Simple risk score based on the China Acute Myocardial Infarction registry for predicting in-hospital mortality among patients with non-ST-segment elevation myocardial infarction: results of a prospective observational cohort study

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To cite: Song C, Fu R, Li S, et al. Simple risk score based on the China Acute Myocardial Infarction registry for predicting in-hospital mortality among patients with non-ST-segment elevation myocardial infarction: results of a prospective observational cohort study. BMJ Open 2019;9:e030772. doi:10.1136/bmjopen-2019-030772

ABSTRACT

Objectives To simplify our previous risk score for predicting the in-hospital mortality risk in patients with non-ST-segment elevation myocardial infarction (NSTEMI) by dropping laboratory data.

Design Prospective cohort.

Setting Multicentre, 108 hospitals across three levels in China.

Participants A total of 5775 patients with NSTEMI enrolled in the China Acute Myocardial Infarction (CAMI) registry.

Primary outcome measures In-hospital mortality.

Results The simplified CAMI-NSTEMI (SCAMI-NSTEMI) score includes the following nine variables: age, body mass index, systolic blood pressure, Killip classification, cardiac arrest, ST-segment depression on ECG, smoking status, previous angina and previous percutaneous coronary intervention. Within both the derivation and validation cohorts, the SCAMI-NSTEMI score showed a good discrimination ability (C-statistics: 0.76 and 0.83, respectively); further, the SCAMI-NSTEMI score had a diagnostic performance superior to that of the Global Registry of Acute Coronary Events risk score (C-statistics: 0.78 and 0.73, respectively; p<0.0001 for comparison). The in-hospital mortality increased significantly across the different risk groups.

Conclusions The SCAMI-NSTEMI score can serve as a useful tool facilitating rapid risk assessment among a broader spectrum of patients admitted owing to NSTEMI.

INTRODUCTION

Acute myocardial infarction (AMI) is a leading cause of mortality worldwide, accounting for 2.4 million mortalities in the USA and more than 4 million mortalities in Europe and northern Asia. AMI is commonly divided into ST-segment elevation myocardial infarction (STEMI) and non-STEMI (NSTEMI) based on the presence or absence of ST-segment elevation on ECG. NSTEMI compromises approximately 70% of all myocardial infarction cases. Patients with NSTEMI have varying prognoses. Accurate risk stratification of patients with NSTEMI is important, as it can not only help identify high-risk patients who will benefit from prompt revascularisation but also avoid inappropriate use of aggressive treatment among low-risk patients. Many risk scores have been developed for estimating mortality risk in patients with acute coronary syndrome (ACS), including the Global Registry of Acute Coronary Events (GRACE) risk score, Acute Coronary Treatment and Intervention Outcomes Network (ACTION) risk score, Canadian ACS risk score, and ProACS risk score. However, these scores included only a small number of Chinese patients. Additionally, to our knowledge, no risk scores have been focused on patients with NSTEMI. To bridge the knowledge gap, our team previously developed and validated a novel risk score for predicting the
in-hospital mortality risk among patients with NSTEMI based on the China Acute Myocardial Infarction (CAMI) registry (ie, CAMI-NSTEMI score).7

Early risk assessment is of clinical significance among patients with NSTEMI. A large-scale meta-analysis found that among high-risk patients with NSTEMI, an early invasive strategy was associated with a lower in-hospital mortality.8 In addition, there is evidence indicating that among high-risk patients with NSTEMI, coronary angiography early within the initial 12 hours was associated with better outcomes.9

However, our original CAMI-NSTEMI score includes the white blood cell (WBC) count and creatinine level which might restrict its use at the time of the first medical contact before obtaining laboratory test results. Delayed stratification may have an adverse impact on patient outcomes, especially for these high-risk patients.

The objective of our study was to collect laboratory data from the previous CAMI-NSTEMI risk score and consequently develop and validate a simplified risk score which can save time in terms of score calculation and allow for early risk assessment.

METHODS
CAMI registry
The CAMI registry was designed as an integrated research and educational platform to reflect patients with AMI in China. The detailed description of the CAMI study design has been published previously.10 In brief, the CAMI registry was a prospective multicentre registry that aimed to reflect the patient characteristics, medical care and management of Chinese patients with AMI. Multi-teams with various roles cooperated to ensure smooth execution of the project. A total of 108 hospitals across three levels (provincial, prefectural and county) from 27 provinces and 4 municipalities participated in the project which assures a good representation of the contemporary cohort of AMI in China. The CAMI registry enrolled patients within 7 days of ischaemia symptoms, who had a diagnosis of AMI according to the Third Universal Definition of Myocardial Infarction.11 Patient characteristics, physical examination results and laboratory test results were collected and submitted to an electronic web-based system.

CAMI-NSTEMI score
We previously developed and validated a novel risk score, that is, CAMI-NSTEMI risk score, to predict the in-hospital mortality risk among patients with NSTEMI.7 Briefly, the CAMI-NSTEMI score was derived from a cohort of patients with NSTEMI registered in the CAMI registry between January 2013 and September 2014. Data were extracted by trained researchers using standard definitions to reduce measure and report bias. We excluded those with missing or invalid data on age, body mass index (BMI), admission diagnosis and in-hospital outcome and those diagnosed with left bundle branch block (LBBB) and finally included 5775 patients to develop and validate the risk score. The primary outcome of our study was in-hospital mortality, which was evaluated by trained cardiologists during hospitalisation. We did not take actions to blind assessment and predictors of the outcome because of the hard outcome (in-hospital mortality) measure. Using a multivariable logistic regression model, we identified 11 independent predictors of in-hospital mortality: age, BMI, systolic blood pressure, Killip classification, cardiac arrest, ST-segment depression on ECG, serum creatinine level, WBC count, smoking status, previous angina and previous percutaneous coronary intervention. Although cardiac biomarkers are more available than the serum creatinine level and WBC count, the CAMI-NSTEMI risk score did not include cardiac biomarkers because the CAMI registry was a multicentre registry including 108 participating hospitals. The type of cardiac enzymes and the corresponding normal range differed across hospitals. Including cardiac biomarkers may reduce the diagnostic performance of the risk score. Therefore, based on these 11 predictors, we developed and validated the CAMI-NSTEMI risk score to predict the in-hospital mortality risk among the patients with NSTEMI. The detailed definition regarding each variable was described in the protocol.10

Statistical analysis
Continuous data were presented as mean ± SD and were compared using the Student’s t-test. Categorical variables were summarised as counts and percentages and were compared using the χ² test or Fisher’s exact test, as appropriate. All analyses were performed using the SAS V.9.4 system (SAS Institute). All p values were two-tailed, and a p value of <0.05 was considered statistically significant. We did not calculate the sample size, as this was a registry-based retrospective study, and we wanted to enrol as many patients as possible. We used simple imputation methods to deal with missing data, which were imputed with the median or mode values of the available cases. The methods for developing and validating simplified CAMI-NSTEMI (SCAMI-NSTEMI) risk score were the same as those for the original CAMI-NSTEMI score, which have been reported previously.7 Briefly, the entire cohort was divided into the derivation (n=4332) cohort and the validation (n=1443) cohort chronologically. To develop the simplified risk score, we first fitted variables with p values of <0.25 in the univariable selection into the logistic multivariable regression model. The WBC count and creatinine level were not included in the multivariable model. Thereafter, the multivariable model was constructed using stepwise variable selection with entry and exit criteria (p<0.05). We attributed integer numbers to each variable according to the coefficient. The area under the receiver-operating characteristic curve (AUC) and Hosmer-Lemeshow (HL) goodness-of-fit test were used to assess discrimination and calibration of the risk score. The scoring system was divided into three risk groups (low, intermediate and high risks) according

Song C, et al. BMJ Open 2019;9:e030772. doi:10.1136/bmjopen-2019-030772
to tertiles. We compared the diagnostic performance between the CAMI-NSTEMI score and GRACE score by calculating the AUC, net reclassification improvement (NRI) and integrated discriminatory index (IDI).12

**Patient and public involvement**

We did not involve patients or the public directly in our work.

**RESULTS**

**Patient characteristics**

From January 2013 to September 2014, a total of 6209 patients diagnosed with NSTEMI were registered in the CAMI registry. We excluded 393 patients owing to incomplete or invalid data on age, BMI, admission diagnosis and in-hospital outcome. We also excluded 41 patients with LBBB and finally included 5775 patients. A total of 342 patients (5.9%) died during hospitalisation. As shown in table 1, most patient characteristics were imbalanced between the groups. The patients who died during hospitalisation were older and more likely to present with diabetes mellitus or hypertension than the in-hospital survivors. Further, they had a lower BMI, and a lower proportion of male and current smokers.

Regarding clinical presentation, the patients who died during hospitalisation had higher heart rate, lower systolic blood pressure and higher Killip classification than the in-hospital survivors. A higher proportion of patients who died during hospitalisation presented with ST-segment depression on ECG and cardiac arrest. The laboratory test showed that the patients who died during hospitalisation had higher platelet count, serum creatinine level, WBC count and serum potassium level but lower haemoglobin level than the in-hospital survivors (table 1).

**SCAMI-NSTEMI score**

A univariable analysis was first performed to explore the unadjusted association between each baseline predictor and outcome (online supplementary table 1). Variables with p values of <0.25 were selected to enter into the multivariable logistic regression model. In the multivariable analysis, a total of nine variables were identified as independent risk factors of in-hospital mortality and used to develop the SCAMI-NSTEMI risk model: age, BMI, systolic blood pressure, Killip classification, cardiac arrest, ST-segment depression on ECG, smoking status, previous angina and previous percutaneous coronary intervention (table 2). We attributed integer numbers to each variable based on the coefficient in the multivariable logistic regression model (table 3) and established the SCAMI-NSTEMI risk score. The in-hospital mortality risk corresponding to each point is shown in online supplementary table 2.

Within the derivation cohort (n=4332), 248 patients died during hospitalisation. The AUC for the SCAMI-NSTEMI model was 0.7771 (95% CI: 0.7472 to 0.8071) which was slightly higher than that for the SCAMI-NSTEMI

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**Table 1 Baseline characteristics of patients who died vs survived**

|                        | In-hospital survivors (n=5433) | In-hospital deaths (n=342) | p value    |
|------------------------|-------------------------------|---------------------------|------------|
| Age (years)            | 64.92±11.98                   | 72.13±11.16               | <0.01      |
| Male                   | 3754/5433 (69.1)              | 187/342 (54.7)            | <0.01      |
| BMI (kg/m²)            | 24.09±3.05                    | 23.02±3.11                | <0.01      |
| DM                     | 1249/5418 (23.1)              | 98/342 (28.7)             | 0.02       |
| Hypertension           | 3154/5423 (58.2)              | 209/342 (61.1)            | 0.28       |
| Hyperlipidaemia        | 456/5421 (8.4)                | 14/342 (4.1)              | <0.01      |
| LVEF (%)               | 55.10±11.76                   | 46.75±13.01               | <0.01      |
| Previous angina        | 2074/5408 (38.4)              | 144/342 (42.1)            | 0.17       |
| Previous MI (>1 month) | 585/5411 (10.8)               | 63/342 (18.4)             | <0.01      |
| Previous heart failure | 263/5412 (4.9)                | 48/342 (14.0)             | <0.01      |
| Previous PCI           | 358/5400 (6.6)                | 12/342 (3.5)              | <0.01      |
| Previous CABG          | 48/5411 (0.9)                 | 4/342 (0)                 | 0.55       |
| Previous stroke        | 542/5410 (10.0)               | 46/342 (13.5)             | 0.05       |
| Previous renal dysfunction | 137/5400 (2.5)              | 15/341 (4.4)              | 0.06       |
| Previous COPD          | 131/5382 (2.4)                | 16/340 (4.7)              | 0.02       |
| Family history of premature CAD | 168/5417 (3.1) | 6/342 (1.8) | 0.13 |
| Previous peripheral vascular disease | 64/5406 (1.2) | 5/342 (1.5) | 0.60 |
| Smoking status         |                               |                           | <0.01      |
| Current smoker         | 1967/5406 (36.4)              | 60/339 (17.7)             |           |
| Previous smoker        | 721/5406 (13.3)               | 46/339 (13.6)             |           |
| Non-smoker             | 2718/5406 (50.3)              | 233/339 (68.7)            |           |
| Prior use of medication (within 1 week) |                           |                           |           |
| Aspirin                | 1003/5405 (18.6)              | 69/339 (20.4)             | 0.42       |
| Thienopyridines        | 338/5386 (6.3)                | 29/339 (8.6)              | 0.11       |
| Statins                | 764/5327 (14.3)               | 54/334 (16.2)             | 0.36       |
| HR (beats/min)         | 79.19±19.90                   | 89.97±25.39               | <0.01      |
| SBP (mm Hg)            | 134.64±25.67                  | 121.87±28.71              | <0.01      |
| Killip classification  |                               |                           | <0.01      |
| I                      | 3873/5393 (71.8)              | 127/339 (37.5)            |           |
| II                     | 989/5393 (18.3)               | 93/339 (27.4)             |           |
| III                    | 382/5393 (7.1)                | 52/339 (15.3)             |           |
| IV                     | 149/5393 (2.8)                | 67/339 (20.3)             |           |
| ST segment depression  | 2917/5340 (54.6)              | 223/335 (66.6)            | <0.01      |
| Heart arrest           | 29/5404 (0.5)                 | 14/340 (4.1)              | <0.01      |
| Time to hospital       |                               |                           | 0.68       |
| 1–7 days               | 2139/5345 (40.0)              | 140/334 (41.9)            |           |
| 12–24 hours            | 758/5345 (14.2)               | 40/334 (12.0)             |           |
| 6–12 hours             | 772/5345 (14.4)               | 54/334 (16.2)             |           |
| <6 hours               | 1676/5345 (31.4)              | 100/334 (30.5)            |           |
| PLT (109/L)            | 208.26±72.23                  | 217.53±117.26             | 0.16       |
| Hb (g/L)               | 131.81±21.95                  | 121.82±26.27              | <0.01      |

Continued
SCAMI-NSTEMI score (AUC: 0.8286; 95% CI: 0.8286 to 0.9055), which was slightly higher than that for the CAMI-NSTEMI model was 0.8614 (95% CI: 0.8173 to 0.9055). The AUC value for comparison; figure 1A). Within the validation cohort (n=1443), 94 died during hospitalisation. The AUC value for the SCAMI-NSTEMI score in relation to the GRACE risk score was 0.7819 (95% CI: 0.7567 to 0.8072, p<0.001 for comparison; online supplementary figure 1). The NRI and IDI for the SCAMI-NSTEMI score and GRACE risk score within the entire cohort (0.8080 vs 0.7819, p<0.0001 for comparison) reached statistical significance (p<0.0001; online supplementary figure 2). The NRI and IDI for the SCAMI-NSTEMI score in relation to the GRACE score were 0.7272 (95% CI: 0.6995 to 0.7548), respectively, and 0.8748, p=0.003 for comparison; figure 1B). Within the validation cohort, a similar trend was observed. The event rate was 1.04%, 2.65% and 15.21% in the low-risk, intermediate-risk and high-risk groups. Within the validation cohort, a similar trend was observed. The event rate was 1.04%, 2.65% and 15.21% in the low-risk, intermediate-risk and high-risk groups.

The SCAMI-NSTEMI score ranged from 0 to 36. The in-hospital mortality increased across the tertiles: 1.28% in tertile I (score range: 0–14), 3.33% in tertile II (score range: 15–18), and 10.53% in tertile III (score range: ≥19) (p=0.001 for tertile II vs tertile I; p<0.001 for tertile III vs tertile I). Therefore, these three tertiles were defined as the low-risk, intermediate-risk and high-risk groups. Within the validation cohort, a similar trend was observed. The event rate was 1.04%, 2.65% and 15.21% in the low-risk, intermediate-risk and high-risk groups, respectively.

### Table 1

| Predictor Categories | Score | Predictor Categories | Score |
|---------------------|-------|---------------------|-------|
| Age (years) <57     | 0     | Killip classification | I     |
| (57–66)             | 2     | II                  | 3     |
| (66–75)             | 3     | III                 | 6     |
| ≥75                 | 4     | IV                  | 9     |
| BMI (kg/m<sup>2</sup>) <20.04 | 2     | Heart arrest        | No    | 0     |
| (20.04–23.88)       | 1     | Yes                 | 6     |
| (23.88–25.86)       | 1     | Smoking status      | Non-smoker | 4 |
| ≥25.86              | 0     | Ex-smoker           | 2     |
| SBP (mm Hg) <118.5  | 5     | Current-smoker      | 0     |
| (118.5–130)         | 4     | Prior MI            | No    | 0     |
| (130–150)           | 2     | Yes                 | 3     |
| ≥150                | 0     | Prior PCI           | No    | 6     |
| ST-segment depression | No   | Yes                 | 0     |
| (score: <150)       | 2     | Yes                 | 2     |

### Table 2

| Predictor | OR | 95% CI | P value |
|-----------|----|--------|---------|
| Age (per 1-year increase) | 1.027 | 1.014 to 1.041 | <0.0001 |
| BMI (per one 1 kg/m<sup>2</sup> increase) | 0.946 | 0.903 to 0.990 | 0.0170 |
| SBP (per 1 mm Hg increase) | 0.983 | 0.977 to 0.988 | <0.0001 |
| Killip classification | 1.707 | 1.492 to 1.953 | <0.0001 |
| ST-segment depression | 1.516 | 1.134 to 2.207 | 0.0049 |
| Heart arrest | 3.103 | 2.70 to 7.578 | 0.0129 |
| Non-smoker vs current smoker | 1.900 | 1.338 to 2.698 | 0.0003 |
| Ex-smoker vs current smoker | 1.393 | 0.858 to 2.261 | 0.1804 |
| Previous MI | 1.719 | 1.167 to 2.533 | 0.0061 |
| Previous PCI | 0.334 | 0.148 to 0.753 | 0.0082 |

BMI, body mass index; SBP, systolic blood pressure; MI, myocardial infarction; PCI, percutaneous coronary intervention; PLT, platelet count; SBP, systolic blood pressure; WBC, white blood cell count.

Comparison between the CAMI-NSTEMI score and GRACE risk score

We first compared the diagnostic performance between the SCAMI-NSTEMI score and the original CAMI-NSTEMI score. The AUC for the CAMI-NSTEMI score was higher than that for the SCAMI-NSTEMI score within the entire cohort (0.8080 vs 0.7819, p<0.0001 for comparison; online supplementary figure 1).

We then compared the diagnostic performance between the SCAMI-NSTEMI score and GRACE risk score within the entire cohort. The AUC for the SCAMI-NSTEMI score and GRACE risk score was 0.7819 (95% CI: 0.7567 to 0.8072) and 0.7272 (95% CI: 0.6995 to 0.7548), respectively, and the difference reached statistical significance (p<0.0001; online supplementary figure 2). The NRI and IDI for the SCAMI-NSTEMI score in relation to the GRACE score were 38.9% (p<0.0001) and 5.78% (p<0.0001), respectively.

### DISCUSSION

We developed and validated a simplified risk score to assess the in-hospital mortality risk of patients with NSTEMI.

### Table 3

| Predictor Categories | Score |
|---------------------|-------|
| Age (years) <57     | 0     |
| Killip classification | I     |
| (57–66)             | 2     |
| (66–75)             | 3     |
| ≥75                 | 4     |
| BMI (kg/m<sup>2</sup>) <20.04 | 2     |
| (20.04–23.88)       | 1     |
| (23.88–25.86)       | 1     |
| ≥25.86              | 0     |
| SBP (mm Hg) <118.5  | 5     |
| (118.5–130)         | 4     |
| (130–150)           | 2     |
| ≥150                | 0     |
| ST-segment depression | No   |
| (score: <150)       | 2     |

BM, body mass index; MI, myocardial infarction; PCI, percutaneous coronary intervention; SBP, systolic blood pressure.
The simplified risk score incorporated nine variables, which are easily obtained during routine medical history-taking and bedside examination without the need to wait for laboratory test results. This allows timely risk stratification and treatment strategy selection, as well as risk assessment among a broader spectrum of patients with AMI, especially for those with missing variables during the first presentation. The SCAMI-NSTEMI score demonstrated good discrimination and calibration abilities, as well as better diagnostic performance, compared with the GRACE risk score.

Comparison with previous risk scores

Many risk scores have been developed to predict the short-term and long-term outcomes of patients with AMI, and the GRACE risk score is the most validated and commonly used risk prediction parameter by clinicians.3-14 In addition, the GRACE risk score performed better than the Thrombolysis in Myocardial Infarction risk score in Chinese patients with NSTEMI.15 Therefore, we compared the SCAMI-CAMI risk score with the GRACE risk score. These two scores differ in the following two aspects.

First, the SCAMI-NSTEMI risk score was derived from a more recent cohort. The original GRACE risk score was developed from a cohort of patients with ACS enrolled in the GRACE registry from 1 April 1999 to 31 March 2001. Patient profile and AMI management have evolved significantly over time, and it is reasonable to update the risk scores periodically.

Second, the SCAMI-NSTEMI score better represented unique prognostic factors among patients from Asia. While the GRACE registry was a multicentre registry covering the USA, Europe and Australia, only a few participants from Asia were enrolled. The risk factors of in-hospital mortality may differ across various ethnic groups.

As Asia is the most populous continent worldwide, it is appropriate to develop a risk score more suitable for Asian patients. This is of clinical significance because NSTEMI affects a broad spectrum of patients with various prognoses, and a risk prediction parameter with high accuracy is important for the triage and management of patients with NSTEMI.

Obesity and smoker’s paradox

Although obesity and smoking are well-established risk factors of coronary artery disease, our study found that the patients with a higher BMI had a lower in-hospital mortality than those with a normal BMI, and the current smokers had a lower in-hospital mortality than the current non-smokers. These phenomena are referred to as ‘obesity paradox’9 and ‘smoker’s paradox,’10 respectively. The possible explanations for obesity paradox include the following: patients with obesity are younger than patients with normal weight and more likely to receive aggressive treatment.11 In addition, when patients develop AMI, their metabolic demands increase sharply, and body fat may serve as nutritional reserves.12

Regarding smoker’s paradox, the observed association may be subject to selection bias. The distribution of the risk factors was significantly different between the smokers and non-smokers. It is likely that we did not adjust for some unmeasured variables which may lead to selection bias. Conversely, the CAMI registry did not collect data on patients who died before hospitalisation. Failing to account for pre-hospital mortalities may also lead to selection bias.13 In addition to selection bias, smoker’s paradox may be explained by the biological effect of smoking. Smoking could lead to a chronic ischaemic state (ischaemic preconditioning)14; therefore, smokers may have better tolerance for an acute ischaemic event, such as AMI.
Clinical implications

First, the simplified score can help save time in risk estimation at the first medical contact, that is, time of the first contact of the patient with the physician before obtaining laboratory test results. This may be beneficial particularly for high-risk patients with NSTEMI. A large-scale meta-analysis included 5324 patients from eight trials and found that an early invasive strategy was associated with a lower mortality among high-risk patients, including those with elevated cardiac biomarkers at baseline, diabetes mellitus, a GRACE risk score more than 140 and aged 75 years.9 Consistently, a recent randomised trial showed that coronary angiography within the initial 12 hours was related to a lower risk of ischaemic outcomes among high-risk patients.9 Therefore, early risk assessment enables high-risk patients with NSTEMI to receive revascularisation as soon as possible and may help improve their outcomes. Second, the SCAMI-NSTEMI score may help in better identification of high-risk patients. The current guidelines recommend prompt revascularisation in very high-risk patients with characteristics including cardiogenic shock, severe left ventricular dysfunction and haemodynamic instability.16 However, many other baseline characteristics affect the mortality risk, and a patient may still be at a high risk even without the above-mentioned clinical presentation. Our study first identified independent risk factors based on the variables that can be easily obtained in clinical practice and then integrated these risk factors to establish the risk score system. Therefore, our score may help in better identifying patients at a high risk for in-hospital mortality with the absence of severe clinical presentation.

In addition, the SCAMI-NSTEMI score excluded laboratory test variables; this may broaden the applicability of the risk score in the management of AMI, especially in developing countries. Compared with the GRACE risk score, the SCAMI-NSTEMI score does not include the troponin level. Approximately 18.6% of hospitals do not have the capability to examine the troponin level in China. Even among hospitals with troponin-level testing capabilities, only 55.9% use the assay for >80% of patients with AMI.17 Similarly, many patients may not have available data on the creatinine level at initial presentation. In a large-scale AMI cohort in the ACTION registry, approximately 11.6% of patients did not have available data on the initial or peak creatinine level.18 Our SCAMI-NSTEMI score did not include the laboratory test variable and therefore enabled the providers to risk-stratify more patients admitted owing to suspected or confirmed AMI.

Limitations

Our study has several limitations. First, external validation of the SCAMI-NSTEMI score in a larger independent cohort from China and other countries is required in future studies. Second, we only assessed the in-hospital outcome; future studies are needed to examine whether the SCAMI-NSTEMI score is suitable for long-term risk prediction. Third, the CAMI registry did not collect data on the specific type and amount of tobacco products the patients used. Finally, all participants were from China. Our score requires further validation in another ethnic group.

CONCLUSIONS

The SCAMI-NSTEMI score, which was easier to calculate than the original score, showed good diagnostic performance and may aid in rapid risk stratification in more patients admitted owing to NSTEMI.

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Acknowledgements We appreciate the TIMI Study Group and the Duke Clinical Research Institute for their kind help in the design, conduct and data analysis of China Acute Myocardial Infarction registry. We also thank all the investigators and coordinators for their active participation and great contribution in data collection and patients enrolment. We appreciate professional editors at Editage for editing the English text.

Contributors RF and CS were major contributors in writing the manuscript, KD and YI contributed substantially to the conception and design of the study. YW, HX, XG revised it critically for important intellectual content. QL and CW contributed to data collection and follow up. SL, JL and JY made contribution to analysis and interpretation of data.

Funding This work was supported by CAMS Innovation Fund for Medical Sciences (CIFMS) (2016-I2M-1-009), the Eleventh Five-Year Planning Project of the Scientific and Technological Department of China (2011BA11B02) and Fundamental Research Funds for the Central Universities (2018-F04).

Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The China Acute Myocardial Infarction registry was approved by the Institutional Review Board Central Committee at Fuwai Hospital, Chinese Academy of Medical Sciences.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

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