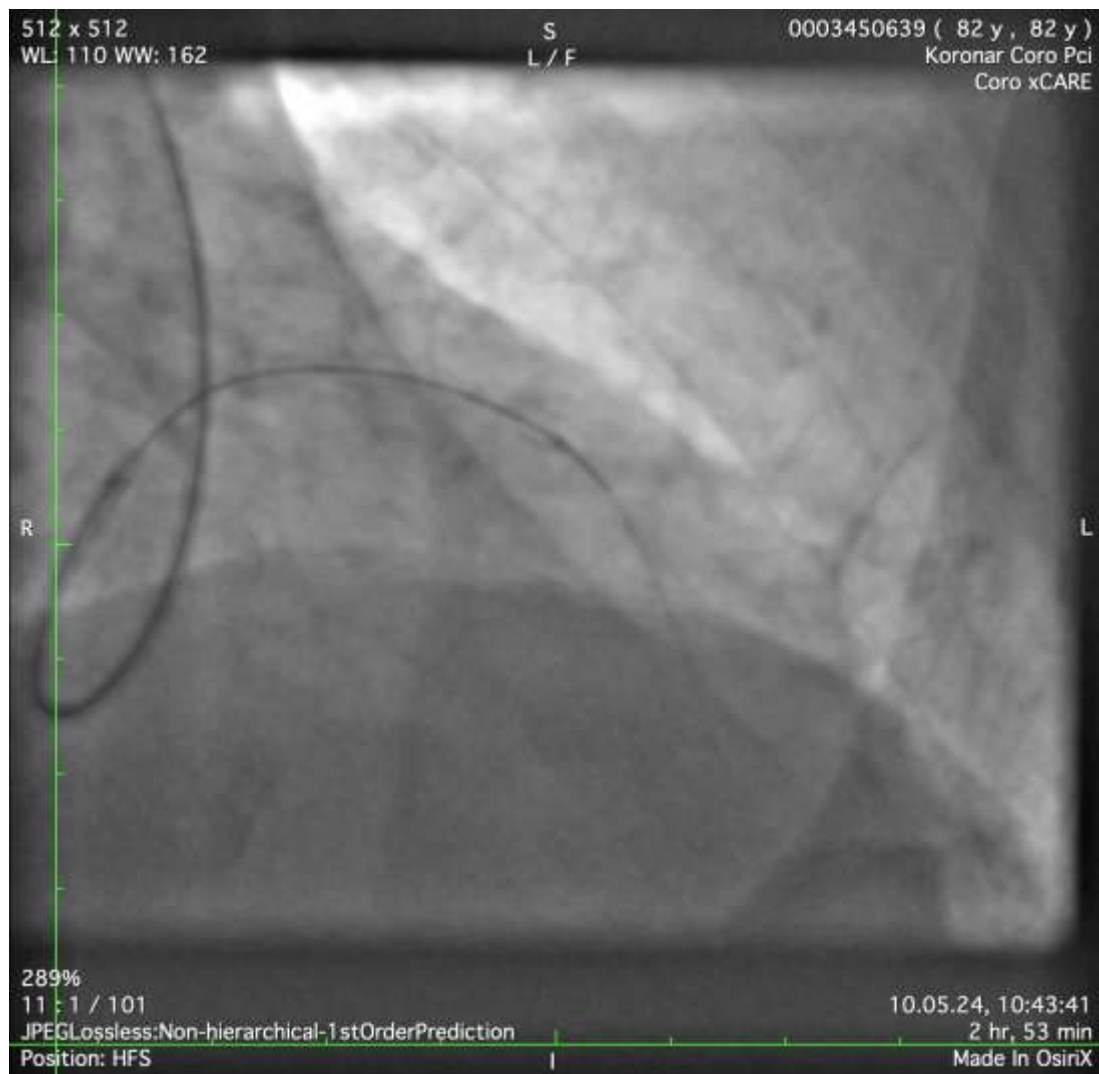
LESION PREPARATION: ORBITAL ARTHEREKTOMIE

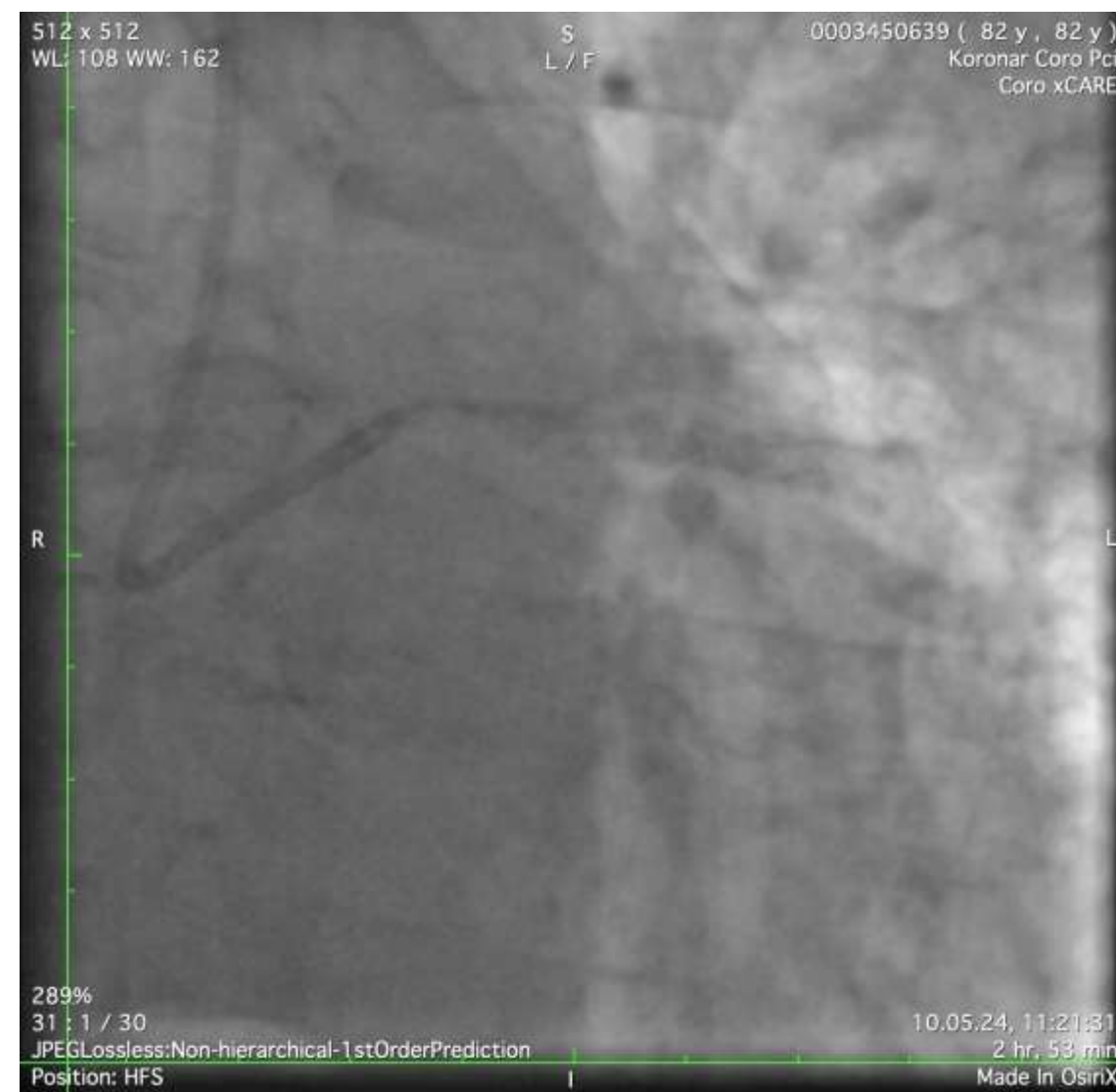
Video: Dual mechanism of action

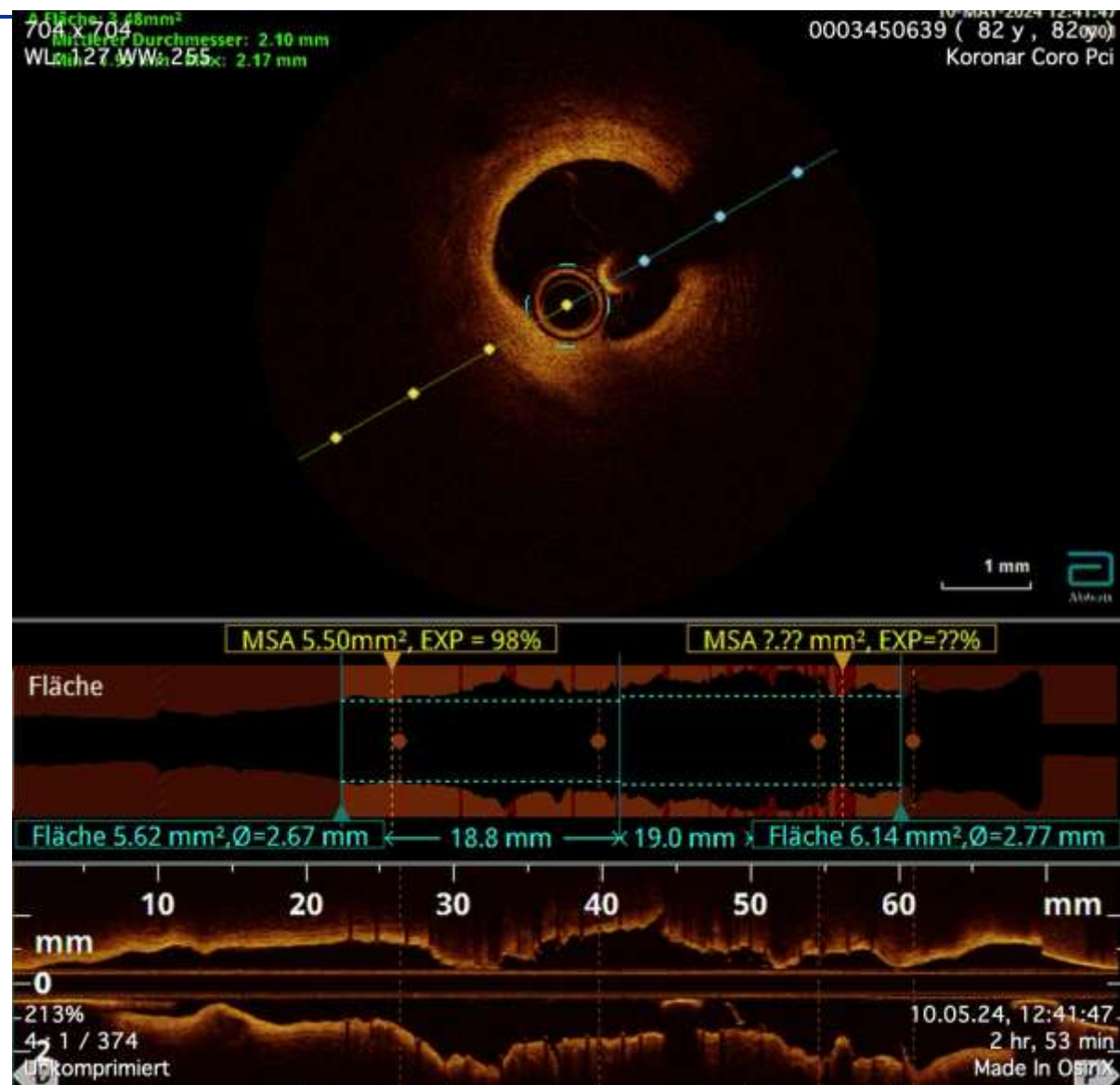
The Diamondback 360™ Coronary Orbital Atherectomy System (OAS) enables modification of intimal and medial calcium through differential sanding and fracturing of deep calcium.



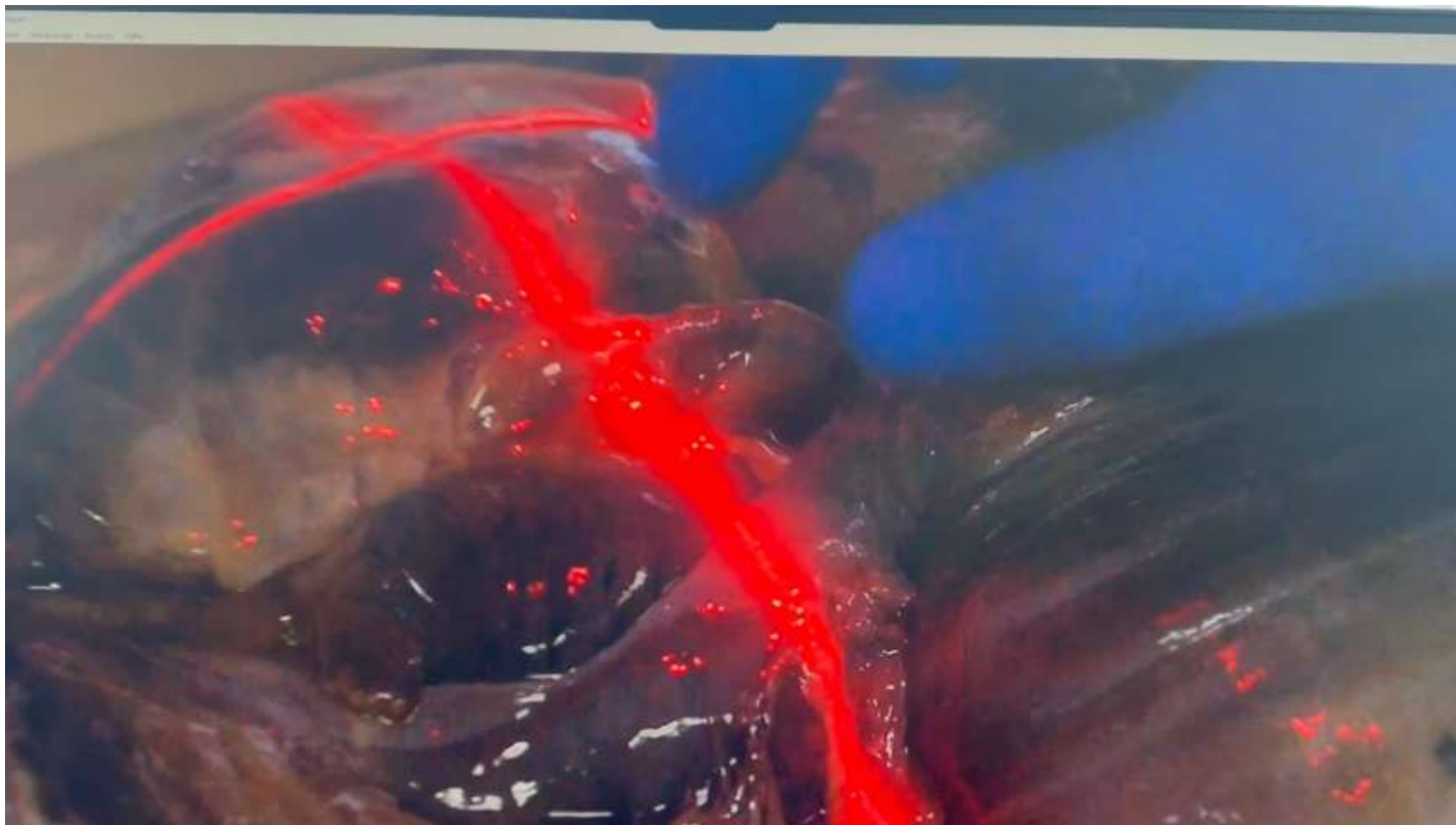








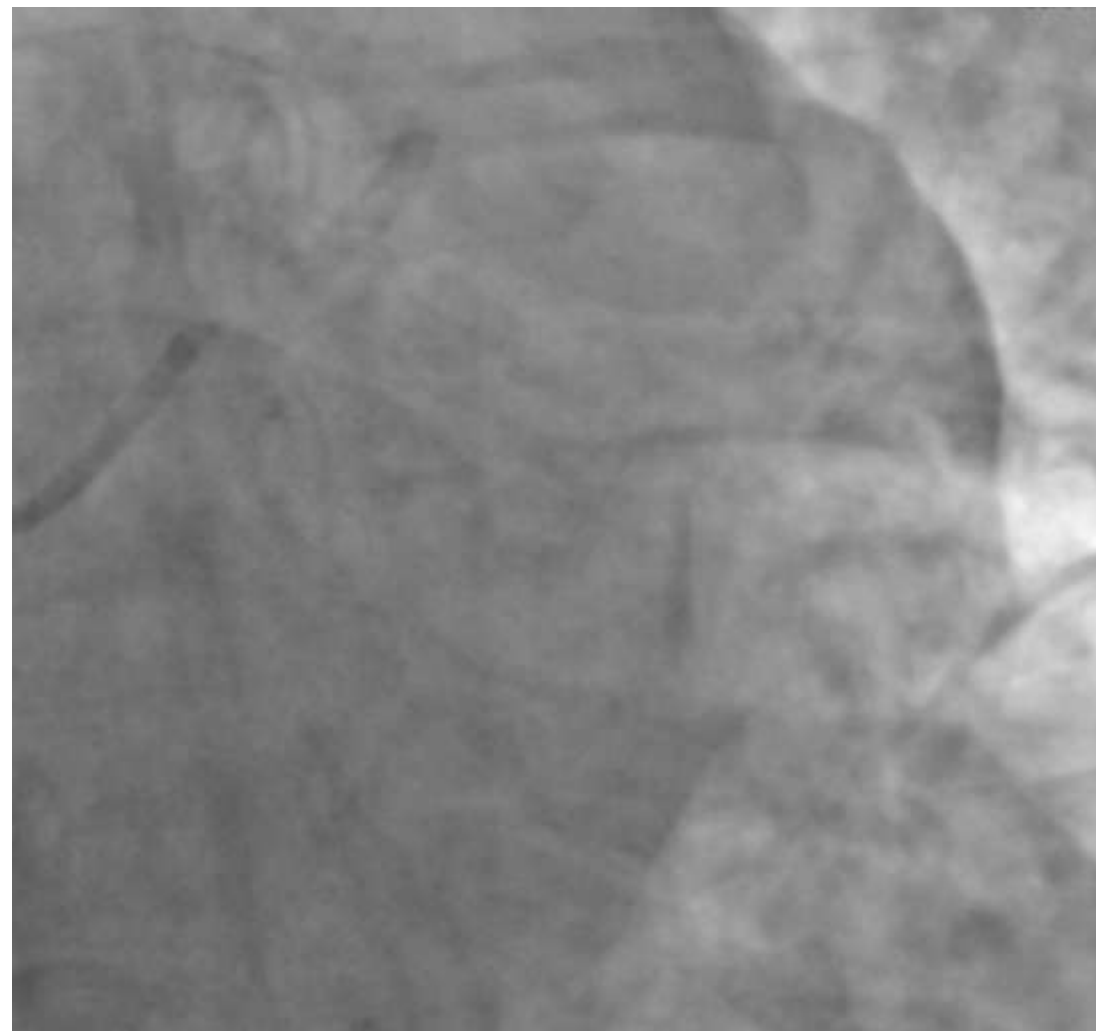
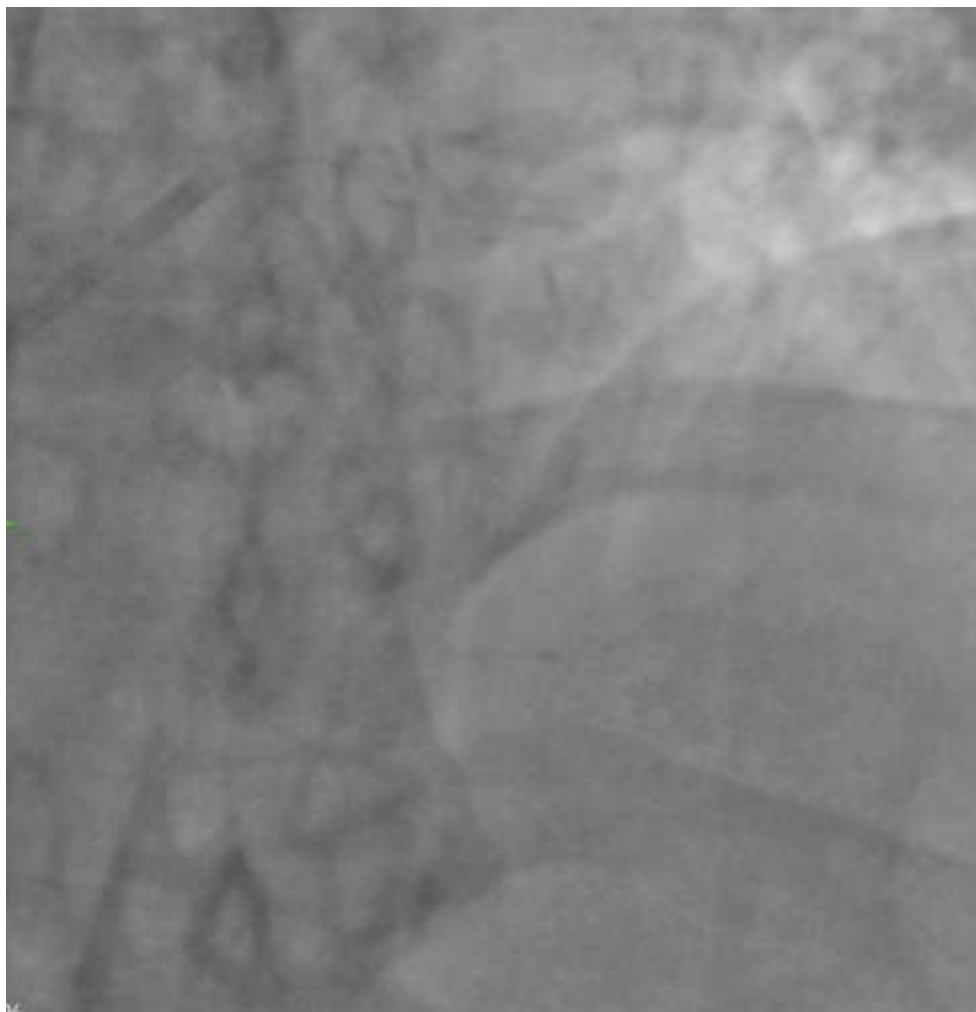
LESION PREPARATION: SHOCKWAVE

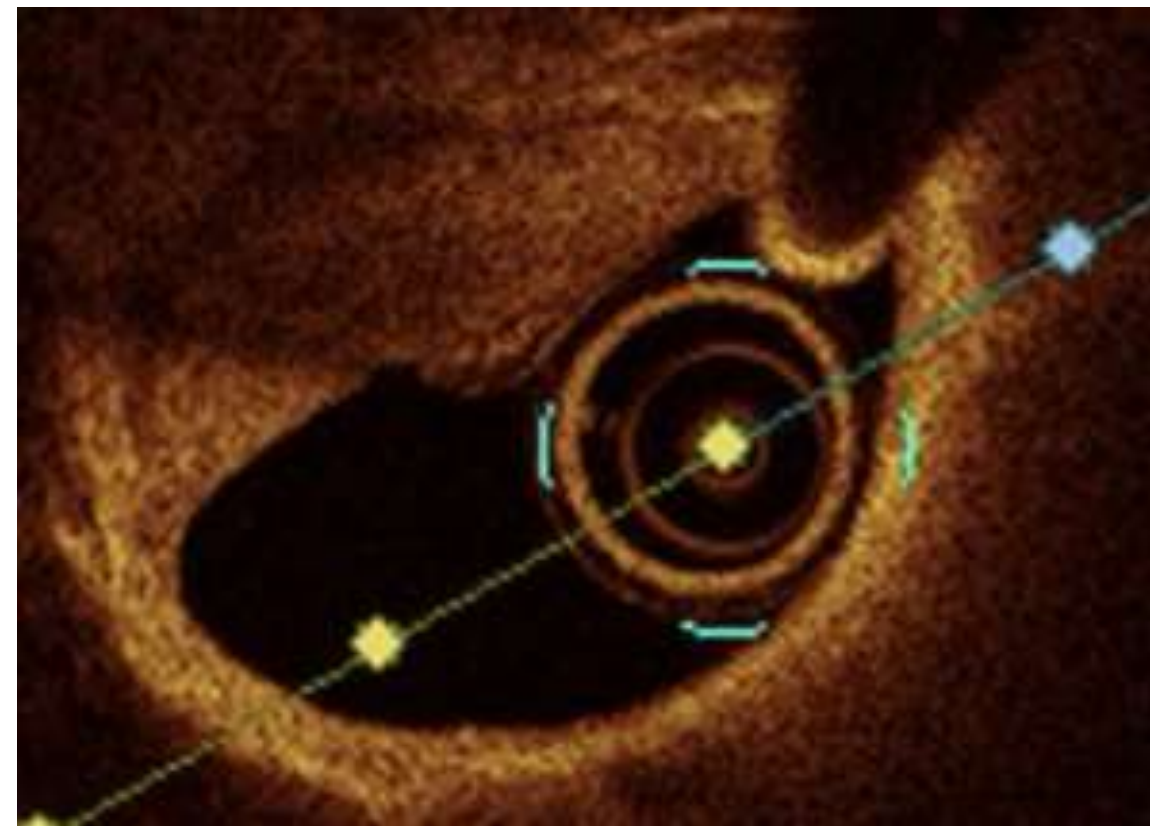
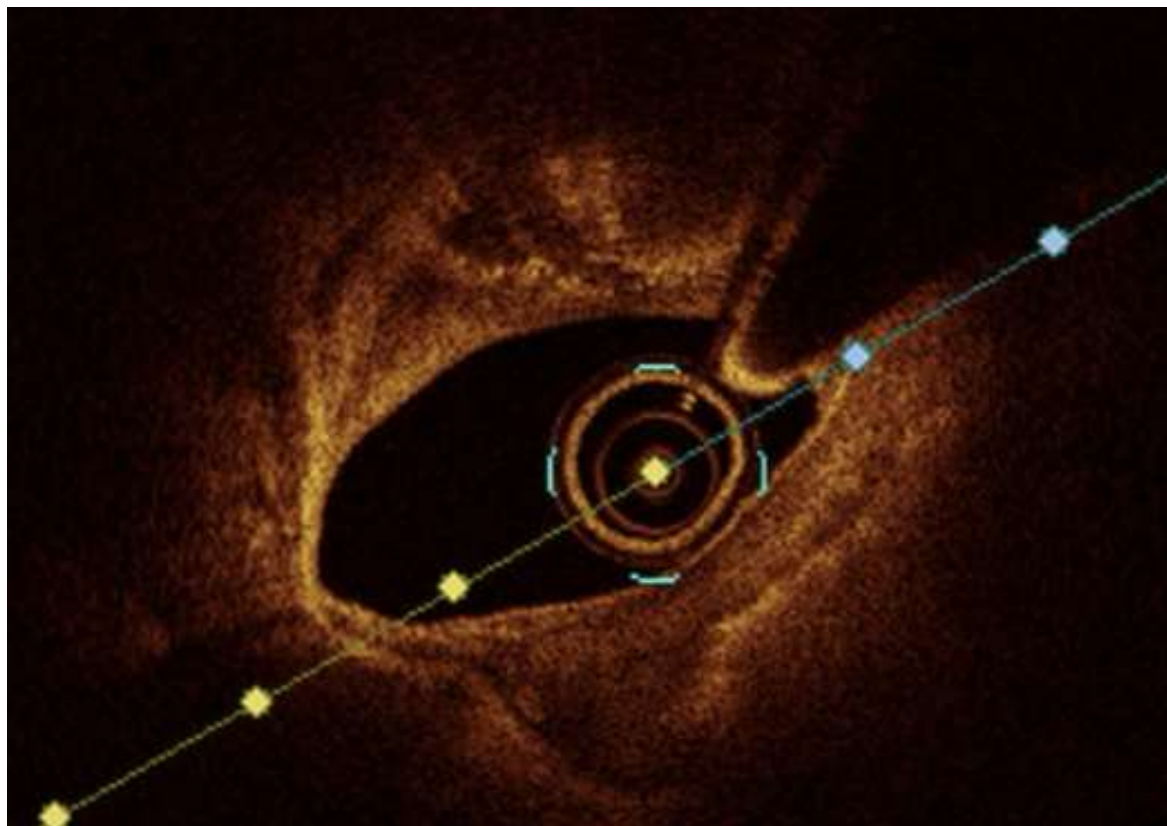


Expanding and collapsing vapor bubble creates a short burst of **sonic pressure waves**.

Sonic pressure waves travel through the vessel with an effective pressure of **~50 atm**.

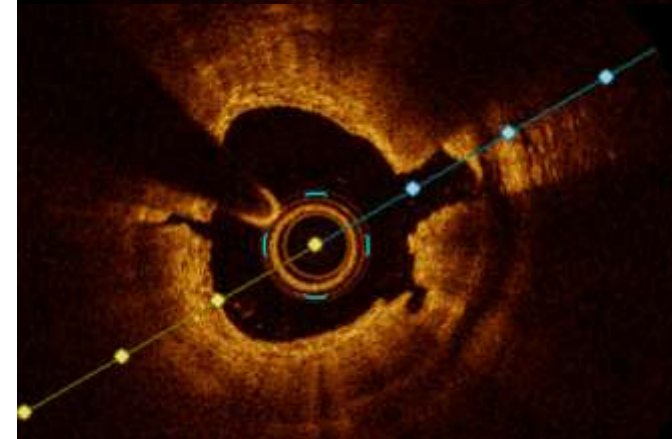
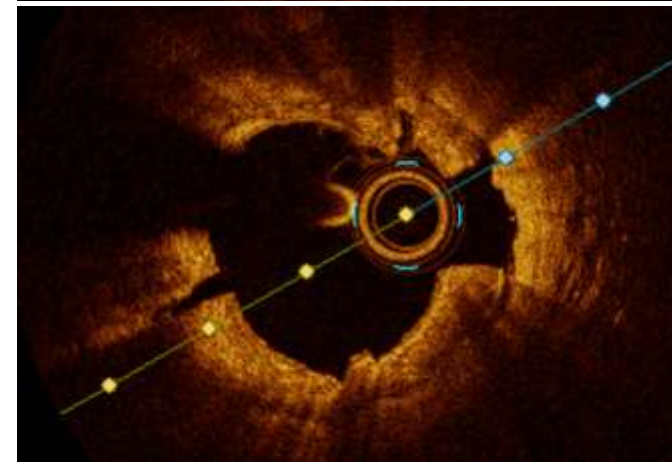
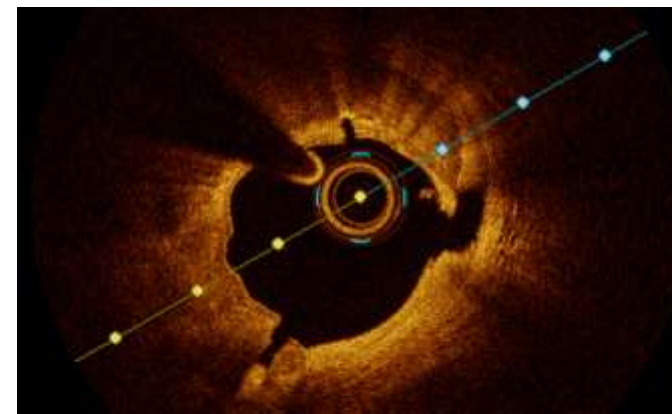
A **localized field effect** within the vessel fractures both **intimal and medial** calcium.

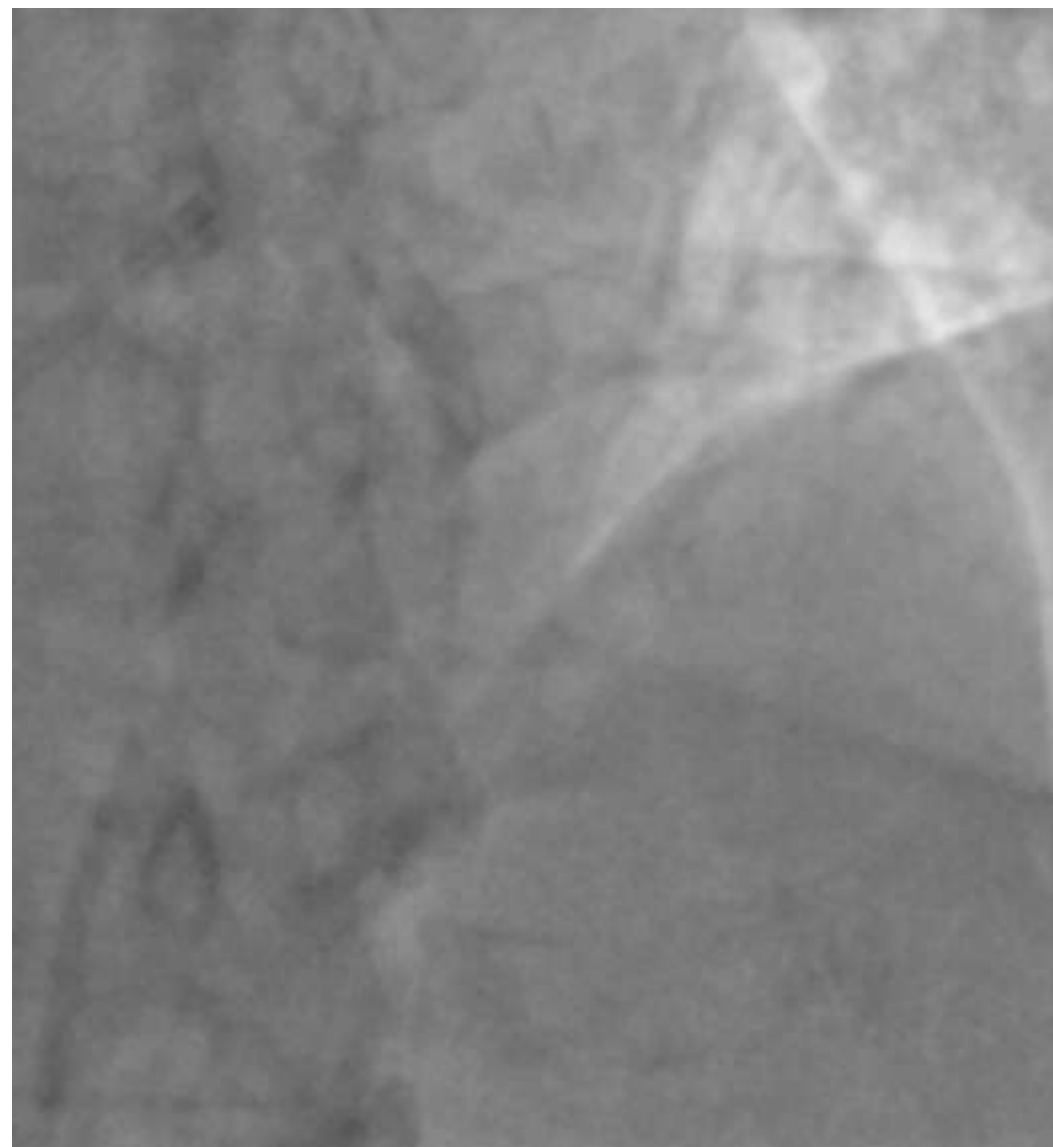




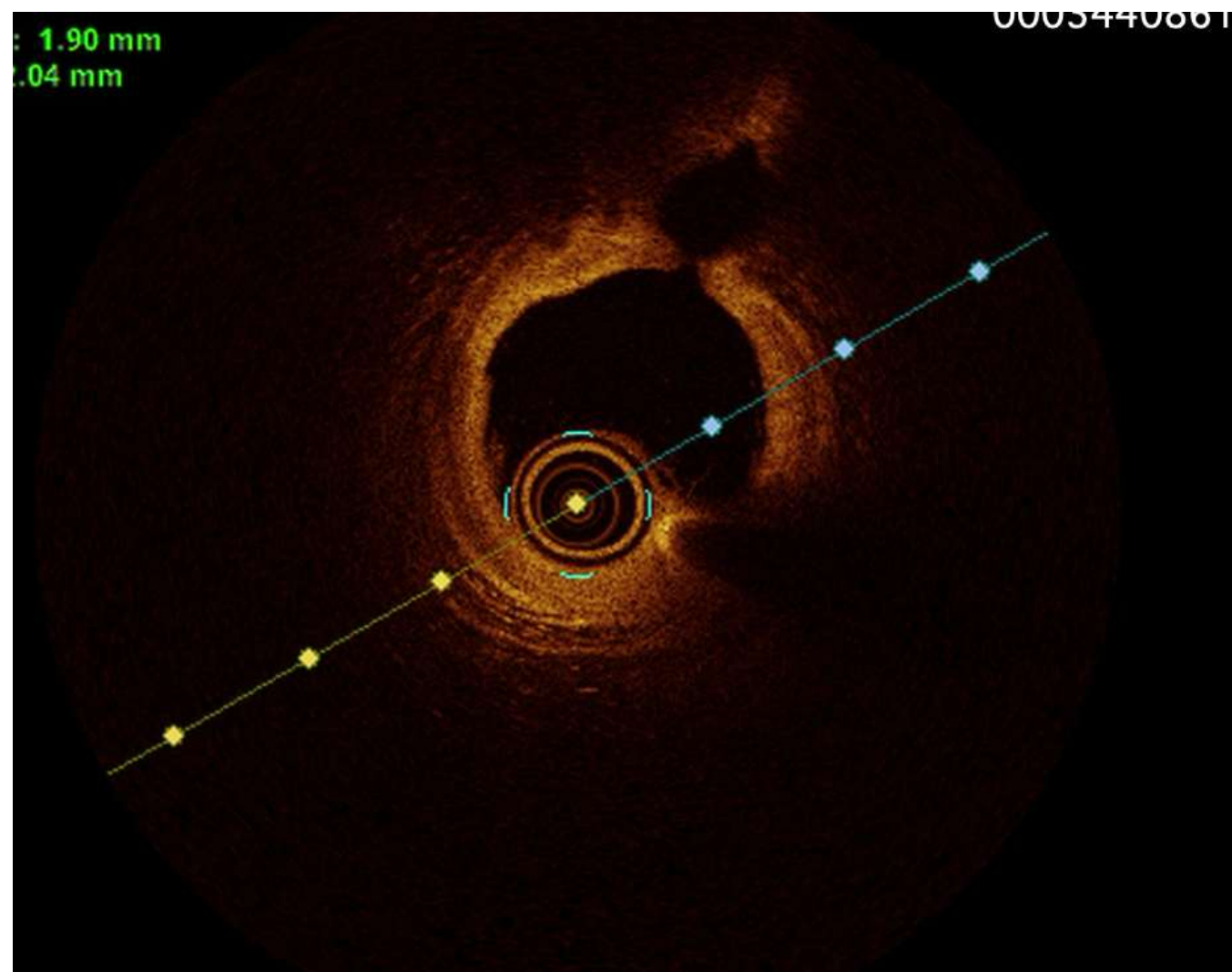


Shockwave 2.5/12 from distal to proximal





POT NC 3.5/15



EF < 35% ?

2018 Guidelines on myocardial revascularization	Class	Level	2024 Guidelines	Class	Level
Recommendations for revascularization in patients with chronic coronary syndrome					
Revascularization to improve outcomes - In CCS patients with LV ejection fraction $\leq 35\%$					
In patients with one- or two-vessel disease, PCI should be considered as an alternative to CABG when complete revascularization can be achieved.	Ila	C	In selected CCS patients with functionally significant MVD and LVEF $\leq 35\%$ who are at high surgical risk or not operable, PCI may be considered as an alternative to CABG.	Ilb	B
In patients with three-vessel disease, PCI should be considered based on the evaluation by the Heart Team of the patient's coronary anatomy, the expected completeness of revascularization, diabetes status, and comorbidities.	Ila	C			

2024 ESC Guidelines for the management of chronic coronary syndromes
(European Heart Journal; 2024 – doi: 10.1093/eurheartj/ehae177)

Revascularization to improve outcomes

In CCS patients with LVEF $\leq 35\%$, it is recommended to choose between revascularization or medical therapy alone, after careful evaluation, preferably by the Heart Team, of coronary anatomy, correlation between coronary artery disease and LV dysfunction, comorbidities, life expectancy, individual risk-to-benefit ratio, and patient perspectives.

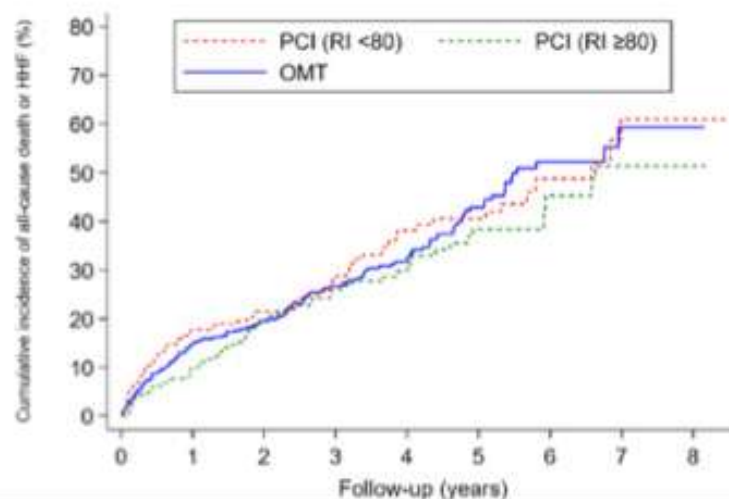


2024 ESC Guidelines for the management of chronic coronary syndromes
(European Heart Journal; 2024 – doi: 10.1093/eurheartj/ehae177)

REVIVED BCIS2

PCI with Complete vs Incomplete Revascularisation Signals towards Improved Outcomes¹

Figure S4: Primary Outcome by Completeness of Revascularization



	PCI	OMT	Hazard Ratio (95% CI)
RI ≥80	56/171	134/353	0.87 (0.64 to 1.19)
RI <80	64/163		1.02 (0.76 to 1.37)

Completeness of revascularization was assessed using the BCIS-JS Revascularization Index (RI): $(BCIS-JS_{pre} - BCIS-JS_{post}) / BCIS-JS_{pre}$ ^{2,3}

PCI patients with RI ≥80%

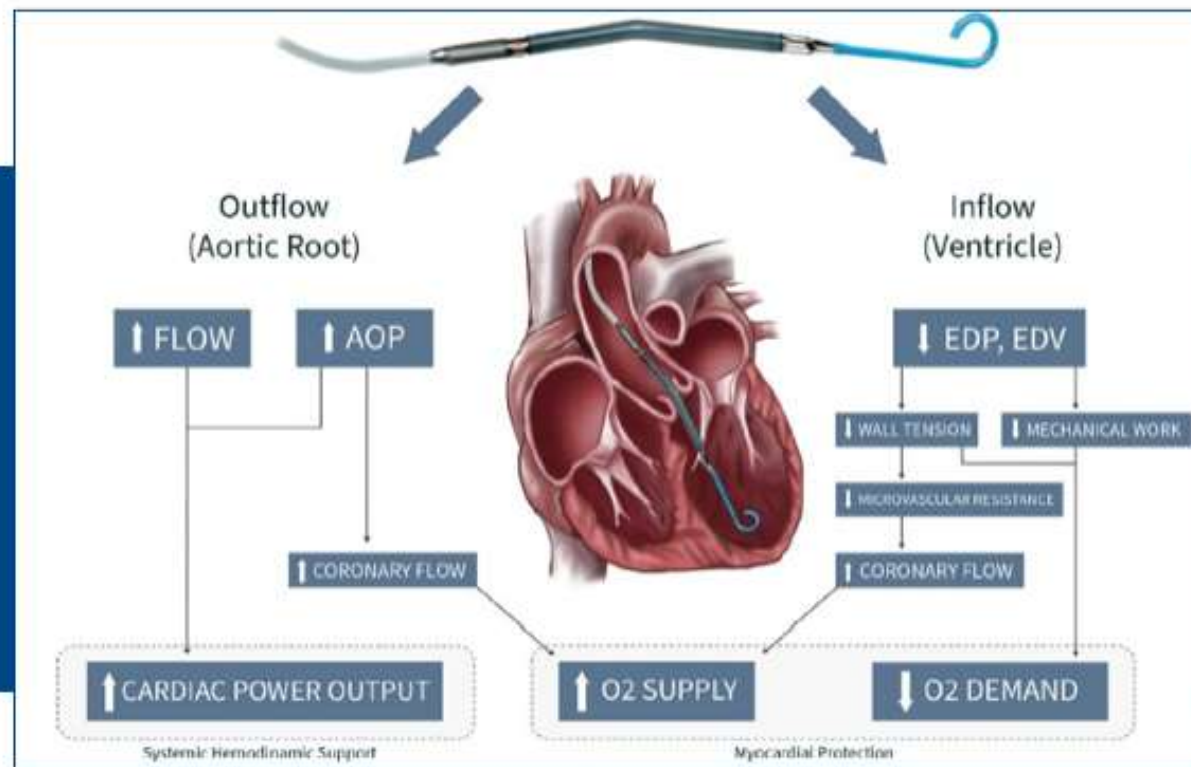
- 13% reduction in all-cause death or HF hospitalization

PCI patients with RI <80%

- No benefit observed

1. Perera, D. et al. *N. Engl. J. Med.* **387**, 1351–1360 (2022)
 2. Vergallo, R. & Liuzzo, G. *Eur. Heart J.* **43**, 4775–4776 (2022).
 3. Silva, K. D. et al. *Am. J. Cardiol.* **111**, 172–177 (2013)

Hemodynamic Effects of Impella Devices



Attlinger-Toller, A. et al. *Front. Cardiovasc. Med.* 9, 856870 (2022)

Bailout Use of Impella during PCI was Associated with Increased Mortality

Outcomes of bailout percutaneous ventricular assist device versus prophylactic strategy in patients undergoing nonemergent percutaneous coronary intervention

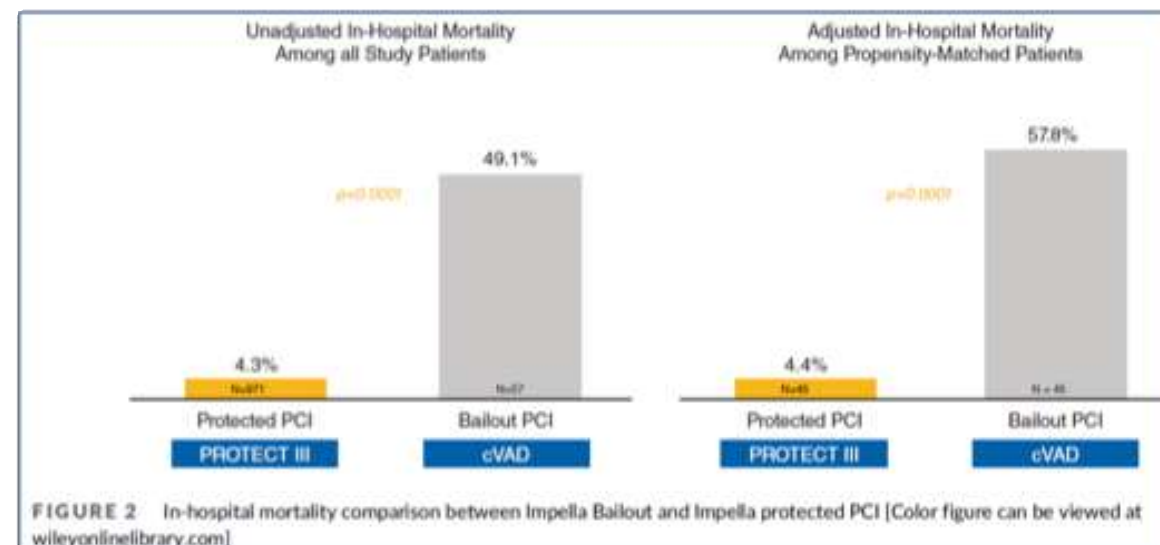
Brian P. O'Neill MD¹ | Cindy Grines MD² | Jeffrey W. Moses MD³ |
E. Magnus Ohman MD⁴ | Alexandra Lansky MD⁵ | Jeffery Popma MD⁶ |
Navin K. Kapur MD⁷ | Theodore Schreiber MD⁸ | Salvatore Mannino MD⁹ |
William W. O'Neill MD¹ | Amin M. Medjania MD¹⁰ | Ehtisham Mahmud MD¹¹

Data source: cVAD Impella US registry
cVAD Bailout Subjects Selection Criteria:

- No CS on admission to hospital
- Elective or Urgent PCI
- No CS prior to start of PCI
- Impella pump support initiated during PCI (after the start of PCI)
- Indication of Impella is either bailout or CS

TABLE 7 Multivariate logistic regression analysis of factors predictive of in-hospital mortality

Variables	Odds ratio (95% CI)	p value
All patients		
Age (per 1 years)	1.06 (1.03–1.10)	<.0001
Female gender	1.76 (0.89–3.48)	.10
BSA (per 1 m ²)	0.82 (0.19–3.50)	.79
Heart rate (per 1 bpm)	1.02 (1.01–1.03)	.0031
LVEF (per 5%)	0.95 (0.86–1.05)	.36
Prior PCI	1.18 (0.63–2.21)	.61
Urgent PCI	1.80 (0.97–3.33)	.062
Impella initiated during PCI	23.23 (10.45–51.78)	<.0001
Distal lesion location	1.42 (0.68–2.93)	.3



-
- Protect II: Impella 2.5 vs IABP – MACE 30 d 35% vs 40%
 - Protect III: Impella 2.5 & CP in High Risk PCI – Reduction primary endpoint (Death, Stroke, MI, Revasc.) after 90 days
 - DanGer-Shock: MI & cardiogenic shock – Trend to reduced 6 months mortality with Impella CP

The Impella Pumps in the Guidelines

Impella for the first time has now a European recommendation for high-risk patients with **chronic coronary syndrome (IIbC)**

ESC European Society of Cardiology
European Heart Journal (2024) 45, 1–132
https://doi.org/10.1093/eurheartj/ehae177

ESC GUIDELINES

2024 ESC Guidelines for the management of chronic coronary syndromes

Developed by the task force for the management of chronic coronary syndromes of the European Society of Cardiology (ESC)

Endorsed by the European Association for Cardio-Thoracic Surgery (EACTS)

Authors/Task Force Members: Christiaan Vrints [✉], (Chairperson) (Belgium), Felicità Andreotti [✉], (Chairperson) (Italy), Konstantinos C. Koskinas[✉], (Task Force Co-ordinator) (Switzerland), Xavier Rossello [✉], (Task Force Co-ordinator) (Spain), Marianna Adamo [✉] (Italy), James Ainslie (United Kingdom), Adrian Paul Banning [✉] (United Kingdom), Andrzej Budaj [✉] (Poland), Ronny R. Buechel [✉] (Switzerland), Giovanni Alfonso Chiariello [✉] (Italy), Alaide Chieffo [✉] (Italy), Ruxandra Maria Christodorescu [✉] (Romania), Christi Deaton [✉] (United Kingdom), Torsten Doenst [✉] (Germany), Hywel W. Jones (United Kingdom), Vijay Kunadian [✉] (United Kingdom), Julinda Mehilli [✉] (Germany), Milan Milojevic [✉] (Serbia), Jan J. Piek [✉] (Netherlands), Francesca Pugliese [✉] (United Kingdom), Andrea Rubboli [✉] (Italy), Anne Grete Semb [✉] (Norway), Roxy Senior [✉] (United Kingdom), Jurrien M. ten Berg [✉] (Netherlands), Eric Van Belle [✉] (France), Emeline M. Van Craenenbroeck [✉] (Belgium), Rafael Vidal-Perez [✉] (Spain), Simon Winther [✉] (Denmark), and ESC Scientific Document Group

Vrints, C. et al. 2024 Eur. Hear. J. 45, 3415–3537 [2024]

In **HFrEF patients with complex CAD** undergoing PCI, the guideline states that „mechanical cardiac support, such as the microaxial flow pump, may **minimize the risk of severe complications** and provide **haemodynamic stability**, facilitating the achievement of **complete revascularization**.“

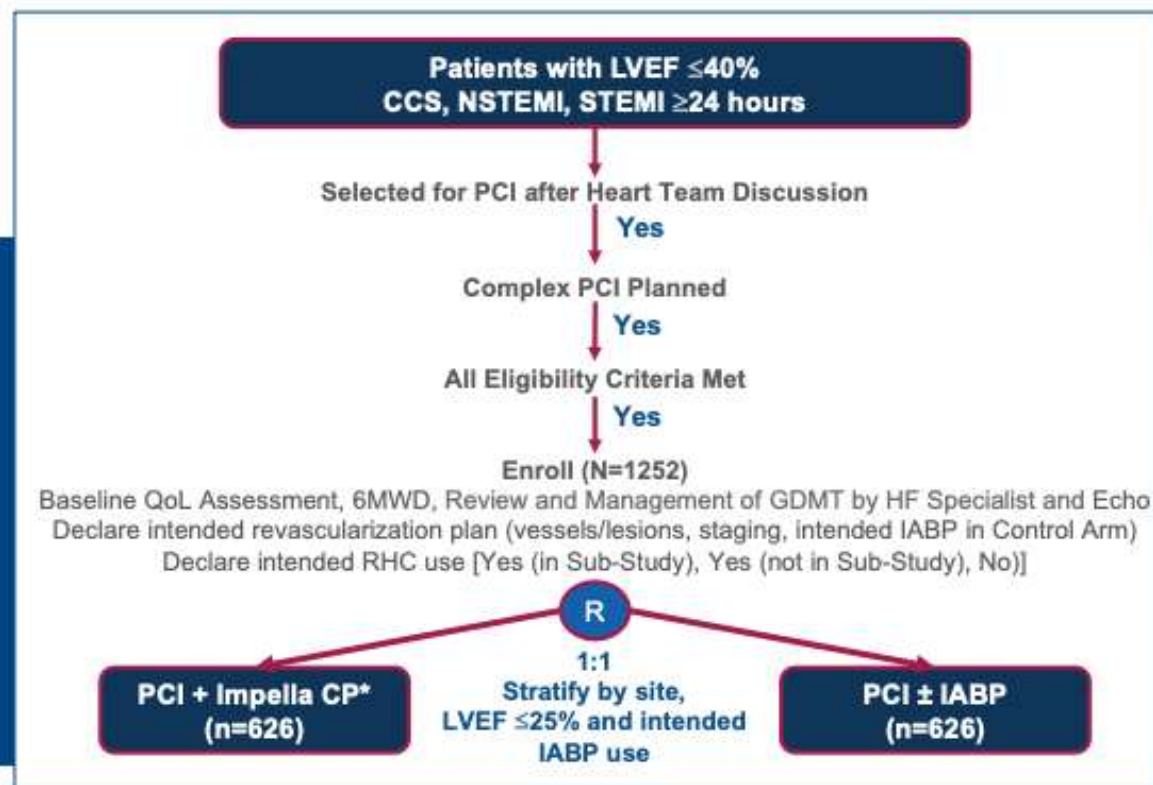
Management of chronic coronary syndrome patients with chronic heart failure—Section 5

In HF patients with LVEF ≤35% in whom obstructive CAD is suspected, ICA is recommended with a view towards improving prognosis by CABG, taking into account the risk-to-benefit ratio of the procedures.	I	B
In HF patients with LVEF >35% and suspected CCS with low or moderate (>5%–50%) pre-test likelihood of obstructive CAD, CCTA or functional imaging is recommended.	I	C
In patients with HFpEF with angina or equivalent symptoms and normal or non-obstructive epicardial coronary arteries, PET or CMR perfusion or invasive functional coronary testing should be considered to detect or rule out coronary microvascular dysfunction.	IIa	B
In selected patients with HFrEF undergoing high-risk PCI for complex CAD, the use of a microaxial flow pump may be considered in experienced centres.	IIb	C
It is recommended that CCS patients with heart failure be enrolled in a multidisciplinary heart failure management programme to reduce the risk of heart failure hospitalization and to improve survival.	I	A
Sacubitril/valsartan is recommended as a replacement for an ACE-I or ARB in CCS patients with HFrEF to reduce the risk of heart failure hospitalization and death.	I	B

IIBc



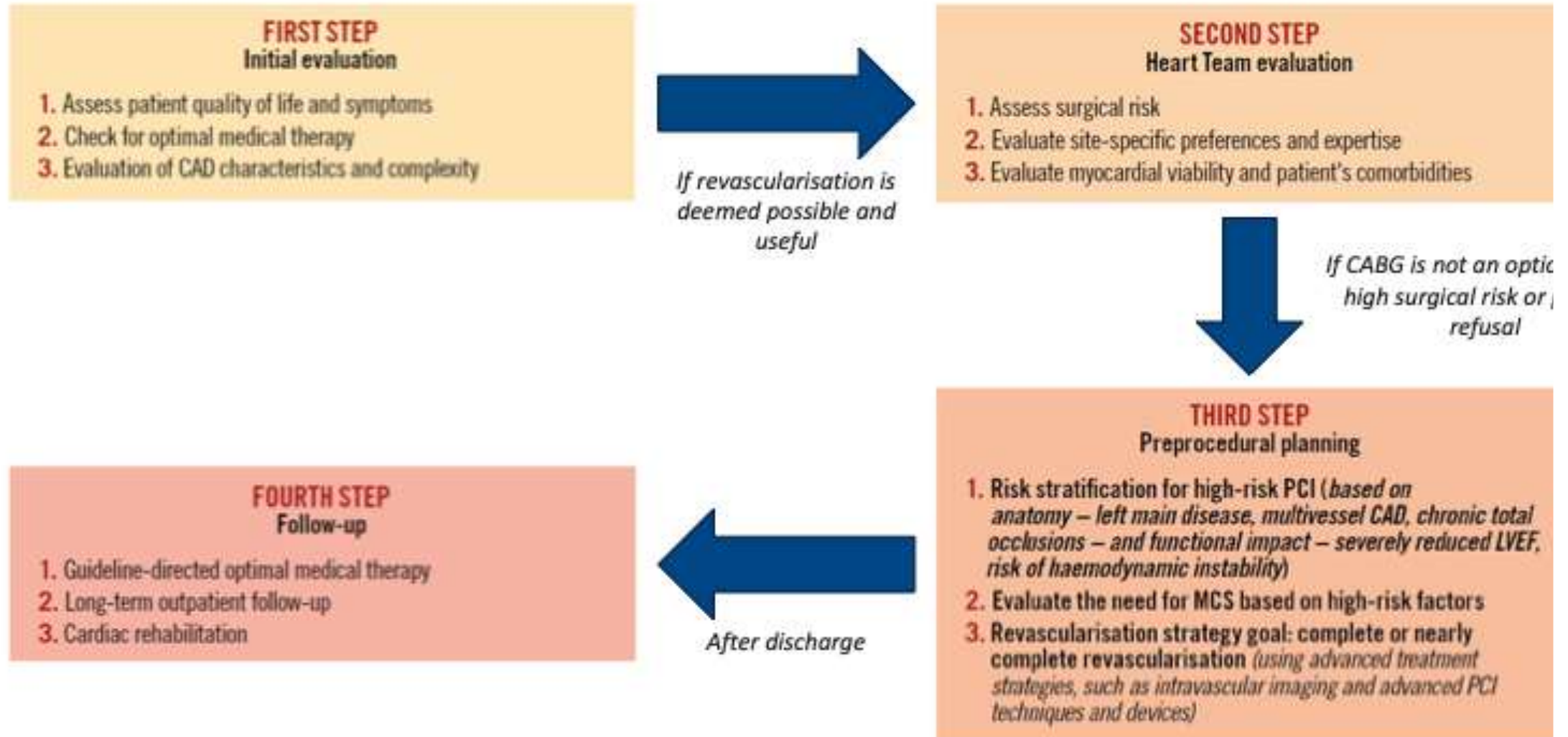
Study Design of PROTECT IV



Primary Endpoint: All-cause death, stroke, durable LVAD/heart transplant MI or hospitalization for cardiovascular causes measured through 3 year follow-up, min. 1 year follow-up in all patients

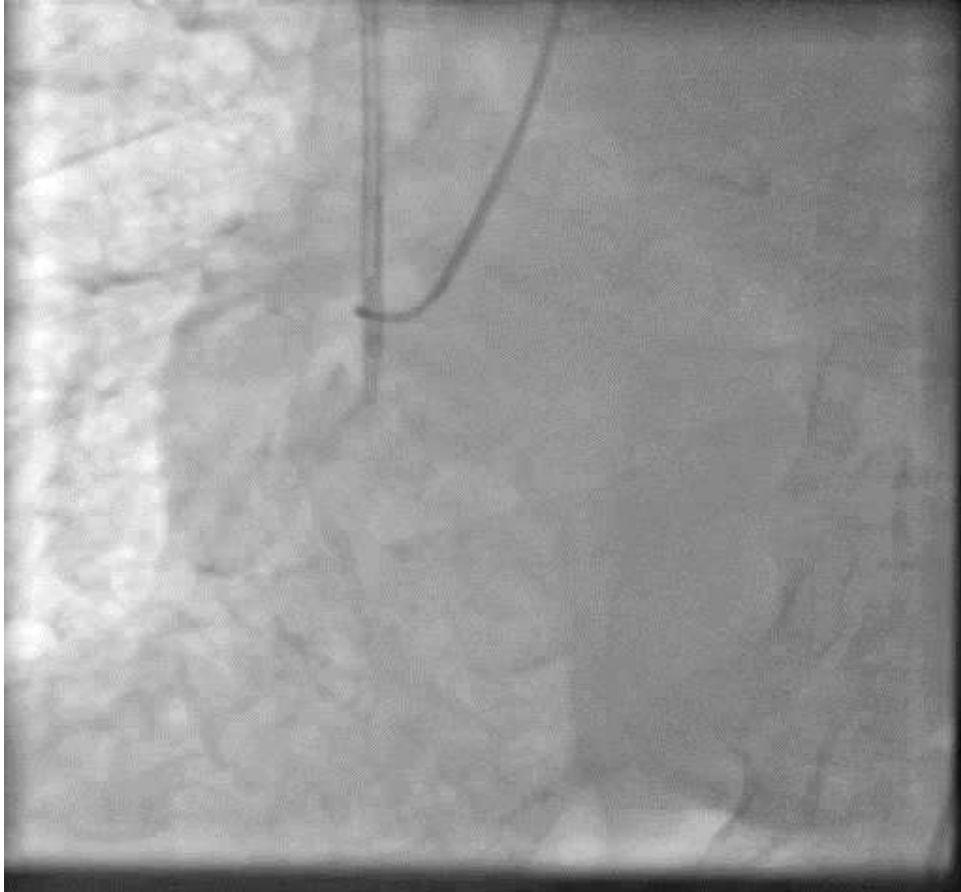
NCT04763200; <https://clinicaltrials.gov/study/NCT04763200?term=NCT04763200&rank=1#study-overview>; 01/20/2025

EXPERT CONSENSUS



Case presentation

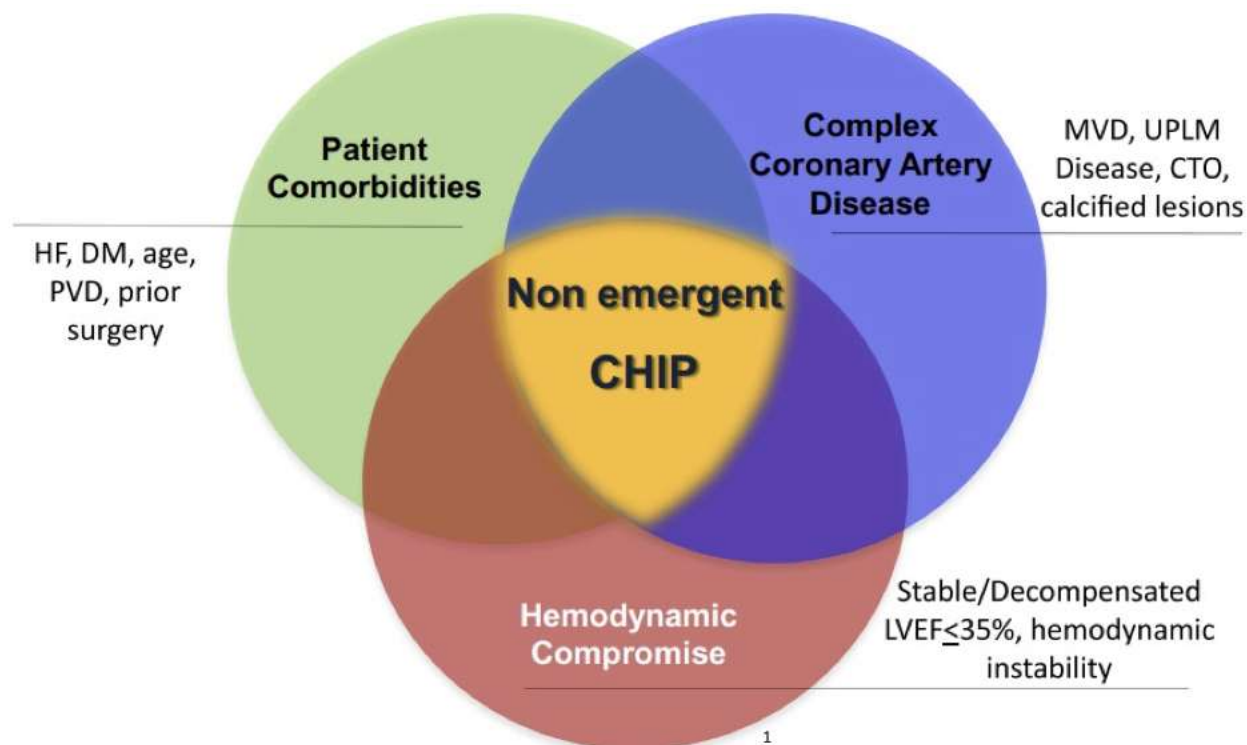
- 73 years old male
- Presentation in the emergency department with acute heart failure symptoms
- Hs-Troponin elevated, no ST-Elevation
- TTE: EF 30%, no relevant valve disease, normal RV-Function (TAPSE > 20 mm)
- History of arterial hypertension, Diabetes



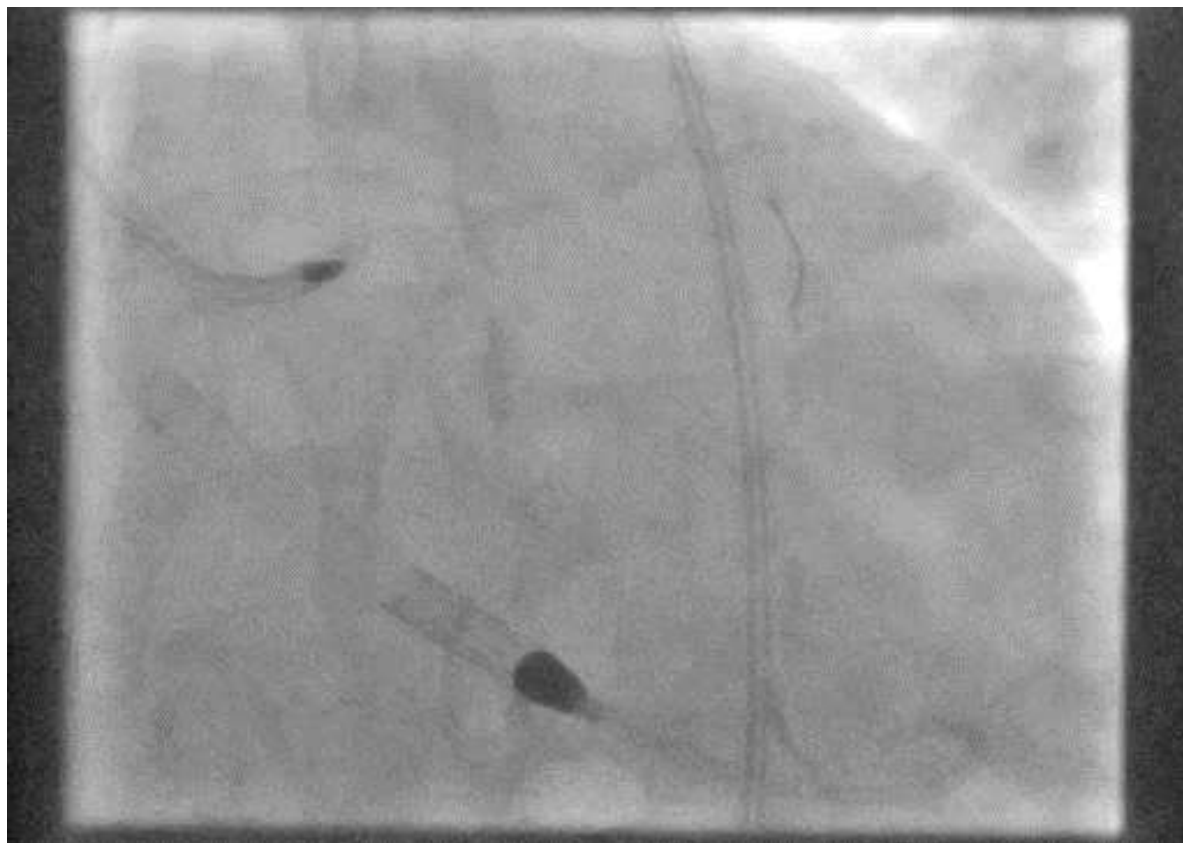
Pressure dumping following intubation of
LCA

CHIP ?

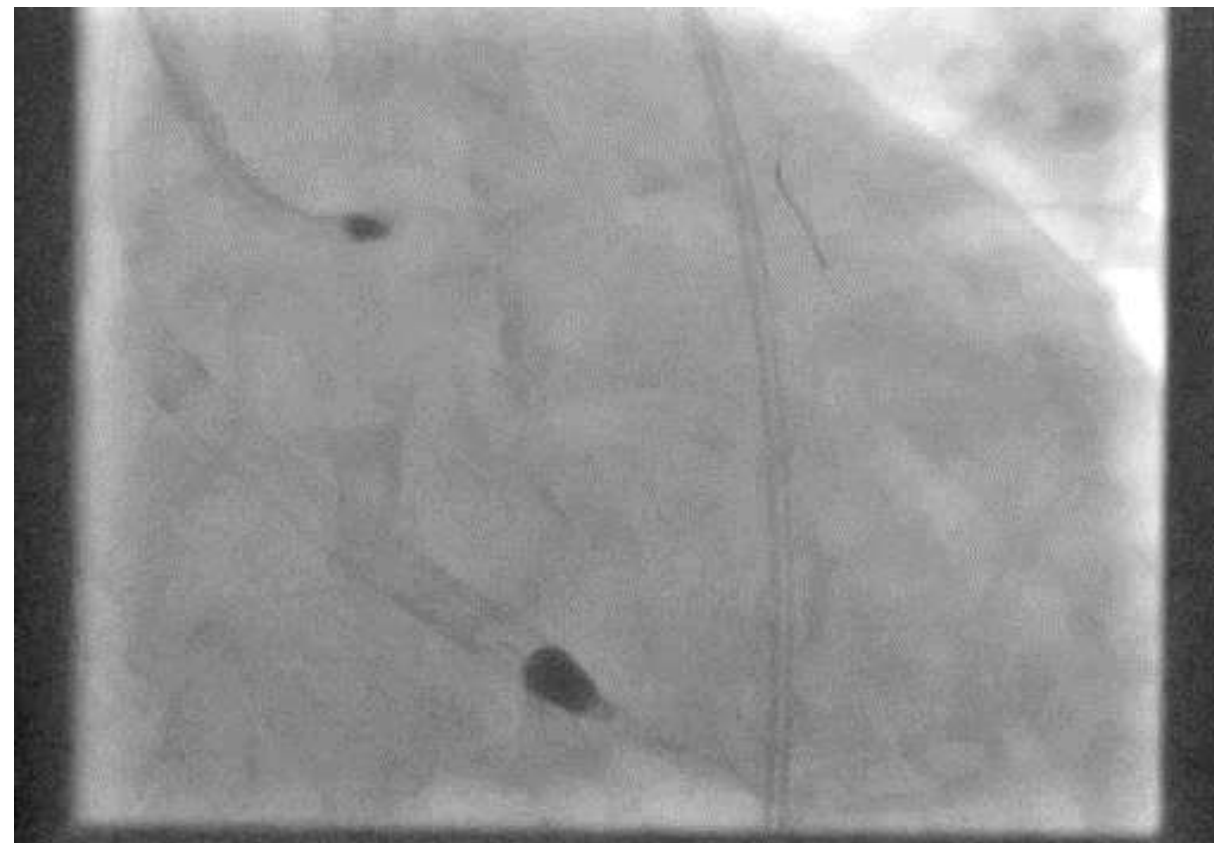
- DM, HF
- UPLM & CTO
- EF < 35%



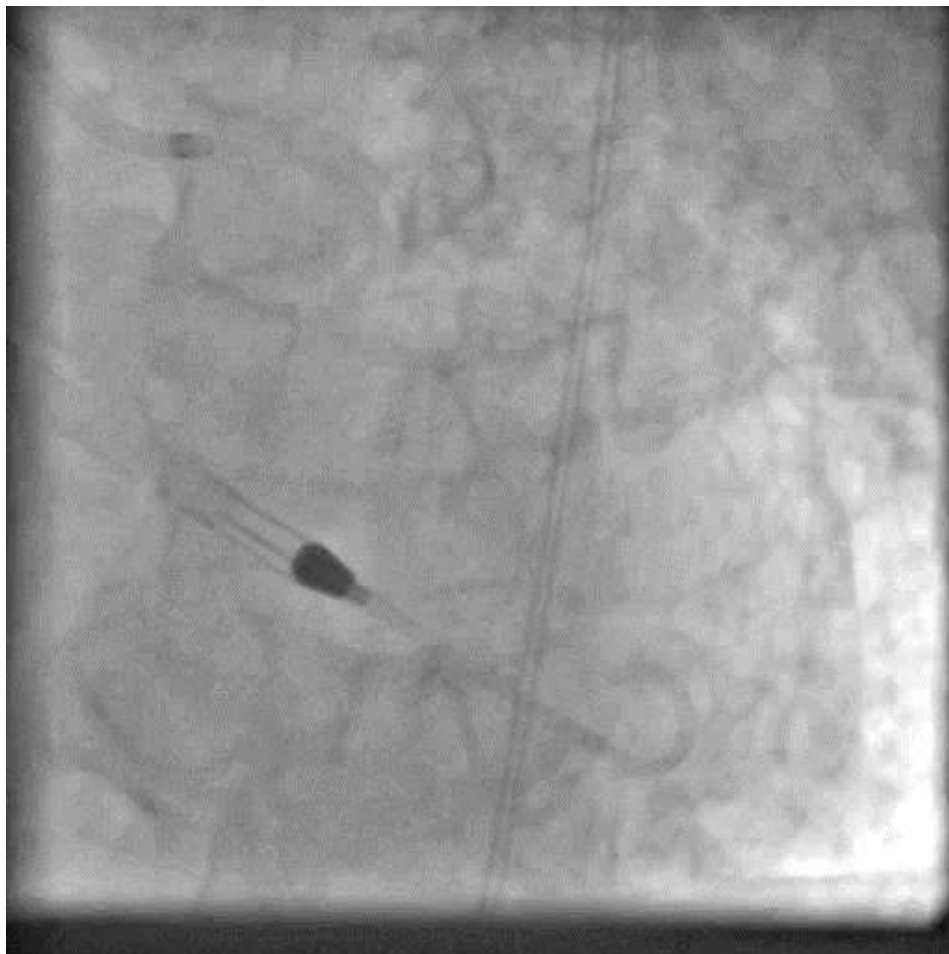




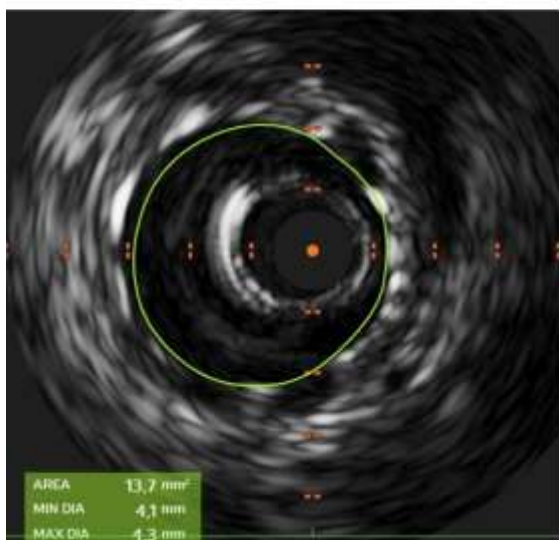
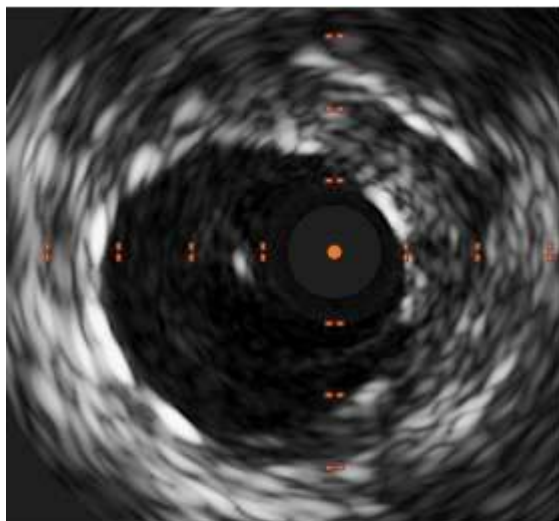
JL 4,0-SH , 1.75 mm Burr



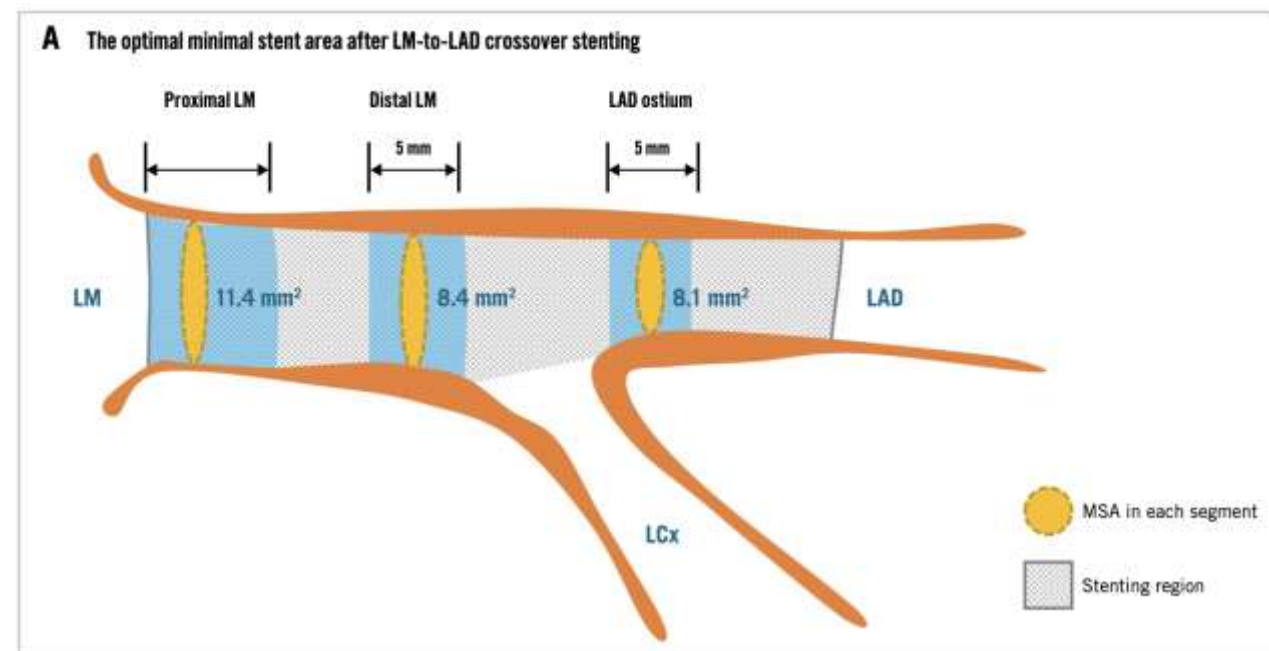
Total :90 seconds of rotablation



Provisional technique, Xience 3,5/33 mm, POT with 4,5mm NC

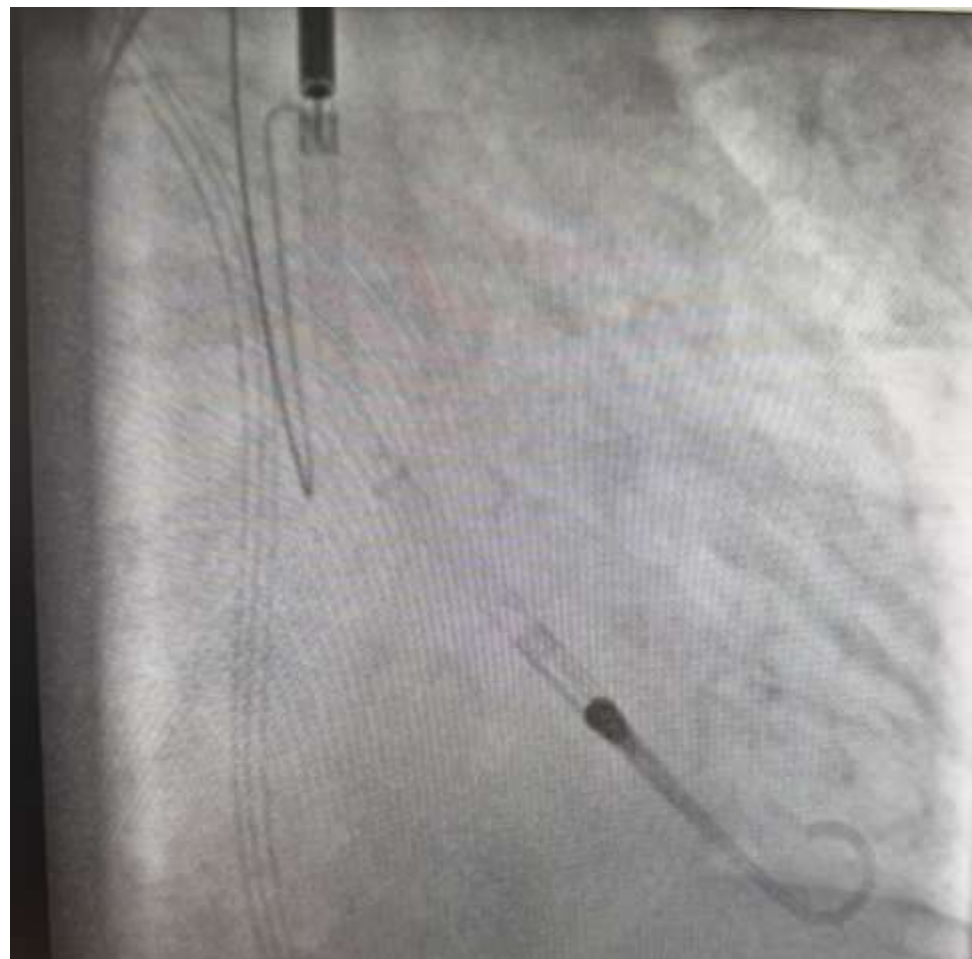


Optimal minimal stent area after left main crossover stenting and 5-year MACE.



EuroIntervention 2025;21:e1069-e1080 • Ju Hyeon Kim *et al.*

Recommendations	Class	Level
<i>Assessment of procedural risks and post-procedural outcomes</i>		
Intracoronary imaging guidance by IVUS or OCT is recommended when performing PCI on anatomically complex lesions, in particular left main stem, true bifurcations, and long lesions.	I	A





Sağ

ol!

IMPELLA PROCEDURE WITH SINGLE ACCESS

Use of the Impella CP with SmartAssist 14F sheath for single-access PCI procedures may:

- Provide an optimal choice for patients with limited vascular access
- Reduce the number of access sites
- Reduce complications related to multiple access sites



Johnson & Johnson
MedTech

IMP-2060. v3



ABIOMED