FINAL PROGRESS REPORT

1. **Valuation of a simple tool for chest pain patient risk-stratification in North America**

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**Purpose:** The overall purpose of this pilot study was to determine the feasibility and practicality of conducting a large R01-funded clinical trial to determine the value of the HEART score in discriminating low- from moderate-risk chest pain (CP) among emergency department (ED) patients in the U.S.

**Scope:** The scope of the project was limited to demonstrating feasibility of and collecting preliminary data for a future R01 proposal.

**Methods:** This was a single-site, prospective, observational cohort study to test our ability to administer the history, electrocardiogram findings, age, risk factors, and troponin value (HEART) score and collect key elements in real-time clinical practice.

**Results:** Data collection is now complete and our results are as follows: Patients screened = 2,637; Patients study eligible = 446 (0.169 [95%CI=0.155,0.184]); Patients enrolled = 293 (0.657 [95%CI=0.611,0.701]); Data collection forms completed = 293 (1.000 [95% CI=0.987,1.000]); Lost to follow-up = 64 (0.218 [95%CI=0.172,0.270]). We conclude that it is feasible and practical to conduct a large R01-funded clinical trial to determine the value of the HEART score in discriminating low- from moderate-risk CP among ED patients in the U.S.

**Key Words:** HEART score, Cardiac Chest Pain, Emergency Department, Risk stratification, Decision Aids

**Purpose**

The objective of this pilot study was to determine the feasibility and practicality of conducting a large, R01-funded clinical trial to determine the value of a promising, new quantitative cardiac

risk-calculator, the HEART score (History, Electrocardiogram findings, Age, Risk factors, and Troponin value), in discriminating low- from moderate-risk potential cardiac chest pain (CP) after inconclusive evaluation among emergency department (ED) patients in the U.S.

**Scope**

Practice variability is an important issue in emergency medicine. It contributes to over-, under-, or misuse of healthcare resources and can put patients' health at risk. Decision aids and practice guidelines are ways to standardize care, optimize resource utilization, and protect patients. Each year in the U.S., more than 9 million people present to the ED with acute CP. Creating a uniform practice around the disposition of these patients with undifferentiated CP who are at risk for acute coronary syndrome (ACS) is especially problematic. These disposition decisions are based largely on clinical judgment and driven by provider risk tolerance rather than objective evidence because current quantitative cardiac risk-stratification scoring systems have a poor performance when applied to ED patients, and missed ACS can have devastating psychological and financial consequences for physicians as well as patients.

A promising new quantitative cardiac risk-calculator, the HEART score (History, Electrocardiogram findings, Age, Risk factors, and Troponin value), has been proposed recently as a useful aid for guiding disposition decisions for patients with potential cardiac CP after inconclusive ED evaluation. Derived and validated on Dutch ED patients and externally validated in an Asian-Pacific cohort, this simple outcome predictor has been shown to accurately quantify the likelihood of a major adverse cardiac event (MACE) within 30 days of an index visit and has outperformed other decision aids in rigorously controlled clinical trials.

What we don't know is the performance characteristics of the HEART score when applied in the context of the U.S. healthcare system (e.g., population demographics and disease prevalence, patient expectations and clinician practice, medical-legal climate), the feasibility and practicality of studying it in the setting of a busy U.S. ED, and what its relative ease of use is compared with other options. The overall objective of this pilot study was to determine the feasibility and practicality of conducting a large R01-funded clinical trial to determine the value of the HEART score in discriminating low- from moderate-risk CP among ED patients in the U.S. The rationale for this pilot study was that an instrument that will guide clinical practice and impact disposition decisions must be tested for accuracy and convenience in order to be effectively used in a busy ED practice.

Our central hypothesis was that the HEART score will be feasible to test and will have acceptable reliability and superior ease of use,[#] making it suitable as a decision aid to safely reduce unnecessary admissions and to promote provider disposition consistency.

Baystate Health, Inc. is a not-for-profit, hospital-based, integrated healthcare delivery system serving Western New England. The main campus of Baystate Health, Baystate Medical Center is a 716-bed research and teaching hospital located in Springfield, MA, that functions as the main campus of the University of Massachusetts Medical School-Baystate. The Baystate Medical Center Emergency Department is one of the busiest in the Northeast. The department has a large (40+ full-time University of Massachusetts Medical School-Baystate faculty), diverse group of emergency medicine board-certified clinicians practicing in an academic setting. We serve a population base of over one million people and care for more than 122,000 adult patients annually. The patient population eligible the study were the over 12,000 patients seen annually with a chief complaint of “chest pain,” at least one ECG, and a troponin level drawn, which indicates some level of clinical suspicion for cardiac CP. The average age is 56.9 years, men constituted 47%; 79% are White, and 27% identify as Hispanic. The ratio of those admitted versus discharged is approximately 2:1, with a median length of hospital stay of 1 day for admitted patients.

**Methods**

This was a single-site, prospective, observational cohort study to test our ability to administer the HEART score and collect key elements in real-time clinical practice. Our research coordinator and her team of research associates enrolled a convenience sample of almost 300 ED patients with CP over 12 months. The data were analyzed using conventional descriptive statistics (the mean, standard deviation, median, interquartile range, and extremes for continuous variables and proportions for binary and categorical variables) and effect sizes (e.g., Cohen’s w, c-statistics). Feasibility was defined as enrollment of >66% of eligible subjects, >90% completion of data key elements, and <5% of subjects lost to follow-up (consistent with benchmarks established by similar studies conducted in our ED

**Results**

The award was activated in August 2016. As planned, the IRB process was completed and all regulatory requirements were met prior to study activation.

[#] Testing the HEART score’s ease of use was rendered irrelevant before Aim 3 could be completed, as the comparators yielded to the widespread adoption of the HEART score in clinical practice, demonstrating this point.

Recruitment of research associates and all training took place during the first 6 months of the award period. Data collection is complete and our results are as follows: Patients screened = 2,637; Patients study eligible = 446 (0.169 [95%CI=0.155,0.184]); Patients enrolled = 293 (0.657 [95%CI=0.611,0.701]); Data collection forms completed = 293 (1.000 [95% CI=0.987,1.000]); Lost to follow-up = 64 (0.218 [95%CI=0.172,0.270]).

Though our lost-to-follow-up rate was slightly higher than projected, it was still acceptable for a prospective clinical trial. We conclude that it is feasible and practical to conduct a large R01-funded clinical trial to determine the value of the HEART score in discriminating low- from moderate-risk CP among ED patients in the U.S. Preparation of an R01 is ongoing, with an expected submission date of October 16, 2019, after additional preliminary data are collected.

**List of Publications and Products from the Study**

This was a pilot study to determine our ability to screen and enroll subjects for the purpose of supporting an R01 submission, so the findings were not intended for publication. However, our preliminary results were presented at the 21st Annual New England Region Society for Academic Emergency Medicine Research Forum in March 2018 in Worcester, MA (oral presentation), and our study was selected for a lightning oral presentation at the National Society for Academic Emergency Medicine meeting in May 2018 in Indianapolis, IN.