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Performance of the EDACS-Accelerated Diagnostic Pathway in a Cohort of US Patients with Acute Chest Pain

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Abstract

Background—The Emergency Department Assessment of Chest pain Score – Accelerated Diagnostic Protocol (EDACS-ADP) is a decision aid designed to safely identify Emergency Department (ED) patients with chest pain for early discharge. Derivation and validation studies in Australasia have demonstrated high sensitivity (99-100%) for major adverse cardiac events (MACE).

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Objectives—To validate the EDACS-ADP in a cohort of US ED patients with symptoms suspicious for acute coronary syndrome (ACS).

Methods—A secondary analysis of participants enrolled in the HEART Pathway Randomized Controlled Trial was conducted. This single-site trial enrolled 282 ED patients 21 years old with symptoms concerning for ACS, inclusive of all cardiac risk levels. Each patient was classified as low-risk or at-risk by the EDACS-ADP based on EDACS, ECG, and serial troponins. Potential early discharge rate and sensitivity for MACE at 30 days, defined as cardiac death, myocardial infarction (MI), or coronary revascularization were calculated.

Results—MACE occurred in 17/282 (6.0%) participants, including no deaths, 16/282 (5.6%) with MI, and 1/282 (0.4%) with coronary revascularization without MI. The EDACS-ADP identified 188/282 patients (66.7%, 95% CI 60.8-72.1%) as low-risk. Of these, 2/188 (1.1%, 95% CI 0.1-3.9%) had MACE at 30 days. EDACS-ADP was 88.2% (95% CI 63.6-98.5%) sensitive for MACE, identifying 15/17 patients. Of the 2 patients identified as low-risk with MACE, 1 had MI and 1 had coronary revascularization without MI.

Conclusions—Within a US cohort of ED patients with symptoms concerning for ACS, sensitivity for MACE was 88.2%. We are unable to validate the EDACS-ADP as sufficiently sensitive for clinical use.

Keywords

chest pain; decision aids; acute coronary syndrome

Introduction

Current care patterns for patients with acute chest pain do not accurately focus health care resources, such as comprehensive cardiac testing, on patients most likely to benefit. Among low-risk patients, who have ACS rates as low as 2%, stress testing and cardiac imaging is associated with a substantial number of false positive and non-diagnostic tests, which leads to additional unnecessary and often invasive procedures.¹ Health system leaders, clinicians, and educators are building consensus on the need to more efficiently evaluate patients with acute chest pain.²

The Emergency Department Assessment of Chest pain Score – Accelerated Diagnostic Protocol (EDACS-ADP) is a decision aid designed to safely identify Emergency Department patients with chest pain for early discharge. Derived and validated in patients presenting with symptoms concerning for ACS to urban EDs in Australia and New Zealand, the EDACS-ADP identified 42-51% of patients as low-risk (suitable for early discharge) while maintaining high sensitivity (99-100%) for major adverse cardiac events (MACE). The EDACS-ADP has yet to be externally validated in a cohort of US ED patients with suspected ACS. Therefore, the objective of this analysis is to determine if EDACS-ADP can classify 20% or more patients as safe for early discharge while maintaining high sensitivity and negative predictive value (NPV) for MACE in a cohort of US ED patients with acute chest pain. The precise value of an acceptable sensitivity and NPV for MACE is a matter of considerable debate. However, many believe that a successful chest pain risk stratification

strategy must achieve >99% NPV (corresponding with a <1% missed MACE rate among patients with a low-risk assessment), and approach a 99% sensitivity.³

Methods

Study design

A secondary analysis of participants enrolled in the HEART Pathway Randomized Controlled Trial (RCT) was conducted. Participants were enrolled from September 2012, through February 2014, and all gave written informed consent at the time of study entry. The HEART Pathway trial was approved by the Internal Review Board of the sponsoring organization and was registered with clinicaltrials.gov (clinical trial number NCT01665521) prior to enrollment. Methods of the HEART Pathway trial have been previously described.⁴

Study setting

Participants were enrolled from the ED of (institution name withheld for review). The study institution is a tertiary care academic medical center located in the Piedmont Triad area of North Carolina, serving urban, suburban, and rural populations. The ED is staffed by board certified or board eligible emergency physicians 24 hours per day, 7 days a week who directly provide care and oversee care provided by residents, physician assistants, and nurse practitioners. ED patient volume during the enrollment period consisted of approximately 104,000 patient encounters per year. Cardiac testing modalities routinely available to study participants included exercise stress echocardiogram (ESE), dobutamine stress echocardiogram (DSE), coronary computed tomography angiography (CCTA), stress nuclear imaging, stress cardiac magnetic resonance (CMR) imaging, and invasive coronary angiography. Serum troponin measurements were performed using the ADVIA Centaur platform TnI-Ultra™ assay (Siemens, Munich Germany). This assay has a 99th percentile of the upper reference limit and 10% CV at 0.04 micrograms/L, which was also the clinical threshold for detection of myocardial injury during the study period.

Participants

Adult patients with symptoms suggestive of ACS were screened during enrollment hours (6 days excluding Saturday, 80 hours/week). Eligibility criteria were: chest pain or other symptoms suggestive of ACS, age ≥ 21 years, and the provider ordering an ECG and troponin for the evaluation of ACS. Patients were excluded for: new ST-segment elevation ≥1mm, hypotension, life expectancy <1 year, a non-cardiac medical, surgical, or psychiatric illness determined by the provider to require admission, prior enrollment, non-English speaking, and incapacity or unwillingness to consent.

Data collection

Data elements were collected prospectively in accordance with standards of Good Clinical Practice, Standardized Reporting Guidelines,⁵ and Key Data Elements and Definitions.⁶ Electronic medical records (EMR) were used as the source for data elements reliably contained in the medical record. Study coordinators used REDCap data collection templates to prospectively collect and store data from patients and care providers for data elements not reliably present in the EMR.

Follow up was conducted during the index visit using structured record review. At 30 days, a structured record review was followed by a telephone interview using a validated scripted follow-up dialogue⁷ to further clarify events since discharge, identify events occurring at other care facilities, and to determine health care utilization since discharge. Outcome events reported at other health care facilities were confirmed using a structured review of those medical records. Incomplete follow up at 30 days was handled using the following algorithm: participants with ongoing visits in the EMR were considered to have complete information and were classified based on the data available in the medical record; participants with no ongoing visits were considered lost to follow up at the point of last contact. The Social Security Death Master File was used to search for participants unable to be contacted one year after their index visit. In the event of discrepancy between a participant's self-reported event and the medical record, the medical record was considered correct.

EDACS-ADP

The EDACS-ADP decision rule was applied to all of the study participants to risk stratify patients into low-risk or at-risk groups. EDACS consists of clinical characteristics that were assigned positive or negative point values which included age, sex, age between 18-50 years with either known CAD or ≥ 3 risk factors, signs/symptoms of diaphoresis, radiation of pain, pain worse with inspiration, and pain reproduced by palpation. The EDACS-ADP identifies patients appropriate for early discharge if they have an EDACS < 16 , no new ischemia on ECG, and negative serial troponin results at 0 and 2 hours after ED arrival. All of the data elements necessary to risk stratify patients based on EDACS-ADP were collected prospectively from patients enrolled in the HEART Pathway RCT. For patients with incomplete or missing data a review of the EMR blinded to patient outcomes was conducted. The determinants of the EDACS-ADP are summarized in Table 1.

Study Measures

Our primary outcome was the rate of MACE within 30 days of presentation, defined as the composite of cardiac death, myocardial infarction (MI), or coronary revascularization. The definition of MACE and its components were based on the standardized reporting guidelines for studies evaluating risk stratification of ED patients with potential ACS and ACC key data elements and definitions for measuring the clinical management and outcomes of patients with ACS.^{8,9} Myocardial infarction was defined based on the Universal Definition of Myocardial Infarction.¹⁰ Coronary revascularization was defined as coronary artery bypass grafting, stent placement, or other percutaneous coronary intervention. A consensus of two reviewers (CDM, BCH), blinded to EDACS risk assessment, adjudicated elements required to measure the occurrence of MACE. To make these assessments, reviewers were provided participant's index and discharge records, follow-up call information, records obtained from follow-up, and study definitions. Any disagreements were settled by consensus between the two reviewers, or the involvement of a third reviewer.

Data Analysis

The percentage of patients identified by EDACS-ADP as safe for early discharge (low-risk), the sensitivity, specificity, and positive and negative predictive values of EDACS-ADP for

MACE were calculated. Corresponding 95% exact binomial confidence intervals were also computed. Consistent with prior ADP studies, patients with incomplete follow-up (only vital status known) were considered to be free of 30-day MACE events.¹¹⁻¹⁴ Statistical analysis was performed using SAS 9.4 (Cary, North Carolina).

Results

From 9/2012-2/2014, 282 patients with symptoms suggestive of ACS were enrolled in the HEART Pathway RCT. Data needed to determine risk by EDACS-ADP were available on all 282 participants. All patients were assessed for adverse events: 96.5% (272/282) had 30 day follow-up by telephone or structured record review and 3.5% (10/282) had their vital status assessed using the Social Security Death Master File. MACE occurred in 17/282 (6.0%); there were no deaths, 16 patients had MI, and one patient had coronary revascularization without MI. Patient characteristics are summarized in Table 2.

The EDACS-ADP identified 188/282 patients (66.7%, 95% CI 60.8-72.1%) as low-risk. Of these, 2/188 (1.1%, 95% CI 0.1-3.9%) had MACE at 30 days. EDACS-ADP was 88.2% (95% CI 63.6-98.5%) sensitive for MACE, identifying 15/17 patients with MACE. Specificity was 70.2% (95% CI 64.3-75.6%), PPV (positive predictive value) was 16.0% (95% CI 9.2-25.0%), and NPV was 98.9% (95% CI 96.2-99.9%).

Table 2 provides the frequencies of the EDACS-ADP risk assessment determinants. The performance characteristics of the EDACS-ADP are summarized in Table 3. Of the 2 patients identified as low-risk with MACE, 1 had MI and 1 had coronary revascularization during the index visit (see Table 4).

Discussion

The primary finding of this analysis is that the EDACS-ADP did not withstand rigorous validation in a cohort of US patients with chest pain representing the entire risk spectrum. Although the EDACS-ADP was able to classify greater than 20% of patients as safe for early discharge, it did not maintain sufficient sensitivity or NPV for MACE. Among patients identified by EDACS-ADP for early discharge, 1.1% of had MACE (with the upper bound of the 95% confidence interval for missed MACE of 3.9%). While there is considerable debate about the acceptable missed MACE rate, many believe that a successful ADP must achieve >99% NPV (corresponding with a <1% missed MACE rate among patients with a low-risk assessment).³ Further study or refinement of this decision rule may be warranted prior to implementation.

In the EDACS-ADP study, Than and colleagues identified 51.3% of patients with acute chest pain as safe for early discharge while maintaining 99-100% sensitivity for MACE. The lower sensitivity of EDACS-ADP (88.2%) in our study may be explained in part by differences in health systems. For example, it is well documented that revascularization procedures are much more common in the US compared to other developed countries.^{15,16} Among the 2 patients in our analysis with MACE who were identified for early discharge by 2-Hour Accelerated Diagnostic Protocol (ADAPT), 1 had a revascularization procedure without MI. While the derivation and validation of EDACS-ADP included coronary

revascularization in their MACE composite endpoint, it is not clear in how often revascularization was the cause of the MACE events in these cohorts. However, prior studies by the creators of EDACS report low revascularization rates.¹⁷ Revascularization events accounted for only 8.6% (26/302) of MACE events in the ADAPT Trial and 1.2% (1/82) of MACE events in their recent randomized trial. This differs from our cohort, in which 41% (7/17) of patients with MACE underwent revascularization. Therefore, health system differences may explain differences in revascularization rates. These differences highlight the difficulty in generalizing results of chest pain risk stratification studies conducted in other healthcare systems to US patient populations.

The importance of missing revascularization events in patients identified as safe for early discharge is unclear. While revascularization improves mortality and re-infarction rates among patients with acute or prior MIs, recent studies have questioned the utility of revascularization in patients without acute troponin elevations.¹⁸ The COURAGE trial and recent systematic reviews have failed to show a difference in risk of MI or death among patients with stable coronary artery disease receiving percutaneous coronary intervention when compared to medical management.¹⁹⁻²² Though this represents a different cohort, both contain patients presenting emergently with symptoms of acute coronary syndrome. Furthermore, in individual patients it is often difficult to adjudicate if revascularizations are “appropriate” and determine the relationship between the procedure and the occurrence or lack of occurrence of downstream MACE. Further study is needed to determine the importance of identifying patients for early discharge who would have otherwise undergone revascularization.

Limitations

Our analysis has several limitations. Small sample size and enrollment from a single academic medical center may limit generalizability. The MACE rate of our cohort was only 6% compared to a 13% MACE rate for the EDACS-ADP validation cohort, indicating our cohort may have been lower-risk. However, since EDACS-ADP is unlikely to be used by US providers in patients with obvious ACS on initial ED presentation or known coronary artery disease, conducting this study within a lower-risk cohort may add external validity to our findings. Furthermore, the EDACS-ADP was expected to have high sensitivity within a lower-risk cohort.

Another potential limitation of this analysis is incomplete follow-up on 10 patients (3.5% of participants), which may have caused misclassification and underestimation of MACE. However, none of these patients appeared in the Social Security Death Master File. Furthermore, given that all known MACE events occurred during the index visit, the likelihood of MACE occurring shortly after discharge among these patients seems low. In addition, differences existed in the timing of troponin measurement in the HEART Pathway RCT compared to the EDACS-ADP studies. In the HEART Pathway RCT serial troponins were obtained at 0 and 3 hours after arrival rather than at 0 and 2 hours as required by the EDACS-ADP. However, a second measure of troponin at >2 hours should not harm the sensitivity of the EDACS-ADP.^{23,24} Finally, more sensitive troponin assays are on the horizon than the one used in this analysis, but these assays have yet to be approved for

clinical use in the US. The performance of EDACS combined with the highest sensitivity troponin assays in this cohort is unclear.

Conclusions

Within a US cohort of ED patients with symptoms concerning for ACS, 1.1% of patients identified as low-risk by EDACS-ADP had MACE within 30 days. Sensitivity for detection of MACE by the EDACS-ADP is lower in this cohort than what was reported in the derivation and validation studies. Implementation of EDACS-ADP into clinical practice within US EDs should wait until refinements or further safety analyses are performed.

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Table 1

Frequency of EDACS determinants.

EDACS		
Clinical Characteristic	Score	Number (Percent)
Age		
18-45	+2	86 (30.5)
46-50	+4	49 (17.4)
51-55	+6	44 (15.6)
56-60	+8	34 (12.1)
61-65	+10	27 (9.6)
66-70	+12	15 (5.3)
71-75	+14	12 (4.3)
76-80	+16	6 (2.1)
81-85	+18	7 (2.5)
86+	+20	2 (0.7)
Male Sex	+6	120 (42.6)
Aged 18-50 years and either: (i) known CAD or (ii) ≥ 3 risk factors	+4	45 (16.0)
Symptoms and signs		
Diaphoresis	+3	66 (23.4)
Radiates to arm or shoulder	+5	98 (34.8)
Pain occurred or worsened with inspiration	-4	46 (16.3)
Pain is reproduced by palpation	-6	35 (12.4)
EDACS		
Low-risk	EDACS <16	212 (75.2)
At-risk	EDACS ≥ 16	70 (24.8)
EDACS ADP		
Low-risk	Meets all criteria: (i) EDACS <16 (ii) No new ischemia on ECG (iii) negative serial troponins	188 (66.7)
At-risk	Meets any of criteria: (i) EDACS ≥ 16 (ii) New ischemia on ECG (iii) Positive Serial troponin	94 (33.3)

Table 2

Characteristics of the HEART Pathway RCT cohort.

Patient Characteristics	
Age —mean $\pm$ SD*	53.3 $\pm$ 12.1
Gender	
Female	162 (57.4%)
Race † ‡	
Caucasian	183 (64.9%)
African American	94 (33.7%)
Asian	1 (0.4%)
Native American	2 (0.7%)
Other	2 (0.7%)
Ethnicity	
Hispanic	5 (1.8%)
Not Hispanic	277 (98.2%)
Risk Factors	
Current smoking	76 (27.0%)
Recent Cocaine (last 90 days)	6 (2.1%)
Hypertension	157 (55.7%)
Hyperlipidemia	121 (42.9%)
Diabetes	58 (20.6%)
Family history of coronary disease	102 (36.2%)
BMI >30 (kg/m ²)	152 (53.9%)
TIMI risk score >1	123 (43.6%)
Prior Coronary Disease	57 (20.2%)
Prior MI	45 (16.0%)
Prior PCI	33 (11.7%)
Prior CABG	10 (3.5%)
Prior Cerebral Vascular Disease	12 (4.6%)
Prior Peripheral Vascular Disease	8 (2.8%)
Insurance status	
Insured	211 (74.8%)
Private	139 (49.2%)
Medicare	42 (14.9%)
Medicaid	30 (10.6%)
Uninsured	69 (24.5%)

Table 3

Test characteristics of the EDACS-ADP for detection of MACE at 30 days.

EDACS-ADP	30 Day MACE		Total (n)
	Yes (n)	No (n)	
At-risk	15	79	94
Low-risk	2	186	188
Total (n)	17	265	282

Early Discharge (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)	PPV [†] (95% CI)	NPV [‡] (95% CI)
66.7(60.8-72.1)	88.2(63.6-98.5)	70.2(64.3-75.6)	16.0(9.2-25.0)	98.9(96.2-99.9)

Table 4
Characteristics of the 2 patients with missed MACE by EDACS-ADP

Age	Sex	Race	CAD history	first troponin mg/L (99 th percentile)	second troponin mg/L (99 th percentile)	Objective Cardiac Testing	MACE [†]
60	Female	Caucasian	None	0.011 (0.04)	0.012 (0.04)	Peak troponin of 0.94 mg/L; no cardiac catheterization performed	NSTEMI
73	Female	Caucasian	None	<0.006 (0.04)	0.011 (0.04)	Positive exercise stress echocardiogram; 90% stenosis of the LAD on coronary angiogram; coronary stent placed	PCI

CAD= coronary artery disease, MACE= major adverse cardiac events, NSTEMI=Non ST-segment elevation Myocardial Infarction, PCI = percutaneous coronary intervention, LAD=Left Anterior Descending