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COMMENT

The reality and serendipity of cuffless blood pressure monitoring

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Of all the major professions seeking effective means with which to integrate the broad scope of the modern digital revolution, medicine is perhaps the slowest. This is understandable, given the very nature of medical treatment and management which, by necessity, involves accurate diagnosis and mitigation of risk. Indeed, there are many areas in the medical ecosystem that already benefit from digital platforms, but an important aspect of the digital revolution is to devolve medical care predominantly from structured institutions and specific health professions to the involvement of active patient engagement. This has been seen as a critical pathway in the 'future of hypertension' [1]. Given the ubiquitous use of mobile and wearable devices with paired applications, these technologies can lend themselves effectively in the digital landscape [2] to address some of the underlying deficiencies of the management and treatment of hypertension: the general lack of individual awareness of the status of one's blood pressure (BP) and the reliance on occasional clinical or intermittent brachial cuff measurements to take into account BP variability [3]. This awareness, present in the medical and engineering science professions, has led to an increasing interest in the development of devices using cuffless methods for BP monitoring [4, 5].

The main types of devices for cuffless measurement of BP that are commercially available are generally wrist-worn watch-type devices which detect a peripheral photoplethysmography (PPG) signal with or without an electrocardiography (ECG) signal [4]. PPG-based devices determine arterial BP by surrogate metrics and algorithms related to pulse propagation time, usually in reference to the ECG, or analysis of the PPG pulse contour, and do not measure any parameters related to force. The PPG signal is generally detected at the wrist where the device is worn and can also be obtained from the finger of the contralateral hand in contact with the device. Although these devices are perceived to enhance the possibility of continuous and unobtrusive measurement of BP, they present formidable challenges in obtaining reliable and well-calibrated BP readings [6]. Clearly, cuffless devices purporting to measure BP must be trusted to give BP values that are similar to those from conventional cuff-based measurements, and also, they must be able to fiducially reflect physiological changes in BP. These challenges have not been adequately addressed by currently available devices, resulting in qualified opinions from professional societies regarding their use in diagnosis and treatment of hypertension [7, 8].

The study by Han et al. [9] in this issue of *Hypertension Research* describes a strategy aimed at addressing the realistic issues involved in using a wrist-worn cuffless BP device in terms of feasibility and stability. Participants ($n = 760$) in the study were given a Samsung Galaxy Watch (Watch 3 or Active 2) paired to the online Samsung Health Monitor application. The study reports the analysis of the data collected by the participants over specific dates covering a time period of one month. This was done so as to cover the one-month period for which, as stated by the manufacturer, the device requires only a single initial calibration session using a conventional brachial cuff sphygmomanometer. The device will not output any data after one month until it is recalibrated. The study was essentially an observational excercise aimed at examining the realistic behaviour of the participants with the use of the device and to obtain quantitative data on device performance in obtaining BP measurements when activated by the user. Participants were instructed to use the device for at least

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20 days within the one-month period and they were left to their own decision on how to use the device in monitoring their BP with respect to frequency of measurements.

A significant outcome of the study was related not only to what was prescribed by the investigators, but to what was decided by the participants themselves. More than 75% ($n = 574$) of the whole cohort decided on their own accord to conduct additional calibration sessions after the initial calibration in the study. There is no explicit description of what caused this deviation from the suggested study protocol in so many participants, but one interpretation might be that the participants did not accept that a long time between calibrations engendered trust in the BP measurements, and so a decision was made to recalibrate the device to produce increased confidence in the readings. Thus, in a serendipitous fashion, this enabled the investigators to uncover highly significant information that can potentially inform users, clinicians, and device manufacturers on the relevance of calibration procedures for cuffless BP devices.

Because recalibration was conducted at different times within the one-month period of the study, the investigators selected periods that had at least 7 days before and 7 days after recalibration. There was no difference in average systolic BP (SBP) before (122.1 ± 12.3 mmHg) and after (121.0 ± 12.1 mmHg) calibration. However, the pre-post calibration absolute SBP difference was 6.8 ± 5.6 mmHg, with a range of 0–33.8 mmHg. Subdivision of the absolute SBP differences showed that 46.7% were below 5 mmHg, 77.2% below 10 mmHg and 91.4% below 15 mmHg. The pre-post calibration absolute SBP differences were also related to the level of SBP, with the differences increasing to 9.4 ± 7.1 mmHg in participants with uncontrolled hypertension (average of all BP readings >135/85 mmHg, irrespective of the use of antihypertensive medication). Logistic modelling analysis was used to uncover likely factors that might influence the pre-post calibration absolute SBP differences by testing age, sex, average SBP and heart rate for 7 days pre calibration, and the difference in average heart rate 7 days pre and post calibration. For pre-post calibration differences of ≥5 mmHg, the only significant factor was an increased average SBP in the 7 days before calibration. Further statistical modelling showed that when considering only intrinsic device factors responsible for variation in calibration, the overall procedure was highly stable with intrinsic factors contributing a deviation of SBP of 0.022 ± 0.002 mmHg per day.

The analysis of pre-post calibration absolute SBP differences highlights important aspects of the realistic use of wearable devices for cuffless BP monitoring. The prescribed calibration procedure is to take three simultaneous measurements in a comfortable seated position over 3–5 min with the cuffless device and the brachial cuff sphygmomanometer on the contralateral arm. Although there may be some variation of the three readings, it is not clear if these are used in any way to perform an actual calibration curve. If so, it is possible that the slope of the curve would depend on the physiological variability of blood pressure at the time of measurement, that is, the curve could be different at different times when the calibration is performed. However, if the average variation is small, the sensitivity of the calibration curve would be reduced, and the procedure would effectively constitute a single-point calibration. This implies that the device would need to have a calibration curve that could translate metrics of the PPG signals to BP values, but it would most likely be a proprietary algorithm that would depend on the initial calibration. For a single-point calibration curve the intercept would need to go through zero or a slope be predetermined with the curve intersecting the measured point. Clearly, an obvious modification to the calibration procedure is to obtain at least two sets of readings at difference levels of BP to construct a two-point calibration curve. Physiological BP could be changed by performing manoeuvres (eg breathing or exercise) known to alter BP.

The study by Han et al. [9] delivers important information on the feasibility of BP monitoring in realistic settings using the Samsung Galaxy Watch employing cuffless techniques. It shows a variable adherence to the device, with only around 20% of the participants taking daily measurements, but 75% of the cohort decided that a single device calibration was not sufficient for the one-month duration of the study. It highlights the important impact of reliable calibration procedures on the reliability of subsequent BP measurements and how they may be influenced by the actual BP at time of calibration, with differences being more pronounced in those with hypertension. For the whole cohort, the distribution of age-related BP is broadly similar to that obtained by conventional cuff BP measurements but given the observational features of this study, there may have been some selection bias in those deciding to wear the device and interact with the paired mobile application.

The demonstration of the broad similarity with cuff-based findings is important; it will be instrumental in providing evidence that involvement of individuals using wearable cuffless devices for BP monitoring will not only increase awareness but also contribute to improved treatment as has been shown by studies on home monitoring of BP with conventional brachial cuff devices [10]. Another important aspect of the study by Han et al. [9] is that it has been conducted in the broad scope of the aims of professional societies who have already published position statements [8, 11] with the view that wearable and smart devices will be integrated in the way hypertension will be managed in the future [1]. However, in addition to the issues related to calibration, the wearable devices need to demonstrate that they can track BP changes reliably; that is, in an individual in whom BP is made

to change, and not only across groups with different levels of resting BP. This issue involves the difference in testing protocols as is seen in cuffless devices tested according to current standards for cuff devices [12] or others tested with non-standard protocols [13], all showing acceptable agreement with reference cuff-devices, but under static conditions.

Given the perceived importance of wearable and smart devices deployed for cuffless BP monitoring and the implications for the future of hypertension treatment and management [1], and the formidable challenges posed by the fundamental differences of cuff-based and cuffless devices [6, 14], the study by Han et al. [9] reporting data on the use of the Samsung Galaxy Watch in the broad spectrum of real-life situations will make a significant contribution to the devolution of BP monitoring from the clinician to the individual.

Compliance with ethical standards

Conflict of interest The author declares no competing interests.

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