Estimating risk of adverse outcomes in the 'average patient' with acute coronary syndromes: comparing a risk model from a clinical trial to that developed in an unselected cohort in the GRACE registry

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K.A. Eagle*, J.M. Gore, R.J. Goldberg, C.B. Granger, C.M. Sullivan, I. Sadiq, K.A.A. Fox

*University of Michigan Health System, Ann Arbor, Michigan, USA

Background: A number of decision aids and risk-prediction tools derived from clinical trial data have been reported recently. Evidence suggests that patients with ACS who are enrolled in clinical trials have a much lower risk of coronary events than that seen in routine daily practice. The aim of this study was to use data from the multinational GRACE registry to assess whether the risk model developed from the TIMI 11B randomized clinical trial is robust for the average patient.

Methods: Data from 6420 patients enrolled in GRACE were analyzed, using the TIMI 11B risk model to predict subsequent MI, coronary revascularization, or death after hospitalization for NSTEMI. The independent clinical predictors from the TIMI 11B study were compared with an independent multivariate model identified by analyzing this broad group of patients.

Results: Variables that were common to both the TIMI 11B and GRACE models were prolonged chest pain, elevated cardiac markers, and ST-segment changes. In the GRACE model, Killip class also emerged as an important predictor. To create a stepwise estimate for GRACE patients, a recalibrated TIMI 11B model that depended on the number of TIMI variables, was applied (Figure). The GRACE model, which included three TIMI variables and three new variables, was transformed into a simple additive tool.

Conclusion: Predictors of outcome from a randomized clinical trial differ markedly when evaluated in an independent but similarly selected population of ACS patients. This study highlights concerns that risk models developed from clinical trial data may not be accurate in the 'real' world

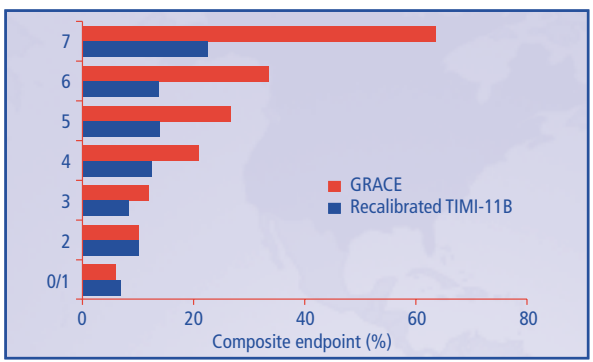

Figure. Recalibrated TIMI 11B model and GRACE model for prediction of coronary events in patients with ACS. Adapted from Eagle KA et al. Eur Heart J 2001; 22 (suppl): 524