NAPLES

Novel Approaches for Preventing or Limiting Event Study

Randomised Comparison of Bivalirudin Monotherapy versus Unfractionated Heparin plus Tirofiban in Diabetic Patients Undergoing Elective Coronary Stenting

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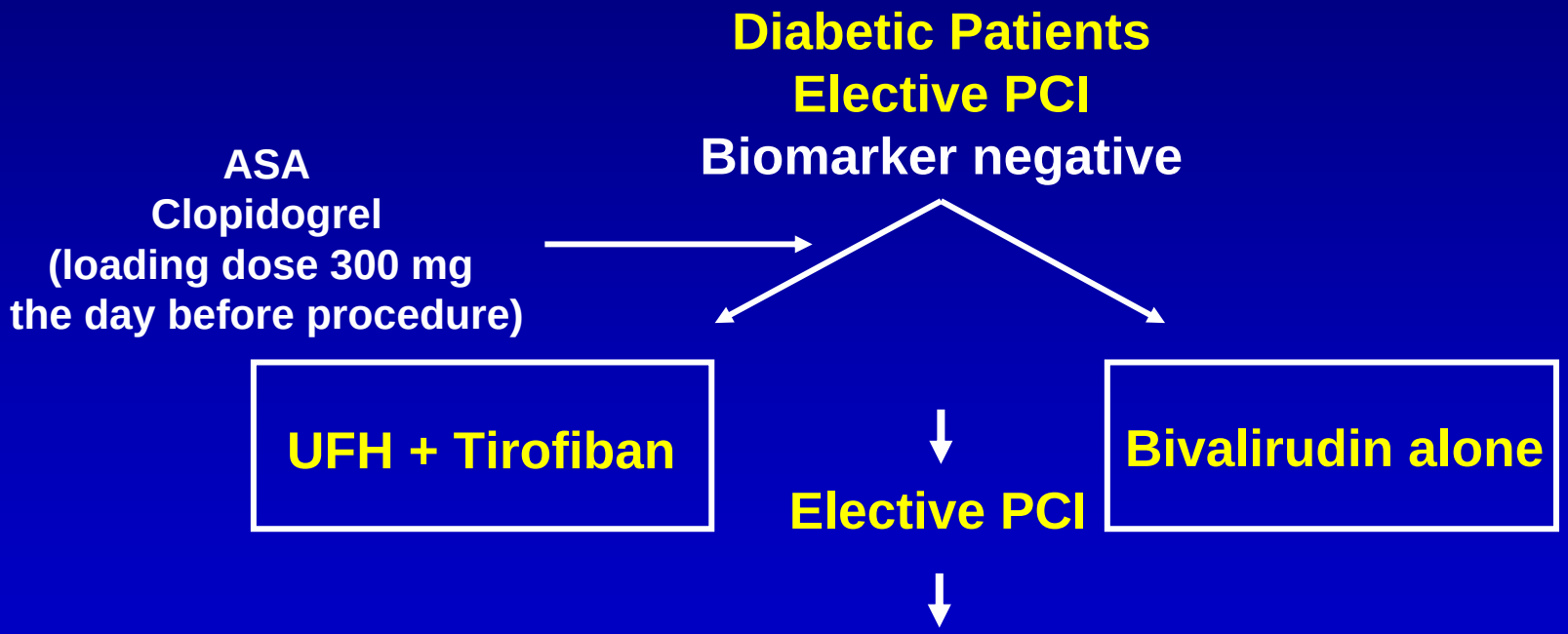
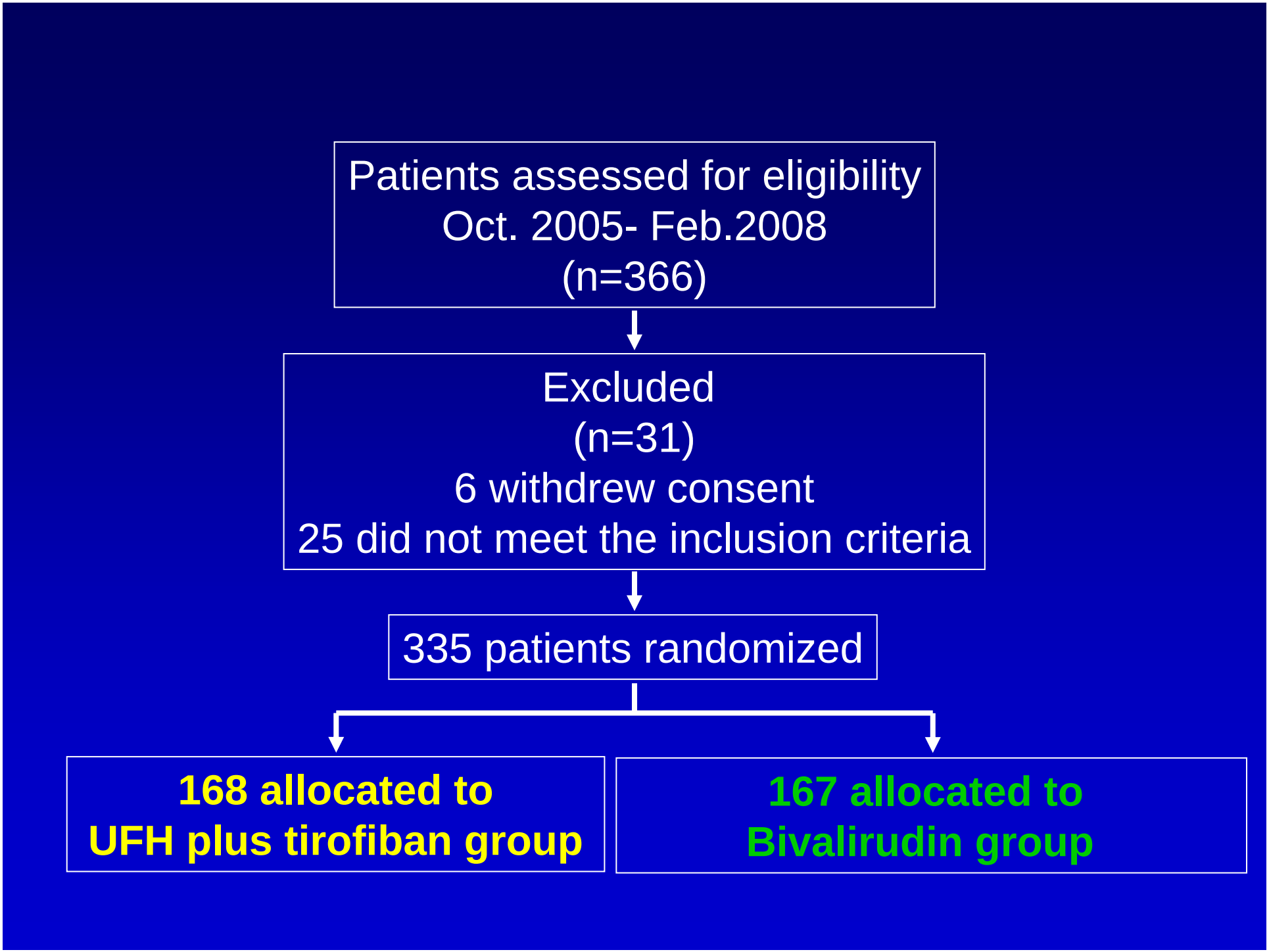
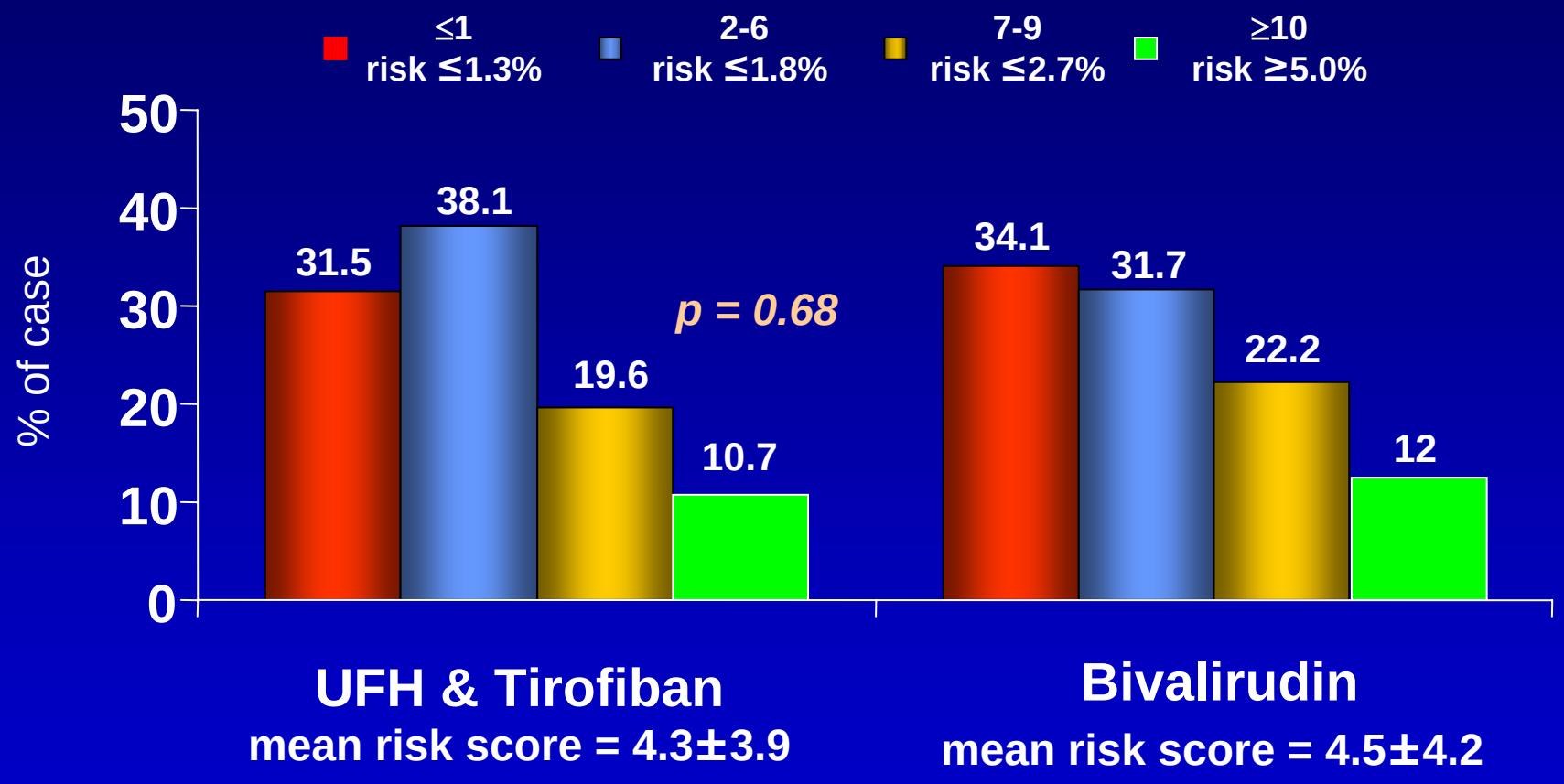
DESIGN: Prospective, randomized, double-arm, single-center clinical study




Patients assessed for eligibility
Oct. 2005- Feb.2008
(n=366)
Excluded
(n=31)
6 withdrew consent
25 did not meet the inclusion criteria
335 patients randomized
168 allocated to
UFH plus tirofiban group
167 allocated to
Bivalirudin group

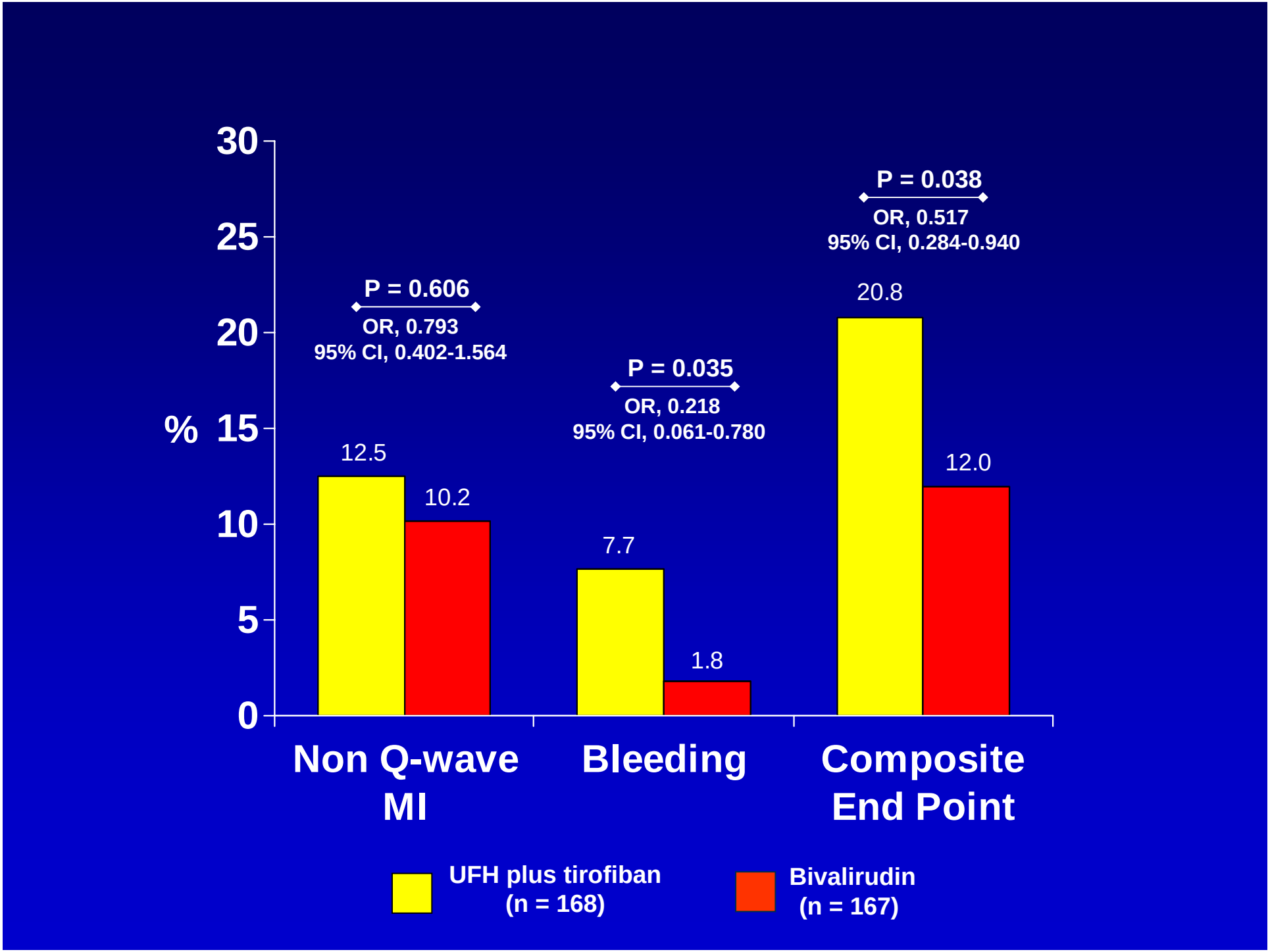
Bleeding risk score*



* According to Nikolsky E. et al. *Eur Heart J* 2007; 28: 1936-45

30-day outcome

	UFH + Tirofiban (N=168)	Bivalirudin alone (N=167)	P value
Net clinical outcome	35 (20.8%)	20 (12%)	0.038
Death	0	0	
MI	21 (12.5%)	17 (10.2%)	0.61
Q-wave MI	0	0	
Non Q-wave MI	21 (12.5%)	17 (10.2%)	0.61
Unplanned revasc	0	0	
Bleeding	13 (7.7%)	3 (1.8%)	0.018
Major	3 (1.8%)	1 (0.6%)	0.623
Minor	10 (6%)	2 (1.2%)	0.035


30
25
20
15
10
5
0
%
P = 0.606
OR, 0.793
95% CI, 0.402-1.564
P = 0.035
OR, 0.218
95% CI, 0.061-0.780
P = 0.038
OR, 0.517
95% CI, 0.284-0.940
12.5
10.2
7.7
1.8
20.8
12.0
Non Q-wave MI
Bleeding
Composite End Point
UFH plus tirofiban (n = 168)
Bivalirudin (n = 167)

Conclusions

- In diabetic patients undergoing elective PCI the antithrombotic strategy of bivalirudin monotherapy compared with unfractionated heparin plus tirofiban is safe and feasible.

- Antithrombotic regimen with bivalirudin alone suppresses adverse 30-day ischaemic events to a similar extent as does unfractionated heparin plus tirofiban.

- Bivalirudin administration compared with unfractionated heparin plus tirofiban is associated with a reduction of bleeding.

- Bivalirudin administration, compared with unfractionated heparin plus tirofiban, results in a significant decrease of the composite end-point of 30-day death, urgent revascularization, myocardial infarction and bleeding.