Role of wrist-based blood pressure monitoring in clinical practice

A pilot study to explore the feasibility and utility of around the clock wrist-based blood pressure measurements during patient transition of care

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STUDY PROTOCOL

Table of Contents

1. Purpose

We propose a pilot clinical study to test the overarching hypothesis that frequent and longitudinal blood pressure monitoring with FDA approved consumer wrist based device during the patient transition from inpatient to home to the first clinic visit will elicit valuable BP data that can assist in physician treatment of hypertension

2. Background

Wrist based health devices, often with mobile connectivity, that continuously or near continuously track heart rate, blood pressure, temperature, activity and sleep are growing in everyday popularity and beginning to enter the sphere of clinical relevance. However, their accuracy and utility for clinical use is largely unstudied. As these consumer devices, some of which are FDA approved, become more commonplace, it is paramount to understand their function, know their limitations, and be able to interpret results appropriately before incorporating them into our clinical practice. The AHA/ACC 2017 guideline makes a 1A recommendation for clinical use of out of office BP measurements(*1*). This recommendation is based on evidence that out of office BP and frequent and longitudinal BP measurements are important in predicting cardiovascular risk and monitoring treatment efficacy(*2-5*). This trend towards consumer driven digital health monitoring and the new AHA/ACC guideline are essentially advancing a consumer based precision medicine strategy for diagnosis and monitoring of hypertension. As this becomes commonplace in our patient population, we need rigorous clinical study of wrist base BP monitoring to better understand its role patient care.

3. Study Design

We will recruit patient volunteers from the Scripps Green Hospital and Scripps Memorial Hospital inpatient teaching services. Inclusion criteria will be adults >18, with normotensive or hypertensive history, all races and genders. Exclusion criteria will be patients for which an admission diagnosis is hypertensive urgency or emergency or are physically or mentally unable to manage the wrist based BP monitor. The study is observational only, participation in the study will not affect routine care. On the estimated last 24-48 hours of admission subjects will start wrist based blood pressure monitoring.

Wrist based BP measurements will be performed several times during the day and several times at night automatically.

Healthcare workers will be briefed before the initiation of the study to not use wrist based blood pressure measurements in their management, and patients will be briefed that wrist based blood pressure monitoring is for study purposes only. Wrist based BP monitoring will continue through discharge home until the first clinic visit, which we will attempt to schedule for approximately one week post discharge. Patients will be briefed prior to initiation of study and at the end of the study. They will be counselled not to adjust antihypertensive regimen without prior discussion with their primary care physician. A 24/7 phone number will be provided for study subjects to call with questions or concerns during and after the study. Dr. Song and/or study coordinators will contact each participant by phone at least once during the study period to answer questions and as a reminder to frequently measure blood pressure.

In the pilot phase, we plan to recruit 10 subjects to evaluate study design and generate preliminary data and calculate power. In the second phase, we preliminarily estimate a sample size of 64 with α=0.05 and power (1-β) of 0.95, in order to obtain significance between day time mean BP and night time mean BP using SBP means and standard errors from the MAPEC trial(*6*).

Following in person informed consent, participants will be supplied with the Omron HeartVue (v1.0) blood pressure monitoring device for use during the course of the study. Participants will return the study wristband at the completion of the study in a prepaid envelope or leave the device at their primary care physicians office.

At the close of the study, study participants will be asked to fill out a post-study questionnaire. The questionare will be given to participants on enrollment and participants will be asked to return the questionare along with the device at the completion of the study period. The survey and the wrist based BP device will be returned by mail using a prepaid envelope.

Patient data will be de-identified using a code that can be deciphered only by Dr. Michael Song. The key for the code will be destroyed at the completion of the study. Patient date will be gathered from EPIC and inputted into a spreadsheet that will be stored on the Scripps Health database. Wrist based BP, heart rate and activity data will be evaluated by the investigators and study coordinators/assistants and manually inputted in the previously mentioned spreadsheet.

4. Endpoints

The primary endpoints for this study are blood pressure measurements. Blood pressure measurements will be sought using the Omron HeartVue, traditional hospital healthcare provider performed, ambulatory clinic blood pressure and home blood pressure as measured by traditionally available upper arm based device. The Omron device will also measure heart rate, activity and sleep.

5. Subject Selection

Number of Subjects: A total of 10 + 64 (estimated) subjects will be enrolled.

Nature of Study Population: Men and women 18 years and older will be eligible for participation. We aim to enroll 50% females across all age groups.

6. Inclusion and Exclusion Criteria

Individuals 18 years of age or older with and without the known diagnosis of hypertension (regardless of level of control or therapeutic regimen), able to operate HeartVue device, able to read, write, and speak English, level of "digital savviness" and owning an iOS or Android device will be recruited for participation in this pilot study.

Inclusion Criteria:

- Consortium members within the All of Us Research Program
- ≥18 years of age
- Own an iOS or Android device

Exclusion Criteria:

- Inability to give informed consent
- <18 years of age
- Inability to understand written English language
- Hypertensive urgency or emergency as an admission diagnosis

7. Data Storage and Analysis

The collection and processing of personal data from subjects enrolled in this study will be limited to the data needed to investigate this study's hypothesis and the clinical data typically used as covariates in the analysis of cardiovascular clinical studies. Access to data will be limited to those authorized by Principal Investigator and study sponsor. Individual blood pressure values will be securely transmitted to Omron servers via the Connect App interface. The ConnectApp data will only be accessible to the patient, Omron and investigators.

8. Possible Benefits

- There are no guaranteed health benefits to participants of this study.
- Participants may learn new insights regarding the overall control of their blood pressures, which could potentially be used to fully optimize their medical and lifestyle interventions for blood pressure control.
- Provide the research community with a better understanding of blood pressure changes in various non-clinical settings.

9. Possible Risks

The personal risk of harm from participation in this study is considered to be minimal. The Omron HeartVue device has been cleared for personal use by the FDA for measuring blood pressure outside of the clinic. There are no experimental uses or procedures being tested in this protocol.

In spite of all the safety measures that we will use, we cannot guarantee that the subject's identity will never become known.

10. Risk Management

Loss of Privacy

Only Dr. Michael Song will have access to a research subject's fully identified medical information. The information that matches the code to the identifying information will be kept in a safeguarded database that is password protected and any paper files will be kept in a secure location.

Information from analysis of de-identified medical information will be placed in a controlled-access Scripps Health database.

11. Informed Consent

Study purpose, methods, materials, risks, benefits and alternatives will be available to the participant. Informed consent will be obtained initially in person.

12. Subject Withdrawal

Subject participation is voluntary and the subject can discontinue participation at any time without loss of benefits or penalty. If the decision to terminate study participation is reached, the subject will be asked to return their Omron HeartVue device at no charge to the subject and their app will be deactivated once the subject notifies our study team of the withdrawal. Data that has already been collected will still be used in the study and cannot be deleted. If the subject terminates the study early, there will be no penalty or loss of benefits to which they are otherwise entitled. The study oversight team has the option to recruit additional participants to replace any subjects that withdrew early from the study.

13. Oversight and Monitoring of the Study

The Principal Investigator Dr. Nicholson and Dr. Song will be responsible for the oversight of this study and for the team of individuals conducting the study with the assistance of CRS.

14. Record Retention

De-identified clinical information will be stored in a safeguarded database that is password protected. At the appropriate time, the code that links the participant to the clinical data will be destroyed. Related health and trait information may be kept indefinitely.

The electronic informed consent forms, including HIPAA authorization will be stored in a Scripps health database

15. Publication

The results of this research may be presented at meetings or in publication. However, the subject's identity will not be disclosed in those presentations.

16. Study Leadership

Dr. Nicholson

Dr. Song

Dr. Topol

Dr. Steinhubl

17. Cost and Compensation

Subjects will not be paid for participation in the study. There is no cost to the subject for study participation. After the study is closed, participants will be return the HeartVue device. When an updated FDA approved HeartVue device is released (plan for mid to late 2018) participants may be asked to utilize the new device, at no participant cost.

18. Participant Facing Text and Workflow

See Section 20. Appendix.

19. References

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4. R. C. Hermida, D. E. Ayala, J. R. Fernandez, A. Mojon, M. H. Smolensky, Hypertension: New perspective on its definition and clinical management by bedtime therapy substantially reduces cardiovascular disease risk. *Eur J Clin Invest*, (2018).
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