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A protocol for digital cardiovascular prevention feasibility study using hybrid home blood pressure telemonitoring system

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Abstract

Aim: The DICAP feasibility study aims to determine chronological blood pressure (BP) control status and BP variability up to the end of life in different life settings in the community and their clinical implications.

Methods: A simple, easy-to-use automated hybrid BP telemonitoring system combined cellular and Bluetooth BP monitors, the DICAP (DIgital Cardiovascular Prevention) system, was devised to obtain all the different BP values measured in a time series in different settings in 500 community-dwelling individuals in their homes and local elderly care facilities.

Expected results and Perspectives: This study will confirm the feasibility of collecting BP variability over time until the end of life for the management of hypertension in all community-dwelling patients, including those unfamiliar with digital technology and those in diverse residential settings, such as elderly care facilities. This feasibility study has the potential to serve as a basis for future community and disaster medicine initiatives worldwide.

Keywords: Community, home blood pressure, telemonitoring system, DICAP, elderly, hypertension

INTRODUCTION

Importance of lifetime hypertension control and blood pressure variability

Hypertension is a risk factor for both the onset and the aggravation of cardiovascular diseases. The effective management of hypertension is complicated by individual pathologies and comorbidities, especially among the elderly. In parallel with aging, all of the forms of BP variability increase, i.e., over different time periods, such as the shorter orthostatic variability, day-by-day variability, and longer seasonal variability[1]. These increases in BP variability are associated with organ damage and cardiovascular disease[2-10]. In the very late life stage, BP decreases[11] and BP variability increases in association with cognitive dysfunction[12,13]. The control of BP and the risks associated with BP among very elderly, frail patients can be expected to differ from those in younger elderly patients[14-16], but real-world BP data over a trajectory until the end of life within the same individuals are lacking.

History of disaster telemedicine and current unmet needs

At the time of the 2011 Great East Japan Earthquake, we established the Disaster Cardiovascular Prevention (DCAP) system (which uses personal authentication and digital data transmission technology) in Minamisanriku Town in Miyagi Prefecture, Japan, that was greatly damaged by the earthquake[17-19], and we promptly implemented this home BP telemonitoring program for disaster survivors in response to the earthquake. This system was useful in identifying individuals with "disaster hypertension"[20,21], and contributed to achieving successful long-term management of hypertension, substantially lowering individuals' home systolic BP from ~ 150-160 mmHg at the initiation to ~ 120-130 mmHg (with adequate seasonal variation of home BP) for ≥ 10 years. However, after the passage of 10 or more years, some patients could not attend because their mobility was markedly decreased (e.g., immobilization at home or transferal to a care facility). It also gradually became difficult for some of the patients to monitor their home BP due to advanced cognitive dysfunction[22].

Recent advance and challenges in digital hypertension

Remarkable progress has been made in the "digital hypertension" research field concerning digital communication technology, artificial intelligence (AI), digital therapeutics, and the widespread use of smartphone applications[23-29]. One of the newest potential digital links between home healthcare and medical practice is home BP monitoring over an individual's lifetime trajectory[30-33]. The ability of telemonitoring advances to facilitate the sharing of patients' precise data with their physicians is promising, and it can alleviate the burden on both patients and caregivers[34-36]. However, the latest devices and applications often surpass elderly individuals' familiarity with technology, and it can be challenging for these individuals to adopt new technology without suitable adjustments or support.

Concept and rationale of the DICAP feasibility study

It is essential to compile the chronological BP data for patients across various living conditions over an extended period [Figure 1][1]. We have designed a hybrid DICAP (DIgital CArdiovascular Prevention) telemonitoring system that integrates a user-friendly cellular BP monitoring device (without using smartphones or apps) and Bluetooth devices. We have initiated a long-term assessment of BP measurements among residents, commencing a DICAP feasibility study to evaluate BP control status and variability in different living conditions within the community, aiming to elucidate their clinical implications.

METHODS

Study objectives

The DICAP feasibility study aims to determine chronological BP control status and BP variability up to the end of life in different life settings in the community and their clinical implications.

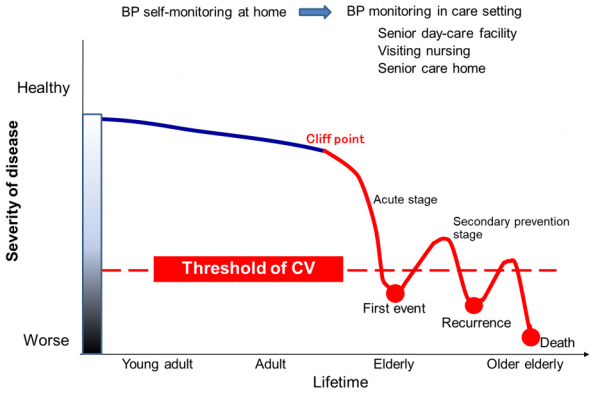

Figure 1. Trajectory of cardiovascular disease from the early stage to the late stages[1]. BP: blood pressure.

Each participant's BP control status, and diurnal, day-by-day, and seasonal BP variability will be evaluated in relation to their home and facility measurement conditions (indoor temperature, living environment). The associations of these BP metrics with (*i*) organ damage (proteinuria, eGFR) and cardiovascular events (stroke, coronary heart disease, heart failure, and aortic dissection, *etc.*) and death; (*ii*) lifestyle (smoking habit, alcohol consumption, *etc.*) and environmental factors (room temperature, seasons); (*iii*) cognitive function (MoCA-J score) and frailty (assessed by SPPB).

As an assessment of the BP management system's feasibility in the community, the study will also evaluate the participants' adherence to the self-measured home BP monitoring and the persistence rate of home BP measurements.

Study design

This will be a prospective, multi-institutional, observational study performed in Minamisanriku Town. The enrollment target is set at 500 participants; enrollment began in October 2022 and the follow-up is expected to continue until March 31, 2034. The study is being conducted in collaboration with Minamisanriku Hospital, which is the regional core hospital of Minamisanriku Town, and several local care facilities and services [Supplementary Table 1]. Patients attending Minamisanriku Hospital will be asked to provide written informed consent to participate in the study and to conduct daily home BP monitoring during the study period. In principle, BP measurements will be performed by the participants' self-measurement at home and by facility staff during nursing care. Patient background information such as office BP data, medical history, medication information, and blood and urine test results will be obtained from the patients' medical records. The study protocol was approved by the Jichi Medical University Bioethics Committee for medical Research (Rindai 22-101) and is registered in the University Hospital Medical Information Network (#UMIN000049938).

Patient information and follow-up

The inclusion and exclusion criteria for this study are shown in Table 1. Subjects who meet these eligibility criteria will be directly informed by a physician about the purpose and contents of the study before their written informed consent is obtained. The participating physicians will also assign a research ID number to each subject. For patients who have difficulty making their own consent decisions, their spouse or consanguine child may consent on their behalf.

Table 1. Study inclusion and exclusion criteria

Inclusion criteria
(1) Patients with at least one cardiovascular risk factor, history of cardiovascular disease, or autonomic nervous dysfunction (2) Patients aged ≥ 20 years
Exclusion criteria
Patients meeting one or more of the following criteria: (1) Cerebrovascular disease (except for asymptomatic or transient ischemic attack) within the past 6 months (2) Requiring hemodialysis (3) undergoing treatment for serious diseases (cancer, collagen disease, *etc.*)

The following information will be collected from the medical records of Minamisanriku Hospital: patient profiles, drug information, routine laboratory tests, electrocardiography, MoCA-J (cognitive function test), SPPB (frailty), InBody (body composition), CAVI (arterial stiffness), 24-hr BP monitoring, *etc*.

The cardiovascular outcomes (stroke and myocardial infarction), other outcomes (hospitalized angina pectoris, hospitalized heart failure, aortic dissection, peripheral artery disease, renal failure, doubling of serum creatinine, atrial fibrillation, dementia, and primary nursing care), and all-cause mortality will be followed.

The DICAP system: Concept and novel approaches

We developed the hybrid DICAP telemonitoring system combined with Cellular BP monitoring and Bluetooth devices. The present feasibility study explores the potential of data linkage and its application within the community, encompassing healthcare and medical services, including disease management. The study also seeks to contribute to further advances in community healthcare infrastructures. We introduce three innovative approaches that are currently viable and require validation.

(1) We introduce a DICAP system equipped with automatic communication for the continuous collection of home BP data [Figure 2]; (2) The implementation of BP measurements at multiple senior-care facilities will be investigated, with the aim of connecting individual BP data monitored at any of the study sites and sharing them with attending physicians; (3) The establishment of a comprehensive report system to help physicians provide feedback on BP measurement results to each patient is also being examined. The portal of the data server includes a 'management interface' where the BP measurement history. The time-trends of BP measured in different conditions and metrics of BP variability will be displayed. The study primarily involves elderly patients, yet this healthcare platform will be suitable for individuals across a broad age range and will be made available for use in diverse communities.

New cellular BP monitor for home BP telemonitoring (the LPWA system)

In this study, we initiated the implementation of a validated cellular BP monitoring device (UA-767LPWA, A&D Corp., Tokyo). This device is enhanced with an automatic direct transmission function, enabling it to operate through a public line, based on the hard and algorism of BP measurement of the previously validated device (UA-1020 upper-arm BP monitor manufactured by A&D Corp.)[37]. This monitor does not require the mobile application to send the data to the cloud data server [Figure 2]; thus, this approach ensures that even patients without familiarity with digital devices can effortlessly engage with the system. This system uses LPWA (low-power wide area) network technology, which facilitates affordable and high-speed data transmission. Patients independently monitor their BP at home, and the results are documented on their personal devices before being securely transmitted to a data server through authenticated channels.

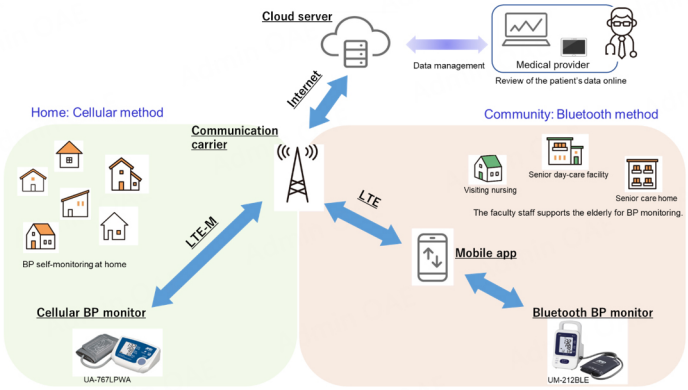

Figure 2. Platform of a cloud-based community healthcare system, DICAP, combined with Cellular (left) and Bluetooth (right) BP telemonitoring at home and multiple sites. BP: blood pressure; LTE: long-term evolution; LTE-M: long-term evolution for machines.

The BP monitor is also equipped with a temperature sensor, allowing for concurrent environmental temperature measurements during BP measurements.

BP telemonitoring with a Bluetooth BP monitor for the elderly at multiple sites

Blood-pressure measurements by validated Bluetooth BP monitoring device (UM-212BLE, A&D Corp., Tokyo)[38] conducted at multiple senior-care facilities involve the coordination of monitored individual BP data on a cloud data server, independent of the facility[Figure 2]. In the present study, these data are shared with attending physicians at Minamisanriku Hospital. BP measurements transmitted from patients' homes are similarly integrated into the data server. BP assessments at senior-care facilities catering to day service users, elderly residents in assisted living facilities, and those receiving in-home nursing care are conducted with the support of nurses and facility staff. For the present investigation, each of the participating facilities uses devices equipped with Bluetooth systems and a dedicated data collection app. A single device can facilitate BP monitoring for multiple users. All of the data obtained are stored in the designated data server for this study. By conducting analyses of this diverse dataset, we seek to validate the efficacy of remote BP monitoring within a community and identify potential issues. Our findings can serve as the foundation for future endeavors in regional and disaster healthcare globally.

BP measurement protocol

Participants who self-measure their BP at home will be loaned a home BP monitor (model UA-767LPWA manufactured by A&D Corp.) with each ID set. In accordance with The Japanese Society of Hypertension 2019 Guidelines for the Treatment of Hypertension (JSH2019)[15], each participant will measure his or her BP twice a day in the sitting position, once after waking up and once before going to bed. The first measurement should be taken after a 1-min rest, and the second measurement should be taken approx. 1 min after the first measurement. BP and temperature readings are automatically recorded in the internal memory of the monitor and transmitted to the cloud server in a state linked to the participant's ID. Room temperature is one of the important determinants of BP, especially in the elderly[39-42]. In principle, the daily home BP measurements will continue without lapses during the study period.

Each care facility will be loaned a validated home BP monitor (model UM-212BLE, A&D)[38] and a tablet device with a dedicated data collection application. Each participant's BP will be measured at least once a day by staff at each facility in accordance with the JSH2019 guidelines. When each BP measurement is completed, the BP result linked to the participant's ID is sent to the cloud server.

The preliminary results of the first 221 subjects have been enrolled and have self-measured their home BP using the above-described cellular BP monitor, and > 180,000 home BP data have been collected on the data server since this system began operating. Each participant's home BP has been measured an average of 23.0 times/week; 77.4% of the participants have been monitoring their BP > 20 times/week, and 92.3% have been monitoring their BP > 12 times/week, thus showing excellent adherence rates [Figure 3]. We will initiate a Bluetooth system for monitoring the users' BP at the multiple care-service sites by the end of 2023.

Statistical analyses

The study results will be presented using descriptive statistics (mean ± standard deviation, or number and proportion). Between-group comparisons of mean values will be performed by a one-way analysis of variance (ANOVA), and differences in prevalence rates between groups will be evaluated using the $\chi 2$-test or Fisher's exact test. The cumulative incidence of the all-combined and each cardiovascular outcome (stroke, myocardial infarction, hospitalized angina pectoris, hospitalized heart failure, and aortic dissection) and other outcomes (peripheral artery disease, renal failure, doubling of serum creatinine, atrial fibrillation, dementia, , and primary nursing care), and all-cause mortality in different groups will be determined by the Kaplan-Meier method, and the hazard ratio (HR) and corresponding 95% confidence interval (CI) values will be calculated using Cox proportional hazards models. All statistical analyses will be performed with SAS software (SAS Institute, Cary, NC). Two-sided *P*-values < 0.05 will be accepted as significant.

DISCUSSION

Benefits of using an LPWA network for telemonitoring

This study first introduces a new cellular BP monitor that uses an LPWA network so that even people unfamiliar with the application can measure their BP easily, and the objective data will be shared with medical institutions in real time and used for diagnosis.

Blood pressure variability late in the life

This study will confirm the feasibility of long-term BP monitoring in different settings, and the clinical implications of BP variability later in their life. Increased BP variability is a risk factor for the development of cardiovascular diseases and cognitive decline, leading to a worsening prognosis. In very older adults, there have been reports of a decline in BP occurring several years before death[11], but there is a lack of longitudinal evidence regarding diurnal, day-by-day, seasonal BP variabilities as well as the status of BP control in the later stages of life, continuing until the end of life.

With the DCAP system, we have telemonitored and stocked all the participants' daily home BPs for 10 years or more in the Minamisanriku area; therefore, we will clarify the clinical implication of longer-term BP variabilities and BP control status later in life by integrating the newly collected data from this DICAP system.

Blood pressure variability in different out-of-home settings in community

Even when older patients could not live themselves at home, the new DICAP system will soon start obtaining BP measurements in various settings beyond the home, including daycare facilities for the elderly, elderly housing, and home nursing care, as part of our efforts to implement multifaceted remote BP monitoring. Within healthcare systems, we aim to connect healthcare professionals through a unified cloud data server, ensuring accurate and real-time BP monitoring for community residents over the long term in cooperation with multiple facilities, and we are in the process of preparing for the implementation of a home BP measurement and data collection system.

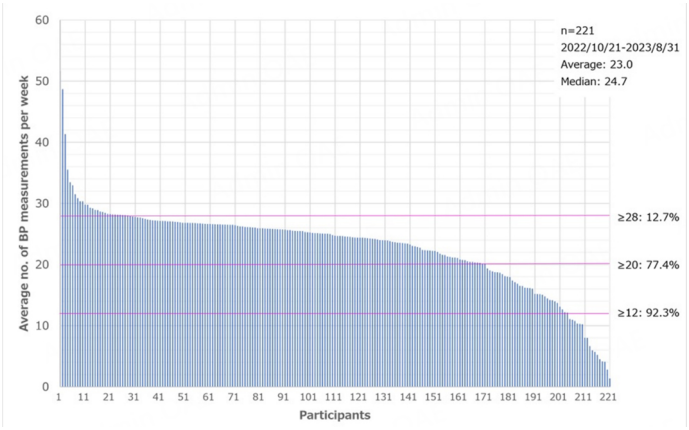

Figure 3. Average number of BP measurements per week. BP: blood pressure.

Limitations

This study is a feasibility study conducted in a single town inhibited by Japanese residents, involving a small sample size (~ 500 participants). The LPWA BP monitor used in this study has limited market penetration at this time.

Perspectives

In this research, we will continue accumulating data and will evaluate the relationships of BP variability with different situations with environmental, behavioral, risk factors, and age-related clinical outcomes including cardiovascular events, cognitive function, frailty, falls, *etc*. Our newly developed DICAP system introduces a novel cellular BP monitor that can automatically transmit measurements without the need for a specific app. We initiated its use in Minamisanriku Town as a feasibility study to confirm the possibility of the study participants' high rate of adherence to home BP monitoring. This healthcare platform will be suitable for individuals across a broad age range and will be made available for use in various regions and communities globally.

DECLARATIONS

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Authors' contributions

Made substantial contributions to the conception and design of the study: Kario K, Nishizawa M, Yasui N, Fujiwara T, Kunigita T, Harada N, Hoshide S

Participated in patient data collection: Nishizawa M

Performed data analyses and interpretation: Kario K, Nishizawa M, Yasui N, Hoshide S

Performed data acquisition and provided administrative, technical, and material support: Fujiwara T, Kunigita T

Drafted and revised the manuscript: Kario K, Harada N

Availability of data and materials

Not applicable.

Financial support and sponsorship

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Conflicts of interest

KK has received research grants from Omron Healthcare Co., A&D Co., and Fukuda Denshi Co. MN has received honoraria for lectures from Daiichi-Sankyo Co. and Novartis Pharma. NY, TF, and TK are employees of A&D Co. All other authors declare that they have no conflicts of interest.

Ethical approval and consent to participate

The study is being conducted in accordance with the Declaration of Helsinki and was approved by the Jichi Medical University Bioethics Committee for medical Research (Rindai 22-101). Participants' written informed consent to participate in the study has been obtained.

Consent for publication

The participants' data are anonymized, and consent for the use of these data was obtained from the participants.

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