Pregnancy Hypertension 17 (2019) 69–74

Contents lists available at ScienceDirect

Pregnancy Hypertension

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

A clinical evaluation of blood pressure measurement by iHealth BP5 in pregnancy

A. Hofstede, H. Wollaars, J. van Drongelen*

Department of Obstetrics and Gynecology, Radboud University Medical Center, Nijmegen, The Netherlands

ARTICLE INFO

Keywords:
Blood pressure
Pregnancy
Monitor
Smartphone device
European Society of Hypertension International Protocol

ABSTRACT

Objective: To evaluate the value of blood pressure measurement by the smartphone device iHealth BP5 in pregnant women in a clinical setting, as compared to the Omron M6 Comfort and aneroid manometer.

Materials and methods: Women with a gestational age of thirty weeks or more who visited the outpatient clinic for routine visit were eligible for inclusion. For the clinical evaluation we used an adjusted form of the European Society of Hypertension International Protocol. We performed six blood pressure measurements per patient, divided over the iHealth BP5, Omron M6 Comfort and aneroid monitor. Statistical analysis consisted of repeated measurement ANOVA and Bland-Altman plots.

Results: We included 45 women. The mean blood pressure differences between all tested devices were less than ± 5 mmHg. These differences did not relate to gestational age, BMI or arm circumference. Bland-Altman plots showed good agreement of both iHealth BP5 and Omron M6 Comfort, without any systematic effects, as compared to the aneroid manometer.

Conclusion: The iHealth BP5 is as good as the frequently used Omron M6 Comfort and can be used for blood pressure measurement during pregnancy.

Condensed abstract: In 45 women the mean blood pressure differences between the Omron M6 Comfort, iHealth BP5 and the aneroid manometer were less dan ± 5 mmHg. These differences did not relate to gestational age, BMI or arm circumference. Bland-Altman plots showed good agreement of both iHealth BP5 and Omron M6 Comfort, without any systematic effects, as compared to the aneroid manometer.

The iHealth BP5 is as good as the frequently used Omron M6 Comfort and can be used for blood pressure measurement during pregnancy.

1. Introduction

Gestational hypertensive disease (GHD) complicates pregnancies in 12% of the cases [1]. It can lead to both maternal and fetal morbidity and mortality. As early stage GHD does not relate to profound physical complaints, it is obligatory that blood pressure is measured frequently throughout pregnancy.

The aneroid manometer is the gold standard to measure blood pressure auscultatary in pregnant women. In many hospitals in a developed country setting, standard automatic oscillometric blood pressure monitors are frequently used for outpatient blood pressure measurements. Both aneroid and oscillometric monitors have a few disadvantages. First, patients have to visit the outpatient clinic for measurement on a frequent base. Second, patients that suffer from a white coat effect or white coat hypertension can obtain an overestimation of the blood pressure and unnecessary treatment [2–4]. In office measurements do not always accurately describe the actual blood pressure of patients [5]. The use of self-measurement of the blood pressure at home may overcome these disadvantages.

Oscillometric smartphone coupled devices seem to be ideal for blood pressure measurement at home, especially in combination with the use of telemedicine [6–10]. Smartphone devices are patient friendly and could be cost-effective when leading to less outpatient visits [11,12]. Recently smartphone apps that use photoplethysmographic signal, recorded by smartphone cameras, were found not to be accurate enough for use during pregnancy [13]. Although some smartphone blood pressure devices have been validated in a healthy non-pregnant study population, it remains unclear if one may extrapolate this to the pregnant situation in a clinical setting [14].

This study investigates the value of the oscillometric smartphone

* Corresponding author at: Department of Obstetrics and Gynecology, 791, Radboud University Nijmegen Medical Centre, PO Box 9101, 6500 HB Nijmegen, The Netherlands.

E-mail address: joris.vandrongelen@radboudumc.nl (J. van Drongelen).

https://doi.org/10.1016/j.preghy.2019.05.011
Received 9 January 2019; Received in revised form 10 April 2019; Accepted 8 May 2019
Available online 09 May 2019

coupled device, iHealth BP5, in measuring blood pressure in pregnant women. For this we compare the iHealth BP5 with the Omron M6 Comfort and the aneroid manometer in a clinical setting. We tested the device in pregnant women with a gestational age of 30 weeks or more, as one may expect that haemodynamic changes and fat accumulation seen in the second and third trimester of pregnancy may affect inaccuracy in blood pressure measurement. We hypothesized that the iHealth BP5 measures blood pressure as reliable as the Omron M6 Comfort, as compared to the gold standard aneroid manometer.

2. Materials and methods

2.1. Tested devices

The iHealth BP5 device is an upper arm oscillometric blood pressure monitor that communicates with a mobile application by wireless communication (Bluetooth). It is compatible with IOS and Android smartphones. It has a cuff circumference of 22–42 cm (size M and L) and weights 135 g (excluding cuff). The cuff pressure range is 0–295 mmHg and iHealth BP5claims to have an accuracy of ± 3 mmHg in a non-pregnant setting. The pulse rate range is 40–180 beats/min and should have an accuracy of 5% [15]. The application for the smartphone is called 'iHealth Myvitals' and is to be installed before use (Table 1).

The Omron M6 Comfort is an oscillometric blood pressure monitor and is used for blood pressure measurement in our obstetric outpatient clinic [16]. It has a cuff circumference of 22–42 cm and weights 380 g. The cuff pressure range is 0–299 mmHg and the pulse rate range is 40–80 beats/min.

2.2. Gold standard device

In line with literature, we used the aneroid manometer as the gold standard. One observer, trained in blood pressure measurement, performed the measurements. The observer had adequate hearing and sight. The aneroid manometer was calibrated accurately.

2.3. Familiarization

Before study measurements were performed, we did test measurements to rule out any procedural problems.

2.4. Recruitment

The Nijmegen Medical Center Medical Ethics Committee approved the study protocol for this clinical evaluation study before patient enrolment (filenumber: 2016–2699). Pregnant women with a gestational age of 30 weeks or more who visited the clinic of Obstetrics and Gynecology of the Radboud University Medical Center in the Netherlands were asked to participate. Subjects with a heart rhythm other than sinusrhythm were excluded.

Table 1
Device details.

Brand	iHealth	Model	BP5-O89ADA
Manufacturer	Andon Health Co. Ltd		
Location	Upper arm		
Method	Oscillometry		
Purpose	Self/home measurement		
Operation	Automatic		
Arm cuff	22–42 cm		

2.5. Procedure

We used a clinical evaluation protocol that was based on The European Society of Hypertension International Protocol revision 2010 (ESH-IP) [17]. We adjusted this protocol to a clinical setting applicable for pregnant women, as the ESH-IP is designed for validation studies in an artificial setting in a non-pregnant population. We adjusted the ESH-IP on the following points: 1. Comparison of the monitor of interest to an aneroid manometer instead of a mercury manometer, as a mercury manometer is not allowed inside our hospital for safety reasons. 2. Blood pressure ranges were adjusted to suitable ranges for a healthy pregnant population, as such population is characterized by a much lower blood pressure than a non-pregnant population [18,19]. 3. One observer that measured blood pressures instead of two, as this resembles the outpatient clinical situation. We added a second monitor of interest, as we aimed to compare the iHealth BP5 in comparison to the Omron M6 Comfort that is used in our clinic.

Our protocol consisted of ten minutes of rest before each participant underwent six blood pressure measurements in total. The measurements consisted of two rounds. Each round consisted of three measurements; first the aneroid monitor, second the Omron M6 Comfort and third iHealth BP5. This method was chosen to effectuate the observer to be blinded when the aneroid measurement was taken. Blood pressure measurements were performed on the arm of preference of the participant. All measurements in one participant were performed on the same arm.

2.6. Statistic analysis

SPSS Statistics 22 was used for statistical analysis. The analysis was divided into two comparisons. Comparison 1: iHealth BP5 versus aneroid manometer, and comparison 2: Omron M6 Comfort versus aneroid manometer. We used a repeated measurements ANOVA to test differences in mean systolic and diastolic blood pressure. With regression analysis we evaluated the influence of BMI before pregnancy, BMI during pregnancy, pregnancy duration and arm circumference on blood pressure accuracy. For possible bias between the first and second round an univariate regression analysis was performed. At last, Bland-Altman plots were created to search for a systematic effect of blood pressure on the differences between the tested monitors.

3. Results

We performed 18 successful test measurements with the aneroid, Omron M6 Comfort and iHealth BP5. Thereafter, a total of 45 participants enrolled into the study. We had complete measurements in 44 participants. 1 Participant was excluded in the comparison between iHealth BP5 and aneroid, because of device failure. The overall mean aneroid systolic and diastolic blood pressures were 110,5 mmHg (90–140 mmHg) and 67,1 mmHg (38–86 mmHg), respectively (Table 2 and 3).

We performed a repeated measurements ANOVA to test for blood pressure differences between the tested devices and the gold standard (Appendix 2). This showed small, but significant, differences in diastolic blood pressure in iHealth BP5 and systolic and diastolic blood pressures in Omron M6 Comfort, as compared to the aneroid measurement (Fig. 1). Only the blood pressure difference in systolic blood pressure between iHealth BP5 and aneroid manometer was not statistical significant. All mean differences fell within ± 5 mmHg. The mean differences between the devices could not be explained by confounding variables, such as BMI before and during pregnancy, pregnancy duration or arm circumference through linear regression analysis (data not shown). Blood pressures measured in the first round slightly differed

Table 2
Screening and recruitment details.

		Recruitment ranges			
			mmHg	All	On Rx*
Total screened	45	SBP†			
Total excluded comparison iHealth BP5 – Aneroid	0	Low	< 90	0	0
Total excluded Omrom M6 Comfort – Aneroid	1		90–99	12	0
Ranges complete	0	Medium	100–120	27	3
Range adjustment	0	High	121–140	6	0
Arrhythmias	0		> 140	0	1
Device failure		DBP			
Aneroid	0	Low	< 40	1	0
iHealth BP5	0		40–49	0	0
Omron M6 Comfort	1	Medium	50–80	39	2
Poor quality sounds	0	High	81–90	5	2
Cuff size unavailable			> 90	0	0
Aneroid	0				
iHealth BP5	0				
Omron M6 Comfort	0				
Observer disagreement	0				
Distribution	0				
Other reasons	0				
Total recruited	45				

* Number of patients on antihypertensive medication.
† SBP systolic blood pressure, DBP diastolic blood pressure.

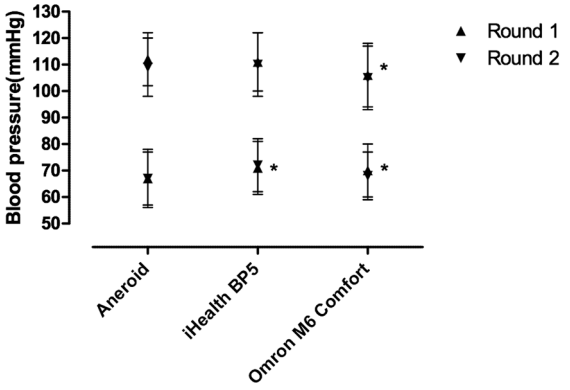
Table 3
Participant details.*

Sex			
Male: Female	0: 45	Recruitment BP (mmHg)†	
Age (years)		SBP	
Mean (SD)	32,8 (4,7)	Range (Low: High)	90:140
BMI (kg/m^2)		Mean (SD)	110,5 (10,2)
Before pregnancy		DBP	
Mean (SD)	24,1(4,0)	Range (Low: High)	38:86
During pregnancy		Mean (SD)	67,1 (9,6)
Mean (SD)	27,9 (3,9)		
Pregnancy duration (weeks)			
Mean (SD)	34,8 (3,1)		
Arm circumference (cm)			
Mean (SD)	27,7 (2,68)		
Cuff for test device			
Standard	44		
Large	1		

* See Appendix 1 for more details.
† BP, blood pressure based on the aneroid monitor.

(1 mmHg) from the blood pressures measured in the second round when analyzed by univariate regression, but this was consistent amongst all three devices.

In the Bland-Altman plots (Figs. 2 and 3) the mean blood pressure of two devices are plotted against their difference. The plots showed no systematic effect of blood pressure ranges on the difference between the tested monitors. Blood pressure differences were numerically small and with a small distribution. In the comparison of iHealth BP5 and aneroid measurement (Fig. 2) no systolic blood pressure values and three diastolic blood pressure values exceeded a difference of 15 mmHg. In the comparison of Omron M6 Comfort and aneroid measurement (Fig. 3) four systolic blood pressure values and one diastolic blood pressure values exceeded a difference of 15 mmHg.



Legend: * represents a p-value of <0.05 between the aneroid and the tested device.

Fig. 1. Mean systolic and diastolic blood pressures in the aneroid, iHealth BP5 and Omron M6 Comfort device. Legend: * represents a p-value of < 0.05 between the aneroid and the tested device.

4. Discussion

In this study we investigated the clinical use of the iHealth BP5 in measuring blood pressure in pregnant women, as compared to the Omron M6 Comfort and the gold standard aneroid manometer. We found that iHealth BP5 measures blood pressure as good as Omron M6 Comfort. Because of the advantages of smartphone coupled devices (a.o. patient friendly and less visits to the outpatient clinic), they could improve and complement the standard obstetric care.

The iHealth BP5 produces blood pressures as reliable as the Omron M6 Comfort during pregnancy. In the repeated measurements ANOVA we found small mean differences within ± 5 mmHg as compared to the gold standard and we do not consider this to be clinical relevant. These differences were not caused by variables in subjects, such as pre-pregnancy BMI, pregnancy duration and arm circumference. In addition, the Bland Altman plots showed no systematic effect of blood pressure ranges on the difference between iHealth BP5, Omron M6 Comfort and the gold standard. Our results correspond with literature on non-pregnant individuals that also showed small mean differences and no systematic effect of blood pressure ranges on the difference between the devices [14,16]. This suggests that the iHealth BP5 and the Omron M6 Comfort are comparable and both suitable for pregnant women in all blood pressure groups.

Along with research our study also has some potential methodological imperfections that need to be addressed. First, we adjusted the ESH-IP for blood pressure evaluation during pregnancy. Pregnancy is characterized by immense vasodilation and as a result low blood pressures as compared to non-pregnancy. Therefore blood pressure ranges as proposed by the ESH-IP need to be adjusted to have sufficient variation amongst the blood pressure range groups. The normal blood pressure during pregnancy is 110/65 mmHg [19,20]. Based on this we used blood pressure range for low (< 100/50 mmHg), medium (≥100/50 and ≤ 120/80 mmHg) and high (> 120/80 mmHg). This resulted in an equal distribution in our population amongst the blood pressure groups. According to a recent systematic review, only one-third of blood pressure validation studies in pregnancy were able to adhere to protocol [21]. Given the importance of accurate blood pressure measurement in pregnancy there should be a validation protocol design especially for pregnant women. Second, we used an aneroid manometer as a gold standard, instead of a mercury manometer as proposed by the ESH-IP. As we intended to perform a clinical evaluation of the blood pressure devices, we were not allowed to use an mercury manometer

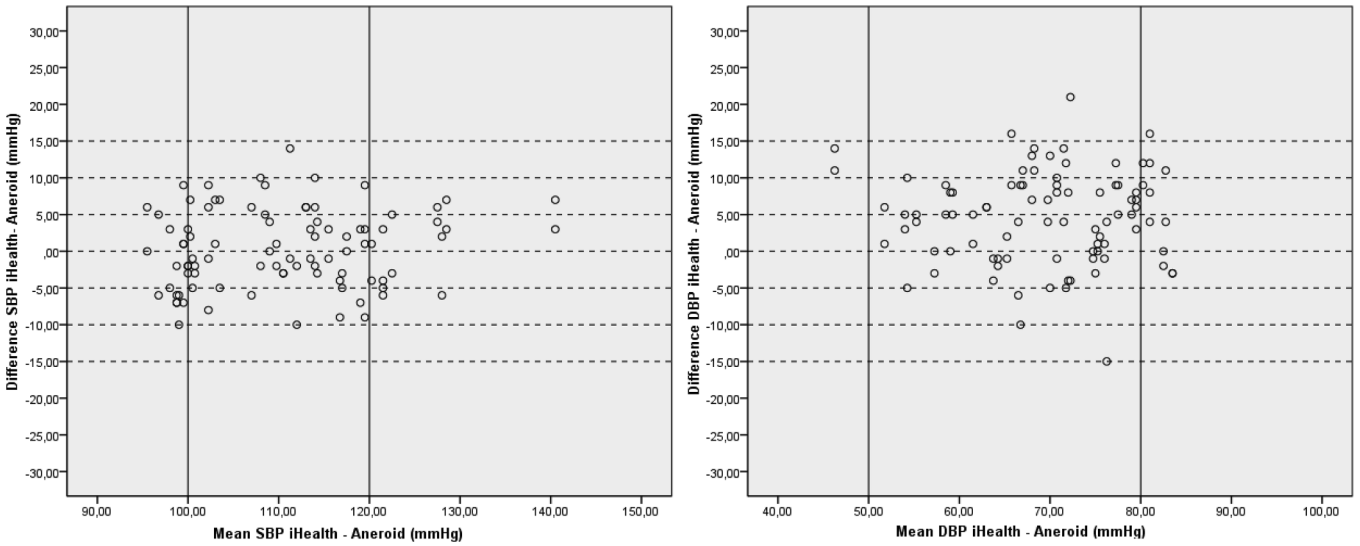


Fig. 2. The mean systolic and diastolic blood pressure differences between the iHealth BP5 and aneroid manometer.

for safety reasons. We expect this did not influence our result, as the aneroid manometer was validated and calibrated on a mercury manometer. Third, one non-blinded observer performed the measurements with the aneroid manometer, instead of two blinded observers as proposed by the ESH-IP. We intended to do a clinical evaluation and in daily practice where blood pressure is normally measured once by just one observer. To correct for the non-blinded observer every round of measurements started with the aneroid manometer. As a result, the observer was not influenced by the blood pressure measured by the iHealth BP5 and the Omron M6 Comfort. Thereby, the difference between the first and second round of measurements was only ± 1 mmHg. As we do not consider this to be clinical relevant, we expect the effect of the non-blinded observer did not influence our results significantly.

This is the first study that evaluates the iHealth BP5 smartphone device for a pregnant population. We conclude iHealth BP5 measures blood pressure reliable as compared to the gold standard. Our study can be directly translated to the clinical practice and suggests that iHealth BP5 can be safely used in a pregnant population. The use for self measurement should be investigated in the future.

5. Perspectives

The smartphone device iHealth BP5 can be used during pregnancy. This study, and studies mentioned above, show us that there is a need for a validation protocol especially for pregnant women. The use of smartphone devices for the measurement of blood pressure during pregnancy could make the healthcare for pregnant women more patient friendly and cost-effective when leading to less outpatient visits.

Sources of funding

This study was supported by the Radboud University Medical Center in Nijmegen. We did not receive external funding.

Declaration of Competing Interest

The authors report no conflicts of interest.

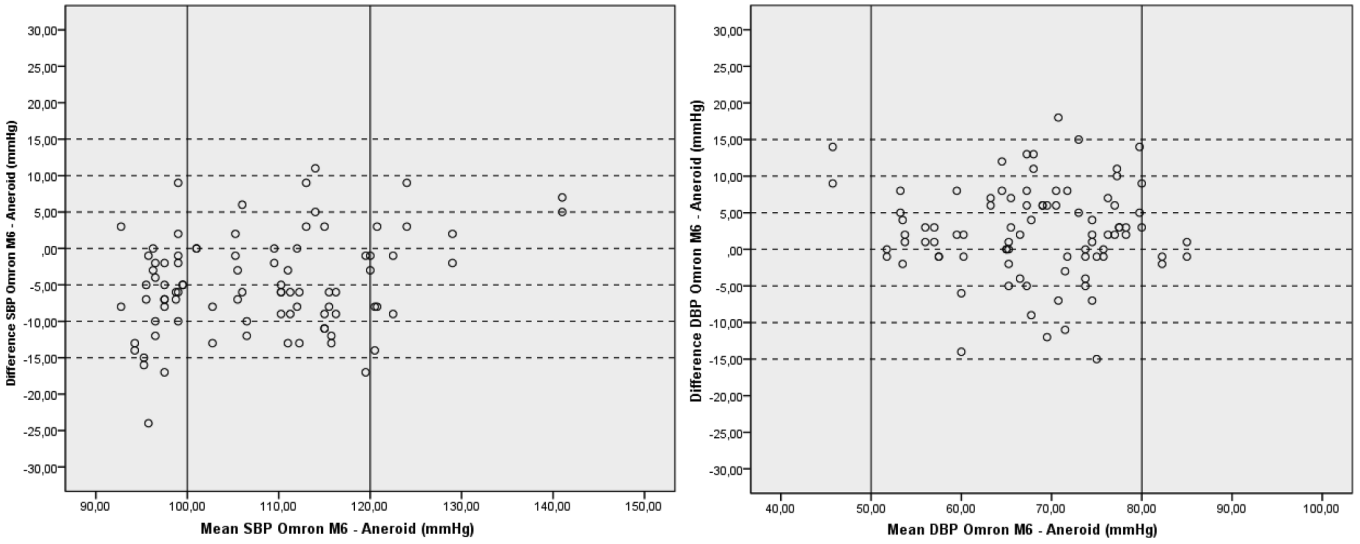


Fig. 3. The mean systolic and diastolic blood pressure differences between the Omron M6 Comfort and the aneroid manometer.

Appendix

Appendix 1. Participants details

Sex		Diagnosis	
Male: Female	0: 45	Normal	41
Age (years)		Hypertension	1
Range (Low: High)	24: 43	Gestational hypertension	1
Mean (SD)	32,8 (4,7)	Pre-eclampsia	2
BMI (kg/m^2)		Antihypertensives	
Before pregnancy		None	41
Range (Low: High)	17,7: 36,7	Calcium channel blockers	1
Mean (SD)	24,1(4,0)	Methyldopa	4
During pregnancy		Arm circumference (cm)	
Range (Low: High)	21,9: 40,8	Range (Low: High)	22,5: 36,5
Mean (SD)	27,9 (3,9)	Mean (SD)	27,7 (2,68)
Pregnancy duration (weeks)		Cuff for test device	
Range (Low: High)	30: 40,1	Standard	44
Mean (SD)	34,8 (3,1)	Large	1
Parity 16 weeks			
Range (Low: High)	0:04		
Mean (SD)	1 (1)	Recruitment BP (mmHg)*	
Parity 20 weeks		SBP	
Range (Low: High)	0:04	Range (Low: High)	80:147
Mean (SD)	1 (1)	Mean (SD)	109 (10,7)
Gravidity		DBP	
Range (Low: High)	1:11	Range (Low: High)	38:91
Mean (SD)	2 (1)	Mean (SD)	69,4 (9,2)

*BP, blood pressure based on all three monitors.

Appendix 2. Repeated measurements ANOVA

		Mean diff (mmHg)*	SE (mmHg)	95%CI	p
Osc-An	SBP	−4,94	0,84	[−7,04 to −2,84]	0,000
	DBP	2,35	0,79	[0,38–4,32]	0,014
Dev-An	SBP	0,30	0,61	[−1,21 to 1,80]	1,000
	DBP	4,52	0,71	[2,75–6,30]	0,000
Dev-Osc	SBP	5,24	0,73	[3,43–7,05]	0,000
	DBP	2,17	0,46	[1,03–3,31]	0,000

Appendix 3. Validation results

		≤5 mmHg	≤10 mmHg	≤15 mmHg	Grade 1	Mean diff (mmHg)	SD (mmHg)	Result
Pass requirement*	Two of	67 (74%)	79 (79%)	87 (97%)				
	All of	59 (66%)	74 (74%)	85 (94%)				
Achieved	Omr-An SBP**	56 (62%)	89 (98%)	90 (100%)	failed	−4,94	5,59	Pass
	Omr-An DBP	46 (51%)	73 (81%)	87 (97%)	failed	2,35	5,24	
Achieved	iHealth-An SBP	56 (62%)	89 (98%)	90 (100%)	failed	0,30	3,97	Pass
	iHealth-An DBP	46 (51%)	73 (81%)	87 (97%)	failed	4,52	4,69	
Achieved	iHealth-Osc SBP	49 (56%)	70 (80%)	83 (94%)	failed	5,24	4,83	Pass
	iHealth-Osc DBP	69 (78%)	84 (95%)	87 (99%)	pass	2,17	3,03	

*Minimal number of measurements needed to pass the criteria of the adjusted ESH-IP.
**An: aneroid monitor. Osc: oscillometric monitor (Omron M6). Dev: smartphone device iHealth.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.preghy.2019.05.011.

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