Hypertension

REVIEW

The Microsoft Research Aurora Project: Important Findings on Cuffless Blood Pressure Measurement

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ABSTRACT: Conventional blood pressure (BP) measurement devices based on an inflatable cuff only provide a narrow view of the continuous BP profile. Cuffless BP measuring technologies could permit numerous BP readings throughout daily life and thereby considerably improve the assessment and management of hypertension. Several wearable cuffless BP devices based on pulse wave analysis (applied to a photoplethysmography or tonometry waveform) with or without use of pulse arrival time are now available on the market. The key question is: Can these devices provide accurate measurement of BP? Microsoft Research recently published a complex article describing perhaps the most important and highest resource project to date (Aurora Project) on assessing the accuracy of several pulse wave analysis and pulse wave analysis-pulse arrival time devices. The overall results from 1125 participants were clear-cut negative. The present article motivates and describes emerging cuffless BP devices and then summarizes the Aurora Project. The study methodology and findings are next discussed in the context of regulatory-cleared devices, physiology, and related studies, and the study strengths and limitations are pinpointed thereafter. Finally, the implications of the Aurora Project are briefly stated and recommendations for future work are offered to finally realize the considerable potential of cuffless BP measurement in health care.

Key Words: blood pressure determination ■ calibration ■ cuffless ■ pulse arrival time ■ pulse wave analysis ■ validation study ■ wearable electronic devices

Inflatable cuff devices based on the manual auscultatory or automated oscillometric method have been impressively helpful in identifying people with elevated blood pressure (BP) who are at risk of cardiovascular disease and in monitoring and guiding treatment induced BP decline and thereby risk reduction.[1] However, the intermittent BP measurements from cuff devices provide only snapshot information about the continuous BP profile and ignore BP fluctuations during real-life conditions, which are undoubtedly important in inducing arterial and other organ damage. Another consequence of assessing narrow parts of the individual's diurnal BP profile is the generation of new conditions and diagnoses, such as white coat hypertension and masked hypertension, which are believed to affect more than one-third of untreated or treated people. In fact, these are artifacts of selective sampling within the 24-hour BP profile and products of comparing BP measurements taken in different settings and conditions, as provided by the currently available BP measurement methods (office, ambulatory, home monitoring). A third drawback of the devices is that the cuff inflation itself can influence the BP level.[2–4]

THE POTENTIAL OF CUFFLESS BLOOD PRESSURE MEASUREMENT

Cuffless BP measuring technologies may permit the development of wearable devices without the intrusive presence and function of the cuff, which can obtain numerous BP readings for days, weeks, or months in all settings and activities. Thus, they can inform on the full picture of the BP profile and behavior and avoid diagnostic issues due to assessing snapshot BP data. Other cuffless BP technologies might be implemented in smartphones, allowing

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Nonstandard Abbreviations and Acronyms

BP	blood pressure
DBP	diastolic blood pressure
ECG	electrocardiography
PAT	pulse arrival time
PPG	photoplethysmography
PWA	pulse wave analysis
SBP	systolic blood pressure

BP measurement in the wide population of smartphone users without the need of a dedicated device. As shown in Table 1, such solutions have considerable advantages and could completely change the management of hypertension, at the level of population screening, diagnosis, and long-term monitoring of treatment.

THE EMERGING MARKET OF CUFFLESS BP DEVICES

Many companies have recently entered the BP monitoring field by developing cuffless BP devices, including big technology companies specializing in electronics and software (eg, Microsoft) and in telecommunications and smartphones (eg, Samsung), and small start-up companies developing novel sensors and smart devices. Thus, cuffless BP devices are now available on the market and are garnering great interest from doctors, patients, members of the public, and researchers.[5–10] It is important to note that these devices are heterogenous in several respects. First, they use different principles and methods for estimating BP.[11] Second, they are implemented in different types of devices (eg, wrist bands, smartwatches, smartphones, dedicated devices). Third, they have different intended uses (eg, wearable devices, occasional monitors, continuous monitors for critical care settings).

As shown in Table 2, most, if not all, of the regulatory-cleared devices are based on pulse wave analysis (PWA) with or without the use of pulse arrival time (PAT).[12] The PWA devices record a photoplethysmography (PPG) waveform indicative of distal blood volume oscillations during the cardiac cycle, or a tonometry waveform indicative of peripheral artery forces during the cardiac cycle, and extract features from the waveform and map or calibrate these features to BP values using machine learning or other data-driven techniques. The PWA-PAT devices also record an electrocardiography (ECG) waveform to extract PAT as the time delay between the ECG and hemodynamic waveforms and possibly other features. Most of the devices require periodic (eg, monthly) BP measurements with a standard arm cuff device as a part of the calibration procedure (cuff calibration), but a few devices use only demographics information (eg, age, sex, height, and weight) for calibration to BP units (demographic calibration). The key question is: can these devices provide accurate measurement of BP?

THE MICROSOFT RESEARCH AURORA PROJECT ON ASSESSING THE ACCURACY OF CUFFLESS BP DEVICES

Recently, a Microsoft Research team of 23 investigators published a complex article describing perhaps the most important and highest resource project to date (Aurora Project) on assessing the accuracy of PWA and PWA-PAT devices.[13] In brief, they showed clear-cut negative results.

Figure 1 provides an overview of the Aurora Project design and the salient aspects of the methodology, including the participants, measurements, and data analysis. Several PWA and PWA-PAT devices were investigated against (1) dual-observer manual auscultatory cuff BP measurement at least 1 day after cuff BP calibration in the supine and seated postures (auscultation cuff arm) and (2) a validated oscillometric ambulatory arm cuff BP monitor over a 24-hour period, again after cuff BP calibration (ambulatory cuff arm) (Figure 1A).

A total of 1125 adults were included, with 642 participants in the auscultation cuff arm of the study and 483 participants in the ambulatory cuff arm (Figure 1B). Many of the participants had a history of hypertension (34%) or were older than 50 years [age 45.1 (mean) ± 11.3 (SD)].

Wrist wearable devices were developed to record (i) a tonometry waveform from the radial artery, (ii) a PPG waveform from the anterior (volar, palm-side) arm

Table 1. How Cuffless BP Measurement Might Change the Epidemiology and Management of Hypertension

Hypertension screening	• Effective screening of healthy adults using technologies embedded in wearable devices (eg, wrist wearables, smartwatches) and smartphones, and identification of many with undiagnosed hypertension (20–40% of hypertensive population). • Screening at no cost to the healthcare system.
Hypertension diagnosis	• Accurate diagnosis by detailed information of the 24-h BP profile and behavior using wearable devices, which provide measurements in all settings, positions, and activities for days or weeks. • Potential elimination of the selective assessment of office and out-of-office BP (home or ambulatory). • Potential elimination of white coat and masked hypertension phenotypes.
Monitoring treatment	• Complete and unbiased evaluation and reporting of BP between office visits. • More accurate assessment of antihypertensive drug treatment effects on BP. • Facilitation of self-monitoring of BP by patients to potentially improve long-term adherence to treatment and BP control.

Table 2. Some Pulse Wave Analysis (PWA) and PWA-Pulse Arrival Time (PAT) Devices With Regulatory Approval

Device manufacturer	Device type	Cuffless BP method	Regulatory approval
Healthstats	Wrist wearable	PWA of radial artery tonometry waveform	FDA cleared
LiveMetric	Wrist wearable		FDA cleared
Sotera	Chest/hand wearable	PWA of thumb PPG waveform + PAT/ECG	FDA cleared
Aktiia	Wristband	PWA of distal vessel PPG waveform	CE marked
Biobeat	Wrist or chest wearable		FDA cleared
Samsung	Smartwatch		S Korea approved

surface (perhaps better in quality than the more common PPG waveform from the posterior [dorsal] wrist surface obtained with several regulatory-approved cuffless devices),[6–8] and (iii) time-synchronized ECG waveforms (i, ii, and iii in Figure 1C and 1D). The instrumentation also included an accelerometer (iv in Figure 1C and 1D) to track (a) arm posture and thereby potentially correct for hydrostatic effects (ie, increase/decrease in local BP when the hand is moved below/above heart level) and (b) activity level for identifying data with substantial artifact. Waveforms of insufficient quality were excluded from ensuing analysis.

Four regression models were developed to predict systolic BP (SBP) and diastolic BP (DBP) from features of the (1) tonometry and ECG waveforms (eg, similar to the Food and Drug Administration (FDA)-cleared Healthstats and LiveMetric devices[9,10] but also including additional ECG information); (2) PPG and ECG waveforms (eg, similar to the FDA-cleared Sotera device[5]); (3) PPG waveform (eg, similar to the FDA-cleared Biobeat, CE-marked Aktiia, and South Korea regulator-approved Samsung devices[6–8]); and (4) ECG waveform alone (Figure 1D; Table 2). The models also considered the time of day, which may help in tracking typical diurnal BP variations (eg, BP is lower at night), and arm posture via the accelerometer (see, for example, the study by Shaltis et al[14]) as non-waveform features for predicting BP. The cuff BP values from the initial calibration were likely used to set the regression model intercept. Separate models were trained for each study arm (auscultation cuff arm and ambulatory cuff arm). The models were tested using data from participants that were not included in the model training.

It is crucial to note that for comparison, another regression model was similarly trained and tested to predict SBP and DBP from only the cuff BP values from the initial calibration and the time of day (baseline model) (Figure 1D). This baseline model thus did not use any waveform features (ie, did not use an actual measurement) in contrast to the other 4 models (waveform feature models).

None of the 4 waveform feature models were able to predict next day auscultatory cuff SBP or DBP with meaningfully lower errors than the baseline model, as shown in Table V in the original Microsoft Research publication[13] and summarized here in Figure 2A. Similarly, none of the 4 waveform feature models were able to predict 24-hour average ambulatory cuff SBP or DBP with meaningfully lower errors than the baseline model, as shown in Figure 7 in the Microsoft Research publication[13] and summarized here in Figure 2B. The BP errors were lower in normotensive and in younger participants, but still were similar for the waveform feature models and baseline model (Figure 7 and Table V in the Microsoft Research publication[13] and Figure 2A and 2B). Note that the magnitude of the BP errors in Figure 2A and 2B is quantified as the unbiased root-mean-squared-error, which is equivalent to the square root of the sum of the bias error (mean of error) squared and the precision error (SD of error) squared, and thereby represents the overall error. The precision error was generally the dominant component of the root-mean-squared-error in the Aurora Project and thus mainly affected the accuracy of the models. The 4 waveform feature models also could not predict ambulatory cuff SBP or DBP at any time of day better than the baseline model, as stated in the Microsoft Research publication.[13] Other classic machine learning techniques beyond the used regression offered no better results, as indicated in Table VI in the original publication.[13]

In sum, cuffless BP devices based on PWA and PWA-PAT, which are similar to some regulatory-cleared devices (Table 2), were of no additional value in measuring resting auscultatory or 24-hour ambulatory cuff BP when compared with a baseline model in which BP was predicted without an actual measurement. Microsoft Research has made sample data and code publicly available on Github, with full data available on request[15] and may possibly be no longer pursuing cuffless BP research and development.[16]

THE AURORA PROJECT IN RELATION TO THEORY AND OTHER STUDIES

The experimental findings from the Aurora Project are consistent with the notion that PWA and PAT devices for cuffless BP measurement suffer from lack of consistent theoretical basis and potentially confounding physiology.[12] For example, PPG waveform amplitude can increase with stroke volume or decrease with smooth muscle contraction of distal vessels despite higher BP in both cases.[17] Although pulse transit time in central large arteries may track BP well,[18] PAT to a peripheral waveform measurement site such as the wrist is confounded by smooth muscle contraction and the pre-ejection period, which can both change irrespective of the BP level.[19]

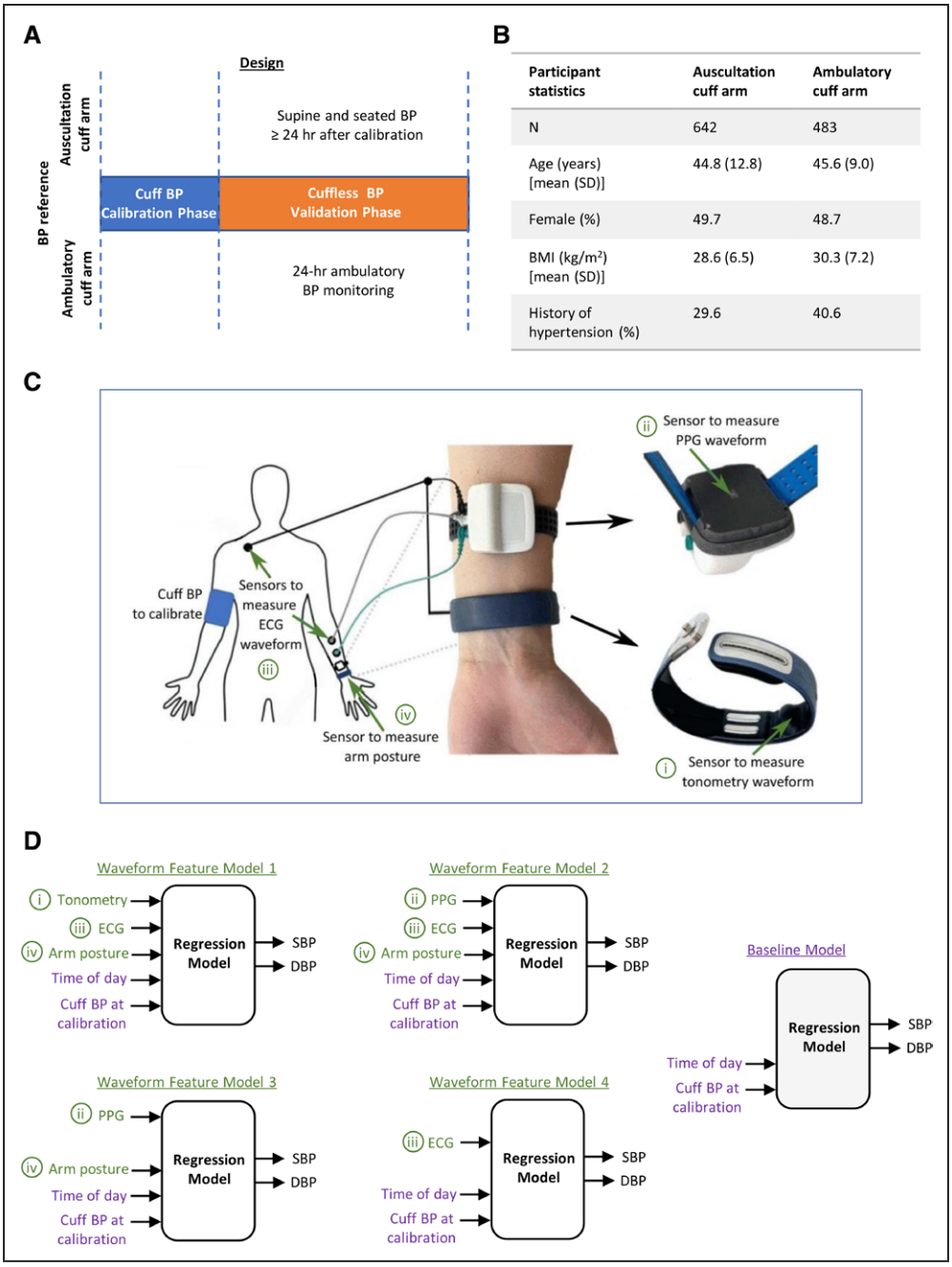

Figure 1. Overview of the methodology of the Microsoft Research Aurora Project to assess the accuracy of pulse wave analysis (PWA) and pulse arrival time (PAT) devices for cuffless blood pressure (BP) measurement.
A, Study design. **B**, Participants. **C**, Wearable wrist devices for measuring (i) tonometry, (ii) photoplethysmography (PPG), and (iii) electrocardiogram (ECG) waveforms, as well as for tracking (iv) arm posture and waveform artifact via an accelerometer. Adapted from reference.[13] **D**, Four waveform feature models for predicting systolic and diastolic BP (SBP and DBP) from features of different waveforms (ie, measurement component in green) and nonwaveform features that could be predictive of subsequent BP (ie, a nonmeasurement component in purple) and a baseline model for predicting SBP and DBP from the nonwaveform features alone.

The Aurora Project results are also consistent with a few recent independent studies. In a similar study, we explored finger PPG waveform analysis and PAT during a battery of interventions (slow breathing, cold pressor, mental arithmetic, and nitroglycerin) in 32 adults and found that a regression model could provide some value in predicting the changes in auscultation SBP (9.5 mm Hg error versus 10.9 mm Hg for a baseline model; $P<0.05$) but not DBP.[17] In another study, we compared the cuff-calibrated Aktiia device against 24-hour ambulatory cuff BP monitoring in 45 adults, and showed that the cuffless device was unable to track the BP drop during nighttime sleep (SBP/DBP of 5.1/3.8 mm Hg with cuffless device versus

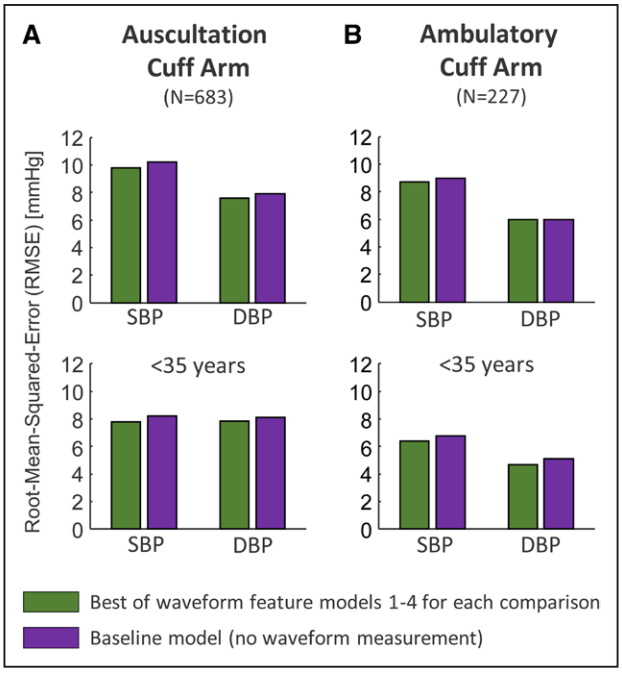

Figure 2. Summary of the main Aurora Project results. Blood pressure (BP) errors of the best of the four waveform feature models versus BP errors of the baseline model overall and for younger participants.

The errors were specifically for predicting next day BP for the auscultation cuff arm of the study and 24-hour average BP for the ambulatory cuff arm. The bar graphs were constructed from Table V and Figure 7 in the Microsoft Research publication.[13] Error here is quantified as the unbiased root-mean-squared-error (RMSE), which is equivalent to the square root of the sum of the bias error (mean of error) squared and the precision error (SD of error) squared, and thereby represents the overall error. The RMSEs of the waveform feature models (Figure 1C and 1D) were comparable to the RMSEs of the baseline model, which did not use any measurement to predict BP (Figure 1D). Hence, PWA and PWA-PAT devices showed essentially no value in measuring resting or 24-hour ambulatory BP in the Aurora Project.

18.0/13.8 mm Hg with cuff device).[20] The inability of this device to track the nighttime BP decline was acknowledged in a recent publication led by the manufacturer, with a statement that conversion factors need to be applied.[21] In a third study by Falter et al in 40 adults, the cuff-calibrated Samsung device showed a systematic bias toward the cuff BP at calibration and could not accurately measure SBP and DBP when compared with 24-hour ambulatory cuff BP monitoring (SBP/DBP errors of 15.6/12.6 mm Hg, which are computed here from the reported values to be comparable to errors in Figure 2).[22]

On the other hand, the Aurora Project findings are in stark contrast to 2 other recent studies with manufacturer involvement. One of these studies reported that the cuff-calibrated Biobeat device could almost perfectly predict average daytime and average nighttime ambulatory cuff SBP and DBP in 28 adults (correlation coefficients of 0.97–0.99).[6] The other study showed that the demographics-calibrated LiveMetric device could predict invasive SBP and DBP well in 34 patients (correlation coefficients of 0.91 and 0.86).[10]

AURORA PROJECT STRENGTHS AND WEAKNESSES

The Aurora Project is most important due to several notable strengths. Firstly, due to the unique expertise of the large Microsoft Research investigative team, the research project was meticulously and well conducted, which has not always been the case in the field of cuffless BP measurement.[23] The Microsoft Research team demonstrated full command of the subject matter by including a plethora of relevant information in their publication. Secondly, because of the vast resources available to this large company, the study was comprehensive in that several PWA and PWA-PAT devices were tested in a large number of diverse participants. Thirdly, Microsoft Research was fully transparent by providing their study data for free to the public.[15]

A key technical strength of the Aurora Project was in including and presenting data on the baseline models.[23] PWA and PWA-PAT devices predict BP from features of hemodynamic waveforms (ie, an actual measurement component) and from nonwaveform features such as demographics, time of day, and the cuff BP values used for the initial calibration of the device (ie, a nonmeasurement component). The nonmeasurement component has value in predicting BP after the calibration. If BP can be predicted at least as well without a measurement component, then there would be no need for a cuffless BP device at all. It is thus crucial to show the value of the measurement component over the nonmeasurement component by comparing the devices with baseline models in which BP is predicted exclusively from the nonmeasurement component. Note that baseline models have not previously been a factor in BP measurement, because cuff devices typically predict BP from an actual measurement alone (eg, oscillometric cuff pressure waveform). The Aurora Project results are a shining example of the pitfall in excluding baseline models in the assessment of PWA and PWA-PAT devices. The 4 waveform feature models produced SBP and DBP errors <10 mm Hg (Figure 2), which may seem reasonably good. However, only when compared with the baseline model, which produced comparable errors (Figure 2), it becomes clear that the waveform feature models provided no additional value in BP measurement. Without reporting baseline model results, it may be difficult to conclude if low BP errors are actually meaningful.

Another strength was in the certainty of the clear-cut negative results. Because of the study design, Microsoft Research was able to investigate many different analytical methods for predicting BP from the measured waveforms and may have settled upon the best implementation of each of the methods. Their results could

thus be viewed as a best-case scenario for the PWA and PWA-PAT devices.

However, as with any study, there were weaknesses. Firstly, and most importantly, the Aurora Project did not include any interventions to change BP appreciably, such as the interventions mentioned above, physical exercise, or BP-lowering medications.[18] Such interventions are important for cuffless device testing by producing BP changes for detection that are larger than the noise floor of reference cuff devices in resting conditions. Still, it is notable that hypertensive and older participants, who are known to show higher BP variability than normotensive and younger people, were included. Secondly, contemporary deep learning was not applied to maximize performance, which may be due to an insufficient amount of data for such analyses. For example, the ambulatory cuff BP results were only from 227 (out of 483) participants who had at least 17 waveform measurements of sufficient quality over the 24-hour period (Figure 2B). Nevertheless, it would be surprising if deep learning could be effective when classic machine learning completely fails. Thirdly, this study may not be germane to hospitalized patients (eg, the Sotera device is intended for this setting). Lastly, while the Microsoft Research team clearly showed the crucial comparisons between the waveform feature and baseline models, they focused their discussion on other topics, such as the importance of using an optimal reference and studying older and hypertensive participants.

IMPLICATIONS AND RECOMMENDATIONS

The Aurora Project conducted by the prestigious Microsoft Research probably is the most comprehensive and important study to date on assessing the accuracy of PWA and PWA-PAT devices for cuffless BP measurement. However, this study does not provide explicit evidence that regulatory-approved PWA and PWA-PAT devices (Table 2) do not provide accurate BP measurements. Yet, this compelling study does at least advise to take caution in using these new devices, particularly in the healthcare setting but also by apparently healthy people, until adequate data on their performance and accuracy become available. The findings of the Aurora Project also support the recent recommendation by the European Society of Hypertension Working Group of BP Monitoring and Cardiovascular Variability that at the present time cuffless BP devices should not be used in clinical practice.[11]

Although the scientific community, patients, and the public are eager to adopt cuffless BP devices in routine use, further research is needed to bring these technologies to primetime. On the technology development front, pursuing breakthroughs in machine learning and arterial waveform sensing might help improve PWA and pulse transit time methods, whereas conceiving new cuffless BP measurement principles with strong theoretical underpinnings may have more upside. On the technology validation front, there is an urgent need for establishing protocols that are specific for validating cuffless devices, as the current standard for testing automatic cuff devices[24] is not applicable to cuffless devices.[11,23] These protocols must include clinically meaningful BP changes (eg, nighttime decline, treatment response) for testing the ability of cuffless devices to track these changes. However, developing detailed protocols is challenging, and the current ones require further vetting.[11] Ultimately, clinical adoption of a given cuffless BP device should only occur upon passing an appropriate validation standard that is conducted independently of the manufacturer and published in a peer-reviewed venue.[11,23] It is also important that manufacturers offer a supporting theory on precisely how their devices work to give confidence that the devices can generalize to conditions not seen in the standardized testing. These recommendations for future work may be worthwhile to pursue to finally realize the considerable potential of cuffless BP measurement technologies for health care as shown in Table 1.

ARTICLE INFORMATION

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R.M. holds NIH grants and pending and issued patents on cuffless blood pressure measurement methods other than pulse wave analysis and pulse arrival time. Some of the patents have been licensed or optioned to Digitouch Health and Samsung Advanced Institute of Technology. S.G.S. and C.L. hold pending patents on cuffless blood pressure measurement methods other than pulse wave analysis and pulse arrival time. K.G.K. and A.P.A. have contributed to validation studies by various manufacturers of blood pressure measurement technologies. G.S.S. has received honoraria for lectures and for consulting services and research grants from several manufacturers of blood pressure monitoring technologies including manufacturers of cuffless devices (Aktiia SA, Maisense, Samsung Research America, Inc).

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