



# Predictors of Outcomes in Patients Undergoing Elective or Primary PCI

## The RIVIERA Study

*Registry on Intra-Venous Anticoagulation In the Elective and Primary Real World of Angioplasty*

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# Objectives

- **Characterize current practice** patterns in modern PCI with a wide representation of countries around the world
- **Investigate use of anticoagulation** with UFH or LMWH during elective or primary PCI, in patients not pretreated with UFH or LMWH
- **Identify independent predictors** of adverse clinical and angiographic complications



# Methods (I)

- RIVIERA: multinational, prospective, observational study
- Inclusion criteria:
  - Centers with > 100 cases / year
  - Balance between centers using UFH or enoxaparin
  - First 10 consecutive, eligible patients per month
  - Admitted for elective *or* primary PCI and > 21 years
- Exclusion criteria:
  - Therapeutic doses of anticoagulant before PCI
  - Enrolled in clinical trial
- In-hospital clinical and angiographic complications recorded on CRF



## Methods (II)

- Clinical outcomes:
  - In-hospital death or MI, death, MI\*, bleeding\*\*
- Angiographic complications:
  - No reflow
  - Thrombus at lesion site
  - Occlusion of collateral branches
  - Distal embolism
  - Coronary dissection
  - Acute vessel closure
  - Coronary rupture
  - Other

\*MI: new significant Q waves in  $\geq 2$  contiguous leads; elevation in CK or CK-MB  $\geq 3 \times$  ULN  $< 2$  days of revascularization or  $\geq 2 \times$  ULN outside the setting of revascularization

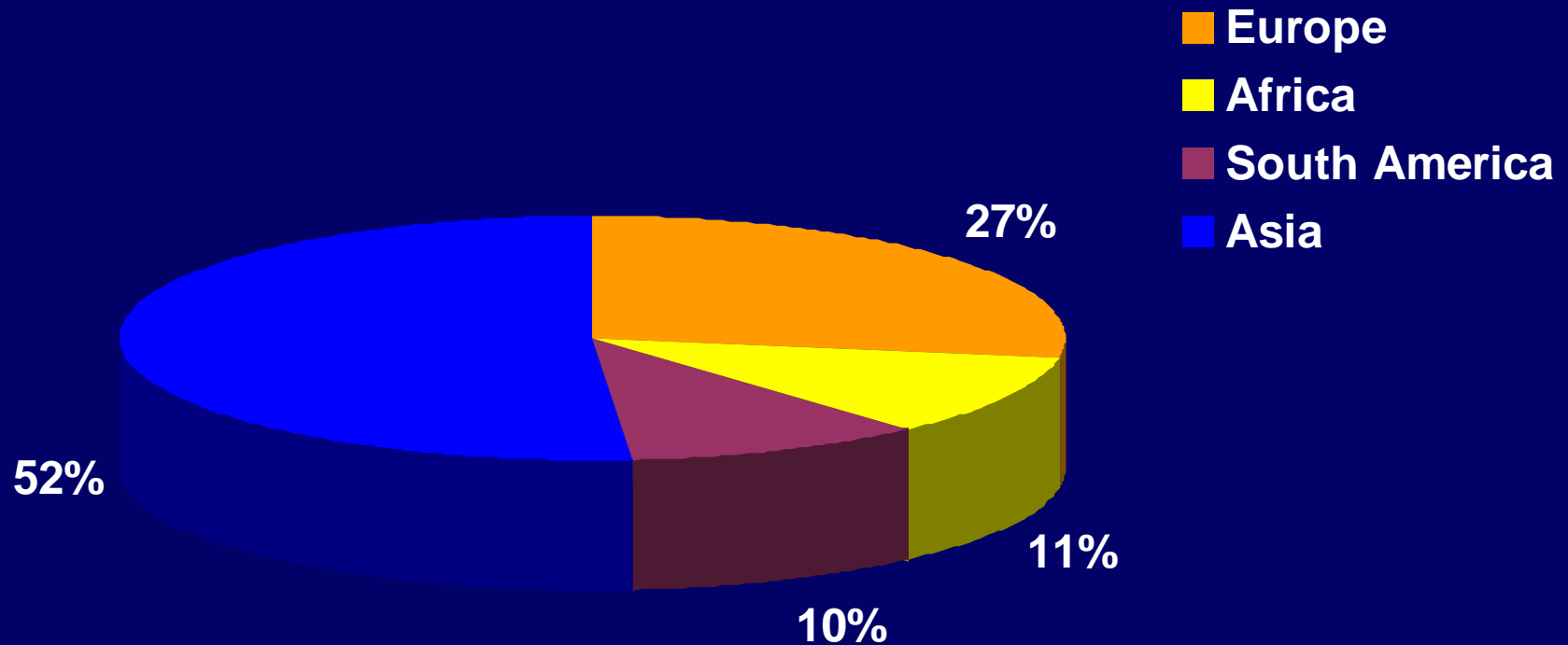
\*\*Major bleeding: resulting in death; intracranial, intraocular or retroperitoneal; clinically overt with a decrease in hemoglobin  $> 4$  g/dL; transfusion of  $\geq 2$  units of PRBC or whole blood.

# **Baseline Characteristics**



# Enrolment

7962 consecutive patients enrolled for elective or primary PCI in 144 hospitals across 23 countries





# Baseline Characteristics (I)

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## Demographics

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Age (years, mean)	59
Male sex (%)	77
Race (%)	
Caucasian	43
Asian	51
African	1.2
Hispanic	4.7

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# Baseline Characteristics (II)

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## Medical history (%)

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Current smoker	30
Hypercholesterolemia	46
Diabetes	32
BMI (kg/m <sup>2</sup> , mean)	27
Hypertension	62
Myocardial infarction	31
CABG	5
PTCA	13

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# Baseline Characteristics (III)

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## Clinical presentation (%)

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Asymptomatic or stable angina	45
NSTEMI-ACS	36
STEMI $\leq$ 12 hours onset	9
STEMI $>$ 12 hours onset and $<$ 30 days	11
Other	7

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# Procedural Characteristics (I)

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## Procedural characteristics (%)

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Elective PCI	92
Primary PCI	8
Femoral approach	89
Radial approach	11
Guiding catheter	
5 F	1.8
6 F	74.6
7 F	22.8
8 F	0.7

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# Procedural Characteristics (II)

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## Procedural characteristics

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Number of stents placed (%)

0	5
1	67
2	22
3	5
> 3	1

Total stent length (mm, mean) 27

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# In-Hospital Treatment

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Anticoagulation therapy (%)	
UFH only	36
Enoxaparin only	58
UFH + enoxaparin, or other drug	6
Aspirin	95
Clopidogrel	89
Ticlopidine	12
GP IIb/IIIa inhibitors	18

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# Antithrombotic Therapy

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Anticoagulation therapy, U/kg	Mean $\pm$ SD
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UFH	109 $\pm$ 37
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Enoxaparin	80 $\pm$ 23
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Other LMWH	69 $\pm$ 14
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Other antithrombotic therapy, mg	
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Clopidogrel loading dose	310 $\pm$ 127
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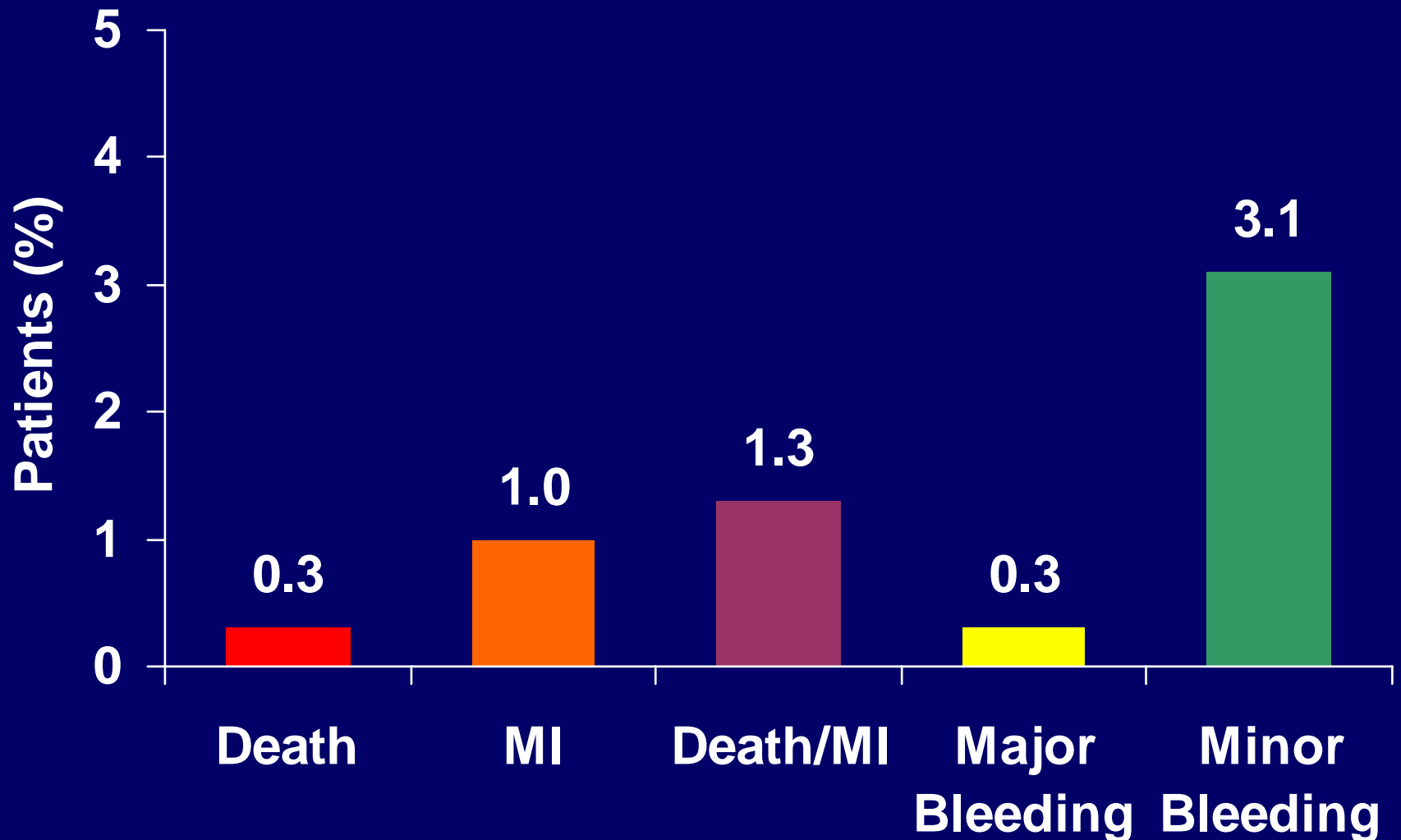
Ticlopidine loading dose	447 $\pm$ 126
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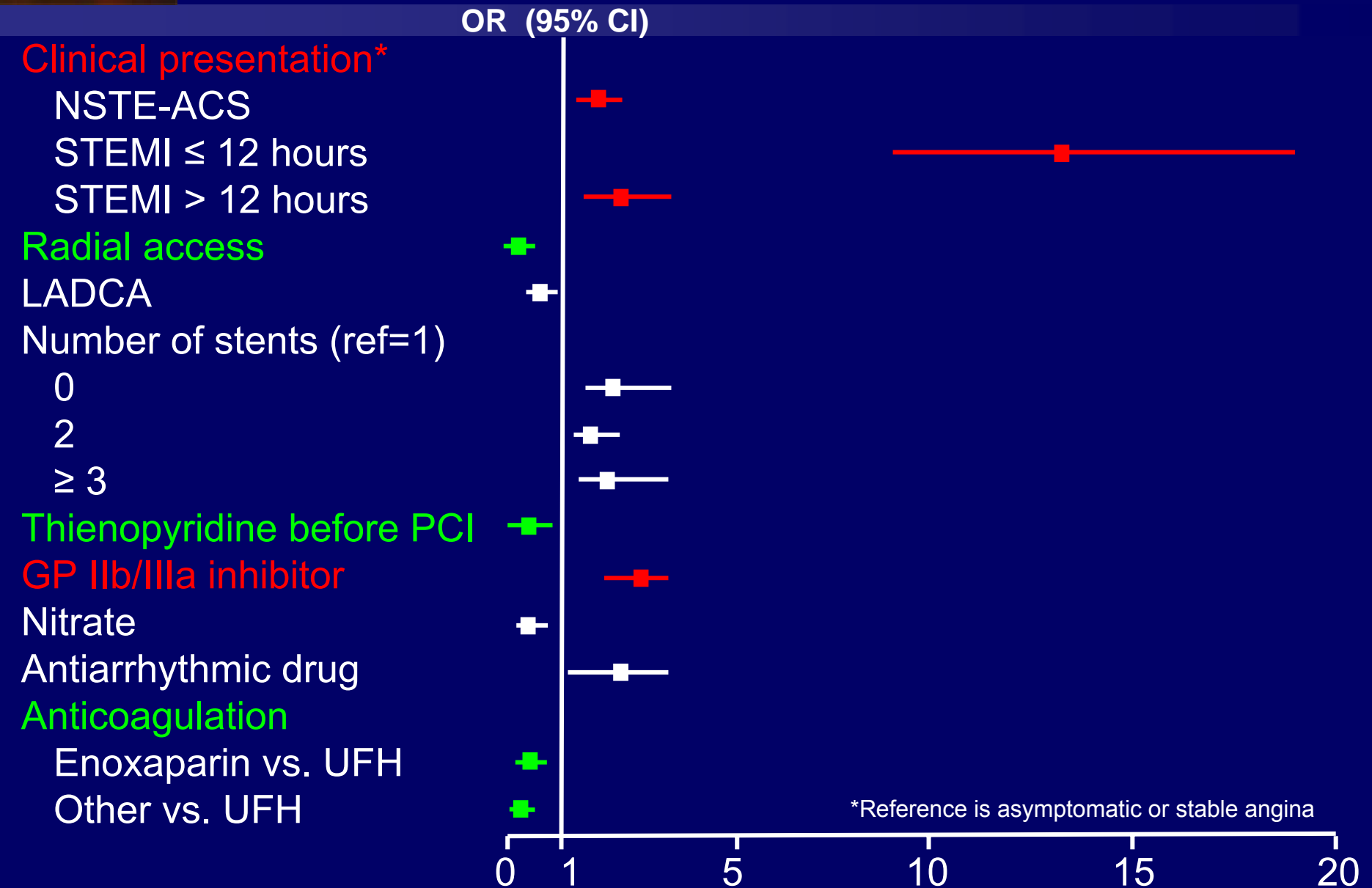
# Study Results



# In-Hospital Outcomes



# Independent Predictors of Death or MI



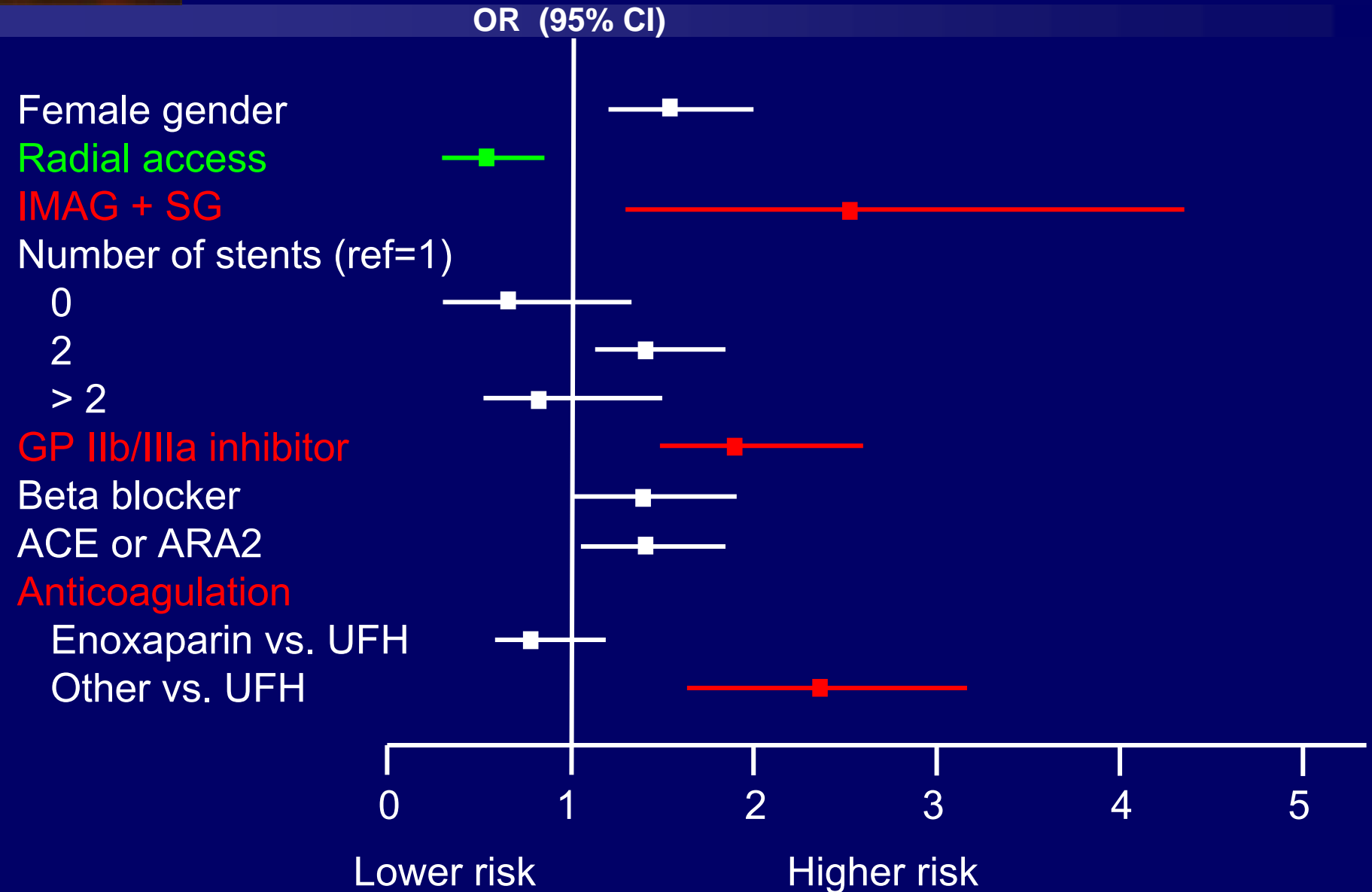


# Independent Predictors of Death

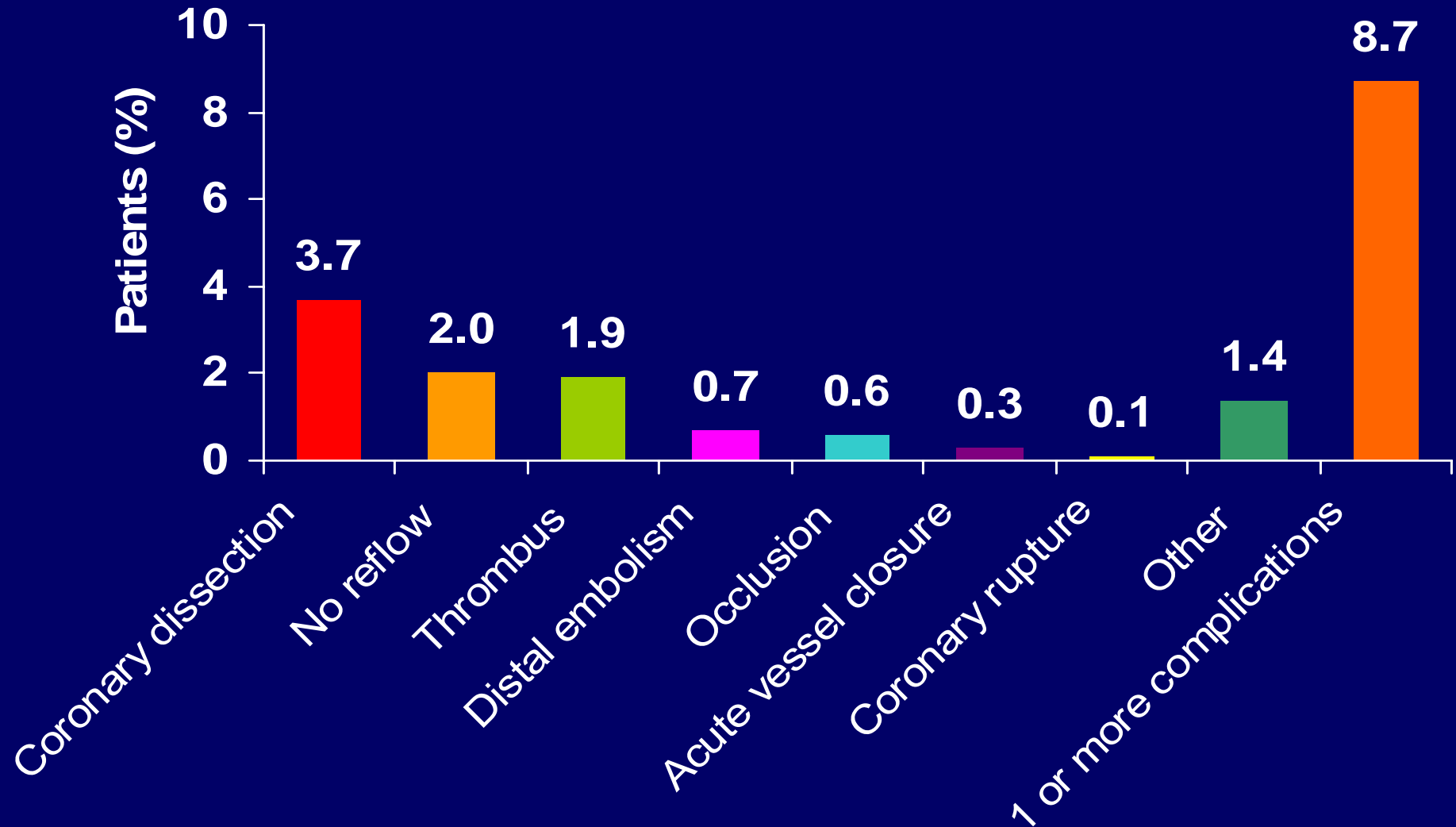
Variable	OR (95% CI)	<i>P</i>
Female gender	6.25 (2.0-20.0)	0.002
Clinical presentation*		
NSTE-ACS	8.12 (0.93-70.63)	0.004
STEMI ≤ 12 hours	10.54 (0.89-124.42)	
STEMI > 12 hours	43.90 (4.86-396.79)	
PCI of left main trunk	22.18 (4.89-109.86)	<0.001
Thienopyridine pretreatment	0.06 (0.02-0.20)	<0.001
Statin	0.21 (0.07-0.65)	0.007
Nitrate	0.17 (0.05-0.56)	0.004

\*Reference is asymptomatic or stable angina

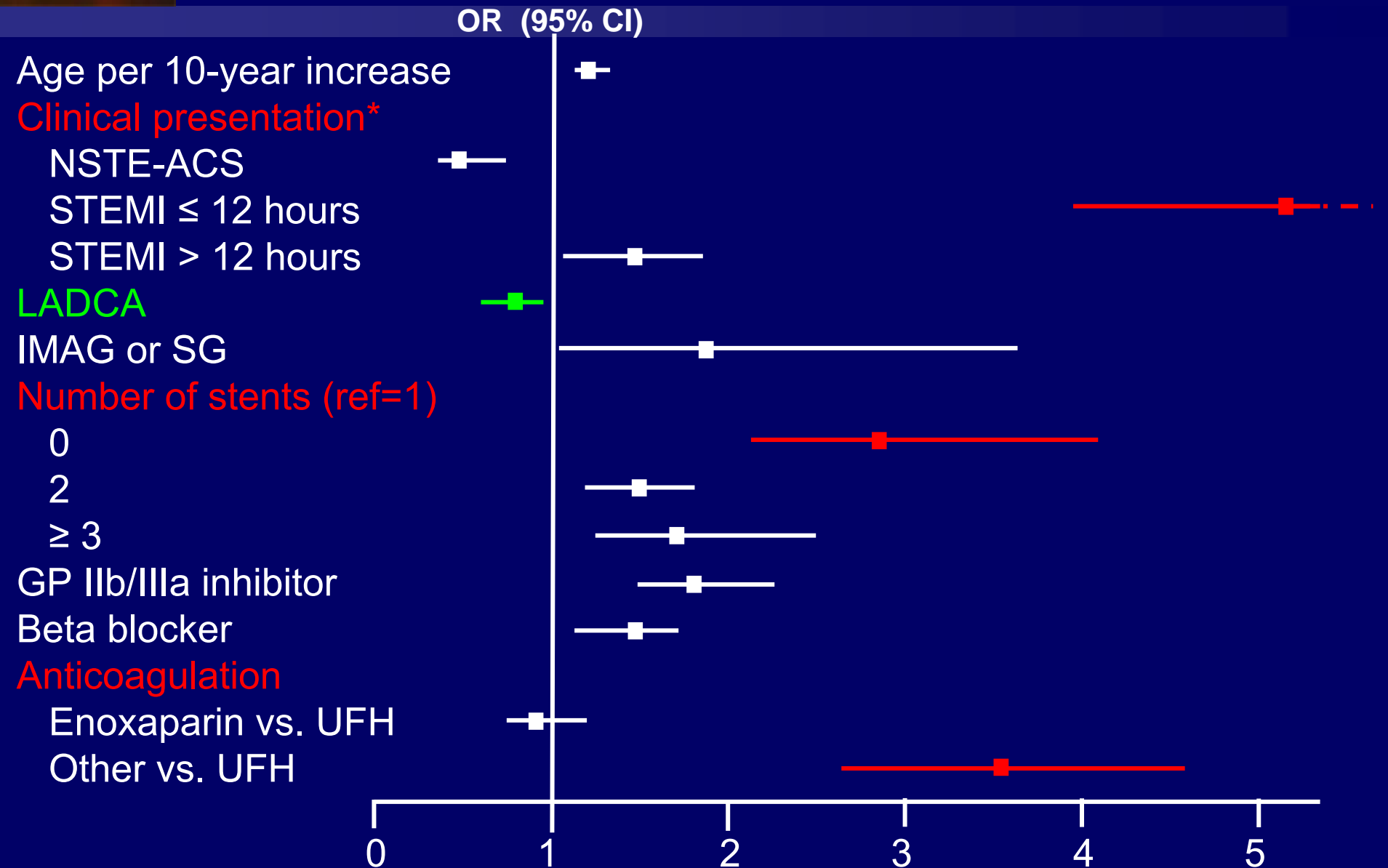
# Independent Predictors of Bleeding



# Angiographic Complications



# Independent Predictors of Any Angiographic Complications





# Conclusions (I)

- Rates of ischemic and bleeding complications were lower than those usually reported in RCTs or Registries
- We have identified several factors associated with an increased risk of major complications in RIVIERA:
  - PCI of the left main trunk (more death)
  - PCI of grafts (more bleeding)
  - Clinical presentation (more angiographic and ischemic complications)



## Conclusions (II)

- Many of the risk factors are modifiable, suggesting that improvements can be made in the clinical outcomes:
  - Statin, thienopyridine pretreatment, enoxaparin (less ischemic events)
  - GP IIb/IIIa inhibitors (more bleeding)
  - UFH + enoxaparin (more bleeding)
  - Radial access (less bleeding and ischemic events)