Secondary Prevention Risk Interventions Via Telemedicine and Tailored Patient Education (SPRITE)
A Randomized Trial to Improve Postmyocardial Infarction Management

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Background—Secondary prevention by risk factor modification improves patient outcomes, yet it is often not achieved in clinical practice. Reasons for failure stem from challenges of prioritizing risk factor reduction and engaging patients in changing their behaviors. We hypothesize that a novel telemedicine intervention with tailored patient education could improve cardiovascular risk factors.

Methods—To evaluate this intervention, we propose enrolling 450 patients with a recent myocardial infarction and hypertension into a 3-arm randomized, controlled trial. The first arm (n=150) will receive home blood pressure (BP) monitors plus a nurse-delivered, telephone-based tailored patient education intervention and will be enrolled into HealthVault, a Microsoft electronic health record platform. The second arm (n=150) will also receive BP monitors plus a tailored patient education intervention and be enrolled in HeartVault. However, the patient education intervention will be delivered by a Web-based program and will cover topics identical to those in the nurse-delivered intervention. Both arms will be compared with a control group receiving standard care (n=150). All participants will have an in-person assessment at baseline and at completion of the study, including standardized measurements of BP, LDL cholesterol, and glycosylated hemoglobin (in diabetic subjects). The study design will allow assessment of a telephone-based, nurse-administered disease management program versus standard care. The main outcome of interest is the reduction in systolic BP in each intervention group compared with the control group at 12 months. Secondary outcomes assessed will include reductions in LDL cholesterol, body weight, and glycosylated hemoglobin, as well as adherence to evidence-based therapies and improvement in health behaviors.

Conclusion—If successful in optimizing BP control, managing other coronary heart disease risk factors, and demonstrating a lower cost, the Web-based disease management tool has the potential to enhance coronary artery disease management, quality of care, and ultimately, patient outcomes.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT00901277.

Key Words: myocardial infarction • disease management • hypertension • Internet

Coronary heart disease (CHD) accounts for the greatest proportion of morbidity and mortality in the United States, with an estimated 770,000 Americans having a first myocardial infarction (MI) and an additional 430,000 having a recurrent MI in 2008. The American Heart Association/American College of Cardiology 2007 guidelines for post-MI secondary prevention emphasize 3 separate components of optimal risk reduction for further cardiac events: (1) control of the CHD risk factors (blood pressure [BP], LDL cholesterol [LDL-C], and blood sugar) within recommended parameters; (2) use of specific evidence-based medications proven to reduce further events; and (3) adoption of healthy behaviors, such as a heart-healthy diet and tobacco cessation. To date, much of the focus on improvement of evidence-based care has been on the in-hospital, acute-care phase, yet the greater challenge in improving CHD outcomes is in the transition from hospital to home and the achievement of target risk factor modification in the ambulatory setting.

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In the transition from hospital to ambulatory and home care, the challenges of CHD risk management differ significantly from those of the inpatient setting. The overwhelming
benefit of evidence-based medical therapy, as well as secondary risk modification for MI patients, however, has fallen well short of its full potential in actual practice, and failure to use proven treatments contributes to higher patient morbidity and mortality. For example, despite >4 decades of clinical trials demonstrating reductions in morbidity and mortality with adequate BP control, fewer than one third of US hypertensive patients have their BP at goal. These failures highlight the need for new methods of disease management that extend beyond traditional medical care to improve patient outcomes in ambulatory practice.

Home BP monitoring has been examined as a method to improve BP control by engaging patients in monitoring their own health parameters. Individual BP monitoring is thought to improve the recognition of BP control, which may lead to improved medication adherence and better BP control. A recent meta-analysis of 18 randomized, controlled trials that compared home BP monitoring to usual care found that home BP monitoring resulted in small improvements in BP control. Team-based care nurses or pharmacists have also been shown to positively impact BP control and medication adherence. Despite the use of telephone contact with healthcare extenders to influence patient behavior and improve BP control, these interventions have not gained widespread adoption. The lack of widespread implementation may be due to concerns about their scalability. Hiring, training, and retaining nonphysician staff require a large number of willing and eligible patients to achieve the economies of scale for the delivery of high-quality and comprehensive risk factor management.

Telemedicine or remote monitoring in patients’ homes has been offered as a plausible solution for improving ambulatory medical care. To date, most telemedicine efforts showing improved outcomes for CHD risk factors have used telephone-based interventions. More recently, a number of Internet- and Web-based tools have emerged to further enable communication between patients and providers and among providers. A recent study, for example, demonstrated that Web-based communication with pharmacist care management improved BP control in hypertensive patients. Web-based monitoring may be more acceptable and effective than clinic-based monitoring and management as well as more scalable and cost-effective than traditional disease management or telephone-based programs. The degree to which Web-based communication, coupled with a Web-based, tailored disease management and education program, improves risk factor control beyond traditional telemedicine disease management provided by health care personnel is unknown. The American Heart Association has developed a Web-based interactive communication tool, Heart360 (available at http://www.heart360.org), based on Microsoft’s HealthVault (available at http://www.healthvault.com) electronic health record platform. Heart360 is designed to facilitate better information exchange among patients and their providers as well as to promote patient engagement in their own disease management (Figure 1). Heart360 is a patient-controlled disease management and monitoring platform whereby individuals can input health-related information, such as BP, heart rate, blood glucose measurements, weight, laboratory values, and medications. However, this tool is not intended as a medical record, but Heart360 and HealthVault have been developed in accordance with regulatory requirements for data security and data privacy.

Leveraging Heart360 and HealthVault as a new telemedicine tool, we propose a novel study, Secondary Prevention Risk Interventions via Telemedicine and Tailored Patient Education (SPRITE), to simultaneously evaluate 2 CHD risk reduction interventions in a randomized, controlled trial. Both intervention groups will receive ambulatory BP monitors and will use HealthVault for Web-based data tracking of home BP measurements. Both groups will receive tailored education and self-management support promoting CHD risk reduction but will differ in the way they receive this intervention, with the first group receiving the intervention by telephone from a nurse and the second group receiving the content by an interactive, Web-based format. This study design will evaluate the effect of the 2 interventions compared with usual care on risk factor modification, process of care, and cost of disease management.

**Secondary Risk Prevention Barriers**

There are several unique challenges for both patients and providers in the transition from hospitalization to the outpatient care setting. The inpatient measures of MI quality of care rely very little on the patient’s engagement, as he/she is a passive participant in his/her care, undergoing daily BP measurement, laboratory analyses, and medications. However, after discharge, patients are required to make day-to-day decisions about such actions as what to eat, whether to take their medication, or whether to exercise, all of which can have substantial effects on their clinical outcomes. These day-to-day decisions and tasks are referred to as self-management. Self-management consists of the following components: promoting physical/psychological health; interacting with healthcare providers and adhering to treatment recommendations; monitoring health status and making associated care decisions; and managing the impact of the illness on physical, mental, social, and economic wellbeing.
Augmenting the health provider–patient dyad by telemedicine can help patients achieve risk factor modification goals. Additionally, we aim to improve patient motivation to change behavior, and provide tools that support this change. We propose a 3-arm randomized, controlled trial with 450 post-MI survivors to test the impact and benefit of using a tailored Web-based intervention to support engagement in secondary prevention. The 2 arms will allow assessment of the clinical impact and benefit of using a tailored Web-based intervention compared with having healthcare personnel implement a tailored intervention.

Study Site and Population

The study will identify patients treated at a large, nonprofit, tertiary-care healthcare system in a suburban setting through an electronic medical record search. Patients approached for inclusion in the study will be ≥18 years old, have been discharged within the last 3 years with both the diagnosis of acute MI (International Classification of Diseases, 9th revision codes 410.01 to 410.91) and hypertension (code 401.X or clinical diagnosis), have received a cardiac catheterization at the time of the acute MI, and have at least 1 follow-up visit with a primary care and/or cardiology provider within the past year. Before invitation to participate, a chart review of eligible patients will be conducted, and patients will be excluded if they have a diagnosis of metastatic cancer, an active diagnosis of psychosis or dementia, are currently receiving hemodialysis, or have had a transplant of any solid organ. At the time of the enrollment interview, patients will be further excluded if they do not have a telephone line or a computer with Internet access, refuse to provide informed consent, are a resident in a nursing home or are receiving home health care, have severely impaired hearing or speech (patients must be able to respond to phone calls), are participating in another behavioral or medication adherence study, report New York Heart Association class IV heart failure, or do not plan to have long-term follow-up with a primary care provider and/or cardiologist.

Interventions

Eligible participants will be randomized to 1 of 3 arms for 12 months (Figure 1): (1) standard care (control group); (2) a nurse-administered behavioral and education self-management intervention plus the use of HealthVault; or (3) a Web-based behavioral and education self-management intervention plus the use of HealthVault. Subjects randomized to the control arm will receive educational handouts about CHD at their baseline assessment but will continue with their regular medical care throughout the remainder of the study. All participants will have an in-person assessment performed by a research assistant at the time of enrollment and at the end of the study.

Heart360 and HealthVault are a Web-based portal developed by the American Heart Association that uses Microsoft’s HealthVault electronic health record platform to allow patients to upload health parameters for their own tracking and review as well as to allow access to designated providers (Figure 2). Both intervention arms in our study will leverage the use of HealthVault and Heart360 to give participants the ability to upload their BP and glucose measurements to allow self-management and tracking of these parameters, as well as communication of these measurements to the study team and their providers. The 2 intervention arms will be similar, the difference being whether subjects receive disease management from a nurse using a tailored telephone-based intervention that has been validated in previous studies12,36,37 or a novel, tailored, Web-based intervention without direct communication with a healthcare provider that has yet to be tested in a randomized, clinical investigation. The 2 arms will allow assessment of the clinical impact and benefit of using a tailored Web-based intervention compared with having healthcare personnel implement a tailored intervention.

Subjects randomized to either of the intervention arms will be provided their own home BP monitor (Omron HEM 790-IT). For participants in the intervention groups, the primary mode of BP transmission will be through HealthVault, and training demonstra-
tions and written instructions will be provided for proper use of the device for BP measurements. In addition, verbal and written directions will be provided for the “plug-and-play” uploads of the BP measurements. The purpose of self-monitoring and providing BP machines to participants is to increase their awareness of their BP readings and then ideally to increase activities that promote maintenance of BP control.

The study team will monitor all measurements uploaded into HealthVault by participants and will send reminders when patients do not regularly upload BP measurements as part of the study. Measurements uploaded into HealthVault that fall outside prespecified safety parameters for BP (systolic BP ≥180 mm Hg or diastolic BP ≥110 mm Hg), heart rate (<40 or >110 beat per minute), and glucose values (<70 or >350 mg/dL) will trigger a written notification of the value(s) sent by e-mail from the study team to the patient’s primary physician. However, the study team will not actively provide medical intervention to enrolled patients or provide specific treatment recommendations to the patients’ providers. In addition, if a patient’s mean BP during a 3-month period is >140/90 mm Hg, a written notification of the values will be sent to his or her primary provider but without any intervention or specific recommendations for treatment by the study team.

Baseline Assessment and Randomization

Baseline assessments will include BP, LDL-C, and glycosylated hemoglobin (for diabetic subjects) measurements for all subjects during the enrollment visit, with blood samples acquired for the latter 2 measurements. Subjects will also be surveyed about their current demographics and health behaviors. After the subject has completed the baseline assessment, each patient will be randomly assigned to 1 of the 3 intervention arms (control, nurse administered, or Web based). Participants will be randomized in blocks (size <10) within a single stratification factor, diabetic status. In addition, because there are 2 nurse interventionists for the nurse-administered arm, patients will be randomly allocated to the nurses to ensure an even distribution of patients between nurses. Subjects will be asked to complete a final health and behavioral survey at 12 months with repeat measurements of BP, LDL-C, and glycosylated hemoglobin (for diabetic subjects). Trained research personnel will perform all assessments.

Behavioral and Education Tools

A multifaceted, tailored approach to behavioral management will be used in the 2 intervention arms of SPRITE because no single factor has been shown to consistently improve CHD outcomes.38 Tailored feedback has been demonstrated to be effective in multiple health behaviors.39,40 Monthly assessments will be performed either by a nurse-telephone interaction (by trained research personnel) or by a Web-based interaction, depending on the intervention group. We have shown effectiveness with an early version of this education program,36 which addresses up to 13 health behaviors focused on improving patient management of CHD and related health behaviors. Maintaining or developing motivation to overcome resistance is the key for individuals attempting to initiate and maintain behavior changes. The current study will add to this understanding of
effectiveness by leveraging a Web-based platform delivered to 1 arm of our study.

In both intervention arms, patients will be provided evidence-based recommendations regarding lifestyle behaviors and will be advised on how to achieve their goals with respect to these behaviors. In the telephone-based intervention, verbal information will be reinforced with written and visual material provided to the patient in some instances. Financial barriers will be addressed by recommending a low-cost diet and inexpensive methods of exercising. All intervention components are designed to be culturally sensitive. The behavioral modules include diet, exercise, smoking, alcohol, stress reduction, memory, literacy, social environment, patient-provider relationship, missed appointments, medication management, side effects, and knowledge/risk perception (Figure 3). All of these measures have been used in prior clinical trials and are easy to implement, reliable, and sensitive to change.12,38 Each module will query the patient on his/her current beliefs and health practices. In addition, we will include valid and reliable measures of patients’ disease knowledge, their cardiovascular risk according to the Framingham CHD risk score,41 and health-related literacy with the use of REALM.42 Based on the patient’s responses to a series of questions, there will be a provision for tailored feedback to reinforce evidence-based behavior for disease and lifestyle management. Each encounter should take 10 to 20 minutes in either the telephone or Web-based intervention. All material provided will be at a sixth-grade reading level, tested on study staff and volunteers, and approved by the institutional review board before use in the study. We have considered the possibility of contamination and counterintervention. For example, anyone can register and use Heart360 and HealthVault; as a result, it is possible that our control group patients may gain access to this tool under their own volition. In addition, patients may enroll in other formal or organized disease management programs during the study. To assess the possibility and extent that patients may engage in using these tools outside the current study, at the 12-month follow-up assessment, we will determine how many patients in the control group during 12 months of follow-up may engage in using these tools outside the current study, at 12 months of follow-up. Secondary hypotheses that will be tested include the following: (1) post-MI patients who receive the nurse-administered intervention will have their LDL-C reduced by 20 mg/dl, more than control patients during 12 months of follow-up; (2) post-MI patients with diabetes who receive the nurse-administered intervention will have their glycosylated hemoglobin reduced by 0.5% more than control patients during 12 months of follow-up; (3) post-MI patients who receive the nurse-administered intervention will have higher use of evidence-based medical therapies (for example, antiplatelet agents, statins, and angiotensin-converting enzyme inhibitors) compared with control patients at 12 months of follow-up; (4) post-MI patients who receive the nurse-administered intervention will have improved health behaviors (for example, physical activity, improved diet, lower body mass index) compared with control patients during 12 months of follow-up; (5) post-MI patients who receive the nurse-administered intervention will have reduced Framingham risk scores compared with control patients at 12 months of follow-up; and (6) post-MI patients who receive the Web-based intervention will reduce SBP more than those patients randomized to the control group during 12 months of follow-up. The overall goals of the study include an assessment of the feasibility of Web-based communication and disease management in high-risk as well as low-socioeconomic status and minority patient subgroups. As part of our assessment, we will also examine the costs of both telemedicine interventions and determine whether 1 communication strategy is more cost advantageous than the other, however, a formal cost-effectiveness analysis has not been prespecified.

At the 12-month follow-up, all participants will be required to complete a survey about their experience with the study. Qualitative assessments to be collected include, but will not be limited to, use of Heart360 and HealthVault, uploading of BP in a Web-based interface, satisfaction with the disease management modules and intervention technology used, likelihood of Heart360 use after study completion, self-assessment of achieving risk factor modification, and perceptions of the value of the intervention tools. We will also query providers who provided care to patients enrolled in the study to gain feedback on the usefulness of safety notifications and 3-month BP assessments.

Sample Size Considerations
The sample size estimate of 150 subjects per intervention group is based on the size needed to assess the primary hypothesis that the nurse-administered intervention would lead to BP improvements of

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Figure 3. Schedule of frequency and timing of intervention modules.
5 mm Hg over the control group at 12 months with 80% power, a type I error rate (α) of 0.05, and an assumed attrition rate of 15%.43 We used data from the Take Control of Your Blood Pressure study37 and the Veteran–Study to Improve the Control of Hypertension16 to estimate the quantities needed for the sample size calculation.

Primary and Secondary Analyses

All primary and secondary analyses will be based on intention-to-treat principles. Patients will be analyzed in the arm to which they were randomized, regardless of treatment compliance. The primary outcome, systolic BP, is a continuous measure that will be measured in person by the study research assistants at baseline and at the 12-month follow-up. A linear mixed modeling approach will be used to estimate differences in outcome at 12-month follow-up.44 Variables in the model will include time (baseline vs 12 months), time × intervention arm interaction terms, and diabetic status (a stratification variable). Baseline will be retained as part of the response vector, and a common intercept for all intervention arms will be modeled to reflect baseline equality of groups. This approach is appropriate for a randomized trial and is equivalent in efficiency to longitudinal ANCOVA model.45 Parameters in the model will be estimated with the SAS procedure MIXED (SAS Institute, Cary, NC). As most of the secondary study outcomes are continuous and longitudinal, they will be analyzed by a similar linear mixed modeling approach, as described earlier.

Study Implementation

Although the investigators have experience from several studies for risk modification by using education and behavioral interventions,12,36,37 disease management programs can provide vexing challenges. For SPRITE, we will use our prior experience to continue to improve and refine our understanding of the role and impact of telemedicine on CHD risk factors with a special emphasis on vulnerable populations, such as underrepresented groups and low-socioeconomic status populations. We will use qualitative analyses to assess participants’ acceptance and feasibility of using the telemedicine equipment and intervention. Even though patients with a current MI would be more likely to be influenced by the “teachable moment” of their diagnosis, we have the opportunity to assess the ability of our intervention coupled with HealthVault to influence patients in the chronic phase of their diagnosis, wherein the inertia to change their behaviors may be greater. For patients using the technology, it will be important to quantify the continued use of HealthVault and its modules after completion of SPRITE.

Beyond the intervention tool, we are also using other innovative electronic tools for identifying eligible participants for SPRITE. We are leveraging our local electronic clinical data repository to identify patients for the study. This database provides access to clinical information collected as a by-product of patient care and is intended to facilitate exploration of aggregate clinical data in support of operations, quality, and research. The system compiles data from multiple source systems (laboratory, pharmacy, radiology, physician order entry, billing, etc) and allows the researcher to filter through the information to define a clinical cohort and streamline electronic chart review. The challenge of this retrospective identification of eligible participants during the course of the study will be identifying an adequate number of subjects with hypertension and also with a recent MI to achieve our enrollment goal, but given the volume of patients seen in our healthcare system, we are confident that we can meet our target sample size.

HealthVault and Heart360 continue to evolve and undergo upgrades for new features, components, and monitoring equipment. These upgrades will add technical challenges to ensure that updates do not interrupt participants’ ability to access content and upload their personal disease data. Furthermore, it will pose challenges to the study team to ensure that the back-end infrastructure is supported with the successful evolution of the technology platforms and that participants are educated on the new functionality added during the study. We have anticipated these issues and have developed plans to ensure a seamless transition for patients in our study and mechanisms to communicate updates as they are launched.

Other challenges exist for telemedicine approaches to disease management. The design of our study does not directly engage the individual providers for each of our enrolled participants. However, we do notify providers when patients’ mean BP values are not at goal during a 3-month period or are in ranges that raise safety concerns, but we rely on the provider to make an independent assessment and treatment decision. Patients can allow their providers to view the data that they upload to HealthVault, and we will notify providers when their patients consistently have BP, heart rate, or glucose readings that could cause acute morbidity. The success of any telemedicine program may require provider engagement to actively manage medication initiation or titration, monitoring of patient’s progress toward risk reduction goals, and supplementation of telemedicine education at provider visits. Furthermore, the durability of risk factor modification and persistence in using telemedicine programs is unknown, and we will not know its effects on long-term outcomes. Also, it is unknown whether the Web-based education program can be more broadly disseminated beyond our single center and whether computer literacy may limit widespread use of the tool. Finally, other self-management programs have found positive “halo-effects” of the intervention on unintended disease targets,46 and we should also be able to determine whether we achieve overall improvement in multiple areas of secondary prevention with our intervention or whether the effect will be limited to BP control.

Summary

Web-based disease management holds the promise to transform risk factor modification if patients are active participants and this care is coordinated. Web-based communication coordinated by pharmacist care has been shown to be effective in BP management19; however, the benefit of Web-based disease management and tailored education has not been investigated. SPRITE could leap forward Web communication for post-MI CHD risk management for several reasons. First, our intervention is 1 of the first to test the feasibility and acceptability of HealthVault and a Web-based, interactive self-management education program intervention, and we will assess the degree to which these intervention components can be implemented among all patients, including underrepresented minorities and those of low socioeconomic status. Our study also builds on previous interventions that have demonstrated improved hypertension outcomes with tailored disease management. Unique to our study is the “personally tailored” education that has been replaced with a Web-based tailored intervention. Finally, data collected will be instrumental in answering larger questions of effectiveness, tailoring, and maintenance and sustainability of behaviors for 12 months among individuals at significant morbidity and mortality risk.

The Web-based tailored education intervention, if found efficacious and financially self-sustaining, could be widely implemented and quickly scaled to provide active and tailored disease management to a broad population of patients, particularly in resource-constrained or personnel-deprived health systems. This system of care may be transformational by freeing patients and their providers from the need of regular office visits for straightforward, goal-directed risk factor modification and education. If our study shows BP control in the Web-based behavior and education intervention that is similar to the 1 provided by a nurse, this platform could be evaluated further for its scalability to a large number of patients, given the economies of scale and scope provided by Web-based technology. However, rapid adoption by health
systems and providers requires the appropriate reimbursement framework to cover Web-based patient management.

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