The Chest Pain Choice Decision Aid
A Randomized Trial

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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.

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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 of 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. 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\textsuperscript{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\textsuperscript{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\textsuperscript{4} 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 \textgreater\textsuperscript{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, \textless\textsuperscript{0.01 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 \textgeq\textsuperscript{1.0} 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),\textsuperscript{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,\textsuperscript{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\textsuperscript{4} as acute myocardial infarction, coronary stenosis \textgreater\textsuperscript{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 serial 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 (\textless\textsuperscript{3} 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.\textsuperscript{10} 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.
Your Chest Pain Diagnosis

Our initial evaluation has NOT shown any evidence of a heart attack. This conclusion is based on a blood test (to look for troponins — enzymes that are released when the heart muscle is damaged) and an electrocardiogram (to check that your heart is getting enough oxygen and blood). Over the next few hours, two additional blood tests (troponins) will be taken to definitively rule out a heart attack.

Even if these tests do confirm our diagnosis, your chest pain may indicate possible warning signs of a future heart attack.

Further Tests

A STRESS TEST EVALUATION may more precisely determine if your heart is functioning correctly by viewing blood flow to your heart while at rest and under stress. Examining your risk will help you to determine whether you would like to have a stress test now or would like assistance in making a clinic appointment.6

Your Personal Risk Evaluation

Your risk of having a heart attack or of having a prior heart attack diagnosis in the next 45 days can be determined by comparing you to people with similar factors who also came to the Emergency Department with chest pain.

Would You Like to Have a Stress Test Now or Make an Appointment?

☐ I would like to be admitted to the observation unit for an ECG (electrocardiogram) stress test. I realize that this could add to the cost of my evaluation and lengthen my emergency stay.

☐ I would like to be seen by a Mayo Clinic heart doctor within 24-72 hours and would like assistance in scheduling this appointment.

☐ I would like to schedule an appointment on my own to consult with my primary care physician.

☐ I would like my Mayo Clinic emergency department doctor to make this decision for me.

Stress test options include nuclear stress testing, ultrasound stress testing, and exercise ECG (electrocardiogram) stress testing. Nuclear stress testing includes exposure to radioactive substances which have been used in the past. The test can help determine the extent of your heart’s ability to pump blood. Your doctor can help you explore which option may be best for you.

1 Stress test options include nuclear stress testing, ultrasound stress testing, and exercise ECG (electrocardiogram) stress testing. Nuclear stress testing includes exposure to radioactive substances which have been used in the past. The test can help determine the extent of your heart’s ability to pump blood. Your doctor can help you explore which option may be best for you.

Figure 1. The Chest Pain Choice decision aid. Decision aid used to facilitate a discussion between clinicians and patients regarding whether to be admitted to the emergency department observation unit for cardiac stress testing or to follow up with a clinician within 24 to 72 hours. Reproduced with permission from Pierce et al.6

Allocation

Patients were randomized to either usual care or shared decision making through a Web-based, computer-generated allocation sequence in a 1:1 concealed fashion. We used dynamic allocation, a method of sequential treatment assignment that minimizes imbalances in selected prognostic factors between groups, to generate treatment assignments.3 Patients were stratified by age and sex; these 2 prognostic factors were chosen because of the known association of age and sex with cardiovascular risk and the reliability and availability of these data at the time of enrollment. Patients were enrolled between the hours of 7 AM and 11 PM, 5 to 6 days per week when study coordinators were available to recruit patients.

Outcome Measures

The primary outcome of the trial was patient knowledge (see the online-only Data Supplement for the 7 knowledge questions included on the postvisit patient survey). Additional outcomes included (1) the degree of decisional conflict patients experienced related to feeling uninformed, (2) the degree of trust in the physician, (3) patient engagement in the decision-making process, (4) patient and clinician satisfaction with and acceptability of the decision aid, (5) the proportion of patients who decided to undergo observation unit admission and cardiac stress testing, and (6) a major adverse cardiac event. A major adverse cardiac event was defined as acute myocardial infarction,12 ventricular arrhythmia, cardiogenic shock, brady‐cardia requiring therapeutic intervention, or death attributed to a cardiac or unknown cause occurring after discharge (excluding any index events) but within 30 days of the ED visit. Although the quantitative pretest probability tool developed by Kline and colleagues4 predicts the 45-day risk of ACS, we chose a 30-day time interval for follow-up to comply with existing consensus recommendations for reporting of studies involving risk stratification of ED patients with potential ACS.5 Thus, the 45-day risk of ACS was communicated to patients in the context of the trial, and outcomes were assessed at 30 days. Two investigators who were blinded to allocation assessed outcomes in all enrolled patients. A third investigator (H.H.T.), who was also blinded to allocation, reviewed all potentially positive outcomes. Disagreements were resolved by consensus.

Data Collection

Outcome data were collected by means of self-administered written surveys completed by patients and clinicians immediately after the ED encounter. The patient surveys6 included socioeconomic questions, questions regarding the patient’s comfort level in understanding different types of numeric information, and 7 items to assess patient knowledge (online-only Data Supplement). Five of these questions were addressed in the decision aid, and 2 control questions were not. We used the Decisional Conflict Scale13 to evaluate participant confidence in their knowledge of the information received and the resulting decisional efficacy and satisfaction (ranked 0 for strongly agree to 5 for strongly disagree). We used 10 questions from the Trust in Physician Scale14,15 to compare the degree of physician trust between groups (ranked 1 for completely trust to 5 for not at all trust). Data from each scale were analyzed as continuous variables.

A study nurse surveyed clinicians after each ED encounter regarding the decision to undergo ED observation unit admission and cardiac stress testing and their perception of patient involvement in the decision. The clinicians also reported their satisfaction with the decision aid by responding whether they would recommend other providers use the decision aid and whether they would want to present information about other choices in the same way.

We also video recorded the clinical encounter in both study arms to determine the degree of patient participation in the decision‐making process. We used the OPTION (observing patient involvement) scale16 to measure the extent to which clinicians involved patients in decision making on the video recordings. The instrument reflects the quality of the patient‐clinician discussion and addresses
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 reliability\(^1\) 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 Project\(^1\) for those who lived in Olmsted County and the Social Security Death Index\(^1\) 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 \(\alpha=0.05\). 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 approximately 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.\(^6\)\(^,\)\(^2\)\(^0\) 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...
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

<p>| Table 2. Effect of Decision Aid on Patient Knowledge, Decisional Conflict, Trust, Degree of Patient Participation, and Acceptability of Decision Aid |
|--------------------------------------------------|-----------------|--------------------|-----------------|</p>
<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>Decisionsal conflict and trust</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decisionsal 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>
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<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>
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<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>
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</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>
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<td>0.0051</td>
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<tr>
<td>Just right (3–5)</td>
<td>93 (93)</td>
<td>82 (80)</td>
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<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>
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<tr>
<td>Not clear at all (1–2)</td>
<td>3 (3)</td>
<td>19 (19)</td>
<td></td>
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<tr>
<td>Helpfulness of the information</td>
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<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>
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<tr>
<td>Somewhat helpful (3–5)</td>
<td>45 (45)</td>
<td>50 (50)</td>
<td></td>
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<tr>
<td>Not helpful at all (1–2)</td>
<td>2 (2)</td>
<td>16 (16)</td>
<td></td>
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<tr>
<td>Would recommend to others</td>
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<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>
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</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>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>16 (21)</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      |
| Follow-up with a cardiologist           | 26 (26)      | 2 (2)      | 0.9721  |
| Follow-up with a primary-care physician | 13 (13)      | 7 (7)      | 0.1195  |
| 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)      | 0.2439  |
| Rehospitalization                       | 2 (2)        | 0 (0)      |         |

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.

There were no major adverse cardiac events after discharge in either group.

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.
timely access to outpatient follow-up, however, may be essential for cost-effective delivery of emergency care.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.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.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.