



Functional versus Culprit-only Revascularization in Elderly Patients with Myocardial Infarction and Multivessel Disease: the **FIRE Trial**



What's new

From a dataset of 4 million PCI patients
Matched comparison angio- vs. physio-guided
Mortality reduction in ACS and older patients

FLORIDA study – primary endpoint : All-cause mortality

	1. quarter	1 year	3 years			
	FFR	Angio	FFR	Angio	FFR	Angio
Death	1.0	2.3	3.3	4.9	9.6	12.6

- 24 % relative risk reduction for FFR-utilization
- Number-needed to treat (NNT) = 34 to prevent one death by FFR-use

FLORIDA study – Conclusions:

FLORIDA (Fractional **F**low Reserve In cardiovascular **Di**SeAse) reveals for the first time within a large, all-comer, well-matched study population undergoing coronary angiography for suspected coronary artery disease:

- Significant reduced longterm-mortality with a 24% relative-risk-reduction associated with the use of FFR during diagnostic angiography for ACS or CCS.
- This effect was most pronounced in patients, where revascularisation-therapy was deferred as well as in high-risk subgroups including patients aged ≥ 75 years and those presenting with ACS as their index event.

→ FLORIDA strengthens the use of FFR in everyday clinical practice as an evidence-based diagnostic and prognostically meaningful tool to guide coronary revascularization therapy.

FLORIDA study – Mortality benefit most pronounced in high-risk subgroups

	ACS (n=1258)	CCS (n=2704)
FFR	10.2	9.3
Angio	14.0	12.0
Relative risk reduction (%)	27%	22%
Number needed to treat (NNT)	27	38

FLORIDA study – Mortality benefit most pronounced in high-risk subgroups

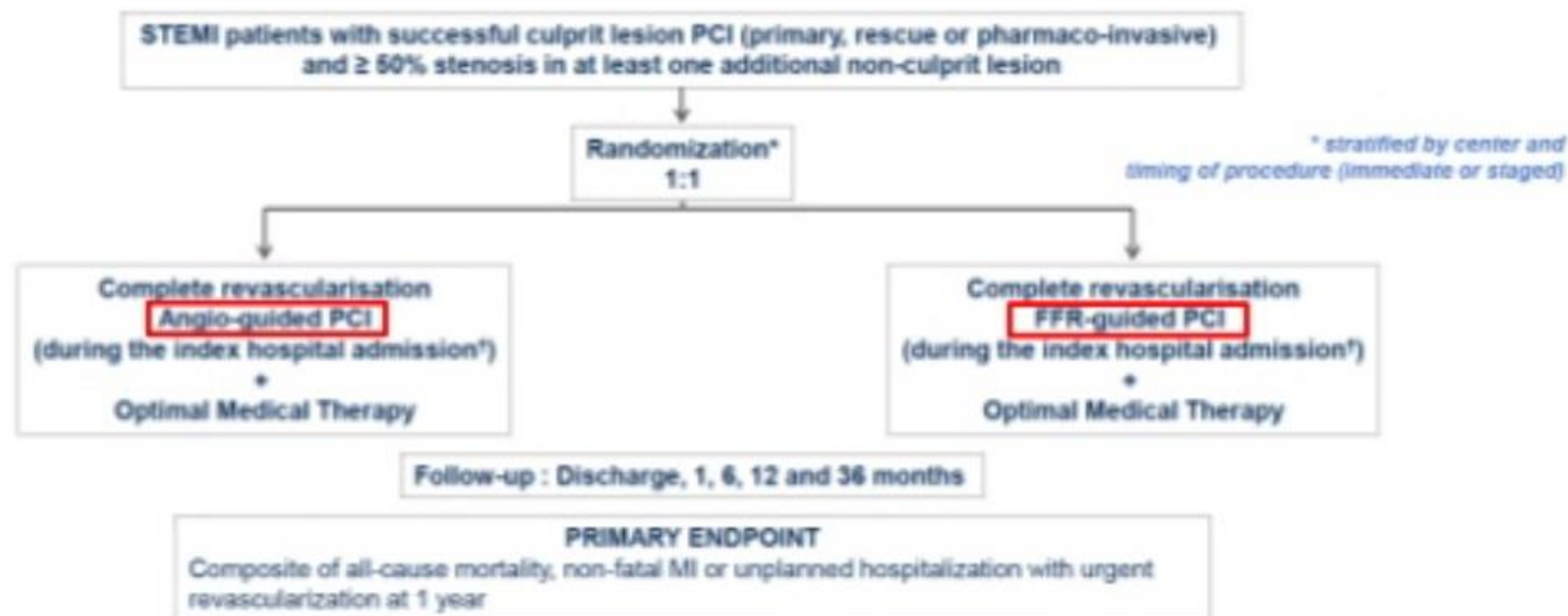
Similar prognostic benefits were observed for the FLORIDA-subgroup of "old-patients" (≥ 75 years)

	Old (n=1471)	All (n=3962)
FFR	14.9	9.6
Angio	20.1	12.6
Relative risk reduction (%)	26%	24%
Number needed to treat (NNT)	20	34

Università degli Studi di Ferrara

What's new from ACC

FLOWER MI Study Design



Baseline characteristics

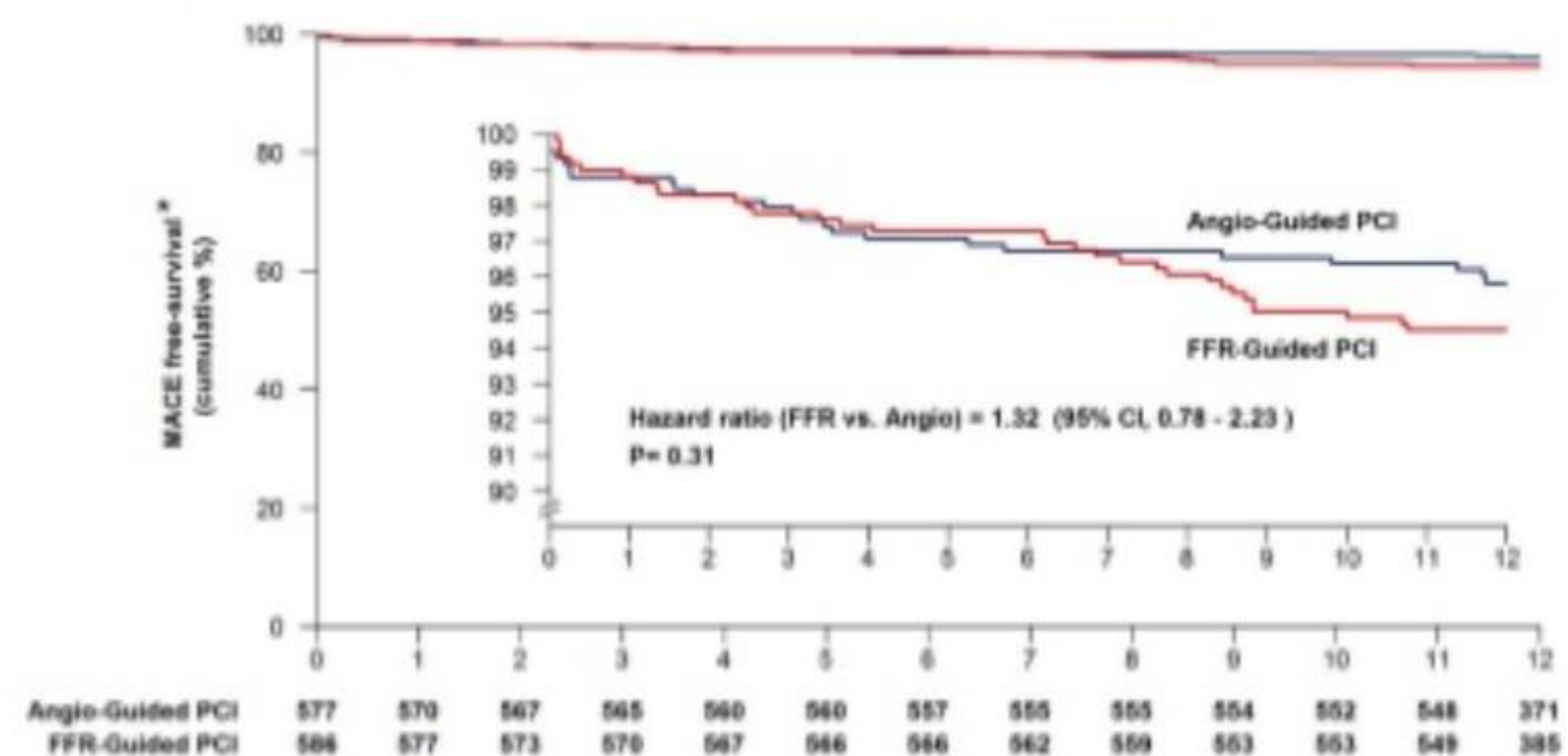
Characteristics	FFR-Guided PCI (n=586)	Angio-Guided PCI (n=577)
Age (year)	62.5 \pm 11.0	61.9 \pm 11.4
BMI (kg/m ²)	26.7 (24.2-29.1)	26.6 (24.4-29.7)
Male	85.0	81.1
Hypertension	43.2	45.4
Diabetes mellitus	18.3	14.2
Hypercholesterolemia	39.6	41.1
Current smoker	40.1	36.4
Previous MI	7.7	5.4
Previous PCI	10.1	7.6
Previous stroke	2.7	3.0
Peripheral-vessel disease	2.7	4.0
Chronic renal insufficiency	1.9	12.1

Clinical presentation	FFR-Guided PCI (n=586)	Angio-Guided PCI (n=577)
Location of infarction		
- Anterior	29.8	34.6
Arteries with stenosis		
- 2	72.4	77.5
- 3	25.8	19.9
Killip class ≥ 2	6.7	5.3
LVEF (%)	50 (45-60)	50 (45-58.3)

Again 62 years old STEMI patients
Again Very low risk population

What's new from ACC

Primary outcome



Primary outcome

Primary outcome at 1 year	FFR-Guided PCI (n=586)	Angio-Guided PCI (n=577)	HR (95% CI)	P Value
MACE*	5.5	4.2	1.32 (0.78-2.23)	0.31
Death from any cause	1.5	1.7	0.89 (0.36-2.20)	-
Myocardial infarction	3.1	1.7	1.77 (0.82-3.84)	-
Unplanned hospitalization leading to urgent revascularization	2.6	1.9	1.34 (0.62-2.92)	-
* % of non-culprit lesions treated	53.3	27.3		

Again Hypothesis 15% of 1-year primary outcome Reality 5% !?!
Again Terrific underpowered analysis



Our Current Roadmap (Hope!!!)

Start enrolment August 2019

Methodological Manuscript August 2020

700° enrolled patient October 2020

End enrolment August 2021

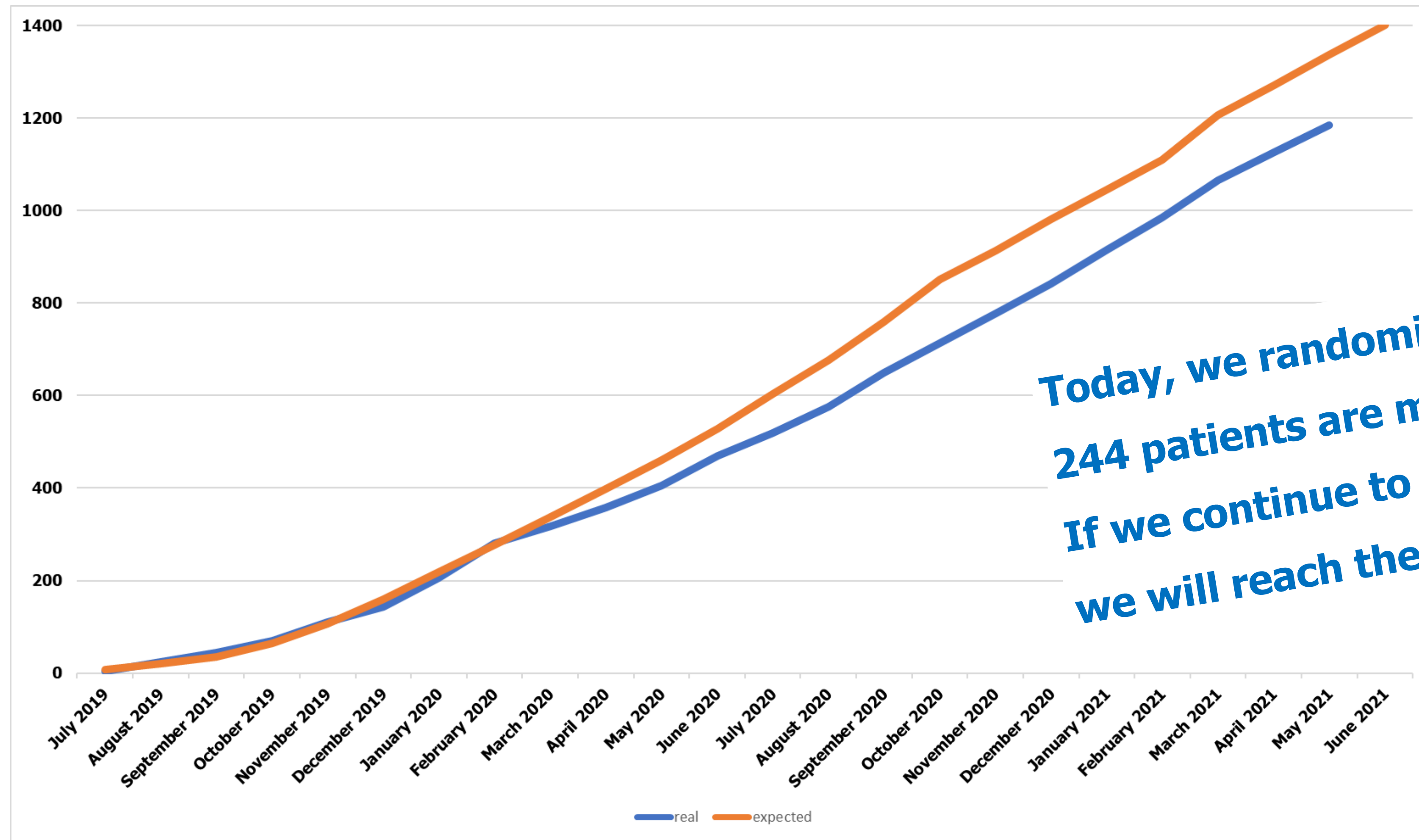
End primary endpoint follow-up August 2022

Main result presentation/publication ESC (August) 2023

Subanalyses, substudies, extended follow-up 2023-2027



Where we are ...



Today, we randomized 1156 patients
244 patients are missing
If we continue to enroll 60 pts/month ...
we will reach the sample size in September 2021



What we did ...

CENTERS	WEEKS IN 2021	N° OF PATIENTS ENROLLED	% ACHIEVED
FERRARA	19	89	100
REGGIO EMILIA	19	65	100
RIMINI	19	23	100
BOLOGNA MAGGIORE	19	18	95
SIRACUSA	19	17	89
TORINO RIVOLI	19	15	79
LA SPEZIA	19	11	58
MESTRE	19	10	53
VERONA BORGO TRENTO	19	8	42
GROSSETO	19	6	32

MODENA BAGGIOVARA	19	5	26
MESSINA POLICLINICO	19	5	26
RAVENNA	19	4	21
GIACCONE	19	3	16
MCH COTIGNOLA	19	1	5
MADDALONI	19	0	0
AGRIGENTO	19	0	0
CATANIA	19	0	0
CARDARELLI	19	0	0
CASERTA	19	0	0
MONCALIERI	19	0	0
PAVIA	19	0	0
SAVIGLIANO	19	0	0



What we did ...

CENTERS	WEEKS IN 2021	N° OF PATIENTS ENROLLED	% ACHIEVED
LA PAZ	19	13	68
LA FE	19	11	58
VALLADOLID	19	6	32
SAN CARLOS	19	4	21
SANTIAGO	19	1	5
VIGO	19	1	5
MARANON	19	0	0
CIUDAD REAL	19	0	0
LUGO	19	0	0
LA CORUNA	19	0	0

Monitoring of Adverse Events

PRIMARY ENDPOINT (JULY 2020) – MEDIAN FUP VALUE

CUMULATIVE MONTHS OF FUP	N° OF PATIENTS ENROLLED	MEDIAN FUP VALUE
8951	1125	7.1



SERIOUS ADVERSE EVENTS

DEATH	ANY MI	STROKE	ANY REVASCULARIZATION
54	20	4	14

93 patients met primary endpoint criteria

Next steps - Baseline Characteristics

We are reviewing eCRF of enrolled patients

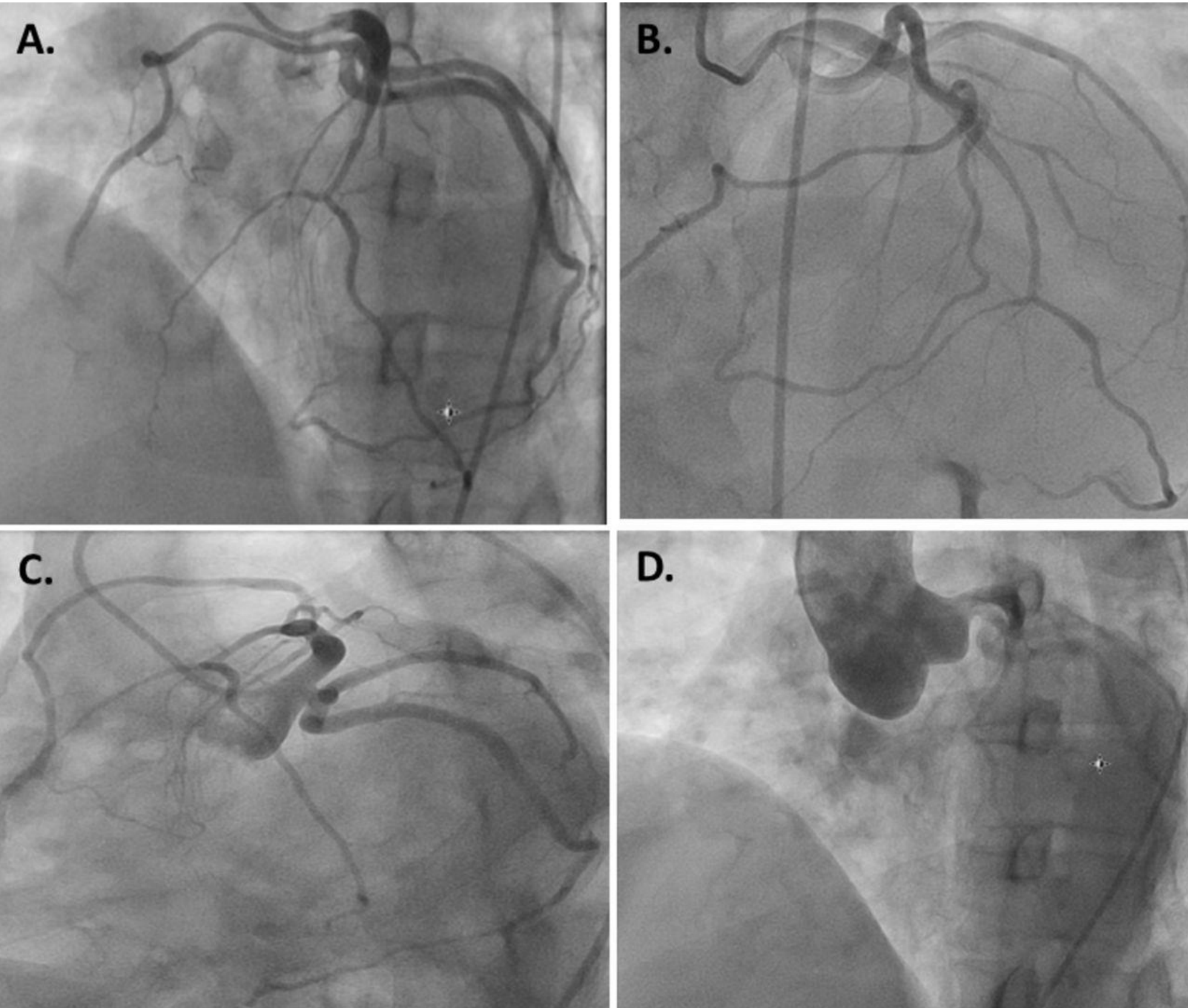
**It is crucial to complete within September 2021
the baseline eCRF**

We will generate potential queries

We will help you to fill the missing pieces



Next steps – Angio Core lab



We need a copy of the index angio for the core lab

You have 2 options:

- **Do a copy of the angio and we will organize the withdrawal**
- **We have a web-based cloud and you can upload here your cases**

Next steps – Adverse event adjudication

The CEC started its activities

What we need:

- **Report as soon as possible the adverse events**
- **Send us source docs for the adjudication**
- **We will contact you to complete 1-year follow-up**

