# The Minimizing Adverse Haemorrhagic Events By Transradial Access Site And Systemic Implementation of Angiox-MATRIX

## Final 1-Year Results


NCT01433627

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*on behalf of the **MATRIX Group***

# Declaration of Interest

I, Marco Valgimigli,

Served as a speaker, or advisor or consultant for:

The Medicines Company and Terumo

# Background

- MATRIX −the largest RCT comparing TRA vs TFA in ACS− reported a 30-day net adverse clinical events (NACE) benefit, driven by mortality and bleeding, in favor of the radial approach
- It is unknown whether the short-term benefits of radial access are maintained at longer-term follow-up
- Multiple studies reported on longer-term comparative effectiveness of bivalirudin vs UFH±GPI, but results remain controversial and in none of them access site was randomly allocated
- No study has so far randomized pts receiving bivalirudin to continue or stop the Tx after PCI

# MATRIX Program

NCT01433627

## NSTEACS or STEMI with invasive management

**Aspirin+P2Y12 blocker**

**1:1**

**Trans-Radial Access** | **ACCESS** | **Trans-Femoral Access**

**1:1**

**Bivalirudin** Mono-Tx | **ANTITHROMBIN TYPE** | **Heparin** ±GPI

**1:1**

**Stop Infusion** | **Prolong≥ 4 hs infusion** | **TREATMENT DURATION**

30-day results avaialble at Lancet. 2015; 385(9986):2465-76 and N Engl J Med 2015; 373: 997–1009

# Study Organization and Sites

**Sponsor** Italian Society of Interventional Cardiology

**Grant suppliers:** The Medicines Company and Terumo

**Principal Investigator:** **Marco Valgimigli,** *MD, PhD*

**Study Director:** **Maria Salomone**. *MD, PhD*

78 Sites across 4 EU countries recruited patients

**National Coordinating Investigators and CROs**

Paolo Calabrò, MD, PhD, *Italy*; Trial Form Support
Arnoud W J van't Hof, MD, *The Netherlands*; Trial Form Support
Manel Sabate', MD, PhD, *Spain;* FLS-Research Support
Elmir Omerovic, MD, PhD, *Sweden;* Gothia Forum

**Clinical Event Committee**

**P. Vranckx,** *Chair*
**S. Leonardi** *Co-Chair*
P. Tricoci

**Statistical Committee (CTU)**

**P.Jüni,** MD, Chair
M. Rothenbühler
Dik Heg

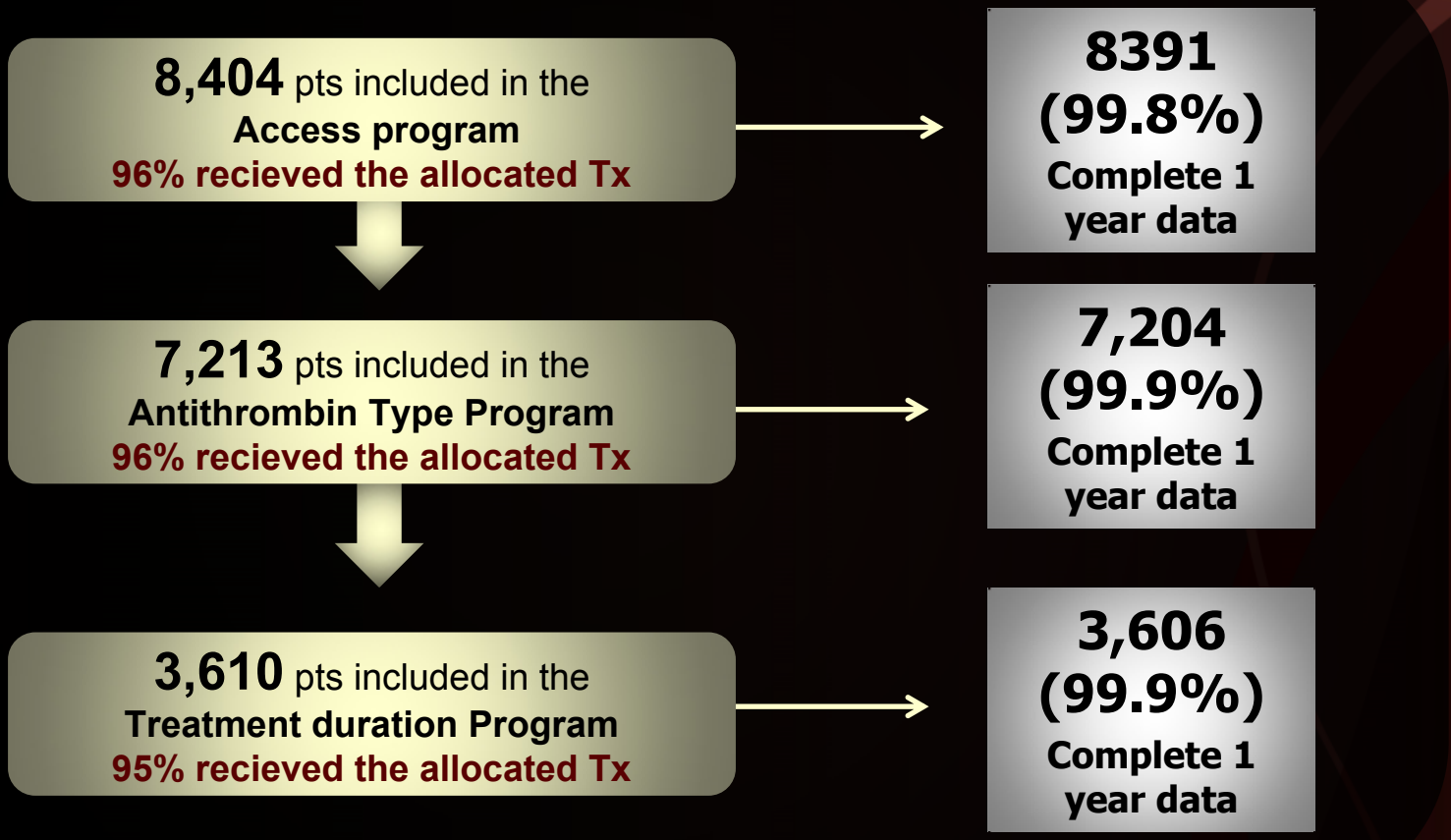
**Data Mng**

**E. Frigoli**,
Project Leader

# Endpoints

- Co-primary outcomes at 30 days for MATRIX *Access* and MATRIX *Antithrombin* were:
  - **MACE: composite of death, MI and stroke**
  - **NACE: composite of death, MI, stroke and major bleeding (BARC 3 or 5)**
- The primary outcome at 30 days for MATRIX *Treatment Duration* was composite of **urgent target vessel revascularisation, definite stent thrombosis, or net adverse clinical events ( NACE +)**
- Secondary outcomes included all primary EPs within 1 year and each component of the composite outcomes

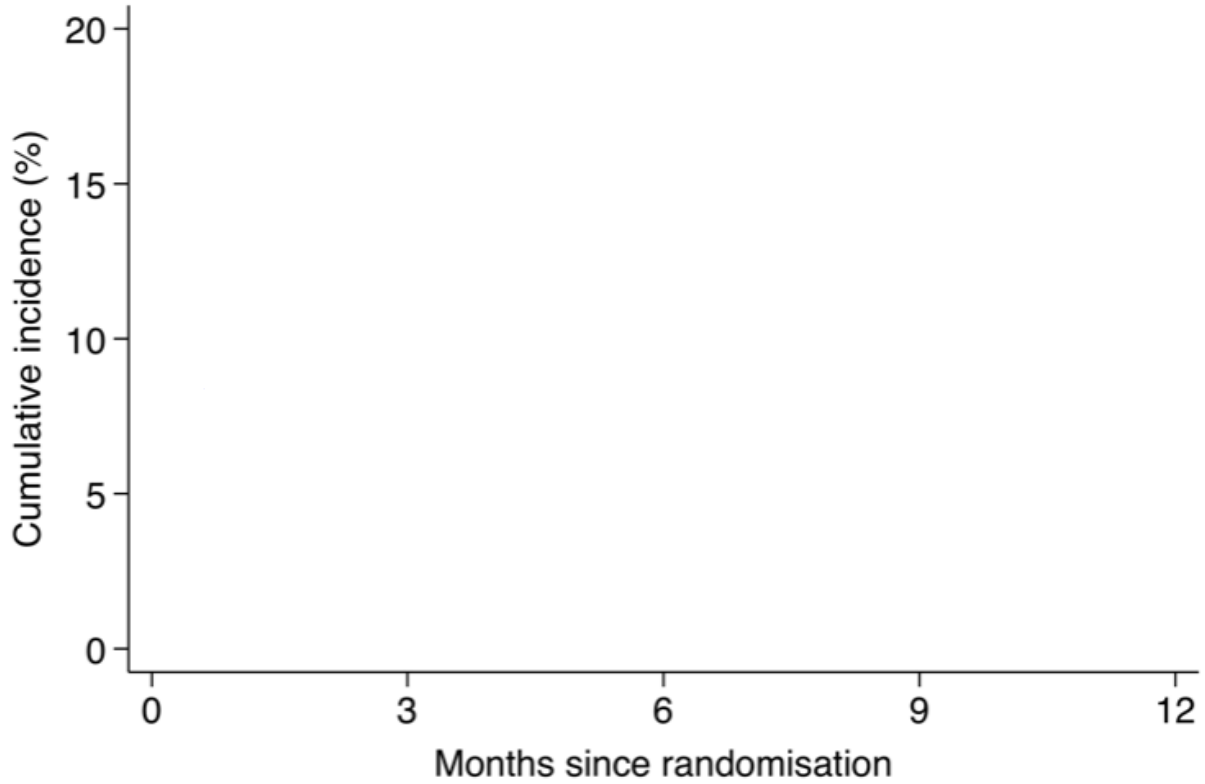
# Patient disposition, baseline characteristics and drug adherence




- Baseline characteristics were well matched
- Adherence to secondary prevention medications was similarly high

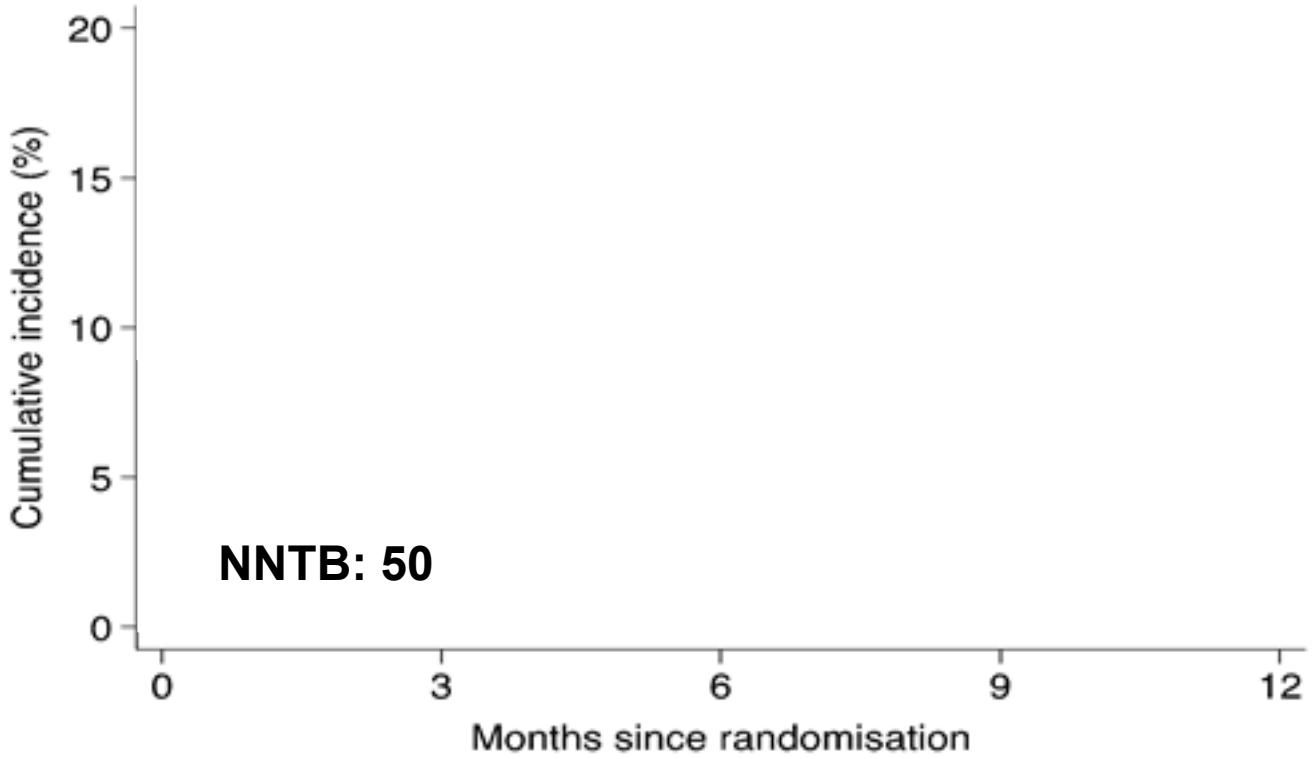
ACCESS

# 1-Year Major Adverse CV events



ACCESS

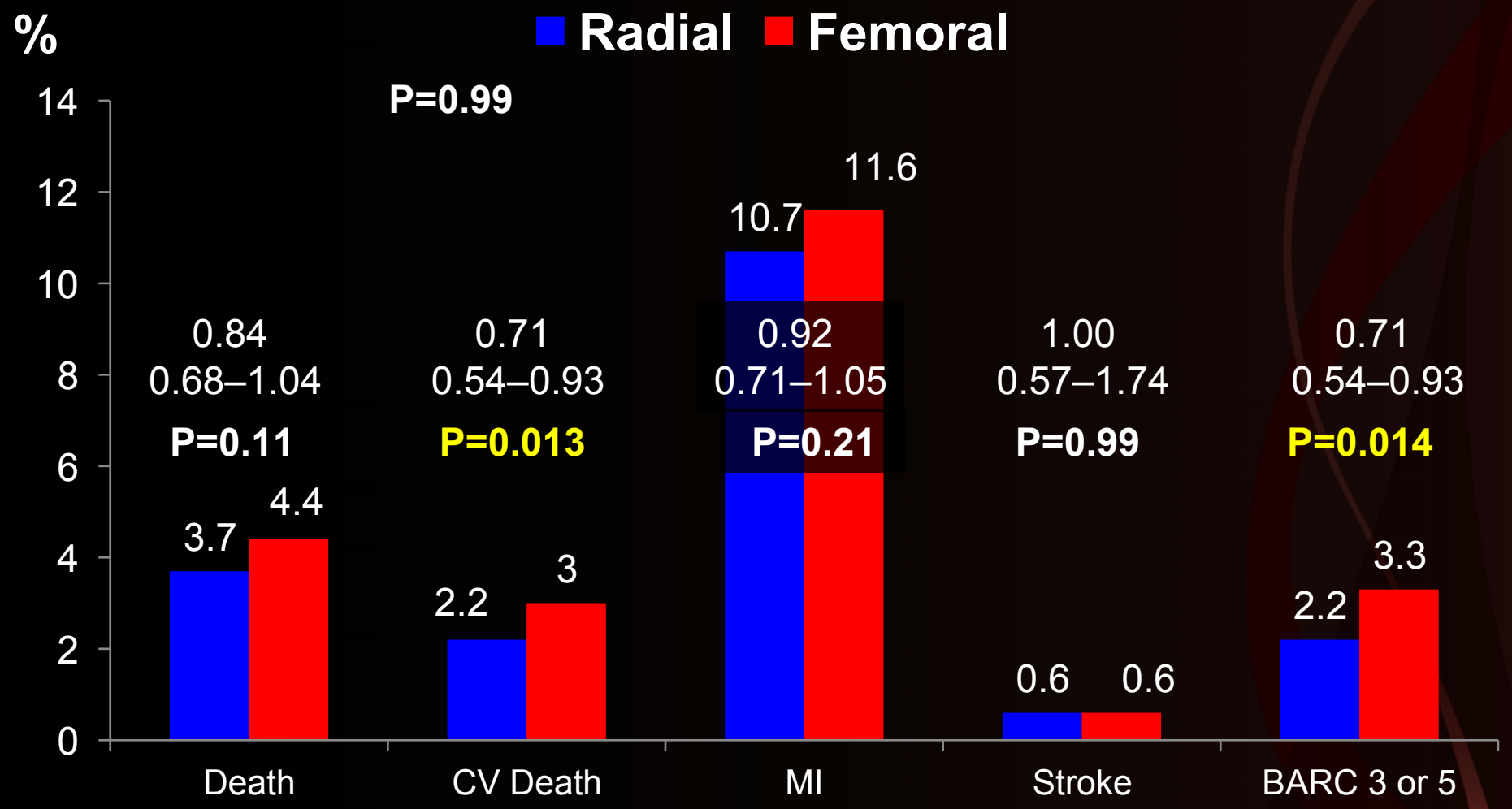
# 1-Year Net Adverse Clinical Events



ACCESS

# 1 Year NACE Components

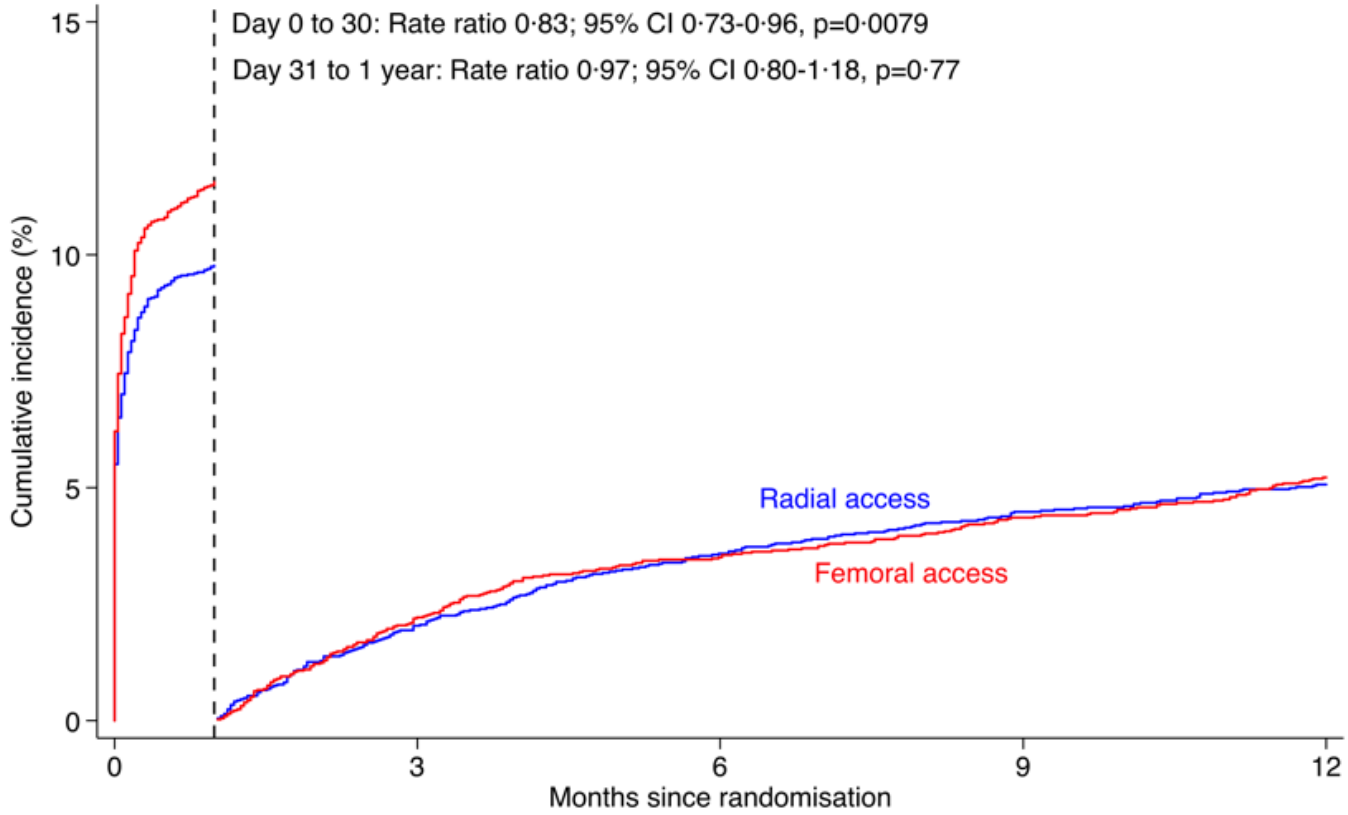
*(CV) Death, MI, Stroke and BARC 3 or 5*



ACCESS

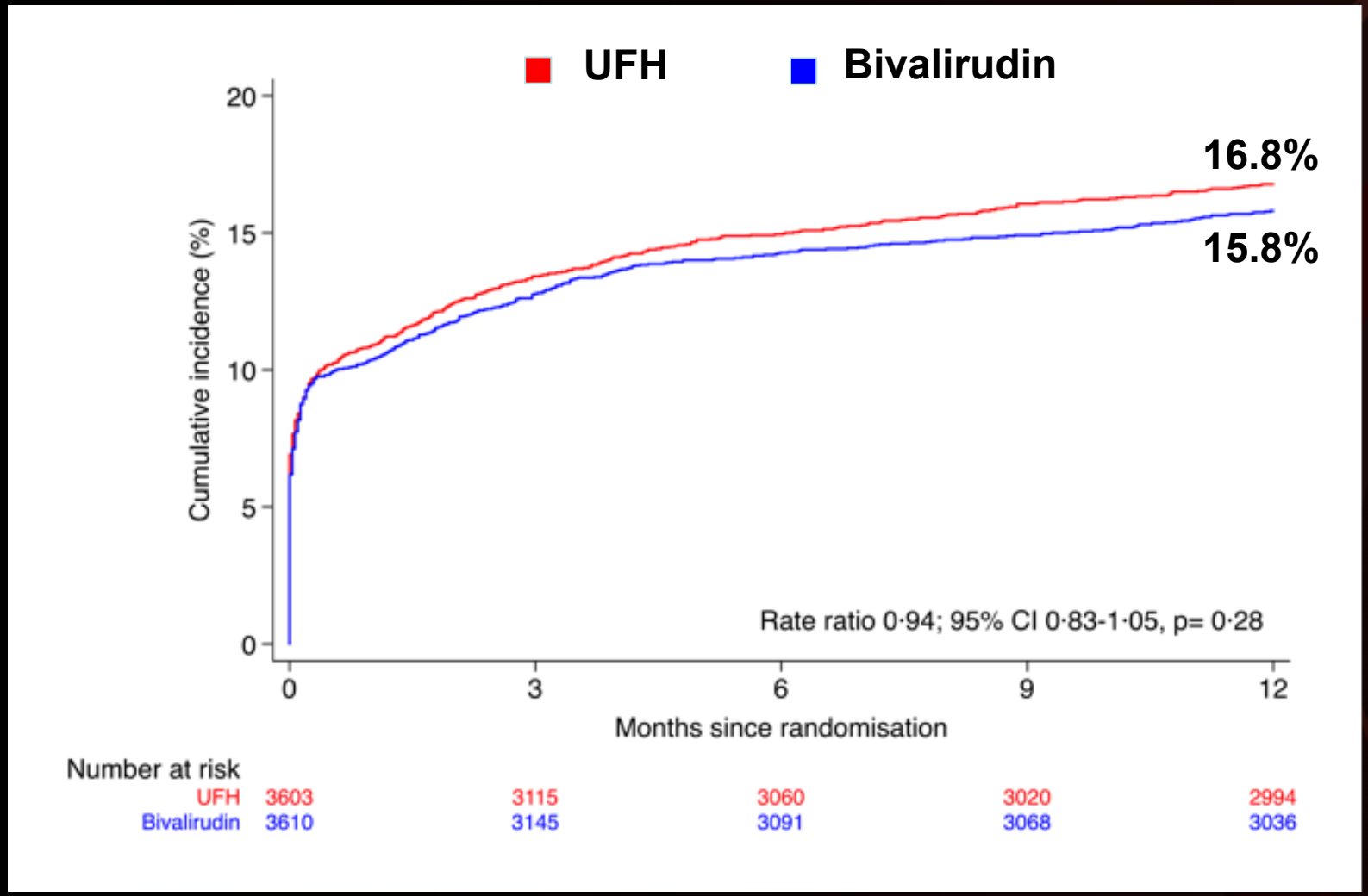
# 1-Year Net Adverse Clinical Events

## Period Analysis

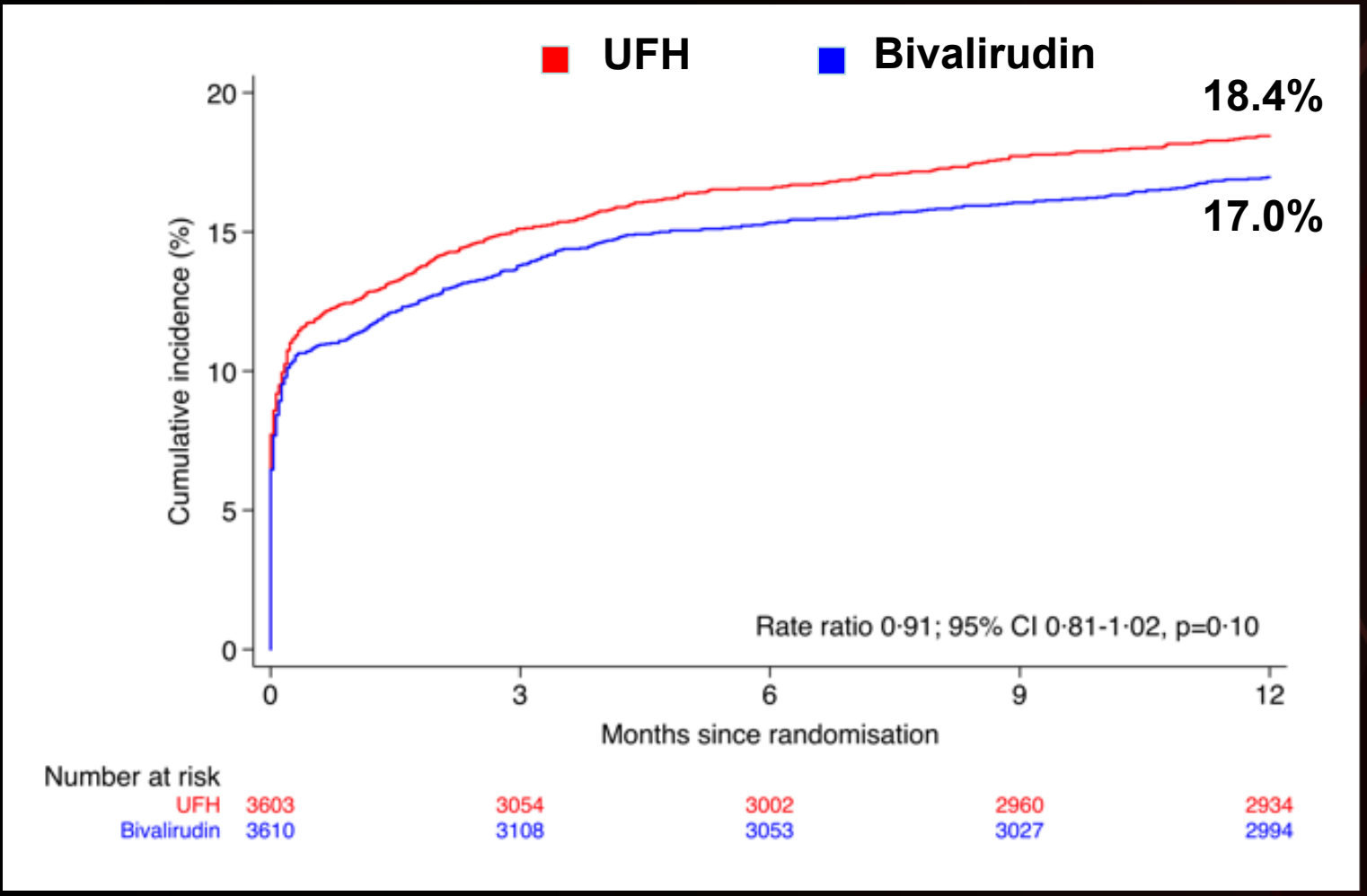


ANTITHROMBIN

# 1-Year Major Adverse CV Events



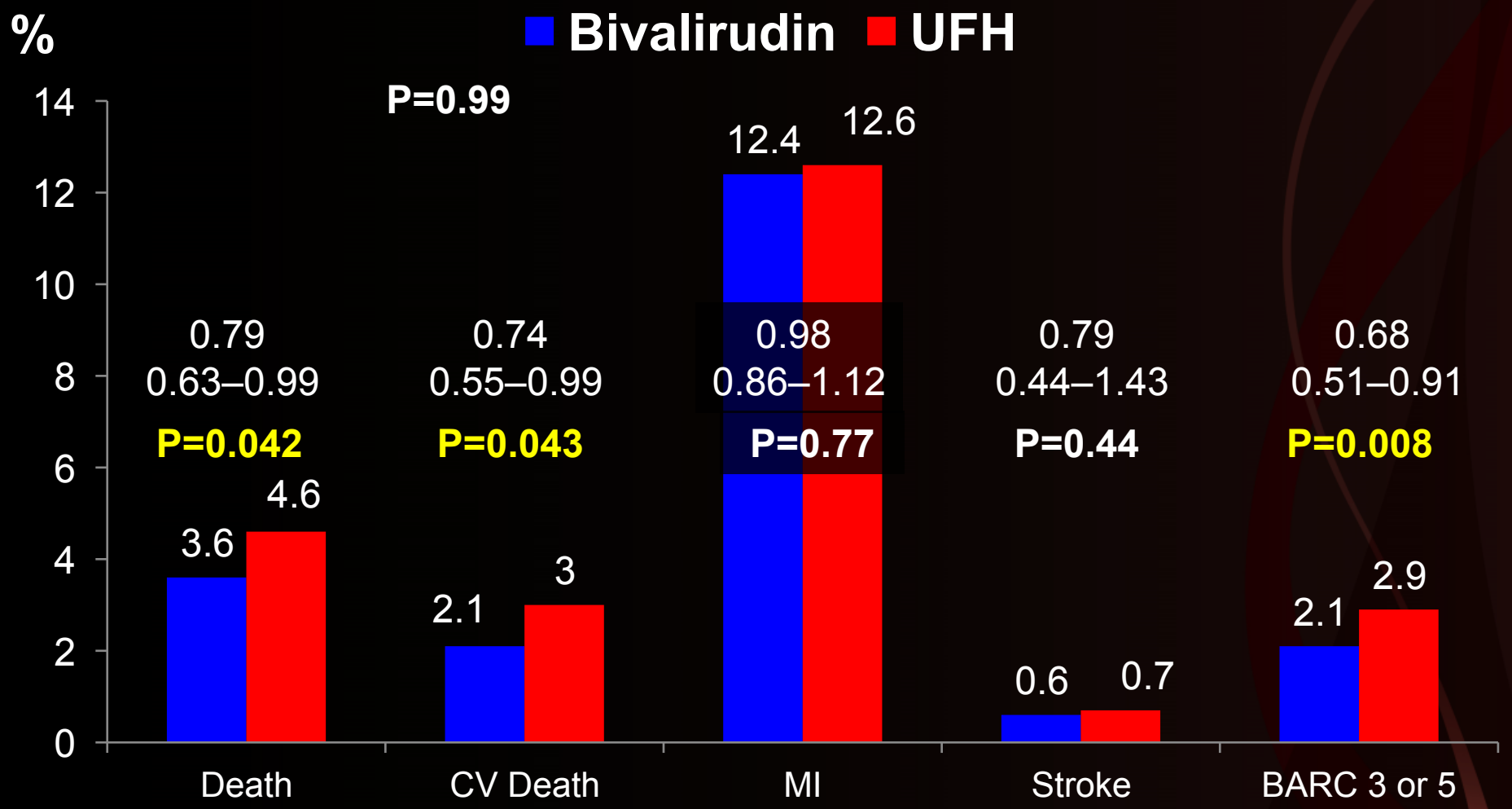
# 1-Year Net Adverse Clinical events



ANTITHROMBIN

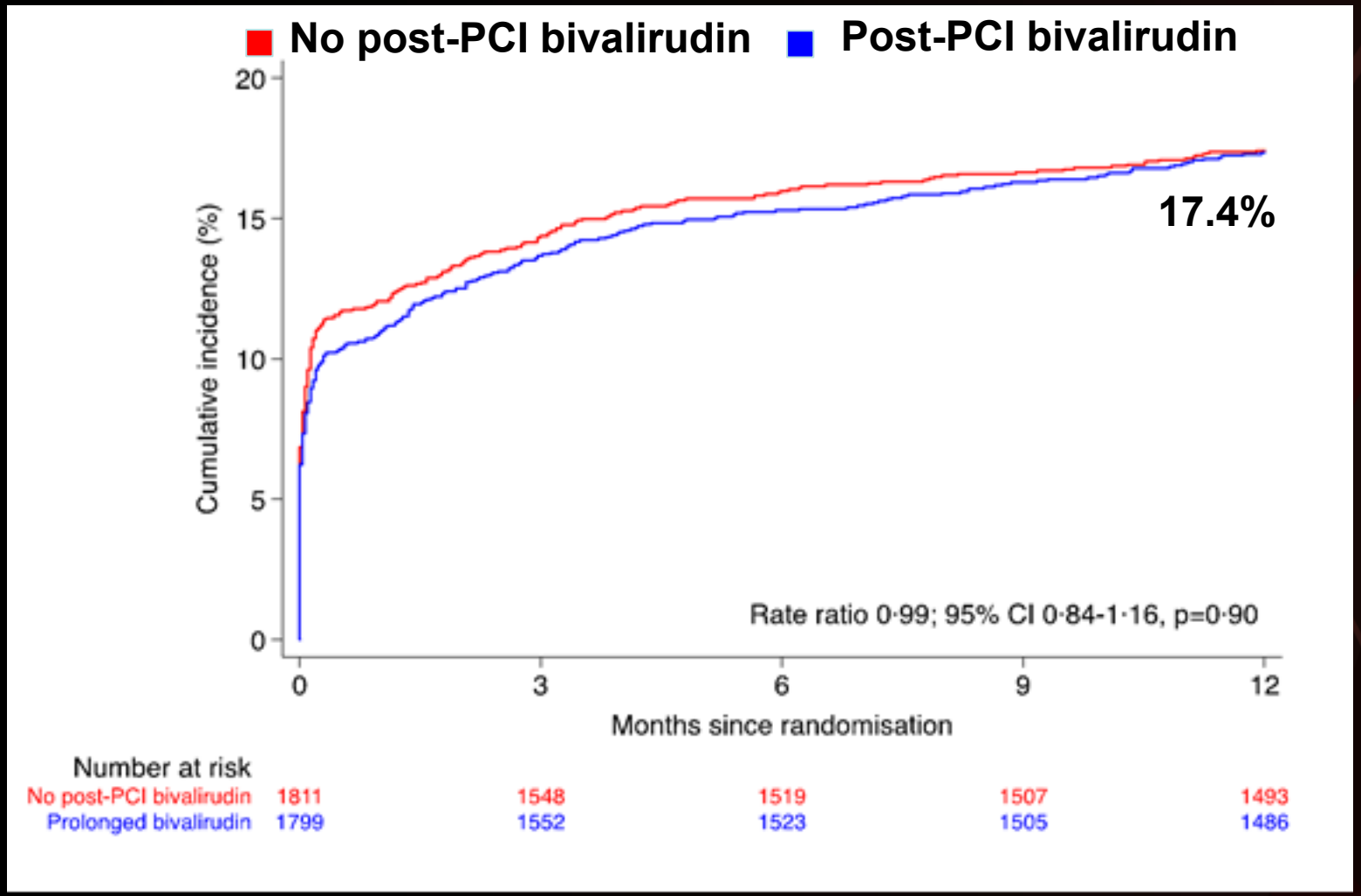
# 1 Year NACE Components

*(CV) Death, MI, Stroke and BARC 3 or 5*



# 1-Year Net Adverse Clinical Events +

*Urgent TVR, definite ST, or Net adverse clinical events*



# Post-PCI Bivalirudin Rx

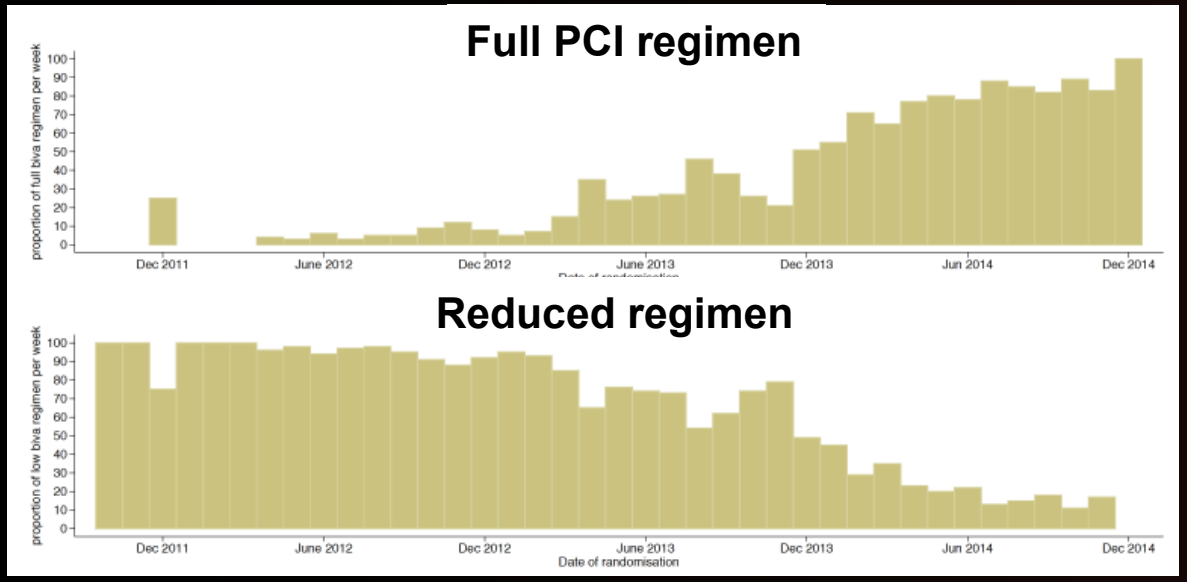
## Regimens and temporal distribution

- Bivalirudin could be administered at*:
  - the full PCI dose (1.75mg/kg/h) for up to 4 hours

or

  - the reduced dose of 0.25 mg/Kg/h for at least 6 hours

*: with the choice between those two regimens made at the discretion of the treating physicians



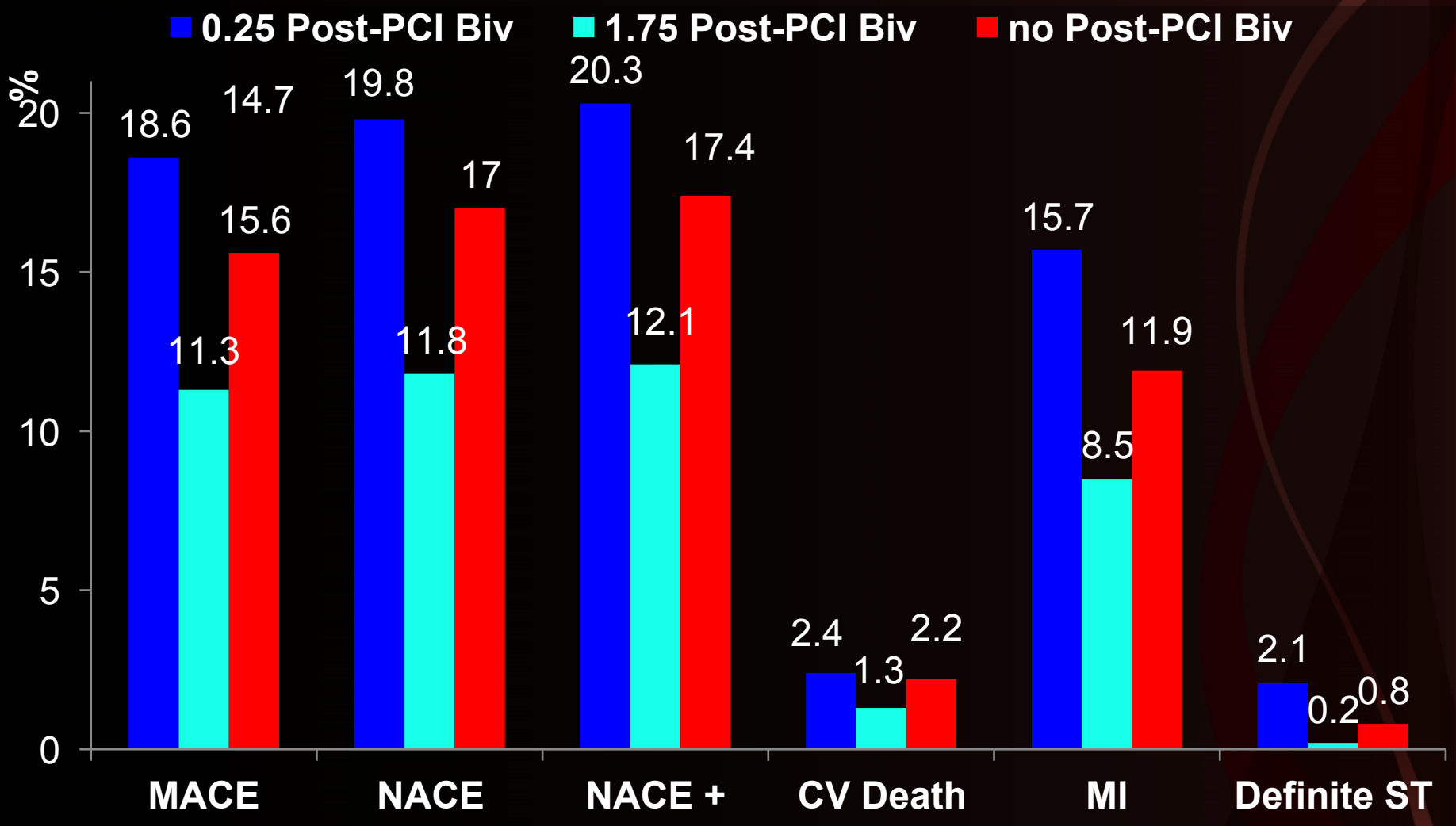

**34%**
Infusion duration: **264**'

**59%**
Infusion duration: **433**'

N=119 (**6.6%**) received no post-PCI bivalirudin in the post-PCI bivalirudin arm

# Exploratory Analysis*

## Efficacy endpoints according to bivalirudin regimen




* The choice of post-PCI bivalirudin regimen was at discretion of the investigator

# MATRIX@1 year: Summary

- The radial access reduced the 1 year NACE rates, owing to a durable effect on CV death and bleed
- The use of bivalirudin did not reduce MACE or NACE rates although its effects on mortality and bleeding persisted at 1 year as compared to UFH±GPI
- Post-PCI bivalirudin infusion did not reduce 1 year NACE+ rates compared to no post-PCI bival. *However, the post-PCI low regimen was associated to higher and the full dose to lower ischemic risks at exploratory analysis.*

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Doctopic: Primary Research

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# Radial versus femoral access and bivalirudin versus unfractionated heparin in invasively managed patients with acute coronary syndrome (MATRIX): final 1-year results of a multicentre, randomised controlled trial

*Marco Valgimigli, Enrico Frigoli, Sergio Leonardi, Pascal Vranckx, Martina Rothenbühler, Matteo Tebaldi, Ferdinando Varbella, Paolo Calabrò, Stefano Garducci, Paolo Rubartelli, Carlo Briguori, Giuseppe Andó, Maurizio Ferrario, Ugo Limbruno, Roberto Garbo, Paolo Sganzerla, Filippo Russo, Marco Nazzaro, Alessandro Lupi, Bernardo Cortese, Arturo Ausiello, Salvatore Ierna, Giovanni Esposito, Giuseppe Ferrante, Andrea Santarelli, Gennaro Sardella, Nicoletta de Cesare, Paolo Tosi, Arnoud van 't Hof, Elmir Omerovic, Salvatore Brugaletta, Stephan Windecker, Dik Heg, Peter Jüni, on behalf of the MATRIX Investigators*