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External validation, extension and recalibration of Braunwald's simple risk index in a community-based cohort of patients with both STEMI and NSTEMI

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Abstract

Background: Using the simple risk index (SRI) that is based on age, heart rate and systolic blood pressure, we sought to evaluate the ability to predict outcome in AMI patients in a community-based population.
Methods and results: We identified and evaluated 3684 consecutive patients with an admission diagnosis of possible AMI, who attended between 1st September and 30th November 1995. Two thousand one hundred fifty three patients had confirmed evidence of WHO definition AMI, of whom 1656 survived to hospital discharge. We evaluated the ability of the SRI to predict mortality over 30 days using the score generated by the equation (heart rate $\times$ [age / 10]^2) / systolic blood pressure. The SRI was a strong (*c*-statistic = 0.77 CI 0.74 – 0.79) predictor of 30-day mortality in both STEMI and all consecutive cases of WHO definition AMI. However, the model showed poor calibration when used on a community-based population with 30-day mortality being underestimated across all risk quintiles. Consequently we sought to recalibrate the quantitative aspects of the model for the total AMI population in the following way (Risk Index; 30-day mortality) ($\leq$29.2; 9.2%), (29.3 – 37.8; 23.9%), (37.9 – 47.3; 34.6%), (47.4 – 61.5; 40.3%), ($\geq$61.6; 65.5%).
Conclusion: We have externally validated the SRI in an unselected cohort of consecutive WHO definition AMI patients. However, the original model consistently underestimated the likelihood of death at 30 days regardless of the calculated risk score. We have therefore suggested corrections to the risk estimates, to allow its application in an unselected community cohort.

Keywords: Myocardial infarction; Blood pressure; Heart rate; Epidemiology

1. Background

Many methods for risk adjustment have been derived in an attempt to reliably compare care at different clinical centres and also at different points in time. With the exception of age and gender standardisation, most of the risk models have been derived from randomised control trial (RCT) populations and tend to be limited by complexity and also exclusion of patients with higher risk profiles. For hospitals to be accountable for the care they provide to AMI patients, they need to be able to reliably compare their performance.

A limitation to the reporting of outcomes is the challenge of comparing institutions with patients who have different risk profiles. Without adjustment for these baseline differences, comparisons of crude mortality rates favour hospitals

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that admit the lowest-risk patients. Meaningful evaluations of hospital performance need to consider baseline differences in patient characteristics that could confound comparisons among them.

There have been a number of risk scores for the prediction of outcome following acute myocardial infarction, including those proposed by the following groups: Thrombolysis In Myocardial Infarction (TIMI), Global Utilization of Streptokinase and tPA for Occluded arteries (GUSTO), Platelet glycoprotein IIb/IIIa in Unstable angina: Receptor Suppression Using Integrillin Therapy (PURSUIT), Predicting Risk of Death in Cardiac Disease Tool (PREDICT), and the Cooperative Cardiovascular Project (CCP).[1–7] However, most of these risk scores have been derived and validated in randomised control trial (RCT) populations. Patients recruited into large (and small) RCT tend to be younger, more often male, undergo more revascularisation and have fewer comorbid conditions [8]. When such prognostic scores are used in the non-trial setting of day-to-day clinical practice they may have limited utility in appropriate risk stratification [9]. Their use in a community-based cohort of patients therefore requires additional evaluation and validation.

The SRI was derived from highly selected patients enrolled into the Intravenous nPA for Treatment of Infarcting Myocardium Early (InTIME II) study, a RCT comparing fibrinolytic agents [10]. It was externally validated in the Thrombolysis and Thrombin Inhibition in Myocardial Infarction (TIMI) 9A and 9B trial populations [11,12]. Subsequently, Morrow et al. claimed that the simple risk index, could be used as a tool for rapid risk assessment in patients with ST-elevation myocardial infarction in a routine clinical setting [2]. The primary goal of our investigation was to assess the prognostic performance and externally validate the SRI in a community-based cohort of patients with AMI.

2. Methods

2.1. The EMMACE-1 project

The EMMACE-1 project was supported by a UK National Health Service (NHS) Research and Development grant being carried out on behalf of the Yorkshire Cardiology Working Group. We obtained ethical approval and the co-operation of all consultants and clinical audit departments in 20 adjacent hospitals. Further study details have been published previously [13,14].

2.2. Patient population

Over a three-month period (1 September to 30 November 1995) 3684 potential cases of acute MI were identified in 20 adjacent hospitals comprising all units admitting such patients in the UK Yorkshire Health Region. Cases were identified from coronary care registers, patient administration databases, and biochemistry records of cardiac enzyme requests. Medical records were evaluated and 2153 consecutive cases, regardless of age or place of care within the hospital, of acute WHO definition MI were confirmed, of which 1643 patients were discharged from hospital alive after a first event.

A 250 item case record form of demographic, clinical, and treatment variables was completed for each patient according to a standardised operations manual and entered on to a computer database. Only the first presentation with acute MI (during the recruitment window) was included and patients who were transferred to a tertiary centre were counted only once for the index admission. Clinical characteristics on admission were taken from the following sources in order of preference: emergency department medical notes; admitting medical team's first clerking; and nursing notes.

Two senior research nurses and an experienced cardiology registrar gathered data from the case notes. Quality of data abstraction from case notes and data entry on the computerised databases were formally assessed. After a pilot phase of data abstraction from case notes, the inter-observer agreement was 98% without any systematic bias. The accuracy of the data entry was excellent, with less than 1% discrepancy and, again without systematic bias.

2.3. Simple risk index

We initially used the same inclusion criteria as the thrombolysis trial population (InTime II trial) used for derivation of the SRI [10]. Individual patients were excluded if there was any history of cerebrovascular disease, a SBP of more than 180 mm Hg or a diastolic blood pressure of more than 110 mm Hg, cardiogenic shock, or an increased risk of severe bleeding. They were also excluded if they had severe bradycardia or tachyarrhythmias because these patients typically required specific interventions. We then performed our analysis on patients with STEMI and on the total EMMACE-1 population of AMI patients, this time not adopting any exclusion criteria. This is the unselected group of patients our results are based on.

After calculating SRI, 5 categories of increasing risk were obtained as defined by Morrow et al. [2]. Scores of ≤ 12.5 were in risk group 1 (the lowest-risk group), >12.5 to 17.5, >17.5 to 22.5, and >22.5 to 30 were in risk groups 2, 3 and 4, respectively (corresponding to progressively increasing risk categories) and patients with scores of >30 were in the highest risk group, 5. Observed 30-day mortality was then calculated for each risk group. Subsequently, the SRI scores and 30-day mortality were then recalibrated for the EMMACE-1 population ensuring equal numbers of deaths in each risk group. The recalibrated risk index quintiles are as follows (risk score ; risk group), (≤ 29.2 ; risk group 1), (29.3–37.8 ; risk group 2), (37.9–47.3 ; risk group 3), (47.4–61.5 ; risk group 4) and (≥ 61.5 ; risk group 5).