Grant Final Report

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Can Risk Score Alerts Improve Office Care for Chest Pain?

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Abstract

Purpose: The overall goal of this study was to characterize the management of chest pain in primary care offices and implement a program to improve the safety and efficiency of such evaluations using decision support tools within an advanced electronic health record.

Scope: We studied primary care patients with chest pain within a multispecialty integrated group practice consisting of 15 health centers with 300 primary care clinicians caring for approximately 300,000 patients.

Methods: Primary care clinicians were randomly assigned to receive a set of electronic alerts that recommended risk-appropriate care based on the Framingham Risk Score (FRS). The primary outcomes measures included performance of an electrocardiogram and administration of aspirin therapy for high risk patients (FRS $\geq$ 10%); and avoidance of cardiac stress testing for low risk patients (FRS < 10%).

Results: Few patients (6%) were evaluated in the emergency department, though these patients resulted in significant health care costs. Over one-third of diagnoses of acute myocardial infarction were missed and not directly referred to the emergency department. While the alerts were generally well received by clinicians, the intervention did not alter care patterns among either high risk or low risk patients.

Key Words: chest pain, acute myocardial infarction, electronic health record, quality improvement

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Final Report

Purpose

With a randomized, controlled study design we implemented and evaluated an intervention to improve the treatment of primary care patients with acute chest pain in a large, integrated health care delivery system. The study had the following specific aims:

Specific Aim 1: To identify predictors of risk-appropriate evaluation and treatment of patients presenting to primary care offices with acute chest pain; including race, sex, and other clinical factors.

Specific Aim 2: To determine whether rates of appropriate evaluation and treatment of patients with acute chest pain can be improved through the use of point-of-care electronic risk alerts that provide individual patient cardiac risk profiles and tailored evaluation and treatment recommendations to primary care clinicians.

Specific Aim 3: To perform a cost analysis for evaluation of patients with acute chest pain.

Scope

The detection of acute myocardial ischemia among ambulatory patients with acute chest pain is a challenging and serious problem. Primary care clinicians play a substantial role in the management of acute myocardial infarction, with one-quarter of all hospital admissions for acute myocardial infarction preceded by a primary care evaluation. The challenge for the busy primary care clinician is to quickly and reliably identify potentially high risk symptomatic outpatients that require further evaluation and treatment, while limiting unnecessary cardiac stress tests and transfers for hospital-based evaluations. Much of the work on effective evaluation of chest pain has occurred in the emergency department setting, where protocols including chest pain observation units, serial electrocardiograms or cardiac enzymes, and immediate exercise stress testing have been developed.

Unfortunately, most of these strategies are not available in the primary care setting, or would be difficult to implement with the current level of outpatient resources available. It is therefore not surprising that primary care clinicians potentially misdiagnose over 10% of all myocardial infarctions, and such misdiagnosis is a leading cause of malpractice litigation in the primary care setting. New tools are needed in the office setting to risk stratify symptomatic patients. Our group has identified the Framingham Risk Score as a reliable means of risk stratifying this challenging patient population.

Our study was conducted at Harvard Vanguard Medical Associates (HVMA), a multi-specialty group practice in eastern Massachusetts which has 300 primary care clinicians that care for approximately 300,000 patients across 15 ambulatory health centers. All adults 30 years and

older with no prior history of coronary heart disease presenting to one of 14 HVMA health centers with a complaint of non-traumatic chest pain and their evaluating primary care clinician were eligible for inclusion in this study. Since 1997, clinical practices within HVMA have used a common electronic health record (Epic Systems, www.epicsystems.com) that includes clinical notes, diagnostic codes, procedure codes, and laboratory results. The electronic record allows computerized ordering of tests; as well as supports entry of coded chief complaints which are routinely entered by medical assistants when patients enter the exam room. Patients were identified as having a complaint of chest pain by medical assistants after receiving extensive training on appropriate identification of eligible patients. We chose to limit eligibility to patients with no prior history of coronary heart disease to focus on the population of patients that is most challenging diagnostically. Our study occurred over a 15 month period from November 2008 to January 2010.

Methods

Identification of Study Subjects

During the first six months of the project period, we worked closely with the HVMA clinical operations team to train nearly 300 medical assistants at all HVMA outpatient centers to screen all patients for a complaint of non-traumatic chest pain at the time of patient check-in. The medical assistants were trained to enter a coded "chief complaint" into Epic for all patients who screen positive, which allowed for prospective identification of patients with chest pain as well as provide the triggering data field for our electronic risk alerts. This chief complaint coded field already existed within Epic and is used by HVMA for a variety of initiatives to track patient care and conduct quality improvement programs, such as for smoking cessation. Entry of this code can be linked to specific office encounters with individual providers, allowing measurement of performance of office procedures, laboratory tests, and electronic referrals.

Dr. Sequist and members of the HVMA-based project management team worked directly with the clinical operations leadership at HVMA to coordinate on-site training sessions with the medical assistants. The uniform entry of reason for visit codes was vital to the success of this project. The project team therefore engaged in continuous quality improvement on this process throughout the pre-intervention period and during the randomized intervention. This was performed by conducting random electronic chart reviews of all patients presenting to internal medicine and urgent care clinics to verify entry of "chest pain" as a reason for visit when appropriate. This methodology allowed for timely feedback to the local practice manager and medical assistants to improve our data collection mechanism. Our project timeline included a 6 month period to train the medical assistants and conduct the above mentioned quality improvement process. We found that this process took closer to 12 months to ensure accurate capture of patients presenting with a complaint of chest pain. During visits for which chest pain was the primary complaint, nearly three-quarters (70%) of encounters coded by the clinicians were captured by the medical assistants. We also reviewed charts for which medical assistants coded chest pain, and clinicians had not entered a similar ICD-9 diagnostic code. We found that the majority of these charts referenced the presence of chest pain (45%), cough with pain (30%), heartburn (8%), or palpitations (4%) in the text of the clinician note. Eligible primary care

clinicians included any primary care physician, nurse practitioner, or physician assistant evaluating a patient complaining of chest pain during the study period.

Data Sources

We collected data via a combination of clinician survey and electronic medical record extracts. We conducted two separate clinician surveys, at baseline prior to the randomized intervention, and at follow up following the completion of the randomized intervention. The baseline clinician survey was designed to assess physician risk attitudes. We designed this survey based on the Jackson Personality Index (JPI) and the Stress from Uncertainty (SUS) scale, which have been used by members of our study team to evaluate chest pain care patterns. The JPI uses 6 individual items to produce a score ranging from 6 (low risk tolerance) to 30 (high risk tolerance). The SUS relies on 13 individual items to produce a score ranging from 13 (low stress from uncertainty) to 78 (high stress from uncertainty). These surveys were implemented among 292 primary care clinicians at baseline using a 3 step process involving an initial paper mailing to clinicians, followed by an email reminder, and a final paper mailing to non-responders. We achieved a survey response rate of 79% for the JPI survey and 73% for the SUS survey. We categorized physicians in three groups based on the lowest quartile ("risk avoiders"), the 2nd and 3rd quartiles ("risk neutral"), and the upper quartile ("risk seekers") and included this as an independent variable in our final predictive models.

We also surveyed clinicians following completion of the randomized intervention. The survey was designed to assess clinician perceptions regarding management of chest pain, usage patterns of the electronic health record, and attitudes towards the electronic alerts. Clinicians were asked to report their comfort level on a 4-point ordinal scale ranging from 'very comfortable' to 'very uncomfortable' when evaluating patients with chest pain. Clinicians also reported how often they felt the Framingham Risk Score represented a valid tool when evaluating patients complaining of chest pain on a 5-point ordinal scale ranging from 'always' to 'never'. Clinicians in the intervention group rated the effectiveness of the electronic alerts at improving care for 'high risk' and 'low risk' patients on a 3-point scale of 'very effective', 'somewhat effective', and 'not effective'. Finally, intervention clinicians rated whether they felt the threshold of 10% for the Framingham Risk Score to identify high versus low risk patients was 'too high', 'too low', or 'about right'. The survey instrument underwent cognitive testing on a convenience sample of 5 primary-care physicians to ensure consistency in interpretation of questions. The survey was implemented via an initial paper mailing, followed by a reminder email to non-responders, and a final paper mailing at 4 weeks, achieving a 76% response rate.

We collected all other clinical data from the electronic medical record. This included our primary outcomes of electrocardiogram performance and aspirin administration for high risk patients, and avoidance of exercise stress testing for low risk patients. In addition, we collected details regarding clinical treatment plans, diagnostic considerations, and patient disposition. We reviewed emergency department and hospital discharge summaries for all patients referred to the hospital setting for care. All data were collected using manual chart review.

Finally, we collected all cost data in the outpatient setting from the financial system at HVMA. We focused on costs associated with visits to internal medicine and cardiology, including evaluation and management time, as well as costs of procedures and exams. These latter costs were focused on performance of electrocardiograms and exercise stress tests. To measure inpatient costs, we collected costs from all patients cared for at Brigham and Women's

Hospital, which represented the largest proportion of hospital evaluations for this patient population. These costs were obtained as a sum of all costs related to either the emergency department evaluation or the hospital admission.

Electronic Decision Support Intervention

Primary care clinicians including primary care physicians, nurse practitioners, and physician assistants were randomized to receive point-of-care alerts within the electronic health record during office visits for patients with chest pain. We enrolled all 196 physicians, 65 nurse practitioners, and 52 physician assistants practicing across 15 health centers within HVMA during the study period. We consecutively enrolled patients at least 30 years old on the first occasion of presenting with non-traumatic chest pain to these clinicians during the study period. We excluded any patients with a prior history of cardiovascular disease, emergency department evaluation for chest pain within the prior 30 days, or those patients presenting for a non-urgent annual physical examination.

We developed a set of electronic alerts based on automated calculation of the patient's Framingham Risk Score at the time of the office visit. The required variables were extracted from the electronic record, including patient age, sex, total and HDL cholesterol, smoking status, systolic blood pressure, presence of antihypertensive therapy, and presence of diabetes.

We stratified patients according to their Framingham Risk Score, with 'high risk' patients defined as those with a score >10% and 'low risk' patients defined as those with a score < 10%. We developed two electronic alerts that triggered based on the presence of a coded chief complaint of chest pain entered by the medical assistants The alerts were present in both a passive and active form within each patient's electronic chart. The active alert displayed when clinicians accessed the electronic ordering module of the patient chart, and required acknowledgement from physicians to proceed. Physicians could view the passive alert at any point during an encounter within the electronic visit summary screen. Immediately prior to the intervention, we educated clinicians in both the intervention and control groups regarding the use of these reminders via a one-hour presentation at each center. During office visits for 'high risk' patients complaining of chest pain, clinicians received an alert recommending the performance of an electrocardiogram and the administration of aspirin therapy. The alert facilitated "one-click" electronic ordering of both the electrocardiogram and the aspirin. During office visits for 'low risk' patients complaining of chest pain, clinicians attempting to order cardiac stress tests received an alert recommending against performance of this test based on its low diagnostic yield.

Randomized Intervention

The intervention was randomized at the individual clinician level. Within each health center, we paired clinicians based on training background (physician versus non-physician) and number of patients with chest pain evaluated in the prior 6 months, and then randomly assigned one clinician in each pair to receive electronic reminders. The trial ran for 15 months to ensure enrollment of sufficient sample sizes.

Limitations

While our study benefits from the rigorous design and evaluation, the findings should be interpreted in the context of some limitations. First, we conducted this evaluation in a somewhat unique integrated care setting using an advanced electronic health record, and so our findings may not generalize to other settings. This should have less impact regarding the clinical patterns and outcomes observed in our trial, and serves to heighten the cautionary negative findings related to the decision support system. Second, we relied on medical assistants to identify patients with chest pain, rather than clinician identification. This decision was based on the need to identify patients prior to the evaluation by the clinician in order deliver real-time risk information. We conducted extensive training of all medical assistants including performance feedback, and validated their identification of patients using medical record review.

Results

Aim 1: To identify predictors of risk-appropriate evaluation and treatment of patients presenting to primary care offices with acute chest pain

We enrolled 7,083 adult patients with chest pain. The majority (81%) of patients were classified as low risk based on a Framingham Risk Score < 10%. The clinical evaluation was generally more aggressive among high risk patients compared to low risk patients, including rates of performing electrocardiograms (50% versus 43%, $p < 0.001$) and cardiac stress tests (17% versus 10%, $p < 0.001$). Non-emergent diagnoses were considered most frequently by primary care clinicians, including respiratory infections, musculoskeletal pain, and gastroesophageal reflux disease; and these diagnoses were considered more often among low risk compared to high risk patients. Potential coronary ischemia was considered more commonly among high risk patients compared to low risk patients (25% versus 14%, $p < 0.001$).

Only 6% of patients were evaluated in the emergency department following the primary care visit, and 4% were ultimately hospitalized, with high risk patients more likely than low risk patients to be evaluated in the emergency department (11% versus 5%, $p < 0.01$) and to be hospitalized (7% versus 3%, $p < 0.01$). Among patients evaluated in the emergency department, 55% were hospitalized, 39% underwent cardiac stress testing and 10% underwent cardiac catheterization.

A diagnosis of coronary artery disease was established among 42 (0.6%) patients, more commonly among high risk compared to low risk patients (1.1% versus 0.5%, $p < 0.01$). Acute myocardial infarction occurred among 28 (0.4%) patients, also more commonly among high risk compared to low risk patients (1.1% versus 0.2%, $p < 0.01$). Among 28 confirmed diagnoses of acute myocardial infarction, 10 (36%) represented missed diagnoses in the primary care setting, with the patient not being directly referred to the emergency department for management. There were no deaths observed in the 7,083 enrolled patients.

Regarding the physician baseline surveys, the mean JPI composite score was 8.9 (standard deviation 4.5) and the mean SUS composite score was 32.6 (standard deviation 10.4). Clinician background (physician, nurse practitioner, physician assistant) was not associated with either the SUS or JPI composite score. While there was significant variation in risk tolerance and stress

from uncertainty among clinicians, in multivariable models, the JPI and SUS composite scores were not significantly associated with performance of extended clinical evaluation (performance of electrocardiogram, cardiac stress testing, or emergency department triage) for chest pain.

We analyzed baseline predictors of treatment patterns for patients presenting with chest pain. Among high risk patients, women were much less likely than men to receive aspirin therapy (OR 0.67, $p = 0.02$) and an electrocardiogram (OR 0.74, $p = 0.02$). Older age was associated with higher rates of aspirin therapy (OR 1.2 (per decade), $p = 0.02$). Patient race, insurance status, and comorbid conditions (diabetes, hypertension) were not consistently associated with care patterns. Among low risk patients, older age was associated with higher rates of aspirin therapy (OR 1.9, $p < 0.01$), cardiac stress testing (OR 1.6, $p < 0.01$), and performance of electrocardiogram (OR 1.2, $p < 0.01$). Female patients were less likely than male patients to receive aspirin therapy (OR 0.44, $p < 0.01$), cardiac stress testing (OR 0.53, $p < 0.01$), and electrocardiograms (OR 0.72, $p < 0.01$). There was no consistent association between patient race or insurance status and care patterns. The presence of diabetes was not associated with care patterns, however the presence of hypertension was associated with higher rates of aspirin therapy (OR 1.6, $p < 0.01$), cardiac stress testing (OR 1.3, $p < 0.01$), and electrocardiogram performance (OR 1.2, $p = 0.01$). Among both high and low risk patients, clinician risk tolerance (JPI score) was not associated with clinical care patterns.

Aim 2: To determine whether rates of appropriate evaluation and treatment of patients with acute chest pain can be improved through the use of point-of-care electronic risk alerts that provide individual patient cardiac risk profiles and tailored evaluation and treatment recommendations to primary care clinicians

We randomized 292 primary care clinicians caring for 7,083 adult patients with chest pain. The mean number of eligible patients among both intervention and control clinicians was 24 (range 1 to 89). Among high risk patients, there was no difference between the intervention and control groups in rates of performing electrocardiograms (51% versus 48%, $p = 0.33$) or administering aspirin (20% versus 18%, $p = 0.43$). Among low risk patients, there was no difference between intervention and control groups in rates of cardiac stress testing (10% versus 9%, $p = 0.4$).

Among 212 responding clinicians who evaluated patients with chest pain during the study, nearly three-quarters (72%) of clinicians reported most commonly using the electronic order entry feature which would display our electronic alerts while the patient was still in the office with them, with 28% using this feature after the patient leaves the office. Most clinicians reported being “very” (57%) or “somewhat” (36%) comfortable treating patients complaining of chest pain. The majority of clinicians felt that the Framingham Risk Score represented a valid tool either “often” (40%) or “sometimes” (47%) when evaluating patients complaining of chest pain; with 5% feeling it was “always” valid, and only 8% feeling it was “rarely” or “never” valid.

Among clinicians in the intervention group, a majority felt that the electronic alerts for high risk patients were “very” (9%) or “somewhat” (49%) effective at improving their management of chest pain. Similarly, 52% of clinicians felt that the alerts for low risk patients were very or somewhat effective at improving their management of chest pain. A large majority of clinicians (81%) felt that the cut-off of 10% for the Framingham Risk Score to identify high risk patients was “about right”, with 7% feeling it was too low and 12% feeling it was too high.

We conducted a post-hoc analysis among the subgroup of intervention clinicians that reported the alerts to be very or somewhat effective at improving management of chest pain, and still found no effect of the intervention for both high and low risk patients.

Aim 3: To perform a cost analysis for the evaluation of patients with acute chest pain

From data on patient dispositions and test patterns, and using clinical test cost data from HVMA and hospital cost data from Brigham and Women's Hospital (BWH), average patient costs were estimated for patients sent home, patients that received tests at HVMA and then were sent home, and for patients that received tests at HVMA and were sent to the ED. Costs per patient were based on unit test costs and the probability tests were performed. Costs for patients that went to hospitals other than BWH (n = 367) were extrapolated from the BWH cohort (n = 114).

The largest driver of costs was the decision to triage to the emergency department for further evaluation. Patients evaluated in the outpatient setting incurred average costs of $363 per episode. Patients evaluated in the emergency department incurred a wide range of costs based on whether they were discharged home or admitted to the hospital for further evaluation. Of note, patients discharged home immediately from the emergency department incurred average costs of $1,087, a three-fold increase from patients discharged home from the primary care visit. Patients admitted to the hospital incurred average costs ranging from a low of $3,192 for those admitted to the chest pain observation unit to a high of $47,575 for those admitted to the intensive care unit. (Figure in Appendix A has additional detail.)

Discussion/ Conclusions/ Significance

In a large cohort of primary care patients presenting with chest pain, we demonstrated substantial gaps in quality and safety, with high risk patients not receiving recommended care and low risk patients undergoing many low-yield tests. Our electronic alerts provided evidence-based recommendations based on real-time calculation of the Framingham Risk Score. While these alerts followed established recommendations regarding the use of electronic health records and decision support, they did not significantly impact clinical practice patterns.

The design and delivery of electronic decision support systems play a large role in their effectiveness. The Framingham Risk Score represents a promising decision support tool as coronary risk factors are important predictors of poor cardiovascular outcomes among patients with chest pain. An important limitation to using the Framingham Risk Score is the complexity of gathering the required information and calculating the score. The electronic health record can automate this calculation and provide real time, risk-based recommendations directly integrated into the workflow without requiring additional information input on the part of clinicians.

Our surveys indicate that the electronic alerts were well received by clinicians. Rather than a failure of integration into the clinical workflow or problems with usability, it may be that the clinical benefits of electronic decision support as a stand-alone intervention do not extend to complex clinical scenarios such as the evaluation of acute chest pain. Clinicians bring significant clinical intuition and experience to these encounters, and our electronic alerts were not sufficient to overcome these aspects of the decision-making process. These alerts may be more effective when incorporated into a broader program focused on improving the management of chest pain involving all members of the health care team.

To our knowledge, this is the largest prospective analysis of the management of chest pain in primary care, as well as the largest evaluation of the impact of decision support in this setting. Errors in diagnosis represent the leading ambulatory patient safety concern, and our data showed that while the occurrence of acute myocardial infarction was infrequent, misdiagnosis was common. Over one-third of acute myocardial infarctions were misdiagnosed, compared to less than 5% in the emergency department setting. This is perhaps not surprising, given that only one-half of high risk patients had an electrocardiogram performed, which is widely recognized as essential to the successful evaluation of patients with chest pain. The challenges to improving patient safety in the outpatient setting are substantial, particularly as primary care physicians do not view errors in diagnosis as an important patient safety concern.

While many high risk patients did not receive aggressive care, it is important to recognize the majority of the patients in our study were low risk, and approximately 10% of these patients underwent cardiac stress testing despite the limited yield. Current guidelines recommend against the use of such testing for low risk patients based on the poor positive predictive value. The common use of this low yield test represents a key area for improving efficiency. Prior studies of decision support have focused on reducing unnecessary testing represented by avoiding redundant testing, though greater value may be achieved by avoiding tests that are not needed at the outset, such as exercise testing in low risk patients. Another important aspect of our study are the implications for achieving high value in health care delivery. Chest pain evaluations are associated with significant costs, both in the outpatient and inpatient setting. However, many patients receive inpatient evaluations of limited benefit, yet incur substantial health care costs.

Implications

Electronic health records are increasingly promoted as an important patient safety tool, as well as having great potential to increase the efficiency of health care and reduce unnecessary testing. As the nation considers a substantial investment to support the broad implementation of electronic health records, the failure of our intervention highlights the need for deeper insight into how to use them to change physician behavior. While there are data to support the use of decision support to improve quality and medication safety in some clinical areas, our data add to prior evidence suggesting that these benefits are not universally realized.

List of Publications and Products

The following manuscripts of the study findings are currently under peer review:

Sequist,TD. Morong,S, Marston,A, Keohane CA, et al. Electronic Risk Alerts to Improve Primary Care Management of Chest Pain: A Randomized, Controlled Trial.

Allen AS, Orav EJ, Lee TH, et al. Clinician Personality and the Evaluation of Higher Risk Patient Symptoms.