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Clinical Accuracy of the G.LAB MD41A0 Upper Arm Blood Pressure Monitor in Pregnancy and Pre-Eclampsia Using the AAMI/ESH/ISO as Reference Standard

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Objective: Validation of blood pressure (BP) monitors in pregnant women are needed to ensure the accurate measurement of BP in pregnancy. Therefore the study aimed to evaluate the measurement accuracy of the G.LAB MD41A0 oscillometric automatic upper-arm blood pressure monitor in pregnancy and pre-eclampsia women according to the AAMI/ESH/ISO Universal Standard (ISO 81060–2:2018).

Methods: A total of 45 pregnant women were included in the cross-sectional validation study. The same left-arm sequential method was used for blood pressure measurement, and the blood pressure differences between the test device and the mercury standard reference were assessed according to the AAMI/ESH/ISO Universal Standard.

Results: The participants included 15 normotensives, 15 gestational hypertension and 15 pre-eclampsia. The average (mean ± SD) differences between the device and mercury standard was −0.84±3.88 mmHg and −0.58±3.35 mmHg for systolic and diastolic blood pressure, respectively, for the validation Criterion 1. The SD of the averaged differences between the device and reference readings per participant was 2.92 mmHg and 2.28 mmHg for systolic and diastolic blood pressure, respectively, for the Criterion 2 of the universal standard.

Conclusion: The G.LAB MD41A0 automatic upper-arm blood pressure monitor fulfills the criteria of the AAMI/ESH/ISO Universal Standard and can be recommended for clinical use and self-measurement in pregnancy and pre-eclampsia.

Keywords: blood pressure monitor, validation, universal standard, pregnancy, pre-eclampsia

Introduction

Non-invasive sphygmomanometers should be evaluated the accuracy of blood pressure (BP) measurement before being recommended in practice. Different validation protocols were used to assess the accuracy of BP measurement devices in the past and strict adherence to these protocols was necessary for accuracy and statistical validity, which showed differences in sample size, procedures, results assessment, etc.[1–3] To unify the standards, a universal validation protocol was issued by the Association for the Advancement of Medical Instrumentation (AAMI), the European Society of Hypertension (ESH) and the International Organization for Standardization (ISO) as an international standard.[4–7] Most devices were validated in the general population according to these protocols, and only a few studies chose specific populations as participants, including children, pregnant women, arrhythmic patients, etc.

Hypertension is one of the most common medical disorders complicating pregnancy. Furthermore, gestational hypertension and pre-eclampsia are leading causes of preventable maternal morbidity and mortality, occurring in around

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10% of pregnancies worldwide with gestational hypertension of 6% and pre-eclampsia of 4%.[8,9] It is crucial to focus on the accuracy of BP measurements during this stage to ensure the safety of these patients. Many significant hemodynamic changes occur during pregnancy, such as increased heart rate, blood volume, cardiac output, decreased peripheral vascular resistance and arterial compliance, etc., which affects the accuracy of BP measurement.[10,11] Effective and sustainable monitoring and management of hypertension is important to prevent maternal-fetal adverse outcomes and because hemodynamic and vascular changes occur during pregnancy, pregnant women are regarded as a specific population needing to be validated for noninvasive BP measurement devices to ensure the accurate measurement of BP in pregnancy, which is recommended by the validation protocols.[12,13]

As an automated oscillometric upper-arm blood pressure monitor, the G.LAB MD41A0 [Grandway Technology (Shenzhen) Limited, China] had been validated in the general population before being used in practice and showed good BP measurement accuracy, followed by validation in special populations among patients of diabetes mellitus and atrial fibrillation according to the ISO 81060–2:2018.[14,15] To further assess its measurement accuracy in pregnancy and pre-eclampsia, this study aimed to evaluate the accuracy of the G.LAB MD41A0 for clinical use and self-measurement in pregnant women according to the AAMI/ESH/ISO Universal Standard.[4–7]

Methodology

Participants

The study used a cross-sectional design involving three categories of pregnant women recruited in the second or the third trimesters of pregnancy, and included women with normotensive pregnancy, women with gestational hypertension and those with pre-eclampsia. Pre-eclampsia was defined as elevated systolic blood pressure (SBP) of at least 140 mmHg and/or diastolic blood pressure (DBP) of at least 90 mmHg with proteinuria, and gestational hypertension was defined as new onset in pregnancy with BP ≥140 mmHg and/or ≥90 mmHg without proteinuria.[16,17] All participants were recruited from the outpatients or inpatients at obstetrics and gynecology clinic of a tertiary general hospital. The exclusion criteria were participants with arm circumference outside the cuff range, poor quality of Korotkov sounds, arrhythmia, atrial fibrillation, etc., according to the AAMI/ESH/ISO Universal Standard.

The study complied with the Declaration of Helsinki. The protocol of the study was approved by the ethical committee of the Xijing Hospital, and written informed consent was obtained from all participants for study participation before the study.

Tested Device

The test device, G.LAB MD41A0, is an oscillometric digital automatic upper-arm blood pressure monitor for clinical use and self-measurement, which is fixed directly to the arm cuff. The test device has a size of 164mm*99mm*46mm, with a 4.8-inch LCD screen. It is supplied with four AAA batteries and has a 4-user (240 x 4) memory capacity to store the measurement readings for each user. A standard cuff is available with the test device for upper arm circumference of 22–44 cm, which was used in the study following the manufacturer's instructions.

Procedures and Measurements

The AAMI/ESH/ISO Universal Standard was strictly followed.[4] The validation process was performed by two observers and one supervisor who were retrained for BP measurements according to the protocol. Before the validation process, the participant seated with the back supported, legs uncrossed, feet flat on the floor, and rested for more than five minutes. The arm of the participant was put with the middle of the upper arm at heart level and avoiding talking or motions. The same left arm sequential measurement method was used for the validation process with parallel-connected two standard mercury sphygmomanometers being used as reference devices (Yuwell, Jiangsu Yuyue Medical Equipment & Supply Co., Ltd., China) with four cuffs for arm circumference of 18–23 cm, 23–28 cm, 28–35 cm and 33–44 cm by the two observers, and the G.LAB MD41A0 (tested device) by the supervisor.

During the reference BP measurements, the Korotkoff K5 was used for reference DBP. The two observers were blinded to each other's measurement results and the test device values. The test device measurements were recorded by

the supervisor who also checked the observers' results. A total of seven sequential measurements were included in the formal analysis by reference and tested device in turn with at least 1 min between each measurement.

Statistical Analysis

Data were presented as mean±SD, frequencies, or percentages according to the AAMI/ESH/ISO Universal Standard. The IBM SPSS Statistics 27.0 (IBM Corp., Armonk, NY, USA) was used for data analysis. The analysis of variance method was used to compare the general characteristics among the three groups. Furthermore, the Bland–Altman scatter plots were used to present the device–observer BP differences against the average between the device and observer values according to the universal standard.

Results

A total of 45 pregnant women were included in the study with 10 in the second trimester and 35 in the third trimester of pregnancy. There were 15 participants in each of the normotensives, gestational hypertension, and pre-eclampsia groups. The average age of all the included participants was 32.2±4.4 years, the average gestational duration was 27.5±8.8 weeks, and the average arm circumference was 28.8±4.1 cm. The average recruitment SBP was 139.2±21.7 mmHg and the average recruitment DBP was 93.6 ±14.0 mmHg. The difference between the two observers' reference BP measurements was 0.1±1.7 mmHg and 0.1±1.4 mmHg with a range from −4 mmHg to 4 mmHg for SBP and DBP, respectively (Table 1).

The difference between the tested device and reference measurement was −0.84±3.88 mmHg for SBP, and −0.58 ±3.35 mmHg for DBP, for Criterion 1. The SD of intra-individual difference was 2.92 mmHg and 2.28 mmHg for SBP and DBP respectively, for the Criterion 2 of the validation protocol. Therefore, the device passed criteria 1 and 2 for both SBP and DBP according to the Universal Standard (ISO 81060–2:2018) (Table 2).

Table 1 General Characteristics of Included Participants

Items	Normotensive (*n*=15)	Gestational Hypertension (*n*=15)	pre-eclampsia (*n*=15)	Total (*n*=45)
Age (years)	29.6±3.0	31.9±4.9	35.1±3.5*#	32.2±4.4
Gestational age (weeks)	19.2±6.9	30.6±7.8*	32.6±4.8*	27.5±8.8
BMI	18.5±6.9	28.9±6.3	30.3±4.1	28.9±5.6
Arm circumference (cm)	28.3±3.5	28.5±4.4	29.6±4.6	28.8±4.1
Entry SBP (mmHg)	112.2±14.2	146.8±5.5*	158.4±3.6*	139.2±21.7
Entry DBP (mmHg)	77.2±8.6	99.0±8.4*	104.5±5.3*#	93.6±14.0

Notes: *P<0.05 vs normotensive; #P<0.05 vs gestational hypertension.
Abbreviations: SBP, systolic blood pressure; DBP, diastolic blood pressure.

Table 2 Validation Study Results

	Pass requirement	Achieved	
		SBP	DBP
Criterion 1 (135 comparisons)			
Mean BP difference (mmHg)	≤5	−0.84	−0.58
SD of BP (mmHg)	≤8	3.88	3.35
		Pass	Pass
Criterion 2 (45 subjects)			
SD of intra-individual difference (mmHg, SBP/DBP)	≤6.89/6.91	2.92	2.28
		Pass	Pass
Result		Pass	

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

The Bland–Altman scatter plots of the tested device and reference blood pressure difference against the device-reference average showed that all 135 points (100%) were within ±10mmHg for both SBP and DBP (Figure 1). Furthermore, the numbers of measurements differing from the reference within 5 mmHg were 111 (84.4%) for SBP and 120 (90.4%) for DBP, respectively.

As for the subgroup with 15 pre-eclampsia participants, the average age was 35.1±3.5 years; mean arm circumference was 29.6±4.6 cm; mean SBP and DBP were 158.4±3.6 mmHg and 104.5±5.3 mmHg, respectively. The difference between the simultaneous two observers' reference BP measurements was 0.2±1.9 mmHg and 0.1±1.7 mmHg for SBP

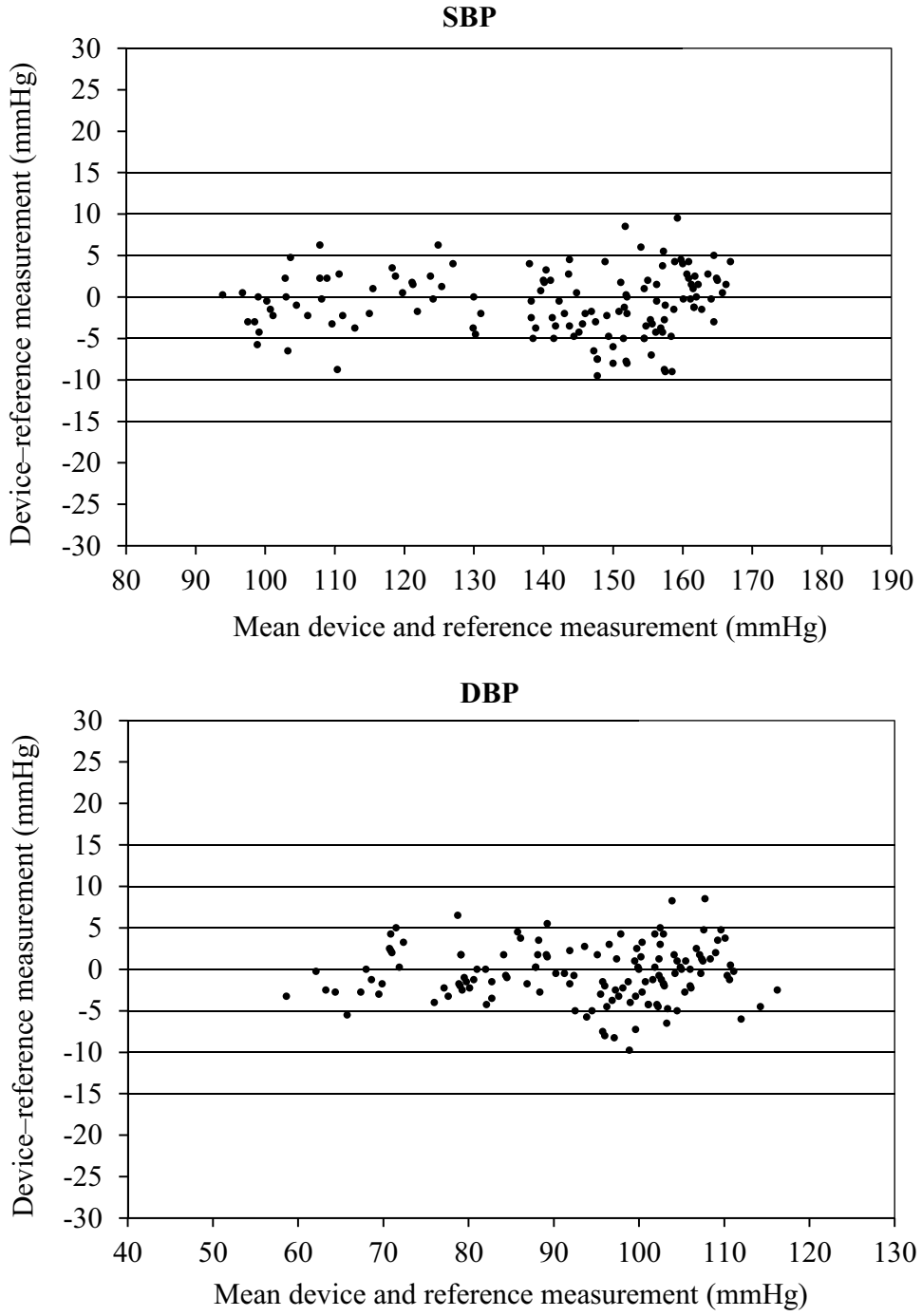

Figure 1 Bland–Altman scatter plots of the device-reference blood pressure differences against their average.
Abbreviations: SBP, systolic blood pressure; DBP, diastolic blood pressure.

and DBP, respectively. The difference between the tested device and reference measurement was −1.64±4.61 mmHg for SBP and −0.77±3.48 mmHg for DBP, respectively, for Criterion 1. Furthermore, the SD of intra-individual difference was 3.91 and 2.58 mmHg for SBP and DBP respectively for Criterion 2 according to the universal standard. Furthermore, the numbers of the device-reference BP differences were all within ±10mmHg for both SBP and DBP; 75.6% for SBP and 90.1% for DBP within 5 mmHg respectively.

Discussion

The study evaluated the accuracy of the G.LAB MD41A0, an automatic oscillometric upper-arm device, in pregnancy and pre-eclampsia according to the AAMI/ESH/ISO Universal Standard. The validation results showed that the tested device fulfills both criterion 1 and criterion 2 of the universal standard for both SBP and DBP in pregnancy and pre-eclampsia.

The collaboration among AAMI, ESH, and ISO had developed a standardized suitably powered "universal protocol" that superseded all previous protocols, which makes BP device validation studies easier to undertake and analyze including in both non-pregnant and pregnant populations.[4–7] The study adhered to the AAMI/ESH/ISO Universal Standard for validation among normotensives, gestational hypertension, and pre-eclampsia, and the results showed good performance of the tested device in pregnant women and also in the 15 subgroup participants with pre-eclampsia.

With the issuing of the universal validation protocol by the AAMI/ESH/ISO, more and more validation studies used the AAMI/ESH/ISO as the reference standard. However, the validation studies in special populations remain in the minority, especially in pregnancy and pre-eclampsia populations. The present validation study focused on the pregnancy and pre-eclampsia participants according to the universal standard without any major or minor violations, which provided valuable evidence for BP measurement in the special population of pregnancy and pre-eclampsia. However, the accuracy of BP measurement in real practice needs to be improved. Self or home BP measurement and those among special population are recommended to strictly follow the BP measurement guidelines and the use instructions of the devices to obtain accurate results.

Conclusion

The G.LAB MD41A0 automated upper-arm blood pressure monitor has passed all the requirements of the AAMI/ESH/ISO Universal Standard (ISO 81060–2:2018) in pregnancy and pre-eclampsia and can be recommended for clinical use and self-measurement in this specific population.

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Disclosure

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