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Evaluation of the Accuracy of Cuffless Blood Pressure Measurement Device: Challenges and Proposals

Ramakrishna Mukkamala, Mohammad Yavarimanesh, Keerthana Natarajan, Jin-Oh Hahn, Konstantinos G. Kyriakoulis, Alberto P. Avolio, George S. Stergiou

***Abstract*—The challenges in evaluating cuffless blood pressure (BP) measurement devices are described, and proposals are made for overcoming them.**

***Clinical Relevance*—This commentary can facilitate understanding of emerging cuffless BP measurement devices.**

Cuffless blood pressure (BP) measurement devices offer great promise for mitigating the burden of hypertension. There are two types of cuff-less devices: cuff-calibrated and calibration-free. The cuff-calibrated devices require periodic measurements with cuff devices to yield cuff-less measurements in units of mmHg in between the "cuff calibrations". Studies of both types of devices have been increasingly appearing in the literature, and cuff-calibrated devices are now emerging on the market. So, understanding how well these devices work is more important now than ever.

However, it is not straightforward to evaluate the accuracy of cuffless devices against standard devices. There are at least three challenges. Firstly, standardized protocols for testing BP measurement accuracy exist but are intended for automatic cuff devices. While these protocols require a subject cohort covering a wide BP range, they do not invoke BP changes within a subject and are thus not at all applicable to cuff-calibrated devices. Secondly, BP variations are crucial for device evaluation but difficult to obtain. For cuff-calibrated devices, intra-subject BP changes are mandatory. However, BP interventions are cumbersome and can even be unsafe, whereas natural BP variations in a person over time may not be large enough. For calibration-free devices, the subject cohort must exhibit a wide BP range. However, identifying such a cohort can be costly, especially for academic studies Thirdly, machine learning, in which all data about a person in addition to the physiologic measurement are used as input to predict BP is often employed in cuff-less devices, but is basically a "black box". As a result, it is unclear if the attained BP measurement accuracy of especially calibration-free devices is simply due to demographic inputs such as age and gender, which are known to correlate with BP, or the actual physiologic measurement itself.

These three challenges are evident in recent literature, which makes interpretation difficult. To further illustrate the difficulty of interpretation, we performed a basic simulation. The simulation involved generating ten pairs of cuff-less and reference cuff BP measurements from 100 subjects wherein the cuff-less measurements had zero correlation with the reference measurements outside of age and gender. As exemplified in Figure 1, typical ways of presenting the results suggest good accuracy even though there is no correlation!

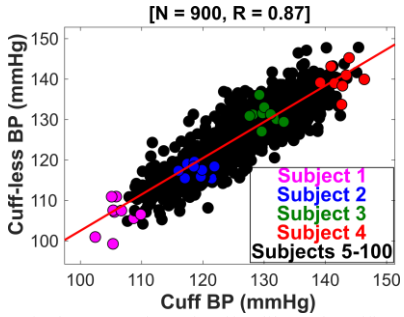

Figure 1: Typical presentation of cuff-calibrated, cuffless BP results.

Due to these challenges, we make some proposals. Most importantly, we suggest to present the results in an informative way. For cuff-calibrated devices, instead of plotting cuffless BP versus cuff BP as in Figure 1, plot the change in cuffless BP relative to the calibration measurement versus the reference cuff BP change (see colored datapoints). Also show the BP errors of the cuffless device side-by-side with the BP errors of a baseline device in which the cuff BP for calibration is used to predict BP. For calibration-free devices, rather than only plotting the correlation and BP errors, put these plots side-by-side with those of a baseline model in which demographics alone are used to predict BP. The results presented in these ways will clearly indicate whether the cuffless devices offer added value or not. We also recommend to make every effort to include significant BP variations. There is IEEE standard 1708 for cuff-calibrated devices, which requires invoking BP changes within subjects. However, the way the changes is made is not specified. We suggest to use at least three distinct interventions. For calibration-free devices, we suggest following the standardized protocols for now. We further propose to use manual auscultation as the reference for initial laboratory studies and then an ambulatory cuff device as reference for subsequent and necessary field studies. We hope these and other proposals facilitate understanding of the capabilities and limitations of emerging cuffless devices.

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R. Mukkamala is with the Departments of Bioengineering and Anesthesiology and Perioperative Medicine, University of Pittsburgh, Pittsburgh, PA, USA (email: rmukkamala@pitt.edu).

M. Yavarimanesh and K. Natarajan are with the Department of Electrical and Computer Engineering, Michigan State University, East Lansing, MI, USA.

J-O. Hahn is with the Department of Mechanical Engineering, University of Maryland, College Park, MD, USA.

K. G. Kyriakoulis and G. S. Stergiou are with the School of Medicine, National and Kapodistrian University of Athens, Athens, Greece.

A. P. Avolio is with the Department of Biomedical Sciences, Macquarie University, Sydney, NSW, Australia.