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A Protocol Design for Evaluation of Wearable Cuff-less Blood Pressure Measuring Devices

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Abstract— **This paper proposes one of the unique requirements in the validation protocol of the IEEE P1708 standard in assessing wearable cuff-less blood pressure (BP) measuring devices. Based on principles that are different from that of the conventional cuff-based devices, the cuff-less BP measurement approaches often require an individual calibration procedure. In this study, we used data from an experiment carried out on 28 subjects with a total of 139 sets of BP measurements as an example to show that breakdown of the performance evaluation of cuff-less devices according to the change of BP from the point of calibration is crucial for understanding and interpreting the overall accuracy of the device.**

I. Introduction

Blood pressure measured in a clinical setting by a trained physician using the auscultative technique with the mercury column has been used as the standard parameter for clinical diagnosis [1]. It is however becoming increasingly clear that this reading is often inadequate or even misleading to represent a patient's true BP status [1]. On the other hand, home (or self) BP monitoring (HBPM) and ambulatory BP monitoring (ABPM) have the following advantages [2-4] : (1) eliminate the white-coat effect; (2) helpful to the assessment of clinic effects, drug effects and work influence on BP; (3) better predict cardiovascular events and mortality; and (4) cost effective. Therefore, in 2008, the American Heart Association, American Society of Hypertension, and Preventive Cardiovascular Nurses Association published a joint scientific statement that called to an action on using HBPM [1].

Current devices employed for HBPM and ABPM are usually developed on the oscillometric method, which has to be used with an inflatable cuff during measurement. Patients sometimes find the cuff pressure intolerable [4]. Moreover, for an accurate measurement, an appropriate cuff size must be selected according to the upper-arm circumference of users [5]. Educating users with appropriate sized cuff for the out-of-office BP measurement is necessary [5], which is however an additional workload to the nurses.

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In the past few years, there is an emerging interest in developing wearable, non-invasive and cuff-less BP measuring devices. Leading investigators in this field suggest that BP can be estimated indirectly from pulse transit time (PTT) which is the time taken for the pulse wave to travel along the artery and arrive at the periphery. Models that relate BP and PTT have been developed based on many physiological parameters, e.g. elastic modulus, dimensions and stiffness of the intervening vessels. Experimental results have also shown that the relationship is approximately linear [6-9]. Based on these models, systems that use electrocardiogram (ECG) and/or photoplethysmograph (PPG) sensors have been proposed for the cuff-less and continuous measurement of BP [9-11].

II. Need for a New Standard

As wearable cuff-less BP measuring devices are becoming increasingly popular, it is important to develop a standard protocol for evaluating the accuracy of these devices. Regulation and guidelines are needed for manufacturers to qualify and validate their products, potential purchasers or users would have some basis to evaluate and select prospective products, and health care professionals have a right to understand the manufacturing practices using these devices.

Up-to-date, there is no defined and independent standard for wearable cuff-less devices. Existing standards for evaluating sphygmomanometers are set up by the American Association for the Advancement of Medical Instrumentation (AAMI) [12], the British Hypertension Society (BHS) [13] and the European Society of Hypertension (ESH) [14]. They are only intended for devices that are used with an occluding or inflatable cuff and therefore, do not cover all aspects needed for the cuff-less devices. As a result, validating approaches of wearable cuff-less devices vary largely from study to study, in terms of the evaluation protocol, the accuracy measures, as well as the graphical plots they reported.

III. Rationale for the Specific Provisions of the Protocol

Since the physiological parameters in the estimation model of cuff-less BP devices are often subject dependent, a calibration procedure is required for each individual user before measurement. As BP varies with time, its long-term variability may be as large as 14.7 mmHg for SBP and 10.8 mmHg for DBP in severe hypertensives [15]. Devices that claim to measure continuous BP should be assessed if they are able to trace and record this variation accurately.

Existing evaluation protocols require the subjects to seat quietly for three measurements in order to reduce the effect of BP variation on the assessment of accuracy of devices. These

protocols may suffice in the evaluation of traditional cuff-based device, but not the cuff-less ones. To evaluate whether a device has been properly calibrated, the evaluation protocol should require the test set to consist of BP data that distribute widely around the BP measured at calibration.

This study proposes a validating protocol for assessing devices that aim to measure continuous BP or track BP variations. In the following sections of this paper, the rationale of this protocol is explained and supported by the experimental data of a recent study. For illustration purposes, only the estimation results of SBP were provided.

IV. Experimental Data

BP data was collected from a study conducted on 28 healthy subjects aged 23-37 years [16]. All measurements were taken in a sitting position. Individual calibration was performed using a cuff BP and a hydrostatic method [17].

3 measurements were made by the cuff-less approach, where the first measurements were used for calibration objective and not included for accuracy assessment. Before and after each measurement, cuff BP were taken and their average was used as the reference. Each cuff BP consisted of a reading reported by an experienced registered nurse using a mercury sphygmomanometer and a reading simultaneously obtained from a validated oscillometric device (Omron HEM-907; passed both the AAMI and ESH protocols) that is connected to the mercury column by a Y-tube.

Subjects were then directed to run on a treadmill for three minutes. Another 3 sets of data were measured after exercise. After excluding 1 dataset where error was reported in obtaining the reference BP, a total of 139 datasets were used for the following assessment.

The measuring accuracy was analyzed by mean absolute difference (MAD), mean difference (MD), standard deviation of differences (SD), as well as the cumulative percentages of differences falling within 5, 10, 15mmHg ($CP_{5,10,15}$) between the estimated and reference BP. BP changes of each dataset were calculated as the differences between the reference BP of each dataset and the cuff BP measured at calibration for the same subject.

V. Results

The results were summarized in Table I. To include the effect of intra-subject variability, the accuracy was analyzed using all the datasets instead of averaging the data for each subject. The analysis was broken down into three levels: first on the datasets collected before and after exercise, respectively; then for all 139 datasets collected before and after exercise; and finally dividing the 139 datasets into 3 groups according to the BP changes of each dataset.

BP changes of the subset of data collected before exercise were generally small with averaged absolute BP changes of 2.1mmHg. For those subset of data collected after exercise, this averaged change increased to 19.7 mmHg. Fig.1 shows the Bland-Altman plot of the estimation results. Fig. 2 shows the distribution of BP changes with respect to the cuff BP measured at calibration of all datasets. Fig. 3 shows the scatter plot of the measuring differences vs. BP changes.

TABLE I
DEVICE ACCURACY REPORT (SYSTOLIC BLOOD PRESSURE)

BP Change (mmHg)	MAD (mmHg)	MD (mmHg)	SD (mmHg)	CP_5 (%)	CP_{10} (%)	CP_{15} (%)
Before Exercise (N=56)						
	2.9	0.5	3.9	82.1	98.2	100.0
After Exercise (N=83)						
	9.4	-4.2	10.8	27.7	59.0	80.7
Overall (N=139)						
	6.8	-2.3	9	49.6	74.8	88.5
Accuracy at different BP change levels						
0~15	4.4	0.2	6	65.9	92.0	97.7
15~30	9.8	-3.4	11.2	22.2	50.0	80.6
>30	14	-14	8.3	20.0	33.3	53.3

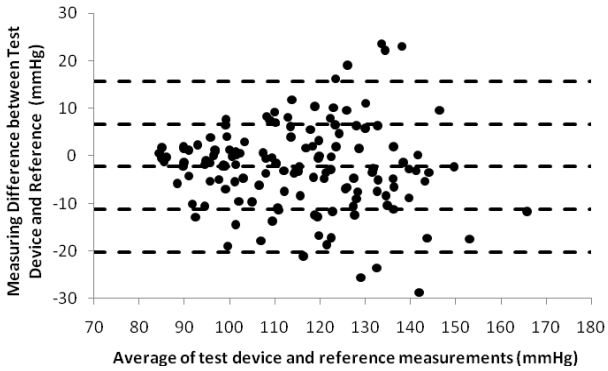

Fig. 1. Scatter plot of average blood pressure of test device and reference measurements versus the differences of them.

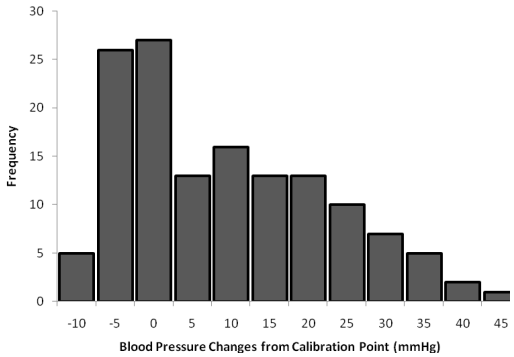

Fig.2. Histogram of blood pressure changes from the calibration point.

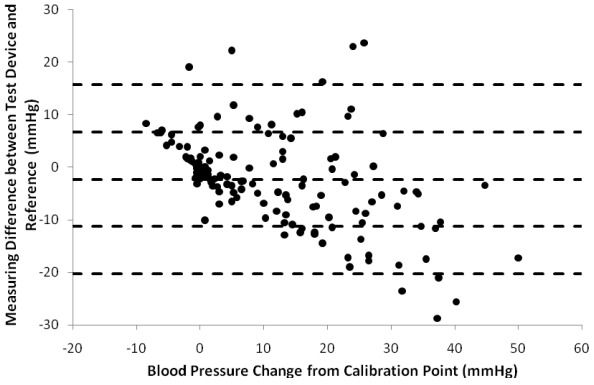

Fig. 3. Scatter plot of blood pressure change as compared to the calibration point versus the measuring difference.

VI. Discussion and Conclusion

AAMI, BHS and ESH protocols recommend using Bland-Altman plot (Fig.1) to analyze the agreement between test device and the reference. This plot effectively portrays the accuracy for the test device at different levels of BP.

From Table I, it is apparent that the estimated BP deviated further away from the reference for larger changes of BP from that measured at calibration. This can be clearly illustrated by Fig. 3. Around the calibration point, i.e. when change of BP is approximately zero, the measuring differences are small. As change of BP increases, the differences deviated away from the central line.

For the 56 datasets that were measured after calibration, the MAD between the test approach and reference BP was only 2.9mmHg (MD±SD = 0.5±3.9mmHg), which is significantly smaller than the MAD reported for the 83 datasets collected after exercise. Nevertheless, it is unfair to directly compare the two numbers and conclude that the cuff-less approach performs better in one condition. The differences found in the evaluating parameters are in fact resulted from the different distribution of BP changes of the two sets of data. This demonstrates the importance of setting a requirement in the validating protocol for the cuff-less devices on the distribution of BP changes in order that the reported estimation differences can be compared from one study to another.

The requirement on the range of BP changes must be carefully selected in the protocol design and should be determined according to the statistical analysis of BP data. Based on the study of *Mancia et al.* [15] and the assumption that long-term BP is normally distributed, the required percentage of samples suggested at each interval of BP changes is estimated and presented in Table II. It is suggested that evaluation of cuff-less BP devices should take into account the distribution of BP changes induced by the protocol and report estimation differences separately for different ranges of BP changes.

TABLE II
INDUCED BLOOD PRESSURE CHANGES

	Changes of BP from the Point of Calibration (mmHg)			
SBP	-30 – -15	-15 – 0	0 – 15	15 – 30
DBP	-20 – -10	-10 – 0	0 – 10	10 – 20
Percentage of Samples Required	13.6%	34.1%	34.1%	13.6%

In this study, we only focus on the required distribution of induced BP changes, the method that to be used to achieve this goal is not restricted. In the future, we need to address whether the mechanism of inducing BP variation will influence the evaluation results; and how to evaluate and qualify the frequency of calibration which is necessary to maintain a consistent accuracy performance.

To facilitate the proficiency of wearable cuff-less BP measuring devices for self and ambulatory BP measuring, there is an intensive need for establishing a standard for this kind of new devices. A standardized and efficient evaluation protocol will not only regulate the potential market of the devices, but also provide purchasers with reliable information in comparing and choosing prospective products to buy.

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