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Chest Pain Risk Stratification:

A Comparison of the 2-Hour Accelerated Diagnostic Protocol (ADAPT) and the HEART Pathway

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Abstract

Background—The 2-hour accelerated diagnostic protocol (ADAPT) and the history electrocardiogram age risk factors troponin (HEART) Pathway are decision aids designed to identify Emergency Department (ED) patients with chest pain who are safe for early discharge. Both have demonstrated high sensitivity (>99%) for major adverse cardiac events (MACE) at 30 days and early discharge rates ~20%. The objective of this study is to compare the sensitivity and early discharge rates of the ADAPT and HEART Pathway decision aids in a cohort of ED patients with acute chest pain.

Methods—A secondary analysis of participants enrolled and randomized to the HEART Pathway arm of the HEART pathway randomized controlled trial was conducted. Each patient was prospectively classified as low risk (suitable for early discharge) or high risk by ADAPT and the HEART Pathway. Sensitivity for MACE at 30 days and the number of patients identified as low-risk were calculated for each decision aid. Decision aid performance was compared using McNemar's test.

Results—MACE occurred in 8 of 141 (5.7%); there were no deaths, 7 patients had myocardial infarction, and 1 patient had coronary revascularization without myocardial infarction. ADAPT and the HEART pathway identified all patients with MACE as high risk; sensitivity for MACE of 100% [95% confidence interval (CI): 63–100%]. ADAPT identified 34 of 141 patients (24%; 95% CI: 17–32%) as low-risk, whereas the HEART pathway identified 66 of 141 patients (47%, 95% CI: 38–55%) as low risk ($P < 0.001$).

Conclusions—Within a cohort of ED patients with acute chest pain, ADAPT and the HEART pathway had high sensitivity for MACE. The HEART pathway outperformed ADAPT by correctly identifying more patients as low risk and safe for early discharge.

Keywords

chest pain; decision aids; acute coronary syndrome

Current care patterns for patients with acute chest pain do not accurately focus health care resources, such as admissions, observation unit stays, stress testing, and coronary angiography, on patients most likely to benefit. Among low-risk patients, hospital stays for stress testing and cardiac imaging are associated with a substantial number of false positive and nondiagnostic tests, which lead to additional unnecessary and often invasive procedures.¹ Consensus is building among health system leaders regarding the need to more efficiently evaluate the nearly 10 million patients, who present to U.S. Emergency Departments (ED) annually complaining of chest pain.²

Decision aids, like the 2-hour accelerated diagnostic protocol (ADAPT) and History electrocardiogram Age Risk factors Troponin (HEART) Pathway have been developed to more accurately risk stratify ED patients with acute chest pain and avoid unnecessary testing in low-risk patients. In prior studies, both ADAPT and the HEART pathway have demonstrated high sensitivity for detecting acute coronary syndrome (ACS) events while identifying >20% of patients as low risk and appropriate for early discharge.^{3,4} However, a recent validation of ADAPT in the US demonstrated much lower sensitivity,⁵ and ADAPT has yet to be compared with the HEART pathway.

The objective of this analysis is to compare the sensitivity and early discharge rates of the ADAPT and HEART pathway decision aids in a cohort of ED patients with symptoms suspicious for an ACS. Although the precise values of an acceptable sensitivity for major adverse cardiac events (MACE) or early discharge rate are matters of considerable debate, ideally, a chest pain risk stratification strategy should have a high early discharge rate (>20%) while maintaining a sensitivity for MACE of >99%.^{4,6}

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) before enrollment.

Methods of the HEART pathway trial have been previously described.⁷ Adult patients presenting to the ED with symptoms suggestive of ACS without ST-elevation on electrocardiogram (ECG) were enrolled. Patients were randomized with equal probability to risk stratification using the HEART pathway or usual care (based on American College of

Cardiology/American Heart Association guidelines). In the HEART pathway arm, ED providers used a clinical decision aid, the HEART score, and serial troponin measures at 0 and 3 hours to guide disposition decisions.

Study Setting

Participants were enrolled from the ED of Wake Forest Baptist Health. 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, dobutamine stress echocardiogram, coronary computed tomography angiography, stress nuclear imaging, stress cardiac magnetic resonance imaging, and invasive coronary angiography. Serum troponin measurements were performed using a contemporary assay: the ADVIA Centaur platform TnI-Ultra (Siemens, Munich Germany). This assay has a 99th percentile of the upper reference limit and 10% coefficient of variation at 0.04 µg/L, which was also the clinical threshold for detection of myocardial injury during the study period.

Participants

Patients at least 21 years old presenting with symptoms suggestive of ACS were screened during enrollment hours (6 days excluding Saturday, 80 hours/week). Eligibility criteria included the provider ordering an ECG and troponin for the evaluation of ACS. Patients were determined ineligible for the following reasons: new ST-segment elevation ≥ 1 mm, hypotension, life expectancy <1 year, a noncardiac 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,⁸ and Key Data Elements and Definitions.⁹ 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 dialogue¹⁰ 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. In the event of discrepancy between a participant's self-reported event and the medical record, the medical record was considered correct.

Accelerated Diagnostic Protocol

The ADAPT decision aid was applied to all of the study participants to risk stratify patients into low-risk or high-risk groups. ADAPT identifies patients as low-risk and appropriate for early discharge if they have a thrombolysis in myocardial infarction score of 0, 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 ADAPT were collected prospectively from patients enrolled in the HEART pathway RCT. However, during the HEART pathway RCT serial troponins were measured at 0 and 3 hours, which differs slightly from the 0 and 2 hour measures recommended for ADAPT. For patients with incomplete or missing data, a review of the EMR blinded to patient outcomes was conducted.

Study Measures

MACE within 30 days of presentation was 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 American College of Cardiology (ACC) key data elements and definitions for measuring the clinical management and outcomes of patients with ACS.^{11,12} MI was defined based on the Universal Definition of MI.¹³ Coronary revascularization was defined as coronary artery bypass grafting, stent placement, or other percutaneous coronary intervention. A consensus of two reviewers (C.D.M., B.C.H.), blinded to Emergency Department Assessment of Chest Pain Score - Accelerated Diagnostic Protocol 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 ADAPT and the HEART Pathway as safe for early discharge (low-risk), the sensitivity, specificity, and positive and negative predictive values of ADAPT for MACE were calculated. Corresponding 95% exact binomial confidence intervals were also computed. Patients with incomplete follow-up (2.8%, 4/141) were considered to be free of 30-day MACE events. Decision aid performance was compared using McNemar's test and net reclassification improvement. Statistical analysis was performed using SAS 9.4 (Cary, NC).

RESULTS

From September 2012 to February 2014, 141 patients with symptoms suggestive of ACS were enrolled in the HEART Pathway arm of the HEART Pathway RCT. Data needed to determine risk by ADAPT were available on all 141 participants. Follow-up for 30 day events was complete for 97.2% (137/141) of participants. MACE occurred in 8/141 (5.7%); there were no deaths, 7 patients had MI, and 1 patient had coronary revascularization without MI. Patient characteristics are summarized in Table 1. Table 2 provides the frequencies of the ADAPT risk assessment determinants.

ADAPT identified 34 of 141 patients [24.1%, 95% confidence interval (CI): 17.3–32.0%] as low-risk, whereas the Heart Pathway identified 66 of 141 patients (46.8%; 95% CI: 38.3–55.4%) as low risk, an absolute difference of 22.7% (95% CI: 11.9–33.5%), $P < 0.001$. Of these, none had MACE at 30 days. ADAPT was 100% (95% CI: 63.0–100%) sensitive for MACE, with a specificity of 25.6% (95% CI: 18.4–33.8%). The performance characteristics of the ADAPT and the HEART Pathway are summarized in Table 3. Compared with ADAPT, the Heart Pathway was able to correctly reclassify 32 patients without MACE as low risk, yielding a net reclassification improvement of 24.1% (95% CI: 17.1–32.2%).

DISCUSSION

Among patients with acute chest pain, both the HEART Pathway and ADAPT were highly sensitive for adverse cardiac events. However, the HEART pathway identified 23% more patients for early discharge than ADAPT while maintaining 100% sensitivity for MACE. Thus, the HEART pathway compared with ADAPT substantially increased the proportion of patients in this ED cohort identified for early discharged without objective cardiac testing. This study provides important evidence for health systems, EDs, and individual practitioners considering which decision support tool to implement and ways to improve the value of care for patients with acute chest pain.

This analysis is the first to compare the test characteristics of the HEART pathway with that of ADAPT. Both decision aids have previously demonstrated high sensitivity for adverse cardiac events and an ability to identify more patients for early discharge than usual care.^{3,4,14–16} A recent randomized trial showed that compared to usual care, use of the HEART Pathway increased early discharges by 21.3% (39.7% vs. 18.4%), decreased length of stay by 12 hours (10 vs. 22 hours) and objective cardiac testing at 30 days by 12% (69% vs. 57%) without increasing adverse events.⁴ In a randomized trial comparing ADAPT to usual care, ADAPT demonstrated a sensitivity for MACE of 98% and increased early discharges by 8.3% compared with usual care (19.3% vs. 11%).¹⁶

The test characteristics of ADAPT in our analysis are consistent with results from prior publications by Than et al.^{3,16} In these studies, ADAPT identified approximately 20% of patients with acute chest pain as safe for early discharge while maintaining high sensitivity for MACE.^{3,16} The reported sensitivities of ADAPT for MACE in the Asia Pacific Region are 99.7%,³ 99.6%,¹⁷ and 97.9%.¹⁶ In addition, a modified application of ADAPT (utilizing high-sensitivity cardiac cTn rather than contemporary cTn) within the APACE cohort of 909

patients with acute chest pain from Italy, Switzerland, and Spain reported 100% sensitivity for MACE.¹⁸ However, our results differ from a recent application of ADAPT to a cohort of U.S. patients with chest pain, which demonstrated lower sensitivity for MACE (84%) and a much higher early discharge rate (48%).⁵

High sensitivities for ED chest pain risk stratification decision aids often come at the expense of identifying patients for early discharge. Maximizing sensitivity results in many false-positive cases (patients identified as high risk without an event at 30 days) and low numbers of true negatives (patients identified as low-risk without an event at 30 days). In this comparison study, the HEART pathway was better than ADAPT in achieving a balance between the need for high sensitivity and limiting the number of false positive patients. The HEART pathway identified a much larger number of patients for early discharge than ADAPT. However, the HEART pathway's 49.6% specificity and ability to identify 47% as low-risk leaves substantial room for improvement. New decision aids or modifications to the HEART pathway should seek to maintain a high sensitivity (>99%) while increasing the percentage of low-risk patients identified for early discharge.

To improve the value of care for patients with chest pain it is important that we have tools capable of identifying low-risk patients for early discharge from the ED, focusing objective cardiac testing and hospitalizations on patients at higher risk. The ability of the HEART score to identify 23% more patients for early discharge relative to ADAPT is likely to translate into reduce costs, radiation exposure (from stress testing and angiography), and decrease false positive and nondiagnostic testing.¹⁹ As the U.S. healthcare system switches from fee-for-service to value based payment models, tools, which can avoid potentially unnecessary objective cardiac testing and admissions, will be increasingly implemented. Our data suggest that the HEART Pathway is superior to the ADAPT decision aid in providing value.

Limitations

Our analysis has a small sample size and enrollment from a single academic medical center may limit generalizability. Our cohort differs from the cohorts in which ADAPT was derived and validated. For example, the MACE rate of our cohort was only 6% compared with a 15.3% MACE rate for the ADAPT validation cohort, indicating our cohort may have been lower-risk. Another potential limitation of this analysis is incomplete follow-up on 4 patients (2.8% of participants), which may have caused misclassification and underestimation of MACE. However, none of these patients appeared in the Social Security Death Master File for 1 year following index visit. 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 with the ADAPT 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 ADAPT. The longer time between serial troponins could have improved the sensitivity of ADAPT in this cohort.

CONCLUSIONS

Within a U.S. cohort of ED patients with symptoms concerning for ACS, both the HEART pathway and ADAPT were 100% sensitive for MACE at 30 days. However, the HEART pathway outperformed ADAPT by identifying 23% more patients as low risk and safe for early discharge. These findings suggest that implementation of the HEART pathway will safely allow the discharge of more patients than the ADAPT decision aid. This study has important implications for health systems, EDs, and providers considering which risk stratification tool to incorporate into their clinical practice.

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DISCLOSURES

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TABLE 1

Characteristics of the HEART Pathway Arm of the HEART Pathway RCT Cohort

Patient Characteristics	
Age—mean $\pm$ SD	53.4 $\pm$ 12.0
Gender	
Female	81 (57.4%)
Race	
Caucasian	90 (63.8%)
African American	48 (34.0%)
Asian	1 (0.7%)
Native American	1 (0.7%)
Other	1 (0.7%)
Ethnicity	
Hispanic	1 (0.7%)
Not Hispanic	140 (99.3%)
Risk factors	
Current smoking	42 (29.8%)
Recent cocaine (last 90 days)	3 (2.1%)
Hypertension	75 (53.2%)
Hyperlipidemia	61 (43.3%)
Diabetes	31 (22.0%)
Family history of coronary disease	44 (31.4%)
BMI >30 (kg/m ²)	71 (50.4%)
TIMI risk score >1	60 (42.6%)
Prior coronary disease	28 (19.9%)
Prior MI	21 (14.9%)
Prior PCI	14 (9.9%)
Prior CABG	7 (5.0%)
Prior cerebral vascular disease	3 (2.1%)
Prior peripheral vascular disease	4 (2.8%)
Insurance status	
Insured	105 (74.5%)
Private	71 (50.4%)
Medicare	21 (14.9%)
Medicaid	13 (9.2%)
Uninsured	36 (25.5%)

BMI indicates body mass index; CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention; SD, standard deviation; TIMI, thrombolysis in myocardial infarction.

TABLE 2

Frequency of ADAPT Determinants

Clinical Characteristic	Number (%)
cTnI at time 0 hour normal	133 (94.3)
cTnI at time 2 hours normal	131/140 (93.6)
No ischemic change on ECG	135 (95.7)
TIMI = 0	38 (26.9)

TIMI indicates thrombolysis in myocardial infarction.

TABLE 3

Performance Characteristics of the ADAPT and the HEART Pathway

Risk Stratification Strategy	30 Day MACE				
	Yes (n)	No (n)	Total (n)		
ADAPT high risk	8	99	107		
ADAPT low risk	0	34	34		
Total (n)					
HEART high risk	8	67	75		
HEART low risk	0	66	66		
Total (n)					
	% Low risk (95% CI)	Sensitivity, % (95% CI)	Specificity, % (95% CI)	PPV % (95% CI)	NPV % (95% CI)
ADAPT	24.1 (17.3, 32.0)	100 (63.1, 100)	25.6 (18.4, 33.8)	7.5 (3.3, 14.2)	100 (89.7, 100)
HEART	46.8 (38.3, 55.4)	100 (63.1, 100)	49.6 (40.8, 58.4)	10.7 (4.3, 18.1)	100 (94.5, 100)

NPV indicates negative predictive value; PPV positive predictive value.