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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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.

Nécrosette infarction versus traditionally defined non-ST-segment elevation myocardial infarction (NSTEMI) and in-hospital course. Findings from the Global Registry of Acute Coronary Events (GRACE)

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Background: Recently published guidelines state that patients with minimal myocardial injury should be classified as having an MI. In this study, we hypothesized that NSTEMI patients who have Tn+ T or I marker but whose CK-MB levels are undetectable (nécrosette infarction) have a similar short-term prognosis as those with undetectable levels of both biochemical markers (UA). We examined the value of a Tn+ marker in the prediction of adverse outcomes.

Methods and results: Data from patients with ACS enrolled in the multinational GRACE registry were analyzed. Of the 3479 patients, 49% had UA and 51% had NSTEMI (626 Tn+ patients; 1160 Tn+ and CK-MB+ patients). NSTEMI patients who were positive for both biochemical markers (Tn+ and CK-MB+) had significantly higher rates of hospital mortality or recurrent MI than patients with nécrosette infarction (OR 2.3, 95% CI 1.6–3.2). Patients with nécrosette infarction were also more likely to die or have a recurrent MI (OR 3.2, 95% CI 2.2–4.9) than patients with UA (Figure).

Conclusions: Patients with nécrosette infarction are at intermediate risk for adverse outcomes but have a more favorable prognosis than patients with NSTEMI who are Tn and CK-MB positive. As a consequence, patients with nécrosette infarction should receive more aggressive treatment than patients with UA.

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): S24

Figure. In-hospital outcomes of patients with ACS