Preliminary assessment of video-based blood pressure measurement according to ANSI/AAMI/ISO81060-2:2013 guideline accuracy criteria: Anura smartphone app with transdermal optimal imaging technology

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Objective A new smartphone app called Anura can measure blood pressure (BP) any time and any place without cuffs or special equipment from video of the face. This study assessed its accuracy in close conformity with the American National Standards Institute/Association for the Advancement of Medical Instrumentation/International Organization for Standardization (ANSI/AAMI/ISO) 81060-2:2013 standard for BP measurement devices.

Methods We validated Anura in reference to auscultation using a mercury sphygmomanometer and then assessed accuracy against the two accuracy criteria described in the guideline (n=85 subjects; three measurement pairs per subject).

Results The mean difference between the Anura measurement and its paired auscultatory reference measurement across all 255 measurement pairs was −0.4±6.7 mmHg for systolic blood pressure (SBP) and 1.2±7.0 mmHg for diastolic blood pressure (DBP). Both are within the acceptable limit of 5±8 mmHg and thus satisfy accuracy criterion 1. When mean differences are averaged for each subject, the mean across all 85 subjects is −0.4±5.8 mmHg for SBP and 1.2±6.7 mmHg for DBP. Both are within acceptable limits (based on the mean difference) and thus satisfy accuracy criterion 2.

Conclusions Anura meets ANSI/AAMI/ISO 81060-2:2013 standard with respect to BP measurement accuracy. As the ANSI/AAMI/ISO 81060-2:2013 standard has not been developed for cuffless devices, further research assessing additional accuracy issues specific to such devices is needed. *Blood Press Monit* 25: 295–298

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Introduction

Diagnosing and managing hypertension through regular blood pressure (BP) measurement is crucial for addressing the global burden of cardiovascular disease [1]. However, existing devices use bulky inflatable cuffs to measure BP; this makes them uncomfortable for taking measurements and inconvenient to transport. This discomfort and inconvenience limit their regular use, particularly for measuring BP outside of the home over the course of one's daily activities.

These problems could be addressed by measuring BP using the Anura smartphone application (www.anura.ai, Nuralogix). Anura uses a novel variant of video photoplethysmography technology called transdermal optical imaging to extract blood flow information from imperceptible color changes in the face that are captured using a conventional smartphone camera [2,3]. Anura uses this information (over 150 features extracted from a continuous blood flow signal) to calculate a brachial BP equivalent (without prior calibration) using a BP prediction model trained with advanced machine learning algorithms [3]. Anura could be implemented on any modern smartphone to continuously and conveniently monitor BP in any place and at any time. A proof-of-concept study on the iPhone demonstrated the accuracy of this technology to the international accuracy standard of 5±8 mmHg in normotensive subjects [3]. These BP prediction models have since been updated to predict a full range of BPs. These revised models have been implemented on the Anura smartphone application, but their accuracy has yet to be validated.

The present study conducted a preliminary assessment of Anura BP measurement accuracy in close conformity with the American National Standards Institute/Association for the Advancement of Medical Instrumentation/International Organization for Standardization (ANSI/AAMI/ISO) 81060-2:2013 guideline for the validation of automated non-invasive sphygmomanometers [4]. This standard forms the basis for regulatory agency approval of cuff-based sphygmomanometers in the USA and

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elsewhere, and it facilitates comparisons of device accuracy. This is currently the most applicable standard for Anura (despite Anura being cuff-less) because no cuff-less standard currently exists for calibration-free devices. We assessed the accuracy of Anura relative to a mercury sphygmomanometer on subjects that closely matched the age, sex and reference BP distributions stipulated in the standard.

Methods

Features of the Anura smartphone application

Anura is a smartphone application that determines BP from facial blood flow information obtained from video of the face. It is not yet officially labeled for use as a BP measurement device. The version under test was deployed on an iPhone 6s Plus running iOS 12. It is intended to be used in ambient light with the smartphone held in hand and the user looking at the screen with their face in full view of the front-facing camera. See Supplemental Methods, supplement digital content 1, *http://links.lww.com/BPMJ/A120* for additional details.

Subjects

To validate Anura on subjects that were not previously used in training BP prediction models, we recruited adults (18+ years old and not pregnant) at the General Clinic of the Zhejiang Elderly Guanhuai Hospital and the ECG Clinic of the Affiliated Hospital of Hangzhou Normal University (Hangzhou, China). The study was approved by institutional review boards at both institutions and all subjects provided written informed consent prior to participating in the study.

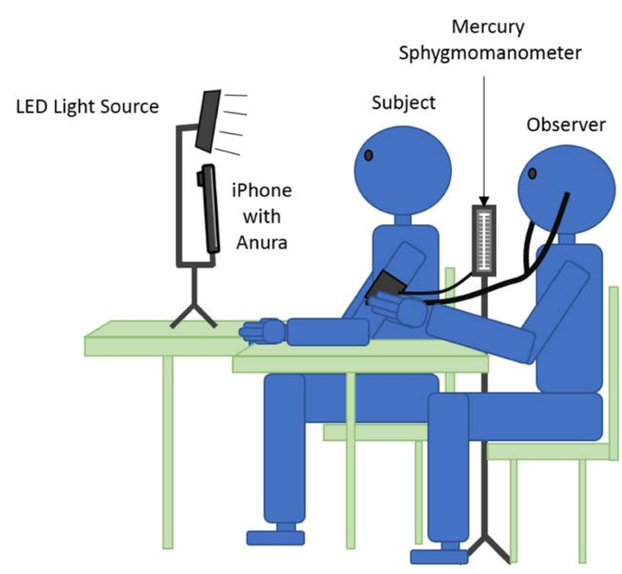
We included 85 subjects in the study based on several criteria. The first was that the subject's left arm circumference was within allowable limits for the reference sphygmomanometer arm cuff (20–34 cm). The second was that the subject was free from arrhythmia. The third was that we were able to obtain three valid BP measurement pairs from the subject. We considered valid measurements to be those with clearly discernable Korotkoff sounds during auscultation and good quality blood flow signal (based on a minimum signal-to-noise ratio threshold) during Anura measurement (14 subjects were excluded for inadequate signal quality). We further required measurements to be free from undue movement of the head, arm or body. The fourth was that all the subject's reference systolic blood pressures (SBPs) were within 12 mmHg of one another and all the subject's reference diastolic blood pressures (DBPs) were within 8 mmHg of one another. The fifth was that quotas for the subject's sex and reference BPs (based on the ANSI/AAMI/ISO 81060-2:2013 standard) had not already been met by other participants.

Experimental set-up and procedure

We had subjects sit quietly during the set-up process (see Fig. 1 for set-up details) and then proceeded to measure BPs using Anura and then the reference mercury sphygmomanometer. Specifically, we measured BP on the Anura test device by triggering a 60-s BP measurement with a button on the screen. The subject was asked to face the iPhone and remain perfectly still for the duration of the recording. We then immediately measured reference BP via auscultation with the mercury sphygmomanometer. We measured SBP as the pressure corresponding to the onset of the 'tapping' sound and DBP as the pressure corresponding to the disappearance of the last audible Korotkoff sound. We designated this first measurement pair as practice and discarded it.

We took three additional measurement pairs and recorded SBP and DBP for each auscultation to the nearest 2 mmHg. If Korotkoff sounds were difficult to distinguish or the subject moved during a measurement then that measurement pair was discarded and another one was taken. We continued taking measurement pairs (up to a maximum of eight) until three valid pairs were obtained. We excluded any subject where arrhythmia was detected, where three satisfactory measurement pairs could not be

Fig. 1



Experimental set-up. We seated each subject in a quiet room so that their feet were flat on the floor and their left forearm was supported at heart level. We connected subjects to an appropriately sized blood pressure cuff, connected to a mercury sphygmomanometer (Jiangsu Yuyue Medical Equipment and Supply Company). This sphygmomanometer was calibrated immediately prior to the beginning of the study. It was operated by a single nurse observer who was trained in accurate blood pressure measurement. To prevent the potential impact of motion, we mounted an iPhone atop a stand approximately 50 cm from the subject with the front-facing 'selfie cam' trained on the subject's face. To ensure consistent illumination of the face from one subject to the next, we positioned a white LCD light source (LED 50-A set to 3200K color and 35% light intensity, Visico) atop the iPhone on the same stand.

obtained, or where the SBP or DBP range was more than 12 mmHg or 8 mmHg, respectively.

Due to unreliable internet connectivity at the study locations, we modified the application to save videos to the phone instead of extracting blood flow signals from live video and generating a prediction in real-time. We conducted blood flow signal extraction and BP determination offline and recorded predictions for analysis.

Analysis

We analyzed our data according to the two accuracy criteria in the ANSI/AAMI/ISO 81060-2:2013 standard (see Supplemental Methods, supplement digital content 1, *http://links.lww.com/BPMJ/A120* for details). We further visualized agreement using a Bland–Altman plot.

Results

We recruited 85 subjects whose characteristics are listed in Table 1. The mean difference between the reference and Anura measurements over all 255 measurement pairs was –0.4 ± 6.7 mmHg for SBP and 1.2 ± 7.0 mmHg for DBP (Table 2), thus satisfying accuracy criterion 1 (≤5 ± ≤8 mmHg) for both systolic and diastolic pressures. The mean of subject differences between reference and Anura measurements was –0.4 ± 5.8 mmHg for SBP, and 1.2 ± 6.7 mmHg for DBP. These values are below the 6.93 mmHg threshold for SBP and the 6.84 mmHg threshold for DBP, thus satisfying criterion 2 for both systolic and diastolic pressures.

We visualized model performance in terms of agreement using a Bland–Altman plot (Fig. 2). Nearly all predictions were within 15 mmHg of reference measurements for both SBP and DBP. BPs in the lower end of the range tended to be overpredicted and those at the higher end of the range tended to be under-predicted for both SBP and DBP. Predictions for SBP are best (appear to be free of bias) for reference pressures between 110 and 150 mmHg. Predictions for DBP are best for reference pressures between 75 and 85 mmHg.

Discussion

Anura BP measurement satisfied both accuracy criteria of the ANSI/AAMI/ISO 81060-2:2013 standard. Predictions tracked observed values quite well, except for some minor squeezing on the low and high ends of the range. We expected this reduction of prediction accuracy because the relative scarcity of subjects at the lowest and highest ends of the BP range also limited training (and thus prediction accuracy) at these BPs.

Video-based BP measurement tools have several advantages. Their continuous measurement means that naturally occurring and cyclic BP fluctuations can be accounted for in one short continuous measurement rather than three instantaneous measurements. Video-based BP is contactless and therefore comfortable because no cuffs are required. Finally, video-based BP can be implemented on any modern smartphone and does not require special equipment. The ubiquity of smartphones makes it convenient to measure BP at any time and any place.

Some limitations of our work are as follows. First, our study was done under controlled conditions and so our findings might not generalize well beyond the lab. Lighting was controlled, the smartphone was mounted on a stand, and the study population was highly homogeneous in terms of ethnicity and skin tone (all Chinese adults). However, this is unlikely to be an issue since Anura has robust mechanisms to address variable lighting conditions and motion (see Supplemental Methods, supplement digital content 1, *http://links.lww.com/BPMJ/A120*), and BP prediction models were trained on an ethnically diverse subject population. Second, our study differed from ANSI/AAMI/ISO 81060-2:2013 on a few aspects: (1) we satisfied most (but not all) of the required BP distribution, (2) we accommodated cuff sizes up to 34 cm rather than 42 cm (potentially

Table 2 Validation results

	Anura BP mean ± SD (min–max)
Criterion 1: individual measurements	
SBP (mmHg)	−0.4 ± 6.7 (94–176)
DBP (mmHg)	1.2 ± 7.0 (56–98)
Criterion 2: subjects	
SBP (mmHg)	−0.4 ± 5.8 (97–169) SD threshold: 6.93 mmHg
DBP (mmHg)	1.2 ± 6.7 (57–95) SD threshold: 6.84 mmHg

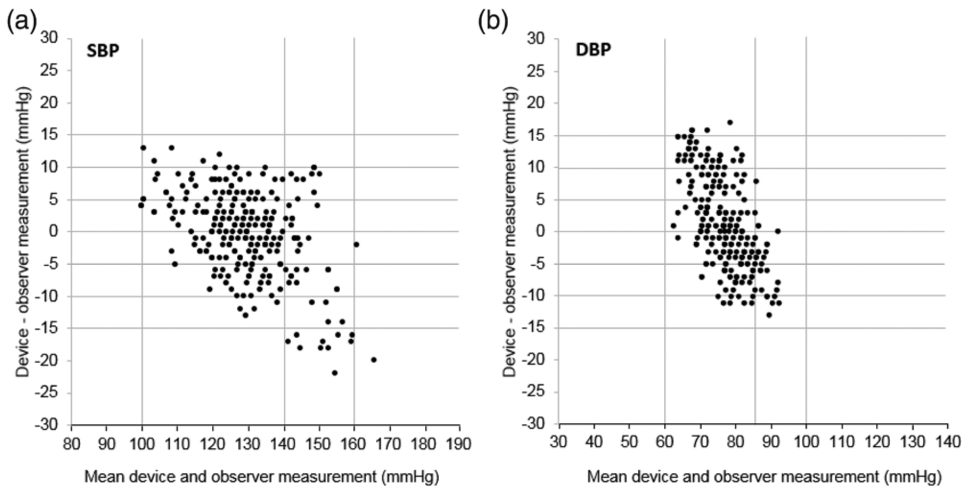
BP, blood pressure; DBP, diastolic blood pressure; SBP, systolic blood pressure.

Table 1 Subject characteristics

	Required minimum as per ANSI/AAMI/ISO 81060-2:2013 guidelines	Anura BP
Female (%)	30	49
Age (years), mean ± SD (min–max)	–	61.6 ± 14.1 (21–89)
Reference SBP (mmHg), mean ± SD (min–max)	–	130.0 ± 14.5 (94–176)
≥160 mmHg (%)	5	5.1
≥140 mmHg (%)	20	23.1
≤100 mmHg (%)	5	3.1
Reference DBP (mmHg), mean ± SD (min–max)	–	76.4 ± 9.1 (56–98)
≥100 mmHg (%)	5	0.0
≥85 mmHg (%)	20	18.0
≤60 mmHg (%)	5	6.3

BP, blood pressure; DBP, diastolic blood pressure; SBP, systolic blood pressure.

Fig. 2



Standardized Bland–Altman scatterplot of differences between device (Anura) and observer measurements for systolic blood pressure (a) and diastolic blood pressure (b).

excluding some larger subjects from our study) and (3) we had one observer collecting reference BP measurements instead of two. It is yet unclear whether these would affect prediction accuracy to any appreciable degree.

Conclusion

This preliminary assessment shows that Anura measures BP with comparable accuracy to cuff-based devices and thus could eventually serve as a viable alternative for BP measurement. This will likely require refining BP prediction models with additional data at very low and very high BPs (to boost accuracy at those BPs). As the ANSI/AAMI/ISO 81060-2:2013 standard has not been developed for cuffless devices, further research assessing additional accuracy issues specific to such devices is needed (e.g. variable lighting conditions, skin tone, ethnicity, motion artifact, etc.) [5].

Acknowledgements

Conflicts of interest

There are no conflicts of interest.

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