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Limitations of Risk Score Models in Patients with Acute Chest Pain

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Abstract

Objectives—Cardiac multidetector computed tomography (CMCT) has potential to be used as a screening test for patients with acute chest pain, but several tools are already used to risk-stratify this population. Risk models exist that stratify need for intensive-care (Goldman), short-term prognosis (Thrombolysis in Myocardial Infarction, TIMI), and one-year events (Sanchis). We applied these cardiovascular risk models to candidates for CMCT and assessed sensitivity for prediction of in-hospital NSTEMI. We hypothesized that none of the models would achieve a sensitivity of 90% or greater, thereby justifying use of CMCT in patients with acute chest pain.

Methods—We analyzed TIMI, Goldman, and Sanchis in 148 consecutive patients with chest pain, non-diagnostic ECG, and negative initial cardiac biomarkers who previously met inclusion and exclusion criteria for the ROMICAT Study. NSTEMI was adjudicated and risk scores were categorized based on established criteria. Risk score agreement was assessed with weighted kappa statistics.

Results—Overall 17/148 (11%) patients had NSTEMI. For all risk models, sensitivity was poor (range 35–53%) and 95% confidence intervals did not cross above 77%. Agreement to risk-classify patients was poor to moderate (weighted kappa range 0.18–0.43). Patients categorized as “low risk” had non-zero rates of NSTEMI using all three scoring models (range 8–9%).

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Conclusions—Available risk scores had poor sensitivity to detect NSTEMI in patients with acute chest pain. Because of the small number of patients in this data set, these findings require confirmation in larger studies.

Keywords

Chest pain; computed tomography; myocardial infarction; risk

Introduction

Prior studies suggest that between 2–5% of ED patients with chest pain who are sent home develop myocardial infarction (MI) within 30 days.^{1–2} Cardiac multidetector computed tomography is emerging as a promising diagnostic tool in patients who present to the emergency department (ED) with acute chest pain.^{3–7} Cardiac computed tomography may be most useful for patients with normal or non-diagnostic electrocardiograms (ECG) and negative initial cardiac biomarkers because in these patients neither the clinical history, physical exam, ECG nor biomarker assays can establish or exclude acute myocardial ischemia.

Several tools used for cardiovascular risk-stratification include the Goldman risk score (see Figure 1),^{8–9} the Thrombolysis In Myocardial Infarction (TIMI) risk score (see Table 1),¹⁰ and a novel risk model recently published by Sanchis and colleagues (subsequently referred to here as the Sanchis score).¹¹ The Goldman risk score uses elements of the history, physical exam, and ECG to determine 72-hour risk of major adverse cardiac events (dysrhythmia, pump failure, and ischemia) in patients with acute chest pain.^{8–9} The TIMI risk score uses elements of the history, ECG, and results of cardiac biomarkers to predict 14-day risk of death and ischemic events in patients with non-ST elevation myocardial infarction (NSTEMI) or unstable angina,¹⁰ and has been shown to predict 30-day risk of adverse cardiac outcomes (death, MI, revascularization) for undifferentiated ED patients with suspected myocardial ischemia.¹² Recently, the Sanchis score was derived to predict mortality or myocardial infarction at one-year in low risk patients with chest pain.¹¹

Identification of patients at highest risk for the development of NSTEMI is essential to initial ED diagnostic and therapeutic management based on recently published guidelines.^{13–14} Most importantly, sensitive screening tools for NSTEMI would theoretically improve resource utilization and ED efficiency. Unfortunately, no highly sensitive tools exist to detect NSTEMI in low-risk patients with chest pain,¹⁵ and none of the above risk prediction models were originally derived from patients who were candidates for cardiac computed tomography. Thus, it remains unclear whether any of these tools may predict in-hospital NSTEMI for this patient population.¹⁶

We tested the diagnostic accuracy (e.g. sensitivity and specificity) of three risk models in patients who were enrolled in the ROMICAT study,⁵ a prospective cohort that addressed the utility of cardiac multidetector computed tomography for low-to-intermediate risk patients with chest pain. We hypothesized that none of the three risk score models would achieve a threshold of 90% sensitivity to detect in-hospital NSTEMI. We also tested our secondary hypothesis that risk score models would demonstrate poor agreement. Thus, we compared

the test characteristics and agreement of three cardiovascular risk models (Goldman, TIMI, and Sanchis) to predict NSTEMI in patients who were enrolled in the ROMICAT study.

Methods

Study Design

We conducted this descriptive study as a secondary data analysis of the ROMICAT study,⁵ a prospective observational cohort study on consecutive adult patients presenting to the ED with acute chest pain in whom initial ED evaluation was inconclusive and who were awaiting admission to the hospital. The aims of the ROMICAT study were to assess the incremental value of cardiac multidetector computed tomography in the evaluation of intermediate-risk ED patients with chest pain. In the absence of validated risk-stratification tools that may predict in-hospital NSTEMI in candidates for cardiac multidetector computed tomography, we chose to evaluate the Sanchis, TIMI, and Goldman risk models because all three were originally intended to be applied to patients with acute chest pain. Our institutional review board approved this study. All patients provided written consent.

Study Setting and Population

The study took place at a university hospital tertiary referral center with over 70,000 adult ED visits annually. The ROMICAT study included consecutive adult patients presenting to the ED with acute chest pain in which the initial ED evaluation was inconclusive (i.e. non-diagnostic ECG and negative initial cardiac biomarkers), but in whom the clinical suspicion for acute coronary syndrome was high enough to warrant admission. Patients were enrolled in the ED while awaiting admission to the hospital. All patients were candidates for cardiac multidetector computed tomography, as defined by the specific inclusion and exclusion criteria of the ROMICAT study,⁵ summarized in Table 2.

Study Protocol

The study was conducted over two distinct time periods: the first between September 2004 and March 2005 two days per week from 9am to 5pm; the second between May and July 2005 on weekdays from 7am to 7pm. Study investigators prospectively collected data about each patient's demographics, risk factor profile, and clinical course using a uniform data collection worksheet. A separate investigator calculated risk scores, thus assuring blinding of data collection. Patients received the standard clinical care during index hospitalization including serial ECGs and cardiac biomarkers, and subsequent cardiac testing (e.g. exercise testing, stress perfusion imaging, or cardiac catheterization) as deemed clinically indicated. Medical records were reviewed to obtain data about all diagnostic tests. Presence of risk factors was established from actual measurements obtained during the hospitalization (i.e. hypertension, hypercholesterolemia, and diabetes mellitus). History of coronary artery disease (CAD) was defined as a history of myocardial infarction, prior stent placement or bypass grafting. Hypertension was defined as systolic blood pressure (SBP) of at least 140 mm Hg or diastolic blood pressure (DBP) of at least 90 mm Hg (from the ED record), or chronic treatment for hypertension. Hyperlipidemia was defined as total cholesterol >200mg/dl (fasting blood sample) or chronic treatment with lipid lowering medications. Diabetes was defined as a fasting plasma glucose ≥ 126 mg/dL or chronic treatment with

either insulin or an anti-hyperglycemic agent. Participants were considered to be current smokers if they smoked at least one cigarette per day for the last year. Framingham risk scores for each patient were calculated using cholesterol levels from blood drawn during the index hospitalization and blood pressure measurements recorded from the ED record, based on an algorithm that is described elsewhere.¹⁷

Measurements

Each patient's Goldman risk score was calculated using information from the initial physician evaluation and ECG. Score calculation is described elsewhere.⁹ Briefly, a score of 0.7% (very low), 3.6% (low), 7.7% (intermediate), and >16% (high) was assigned based on an algorithm (Figure 1) that analyzes clinical characteristics including elements of the history (known unstable coronary disease), physical examination (systolic blood pressure below 110 and presence of bilateral rales), and ECG (suspected ischemia or infarction). For our data analysis, we categorized patients into 3 risk groups based on the Goldman algorithm: low (0.7%), intermediate (3.6%), and high (>7.7%).

We also calculated the TIMI risk score derived¹⁰ from the TIMI-11B study.¹⁸ The score is additive, without weighting, based on 7 risk factors (Table 1). For individual patients, the score ranges between 0–7. We split patients into low (0–2), intermediate (3–4), and high (5–7) risk groups.

Sanchis risk scores for each patient were calculated based on the criteria described by Sanchis and colleagues.¹¹ Briefly, the chest pain score is based on 18 historical criteria derived from a study by Geleijnse and colleagues,¹⁹ as well as 4 additional elements of the history. The score ranges from 0–6 based on the following scoring system: Geleijnse chest pain score at least 10 (1 point), 2 or more chest pain episodes within 24 hours (1 point), age greater than 66 years (1 point), insulin dependent diabetes mellitus (2 points), and prior percutaneous transluminal coronary angioplasty (1 point). Risk categories were assigned according to score: low-risk (0–1 points), intermediate-risk (2 points), and high-risk (3–6 points).

The outcome was NSTEMI during the index hospitalization, defined according to the joint American Heart Association/ American College of Cardiology/ European Society of Cardiology guidelines.^{20–22} To establish this diagnosis, an outcome panel of two physicians (one cardiologist and one emergency physician) reviewed the patient data forms containing prospectively collected information on the history and nature of chest pain, risk factors and medical history, as well as medical records pertaining to the hospital admission of enrolled patients.²³ These included physician notes, a discharge summary, and the results of cardiac biomarkers, ECG and other tests performed including stress perfusion imaging or invasive coronary angiography. The outcome panel was blinded to risk scores. Disagreement between panelists regarding NSTEMI occurred on one case, and was solved by consensus of an additional cardiologist blinded to risk scores.

Data Analysis

Risk score test characteristics (sensitivity, specificity, positive and negative predictive values) were calculated by dichotomization of risk scores (using low risk as the

comparison). 95% confidence intervals (CI) were calculated using the estimated standard error method. Risk score agreement was assessed with weighted kappa statistics for ordinal risk categories (low, moderate, high). As the sample size was fixed, we did not perform any additional sample size calculations.

As a secondary analysis to check whether each model had any predictive capability in our population, we analyzed the association with NSTEMI for each risk model using Student's t-test for continuous risk scores. Risk estimates were calculated using odds ratios (OR) with low risk category as the comparison. All p values were two-tailed with a value <0.05 considered significant. Analyses were performed using SPSS software (version 14, Chicago, IL) and intercooled STATA (version 8.2, College Station, TX).

Results

Characteristics of Study Subjects

During the recruitment period, 413 consecutive patients were screened for enrollment. During this period, 241 patients met exclusion criteria and 24 refused participation, leaving 148 enrolled patients for data analysis. Major reasons for ineligibility were the following: elevated creatinine ($n=65$), initially positive Troponin or ECG changes indicative of myocardial ischemia ($n=52$), and immediate discharge from the ED ($n=50$). The mean age was 54.6 ± 12.3 years, 61 (41%) were female, 21 (14%) were Hispanic, and 9 (6%) were African American. Selected demographics, cardiac risk factors, medical history, and Framingham scores for patients with and without NSTEMI are shown in Table 3. Overall, 17 out of 148 (11%) patients had NSTEMI during index hospitalization. Proportions of patients with NSTEMI using categories for each risk model are summarized in Table 4.

Test Characteristics

Test characteristics of each risk score model (dichotomized, low risk as the comparison) for prediction of NSTEMI are summarized in Table 5, with the published diagnostic accuracy of cardiac multidetector computed tomography from the ROMICAT study included for comparison. No risk model achieved confidence intervals that crossed above 90% sensitivity to predict NSTEMI. Overall, sensitivity was poor (range 35–53%) and specificity was only moderate (range 72–86%). The negative predictive value of low risk scores were good (range 91–92%), but the positive predictive values were extremely limited (range 20–28%).

Agreement Between Risk Models

We used weighted kappa statistics (see Table 6) to evaluate whether each risk model agreed upon risk category designations. Agreement in general was poor to moderate (range 0.18–0.43).

Secondary Analysis: Risk of NSTEMI

Patients categorized as “low risk” had non-zero rates of NSTEMI using all three scoring models (Goldman 7.8%, TIMI 9%, Sanchis 8.3%). Mean risk scores were significantly associated with NSTEMI using TIMI (2.1 ± 1.5 vs. 1.1 ± 1.1 , $p=0.001$) and Sanchis (1.3 ± 1.0 vs. 0.6 ± 0.7 , $p=0.001$), but not Goldman (3.7 ± 3.3 vs. 2.0 ± 2.5 , $p=0.055$).

Discussion

This study demonstrates that three widely used cardiovascular risk stratification tools (TIMI, Goldman, and Sanchis) have inadequate sensitivity (far below a reasonable standard of 90%) to detect NSTEMI in ED patients who were candidates for cardiac multidetector computed tomography. The implications of these results are that existing cardiac risk prediction models demonstrate limited diagnostic accuracy in this population, and should not be used as screening tools. New instruments with higher sensitivity are needed for prompt and accurate triage of patients with acute chest pain.

The most important finding of the present study is that all risk models failed to demonstrate a high sensitivity (range 35–53%) and thus were inadequate to guide early triage (i.e. discharge) of patients with acute chest pain. All three risk models compared unfavorably with the 100% sensitivity (CI 81–100) of cardiac multidetector computed tomography reported in ROMICAT.⁵ While we found that each dichotomized risk model had negative predictive values ranging from 91–92%, there was only moderate specificity (range 72–86%). Patients categorized as “low risk” had clinically consequential rates of NSTEMI using all four scoring models (range 7.8–9%).

In our secondary analysis, we found that mean risk scores were significantly associated with NSTEMI using the TIMI and Sanchis models. When dichotomized using low risk (the comparison group) vs. any other risk (combination of intermediate and high risk categories), all models were associated with significantly increased odds of NSTEMI (see Table 5). Interestingly, agreement between TIMI, Sanchis, and Goldman models to label patients as “high risk” was actually poor to moderate (kappa 0.18–0.43). This confirmed our secondary hypothesis that even risk models originally developed in patients with acute chest pain largely “disagree” about which patients should be designated into risk categories.

Limitations

We report a single center experience which may limit generalizability of our data. However, overall our patient population was fairly heterogeneous (41% women, 14% Hispanic, 6% African American) and may represent a general ED population. A limit to the validity of our study is the absence of a perfect gold standard for NSTEMI. In order to minimize this limitation we utilized an adjudication method with adherence to ESC-ACC guidelines²⁰ and consensus of a 2nd cardiologist when necessary. The fact that our database was derived from patients enrolled in the ROMICAT study, with built-in exclusion criteria (allergy to contrast, creatinine, etc.), may limit both the application of these risk scores to our patients as well as the extrapolation of these results to undifferentiated chest pain patients. Unfortunately, no highly sensitive tools currently exist to detect NSTEMI in low-to-intermediate risk ED patients with chest pain based on the initial evaluation. Finally, the number of events in the study was quite small with only 17 (11%) NSTEMI patients in the data set. As a result, the statistical power of multivariate regression modeling would be limited. Thus we did not attempt to derive a new risk model to predict NSTEMI, which may be reserved for larger multicenter trials.

Conclusions

Available risk scores lacked appropriate sensitivity to detect NSTEMI for patients with acute chest pain. Because of the small number of patients with NSTEMI in this data set, these findings require further confirmation in larger studies. New screening instruments and technologies with higher sensitivity to detect NSTEMI in this population are needed.

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Figure 1. Goldman Risk Score Algorithm

The Goldman Risk Score categorizes patients into discrete risk groups based on risk of major adverse cardiac events (dysrhythmia, pump failure, or ischemia) within 72 hours of initial presentation. Goldman risk factors included systolic blood pressure below 110 mm Hg, bilateral rales heard above the bases on physical examination, and known unstable ischemic heart disease (defined as a worsening of previously stable angina, a new onset of angina, or pain that was the same as previous myocardial infarction). The derivation and validation of the above protocol are from Goldman et al.,⁸⁻⁹ and adapted with permission. Because patients enrolled in ROMICAT had nondiagnostic ECGs, there were no patients classified as “High Risk” in this study, leaving 3 Goldman risk categories (Very Low, Low, and Intermediate) for analysis. For consistency with TIMI and Sanchis, we use the nomenclature of Low (“Very Low” in figure), Intermediate (“Low” in figure), and High (“Intermediate” in figure) to refer to these three Goldman categories in the text. Abbreviations: AMI = acute myocardial infarction, ECG = electrocardiogram, RF = Goldman risk factor.

Table 1

TIMI Risk Scoring Criteria.*

1	Age > 65 yr
2	Documented prior coronary stenosis > 50%
3	Three or more conventional cardiac risk factors
4	Use of aspirin in preceding 7 days
5	Two or more anginal events in the past 24 hours
6	ST-segment elevation or depression > 1 mm
7	Elevated cardiac biomarkers

* Derived from the TIMI-11B study,¹⁸ the score is additive without weighting (0–7). We categorized patients into 3 risk groups: low (0–2), intermediate (3–4), and high (5–7).

Table 2**Inclusion and Exclusion Criteria.**

Inclusion Criteria	
-	Age >18 years
-	>5 minutes of chest pain within the previous 24 hours
-	No or non-diagnostic ECG changes
-	Normal initial cardiac biomarkers
-	Admitted for rule out myocardial infarction through standard care protocols
-	Sinus rhythm
-	Ability to perform a breath hold of 10–15 seconds
Exclusion Criteria	
-	Elevated Troponin I or CK-MB levels in the initial blood sample obtained in the ED
-	New diagnostic ECG changes (ST-segment elevation or depression > 1mm or T-wave inversion >4 mm in >2 anatomically contiguous leads)
-	Hemodynamic or clinical instability (systolic blood pressure <80 mmHg, clinically significant atrial or ventricular arrhythmias, persistent chest pain despite therapy)
-	Known allergy to iodinated contrast agent
-	Serum creatinine >1.3 mg/dl
-	Metformin treatment, hyperthyroidism
-	Inability to provide informed consent
-	Perceived interference with standard clinical care of patients

Table 3

Baseline Clinical Characteristics.

Characteristic	All Patients (n=148)	Patients With NSTEMI (n=17)	Patients Without NSTEMI (n=131)
	N (%)	N (%)	N (%)
Mean Age ($\pm$ SD)	54.6 $\pm$ 12.3	54.0 $\pm$ 11.8	58.6 $\pm$ 15.9
Male Gender	87 (59)	15 (88)	72 (55)
Known CAD	24 (16)	9 (53)	15 (12)
<i>Cardiac Risk Factors</i>			
Tobacco Use	56 (38)	10 (59)	46 (37)
Hypertension	71 (50)	12 (71)	59 (47)
Hypercholesterolemia	78 (53)	11 (65)	67 (54)
Family History	75 (51)	11 (65)	64 (51)
Diabetes Mellitus	14 (10)	4 (24)	10 (8)
<i>Framingham Risk Score</i>			
Mean Score (% $\pm$ SD)	9.7 $\pm$ 7.2	12.4 $\pm$ 7.9	9.3 $\pm$ 7.0
TOTAL	148 (100)	17 (11)	131 (89)

Abbreviations: SD = standard deviation, CAD = coronary artery disease, NSTEMI = non-ST elevation myocardial infarction.

Table 4

Proportions of Patients with NSTEMI Using Risk Categories.

Risk Model	Low Risk	Moderate Risk	High Risk
	N (%)	N (%)	N (%)
Goldman	8/102 (8)	3/24 (13)	6/22 (27)
TIMI	11/122 (9)	5/25 (20)	1/1 (100)
Sanchis	10/121 (8)	5/22 (23)	2/3 (67)

[‡]For use of Sanchis, only 146 patients could be categorized due to 2 patients with incomplete historical data.

Abbreviations: NSTEMI = non-ST elevation myocardial infarction, TIMI = Thrombolysis in Myocardial Infarction.

Table 5

Test Characteristics for Prediction of NSTEMI.

Parameter:	Risk Score:									
	Goldman		TIMI		Sanchis		CMCT [‡]			
	%	95%-CI	%	95%-CI	%	95%-CI	%	95%-CI	%	95%-CI
Sensitivity	53	29 – 77	35	13 – 58	41	18 – 65	100	81–100		
Specificity	72	64 – 79	85	79 – 91	86	80 – 92	46	35–57		
NPV	92	87 – 97	91	86 – 96	92	87 – 97	100	93–100		
PPV	20	8 – 31	23	7 – 39	28	10 – 46	23	13–35		
	OR	95%-CI	OR	95%-CI	OR	95%-CI	OR	95%-CI	OR	95%-CI
Odds of NSTEMI [†]	2.9	1.03–8.0	3.0	1.01–9.1	4.3	1.46–12.8	∞	-		

* For all test characteristics, risk scores were dichotomized using the composite of high- and intermediate-risk scores compared versus low-risk scores.

[†] For odds ratios, low risk categories were used for the comparison group.

[‡] Figures for diagnostic accuracy of CT-based presence of any coronary plaque to predict NSTEMI during index hospitalization were adapted directly from ROMICAT.⁵

Abbreviations: TIMI = Thrombolysis In Myocardial Infarction risk score, CMCT = cardiac multidetector computed tomography angiography, NSTEMI = non-ST elevation myocardial infarction, CI = 95% confidence intervals, OR = odds ratio, NPV = negative predictive value, PPV = positive predictive value.

Table 6Agreement of Risk Scores For the Prediction of NSTEMI Using Weighted Kappa Statistics.[†]

Risk Model:	Goldman	TIMI	Sanchis
Goldman	-	0.30	0.18
TIMI	0.30	-	0.43
Sanchis	0.18	0.43	-

[†] Weighted kappa statistics were used to compare correlations of ordinal categories (low, moderate, high).

Abbreviations: NSTEMI = non-ST elevation myocardial infarction, TIMI = Thrombolysis in Myocardial Infarction, Sanchis = Sanchis chest pain risk score.