A Clinical Decision Rule to Identify Emergency Department Patients at Low Risk for Acute Coronary Syndrome Who Do Not Need Objective Coronary Artery Disease Testing: The No Objective Testing Rule

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Study objective: We derive a clinical decision rule for ongoing investigation of patients who present to the emergency department (ED) with chest pain. The rule identifies patients who are at low risk of acute coronary syndrome and could be discharged without further cardiac testing.

Methods: This was a prospective observational study of 2,396 patients who presented to 2 EDs with chest pain suggestive of acute coronary syndrome and had normal troponin and ECG results 2 hours after presentation. Research nurses collected clinical data on presentation, and the primary endpoint was diagnosis of acute coronary syndrome within 30 days of presentation to the ED. Logistic regression analyses were conducted on 50 bootstrapped samples to identify predictors of acute coronary syndrome. A rule was derived and diagnostic accuracy statistics were computed.

Results: Acute coronary syndrome was diagnosed in 126 (5.3%) patients. Regression analyses identified the following predictors of acute coronary syndrome: cardiac risk factors, age, sex, previous myocardial infarction, or coronary artery disease and nitrate use. A rule was derived that identified 753 low-risk patients (31.4%), with sensitivity 97.6% (95% confidence interval [CI] 93.2% to 99.5%), negative predictive value 99.6% (95% CI 98.8% to 99.9%), specificity 33.0% (95% CI 31.1% to 35.0%), and positive predictive value 7.5% (95% CI 6.3% to 8.9%) for acute coronary syndrome. This was referred to as the no objective testing rule.

Conclusion: We have derived a clinical decision rule for chest pain patients with negative early cardiac biomarker and ECG testing results that identifies 31% at low risk and who may not require objective testing for coronary artery disease. A prospective trial is required to confirm these findings. [Ann Emerg Med. 2016;67:478-489.]

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INTRODUCTION

Background

In 2007 to 2008, more than 5.5 million people presented to emergency departments (EDs) in the United States with a primary complaint of chest pain, yet only 13% of those received a diagnosis of acute coronary syndrome.[1] Current risk-stratification processes for the identification of patients with acute coronary syndrome require physicians to conduct a detailed clinical assessment incorporating historical features, risk factors, ECG, and serial troponin testing over at least 3 to 12 hours.[2-4] Patients with negative results after this initial assessment do not receive a diagnosis of acute myocardial infarction but may still be at risk for short- and long-term events.[5-7] Therefore, current guidelines recommend an objective test in the form of functional or anatomic testing for coronary artery disease,[8,9] with a negative result indicating that the patient is at low risk for future adverse events including myocardial infarction and death.[10-12]

Importance

Although there is no disagreement about the need to identify patients with an acute myocardial infarction, the practice of obligatory objective testing for coronary artery disease in patients with negative results on cardiac biomarker testing has been questioned.[13-15] High-sensitivity

Editor's Capsule Summary

What is already known on this topic

Clinical decision rules exist to stratify patients by risk for the presence of an acute coronary syndrome.

What question this study addressed

Can a decision rule be derived to identify patients with chest pain with a 30-day risk of acute coronary syndrome of less than 1% who would not need testing beyond an ECG and troponin measurement?

What this study adds to our knowledge

In this cohort of 2,396 patients, 126 (5.3%) of whom had acute coronary syndrome within 30 days, a clinical decision rule was derived, with a sensitivity of 99.2% (95% confidence interval [CI] 95.7% to 99.98%) and a specificity of 30.2% (95% CI 28.3% to 32.2%). This model, which includes 5 variables (age, sex, risk factors, previous myocardial infarction or coronary artery disease, and nitrate use), identified 31.1% of the patients as being at low risk.

How this is relevant to clinical practice

If validated in a different cohort of patients, this rule may provide support for the rapid discharge of selected patients from the emergency department.

troponin assays have improved the identification of acute myocardial infarction[7] and can identify a high proportion of patients at risk for major adverse cardiac events when used in combination with ECGs and risk-stratification tools.[16-18] A number of studies also have found that objective testing adds limited diagnostic information beyond clinical data and biomarkers,[10] particularly for younger individuals.[19,20] Studies report low positive predictive values[12] and high rates of indeterminate objective tests (up to 25%).[3,21] This may ultimately place patients at unnecessary risk by necessitating further invasive investigations such as coronary angiography. Finally, the economic costs of this practice are high.[22] A robust evidence-based alternative process for evaluation is required before clinicians will consider discharging patients without an objective test.

Goals of This Investigation

This study focuses on patients presenting to the ED with symptoms of possible acute coronary syndrome who have normal 0- and 2-hour troponin levels and nonischemic presentation ECGs. These patients routinely undergo objective testing. The aim was to derive a clinical decision rule that identifies patients from this cohort at very low risk of acute coronary syndrome who could be considered for early discharge without objective testing.[23]

MATERIALS AND METHODS

Study Design and Setting

This is a secondary analysis of data from 2 studies on ED patients with potential acute coronary syndrome. The first was a prospective observational study of adult patients presenting to the EDs of 2 tertiary care hospitals in Australia and New Zealand between November 2007 and January 2011. There were 1,184 patients enrolled in New Zealand and 988 in Australia. The second was a nonrandomized interventional trial conducted at the Australian site between February 2011 and July 2013. Data were available from 1,016 individuals in this study, and the criteria for enrollment were the same as that of the prospective observational study. The intervention was an accelerated protocol in which a subgroup of patients could undergo 2-hour rather than 6-hour troponin testing (described further below). This intervention did not change patient care during the first 2 hours in the ED. Thus, the data for this study were not influenced by the intervention. The study protocols were approved by the institutions' Human Research and Ethics Committees and complied with the Declaration of Helsinki. Informed consent was obtained from all participants.

Selection of Participants

Patients were recruited for both studies during working hours (8 AM to 5 PM) and included if they were aged 18 years or older, presented to the ED with at least 5 minutes of chest pain suggestive of acute coronary syndrome, and were undergoing testing for acute coronary syndrome.
In accordance with American Heart Association case definitions,[24] pain suggestive of acute coronary syndrome included acute chest, epigastric, neck, jaw, or arm pain, or discomfort or pressure without an apparent noncardiac source. Research staff identified all eligible patients who presented during work hours, using the ED admissions database and in collaboration with the treating clinicians. Patients were excluded for the following reasons: there was a clear non–acute coronary syndrome cause for their symptoms, they were unwilling or unable to provide informed consent (eg, language barrier), staff considered that recruitment was inappropriate (eg, terminal illness), they were transferred from another hospital, they were pregnant, they were recruited to the study within the previous 45 days, or they were unable or unwilling to be contacted after discharge. Perceived high risk was not an exclusion criterion. Consecutive eligible cases at each site were included.