JACC: BASIC TO TRANSLATIONAL SCIENCE
VOL. 2, NO. 6, 2017

ISSN 2452-302X
https://doi.org/10.1016/j.jacbts.2017.11.001

EDITORIAL COMMENT

The Slow Evolution of Blood Pressure Monitoring

But Wait, Not So Fast!*

Florian Rader, MD, MSc, Ronald G. Victor, MD

The history of blood pressure (BP) measurement is one with surprisingly few impactful advances. As eloquently described by Jeremy Booth (1), the estimation of BP originated in 1733, when Sir Stephen Hales introduced a brass pipe connected to a glass tube into a horse's leg artery, and observed the rise of the blood column to "8 feet and 3 inches above the level of the left ventricle." Almost 100 years later (1828), Jean Léonard Marie Poiseuille described the first mercury manometer for the measurement of arterial pressure in his doctoral dissertation. Carl Ludwig improved Poiseuille's manometer, and added the ability of real-time tracing of the arterial pressure wave with his kymograph. These pressure tracings looked much like those obtained from standard arterial lines in modern clinical intensive care. To obtain a BP estimate noninvasively was not possible until 1855, when Vierodt was the first to quantify arterial BP by measuring the pressure required to obliterate an artery. This same principal was applied in the revolutionary method developed by Riva-Rocci in 1896 and was further improved by adding a wider inflatable arm cuff by von Recklingshausen in 1901. Although these methods focused on the estimation of systolic BP, several years later, small changes in BP amplitude (i.e., oscillations) during cuff deflation were appreciated on the sphygmomanometer and would define diastolic BP. The Russian surgeon Nicolai Korotkoff reported in 1905 that these oscillations can easily be heard with a stethoscope to determine both systolic and diastolic BP, which ultimately has defined the clinical assessment of BP to the present day. In the past century, there have been many refinements regarding optimal cuff sizing, rate of cuff deflation pressure, accuracy of Korotkoff sound detection by automated methods, and importantly, smaller wearable devices for the estimation of ambulatory (i.e., daytime, nighttime, and 24-h average) BP have improved the detection and management of hypertension (HTN) immensely (2). It also has become clear that summary data of BP readings obtained in daily life surpass by far the predictive power for cardiovascular events of isolated in-clinic measurements, because these are flawed by overestimation (i.e., white-coat HTN), underestimation (i.e., masked HTN), and ignorance of the variability and especially in older patients, the lability (i.e., from orthostatic hypotension) of the true BP. Furthermore, cuff inflation is annoying to patients, and even ambulatory BP assessment is intermittent (usually in 30- to 60-min intervals), not continuous. Therefore, an ideal BP monitor would have the following features: 1) continuous rather than intermittent BP estimation; 2) portable (i.e., "wearable") for ambulatory and nighttime BP estimation; 3) high degree of accuracy and precision consistent with direct intra-arterial BP measurements; and 4) reimbursable, the last being one major obstacle for widespread use of ambulatory BP monitoring today. Many continuous or cuffless techniques have been developed (3,4), but none of them have been able to enter the clinical arena,

*Editorials published in *JACC: Basic to Translational Science* reflect the views of the authors and do not necessarily represent the views of *JACC: Basic to Translational Science* or the American College of Cardiology.

From the Hypertension Center of Excellence, Cedars-Sinai Heart Institute, Los Angeles, California. Dr. Victor has received research funding from ReCor Medical. Dr. Rader has reported that he has no relationships relevant to the contents of this paper to disclose.

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nor are they currently endorsed by any of the societal guidelines (5-7). Therefore, it is with great interest to read in this issue of *JACC: Basic to Translational Science* the study by Watanabe et al. (8)—an attempt to break the rigid boundaries of BP monitoring.

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Watanabe et al. (8) describe a new noninvasive method of estimating BP continuously and without a BP cuff—with a photoplethysmograph (PTG), which measures pulsatile changes in index finger blood volume derived from a photodetector opposing a light-emitting diode. To calibrate pulse wave analysis does require a BP measurement with a regular upper arm cuff, thus, they call it a cuff-free not a cuffless method. The device uses (like other similar technologies) a proprietary algorithm, which is more or less a black box generating BP estimates based on pulse wave analysis and the calibration cuff BP. This study followed recommended guidelines for the evaluation of noninvasive BP devices and employed comparisons of PTG-derived BP readings with both auscultatory and oscillometric BP devices both at rest and during leg rise to evaluate its performance during BP fluctuations. These measurements were repeated 1 month later. Furthermore, BP fluctuations after intracoronary nitroglycerine injection—which caused a mean BP drop of 30 mm Hg—were also measured by PTG- and compared with regular BP cuff readings. The correlation of the PTG method with standard BP measurement methods appears to be robust, and at least the summary statistics are promising. One advantage of this method to other similar methods, such as pulse transition time-based algorithms (9), is that PTG does not require an electrode to time the pulse wave analysis with the electrical activation of the left ventricle (i.e., QRS complex), thus making this technology potentially more versatile and "wearable." In addition, this new device provides much improved patient comfort compared with ambulatory BP monitoring, an advantage that also was demonstrated by surveying subjects in this study.

As promising as these results initially appear, there are several limitation to this study:

1. Although currently not required by international standards, it is advisable to perform an independent validation of a new BP device; several of the coauthors are employees of the manufacturer, and 3 of them hold the patent for this device, thus have a significant conflict of interest.
2. The accuracy of the reference device for standard cuff BP measurements (UA-1020G. A&D Medical, San Jose, California) is unknown (2 of 4 similar BP devices have a "questionable" recommendation from dabl Educational Trust, an independent company that validates BP monitors according to strict guidelines including those of the European Society of Hypertension).
3. The reference device for ambulatory BP measurement is not listed, and thus its accuracy is unknown.
4. This method still requires a BP measurement with a standard cuff as calibration. It is a concern that if this technology is introduced as a wearable monitor, changes in body position, exercise, body hydration, perspiration, and so on can alter the waveform signal, and thus repeat calibration under these conditions may be warranted.
5. There is a deviation of the PTG BP measurements from regular cuff pressure values in the higher BP range (with fewer data points); the new method appears to overestimate such high-range values under static conditions while underestimating mid- to higher range values under "BP-rise" conditions (i.e., during leg raise). There was a late (at approximately 27 min) mean systolic BP deviation of almost 20 mm Hg after intracoronary nitroglycerin injection.
6. All measurements were conducted in a completely still body position, which does not represent conditions encountered when evaluating a wearable device. Much more data are needed under true ambulatory conditions, if this method is to replace regular cuff-based ambulatory BP monitors.
7. The mean age of the study subjects was 47 years, compared with the recent SPRINT hypertension trial (Systolic Blood Pressure Intervention Trial) (10) as an example, where the mean age was 68 years. In addition, only 30% of subjects were hypertensive. More work is to be done in a strictly hypertensive population.

We welcome the attempt to advance the rather static field of BP monitoring and appreciate the meticulous conduct of the experiments in this study. However, this new technology needs to be further evaluated to address our concerns (which will likely be shared by the HTN community) before it can be recommended as a more convenient alternative to existing rigorously validated ambulatory, clinic, or home oscillometric BP monitors for the assessment and management of HTN.

ADDRESS FOR CORRESPONDENCE: Dr. Florian Rader, Hypertension Center of Excellence, Cedars-Sinai Heart Institute, 127 South San Vicente Boulevard, Suite A3408, Los Angeles, California 90048. E-mail: florian.rader@cshs.org.

REFERENCES

1. Booth J. A short history of blood pressure measurement. Proc R Soc Med 1977;70:793–9.

2. Pickering TG, Shimbo D, Haas D. Ambulatory blood-pressure monitoring. N Engl J Med 2006; 354:2368–74.

3. Silke B, McAuley D. Accuracy and precision of blood pressure determination with the Finapres: an overview using re-sampling statistics. J Hum Hypertens 1998;12:403–9.

4. Imholz BP, Wieling W, van Montfrans GA, Wesseling KH. Fifteen years experience with finger arterial pressure monitoring: assessment of the technology. Cardiovasc Res 1998;38:605–16.

5. Mancia G, Fagard R, Narkiewicz K, et al., Task Force for the Management of Arterial Hypertension of the European Society of Hypertension and the European Society of Cardiology. 2013 ESH/ESC practice guidelines for the management of arterial hypertension. Blood Press 2014;23:3–16.

6. James PA, Oparil S, Carter BL, et al. 2014 evidence-based guideline for the management of high blood pressure in adults: report from the panel members appointed to the Eighth Joint National Committee (JNC 8). JAMA 2014;311: 507–20.

7. Leung AA, Daskalopoulou SS, Dasgupta K, et al., Hypertension Canada. Hypertension Canada's 2017 guidelines for diagnosis, risk assessment, prevention, and treatment of hypertension in adults. Can J Cardiol 2017;33:557–76.

8. Watanabe N, Bando YK, Kawachi T, et al. Development and validation of a novel cuff-less blood pressure monitoring device. J Am Coll Cardiol Basic Trans Science 2017;2:631–42.

9. Forouzanfar M, Ahmad S, Batkin I, Dajani HR, Groza VZ, Bolic M. Coefficient-free blood pressure estimation based on pulse transit time-cuff pressure dependence. IEEE Trans Biomed Eng 2013;60:1814–24.

10. SPRINT Research Group, Wright JT Jr., Williamson JD, Whelton PK, et al. A randomized trial of intensive versus standard blood-pressure control. N Engl J Med 2015;373: 2103–16.

KEY WORDS ambulatory blood pressure monitoring, blood pressure, diagnosis