Original Article

Henry Ford HEART Score Randomized Trial
Rapid Discharge of Patients Evaluated for Possible Myocardial Infarction

Tiberio M. Frisoli, MD; Richard Nowak, MD; Kaleigh L. Evans, MD; Michael Harrison, MD, PhD; Maath Alani, MD; Saira Varghese, MD; Mehnaz Rahman, MD; Samantha Noll, MD; Katherine R. Flannery, MD; Alex Michaels, MD; Mishel Tabaku, RCIS; Gordon Jacobsen, MS, MD; James McCord, MD

Background—Hospital evaluation of patients with chest pain is common and costly. The HEART score risk stratification tool that merges troponin testing into a clinical risk model for evaluation emergency department patients with possible acute myocardial infarction (AMI) has been shown to effectively identify a substantial low-risk subset of patients possibly safe for early discharge without stress testing, a strategy that could have tremendous healthcare savings implications.

Method and Results—A total of 105 patients evaluated for AMI in the emergency departments of 2 teaching hospitals in the Henry Ford Health System (Detroit and West Bloomfield, MI), between February 2014 and May 2015, with a modified HEART score ≤3 (which includes cardiac troponin I <0.04 ng/mL at 0 and 3 hours) were randomized to immediate discharge (n=53) versus management in an observation unit with stress testing (n=52). The primary end points were 30-day total charges and length of stay. Secondary end points were all-cause death, nonfatal AMI, rehospitalization for evaluation of possible AMI, and coronary revascularization at 30 days. Patients randomized to early discharge, compared with those who were admitted for observation and cardiac testing, spent less time in the hospital (median 6.3 hours versus 25.9 hours; $P<0.001$) with an associated reduction in median total charges of care ($2953 versus $9616; $P<0.001$). There were no deaths, AMIs, or coronary revascularizations in either group. One patient in each group was lost to follow-up.

Conclusions—Among patients evaluated for possible AMI in the emergency department with a modified HEART score ≤3, early discharge without stress testing as compared with transfer to an observation unit for stress testing was associated with significant reductions in length of stay and total charges, a finding that has tremendous potential national healthcare expenditure implications.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT03058120

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Key Words: acute coronary syndrome ■ chest pain ■ length of stay ■ myocardial infarction ■ troponin

The evaluation of chest pain accounts for >8 million emergency department (ED) visits annually, the second most common reason for ED visits in the United States.[1] Estimations are that 85% of individuals evaluated for possible acute myocardial infarction (AMI) in the ED are ultimately found to not have an AMI.[2–4] A study showed that 2.1% of patients with AMI are inadvertently discharged from the ED, and patients with AMI sent home from the ED had a risk-adjusted mortality rate of nearly twice that of those admitted to the hospital.[5] Consequently, many of the 8 to 10 million patients who present annually to EDs in the United States with possible AMI[6] are admitted for further observation and cardiac testing. Guidelines recommend a period of observation with serial cardiac markers and noninvasive cardiac testing during the ED evaluation or within 72 hours of ED discharge for patients with symptoms suspicious for AMI but without objective evidence of myocardial ischemia.[7] This includes a large and heterogeneous patient population. The total cost of evaluating patients for possible AMI in the ED is estimated at $5 to $10 billion annually in the United States.[8]

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Importantly, these guideline recommendations are made despite an absence of prospective randomized trial evidence that such noninvasive testing during index chest pain hospitalization reduces risk of major adverse cardiac events (MACEs). In a study of 832 patients who presented to the hospital with chest pain, 31% received inpatient or outpatient electrocardiogram (ECG) stress testing.[9] The rates of death and myocardial infarction at 30 days were no different between those who received inpatient stress testing, outpatient stress testing, or no stress testing (1.0% versus 1.4% versus 1.3%). In a large retrospective analysis of >400 000 patients who presented to the ED with chest pain but were ruled out for AMI, the rates of AMI

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From the Heart and Vascular Institute (T.M.F., M.T., J.M.), Department of Emergency Medicine (R.N., M.H., S.N., K.R.F.), Department of Internal Medicine (K.L.E., M.A., S.V., M.R., A.M.), and Biostatistics Division, Department of Public Health Sciences (G.J.), Henry Ford Hospital, Detroit, MI.

Correspondence to Tiberio M. Frisoli, MD, Heart and Vascular Institute, K14 Henry Ford Hospital, 2799 W, Grand Blvd, Detroit, MI 48202. E-mail tfrisoli@gmail.com

WHAT IS KNOWN

- The evaluation of chest pain is the second most common reason for emergency department visits in the United States and is responsible for a huge healthcare expenditure.
- Emergency department patients with symptoms compatible with acute coronary syndrome but who fall in a low-risk category as determined by application of a HEART score have low 30-day major adverse cardiac event rates, in the range of ≤0.5%.

WHAT THE STUDY ADDS

- Among patients presenting to the emergency department with chest pain who were ruled out for acute myocardial infarction and who were deemed low risk by a modified HEART score ≤3, early discharge without cardiac testing as compared with admission to an observation unit for cardiac testing was associated with >4- and 3-fold reductions in length of stay and total related charges at 30 days, respectively.
- Because this subset represents a significant minority of all emergency department chest pain patients, use of the modified HEART score to guide early discharge of low-risk patients has tremendous national cost- and hospitalization time-saving implications.

at 7 and 190 days of follow-up were low (0.11% and 0.33%, respectively). Patients who did not undergo testing were not more likely to experience AMI than those who did undergo testing; further, those who underwent testing were more likely to undergo cardiac catheterization and revascularization procedures, without an improvement in AMI rate.[10] That revascularization does not seem to be associated with improvement in death or AMI in this patient population is worthy of emphasis.

Although studies of myocardial perfusion imaging or coronary computed tomographic angiography (CCTA) demonstrate similar ability to identify low-risk patients with ≤1% risk of a 30-day MACE,[11–13] observational data suggest marginal diagnostic benefit with high false-positive rates in low-risk patients.[14–16] Furthermore, a widespread advanced cardiac testing strategy may lead to patient harm, including radiation exposure,[17] injuries caused by iodinated contrast, or complications of downstream invasive coronary angiography.

The HEART score (HS) was originally designed to aid in the risk stratification of patients in the ED evaluated for possible AMI and incorporates elements of the history, risk factors, ECG, and cardiac troponin (cTn) levels. Prior studies have shown that patients with HS ≤3 have 30-day MACE rates of 0.6% to 3.6%.[18,19] These rates are generally higher than would be acceptable for an emergency physician to discharge a patient without further testing.[20] However, the original HS allows for a patient to be deemed low risk with an elevated cTn, and one study of 1070 patients with HS ≤3 and normal serial cTnI levels showed a 30-day MACE rate of 0%.[21]

The purpose of our study was not to show that there would be cost and length of stay savings with early discharge as compared with observation for stress testing—this is intuitively expected—but rather to quantify this reduction. Furthermore, in contradistinction to other HS trials that included patients of all HSs, our trial's study population consisted exclusively of patients with a low-risk–modified HS (m-HS). This was done to isolate assessment of the risk stratification and early discharge benefit of the m-HS to those patients for whom the score has most utility: truly low-risk patients.

Methods

Study Design and Population

This was a prospective, randomized, controlled trial conducted from February 2014 to May 2015 at 2 hospitals within the Henry Ford Health System in Michigan (Detroit and West Bloomfield). This study included patients who (1) presented to the ED with symptoms suspicious for AMI as evidenced by the responsible physician ordering cTnI, (2) had AMI excluded with 2 cTnI values <0.04 ng/mL at least 3 hours apart, (3) were triaged to the observation unit (OU) by the ED physician, and (4) had an m-HS of ≤3. Patients were randomized in a 1:1 fashion to discharge from the ED versus transfer to the OU for stress testing.

The original HS consisted of 5 components: history, ECG, age, risk factors, and cTn. To calculate an HS, each component is assigned a number on a scale of 0 to 2, and then component scores are summed to produce the final score (0–10). The m-HS eliminated the cTn component of the score, instead requiring cTnI <0.04 ng/mL at 0 and 3 hours; therefore, the m-HS ranges from 0 to 8. The cTnI ultra-assay was used (Siemens Healthcare, Erlangen, Germany) with a 99th percentile of 0.04 ng/mL with a coefficient of variation of <10% at this cut point.

The components of m-HS are shown (Table 1). The history component of the m-HS was determined by the ED physician and is divided into high (2 points), moderate (1 point), and low (0 points) suspicion for AMI. Importantly, this is the variable that introduces subjective clinical impression into the risk stratification tool. The ECG was interpreted by the ED physician. Patients who

Table 1. Components of the Modified HEART Score

Modified HEART Score		Points
History	High suspicion	2
	Moderate suspicion	1
	Low suspicion	0
ECG	ST-depression ≥0.5 mm	2
	LBBB, RBBB, LVH, paced rhythm	1
	Normal or nonspecific	0
Age, y	>65	2
	45–65	1
	<45	0
Risk factors*	≥3 or known CAD†	2
	1–2 risk factors	1
	None	0

CAD indicates coronary artery disease; ECG, electrocardiogram; LBBB, left bundle branch block; LVH, left ventricular hypertrophy; and RBBB, right bundle branch block.

*Risk factors: hypertension (any medication prescribed), diabetes mellitus (any medication prescribed), hyperlipidemia (any medication prescribed), current smoker, or family history of CAD (first-degree relative with myocardial infarction/revascularization <55 year old for women and <45 year old for men)

†CAD=myocardial infarction, percutaneous coronary intervention, coronary artery bypass graft, or left main >50% stenosis, other vessel >70%.

met criteria for 1 point could not receive 2 points even if they had ST-segment depression.

The authors assume responsibility for the accuracy and completeness of the data and all analyses. The Henry Ford Hospital Institutional review board approved the study, and written informed consent was obtained from all participants.

Study Population

Eligible patients were at least 21 years old who presented to the ED with symptoms suspicious for AMI. The ED physician's intention to send the patient to the OU for stress testing was required for patient enrollment. Exclusion criteria were cTnI >0.04 ng/mL at 0 or 3 hours, clinical presentation warranting admission, inability or unwillingness to consent, or trauma as pathogenesis of presenting symptoms.

Randomization and Study Treatment

Patients were randomly assigned in a 1:1 fashion to discharge from the ED without cardiac testing or standard of care, which was admission to the OU for cardiac testing. The randomization sequence was generated and integrated into a secure electronic database. Study investigators and staff were blinded to the randomization sequence. Randomization allocation cards, the sequence for which was generated with an on-line randomization program, were included for each patient in a sealed envelope, which was placed inside the larger envelope that included informed consent. For each patient, the person

Table 2. Patient Characteristics

Variable	Total (n=105)	Early Discharge (n=53)	Control (n=52)	Effect Size
Age (±SD)	50±9	49±9	51±9	0.22 (SMD)
Female	54 (51%)	22 (42%)	32 (62%)	0.20–0.97* (OR CI)
White	15 (14%)	9 (17%)	6 (12%)	
Black	78 (74%)	36 (69%)	42 (82%)	0.19–1.76 (OR CI)
Hypertension	67 (64%)	34 (64%)	33 (64%)	0.46–2.28 (OR CI)
Diabetes mellitus	23 (22%)	14 (26%)	9 (17%)	0.67–4.40 (OR CI)
Hyperlipidemia	23 (22%)	12 (23%)	11 (21%)	0.43–2.75 (OR CI)
Tobacco use	54 (52%)	27 (51%)	27 (52%)	0.45–2.07 (OR CI)
Family history CAD	27 (26%)	15 (28%)	12 (23%)	0.55–3.17 (OR CI)
Modified HEART score				
0	0 (0%)	0 (0%)	0 (0%)	0.03 (SMD)
1	20 (19%)	11 (5.4%)	9 (21.1%)	
2	58 (55%)	28 (53%)	30 (58%)	
3	27 (26%)	14 (26%)	13 (25%)	
History				
0	78 (75%)	39 (74%)	39 (75%)	0.02 (SMD)
1	27 (26%)	14 (26%)	13 (25%)	
2	0 (0%)	0 (0%)	0 (0%)	
ECG				
0	98 (93%)	50 (94%)	48 (92%)	0.08 (SMD)
1	7 (7%)	3 (6%)	4 (8%)	
2	0 (0%)	0 (0%)	0 (0%)	
Age				
0	28 (27%)	15 (28%)	13 (25%)	0.10 (SMD)
1	74 (70%)	37 (70%)	37 (71%)	
2	3 (3%)	1 (2%)	2 (4%)	
Risk factors				
0	14 (13%)	8 (15%)	6 (12%)	0.12 (SMD)
1	80 (76%)	37 (70%)	43 (83%)	
2	11 (10%)	8 (15%)	3 (6%)	

CAD indicates coronary artery disease; ECG, electrocardiogram; OR CI, 95% confidence interval of the odds ratio; and SMD, standardized mean difference.

*Statistically significant numbers.

obtaining consent was blinded to randomization until after the patient had signed informed consent.

End Points

The primary end points were total 30-day charges and length of stay in the hospital. Charges were determined from comprehensive hospital billing records incorporating the period from ED admission to 30 days post-discharge. Any postdischarge visit, tests, or other medical service relevant to the index ED visit was included in the total charge calculation. The secondary end point was a composite of all-cause death, nonfatal AMI, return visit to the ED for AMI evaluation, hospital admission for AMI evaluation, and coronary revascularization at 30 days after presentation. Follow-up at 30 days was determined by review of the electronic medical record, phone call, and check of the Social Security Death Registry.

Statistical Analysis

The study variables have been summarized using means, SDs, and medians for numeric data along with frequencies and percentages for categorical or ordinal data. The 2 study groups have been compared using the Wilcoxon rank-sum test for numeric data, the standard χ^2 test for categorical data, and the Cochran–Armitage trend test for ordinal data. Resulting $P<0.05$ has been considered statistically significant.

No formal power calculation was done; rather the data were preliminarily analyzed after the first 50 patients, and when it was clear, the end points would clearly demonstrate statistically significant differences, the investigators arbitrarily chose to enroll ≈100 patients. Ultimately, 105 patients were enrolled.

Results

Baseline demographics are shown in Table 2. There were no significant differences between groups in terms of age, race, or m-HS components; there were significantly more women in the standard of care arm compared with the early discharge arm.

The allocation, testing, and follow-up for the 105 enrolled patients are summarized in Figure. Of the 53 patients allocated to early discharge, 51 were in fact discharged and 2 were admitted but neither underwent stress testing. There were 3 of 53 who underwent outpatient follow-up stress testing. Of the 52 allocated to stress testing, 42 underwent stress testing on index admission. There was 1 patient in each group was lost to follow-up. However, the Social Security Death Registry was checked on all patients, and there were no recorded deaths at 30 days.

Patients randomized to early discharge without testing, as compared with those who were admitted to observation for stress testing, had a significantly shorter length of stay: median 6.3 versus 25.9 hours ($P<0.001$) and mean 9.0±8.2 versus 27.2±11.8 hours ($P<0.001$; Table 3). Similarly, there was a significant difference in charges: median $2953 versus $9616 ($P<0.001$) and mean $3655±$1894 versus $10 137±$3988 (Table 3). Not unexpectedly much of the charges difference came from stress testing and charges related to OU services (Table 3). Because all 3 stress tests done in the early discharge group were performed after discharge and out of the Henry Ford system, charges were extrapolated based on what the tests would have cost within the health system. Those in the early discharge arm spent significantly less time in the ED: median 361 minutes (interquartile range, 300–450 minutes) versus 475 minutes (interquartile range, 354–600 minutes; $P=0.001$).

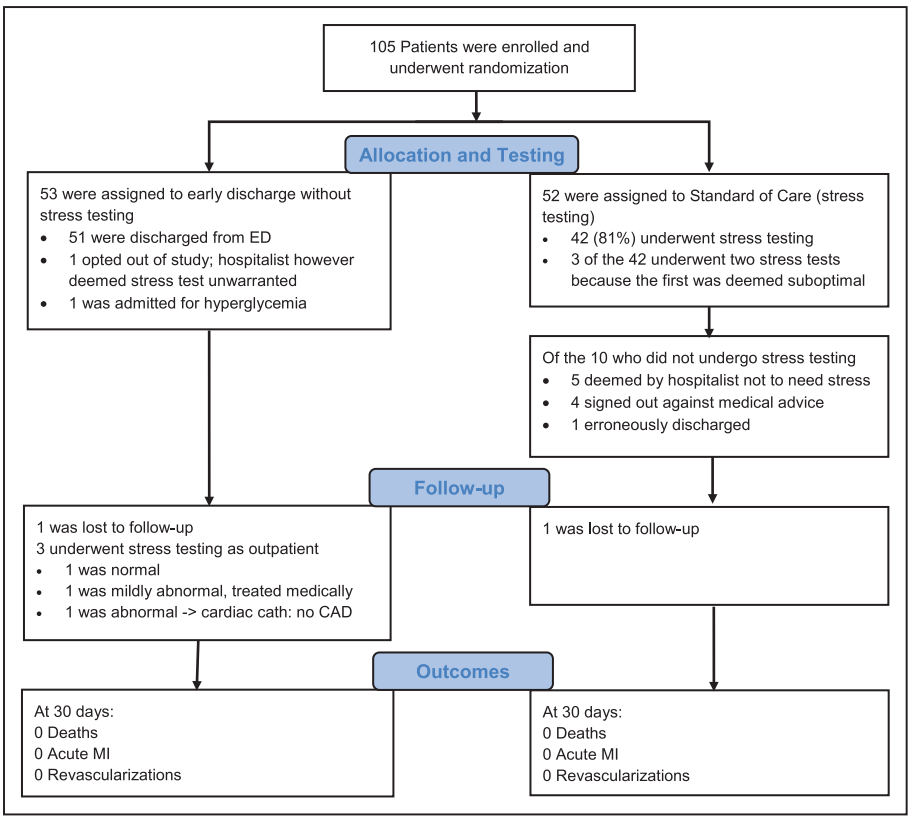

Figure. Enrollment, randomization, testing, and follow-up of the study patients. CAD indicates coronary artery disease; and ED, emergency department.

Table 3. Length of Stay and 30-Day Charges, Early Discharge vs Standard Care Groups

Variable	Early Discharge (n=53)	Standard Care (n=52)
Length of stay, median (95% CI)	6.3 h (5.7–6.9 h)	25.9 h (23.0–28.8 h)
30-d charges, median (95% CI)	$2953 ($2614–$3292)	$9616 ($8663–$10 569)
OU-related charges, mean±SD	$388±$1097	$2730±$1588
Stress test–related charges, mean±SD	$129±$643	$2627±$1696

CI indicates confidence interval; and OU, observation unit.

Of the 42 patients who had a stress test (Figure), 1 (2%) patient had an abnormal stress test. It was a pharmacological nuclear test, read as minimal ischemic burden (summed difference score=2). This patient had consultation by cardiology, which offered medical therapy or cardiac catheterization. The patient chose medical therapy; at outpatient follow-up, a cardiologist (not the one that performed the inpatient consultation) inspected the stress test and interpreted the defect as breast artifact and recommended medical therapy alone. Of the 45 stress tests in 42 patients, there were 2 (4%) exercise stress tests without imaging, 27 (60%) exercise echocardiograms (including 1 done as outpatient in a patient who had signed out against medical advice before OU stress testing), 10 (22%) dobutamine echocardiograms, 1 (2%) exercise nuclear test, and 6 (13%) pharmacological nuclear tests.

In the early discharge arm, 3 of 53 (6%) patients had stress testing done as outpatients within 30 days after discharge (Figure). All 3 were done out of the Henry Ford Health System of hospitals. One of these led to coronary angiography but not to a revascularization procedure. There were no deaths, AMIs, cardiac revascularization procedures, hospitalizations, or return visits to the ED for evaluation for possible AMI in either group at 30 days.

Discussion

Among patients presenting to the ED with chest pain who were ruled out for AMI and who were deemed low risk by an m-HS ≤3, early discharge without cardiac testing as compared with admission to an OU for cardiac testing was associated with >4- and 3-fold reductions in length of stay and total related charges at 30 days, respectively. There were no patients in either group who returned to the ED or were admitted to the hospital at 30 days. Importantly, the strategy of early discharge appeared to be safe with no deaths, AMIs, or revascularization procedures observed. Our trial was underpowered for safety, an end point which given the known low event rates in this subset of patient would require a trial of thousands of patients to evaluate. Because these low-risk ED chest pain patients represent a significant minority of all ED chest pain patients, their discharge from the ED without further observation and cardiac testing would lead to a potential cost savings of billions of dollars annually.

The American Heart Association/American College of Cardiology guidelines state it is reasonable (class IIa recommendation) to choose observation and stress testing in patients with symptoms consistent with acute coronary syndrome (ACS) without objective evidence of myocardial ischemia.[7] This recommendation includes an enormous and heterogeneous group of patients. With these recommendations and the medical-legal concerns of missing patients with ACS, the standard of care in the United States has become admission to an OU and further cardiac testing. In a survey of ED physicians, the majority thought that a missed ACS rate of >0.5% is unacceptable.[20]

When low-risk patients are evaluated with cardiac testing, the likelihood for false positives is high. One study of stress testing and CCTA in OU patients found the false-positive rate for CCTA, stress testing with imaging, and stress testing without imaging to be 43%, 67%, and 75%, respectively.[14] These numbers would likely have been even higher had the study more selectively identified low-risk OU patients with use of an m-HS. Another study of patients evaluated for possible ACS in the ED showed that patients randomized to CCTA received 3× the rate of revascularization procedures.[12] Data suggest that these revascularization procedures do not improve patient outcomes in these low-risk patients.[10]

Admission to an OU for further cardiac testing is not only expensive and time consuming but also harmful. A widespread advanced cardiac testing strategy may lead to patient harm, including radiation exposure.[13] The National Council on Radiation Protection and Measurement estimated that Americans were exposed to >7× as much ionizing radiation from medical procedures in 2006 as in 1980.[22] According to the US Food and Drug Administration, a dose of 10 mSv may be associated with an increase in the possibility of fatal cancer of ≈1 chance in 2000, which can be a public health concern if a large number of people undergo an increased number of tests involving radiation exposure.[23] The average radiation exposure for various procedures are not insignificant: percutaneous coronary intervention (15 mSv), stress nuclear (11.4 mSv), and CCTA (16 mSv).[24] It should be noted that newer CCTA techniques have lowered the amount of radiation exposure.[25]

There is evidence that the HS compares favorably to other chest pain decision aid tools. The Thrombolysis in Myocardial Infarction score has been applied to patients with chest pain of unclear pathogenesis in the ED. However, the Thrombolysis in Myocardial Infarction score was originally derived and validated in a patient population with definite AMI or unstable angina and did not include patients with an uncertain diagnosis.[26] When applied to patients in the ED with chest pain of unclear pathogenesis, the Thrombolysis in Myocardial Infarction score has not performed as well,[27] with a poor prognostic ability to predict adverse events at 30 days (area under the curve of 0.66).[28] In a prospective multicenter study of 2440 patients with undifferentiated chest pain, the HS outperformed the Thrombolysis in Myocardial Infarction score.[29] Another decision aid, the ADAPT 2-hour accelerated diagnostic protocol (2-Hour Accelerated Diagnostic Protocol to Assess Patients With Chest Pain Symptoms Using Contemporary Troponins as the Only Biomarker), using a modified Thrombolysis in Myocardial Infarction score, was studied in a randomized controlled trial[30] and showed a lesser increase in early discharges (8.3% absolute increase) than a comparable study

using the m-HS.[29] Other risk assessment models, the Sanchis and Goldman scores, were found to have low sensitivity for prediction of in-hospital ACS when applied prospectively to 148 consecutive patients who presented with chest pain, nondiagnostic ECG, and negative cardiac biomarkers.[31]

Our study is the only prospective, randomized trial done in the United States that exclusively applied the m-HS to low-risk ED patients. Most studies have been retrospective or observational. Mahler et al[32] performed a prospective, single-center, randomized trial of 282 patients in the United States using the HS (described as the HEART Pathway); however, this study applied the HS to a broader population, including higher risk patients. Patients were randomized to either the standard of care without use of the HS or to the HEART Pathway where an HS was calculated to guide testing and disposition decisions. Patients were considered low risk if they had an HS ≤3 with normal serial cTnI for 3 hours and high risk if they had an HS ≥4 or an elevated cTnI for 3 hours. Compared with usual care, those randomized to the HEART Pathway underwent decreased cardiac testing at 30 days by 12% (69% versus 57%; P=0.048) and length of stay by 12 hours (10 versus 22 hours; P=0.013). However, in our trial, cardiac testing at 30 days was decreased by 75% (81% versus 6%; P<0.001) and length of stay by 20 hours (26 versus 6 hours; P<0.001). The more significant differences in our study are likely because of higher risk patients enrolled in the Mahler et al[32] study in which the majority (88%) with an HS ≥4 or elevated cTnI were admitted to the OU or hospital. However, even the low-risk patients randomized to HEART Pathways had stress testing at 30 days of 32% as compared with 6% in our study.

The low false-positive stress test rate in our trial can partly be explained by the high rate of stress echocardiograms, which was chosen at the discretion of the ordering physician. Stress echocardiography is known to be associated with less false-positive tests, downstream invasive testing, and revascularization procedures as compared with stress myocardial perfusion imaging, CCTA, or exercise ECG testing.[13,33]

Limitations of the present study include its single-center design and small sample size, which may limit generalizability. Also, the m-HS was not applied to all low-risk chest pain ED patients but rather to those the ED provider chose to contact the research team about. A complete CONSORT diagram (Consolidated Standards of Reporting Trials flow diagram that includes progress of enrollment) is not available for this study because we did not track every patient who presented to the ED with chest pain during the trial's duration. In our trial, it was up to the ED provider to determine whether the patient should be considered for enrollment. This is a limitation of our study because it may introduce bias. A prior trial found that 36% of all chest pain ED patients were low risk by HS.[29] Although the cited trial used the HS and not the m-HS, only 7.9% of patients had an elevated troponin, so it is reasonable to suspect that a large minority of ED chest pain patients would have an m-HS of ≤3.

Another limitation is that the primary end point was charges, which may not accurately represent cost of care. A formal economic cost analysis was not done, and medical charges were used as surrogate of overall potential economic impact. Generalization of savings is dependent on the healthcare system. In addition, the small sample size and the short follow-up could affect cost estimations. However, the differences between the 2 groups were so great, implementation of an m-HS strategy with early discharge would clearly have a positive time savings and economic impact.

This study was not powered to detect differences in MACEs. A larger multicenter randomized trial is needed to prove safety.

Conclusions

Application of the m-HS decision aid in the evaluation of patients in the ED with possible AMI, with early discharge without cardiac testing for those who fall in a low-risk category, resulted in a tremendous charges and length of stay savings as compared with those admitted with intention of stress testing. Nationwide application of the m-HS in a manner comparable to what was done in this study could save billions of dollars annually. The safety of such a management strategy has been suggested in past trials; confirmation will require a large randomized trial.

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Dr Frisoli had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Disclosures

None.

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