

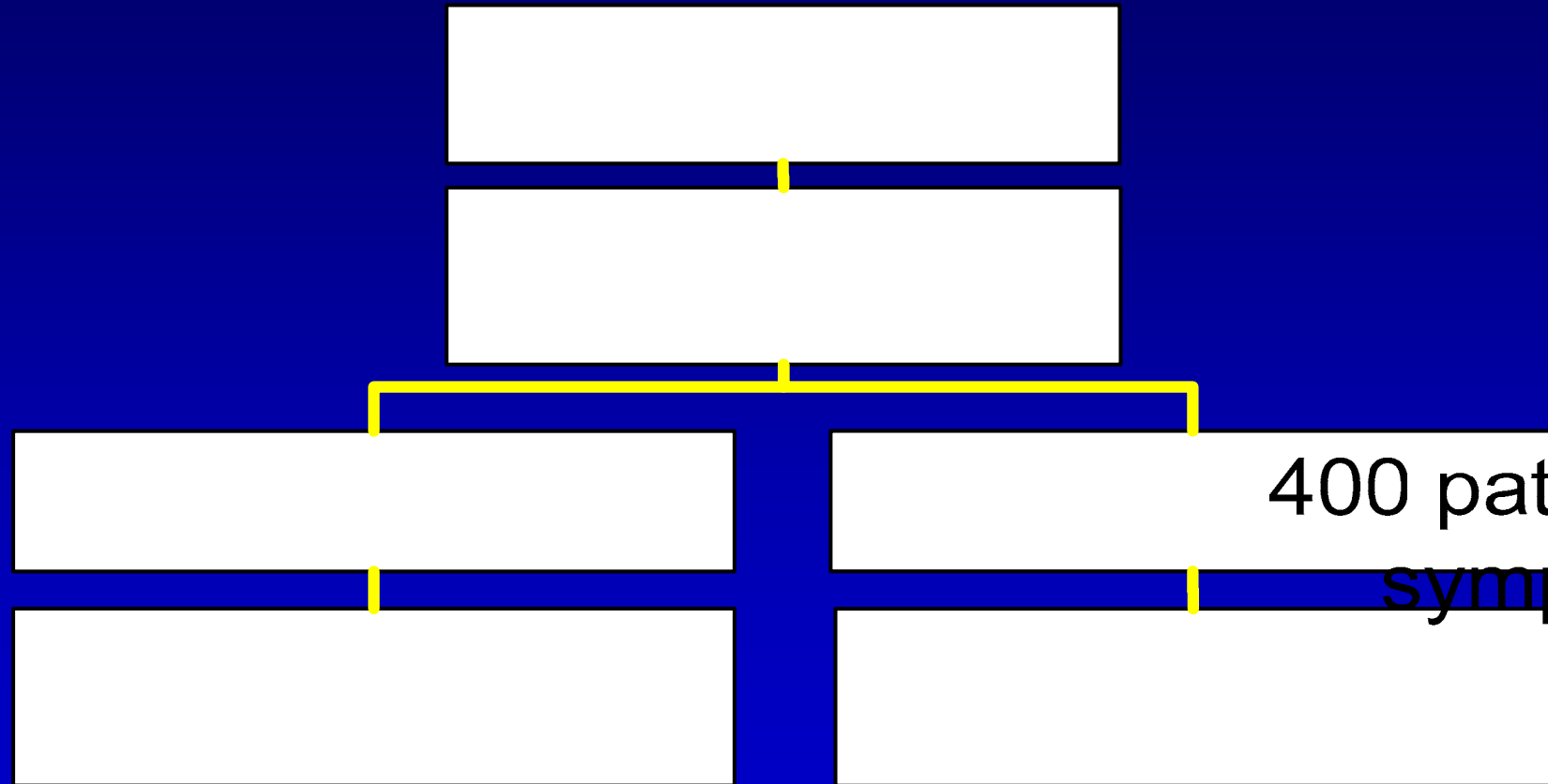
ClinicalTrials.gov Identifier: NCT00251823

ASSIST

A Safety and Efficacy Study of
Integrilin Facilitated PCI versus
Primary PCI in ST Elevation
Myocardial Infarction

Principal Investigator: Michel Le May, MD

Trial Design

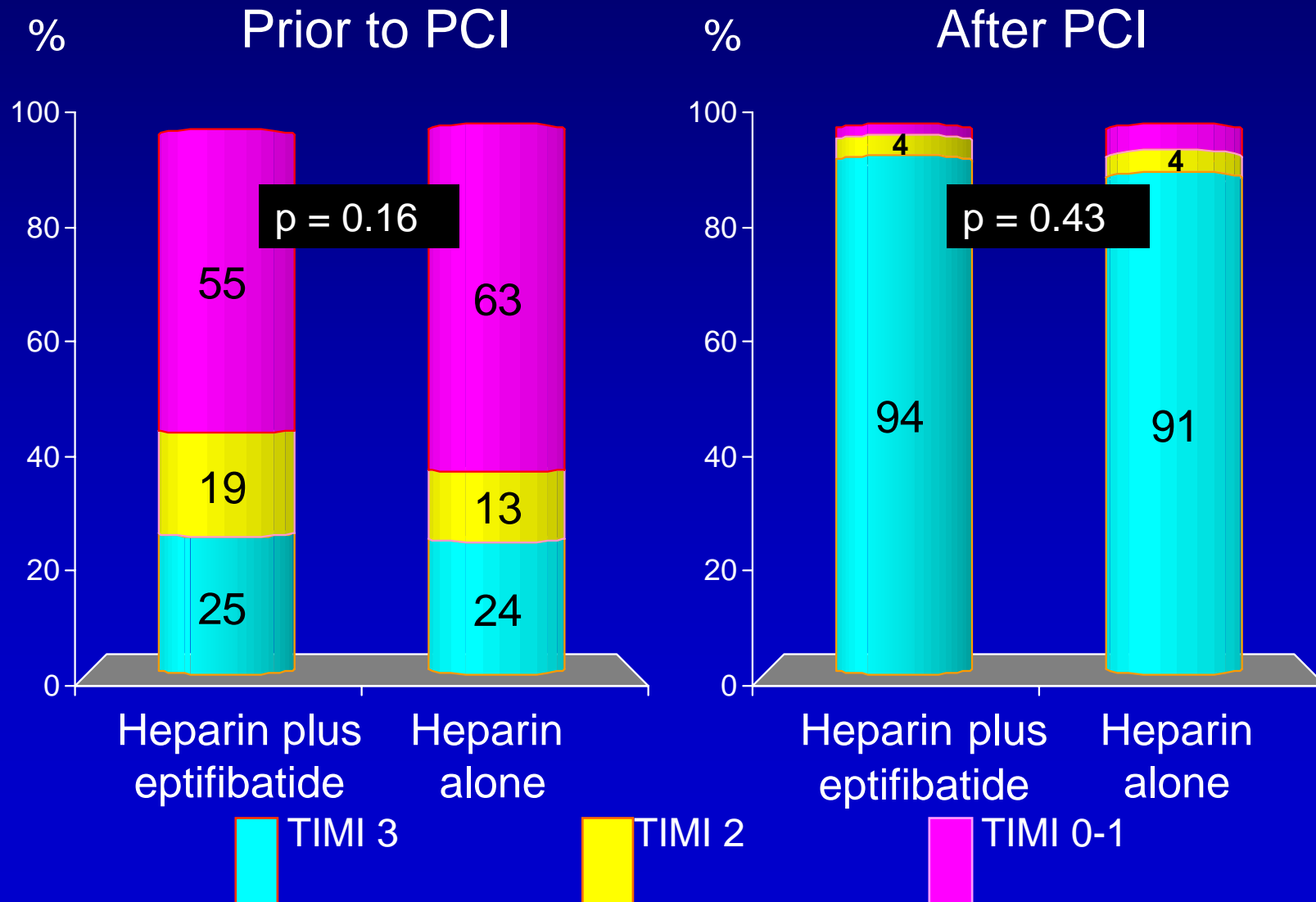


400 patients with
symptom ons

Aspirin 160 m
logre
heparin 60 units/

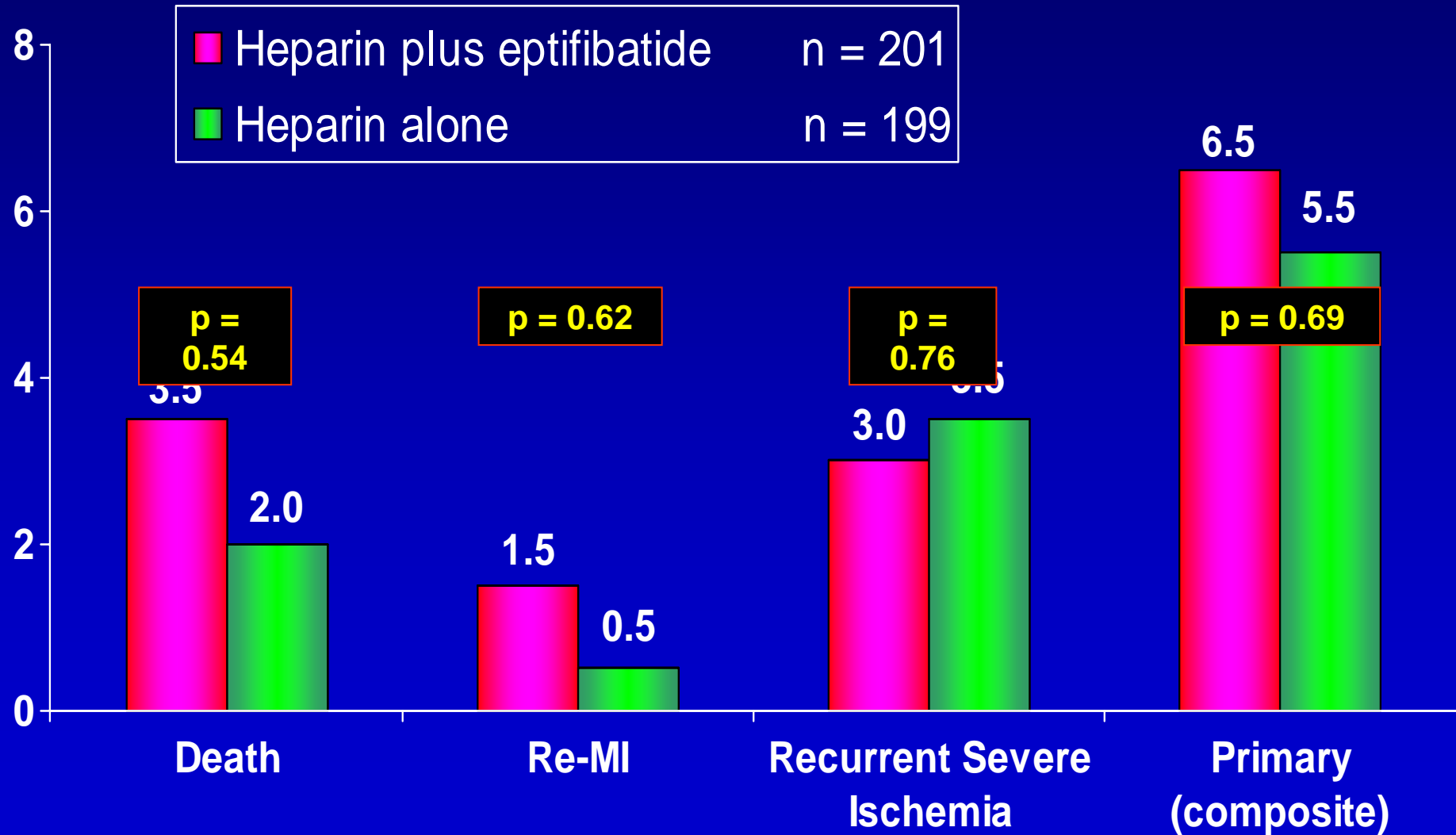
Primary endpoint
Death, Reinfarction, Recurrent Severe Ischemia at 30 Days.

Infarct-Related Artery TIMI Flow Rates



Events Within 30 Days

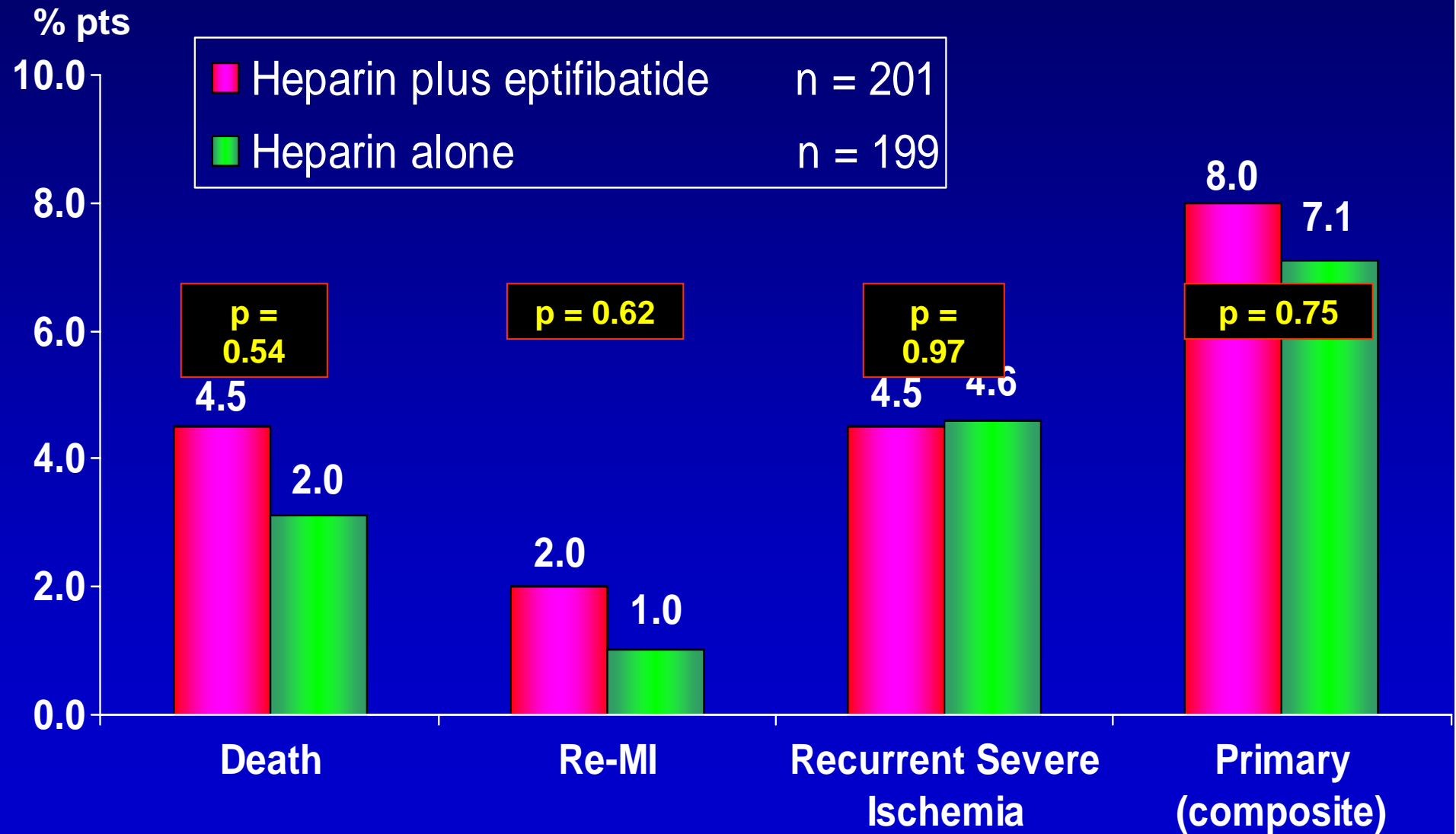
% pts



Clinical Events at 30 Days

| | Heparin plus Eptifibatide (n = 201) | Heparin Alone (n = 199) | p value | R R (95% CI) |
|----------------------------|---|---|--------------------|---------------------|
| Death, % | 3.5 | 2.0 | 0.54 | 1.76 (0.51, 6.11) |
| Reinfarction, % | 1.5 | 0.5 | 0.62 | 3.00 (0.31, 29.1) |
| Death or ReMI, % | 5.0 | 2.5 | 0.49 | 2.03 (0.68, 6.05) |
| Severe Rec. Ischemia, % | 3.0 | 3.5 | 0.76 | 0.84 (0.28, 2.56) |
| Primary Outcome, % | 6.5 | 5.5 | 0.69 | 1.18 (0.52, 2.70) |
| C H F, % | 7.5 | 11.0 | 0.22 | 0.65 (0.33, 1.29) |
| Cardiogenic Shock, % | 4.0 | 3.0 | 0.60 | 1.33 (0.45, 3.92) |
| Stroke, % | 0 | 0.5 | 0.50 | |
| Hemorrhagic | 0 | 0.5 | | |

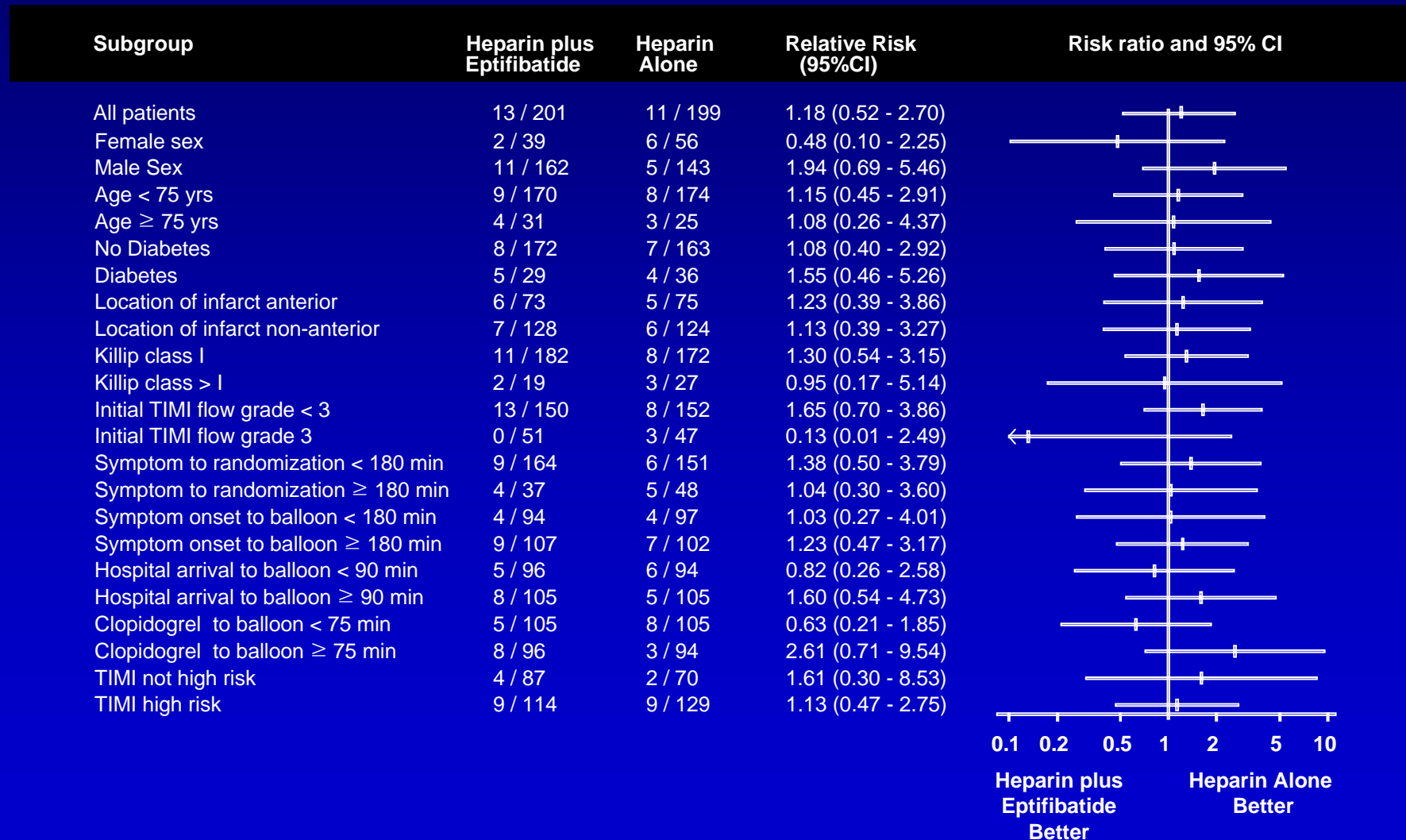
Events Within Six Months



Clinical Events at Six Months

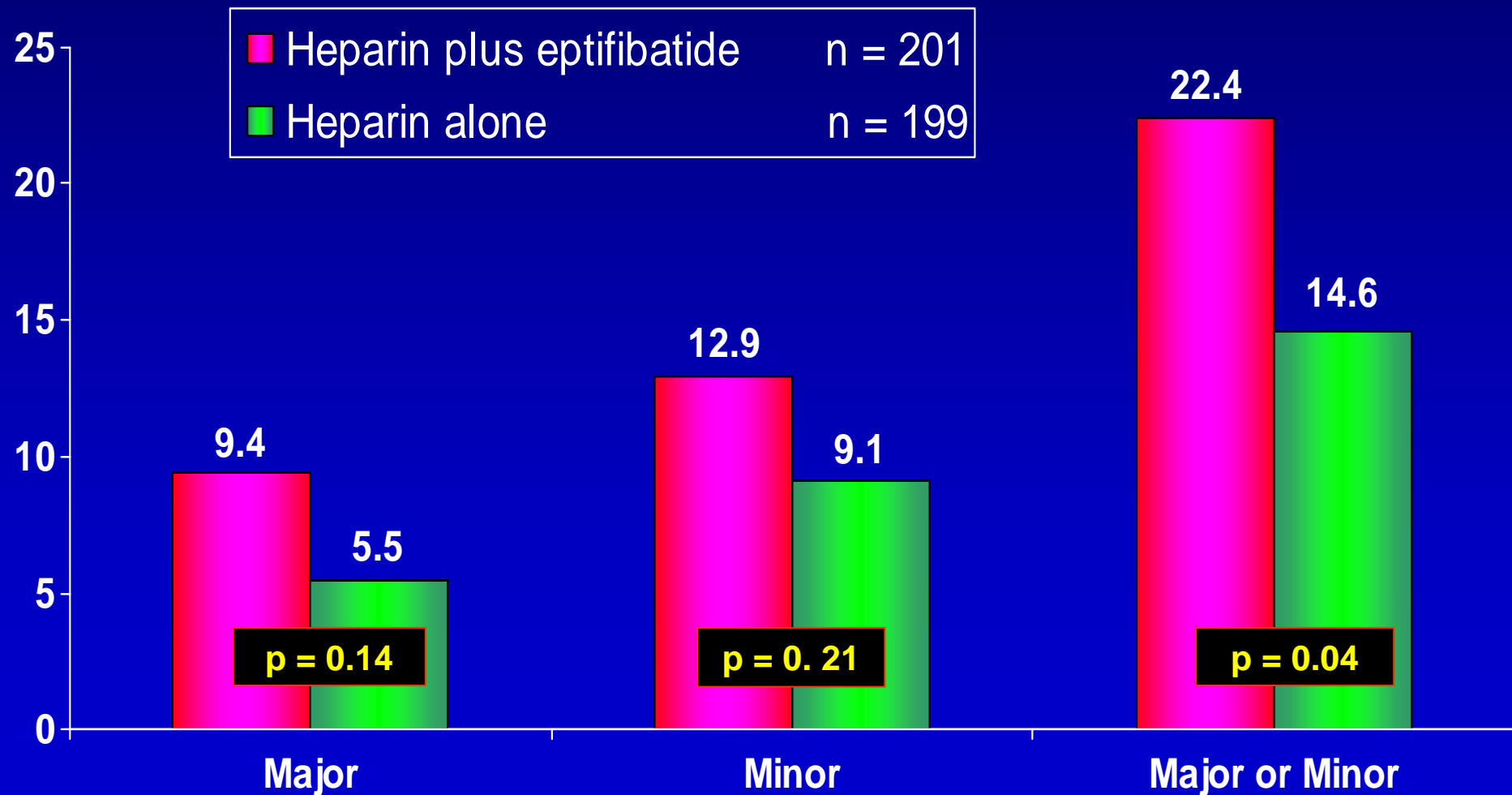
| | Heparin plus Eptifibatide (n = 201) | Heparin Alone (n = 199) | p value | R R (95% CI) |
|---------------------------|--|--|--------------------|---------------------|
| Death,% | 4.5 | 3.0 | 0.45 | 1.49 (0.52, 4.27) |
| Reinfarction,% | 2.0 | 1.0 | 0.68 | 1.98 (0.36, 10.9) |
| Death or ReMI,% | 6.5 | 3.6 | 0.18 | 1.88 (0.73, 4.81) |
| Severe Rec. Ischemia,% | 4.5 | 4.6 | 0.97 | 0.98 (0.38, 2.52) |
| Primary Outcome,% | 8.0 | 7.1 | 0.89 | 1.13 (0.54, 2.38) |
| C H F,% | 7.5 | 12.2 | 0.11 | 0.58 (0.30, 1.14) |
| Cardiogenic Shock,% | 4.0 | 4.6 | 0.77 | 0.87 (0.33, 2.29) |
| Stroke,% | 0 | 2.0 | 0.06 | |
| Hemorrhagic | 0 | 1.0 | | |

Primary Outcome Subgroup Analysis



TIMI Bleeding Events During Initial Hospitalization

% pts



Revascularization 30 Days and Six Months

| | Heparin plus Eptifibatide | Heparin Alone | p value | R R (95% CI) |
|--------------------------|--------------------------------------|--------------------------|----------------|---------------------|
| 30 Days | | | | |
| Non-protocol PCI, % | 19.4 | 18.6 | 0.84 | 1.05 (0.6, 1.7) |
| Repeat TVR, % | 4.0 | 2.0 | 0.38 | 1.76 (0.5, 6.1) |
| Bypass Surgery, % | 5.0 | 3.0 | 0.32 | 1.68 (0.6, 4.7) |
| Any Revascularization, % | 23.9 | 21.1 | 0.51 | 1.17 (0.7, 1.9) |
| Six Months | | | | |
| Non-protocol PCI, % | 19.9 | 19.1 | 0.84 | 1.05 (0.6, 1.7) |
| Repeat TVR, % | 4.0 | 3.0 | 0.60 | 1.33 (0.5, 3.9) |
| Bypass Surgery, % | 5.0 | 4.0 | 0.65 | 1.25 (0.5, 3.2) |
| Any Revascularization, % | 24.4 | 22.6 | 0.68 | 1.10 (0.7, 1.8) |

Conclusions

In pts with acute STEMI pretreated with high dose clopidogrel, as compared with PCI with heparin alone,

PCI with eptifibatide initiated before catheterization

- 1) does not improve clinical outcomes and
- 2) is associated with more bleeding.