EVALUATION OF A TELEMEDICINE SERVICE FOR THE SECONDARY PREVENTION OF CORONARY ARTERY DISEASE

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Evaluation of a Telemedicine Service for the Secondary Prevention of Coronary Artery Disease

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ABSTRACT

PURPOSE: Efficient ways are needed to implement the secondary prevention (SP) of coronary heart disease. Because few studies have investigated Web-based SP programs, our aim was to determine the usefulness of a new Web-based telemonitoring system, connecting patients provided with self-measurement devices and care managers via mobile phone text messages, as a tool for SP.

METHODS: A single-blind, randomized controlled, clinical trial of 203 acute coronary syndrome (ACS) survivors, was conducted at a hospital in Madrid, Spain. All patients received lifestyle counseling and usual-care treatment. Patients in the telemonitoring group (TMG) sent, through mobile phones, weight, heart rate, and blood pressure (BP) weekly, and capillary plasma lipid profile and glucose monthly. A cardiologist accessed these data through a Web interface and sent recommendations via short message service. Main outcome measures were BP, body mass index (BMI), smoking status, low-density lipoprotein-cholesterol (LDL-c), and glycated hemoglobin A_{1c} (HbA_{1c}).

RESULTS: At 12-month follow-up, TMG patients were more likely (RR = 1.4; 95% CI = 1.1-1.7) to experience improvement in cardiovascular risk factors profile than control patients (69.6% vs 50.5%, *p = 0.*010). More TMG patients achieved treatment goals for BP (62.1% vs 42.9%, p = .012) and HbA1c (86.4% vs 54.2%, *p = 0.*018), with no differences in smoking cessation or LDL-c. Body mass index was significantly lower in TMG (-0.77 kg/m^2 vs +0.29 kg/m^2, p = 0.005).

CONCLUSIONS: A telemonitoring program, via mobile phone messages, appears to be useful for improving the risk profile in ACS survivors and can be an effective tool for secondary prevention, especially for overweight patients.

Key Words

acute coronary syndrome, cardiovascular risk factors, secondary prevention, telemedicine, telemonitoring

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INTRODUCTION

Cardiovascular disease (CVD) is a major target of health policies in Western countries due to its associated mortality, morbidity, and health care costs. It causes nearly half of all deaths in Europe (49%)[1] and to a great extent, results from a number of modifiable cardiovascular risk factors (CRF). Effective secondary prevention (SP) can thus, reduce the burden of CVD. Cardiac rehabilitation (CR) programs have been proven highly beneficial; however, only one-third of eligible patients attend CR programs in Europe.[2] Program accessibility is a major limitation, as most CR programs are frequently found in hospitals in large urban areas, and unfortunately, those who do not attend CR have poorer risk factor knowledge and higher baseline risk.[3] Therefore, innovative models for SP are essential to increase access and uptake to accommodate
the diverse nature of people and communities.

Although efficacious ways for SP delivery are needed, few studies have investigated Web-based alternative SP programs.[4,5] Such investigations have focused on a single CRF (ie, only lipid or exercise management), had small sample sizes, or were of limited duration.[6] To be successful, follow-up strategies need to embrace overall risk reduction, and at the same time, interventions must be accessible and relevant to clinical practice. Our aim was to analyze the efficacy of a new telemonitoring system for the follow-up of patients with coronary heart disease (CHD), connecting patients, provided with self-measurement devices, and care managers through mobile phone messages over the Web, and integrating the monitoring of several risk factors.

METHODS

The study was a single-blind, randomized controlled, clinical trial (RCT) involving 203 acute coronary syndrome patients, followed for 12 months. Approval by the local ethics committee was obtained and the study was conducted at a tertiary referral hospital in Madrid, Spain, between December 2007 and January 2010. Written informed consent was obtained from each participant. The technological platform has been described elsewhere[7] and previous examples of its application have been published.[8,9]

Participants

Patients admitted to the hospital for an acute coronary syndrome were eligible if they had at least 1 CRF, such as: (1) tobacco smoking, (2) low-density lipoprotein-cholesterol (LDL-c) ≥100 mg/dL, (3) hypertension, or
(4) diabetes mellitus. Ineligible patients were those physically or mentally unable to use the technical equipment needed for telemonitoring and did not have a support person, and those who had previously participated in a telemedicine project. Patients were randomly allocated to either the control group (CG) or the

telemedicine intervention group (TMG), stratified by the presence of diabetes by creating 2 different randomization lists, 1 for diabetic patients and 1 for nondiabetic patients. Each patient met with his or her cardiologist for 3 clinical visits during the study period, and was provided with written recommendations and verbal information about CVD prevention.

At initial and final visits, clinical data were collected by physicians blinded to the intervention, a fasting blood sample was drawn, and the patient completed 2 questionnaires: the Short Form 36 (SF-36)[10] and the State-Trait Anxiety Inventory for adults,[11] to assess quality of life (QoL) and anxiety, respectively.

Intervention

Patients randomized to the TMG were temporarily provided with an automatic sphygmomanometer (Omron M4-I; Omron Corporation, Kyoto, Japan), a glucose and lipid meter (Cardiochek, Polymer Technology System, Inc, Indianapolis, IN) and a cellular phone (Nokia 3510i, Nokia Corporation, Espoo, Finland). Patients, and support persons if needed, were taught to measure their blood pressure (BP), heart rate and weight (weekly), and glucose and lipids (monthly), and to send the results through their mobile phones following a structured questionnaire (Wireless Application Protocol session). A cardiologist accessed biological and clinical data via a secure Web application (see the Figure) and, through this application, sent individualized short message service text messages with recommendations to the patients during the 12-month follow-up period. At exit, subjects in the TMG completed an additional questionnaire to evaluate satisfaction with the program.

Outcomes

Outcome measures were resting BP, body mass index (BMI), smoking status, LDL-c, and glycated hemoglobin A_{1c} (HbA_{1c}), all measured at the initial and final visits for comparison. Smoking status was determined by self-report and confirmed by a 1-step cotinine immunoassay in urine (One-Step Cotinine Test Cassette; ULTI MED, Ahrensburg, Deutschland).

The primary outcome was "cardiovascular risk improvement," defined as the proportion of patients who achieve the goal of treatment in at least 1 CRF without exacerbation of any of the others. Treatment goals were as follows: (1) smoking cessation, (2) LDL-c less than 100 mg/dL, (3) BP lower than 140/90 mmHg, and (4) HbA_{1c} less than 7%. Exacerbation of a CRF was defined as a 10% or more increase in BP, LDL-c, or HbA1c, with respect to initial levels.

Secondary outcomes were: proportion of patients achieving the treatment goal in each 1 of the outcome measurements, quantitative changes in LDL-c, BP, BMI, and HbA1c (in diabetic patients), and changes in quality of life and level of anxiety.

Statistical Analysis

We estimated that a sample size of 196 patients, 98 in each group, was required to detect a cardiovascular risk profile improvement of 70% in the TMG in contrast to 50% in the CG, with a statistical power of 80% and a level of significance less than 0.05, assuming a 10% loss to follow-up. Baseline characteristics are presented as mean, median, and standard deviation. For interval-level data, differences between TMG and CG were compared using independent Student *t* tests and pre-post comparisons were analyzed using *t* tests for paired data. For the main outcome variables, the relative risk (RR) and 95% confidence interval (CI) were estimated. The significance of differences in percentages between groups was assessed using a χ^2 test. For all analyses, an alpha level of 0.05 and two-tailed testing were used. Data were analyzed on an intention to treat basis. All statistical analysis was performed using SPSS v14.0 (IBM Corporation, Armonk, NY).

RESULTS

A total of 243 patients were offered to participate in the trial and 40 (16.5%) of them refused. A total of
203 patients were randomized, 102 (30 diabetic patients) to the TMG and 101 (26 diabetic patients) to the CG. Baseline characteristics of patients are summarized in Table 1. There were no clinically relevant differences between the groups.

Four patients were lost to follow-up (1.9%) and 5 died (2.5%), all in the CG. Seventeen patients left the study (8.4%), 12 in the TMG (11.8%) and 5 in the CG (4.9%) (RR = 2.38; 95% CI = 0.87-6.50; p = 0.08).

Reasons for leaving the program in the TMG were stress associated with the use of the telemonitoring equipment in 3 patients, personal reasons in 7, and inability to handle the equipment in 2 patients; in the CG, all 5 attributed it to personal reasons.

Analysis on the basis of intention to treat showed that patients in the TMG were more likely (RR = 1.4; 95% CI = 1.1-1.7) to experience improvement in their CRF profile than patients in the CG (*P = 0.*010) at the end of 12 months. More TMG patients achieved the treatment goal in BP (62.1% vs 42.9%, *P = 0.*012; RR = 1.4, 95% CI = 1.1-1.9) and in HbA1c among diabetic patients (86.4% vs 54.2%, *P = 0.*018; RR = 1.6; 95% CI = 1.1-2.4); there were no between-group differences for smoking cessation (80.7% vs 81.0%, *P = 0.*964; RR = 1.0; 95% CI = 0.9-1.1) or LDL-c (76.2% vs 76.6%, *P = 0.*948; RR = 1.0; 95% CI = 0.9-1.2).

Quantitative changes in continuous variables with comparison of the difference between the groups are summarized in Table 2. Patients in the TMG showed significant changes in all variables with the exception of diastolic BP (DBP) (systolic BP [SBP], $p = 0.0460$; DBP, $p = 0.237$; LDL-c, $p = 0.027$; HbA1c, $p = 0.001$; BMI in overweight patients $p = 0.003$). In the CG, significant reductions were obtained in LDL-c and DBP (SBP, $p = 0.780$; DBP, $p = 0.001$; LDL-c, $p = 0.098$; HbA1c, $p = 0.239$; BMI, p= 0.299). Body mass index diminished in the TMG and increased slightly in the CG. Triglyceride levels also decreased significantly in the TMG ($p < 0.0001$), but not in the CG ($p = 0.435$). No differences between groups were found in physical activity (75% TMG vs 73% CG, $p = 0.756$) or medication adherence (99% in both groups, $p = 0.980$) both self-reported by patients. Nutritional habits were not explored. There were no significant differences between the scores obtained in SF-36 and State-Trait Anxiety Inventory tests at the initial visit in the 2 groups and changes were not significant between groups. At 12 months, the SF-36 "physical health" scale showed a 2.8 points increase in the TMG ($p = 0.011$) and a 1.5 point increase in the CG ($p = 0.16$). The change was smaller in the "mental health" scale, with a 0.5 points increase in the TMG ($p = 0.64$) and a 0.5 point decrease ($p = 0.73$) in the CG.

Adherence to protocol was measured by the percentage of WAP sessions held (89.2% ± 16.0). Almost all patients (98%) completed more than 50% of WAP sessions and more than 83% completed more than 75% of them. Only 0.5 messages per patient were missed, due to the mobile phone being turned off. Familial support of the TMG patients was analyzed in 4 different levels: never (58% of patients), only first week (10%), 1 month (7%), and always (25%).

DISCUSSION

Traditionally, health care systems have focused on the management of acute, hence episodic diseases, and have not developed effective clinical pathways for the care of chronic patients. Consequently, they are not provided with the structural and human resources needed to implement health care models focused on disease prevention and continuous care, as internationally recommended.[1,12]

One important application of telemonitoring is the observation of chronically ill patients between clinical visits or admissions, with the advantage of having multiple biological data for making treatment decisions. It can also improve quality of care by promoting self-management and compliance with prescribed medications.[13]

Another key point is that randomized clinical trials (RCTs) are needed to demonstrate the clinical efficacy of these innovative systems before they can be widely applied in routine patient care. This RCT demonstrates that an Internet/Web-based telemonitoring system, connecting patients and care managers via mobile phone, improved the cardiovascular risk profile compared with usual care for at least 1 year. The study was not designed to analyze clinical events, but a correlation between an adequate CRF control and a reduction of major ischemic events and hospital admissions has been demonstrated.[14]

Numerous studies have analyzed the effect of monitoring programs for the control of CRF based on telephone or the Internet.[13] However, only a few have investigated the benefit of multifactorial secondary CRF prevention,[4,15-22] with 2 focusing only on lipid control.[5,23] These telehealth interventions were associated with a nonsignificant reduction in all-cause mortality and better control of CRF (LDL-c, SBP, BMI, and smoking status) in a recent meta-analysis.[24] In most of these, the intervention was predominantly delivered by telephone,[15-23] and the Internet was employed in 2; one was a pilot study with 15 patients[4] and the other included only 135 patients.[5] To the best of our knowledge, this is the first RCT on secondary CVD prevention based on a cellular phone system over the Web, with the clear advantage of an asynchronous communication not requiring Internet access by patients.

Our intervention was particularly effective for overweight individuals, while also secondarily improving diabetes control. In other RCT with CHD patients,[5,17] telephone or Internet-based interventions were also useful for BMI reduction. This suggests that remote monitoring may be particularly useful for the control of overweight, a CRF difficult to modify and for which purpose and perseverance are very important. In our study, glycemic control was superior in the TMG, probably due to life style changes and weight loss, given that no changes in diabetes treatment were made remotely. Changes in triglycerides also favored telemonitoring, probably for the same reason. Nutritional habits are presumably the main underlying mechanism explaining the difference found in the risk profile between the groups. Nevertheless, these were beyond the scope of this study.

It could also be possible that some real changes in physical activity, medication adherence, or both were not detected because of being self-reported by patients.

Most patients in the study reached the therapeutic goal for LDL-c and quit smoking, with no significant differences between groups. This can be explained in part by the high rate of statin therapy in our study population (100% in both groups at 12 months). Regarding smoking cessation, telemonitoring has not been superior to usual care in other RCT with CHD patients, in which smoking status was confirmed by biochemical analysis16-19 with one exception.15 Possible reasons could be awareness of the negative cardiovascular effects of smoking by patients and improved usual-care practices regarding medical advice. Previous studies have found a correlation between knowledge and adherence to lifestyle changes.22 Although we did not measure patient knowledge of CRF, most messages sent by the physician contained reminders of treatment goals and healthy lifestyle habits. Hence, we consider this an additional source of learning for patients.

This study has important strengths in the nature and simplicity of the intervention and the compliance and excellent acceptance by patients. This telemonitoring modality allowed patients to access the program from their homes or other places at their convenience. They did not need to have Internet access and the technology was easy to use, even for older patients. The case manager remains the key component of the system, interacting with patients asynchronously via secure communication lines and providing direct feedback on CRF. In a recent meta- analyses of quality improvement strategies to lower BP,25 interventions targeting patients (education and self-monitoring) or in which a health care team member was added, produced the largest reductions in BP. This study also had limitations. Firstly, patients were not blinded to the intervention, and could have shared telemonitoring data with their family physicians. However, although this could have influenced the results of the study, we do not consider it a disadvantage in daily practice. Secondly, the population of the study was relatively small and the duration of the follow-up was only 1 year; therefore, our results require replication in larger trials.

CONCLUSIONS

Our study demonstrates the security and efficacy of a telemonitoring system connecting patients, provided with self-measurement devices, and care managers through cellular phone messages over the Internet for the secondary prevention of CHD. The integrated monitoring of several risk factors in patients after an acute coronary syndrome improved their CVD risk profile. This kind of intervention seems particularly useful in overweight and diabetic individuals, possibly reinforcing patient perseverance. Importantly, it is feasible and has a potentially broad application. Further investigations are required to probe this strategy in high-risk populations. We expect that this kind of program could be offered, as part of routine care, to all eligible patients at the time of acute admissions, or shortly thereafter.

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Table 1. Clinical and Demographic Data of Patients

	TM Group (n = 102)	Control Group (n = 101)	*p* Value
Age, years, M (SD)	60.6 (11.5)	61 (12.1)	0.827
Men, n (%)	83 (81.4)	80 (79.2)	0.698
STEMI, n (%)	51 (50.0)	47 (46.5)	0.242
NSTEMI, n (%)	51 (50.0)	49 (48.5)	0.883
CABG, n (%)	5 (4.9)	8 (7.9)	0.437
PCI, n (%)	49 (48.0)	33 (32.7)	0.081
Ictus, n (%)	3 (2.9)	4 (4.0)	0.195
LVEF, %, M (SD)	52.8 (8.7)	50.8 (9.8)	0.184
Current smoker, n (%)	78 (76.5)	75 (74.3)	0.759
Menopausal, n (%)	14 (73.7)	15 (71.4)	0.662
Exercise practice, n (%)	38 (37.3)	38 (37.6)	0.997
BMI, kg/m2, M (SD)	28.2 (5.3)	27.7 (3.5)	0.464
AC, cm, M (SD)	102.9 (11.0)	103.3 (9.7)	0.814
Systolic BP, mm Hg, M (SD)	137.6 (23.9)	136.0 (22.8)	0.633
Diastolic BP, mm Hg, M (SD)	79.3 (13.5)	82.9 (15.1)	0.074
Total cholesterol, mg/dL, M (SD)	184.6 (46.1)	187.9 (46.9)	0.617
HDL-c, mg/dL, M (SD)	43.3 (16.3)	40.3 (10.5)	0.126
LDL-c, mg/dL, M (SD)	109.5 (35.0)	118.9 (42.2)	0.092
HbA1c, %, M (SD)	6.3 (1.2)	6.2 (1.2)	0.413
Glycemia, mg/dL, M (SD)	118.6 (44.0)	113.8 (40.9)	0.431
Creatine, mg/dL, M (SD)	0.9 (0.3)	0.9 (0.3)	0.613

Table 2. Quantitative Changes in Biological Variables After 12 Months of Follow-up

Biological Variables	TM Group (n = 87)	Control Group (n = 83)	*p* Value
Systolic BP, mm Hg, M (SD)			
Initial visit	136.5 (23.8)	136.8 (22.8)	
Final visit	131.4 (20.3)	136.0 (18.2)	
Difference, M (95% CI)	–5.1 (–12.09 to –0.10)	–0.81 (–6.5 to 4.9)	0.312
Diastolic BP, mm Hg, M (SD)			
Initial visit	78.6 (13.5)	83.8 (14.8)	
Final visit	76.5 (10.3)	77.4 (9.92)	
Difference, M (95% CI)	–2.05 (–5.46 to 1.37)	–6.4 (–10.2 to –2.6)	0.092
BMI, all patients, M (SD)			
Initial visit	27.9 (4.1)	27.8 (3.4)	
Final visit	27.5 (3.9)	28.1 (3.8)	
Difference, M (95% CI)	–0.37 (–0.8 to 0.04)	0.38 (–0.11 to 0.85)	0.022
BMI, overweight patientsb, M (SD)			
Initial visit	29.6 (3.37)	29.1 (2.66)	
Final visit	28.8 (3.7)	29.4 (3.19)	
Difference, M (95% CI)	–0.77 (–1.27 to –0.27)	0.29 (–0.26 to 0.84)	0.005d

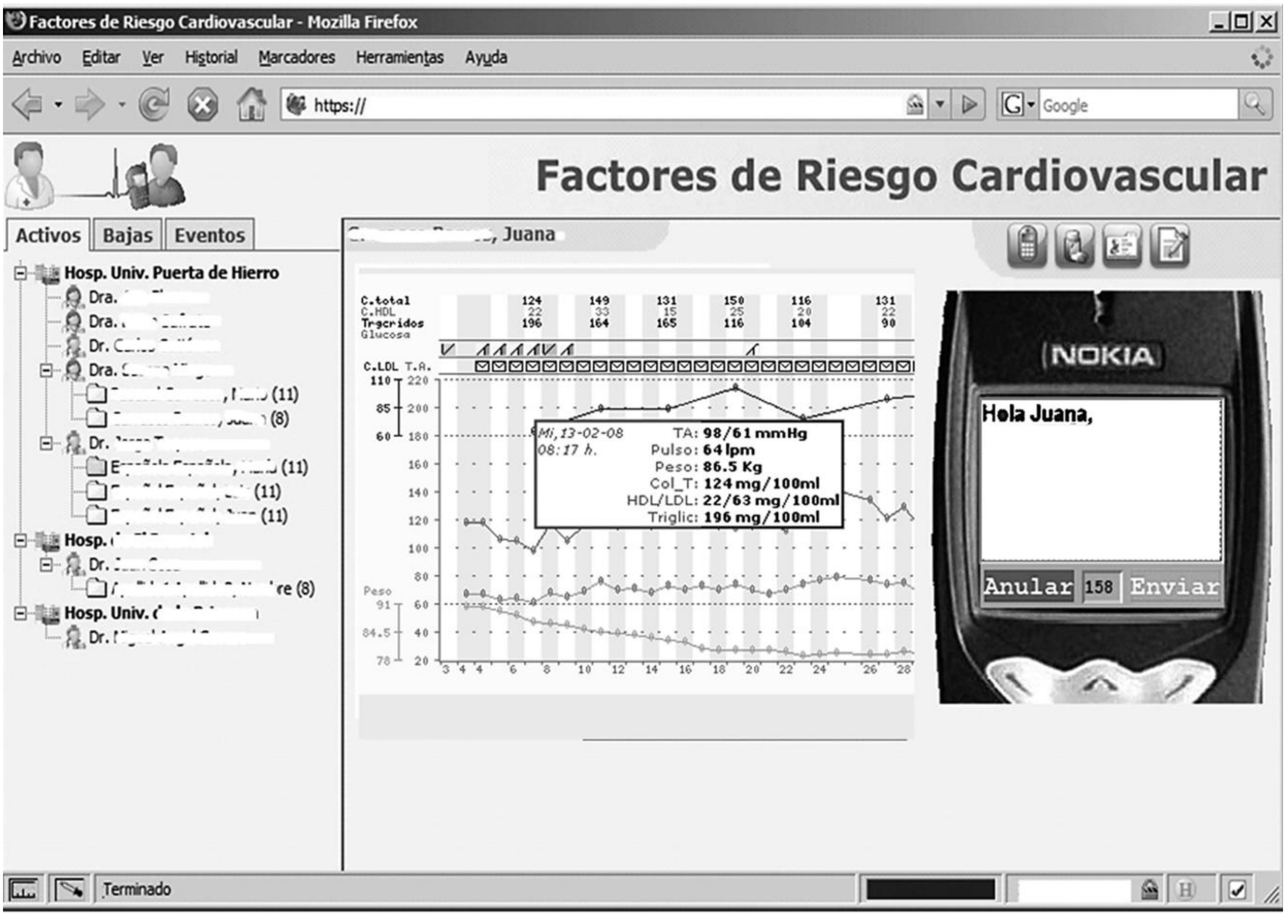

Figure. Health care professional interface: Web application for the follow-up of patients. Folders, on the left side of the screen, contain clinical measurements messaged by patients. Data (center of the screen) are graphically and numerically displayed by clicking on patient folders.