Pregnancy Hypertension 15 (2019) 37–41

Contents lists available at ScienceDirect

Pregnancy Hypertension

journal homepage: www.elsevier.com/locate/preghy

Validation of the iHealth Track and Omron HEM-9210T automated blood pressure devices for use in pregnancy

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ARTICLE INFO

Keywords:
Home blood pressure monitors
Gestational hypertension
Pregnancy
Blood pressure
Validation
Preeclampsia
Telemonitoring
eHealth
Telemedicine

ABSTRACT

Objective: Self monitoring of blood pressure in pregnancy is increasingly popular with both health care professionals and patients. We assessed the validity of the iHealth Track and Omron HEM-9210T automated blood pressure devices (with Bluetooth connectivity) for the use in telemonitoring of blood pressure in pregnancy.
Methods: In this prospective observational study, the revised 2010 International Protocol of the European Hypertension Society (EHS) was used for the validation of the two devices against auscultatory sphygmomanometry by two independent observers who took 13 same arm measurements in 33 pregnant women, of which 10 were diagnosed with preeclampsia. The measurements were alternated between the test device and a calibrated aneroid sphygmomanometer following the protocol. Both automated devices were assessed sequentially in the same women.
Results: In the group of 33 women, the iHealth Track passed the EHS 2010 validation criteria with 86/98/99 of 99 device-observer systolic measurement comparisons and 88/96/98 of 99 device-observer diastolic measurement comparisons within the 5/10/15 mmHg boundaries respectively. The Omron HEM-9210T passed the same criteria with 85/94/99 of 99 device-observer systolic measurement comparisons and 82/95/99 of 99 device-observer diastolic measurement comparisons.
Conclusions: The iHealth Track and Omron HEM-9210T automated blood pressure monitors are validated for use in pregnancy. These two devices can now be added to the short list of validated devices in pregnancy and can be used for self-measurement of blood pressure in a telemonitoring setting of pregnant patients with (a high risk of) hypertensive disease.

1. Introduction

The proportion of women at increased risk for hypertension in pregnancy is growing, caused by factors such as life style, obesity, advanced maternal age at conception and concurrent heart or kidney disease [1].

Accurate blood pressure (BP) measurement is essential for diagnosis and management of hypertension in pregnancy. In clinical practice, BP is measured using auscultatory sphygmomanometry or using automated devices validated for use in pregnancy. Besides clinical measurements, self monitoring of BP in pregnancy is increasingly popular with both health care professionals and patients. Guidelines now recommend home monitoring for patients with chronic hypertension and gestational hypertension [2,3]. Possible advantages of home monitoring include the potential to rule out white coat hypertension, reduce the burden and costs of clinic visits and enhance patient satisfaction and autonomy [1]. With help of telemonitoring, women at high risk for or even established hypertensive disorders of pregnancy (HDP) or preeclampsia can be monitored (more) frequently without interfering all too much with daily activities [4]. Patients' acceptability and willingness for home blood pressure measurements is generally good, as they report increased reassurance, empowerment and less anxiety [5]. Professional guidelines regarding preeclampsia caution against automated blood pressure measuring devices for establishing the diagnosis of preeclampsia and institution of treatment, because both overestimation as well as underestimation of blood pressure (BP) can occur in comparison with auscultatory measurements [3,6].

While numerous automated BP devices are freely available, few monitors are validated for accurate use in pregnancy with or without hypertensive disorders such as preeclampsia. It is essential that new devices are compared to gold standard measurement methods to rule out over- or underestimation of BP values during pregnancy. Previous studies found several home monitors valid for use in pregnant women, according to different international validation protocols [7–9]. Other

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https://doi.org/10.1016/j.preghy.2018.10.008
Received 3 July 2018; Received in revised form 31 October 2018; Accepted 31 October 2018
Available online 02 November 2018

devices did not pass validation requirements recently and are therefore not recommended for use in pregnancy [10].

In order to offer pregnant patients an automated BP device with an integrated platform for telemonitoring of blood pressure, we chose to assess the validity of two devices according to the revised 2010 International Protocol of the European Hypertension Society [11].

2. Methods

In this prospective observational study the revised 2010 International Protocol of the European Hypertension Society was used for the validation of two different devices. This study was exempted from approval of the Medical Research Ethics Committee of the University Medical Center in Utrecht (reference number 16-637), as the Committee confirmed that the Dutch Medical Research Involving Human Subjects Act (WMO) did not apply to this study.

2.1. Device details

The iHealth Track is a fully automated oscillometric BP monitor by Andon Health Co, China. The accessory cuff can be used, according to the manual, for arm circumferences of 22–42 cm. Its Bluetooth functionality allows data synchronization with different health apps on smartphone and tablet. This monitor is previously validated in a general population according to the American National Standards Institute/Association for the Advancement of Medical Instrumentation/International Organization for Standardization (ANSI/AAMI/ISO) 81060-2:2013 standard.

The Omron HEM-9210T (Omron Healthcare Co. Ltd., Kyoto, Japan) is an automated oscillometric device for BP measurement on the upper arm. The wide-range cuff is used for arms 22–42 cm in circumference. Data can also be transferred to a database using Bluetooth connection. This device is validated in a general population using 85 subjects according to the ANSI/AAMI/ISO criteria [12].

2.2. Recruitment

The EHS protocol requires 33 subjects within one specific group. Pregnant women with age over 21 years old were recruited on the maternal ward of an academic teaching hospital (Utrecht University Medical Center). All subjects were at least 25 weeks pregnant and were hospitalized for different reasons (e.g. preeclampsia, preterm rupture of membranes, need for i.v. medication) but without discomfort or contractions, as this could possibly alter blood pressure. Exclusion criteria for the validation were unclear Korotkoff sounds, arrhythmia, or arm circumference above or below the device prescription (22–42 cm). A subgroup of the recruited patients was diagnosed with preeclampsia. Preeclampsia was defined as de-novo hypertension in pregnancy (a blood pressure equal to > 140 and/or > 90 mmHg on two separate measurements) with proteinuria or new-onset thrombocytopenia, renal insufficiency, neurological complications, liver involvement or fetal growth restriction [13].

2.3. Procedures

Overseen by an independent supervisor [JH], measurements were performed and recorded by two observers blinded from both each other's readings and from the device readings, after being acquainted with all devices and procedures. Subjects rested for 5 min in seating position before two separate observers started using two calibrated aneroid sphygmanometers (HEINE GAMMA XXL LF) as this is our Unit's gold standard since mercury sphygmanometers are prohibited for clinical use [14]. The supervisor measured the BP with the automated devices and checked the agreement of the BP values retrieved by the blinded observers. Both iHealth Track and Omron HEM-9210T were assessed sequentially in the same subjects, following this order and with 30–60 s rest between readings: *Entry measurements*: Observer 1, Observer 2, Device, *Validation measurements*: Observer 1 – Observer 2 – Device – Observer 1 – Observer 2 – Device – Observer 1 – Observer 2 – Device – Observer 1 – Observer 2. The last seven measurements were analysed following the protocol.

Table 1
Characteristics of all 33 subjects and the subgroup of 10 patients with preeclampsia (DBP, diastolic blood pressure; SBP, systolic blood pressure).

	All	Preeclampsia
Total women, n(%)	33	10 (30.3%)
Age (years)		
Range (Low: High)	22:40	22:39
Mean (SD)	31.0 (4.9)	30.7 (6.5)
Recruitment SBP (mmHg)		
Range (Low:High)	100:155	135:155
Mean (SD)	127.5 (16.3)	145.5 (6.7)
Recruitment DBP (mmHg)		
Range (Low:High)	50:105	80:105
Mean (SD)	78.7 (12.6)	90.7 (7.9)
Arm circumference (cm)		
Range (Low: High)	25:40	26:33
Mean (SD)	29.1 (2.6)	29.2 (2.1)
Gestational age at study day		
Mean (SD)	30.9 (3.6)	31.9 (2.9)
Body mass index pre-pregnancy (kg/m^2)		
Mean (SD)	25.7 (5.4)	27.3 (4.0)
Main reason for admission, n (%)		
Preeclampsia	10 (30.3)	10 (100)
Preterm rupture of membranes	8 (24.2)	–
Fetal growth retardation	4 (12.1)	–
Asymptomatic cervical shortening	4 (12.1)	–
Fetal congenital abnormalities	2 (6.1)	–
Antepartum haemorrhage	2 (6.1)	–
Other	3 (9.1)	–
Antihypertensive medication		
n (%)	6 (18.1)	6 (60)

2.4. Analysis

Observer – device differences were classified for systolic and diastolic values in three groups; within 5, 10 and 15 mmHg variability. Details of this procedure are published in the protocol [11]. The pass requirements of Part 1 (See Results – Tables 2 and 3) state that within these 3 variability groups, of 99 device-observer measurement comparisons, at least two of 73/87/96 boundaries OR all of the 65/81/93 boundaries should be met. The pass requirements of Part 2 (See Results – Tables 2 and 3) state that at least 24 of 33 subjects should have two or three absolute differences between observer and device measurements within 5 mmHg. No more than 3 subjects are allowed to have none of the absolute differences between observer and device measurements within 5 mmHg. Differences between observers and devices and 95% limits of agreement were visualized in Bland-Altman plots.

3. Results

Thirty-three women were included in the study, of which 10 were diagnosed with preeclampsia. The characteristics are presented in Table 1. The differences between the two observers were 0.1 ± 2.4 mmHg for systolic and −0.1 ± 2.5 mmHg for diastolic measures, with a range from −4 to + 4 mmHg.

In the group of 33 women, the iHealth Track passed the EHS 2010 validation criteria with 86/98/99 of 99 device-observer SBP measurement comparisons and 88/96/98 of 99 device-observer DBP measurement comparisons within the 5/10/15 mmHg boundaries respectively

Table 2
Pass requirements and validation results for iHealth Track automated BP device according to the European Society of Hypertension International Protocol Revision 2010. Results are in absolute numbers (measurements in Part 1, subjects in Part 2). (DBP, diastolic blood pressure; SBP, systolic blood pressure).

	≤5 mmHg	≤10 mmHg	≤15 mmHg	Grade 1	Mean difference (mmHg)	SD (mmHg)
Part 1						
Pass requirements						
Two of	73	87	96			
All of	65	81	93			
Achieved						
SBP	86	98	99	PASS	−0,1	3,4
DBP	88	96	98	PASS	−0,1	4,0
Part 2	2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg		Grade 2		Grade 3
Pass requirements	≥24	≤3				
Achieved						
SBP	31	1		PASS		PASS
DBP	31	1		PASS		PASS
Part 3						PASS

(See Table 2 for pass requirements and results) The mean difference (SD) between the observers and the iHealth Track was −0.1 (3.4) for systolic BP and −0.1 (4.0) for diastolic PB measurements, respectively.

Bland-Altman plots of the results are shown for both systolic and diastolic blood pressure (Fig. 1) and present the differences between the iHealth Track readings and its corresponding observer readings (the better of the previous and next observer readings) plotted against the mean of the device and the better observer measurements.

The Omron HEM-9210T passed the EHS 2010 validation criteria with 85/94/99 of 99 device-observer SBP measurement comparisons and 82/95/99 of 99 device-observer DBP measurement comparisons within the 5/10/15 mmHg boundaries respectively (See Table 3 for pass requirements and results) The mean difference (SD) between de observers and the iHealth Track was −0,8 (3,7) for systolic BP and −1,1 (−4,2) for diastolic PB measurements, respectively.

Bland-Altman plots of the results are shown for both systolic and diastolic blood pressure (Fig. 2) and present the differences between the Omron HEM-9210T readings and its corresponding observer reading (the better of the previous and next observer readings) plotted against the mean of the device and the better observer measurements.

As shown in the Bland-Altman plots for both devices (Figs. 1 and 2), agreement between each of the two automated devices and the better observer readings was satisfactory too in the higher BP range, as the majority of the differences is within the 95% limits of agreement. Most of these readings are from preeclampsia patients, presented by the white dotted bullets.

4. Discussion

4.1. Key findings

This validation study shows that both the iHealth Track and the Omron HEM-9210T automated BP devices fulfill the validation requirements of the revised 2010 International Protocol of the European Hypertension Society in a population of pregnant women, including a subgroup of pregnant women with preeclampsia.

Previous studies validated the use of the iHealth Track and the Omron HEM-9210T in general populations using the ANSI/AAMI/ISO criteria [12,15]. This validation study of a population subgroup ensures the accuracy of both devices when used in pregnancy. This allows the use of the two monitors in both clinical and home conditions of BP measuring in pregnancy.

4.2. Validation in pregnancy and preeclampsia

Altered hemodynamics of pregnant women are supposedly the reason for differences in BP readings compared to a general, non pregnant population [16]. It is therefore recommended that, prior to standard clinical use, the device has been tested specifically in pregnant patients. As mentioned before, few automated devices have been validated for use in pregnancy [17].

Even more profound changes in hemodynamics can be found in pregnancies complicated with preeclampsia. Our study included 10 (out of a total of 33) women with preeclampsia and a wide range of blood

Table 3
Pass requirements and validation results for Omron HEM-9210T automated BP device according to the European Society of Hypertension International Protocol Revision 2010. Results are in absolute numbers (measurements in Part 1, subjects in Part 2). (DBP, diastolic blood pressure; SBP, systolic blood pressure).

	≤5 mmHg	≤10 mmHg	≤15 mmHg	Grade 1	Mean difference (mmHg)	SD (mmHg)
Part 1						
Pass requirements						
Two of	73	87	96			
All of	65	81	93			
Achieved						
SBP	85	94	99	PASS	−0,8	3,7
DBP	82	95	99	PASS	−1,1	4,2
Part 2	2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg		Grade 2		Grade 3
Pass requirements	≥24	≤3				
Achieved						
SBP	30	1		PASS		PASS
DBP	30	0		PASS		PASS
Part 3						PASS

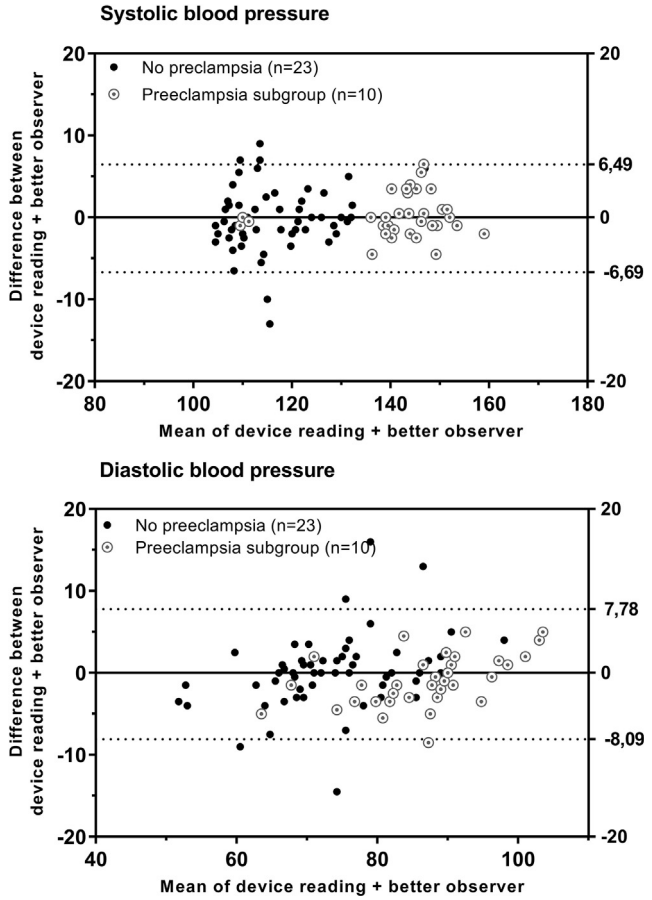

Fig. 1. Bland-Altman plots showing differences of systolic (upper plot) and diastolic (lower plot) blood pressure in pregnancy (including a subgroup with preeclampsia) between the **iHealth Track** readings and the better of two observer readings in 33 participants (n = 99). The two dotted lines represent the 95% limits of agreement of the total group of 33.

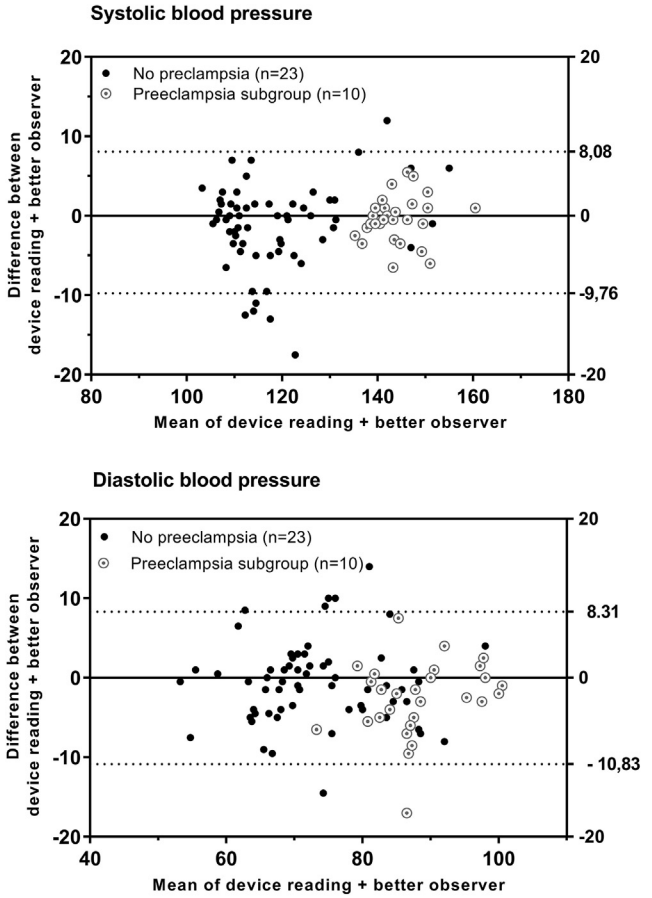

Fig. 2. Bland-Altman plots showing differences of systolic (upper plot) and diastolic (lower plot) blood pressure in pregnancy (including a subgroup with preeclampsia) between the **Omron HEM-9210T** readings and the better of two observer readings in 33 participants (n = 99). The two dotted lines represent the 95% limits of agreement of the total group of 33.

pressure values up to 160 mmHg systolic and 110 mmHg diastolic. This resulted in a wider range of baseline blood pressure values, including severe hypertension, eventually leading to a more valuable report. However, this particular subgroup of 10 preeclampsia patients does not allow direct extrapolation to validation of these two devices in preeclampsia. Additional validation reports of these devices for the use in preeclampsia would be recommended.

Home blood pressure monitoring in a pregnant population with (a high risk of) hypertensive disease is being used to detect hypertension in pregnancy, to evaluate the effects of the start or alterations of antihypertensive medication and to improve hypertension control with thresholds up to 160 systolic BP and 100 diastolic BP. As values exceed these thresholds, clinical evaluation is essential in order to assess symptoms of hypertensive disease and review changes in kidney and liver function as well as effects on the fetus. The use of the iHealth Track and Omron HEM-9210T is unlikely to prevent or postpone the onset of severe hypertension or preeclampsia, but may contribute to earlier detection, better BP control, reduction of burden and costs of hospital visits and admissions and greater patient satisfaction. Previous validation studies in preeclampsia patients of recent years show contrasting results. The Microlife 3BTO-A is validated for use in pregnancy complicated with preeclampsia but failed to pass the criteria of the International Protocol in a following study by Nouwen et al. several years later [18,19]. In the same report, the Omron M7 passed for diastolic BP in preeclampsia, but failed for systolic BP measurements in the same study group.

4.3. Strengths and limitations

While validated automated BP measuring devices for use in pregnancy are scarce, this study completed the validation trajectory of two devices of two different producers for use in pregnancy. This is a useful addition to the list of validated devices in pregnancy. Other strengths of this study include the use of an international standard protocol and the inclusion of pregnant patients both with and without preeclampsia. We chose to validate two monitors with Bluetooth functionality. In order to enhance maintenance and persistence of self-monitoring during pregnancy, we think easy connectivity with a smartphone is essential for telemonitoring. As there are no positive validation reports of devices with this function, to the best of our knowledge, these two monitors are now the first to be used by pregnant women.

Although we tried to follow the EHS validation protocol to full extent as prescribed, we were not able to use mercury sphygmomanometers. The use of mercury is no longer allowed in the Netherlands for safety reasons and they were replaced with calibrated aneroid sphygmomanometers many years ago. The study group consisted of inpatients, hospitalized in pregnancy due to different complications. We cannot ascertain that the measurements from admitted patients would correspond with self measurements at home, in a less controlled setting. The ESH protocol advises the subjects to rest for 10–15 min in upright position to start validating in a rested state. In telemonitoring instructions, patients at home are also advised to rest prior to BP measurement. The use of antihypertensive medication in a number of subjects could have possibly reduced variability in BP.

4.4. Clinical implications

Potential advantages of the use of home blood pressure monitoring in pregnancy include the exclusion of the 'white coat effect', improvement of patient empowerment, reduction of outdoor patient clinic visits and the ability of (more) frequent monitoring with less interference with daily life. Women of reproductive age are frequent users of Internet, smartphones and applications [20]. The introduction of automated BP devices with Bluetooth connectivity facilitates the pathway of telemonitoring of blood pressure and other maternal parameters as weight, heart rate, dietary intake or symptoms of hypertensive disease. After synchronization of BP values with their own customized smartphone application, this can be shared with health care providers in special telemonitoring units on a daily basis. Prenatal care is integrating mobile technology more and more in order to offer personalized pathways after individual risk stratification. The validation of these two Bluetooth connected automated BP monitors may contribute to remote monitoring in perinatal care.

Conflict of interest

All authors report no conflict of interest.

Acknowledgements

The work described in this study was carried out in the context of the e-Health Citrien program, which is part of and funded by the Dutch Federation of University Medical Centers (NFU).

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