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# Measuring Blood Pressure in the Office: The Argument for Wider Clinical Use of Automated Devices

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## Abstract

**Objective:** Accurate measurement of blood pressure (BP) remains a fundamental step in diagnosing and managing hypertension. The aim of this study is to evaluate the accuracy of office BP measurement using an automated office blood pressure (AOBP) device (BpTRU®) performed in a 5-minute cycle.

**Participants and methods:** 117 consecutive patients (mean age 55 ± 17 years, 60% women) referred for management of hypertension over a nine-month period are included in this study. BP readings with the BpTRU® device (BP recorded five times in five minutes), mean awake ambulatory blood pressure (ABP), and routine BP readings taken in the patient's primary care physician (PCP) office were compared.

**Results:** Average of 5 BP readings for mean blood pressure using the AOBP device was similar to the mean awake ABP (systolic BP 133 ± 4 mmHg vs.135 ± 3 mmHg; (p = 0.2) and diastolic BP 80 ± 2 mmHg vs. 79 ± 2 mmHg; (p = 0.7)). Both systolic AOBP and awake ABP values were significantly lower than the systolic BP recorded in PCP office (144 ± 5 mmHg) (p < 0.001). The coefficient of correlation between the mean systolic/diastolic AOBP and the mean of awake ABP (r = 0.70/0.72) was highly significant (p < 0.001). With the AOBP device, the first systolic reading was significantly higher than the average of the 2nd to 6th systolic readings (141 ± 2 mmHg vs. 133 ± 4 mmHg, p < 0.001).

**Conclusion:** BP measurement performed with the AOBP device in a 5-minute cycle more accurately measures BP in a physician office setting when compared to single BP measurement. Relying on the first BP measurement or a single reading may lead to over estimation of BP.

**Keywords:** Hypertension; Automated blood pressure device; Ambulatory blood pressure; White coat effect

## Background

Hypertension is a well-established risk factor for heart disease, stroke, and kidney disease [1,2], and the treatment of hypertension is a leading reason for physician visits in the United States [3]. It is critical to measure blood pressure accurately in order to appropriately guide its management. Most therapeutic decisions regarding hypertension management are still largely based on casual blood pressure measurements taken in the physician's office. These measurements are limited given that they are only snapshots of a very dynamic entity. They can be rife with operator errors, rely on only one or two measurements, and are often skewed by the white-coat effect, which can all lead to inaccurate blood pressure readings, and as a consequence, inappropriate therapy and increased health-care costs [4].

While the 24-hour ambulatory blood pressure monitoring (ABPM) measurements have been shown to be a good predictor of cardiovascular disease and a better reflector of 'true' blood pressure [5-7], it is expensive and may be cumbersome to use, and not widely available. Automated blood pressure measurement devices (such as the BpTRU® device) in the office have been reported to correlate closely with ABPM measurements, and to produce accurate, consistent, and reliable readings, as well as reduce measurement errors related to the white coat effect [8-11].

In this study, we report the Cleveland Clinic experience of using an automated office blood pressure measurement device, and the potential for its widespread application and utility in a large, busy, healthcare system. The specific aims of this study are 1) to assess whether blood pressure measurements obtained with the automated BpTRU® device (BpTRU® Medical Devices, Coquitlam, BC Canada) during a five minute period (using one-minute intervals) correlate with 24-hour awake blood pressure measurements, and 2) to assess the differences in blood pressure measurements obtained with the BpTRU® device compared to usual office blood pressure readings. We also briefly review other studies that examined the use of the BpTRU® device.

## Methods

### Patient population

Eligible subjects involved in this study were patients with known hypertension, who were referred by their primary care physician's (PCP) office in the Cleveland Clinic health system to the Department of Nephrology and Hypertension at the Cleveland Clinic for ABPM, for whom BpTRU® measurement of blood pressure was also obtained in our clinic before the 24-hour ambulatory monitor was placed, between the period of January 1, 2009 and September 30, 2009. Patients whose anti-hypertensive medication regimen was not consistent through the duration of PCP office referral and the time of 24-hour ABPM study were excluded. A retrospective chart review of the

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Cleveland Clinic electronic medical record was performed to obtain clinical data including age, gender, race, last PCP office blood pressure measurement prior to being seen by a hypertension specialist, and co-morbid conditions including diabetes, stroke, chronic kidney disease (CKD), and cardiovascular disease.

## Procedures

### BpTRU® Blood Pressure Measurement

The BpTRU® device uses the oscillometric technique used by most ambulatory and home blood pressure monitors. An appropriately sized blood pressure cuff was placed on the patient's arm and the patient was positioned for blood pressure measurement based on the American Heart Association criteria [14]. The blood pressure cuff was placed with the bladder midline in the upper arm over the brachial artery pulsation, without restrictive clothing, such that the middle of the cuff is at the level of the right atrium. The first reading was taken by a trained technician using the BpTRU® to verify that the cuff had been placed in the correct position so that the readings were valid. This initial reading was taken while the technician was present, and then discarded. Five additional measurements were subsequently taken at intervals of one minute while the patient was alone in the room, which were then averaged and taken as the mean BpTRU® blood pressure measurement. The BpTRU® device displays the mean of the last five blood pressure and heart rate measurements, as well as the individual readings for purposes of verification.

### 24-hour Ambulatory Blood Pressure Measurement

After the BpTRU® measurement was performed, a 24-hour ABPM was placed on the same day for obtaining blood pressure measures for the next 24 hours. This was done utilizing a Space Labs 90207® device (Space Labs Inc., Issaquah, Washington, USA). The device was programmed and placed on the non-dominant arm, and patients went home with the device with instructions to engage in their routine daily activities. Systolic and diastolic blood pressure and heart rate measurements were taken automatically every twenty minutes during the day and every hour at night for a 24-hour period. Awake and sleep times were determined by patient self-report. The devices were returned at the end of the 24-hour period, and data from the device was analyzed by the Space Labs Ambulatory Blood Pressure Report Management System® for mean 24-hour, mean awake, and mean sleep time systolic and diastolic blood pressures.

### Blood Pressure Measurement in PCP office

All patients in this study were referred from a PCP office within the Cleveland Clinic health system. This includes family medicine and internal medicine clinics at the Cleveland Clinic main campus, as well as satellite clinics in the greater Cleveland area. Blood pressure measurements were taken with an aneroid-based sphygmomanometer by a medical assistant, nurse, nurse practitioner, or physician. The blood pressure from the last PCP office visit was taken from the electronic medical record and recorded as the PCP blood pressure. All PCP blood pressure measurements were within three months of ABPM and BpTRU® recordings.

### Statistical Analysis

Blood pressure readings with the BpTRU® device using one-minute intervals, mean awake ambulatory blood pressure, and blood pressure readings taken in the PCP office were compared using analysis of variance with minimum level of statistical significance set at $p < 0.001$. Mean ± Standard Error of Mean (SEM) was calculated for each modality of blood pressure measurement. Pearson coefficients of correlation were computed comparing the mean BpTRU® readings and the mean awake ambulatory blood pressures. Individual data for the mean BpTRU® readings and the mean awake ambulatory blood pressures were assessed using a Bland-Altman plot.

## Results

We studied 117 consecutive known hypertensive patients, of which 70 (60%) were female and 47 (40%) were male. The age range of the patients was 16-92 years. 65% of patients in this study were Caucasian, and 24% were African American. Based on review of the electronic medical records of listed prior diagnoses, 22 (19%) patients had diabetes mellitus, 12 (10%) had coronary artery disease, 7 (6%) had CKD, and 6 (5%) had prior stroke. All subjects were on at least one anti-hypertensive medication at the time of the study.

The mean automated systolic and diastolic blood pressures using the BpTRU® device was similar to the mean awake ambulatory blood pressure (systolic BP 133 ± 4 mmHg vs.135 ± 3 mmHg; ($p = 0.2$) and diastolic BP 80 ± 2 mmHg vs. 79 ± 2 mmHg; ($p = 0.7$)). The Pearson coefficient of correlation between the systolic and diastolic blood pressures taken by the BpTRU® device and the mean awake ambulatory blood pressure was highly significant ($r = 0.70 / 0.72$, $p < 0.001$). (Figure 1A,B)

The Bland-Altman plots of agreement between mean daytime ambulatory blood pressure and BpTRU® reveal a mean difference ± SEM for systolic and diastolic blood pressures of -2 ± 16 mmHg and 0 ± 8 mmHg, respectively (Figure 2A,B).

Both BpTRU® and awake ambulatory systolic blood pressure values were significantly lower than the systolic blood pressure recorded at the PCP office (systolic BP 144 ± 5 mmHg; $p < 0.001$) (Figure 3). With the BpTRU® device, the first systolic reading was found to be significantly higher than the average of the 2nd to 6th systolic readings (141 ± 2 mmHg vs. 133 ± 4 mmHg; $p<0.001$)

## Discussion

Health care professionals experience many obstacles when managing patients with hypertension. Some of these barriers include inconsistent office blood pressure measurements and the white coat effect. This calls for the need for a measurement approach that is more efficient, reliable, practical, and accurate. ABPM is considered to be the current gold-standard in blood pressure measurement; however, its chronic use may be costly and impractical, especially for monitoring blood pressure after every lifestyle modification or medication change. This study shows that an automated blood pressure monitor can be effectively and efficiently used in a large, busy office setting to measure blood pressure more accurately. This study was conducted in a clinical setting and the blood pressure readings were obtained as part of routine clinical care to reflect real-life practice.

Our results are consistent with several studies that have shown evidence that the BpTRU® device may be used as an alternative modality to help make clinical decisions regarding hypertension diagnosis and management [8-11]. Various intervals from between 1 to 5 minutes between the blood pressure measurements have been used with fairly good results. This study also compellingly shows that using the BpTRU® device with one-minute intervals, discarding the first reading, and taking the mean of the 2nd through 6th readings, is similar to the mean awake blood pressure on ABPM.

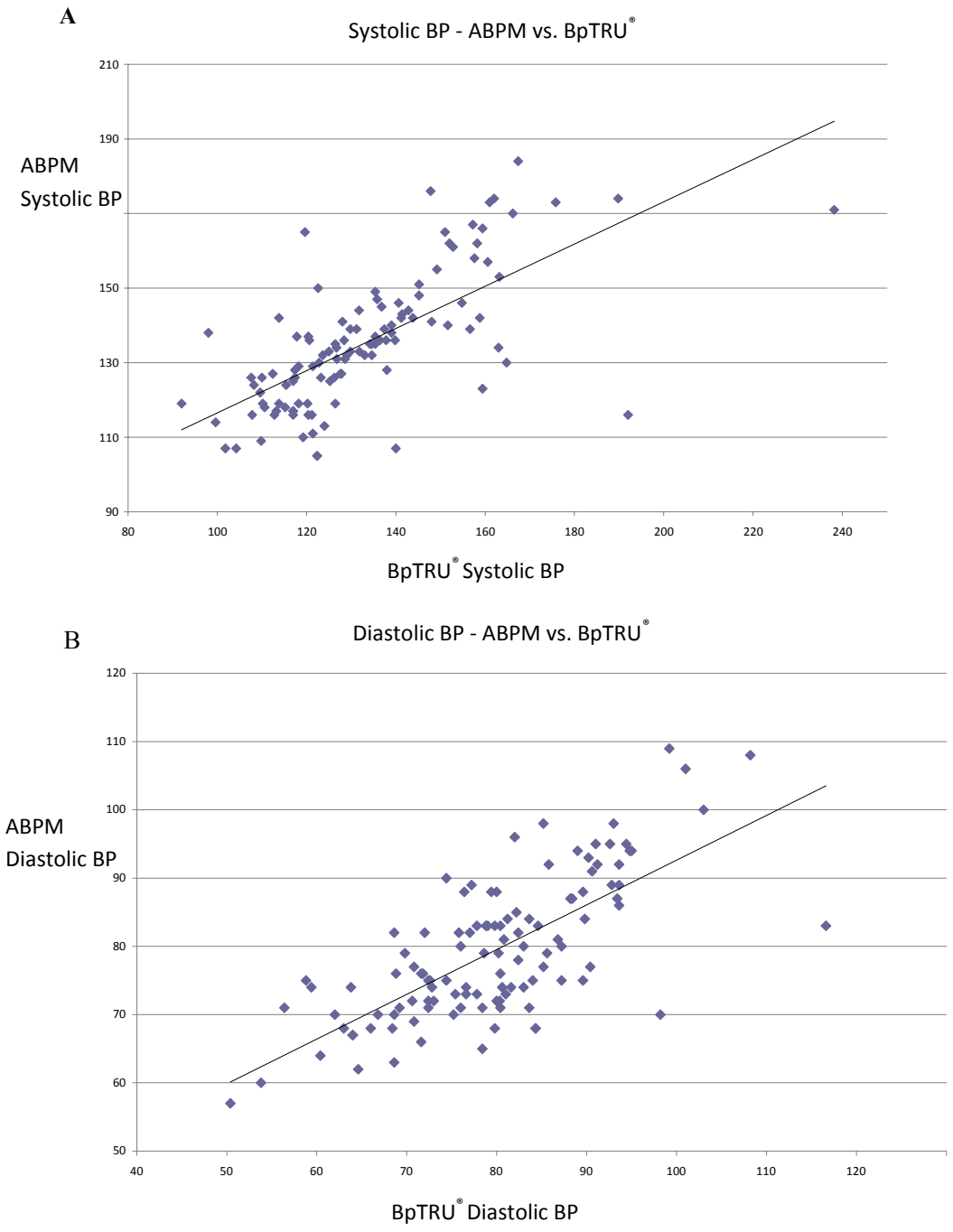


**Figure 1:** Scatter plots of mean daytime ambulatory blood pressure (ABP) against mean BpTRU for systolic (upper panel) and diastolic (lower panel) blood pressures. The solid line represents the regression line with Pearson correlation coefficients of 0.70 and 0.72, respectively, p<0.001.

In an earlier study, Myers et al. [15] studied 22 hypertensive patients using 2-minute intervals with the BpTRU®, and compared the mean of the 2nd and 3rd readings to mean wake-period ABPM. Their findings indicated that the 24-hour mean awake ambulatory blood pressure was lower than the mean BpTRU® reading [15]. It is possible that taking only 3 consecutive recordings did not allow for enough time to reduce the white coat effect. A subsequent study reported by Myers with two groups of 200 patients each who had BpTRU® measurements at either 1- or 2-minute intervals, utilizing the average of 5 readings, and comparing each group to their respective 24-hour mean awake ambulatory blood pressures, found that the mean BpTRU® was similar to 24-hour mean awake ambulatory blood pressure for both intervals (except for diastolic blood pressure readings, which were significantly lower when compared to ABPM) [9]. The same study group led by Myers also reported findings from 309 patients comparing the last PCP blood pressure, mean awake ambulatory blood pressure, and BpTRU®

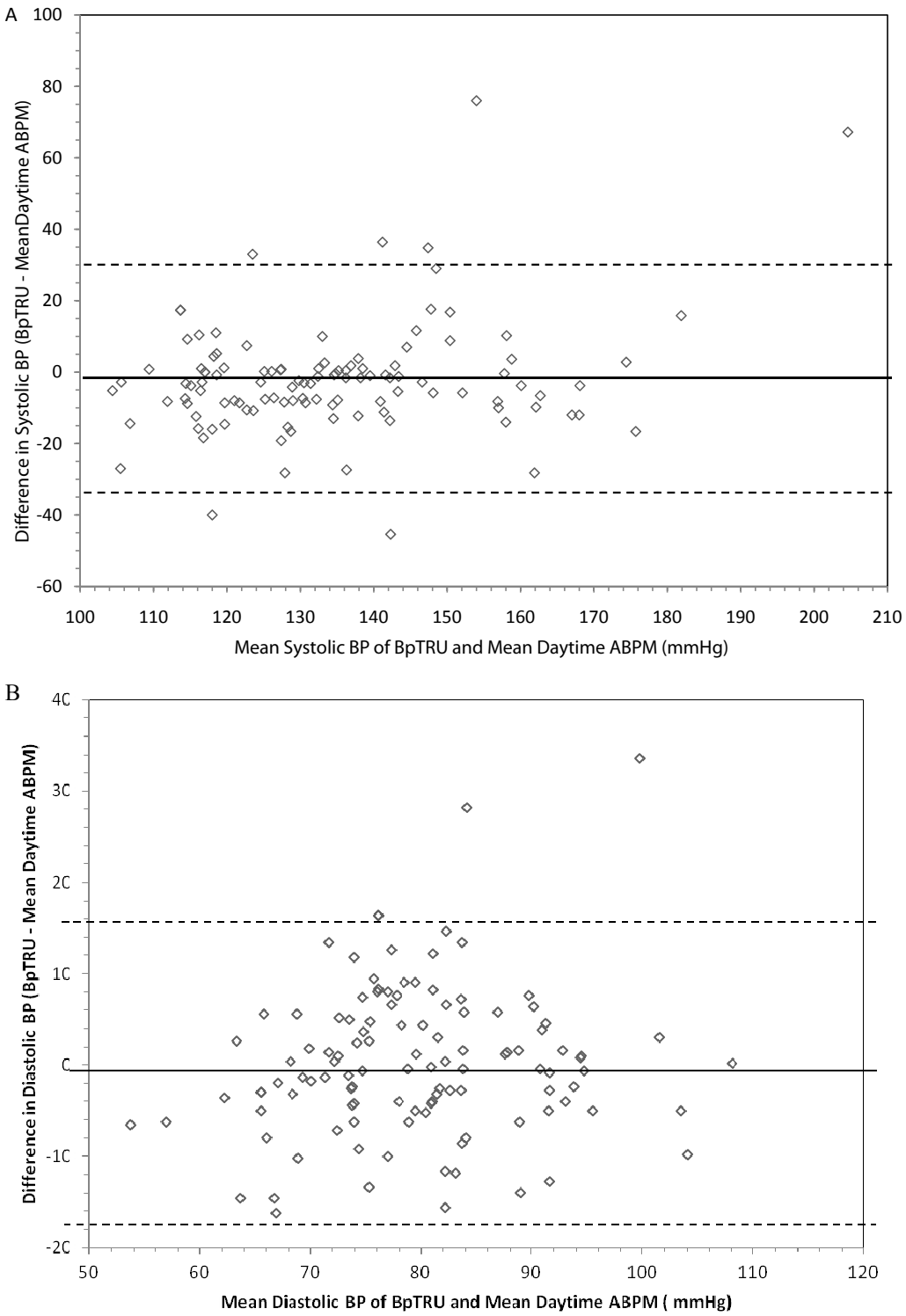


**Figure 2:** Bland-Altman plots of BpTRU and mean daytime ambulatory blood pressure (ABP) for systolic (upper panel) and diastolic (lower panel) blood pressures. The solid horizontal line represents the mean difference between the two measurement techniques. The dashed horizontal lines represent ± 2 standard deviations.

using 1- and 2-minute intervals. Blood pressure recorded with BpTRU® was similar to the mean awake ambulatory blood pressure, and both these measures were significantly lower than the last PCP blood pressure, indicating that the white coat response was significantly lower with BpTRU® compared with last PCP blood pressure [10]. Another study by Myers et al. [11] in 62 patients compared manual blood pressure recorded by a technician with 3 BpTRU® readings on separate occasions - before ABPM, just prior to ABPM, and after

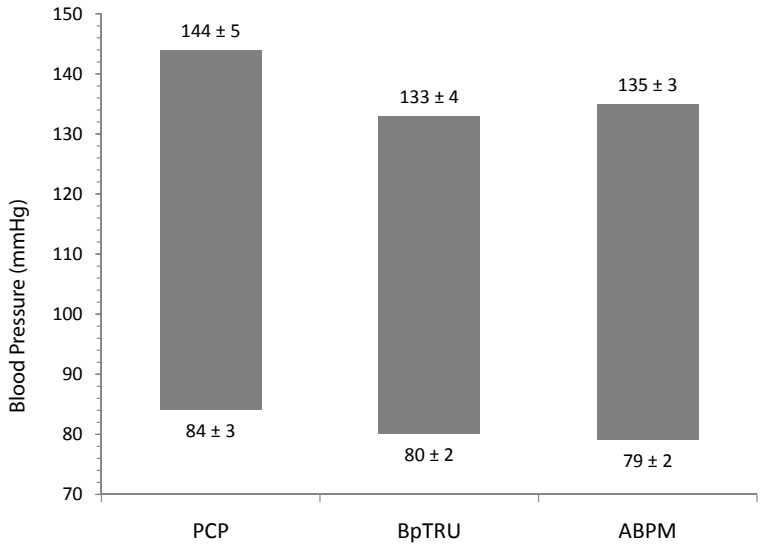


**Figure 3:** Systolic and diastolic blood pressure measurements (PCP office, BpTRU, and ambulatory measurements (ABP)), Mean ± SEM. ($p < 0.001$ for BPTru® and ABPM compared to PCP).

ABPM - using intervals of 1 or 2 minutes for the BpTRU® recordings. They reported no differences among the three BpTRU® readings, and they were all similar to the mean awake ambulatory blood pressure with good agreement among the three BpTRU® readings, thus demonstrating consistent visit-to-visit measurements [11]. Beckett and Godwin investigated 481 known hypertensive patients in a research setting using the BpTRU® and 24-hour ABPM. They had a similar design as our study in that they compared the mean of the 2nd through 6th BpTRU® readings to 24-hour mean awake ambulatory blood pressures, and found that they were similar. They also found that the initial BpTRU® reading was significantly higher than the mean BpTRU® and mean awake ambulatory blood pressure measurements. They reported using between 1 - 2 minute intervals on the BpTRU® measurements, and conducted their study primarily in a research setting, rather than a clinical setting [8]. Culleton et al. [12] studied 107 patients and compared 24-hour mean awake ambulatory blood pressure with the mean of the 2nd through 6th BpTRU® readings using 5-minute intervals found that the white coat effect was reduced with BpTRU® , however, it underestimated blood pressure compared to 24-hour mean awake ambulatory blood pressure. It was suggested that a protocol of 5-minute intervals not be used on the basis of these results. Besides, the use of five-minute intervals would take much more time than could practically be useful in a typical office setting. Graves et al. [13] reported a 92% agreement between a mean of 6 blood pressure readings taken at 3-minute intervals with the BpTRU® device and the mean readings from a nurse specialist's measurement, however, this was not compared to ambulatory blood pressure readings [13]. A recent randomized controlled trial in 555 patients comparing manual office blood pressure with BpTRU® measurements confirmed that the accuracy of automated office blood pressure in relation to the awake ambulatory blood pressure was better than manual office blood pressure, and the white coat effect was significantly reduced as well [16].

The white coat effect, which is a transient elevation in office BP caused by an alerting reaction when BP is measured by a physician or a nurse, can last for several minutes. Mancia et al quantitatively described the white coat effect in patients who underwent intra-arterial monitoring during which time a physician checked their blood pressure repeatedly in 10 or 15 minute periods, and showed that almost all patients demonstrated the white coat effect [17]. Utilizing an AOBP device may help reduce this phenomenon, as noted in this study and reported in other studies using this device.

The potential cost implications for the AOBP device should also be considered. Oftentimes, due to a white coat effect, single blood pressure measurements in the PCP office often leads to over-treatment with antihypertensive agents. In one study, upwards of 25% of patients followed for one year with ABPM after discontinuation of antihypertensive therapy were able to remain off drug therapy [18]. This indicates that the drug therapy was probably initially started because of white coat effect, suggesting wasted healthcare dollars. Utilizing an AOBP device could thus be potentially cost-effective, and more studies are needed to examine this.

This study has the inherent limitations of a retrospective review. One limitation of this study is the measurement of blood pressure in the PCP office. Although all PCP offices are within the Cleveland Clinic health system and utilize aneroid-based sphygmomanometers to measure office blood pressures, the technique and apparatus was not regulated or standardized, and different health care personnel with varying degrees of awareness of blood pressure measurement techniques were involved in these measurements. This re-emphasizes the point, however, that it is difficult to standardize routine office blood pressure measurements. One of the aims of this study was to compare the BpTRU® device against *routine (casual)* office blood pressure measurements. If this were done prospectively with a standardized approach to office blood pressure measurements, this would not emulate real life. The Hawthorne effect would also likely play a large role in confounding the data.

Another potential limitation of this study is that the threshold for defining hypertension or therapeutic goals based on AOBP device readings are yet to be clarified. Long-term outcome studies utilizing

AOBP device measurement in the general population are needed to ascertain this information.

## Conclusions

Accurate blood pressure measurement is important in the diagnosis of hypertension, and its treatment is difficult to monitor optimally on the basis of traditional office blood pressure measurements. To better manage patients with hypertension, we need to consider better and more accurate modalities of blood pressure measurement, such as ABPM, automated measurements in the office, and measurements in the patient's home.

Office blood pressure measurements provide information about cardiovascular and mortality risk, however, blood pressure is a dynamic entity with inherent minute-to-minute variability, and measurements will not be accurate if the correct technique is not followed. Traditional office sphygmomanometry with a single blood pressure measurement is a snapshot, and may not accurately reflect a patient's blood pressure in the real world and in real time. There is increasing evidence that ABPM measurements more accurately represent a patient's true blood pressure and are better predictors of cardiovascular risk than routine office blood pressures measurements. Given that ABPM may not be readily available, costly, and often not practical to use on a long-term basis with every office visit or medication adjustment, the need for a reliable office blood pressure measurement modality is crucial.

This study demonstrated two important concepts regarding hypertension and blood pressure measurements. We have shown that blood pressure measurements performed with an automated device using one-minute intervals in a 5-minute cycle more accurately measures systolic blood pressure in a physician office setting when compared to usual blood pressure measurement performed in the PCP office, using ABPM as the gold-standard. We have also illustrated that relying on the first blood pressure measurement (from the automated device) or a single PCP office reading may lead to over estimation of blood pressure, likely as a result of the white coat effect. This data suggests that an automated device would be superior to routine office blood pressure measurements and closely approximates ABPM. It also suggests that the problems with white coat effect experienced in the office may be reduced when using an automated device. With its accuracy, efficiency, and ease of use, the BpTRU® device used in our study shows promise as an adjunct to the diagnosis and management of hypertension, and automated blood pressure devices should be strongly considered for routine use in the physician office setting.

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