

Accepted Manuscript

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PII: S0002-9343(16)30844-0

DOI: [10.1016/j.amjmed.2016.07.029](https://doi.org/10.1016/j.amjmed.2016.07.029)

Reference: AJM 13667

To appear in: *The American Journal of Medicine*

Received Date: 15 July 2016

Revised Date: 22 July 2016

Accepted Date: 26 July 2016

Please cite this article as: Milani RV, Lavie CJ, Bober RM, Milani AR, Ventura HJ, Improving Hypertension Control and Patient Engagement Using Digital Tools, *The American Journal of Medicine* (2016), doi: 10.1016/j.amjmed.2016.07.029.

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

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Running Title: Digital Tools in Hypertension Control

Word Count:

Key Words: hypertension, chronic disease, patient engagement

Disclosures: none

Funding: none

Authorship: All authors had access to the data and a role in development of the manuscript.

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Abstract

Background: Hypertension is present in 30% of the adult U.S. population and is a major contributor to cardiovascular disease. The established office-based approach yields only 50% blood pressure control rates and low levels of patient engagement. Available home technology now provides accurate, reliable data that can be transmitted directly to the electronic medical record.

Methods: We evaluated blood pressure control in 156 patients with uncontrolled hypertension enrolled into a home-based digital medicine blood pressure program and compared them to 400 patients (matched to age, gender, body mass index and blood pressure) in a usual care group after 90 days. Digital medicine patients completed questionnaires on-line, were asked to submit ≥ 1 blood pressure reading/week, and received medication management and lifestyle recommendations via a clinical pharmacist and a health coach. Blood pressure units were commercially available, that transmitted data directly to the electronic medical record.

Results: Digital Medicine patients averaged 4.2 blood pressure readings per week. At 90-days 71% of digital medicine versus 31% of usual care patients had achieved target blood pressure control. Mean drop in systolic/diastolic blood pressure was 14/5 mmHg in digital medicine versus 4/2 mmHg in usual care ($p < 0.001$). Excess sodium consumption decreased from 32% to 8% in the digital medicine group ($p = 0.004$). Mean patient activation increased from 41.9 to 44.1 ($p = 0.008$) and the percentage of patients with low patient activation decreased from 15% to 6% ($p = 0.03$) in the digital medicine group.

Conclusion: A digital hypertension program is feasible and associated with significant improvement in blood pressure control rates and lifestyle change. Utilization of a virtual health intervention using connected devices improves patient activation and is well accepted by patients.

Introduction

Hypertension is a major contributor to cardiovascular disease and is the leading risk factor contributing to the global disease burden, representing approximately ten percent of all global healthcare spending. (1,2) Despite effective pharmacologic and non-pharmacologic therapies, the current office-based approach produces suboptimal results in which approximately half of the 80 million United States (US) adults with hypertension remain uncontrolled. (3,4) Several factors account for these poor outcomes, including the use of suboptimal doses of medications, lack of patient engagement, and limited resources and time to educate and provide lifestyle recommendations. (5) Although many types of interventions have been tested, recent systematic reviews conclude that what is needed is a reorganization of clinical practice and empowerment of nonphysician practitioners to adjust anti-hypertensive therapy.(6)

Home blood pressure monitoring addresses several limitations of traditional office-based care, including a larger sample of biologic data, reducing misclassification due to white-coat or masked hypertension, and an ability to take more timely action and course correct therapy.(3) Current technology is accurate and easy to use, and home-based blood pressure measurements better predicts cardiovascular risk than office measurements. (7) Moreover, home blood pressure monitoring avoids the inconvenience of an office-based encounter and in and of itself, enhances patient engagement, which independently plays an important role in medication and lifestyle adherence. (7-10)

We sought to evaluate the effectiveness of a remote, home-based telemonitoring program in a clinical setting using commercially available technologies, on blood pressure control and patient engagement in patients with uncontrolled hypertension.

Methods

We identified adult patients with the diagnoses of hypertension at the Ochsner Health System who had elevated blood pressure (systolic pressure > 140 mmHg or diastolic pressure > 90 mmHg) at each of the 3 most recent physician visits within the previous 18 months. Patients meeting these requirements were enrolled by their physician during an office encounter or through an offer letter by their physician. Patients were required to possess a smartphone as well as purchase a wireless blood pressure unit from a list of preselected vendors based on the smartphone's operating system (OS). For Android phones the vendor option was Withings, for Apple iPhones, the options included Withings, and iHealth. The electronic medical record (Epic Systems®) provided a direct interface to Withings regardless of OS as well as a secure interface to Apple HealthKit, thus providing an array of device options for units that interfaced with HealthKit. Patients also were required to have an active account in the patient portal (Epic MyChart®), which was free; if patients did not have an active account, they were given the opportunity to sign up for one.

Program details, questionnaires, and electronic consent to participate took place on-line through MyChart. Questionnaires assessed factors related to hypertension and chronic disease management, including dietary sodium and alcohol consumption, depression, medication adherence, patient activation, physical activity, health literacy, social circumstances (i.e. medication affordability, number living in home, etc.) and screening for obstructive sleep apnea. (5) Additional clinical data was obtained from the electronic medical record, including serum sodium, potassium, and creatinine, estimated glomerular filtration rate (eGFR), thyroid function tests, and body mass index (BMI). This data was used to create a patient phenotype that assisted in the design of the intervention process.

Patients were asked to take no less than one blood pressure reading per week but were encouraged to take 3-4 per week. If the care team had not received a blood pressure reading for 8 days, patients would receive an automated text, alerting them that a blood pressure measurement was needed. Blood pressure units were purchased and initial training and setup was provided at the Ochsner O Bar, a patient-facing service that

provides information, training and tech support for patients interested in apps, wearables and connected home devices. (11)

A second group of patients who met eligibility criteria but whose physician was not participating in the program were followed. Of these, 400 patients were matched to the digital medicine group according to age, gender, BMI, and initial blood pressure, and were followed as a usual care group over time. Usual care patients received routine care through their primary care physician and averaged 0.8 visits over 90 days.

Doctoral pharmacists and health coaches participated in the intervention that included education, drug management and lifestyle recommendations as per hypertension guidelines. (12,13) Each pharmacist received training in hypertension management as well as use of the custom tools within the electronic medical record created to facilitate optimal management. Pharmacists and health coaches were also educated regarding the importance of patient engagement and methods used to enhance engagement and lifestyle change.

We developed a health capability score composed of four patient domain factors impacting chronic disease outcomes: social isolation, capabilities to process and understand health information (health literacy), engagement in their disease process (patient activation), and economic barriers impacting treatment plans (medication affordability). One point was assigned to any deficiency in each component with a higher score indicating declining health capability.

Interventions

Pharmacists contacted patients by phone and discussed the screening results as well as treatment options for improving blood pressure control. Patients were encouraged to be an active participant in their hypertension management and worked with the pharmacist to co-create the treatment plan by choosing among various lifestyle and medication options. Patients were also directed to a dedicated hypertension website

that offered further educational and lifestyle materials including custom videos and downloadable handouts.

Those who screened positive for depression or obstructive sleep apnea were referred to their physician or to the appropriate specialist based on physician preference. Patients who screened positive for excess dietary sodium received focused education on the importance of reducing dietary sodium and were additionally asked if other individuals were involved in the purchase or preparation of their meals. If affirmative, and following patient consent, these individuals were contacted by automated email at the behest of the patient, and provided video education and other educational resources on the importance of choosing low sodium foods when purchasing or preparing meals.

Patients with medication affordability issues were as much as possible, switched to generics or less expensive combination agents, and when appropriate and feasible, enrolled in medication assistance programs. Those with medication adherence issues were provided educational materials, pill reminder apps and resources, as well as a simplified medication regimen when possible.

Patients received monthly reports (Figure 1) detailing their progress along with lifestyle tips based on their screening phenotype. Physicians also received monthly reports on their patient's progress. Incoming blood pressure data was analyzed via internally developed algorithms as to its validity and directional change, and alerts were established to highlight which patients needed what intervention and when.

Outcomes

The primary outcome was the proportion of patients with controlled blood pressure, defined as a blood pressure < 140/90 mmHg or < 130/80 if diabetes or chronic kidney disease was present, at 90 days. Other outcomes included change in systolic blood pressure and diastolic blood pressure at 90 days, and improvement in patient engagement using patient activation measure. (8)

Statistical Analysis

Statistical analysis was performed using SPSS version 16.0 (SPSS Inc., Chicago, IL). Results are expressed as mean \pm standard deviation (SD), or as n (%) where appropriate. Analysis of differences between groups was performed using Student's t-test for continuous variables, Chi-square test for categorical variables and ANOVA for differences among frequencies for several groups. Logistic regression was used in the health capability analysis in which the response variable was blood pressure control at 90 days. In all analysis, two-sided $P < 0.05$ was considered significant.

Results

Of the initial 195 patients who were offered the digital medicine program, 156 accepted enrollment and 39 declined participation. The baseline characteristics of the digital medicine (n=156) and usual care groups (n=400) are outlined in Table 1. There were no significant differences in age, gender, BMI, baseline blood pressure measures, and other characteristics.

Table 2 highlights additional baseline data in the digital medicine group. Of note, the high prevalence of lifestyle contributing factors, including physical inactivity and high dietary sodium.

Table 3 describes the changes in blood pressure metrics and other health metrics at 90 days in the digital medicine (a) and usual care (b) groups. Blood pressure including systolic, diastolic, mean arterial pressure (MAP) and pulse pressure improved significantly in both groups ($p < 0.001$). At 90 days, 71% of patients in the digital medicine group achieved blood pressure control compared to 31% of the usual care group ($p < 0.001$). Over the 90-day period, the usual care group had an average of 0.8 ± 0.4 blood pressure recordings noted in the electronic medical record compared to 55 ± 16 recordings (averaging 4.2/week) in the digital medicine group ($p < 0.0001$).

Table 4 describes the patient characteristics of digital medicine patients who achieved 90-day blood pressure control (n = 111; 71%) compared to those who had not achieved blood pressure control (n=45; 29%). Those patients who had not achieved 90-day blood pressure control had higher entry systolic and diastolic blood pressures, were more

likely to suffer depression, have diabetes, be unable to afford their medication, and take more anti-hypertensive medications.

Other characteristics of interest in the poorly controlled group, but of borderline statistical significance, were trends towards a higher prevalence of social isolation, and poor health literacy. The mean health capability score was twofold higher in the poorly controlled group than in those patients achieving blood pressure control (0.80 ± 0.82 versus 0.39 ± 0.64 ; $p=0.002$) and more than half of the poorly controlled group exhibited some impairment in health capability.

Table 5 describes the likelihood of achieving blood pressure control based on the health capability score. Relative to a health capability score of zero, the odds ratio of achieving blood pressure control with a health capability score of 1 was 0.58 (CI 0.26 – 1.3; $p=0.20$), and 0.17 (CI 0.06 – 0.50; $p=0.001$) when the health capability score was ≥ 2 .

Discussion

There are two important findings from this investigation. First, it is feasible to significantly improve hypertension control as well as enhance patient activation using a digital health monitoring and intervention program. Second, patient-oriented factors comprising an individual's health capability have a significant clinical impact in achieving blood pressure control.

Management of chronic disease is a multidimensional process that is influenced by the three parties governing care: the clinician, the patient, and the health delivery system.

(5) The most common chronic disease is hypertension, with a prevalence of 30% of the adult US population, yet only 50% of hypertension patients achieve blood pressure

control. (4,14) Poor blood pressure control increases morbidity and mortality, and due to only modest national control rates, hypertension-related deaths have increased 23% in the last decade compared to a 21% reduction in all other causes of death combined.

(15) Failure in controlling blood pressure has been linked to therapeutic inertia, present in up to 87% of patients with poorly controlled hypertension. (5,16) We have shown that

redesigning care delivery using a digital health program can substantially improve blood pressure control, with 71% of previously uncontrolled hypertension patients achieving blood pressure control within 90 days compared to only 31% of usual care patients. These improvements in blood pressure control are also timely, as delays in controlling elevated blood pressure have been demonstrated to impact outcomes; delays of greater than 1.4 months before medication intensification and delays greater than 2.7 months before blood pressure follow-up after medication intensification are associated with increases in cardiovascular events and all-cause mortality. (17)

It is noteworthy that the intervention impacted all three domains of care, and included a focused characterization and intervention in the patient domain. We report that patient activation was significantly improved by the intervention, with a reduction of those who were classified as poorly activated by 60% ($p=0.03$). This was likely due to several factors, including self-measurement of blood pressure, co-creation of treatment goals, and regular feedback in the manner of monthly reports, intermittent texts and phone calls. In patients with chronic disease, increasing patient activation can improve medication adherence, decrease adverse outcomes, and reduce total healthcare costs. (8,18,19) It is notable that the intervention included education and resources towards lifestyle changes that was delivered not only to the patient, but also to members of the patient's social network who had influence over diet, resulting in a significant reduction in dietary sodium consumption. (20)

Although the digital medicine program achieved quality improvements over usual care, 29% of patients failed to reach target blood pressure goals by 90 days. These patients had higher entry blood pressure and were more likely diabetic, but also exhibited a threefold higher prevalence of depressive symptoms. Additionally, they noted a greater difficulty in paying for their medication and trended towards more social isolation and lower health literacy. Taken together the health capability score provided a measure of the likelihood of achieving blood pressure control as viewed from the patient domain.

Compared to patients with a health capability score of 0, those with a score of ≥ 2 had a likelihood of only 17% of achieving blood pressure control at 90 days ($p=0.001$).

Limitations

First, this was a single-center study and patients were not prospectively randomized into intervention (digital medicine) and usual care groups. Second, only patients who possessed a smartphone were eligible to enroll, which raises issues regarding education, socioeconomic, and motivational biases. However, the mean age of our population was 68 years and on screening, 23% lacked common technology skills, suggesting that our cohort was not biased towards a younger, more tech savvy population.

Conclusion

A digital health program in the clinical care setting can be an effective mechanism of delivering hypertension management, outperforming traditional office-based care. The program was well accepted by patients and has the additional value of improving patient engagement. Factors in the patient domain, such as health literacy, patient activation, social isolation, and medication affordability play a significant role in disease control and should be considered in population health management strategies.

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ACCEPTED MANUSCRIPT

Figure Legend

Figure 1 - Monthly patient report in the digital medicine program.

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Table 1

Baseline characteristics in the Usual Care and Digital Medicine groups.

	Usual Care (n=400)	Digital Medicine (n=156)	p-value
Age (years)	68 ± 10	68 ± 10	NS
Gender (% female)	54%	54%	NS
Body mass index (kg/m ²)	31.7 ± 7.4	30.8 ± 6.3	NS
% Black	23%	22%	NS
% Diabetic	36%	29%	NS
Baseline systolic pressure (mmHg)	147 ± 5	147 ± 14	NS
Baseline diastolic pressure (mmHg)	81 ± 8	81 ± 12	NS
Mean arterial pressure (mmHg)	103 ± 6	103 ± 12	NS
Pulse pressure (mmHg)	65 ± 9	66 ± 16	NS
Creatinine (mg/dl)	1.0 ± 0.5	1.1 ± 0.5	NS
eGFR (ml/min/1.73m ²)	55.2 ± 9.9	56.5 ± 8.9	NS
TSH (ulU/ml)	2.0 ± 1.0	1.9 ± 1.5	NS
% Obese	54%	52%	NS

Table 2

Additional baseline characteristics of the Digital Medicine group (n=156).

Physically inactive (%)	76%
Lives alone (%)	17%
Depression (%)	17%
Poor health literacy (%)	6%
Medication affordability issue (%)	12%
Obstructive sleep apnea screen + (%)	22%
High dietary sodium intake (%)	32%
Low medication adherence (%)	17%
Low patient activation (%)	15%
Number of antihypertensive meds	3.7 ± 1.5
Poor technology skills (%)	23%

Table 3

(a) Changes in blood pressure and health metrics in the Digital Medicine group at 90 days (n=156).

	Baseline	90-days	p-value
Systolic blood pressure (mmHg)	147 ± 19	133 ± 12	<0.001
Diastolic blood pressure (mmHg)	81 ± 12	76 ± 9	<0.001
Mean arterial pressure (mmHg)	103 ± 12	95 ± 9	<0.001
Pulse pressure (mmHg)	66 ± 16	57 ± 11	<0.001
High dietary sodium intake (%)	32%	8%	0.004
Patient activation score	41.9 ± 6.6	44.1 ± 6.7	0.008
Low patient activation (%)	15%	6%	0.03

(b) Changes in BP metrics in the Usual Care group at 90 days (n=400).

	Baseline	90-days	p-value
Systolic blood pressure (mmHg)	147 ± 5	143 ± 14	<0.001
Diastolic blood pressure (mmHg)	81 ± 8	79 ± 9	<0.001
Mean arterial pressure (mmHg)	103 ± 6	100 ± 7	<0.001
Pulse pressure (mmHg)	65 ± 9	63 ± 9	<0.001

Table 4

Differences in characteristics between Digital Medicine patients who at 90 days achieved blood pressure control (n=111) and did not achieve blood pressure control (n=45).

	Blood Pressure Controlled at 90 days (n=111)	Blood Pressure Uncontrolled at 90 days (n=45)	p-value
Age (years)	67 ± 10	70 ± 10	NS
Gender (% female)	51%	57%	NS
Body mass index (kg/m ²)	30.2 ± 6.1	31.9 ± 6.8	NS
% Black	17%	30%	0.09
% Diabetic	21%	46%	0.002
Baseline systolic pressure (mmHg)	143 ± 19	154 ± 13	0.001
Baseline diastolic pressure (mmHg)	81 ± 12	82 ± 10	NS
90-day systolic pressure (mmHg)	127 ± 8	148 ± 7	<0.001
90-day diastolic pressure (mmHg)	74 ± 8	81 ± 10	<0.001
Creatinine (mg/dl)	1.0 ± 0.4	1.2 ± 0.7	NS
eGFR (ml/min/1.73m ²)	57.5 ± 7.9	54.2 ± 11.0	NS
% Obese	48%	59%	NS
Physically inactive (%)	75%	77%	NS
Lives alone (%)	15%	25%	0.12
Depression (%)	11%	32%	0.002
Poor health literacy (%)	5%	11%	0.12

Medication affordability issue (%)	6%	27%	<0.001
Obstructive sleep apnea screen + (%)	26%	39%	0.11
High dietary sodium intake (%)	34%	27%	NS
Low medication adherence (%)	15%	18%	NS
Low patient activation (%)	14%	16%	NS
Poor technology skills (%)	15%	34%	0.07
Number of entry antihypertensive meds	3.2 ± 1.5	4.4 ± 1.5	<0.001
Blood pressure submissions/week	4.3 ± 3.8	4.3 ± 3.2	NS
Low health capability (%)	32%	55%	<0.01
Health capability score	0.39 ± 0.64	0.80 ± 0.82	0.002

Table 5

Health capability score and 90-Day blood pressure control in Digital Medicine patients.

Health Capability score	0	1	2+
Blood Pressure Controlled	79% (76)	67% (28)*	39% (7)†
Blood Pressure Uncontrolled	21% (20)	33% (14)	61% (11)

* OR=0.58 (CI 0.26 – 1.3; p=0.20) † OR=0.17 (CI 0.06 – 0.50; p=0.001)



Hypertension Digital Medicine Report

Test Patient

December 2014

What is High Blood Pressure?

High blood pressure, also called hypertension, occurs when the pressure inside your arteries is higher than it should be. One in three American adults has high blood pressure, and if it is not controlled, it can cause damage to your eyes, brain, heart, blood vessels and kidneys; as a result, high blood pressure is a leading cause of heart attack and stroke. High blood pressure has no warning signs or symptoms, so monitoring your blood pressure readings and getting it under control is very important to your health and well-being.

Your Results

Excellent 😊

Systolic



Diastolic



Your Progress



Your Risk

With your current medical conditions, the 10 year estimated risk of heart attack and stroke is:

16%

You can reduce your risk to:

10% if your blood pressure was 120 mm/Hg

6% if your HDL cholesterol was at least 60 mg/dL



Try these physical activities to reduce your blood pressure:

- Take your children or grandchildren to the park.
- Take a 30-minute window-shopping walk around the mall when weather is bad.



Did you know that the more alcohol you drink, the higher your blood pressure? The good news is that by reducing your alcohol intake, ideally to less than 2 alcoholic drinks per day, you can effectively lower blood pressure.

Clinical Significance

- Hypertension can be safely and effectively managed using a digital health platform, achieving better blood pressure control than traditional office-based care
- A digital platform for managing chronic disease is well accepted by patients and enhances patient engagement
- Factors in the patient domain including health literacy, patient activation, social isolation and medication affordability play a significant role in chronic disease control and should be considered in population health management strategies