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A new score for the diagnosis of acute coronary syndrome in acute chest pain with non-diagnostic ECG and normal troponin

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ABSTRACT

Background Acute coronary syndrome (ACS) represents a difficult diagnostic challenge in patients with undifferentiated chest pain. There is a need for a valid clinical score to improve diagnostic accuracy.

Objectives To compare the performance of a model combining the Thrombolysis in Myocardial Infarction (TIMI) score and a score describing chest pain (ACS diagnostic score: ACSD score) with that of both scores alone in the diagnosis of ACS in ED patients with chest pain associated with a non-diagnostic ECG and normal troponin.

Methods In this observational cohort study, we enrolled 809 patients admitted to a chest pain unit with normal ECG and normal troponin. They were prospectively evaluated in order to calculate TIMI score, chest pain characteristics score and ACSD score. Diagnosis of ACS was the primary outcome and defined on the basis of 2 cardiologists after reviewing the patient medical records and follow-up data. Mortality and major cardiovascular events were followed for 1 month for patients discharged directly from ED. Discriminative power of scores was evaluated by the area under the ROC curve.

Results ACS was confirmed in 90 patients (11.1%). The area under the ROC curve for ACSD score was 0.85 (95% CI 0.80 to 0.90) compared with 0.74 (95% CI 0.67 to 0.81) for TIMI and 0.79 (95% CI 0.74 to 0.84) for chest pain characteristics score. A threshold value of 9 appeared to optimise sensitivity (92%) and negative predictive value (99%) without excessively compromising specificity (62%) and positive predictive value (23%).

Conclusions The ACSD score showed a good discrimination performance and an excellent negative predictive value which allows safely ruling out ACS in ED patients with undifferentiated chest pain. Our findings should be validated in a larger multicentre study.

Key messages

Diagnosis of acute coronary syndrome is challenging. Our new score (acute coronary syndrome diagnosis score) could be helpful to rapidly rule out ACS when ECG and troponin are normal.

INTRODUCTION

Chest pain is a frequent complaint in the Emergency Department (ED) worldwide. In the USA 5–8 million patients per year are checking for chest pain.[1] More than 60% of these patients are hospitalised for clinical suspicion of acute coronary syndrome (ACS); yet, this diagnosis is confirmed in only 20%.[2] In addition, missed diagnosis of ACS is not rare as 2–4% of patients with ACS are discharged home because they are considered as not having an ischaemic heart disease.[3 4] Indeed, patients who present to ED with chest pain suggestive of ACS have considerable clinical symptoms overlap with those who present with non-cardiac chest pain. This is particularly challenging in patients with negative ECG findings and normal biological tests where the prevalence of cardiac events reaches 9.4% at long-term follow-up.[5–7] Thus, the use of clinical prediction rules could help to reduce diagnostic errors; however, scores tailored to these patients are surprisingly lacking. On the basis of items reflecting clinical characteristics of chest pain, the score previously reported by Geleijnse *et al*[8] and included by Sanchis *et al*[9] in its prognostic score could be suitable for the diagnosis of ACS but was not assessed as such. The Thrombolysis in Myocardial Infarction (TIMI) score[10] with others like history, electrocardiogram, age, risk factors, and troponin (HEART), Global Registry of Acute Coronary Events (GRACE) and Banach scores[11–13] are the most used scales to risk stratify patients with chest pain, but it was not validated as a method to determine who has ACS.[14–18] The Geleijnse score reflects the character of the pain and the TIMI score reflects the cardiovascular risk factors, but each score separately does not have a satisfactory performance to eliminate Myocardial Infarction (MI). We hypothesised that combining these two scores could have a better diagnostic performance of ACS than each score considered alone.

Aims of study

Evaluation of a score combining the TIMI score and the Geleijnse score in ruling out ACS in a cohort of patients presenting to the ED for chest pain with inconclusive ECG and normal troponin. The performance of this new score was compared with both scores alone.

MATERIALS AND METHODS

Study design

This is a prospective study performed in the ED between May 2007 and December 2010. The study protocol was approved by the hospital research

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ethics committee. All patients attending with chest pain were assessed on a three-bed chest pain unit (CPU) located in the ED, staffed full time by an emergency physician and a nurse. Our CPU diagnostic testing protocol included serial ECG and troponin testing with the possibility of stress testing (see online supplementary appendix 1).

Study population

We included all consecutive patients over 30 years old evaluated in the ED for non-traumatic chest pain as a main complaint within the previous 24 h. We excluded patients with ECG findings suggesting acute cardiac ischaemia according to Standardised Reporting Guidelines[19] (T and T segment (ST) wave deviations or pathological Q waves in more than two contiguous leads, or new left bundle branch block), patients with complete atrioventricular block, pacemaker, initial troponin T level >0.01 ng/mL or those presenting with other obvious causes of chest pain.

Study protocol

Baseline data and clinical course were recorded in real time by the CPU physician using a standard chart created for all CPU patients that had all the required variables without reference to any of the risk scores evaluated in this investigation. They included demographic characteristics, cardiovascular risk factors, history of cardiac ischaemia, description of chest pain, clinical findings of physical exam, ECG findings and results of troponin T (Roche, Diagnostics (Basel, Switzerland), lower limit of detection 0.01 ng/mL; 99th centile <0.01 ng/mL; 10% coefficient of variation 0.035 ng/mL). Troponin T >0.01 was considered positive. In all patients, the Geleijnse and the TIMI scores were calculated by separate investigators assuring blinding of data collection. The ACS diagnostic score (ACSD score) was calculated as the total of Geleijnse and TIMI scores added (see online supplementary appendix 2). Diagnosis of ACS was defined on the basis of two cardiologists according to prespecified criteria rigorously applied to each individual case after reviewing the patient medical records and follow-up data: this final diagnostic decision was taken essentially following secondary ECG changes and/or significant delayed troponin elevation or other positive cardiac investigation according to Standardised Reporting Guidelines.[16] A third cardiologist's opinion was required in case of disagreement. Cardiologists, who separated patient's outcomes as positive or negative for ACS, were blinded to the data collection forms. All patients with CPU discharge diagnosis of ACS were admitted to our cardiology department and followed up until hospital discharge. Patients directly discharged home from the ED were followed up 7 days and 30 days later by telephone contact. We collected mortality and major cardiovascular events: acute myocardial infraction, a newly significant coronary artery stenosis that prompted new medical therapy, revascularisation or death that was likely due to coronary artery disease.

Data analysis

Patients were divided into two groups: ACS group and non-ACS group. Continuous variables were expressed as the mean±SD and compared by the Student's t test. Categorical variables were expressed as percentages and compared by the χ^2 test. The Receiver Operating Characteristic Curve (ROC) curves were used to test the overall discriminatory power of the ACSD score, the Geleijnse score and the TIMI score for diagnosing ACS. The ROC curves corresponding to each score were compared using the z-statistic test according to the Hanley and McNeil method. Sensitivity, specificity, and positive and negative predictive values were calculated for each score using the best cut-off value determined with the ROC curve data. The best cut-off value was considered as the point which optimises sensitivity and negative predictive value without excessively compromising specificity and positive predictive value. The score calibration which evaluates the degree of fit between predicted and observed numbers of patients with ACS was evaluated by Hosmer-Lemeshow χ^2 test. A smaller value of the χ^2 test means good fit between the observed and predicted rate of ACS. A value of $p \leq 0.05$ was considered statistically significant. All analyses have been performed using the SPSS software (V.11.0, SPSS, Chicago, Illinois, USA).

RESULTS

During the study period 3529 patients were assessed in the CPU; of these 809 patients were included. Reason for exclusion was initial positive troponin (n=1309), abnormal ECG (n=821), patients assessed more than 24 h after the onset of chest pain (n=230), unwilling to participate (n=170), evident cause of chest pain (n=113) and missed patients' data (n=77) (figure 1). Baseline clinical features of included patients are summarised in table 1. Most of the patients have at least one cardiovascular risk factor including smoking (38.8%), history of arterial hypertension (34.1%) and diabetes (24.1%). The diagnosis of ACS was confirmed in 90 patients (11.1%) and among them, only 3 patients (3.3%) were positive at the second troponin testing. The mean TIMI was 2.1±1.4 (SD), and all these patients were treated with clopidogrel, aspirin and heparin in the emergency department. No thrombolysis was performed

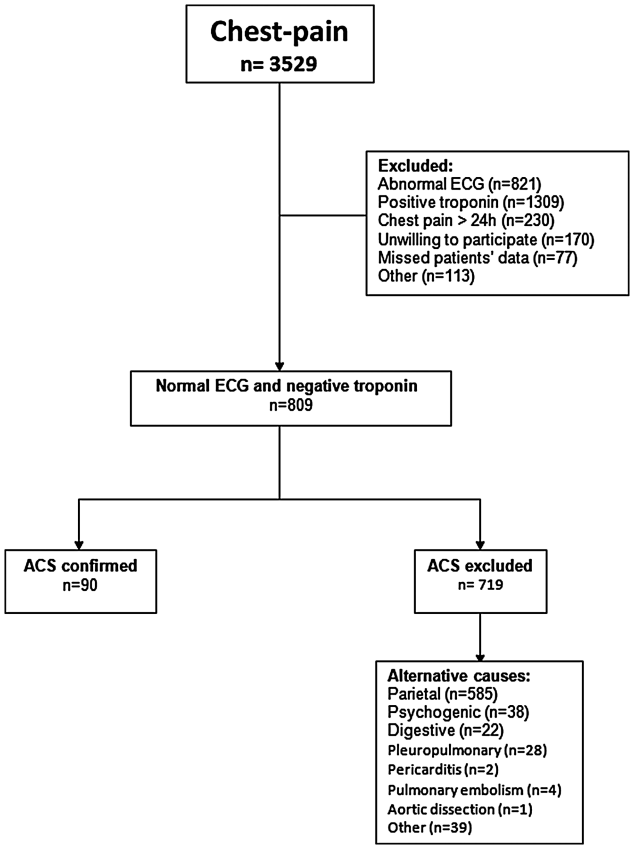

Figure 1 Flow chart of the study enrolment population. ACS, acute coronary syndrome.

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Table 1 Patients' characteristics

	Patients	
	n=809	
Average age years(SD)	51.9	(13.5)
Male sex n (%)	468	(57.8)
Cardiovascular risk factors n (%)		
Smoking	314	(38.8)
Hypertension	276	(34.1)
Diabetes	195	(24.1)
Hypercholesterolaemia	112	(13.8)
Coronary disease	141	(17.4)
Obesity	31	(3.8)
Number of risk factors n (%)		
None	243	(30)
1	311	(38.4)
2	153	(18.9)
≥3	101	(12.5)
Chest pain characteristics n (%)		
Location		
Substernal	400	(49.4)
Precordial	309	(38.2)
Epigastric	14	(1.7)
Radiation		
None	450	(55.6)
Arm	197	(24.4)
Back, neck, jaw	133	(16.4)
Influenced by		
Nitroglycerin	32	(4)
Stature	40	(4.9)
Breathing	209	(25.8)
Chest pain origin n (%)		
Acute coronary syndrome	90	(11.1)
Non-ischaemic	719	(88.9)

during this study and percutaneous coronary intervention was performed in 33 patients (36%). Overall mortality was about 1.7% and it was higher in patients with ACS (6.6%). The mean ACSD score was 12.9±3.5 in the ACS group compared with 7.6 ±3.6 in the non-ACS group. The characteristics of the ACSD score according to the cut points are depicted in table 2. The area under the ROC curve for the ACSD score was 0.85 (95% CI 0.80 to 0.90) compared with 0.79 (95% CI 0.74 to 0.84) for the Geleijnse score and 0.74 (95% CI 0.67 to 0.81) for the TIMI score (figure 2). The best threshold value for the ACSD score is 9 yielding a sensitivity of 92%, a specificity of 62%, a negative predictive value of 99% and a positive predictive value of 23% (table 3). The rate of ACS predicted by the scores and the rate of observed ACS defined according to current international guidelines were not different when compared with the χ^2 of Hosmer-Lemeshow statistics.

DISCUSSION

Despite substantial medical technology advances and the availability of troponin assay, the diagnosis of ACS remains challenging in the ED setting. This issue is even more problematic in patients with chest pain associated with non-diagnostic ECG and normal troponin in whom the diagnostic uncertainty is the greatest. Our study has the objective to validate in this category of patients, a new ACSD model combining a score describing chest pain characteristics and the TIMI score. We showed that our score (the ACSD score) had a good discriminative value with an excellent calibration. Diagnostic performance, as assessed by the area under the ROC curve of the ACSD score was significantly higher compared with Geleijnse score and TIMI score considered alone. The best threshold value of the ACSD score is 9 providing a good sensitivity (92%) and an excellent negative predictive value (99%), which is rated as good for the emergency rule-out for ACS.

ECG and cardiac troponin currently form the diagnostic cornerstones of clinical assessment of patients with chest pain. Unfortunately, ECG has a low sensitivity[20 21] and normal biochemical markers are not infrequent.[22] Surprisingly, there are only a few published decision rules to help clinicians to differentiate ACS from benign causes of chest pain. Most of the available models have either not been validated or have demonstrated mixed results.[23–26] Moreover, no specific score exists to detect ACS in the selected group of patients with normal ECG and troponin. Yet, the rate of true ACS in this category of patients is significant suggesting the need for new instruments with higher sensitivity for prompt triage of patients with acute chest pain. In a recent study comparing several risk scores in patients with non-diagnostic ECG and normal troponin, 8% had positive exercise ECG, and almost two-thirds of these had coronary stenoses 50% or greater at angiography.[10]

The Geleijnse score is based on detailed characteristic variables of chest pain without considering the patient's underlying health status which limits its usefulness as a diagnostic tool for ACS. This could explain its low performance for predicting ACS in our study. The improvement of the Geleijnse score when added to the TIMI score suggests the importance of combining items related to pain characteristics and underlying cardiovascular risk factors in the diagnostic process of ACS. Others scores such as HEART,[11] GRACE[12] and Banach[13] scores were previously proposed mainly for prognostic information. Many patients presenting with possible ischaemic chest pain syndromes are hospitalised for observation and diagnostic testing. This triage could be substantially reduced by applying the ACSD score with regard to its excellent negative predictive value and its good sensitivity. In addition, all the variables of our score are readily available, an important condition for large clinical use. The fact that we included the TIMI score in the ACSD score is attractive in regard to this issue because the TIMI risk score is one of the most widely used risk models in patients with ACS.[27] New technologies such as the 64-slice or greater cardiac multidetector tomography will probably become the near future

Table 2 Performance of the ACSD score

ACSD score	Risk class	Se (95% CI)	Sp (95% CI)	PPV (95% CI)	NPV (95% CI)	LR+ (95% CI)	LR− (95% CI)
≤4	≥I	100 (97.1 to 100)	1.1 (0.3 to 1.7)	11 (8.8 to 13)	100 (97 to 100)	1 (0.7 to 1.7)	0
>4 <10	≥II	100 (97.1 to 100)	20 (17.3 to 22)	13 (11.7 to 15)	100 (97.1 to 100)	1.2 (0.4 to 1.9)	0
≥10	≥III	74 (97.1 to 100)	78 (75 to 80)	30 (27 to 33)	96 (94 to 97)	3.3 (2.0 to 4.5)	0.3 (0 to 0.6)

ACSD, acute coronary syndrome diagnostic score; Se, Sensitivity; Sp, Specificity; PPV, positive predictive value; NPV, negative predictive value; LR, likelihood ratio.

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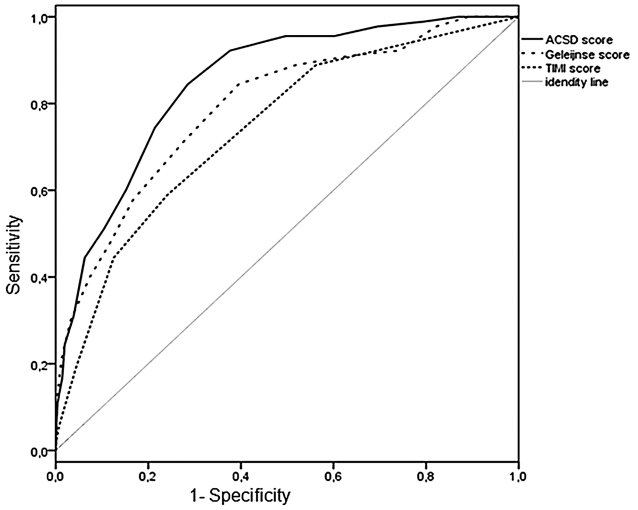

Figure 2 Receiver-operating characteristic curves of the acute coronary syndrome diagnostic score (ACSD score, area under ROC curve = 0.85 (95% CI 0.80 to 0.90)), the Geleijnse chest pain score (area under ROC curve = 0.79 (95% CI 0.74 to 0.84)) and the Thrombolysis in Myocardial Infarction score (TIMI, area under ROC curve = 0.74 (95% CI 0.67 to 0.81)) for the diagnosis of acute coronary syndrome.

diagnostic tool in ED patients with chest pain.[28] However, in most low-income countries this category of medical facilities is unlikely to be available sooner.

STUDY LIMITATIONS

This study has some limitations which should be considered. First, it must be stressed that our cohort included patients from the unique CPU of the country which may not be relevant to other EDs. Second, although we did not include all eligible patients, enrolled and non-enrolled patients are likely to have a similar clinical profile because no selection was applied in the inclusion procedure. Another limit to the validity of our study is the lack of a standardised gold standard for the definition of ACS. However, to establish the ACS diagnosis, we required the opinion of at least two blinded experts which reflect our routine clinical practice and actually, current definitions of scientific societies. Therefore, we believe that the rate of misclassification in our study population is negligible. Third, we did not define the acceptable miss rate for ACS with which to compare the performance of this decision rule. Ideally, this rate should be near zero. At the point of maximal accuracy, the sensitivity of the ACSD score is only 92%, which translates into a miss rate of 8%. However, with regard to the fact that in a non-selected group of patients with chest pain, the rate of false negative is near 10%, we believe that in patients similar to those included in our study, this rate is likely to be higher than 8%. An external validation to check the validity of our results in a new population of patients is needed. Moreover, we also need to prove the benefit of our score when implemented in the clinical setting. Fourth, our score is a combination of TIMI and Geleijnse scores, the latter score is one which is not widely used and its inclusion needs to be further justified with respect to reliability and validity. In addition, combining the two scores assumes that the 'points' for each are of similar magnitude. Nevertheless, we demonstrated that using this method of combination, we achieved a score with a diagnostic performance that is superior to both scores alone. Lastly, we excluded patients with ST segment deviation and positive cardiac biomarkers, both of which are required to calculate the TIMI score. This means that we considered a slightly modified version of the original TIMI score which did not represent a potential bias to our results. We also acknowledge that the diagnosis of ACS may have been influenced by some of the clinical variables used to construct the scores. This may have inflated estimates of diagnostic parameters but this has not significantly altered our conclusions.

Table 3 Diagnostic performance of the acute coronary syndrome diagnostic score (ACSD), the TIMI score and the Geleijnse score

Scores			
	ACSD*	**TIMI**	**Geleijnse[8]**
Cut-off	9	3	10
Area under the ROC (95% CI)	0.85 (0.80 to 0.90)*	0.74 (0.67 to 0.81)	0.79 (0.74 to 0.84)
Sensitivity (%)	92 (86–100)	56 (43–69)	40 (27–53)
Specificity (%)	62 (57–63)	14 (12–16)	19 (16–22)
PPV (%)	23 (18–27)	5 (3–7)	3 (2–4)
NPV (%)	99 (98–100)	82 (75–89)	81 (75–87)
Hosmer-Lemeshow calibration test			
χ^2	8.365	4.683	6.403
p Value	0.399	0.197	0.494

*p<0.05 versus TIMI and Geleijnse scores.
ACSD, acute coronary syndrome diagnostic score; NPV, Negative Predictive Value; PPV, Positive Predictive Value; TIMI, Thrombolysis in Myocardial Infarction.

CONCLUSION

In summary, we developed a clinical diagnostic score to detect ACS in a population of patients with acute chest pain who did not have evidence of new cardiac ischaemia on their ECG and did not have troponin elevation. As these patients have been recognised to have a substantial percentage of coronary disease, our model may limit the number of those mistakenly discharged from the ED.

Contributors SN conceived the study, and designed the trial. SN, MHA, RB, MHG, and HB supervised the conduct of the trial and data collection. HB, MBA, ML, ZM, KB, ZD, and undertook recruitment of patients and managed the data, including quality control. SN, WB and FN performed statistical analysis and analysed the data. SN and MHG drafted the manuscript, and all authors contributed substantially to its revision. SN takes responsibility for the paper as a whole.

Competing interests None.

Ethics approval Institutional review and ethics board of the University Hospital of Monastir, Tunisia.

Provenance and peer review Not commissioned; externally peer reviewed.

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