Role of glycoprotein IIb/IIIa antagonists in patients with acute coronary syndromes (ACS): comparison of clinical trial data with the Global Registry of Acute Coronary Events (GRACE)

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Objective: Patients enrolled in clinical trials tend to be highly selected, whereas GRACE offers an opportunity to assess the results of randomized trials in an unselected patient population. We examined the use of GP IIb/IIIa inhibitors and UFH in ACS patients enrolled in GRACE. We compared early CEPs in GRACE patients with those seen in randomized clinical trials.

	PRISM/GRACE			PRISM-PLUS/GRACE			PURSUIT/GRACE		
	UFH	GP IIb/IIIa	Both	UFH	GP IIb/IIIa	Both	UFH	GP IIb/IIIa	Both
	Patients (%)								
Recurrent MI	3.1/0.6	2.6/0.6	-*/1.6	7.1/0.6	7.0/0.8	2.7/1.6	10.4/0.6	9.3/0.6	-*/2.3
CEP	11.2/35.8	10.3/38.8	-*/41.6	10.4/35.5	7.7/33.6	3.3/41.6	11.6/35.9	10.1/38.2	-*/42.8
Mortality	1.6/3.2	1.0/3.0	-*/1.2	1.1/3.3	4.6/3.8	1.5/1.2	2.0/3.0	1.5/3.5	-*/1.4

*Not applicable for the trial

Table. Outcomes of patients in three randomized clinical trials versus patients in GRACE

Methods and results: The baseline characteristics (stratified by type of ACS), and in-hospital events of GRACE patients were compared with those of patients from the PURSUIT, PRISM and PRISM-PLUS studies. The GRACE population was divided into patients receiving UFH alone, GP IIb/IIIa inhibitors alone, or both. Patients who received neither UFH nor GP IIb/IIIa inhibitors were excluded from the analysis. The criteria for inclusion and exclusion applied in these three clinical trials were used to compare the study findings.

The GRACE data show that patients qualifying for enrollment in clinical trials had a mean age of 65 years and were more likely to be male (~70%). They also had a higher incidence of diabetes (24%), MI (39%), CHF (13%), PCI (19%) and CAGB (16%). Thus, patients enrolled in these clinical trials were younger and possessed fewer comorbid conditions than patients included in GRACE. Unfractionated heparin in combination with GP IIb/IIIa inhibitors significantly reduced the risk for mortality. However, the rates of mortality and recurrent MI and CEP were still higher in GRACE patients than in patients in clinical trials.

Conclusion: The results of randomized clinical trials do not necessarily reflect outcomes for the full spectrum of ACS patients treated in routine clinical practice.