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Editorial

Evaluation of Applicability and Accuracy of a New Form of Cuffless Blood Pressure Measurement Device, CART-I Plus

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▸ See the article "Feasibility and Effectiveness of a Ring-Type Blood Pressure Measurement Device Compared With 24-Hour Ambulatory Blood Pressure Monitoring Device" in volume 54 on page 93.

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Blood pressure (BP) is a vital sign routinely assessed in clinical practice and is a key determinant of cardiovascular disease risk. Accurate BP measurement is the most important factor in the diagnosis, treatment, and prognostic assessment of hypertension, a major global risk factor for disability and mortality. BP can vary significantly depending on the measurement environment, site, and clinical circumstances. Recent hypertension guidelines recommend using home BP measurement or ambulatory BP monitoring (ABPM) methods in addition to clinic BP measurements. Upper arm cuff BP device is widely used for the office, home, and ambulatory BP measurement in clinical practice, and is the reference for assessing novel BP measurement technologies.[1)2)] Despite its widespread use, cuff-based BP measurement has limitations. It offers only intermittent measurements and is prone to errors related to cuff size, shape, and positioning. These limitations can potentially impact the accuracy of BP readings, as cuff-based BP methods are unable to capture rapid and dynamic changes in response to daily challenges.

Recent developments in cuffless technologies, embedded in wearable devices and smartphones, aim to address these limitations.[3)] These innovations enable comfortable and continuous BP monitoring, avoiding cuff-related issues and providing detailed information on circadian patterns. Cuffless BP measurement technologies in wearable devices and smartphones have the potential to enhance hypertension awareness, enable self-monitoring, and improve treatment adherence.[4)] However, their widespread adoption is currently driven more by financial considerations than scientific validation.

The study conducted by Lee et al.[5)] published in the current issue of the *Korean Circulation Journal* demonstrated that CART-I Plus, a ring-type cuffless BP monitoring device, exhibits promising accuracy in estimating BP measurements across various time periods when compared to traditional 24-hour ABPM. Moreover, the CART-I Plus demonstrated improved accuracy and strong correlations with ABPM readings when compared to wrist-worn cuffless BP devices and photoplethysmogram (PPG)-based smartwatches used in previous studies. The device also showed a perfect area under the curve of 1 in receiver operating characteristic analysis for both systolic BP and 24-hour BP measurements.[5)] These findings suggest that the CART-I Plus has significant potential for continuous BP monitoring in clinical practice, offering a user-friendly and potentially transformative approach to hypertension management.

Data Sharing Statement

The data generated in this study is available from the corresponding author upon reasonable request.

Author Contributions

Conceptualization: Shin JH; Investigation: Shin JH; Validation: Shin J; Writing - original draft: Shin JH; Writing - review & editing: Shin JH, Shin J.

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However, before recommending these devices for clinical use, fundamental questions regarding their accuracy, performance, and implementation need to be addressed. This is particularly important for cuffless devices, which require different validation protocols than classic cuff-based BP monitors. The Association for the Advancement of Medical Instrumentation/European Society of Hypertension (ESH)/International Organization for Standardization (ISO) Universal Standard (ISO 81060-2:2018),[6] the established validation protocol for cuff-based BP devices, is considered unsuitable for the validation of cuffless devices. This is due to the need for individual user calibration, measurement of intra-personal BP changes and the presence of unique features. Therefore, more sophisticated validation procedures are necessary, including addressing issues related to individual cuff calibration, post-calibration measurement stability, the capability to track BP changes, and the integration of machine learning technology.[7] Currently, there are no generally accepted protocols for validating cuffless BP measuring devices to ensure adequate accuracy for clinical use. The ESH Working Group on BP Monitoring and Cardiovascular Variability has recently recommended procedures for validating intermittent cuffless BP devices. The ESH recommends six validation tests for cuffless BP devices. These include the static test for absolute BP accuracy, device position test for hydrostatic pressure effect robustness, treatment test for BP decrease accuracy, awake/asleep test for BP change accuracy, exercise test for BP increase accuracy, and recalibration test for cuff calibration stability over time. Successful completion of all required tests is necessary for clinical recommendation of a cuffless BP device according to its type.[8] The aforementioned study presented the results of the awake/asleep test, one of the six tests recommended by the ESH. Although the sample did not reach the computed size of 35 in the validation protocol and BP distribution was not specified in detail, the results from 33 participants were satisfactory and were able to meet the test criteria, which requires a mean difference of ≤5 mmHg and standard deviation of ≤8 mmHg in the awake-asleep systolic BP/diastolic BP change between the test and reference devices, and a correlation coefficient of ≥0.70 in the awake-asleep BP changes (for both systolic and diastolic BPs) between the test device and a validated oscillometric upper arm cuff device as reference. The results suggest that CART-I Plus can accurately track awake/asleep BP changes. However, according to the ESH recommendations, further validation tests are required for the use of CART-I Plus in the evaluation and management of hypertension due to its requirement for individual user cuff calibration.

In the study by Lee et al.,[5] it was noted that simultaneous BP measurements via ABPM and CART-I Plus worn on the same arm were not possible. CART-I Plus is classified as an intermittent device according to the ESH validation recommendation for cuffless devices.[8] The test data from CART-I Plus were averaged readings from a 15-minute time window around the ABPM readings. Another recent study investigated the potential of a PPG-based, cuffless, watch-like device for 24-hour ABPM compared to the conventional oscillometric brachial cuff, with a test data window limited to 20 seconds around ambulatory BP measurements.[9] The width of the time window could be an important factor in the error between test and reference values, for which there is no specific recommendation. Theoretically, as the test readings are taken at a separate time from the ABPM time point, the test readings should be different from the reference readings, not because of the accuracy of the device, but because of the intrinsic changes in BP. On the condition that the test readings close to the ABPM time point are accurate, the other test readings of the CART-I Plus could reflect real features of the individual's BP that cannot be detected by ABPM measured at 20-minute intervals.

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Cuffless BP monitoring has the potential to optimally estimate the true burden of hypertension over time. This can be achieved by offering a comprehensive evaluation of BP levels and behavior throughout various daily circumstances and extended durations, requiring minimal user intervention and avoiding discomfort associated with cuff inflation. Therefore, cuffless BP devices have considerable potential to transform the diagnosis and management of hypertension. This study provides valuable information about the accuracy and potential clinical implications of the CART-I Plus device, paving the way for further research and development in the field of cuffless BP monitoring technology.

REFERENCES

1. Kim HL, Lee EM, Ahn SY, et al. The 2022 focused update of the 2018 Korean Hypertension Society guidelines for the management of hypertension. *Clin Hypertens* 2023;29:11. PUBMED | CROSSREF
2. Stergiou GS, Palatini P, Parati G, et al. 2021 European Society of Hypertension practice guidelines for office and out-of-office blood pressure measurement. *J Hypertens* 2021;39:1293-302. PUBMED | CROSSREF
3. Lee HY, Burkard T. The advent of cuffless mobile device blood pressure measurement: remaining challenges and pitfalls. *Korean Circ J* 2022;52:198-204. PUBMED | CROSSREF
4. Choi DJ, Park JJ, Yoon M, et al. Self-monitoring of blood pressure and feed-back using APP in treatment of uncontrolled hypertension (SMART-BP): a randomized clinical trial. *Korean Circ J* 2022;52:785-94. PUBMED | CROSSREF
5. Lee H, Park S, Kwon H, Cho B, Park JH, Lee HY. Feasibility and effectiveness of a ring-type blood pressure measurement device compared with 24-hour ambulatory blood pressure monitoring device. *Korean Circ J* 2024;54:93-104. PUBMED | CROSSREF
6. Stergiou GS, Alpert B, Mieke S, et al. A universal standard for the validation of blood pressure measuring devices: Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO) collaboration statement. *J Hypertens* 2018;36:472-8. PUBMED | CROSSREF
7. Stergiou GS, Mukkamala R, Avolio A, et al. Cuffless blood pressure measuring devices: review and statement by the European Society of Hypertension working group on blood pressure monitoring and cardiovascular variability. *J Hypertens* 2022;40:1449-60. PUBMED | CROSSREF
8. Stergiou GS, Avolio AP, Palatini P, et al. European Society of Hypertension recommendations for the validation of cuffless blood pressure measuring devices: European Society of Hypertension working group on blood pressure monitoring and cardiovascular variability. *J Hypertens* 2023;41:2074-87. PUBMED | CROSSREF
9. Proença M, Ambühl J, Bonnier G, et al. Method-comparison study between a watch-like sensor and a cuff-based device for 24-h ambulatory blood pressure monitoring. *Sci Rep* 2023;13:6149. PUBMED | CROSSREF

https://doi.org/10.4070/kcj.2024.0016