Validation of Uright model TD 3127AT wireless-portable ambulatory blood pressure monitoring device with timer trigger modification, standard cuff size, in normotensive and mild hypertensive patients of Thailand registry (Thai valid ambulatory blood pressure monitoring)

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Background **Nowadays, automated blood pressure (BP) monitoring devices are commonly used by patients as a part of standard medical care for hypertension. The timer trigger was modified into a wireless automated home BP monitoring (HBPM) device to expand its potential use as ambulatory BP monitoring. However, the BP measurement accuracy in this modified device remains unknown.**

Objective **We aimed to assess the accuracy of Uright model TD 3127AT, which is an automated HBPM device with a timer trigger modification, following an International Organization for Standardization (ISO) 81060-2:2018 guidelines in the Thai population.**

Methods **This cross-sectional study included normotensive and hypertensive Thai participants following the ISO 81060-2:2018 guidelines from August 2021 to February 2022. This study aimed to compare the BP readings from an automated sphygmomanometer, Uright model TD 3127AT, TaiDoc Technology Corporation, with a timer trigger to a standard manual BP measurement.**

Result **BPs were measured in 85 participants with a mean age ± SD of 38.39 ± 13.91 years, and 69% were females. The mean SBP ± SD (range) was 117.46 ± 18.63 (84–176) mmHg and the mean DBP ± SD (range) was 74.84 ± 10.70 (42–108) mmHg. The mean BP difference between observers and devices was 0.66 ± 6.81 mmHg for SBP and −0.96 ± 6.33 mmHg for DBP. The SD of the averaged pair determination per individual was ±4.45 mmHg for SBP and ±3.46 mmHg for DBP. The accuracy of the timer-triggered device was found to be acceptable when evaluated according to the ISO 81060-2: 2018 guidelines.**

Conclusion **An automated sphygmomanometer, Uright model TD 3127AT, TaiDoc Technology Corporation, with timer trigger modification passed the ISO 81060-2:2018 guidelines. *Blood Press Monit* 27: 397–401 Copyright © 2022 The Author(s). Published by Wolters Kluwer Health, Inc.**

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Introduction

Hypertension is one of the most reported cardiovascular disease (CVD) risk factors. Approximately 32% of CVD risk is associated with hypertension in the global population [1], and hypertension account for 66% of stroke and 55% of ischemic heart disease in Thailand [2]. White coat and masked hypertension recently gained the healthcare industry's interest because of their association with mortality [1,3–5].

White coat and mask hypertension increase the mortality rate and are only diagnosed through out-of-office blood pressure (BP) monitoring. Ambulatory BP monitoring (ABPM) and home BP monitoring (HBPM) are the standard BP assessments outside hospital settings that are specifically designed to diagnose white coat and masked hypertension [6].

The inconvenience of ABPM includes an attached wire that might disturb the sleep of patients. The 3127 AT

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model, which already passed the European Society of Hypertension quality control, was selected as an innovation model to be modified by adding a timer for BP measurement [7]. The modified device was called Uright TD 3127AT, and this device is quite universally accessible in resource-limited clinical settings compared with ABPM in terms of cost and logistic issues. However, no study has validated its use as an ABPM.

Therefore, an effort was made to invent or modify readily available BP devices to perform a similar task to overcome its inconvenience and budget constraint. However, no current evidence has validated their BP measurement accuracy. This study aims to validate modified (timer-added) TD 3127AT model device accuracy in accordance with the International Organization for Standardization (ISO) 81060-2:2018 guidelines [8].

Methods

Study population

Outpatients with and without hypertension (HT) were recruited from the Department of Medicine, Faculty of Medicine, Chulalongkorn University, and Cardiac Center, King Chulalongkorn Memorial Hospital (KCMH Bangkok, Thailand). A total of 85 subjects were required. Individuals aged more than 18 years in both sexes (>30% each) and distributed levels of SBP and DBP across different hypertension classes were included following the ISO 81060-2:2018 guidelines [8]. Participants who were pregnant had chronic atrial fibrillation or had dementia were excluded.

The study protocol was approved by KCMH ethical committee. Written informed consent was obtained from all participants.

Device

Our test device will be mentioned in this text as a 'test device', which means 'Uright model TD 3127AT, TaiDoc Technology Corporation'. The test device is an upper-arm oscillometric device (Thai FDA approval number: TWN6200241, 11 January 2020) with a pressure measurement range of 0–300 mmHg, SBP measurement range of 60–255 mmHg, DBP measurement range of 30–195 mmHg, and pulse rate range 40–199 beat/min. The digital display showed readings of SBP, DBP, and pulse rate. Cuff inflation was controlled by an automatic pressure pumping system, and its deflation was controlled by an automatic pressure release valve. The power supply was driven by four alkaline batteries (1.5 V, LR03T), which enable consecutive 400–500 measurements. Wide cuff size (24–43 cm) is only available in Thailand. To ensure the determination of appropriate cuff size, the participant's arm circumference was matched, and the corresponding cuff was selected. The timer chipset (microcontroller, microchip pic12f1572 8 bit), which was developed by a Thai engineer, was set as an automatic trigger time every 15 and 30 min (Supplementary data, Supplemental Digital Content 1, *http://links.lww.com/BPMJ/A179*).

Procedure

Our procedure was designed following the ISO 2018 guidelines [8]. A team of four well-trained medical professional physicians conducted the validation procedures as observers.

With a random selection, two of them used a dual-headed stethoscope with a Y-shape tube (3M Littmann Classic II Teaching Stethoscope with combination chest piece) to simultaneously measure the BP with a traditional auscultatory technique from a standard mercury sphygmomanometer (Baumanometer mercury-gravity manometers, W.A. Baum Co., Inc., New York, USA). Bladder dimensions of approximately 80% length and 40% width of arm circumference were used to define a proper cuff size [8].

Average BP measurements were reported by two observers to a third observer who supervised and monitored the measurement process. Each observer was blinded to each other by a physical partition that was specifically designed to separate both during the measurement.

When the subject was ready after a 5–10 min rest while sitting in a quiet standard examination room with proper back support, the BP is sequentially measured with the subject's arm resting at the heart level. Two observers simultaneously measure the BP using the standard mercury sphygmomanometer with the dual head stethoscope, followed by the test device, which starts measuring by a predetermined timer trigger. These warm-up measurements were excluded from the calculation of the accuracy assessment. Thereafter, BP was measured by the observers, then by the device, and alternatively by observers until a total of nine sequential same-arm measurements are obtained (Fig. 1a). Subjects with SBP difference of more than 12 mmHg and/or DBP of more than 8 mmHg in any two of the four reference BP measurements will be excluded.

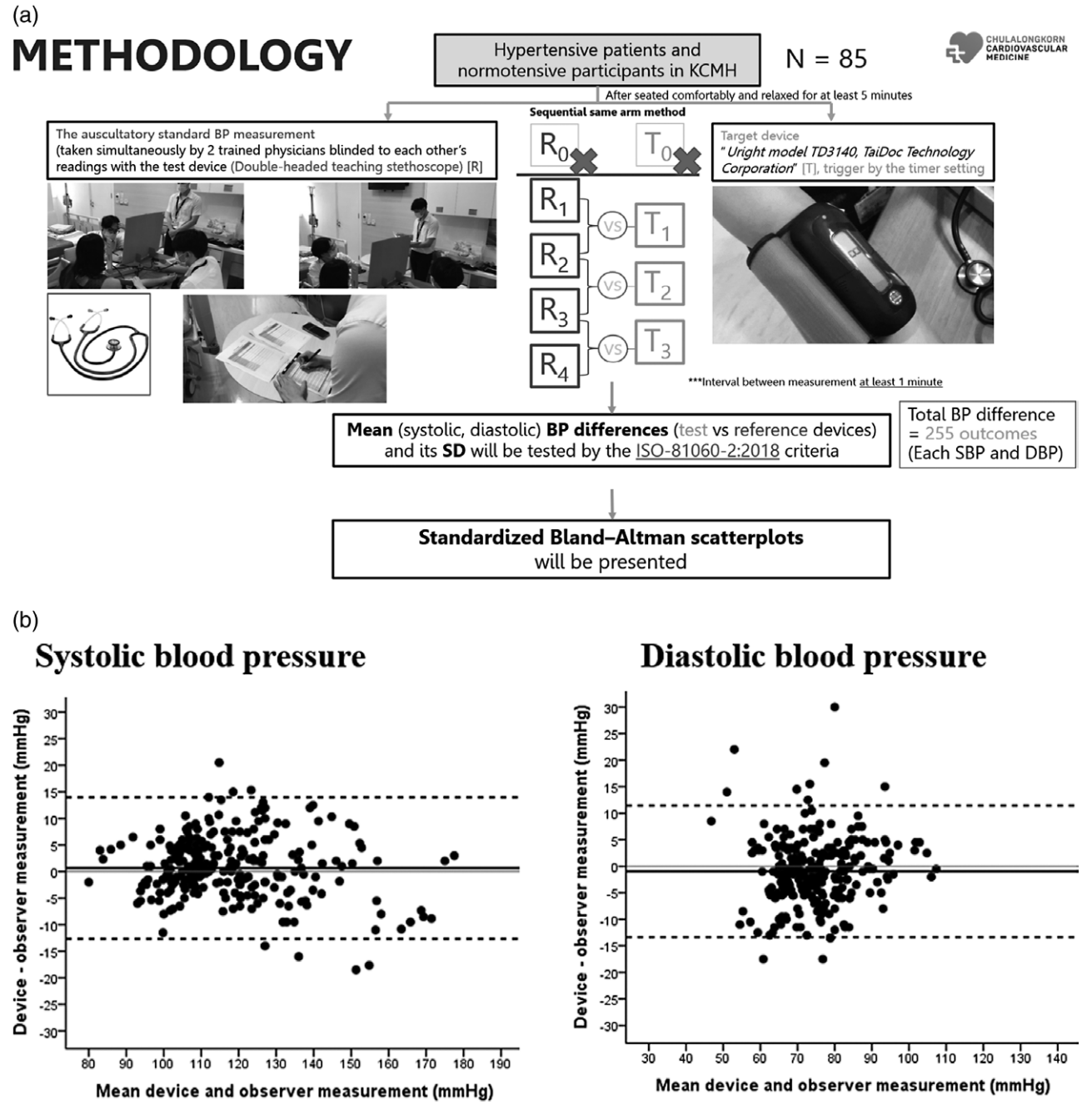
Each test device reading value was compared with the observer measurements' mean value, which was immediately taken before and after the test device reading. Hence, three comparison measurements were obtained for each subject.

Following the ISO guidelines, we allowed interobserver variation of more than 4 mmHg; otherwise, another measurement must be taken, at a maximum of eight pairs [8].

Statistical analysis

We followed criteria 1 and 2 to follow the ISO standard [8]. Mean BP difference and SD were calculated to represent those criteria. Data discrepancies were displayed with Bland–Altman plots. A logistic regression model will be performed to analyze the factors that affect the differences in BP measurement. To analyze the data, we used R programming (Vienna, Austria). *P*-values of <0.05 were configured as significance.

Fig. 1



(a) Summary methods. (b) Standardized Bland–Altman scatterplots of the comparison BP difference between the Uright model 3127AT device with timer trigger modification and observer measurements opposed to the mean BP of the both methods of the SBP and DBP.

Results

Table 1 demonstrates the baseline characteristics of 85 participants. Of the participants, the mean age was 38.39 ± 13.91 years, and 69% were females. The upper-arm circumference was 25.96 ± 3.04 cm (range: 21–33 cm); therefore, all participants used a wide-sized cuff. Upper-arm size distribution has been demonstrated in Table 1. Three consensuses verification pairs of the observer BP and test device BP were gathered. The ranges of SBP and DBP were 84–176 mmHg and 42–108 mmHg for the observer assessment and 79–167 mmHg and 49–107 mmHg for the test device BP, respectively.

Table 1 Baseline demographics of the study participants

Variables	Values
Age (mean+ SD, years)	38.4 ± 13.9
Men: women, *n* (%)	26 (30.6): 59 (69.4)
BMI (mean + SD, kg/m^2)	23.1 ± 3.8
HT, *n* (%)	18 (21.2)
Diabetes, *n* (%)	8 (9.4)
Upper-arm circumference (mean + SD, cm)	26.0 ± 3.0
Size distribution, (%)	
24.0–33.5 cm	100
33.6–43 cm	0
24.0–28.75 cm	87
38.25–43.0 cm	0
24.0–26.375 cm	56
40.625–43.0 cm	0
Reference: SBP	
≥160 mmHg, (%)	5.8
≥140 mmHg, (%)	20
≤100 mmHg, (%)	16
Reference: DBP	
≥100 mmHg, (%)	4.7
≥85 mmHg, (%)	29
≤60 mmHg, (%)	7

HT, hypertension.

Table 2 Difference blood pressure outcome between test device and observer measurements

ISO-81060-2:2018 criteria	SBP (mmHg)	DBP (mmHg)	Pass/fail
Criteria 1			Pass
Mean	0.66	−0.96	
SD	6.81	6.33	
Criteria	Mean BP difference ≤ ±5.0 mmHg SD of BP difference ≤ 8.0 mmHg		
Criteria 2			Pass
Mean	0.66	−0.96	
SD	4.45	3.46	
Criteria for SD[a]	≤6.9	≤6.87	

[a]According to ISO 81060-2:2018, a definition of the criteria for SD in criteria 2 changes interactively depending on the gathered mean BP differences.

Standardized Bland–Altman scatterplots of BPs showed differences between the observer and test device measurements with a total of 255 pairs each of SBP and SBP, as shown in Fig. 1b.

Table 2 demonstrates the summary results of the differences between the observer and test device measurements. The mean BP differences and SD of BP difference met both criterion 1, that is mean BP difference less than or equal to ±5 mmHg and SD of less than or equal to ±8.0 mmHg (0.66 ± 6.81 mmHg for SBP and −0.96 ± 6.33 mmHg for DBP), and criterion 2, which were collected from mean BP differences, that is maximum permissible SD of 6.9 and 6.87 for a mean SBP difference of 0.66 mmHg and mean DBP difference of −0.96 mmHg, respectively (0.66 ± 4.45 mmHg for SBP and −0.96 ± 3.46 mmHg for DBP), of the ISO 81060-2:2018 guidelines [8].

Discussion

Both ABPM and HBPM had proved an advantage over office BP and improve hypertensive treatment adherence [9].

Our study demonstrated the accuracy of Uright model 3127AT with timer modification device in the Thai general population regarding the ISO 81060-2:2018 guidelines. The results showed that the test device accomplishes criteria 1 and 2 of the standard ISO measurements for both SBP and DBP, indicating that this timer-modified device was reliable, accurate, and applicable to the Thai general population.

According to the 2019 NICE HT guideline, hypertension diagnosis is confirmed using the average of at least 14 BP readings from ABPM that recorded BP every 15–30 min in the daytime (8:00 a.m. to 8:00 p.m.) [10].

Other than validating the use in the Thai population, the study provides the accuracy of this modified device that can automatically measure BP every 15–30 min, displays real-time tracking through a smartphone application for positive reinforcement in medication compliance, records stores for in charge physician to maintain antihypertensive medication optimization and discloses masked, white coat, or postprandial hypertension in that particular patient. This information can then promote tailor-made or patient-centered care.

Moreover, this modified version is convenient to wear at nighttime to assess nocturnal dip. Continuous BP monitoring reliably predicts long-term worse prognosis in patients with different surge patterns, such as nocturnal, morning, etc. Additionally, the new trend in work-related health issues has gained attention as occupation-related high BP is associated with work-related health providers [11]. The modified device usage in outside settings is a novel trend to expand its clinical benefits. This modified device is more affordable and user-friendly than the standard ABPM.

The discrepancies between the test device and the standard sphygmomanometer are worth mentioning. The arterial wall stiffness and decreased arterial wall compliance become conspicuous with aging and other atherosclerosis-related risk factors [12]. These changes render an increased SBP and decreased DBP, which leads to pulse pressure widening and isolated systolic hypertension. Thus, elderly patients with risk factors, such as diabetes and HT, might have the readings using the oscillometric technique that differ from other measurement techniques [13].

Our findings provide novel information on the test device accuracy in the selected enrolled population, mainly patients with moderate hypertension and medium cuff size. Thai patients generally have slender arms, whereas some other countries, such as the USA, might require a larger cuff size in a significant proportion of their patients. Thus, our study outcome might not be translated to patients with thick arms [14].

Our study has limitations. First, this test device has not been tested for the conventional ABPM. Hence, this method is the first step to paving the way to the official

validation of clinically proven ABPM usage. However, further studies are required to assess its validity compared with standard ABPM. Second, the number of hypertensive participants was quite small, and the result might not apply to the more severe hypertensive population but translates it into a larger-scale population with a normotensive or mild hypertensive range. Third, we only use the standard cuff size of the test device measurement, and no small cuff size or large cuff size was tested. Finally, the arm circumference distribution of the patients was not evenly recorded, and the extreme category data remain unknown. This result arises from the local anthropology of the Thai population, which has an average upper-arm circumference of 26 ± 2.6 cm [15].

Conclusion

To the best of our knowledge, this study is the first to demonstrate the test device, Uright model 3127AT with timer modification, which has passed the validation criteria based on ISO 81060-2: 2018 guidelines for self-BP monitoring. Comparing the BP measurement with ABPM is required in future studies for its adaptive use as an ABPM.

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All authors had access to the data and contributed to the writing of the manuscript.

Conflicts of interest

There are no conflicts of interest.

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