The Chest Pain Choice Decision Aid

A Randomized Trial

Erik P. Hess, MD; Meghan A. Knoedler, RN; Nilay D. Shah, PhD; Jeffrey A. Kline, MD; Maggie Breslin, MDes; Megan E. Branda, MS; Laurie J. Pencille, RN; Brent R. Asplin, MD, MPH; David M. Nestler, MD; Annie T. Sadosty, MD; Ian G. Stiell, MD; Henry H. Ting, MD, MBA; Victor M. Montori, MD

Background—Cardiac stress testing in patients at low risk for acute coronary syndrome is associated with increased false-positive test results, unnecessary downstream procedures, and increased cost. We judged it unlikely that patient preferences were driving the decision to obtain stress testing.

Methods and Results—The Chest Pain Choice trial was a prospective randomized evaluation involving 204 patients who were randomized to a decision aid or usual care and were followed for 30 days. The decision aid included a 100-person pictograph depicting the pretest probability of acute coronary syndrome and available management options (observation unit admission and stress testing or 24–72 hours outpatient follow-up). The primary outcome was patient knowledge measured by an immediate postvisit survey. Additional outcomes included patient engagement in decision making and the proportion of patients who decided to undergo observation unit admission and cardiac stress testing. Compared with usual care patients (n=103), decision aid patients (n=101) had significantly greater knowledge (3.6 versus 3.0 questions correct; mean difference, 0.67; 95% CI, 0.34–1.0), were more engaged in decision making as indicated by higher OPTION (observing patient involvement) scores (26.6 versus 7.0; mean difference, 19.6; 95% CI, 1.6–21.6), and decided less frequently to be admitted to the observation unit for stress testing (58% versus 77%; absolute difference, 19%; 95% CI, 6%–31%). There were no major adverse cardiac events after discharge in either group.

Conclusions—Use of a decision aid in patients with chest pain increased knowledge and engagement in decision making and decreased the rate of observation unit admission for stress testing.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT01077037.


Key Words: acute coronary syndrome ■ myocardial infarction ■ diagnosis ■ emergencies

To avoid missing a diagnosis of acute coronary syndrome (ACS), emergency department (ED) physicians often admit patients to observation units or monitored beds for formal diagnostic testing,1 including cardiac imaging and cardiac stress testing, at a very-low-risk threshold, resulting in false-positive test results, unnecessary downstream procedures, exposure to ionizing radiation, and increased cost. To assist clinicians and patients in making risk-informed evaluation decisions, Kline and colleagues2,3 derived and validated a Web-based quantitative pretest probability calculator for use in patients presenting to the ED with chest pain. The pretest probability Web tool provides an estimate of the risk for ACS within 45 days of the ED visit from data readily available from the initial presentation, examination, and laboratory tests. The impact of the pretest probability instrument was recently tested in a clinical trial in which patients with chest pain were randomized to receive care from clinicians armed with the patient’s pretest probability (%) for ACS or usual care.4 The intervention group had less ionizing radiation exposure, with no significant difference in the rate of cardiac stress testing between groups.

Decision aids are evidence-based tools developed to educate and engage patients in decisions regarding their care. A
recent systematic review of 86 randomized trials of decision aids in health care\(^5\) indicated that decision aids increase patient knowledge, decrease patient uncertainty related to feeling uninformed, increase patient engagement in decision making, and improve patient-provider communication.

Based on the findings reported by Kline and colleagues\(^2,3\) and previous data regarding the effect of decision aids, we designed a decision aid for use during the clinical encounter and tested its impact in low-risk patients with chest pain. We hypothesized that use of a decision aid to facilitate a patient-centered discussion would increase patient knowledge, increase engagement in decision making, and decrease the proportion of patients who decide to be admitted to the observation unit for stress testing.

**WHAT IS KNOWN**

- To avoid missing a diagnosis of acute coronary syndrome, clinicians often admit patients to observation units or monitored beds for cardiac investigations at a very-low-risk threshold, resulting in false-positive test results, unnecessary downstream procedures, exposure to ionizing radiation, and increased cost.
- Decision aids, which are evidence-based tools developed to educate and engage patients in decisions regarding their care, have been shown to increase patient knowledge, decrease patient uncertainty related to feeling uninformed, increase patient engagement in decision making, and improve patient-provider communication.

**WHAT THE STUDY ADDS**

- Patients randomized to the Chest Pain Choice decision aid had significantly greater knowledge, were more engaged in the decision-making process, and decided less frequently to be admitted to the observation unit for cardiac stress testing.
- Shared decision-making interventions in patients with acute cardiovascular conditions may have a positive impact on knowledge transfer and decisional quality and match resource use to patient needs and preferences.
- Further work is needed to assess what, if any, synergies emerge when policies sensitive to professional preferences, including managing the risk of liability and considering throughput of generously reimbursed clinical services, are aligned with patient preferences.

**Methods**

The Mayo Clinic Institutional Review Board approved all study procedures. Patients and clinicians provided written informed consent before participation. The study protocol has been published\(^6\) and is summarized herein.

**Design and Setting**

This parallel, 2-arm, randomized trial took place in the ED of Saint Mary’s Hospital at the Mayo Clinic (Rochester, MN), a tertiary-care academic ED with an annual census of 73,000 patient visits. The ED has a 10-bed observation unit in which protocols for evaluation and risk stratification of patients presenting to the ED with symptoms suggestive of ACS are incorporated into the flow of patient care.

**Participants**

Eligible clinicians included physicians caring for patients with chest pain. Eligible patients included adults aged \( \geq 17 \) years who presented to the ED with primary symptoms of nontraumatic chest pain and who were being considered for admission to the ED observation unit for monitoring and cardiac stress testing within 24 hours. Because the study was designed to include patients at low risk for ACS, patients with elevated initial cardiac troponin T levels above the 99th percentile reference limit (99th percentile, \(<0.01 \text{ ng/mL} \); lower limit of detection, 0.01 ng/mL; 10% coefficient of variation, 0.035 ng/mL [Roche Diagnostics; Basel, Switzerland]), known coronary artery disease (defined as \( \geq 1 \) 50% stenosis on cardiac catheterization; prior electrocardiographic changes indicative of ischemia, eg, ST-segment depression, T-wave inversion, or left bundle branch block; perfusion defects or wall motion abnormalities on previous exercise, pharmacological, or rest imaging studies; previous documentation of acute myocardial infarction; or, if no records were available, patient self-report of coronary artery disease),\(^7\) cocaine use within the previous 72 hours by clinician history, or pregnancy were excluded. A Good Clinical Practice-certified study nurse, in collaboration with the treating physician, determined patient eligibility and obtained consent after the results of the initial ECG and first cardiac troponin T levels were available.

**Intervention**

Using methods previously described for decision aid development,\(^5,8-9\) we designed and refined a decision aid with the goal of enabling patients to participate in the decision to undergo urgent cardiac stress testing or follow-up with a physician within 72 hours. Figure 1 shows the decision aid used in the trial. It describes for patients the rationale for and results of the initial evaluation (ECG interpretation, results of initial cardiac troponin testing, and plan for serial cardiac markers) as well as the rationale for further cardiac stress testing. The decision aid depicts the patient’s pretest probability of ACS (defined by Kline and colleagues\(^2\) as acute myocardial infarction, coronary stenosis \(>60\)% prompting new medical management or revascularization, ventricular arrhythmia, cardiogenic shock, or bradycardia requiring therapeutic intervention) within 45 days using a risk communication pictograph. It also provides explicit management options (urgent cardiac stress testing, follow-up with a cardiologist in 24–72 hours, follow-up with the patient’s own primary-care physician, or clinician making the decision on the patient’s behalf). Patients were informed that the decision aid was adjunctive to standard care. Urgent outpatient follow-up was available to patients in both arms of the study.

All enrolled patients underwent serial cardiac troponin T testing at 0, 3, and 6 hours from the time of presentation to rule out acute myocardial infarction. To fit the decision aid within the flow of care, clinicians discussed with their patients whether to obtain an urgent cardiac stress test or to follow up as an outpatient after the initial ECG and first troponin results were available but before subsequent serial troponin levels were obtained. Patients were informed that the attending physician could escalate the management plan in response to new data (eg, an abnormal second or third serum troponin level).

Participating clinicians were oriented during a 1-hour training session given by the lead investigator (E.P.H.) as well as a brief \((\leq 3 \text{ min})\) demonstration from the study coordinator on how to use the decision aid before meeting the first enrolled patient and as needed. This approach to delivering the decision aid has been effectively used in our prior decision aid studies.\(^8\) Participants in the usual care arm discussed ED observation unit admission and urgent cardiac stress testing in the usual manner. No specific interventions, other than video and audio recording of the patient-clinician disposition discussion, were performed in the control group.
Assessment of outcomes was performed by trained research nurses who were blinded to allocation. We assessed primary outcomes — heart attack diagnosis, heart attack death, or recurrent heart attack diagnosis — and secondary outcomes during the initial 45 days at study entry. We found that using a decision aid facilitated patient participation in the decision-making process, led to an increase in patient knowledge, and improved patient satisfaction with the decision. As a result, these investigators recommended that decision aids be used in future studies of the Chest Pain Choice Trial.

The study had several limitations. First, the decision aid was developed specifically for this study and may not be generalizable to other settings. Second, the decision aid was designed to be used by clinicians and patients, and the study was not evaluated in patients who were not able to read or understand the decision aid. Third, the study only included patients who were able to give informed consent and were willing to participate. Fourth, the study was designed to include patients who were able to undergo cardiac stress testing, and the study did not evaluate the feasibility of using decision aids in patients who were not able to undergo cardiac stress testing. Fifth, the study did not evaluate the cost-effectiveness of using decision aids in this setting. Sixth, the study did not evaluate the impact of decision aids on health outcomes.

In conclusion, the Chest Pain Choice Trial is the first randomized controlled trial to evaluate the use of a decision aid in the context of cardiac stress testing. The results of this study suggest that decision aids can be used to facilitate patient participation in the decision-making process, lead to an increase in patient knowledge, and improve patient satisfaction with the decision. These results suggest that decision aids have the potential to improve the quality of care provided to patients who undergo cardiac stress testing.
12 observable clinician behaviors that promote patient involvement, and the clinician is rated from 0 (behavior not observed) to 4 (behavior observed and executed to a high standard) on each dimension. Two trained raters watched 30 videos independently and in duplicate to assess for interrater reliability17 of scoring, and the remaining videos were scored by 1 of the trained raters.

A study nurse reviewed the electronic medical record and conducted telephone follow-up for all enrolled patients using a structured instrument starting at 30 days. For patients who were unable to be contacted by telephone, we ascertained outcomes using the resources of the Rochester Epidemiology Project18 for those who lived in Olmsted County and the Social Security Death Index19 for patients who lived outside Olmsted County.

Statistical Analysis
Continuous and categorical outcomes were compared using the Fisher exact test for categorical outcomes and the Wilcoxon rank sum test for continuous outcomes. All analyses were based on 2-sided tests at a significance level of 0.05. Mean and median differences have 95% CIs calculated using a nonparametric 2-sided CI. All differences and 95% CIs were determined using the decision aid arm as the reference. We determined a priori that a sample size of 200 would provide 90% power to detect a 25.7% increase in mean knowledge for the decision aid arm, assuming that patients in the control group will, on average, answer 4 of the 7 questions correctly, equal variances between the 2 arms, and α=0.05. Mean knowledge was analyzed as a continuous variable. This number of patients would also provide 95% power to detect a 20% decrease in the proportion of patients who decided to be admitted to the ED observation unit for cardiac stress testing, assuming a 90% baseline admission rate in the control group using a 2-sided hypothesis test at a 5% significance level. We followed the intention-to-treat principle in the conduct of the trial and in all analyses. We used SAS version 9.2 software for the statistical analyses.

Results
There were 310 patients assessed for eligibility (Figure 2). We randomized 208 patients, with 51 clinicians participating in the study from February to November 2010. The study cohort comprised ≈17% of patients presenting to the ED with chest pain in whom a troponin level test was ordered as a component of the evaluation during the study period. There were 3 postrandomization exclusions and 1 patient who withdrew consent, leaving 204 patients (101 intervention, 103 control) in the final analysis. In all 3 postrandomization exclusions, additional information became available after randomization but before the patient-clinician disposition discussion indicating that patients were not eligible. The principal investigator, blinded to allocation and to patient outcome, reviewed and approved all postrandomization exclusions as prespecified in the study protocol.6,20 A total of 202 (99%) patients completed the postvisit survey. We video recorded the patient-clinician disposition discussion in 200 (98%) encounters. The main reasons for missing recordings

Figure 2. Participant flow diagram. STEMI indicates ST-segment elevation myocardial infarction.
were technical difficulties with recording equipment and patient refusal. We contacted 199 (98%) patients by telephone for 30-day follow-up. The remaining 5 (2%) patients lived outside of Olmsted County and did not have a death recorded in the Social Security Death Index database. Table 1 summarizes the characteristics of the participants at baseline. There were 74 (36%) patients who graduated from college or had a graduate degree and 47 (23%) whose highest level of education was high school or general education development diploma. All patient characteristics were balanced between groups except for hypertension. Because none of the baseline characteristics were significantly associated with any of the outcomes, between-group comparisons were not adjusted. No difference was found in patient comfort level in receiving numeric information (P=0.54).

### Patient Knowledge, Decisional Conflict, and Trust

Patients randomized to the shared decision-making arm answered a greater number of questions in the knowledge questionnaire correctly (Table 2). They also had greater knowledge regarding their exact pretest probability of ACS within 45 days (25% versus 1%; mean difference, 24%; 95% CI, 22%–26%). Patients who used the decision aid also experienced less decisional conflict when engaging in management decisions regarding their care. Use of the decision aid did not alter patients’ trust in their physicians.

### Patient Engagement and Satisfaction

Analysis of the video-recorded visits (100 decision aid visits and 100 usual care visits) revealed that patient involvement in clinical decision making was significantly greater in the shared decision-making arm than in the usual care arm (Table 2) as judged by the OPTION scale (interobserver agreement for the OPTION scale score, 0.95). Patients who used the decision aid reported greater satisfaction with the decision-making process (strongly agree, 61% versus 40%; absolute difference, 21%; 95% CI, 7%–33%).

### Acceptability

The decision aid was acceptable, clear, and helpful to patients and clinicians (Table 2). Of the 51 clinicians who used the decision aid, 50 (98%) considered it helpful, and 32 (63%) indicated their desire to use the decision aid again if given the opportunity. Most clinicians indicated a desire to use a decision aid for other clinical management decisions.

### Management and 30-Day Outcomes

A lower proportion of patients who used the decision aid decided to be admitted to the observation unit for stress testing (58% versus 77%, P<0.0001) (Table 3). Use of the decision aid was also associated with a lower frequency of cardiac stress testing within 30 days of the ED visit (75% versus 91%, P=0.002). Patients in the usual care arm were more likely to defer to the ED physician in making decisions regarding their care.

Thirty-four of 39 (87%) patients in the decision aid arm who elected to follow up as an outpatient were seen in the outpatient setting as planned. Thirty-three of 34 (97%) were seen within 72 hours of the ED visit. Six of 16 patients in the usual care arm who opted for outpatient follow-up made their outpatient appointment. One of 6 (17%) was seen within 72 hours of the ED visit. All 15 patients who did not make their outpatient appointment were contacted by telephone at 30 days, had elected not to make their appointment, and were confirmed not to have a major adverse cardiac event.

Three patients had repeat ED visits following their exposure to the study. All 3 had been randomized to the shared decision-making arm, admitted to the observation unit, and elected to undergo cardiac stress testing. Two of the 3 repeat visits were for skin-related symptoms, and 1 was for headache. Two patients in the shared decision-making arm were hospitalized within 30 days. One patient opted to be admitted to the observation unit for cardiac stress testing and was dismissed after negative nuclear perfusion test results for cardiac ischemia. Two weeks later, the patient had an acute
stroke and was admitted to the neurology service. A second patient elected to follow up with the physician as an outpatient, developed gastroenteritis within 24 hours, and was hospitalized. None of these repeat ED visits or hospitalizations were for a cardiac event.

All 5 patients who underwent coronary revascularization were admitted to the hospital and revascularized during the index presentation. The only patient with an acute myocardial infarction was randomized to the shared decision-making arm. That patient had elevations in serial cardiac troponin measurements before stress testing, was admitted to the hospital, and underwent coronary angiography with stent placement. Excluding the index presentation, there were no deaths or major adverse cardiac events within 30 days.

Figure 3 shows the management decision across the range of pretest probabilities according to study arm. The pretest probabilities ranged from 0% to 11.4%. A lower proportion of patients randomized to the decision aid arm opted to be admitted to the observation unit for cardiac stress testing in all quartiles, with the greatest difference between study arms noted in the lowest quartile.

Discussion

Main Findings

The Chest Pain Choice decision aid increased patient knowledge, decreased patients’ decisional conflict related to feeling uninformed, did not significantly affect physician trust, and

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Decision Aid</th>
<th>Usual Care</th>
<th>P Value or MD (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient knowledge</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seven knowledge questions</td>
<td>3.6 (3.4–3.9)</td>
<td>3.0 (2.7–3.2)</td>
<td>0.67 (0.34–1.0)</td>
</tr>
<tr>
<td>Correctly assessed 45-d risk for ACS</td>
<td>24 (25)</td>
<td>1 (1)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Decisional conflict and trust</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decisional Conflict Scale</td>
<td>22.3 (18.1–26.4)</td>
<td>43.3 (32.2–39.6)</td>
<td>−13.6 (−19.1 to −8.1)</td>
</tr>
<tr>
<td>Perception of knowledge</td>
<td>22.8 (18.4–27.3)</td>
<td>40.6 (36.4–44.8)</td>
<td>−17.8 (−23.9 to −11.6)</td>
</tr>
<tr>
<td>Value clarification</td>
<td>24.2 (19.2–29.2)</td>
<td>41.1 (36.8–45.4)</td>
<td>−16.9 (−23.5 to −10.4)</td>
</tr>
<tr>
<td>Adequacy of support</td>
<td>18.5 (14.1–22.9)</td>
<td>29.2 (24.8–33.6)</td>
<td>−10.7 (−16.9 to −4.5)</td>
</tr>
<tr>
<td>Perception of uncertainty</td>
<td>24.7 (20.1–29.2)</td>
<td>36.8 (32.2–41.4)</td>
<td>−12.2 (−18.6 to −5.7)</td>
</tr>
<tr>
<td>Perception of quality of decision</td>
<td>20.5 (16.1–24.9)</td>
<td>29.7 (25.5–33.8)</td>
<td>−9.2 (−15.2 to −3.1)</td>
</tr>
<tr>
<td>Trust in physician</td>
<td>83.4 (79.4–87.3)</td>
<td>79.3 (75.4–83.2)</td>
<td>4.1 (−1.4 to 9.6)</td>
</tr>
<tr>
<td>Patient participation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OPTION scale</td>
<td>26.6 (24.9–28.2)</td>
<td>7.0 (5.9–8.1)</td>
<td>19.6 (1.6–21.6)</td>
</tr>
<tr>
<td>Acceptability</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amount of information</td>
<td></td>
<td></td>
<td>0.0051</td>
</tr>
<tr>
<td>Just right (3–5)</td>
<td>93 (93)</td>
<td>82 (80)</td>
<td></td>
</tr>
<tr>
<td>Too much (6–7)</td>
<td>2 (2)</td>
<td>1 (1)</td>
<td></td>
</tr>
<tr>
<td>Too little (1–2)</td>
<td>5 (5)</td>
<td>19 (19)</td>
<td></td>
</tr>
<tr>
<td>Clarity of information</td>
<td></td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Extremely clear (6–7)</td>
<td>62 (62)</td>
<td>37 (37)</td>
<td></td>
</tr>
<tr>
<td>Somewhat clear (3–5)</td>
<td>35 (35)</td>
<td>45 (45)</td>
<td></td>
</tr>
<tr>
<td>Not clear at all (1–2)</td>
<td>3 (3)</td>
<td>19 (19)</td>
<td></td>
</tr>
<tr>
<td>Helpfulness of the information</td>
<td></td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Extremely helpful (6–7)</td>
<td>53 (53)</td>
<td>34 (34)</td>
<td></td>
</tr>
<tr>
<td>Somewhat helpful (3–5)</td>
<td>45 (45)</td>
<td>50 (50)</td>
<td></td>
</tr>
<tr>
<td>Not helpful at all (1–2)</td>
<td>2 (2)</td>
<td>16 (16)</td>
<td></td>
</tr>
<tr>
<td>Would recommend to others</td>
<td></td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Yes (1–2)</td>
<td>75 (75)</td>
<td>45 (45)</td>
<td></td>
</tr>
<tr>
<td>Not sure (3–5)</td>
<td>23 (23)</td>
<td>46 (46)</td>
<td></td>
</tr>
<tr>
<td>No (6–7)</td>
<td>2 (2)</td>
<td>8 (8)</td>
<td></td>
</tr>
<tr>
<td>Would want to use for other decisions</td>
<td></td>
<td></td>
<td>0.1378</td>
</tr>
<tr>
<td>Yes (1–2)</td>
<td>64 (64)</td>
<td>50 (50)</td>
<td></td>
</tr>
<tr>
<td>Not sure (3–5)</td>
<td>30 (30)</td>
<td>40 (40)</td>
<td></td>
</tr>
<tr>
<td>No (6–7)</td>
<td>6 (6)</td>
<td>10 (10)</td>
<td></td>
</tr>
</tbody>
</table>

Data are presented as n (%) or mean (95% CI), unless otherwise indicated. MD indicates mean difference; ACS, acute coronary syndrome; OPTION, observing patient involvement.
increased patient engagement in decision making. Patients who used the decision aid were more satisfied with the decision-making process, and the decision aid was acceptable and helpful to patients and clinicians. A lower proportion of patients randomized to the shared decision-making arm decided to be admitted to the observation unit for stress testing. There were no major adverse cardiac events after discharge in either group.

Section 3506 of the 2010 Patient Protection and Affordable Care act includes provisions to facilitate shared decision making between patients and clinicians, to certify patient decision aids, to establish shared decision-making resource centers, and to provide grants to healthcare providers to assess shared decision-making tools. Because cardiovascular disease is a leading cause of morbidity and mortality in the United States and there are several alternative strategies for evaluation and management in patients with ACS, shared decision making in cardiovascular disease is a high-impact area for physicians to engage patients in healthcare decisions.

To our knowledge, the current investigation represents the first trial of shared decision making for patients with possible ACS presenting to the ED and suggests that shared decision making may be feasible in this setting. It also provides important insights into the potential impact of incorporating validated prediction models in a patient-centered way into the flow of care and the impact of a decision aid on the patient and physician experience of care in the acute setting. Data from this investigation suggest that shared decision-making interventions in patients with acute cardiovascular conditions may have a positive impact on knowledge transfer and decisional quality and match resource use to patient needs and preferences. As such, further research on shared decision making in other cardiovascular conditions, such as the management of coronary disease (medicines alone, percutaneous coronary intervention, or coronary artery bypass graft surgery), heart failure (resynchronization therapy, left ventricular assist devices, implantable cardioverter-defibrillators), valvular heart disease,21 and atrial fibrillation (rate versus rhythm control or ablation) is warranted.22

Study Limitations and Strengths
This study has several limitations. The decision aid may be more difficult to implement in healthcare settings with less-reliable access to outpatient follow-up. Reliable and

### Table 3. Management and Thirty-Day Outcomes

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Decision Aid</th>
<th>Usual Care</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac stress testing performed*</td>
<td>75 (75)</td>
<td>94 (91)</td>
<td>0.0024</td>
</tr>
<tr>
<td>Exercise treadmill testing</td>
<td>33 (44)</td>
<td>53 (56)</td>
<td>0.0073</td>
</tr>
<tr>
<td>Stress echocardiography</td>
<td>24 (32)</td>
<td>20 (21)</td>
<td>0.4982</td>
</tr>
<tr>
<td>Nuclear perfusion testing</td>
<td>24 (31)</td>
<td>21 (22)</td>
<td>0.4687</td>
</tr>
<tr>
<td>Coronary angiography performed</td>
<td>7 (7)</td>
<td>9 (9)</td>
<td>0.7958</td>
</tr>
<tr>
<td>Coronary revascularization</td>
<td>3 (3)</td>
<td>2 (2)</td>
<td>0.6782</td>
</tr>
<tr>
<td>Percutaneous coronary intervention</td>
<td>2 (2)</td>
<td>2 (2)</td>
<td>~1</td>
</tr>
<tr>
<td>Coronary artery bypass grafting</td>
<td>1 (1)</td>
<td>0 (0)</td>
<td>0.4951</td>
</tr>
</tbody>
</table>

#### Outcomes

- **Management decision**<0.0001
- Observation unit admission and cardiac stress testing 58 (58) 77 (77)
- Follow-up with a cardiologist 26 (26) 2 (2)
- Follow-up with a primary-care physician 13 (13) 7 (7)
- Let emergency physician decide 3 (3) 14 (14)
- Admitted to the hospital 6 (6) 6 (6) 0.9721
- Repeat emergency department visit 3 (3) 0 (0) 0.1195
- Rehospitalization 2 (2) 0 (0) 0.2439

#### Cardiac events

- Acute myocardial infarction 1 (1) 0 (0) 0.4975
- Death of cardiac or unknown cause 0 0
- Major adverse cardiac event within 30 d† 0 0

Data are presented as n (%).
*Within 30 d of the emergency department visit.
†Excluding the index event.

Figure 3. Proportion of patients who decided to be admitted to the observation unit for stress testing according to pretest probability quartile. DA indicates decision aid; UC, usual care.

![Figure 3](http://circoutcomes.ahajournals.org/Downloaded from)

Admitted to observation unit for stress testing
Not admitted to the observation unit for stress testing
timely access to outpatient follow-up, however, may be essential for cost-effective delivery of emergency care.\textsuperscript{23} The decision aid and quantitative pretest probability instrument only apply to patients who present with chest pain. The tool does not apply to patients with potential ACS with nonchest pain syndromes, such as shortness of breath, fatigue, or nausea and vomiting.

The study was not powered to detect a difference in major adverse cardiac events between groups. Given the medical and legal implications of missing a diagnosis of ACS, however, we believe it is important to have a very low rate of adverse events for clinicians to consider using the decision aid in practice.

There were 4 patients who were randomized but not included in the final analysis. One patient initially consented to participate in the study but subsequently withdrew consent after additional consideration. In the other 3 cases, it was determined that the patient did not meet eligibility criteria before the patient-clinician disposition discussion, and the primary investigator approved each postrandomization exclusion while blinded to allocation or outcomes as prespecified in the study protocol.

Thirteen percent of the patients in the decision aid arm who elected not to be admitted to the observation unit for cardiac stress testing also decided not to follow up as an outpatient, suggesting that these patients found their individual pretest probability for ACS to be acceptable and opting not to undergo additional evaluation. When informed and given the choice, these patients opted for less-intensive evaluation. When given the opportunity to make decisions based on their own risk tolerance, clinicians more frequently ordered diagnostic investigations. However, if doing so requires withholding information, limiting patient autonomy, and transferring additional charges to the patient, this may not be ethically justifiable.

There were 5 patients who we were unable to contact by telephone for follow-up assessment. In these cases, we searched the Social Security Death Index to assess vital status, and none of the patients were listed in this database. Although there is likely a time lag for mortality data, the number of patients who were unable to be contacted by telephone is a small proportion of those included in the study (2\%) and unlikely to bias the results.

The trial was conducted in a single center in which 36\% of participants graduated from college or had a graduate degree. We designed the decision aid to include plain language, avoided use of medical jargon, used a large font size and clear style, and presented risk information as natural frequencies and in graphic format. Evidence suggests that presenting information in this way decreases cognitive load and facilitates knowledge transfer in patients with limited health literacy.\textsuperscript{24,25} In addition, single-center studies may overestimate the magnitude of effect of the intervention, suggesting that the findings should be confirmed in a larger multicenter trial.\textsuperscript{26}

We randomized at the patient level, increasing the risk of contamination (use of the intervention by individuals in the control arm). To decrease the likelihood of contamination, we ensured that access to the quantitative pretest probability calculator and decision aid was password protected. We also assessed for evidence of contamination when reviewing videos of the clinical encounter and did not observe clinicians using alternative risk scores in the control group. Moreover, even if contamination were to occur, it would likely bias the effect estimate in the direction of the null hypothesis, decreasing the likelihood of observing differences in important outcomes between the intervention and the control groups.

Strengths of this study include a rigorous randomized trial design that addressed the efficacy of one, if not the first, decision aid for patients who present to the ED with chest pain and the first decision aid designed to facilitate patient involvement in the choice of whether to undergo urgent cardiac stress testing or to follow up with a physician on an outpatient basis. Our decision aid is innovative in that it departs from the paternalistic model of basing the decision to obtain further testing primarily on the physician’s assessment of the risk for an adverse outcome.

**Unanswered Questions and Future Research**

Given that there were no major adverse cardiac events within 30 days of discharge, additional studies are needed to assess the utility of cardiac stress testing in patients presenting to the ED with chest pain but who are at low risk for ACS. Further multicenter studies are also needed to evaluate the efficacy and safety of the decision aid in diverse healthcare settings.

The results suggest that the rate of cardiac stress testing of low-risk patients presenting to the ED with chest pain to rule out acute myocardial infarction may have been more appropriately tailored to the risk for cardiac events by patient involvement in decision making. Further work will also need to assess what, if any, synergies emerge when policies sensitive to professional preferences, including managing the risk of liability and considering throughput of generously reimbursed clinical services, are aligned with these patient preferences.

**Conclusions**

Use of a decision aid in patients presenting to the ED with chest pain increased patient knowledge, increased engagement in the decision-making process, and decreased the frequency of observation unit admission for cardiac stress testing. Patient-centered approaches to decision making may improve healthcare delivery for patients with potential acute cardiovascular conditions.

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**Disclosures**

The investigative team has not had and does not have any for-profit-seeking intentions for the Chest Pain Choice decision aid. Our decision aids are freely available at http://shareddecisions.mayoclinic.org.

**References**

The Chest Pain Choice Decision Aid: A Randomized Trial

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Appendix 1. Seven Knowledge Questions included in the Post-Visit Patient Survey*

1. If the result of the cardiac stress test we discussed is negative, there is an increased certainty that my chest pain is not due to my heart.
2. If the result of the cardiac stress test we discussed is positive, this may be false positive and lead to additional testing that is unnecessary.
3. None of the cardiac stress tests we discussed expose me to radiation.
4. I understand that I can follow-up with a heart specialist (cardiologist) within 24-48 hours for additional evaluation.
5. I understand that I can follow-up with my own doctor at the next available visit for additional evaluation if that is my preference.
6. Radiation exposure may increase my lifetime risk for cancer.
7. Of 100 people like you, how many do you think will develop a heart attack or pre-heart attack diagnosis within the next 45 days?

*Questions 1-6 included the answer options “True/yes,” “False/no,” and “Don’t know.” Question 7 was an open-ended question with no suggested answers.