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Original Contribution

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 1-year events (Sanchis). We applied these cardiovascular risk models to candidates for CMCT and assessed sensitivity for prediction of in-hospital acute coronary syndrome (ACS). 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, nondiagnostic electrocardiogram, and negative initial cardiac biomarkers who previously met inclusion and exclusion criteria for the Rule-Out Myocardial Infarction Using Coronary Artery Tomography Study. ACS was adjudicated, and risk scores were categorized based on established criteria. Risk score agreement was assessed with weighted κ statistics.

Results: Overall, 17 (11%) of 148 patients had ACS. 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 κ range, 0.18-0.43). Patients categorized as "low risk" had nonzero rates of ACS using all 3 scoring models (range, 8%-9%).

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

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1. Introduction

Prior studies suggest that between 2% and 5% of emergency department (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 ED with acute chest pain [3-7]. Cardiac computed tomography may be most useful for patients with normal or nondiagnostic electrocardiograms (ECGs) and negative initial cardiac biomarkers because, in these patients, neither the clinical history, physical examination, ECG, nor biomarker assays can establish or exclude acute myocardial ischemia.

Several tools used for cardiovascular risk stratification include the Goldman risk score (see Fig. 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 [11] (subsequently referred to here as the Sanchis score). The Goldman risk score uses elements of the history, physical examination, 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, and revascularization) for undifferentiated ED patients with suspected myocardial ischemia [12]. Recently, the Sanchis score was derived to predict mortality or MI at 1 year in low-risk patients with chest pain [11].

Table 1 TIMI risk scoring criteria [a]

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

[a] 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).

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 acute coronary syndromes (ACS) would theoretically improve resource use and ED efficiency. Unfortunately, no highly sensitive tools exist to detect ACS 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 ACS for this patient population [16].

We tested the diagnostic accuracy (eg, sensitivity and specificity) of 3 risk models in patients who were enrolled in the ROMICAT study [5], a prospective cohort that addressed the use of cardiac multidetector computed tomography for low- to intermediate-risk patients with chest pain. We

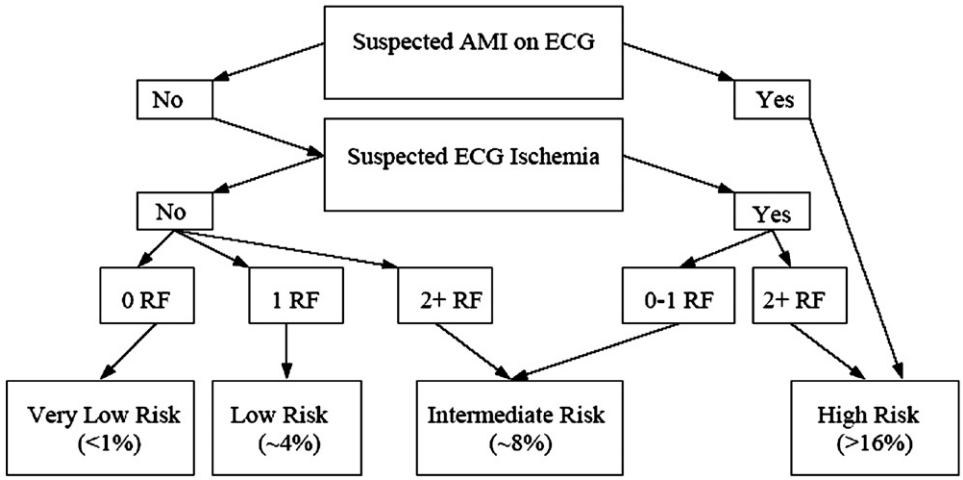

Fig. 1 Goldman risk score algorithm. The Goldman risk score categorizes patients into discrete risk groups based on risk of major adverse cardiac events (dysrhythmia, pump failure, or ischemia) within 72 hours of initial presentation. Goldman risk factors included SBP of below 110 mm Hg, bilateral rales 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 MI). 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 3 Goldman categories in the text. AMI indicates acute MI; RF, Goldman risk factor.

hypothesized that none of the 3 risk score models would achieve a threshold of 90% sensitivity to detect in-hospital ACS. We also tested our secondary hypothesis that risk score models would demonstrate poor agreement. Thus, we compared the test characteristics and agreement of 3 cardiovascular risk models (Goldman, TIMI, and Sanchis) to predict ACS in patients who were enrolled in the ROMICAT study.

2. Methods

2.1. 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 ACS 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.

2.2. Study setting and population

The study took place at a university hospital tertiary referral center with more than 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 (ie, nondiagnostic 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.

2.3. Study protocol

The study was conducted over 2 distinct periods: the first between September 2004 and March 2005, two days per week from 9 AM to 5 PM; the second between May and July 2005 on weekdays from 7 AM to 7 PM. Study investigators prospectively collected data about each patient's demographics, risk factor profile, and clinical course using a uniform data collection work sheet. 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 (eg, 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 (ie, hypertension, hypercholesterolemia, and diabetes mellitus). History of coronary artery disease was defined as a history of MI, prior stent placement, or bypass grafting. Hypertension was defined as systolic blood pressure (SBP) of at least 140 mm Hg or diastolic blood pressure of at least 90 mm Hg (from the ED record) or chronic treatment for hypertension. Hyperlipidemia was defined as total cholesterol of greater than 200 mg/dL (fasting blood sample) or chronic treatment with lipid-lowering medications. Diabetes was defined as a fasting plasma glucose of greater than or equal to 126 mg/dL or chronic treatment with either insulin or an antihyperglycemic agent. Participants were considered to be current smokers if they smoked at least 1 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].

Table 2 Inclusion and exclusion criteria

Inclusion criteria
Age of >18 y
>5 min of chest pain within the previous 24 h
No or nondiagnostic ECG changes
Normal initial cardiac biomarkers
Admitted to rule out MI through standard care protocols
Sinus rhythm
Ability to perform a breath hold of 10-15 s
Exclusion criteria
Elevated troponin I or creatine kinase-MB levels in the initial blood sample obtained in the ED
New diagnostic ECG changes (ST-segment elevation or depression of >1mm or T-wave inversion of >4 mm in >2 anatomically contiguous leads
Hemodynamic or clinical instability (SBP of <80 mm Hg, clinically significant atrial or ventricular arrhythmias, persistent chest pain despite therapy)
Known allergy to iodinated contrast agent
Serum creatinine level of >1.3 mg/dL
Metformin treatment, hyperthyroidism
Inability to provide informed consent
Perceived interference with standard clinical care of patients

2.4. 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 greater than 16% (high) was assigned based on an algorithm

(Fig. 1) that analyzes clinical characteristics including elements of the history (known unstable coronary disease), physical examination (SBP 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 derived [10] 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 and 7. We split patients into low- (0-2), intermediate- (3-4), and high-risk (5-7) 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 historic criteria derived from a study by Geleijnse and colleagues [19], as well as 4 additional elements of the history. The score ranges from 0 to 6 based on the following scoring system: Geleijnse chest pain score of 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 ACS 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 2 physicians (1 cardiologist and 1 emergency physician) reviewed the patient data forms containing prospectively collected information on the history and nature of chest pain, risk factors and medical history, and 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 ACS occurred on 1 case and was solved by consensus of an additional cardiologist blinded to risk scores.

2.5. Data analysis

Risk score test characteristics (sensitivity, specificity, and positive and negative predictive values) were calculated by dichotomization of risk scores (using low risk as the comparison). Using the estimated SE method, 95% confidence intervals (CI) were calculated. Risk score agreement was assessed with weighted κ statistics for ordinal risk categories (low, moderate, and high). Because 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 ACS for each risk model using Student t test for continuous risk scores. Risk estimates were calculated using odds ratios (ORs), with low-risk category as the comparison. All P values were 2-tailed, with a value of less than .05 considered significant. Analyses were performed using SPSS (version 14; SPSS, Chicago, Ill) and STATA (version 8.2; STATA Corporation, College Station, Tex) software.

3. Results

3.1. 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 women, 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 ACS are shown in Table 3. Overall, 17 (11%, 4 ACS, 13 unstable angina pectoris) of 148 patients had ACS during index hospitalization. Proportions of patients with ACS using categories for each risk model are summarized in Table 4.

3.2. Test characteristics

Test characteristics of each risk score model (dichotomized, low risk as the comparison) for prediction of ACS 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 CIs that crossed above 90% sensitivity to

Table 3 Baseline clinical characteristics

Characteristic	All patients (n = 148)	Patients with ACS (n = 17)	Patients without ACS (n = 131)
	n (%)	n (%)	n (%)
Age, mean ± SD	54.6 ± 12.3	54.0 ± 11.8	58.6 ± 15.9
Male sex	87 (59)	15 (88)	72 (55)
Known CAD	24 (16)	9 (53)	15 (12)
Cardiac risk factors			
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)
Framingham risk score			
Score (%), mean ± SD	9.7 ± 7.2	12.4 ± 7.9	9.3 ± 7.0
Total	148 (100)	17 (11)	131 (89)

CAD indicates coronary artery disease.

Table 4 Proportions of patients with ACS using risk categories

Risk model	Low risk, n (%)	Moderate risk, n (%)	High risk, n (%)
Goldman	8/102 (8)	3/24 (13)	6/22 (27)
TIMI	11/122 (9)	5/25 (20)	1/1 (100)
Sanchis[a]	10/121 (8)	5/22 (23)	2/3 (67)

[a] For use of Sanchis, only 146 patients could be categorized because of 2 patients with incomplete history data.

predict ACS. 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%).

3.3. Agreement between risk models

We used weighted κ 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).

3.4. Secondary analysis: risk of ACS

Patients categorized as "low risk" had nonzero rates of ACS using all 3 scoring models (Goldman, 7.8%; TIMI, 9%; and Sanchis, 8.3%). Mean risk scores were significantly associated with ACS using TIMI (2.1 ± 1.5 vs 1.1 ± 1.1; P = .001) and Sanchis (1.3 ± 1.0 vs 0.6 ± 0.7; P = .001) but not Goldman (3.7 ± 3.3 vs 2.0 ± 2.5; P = .055).

4. Discussion

This study demonstrates that 3 widely used cardiovascular risk stratification tools (TIMI, Goldman, and Sanchis) have inadequate sensitivity (far below a reasonable standard of 90%) to detect ACS 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 (ie, discharge) of patients with acute chest pain. All 3 risk models compared unfavorably with the 100% sensitivity (95% CI, 81-100) of cardiac multidetector computed tomography reported in ROMICAT [5]. Although 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 ACS using all 4 scoring models (range, 7.8%-9%).

In our secondary analysis, we found that mean risk scores were significantly associated with ACS 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 ACS (see Table 5). Interestingly, agreement between TIMI, Sanchis, and Goldman models to label patients as "high risk" was

Table 6 Agreement of risk scores for the prediction of ACS using weighted κ statistics[a]

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

[a] Weighted κ statistics was used to compare correlations of ordinal categories (low, moderate, and high).

Table 5 Test characteristics for prediction of ACS[a]

Parameter:	Risk score						CMCT[b]	
	Goldman		TIMI		Sanchis			
	%	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
Odds of ACS[c]	2.9	1.03-8.0	3.0	1.01-9.1	4.3	1.46-12.8	∞	—

CMCT indicates cardiac multidetector computed tomography angiography; NPV, negative predictive value; PPV, positive predictive value.

[a] For all test characteristics, risk scores were dichotomized using the composite of high- and intermediate-risk scores compared vs low-risk scores.

[b] Figures for diagnostic accuracy of computed tomography–based presence of any coronary plaque to predict ACS during index hospitalization were adapted directly from ROMICAT [5].

[c] For ORs, low-risk categories were used for the comparison group.

actually poor to moderate (κ range, 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.

5. Limitations

We report a single-center experience that may limit generalizability of our data. However, overall, our patient population was fairly heterogeneous (41% women, 14% Hispanic, and 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 ACS. To minimize this limitation, we used an adjudication method with adherence to European Society of Cardiology/American College of Cardiology guidelines [20] and consensus of a second 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 and the extrapolation of these results to patients with undifferentiated chest pain. Unfortunately, no highly sensitive tools currently exist to detect ACS 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%) ACS 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 ACS, which may be reserved for larger multicenter trials.

5. Conclusions

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

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