

# SEPIA-ACS1 – TIMI 42 *Protocol Design*

*Dose Ranging Study of Otamixaban - a Novel, Intravenous, Direct Xa Inhibitor*

**Mod-to-High Risk NSTEMI ACS w/ Planned Early Inv Strategy**

Aspirin +  
clopidogrel  
at randomization

R

Bail-out  
eptifibatide in  
otamixaban groups  
if rec. ischemia or  
thrombotic  
complic. during  
PCI

Otamix  
Group 1  
(n=450)

Otamix  
Group 2  
(n=450)

Otamix  
Group 3  
(n=450)

Otamix  
Group 4  
(n=450)

Otamix  
Group 5  
(n=450)

UFH +  
Eptifi.  
(n=450)

Coronary angiography ± PCI (Day 1-3)

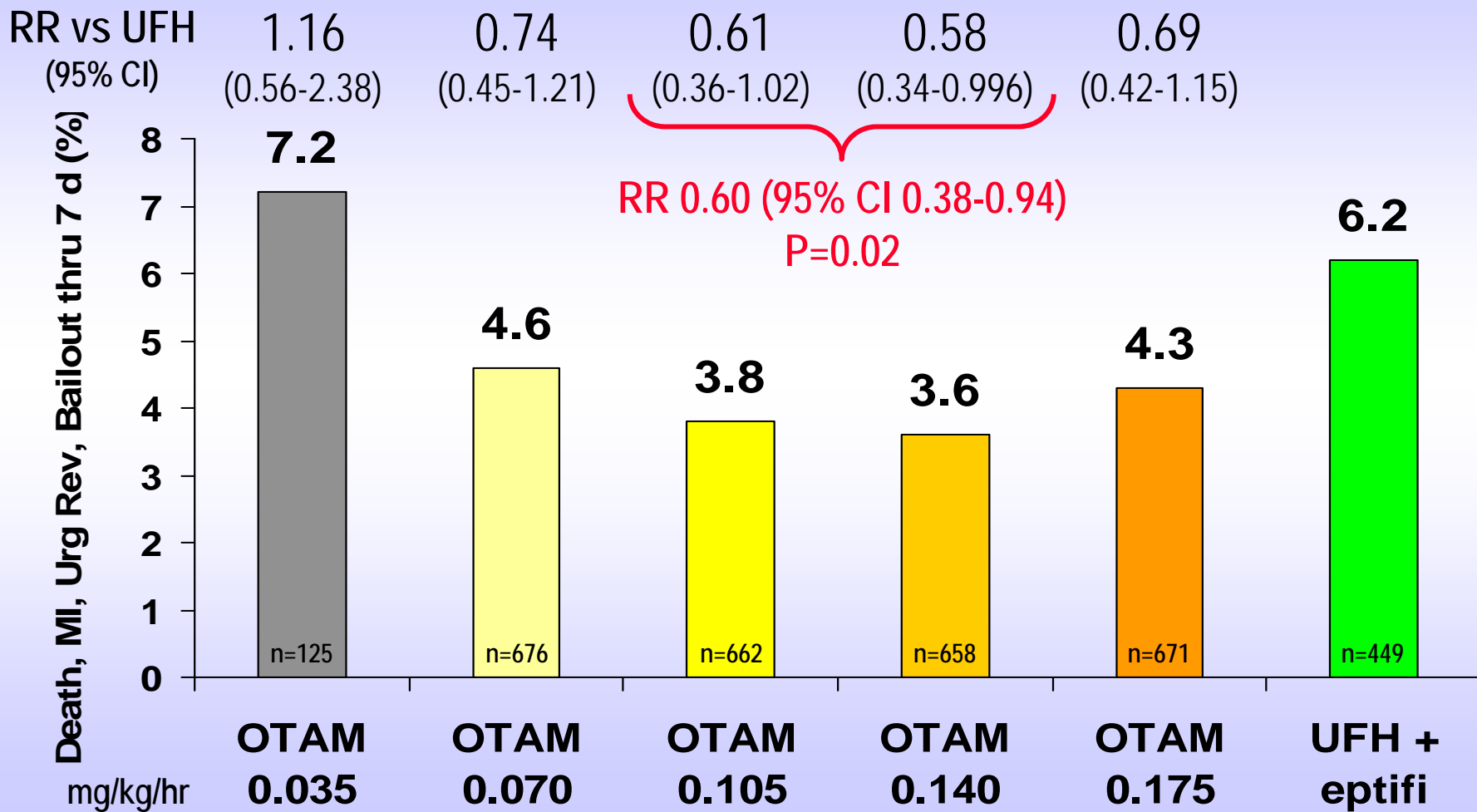
Study drug  
until end of PCI,  
as clin. indicated,  
until Day 4 or hospital d/c,  
whichever comes first

1° EP: Death, MI, Urgent Revasc, Bail-out IIb/IIIa thru 7 d

Day 30 Visit, Day 90 Tel f/up, Day 180 Tel. f/up

# SEPIA-ACS1 – TIMI 42 *Efficacy Results*

*1° Outcome: Death, MI, Urg Revasc, or Bailout GP IIb/IIIa*



*P=0.34 for trend across OTAM*



# SEPIA-ACS1 – TIMI 42 *Safety Results*

*TIMI Major or Minor Bleed unrelated to CABG*  
*(defined as bleed with ↓ in Hgb of ≥3 g/dL or ICH)*

RR vs UFH	0.61	0.61	1.15	1.26	2.02
(95% CI)	(0.14-2.70)	(0.27-1.38)	(0.57-2.32)	(0.63-2.52)	(1.07-3.85)

