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On behalf of the FATA Investigators

Washington DC, October 14th 2008

Study design

FATA TRIAL

Spontaneous, randomized, multicenter, controlled, open-label trial

STEMI < 6 hours

680 patients ≥ 18 years with STEMI <6h undergoing primary PCI (no LBBB)

ASA 250 mg i.v. and UFH 70 IU/kg

↓

RANDOMIZATION 1:1

Abcixmab

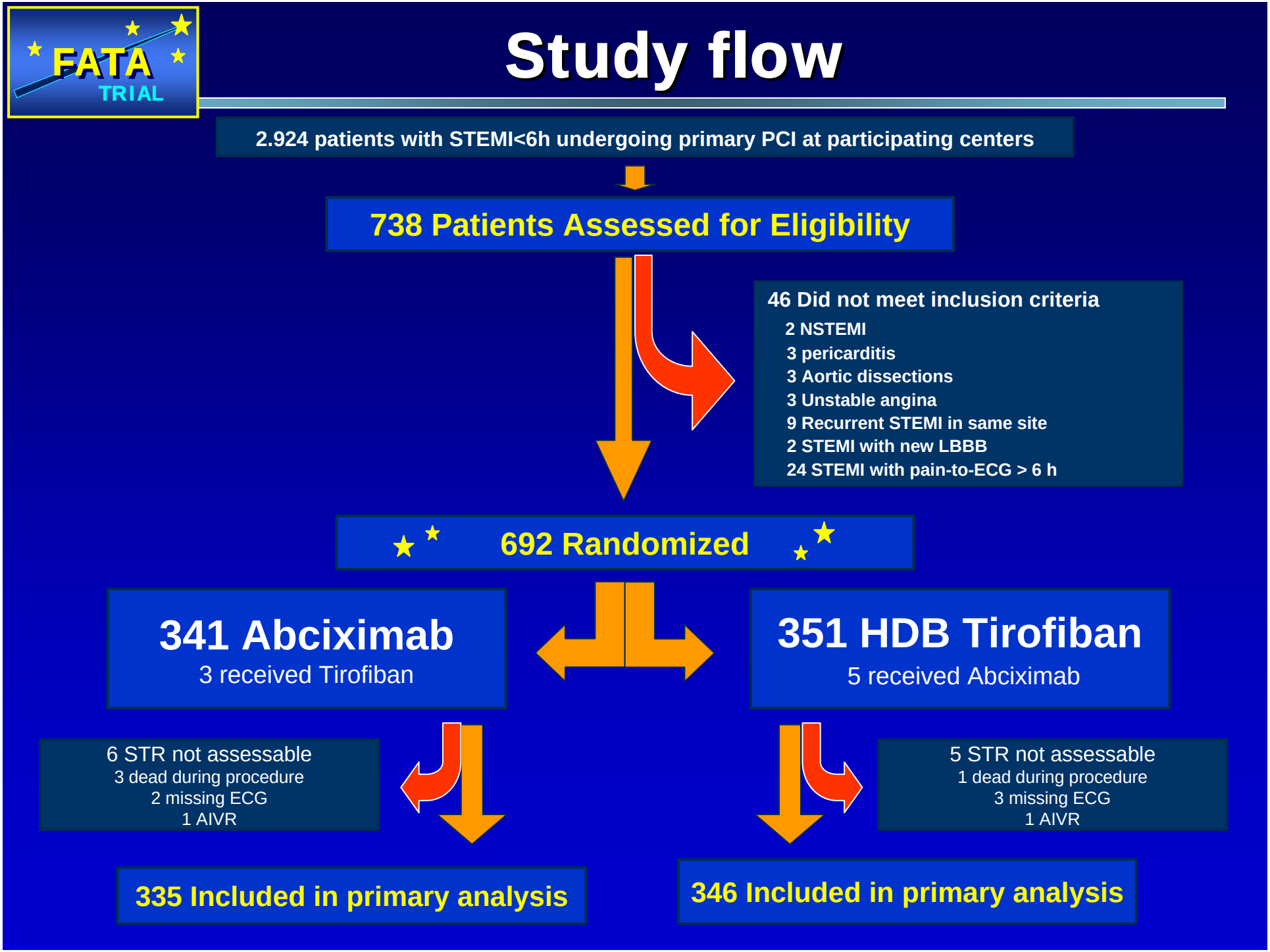
Bolus 0.25 mg/kg, followed by 12h infusion of 0.125 µg/kg/min

Tirofiban HDB

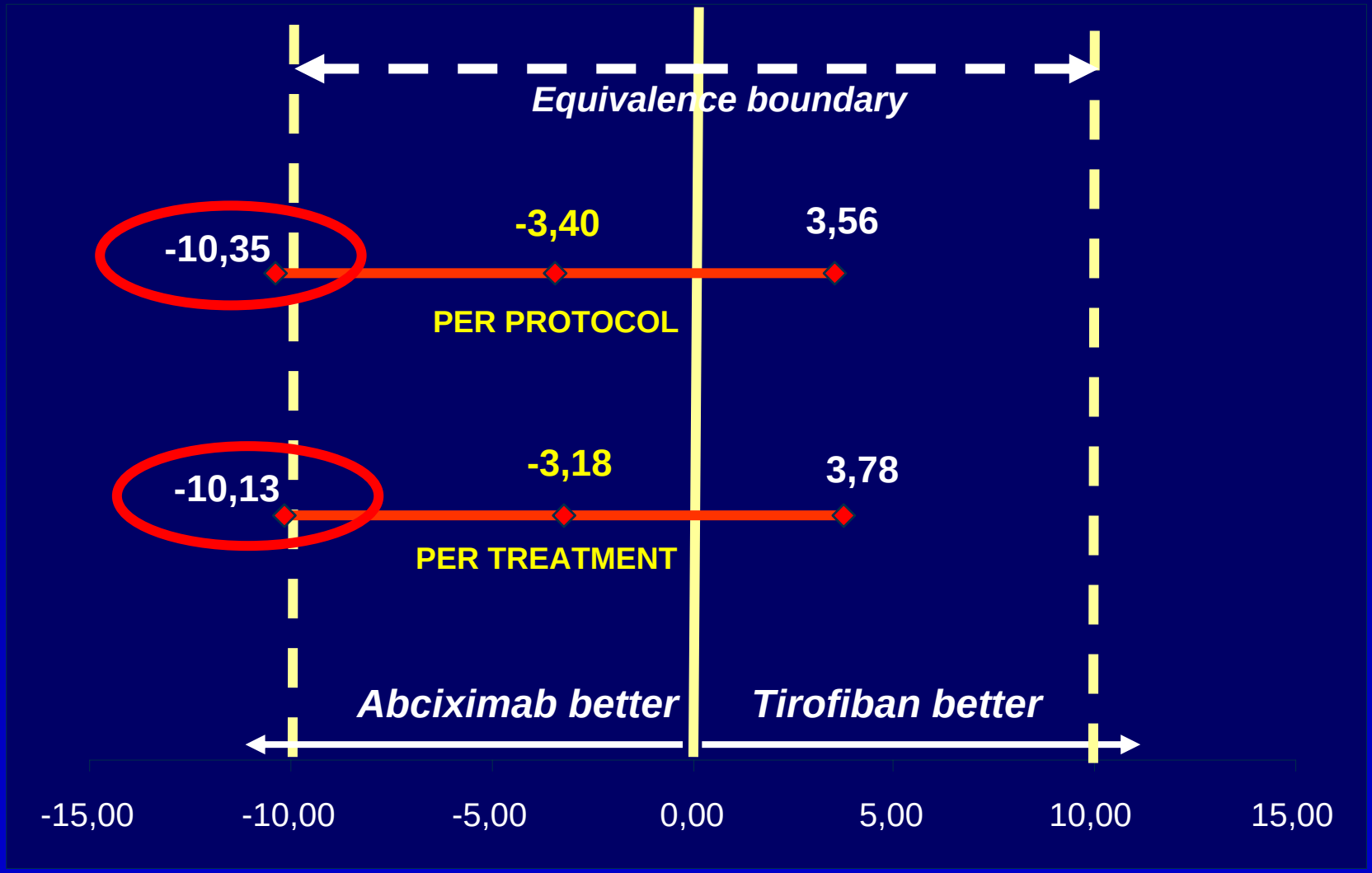
Bolus 25 µg/kg, followed by 18h infusion of 0.15 µg/kg/min

PRIMARY PCI

- **Primary Endpoint: Rate of complete ST-segment resolution (STR) 90 minutes after first balloon inflation Abciximab vs Tirofiban**

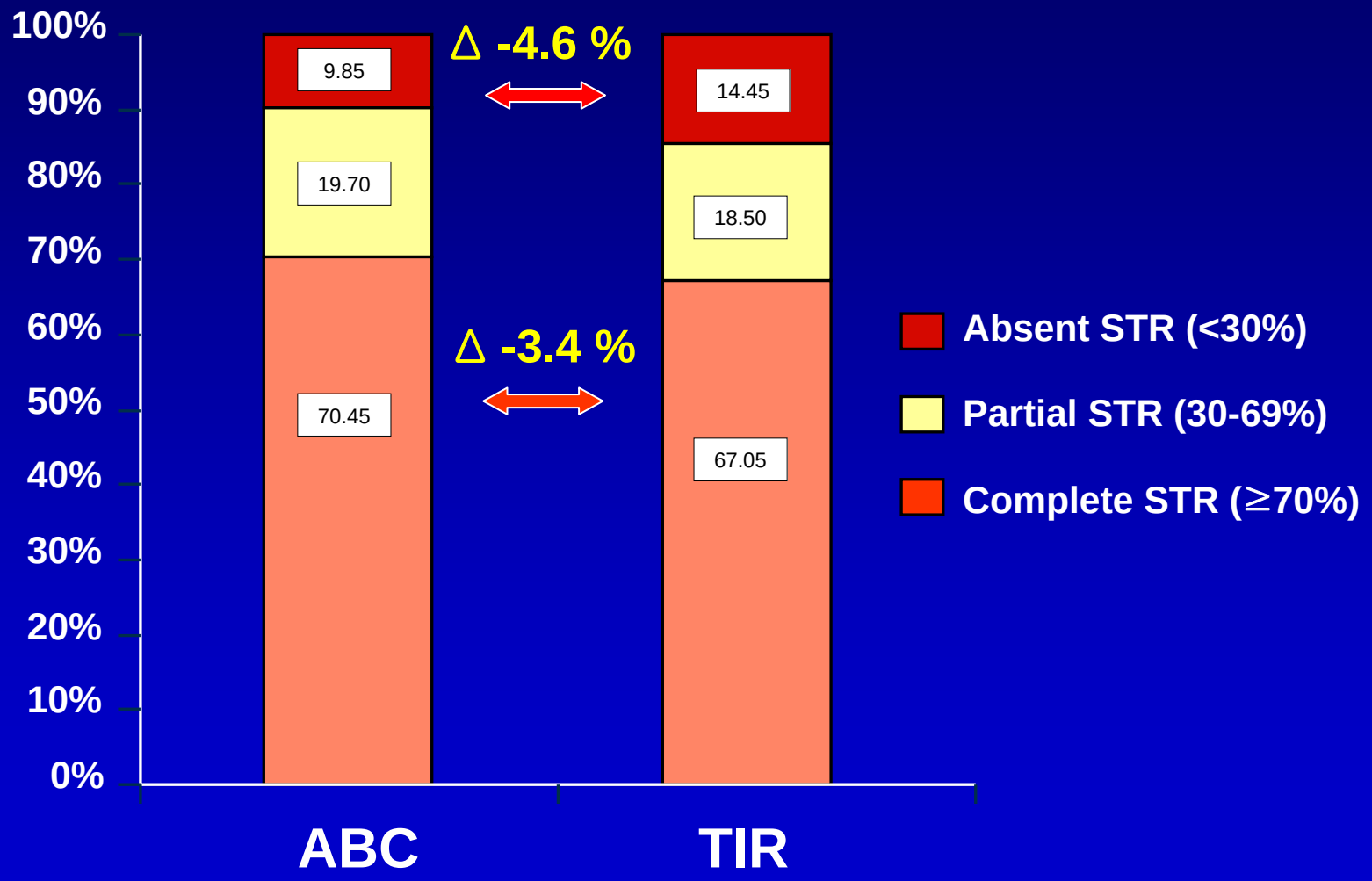

FATA
TRIAL
Study flow
2.924 patients with STEMI<6h undergoing primary PCI at participating centers
738 Patients Assessed for Eligibility
46 Did not meet inclusion criteria
2 NSTEMI
3 pericarditis
3 Aortic dissections
3 Unstable angina
9 Recurrent STEMI in same site
2 STEMI with new LBBB
24 STEMI with pain-to-ECG > 6 h
692 Randomized
341 Abciximab
3 received Tirofiban
351 HDB Tirofiban
5 received Abciximab
6 STR not assessable
3 dead during procedure
2 missing ECG
1 AIVR
5 STR not assessable
1 dead during procedure
3 missing ECG
1 AIVR
335 Included in primary analysis
346 Included in primary analysis

Primary Endpoint

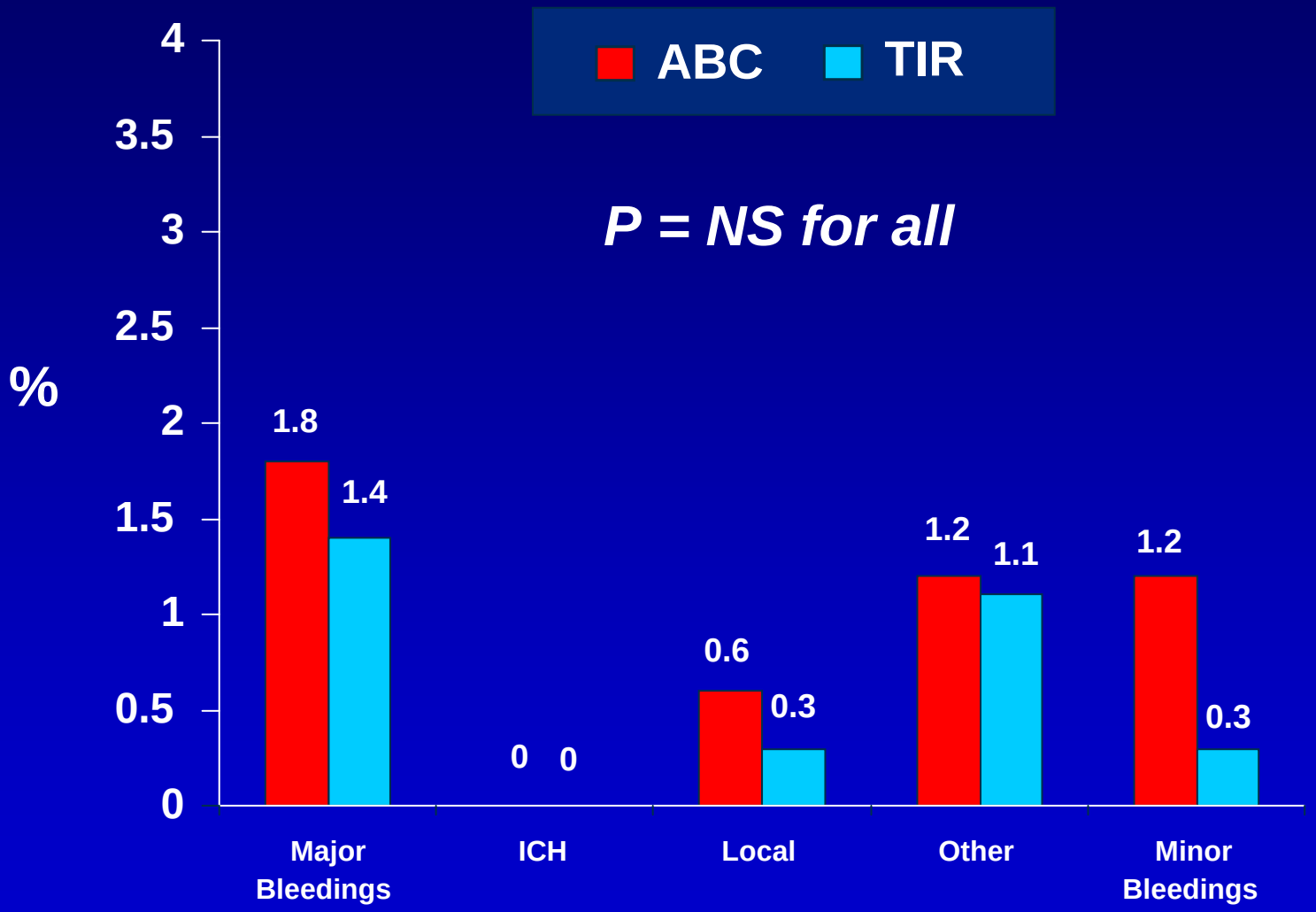


= EQUIVALENCE NOT DEMONSTRATED

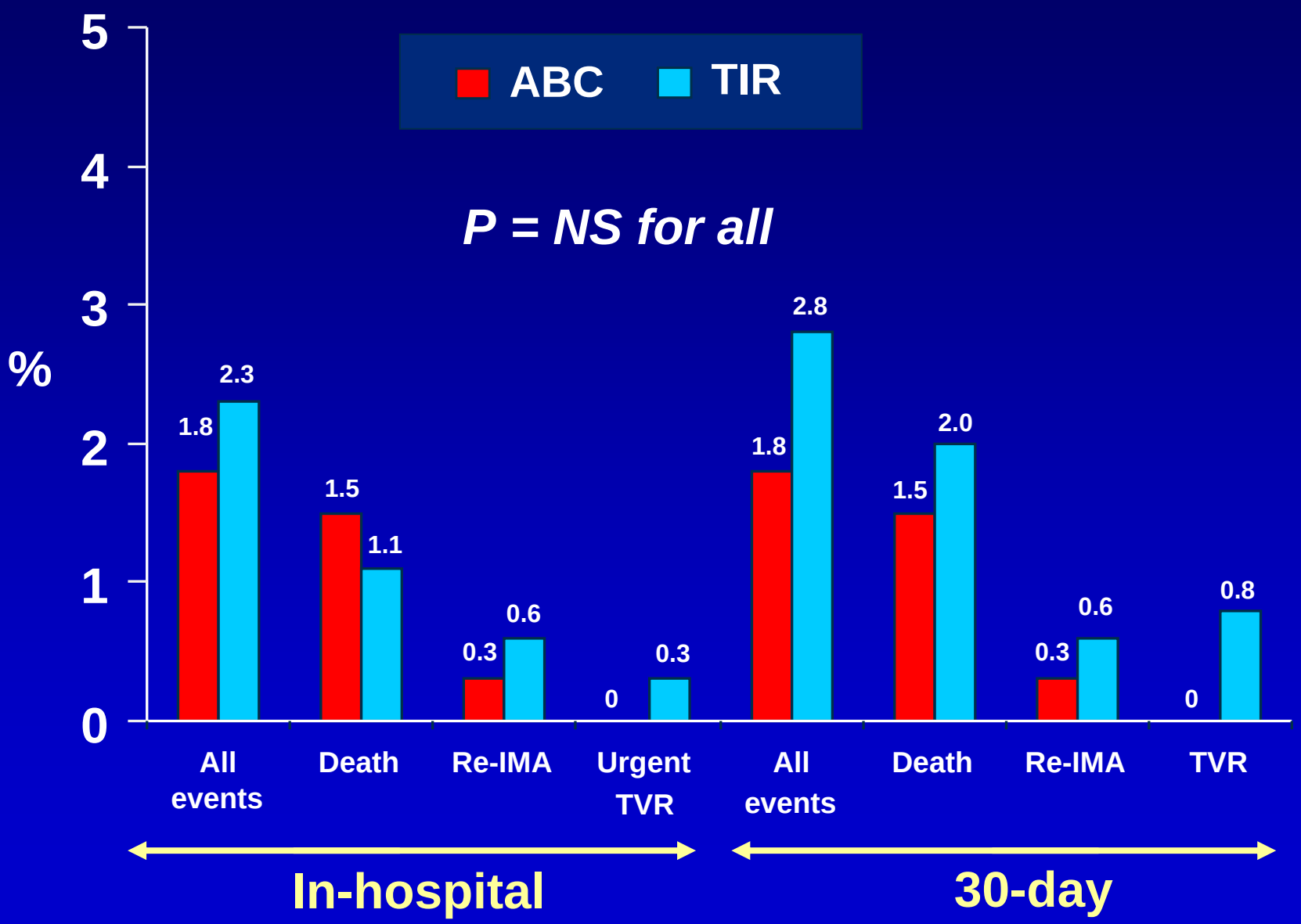
ST-resolution



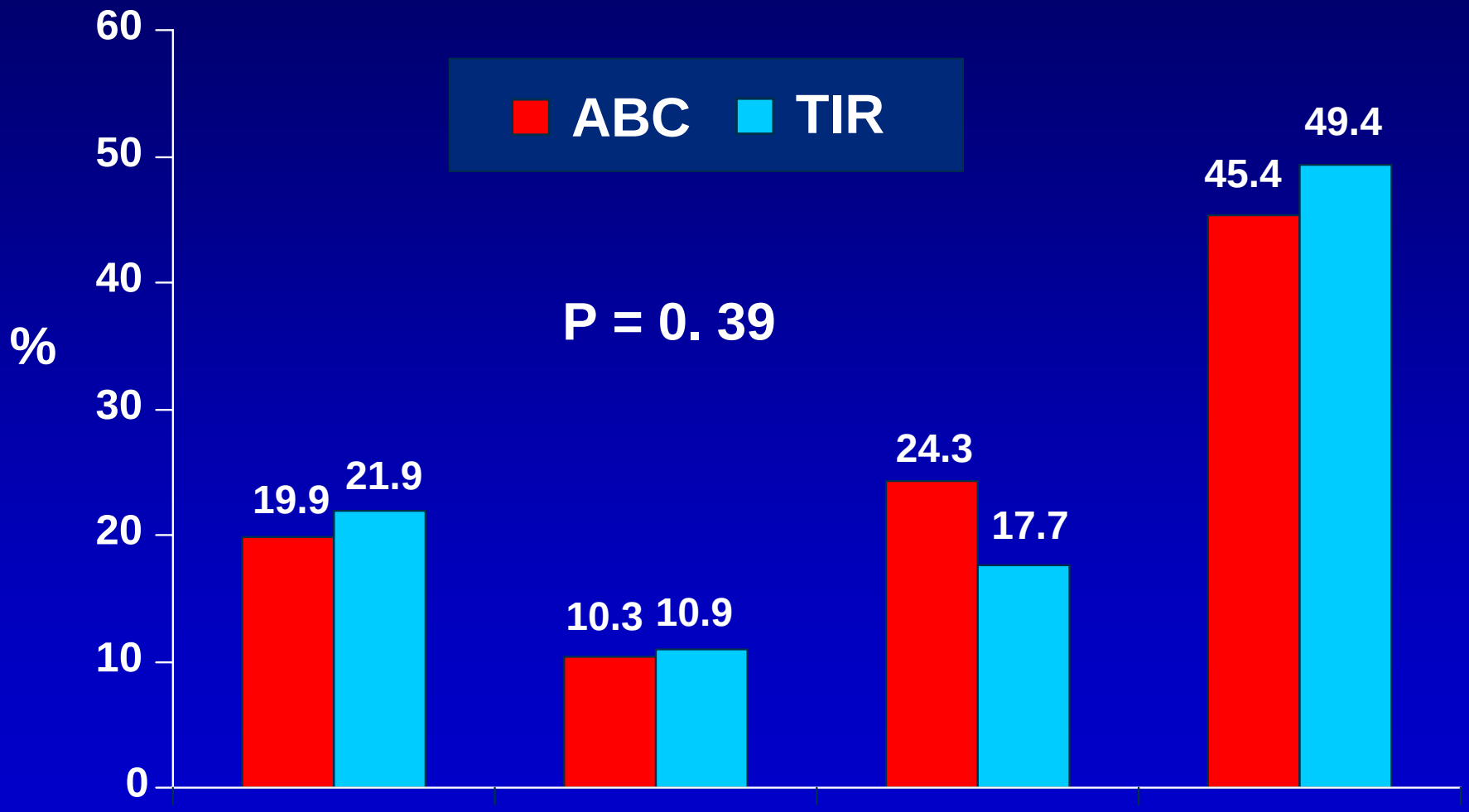
Safety endpoints



Clinical endpoints



Myocardial Blush



Multivariable predictors of complete STR

	OR	95.0% C.I.	*P*
Anterior myocardial infarction	0.371	0.260 - 0.529	<.0001
Pain-to-balloon (each min increment)	0.998	0.996 - 1.000	0.040
Pre-procedural TIMI grade flow >0	1.643	1.139– 2.369	0.008
Hypertension	0.618	0.426- 0.897	0.011
Age (each increment year)	0.999	0.982- 1.015	0.870
Male gender	0.904	0.583- 1.403	0.652
Diabetes	1.210	0.764- 1.917	0.416
Abciximab	1.145	0.807– 1.624	0.449
Current smoker	1.384	0.923 – 2.075	0.116
Prior myocardial infarction	0.793	0.346 - 1.818	0.583
Number of vessel diseased	0.996	0.782 - 1.268	0.971

Conclusions

- This study **failed to show the equivalence of HDB tirofiban as compared to standard abciximab** to achieve complete ST-resolution in the setting of pPCI

- The **absolute difference** in rates of complete ST-resolution observed between abciximab and tirofiban **was small** (3.4%), and the question whether this legitimate

- Further studies are necessary to clarify:could translate into a different clinical benefit is
  - If there is a clinical difference between the two drugs
  - If the two drugs have different profiles of efficacy in different patients